

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION**

----- X		
ISLET SCIENCES, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	
	:	
AVOLYNT, INC., BRIGHTHAVEN	:	5:19-CV-145-D
VENTURES, LLC, WILLIAM WILKISON,	:	
and JAMES GREEN,	:	
	:	
Defendants.	:	
	:	
And	:	
	:	
AVOLYNT, INC., BRIGHTHAVEN	:	
VENTURES, LLC, WILLIAM WILKISON,	:	
and JAMES GREEN,	:	
	:	
Third-Party Plaintiffs,	:	
	:	
v.	:	
	:	
ISLET SCIENCES, INC., JOHN F. STEEL,	:	
IV., LARRY K. ELLINGSON, JAMES A.	:	
HARPER, RICHARD D. PILNIK, EUGENE	:	
M. MANNHEIMER, and GARY R.	:	
KEELING	:	
	:	
Counterclaim/Third-Party Defendants.	:	
----- X		


**ORDER GRANTING PLAINTIFF  
ISLET SCIENCES INC. AND THIRD-PARTY DEFENDANTS'  
MOTION TO ISSUE LETTERS OF REQUEST**

THIS MATTER came before the Court on the Motion of Plaintiff Islet Sciences, Inc. ("Islet") and Third-Party Defendants Islet, Steel, Ellingson, Harper, Pilnik, Mannheimer, and Keeling (collectively, the "Islet Parties") to Issue Letters of Request (ECF No. 137). After

considering the matters set forth in the Motion and the accompanying Memorandum in Support (ECF No. 138), and Defendants' Memorandum in Opposition (ECF No. 145), the Court ORDERS that the Letters of Request to Glenmark and Torrent (ECF Nos. 138-1 & 138-2) be issued.

Accordingly, along with this Order, the Court enters signed and dated copies of the Letters of Request and will transmit copies of the Letters to the Indian Ministry of Law and Justice at the address listed in the Letters.

SO ORDERED. This the 4 day of February, 2021.

  
\_\_\_\_\_  
James C. Dever III  
United States District Judge

**REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE PURSUANT TO THE  
HAGUE CONVENTION OF 18 MARCH 1970 ON THE TAKING OF EVIDENCE  
ABROAD IN CIVIL AND COMMERCIAL MATTERS**

**1. SENDER**

United States District Court  
for the Eastern District of North Carolina  
Western Division  
310 New Bern Ave. #174  
Raleigh, North Carolina 27601  
United States

**2. CENTRAL AUTHORITY OF  
REQUESTED STATE**

The Ministry of Law and Justice  
4<sup>th</sup> Floor, A-Wing  
Shastri Bhawan, New Delhi  
110001, India

**3. PERSON TO WHOM THE  
EXECUTED REQUEST IS TO BE  
RETURNED**

Alec P. Harris  
ARMSTRONG TEASDALE LLP  
4643 S. Ulster St. Ste. 800  
Denver, Colorado 80237  
Phone: +1 (720) 200-0676  
FAX: +1 (720) 200-0679  
aharris@armstrongteasdale.com

**4. SPECIFICATION OF THE DATE  
BY WHICH THE REQUESTING  
AUTHORITY REQUIRES  
RECEIPT OF THE RESPONSE TO  
THE LETTER OF REQUEST**

In order for Islet Sciences, Inc. to comply with its deadline to collect evidence in the above-captioned action, the Court respectfully requests that the Central Authority issue its response in such time as to permit the Letter of Request to be fully executed before March 1, 2021.

**IN CONFORMITY WITH ARTICLE 3 OF THE CONVENTION, THE UNDERSIGNED  
APPLICANT HAS THE HONOUR TO SUBMIT THE FOLLOWING REQUEST:**

**5.**

- |                                                                |                                                                                                                                                                            |
|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>a. REQUESTING JUDICIAL<br/>AUTHORITY</b>                    | United States District Court<br>for the Eastern District of North Carolina<br>Western Division<br>310 New Bern Ave. #174<br>Raleigh, North Carolina 27601<br>United States |
| <b>b. TO THE COMPETENT<br/>AUTHORITY OF</b>                    | The Republic of India                                                                                                                                                      |
| <b>c. NAMES OF THE CASE AND<br/>ANY IDENTIFYING<br/>NUMBER</b> | Islet Science, Inc. v. Avolynt, Inc. et al.<br>United States District Court for the Eastern<br>District of North Carolina<br>Western Division<br>No. 5:19-CV-145-D         |

**6. NAMES AND ADDRESSES OF  
THE PARTIES AND THEIR  
REPRESENTATIVES**

- |                      |                                                                                                                                                                                               |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>a. PLAINTIFF</b>  | Islet Sciences, Inc.<br>1001 South Pointe<br>Miami, Florida 33139<br><br>Represented by:<br>Alec P. Harris<br>ARMSTRONG TEASDALE LLP<br>4643 S. Ulster St. Ste. 800<br>Denver, Colorado 80237 |
| <b>b. DEFENDANTS</b> | Avolynt, Inc.<br>3200 E. Highway 54, Suite 100<br>Research Triangle Park, North Carolina 27709                                                                                                |

Brighthaven Ventures, LLC  
3200 E. Hwy 54, Suite 100  
Research Triangle Park, North Carolina 27709

William Wilkison  
Raleigh, North Carolina

James Green  
Raleigh, North Carolina

All Defendants represented by:  
K. Alan Parry  
Parry Law, PLLC  
Suite 351  
Chapel Hill, North Carolina 527517

**c. COUNTERCLAIM  
DEFENDANTS**

Islet Sciences, Inc.  
John F. Steel, IV  
Larry K. Ellingson  
James A. Harper  
Richard D. Pilnik  
Eugene M. Mannheimer  
Gary R. Keeling

All Counterclaim Defendants represented by:  
Alec P. Harris  
ARMSTRONG TEASDALE LLP  
4643 S. Ulster St. Ste. 800  
Denver, Colorado 80237

**7. NATURE AND PURPOSE OF  
PROCEEDINGS AND SUMMARY  
OF FACTS**

Plaintiff Islet Sciences, Inc. is a United States of America corporation.

Defendant Avolynt Inc. is a United States of America corporation.

Defendant Brighthaven Ventures, Inc. is a United States of America limited liability company.

Defendant William Wilkison is a resident of the United States of America.

Defendant James Green is a resident of the United States of America.

This civil action is currently pending in the United States District Court for the Eastern District of North Carolina. This action was brought by Plaintiff to recover damages caused by Defendants' breach of a joint venture and for Plaintiff's assistance given to Defendants to preserve and extend the technology and intellectual property rights pertaining to a revolutionary drug, the "Remo Technology," used to treat metabolic diseases, such as diabetes and Non-Alcoholic SteatoHepatitis.

Defendant Brighthaven Ventures, LLC ("BHV") entered into an exclusive license agreement with Kissei Pharmaceutical Co., Ltd. ("Kissei"), a Japanese pharmaceutical company, to develop and commercialize Remogliflozin and its related salt, Remogliflozin Etabonate, in various international markets. BHV also developed its own intellectual property related to Remogliflozin, specifically, a patent for bi-phasic release of the drug (PCT/US2011/043,143). Collectively, the products, systems, processes, and methods related to Remogliflozin, Remogliflozin Etabonate, and the bi-phasic release are known as "the Remo Technology."

In 2012, BHV was on the verge of losing this pharmaceutical intellectual property due to its failure to commercialize and patent the technology, so it turned to Islet for assistance. A joint venture was formed. However, after

BHV received the expertise and financial assistance it needed, it scuttled the venture.

Islet's critical assistance accomplished Defendants' desired goals: the preservation of the Remo technology license, the filing of global patent rights, and subsequent commercialization of the Remo Technology with multiple international pharmaceutical companies poised to bring the Remo Technology to the world. Those international pharmaceutical companies include Glenmark Pharmaceuticals Ltd. ("Glenmark") and Torrent Pharmaceuticals Ltd ("Torrent").

Defendants formed agreements with Glenmark and Torrent to develop and commercialize the Remo Technology in India. Specifically, Glenmark was instrumental in conducting clinical trials of the Remo technology in India, as well as preserving Defendants' intellectual property in India. Glenmark then obtained regulatory approval for the Remo Technology. Subsequently, Glenmark and Torrent entered into an agreement to market the Remo Technology in India.

**8. EVIDENCE TO BE OBTAINED OR  
OTHER JUDICIAL ACT TO BE  
PERFORMED**

The deposition testimony of Glenmark, along with documentary evidence in paragraph 11 below. The testimony of Glenmark and any relevant documents in its possession will be used in Islet's claims against Avolynt, BHV, William Wilkison, and James Green, as well as serve as evidence at the trial of the pending lawsuit should Glenmark be unavailable to testify. It will also be used by Counterclaim Defendants in their defense against the counterclaims filed in this case by Avolynt, BHV, William Wilkison, and James Green.

**9. IDENTITY AND ADDRESS OF  
PERSON TO BE EXAMINED**

Glenmark Pharmaceuticals Limited

Registered Office

B/2, Mahalaxmi Chambers, 22, Bhulabhai  
Desai Road, Mumbai – 400 026.

Corporate Office

Glenmark House, B. D. Sawant Marg,  
Chakala, Off Western Express Highway,  
Andheri (E), Mumbai - 400 099.

**10. STATEMENT OF THE SUBJECT  
MATTER ABOUT WHICH THE  
PERSONS NAMED IN  
PARAGRAPH 9 ARE TO BE  
EXAMINED**

Glenmark is to be examined regarding its efforts to develop, seek regulatory approval for, and commercialize and market the Remo Technology in India. Glenmark is to be examined regarding any knowledge of the market for the Remo Technology, and competing drugs. Glenmark is also to be examined regarding any knowledge of relationships and agreements between the Defendants and third parties, including, but not limited to, Islet, Kissei, Torrent, and Libbs, a Brazilian pharmaceutical company. Additionally, Glenmark will be examined regarding any knowledge concerning the value of the Remo Technology.

For purposes of clarity, products, systems, processes, or methods that include Remo Technology are part of this definition, such as combination therapies (Remo-M or Remozen-M), described for exemplary purposes in Glenmark's press release, *Glenmark receives approval for combination of Remogliflozin Etabonate and Metformin Hydrochloride for adults with type 2 diabetes in India* (August 19, 2019).



**11. DOCUMENTS OR OTHER  
PROPERTY TO BE PRODUCED**

The documents listed in Appendix 1 are herein requested to be produced for inspection and copying.

**12. OATH OR AFFIRMATION**

Glenmark's deposition testimony is requested to be taken under oath.

**13. SPECIAL METHODS OR  
PROCEDURE**

N/A

**14. REQUEST FOR ATTENDANCE  
OR PARTICIPATION OF  
JUDICIAL PERSONNEL**

This court respectfully requests that counsel for Islet (Alec P. Harris, ARMSTRONG TEASDALE LLP, 4643 S. Ulster St. Ste. 800, Denver, Colorado 80237, Tel: +1 (720) 200-0676, Email: aharris@armstrongteasdale.com be notified of the date, time, and place of the examination. The examination will take place at a time and location to be determined by the Ministry of Justice and/or Islet, but no later than March 1, 2021.

**15. FEES AND COSTS**

The fees and costs incurred which are reimbursable under Article 14 or 26 will be borne by the Islet Parties.

**16. DATE OF REQUEST**

February 4, 2021

**17. SIGNATURE AND SEAL OF THE  
REQUESTING AUTHORITY**

4 - Dever  
United States District Judge  
E.D.N.C.



**Appendix 1 to Letter of Request to Glenmark Pharmaceuticals Ltd.**

**INSTRUCTIONS**

The following instructions shall apply to the requests that follow:

1. The following rules of construction shall apply: (a) the use of the singular form of any word includes the plural and vice versa; (b) the terms “any” or “each” shall be construed to include and encompass “all;” (c) the connectives “and” and “or” shall be construed either disjunctively or conjunctively as necessary to bring within the scope of this document request all documents that might otherwise be construed to be outside of the scope of this document request; (d) the use of the word “the” shall not be construed as limiting the scope of any request; and (e) “including” or “include” shall be construed without limitation.

2. If any of the following requests cannot be responded to in full after exercising reasonable diligence to secure the information requested, so state and supply the response for those portions to which you are able to respond. If any response is qualified in any particular respect, set forth the details of such qualification.

3. If, in responding to these requests, you encounter any purported ambiguities, please so state, set forth the matter deemed ambiguous, and the construction used in responding, and respond in full to any aspects of the request that you do not assert to be ambiguous.

4. These requests seek non-privileged documents within your possession, custody, and control, and each request should be read with that limitation. However, if you withhold or redact any document on the basis of privilege or other protection, please identify that document and the basis for withholding in a privilege log.

5. You can designate materials confidential under the Protective Order entered by the U.S. District Court for the Eastern District of North Carolina on June 23, 2020 [attached hereto as Attachment 1].

6. The time limitation for these requests are for the materials in Your possession concerning the Remo Technology.

### **DEFINITIONS**

1. “You” or “Your” means Glenmark Pharmaceuticals Ltd. and all of its agents, employees, representatives, affiliated entities, attorneys, and all other persons or entities acting or purporting to act on its behalf, whether such person or entity is organized or located in India or another country.

2. “Affiliates” refers to persons or business entities that share ownership, management, or common business purpose.

3. “Islet” or “Plaintiff” means Plaintiff Islet Sciences, Inc., a United States business entity, and all persons or entities acting or purporting to act on its behalf.

4. “BHV” refers to Brighthaven Ventures, LLC, a United States business entity, and all persons or entities acting or purporting to act on its behalf.

5. “Avolynt” refers to Avolynt, Inc. a United States business entity, and all persons or entities acting or purporting to act on its behalf. It is also the parent of BHV.

6. “Green” refers to James Green, a natural person, former officer of Islet, former Chief Executive Officer of BHV, and current Chief Executive Officer of Avolynt.

7. “Wilkison” refers to William Wilkison, a natural person, former officer of Islet, former Chief Scientific Officer of BHV, and current Chief Scientific Officer of Avolynt.

8. “Defendants” refers to Avolynt, BHV, Wilkison, and Green.

9. “Third Party” means any person or entity other than You, Islet, or Defendants.

10. “FDA” means the United States Food and Drug Administration, and all past and present officers, directors, agents, employees, consultants, attorneys, and other persons or entities

acting or purporting to act on its behalf.

11. “CDSCO” means the Central Drugs Standard Control Organization of India, and all past and present officers, directors, agents, employees, consultants, attorneys, and other persons or entities acting or purporting to act on its behalf.

12. “EMA” means the European Medicines Agency, and all past and present officers, directors, agents, employees, consultants, attorneys, and other persons or entities acting or purporting to act on its behalf.

13. “Remo Technology” means any product, system, process, or method concerning the molecule remogliflozin, its salt carrier remogliflozin etabonate, and its bi-phasic release technology, all of which are described in Defendants’ PCT Application No.

PCT/US2011/043143. Products, systems, processes, or methods that include Remo Technology are part of this definition, such as combination therapies (Remo-M or Remozen-M), described for exemplary purposes in Your press release, *Glenmark receives approval for combination of Remogliflozin Etabonate and Metformin Hydrochloride for adults with type 2 diabetes in India* (August 19, 2019).

14. The term “document” or “documents” are used in the broadest possible sense and include, without limitation, all originals, copies, drafts, and recordings of any written, typewritten, handwritten, printed, graphic, electronic, digital or otherwise recorded matter, including forms of information translatable or convertible into a reasonably usable form.

“Document” or “documents include, without limitation, the following items: electronic mail (e-mails); Microsoft PowerPoint slides and/or presentations; Microsoft Excel spreadsheets; Microsoft Word documents or other word processing program; licenses; agreements; communications; letters; memoranda; records; books; text messages; facsimiles; summaries or

handwritten notes or other records of personal conversations or interviews; diaries; appointment books or electronic entries; accounts; invoices; analytical records; reports, records or summaries of meetings or conferences; reports, records or summaries of consultants; reports, records or summaries of negotiations; brochures; pamphlets; circulars; any other document or writing or form of information convertible into a document, including information contained within or accessible by a computer or computer accessory and the underlying documents supporting computer entries.

15. “Communication” means any communication, however made, including, but not limited to, correspondence, contract, discussion, or any other kind of oral or written exchange between two or more persons, including, but not limited to, all telephone conversations, face-to-face conversations, meetings, visits, conferences, e-mail messages, texts, internal and external discussions, and documents, however the same are transcribed, sent, or given.

16. The term “person” refers to natural persons, organizations, firms, corporations, and other legal entities, and the acts “of” a person are defined to include the acts of directors, officers, owners, members, employees, agents, or attorneys acting on the person’s behalf.

### **DOCUMENT REQUESTS**

1. Your draft and final versions of licenses and agreements related to the Remo Technology, including but not limited to those with Defendants or any Third Party.

2. Documents and communications relating to application to any regulatory or licensing agencies (including the FDA or Central Drugs Standard Control Organization in India) for the Remo Technology.

3. Documents and communications relating to Your assessments or predictions of approval of the Remo Technology by any regulatory or licensing agencies (including the FDA,

EMA or CDSCO).

4. Documents and communications relating to Your assessments or predictions of past, present, or future outcomes of any clinical trials for the Remo Technology, since the beginning of Your involvement with the Remo Technology. This request includes, without limitation, analyses of the likelihood that products using the Remo Technology will be approved for marketing.

5. Documents and communications mentioning Islet or John Steel.

6. Documents and communications concerning the BHV and Islet Joint Venture business dealings [for example, Attachment 2 (Term Sheet) and Attachment 3 (Proposed Press Release)].

7. Documents and communications related to payments that Defendants agreed to provide to any person or business entity related to the Remo Technology, including but not limited to milestone payments, licensing payments, royalties, equity payments, reimbursements (for example, developmental, clinical, or any other type), or revenue splits.

8. Documents and communications related to payments that You agreed to provide to any person or business entity related to the Remo Technology, including but not limited to milestone payments, licensing payments, royalties, equity payments, reimbursements (for example, developmental, clinical, or any other type), or revenue splits.

9. Documents created by Third Parties (such as but not limited to, consultants, government agencies, etc.), regarding the Remo Technology.

10. Documents and communications exchanged with any Third Parties related to the Remo Technology.

11. Documents created for any due diligence related to the Remo Technology, but not

shared with Defendants.

12. Documents and communications related to the value of any patents related to PCT Application No. PCT/US2011/043143.

13. Documents and communications that show the value of Your contribution to any product that contains the Remo Technology. For purposes of clarity, we seek information that shows Your technical or business contribution, as opposed to the benefits the Remo Technology provided to Your products.

14. Documents and communications sufficient to show the value of the Remo Technology, in any country for which you have information, on an annual basis since the beginning of Your involvement with the Remo Technology, including financial forecasts; sales, revenue, cash flow, or profit projections or analyses; asset calculations; valuations; agreement terms; market analyses; or risk assessments.

15. Documents and communications sufficient to show Your identification of competitors or alternatives to the Remo Technology in any country for which you have information, since the beginning of Your involvement with the Remo Technology.

16. Documents and communications sufficient to show actual and projected, market size for the Remo Technology in any country for which you have information since the beginning of Your involvement with the Remo Technology.

17. Documents and communications sufficient to show actual and projected, market penetration of the Remo Technology in any country for which you have information since the beginning of Your involvement with the Remo Technology.

THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION  
No. 5:19-cv-145-D

ISLET SCIENCES, INC.,	)	
	)	
Plaintiff	)	
	)	
v.	)	
	)	
AVOLYNT, INC., BRIGHTHAVEN	)	
VENTURES, LLC, WILLIAM WILKISON,	)	
and JAMES GREEN,	)	
	)	
Defendants	)	
and	)	CASE NO.5:19-cv-145-D
	)	
AVOLYNT, INC., BRIGHTHAVEN	)	
VENTURES, LLC, WILLIAM	)	
WILKISON, and JAMES GREEN,	)	
	)	
Counterclaim Plaintiffs,	)	
	)	
v.	)	
	)	
ISLET SCIENCES, INC., JOHN F. STEEL,	)	
IV., LARRY K. ELLINGSON,	)	
JAMES A. HARPER, RICHARD D.	)	
PILNIK, EUGENE M. MANNHEIMER,	)	
and GARY R. KEELING,	)	
	)	
Counterclaim-Defendants.	)	

**PROTECTIVE ORDER**  
**(AS MODIFIED)\***

**1. PURPOSE**

Disclosure and discovery activity in this Action are likely to involve production of confidential, proprietary, or private information for which special protection from public

\* See paragraph 8.



disclosure and from use for any purpose other than prosecuting this Action may be warranted. Accordingly, the Court hereby issues the following Protective Order. This Order does not confer blanket protections on all disclosures or responses to discovery. Rather, the protection it affords from public disclosure and unauthorized use extends only to the limited information or items that are entitled to confidential treatment according to the terms of this Order. The parties to this Action may modify or replace this order according to the provisions of Section 10 below.

## **2. DEFINITIONS**

**2.1.** The “**Action**” shall refer only to the above-captioned case(s) and shall not include related cases unless this Protective Order is amended to explicitly cover such related cases.

**2.2.** The “**Agreement**” shall refer to the Agreement to Be Bound attached hereto as Exhibit A. All executed Agreements to this Protective Order are Confidential Information pursuant to this Protective Order.

**2.3.** “**Confidential Information**” shall mean information (regardless of how it is generated, stored, or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26. Confidential Information not designated under a more restrictive designation shall be marked or otherwise designated “CONFIDENTIAL.”

**2.4.** “**Designated In-House Counsel**” shall mean In-House Counsel who seek access to “Highly Confidential Information” in this Action.

**2.5.** “**Disclosure or Discovery Material**” shall mean all items or information, regardless of the medium or manner in which it is generated, stored, or maintained (including, among other things, testimony, transcripts, and tangible things), that are produced or generated in disclosures or responses to discovery in this matter.

**2.6.** “**Expert**” shall mean a person with specialized knowledge or experience in a matter pertinent to the litigation who (1) has been retained by a Party or its counsel to serve as an

expert witness or as a consultant in this Action, (2) is not a current employee of a Party for purposes other than this Action, and (3) at the time of retention, is not anticipated to become an employee of a Party.

**2.7. “Final Disposition”** shall mean that (1) final judgment has been entered and any appeals of the final judgment have concluded, or (2) all claims of any kind asserted in the Action have been dismissed with prejudice by the Party or Parties who brought such claims.

**2.8. “Highly Confidential Information”** shall mean extremely sensitive “Confidential Information,” the disclosure of which to another Party or Non-Party would create a substantial risk of serious harm that could not be avoided by less restrictive means. Highly Confidential Information not designated with a more restrictive designation, to the extent possible, shall be marked or otherwise designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY.”

**2.9. “In-House Counsel”** shall mean attorneys who are employees of a Party or Non-Party. In-House Counsel does not include Outside Counsel.

**2.10. “Non-Party”** shall mean any natural person, partnership, corporation, association, or other legal entity not named as a Party to this Action

**2.11. “Outside Counsel”** attorneys who are not employees of a Party to this Action but are retained to represent or advise a Party to this Action and have appeared in this Action on behalf of that Party or are affiliated with a law firm which has appeared on behalf of that Party.

**2.12. “Party”** shall mean any party to this Action, including all of its officers, directors, employees, consultants, Experts, and Outside Counsel (and their support staffs).

**2.13. “Producing Party”** shall mean a Party or Non-Party that produces Disclosure or Discovery Material in this Action. Any Producing Party may designate information or items under the provisions of this Protective Order.

**2.14. “Professional Vendors”** shall mean persons or entities that provide litigation support services (e.g., photocopying; videotaping; translating; preparing exhibits or demonstrations; and organizing, storing, or retrieving data in any form or medium) and their employees and subcontractors.

**2.15. “Protected Material”** shall mean any Disclosure or Discovery Material that is designated under this Protective Order.

**2.16. “Receiving Party”** shall mean a Party or Non-Party that receives Disclosure or Discovery Material in this Action.

### **3. DESIGNATING CONFIDENTIAL INFORMATION**

**3.1. Manner and Timing of Designations.** Designation under this Order requires the Producing Party to affix the applicable legend (“CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY”) to each page or item that contains or embodies protected material. For testimony given in a deposition or other proceeding, the Producing Party shall specify all protected testimony and the level of protection being asserted. It may make that designation during the deposition or proceeding, or may invoke, on the record or by written notice to all parties within three business days, a right to have up to 21 days from the deposition or proceeding to make its designation.

**3.1.1.** A Party or Non-Party that makes original documents or materials available for inspection need not designate them for protection until after the inspecting party has identified which material it would like copied and produced. During the inspection and before the designation, all material shall be treated as “HIGHLY CONFIDENTIAL –

OUTSIDE COUNSEL ONLY.” After the inspecting party has identified the documents it wants copied and produced, the producing party must designate the documents, or portions thereof, that qualify for protection under this Order.

3.1.2. Parties shall give advance notice if they expect a deposition or other proceeding to include designated material so that the other parties can ensure that only authorized individuals are present at those proceedings when such material is disclosed or used. The use of a document or thing as an exhibit at a deposition shall not in any way affect its designation. Transcripts containing designated material shall have a legend on the title page noting the presence of designated material, and the title page shall be followed by a list of all pages (including line numbers as appropriate) that have been designated, and the level of protection being asserted. The Producing Party shall inform the court reporter of these requirements. Any transcript that is prepared before the expiration of the 21-day period for designation shall be treated during that period as if it had been designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY” unless otherwise agreed. After the expiration of the 21-day period, the transcript shall be treated only as actually designated.

**3.2. Inadvertent Failure to Designate.** An inadvertent failure to designate or an inadvertent mis-designation of confidential information or items does not, standing alone, waive the Producing Party’s right to secure protection under this Order for such material. Upon discovery of the inadvertently undesignated or mis-designated confidential information or items, the Producing Party must promptly notify the Receiving Party of the error, including (1) an identification of each item or piece of information that was undesignated or mis-designated, and (2) the proper designation for each such item or piece of information. The Producing Party shall

further, if applicable, produce a properly designated replacement for each such item. Upon prompt notification by the Producing Party, the Receiving Party must make reasonable efforts to assure that the material is treated in accordance with the provisions of this Order, and within a reasonable time following receipt of any replacement items with a corrected designation, return or destroy the undesignated or mis-designated item(s). The provisions of this section do not apply to inadvertently disclosed attorney-client privileged communications or protected attorney work product materials. Any inadvertently disclosed attorney-client privileged communications or protected attorney work product material shall be handled pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence.

**3.3. Over-Designation Prohibited.** Any Party or Non-Party who designates information or items for protection under this Order as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY,” shall use best efforts to only designate the specific material that qualifies under the appropriate standards. To the extent practicable, only those parts of documents, items, or oral or written communications that require protection shall be designated. Designations with a higher confidentiality level when a lower level would suffice are prohibited. Designation under this Order is allowed only if the designation is necessary to protect material that, if disclosed to persons not authorized to view it, would cause competitive or other recognized harm. If a Producing Party learns that information or items that it designated for protection do not qualify for protection at all or do not qualify for the level of protection initially asserted, that Producing Party must promptly notify all Parties that it is withdrawing the mistaken designation and, if applicable, re-produce the item with the appropriate designation, if any.

#### **4. CHALLENGING DESIGNATIONS OF CONFIDENTIAL INFORMATION**

**4.1. Timing of Challenges.** Any Party or Non-Party may challenge a designation of confidentiality at any time. Unless a prompt challenge to a Producing Party's confidentiality designation is necessary to avoid foreseeable, substantial unfairness, unnecessary economic burdens, or a significant disruption or delay of the litigation, the right to challenge a confidentiality designation is not waived by electing not to mount a challenge promptly after the original designation is disclosed.

**4.2. Meet and Confer.** The parties shall attempt to resolve each challenge to a confidentiality designation in good faith by meeting and conferring about each challenged designation prior to seeking judicial intervention. To initiate the meet and confer process under this section, the challenging party shall provide written notice that identifies the designated material, the then-current designation of each challenged item, and the proposed new designation (if any) for each challenged item.

**4.3. Judicial Intervention.** A challenging party may only seek judicial intervention if the parties involved in the dispute cannot resolve the dispute through the meet and confer process.

4.3.1. To initiate judicial intervention, the challenging party shall provide written notice to the Producing Party stating (1) that it believes the meet and confer process under section 4.2 has failed to resolve the challenge, and (2) identifying the designated material for which the challenge has not been resolved.

4.3.2. Within 14 calendar days of receipt of such written notice, the Producing Party shall file a motion with the Court under the Court's Local Civil Rules establishing the basis for each remaining challenged designation. Such motion shall be a "Discovery

Motion” under the local rules. The Producing Party shall bear the burden of establishing that each remaining challenged designation is proper.

4.3.3. Failure by the Producing Party to timely file a motion pursuant to section 4.3.2 shall be deemed an agreement by the Producing Party that the remaining challenged materials were improperly designated, and the remaining challenged materials shall be immediately treated as re-designated as proposed by the challenging party.

4.3.4. Following a successful challenge, or in the event the Producing Party fails to timely file a motion pursuant to section 4.3.2, and unless otherwise ordered by the Court, the Producing Party shall reproduce or re-designate, as appropriate, the remaining challenged designated material accordingly within 14 days or as otherwise agreed by the challenging and designating parties.

## **5. ACCESS TO AND USE OF PROTECTED MATERIAL**

**5.1. Basic Principles.** A Receiving Party may use Protected Material only for this Action. Protected Materials may be disclosed only to the categories of persons and under the conditions described in this Order.

**5.2. Access to Protected Material Designated “CONFIDENTIAL.”** Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may disclose any material designated CONFIDENTIAL only to:

- (a) The Receiving Party’s Outside Counsel in this action and employees of Outside Counsel to whom disclosure is reasonably necessary;
- (b) The officers, directors, and employees of the Receiving Party to whom disclosure is reasonably necessary, and who have signed the Agreement;
- (c) Experts retained by the Receiving Party’s Outside Counsel to whom disclosure is reasonably necessary, and who have signed the Agreement;

- (d) The Court and its personnel;
- (e) Outside court reporters and their staff, professional jury or trial consultants, and professional vendors to whom disclosure is reasonably necessary, and who have signed the Agreement;
- (f) During their depositions, witnesses in the action to whom disclosure is reasonably necessary and who have signed the Agreement; and
- (g) The author or recipient of a document containing the material, or a custodian or other person who otherwise possessed or knew the information.

**5.3. Access to Protected Material Designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY.”** Unless permitted in writing by the Producing Party, a Receiving Party may disclose material designated HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY without further approval only to:

- (a) The Receiving Party’s Outside Counsel in this Action and employees of Outside Counsel to whom it is reasonably necessary to disclose the information;
- (b) The Court and its personnel;
- (c) Outside court reporters and their staff, professional jury or trial consultants, and professional vendors to whom disclosure is reasonably necessary, and who have signed the Agreement; and
- (d) The author or recipient of a document containing the material, or a custodian or other person who otherwise possessed or knew the information.

**5.4. Procedures for Approving or Objecting to Disclosure of Protected Material Designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY” to In-House Counsel or Experts.** Unless agreed to in writing by the Producing Party:



(a) A party seeking to disclose to In-House Counsel any material designated **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY** must first make a written request to the Producing Party providing the full name of the specific in-house counsel, the city and state of such counsel's residence, and such counsel's current and reasonably foreseeable future primary job duties and responsibilities in sufficient detail to determine present or potential involvement in any competitive decision-making.

(b) A party seeking to disclose to an Expert any information or item that has been designated **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY** must first make a written request to the Producing Party that (1) identifies the general categories of **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY** information that the Receiving Party seeks permission to disclose to the Expert, (2) sets forth the full name of the Expert and the city and state of his or her primary residence, (3) attaches a copy of the Expert's current resume or curriculum vitae, (4) identifies the Expert's current employer(s), and (5) identifies each person or entity from whom the Expert has received compensation or funding for work in his or her areas of expertise (including in connection with litigation) in the past four years. If the Expert believes any of this information at (4) - (5) is subject to a confidentiality obligation to a third party, then the Expert should provide whatever information the Expert believes can be disclosed without violating any confidentiality agreements, and the party seeking to disclose the information to the Expert shall be available to meet and confer with the Producing Party regarding any such confidentiality obligations.

(c) A party that makes a request and provides the information specified in paragraphs 5.4(a) or 5.4(b) may disclose the designated material to the identified In-House

Counsel or Expert unless, within seven business days of delivering the request, the party receives a written objection from the Producing Party providing detailed grounds for the objection.

(d) Should the Producing Party object to the identified In-House Counsel or Expert, the party that made the request may challenge the objection by meeting and conferring with the Producing Party in good faith to resolve the objection. Should the parties be unable to resolve the objection through the meet and confer process, the party that made the request may seek judicial intervention by filing a motion under the Court's Local Civil Rules.

#### **6. UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL**

If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed Protected Material to any person or in any circumstance not authorized under this Protective Order, the Receiving Party must immediately (a) notify in writing the Producing Party of the unauthorized disclosures, (b) use its best efforts to retrieve all unauthorized copies of the Protected Material, (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Order, and (d) request such person or persons to execute the "Acknowledgment and Agreement to Be Bound" that is attached hereto as Exhibit A.

#### **7. FILING PROTECTED MATERIAL**

In accordance with § V.G(1)(e) of the Court's Electronic Case Filing Administrative Policies and Procedures Manual ("Policy Manual"), in the event that a filing Party seeks to file materials that have been designated "CONFIDENTIAL," "HIGHLY CONFIDENTIAL — OUTSIDE ATTORNEYS' EYES ONLY," by another Party, individual or non-party, the filing Party shall provisionally file the materials under seal in accordance with Local Civil Rule 79.2, with notice served on the Party, individual or non-party who desires to maintain the materials under seal. In accordance § V.G(1)(e)(i), the filing Party will submit a notice of filing in lieu of a motion to seal and the filing of these third party material under seal, by itself, shall not be

binding on the Court. However, documents submitted under seal in accordance with § V.G(1)(e) will remain under seal pending the Court's ruling on the motion to seal. Within seven (7) days after such notice, the Party, individual or non-party shall file a motion to seal and supporting memorandum in accordance with § V.G(1) of the Policy Manual. Where a Party seeks to submit documents to the Court which have been designated "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL — OUTSIDE ATTORNEYS' EYES ONLY" by the submitting Party, the submitting Party may, in its discretion, bring a motion to file such documents under seal pursuant to Local Civil Rules 7.1, 79.2, and § V.G(1) of the Court's Policy Manual. Where a submitting Party intentionally declines to seek an order sealing documents submitted to the Court designated as containing its own Confidential Information, the submitted material will no longer qualify for protection and subsequent treatment as containing Confidential Information under this Stipulated Protective Order.

In accordance with the Section G of the Policy Manual, except for motions filed under seal in accordance with Section V.G(1)(f) of the Policy Manual, each time a Party seeks to file under seal, said Party shall accompany the request with a motion to seal. The motion to seal may be filed without a supporting memorandum only if the filing Party can cite a statute or rule (federal, local or standing order) that requires the filing to be sealed. Absent such authority, the filing Party must submit a supporting memorandum that specifies: (i) the exact document or item, or portions thereof, for which filing under seal is requested; (ii) how such request to seal overcomes the common law or the First Amendment presumption to access; (iii) the specific qualities of the material at issue which justify sealing such material, taking into account the balance of competing interest in access; (iv) the reasons why alternatives to sealing are inadequate; and (v) whether there is consent to the motion. In addition to the motion and

supporting memorandum of law, the filing Party must set out such findings in a proposed order to seal.

**8. INADVERTENT PRODUCTION OF PRIVILEGED OR OTHERWISE PROTECTED MATERIAL**

Unless otherwise ordered by the court, the inadvertent production of privileged or otherwise protected material shall be governed by the "Order Pursuant to Federal Rule of Evidence 502(d) Regarding Production of Documents," entered contemporaneously herewith.

**9. PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN OTHER LITIGATION**

**9.1. Subpoenas and Court Orders.** This Order in no way excuses non-compliance with a lawful subpoena or court order. The purpose of the duties described in this section is to alert the interested parties to the existence of this Order and to give the Producing Party an opportunity to protect its confidentiality interests in the court where the subpoena or order issued.

**9.2. Notification Requirement.** If a Party is served with a subpoena or a court order issued in other litigation that compels disclosure of any Protected Material in this Action, that Party must:

- (a) Promptly notify the Producing Party in writing. Such notification shall include a copy of the subpoena or court order; and
- (b) Promptly notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Order. Such notification shall include a copy of this Order.

**9.3. Wait For Resolution of Protective Order.** If the Producing Party timely seeks a protective order, the party served with the subpoena or court order shall not produce any Protected Material in this Action before a determination by the court where the subpoena or order issued, unless the party has obtained the Producing Party's permission. The Producing Party shall bear the burden and expense of seeking protection of its confidential material in that court.

**10. MODIFICATION OR REPLACEMENT OF THIS PROTECTIVE ORDER**

**10.1. General Principles.** A Party or Parties to this Action may request modification or replacement of this Protective Order by moving the Court.

**10.2. Manner of Making Amendments.** Any proposed amendments to the Protective Order must be presented to the Court by filing two copies of the entire Protective Order. The first copy shall include markings indicating the proposed amendments, and the second copy shall be a clean copy for entry by the Court.

**10.3. By Stipulation.** The Parties may submit stipulated amendments to this Protective Order, or a stipulated replacement protective order, for entry by the Court at any time.

**10.4. On Motion.** A Party or Parties may move the Court for entry of amendments to this Protective Order without the agreement of all Parties.

10.4.1. Prior to moving the Court, the requesting party or parties must meet and confer with the other parties regarding any proposed amendments. Only upon a failure to reach agreement regarding any proposed amendments may the requesting party or parties move the Court under the Court's Local Civil Rules for entry of the proposed amendments.

10.4.2. Should different Parties have competing proposed amendments to the same portion or portions of this Protective Order, or competing proposals for new

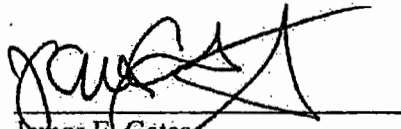
provisions to this Protective Order, rather than filing a motion under the Court's Local Civil Rules, the Parties shall file a joint motion indicating the competing proposed amendments and setting forth the reasons supporting each proposed amendment, and, if applicable, the opposing party's or parties' responses thereto. Such joint motion shall also include all other proposed amendments to this Protective Order, whether by one or both parties, whether opposed or agreed upon by the parties, and setting forth the parties' respective positions on such proposed amendments.

10.4.3. Within 7 calendar days of resolution of a motion under section 10.4, and if applicable, the moving Party or Parties, or if by joint motion under section 10.4.2, the Parties jointly, shall file the amended protective order according to section 10.2.

## **11. FINAL DISPOSITION**

Within 60 days after Final Disposition of this action, each Receiving Party shall return all designated material to the Producing Party or destroy such material, including all copies, abstracts, compilations, summaries, and any other format reproducing or capturing any designated material. If requested by the Producing Party, the Receiving Party must submit a written certification to the Producing Party by the 60 day deadline that (1) identifies (by category, where appropriate) all the designated material that was returned or destroyed, and (2) affirms that the receiving party has not retained any copies, abstracts, compilations, summaries, or any other format reproducing or capturing any of the designated material. This provision shall not prevent counsel from retaining an archival copy of all pleadings, motion papers, trial, deposition, and hearing transcripts, legal memoranda, correspondence, deposition and trial exhibits, expert reports, attorney work product, and consultant and expert work product, even if such materials contain designated material. Any such archival copies remain subject to this Order.

SO ORDERED this 23rd day of June, 2020.



James E. Gates  
United States Magistrate Judge

**EXHIBIT A**

**ACKNOWLEDGEMENT AND AGREEMENT TO BE BOUND**

I, \_\_\_\_\_ [print or type full name],  
of \_\_\_\_\_  
[print or type full address], declare under penalty of perjury that I have read in its entirety and understand the Protective Order that was issued by the United States District Court for the Eastern District of North Carolina on \_\_\_\_\_ in the case of *Islet Sciences, Inc. v. Avolynt, Inc. et al.*, Case No. 5:19-cv-145-D.

I agree to comply with and to be bound by all the terms of this Protective Order and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Protective Order to any person or entity except in strict compliance with the provisions of this Order. I also agree to notify any stenographic or clerical personnel who are required to assist me of the terms of this Order.

I understand that I am to retain all copies of any Protected Material, however designated, in a secure manner, and that all copies are to remain in my personal custody until I have completed my assigned duties, whereupon the copies and any writings prepared by me containing any information designated as Protected Material are to be returned to counsel who provided me with such material or destroyed, with certification of destruction.

I further agree to submit to the jurisdiction of the United States District Court for the Eastern District of North Carolina for the purpose of enforcing the terms of this Protective Order, even if such enforcement proceedings occur after termination of this Action.



*CONFIDENTIAL*

*Exhibit A – Acknowledgment and Agreement to Be Bound*

Date: \_\_\_\_\_

Printed name: \_\_\_\_\_

Signature: \_\_\_\_\_

Brighthaven Ventures L.L.C. / Lakota  
DRAFT NON-BINDING PROPOSAL

**Joint Venture Agreement**  
**for Development and Commercialization of Remogliflozin-etabonate**  
**Summary for Non-Binding Terms**  
**August 14, 2010**

This document is for discussion purposes only and does not constitute a binding agreement or letter of intent between the parties or an agreement to negotiate an agreement and there shall be no agreement between the parties unless and until there is a definitive agreement signed by both parties containing additional terms and conditions typically contained in license agreements concerning like subject matter. This document creates no obligation upon either party to enter into a transaction with the other party and neither party shall have any obligation arising out of this document. The terms set forth in this document are subject to all requisite corporate approvals, due diligence reviews, and appropriate tax and accounting considerations. This document and its terms are confidential, and neither party shall disclose the existence of this document or its terms without the prior written consent of the other party.

**General:** Brighthaven Ventures L.L.C. ("BHV") has a worldwide license from Kissei Pharmaceuticals for the development and commercialization of the novel SGLT2 inhibitor remogliflozin-etabonate ("remo"). Under the terms of a definitive agreement (the "Agreement"), BHV and Lakota ("Lakota") would collaborate to develop and commercialize products in the Field (defined below) in the Territory. Collectively BHV and Lakota shall be referred to as the "Parties."

**Joint Venture:** A new Limited Liability Company (the "LLC") will be created by the Parties. BHV will license certain rights to remo to the LLC. Lakota will contribute capital and project management to the LLC sufficient to fund the LLC liabilities and conduct the Development Plan through phase IIb. The equity ownership in the LLC shall be allocated 80% to Lakota and 20% to BHV. The JV will be managed by a Board with five Directors. Lakota may appoint one Lakota Director and one independent director. BHV may appoint one BHV Director and one independent director. One independent Director will be appointed by mutual consent of the Parties.

**License Grant:** To the LLC, BHV will grant an exclusive, sub-licensable, transferable license under the Kissei IP to research, develop, make, have made, manufacture, use, sell, offer for sale, promote, import or export Products in the Field and in the Territory. The general terms of the License Agreement to be agreed by the Parties will closely follow those from the BHV license agreement with Kissei dated December 10, 2010. The Term would commence as of the effective date of the License Agreement, and would continue in full force and effect until the expiration of the LLC's obligation to pay royalties; or until otherwise terminated.

**Initial Territory:** North America and Countries of the European Union.

**Secondary Territory:** Those countries outside of North America and the EU with the exception of Japan, Korea, Taiwan, China. License to the Secondary Territory will be granted

at the earlier of a) the LLC initiating phase III development, or b) the election of BHV to execute its change of control Tag-Along Rights or Lakota to execute its Drag-Along Rights.

**Field:** Prevention, diagnosis and treatment of human metabolic diseases of Type 1 and Type 2 diabetes mellitus.

**Commercialization:** LLC will be responsible for commercializing remo in the Territory

**Manufacturing:** LLC will be responsible for manufacturing drug product to support Commercialization in the Territory.

**Joint Development Committee:** The development program for remo in the Territory will be established in a written Development Plan, which would be managed by a Joint Development Committee (the "JDC"). The JDC would meet regularly, no less than quarterly. Final decisions related to the approval, modification, content control, steering and implementation of the development plan would be made by unanimous consent based on commercially reasonable judgment; provided, however, that any disputes would be raised to the JSC for final decision. So long as Dr. Wilkison and Mr. Green are members of the Lakota management team, the regular meetings of the JDC will be suspended and development decisions made by Lakota.

**Joint Steering Committee:** The parties would form a Joint Steering Committee to oversee and coordinate the parties' activities under the Agreement with respect to the development and commercialization of Products in the Field in the Territory (the "JSC"). The JSC will be responsible for resolving disputes that may arise among the parties' respective representatives on committees formed under the Agreement (such as the JDC) and making certain strategic decisions regarding Products to be defined in the Agreement. Such committee would consist of equal numbers of members appointed by each party, and would operate by unanimous consent; provided that the LLC Board will have the casting vote on any disputed matters. The JSC will meet at least twice a year and each Party will update the other Party on the ongoing developments in its territories. So long as Dr. Wilkison and Mr. Green are members of the Lakota management team, the regular meetings of the JSC will be suspended and strategic decisions made by Lakota.

**BHV Liabilities:** LLC will assume responsibility for a) obligations related to outstanding loans from the North Carolina Biotechnology Center, and b) payments due to Kissei as agreed under the License Agreement between BHV and Kissei.

**Supply Terms:** BHV will supply LLC with API in sufficient quantity to support the Development Plan. BHV will be responsible for all expenses related to the transport, insurance, storage and maintenance of the remaining API provided however that the LLC will reimburse BHV for direct expenses related to such activities on a pass-through basis. The LLC will gain rights to the remaining API at the earlier of a)

the LLC initiating phase III development, or b) the election of BHV to execute its change of control Tag-Along Rights or Lakota to execute its Drag-Along Rights.

**Tag-Along:** Each party will have pro-rata tag-along rights to participate in any sale of LLC equity. In addition, BHV will have the right to sell up to 100% of its stake in the LLC to any acquirer of a controlling interest of Lakota.

**Drag-Along:** Lakota will have the right to require BHV participate in the sale of the LLC, up to 80% of its stake in the LLC to an acquirer of a controlling interest of Lakota.

**Upfront Payment:** Lakota will issue 1,500,000 common shares to BHV.

**Contingent Payments:** Lakota and BHV will split pro-rata any upfront and contingent compensation received from a license, sale, or other disposition of the remo program over and above the following milestones and royalties that are due Kissei:

Phase III start:	\$10,000,000
NDA Filing:	\$15,000,000
MAA Filing:	\$ 7,500,000
FDA Approval:	\$25,000,000
EMEA Approval:	\$10,000,000
Royalty:	14%

**Diligence:** The license will include a diligence clause where if remo is not actively being developed, rights granted in the license will revert back to BHV. Lakota agrees to initiate the process of clinical trial material manufacture and initiation of Development Plan within 60 calendar days of executing the Agreement.

**Employment Agreements:** Dr. Wilkison and Mr. Green join Lakota with the titles/roles of Chief Operating Officer and Chief Business Officer, respectively. They will have employment agreements with Lakota that will include compensation, terms and conditions customary and commensurate with their role at the company as well as an upfront grant of 1,000,000 common shares of Lakota to be allocated evenly between Dr. Wilkison and Mr. Green in connection with their employment with Lakota.

**General Terms &**

**Conditions:** The parties will negotiate in good faith additional customary and reasonable terms and conditions as part of the Agreement, including, without limitation, termination, improvements and grant-backs, change of control, payment reports and provisions related to warranties, confidentiality, limitation on liability, patent prosecution and enforcement and indemnification.

**Governing Law:** TBD

**Confidentiality:** This Term Sheet is subject to the confidentiality terms set forth in the CDA between parties. The existence and content of this summary of proposed terms, and the fact that negotiations may be ongoing between the parties, constitute "Confidential Information".

CONFIDENTIAL DRAFT

**ISLET SCIENCES**

## **Islet Sciences and BHV Pharma Sign Exclusive License Agreement for Late Stage SGLT2 Inhibitor Remogliflozin-Etabonate for Type 2 Diabetes**

NEW YORK. January X, 2013 --Islet Sciences, Inc., (ISLT) a clinical stage company engaged in the research, development and commercialization of therapeutics in the field of diabetes, announced today that it has entered into a license agreement with BHV Pharma for exclusive rights to develop and commercialize Remogliflozin-Etabonate, a novel, highly selective Sodium Glucose Transporter 2 (SGLT2) inhibitor in phase IIb development for type 2 diabetes. The agreement provides Islet Sciences exclusive global rights excluding Japan, Korea, Taiwan and China.

SGLT2 inhibitors are an important emerging class of compounds that will be the only orally available treatment for type 2 diabetics providing significant HbA1c lowering with clinically relevant weight loss. More importantly, SGLT2 inhibition provides patients this benefit through an insulin independent, beta-cell sparing mechanism.

"As a diabetes focused company, we are excited to add remogliflozin to our pipeline of novel therapeutics. This transaction is another step in transforming Islet Sciences into an industry leader in diabetes research and development," stated John Steel, Islet Sciences Chairman and Chief Executive Officer.

James Green, Chief Business Officer of BHV Pharma added, "We look forward to working with Islet Sciences to continue the development of what will very likely become the most important molecule in an exciting new class of anti-diabetic therapy, not only in terms of HbA1c lowering and weight loss, but also as it relates to some of the potential side effects we've seen with other compounds in the class."

BHV is eligible to receive payments if certain development and regulatory milestones are achieved. BHV will also receive royalties on net sales. Specific financial terms of the Agreement were not disclosed.

### **About Remogliflozin Etabonate**

Remogliflozin is a once-daily, new chemical entity (NCE) that selectively inhibits the sodium glucose transporter 2. The compound has been assessed for efficacy, tolerability and safety in over twenty clinical trials, including two 12-week phase IIb studies in type II diabetics. Other studies that have been completed in the development of this compound include standard toxicology, pharmacology, safety and food and drug interaction studies.

## **About Islet Sciences, Inc.**

Islet Sciences is a development-stage biotechnology company with patented technologies focused on transplantation therapy for patients with diabetes. The Company's transplantation technology includes proprietary methods for the culturing, isolation, maturation, and immunoprotection (microencapsulation) of islet cells. For more information: [www.isletsciences.com](http://www.isletsciences.com)

## **About BHV Pharma**

BHV, a Research Triangle Park-based clinical-stage drug development company, is focused on developing therapeutics for the treatment of metabolic diseases. <http://www.bhvpharma.com>

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements for Islet Sciences 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. Factors that could cause future results to materially differ from the recent results or those projected in forward-looking statements include the risks described in the Islet Science's reports filed with the Securities and Exchange Commission. The companies' further development is highly dependent on future medical and research developments and market acceptance, which is outside their control.

Islet Sciences Investor Contact:

Jeff Ramson<sup>[1]</sup><sub>SEP</sub>

ProActive Capital Group

(646) 863-6893<sup>[1]</sup><sub>SEP</sub>

[iramson@proactivecapitalgroup.com](mailto:iramson@proactivecapitalgroup.com)

BHV Investor Contact:

BHV Pharma

919.904.4248

[info@bhvpharma.com](mailto:info@bhvpharma.com)

## Reactive Q&A

### 1. What are the financial terms of the Agreement?

Financial terms were not disclosed but include payments in the event certain development and regulatory milestones are met. Royalties will be due on net sales.

### 2. How does remo fit strategically into Islet's mission?

Islet's mission is to better the lives of patients suffering from diabetes. As an insulin independent mechanism, we believe SGLT2 inhibition in general, and remogliflozin in particular, will help Islet continue to produce positive outcomes for the world's diabetic population.

### 3. Are you thinking of developing remogliflozin for type 1 diabetes?

Based on what we know about the mechanism and previous clinical results, we believe remogliflozin may work well for type 1 diabetics in potentially reducing the frequency and amount of insulin required to maintain glycemic control. At this time, however, our near term development objective for remogliflozin is specific to type 2 diabetes with an intermediate term objective around type 1.

### 4. What are your near term development plans for remogliflozin?

We expect to initiate a phase 2b trial in 2013 after which we expect to have an end of phase 2 meeting with the USFDA. The trial will look very similar to the two previous 12-week phase 2b studies conducted with remogliflozin.

### 5. Does Islet expect to develop remogliflozin through phase 3?

We are presently focused on completing phase 2. We do however recognize the value of a commercialization partner with a global reach in primary care, so we anticipate partnering the program at a time and in a way that makes the most sense for the program and Islet shareholders. Right now though, we are focused on preparing for the upcoming phase 2b trial and progressing the rest of our pipeline.

### 6. How do you plan to differentiate remogliflozin from other SGLT2's in development?

Remogliflozin has been studied in over 20 clinical trials including two 12-week phase 2b clinical studies. Phase 2b data demonstrated best in class efficacy with certain doses showing greater than 1% HbA1c lowering with very strong postprandial effect, as well as very low incidence rates of genital fungal infections relative to what we have seen with other SGLT2 inhibitors. We expect to positively differentiate remogliflozin as a class leading molecule in both efficacy and tolerability.

### 7. Is GSK still involved with the program?

No. GSK terminated its license to remogliflozin in 2009 and retains no residual rights.

### 8. Why did GSK terminate its license to remogliflozin?

That decision was made by GSK for reasons that were specific to what GSK was going through at that time.



**REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE PURSUANT TO THE  
HAGUE CONVENTION OF 18 MARCH 1970 ON THE TAKING OF EVIDENCE  
ABROAD IN CIVIL AND COMMERCIAL MATTERS**

**1. SENDER**

United States District Court  
for the Eastern District of North Carolina  
Western Division  
310 New Bern Ave. #174  
Raleigh, North Carolina 27601  
United States

**2. CENTRAL AUTHORITY OF  
REQUESTED STATE**

The Ministry of Law and Justice  
4<sup>th</sup> Floor, A-Wing  
Shastri Bhawan, New Delhi  
110001, India

**3. PERSON TO WHOM THE  
EXECUTED REQUEST IS TO BE  
RETURNED**

Alec P. Harris  
ARMSTRONG TEASDALE LLP  
4643 S. Ulster St. Ste. 800  
Denver, Colorado 80237  
Phone: +1 (720) 200-0676  
FAX: +1 (720) 200-0679  
aharris@armstrongteasdale.com

**4. SPECIFICATION OF THE DATE  
BY WHICH THE REQUESTING  
AUTHORITY REQUIRES  
RECEIPT OF THE RESPONSE TO  
THE LETTER OF REQUEST**

In order for Islet Sciences, Inc. to comply with its deadline to collect evidence in the above-captioned action, the Court respectfully requests that the Central Authority issue its response in such time as to permit the Letter of Request to be fully executed before March 1, 2021.

**IN CONFORMITY WITH ARTICLE 3 OF THE CONVENTION, THE UNDERSIGNED  
APPLICANT HAS THE HONOUR TO SUBMIT THE FOLLOWING REQUEST:**

**5.**

- |                                                                |                                                                                                                                                                            |
|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>a. REQUESTING JUDICIAL<br/>AUTHORITY</b>                    | United States District Court<br>for the Eastern District of North Carolina<br>Western Division<br>310 New Bern Ave. #174<br>Raleigh, North Carolina 27601<br>United States |
| <b>b. TO THE COMPETENT<br/>AUTHORITY OF</b>                    | The Republic of India                                                                                                                                                      |
| <b>c. NAMES OF THE CASE AND<br/>ANY IDENTIFYING<br/>NUMBER</b> | Islet Science, Inc. v. Avolynt, Inc. et al.<br>United States District Court for the Eastern<br>District of North Carolina<br>Western Division<br>No. 5:19-CV-145-D         |

**6. NAMES AND ADDRESSES OF  
THE PARTIES AND THEIR  
REPRESENTATIVES**

- |                      |                                                                                                                                                                                         |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>a. PLAINTIFF</b>  | Islet Sciences, Inc.<br>1001 South Pointe<br>Miami, Florida 33139<br><br>Represented by:<br>Alec P. Harris<br>ARMSTRONG TEASDALE LLP<br>4643 S. Ulster St. Ste. 800<br>Denver, CO 80237 |
| <b>b. DEFENDANTS</b> | Avolynt, Inc.<br>3200 E. Highway 54, Suite 100<br>Research Triangle Park, North Carolina 27709                                                                                          |

Brighthaven Ventures, LLC  
3200 E. Hwy 54, Suite 100  
Research Triangle Park, North Carolina 27709

William Wilkison  
Raleigh, North Carolina

James Green  
Raleigh, North Carolina

All Defendants represented by:  
K. Alan Parry  
Parry Law, PLLC  
Suite 351  
Chapel Hill, North Carolina 27517

**c. COUNTERCLAIM  
DEFENDANTS**

Islet Sciences, Inc.  
John F. Steel, IV  
Larry K. Ellingson  
James A. Harper  
Richard D. Pilnik  
Eugene M. Mannheimer  
Gary R. Keeling

All Counterclaim Defendants represented by:  
Alec P. Harris  
ARMSTRONG TEASDALE LLP  
4643 S. Ulster St. Ste. 800  
Denver, Colorado 80237

**7. NATURE AND PURPOSE OF  
PROCEEDINGS AND SUMMARY  
OF FACTS**

Plaintiff Islet is a United States of America corporation.

Defendant Avolynt Inc. is a United States of America corporation.

Defendant Brighthaven Ventures, Inc. is a United States of America limited liability company.

Defendant William Wilkison is a resident of the United States of America.

Defendant James Green is a resident of the United States of America.

This civil action is currently pending in the United States District Court for the Eastern District of North Carolina. This action was brought by Plaintiff to recover damages caused by Defendants' breach of a joint venture and for Plaintiff's assistance given to Defendants to preserve and extend the technology and intellectual property rights pertaining to a revolutionary drug, the "Remo Technology," used to treat metabolic diseases, such as diabetes and Non-Alcoholic SteatoHepatitis.

Defendant Brighthaven Ventures, LLC ("BHV") entered into an exclusive license agreement with Kissei Pharmaceutical Co., Ltd. ("Kissei"), a Japanese pharmaceutical company, to develop and commercialize Remogliflozin and its related salt, Remogliflozin Etabonate, in various international markets. BHV also developed its own intellectual property related to Remogliflozin, specifically, a patent for bi-phasic release of the drug (PCT/US2011/043,143). Collectively, the products, systems, processes, and methods related to Remogliflozin, Remogliflozin Etabonate, and the bi-phasic release are known as "the Remo Technology."

In 2012, BHV was on the verge of losing this pharmaceutical intellectual property due to its failure to commercialize and patent the technology, so it turned to Islet for assistance. A joint venture was formed. However, after

BHV received the expertise and financial assistance it needed, it scuttled the venture.

Islet's critical assistance accomplished Defendants' desired goals: the preservation of the Remo technology license, the filing of global patent rights, and subsequent commercialization of the Remo Technology with multiple international pharmaceutical companies poised to bring the Remo Technology to the world. Those international pharmaceutical companies include Glenmark Pharmaceuticals Ltd. ("Glenmark") and Torrent Pharmaceuticals Ltd ("Torrent").

Defendants formed agreements with Glenmark and Torrent to develop and commercialize the Remo Technology in India. Specifically, Glenmark was instrumental in conducting clinical trials of the Remo technology in India, as well as preserving Defendants' intellectual property in India. Glenmark then obtained regulatory approval for the Remo Technology. Subsequently, Glenmark and Torrent entered into an agreement to market the Remo Technology in India.

**8. EVIDENCE TO BE OBTAINED OR  
OTHER JUDICIAL ACT TO BE  
PERFORMED**

The deposition testimony of Torrent, along with documentary evidence in paragraph 11 below. The testimony of Torrent and any relevant documents in its possession will be used in Islet's claims against Avolynt, BHV, William Wilkison, and James Green, as well as serve as evidence at the trial of the pending lawsuit should Torrent be unavailable to testify. It will also be used by Counterclaim Defendants in their defense against the counterclaims filed in this case by Avolynt, BHV, William Wilkison, and James Green.

**9. IDENTITY AND ADDRESS OF  
PERSON(S) TO BE EXAMINED**

Torrent Pharmaceuticals Ltd  
Torrent House, Off. Ashram Road,  
Ahmedabad – 380009, Gujarat, India

**10. STATEMENT OF THE SUBJECT  
MATTER ABOUT WHICH THE  
PERSONS NAMED IN  
PARAGRAPH 9 ARE TO BE  
EXAMINED**

Torrent is to be examined regarding its efforts to develop, seek regulatory approval for, and commercialize and market the Remo Technology in India. Torrent is to be examined regarding any knowledge of the market for the Remo Technology, and competing drugs. Torrent is also to be examined regarding any knowledge of relationships and agreements between the Defendants and third parties, including, but not limited to, Islet, Kissei, Glenmark, and Libbs, a Brazilian pharmaceutical company. Additionally, Torrent will be examined regarding any knowledge concerning the value of the Remo Technology.

For purposes of clarity, products, systems, processes, or methods that include Remo Technology are part of this definition, such as combination therapies (such as Zucator M), described for exemplary purposes in Glenmark and Torrent's joint press release, *Glenmark & Torrent sign licensing agreement for co-marketing Remogliflozin Etabonate in India* (July 11, 2019), as well as Torrent's Zucator M Abbreviated Prescribing Information.

**11. DOCUMENTS OR OTHER  
PROPERTY TO BE PRODUCED**

The documents listed in Appendix 1 are herein requested to be produced for inspection and copying.

**12. OATH OR AFFIRMATION**

Torrent's deposition testimony is requested to

be taken under oath.

**13. SPECIAL METHODS OR  
PROCEDURE**

N/A

**14. REQUEST FOR ATTENDANCE  
OR PARTICIPATION OF  
JUDICIAL PERSONNEL**

TEASDALE LLP, 4643 S. Ulster St. Ste. 800,  
Denver, Colorado 80237, Tel: +1 (720) 200-  
0676, Email: aharris@armstrongteasdale.com  
be notified of the date, time, and place of the  
examination. The examination will take place  
at a time and location to be determined by the  
Ministry of Justice and/or Islet, but no later  
than March 1, 2021.

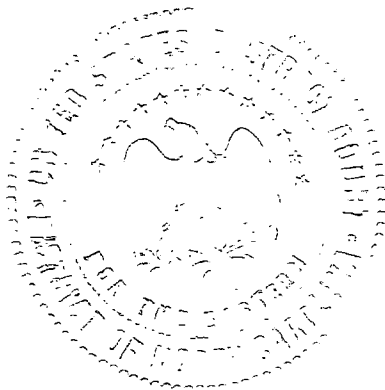
**15. FEES AND COSTS**

The fees and costs incurred which are  
reimbursable under Article 14 or 26 will be  
borne by the Islet Parties.

**16. DATE OF REQUEST**

February 4, 2021

**17. SIGNATURE AND SEAL OF THE  
REQUESTING AUTHORITY**



4 - Dever  
United States District Judge  
E.D.N.C.

**Appendix 1 to Letter of Request to Torrent Pharmaceuticals Ltd.**

**INSTRUCTIONS**

The following instructions shall apply to the requests that follow:

1. The following rules of construction shall apply: (a) the use of the singular form of any word includes the plural and vice versa; (b) the terms “any” or “each” shall be construed to include and encompass “all;” (c) the connectives “and” and “or” shall be construed either disjunctively or conjunctively as necessary to bring within the scope of this document request all documents that might otherwise be construed to be outside of the scope of this document request; (d) the use of the word “the” shall not be construed as limiting the scope of any request; and (e) “including” or “include” shall be construed without limitation.

2. If any of the following requests cannot be responded to in full after exercising reasonable diligence to secure the information requested, so state and supply the response for those portions to which you are able to respond. If any response is qualified in any particular respect, set forth the details of such qualification.

3. If, in responding to these requests, you encounter any purported ambiguities, please so state, set forth the matter deemed ambiguous, and the construction used in responding, and respond in full to any aspects of the request that you do not assert to be ambiguous.

4. These requests seek non-privileged documents within your possession, custody, and control, and each request should be read with that limitation. However, if you withhold or redact any document on the basis of privilege or other protection, please identify that document and the basis for withholding in a privilege log.

5. You can designate materials confidential under the Protective Order entered by the U.S. District Court for the Eastern District of North Carolina on June 23, 2020 [attached hereto as Attachment 1].



6. The time limitation for these requests are for the materials in Your possession concerning the Remo Technology.

#### **DEFINITIONS**

1. “You” or “Your” means Torrent Pharmaceuticals Ltd. and all of its agents, employees, representatives, affiliated entities, attorneys, and all other persons or entities acting or purporting to act on its behalf, whether such person or entity is organized or located in India or another country.

2. “Affiliates” refers to persons or business entities that share ownership, management, or common business purpose.

3. “Islet” or “Plaintiff” means Plaintiff Islet Sciences, Inc., a United States business entity incorporated in the state of Nevada, and all persons or entities acting or purporting to act on its behalf.

4. “BHV” refers to Brighthaven Ventures, LLC, a United States business entity organized in the state of North Carolina, and all persons or entities acting or purporting to act on its behalf.

5. “Avolynt” refers to Avolynt, Inc. a United States business entity incorporated in the state of Delaware and the parent entity of BHV.

6. “Green” refers to James Green, a natural person, former officer of Islet, former Chief Executive Officer of BHV, and current Chief Executive Officer of Avolynt.

7. “Wilkison” refers to William Wilkison, a natural person, former officer of Islet, former Chief Scientific Officer of BHV, and current Chief Scientific Officer of Avolynt.

8. “Defendants” refers to Avolynt, BHV, Wilkison, and Green.

9. “Third Party” means any person or entity other than You, Islet, or Defendants.

10. “FDA” means the United States Food and Drug Administration, and all past and present officers, directors, agents, employees, consultants, attorneys, and other persons or entities acting or purporting to act on its behalf.

11. “CDSCO” means the Central Drugs Standard Control Organization of India, and all past and present officers, directors, agents, employees, consultants, attorneys, and other persons or entities acting or purporting to act on its behalf.

12. “EMA” means the European Medicines Agency, and all past and present officers, directors, agents, employees, consultants, attorneys, and other persons or entities acting or purporting to act on its behalf.

13. “Remo Technology” means any product, system, process, or method concerning the molecule remogliflozin, its salt carrier remogliflozin etabonate, and its bi-phasic release technology, all of which are described in Defendants’ PCT Application No. PCT/US2011/043143. Products, systems, processes, or methods that include Remo Technology are part of this definition, such as combination therapies (such as Zucator M), described for exemplary purposes in Your press release, *Glenmark & Torrent sign licensing agreement for co-marketing Remogliflozin Etabonate in India* (July 11, 2019), as well as Your Zucator M Abbreviated Prescribing Information [attached as Attachment 4].

14. The term “document” or “documents” are used in the broadest possible sense and include, without limitation, all originals, copies, drafts, and recordings of any written, typewritten, handwritten, printed, graphic, electronic, digital or otherwise recorded matter, including forms of information translatable or convertible into a reasonably usable form. “Document” or “documents include, without limitation, the following items: electronic mail (e-mails); Microsoft PowerPoint slides and/or presentations; Microsoft Excel spreadsheets;

Microsoft Word documents or other word processing program; licenses; agreements; communications; letters; memoranda; records; books; text messages; facsimiles; summaries or handwritten notes or other records of personal conversations or interviews; diaries; appointment books or electronic entries; accounts; invoices; analytical records; reports, records or summaries of meetings or conferences; reports, records or summaries of consultants; reports, records or summaries of negotiations; brochures; pamphlets; circulars; any other document or writing or form of information convertible into a document, including information contained within or accessible by a computer or computer accessory and the underlying documents supporting computer entries.

15. “Communication” means any communication, however made, including, but not limited to, correspondence, contract, discussion, or any other kind of oral or written exchange between two or more persons, including, but not limited to, all telephone conversations, face-to-face conversations, meetings, visits, conferences, e-mail messages, texts, internal and external discussions, and documents, however the same are transcribed, sent, or given.

16. The term “person” refers to natural persons, organizations, firms, corporations, and other legal entities, and the acts “of” a person are defined to include the acts of directors, officers, owners, members, employees, agents, or attorneys acting on the person’s behalf.

#### **DOCUMENT REQUESTS**

1. Your draft and final versions of licenses and agreements related to the Remo Technology, including but not limited to those with Defendants or any Third Party.

2. Documents and communications relating to application to any regulatory or licensing agencies (including the FDA or Central Drugs Standard Control Organization in India) for the Remo Technology.

3. Documents and communications relating to Your assessments or predictions of approval of the Remo Technology by any regulatory or licensing agencies (including the FDA, EMA or CDSCO).

4. Documents and communications relating to Your assessments or predictions of past, present, or future outcomes of any clinical trials for the Remo Technology, since the beginning of Your involvement with the Remo Technology. This request includes, without limitation, analyses of the likelihood that products using the Remo Technology will be approved for marketing.

5. Documents and communications mentioning Islet or John Steel.

6. Documents and communications concerning the BHV and Islet Joint Venture business dealings [for example, Attachment 2 (Term Sheet) and Attachment 3 (Proposed Press Release)].

7. Documents and communications related to payments that Defendants agreed to provide to any person or business entity related to the Remo Technology, including but not limited to milestone payments, licensing payments, royalties, equity payments, reimbursements (for example, developmental, clinical, or any other type), or revenue splits.

8. Documents and communications related to payments that You agreed to provide to any person or business entity related to the Remo Technology, including but not limited to milestone payments, licensing payments, royalties, equity payments, reimbursements (for example, developmental, clinical, or any other type), or revenue splits.

9. Documents created by Third Parties (such as but not limited to, consultants, government agencies, etc.), regarding the Remo Technology.

10. Documents and communications exchanged with any Third Parties related to the

Remo Technology.

11. Documents created for any due diligence related to the Remo Technology, but not shared with Defendants.

12. Documents and communications related to the value of any patents related to PCT Application No. PCT/US2011/043143.

13. Documents and communications that show the value of Your contribution to any product that contains the Remo Technology. For purposes of clarity, we seek information that shows Your technical or business contribution, as opposed to the benefits the Remo Technology provided to Your products.

14. Documents and communications sufficient to show the value of the Remo Technology, in any country for which you have information, on an annual basis since the beginning of Your involvement with the Remo Technology, including financial forecasts; sales, revenue, cash flow, or profit projections or analyses; asset calculations; valuations; agreement terms; market analyses; or risk assessments.

15. Documents and communications sufficient to show Your identification of competitors or alternatives to the Remo Technology in any country for which you have information, since the beginning of Your involvement with the Remo Technology.

16. Documents and communications sufficient to show actual and projected, market size for the Remo Technology in any country for which you have information since the beginning of Your involvement with the Remo Technology.

17. Documents and communications sufficient to show actual and projected, market penetration of the Remo Technology in any country for which you have information since the beginning of Your involvement with the Remo Technology.

THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION  
No. 5:19-cv-145-D

ISLET SCIENCES, INC., )

Plaintiff )

v. )

AVOLYNT, INC., BRIGHTHAVEN )  
VENTURES, LLC, WILLIAM WILKISON, )  
and JAMES GREEN, )

Defendants )

and )

CASE NO.5:19-cv-145-D

AVOLYNT, INC., BRIGHTHAVEN )  
VENTURES, LLC, WILLIAM )  
WILKISON, and JAMES GREEN, )

Counterclaim Plaintiffs, )

v. )

ISLET SCIENCES, INC., JOHN F. STEEL, )  
IV., LARRY K. ELLINGSON, )  
JAMES A. HARPER, RICHARD D. )  
PILNIK, EUGENE M. MANNHEIMER, )  
and GARY R. KEELING, )

Counterclaim-Defendants. )

**PROTECTIVE ORDER**  
**(AS MODIFIED)\***

**1. PURPOSE**

Disclosure and discovery activity in this Action are likely to involve production of confidential, proprietary, or private information for which special protection from public

\* See paragraph 8.

disclosure and from use for any purpose other than prosecuting this Action may be warranted. Accordingly, the Court hereby issues the following Protective Order. This Order does not confer blanket protections on all disclosures or responses to discovery. Rather, the protection it affords from public disclosure and unauthorized use extends only to the limited information or items that are entitled to confidential treatment according to the terms of this Order. The parties to this Action may modify or replace this order according to the provisions of Section 10 below.

## **2. DEFINITIONS**

**2.1.** The “**Action**” shall refer only to the above-captioned case(s) and shall not include related cases unless this Protective Order is amended to explicitly cover such related cases.

**2.2.** The “**Agreement**” shall refer to the Agreement to Be Bound attached hereto as Exhibit A. All executed Agreements to this Protective Order are Confidential Information pursuant to this Protective Order.

**2.3.** “**Confidential Information**” shall mean information (regardless of how it is generated, stored, or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26. Confidential Information not designated under a more restrictive designation shall be marked or otherwise designated “CONFIDENTIAL.”

**2.4.** “**Designated In-House Counsel**” shall mean In-House Counsel who seek access to “Highly Confidential Information” in this Action.

**2.5.** “**Disclosure or Discovery Material**” shall mean all items or information, regardless of the medium or manner in which it is generated, stored, or maintained (including, among other things, testimony, transcripts, and tangible things), that are produced or generated in disclosures or responses to discovery in this matter.

**2.6.** “**Expert**” shall mean a person with specialized knowledge or experience in a matter pertinent to the litigation who (1) has been retained by a Party or its counsel to serve as an

expert witness or as a consultant in this Action, (2) is not a current employee of a Party for purposes other than this Action, and (3) at the time of retention, is not anticipated to become an employee of a Party.

**2.7. “Final Disposition”** shall mean that (1) final judgment has been entered and any appeals of the final judgment have concluded, or (2) all claims of any kind asserted in the Action have been dismissed with prejudice by the Party or Parties who brought such claims.

**2.8. “Highly Confidential Information”** shall mean extremely sensitive “Confidential Information,” the disclosure of which to another Party or Non-Party would create a substantial risk of serious harm that could not be avoided by less restrictive means. Highly Confidential Information not designated with a more restrictive designation, to the extent possible, shall be marked or otherwise designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY.”

**2.9. “In-House Counsel”** shall mean attorneys who are employees of a Party or Non-Party. In-House Counsel does not include Outside Counsel.

**2.10. “Non-Party”** shall mean any natural person, partnership, corporation, association, or other legal entity not named as a Party to this Action

**2.11. “Outside Counsel”** attorneys who are not employees of a Party to this Action but are retained to represent or advise a Party to this Action and have appeared in this Action on behalf of that Party or are affiliated with a law firm which has appeared on behalf of that Party.

**2.12. “Party”** shall mean any party to this Action, including all of its officers, directors, employees, consultants, Experts, and Outside Counsel (and their support staffs).



**2.13. “Producing Party”** shall mean a Party or Non-Party that produces Disclosure or Discovery Material in this Action. Any Producing Party may designate information or items under the provisions of this Protective Order.

**2.14. “Professional Vendors”** shall mean persons or entities that provide litigation support services (e.g., photocopying; videotaping; translating; preparing exhibits or demonstrations; and organizing, storing, or retrieving data in any form or medium) and their employees and subcontractors.

**2.15. “Protected Material”** shall mean any Disclosure or Discovery Material that is designated under this Protective Order.

**2.16. “Receiving Party”** shall mean a Party or Non-Party that receives Disclosure or Discovery Material in this Action.

### **3. DESIGNATING CONFIDENTIAL INFORMATION**

**3.1. Manner and Timing of Designations.** Designation under this Order requires the Producing Party to affix the applicable legend (“CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY”) to each page or item that contains or embodies protected material. For testimony given in a deposition or other proceeding, the Producing Party shall specify all protected testimony and the level of protection being asserted. It may make that designation during the deposition or proceeding, or may invoke, on the record or by written notice to all parties within three business days, a right to have up to 21 days from the deposition or proceeding to make its designation.

3.1.1. A Party or Non-Party that makes original documents or materials available for inspection need not designate them for protection until after the inspecting party has identified which material it would like copied and produced. During the inspection and before the designation, all material shall be treated as “HIGHLY CONFIDENTIAL –

OUTSIDE COUNSEL ONLY.” After the inspecting party has identified the documents it wants copied and produced, the producing party must designate the documents, or portions thereof, that qualify for protection under this Order.

3.1.2. Parties shall give advance notice if they expect a deposition or other proceeding to include designated material so that the other parties can ensure that only authorized individuals are present at those proceedings when such material is disclosed or used. The use of a document or thing as an exhibit at a deposition shall not in any way affect its designation. Transcripts containing designated material shall have a legend on the title page noting the presence of designated material, and the title page shall be followed by a list of all pages (including line numbers as appropriate) that have been designated, and the level of protection being asserted. The Producing Party shall inform the court reporter of these requirements. Any transcript that is prepared before the expiration of the 21-day period for designation shall be treated during that period as if it had been designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY” unless otherwise agreed. After the expiration of the 21-day period, the transcript shall be treated only as actually designated.

**3.2. Inadvertent Failure to Designate.** An inadvertent failure to designate or an inadvertent mis-designation of confidential information or items does not, standing alone, waive the Producing Party’s right to secure protection under this Order for such material. Upon discovery of the inadvertently undesignated or mis-designated confidential information or items, the Producing Party must promptly notify the Receiving Party of the error, including (1) an identification of each item or piece of information that was undesignated or mis-designated, and (2) the proper designation for each such item or piece of information. The Producing Party shall

further, if applicable, produce a properly designated replacement for each such item. Upon prompt notification by the Producing Party, the Receiving Party must make reasonable efforts to assure that the material is treated in accordance with the provisions of this Order, and within a reasonable time following receipt of any replacement items with a corrected designation, return or destroy the undesignated or mis-designated item(s). The provisions of this section do not apply to inadvertently disclosed attorney-client privileged communications or protected attorney work product materials. Any inadvertently disclosed attorney-client privileged communications or protected attorney work product material shall be handled pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence.

**3.3. Over-Designation Prohibited.** Any Party or Non-Party who designates information or items for protection under this Order as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY,” shall use best efforts to only designate the specific material that qualifies under the appropriate standards. To the extent practicable, only those parts of documents, items, or oral or written communications that require protection shall be designated. Designations with a higher confidentiality level when a lower level would suffice are prohibited. Designation under this Order is allowed only if the designation is necessary to protect material that, if disclosed to persons not authorized to view it, would cause competitive or other recognized harm. If a Producing Party learns that information or items that it designated for protection do not qualify for protection at all or do not qualify for the level of protection initially asserted, that Producing Party must promptly notify all Parties that it is withdrawing the mistaken designation and, if applicable, re-produce the item with the appropriate designation, if any.

#### **4. CHALLENGING DESIGNATIONS OF CONFIDENTIAL INFORMATION**

**4.1. Timing of Challenges.** Any Party or Non-Party may challenge a designation of confidentiality at any time. Unless a prompt challenge to a Producing Party's confidentiality designation is necessary to avoid foreseeable, substantial unfairness, unnecessary economic burdens, or a significant disruption or delay of the litigation, the right to challenge a confidentiality designation is not waived by electing not to mount a challenge promptly after the original designation is disclosed.

**4.2. Meet and Confer.** The parties shall attempt to resolve each challenge to a confidentiality designation in good faith by meeting and conferring about each challenged designation prior to seeking judicial intervention. To initiate the meet and confer process under this section, the challenging party shall provide written notice that identifies the designated material, the then-current designation of each challenged item, and the proposed new designation (if any) for each challenged item.

**4.3. Judicial Intervention.** A challenging party may only seek judicial intervention if the parties involved in the dispute cannot resolve the dispute through the meet and confer process.

4.3.1. To initiate judicial intervention, the challenging party shall provide written notice to the Producing Party stating (1) that it believes the meet and confer process under section 4.2 has failed to resolve the challenge, and (2) identifying the designated material for which the challenge has not been resolved.

4.3.2. Within 14 calendar days of receipt of such written notice, the Producing Party shall file a motion with the Court under the Court's Local Civil Rules establishing the basis for each remaining challenged designation. Such motion shall be a "Discovery

Motion” under the local rules. The Producing Party shall bear the burden of establishing that each remaining challenged designation is proper.

4.3.3. Failure by the Producing Party to timely file a motion pursuant to section 4.3.2 shall be deemed an agreement by the Producing Party that the remaining challenged materials were improperly designated, and the remaining challenged materials shall be immediately treated as re-designated as proposed by the challenging party.

4.3.4. Following a successful challenge, or in the event the Producing Party fails to timely file a motion pursuant to section 4.3.2, and unless otherwise ordered by the Court, the Producing Party shall reproduce or re-designate, as appropriate, the remaining challenged designated material accordingly within 14 days or as otherwise agreed by the challenging and designating parties.

## **5. ACCESS TO AND USE OF PROTECTED MATERIAL**

**5.1. Basic Principles.** A Receiving Party may use Protected Material only for this Action. Protected Materials may be disclosed only to the categories of persons and under the conditions described in this Order.

**5.2. Access to Protected Material Designated “CONFIDENTIAL.”** Unless otherwise ordered by the Court or permitted in writing by the Producing Party, a Receiving Party may disclose any material designated CONFIDENTIAL only to:

- (a) The Receiving Party’s Outside Counsel in this action and employees of Outside Counsel to whom disclosure is reasonably necessary;
- (b) The officers, directors, and employees of the Receiving Party to whom disclosure is reasonably necessary, and who have signed the Agreement;
- (c) Experts retained by the Receiving Party’s Outside Counsel to whom disclosure is reasonably necessary, and who have signed the Agreement;

(d) The Court and its personnel;

(e) Outside court reporters and their staff, professional jury or trial consultants, and professional vendors to whom disclosure is reasonably necessary, and who have signed the Agreement;

(f) During their depositions, witnesses in the action to whom disclosure is reasonably necessary and who have signed the Agreement; and

(g) The author or recipient of a document containing the material, or a custodian or other person who otherwise possessed or knew the information.

**5.3. Access to Protected Material Designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY.”** Unless permitted in writing by the Producing Party, a Receiving Party may disclose material designated HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY without further approval only to:

(a) The Receiving Party’s Outside Counsel in this Action and employees of Outside Counsel to whom it is reasonably necessary to disclose the information;

(b) The Court and its personnel;

(c) Outside court reporters and their staff, professional jury or trial consultants, and professional vendors to whom disclosure is reasonably necessary, and who have signed the Agreement; and

(d) The author or recipient of a document containing the material, or a custodian or other person who otherwise possessed or knew the information.

**5.4. Procedures for Approving or Objecting to Disclosure of Protected Material Designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY” to In-House Counsel or Experts.** Unless agreed to in writing by the Producing Party:

(a) A party seeking to disclose to In-House Counsel any material designated HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY must first make a written request to the Producing Party providing the full name of the specific in-house counsel, the city and state of such counsel's residence, and such counsel's current and reasonably foreseeable future primary job duties and responsibilities in sufficient detail to determine present or potential involvement in any competitive decision-making.

(b) A party seeking to disclose to an Expert any information or item that has been designated HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY must first make a written request to the Producing Party that (1) identifies the general categories of HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY information that the Receiving Party seeks permission to disclose to the Expert, (2) sets forth the full name of the Expert and the city and state of his or her primary residence, (3) attaches a copy of the Expert's current resume or curriculum vitae, (4) identifies the Expert's current employer(s), and (5) identifies each person or entity from whom the Expert has received compensation or funding for work in his or her areas of expertise (including in connection with litigation) in the past four years. If the Expert believes any of this information at (4) - (5) is subject to a confidentiality obligation to a third party, then the Expert should provide whatever information the Expert believes can be disclosed without violating any confidentiality agreements, and the party seeking to disclose the information to the Expert shall be available to meet and confer with the Producing Party regarding any such confidentiality obligations.

(c) A party that makes a request and provides the information specified in paragraphs 5.4(a) or 5.4(b) may disclose the designated material to the identified In-House

Counsel or Expert unless, within seven business days of delivering the request, the party receives a written objection from the Producing Party providing detailed grounds for the objection.

(d) Should the Producing Party object to the identified In-House Counsel or Expert, the party that made the request may challenge the objection by meeting and conferring with the Producing Party in good faith to resolve the objection. Should the parties be unable to resolve the objection through the meet and confer process, the party that made the request may seek judicial intervention by filing a motion under the Court's Local Civil Rules.

#### **6. UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL**

If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed Protected Material to any person or in any circumstance not authorized under this Protective Order, the Receiving Party must immediately (a) notify in writing the Producing Party of the unauthorized disclosures, (b) use its best efforts to retrieve all unauthorized copies of the Protected Material, (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Order, and (d) request such person or persons to execute the "Acknowledgment and Agreement to Be Bound" that is attached hereto as Exhibit A.

#### **7. FILING PROTECTED MATERIAL**

In accordance with § V.G(1)(e) of the Court's Electronic Case Filing Administrative Policies and Procedures Manual ("Policy Manual"), in the event that a filing Party seeks to file materials that have been designated "CONFIDENTIAL," "HIGHLY CONFIDENTIAL — OUTSIDE ATTORNEYS' EYES ONLY," by another Party, individual or non-party, the filing Party shall provisionally file the materials under seal in accordance with Local Civil Rule 79.2, with notice served on the Party, individual or non-party who desires to maintain the materials under seal. In accordance § V.G(1)(e)(i), the filing Party will submit a notice of filing in lieu of a motion to seal and the filing of these third party material under seal, by itself, shall not be



binding on the Court. However, documents submitted under seal in accordance with § V.G(1)(e) will remain under seal pending the Court's ruling on the motion to seal. Within seven (7) days after such notice, the Party, individual or non-party shall file a motion to seal and supporting memorandum in accordance with § V.G(1) of the Policy Manual. Where a Party seeks to submit documents to the Court which have been designated "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL — OUTSIDE ATTORNEYS' EYES ONLY" by the submitting Party, the submitting Party may, in its discretion, bring a motion to file such documents under seal pursuant to Local Civil Rules 7.1, 79.2, and § V.G(1) of the Court's Policy Manual. Where a submitting Party intentionally declines to seek an order sealing documents submitted to the Court designated as containing its own Confidential Information, the submitted material will no longer qualify for protection and subsequent treatment as containing Confidential Information under this Stipulated Protective Order.

In accordance with the Section G of the Policy Manual, except for motions filed under seal in accordance with Section V.G(1)(f) of the Policy Manual, each time a Party seeks to file under seal, said Party shall accompany the request with a motion to seal. The motion to seal may be filed without a supporting memorandum only if the filing Party can cite a statute or rule (federal, local or standing order) that requires the filing to be sealed. Absent such authority, the filing Party must submit a supporting memorandum that specifies: (i) the exact document or item, or portions thereof, for which filing under seal is requested; (ii) how such request to seal overcomes the common law or the First Amendment presumption to access; (iii) the specific qualities of the material at issue which justify sealing such material, taking into account the balance of competing interest in access; (iv) the reasons why alternatives to sealing are inadequate; and (v) whether there is consent to the motion. In addition to the motion and

supporting memorandum of law, the filing Party must set out such findings in a proposed order to seal.

**8. INADVERTENT PRODUCTION OF PRIVILEGED OR OTHERWISE PROTECTED MATERIAL**

Unless otherwise ordered by the court, the inadvertent production of privileged or otherwise protected material shall be governed by the "Order Pursuant to Federal Rule of Evidence 502(d) Regarding Production of Documents," entered contemporaneously herewith.

**9. PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN OTHER LITIGATION**

**9.1. Subpoenas and Court Orders.** This Order in no way excuses non-compliance with a lawful subpoena or court order. The purpose of the duties described in this section is to alert the interested parties to the existence of this Order and to give the Producing Party an opportunity to protect its confidentiality interests in the court where the subpoena or order issued.

**9.2. Notification Requirement.** If a Party is served with a subpoena or a court order issued in other litigation that compels disclosure of any Protected Material in this Action, that Party must:

- (a) Promptly notify the Producing Party in writing. Such notification shall include a copy of the subpoena or court order; and
- (b) Promptly notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Order. Such notification shall include a copy of this Order.

**9.3. Wait For Resolution of Protective Order.** If the Producing Party timely seeks a protective order, the party served with the subpoena or court order shall not produce any Protected Material in this Action before a determination by the court where the subpoena or order issued, unless the party has obtained the Producing Party's permission. The Producing Party shall bear the burden and expense of seeking protection of its confidential material in that court.

**10. MODIFICATION OR REPLACEMENT OF THIS PROTECTIVE ORDER**

**10.1. General Principles.** A Party or Parties to this Action may request modification or replacement of this Protective Order by moving the Court.

**10.2. Manner of Making Amendments.** Any proposed amendments to the Protective Order must be presented to the Court by filing two copies of the entire Protective Order. The first copy shall include markings indicating the proposed amendments, and the second copy shall be a clean copy for entry by the Court.

**10.3. By Stipulation.** The Parties may submit stipulated amendments to this Protective Order, or a stipulated replacement protective order, for entry by the Court at any time.

**10.4. On Motion.** A Party or Parties may move the Court for entry of amendments to this Protective Order without the agreement of all Parties.

10.4.1. Prior to moving the Court, the requesting party or parties must meet and confer with the other parties regarding any proposed amendments. Only upon a failure to reach agreement regarding any proposed amendments may the requesting party or parties move the Court under the Court's Local Civil Rules for entry of the proposed amendments.

10.4.2. Should different Parties have competing proposed amendments to the same portion or portions of this Protective Order, or competing proposals for new

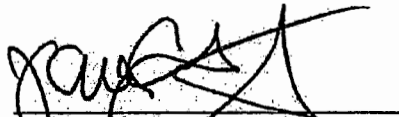
provisions to this Protective Order, rather than filing a motion under the Court's Local Civil Rules, the Parties shall file a joint motion indicating the competing proposed amendments and setting forth the reasons supporting each proposed amendment, and, if applicable, the opposing party's or parties' responses thereto. Such joint motion shall also include all other proposed amendments to this Protective Order, whether by one or both parties, whether opposed or agreed upon by the parties, and setting forth the parties' respective positions on such proposed amendments.

10.4.3. Within 7 calendar days of resolution of a motion under section 10.4, and if applicable, the moving Party or Parties, or if by joint motion under section 10.4.2, the Parties jointly, shall file the amended protective order according to section 10.2.

## **11. FINAL DISPOSITION**

Within 60 days after Final Disposition of this action, each Receiving Party shall return all designated material to the Producing Party or destroy such material, including all copies, abstracts, compilations, summaries, and any other format reproducing or capturing any designated material. If requested by the Producing Party, the Receiving Party must submit a written certification to the Producing Party by the 60 day deadline that (1) identifies (by category, where appropriate) all the designated material that was returned or destroyed, and (2) affirms that the receiving party has not retained any copies, abstracts, compilations, summaries, or any other format reproducing or capturing any of the designated material. This provision shall not prevent counsel from retaining an archival copy of all pleadings, motion papers, trial, deposition, and hearing transcripts, legal memoranda, correspondence, deposition and trial exhibits, expert reports, attorney work product, and consultant and expert work product, even if such materials contain designated material. Any such archival copies remain subject to this Order.

SO ORDERED this 23rd day of June, 2020.



James E. Gates  
United States Magistrate Judge

**EXHIBIT A**

**ACKNOWLEDGEMENT AND AGREEMENT TO BE BOUND**

I, \_\_\_\_\_ [print or type full name],  
of \_\_\_\_\_  
[print or type full address], declare under penalty of perjury that I have read in its entirety and  
understand the Protective Order that was issued by the United States District Court for the  
Eastern District of North Carolina on \_\_\_\_\_ in the case of *Islet Sciences, Inc.*  
*v. Avolynt, Inc. et al.*, Case No. 5:19-cv-145-D.

I agree to comply with and to be bound by all the terms of this Protective Order and I  
understand and acknowledge that failure to so comply could expose me to sanctions and  
punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner  
any information or item that is subject to this Protective Order to any person or entity except in  
strict compliance with the provisions of this Order. I also agree to notify any stenographic or  
clerical personnel who are required to assist me of the terms of this Order.

I understand that I am to retain all copies of any Protected Material, however designated,  
in a secure manner, and that all copies are to remain in my personal custody until I have  
completed my assigned duties, whereupon the copies and any writings prepared by me  
containing any information designated as Protected Material are to be returned to counsel who  
provided me with such material or destroyed, with certification of destruction.

I further agree to submit to the jurisdiction of the United States District Court for the  
Eastern District of North Carolina for the purpose of enforcing the terms of this Protective Order,  
even if such enforcement proceedings occur after termination of this Action.

*CONFIDENTIAL*

*Exhibit A – Acknowledgment and Agreement to Be Bound*

Date: \_\_\_\_\_

Printed name: \_\_\_\_\_

Signature: \_\_\_\_\_

Brighthaven Ventures L.L.C. / Lakota  
DRAFT NON-BINDING PROPOSAL

**Joint Venture Agreement**  
**for Development and Commercialization of Remogliflozin-etabonate**  
**Summary for Non-Binding Terms**  
**August 14, 2010**

This document is for discussion purposes only and does not constitute a binding agreement or letter of intent between the parties or an agreement to negotiate an agreement and there shall be no agreement between the parties unless and until there is a definitive agreement signed by both parties containing additional terms and conditions typically contained in license agreements concerning like subject matter. This document creates no obligation upon either party to enter into a transaction with the other party and neither party shall have any obligation arising out of this document. The terms set forth in this document are subject to all requisite corporate approvals, due diligence reviews, and appropriate tax and accounting considerations. This document and its terms are confidential, and neither party shall disclose the existence of this document or its terms without the prior written consent of the other party.

**General:** Brighthaven Ventures L.L.C. ("BHV") has a worldwide license from Kissei Pharmaceuticals for the development and commercialization of the novel SGLT2 inhibitor remogliflozin-etabonate ("remo"). Under the terms of a definitive agreement (the "Agreement"), BHV and Lakota ("Lakota") would collaborate to develop and commercialize products in the Field (defined below) in the Territory. Collectively BHV and Lakota shall be referred to as the "Parties."

**Joint Venture:** A new Limited Liability Company (the "LLC") will be created by the Parties. BHV will license certain rights to remo to the LLC. Lakota will contribute capital and project management to the LLC sufficient to fund the LLC liabilities and conduct the Development Plan through phase IIb. The equity ownership in the LLC shall be allocated 80% to Lakota and 20% to BHV. The JV will be managed by a Board with five Directors. Lakota may appoint one Lakota Director and one independent director. BHV may appoint one BHV Director and one independent director. One Independent Director will be appointed by mutual consent of the Parties.

**License Grant:** To the LLC, BHV will grant an exclusive, sub-licensable, transferable license under the Kissei IP to research, develop, make, have made, manufacture, use, sell, offer for sale, promote, import or export Products in the Field and in the Territory. The general terms of the License Agreement to be agreed by the Parties will closely follow those from the BHV license agreement with Kissei dated December 10, 2010. The Term would commence as of the effective date of the License Agreement, and would continue in full force and effect until the expiration of the LLC's obligation to pay royalties; or until otherwise terminated.

**Initial Territory:** North America and Countries of the European Union.

**Secondary Territory:** Those countries outside of North America and the EU with the exception of Japan, Korea, Taiwan, China. License to the Secondary Territory will be granted



at the earlier of a) the LLC initiating phase III development, or b) the election of BHV to execute its change of control Tag-Along Rights or Lakota to execute its Drag-Along Rights.

**Field:** Prevention, diagnosis and treatment of human metabolic diseases of Type 1 and Type 2 diabetes mellitus.

**Commercialization:** LLC will be responsible for commercializing remo in the Territory

**Manufacturing:** LLC will be responsible for manufacturing drug product to support Commercialization in the Territory.

**Joint Development Committee:** The development program for remo in the Territory will be established in a written Development Plan, which would be managed by a Joint Development Committee (the "JDC"). The JDC would meet regularly, no less than quarterly. Final decisions related to the approval, modification, content control, steering and implementation of the development plan would be made by unanimous consent based on commercially reasonable judgment; provided, however, that any disputes would be raised to the JSC for final decision. So long as Dr. Wilkison and Mr. Green are members of the Lakota management team, the regular meetings of the JDC will be suspended and development decisions made by Lakota.

**Joint Steering Committee:** The parties would form a Joint Steering Committee to oversee and coordinate the parties' activities under the Agreement with respect to the development and commercialization of Products in the Field in the Territory (the "JSC"). The JSC will be responsible for resolving disputes that may arise among the parties' respective representatives on committees formed under the Agreement (such as the JDC) and making certain strategic decisions regarding Products to be defined in the Agreement. Such committee would consist of equal numbers of members appointed by each party, and would operate by unanimous consent; provided that the LLC Board will have the casting vote on any disputed matters. The JSC will meet at least twice a year and each Party will update the other Party on the ongoing developments in its territories. So long as Dr. Wilkison and Mr. Green are members of the Lakota management team, the regular meetings of the JSC will be suspended and strategic decisions made by Lakota.

**BHV Liabilities:** LLC will assume responsibility for a) obligations related to outstanding loans from the North Carolina Biotechnology Center, and b) payments due to Kissel as agreed under the License Agreement between BHV and Kissel.

**Supply Terms:** BHV will supply LLC with API in sufficient quantity to support the Development Plan. BHV will be responsible for all expenses related to the transport, insurance, storage and maintenance of the remaining API provided however that the LLC will reimburse BHV for direct expenses related to such activities on a pass-through basis. The LLC will gain rights to the remaining API at the earlier of a)

the LLC initiating phase III development, or b) the election of BHV to execute its change of control Tag-Along Rights or Lakota to execute its Drag-Along Rights.

**Tag-Along:** Each party will have pro-rata tag-along rights to participate in any sale of LLC equity. In addition, BHV will have the right to sell up to 100% of its stake in the LLC to any acquirer of a controlling interest of Lakota.

**Drag-Along:** Lakota will have the right to require BHV participate in the sale of the LLC, up to 80% of its stake in the LLC to an acquirer of a controlling interest of Lakota.

**Upfront Payment:** Lakota will issue 1,500,000 common shares to BHV.

**Contingent Payments:** Lakota and BHV will split pro-rata any upfront and contingent compensation received from a license, sale, or other disposition of the remo program over and above the following milestones and royalties that are due Kissei:

Phase III start:	\$10,000,000
NDA Filing:	\$15,000,000
MAA Filing:	\$ 7,500,000
FDA Approval:	\$25,000,000
EMEA Approval:	\$10,000,000
Royalty:	14%

**Diligence:** The license will include a diligence clause where if remo is not actively being developed, rights granted in the license will revert back to BHV. Lakota agrees to initiate the process of clinical trial material manufacture and initiation of Development Plan within 60 calendar days of executing the Agreement.

**Employment Agreements:** Dr. Wilkison and Mr. Green join Lakota with the titles/roles of Chief Operating Officer and Chief Business Officer, respectively. They will have employment agreements with Lakota that will include compensation, terms and conditions customary and commensurate with their role at the company as well as an upfront grant of 1,000,000 common shares of Lakota to be allocated evenly between Dr. Wilkison and Mr. Green in connection with their employment with Lakota.

**General Terms &**

**Conditions:** The parties will negotiate in good faith additional customary and reasonable terms and conditions as part of the Agreement, including, without limitation, termination, improvements and grant-backs, change of control, payment reports and provisions related to warranties, confidentiality, limitation on liability, patent prosecution and enforcement and indemnification.

**Governing Law:** TBD

**Confidentiality:** This Term Sheet is subject to the confidentiality terms set forth in the CDA between parties. The existence and content of this summary of proposed terms, and the fact that negotiations may be ongoing between the parties, constitute "Confidential Information".

CONFIDENTIAL



ISLET SCIENCES

### **Islet Sciences and BHV Pharma Sign Exclusive License Agreement for Late Stage SGLT2 Inhibitor Remogliflozin-Etabonate for Type 2 Diabetes**

NEW YORK. January X, 2013 --Islet Sciences, Inc., (ISLT) a clinical stage company engaged in the research, development and commercialization of therapeutics in the field of diabetes, announced today that it has entered into a license agreement with BHV Pharma for exclusive rights to develop and commercialize Remogliflozin-Etabonate, a novel, highly selective Sodium Glucose Transporter 2 (SGLT2) inhibitor in phase IIb development for type 2 diabetes. The agreement provides Islet Sciences exclusive global rights excluding Japan, Korea, Taiwan and China.

SGLT2 inhibitors are an important emerging class of compounds that will be the only orally available treatment for type 2 diabetics providing significant HbA1c lowering with clinically relevant weight loss. More importantly, SGLT2 inhibition provides patients this benefit through an insulin independent, beta-cell sparing mechanism.

"As a diabetes focused company, we are excited to add remogliflozin to our pipeline of novel therapeutics. This transaction is another step in transforming Islet Sciences into an industry leader in diabetes research and development," stated John Steel, Islet Sciences Chairman and Chief Executive Officer.

James Green, Chief Business Officer of BHV Pharma added, "We look forward to working with Islet Sciences to continue the development of what will very likely become the most important molecule in an exciting new class of anti-diabetic therapy, not only in terms of HbA1c lowering and weight loss, but also as it relates to some of the potential side effects we've seen with other compounds in the class."

BHV is eligible to receive payments if certain development and regulatory milestones are achieved. BHV will also receive royalties on net sales. Specific financial terms of the Agreement were not disclosed.

#### **About Remogliflozin Etabonate**

Remogliflozin is a once-daily, new chemical entity (NCE) that selectively inhibits the sodium glucose transporter 2. The compound has been assessed for efficacy, tolerability and safety in over twenty clinical trials, including two 12-week phase IIb studies in type II diabetics. Other studies that have been completed in the development of this compound include standard toxicology, pharmacology, safety and food and drug interaction studies.

## **About Islet Sciences, Inc.**

Islet Sciences is a development-stage biotechnology company with patented technologies focused on transplantation therapy for patients with diabetes. The Company's transplantation technology includes proprietary methods for the culturing, isolation, maturation, and immunoprotection (microencapsulation) of islet cells. For more information: [www.isletsciences.com](http://www.isletsciences.com)

## **About BHV Pharma**

BHV, a Research Triangle Park-based clinical-stage drug development company, is focused on developing therapeutics for the treatment of metabolic diseases. <http://www.bhvpharma.com>

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements for Islet Sciences 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. Factors that could cause future results to materially differ from the recent results or those projected in forward-looking statements include the risks described in the Islet Science's reports filed with the Securities and Exchange Commission. The companies' further development is highly dependent on future medical and research developments and market acceptance, which is outside their control.

### **Islet Sciences Investor Contact:**

Jeff Ramson <sup>(1)</sup><sub>SEP</sub>

ProActive Capital Group

(646) 863-6893 <sup>(1)</sup><sub>SEP</sub>

[jramson@proactivecapitalgroup.com](mailto:jramson@proactivecapitalgroup.com)

### **BHV Investor Contact:**

BHV Pharma

919.904.4248

[info@bhvpharma.com](mailto:info@bhvpharma.com)

## Reactive Q&A

### 1. What are the financial terms of the Agreement?

Financial terms were not disclosed but include payments in the event certain development and regulatory milestones are met. Royalties will be due on net sales.

### 2. How does remo fit strategically into Islet's mission?

Islet's mission is to better the lives of patients suffering from diabetes. As an insulin independent mechanism, we believe SGLT2 inhibition in general, and remogliflozin in particular, will help Islet continue to produce positive outcomes for the world's diabetic population.

### 3. Are you thinking of developing remogliflozin for type 1 diabetes?

Based on what we know about the mechanism and previous clinical results, we believe remogliflozin may work well for type 1 diabetics in potentially reducing the frequency and amount of insulin required to maintain glycemic control. At this time, however, our near term development objective for remogliflozin is specific to type 2 diabetes with an intermediate term objective around type 1.

### 4. What are your near term development plans for remogliflozin?

We expect to initiate a phase 2b trial in 2013 after which we expect to have an end of phase 2 meeting with the USFDA. The trial will look very similar to the two previous 12-week phase 2b studies conducted with remogliflozin.

### 5. Does Islet expect to develop remogliflozin through phase 3?

We are presently focused on completing phase 2. We do however recognize the value of a commercialization partner with a global reach in primary care, so we anticipate partnering the program at a time and in a way that makes the most sense for the program and Islet shareholders. Right now though, we are focused on preparing for the upcoming phase 2b trial and progressing the rest of our pipeline.

### 6. How do you plan to differentiate remogliflozin from other SGLT2's in development?

Remogliflozin has been studied in over 20 clinical trials including two 12-week phase 2b clinical studies. Phase 2b data demonstrated best in class efficacy with certain doses showing greater than 1% HbA1c lowering with very strong postprandial effect, as well as very low incidence rates of genital fungal infections relative to what we have seen with other SGLT2 inhibitors. We expect to positively differentiate remogliflozin as a class leading molecule in both efficacy and tolerability.

### 7. Is GSK still involved with the program?

No. GSK terminated its license to remogliflozin in 2009 and retains no residual rights.

### 8. Why did GSK terminate its license to remogliflozin?

That decision was made by GSK for reasons that were specific to what GSK was going through at that time.

## ZUCATOR M

Abbreviated Prescribing information for Zucator M (Remogliflozin Etabonate and Metformin Hydrochloride Tablets, 100, 500 mg and 100, 1000 mg) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Zucator M contains Remogliflozin Etabonate and Metformin Hydrochloride. Remogliflozin Etabonate inhibits the sodium-glucose transport proteins (SGLT), which are responsible for glucose reabsorption in the kidney. Metformin Hydrochloride exerts its glucose-lowering effect by reduction of hepatic glucose production through inhibition of gluconeogenesis and glycogenolysis; by modestly increasing insulin sensitivity, improving peripheral glucose uptake and utilization; and by delaying intestinal glucose absorption.

**INDICATIONS:** Zucator M is indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: in patients insufficiently controlled on their maximally tolerated dose of metformin alone, in patients already being treated with the combination of remogliflozin and metformin as separate tablets.

**DOSAGE AND ADMINISTRATION:** Zucator M should be taken twice daily with meals to reduce the gastrointestinal adverse reactions associated with metformin. All patients should continue their diet with an adequate distribution of carbohydrate intake during the day. Dosing must be individualized for patients with impaired renal function.

**WARNINGS & PRECAUTIONS:** Renal impairment, lactic acidosis, diabetic ketoacidosis, administration of iodinated contrast agent, cardiac function, surgery, urinary tract infections, lower limb amputations, necrotising fasciitis of the perineum (Fournier's gangrene), elderly, urine laboratory assessments.

**ADVERSE REACTIONS:** Anaemia, vertigo, abdominal pain, constipation, diarrhoea, gastritis, asthma, fatigue, pyrexia, bacteriuria, genital infection fungal, vulvovaginal candidiasis, vulvovaginitis, blood bicarbonate abnormal, blood creatinine increased, blood/acid increased, glomerular filtration rate decreased, weight decreased, diabeticketoacidosis, dyslipidaemia, hypercholesterolaemia, hyperlactacidaemia, hypertriglyceridaemia, hypoglycaemia, lactic acidosis, polydipsia, pain in extremity, dizziness, headache, dysuria, ketonuria, pollakiuria, polyuria, renal failure, pruritus genital, vaginal discharge, vulvovaginal pruritus, hyperhidrosis, intertrigo, urticarial, orthostatic hypotension, lactic acidosis, decrease of vitamin b 12 absorption, erythema pruritus, urticaria.

**MARKETED BY:**



**TORRENT PHARMACEUTICALS LTD.**

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

Torrent Pharmaceuticals Ltd.

**IN/Zucator M 500, 1000/JAN-20/01/ABPI**

(Additional information is available on request)