COLLABORATION AND LICENSE AGREEMENT

by and among

TRANSITION THERAPEUTICS INC.

and

ELI LILLY and COMPANY

COLLABORATION AND LICENSE AGREEMENT

This Agreement (the "Agreement"), effective as of July 23, 2013 (the "Effective Date"), is entered into by and among Transition Therapeutics Inc., a Canadian corporation, with a place of business at 101 College Street, Suite 220, Toronto, Ontario, M5G 1L7, (hereinafter referred to as "Transition") and Eli Lilly and Company, an Indiana corporation with a place of business at Lilly Corporate Center, Indianapolis, Indiana, 46285 ("Lilly"). Transition and Lilly may be referred to herein individually as a "Party" or collectively as the "Parties". Reference to a Party shall be deemed to include that Party's Affiliates.

Recitals:

A. Lilly is a pharmaceutical company having expertise in the discovery, development, manufacturing and commercialization of innovative human pharmaceutical products.

B. Transition is a biotechnology company having expertise in the preclinical and clinical development of human pharmaceutical products.

C. Lilly and Transition desire to enter into a collaboration and license under which the Parties would develop and commercialize specific *(deleted text: class of compounds)* compounds under the terms and conditions set forth in this Agreement.

In consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

Agreement:

1. DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1 **"Adverse Event" or "Adverse Experience"** shall mean any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the Licensed Product (marketed or investigational).

1.2 "**Affiliate**" means with respect to any Party, any person or entity controlling, controlled by or under common control with such Party. For purposes of this Article 1.2, "control" shall mean (a) in the case of a corporate entity, direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such corporate entity and (b) in the case of an entity that is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise

1.3 **"Applicable Laws"** shall mean all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority that may be in effect from time to time and applicable to the activities contemplated by this Agreement.

1.4 "**Backup Compound(s)**" means *(deleted text: characteristic properties of back-up compounds).*

1.5 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.6 "**Calendar Year**" means the respective periods of twelve (12) months commencing on January 1 and ending on December 31.

1.7 "**cGMP**" means current good manufacturing practices as promulgated under the United States Federal Food, Drug, and Cosmetic Act, as amended, and similar requirements of jurisdictions outside the United States applicable to manufacture of Clinical Materials or a Licensed Product.

1.8 "**GLP**" means current good laboratory practices as agreed to by the Parties from time to time but consistent with conventional norms and at least adequate to support submission of studies for Regulatory Approval.

1.9 "**GCP**" means good clinical practices in compliance with the current quality standards and regulations for clinical trials involving human subjects in the U.S.

1.10 "**GRP**" means good research practices as agreed to by the Parties from time to time but consistent with conventional norms and at least adequate to support submission of studies for Regulatory Approval.

1.11 "**Clinical Material(s)**" means Licensed Product formulated in accordance with the Specifications and applicable United States, European or Canadian laws, rules and regulations (a) for preclinical activities, and (b) for administration to subjects in clinical trials.

1.12 "**Combination(s)**" means a regulatory agency approved pharmaceutical product containing the Lead Compound or Backup Compound and one or more additional active pharmaceutical ingredients as an admixture.

1.13 "**Commercialization**" or "**Commercialize**" means activities taken before and after obtaining Regulatory Approval relating specifically to the pre-launch, launch, promotion, marketing, sales force recruitment, pricing determination, manufacturing, sale and distribution of a pharmaceutical product and post-launch medical activities, including without limitation: (a) manufacturing and distribution for commercial sale; (b) strategic marketing, sales force detailing, advertising, and market and product support; (c) medical education and liaison and any phase IV clinical trials; (d) all customer support and product distribution, invoicing and sales activities; (e) all post-approval regulatory activities, including those necessary to maintain Regulatory Approvals; and (f) target product profile, pricing, formulary and reimbursement related activities including pricing and reimbursement approvals.

1.14 "**Commercializing Party**" means the Party responsible for Commercialization of Licensed Products as further set forth in Article 4.

1.15 "**Commercially Reasonable Efforts**" means with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, reasonable, good faith

efforts to accomplish such objective as such Party would normally use to accomplish a similar objective of such Party under similar circumstances, it being understood and agreed that with respect to the Development or Commercialization of a Licensed Product such efforts shall be similar to those efforts and resources commonly used by a Party for a similar biological or pharmaceutical product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the exclusivity of the product in view of its patent protection, patent life and other proprietary position of the product, and the likelihood of Regulatory Approval given the regulatory structure involved, provided such efforts are substantially and materially consistent with industry practices and standards.

1.16 **"Compliance"** shall mean the adherence by the Parties in all material respects to all Applicable Laws and Party Specific Regulations, in each case with respect to the activities to be conducted under this Agreement.

1.17 "**Confidential Information**" means all confidential or proprietary information of one Party or its Affiliates, regardless of its form or medium as provided to the other Party in connection with the purpose of this Agreement; provided that, Confidential Information shall not include any information that the receiving Party can show by competent evidence: (i) is already known to them at the time it is disclosed them; (ii) is or becomes generally known to the public through no act or omission of the receiving Party in violation of the terms of this Agreement; (iii) has been lawfully received by the receiving Party from a Third Party without restriction on its disclosure and without, to the knowledge of the receiving Party, a breach by such Third Party of an obligation of confidentiality to the disclosing Party; or (iv) has been independently developed by the receiving Party without use of or reference to the Confidential Information.

1.18 "**Control**", "**Controls**" or "**Controlled by**" means (except as used in Article 1.2, above), with respect to any item of or right under Patents or Know-How, the ability of a Party whether through ownership, license or other right (other than pursuant to this Agreement) to grant access to, license or sublicense such item or right without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.

1.19 "**Data Exclusivity Period**" means the period during which the FDA (or, in countries other than the United States, an equivalent regulatory agency) prohibits reference, without the consent of the owner of the regulatory submission materials, to the clinical and other data that is contained in such materials, and that is not published or publicly available outside of such submission.

1.20 "**Develop**" or "**Development**" or "**Developing**" means research, discovery, process development, manufacturing for preclinical and clinical uses, and preclinical and clinical drug or biological development activities, including, without limitation, test method development and stability testing, toxicology, formulation, quality assurance/quality control development, statistical analysis, preclinical and clinical studies and regulatory affairs, in each case, of a Licensed Product for use in the Field, and to the extent normally undertaken during the development (as opposed to Commercialization) phase of such Licensed Product's life cycle. Development shall exclude all Phase IV clinical trials.

1.21 "**EMEA**" means the European Medicines Evaluation Agency or any successor agency thereto.

1.22 "**EU**" means the member countries of the European Union, as the same may exist from time to time.

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

1.24 "**Field**" means all pharmaceutical uses for human or animal administration.

1.25 "**Final Data**" means *(deleted text: specific data at the completion of the trial).*

1.26 "**First Commercial Sale**" means, with respect to any Licensed Product, the first sale to a Third Party for end use or consumption of such Licensed Product in a country after Regulatory Approval has been granted by the Regulatory Authority of such country.

1.27 "**GAAP**" means Generally Accepted Accounting Principles as the same may be in effect from time to time.

1.28 **"Governmental Authority"** shall mean any court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, state or local authority or any political subdivision thereof, or any association of countries.

1.29 "**IND**" means an Investigational New Drug application in the United States or a submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.30 "**IND Option**" is as defined in Article 2.1(c).

1.31 "**Initial Development**" is as defined in Article 2.1(a) below.

1.32 "**Initial Development Plan**" is the Development plan attached hereto as an Exhibit which can be modified from time to time and is incorporated herein by reference.

1.33 "**Joint Development Committee**" or "**JDC**" means the committee composed of Transition and Lilly representatives established pursuant to Section 2.2.

1.34 "**Jointly Owned Patents**" is as described in Article 14.1(b).

1.35 "**Kit(s)**" means a regulatory agency approved combined package of a Lead Compound or Backup Compound, with another active pharmaceutical ingredient(s) in a separate formulation(s) and/or delivery mechanism(s).

1.36 "**Know-How**" means any proprietary scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, safety information, practices, methods, techniques, specifications, formulations, formulae,

knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data.

1.37 "**Lead Compound(s)**" means a Lilly *(deleted text: class of compounds)*, selected by the Parties for Initial Development which at the Effective Date is *(deleted text: specific identifying number of lead compound)*.

1.38 "**Licensed Product**" means any product containing a Lead Compound or a substituted Backup Compound including Combination(s) or Kit(s) (marketed or investigational).

1.39 **"Substituted Backup Compound"** means a Backup Compound mutually agreed by the Parties in the event the Lead Compound is dropped.

1.40 "**Lilly Know-How**" means all information (excluding any published Lilly Patents) that (a) is (i) Controlled as of the Effective Date by Lilly or (ii) is made by or on behalf of Lilly or its Affiliates, alone or jointly, in the course of performing their obligations or duties under this Agreement and (b) is reasonably necessary for manufacture, development or use of the Licensed Product, Lead Compounds or Backup Compounds.

1.41 "**Lilly Patents**" means Patents Controlled by Lilly that contain one or more claims to Licensed Products, Lead Compounds or Backup Compounds including without limitation *(deleted text: specific patent application number)* and including any provisionals, substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, reexaminations, extensions, supplementary protection certificates and the like arising therefrom.

1.42 "**Net Sales**" means, with respect to a Licensed Product, the gross amount invoiced by the Commercializing Party (including its Affiliates) or any Sublicensee thereof to unrelated Third Parties, excluding any Sublicensee, for such Licensed Product, less:

(a) Trade, quantity and cash discounts allowed;

(b) Commissions, discounts, refunds, rebates (including but not limited to wholesaler inventory management fees), chargebacks, retroactive price adjustments, and other allowances which effectively reduce the net selling price;

(c) Actual Licensed Product returns and allowances;

(d) That portion of the sales value associated with drug delivery systems;

(e) Any tax imposed on the production, sale, delivery or use of the Licensed Product, without limitation, sales, excise or value added taxes;

(f) Allowances for distribution expenses; and

(g) Any other similar and customary deductions.

Such amounts shall be determined from the books and records of the Commercializing Party, its Affiliate or its Sublicensee, maintained in accordance with U.S. generally accepted accounting principles, "GAAP", or, in the case of Sublicensees, such similar accounting principles, consistently applied. The Commercializing Party further agrees in determining such amounts, it will use its then current standard procedures and methodology, including its then current standard exchange rate methodology, for the translation of foreign currency sales into U.S. Dollars or, in the case of Sublicensees, such similar methodology, consistently applied.

(i) In the event that the Licensed Product is a Combination or Kit, the Net Sales of the Licensed Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination or Kit (as defined in the standard Net Sales definition) by the fraction, A / (A+B) where A is the weighted average sale price of the Lead Compound or Backup Compound when sold separately in finished form, and B is the weighted average sale price of the other product(s) sold separately in finished form.

(ii) In the event that the weighted average sale price of the Lead Compound or Backup Compound can be determined but the weighted average sale price of the other product(s) cannot be determined, Net Sales of the Licensed Product, for purposes of determining royalty payments, shall be calculated by multiplying the Net Sales of the Combination or Kit (as defined in the standard Net Sales definition) by the fraction A / C where A is the weighted average sale price of the Lead Compound or Backup Compound when sold separately in finished form and C is the weighted average selling price of the Combination or Kit.

(iii) In the event that the weighted average sale price of the other product(s) can be determined but the weighted average sale price of the Lead Compound or Backup Compound cannot be determined, Net Sales of the Licensed Product, for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination or Kit (as defined in the standard Net Sales definition) by the following formula: one (1) minus B / C where B is the weighted average sale price of the other product(s) when sold separately in finished form and C is the weighted average selling price of the Combination or Kit.

(iv) In the event that the weighted average sale price of both the Lead Compound or Backup Compound and the other product(s) in the Combination or Kit cannot be determined, the Net Sales of the Licensed Product, for purposes of determining royalty payments, shall be deemed to be equal to fifty percent (50%) of the Net Sales of the Combination or Kit (as defined in the standard Net Sales definition).

(v) The weighted average sale price for a Licensed Product or other product(s), shall be calculated once each Calendar Year and such price shall be used during all applicable royalty reporting periods for the entire following Calendar Year. When determining the weighted average sale price of a Licensed Product or other product(s), the weighted average sale price shall be calculated by dividing the sales dollars (translated into U.S. dollars) by the units of active ingredient sold during the twelve (12) months (or the number of months sold in a partial Calendar Year) of the preceding Calendar Year for the respective Licensed Product or other product(s). In the initial Calendar Year, a forecasted weighted average sale price will be used for the Licensed Product or other product(s). Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the first

royalty payment of the following Calendar Year.

Notwithstanding the above, if Lilly exercises the POC Option, in no event shall the royalty in accordance with Article 9.4 for a Licensed Product that is a Combination or Kit be less than (*deleted text: specific royalty rate)* of Net Sales as calculated without applying the adjustments in (i) to (v) above.

1.43 **"Party Specific Regulations"** shall mean all judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreement.

1.44 "**Patent(s)**" means all patents and patent applications Controlled by either Party or both Parties in any country or supranational jurisdiction including any provisionals, substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, reexaminations, extensions, supplementary protection certificates and the like.

1.45 "**Patent Prosecution**" means the responsibility and authority for (a) preparing, filing and prosecuting applications (of all types) for any Patent, (b) paying, filing and maintenance fees relating to any Patent, (c) managing any interference, opposition, re-issue, reexamination, revocation, nullification, or cancellation proceeding relating to the foregoing, (d) deciding to abandon Patent(s) and (e) settling any interference, opposition, revocation, nullification or cancellation proceeding.

1.46 "**POC Materials**" means the information set out in Article 4.2(b).

1.47 "**POC Study"** means the clinical proof of concept study in osteoarthritis to be conducted by Transition if Transition exercises the IND Option.

1.48 "**Regulatory Approval**" means all approvals from the relevant Regulatory Authority to market and sell a Licensed Product in any country (including all applicable pricing and reimbursement approvals), including approval of a BLA.

1.49 "**Regulatory Authority**" means any applicable government regulatory authority involved in granting approvals for the conduct of clinical trials or the manufacturing, marketing, sale, reimbursement or pricing of a Licensed Product in a country, including in the United States the FDA.

1.50 "**Related Party**" means, with respect to a Party, its Affiliates and Sublicensees.

1.51 "**Specifications**" means the specifications for the Licensed Product as agreed upon by the Joint Development Committee.

1.52 "**Sublicensee**" means a Third Party that is granted a sublicense under the licenses granted to a Party under this Agreement.

1.53 "**Third Party**" means an entity other than (a) Lilly and its Affiliates, and (b) Transition and its Affiliates. Third Parties cannot be debarred or disqualified by any regulatory authority.

1.54 "**Transition Know-How**" means all information (excluding any published Tranistion Patents) that (a) is (i) Controlled as of the Effective Date by Transition or (ii) is made by or on behalf of Transition or its Affiliates, alone or jointly, in the course of performing their obligations or duties under this Agreement and (b) is reasonably necessary for manufacture, development or use of the Licensed Product, Lead Compounds or Backup Compounds.

1.55 "**Transition Patents**" means Patents Controlled by Transition that contain one or more claims to Licensed Products, Lead Compounds or Backup Compounds and including any provisionals, substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, reexaminations, extensions, supplementary protection certificates and the like arising therefrom.

1.56 "**United States**" or "**US**" means the United States of America and its territories and possessions, including without limitation the Commonwealth of Puerto Rico and the U.S. Virgin Islands.

1.57 "**Valid Claim**" means a claim of an issued and unexpired Patent included within the Transition Patents, Lilly Patents or Jointly Owned Patents in a country which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is not appealable or is not appealed within the time allowed for appeal, and has not been abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise in such country.

2. SCOPE AND GOVERNANCE OF THE COLLABORATION

2.1 **General**

(a) Scope

Pursuant to and subject to the terms of this Agreement, the Parties agree to use Commercially Reasonable Efforts to collaborate with respect to the worldwide Development and Commercialization of a Licensed Product in the Field with the goal of obtaining Regulatory Approval for a Licensed Product. Except as otherwise permitted in this Agreement, the Parties shall collaborate exclusively and diligently with each other and neither Party shall alone or in collaboration with or through the grant of any rights to any Third Party, Develop Licensed Products for use in the Field. Transition will be solely responsible for the initial Development of the Lead Compound as a stand-alone agent from a pre-IND submission to the POC Study ("Initial Development"). The Initial Development is to be in compliance with appropriate regulatory standards, the Parties' compliance policies and applicable laws. Lilly and Transition or the Commercializing Party may substitute a Lead Compound with a Backup Compound at any time during Development only upon mutual consent by the Parties.

(b) Filing IND

Transition shall file an IND for the Lead Compound within nine (9) months of the Effective Date which may be extended on mutual agreement of the Parties by an additional six (6) months in the event of technical or regulatory issues with the Lead Compound.

(c) IND Option

Transition is not obligated to perform a POC Study for the Lead Compound and within sixty (60) days after the receipt of feedback from the FDA from an IND submission for the Lead Compound, Transition in its sole discretion has the option ("IND Option") of delivering written notice to Lilly that (i) it wishes to proceed with clinical studies to a POC Study as outlined in the Initial Development Plan, or (ii) it is discontinuing Development of the Lead Compound and Backup Compounds whereupon the Agreement will be immediately terminated. Effective on the receipt by Lilly of a written notice under Article 2.1(c)(i), Lilly grants to Transition the license under Article 10.2 and Transition shall make the payment to Lilly in accordance with Article 9.1.

(d) Development and Commercialization After Initial Development

Responsibility for Development and Commercialization by Lilly or Transition after Initial Development will be determined in accordance with Article 4 based on the exercise of the POC Option by Lilly and the payment to Transition of the amounts due under Article 9. Responsibility for manufacture of Clinical Materials and Licensed Product shall be as detailed in Article 6.

(e) Guiding Principles

The Joint Development Committee and any appointed sub-committees as set forth in this Article 2 shall perform its responsibilities under this Agreement based on the principles of good faith, prudence and good scientific and business judgment. None of such committees shall have any power to amend, modify or waive compliance under this Agreement. Notwithstanding anything to the contrary in this Agreement, no decision by either Party, or any committee set forth in this Article 2, will be effective if such decision requires the other Party to breach any obligation under this Agreement or to perform any activities that are materially different or greater in scope than those provided for specifically under this Agreement.

2.2 **Joint Development Committee**

(a) **Membership**

The Parties shall establish a Joint Development Committee, "JDC", to coordinate and oversee activities on which the Parties collaborate under this Agreement. The JDC shall consist of an equal number of representatives from each Party provided there are at least two (2) representatives from each Party. Each Party shall notify the other of its representatives to the JDC within thirty (30) days of the Effective Date. Each Party may replace any of its appointed JDC representatives or its co-chair at any time upon five (5) days prior written notice to the other Party. Each Party shall designate one (1) of its representatives as a co-chair of the JDC. The co-chairs shall have the responsibility to call meetings, circulate meeting agendas, draft minutes for

each JDC meeting and circulate such minutes either in writing or electronically for both Parties' approval.

(b) **Responsibilities**

The responsibilities of the JDC shall be:

(i) to provide a vehicle by which the Parties may share information regarding the overall strategy for the Development of Licensed Product(s);

(ii) to generate, approve and implement the plans for Development of Licensed Products, including any clinical trials, and any subsequent amendments to such plans;

(iii) to facilitate the exchange of information between the Parties with respect to the Development activities hereunder and to establish procedures for the efficient sharing of information necessary for the Parties to fulfill their respective responsibilities with respect to Development of Licensed Products hereunder;

(iv) to review and endorse an overall regulatory strategy established for the Licensed Products (marketed and investigational) in each country;

(v) to provide a forum to receive executive level updates regarding Commercialization of Licensed Products and to provide input regarding Commercialization strategy;

(vi) to create such subcommittees as the JDC may find necessary or desirable from time to time;

(vii) to oversee the activities of subcommittees created under this Agreement, and to resolve any issues that such subcommittees cannot resolve;

(viii) approval of Third Party contractors utilized by a Party to perform its Development and Commercialization activities under this Agreement;

(ix) review the Development plans, recommend any amendments or changes to the Development plans and approve any such amendments or changes;

(x) to review and approve Backup Compounds submitted by Lilly; and

(xi) to perform such other functions as appropriate to further the purposes of this Agreement, as determined by the Parties.

(c) **Decision Making**

The JDC shall make decisions unanimously, with each Party's representatives collectively having one (1) vote, which vote is to be cast by such Party's co-chair, or, in the absence of the co-chair, another of such Party's representatives on the JDC designated by any such Party's co-chair. At least one (1) representative from each Party shall be present at all

meetings of the JDC, provided, however, that no Party shall have the right to boycott meetings as a means to avoid action by the JDC. If the JDC is unable to unanimously agree with respect to any issue relating to Development or Commercialization, Transition shall have the tie-breaking vote when Lilly is not the Commercializing Party, and Lilly shall have the tie-breaking vote when Lilly is the Commercializing Party.

(d) **Limitations**

The JDC shall have no authority (a) to amend or interpret this Agreement, or (b) to determine whether or not a breach of this Agreement has occurred.

2.3 **JDC Meetings**

JDC meetings shall be held at least semi-annually or as mutually agreed by the Parties. With the consent of the representatives of each Party serving on the JDC, other representatives of each Party may attend meetings as non-voting observers (provided such non-voting observers have confidentiality obligations to such Party that are at least as stringent as those set forth in this Agreement). A JDC meeting may be held by face-to-face, audio, video or other electronic means with the consent of each Party. Each Party shall be responsible for all of its own expenses of participating in the JDC meetings.

2.4 **Committee Structure Following First Commercial Sale**

As soon as practicable following the first anniversary of the First Commercial Sale of a Licensed Product, the Parties shall review the committee structure provided for in this Article 2 and eliminate committees or adjust their responsibilities so as to reflect the then current status of collaborative Development efforts, if any, and the commencement of Commercialization.

3. PRODUCT DEVELOPMENT

3.1 **Development Plans**

Transition shall be responsible for the preparation of a plan for Initial Development of the Lead Compound. The Commercializing Party shall be responsible for all plans following Initial Development through receipt of Regulatory Approval and beyond. The Development plans shall include: (a) a description of the activities to be conducted and the relevant deliverables; and (b) estimated timelines for the performance of activities. An Initial Development plan is attached hereto as an Exhibit entitled “Initial Development Plan”.

On no less than an annual basis, the JDC shall review the Development plans, recommend any amendments or changes to the Development plans and approve any such amendments or changes.

3.2 **Conduct of Initial Development**

(a) Transition shall conduct the Initial Development, and Lilly will provide reasonable clinical and regulatory assistance (not to exceed 40 hours annually, or greater at the discretion of Lilly) in advancing the Lead Compound (or substitute Backup Compound) through

the Initial Development. Lilly will also promptly after the Effective Date transfer to Transition all Lilly Know-How, Clinical Materials and other information reasonably necessary for Transition to conduct the Initial Development including without limitation, information relating to Lilly's Backup Compounds existing at the Effective Date, and provide such consultation or other assistance as Transition may reasonably request to assist Transition in becoming familiar with such Lilly Know-How, Clinical Materials and the like. The JDC will ensure that the design and execution of the Initial Development meets acceptable industry standards and critical success factors.

(b) During the Initial Development, Lilly will provide Backup Compounds as available and if specifically requested by Transition, advise and be required to approve key drug substance and drug product related chemistry and manufacturing control (CMC) activities. Specifically, these include:

(i) Drug substance and medicinal drug product specification.

(ii) Manufacturing strategies including route-selection for drug substance and formulation process selection for drug product.

(iii) Container closure selection for drug substance and drug product.

(iv) Stability program design for drug substance and drug product.

3.3 **Initial Development Program Reports**

Transition shall keep the JDC generally informed of the progress of the Initial Development at least quarterly, and provide Lilly with the data from any preclinical or proof of concept studies. By way of example, Transition shall provide Lilly with development reports at the conclusion of development studies including, but not limited to: manufacturing history reports, analytical method development and qualification reports, toxicology reports, IND safety reports and/or DSUR (as applicable), and clinical reports. These reports may be written by the Third Party contractors (i.e., thirds party contract manufacturers, analytical testing laboratories or clinical organizations), according to their local procedures and good documentation practices. All such reports shall be subject to the provisions of Article 11.

3.4 **Development Costs**

Lilly shall be responsible for all costs incurred by it prior to the Effective Date and for all costs incurred by Lilly, whether prior to the Effective Date or during the Term, relating to Lead Compounds and Licensed Products. Transition will be responsible for all Transition's costs of the Initial Development and Transition's costs if Lilly has delivered the written notice in accordance with Article 4.2(a)(ii) and Transition decides to continue with the Development and Commercialization of a Lead Compound or Backup Compound. Transition's costs will include personnel costs and other expenses incurred internally by Transition as well as amounts incurred by Transition with respect to Third Parties, including amounts paid to Third Parties in connection with the conduct of the Initial Development. If Lilly delivers written notice that it wishes to exercise the POC Option in accordance with Article 4.2(a)(i) and has paid Transition the payment in accordance with Article 9.2, Lilly as the Commercializing Party will be responsible

for all Development costs incurred after the date of the written notice. If Transition is the Commercializing Party, Transition will be responsible for all of Transition's Development costs after it is deemed the Commercializing Party in accordance with Article 4.4.

3.5 **Rights to Engage Subcontractors**

Except as set forth below, each Party shall have the right to engage Third Party contractors to perform any portion of its obligations hereunder (subject to approval of the JDC), provided that each Party shall be responsible for ensuring that, prior to any such engagement, any subcontractors are subject to written agreements ("Third Party Agreements") containing terms and conditions: (i) consistent with the relevant terms and conditions of this Agreement protecting the rights of the Parties under this Agreement including imposing obligations of confidentiality on each such subcontractor; (ii) that vests ownership of any and all inventions developments or manufacturing Know-How by such subcontractor relating to Licensed Products in the course of performing such subcontracted work in the contracting Party; (iii) that does not impose any payment obligations or liability on the other Party without the prior written consent of the other Party (iv) that allows for the free transferability of any rights, information or Know-How to the other Party pursuant to this Agreement and (v) that is otherwise consistent with the terms of the Development plans to the extent applicable. Each Party shall exercise oversight of its own Third Party contractors and shall cause its existing contractors to cooperate with the other Party as necessary for them to fulfill its Development and Commercialization activities under this Agreement.

4. **OPTIONS**

4.1 **Grant of POC Option**

Transition grants Lilly the option to assume responsibility, at Lilly's expense, for the worldwide Development and Commercialization of the Licensed Product after receipt of the Final Data and POC Materials for the POC Studies ("POC Option").

4.2 **Exercise of POC Option**

(a) Within ninety (90) days after receipt of the Final Data and the POC Materials for the POC studies, ("POC Option Period"), Lilly will deliver written notice to Transition that Lilly (i) wishes to exercise the POC Option and pay Transition the payment in accordance with Article 9.2, or (ii) does not wish to exercise the POC Option and Transition, at is discretion, can Develop and Commercialize Licensed Products. If Lilly does not deliver any written notice under this Article 4.2 (i) or it does not make the payment in accordance with Article 9.2, then the POC Option will expire on the end of the POC Option Period.

(b) "POC Materials" means the supportive POC Studies information outlined in this Section 4.2(b) to the extent available when the Final Data is provided by Transition to Lilly: *(deleted text: specific reports to be provided)*

4.3 **Lilly's Rights and Obligations on Exercise of POC Option**

If Lilly (a) delivers written notice to Transition in accordance with Article 4.2(a)(i) and has paid Transition the payment due under Articles 9.2, effective on the expiry of the POC Option Period: (a) Lilly shall be deemed the Commercializing Party and will use Commercially Reasonable Efforts to Develop and Commercialize Licensed Products, (b) Transition shall cease to conduct and fund the Development of the Licensed Product except for those costs already incurred by Transition prior to Lilly's written notice to Transition, (c) the licenses in accordance with Sections 10.1 and 10.2 will be terminated, (d) Transition shall transfer to Lilly as soon as practicable, all Transition Know-How, regulatory materials, ownership of any regulatory submissions, and other information necessary to Develop the Lead Compounds so as to permit Lilly to continue Development efforts with respect to the Lead Compounds, and (e) Transition grants to Lilly the license under Article 10.3. In consideration of Transition's Development of the Licensed Product and the license granted to Lilly in this Article 4.3 and Article 10.3, Lilly shall pay Transition the payments in Articles 9.3 and 9.4.

4.4 **Transition's Rights and Obligations if POC Option Not Exercised**

If Lilly delivers a written notice to Transition in accordance with Article 4.2(a)(ii), does not deliver a written notice in accordance with Article 4.2, or has not paid Transition a payment due under Articles 9.2, Transition, in its discretion, may at its own expense or with a Third Party, Develop and Commercialize Licensed Products without any further obligations to Lilly; except for those payment obligations under Article 9.5. If Transition elects to Develop and Commercialize Licensed Products under this Article 4.4 it will deliver written notice to Lilly and Transition shall be deemed the Commercializing Party effective the earlier of the date of the written notice in accordance with Article 4.2(a)(ii), the expiry of the POC Option Period if Lilly does not deliver written notice under Article 4.2, or thirty (30) days after a payment under Article 9.2 was due and owed by Lilly. If Transition is the Commercializing Party it shall pay Lilly the payments in Article 9.5, and if Transition Develops and Commercializes Licensed Products with a Third Party, the only responsibility of the JDC shall be to provide a forum for Lilly to receive executive level updates regarding Development and Commercialization of Licensed Products.

4.5 **Lilly's Transfer and Assistance Obligations**

Following Transition becoming the Commercialization Party pursuant to Article 4.4, Lilly shall (a) cease to Develop and Commercialize such Licensed Product(s), (b) transfer to Transition, at reasonable transportation cost to Transition, as soon as practicable all Lilly Know-How, materials, and other information reasonably necessary to permit Transition to continue to Develop and Commercialize such Licensed Product(s), including without limitation, preclinical study reports, pharmacology study reports, toxicology reports, active pharmaceutical ingredient and related materials, manufacturing documentation and any regulatory materials, (c) assign to Transition as soon as practicable all regulatory filings and approvals for such Licensed Product(s) (marketed and investigational), (d) grant to Transition the license under Article 10.2, which license shall be deemed granted and effective immediately upon Transition becoming the Commercialization Party under Article 4.4, and (e) without charge and for a period of ninety (90) days from Lilly's receipt of Transition's written notice under Article 4.4 provide such consultation or other assistance as Transition may reasonably request to assume the Development and Commercialization of such Licensed Product(s). Further, for the avoidance of doubt, the license granted to Lilly pursuant to Article 10.3 shall terminate immediately upon Lilly's receipt

of Transition's written notice under Article 4.4.

4.6 Transition's Refusal to Continue Development.

If Lilly does not exercise or fails to timely exercise its POC Option and Transition does not assume responsibility for Development of the Licensed Product after the POC Option Period then the Agreement shall terminate including all licenses and each Party shall return all Confidential Information of the other in respect to the Licensed Product. If either Party later determines to reinitiate Development of the same Licensed Product using the POC Materials then they must first obtain the other Parties permission under financial terms to be mutually agreed between the Parties.

5. COMMERCIALIZATION

5.1 **Overview**

The Commercializing Party as provided in Article 4 shall have full responsibility and authority for all aspects of the worldwide Commercialization of Licensed Products in the Field at its sole expense. The Commercializing Party shall not be obligated to launch Licensed Products in all countries but shall use its Commercially Reasonable Efforts in view of applicable local intellectual property and drug regulatory laws and the particular competitive environment. The Commercializing Party shall use Commercially Reasonable Efforts to Develop and Commercialize Licensed Products, in compliance with the terms and conditions of the Agreement. The Commercializing Party shall book all sales of the Licensed Products, and shall have the sole right and obligation to determine all pricing of the Licensed Products. The Commercializing Party shall bear all of the costs and expenses incurred in connection with all such Commercialization activities.

5.2 **Compliance**

(a) Compliance with this Agreement. Each of the Parties shall, and shall cause their respective Affiliates to, comply in all material respects with the terms of this Agreement.

(b) Compliance with Applicable Laws. Each of the Parties shall, and shall cause their respective Affiliates to, conduct all activities under this Agreement in such a manner as to comply in all material respects with all Applicable Laws.

(c) Compliance Agreement. From time to time, the Parties shall discuss activities necessary to insure Compliance. If either Party requests, the Parties will negotiate in good faith and execute a written Compliance Agreement that will set forth and define the compliance policies, standards, and procedures the Parties will adhere to when conducting activities under this Agreement. The Compliance Agreement may also include provisions relating to interactions between the respective compliance organizations of the Parties, sharing of Compliance related information, execution of training, implementation and monitoring activities, and resolution of Compliance issues that may arise in accordance the rule established in Section 1.6.

(d) Responsibility for Compliance; Disputes Regarding Compliance Matters. Each Party is solely responsible to ensure Compliance by it and its Affiliates. With respect to

joint activities, in the event of any conflict between the Parties as to how to ensure Compliance that the Parties are unable to resolve, the more conservative view (i.e., the view least likely to risk non-Compliance) shall prevail.

(e) Foreign Corrupt Practice Act. In connection with a Party's performance of its obligations under this Agreement each Party confirms to the other Party that such first Party has not given or promised to give, and will not make, offer, agree to make or authorize any payment or transfer anything of value, directly or indirectly, (i) to any Government or Public Official, as defined herein; (ii) any political party, party official or candidate for public or political office; (iii) any person while knowing or having reason to know that all or a portion of the value will be offered, given, or promised, directly or indirectly, to anyone described in clauses (i) or (ii) above; or (iv) any owner, director, employee, representative or agent of any actual or potential customer of the other Party. Each Party agrees to comply with all applicable anti-bribery laws in the countries where such Party has its principal place of business or where such Party conducts activities under this Agreement. Additionally, each Party will use commercially reasonable efforts to comply with requests for information from the other Party, including answering questionnaires and narrowly tailored audit inquiries, to enable the other Party to comply with applicable anti-bribery laws. For purposes of this Agreement, "Government or Public Official" is any officer or employee or anyone acting in an official capacity on behalf of: a government or any department or agency thereof; a public international organization (such as the United Nations, the International Monetary Fund, the International Red Cross, and the World Health Organization), or any department, agency or institution thereof; or a government-owned or controlled company, institution, or other entity, including a government-owned hospital or university.

(f) Notice of Inspections. During the Term of this Agreement, each Party shall provide the other Party with prompt notice of any governmental or regulatory review, audit or inspection of its facility, processes, or products that relate to the subject matter of this Agreement. The audited Party shall provide the non-audited Party with the results of any such review, audit or inspection to the extent it relates to the subject matter of this Agreement. To the extent practicable, the non-audited Party shall be given the reasonable opportunity to provide assistance to the audited Party in responding to any such review, audit or inspection to the extent it relates to the subject matter of this Agreement.

(g) Books and Records. During the Term of this Agreement and for a period of three (3) years thereafter, at reasonable times and upon reasonable notice, each Party shall have the right to audit, review, and copy the records of the other Party relating to compliance by such other Party with the terms of this Article 5.3.

(h) All audit results under Article 5.3(c) and records under Article 5.3(d) shall be subject to the provisions of Article 11.

6. MANUFACTURE AND SUPPLY

6.1 General

Within thirty (30) days of the Effective Date, Lilly will transfer to Transition sufficient

active pharmaceutical ingredient of Lead Compound to Transition to allow Transition to conduct all activities up to the end of the POC Option period. Transition shall be responsible for the manufacture of final drug product to complete the clinical studies up to and including the POC Study. The Commercializing Party or owner of the submission shall manufacture or have manufactured all Clinical Materials and Licensed Products for its Development and Commercialization activities. Each Party agrees that it shall transfer to the Commercializing Party all manufacturing Know-How including materials and documentation in its possession, and provide such advice, counsel and other assistance as is necessary or useful to assist in such transfer.

6.2 **Limited Warranty**

Each Party warrants to the other that Clinical Materials and Licensed Products delivered hereunder, whether manufactured by such Party or by Third Parties for such Party, (a) will comply with cGMP and other applicable FDA and other rules and regulations of the U.S., EMEA and other relevant jurisdictions, (b) will conform to the Specifications at the time of delivery, and (c) will not be adulterated or misbranded.

6.3 **Lilly Process Development**

Notwithstanding Article 2.1(a) and subject to approval by the JDC, Lilly at its expense shall have the right to perform process development related to the Licensed Product or in anticipation of supplying a Lilly clinical trial prior to exercising the POC Option under Article 4.2.

6.4 **Quality Agreements**

As applicable, depending on the Commercializing Party, an appropriate Quality Agreement will be entered into within 90 days of Lilly exercising POC option and shall include the specifications for the Licensed Product, Licensed Product audit rights, and, if known, the shelf-life of the Licensed Product. Transition will use its best efforts to transfer its existing Quality Agreements for the Licensed Product to Lilly, or will assist Lilly to enter into new Quality Agreements with Third Party manufacturers of the Licensed Product. In the event the information in the Quality Agreement conflicts with this Agreement, the terms of the Quality Agreement will control quality related matters.

7. **RECORDS**

Each Party shall maintain appropriate records, whether paper or electronic, of (a) all significant Development, manufacturing and Commercialization events and activities conducted by it or on its behalf related to a Licensed Products (marketed or investigational); and (b) all significant information generated by it or on its behalf in connection with Development of Licensed Products (marketed or investigational) under this Agreement, in each case in accordance with such Party's usual documentation and record retention practices. Such records shall be in sufficient detail to properly reflect, in good scientific manner, all significant work done and results of studies and trials undertaken and further shall be at a level of detail appropriate for patent and regulatory purposes. If reasonably necessary for a Party to perform its work under this Agreement or to exercise its rights under this Agreement that Party may request

that, and the other Party shall provide within a reasonable timeframe, such information and data regarding its activities hereunder as is reasonably available and reasonably related to the work under this Agreement. Neither Party is required to generate additional data or prepare additional reports to comply with the foregoing obligation. All such reports, information and data provided shall be subject to the provisions of Article 11.

8. REGULATORY

8.1 **Regulatory and Safety**

The JDC will provide oversight for the worldwide regulatory strategy used to obtain Regulatory Approval of Licensed Products including any IND application, sponsorship or strategy. The Commercialization Party will have responsibility for all regulatory activities as outlined in Article 8.5 Regulatory Obligations of this Agreement.

8.2 **Product Labeling; Promotional Materials**

The Commercializing Party shall be responsible for design and supply of the product labeling and promotional materials for the Licensed Products. The Commercializing Party shall be responsible as to the manner in which Licensed Products shall be presented and described to the medical community in any promotional materials and the placement of the names and logos of the Parties therein, in each case as permitted by applicable law and consistent with the labeling for the Licensed Products approved by the applicable Regulatory Authority. To the extent permitted by applicable law, in Commercialization under this Agreement, product labeling shall identify the Licensed Products as originating from the Commercializing Party. Responsibilities for product labeling and promotional materials will be identified in the separate Safety Regulatory Agreement (as defined in Article 8.3.b.).

8.3 **Regulatory Matters and Safety Reporting**

(a) **Regulatory and Safety Responsibilities**

Transition shall be responsible for all regulatory activities and will be the owner of all regulatory submissions throughout the Initial Development and the Development and Commercialization of Licensed Products if Transition is deemed the Commercializing Party hereunder, subject to any sublicense, collaboration or like agreement entered into by Transition in respect to Licensed Products. If Lilly is deemed the Commercializing Party hereunder it shall be responsible for all regulatory activities and will be the owner of all regulatory submissions in the Development and Commercialization of Licensed Products (marketed or investigational) after it is deemed the Commercializing Party. Regulatory activities include without limitation (i) management and monitoring of safety and Adverse Event/experience information for the Licensed Products (marketed or investigational), (ii) regulatory reporting of safety information to the applicable Regulatory Authority; (iii) reviewing and approving of safety information for inclusion in the Licensed Product label in a particular country and the global Core Data Sheet, (iv) ownership and management of the global safety database. Each Party agrees to cooperate as reasonably requested by the other in the course of fulfilling the regulatory responsibilities.

(b) **Creation of Safety and Regulatory**

Subject to the terms of this Agreement, should Lilly exercise its POC Option in accordance with Articles 4.2 and within a reasonable time after the transfer of safety data, documents and reports to Lilly, Lilly and Transition shall define the safety and regulatory responsibilities for both parties in a written agreement (hereafter referred to as the "Global Safety and Regulatory Agreement"). These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, documentation, communication and exchange, as between the Parties, of Adverse Event reports, pregnancy reports and other safety information concerning the Licensed Product for all indications. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill and comply with local and national regulatory reporting obligations. Should Lilly exercise its POC Option, then Lilly shall establish, hold and maintain the global safety databases for each Licensed Product (the "Global Safety Database") into which it shall enter information on all serious Adverse Events and suspected reactions concerning the Licensed Product (marketed or investigational) occurring anywhere in the world and reported to either of the Parties. Such Global Safety Database shall comply in all material respects with all laws reasonably applicable to pharmacovigilance anywhere where the Licensed Products (marketed or investigational) are being or have been Developed or Commercialized.

(c) **Use of Third Parties**

Each Party agrees that if it contracts with a Third Party for clinical research to be performed by such Third Party relating to the Licensed Products (marketed or investigational), then that Party agrees to require such Third Party to report to the contracting Party the information set forth in part (b) above.

8.4 **Recalls**

The holder of the IND will be responsible for any recall decision, which shall be made only after reasonable consultation with the other Party. After submission of the NDA or its equivalent elsewhere, the Commercializing Party shall be responsible for any such decision, which shall be made only after consultation with the other Party. If the Commercializing Party, in its discretion, recalls, detains or retains the Licensed Product (voluntarily or by order of a Regulatory Authority), the other Party agrees to reasonably cooperate in such actions, at the Commercializing Party's sole expense. Both parties are obliged to act in good faith to accomplish this action in a manner required by applicable regulations.

8.5 **Regulatory Obligations**

The Commercializing Party shall be responsible for the regulatory strategy, including strategy for filings and label content. The Commercializing Party shall also be solely responsible for all regulatory activities in connection with seeking Regulatory Approvals in a country, including without limitation communicating and preparing and filing all reports including, without limitation and as appropriate, all INDs and NDAs with all Regulatory Authorities. Notwithstanding the above, during the Initial Development, the JDC will endorse the regulatory strategy and Transition will be responsible for all regulatory activities. The Parties agree to cooperate with each other as requested in preparing and filing all reports, and each Party shall have reasonable access to all reports in the possession of the other Party for its review prior to

filing with a Regulatory Authority, and all clinical results and data relating to Development. The Commercializing Party shall pay all governmental fees associated with obtaining and maintaining any and all Regulatory Approvals, except during the Initial Development Transition shall be responsible for paying such fees. All such reports and clinical results and data shall be subject to the provisions of Article 11.

8.6 **Pharmacovigilence Audit Rights**

Upon reasonable notification, the Parties are entitled to conduct an audit of pharmacovigilance procedures and practices that require evaluation including on-site evaluations.

9. **PAYMENTS**

9.1 **Upfront Payment**

Transition will pay Lilly one million U.S. dollars ($1,000,000) within thirty (30) days of Transition delivering written notice to Lilly in accordance with Article 2.1(c)(i).

9.2 **Payment after Completion of POC Studies**

Pursuant to Lilly exercising the POC Option in accordance with Article 4.2(a)(i), Lilly will pay Transition six million U.S. dollars ($6,000,000) within ninety (90) days after receipt of the Final Data for the POC Studies, which payment shall be non-refundable and non-creditable against any payments due under this Agreement.

9.3 **Milestone Payments**

Within thirty (30) days of achieving the following milestones, if Lilly is the Commercializing Party, then Lilly will make the following non-refundable payments to Transition. For clarification, each milestones will be payable only once upon the first time each event occurs and all amounts are in U.S. dollars. *(deleted text: table of milestone payments. Total milestones under Sections 9.2 and 9.3 is $130 million US dollars.)*

9.4 **Royalties**

If Lilly is the Commercializing Party then Lilly will pay Transition on a quarterly basis a royalty of *(deleted text: specific royalty rate)* on annual Net Sales of Licensed Products. The royalty rate will remain unchanged regardless of whether or not Licensed Product is a stand-alone product, combination or kit

9.5 **Payments When Transition is the Commercializing Party**

If Transition is deemed the Commercializing Party in accordance with Article 4.4 it will pay Lilly the following:

(i) a *(deleted text: specific royalty rate)* royalty on the worldwide annual Net Sales of Licensed Products Commercialized by Transition; and

(ii) *(deleted text: specific royalty rate)* of upfront, milestone and license fees received by Transition from any Third Party for Development or Commercialization rights to a Licensed Product.

9.6 **Payments When Lilly Independently Develops an** *(deleted text: specific class of compounds)*

If Lilly does not exercise the POC Option and Transition assumes responsibility for Development of a Licensed Product, Lilly will pay Transition a *(deleted text: specific royalty rate)* royalty on the worldwide annual Net Sales of products comprising a *(deleted text: specific class of compounds)* compound independently developed by Lilly that meets the following criteria: *(deleted text: properties of compounds).*

9.7 **Royalty Payments**

Royalty obligations in respect to each Licensed Product under Articles 9.4, 9.5 and 9.6 shall commence on the date of the First Commercial Sale of the Licensed Product and expire, on a country by country basis, on the latest of the following dates:

(a) the tenth (10th) anniversary of the date of First Commercial Sale of the Licensed Product in such country;

(b) the expiration in such country of the last-to-expire Lilly Patent, Transition Patent, or Jointly Owned Patent having a Valid Claim covering the manufacture, use or sale of the Licensed Product as Commercialized in such country;

(c) the expiration of any Data Exclusivity Period for the Licensed Product in such country.

If a Licensed Product is re-launched, for example, without limitation, as a new dosage form, new administration form or for a new indication then such re-launched Licensed Product's royalty term shall be calculated under parts (b) or (c) as applicable but not part (a).

If, on a country by country basis, during any Calendar Year, generic versions of the Licensed Product have a market share within that country (based upon unit volume of all dosages and other presentations combined) of at least *(deleted text: specific rate*), the Net Sales for that country for purposes of calculating the royalty due hereunder shall be reduced by *(deleted text: specific rate*).

9.8 **Third Party Royalties**

Lilly (or its Affiliate or Sublicensee) shall be responsible, at its sole expense and discretion, for obtaining any agreements with Third Parties for any Third Party rights which, in the good faith opinion of Lilly, would be necessary to make, use, import, Develop, or sell the Lead Compound or Backup Compound in a particular country.

9.9 **Reports; Payment of Royalty**

During the Term, following the First Commercial Sale of a Licensed Product by the Commercializing Party, the Commercializing Party shall furnish to the other Party a quarterly written report for the Calendar Quarter showing the Net Sales of Licensed Products subject to royalty payments sold by the Commercializing Party and its Related Parties on a country-by-country basis during the reporting period and the royalties payable under this Agreement. Reports shall be due on the sixtieth (60th) day following the close of each Calendar Quarter. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. The Commercializing Party shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined.

9.10 **Audits**

The Commercializing Party will keep and maintain (and to the extent applicable, will cause its Affiliates, and their respective Sub-licensees, distributors, assignees and transferees to keep and maintain) proper and complete records and books of account in such form and detail as is necessary for the determination of the amounts payable by the Commercializing Party (on behalf of itself and its Affiliates and their respective Sub-licensees, distributors, assignees and transferees) to the other Party under this Agreement and for the purposes of this Agreement.

Upon the written request of the other Party and not more than once in each Calendar Year, the Commercializing Party shall permit an independent certified public accounting firm of nationally recognized standing selected by the other Party and reasonably acceptable to the Commercializing Party, at the other Party's expense, to have access during normal business hours to such of the records of the Commercializing Party as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than thirty-six (36) months prior to the date of such request. Any given period may not be audited more than once. The other Party may consider in good faith, at its sole discretion and choice, the use of the Commercializing Party's then current external auditor to perform such audit. The accounting firm shall disclose to the other Party and the Commercializing Party only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to the other Party. This right to audit shall remain in effect throughout the Term of this Agreement and for a period of two (2) years after the termination of this Agreement.

If such accounting firm identifies a discrepancy made during such period, the Commercializing Party shall pay the other Party the amount of the discrepancy within sixty (60) days of the date the other Party delivers to the Commercializing Party such accounting firm's written report so concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by the other Party unless the underpayment exceeded the greater of A) five percent (5%) of the amount owed by the Commercializing Party to the other Party for such Calendar Year or B) $100,000, in which case, the expense of the audit shall be borne by the Commercializing Party. The Commercializing Party shall pay interest on any underpayment as the rate set forth in Article 9.12.

The Commercializing Party shall include in each sublicense granted by it pursuant to this

Agreement a provision requiring the Sublicensee to make reports to the other Party, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by the other Party's independent accountant to the same extent required of the Commercializing Party under this Agreement.

The Parties shall treat all financial information subject to review in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause their accounting firms to enter into an acceptable confidentiality agreement obligating them to retain all such information in confidence pursuant to such confidentiality agreement.

9.11 Payment Method

All payments to be made by the Commercializing Party to the other Party under this Agreement shall be made in United States dollars by bank wire transfer in immediately available funds to a bank account designated in writing by the other Party.

9.12 Late Payment

All late payments under the Agreement shall bear interest at the rate of 1% greater than the U.S. commercial prime rate as published by the Wall Street Journal on the date such payment was due until the date such payment is made.

9.13 Tax Withholding

If laws, rules or regulations require the Commercializing Party to withhold income taxes or other taxes imposed upon payments due hereunder, the Commercializing Party shall make such withholding payments as required and subtract such withholding payments from the payments due. The Commercializing Party shall submit original receipts or other appropriate proof of payment of the withholding taxes to the other Party within a reasonable period of time to allow the other Party to document such tax withholdings for purposes of claiming foreign tax credits and similar benefits and shall cooperate with reasonable requests of the other Party (without acting to the detriment of the Commercializing Party) related to the other Party obtaining such credits and benefits. However, Lilly agrees that all payments to Transition pursuant to this Agreement will be made by a Lilly U.S. based entity.

10. LICENSES

10.1 License to Transition

Lilly grants to Transition an exclusive, worldwide, royalty bearing license, with the right to grant sublicenses, under the Lilly Patents, Lilly rights in Jointly Owned Patents and Lilly Know-How to Develop Licensed Products in the Field.

10.2 License to Transition After Exercise of IND Option

Pursuant to Article 2.1(c), Lilly grants to Transition an exclusive, worldwide, royalty bearing license, with the right to grant sublicenses, under the Lilly Patents, Lilly rights in Jointly Owned Patents and Lilly Know-How to Develop, make, have made, use, sell, offer to sell,

import and Commercialize Licensed Products in the Field.

10.3 License to Lilly

If Lilly is deemed the Commercializing Party in accordance with Article 4.3, then Transition grants to Lilly an exclusive even to transition, worldwide, royalty bearing license, with the right to grant sublicenses, under the Transition Patents, Transition rights in Jointly Owned Patents and Transition Know-How to Develop, make, have made, use, sell, offer to sell, import and Commercialize Licensed Products in the Field.

10.4 No Implied Licenses

Except as necessary to perform their obligations and duties under this Agreement and as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party.

11. CONFIDENTIALITY; PUBLICATION

11.1 Nondisclosure Obligation

Except as provided in this Article 11.1, all Confidential Information disclosed by one Party to the other Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, until five (5) years following the Term of this Agreement

Each Party may disclose Confidential Information of the other Party, without such other Party's prior written consent, to its Affiliates' directors, employees, agents, consultants, Sublicensees, subcontractors as provided in Article 3.5, suppliers, and other persons or entities who:

(a) need to know such Confidential Information to assist the Party in fulfilling its obligations hereunder; and

(b) are bound by written confidentiality and non-use obligations consistent with those the Party uses to protect its own Confidential Information.

Each Party shall promptly disclose to the other Party any breach of this provision by it, or its Affiliates, directors, officers, employees, agents, consultants, Sublicensees, Subcontractors, suppliers, or other persons or entities permitted hereunder.

Each Party may also disclose the Confidential Information of the other Party, without such other Party's prior written consent, to any person, entity, or government or regulatory authority to the extent that the law requires such disclosure, including filings pursuant to applicable securities or tax laws and regulations. The Party disclosing such Confidential Information shall cooperate with the other Party and take such actions to preserve the confidentiality of such Confidential Information, such as requesting confidential treatment. In addition, each Party may also disclose the other Party's Confidential Information, without the

other Party's prior written consent, to any person, entity, or government or Regulatory Authority to the extent that such disclosure is necessary for obtaining, maintaining, or amending any Regulatory Approvals or satisfying any other regulatory obligation regarding Licensed Products, or, in the case of the Commercializing Party, in connection with the Commercialization of Licensed Products including under a confidentiality agreement to actual or potential sublicensees or permitted assignees. Each Party may also disclose the Confidential Information of the other Party, without such other Party's prior written consent, pursuant to an order of a Regulatory Authority or court of competent jurisdiction, provided that it promptly notifies the other Party of the required disclosure and cooperates with the other Party in order to provide such Party an opportunity to take legal action to prevent or limit such disclosure and, if asked, reasonably assist the other Party in pursuing such action.

Each Party may also disclose the Confidential Information of the other Party, without such other Party's prior written consent, as is necessary to pursue or defend against a legal or regulatory action by one Party against the other with respect to this Agreement. A Party disclosing the other Party's Confidential Information, pursuant to this exception, will promptly disclose to the other Party the Confidential Information to be disclosed and shall use reasonable efforts to minimize the disclosure of the other Party's Confidential Information, including, without limitation, by seeking to file pleadings under seal.

11.2 **Publications**

The JDC shall establish procedures for determining when publications, scientific presentations and the like relating to the Initial Development are appropriate and providing for review by the Parties of any publications to protect Confidential Information. The appropriateness of all publications relating to the Development or Commercialization of Licensed Products after the expiry of the POC Option shall be determined by the Commercializing Party.

11.3 **Publicity; Use of Names**

(a) Within ten (10) days of the Effective Date, the Parties shall issue a mutually acceptable press release announcing the execution of this Agreement. Prior to Lilly or Transition being deemed the Commercializing Party under Article 4, either Party may issue any subsequent press release relating to this Agreement or activities conducted hereunder upon prior written approval of the other Party, such approval not to be unreasonably withheld or delayed; provided, however, that no approval of the other Party shall be required if a subsequent press release solely discloses the information that (1) a commercialization milestone under this Agreement has been achieved and/or any payments associated therewith have been received; (2) the filing and/or approval of the drug application in the U.S., Canada, European Union, Japan or China; (3) commercial launch of a Licensed Product or any information that has previously been approved and disclosed as permitted by this Article 11.3. In the case of items (1)-(3) of the preceding sentence, the disclosing Party shall provide the other Party a copy of such proposed disclosures at least five (5) business days prior to the proposed release and consider in good faith any comments the other Party may make, where practicable, and in light of any reporting obligations of such disclosing Party under applicable laws, rules or regulations, including without limitation the rules and regulations promulgated by the United States Securities and

Exchange Commission, the Canadian Securities Administrators or any other governmental agency. Except as otherwise provided in this Article 11.3(a), neither Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Party; provided however, that nothing herein shall prohibit the use of the trademark or trade name of a Licensed Product. In addition and notwithstanding anything to the contrary herein, (a) if the relevant text of a proposed press release has already previously been reviewed and approved for disclosure by the other Party then such text may be disclosed or republished in such proposed press release provided that the Party issuing such press release provides notice to the other Party of such press release at least five (5) business days prior to the issuance of such press release, where practicable, and (b) if the relevant text of a proposed public announcement such as a corporate presentation or comments to analysts or investors has already previously been reviewed and approved for disclosure by the other Party (whether in the form of an approved press release or prior approved presentation materials, Q&A script or the like) or it has been substantially made available through press releases, presentations or comments to analysts prior to the Effective Date, then such text may be included in such proposed public announcement (but not a press release) without resubmission and review by the other Party. The Parties also agree that following the Effective Date, Transition can disclose the mechanism of action of the Licensed Product as well as selected data, approved by Lilly, from animal efficacy studies. Notwithstanding the foregoing, after Lilly or Transition are deemed the Commercializing Party under Article 4, the Commercializing Party may issue press releases relating to this Agreement or activities conducted hereunder without the prior approval of the other Party.

(b) Neither Party shall disclose the existence or terms of this Agreement pursuant to a press release or otherwise except as provided in this Article 11. Notwithstanding the terms of this Article 11, either Party shall be permitted to disclose the existence and terms of this Agreement and the conduct of the collaboration under this Agreement, to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable laws, rules or regulations, including without limitation the rules and regulations promulgated by securities law regulatory agencies or any other governmental agency. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Article 11.3(b), the Parties will consult with one another on the terms of this Agreement for which confidential treatment will be sought in making any such disclosure. If a Party wishes to disclose this Agreement or any of the terms hereof in accordance with this Article 11.3(b), such Party agrees, at its own expense, to seek confidential treatment of the portions of this Agreement or such terms as may be reasonably requested by the other Party, provided that the disclosing Party shall always be entitled to comply with legal requirements.

(c) Except to the extent in the public domain, either Party may also disclose the existence and terms of this Agreement, activities conducted by the Parties relating to the Lead Compound or Backup Compound or the results from such activities, to its attorneys and advisors, and to potential Sublicensees, sources of financing and permitted assignees, in each case under an agreement or in the case of attorneys, a professional obligation, to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially similar to the terms contained in this Agreement.

12. REPRESENTATIONS AND WARRANTIES

12.1 Representations and Warranties of Transition

Transition represents and warrants to Lilly that as of the Effective Date:

(a) it has the full right, power and authority to enter into this Agreement, to perform the collaboration, and the fulfillment of its obligations and performance of its activities hereunder do not materially conflict with, violate, or breach or constitute a default under any material contractual obligation or court or administrative order by which Transition is bound; and

(b) all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by Transition as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained.

12.2 Representations and Warranties of Lilly

Lilly represents and warrants to Transition that as of the Effective Date:

(a) it has the full right, power and authority to enter into this Agreement, to perform the collaboration, to grant the licenses granted under Articles 10.1 and 10.2, and the fulfillment of its obligations and performance of its activities hereunder do not materially conflict with, violate, or breach or constitute a default under any material contractual obligation or court or administrative order by which Lilly is bound;

(b) to the knowledge of Lilly, there are no legal claims, judgments or settlements against or owed by Lilly or pending legal claims or litigation, in each case relating to the Lilly Patents;

(c) all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by Lilly as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained;

(d) Lilly does not have any current knowledge that would cause any of its representations or warranties to Transition to be incorrect or untrue.

(e) it is the owner or exclusive licensee of or otherwise Controls the right, title and interest in and to the Lilly Patents and related Lilly Know-How, and has the right to grant to Transition the licenses that it purports to grant hereunder and has not granted any Third Party rights that would interfere or be inconsistent with Transition's rights hereunder;

(f) the Lilly Patents and Lilly Know-How are not subject to any existing royalty or other payment obligations to any Third Party;

(g) it is not aware of any other Patents, Know-How, or other intellectual property right Controlled by Lilly or its Affiliates, other than that which is licensed hereunder to Transition, which the Development, manufacture, use, sale and/or Commercialization of

Products as contemplated hereunder would infringe;

(h) as of the Effective Date, any issued Lilly Patents are valid and enforceable and it is not aware of any action, suit, inquiry, investigation or other proceeding threatened, pending, or ongoing brought by any Third Party that challenges or threatens the validity or enforceability of any of the Lilly Patents or that alleges the use of the Lilly Patents or the related Lilly Know-How or the development, manufacture, commercialization and use of the Lead Compounds, Backup Compounds or Licensed Products would infringe or misappropriate the intellectual property or intellectual property rights of any Third Party (and it has not received any notice alleging such an infringement or misappropriation). In the event that Lilly becomes aware of any such action or proceeding, it shall immediately notify Transition in writing;

(i) it has disclosed to Transition a complete and accurate record of all material information and data relating to the results of all pre-clinical and clinical studies on Licensed Products, in particular Lead Compounds, conducted by or on behalf of Lilly including, without limitation, the status and interim results of all ongoing clinical and preclinical studies, and the clinical development and Regulatory Approval activities undertaken to date, and all such information and data is complete and accurate in all material respects.

12.3 No Other Representations or Warranties

EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

13. INDEMNIFICATION

13.1 By Lilly

Lilly agrees to indemnify and hold harmless Transition, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "Transition Indemnitee(s)") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "Losses") first arising after the Effective Date to the extent arising from (a) the Development, manufacture, use, Commercialization or sale of Licensed Products by Lilly, or any of its Related Parties or Subcontractors, (b) the use of Licensed Products manufactured or sold by Lilly or any of its Related Parties or Subcontractors by any purchasers thereof including without limitation any product liability claim, (c) the use by Lilly or any of its Related Parties or Subcontractors of the Lilly Patents, Transition Patents, Lilly Know-How or Transition Know-How, (d) the negligence, illegal conduct or willful misconduct of Lilly or (e) Lilly's material breach of this Agreement, except to the extent such Losses arise out of any of Transition Indemnitee's negligence, illegal conduct or willful misconduct or breach

of this Agreement.

13.2 **By Transition**

Transition agrees to indemnify and hold harmless Lilly, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "Lilly Indemnitee(s)") from and against all Losses first arising after the Effective Date to the extent arising from (a) the Development, manufacture, use, Commercialization or sale of Licensed Products by Transition, or any of its Related Parties or Subcontractors, (b) the use of Licensed Products manufactured or sold by Transition or any of its Related Parties or Subcontractors by any purchasers thereof, including without limitation any product liability claim (c) the use by Transition or any of its Related Parties or Subcontractors of the Transition Patents, Lilly Patents, Transition Know-How or Lilly Know-How, (d) the negligence, illegal conduct or willful misconduct of Transition in the performance of this Agreement or (e) Transition' material breach of this Agreement, except to the extent such Losses arise out of any of Lilly Indemnitee's negligence, illegal conduct or willful misconduct or breach of this Agreement.

13.3 **Defined Indemnification Terms**

Either of the Lilly Indemnitee or the Transition Indemnitee shall be an "Indemnitee" for the purpose of this Article 13, and the Party that is obligated to indemnify the Indemnitee under Article 13.1 or Article 13.2 shall be the "Indemnifying Party".

13.4 **Defense**

If any such claims, demands, actions or other proceedings are made, the Indemnitee shall be defended at the Indemnifying Party's sole expense by counsel selected by Indemnifying Party and reasonably acceptable to the Indemnitee, provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such claim, demand, action or other proceeding subject to the terms of this Article 13.

13.5 **Settlement**

The Indemnifying Party may settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee where the only liability to the Indemnitee is the payment of money and the Indemnifying Party makes such payment, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld.

13.6 **Notice**

The Indemnitee shall notify the Indemnifying Party promptly of any claim, demand, action or other proceeding under Article 13.1 or Article 13.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.

13.7 **Permission by Indemnifying Party**

The Indemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any admission as to liability or fault without the express written permission of the Indemnifying Party.

13.8 Limitation of Liability

NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS ARTICLE 13.8 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE 13, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 11.

14. INVENTIONS; PATENT PROVISIONS

14.1 Ownership of Intellectual Property

(a) Lilly shall remain the sole and exclusive owner of all Lilly Patents, and Lilly Know-How that Lilly Controlled as of the Effective Date, and Transition shall remain the sole and exclusive owner or rights holder of all Transition Patents, and Transition Know-How that Transition Controlled as of the Effective Date.

(b) Transition shall own all data, results and inventions, whether patentable or not, conceived or reduced to practice in the course of conducting this collaboration solely by Transition or its consultants or subcontractors, together with all intellectual property rights therein. Lilly shall own all data, results and inventions, whether patentable or not, conceived or reduced to practice in the course of conducting this collaboration solely by Lilly or its consultants or subcontractors, together with all intellectual property rights therein. Any patents issuing on such data, results or inventions solely owned by Transition or Lilly, as the case may be, shall be deemed "Transition Patents" and "Lilly Patents," respectively, and included in and subject to the licenses granted under Article 10. Transition and Lilly shall jointly own all data, results and inventions, whether patentable or not, conceived or reduced to practice by Transition and Lilly jointly, together with all intellectual property rights therein, with each Party owning an undivided half interest and the right to exploit with the consent of the other Party, except as otherwise provided in this Agreement ("Jointly Owned Patents").

14.2 Patent Filing, Prosecution and Maintenance

Prior to a Party being deemed the Commercializing Party, Lilly shall have sole-decision-making authority for all actions relating to Patents to Licensed Products (including the Lilly Patents, Transition Patents and Jointly Owned Patents). After a Party is deemed the Commercializing Party under Article 4, the Commercializing Party shall have sole-decision-making authority for all actions relating to Patents to Licensed Products (including the Lilly Patents, Transition Patents and Jointly Owned Patents). The sole-decision making authority for all actions relating to Patents to Licensed Products (including the Lilly Patents, Transition

Patents and Jointly Owned Patents) shall be referred to as the "IP Party" in this Article 14. Actions relating to Patents to Licensed Products include without limitation Patent Prosecution, defense, listing in regulatory publications (such as the FDA Orange Book and any foreign equivalent), patent term extension, abandonment, maintenance and enforcement, all of which will be conducted at the IP Party's sole expense. The IP Party shall establish an overall strategy for the filing, prosecution and maintenance of the Lilly Patents, Transition Patents and Jointly Owned Patents. The primary objective of such strategy shall be to provide patent exclusivity for the Licensed Products and uses thereof in the major pharmaceutical markets. The IP Party shall keep the JDC and other Party informed of the status of all actions taken with respect to the Lilly Patents, Transition Patents and Jointly Owned Patents. In particular, the IP Party shall (a) regularly and promptly provide the other Party with copies of all prospective patent applications and patent applications filed hereunder for such Patents and other material submissions and correspondence with government agencies concerning such Patents, in sufficient time to allow for review and comment by the other Party and (b) provide the other Party and its patent counsel with an opportunity to consult with the IP Party and its patent counsel regarding the filing and contents of any such application, amendment, submission or response, and the advice and suggestions of the other Party and its patent counsel shall be taken into consideration in good faith by the IP Party and its patent counsel.

14.3 Patent and Trademark Oppositions

The Commercializing Party will decide whether and how to participate in Patent and trademark oppositions and undertake activities intended to invalidate Third Party Patents or trademarks when necessary.

14.4 Costs of Patent Prosecution

All costs for Patent Prosecution of Patents relating to Licensed Products including the Lilly Patents, Transition Patents, and Jointly Owned Patents shall be borne by the IP Party. However, the IP Party may in its sole discretion elect to discontinue Patent Prosecution in any country on a Patent-by-Patent basis. The IP Party shall give prompt notice to the other Party if it declines to pay costs for the filing, prosecution or maintenance of a Patent in any country, and in such case, the other Party shall have the right to file, prosecute or maintain such Patent at its own expense. If the other Party decides to file, prosecute or maintain such Patent, the IP Party shall promptly deliver to the other Party copies of all necessary files related to the Patent with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for the other Party to assume such responsibility and shall promptly assign such Patent to the other Party. As of the date of the notice, such Patent shall no longer be included in the Lilly Patents, Transition Patents or Jointly Owned Patents, as applicable, under this Agreement or be included in this Agreement.

14.5 Patent and Trademark Prosecution Cooperation

With respect to all Patent Prosecution each Party shall:

(a) execute any instruments to document their respective ownership consistent with this Agreement as reasonably requested by the other Party;

(b) make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable the appropriate Party hereunder to undertake its Patent Prosecution responsibilities;

(c) cooperate, if necessary and appropriate, with the other Party in gaining Patent term extensions; and

(d) endeavor in good faith to coordinate its efforts under this Agreement with the other Party to minimize or avoid interference with the Patent Prosecution of the other Party's Lilly Patents or Transition Patents, as applicable.

14.6 **Enforcement**

(a) **Notice**

Each Party shall promptly provide written notice to the other Party reasonably detailing any known or alleged infringement of any Patent owned or Controlled by either Party and subject to a license under this Agreement.

(b) **Enforcement of Intellectual Property Rights**

The Commercializing Party shall have the right to institute and direct legal proceedings against any Third Party believed to be infringing or misappropriating or otherwise violating a Patent or Know-How or Confidential Information covering the Lead Compounds, Backup Compounds or Licensed Products. If the Commercializing Party does not abate such violation of intellectual property rights of Patents including by commencement of a lawsuit against the accused person if necessary, within sixty (60) days after receiving notice of such infringement of such Patent and immediately after notice of other violation of such Know-How or Confidential Information, then the other Party shall be entitled (but shall not be obligated) to take all actions reasonably necessary to abate such violation, including commencement of a lawsuit against the accused person if necessary; provided, however, the other Party shall consult in advance with the Commercializing Party, regarding such action and may not undertake any enforcement action without the prior approval of the JDC. The primary objective of any patent enforcement action shall be to preserve exclusivity for the Licensed Product and uses thereof in the major pharmaceutical markets. All amounts recovered from enforcement of any such rights by Lilly relating to the intellectual property licensed under this Agreement shall be first used to reimburse each Party's costs and expenses incurred in connection with such action, and any remainder of such recovery shall be deemed "Net Sales" for which the Commercializing Party shall pay the other Party a royalty under Article 9.4, 9.5 and 9.6 as the case may be, provided that in the event that the recovery shall be in the form of reasonable royalties, then the Commercializing Party shall pay to the other Party *(deleted text: specific rate*) of the amount of such royalties received by the Commercializing Party. The Parties shall keep each other informed of the status of and of their respective activities regarding any enforcement action pursuant to this Article.

(c) **Cooperation in Enforcement Proceedings**

For any action by a Party pursuant to subarticle (b), above, in the event that such Party is

unable to initiate or prosecute such action solely in its own name, the other Party will join such action voluntarily and will execute all documents necessary for such Party to initiate, prosecute and maintain such action. If either Party initiates an enforcement action pursuant to Article 14.6(b), then the other Party shall cooperate to the extent reasonably necessary and at the first Parties' sole expense (except for the expenses of the non-controlling Party's counsel, if any). Upon the reasonable request of the Party instituting any such action, such other Party shall join the suit and can be represented in any such legal proceedings using counsel of its own choice. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties reasonably the subject thereof.

14.7 **Defense**

(a) Each Party shall notify the other in writing of any allegations it receives from a Third Party that the manufacture, production, use, development, sale or distribution of any Licensed Product or any technology or intellectual property licensed by a Party under this Agreement infringes the intellectual property rights of such Third Party. Such notice shall be provided promptly, but in no event after more than fifteen (15) business days, following receipt of such allegations.

(b) In the event that a Party receives notice that it or any of its Affiliates have been individually named as a defendant in a legal proceeding by a Third Party alleging infringement of a Third Party's Patents or other intellectual property right as a result of the manufacture, production, use, development, sale or distribution of Licensed Products or any technology or intellectual property licensed by a Party under this Agreement, such Party shall immediately notify the other Party in writing and in no event notify such other Party later than ten (10) business days after the receipt of such notice. Such written notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties reasonably the subject thereof. In such event, the Parties shall agree how best to mitigate or control the defense of any such legal proceeding; provided however, the Commercializing Party shall assume the primary responsibility for the conduct of the defense of any such claim at the Commercializing Party's expense. The other Party shall have the right, but not the obligation, to participate and be separately represented in any such suit at its sole option and at its own expense. The other Party shall reasonably cooperate with the Commercializing Party conducting the defense of the claim. If a Party or any of its Affiliates have been individually named as a defendant in a legal proceeding relating to the alleged infringement of a Third Party's Patents or other intellectual property right as a result of the manufacture, production, use, development, sale or distribution of Licensed Products, the other Party shall be allowed to join in such action, at its own expense.

(c) **Status; Settlement**

The Parties shall keep each other informed of the status of and of their respective activities regarding any infringement litigation initiated by a Third Party concerning a Party's manufacture, production, use, development, sale or distribution of Licensed Products or settlement thereof; provided, however, that no settlement or consent judgment or other voluntary final disposition of a suit under this Article 14.7(c) may be undertaken by a Party without the

consent of the other Party which consent shall not be unreasonably withheld or delayed.

15. TERM AND TERMINATION

15.1 Term and Expiration

This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Articles 15.2 or 15.3, this Agreement shall continue in effect until the expiration of all payment obligations hereunder (the "Term"). Upon the natural expiration of this Agreement contemplated in this Article 15.1, Lilly's licenses, or Transition's licenses in the event Transition is the Commercialization Party, granted under this Agreement shall become fully paid-up, exclusive, and perpetual licenses.

15.2 Termination by Lilly

Lilly may terminate this Agreement by giving thirty (30) days advance written notice to Transition, if Transition has not filed an IND for the Lead Compound in accordance with Article 2.1(b), or if the Parties mutually agree not to continue Development of the Lead Compound or Backup Compound.

15.3 Unilateral Termination by Transition

Except for when Lilly is the Commercializing Party as provided in Article 4.3, Transition shall have the right to terminate this Agreement, in its entirety on a worldwide basis, in its sole discretion by giving thirty (30) days advance written notice to Lilly.

15.4 Termination for Cause

This Agreement may be terminated at any time during the Term upon written notice by either Party if the other Party is in material breach of its obligations under this Agreement and has not cured such breach within [ninety (90) days] after receiving written notice requesting cure of the breach.

15.5 Effect of Termination

(a) If Transition terminates this Agreement pursuant to Article 15.3 or if Lilly terminates the Agreement pursuant to Article 15.2, then:

(i) Transition shall use its Commercially Reasonable Efforts to transfer to Lilly as soon as practicable, and in accordance with Subparagraphs (iii) and (iv) below, all Transition Know-How, regulatory materials and other information reasonably necessary to the Licensed Product as promptly as practicable so as to permit Lilly to continue Development efforts with respect to Licensed Product should Lilly elect to do so. In addition, for a period of ninety (90) days from the effective date of termination, Transition will without charge provide such consultation or other assistance as Lilly may reasonably request to assist Lilly in becoming familiar with such Transition Know-How, regulatory filings and the like in order that Lilly may prepare to undertake Development and Commercialization of the Licensed Product.

(ii) The right to Develop and Commercialize Licensed Product shall be exclusively with Lilly and any licenses granted to Transition under Articles 10.1 and 10.2 shall terminate. Transition shall grant and hereby grants Lilly, effective as of the date of termination, a worldwide, royalty-bearing, sublicenseable, exclusive license under the Transition Patents and Transition Know-How and Jointly Owned Patents as the same exist as of the effective date of termination, to make, have made, use, sell, offer for sale and import Licensed Product. In consideration for such license and provided Transition completes the POC Study and provides the Final Data of same to Lilly, Lilly shall pay to Transition *(deleted text: specific royalty rate)* of the worldwide annual net sales of any Licensed Product that is or was discovered or developed by Transition pursuant to their development activities under this Agreement. Net sales of any such product shall be calculated in the same manner as set forth in the definition of "Net Sales" in Article 1.33 and the payment and audit provisions of Articles 9.11 through 9.15 (inclusive) shall apply *mutatis mutandis* for the royalties payable to Transition under this Article 15.5(a)(ii).

(iii) Unless Lilly and Transition agree otherwise, all activities underway at the time of termination shall be transferred to Lilly or terminated as soon as possible except that Transition will continue to be responsible for any pre-clinical or clinical studies to the extent that Transition's then current ethical guidelines would require Transition to complete such studies. All costs of continuing trials for ethical reasons or winding down activities shall continue to be borne by Transition until completion of such activities. For the sake of clarity the costs of winding down activities shall include any incurred costs or otherwise unavoidable wind down costs that would otherwise have been payable by Transition. For the sake of clarity the costs of continuing trials for ethical reasons shall be the costs, if any, to continue treatment of current patients under treatment in the trial in accordance with Transition's ethical guidelines.

(iv) Transition shall transfer to Lilly all INDs, and other regulatory filings and approvals held by Transition, on a country-by-country basis, for Licensed Product. In the event that in any country such a transfer is not legally possible, then Transition shall (and shall cause its Affiliates to) and subject to the rights of a Sublicensee under this Agreement that has been granted rights by Transition, take all reasonable actions that are permitted by the applicable Regulatory Authority to permit Lilly to also have the benefit of the relevant marketing authorizations, INDs and other regulatory filings and approvals that exist at the time of termination for Licensed Product, including allowing Lilly to cross reference data and information on file with any Regulatory Authority.

(b) If Transition terminates this Agreement pursuant to Article 15.4, then, effective immediately upon the expiration of the cure period specified therein (the "**Termination Date**"), Lilly shall cease to have any rights to Develop and Commercialize the Licensed Products and all such rights shall be exclusively given to Transition, subject only to Transition's payment obligations under Article 9.5. Promptly following the Termination Date and except to the extent Regulatory Authorities and applicable laws require Lilly to complete any studies, Lilly shall comply with the same transfer and assistance obligations of Article 4.5 for a period of ninety (90) days following the Termination Date. For the avoidance of doubt, for purposes of this Article 15.5(b), Lilly's license under Article 10.3 shall be deemed terminated and Transition's licenses under Articles 10.1 and 10.2 shall be deemed granted and effective, immediately upon the Termination Date.

(c) If either Party has the right to terminate this Agreement under Article 15.4, it may at its sole option, elect either to (i) terminate this Agreement and pursue any legal or equitable remedy available to it or (ii) maintain the Agreement in effect and pursue any legal or equitable remedy available to it.

15.6 **Survival**

The following provisions shall survive the termination or expiration of this Agreement for any reason: Articles 1, 4.5, 5.3(d), 6.2, 7, 9.1 to 9.5 and 9.7 (to the extent payments have accrued prior to termination), 9.6, 9.8 to 9.13, 10.1 and 10.2 (solely for purposes of Transition's rights pursuant to 15.5(b)), 10.4, 11, 12, 13 (with respect to actions undertaken prior to the effective date of termination and giving rise thereto), 14.1, 14.2 to 14.7 (solely for purposes of Transition's rights pursuant to 15.5(b) or Lilly's rights pursuant to 15.5(a)(ii)), 15, 16, and 17. The terms from Article 8 of this Agreement, as pertains to both parties regulatory or safety obligations, will survive termination of this agreement per applicable regulations.

16. **DISPUTE RESOLUTION**

16.1 **Disputes**

The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in Section 16.2 if and when such a dispute arises between the Parties.

16.2 **Mediation Procedures**

If any dispute, controversy or claim arises between the Parties that cannot be resolved the Parties agree to attempt to resolve such dispute, controversy or claim (except as to any issue relating to intellectual property) by non-binding mediation administered by the American Arbitration Association ("AAA") in accordance with its commercial mediation rules. Unless otherwise agreed by the Parties, the mediation shall be held in New York, New York and shall be attended by the Chief Executive Officer of Transition or designee and the Chief Executive Officer of Lilly or designee. The mediation shall be held on a mutually agreeable date which shall not be later than thirty (30) days following any Party's request for mediation. The fees of the mediator shall be shared equally by the Parties.

17. **MISCELLANEOUS**

17.1 **Force Majeure**

Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, but not limited to, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other

labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

17.2 **Article 365(n) of the Bankruptcy Code**

All rights and licenses granted under or pursuant to any Article of this Agreement are, and shall otherwise be deemed to be, for purposes of Article 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Article 101(35A) of the U.S. Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. The Parties agree that a Party that is a licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code, and that upon commencement of a bankruptcy proceeding by or against the licensing Party (such Party, the "Involved Party") under the U.S. Bankruptcy Code, the other Party (such Party, the "Noninvolved Party") shall be entitled to a complete duplicate of or complete access to (as such Noninvolved Party deems appropriate), any such intellectual property and all embodiments of such intellectual property, provided the Noninvolved Party continues to fulfill its payment or royalty obligations as specified herein in full. Such intellectual property and all embodiments thereof shall be promptly delivered to the Noninvolved Party (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by the Noninvolved Party, unless the Involved Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the Involved Party upon written request therefor by Noninvolved Party. The foregoing is without prejudice to any rights the Noninvolved Party may have arising under the U.S. Bankruptcy Code or other applicable law. To the extent the laws of Ontario or Canada are applicable to the subject matter of this Article 17.2, the Parties agree that their intent is to effect a result as similar as possible to that which is otherwise intended by this provision, including the benefit of Article 32(5) of the Companies' Creditors Arrangement Act and Article 65.11(7) of the Bankruptcy and Insolvency Act, as currently proposed.

17.3 **Assignment**

Neither Party may assign its rights and obligations under this Agreement without the prior written consent of the other Party such consent not to unreasonably withheld, provided that (a) either Party may assign its rights and obligations under this Agreement to (i) its Affiliates, (ii) as part of a sale of all or substantially all of its assets or all of its assets to which this Agreement relates to a Third Party, or (iii) as part of a merger with, sale of stock to, or other consolidation, amalgamation or reorganization and (b) Transition may assign rights to a financing entity, and in each of the foregoing cases without such consent from the other Party.

17.4 **Severability**

If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the

invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

17.5 **Notices**

All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Transition, to:	Tony Cruz Chief Executive Officer Transition Therapeutics Inc. 101 College Street, Suite 220 Toronto, Ontario, Canada M5G 1L7
	(deleted text: fax number)
with copy to:	Carl Damiani VP Business Development Transition Therapeutics Inc. 101 College Street, Suite 220 Toronto, Ontario, Canada M5G 1L7
	(deleted text: fax number)
if to Lilly, to:	Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285 Attn: Office of Alliance Management
	(deleted text: fax number)
with copy to:	Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285 Attn: General Patent Counsel
	(deleted text: fax number)

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been

given: (a) when delivered if personally delivered or sent by facsimile on a business day (provided that if given by facsimile, the transmitting Party received confirmation of complete transmission); (b) on the business day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth business day following the date of mailing if sent by mail.

17.6 Applicable Law and Litigation

All questions of inventorship will be determined in accordance with U.S. patent laws. In respect to all other Patent issues, the rights of the Parties will be governed by the laws of the jurisdiction in which the applicable Patent is filed or granted. In all other respects, this Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to any rules of conflict of laws.

17.7 Entire Agreement; Amendments

The Agreement contains the entire understanding of the Parties with respect to the collaboration and licenses granted hereunder. All express or implied agreements and understandings, either oral or written, with regard to the collaboration and the licenses granted hereunder are superseded by the terms of this Agreement. The Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

17.8 Headings

The captions to the several Articles hereof are not a part of the Agreement, but are merely for convenience to assist in locating and reading the several Articles and Articles of this Agreement.

17.9 Independent Contractors

It is expressly agreed that Transition and Lilly shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Transition nor Lilly shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

17.10 Waiver

The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

17.11 Cumulative Remedies

No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

17.12 **Waiver of Rule of Construction**

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

17.13 **Construction**

Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein means including, without limiting the generality of any description that precedes such term. References to "Article" or "Articles" are references to the numbered Articles of this Agreement, unless expressly stated otherwise.

17.14 **Use of Third Parties**

It is understood that when a Party engages any Third Party to manufacture any Licensed Product, that engagement may require a limited license or limited sublicense of rights obtained from the other Party under this Agreement. In addition to Transition's rights to sublicense under Article 10, the Party engaging such Third Party (or non-licensed Affiliate) may disclose Confidential Information of the other Party solely as necessary to fulfill the business purposes of the engagement, and then only pursuant to terms and conditions that are substantially as protective of that Confidential Information as the terms and conditions of this Agreement. Notwithstanding any delegation of obligations under this Agreement by a Party to its Affiliates or to a Third Party, whether related to manufacture of Licensed Product (marketed or investigational) or otherwise, the Party shall remain primarily liable and responsible for the performance of all of its obligations under this Agreement and for causing such Affiliates or Third Parties to act in a manner consistent herewith. In addition, such Party shall assure that any intellectual property developed by its Affiliates or such Third Parties shall be Controlled by that Party and included in and subject to the licenses set forth in Article 10. The Party contracting with such Third Party shall not agree to any term that would make it unable to comply with its obligations under this Agreement.

17.15 **Counterparts**

The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the parties.

The Parties have executed this Agreement as of the Effective Date.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

TRANSITION THERAPEUTICS INC.

By: _____
Name: Tony Cruz
Title: Chief Executive Officer

ELI LILLY and COMPANY

By: _____
Name:
Title:

EXHIBIT A: Initial Development Plan

(deleted text: details of Initial Development Plan)