SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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Islet Sciences, Inc

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): March 3, 2015

Islet Sciences, Inc. (Exact Name of Registrant as Specified in Charter)

Nevada

001-34048

(State or Other Jurisdiction of Incorporation) (Commission File Number)

87-0531751 (IRS Employer

Identification No.)

6601 Six Forks Rd., Suite 140 Raleigh, North Carolina 27615

(Address of Principal Executive Offices)

Registrant's telephone number, including area code: (919) 480-1518

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

As previously reported in the Current Report on Form 8-K filed on October 2, 2014 by Islet Sciences, Inc., a Nevada corporation (the "Company"), on September 30, 2014, the Company entered into an agreement and plan of merger (the "Merger Agreement") by and among the Company, Brighthaven Ventures, L.L.C., a North Carolina limited liability company ("BHV"), Avogenx, Inc., a Delaware corporation and a direct wholly owned subsidiary of the Company ("Avogenx"), Islet Merger Sub, Inc., a Nevada corporation and a direct wholly owned subsidiary of the members of BHV (the "BHV Members"). On March 3, 2015, the Company entered into an exclusive license agreement (the "License Agreement") with BHV, and in connection therewith the parties to the Merger Agreement entered into a termination agreement (the "Termination Agreement") terminating the Merger Agreement.

Pursuant to the License Agreement, if certain conditions are met as described below, the Company will receive (i) an exclusive sublicense to develop and commercialize pharmaceutical preparations containing the novel sodium-glucose cotransporter 2 inhibitors ("SGLT2") remogliflozin and remogliflozin etabonate (the "Products") and (ii) an exclusive license to a biphasic formulation technology for the development and commercialization of the Products. BHV holds an exclusive license for the development and commercialization of the Products from their current owner, Kissei Pharmaceutical Co., Ltd. ("Kissei"). The Products are currently in Phase IIb development for Type II Diabetes and Non-alcoholic Steatohepatitis, commonly referred to as "NASH."

The licenses granted under the License Agreement will become effective only if, on or before May 31, 2015, (i) the Company receives not less than \$10,000,000 in additional equity or debt financing and (ii) the Company pays to BHV \$5,000,000 as an upfront payment for the license. In the event that these conditions are not met, the Company will not receive any rights to the Products, and the License Agreement will automatically terminate on May 31, 2015. Upon effectiveness, the territory for the licenses granted under the License Agreement is all countries of the world except for Japan, Korea, Taiwan, China and Latin America (Brazil, Argentina, Bolivia, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela) (the "Territory").

Upon effectiveness of the licenses under the License Agreement, the Company will be required to pay BHV and Kissei up to \$35.1 million pre-regulatory approval and up to an additional \$76.75 million post-regulatory approval if certain development, regulatory and commercial milestones are successfully achieved. Royalties under the License Agreement will be due to BHV and Kissei on net sales in the Territory during the term of the License Agreement. In addition to the upfront and milestone payments and royalties payable by the Company to BHV, in the event that the Company grants any option, sublicense or other right, or otherwise transfers or assigns any right, in the Products to a third party, the Company will be required to pay to BHV a percentage of such compensation under certain circumstances.

Pursuant to the Termination Agreement entered into simultaneously with the License Agreement, the Merger Agreement was terminated effective immediately. The Termination Agreement provides that certain provisions of the Merger Agreement will survive, including provisions relating to confidentiality and the Company's obligation to pay BHV's expenses incurred in connection with the Merger Agreement. In addition, the Termination Agreement contains general releases by the parties, requires the Company to indemnify BHV and the BHV Members and provides that the Company will be responsible for all costs and expenses incurred by any party to the Termination Agreement (including BHV and the BHV Members) in connection with the Termination Agreement, the Merger Agreement and the transactions contemplated thereby and the entry into and the negotiation of the License Agreement. As a result of the termination of the Merger Agreement, Avogenx withdrew its previously filed registration statement on Form S-4 relating to the Merger Agreement.

James Green, the Company's President, Chief Executive Officer and director, and William Wilkison, the Company's Chief Operating Officer and director, are the BHV Members. Each of Mr. Green and Dr. Wilkison owns 50% of the outstanding membership interests of BHV. The compensatory arrangements that the Company has with each of Mr. Green and Dr. Wilkison were disclosed in the Company's Current Reports on Form 8-K, dated October 25, 2013 and May 22, 2014, respectively as well as the Company's Annual Report on Form 10-K for the fiscal year ended April 30, 2014, all of which are incorporated by reference herein.

The foregoing description of the License Agreement and Termination Agreement is only a summary and is qualified in its entirety by reference to the License Agreement and Termination Agreement, which are attached hereto as Exhibits 10.1 and 10.2 and incorporated by reference herein. Portions of the License Agreement will be subject to a Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The omitted material will be included in the request for confidential treatment. The License Agreement and Termination Agreement have been included as exhibits hereto solely to provide investors and security holders with information regarding its terms. It is not intended to be a source of financial, business or operational information about the Company or its subsidiaries or affiliates. The representations, warranties and covenants contained in the License Agreement and Termination Agreements; may be subject to qualifications and limitations agreed upon by the parties in connection with negotiating the terms of the agreements; and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors or security holders. Investors and security holders should not rely on the representations, warranties and covenants or any description thereof as characterizations of the actual state of facts or condition of the Company or their respective subsidiaries or affiliates. Moreover, information concerning the subject matter of the representations, warranties and covenants or any description thereof as characterizations of the actual state of facts or condition of the Company or their respective subsidiaries or affiliates. Moreover, information concerning the subject matter of the representations, warranties and covenants may change after the date of the License Agreement or Termination Agreement, which subsequent information may or may not be fully reflected in public disclosures.

Item 1.02 Termination of a Material Definitive Agreement.

The information set forth in Item 1.01 is incorporated by reference into this Item 1.02.

Item 8.01 Other Events.

On March 3, 2015, the Company issued a press release announcing that it had entered into the License Agreement and Termination Agreement. The press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

On March 5, 2015, the Company issued a press release announcing the issuance of a U.S. patent for using SGLT2 inhibitors to Treat NASH/NAFLD. The press release is attached hereto as Exhibit 99.2 and is incorporated by reference herein.

On March 9, 2015, the Company issued a press release announcing that Dr. William Wilkison was invited to present at the conference held by the European Association for the Study of Liver. The press release is attached hereto as Exhibit 99.3 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No | Description | |
|---------------|--|--|
| <u>10.1</u> | Exclusive License Agreement between the Company and Brighthaven Ventures, L.L.C.* | |
| <u>10.2</u> | Termination Agreement among the Company, Brighthaven Ventures, L.L.C., Avogenx, Inc., Islet Merger Sub, Inc., and each of the members of BHV | |
| <u>99.1</u> | Press Release dated March 3, 2015 | |
| <u>99.2</u> | Press Release dated March 5, 2015 | |
| <u>99.3</u> | Press Release dated March 9, 2015 | |

* Portions of such exhibit have been omitted pursuant to a request for confidential treatment submitted to the Securities and Exchange Commission.



SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Islet Sciences, Inc.

Dated: March 9, 2015

By:/s/ James Green

Name: James Green Title: Chief Executive Officer

Note: Throughout this document, certain confidential material contained herein has been omitted and has been separately filed with the Commission. Each omission has been marked with an [***].

EXCLUSIVE LICENSE AGREEMENT

This EXCLUSIVE LICENSE AGREEMENT (this "<u>Agreement</u>") is dated as of the 3rd day of March, 2015 (the "<u>Execution</u> <u>Date</u>") by and between Brighthaven Ventures, L.L.C., a North Carolina limited liability company having its registered office at 3200 East Hwy. 54, Suite 100, Research Triangle Park, NC 27709 ("<u>BHV</u>") and Islet Sciences, Inc., a Nevada corporation having its principal place of business at 6601 Six Forks Rd., Suite 140, Raleigh, NC 27615 ("<u>ISLT</u>"). Each of BHV and ISLT is referred to herein as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

WITNESSETH THAT:

WHEREAS, BHV holds a license from Kissei Pharmaceutical Co., Ltd., a corporation organized and existing under the laws of Japan ("<u>Kissei</u>"), for the development and commercialization of pharmaceutical preparations containing the novel SGLT2 inhibitors remogliflozin and remogliflozin etabonate (as further defined herein, "<u>Products</u>") in all countries of the world except for Japan, Korea and Taiwan, under the Exclusive License Agreement between BHV and Kissei dated December 1, 2010 (as further defined herein, the "<u>Kissei Agreement</u>");

WHEREAS, BHV has been assigned certain patent applications related to a biphasic formulation technology that is useful in development of the Products (as further defined herein, "Biphasic Patents");

WHEREAS, BHV and ISLT executed a Termination Agreement on the Execution Date (the "Termination Agreement");

WHEREAS, BHV desires to grant to ISLT an exclusive sublicense under the Kissei Agreement to make, have made, use, sell, offer to sell and import Products in the Field in the Territory;

WHEREAS, BHV desires to grant to ISLT an exclusive license under the Biphasic Patents and Biphasic Know-How (as defined herein) in the Field in the Territory, including to make, have made, use, sell, offer to sell and import Products in the Field in the Territory; and

WHEREAS, BHV is willing to grant such an exclusive sublicense and license to ISLT, under the terms and conditions hereinafter appearing;

NOW, THEREFORE, in consideration of the covenants and obligations expressed herein, and intending to be legally bound, the Parties hereto agree as follows:

Article 1

DEFINITIONS

As used in this Agreement, the following words and phrases shall have the following meanings:

"AAA" has the meaning set forth in Section 20.6.

"<u>Affiliate</u>" means any person, corporation, firm, partnership, limited liability company or other entity that controls, is controlled by or is under common control with a Party to this Agreement. For purposes of this definition, an entity will be regarded as in "control" of another corporation if (a) it owns or directly or indirectly controls at least 50% of the voting securities of the other corporation or such lesser maximum percentage permitted in those jurisdictions where majority ownership by foreign entities is prohibited, (b) it owns or has a right to at least 50% of the net assets of an entity without voting securities, or (c) it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the entity, whether through contract or otherwise.

"Agreed Supply Criteria" has the meaning set forth in Section 9.2.

"Agreement" has the meaning given in the preamble of this Agreement.

"API" means the active pharmaceutical ingredient for the Compound.

"<u>BHV</u>" has the meaning given in the preamble of this Agreement.

"<u>BHV Confidential Information</u>" has the meaning set forth in Section 15.1.

"BHV Development Data" has the meaning set forth in Section 6.11.

"BHV Members" means the members of BHV.

"BHV Milestone Amounts" has the meaning set forth in Section 4.3.

"BHV Milestones" has the meaning set forth in Section 4.3.

"<u>Biphasic Know-How</u>" means (i) all Know How (whether or not relating to the Compound or the Product) Controlled by BHV on the Effective Date that is reasonably necessary or useful for development or commercialization of products and services under the Biphasic Patents, and (ii) any BHV Development Data included in this definition pursuant to Section 6.11.

"<u>Biphasic Patents</u>" means, within the Territory in each case, the Patents identified on <u>Exhibit B</u> (whether or not claiming the Compound or the Product, a use for the Compound or the Product or a method of making the Compound or the Product or otherwise covering the Compound or the Product), any Patents included in this definition pursuant to Section 14.1, and any continuations, continuations-in-part, divisions, or other patent applications, in each case to the extent claiming priority from such Patents, and all Patents that may issue on any of the foregoing.

"<u>Biphasic Product</u>" means any product or service that does not contain or utilize the Compound and whose development, manufacture, use, distribution, importation or commercialization (i) is covered by a Valid Claim in a Biphasic Patent or (ii) uses, incorporates or is based on Biphasic Know-How.

"[***]" [***].

"Bulk Form" has the meaning set forth in Section 5.2.

"Change-in-Control of BHV" has the meaning set forth in Section 14.5(b).

"Collateral" has the meaning set forth in Article 32.

"<u>Combination Product</u>" means any and all pharmaceutical preparations in the Field in finished dosage package forms ready for sale to a Third Party which contain the Compound as well as an additional therapeutically or prophylactically active ingredient.

"<u>Commercial Plan</u>" means the plan for commercialization of Products in the Field in the Territory agreed to by the Parties pursuant to Section 7.2, as the same may be amended from time to time in accordance with Section 6.2 or 7.3(b) of this Agreement. The Commercial Plan shall include specific activities of ISLT, targeted timelines and appropriate budgets.

"<u>Commercially Reasonable Efforts</u>" means such efforts and resources that a reasonable pharmaceutical development company would use to develop and commercialize its own compounds and products having comparable commercial potential, stage of development, medical/scientific, technical and regulatory profile, and intellectual property protection.

"Committee Date" has the meaning set forth in Section 6.2.

"Compound" means (i) KGT-1650 (remogliflozin) and KGT-1681 (remogliflozin etabonate), and (ii) if a "Qualifying Event" (as defined in the Kissei Agreement) has occurred pursuant to Section 2.02 of the Kissei Agreement, the compounds with the internal Kissei code names of KGT-1251 and KGT-1075 and such other compounds included in the Kissei Patents, or discovered, invented or generated by Kissei with SGLT2 selective inhibitory effect as their primary mechanism of pharmacological activity within the scope of clause (i) of the "Field" definition in this Agreement (but excluding compounds with effects on proteins other than SGLT2 selective inhibitory effect as their primary mechanism, and all prodrugs, metabolites, salts, hydrates, solvates, polymorphs, enantiomers and isomers thereof.

"Conducting Party" has the meaning set forth in Section 6.6.

"Confidentiality Agreement," means the Agreement, dated as of September 10, 2013, between Islet and BHV.

"<u>Control</u>" means, with respect to any Patent, Know-How or other intellectual property right, that the Party (or its Affiliate) controlling such right owns a transferable interest or has a license to practice such Patent, Know-How or right and has the ability to grant the other Party access, a license or a sublicense (as applicable) to practice such Patent, Know-How or right without violating the rights of any Third Party.

"Cost of Manufacture" means, with respect to the Compound or any Product, the actual fully allocated cost of manufacturing the Compound or such Product determined in accordance with International Financial Reporting Standards (except to the extent specifically modified below), which consists of (i) the direct and indirect cost of any raw materials, intermediates, packaging materials and labor (including benefits) utilized in such manufacturing (including formulation, finishing, quality control and stability testing, labeling and packaging, as applicable), (ii) an appropriate share of factory overhead allocated to the Compound or the Product being manufactured, (iii) handling charges like transportation costs and insurance related thereto and (iv) the net cost or credit of any value-added taxes actually paid or utilized by such Party or Affiliate in respect of the manufacture of the Compound or such Products. For the avoidance of doubt, "Cost of Manufacture" for any period excludes any allocation of cost related to excess or unutilized capacity. It is understood and agreed that in the case of Products or Compound manufactured by Third Parties, such payments made to such Third Parties for the acquisition of such Products or Compound, as well as the net cost or credit of any value-added taxes actually paid or utilized by the purchaser in respect of such acquisition of such Products or Compound shall be considered Cost of Manufacture.

"<u>Data Exclusivity</u>" has the meaning set forth in Section 5.1(d).

"Development Plan" means the plan for clinical development of the Compound agreed to by the Parties, as the same may be amended from time to time in accordance with Section 6.2 or 6.3(b) of this Agreement. The Development Plan shall include specific activities of ISLT, targeted timelines and appropriate budgets. The initial Development Plan as agreed to by the Parties as of the Execution Date has been signed and acknowledged by each Party and copies of such signed document have been exchanged between the Parties concurrently with the execution of this Agreement.

"Dispute" has the meaning set forth in Section 20.1.

"Dollars" means United States Dollars.

"Dosage Form" has the meaning set forth in Section 5.2.

"Dr. Wilkison" means Dr. William Wilkison.

"Effective Date" has the meaning set forth in Article 33.

"Effectiveness Condition" has the meaning set forth in Article 33.

"EMA" means the European Medicines Agency, or any successor organization thereto.

"[***]" means [***].

"Execution Date" has the meaning given in the preamble of this Agreement.

"FDA" means the United States Food and Drug Administration, or any successor agency thereto.

"<u>Field</u>" means (i) in relation to the Kissei Patents and the Kissei Know-How, the treatment, palliation or prevention of human disease, including but not limited to diabetes in human beings, and (ii) in relation to the Biphasic Patents and the Biphasic Know-How, all fields, uses and applications, including but not limited to the treatment, palliation or prevention of human disease, including but not limited to diabetes in human beings.

"Financing Period" has the meaning set forth in Article 33.

"<u>Former Kissei-GSK Agreement</u>" means the license agreement on SGLT2 inhibitors including the Compound made between Kissei and GSK dated October 23, 2002 as amended and terminated thereafter.

"GSK" means Kissei's former licensee of the Compound, SmithKline Beecham Corporation d/b/a GlaxoSmithKline.

"<u>GSK Know-How</u>" means all Know-How generated by GSK under the Former Kissei-GSK Agreement and Controlled by Kissei or its Affiliates, licensees (other than BHV), sublicensees and contractors (including but not limited to manufacturing contractors) by transferring from GSK to Kissei or granting to Kissei by GSK on the Kissei License Effective Date as specified in the <u>Exhibit C</u> hereof and all Know-How generated by GSK under the Former Kissei-GSK Agreement which becomes Controlled by Kissei or its Affiliates, licensees (other than BHV), sublicensees and contractors (including but not limited to manufacturing contractors) by transferring from GSK to Kissei or granting to Kissei by GSK during the term of the Kissei Agreement to be added to <u>Exhibit C</u> hereof.

"<u>Improvement</u>" means any and all technical information, patentable or non-patentable, owned, owned jointly or Controlled by either Party or its Affiliates which cover any improvement, invention or discovery concerning the Compound or any Product including, without limitation, new or improved methods of manufacture, formulas, uses, indications, methods of delivery and dosage forms thereof.

"<u>IND</u>" means an Investigational New Drug Application (as defined in 21 C.F.R. Part 312 or any successor regulations) filed with FDA in conformance with applicable laws and regulations, for the purposes of initiating clinical trials of a pharmaceutical compound in the United States.

"Indemnitee" has the meaning set forth in Section 23.3.

"Indemnitor" has the meaning set forth in Section 23.3.

"[***]" means [***].

"IP Claims" has the meaning set forth in Section 13.5.

"ISLT" has the meaning given in the preamble of this Agreement.

"ISLT Confidential Information" has the meaning set forth in Section 15.4.

"ISLT Development Data" has the meaning set forth in Section 6.11.

"<u>ISLT Know-How</u>" means all Know-How which becomes Controlled by ISLT or its Affiliates, Sublicensees and contractors (including but not limited to manufacturing contractors) during the term of this Agreement.

"Key Regulatory Event" has the meaning set forth in Section 6.9.

"Kissei" has the meaning given in the recitals of this Agreement.

"Kissei Agreement" means the Exclusive License Agreement between BHV and Kissei dated December 1, 2010, as amended from time to time.

"Kissei Know-How" means all Know-How including GSK Know-How Controlled by Kissei or its Affiliates, licensees (other than BHV), sublicensees and contractors (including but not limited to manufacturing contractors) on the Kissei License Effective Date and all Know-How including GSK Know-How which becomes Controlled by Kissei or its Affiliates, licensees (other than BHV), sublicensees and contractors (including but not limited to manufacturing contractors) during the term of the Kissei Agreement.

"Kissei License Effective Date" means December 1, 2010.

"Kissei Milestones" has the meaning set forth in Section 4.2.

"<u>Kissei Patents</u>" means all Patents that relate to the Compound and Products in the Territory Controlled by Kissei or its Affiliates and licensees (other than BHV) and sublicensees as of the Kissei License Effective Date, and all Patents that relate to the Compound, Products or Improvements thereof in the Territory that become Controlled by Kissei or its Affiliates during the term of the Kissei Agreement, which are listed on <u>Exhibit A</u>, as amended and updated from time to time under the terms of the Kissei Agreement.

"Know-How" means all present and future technical information specifically relating to the Compound or the Products in the Field, including, all biological, toxicological, chemical information, biochemical information, metabolic, non-clinical, pre-clinical, clinical, pharmacological, pharmacokinetic data, physico-chemical properties, assay, formulation, quality control, synthetic process, and manufacturing method and data, specifications, and any other information relating thereto.

"Latin America" means Brazil, Argentina, Bolivia, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela.

"<u>MAA</u>" means a Marketing Authorization Application submitted to EMA for the purpose of obtaining European Commission approval for the marketing of a Product for the countries located within the European Union.

"<u>Major Countries</u>" means [***].

"Management Committee" has the meaning set forth in Section 6.2.

"<u>Marketing Approval</u>" means (i) the approval of an NDA in the United States, the approval of an MAA in the EU, and any corresponding approvals in any countries of the Territory, and (ii) any pricing and reimbursement approvals, at a pricing and reimbursement level which is determined to be commercially reasonable, in any country of the Territory, to the extent the applicable regulatory authorities having jurisdiction over such country require a pricing or reimbursement approval prior to marketing or sale of a product in such country.

"<u>Milestone Event</u>" means an event that constitutes a Kissei Milestone or a BHV Milestone, as further described in Sections 4.2 and 4.3, respectively.

"Milestones" means the Kissei Milestones and the BHV Milestones.

"<u>Mr. Green</u>" means Mr. James Green.

"<u>NDA</u>" means a new drug application (as defined in 21 C.F.R. 314.50 *et. seq.* or any successor regulations) submitted to the FDA in conformance with applicable laws and regulations, to obtain FDA approval for the marketing of a pharmaceutical products in the United States and all subsequent amendments and supplements to such NDA.

"<u>Net Sales</u>" means with respect to any Product, the gross amounts invoiced by ISLT, its Affiliates or Sublicensees from Third Party customers for sales or other transfers or disposition of a Product, less:

- (i) customary trade, quantity, and cash discounts or rebates actually allowed on Product;
- (ii) credits or allowances given to customers for rejections or returns of Product or on account of retroactive price reductions affecting such Product;
- (iii) sales taxes, excise taxes, use taxes, import/export duties or other governmental charges actually due or incurred with respect to the production, importation, use or sale of a Product to Third Parties;
- (iv) transportation charges to the extent that they are included in the price or otherwise paid by the purchaser, including insurance, for transporting Product; and
- (v) Product rebates and Product chargebacks including those granted to managed-care entities and government agencies; and

Sales or transfers of Products among ISLT, its Affiliate and/or its Sublicensee shall be excluded from the computation of Net Sales, and no royalties will be payable on such sales.

"Partnering Payments" has the meaning set forth in Section 5.7.

"Patent" means all patents and patent applications, including provisionals and priority filings, and which specifically or generically claim the Compound or Product, claim a use for the Compound or Product, claim a method of making the Compound or Product or otherwise covers the Compound or Product, including but not limited to the patent applications listed on Exhibit A, together in all cases with any continuations, continuations-in-part, divisions, patents of addition, reexaminations, reissues, renewals as well as extensions and supplementary protection certificates of any of the foregoing.

"Proceeds" has the meaning set forth in the UCC.

"<u>Product</u>" means any and all pharmaceutical preparations in the Field in finished dosage package forms ready for sale to Third Party which contain the Compound as a sole active ingredient.

"[***]" means [***].

"<u>Regulatory Filings</u>" means (i) with respect to the United States, any IND or NDA, and (ii) with respect to countries or jurisdiction outside the United States but still within the Territory, any filings, registrations or applications equivalent to an IND or NDA.

"Requesting Party" has the meaning set forth in Section 6.6.

"Revenues" means any consideration in any form, including without limitation any upfront and contingent payments, milestone payments (whether based on development, regulatory or sales events or otherwise), royalties, revenue or profit share payments, earn-out payments and any other payment or compensation, payable to ISLT or any of its Affiliates as a result of any transaction or series of transactions entered into in which any rights, including without limitation any development, commercialization, distribution, promotion or marketing rights, in or to the Compound or any Product are optioned, licensed, sublicensed, sold, assigned (including without limitation by assignment of this Agreement), transferred, conveyed, divested or otherwise disposed of to any Third Party.

"<u>Royalty Period</u>" has the meaning set forth in Section 5.8.

"<u>Royalty Report</u>" has the meaning set forth in Section 5.8.

"Royalty Term" has the meaning set forth in Section 5.1(b).

"<u>Rules</u>" has the meaning set forth in Section 20.2.

"<u>Sublicensee</u>" means any Third Party to which ISLT has granted a sublicense or any other right (including without limitation any option right, right of negotiation or refusal or immunity from suit, or any development, commercialization, distribution, promotion or marketing rights) under any of the licenses granted under this Agreement.

"Termination Agreement" has the meaning given in the recitals of this Agreement.

"Territory" means all countries of the world, except for Japan, Korea, Taiwan, China and Latin America.

"Third Party" means any party other than a Party to this Agreement and such Party's Affiliates.

"Trademark" has the meaning set forth in Section 8.1.

"Transferee" has the meaning set forth in Section 17.8.

"<u>UCC</u>" means the Uniform Commercial Code as from time to time in effect in the State of North Carolina; provided that, if perfection or the effect of perfection or non-perfection or the priority of the security interest in any Collateral is governed by the Uniform Commercial Code as in effect in a jurisdiction other than the State of North Carolina, "<u>UCC</u>" means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions hereof relating to such perfection, effect of perfection or non-perfection or priority. "<u>Upfront Payment</u>" has the meaning set forth in Section 4.1.

"<u>Valid Claim</u>" means any claim contained in an issued and unexpired Kissei Patent or Biphasic Patent which has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency or competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through abandonment, reissue, disclaimer or otherwise.

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GRANT

2.1 Grants of Rights.

(a) Subject to the terms and conditions set forth in this Agreement, effective as of the Effective Date, BHV hereby grants to ISLT an exclusive sublicense, with the right to grant further sublicenses (only in accordance with Section 2.2), under BHV's rights under the Kissei Patents and the Kissei Know-How under the Kissei Agreement to make, have made and use the Compound in the Field in the Territory, and to make, have made, use, sell, offer to sell and import the Product in the Field in the Territory.

(b) Subject to the terms and conditions set forth in this Agreement, effective as of the Effective Date, BHV hereby grants to ISLT an exclusive license, with the right to grant sublicenses (only in accordance with Section 2.2), under BHV's rights under the Biphasic Patents and the Biphasic Know-How (i) to make, have made and use the Compound in the Field in the Territory, and to make, have made, use, sell, offer to sell and import the Product in the Field in the Territory, and (ii) to make, have made, use, sell, offer to sell and import the Field in the Territory.

2.2 <u>Sublicenses</u>. In the event that ISLT wishes to grant a sublicense to any Third Party, ISLT shall inform BHV of the name, location and other details of such Third Party and shall not grant such sublicense without obtaining BHV's prior written approval therefor, such approval not to be unreasonably withheld; provided, however, that ISLT may use subcontractors in the drug development, non-clinical and clinical testing, formulation and manufacturing of the Compound, and manufacturing and distribution subcontractors with respect to the sale and distribution of the Product, each in any country in the Territory without the prior written approval of BHV. Any sublicense granted by ISLT shall be subject to the terms and conditions of this Agreement.

2.3 <u>Kissei Agreement</u>. All rights and licenses granted by BHV under this Agreement under the Kissei Patents and Kissei Know-How are subject to the grant of rights in the Kissei Agreement. For clarity, clause (ii) of the "Field" definition in this Agreement shall not be construed to grant to ISLT any rights in relation to the Kissei Patents or the Kissei Know-How that are broader than the scope of clause (i) of such "Field" definition.

2.4 <u>No Implied Licenses</u>. No right or license is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. For clarity, notwithstanding the grants to ISLT of the license and sublicense set forth in this Article 2, BHV shall have the right to perform its obligations under this Agreement, including but not limited to BHV's activities in relation to the Development Plan.

DISCLOSURE OF KNOW-HOW

3.1 <u>Disclosure of Kissei Know-How and Biphasic Know-How</u>. Within ninety (90) days after the Effective Date, BHV shall disclose and deliver to ISLT, or make available to ISLT, all of the Kissei Know-How and Biphasic Know-How in the possession of BHV as is, and from time to time thereafter during the term of this Agreement, BHV shall disclose or make available to ISLT such future Kissei Know-How as comes into the possession of BHV, if any.

3.2 <u>Use of Kissei Know-How and Biphasic Know-How</u>. ISLT shall have the right to use the Know-How received from BHV pursuant to Section 3.1 hereof under the license and sublicense granted in Article 2, and to disclose such Know-How to its Affiliate(s) and its Sublicensee(s), if any, in the Territory for their use and for the sole purpose of this Agreement.

3.3 <u>Disclosure of ISLT Know-How</u>. ISLT agrees to provide BHV, from time to time during the term of this Agreement, with any and all ISLT Know-How. BHV, to satisfy its obligation to disclose BHV Know-How (as defined in the Kissei Agreement) under the Kissei Agreement, and subject to the limitations on the use of such disclosed Know-How in the Kissei Agreement, may disclose ISLT Know-How to Kissei for use by Kissei pursuant to the Kissei Agreement.

Upfront Payment; Milestone Payments

4.1 <u>Upfront Payment</u>. In partial consideration of the rights granted by BHV to ISLT on the Effective Date pursuant to this Agreement, BHV shall be entitled to an upfront payment of five million dollars (US \$) (\$5,000,000) (the "<u>Upfront Payment</u>"), which shall be paid by ISLT to BHV on the Effective Date.

4.2 <u>Kissei Milestone Payments</u>. In addition to the other milestones required to be paid under this Article 4, and in partial consideration of the license rights under the Kissei Patents and Kissei Know-How granted to ISLT by BHV as of the Effective Date hereunder, ISLT shall pay directly to Kissei on behalf of BHV the following milestone amounts within twenty (20) days of the occurrence of the corresponding events described below (the "<u>Kissei Milestones</u>"), and shall copy BHV on its remittances to Kissei:

| _ | Milestone Event | Milestone Payment (US \$): |
|-------|-----------------|----------------------------|
| (i) | [***] | [***] |
| (ii) | [***] | [***] |
| (iii) | [***] | [***] |
| (iv) | [***] | [***] |
| (v) | [***] | [***] |

For clarity, the each of the Kissei Milestones shall become payable upon achievement of such Kissei Milestone by ISLT or any of its Affiliates or Sublicensees. Within five (5) days of the occurrence of each Kissei Milestone, ISLT shall notify BHV in writing of such occurrence.

4.3 BHV Milestone Payments.

(a) In addition to the other milestones required to be paid under this Article 4, and in partial consideration of the license rights under the Kissei Patents, Kissei Know-How, Biphasic Patents and Biphasic Know-How granted to ISLT by BHV as of the Effective Date hereunder, ISLT shall pay to BHV the following milestone amounts within thirty (30) days of the occurrence of the corresponding events described below (the "<u>BHV Milestones</u>", and the amounts payable in connection with the BHV Milestones, the "<u>BHV Milestone Amounts</u>"):

| | Milestone Event | Milestone Payment (US \$): |
|--------|-----------------|----------------------------|
| (i) | [***] | [***] |
| (ii) | [***] | [***] |
| (iii) | [***] | [***] |
| (iv) | [***] | [***] |
| (v) | [***] | [***] |
| (vi) | [***] | [***] |
| (vii) | [***] | [***] |
| (viii) | [***] | [***] |
| (ix) | [***] | [***] |
| (x) | [***] | [***] |

(b) For clarity, each of the BHV Milestones shall become payable upon achievement of such BHV Milestone by ISLT or any of its Affiliates or Sublicensees. Within five (5) days of the occurrence of each BHV Milestone, ISLT shall notify BHV in writing of such occurrence.

(c) In the event that any BHV Milestone listed after the [***] in the table above is achieved and the BHV Milestone Amount for the [***] has not yet been paid at such time, ISLT shall pay to BHV the BHV Milestone Amount for the [***] together with the BHV Milestone Amount for such other BHV Milestone.

4.4 <u>Non-Refundable</u>. Any payments made by ISLT in accordance with this Agreement shall, once they are paid, not be refundable nor creditable for any reason whatsoever.

4.5 <u>Single Payments</u>. The milestone payments specified above in this Article 4 shall be made only one time upon the first occurrence of the Milestone Event described above, regardless of how many times such Milestone Event may be achieved.

4.6 <u>Payment in Cash</u>. All payments under this Agreement shall be paid in cash.

Royalties

5.1 <u>Royalty Rates and Term of Royalty</u>. In partial consideration of the license rights under the Kissei Patents, Kissei Know-How, Biphasic Patents and Biphasic Know-How granted to ISLT by BHV as of the Effective Date hereunder, ISLT shall pay on Net Sales of all Products by ISLT, its Affiliates and any Sublicensees, a non-refundable royalty, as follows:

(a) In countries of the Territory where Valid Claims exist or Data Exclusivity exists, [***] of Net Sales in such country from the date of first commercial sale of a Product until the expiration of all Valid Claims and the Data Exclusivity, on a country-by-country basis, or

(b) In countries of the Territory where all Valid Claims and Data Exclusivity in such country have expired sooner than the date which is [***] from first commercial sale of the Product in such country (the "<u>Royalty Term</u>"), [***] of Net Sales for the remainder of the Royalty Term.

(c) The Parties acknowledge and agree that ISLT shall have no obligation to pay Kissei or BHV any royalties for Net Sales of a Product accruing in a particular country after the expiration of the applicable Royalty Term for such Product in such country.

(d) For the purpose of this Section 5.1, the "<u>Data Exclusivity</u>" means a period of exclusivity granted by a regulatory authority during which no Third Party may sell a generic product that competes with a Product.

(e) ISLT shall make the royalty payments required under Sections 5.1(a) and 5.1(b) directly to Kissei or to BHV as follows:

(i) In countries of the Territory where Valid Claims under the Kissei Patents exist or Data Exclusivity exists, [***] of Net Sales in such country from the date of first commercial sale of a Product until the expiration of all such Valid Claims and the Data Exclusivity, on a country-by-country basis, shall be paid by ISLT directly to Kissei on BHV's behalf, and ISLT shall copy BHV on its remittances to Kissei;

(ii) In countries of the Territory where all Valid Claims under the Kissei Patents and Data Exclusivity in such country have expired sooner than the date which is [***] from first commercial sale of the Product in such country, [***] of Net Sales shall be paid by ISLT directly to Kissei on BHV's behalf for the remainder of the Royalty Term, and ISLT shall copy BHV on its remittances to Kissei; and

(iii) After the application of Section 5.1(e)(i) and 5.1(e)(i) above, if applicable, all remaining royalty payments required to be paid by ISLT under Sections 5.1(a) and 5.1(b) shall be paid to BHV.

5.2 <u>No Bulk Form Sales, Bundling or Barter</u>. ISLT and its Affiliates and Sublicensees shall not sell or distribute Products in Bulk Form, bundled with other products or services, or for consideration other than cash. For purposes of this Section 5.2, "<u>Bulk Form</u>" means bulk active pharmaceutical ingredient or any pharmaceutical ingredient that as sold is not in Dosage Form, and "<u>Dosage Form</u>" means a pharmaceutical product that as sold is in individual dosage amounts in the form approved for sale to end users pursuant to a Marketing Approval. Without limiting ISLT's liability or BHV's remedies for breach of this Section 5.2:

(i) if ISLT or its Affiliates or Sublicensees sell a Product in Bulk Form to a Third Party for resale, then the gross amount to be included in the calculation of Net Sales arising from such sale shall be the gross amount that would have been received if such Product had been sold in Dosage Form, to be determined using the average units of Product in Dosage Form expected from the quantity of Product in Bulk Form sold and the average gross amount received by ISLT or its Affiliates or Sublicensees for the same Product in Dosage Form sold in the same country during the preceding three calendar months. If there have been no sales of the same Product during the preceding three calendar months in the same country, the gross amount to be included in the calculation of Net Sales arising from such sale shall be the gross amount that would have been received if such Product had been sold in Dosage Form, to be determined in the manner set forth in the immediately preceding sentence for the same Product in Dosage Form sold in the United States during the preceding three calendar months; and

(ii) if ISLT or its Affiliates or Sublicensees sell a Product either for consideration other than cash or bundled with other products or services, the Net Sales of such Product will be calculated based on the average unit price of such Product when sold

(other than as part of a bundle) in cash transactions in such country during the preceding three calendar months. If ISLT or its Affiliates or Sublicensees do not separately sell such Product in such country, the Net Sales for such Product will be calculated based on the average unit price of such Product when sold (other than as part of a bundle) in cash transactions in the United States during the preceding three calendar months.

5.3 <u>Accrual of Royalties</u>. No royalty shall be payable on a Product made or used for tests or development purposes, or distributed as samples and for which no payment is received by ISLT, or its Affiliates or Sublicensees. No royalties shall be payable on sales among ISLT, its Affiliates or its Sublicensees, but royalties shall be payable on subsequent sales by ISLT, its Affiliates or its Sublicensees to a Third Party.

5.4 <u>Third Party Royalties</u>. In the event that (i) the Compound or a Product is deemed by a court of competent jurisdiction to infringe a valid claim of a patent owned or Controlled by a Third Party ([***]) in any given country of the Territory, or (ii) ISLT determines, after consultation with BHV (and Kissei as required under Section 5.03 of the Kissei Agreement), that it is necessary to pay royalties or other fees to any Third Party ([***]) to obtain a license to practice any Third Party's rights in order to market, manufacture or develop the Compound or a Product in any given country of the Territory, then in such event, and provided that BHV is entitled to deduct such amounts from its payment obligations under the Kissei Agreement, ISLT may deduct [***] of such royalties due to such Third Parties (or such amounts expended in settlement of such claim, or for securing such rights) in any calendar quarter from the royalties otherwise due under this Agreement with respect to Net Sales of such Product in such country during such calendar quarter. The amount of the reduction in the royalty rate, however, shall in no case exceed [***] of the amounts that would have been payable according to Section 5.1 but for this provision. In the event that ISLT is obligated with respect to any calendar quarter to pay royalties both to Kissei and to BHV under Section 5.1, then any amount that ISLT is entitled to deduct from royalties pursuant to this Section 5.4 shall be deducted on a pro-rata basis from the royalties otherwise due to each of Kissei and BHV under Section 5.1 (*i.e.*, in proportion to the royalties otherwise payable to each of them). [***].

5.5 <u>Compulsory Licenses</u>. Should a compulsory license be granted to a Third Party under the applicable laws of any country in the Territory under the Patents licensed hereunder to ISLT, and provided that BHV is entitled to adjust its royalty obligation under the Kissei Agreement in the same manner, the royalty rate payable hereunder for sales of Products in such country shall be adjusted to match any lower royalty rate granted to such Third Party for such country, with respect to the sales of such Products, and during such periods, for which such Third Parties sell under the compulsory license material quantities of products that compete with the Products then marketed and sold by ISLT in that country. Notwithstanding the foregoing, in the event that ISLT is obligated, with respect to any calendar quarter in which a compulsory royalty is in effect in a country of the Territory, to pay royalties both to Kissei and to BHV under Section 5.1, then (a) the royalty rate granted to such Third Party for such country, times (ii) [1 + (A / B)], where A equals the royalty then otherwise payable to BHV pursuant to Section 5.1(e)(ii) and B equals the royalty payment then otherwise payable to Kissei pursuant to Section 5.1(e)(ii), as applicable, and (b) ISLT will pay such royalties to Kissei and BHV on a pro-rata basis based on the proportion of royalties then otherwise payable to Kissei and BHV. [***].

5.6 [***]. [***].

5.7 <u>Partnering Payments</u>. ISLT shall pay to BHV [***] of all Revenues for which a right for ISLT or any of its Affiliates to receive payment from any Third Parties arose prior to [***], even if such payments are received after [***] (the "<u>Partnering Payments</u>"). Notwithstanding the foregoing, if the BHV Milestone for the [***] is achieved by a Sublicensee of ISLT and such achievement also results in the receipt by ISLT or any of its Affiliates of Revenues, then BHV will only be entitled to a single payment in respect of such achievement in an amount equal to the greater of the BHV Milestone Amount for the [***] pursuant to Section 4.3 or the amount that is payable based on such Revenues pursuant to this Section 5.7. For the avoidance of doubt, the obligations of this Section 5.7 will not apply to Revenues for which a contingent right to receive payment does not arise until after [***], even if such Revenues are earned as part of a transaction that previously resulted in payment obligations for ISLT under this Section 5.7.

5.8 <u>Royalty Reports; Records</u>. During the term of this Agreement, ISLT shall furnish or cause to be furnished to BHV on a quarterly basis a written report or reports (the "<u>Royalty Report</u>") covering the immediately preceding calendar quarter (ending on the last day of March, June, September and December, as applicable; each such calendar quarter being sometimes referred to herein as a "<u>Royalty Period</u>") showing:

- (a) the Net Sales of all Products in each country of the Territory during the Royalty Period;
- (b) the royalties, payable in Dollars, which shall have become payable hereunder in respect to such Net

Sales;

(c) all Revenues;

(d) the Partnering Payments, payable in Dollars, which shall have become payable hereunder in respect to such Revenues;

(e) withholding taxes, if any required by law to be deducted in respect of such royalties and Partnering Payments; and

(f) the exchange rates used in determining the amount of Dollars.

BHV may disclose all Royalty Reports to Kissei.

5.9 Exchange Rates; Reports. With respect to sales of Products invoiced and Revenues payable in Dollars, the Net Sales and royalty and Partnering Payments payable shall be expressed in Dollars. With respect to sales of Products invoiced and Revenues payable in a currency other than Dollars, the Net Sales and royalty and Partnering Payments payable shall be expressed in the domestic currency of the country where such sale was made or Revenue became payable, as applicable, together with the Dollar equivalent of the royalty and Partnering Payments payable, calculated using the exchange rates normally used by ISLT in its management and financial reporting. Royalty Reports shall be due on the thirtieth (30th) day with respect to the United States, and on the sixtieth (60th) day for the rest of the Territory, following the close of each respective Royalty Period. All royalties and Partnering Payments payable and accurate records in sufficient detail to enable the royalties and Partnering Payments payable hereunder to be determined and substantiated. A final Royalty Report shall be due upon the expiration or termination of this Agreement.

5.10 <u>Withholding Tax</u>. Any tax paid or required to be withheld by ISLT on account of the milestones or royalties or Partnering Payments payable to BHV under this Agreement shall be deducted from the amount of the milestones or royalties or Partnering Payments otherwise due, provided in respect of Milestones and royalties that BHV is entitled to deduct such withheld amounts from its payment obligations under the Kissei Agreement. ISLT shall secure and send to BHV written proof of any such taxes withheld and paid by ISLT, its Affiliates or its Sublicensees for the benefit of BHV in a form sufficient to satisfy the United States Internal Revenue Service and any other taxing agency having authority to tax such transaction.

5.11 <u>Late Payments</u>. ISLT shall pay interest to Kissei or BHV, as applicable, on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of (a) LIBOR plus 2%, compounded monthly or (b) the highest rate permitted by applicable law, calculated on the number of days such payments are paid after the date such payments are due. In addition, each Party shall reimburse the other Party for all costs and expenses, including without limitation attorney fees and legal expenses, incurred by the other Party in the collection of late payments payable by such Party.

5.12 Audit Rights. BHV shall have the right to have a public accounting firm of its own selection, except one to whom ISLT or its Affiliate or its Sublicensee(s), if any, may have reasonable objection, and at its own expense (except if the result of such audit results in a variation or error exceeding ten percent (10%) of the payments that were required to be paid pursuant to this Agreement, in which case ISLT shall be responsible for the cost of such audit), examine the relevant books and records of account of ISLT and its Affiliate(s) and its Sublicensee(s), if any, during reasonable business hours upon reasonable prior written notice to ISLT and not more often than once each calendar year, for not more than three (3) previous years, to determine whether appropriate accounting and payment have been made to Kissei and BHV hereunder. The foregoing right includes the right for BHV to conduct such an audit on behalf of or at the request of Kissei, and to the extent required for compliance of BHV with the Kissei Agreement, Kissei may participate in any audit conducted under this Section 5.12. BHV may exercise such right until the end of three (3) years after the termination or expiration of this Agreement. ISLT shall promptly pay to Kissei or BHV, as applicable under Article 4 or Article 5, the full amount of any underpayment, together with interest thereon in accordance with Section 5.11. Said public accounting firm shall treat as confidential, and shall not disclose to BHV, any

information other than information which shall be given to BHV pursuant to any provision of this Agreement. ISLT may require said public accounting firm to sign a confidential disclosure agreement before the audit commences.

5.13 <u>Royalties for Combination Products</u>. In the event that ISLT or its Affiliate or Sublicensee develops a Combination Product, the following provisions will apply with respect to the calculation of royalties on the sale of such Combination Products. Net Sales of Combination Products shall be calculated separately from Net Sales of Products.

For purposes of calculating the amount of Net Sales with respect to Combination Products sold in each Royalty Period, the Parties agree to use the following formula:

[A/(A+B)] x Total Net Sales of Combination Products for such Royalty Period

Where:

A equals the actual average of the invoice price of the most frequently prescribed dose of the Product containing the same Compound that is part of the Combination Product in each of the Major Countries, if such Product is sold separately (i.e. not as part of a Combination Product), and

B equals the sum of the actual average of the invoice prices of the most frequently prescribed dose of all other therapeutically or prophylactically active ingredients in the Combination Product other than the Compound in each of the Major Countries, if such other active ingredients are sold separately.

For purposes of calculating Net Sales for Combination Products, if the Product or the other therapeutically or prophylactically active ingredients are not sold separately in all of the Major Countries, then the Parties will calculate the averages referenced above, using the prices in those Major Countries for which the Product and the other ingredients are sold separately. If, however, the Product or the other therapeutically or prophylactically active ingredients are not sold separately in any of the Major Countries, then the Parties will negotiate in good faith an appropriate calculation of Net Sales that are subject to the royalty payment obligation under this Agreement so as to fairly allocate the relative value of the active ingredients in the Combination Product; provided, however, that the Parties agree that the multiplier applied to the royalty rate or Net Sales totals for such Combination Product will be less than 1 and not a negative number; provided, further, that the multiplier shall not in any event be a fraction that is smaller than the fraction that BHV has negotiated pursuant to the Kissei Agreement for such Combination Product.

5.14 <u>Biphasic Products</u>. In the event that ISLT or any of its Affiliates or Sublicensees desires to make, have made, use, sell, offer to sell or import any Biphasic Product, ISLT shall notify BHV of the relevant Biphasic Product in writing, and the Parties shall, prior to any commercialization of such Biphasic Product, [***].

Development

6.1 <u>Development Efforts</u>. ISLT shall pursue its development of the Product in the Territory using Commercially Reasonable Efforts. Without limiting the foregoing, ISLT shall use best efforts to initiate the Development Plan as soon as possible after the Effective Date and shall perform all of its obligations under the Development Plan in accordance with the timelines set forth therein.

6.2 <u>Management Committee</u>. The Development Plan shall be managed, and the Parties' activities under this Agreement with respect to the development and commercialization of the Products in the Field in the Territory shall be overseen and coordinated, by a three (3) person committee of ISLT management (the "<u>Management Committee</u>") that includes the Chief Operating Officer of ISLT and two (2) additional members of ISLT management appointed by ISLT's board of directors. The Management Committee may amend the Development Plan or Commercial Plan from time to time in writing. Actions may be taken by the Management Committee only with approval of a majority of its members, which majority must include the Chief Operating Officer. At such time as the Management Committee determines, the Management Committee will expand to five (5) members and will include the Chief Executive Officer and Chief Operating Officer. The Management Committee will expand to five (5) members including the Chief Executive Officer and Chief Operating Officer. The Management Committee will require approval of a majority of the members including the Chief Executive Officer and Chief Operating Officer. The Management Committee shall hold the decision-making authority described in this Section 6.2 for as long as Mr. Green remains Chief Executive Officer of ISLT and Dr. Wilkison remains Chief Operating Officer of ISLT, unless otherwise agreed by the Parties in writing. If Mr. Green ceases to be the Chief Executive Officer or Dr. Wilkison ceases to be the Chief Operating Officer (the date of the first such occurrence, the "<u>Committee Date</u>"), unless otherwise agreed by the Parties in writing, the Joint Development Committee and Joint Steering Committee shall be formed as soon as possible thereafter pursuant to Sections 6.3, 7.3 and 7.4, respectively, and shall become responsible for such decision-making, as described in such Sections.

6.3 Joint Development Committee.

(a) <u>Composition</u>. Effective upon the Committee Date, the Parties hereby agree to form a Joint Development Committee for managing development activities under this Agreement. The Joint Development Committee shall be comprised of four members, with two members to be appointed by each of BHV and ISLT. Each Party shall appoint to the Joint Development Committee and be represented on the Joint Development Committee at all times by (i) one or more members of its senior management with primary responsibility for research, and (ii) one or more other members of its senior management. Subject to the foregoing, a member of the Joint Development Committee may be replaced at any time in the discretion of the Party that appointed such Joint Development Committee member.

(b) <u>Responsibility; Decision Making</u>. The Joint Development Committee shall be responsible for managing the development program for the Compound and the Products in the Field in the Territory, and may amend the Development Plan from time to time in writing. At each Joint Development Committee meeting, at least one member appointed by each of BHV and ISLT must be present to constitute a quorum. Decisions shall be made by unanimous vote based on commercially reasonable judgment, with all the members representing BHV collectively having one vote and all the members representing ISLT collectively having one vote. Any disputes will be raised to the Joint Steering Committee for final decision.

(c) <u>Meetings</u>. The Joint Development Committee shall meet regularly, but in no event less than once each calendar quarter. Participation in any meeting of the Joint Development Committee may be in person, by telephone, by video conference or by other means of telecommunication that enables all members of the Joint Development Committee participating in the meeting to communicate simultaneously with each other. A member of the Joint Development Committee may, by written notice to each of the other members of the Joint Development Committee, designate a proxy with voting authority to attend such meeting in the member's place. In addition, the Joint Development Committee may act without a formal meeting by a written consent signed, in one original or multiple counterparts, by all the members of the Joint Development Committee. Representatives of either Party, in addition to the members of the Joint Development Committee, may attend Joint Development Committee meetings as nonvoting observers at the invitation of either Party.

(d) <u>Minutes</u>. The Joint Development Committee shall keep accurate minutes of its meetings and record all decisions and all actions recommended or taken. Draft minutes shall be delivered to the members of the Joint Development Committee within twenty (20) days after each meeting. The members of the Joint Development Committee shall elect or appoint a secretary for each meeting and such secretary shall be responsible for the preparation and circulation of the draft minutes. Draft minutes shall be edited by the members of the Joint Development Committee and shall be issued in final form only with their approval and agreement as

evidenced by their signatures on the minutes. Minutes of Joint Development Committee meetings shall be BHV Confidential Information and ISLT Confidential Information.

6.4 <u>Coordination of Compound Development Activities</u>. Each Party shall provide to the other Party the draft protocols for any non-clinical or clinical studies related to the Compound or any Product prior to the Party's commencement of such studies, and BHV shall be permitted to disclose such draft protocols to Kissei. The Party receiving such protocols will have ten (10) days from receipt thereof to review and comment on the protocols. The Party that is proposing such protocols shall take into account the comments from the other Party (including any comments of Kissei that BHV may relay to ISLT). ISLT shall consider in good faith BHV's and Kissei's views and suggestions regarding the development program for the Compound and any Product in the Field in the Territory, but shall develop the Compound and Products in the Field in the Territory with its own responsibility and, subject to Sections 6.1, 6.2 and 6.3, shall have the sole responsibility for such decisions and expenses. BHV shall consider in good faith ISLT's views and suggestions regarding the development program for the Compound or Product outside the Territory, but shall have the right to develop the Compound and any Product outside the Territory with its own responsibility for such decisions and expenses.

6.5 <u>Development Goal</u>. ISLT agrees that it shall conduct development activities with the goal of developing the Compound and/or Product [***].

6.6 <u>Development Costs</u>. ISLT shall be responsible for all costs incurred by it in non-clinical and clinical development activities related to the Compound and Products in the Field in the Territory. ISLT shall not be responsible for any costs incurred by BHV or Kissei in non-clinical and clinical development activities related to the Compound and Products outside the Territory. In the event that one Party (the "<u>Requesting Party</u>") requests that the other Party conduct an activity in its territory that the other Party (the "<u>Conducting Party</u>") would not have conducted for its own purposes, and if such request is approved by the Conducting Party, the Conducting Party shall propose a budget to the Requesting Party to cover its costs in conducting such activity. If such budget is accepted by the Requesting Party, the Conducting Party shall conduct such activity at the Requesting Party's expense in accordance with the budget proposed and any other mutually agreed terms.

6.7 <u>Regulatory Filings</u>. In the event that ISLT or its Affiliate or its Sublicensee(s), if any, intends to file Regulatory Filings in Major Countries for the Compound or a Product, including any supplements which may have significant impact on development outside the Territory, as reasonably determined by ISLT, or annual reports thereto, ISLT shall submit to BHV an English summary thereof reasonably in advance and BHV may provide such summary to Kissei, and BHV may give comments thereon (and may relay comments from Kissei), if any, within thirty (30) days from the receipt thereof, and ISLT shall take into account any such comments as far as it is scientifically and objectively appropriate and reasonable.

6.8 Development Status Report. Within fifteen (15) days following the close of each calendar half-year during the term of this Agreement, ISLT will issue a development status report on development activities of ISLT and its Affiliates or its Sublicensee(s) in the Territory, if any, during the immediately preceding six (6) month period, and BHV may provide a copy of such report to Kissei. In the event that any unexpected or unusual findings including adverse drug reactions are found during the course of the development by either ISLT or BHV and their respective Affiliate(s) or its Sublicensee(s), if any, of the Compound or a Product, and which may require reporting to relevant regulatory authorities, each Party shall promptly inform the other Party and Kissei of such findings and, where necessary, both Parties hereto shall discuss the matter promptly.

6.9 <u>Key Regulatory Events</u>. ISLT will keep a record of the current Development Plan for the Compounds in the Field in the Territory. The Development Plan shall include the proposed dates of starting Phases I, IIa, IIb and III clinical studies for the Compound as well as the dates of the Regulatory Filings for the Compound (each, a "<u>Key Regulatory Event</u>") in the Major Countries of the Territory. ISLT and BHV also agree to inform each other once the actual date for each Key Regulatory Event has occurred in each of the Major Countries of the Territory, and BHV may inform Kissei of such occurrence.

6.10 <u>Manufacturing</u>. [***]. ISLT will be responsible for all reasonable expenses related to the transport, insurance, storage, and maintenance of such API. Subject to the terms and conditions of this Agreement, and except as set forth in this Section 6.10, ISLT shall have sole responsibility for performing or obtaining manufacture of all quantities of Compound (including API) and Products required for performance of its obligations under this Agreement. The Parties will work together in good faith to achieve the most cost effective manufacturing for global commercial products. The Parties agree that the material to be used for the Phase III clinical trials shall be supplied through the product supply chains which have been assembled for commercial supply of the Product.

6.11 Exchange of Development Data. ISLT agrees to provide BHV, and BHV may provide Kissei, from time to time, with ISLT Development Data relating to the Compound and the Products for the purpose of allowing BHV and Kissei to conduct their own development programs with respect to the Compound outside the Territory, including a right to file such ISLT Development Data with regulatory agencies. Similarly, BHV agrees to provide ISLT, from time to time, with BHV Development Data relating to the Compound and the Products for the purpose of allowing ISLT to further its own development program with respect to the Compound in the Field in the Territory, including a right to file such BHV Development Data with regulatory agencies in the Territory. Any such BHV Development Data that is provided to ISLT shall be included in the definition of Biphasic Know-How for purposes of this Agreement. For purpose of this Section 6.11, "ISLT Development Data" means the integrated summary reports of efficacy and safety data, all study reports for clinical and non-clinical studies, copies of the Regulatory Filings which are equivalent to an IND for all Major Countries and other information reasonably requested by BHV, in each case to the extent Controlled by ISLT or its Affiliates, and "<u>BHV Development Data</u>" means the integrated summary reports for clinical and non-clinical studies, copies of the Regulatory for clinical and non-clinical studies, copies of the Regulatory and safety data, all study reports for clinical and non-clinical studies and safety data, all study reports for clinical and non-clinical studies of efficacy and safety data, all study reports for clinical and non-clinical studies, copies of the Regulatory Filings which are equivalent to an IND for all countries outside the Territory and other information reasonably requested by BHV.

Marketing and Commercialization

7.1 <u>Commercialization Efforts</u>. ISLT shall use Commercially Reasonable Efforts, at its own expense, to promote, market, distribute and sell the Products in the Field in the Territory. Without limiting the foregoing, ISLT shall use best efforts to initiate the Commercial Plan as soon as possible and shall perform all of its obligations under the Commercial Plan in accordance with the timelines set forth therein.

7.2 <u>Commercial Plan</u>. The Parties shall use their best efforts to agree on an initial Commercial Plan as soon as reasonably possible after the Effective Date. ISLT shall not withhold its written agreement to any Commercial Plan proposed by BHV that is commercially reasonable.

7.3 Joint Commercialization Committee.

(a) <u>Composition</u>. Effective upon the Committee Date, the Parties hereby agree to form a Joint Commercialization Committee for managing commercial activities under this Agreement. The Joint Commercialization Committee shall be comprised of four members, with two members to be appointed by each of BHV and ISLT. Each Party shall appoint to the Joint Commercialization Committee and be represented on the Joint Commercialization Committee at all times by (i) one or more members of its senior management with primary responsibility for commercialization, and (ii) one or more other members of its senior management. Subject to the foregoing, a member of the Joint Commercialization Committee may be replaced at any time in the discretion of the Party that appointed such Joint Commercialization Committee member.

(b) <u>Responsibility; Decision Making</u>. The Joint Commercialization Committee shall be responsible for managing the commercialization program for the Products in the Field in the Territory, and may amend the Commercialization Plan from time to time in writing. At each Joint Commercialization Committee meeting, at least one member appointed by each of BHV and ISLT must be present to constitute a quorum. Decisions shall be made by unanimous vote based on commercially reasonable judgment, with all the members representing BHV collectively having one vote and all the members representing ISLT collectively having one vote. Any disputes will be raised to the Joint Steering Committee for final decision.

(c) <u>Meetings</u>. The Joint Commercialization Committee shall meet regularly, but in no event less than once each calendar quarter. Participation in any meeting of the Joint Commercialization Committee may be in person, by telephone, by video conference or by other means of telecommunication that enables all members of the Joint Commercialization Committee participating in the meeting to communicate simultaneously with each other. A member of the Joint Commercialization Committee may, by written notice to each of the other members of the Joint Commercialization Committee, designate a proxy with voting authority to attend such meeting in the member's place. In addition, the Joint Commercialization Committee may act without a formal meeting by a written consent signed, in one original or multiple counterparts, by all the members of the Joint Commercialization Committee. Representatives of either Party, in addition to the members of the Joint Commercialization Committee, may attend Joint Commercialization Committee meetings as nonvoting observers at the invitation of either Party.

(d) <u>Minutes</u>. The Joint Commercialization Committee shall keep accurate minutes of its meetings and record all decisions and all actions recommended or taken. Draft minutes shall be delivered to the members of the Joint Commercialization Committee within twenty (20) days after each meeting. The members of the Joint Commercialization Committee shall elect or appoint a secretary for each meeting and such secretary shall be responsible for the preparation and circulation of the draft minutes. Draft minutes shall be edited by the members of the Joint Commercialization Committee and shall be issued in final form only with their approval and agreement as evidenced by their signatures on the minutes. Minutes of Joint Commercialization Committee meetings shall be BHV Confidential Information and ISLT Confidential Information.

7.4 Joint Steering Committee.

(a) <u>Composition</u>. Effective upon the Committee Date, the Parties hereby agree to form a Joint Steering Committee for managing development and commercial activities under this Agreement. The Joint Steering Committee shall be comprised of four members, with two members to be appointed by each of BHV and ISLT. Each Party shall appoint to the Joint Steering Committee and be represented on the Joint Steering Committee at all times by members of its senior management. Subject to the foregoing, a member of the Joint Steering Committee may be replaced at any time in the discretion of the Party that appointed such Joint Steering Committee member.

(b) <u>Responsibility; Decision Making</u>. The Joint Steering Committee shall have the following responsibilities:

(i) Oversee the development and commercialization activities of the Parties with respect to the Compound and the Products in the Field in the Territory;

(ii) Facilitate updates between the Parties regarding ongoing development and commercialization of the Compound and Products in accordance with Articles 6 and 7; and

(iii) Resolve disputes that may arise among the Parties' respective representatives on the Joint Development Committee, Joint Commercialization Committee or any other committees that the Parties have mutually agreed to form with respect to activities under this Agreement.

At each Joint Steering Committee meeting, at least one member appointed by each of BHV and ISLT must be present to constitute a quorum. Decisions shall be made by unanimous vote based on commercially reasonable judgment, with all the members representing BHV collectively having one vote and all the members representing ISLT collectively having one vote; provided, however, that any disputes shall be resolved in accordance with Section 7.4(c).

(c) <u>Joint Steering Committee Dispute Resolution</u>.

(i) Any disputed matters within the scope of the Joint Steering Committee's authority will be decided by the Chief Executive Officers of ISLT and BHV (or their respective designees) acting together; provided, however, that any disputed matter regarding management of activities under the Commercial Plan shall be resolved by the Chief Executive Officer of ISLT.

(ii) If, at any time during the term of this Agreement, resolution of a disputed matter within the scope of the Joint Steering Committee's authority is required while Mr. Green remains the Chief Executive Officer of ISLT and a controlling principal in BHV, then a disinterested representative of ISLT appointed by ISLT's board of directors will act in the stead of Mr. Green in resolving such matter.

(iii) Notwithstanding anything to the contrary in this Agreement, after the Committee Date, any disagreement regarding a proposed amendment to the Development Plan or Commercial Plan may only be resolved through a mutually agreed amendment memorialized by a written instrument that is duly executed by both Parties; provided, however, that BHV shall not withhold its written agreement to any amendment to the Commercial Plan proposed by ISLT that is commercially reasonable.

(iv) Nothing in this Section 7.4(c) shall limit, modify or operate to relieve ISLT of any of its obligations under this Agreement, including without limitation ISLT's obligations under Sections 6.1 and 7.1.

(d) <u>Meetings</u>. The Joint Steering Committee shall meet at least twice each calendar year. Participation in any meeting of the Joint Steering Committee may be in person, by telephone, by video conference or by other means of telecommunication that enables all members of the Joint Steering Committee participating in the meeting to communicate simultaneously with each other. A member of the Joint Steering Committee may, by written notice to each of the other members of the Joint Steering Committee, designate a proxy with voting authority to attend such meeting in the member's place. In addition, the Joint Steering Committee may act without a formal meeting by a written consent signed, in one original or multiple counterparts, by all the members of the Joint Steering Committee Tarty, in addition to the members of the Joint Steering Committee, may attend Joint Steering Committee meetings as nonvoting observers at the invitation of either Party.

(e) <u>Minutes</u>. The Joint Steering Committee shall keep accurate minutes of its meetings and record all decisions and all actions recommended or taken. Draft minutes shall be delivered to the members of the Joint Steering Committee within twenty (20) days after each meeting. The members of the Joint Steering Committee shall elect or appoint a secretary for each meeting and such secretary shall be responsible for the preparation and circulation of the draft minutes. Draft minutes shall be edited by the members of the Joint Steering Committee and shall be issued in final form only with their approval and agreement as evidenced by their signatures on the minutes. Minutes of Joint Steering Committee meetings shall be BHV Confidential Information and ISLT Confidential Information.

7.5 <u>Coordination of Product Marketing and Commercialization</u>. ISLT shall consider in good faith BHV's views and suggestions regarding the marketing of the Products in the Field in the Territory, but ISLT shall market the Products in the Field in the Territory with its own responsibility and, subject to Sections 7.1 and 7.3, shall have the sole responsibility for such decisions and expenses. BHV shall consider in good faith ISLT's views and suggestions regarding the marketing of the Products outside the Territory, but BHV may market the Products outside the Territory with its own responsibility and shall have the sole responsibility for such decisions and expenses. To the extent the Parties deem appropriate, they may agree to collaborate regarding participation in international medical or scientific conferences as well as pre- and post-launch promotional activities involving the Product which are applicable and beneficial both in the Territory and the Field, or outside the Territory.

7.6 <u>Commercialization</u>. Within ninety (90) days following receipt by ISLT or its Affiliate or its Sublicensee(s), if any, of a Marketing Approval of the Product for each Major Country, ISLT shall, and shall make its Affiliate and its Sublicensee(s), if any, start the marketing and sales of the Product in such Major Country with Commercially Reasonable Efforts, at its own expense, and to use Commercially Reasonable Efforts to promote, market, distribute and sell the Product consistent with accepted pharmaceutical business practice and applicable legal requirements.

7.7 Package Design. The design of the package of the Product for sale in the Field in the Territory will be decided by ISLT at its sole discretion. However, ISLT shall furnish BHV with copies of all Product packages, package inserts and monographs as well as major promotional materials such as brochures, pamphlets and the like to be used for marketing of the Product in the Field in the Territory for BHV's archives. BHV may request and provide additional copies to Kissei. It is understood and agreed, however, that ISLT is not granting any rights to BHV (or to Kissei) to use the ISLT corporate trademarks or ISLT corporate trade dress, without ISLT's prior consent. Unless prohibited by law, regulation, rule, regulatory agency policy or informal regulatory agency guidance in a country in the Territory, all of such packages, package inserts, monographs and promotional materials shall properly and clearly indicate in such reasonable shape, size and color so as to render the indication plainly discernible and as specified or approved by Kissei the words, "manufactured and sold by ISLT (or its designee) under license from Kissei Pharmaceutical Co., Ltd., Matsumoto, Japan", or an equivalent wording in a relevant language in each country of the Territory. BHV shall use reasonable efforts to obtain such approval from Kissei within a commercially reasonable time so as not to delay the commercialization under Section 7.6.

7.8 <u>Kissei Option to Co-Promote</u>. The Parties acknowledge that under Section 7.04 of the Kissei Agreement, Kissei has retained the option to participate, at Kissei's expense, in the promotion of the Product in the Field in the United States, and in the event of Kissei's exercise of such option, ISLT will enable such participation by Kissei, in accordance with the following:

(a) Kissei will have the right to co-promote the Product for not more than ten percent (10%) of total projected details in any quarter. The amount of the actual details to be performed by Kissei shall be agreed upon by ISLT, BHV and Kissei, and such co-promotion effort shall be at Kissei's expense;

(b) Kissei's exercise, or failure to exercise, of this option will not affect the other terms and conditions contained in this Agreement;

(c) Kissei's co-promotion rights will expire in the event that Kissei becomes an Affiliate of any party other than BHV or its Affiliates due to merger, consolidation, corporation combination or acquisition; and

(d) In the event that Kissei exercises its rights to co-promote the Product hereunder, it shall do so in conformity with the commercialization strategy and marketing plan specified by ISLT.

Article 8

Trademark

8.1 Choice of Trademark. Promptly after the start by ISLT of the Phase III clinical study for the Compound in the Field in the Territory, BHV may propose to ISLT a trademark(s) which BHV considers to be suitable for the promotion, marketing, sales and distribution of the Product in the Field in the Territory. In the event that ISLT considers that such proposed trademark(s) are appropriate for the promotion, marketing, sales and distribution of the Product in the Field in the Territory, ISLT will inform BHV to that effect. In such case, BHV shall, subject to any rights of Kissei in the trademark(s), transfer and assign BHV's rights to the trademark(s) (if any) to ISLT in the Territory free-of-charge. However, in the event that ISLT considers that any trademark(s) proposed by BHV are inappropriate for the promotion, marketing, sales and distribution of the Product in any country of the Territory, ISLT may select trademark(s) of its own choice to be used for the Product in the Field in the Territory. The trademark so selected by ISLT shall become the trademark for the Product in the Field in the Territory (hereinafter, the "Trademark"), and ISLT shall own all worldwide rights to the Trademark; provided, however, that ISLT shall exclusively license the rights to the Trademark(s) to BHV for subsequent license to Kissei in accordance with Section 8.01 of the Kissei Agreement for use in Japan, Korea and Taiwan, and for use by BHV in all other countries outside the Territory, in each case on a royalty-free basis. Kissei and BHV may file and register such license, where required to be registered, with the patent offices located in their respective territories and ISLT shall cooperate on such procedure. Notwithstanding the forgoing, ISLT shall bear the cost necessary for obtaining and maintaining the trademark(s) in the Territory and BHV shall bear the cost necessary for obtaining and maintaining the trademark(s) outside the Territory (other than in Japan, Korea and Taiwan).

8.2 <u>Rights on Termination</u>. In the event of the termination of this Agreement, ISLT shall transfer and assign to BHV the rights to the Trademark in the Territory without charge. ISLT shall thereafter refrain from using the Trademark and any other trademark confusingly similar thereto for any products in any countries of the Territory.

8.3 <u>Rights on Expiration</u>. Upon expiration of this Agreement in its entirety (but not its earlier termination), ISLT shall retain the rights to the Trademark in the Territory. BHV shall retain the exclusive license to the Trademark(s) outside the Territory. BHV shall thereafter refrain from using the Trademark or any other trademark confusingly similar thereto for any products in any countries of the Territory.

Article 9

Supply

9.1 <u>Manufacturing Process</u>. ISLT and BHV shall fully co-operate with each other and Kissei with respect to establishing the proper manufacturing process and quality control specifications for the Compound and for the Products in the Field in the Territory. Specifically, the Parties agree to freely exchange information concerning formulation, regulatory requirements, quality control, and other information concerning the manufacturing process. ISLT agrees that BHV may share such information with Kissei.

9.2 <u>Rights to Supply Active Drug Substance</u>. ISLT will have the right and responsibility to manufacture its own active drug substance and finished forms of the Product for sale in the Field in the Territory. If, however, Kissei desires to manufacture or supply active drug substance for ISLT, BHV may present to ISLT Kissei's then current capabilities and plans for manufacture of the drug substance and its ability to meet the commercial supply criteria set forth on <u>Exhibit D</u> hereto (the "<u>Agreed Supply Criteria</u>"). If BHV can demonstrate to the satisfaction of ISLT that Kissei can meet the Agreed Supply Criteria prior to the time that a Product enters Phase III clinical trials, Kissei may, at its option, elect to supply [***] for active drug substance with respect to the Territory at a price equal to [***]. It is acknowledged that Kissei will have the right to manufacture its own Compound and finished forms of the Product for sale outside the Territory. BHV will have the option to purchase its and/or Kissei's respective requirements for their respective territories from ISLT at a price [***]. In the event that Kissei is to supply to ISLT, or ISLT is to supply to BHV, the relevant parties shall negotiate in good faith a separate supply agreement which shall contain such terms and conditions which are customary for the pharmaceutical industry.

Quality Control

ISLT and BHV shall at all times during the term of this Agreement comply with the regulations concerning the manufacture of the Compound and any Product as may be required by the relevant authorities in the Territory. In the event that one Party is manufacturing or supplying Compound or Product for the other Party, (i) each Party acknowledges that its manufacturing facilities for the Compound or Product may be inspected by representatives of the health (or other relevant) authorities in certain countries, and (ii) each Party acknowledges that its manufacturing facilities for the Compound or Product may be inspected by representatives of the Compound or Product may be inspected by representatives of the other Party; provided, however, that the Party seeking to inspect such a facility, must give reasonable notice to the other Party, and the inspection must be conducted during reasonable business hours and in a manner which does not materially interfere with the operations of such facility.

Article 11

Disclaimer and Warranties

11.1 <u>Disclaimer</u>. BHV does not represent or warrant that ISLT can successfully develop, obtain Marketing Approvals for, or market the Products or any Biphasic Products in the Territory by using and relying upon the Kissei Patents, Kissei Know-How, Biphasic Patents and Biphasic Know-How licensed by BHV hereunder.

11.2 <u>BHV</u>. BHV represents and warrants to ISLT that as of the Execution Date:

(a) BHV is a limited liability company duly organized, validly existing and in good standing under the laws of the State of North Carolina.

(b) To BHV's knowledge, (i) it has full right and authority under the Kissei Agreement to use the Kissei Patents in the Field in the Territory, (ii) it owns the Biphasic Patents and has the right to use the Biphasic Patents in the Field in the Territory, and (iii) it has full right and authority to enter into this Agreement and to grant the sublicense and license to ISLT as herein described.

(c) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of BHV enforceable against BHV in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other laws affecting creditors' rights generally from time to time in effect, and to general principles of equity.

(d) The execution, delivery and performance of this Agreement does not conflict with any other agreement, contract, instrument or understanding, oral or written, to which BHV is a Party, or by which it is bound, nor will it violate any law or regulation of any legislature, court, governmental body, administrative agency or other authority having jurisdiction over BHV.

(e) Attached hereto as <u>Exhibit A</u> is, to BHV's knowledge, a complete and accurate list of all patents and patent applications included within the Kissei Patents. BHV will update <u>Exhibit A</u> on a periodic basis during the term of this Agreement to include additional Kissei Patents that may be filed or issued or become modified in some respect after the Effective Date, in each case to the extent that BHV has been made aware of such occurrence by Kissei.

(f) Attached hereto as <u>Exhibit B</u> is a complete and accurate list of all patents and patent applications included within the Biphasic Patents. BHV has obtained the assignment of all right, title and interest in the Biphasic Patents from the inventors named therein. BHV has not received any communication which expressly threatens interference actions or other litigation before any patent office, court or any other governmental entity in any jurisdiction with respect to the Biphasic Patents.

(g) BHV does not represent or warrant that the Kissei Patents, Kissei Know-How, Biphasic Patents or Biphasic Know-How will not infringe any intellectual property owned by any Third Party in the Territory.

(h) BHV has not granted, and will not grant during the term of this Agreement, any right to any Third Party relating to the Kissei Patents, Kissei Know-How, Biphasic Patents or Biphasic Know-How in the Field in the Territory which would conflict with the rights granted to ISLT hereunder.



(i) BHV has taken reasonable measures to protect the confidentiality of the Kissei Know-How and Biphasic Know-How, and will during the term of Agreement continue to take reasonable measures to protect the confidentiality of the Kissei Know-How and Biphasic Know-How. On occasions where BHV has granted access to Third Parties to Kissei Know-How or Biphasic Know-How, such access has been granted pursuant to an enforceable written confidentiality agreement containing restrictions on the use of such Kissei Know-How or Biphasic Know-How with a term of at least five (5) years.

(j) As of the ninetieth (90th) date after the Effective Date, BHV has provided ISLT according to Section 3.1 with all Kissei Know-How and Biphasic Know-How in the possession of BHV as of the Effective Date.

(k) As of the Execution Date, (i) the Kissei Agreement is in full force and effect; (ii) to BHV's knowledge, there has been no breach of the Kissei Agreement by BHV, nor any accusation by Kissei of any such breach against BHV; and (iii) there has been no amendment, update, or any other modification of the Kissei Agreement subsequent to the Fourth Amendment to the Kissei Agreement dated August 28, 2014.

11.3 <u>ISLT</u>. ISLT represents and warrants to BHV that as of the Execution Date:

Nevada.

(a) ISLT is a corporation duly organized, validly existing and in good standing under the laws of the State of

(b) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of ISLT enforceable against ISLT in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other laws affecting creditors' rights generally from time to time in effect, and to general principles of equity.

(c) The execution, delivery and performance of this Agreement does not conflict with any other agreement, contract, instrument or understanding, oral or written, to which ISLT is a Party, or by which it is bound, nor will it violate any law or regulation of any legislature, court, governmental body, administrative agency or other authority having jurisdiction over ISLT.

(d) It has not knowingly performed any acts that are inconsistent with the terms and purposes of this Agreement or that may infringe upon any of the rights of BHV hereunder.

(e) It has thoroughly studied all Know-How provided to ISLT prior to execution of this Agreement and significant data concerning the Compound and the Product provided to ISLT prior to execution of this Agreement, including but not limited to their safety and efficacy and risk/benefit, and ISLT has made its own judgment to enter into this Agreement at its own risk.

11.4 Limitation of Warranty. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, NON-INFRINGEMENT, OR VALIDITY OF ANY PATENT, WITH RESPECT TO ANY OF THE MATERIALS, INFORMATION, SERVICES OR LICENSES PROVIDED PURSUANT TO THIS AGREEMENT.

11.5 <u>Performance by Affiliates</u>. The Parties recognize that each Party may perform some or all of its obligations under this Agreement through its Affiliates; provided, however, that each Party will remain responsible and liable for the performance by its Affiliates and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

Intellectual Property

12.1 <u>Obligation to Disclose</u>. BHV will promptly disclose to ISLT all inventions and discoveries that come within the Kissei Patents and the Kissei Know-How that arise during the course of this Agreement and of which BHV is made aware by Kissei. BHV will provide ISLT with the information received from Kissei regarding such matters.

12.2 Prosecution and Maintenance.

(a) ISLT acknowledges that Kissei has retained full responsibility, including financial responsibility, for all Kissei Patents, including applications and maintenance worldwide. BHV will use reasonable efforts to cause Kissei to promptly file patent applications in the Territory for patentable Improvements made by Kissei. Subject to the Kissei Agreement, BHV will share with ISLT all patent prosecution materials provided by Kissei related to the Territory and will use reasonable efforts to allow for ISLT to comment thereon. ISLT will make recommendations for the patent application and prosecution in the Territory and BHV will use reasonable efforts to cause Kissei to duly consider all suggestions and recommendations made by ISLT; provided, however, ISLT acknowledges that Kissei shall have the right of final decision. With regard to the geographic scope of any patent application, BHV will inform ISLT of Kissei's proposed list of intended countries for filing in the Territory. Should ISLT desire applications to be filed in additional countries in the Territory beyond Kissei's suggested proposal, BHV will use reasonable efforts to cause Kissei to file in those additional countries, but ISLT will bear corresponding financial responsibility.

(b) The Parties acknowledge that the Kissei Agreement provides that if Kissei elects to abandon any part of Kissei Patents in the Territory, Kissei must provide thirty (30) days' notice of such election, and BHV has the right, at its discretion, to assume responsibility, including financial responsibility, for such part of the Kissei Patents. In the event that BHV assumes responsibility for any such Kissei Patents, BHV shall, subject to the Kissei Agreement, provide ISLT with a reasonable review period and allow for ISLT comment on any such patent application as well as any patent prosecution of such Kissei Patents to be filed by BHV. ISLT will make recommendations for the patent application and prosecution and BHV will duly consider all suggestions and recommendations made by ISLT; provided, however, that BHV shall have the right of final decision. In the event that BHV elects not to assume responsibility for any such Kissei Patent, BHV shall provide commercially reasonable notice to ISLT of that election and, if ISLT so requests, contact Kissei and convey ISLT's request to assume responsibility for prosecution of any such Kissei Patent. If Kissei approves such request, then ISLT will assume responsibility, including financial responsibility, for maintenance of any such Kissei Patent. If ISLT assumes responsibility for a Kissei Patent under this Section 12.2(b), ISLT may offset any fees incurred by ISLT in maintaining such Kissei Patent shall not be reduced by operation of this Section 12.2(b).

(c) BHV shall have full responsibility for prosecution and maintenance of the Biphasic Patents worldwide. BHV shall provide ISLT with a reasonable review period and allow for ISLT comment on any patent application as well as any patent prosecution of Biphasic Patents to be filed by BHV in the Territory. ISLT will make recommendations for the patent application and prosecution in the Territory and BHV will duly consider all suggestions and recommendations made by ISLT; provided, however, that BHV shall have the right of final decision. In the event that BHV elects not to prosecute or maintain any Biphasic Patent in the Territory, BHV shall provide thirty (30) day notice of that election and ISLT shall have the right, at its discretion, to assume responsibility, including financial responsibility, for prosecution and maintenance of any such Biphasic Patent. If ISLT assumes responsibility for a Biphasic Patent under this Section 12.2(c), ISLT may offset any fees incurred by ISLT in maintaining such Biphasic Patent this Agreement. For clarity, any payment required to be paid to Kissei under this Agreement shall not be reduced by operation of this Section 12.2(c).

(d) [***]. Any and all Biphasic Patents shall remain the property of BHV. [***].

12.3 <u>Updates to Exhibits A and B</u>. To achieve the purpose of making updates and modifications to <u>Exhibits A</u> and <u>B</u> on the developed and/or marketed Product by ISLT, BHV shall send a list of additional patents to be included in the Kissei Patents upon receipt of any such list from Kissei, and BHV shall, as appropriate from time-to-time such as upon the grant of a patent, send updates to the Biphasic Patents listed in <u>Exhibit B</u>.

12.4 Validity Challenge.

(a) Pre-Launch. In the event that a Third Party attacks the validity of any particular Kissei Patents or Biphasic Patents in any country of the Territory prior to the time that any Product is launched in any country of the Territory, BHV will use reasonable efforts to allow ISLT to provide input and comment on the conduct of the defense of such claim, and ISLT shall give all reasonable assistance (excluding financial assistance) to Kissei and BHV in connection with such defense. The Parties acknowledge that Kissei has the first right to control the suit and proceeding with respect to such pre-launch defense of Kissei Patents under the Kissei Agreement. In the event that BHV assumes control and defense of a claim in the Territory in accordance with the Kissei Agreement, BHV shall not agree to any settlement of the suit without the prior written consent of ISLT. BHV shall control any suit and proceeding with respect to such pre-launch defense of Biphasic Patents in the Territory, and BHV shall not agree to any settlement of the suit without the prior written consent of ISLT. In the event that neither Kissei nor BHV elects to assume control or defense of such a suit or claim with respect to the Kissei Patents in the Territory, BHV shall notify ISLT of that election within in a commercially reasonable time and, if ISLT so requests, contact Kissei and convey ISLT's request to assume control or defense of such suit or claim with respect to the Kissei Patents. If Kissei approves such request, then ISLT, at its discretion, may assume control or defense of such claim. In the event that BHV elects not to assume control or defense of such a suit or claim with respect to the Biphasic Patents in the Territory, then ISLT, at its discretion, may assume control or defense of such claim. In the event that ISLT assumes control or defense of any action under this Section 12.4(a), ISLT will assume all responsibility, including financial responsibility for the legal action. BHV shall give all reasonable assistance (excluding financial assistance) to ISLT. BHV may be represented by counsel of its own selection in such legal action. ISLT shall reimburse BHV for reasonable costs and shall not agree to any settlement of the suit without the prior written consent of BHV.

(b) Post-Launch. The Parties acknowledge that the Kissei Agreement provides that if a Third Party attacks the validity of any Kissei Patents in any country of the Territory as it relates to a marketed Product, BHV has the first right to promptly take legal action as is required to defend the validity of such Kissei Patents. In addition, the Parties agree that BHV has the sole right to take legal action as is required to defend the validity of any Biphasic Patents. ISLT shall give all reasonable assistance (excluding financial assistance) to BHV in connection with any defense under this Section 12.4(b). BHV shall have the right to control the suit and proceeding; provided, however, that BHV shall not agree to any settlement of the suit in the Territory without the prior written consent of ISLT. In the event that neither Kissei nor BHV elects to assume control or defense of such a suit or claim with respect to the Kissei Patents in the Territory, BHV shall notify ISLT of that election within in a commercially reasonable time and, if ISLT so requests, contact Kissei and convey ISLT's request to assume control or defense of such suit or claim. In the event that BHV elects not to assume control or defense of such claim. In the event that BHV elects not to assume control or defense of such claim. In the event that BHV elects not to assume control or defense of such a suit or claim with respect to the Siscei approves such request, then ISLT, at its discretion, may assume control or defense of any action under this Section 12.4(b), ISLT will assume all responsibility, including financial responsibility for the legal action. BHV shall give all reasonable assistance (excluding financial assistance) to ISLT. BHV may be represented by counsel of its own selection in such legal action. ISLT shall reimburse BHV for reasonable costs and shall not agree to any settlement of the suit without the prior written consent of BHV.

12.5 <u>Patent Term Extension</u>. ISLT shall cooperate with Kissei and BHV in obtaining any extension of the term of the Kissei Patents or Biphasic Patents or any other similar period of exclusivity, which may be available under the laws and regulations in any country of the Territory.

Article 13

Infringement

13.1 <u>Notification of Infringement</u>. If either Party learns of any misappropriation or unauthorized disclosure of Kissei Know-How or Biphasic Know-How, or any infringement or threatened infringement by a Third Party of any Kissei Patents or Biphasic Patents, in each case in the Field in the Territory, then subject to the Kissei Agreement, as applicable, such Party will promptly notify the other Party and will provide such other Party with all available evidence of such misappropriation or infringement. BHV may share any such information with Kissei.

13.2 <u>Infringement Proceedings</u>. To the extent permitted under the Kissei Agreement, the Parties' rights and obligations with respect to any Third Party misappropriation or infringement in the Field in the Territory shall be as follows:

(a) ISLT will have the right, but not the obligation, to institute, prosecute and control at its own expense and in its own name, any action or proceeding with respect to infringement of a claim of a Kissei Patent or Biphasic Patent, or any misappropriation or unauthorized disclosure of Kissei Know-How or Biphasic Know-How, in the Field in the Territory, by counsel of its

own choice, and will consult with BHV on any actions that ISLT proposes to take in such action or proceeding, and BHV may involve Kissei in such consultations. BHV will cooperate with ISLT and use reasonable efforts to cause Kissei to cooperate with ISLT in any such action or proceeding brought by ISLT against a Third Party, and BHV and Kissei will have the right to consult with ISLT and to participate in and be represented by independent counsel of their own choice in such litigation at their own expense; provided, however, that ISLT and its counsel shall remain in control of such litigation and make all significant decisions relating to the prosecution of such action.

(b) If ISLT fails to bring an action or proceeding or otherwise take appropriate action in ISLT's discretion to abate such infringement, misappropriation or unauthorized disclosure in the Field in the Territory within a period of ninety (90) days of written notice by BHV to ISLT requesting such action or at least thirty (30) days prior to the expiration of the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions or proceedings, BHV will have the right, but not the obligation, to bring and control, by counsel of its own choice, at its own expense, any such infringement, misappropriation or unauthorized disclosure action or proceeding. ISLT will cooperate with BHV (and at BHV's reasonable request, with Kissei) in any such action or proceeding brought by BHV (or by Kissei in a manner consistent with the Kissei Agreement) against a Third Party, and will have the right to consult with BHV and to participate in and be represented by independent counsel of its own choice in such litigation at its own expense; provided, however, that BHV (or Kissei, as applicable) and its counsel shall remain in control of such litigation and make all significant decisions relating to the prosecution of such action.

(c) If one Party brings any such action or proceeding under this Section 13.2, the other Party agrees, at the request and expense of the first Party, to be joined as a Party plaintiff to the extent necessary to prosecute the action or proceeding and to give the first Party reasonable assistance and authority to file and prosecute the suit. Any amounts recovered by either Party pursuant to this Section 13.2 will first be used to reimburse the Parties for any out-of-pocket litigation expenses (including reasonable attorney's fees and expenses) and any other legal expenses incurred pursuant to such enforcement. If ISLT brings an action under this Section 13.2, then any remaining amounts recovered by ISLT will be deemed Net Sales subject to the applicable royalty rate under Section 5.1. If BHV brings an action under this Section 13.2, then any remaining amounts will be divided between the Parties in proportion to their actual monetary contribution to the out-of-pocket costs of bringing such action. The Parties acknowledge that the foregoing allocation of recoveries shall be subject to the obligation to make reimbursements and payments to Kissei under the Kissei Agreement.

13.3 <u>Settlement with a Third Party</u>. The Party that controls the prosecution of a given action under Section 13.2 will also have the right, subject to the Kissei Agreement, to control settlement of an action described above; provided, however, that no settlement will be entered into with respect to a Patent without the written consent of the party owning such Patent, if such settlement would require the party to be subject to an injunction or make a monetary payment in excess of US\$10,000 or would restrict the claims in or invalidate any of the Patents.

13.4 Special Matters Pertaining to [***]. Notwithstanding any other provision in this Agreement, the Parties agree that ISLT shall be responsible for defending and managing all suits and claims brought by [***] based on infringement, invalidity or interference of the [***] or any acts under the licenses granted to ISLT in this Agreement [***]. ISLT will be financially responsible for all costs, expenses, fees, settlement amounts, and damages related to [***], with respect to activities in the Territory, including the costs and expenses associated with defending Kissei and BHV. ISLT will control the defense and settlement of the [***], at its own expense, with legal counsel of its own choosing. Any settlement of [***] will require the prior written approval of Kissei and BHV, which approval will not be unreasonably withheld or delayed. In the event that ISLT and its Affiliates determine that it is necessary to pay royalties or other fees to [***] to obtain a license in order to market or develop the Compound or a Product in any given country of the Territory, then in such event, and provided that BHV is entitled to deduct such amounts from its payment obligations under the Kissei Agreement, ISLT and its Affiliates may deduct [***] of such royalties due to [***] (or such amounts expended in settlement of such claim, or for securing such rights) from the royalties otherwise due with respect to Net Sales of such Product in such country. The amount of the reduction in the royalty rate, however, shall in no case exceed [***] of the amounts that would have been payable according to Section 5.1 but for this provision. In the event that ISLT is obligated with respect to any calendar quarter to pay royalties both to Kissei and to BHV under Section 5.1, then any amount that ISLT is entitled to deduct from royalties pursuant to the second preceding sentence shall be deducted on a pro-rata basis (i.e., in proportion to the royalties otherwise payable to each of them) from the royalties otherwise due to each of Kissei and BHV under Section 5.1. In addition, in the event that ISLT grants a royalty free sublicense to [***] in settlement of [***] and such sublicense results in product sales, such sales will not be included in Net Sales hereunder, and no royalties will be due hereunder, provided in each case that BHV is relieved of its royalty obligation with respect to such product sales under the Kissei Agreement. If, however, ISLT grants a royalty bearing sublicense to [***] in settlement of [***], and ISLT is receiving royalties from [***], then in such event, in addition to the amounts otherwise owed under this Agreement, ISLT will pass on to BHV any such royalties received by ISLT in respect of such settlement sublicense to the extent they apply to a license under the Kissei Patents, after first deducting any amounts incurred by ISLT in settlement or defense of, or damages related to, [***], including but not limited to any royalties that may be payable to [***].

Special Matters Pertaining to [***]. Notwithstanding any other provision in this Agreement, the Parties agree that 13.5 ISLT shall, at its sole expense, be exclusively responsible for defending and managing all suits and claims brought [***] based on infringement, invalidity or interference of the [***] or any acts under the licenses granted to ISLT in this Agreement (the "IP Claims"). ISLT will be financially responsible for all costs, expenses, fees, settlement amounts, and damages related to the IP Claims, with respect to activities in the Territory, including the costs and expenses associated with defending Kissei and BHV. ISLT will conduct the defense and management of the IP Claims in its commercially reasonable discretion. BHV will reasonably cooperate with ISLT and will use reasonable efforts to cause Kissei to cooperate with ISLT in the defense of such IP Claims, excluding financial support. In addition, Kissei and BHV will have the right to participate, at their own expense and with counsel of their choice, in the defense of any IP Claim the defense of which has been assumed by ISLT; provided, however, that ISLT and its counsel shall remain in control of such defense and shall make all significant decisions relating thereto. If (i) the Compound or a Product is deemed by a court of competent jurisdiction to infringe a valid claim of a Patent owned or controlled by [***] in any given country of the Territory, or (ii) ISLT determines, in its commercially reasonable discretion, that it is reasonably necessary to pay royalties or other fees to [***] to obtain a license to practice any patent or patent application owned or controlled by [***] in order to market or develop the Compound or a Product in the Field in any given country of the Territory, then ISLT may negotiate and enter into a license arrangement with [***] on commercially reasonable terms, provided, however, that ISLT shall keep BHV informed of the progress of such negotiation (and BHV may inform Kissei), provided further that such license agreement shall be only entered following full mutual consultation with BHV and shall not be entered into without and BHV's prior written approval if Kissei or BHV will bear a portion of royalties to be paid under such license as provided in sub-section (b)(ii) below, such approval not to be unreasonably withheld. BHV and ISLT will share responsibility for all royalties due to [***] for such a license as follows:

(a) ISLT will bear [***] of all license fees, milestones or any other payments that are not royalties based upon sales of a Product made to [***] in the Territory; and

(b) If such license with [***] includes royalties upon sales of a Product in the Territory:

(i) ISLT will bear all such royalties up to an amount equal to [***] of Net Sales of the Product in the relevant portion of the Territory; and

(ii) Thereafter, provided that BHV is entitled to deduct such offset amounts from its payment obligations under the Kissei Agreement, ISLT may offset [***] of any additional royalties due over the [***] threshold described above from the amounts otherwise due under Section 5.1 in a given calendar quarter with respect to Net Sales of such Product in such country. In the event that ISLT is obligated with respect to any calendar quarter to pay royalties both to Kissei and to BHV under Section 5.1, then any amount that ISLT is entitled to deduct from royalties pursuant to this Section 13.5(b)(ii) shall be deducted on a pro-rata basis (i.e., in

proportion to the royalties otherwise payable to each of them) from the royalties otherwise due to each of Kissei and BHV under Section 5.1.

13.6 <u>Patent Marking</u>. ISLT and its Affiliates and Sublicensees shall cause all Products sold in the United States to be marked with all applicable U.S. Patent Numbers, to the full extent permitted by United States law. ISLT and its Affiliates and Sublicensees shall similarly cause all Products shipped to or sold in any other country to be marked in such a manner as to conform with the patent laws and practices of such country.

Improvements & Grant-back

14.1 <u>BHV Improvements</u>. In the event that any Improvements result from the activities undertaken by BHV pursuant to this Agreement, patentable and non-patentable inventions shall be owned by BHV and patent applications shall be filed under the name of BHV and at BHV's expense. Any Patents on such Improvements that are Controlled by BHV in the Territory shall be included in the definition of Biphasic Patents for purposes of this Agreement.

14.2 ISLT Improvements. In the event that any Improvements result from the activities undertaken by ISLT pursuant to this Agreement, patentable and non-patentable inventions shall be owned by ISLT and patent applications shall be filed under the name of ISLT and at ISLT's expense. ISLT agrees to grant and hereby grants, on behalf of itself and its Affiliates, to BHV an exclusive, royalty-free license with the right to sublicense under any Improvement patent applications and patents obtained, owned by ISLT or any of its Affiliates, solely for the purpose of manufacturing, using, researching, developing, filing a new drug application, obtaining the registration and marketing, selling, offering for sale and importing the Compound or any Product (including a Combination Product, provided that such license shall not extend to any therapeutically or prophylactically active ingredient other than the Compound) outside the Territory during and after the term of this Agreement.

14.3 <u>Grant Back</u>. ISLT agrees to grant and hereby grants, on behalf of itself and its Affiliates, to BHV the royalty-free, non-exclusive right and license to use all of the ISLT Know-How (including the patents obtained thereon) resulting from the activities undertaken by ISLT, its Affiliate and its Sublicensees, if any, pursuant to this Agreement, and to disclose and sublicense the same to BHV's Affiliates and licensee(s) (including Kissei), if any, for the sole purpose of manufacturing, using, researching, developing, filing a new drug application, obtaining the registration and marketing, selling, offering for sale and importing of the Compound or any Product (including a Combination Product, provided that such license shall not extend to any therapeutically or prophylactically active ingredient other than the Compound) outside the Territory during and after the term of this Agreement. To the extent available and authorized in writing by Kissei, BHV will ensure that ISLT has the right to use free of charge all Know-How relating to the Compound or a Product developed by Kissei's licensees in Japan, Korea, Taiwan and China during the course and as a result of developing the Compound or Product. Such ISLT rights shall be limited solely to the development, formulation, manufacture, use, sale, or import of the Compound, the Product or the Combination Product in the Field in the Territory.

14.4 <u>Joint Inventions</u>. BHV and ISLT shall jointly own all inventions that are conceived and reduced to practice by one or more employees, agents or consultants of BHV or its Affiliate, together with one or more employees, agents or consultants of ISLT or its Affiliate. Notwithstanding the foregoing, the respective ownership and other rights of ISLT and Mr. Green and Dr. Wilkison in any inventions conceived or reduced to practice by either of such individuals shall be determined in a manner consistent with Mr. Green's and Dr. Wilkison's respective employment agreements with ISLT.

14.5 Future Rights.

(a) If, in the future, ISLT develops a product comprising an SGLT2 inhibitor compound conceived of and reduced to practice by ISLT, ISLT may not launch such product in the Territory without BHV's prior written approval, which approval will not be unreasonably withheld or delayed; provided, however, that such approval will be deemed to have been given by BHV automatically, and without further action on the part of BHV, in the event that either of the following situations have occurred:

(i) a Change-in-Control of BHV; or

(ii) ISLT offers to BHV, in the future, but prior to the launch of such product in the Territory, marketing rights to such product outside the Territory on a royalty-free basis.

(b) For purposes of this Section 14.5, the term "<u>Change-in-Control of BHV</u>" shall mean the date upon which a Third Party acquires the power to direct the management of BHV, including without limitation, by acquisition of a majority of the membership units of BHV, or by merger, consolidation or by any other corporate combination.

Confidentiality

15.1 <u>BHV Confidential Information</u>. Subject to any other provisions of this Agreement, ISLT, for itself and its Affiliates and its Sublicensee(s), if any, agrees that it shall, until five (5) years after the later expiration or termination of the Kissei Agreement or this Agreement or ten (10) years from the Effective Date, whichever is longer, hold in confidence all BHV Confidential Information hereunder and shall not disclose such BHV Confidential Information to any Third Party nor use such BHV Confidential Information for any commercial purpose other than the purpose of this Agreement, without first obtaining the written consent of BHV (and, in the case of the Kissei Know-How, Kissei). The term "BHV Confidential Information" means any information furnished to ISLT by BHV under this Agreement or the Confidentiality Agreement, including any and all Kissei Know-How and Biphasic Know-How, except as follows:

(a) Such information is a part of the public domain prior to the disclosure by BHV to ISLT hereunder; or

(b) Such information becomes a part of the public domain after the disclosure by BHV to ISLT hereunder without any breach by ISLT of this Agreement; or

(c) Such information which ISLT can demonstrate that it had independently developed prior to the disclosure by BHV to ISLT hereunder; or

(d) Such information is disclosed to ISLT by a Third party who has the right to make such disclosure without obligation of confidentiality.

Nothing contained herein shall prevent ISLT and its Affiliate and its Sublicensee(s), if any, from disclosing such BHV Confidential Information to the extent that (i) such BHV Confidential Information is disclosed in connection with the securing of the necessary governmental authorizations for the marketing of the Products in the Field in the Territory, or (ii) such BHV Confidential Information is required to be disclosed by law or for the purpose of complying with governmental regulations, or (iii) such BHV Confidential Information is disclosed under an appropriate secrecy agreement to outside research institutions performing experiments and tests on the Compound and/or the Products on behalf of ISLT so as to perform the purpose of this Agreement, or (iv) such BHV Confidential Information is disclosed for due performance of this Agreement, including without limitation in support of a sublicense permitted hereunder, under an appropriate secrecy agreement.

15.2 <u>Publication</u>. In the event that ISLT or its Affiliates or Sublicensee(s), if any, wishes to publish any results of clinical, non-clinical or other studies conducted by ISLT or its Affiliates or its Sublicensee(s), if any, hereunder, ISLT agrees to submit to such studies to BHV (and BHV may submit such studies to Kissei) for BHV's review and approval prior to any publications, manuscripts of such publications and BHV shall not unreasonably withhold or delay such approval and shall use reasonable efforts to obtain approval from Kissei pursuant to Section 15.02 of the Kissei Agreement. In the event that BHV wishes to publish any results of clinical, non-clinical or other studies conducted by BHV or its Affiliates, if any, hereunder, BHV agrees to submit to ISLT for its review and approval prior to any publications, manuscripts of such publications and ISLT shall not unreasonably withhold or delay such approval.

15.3 <u>Ownership of Know-How</u>. All Kissei Know-How disclosed by BHV to ISLT shall remain the intellectual property of Kissei, and all Biphasic Know-How disclosed by BHV to ISLT shall remain the intellectual property of BHV, but exclusively licensed in each case to ISLT in the Field in the Territory pursuant to the terms of this Agreement. In the event that a court or other legal or administrative tribunal, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of ISLT based on the insolvency or bankruptcy of ISLT, ISLT shall promptly notify the court or other tribunal (a) that the Kissei Know-How remains the property of Kissei, (b) that the Biphasic Know-How remains the property of BHV, and (c) of the confidentiality obligations under this Agreement. In addition, ISLT shall, to the extent permitted by law, take all steps necessary or desirable to maintain the confidentiality of the Kissei Know-How and Biphasic Know-How and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement. All ISLT Know-How disclosed by ISLT to BHV shall remain the intellectual property of ISLT, but licensed outside the Territory pursuant to Section 14.3 of this Agreement. In the event that a court or other legal or administrative tribunal, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of BHV based on the insolvency or bankruptcy of BHV, BHV shall promptly notify the court or other tribunal (a) that the ISLT Know-How received from ISLT remains the property of ISLT and (b) of the confidentiality obligations under this Agreement. In addition, BHV shall, to the extent permitted by law, take all steps necessary

or desirable to maintain the confidentiality of the ISLT Know-How and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement.

15.4 <u>ISLT Confidential Information</u>. Subject to any other provisions of this Agreement, BHV, for itself and its Affiliates and sublicensees, agrees that it shall, during the term of this Agreement and for a period of five (5) years thereafter or ten (10) years from the Effective Date, whichever is longer, hold in confidence all ISLT Confidential Information hereunder and shall not disclose such ISLT Confidential Information to any Third Party nor use such ISLT Confidential Information the written consent of ISLT. The term "<u>ISLT Confidential Information</u>" means information furnished to BHV by ISLT under this Agreement or the ConfidentialIISLT Know-How, except as follows:

(a) Such information is a part of the public domain prior to the disclosure by ISLT to BHV hereunder; or

(b) Such information becomes a part of the public domain after the disclosure by ISLT to BHV hereunder without any breach by BHV of this Agreement; or

(c) Such information which BHV can demonstrate that it had independently developed prior to the disclosure by ISLT to BHV hereunder; or

(d) Such information is disclosed to BHV by a Third Party who has the right to make such disclosure without obligation of confidentiality.

Nothing contained herein shall prevent Kissei or BHV or their Affiliates or licensees, if any, from disclosing any of such ISLT Confidential Information to the extent that (i) such ISLT Confidential Information is disclosed in connection with the securing of necessary governmental authorizations for the marketing of any Product containing the Compound (including the Marketing Approvals), or (ii) such ISLT Confidential Information is required to be disclosed by law or for the purpose of complying with governmental law, rules or regulations, or (iii) such ISLT Confidential Information is disclosed under an appropriate secrecy agreement to outside research institutions performing experiments and tests on the Compound and/or a Product on behalf of BHV or Kissei so as to perform the purpose of this Agreement, or (iv) such ISLT Confidential Information is disclosed for due performance of this Agreement, including without limitation in support of a sublicense permitted hereunder, under an appropriate secrecy agreement.

Article 16

Safety Information

16.1 <u>Safety Data Exchange</u>. ISLT and BHV shall each promptly inform the other in writing (and BHV may inform Kissei) with respect to any significant information it comes to know of (from any

source) relating in any way to the safety or efficacy of the Compound or Product including possible adverse drug reactions. Each Party shall promptly notify the other Party by telephone or facsimile as soon as it learns of any inquiry, contact or communication received from or sent to any regulatory agency, which relates in any way to the Compound or a Product, and shall promptly furnish the other Party with copies of all such communications to the extent available (and BHV may furnish any such copies to Kissei). ISLT will be responsible for reporting all adverse events to the appropriate regulatory authorities in the Territory, including the FDA and EMA, in accordance with the appropriate laws and regulations of the respective countries. Each Party will designate a safety liaison to be responsible for communicating with the other Party regarding the reporting of adverse events.

16.2 <u>Safety Data Exchange Procedures</u>. ISLT and BHV shall execute a separate agreement within a reasonable time (not to exceed ninety (90) days) after the Effective Date of this Agreement to mutually exchange material information on the Compound and the Product relating to, among other things, the safety thereof including adverse drug reactions. Such agreement shall be made in accordance with the current ICH guidelines on the drug safety reporting.

Article 17

Term and Termination

17.1 Term. Except as otherwise expressly set forth in Article 33, this Agreement shall come into force and effect on the Effective Date. Unless sooner terminated by any other provision of this Agreement, the term of the Agreement shall expire with respect to each Product on a country-by-country basis upon the date of expiration of all royalty obligations in the countries in the Territory. Upon (i) expiration of this Agreement with respect to a Product in a country (but not its earlier termination), ISLT will continue to have a royalty-free, perpetual right to continue to use the Kissei Know-How and Biphasic Know-How to make, have made, use, sell, offer to sell and export such Product in the Field in such country, and (ii) expiration of this Agreement in its entirety (but not its earlier termination), ISLT will continue to have a royalty-free, perpetual right to continue to have a royalty-free, perpetual right product in the Field in such country, and (ii) expiration of this Agreement in its entirety (but not its earlier termination), ISLT will continue to have a royalty-free, perpetual right to continue to have a royalty-free, perpetual right to continue to have a royalty-free, perpetual right product in the Field in such country, and (ii) expiration of this Agreement in its entirety (but not its earlier termination), ISLT will continue to have a royalty-free, perpetual right to continue to use the Kissei Know-How and Biphasic Know-How to make, have made, use, sell, offer to sell and export the Compound and the Products and Biphasic Products in the Field in the Territory.

17.2 <u>Termination for Breach or Insolvency</u>. Notwithstanding the stipulation in Section 17.1 hereof, this Agreement shall terminate upon the occurrence of any of the following itemized events:

(a) Either Party notifies the other Party of the fact of default or material breach of any provision in this Agreement by the notified Party, and the notified Party fails to cure such default or breach within ninety (90) days from the date of notification, and the notifying Party subsequently provides written notice of termination to the notified Party, provided that notice of termination is given within six (6) months of the notice of the default or breach and prior to cure of the default or breach; or

(b) Either Party provides written notice of termination to the other Party after the other Party files in any court or agency pursuant to any statute or regulation pertaining to bankruptcy, solvency, or payment of debts, of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the notified Party or of its assets, or if the notified Party proposes a written agreement of composition or extension of its debts, or if the notified Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the notified Party shall propose or be a party to any dissolution or liquidation, or if the notified Party shall pledge its assets used for performance under this Agreement, or shall make an assignment, for the benefit of

creditors. Such termination shall automatically take effect on the sixtieth (60) day following written notice of termination pursuant to this Section 17.2(b).

For the avoidance of doubt, any failure of ISLT to comply with its obligations under Articles 4, 5, 6 or 7 shall constitute a material breach of this Agreement.

17.3 <u>Termination by ISLT</u>. ISLT may, at its discretion, terminate this Agreement for specific commercial, strategic or intellectual property reasons, upon (i) sixty (60) days' prior written notice to BHV, if a Product has not been launched in any country of the Territory, or (ii) six (6) months' prior written notice to BHV, if a Product has been launched in any country of the Territory. For the avoidance of doubt, neither Mr. Green nor Dr. Wilkison, in their respective capacities as officers of ISLT, shall have the right to cause ISLT to exercise its right to terminate this Agreement pursuant to this Section 17.3.

17.4 <u>Termination for [***] or Breach of Termination Agreement.</u>

(a) BHV shall have the right to terminate this Agreement and/or any licenses hereunder immediately upon written notice to ISLT if ISLT or any of its Affiliates or Sublicensees directly, or through assistance granted to a Third Party, commences or participates (except as such participation may be required by applicable law) in any [***].

(b) BHV shall have the right to terminate this Agreement immediately upon written notice to ISLT if BHV notifies ISLT of the fact of default or breach of any provision in the Termination Agreement by ISLT, and ISLT fails to cure such default or breach within ninety (90) days from the date of notification, provided that notice of termination is given within six (6) months of the notice of the default or breach and prior to cure of the default or breach.

17.5 <u>Return of BHV Confidential Information</u>. Upon the termination of this Agreement, ISLT shall return to BHV all BHV Confidential Information, including any documents that embody the Kissei Know-How or Biphasic Know-How, without delay, including copies, excerpts and the like as disclosed by BHV under this Agreement.

17.6 <u>Supply of Compound and Product</u>. To the extent ISLT or its Affiliate or Sublicensee is engaged in the manufacture of the Compound or Products as of the date notice of termination is given, ISLT or such Affiliate or Sublicensee shall, at BHV's option, manufacture and supply BHV's requirements for the Compound and/or Products from the effective date of such termination until such time as BHV secures an alternative commercial manufacturing source reasonably satisfactory to BHV, or until twenty-four (24) months after the effective date of termination, whichever is earlier. In addition, at BHV's option, as of the effective date of such termination:

(a) ISLT and its Affiliates and Sublicensees shall permit BHV to purchase all or any part of ISLT's and ISLT's Affiliates' and/or Sublicensees' worldwide unsold inventory of raw materials for the Compound and Products, work-in-progress Compound and Products and finished Compound and Products;

(b) ISLT and its Affiliates and Sublicensees shall assign to BHV any Third Party manufacturing contract relating to the Compound and Products to which ISLT or any of ISLT's Affiliates or Sublicensees is a party (or the applicable provisions thereof, as the case may be). All Products supplied to BHV by ISLT and its Affiliates and Sublicensees pursuant to this Section 17.6 shall be supplied at [***] of ISLT's or its Affiliates' or Sublicensees' cost of goods (as determined in accordance with generally accepted accounting principles in the United States) or [***] of ISLT's or its Affiliates' or Sublicensees' out-of-pocket procurement cost; and

(c) BHV shall be responsible for all costs and expenses related to securing an alternative commercial manufacturing source, excluding ISLT's costs and expenses related to technology transfer from ISLT to such source, which shall be borne by ISLT.

17.7 <u>Additional Effects of Termination</u>. Termination of this Agreement for any reason shall be without prejudice to:

(a) The obligation of confidentiality provided for in Article 15 hereof;

(b) BHV's right to receive all payments that have or may become payable under Articles 4 and 5 hereof or Section 12.2(d) hereof (including any payments that are required to be paid directly to Kissei), and all associated rights such as the right to receive Royalty Reports and the rights of indemnification of BHV and the BHV Members;

(c) BHV's right of inspecting books and account of ISLT and its Affiliate(s) and its sublicensee(s), if any, relative to the calculation of royalty payments and Partnering Payments (as per Section 5.12 hereof);

(d) The obligations of ISLT to provide BHV as per Section 3.3 hereof with all of the ISLT Know-How obtained before the termination of this Agreement;

(e) BHV's license right of the Trademark provided in Section 8.1 hereof (including any sublicenses granted thereunder); provided, however, that such license (and at BHV's election any such sublicense) shall be expanded to include the Territory as of the date of termination of this Agreement, and ISLT may terminate such license at any time with respect to all or a part of the licensed territory in the event that: (i) BHV and its sublicensees cease using the Trademark in a country in which it is licensed hereunder, (ii) ISLT elects to assign the Trademark to BHV in such a country, (iii) BHV or its sublicensee fails to meet the applicable quality standards set forth in this Agreement and does not remedy such failure within six (6) months following written notice of such failure from ISLT, or (iv) a Product using the Trademark has not been launched in any country of the Territory prior to the date of termination of the Agreement. For clarity, termination of the Trademark license under clauses (i) and (ii) above shall be permitted only on a country-by-country basis;

(f) BHV's right provided for in Section 14.2 hereof (including any sublicenses granted thereunder), provided, however that such license (and at BHV's election any such sublicense) shall be expanded to include the Territory as of the date of termination of this Agreement;

(g) BHV's rights provided for in Section 14.3 hereof (including any sublicenses granted thereunder), provided, however that such license (and at BHV's election any such sublicense) shall be expanded to include the Territory as of the date of termination of this Agreement; or

(h) Any other remedies which either Party may then or thereafter have hereunder or otherwise.

In addition, without limiting the foregoing, the provisions of Sections 3.3, 4.1, 4.2 (to the extent related to Milestones that occurred prior to termination), 4.3 (to the extent related to Milestones that occurred prior to termination), 4.4, 4.5, 4.6, 5.12, 11.4, 11.5, 13.4, 13.5, 14.2, 14.3, 14.4, 17.1 (but only upon expiration of this Agreement in its entirety and not its earlier termination), 17.5, 17.6, 17.7 and 17.8, and Articles 1 (to the extent required to give effect to other surviving rights and obligations), 8, 15, 18, 19, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31 and 32 are intended to and shall survive termination or expiration of this Agreement in accordance with the terms of such Articles and Sections. For clarity, the license and sublicense rights granted to ISLT under Article 2 shall not survive termination of this Agreement under any circumstances.

17.8 <u>Transfer of Marketing Approvals</u>. In the event of termination of this Agreement, ISLT shall, and shall cause its Affiliates and its Sublicensee(s), if any, to, provide BHV and/or its Affiliate and/or any Third Party appointed by BHV (hereinafter referred to as "<u>Transferee</u>") with reasonable assistance, excluding financial assistance, in the transfer, to the extent permissible under the laws or regulations of the Territory, to the Transferee of the Marketing Approvals or any other authorization, approval or license (including Regulatory Filings, drug dossiers and any drug master files) which ISLT or its Affiliate or its Sublicensee(s), if any, has with respect to the Compound or any Product in each country of the Territory. Such assistance shall include, among others, an authorization by ISLT or its Affiliate or its Sublicensee(s), if any, given to the Transferee to access the Marketing Approvals, Regulatory Filings, drug dossiers and drug master files filed by ISLT or its Affiliates or its Sublicensee(s), if any, with the competent health authorities with respect to the Compound and/or the Product in each country of the Territory, the provision by ISLT, if necessary, to the Transferee of the ISLT Know-How and such other acts which the Transferee may reasonably request of ISLT in order to transfer the Marketing Approvals and Regulatory Filings with respect to the Compound or any Such termination described above, ISLT will transfer to BHV all material, documented, ISLT Know-How related to Products or Compound, including development data and manufacturing Know-How and ISLT hereby grants to BHV a paid-up, perpetual, exclusive, world-wide license with the right to sublicense to use such ISLT Know-How to make, use, sell, offer for sale and import Products.

Article 18

Announcement

Unless otherwise required by applicable law and regulations, no public announcement or other disclosure to Third Parties concerning the existence of or terms or provisions of this Agreement shall be made, either directly or indirectly, by any Party to this Agreement without first obtaining the written approval of the other Party and agreement upon the nature and text of such announcement or disclosure. The Party desiring to make any such public announcement or other disclosure shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time prior to public release, and shall provide the other Party with a written copy thereof, in order to allow such other Party to review, comment upon and approve the announcement or other disclosure, which such approval shall not be unreasonably withheld or delayed. A Party shall not be required to seek the permission of the other Party to repeat any information as to the existence and terms of this Agreement that has already been publicly disclosed by such Party

in accordance with the foregoing or by the other Party. Either Party may disclose the terms of this Agreement to such Party's existing investors, directors and professional advisors and to potential investors, acquirors or merger partners and their professional advisors who are in each case bound by written or professional obligations of non-disclosure and non-use that are at least as stringent as those contained in Article 15 or are customary for such purpose.

Governing Law

This Agreement shall be governed by and interpreted in accordance with the internal substantive laws of the State of North Carolina, U.S.A., without giving effect to any choice of law rules.

Article 20

Dispute Resolution

20.1 <u>Organization Resolution</u>. The Parties will try to settle their differences amicably between themselves. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the performance or alleged non-performance of a Party of its obligations under this Agreement which is not subject to the final decision of the Management Committee as specified herein ("<u>Dispute</u>"), a Party may notify the other Party in writing of such Dispute. If the Parties are unable to resolve the Dispute within sixty (60) days of receipt of the written notice by the other Party, the Parties shall attempt to resolve such Dispute as follows:

(a) Until the Committee Date, any such Dispute will be elevated for resolution by, on the one hand, representatives of BHV with authority to resolve the dispute, and on the other hand, the Management Committee. In this case, the Management Committee will take action by approval of a majority of its members, but the approval of the Chief Operating Officer (and Chief Executive Officer, if applicable) would not be required.

(b) From and after the Committee Date, any such Dispute will be referred to the respective representatives of the Parties with authority to resolve the Dispute, who shall attempt for an additional thirty (30) days to resolve such Dispute in good faith. If the matters are not resolved by the respective representatives of each Party within such thirty (30) day period, such Dispute will be referred to the Chief Executive Officers of each of the Parties (or any other representative designated by the board of directors of the applicable Party) who will use their good faith efforts to resolve the Dispute within thirty (30) days after it was referred to the Chief Executive Officers (or other such representative). For clarity, Mr. Green and Dr. Wilkison shall not have authority to resolve any Dispute on behalf of ISLT under this Section 20.1(b) for so long as they remain controlling principals in BHV.

20.2 <u>Arbitration</u>. Subject to Section 20.1, any Dispute that is not resolved as provided in Section 20.1, whether before or after termination of this Agreement, will be resolved by final and binding arbitration. Such Disputes will be finally settled under the applicable rules of the American Arbitration Association (the "<u>Rules</u>") or such other arbitration rules as the Parties may agree upon. Arbitration proceedings will be held in Raleigh, North Carolina, U.S.A, or in another place which is mutually agreeable to the Parties. The arbitration will be conducted by three (3) arbitrators knowledgeable in the subject matter that is at issue in the Dispute and who are selected by mutual agreement of the Parties or, failing such agreement, will be selected according to the Rules.

20.3 <u>Binding Decision</u>. The decision by the arbitrator will be binding and conclusive upon the Parties, their successors and permitted assigns and the Parties will comply with such decision in good faith. Each Party hereby submits itself to the jurisdiction of the courts of the place where the arbitration is held, but only for the entry of judgment with respect to the decision of the arbitrators hereunder. Notwithstanding the foregoing, judgment upon the award may be entered in any court having jurisdiction over the Parties. Whether a claim, Dispute or other matter in question would be barred by the applicable statute of limitations, which statute of limitations will apply to any claim or Dispute will also be determined by binding arbitration pursuant to this Article 20.

20.4 <u>Discovery</u>. During the period beginning with the selection of the arbitrators and ending upon the conclusion of the arbitration proceedings, the Parties may conduct such discovery that is permitted under the Rules. In conducting the arbitration, the arbitrators will apply the Rules as they apply to matters of evidence.

20.5 <u>Expenses</u>. The fees and expenses of the arbitrators, the fees and expenses of a court reporter, and any expenses for a hearing room, will be shared equally by the Parties. The Parties will otherwise bear their respective expenses of the arbitration, unless otherwise determined by the arbitrators.

20.6 <u>Expedited Arbitration for Certain Matters</u>. Notwithstanding the foregoing provisions of this Article 20, any Disputes related to whether a breach of Article 4, 5, 6, 7, 15, 17 or 23 or Section 14.5 has occurred shall be resolved through binding arbitration administered by the American Arbitration Association ("<u>AAA</u>") as follows:

(a) A Party may submit such dispute to arbitration by notifying the other Party and the AAA, in writing, of such dispute. Within ten (10) days after receipt by the receiving Party of such notice, the Parties shall designate in writing a single arbitrator to resolve the dispute; provided, however, that if the Parties cannot agree on an arbitrator within such 10-day period, or if the arbitrator agreed to by the Parties declines to serve, an arbitrator shall be selected, within fifteen (15) days after notice from either Party of such inability to agree on an arbitrator willing to serve, by the office of the AAA responsible for administered arbitrations in the southeast region of the United States. The arbitrator shall be a lawyer with pharmaceutical industry legal experience who is available to serve on the timetable established in this Section 20.6, and shall not be an Affiliate, or an employee, consultant, legal advisor, officer, director or stockholder of, or have any conflict of interest with respect to, any Party.

(b) The Party submitting a dispute to arbitration shall include with its notice pursuant to Section 20.6(a) a written summary of the disputed issues, not to exceed ten (10) pages per disputed issue, and a proposed ruling on the merits of each such issue. Within ten (10) days thereafter, the other Party shall provide a written response, not to exceed ten (10) pages per disputed issue, as well as such other Party's proposed ruling on the merits of each disputed issue, to the Party initiating such arbitration and to the AAA.

(c) Within ten (10) days after the selection of the arbitrator and in any event within thirty (30) days after the notice initiating the arbitration pursuant to Section 20.6(a), the arbitrator and the Parties shall meet. During such meeting, the arbitrator shall establish a schedule for the production of documents and the conduct of depositions. Such schedule shall allow the Parties ten (10) days to submit requests for documents, thirty (30) days to produce requested documents and an additional thirty (30) days to depose witnesses; provided that the arbitrator may, in his or her discretion, extend such period for deposing witnesses if reasonably necessary to accommodate limitations on the availability of witnesses. Each Party shall be entitled to take five depositions of no longer than two seven-hour days apiece.

(d) The arbitrator shall set a date for a hearing, which shall be no later than one hundred ten (110) days after the notice initiating the arbitration pursuant to Section 20.6(a). Prior to such hearing, the Parties shall submit written memoranda not to exceed one hundred (100) pages as well as witness lists and trial exhibits. At the hearing, in accordance with a schedule established by the arbitrator, the Parties shall present evidence with respect to each of the disputed issues. The hearing shall be limited to two weeks, with each Party afforded equal time to present its case (cross-examination time shall be counted as part of the time of the Party conducting it). The Parties shall have the right to be represented by counsel.

(e) The arbitrator shall use his or her best efforts to rule on each disputed issue within ten (10) days after the completion of the hearing described in Section 20.6(d). All rulings of the arbitrator shall be in writing and shall be delivered to the Parties. The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive upon all Parties. Either Party may bring an action in any court of competent jurisdiction to enforce a final award entered by the arbitrator.

(f) The (i) attorneys' fees of the Parties in any arbitration, (ii) fees of the arbitrator and (iii) costs and expenses of the arbitration, shall be borne by the non-prevailing Party or, if neither Party is the prevailing Party as to all disputed issues, by the Parties in inverse proportion to the proportion of the dispute on which they prevailed, respectively, as determined by the arbitrator. Prior to such determination, each Party shall bear its own attorneys' fees and fifty percent (50%) of any fees of the arbitrator and costs and expenses of the arbitration; provided that the arbitrator shall, in his or her final award, require the non-prevailing Party (or the Party that prevails on less than fifty percent (50%) of the dispute) to reimburse the other Party for the excess share of such costs and expenses borne by such other Party prior to such determination.

(g) Any arbitration meeting or hearing pursuant to this Section 20.6 shall be conducted in the English language in Raleigh, North Carolina.

20.7 <u>Disputes not Subject to Arbitration</u>. Notwithstanding the Parties' agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, validity, enforceability or infringement of, patents or trademarks or the misappropriation of trade secrets, shall not be subject to arbitration under this Agreement, and the Parties may pursue whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.

Article 21

Notices

21.1 Any notice required to be given under this Agreement shall be given in the English language by sending such notices by personal delivery, postage-prepaid registered airmail or an internationally recognized overnight courier service addressed to the other Party at the address listed below:

For Brighthaven Ventures, L.L.C.

3200 East Hwy 54, Suite 100 Research Triangle Park, NC 27709 Attention: Chief Executive Officer

For Islet Sciences, Inc.

6601 Six Forks Rd., Suite 140 Raleigh, NC 27615 Attention: Chief Financial Officer

Either Party may notify the other Party of a different address to receive the other Party's notices in accordance with the manner described in this Section 21.1.

21.2 In the case where any notice is sent by airmail, such notice shall be sent return receipt requested and is deemed to be received by the other Party upon endorsement by an employee or agent of the other Party of such receipt.

Force Majeure

22.1 Neither Party shall be liable for any failure to perform as required by this Agreement by reason of Force Majeure, to the extent such failure to perform is due to circumstances reasonably beyond the control of such Party, including but not limited to requisition or interference by any government, state or local authorities, war, riots, civil disturbances, strikes or other labor disputes, accidents, failure to secure required governmental approval, civil disorders or acts of aggression, acts of God, energy or other conservation shortages, diseases, or other such occurrences. For clarity, this Article 22 shall not affect or limit either Party's right to terminate this Agreement in accordance with Article 17.

22.2 If and when any Party is hindered in its performance of its obligations under this Agreement by reason of Force Majeure, the performance shall be suspended during, but not longer than, the continuance of such circumstances.

22.3 Either Party hereto whose performance of obligations has been hindered by reason of Force Majeure shall, to the extent possible, inform the other Party immediately, and shall use reasonable efforts to overcome the effect of the Force Majeure.

22.4 Nothing in this Article 22 shall relieve either Party of any obligation to make any payment under this Agreement.

Article 23

Indemnification

23.1 <u>Indemnification by BHV</u>. BHV shall defend, indemnify and hold ISLT and its Affiliates and all the officers, directors, and employees thereof harmless from and against all suits, claims, liabilities (including, for the avoidance of doubt, product liability claims), costs, damages, judgments and other expenses (including, but not limited to, reasonable legal fees and expenses) arising from:

(a) BHV's material breach of any term of this Agreement;

(b) The gross negligence, recklessness or willful misconduct or fraud on the part of BHV or any of its Affiliates or any of its or their officers, directors or employees with respect to the Compound or Product produced by BHV or in the performance of this Agreement; or

(c) Any claims made by a Third Party against ISLT relating to (i) any product liability claim related to the Compound or Product arising prior to the Effective Date, or (ii) any product liability claim related to the Compound or Product produced, manufactured, supplied, used, tested, sold or distributed by or on behalf of BHV or its Affiliates outside the Territory at any time (including the time prior to the Effective Date);

provided, however, that BHV shall not be required to indemnify ISLT to the extent that any such claims arose out of or resulted from the negligence, recklessness or willful misconduct or fraud of ISLT or any of its Affiliates or Sublicensees.

23.2 <u>Indemnification by ISLT</u>. ISLT shall defend, indemnify and hold BHV and its Affiliates and all the officers, directors, and employees thereof harmless from and against all suits, claims, liabilities (including, for the avoidance of doubt, product liability claims and, to the extent applicable, any defense, indemnity or hold harmless obligations of BHV to Kissei pursuant to the Kissei Agreement), costs, damages, judgments and other expenses (including, but not limited to, reasonable legal fees and expenses) arising from:

(a) ISLT's material breach of any term of this Agreement;

(b) The gross negligence, recklessness or willful misconduct or fraud on the part of ISLT or any of its Affiliates or Sublicensee(s) or any of its or their officers, directors or employees with respect to the Compound or Product produced by ISLT or in the performance of this Agreement;

(c) Any claims made by a Third Party relating to any product liability claim related to the Compound or the Products produced, manufactured, supplied, used, tested, sold or distributed by or on behalf of ISLT or its Affiliates or Sublicensee(s) in the Territory at any time after the Effective Date; or

(d) Any other claims made by a Third Party relating to any exercise of any license or other right under this Agreement by ISLT or any of its Affiliates or Sublicensees;

provided, however, that ISLT shall not be required to indemnify BHV to the extent that any such claims arose out of or resulted from the negligence, recklessness or willful misconduct or fraud of Kissei or BHV or any of their Affiliates or other licensees.

23.3 Indemnification Procedures. A Party which intends to claim indemnification under Section 23.1 or 23.2 hereof (the "Indemnitee") will promptly notify the other Party (the "Indemnitor") in writing of any claim, lawsuit or other action in respect of which the Indemnitee or any of its directors, officers, employees, and Affiliates (as the case may be) intend to claim such indemnification within a reasonable period of time after the assertion of such claim; provided, however, that the failure to provide written notice of such claim within a reasonable period of time will not relieve the Indemnitor of any of its obligations hereunder, except to the extent that the Indemnitor is materially prejudiced by such failure to provide prompt notice. The Indemnitor will have the right to assume the complete control of the defense, compromise or settlement of any such claim (provided that no settlement of any claim will include any admission of wrongdoing on the part of an Indemnitee, without the prior written consent of such Indemnitee, which such consent will not be unreasonably withheld). The Indemnitor may, at its own expense, employ of legal counsel to defend the claim at issue. The Indemnitee may, in its sole discretion and at its own expense, employ legal counsel to represent it (in addition to the legal counsel employed by the Indemnitor) in any such matter, and in such event legal counsel selected by the Indemnitee will be required to confer and cooperate with such counsel of the Indemnitor in such defense, compromise or settlement for the purpose of informing and sharing information with the Indemnitor. The Indemnitee will, at its own expense, make available to Indemnitor those employees, officers and directors or Indemnitee whose assistance, testimony or presence is necessary, useful or appropriate to assist the Indemnitor in evaluating, defending or settling any such claim; provided, however, that any such access will be conducted in such a manner as not to interfere unreasonably with the operations of the businesses of Indemnitee; and will otherwise fully cooperate with the Indemnitor and its legal counsel in the investigation and defense of such claim.

23.4 Post Agreement Obligations. Following termination of this Agreement, in the event that BHV or its Affiliates ever sell, market, distribute the Product in any country which was formerly in the Territory, then in such event, BHV shall defend, indemnify and hold ISLT and its Affiliates and all the officers, directors, and employees thereof harmless from and against all suits, claims, liabilities (including, for the avoidance of doubt, product liability claims), costs, damages, judgments and other expenses (including, but not limited to, reasonable legal fees and expenses) arising from any claims made by a Third Party against ISLT relating to any product liability claim related to the Compound or Products produced, manufactured, supplied, used, tested, sold or distributed by or on behalf of BHV or its Affiliates or other sublicensee(s) in the Territory, unless such product liability shall be caused by the negligence, recklessness or willful misconduct or fraud on the part of ISLT or any of its Affiliate or sublicensees or any of its or their officers, directors or employees.

23.5 <u>Insurance</u>. After the execution of this Agreement, ISLT and BHV (or their respective Affiliates, contractors or sublicensees) shall acquire and maintain an appropriate product liability insurance respectively, at its sole cost and expense, against all liability, including personal injury, physical injury, or property damage arising out of their manufacture, sale, distribution, or marketing of a Product in their own territory. ISLT and BHV shall provide written proof of the existence of such insurance to the other Party upon the other Party's request.

23.6 <u>Disclaimer</u>. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 15 OR INFRINGEMENT OR MISAPPROPRIATION OF THE OTHER PARTY'S INTELLECTUAL PROPERTY, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, REGARDLESS OF THE FORM OF CLAIM OR ACTION (WHETHER BASED ON THEORIES OF CONTRACT, NEGLIGENCE, TORT (INCLUDING WITHOUT LIMITATION STRICT LIABILITY) OR OTHERWISE); PROVIDED, HOWEVER, THAT THIS SECTION 23.6 SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S OBLIGATION TO INDEMNIFY THE OTHER PARTY FOR CLAIMS MADE BY THIRD PARTIES UNDER THIS ARTICLE 23.

23.7 <u>Waiver of Jury Trial</u>. TO THE FULLEST EXTENT PERMITTED BY LAW, EACH OF THE PARTIES HEREBY WAIVES TRIAL BY JURY IN ANY JUDICIAL PROCEEDING DIRECTLY INVOLVING ANY MATTERS (WHETHER SOUNDING IN TORT, CONTRACT OR OTHERWISE) IN ANY WAY ARISING OUT OF, RELATED TO, OR CONNECTED WITH THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.

Article 24

Non-assignability; Third Party Beneficiaries

This Agreement is personal to the Parties hereto and shall not be assignable in whole or in part by either Party without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed; provided, however, that a Party shall not withhold consent for the other Party to assign all of its rights under this Agreement to its Affiliate or to any non-Affiliate entity with

which such Party may merge or consolidate (or engage in some other form of corporate combination), or to which it may transfer all or substantially all of its assets to which this Agreement relates; provided, further, in each case that (i) as a condition to such consent and to the effectiveness of any assignment of this Agreement, whether in whole or in part, the assignee first agrees in writing with the non-assigning Party unconditionally to be bound by the terms of this Agreement, and (ii) the assigning Party shall not be relieved of its obligations under this Agreement but shall be jointly and severally liable with the assignee hereunder. All successors and permitted assignees of a Party shall be subject to, and will be bound, by all the terms and conditions of this Agreement; provided that existing intellectual property rights of any successor or assignee shall not be included in the technology licensed hereunder or otherwise subject to this Agreement by virtue of such assignment. Any attempted assignment made contrary to the provisions hereof will be void.

Article 25

Original Text

This text of this Agreement in the English language shall be the original text, and any text in another language, even if such a text is made by translation of the text in English language or prepared by any of the Parties hereto for the purpose of its own convenience, shall have no meaning for any purpose between the Parties hereto.

Entire Agreement

This Agreement, together with the Termination Agreement, shall constitute the entire agreement between the Parties hereto concerning the subject matter hereof and shall supersede any other agreements, whether oral or written, express or implied by and between the Parties, with the exception of the Confidentiality Agreement, which shall continue in force and effect unless and until the Effective Date occurs, and may not be changed or modified or revised except as specifically agreed upon by the Parties in writing.

Article 27

Severability

27.1 In the event any portion of this Agreement shall be held illegal, void or ineffective, the remaining portions hereof shall remain in full force and effect.

27.2 If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule or law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform to such statute or rule or law.

27.3 If the invalidity or unenforceability of any term or provision described in Section 27.1 or Section 27.2 causes a material adverse change in either the risks or benefits of this Agreement to either Party, the Parties shall negotiate in good faith a commercially reasonable substitute or replacement for the invalid or unenforceable provision.

Article 28

Independent Contractors; No Partnership

The Parties hereto are independent contractors. In making and performing this Agreement, the Parties are acting, and intend to be treated, as independent entities performing a contract, and nothing contained in this Agreement is to be construed or implied or deemed to create an agency, partnership, joint venture or an employee/employer relationship between BHV and ISLT. This Agreement is not, and will not be deemed to be, a partnership agreement or joint venture agreement, expressly or by implication. Employees of each Party remain employees of said Party and will be considered at no time agents of or owing a fiduciary duty to the other Party. Neither Party hereto will have any implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any other contract, agreement or undertaking with any Third Party.

Amendment

The Parties hereto may amend, modify or alter any of the provisions of this Agreement, but such amendment, modification or alteration will be valid and binding on either Party only if memorialized by a written instrument that explicitly refers to this Agreement and is duly executed by both Parties hereto. For the avoidance of doubt, neither Mr. Green nor Dr. Wilkison, in their respective capacities as officers of ISLT, shall have the right to agree on behalf of ISLT to any amendment, modification or alteration of any of the provisions of this Agreement.

Article 30

Consideration

30.1 <u>General</u>. The Parties acknowledge that each of the licenses and rights granted by BHV in Article 2 and each of the provisions of this Agreement individually and collectively, constitute good, valuable, and sufficient consideration for each and all of the fees and payments called for hereunder and for each and all of the other obligations of ISLT, its Affiliates and Sublicensees; the Parties further acknowledge that the individual and collective rights under and access to the Kissei Patents, Kissei Know-How, Biphasic Patents and Biphasic Know-How renders the way in which those fees and payments hereunder are determined, and their duration, appropriate and desirable as a matter of convenience.

30.2 <u>Allocation</u>. The Parties agree that, for U.S. federal income tax purposes and all applicable state income tax purposes, (i) they will treat the grant of the exclusive sublicense described in Section 2.1(a) and the grant of the exclusive license described in Section 2.1(b) as sales rather than licenses, and (ii) they will allocate each payment required under Sections 4.1, 4.3, 5.1(e)(iii) and 5.7 among the assets acquired or deemed to be acquired for such purposes as follows:

| [***] | [***] | |
|-------|-------|--|
| [***] | [***] | |
| Total | 100% | |

Each of the Parties acknowledges and agrees that any discharge of liabilities of BHV to Kissei pursuant to this Agreement, including as a result of payments to be made by ISLT to Kissei pursuant to Sections 4.2, 5.1(e)(i) or 5.1(e)(ii), is occurring as a result of the transfer of the rights under the Kissei Patents and the Kissei Know-How described in Section 2.1(a) and that it will not take any position inconsistent with such treatment for U.S. federal income tax purposes or any applicable state income tax purposes.

Article 31

Counterparts

This Agreement may be executed by the Parties in one or more identical counterparts, all of which together will constitute this Agreement. If this Agreement is executed in counterparts, no signatory hereto will be bound until both Parties have duly executed a counterpart of this Agreement.

Security Interest

As security for the payment or performance, as the case may be, in full of ISLT's obligations hereunder, ISLT hereby assigns and pledges to BHV, its successors and assigns, and hereby grants to BHV, its successors and assigns, a security interest in all right, title or interest of ISLT in, to or under this Agreement and all Proceeds thereof (collectively, the "<u>Collateral</u>"). ISLT hereby irrevocably authorizes BHV at any time and from time to time to file in any relevant jurisdiction any initial financing statement with respect to the Collateral or any part thereof and amendments thereto that describe the Collateral and contain information required by Article 9 of the UCC or the analogous legislation of each applicable jurisdiction for the filing of such financing statement or amendment, and ISLT agrees to provide such information to BHV promptly upon any reasonable request. In addition, ISLT agrees to execute, acknowledge, deliver and cause to be duly filed all such further instruments and documents and to take all such actions as BHV may from time to time reasonably request to better assure, preserve, protect and perfect the security interest in the Collateral and the rights and remedies created hereby, including the filing of any additional financing statements or other documents, including with the United States Patent and Trademark Office (or any successor office), in connection herewith or therewith.

Article 33

Effectiveness of Agreement

Notwithstanding anything to the contrary in this Agreement or the Termination Agreement, the terms and provisions of this Article 33 and Articles 1 (to the extent necessary to enforce, interpret or carry out the purposes of this Article 33), 18, 19, 21, 24-29, 31 and 32, and Sections 4.1, 11.4, 23.6 and 23.7, are the only terms and provisions of this Agreement that are in force and effect and binding on the Parties as of the Execution Date. The other terms and provisions of this Agreement shall not come into force or effect, or in any way become binding upon either of the Parties, unless and until the Effectiveness Condition has been met. The effectiveness of such other terms and provisions is subject in all regards to: (x) ISLT's receipt of a minimum of ten million dollars (US \$) (\$10,000,000) in equity or debt financing following the Execution Date, and (y) ISLT's payment to BHV of the Upfront Payment; in each case prior to the end of the Financing Period (collectively, the "Effectiveness Condition"). The "Financing Period" shall constitute that period of time beginning on the Execution Date and ending on May 31, 2015. The "Effective Date" means the date, if any, prior to the end of the Financing Period, on which the Effectiveness Condition is met. If the Effective Date occurs, then all such other terms and provisions of this Agreement shall come into force and effect and become binding on the Parties on the Effective Date. If the Effectiveness Condition is not met by 5:00 PM Eastern Time on the last day of the Financing Period, then automatically and without further action required by either Party, this Agreement, all terms and provisions hereof and the transactions contemplated hereby shall be rescinded and become null and void in their entirety at such time, and neither Party shall have any further obligation to the other Party whatsoever in relation to this Agreement, except as expressly set forth in the Termination Agreement, which agreement shall not be affected in any way by any modification, termination, cancellation or rescission of this Agreement. Notwithstanding the foregoing, Sections 11.4, 23.6 and 23.7 of this Agreement (but not any other provision of this Agreement) shall continue in full force and effect in perpetuity.

[signature page to follow]



[Signature Page to Exclusive License Agreement]

IN WITNESS WHEREOF, the Parties by their respective authorized representatives, have executed this Agreement.

BRIGHTHAVEN VENTURES, L.L.C.

By: /s/ Bentley Cheatham

Bentley Cheatham, Ph.D.

Title: Chief Executive Officer

ISLET SCIENCES, INC.

By: <u>/s/ Steven R. Delmar</u>

Printed: Steven R. Delmar

Title: CFO

EXHIBIT A

Kissei Patents

- 1. Application number: PCT/JP01/11348 (KGT-1681)
- Publication number: WO02/053573
- 2. Application number: PCT/JP2005/013262
- Publication number: WO2006/009149
- 3. Application number: PCT/JP2006/305295 Publication number: WO2006/098413

EXHIBIT B

Biphasic Patents

| United States (Appl. No. 13/809,222) | Hong Kong (Appl. No. 13113810.6) | |
|---|--|--|
| Australia (Appl. No. 2011276254) | Israel (Appln. No. 224,142) | Russian Federation (Appln. No. 201305481) |
| | India (Appln. No. 1194/DELNP/2013) | South Africa (Appln. No. 2013/00877) |
| Canada (Appl. No. 2,804,926) | | |
| Europe (Appln. No. 11804320.7) | Malaysia (Appln. No. PI 2013000072) | PCT/2011/043143 |
| | | United States Provisional Appl. No. 62/011,95 |

EXHIBIT C

GSK Know-How

- All clinical study documents on KGT-1650 and KGT-1681 transferred from GSK to Kissei
- All non-clinical study documents on KGT-1650 and KGT-1681 transferred from GSK to Kissei
- All CMC documents on KGT-1650 and KGT-1681 transferred from GSK to Kissei

The Parties acknowledge that certain GSK Know-How refers to KGT-1650 and KGT-1681 as GSK-189074 and GSK-189075, respectively.

EXHIBIT D

Agreed Supply Criteria

1. Qualitative Criteria for Supply

| Business Requirement | Necessary Criteria |
|---|--|
| Assurance of Supply (including regulatory) | • All of the criteria listed in Supply Agreement Criteria (below) will be included in a Supply Agreement to be negotiated with ISLT. |
| | • Capacity available and qualified to support ISLT forecast demand, including the potential for production in excess of forecast (the amount of such excess capacity will be at least equal to the amount originally forecasted, so that taken together the total available capacity available to ISLT will be equal to twice (2x) the amount of its forecast demand), within an agreed upon lead-time. |
| | • BHV and all of its manufacturing contractors must demonstrate that there are no outstanding issues with any local Governmental or Ministerial or Regulatory body such as; an ongoing investigation for breach of environmental consent limits or FDA warning letter that may compromise their ability to make and supply product. |
| | • BHV and all of its manufacturing contractors shall be responsible for maintaining effective compliance with all applicable Environmental Health and Safety laws and regulations, including but not limited to Occupational Exposure Limits / employee protection procedures. Compliance will be confirmed in an audit, and any required corrective actions must be put in place to an agreed timeframe at BHV expense. |
| Quality | • BHV and all of its contractors will have a demonstrated successful track record of FDA audits (at least 1 in the last 24 months) with no significant outstanding 483's at the time they confirm the decision to supply ISLT. If a contractor has not ever been audited by FDA, such contractor will submit to an audit to be conducted by ISLT to determine the regulatory acceptability of such contractor for the Territory. |
| | • The product manufactured by BHV will meet all the requirements agreed by ISLT including, chemical and physical specifications and be suitable for onward processing. Responsibility and cost for any failed batches and rework (if required and if possible via an approved method) by BHV or any of its contractors will rest with BHV. |
| | • BHV and its contractor shall work in a manner consistent with current Good Manufacturing Practice (cGMP) as outlined in the Code of Federal Regulations 21 (CFR21) issued by the Food and Drug Administration (FDA). Compliance to this standard will be confirmed by audit with corrective action put in place to an agreed time frame at BHV expense. |
| Service | • BHV to match the ISLT preferred supplier competency profile for manufacturers of registered stages summarized below and will undertake corrective actions to resolve major issues within 12 months of the assessment. |
| Cost | • BHV to provide Open book costing in support of discussion around cost of goods and continuous improvement initiatives. |

2. Supply Agreement Criteria

| Business Requirement | Supply Agreement Criteria |
|--|--|
| Assurance of Supply (including regulatory) | Supply chain management competency |
| | • Risk mitigation / contingency plans for product and supply chain |
| | • Inventory policy of Final product. |
| | • Manufacturing Schedule adherence targets to be met. |
| | • Technical competency and resource to troubleshoot process issues |
| | Achieve target yield performance Vs standard |
| Quality | • Really Right First Time target> 98% |
| | • Out Side Specification target >98% |
| | • Resource to support Chemistry Manufacturing Controls (CMC) section of ISLT regulatory filing if required |
| Service | Communication / language to be English |
| | • Packaging of API to meet ISLT requirements |
| Cost | • Target price |
| | • Funding of ISLT costs if ISLT assistance required to help BHV resolve their manufacturing issues |

The above criteria will be applied mutatis mutandis to the situation where ISLT supplies Compound to BHV.

TERMINATION AGREEMENT

This TERMINATION AGREEMENT dated as of March 3, 2015 (this "<u>Agreement</u>") is entered into by and among Islet Sciences, Inc., a Nevada corporation ("<u>Islet</u>"), Brighthaven Ventures, L.L.C., a North Carolina limited liability company ("<u>BHV</u>"), Avogenx, Inc., a Delaware corporation and a direct wholly owned subsidiary of Islet ("<u>Holdco</u>"), Islet Merger Sub, Inc., a Nevada corporation and a direct wholly owned subsidiary of Holdco ("<u>Islet Merger Sub</u>"), and each of the members of BHV (the "<u>BHV Members</u>"). Islet, BHV, Holdco, Islet Merger Sub and the BHV Members are each hereinafter referred to as a "party" and collectively as the "parties."

WHEREAS, Islet, BHV, Holdco, Islet Merger Sub and the BHV Members entered into the Agreement and Plan of Merger dated as of September 30, 2014 (the "Merger Agreement") pursuant to which Islet Merger Sub agreed to merge with and into Islet with Islet as the surviving entity, and Holdco would acquire all of the outstanding membership interests of BHV in consideration for the issuance of an aggregate of 30 million shares of common stock of Holdco to the BHV Members (subject to adjustment as provided in the Merger Agreement), and additional milestone payments, such that following the completion of such transactions, Islet and BHV would each be wholly owned subsidiaries of Holdco;

WHEREAS, BHV holds a license from Kissei Pharmaceutical Co., Ltd., a corporation organized and existing under the laws of Japan ("<u>Kissei</u>"), for the development and commercialization of pharmaceutical preparations containing the novel SGLT2 inhibitors remogliflozin and remogliflozin etabonate in all countries of the world except for Japan, Korea and Taiwan, under the Exclusive License Agreement between BHV and Kissei dated December 1, 2010, as amended (the "<u>Kissei Agreement</u>");

WHEREAS, BHV has been assigned certain patent applications related to a biphasic formulation technology that is useful in development of such pharmaceutical preparations (the "<u>Biphasic Patents</u>");

WHEREAS, Islet and BHV have determined it to be mutually favorable to terminate the Merger Agreement, and in connection therewith Islet and BHV desire to enter into an exclusive license agreement dated as of the date hereof, which license agreement includes (i) an exclusive sublicense under the Kissei Agreement and (ii) an exclusive license under the Biphasic Patents, in each case subject to the terms and conditions set forth therein (the "License Agreement");

WHEREAS, pursuant to Section 8.1(a) of the Merger Agreement, the Merger Agreement may be terminated any time prior to the Effective Time, by action taken or authorized by the Board of Directors or Board of Managers of the terminating parties, by the mutual consent of Islet and BHV; and

WHEREAS, a majority of the independent directors of Islet, in consultation with their advisors, have carefully considered this Agreement and the License Agreement and have determined these agreements to be in the best interest of Islet and its shareholders, and the Board of Managers of BHV and each BHV member has similarly considered this Agreement and the License Agreement and determined these agreements to be in the best interest of BHV and each BHV member has similarly considered this Agreement and the License Agreement and determined these agreements to be in the best interest of BHV and its members.

NOW, THEREFORE, in consideration of the foregoing and the respective covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

Section 1. Merger Agreement Termination and Related Matters.

(a) <u>Termination</u>. The parties hereto have received the required approvals to terminate the Merger Agreement as set forth in Section 8.1(a) of the Merger Agreement and mutually agree that the Merger Agreement is hereby terminated, effective immediately upon the execution of this Agreement by each of the parties hereto.

(b) <u>Survival of Certain Provisions</u>. Notwithstanding <u>Section 1(a)</u> of this Agreement, Section 6.2 (Access to Information; Confidentiality), Section 6.7 (Fees and Expenses; Taxes), Section 8.2 (Effect of Termination), and ARTICLE IX (General Provisions) of the Merger Agreement (collectively, the "<u>Surviving Provisions</u>") shall survive the termination of the Merger Agreement.

(c) <u>Fees and Expenses; Taxes</u>. Without limiting the provisions of Section 6.7 (Fees and Expenses; Taxes) of the Merger Agreement, all costs and expenses incurred by any party hereto in connection with this Agreement, the Merger Agreement and the transactions contemplated hereby or thereby and the entry into and negotiation of the License Agreement (including any agreements entered into in connection with the License Agreement) shall be paid by Islet or, to the extent previously paid by BHV or any BHV Member, reimbursed to BHV or such BHV Member.

Section 2. <u>Mutual Releases</u>.

(a) Islet Release. To the fullest extent permitted by applicable law, each of Islet, Holdco and Islet Merger Sub, on behalf of itself, its subsidiaries and affiliates and the respective future, present and former directors, officers, shareholders, partners, members, managers, employees, representatives, advisors, agents, attorneys, successors and assigns of each of the foregoing (collectively, the "Islet Releasing Parties"), hereby unequivocally, knowingly, voluntarily, unconditionally and irrevocably waives, fully and finally releases, remises, exculpates, acquits and forever discharges BHV and the BHV Members (each a "BHV Party" and collectively, the "BHV Parties"), each BHV Party's subsidiaries and affiliates and the respective future, present and former directors, officers, shareholders, partners, members, managers, employees, representatives, advisors, agents, attorneys, successors and assigns of each of the foregoing (collectively, the "BHV Released Parties") from any and all actions, causes of action, suits, debts, accounts, bonds, bills, covenants, contracts, controversies, obligations, claims, counterclaims, setoffs, debts, demands, damages, costs, expenses, compensation and liabilities of every kind and any nature whatsoever, in each case whether absolute or contingent, liquidated or unliquidated, known or unknown, and whether arising at law or in equity, which such Islet Releasing Party had, has or may have based upon, arising from, in connection with or relating to the Merger Agreement, any agreement, instrument or other document delivered in connection therewith or the transactions contemplated thereby; provided, however, that the foregoing shall not limit the rights and obligations of the parties hereto under (i) this Agreement, (ii) the Surviving Provisions, (iii) the confidentiality agreement, dated as of September 10, 2013 between Islet and BHV (the "Confidentiality Agreement"), (iv) the Employment Agreements by and between Islet and the BHV Members, dated as of October 30, 2013, (v) the Islet by-laws, (vi) the License Agreement and any related agreements, or (vii) any agreements entered into among any of the parties following the date hereof. Each Islet Releasing Party shall refrain from, directly or indirectly, asserting any claim or demand or commencing, instituting, maintaining, facilitating, aiding or causing to be commenced, instituted or maintained any legal or arbitral proceeding of any kind against any BHV Released Party based upon any matter released under this <u>Section 2(a)</u>.

(b) BHV Release. To the fullest extent permitted by applicable law, each BHV Party, on behalf of itself, its subsidiaries and affiliates and the respective future, present and former directors, officers, shareholders, partners, members, managers, employees, representatives, advisors, agents, attorneys, successors and assigns of each of the foregoing (collectively, the "BHV Releasing Parties"), hereby unequivocally, knowingly, voluntarily, unconditionally and irrevocably waives, fully and finally releases, remises, exculpates, acquits and forever discharges each of Islet, Holdco and Islet Merger Sub, each of its subsidiaries and affiliates and the respective future, present and former directors, officers, shareholders, partners, members, managers, employees, representatives, advisors, agents, attorneys, successors and assigns of each of the foregoing (collectively, the "Islet Released Parties") from any and all actions, causes of action, suits, debts, accounts, bonds, bills, covenants, contracts, controversies, obligations, claims, counterclaims, setoffs, debts, demands, damages, costs, expenses, compensation and liabilities of every kind and any nature whatsoever, in each case whether absolute or contingent, liquidated or unliquidated, known or unknown, and whether arising at law or in equity, which such BHV Releasing Party had, has or may have based upon, arising from, in connection with or relating to the Merger Agreement, any agreement, instrument or other document delivered in connection therewith or the transactions contemplated thereby; provided, however, that the foregoing shall not limit the rights and obligations of the parties hereto under (i) this Agreement, (ii) the Surviving Provisions, (iii) the Confidentiality Agreement, (iv) the Employment Agreements by and between Islet and the BHV Members, dated as of October 30, 2013. (v) the Islet by-laws, (vi) the License Agreement and any related agreements, or (vii) any agreements entered into among any of the parties following the date hereof. Each BHV Releasing Party shall refrain from, directly or indirectly, asserting any claim or demand or commencing, instituting, maintaining, facilitating, aiding or causing to be commenced, instituted or maintained, any legal or arbitral proceeding of any kind against any Islet Released Party based upon any matter released under this Section 2(b).

Section 3. Indemnification.

(a) Islet shall, notwithstanding any termination of this Agreement, indemnify and hold harmless BHV, its subsidiaries and affiliates and the respective directors, officers, shareholders, partners, members, managers, employees, representatives, advisors, agents, attorneys, successors and assigns of each of the foregoing, including without limitation the BHV Members (the "<u>BHV Indemnified</u> <u>Parties</u>"), to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable costs of preparation and reasonable attorneys' fees) and expenses (collectively, "<u>Losses</u>"), as incurred, arising out of or relating to (i) the negotiation of and entry into this Agreement, the License Agreement and the transactions contemplated by the foregoing and any agreements entered into in connection therewith, (ii) the negotiation, entry into and termination of the Merger Agreement and the transactions contemplated by the Merger Agreement or (iii) any matter released under <u>Section 2(a)</u> of this Agreement.

(b) If any action, claim, suit, investigation or proceeding (including, without limitation, an investigation or partial proceeding, such as a deposition), whether commenced or threatened (a "Proceeding") shall be brought or asserted against any BHV Indemnified Party, such BHV Indemnified Party shall within ten (10) days notify Islet in writing, and Islet shall have ten (10) days from receipt of such notice (or such lesser number of days set forth in such notice as may be required by court proceeding in the event of a litigated matter) to notify the BHV Indemnified Party that it desires to defend the BHV Indemnified Party against such Proceeding. After provision of such notice, Islet may assume the defense thereof in accordance with Section 3(c) below, including the employment of counsel reasonably satisfactory to the BHV Indemnified Party and the payment of all fees and expenses incurred in connection with defense thereof, and the BHV Indemnified Party shall deliver to Islet, promptly following the BHV Indemnified Party relating to the Proceeding. The failure of any BHV Indemnified Party to give notice of a Proceeding shall not relieve Islet of its obligations or liabilities pursuant to this Agreement, except (and only) to the extent that it shall be finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) that such failure shall have proximately and materially adversely prejudiced Islet.

(c)

1) In the event that Islet notifies the BHV Indemnified Party in accordance with <u>Section 3(b)</u> that it elects to defend the BHV Indemnified Party against a Proceeding, Islet shall have the right to defend the BHV Indemnified Party by appropriate proceedings and shall have the sole power to direct and control such defense, with counsel of its choosing, at its expense (which choice of counsel shall be subject to the BHV Indemnified Party's prior written consent, not to be unreasonably withheld, conditioned or delayed); provided, that Islet must conduct the defense of the Proceeding actively and diligently in order to preserve its rights in this regard. Once Islet has elected to assume the defense in compliance with this <u>Section 3(c)</u>, the BHV Indemnified Party shall have the right to participate in any such defense and to employ separate counsel of its choosing at such BHV Indemnified Party's expense; provided, however, that the BHV Indemnified Party shall be entitled to employ separate counsel at the reasonable expense of Islet if requested by Islet to participate in any such defense.

2) Notwithstanding the foregoing, the BHV Indemnified Party shall have the sole power to direct and control the defense of the Proceeding (and Islet shall not have the right to defend or elect to defend the BHV Indemnified Party against a Proceeding, but shall remain obligated to indemnify the BHV Indemnified Party against all costs, including attorneys fees, associated with the Proceeding) if (i) Islet fails to assume the defense or fails to conduct the defense of the Proceeding actively and diligently, (ii) the BHV Indemnified Party reasonably believes (A) the Proceeding relates to or may result in any Adverse Claim Consequences (as defined below), (B) counsel for Islet could not adequately represent the interests of the BHV Indemnified Party in such Proceeding because the BHV Indemnified Party's interests could be in conflict with those of Islet or Islet's control of such Proceeding would be reasonably likely to prejudice the rights of the BHV Indemnified Party or (C) there are one or more legal or equitable defenses available to the BHV Indemnified Party that are different from or in addition to those available to Islet, or (iii) the Proceeding seeks non-monetary relief, relates to a criminal action or involves claims by a governmental authority.

3) If Islet assumes the defense of a Proceeding, Islet shall not, without the prior written consent of the BHV Indemnified Party, settle, compromise or offer to settle or compromise any Proceeding if the terms of such settlement do not contain a release of the BHV Indemnified Parties, which release shall be in form and substance reasonably satisfactory to the BHV Indemnified Party, or (i) would result in the imposition of an order that would restrict any future activity or conduct of the BHV Indemnified Party, (ii) would result in a finding or admission of wrongdoing or violation of law by the BHV Indemnified Party, (iii) would result in any monetary liability of the BHV Indemnified Party that will not be paid or reimbursed by Islet or (iv) relates to any ongoing business of the BHV Indemnified Party, which, in the case of a BHV Indemnified Party, shall include the business of BHV (any of the foregoing, "Adverse Claim Consequences").

(d) All fees and expenses of each BHV Indemnified Party (including reasonable fees and expenses to the extent incurred in connection with investigating, preparing to defend or defending such Proceeding in a manner not inconsistent with this <u>Section 3</u>) shall be paid to the BHV Indemnified Party promptly and periodically, but no later than twenty (20) business days after written notice thereof to Islet (regardless of whether it is ultimately determined that a BHV Indemnified Party is not entitled to indemnification hereunder; provided, that Islet may require such BHV Indemnified Party to undertake to reimburse all such fees and expenses to the extent it is finally judicially determined that such BHV Indemnified Party is not entitled to indemnification hereunder). Islet shall pay (as incurred) all expenses, including reasonable fees and expenses of counsel, that a BHV Indemnified Party may incur in enforcing the indemnity and other obligations provided for in this <u>Section 3</u>.

(e) If Islet or any of its successors and assigns (i) consolidates with or merges into any other entity and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfers or conveys all or substantially all of its properties and assets to any person, then, and in each such case, to the extent necessary, proper provision shall be made so that the successors and assigns of Islet, as the case may be, shall assume the obligations set forth in this <u>Section 3</u>.

(f) The indemnification and advancement of expenses provided by, or granted pursuant to, this Agreement shall not be deemed exclusive of any other rights to which any BHV Indemnified Party may be entitled under any other by-law, agreement, or otherwise, including without limitation the Employment Agreements by and between Islet and the BHV Members, dated as of October 30, 2013, as well as the Islet by-laws.

Section 4. Entire Agreement; No Third Party Beneficiaries. This Agreement constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, among the parties with respect to the subject matter hereof, other than the Confidentiality Agreement, the Surviving Provisions of the Merger Agreement set forth in Section 1(b), and the Employment Agreements and by-laws set forth in Section 2, all of which shall survive the execution and delivery of this Agreement in accordance with their terms (and, with respect to the Confidentiality Agreement, the terms of the License Agreement). Except as provided in Section 2 and Section 3 (which are intended for the benefit of only the persons specifically listed therein), this Agreement is not intended to confer upon any person other than the parties any rights or remedies hereunder.

Section 5. <u>Counterparts</u>. This Agreement may be executed in counterparts, each of which shall be considered one and the same agreement, and this Agreement shall become effective when a counterpart signed by each party shall be delivered to the other party, it being understood that both parties need not sign the same counterpart. Facsimile or electronic execution and facsimile or electronic delivery of this Agreement are legal, valid and binding for all purposes.

Section 6. <u>Governing Law</u>. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without regard to any applicable conflicts of law.

Section 7. Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been given (a) when delivered by hand (with written confirmation of receipt), (b) when received by the addressee if sent by a nationally recognized overnight courier (with confirmation of delivery), (c) on the date sent by e-mail (with confirmation of receipt) if sent during normal business hours of the recipient, and on the next business day if sent after normal business hours of the recipient or (d) on the third day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent to the respective parties at the following addresses or e-mail addresses (or at such other address or e-mail address for a party as shall be specified for such purpose in a notice given in accordance with this Section 7).

(a) if to Islet, to:

Islet Sciences, Inc. 6601 Six Forks Rd., Suite 140 Raleigh, North Carolina 27615 Attention: Chief Financial Officer E-mail: steve@isletsciences.com

with a copy to:

Ofsink, LLC 230 Park Avenue, Suite 851 New York, New York 10169 Attention: Darren L. Ofsink, Esq. E-mail: dofsink@golawintl.com

(b) if to BHV, to:

Brighthaven Ventures, L.L.C. 3200 East Hwy 54, Suite 100 Research Triangle Park, NC 27709 Attention: James Green E-mail: info@bhvpharma.com

with a copy to:

Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P. 2300 Wells Fargo Capitol Center Post Office Box 2611 Raleigh, North Carolina 27602-2611 Attention: Heyward D. Armstrong, Esq. E-mail: harmstrong@smithlaw.com

Section 8. <u>Amendment</u>. This Agreement may only be amended, modified or supplemented by an agreement in writing signed by each party hereto.

Section 9. <u>Severability</u>. Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to that jurisdiction, be ineffective to the extent of such invalidity or unenforceability and, shall not render invalid or unenforceable the remaining terms and provisions of this Agreement or affect the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction. Upon such determination that any term or other provision of this Agreement is invalid or unenforceable, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

Section 10. Submission to Jurisdiction. Each party irrevocably submits to the jurisdiction of (a) any court sitting in New Castle County, Delaware, including the Delaware Court of Chancery, and (b) the United States District Court for the District of Delaware, for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby (excluding, for the avoidance of doubt, any suit, action or other proceeding arising out of the License Agreement). Each party agrees to commence any action, suit or proceeding relating hereto either in the United States District Court for the District of Delaware or, if such suit, action or other proceeding may not be brought in such court for reasons of subject matter jurisdiction, in any court sitting in New Castle County, Delaware. Each party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or any transaction contemplated hereby (excluding, for the avoidance of doubt, any suit, action or other proceeding arising out of the License Agreement) in (i) any court sitting in New Castle County, Delaware, including the Delaware Court of Chancery, or (ii) the United States District Court for the District of Delaware, and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each party further irrevocably consents to the service of process out of any of the aforementioned courts in any such suit, action or other proceeding by the mailing of copies thereof by mail to such party at its address set forth in this Agreement, such service of process to be effective upon acknowledgment of receipt of such registered mail; provided that nothing in this Section 10 shall affect the right of any party to serve legal process in any other manner permitted by law. The consent to jurisdiction set forth in this Section 10 shall not constitute a general consent to service of process in the State of Delaware and shall have no effect for any purpose except as provided in this Section 10. The parties agree that a final judgment in any such suit, action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

Section 11. <u>Cumulative Remedies</u>. The remedies provided herein are cumulative and not exclusive of any remedies provided by law.

Section 12. <u>WAIVER OF JURY TRIAL</u>. TO THE FULLEST EXTENT PERMITTED BY LAW, EACH OF THE PARTIES HEREBY WAIVES TRIAL BY JURY IN ANY JUDICIAL PROCEEDING DIRECTLY INVOLVING ANY MATTERS (WHETHER SOUNDING IN TORT, CONTRACT OR OTHERWISE) IN ANY WAY ARISING OUT OF, RELATED TO, OR CONNECTED WITH THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.

[Remainder of this Page Intentionally Left Blank]

[Signature Page to Termination Agreement]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed by their respective officers thereunto duly authorized, all as of the date first set forth above.

ISLET SCIENCES, INC. By: <u>/s/ Steven Delmar</u> Name: Steven Delmar Title: CFO BRIGHTHAVEN VENTURES, L.L.C.

By: <u>/s/ Bentley Cheatham</u> Name: Bentley Cheatham Title: CEO

AVOGENX, INC.

By: <u>/s/ Steven Delmar</u> Name: Steven Delmar Title: CFO

ISLET MERGER SUB, INC.

By: <u>/s/ Steven Delmar</u> Name: Steven Delmar Title: CFO

BHV MEMBERS:

<u>/s/ James T. Green</u> James T. Green

<u>/s/ William Wilkison</u> William Wilkison

Islet Sciences Enters Into Exclusive License Agreement for Phase 2 SGLT2 Inhibitor Remogliflozin Etabonate

RALEIGH, North Carolina March, 3 2015 - Islet Sciences, Inc. (OTCQB: ISLT), a biopharmaceutical company developing new medicines and technologies for the treatment of metabolic disease, announced today that it has entered into a license agreement with Brighthaven Ventures, LLC ("BHV") for exclusive rights to develop and commercialize SGLT2 inhibitor remogliflozin etabonate ("remogliflozin"). Remogliflozin is in phase 2b development for type 2 diabetes and non-alcoholic steatohepatitis ("NASH").

Upon effectiveness of the agreement, Islet Sciences will be granted exclusive rights to remogliflozin in the global territory outside of Japan, Korea, Taiwan, China, and Latin America. In addition to an upfront fee of \$5 million, Islet is required to pay up to \$35.1 million pre-regulatory approval and up to \$76.75 million post-regulatory approval if certain development, regulatory and commercial milestones are successfully achieved. Royalties under the license agreement are due on net sales in the territory during the term of the agreement. The exclusive license will only become effective upon Islet raising a minimum of \$10 million and paying BHV the upfront fee by May 31, 2015.

On September 30, 2014, Islet entered into a merger agreement with BHV with the parent company to be named Avogenx. Concurrent with entering into the exclusive license agreement, the previously executed merger agreement has been terminated. As a result of the termination of the merger agreement, Avogenx is submitting a request to the Securities and Exchange Commission to withdraw its previously filed Form S-4 registration statement related to the merger.

"Islet is excited to assume responsibility for the global development plan for remogliflozin," said Islet CEO James Green. "With the significant unmet need for both NASH and diabetes, Islet is very encouraged by the data suggesting remogliflozin can emerge as the most positively differentiated SGLT2 inhibitor with improvements in efficacy and common side effects of SGLT2 inhibition, namely LDL cholesterol and fungal infections, compared to other molecules in the class."

"BHV is excited to enter into this exclusive license agreement, which we believe will accelerate the development and commercialization of remogliflozin," said BHV CEO Dr. Bentley Cheatham. "We look forward to partnering with Islet to deliver an exciting new alternative for patients suffering from diabetes and NASH"

About Remogliflozin

Remogliflozin is a selective SGLT2 inhibitor in phase 2b clinical development for type 2 diabetes and NASH. Remogliflozin has been dosed in over 800 people in more than twenty clinical trials. In twelve-week phase 2b clinical studies, remogliflozin demonstrated HbA1c lowering greater than 1% with no significant adverse events and low incidence rates of genitourinary infections, a common side effect associated with SGLT2 inhibitors. Remogliflozin also demonstrated strong postprandial glucose disposal and improvements in both insulin sensitivity and beta cell function. In patients with impaired renal function, remogliflozin showed little plasma accumulation relative to patients with normal renal function and, therefore, no dose adjustment is expected for this large (>35%) segment of the diabetic population. The review by a central IRB and the U.S. Food and Drug Administration of the protocol for a phase 2b clinical study of remogliflozin was conducted in late 2014. Clinical site selection is underway with initial dosing expected to commence Q2 of 2015. The study is designed as a 12-week double blind, placebo controlled, and dose-ranging study of remogliflozin in type 2 diabetics.

About Islet Sciences

Islet Sciences, Inc., a biopharmaceutical company based in Raleigh, NC, is developing new medicines and technologies for the treatment of metabolic disease. In addition to remogliflozin, the Company's pipeline includes immune-modulating small molecule IL-12 antagonists targeting beta-cell preservation and inflammation, a cell-based transplantation therapy for insulin-dependent diabetes, and a PCR-based molecular diagnostic measuring beta-cell loss for the diagnosis of type 1 diabetes or onset of insulin-dependent type 2 diabetes. For more information, please visit http://www.isletsciences.com.

About BHV Pharmaceuticals

BHV, a Research Triangle Park-based clinical-stage drug development company, is focused on developing therapeutics for the treatment of diseases such as diabetes, obesity, and NASH.

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements reflect current expectations as of the date of this press release and involve certain risks and uncertainties. Actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, and such forward-looking statements are not predictions of future events. Factors that could cause future results to materially differ from the recent results or those projected in forward-looking statements include the Company's ability to raise the minimum \$10 million of funding required by the license agreement, the failure of the license agreement to become effective by May 31, 2015, the Company's ability to develop and commercialize remogliflozin, and the other risks described in Islet Science, Inc.'s reports filed with the Securities and Exchange Commission. The development and commercialization of remogliflozin is highly dependent on future medical and research developments and market acceptance, which are outside of Islet's and BHV's control.

Contact:

Steve Delmar, Chief Financial Officer Islet Sciences, Inc. 6601 Six Forks Rd, Suite 140 Raleigh, NC 27615 919.480.1518 info@isletsciences.com

Islet Sciences, Inc. Confirms Issuance of U.S. Patent for using SGLT2 inhibitors to treat NASH/NAFLD

RALEIGH, North Carolina, March 5, 2015 - <u>Islet Sciences, Inc.</u> (OTCQB: ISLT), a biopharmaceutical company developing new medicines and technologies for the treatment of metabolic disease, announced today a Notice of Claims Allowance for the U.S. Patent Application No. 12/511,654 entitled "Progression inhibitor for disease attributed to abnormal accumulation of liver fat" (Patent number: US8,951,976). This patent provides for the pharmaceutical compositions which comprise as an active ingredient a sodium/glucose co-transporter 2 inhibitors including remogliflozin etabonate as highly suitable as an agent for the inhibition of progression of non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH), hypernutritive fatty liver, alcoholic fatty liver disease, diabetic fatty liver or acute fatty liver of pregnancy.

On March 3, 2015, Islet Sciences, Inc. ("Islet") entered into an exclusive license agreement with Brighthaven Ventures, L.L.C. for rights to develop and commercialize a novel SGLT2 inhibitor, remogliflozin etabonate, in the licensed territory. This US patent is an integral part of the patent portfolio licensed in the agreement. The exclusive license will only become effective upon Islet raising a minimum of \$10 million and paying BHV the upfront fee by May 31, 2015.

"This U.S. patent adds significant value to the development of remogliflozin etabonate as a NASH/NAFLD drug," said James Green, CEO of Islet Sciences. "We are pleased to announce this significant milestone which clearly strengthens the patent estate around the remogliflozin program."

About Remogliflozin

Remogliflozin is a selective SGLT2 inhibitor in phase 2b clinical development for type 2 diabetes and NASH. Remogliflozin has been dosed in over 800 people in more than twenty clinical trials. In twelve-week phase 2b clinical studies, remogliflozin demonstrated HbA1c lowering greater than 1% with no significant adverse events and low incidence rates of genitourinary infections and little or no increases in LDLc, a common side effect associated with SGLT2 inhibitors. Remogliflozin also demonstrated strong postprandial glucose disposal and improvements in both insulin sensitivity and beta cell function. In patients with impaired renal function, remogliflozin showed little plasma accumulation relative to patients with normal renal function and, therefore, no dose adjustment is expected for this large (>35%) segment of the diabetic population. The review by a central IRB and the U.S. Food and Drug Administration of the protocol for a phase 2b clinical study of remogliflozin was conducted in late 2014. Clinical site selection is underway with initial dosing expected to commence Q2 of 2015. The study is designed as a 12-week double blind, placebo controlled, and dose-ranging study of remogliflozin in type 2 diabetics. A phase 2b clinical study for NASH is anticipated to commence in 2015.

About NASH/NAFLD

NAFLD occurs worldwide with a similar prevalence to obesity and type 2 diabetes. In the United States, it has emerged as the most common form of liver disease with population-based studies estimating prevalence as high as 30% of the general population. In children aged 2-19 years, the prevalence is approximately 10%. NAFLD includes a spectrum of liver disease ranging from simple steatosis (fat deposition) to necrosis and inflammation characteristic of NASH. The prevalence of NASH in the United States is approximately 15%. Patients with NASH have an increased risk for disease progression to liver fibrosis (scarring) and irreversible liver damage (cirrhosis). Up to 50% of patients with NASH will develop progressive fibrosis over a 4-6 year period with up to 25% progressing to cirrhosis. NASH cirrhosis is now the third most common cause of liver transplantation in the United States. It is associated with an increased risk of hepatocellular carcinoma and mortality in patients awaiting liver transplant and can also recur post-transplant.

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Islet Sciences, Inc. COO to Present at EASL: Remogliflozin Etabonate as Novel Treatment for Non-alcoholic Steatohepatitis (NASH)

Islet Sciences' William Wilkison, Ph.D. to Present Efficacy Results at the 2015 International Liver Conference

RALEIGH, North Carolina March, 9 2015 - <u>Islet Sciences, Inc.</u> (OTCQB: ISLT), a biopharmaceutical company developing new medicines and technologies for the treatment of metabolic disease, announced today that Chief Operating Officer, Dr. William Wilkison, was invited to present clinical and preclinical data highlighting the unique properties of selective sodium glucose transporter 2 (SGLT2) inhibitor, remogliflozin etabonate, as a novel treatment for non-alcoholic steatohepatitis (NASH) and its precursor, non-alcoholic fatty liver disease (NAFLD). The data will be presented at the 50th International Liver Conference held in Vienna, Austria April 22 – 26, 2015 by the European Association for the Study of Liver (EASL).

The etiology of non-alcoholic steatohepatitis (NASH) is due, in part, to a combination of insulin resistance and oxidative stress. To date, studies with anti-diabetics or anti-oxidants have resulted in small effects on reversal of these factors in NASH patients. Remogliflozin etabonate (Remo) is an SGLT2 inhibitor shown to reduce HbA1c, improve insulin sensitivity and beta cell function, as well as reduce adiposity and body weight in type 2 diabetics. Additionally, unlike other SGLT2 inhibitors, Remo demonstrates intrinsic anti-oxidant activity, which may reverse the steatohepatitis and oxidative stress required to progress and maintain NASH. Remo is expected to enter phase 2b for NASH in 2015.

William Wilkison, Ph.D., Islet Sciences' Chief Operating Officer, stated, "We are excited to present our data on remogliflozin etabonate at this important meeting. The ability of Remo to increase insulin sensitivity and lower liver enzymes which we've demonstrated in our previous clinical studies, combined with significant reductions in liver steatosis and inflammation markers in pre-clinical studies make for a compelling opportunity for addressing NAFLD/NASH. Importantly, the positive effects on reducing oxidative stress make Remo unique, and a potentially meaningful differentiator as a best-in-class SGLT2 inhibitor."

Arun Sanyal, M.D., Professor of Medicine at Virginia Commonwealth University Medical Center and former President of the American Association for the Study of Liver Diseases (AASLD) commented, "The combination of two distinct mechanisms of action – improved insulin sensitivity via selective SGLT2 inhibition and inherent antioxidant activity – into a single, small molecule, oral drug may be significant for the future treatment of NAFLD/NASH, which is becoming an even greater public health issue as the global incidence of obesity and diabetes continue to rise."

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