Current Agreements

## Dealdoc

# Development and licensing agreement for obeticholic acid (INT-747)

Sumitomo Dainippon Pharma
Intercept Pharmaceuticals

Mar 30 2011

# Development and licensing agreement for obeticholic acid (INT-747)

| | |
|---|---|
| **Companies:** | Sumitomo Dainippon Pharma<br>Intercept Pharmaceuticals |
| **Announcement date:** | Mar 30 2011 |
| **Deal value, US$m:** | 315.0 : sum of initial and milestone payments |


- Details
- Financials
- Termsheet
- Press Release
- Filing Data
- Contract


## Details

| | |
|---|---|
| **Announcement date:** | Mar 30 2011 |
| **Start date:** | Mar 29 2011 |
| **Industry sectors:** | Bigpharma<br>Pharmaceutical |
| **Compound name:** | Obeticholic acid, INT-747 |
| **Exclusivity:** | Exclusive |
| **Asset type:** | Compound |
| **Therapy areas:** | Genitourinary » Chronic kidney disease (CKD)<br>Immunology » Other autoimmune<br>Metabolic » Cirrhosis<br>Metabolic » Liver disease<br>Metabolic » Liver disease » Nonalcoholic steatohepatitis (NASH) |
| **Technology types:** | Small molecules |
| **Deal components:** | CRADA<br>Development<br>Licensing<br>Option |
| **Stages of development:** | Phase I<br>Phase II |
| **Geographic focus:** | Asia » China<br>Asia » Japan<br>Asia » South Korea<br>Asia » Taiwan |

## Financials

| | |
|---|---|
| **Deal value, US$m:** | 315.0 : sum of initial and milestone payments |
| **Upfront, US$m:** | 15.0 : initial payment |
| **Milestones, US$m:** | 300.0 : milestone payments associated with the successful development and commercialization of OCA |
| **Royalty rates, %:** | n/d : tiered double-digit royalties from DSP based on sales in its territory |
| **Semi-quant royalties:** | Double digit |

## Termsheet

Exclusive licensing agreement for the development and commercialization of Intercept's first-in-class FXR agonist obeticholic acid (OCA, also known as INT-747).

DSP will advance OCA in Japan and China for the treatment of chronic liver diseases, with an initial focus on primary biliary cirrhosis (PBC) and nonalcoholic steatohepatitis (NASH).

Intercept is currently preparing for the initiation of a Phase III PBC program in the US and Europe and, under the company's cooperative research and development agreement (CRADA) with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a large placebo-controlled trial of OCA in NASH patients recently started enrolling in the US.

Intercept will receive an initial payment from DSP of $15 million and will be eligible to receive approximately $300 million in additional milestone payments associated with the successful development and commercialization of OCA.

Upon launch of OCA, Intercept will be entitled to receive tiered double-digit royalties from DSP based on sales in its territory.

DSP has the exclusive option to add several other Asian countries to its territory, including Korea and Taiwan, and to pursue additional indications.

DSP will be responsible for the costs of developing and commercializing OCA in its territory.

## Press Release

Dainippon Sumitomo Pharma Co., Ltd. and Intercept Pharmaceuticals Announce Agreement to Develop and Commercialize Obeticholic Acid (INT-747) for Chronic Liver Disease; Dainippon Pays Intercept $15 Million and up to $300 Million 3/30/2011

OSAKA, Japan and NEW YORK, March 30, 2011 /PRNewswire/ -- Dainippon Sumitomo Pharma Co, Ltd. (DSP) and Intercept Pharmaceuticals, Inc. (Intercept) today announced that they have entered into an exclusive licensing agreement for the development and commercialization of Intercept's first-in-class FXR agonist obeticholic acid (OCA, also known as INT-747). DSP will advance OCA in Japan and China for the treatment of chronic liver diseases, with an initial focus on primary biliary cirrhosis (PBC) and nonalcoholic steatohepatitis (NASH). Intercept is currently preparing for the initiation of a Phase III PBC program in the US and Europe and, under the company's cooperative research and development agreement (CRADA) with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a large placebo-controlled trial of OCA in NASH patients recently started enrolling in the US.

Under the terms of the licensing agreement, Intercept will receive an initial payment from DSP of $15 million and will be eligible to receive approximately $300 million in additional milestone payments associated with the successful development and commercialization of OCA. Upon launch of OCA, Intercept will be entitled to receive tiered double-digit royalties from DSP based on sales in its territory. DSP has the exclusive option to add several other Asian countries to its territory, including Korea and Taiwan, and to pursue additional indications. DSP will be responsible for the costs of developing and commercializing OCA in its territory.

"OCA is an important strategic addition to our growing pipeline of hepatology drugs and reflects DSP's strong commitment to specialty therapeutic areas," said Masayo Tada, President and CEO of DSP. "There is a very high unmet medical need in the hepatology area in Asia and DSP's marketed products SUMIFERON®, a natural alpha interferon, and MIRIPLA®, a therapeutic agent for hepatocellular carcinoma, benefit many thousands of liver patients in Japan. We strongly believe that OCA has the potential to significantly add to the treatment options DSP can make available to these patients and are looking forward to working with Intercept to bring OCA to the market as an important new therapy for PBC and the first drug approved for NASH."

"This agreement is an important milestone for our OCA program and provides additional confirmation of our drug's potential," said Mark Pruzanski, MD, President and CEO of Intercept. "We are excited to be partnering in Asia with DSP, given its proven track record in the development and commercialization of drugs in the hepatology area. This collaboration with DSP will provide important development support as we advance OCA in parallel for PBC, NASH and possibly other indications."

About Obeticholic Acid (OCA or INT-747)

OCA is a potent, first-in-class farnesoid X receptor (FXR) agonist derived from the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist. Intercept has previously announced positive Phase II results from randomized clinical trials in patients with primary biliary cirrhosis (PBC) and in type 2 diabetics with nonalcoholic fatty liver disease. The clinical data and mechanism of action support OCA's potential as a novel, hepatoprotective agent in a broad range of chronic liver diseases.

About Primary Biliary Cirrhosis (PBC)

PBC is the most common autoimmune chronic liver disease that primarily afflicts women over the age of 40. PBC causes substantial loss of intrahepatic bile ducts, resulting in impaired bile flow (cholestasis) and progressive fibrosis that leads eventually to cirrhosis. It is estimated that there are approximately 50,000 PBC patients in Japan and more than 400,000 in China. Given inadequate treatment options, up to 50% of such patients worldwide continue to be at significant risk of progression to liver transplant or death.

About Nonalcoholic Steatohepatitis (NASH)

NASH is a more serious form of nonalcoholic fatty liver disease (NAFLD) and occurs in patients who drink little or no alcohol. NASH occurs most commonly in obese and insulin resistant patients, but is also seen in lean individuals. In a report of a 5-10 year follow-up study, up to 25% of NASH patients progressed to cirrhosis of the liver. The prevalence of NASH in Japan is estimated to be at least 1% of the adult population and pediatric disease is also becoming more common, while in the US it is estimated that 3-5% of the population has the disease in association with higher obesity rates. There is currently no approved treatment for NASH.

About Intercept Pharmaceuticals, Inc.

Intercept is a biotechnology company focused on discovering and developing small molecule drugs for the treatment of chronic liver and metabolic diseases. The company's most advanced programs are focused on the development of modified bile acids that are selective for FXR, a nuclear receptor, and TGR5, a G protein-coupled receptor. Bile acid signaling through these receptors regulates key aspects of lipid, glucose and overall energy metabolism, while also serving to maintain the functional integrity of the liver, intestine and kidneys, organs that are exposed to bile acid flux. For more information about Intercept, please go to www.interceptpharma.com. CONTACT: Mark Pruzanski, M.D. or Barbara Duncan, both of Intercept, +1-646-747-1000. For information about Intercept's majority shareholder Genextra S.p.A., please go to www.genextra.it.

About Dainippon Sumitomo Pharma Co., Ltd. (DSP)

DSP is a multi-billion dollar, top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical products. DSP aims to produce innovative pharmaceutical products in the central nervous system (CNS) field and other specialty areas. Today, DSP has more than 7,000 employees worldwide. Additional information about DSP is available through its corporate website at http://www.ds-pharma.com/

## Filing Data

*Not available.*

## Contract

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.

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

“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 inprocess 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).

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



“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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



"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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



"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 negotiationsthat 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.

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



“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).

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

6

"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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

7

"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.

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

8

“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.

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

9

“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.

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

11

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;

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

12

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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

18

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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

19

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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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").

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

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$[***]

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



(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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



(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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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 (10th) 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.

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



(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.

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



(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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

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.

18 Desbrosses Street

New York, NY 10013

Fax: +1-646-747-1001

If to DSP:

Director of Business Development

6-8, Doshomachi 2-Chome

Chuo-ku, Osaka 541-0045, Japan

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 (5th ) 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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



[SIGNATURES FOLLOW ON THE NEXT PAGE.]

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.



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

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.

45

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:

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended.