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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2020**

**OR**

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

**For the transition period from to**

**Commission file number: 001-35668**

# Intercept Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Its Charter)

| **Delaware** | **22-3868459** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |

**10 Hudson Yards, 37th Floor**
**New York, NY 10001**
(Address of Principal Executive Offices and Zip Code)
**(646) 747-1000**
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.001 per share | ICPT | Nasdaq Global Select Market |

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 every Interactive Data File required to be submitted 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 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 | ☐ | 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, was $1,259.3 million (computed by reference to the closing price of $47.91 on such date as reported by the Nasdaq Global Select Market). Common stock held by our executive officers, directors and certain stockholders as of such date has been excluded from this calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the registrant's common stock outstanding as of December 31, 2020 was 33,015,614.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference to the registrant's definitive proxy statement related to its 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**Intercept Pharmaceuticals, Inc.**
**Annual Report on Form 10-K**
**For the Fiscal Year Ended December 31, 2020**

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

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, including, but not limited to, statements regarding the progress, timing and results of our clinical trials, including our clinical trials for the treatment of nonalcoholic steatohepatitis (“NASH”), the safety and efficacy of our approved product, Ocaliva (obeticholic acid or “OCA”) for primary biliary cholangitis (“PBC”), and our product candidates, including OCA for liver fibrosis due to NASH, the timing and acceptance of our regulatory filings and the potential approval of OCA for liver fibrosis due to NASH, the review of our New Drug Application for OCA for the treatment of liver fibrosis due to NASH by the U.S. Food and Drug Administration (the “FDA”), our intent to work with the FDA to address the issues raised in a complete response letter (“CRL”), the potential commercial success of OCA, as well as our strategy, future operations, future financial position, future revenue, projected costs, financial guidance, prospects, plans and objectives.

These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “possible,” “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of their dates, and we undertake no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by our management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks.

The following represent some, but not necessarily all, of the factors that could cause actual results to differ materially from historical results or those anticipated or predicted by our forward-looking statements:

- our ability to successfully commercialize Ocaliva for PBC;
- our ability to maintain our regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which we have or may receive marketing authorization;
- our ability to timely and cost-effectively file for and obtain regulatory approval of our product candidates on an accelerated basis or at all, including OCA for liver fibrosis due to NASH following the issuance of the CRL by the FDA; any advisory committee recommendation or dispute resolution determination that our product candidates, including OCA for liver fibrosis due to NASH, should not be approved or approved only under certain conditions; or any future determination that the regulatory applications and subsequent information we submit for our product candidates, including OCA for liver fibrosis due to NASH, do not contain adequate clinical or other data or meet applicable regulatory requirements for approval;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, including OCA for liver fibrosis due to NASH, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), any risk mitigation programs such as a REMS, and any related restrictions, limitations and/or warnings contained in the label of any of our products or product candidates;
- any potential side effects associated with Ocaliva for PBC, OCA for liver fibrosis due to NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions, or otherwise limit the sale of such product or product candidate, including in connection with the newly identified safety signal ("NISS") relating to Ocaliva identified by the FDA in May 2020;
- the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, retaining patients, meeting specific endpoints in the jurisdictions in which we intend to seek approval or completing and timely reporting the results of our NASH or PBC clinical trials;

- the outcomes of ongoing discussions with the FDA and the European Medicines Agency ("EMA") regarding the feasibility of the COBALT and 401 trials;
- our ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom we are substantially dependent for, among other things, the manufacture and supply of our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our clinical trial activities;
- our ability to identify, develop and successfully commercialize our products and product candidates, including our ability to successfully launch OCA for liver fibrosis due to NASH, if approved;
- our ability to obtain and maintain intellectual property protection for our products and product candidates, including our ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights;
- the size and growth of the markets for our products and product candidates and our ability to serve those markets;
- the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH or our other product candidates among physicians, patients and healthcare payors;
- the availability of adequate coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our ability to obtain adequate pricing for such products;
- our ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties;
- competition from existing drugs or new drugs that become available;
- our ability to prevent system failures, data breaches or violations of data protection laws;
- costs and outcomes relating to any disputes, governmental inquiries or investigations, regulatory proceedings, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation;
- our collaborators' election to pursue research, development and commercialization activities;
- our ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise;
- our need for and ability to generate or obtain additional financing;
- our estimates regarding future expenses, revenues and capital requirements and the accuracy thereof;
- our use of cash and short-term investments;
- our ability to acquire, license and invest in businesses, technologies, product candidates and products;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to manage the growth of our operations, infrastructure, personnel, systems and controls;

- our ability to obtain and maintain adequate insurance coverage;

- the impact of COVID-19, including any impact on our results of operations or financial position, related quarantines and government actions, delays relating to our regulatory applications, disruptions relating to our ongoing clinical trials or involving our contract research organizations, study sites or other clinical partners, disruptions relating to our supply chain or involving our third-party manufacturers, distributors or other distribution partners, facility closures or other restrictions, and the extent and duration thereof;

- the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the potential impact of Brexit; and

- the other risks and uncertainties identified under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K and in our other periodic filings filed with the U.S. Securities and Exchange Commission.

**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 the Company in the United States and/or other countries. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights to these trademarks and trade names.

## SUMMARY RISK FACTORS

Investing in our securities involves a high degree of risk. Investors should carefully consider the risks and uncertainties discussed under the caption "Risk Factors" and elsewhere in this Annual Report on Form 10-K before deciding whether to invest in our securities. The following is a list of some of these risks:

### *Risks Related to Our Financial Position and Need for Additional Capital*

- We are currently dependent on the successful commercialization of Ocaliva for PBC. To the extent Ocaliva is not commercially successful, our business, financial condition and results of operations may be materially and adversely affected and the price of our common stock may decline.
- We have never been profitable. We expect to incur losses for the foreseeable future, and we may never achieve or sustain profitability.
- We will require substantial additional funding, which may not be available to us on acceptable terms, if at all. If adequate funds are not available to us, we may be required to delay, limit, reduce or cease our operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- 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.

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

- We cannot be certain whether Ocaliva will receive full approval for PBC in jurisdictions where it has previously received accelerated or conditional approval, or that Ocaliva will be approved for PBC in any jurisdictions beyond those in which it is currently approved. Furthermore, OCA may not be approved on an accelerated basis, or at all, for NASH or any other indication beyond PBC and we may not receive regulatory approval for any other product candidate. Without regulatory approval, we will not be able to market and commercialize our product candidates.
- We are developing product candidates for the treatment of rare diseases or diseases for which there are no or limited therapies, such as PBC and NASH, and for some of which there is little clinical experience, and our development approach involves new endpoints and methodologies. As a result, there is a heightened risk that we will not be able to gain agreement with regulatory authorities regarding an acceptable development plan, that 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.
- Delays or difficulties in the commencement, enrollment and completion of our clinical trials and studies could increase our product development costs and delay, limit or prevent us from obtaining regulatory approval for OCA and our other product candidates.
- COVID-19 could materially and adversely affect our clinical trials.
- 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 or our collaborators advance through clinical trials, including OCA, may not have favorable results in later clinical trials or receive or maintain regulatory approval.
- Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require that our products be taken off the market or include new or additional safety warnings. Any such events may limit our existing and future product sales and materially and adversely affect our business, financial condition and results of operations.
- We may not be able to obtain or, if approved, maintain orphan drug exclusivity for our approved products or product candidates, which could cause our revenues to suffer.

***Risks Related to the Commercialization of Our Products***

- Sales of Ocaliva may be adversely affected by safety and labeling changes required by the FDA.
- We are subject to uncertainty relating to pricing and reimbursement. Failure to obtain or maintain adequate coverage, pricing and reimbursement for Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, or our other future approved products, if any, could have a material adverse impact on our ability to commercialize such products.
- Legislative and regulatory healthcare reform may adversely affect our business.
- Ocaliva and our other future approved products, if any, may not achieve broad market acceptance among physicians, patients and healthcare payors, and revenues generated from their sales may be limited as a result.
- If we fail to develop OCA for additional indications such as NASH, our commercial opportunity will be limited.

***Risks Related to Our Business and Strategy***

- 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 face rapid technological change and competition from other biotechnology and pharmaceutical companies. Our operating results will suffer if we fail to compete effectively.
- Our business and operations would suffer in the event of system failures, data breaches or violations of data protection laws.

***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 such as Ocaliva and product candidates such as OCA for liver fibrosis due to NASH, others may compete against us more directly, which could harm our business, possibly materially.
- If we do not obtain protection under the Hatch-Waxman Act in the United States (and similar legislation outside of the United States) extending the terms of our patents and/or providing data or other exclusivity for our products and product candidates, our business may be materially harmed.
- We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and such litigation may divert the attention of our management and scientific personnel and adversely affect our development and commercialization efforts.

***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 effectively service our debt.
- We may incur substantially more debt or take other actions that would affect our ability to pay the principal of and interest on our debt.

***Risks Related to Ownership of Our Common Stock***

- We have previously been, and are currently, subject to securities class action litigation and may be subject to similar or other litigation in the future. Such matters can be expensive, time-consuming and 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 to incur substantial losses.

# PART I

## Item 1. Business

### Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases with high unmet medical need utilizing our proprietary bile acid chemistry. Our first marketed product, Ocaliva® (obeticholic acid or "OCA"), is a farnesoid X receptor ("FXR") agonist approved in the United States, the European Union and several other jurisdictions for the treatment of primary biliary cholangitis ("PBC") in combination with ursodeoxycholic acid ("UDCA") in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. In addition to commercializing OCA for PBC under the Ocaliva brand name, we are currently developing OCA for additional indications, including nonalcoholic steatohepatitis ("NASH"). We are also developing other product candidates in various stages of clinical and preclinical development. We believe that OCA and our other product candidates have the potential to treat orphan and other more prevalent liver diseases such as NASH for which there are currently limited therapeutic options.

Ocaliva was approved for PBC by the U.S. Food and Drug Administration ("FDA") in May 2016 under the accelerated approval pathway. We commenced sales and marketing of Ocaliva in the United States shortly after receiving approval, and Ocaliva is now available to U.S. patients primarily through a network of specialty pharmacy distributors. Ocaliva received conditional approval for PBC from the European Commission in December 2016 and we commenced our European commercial launch in January 2017. We have submitted dossiers and obtained, or are otherwise pursuing, reimbursement from a number of national authorities in Europe. Since January 2017, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada, Israel and Australia, and we are pursuing marketing approval of Ocaliva for PBC in our other international target markets. Ocaliva received orphan drug designation in both the United States and the European Union for the treatment of PBC.

Our lead product candidate is OCA for the potential treatment of NASH. In February 2019, we announced topline results from the planned 18-month interim analysis of our pivotal Phase 3 clinical trial of OCA in patients with liver fibrosis due to NASH, known as the REGENERATE trial. In the primary efficacy analysis, once-daily OCA 25 mg met the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH at the planned 18-month interim analysis. Adverse events were generally mild to moderate in severity and the most common were consistent with the known profile of OCA. Interim analysis results at 18 months were based on surrogate endpoints and the impact on clinical outcomes has not been confirmed. The REGENERATE trial is ongoing and is expected to continue through clinical outcomes for verification and description of the clinical benefit of OCA. OCA also achieved the primary endpoint in a Phase 2b clinical trial for the treatment of NASH that completed in late July 2014, known as the FLINT trial, which was sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, a part of the National Institutes of Health. OCA has received breakthrough therapy designation from the FDA for the treatment of NASH patients with liver fibrosis. In September 2019, we submitted a New Drug Application ("NDA") to the FDA seeking accelerated approval of OCA for liver fibrosis due to NASH. In November 2019, the FDA accepted our NDA for filing and granted a priority review designation of OCA for liver fibrosis due to NASH. In December 2019, we submitted a Marketing Authorization Application ("MAA") to the European Medicines Agency (the "EMA") seeking conditional approval of OCA for liver fibrosis due to NASH. In January 2020, the EMA validated our MAA and thereby confirmed that our MAA was sufficiently complete to begin the formal review process. In June 2020, we received a complete response letter ("CRL") from the FDA stating that our NDA for OCA for the treatment of liver fibrosis due to NASH could not be approved in its present form. The CRL indicated that, based on the data the FDA had reviewed, the FDA has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. At that time, the FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE trial in support of potential accelerated approval and that the long-term outcomes phase of the trial should continue. We are in discussions with the FDA with respect to the potential resubmission of our NDA seeking accelerated approval of OCA for the treatment of liver fibrosis due to NASH. We had our end of review meeting with the FDA in October 2020 to discuss the FDA's risk-benefit assessment in the CRL based on its review of the available data, as well as our proposed resubmission of our NDA for the treatment of liver fibrosis due to NASH. The meeting was

constructive and the FDA has provided us with helpful guidance regarding supplemental data we can provide to further characterize OCA's efficacy and safety profile that could support resubmission based on our Phase 3 REGENERATE 18-month biopsy data, together with a safety update from our ongoing studies. We are advancing accordingly and plan to hold additional meetings with the FDA with the goal of achieving sufficient alignment to proceed on this basis and potentially resubmit our NDA for the treatment of liver fibrosis due to NASH by the end of 2021. In addition, we continue to work collaboratively with the EMA on its review of our MAA.

As part of our product development activities, we expect to continue to invest in evaluating the potential of OCA in progressive non-viral liver diseases. We are currently conducting a Phase 3 clinical trial in NASH patients with compensated cirrhosis, known as the REVERSE trial. In January 2020, we announced that we completed enrollment of the REVERSE trial with over 900 patients randomized. We are also studying OCA in combination with bezafibrate, a pan-peroxisome proliferator-activated receptor agonist, in patients with PBC and potentially may study such combination in other liver diseases. In addition, we have other compounds in early stages of research and development in our pipeline.

**Liver Function, Bile Acids and Progressive Non-Viral Liver Diseases**

The liver performs many functions that are vital for maintaining health, including the regulation of bile acid metabolism. Bile acids are natural detergent-like emulsifying agents that are released from the gallbladder into the intestine when food is ingested, and are essential for the absorption of dietary cholesterol and other nutrients. Cholesterol bound by bile acids is taken up by the liver, where the cholesterol is then converted into one of two primary bile acids. The bile acids are then actively secreted into bile ducts, which eventually empty into the gallbladder. This digestive cycle of bile flow from gallbladder to intestine to liver and back is called the enterohepatic recirculation of bile.

In addition to facilitating nutrient absorption, bile acids act as important signals that help regulate multiple other biological functions. They are also complex signaling molecules that integrate metabolic and immune pathways involved in the healthy functioning of various tissues and organs. For example, the actions of bile acids in the liver, intestine and kidney regulate repair mechanisms that modulate inflammation and fibrosis (scarring), which can lead to progressive organ damage.

The biological effects of bile acids are mediated through dedicated receptors. The best understood receptor is FXR, a nuclear receptor that regulates bile acid synthesis and clearance from the liver, thereby preventing excessive bile acid build-up in the liver, which may be toxic. As such, FXR is a target for the treatment of several liver diseases such as PBC that involve impaired bile flow, a condition called cholestasis. In cholestasis, the liver is typically exposed to higher than normal levels of bile acids, which can cause significant damage over time. In addition, bile acid activation of FXR is believed to induce anti-fibrotic, anti-inflammatory, anti-steatotic and other mechanisms that are necessary for the normal regeneration of the liver. As a result, FXR is also a target for the treatment of more common liver diseases such as NASH and alcoholic hepatitis. Further, based on the discovery of similar FXR-mediated protective mechanisms in other organs exposed to bile acids, we believe that FXR may also be a potential target for the treatment of a number of intestinal, kidney and other diseases.

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 FXR. We believe that OCA has broad liver-protective properties and may effectively counter a variety of chronic insults to the liver that cause fibrosis (scarring), which can eventually lead to cirrhosis, liver transplant and death. Due to OCA's bile acid-like properties, it circulates enterohepatically and engages FXR in both the liver and intestine. FXR engagement in the liver is believed to be critical to successfully treat pathologic injury due to progressive underlying disease.

By virtue of our patent portfolio and the proprietary know-how of our employees and collaboration partners, we believe that we hold a leading position in the fields of bile acid chemistry and therapeutics. Our research and development efforts have resulted in a pipeline of bile acid analogs in addition to OCA and through our on-going work with our collaboration partners such as Professor Roberto Pellicciari, Ph.D., one of our co-founders, and TES Pharma S.r.l., we are continuing our research to rationally design compounds that bind selectively and potently to FXR and other bile acid receptors.

**Our Strategy**

Our objective is to develop and commercialize novel therapeutics for the treatment of progressive non-viral liver diseases with high unmet medical need. The key elements of our strategy are to:

- *Further strengthen our foundational PBC business.* We intend to further strengthen our foundational PBC business through expanding access to Ocaliva to eligible patients by increasing Ocaliva's penetration in the markets where it has been approved and pursuing regulatory approval for Ocaliva in our target markets where it has not yet been approved. In addition, we continue to work to execute on our post-marketing regulatory commitments with respect to Ocaliva in the U.S. and Europe.

- *Execute on our clinical and regulatory goals and timelines*. We remain focused on progressing our development program in liver fibrosis due to NASH in the United States and Europe and are working to potentially resubmit our NDA to the FDA by the end of 2021. We also expect to continue REGENERATE through clinical outcomes and to progress our Phase 3 REVERSE trial for NASH patients with compensated cirrhosis. We also plan to advance our Phase 2 study evaluating bezafibrate in combination with OCA for PBC as part of a broader early development program.

- *Expand our portfolio and pipeline*. We intend to identify additional opportunities to develop OCA and our other product candidates, alone or in combination, in rare liver diseases. In addition, we intend to initiate a first-in-human clinical trial of our INT-787 compound, which is an FXR agonist that we are currently evaluating in preclinical studies

- *Expand and protect our intellectual property.* We intend to continue to expand and aggressively prosecute our intellectual property in the area of bile acid chemistry and therapeutics with the objective of maintaining a valuable intellectual property portfolio and to vigorously defend and enforce our intellectual property rights protecting Ocaliva.

**History and Development of the Company**

In September 2002, we were incorporated in Delaware and shortly thereafter began operations in New York. In October 2012, following several rounds of private funding, we completed our initial public offering (the "IPO") and received net proceeds of approximately $78.7 million therefrom. We used the proceeds from our IPO to fund, among other things, preclinical and clinical development activities, including our Phase 3 POISE trial studying OCA for PBC and work performed in anticipation of our submission of regulatory filings for the approval of OCA for PBC. In addition, between June 2013 and April 2015, we completed four registered public offerings of our common stock and received aggregate net proceeds of approximately $803.4 million therefrom.

In March 2014, we announced the results of our Phase 3 POISE trial of OCA for PBC. In November 2014, results from the FLINT Phase 2b clinical trial of OCA for liver fibrosis due to NASH were published in *The Lancet*. Both of these trials met their primary endpoints.

In June 2015, we submitted a NDA to the FDA seeking accelerated approval of OCA for PBC and a MAA to the EMA seeking conditional approval of OCA for PBC. In September 2015, we announced the initiation of our Phase 3 REGENERATE trial of OCA in patients with liver fibrosis due to NASH.

In May 2016, Ocaliva was approved for PBC by the FDA. We commenced sales and marketing of Ocaliva in the United States shortly after receiving approval. In July 2016, we issued and sold $460.0 million aggregate principal amount of 3.25% Convertible Senior Notes due 2023 (the "2023 Convertible Notes") in a registered public offering and received net proceeds of approximately $447.6 million therefrom. In December 2016, Ocaliva received conditional approval for PBC from the European Commission.

In January 2017, we commenced our European launch of Ocaliva for PBC. Since January 2017, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada,

Israel and Australia, and we are pursuing marketing approval of Ocaliva for PBC in our other international target markets. In July 2017, we announced positive results from our Phase 2 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, as well as positive top-line results from our Phase 2 AESOP trial of OCA for primary sclerosing cholangitis ("PSC").

In February 2018, we announced our Phase 3 REVERSE trial of OCA for liver fibrosis due to NASH patients with compensated cirrhosis. In April 2018, we issued and sold an aggregate of approximately 4.3 million shares of common stock in a registered public offering and a concurrent private placement (the "2018 Concurrent Private Placement") exempt from the registration requirements of the Securities Act of 1933, as amended, and received net proceeds of approximately $261.4 million therefrom. In December 2018, we entered into an agreement (the "Aralez Agreement") with Aralez Pharmaceuticals Canada Inc. ("Aralez"), pursuant to which we acquired (i) Aralez's license to develop and commercialize bezafibrate in the United States, (ii) Aralez's investigational new drug application ("IND") on file with the FDA and other associated regulatory documentation and (iii) a non-exclusive license to certain of Aralez's intellectual property. We are evaluating the efficacy, safety and tolerability of bezafibrate in combination with OCA in patients with PBC in a Phase 2 study, with the longer-term goal of developing and seeking regulatory approval for a fixed dose combination regimen in this indication and potentially other liver diseases.

In February 2019, we announced topline results from our pivotal Phase 3 REGENERATE trial in patients with liver fibrosis due to NASH. In the primary efficacy analysis, once-daily OCA 25 mg met the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH at the planned 18-month analysis. Adverse events were generally mild to moderate in severity and the most common were consistent with the known profile of OCA.

In May 2019, we issued and sold $230.0 million aggregate principal amount of 2.00% Convertible Senior Notes due 2026 (the "2026 Convertible Notes" and together with the 2023 Convertible Notes, the "Convertible Notes") in a registered public offering and received net proceeds of approximately $223.4 million therefrom. In May 2019, we issued and sold 2,760,000 shares of common stock in a registered public offering ("the 2019 Public Offering") and 119,760 shares of common stock in a concurrent private placement of common stock (the "2019 Concurrent Private Placement") and received net proceeds of approximately $227.3 million.

In September 2019, we submitted a NDA to the FDA seeking accelerated approval of OCA for liver fibrosis due to NASH. In November 2019, the FDA accepted our NDA for filing and granted a priority review designation for OCA for liver fibrosis due to NASH. Under PDUFA, the FDA has set a target action date of June 26, 2020 for the completion of its review of our NDA, after giving effect to a 90-day extension of its initial target action date. The FDA has also notified us that it has tentatively scheduled an advisory committee meeting relating to our NDA for April 22, 2020.

In December 2019, we submitted a MAA to the EMA seeking conditional approval of OCA for liver fibrosis due to NASH. In January 2020, the EMA validated our MAA and thereby confirmed that our MAA was sufficiently complete to begin the formal review process.

In June 2020, we received a complete response letter ("CRL") from the FDA stating that our NDA for OCA for the treatment of liver fibrosis due to NASH could not be approved in its present form. The CRL indicated that, based on the data the FDA had reviewed, the FDA has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. At that time, the FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE trial in support of potential accelerated approval and that the long-term outcomes phase of the trial should continue.

In October 2020, we had our end of review meeting with the FDA to discuss the FDA's risk-benefit assessment in the CRL based on its review of the available data, as well as our proposed resubmission of our NDA for the treatment of liver fibrosis due to NASH. The meeting was constructive and the FDA has provided us with helpful guidance regarding supplemental data we can provide to further characterize OCA's efficacy and safety profile that could support resubmission based on our Phase 3 REGENERATE 18-month biopsy data, together with a safety update from our ongoing studies.

In December 2020, we announced that Mark Pruzanski, M.D. would retire from his position as President and Chief Executive Officer and that Jerome (Jerry) Durso, our Chief Operating Officer at the time, would succeed Dr. Pruzanski as our President and Chief Executive Officer, effective as of January 1, 2021. We also announced that Mr. Durso would be appointed to the Board of Directors (the "Board") following the transition and that Dr. Pruzanski would remain as a director on the Board and retained adviser to us.

For information regarding our financial condition and results of operations, including our revenues, net loss and total assets, see our audited consolidated financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.

**Our First Approved Product**

***Ocaliva***

Ocaliva was approved for PBC by the FDA in May 2016 under the accelerated approval pathway. We commenced sales and marketing of Ocaliva in the United States shortly after receiving approval, and Ocaliva is now available to U.S. patients primarily through a network of specialty pharmacy distributors. Ocaliva received conditional approval for PBC from the European Commission in December 2016 and we commenced our European commercial launch in January 2017. We have submitted dossiers and obtained, or are otherwise pursuing, reimbursement from a number of national authorities in Europe. Since January 2017, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada, Israel and Australia, and we are pursuing marketing approval of Ocaliva for PBC in our other international target markets. Ocaliva received orphan drug designation in both the United States and the European Union for the treatment of PBC.

***Overview of PBC***

PBC is a rare liver disease that primarily results from autoimmune destruction of the bile ducts that transport bile acids out of the liver, resulting in cholestasis. The build-up of bile acids in the liver damages liver cells. These damaged liver cells, in turn, release abnormal amounts of serum alkaline phosphatase ("ALP"), a liver enzyme that is a key biomarker of the disease pathology. As shown in numerous clinical trials of treatment with UDCA (available generically as ursodiol), a positive therapeutic response is primarily determined by sustained reduction of ALP levels, along with maintenance of normal bilirubin levels, indicating adequately compensated liver function. This biochemical improvement has been shown to correlate well with improved clinical outcomes such as transplant-free survival. As the disease progresses, it causes progressive liver damage marked by chronic inflammation and fibrosis. Despite its rarity, PBC is the most common cholestatic liver disease and is among the leading indications for liver transplant among women in the United States. Disease progression in PBC varies significantly, with median survival in untreated patients estimated to be 7.5 years if symptomatic at diagnosis and up to 16 years if asymptomatic at diagnosis. PBC patients whose disease is progressing have persistently elevated levels of ALP and other liver enzymes, with abnormal bilirubin levels heralding more advanced disease. Data from published long-term studies demonstrate that a significant portion of such patients with advancing disease progress to liver failure, transplant or death within five to ten years.

Based on our analysis of 2016 industry data, there were approximately 290,000 people with PBC at the time of our U.S. launch in the United States, certain European countries, Canada, Australia and New Zealand. An estimated 90% of PBC patients are women, with approximately one in 1,000 women over the age of 40 afflicted by the disease. The mean age of diagnosis is about 40 years old and the typical initial presentation occurs between the ages of 30 and 65 years old. A majority of PBC patients are asymptomatic at the time of initial diagnosis, but most develop symptoms over time. Fatigue and pruritus are the most common symptoms in PBC patients. Less common symptoms include dry eyes and mouth, as well as jaundice, which can be seen in more advanced disease. Based on the guidelines of the American Association for the Study of Liver Disease and the European Association for the Study of the Liver, the clinical diagnosis of PBC is established based on the presence of (i) a positive antimitochondrial antibody ("AMA"), a marker of this autoimmune disease seen in up to 95% of PBC patients and (ii) elevated serum levels of ALP. In the earlier stages of PBC, ALP is often the only abnormally elevated liver enzyme, rising to between two to ten times higher than normal values. Bilirubin is a marker of liver function and is also monitored in PBC to provide an indication of how well the liver is

functioning. Liver biopsy can be used to confirm the diagnosis of PBC, but is not required and is becoming less-frequently performed.

A number of published clinical studies have demonstrated that lower levels of ALP, both independently or in conjunction with normal bilirubin levels, correlate with a significant reduction in adverse clinical outcomes such as liver transplant and/or death in PBC patients. These studies include the result of meta-analyses of PBC clinical outcomes data of more than 6,000 PBC patients from 15 academic centers in eight countries that have been compiled by the Global PBC Study Group, which we sponsored, as well as a dataset of over 6,000 PBC patients across the United Kingdom compiled by the UK PBC Group.

Prior to Ocaliva, the only approved drug indicated for the treatment of PBC was UDCA, which is widely considered the standard first-line therapy for PBC patients. In patients for whom UDCA is effective, the treatment slows the progression of PBC, reducing the likelihood of liver failure and the need for transplant.

***Phase 3 POISE Trial***

Ocaliva's accelerated approval in the United States and conditional approval in the European Union was supported by the results of our Phase 3 POISE trial, which was completed in March 2014. The data from the POISE trial showed that Ocaliva, at both a once-daily 10 mg dose and a once-daily 5 mg dose titrated to 10 mg, met the trial's primary endpoint of achieving a reduction in ALP to below a threshold of 1.67 times the upper limit of normal ("ULN"), with a minimum of a 15% reduction in ALP level from baseline, and a normal bilirubin level after 12 months of therapy. The percentage of patients meeting the POISE trial's primary endpoint was 10% in the placebo group, 47% in the 10 mg Ocaliva group and 46% in the Ocaliva titration group (both dose groups $p < 0.0001$ as compared to placebo) in an intent-to-treat analysis. The placebo group experienced a mean decrease in ALP from baseline of 5%, compared to a mean decrease of 39% in the 10 mg Ocaliva dose group and 33% in the Ocaliva titration group (both dose groups $p < 0.0001$ as compared to placebo). Pruritus, generally mild to moderate, was the most frequently reported adverse event associated with Ocaliva treatment and was observed in 38% of patients on placebo, 70% of patients in the 10 mg Ocaliva group and 56% of patients in the Ocaliva titration group. Eight patients discontinued due to pruritus, of whom none were in the placebo group, seven (10%) were in the 10 mg Ocaliva group and one (1%) was in the Ocaliva titration group. Decreases in high density lipoprotein ("HDL") cholesterol were also observed during treatment.

Following the completion of the double-blind portion of the POISE trial described above, patients were given the option to enroll in a five-year open-label long-term safety and efficacy extension trial, which has been completed. Patients received Ocaliva at a once-daily 5 mg dose for three months, after which patients were titrated based on tolerability. The data from the open-label extension portion of the trial showed that 46% of patients responded after 12 months of treatment with Ocaliva and 50% to 56% of patients responded after 48 to 72 months of treatment with Ocaliva (based on the same criteria used to define the primary endpoint in the 12 month placebo controlled trial). Reductions in ALP were sustained through the double-blind and extension portions of the trial and total bilirubin levels remained stable and within the normal range for most patients for the duration of the trial (ALP $p < 0.0001$ for all post-baseline visits; total bilirubin: p-values were not consistently significant throughout the extension portion of the POISE trial). Adverse events were consistent with the safety profile of Ocaliva in patients with PBC. The most commonly reported adverse events were pruritis and fatigue, which were generally mild to moderate in severity.

***Ongoing Confirmatory Clinical Outcomes Trial and Other Post Marketing Requirements***

In connection with Ocaliva's accelerated approval in the United States and conditional approval in the European Union, we committed to conduct a Phase 4 confirmatory outcomes trial of Ocaliva, known as the COBALT trial, and other clinical trials to satisfy post-marketing regulatory requirements. Continued approval of Ocaliva for PBC in the United States, the European Union and other jurisdictions is contingent upon the verification and description of clinical benefit in the COBALT trial and our satisfaction of our other post-marketing regulatory requirements. Any delay or failure by us to satisfy such requirements, including any delay or failure relating to our Phase 4 COBALT trial, may jeopardize the continued approval of Ocaliva for PBC in the United States, European Union and other jurisdictions.

The goal of the COBALT trial is to confirm that reduction of ALP based upon Ocaliva treatment is associated with a longer-term benefit on liver-related clinical outcomes. COBALT is designed to assess the effect of a once-daily dose of 5 mg or 10 mg of Ocaliva in approximately 430 PBC patients with an inadequate therapeutic response to UDCA or who are unable to tolerate UDCA. In this trial, eligible patients with PBC continue their UDCA treatment, except for those patients unable to tolerate UDCA, have been randomized into one of two treatment arms of approximately 215 patients each. Patients have been randomized to receive either (i) placebo or (ii) Ocaliva starting at 5 mg and increasing over the course of the trial to 10 mg of Ocaliva based on tolerability. Dosing frequency has been determined by disease stage. The primary endpoint of the trial is based on clinical outcomes as measured by time to first occurrence of any of the following adjudicated events: death (all-cause), liver transplant, Model of End Stage Liver Disease ("MELD") score greater than 15, uncontrolled ascites or hospitalization due to variceal bleeding, hepatic encephalopathy or spontaneous bacterial peritonitis. The study evaluates subjects across the spectrum of PBC disease, including early and advanced PBC.

Further, as part of our post-marketing requirements for Ocaliva, we are undertaking a Phase 4 clinical trial of Ocaliva in patients with PBC who have moderate to severe hepatic impairment (Child-Pugh B and C) (known as the 401 trial). This double-blind, placebo-controlled study is designed to evaluate the pharmacokinetics of Ocaliva and its conjugates, as well as safety and tolerability. Additional objectives include an evaluation of Ocaliva treatment compared to placebo on liver biochemistry, Child-Pugh scores and non-invasive markers of liver fibrosis and stiffness. The trial as designed is targeted to enroll approximately 50 patients in the United States, Europe and other jurisdictions for 48 weeks.

While we remain blinded to safety and efficacy data in the ongoing COBALT trial and 401 trial, a data monitoring committee ("DMC") reviewed the unblinded results of a pre-specified interim efficacy analysis of the COBALT trial and separately reviewed unblinded safety and pharmacokinetic data from both the COBALT and 401 trials. Following these reviews, the DMC stated that it was not feasible to continue the COBALT trial as designed and noted the challenges in enrolling and maintaining placebo-controlled post-marketing studies in this rare disease setting. No acute safety concerns were noted by the DMC. Given the feasibility concerns noted by the DMC as well as the potential confounding impact of subjects discontinuing treatment and/or transitioning from investigational product to commercial drug during clinical trials, we continue to discuss with the FDA and the EMA proposed modifications to the COBALT trial as well as proposals with respect to the 401 trial. We have notified the FDA and the EMA of the DMC's recommendation and, as they previously advised, are in ongoing discussions with the FDA on the matter and are seeking formal EU scientific advice with respect to potential alternative study designs. In addition, future changes to our Ocaliva label related to the most advanced PBC patients will influence the modifications to our study design. Both the COBALT and 401 trials are ongoing but not currently enrolling patients.

We are also undertaking a Phase 2 clinical trial of Ocaliva in pediatric patients with biliary atresia, a life-threatening condition in infants in which the bile ducts inside or outside the liver do not have normal openings. This trial, known as the CARE trial, is a part of an EMA-approved Pediatric Investigation Plan ("PIP") supporting the conditional approval of Ocaliva for PBC in the European Union as PBC is not believed to occur in the pediatric population. The CARE trial is designed to evaluate the effects of 11 weeks of Ocaliva treatment where patients with biliary atresia are randomized to varying doses. The primary endpoint is to evaluate the pharmacokinetics and the safety and tolerability of Ocaliva treatment. In addition, Ocaliva's effect on hepatobiliary indices and biomarkers will be assessed. This trial is targeted to enroll approximately 60 patients in the United States and Europe.

***Ocaliva Label Update***

In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. As a result, in September 2017, we issued a Dear Health Care Provider ("DHCP") letter, and the FDA also subsequently issued its own drug safety communication to reinforce recommended label dosing. Both communications remind healthcare providers of the importance of the recommended reduced dosing of Ocaliva in PBC patients with moderate or severe hepatic impairment, while reiterating the importance of monitoring PBC patients for progression of their disease and the occurrence of liver-related adverse reactions. In addition to the DHCP letter, we took actions to enhance education about appropriate use of Ocaliva. These initiatives included: reeducating physicians on the label, with a focus on ensuring appropriate dosing for patients with moderate or severe hepatic

impairment; enhancing monitoring of patients for liver-related adverse reactions; and adjudicating reported cases of serious liver injury, including in patients with no or mild hepatic impairment.

In February 2018, we announced that the Ocaliva label in the United States had been updated by the FDA to include a boxed warning and a dosing table that reinforced the then-existing dosing schedule for patients with Child-Pugh Class B or C or decompensated cirrhosis. In addition, the FDA issued an updated drug safety communication to accompany the revised label. We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis.

The FDA has notified us that, in the course of its routine safety surveillance, in May 2020 the FDA began to evaluate a newly identified safety signal, or NISS, regarding liver disorder for Ocaliva which the FDA classified as a potential risk. The FDA has informed us that its review of the NISS is focused on a subset of the cirrhotic, or more advanced, PBC patients who have taken Ocaliva. As part of our routine pharmacovigilance efforts, we worked with the FDA to reconcile our internal safety database with the FDA Adverse Event Reporting System database and we completed a comprehensive assessment of all available data, including data from our completed clinical trials, blinded reviews of ongoing clinical trial data, unblinded reviews of certain ongoing clinical trial data by the DMC, post-marketing data and natural history data, which we submitted to the FDA and had a meeting earlier in 2021 to discuss. We are working with the FDA to align on changes to the Ocaliva label regarding patients with the most advanced stages of PBC. Based on our communications with the FDA, this update will come in the form of a safety labeling change. These communications are ongoing.

**Our Product Candidates**

The following summarizes the current status and the anticipated next steps in our development plans for our product candidates. We continually evaluate each product candidate in an effort to efficiently allocate research and development funds to projects we deem to be in our best interests based on, among other factors, the product candidate's performance in pre-clinical and/or clinical studies, our expectations regarding the potential future regulatory approval of the product candidate and our view of the potential commercial viability of the product candidate in light of market conditions.

***OCA for liver fibrosis due to NASH***

Our lead product candidate is OCA for the potential treatment of liver fibrosis due to NASH. In February 2019, we announced topline results from the planned 18-month interim analysis of our pivotal Phase 3 clinical trial of OCA in patients with liver fibrosis due to NASH, known as the REGENERATE trial. In the primary efficacy analysis, once-daily OCA 25 mg met the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH at the planned 18-month interim analysis. Adverse events were generally mild to moderate in severity and the most common were consistent with the known profile of OCA. OCA has received breakthrough therapy designation from the FDA for the treatment of NASH patients with liver fibrosis. In September 2019, we submitted a NDA seeking accelerated approval of OCA for liver fibrosis due to NASH in the United States and, in December 2019, we submitted a MAA seeking conditional approval of OCA for liver fibrosis due to NASH in Europe. The FDA subsequently accepted our NDA for filing and granted a priority review designation for OCA for liver fibrosis due to NASH. In January 2020, the EMA validated our MAA and thereby confirmed that our MAA was sufficiently complete to begin the formal review process. In June 2020, we received a complete response letter ("CRL") from the FDA stating that our NDA for OCA for the treatment of liver fibrosis due to NASH could not be approved in its present form. The CRL indicated that, based on the data the FDA had reviewed, the FDA has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. At that time, the FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE trial in support of potential accelerated approval and that the long-term outcomes phase of the trial should continue. In October 2020, we had our end of review meeting with the FDA to discuss the FDA's risk-benefit assessment in the CRL based on its review of the available data, as well as our proposed resubmission of our NDA for the treatment of liver fibrosis due to NASH. The meeting was constructive and the FDA has provided us with helpful guidance regarding supplemental data we can provide to further characterize OCA's efficacy and safety profile that could support resubmission based on our Phase 3 REGENERATE 18-month biopsy data, together with a safety update from our ongoing studies. We are advancing

accordingly and plan to hold additional meetings with the FDA with the goal of achieving sufficient alignment to proceed on this basis and potentially resubmit our NDA for the treatment of liver fibrosis due to NASH by the end of 2021. We also continue to work collaboratively with the EMA on its review of our MAA. In addition, we have conducted a number of other trials and studies in connection with our NASH development program, and our Phase 3 trial in NASH patients with compensated cirrhosis, known as the REVERSE trial, is ongoing.

***Overview of NASH***

NASH is a serious progressive liver disease caused by excessive fat accumulation in the liver (steatosis) that induces chronic inflammation, resulting in progressive fibrosis (scarring) that can lead to cirrhosis, eventual liver failure, cancer and death. More than 20% of patients with NASH are estimated to progress to cirrhosis within a decade of diagnosis and, compared to the general population, have a ten-fold greater risk of liver-related mortality. The proportion of liver transplants attributable to NASH has increased rapidly in recent years with NASH currently the second leading cause of liver transplantation in the United States and, in females, the leading cause. NASH is anticipated to become the leading indication for liver transplantation in Europe within the next decade. Additionally, NASH is now considered to be the leading, and a rapidly increasing, cause of hepatocellular carcinoma (primary liver cancer), of which up to 40% of cases in NASH patients develop prior to developing cirrhosis.

Although difficult to precisely estimate, epidemiology research estimates that the global prevalence of NASH is approximately 3 – 5% and is expected to increase markedly by 2030. Fibrosis is the most robust predictor of long-term overall mortality, liver transplantation and liver-related events in patients with NASH and advanced fibrosis is associated with a substantially higher risk of liver-related morbidity and mortality in patients with NASH. We believe that a majority of NASH patients diagnosed and under specialist care have fibrosis of stage 2 or greater. Although the prevalence of NASH is lower in children, it has also become a serious disease burden in the pediatric population. Other common co-existing conditions such as obesity and type 2 diabetes, which are present in a majority of NASH patients, raise important risks. NASH has been linked in both developed and developing countries to the adoption of a Western diet, with increased consumption of processed foods containing polyunsaturated fatty acids and fructose.

Generally in clinical trials in NASH, a definitive diagnosis requires a histologic assessment of a liver biopsy for several key features associated with NASH, including, but not limited to, steatosis, lobular inflammation and hepatocyte ballooning. However, we believe that the majority of NASH patients currently under treater care have been assessed for liver fibrosis without a liver biopsy. Several imaging and circulating biomarkers are being investigated as non-invasive diagnostic methods, including transient elastography (an ultrasound technology approved in the United States and Europe for the measurement of liver fibrosis), magnetic resonance imaging and serum biomarkers. NASH diagnosis rates in the United States and the EU5 countries are very low, owing to a lack of approved treatment options and a lack of validated non-invasive diagnosis options. We believe the availability of novel therapeutics and non-invasive technologies will be instrumental in improving diagnosis rates.

There are currently no medications approved for the treatment of NASH in the United States or Europe. However, various therapeutics are used “off-label”, such as vitamin E (an antioxidant), insulin sensitizers (e.g., metformin, pioglitazone), pentoxifylline and UDCA. Lifestyle changes, including modification of diet and exercise to reduce body weight, as well as treatment of concomitant diabetes and dyslipidemia, are commonly accepted as the standard of care, but have not conclusively been shown to prevent disease progression. Although some of the off-label treatments described above have been studied as possible treatments for NASH, none has been approved by the FDA or EMA as a treatment for this disease. Currently, treatment options for NASH patients with advanced cirrhosis are limited. Although liver transplant can be life-saving, many patients fail to receive a donor organ in time, and for those who do, there are very significant clinical risks, such as infection and organ rejection, as well as significant costs. In addition, the post-transplant recurrence rate of NASH has been shown to be as high as 25% at 18 months. Given the lack of available treatment options, we believe that there is a significant unmet need for novel therapies for NASH, particularly in those patients with advanced fibrosis and cirrhosis and those with a high risk of disease progression due to other co-morbidities such as type 2 diabetes.

FXR activation has been shown to play a key role in the regulation of the metabolic pathways relevant to NASH, highlighting FXR as a potential drug target for treatment of the disease. Given the significant unmet medical need of patients with NASH, we believe that the ability of OCA to potently activate FXR has the potential to convey clinical

benefit by improving key histologic parameters of the disease. This is supported by our preclinical and clinical results to date, and is being further investigated in our ongoing clinical trial program.

***Phase 3 REGENERATE Trial***

We are currently conducting a pivotal Phase 3 clinical trial of OCA in patients with liver fibrosis due to NASH, known as the REGENERATE trial. REGENERATE is a randomized, double-blind, placebo-controlled, multicenter study assessing the safety and efficacy of OCA on liver-related clinical outcomes in patients with liver fibrosis due to NASH. Patients with biopsy proven NASH with fibrosis are randomized 1:1:1 to receive placebo, OCA 10 mg or OCA 25 mg once daily. In August 2019, we announced the completion of the enrollment of the clinical outcomes cohort of REGENERATE, with 2,480 adult NASH patients with fibrosis randomized at over 300 qualified centers worldwide. REGENERATE will continue through clinical outcomes for verification and description of clinical benefit. The end-of-study analysis will evaluate the effect of OCA on all-cause mortality and liver-related clinical outcomes.

An 18-month interim analysis was conducted to assess the effect of OCA in liver histology comparing month 18 biopsy with baseline. Patients without a repeat biopsy due to study discontinuation or other reason were treated as non-responders in the primary efficacy analysis and full efficacy analysis (each as described below). A smaller exploratory cohort of patients with stage 1 liver fibrosis and at least one accompanying comorbidity (specified as diabetes, obesity or alanine transaminase (“ALT”) greater than 1.5 times ULN) were also enrolled in REGENERATE, but were not included in the primary efficacy analysis. As described below, these patients were included in the full efficacy analysis and safety analysis. The end-of-study analysis will evaluate the effect of OCA on all-cause mortality and liver-related clinical outcomes.

In February 2019, we announced topline results from the REGENERATE trial. In the primary efficacy analysis, once-daily OCA 25 mg met, with statistical significance, the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH (defined as no worsening of hepatocellular ballooning, no worsening of lobular inflammation and no worsening of steatosis) at the planned 18-month analysis and adverse events were generally mild to moderate in severity and the most common were consistent with the known profile of OCA. Although a numerically greater proportion of patients in both OCA treatment arms compared to placebo achieved the primary endpoint of NASH resolution with no worsening of liver fibrosis in the primary efficacy analysis, this result did not reach statistical significance. NASH resolution is defined as the overall histopathologic interpretation of (i) no fatty liver disease or (ii) fatty liver disease (simple or isolated steatosis) without steatohepatitis AND a nonalcoholic fatty liver disease (“NAFLD”) activity score (“NAS”) of 0 for ballooning and 0-1 for inflammation. As agreed with the FDA, in order for the primary objective to be met, the study was required to achieve one of the two primary endpoints. In November 2019, the results of the 18-month interim analysis from the REGENERATE trial were published in *The Lancet*.

The “primary efficacy analysis” (Intent-to-Treat or “ITT”) assessed efficacy at 18 months in 931 patients with stage 2 or 3 liver fibrosis due to NASH. Overall study discontinuations in the primary efficacy analysis population were balanced across treatment arms: 16% in placebo, 17% in OCA 10 mg and 15% in OCA 25 mg. An additional pre-specified “full efficacy analysis” at 18 months added an exploratory cohort of 287 NASH patients with stage 1 liver fibrosis and additional risk factors who were at increased risk of progression to cirrhosis (N = 1,218).

Set forth below is a summary of the 18-month primary efficacy analysis and additional full efficacy analysis from the REGENERATE trial.

*Fibrosis Improvement at Month 18*

| **Primary Efficacy Analysis (ITT population: NASH with stage 2 and 3 liver fibrosis)** | **Placebo n = 311** | **OCA 10 mg n = 312** | **OCA 25 mg n= 308** |
|---|---|---|---|
| **Fibrosis improvement (≥ 1 stage) with no worsening of NASH*** | **11.9%** | **17.6% p = 0.0446** | **23.1% p = 0.0002**** |
| Additional Full Efficacy Analysis (ITT population plus stage 1 liver fibrosis patients) | Placebo n=407 | OCA 10 mg n = 407 | OCA 25 mg n = 404 |
| Fibrosis improvement (≥ 1 stage) with no worsening of NASH* | 10.6% | 15.7% p = 0.0286 | 21% p < 0.0001 |
| * Defined as no worsening of hepatocellular ballooning, no worsening of lobular inflammation and no worsening of steatosis. | | | |
| ** Statistically significant in accordance with the statistical analysis plan agreed with the FDA. | | | |

*NASH Resolution at Month 18*

| **Primary Efficacy Analysis (ITT population: NASH with stage 2 and 3 liver fibrosis** | **Placebo n = 311** | **OCA 10 mg n = 312** | **OCA 25 mg n = 308** |
|---|---|---|---|
| **NASH resolution‡ with no worsening of liver fibrosis stage** | **8.0%** | **11.2% p = 0.1814** | **11.7% p = 0.1268** |
| Additional Full Efficacy Analysis (ITT population plus stage 1 liver fibrosis patients) | Placebo n = 407 | OCA 10 mg n = 407 | OCA 25 mg n = 404 |
| NASH resolution‡ with no worsening of liver fibrosis stage | 7.9% | 11.3% p = 0.0903 | 14.9% p = 0.0013 |
| ‡ Defined as the overall histopathologic interpretation of (i) no fatty liver disease or (ii) fatty liver disease (simple or isolated steatosis) without steatohepatitis AND a NAS of 0 for ballooning and 0-1 for inflammation. | | | |

The “safety population” in the planned 18-month analysis of REGENERATE included 1,968 randomized patients who received at least one dose of investigational product (OCA or placebo).

Adverse events were generally mild to moderate in severity and the most common were consistent with the known profile of OCA. The frequency of serious adverse events was similar across treatment arms (11% in placebo, 11% in OCA 10 mg and 14% in OCA 25 mg) and no serious adverse event occurred in > 1% of patients in any treatment arm. There were 3 deaths (2 in placebo: bone cancer and cardiac arrest, 1 in OCA 25 mg: glioblastoma) and none were considered related to treatment.

The most common adverse event reported was dose-related pruritus (19% in placebo, 28% in OCA 10 mg and 51% in OCA 25 mg). The large majority of pruritus events were mild to moderate, with severe pruritus occurring in a small number of patients (< 1% in placebo, < 1% in OCA 10 mg and 5% in OCA 25 mg). A higher incidence of pruritus associated treatment discontinuation was observed for OCA 25 mg (< 1% in placebo, < 1% in OCA 10 mg and 9% in OCA 25 mg). According to the clinical study protocol, investigator assessed severe pruritus mandated treatment discontinuation.

Consistent with observations from previous NASH studies, OCA treatment was associated with an increase in low density lipoprotein (“LDL”) cholesterol, with a peak increase of 22.6 mg/dL at four weeks and subsequently reversing and approaching baseline at month 18 (4.0 mg/dL increase from baseline). Statin therapy was initiated in 10% of placebo patients and 24% of each OCA treatment arm. Among OCA patients who initiated statins, LDL cholesterol increases reversed and fell to below baseline levels by month 6. Triglycerides rapidly and continually decreased in the OCA treatment arms through month 18. There were few and varied serious cardiovascular events and incidence was balanced across the three treatment arms (2% in placebo, 1% in OCA 10 mg and 2% in OCA 25 mg).

In patients with type 2 diabetes, OCA treatment was associated with an early transient increase in fasting glucose and hemoglobin A1c with return to levels similar to placebo by month 6. No clinically meaningful changes were noted in non-diabetic patients.

With respect to hepatobiliary events, more patients (3%) on OCA 25 mg experienced gallstones or cholecystitis compared to < 1% on placebo and 1% on OCA 10 mg. While numerically higher in the OCA 25 mg treatment arm, serious hepatic adverse events were uncommon with < 1% incidence in each of the three treatment arms.

***Phase 3 REVERSE Trial***

We are currently conducting a Phase 3 clinical trial in NASH patients with compensated cirrhosis, known as the REVERSE trial. REVERSE is a randomized, double-blind, placebo-controlled, multicenter trial evaluating the safety and efficacy of OCA in NASH patients with compensated cirrhosis. In January 2020, we announced that we completed enrollment of the REVERSE trial with over 900 patients with a biopsy-confirmed diagnosis of cirrhosis due to NASH randomized.

The primary endpoint for REVERSE is the percentage of subjects with histological improvement in fibrosis by at least one stage with no worsening of NASH using the NASH Clinical Research Network scoring system after 18 months of treatment. Patients are randomized 1:1:1 into one of three treatment arms receiving a once-daily dose of placebo, OCA 10 mg or OCA 10 mg for the first three months with titration in accordance with the study protocol up to OCA 25 mg for the remaining study period. Patients who successfully complete the double-blind phase of REVERSE will be eligible to enroll in an open-label extension phase for up to 12 additional months.

***Phase 2 CONTROL Trial***

In December 2015, we initiated a Phase 2 clinical trial, known as the CONTROL trial, to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. CONTROL enrolled approximately 80 NASH patients who were naïve to statin therapy or had undergone a statin washout period. Statin-naïve or washout patients were randomized to receive one of three doses of OCA (5 mg, 10 mg or 25 mg) or placebo. The study included a 16-week double-blind phase followed by an optional long-term safety extension (“LTSE”).

In July 2017, we announced that CONTROL met its primary objective by showing that newly initiated treatment with atorvastatin rapidly reversed OCA-associated increases in LDL cholesterol 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. OCA treatment in the absence of statin therapy over the first four weeks resulted in an increase in LDL cholesterol 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 cholesterol 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 OCA 5 mg group, 10% of patients in the OCA 10 mg group and 55% of patients in the OCA 25 mg group. All adverse events were mild to moderate and two patients discontinued treatment in the OCA 25 mg group due to pruritus. Over 95% of the patients completing the double-blind phase of CONTROL enrolled in the LTSE phase of the trial. During the LTSE phase of CONTROL, there was one patient death, which the principal investigator determined was unlikely related to OCA.

***Phase 2 Sumitomo Dainippon Trial***

In October 2015, we announced the results of a 72-week Phase 2 dose ranging trial of OCA in 200 adult patients with NASH in Japan. The trial was conducted by our former collaborator, Sumitomo Dainippon Pharma Co., Ltd. (“Sumitomo Dainippon”). In this trial, 202 Japanese biopsy-proven NASH patients (NAS of 5-8) were randomized into one of four arms to receive either a 10 mg, 20 mg or 40 mg dose of OCA or placebo, and 200 of these patients (50 per group) initiated treatment for a 72-week double-blind treatment phase, followed by a 24-week off treatment phase. The primary endpoint was histologic improvement defined as at least a two-point improvement in NAS with no worsening of fibrosis.

The primary efficacy analysis was conducted on an ITT basis, testing the dose dependent effects of once daily OCA (10 mg, 20 mg and 40 mg) versus placebo on the primary endpoint. The ITT analysis included all randomized patients who received treatment (50 per group), and patients who discontinued or did not have a repeat biopsy were treated as non-responders. A pre-specified completer analysis was conducted on the patients who had biopsies at both baseline and 72 weeks (45, 44, 44 and 37 patients in the placebo, OCA 10 mg, OCA 20 mg and OCA 40 mg groups, respectively).

The Sumitomo Dainippon trial did not meet statistical significance for the primary endpoint. The ITT results in the table below show a dose dependent increase in the percentage of OCA-treated patients compared to placebo who achieved the primary endpoint (p = 0.053). Dose-dependent trends not reaching statistical significance were observed for several other pre-specified histologic endpoints, including the percentage of patients with steatosis and inflammation improvement, ballooning resolution and NASH resolution. No difference was seen in fibrosis improvement in the OCA groups compared to placebo.

| ITT Results | Placebo N = 50 | OCA 10 mg N = 50 | OCA 20 mg N = 50 | OCA 40 mg N = 50 | |
|---|---|---|---|---|---|
| NAS improvement > 2 points with | 10 (20%) | 11 (22%) | 14 (28%) | 19 (38%) | p = 0.053* |
| no worsening of fibrosis | | p = 0.8070** | p = 0.3378** | p = 0.0496** | |

* Primary efficacy analysis is a stratified Cochran-Armitage test with multiple contrast coefficients. Statistical significance is based on a p-value < 0.05.

** The secondary efficacy analysis is a Cochran-Mantel-Haenszel (“CMH”) test stratified by baseline fibrosis stage for Pairwise comparison of each OCA group compared to the placebo group. The multiplicity was not adjusted.

In the completer analysis, similar dose dependent effects were observed, with 51% of patients in the OCA 40 mg dose group compared to 22% in the placebo group meeting the primary endpoint (p = 0.0061).

With the exception of dose dependent pruritus, OCA appeared to be generally safe and well tolerated. The number of pruritus associated discontinuations were 0, 0, 2 and 5 patients in the placebo, OCA 10 mg, OCA 20 mg and OCA 40 mg groups, respectively. Changes in lipid parameters, including LDL cholesterol, HDL cholesterol and triglycerides, appeared to be consistent with previously reported lipid changes in Western NASH patients. No other meaningful differences in the rate of adverse events between the OCA and placebo groups were noted.

***Phase 2b FLINT Trial***

In November 2014, the results from a Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, which was sponsored by the NIDDK, a part of the National Institutes of Health, were published in *The Lancet.* The FLINT trial was a double-blind, placebo-controlled trial of a once-daily dose of OCA 25 mg or placebo given for 72 weeks in 283 patients with biopsy-proven NASH. OCA achieved the primary endpoint in the FLINT trial, which was defined as an improvement of two or more points in NAS with no worsening of liver fibrosis.

The percentage of patients meeting the primary histological endpoint, based on liver biopsies, in the FLINT trial was 45% in the OCA treatment group and 21% in the placebo group (p = 0.0002, n = 219). The mean pre-treatment baseline NAS for patients in the OCA treatment group was 5.3 of a total possible score of eight (comprised of a NAS of 0-2 for hepatocellular ballooning, 0-3 for lobular inflammation and 0-3 for steatosis). Subgroup analyses showed significant response rates in the OCA treatment group in patients with risk factors for disease progression, including baseline fibrosis stage, co-morbid type 2 diabetes mellitus, ALT, insulin resistance and severe obesity (each factor p < 0.05 for OCA compared to placebo based on 95% confidence interval of published odds ratios).

A significantly greater number of OCA-treated patients also achieved the secondary endpoint of improvement of at least one fibrosis stage (35% versus 19%, p = 0.004), with OCA showing greater response rates as compared to placebo across all stages of fibrosis. Based on our retrospective analyses of the FLINT data, more OCA-treated patients exhibited fibrosis improvement of at least two fibrosis stages (15% versus 6%, not significant) and exhibited fibrosis improvements regardless of baseline fibrosis stage and a significantly greater number of OCA-treated patients also achieved complete

resolution of fibrosis (17% versus 5%, p = 0.0018). Also, our retrospective analysis of the FLINT data showed that fewer OCA-treated patients progressed to bridging fibrosis (15% versus 18%, not significant) or to cirrhosis (2% versus 5%, not significant). Retrospective analyses after the unblinding of results can potentially introduce bias and regulatory authorities typically give greatest weight to results from pre-specified analyses as compared to retrospective analyses. The NASH Clinical Research Network fibrosis staging system was used to categorize the pattern of fibrosis and architectural remodeling of the liver: no fibrosis (F0), perisinuoidal or periportal fibrosis (F1), perisinusoidal and periportal fibrosis (F2), bridging fibrosis (F3) and cirrhosis (F4). Fibrosis sub-stages 1a, 1b and 1c were considered F1 for the analysis.

The secondary endpoint of NASH resolution, based on a global histological assessment, also showed improvement, although not statistically significant (22% versus 13%, p = 0.0832). A central reading of all baseline and end-of-trial biopsies was performed at the end of the trial, based on which only 80% of patients were confirmed to have definite NASH, while the remaining 20% were diagnosed as borderline NASH (10%) or not-NASH (10%). A retrospective subgroup analysis on the completer population comprised only of definite NASH patients at baseline showed that a significantly greater number of OCA-treated patients achieved NASH resolution compared with placebo-treated patients (19% versus 8%; p = 0.0278).

In an additional retrospective analysis of data from the FLINT trial conducted in a REGENERATE-matched patient cohort published in 2018, (i) approximately 40% of OCA-treated patients as compared to approximately 21% of patients on placebo achieved at least a one-stage improvement in liver fibrosis without any worsening of NASH (p = 0.02) and (ii) approximately 20% of OCA-treated patients as compared to approximately 7% of patients on placebo achieved NASH resolution with no worsening of fibrosis (p = 0.03) using the definition we selected for NASH resolution in the REGENERATE trial.

In the FLINT trial, more OCA-treated patients experienced significant improvements in the major histological features of NASH, including steatosis (61% versus 38%, p = 0.001), lobular inflammation (53% versus 35%, p = 0.006) and hepatocellular ballooning (46% versus 31%, p = 0.03), as compared to the placebo treatment group. Trends were similar between the two treatment groups for portal inflammation, which is not a component of NAS and is typically mild in adult NASH patients.

The histological improvements observed in OCA-treated patients versus placebo were accompanied by statistically significant reductions in relevant biochemical parameters, including the serum liver enzymes ALT (p < 0.0001), aspartate aminotransferase (“AST”) (p = 0.0001) and gamma-glutamyl transferase (“GGT”) (p < 0.0001), each of which were above generally accepted normal limits at baseline, and total bilirubin (p = 0.002). A modest but statistically significant increase in ALP (p < 0.0001) in the OCA treatment group was also observed, but levels remained within typical normal limits.

OCA treatment was associated with serum lipid changes, including increases in total cholesterol and LDL cholesterol and a decrease in HDL cholesterol, that developed within 12 weeks of treatment initiation, then reversed through the end of treatment and returned to baseline during the 24-week post-treatment follow-up phase. Based on these observations, lipid management was emphasized partway into the trial, using accepted guidelines. At 72 weeks as compared to baseline, the following effects were observed in the OCA treatment group: an increase in mean total cholesterol (0.16 mmol/L or 6 mg/dL increase OCA versus 0.19 mmol/L or 7mg/dL decrease placebo, p = 0.0009), an increase in mean LDL cholesterol (0.22 mmol/L or 9 mg/dL increase OCA versus 0.22 mmol/L or 8 mg/dL decrease placebo, p < 0.0001), a decrease in mean HDL cholesterol (0.02 mmol/L or 1 mg/dL decrease OCA versus 0.03 mmol/L or 1 mg/dL increase placebo, p = 0.01) and a decrease in triglycerides (0.22 mmol/L or 20 mg/dL decrease OCA versus 0.08 mmol/L or 7 mg/dL decrease placebo, p = 0.88, not significant). These changes in cholesterol levels, along with the achievement of predefined efficacy criteria, played a role in the decision of the FLINT data and safety monitoring board to terminate the treatment phase of the FLINT trial, and the publication of the FLINT results noted the need for further study of these changes.

A post-hoc analysis showed OCA-treated patients who initiated statins during the FLINT trial (n = 26) experienced a rapid reversal of their observed mean LDL cholesterol increase to below baseline levels, with a mean decrease after 72 weeks of treatment of -18.9 mg/dL. In contrast, other OCA-treated patients with no reported initiation or change in statin therapy experienced an increase in LDL cholesterol that peaked at week 12 and was sustained over the 72-week treatment period. Patients treated with statins at baseline who maintained statin treatment over the duration of the study (n = 50) experienced a mean LDL cholesterol increase of 8.7 mg/dL at 72 weeks. Patients not treated with statins during the study

(n = 65) experienced a mean LDL cholesterol increase of 16.0 mg/dL. Treatment related LDL cholesterol increases in all groups reversed with treatment discontinuation. This analysis suggests that the OCA-associated LDL cholesterol increase reaches a maximum peak and plateaus soon after initiation of therapy and that concomitant statin use in NASH patients receiving OCA may mitigate treatment-related LDL cholesterol increases.

In the FLINT trial, statistically significant weight loss of an average of 2.3 kilograms was observed in OCA patients compared to no weight loss in the placebo group ($p = 0.008$), and this weight loss reverted towards baseline during the 24-week follow-up phase. A pre-specified sensitivity analysis conducted by the investigators showed that weight loss was not a driver of the primary endpoint. An increase in a marker of hepatic insulin resistance known as homoeostasis model assessment – estimated insulin resistance ("HOMA-IR") (calculated using the product of fasting plasma insulin and glucose) was observed at 72 weeks in the OCA treatment group ($p = 0.01$). However, there was an imbalance in baseline plasma insulin levels (201 pmol/L OCA versus 138 pmol/L placebo), and an even larger relative and absolute increase in HOMA-IR was observed in the placebo group at the conclusion of the 24-week follow-up phase. This is potentially attributable to the inherent variability in HOMA-IR measurements, particularly in patients with type 2 diabetes, that have been shown to make single time-point to time-point changes of this magnitude clinically uninterpretable. There were virtually no changes in mean hemoglobin A1c, a measure of average blood sugar control over a period of approximately three months, in either OCA or placebo groups at 72 weeks. In an earlier study of OCA in diabetic NAFLD patients employing the hyperinsulinemic-euglycemic insulin clamp, the gold standard for detecting changes in insulin resistance, OCA improved the glucose disposal rate consistent with reduced insulin resistance.

OCA was generally well tolerated in the FLINT trial. Adverse events were generally mild to moderate in severity and the incidence in the OCA and placebo treatment groups was similar for all symptoms except pruritus. Pruritus occurred more frequently in the OCA treatment group than in the placebo treatment group (23% vs. 6%, $p < 0.0001$) and at a higher grade (predominately moderate pruritus) but resulted in only one patient discontinuation. The incidence of severe or life-threatening events was not different between the two treatment groups and most of the events in both groups were deemed to be unrelated to treatment, including all severe or life-threatening cardiovascular events. There were two patient deaths in the Phase 2b FLINT trial and neither death was considered related to OCA treatment.

***OCA and Bezafibrate***

In December 2018, we entered into the Aralez Agreement, pursuant to which we acquired (i) Aralez's license to develop and commercialize bezafibrate in the United States (as amended and restated in connection therewith, the "Bezafibrate License"), (ii) Aralez's IND on file with the FDA and other associated regulatory documentation and (iii) a non-exclusive license to certain of Aralez's intellectual property. Pursuant to the Aralez Agreement, we paid $9.0 million to Aralez in connection with the closing of the transactions in December 2018 and are obligated to make a $2.0 million milestone payment to Aralez based on the occurrence of specified regulatory-related events. Bezafibrate, a PPAR agonist that has been studied in PBC, is not approved in the U.S. for any indication. We are evaluating the efficacy, safety and tolerability of bezafibrate in combination with OCA in patients with PBC in a Phase 2 study outside of the United States, and we filed an IND with the FDA in January 2021 to prepare to expand such development into the United States, with the longer-term goal of developing and seeking regulatory approval for a fixed dose combination regimen in this indication and potentially may study this combination in other liver diseases. Pursuant to the Bezafibrate License, we are also obligated to make a $2.5 million milestone payment based on the occurrence of specified regulatory-related events with respect to such a combination product, as well as mid-single digit percentage royalty payments based on the net sales of such a combination product.

***Other Product Candidates***

The discovery and development of safe and effective new product candidates and the development of additional uses for our existing product candidates and approved products, are important for the continued strength of our business. We, together with our collaborators, have discovered several bile acid chemistry-based compounds that are in the early stages of research and development. Among these compounds is INT-787. INT-787 is an FXR agonist that we are currently evaluating in preclinical studies. INT-787 has distinct pharmacological properties that differ from those of OCA and has shown potential anti-fibrotic and anti-inflammatory effects in animal models. We believe that bile acid analogs may have

utility in a broad range of diseases beyond non-viral liver disease and we have in the past, and may in the future, explore the potential application of our development compounds outside of our core areas of focus.

The process from discovery to development to regulatory approval of a product candidate can take more than ten years. Product candidates can fail at any stage of the process, and product candidates may not receive regulatory approval even after many years of research and development and significant investment. In addition, we may decide to terminate or deprioritize the development of our product candidates due to a number of factors, including our views of the relevant regulatory development pathway, competitive landscape, commercial viability of the product candidate, or superior alternative uses of capital. For example, we have studied OCA for PSC, a rare, serious, chronic cholestatic liver disease characterized by a progressive, autoimmune-based destruction of bile ducts with eventual onset of cirrhosis. While we believe that the results of our Phase 2 AESOP trial announced in 2017 established a proof of concept of OCA in a second cholestatic liver disease, we have deprioritized development of OCA in PSC based, in part, on the lack of clarity on the regulatory pathway for this rare but serious disease. In addition, we are no longer actively developing INT-767, an orally administered dual FXR and TGR5 agonist derived from the primary human bile acid chenodeoxycholic acid.

***Competition***

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 financial, sales and marketing, manufacturing and distribution, legal, regulatory and product development resources substantially greater than ours. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

The ability of Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, and other future approved products, if any, to compete with products sold by other companies will depend on a number of factors, including efficacy, safety and tolerability, reliability, convenience of dosing, price, the level of branded and generic competition and reimbursement. We believe that the competitive environment for Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH is as follows.

***Ocaliva for PBC***

Ocaliva competes with UDCA (or ursodiol), a first-line therapy approved for the treatment of PBC that is available generically at a significantly lower cost than Ocaliva. Additional product candidates in Phase 3 or earlier clinical or preclinical development for the treatment of PBC include Genfit SA's dual PPAR alpha/delta agonist (elafibranor), CymaBay's PPAR delta agonist (seladelpar), Genkyotex's NOX1/NOX4 inhibitor (setanaxib), HighTide's AMPK activator/FXR agonist combination (HTD1801) and Fast Forward Pharmaceuticals BV's anti-CD40 monoclonal antibody (FFP104). Additionally, several companies have product candidates aimed at the cholestatic-induced pruritus associated with PBC, including apical sodium dependent bile acid transport inhibitors being developed by GlaxoSmithKline plc (GSK2330672).

Off-label uses of other potential treatments may also compete with Ocaliva for PBC. For example, while fibrates are not approved for use in PBC, off-label use of fibrate drugs has been reported. Bezafibrate, a fibrate that is not approved by the FDA for any indication and is only available outside of the United States, has been studied in PBC.

***OCA for Liver Fibrosis Due to NASH***

There are currently no medications approved for the treatment of NASH. However, various therapeutics are used off-label for the treatment of NASH, including vitamin E (an antioxidant), insulin sensitizers (e.g., metformin, pioglitazone), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and UDCA. There are several product candidates in Phase 3 or earlier clinical or preclinical development for the treatment of NASH, including Madrigal's THR beta agonist (resmetirom), Novo Nordisk's GLP1 agonist (semaglutide), and Inventiva's pan-PPAR agonist (lanifibranor), as well as

FXR agonists from Novartis AG (tropifexor, nidufexor), Metacrine (MET409, MET642), Terns Pharmaceuticals (TERN-101), Gilead Sciences, Inc. (cilofexor) and Enanta Pharmaceuticals, Inc. (EDP-305).

Additional pharmaceutical and biotechnology companies with product candidates in development for the treatment of NASH include AstraZeneca plc, Altimmune Inc., Boehringer Ingelheim GmbH, Bristol-Myers Squibb Company, Durect Corporation, Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Immuron Ltd., Ionis Pharmaceuticals, Inc., Islet Sciences, Inc., Madrigal Pharmaceuticals, Inc., MediciNova, Inc., MiNA Therapeutics, NGM Biopharmaceuticals, Inc., NuSirt Sciences Inc., Pfizer Inc., Viking Therapeutics, Inc. and Zydus Pharmaceuticals (USA) Inc. NASH is a complex disease and we believe that it is unlikely that any one therapeutic option will be optimal for every NASH patient.

In addition, many universities and private and public research institutions may become active in our target disease areas. The results from our clinical 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 or product candidates obsolete and noncompetitive. Our ability to compete may also be affected because, in many cases, insurers or other third-party payors seek to encourage the use of generic products.

***Intellectual Property***

Protecting our intellectual property, such as our patents, is a key part of our strategy. We are the owner of record of numerous issued U.S. and non-U.S. patents with claims directed to pharmaceutical compounds, pharmaceutical compositions, methods of making these compounds and methods of using these compounds in various indications. In addition, we are the owner of record of numerous pending U.S. and non-U.S. patent applications, and regularly pursue additional patent applications in various jurisdictions. We also have numerous trademark and service mark registrations and pending trademark and service mark applications in the United States and abroad.

The patent portfolio for OCA contains U.S. and non-U.S. patents and patent applications directed to compositions of matter, methods of use and manufacturing methods. Our primary composition of matter patent for OCA was to expire in 2022. In light of the U.S. marketing approval of Ocaliva for PBC in May 2016, we applied for an extension of the patent term for this patent in the United States into 2027, which extension has been granted. In addition, in connection with the conditional approval of Ocaliva for PBC in the European Union, we have applied for supplementary patent certification (“SPC”) to extend the patent term for this patent in the European Union into 2027. To date, we have received grants of SPC in Austria, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Norway, Portugal, Spain and Sweden and we expect to take similar actions in other jurisdictions and countries where similar regulations exist.

The table set forth below summarizes the U.S. patents covering OCA that are listed in the FDA’s Orange Book List of Approved Drug Products With Therapeutic Equivalence Evaluations (the “Orange Book”). The issued patents covering OCA are expected to expire in 2022 at the earliest and 2036 at the latest if the appropriate maintenance, renewal, annuity, or other government fees are paid. We expect that the patents in the OCA portfolio that are listed in the Orange Book would expire as set forth below, assuming the appropriate maintenance, renewal, annuity or other governmental fees are paid.

| Patent No. | Type of Patent(1) | Brief Summary of Patent | U.S. Patent Expiration |
|---|---|---|---|
| RE 48,286 | Composition of Matter | Claims OCA compound | 2027 |
| 8,058,267 | Method of Use | Claims methods of treating PBC with OCA | 2022 |
| 8,377,916 | Method of Use | Claims methods of treating PBC with OCA | 2022 |
| 9,238,673 | Composition of Matter | Claims OCA active pharmaceutical ingredient ("API") | 2033 |
| 10,047,117 | Method of Use | Claims methods of treating FXR mediated diseases with OCA API | 2033 |
| 10,052,337 | Composition of Matter | Claims OCA finished drug product | 2036 |
| 10,174,073 | Composition of Matter | Claims OCA API produced by a specified process | 2033 |
| 10,751,349 | Composition of Matter | Claims OCA finished drug product | 2036 |
| 10,758,549 | Method of Use | Claims methods of treating PBC with OCA | 2036 |

(1) You should read the risk factors included elsewhere in this Annual Report on Form 10-K for important information about risks posed by the loss of patent protection, in particular the risks described under "Risk Factors — Risks Related to Our Intellectual Property."

In addition, we have intellectual property protecting OCA that we would expect to list in the Orange Book if OCA is approved for the treatment of NASH.

We may 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. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Our commercial success will depend in part on our ability to obtain and maintain patent, trademark and trade secret protection covering our products such as Ocaliva and product candidates, as well as our ability to successfully defend our intellectual property against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products is dependent upon the extent to which we have regulatory exclusivity or intellectual property-based exclusivity rights under valid and enforceable patents or other intellectual property that cover our products. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from launching generic versions of our products, from using our proprietary technologies or from marketing products that are very similar or identical to ours. The patent positions of 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 foreign jurisdictions, and the legal standards relating to the patentability, validity and enforceability of pharmaceutical patents are evolving.

Changes in either the patent laws or in interpretations of patent laws in U.S. and foreign jurisdictions may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that we currently own or that may issue from the applications we have filed or may file in the future or those that we may license from third parties. Additionally, our currently pending or future patent applications may not result in issued patents, and any term extensions that we seek may not be granted. Further, if any patents we obtain or license are deemed invalid or unenforceable, it could impact our ability to commercialize or license our technology or enable third parties to develop and market products that are similar or identical to ours.

**Manufacturing and Supply**

We do not own or operate manufacturing facilities for the production of Ocaliva, OCA or any of our other product candidates, and we do not have any plans to develop our own manufacturing operations in the foreseeable future. We rely on third-party contract manufacturers for all of our required raw materials, API and finished product for our commercial sales and for our clinical trials and preclinical studies.

We source the manufacture and commercial supply of API from such manufacturers, for use in Ocaliva and, if approved, OCA for liver fibrosis due to NASH. We believe that we have secured supplies of API sufficient to meet our PBC and NASH commercial supply requirements during the initial stages of our NASH launch following the expected approval of OCA for liver fibrosis due to NASH. One such supply agreement is with PharmaZell GmbH ("PharmaZell"). That contract does not require us to purchase a specific percentage of our annual commercial requirements of API from PharmaZell. We have also qualified an additional API supplier from which we may currently acquire API on a purchase order basis and continue to engage in activities intended to ensure that our long-term commercial supply requirements are satisfied. In connection with such efforts, we entered into an agreement with a third potential supplier of API for the manufacture of Ocaliva and, if approved, OCA for liver fibrosis due to NASH, under which we may in the future be obligated to purchase a portion of our API requirements in the event of the achievement of agreed regulatory and product development milestones.

We do not have long-term supply agreements for any of our product candidates other than OCA, and regularly obtain supplies and services relating to our product candidates from third-party contract manufacturers on a purchase order basis. Contract manufacturers are subject to extensive governmental regulation and we depend on them for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products, including Ocaliva. We intend to continue to rely on third-party manufacturers for the manufacture of clinical supplies of our product candidates and commercial supplies of our approved products, including Ocaliva and, if approved, OCA for liver fibrosis due to NASH. We believe this manufacturing strategy will enable us to direct financial resources to the development and commercialization of products rather than diverting resources to establishing a manufacturing infrastructure. If PharmaZell and our other current and future suppliers are not able to meet our on-going commercial supply requirements, including those relating to Ocaliva or, if approved, OCA for liver fibrosis due to NASH, on acceptable terms, or at all, our business may be materially and adversely affected. See "Risk Factors — Risks Related to the Development and the Regulatory Review and Approval of Our Products and Product Candidates — We rely entirely on third parties for the manufacture of our product requirements for our preclinical studies and clinical trials, as well as our commercial supply of Ocaliva and, if approved, OCA for liver fibrosis due to NASH and our other product candidates, and also depend on third-party vendors and CROs for certain of our clinical trial and product development activities. Our business could be harmed if our third-party manufacturers fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices, or if our third-party vendors or CROs assisting us with our clinical trials and product development activities fail to comply with their contractual commitments or applicable regulatory obligations or if we lose our relationships with our third-party vendors and CROs."

**Sales and Marketing**

Ocaliva is our first approved product and the commercial launch of Ocaliva for PBC is our first product launch. We are commercializing Ocaliva for PBC using a combination of our internal commercial organization, a contract sales organization and third-party distributors depending on the jurisdiction. We are developing our commercialization strategy for OCA for liver fibrosis due to NASH, if approved, and have not yet decided on our commercialization strategy for OCA for other indications or for our other product candidates, in each case, if approved. We intend to continue to evaluate how best to commercialize our product candidates, if approved, in the United States and internationally, and may choose to collaborate with third parties that have sales and marketing capabilities and established distribution systems, either to augment our own capabilities or in lieu thereof.

**Customers**

We commenced our commercial launch of Ocaliva for the treatment of 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. Since January 2017, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada, Israel and Australia. We recognized net product sales of Ocaliva of $312.7 million, $249.6 million and $177.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. We sell Ocaliva to a limited number of specialty pharmacies which dispense the product directly to patients. The specialty pharmacies are referred to as our customers. For a discussion of our customer concentration, see Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

**Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local level, and analogous authorities in other countries extensively regulate, among other things, the research, development, testing, manufacture, recordkeeping, approval, labeling, packaging, promotion, storage, advertising, distribution, marketing, sampling, post-approval monitoring and reporting and export and import of products such as Ocaliva and those we are developing. Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the European Commission following a favorable assessment provided by the EMA through the MAA process for a product falling within the scope of the Centralized procedure or a national MAA process (albeit through the process of Mutual Recognition or Decentralized procedure) before they may be legally marketed in the European Union. Our product candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

***United States Government Regulation***

*NDA Approval Processes*

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, as amended (the "FDCA") and implementing regulations. An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice regulations;
- submission to the FDA of an IND, which must take effect before human clinical testing may begin;
- approval by an independent institutional review board ("IRB"), representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices ("GCP") to establish the safety and efficacy of the new drug product for each indication for which FDA approval is sought;
- preparation and submission to the FDA of a NDA;
- review of the new drug product by an FDA advisory committee, where appropriate or if applicable, although the FDA is not bound by the recommendation of an advisory committee;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the new drug product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices ("cGMP") requirements and to assure that the facilities, methods and controls are adequate to preserve the new drug product's identity, strength, quality and purity;

- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCP and the integrity of the clinical data;

- payment of user fees and procurement of FDA approval of the NDA; and

- compliance with any post-approval requirements, including, as applicable, Risk Evaluation and Mitigation Strategies ("REMS") and post-approval studies required by the FDA.

*Preclinical and Clinical Studies*

Once a pharmaceutical candidate is identified for development, it enters the preclinical or nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some nonclinical testing may continue even after the IND is submitted. In order to conduct clinical research, an IND sponsor must submit an IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, or any time thereafter, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or continue. A clinical hold may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to the FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An IRB at each institution must, among other things, review and approve the protocol before a clinical trial commences at such institution, and approve the consent form that must be provided to each research subject or the subject's legal representative, monitor the study until completed and otherwise comply with regulations applicable to the IRB.

Human clinical trials are typically conducted in three sequential phases, although the phases may overlap or be combined:

- *Phase 1.* The drug is initially introduced into healthy human subjects and tested to assess pharmacological actions, safety, dosage tolerance, absorption, metabolism, distribution and elimination and, in some cases, early evidence of effectiveness. In the case of some products intended for the treatment of severe or life-threatening diseases, such as cancer, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- *Phase 2.* Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population generally at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling, should it ultimately be approved for marketing. In most cases the FDA requires two adequate and well-controlled Phase 3 clinical trials with statistically significant results to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in certain instances.

Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or

terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, or the clinical monitoring board or data monitoring committee. This group typically provides recommendations to the trial sponsor for whether or not a trial may move forward at designated check points. These decisions are based on the data monitoring committee's independent review of data from the ongoing trial.

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose clinical trial information related to the product, patient population, phase of investigation, clinical trial sites and investigator, and other aspects of the clinical trial on a public website maintained by the U.S. National Institutes of Health. Sponsors are also obligated to disclose the results of these clinical trials after completion. For a new product or a new indication for a previously approved product, sponsors can delay submission of clinical study results for up to two years until the product has been approved or approved for the new use. Competitors and others may use this publicly-available information to gain knowledge regarding the design and progress of our development programs.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points, including prior to the submission of an IND, at the end of Phase 2 and before a NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice and feedback on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial(s) that they believe will support the approval of the new drug. If a Phase 2 clinical trial is the subject of discussion at the end of Phase 2 meeting with the FDA, a sponsor may be able to request a special protocol assessment ("SPA"), the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

According to published guidance on the SPA process, a sponsor which meets the prerequisites may make a specific request for an SPA and provide information regarding the design and size of the proposed clinical trial. The FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement is generally expected to be binding on the FDA, in that the critical design elements agreed to as part of an SPA agreement may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began. The presence of an SPA agreement does not guarantee that a marketing application will be filed or approved, even if the trial is conducted in accordance with the protocol and achieves the specified endpoints. In rare cases, the FDA may rescind an SPA agreement.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the quality, purity and potency of the drug prior to release. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf-life.

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests and other control mechanisms, proposed labeling and other relevant information are submitted to the FDA as part of a NDA requesting approval to market the product. The submission of a NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. Currently, the application fee is approximately $2.9 million for NDAs with clinical data and approximately $1.5 million for NDAs without clinical data. The sponsor under an approved NDA is also subject to annual program user fees, currently approximately $336,000. Program fees are assessed for each approved prescription drug product identified in an approved application, up to five program fees per application. These fees are typically modified annually. The FDA reviews all

NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept a NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the NDA is accepted for filing, the FDA begins an in-depth review. NDAs receive either standard or, as discussed more fully below, priority review. The FDA may refuse to approve a NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA reviews a NDA to determine, among other things, whether a product is safe, effective, and can be properly manufactured for its intended use or uses. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee. Before approving a NDA, the FDA will inspect the facility or facilities where the product is manufactured and tested to ensure compliance with cGMPs. An approval letter from the FDA authorizes commercial marketing of the product and specifies the prescribing information for the approved indication(s).

*Fast Track, Breakthrough Therapy, Priority Review and Accelerated Approval*

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track designated products, sponsors may have a higher number of interactions with the FDA and the FDA may initiate review of sections of a fast track product's NDA before the application is complete.

A product may also be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product 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 take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

The FDA may also designate a product for priority review if it would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition. Certain other applications may also qualify for priority review. The FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. A priority designation by the FDA is intended to direct the agency's attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

In addition, the FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. In the case of unprecedented accelerated approval endpoints, this determination occurs during the review of the NDA. Unless otherwise informed by the FDA, an applicant must submit to the FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120

days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the FDA, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

As a condition of a grant of accelerated approval, the FDA may require that the sponsor perform one or more controlled post-marketing clinical trials. Approval of a drug may be withdrawn if these trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug (e.g., show a significantly smaller magnitude or duration of benefit than was anticipated based on the observed effect on the surrogate).

Ocaliva was granted fast track designation by the FDA for the treatment of patients with PBC who have an inadequate response to or are intolerant of UDCA. In August 2015, the FDA accepted for review our NDA and granted priority review for Ocaliva in PBC. On May 27, 2016, Ocaliva was approved under the accelerated approval pathway in the United States for PBC in combination with UDCA in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

In January 2015, OCA for liver fibrosis due to NASH was granted breakthrough therapy designation by the FDA for the treatment of patients with NASH with liver fibrosis. In November 2019, the FDA accepted for review our NDA and granted priority review for OCA for liver fibrosis due to NASH. In June 2020, we received a complete response letter ("CRL") from the FDA stating that our NDA for OCA for the treatment of liver fibrosis due to NASH could not be approved in its present form. The CRL indicated that, based on the data the FDA had reviewed, the FDA has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. At that time, the FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE trial in support of potential accelerated approval and that the long-term outcomes phase of the trial should continue. We are in discussions with the FDA with respect to the potential resubmission of our NDA seeking accelerated approval of OCA for the treatment of liver fibrosis due to NASH. We had our end of review meeting with the FDA in October 2020 to discuss the FDA's risk-benefit assessment in the CRL based on its review of the available data, as well as our proposed resubmission of our NDA for the treatment of liver fibrosis due to NASH. The meeting was constructive and the FDA has provided us with helpful guidance regarding supplemental data we can provide to further characterize OCA's efficacy and safety profile that could support resubmission based on our Phase 3 REGENERATE 18-month biopsy data, together with a safety update from our ongoing studies. We are advancing accordingly and plan to hold additional meetings with the FDA with the goal of achieving sufficient alignment to proceed on this basis and potentially resubmit our NDA for the treatment of liver fibrosis due to NASH by the end of 2021.

*Post-approval Requirements*

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA post-approval, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if safety or other problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in new labeling information (e.g., warnings), customer training and/or education requirements, restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require studies, trials, analyses, and surveillance programs to monitor or evaluate the effect of approved products that have been commercialized, and the FDA has the power to limit further marketing of a product, or seek withdrawal of approval, based on the results of these post-marketing programs.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon

the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Failure to comply with the applicable U.S. requirements at any time during the product development process or approval process, or after approval, may subject us to judicial, regulatory or statutory sanctions, any of which could have a material adverse effect on us.

These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning or untitled letters;
- product recalls;
- product seizures;
- total or partial suspension of production or distribution; and
- injunctions, fines, disgorgement, civil penalties and criminal prosecution.

The FDA and other U.S. state and federal authorities regulate marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in a manner otherwise consistent with the provisions of the approved label and FDA regulations. The FDA and other authorities actively enforce the laws and regulations prohibiting false, misleading, deceptive, or off-label promotional practices; violations of these prohibitions can lead to significant liability. Additional regulations apply for advertising and promotion of products approved under the accelerated approval pathway. For example, unless otherwise informed by the FDA, an applicant must submit to the FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the FDA, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

From time to time, legislation is introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

In accordance with the applicable requirements under the accelerated approval pathway, we initiated our Phase 4 COBALT clinical outcomes confirmatory trial for Ocaliva in PBC in December 2014, following discussions with the FDA. The study evaluates subjects across the spectrum of PBC disease, including early and advanced PBC. We have also agreed to evaluate the safety and efficacy of Ocaliva in patients with moderate to severe hepatic impairment in a study known as the 401 trial and as monotherapy in patients with PBC. In addition, we have 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

are in discussions with the FDA and the EMA with respect to the status of the COBALT trial and the 401 trial and proposals for modifications to these post-marketing studies.

*Risk Evaluation and Mitigation Strategy*

The Food and Drug Administration Amendments Act of 2007 created a new section of the FDCA which authorizes the FDA to require a REMS as a condition of NDA approval, or based upon new safety information regarding an approved drug, when the FDA determines a REMS is necessary to ensure that the benefits of a drug outweigh the potential risks. Under a REMS, the FDA may require various measures to address serious risks, such as medication guides, communication plans, training or registries, as well as steps to monitor and assess the effectiveness of those measures. Such requirements may impose significant burdens on prescribers, pharmacists or patients. The requirement for a REMS may materially affect the potential market and profitability of a drug.

We do not have a REMS for Ocaliva for the treatment of PBC.

*Patent Term Extension and Data Exclusivity*

Depending upon the timing, duration and specifics of FDA approval of the use of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, (the “Hatch-Waxman Act”). The Hatch-Waxman Act permits an extension of a patent term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, the extension of patent term cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent term extension period is generally one-half the time between the effective date of an IND, and the submission date of a NDA, plus the time between the submission date of a NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. Our primary composition of matter patent for OCA was to expire in 2022, but in light of the U.S. marketing approval of Ocaliva for PBC in May 2016, we applied for an extension of the patent term for this patent in the United States into 2027, which extension has been granted. In addition, in connection with the conditional approval of Ocaliva for PBC in the European Union, we have applied for SPC to extend the patent term for this patent in the European Union into 2027. To date, we have received grants of SPC in Austria, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Norway, Portugal, Spain and Sweden and we expect to take similar actions in other jurisdictions and countries where similar regulations exist.

Data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of a NDA for a new chemical entity. A drug is considered a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance as further defined in FDA regulations. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (“ANDA”) or a 505(b)(2) NDA for a drug with the same active moiety. However, an application may be submitted four years from the NDA approval date if it contains a paragraph IV certification that a reference product patent is invalid or not infringed by the ANDA or 505(b)(2) product. The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active moiety for other conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA may be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

*Pediatric Exclusivity and Pediatric Use*

Under the Best Pharmaceuticals for Children Act, sponsors may obtain a six month extension of unexpired regulatory exclusivities and terms of unexpired Orange Book-listed patents relating to their drug, if pediatric studies substantially complying with a written request are completed and submitted by the sponsor to the FDA within the statutory time frame. We have not received such a written request from the FDA for such pediatric studies, although we may ask the FDA to issue a written request for such studies in the future.

In addition, under the Pediatric Research Equity Act (the "PREA"), a NDA or supplement to a NDA for certain drugs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver. However, the FDA has recently issued guidance limiting a sponsor's ability to waive the PREA study requirements.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting a NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any applications from any other party to market the same drug for the same indication for seven years, except in very limited circumstances such as where there is a demonstration of clinical superiority. Orphan drug exclusivity, however, could also work to block the approval of one of our product candidates for seven years if a competitor develops the same drug as one of our product candidates and obtains approval and orphan exclusivity for the same indication or disease for which our product candidate is being developed. Orphan drug exclusivity would not block approval of the same drug developed by a competitor for a use different from our orphan-protected approved use. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to orphan exclusivity for the full scope of its approved use.

As in the United States, we may apply for designation of a product as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication. The market exclusivity period for the authorized therapeutic indication may be reduced to six years if, at the end of the fifth year, it is established that the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, a competing similar medicinal product may in limited circumstances be authorized prior to the expiration of the market exclusivity period, including if it is shown to be safer, more effective or otherwise clinically superior to the orphan-designated product.

OCA has received orphan drug designation in the United States and the European Union for the treatment of PBC and PSC. In the United States, Ocaliva has also received orphan exclusivity for its approved PBC indication that runs until May 27, 2023.

***Regulation Outside of the United States***

In addition to regulations in the United States, we are subject to regulations of other countries governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence

clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications under the centralized, decentralized or mutual recognition marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the European Commission on the basis of an opinion provided by the EMA's Committee for Medicinal Products for Human Use (the "CHMP"). A centralized marketing authorization is valid for all European Union member states and the European Economic Area States (Iceland, Liechtenstein and Norway). The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authorities in each of the European Union member states chosen by the applicant in which the product is to be marketed. One national competent authority, selected by the applicant (Reference Member State) leads the assessment of the application for marketing authorization. The competent authorities of the other chosen European Union member states concerned by the procedure (Concerned Member States) are subsequently required to review the initial evaluation and, if the assessment is positive and all issues are resolved, grant marketing authorization for their territory on the basis of the assessment, except where grounds of potential serious risk to public health require the application for authorization to be refused. The mutual recognition procedure provides for mutual recognition of a marketing authorization which has already been granted by the national competent authority of a European Union member state by the competent authorities of the other European Union member states where further marketing authorizations are progressively sought. The holder of a national marketing authorization may submit an application to the competent authority of a European Union member state requesting the recognition of the marketing authorization granted by the competent authority of another European Union member state.

Prior to obtaining a marketing authorization in the European Union submitted as a full stand-alone dossier, applicants have to demonstrate compliance with all measures included in an EMA-approved PIP covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver, or (3) a deferral for one or more of the measures included in the PIP. In the case of orphan medicinal products, completion of an approved PIP can result in an extension of the aforementioned market exclusivity period from ten to twelve years.

It is also possible that a centralized marketing authorization could be conditional on post-approval studies and not considered a full approval, but subject to annual renewal until comprehensive data are provided to confirm the benefit/risk assessment. A manufacturer's 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. Conditional marketing authorizations can be granted, based on a clinical dataset that is not comprehensive. Granting of such an authorization may be granted for a limited number of medicinal products for human use referenced in the applicable European Union law governing conditional marketing authorization, 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.

Similarly to the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual European Union member states both before and after grant of the manufacturing and marketing authorizations. This includes European Union cGMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures. We and our third-party manufacturers are required to ensure that all of our processes, methods, and equipment are compliant with cGMP.

Failure by us or by any of our third-party partners, including suppliers, manufacturers, and distributors to comply with European Union laws and the related national laws of individual European Union member states governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and manufacturing and marketing of such products, both before and after grant of marketing authorization, may result in administrative, civil or criminal penalties. These penalties could include delays in or refusals to authorize the conduct of clinical trials or the grant of marketing authorizations, product withdrawals and recalls, product seizures, suspensions, withdrawals, or variations of previously granted marketing authorizations, total or partial suspensions of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

In October 2016, the CHMP of the EMA adopted a positive opinion recommending the granting of a conditional marketing authorization of Ocaliva in PBC. Based on the CHMP's positive recommendation, the European Commission granted a conditional marketing authorization of Ocaliva in PBC in December 2016. Although we have successfully renewed our conditional marketing authorization in the European Union in the past, there can be no assurance that we will be able to continue to do so in the future. Failure to renew our conditional marketing authorization would prevent us from continuing to market Ocaliva for PBC in Europe. PBC is not believed to occur in the pediatric population. Therefore, in accordance with applicable regulations, the PBC marketing authorization required demonstration of compliance with all measures included in an EMA-approved Pediatric Investigation Plan for OCA for the treatment of biliary atresia, a pediatric cholestatic disease.

***Pricing and Reimbursement***

Sales of our products will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government healthcare programs, commercial insurance plans and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority for federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of new or more restrictive price controls and cost-containment measures in the jurisdictions in which we operate could materially and adversely impact our net sales and financial results.

Third-party payers are responsible for managing overall pharmaceutical drug spending for their client membership. Third-party payers continue to scrutinize and manage the prices charged for pharmaceutical products and services, and many also limit reimbursement for newly-approved or innovating products and indications. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may (i) not cover our approved products as part of their plans' benefits, (ii) apply utilization management restrictions or high patient cost-sharing obligations or (iii) restrict the level of reimbursement for our approved products and any such actions may affect our ability to sell our approved products on a profitable basis or at all.

Medicare is a U.S. federal healthcare program that provides coverage for certain healthcare items and services to individuals aged 65 years or older, as well as individuals of any age with certain disabilities and illnesses. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D of the MMA, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which provide coverage for outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as part of Medicare Advantage plans. Unlike Medicare Part A and B, Part D prescription drug plan sponsors are not required to pay for all outpatient drugs, and each Part D plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D plan drug formularies must include at least two drugs within each therapeutic category and class of Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutics committee. Part D plan coverage and reimbursement may increase demand for our products for which we receive marketing approval in the United States. Moreover, while Part D provides prescription drug benefits only to Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in reimbursement by Medicare may result in a similar reduction in payments from non-governmental payors. Medicare Part D may affect reimbursement of our products upon approval.

Medicaid is a U.S. healthcare program that provides coverage for certain healthcare items and services to low-income children, families, pregnant women and people with disabilities. It is jointly funded by the federal and state governments, and it is administered by individual states within parameters established by the federal government. Therefore, coverage and reimbursement for drugs may vary by state Medicaid program. A manufacturer must enter into a Medicaid Drug Rebate Agreement to have its products covered by Medicaid. Under the Medicaid program, and per the Medicaid Drug Rebate Agreement, manufacturers agree to report certain prices to the government and pay rebates to state Medicaid programs based on Medicaid utilization of the manufacturer's covered drugs.

In addition to the Medicaid Drug Rebate Program, federal law requires companies to participate in the Public Health Service's 340B Drug Pricing Program in order to have the manufacturer's drugs covered under Medicaid. The 340B Drug Pricing Program requires participating manufacturers to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "ACA"), extended eligibility to participate in the 340B program to certain additional types of hospitals (including critical access hospitals, sole community hospitals, rural referral centers and freestanding cancer hospitals). For purposes of these newly eligible covered entities, the ACA specifically excluded from the definition of "covered outpatient drugs" certain drugs designated as "orphan drugs" under section 526 of the FDCA. We are also required as a condition of Medicaid participation to discount our products to authorized users of the Federal Supply Schedule of the General Services Administration, including the TRICARE retail pharmacy program, under which additional laws and requirements apply.

These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate prices, or offer required discounts or rebates can subject manufacturers to substantial penalties.

In 2010, the ACA was enacted to, among other things, expand access and increase consumer insurance protections while reducing the cost of health care for consumers. The law substantially changed the way health care is financed by both governmental and private insurers in the United States. The ACA requires manufacturers to provide discounts on the prices of brand named drugs in the coverage gap under Medicare Part D and increased the rebates paid by pharmaceutical companies on drugs covered by Medicaid. The ACA also imposes an annual fee, which increases each year, on sales by branded pharmaceutical manufacturers. Since its enactment, there have been a number of judicial, executive and legislative challenges to the ACA, including tax legislation that removed the financial penalties for people who do not carry health insurance (known as the "individual mandate") and an Executive Order signed in October 2017 by former President Trump directing federal agencies to modify how the ACA is implemented. Congress may continue to consider legislation to repeal and replace some or all elements of the ACA. Further, in December 2018, a federal district court in Texas ruled that the entire ACA was unconstitutional because it could not be considered an exercise of Congressional taxing authority following the repeal of the individual mandate penalties. In December 2019, a federal court of appeals upheld the district court's decision that the ACA individual mandate was unconstitutional absent financial penalties, but remanded the case back to the district court to determine whether the remaining provisions of the ACA were nonetheless valid. However, in March 2020, before the district court could rule on the ACA's remaining provisions, the U.S. Supreme Court agreed to review the case and oral arguments were held in November 2020. A decision is expected before June 2021. We cannot predict the outcome of this, or any other, litigation regarding the ACA or the impact it may have on our business.

There has been particular and increasing legislative and enforcement interest in the United States with respect to drug pricing practices, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. At the federal level, there have been several U.S. Congressional inquiries, proposed bills, and proposed administrative rules designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The outcome and potential effects of these proposals, and other proposals that may be forthcoming is unclear. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before its cost may be funded within the respective national healthcare systems. The requirements governing drug pricing vary widely from country to country. For example, European Union member states can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and may control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profits the medicinal product generates for the company placing it on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products on cost-effectiveness grounds. Historically, products launched in countries in the European Union do not follow price structures of the United States and generally their prices tend to be significantly lower.

***U.S. Fraud and Abuse Laws***

Interactions and arrangements with third-party payors, healthcare providers and professionals and customers, including patients and patient advocacy groups, are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may restrict certain marketing and contracting practices. These laws include, federal and state anti-kickback and false claims statutes as well as other statutes and regulations pertaining to healthcare fraud and abuse. Other pharmaceutical companies have settled alleged or admitted violations of these fraud and abuse laws with state and federal authorities in recent years and in some cases these settlements have amounted to hundreds of millions, or even billions, of dollars in damages, fines, and penalties, as well as the imposition of compliance program obligations through Corporate Integrity Agreements and other means. Lawsuits, or enforcement actions brought under fraud and abuse laws, can be extremely costly to defend, even if a company has strong defenses and ultimately succeeds in getting the allegations or enforcement action dismissed.

The federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)) prohibits, among other things, knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for any good or service, for which payment may be made under federal and state healthcare programs such as Medicare, Medicaid or other federally financed healthcare programs. Remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted by regulators to include for example, cash payments, gifts, discounts, coupons, and the furnishing of free or discounted services or supplies, and other items or services of value to the recipient. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers, formulary managers and patients, among others. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for such exceptions or safe harbors.

The federal False Claims Act imposes civil penalties, including treble damages and significant per-claim penalties, which may be pursued through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The government and *qui tam* relators have brought False Claims Act actions against pharmaceutical companies on the theory that their practices have caused false claims to be presented to the government. There is also a separate false claims provision imposing criminal penalties.

Other federal healthcare fraud-related laws also impose criminal liability for violations. The Criminal Healthcare Fraud statute (18 U.S.C. §1347) prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. Federal criminal law also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

A number of states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act that apply to items and services reimbursed under Medicaid and other state programs. Some state anti-kickback statutes apply not just to government payors, but to all payors, including commercial payors and patients.

***Other Laws***

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "HIPAA"), imposes obligations, on "covered entities," including health plans and healthcare providers, and their business associates with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Although drug manufacturers are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. We are also subject to state, federal and international privacy and security laws governing the processing and security of personal identifiable information.

The federal Physician Payments Sunshine Act requirements under the ACA, and its implementing regulations, require manufacturers of drugs, devices, biologics and medical supplies to report to the U.S. Department of Health and Human Services information related to certain direct and indirect payments and other transfers of value made to covered recipients, such as physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law. We are also subject to similar laws in several states and various European Union countries where we have operations. Some of these state and EU laws are broader in scope than federal laws.

In addition, several states now require prescription drug companies to report expenses relating to the marketing and promotion of drug products. Several states prohibit providing certain payments or items of value to healthcare providers or other enumerated individuals or entities, as well as various other marketing-related activities. Certain states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Nevada and Massachusetts require pharmaceutical companies to implement compliance programs and marketing codes. Several additional states are considering similar proposals. Some of the state laws are broader in scope than federal laws. Compliance with these laws is challenging and requires significant time and resources, and any failure to comply with such laws could result in significant civil penalties and other adverse consequences.

**Human Capital Resources**

As of December 31, 2020, we had 498 employees, of which 359 were based in the United States, including at our facilities in New York and San Diego, and 139 were based outside the United States, including at our offices in London. A significant percentage of our employees have obtained advanced degrees in their professions. We consider the intellectual capital of our employees to be an essential driver of our business and key to our future prospects. Given our unique opportunity as a leader in the treatment of progressive non-viral liver disease coupled with our disciplined management of our financial resources, we continue to be able to fill the vacated positions and, if needed, grow our headcount in support of our commercial organization and our pipeline of research and development programs and product candidates. We monitor our compensation programs closely and provide what we consider to be a very competitive mix of compensation and insurance benefits for all our employees, as well as participation in our equity programs. None of our employees is represented by a labor union and we consider our employee relations to be good. In addition, we continually evaluate our headcount with respect to our business needs and opportunities and seek to balance in house expertise and capacity with outsourced expertise and capacity. In August 2020, we adopted a plan to reduce our workforce in light of the receipt of the CRL from the FDA regarding our NDA for OCA for liver fibrosis due to NASH (the "2020 Workforce Plan"). The 2020 Workforce Plan sought to streamline our operations and reduce operating expenses, while maintaining the critical resources needed to continue to support the NASH and PBC clinical programs, pursue the approval of OCA for the treatment of liver fibrosis due to NASH and support our successful PBC business.

**Corporate and Available Information**

We were incorporated in Delaware in September 2002. Our principal executive offices are located at 10 Hudson Yards, 37th Floor, New York, NY 10001 and our telephone number is (646) 747-1000. We have several additional offices, including those in San Diego, California and London, United Kingdom. Our corporate website address is *www.interceptpharma.com*. We make available on our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as

reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). Our SEC reports can be accessed through the Investors & Media section of our internet website. The references to *www.interceptpharma.com* herein are inactive textual references only, and the information found on our internet website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC. The SEC maintains an internet website that contains reports, proxy and information statements and other information about issuers, like us, that file electronically with the SEC. The address of that site is *http://www.sec.gov*.

## Item 1A. Risk Factors

*Investing in our securities involves a high degree of risk. The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered before deciding whether to invest in our securities. 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. If any of the following risks, or such unknown risks, occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In that case, the market price of our securities could decline, and you may lose all or part of your investment.*

### Risks Related to Our Financial Position and Need for Additional Capital

***We are currently dependent on the successful commercialization of Ocaliva for PBC. To the extent Ocaliva is not commercially successful, our business, financial condition and results of operations may be materially and 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 UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

Our ability to generate profits from operations and become profitable currently depends on the commercial success of Ocaliva for PBC. However, the successful commercialization of Ocaliva for PBC is subject to many risks. We have not launched or commercialized a drug before Ocaliva, and there is no guarantee that we will be able to do so successfully. There are numerous examples of unsuccessful product launches and commercial efforts, as well as failures to meet expectations of market potential, including by pharmaceutical companies with greater experience and resources than us.

The commercial success of Ocaliva for PBC 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. As such, there is significant uncertainty in the degree of market acceptance that Ocaliva will have for PBC. For example, if the patient population suffering from PBC is smaller than we estimate, or even if the patient population matches our estimates but Ocaliva is not widely accepted as a treatment for PBC, the commercial potential of Ocaliva for PBC 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. In the fourth quarter of 2020, we continued to see a lower level of prescriptions for new patients than we did prior to the outbreak of COVID-19 and related public health safety measures. While the future impact of COVID-19, the governmental responses thereto and the resulting rate of prescriptions for new patients remains difficult to predict, we did see some improvement in the fourth quarter relative to the third quarter. We continue to monitor the situation; if the rate of prescriptions for new patients declines in the future, we may see a reduction in net sales of Ocaliva, which could negatively affect our business, financial condition and results of operations. 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 for PBC. Furthermore, any negative development in any other development program for 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 materially and adversely impact the commercial results and potential of Ocaliva for PBC. See "—Risks Related to the Development and the Regulatory Review and Approval of Our Products and Product Candidates" and "—Risks Related to the Commercialization of Our Products" below.

As a result, it is uncertain whether Ocaliva net sales for PBC will sustain our operations and it may take a significant amount of time before Ocaliva net sales for PBC sustain our operations. Furthermore, Ocaliva may not receive regulatory approval for PBC in jurisdictions beyond those in which it is currently approved, which may also limit our prospects. If the commercialization of Ocaliva for PBC is unsuccessful or perceived to be unsuccessful, the long-term prospects of Ocaliva for PBC, as well as the long-term prospects of our company, may be materially and adversely affected.

***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 incurred net losses of $274.9 million, $344.7 million and $309.2 million for the years ended December 31, 2020, 2019 and 2018, respectively. To date, we have financed our operations primarily through public offerings and private placements of our securities, sales of product and payments received under licensing and collaboration agreements. At December 31, 2020, we had $477.2 million in cash, cash equivalents, restricted cash and investment debt securities.

We have devoted substantially all of our resources to the development of our product candidates, including the conduct of our clinical trials, the launch and commercialization of Ocaliva for PBC, preparation for a potential launch of OCA for liver fibrosis due to NASH and general and administrative operations, including the protection of our intellectual property.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to be significant as we, among other things, develop and seek regulatory approval for our product candidates, including OCA for liver fibrosis due to NASH, maintain our regulatory approvals and commercialize our approved products. 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. 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 currently expect to continue our Phase 3 clinical program of OCA for liver fibrosis due to NASH, including our Phase 3 REGENERATE trial in patients with liver fibrosis due to NASH through clinical outcomes for verification and description of clinical benefit and our Phase 3 REVERSE trial for NASH patients with compensated cirrhosis. Our expenses could increase if we are required by the FDA or the EMA to perform studies or trials in addition to those currently expected, if our current trials are modified for any reason, or if there are any issues or delays in completing our clinical trials or the development of any of our product candidates, due to COVID-19 or otherwise. For example, in June 2020 we received a CRL from the FDA with respect to our NDA for OCA for liver fibrosis due to NASH. The CRL indicated that, based on the data the FDA had reviewed, the FDA has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE trial in support of potential accelerated approval and that the long-term outcomes phase of the trial should continue. Although we are in discussions with the FDA with respect to the potential resubmission of our NDA seeking accelerated approval of OCA for the treatment of liver fibrosis due to NASH, there is no assurance that we will be successful or that OCA will be approved for liver fibrosis due to NASH on an accelerated basis, or at all. Accordingly, our previously anticipated U.S. commercial launch of OCA for liver fibrosis due to NASH has been postponed, we do not expect to generate revenues for this indication until it has been approved, and we may incur significantly greater costs than previously anticipated in connection with the development of OCA for liver fibrosis due to NASH.

We intend to continue to develop OCA and our other existing product candidates, alone or in combination, for non-viral liver diseases. If OCA or any of our other product candidates fails in clinical trials or does not gain or maintain regulatory approval, or if OCA or any of our other product candidates does 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 predict with certainty the timing or amount of our expenses, whether such expenses may increase, or when, or if, we will be able to achieve profitability. The amount of our future net losses will depend, in part, on our future expenses, whether and by how much such expenses increase and our ability to generate revenues.

***We will require substantial additional funding, which may not be available to us on acceptable terms, if at all. If adequate funds are not available to us, we may be required to delay, limit, reduce or cease our operations.***

We are currently developing OCA for additional indications, including NASH, and other product candidates through various stages of clinical and preclinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. If, for example, the FDA, EMA or other regulatory authorities require that we perform additional studies beyond those that we currently expect, our expenses could increase materially beyond what we currently anticipate, and the timing of any potential product approval may be delayed.

In addition, we have incurred and anticipate that we will continue to incur significant research and development, product sales, marketing, manufacturing and distribution expenses relating to the commercialization of Ocaliva for PBC. As part of our longer-term strategy, we anticipate that we will incur significant expenses in connection with our research and development efforts, the commercialization of our other products such as OCA for liver fibrosis due to NASH, if approved, and the build-out of our general and administrative infrastructure in the United States and abroad. We may also engage in business development activities that involve potential in- or out-licensing of products or technologies or acquisitions of other products, technologies or businesses.

As of December 31, 2020, we had $477.2 million in cash, cash equivalents, restricted cash and investment debt securities. We currently expect to continue to incur significant operating expenses in the fiscal year ending December 31, 2020. These expenses are planned to support, among other initiatives, the continued commercialization of Ocaliva for PBC in the United States and our other markets, our continued clinical development of OCA for PBC and NASH and our other earlier stage research and development programs. Although we believe that our existing capital resources, together with our net sales of Ocaliva for PBC, will be sufficient to fund our anticipated operating requirements for the next twelve months, we may need to raise additional capital to fund our operating requirements beyond that period. Furthermore, in light of our receipt in June 2020 of a CRL from the FDA with respect to our NDA for OCA for liver fibrosis due to NASH and the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, any delays in, or unanticipated costs associated with, our development, regulatory or commercialization efforts could significantly increase the amount of capital required by us to fund our operating requirements. Accordingly, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our forecasts regarding the period of time that our existing capital resources will be sufficient to meet our operating requirements and the timing of our future funding requirements, both near and long-term, will depend on a variety of factors, many of which are outside of our control. Such factors include, but are not limited to:

- our ability to successfully commercialize Ocaliva for PBC;
- our ability to maintain our regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which we have or may receive marketing authorization;
- our ability to timely and cost-effectively file for and obtain regulatory approval of our product candidates on an accelerated basis or at all, including OCA for liver fibrosis due to NASH following the issuance of the CRL by the FDA; any advisory committee recommendation or dispute resolution determination that our product candidates, including OCA for liver fibrosis due to NASH, should not be approved or approved only under certain conditions; or any future determination that the regulatory applications and subsequent information we submit for our product candidates, including OCA for liver fibrosis due to NASH, do not contain adequate clinical or other data or meet applicable regulatory requirements for approval;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, including OCA for liver fibrosis due to NASH, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), any risk mitigation programs such as a REMS, and any related restrictions, limitations and/or warnings contained in the label of any of our products or product candidates;

- any potential side effects associated with Ocaliva for PBC, OCA for liver fibrosis due to NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions or otherwise limit the sale of such product or product candidate, including in connection with the NISS relating to Ocaliva identified by the FDA in May 2020;
- the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, retaining patients, meeting specific endpoints in the jurisdictions in which we intend to seek approval or completing and timely reporting the results of our NASH or PBC clinical trials;
- the outcomes of ongoing discussions with the FDA and the EMA regarding the feasibility of the COBALT and 401 trials;
- our ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom we are substantially dependent for, among other things, the manufacture and supply of our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our clinical trial activities;
- our ability to identify, develop and successfully commercialize our products and product candidates, including our ability to successfully launch OCA for liver fibrosis due to NASH, if approved;
- our ability to obtain and maintain intellectual property protection for our products and product candidates, including our ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights;
- the size and growth of the markets for our products and product candidates and our ability to serve those markets;
- the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH or our other product candidates among physicians, patients and healthcare payors;
- the availability of adequate coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our ability to obtain adequate pricing for such products;
- our ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties;
- competition from existing drugs or new drugs that become available;
- our ability to prevent system failures, data breaches or violations of data protection laws;
- costs and outcomes relating to any disputes, governmental inquiries or investigations, regulatory proceedings, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation;
- our collaborators' election to pursue research, development and commercialization activities;
- our ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise;
- our need for and ability to generate or obtain additional financing;

- our estimates regarding future expenses, revenues and capital requirements and the accuracy thereof;
- our use of cash and short-term investments;
- our ability to acquire, license and invest in businesses, technologies, product candidates and products;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to manage the growth of our operations, infrastructure, personnel, systems and controls;
- our ability to obtain and maintain adequate insurance coverage;
- the impact of COVID-19, including any impact on our results of operations or financial position, related quarantines and government actions, delays relating to our regulatory applications, disruptions relating to our ongoing clinical trials or involving our contract research organizations, study sites or other clinical partners, disruptions relating to our supply chain or involving our third-party manufacturers, distributors or other distribution partners, facility closures or other restrictions, and the extent and duration thereof;
- the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the potential impact of Brexit; and
- the other risks and uncertainties identified under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K and in our other periodic filings filed with the SEC.

We have no committed external sources of funding and additional funds may not be available when we need them on terms that are acceptable to us, or at all. In addition, in recent months global markets have experienced significant volatility in connection with concerns over the impact of COVID-19, and such concerns may in the future materially and adversely affect our ability to raise funds. If adequate funds are not available to us, we may not be able to make scheduled debt payments on a timely basis, or at all, and may be required to delay, limit, reduce or cease our operations.

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

Unless and until we generate sufficient cash flow from sales of our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, we expect to finance our future cash needs through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances and licensing arrangements, or a combination of these sources. Additional funding may not be available to us on acceptable terms, if at all.

The terms of any future financing may adversely affect the interests of our existing securityholders. For example, 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 licensing or 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 organization. Prior to the launch and commercialization of Ocaliva for PBC, our operations were limited to developing our technology, undertaking preclinical studies and clinical trials of our product candidates and preparing for the commercial launch of Ocaliva for PBC. Other than Ocaliva for PBC, none of our other product candidates have received regulatory approval. Consequently, any predictions regarding our future success or viability may not be as accurate as they could be if we had a longer operating history or greater experience commercializing approved products.

The commercialization of Ocaliva for PBC has been and will continue to be, and, if approved, the commercialization of OCA for liver fibrosis due to NASH will be, expensive and time-consuming, and we cannot be certain that we will be able to generate sufficient revenues from sales of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH in our target markets to offset such costs. 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 and year-to-year due to a variety of factors, many of which are outside of our control. Such factors include, but are not limited to:

- our ability to successfully commercialize Ocaliva for PBC;
- our ability to maintain our regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which we have or may receive marketing authorization;
- our ability to timely and cost-effectively file for and obtain regulatory approval of our product candidates on an accelerated basis or at all, including OCA for liver fibrosis due to NASH following the issuance of the CRL by the FDA; any advisory committee recommendation or dispute resolution determination that our product candidates, including OCA for liver fibrosis due to NASH, should not be approved or approved only under certain conditions; or any future determination that the regulatory applications and subsequent information we submit for our product candidates, including OCA for liver fibrosis due to NASH, do not contain adequate clinical or other data or meet applicable regulatory requirements for approval;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, including OCA for liver fibrosis due to NASH, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), any risk mitigation programs such as a REMS, and any related restrictions, limitations and/or warnings contained in the label of any of our products or product candidates;
- any potential side effects associated with Ocaliva for PBC, OCA for liver fibrosis due to NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions or otherwise limit the sale of such product or product candidate, including in connection with the NISS relating to Ocaliva identified by the FDA in May 2020;
- the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, retaining patients, meeting specific endpoints in the jurisdictions in which we intend to seek approval or completing and timely reporting the results of our NASH or PBC clinical trials;
- the outcomes of ongoing discussions with the FDA and EMA regarding the feasibility of the COBALT and 401 trials;
- our ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom we are substantially dependent for, among other things, the manufacture and supply of our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our clinical trial activities;

- our ability to identify, develop and successfully commercialize our products and product candidates, including our ability to successfully launch OCA for liver fibrosis due to NASH, if approved;
- our ability to obtain and maintain intellectual property protection for our products and product candidates, including our ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights;
- the size and growth of the markets for our products and product candidates and our ability to serve those markets;
- the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH or our other product candidates among physicians, patients and healthcare payors;
- the availability of adequate coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our ability to obtain adequate pricing for such products;
- our ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties;
- competition from existing drugs or new drugs that become available;
- our ability to prevent system failures, data breaches or violations of data protection laws;
- costs and outcomes relating to any disputes, governmental inquiries or investigations, regulatory proceedings, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation;
- our collaborators' election to pursue research, development and commercialization activities;
- our ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise;
- our need for and ability to generate or obtain additional financing;
- our estimates regarding future expenses, revenues and capital requirements and the accuracy thereof;
- our use of cash and short-term investments;
- our ability to acquire, license and invest in businesses, technologies, product candidates and products;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to manage the growth of our operations, infrastructure, personnel, systems and controls;
- our ability to obtain and maintain adequate insurance coverage;

- the impact of COVID-19, including any impact on our results of operations or financial position, related quarantines and government actions, delays relating to our regulatory applications, disruptions relating to our ongoing clinical trials or involving our contract research organizations, study sites or other clinical partners, disruptions relating to our supply chain or involving our third-party manufacturers, distributors or other distribution partners, facility closures or other restrictions, and the extent and duration thereof;

- the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the potential impact of Brexit; and

- the other risks and uncertainties identified under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K and in our other periodic filings filed with the SEC.

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

***We cannot be certain whether Ocaliva will receive full approval for PBC in jurisdictions where it has previously received accelerated or conditional approval, or that Ocaliva will be approved for PBC in any jurisdictions beyond those in which it is currently approved. Furthermore, OCA may not be approved on an accelerated basis, or at all, for NASH or any other indication beyond PBC and we may not 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, testing, manufacture, packaging, labeling, storage, approval, promotion, advertising, distribution, marketing and export and import, among other things, of our products and product candidates are subject to extensive regulation by the FDA in the United States, the EMA in Europe and various 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 NDA, from the FDA, or a MAA, from the European Commission, respectively. Currently, our ability to generate product sales depends on the successful marketing of Ocaliva for PBC in the jurisdictions in which it has received regulatory approval. In the future, our ability to generate product sales in addition to those of Ocaliva for PBC will depend on whether we are successful in obtaining regulatory approval of our other product candidates, including OCA for liver fibrosis due to NASH.

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 UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. In the United States, Ocaliva was approved for PBC under the accelerated approval pathway. Accelerated approval was granted for Ocaliva for PBC based on a reduction in ALP; however, an improvement in survival or disease-related symptoms has not yet been established. Continued approval of Ocaliva for PBC in the United States is contingent upon the verification and description of clinical benefit in confirmatory trials and our satisfaction of our other post-marketing regulatory requirements. Any delay of the COBALT trial or failure by us to confirm the clinical benefit of Ocaliva for PBC due to COVID-19 or other factors may jeopardize the continued approval of Ocaliva for PBC. As specified by the applicable post-marketing requirements, our COBALT trial includes patients across the spectrum of PBC disease, including early and advanced PBC. We have agreed to evaluate the safety and efficacy of Ocaliva in patients with moderate to severe hepatic impairment and as a monotherapy in patients with PBC. In addition, we 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, and we have fulfilled this commitment.

We commenced our commercial launch of Ocaliva for PBC in certain European countries in 2017 following the European Commission's grant of conditional approval in December 2016. Our marketing authorization in the European Union is conditioned on the successful completion of the COBALT trial and in our 401 trial evaluating the safety and efficacy of Ocaliva in patients with moderate to severe hepatic impairment.

Since January 2017, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada, Israel and Australia, and we are pursuing marketing approval of Ocaliva for PBC in our other international target markets. If obtained, continued approval of Ocaliva for PBC in such jurisdictions may be

contingent upon the verification and description of clinical benefit in confirmatory trials. Any delay or failure in satisfying the post-marketing regulatory commitments and requirements to which we are or may become subject, including our COBALT trial, may jeopardize the continued approval of Ocaliva for PBC in the United States, European Union and other jurisdictions. In some markets where regulatory approval has been obtained for Ocaliva, discussions with national public health system authorities regarding reimbursement are ongoing.

While we remain blinded to safety and efficacy data in the ongoing COBALT trial and 401 trial, the DMC reviewed the unblinded results of a pre-specified interim efficacy analysis of the COBALT trial and separately reviewed unblinded safety and pharmacokinetic data from both the COBALT and 401 trials. Following these reviews, the DMC stated that it was not feasible to continue the COBALT trial as designed and noted the challenges in enrolling and maintaining placebo-controlled post-marketing studies in this rare disease setting. No acute safety concerns were noted by the DMC. Given the feasibility concerns noted by the DMC as well as the potential confounding impact of subjects discontinuing treatment and/or transitioning from investigational product to commercial drug during clinical trials, we continue to discuss with the FDA and the EMA proposed modifications to the COBALT trial as well as proposals with respect to the 401 trial. We have notified the FDA and the EMA of the DMC's recommendation and, as they previously advised, are in ongoing discussions with the FDA on the matter and are seeking formal EU scientific advice with respect to potential alternative study designs. In addition, future changes to our Ocaliva label related to the most advanced PBC patients will influence the modifications to our study design. If we are unable to satisfactorily address the data monitoring committee's recommendation with the FDA and/or the EMA and the COBALT trial cannot be timely completed, cannot be completed as designed or fails, we may not be able to maintain our previously granted marketing approval of Ocaliva for PBC. Ocaliva is not approved for any indication other than PBC. We currently have no other products approved for sale and we cannot guarantee that we will ever have additional marketable products or that OCA will be approved for use in additional indications such as NASH. 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 a NDA or a 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 not guaranteed. Even after the submission of a NDA, the FDA may decide not to accept the submission for filing and review or may determine that the submission does not support approval. For example, in June 2020 we received a CRL from the FDA with respect to our NDA for OCA for liver fibrosis due to NASH. The CRL indicated that, based on the data the FDA had reviewed, the FDA had determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue. Similarly, there are a number of factors that may result in delays in the EMA's review process following the submission of a MAA, or the EMA may determine that the submission does not support approval on a conditional basis, or at all. The United Kingdom left the European Union on January 31, 2020, in what is often referred to as "Brexit," and the end of the transition period was December 31, 2020. At present, the regulatory framework in the United Kingdom is currently aligned with European Union directives and regulations. However, over time, Brexit may result in material changes to the regulatory regime applicable to many of our current operations, including those relating to Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, because of the nature of the Brexit deal (the EU-UK Trade and Cooperation Agreement) between the United Kingdom and the EU, such that the UK is no longer a member of the single market or the customs union. COVID-19 could also affect the operations of the FDA, EMA and other health authorities, which could delay our clinical development efforts and the review and approval of our product candidates, including OCA for liver fibrosis due to NASH.

As is the case with the approval of Ocaliva for PBC, any future approvals or potential future 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, for example, regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory endpoint requirements, regulatory questions regarding safety or risk-benefit profile, 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 approved products. Initial and continued regulatory approval is also dependent on successfully passing regulatory inspection requirements applicable to us, our clinical sites and our key vendors, including requirements

that we and such parties comply with applicable good clinical, pharmacovigilance, laboratory and manufacturing practices regulations. Critical findings could jeopardize or delay the approval of our NDAs or MAAs or impair our ability to maintain our marketing approvals.

Prior to receiving regulatory approval, we must finalize the product label for each of our product candidates in each jurisdiction in which we seek regulatory approval. Even if our product is approved, the FDA, EMA or other applicable regulatory authorities may limit the indications or uses for which our product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials, risk mitigation programs such as a REMS, monitoring or reporting as a condition of approval. Also, regulatory approval for our approved products may be withdrawn. In addition, obtaining regulatory approval for the marketing of our product in one country does not ensure that we will be able to obtain regulatory approval for such product in any other country.

In order to obtain and/or maintain regulatory approval for OCA for indications other than PBC, we will need to complete additional clinical trials and studies. For example, in connection with our Phase 3 clinical program of OCA for liver fibrosis due to NASH, we are currently conducting our Phase 3 REGENERATE trial in patients with liver fibrosis due to NASH through clinical outcomes for verification and description of clinical benefit and our Phase 3 REVERSE trial for NASH patients with compensated cirrhosis. While our ongoing Phase 3 REGENERATE and REVERSE trials are fully enrolled and we have taken measures intended to minimize disruptions and protect and retain patients participating in such trials due to COVID-19, we cannot predict the degree to which such measures will ultimately prove effective. Our ability to obtain and maintain the regulatory approvals necessary to commercialize OCA for indications other than PBC, including NASH, will depend on our ability to successfully design, conduct and complete these trials, the efficacy, safety and risk-benefit profile of OCA demonstrated by such trials and our ability to prepare and submit complex regulatory filings in accordance with applicable regulatory requirements.

There can be no assurance that OCA will receive marketing approval on an accelerated or conditional basis, or at all, for PBC in jurisdictions where it has not yet been approved or for NASH in any jurisdiction, or that any of our other product candidates will receive marketing approval for any indication in any jurisdiction. We cannot predict whether our clinical trials and studies for our product candidates, including OCA for PBC, NASH or any other indication, will be successful, whether regulatory authorities will agree with our conclusions relating to the clinical trials and studies we conduct, or whether such regulatory authorities will require us to conduct additional clinical trials or studies. For example, while OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis and we filed a NDA in the United States and a MAA in Europe based on the results from the 18-month analysis of our Phase 3 REGENERATE trial in patients with liver fibrosis due to NASH, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulatory authorities in the United States, Europe or our other target markets will approve OCA for liver fibrosis due to NASH on an accelerated or conditional basis, or at all. Our Phase 3 REGENERATE trial remains blinded after the interim analysis and is expected to continue to follow patients until the occurrence of a pre-specified number of adverse clinical outcomes, including progression to cirrhosis, for verification and description of clinical benefit.

If we are unable to obtain regulatory approval for OCA for PBC in the jurisdictions in which it is not currently approved or obtain regulatory approval in the United States, European Union and other jurisdictions for OCA for other indications, such as NASH, or for our other product candidates, we may 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 and NASH, and for some of which there is little clinical experience, and our development approach involves new endpoints and methodologies. As a result, there is a heightened risk that we will not be able to gain agreement with regulatory authorities regarding an acceptable development plan, that 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 or limited treatments. As a result, the design and conduct of our clinical trials for these indications is subject to heightened risk.

In the United States, the FDA generally requires two adequate and well-controlled pivotal clinical trials to approve a NDA. Furthermore, for full approval of a NDA, the FDA requires a demonstration of efficacy based on a clinical benefit endpoint. The FDA may grant accelerated approval based on a surrogate endpoint reasonably likely to predict clinical benefit. Even though our pivotal clinical trials for a specific indication, such as our Phase 3 REGENERATE trial of OCA in patients with liver fibrosis due to NASH and our Phase 3 REVERSE trial for NASH patients with compensated cirrhosis, may achieve their primary endpoints and are reasonably believed by us to be likely to predict clinical benefit, the FDA may not accept the results of such trials or approve our product candidate on an accelerated basis, or at all. It is also possible that the FDA may refuse to accept for filing and review any regulatory application we submit for regulatory approval in the United States. Even if our regulatory application is accepted for review, there may be delays in the FDA's review process and the FDA may determine that such regulatory application does not contain adequate clinical or other data or support the approval of the product candidate. In such a case, the FDA may issue a CRL that may require that we conduct and/or complete additional clinical trials and preclinical studies or provide additional information or data before it will reconsider our application for approval. For example, in June 2020 we received a CRL from the FDA regarding our NDA for OCA for liver fibrosis due to NASH. The CRL indicated that, based on the data the FDA had reviewed, the FDA had determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue. The requirements imposed by the FDA may be substantial, expensive and time-consuming, and there is no guarantee that we will continue to pursue any such application or that the FDA will ultimately decide that any such application supports the approval of the product candidate on an accelerated basis, or at all. The FDA may also refer any regulatory application to an advisory committee for review and recommendation as to whether, and under what conditions, the application should be approved. While the FDA is not bound by the recommendation of an advisory committee, it considers such recommendations carefully when making decisions.

Even if we receive accelerated approval for any of our product candidates, we may be required to conduct or complete a post-approval clinical outcomes trial to confirm the clinical benefit of such product candidates by demonstrating the correlation of the surrogate endpoint therapeutic response in patients with a significant reduction in adverse clinical outcomes over time. For example, interim analysis results at 18 months in our Phase 3 REGENERATE trial were based on surrogate endpoints and the impact on clinical outcomes has not been confirmed. The REGENERATE trial is ongoing for verification and description of clinical benefit of OCA for liver fibrosis due to NASH. There can be no assurance that the clinical outcomes portion of our REGENERATE trial will confirm that the surrogate endpoint used as the basis of the regulatory submissions we have made or expect to make seeking approval of OCA for liver fibrosis due to NASH will eventually show an adequate correlation with clinical outcomes. In addition, as a condition of the accelerated approval of Ocaliva for PBC in the United States, we are required to conduct a clinical outcomes study with respect to Ocaliva for PBC. Following discussions with regulatory authorities, we initiated our COBALT clinical outcomes confirmatory trial for PBC in December 2014 prior to the approval of Ocaliva for PBC. The COBALT trial includes subjects across the spectrum of PBC disease, including early and advanced PBC. We have also agreed to evaluate the safety and efficacy of Ocaliva in patients with moderate to severe hepatic impairment in the 401 trial and as a monotherapy in patients with PBC. There can be no assurance that our COBALT trial conducted as part of our post-marketing obligations will confirm that the surrogate endpoint used for accelerated approval of Ocaliva for PBC will eventually show an adequate correlation with clinical outcomes or that our clinical 401 trial in PBC patients with moderate to severe hepatic impairment will be successful.

While we remain blinded to safety and efficacy data in the ongoing COBALT trial and 401 trial, the DMC reviewed the unblinded results of a pre-specified interim efficacy analysis of the COBALT trial and separately reviewed unblinded safety and pharmacokinetic data from both the COBALT and 401 trials. Following these reviews, the DMC stated that it was not feasible to continue the COBALT trial as designed and noted the challenges in enrolling and maintaining placebo-controlled post-marketing studies in this rare disease setting. No acute safety concerns were noted by the DMC. Given the feasibility concerns noted by the DMC and the potential confounding impact of subjects discontinuing treatment and/or transitioning from investigational product to commercial drug during clinical trials, we continue to discuss with the FDA and the EMA proposed modifications to the COBALT trial as well as proposals with respect to the 401 trial. We have notified the FDA and the EMA of the DMC's recommendation and, as they previously advised, are in ongoing discussions with the FDA on the matter and are seeking formal EU scientific advice with respect to potential alternative study designs.

In addition, future changes to our Ocaliva label related to the most advanced PBC patients will influence the modifications to our study design. If we are unable to satisfactorily address the DMC's recommendation with the FDA and/or the EMA and the COBALT trial cannot be timely completed, cannot be completed as designed or fails, we may not be able to maintain our previously granted marketing approval of Ocaliva for PBC. Similarly, if approved based on a surrogate endpoint, continued approval of OCA for other indications, or of any of our other product candidates, may be contingent upon the verification and description of clinical benefit in confirmatory trials.

Our marketing authorization in the European Union for Ocaliva for the treatment of PBC is not a full approval. Instead, it is conditional on the conduct of certain post-approval studies, including the COBALT trial. Our ability to maintain conditional marketing authorization of Ocaliva for PBC in the European Union is limited to specific circumstances and subject to several conditions and obligations that we may be unable to satisfy in whole or at all, including the completion of one or more clinical outcomes trials to confirm the clinical benefit of Ocaliva for 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 (i) the risk-benefit balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (iii) unmet medical needs will be fulfilled and (iv) 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 obligations relating to the timely and successful completion of ongoing or new studies and 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. Although we have successfully renewed our conditional marketing authorization in the European Union in the past, there can be no assurance that we will be able to continue to do so in the future. Failure to renew our conditional marketing authorization would prevent us from continuing to market Ocaliva for PBC in Europe.

Our ongoing Phase 3 REGENERATE trial of OCA in patients with liver fibrosis due to NASH incorporates an interim primary surrogate endpoint that may serve as the basis for accelerated approval in the United States and as the basis for a conditional approval in Europe. Accelerated approval in the United States and conditional approval in the European Union for OCA for liver fibrosis due to NASH are subject to similar risks as discussed above in relation to OCA for PBC. In the REGENERATE primary efficacy analysis, once-daily OCA 25 mg met, with statistical significance, the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH (defined as no worsening of hepatocellular ballooning, no worsening of lobular inflammation and no worsening of steatosis) at the planned 18-month analysis. Although a numerically greater proportion of patients in both OCA treatment groups compared to placebo achieved the primary endpoint of NASH resolution with no worsening of liver fibrosis in the primary efficacy analysis, this result did not reach statistical significance. As agreed with the FDA, in order for the primary objective to be met, the study was required to achieve one of the two primary endpoints. Notwithstanding the results of the REGENERATE 18-month analysis, the recent CRL issued by the FDA indicated that, based on the data the FDA had reviewed, the FDA had determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue. Although we are in discussions with the FDA with respect to the potential resubmission of our NDA seeking accelerated approval of OCA for the treatment of liver fibrosis due to NASH, there is no assurance that we will be successful or that OCA will be approved for liver fibrosis due to NASH on an accelerated basis, or at all. Furthermore, in November 2018, the EMA issued a draft position paper in which it presented its preliminary views with respect to various NASH clinical development matters, including with respect to potential surrogate endpoints, and requested comments thereon by August 2019. Although we did not reach agreement with the EMA on the definition and analysis of a surrogate endpoint prior to the readout of the 18-month analysis of the REGENERATE trial, we believe that the totality of the REGENERATE interim analysis data supports the MAA we filed with the EMA. However, the data that we have submitted to the EMA may not ultimately be found by the EMA to be sufficient for marketing approval on a conditional basis, or at all. In June 2019, the FDA issued new draft guidance on the development of drugs for the treatment of NASH patients with compensated cirrhosis. Although we believe that, if successful, our Phase 3 REVERSE trial will support a regulatory submission seeking accelerated approval of OCA for liver fibrosis due to NASH with compensated

cirrhosis in the U.S., we do not know if achievement of the primary endpoint will ultimately be found sufficient by the FDA for approval on an accelerated basis, or at all.

While OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis and we have filed a NDA in the United States and a MAA in Europe for approval of OCA for liver fibrosis due to NASH based on the results from the 18-month interim analysis of our Phase 3 REGENERATE trial, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulatory authorities in the United States, Europe or our other target markets will approve OCA for liver fibrosis due to NASH on an accelerated or conditional basis, or at all. There may be delays in the FDA and EMA review processes and the FDA and/or the EMA may also require that we continue our Phase 3 REGENERATE trial until completion to assess the 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 the EMA. As a result, we may face difficulty in establishing an acceptable registration strategy with respect to our Phase 3 REGENERATE and REVERSE trials, as well as other trials we may conduct in other subpopulations of NASH patients.

Prior to any approval of OCA for liver fibrosis due to NASH or OCA for PBC in jurisdictions in which it is not currently approved or the approval of our other product candidates, the FDA, EMA or other applicable regulatory authorities may require additional preclinical studies and/or clinical trials, which may be expensive and time consuming to conduct and complete. Consequently, any such requirement 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 such approval, any risk mitigation programs such as a REMS, and any related restrictions, limitations and/or warnings contained in the label of our approved products could impact our commercial success in our target markets including with respect to future revenues generated by Ocaliva.

***Delays or difficulties in the commencement, enrollment and completion of our clinical trials and studies could increase our product development costs and delay, limit or prevent us from obtaining regulatory approval for OCA and our other product candidates.***

Delays or difficulties in the commencement, enrollment and completion of our clinical trials and studies could increase our product development costs and limit or prevent us from obtaining or maintaining regulatory approval for OCA and our other product candidates. We are currently conducting a number of clinical trials, including our Phase 4 COBALT clinical outcomes confirmatory trial of Ocaliva for PBC, our Phase 3 REGENERATE trial of OCA in patients with liver fibrosis due to NASH through clinical outcomes in order to confirm clinical benefit and our Phase 3 REVERSE trial of OCA for NASH patients with compensated cirrhosis. We are also conducting our CARE trial of OCA in pediatric patients with biliary atresia as a part of an EMA-approved PIP supporting the conditional approval of Ocaliva for PBC. The results from these clinical trials and our other clinical trials and studies may not be available when we anticipate and we may be required to conduct additional clinical trials or studies not currently planned in order for our product candidates, including OCA for PBC and NASH, to be approved or to maintain approvals in the U.S., Europe or the other jurisdictions in which our products are approved. In addition, our clinical programs are subject to a number of risks and uncertainties, such as the results of other trials, patient enrollment, safety issues or regulatory interactions that could result in a change of trial design or timing. For example, we recently paused enrollment in our Phase 4 COBALT confirmatory outcomes trial evaluating Ocaliva for PBC and in our Phase 4 clinical trial of Ocaliva in patients with PBC who have moderate to severe hepatic impairment (Child-Pugh B and C) known as the 401 trial pending the results of discussions with the FDA and the EMA regarding proposals with respect to such trials. Any delays or difficulties completing such trials as a result of the pause in enrollment could increase our product development costs and limit or prevent us from obtaining or maintaining regulatory approval. Consequently, we do not know whether our current or future clinical trials or studies of OCA or our other product candidates will be completed on schedule, if at all.

The commencement, enrollment and completion of our clinical trials and studies may be delayed, suspended or otherwise adversely affected for a variety of reasons, including:

- our inability to obtain sufficient funds to complete or continue our clinical trials;

- our inability to reach agreements on acceptable terms with prospective contract research organizations ("CROs") and trial sites, the terms of which may be subject to extensive negotiation and may vary significantly among our various CROs and trial sites;

- clinical holds, other regulatory objections to our commencing or continuing a clinical trial or our inability to obtain regulatory approval to commence clinical trials in countries that require such approvals;

- our discussions with the FDA, EMA or other regulatory authorities prior to, or following, the initiation of our clinical trials, regarding, among other matters, the scope or design of our clinical trials, including trial endpoints, protocols and statistical analysis plans, and any modifications thereto;

- our 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;

- any delay in receiving results from, or failure to achieve the necessary results in, our clinical trials;

- our inability to obtain approval from institutional review boards or independent ethics committees to conduct our clinical trials at their respective sites;

- any data monitoring committee recommendation that our clinical trials be modified, suspended or terminated due to safety, lack of efficacy or other reasons;

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

- any breach of the terms of any relevant agreement by us, our current or future collaborators that have responsibility for the clinical development of any of our product candidates or investigators conducting clinical trials on our product candidates;

- our inability to timely manufacture, or obtain from our contract manufacturers, sufficient quantities of our product candidate required for our clinical trials; and

- any difficulty recruiting, enrolling or retaining patients in our clinical trials based on, among other factors, the enrollment criteria for our clinical trials, the rarity of the disease, the characteristics of the population being studied, the risks of the procedures that may be required as part of the clinical trials, such as a liver biopsy, the availability of our products to patients generally following the approval of such products or competition from other clinical trial programs recruiting patients for the same indications as our product candidates.

For example, our Phase 3 REGENERATE trial is a large and complicated clinical trial in a disease without any approved therapies and involves serial liver biopsies over many years. While we announced topline results from the 18-month analysis of our pivotal Phase 3 REGENERATE trial in February 2019, the study is currently planned to continue through clinical outcomes in order to confirm clinical benefit and there can be no assurance that we will retain a sufficient number of patients in the full study cohort or complete the clinical outcomes trial in accordance with the study protocol or on a timely basis, if at all. Similarly, our COBALT clinical outcomes confirmatory trial for PBC includes subjects across the spectrum of PBC disease, including early and advanced PBC. Enrolling and retaining patients in such trials is challenging and there can be no assurance that we will complete the clinical outcomes trial in accordance with the study protocol or on a timely basis, if at all. As we engage in other large and complicated trials and trials in advanced disease populations, we may experience a number of challenges that may negatively affect or delay our plans and development programs.

We have in the past experienced difficulties enrolling and retaining patients enrolled in our clinical trials. Difficulties in enrolling and retaining patients, including due to COVID-19, may delay our clinical trials or result in negative or inconclusive outcomes, and we or our collaborators may decide, or regulatory authorities may require us, to conduct additional clinical trials or additional analyses of existing clinical trials. Any delay or compromises with respect to the validity of our clinical trials may have a material adverse effect on our business or decrease our competitive position relative to other biotechnology or pharmaceutical companies with whom we compete.

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

***COVID-19 could materially and adversely affect our clinical trials.***

COVID-19 is a global pandemic, affecting the U.S., Europe, and other countries in which we are engaged in, or plan to engage in, clinical development activities. We continue to closely monitor the COVID-19 pandemic and, together with our contract research organizations, study sites and other partners, have taken measures intended to minimize disruptions and protect and retain patients enrolled in our clinical trials, including, where appropriate, the use of telemedicine, home care visits, direct delivery of investigational product and other measures. Notwithstanding our efforts, some of the sites participating in our clinical trials have been affected by site closings or reduced capacity, particularly in regions that are experiencing heightened impact from COVID-19. While we continue to monitor the situation closely, if there was a meaningful negative impact on the data capture or data quality of any of our clinical trials, such trials may not be successful or we could be required to repeat, extend the duration of, increase the size of, or otherwise modify such trials, which could prevent or significantly delay the potential commercialization of our product candidates and require greater expenditures. We cannot at this time predict with certainty the scope of the impact of COVID-19 on our ability to execute our clinical trials. The extent to which COVID-19 may impact our clinical trials will depend on future developments, which are highly uncertain, such as the continued geographic spread of the disease, the duration of the pandemic, public health restrictions on travel and in-person interactions, business closures and disruptions, and the effectiveness of actions taken to contain and treat the disease. As a result, our clinical trials may not be successful or we may experience issues due to COVID-19 that could severely impact our clinical trials, including:

- delays, interruptions or difficulties in the enrollment, scheduling and retention of patients in our clinical trials;
- delays, interruptions or difficulties in the conduct of key clinical trial activities, such as clinical trial site monitoring and inspection readiness activities;
- trial conduct issues, including protocol deviations (e.g., failure to timely collect liver biopsies or other required laboratory data), data capture issues and data quality issues;
- delays or interruptions in the supply or administration of investigational product to patients in our clinical trials;
- delays or interruptions in the supply of necessary equipment or materials to clinical sites;
- delays or difficulties obtaining approvals from regulatory authorities, institutional review boards or ethics committees of clinical trial protocols and related clinical documentation (or amendments and addendums thereto);
- delays, interruptions or difficulties in clinical site initiations, including in connection with the recruitment of clinical site investigators and clinical site staff;
- the redeployment of healthcare resources, including clinical site investigators and clinical site staff supporting the conduct of our clinical trials, to assist in the treatment of COVID-19 patients;

- the diversion of human capital, including employees, independent contractors, vendors and other third parties, otherwise focused on the conduct of our clinical trials due to sickness, safety concerns or government or employer imposed travel or working restrictions;

- new federal, state and local government regulations or guidance that require us to change the way we conduct our clinical trials, require the interruption or termination of our clinical trials or that result in significant and unexpected new costs;

- delays or difficulties in interactions with regulatory authorities, institutional review boards, ethics committees and key consultants and vendors due to layoffs, temporary leaves, terminations or other actions limiting available employee resources; and

- the refusal of regulatory authorities to accept clinical trial data from clinical trials that have been negatively affected by COVID-19.

Any such delay, interruption or issue could materially and adversely affect our business, financial condition and results of operations.

***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 or our collaborators advance through clinical trials, including OCA, may not have favorable results in later clinical trials or receive or maintain regulatory approval.***

Clinical failure can occur at any stage of 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 our product candidates. 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 clinical trials, including trial endpoints, protocols and statistical analysis plans, can determine whether such trials will support product approvals, and flaws in the design of such trials may not become apparent until such trials are well-advanced. We may be unable to design and execute clinical trials to support regulatory approval. Further, clinical trials of product candidates 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 sufficient efficacy for any indication, we will not be able to obtain or maintain regulatory approval for them, and our prospects and business may be materially and adversely affected.

There may be significant variability in the safety and/or efficacy results we see in different trials studying OCA or our other product candidates due to numerous factors, including differences in the underlying disease being studied, changes or differences in trial protocols or statistical analysis plans, differences in the composition of the patient populations or clinical trial sites, differences in adherence to the dosing regimen and other aspects of the trial protocols and differences in the rate of dropouts 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 on our product candidates will demonstrate consistent or adequate efficacy and safety or result in the approval of our product candidates by regulatory authorities. If we are unable to bring any of our current or future product candidates to market, acquire any previously approved products or maintain approval for our approved products, our ability to create long-term stockholder value will be limited.

Although Ocaliva for PBC has received accelerated approval in the United States and conditional approval in the European Union, its full approval depends on the timely completion and results of post-marketing clinical trials, including our Phase 4 COBALT trial. We cannot assure you that these trials will be timely completed or that the results of such trials

will support the full approval of Ocaliva in the United States, European Union or our other target markets where Ocaliva has not received full approval.

In December 2014, we received comprehensive datasets from the Phase 2b FLINT trial for the treatment of NASH, which met its primary endpoint with statistical significance. In October 2015, we announced that the Phase 2 dose ranging trial of OCA in 200 adult NASH patients in Japan conducted by our former collaborator, Sumitomo Dainippon, did not meet its primary endpoint with statistical significance. In the Sumitomo Dainippon 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 Sumitomo Dainippon Phase 2 trial involved different doses of OCA being administered to the trial subjects than those utilized in the Phase 2b FLINT trial. Furthermore, the baseline characteristics between the patients in the Japanese Phase 2 dose ranging 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.

In February 2019, we announced topline results from the 18-month analysis of our pivotal Phase 3 REGENERATE trial in patients with liver fibrosis due to NASH. In the primary efficacy analysis, once-daily OCA 25 mg met, with statistical significance, the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH (defined as no worsening of hepatocellular ballooning, no worsening of lobular inflammation and no worsening of steatosis) at the planned 18-month analysis. Although a numerically greater proportion of patients in both OCA treatment groups compared to placebo achieved the primary endpoint of NASH resolution with no worsening of liver fibrosis in the primary efficacy analysis, this result did not reach statistical significance. As agreed with the FDA, in order for the primary objective to be met, the study was required to achieve one of the two primary endpoints. Notwithstanding the results of the REGENERATE 18-month analysis, the recent CRL issued by the FDA indicated that, based on the data the FDA had reviewed, the FDA had determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue. Although we are in discussions with the FDA with respect to the potential resubmission of our NDA seeking accelerated approval of OCA for the treatment of liver fibrosis due to NASH, there is no assurance that we will be successful or that OCA will be approved for liver fibrosis due to NASH on an accelerated basis, or at all. While OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis and we filed a NDA in the United States and a MAA in Europe for approval of OCA for liver fibrosis due to NASH based on the results from the 18-month analysis of our Phase 3 REGENERATE trial in patients with liver fibrosis due to NASH, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulatory authorities in the United States, Europe or our other target markets will approve OCA for liver fibrosis due to NASH on an accelerated or conditional basis, or at all. Additionally, interim analysis results at 18 months were based on surrogate endpoints and the impact on clinical outcomes has not been confirmed. Our Phase 3 REGENERATE trial remains ongoing through clinical outcomes for verification and description of clinical benefit of OCA for liver fibrosis due to NASH.

***Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require that our products be taken off the market or include new or additional safety warnings. Any such events may limit our existing and future product sales and materially and adversely affect our business, financial condition and results of operations.***

OCA has been shown to be a potent FXR agonist. With the exception of the endogenous human bile acid chenodeoxycholic acid 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, including OCA, could arise either during clinical development or, if approved, after the approved product has been marketed. Serious adverse events, including deaths, in patients taking OCA have occurred in clinical trials and in the post-marketing setting, and we cannot assure you that additional serious adverse events in patients taking OCA in clinical trials or in the post-marketing setting will not occur.

The most common side effects observed in clinical trials of OCA for PBC were pruritus, fatigue, headaches, nausea, constipation and diarrhea. In our Phase 3 POISE trial, pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment for PBC and was observed in 38% of patients on placebo, 70% of patients in the OCA 10 mg 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%) were in the OCA 10 mg group and one (1%) was in the OCA titration group. Pruritus also has been observed in other clinical trials of OCA. Decreases in high density lipoprotein HDL cholesterol were also observed during treatment in our Phase 3 POISE trial. In our Phase 2 trials for OCA for PBC, a dose-response relationship was observed in 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.

In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. As a result, in September 2017, we issued a Dear Health Care Provider (“DHCP”) letter, and the FDA also subsequently issued its own drug safety communication to reinforce recommended label dosing. Both communications remind healthcare providers of the importance of the recommended reduced dosing of Ocaliva in PBC patients with moderate or severe hepatic impairment, while reiterating the importance of monitoring PBC patients for progression of their disease and the occurrence of liver-related adverse reactions. In addition to the DHCP letter, we took actions to enhance education about appropriate use of Ocaliva. These initiatives included: reeducating physicians on the label, with a focus on ensuring appropriate dosing for patients with moderate or severe hepatic impairment; enhancing monitoring of patients for liver-related adverse reactions; and adjudicating reported cases of serious liver injury, including in patients with no or mild hepatic impairment. In February 2018, we announced that the Ocaliva label in the United States had been updated by the FDA to include a boxed warning and a dosing table that reinforced the then-existing dosing schedule for patients with Child-Pugh Class B or C or decompensated cirrhosis. In addition, the FDA issued an updated drug safety communication to accompany the revised label. We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis.

The FDA has notified us that, in the course of its routine safety surveillance, in May 2020 the FDA began to evaluate a newly identified safety signal, or NISS, regarding liver disorder for Ocaliva which the FDA classified as a potential risk. The FDA has informed us that its review of the NISS is focused on a subset of the cirrhotic, or more advanced, PBC patients who have taken Ocaliva. As part of our routine pharmacovigilance efforts, we worked with the FDA to reconcile our internal safety database with the FDA Adverse Event Reporting System database and we completed a comprehensive assessment of all available data, including data from our completed clinical trials, blinded reviews of ongoing clinical trial data, unblinded reviews of certain ongoing clinical trial data by the DMC, post-marketing data and natural history data, which we submitted to the FDA and had a meeting earlier in 2021 to discuss. We are working with the FDA to align on changes to the Ocaliva label regarding patients with the most advanced stages of PBC. Based on our communications with the FDA, this update will come in the form of a safety labeling change. These communications are ongoing and any safety concerns associated with Ocaliva, perceived or real, may adversely affect the successful development and commercialization of our product candidates and approved products, including Ocaliva, and materially and adversely affect our business including future revenue generated by Ocaliva.

Ocaliva is contraindicated for PBC patients with complete biliary obstruction in the United States and the European Union. For PBC 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.

In the 18-month analysis of our pivotal Phase 3 REGENERATE trial in patients with liver fibrosis due to NASH, the safety population included 1,968 randomized patients who received at least one dose of investigational product (OCA or placebo) with exposures up to 37 months. Adverse events were generally mild to moderate in severity and the most common were consistent with the known profile of OCA. The frequency of serious adverse events was similar across

treatment groups (11% in placebo, 11% in OCA 10 mg and 14% in OCA 25 mg), and no serious adverse event occurred in > 1% of patients in any treatment group. There were 3 deaths in the study (2 in placebo: bone cancer and cardiac arrest and 1 in OCA 25 mg: glioblastoma) and none were considered related to treatment. The most common adverse event reported was dose-related pruritus (19% in placebo, 28% in OCA 10 mg and 51% in OCA 25 mg). The incidence of pruritus across all three treatment groups was highest in the first three months and decreased thereafter. The large majority of pruritus events were mild to moderate, with severe pruritus occurring in a small number of patients (< 1% in placebo, < 1% in OCA 10 mg and 5% in OCA 25 mg). A higher incidence of pruritus-associated treatment discontinuation was observed for OCA 25 mg (< 1% in placebo, < 1% in OCA 10 mg and 9% in OCA 25 mg). According to the clinical study protocol, investigator assessed severe pruritus mandated treatment discontinuation. Consistent with observations from previous NASH studies, OCA treatment was associated with an increase in low density lipoprotein ("LDL") cholesterol, with a peak increase of 22.6 mg/dL at 4 weeks and subsequently reversing and approaching baseline at month 18 (4.0 mg/dL increase from baseline). Triglycerides rapidly and continually decreased in the OCA treatment groups through month 18. There were few and varied serious cardiovascular events and incidence was balanced across the three treatment groups (2% in placebo, 1% in OCA 10 mg and 2% in OCA 25 mg). In patients with type 2 diabetes, OCA treatment was associated with an early transient increase in fasting glucose and hemoglobin A1c with return to levels similar to placebo by month 6. No clinically meaningful changes were noted in non-diabetic patients.

With respect to hepatobiliary events, more patients (3%) on OCA 25 mg experienced gallstones or cholecystitis compared to < 1% on placebo and 1% on OCA 10 mg. While hepatic serious adverse events were rare (< 1% incidence in each of the three treatment groups), more occurred in the OCA 25 mg group with no pattern attributable to OCA.

In the Phase 2b FLINT trial, pruritus occurred more frequently in the OCA treatment group than in the placebo treatment group (23% vs. 6%, $p < 0.0001$) and at a higher grade (predominately moderate pruritus). OCA treatment was also 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. These changes in cholesterol levels, along with the achievement of pre-defined efficacy criteria, played a role in the decision of the FLINT data and safety monitoring board to terminate the treatment phase of the Phase 2b FLINT trial, and the publication of the FLINT results noted the need for further study of these changes. There were two patient deaths in the Phase 2b FLINT trial, and neither death was considered related to OCA treatment.

Furthermore, the Phase 2 dose ranging trial of OCA in 200 adult NASH patients in Japan conducted by our former collaborator, Sumitomo Dainippon, did not meet statistical significance for the primary endpoint. The primary endpoint in the Sumitomo Dainippon trial was histologic improvement defined as at least a two-point improvement in the nonalcoholic fatty liver disease activity score with no worsening of fibrosis. 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.

In December 2015, we initiated a Phase 2 clinical trial, known as the CONTROL trial, to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. CONTROL enrolled 80 NASH patients who were naïve to statin therapy or had undergone a statin washout period. The study included a 16-week double-blind phase followed by an optional long-term safety extension ("LTSE") phase of the 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 OCA 5 mg group, 10% of patients in the OCA 10 mg group and 55% of patients in the OCA 25 mg group. All adverse events were mild to moderate and two patients discontinued treatment in the OCA 25 mg group due to pruritus. Over 95% of the patients completing the double-blind phase of CONTROL enrolled in the LTSE phase of the trial.

During the LTSE phase of CONTROL, there was 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 decline 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 OCA 25 mg 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 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.

Additional or unforeseen side effects relating to 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 for PBC in the United States, Europe and certain of our other target markets, OCA is currently 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 PBC, NASH and other potential indications. Furthermore, our commercial sales of Ocaliva for PBC may be materially and adversely affected.

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

In addition, our product candidates are being developed as potential treatments for severe, life threatening diseases and, as a result, our trials will necessarily be conducted in patient populations that are more prone than the general population to exhibit certain disease states or adverse events. For example, our Phase 3 REVERSE trial in NASH patients with compensated cirrhosis has expanded our NASH development program into a more advanced NASH patient population and accordingly imposes certain eligibility requirements for uptitration, as well as certain monitoring requirements thereafter. Ocaliva is prescribed 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 clinical trials or by patients using our approved products are related to our product candidates or approved products or some other factor. As a result, we and our development programs may be negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our product candidates or approved products. We cannot assure you that additional or more severe adverse side effects related to OCA or our other product candidates will not be observed in our clinical trials or in the commercial setting. If observed, such adverse side effects could delay or preclude regulatory approval of OCA, limit commercial use or result in the withdrawal of previously granted marketing approvals.

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

- we may be required to modify, suspend or terminate our clinical trials;

- we may be required to modify or include additional dosage and administration instructions, warnings and precautions, contraindications, boxed warnings, limitations, restrictions or other statements in the product label for our approved products, or issue field alerts to physicians and pharmacies or implement other risk mitigation programs;
- we may be required to conduct costly additional clinical trials;
- we may be subject to limitations on how we may promote our approved products;
- sales of our approved products may decrease significantly;
- regulatory authorities may require us to take our approved products off the market;
- we may be subject to regulatory investigations, government enforcement actions, litigation or product liability claims; and
- our products may become less competitive or our reputation may suffer.

***Breakthrough therapy designation for OCA may not lead to faster development or regulatory processes or increase the likelihood that the FDA will approve OCA for the treatment of NASH patients with fibrosis.***

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 marketing approval by the FDA.

In January 2015, we received breakthrough therapy designation for OCA for the treatment of NASH patients with liver fibrosis. However, there is no guarantee that the receipt of breakthrough therapy designation will result in a faster development process, review or approval of OCA for liver fibrosis due to NASH or increase the likelihood that OCA will be granted marketing approval for NASH patients with liver fibrosis. Notwithstanding our receipt of breakthrough therapy designation, in June 2020 we received a CRL from the FDA with respect to our NDA for OCA for liver fibrosis due to NASH. Although we are in discussions with the FDA with respect to the potential resubmission of our NDA seeking accelerated approval of OCA for the treatment of liver fibrosis due to NASH, there is no assurance that the outcome of these discussions will lead to resolution of the issues identified in the CRL or that if we resubmit our NDA that it will be approved. Similarly, any future breakthrough therapy designation relating to any other potential indication of OCA or our other product candidates will neither guarantee a faster development process, review or approval nor improve the likelihood of the grant of marketing approval by the FDA compared to conventional FDA procedures. In addition, the FDA may withdraw any breakthrough therapy designation at any time. While we may seek breakthrough therapy designation for one or more of our product candidates in the future, we can give no assurance that the FDA will grant such status.

***We may not be able to obtain or, if approved, maintain orphan drug exclusivity for our approved products or product candidates, which could 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. OCA has received orphan drug designation in the United States and the European Union for the treatment of PBC and PSC.

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 FDA or the EMA from approving another marketing application for the same product during the exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. 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 a sufficient quantity of the product to meet the needs of patients with the rare disease or condition. In addition, the European exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify maintenance of market exclusivity.

Any failure to maintain orphan drug status may subject us to mandatory price discounts in Europe and result in the loss of 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 or EMA may subsequently approve another product for the same condition if the FDA or EMA concludes that the later product is clinically superior (i.e., it is shown to be safer, more effective or makes a major contribution to patient care). Any inability to secure or maintain orphan drug status or the exclusivity benefits of this status could have a material adverse impact on our ability to develop and commercialize our product candidates and approved products.

***We rely entirely on third parties for the manufacture of our product requirements for our preclinical studies and clinical trials, as well as our commercial supply of Ocaliva and, if approved, OCA for liver fibrosis due to NASH and our other product candidates, and also depend on third-party vendors and CROs for certain of our clinical trial and product development activities. Our business could be harmed if our third-party manufacturers fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices, or if our third-party vendors or CROs assisting us with our clinical trials and product development activities fail to comply with their contractual commitments or applicable regulatory obligations or if we lose our relationships with our third-party vendors and CROs.***

We do not manufacture the pharmaceutical products that we sell or the product candidates that we are developing. We rely on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredient and finished product for our commercial sales and for our existing and anticipated clinical trials and preclinical studies. Any inability by our contract manufacturers to continue to provide services to us for any reason, including due to COVID-19 and related government-imposed shelter-in-place mandates, restrictions on travel and in-person interactions, business closures and disruptions and other public health safety measures, could disrupt the supply chain for our pharmaceutical products and product candidates and materially and adversely affect our commercialization efforts and clinical development program, and we may be unable to identify, qualify and engage replacement suppliers on terms that are favorable to us on a timely basis, if at all. The extent to which COVID-19 impacts the operations of our third-party contract manufactures will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the geographic spread of the disease, the duration of the outbreak, public health safety measures and the effectiveness of the actions taken to contain and treat the disease.

We rely on PharmaZell GmbH and other suppliers for the manufacture and commercial supply of API for use in Ocaliva and, if approved, OCA for liver fibrosis due to NASH. We are currently dependent upon a limited number of suppliers, with whom we have contractual arrangements, although we are working on developing further sources of supply. While we have procured supplies of API for the commercialization of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH that we believe will be sufficient to meet our requirements during the initial stages of a potential NASH launch, we may not be able to procure sufficient supplies of API on an ongoing basis. If these suppliers are unable to provide adequate supply, we may not be able to meet our long-term commercial supply requirements of API for the manufacture of Ocaliva or, if approved, OCA for liver fibrosis due to NASH or other indications on acceptable terms, or at all. We do not have agreements for long-term supplies of any of our product candidates other than OCA. We currently obtain supplies and services relating to our other product candidates from our third-party contract manufacturers on a purchase order basis.

The facilities used by any contract manufacturer to manufacture OCA or any of our other product candidates are subject to inspection by the FDA and regulators in other jurisdictions. 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, including Ocaliva. If our manufacturers are unable to meet our requirements in accordance with our product specifications and applicable current Good Manufacturing Practices ("cGMP") requirements, our products or product candidates will not be approved or, if already approved, may be subject to recall. In addition, if COVID-19 or related public health safety measures prevent the FDA, EMA or other relevant regulators from conducting manufacturing inspections or other regulatory activities with respect to manufacturing, it could significantly impact the ability of the FDA, EMA or such other regulators to timely review and process our regulatory submissions, which could have a material and adverse effect on our business and financial condition.

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

- the possibility that we are unable to enter into or renew our manufacturing agreements with third parties on acceptable terms, or at all;
- the possible termination, breach or non-performance by our third-party manufacturers of our manufacturing agreements based on factors beyond our control; and
- our inability to timely identify and qualify a replacement for any of our third-party manufacturers in the event any such third-party manufacturer fails to meet our product requirements or following the termination, expiration or nonrenewal of our agreements with such third-party manufacturer.

Any of these factors could disrupt the supply of our product candidates or approved products, cause us to incur higher costs, delay the approval of our product candidates or prevent or disrupt the commercialization of our approved products. Furthermore, if any of our product candidates, including OCA for liver fibrosis due to NASH, are approved and our contract manufacturers fail to deliver the required commercial quantities of API or 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 such product candidate following its approval and could lose potential revenue. It may take several years to establish an alternative long-term source of supply and to have any such new source approved by the regulatory authorities that regulate our products in the United States, Europe and our other target markets.

We depend on third-party vendors and CROs for certain of our clinical trial and product development activities. If any of these providers fail to comply with their contractual commitments or applicable regulatory obligations, including due to COVID-19 and related government-imposed shelter-in-place mandates, restrictions on travel and in-person interactions, business closures and disruptions and other public health safety measures, our business could be materially and adversely affected. In addition, if we are unable to maintain our relationship with any one or more of these providers, we could experience a significant delay in both identifying another comparable provider and then contracting for its services, which could materially and adversely affect our clinical trial and product development efforts. We may be unable to retain an alternative provider on reasonable terms, or at all. Even if we locate an alternative provider, it is likely that such a provider will need additional time to respond to our needs and may not provide the same type or level of services as the original provider. Any third-party vendors and CROs that we retain are subject to the FDA's regulatory requirements and similar foreign standards and we do not have control over compliance with these regulations by these providers. The FDA, EMA and other relevant regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If these regulations are not adhered to by these providers, or if such providers fail to timely correct any non-compliance or if COVID-19 or related public health safety measures prevent the FDA, EMA or other relevant regulatory authorities from conducting inspections or other regulatory activities, the commercialization and development of our product candidates or approved products could be delayed, which could materially and adversely harm our business and financial condition.

***Even though we have received conditional approval of Ocaliva for PBC, we and our contract manufacturers are still subject to strict, ongoing regulatory requirements.***

Even though we have received conditional approval of Ocaliva for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA, we and our contract manufacturers are subject to ongoing regulatory requirements relating to, among other things, Ocaliva's manufacturing, packaging, labeling and storage. In addition, we and our contract manufacturers and our contract manufacturers' facilities are required to comply with extensive FDA and EMA requirements and the requirements of other similar regulatory authorities, including requirements that quality control and manufacturing procedures conform to current cGMPs. As such, we and our contract manufacturers are subject to periodic cGMP inspections and other inspections and audits required by law or industry standard and must continue to expend time, money and effort to ensure compliance with applicable manufacturing, production and quality control requirements. We are also required to report certain adverse reactions and production problems, if any, to the FDA, EMA and other similar regulatory authorities 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 generally must be consistent with the information in the product's approved label.

If a regulatory authority such as the FDA identifies previously unknown problems with one of our products, 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 one of our products, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. In addition, if we or our contract manufacturers, other third-party vendors or collaborators fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue Form 483 notices or Warning Letters, in the case of the FDA, or similar notices, in the case of other regulatory agencies;
- mandate modifications to our 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 may include the imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- recall our products;
- suspend any of our ongoing clinical studies;
- impose administrative, civil or criminal penalties;
- withdraw regulatory approval or require changes to our product label, including the inclusion of additional warnings or changes to the approved indication;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- impose restrictions on our operations or those of our contract manufacturers, including costly new manufacturing requirements; or
- seize or detain products.

## Risks Related to the Commercialization of Our Products

***Sales of Ocaliva may be adversely affected by safety and labeling changes required by the FDA***.

In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. As a result, in September 2017, we issued a DHCP letter and the FDA also subsequently issued its own drug safety communication to reinforce recommended label dosing. Both communications remind healthcare providers of the importance of the recommended reduced dosing of Ocaliva in PBC patients with moderate or severe hepatic impairment, while reiterating the importance of monitoring PBC patients for progression of their disease and the occurrence of liver-related adverse reactions. In February 2018, we announced that the Ocaliva label in the United States had been updated by the FDA to include a boxed warning and a dosing table that reinforced the then-existing dosing schedule for patients with Child-Pugh Class B or C or decompensated cirrhosis. In addition, the FDA issued an updated drug safety communication to accompany the revised label. We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis.

The FDA has notified us that, in the course of its routine safety surveillance, in May 2020 the FDA began to evaluate a newly identified safety signal, or NISS, regarding liver disorder for Ocaliva which the FDA classified as a potential risk. The FDA has informed us that its review of the NISS is focused on a subset of the cirrhotic, or more advanced, PBC patients who have taken Ocaliva. As part of our routine pharmacovigilance efforts, we worked with the FDA to reconcile our internal safety database with the FDA Adverse Event Reporting System database and completed a comprehensive assessment of all available data, including data from our completed clinical trials, blinded reviews of ongoing clinical trial data, unblinded reviews of certain ongoing clinical trial data by the DMC, post-marketing data and natural history data, which we submitted to the FDA and had a meeting earlier in 2021 to discuss. We are working with the FDA to align on changes to the Ocaliva label regarding patients with the most advanced stages of PBC. Based on our communications with the FDA, this update will come in the form of a safety labeling change. These communications are ongoing and any safety concerns associated with Ocaliva, perceived or real, may adversely affect the successful development and commercialization of our product candidates and approved products, including Ocaliva, and materially and adversely affect our business including future revenue generated by Ocaliva.

***We are subject to uncertainty relating to pricing and reimbursement. Failure to obtain or maintain adequate coverage, pricing and reimbursement for Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, or our other future approved products, if any, could have a material adverse impact on our ability to commercialize such products.***

The availability and extent of coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our ability to obtain adequate pricing for such products are key factors that will affect our future commercial prospects. 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. Sales of our products depend and will depend substantially, both domestically and internationally, on the extent to which their cost will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Accordingly, the coverage and reimbursement decisions of such governmental and private healthcare payors could reduce the demand for, or the price paid for, our products. If these payors do not consider our products to be cost-effective alone, or relative to other approved therapies, they may not cover our products or, if they do, they may apply utilization management restrictions, high patient cost-sharing obligations, or restrict the level of reimbursement.

Third-party payors are increasingly challenging the prices charged for pharmaceuticals products, and many also limit reimbursement for newly-approved products and indications. Third-party payors often attempt to contain healthcare 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 provide adequate payment for our products. Similarly, the

containment of healthcare costs has become a priority for federal and state governments and the pricing of pharmaceutical products has been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, requirements for substitution of generic products and requirements to demonstrate a specific degree of improvement in terms of medical benefit compared to existing therapies. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could adversely affect our ability to successfully commercialize our products. In addition, we may be required to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products to payors' satisfaction. Such studies might require us to commit a significant amount of management's time and our financial and other resources and our products might not ultimately be considered cost-effective.

We do not know if Ocaliva for PBC will obtain and maintain broad acceptance from third-party payors in the jurisdictions in which it is, or may in the future be, approved. In addition, even if OCA for liver fibrosis due to NASH is approved, we do not know if it will obtain and maintain broad acceptance from third-party payors. The coverage determination process is a time-consuming and costly process that requires us to provide scientific and clinical support for the use of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH to each payor separately, with no assurance that coverage will be obtained or maintained. The market for a drug depends 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 drug in their formularies or 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. 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. If we are unable to obtain and maintain adequate coverage from third-party payors, the adoption of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH by physicians and patients may be limited. This in turn could affect our ability to successfully commercialize Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH and have a material adverse impact our profitability, results of operations, financial condition and future success.

We cannot be certain that we will be able to obtain and maintain adequate coverage, pricing and reimbursement for our products, including Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, or our other future approved products, if any. If coverage or reimbursement is not available or is available on a limited basis, or if we are unable to obtain and maintain adequate pricing, we may not be able to successfully commercialize Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, or our other future approved products, if any.

***Legislative and regulatory healthcare reform may adversely affect our business.***

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "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 (collectively, the "ACA"), became law in the United States. Among other things, the purpose of the ACA was to reduce the cost of healthcare and substantially change the way healthcare 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 each year, on sales by branded pharmaceutical manufacturers. Since its enactment, there have been a number of judicial, executive and legislative challenges to the ACA, including tax legislation that removed the financial penalties for people who do not carry health insurance and an Executive Order signed in October 2017 by former President Trump directing federal agencies to modify how the ACA is implemented. There is still uncertainty over whether the ACA will

undergo additional revisions, and we cannot predict the impact of any future modifications. Further, in December 2018, a federal district court in Texas ruled that the entire ACA was unconstitutional because it could not be considered an exercise of Congressional taxing authority following the repeal of the individual mandate penalties. In December 2019, a federal court of appeals upheld the district court's decision that the ACA individual mandate was unconstitutional absent financial penalties, but remanded the case back to the district court to determine whether the remaining provisions of the ACA were nonetheless valid. However, in March 2020, before the district court could rule on the ACA's remaining provisions, the U.S. Supreme Court agreed to review the case and oral arguments were held in November 2020. A decision is expected sometime before June 2021. We cannot predict the outcome of this, or any other, litigation regarding the ACA or the impact it may have on our business.

Reimbursement in the European Union and many other territories must be negotiated on a country-by-country basis and in many countries a product cannot be commercially launched until reimbursement is approved. The timing to complete the negotiation process in each country is highly uncertain. 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 and may involve multiple government agencies in a given country. Prices for drugs in Europe are generally lower than in the United States and tend to 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 their healthcare systems 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 Ocaliva and our other future approved products, if any, 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 proposed or considered by the executive branch and the United States Congress. For example, in June 2020, the Centers for Medicare & Medicaid Services released a proposed rule in a bid to update and expand key regulations governing the Medicaid Drug Rebate Program. If finalized as written, these changes will impact manufacturers' commercial strategies, government payor program liabilities, lifecycle management plans, patient assistance regimes, and other important considerations. In November 2020, the Department of Health and Human Services finalized a rule that eliminates the safe harbor shielding Medicare Part D rebates from the Anti-Kickback Statute and a rule that will tie certain Medicare Part B drug prices to those paid by other countries. The rule is currently being challenged in litigation and we cannot predict the outcome of this, or any other, litigation or the impact it may have on our business. Further, it is not known if the rule will be withdrawn by the new President Biden administration. There have also been recent state legislative efforts to address drug costs, which have generally focused on increasing transparency around drug costs or limiting drug prices. In addition, it is possible that additional governmental action is taken to address pricing concerns arising in connection with COVID-19. We cannot predict the success or impact of any such current or future federal or state legislative efforts.

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

The commercial success of Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, and our other future approved products, if any, will depend upon their acceptance among the medical community, including third-party payors, healthcare providers and professionals and customers, including patients and patient advocacy groups. In order for Ocaliva to be commercially successful for PBC, we need to demonstrate its utility as a cost-effective treatment for PBC patients who have an inadequate response to UDCA or who are unable to tolerate UDCA. 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. We cannot be certain that Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, or our other future approved products, if any, will achieve an adequate level of acceptance among the medical community, including physicians, healthcare payors and patients.

In addition, we are closely evaluating the impact of COVID-19 on our ability to effectively market, sell and distribute Ocaliva for PBC. Our field-based employees are generally working remotely and are interacting with healthcare professionals via digital communication technologies such as, where appropriate, video conferences, emails and phone calls. Many of the healthcare professionals that we call on are working from home and facing additional demands on their time due to COVID-19. We are experiencing increased competition for virtual appointments with healthcare professionals, which may result in the cancellation of diagnostic, elective, specialty and other procedures and appointments to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. Our increased utilization of virtual interactions and the reduced quantity of such interactions during the COVID-19 pandemic, may reduce the effectiveness of our sales personnel and negatively affect physician awareness and sales of Ocaliva. In the fourth quarter of 2020, we continued to see a lower level of prescriptions for new patients than we did prior to the outbreak of COVID-19. Although new patient starts currently account for only a small percentage of total Ocaliva prescriptions, our future sales of Ocaliva could be negatively impacted if prescriptions for new patients do not return to levels seen prior to the outbreak of COVID-19. It is also possible that COVID-19 may negatively affect our product sales in the future due to patient challenges in accessing healthcare providers, significant increases in unemployment and the resulting loss of individual health insurance coverage, and an inability to access government healthcare programs due to backlogs or other factors. As public health restrictions on travel and in-person interactions are modified or relaxed, we may continue to face challenges that limit our ability to fully resume in-person interactions, including the potential for additional outbreaks, limited access to personal protective equipment, the need to navigate varying restrictions for entering healthcare facilities and employee illness and childcare obligations during school closures. We also expect that the conversion of medical conferences to a virtual format may reduce our ability to appropriately disseminate scientific information and conduct disease state education. The long-term effects of COVID-19 are unknown and it is possible that following the pandemic, healthcare institutions could alter their policies with respect to in-person visits by pharmaceutical company representatives.

The degree of market acceptance of our approved products depends on a number of factors, including:

- limitations, warnings, precautions, boxed warnings, contraindications, restrictions or other statements contained in the product labels of our products, or any risk mitigation programs such as a REMS required for our products by the FDA, EMA or other relevant regulatory authorities;
- changes in the standard of care or availability of alternative therapies at similar or lower costs for the targeted indications for any of our products, such as UDCA for the treatment of PBC;
- limitations in the approved indications for our products;
- demonstrated and perceived clinical safety and efficacy compared to competitive products;
- a lack of adverse side effects, including deaths and other serious adverse events;
- sales, marketing and distribution support;
- the availability of reimbursement from managed care plans and other third-party payors;
- the timing of the market introduction of competitive products;
- the degree of cost-effectiveness;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- the extent to which our products are approved for inclusion on formularies of hospitals and managed care organizations;

- whether and to what extent our products are recommended under physician treatment guidelines for the treatment of the indications for which we have received regulatory approval;
- adverse publicity concerning our products or favorable publicity concerning competitive products;
- the convenience and ease of administration of our products;
- potential product liability claims; and
- the effects of COVID-19 and related government-imposed shelter-in-place mandates, restrictions on travel and in-person interactions, business closures and disruptions and other public health safety measures.

In addition, the potential market opportunity for Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, and our other future approved products, if any, is difficult to precisely estimate. For example, our estimates of the potential market opportunity for Ocaliva for PBC include a number of key assumptions related to prevalence rates, patients' access to healthcare, diagnosis rates and patients' response to or tolerance of Ocaliva, 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 for PBC could be smaller than our estimates of our potential market opportunity. If the actual market opportunity for Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, or our other future approved products, if any, is smaller than we expect, our product revenue may be limited and our financial condition and results of operations may be materially and adversely affected.

If Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, or our other future approved products, if any, do not achieve an adequate level of acceptance among the medical community, including physicians, healthcare payors and patients, sufficient revenue may not be generated from these products and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of Ocaliva for PBC, OCA for liver fibrosis due to NASH, if approved, and our other future approved products, if any, may require significant resources and may never be successful.

***We have limited sales, marketing and distribution experience and we will need to continue 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 and distribution experience as a commercial organization. Ocaliva is our first approved product and the commercial launch of Ocaliva for PBC was our first product launch. We are commercializing Ocaliva for PBC using a combination of our internal commercial organization and third-party distributors, depending on the jurisdiction. We are developing our commercialization strategy for OCA for liver fibrosis due to NASH, if approved, and have not yet decided on our commercialization strategy for OCA for other indications or for our other product candidates, in each case, if approved. To develop internal sales, distribution and marketing capabilities, we have invested, and expect to continue to invest, significant amounts of financial and management resources.

Recruiting and training a commercial organization is expensive, time-consuming and could delay any product launch. We can provide no assurance that we will correctly forecast the needs for growth of our commercial organization given our reliance on approvals from regulatory authorities for our product candidates. If the commercial launch of a product 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 example, we expanded our commercial organization in anticipation of a potential U.S. commercial launch of OCA for liver fibrosis due to NASH. However, in June 2020, we received a CRL from the FDA with respect to our NDA for OCA for liver fibrosis due to NASH. Although we are in discussions with the FDA with respect to the potential resubmission of our NDA seeking accelerated approval of OCA for the treatment of liver fibrosis due to NASH, there is no assurance that we will be successful or that OCA will be approved for liver fibrosis due to NASH on an accelerated basis, or at all. Accordingly, our

previously anticipated U.S. commercial launch of OCA for liver fibrosis due to NASH has been postponed, we do not expect to generate revenues for this indication until it has been approved, and we may incur significantly greater costs than previously anticipated in connection with the development of OCA for liver fibrosis due to NASH. In August 2020, we adopted the 2020 Workforce Plan to reduce our workforce in light of the receipt of the CRL from the FDA. The 2020 Workforce Plan sought to streamline our operations and reduce operating expenses, while maintaining the critical resources needed to continue to support the NASH and PBC clinical programs, pursue the approval of OCA for the treatment of liver fibrosis due to NASH and support our successful PBC business. The 2020 Workforce Plan resulted in a workforce reduction of approximately 25%, or approximately 170 employees, and largely affected the commercial infrastructure we had developed in anticipation of a potential U.S. commercial launch of OCA for liver fibrosis due to NASH. The 2020 Workforce Plan was implemented during the third quarter of 2020, immediately after its announcement, and was substantially completed by the end of 2020.

For approved products 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 our products; and
- our sales and marketing efforts may not be successful.

We may utilize the services of third-party collaborators in certain jurisdictions. We may have limited or no control over the sales, marketing and distribution activities of these third parties, and our future revenues may depend heavily on their success.

In addition, the effects of COVID-19 and related government-imposed shelter-in-place mandates, restrictions on travel and in-person interactions, business closures and disruptions and other public health safety measures may negatively impact our and our third-party collaborators' productivity, limit the conduct of business operations and impair our and our third-party collaborators' ability to execute our sales, marketing and distribution strategy.

***We could incur significant liability if it is determined that we have improperly promoted or are improperly promoting Ocaliva for PBC or any of our product candidates prior to their approval.***

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 in a manner inconsistent with applicable regulatory guidance. The FDA, the U.S. Department of Justice ("DOJ") and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting the improper promotion of approved products, as well as 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 received inquiries or been the subject of investigations by various governmental authorities in the United States and abroad. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper off-label promotion, as well as promotion that is determined to be false or misleading, even if related to approved indications.

While we have implemented a corporate compliance program based on what we believe are current best practices, we cannot provide any assurance that governmental authorities, including the DOJ, SEC or FDA, will find that our business practices comply with all current or future administrative or judicial interpretations of potentially applicable laws and regulations. In addition, government and regulatory agencies may hold us responsible for any actions by our sales representatives and other employees or contingent workers to the extent that they do not comply with applicable laws and regulations. If we fail to comply with any of these laws and regulations, we could be subject to a range of penalties,

including the issuance of an untitled letter, a warning letter, injunction, seizure, criminal and significant civil penalties, fines, damages, disgorgement, curtailment or restructuring of our operations, exclusion, disqualification or debarment from participation in federally- or state-funded healthcare programs or other sanctions or litigation, any of which could have a material adverse impact on our business, financial condition and results of operations.

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

In addition to FDA restrictions on the 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 including 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 generally prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for the payment for goods (including drugs) or services to third-party payers (including Medicare and Medicaid) that are false or fraudulent. The federal civil monetary penalties statute, likewise, imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to generate business, including the purchase or prescription of a particular product 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. In addition, such exemptions and safe harbors are subject to change from time to time.

The Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economic and Clinical Health Act, "HIPAA") created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or obtain, by means of false or fraudulent pretenses, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. HIPAA also imposes significant requirements on the receipt and transfer of protected health information.

In addition, the federal transparency requirements under the Physician Payments Sunshine Act require certain manufacturers of drugs, including us, for which payment is available under certain federal healthcare programs annually to report information related to payments and other transfers of value to physicians and teaching hospitals, and physician ownership and investment interests. Beginning in 2021, the federal reporting requirements will also apply to payments and transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives.

Finally, we must offer discounted pricing or rebates on Ocaliva and our future approved products, if any, under various federal and state healthcare programs, and report specific prices to government agencies under healthcare programs. The calculations necessary to determine the prices reported are complex and the failure to report prices accurately may expose us to significant penalties.

There are foreign and state law equivalents of these laws and regulations, such as anti-kickback, false claims, transparency and data privacy and security laws, to which we are currently and/or may in the future be subject. We may

also be subject to foreign and state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Many of these laws differ from each other in significant ways, thus increasing the cost and complexity of our compliance efforts.

A number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, including 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 improper promotional activities; and submitting inflated best price information to the Medicaid Drug Rebate Program to reduce liability for Medicaid rebates.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil penalties, damages, fines, imprisonment, exclusion of products from reimbursement under United States federal or state healthcare programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially and adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with these laws may prove costly.

***We may not be successful in establishing, implementing 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. If any strategic collaborator fails to perform its obligations under, or terminates, its agreement with us, our business could be substantially harmed.***

Developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, expanding manufacturing capabilities and marketing approved products are expensive, complex and time-consuming undertakings. As a result, we have in the past entered into, and may in the future seek to enter into, collaborations with third parties upon whom we may rely for financial resources and for development, regulatory and commercialization expertise for selected products or product candidates and in selected jurisdictions. We may establish collaborations with respect to the development and commercialization of OCA in various jurisdictions and for our other product candidates. Additionally, we may enter into sales and marketing arrangements with third parties with respect to our approved products in all or certain jurisdictions.

Our collaborators may fail to develop our product candidates or effectively commercialize our products for a variety of reasons, including a lack of sufficient resources, a decision not to devote the necessary resources due to internal constraints, such as limited cash or human resources, a change in strategic focus, a failure to obtain the necessary regulatory approvals or business disruptions from COVID-19.

If we are unable to enter into new arrangements or maintain such arrangements on acceptable terms, or at all, we may be unable to effectively market and sell our products in certain of our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration and similar 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 or approved product, we expect to relinquish some or all of the control over the future success of that product candidate or approved product to the third party. Our collaboration partner may not devote sufficient resources to development or commercialization or may otherwise fail in their development or 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 may be unsuccessful. In some cases, we may be responsible for continuing preclinical and initial clinical development of a partnered product candidate or research program, 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, we may incur increased costs and we may be forced to limit the number of products or product candidates we can commercially

develop or the territories in which we can commercialize them. If we fail to achieve successful collaborations, our operating results and financial condition could be materially and adversely affected.

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

To date, we have focused the majority of our development efforts on the development of OCA. One of our strategies is to pursue clinical development of OCA for liver fibrosis due to NASH and other progressive non-viral liver diseases, to the extent that we have sufficient funding to do so.

PBC is an orphan disease and the potential market size for Ocaliva for PBC is relatively 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 increase market share and 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 in patients for a long period of time and a definitive diagnosis of NASH is often 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 commercially successful.

The completion of development, securing of approval and commercialization of OCA for additional indications such as liver fibrosis due to NASH will require substantial additional funding, is subject to numerous risks and we may not be successful. 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 regulatory approval to market OCA for the treatment of liver fibrosis due to NASH or any other 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 liver fibrosis due to NASH or other additional indications, our commercial opportunity will be limited and our business prospects will suffer.

**Risks Related to Our Business and Strategy**

***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 CROs for certain of our clinical trial and product development activities, and contract manufacturers for the production of API and finished drug product for our commercial sales, clinical trials and preclinical studies. We will likely also use the services of third-party vendors in connection with our future commercialization activities, including product sales, marketing and distribution. Our agreements with third-party service providers are typically on a study-by-study and/or project-by-project basis. Typically, we may terminate these 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. If these providers do not adhere to applicable governing practices and standards, the commercialization of Ocaliva and our other approved products, if any, and the development of OCA 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. 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 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 have the specialized expertise required to achieve our business objectives. Identifying, qualifying and managing the performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. Despite our growth, we have limited internal resources 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, our business may be materially and adversely affected. We may further be subject to the imposition of civil or criminal penalties if our third party service providers violate 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 do not have rights under our agreements and that 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 or enforce such arrangements.

The effects of COVID-19 and related government-imposed shelter-in-place mandates, restrictions on travel and in-person interactions, business closures and disruptions and other public health safety measures may negatively impact our and our third-party service providers' productivity, limit the conduct of business operations and impair our and our third-party service providers' ability to conduct operations.

***We face rapid technological change and competition from other biotechnology and pharmaceutical companies. 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 financial, sales and marketing, manufacturing and distribution, legal, regulatory and product development resources substantially greater than ours. Large pharmaceutical companies, in particular, have extensive experience in research, clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater sales and marketing capabilities and often have collaborative arrangements in our target markets. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our products or product candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA, EMA or other regulatory 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 that we may compete with include 89bio, Inc., AbbVie Inc., Acorda Therapeutics, Inc., Affimune Limited, Akcea Therapeutics, Inc., Akero Therapeutics, Inc., Albireo Pharma, Inc., Altimmune, Inc., Arrowhead Pharmaceuticals, Inc., AstraZeneca plc, Blade Therapeutics, Inc., Boehringer Ingelheim GmbH, Bristol-Myers Squibb Company, Can-Fite BioPharma Ltd., Cirius Therapeutics, Inc., Corcept Therapeutics Incorporated, CymaBay Therapeutics, Inc., Dr. Falk Pharma GmbH, Durect Corporation, Eli Lilly and Company, Enanta Pharmaceuticals, Inc., Forma Therapeutics, Inc. Galectin Therapeutics Inc., Galecto Biotech AB, Galmed Pharmaceuticals Ltd., Genfit SA, Genkyotex, Gilead Sciences, Inc., GlaxoSmithKline plc, GRI Bio, Inc., Hanmi Pharmaceutical Co., Ltd., Hepion Pharmaceuticals, Inc., HighTide Therapeutics Inc., Immuron Limited, Inventiva, Ionis Pharmaceuticals, Inc., Kowa Company, Ltd., Lipocine Inc., Madrigal Pharmaceuticals, Inc., MediciNova, Inc., Metacrine, Inc., Mitsubishi Tanabe Pharma Corporation, Nash Pharmaceuticals Inc., NGM Biopharmaceuticals, Inc., NorthSea Therapeutics B.V., Novartis AG, Novo Nordisk A/S, NuSirt Biopharma, Inc., Oramed Pharmaceuticals Inc., Pfizer Inc., Poxel SA, Sagimet Biosciences Inc., Second Genome, Inc., Sinew Pharma Inc., Terns Pharmaceuticals, Inc., Theratechnologies, Inc., Viking Therapeutics, Inc., Yagrit International Ltd and Zydus Pharmaceuticals (USA) Inc. Ocaliva competes with UDCA (or ursodiol), a first-line therapy approved for the treatment of PBC that is available generically at a significantly lower cost than Ocaliva. Although we have a license to develop and commercialize bezafibrate in the United States, bezafibrate has been studied in multiple clinical trials for the treatment of liver diseases including PBC and NASH outside of the United States. Genfit's elafibranor and CymaBay's seladelpar are in late-stage studies for treatment of PBC. Novo Nordisk's

semaglutide, Madrigal's resmetirom, and Inventiva's lanifibranor are currently in late-stage development for treatment of NASH.

In addition, many universities and private and public research institutions may become active in our target disease areas. The results from our clinical 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 or product candidates obsolete and noncompetitive. Our ability to compete may also be affected because, in many cases, insurers or other third-party payors seek to encourage the use of generic products.

Off-label uses of other potential treatments may limit the commercial potential of our products and 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. In NASH, a number of treatments, including vitamin E (an antioxidant), insulin sensitizers (e.g., metformin, pioglitazone), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and UDCA, 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, improvements in certain histological measures of NASH were reported with vitamin E and pioglitazone.

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, enroll and retain patients for our clinical trials;
- the efficacy, safety and tolerability of Ocaliva, OCA for liver fibrosis due to NASH, if approved, and our other future approved products, if any;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to maintain productive relationships with regulatory authorities;
- the timing and scope of regulatory approvals, if any;
- our ability to commercialize and market Ocaliva, OCA for liver fibrosis due to NASH, if approved, and our other future approved products, if any;
- the price of our products;
- our ability to obtain adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect our intellectual property rights related to our products;
- our ability to manufacture and sell commercial quantities of Ocaliva, OCA for liver fibrosis due to NASH, if approved, and our other future approved products, if any, to the market; and
- the acceptance of our products by physicians and other healthcare providers.

If our competitors market products that are more effective or safe or less expensive than our products or that reach the market sooner than our products, 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 other technologies. 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, products or product candidates obsolete, less competitive or not economical.

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

We have formed a number of subsidiaries in jurisdictions outside of the United States in connection with or in anticipation of our commercial or other business activities in those jurisdictions. We are commercializing Ocaliva for PBC using a combination of our internal commercial organization and third-party distributors, depending on the jurisdiction. Our variety of international operations and business relationships subject us to additional risks that may materially and adversely affect our business and ability to attain or sustain profitability, including:

- the enhanced anti-bribery and anti-corruption regimes now implemented in most European Union member states and elsewhere, including the UK Bribery Act (thought to be one of the strictest anti-bribery laws in the world) and the escalation of investigations and prosecutions pursuant to such laws;
- compliance with complex import and export control laws;
- restrictions on direct investments by foreign entities and country-specific trade restrictions;
- differing regulatory requirements for medicine approvals and access to medicines across our various international markets and as a result the potential inability to obtain any necessary foreign regulatory, pricing or reimbursement approvals for our products in a timely manner, or at all;
- variances in payment terms and uncertainty regarding the collectability of accounts receivable from our counterparties in our international business;
- difficulties in staffing and managing international operations;
- the potential for reduced protection for our intellectual property rights;
- the potential for third-party patent rights in countries outside of the United States;
- cross border trade of medicines by third parties within the European single market (for example the impact of parallel trade within the European Economic Area);
- unexpected changes in tariffs, trade barriers and regulatory requirements and the imposition of governmental controls;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including countries in Europe;
- compliance with tax, employment, immigration and labor laws applicable to our employees working or traveling abroad;
- compliance with data protection laws, including regimes relating to cross-border transfer mechanisms;
- taxes in other countries;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other transactional risks incident to doing business in foreign countries;

- potential for production shortages resulting from events affecting raw material supply or manufacturing capabilities abroad;

- business interruptions resulting from geo-political actions, including war and terrorism, global health emergencies, such as COVID-19, natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or social unrest; and

- increasingly complex standards for complying with international laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations.

Since the United Kingdom referendum on European Union membership in June 2016, there has been some political and economic uncertainty, including in the regulatory framework applicable to the operations of biotechnology and pharmaceutical companies, and this uncertainty may persist now that the impact of Brexit is being realized. There may be disruption and uncertainties in the free movement of goods, services and people between the United Kingdom and the European Union, and at a more detailed level disruption to, and uncertainty regarding the application and interpretation of, national and international laws and regulations. There may also be unforeseen consequences and uncertainties in cross border trade in goods and services, immigration and employment, data protection and digital trade, state aid and fair competition. Over the last few years our international business has undertaken significant planning and operational readiness work for Brexit involving business functions such as supply chain, quality, finance/tax, regulatory, pharmacovigilance and legal. Brexit could materially change the regulatory regime applicable to our operations, including with respect to Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH and our other product candidates. Such consequences and uncertainties could make it more difficult and expensive for us to do business, complicate our clinical, manufacturing and regulatory strategies and impair our ability to obtain and maintain regulatory approval for, and, if approved, commercialize, our products and product candidates in Europe. In addition, our ability to continue to conduct our international operations out of the United Kingdom, where the headquarters for our international operations is located, may be materially and adversely affected. While we have undertaken a number of Brexit-related contingency planning initiatives, we cannot make any assurances regarding the extent to which our business may be adversely affected thereby.

In addition, we are subject to the anti-bribery and anticorruption laws of the United States, as well as of foreign jurisdictions where we operate, including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act. Generally, these laws prohibit paying or offering anything of value to a foreign government official for the purpose of obtaining or retaining business but they can also have a much wider, extraterritorial scope, as is the case with the UK Bribery Act (thought to be one of the strictest anti-bribery laws in the world). U.S. and foreign regulators have increased their enforcement of anti-bribery and anticorruption laws in recent years, and failure to comply with these laws could result in various adverse consequences, including:

- the possible delay in approval or refusal to approve our product candidates;

- recalls, seizures or withdrawal from the market of an approved product;

- disruption in the supply or availability of our products or suspension of export or import privileges;

- the imposition of civil or criminal sanctions;

- the prosecution of executives overseeing our international operations; and

- damage to our reputation.

Any significant impairment of our ability to develop our product candidates or sell our approved products outside of the United States could adversely impact our business and financial results.

***Our business and operations would suffer in the event of system failures, data breaches or violations of data protection laws.***

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, process, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the volume of data we retain, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. 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. Our information security systems and those of our third party vendors are subject to laws and regulations, or may become subject to new laws and regulations, requiring that we enact certain measures to protect the privacy and security of certain information we collect or use in our business. A security breach or privacy violation that leads to disclosure or modification of, or prevents access to, personal information or other protected information, whether caused by internal or external parties, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to notification requirements under certain agreements with third parties, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal information, resulting in increased costs or loss of revenue. Similarly, the loss or unauthorized disclosure of clinical trial data from completed, ongoing or planned clinical trials could prevent us from obtaining regulatory approval or delay our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and be subject to regulatory fines and penalties. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the reliance on remote working technologies by our employees and third party partners due to COVID-19 and related government-imposed shelter-in-place mandates, restrictions on travel and in-person interactions and other public health safety measures and the prevalent use of mobile devices that access confidential and personal information increases the risk of data security breaches, which could lead to the loss of confidential information, personal information, trade secrets or other intellectual property. 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. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Significant disruptions of our information technology systems or breaches of data security could have a material adverse effect on our business, financial condition and results of operations.

In the United States, numerous federal and state laws, including, without limitation, HIPAA 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 as well as consumer rights with regard to such information. For example, California recently passed the California Consumer Privacy Act of 2018, which became effective on January 1, 2020 and other states are developing similar privacy laws. Various foreign countries where we may process personal information also have, or are developing, privacy and data protection laws governing the collection, use, disclosure and storage of personal information.

In July 2016, U.S. and European Commission officials adopted a framework called the European Union-U.S. Privacy Shield (the “EU Privacy Shield”) to govern transfers of personal data from the European Economic Area (“EEA”) to the U.S. We adopted the European Union-U.S. Privacy Shield and have certified to its requirements since October 2016. We also adopted the Swiss-U.S. Privacy Shield (the “Swiss Privacy Shield”) in order to legitimize the transfer of personal data from Switzerland to the U.S. In May 2018, the General Data Protection Regulation (the “GDPR”) took effect in the EEA. The GDPR imposes more stringent data protection requirements, and provides for greater penalties for noncompliance, than previous EEA data protection legislation. In addition, although we have implemented certain measures as a result of

Brexit to allow for the transfer of personal data between EEA member states and the United Kingdom, we may need to develop additional mechanisms to permit for the transfer of this data. Implementation of the GDPR and other changes in privacy and data protection laws or regulations could require changes to certain of our business practices, thereby increasing our costs. While we are engaging in activities to comply with the GDPR requirements and other data protection laws, we may be unsuccessful in these efforts.

On July 16, 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU Privacy Shield as a data transfer mechanism for transferring personal data from the EEA to the U.S., effective immediately. On September 20, 2020, the Swiss Federal Data Protection and Information Commissioner invalidated the Swiss Privacy Shield. Therefore, the EU Privacy Shield and the Swiss Privacy Shield no longer qualify as appropriate safeguards for the transfer of personal data from the EEA or Switzerland to the U.S. and transfers made under those frameworks could attract regulatory scrutiny and penalties for non-compliance. There is no "grace period" to allow organizations to implement an alternative data transfer mechanism to the EU Privacy Shield and the Swiss Privacy Shield. While the European Commission approved Standard Contractual Clauses ("SCCs") and Binding Corporate Rules remain a valid mechanism to transfer personal data to third countries outside the EEA and Switzerland, the CJEU's ruling has also imposed enhanced due diligence obligations on organizations acting as data exporters and relying on SCCs to ensure that the laws of the country to which personal data is transferred offers a level of data protection that is essentially equivalent to the EEA. In addition, the European Commission is in the process of updating the SCCs to align them with the GDPR. As a result of the CJEU's ruling, the status of the transfers of personal data from the EEA or Switzerland to the U.S. is currently subject to significant regulatory uncertainty and we are actively monitoring developments in this area. To the extent we are not able to employ suitable data transfer mechanisms to facilitate international transfers of data, our ability to conduct our business may be materially adversely impacted.

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. There is a degree of uncertainty associated with the legal and regulatory environment around privacy and data protection laws, which continue to develop in ways we cannot predict, including with respect to evolving technologies, such as cloud computing. Privacy and data protection laws may be interpreted and applied inconsistently from country to country and impose inconsistent or conflicting requirements. As a result, our practices may not comply in the future with all such privacy and data protection laws. Varying jurisdictional requirements could increase the costs and complexity of compliance or require us to change our business practices in a manner adverse to our business. A determination that we have violated any privacy or data protection laws could result in significant damage awards, fines and other penalties that could, individually or in the aggregate, materially harm our business and reputation. For example, administrative fines of up to the greater of €20 million or 4% of our global turnover may be imposed for breaches of the GDPR. We may also be liable should any individual who has suffered financial or non-financial damage arising from our infringement of the GDPR or other applicable data protection laws exercise his or her right to receive compensation against us.

In addition, our marketing activities and the marketing activities of any third parties on which we rely are subject to various regulations, including privacy and data protection laws, consumer protection laws and competition laws. Such laws may impair our ability, or the ability of third parties on which we rely, to collect information. Such regulations may have a negative effect on businesses and may increase the potential civil liability and cost of operating our business.

***We have significantly expanded our operations and plan to continue our expansion to support our future development strategy for OCA for indications other than PBC, including liver fibrosis due to NASH. We may experience difficulties in managing our significant growth.***

We have significantly expanded our operations, including the size of our employee base, as we pursue our future development and commercialization strategy. As we advance our preclinical and clinical development programs for OCA and our other product candidates, seek regulatory approval in the United States and elsewhere and pursue our commercialization strategy, we may need to increase our product development, scientific, commercial and administrative headcount. Such an evolution may impact our strategic focus and our deployment and allocation of resources. Our management, personnel and systems may experience difficulty in adjusting to our growth and strategic focus.

We may also anticipate needs for growth that do not materialize. For example, we expanded our commercial organization in anticipation of a potential U.S. commercial launch of OCA for liver fibrosis due to NASH. However, in June 2020, we received a CRL from the FDA with respect to our NDA for OCA for liver fibrosis due to NASH. Although we are in discussions with the FDA with respect to the potential resubmission of our NDA seeking accelerated approval of OCA for the treatment of liver fibrosis due to NASH, there is no assurance that we will be successful or that OCA will be approved for liver fibrosis due to NASH on an accelerated basis, or at all. In August 2020, we adopted the 2020 Workforce Plan to reduce our workforce in light of the receipt of the CRL from the FDA. The 2020 Workforce Plan sought to streamline our operations and reduce operating expenses, while maintaining the critical resources needed to continue to support the NASH and PBC clinical programs, pursue the approval of OCA for the treatment of liver fibrosis due to NASH and support our successful PBC business. The 2020 Workforce Plan resulted in a workforce reduction of approximately 25%, or approximately 170 employees. The 2020 Workforce Plan was implemented during the third quarter of 2020, immediately after its announcement, and was substantially completed by the end of 2020. We can provide no assurance that we will correctly forecast the needs for growth given our reliance on approvals from regulatory authorities for our product candidates.

In addition, in order to continue to meet our obligations as a public company and to support our anticipated longer-term growth, we may need to increase our general and administrative capabilities. We have also expanded our operations geographically and formed a number of subsidiaries outside of the United States. In addition to our U.S. offices, we have an office in London, which serves as the headquarters for our international operations, and regional offices in a number of other countries, and we may further expand our geographical footprint. Our management, personnel and systems 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 require in the United States, Europe and other jurisdictions;
- develop, expand or adjust our commercial infrastructure;
- manage our clinical programs effectively, which are often conducted at numerous domestic and international clinical sites, and advance our other development efforts; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage our growth and the increased complexity of our operations, our business may be materially and 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 due to the intense competition for such individuals 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 the members of our executive team, as well as other key employees and consultants. If we lose one or more of our executive officers or other key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or other key employees or consultants may terminate their employment at any time and replacing such individuals may be difficult and time-consuming because of the limited number of individuals in our industry with

the necessary breadth of skills and experience. 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 such individuals.

We also have key advisors and consultants who assist us in operating our business. 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 such individuals typically 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 assist other companies that compete with us.

***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, the SEC or other domestic or foreign regulators, provide accurate information to the FDA, the SEC or other domestic or foreign regulators, comply with healthcare 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 healthcare industry are subject to extensive regulation in the United States and abroad intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Such laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive 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 and implemented a corporate compliance program, 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 inquires, investigations or other actions or lawsuits stemming from a failure to comply with applicable laws or regulations. The outcome of any such inquiry, investigation, action or lawsuit could have a significant negative impact on our business, including as a result of the imposition of significant fines or other sanctions. In addition, the institution of any such inquiry, investigation, action or lawsuit could negatively impact the market price of our securities.

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

The use of our product candidates in clinical trials and the sale of any products for which we have obtained or may obtain marketing approval, such as Ocaliva for 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, healthcare providers or others. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, product liability claims may result in:

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

- the inability to develop and commercialize our products and product candidates or the withdrawal of our products from the market.

We have obtained limited product liability insurance coverage. 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. Large judgments have been awarded in class action lawsuits based on the unanticipated side effects of drug products. 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.

**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 such as Ocaliva and product candidates such as OCA for liver fibrosis due to NASH, others may compete against us more directly, which could harm our business, possibly materially.***

Our commercial success will depend in part on our ability to obtain and maintain patent, trademark and trade secret protection covering Ocaliva, OCA for liver fibrosis due to NASH, if approved, and our other product candidates, as well as our ability to successfully defend our intellectual property against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products is dependent upon the extent to which we have regulatory exclusivity or intellectual property-based exclusivity rights under valid and enforceable patents or other intellectual property that cover our products. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from launching generic versions of our products, from using our proprietary technologies or from marketing products that are very similar or identical to ours. For example, we have received paragraph IV certification notice letters from several generic drug manufacturers indicating that each such company has submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of our 5 mg and 10 mg dosage strengths of Ocaliva (obeticholic acid) for PBC prior to the expiration of certain patents protecting Ocaliva. We have initiated patent infringement suits against each of these generic drug manufacturers in the United States District Court for the District of Delaware. While we intend to vigorously defend and enforce our intellectual property rights protecting Ocaliva, we can offer no assurance as to when the lawsuits will be decided, or whether the lawsuits will be successful. If a generic equivalent of Ocaliva is approved and enters the market before the expiration of our patents protecting Ocaliva, our business may be materially and adversely affected. See Note 19 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information.

The patent positions of 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 foreign jurisdictions, and the legal standards relating to the patentability, validity and enforceability of pharmaceutical patents are evolving. Changes in either the patent laws or in interpretations of patent laws in U.S. and foreign jurisdictions may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that we currently own or that may issue from the applications we have filed or may file in the future or those that we may license from third parties. Additionally, our currently pending or future patent applications may not result in issued patents, and any term extensions or reissues that we seek may not be granted. Further, if any patents we obtain or license are deemed invalid or unenforceable, it could impact our ability to commercialize or license our technology or we may not be able to prevent third parties from launching generic versions of our products, or from developing or marketing products that are similar or identical to ours.

There have been numerous changes to the patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. In September 2011, the America Invents Act was signed into law. The final substantive provisions of the America Invents Act became effective in March 2013. The America Invents Act included a number of significant changes to U.S. patent law that affect the way patent applications are filed, prosecuted and litigated, including, among other things, changing from a “first to invent” to a “first inventor to file” system and creating processes, such as Inter Partes Review (“IPR”) and other post-grant review processes, that permit third parties to

challenge the validity of granted patents before the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office (the "USPTO"). The IPR process, for example, permits any person to challenge the validity of a patent on the grounds that it was anticipated or made obvious by prior art. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 may be 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, nullity, invalidity or other similar proceedings before U.S. or non-U.S. patent offices or courts.

The degree to which our patents protect our products may be limited due to a number of factors. For example:

- others may be able to develop and market products that are similar to our products or product candidates but not covered by the claims of our patents;
- we might not have been the first to conceive of the inventions covered by our patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- patents that we obtain may not provide us with competitive advantages or exclusivity in a particular product area or indication or for the length of time we have anticipated; or
- the patents of others may have an adverse effect on our business.

We are the owner of record of numerous issued U.S. and non-U.S. patents and patent applications with claims directed to pharmaceutical compounds, pharmaceutical compositions, formulations, methods of making these compounds and methods of using these compounds in various indications.

Our issued patents for OCA are expected to expire between 2022 and 2036 if the appropriate maintenance, renewal, annuity, or other government fees are paid. Without patent protection, including patent protection covering the composition of matter, methods of using and formulations of our products and product candidates, our ability to stop others from making, using, selling, offering to sell or importing our products and product candidates may be limited.

Due to the patent laws of a specific country in which we are seeking patent protection, the decisions of a patent examiner in a specific country in which we are seeking patent protection or our own filing strategies, we ultimately may not obtain patent coverage for all of our products and product candidates for which we have filed a patent application. While we regularly pursue patent protection in the United States and other countries to obtain claim coverage for our inventions, we cannot be certain that such patent rights will be granted or that the scope of any patent granted will prevent third parties from making, using, selling, offering for sale or importing the same or similar products.

***If we do not obtain protection under the Hatch-Waxman Act in the United States (and similar legislation outside of the United States) extending the terms of our patents and/or providing data or other 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, U.S. patents may be eligible for a limited extension of patent term under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). The Hatch-Waxman Act permits an extension of patent term for one patent of up to five years as compensation for patent term lost during product development and the FDA regulatory review process, so long as the total period of patent term extension does not exceed 14 years from the date of approval. 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 scope of patent protection afforded could be less than what is requested. If we are unable to obtain patent term extension or the term of any such extension is less than what we request, the period during which we will have the right to exclusively market our products may be shorter than anticipated, our competitors may obtain approval of competing products following our patent expiration and our revenue could be reduced, possibly materially.

In October 2020, the USPTO granted to the Company a reissue patent, U.S. Patent No. RE 48,286 (the "'286 Patent"). By operation of law, our primary composition of matter patent protecting Ocaliva, U.S. Patent No. 7,138,390 (the "'390 Patent"), was withdrawn and replaced by the '286 Patent, which contains composition of matter claims to OCA. The '286 Patent has been substituted in any litigation where the '390 Patent was asserted. The '286 Patent, like its predecessor the '390 Patent, was scheduled to expire in 2022. In light of the U.S. marketing approval of Ocaliva for PBC in May 2016, and pursuant to the Hatch-Waxman Act, we previously applied for an extension of the patent term for the '390 Patent in the U.S. seeking to extend the term of the '390 Patent into 2027. After the '286 Patent issued, the application for extension of patent term was transferred to the '286 Patent. In November 2020, the Company was informed by the USPTO that its petition for a five-year patent term extension had been granted. Accordingly, the patent term extension originally intended to extend the term of the '390 Patent into 2027 will extend the term of the '286 Patent into 2027. Similarly, in connection with the conditional approval of Ocaliva for PBC in the European Union, we applied for supplementary patent certification ("SPC") to extend the patent term for the European analogue of the '390 Patent (now the '286 Patent) in most of the European Union into 2027. To date, we have received grants of SPC in Austria, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Norway, Portugal, Spain and Sweden. We have also taken similar actions in other jurisdictions and countries where regulations providing for patent term extension exist. The issued patents for OCA are expected to expire between 2022 and 2036 if the appropriate maintenance, renewal, annuity, or other government fees are paid. The substitution in the U.S. of the '286 Patent for the '390 Patent has no effect on foreign patent rights.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and such litigation may divert the attention of our management and scientific personnel and adversely affect our development and commercialization efforts.***

If we choose to file patent infringement lawsuits or engage in other adversarial proceedings to stop another party from making, using, selling, offering for sale or importing the inventions claimed in any of our patents, that individual or company alleged to be infringing 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, consume time and resources and divert the attention of management and scientific personnel even if we are successful in defending our rights. In addition, there is a risk that such court or adjudicating body will decide that such patents are invalid, unenforceable or not infringed, and that we do not have the right to stop the other party from making, using, selling, offering for sale or importing the inventions. For example, we have received paragraph IV certification notice letters from several generic drug manufacturers indicating that each such company has submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of our 5 mg and 10 mg dosage strengths of Ocaliva (obeticholic acid) for PBC prior to the expiration of certain patents protecting Ocaliva. We have initiated patent infringement suits against each of these generic drug manufacturers in the United States District Court for the District of Delaware. Such lawsuits may be expensive and divert our management's time and attention. In addition, to the extent such lawsuits are not successful, and a generic equivalent of Ocaliva is approved and enters the market before the expiration of our patents protecting Ocaliva, our business may be materially and adversely affected. See Note 19 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information.

Over the past 20 years, the U.S. Supreme Court and the U.S. Congress have modified certain examination procedures utilized by the USPTO in granting patents, which has raised the standard of patentability for some types of inventions. Such modifications may reduce the likelihood that we will be able to obtain patent protection and increase the likelihood of challenges to our patents or the patents we license.

***We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and/or delay, halt or increase the costs of our commercialization efforts.***

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that the use, manufacture, sale, offer for sale or importation of our products will not infringe third-party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization partners 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. The defense of these lawsuits is often costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is also a risk that a court could decide that we or our manufacturing or commercialization partners are infringing the third party's patents and order us or our partners to stop the activities covered by the patents. In that event, we or our partners may be required to halt or delay commercialization or development of the relevant product or product candidate. In addition, there is a risk that a court could order us or our partners to pay the other party damages for having violated the other party's patents, and we may be subject to indemnification obligations with respect to any such payments made by our partners. There is a vast array of patents and patent applications that claim various pharmaceutical inventions and because the scope of a patent's claims is subject to interpretation by the courts, it is not always clear to industry participants which patents cover various types of products, product candidates or methods of use. In addition, interpretation of a patent's claims can vary from court to court.

If we are sued for patent infringement, we would need to demonstrate that the relevant patent is not enforceable or that our products, product candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid. Proving invalidity, non-infringement and/or unenforceability is difficult, and we may not be successful. 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 such proceedings, we may incur substantial costs and divert our management's time and attention, which could have a material adverse effect on our business. 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, we may incur substantial monetary damages, encounter significant delays in the commercialization of our products and product candidates 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 or file with respect to a 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, derivation or other similar 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, 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 financial and other resources. In addition, uncertainties resulting from the initiation

and continuation of any such litigation could have a material adverse effect on the market price of our securities and 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 as a result of non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on our patents and patent applications are required to be paid to the USPTO and foreign patent offices in several stages over the lifetime of such patents and patent applications. In addition, the USPTO and foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We have implemented systems and engaged reputable third-party service providers to help ensure that we comply with such requirements on a timely basis, but inadvertent lapses may occur and there are situations in which noncompliance can result in abandonment or lapse of the relevant patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Any such event may impair our competitive position in the relevant jurisdiction and have a material adverse effect on our financial condition or results of operations.

***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets or other proprietary information of their former employers. In addition, if we are not able to adequately prevent disclosure of our trade secrets and other proprietary information, the value of our technology, products and product candidates 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, which could result in substantial costs and be a distraction to our management even if we are successful.

We may 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, and may not prevent others from independently and lawfully developing similar or identical products that circumvent our intellectual property. 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 proprietary information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information.

Third parties, including competitors of ours, may also independently discover our trade secrets or other proprietary information. In addition, we may be required under U.S. or foreign transparency initiatives or other regulations to publicly disclose or otherwise make available certain information that we consider to be proprietary, including pre-clinical and clinical research data. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets or other proprietary information is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes reluctant to protect trade secrets. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain protection of our trade secrets and other proprietary information could adversely affect our competitive business position.

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

We have numerous trademark and service mark registrations and pending trademark and service mark applications in the United States and abroad.

Our trademark applications may not be allowed for registration and 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, we may be unable to overcome such rejections. In addition, the USPTO and

comparable agencies in many other jurisdictions provide third parties with 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 laws. Trademarks remain in force 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 may lead to customer confusion, which could adversely affect our sales or profitability.

## 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 effectively service 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 2023 Convertible Notes that we issued in July 2016 and/or the $230.0 million aggregate principal amount of 2026 Convertible Notes that we issued in May 2019 or any other 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 that 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 are not restricted under the terms of the indentures governing the Convertible Notes or otherwise from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking other actions that could have the effect of diminishing our ability to service our debt when due.

***The accounting method for convertible debt securities that may be settled in cash, such as the Convertible Notes, could have a material effect on our reported financial results.***

Under Accounting Standards Codification Subtopic 470-20, “Debt with Conversion and Other Options” (“ASC 470-20”), an entity must separately account for the liability and equity components of 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 sheets, and the value of the equity component is treated as original issue discount for purposes of accounting for the debt component of the Convertible Notes. As a result, we are 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. Because ASC 470-20 requires interest to include both the current period’s amortization of the debt discount and the instrument’s coupon interest, we report lower net income in our financial results, which could adversely affect the market price of our common stock and the market 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.

## Risks Related to Ownership of Our Common Stock

***Ownership in our common stock is highly concentrated and your ability to influence corporate matters may be limited as a result.***

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock together beneficially own a significant percentage of our common stock based on reports filed with the SEC. If these stockholders were to choose to act together, they would be able to significantly influence matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization, as well as our management and affairs. This concentration of voting power could delay or prevent an acquisition of us on terms that other securityholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other securityholders and they may act in a manner that advances their best interests and not necessarily those of other securityholders, including seeking a premium value for their common stock, and might affect the market price of our common stock and the Convertible Notes.

***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. (“Genextra”) is one of our largest stockholders and owns a significant minority percentage of our outstanding common stock. 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 other holders of common stock will be able to affect the way we are managed and could delay or prevent an acquisition of us on terms that other securityholders may desire.

Furthermore, the interests of Genextra may not always coincide with the interests of other securityholders, and Genextra may act in a manner that advances its best interests and not necessarily those of other securityholders, including seeking a premium value for its common stock, and might affect the market price of our common stock and the Convertible Notes. Our board of directors, which consists of eleven 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 shares of our common stock into the market from time to time, and we cannot predict the effect, if any, that future sales by Genextra may have on the market price of our common stock or the Convertible Notes.

***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 your 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.

***We have previously been, and are currently, subject to securities class action litigation and may be subject to similar or other litigation in the future. Such matters can be expensive, time-consuming and have a material adverse effect on our business, results of operations and financial condition.***

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.

In September 2017, a lawsuit and, in January 2018, a follow-on lawsuit, were filed alleging that we and certain of our officers made material misrepresentations and/or omissions of material fact regarding Ocaliva dosing, use and pharmacovigilance-related matters, as well as our operations, financial performance and prospects. The plaintiffs seek unspecified monetary damages on behalf of the putative class, an award of costs and expenses, including attorney's fees, and rescissory damages.

While we believe that we have a number of valid defenses to the claims described above and intend to vigorously defend ourselves, the matters are in the early stages of litigation and no assessment can be made as to the likely outcome of the matters or whether they will be material to us.

Additionally, in November 2020, a lawsuit and, in December 2020 and February 2021, follow-on lawsuits, were filed alleging that we and certain of our officers made material misrepresentations and/or omissions of material fact during the period from September 28, 2019 to October 7, 2020 relating to our NDA for OCA for the treatment of liver fibrosis due to NASH and the use of Ocaliva in patients with PBC, as well as our operations, financial performance and prospects. The plaintiff seeks unspecified monetary damages on behalf of the putative class, and an award of costs and expenses, including attorney's fees.

We may be subject to additional suits or proceedings brought in the future and, as has been the case with many companies in our industry, we may from time to time receive inquiries and subpoenas and other types of information requests from government authorities and others. While the ultimate outcome of any such investigations, inquiries, information requests and legal proceedings is difficult to predict, adverse resolutions or settlements of those matters may result in, among other things, modification of our business practices, product recalls, significant costs, payments, damages or fines or other administrative, civil or criminal remedies, liabilities or penalties, which may have a material adverse effect on our business, results of operations and financial condition. In addition, monitoring and defending against legal actions, whether or not meritorious, and responding to investigations, inquiries and information requests is expensive, 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 such matters. 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 a 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 to incur substantial losses.***

The market 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 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 and elsewhere in this Annual Report on Form 10-K, the factors that may result in wide fluctuations in the price of our common stock include any:

- delay, failure or receipt of regulatory approval for our product candidates, including OCA for liver fibrosis due to NASH;

- delay, failure or receipt of additional marketing authorizations for Ocaliva or our product candidates, including OCA for liver fibrosis due to NASH, in our target markets;
- failure to successfully commercialize our approved products in the United States, Europe and our other target markets, or our inability to maintain regulatory approval for Ocaliva or our other approved products in such markets;
- clinical trial failure, including any such failure resulting from issues, delays or difficulties in identifying patients, enrolling patients, treating patients, retaining patients, meeting specific endpoints in the jurisdictions in which we intend to seek approval or completing and timely reporting the results of our clinical trials, such as our NASH and PBC trials;
- the effects of COVID-19 and related government-imposed shelter-in-place mandates, restrictions on travel and in-person interactions, business closures and disruptions and other public health safety measures;
- inability to obtain additional funding;
- delay in filing an investigational new drug application, NDA, MAA or comparable submission for any of our product candidates, and any adverse development or perceived adverse development with respect to the regulatory review of any such submission;
- potential side effects associated with Ocaliva for PBC, OCA for liver fibrosis due to NASH or our other product candidates;
- inability to obtain adequate product supply of Ocaliva, OCA for liver fibrosis due to NASH or any of our other product candidates or the inability to do so at acceptable prices;
- results of clinical trials of our competitors' products and product candidates;
- regulatory or advisory committee actions or recommendations with respect to our products or product candidates, including Ocaliva or OCA for liver fibrosis due to NASH, or our competitors' products or product candidates;
- changes in laws or regulations applicable to our products or product candidates;
- failure to meet or exceed financial projections or guidance 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;
- disputes, governmental inquiries or investigations, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation;
- 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, or prevent system failures, data breaches or violations of data protection laws;
- market conditions for biopharmaceutical stocks in general; and
- general economic, industry, market and political conditions

Any of these factors could also affect the trading price of the Convertible Notes.

Furthermore, 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 securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. A number of factors, including global health emergencies (e.g., COVID-19), general economic, political and market conditions, recessions, interest rate changes or international currency fluctuations may negatively impact the market price of our securities, 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 are currently subject to 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, you could incur substantial losses.

***If our stockholders sell substantial amounts of our common stock, the market price of our common stock or the Convertible Notes may decline even if our business is doing well.***

A significant number of shares of our common stock are held by a small number of stockholders, including Genextra. Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock or the Convertible Notes. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate. We have also registered the offer and sale of the shares of common stock that we may issue under our equity compensation plans, including upon the exercise of stock options. These shares may be freely sold in the public market upon issuance.

Additionally, sales of our common stock by our executive officers or directors, even when done during an open trading window under our policies with respect to insider sales or done under a trading plan adopted in accordance with the guidelines set forth by Rule 10b5-1, may adversely impact the market price of our common stock or the Convertible Notes. Although we do not expect that the relatively small volume of such sales would itself significantly impact the market price of our common stock or the Convertible Notes, the market could react negatively to the announcement of such sales, which could in turn affect the market price of our common stock and the Convertible Notes.

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

We may in the future raise funds through the issuance and sale of additional shares of our common stock or other securities convertible into or exchangeable for our common stock. For example, in May 2019, we issued and sold an aggregate of 2,879,760 shares of common stock and $230.0 million aggregate principal amount of the 2026 Convertible Notes, in April 2018, we issued and sold an aggregate of 4,257,813 shares of common stock and in July 2016, we issued

and sold $460.0 million aggregate principal amount of the 2023 Convertible Notes. Conversions of the Convertible Notes will dilute the ownership interests of existing shareholders to the extent that we elect to deliver shares of our common stock (or a combination of cash and shares of our common stock) in connection therewith. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could depress the price of our common stock. We may also issue shares of common stock, stock options, restricted stock, restricted stock units or other stock-based awards under our existing or future equity incentive plans or other employee or director compensation plans. The issuance of additional shares of common stock (including pursuant to conversions of the Convertible Notes) or other securities convertible into or exchangeable for our common stock, or the perception that such issuances may occur, may materially and adversely affect the price of our common stock and the Convertible Notes.

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

Provisions in our restated certificate of incorporation and restated bylaws, as well as provisions of Delaware law, may discourage, delay or prevent a merger, acquisition or other change in control that our securityholders consider favorable, including transactions in which securityholders might otherwise receive a premium for their securities. 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 (the “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 securityholders to receive a premium for their securities, and could also affect the price that some investors are willing to pay for our common stock or the Convertible Notes.

Certain provisions of the Convertible Notes could also make it more difficult or more expensive for a third party to acquire us. For example, if an acquisition event constitutes a “fundamental change” under the terms of the Convertible Notes, holders of the Convertible Notes will have the right to require us to purchase their Convertible Notes for cash. Similarly, if an acquisition event constitutes a “make-whole fundamental change” under the terms of the Convertible Notes, we may be required to increase the conversion rate for holders who convert their Convertible Notes in connection with such make-whole fundamental change.

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 or the Convertible Notes. They

could also deter potential acquirers of our company, thereby reducing the likelihood that our securityholders could receive a premium for their securities 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, subject to certain conditions. 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.

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 by shifting the burden of such losses and expenses to us. Although we carry 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 securityholders who may choose to bring a claim against our company.

***We do not intend to pay dividends in the foreseeable future.***

We do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of shares of our common stock will provide a return to stockholders, which may not occur. Investors seeking cash dividends should not invest in our common stock. You may not realize any return on your investment in our common stock and may lose some or all of your investment.

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

We have significant net operating loss carryforwards ("NOLs") for U.S. Federal, state and foreign income tax purposes. The enactment of the Tax Cuts and Jobs Act enacted in 2017 (the "TCJA") modified the ability of companies to utilize U.S. Federal NOLs arising in tax years beginning on or after January 1, 2018, by providing that such NOLs may be carried-forward indefinitely and used to offset up to 80 percent of taxable income in any given future year. Existing NOLs that arose in tax years beginning prior to January 1, 2018, were not affected by the TCJA and are generally eligible to be carried-forward for up to 20 years and used to fully offset taxable income in future years. If not utilized, our pre-2018 NOLs will expire for U.S. Federal income tax purposes between 2024 and 2037. We also have certain state and foreign NOLs in varying amounts depending on the different state and foreign tax laws.

In addition, our ability to utilize our NOLs may be limited under Section 382 of the Internal Revenue Code or applicable state and foreign tax law. 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. As a result, we may not be able to take full advantage of our NOL carryforwards for U.S. Federal, state, and foreign income tax purposes.

## General Risk Factors

***We may use our limited financial and human resources to pursue a particular research program or product candidate that is ultimately unsuccessful or less successful than other programs or product candidates that we may have forgone or delayed.***

Because we have limited resources, we may forego or delay the development of certain programs or product candidates that later prove to have greater commercial potential than the programs or product candidates that we do pursue. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. If we fail to accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements or we may allocate our limited internal resources to that product candidate when it would have been more advantageous to enter into such an arrangement. Any such failure could have a material adverse effect on our business, financial condition or results of operations.

***If we engage in a licensing transaction, acquisition, reorganization or business combination, we will face a variety of risks that could adversely affect our business operations and our securityholders.***

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 businesses, entering into a business combination with another company or otherwise partnering with another company. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' ownership;
- incur substantial debt that may place strains on our operations;
- be required to dedicate substantial operational, financial and management resources to integrate new products, technologies or businesses;
- assume substantial actual or contingent liabilities;
- impair our ability to make payments of interest and principal on our outstanding debt, including the Convertible Notes;
- reprioritize our development programs or cease development and commercialization activities with respect to certain of our product candidates or approved products; or
- merge or otherwise enter into a business combination with another company, which may result in our stockholders receiving cash and/or securities of the other company on terms that certain of our stockholders may not deem desirable.

***Our insurance policies are expensive and only protect us from some business risks, which 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, cyber liability, products liability and directors' and officers' insurance. We do not know, however, if our current levels of coverage are adequate or if we will be able to obtain insurance with adequate levels of coverage in the future, if at all. Any significant uninsured liability, including significant uninsured liabilities resulting from COVID-19 or related government-imposed shelter-in-place mandates, restrictions on travel and in-person interactions, business closures and disruptions, and other public health safety measures, may require us to pay substantial amounts, which could materially and adversely affect our

financial position and results of operations. Furthermore, any increase in the volatility of our stock price, among other factors, may result in us being required to pay substantially higher premiums for our directors' and officers' insurance, and may make it difficult for us to obtain adequate coverage on reasonable terms, if at all.

***We must comply with environmental, health and safety laws and regulations.***

Our activities involve the controlled storage, use and disposal of hazardous materials. We are subject to federal, state, city and local laws and regulations, in and outside the United States, governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures we use for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, regulatory authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage.

***Failure to establish and maintain adequate financial 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 a demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002 and related rules and regulations, expanded disclosure requirements, accelerated reporting requirements and complex accounting rules. Responsibilities imposed 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.

In particular, our compliance with Section 404 of the Sarbanes-Oxley Act has required and will continue to require that we incur substantial accounting-related expenses 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. If we are not able to comply with the requirements of the Sarbanes-Oxley Act, we could be subject to sanctions or investigations by the SEC, the Nasdaq Global Select Market or other regulatory authorities, which would require additional financial and management resources and could adversely affect the market price of our securities. Furthermore, if we cannot provide reliable financial reports or prevent fraud, including as a result of remote working by our employees in connection with COVID-19 and related government-imposed shelter-in-place mandates and other public health safety measures, our business and results of operations would likely be materially and adversely affected.

***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.

***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, such as the TCJA, 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 in different jurisdictions, the outcome of audits or other examinations by the U.S. Internal Revenue Service and tax regulators in other jurisdictions, the accuracy of our estimates for unrecognized tax benefits, the realization of deferred tax assets and changes to our ownership or capital structure.

The impact on our effective income tax rate resulting from these factors may be significant and could adversely affect our results of operations.

***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 us or our securities, the price of our securities and trading volume in our securities could decline.***

The market for our common stock and the Convertible Notes 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 and the price of the Convertible Notes may decline. If one or more of the analysts covering us fail to regularly publish reports on us, demand for our common stock and the Convertible Notes may decline, which could cause our stock price and the price of the Convertible Notes and trading volume to decline.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our corporate headquarters are located at 10 Hudson Yards in New York, New York, where we lease and occupy an aggregate of approximately 45,600 square feet of office space. The lease covering this property is currently scheduled to expire in March 2022.

Our research and development operations are based in San Diego, California, where we lease and occupy an aggregate of approximately 34,000 square feet of space. The lease covering this property is currently scheduled to expire in October 2025.

We also lease and occupy approximately 8,600 square feet of office space in London, United Kingdom, which serves as the headquarters for our international operations. The lease covering this property is currently scheduled to expire in May 2024.

We believe that our existing facilities are adequate for our immediate needs and that, should it be needed, additional space can be leased to accommodate any future growth.

**Item 3. Legal Proceedings**

For a description of our significant legal proceedings, see Note 19 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K and incorporated by reference herein.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

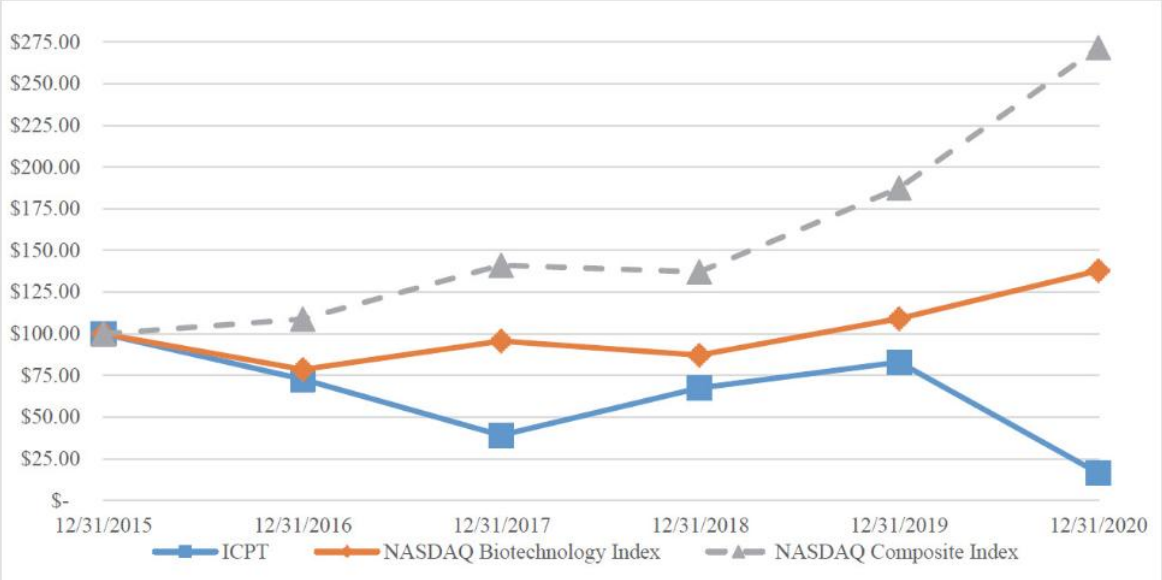
**Market Information and Stockholders**

Our common stock trades on the Nasdaq Global Select Market under the symbol "ICPT". As of December 31, 2020, there were 33,015,614 shares of our common stock issued and outstanding and approximately 199 stockholders of record. A significantly larger number of stockholders may hold their shares in "street name" through banks, brokers and other nominees. The number of stockholders of record does not include stockholders who hold their shares in "street name."

**Stock Price Performance Graph**

The following graph compares the cumulative total stockholder return for our common stock to the cumulative total stockholder return for the Nasdaq Composite Index and the Nasdaq Biotechnology Index, in each case, for the period from December 31, 2015 through December 31, 2020. The graph assumes an initial investment of $100 in our common stock at the closing price of $149.35 on December 31, 2015 and in the Nasdaq Composite Index and the Nasdaq Biotechnology Index on December 31, 2015 and the reinvestment of dividends. The stock performance shown below is not intended to forecast or be indicative of the possible future performance of our common stock, and we do not make or endorse any predications as to future stockholder returns. The following stock performance information shall not be deemed to be "soliciting material," "filed" with the U.S. Securities and Exchange Commission (the "SEC"), incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or subject to the liabilities of Section 18 of the Exchange Act, except to the extent that we specifically incorporate it by reference into a document filed under the Securities Act or the Exchange Act.

**Comparison of Cumulative Total Return**
**Among Intercept Pharmaceuticals, Inc., the Nasdaq Composite Index and**
**the Nasdaq Biotechnology Index**



| | December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
| $100 investment in stock or index | | | | | | |
| Intercept Pharmaceuticals, Inc. | $ 100.00 | $ 72.75 | $ 39.12 | $ 67.49 | $ 82.97 | $ 16.54 |
| Nasdaq Composite Index | $ 100.00 | $ 108.87 | $ 141.13 | $ 137.12 | $ 187.44 | $ 271.64 |
| Nasdaq Biotechnology Index | $ 100.00 | $ 78.65 | $ 95.67 | $ 87.19 | $ 109.08 | $ 137.90 |

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future.

**Recent Sales of Unregistered Securities**

Not applicable.

**Issuer Purchases of Equity Securities**

The following table provides certain information with respect to purchases of our common stock during the three months ended December 31, 2020.

| Period | Total Number of Shares Purchased (1) | Average Price Paid per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs | Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|
| October 1, 2020 through October 31, 2020 | 1,467 | $ 42.08 | — | — |
| November 1, 2020 through November 30, 2020 | 1,297 | $ 36.16 | — | — |
| December 1, 2020 through December 31, 2020 | — | $ — | — | — |
| Total | 2,764 | $ 39.30 | — | — |

(1) Represents shares of common stock withheld to satisfy taxes associated with the vesting of restricted stock awards.

**Item 6. Selected Financial Data**

The selected consolidated financial data set forth below should be read together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited consolidated financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The selected consolidated financial data in this section are not intended to replace our audited consolidated financial statements and accompanying notes. Our historical results are not necessarily indicative of our future results.

The selected consolidated statements of operations data for the years ended December 31, 2020, 2019 and 2018 and the selected consolidated balance sheet data as of December 31, 2020 and 2019 have been derived from our audited consolidated financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The selected consolidated statements of operations data for the years ended December 31, 2017 and 2016 and the selected

consolidated balance sheet data as of December 31, 2018, 2017 and 2016 have been derived from our audited consolidated financial statements and accompanying notes that are not included in this Annual Report on Form 10-K.

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2020 | 2019 | 2018 | 2017 | 2016 |
| | (in thousands, except per share data) | | | | |
| **Consolidated Statement of Operations Data:** | | | | | |
| Revenue: | | | | | |
| Product revenue, net | $ 312,690 | $ 249,570 | $ 177,782 | $ 129,175 | $ 18,169 |
| Licensing revenue | — | 2,432 | 2,022 | 1,781 | 6,782 |
| Total revenues | 312,690 | 252,002 | 179,804 | 130,956 | 24,951 |
| Operating expenses: | | | | | |
| Cost of sales | 5,322 | 4,212 | 2,519 | 1,371 | — |
| Selling, general and administrative | 332,493 | 317,418 | 255,474 | 273,698 | 273,596 |
| Research and development | 191,485 | 242,799 | 207,301 | 191,499 | 153,893 |
| Restructuring | 14,630 | — | — | — | — |
| Total operating expenses | 543,930 | 564,429 | 465,294 | 466,568 | 427,489 |
| Operating loss | (231,240) | (312,427) | (285,490) | (335,612) | (402,538) |
| Total other income (expense), net | (43,640) | (32,254) | (23,752) | (24,755) | (10,292) |
| Net loss | $ (274,880) | $ (344,681) | $ (309,242) | $ (360,367) | $ (412,830) |
| Net loss per common and potential common share, basic and diluted | $ (8.34) | $ (10.89) | $ (10.86) | $ (14.38) | $ (16.74) |
| Weighted average common and potential common shares outstanding, basic and diluted | 32,970 | 31,654 | 28,464 | 25,054 | 24,663 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2020 | 2019 | 2018 | 2017 | 2016 |
| | | | (in thousands) | | |
| **Consolidated Balance Sheet Data:** | | | | | |
| Cash, cash equivalents, restricted cash and investment debt securities | $ 477,170 | $ 657,347 | $ 436,160 | $ 414,917 | $ 689,385 |
| Total assets | 580,489 | 754,886 | 509,167 | 484,347 | 739,253 |
| Accounts payable, accrued expenses and other liabilities | 171,039 | 153,968 | 105,109 | 94,777 | 65,551 |
| Long-term debt (1) | 560,582 | 532,078 | 371,250 | 355,677 | 341,356 |
| Accumulated deficit | (2,398,346) | (2,123,466) | (1,778,785) | (1,469,543) | (1,108,460) |
| Total stockholders' (deficit) equity | (166,853) | 51,556 | 19,130 | 16,386 | 314,932 |

(1) Reflects $690.0 million aggregate principal amount of Convertible Notes, less unamortized debt discounts and unamortized debt issuance costs as of December 31, 2020 and 2019 and $460.0 million aggregate principal amount of 2023 Convertible Notes, less unamortized debt discounts and unamortized debt issuance costs as of December 31, 2018, 2017 and 2016. See Note 9 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further information regarding the Convertible Notes.

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

*You should read the following discussion and analysis together with our audited consolidated financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements, which involve risks and uncertainties. As a result of many factors, such as those described under "Cautionary Note Regarding Forward-Looking Statements," "Risk Factors" and elsewhere in this Annual Report on Form 10-K, 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 progressive non-viral liver diseases with high unmet medical need utilizing our proprietary bile acid chemistry. Our first marketed product, Ocaliva® (obeticholic acid or "OCA"), is a farnesoid X receptor ("FXR") agonist approved in the United States, the European Union and several other jurisdictions for the treatment of primary biliary cholangitis ("PBC") in combination with ursodeoxycholic acid ("UDCA") in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. In addition to commercializing OCA for PBC under the Ocaliva brand name, we are currently developing OCA for additional indications, including nonalcoholic steatohepatitis ("NASH"). We are also developing several product candidates in various stages of clinical and preclinical development. We believe that OCA and our other product candidates have the potential to treat orphan and other more prevalent liver diseases such as NASH for which there are currently limited therapeutic options.

Ocaliva was approved for PBC by the U.S. Food and Drug Administration ("FDA") in May 2016 under the accelerated approval pathway. We commenced sales and marketing of Ocaliva in the United States shortly after receiving approval, and Ocaliva is now available to U.S. patients primarily through a network of specialty pharmacy distributors. Ocaliva received conditional approval for PBC from the European Commission in December 2016 and we commenced our European commercial launch in January 2017. We have submitted dossiers and obtained, or are otherwise pursuing, reimbursement from a number of national authorities in Europe. Since January 2017, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada, Israel and Australia, and we are pursuing marketing approval of Ocaliva for PBC in our other international target markets. Ocaliva received orphan drug designation in both the United States and the European Union for the treatment of PBC. In addition, we continue to work to execute on our post-marketing regulatory commitments with respect to Ocaliva in the U.S. and Europe.

Our lead product candidate is OCA for the potential treatment of NASH. In February 2019, we announced topline results from the planned 18-month interim analysis of our pivotal Phase 3 clinical trial of OCA in patients with liver fibrosis due to NASH, known as the REGENERATE trial. In the primary efficacy analysis, once-daily OCA 25 mg met the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH at the planned 18-month interim analysis. Adverse events were generally mild to moderate in severity and the most common were consistent with the known profile of OCA. Interim analysis results at 18 months were based on surrogate endpoints and the impact on clinical outcomes has not been confirmed. The REGENERATE trial is ongoing and is expected to continue through clinical outcomes for verification and description of the clinical benefit of OCA. OCA also achieved the primary endpoint in a Phase 2b clinical trial for the treatment of NASH that completed in late July 2014, known as the FLINT trial, which was sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, a part of the National Institutes of Health. OCA has received breakthrough therapy designation from the FDA for the treatment of NASH patients with liver fibrosis. In September 2019, we submitted a New Drug Application ("NDA") to the FDA seeking accelerated approval of OCA for liver fibrosis due to NASH. In November 2019, the FDA accepted our NDA for filing and granted a priority review designation of OCA for liver fibrosis due to NASH. In December 2019, we submitted a Marketing Authorization Application ("MAA") to the European Medicines Agency (the "EMA") seeking conditional approval of OCA for liver fibrosis due to NASH. In January 2020, the EMA validated our MAA and thereby confirmed that our MAA was sufficiently complete to begin the formal review process. In June 2020, we received a complete response letter ("CRL") from the FDA stating that our NDA for OCA for the treatment of liver fibrosis due to NASH could not be approved in its present form. The CRL indicated that, based on the data the FDA had reviewed, the FDA has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. At that time, the FDA recommended that we submit additional post-interim analysis efficacy and safety data from the

ongoing REGENERATE trial in support of potential accelerated approval and that the long-term outcomes phase of the trial should continue. We are in discussions with the FDA with respect to the potential resubmission of our NDA seeking accelerated approval of OCA for the treatment of liver fibrosis due to NASH. We had our end of review meeting with the FDA in October 2020 to discuss the FDA's risk-benefit assessment in the CRL based on its review of the available data, as well as our proposed resubmission of our NDA for the treatment of liver fibrosis due to NASH. The meeting was constructive and the FDA has provided us with helpful guidance regarding supplemental data we can provide to further characterize OCA's efficacy and safety profile that could support resubmission based on our Phase 3 REGENERATE 18-month biopsy data, together with a safety update from our ongoing studies. We are advancing accordingly and plan to hold additional meetings with the FDA with the goal of achieving sufficient alignment to proceed on this basis and potentially resubmit our NDA for the treatment of liver fibrosis due to NASH by the end of 2021. In addition, we continue to work collaboratively with the EMA on its review of our MAA.

As part of our product development activities, we expect to continue to invest in evaluating the potential of OCA in progressive non-viral liver diseases. We are currently conducting a Phase 3 clinical trial in NASH patients with compensated cirrhosis, known as the REVERSE trial. In January 2020, we announced that we completed enrollment of the REVERSE trial with over 900 patients randomized. We are also studying OCA in combination with bezafibrate, a pan-peroxisome proliferator-activated receptor agonist, in patients with PBC and potentially may study such combination in other liver diseases. In addition, we have other compounds in early stages of research and development in our pipeline.

**Capital Markets Activities During the Periods Under Review**

In May 2019, we issued and sold (i) 2,760,000 shares of common stock in a registered public offering (including 360,000 shares issued and sold upon the exercise in full of the underwriters' option to purchase additional shares), at a price to the public of $83.50 per share (the "2019 Public Offering") and (ii) 119,760 shares of common stock (the "2019 Private Placement Shares") in a concurrent private placement of common stock (the "2019 Concurrent Private Placement") exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), at a purchase price per share equivalent to the price to the public set in the 2019 Public Offering and pursuant to a securities purchase agreement (the "2019 Securities Purchase Agreement") that the Company entered into with Samsara BioCapital, L.P. ("Samsara"), one of our existing stockholders. Pursuant to the 2019 Securities Purchase Agreement, we granted to Samsara certain registration rights requiring us, upon request of Samsara on or after July 9, 2019 and subject to certain terms and conditions, to register the resale by Samsara of its 2019 Private Placement Shares. Such registration rights expire upon the earlier of (i) May 8, 2020 and (ii) the date that all of the 2019 Private Placement Shares have been sold or can be sold publicly under Rule 144 of the Securities Act on a single day. We received net proceeds from the 2019 Public Offering and the 2019 Concurrent Private Placement of approximately $227.3 million, after deducting underwriting discounts, commissions and estimated offering expenses of approximately $13.9 million.

In May 2019, we also issued and sold $230.0 million aggregate principal amount of 2.00% Convertible Senior Notes due 2026 (the "2026 Convertible Notes"). We received net proceeds from the sale of the 2026 Convertible Notes of $223.4 million, after deducting underwriting discounts, commissions and estimated offering expenses of approximately $6.6 million.

**Financial Overview**

***Revenue***

We commenced our commercial launch of Ocaliva for the treatment of 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. Since January 2017, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada, Israel and Australia. We sell Ocaliva to a limited number of specialty pharmacies which dispense the product directly to patients. The specialty pharmacies are referred to as our customers.

***Product Revenue, Net***

We recognize revenue upon shipment of Ocaliva to our customers. We provide the right of return to our customers for unopened product for a limited time before and after its expiration date.

Under Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), we have written contracts with each of our customers that have a single performance obligation — to deliver products upon receipt of a customer order — and these obligations are satisfied when delivery occurs and the customer receives Ocaliva. We evaluate the creditworthiness of each of our customers to determine whether collection is reasonably assured. We estimate variable revenue by calculating gross product revenues based on the wholesale acquisition cost that we charge our customers for Ocaliva, and then estimating our net product revenues by deducting (i) estimated government rebates and discounts related to Medicare, Medicaid and other government programs, (ii) estimated costs of incentives offered to certain indirect customers including patients and (iii) trade allowances, such as invoice discounts for prompt payment and customer fees.

We recognized net sales of Ocaliva of $312.7 million, $249.6 and $177.8 million for the years ended December 31, 2020, 2019 and 2018, respectively.

We have received paragraph IV certification notice letters from several generic drug manufacturers indicating that each such company has submitted to the FDA an Abbreviated New Drug Application ("ANDA") seeking approval to manufacture and sell a generic version of our 5 mg and 10 mg dosage strengths of Ocaliva® (obeticholic acid) for PBC prior to the expiration of certain patents protecting Ocaliva. We have initiated patent infringement suits against each of these generic drug manufacturers in the United States District Court for the District of Delaware. While we intend to vigorously defend and enforce our intellectual property rights protecting Ocaliva, we can offer no assurance as to when the lawsuits will be decided, whether the lawsuits will be successful, or that a generic equivalent of Ocaliva will not be approved and enter the market before the expiration of such patents. See Note 19 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information.

*Licensing Revenue*

In March 2011, we entered into an exclusive license agreement (the "Sumitomo Agreement") with Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon"), pursuant to which we granted to Sumitomo Dainippon an exclusive license to research, develop and commercialize OCA for the treatment of PBC and NASH in Japan and China (excluding Taiwan) and an option to research, develop and commercialize OCA in certain countries outside of such territories (the "Country Option"). We received an upfront payment from Sumitomo Dainippon of $15.0 million under the terms of the Sumitomo Agreement. In October 2019, we and Sumitomo Dainippon mutually agreed to terminate with immediate effect the Sumitomo Agreement. In connection with the termination of the Sumitomo Agreement, Sumitomo Dainippon agreed to return to us the rights to develop and commercialize OCA in China and we agreed to forego any further milestone or royalty payments relating to the development and commercialization of OCA in China. No payment was due from us to Sumitomo Dainippon as a result of the termination of the Sumitomo Agreement.

We recognized licensing revenue of $0, $2.4 million and $2.0 million for the years ended December 31, 2020, 2019 and 2018, respectively.

***Selling, General and Administrative Expenses***

We have incurred and expect to continue to incur significant selling, general and administrative expenses as a result of, among other initiatives, the launch and commercialization of Ocaliva for PBC in the United States, Europe and our other target markets. In addition, we have incurred significant selling, general and administrative expenses and may in the future incur similar expenses in connection with the preparation for the potential commercialization of OCA for liver fibrosis due to NASH, if approved, and our other future approved products, if any, and any build-out of our general and administrative infrastructure in the United States and abroad.

***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, pursuing regulatory approvals and engaging in other product development activities. We recognize research and development expenses as they are incurred.

We have incurred and expect to continue to incur significant research and development expenses as a result of, among other initiatives, our clinical development programs for OCA for PBC and NASH, our other earlier stage research programs and our regulatory approval efforts.

**Results of Operations**

***Comparison of the Years Ended December 31, 2020 and 2019***

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

| | Years Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands) | |
| Revenue: | | |
| Product revenue, net | $ 312,690 | $ 249,570 |
| Licensing revenue | — | 2,432 |
| Total revenue | 312,690 | 252,002 |
| | | |
| Operating expenses: | | |
| Cost of sales | 5,322 | 4,212 |
| Selling, general and administrative | 332,493 | 317,418 |
| Research and development | 191,485 | 242,799 |
| Restructuring | 14,630 | — |
| Total operating expenses | 543,930 | 564,429 |
| | | |
| Other income (expense): | | |
| Interest expense | (48,054) | (41,144) |
| Other income, net | 4,414 | 8,890 |
| Total other (expense), net | (43,640) | (32,254) |
| Net loss | $ (274,880) | $ (344,681) |

*Revenues*

Product revenue, net was $312.7 million and $249.6 million for the years ended December 31, 2020 and 2019, respectively. For the years ended December 31, 2020 and 2019, product revenue, net was comprised of U.S. Ocaliva net sales of $234.0 million and $187.5 million, respectively, and ex-U.S. Ocaliva net sales of $78.7 million and $62.1 million, respectively. We commenced our commercial launch of Ocaliva for the treatment of PBC in the United States and certain European countries in June 2016 and January 2017, respectively. Since January 2017, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada, Israel and Australia. For the years ended December 31, 2020 and 2019, licensing revenue was $0 and $2.4 million, respectively. In the case of the year ended December 31, 2019, revenues were related to the amortization of upfront payments under the Sumitomo Agreement.

*Cost of sales*

Cost of sales was $5.3 million and $4.2 million for the years ended December 31, 2020 and 2019, respectively. Our cost of sales for the years ended December 31, 2020 and 2019 consisted primarily of packaging, labeling, materials and related expenses.

*Selling, general and administrative expenses*

Selling, general and administrative expenses were $332.5 million and $317.4 million for the years ended December 31, 2020 and 2019, respectively. The $15.1 million net increase between periods was primarily driven by increases in expenses during the first half of 2020 relating to our launch preparation activities associated with the potential approval and commercialization of OCA for liver fibrosis due to NASH.

*Research and development expenses*

Research and development expenses were $191.5 million and $242.8 million for the years ended December 31, 2020 and 2019, respectively. The $51.3 million net decrease between periods was primarily driven by UK R&D tax credits of $22.0 million recognized as a reduction of research and development expenses and lower NASH development costs, including the conclusion of enrollment activities for the REGENERATE and REVERSE studies.

*Restructuring expenses*

Restructuring expenses were $14.6 million and $0 for the years ended December 31, 2020 and 2019, respectively. The increase between periods was primarily driven by severance costs and other related termination benefits incurred in conjunction with the 2020 Workforce Plan.

*Interest expense*

Interest expense was $48.1 million and $41.1 million for the years ended December 31, 2020 and 2019, respectively. For the years ended December 31, 2020 and 2019, interest expense related to the $230.0 million aggregate principal amount of 2.00% Convertible Senior Notes due 2026 (the “2026 Convertible Notes”) that we issued in May 2019 and the $460.0 million aggregate principal amount of 3.25% Convertible Senior Notes due 2023 (the “2023 Convertible Notes” and together with the 2026 Convertible Notes, the “Convertible Notes”) that we issued in July 2016.

*Other income, net*

Other income, net was $4.4 million and $8.9 million for the years ended December 31, 2020 and 2019, respectively. Such income is primarily attributable to interest income earned on cash, cash equivalents and investment debt securities.

*Income taxes*

For the years ended December 31, 2020 and 2019, 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 Years Ended December 31, 2019 and 2018***

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

| | Years Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| | (in thousands) | |
| Revenue: | | |
| Product revenue, net | $ 249,570 | $ 177,782 |
| Licensing revenue | 2,432 | 2,022 |
| Total revenue | 252,002 | 179,804 |
| | | |
| Operating expenses: | | |
| Cost of sales | 4,212 | 2,519 |
| Selling, general and administrative | 317,418 | 255,474 |
| Research and development | 242,799 | 207,301 |
| Total operating expenses | 564,429 | 465,294 |
| | | |
| Other income (expense): | | |
| Interest expense | (41,144) | (30,523) |
| Other income, net | 8,890 | 6,771 |
| Total other (expense), net | (32,254) | (23,752) |
| Net loss | $ (344,681) | $ (309,242) |

*Revenues*

Product revenue, net was $249.6 million and $177.8 million for the years ended December 31, 2019 and 2018, respectively. For the years ended December 31, 2019 and 2018, product revenue, net was comprised of U.S. Ocaliva net sales of $187.5 million and $140.8 million, respectively, and ex-U.S. Ocaliva net sales of $62.1 million and $37.0 million, respectively. We commenced our commercial launch of Ocaliva for the treatment of PBC in the United States and certain European countries in June 2016 and January 2017, respectively. Since January 2017, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada, Israel and Australia. For the years ended December 31, 2019 and 2018, licensing revenue was $2.4 million and $2.0 million, respectively, in each case, related to the amortization of upfront payments under the Sumitomo Agreement.

*Cost of sales*

Cost of sales was $4.2 million and $2.5 million for the years ended December 31, 2019 and 2018, respectively. Our cost of sales for the years ended December 31, 2019 and 2018 consisted primarily of packaging, labeling, materials and related expenses.

*Selling, general and administrative expenses*

Selling, general and administrative expenses were $317.4 million and $255.5 million for the years ended December 31, 2019 and 2018, respectively. The $61.9 million net increase between periods was primarily driven by increases in expenses relating to our launch preparation activities associated with the potential approval and commercialization of OCA for liver fibrosis due to NASH.

*Research and development expenses*

Research and development expenses were $242.8 million and $207.3 million for the years ended December 31, 2019 and 2018, respectively. The $35.5 million net increase between periods was primarily driven by increases in OCA for liver fibrosis due to NASH development program expenses and costs associated with the preparation of the NASH NDA submission.

*Interest expense*

Interest expense was $41.1 million and $30.5 million for the years ended December 31, 2019 and 2018, respectively. For the year ended December 31, 2019, interest expense related to the 2026 Convertible Notes that we issued in May 2019 and the $460.0 million aggregate principal amount of 3.25% Convertible Senior Notes due 2023 (the "2023 Convertible Notes" and together with the 2026 Convertible Notes, the "Convertible Notes") that we issued in July 2016. For the year ended December 31, 2018, interest expense related only to the 2023 Convertible Notes.

*Other income, net*

Other income, net was $8.9 million and $6.8 million for the years ended December 31, 2019 and 2018, respectively. Such income is primarily attributable to interest income earned on cash, cash equivalents and investment debt securities.

*Income Taxes*

For the years ended December 31, 2019 and 2018, 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**

***Cash Flows***

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Net cash (used in) provided by: | | | |
| Operating activities | $ (170,026) | $ (236,613) | $ (240,714) |
| Investing activities | 162,817 | (188,988) | (48,070) |
| Financing activities | (693) | 457,519 | 263,545 |
| Effect of exchange rate changes | (1,224) | (386) | (1,526) |
| Net (decrease) increase in cash, cash equivalents and restricted cash | $ (9,126) | $ 31,532 | $ (26,765) |

*Operating Activities.* Net cash used in operating activities of $170.0 million during the year ended December 31, 2020 was primarily a result of our $274.9 million net loss, partially offset by $60.8 million in stock-based compensation, $16.6 million for accretion of the discount on the 2023 Convertible Notes, $9.4 million for accretion of the discount on the 2026 Convertible Notes, $6.1 million for non-cash operating lease costs, $3.1 million of depreciation and a net increase in operating assets and liabilities of $2.0 million. Cash flows for the year ended December 31, 2020 include cash receipts of $20.7 million reflecting payments from the HMRC for the U.K. R&D tax credit claims.

Net cash used in operating activities of $236.6 million during the year ended December 31, 2019 was primarily a result of our $344.7 million net loss and a gain on lease termination of $2.0 million, partially offset by $56.0 million in stock-based compensation, a net increase in operating assets and liabilities of $19.3 million, $15.3 million for accretion of the discount on the 2023 Convertible Notes, $5.9 million for accretion of the discount on the 2026 Convertible Notes, $5.4 million for non-cash operating lease costs, $3.7 million of depreciation and $2.7 million for loss on the disposal of fixed assets.

Net cash used in operating activities of $240.7 million during the year ended December 31, 2018 was primarily a result of our $309.2 million net loss and a net decrease in operating assets and liabilities of $2.8 million, partially offset by $49.9 million in stock-based compensation, $14.0 million for accretion of the discount on the 2023 Convertible Notes, and $4.6 million of depreciation.

*Investing Activities.* For the year ended December 31, 2020, net cash provided by investing activities primarily reflects the sales and maturities of investment debt securities of $497.4 million, partially offset by the purchases of investment debt securities of $330.7 million.

For the year ended December 31, 2019, net cash used in investing activities primarily reflects the purchases of investment debt securities of $603.0 million, partially offset by the sales of investment debt securities of $415.2 million.

For the year ended December 31, 2018, net cash used in investing activities primarily reflects the purchase of investment debt securities of $436.1 million, partially offset by the sale of investment debt securities of $388.2 million.

*Financing Activities.* Net cash used in financing activities in the year ended December 31, 2020 consisted primarily of $2.0 million from payments of employee withholding taxes related to stock-based awards offset by $1.3 million of net proceeds from the exercise of options to purchase common stock.

Net cash provided by financing activities in the year ended December 31, 2019 consisted primarily of net proceeds received from the 2019 Public Offering and 2019 Concurrent Private Placement in May 2019 of $227.3 million and net proceeds from the issuance of the 2026 Convertible Notes of $223.4 million.

Net cash provided by financing activities in the year ended December 31, 2018 consisted primarily of net proceeds of approximately $261.4 million from the 2018 Public Offering and 2018 Concurrent Private Placement in April 2018 and $2.2 million from the exercise of options to purchase common stock net of payments of employee withholding taxes related to stock-based awards.

***2019 Public Offerings and 2019 Concurrent Private Placement***

In May 2019, we issued and sold an aggregate of 2,879,760 shares of common stock in the 2019 Public Offering and 2019 Concurrent Private Placement. We received net proceeds from the 2019 Public Offering and the 2019 Concurrent Private Placement of approximately $227.3 million, after deducting underwriting discounts, commissions and estimated offering expenses of approximately $13.9 million.

***2026 Convertible Notes***

In May 2019, we issued and sold $230.0 million aggregate principal amount of 2.00% Convertible Senior Notes due 2026 (the “2026 Convertible Notes”). We received net proceeds from the sale of the 2026 Convertible Notes of $223.4 million, after deducting underwriter discounts, commissions, and estimated offering expenses of approximately $6.6 million.

The 2026 Convertible Notes were issued pursuant to a Second Supplemental Indenture, dated as of May 14, 2019 (the “Second Supplemental Indenture”), which supplements the Indenture (the “Base Indenture”), as supplemented by a First Supplemental Indenture (the “First Supplemental Indenture” and collectively with the Base Indenture and the Second Supplemental Indenture, the “Indenture”), each dated as of July 6, 2016, by and between us and U.S. Bank National Association, as trustee. The 2026 Convertible Notes are senior unsecured obligations of ours, bear interest at a fixed rate of 2.00% per annum (payable semi-annually on May 15 and November 15 of each year, beginning on November 15, 2019) and will mature on May 15, 2026, unless earlier repurchased, redeemed or converted. The 2026 Convertible Notes are convertible at the option of holders, under certain circumstances and during certain periods, into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate of the 2026 Convertible Notes is 9.2123 shares of our common stock per $1,000 principal amount of 2026 Convertible Notes, which is equivalent to an initial conversion price of approximately $108.55 per share of our common stock. The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its 2026 Convertible Notes in connection with such a corporate event in certain circumstances. If we undergo a fundamental change (as defined in the Indenture), holders may require us to repurchase for cash all or any portion of their 2026 Convertible Notes at a fundamental change repurchase price equal to 100% of the principal amount

of the 2026 Convertible Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, if certain make-whole fundamental changes occur, we will, in certain circumstances, increase the conversion rate for any 2026 Convertible Notes converted in connection with such make-whole fundamental change. We may not redeem the 2026 Convertible Notes prior to May 20, 2023. We may redeem for cash all or any portion of the 2026 Convertible Notes, at our option, on or after May 20, 2023, under certain circumstances at a redemption price equal to 100% or the principal amount of the 2026 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. The Indenture provides for customary events of default.

***2018 Public Offering and 2018 Concurrent Private Placement***

In April 2018, we issued and sold an aggregate of 4,257,813 shares of common stock in the 2018 Public Offering and 2018 Concurrent Private Placement. We received net proceeds from the 2018 Public Offering and the 2018 Concurrent Private Placement of approximately $261.4 million, after deducting underwriting discounts, commissions and estimated offering expenses of approximately $11.1 million.

**Future Funding Requirements**

As of December 31, 2020, we had $477.2 million in cash, cash equivalents, restricted cash and investment debt securities. We currently expect to continue to incur significant operating expenses in the fiscal year ending December 31, 2021. These expenses are planned to support, among other initiatives, the continued commercialization of Ocaliva for PBC in the United States and our other markets, our continued clinical development of OCA for PBC and NASH and our other earlier stage research and development programs. Although we believe that our existing capital resources, together with our net sales of Ocaliva for PBC, will be sufficient to fund our anticipated operating requirements for the next twelve months following the filing of this report, we may need to raise additional capital to fund our operating requirements beyond that period. Furthermore, in light of our receipt of the CRL from the FDA in June 2020 with respect to our NDA for OCA for liver fibrosis due to NASH and the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, any delays in, or unanticipated costs associated with, our development, regulatory or commercialization efforts could significantly increase the amount of capital required by us to fund our operating requirements. Accordingly, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our forecasts regarding the period of time that our existing capital resources will be sufficient to meet our operating requirements and the timing of our future funding requirements, both near and long-term, will depend on a variety of factors, many of which are outside of our control. Such factors include, but are not limited to:

- our ability to successfully commercialize Ocaliva for PBC;
- our ability to maintain our regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which we have or may receive marketing authorization;
- our ability to timely and cost-effectively file for and obtain regulatory approval of our product candidates on an accelerated basis or at all, including OCA for liver fibrosis due to NASH following the issuance of the CRL by the FDA; any advisory committee recommendation or dispute resolution determination that our product candidates, including OCA for liver fibrosis due to NASH, should not be approved or approved only under certain conditions; or any future determination that the regulatory applications and subsequent information we submit for our product candidates, including OCA for liver fibrosis due to NASH, do not contain adequate clinical or other data or meet applicable regulatory requirements for approval;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, including OCA for liver fibrosis due to NASH, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), any risk mitigation programs such as a REMS, and any related restrictions, limitations and/or warnings contained in the label of any of our products or product candidates;

- any potential side effects associated with Ocaliva for PBC, OCA for liver fibrosis due to NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions or otherwise limit the sale of such product or product candidate, including in connection with the NISS relating to Ocaliva identified by the FDA in May 2020;
- the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, retaining patients, meeting specific endpoints in the jurisdictions in which we intend to seek approval or completing and timely reporting the results of our NASH or PBC clinical trials;
- the outcomes of ongoing discussions with the FDA and the EMA regarding the feasibility of the COBALT and 401 trials;
- our ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom we are substantially dependent for, among other things, the manufacture and supply of our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our clinical trial activities;
- our ability to identify, develop and successfully commercialize our products and product candidates, including our ability to successfully launch OCA for liver fibrosis due to NASH, if approved;
- our ability to obtain and maintain intellectual property protection for our products and product candidates, including our ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights;
- the size and growth of the markets for our products and product candidates and our ability to serve those markets;
- the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH or our other product candidates among physicians, patients and healthcare payors;
- the availability of adequate coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our ability to obtain adequate pricing for such products;
- our ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties;
- competition from existing drugs or new drugs that become available;
- our ability to prevent system failures, data breaches or violations of data protection laws;
- costs and outcomes relating to any disputes, governmental inquiries or investigations, regulatory proceedings, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation;
- our collaborators' election to pursue research, development and commercialization activities;
- our ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise;
- our need for and ability to generate or obtain additional financing;
- our estimates regarding future expenses, revenues and capital requirements and the accuracy thereof;

- our use of cash and short-term investments;
- our ability to acquire, license and invest in businesses, technologies, product candidates and products;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to manage the growth of our operations, infrastructure, personnel, systems and controls;
- our ability to obtain and maintain adequate insurance coverage;
- the impact of COVID-19, including any impact on our results of operations or financial position, related quarantines and government actions, delays relating to our regulatory applications, disruptions relating to our ongoing clinical trials or involving our contract research organizations, study sites or other clinical partners, disruptions relating to our supply chain or involving our third-party manufacturers, distributors or other distribution partners, facility closures or other restrictions, and the extent and duration thereof;
- the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the potential impact of Brexit; and
- the other risks and uncertainties identified under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K and in our other periodic filings filed with the SEC.

We have no committed external sources of funding and additional funds may not be available when we need them on terms that are acceptable to us, or at all. In addition, in recent months global markets have experienced significant volatility in connection with concerns over the impact of COVID-19, and such concerns may in the future materially and adversely affect our ability to raise funds. If adequate funds are not available to us, we may not be able to make scheduled debt payments on a timely basis, or at all, and may be required to delay, limit, reduce or cease our operations.

**Contractual Obligations**

Our contractual obligations as of December 31, 2020 consisted primarily of obligations under the Convertible Notes, and lease agreements. The following table summarizes our material contractual obligations as of December 31, 2020 and the effect such obligations are expected to have on our liquidity and cash flows in future years:

| | Payments Due By Period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 year | 1 - 3 years | 3 - 5 years | More than 5 years |
| Contractual Obligations: | (in thousands) | | | | |
| Operating leases (1) | $ 16,288 | $ 7,884 | $ 5,759 | $ 2,645 | $ — |
| Convertible Notes (2) | 752,100 | 19,550 | 491,625 | 9,200 | 231,725 |
| Total | $ 768,388 | $ 27,434 | $ 497,384 | $ 11,845 | $ 231,725 |

(1) For a description of our material operating leases, see “Properties” above. The obligations represent payments for all operating leases, including short-term operating leases exempt under ASC Topic 842, Leases (“ASC 842”) and leases that have yet to commence. Operating expenses associated with our leased office buildings are not included in the table above.

(2) Represents 2023 Convertible Notes and 2026 Convertible Notes (including future interest payments at a fixed rate of 3.25% and 2.00% per year, respectively).

We enter into contracts in the normal course of business with contract research organizations for our clinical trials, contract manufacturing organizations for the manufacture and supply of our clinical and commercial product needs and other vendors for other research and development and commercial activities, as well as services and products for operating

purposes. Our agreements generally provide for termination with notice. Such agreements are cancelable contracts and are not included as purchase commitments.

**Off-Balance Sheet Arrangements**

As of December 31, 2020, we did not have any off-balance sheet arrangements.

**Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our audited consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our audited consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results could differ from these estimates.

While our significant accounting policies are more fully described in Note 2 to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

***Revenue Recognition***

Effective January 1, 2018, we began recognizing revenue under ASC 606. The core principle of this revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle: (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenue when the company satisfies a performance obligation.

*Product Revenue, Net*

Under ASC 606, we have written contracts with each of our customers that have a single performance obligation — to deliver products upon receipt of a customer order — and these obligations are satisfied when delivery occurs and the customer receives Ocaliva. We evaluate the creditworthiness of each of our customers to determine whether collection is reasonably assured. The wholesale acquisition cost that we charge our customers for Ocaliva is adjusted to arrive at our estimated net product revenues by deducting (i) estimated government rebates and discounts, (ii) estimated costs of incentives offered to certain indirect customers including patients, and (iii) trade allowances, such as invoice discounts for prompt payment and customer fees.

*Rebates and Discounts*

We contract with the Centers for Medicare & Medicaid Services and other government agencies to make Ocaliva available to eligible patients. As a result, we estimate any rebates and discounts and deduct these estimated amounts from our gross product revenues at the time the revenues are recognized. Our estimates of rebates and discounts are based on the government mandated discounts, which are statutorily-defined and applicable to these government funded programs, and our historical experience with actual payments and redemptions. These estimates are recorded in accounts payable, accrued expenses and other liabilities on our consolidated balance sheets.

We have been distributing and selling Ocaliva in Europe through our EU marketing authorization since 2017 and are engaged in ongoing price discussions regarding the final price of Ocaliva within one of those jurisdictions. We recognize net product revenues based on our estimate of consideration we expect to retain through final negotiations in that

jurisdiction that will not be subject to a significant reversal. Our estimate is based on benchmarks of pricing approved in other relevant European jurisdictions. We expect the difference between the amounts collected at the invoiced price and the final price for OCA will be returned to the local government. If our estimates regarding the amounts to be refunded to the government change, we will reflect the effect of the change in estimate in net product revenues in the period in which the change in estimate occurs and will include any adjustments against all prior sales. These estimates are recorded in accounts payable, accrued expenses and other liabilities on our consolidated balance sheets.

*Other Incentives*

Other incentives that we offer to indirect customers include co-pay assistance cards provided by us for PBC patients who reside in states that permit co-pay assistance programs. Our co-pay assistance program is intended to reduce each participating patient's portion of the financial responsibility for Ocaliva purchase price to a specified dollar amount. We estimate the amount of co-pay assistance provided to eligible patients based on the terms of the program when product is dispensed by the specialty pharmacies to the patients. These estimates are based on redemption information provided by third-party claims processing organizations and are recorded in accounts payable, accrued expenses and other liabilities on our consolidated balance sheets.

*Trade Allowances*

We provide invoice discounts on Ocaliva sales to certain of our customers for prompt payment and record these discounts as a reduction to gross product revenues. These discounts are based on contractual terms. Reserves for prompt payment discounts are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

***Valuation of Stock-Based Compensation***

We account for stock-based compensation in accordance with ASC Topic 718, *Compensation — Stock Compensation*. We estimate the fair value of stock option awards using the Black-Scholes option pricing model on the date of the grant. The Black-Scholes option pricing model requires the use of assumptions, including with respect to stock price volatility, assumed dividend yield, the expected term of options and the risk-free interest rate, as described below:

- The expected volatility is estimated based on actual historical volatility information of our own ordinary shares.
- The assumed dividend yield is based on our expectation of not paying dividends for the foreseeable future.
- The expected term of options granted represents the period of time the options are expected to be outstanding and is based on the simplified method.
- The risk-free interest rate was based on the rate for U.S. Treasury securities at the date of grant with maturity dates approximately equal to the expected term of the award at the grant date.

Restricted stock unit awards and restricted stock awards without a market condition are valued based on the closing price of our common stock on the date of the grant. The fair value of time-based equity awards is recognized and amortized on a straight-line basis over the requisite service period of the award. The fair value of awards with market conditions is estimated using the Monte Carlo simulation method and expense is recognized on a straight-line basis over the requisite service period of the award. The Company accounts for all forfeitures when they occur. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest and are not forfeited.

We expect to continue to grant stock options and other stock-based awards and the impact of stock-based compensation may fluctuate in future periods due to changes in the value of our common stock, changes to our headcount and the number and value of awards granted.

***Convertible Senior Notes***

The Convertible Notes are accounted for in accordance with ASC Subtopic 470-20, *Debt with Conversion and Other Options*. ASC Subtopic 470-20 requires the issuer of convertible debt that may be settled in shares or cash upon conversion at the issuer's option, such as the Convertible Notes, to account for the liability (debt) and equity (conversion option) components separately. The value assigned to the debt component is the estimated fair value, as of the issuance date, of a similar debt instrument without the conversion option. The amount of the equity component (and resulting debt discount) is calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The resulting debt discount is amortized as additional non-cash interest expense over the expected life of the notes utilizing the effective interest method. For additional information, see Note 9 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

***Income Taxes***

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse.

We determine the need for a valuation allowance by assessing the probability of realizing deferred tax assets, taking into consideration all available positive and negative evidence, including historical operating results, expectations of future taxable income, carryforward periods available, various income tax strategies and other relevant factors. Significant judgment is required in making this assessment and to the extent future expectations change, we would have to assess the recoverability of our deferred assets at that time. At December 31, 2020 and 2019, we maintained a full valuation allowance on our deferred tax assets.

Our tax returns are subject to examination by U.S. Federal, state, and foreign taxing jurisdictions. The impact of an uncertain tax position taken or expected to be taken on an income tax return must be recognized in our financial statements at the largest amount that is more likely than not to be sustained. An uncertain income tax position will not be recognized in our financial statements unless it is more likely than not to be sustained. At December 31, 2020 and 2019, we had no reserves for unrecognized tax benefits.

**Recent Accounting Pronouncements**

See Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a full description of recent accounting pronouncements including the respective expected dates of adoption and expected effects, if any, on our results of operations and financial condition.

**Item 7A. Quantitative and Qualitative Disclosures 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. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents and investment debt securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investment debt securities. If a hypothetical increase in interest rates of 100 basis points were to have occurred on December 31, 2020, this change would not have had a material effect on the fair value of our investment portfolio as of that date due to the conservative and short-term nature of these investments.

We do not believe that our cash, cash equivalents and investment debt securities have significant risk of default or illiquidity. While we believe our cash, cash equivalents and investment debt securities do not contain excessive risk, we cannot provide absolute assurance that, in the future, our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

We contract with CROs, investigational sites, suppliers, facilities, marketing firms and other vendors and suppliers in Europe and internationally. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during 2020, 2019 or 2018.

**Item 8. Financial Statements and Supplementary Data**

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K and incorporated by reference herein. An index of those financial statements is set forth under Item 15. “Exhibits and Financial Statement Schedules”.

**Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and 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 of December 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Management’s Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as a process designed by, or under the supervision of, the company’s principal executive and principal financial officers and effected by the company’s board of directors, management and other personnel, 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 and includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our company’s assets that could have a material effect on the financial statements.

All internal controls, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to consolidated financial statement preparation and presentation. Because of its inherent limitations, internal control over financial reporting may not prevent

or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2020, based on criteria established in the Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2020.

**Attestation Report of Independent Registered Public Accounting Firm**

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report included elsewhere in this Annual Report on Form 10-K.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

Not applicable.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

We have adopted a Global Code of Business Conduct as our “code of ethics,” as defined by regulations promulgated under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, which applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Global Code of Business Conduct is available on our website at www.interceptpharma.com in the Investors & Media section under “Corporate Governance.” We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any future amendment to, or waiver from, a provision of the Global Code of Business Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions by posting such information on our website at www.interceptpharma.com in the Investors & Media section under “Corporate Governance.” The references to www.interceptpharma.com herein are inactive textual references only, and the information found on our internet website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

The remainder of the information required by this item is incorporated by reference to our definitive proxy statement related to our 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**Item 11. Executive Compensation**

The information required by this item is incorporated by reference to our definitive proxy statement related to our 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this item is incorporated by reference to our definitive proxy statement related to our 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this item is incorporated by reference to our definitive proxy statement related to our 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**Item 14. Principal Accounting Fees and Services**

The information required by this item is incorporated by reference to our definitive proxy statement related to our 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

(a) 1. Index to Consolidated Financial Statements


| | |
|---|---|
| Reports of Independent Registered Public Accounting Firm | F-2 |
| Consolidated Balance Sheets | F-6 |
| Consolidated Statements of Operations | F-7 |
| Consolidated Statements of Comprehensive Loss | F-8 |
| Consolidated Statements of Changes in Stockholders' Equity | F-9 |
| Consolidated Statements of Cash Flows | F-10 |
| Notes to Consolidated Financial Statements | F-11 |


2. Index to Consolidated Financial Statements

Financial statement schedules have been omitted from this Annual Report on Form 10-K because they are not applicable, not required or the information required is set forth in the audited consolidated financial statements or accompanying notes.

3. Exhibits

The exhibits filed or furnished as part of this Annual Report on Form 10-K are set forth in the Exhibit Index below, which is incorporated herein by reference.

## Exhibit Index

| Exhibit Number | Exhibit Description | Incorporated herein by reference | | |
|---|---|---|---|---|
| | | Form† | Exhibit | Filing Date |
| 3.1 | Restated Certificate of Incorporation, as amended | Form 10-Q | 3.1 | August 10, 2020 |
| 3.2 | Restated Bylaws | Form 10-Q | 3.2 | August 10, 2020 |
| 4.1 | Form of Common Stock Certificate | Form S-8(1) | 4.3 | November 7, 2012 |
| 4.2 | Indenture, dated as of July 6, 2016, between the Registrant and U.S. Bank National Association, as trustee | Form 8-K | 4.1 | July 6, 2016 |
| 4.3 | First Supplemental Indenture (including the Form of Note), dated as of July 6, 2016, between the Registrant and U.S. Bank National Association, as trustee | Form 8-K | 4.2 | July 6, 2016 |
| 4.4 | Form of Senior Indenture | Form S-3(2) | 4.1 | May 10, 2017 |
| 4.5 | Form of Subordinated Indenture | Form S-3(2) | 4.2 | May 10, 2017 |
| 4.6 | Form of Senior Note | Form S-3(2) | 4.3 | May 10, 2017 |
| 4.7 | Form of Subordinated Note | Form S-3(2) | 4.4 | May 10, 2017 |
| 4.8 | Securities Purchase Agreement, dated April 4, 2018, between the Registrant and the purchasers named therein | Form 8-K | 10.1 | April 10, 2018 |
| 4.9 | Securities Purchase Agreement, dated May 8, 2019, between the Registrant and the purchasers named therein | Form 8-K | 10.1 | May 14, 2019 |
| 4.10 | Second Supplemental Indenture (including the Form of Note), dated as of May 14, 2019, between the Registrant and U.S. Bank National Association, as trustee | Form 8-K | 4.2 | May 14, 2019 |
| 4.11* | Description of Securities of the Registrant | | | |
| 10.1# | Intercept Pharmaceuticals, Inc. 2012 Equity Incentive Plan | Form S-1/A(3) | 10.2.1 | September 27, 2012 |
| 10.2# | Form of Stock Option Grant Notice and Agreement for Directors | Form 10-Q | 10.1 | August 10, 2020 |
| 10.3# | Form of Stock Option Grant Notice and Agreement for Employees and Consultants | Form 10-K | 10.3 | February 25, 2020 |
| 10.4# | Form of Restricted Stock Unit Award Grant Notice and Agreement for Directors | Form 10-Q | 10.2 | August 10, 2020 |

| | | | | |
|---|---|---|---|---|
| 10.5# | Form of Restricted Stock Unit Award Grant Notice and Agreement for Employees and Consultants | Form 10-K | 10.5 | February 25, 2020 |
| 10.6# | Form of Restricted Stock Award Grant Notice and Agreement for Directors | Form 10-Q | 10.3 | May 9, 2014 |
| 10.7# | Form of Restricted Stock Award Grant Notice and Agreement for Employees and Consultants | Form 10-Q | 10.4 | May 9, 2014 |
| 10.8# | Form of Performance Stock Unit Grant Notice and Agreement | Form 10-K | 10.8 | February 25, 2020 |
| 10.9# | Form of Performance Share Grant Notice and Agreement | Form 10-Q | 10.6 | May 10, 2018 |
| 10.10# | Amended and Restated Employment Agreement, effective May 14, 2013, between the Registrant and Mark Pruzanski | Form 10-Q | 10.5 | May 14, 2013 |
| 10.11# | Employment Agreement, effective May 3, 2016, between the Registrant and Sandip S. Kapadia | Form 10-Q | 10.1.1 | August 9, 2016 |
| 10.12# | Employment Agreement, effective February 15, 2017, between the Registrant and Jerome B. Durso | Form 10-Q | 10.1 | May 10, 2017 |
| 10.13# | Employment Agreement, effective April 14, 2017, between the Registrant and David Ford | Form 10-Q | 10.1 | August 3, 2017 |
| 10.14# | Amended and Restated Employment Agreement, effective as of November 27, 2017, between the Registrant and David Shapiro | Form 8-K | 10.2 | December 1, 2017 |
| 10.15# | Employment Agreement, effective January 22, 2018, between the Registrant and Ryan Sullivan | Form 10-Q | 10.1 | August 8, 2019 |
| 10.16# | Employment Agreement, effective February 6, 2018, between the Registrant and Gail Cawkwell | Form 10-Q | 10.2 | August 8, 2019 |
| 10.17# | Employment Agreement, effective November 19, 2019, between the Registrant and Jason Campagna | Form 10-K | 10.17 | February 25, 2020 |
| 10.18# | Employment Agreement, effective June 20, 2015, between the Registrant and Richard Kim | Form 10-Q | 10.3 | August 10, 2020 |
| 10.19# | Retirement and Consulting Agreement, dated as of December 9, 2020, between the Registrant and Mark Pruzanski, M.D. | Form 8-K | 10.2 | December 10, 2020 |
| 10.20# | Amended and Restated Employment Agreement, dated as of December 9, 2020, between the Registrant and Jerome Durso | Form 8-K | 10.1 | December 10, 2020 |
| 10.21#* | Employment Agreement, effective as of December 18, 2020, between the Registrant and Jared Freedberg | | | |

| | | | | |
|---|---|---|---|---|
| 10.22# | Form of Indemnification Agreement for directors and executive officers of the Registrant | Form S-1(3) | 10.7 | September 4, 2012 |
| 10.23 | Base Call Option Confirmation, dated June 30, 2016, between the Registrant and Royal Bank of Canada | Form 8-K | 10.1 | July 6, 2016 |
| 10.24 | Base Call Option Confirmation, dated June 30, 2016, between the Registrant and UBS AG, London Branch | Form 8-K | 10.3 | July 6, 2016 |
| 10.25 | Base Call Option Confirmation, dated June 30, 2016, between the Registrant and Credit Suisse Capital LLC | Form 8-K | 10.5 | July 6, 2016 |
| 10.26 | Additional Call Option Confirmation, dated July 1, 2016, between the Registrant and Royal Bank of Canada | Form 8-K | 10.2 | July 6, 2016 |
| 10.27 | Additional Call Option Confirmation, dated July 1, 2016, between the Registrant and UBS AG, London Branch | Form 8-K | 10.4 | July 6, 2016 |
| 10.28 | Additional Call Option Confirmation, dated July 1, 2016, between the Registrant and Credit Suisse Capital LLC | Form 8-K | 10.6 | July 6, 2016 |
| 10.29 | Lease Agreement between The Irvine Company LLC and the Registrant, dated May 1, 2014 | Form 8-K | 10.1 | May 7, 2014 |
| 10.30 | Second Amendment to Lease, dated as of July 19, 2016, between the Registrant and Irvine Eastgate Office II LLC | Form 10-Q | 10.7 | November 9, 2016 |
| 10.31 | Third Amendment to Lease, dated as of June 21, 2018, between the Registrant and Irvine Eastgate Office II LLC | Form 10-Q | 10.1 | August 7, 2018 |
| 10.32 | Fourth Amendment to Lease, dated as of October 30, 2018, between the Registrant and Irvine Eastgate Office II LLC | Form 10-Q | 10.1 | November 1, 2018 |
| 10.33 | Underlease between the Registrant, Intercept Pharma Europe Ltd. and Performing Right Society, Ltd., dated January 22, 2016 | Form 10-K | 10.12 | February 29, 2016 |
| 10.34 | Lease Agreement, dated December 7, 2016, between the Registrant and Legacy Yards Tenant LP | Form 10-K | 10.17 | March 1, 2017 |
| 10.35 | First Amendment to Lease Agreement, dated June 27, 2017, between the Registrant and Legacy Yards Tenant LP | Form 10-Q | 10.1 | November 6, 2017 |
| 10.36 | Second Amendment to Lease, dated June 22, 2018, between the Registrant and Legacy Yards Tenant LP | Form 10-Q | 10.2 | August 7, 2018 |

| | | | | |
|---|---|---|---|---|
| 10.37 | Third Amendment to Lease, dated November 1, 2019, between the Registrant and Legacy Yards Tenant LP | Form 10-Q | 10.1 | November 5, 2019 |
| 10.38 | Termination of Lease, dated December 31, 2017, between the Registrant and One Hudson Yards Owner LLC | Form 10-K | 10.21 | February 28, 2018 |
| 10.39*++ | Commercial Manufacturing and Supply Agreement, dated August 12, 2016, between the Registrant and PharmaZell GMBH | | | |
| 10.40+ | Amendment #1 to Manufacturing and Supply Agreement, dated December 12, 2017, between the Registrant and PharmaZell GMBH | Form 10-K | 10.2.1 | February 28, 2018 |
| 10.41*++ | Sumitomo Agreement, dated March 29, 2011, between the Registrant and Sumitomo Dainippon Pharma Co., Ltd. | | | |
| 10.42 | Amendment No. 1, dated June 8, 2011, to that certain Sumitomo Agreement, dated March 29, 2011, between the Registrant and Sumitomo Dainippon Pharma Co., Ltd. | Form 10-Q | 10.1 | May 10, 2018 |
| 10.43 | Amendment No. 2, dated September 16, 2011, to that certain Sumitomo Agreement, dated March 29, 2011, between the Registrant and Sumitomo Dainippon Pharma Co., Ltd. | Form 10-Q | 10.2 | May 10, 2018 |
| 10.44+ | Amendment No. 3, dated February 13, 2018, to that certain Sumitomo Agreement, dated March 29, 2011, between the Registrant and Sumitomo Dainippon Pharma Co., Ltd. | Form 10-Q | 10.3 | May 10, 2018 |
| 10.45 | Letter Agreement, dated October 25, 2019, between the Registrant and Sumitomo Dainippon Pharma Co., Ltd. | Form 10-K | 10.41 | February 25, 2020 |
| 21.1* | Subsidiaries of the Registrant | | | |
| 23.1* | Consent of Independent Registered Public Accounting Firm | | | |
| 24.1* | Power of Attorney (included in signature page to this Annual Report on Form 10-K) | | | |
| 31.1* | Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) | | | |
| 31.2* | Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) | | | |

| | |
|---|---|
| 32.1* (4) | Certifications required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) |
| 101* | The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2020 and 2019, (ii) Consolidated Statements of Operations for the Years Ended December 31, 2020, 2019 and 2018, (iii) Consolidated Statement of Comprehensive Loss for the Years Ended December 31, 2020, 2019 and 2018, (iv) Consolidated Statements of Changes in Stockholders' (Deficit) Equity for the Years Ended December 31, 2020, 2019 and 2018, (v) Consolidated Statements of Cash Flows for the Years Ended December 31, 2020, 2019 and 2018 and (vi) Notes to Consolidated Financial Statements |
| 104* | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

* Filed herewith.

\+ Confidential treatment has been received with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission ("SEC").

++ Portions of the exhibit have been omitted pursuant to Regulation S-K, Item 601(b)(10)(iv).

\# Indicates a management contract or compensatory plan or arrangement.

† Unless otherwise specified, the File No. is 001-35668.

(1) Registration Statement on Form S-8 filed by the Registrant, Registration No. 333-184810.

(2) Registration Statement on Form S-1 filed by the Registrant, Registration No. 333-217861.

(3) Registration Statement on Form S-1 filed by the Registrant, Registration No. 333-183706.

(4) This certification "accompanies" the Annual Report on Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.

**Item 16. Form 10-K Summary**

None.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: February 25, 2021

By: /s/ Jerome Durso
Jerome Durso
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 25, 2021

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

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Jerome Durso and Sandip Kapadia, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing required or necessary to be done in and about the premises, as fully and to all intents and purposes as the undersigned could do in person, and hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on February 25, 2021.

| Signature | Title |
|---|---|
| /s/ Jerome Durso<br>Jerome Durso | President and Chief Executive Officer and Director<br>(Principal Executive Officer) |
| /s/ Sandip Kapadia<br>Sandip Kapadia | Chief Financial Officer and Treasurer<br>(Principal Financial Officer and Principal Accounting Officer) |
| /s/ Paolo Fundarò<br>Paolo Fundarò | Chairman of the Board of Directors |
| /s/ Srinivas Akkaraju, M.D., Ph.D.<br>Srinivas Akkaraju, M.D., Ph.D. | Director |
| /s/ Luca Benatti, Ph.D.<br>Luca Benatti, Ph.D. | Director |
| /s/ Daniel Bradbury<br>Daniel Bradbury | Director |

| | |
|---|---|
| /s/ Keith Gottesdiener, M.D.<br>Keith Gottesdiener, M.D. | Director |
| /s/ Nancy Miller-Rich<br>Nancy Miller-Rich | Director |
| /s/ Mark Pruzanski, M.D.<br>Mark Pruzanski, M.D. | Director |
| /s/ Gino Santini<br>Gino Santini | Director |
| /s/ Glenn Sblendorio<br>Glenn Sblendorio | Director |
| /s/ Daniel Welch<br>Daniel Welch | Director |

**INTERCEPT PHARMACEUTICALS, INC.**

**Index to Consolidated Financial Statements**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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Intercept Pharmaceuticals, Inc.:

*Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of Intercept Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, changes in stockholders' (deficit) equity, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 25, 2021 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

*Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

*Critical Audit Matter*

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgment. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Assessing deductions from revenue related to certain rebates and discounts accruals*

As discussed in Note 2 to the consolidated financial statements, the Company records net product revenue by deducting rebates and discounts, among other items. The rebates and discounts are related to arrangements with the Centers for Medicare & Medicaid Services and other government agencies, and are estimated and accrued with a corresponding reduction of gross product revenues when revenue is recognized. The Company had $27.4 million and $9.5 million in rebates and discounts accruals as of December 31, 2020 for a European jurisdiction in which final pricing is subject to ongoing negotiations with the government, and for all other jurisdictions, respectively, which were recorded in accounts payable, accrued expenses and other liabilities on the consolidated balance sheet.

We identified the assessment of deductions from revenue related to certain rebates and discounts accruals as a critical audit matter because evaluating the Company's assumptions involved especially challenging auditor judgment, including specialized knowledge of the regulatory environment in a particular European jurisdiction. Rebates and discounts are estimated based on certain assumptions developed using benchmarks of pricing approved in other relevant European jurisdictions in the case of the European jurisdiction in which final pricing is subject to ongoing negotiations with the government, and, for all other jurisdictions, historical experience with actual payments and redemptions.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls over the Company's rebates and discounts accruals process, including controls related to the significant assumptions used in the Company's estimation of certain rebates and discounts. We evaluated the Company's ability to estimate rebates and discounts by comparing the previously recorded accruals to the actual amounts that were settled and ultimately paid by the Company. We assessed the Company's current period estimates by comparing the accrued amounts to historical payments and redemptions. We also performed sensitivity analyses based on potential changes in certain assumptions and assessed the impact relative to the Company's accruals as of December 31, 2020. In addition, we involved professionals with specialized skills and knowledge of the regulatory environment in the European jurisdiction in which final pricing is subject to ongoing negotiations with the government, who assisted in assessing the Company's assumptions in estimating the rebates and discounts.

/s/ KPMG LLP

We have served as the Company's auditor since 2008.

New York, New York
February 25, 2021

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Intercept Pharmaceuticals, Inc.:

*Opinion on Internal Control Over Financial Reporting*

We have audited Intercept Pharmaceuticals, Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, changes in stockholders' (deficit) equity, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements), and our report dated February 25, 2021 expressed an unqualified opinion on those consolidated financial statements.

*Basis for Opinion*

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

*Definition and Limitations of Internal Control Over Financial Reporting*

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG LLP

New York, New York
February 25, 2021

**INTERCEPT PHARMACEUTICALS, INC.**

**Consolidated Balance Sheets**

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands, except share and per share data) | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 58,151 | $ 70,055 |
| Restricted cash | 7,503 | 4,725 |
| Investment debt securities, available-for-sale | 411,516 | 582,567 |
| Accounts receivable, net of allowance for credit losses of $235 and $0, respectively | 41,549 | 38,044 |
| Prepaid expenses and other current assets | 27,022 | 25,924 |
| Total current assets | 545,741 | 721,315 |
| Fixed assets, net | 6,326 | 5,202 |
| Inventory | 9,027 | 8,462 |
| Security deposits | 7,068 | 6,661 |
| Other assets | 12,327 | 13,246 |
| Total assets | $ 580,489 | $ 754,886 |
| **Liabilities and Stockholders' (Deficit) Equity** | | |
| Current liabilities: | | |
| Accounts payable, accrued expenses and other liabilities | $ 171,039 | $ 153,968 |
| Short-term interest payable | 8,037 | 8,037 |
| Total current liabilities | 179,076 | 162,005 |
| Long-term liabilities: | | |
| Long-term debt | 560,582 | 532,078 |
| Long-term other liabilities | 7,684 | 9,247 |
| Total liabilities | $ 747,342 | $ 703,330 |
| Commitments and contingencies (Note 19) | | |
| Stockholders' (deficit) equity: | | |
| Common stock par value $0.001 per share; 90,000,000 and 45,000,000 shares authorized; 33,015,614 and 32,853,066 shares issued and outstanding as of December 31, 2020 and 2019, respectively | 33 | 33 |
| Additional paid-in capital | 2,233,937 | 2,176,133 |
| Accumulated other comprehensive loss, net | (2,477) | (1,144) |
| Accumulated deficit | (2,398,346) | (2,123,466) |
| Total stockholders' (deficit) equity | (166,853) | 51,556 |
| Total liabilities and stockholders' (deficit) equity | $ 580,489 | $ 754,886 |

See accompanying notes to consolidated financial statements.

**INTERCEPT PHARMACEUTICALS, INC.**

**Consolidated Statements of Operations**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | (in thousands, except per share data) | | |
| Revenue: | | | |
| Product revenue, net | $ 312,690 | $ 249,570 | $ 177,782 |
| Licensing revenue | — | 2,432 | 2,022 |
| Total revenue | 312,690 | 252,002 | 179,804 |
| Operating expenses: | | | |
| Cost of sales | 5,322 | 4,212 | 2,519 |
| Selling, general and administrative | 332,493 | 317,418 | 255,474 |
| Research and development | 191,485 | 242,799 | 207,301 |
| Restructuring | 14,630 | — | — |
| Total operating expenses | 543,930 | 564,429 | 465,294 |
| Operating loss | (231,240) | (312,427) | (285,490) |
| Other income (expense): | | | |
| Interest expense | (48,054) | (41,144) | (30,523) |
| Other income, net | 4,414 | 8,890 | 6,771 |
| Total other (expense), net | (43,640) | (32,254) | (23,752) |
| Net loss | $ (274,880) | $ (344,681) | $ (309,242) |
| Net loss per common and potential common share: | | | |
| Basic and diluted | $ (8.34) | $ (10.89) | $ (10.86) |
| Weighted average common and potential common shares outstanding: | | | |
| Basic and diluted | 32,970 | 31,654 | 28,464 |

See accompanying notes to consolidated financial statements.

**INTERCEPT PHARMACEUTICALS, INC.**

**Consolidated Statements of Comprehensive Loss**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Net loss | $ (274,880) | $ (344,681) | $ (309,242) |
| Other comprehensive (loss) income: | | | |
| Net changes related to available-for-sale investment debt securities: | | | |
| Unrealized (losses) gains on investment debt securities | (202) | 1,509 | 88 |
| Reclassification adjustment for realized gains on investment debt securities included in other income, net | (135) | (8) | (8) |
| Net unrealized (losses) gains on investment debt securities | $ (337) | $ 1,501 | $ 80 |
| Foreign currency translation losses | (996) | (379) | (1,553) |
| Other comprehensive (loss) income | (1,333) | 1,122 | (1,473) |
| Comprehensive loss | $ (276,213) | $ (343,559) | $ (310,715) |

See accompanying notes to consolidated financial statements.

**INTERCEPT PHARMACEUTICALS, INC.**

**Consolidated Statements of Changes in Stockholders' (Deficit) Equity**

**For the Years Ended December 31, 2020, 2019 and 2018**
**(in thousands)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss, Net | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balance - December 31, 2017 | 25,173 | $ 25 | $ 1,486,690 | $ (786) | $ (1,469,543) | $ 16,386 |
| Stock-based compensation | — | — | 49,914 | — | — | 49,914 |
| Issuance of common stock from public and private placement offerings, net of underwriting fees and issuance costs | 4,258 | 5 | 261,357 | — | — | 261,362 |
| Net proceeds from exercise of stock options | 263 | — | 4,363 | — | — | 4,363 |
| Employee withholding taxes related to stock-based awards | — | — | (2,180) | — | — | (2,180) |
| Other comprehensive loss | — | — | — | (1,473) | — | (1,473) |
| Net loss | — | — | — | — | (309,242) | (309,242) |
| Balance - December 31, 2018 | 29,694 | $ 30 | $ 1,800,144 | $ (2,259) | $ (1,778,785) | $ 19,130 |
| Stock-based compensation | — | — | 55,982 | — | — | 55,982 |
| Recognition of debt discount on 2026 Convertible Notes | — | — | 85,915 | — | — | 85,915 |
| Issuance of common stock from public and private placement offerings, net of underwriting fees and issuance costs | 2,880 | 3 | 227,257 | — | — | 227,260 |
| Net proceeds from exercise of stock options | 279 | — | 8,993 | — | — | 8,993 |
| Employee withholding taxes related to stock-based awards | — | — | (2,158) | — | — | (2,158) |
| Other comprehensive income | — | — | — | 1,115 | — | 1,115 |
| Net loss | — | — | — | — | (344,681) | (344,681) |
| Balance - December 31, 2019 | 32,853 | $ 33 | $ 2,176,133 | $ (1,144) | $ (2,123,466) | $ 51,556 |
| Stock-based compensation | — | — | 60,850 | — | — | 60,850 |
| Net proceeds from exercise of stock options | 176 | — | (1,052) | — | — | (1,052) |
| Employee withholding taxes related to stock-based awards | (13) | — | (1,994) | — | — | (1,994) |
| Other comprehensive loss | — | — | — | (1,333) | — | (1,333) |
| Net loss | — | — | — | — | (274,880) | (274,880) |
| Balance - December 31, 2020 | 33,016 | $ 33 | $ 2,233,937 | $ (2,477) | $ (2,398,346) | $ (166,853) |

See accompanying notes to consolidated financial statements.

**INTERCEPT PHARMACEUTICALS, INC.**

**Consolidated Statements of Cash Flows**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Cash flows from operating activities: | | | |
| Net loss | $ (274,880) | $ (344,681) | $ (309,242) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Stock-based compensation | 60,850 | 55,982 | 49,914 |
| (Accretion) amortization of (discount) premium on investment debt securities | 4,006 | (302) | (33) |
| Amortization of deferred financing costs | 2,540 | 2,130 | 1,542 |
| Realized loss on investments | — | — | 8 |
| Depreciation | 3,118 | 3,663 | 4,582 |
| Non-cash operating lease cost | 6,142 | 5,388 | — |
| Gain on lease termination | — | (1,995) | — |
| Loss on the disposal of fixed assets | — | 2,682 | 1,331 |
| Accretion of debt discount | 25,964 | 21,189 | 14,031 |
| Provision for allowance of credit losses, net of write-offs | 235 | — | — |
| Changes in operating assets: | | | |
| Accounts receivable | (2,646) | (12,350) | (9,193) |
| Prepaid expenses and other current assets | (3,075) | (5,353) | (3,682) |
| Inventory | (269) | (1,354) | (3,628) |
| Security deposits | (269) | 2,562 | 7,153 |
| Other assets | 1,385 | (24,665) | — |
| Changes in operating liabilities: | | | |
| Accounts payable, accrued expenses and other current liabilities | 13,863 | 56,411 | 10,332 |
| Operating lease liabilities | (6,990) | (6,767) | — |
| Interest payable | — | 562 | — |
| Deferred revenue | — | (2,432) | (2,022) |
| Long-term other liabilities | — | 12,717 | (1,807) |
| Net cash (used in) operating activities | (170,026) | (236,613) | (240,714) |
| Cash flows from investing activities: | | | |
| Purchases of investment debt securities | (330,713) | (603,014) | (436,071) |
| Sales and maturities of investment debt securities | 497,421 | 415,162 | 388,168 |
| Purchases of equipment, leasehold improvements, and furniture and fixtures | (3,891) | (1,136) | (167) |
| Net cash provided by (used in) investing activities | 162,817 | (188,988) | (48,070) |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of 2026 Convertible Notes, net of issuance costs | — | 223,424 | — |
| Proceeds from issuance of common stock, net of issuance costs | — | 227,260 | 261,362 |
| Proceeds from exercise of options, net | 1,301 | 8,993 | 4,363 |
| Payments of employee withholding taxes related to stock-based awards | (1,994) | (2,158) | (2,180) |
| Net cash (used in) provided by financing activities | (693) | 457,519 | 263,545 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | (1,224) | (386) | (1,526) |
| Net (decrease) increase in cash, cash equivalents and restricted cash | (9,126) | 31,532 | (26,765) |
| Cash, cash equivalents and restricted cash at beginning of period | 74,780 | 43,248 | 70,013 |
| Cash, cash equivalents and restricted cash at end of period | $ 65,654 | $ 74,780 | $ 43,248 |
| Supplemental disclosure of non-cash transactions: | | | |
| Right-of-use asset obtained in exchange for new operating lease obligations | $ 4,721 | $ — | $ — |
| Non-cash investing and financing activities | | | |
| Net increase in accrued fixed assets | $ 368 | $ — | $ — |
| | | | |
| Reconciliation of cash, cash equivalents and restricted cash included in the condensed consolidated balance sheets: | | | |
| Cash and cash equivalents | $ 58,151 | $ 70,055 | $ 43,248 |
| Restricted cash | 7,503 | 4,725 | — |
| Total cash, cash equivalents and restricted cash | $ 65,654 | $ 74,780 | $ 43,248 |

See accompanying notes to consolidated financial statements

**INTERCEPT PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 1. Overview of Business

Intercept Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, including primary biliary cholangitis ("PBC") and nonalcoholic steatohepatitis ("NASH"). The Company currently has one marketed product, Ocaliva (obeticholic acid or "OCA"). Founded in 2002 in New York, the Company has operations in the United States, Europe and Canada.

## 2. Summary of Significant Accounting Policies

***Basis of Presentation and Principles of Consolidation***

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries or investments accounted for under the equity method.

***Use of Estimates***

The preparation of these financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

***Foreign Currency***

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Revenue and expense components are translated to U.S. dollars at weighted-average exchange rates in effect during the period. Foreign currency transaction gains and losses resulting from remeasurement are recognized in Other income, net within the consolidated statements of operations. Gains and losses as a result of foreign currency translation adjustments are recorded as a component of Accumulated other comprehensive loss, net in the equity/(deficit) section of our consolidated balance sheets and as Foreign currency translation gains (losses) within the accompanying consolidated statements of comprehensive loss.

***Cash and Cash Equivalents***

The Company considers all highly liquid securities with an original or remaining maturity of three months or less at acquisition to be cash equivalents.

***Restricted Cash***

Restricted cash relates to short-term bank guarantees which provides financial assurance that the Company will fulfill certain customer obligations entered into in the normal course of business. The cash is restricted as to withdrawal or use while the related bank guarantee in favor of the customer is outstanding.

***Credit Losses***

The allowance for credit losses is based on the Company's assessment of the collectibility of customer accounts. The Company regularly reviews the allowance by considering factors such as historical experience, the aging of the accounts

receivable balances, credit conditions that may affect a customer's ability to pay, current and forecast economic conditions and other relevant factors.

The following table summarizes the allowance for credit losses activity on the Company's trade receivables for the year ended December 31, 2020 (in thousands):

| | | |
|---|---|---|
| Balance at December 31, 2019 | $ | — |
| Provision for credit losses | | 258 |
| Write-offs | | (23) |
| Balance at December 31, 2020 | $ | 235 |

For available-for-sale investment debt securities in an unrealized loss position, the Company first assesses whether it intends to sell the security or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the amortized cost basis is written down to fair value through income. For any investment debt securities that do not meet the criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. Management considers the extent in which the fair value of the security is less than amortized costs, any changes to the rating of the security by a rating agency, changes in interest rates, and any other adverse factors related to the security. If the assessment indicates a credit loss, the present value of cash flows expected to be collected are compared to the amortized cost basis of the security. If the expected present value of cash flows is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded, limited to the amount that the fair value is below the amortized cost basis. Any impairment not recorded through an allowance is recognized in Other comprehensive (loss) income.

Changes in the allowance for credit losses are recorded as a provision for (or reversal of) credit loss expense. Losses are charged against the allowance when management believes the uncollectibility of the security is confirmed or whether either of the criteria regarding intent or requirement to sell is met.

The Company excludes accrued interest from both the fair value and amortized cost basis in the assessment of credit losses on its available-for-sale investment debt securities and will instead elect to write-off any uncollectible accrued interest receivable balances in a timely manner, which is defined by the Company as when interest due becomes 90 days delinquent.

***Investment Debt Securities, Available-For-Sale***

Investment debt securities are considered to be available-for-sale and are carried at fair market value. The estimated fair value of the available-for-sale investment debt securities is determined based on quoted market prices or rates for similar instruments. Unrealized gains and losses, if any, are reported in accumulated other comprehensive income (loss). The cost of investment debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in Other income, net. Realized gains and losses are included in Other income, net. Interest and dividends on available-for-sale securities are included in Other income, net.

***Fair Value of Financial Instruments***

The carrying amounts of certain financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to their short-term maturities.

**INTERCEPT PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

***Concentration of Credit Risk***

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, investment debt securities and accounts receivables from customers.

The Company currently invests its excess cash primarily in money market funds, and high quality, marketable debt instruments of corporations, financial institutions and government sponsored enterprises. The Company has adopted an investment policy that includes guidelines relative to credit quality, diversification and maturities to preserve principal and liquidity.

On a consolidated basis, for the year ended December 31, 2020, the Company's three largest customers (as discussed in more detail below under "Revenue Recognition") accounted for 31%, 30% and 14%, of the Company's net product sales, respectively. On a consolidated basis, for the year ended December 31, 2019, the Company's three largest customers (as discussed in more detail below under "Revenue Recognition") accounted for 32%, 31% and 15%, of the Company's net product sales, respectively. On a consolidated basis, for the year ended December 31, 2018, the Company's three largest customers (as discussed in more detail below under "Revenue Recognition") accounted for 38%, 28% and 16%, of the Company's net product sales, respectively.

On a consolidated basis, the Company's three largest customers accounted for 31%, 17% and 10% of the December 31, 2020 accounts receivable balance, respectively. On a consolidated basis, the Company's three largest customers accounted for 27%, 28% and 7% of the December 31, 2019 accounts receivable balance, respectively. The Company monitors its customers' financial credit worthiness in order to assess and respond to any changes in their credit profile.

***Accounts Receivable***

The Company extends credit to customers based on its evaluation of the customer's financial condition. The Company records receivables for all billings when amounts are due under standard terms. Accounts receivable are stated at amounts due net of applicable prompt pay discounts and other contractual adjustments as well as an allowance for doubtful accounts. The Company will write off accounts receivable when the Company determines that they are uncollectible. The Company has recorded $41.5 million and $38.0 million of accounts receivable as of December 31, 2020 and 2019, respectively, and has recorded an allowance for any credit losses of $0.2 million and $0 as of December 31, 2020 and 2019, respectively.

***Fixed Assets***

Fixed assets are stated at cost, and depreciated over the estimated useful life of the assets. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets, generally three to seven years. Leasehold improvements are amortized over the shorter of the asset's useful life or the life of the lease term. Expenditures for maintenance and repairs are charged to expense as incurred. Upon sale or retirement of assets, the cost of the assets disposed of and the related accumulated depreciation are removed from the balance sheets and any related gains or losses are reflected in the consolidated statements of operations.

***Impairment of Long-Lived Assets***

Long-lived assets consist of fixed assets and right-of-use assets. The Company evaluates long-lived assets for impairment when events and circumstances indicate that the carrying amount of an asset or group of assets may not be fully recoverable. If indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing

**INTERCEPT PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset. There have been no impairments of any long-lived assets in the periods presented.

***Inventory***

Inventories are stated at the lower of cost or estimated realizable value. The Company determines the cost of inventory using the first-in, first-out (or FIFO) method. The Company capitalizes inventory costs associated with the Company's product after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate. In addition, the Company's product is subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of sales to write down such unmarketable inventory to zero. No such charges were recorded in the years ended December 31, 2020, 2019 or 2018.

***Leases***

The Company determines if an arrangement is a lease at inception and records right-of-use (“ROU”) assets and lease liabilities on the consolidated balance sheets at lease commencement based on the present value of remaining lease payments over the lease term. The Company only considers payments that are fixed and determinable at the time of commencement.

Operating lease liabilities are recognized based on the present value of the future minimum lease payments discounted by the Company’s incremental borrowing rate. The Company measures ROU assets based on the corresponding lease liability adjusted for (i) payments made to the lessor at or before the commencement date, (ii) initial direct costs incurred and (iii) tenant incentives under the lease. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that it will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

The Company has elected the practical expedient to exclude short-term leases from its ROU assets and lease liabilities; therefore leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company recognizes lease expense for these leases on a straight-line basis over the lease term. The Company elected the practical expedient not to separate non-lease components from all leases. As the Company’s leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments. The Company’s incremental borrowing rate is the estimated rate that would be required to pay for a collateralized borrowing equal to the total lease payment over the lease term. The Company estimates its incremental borrowing rate based on an analysis of publicly traded debt securities of companies with credit and financial profiles similar to its own.

For short-term leases, the Company does not record ROU assets or lease liabilities, and records rent expense in its consolidated statements of operations on a straight-line basis over the lease term, with the exception of variable lease payments, which are expensed as incurred.

***Convertible Debt***

The Company accounts for convertible debt in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification Subtopic 470-20, “Debt with Conversion and Other Options” (“ASC 470-20”). The Company separately accounts for the liability (debt) and equity (conversion option) components of convertible debt instruments by allocating the proceeds from the issuance. The value assigned to the debt component is the estimated fair

value, as of the issuance date, of a similar debt instrument without the conversion option. The amount of the equity component (and resulting debt discount) is calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The resulting debt discount is amortized as additional non-cash interest expense over the expected life of the notes utilizing the effective interest method. For additional information, see Note 9 — Long-Term Debt.

***Revenue Recognition***

*Product Revenue, Net*

The Company recognizes revenue upon shipment of Ocaliva to its customers. The Company provides the right of return to its customers for unopened product for a limited time before and after its expiration date. Returns are estimated based on historical experience and product shelf lives.

The Company has written contracts with each of its customers that have a single performance obligation — to deliver products upon receipt of a customer order — and these obligations are satisfied when delivery occurs and the customer receives Ocaliva. The Company evaluates the creditworthiness of each of its customers to determine whether collection is reasonably assured. The wholesale acquisition cost that the Company charges its customers for Ocaliva is adjusted to arrive at our estimated net product revenues by deducting (i) estimated government rebates and discounts related to Medicare, Medicaid and other government programs, (ii) estimated costs of incentives offered to certain indirect customers including patients, and (iii) trade allowances, such as invoice discounts for prompt payment and customer fees.

*Rebates and Discounts*

The Company contracts with the Centers for Medicare & Medicaid Services and other government agencies to make Ocaliva available to eligible patients. As a result, the Company estimates any rebates and discounts and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company's estimates of rebates and discounts are based on the government mandated discounts, which are statutorily-defined and applicable to these government funded programs and assumptions developed using historical experience with actual payments and redemptions. The Company recorded $9.5 million and $7.6 million in such estimates as of December 31, 2020 and 2019, respectively, in accounts payable, accrued expenses and other liabilities on the consolidated balance sheets.

The Company contracts with national authorities in Europe to make Ocaliva available to eligible patients. In jurisdictions in which final pricing is subject to ongoing negotiations with the government, the Company estimates the rebate expected to be due and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company's estimates of such liabilities are based on current invoice pricing and total prior units sold and assumptions developed using benchmarks of Ocaliva pricing approved in other relevant European jurisdictions. The Company recorded $27.4 million and $12.7 million in such estimates as of December 31, 2020 and 2019, respectively, in accounts payable, accrued expenses and other liabilities on the consolidated balance sheets.

*Other Incentives*

Other incentives that the Company offers to indirect customers include co-pay assistance cards provided by the Company for PBC patients who reside in states that permit co-pay assistance programs. The Company's co-pay assistance program is intended to reduce each participating patient's portion of the financial responsibility for Ocaliva purchase price to a specified dollar amount. The Company estimates the amount of co-pay assistance provided to eligible patients based on the terms of the program when product is dispensed by the specialty pharmacies to the patients. These estimates are based on redemption information provided by third-party claims processing organizations. The Company recorded $1.3 million and $1.2 million in such estimates as of December 31, 2020 and 2019, respectively, in accounts payable, accrued expenses and other liabilities on the consolidated balance sheets.

**INTERCEPT PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

*Trade Allowances*

The Company provides invoice discounts on Ocaliva sales to certain of its customers for prompt payment and records these discounts as a reduction to gross product revenues. These discounts are based on contractual terms. Trade allowances are recorded in accounts receivable, net of allowance for credit losses on the consolidated balance sheets.

*Licensing Revenue*

The Company accounts for the development, regulatory and sales milestones within an arrangement as variable consideration that is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Because the achievement of the milestones triggering these payments is highly susceptible to factors outside the entity's influence, and the uncertainty about the amount of consideration for some of the milestones is not expected to be resolved for a long period of time, the Company does not expect to record the associated revenue until achievement of each milestone is imminent or has already occurred.

***Research and Development Expenses***

Research and development costs that do not have alternative future use are charged to expense as incurred. This includes the cost of conducting clinical trials, compensation and related overhead for employees and consultants involved in research and development and the cost of the Company's manufacturing activities to supply ongoing and future clinical trials and preclinical studies. For periods prior to commercial launch, all manufacturing costs for OCA were expensed as research and development expenses. The Company will continue to incur manufacturing costs for OCA for other indications such as NASH prior to their potential approval.

***Stock-based Compensation***

The Company accounts for stock-based compensation to employees, non-employee directors and non-employees granted share-based payments for services in accordance with ASC Topic 718, Compensation — Stock Compensation ("ASC 718"). The Company estimates the fair value of stock option awards using the Black-Scholes option pricing model on the date of the grant. Restricted stock unit awards ("RSUs") and restricted stock awards ("RSAs") without a market condition are valued based on the closing price of the Company's common stock on the date of the grant. The fair value of time-based stock options and RSUs is recognized and amortized on a straight-line basis over the requisite service period of the award. Stock options granted to employees generally fully vest over four years and have a term of ten years. The fair value of awards with market conditions is estimated using the Monte Carlo simulation method and expense is recognized on a straight-line basis over the requisite service period of the award. The Company accounts for all forfeitures when they occur.

***Net Loss Per Share***

Basic loss per share is computed by dividing net loss attributable to common stockholders (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Potentially dilutive common shares include the shares of common stock issuable upon the exercise of outstanding stock options and unvested restricted stock units. The Company accounts for the effect of the Convertible Notes on diluted net earnings per share using the if-converted method as they may be settled in cash or shares at the Company's option. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given net losses.

**INTERCEPT PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

***Income Taxes***

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. The Company establishes a valuation allowance when it believes it is more likely than not that deferred tax assets will not be realized.

The Company determines the need for a valuation allowance by assessing the probability of realizing deferred tax assets, taking into consideration all available positive and negative evidence, including historical operating results, expectations of future taxable income, carryforward periods available, various income tax strategies and other relevant factors. Judgment is required in making this assessment and to the extent future expectations change, the Company would have to assess the recoverability of its deferred assets at that time.

The Company's tax returns are subject to examination by U.S. Federal, state, and foreign taxing jurisdictions. The impact of an uncertain tax position taken or expected to be taken on an income tax return must be recognized in the financial statements at the largest amount that is more likely than not to be sustained. An uncertain income tax position will not be recognized in the financial statements unless it is more likely than not to be sustained.

***Segments***

The Company operates in one segment focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases.

***Recently Adopted Accounting Pronouncements***

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, "Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"), which replaces the incurred loss impairment methodology under current U.S. GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 was subsequently updated by ASU No. 2019-04, "Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments", to clarify that entities should include recoveries when estimating the allowance for credit losses. The Company will be required to use a forward-looking expected credit loss model for accounts receivables, loans and other financial instruments. Credit losses relating to available-for-sale investment debt securities will also be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 and must be adopted using a modified retrospective approach, with certain exceptions. The Company adopted ASU 2016-13 on January 1, 2020 and its adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement" ("ASU 2018-13"), which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company adopted ASU 2018-13 on January 1, 2020 and its adoption did not have any impact on the Company's consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income

taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company adopted ASU 2019-12 on January 1, 2021 and its adoption did not have any material impact on the Company's consolidated financial statements and related disclosures.

***Recent Accounting Pronouncements to be Adopted***

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. Either a modified retrospective method of transition or a fully retrospective method of transition is permissible for the adoption of this standard. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, with early adoption permitted. The Company expects the impact of this standard to be material on its consolidated financial statements and related disclosures.

## 3. Cash, Cash Equivalents and Investments

The following table summarizes the Company's cash, cash equivalents and investments as of December 31, 2020 and 2019:

| | As of December 31, 2020 | | | | |
|---|---|---|---|---|---|
| | Amortized Cost | Allowance for Credit Losses | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| | | | (in thousands) | | |
| **Cash and cash equivalents:** | | | | | |
| Cash and money market funds | $ 58,151 | $ — | $ — | $ — | $ 58,151 |
| Total cash and cash equivalents | 58,151 | — | — | — | 58,151 |
| **Investment debt securities:** | | | | | |
| Commercial paper | 55,460 | — | 6 | (9) | 55,457 |
| Corporate debt securities | 355,597 | — | 529 | (67) | 356,059 |
| Total investment debt securities | 411,057 | — | 535 | (76) | 411,516 |
| Total cash, cash equivalents and investment debt securities | $ 469,208 | $ — | $ 535 | $ (76) | $ 469,667 |

**INTERCEPT PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

| | As of December 31, 2019 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| | (in thousands) | | | |
| **Cash and cash equivalents:** | | | | |
| Cash and money market funds | $ 62,557 | $ — | $ — | $ 62,557 |
| Commercial paper | 7,498 | — | — | 7,498 |
| Total cash and cash equivalents | 70,055 | — | — | 70,055 |
| **Investment debt securities:** | | | | |
| Commercial paper | 42,806 | 43 | (1) | 42,848 |
| Corporate debt securities | 538,965 | 835 | (81) | 539,719 |
| Total investment debt securities | 581,771 | 878 | (82) | 582,567 |
| Total cash, cash equivalents and investment debt securities | $ 651,826 | $ 878 | $ (82) | $ 652,622 |

The aggregate fair value for the Company's available-for-sale investment debt securities that have been in an unrealized loss position for less than twelve months or twelve months or longer is as follows:

| | As of December 31, 2020 | | | | | |
|---|---|---|---|---|---|---|
| | Less than 12 months | | 12 months or longer | | Total | |
| | (in thousands) | | | | | |
| | Fair Value | Gross Unrealized Losses | Fair Value | Gross Unrealized Losses | Fair Value | Gross Unrealized Losses |
| Commercial paper | $ 32,970 | $ (9) | $ — | $ — | $ 32,970 | $ (9) |
| Corporate debt securities | 143,076 | (67) | — | — | 143,076 | (67) |
| Total | $ 176,046 | $ (76) | $ — | $ — | $ 176,046 | $ (76) |

| | As of December 31, 2019 | | | | | |
|---|---|---|---|---|---|---|
| | Less than 12 months | | 12 months or longer | | Total | |
| | (in thousands) | | | | | |
| | Fair Value | Gross Unrealized Losses | Fair Value | Gross Unrealized Losses | Fair Value | Gross Unrealized Losses |
| Commercial paper | $ 11,976 | $ (1) | $ — | $ — | $ 11,976 | $ (1) |
| Corporate debt securities | 121,684 | (81) | — | — | 121,684 | (81) |
| Total | $ 133,660 | $ (82) | $ — | $ — | $ 133,660 | $ (82) |

At December 31, 2020, the Company had 66 available-for-sale investment debt securities in an unrealized loss position without an allowance for credit losses. Unrealized losses on corporate debt securities have not been recognized into income because the issuers' bonds are of high credit quality (rated A3/A- or higher), management does not intend to sell and it is likely that management will not be required to sell the securities prior to their anticipated recovery and the decline in fair value is largely due to market conditions and/or changes in interest rates. The issuers continue to make timely interest payments on the bonds. The fair value is expected to recover as the bonds approach maturity.

Accrued interest receivable on available-for-sale investment debt securities totaled $2.5 million at December 31, 2020, is excluded from the estimate of credit losses and is included in Prepaid expenses and other current assets.

**INTERCEPT PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**4. 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. Investment debt securities are classified as Level 2 instruments based on market pricing and other observable inputs.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

| | Total | Fair Value Measurements Using Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| | | (in thousands) | | |
| **December 31, 2020** | | | | |
| **Assets** | | | | |
| Cash and cash equivalents: | | | | |
| Money market funds | $ 15,492 | $ 15,492 | $ — | $ — |
| Available-for-sale investment debt securities: | | | | |
| Commercial paper | 55,457 | — | 55,457 | — |
| Corporate debt securities | 356,059 | — | 356,059 | — |
| Total financial assets | $ 427,008 | $ 15,492 | $ 411,516 | $ — |
| | | | | |
| **December 31, 2019** | | | | |
| **Assets** | | | | |
| Cash and cash equivalents: | | | | |
| Money market funds | $ 19,376 | $ 19,376 | $ — | $ — |
| Commercial paper | 7,498 | — | 7,498 | — |
| Available-for-sale investment debt securities: | | | | |
| Commercial paper | 42,848 | — | 42,848 | — |
| Corporate debt securities | 539,719 | — | 539,719 | — |
| Total financial assets | $ 609,441 | $ 19,376 | $ 590,065 | $ — |

The gross realized gains and losses on sales of available-for-sale investment debt securities were immaterial for the fiscal years ended December 31, 2020, 2019, and 2018.

The aggregate fair value of all available-for-sale investment debt securities (commercial paper and corporate debt securities), by contractual maturity, are as follows:

| | Fair Value as of December 31, 2020 | 2019 |
|---|---|---|
| | (in thousands) | |
| Due in one year or less | $ 328,077 | $ 473,602 |
| Due after one year through two years | 83,439 | 116,463 |
| Total investment debt securities | $ 411,516 | $ 590,065 |

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

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**5. 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) | December 31, 2020 | December 31, 2019 |
|---|---|---|---|
| | | (in thousands) | |
| Office equipment and software | 3 | $ 5,364 | $ 4,386 |
| Leasehold improvements | Shorter of remaining lease term or useful life | 13,237 | 10,489 |
| Furniture and fixtures | 7 | 4,602 | 4,032 |
| Subtotal | | 23,203 | 18,907 |
| Less: accumulated depreciation | | (16,877) | (13,705) |
| Fixed assets, net | | $ 6,326 | $ 5,202 |

Depreciation expense for the years ended December 31, 2020, 2019 and 2018 was approximately $3.1 million, $3.7 million and $4.6 million, respectively.

**6. Inventory**

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

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| | (in thousands) | |
| Work-in-process | $ 8,394 | $ 8,302 |
| Finished goods | 633 | 160 |
| Inventory | $ 9,027 | $ 8,462 |

**7. Leases**

The Company leases various office spaces under non-cancelable operating leases with original lease periods expiring between the first quarter in 2021 and 2025. The Company also enters into leases for equipment. A number of the Company's leases include one or more options to renew, with renewal terms that can extend the lease term. The exercise of lease renewal options is typically at the sole discretion of the Company; therefore, all renewals to extend the lease terms are not included in the ROU assets and lease liabilities as they are not reasonably certain of exercise. The Company regularly evaluates the renewal options and when they are reasonably certain of exercise, includes the renewal period in the lease term. These operating leases do not contain material variable rent payments, residual value guarantees, covenants, or other restrictions.

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Operating lease assets and liabilities are classified on the consolidated balance sheet as follows:

| Leases | Classification | December 31, 2020 | December 31, 2019 |
|---|---|---|---|
| | | (in thousands) | |
| **Assets** | | | |
| Operating lease assets | Other assets | $ 12,327 | $ 13,246 |
| Total leased assets | | $ 12,327 | $ 13,246 |
| | | | |
| **Liabilities** | | | |
| Current | | | |
| Operating lease liabilities | Accounts payable, accrued expenses and other liabilities | $ 7,248 | $ 6,456 |
| Noncurrent | | | |
| Operating lease liabilities | Long-term other liabilities | 7,684 | 9,222 |
| Total operating lease liabilities | | $ 14,932 | $ 15,678 |

Operating lease costs for the years ended December 31, 2020 and 2019, are as follows:

| | | Years Ended December 31, | |
|---|---|---|---|
| Lease Cost | Classification | 2020 | 2019 |
| | | (in thousands) | |
| Operating lease cost | Selling, general and administrative expenses | $ 6,723 | $ 6,176 |
| Short-term lease cost | Selling, general and administrative expenses | 3,688 | 2,203 |
| Variable lease cost | Selling, general and administrative expenses | 1,337 | 829 |
| Sublease income | Other income, net | (125) | (788) |
| Net lease cost | | $ 11,623 | $ 8,420 |

The weighted-average remaining term of the Company's operating leases was 2.8 years and the weighted-average discount rate used to measure the present value of the Company's operating lease liabilities was 5.0% as of December 31, 2020.

Cash payments included in the measurement of the Company's operating lease liabilities reported in operating cash flows were $7.9 million and $7.5 million for the years ended December 31, 2020 and 2019, respectively. During the year ended December 31, 2020, the Company obtained ROU assets of $4.7 million in exchange for new operating lease obligations of $6.1 million.

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Maturities of the Company's operating lease liabilities, which do not include short-term leases, as of December 31, 2020 are as follows:

| Maturity of Lease Liabilities | Operating leases |
|---|---|
| | (in thousands) |
| 2021 | $ 7,875 |
| 2022 | 3,632 |
| 2023 | 2,141 |
| 2024 | 1,612 |
| 2025 | 1,033 |
| Thereafter | — |
| Total lease payments | 16,293 |
| Less: Present value discount | (1,361) |
| Total operating lease liabilities | $ 14,932 |

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

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

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands) | |
| Accounts payable | $ 24,594 | $ 18,975 |
| Accrued employee compensation | 27,154 | 26,483 |
| Accrued contracted services | 62,425 | 74,486 |
| Accrued restructuring | 2,504 | — |
| Accrued rebates, discounts and other incentives | 38,172 | 21,529 |
| Operating lease liabilities | 7,248 | 6,456 |
| Other liabilities | 8,942 | 6,039 |
| Accounts payable, accrued expenses and other liabilities | $ 171,039 | $ 153,968 |

***Research & Development Tax Credit***

The Company has benefited from the U.K. Small and Medium-sized Enterprise R&D Tax Credit scheme, or the SME scheme, under which it can obtain a tax credit of up to 33.4% of eligible research and development expenses incurred by the Company in the U.K. Eligible expenses generally include employment costs for research staff, consumables, software and certain internal overhead costs incurred as part of research projects.

The Company has submitted claims seeking to obtain tax credits for qualifying R&D expenses incurred in the 2015, 2016, and 2017 calendar years. As described further in Note 14, the 2015 and 2016 claim was finalized during the quarter ended June 30, 2020, and therefore the $10.5 million payment received in September 2019, which was previously deferred, was released into income.

With respect to the 2017 claim, in June 2020, the Company received a payment of $9.4 million from Her Majesty's Revenue and Customs ("HMRC"), the U.K.'s government tax authority. Given the claim review has not been finalized for the 2017 year, the $9.4 million credit payment received along with an additional $1.0 million due to foreign currency translation are recorded as a deferred liability within Accounts payable, accrued expenses and other liabilities.

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**9. Long-Term Debt**

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

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands) | |
| 2023 Convertible Notes | $ 460,000 | $ 460,000 |
| 2026 Convertible Notes | 230,000 | 230,000 |
| Long-term debt, gross | 690,000 | 690,000 |
| Less: Unamortized debt discounts and fees | (129,418) | (157,922) |
| Long-term debt, net | $ 560,582 | $ 532,078 |

***2019 Offering***

On May 14, 2019, the Company issued and sold $230.0 million aggregate principal amount of 2.00% Convertible Senior Notes due 2026 (the "2026 Convertible Notes"). The Company received net proceeds from the sale of the 2026 Convertible Notes of $223.4 million, after deducting underwriting discounts, commissions and estimated offering expenses of approximately $6.6 million.

The 2026 Convertible Notes were issued pursuant to a Second Supplemental Indenture, dated as of May 14, 2019 (the "Second Supplemental Indenture"), which supplements the Indenture (the "Base Indenture"), as supplemented by a First Supplemental Indenture (the "First Supplemental Indenture" and collectively with the Base Indenture and the Second Supplemental Indenture, the "Indenture"), each dated as of July 6, 2016, by and between the Company and U.S. Bank National Association, as trustee. The 2026 Convertible Notes are senior unsecured obligations of the Company, bear interest at a fixed rate of 2.00% per annum (payable semi-annually on May 15 and November 15 of each year, beginning on November 15, 2019) and will mature on May 15, 2026, unless earlier repurchased, redeemed or converted. Holders may convert their 2026 Convertible Notes at their option at any time prior to the close of business on the business day immediately preceding February 15, 2026 only under the following circumstances: (i) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ended on June 30, 2019, if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period in which the trading price (as defined in the Indenture) per $1,000 principal amount of 2026 Convertible Notes for each trading day of such five consecutive trading day period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; (iii) if the Company calls any or all of the 2026 Convertible Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (iv) upon the occurrence of specified corporate events. On or after February 15, 2026 until the close of business on the business day immediately preceding the maturity date, holders may convert their 2026 Convertible Notes at any time, regardless of the foregoing circumstances. Upon conversion of the 2026 Convertible Notes, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock (and cash in lieu of any fractional shares) or a combination of cash and shares of the Company's common stock, at the Company's election. The initial conversion rate of the 2026 Convertible Notes is 9.2123 shares of the Company's common stock per $1,000 principal amount of 2026 Convertible Notes, which is equivalent to an initial conversion price of approximately $108.55 per share of the Company's common stock. The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, the Company will increase the conversion rate for a holder who elects to convert its 2026 Convertible Notes in connection with such a corporate event in certain circumstances. The Company may not redeem the 2026 Convertible Notes prior to May 20, 2023. The Company may redeem for cash all or any portion of the 2026 Convertible Notes, at the Company's option, on or after May 20, 2023, if the last reported sale

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price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the 2026 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2026 Convertible Notes. If the Company undergoes a fundamental change (as defined in the Indenture), holders may require the Company to repurchase for cash all or any portion of their 2026 Convertible Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2026 Convertible Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The Indenture provides for customary events of default.

In accordance with ASC 470-20, the Company used an effective interest rate of 9.9% to determine the liability component of the 2026 Convertible Notes. This resulted in the recognition of $137.5 million as the liability component of the 2026 Convertible Notes and the recognition of the residual $85.9 million as the debt discount with a corresponding increase to additional paid-in capital for the equity component of the 2026 Convertible Notes. The underwriting discount and estimated offering expenses totaling $6.6 million were allocated between the debt and equity issuance costs in proportion to the allocation of the liability and equity components of the 2026 Convertible Notes. Accordingly, equity issuance costs of $2.5 million were recorded as an offset to additional paid-in capital and total debt issuance costs of $4.1 million were recorded on the issuance date and are reflected in the consolidated balance sheet as a direct deduction from the carrying value of the associated debt liability. The debt discount and debt issuance costs will be amortized as non-cash interest expense through May 15, 2026.

The fair value of the 2026 Convertible Notes was approximately $142.8 million and $294.9 million at December 31, 2020 and December 31, 2019, respectively, and was determined using Level 2 inputs based on quoted market values.

***2016 Offerings***

On July 6, 2016, the Company issued and sold $460.0 million aggregate principal amount of 3.25% Convertible Senior Notes due 2023 (the "2023 Convertible Notes", and together with the 2026 Convertible Notes, the "Convertible Notes"). The Company received net proceeds from the sale of the 2023 Convertible Notes of $447.6 million, after deducting underwriting discounts, commissions and estimated offering expenses of approximately $12.4 million. The Company used approximately $38.4 million of such net proceeds to fund the cost of the Capped Call Transactions (as defined below) that were entered into in connection with the issuance of the 2023 Convertible Notes.

The 2023 Convertible Notes were issued pursuant to the Base Indenture, as supplemented by the First Supplemental Indenture. The 2023 Convertible Notes are senior unsecured obligations of the Company, bear interest at a fixed rate of 3.25% per year (payable semi-annually on January 1 and July 1 of each year, beginning on January 1, 2017) and will mature on July 1, 2023, unless earlier repurchased, redeemed or converted. Holders may convert their 2023 Convertible Notes at their option at any time prior to the close of business on the business day immediately preceding January 1, 2023 only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ended on September 30, 2016, if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period in which the trading price (as defined in the Indenture) per $1,000 principal amount of 2023 Convertible Notes for each trading day of such five consecutive trading day period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; (iii) if the Company calls any or all of the 2023 Convertible Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (iv) upon the occurrence of specified corporate events. On or after January 1, 2023 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2023 Convertible Notes at any time, regardless of the foregoing circumstances. Upon conversion of the 2023 Convertible Notes,

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the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock (and cash in lieu of any fractional shares) or a combination of cash and shares of the Company's common stock, at the Company's election. The initial conversion rate of the 2023 Convertible Notes is 5.0358 shares of the Company's common stock per $1,000 principal amount of 2023 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 but will not be adjusted for any accrued and unpaid interest. If the Company undergoes a fundamental change (as defined in the Indenture), holders may require the Company to repurchase for cash all or any portion of their 2023 Convertible Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2023 Convertible Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, if certain make-whole fundamental changes occur, the Company will, in certain circumstances, increase the conversion rate for any 2023 Convertible Notes converted in connection with such make-whole fundamental change. The Company may not redeem the 2023 Convertible Notes prior to July 6, 2021. The Company may redeem for cash all or part of the 2023 Convertible Notes, at its option, on or after July 6, 2021, if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the 2023 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. The Indenture provides for customary events of default.

On June 30, 2016, in connection with the pricing of the 2023 Convertible Notes, the Company entered into privately-negotiated capped call transactions (the "Base Capped Call Transactions") with each of Royal Bank of Canada, UBS AG, London Branch, and Credit Suisse Capital LLC (the "Option Counterparties"). On July 1, 2016, in connection with the underwriters' exercise of their over-allotment option in full, the Company entered into additional capped call transactions (the "Additional Capped Call Transactions" and, together with the Base Capped Call Transactions, the "Capped Call Transactions") with the Option Counterparties. The Capped Call Transactions are expected generally to reduce the potential dilution with respect to the Company's common stock and/or offset the cash payments the Company would be required to make in excess of the principal amount of converted 2023 Convertible Notes, as the case may be, upon conversion of the 2023 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 2023 Convertible Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the 2023 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 and/or there would not be an offset of such potential cash payments, in each case, upon conversion of the Convertible Notes to the extent that such market price exceeds the cap price of the Capped Call Transactions. The Capped Call Transactions are considered to be instruments indexed to the Company's own shares and met the criteria to be classified within equity and are therefore not remeasured.

In accordance with ASC 470-20, the Company used an effective interest rate of 8.4% to determine the liability component of the 2023 Convertible Notes. This resulted in the recognition of $334.4 million as the liability component of the 2023 Convertible Notes and the recognition of the residual $113.1 million as the debt discount with a corresponding increase to additional paid-in capital for the equity component of the 2023 Convertible Notes.

The fair value of the 2023 Convertible Notes was approximately $363.7 million and $463.5 million at December 31, 2020 and December 31, 2019, respectively, and was determined using Level 2 inputs based on quoted market values.

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***Interest Expense on Convertible Notes***

The table summarizes the total interest expense recognized in the periods presented:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Contractual interest expense | $ 19,550 | $ 17,825 | $ 14,950 |
| Amortization of debt discount | 25,964 | 21,189 | 14,032 |
| Amortization of debt issuance costs | 2,540 | 2,130 | 1,541 |
| Total interest expense | $ 48,054 | $ 41,144 | $ 30,523 |

Accrued interest on the Convertible Notes was approximately $8.1 million and $8.1 million as of December 31, 2020 and 2019, respectively. The Company recorded debt issuance costs of $19.0 million, which are being amortized using the effective interest method. As of December 31, 2020, and 2019, $10.7 million and $13.2 million, respectively, of debt issuance costs are recorded on the consolidated balance sheets in Long-term debt. Cash payments for interest were $19.6 million and $17.3 million for the years ended December 31, 2020 and 2019, respectively.

**10. Stockholders' Equity and Preferred Stock**

***Increase in Authorized Shares of Common Stock***

On May 28, 2020, at the 2020 Annual Meeting of Stockholders, the Company obtained approval from its stockholders to increase the number of authorized shares of the Company's common stock, par value $0.001, from 45,000,000 shares to 90,000,000 shares. The increase in the authorized shares of common stock was effectuated pursuant to a Certificate of Amendment to the Company's restated certificate of incorporation, filed with the Secretary of the State of Delaware on May 28, 2020.

***2019 Public Offering and Concurrent Private Placement***

On May 14, 2019, the Company issued and sold (i) 2,760,000 shares of common stock in a registered public offering (including 360,000 shares issued and sold upon the exercise in full of the underwriters' option to purchase additional shares), at a price to the public of $83.50 per share (the "2019 Public Offering") and (ii) 119,760 shares of common stock (the "2019 Private Placement Shares") in a concurrent private placement of common stock (the "2019 Concurrent Private Placement") exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), at a purchase price per share equivalent to the price to the public set in the 2019 Public Offering and pursuant to a securities purchase agreement (the "2019 Securities Purchase Agreement") that the Company entered into with Samsara BioCapital, L.P. ("Samsara"), one of the Company's existing stockholders. Pursuant to the 2019 Securities Purchase Agreement, the Company granted to Samsara certain registration rights requiring the Company, upon request of Samsara on or after July 9, 2019 and subject to certain terms and conditions, to register the resale by Samsara of its 2019 Private Placement Shares. Such registration rights have since expired.

*Common Stock*

As of December 31, 2020 and 2019, the Company had 90,000,000 and 45,000,000 authorized shares of common stock, par value $0.001 per share, respectively.

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*Dividends*

Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the Company's board of directors out of funds legally available for dividend payments. The Company has never declared or paid any cash dividends on its common stock, and does not anticipate paying any cash dividends on its common stock in the foreseeable future. The Company intends to retain all available funds and any future earnings to fund the development and expansion of its business. Any future determination to pay dividends will be at the discretion of the board of directors and will depend upon a number of factors, including the results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the board of directors deems relevant.

*Voting*

Holders of common stock are entitled to one vote for each share held with respect to all matters submitted to a vote of the stockholders and do not have cumulative voting rights.

***Preferred Stock***

As of December 31, 2020 and 2019, the Company had 5,000,000 authorized shares of preferred stock, par value $0.001 per share, of which none are issued.

**11. Product Revenue, Net**

The Company recognized net sales of Ocaliva of $312.7 million, $249.6 million and $177.8 million for the years ended December 31, 2020, 2019 and 2018, respectively.

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Product revenue, net: | | | |
| U.S. | $ 233,970 | $ 187,436 | $ 140,822 |
| ex-U.S. | 78,720 | 62,134 | 36,960 |
| Total product revenue, net | $ 312,690 | $ 249,570 | $ 177,782 |

**12. License Agreement**

***Sumitomo Dainippon Pharma Co., Ltd.***

In March 2011, the Company entered into an exclusive license agreement (the "Sumitomo Agreement") with Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon"), pursuant to which the Company granted to Sumitomo Dainippon an exclusive license to research, develop and commercialize OCA for the treatment of PBC and NASH in Japan and China (excluding Taiwan) and an option to research, develop and commercialize OCA in certain countries outside of such territories (the "Country Option"). The Company received an upfront payment from Sumitomo Dainippon of $15.0 million under the terms of the Sumitomo Agreement. In October 2019, the Company and Sumitomo Dainippon mutually agreed to terminate with immediate effect the Sumitomo Agreement. In connection with the termination of the Sumitomo Agreement, Sumitomo Dainippon agreed to return to the Company the rights to develop and commercialize OCA in China and the Company agreed to forego any further milestone or royalty payments relating to the development and

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commercialization of OCA in China. No payment was due from the Company to Sumitomo Dainippon as a result of the termination of the Sumitomo Agreement.

The Company recognized licensing revenue of approximately $0, $2.4 million and $2.0 million for the years ended December 31, 2020, 2019, and 2018, respectively, under the Sumitomo Agreement.

**13. Stock Compensation**

The Company's 2012 Equity Incentive Plan ("2012 Plan") became effective upon the pricing of its initial public offering in October 2012 (the "IPO"). At the same time, the Company's 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, 2020, the number of shares available for issuance under the 2012 Plan increased by 1,211,533 as a result of the automatic increase provisions thereof.

The estimated fair value of the stock options granted in the year ended December 31, 2020 was determined utilizing a Black-Scholes option-pricing model at the date of grant. The fair value of the RSUs granted in the year ended December 31, 2020 was determined utilizing the closing price of the Company's common stock on the date of grant. The fair value of the performance restricted stock units ("PRSUs") granted in the year ended December 31, 2020 was determined utilizing the Monte Carlo simulation method. The Company accounts for all forfeitures when they occur. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest and are not forfeited.

The Company has in the past, and may in the future, grant performance-based awards with vesting terms based on the achievement of specified goals. To the extent such awards do not contain a market condition, the Company recognizes no expense until achievement of the performance requirement is deemed probable. There are no option awards with performance conditions outstanding as of December 31, 2020.

There were approximately 3.3 million and 2.8 million shares available for grant remaining under the 2012 Plan at December 31, 2020 and 2019, respectively.

***Stock Options and Performance-Based Stock Options***

The Company's outstanding option activity for the period from December 31, 2019 through December 31, 2020 is summarized as follows:

| | Number of Options (in thousands) | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Outstanding at December 31, 2019 | 1,981 | $ 99.87 | 7.4 | $ 65,662 |
| Granted | 727 | $ 90.03 | — | $ — |
| Exercised | (22) | $ 52.20 | — | $ — |
| Cancelled/forfeited | (368) | $ 91.18 | — | $ — |
| Expired | (119) | $ 130.35 | — | $ — |
| Outstanding at December 31, 2020 | 2,199 | $ 96.92 | 6.9 | $ 146 |
| Expected to vest | 779 | $ 86.35 | 8.3 | $ — |
| Exercisable | 1,420 | $ 102.73 | 6.1 | $ 146 |

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the deemed fair value of the Company's common stock for those options that had exercise prices lower than

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the deemed fair value of the Company's common stock. The weighted-average grant date fair value of options granted in the years ended December 31, 2020, 2019 and 2018 was $52.48, $74.78 and $41.18 per option, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2020, 2019 and 2018 was $0.9 million, $10.2 million and $14.1 million, respectively. As of December 31, 2020, the total compensation cost related to non-vested option awards not yet recognized is approximately $34.1 million with a weighted average remaining vesting period of 1.20 years.

The Company estimated the fair value of stock options granted in the periods presented utilizing a Black-Scholes option-pricing model utilizing the following assumptions:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Volatility | 61.9 - 87.1 % | 86.9 - 89.9 % | 62 - 73 % |
| Expected term (in years) | 5.5 - 6.0 | 5.5 - 6.0 | 6.0 |
| Risk-free rate | 0.2 - 1.7 % | 1.4 - 2.9 % | 1.8 - 3.0 % |
| Expected dividend yield | — % | — % | — % |

In April 2014, the Company issued 57,063 performance-based options to certain employees that will vest upon the achievement of certain regulatory milestones related to OCA at future dates. In November 2014, the Company issued an additional 10,839 performance-based options that will vest upon the achievement of the same regulatory milestones. As of December 31, 2020, the achievement of such milestones was not met and these performance-based options were cancelled.

***Restricted Stock Units and Awards & Performance-Based Restricted Stock Units and Awards***

The following table summarizes the aggregate RSU, RSA, PRSU and performance restricted share award ("PRSA") activity for the year ended December 31, 2020:

| | Number of Awards (in thousands) | Weighted Average Grant Date Fair Value |
|---|---|---|
| Non-vested awards at December 31, 2019 | 709 | $ 88.39 |
| Granted | 725 | $ 74.68 |
| Vested | (374) | $ 85.06 |
| Forfeited | (261) | $ 89.37 |
| Non-vested awards at December 31, 2020 | 799 | $ 72.43 |

For the years ended December 31, 2020, 2019 and 2018, the weighted-average grant date fair value of RSUs, RSAs, PRSUs and PRSAs granted was $74.68, $107.29 and $65.28, respectively. The total fair value of RSUs, RSAs, PRSUs and PRSAs that vested during the years ended December 31, 2020, 2019 and 2018 was $30.7 million, $29.8 million and $24.0 million, respectively. As of December 31, 2020, there was $45.5 million of unrecognized compensation expense related to unvested RSUs, RSAs, PRSUs, and PRSAs, which is expected to be recognized over a weighted average period of 1.31 years.

During the years ended December 31, 2020, 2019 and 2018, the Company granted a total of 64,900, 57,800 and 51,200 PRSUs to certain of the Company's executive officers. During the year ended December 31, 2018, the Company granted a total of 4,300 PRSAs to certain of the Company's executive officers. The performance criterion for such PRSUs and PRSAs is based on the Total Shareholder Return ("TSR") of the Company's common stock relative to the TSR of the companies comprising the S&P Biotechnology Select Industry Index (the "TSR Peer Group") over a 3-year performance period and is accounted for as a market condition under ASC 718. The TSR for the Company or a member of the TSR

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Peer Group is calculated by dividing (a) the difference of the ending average stock price minus the beginning average stock price by (b) the beginning average stock price. The beginning average stock price equals the average closing stock price over the one calendar month period prior to the beginning of the performance period, after adjusting for dividends, as applicable. The ending average stock price equals the average closing price over the one calendar month period ending on the last day of the performance period, after adjusting for dividends, as applicable. The Company's relative TSR is then used to calculate the payout percentage, which may range from zero percent (0%) to one hundred and fifty percent (150%) of the target award. The Company utilized a Monte Carlo Simulation to determine the grant date fair value of such PRSUs and PRSAs. The Company recorded approximately $8.0 million (of which $2.9 million related to modifications), $4.0 million and $1.3 of stock-based compensation related to such PRSUs and PRSAs during the years ended December 31, 2020, 2019 and 2018, respectively.

Stock-based compensation expense has been reported in the Company's statements of operations as follows:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Selling, general and administrative | $ 45,985 | $ 43,170 | $ 38,361 |
| Research and development | 12,824 | 12,812 | 11,553 |
| Restructuring | 2,041 | — | — |
| Total stock-based compensation | $ 60,850 | $ 55,982 | $ 49,914 |

**14. Research and Development Tax Credit**

The Company has benefited from the U.K. Small and Medium-sized Enterprise R&D Tax Credit scheme, or the SME scheme, under which it can obtain a tax credit of up to 33.4% of eligible research and development expenses incurred by the Company in the U.K. Eligible expenses generally include employment costs for research staff, consumables, software and certain internal overhead costs incurred as part of research projects.

The Company submitted a claim seeking to obtain tax credits for qualifying R&D expenses incurred in the years ended December 31, 2015 and 2016. In September 2019, the Company received a partial payment of $10.5 million from HMRC. In April 2020, the Company received the remaining payment for the 2015 and 2016 claim years of $11.3 million.

The claim for 2015 and 2016 was finalized and approved in the quarter ended June 30, 2020, at which time the Company recorded the U.K. research and development tax credit payments received of $22.0 million as a reduction of research and development expense in the consolidated statements of operations.

**15. Employee Benefit Plans**

The Company maintains a defined contribution plan, which is qualified under section 401(k) of the Internal Revenue Code for U.S. employees. Employees may make contributions by withholding a percentage of their salary up to the Internal Revenue Service annual limit of $19,500 and $26,000 in 2020 for employees under 50 years old and employees 50 years old or over, respectively. The Company's matching contribution vests over four years from the start of employment. The Company made approximately $2.2 million, $1.4 million and $1.9 million in matching contributions for the years ended December 31, 2020, 2019 and 2018, respectively.

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**16. Restructuring Expenses**

On August 31, 2020, the Company adopted a plan to reduce its workforce in light of the previously announced receipt of a complete response letter from the U.S. Food and Drug Administration (the "FDA") with respect to its New Drug Application for OCA for the treatment of liver fibrosis due to NASH (the "2020 Workforce Plan"). The 2020 Workforce Plan sought to streamline the Company's operations and reduce operating expenses, while maintaining the critical resources needed to continue to support the NASH and PBC clinical programs, pursue the approval of OCA for the treatment of liver fibrosis due to NASH and support the Company's successful PBC business. The 2020 Workforce Plan resulted in a workforce reduction of approximately 25%, or approximately 170 employees. The 2020 Workforce Plan was implemented during the third quarter of 2020, immediately after its announcement, was substantially completed by the end of 2020 with expected completion by the end of 2021 upon payments of cash for charges incurred under the 2020 Workforce Plan. In the year ended December 31, 2020 the Company recorded restructuring charges of $14.6 million, which were primarily related to severance costs and other related termination benefits incurred in conjunction with the 2020 Workforce Plan.

The following table reflects total expenses related to restructuring activities recognized within the Consolidated Statements of Operations as restructuring costs:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | (in thousands) | | |
| Employee compensation costs | $ 12,589 | $ — | $ — |
| Equity compensation costs | 2,041 | — | — |
| Total restructuring costs | $ 14,630 | $ — | $ — |

The Company recorded $2.0 million in non-cash stock-based compensation expense in association with the acceleration of the vesting of certain options and RSUs held by terminated employees.

The following table displays a rollforward of the changes to the accrued balances as of December 31, 2020:

| | Severance and Related Costs |
|---|---|
| | (in thousands) |
| Accrued balance at December 31, 2019 | $ — |
| Charges incurred | 13,544 |
| Cash payments made | (10,068) |
| Other reserve adjustments | (972) |
| Accrued balance at December 31, 2020 | $ 2,504 |

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## 17. Income Taxes

The components of loss before income taxes for the years ended December 31, 2020, 2019 and 2018 includes the following:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| United States | $ (126,351) | $ (95,708) | $ (72,655) |
| Foreign | (148,529) | (248,973) | (236,587) |
| Total | $ (274,880) | $ (344,681) | $ (309,242) |

Income tax expense (benefit) differed from the amounts computed by applying the statutory U.S. Federal income tax rate of 21% to loss before income taxes as a result of the following:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Computed "expected" tax benefit | $ (57,725) | $ (72,383) | $ (64,941) |
| State taxes, net of U.S. Federal benefit | — | — | — |
| U.S. Federal tax credits | (5,787) | — | — |
| U.S. Federal valuation allowance | 26,279 | 14,786 | 9,352 |
| Stock-based compensation | 8,098 | 4,609 | 6,423 |
| Officer compensation | 437 | 508 | 22 |
| Foreign valuation allowance | 43,414 | 19,349 | 44,896 |
| Foreign tax rate differences | (12,223) | 32,936 | 4,787 |
| Other | (2,493) | 195 | (539) |
| Total | $ — | $ — | $ — |

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The tax effects of temporary differences that give rise to the deferred tax assets and liabilities at December 31, 2020 and 2019 are presented below:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands) | |
| Deferred tax assets: | | |
| U.S. and state net operating loss and other carryforwards | $ 178,007 | $ 160,079 |
| Foreign net operating loss and other carryforwards | 239,607 | 195,590 |
| Stock compensation | 15,675 | 13,626 |
| Accrued compensation | 5,042 | 4,997 |
| Accrued expense | 11,143 | 1,750 |
| Intangible property | 1,945 | 2,088 |
| Interest limitation | 9,419 | 5,183 |
| Other | 1,749 | 1,406 |
| Deferred tax assets before valuation allowance | 462,587 | 384,719 |
| Valuation allowance | (436,476) | (353,677) |
| Total deferred tax assets | 26,111 | 31,042 |
| Deferred tax liabilities: | | |
| Convertible Notes | (26,111) | (31,042) |
| Total deferred tax liabilities | (26,111) | (31,042) |
| Net deferred tax asset (liability) | $ — | $ — |

***Effects of the Coronavirus Aid, Relief and Economic Security Act***

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). The CARES Act, among other things, made changes to NOLS rules, including the allowance of a five-year carryback period for NOLs arising in tax years beginning after December 31, 2017 and before January 1, 2021 and removed the 80% taxable income limitation for NOL deductions for tax years beginning before January 1, 2021. The enactment of the CARES Act did not result in any material adjustments to the Company's provision for income taxes.

***Net Operating Loss and other carryforwards***

As of December 31, 2020, and 2019, the Company had net operating loss carryforwards ("NOLs") for U.S. Federal income tax purposes of $709.4 million and $693.3 million, respectively, and other carryforwards of $13.7 million and $0.5 million, respectively. The enactment of the Tax Cuts and Jobs Act ("TCJA") modified the ability of companies to utilize NOLs arising in tax years beginning on or after January 1, 2018 by providing that such NOLs may be carried-forward indefinitely and used to offset up to 80 percent of taxable income in any given future year. Existing NOLs that arose in tax years beginning prior to January 1, 2018 were not affected by the TCJA and are generally eligible to be carried-forward for up to 20 years and used to fully offset taxable income in future years. If not utilized, the Company's pre-2018 NOLs and other carryforwards will expire for U.S. Federal income tax purposes between 2024 and 2037. The Company also has certain state NOLs in varying amounts depending on the different state tax laws.

As of December 31, 2020, and 2019, the Company had NOLs for foreign income tax purposes of $1.2 billion and $1.1 billion, respectively. Of our $1.2 billion of foreign tax loss carryforwards, approximately $1.1 billion may be carried forward indefinitely and the remainder will expire during the next 17 years.

In addition, the Company's ability to utilize its NOLs may be limited under Section 382 of the Internal Revenue Code or applicable state and foreign tax law. 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). The Company has evaluated whether one or more ownership changes under Section 382 have occurred since its inception and has determined that there have been at least two such changes. Although the Company believes that these ownership changes have not resulted in material limitations on its ability to use these NOLs, its ability to utilize these NOLs may be limited due to future ownership changes or for other reasons. As a result, the Company may not be able to take full advantage of its carryforwards for U.S. Federal, state, and foreign tax purposes.

***Valuation Allowance***

At December 31, 2020 and 2019, the Company maintained a full valuation allowance on its deferred tax assets since it has not yet achieved sustained profitable operations. As a result, the Company has not recorded any income tax benefit since its inception. In 2020, the valuation allowance for deferred tax assets increased by approximately $82.8 million. This includes an increase of $26.3 million, $4.4 million and $43.4 million for U.S. Federal, state and foreign tax, respectively, and an increase of $8.7 million to equity. The increase in equity primarily relates to the foreign currency translation. In 2019, the valuation allowance for deferred tax assets increased by approximately $14.8 million. This includes an increase of $14.8 million, $2.6 million and $19.3 million for U.S. Federal, state and foreign tax, respectively, partially offset by a decrease of $21.9 million to equity. The decrease to equity primarily related to the U.S. Federal and state impact of the equity component associated with the 2026 Convertible Notes.

***Unrecognized Tax Benefits***

At December 31, 2020 and 2019, the Company had no reserves for unrecognized tax benefits.

The Company and its subsidiaries are subject to taxation in the United States and various foreign jurisdictions. Of the major jurisdictions, the Company is subject to U.S. Federal and state examinations for 2017 and forward, and 2016 and forward, respectively, and examinations in the United Kingdom for 2017 and forward. However, NOLs are subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin.

**18. Net Loss Per Share**

Basic loss per share is computed by dividing net loss attributable to common stockholders (numerator) by the weighted average number of common shares outstanding (denominator) during the period. For the years ended December 31, 2020, 2019 and 2018, as the Company was in a net loss position, the diluted loss per share computations for such periods did not assume the exercise of stock options or vesting of RSUs, or the conversion of Convertible Notes as they would have had an anti-dilutive effect on loss per share.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2020, 2019 and 2018 as the inclusion thereof would have been anti-dilutive:

| | December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Shares issuable upon conversion of Convertible Notes | 4,435 | 4,435 | 2,316 |
| Options | 2,395 | 1,981 | 1,874 |
| Unvested restricted stock units | 902 | 556 | 441 |
| Total | 7,732 | 6,972 | 4,631 |

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## 19. Commitments and Contingencies

***Facility Leases***

In January 2016, Intercept Pharma Europe Ltd. ("IPEL"), a wholly owned subsidiary of the Company, entered into an underlease (sublease) with respect to office space in London, United Kingdom. The Company is the guarantor to the underlease (sublease). IPEL leases approximately 8,600 square feet. The lease covering this property is scheduled to expire in May 2024.

In November 2019, the Company entered into an amendment to the lease agreement with respect to office space at 10 Hudson Yards in New York, New York, where the Company's corporate headquarters are located. The Company leases an aggregate of approximately 45,600 square feet of office space at this property. The lease covering this property is scheduled to expire in March 2022.

In October 2019, the Company entered into a lease agreement with respect to office space in San Diego, California. The Company leases approximately 34,000 square feet. The lease covering this property is scheduled to expire in October 2025.

The Company also leases office space in several other locations.

***Licenses***

The Company acquired a license from a third party to support the portfolio of product candidates. Under the license agreement with Aralez Pharmaceuticals Canada Inc. ("Aralez") the Company has rights to develop and commercialize bezafibrate in the United States. The Company may pay up to $4.5 million upon the achievement of certain milestones, none of which is owed as of December 31, 2020. The Company is obligated to pay royalties to at a mid-single digit percentage of net product sales.

***Legal Proceedings***

The Company is involved in various disputes, legal proceedings and litigation in the course of its business, including the matters described below and, from time to time, governmental inquiries and investigations and employment and other litigation. These matters, which could result in damages, fines or other administrative, civil or criminal remedies, liabilities or penalties, are often complex and the outcome of such matters is often uncertain. The Company may from time to time enter into settlements to resolve such matters.

***Shareholder Litigation***

On September 27, 2017, a purported shareholder class action, initially styled *DeSmet v. Intercept Pharmaceuticals, Inc., et al.*, was filed in the United States District Court for the Southern District of New York, naming the Company and certain of its officers as defendants. The Court appointed lead plaintiffs in the lawsuit on June 1, 2018, and the lead plaintiffs filed an amended complaint on July 31, 2018, captioned Hou Liu and Amy Fu v. Intercept Pharmaceuticals, Inc., et al., naming the Company and certain of its current and former officers as defendants. The lead plaintiffs claim to be suing on behalf of anyone who purchased or otherwise acquired the Company's common stock between June 9, 2016 and September 20, 2017. This lawsuit alleges that material misrepresentations and/or omissions of material fact were made in the Company's public disclosures during the period from June 9, 2016 to September 20, 2017, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to statements regarding Ocaliva dosing, use and pharmacovigilance-related matters, as well as the Company's operations, financial performance and prospects. The plaintiffs seek unspecified monetary damages on behalf of the putative class, an award of costs and expenses, including attorney's fees, and rescissory

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damages. On September 14, 2018, the Company filed a motion to dismiss the amended complaint. On March 26, 2020, the Court granted the Company's motion to dismiss the amended complaint in its entirety, and on March 27, 2020 the Court entered judgment in favor of the Company. On May 8, 2020, the plaintiffs filed a motion to set aside the judgment and grant leave to file a second amended complaint. On September 9, 2020, the Court denied the plaintiffs' motion to set aside the judgment and grant leave to file a second amended complaint, finding that the proposed second amended complaint did not cure the deficiencies identified in the amended complaint. On October 9, 2020, the plaintiffs filed a notice of appeal to the United States Court of Appeals for the Second Circuit and on January 25, 2021, the plaintiffs filed an appellate brief challenging the March 27, 2020 judgment, the September 9, 2020 judgment and other orders entered in this action.

Separately, on December 1, 2017, a purported shareholder demand was made on the Company based on substantially the same allegations as those set forth in the securities case above. In addition, on January 5, 2018, a follow-on derivative suit, styled *Davis v. Pruzanski, et al.*, was filed in New York state court by shareholder Gregg Davis based on substantially the same allegations as those set forth in the securities case above.

On November 5, 2020, a purported shareholder class action, styled *Chauhan v. Intercept Pharmaceuticals, Inc., et al.*, was filed in the United States District Court for the Eastern District of New York, naming the Company and certain of its officers as defendants. The lawsuit was transferred to the United States District Court for the Southern District of New York on January 4, 2021. The plaintiff claims to be suing on behalf of anyone who purchased or otherwise acquired the Company's securities between September 28, 2019 and October 7, 2020. This lawsuit alleges that material misrepresentations and/or omissions of material fact were made in the Company's public disclosures during the period from September 28, 2019 to October 7, 2020, in violation of Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to statements regarding the Company's New Drug Application for OCA for the treatment of liver fibrosis due to NASH and the use of Ocaliva in patients with PBC, as well as the Company's operations, financial performance and prospects. The plaintiff seeks unspecified monetary damages on behalf of the putative class, and an award of costs and expenses, including attorney's fees.

Separately, on December 29, 2020, a follow-on derivative suit, styled *Rabinovich v. Fundarò, et al.*, was filed in the United States District Court for the Southern District of New York by shareholder Delfin Rabinovich based on substantially the same allegations as those set forth in the securities case immediately above. This lawsuit was subsequently transferred to the United States District Court for the District of Delaware on January 28, 2021. On February 1, 2021, a second follow-on derivative suit, styled *Fung v. Fundarò, et al.*, was filed in the United States District Court for the District of Delaware based on the substantially same allegations as those set forth in the securities case immediately above and the *Rabinovich* derivative action.

While the Company believes that it has a number of valid defenses to the claims described above and intends to vigorously defend itself, the matters are in the early stages of litigation and no assessment can be made as to the likely outcome of the matters or whether they will be material to the Company. Accordingly, an estimate of the potential loss, or range of loss, if any, to the Company relating to the matters is not possible at this time.

***Patent Litigation***

The Company has received paragraph IV certification notice letters from six generic drug manufacturers indicating that each such manufacturer has submitted to the FDA an Abbreviated New Drug Application ("ANDA") seeking approval to manufacture and sell a generic version of the Company's 5 mg and 10 mg dosage strengths of Ocaliva® (obeticholic acid) for PBC prior to the expiration of certain patents protecting Ocaliva.

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*Apotex Abbreviated New Drug Application*

In July 2020, the Company received a paragraph IV certification notice (the "Apotex PIV Notice") from Apotex Inc. ("Apotex") indicating that Apotex has submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of the Company's 5 mg and 10 mg dosage strengths of Ocaliva® (obeticholic acid) for PBC prior to the expiration of the Company's U.S. Patents Nos. 9,238,673 (the "'673 Patent"), 10,047,117 (the "'117 Patent"), 10,052,337 (the "'337 Patent"), and 10,174,073 (the "'073 Patent", and collectively with the '673 Patent, '117 Patent and '337 Patent, the "Apotex Challenged Patents"), which are listed for Ocaliva in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (referred to as the "Orange Book"). The Apotex PIV Notice alleges that the Apotex Challenged Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic products described in Apotex's ANDA. Apotex did not make a paragraph IV certification against the Company's U.S. Patents Nos. 7,138,390 (the "'390 Patent"), 8,058,267 (the "'267 Patent") or 8,377,916 the ("'916 Patent"), which are also listed for Ocaliva in the Orange Book. The Company initiated a patent infringement suit against Apotex in the United States District Court for the District of Delaware within 45 days of receipt of the Apotex PIV Notice. As a result, under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), the FDA cannot grant final approval to Apotex's ANDA before November 27, 2023 or a court decision in Apotex's favor, whichever is earlier. Recently, the U.S. Patent and Trademark Office (the "USPTO") awarded the Company two additional Orange Book-listable patents that protect Ocaliva: U.S. Patents Nos. 10,751,349 (the "'349 Patent") and 10,758,549 (the "'549 Patent"). In September and October 2020, the Company received additional amended paragraph IV certification notices from Apotex challenging the '349 Patent and the '549 Patent, respectively. The Company amended its complaint against Apotex in November 2020 to add infringement allegations for the '549 Patent. In January 2021, the Company received a further paragraph IV certification notice from Apotex challenging a reissue patent, U.S. Patent No. RE48,286 (the "'286 Patent"), as described below. The Company is evaluating its legal options, including asserting the '286 Patent against Apotex.

*Lupin Abbreviated New Drug Application*

In July 2020, the Company received a paragraph IV certification notice (the "Lupin PIV Notice") from Lupin Limited ("Lupin") indicating that Lupin has submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of the Company's 5 mg and 10 mg dosage strengths of Ocaliva® (obeticholic acid) for PBC prior to the expiration of the '390 Patent, the '673 Patent, the '117 Patent, the '337 Patent and the '073 Patent (collectively, the "Lupin Challenged Patents"), which are listed for Ocaliva in the FDA's Orange Book. The Lupin PIV Notice alleges that the Lupin Challenged Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic products described in Lupin's ANDA. Lupin did not make a paragraph IV certification against the '267 Patent or the '916 Patent, which are also listed for Ocaliva in the Orange Book. The Company initiated a patent infringement suit against Lupin in the United States District Court for the District of Delaware within 45 days of receipt of the Lupin PIV Notice. As a result, under the Hatch-Waxman Act, the FDA cannot grant final approval to Lupin's ANDA before November 27, 2023 or a court decision in Lupin's favor, whichever is earlier. In September 2020, the Company received an additional amended paragraph IV certification notice from Lupin challenging the '349 Patent and the '549 Patent. The Company amended its complaint against Lupin in November 2020 to add infringement allegations for the '549 Patent and to substitute the '286 Patent for the '390 Patent.

*Amneal Abbreviated New Drug Application*

In July 2020, the Company received a paragraph IV certification notice (the "Amneal PIV Notice") from Amneal Pharmaceuticals of New York, LLC, as U.S. agent for Amneal EU Limited ("Amneal"), indicating that Amneal has submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of the Company's 5 mg and 10 mg dosage strengths of Ocaliva® (obeticholic acid) for PBC prior to the expiration of the '673 Patent, the '117 Patent, the '337 Patent and the '073 Patent (collectively, the "Amneal Challenged Patents"), which are listed for Ocaliva in the FDA's Orange Book. The Amneal PIV Notice alleges that the Amneal Challenged Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic products described in Amneal's

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ANDA. Amneal did not make a paragraph IV certification against the ‘390 Patent, the ‘267 Patent or the ‘916 Patent, which are also listed for Ocaliva in the Orange Book. The Company initiated a patent infringement suit against Amneal in the United States District Court for the District of Delaware within 45 days of receipt of the Amneal PIV Notice. As a result, under the Hatch-Waxman Act, the FDA cannot grant final approval to Amneal’s ANDA before November 27, 2023 or a court decision in Amneal’s favor, whichever is earlier. In October 2020, the Company received an additional amended paragraph IV certification notice from Amneal challenging the ‘349 Patent and the ‘549 Patent. The Company amended its complaint against Amneal in November 2020 to add infringement allegations for the ‘349 Patent and the ‘549 Patent.

*Optimus Abbreviated New Drug Application*

In July 2020, the Company received a paragraph IV certification notice (the “Optimus PIV Notice”) from Optimus Pharma Pvt Ltd (“Optimus”) indicating that Optimus has submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of the Company’s 5 mg and 10 mg dosage strengths of Ocaliva® (obeticholic acid) for PBC prior to the expiration of the ‘390 Patent, the ‘673 Patent, the ‘117 Patent, the ‘337 Patent and the ‘073 Patent (collectively, the “Optimus Challenged Patents”) which are listed for Ocaliva in the FDA’s Orange Book. The Optimus PIV Notice alleges that the Optimus Challenged Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic products described in Optimus’s ANDA. Optimus did not make a paragraph IV certification against the ‘267 Patent or the ‘916 Patent, which are also listed for Ocaliva in the Orange Book. The Company initiated a patent infringement suit against Optimus in the United States District Court for the District of Delaware within 45 days of receipt of the Optimus PIV Notice. As a result, under the Hatch-Waxman Act, the FDA cannot grant final approval to Optimus’s ANDA before November 27, 2023 or a court decision in Optimus’s favor, whichever is earlier. In October 2020, the Company received an additional amended paragraph IV certification notice from Optimus challenging the ‘349 Patent and the ‘549 Patent. The Company amended its complaint against Optimus in November 2020 to add infringement allegations for the ‘549 Patent and to substitute the ‘286 Patent for the ‘390 Patent.

*MSN Abbreviated New Drug Application*

In July 2020, the Company received a paragraph IV certification notice (the “MSN PIV Notice”) from MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (collectively, “MSN”) indicating that MSN has submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of the Company’s 5 mg and 10 mg dosage strengths of Ocaliva® (obeticholic acid) for PBC prior to the expiration of the ‘390 Patent, the ‘673 Patent, the ‘117 Patent, the ‘337 Patent and the ‘073 Patent (collectively, the “MSN Challenged Patents”) which are listed for Ocaliva in the FDA’s Orange Book. The MSN PIV Notice alleges that the MSN Challenged Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic products described in MSN’s ANDA. MSN did not make a paragraph IV certification against the ‘267 Patent or the ‘916 Patent, which are also listed for Ocaliva in the Orange Book. The Company initiated a patent infringement suit against MSN in the United States District Court for the District of Delaware within 45 days of receipt of the MSN PIV Notice. As a result, under the Hatch-Waxman Act, the FDA cannot grant final approval to MSN’s ANDA before November 27, 2023 or a court decision in MSN’s favor, whichever is earlier. In November 2020, the Company received an additional paragraph IV certification notice from MSN challenging the ‘349 Patent, the ‘549 Patent, and the ‘286 Patent. The Company amended its complaint against MSN in November 2020 to add infringement allegations for the ‘549 Patent and to substitute the ‘286 Patent for the ‘390 Patent.

*DRL Abbreviated New Drug Application*

In December 2020, the Company received a paragraph IV certification notice (the “DRL PIV Notice”) from Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd. (collectively, “DRL”) indicating that DRL has submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of the Company’s 5 mg and 10 mg dosage strengths of Ocaliva® (obeticholic acid) for PBC prior to the expiration of the ‘286 Patent, the ‘390 Patent, the ‘673 Patent, the ‘117 Patent, the ‘337 Patent, the ‘073 Patent, the ‘349 Patent and the ‘549 Patent (collectively, the “DRL Challenged Patents”) which are listed for Ocaliva in the FDA’s Orange Book. The DRL PIV Notice alleges that the DRL

**INTERCEPT PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Challenged Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic products described in DRL's ANDA. DRL did not make a paragraph IV certification against the '267 Patent or the '916 Patent, which are also listed for Ocaliva in the Orange Book. The Company initiated a patent infringement suit against DRL in the United States District Court for the District of Delaware within 45 days of receipt of the DRL PIV Notice. As a result, under the Hatch-Waxman Act, the FDA cannot grant final approval to DRL's ANDA before November 27, 2023 or a court decision in DRL's favor, whichever is earlier.

In October 2020, the USPTO granted to the Company a reissue patent, '286 Patent. By operation of law, the '390 Patent was withdrawn and replaced by the '286 Patent, which contains composition of matter claims to OCA and has the same term as the '390 Patent. In November 2020, the Company was informed by the USPTO that its petition for a five-year patent term extension of the '286 Patent had been granted and that the '286 Patent will now expire in 2027. The '286 Patent has been listed in the Orange Book.

These proceedings are costly and time consuming. Successful challenges to the Company's patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use the Company's proprietary technologies without a license from the Company or its collaborators. While the Company intends to vigorously defend and enforce its intellectual property rights protecting Ocaliva, the Company can offer no assurance as to when the lawsuits will be decided, whether the lawsuits will be successful, or that a generic equivalent of Ocaliva will not be approved and enter the market before the expiration of the Company's patents.

**20. Quarterly Financial Data (unaudited)**

The following table summarizes the unaudited quarterly financial data for the years ended December 31, 2020 and 2019:

| | Quarters Ended | | | | |
|---|---|---|---|---|---|
| | March 31, | June 30, | September 30, | December 31, | Total |
| | (in thousands, except for per share amounts) | | | | |
| **2020** | | | | | |
| Total revenue | $ 72,652 | $ 77,249 | $ 79,521 | $ 83,268 | $ 312,690 |
| Operating loss | (83,445) | (52,030) | (55,163) | (40,602) | (231,240) |
| Net loss | (92,983) | (63,281) | (66,469) | (52,147) | (274,880) |
| Net loss per common share - basic and diluted (1) | $ (2.86) | $ (1.92) | $ (2.01) | $ (1.58) | |
| **2019** | | | | | |
| Total revenue | $ 52,252 | $ 66,300 | $ 61,950 | $ 71,500 | $ 252,002 |
| Operating loss | (83,945) | (63,659) | (75,533) | (89,290) | (312,427) |
| Net loss | (90,270) | (71,420) | (84,833) | (98,158) | (344,681) |
| Net loss per common share - basic and diluted (1) | $ (3.03) | $ (2.28) | $ (2.59) | $ (2.99) | |

(1) Basic and diluted net loss per common share is computed independently for each of the quarters presented. Therefore, the sum of quarterly basic and diluted net loss per common share may not equal annual basic and diluted net loss per common share.

# Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934

Description of the Registrant's Common Stock

*References to "Intercept," "our" and the "Company" herein are, unless the context otherwise indicates, only to Intercept Pharmaceuticals, Inc. and not to any of its subsidiaries.*

## Description of Common Stock

### *General*

The following is a summary of information concerning Intercept's common stock, par value $0.001 per share ("Common Stock"). The summaries and descriptions below do not purport to be complete statements of the relevant provisions of our restated certificate of incorporation and restated bylaws and are entirely qualified by, and should be read in conjunction with, these documents, each of which is filed as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.11 is a part.

### *Common Stock*

*Authorized Capital Stock and Shares Outstanding.* Our authorized capital stock consists of 90,000,000 shares of Common Stock and 5,000,000 shares of preferred stock, par value $0.001 per share. As of December 31, 2020, 33,015,614 shares of Common Stock were outstanding, and no shares of preferred stock were outstanding. All of the outstanding shares of our Common Stock are fully paid and nonassessable.

*Annual Meeting.* Annual meetings of our stockholders are held on the date designated in accordance with our restated bylaws. Written notice must be mailed to each stockholder entitled to vote not less than ten nor more than 60 days before the date of the meeting. The presence in person or by proxy of the holders of record of a majority of our issued and outstanding shares entitled to vote at such meeting constitutes a quorum for the transaction of business at meetings of the stockholders. Special meetings of the stockholders may be called for any purpose only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors. Except as may be otherwise provided by applicable law, our restated certificate of incorporation or our restated bylaws, all elections shall be decided by a plurality, and all other questions shall be decided by a majority, of the votes cast by stockholders entitled to vote thereon at a duly held meeting of stockholders at which a quorum is present.

*Voting Rights*. Holders of our Common Stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders and do not have cumulative voting rights.

*Dividends.* Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of Common Stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available for dividend payments.

*Liquidation and Dissolution*. In the event of any liquidation, dissolution or winding-up of our affairs, holders of Common Stock will be entitled to share ratably in any of our assets remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

*Other Rights.* The holders of Common Stock have no preferences or rights of conversion, exchange, preemptive or other subscription rights. There are no redemption or sinking fund provisions applicable to the Common Stock.

*Transfer Agent and Registrar.* VStock Transfer, LLC is transfer agent and registrar for the Common Stock.

*NASDAQ Global Select Market.* Our Common Stock is listed on The Nasdaq Global Select Market under the symbol "ICPT."

***Anti-takeover Effects of Our Restated Certificate of Incorporation, Restated Bylaws and Delaware Law***

The provisions of Delaware law and our restated certificate of incorporation and restated bylaws could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests.

These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

*Delaware Business Combination Statute.* We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which we refer to as the DGCL. With some exception, Section 203 of the DGCL prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved by the board of directors and the holders of at least two-thirds of the outstanding voting stock of the corporation. The shares held by the interested stockholder are not counted as outstanding when calculating the two-thirds of the outstanding voting stock needed for approval. For purposes of Section 203 of the DGCL, a "business combination" is defined broadly to include a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and, subject to certain exceptions, an "interested stockholder" is a person who, together with his or her affiliates and associates, owns, or within three years prior, did own, 15% or more of the corporation's outstanding voting stock.

*Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors.* Our restated bylaws provide that, for nominations to the board of directors or for other business to be properly brought by a stockholder before a meeting of stockholders, a stockholder must first have given timely notice of the proposal in writing to our secretary. For an annual meeting, a stockholder's notice generally must be delivered not less than 90 days nor more than 120 days prior to the first anniversary of the previous year's annual meeting date; provided, that if the date of the annual meeting is more than 30 days before or more than 30 days after the anniversary of the previous year's annual meeting date, such stockholder's notice must be delivered not earlier than the close of business on the 120 day prior to such annual meeting and not later than the close of business on the later of the 90 day prior to such annual meeting or the close of business on the 10 day following the day on which public announcement of the date of such meeting is first made by us. For a special meeting, the notice must generally be delivered not earlier than the 90 day prior to the meeting and not later than the later of (1) the 60 day prior to the meeting or (2) the 10 day following the day on which public announcement of the meeting is first made. Detailed requirements as to the form of the notice and information required in the notice are specified in the restated bylaws. If it is determined that business was not properly brought before a meeting in accordance with our bylaws provisions, such business will not be conducted at the meeting.

*Special Meetings of Stockholders.* Special meetings of the stockholders may be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors.

*No Stockholder Action by Written Consent.* Any action to be effected by our stockholders must be effected at a duly called annual or special meeting of the stockholders provided, however, our restated certificate of incorporation provides that if any one stockholder, together with its affiliates, collectively holds a majority of the voting power of

the then-outstanding shares of our capital stock, action may be taken without a meeting and vote, through the written consent of holders of the requisite number of votes necessary to authorize or take such action at a meeting.

*Board of Directors.* We do not have a classified board of directors. All of our directors are elected annually. The number of directors comprising our board of directors is fixed from time to time by the board of directors.

*Removal of Directors by Stockholders.* Our restated bylaws provide that our directors may be removed with or without cause by the affirmative vote of the holders of a majority of the votes that all our stockholders would be entitled to cast in an annual election of directors, and our restated certificate of incorporation and restated bylaws provide that any vacancy on our board of directors, including a vacancy resulting from an increase in the size of our board of directors, may be filled only by vote of a majority of our directors then in office.

*Super Majority Stockholder Vote Required for Certain Actions.* The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless the corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our restated certificate of incorporation requires the affirmative vote of the holders of at least 80% of our outstanding voting stock to amend or repeal any of the provisions discussed in this section of this Exhibit entitled "Anti-takeover Effects of Our Restated Certificate of Incorporation, Restated Bylaws and Delaware Law." This 80% stockholder vote would be in addition to any separate class vote that might in the future be required pursuant to the terms of any preferred stock that might then be outstanding. The affirmative vote of at least 80% of our outstanding voting stock is also required for any amendment to, or repeal of, our restated bylaws by the stockholders. Our restated bylaws may be amended or repealed by a simple majority vote of the board of directors.

# EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), made effective as of December 18th, 2020, is entered into by Intercept Pharmaceuticals, Inc. (the "Company") and Jared Freedberg ("Executive").

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

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

1. Term of Employment. The Company hereby agrees to employ Executive, and Executive hereby accepts employment with the Company, upon the terms set forth in this Agreement, for the period commencing on February 1st, 2021 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 Term") 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 General Counsel & Company Secretary to perform the duties and responsibilities inherent in such position and such other duties and responsibilities consistent with such position as the President & 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 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 $461,600.00, 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 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 of the Board (the "Compensation Committee") in its sole discretion, of 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 Executive (i) a stock option under its 2012 Equity Incentive Plan (as amended from time to time, the "2012 Plan") to purchase 69,400 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 44,277 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 Executive's continued employment by the Company and the terms of 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 Executive's continued employment by the Company and the terms of 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 at 1.75 times Executive's annual

vacation accrual. 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, unless the Company is acquired by another business venture, in which case none of the previous year's accrued vacation will be subject to a 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 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 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 Invention, Non-Disclosure, and Non-Solicitation Agreement; or (iv) Executive has materially breached this Agreement, 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 General Counsel & Company Secretary (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 sixtieth ($60^{th}$) 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 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 the 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 service-based 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. Any equity or equity-based awards which vest based upon the attainment of performance measures shall be governed by the terms of the applicable award agreement governing termination.

(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 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 service-based 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. Any equity or equity-based awards which vest based upon the attainment of performance measures shall be governed by the terms of the applicable award agreement governing termination following a Change in Control.

(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 equity awards) 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 equity awards) and (ii) second, by reducing or eliminating the vesting of those equity awards that occur 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 Executive'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 are expected to be made. 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 in 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 2012 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 County of New York, State of New York (or, if appropriate, a federal court located within the County of New York, 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. Any purported assignment of this Agreement by Executive shall be null and void. 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 Executive'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 first forth above.

**THE COMPANY:**

**INTERCEPT PHARMACEUTICALS, INC.**

By: /s/ David Ford

Name: David Ford
Title: Chief Human Resources Officer

**EXECUTIVE:**

By: /s/ Jared Freedberg

Name: Jared Freedberg

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 December 15th, 2020 (the "**Agreement**"), which Separation Benefits are conditioned on my signing this Release of Claims ("**Release**") and which I will forfeit unless I execute and do not revoke this Release of Claims, I, on my own behalf and on behalf of my heirs and estate, voluntarily, knowingly and willingly release and forever discharge the Company, its subsidiaries, affiliates, parents, and, in their capacities as such, stockholders, together with each of those entities' respective officers, directors, stockholders, employees, agents, fiduciaries and administrators, each in their capacities as such (collectively, the "**Releasees**") from any and all claims and rights of any nature whatsoever which I now have or in the future may have against them up to the date I execute this Release, whether known or unknown, suspected or unsuspected. This Release includes, but is not limited to, any rights or claims relating in any way to my employment relationship with the Company or any of the other Releasees or the termination thereof, any contract claims (express or implied, written or oral), including, but not limited to, the Agreement, or any rights or claims under any statute, including, without limitation, the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Older Workers' Benefit Protection Act, the Rehabilitation Act of 1973 (including Section 504 thereof), Title VII of the 1964 Civil Rights Act, the Civil Rights Act of 1866 (42 U.S.C. § 1981), the Civil Rights Act of 1991, the Equal Pay Act, the National Labor Relations Act, the Worker Adjustment and Retraining Notification Act, the Family Medical Leave Act, the Lilly Ledbetter Fair Pay Act, the Genetic Information Non-Discrimination Act, the New York State Human Rights Law, the New York City Human Rights Law, and the Employee Retirement Income Security Act of 1974, all as amended, and any other federal, state or local law. This Release specifically includes, but is not limited to, any claims based upon the right to the payment of wages, incentive and performance compensation, bonuses, equity grants, vacation, pension benefits, 401(k) Plan benefits, stock benefits or any other employee benefits, or any other rights arising under federal, state or local laws prohibiting discrimination and/or harassment on the basis of race, color, age, religion, sexual orientation, religious creed, sex, national origin, ancestry, alienage, citizenship, nationality, mental or physical disability, denial of family and medical care leave, medical condition (including cancer and genetic characteristics), marital status, military status, gender identity, harassment or any other basis prohibited by law.

As a condition of the Company entering into this Release, I further represent that I have not filed against the Company or any of the other Releasees, any complaints, claims or lawsuits with any arbitral tribunal, administrative agency, or court prior to the date hereof, and that I have not transferred to any other person any such complaints, claims or lawsuits. I understand that by signing this Release, I waive my right to any monetary recovery in connection with a local, state or federal governmental agency proceeding and I waive my right to file a claim seeking monetary damages in any arbitral tribunal, administrative agency, or court. This Release does not: (i) prohibit or restrict me from communicating, providing relevant information to or otherwise cooperating with the U.S. Equal Employment Opportunity Commission, the New York State Division of Human Rights, a local commission on human rights or any other governmental authority with responsibility for the administration of fair employment practices laws (including with respect to SEC Whistleblowing) or my own attorney 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.

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.

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 or permitted by applicable law or as otherwise agreed to in writing with you.

Pursuant to 18 U.S.C. § 1833(b), I understand that I will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret of the Company that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to my attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding. If I files a lawsuit for retaliation by the Company for reporting a suspected violation of law, I may disclose the trade secret to my attorney and use the trade secret information in the court proceeding, if I (a) file any document containing the trade secret under seal, and (b) do not disclose the trade secret, except pursuant to court order. Nothing in this Agreement is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly allowed by such section.

**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 the Agreement or this Release. For the avoidance of doubt, nothing in this Release 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 Release, 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, I understand that I shall be permitted to retain my contacts and calendars and personal correspondence and any documents or data related to my 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, 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 reimburse me for any reasonable travel and lodging expenses incurred in connection with such matters (at a level of travel consistent with my travel while employed by the Company) and the reasonable fees of any independent counsel retained by me if I reasonably believe separate counsel to be appropriate. I agree not to assist or provide information to any adverse party in any litigation against the Company or any of its current or former employees, except as required under law or formal legal process, unless I provide advance notice to the Company at least 10 days before such assistance or provision of information (or, if I am so required to assist or provide such information within less than 10 days of receipt of such requirement, after I provide timely advance notice to the Company) to allow the Company to take legal action with respect to the matter. Finally, I will undertake to satisfy requests for information from the Company with respect to the above undertaking. *Nothing in this Release is intended to restrict or preclude me from, or otherwise influence me in, testifying fully and truthfully in legal, administrative, or any other proceedings involving the Company, as required by law or formal legal process.*

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

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

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

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

I further acknowledge that:

(1) I first received this Release on the date of the Agreement to which it is attached as Exhibit A;

(2) I understand that, in order for this Release to be effective, I may not sign it prior to the date of my separation of employment with the Company but that if I wish to receive the

Separation Benefits, I must sign and return this Release prior to the sixtieth ($60^{th}$) 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 been given at least twenty-one (21) days to consider, and 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) Any revocation of this release must be made in a signed writing and sent to the following address no later than 5:00 PM on the seventh (7th) day after I have executed this Agreement:

[Address]

(10) 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

(11) 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 Release.

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

Signature: /s/ Jared Freedberg
Jared Freedberg

December 21, 2020
Date signed

**Exhibit 10.39**

**Execution Version**

Certain identified information has been excluded from this exhibit because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed.

# MANUFACTURING AND SUPPLY AGREEMENT

**between**

**INTERCEPT PHARMA EUROPE LTD**.

**and**

**PHARMAZELL GMBH**

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

## RECITALS

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

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

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

## ARTICLE 1
## DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## ARTICLE 2
## MANUFACTURING AND SUPPLY

2.1 Supply Obligations.

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

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

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

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

2.2 Work Orders.

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

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

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

2.3 Delivery Terms; Inspection.

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

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

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

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

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

2.6 Supply Shortage; Inability to Supply.

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

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

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

2.7 Intercept Materials.

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

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

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

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

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

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

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

**ARTICLE 3**
**QUALITY; COMPLIANCE; REGULATORY**

3.1 Quality Control.

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

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

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

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

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

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

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

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

3.2 Maintenance of Facility.

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

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

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

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

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

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

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

3.4 Cooperation with Regulatory Authorities and Regulatory Correspondence.

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

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

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

3.6 Change Requests.

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

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

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

**ARTICLE 4**
**FINANCIALS**

4.1 Price.

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

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

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

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

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

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

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

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

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

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

4.4 Adjustment of Purchase Price.

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

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

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

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

4.5 Audit; Late Payments.

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

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

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

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

## ARTICLE 5
## INTELLECTUAL PROPERTY

5.1 Ownership of Inventions.

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

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

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

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

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

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

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

5.2 Patent Prosecution.

(a) Specified Invention Patents.

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

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

(b) Other PharmaZell Invention Patents.

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

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

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

(c) Joint Invention Patents.

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

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

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

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

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

5.3 Enforcement of Patents.

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

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

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

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

5.4 Third Party Litigation.

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

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

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

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

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

**ARTICLE 6**
**REPRESENTATIONS AND WARRANTIES; COVENANTS**

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

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

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

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

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

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

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

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

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

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

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

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

## ARTICLE 7
## CONFIDENTIALITY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## ARTICLE 8
## TERM AND TERMINATION

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

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

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

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

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

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

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

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

(iv) as provided in Section 10.2.

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

8.3 Effect of Expiration or Termination.

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

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

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

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

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

**ARTICLE 9**
**INDEMNIFICATION**

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

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

9.3 Indemnification Procedure.

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

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

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

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

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

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

9.4 Insurance.

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

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

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

**ARTICLE 10**
**MISCELLANEOUS**

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

If to Intercept to:

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

with copies (which shall not constitute notice) to:

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

and

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

If to PharmaZell to:

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

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

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

10.3 Entire Agreement; Amendment.

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

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

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

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

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

10.7 Dispute Resolution.

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

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

10.8 Arbitration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**[*Signature Page Follows]***

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

INTERCEPT PHARMA EUROPE LTD.

By: /s/ Steve Arnold

Name: Steve Arnold

Title: SVP

Date: August 12, 2016

PHARMAZELL GmbH

By: /s/ Oliver Bolzern

Name: Oliver Bolzern

Title: CEO

Date: August 12, 2016

AGREED TO AND ACCEPTED SOLELY FOR PURPOSES OF SECTION 10.19:

INTERCEPT PHARMACEUTICALS, INC.

By: /s/ Sandip Kapadia

Name: Sandip Kapadia

Title: CFO

Date: August 12, 2016

**[Signature Page to Manufacturing and Supply Agreement]**

**SCHEDULE 1.40**

**Intercept Materials**

[**]

Schedule 1.40 to Manufacturing and Supply Agreement

**SCHEDULE 1.83**

**Form of Work Order**

***FOR ILLUSTRATION PURPOSES ONLY – DO NOT EXECUTE***

**WORK ORDER #____**

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

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

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

**Deliverables:** Quantity of Supplied Materials.

**Delivery Date:** *[Insert desired Delivery Date]*

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

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

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

**OTHER TERMS TO BE ADDED AS AGREED**

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

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

[Remainder of Page Intentionally Blank]

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

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

Schedule 1.83 to Manufacturing and Supply Agreement

**SCHEDULE 2.1(d)**

**Approved Subcontractors and Activities**

| Subcontractor | Activity |
|---|---|
| [**] | [**] |
| [**] | [**] |
| [**] | [**] |
| [**] | [**] |

**SCHEDULE 2.2(a)**

**Existing Work Orders**

[**]

Schedule 2.2(a) to Manufacturing and Supply Agreement

**Schedule 2.2(b)**

**First New Work Order**

[**]

Schedule 2.2(b) to Manufacturing and Supply Agreement

**SCHEDULE 2.7(e)**

**Standard Yields**

[**]

Schedule 2.7(e) to Manufacturing and Supply Agreement

**Exhibit 10.41**

**EXECUTION COPY**

Certain identified information has been excluded from this exhibit because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed.

# LICENSE AGREEMENT

This License Agreement (this "Agreement"), dated as of March 29, 2011 (the "Effective Date**"**), is made by and between DAINIPPON SUMITOMO PHARMA CO. LTD., a company organized under the laws of Japan ("DSP"), having a place of business at 6-8 Doshomachi 2-chome, Chuo-ku, Osaka 541-0045 Japan, and INTERCEPT PHARMACEUTICALS, INC., a company organized under the laws of the State of Delaware ("Intercept"), having a place of business at 18 Desbrosses Street, New York, New York 10013. DSP and Intercept are sometimes referred to herein individually as a "Party" and collectively as the **"**Parties."

## RECITALS

**WHEREAS**, Intercept is a clinical stage biopharmaceutical company engaged in the development of therapeutics for the treatment of metabolic diseases, and is currently developing Obeticoholic acid, a farnesoid X receptor (FXR) agonist, more commonly known as 6α-ethyl-3α,7α-dihydroxy-5β-cholan-24-oic acid (6-ECDCA) or INT-747, in any form (the "Compound")to be used to formulate a new product for therapeutic use in connection with primary biliary cirrhosis ("PBC") and nonalcoholic steatohepatitis ("NASH") (PBC and NASH, collectively the "Field");

**WHEREAS**, Intercept is simultaneously engaged in the development of other indications for the Compound, including in connection with portal hypertension (together with all present and future indications of the Compound, each an "Additional Indication", and collectively, the "Additional Indications");

**WHEREAS,** DSP is a worldwide pharmaceutical company that has significant experience in the development, manufacturing and commercialization of pharmaceutical products in the Territory (as defined hereinafter); and

**WHEREAS**, Intercept desires to grant certain exclusive rights to DSP in the Territory with respect to the development, manufacturing and commercialization of the Compound and the Product in the Field in the Territory and DSP wishes to accept the grant of such rights; all as more particularly set forth in this Agreement.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

## 1. DEFINITIONS

Whenever used in the Agreement with an initial capital letter, the terms defined in this Article 1 shall have the meanings specified below.

**"Actual Costs**" shall mean Intercept's direct costs and indirect costs incurred by sub-contractors of Intercept of materials and labor specifically incurred in Manufacturing or formulating the Clinical Supplies or Commercial Supplies supplied to DSP under the Clinical Supply Agreement or the Commercial Supply Agreement, including but not limited to excipients and packaging components for both the Compound and the Product, as well as in process and release testing, stability testing, development of the Specifications, manufacturing validation, quality assurance and quality control activities necessary to release the Compound or Product to DSP or to a Third Party designated by DSP; together with directly allocable manufacturing overheads specifically attributable to the Manufacture or formulation of the Compound or Product under this Agreement, including depreciation and maintenance costs of fixed assets that are wholly dedicated to and used in manufacturing the Compound or Product for DSP; but excluding corporate, general or administrative overheads. Actual Costs shall be calculated in accordance with Intercept's standard cost accounting policies and with generally accepted accounting principles, consistently applied to the manufacture of pharmaceutical compounds and products.

**"Additional Indications"** shall have the meaning set forth in the second recital of this Agreement.

"**Additional Indications Option**" shall have the meaning set forth in Section 7.2.

"**Additional Indications Option Commencement Notice**" shall have the meaning set forth in Section 7.3.

"**Additional Indications Exercise Period**" shall have the meaning set forth in Section 7.3.

"**Additional Indications Option Fee**" shall have the meaning set forth in Section 7.3.

"**Affiliate**" shall mean any corporation, firm, limited liability company, partnership or other entity that directly controls or is controlled by or is under common control with a Party to this Agreement. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean the possession, directly or indirectly through one or more intermediaries, of the power to direct the management or policies of an entity, whether through the ownership of fifty percent (50%) or more of the voting securities of the other organization or entity or by contract relating to voting rights or corporate governance. Notwithstanding the foregoing, Sumitomo Chemical Co., Ltd. ("Sumitomo Chemical"), the parent company of DSP, shall not be considered an Affiliate for the purposes of this Agreement; provided that DSP shall be permitted to engage in routine reporting of matters concerning this Agreement to Sumitomo Chemical.

"**Clinical Supply Agreement**" shall have the meaning set forth in Section 6.1.

**"Clinical Supplies"** shall mean Compound formulated into Product or matching placebos to be used exclusively for conducting clinical studies to gain Regulatory Approval in the Territory.

"**CMC**" shall mean the Chemistry, Manufacturing and Controls information required to be submitted under Section 505 of the U.S. Food, Drug and Cosmetic Act (as amended) and 21 C.F.R. 312.23(a)(7) and 314.50(d)(1).

**"Commercial Supplies"** shall mean the supply of the Product in bulk formulation (either packaged or pre-packaged) made to DSP by Intercept pursuant to Section 6.2 of this Agreement and the Commercial Supply Agreement.

"**Commercial Supply Agreement**" shall have the meaning set forth in Section 6.2.

**"Commercialize"** shall mean to promote, market, distribute, sell (and offer for sale or contract to sell) or provide product support for a Product, including by way of example: (i) detailing and other promotional activities in support of a Product; (ii) advertising and public relations in support of a Product, including market research, development and distribution of selling, advertising and promotional materials, field literature, direct-to-consumer advertising campaigns, media/journal advertising, and exhibiting at seminars and conventions; and (iii) developing reimbursement programs and information and data specifically intended for managed care organizations, governmental agencies and the like.

**"Commercially Reasonable Efforts**" shall mean with respect to a Party's obligations under this Agreement, including to Develop, Manufacture or Commercialize the Product, those efforts and resources consistent with the usual practices of such Party in pursuing the development or commercialization of its own pharmaceutical products that are of similar market potential and strategic value as such Product, taking into account all relevant factors including product labeling or anticipated labeling, present and future market potential, past performance of such product and such Party's other pharmaceutical products that are of similar market potential, financial return, medical and clinical considerations, past and future regulatory environment and competitive market conditions, all measured by the facts and circumstances at the time such efforts are due. Commercially Reasonable Efforts shall be determined on a country-by-country and indication-by-indication basis for the Product, and it is anticipated that the level of effort will change over time, reflecting changes in the status of the Products and the market(s) or countries involved.

**"Confidential Information**" shall mean with respect to a Party (the "Receiving Party"), all information which is disclosed by the other Party (the "Disclosing Party") to the Receiving Party hereunder or to any of its employees, consultants, Affiliates, licensees or sublicensees, which is marked as confidential or indicated at the time of disclosure as being confidential (and subsequently summarized in writing) except to the extent that the Receiving Party can demonstrate by written record that such information, (i) as of the date of disclosure is demonstrably known to the Receiving Party or its Affiliates other than by virtue of a prior confidential disclosure to such Party or its Affiliates; (ii) as of the date of disclosure is in, or subsequently enters, the public domain, through no fault or omission of the Receiving Party; (iii) is obtained from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the Disclosing Party; or (iv) is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party; or (v) is required to be disclosed by judicial or governmental authority of competent jurisdiction; provided that the Receiving Party shall first provide the Disclosing Party with sufficiently timely notice of such requirement to permit the Disclosing Party to take measures to avoid or limit the scope of the requested disclosure. Confidential Information shall include, without limitation, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including, preclinical data, clinical trial data, databases, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures.

**"Compound"** shall have the meaning set forth in the first recital of this Agreement.

**"Control"** or **"Controlled"** shall mean, when used in reference to intellectual property, other intangible property, or materials, that a Party owns or has a license or sublicense to such intellectual property, other intangible property or materials, and has the ability to grant a license or sublicense or other right to use such intellectual property, other intangible property or materials, as applicable, as provided for herein, without violating the terms of any agreement or other arrangement with any Third Party; provided that where the ability to grant a license or sublicense is subject to a Third Party consent or notice requirement, "Commercially Reasonable Efforts" shall require seeking such consent or providing such notice to the Third Party.

"**Country Option**" shall have the meaning set forth in Section 8.1.

"**Country Option Exercise Notice"** shall have the meaning set forth in Section 8.2.

"**Development**" and "**Develop**" shall mean with respect to the Compound or the Product, all activities relating to preparing and conducting non-clinical studies, clinical studies (Phase I Clinical Trials, Phase II Clinical Trials, Phase III Clinical Trials and Phase IV Clinical Trials), formulation, development, statistical analysis, quality assurance and quality control activities and other product development activities, which may include, but is not limited to, research, and regulatory activities directed toward obtaining Regulatory Approval of the Product in the Field inside or outside the Territory, as the case may be.

"**DSP Defense Costs**" shall have the meaning set forth in Section 12.3.

"**Effective Date**" shall have the meaning set forth in the first line of this Agreement.

"**Eroded Country**" shall have the meaning set forth in Section 9.3.1.

**"Exclusive Period"** shall mean, on a country-by-country basis, the period beginning upon the First Commercial Sale of the Product in the relevant country until the later to occur of (i) the expiration of (x) the Intercept substance patent with respect to Japan or (y) the last to expire of the Intercept patent family members with respect to China, after giving effect, in each of items (x) and (y) to any Patent Term Extensions, and (ii) the date upon which generic drugs relying on the Compound or Product data for Regulatory Approval may be introduced.

**"Field"** shall have the meaning set forth in the first recital of this Agreement, together with any other Additional Indications, which shall each automatically be included in the "Field" upon the exercise by DSP of the Additional Indication Option.

"**First Commercial Sale**" shall mean, on a country-by-country basis, the date of the first arm's length transaction, transfer or disposition for value to a Third Party of a Product by or on behalf of DSP or any Affiliate or sublicensee of DSP in such country after receipt of Marketing Approval, (and any labeling or pricing negotiations that may be required after Marketing Approval for such Product in the Territory.) A First Commercial Sale shall not include any Product sold for use in clinical trials, for research or for other non-commercial uses, or that is supplied as part of a compassionate use or similar program.

**"First Tier Royalty Rate**" shall have the meaning set forth in Section 9.2.3.

**"GMP"** shall mean all applicable Good Manufacturing Practices standards, including, as applicable, those standards required by the MHLW or its equivalent in each country in the Territory.

**"Good Clinical Practices"** or **"GCP"** shall mean all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (i) those standards required by the MHLW or its equivalent in the Territory, and (ii) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

**"Good Laboratory Practices"** or **"GLP"** shall mean all applicable Good Laboratory Practice standards, including, as applicable, (i) those standards required by the MHLW as hereinafter defined or its equivalent in each country in the Territory, and (ii) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time.

**"Improvement**" shall mean any improvements, enhancements or modifications to the Intercept Technology, the Intercept Manufacturing Technology, or other technology claimed in the Intercept Patents (whether patentable or not), which would be useful or necessary in the Manufacture, Development, and Commercialization of the Compound and/or Products, which is conceived, solely by one Party or jointly by one Party with a Third Party or jointly by both Parties.

"**IND**" shall mean the equivalent application of an Investigational New Drug Application to the MHLW or its equivalent in any country in the Territory, such as a clinical trial application or a clinical trial exemption, the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such country.

"**Intercept Change of Control**" shall mean: (i) the liquidation or dissolution of Intercept or the sale or other transfer by Intercept of all or substantially all of its respective assets; or (ii) the occurrence of a tender offer, stock purchase, other stock acquisition, merger, consolidation, recapitalization, reverse split, sale or transfer of assets or other transaction, as a result of which any person or entity (x) becomes the beneficial owner, directly or indirectly (including through multiple entities), of respective securities of Intercept representing more than fifty percent (50%) of the combined voting power with respect to the election of directors of Intercept, (y) obtains the ability to appoint a majority of the Board of Directors of Intercept, or (z) obtains the ability to direct the operations or management of Intercept or any successor to the business of Intercept.

"**Intercept Development Plan**" shall have the meaning set forth in Section 3.1.2.

**"Intercept Know-How"** shall mean the Know-How which Intercept or its Affiliates Control on the Effective Date or during the Term, which information is necessary or useful for the Development, Manufacture or Commercialization of the Product or the Compound in the Field in the Territory.

**"Intercept Manufacturing Know-How"** shall mean all methods, processes, designs, patterns, or know-how, programs, systems, procedures, technical data, technology, information, data, results of tests, studies, and analyses, whether patentable or not, which are specifically related to the manufacturing process of the Compound and/or the Product, including Know-How that is in the case of each of the foregoing Controlled by Intercept (or its Affiliates) as of the Effective Date or during the Term of this Agreement.

**"Intercept Manufacturing Patent"** shall mean any Patent that is Controlled by Intercept (or its Affiliates) as of the Effective Date and/or during the Term, in each case, which is necessary or useful for the Manufacture of the Compound or the Product for Commercialization in the Field in the Territory.

**"Intercept Manufacturing Technology"** shall mean the Intercept Manufacturing Know-How and the Intercept Manufacturing Patents.

**"Intercept Patents"** shall mean all Patents that Intercept Controls as of the Effective Date or during the Term, which Patents are necessary or useful for the purpose of Development, Manufacture or Commercialization of the Compound or the Product in the Field in the Territory, all as more particularly set forth on Exhibit A.

"**Intercept Technology"** shall mean the Intercept Patents and the Intercept Know-How.

**"Joint Steering Committee"** or **"JSC"** shall mean the joint steering committee formed by the Parties as described in Section 3.1.

"**Joint Improvements**" shall mean an Improvement or invention, whether patentable or not, which is invented, made or discovered jointly by or on behalf of the employee(s), licensee(s) (including sublicensees), or contractors (including subcontractors) of both Parties (and/or their Affiliates).

**"Know-How"** shall mean intellectual property including any asset that comprises any of the following items and has a substantial value independent of the services of any individual: inventions, formulae, processes, designs, patterns, or know-how; copyrights; trademarks, trade names, or brand names; franchises; methods, programs, systems, procedures, campaigns, surveys, studies, forecasts, estimates, customer lists, or technical data; and other similar items (whether or not in documentary form and whether or not patentable, copyrightable or otherwise protectable under applicable Laws).

**"Laws"** shall mean all applicable laws, statutes, rules, regulations, directives, decisions, ordinances, guidelines concerning the Development, Manufacturing and Commercialization of the Compound or the Product in the Field in the Territory.

**"Manufacturing"** shall mean all activities related to the production, manufacture, testing, processing, filling, finishing, packaging, labeling, inspection, receiving, holding and shipping of the Compound and/or the Product, the Clinical Supplies or the Commercial Supplies, or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process qualification and validation, commercial manufacture, stability and release testing, quality assurance and quality control. For clarity, **"Manufacture"** has a correlative meaning.

**"Marketing Approval"** shall mean (i) for the United States, the approval of an NDA, and (ii) for jurisdictions in the Territory, the approval from the relevant Regulatory Authority necessary to market and sell the Product in that country, including, where required, pricing approvals.

"**Market Share**" shall have the meaning set forth in Section 9.3.1.

**"MHLW"** shall mean the Japanese Ministry of Health, Labor and Welfare, or a successor agency thereto.

**"NASH**" shall have the meaning set forth in the first recital of this Agreement.

**"Necessary Third Party Patents"** shall mean, on a country-by-country and indication-by-indication basis, the patents that are owned or controlled by a Third Party, which do not infringe the Intercept Technology, but are necessary for the Development, Manufacturing or Commercialization of the Compound or the Product in the Field, as reasonably determined in accordance with Section 4.3.

**"Net Sales"** shall mean the gross amounts invoiced by DSP and its Affiliates and sublicensees for sales or other dispositions of the Product to Third Parties that are not Affiliates or sublicensees in the Field in the Territory, in bona fide, arms-length transactions less the following items, as allocable to such Products (if not previously deducted from the amount invoiced): (i) trade, cash or quantity discounts, credits or allowances actually allowed (provided that such discounts are applied in a normal and customary manner with respect to other similarly situated products of the selling party, and not in a manner which is unreasonably disproportionate to one or more Products when compared to other products of the selling party); (ii) charge back payments, administrative fees, price reductions, rebates allowed or granted, or other forms of consideration to managed care organizations, government agencies or trade customers, including wholesalers and chain and pharmacy buying groups (provided that such discounts are applied in a normal and customary manner with respect to other similarly situated products of the selling party, and not in a manner which is unreasonably disproportionate to one or more Products when compared to other products of the selling party); (iii) credits actually allowed for claims, allowances for damaged goods, retroactive price reductions or returned goods; (iv) prepaid freight, postage, shipping, customs duties and insurance charges; and (v) sales taxes, value added taxes, duties and other governmental charges. Such amounts shall be determined in accordance with Japanese GAAP, consistently applied, or GAAP in effect in a country in the Territory, as permitted by DSP. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. Further, in the case of any sale or other disposal other than in an arm's length transaction exclusively for cash, such as barter or counter-trade, of any Product, or part thereof, Net Sales shall be determined by referencing Net Sales at which substantially similar quantities of the Product are sold in an arm's length transaction for cash. Finally, financial compensation, if any, received by DSP from a subsequent resale of the Product by a third party reseller, if any, shall be included in the calculation of Net Sales.

"**NDA**" shall mean a new drug application or its equivalent filed with a Regulatory Authority in the Territory seeking Regulatory Approval to Commercialize the Product in the Territory for a particular indication within the Field.

"**Non-Territory Data"** shall have the meaning set forth in Section 4.2.2.

"**Patents**" means any patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal, adjustment or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts thereof in any country owned or Controlled by a Party on the Effective Date and during the Term of this Agreement.

**"Patent Term Extension"** means any term extensions, adjustments, supplementary protection certificates, regulatory exclusivity and equivalents thereof offering Patent protection beyond the initial term with respect to any issued Patents.

"**PBC**" shall have the meaning set forth in the first recital of this Agreement.

**"Phase I Clinical Trial"** means a clinical trial in humans, the principal purpose of which is to make a preliminary determination of metabolism, pharmacokinetics, dose findings or preliminary safety in healthy individuals or patients in the Territory.

**"Phase II Clinical Trial"** means a clinical trial in humans, the principal purpose of which is to make a preliminary determination that a given product is safe in the population in the Territory for its intended use and to obtain information about such product's efficacy sufficient to permit the design of further clinical trials, or if no further trials are necessary, to enable an Regulatory Approval.

"**Phase III Clinical Trials**" shall mean a clinical trial of a Product conducted in human patients with a defined dose or a set of defined doses of a Product designed to ascertain efficacy and safety of such Product for the purpose of submitting applications for Regulatory Approval to the competent Regulatory Authorities.

**"Phase IV Clinical Trials"** means post-marketing studies to delineate additional information about a pharmaceutical product's risks and benefits, and optimal use, commenced after receipt of Regulatory Approval for a Product in the indication for which such trial was conducted.

"**Product"** shall mean any pharmaceutical composition or formulation that contains the Compound, whether or not such Product is used as a single agent or in combination with other therapeutically active components, as the term "Product" may be further defined in each of the Clinical Supply Agreement and the Commercial Supply Agreement.

"**Product Development Plan"** shall have the meaning set forth in Section 3.1.1.

"**Quality Assurance Agreement**" shall have the meaning set forth in Section 6.3.5.

**"Regulatory Approval"** shall mean all necessary approvals (including INDs, NDAs, product approvals, import permits, and, in each case any supplements and amendments thereto), licenses, registrations or authorizations of any Regulatory Authority, necessary for the Development, Manufacture, and Commercialization of the Compound or the Product in the Field in the Territory.

**"Regulatory Authority"** shall mean, in a particular country in the Territory, any applicable governmental authority involved in granting Regulatory Approval in the Territory, including the MHLW.

"**Second Tier Royalty Rate**" shall have the meaning set forth in Section 9.2.3.

**"Specifications"** shall mean those tests, methods and acceptance criteria for the Compound and the Product required in the Territory as set forth the in the IND and NDA.

"**Target Actual Cost"** shall have the meaning set forth in Section 6.2.2.

"**Target Country**" shall have the meaning set forth in Section 8.3.

"**Technical Transfer**" shall have the meaning set forth in Section 6.4.1.

"**Technology**" shall mean and include any and all unpatented, proprietary ideas, inventions, discoveries, Confidential Information, biologic materials, data, results, formulae, designs, specifications, methods, processes, formulations, techniques, ideas, know-how, technical information (including, without limitation, structural and functional information), process information, pre-clinical information, clinical information, regulatory filings, and any and all proprietary biological, chemical, pharmacological, toxicological, pre-clinical, clinical, assay, control and manufacturing data and materials.

"**Term**" shall have the meaning set forth in Section 15.1.

"**Territory**" shall mean Japan and China (excluding Taiwan), and such other countries which are the subject of the Country Option, each of which shall be automatically deemed included in the Territory upon the exercise of the Country Option by DSP for such country.

"**Third Party**" shall mean any person or entity other than DSP or Intercept, and their respective Affiliates.

"**Third Tier Royalty Rate**" shall have the meaning set forth in Section 9.2.3.

"**Third Party Offer Notice**" shall have the meaning set forth in Section 9.3.

**"Wholesale Acquisition Cost"** or "**WAC"** shall mean the wholesaler acquisition cost for the Product in the U.S.

## 2. GRANT OF RIGHTS

### 2.1 Exclusive License

**2.1.1 Grant of Exclusive License**. Intercept hereby grants to DSP an exclusive, royalty-bearing license, including the right to grant sublicenses in accordance with Section 2.1.2, under the Intercept Technology to research, Develop, have Developed, make, have made, use, sell, offer for sale, have sold, import, have imported, export and have exported, register, for the purpose of Commercializing the Product in the Territory, for any and all uses within the Field, subject to the terms and conditions of this Agreement. For clarification, the Parties agree that DSP's appointing a sublicensee to engage in the Manufacture of the Compound or the Product outside the Territory for the Development and Commercialization of the Product inside the Territory shall not be deemed a breach of this Agreement.

**2.1.2 Right to Sublicense**. After Intercept's receipt of the Upfront Fee set forth in Section 9.1, DSP shall have the right to grant sublicenses to any Affiliate or Third Party to all or any portion of its rights under the license granted to DSP pursuant to this Section 2; provided, however, that (i) Intercept shall be notified of and approve the sublicensing arrangement, such approval not to be unreasonably withheld, (ii) each such sublicensee agrees to be bound by all applicable Sections of this Agreement, and (iii) DSP shall provide Intercept with a summary of such sublicensing agreements, to include (a) the country in the Territory applicable to such sublicensee, (b) the full legal name of the sublicensee, (c) the applicable indications in the Field, (d) the term and termination provisions of the sublicensing agreement, and (e) the standard of performance applicable to the sublicensee with respect to its obligations under the sub-licensing agreement. Items (a)-(e) inclusive of item (iii) of the preceding sentence shall be set forth in a format substantially similar to Exhibit B, which shall also be executed by the relevant sublicensee affirming its understanding of and willingness to comply with Sections of this Agreement applicable to it.

**2.1.3 Patent Challenge.** Any challenge to the validity, scope or enforceability of any claim in an Intercept Patent by DSP or its Affiliates shall constitute a material breach of this Agreement.

**2.2** **Registration**. Upon DSP's request, but only after Intercept's receipt of the Upfront Fee set forth in Section 9.1, Intercept shall use Commercially Reasonable Efforts, at DSP's sole expense, to register a "*Senyo-Jisshiken Tohroku*" (i.e. registration of the exclusive license with the Japanese Patent Office) for DSP (or the equivalent in any other country in the Territory) with respect to the Intercept Technology and Intercept Patents, which registration shall be transferred or assigned to DSP by Intercept immediately upon issuance for no additional consideration.

**2.3** **No Implied Licenses; Retained Rights.** Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party, whether by implication, estoppel or otherwise

**2.4** **Bankruptcy-Related Rights.**

**2.4.1** **U.S. Bankruptcy Code 365(n).** All rights and licenses granted under this Agreement are hereby deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. The Parties agree that DSP, as the licensee under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code, and that upon commencement of a bankruptcy proceeding by or against Intercept under the U.S. Bankruptcy Code, DSP shall be entitled to a complete duplicate of or complete access to any such intellectual property and all embodiments of such intellectual property, provided that DSP continues to fulfill its payment or royalty obligations in accordance with this Agreement. Such intellectual property and all embodiments thereof shall be promptly delivered to DSP (x) upon any such commencement of a bankruptcy proceeding upon written request therefore by DSP, unless Intercept elects to continue to perform all of its obligations under this Agreement or (y) if not delivered under (x) above, upon the rejection of this Agreement by or on behalf of Intercept upon written request therefor by DSP. The foregoing is without prejudice to any rights DSP may have against Intercept arising under the U.S. Bankruptcy Code or other applicable law.

**2.4.2** **Intellectual Embodiments.** Each Party hereby acknowledges that (i) copies of research data (both clinical and non-clinical), (ii) laboratory samples, (iii) product samples and inventory, (iv) formulae, (v) laboratory notes and notebooks, (vi) data and results related to clinical and non-clinical trials, (vii) regulatory filings and approvals, (viii) rights of reference in respect of regulatory filings and approvals, (ix) pre-clinical research data and results, and (x) marketing, advertising and promotional materials, constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code.

**2.5** **Bankruptcy Assistance.** Each Party agrees not to interfere with the other Party's exercise of rights and licenses to intellectual property licenses granted to the Party pursuant to Section 2.4 or under Section 365(n) of the U.S. Bankruptcy Code and embodiments thereof in accordance with this Agreement and agrees to use Commercially Reasonable Efforts to assist the other Party to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties, as reasonably necessary for the other Party to exercise such rights and licenses in accordance with this Agreement.

## 3. GOVERNANCE

**3.1** **Joint Steering Committee.** The Parties shall use Commercially Reasonable Efforts to establish the JSC within sixty (60) days after the Effective Date. The JSC shall engage in consultation, discussion and decision-making with respect to the following:

**3.1.1** A development plan for the Development of the Product in the Territory (the "Product Development Plan") and any material amendments thereto;

**3.1.2** A development plan for the Development of the Product and the Additional Indications by Intercept and/or its licensees outside the Territory(the "Intercept Development Plan"), and any material amendments thereto;

**3.1.3** Clinical trials to be conducted in connection with the Development of the Compound and the Product in the Field in the Territory; including, as appropriate Phase I Clinical Trials, Phase II Clinical Trials, Phase III Clinical Trials and Phase IV Clinical Trials, including review of synopses of clinical study protocols;

**3.1.4** Nonclinical studies, including CMC and formulations, to be conducted in connection with the Development of the Compound and the Product in the Field in the Territory;

**3.1.5** Development of Additional Indications to be conducted outside the Territory by Intercept and/or its licensees in connection with the Additional Indications Option;

**3.1.6** Matters related to Regulatory Approvals for Product in the Field in the Territory, including the formulation of a plan consistent with this Agreement for the exchange of and reporting to Regulatory Authorities of safety data reported or arising in the course of the Development;

**3.1.7** The activities of any sub-committees;

**3.1.8** Encouraging and facilitating communication between the Parties regarding the progress and results (whether preliminary or final) of the Development and Manufacturing activities for the Compound and the Product in the Field in the Territory, including the coordination of clinical and nonclinical data exchange and preparation of regulatory filings;

**3.1.9** The filing, maintenance, and abandonment, if any, of the Intercept Patents (including the Intercept Manufacturing Patents) and any patents issued on Improvements or Joint Improvements, and all Patent Term Extensions;

**3.1.10** Matters relating to the Manufacture of the Clinical Supplies and the Commercial Supplies, including the details and timing of the Technical Transfer;

**3.1.11** Establish internal rules for the governance and operation of the JSC; and

**3.1.12** Such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon by the Parties in writing from time to time.

**3.2 JSC Membership.** The initial membership of the JSC shall be comprised of three (3) representatives designated by each of DSP and Intercept, at least one(1) of whom from each Party shall be senior enough within its respective organization to have the requisite decision-making authority with respect to the matters set forth in Section 3.1 above, and all of whom shall have appropriate expertise and ongoing familiarity with the Development and Manufacturing of the Product in the Field in the Territory. From time to time, the number and qualifications of the designated members to the JSC may be changed by the mutual written agreement of the Parties, so long as an equal number of members from each of DSP and Intercept is maintained. Each Party shall inform the other Party of its initial representatives to the JSC as soon as practicable after the Effective Date. Each Party may also designate non-voting representatives to attend the meetings from time to time as necessity requires, but only with the consent of the other Party. The JSC shall be chaired by a representative from DSP, who shall be responsible for (i) calling meetings, (ii) preparing and issuing minutes of each such meeting as soon as practicable following each meeting, and (iii) preparing and circulating an agenda for the upcoming meeting, which shall include agenda items proposed by either Party no less than ten (10) calendar days prior to the next scheduled JSC meeting.

**3.3 JSC Meetings.** The JSC shall hold meetings at least once every six months, and more frequently as necessity requires. The first JSC meeting shall be held at a mutually agreed venue and date following the Effective Date. Meetings of the JSC shall be effective only if at least one (1) representative of each Party is present or participating. The JSC may meet either (i) in person at either Party's facilities, or (ii) by audio or video teleconference. Additional meetings of the JSC may also be held with the consent of each Party. Each Party shall be responsible for all of its own expenses incurred in connection with participating in the JSC meetings or any of the other committee meetings.

**3.4 Decision-Making.** The JSC shall endeavor to reach consensus on all matters brought before it pursuant to Section 3.1, with each Party having a single vote, irrespective of the number of representatives actually in attendance at a meeting. The JSC shall use Commercially Reasonable Efforts to resolve the matters brought before it pursuant to Section 3.1. DSP shall have the final decision making authority with respect to Development of the Compound and Product in the Field in the Territory. In the event that either Party has concern about whether the Development and the Commercialization of the Compound and/or the Product is reasonably likely to have a materially negative impact on the Compound or the Product inside or outside the Territory, the Parties shall consult through the JSC for a period of thirty (30) days; failing resolution of which, such matter shall be elevated to the CEO of Intercept and the CEO of DSP, for attempted resolution in good faith within the time frame set forth in Section 16.1.

**3.5 Progress Reports and Exhibit Amendments**. At each meeting of the JSC and, as applicable, that of any sub-committee or new committee established by the JSC, DSP shall provide Intercept with a written report summarizing its activities and progress regarding the Development and Commercialization of the Compound and Product in the Field in the Territory, including its marketing and promotional materials, which may, in DSP's option, be in the local language of the country in the Territory to which it pertains. At each meeting of the JSC, and, as applicable, that of any sub-committee or new committee established by the JSC, Intercept shall provide DSP with a written report summarizing its Development activities of the Compound and Product outside the Territory and its Development activities of the Additional Indications outside the Territory. In addition, at each meeting of the JSC, each Party shall inform the other of any Improvements conceived by or on behalf of such Party, as well as any Joint Improvements. Notwithstanding Section 17.4, upon the notification to the JSC through a progress report (or otherwise) of the filing of a patent application with respect to any Improvement or Joint Improvement, Exhibit A shall be deemed automatically amended, and an updated version of Exhibit A shall be distributed to the Parties together with the meeting minutes.

**3.6 Sub-committees.** From time to time, the JSC may establish and delegate duties to sub-committees to oversee particular projects or activities. Each such sub-committee shall be constituted and shall operate as the JSC determines. Each sub-committee and its activities shall be subject to the oversight, review and approval of, and shall report to, the JSC. It is contemplated that, at the appropriate time, the JSC will expand its scope of activity to include consultation, discussion and decision-making with respect to Commercialization or, alternatively, decide that a separate decision-making committee should be established to govern Commercialization planning and implementation. In the case that the JSC decides that such a new committee should be established, such committee shall be formed and governed according to the same principles as the JSC.

**3.7 Alliance Manager**. Each Party shall designate an alliance manager, who shall be responsible for the day-to-day coordination of the collaboration between the Parties and shall facilitate communication between the Parties. The Alliance Manager, may but need not be, one of the designated members of the JSC.

## 4. DEVELOPMENT AND COMMERCIALIZATION

### 4.1 Commercially Reasonable Efforts.

**4.1.1 DSP's Commercially Reasonable Efforts**. From and after the Effective Date, DSP shall use Commercially Reasonable Efforts to Develop and Commercialize the Compound and the Product in the Field (including with respect to any Additional Indications) in the Territory. Subject to Section 9.4, DSP shall be responsible for all costs and expenses incurred by it in connection with such Development and Commercialization activities.

**4.1.2 Intercept's Commercially Reasonable Efforts.** From and after the Effective Date, Intercept shall use Commercially Reasonable Efforts to Develop the Compound and the Product anywhere outside the Territory, either on its own or through Third Party licensees or subcontractors. In addition, from and after the Effective Date, Intercept shall (i) use Commercially Reasonable Efforts to Develop the Additional Indications outside the Territory in accordance with the Intercept Development Plan outside the Territory and (ii) shall use

Commercially Reasonable Efforts to cause each of its licensees to use Commercially Reasonable Efforts to Develop the Additional Indications outside the Territory.

**4.2 Information and Data Exchange**.

**4.2.1 Intercept Technology.** No later than thirty (30) days following Intercept's receipt of the Upfront Fee set forth in Section 9.1, Intercept shall transfer and otherwise make available to DSP, its Affiliates and its designated Third Party subcontractors the Intercept Technology and all material information and data relating thereto to enable DSP to engage in the Development and Commercialization of the Product in the Field in the Territory. The transfer of the Intercept Technology and related information and data shall be made in readily accessible electronic format wherever possible. Following the payment of the "Upfront Payment" pursuant to Section 9.1, Intercept shall, for no additional consideration, undertake to provide reasonable assistance DSP, its Affiliates and sublicensees.

**4.2.2 Non-Territory Data.** Intercept shall make available to DSP, its Affiliates and Third Party subcontractors any clinical and non-clinical data, post-marketing data and information which is generated by or in connection with Intercept and its licensees' Development of the Compound and Product, both in the Field and with respect to Additional Indications outside the Territory (the "Non-Territory Data"), which data and information may be used by DSP for [***] in connection with its Development, Commercialization and/or Manufacturing, as well as its activities to gain Regulatory Approval for the Product in the Field in the Territory. Intercept shall maintain Non -Territory Data in conformity with all applicable Laws and regulations and in a good scientific manner appropriate for patent and regulatory purposes. Intercept shall use Commercially Reasonable Efforts to cause any Third Party or Affiliate who is engaged in the Development of the Compound or Additional Indications outside the Territory to provide access to DSP and its Affiliates for the Non-Territory Data for [***].

**4.3 Necessary Third Party Patents**. In the event that DSP determines, in the exercise of sound business judgment, it is necessary to license or acquire Necessary Third Party Patents in connection with the Development, Manufacture or Commercialization of the Product in the Field in the Territory, it shall so notify Intercept in writing explaining the reasons therefor, following which the Parties shall engage in good faith discussions concerning such matter. DSP's request for Necessary Third Party Patents shall require Intercept's prior consent, which shall not be unreasonably withheld or delayed.

**4.4 Records.** DSP shall maintain scientific records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which will fully and properly reflect all work done and results achieved in the performance of the Development and Commercialization activities with respect to the Product in the Field in the Territory; all of the foregoing in conformity with standard pharmaceutical industry practices, the terms and conditions of this Agreement, and all applicable Laws and regulations (including re-examination systems for post-marketing information). DSP shall provide Intercept with reasonable access to the scientific records maintained by DSP pursuant to this Section 4.4 which may be used by Intercept in pursuance of its Development activities for the Compound and the Product outside the Territory.

**4.5 Cooperation.** Except as expressly forth herein, each Party shall, at its own cost and expense, provide all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the Development and Commercialization of the Product in the Field in the Territory. Further, Intercept shall provide reasonable assistance to DSP to prepare the regulatory materials for Regulatory Approval and to respond to Regulatory Authorities' inquiries and investigation relating to analysis of data arising from non-clinical studies, pre-clinical studies and/or clinical trials conducted by Intercept. In the event that a Regulatory Authority and/or DSP reasonably requests Intercept to disclose its data and documentation related to the Intercept Technology for an IND or NDA to be prepared or filed outside the Territory, Intercept shall cooperate with this request by providing such Regulatory Authority and DSP with the requested data and documentation. In the event that DSP reasonably requests to audit Intercept and its sub-contractors or licensees, Intercept shall, and shall cause its licensees and sub-contractors to, allow such audit, subject to customary prior notice requirements.

## 5. REGULATORY MATTERS

**5.1 Commercially Reasonable Efforts.** DSP shall use Commercially Reasonable Efforts, at its own expense, with respect to all regulatory activities concerning the Development and Commercialization of the Products in the Field in the Territory. DSP shall have sole responsibility for all pricing and reimbursement approval proceedings relating to each Product in the Field in the Territory. In the event that DSP wishes to commence Development of the Product in China following Intercept's receiving Regulatory Approval in the U.S. and prior to the receipt of Regulatory Approval in Japan, Intercept shall cooperate with DSP based on mutual good faith discussions. Upon reasonable prior notice and during normal business hours, Intercept shall, and shall cause its Affiliates and its Third Party sub-contractors to whom all or a part of the Development outside the Territory has been entrusted or contracted, to allow the inspection by a Regulatory Authority which is required as a condition of Regulatory Approval for the Product in the Field in the Territory. DSP shall use its Commercially Reasonable Efforts to provide any information concerning such inspection to Intercept in a timely manner. Intercept shall manage, but shall permit DSP or its designated representatives to be present at any inspection conducted by such Regulatory Authority. If any issue or concerns are raised concerning the Development of the Compound or the Product in connection with the inspection by such Regulatory Authority, Intercept shall immediately inform and discuss with DSP to solve the issue, including any recommendations made by the Regulatory Authority.

**5.2 Ownership of Regulatory Approvals**. DSP (or its designated Affiliate or sublicensee) shall be the holder of all Regulatory Approvals issued by Regulatory Authorities with respect to the Product in the Field in the Territory and shall be responsible, at its own cost, for preparing and, subject to Section 5.1 hereof, drafting all regulatory filings in the Territory (including any supplements or modifications thereto). DSP (or through its designated Affiliate or sublicensee) shall, subject to Section 5.1 above, be responsible for communicating with and negotiating with all Regulatory Authorities in the Territory and shall keep Intercept informed of the status of regulatory filings.

**5.3** **Pharmacovigilance.** The Parties agree to handle safety information including adverse events occurring or having occurred in connection with the use of the Compound or the Product in accordance with applicable Laws and requirements of relevant Regulatory Authorities. The Parties shall exchange all safety information including adverse events occurring or having occurred in connection with the use of the Compound or the Product. The Parties shall execute a separate agreement relating to safety matters on the Compound or the Product including the procedure for the exchange of safety information during the Term of the Agreement.

## 6. MANUFACTURING

**6.1** **Clinical Supply**. Intercept shall, by itself or through its Third Party contract manufacturers, supply to DSP (or its Affiliates, sublicensees or sub-contractors) all quantities of Clinical Supplies of the Product (packaged or prepackaged) required by DSP to Develop the Product in the Field in the Territory and for quality control analysis. The Parties shall discuss in good faith and cooperate with each other with respect to the negotiation of a manufacturing and clinical supply agreement (the "Clinical Supply Agreement") governing the supply of Clinical Supplies of the Product (packaged or pre-packaged). Intercept undertakes to improve quality assurance system and /or organization to supply DSP (or its Affiliates, sublicensees or sub-contractors) with Clinical Supply, including permitting and causing any of its Third Party sub-contractors to permit, an audit by DSP for quality assurance purposes. The Clinical Supply Agreement shall include, among other customary provisions, the following or substantially equivalent provisions:

**6.1.1** Intercept shall, before entering into any negotiations for an agreement with a Third Party contract manufacturer of Clinical Supplies for supply to DSP (or its Affiliates, sublicensees or sub-contractors) hereunder notify DSP of the fact. Thereafter, DSP shall have the right to provide input within thirty (30) days regarding the terms of such agreement (as well as any amendments thereof), review and comment on the draft agreement and participate in person in the negotiation of such agreement. However, Intercept shall have final determination of the terms**.** Further, Intercept shall provide DSP with an execution copy of each agreement between Intercept and any Third Party contract manufacturer.

**6.1.2** From time to time, DSP shall submit to Intercept purchase orders for quantities of Clinical Supplies and Intercept shall supply or have supplied to DSP such quantities of Clinical Supplies. DSP's sole financial liability with respect to Clinical Supplies shall be to reimburse Intercept for the Actual Costs. DSP shall provide Intercept with non-binding forecasts of DSP's purchase orders for Clinical Supplies which may be placed for the initial [***] ([***]) [***] after the Effective Date, and thereafter DSP shall provide Intercept with non-binding forecasts of DSP's purchase order for Clinical Supplies [***] ([***]) [***] prior to the estimated date of placing the purchase order. The purchase orders for Clinical Supplies shall be placed to allow no less than [***] ([***]) [***] lead time prior to the shipment dates specified in the purchase orders, and upon placement shall be deemed non-cancelable, unless Intercept indicates that it does not have sufficient stock of Clinical Supplies to accommodate the lead time specified in DSP's purchase order, in which event the lead time for the Clinical Supplies for such order shall be determined by mutual agreement of Intercept and DSP through good faith discussions; provided that should the Parties not reach agreement on an adjusted lead time, then DSP may cancel the relevant purchase order. Notwithstanding the foregoing, Intercept shall use best reasonable efforts to comply with the purchase orders. The risk of loss and damage for, and the title in, Clinical Supplies supplied hereunder shall pass to DSP upon delivery of the Clinical Supplies to the carrier designated by DSP. Shipment shall be FCA an international airport or port designated by Intercept as defined in INCOTERMS 2010, as amended. DSP may at any time elect to Manufacture or have Manufactured the Clinical Supplies, provided such election will not terminate any purchase orders for Clinical Supplies submitted by DSP to Intercept prior to notice of such election.

**6.1.3** Intercept shall invoice DSP for such Clinical Supplies with each shipment, clearly setting forth the calculation of the Actual Cost for the shipped order of the Clinical Supplies and DSP shall pay such invoices within thirty (30) days of its receipt of such invoice.

**6.2** **Commercial Supply.** Intercept shall supply DSP (or its Affiliates, sublicensees or sub-contractors) with all DSP's requirements of the Commercial Supplies until such time as DSP provides written notice to Intercept that DSP is ready to commence Manufacturing (or have Manufactured) of the Product on its own or on its behalf. Intercept shall be responsible for the Manufacture of the Commercial Supplies in compliance with the Specifications, GMP and all applicable Laws. The Parties shall discuss in good faith and cooperate with respect to the negotiation of a manufacturing and supply agreement (the "Commercial Supply Agreement") governing the supply of the Commercial Supply by or on behalf of Intercept, to DSP (or its Affiliates, sublicensees or sub-contractors) for the Commercialization of the Product in the Field in the Territory at the initiation of the Phase III Clinical Trials in Japan. In the event that manufacturing batches for the U.S. are conducted prior to the commencement of Phase III Clinical Trials in Japan, Intercept shall afford DSP a reasonable opportunity to comment upon and make suggestions with respect to such manufacturing validation, which Intercept shall use good faith efforts to incorporate on a going-forward basis. The Commercial Supply Agreement shall contain, in addition to other customary terms, the following terms and conditions:

**6.2.1** The transfer price for the first three orders of the Commercial Supply supplied to DSP by or on behalf of Intercept following receipt of Marketing Approval in Japan shall be calculated at the rate of [***] percent ([***]%) of [***] in effect on the date upon which each such order is sent to Intercept by DSP.

**6.2.2** The fourth and subsequent orders of the Commercial Supply supplied to DSP by or on behalf of Intercept following receipt of Marketing Approval in Japan shall be based on the Actual Cost plus [***] percent ([***]%) of the Actual Costs. The target actual cost is less than or equal to $[***] (the "Target Actual Cost"). In the event that the Actual Cost exceeds such Target Actual Cost, Intercept shall use Commercially Reasonable Efforts to reduce the Actual Cost. Should that not be possible, the Parties shall discuss in good faith an increased Target Actual Cost for the Product.

**6.2.3** Intercept shall, before entering into any negotiation for an agreement with a Third Party contract manufacturer of Commercial Supplies to DSP hereunder, notify DSP of the fact. Thereafter, DSP shall have the right to provide input regarding the terms of such agreement (as well as any amendments thereof), review and comment on the draft agreement and participate in person in the negotiation of such agreement. Further, Intercept shall provide DSP with an execution copy of each agreement between Intercept and any Third Party contract manufacturer.

**6.3** **Additional Supply Terms and Conditions.** In addition to the supply terms and conditions to be incorporated in the Clinical Supply Agreement and the Commercial Supply Agreement pursuant to Sections 6.1 and 6.2 respectively, each of the Clinical Supply Agreement and the Commercial Supply Agreement shall also include provisions substantially similar to the following:

**6.3.1** **Conformity.** All Products Manufactured and supplied by or on behalf of Intercept under each of the Clinical Supply and the Commercial Supply Agreement shall strictly conform to (i) the Specifications and (ii) GMP.

**6.3.2** **Change Control.** If Intercept wishes to change the Specifications, the location of the Manufacturing site, the Manufacturing process, or the raw materials, which in the case of each of the foregoing requires approval of the Regulatory Authorities, Intercept shall first obtain the prior written consent of DSP (not to be unreasonably withheld) and provide the information relevant to such proposed change to DSP, following which DSP shall use Commercially Reasonable Efforts to obtain any required approval from the Regulatory Authorities. Intercept shall provide DSP with all reasonable assistance with respect to the foregoing. When Intercept wishes to make any change in the Manufacturing process or the raw materials which, in either case, is subject to a reporting or notification requirement to Regulatory Authorities, Intercept shall notify DSP sufficiently in advance so that DSP may comply with such reporting or notification requirements. Prior to initiating any change in the Specifications, the location of the Manufacturing site, the Manufacturing process, or the raw materials, Intercept and DSP shall discuss in good faith and agree upon the quantity of a reasonable safety stock of the Product to be maintained until completion of the any proposed change.

**6.3.3** **GMP Audit by DSP.** DSP may audit the facilities of Intercept, its Affiliates or its Third Party subcontractors upon reasonable prior notice and during normal business hours. Intercept shall allow and shall cause its Affiliate or its Third Party subcontractors to allow such inspection to the extent such facilities relate to the Manufacture of the Compound and/or the Product. Intercept shall, and shall cause its Affiliates and Third Party sub-contractors, to use Commercially Reasonable Efforts to implement changes reasonably requested by DSP as a result of any GMP audit undertaken pursuant to the preceding sentence.

**6.3.4** **Inspection by Regulatory Authority.** Upon reasonable prior notice and during normal business hours, Intercept shall allow, and shall cause its Affiliates and its Third Party subcontractors to whom all or a part of the Manufacturing process of the Compound and/or the Product has been entrusted or contracted to allow, the inspection by the Regulatory Authority which is required as a condition for obtaining or maintaining Regulatory Approval for the Product in the Field in the Territory. DSP shall use its Commercially Reasonable Efforts to provide any information concerning such audit to Intercept in a timely manner. Intercept shall permit DSP or its designated representatives to be present at any audit conducted by any Regulatory Authority pursuant to this Section 6.3.4. If any issue or concerns are raised concerning the Manufacturing of the Compound or Product in connection with the audit by such Regulatory Authority, Intercept shall immediately inform DSP, including any recommendations made by the Regulatory Authority.

**6.3.5** **Quality Assurance Agreement.** The Parties shall enter into a mutually agreed-upon companion quality agreement (the "Quality Assurance Agreement") with respect to each of the Clinical Supply Agreement and the Commercial Supply Agreement, which shall set forth in detail the quality assurance arrangements and procedures of the Product and the GMP responsibilities between the Parties prior to the Manufacture of the Compound to be used for the first commercial lot of the Product.

**6.4** **Technical Transfer.** In the event that DSP wishes to commence the Manufacture of the Compound and/or Product itself (including having the Product Manufactured), DSP shall raise the issue to the JSC for consultation with Intercept with respect to the timing and other related details of the Technical Transfer of the Intercept Manufacturing Technology so to enable DSP to Manufacture or have Manufactured the Compound and the Product for Commercialization in the Territory.

**6.4.1** **Immediate Transfer.** Following consultation with the JSC, Intercept shall use Commercially Reasonable Efforts to make available, or cause to be made available, in either case, within sixty (60) days to DSP, its Affiliates, and its designated Third Party subcontractors, all relevant information, data, and Intercept Know-How relating to the Intercept Manufacturing Technology. To give effect to the foregoing, DSP shall have the right to obtain transfer and Intercept shall have the obligation to give immediate transfer free of charge to DSP, its Affiliates and its designated Third Party subcontractors, without undue delay, of any and all Intercept Manufacturing Technology necessary to enable DSP to Manufacture or have Manufactured the Compound and/or Product by a Third Party subcontractor to meet DSP's requirements (the foregoing, the "Technical Transfer").

**6.4.2** **Additional Licenses.** In connection with the Technical Transfer, Intercept hereby grants to DSP a non-exclusive right, non-royalty-bearing license, with the right to sublicense to its Affiliates and Third Party subcontractors, with prior notice to and reasonable approval of Intercept, to use the Intercept Manufacturing Technology both in the Territory and outside the Territory to engage in the Manufacture of the Compound and/or Product for Commercialization in the Territory. If any Intercept Manufacturing Technology is within the control or possession of a Third Party, Intercept shall use Commercially Reasonable Efforts to obtain the cooperation and assistance of such Third Party in connection with the Technical Transfer.

**6.4.3** **Assistance and Continued Supply Obligation**. Both Parties acknowledge that the process of DSP's becoming manufacturing-ready may require reasonable assistance from Intercept, which Intercept agrees to provide as reasonably requested. At the request of DSP made pursuant to Section 6.4, Intercept shall facilitate the transfer of the Intercept Manufacturing Technology from Intercept's contract manufacturers to DSP and/or its contract manufacturers, in which case the expenses reasonably incurred for the Technical Transfer shall be borne by DSP. During the Term of this Agreement, Intercept shall remain available to answer technology transfer questions relating to the Intercept Manufacturing Technology. In the event DSP should require any additional technical assistance beyond the Term of this Agreement, Intercept shall provide such assistance at DSP's expense to the extent Intercept has personnel available. Intercept makes no warranty, express or implied, with respect to the Intercept technical assistance. Further, Intercept shall supply the Clinical Supplies and Commercial Supplies to DSP hereunder until DSP indicates that it is ready to Manufacture or have Manufactured the Compound or Product. If, notwithstanding Intercept's Commercially Reasonable Efforts, Intercept reasonably determines that Manufacture and supply of the Commercial Supply are not practicable for a technical and/or economic reason, Intercept's commitment to supply Product may be terminated upon three (3) years prior written notice to DSP, in which event Intercept shall, (i) at DSP's option, (x) assign to DSP certain contracts between Intercept and its subcontractors which are selected by DSP or (y) arrange for DSP to negotiate its own terms and conditions with Intercept's subcontractors designated by DSP, and (ii) bear all reasonable cost and effects arising in connection with the Technical Transfer.

## 7. ADDITIONAL INDICATIONS OPTION

**7.1** **Development of Additional Indications for Products.** The Parties shall cooperate in good faith in generating ideas and concepts for Additional Indications for Products.

**7.2** **Grant of Option**. Subject to the terms and conditions of this Agreement and throughout the Term of the Agreement, Intercept hereby grants to DSP the exclusive option to an exclusive license to Products in the Territory for each and every Additional Indication (both present and future) on the same terms and conditions as provided for the Product in the Field (each such Additional Indication, an "Additional Indication Option"). For the avoidance of doubt, the rights granted to Intercept pursuant to Section 7.3.3 below with respect to Third Parties shall have effect only in the event that DSP declines to exercise a particular Additional Indications Option.

**7.3** **Exercise Period; Exercise of Additional Indications Option**. The period during which DSP may exercise each Additional Indications Option shall commence on the date that Intercept notifies DSP in writing of the "first patient" in a Phase III Clinical Trial for the target Additional Indication by Intercept and/or its licensees outside the Territory (the "Additional Indications Option Commencement Notice") and shall end on the [***] ([***]) [***] of the receipt by DSP of the Additional Indications Option Commencement Exercise Notice (the foregoing period, the "Additional Indications Exercise Period"). DSP may exercise each Additional Indications Option at any time during the Additional Indications Exercise Period by (i) providing written notice to Intercept that DSP has obtained required internal approvals to commence a pivotal clinical study for the target Additional Indication (the "Additional Indications Option Exercise Notice") and (ii) making payment of the applicable fee indicated in Section 7.3.1 below to a bank account designated by Intercept (each payment, an "Additional Indications Option Fee") within thirty (30) calendar days of dispatch of the Additional Indications Option Exercise Notice. The Additional Indications Option shall be deemed duly exercised on the date when Intercept has received both items (i) and (ii) (the "Additional Indications Option Effective Date").

**7.3.1** **Additional Indications Option Fee**. The Additional Indications Option Fee shall be US$[***] ([***] U.S. Dollars) for each Additional Indication. For the sake of clarity, no Additional Indications Option Fee is required to be paid upon the exercise of any Additional Indications Option in China. Upon the exercise of each Additional Indications Option, DSP shall be entitled to exercise the rights granted to it under Section 7.1 with respect to the target Additional Indication in the Territory as it is constituted on the Additional Indications Option Effective Date and as it may thereafter be constituted through the exercise by DSP of the Country Option.

**7.3.2** **License Grant.** Following each Additional Indications Option Effective Date, (i) the definition of "Field" shall be automatically amended and expanded to include the target Additional Indication and (ii) Intercept shall provide DSP with any copies and access to any Know-How or Technology in its Control relating to the target Additional Indication.

**7.3.3** **Non-Exercise of Additional Indication Option.** If DSP declines in writing to exercise any particular Additional Indications Option within the Additional Indications Exercise Period, then Intercept may grant the right to a Third Party to develop and commercialize the target Additional Indication in the Territory; provided that should any discussions with a Third Party not result in a binding written agreement for the target Additional Indication, then DSP's Additional Indications Option with respect to such target Additional Indication shall revive and the provisions of Article 7 shall apply thereto.

**7.4.** **Separate Nature.** For the sake of clarification, the exercise of the Additional Indications Option by DSP in connection with one of the Additional Indications shall not be construed as relieving Intercept of the obligation of complying with Articles 7.1-7.3 above with respect to each Additional Indication.

## 8. COUNTRY OPTION

**8.1** **Grant and Exercise of Country Option**. Intercept hereby grants to DSP the exclusive option to add any or all of the following countries to the Territory: Korea, Taiwan, Malaysia, Vietnam, the Philippines, Thailand, Singapore and Indonesia (the "Country Option"). DSP shall have a separate exclusive option with respect to each of the countries listed in the preceding sentence, such that the exercise by DSP of the Country Option with respect to one country shall not be deemed a waiver of its rights with respect to the other countries listed in the first sentence of this Section 8.1. Upon the exercise of the Country Option by DSP with respect to any particular country, such country shall be automatically deemed a part of the Territory. The exercise of the Country Option with respect to one country shall automatically include all Fields in the Territory.

**8.2** **Country Option Fee**. The Country Option shall be exercisable at DSP's discretion at any time from the Effective Date to the date of issuance of Marketing Approval for Commercialization of the Product in the Field in Japan by providing written notice of its intent to the exercise the Country Option (the "Country Option Exercise Notice"). DSP shall pay an exercise fee of US$[***] ([***] U.S. Dollars) per each country, due within [***] ([***]) [***] following exercise of the relevant Country Option. Unless exercised in accordance with this provision, or as otherwise set forth in this Agreement, the Country Option shall expire on the date upon which Regulatory Approval for the sale of the Product in the Field in Japan is issued.

**8.3** **Third Party Offers**. Notwithstanding the exclusive option granted to DSP in Section 8.1 hereof, following the [***] ([***]) [***] of the Effective Date, in the event that Intercept desires to accept or make a bona fide offer from a Third Party for the exclusive development and/or commercialization rights for the Product in countries listed in the first sentence of Section 8.1 (the "Target Country"), Intercept shall immediately notify DSP in writing and indicate the Target Country, desired indications, and provide a summary of the material financial terms and conditions of the offer (the "Third Party Offer Notice"). Within forty-five (45) calendar days of receipt of the Third Party Offer Notice, DSP shall notify Intercept in writing whether or not it wishes to exercise the Country Option for the Target Country (the "Country Exercise Option Notice"). If DSP desires to exercise the Country Option for the Target Country, DSP shall make the payment of the Country Option Fee for the Target Country to a bank account designated by Intercept no later than thirty (30) calendar days following dispatch of the Country Exercise Option Notice. If DSP declines to exercise the Country Option for the Target Country, then Intercept shall be free to negotiate with the Third Party on terms no less materially favorable than those contained in the Third Party Offer Notice; provided that should such negotiations fail, then DSP's Country Option shall revive with respect to the Target Country.

**8.4** **Right of First Negotiation**. Prior to accepting or making a bona fide offer from or to a Third Party with respect to the exclusive development and commercialization rights for the Compound in the Field (including all Additional Indications) in the U.S. and Canada, Intercept shall promptly deliver a written notice thereof to DSP. Intercept and DSP shall engage in good faith negotiations, but to avoid any confusion, Intercept shall also be free to engage in good faith negotiations with such Third Party Offeror; provided that should the parallel discussions between Intercept and such Third Party and Intercept and DSP not result in a binding agreement, then this Right of First Negotiation shall revive with respect to any subsequent offers from or to third parties with respect to the rights described in this Section 8.4. Further, in the event that DSP terminates the Agreement based on the cessation of development of the Compound or the Product by Intercept, then immediately following such termination, DSP and Intercept shall engage in good faith discussions concerning the exclusive development and commercialization rights for the Compound in the Field (including all Additional Indications) in the U. S. and Canada.

## 9. PAYMENTS

**9.1 Upfront Fee.** DSP shall make a one-time, non-refundable, non-creditable payment to Intercept of US$15,000,000 (Fifteen Million Dollars) ("Upfront Fee") within thirty (30) calendar days of the Effective Date to a bank designated in writing by Intercept. It is acknowledged that this upfront fee shall include the consideration for the rights granted to DSP in Section 8.4. All references to "fiscal year" shall refer to the Japanese fiscal year which ends on March 31 of each calendar year and indicate that it applies to all sub-sections in Article 9 and also Article 10.

**9.2 Milestone Payments.** The milestone payments set forth in this Section 9.2 shall be paid only once, upon the first achievement of the applicable milestone event in the applicable listed geographic area. For purposes of determining whether a milestone event set forth in Sections 9.2.2 and 9.2.3 has occurred (and without creating an obligation to pay the milestone more than once as set forth in the preceding sentence), Net Sales for each fiscal year shall be aggregated for all Products sold in the Territory during the relevant fiscal year.

**9.2.1** Within thirty (30) calendar days following the occurrence of each of the events set forth below for the Product, DSP shall pay to Intercept each of the non-refundable, non-creditable milestone payments set forth below:

| Milestone Event | Milestone Payment |
|---|---|
| **Development Milestones** | |
| Japan | |
| PBC-Commencement of Phase III Clinical Trial | US$[***] |
| PBC-Marketing Approval | US$[***] |
| NASH-2nd indication-Marketing Approval | US$15,000,000.00 |
| Additional Indications-Marketing Approval | US$[***] |
| China | |
| PBC-Commencement of Phase III Clinical Trial | US$[***] |
| PBC-Marketing Approval | US$[***] |
| NASH-2nd indication-Commencement of Phase III Clinical Trial | US$[***] |
| NASH-Marketing Approval | US$10,000,000.00 |
| Additional Indications-Commencement of Phase III Clinical Trial | US$[***] |
| Additional Indications-Marketing Approval | US$[***] |

| | |
|---|---|
| United States | |
| PBC-Marketing Approval | US$3,000,000.00* |
| NASH Successful NIH Clinical Trial | US$[***]** |
| NASH-Marketing Approval | US$[***]*** |
| Other Asian countries | |
| PBC-Initiation of clinical trial | US$[***] |
| PBC-Marketing Approval | US$[***] |
| Additional Indications-Initiation of clinical trial | US$[***] |
| Additional Indications-Marketing Approval | US$[***] |

*In the event that the WAC exceeds US$[***] per day before approval in Japan, then an amount of US$2,000,000.00 shall be paid as an additional milestone payment (i.e., a total of US$5,000,000.00).

**The milestone payment for the NASH NIH clinical trial is conditioned on the results being available no later than [***], and supporting a decision by the JSC to continue Development of the Product for the NASH indication.

***In the event that (i) the NASH Marketing Approval in the U.S. occurs prior to the end of 2017 (i.e., based on a sNDA submission of the NIH clinical trial data) and DSP is able to use these data in support of a NDA submission in Japan, then the additional amount of US$[***] shall be paid (i.e., a total of US$[***]); but (ii) if the NASH Marketing Approval in the U.S. occurs after the Marketing Approval in Japan, then no milestone payment of US$[***] as set forth in the chart above shall be due.

**9.2.2** **Sales Milestones.** Within sixty (60) calendar days following the end of each calendar quarter in which any event set forth below occurs, DSP shall notify Intercept of such event via the reports as indicated in Section 10.1 and within sixty (60) calendar days following the end of such calendar quarter shall pay to Intercept each of the non-refundable, non-creditable milestone payments set forth below. For the avoidance of doubt, in the event that two or more of the events set forth below occur during the same calendar quarter, then DSP shall pay to Intercept the aggregate of the applicable sales milestone payments set forth below in the manner set forth in the first sentence of this Section 9.2.2.:

| | |
|---|---|
| Net Sales exceed US$50 Million (one time only payment) | US$5,000,000.00 |
| Net Sales exceed US$100 Million (one time only payment) | US$10,000,000.00 |

| | |
|---|---|
| Net Sales exceed US$200 Million (one time only payment) | US$20,000,000.00 |
| Net Sales exceed US$400 Million (one time payment only) | US$40,000,000.00 |
| Net Sales exceed US$1,200 Million (one time payment only) | US$120,000,000.00 |

**9.2.3** **Royalty Tiers.** DSP shall pay to Intercept a royalty of [***] percent ([***]%) based on total annual Net Sales of all Products in the Field in the Territory for each fiscal year (i.e. ending on March 31 of each calendar year) in which the Net Sales of all Products in the Territory for such year is less than US$[***] (the "First Tier Royalty Rate"). DSP shall pay to Intercept a royalty of [***] percent ([***]%) based on total annual Net Sales of all Products in the Field in the Territory for each fiscal year in which the Net Sales of all Products in the Territory for such year is US$[***] or more but less than US$[***] (the "Second Tier Royalty Rate"). DSP shall pay to Intercept a royalty of [***] percent ([***]%) based on total annual Net Sales of all Products in the Field in the Territory for each fiscal year in which the Net Sales of all Products in the Territory for such year exceeds US$[***] (the "Third Tier Royalty Rate"). Notwithstanding the foregoing, the transfer price for the [***] of the Commercial Supplies to DSP by Intercept following receipt of Marketing Approval in Japan shall be calculated in accordance with Section 6.2.1 and shall be deemed to including the running royalty payment, and accordingly no further royalty payments by DSP shall be required with respect thereto; however in no event will the transfer price be less than the [***] percent ([***]%) plus the applicable First, Second or Third Tier Royalty Rate.

**9.3** **Reduced Royalty Rates for Net Sales**

**9.3.1** **Reduced Royalty Rates in Countries Excluding Japan**. If at any time [***] of the First Commercial Sale in a country in the Territory (excluding Japan), a generically equivalent product enters the market and captures more than [***] percent ([***]%) of the market share as determined by unit sales ("Market Share") for [***], then the country shall be designated an "Eroded Country" beginning the first day of the next calendar quarter. For the purpose of determining royalty payments due on an Eroded Country's Net Sales, total annual Net Sales will be assessed country-by-country and not aggregated with other country Net Sales in the Territory. The reduced royalty rates that shall apply in an Eroded Country are as follows:

i. Eroded Country Net Sales up to US$[***] assessed at [***] percent ([***]%); and
ii. Eroded Country Net Sales of US$[***] up to (but less than) US$[***] assessed at [***] percent ([***]%); and
iii. Eroded Country Net Sales of US$[***] or more assessed at [***] percent ([***]%).

Thereafter, DSP's Market Share in each subsequent calendar quarter will be assessed and if the Market Share is restored to [***] percent ([***]%) or above then the royalty rates set forth in Section 9.2.3 shall apply again to Net Sales in that country, which shall be aggregated with all other Net Sales (excluding Eroded Country Net Sales), and if the Market Share remains or falls back below [***] ([***]%) in any calendar quarter, then the Eroded Country reduced royalty rates set forth in this Section 9.3.1 shall apply. The JSC shall be responsible for determining the most effective means to implement an effective Market Share, Net Sales and royalty tracking system in the Territory in order to give effect to DSP's royalty payment obligations hereunder.

**9.3.2** **Reduced Royalty Rates in Japan**. The royalty rates set forth in Section 9.2.3 shall remain in effect with respect to total annual Net Sales in Japan until such time as (i) the substance patent in Japan expires (after taking into account all available extensions) and (ii) a generically equivalent product enters the market and captures more than [***] percent ([***]%) of the Market Share for [***]. Thereafter, beginning the first day of the next calendar quarter, Japan shall be designated an Eroded Country and DSP shall pay Intercept a reduced royalty of [***] percent ([***]%) on total annual Net Sales in Japan for [***] of such designation, [***] percent ([***]%) on total annual Net Sales for the [***] of such designation, and then [***] percent ([***]%) on total annual Net Sales thereafter. Once Japan has been designated as an Eroded Country, DSP's Market Share in each subsequent calendar quarter will be assessed and if the Market Share is restored to [***] percent ([***]%) or above then the royalty rates set forth in Section 9.2.3 shall apply again to Net Sales in Japan, which shall be aggregated with all other Net Sales (excluding Eroded Country Net Sales), and if the Market Share remains or falls back below [***] percent ([***]%) then the Eroded Country reduced royalty rates set forth in this Section 9.3.2 shall apply at the applicable royalty rate based on the cumulative number of quarters that had previously passed while Japan had been designated an Eroded Country. The JSC shall be responsible for determining the most effective means to implement an effective Market Share, Net Sales and Royalty tracking system in the Territory in order to give effect to DSP's royalty payment obligations hereunder.

**9.4** **Necessary Third Party Technology Payments**. DSP shall be entitled to deduct [***] percent ([***]%) of all royalties it is required to pay to a Third Party for Necessary Third Party IP under any agreement to license or acquire intellectual property used in the Development or Commercialization of the Product in the Field in the Territory up to a maximum of [***] percent ([***]%) for purposes of Section 9.2.3, or [***] percent ([***]%) for purposes of Section 9.3.1 or 9.3.2 of the applicable royalty rate.

## 10. PAYMENT; RECORDS; AUDITS

**10 .1** **Payment; Reports.** Royalties shall be calculated and reported during the fiscal year for each calendar quarter. All payments due to Intercept under this Agreement shall be paid within sixty (60) calendar days after the end of each calendar quarter. DSP shall deliver to Intercept (i) within thirty (30) calendar days after the end of each calendar quarter a report of gross sales of Product in the Territory and (ii) within sixty (60) days after the end of each calendar quarter, a report certified by DSP as accurate to the best of its ability based on information then available to DSP, setting forth for such calendar quarter the following information on a country-by-country basis and other such information to permit confirmation of the accuracy of the information for which payments are calculated including: (i) gross and Net Sales of Product, (ii) the basis for any adjustments to the royalty payable for the sale of Product, and (iii) the royalty due hereunder for the sale of Product. All payments hereunder shall be payable in U.S. dollars. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Intercept. Conversion of foreign currency to U.S. Dollars shall be made at the Telegraphic Transfer Selling (TTS) rate published by Sumitomo Mitsui Banking Corporation or any other mutually agreed upon source, in effect on the last day of each calendar month within each calendar quarter to the Net Sales that was deemed sold during such month with respect to royalty and sales milestones payments under Sections 9.2.2 and 9.3 and for the previous day of the notification of the development milestone under Section 9.2.1.

**10.2** **Tax Withholding.** Intercept shall be responsible for any income taxes payable by Intercept on payments made to it under this Agreement. If applicable Laws require that taxes be deducted and withheld from a payment due from DSP to Intercept under this Agreement, DSP shall (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing authority; and (iii) send evidence of the proof of payment to Intercept promptly following that payment. Intercept shall provide DSP with documentation necessary for DSP to file an application with the applicable tax authorities to avoid or reduce withholding or other applicable taxes under any applicable tax treaty.

**10.3** **Audits.** During the Term and for a period of three (3) years thereafter, DSP shall keep (and shall cause its Affiliates and sublicensees to keep) complete and accurate records pertaining to the sale or other disposition of Products in the Field in the Territory and calculations of Net Sales and payments required under this Agreement in sufficient detail to permit Intercept to confirm the accuracy of all payments due to it hereunder. Notwithstanding the foregoing, should applicable Law in the Territory require DSP to retain records of the nature described in the preceding sentence for a period longer than that set forth in the preceding sentence, DSP shall retain such records for the longer period; provided that Intercept shall advise of any applicable record-keeping requirements imposed by laws outside the Territory. Intercept shall have the right to cause an independent, certified public accountant reasonably acceptable to DSP to audit such records to confirm Net Sales, royalty, milestone and other payments for a period covering up to but not more than the preceding twelve (12) calendar quarters; provided that any such accountant shall have previously entered into a confidentiality agreement reasonably satisfactory to DSP limiting its disclosure of such information to authorized representatives of the Parties or as required under applicable Laws. Any such inspection shall be for the sole purpose of verifying the calculation of payments on Net Sales of the Products in the Field in the Territory by DSP, and its Affiliates or sublicensees and milestone, royalty and other payments paid by DSP under this Agreement. The accountant shall only disclose to Intercept the findings of the audit and the specific details concerning any discrepancies. No other information shall be provided to Intercept. Such audit rights may be exercised during normal business hours upon reasonable prior written notice to DSP; provided that such audit right may be exercised no more than once in any twelve (12) -month period. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Intercept shall bear the full cost of such audit unless such audit discloses an underpayment by DSP of more than [***] percent ([***]%) of the amount of royalties or other payments due under this Agreement, in which case, DSP shall bear the full cost of such audit.

## 11. TREATMENT OF CONFIDENTIAL INFORMATION

**11.1** **Confidential Obligations**. DSP and Intercept each recognize that the other Party's Confidential Information constitutes highly valuable and proprietary confidential information. Intercept and DSP each agree that during the Term of this Agreement and for five (5) years thereafter, it will keep confidential, and will cause its employees, consultants, contractors, Affiliates and sublicensees to keep confidential, all Confidential Information of the other Party. Neither Intercept nor DSP, nor any of their respective employees, consultants, Affiliates or sublicensees shall use Confidential Information of the other Party for any purpose whatsoever other than exercising any rights granted to it or reserved by it hereunder. Without limiting the foregoing, each Party may disclose information to the extent such disclosure is reasonably necessary to (i) file and prosecute patent applications and/or maintain patents which are filed or prosecuted in accordance with the provisions of this Agreement, or (ii) file, prosecute or defend litigation in accordance with the provisions of this Agreement or (iii) comply with applicable Laws, regulations or court orders; provided, however, that if a Party is required to make any such disclosure of the other Party's Confidential Information in connection with any of the foregoing, it will give reasonable advance notice to the other Party of such disclosure requirement and will use reasonable efforts to assist such other Party in efforts to secure confidential treatment of such information required to be disclosed.

**11.2** **Publication.** If either Party plans to publish or present the results of any studies or other data regarding the Compound, the Product or Additional Indications conducted in and outside the Territory, the Party shall submit the draft of the publication, translated into English, to the other no later than four (4) weeks prior to the planned submission for publication for approval, unless such disclosure requires immediate publication due to disclosure requirements of the U.S. Securities and Exchange Commission, the NASDAQ stock exchange or any other stock exchange on which securities issued by a Party are traded and Intercept has advised DSP of the deadline for disclosure in a sufficiently timely manner. As soon as a Party is aware of a deadline for submitting an abstract for an

upcoming scientific meeting, it shall notify the other Party in writing and the Parties shall use Commercially Reasonable Efforts to exchange comments on the proposed abstract in a timely manner to facilitate the publication/presentation of the proposed abstract. Otherwise, any publication shall need the other Party's prior written consent, which shall not be unreasonably withheld. Any comment, reasonable request for modification or reasonable rejection must be made within as quickly as practically possible from the receipt of the draft. Failure to quickly make such comments shall be conclusively deemed to constitute approval of such publication or presentation. For the avoidance of doubt, this Section 11.2 shall apply to publications made by either Party both in the Territory and outside the Territory.

**11.3** **Publicity**. DSP and Intercept may, by mutual written agreement, issue a press release announcing the execution of this Agreement, which shall be substantially in a form approved by the Parties. Except with respect to such initial release or as otherwise required by applicable Laws (including disclosure requirements of the U.S. Securities and Exchange Commission, the NASDAQ stock exchange or any other stock exchange on which securities issued by a Party are traded), neither Party shall issue an additional press release or public announcement relating to this Agreement without the prior written approval of the other Party, which shall not be unreasonably withheld or delayed. In the event that a Party wishes to refer to the other Party or the transactions under this Agreement in promotional or other communications with prospective customers and investors, such Party shall first provide the other Party with advance notice of such proposed disclosure and the form, substance and intended use of such proposed disclosure and obtain the prior written approval of the other Party to the form, substance and intended use of such proposed disclosure.

## 12. FILING, PROSECUTION AND MAINTENANCE OF PATENT RIGHTS

**12.1 Patent Filing, Prosecution and Maintenance**. Subject to the other terms of this Section 12.1, Intercept shall be responsible for preparing, filing, prosecuting, obtaining and maintaining**,** all Intercept Patents in the Territory. Intercept (i) will provide DSP with a copy of any proposed patent application or prosecution or other document relating to a patent or application within the Intercept Patents and to the Field (and the Additional Indications) for review and comment reasonably in advance of filing which shall under no circumstances be less than thirty (30) days, and (ii) will keep DSP reasonably informed of the status of such filing, prosecution and maintenance.

**12.2 Enforcement**. If, during the Term, either Party learns of any actual, alleged or threatened infringement by a Third Party of any Intercept Patent under this Agreement, such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such infringement. Intercept shall have the first right (but not the obligation), at its own expense and with legal counsel of its own choice, to bring suit (or take other appropriate legal action) against any actual, alleged or threatened infringement of the Intercept Patent in the Field in the Territory; provided that the settlement of such matter shall require DSP's consent, not to be unreasonably withheld or delayed. DSP shall have the right, at its own expense, to be represented in any such action by counsel of DSP's own choice. If Intercept does not file any action or proceeding against any such material infringement, with material infringement determined using reasonable commercial standards (including obtaining the advice of patent counsel), within three (3) months after the later of (i) DSP's notice to Intercept hereunder, (ii) Intercept's notice to DSP hereunder, or (iii) a written justified request from DSP to take action with respect to such infringement, then DSP shall have the right (but not the obligation), at its own expense, to bring suit (or take other appropriate legal action) against such actual, alleged or threatened infringement, with legal counsel of its own choice, including the right to settle any such suit without the prior consent of Intercept, who shall render all assistance reasonably required or requested by DSP. Irrespective of which party is taking the lead with respect to the defense of a claim, the party taking the lead shall keep the other party reasonably informed as to the status of any such action and shall give due regard to the comments and suggestions of the other Party with respect to the defense of such claims. Any damages, monetary awards or other amounts recovered, whether by judgment or settlement, pursuant to any suit, proceeding or other legal action taken under this Section 12.2, shall applied as follows:

(a) first, to reimburse the Parties for their respective costs and expenses (including reasonable attorneys' fees and costs and costs for providing assistance) incurred in prosecuting such enforcement action, and

(b) second, any amounts remaining shall be allocated [***] percent ([***]%) to the Party initiating the legal action and [***] percent ([***]%) to the other Party, if the other Party provides material assistance, as determined using reasonable commercial standards, and if not then, [***] ([***]%) to the initiating Party.

If a Party brings any such action or proceeding hereunder, the other Party agrees to be joined as party plaintiff if necessary to prosecute such action or proceeding, and to give the Party bringing such action or proceeding reasonable assistance and authority to file and prosecute the suit; provided, however, that neither Party shall be required to transfer any right, title or interest in or to any property to the other Party or any Third Party to confer standing on a Party hereunder.

**12.3 Defense.** Each Party shall promptly notify the other Party in writing of any allegation by a third Party that the activity of either of the Parties or their Affiliates or sublicensees pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. Intercept shall have the right to control, at its own expense, the defense of any claim alleging that the Development, Manufacturing or Commercialization of the Product in the Field in the Territory infringes any such Third Party rights. If Intercept fails to proceed in a timely manner with respect to such defense, DSP shall have the option to assume control the defense of such claim. As a general matter, the Parties acknowledge that Intercept, as the licensor of the Intercept Technology shall, in principle, be responsible for all costs associated with maintaining validity of the Intercept Technology. Nonetheless, in light of the fact that Intercept is in an early-stage development company, DSP is willing to bear [***] percent ([***]%) of reasonable and actual costs and expenses incurred by DSP in connection with any defense of which DSP assumes control (the "DSP Defense Costs"), with the remainder being reimbursed by Intercept in the form of reduced royalties owed to it from DSP pursuant to Section 9.3, provided that in the event of an Intercept Change of Control, DSP may reduce the percentage of DSP Defense Costs for which DSP is responsible. Notwithstanding anything to the contrary herein, from the [***] ([***]) anniversary of the Effective Date, the preceding proviso shall become null and void, such that Intercept shall be fully responsible for all actual and reasonable costs incurred by DSP in any defense which it assumes pursuant to this Section 12.3. Irrespective of which Party is taking the lead with respect to the defense of a claim, the Party taking the lead shall keep the other Party reasonably informed as to the status of any such action and shall give due regard to the comments and suggestions of the other Party with respect to the defense of such claims. DSP shall have the right to participate in the defense of any such claim with counsel of its choice at its own expense. Intercept shall not have the right to settle any claim or litigation described in this Section 12.3 without the consent of DSP, such consent not to be unreasonably withheld; notwithstanding which, in the event that DSP assumes control of the defense of any such claim in accordance with this Section 12.3, then DSP shall be entitled to settle such matter in its reasonable discretion. If a Party brings any such action or proceeding hereunder, the other Party agrees to be joined as party plaintiff if necessary to prosecute such action or proceeding, and to give the Party bringing such action or proceeding reasonable assistance and authority to file and prosecute the suit; provided, however, that neither Party shall be required to transfer any right, title or interest in or to any property to the other Party or any Third Party to confer standing on a Party hereunder.

**12.4 Ownership of Improvements.** Intercept shall solely own all Improvements that are made, conceived or reduced to practice solely by one or more employees or contractors of either Intercept arising in connection with the performance by Intercept of its obligations hereunder. Intercept hereby grants to DSP the exclusive right to use all such Intercept Improvements in the Territory during the Term of this Agreement. DSP shall solely own all Improvements that are made, conceived or reduced to practice solely by one or more employees or contractors of DSP arising in connection with the performance by DSP of its obligations hereunder. DSP hereby grants to Intercept the non-exclusive right to use all such DSP Improvements outside the Territory during the Term of this Agreement. Each of DSP and Intercept shall have the right, in its discretion, but subject to the terms and conditions of this Agreement, to file patents applications with respect to their respective Improvements.

**12.5 Joint Improvements**.

**12.5.1 Ownership and Disclosure.** DSP and Intercept shall be joint owners in and to any and all Joint Improvements and any Patents claiming such Joint Improvements. Subject to the terms and conditions of this Agreement, DSP and Intercept, as joint owners of the Joint Improvements, shall have the right to practice and exploit the Joint Improvements without any obligation to account to the other for profits. Any assignment of an interest in a Joint Improvement shall require the prior consent of the other Party, such consent not to be unreasonably withheld. Each Party agrees to be named as a party, if necessary, to bring or maintain a lawsuit involving a Joint Improvement. Each Party shall promptly report to the other Party in writing, through the JSC, and shall cause its Affiliates, licensees (including sublicensees), and contractors (including subcontractors) to so disclose, the invention or conception of any Joint Improvements.

**12.5.2 Prosecution and Maintenance.**

(i) Inside the Territory, DSP shall have the first right to prepare, file, prosecute and maintain Joint Improvements at its own cost and expense. Through its progress reports submitted to the JSC pursuant to Section 3.5, DSP shall keep Intercept informed of the status of all filings related to the Joint Improvements (including the nature of any objections and other information reasonably requested by Intercept) and will provide Intercept with copies, in either English or Japanese, of all substantive documentation submitted to, or received from, the patent offices in connection therewith. DSP shall provide Intercept with the right to comment on the documentation. The Parties shall cooperate reasonably in the prosecution of all Patents covering the Joint Improvements if practicably possible and shall share all material information relating thereto promptly after receipt of such information. If during the Term of this Agreement, DSP intends to allow any Patent claiming a Joint Improvement to expire or intends to otherwise abandon any such Patent in the Territory, or decides not to file patent applications covering or claiming a Joint Invention in the Territory, DSP shall notify Intercept of such intention or decision at least ninety (90) days prior to any filing or payment due date, or any other that requires action, in connection with such Patent in the Territory, and Intercept shall thereupon have the right, but not the obligation to assume responsibility for the preparation, filing, prosecution or maintenance thereof at its sole cost and expense, in the name of and solely owned by Intercept.

(ii) Outside the Territory, Intercept shall have the first right to prepare, file, prosecute and maintain Joint Improvement at its own cost and expense. Intercept shall keep DSP informed of the status of all filings related to the Joint Improvement and will provide Intercept with copies, in either Japanese or English, of all substantive documentation submitted to, or received from, the patent offices in connection therewith. Intercept shall provide DSP with the right to comment on the documentation. The Parties shall cooperate reasonably in the prosecution of all Patents covering the Joint Improvement if practicably possible and shall share all material information relating thereto promptly after receipt of such information. If during the term of this Agreement, Intercept intends to allow any Patent claiming a Joint Improvement to expire or intends to otherwise abandon any such Patent outside the Territory, or decides not to file patent applications covering or claiming a Joint Invention in the Territory, Intercept shall notify DSP of such intention or decision at least ninety (90) days prior to any filing or payment due date, or any other that requires action, in connection with such Patent outside the Territory, and DSP shall thereupon have the right, but not the obligation to assume responsibility for the preparation, filing, prosecution or maintenance thereof at its sole cost and expense, in the name of and solely owned by DSP.

**12.5.3** **Enforcement; Defense**. Through the JSC, the Parties shall develop a process to coordinate the defense of Patents claiming a Joint Improvement, including cost-sharing allocation, both inside and outside the Territory; provided that should the Parties be unable to resolve any disagreement regarding the defense of a Patent claiming a Joint Improvement, such issue shall be resolved in accordance with Section 12.5.4.

**12.5.4** **Ownership and Other Disputes**. The JSC shall resolve any issues regarding inventorship or ownership of Joint Improvements and the defense of any Patent claiming a Joint Improvement pursuant to the provisions of Article 12. In connection with the resolution of this issue, each Party is entitled to have a patent lawyer of its own choosing attend the meeting and submit its written legal opinion. In the event that the JSC is unable to reach a decision, the matter shall be referred for resolution to a patent counsel, reasonably acceptable to both Parties, who is affiliated with a firm of international repute. The decision of such patent attorney shall be rendered in writing and shall be final and binding on the parties. Each Party shall bear its own costs and expenses for legal advice provided to it in accordance with the second sentence of this Section 12.5.3. All costs and expenses incurred in connection with the mutually appointed patent attorney shall be shared equally.

**12.6** **Trademarks.** DSP shall own and have sole control over all matters relating to the use of all trademarks (and all associated goodwill) used in the sale of Products in the Field in the Territory. DSP shall be solely responsible for trademark searches, prosecution of applications to register and to record licenses (if applicable), and maintenance of the Product-related trademarks in the Territory as well as costs and expenses incurred in connection with the foregoing. If Intercept becomes aware of any actual or threatened infringement of any Product-related trademark by a Third Party, it shall promptly notify DSP, who shall be responsible for enforcing the Product-related trademarks.

## 13. REPRESENTATIONS, WARRANTIES AND COVENANTS

**13.1 Intercept's Representations**. Intercept represents and warrants to DSP that as of the Effective Date and throughout the Term of this Agreement:

(a) The execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Intercept corporate action;

(b) This Agreement is a legal and valid obligation binding upon Intercept and enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by the Parties, and does not conflict with any agreement, instrument or understanding to which Intercept is a party or by which it is bound;

(c) Intercept has, to the best of its knowledge, the full right and legal capacity to grant the rights granted to DSP hereunder without violating the rights of any Third Party, and is the sole and exclusive owner of the Intercept Technology and the Intercept Manufacturing Technology, all of which are free and clear of any liens, charges and encumbrances.

(d) To Intercept's best knowledge, there are no pending legal actions, nor is Intercept aware of the receipt of any written notice regarding any pending legal actions or threatened claims (including pending re-examination, opposition or interference), with respect to the Intercept Technology or the Intercept Manufacturing Technology, or litigation seeking to invalidate any Intercept Technology or any Intercept Manufacturing Technology;

(e) Intercept owns the Intercept Patents listed on Exhibit A, has not assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Intercept Patents, Intercept Know-How, or Intercept Manufacturing Technology in the Territory.

(f) Intercept has not granted, and during the Term of this Agreement will not grant, rights to any Third Party under the Intercept Technology or the Intercept Manufacturing Technology that conflict with the rights granted to DSP hereunder.

(g) Intercept is not aware of any safety, efficacy, or regulatory issues, other than the information that has previously been made available to DSP in writing that would preclude DSP from Developing, Manufacturing, or otherwise Commercializing the Products in the Field in the Territory.

(h) To Intercept's best knowledge, DSP's exercise of its rights with respect to the Intercept Technology and the Intercept Manufacturing Technology shall not infringe any patent or other intellectual property right of any Third Party.

(i) All material Development activities with respect to the Product whether clinical, non-clinical or preclinical conducted by Intercept or at its request, has been, and shall be conducted in compliance with all applicable Law, including but not limited to Good Manufacturing Practices, Good Clinical Practice and Good Laboratory Practices.

**13.2 DSP Representations**. DSP represents and warrants to Intercept that as of the Effective Date:

(a) the execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate DSP corporate action; and

(b) this Agreement is a legal and valid obligation binding upon DSP and enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by the Parties does not conflict with any agreement, instrument or understanding to which DSP is a party of or by which it is bound.

(c) to DSP's knowledge, DSP's exercise of its rights with respect to the Intercept Technology and the Intercept Manufacturing Technology shall not infringe any patent or other intellectual property right of any Third Party.

**13.3 Change of Control Covenant.** Intercept shall provide DSP with prior written notice of a proposed or contemplated Intercept Change of Control and shall use Commercially Reasonable Efforts to afford DSP an opportunity to meet with the potential acquirers (or the like) to discuss any necessary or advisable amendments to this Agreement no later than 60 days prior to the effective date of the Intercept Change of Control.

**13.4 Competitive Products.** DSP shall not engage, directly or indirectly, in the commercialization of any other product FXR agonist compound or product in the Field within the Territory. For the avoidance of doubt, this does not include manufacturing, research or development activities. Further, this provision shall not apply to any country in the Territory or any indication with respect to which the nature of the rights granted to DSP under this Agreement are converted to non-exclusive rights by Intercept pursuant to Section 15.2(c) of this Agreement.

**13.5 No Warranties**.

Nothing in this Agreement is or shall be construed as:

(a) a warranty or representation by either Party as to the validity, enforceability, or scope of any patent application or patent licensed hereunder or

(b) a warranty or representation that anything made, used, sold or otherwise disposed of under any license granted pursuant to this Agreement is or will be free from infringement of patents, copyrights, and other rights of third parties.

**EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR OF NON-INFRINGEMENT OF ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS OF THIRD PARTIES, OR ANY OTHER EXPRESS OR IMPLIED WARRANTIES.**

## 14. INDEMNIFICATION

### 14.1 Indemnification.

**14.1.1 DSP Indemnity**. DSP shall indemnify, defend and hold harmless Intercept and its Affiliates and their respective directors, officers, employees, stockholders and agents and their respective successors, heirs and assigns (the "Intercept Indemnitees") from and against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon such Intercept Indemnitees, or any of them, in connection with any Third Party claims, suits, actions, demands or judgments, including, without limitation, personal injury and product liability matters, to the extent arising out of (i) the Development, Manufacture, or Commercialization or use by any person of any the Product Manufactured or sold by DSP or any Affiliate or sublicensee under this Agreement, (ii) any material breach of this Agreement by DSP, or (iii) the negligence or willful misconduct on the part of DSP or any Affiliate or sublicensee, in any such case under this Section 14.1.1, except to the extent of Intercept's responsibility therefor under Section 14.1.2 below.

**14.1.2 Intercept Indemnity**. Subject to Section 14.1.1 above, Intercept shall indemnify, defend and hold harmless DSP, its Affiliates and their respective directors, officers, employees, and agents, and their respective successors, heirs and assigns (the "DSP Indemnitees"), from and against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon such DSP Indemnitees, or any of them, in connection with any Third Party claims, suits, actions, demands or judgments, including, without limitation, personal injury and product liability matters, to the extent arising out of (i) the Manufacture of any the Product Manufactured or by or on behalf of Intercept, (ii) any actions or omissions of Intercept or its Affiliates under this Agreement, (iii) any material breach of this Agreement by Intercept, or (iv) the negligence or willful misconduct on the part of Intercept or any Affiliate, except to the extent of DSP's responsibility therefore under Section 14.1.1 above.

**14.2 Indemnification Procedures**. In the event that any Indemnitee is seeking indemnification under Section 14.1 above from a Party (the "Indemnifying Party"), the other Party shall notify the Indemnifying Party of such claim with respect to such Indemnitee as soon as reasonably practicable after the Indemnitee receives notice of the claim, and the Party (on behalf of itself and such Indemnitee) shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration) and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The indemnification obligations under Article 14 shall not apply to any harm suffered as a direct result of any delay in notice to the Indemnifying Party hereunder or to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnifying Party, which consent shall not be withheld or delayed unreasonably. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnifying Party and its legal representatives in the investigation of any claim, demand, action or other proceeding covered by Section 14.1.

**14.3 Limitation on Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR LOSS, DAMAGE, OR LIABILITY WITH RESPECT TO LOSS OF PROFIT, SPECIAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGE.**

## 15. TERM AND TERMINATION

**15.1 Term; Expiration**. The term of this Agreement (the "Term") shall commence on the Effective Date and expire on a country-by-county basis on the later to occur of (i) the tenth ($10^{th}$) anniversary of the First Commercial Sale of the Product for the first or second indication in such country (whichever is later) or (ii) the expiration date of the Exclusive Period in such country. The Agreement as a whole shall expire on the date upon which the Agreement terminates with respect to the last country in the Territory.

**15.2 Material Breach**. (a) In the case that one of the Parties believes that the other Party has materially breached the Agreement, the JSC shall be notified and meet as soon as possible in order that the Parties attempt to resolve any dispute as to the existence of any such material breach. Failing a consensus decision by the JSC within thirty (30) days of receiving the matter for review, it shall then be referred for "Executive Negotiation" as set forth in Article 16.1. Failing a decision by the business executives within sixty (60) days of receiving the matter for review from the JSC, the non-breaching Party may then proceed to give written notice of termination for material breach.

(b) If pursuant to Section 15.2(a), either Party gives written notice to the other Party of termination for material breach, which notice shall describe such material breach in reasonable detail and whether it has been deemed non-curable or curable by the JSC and senior executives, this Agreement and the rights and options granted herein may be terminated by the non-breaching Party, effective ten (10) days after giving written notice to the breaching Party of termination for non-curable breach, thirty (30) days after giving written notice to the breaching Party of such termination in the case of a curable payment breach, and sixty (60) days after giving written notice to the breaching Party of such termination in the case of any other curable breach. The foregoing notwithstanding, if any curable material breach is cured within the aforesaid thirty (30) or sixty (60) day period, the notice shall be automatically withdrawn and of no effect.

(c) Any exercise by Intercept or DSP of its rights under Section 15.2(b) may be on a country-by-country or indication-by-indication basis, at Intercept's discretion, or DSP discretion, in which case such termination shall be partial in nature and shall only apply to the particular country or indication which is the source of the alleged material breach. Furthermore, Intercept shall have the alternative option, in its sole discretion, instead of terminating the Agreement in part or in whole, to convert the exclusive appointment of DSP under Section 2 of this Agreement into a non-exclusive appointment, and to apply such non-exclusive status on a country-by-country or indication-by-indication basis, at Intercept's sole discretion, in which case such non-exclusivity shall only apply to the particular country or indication which is the source of the alleged material breach.

**15.3 Voluntary Termination.** DSP shall have the right to terminate this Agreement at any time upon ninety (90) days' written notice to Intercept, either in its entirety or on a country-by-country basis or indication-by-indication basis, at the discretion of DSP.

**15.4 Effects of Termination**.

**15.4.1** Upon the expiration of this Agreement or any termination of the entire Agreement by DSP under Section 15.2, as of the effective date of such expiration or termination, DSP thereafter automatically shall have a perpetual, fully sublicensable and transferable, exclusive license in the Territory under the Intercept Technology and Intercept Manufacturing Technology, to Develop, have Developed, make, have made (including Manufacture), use, have used, sell, have sold, offer for sale, import and have imported or otherwise Commercialize any and all Products and to practice the Intercept Technology and the Manufacturing Technology in the Territory. Such license shall not be fully paid-up, but instead shall be payable as follows (subject to Intercept making the transfer of the relevant Manufacturing Technology to DSP):

(a) if before the First Commercial Sale, then [***] percent ([***]%) of royalties that would have become due under Section 9 of this Agreement but for the termination or expiration, for a period equal to the remainder of the Term of the Agreement, had the Agreement not been terminated;

(b) if after the First Commercial Sale, then [***] percent ([***]%) of royalties that would have become due under Section 9 of this Agreement but for the termination or expiration, for a period equal to the remainder of the Term of the Agreement, had the Agreement not been terminated; provided, however, that in the event Intercept does not comply with its obligations under the Commercial Supply Agreement, the applicable rate will be [***] percent ([***]%).

(c) At the end of the period equal to the remainder of the Term of the Agreement, had the Agreement not been terminated, the exclusive license shall be deemed fully paid-up. Intercept shall disclose to DSP all material research, non-clinical and clinical data on Products generated prior to the termination date outside the Territory and DSP shall thereafter have the unrestricted right to use such data and information in the Territory. Intercept shall promptly provide to DSP any other material, information, contracts, etc. which Intercept owns or Controls related to the Intercept Product in the Territory and are reasonably required to allow DSP to continue the Development, Manufacture and Commercialization of Products in the Territory with minimal delay.

(d) The foregoing notwithstanding, in the case that DSP determines, in its sole discretion, upon termination of the Agreement pursuant to this Section 15.4.1 to cease all Development, Manufacturing and Commercialization activities relating to the Compound and the Product, then all licenses and sublicenses shall revert in full to Intercept and DSP shall have no further payment obligations to Intercept. To give effect to the reversion of the licenses and sublicenses, DSP shall be bound by its obligations pursuant to Section 15.4.2 below, except that DSP shall not be bound to disclose to Intercept all material research, non-clinical and clinical data (except for safety data) on Products generated prior to the termination date, nor shall DSP be bound to assign all Regulatory Filings relating to Products in the Territory.

**15.4.2** Upon any termination of the Agreement by Intercept under Section 15.2 , or upon any termination of the Agreement by DSP under Section 15.3, as of the effective date of such termination all relevant licenses and sublicenses granted by Intercept to DSP shall cease and all such licenses and sublicenses shall revert in full to Intercept. If there is a partial termination, only the licenses and sublicenses as to the respective country and/or indication being terminated shall revert to Intercept. In order to revert the licenses and sublicenses, DSP shall be obligated to the following:

(a) DSP shall provide to Intercept (or at Intercept's request, destroy) all remaining Product and disclose to Intercept all material research, non-clinical and clinical data on Products generated prior to the termination date and Intercept shall thereafter have the unrestricted right to use such data and information;

(b) DSP shall assign to Intercept all Regulatory Filings relating to Products in the Territory, if assignment is permitted by applicable Regulatory Authorities; and

(c) DSP shall promptly provide to Intercept any other material, reagents, information, contracts, etc. DSP owns or Controls related to the Intercept Product and are reasonably required to allow Intercept to continue the research, Development, protection, and Commercialization of Products with minimal delay.

**15.4.3** **Remedies**. Except as otherwise expressly set forth in this Agreement, the termination provisions of this Section 15 are in addition to any other relief and remedies available to either Party at law.

**15.4.4** **Joint Improvements.** For the avoidance of doubt, Joint Improvements shall remain jointly owned upon any termination or expiration of the agreement.

**15.4.5** **Surviving Provisions**. Notwithstanding any provision herein to the contrary, the rights and obligations of the Parties set forth in Sections 10.3, 11.1, 12, 14, and 15.4 shall survive the date of termination or expiration of the Agreement (except as otherwise provided for in this Agreement). Without limiting the generality of the foregoing, DSP shall have no obligation to make any milestone or royalty payment to Intercept that has not accrued prior to the effective date of any termination or expiration of this Agreement (except with respect to the payments pursuant to Section 15.4.1), but shall remain liable for all such payment obligations accruing prior to the effective date of such termination.

## 16. DISPUTES

**16.1** **Executive Negotiation**. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the Term of this Agreement that relates to either Party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute, either Party may, by written notice to the other Party, have such dispute referred to their respective senior officials designated below or their successors, for attempted resolution by good faith negotiations within sixty (60) days after such notice is received. Said designated senior officials are as follows:

For Intercept: Chief Executive Officer

For DSP: Chief Executive Officer (or a designated senior executive with decision-making authority).

In the event the designated senior officials are not able to resolve such dispute within the sixty (60) day period, either Party may invoke the provisions of Section 16.2.

**16.2** **Arbitration**. Subject to Section 16.1 and except with respect to disputes relating to the intellectual property or a breach of the confidentiality obligations of this Agreement, any dispute, controversy or claim initiated by either Party arising out of, resulting from or relating to this Agreement, or the performance by either Party of its obligations under this Agreement (other than bona fide Third Party actions or proceedings filed or instituted in an action or proceeding by a Third Party against a Party), whether before or after termination of this Agreement, shall be submitted to the International Court of Arbitration of the International Chamber of Commerce and shall be finally settled by binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Any such arbitration shall be conducted under the then-current Rules of Arbitration of the International Chamber of Commerce Rules of Arbitration by a panel of one or more arbitrators appointed in accordance with such rules. Any such arbitration shall be held in New York, New York if initiated by DSP and in Osaka, Japan if initiated by Intercept. All arbitration proceedings, communications, and documents shall be in the English language. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. Notwithstanding the foregoing, each Party may at any time pursue equitable remedies, including without limitation injunctive relief, to protect its respective Confidential Information as well as its respective intellectual property rights, including Know-How and Patents. For the avoidance of doubt, either Party can take such action without first having to go to the JSC pursuant to Section 3, or the Executive Negotiation pursuant to Section 16.1.

## 17. MISCELLANEOUS

**17.1** **Notification**. All notices, requests and other communications hereunder shall be in writing, shall be addressed to the receiving Party's address set forth below or to such other address as a Party may designate by notice hereunder, and shall be either (i) delivered by hand, (ii) made by facsimile transmission (to be followed with written fax confirmation), (iii) sent by private courier service providing evidence of receipt, or (iv) sent by registered or certified mail, return receipt requested, postage prepaid. The addresses and other contact information for the parties are as follows:

| | |
|---|---|
| If to Intercept: | Intercept Pharmaceuticals, Inc.<br>18 Desbrosses Street<br>New York, NY 10013<br>Fax: +1-646-747-1001 |
| If to DSP: | Director of Business Development<br>6-8, Doshomachi 2-Chome<br>Chuo-ku, Osaka 541-0045, Japan<br>Fax: +81-6-6203-4533 |

All notices, requests and other communications hereunder shall 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 made by telecopy or facsimile transmission, at the time that receipt thereof has been acknowledged by the recipient, (iii) if sent by private courier, on the day such notice is delivered to the recipient, or (iv) if sent by registered or certified mail, on the fifth ($5^{th}$ ) business day following the day such mailing is made.

**17.2** **Governing Law**. This Agreement will be construed, interpreted and applied in accordance with the laws of the state of New York (excluding its conflict of law principles law).

**17.3** **Limitations**. Except as expressly set forth in this Agreement, neither Party grants to the other Party any right or license to any of its intellectual property.

**17.4** **Entire Agreement**. This is the entire Agreement between the Parties with respect to the subject matter hereof and supersedes all prior representations, understandings and agreements between the Parties with respect to the subject matter hereof. No modification shall be effective unless in writing with specific reference to this Agreement and signed by the Parties.

**17.5** **Waiver**. The terms or conditions of this Agreement may be waived only by a written instrument executed by the Party waiving compliance. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term shall be deemed as a continuing waiver of such condition or term or of another condition or term.

**17.6** **Assignment**. Neither this Agreement nor any right or obligation hereunder may be assigned, delegated or otherwise transferred, in whole or part, by either Party without the prior express written consent of the other Party, which may be withheld in the sole discretion of the Party giving such consent.

**17.7** **Force Majeure**. Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any cause beyond the reasonable control of such Party. In event of such force majeure, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

**17.8** **Construction**. The Parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

**17.9** **Severability**. If any provision(s) of this Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable law from time to time in effect during the Term hereof, it is the intention of the Parties that the remainder of this Agreement shall not be affected thereby provided that a Party's rights under this Agreement are not materially affected. The Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid, illegal or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

**17.10** **Further Assurances**. Each Party agrees to execute, acknowledge and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**17.11** **Affiliate Delegation**. DSP may delegate to an Affiliate all or part of its obligations hereunder, provided that it shall provide prior notice to Intercept.

**17.12** **Compliance with Law**. Each Party shall comply with all applicable Laws, including by way of example, but without limitation U.S. export controls and the U.S. Foreign Corrupt Practices Act.

**17.13** **Governing Language.** This Agreement has been executed in English. If any translation of this Agreement conflicts with the English version or contains terms in addition to or different from the English version, the English version shall prevail.

**17.14** **Counterparts**. This Agreement may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**[SIGNATURES FOLLOW ON THE NEXT PAGE.]**

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be executed by their duly authorized representative in two (2) originals.

| **DAINIPPON SUMITOMO PHARMA CO., LTD.** | **INTERCEPT PHARMACEUTICALS, INC.** |
|---|---|
| /s/ Masayo Tada | /s/ Mark Pruzanski |
| Name: Masayo Tada | Name: Mark Pruzanski |
| Title: President and Chief Executive Officer | Title: President and Chief Executive Officer |

**EXHIBIT A**

**INTERCEPT PATENTS**

| Country | Title | Serial No. | Filing Date | Parent PCT | Status | Patent No. |
|---|---|---|---|---|---|---|
| Japan | Steroids As Agonists For FXR | 2002-571512 | Feb. 21, 2002 | PCT/EP2002/001832 WO2002/072598 | Granted | 4021327 |
| Japan | Process For Preparing 3alpha(Beta)-7alpha(Beta)-Dihydroxy-6alpha(Beta)-Alkyl-5beta Cholanic Acid | 2008-511719 | May 19, 2006 | PCT/EP2006/062446 WO2006/122977 | Pending | N/A |
| China | Process For Preparing 3alpha(Beta)-7alpha(Beta)-Dihydroxy-6alpha(Beta)-Alkyl-5beta Cholanic Acid | 200680017025.6 | May 19, 2006 | PCT/EP2006/062446 WO2006/122977 | Pending | N/A |
| Japan | Treatment Of Fibrosis Using FXR Ligands | 2007-503111 | Mar. 14, 2005 | PCT/US2005/008575 WO2005/089316 | Pending | N/A |

**EXHIBIT B**

**Summary of Sublicense Agreements**

**1. Sublicense Agreement**

(a) Full corporate name of sublicensee:

(b) Applicable country:

(c) Applicable indications in the Field:

(d) Standard of sublicensee's performance (e.g. best efforts, commercially reasonable efforts, etc.):

(e) Term of sublicense agreement:

(f) Summary of termination provision:

**2. Sublicensee Confirmation**

I, [Name], the [Title] of [Full Corporate Name of Sublicensee] (the "XX") confirm and acknowledge that the XX is aware of and agrees to comply with the provisions of that certain License Agreement, dated March 29, 2011 by and between Dainippon Sumitomo Pharma Co., Ltd. and Intercept Pharmaceuticals, Inc. (the "Agreement"), which in accordance with their respective terms, are expressly applicable to XX, as a sublicensee appointed pursuant to Section 2.1.2 of the Agreement.

By:

Name:

Title:

Date:

**Exhibit 21.1**

**SUBSIDIARIES OF THE REGISTRANT**

| Name | Jurisdiction of Incorporation or Organization |
|---|---|
| Intercept Pharma International Limited | Republic of Ireland |
| Intercept Pharmaceuticals, LLC | Delaware |
| Intercept Italia S.r.l. | Italy |
| Intercept Pharma Europe Ltd. | England and Wales |
| Intercept Pharma UK & Ireland Ltd | England and Wales |
| Intercept Pharma Ltd | England and Wales |
| Intercept Pharma Canada Inc. | British Columbia |
| Intercept Pharma Switzerland GmbH | Switzerland |
| Intercept Pharma Deutschland GmbH | Germany |
| Intercept Pharma France SAS | France |
| Intercept Pharma Austria GmbH | Austria |
| Intercept Pharma Spain, S.L.U. | Spain |
| Intercept Pharma Portugal Unipessoal Lda | Portugal |
| Intercept Pharma Nederland B.V. | The Netherlands |

**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors
Intercept Pharmaceuticals, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-184810, No. 333-188064, No. 333-206247, No. 333-217863, No. 333-226405, No. 333-233248, and No. 333-248083) on Form S-8 and (No. 333-194974 and No. 333-217861) on Form S-3 of Intercept Pharmaceuticals, Inc. of our reports dated February 25, 2021, with respect to the consolidated balance sheets of Intercept Pharmaceuticals, Inc. as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, changes in stockholders' (deficit) equity, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes and the effectiveness of internal control over financial reporting as of December 31, 2020, which reports appear in the December 31, 2020 annual report on Form 10-K of Intercept Pharmaceuticals, Inc.

/s/ KPMG LLP

New York, New York
February 25, 2021

**Exhibit 31.1**

**CERTIFICATION**

I, Jerome Durso, certify that:

1. I have reviewed this Annual Report on Form 10-K 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(s) 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(s) 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: February 25, 2021

/s/ Jerome Durso
Jerome Durso
President and Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION**

I, Sandip Kapadia, certify that:

1. I have reviewed this Annual Report on Form 10-K 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(s) 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(s) 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: February 25, 2021

/s/ Sandip Kapadia
Sandip Kapadia
Chief Financial Officer and Treasurer
(Principal Financial Officer)

**Exhibit 32.1**

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jerome Durso, President and Chief Executive Officer of Intercept Pharmaceuticals, Inc. (the "Company"), and Sandip Kapadia, Chief Financial Officer and Treasurer of the Company, each hereby certifies that, to the best of his knowledge:

(1) The Company's Annual Report on Form 10-K for the year ended December 31, 2020 to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: February 25, 2021

/s/ Jerome Durso
Jerome Durso
President and Chief Executive Officer
(Principal Executive Officer)

Dated: February 25, 2021

/s/ Sandip Kapadia
Sandip Kapadia
Chief Financial Officer and Treasurer
(Principal Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Exchange Act and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) has been provided to Intercept Pharmaceuticals, Inc. and will be retained by Intercept Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Intercept Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.