SUPPLY AGREEMENT (LZ#49700)

This **SUPPLY AGREEMENT** (this "**Agreement**") is entered into as of September 29, 2015 (the '**Effective Date**"), by and between **BRAEBURN PHARMACEUTICALS**, **INC**., a Delaware corporation ("**Braeburn**"), and **LUBRIZOL ADVANCED MATERIALS**, **INC**., a Delaware corporation ("**Lubrizol**"). Braeburn and Lubrizol are sometimes herein referred to individually as a "**Party**" and together as the "**Parties**."

RECITALS

WHEREAS, Braeburn specializes in long-acting treatment options for individuals with serious neurological and psychiatric disorders;

WHEREAS, Braeburn is developing an implantable drug delivery system (as further defined below, the 'IDDS Product'), including a specific application of the IDDS where risperidone is used as the API (as further defined below, the "Risperidone IDDS Product") and, independently and in conjunction with IDDS Commercial Partners (as further defined below), other applications with different API, and desires to use Lubrizol's implantable thermoplastic polyurethane ("TPU") resin and tubing product as an excipient in the Risperidone IDDS Product and other IDDS Products; and

WHEREAS, on the terms and subject to the conditions of this Agreement, Braeburn desires to purchase the TPU product (as defined further below, the "Product") exclusively from Lubrizol for use as an excipient in the Risperidone IDDS Product and other IDDS Products, and Lubrizol desires to manufacture and sell Product to Braeburn on an exclusive basis for use in IDDS Products protected by Braeburn IP (as defined further below), subject to the terms and conditions set forth below

NOW, THEREFORE, in consideration of the foregoing premises and of the mutual covenants of the Parties hereinafter set forth, the Parties hereto agree as follows:

ARTICLE 1

DEFINITIONS

- 1.1 <u>Definitions</u>. As used in this Agreement, the following terms shall have the meanings set forth below:
- "Active Ingredient" shall have the meaning given to it in Title 21 of the U.S. Code of Federal Regulations Part 201.
- "Affiliate" means any Person which directly or indirectly through one (1) or more intermediaries controls, is controlled by or is under common control with a Party. A Person shall be deemed to "control" another Person if it (a) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

percentage which is the maximum allowed to be owned by a Person in a particular jurisdiction) of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the Person. Notwithstanding the foregoing, the following entities shall not be considered Affiliates of Braeburn: Apple Tree Partners IV, L.P., Apple Tree Partners III, L.P. and their portfolio companies. Notwithstanding the foregoing, Berkshire Hathaway Inc. shall not be considered an Affiliate of The Lubrizol Corporation.

- "Agreement" has the meaning set forth in the Preamble.
- "Alternate Facility" has the meaning set forth in Section 2.1.
- "API" means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product; such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- "Applicable Laws" means, with respect to any jurisdiction, individually and collectively, any federal, state, local, national and supra-national laws, treaties, statutes, ordinances, rules and regulations, directives, orders, guidelines and guidances, including those generated by the agencies or instrumentalities of such jurisdiction, including securities listing organizations, that are in effect from time to time during the Term and applicable to a particular activity hereunder.
 - "Backup Resin" has the meaning set forth in Section 2.6(c).
 - "Backup Supply" has the meaning set forth in Section 2.6(b).
 - "Binding Portion" has the meaning set forth in Section 2.2.
 - "Braeburn" has the meaning set forth in the Preamble.
 - "Braeburn IP" has the meaning set forth in Section 6.2.
 - "Business Day" means a day other than a Saturday or a Sunday on which banking institutions in New York, New York are open for business.
- "Change in Control" means with respect to any Party any of the following events: (a) any Third Party (or group of Third Parties acting in concert) becomes the beneficial owner, directly or indirectly, of more than 50% of the total voting power of the stock then outstanding of such Party normally entitled to vote in elections of directors; (b) such Party consolidates with or merges into a Third Party or any Third Party consolidates with or merges into such Party, in either event pursuant to a transaction in which more than 50% of the total voting power of the stock outstanding of the surviving entity normally entitled to vote in elections of directors is not held

- "Claims" has the meaning set forth in Section 9.1.
- "Confidential Information" has the meaning set forth in Section 7.1 (a).
- "Controls" or "Controlled" means possession of the ability to grant the licenses or sublicenses as provided herein without violating the terms of any agreement or other arrangement with any Third Party.
 - "CTD Format" has the meaning set forth in Section 3.4.
 - "Delivery Point" has the meaning set forth in Section 2.4.
 - "Disclosing Party" has the meaning set forth in Section 7.1(a).
 - "DMF" has the meaning set forth in Section 3.4.
 - "Effective Date" has the meaning set forth in the Preamble.
 - "EMA" means the European Medicines Agency for the Evaluation of Medicinal Products of the European Union, or any successor agency thereto.
- "European Commission" means the executive body of the European Union that has legal authority to grant marketing authorization approvals for pharmaceutical products in the European Union following scientific evaluation and recommendation from the EMA or other applicable Regulatory Authorities.
- "European Union" means all countries that are officially recognized as member states of the European Union, including their territories and possessions, at any particularly time during the Term, presently including: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom.
 - "Excipient" means an inactive ingredient, as defined in Title 21 of the U.S. Code of Federal Regulations Part 201.
 - "Extension Term" has the meaning set forth in Section 10.1.
 - "FDA" means the U.S. Food and Drug Administration, or any successor entity thereto.
 - "Field of Use" means [***].
 - "Forecast" has the meaning set forth in Section 2.2.
 - "GMP" has the meaning set forth in Section 3.1.
 - "GMP Product" means [***].
 - "GMP Supply" has the meaning set forth in Section 2.1.

3

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

"IDDS Commercial Partner" means any Third Party to whom Braeburn has licensed rights to Braeburn IP to develop an IDDS Product to deliver API for one or more therapeutic indications.

- "IDDS Product" means [***].
- "Improvement" means all discoveries, developments, modifications, innovations, updates, enhancements and improvements (whether or not proprietary or protectable under patent, trademark, copyright or similar Applicable Laws).
 - "Indemnitee" has the meaning set forth in Section 9.3.
 - "IPEC" means the International Pharmaceutical Excipients Council.
 - "Losses" has the meaning set forth in Section 9.1.
 - "Lubrizol" has the meaning set forth in the Preamble.
 - "Manufacturing Facility" has the meaning set forth in Section 2.1.
 - "Module 3 Information" has the meaning set forth in Section 3.4.
- "NDA" means any new drug application filed with the FDA pursuant to Part 314 of Title 21 of the U.S. Code of Federal Regulations seeking Regulatory Approval of an IDDS Product, and all amendments and supplements thereto filed with the FDA.

- "Net Sales" means, [***].
- "Nonconforming Product" has the meaning set forth in Section 3.3(a).
- "Nonconformity" has the meaning set forth in Section 3.3(a)
- "Non-GMP Product" means [***].
- "Non-GMP Supply" has the meaning set forth in Section 2.1.
- "Party" and "Parties" have the meaning set forth in the Preamble.
- "Person" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.
 - "PO" has the meaning set forth in Section 2.3.
 - "PQG" means the Pharmaceutical Quality Group.
 - "Product" means GMP Product or Non-GMP Product.
 - "Product Requirements" has the meaning set forth in Section 3.3(b).

4

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

- "Quality Agreement" has the meaning set forth in Section 3.5.
- "Receiving Party" has the meaning set forth in Section 7.1.
- "Regulatory Approval" means any official approval or authorization by the FDA or other Regulatory Authority that is legally required to lawfully import, market, sell, offer for sale and distribute any IDDS Product in a jurisdiction, including approval of an NDA by the FDA or the marketing authorization granted by the European Commission or the competent authorities of the European Union.
- "Regulatory Authority" means any national, supranational, regional, state or local regulatory agency or competent authority, department, bureau, commission, council or other governmental entity with whom Lubrizol is able to conduct business that is involved in granting Regulatory Approval.
- "Regulatory Filing" means any investigational new drug application, or IND, IND annual report, DMF or report related thereto, NDA, marketing authorization application, or other filing with a Regulatory Authority in any jurisdiction that may reasonably be expected to affect the Product.
 - "Required Improvement" has the meaning set forth in Section 5.1.
 - "Risperidone IDDS Product" means [***].
 - "Royalty-Bearing Product" means [***].
 - "Royalty Payment" has the meaning set forth in Section 4.4(b).
 - "Royalty Report" has the meaning set forth in Section 4.4(b).
- "Royalty Term" means, with respect to each Royalty-Bearing Product, on a country-by-country basis, the period beginning on the first commercial sale of that product and ending on the earlier of (a) the later of (i) the expiration of the last valid claim in an issued patent owned or controlled by Braeburn claiming the Royalty-Bearing Product, and (ii) the expiration of the last marketing exclusivity covering the Royalty-Bearing Product granted by a Regulatory Authority, and (b) the approval by a Regulatory Authority of an abbreviated new drug application (or any non-US equivalent) for a product with the Royalty-Bearing Product as the reference product.
 - "Safety Stock" has the meaning set forth in Section 2.5.
 - "Significant Change" has the meaning set forth in Section 3.6.
 - "Specifications" has the meaning set forth in Section 3.3(a).
 - "Supply Failure" means [***].
 - "Term" has the meaning set forth in Section 10.1.

5

- "Third Party" means any Person other than Lubrizol or Braeburn or an Affiliate of Lubrizol or Braeburn.
- "TPU" has the meaning set forth in the Recitals.
- "TPU Improvements" has the meaning set forth in Section 6.1.

ARTICLE 2

REQUIREMENTS; PRODUCT ORDERS

- 2.1 <u>Requirements Contract; Exclusivity.</u> Except as provided in <u>Section 2.6</u>, during the Term and subject to the terms and conditions in this Agreement, Braeburn shall exclusively purchase from Lubrizol, and Lubrizol shall supply to Braeburn, all of Braeburn's requirements for GMP Product in the Field of Use for (a) use in clinical trials for IDDS Products, and (b) use in the manufacture of IDDS Products (collectively, the "'GMP Supply"). Lubrizol shall also supply to Braeburn, from time to time as reasonably requested by Braeburn, Non-GMP Product for research purposes by Braeburn or Braeburn's Third Party commercial partners but not for use in human clinical trials (the "Non-GMP Supply"). Lubrizol shall [***] in accordance with <u>Section 3.2</u> (each, a "Manufacturing Facility"). [***].
- 2.2 <u>Forecasts.</u> Within [***] days after the Effective Date, Braeburn shall deliver to Lubrizol a forecast of its anticipated requirements for the Product for [***] (the "Forecast"). No later than [***]. Except for the first calendar quarter of each Forecast, which shall be binding on the Parties (the **Binding Portion**"). Forecasts shall be nonbinding and used and relied upon by Lubrizol only for Lubrizol's internal capacity planning purposes, including calculation of the quantities required for Backup Supply and Backup Resin.
- 2.3 Purchase Orders. All purchases of the Product shall be pursuant to purchase orders (each, a 'PO") submitted by Braeburn to Lubrizol which shall specify (a) which Product to be ordered (e.g., the GMP Product or Non-GMP Product), (b) the quantity of Product ordered, and (c) the requested delivery date, which shall be no less than [***] days after submission of the PO. POs may be changed only by the mutual written agreement of the Parties. The minimum quantity of Supply that may be ordered in any individual PO is [***]. [***]. This Agreement sets forth the exclusive contract terms between the Parties with respect to, and shall apply to, all orders of the Product. Any terms in any PO, order form, invoice or other notice submitted by either Party to the other Party that are different from or additional to the provisions of this Section 2.3 shall be null and void notwithstanding Lubrizol's delivery of, and Braeburn's acceptance of, Product under any PO, order form, invoice or other notice containing such terms.

6

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

- 2.4 <u>Shipment; Delivery.</u> Product shall be packaged [***] in accordance with mutually agreed terms. Lubrizol shall deliver the Product no more than [***] days before or after the requested date of delivery specified in the PO, provided such Product has been previously validated by Lubrizol. [***].
- 2.5 Capacity. Lubrizol shall maintain capacity adequate to fulfill the Product requirements of Braeburn as specified in the Binding Portion of the [***]. [***]. To help prevent a Supply Failure, Lubrizol shall maintain a minimum inventory of the finished Product for use in the Risperidone IDDS Product and each other IDDS Product for which a Forecast has been provided in its warehouse at all times during the Term specifically designated for use by Braeburn ("Safety Stock"), and to maintain Backup Supply and Backup Resin as provided in Section 2.6 below. Unless otherwise agreed by the Parties in writing, the minimum inventory required as Safety Stock shall be [***]. Lubrizol hereby agrees to give timely notice to Braeburn of any event that would reasonably be expected to adversely affect Lubrizol's capacity or ability to deliver the Product in accordance with the Binding Portion of the [***] or this Agreement. In the event of termination by Braeburn prior to the end of the Term pursuant to Section 10.3, Braeburn agrees to pay Lubrizol for the Safety Stock and, at Braeburn's sole discretion, either take possession of the Safety Stock, or direct Lubrizol to dispose of the Safety Stock. Braeburn shall have the unilateral right to direct Lubrizol to lower the quantity of Safety Stock by written notice to Lubrizol, but both Parties must agree to any increase in the quantity of Safety Stock. Braeburn's obligation to pay for Safety Stock following notice of a reduction in the amount of Safety Stock to be maintained shall extend to the full quantity of Safety Stock maintained by Lubrizol until the Safety Stock is decreased by fulfillment of POs to the new quantity established by written notice by Braeburn.

2.6 <u>Preservation of Supply</u>.

- (a) As described in Section 2.1, it is the intent of the Parties that Lubrizol shall exclusively supply Braeburn with GMP Product for use in the Field of Use during the Term and on the terms and conditions set forth in this Agreement. It is also the intent of the Parties that Lubrizol shall ensure that there is no interruption in provision of Supply due to a temporary interruption in manufacturing ability or capacity at the Manufacturing Facility, including any damage to the Manufacturing Facility outside of Lubrizol's reasonable control. The Parties acknowledge that when there are decreases in demand, the quantities of Backup Supply and Backup Resin will be higher than otherwise required based on the prior Forecast until the Safety Stock is equalized to meet a lower demand level.
- (b) In addition to GMP Product and non-GMP Product manufactured to satisfy a PO pursuant to Section 2.3, and in addition to the maintenance of Safety Stock pursuant to Section 2.5. Lubrizol agrees to manufacture and preserve a separate [***] inventory of finished GMP Product for use in the Risperidone IDDS Product and each other IDDS Product for which a Forecast has been provided that will be stored in a secure, commercial warehouse separate from the Manufacturing Facility campus (the "Backup Supply"). The precise quantity of finished GMP Product to be preserved as Backup Supply shall be no less than the total amount of finished GMP Product specified for the third and fourth quarters in the most recent Forecast provided by Braeburn. [***]. In the event of termination by Braeburn prior to the end of the Term, Braeburn agrees to pay Lubrizol for the Backup Supply and, at Braeburn's sole

7

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

discretion, either take possession of the Backup Supply or direct Lubrizol to dispose of the Backup Supply.

- (c) In addition to maintenance of Backup Supply, Lubrizol shall manufacture and preserve [***] (the "Backup Resin"). The [***]. The Backup Resin shall be actively managed by Lubrizol [***]. In the event of termination by Braeburn prior to the end of the Term, Braeburn agrees to pay Lubrizol for the Backup Resin [***].
 - (d) Notwithstanding any contrary term in this Agreement. [***].

- 3.1 GMP Qualification Activities. Lubrizol agrees to manufacture GMP Product at its Manufacturing Facility according to current good manufacturing practices [***], or, if such guide is updated in a subsequent published version, the most recent version ("GMP"). Lubrizol shall, at its sole cost, update its manufacturing processes as may be required to maintain compliance with GMP. Lubrizol shall also obtain and maintain GMP certification for making the Product at its Manufacturing Facility by a Third Party when and if required by Applicable Laws. Lubrizol further agrees to incorporate any additional manufacturing practices at its Manufacturing Facility as may be required by a Regulatory Authority specific to the Excipient to support Regulatory Approval for an IDDS containing the Product, provided that Braeburn shall bear the costs of incorporating any such manufacturing practices that exceed GMP as defined herein on a pass-through cost basis. Braeburn agrees that Lubrizol shall determine the specific changes in manufacturing practices related to the excipient required to meet specifications by a Regulatory Authority based on Lubrizol's technical expertise, provided that Lubrizol ensures that manufacturing practices are implemented to ensure Regulatory Approval by a Regulatory Authority in a cost-effective manner.
 - 3.2 <u>Use of Alternate Facility.</u> [***].
 - 3.3 Product Warranty; Product Requirements; Recall Notices; Nonconforming Products
- (a) <u>Product Warranty.</u> Lubrizol warrants that Products supplied to Braeburn under this Agreement shall, when delivered to Braeburn, conform with the specifications set forth in <u>Exhibit B</u>, as may be amended from time to time by mutual agreement (the **Specifications**"). A Product that does not conform with the Specifications set forth at <u>Exhibit B</u> at the time it is delivered to Braeburn is referred to in this Agreement as a **Nonconforming Product**," and such Product shall be regarded as having a "**Nonconformity**." Specifications for GMP Products and Non-GMP Products may be changed in connection with a Required Improvement under <u>Article 5</u>. Braeburn acknowledges that any change in Specifications that requires a new validation would require [***] to produce Product batches consistent with revised

8

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Specifications, which shall be set forth in an amendment to Exhibit B. For avoidance of doubt, Braeburn expressly acknowledges that only GMP Products and Non-GMP Products shall be manufactured in accordance with the corresponding Specifications set forth in Exhibit B and under the trade names set forth in Section 1.1. Lubrizol agrees to promptly notify Braeburn in writing after Lubrizol obtains knowledge of its delivery to Braeburn of any Nonconforming Product.

- (b) <u>Product Requirements.</u> Products supplied by Lubrizol to Braeburn under this Agreement shall (i) be manufactured in accordance with Applicable Laws, the Quality Agreement, and, for GMP Products only, in compliance with GMP, and (ii) conform to the applicable PO (collectively, the "**Product Requirements**").
- (c) <u>Recall Notification</u>. Lubrizol shall notify Braeburn within (i) [***] of obtaining knowledge of any situation which may require a recall by Lubrizol of the GMP Product, and (ii) [***] of obtaining knowledge that any batch of Product has a Nonconformity.
- (d) <u>Braeburn's Acceptance Upon Delivery of Products.</u> [***]. If, within [***] days of delivery, Braeburn detects any Nonconformity, Braeburn shall give written notice to Lubrizol specifying the alleged Nonconformity. The Parties agree to work in good faith to verify whether the Product in question has a Nonconformity. Upon confirmation of a Nonconformity, Braeburn may select as its exclusive remedy, and Lubrizol shall provide at its expense, one of the following remedies within [***] days of receipt of Braeburn's notice of such Nonconforming Product: [***].
 - 3.4 Preparation and Filing of DMF and Module 3 Information; Right of Reference.
- (a) Prior to the Effective Date, Lubrizol compiled a comprehensive Type IV drug master file dossier for the Product consistent with the International Conference on Harmonization Common Technical Document format (the "CTD Format") (the "DMF"). Within [***] days after the Effective Date, Lubrizol will deliver to Braeburn the full Module 3 Information (restricted and unrestricted) for the Product intended for use in the Risperidone IDDS Product in CTD Format (the "Module 3 Information"). Braeburn and its Affiliates and sublicensees shall have the right to review the content of the DMF and the Module 3 Information before the DMF is filed with any Regulatory Authorities or before Braeburn and its Affiliates and sublicensees decide to submit the Module 3 Information to any Regulatory Authorities; provided, that Braeburn's sublicensees' right to review the DMF and the Module 3 Information shall be contingent on such sublicensees entering into a long-term confidentiality agreement reasonably acceptable to Lubrizol. Lubrizol shall make any changes to the DMF and provide any additional assistance that, in Braeburn's reasonable determination, are required for Regulatory Approval of the Risperidone IDDS Product or other IDDS Products consistent with requirements applicable to the excipient.
- (b) Upon approval of the DMF and the Module 3 Information by Braeburn, Lubrizol shall file the DMF with the FDA, (ii) duly fulfill all obligations of a holder of a Type IV drug master file dossier under Applicable Laws, (iii) provide letter(s) of authorization to Braeburn permitting Braeburn to reference the DMF for Braeburn's FDA filings with respect to an IDDS Product, and (iv) expeditiously address any issues that may arise with respect to the DMF while the NDA is undergoing review by the FDA.

9

- (c) Upon request of Braeburn, Lubrizol will provide Module 3 information to include in Braeburn's application for Regulatory Approval with the EU and Japan. Lubrizol further agrees to support Braeburn's efforts to obtain Regulatory Approval from other Regulatory Authorities, including in China, Korea, and Taiwan, where there may not be established procedures for filing a DMF and protecting its confidentiality. The Parties agree to work in good faith to determine mutually agreeable approaches to ensure protection of Lubrizol's Confidential Information on a case-by-case basis with each such Regulatory Authority.
- (d) Upon request by Braeburn and upon the terms and restrictions of the foregoing Section 3.4(c). Lubrizol shall provide letter(s) of authorization permitting the FDA or other Regulatory Authorities to reference and review the DMF in conjunction with the Regulatory Filings of a Third Party commercial partner of Braeburn to support Regulatory Approval for an IDDS Product.
- 3.5 Quality Agreement. Within [***] days after the Effective Date, the Parties shall enter into a quality agreement with respect to the Product consistent with the [***] (the "Quality Agreement"). If there are discrepancies regarding quality issues between the Quality Agreement and this Supply Agreement, the Quality Agreement will control.
 - 3.6 Manufacturing Changes. Except insofar as agreed by the Parties pursuant to the Quality Agreement, Lubrizol shall notify Braeburn as soon as

practicable of any significant change to the manufacture of the Product as provided in the Significant Changes Protocol set forth in Exhibit D (each, a "Significant Change"). Exhibit D may be updated from time to time by written agreement among the Parties in accordance with revisions to The IPEC Significant Change Guide for Pharmaceutical Excipients or as may be otherwise agreed among the Parties, including in accordance with Applicable Laws. Lubrizol shall notify Braeburn of any Significant Change to the manufacturing procedures or processes for GMP Product.

- 3.7 <u>Compliance with Laws.</u> The Parties shall comply with all Applicable Laws that pertain to the activities for which each Party is responsible under this Agreement.
- 3.8 Audits. Braeburn shall have the right, at Braeburn's expense and upon [***] days' notice, to audit Lubrizol's Manufacturing Facility and any other facilities that are used to manufacture and store the GMP Product or to maintain Backup Supply or Backup Resin, including to ensure GMP compliance. Such audits will be conducted [***], provided that such designee has entered into a confidentiality agreement reasonably acceptable to Lubrizol.
- 3.9 <u>Inspections</u>. Lubrizol shall promptly (a) notify Braeburn of any Regulatory Authority inspection of its facilities that are used to manufacture or store GMP Product and the results thereof, and (b) provide Braeburn with redacted copies of all inspection-related reports, documents, materials and correspondence which Lubrizol receives, obtains or generates pursuant to any such inspection or in connection with any inquiries, communications or correspondence from any Regulatory Authorities and pertaining to GMP Product, including, without limitation, FDA Forms 483, warning letters or equivalent communications and any related correspondence with FDA.
- 3.10 <u>Complaint Handling</u>. Lubrizol shall cooperate fully with Braeburn in addressing Braeburn's customer complaints that relate to GMP Product and shall take such action to

10

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

promptly resolve such complaints as may be reasonably requested by Braeburn. Lubrizol is responsible for complying with all FDA and applicable foreign regulatory requirements pertaining to the receipt, review, evaluation, and, where applicable, investigation of all complaints received pertaining to GMP Product. Braeburn is responsible for complying with all FDA and applicable foreign regulatory requirements pertaining to the receipt, review, evaluation, and where applicable, investigation of all complaints received pertaining to the IDDS Product and for the reporting of adverse events pertaining to the IDDS Product. Each Party shall reasonably cooperate with the other Party to enable the other Party to fulfill such requirements. Unless otherwise required by Applicable Law, Braeburn shall, within [***] of receipt of such information, provide adverse event and complaint information regarding GMP Product to Lubrizol, and Lubrizol shall, within [***] of receipt of such information, provide any complaint information it may receive regarding the IDDS Product to Braeburn.

- 3.11 <u>Insurance</u>. During the Term, Lubrizol shall maintain commercial general insurance or a program of self-insurance adequate to cover any Claims or Losses arising in connection with the manufacture or sale of GMP Product and until the date of delivery to Braeburn in coverage amounts consistent with normal business practices of prudent companies similarly situated. Lubrizol shall provide Braeburn with written evidence of such insurance upon request.
- 3.12 <u>Integration of Product into IDDS Product</u> Braeburn shall be solely responsible for integrating the Product into the IDDS Product and manufacturing, packaging, labeling and selling the IDDS Product in accordance with Applicable Laws.
- 3.13 <u>Braeburn Notification of Certain Material Events</u> During the Term, Braeburn shall [***] inform Lubrizol [***] of the occurrence of any the following events related to the IDDS Product: (a) any material Regulatory Filing made with a Regulatory Authority, such as an investigational new drug application (IND), or an annual report; (b) any Regulatory Approval granted by a Regulatory Authority; and (c) the first sale of a Royalty-Bearing Product by Braeburn, its Affiliate or a sublicensee to a Third Party on arms' length terms.

ARTICLE 4

FINANCIAL PROVISIONS

- 4.1 <u>Upfront Payment.</u> Within [***] days of receipt of an invoice from Lubrizol on or after the Effective Date, Braeburn shall pay to Lubrizol [***]. This upfront fee shall be non-refundable and non-creditable against any other payments due hereunder.
- 4.2 <u>Pricing: Invoices.</u> Braeburn shall pay to Lubrizol, [***]. The pricing set forth on <u>Exhibit A</u> shall be firm for [***]. After the [***] interval thereafter. [***] <u>Lubrizol shall invoice</u> Braeburn for [***]. Braeburn shall pay the full amount invoiced to it by Lubrizol in accordance with <u>Section 4.5</u> within [***] days of the date of the invoice.

11

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

4.3 <u>Milestone Payments.</u> Within [***] days of receipt of an invoice upon or after the achievement of each of the following milestones, Braeburn shall pay to Lubrizol the corresponding non-refundable, non-creditable payments set forth below in accordance with <u>Section 4.5</u>:

	Milestone	Milestone Payment
1.	[***]	[***]
2.	[***]	[***]
3.	[***]	[***]
4.	[***]	[***]

Braeburn shall provide Lubrizol with written notice of the achievement of milestones [***]. For the sake of clarity, Braeburn will pay each of milestones [***]. Milestones 1 and 2 shall each be paid [***]. Braeburn shall owe no payment for any milestone that is not achieved.

4.4 Royalties.

(a) <u>Royalty Rate</u>. During the Royalty Term and on a Royalty-Bearing Product-by-Royalty-Bearing Product basis, Braeburn shall pay to Lubrizol a royalty at the rate of [***] on Net Sales of Royalty-Bearing Products.

- (b) Royalty Reports. Within [***].
- (c) Royalty Payment. [***].
- 4.5 Payment Method. All amounts specified in, and all payments to be made under, this Agreement shall be in United States Dollars. [***].
- 4.6 <u>Taxes</u>.
- (a) Payment of Tax. The prices set forth on Exhibit A are exclusive of any customs charges and taxes, including value added taxes, all of which are the sole cost, expense and responsibility of Braeburn. If Applicable Laws require that taxes be deducted and withheld from a payment made by Braeburn to Lubrizol pursuant to this Article 4, Braeburn shall (i) deduct those taxes from the payment, (ii) pay the taxes to the proper taxing authority, and (iii) send evidence of the obligation together with proof of payment to Lubrizol within [***] following that payment.
- (b) <u>Cooperation; Tax Residence Certificate.</u> The Parties shall cooperate and use reasonable efforts to reduce the taxes attributable to the payments made hereunder. In addition, Lubrizol shall provide Braeburn any tax forms that may be reasonably necessary in order for Braeburn not to withhold tax or to withhold tax at a reduced rate under any applicable bilateral income tax treaty, including appropriate certification from relevant revenue authorities that Lubrizol is a tax resident of a jurisdiction that is a party to such income tax treaty. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

12

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

- (c) <u>Assessment.</u> Lubrizol or Braeburn may, at its own expense, protest any assessment, proposed assessment, or other claim by any governmental authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by Applicable Laws. The other Party shall reasonably cooperate with the protesting Party, at its request and expense, in any protest by providing records and such additional information as may reasonably be necessary for such Party to pursue such protest.
- 4.7 Records Audit. Braeburn shall maintain, and shall require its Affiliates to maintain, complete and accurate records in sufficient detail to permit Lubrizol to confirm the accuracy of the calculation of Net Sales and royalties. Upon at least [***] prior written notice, [***], Braeburn shall, and shall require its Affiliates to, make such records available [***], by an independent certified public accountant from a nationally recognized firm in the United States selected by Lubrizol and reasonably acceptable to Braeburn, for the sole purpose of verifying the accuracy of the Royalty Reports furnished by Braeburn pursuant to this Agreement; provided, that Braeburn may require such accountant(s) to enter into a customary confidentiality agreement for arrangements of such type. Such accountants shall disclose to Lubrizol, with a copy to Braeburn, only whether the Net Sales and Royalty Payments hereunder are correct or incorrect. With respect to royalties and other payments owed to Lubrizol hereunder, any amounts shown to be owed but unpaid shall be paid within [***]. Any amounts shown to have been overpaid shall be refunded within [***]. [***]. Lubrizol shall hold all information disclosed to it under this Section 4.7 as Confidential Information of Braeburn.

ARTICLE 5

REQUIRED PRODUCT IMPROVEMENTS

- 5.1 General. The Parties intend for the GMP Product to be used by Braeburn, or an IDDS Commercial Partner, as an Excipient in an IDDS Product that contains one or more other components as API, and, accordingly, that Lubrizol shall only be required to meet Regulatory Authority manufacturing requirements applicable to Excipients. The Parties acknowledge that that either Party may identify a GMP Product defect, or otherwise raise a concern about GMP Product integrity, safety, quality, or regulatory compliance that requires a GMP Product modification to meet applicable requirements imposed by a Regulatory Authority as a condition to obtain or maintain Regulatory Approval for an IDDS Product, and which may necessitate a change in Specifications (each a "Required Improvement"). [***].
- 5.2 Implementation of Required Improvements. The Parties agree to work in good faith immediately upon the identification by either Party of a potential Required Improvement to find the most cost-effective solution. The Parties further acknowledge that Lubrizol's technical expertise shall be given priority in evaluating potential Required Improvements and determining the optimal solutions. Lubrizol agrees to implement as soon as possible any Required Improvement that Braeburn reports to Lubrizol as necessary to obtain or maintain Regulatory Approval for an IDDS Product, provided that Braeburn bears all costs for improvements that require manufacturing processes that exceed GMP, consistent with Section 3.1. Lubrizol shall provide reasonable reports regarding Lubrizol's implementation progress to Braeburn upon Braeburn's request. Lubrizol shall update the DMF and the Module 3 Information and provide copies of such documentation to Braeburn upon implementation of the Required Improvement.

13

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

5.3 Regulatory Determination. The Parties agree to work in good faith to implement any changes to the manufacture of GMP Product that may be necessary to support Regulatory Approval. The Parties shall be jointly responsible for making the final decision as to whether a Significant Change may be implemented for the GMP Product in accordance with Section 3.6 and Exhibit D. Notwithstanding the foregoing, Lubrizol agrees to discuss with Braeburn any suggested Significant Change if such change is required by a Regulatory Authority. Lubrizol is not permitted to make any Significant Change that affects the GMP Product without notifying Braeburn, except as may be authorized in a separate Quality Agreement among the Parties. Braeburn shall be solely responsible for making the final determination as to whether such changes require Regulatory Approval for IDDS Products prior to implementation and for filing and obtaining any required Regulatory Approvals for IDDS Products, as necessary.

ARTICLE 6

INTELLECTUAL PROPERTY

6.1 Ownership of Improvements. Any rights in Improvements that relate exclusively to the TPU polymer matrix, TPU resin and/or TPU tubing included within the Product (the "TPU Improvements"), shall be owned solely by Lubrizol. Braeburn shall, and shall cause its Affiliates and sublicensees to, assign all ownership rights in the TPU Improvements to Lubrizol. Any rights in all other Improvements to the IDDS Product made by Braeburn, its Affiliates and/or its sublicensees shall be owned solely by Braeburn, its Affiliates and/or its sublicensees.

6.2 <u>Braeburn IP.</u> All intellectual property rights owned by Braeburn prior to the Effective Date, including, without limitation, rights to the patents relating to the IDDS Product set forth on Exhibit C (the "Braeburn IP"), shall be and remain the property of Braeburn, and Lubrizol shall not acquire any rights therein. Lubrizol agrees, on behalf of itself and its Affiliates, not to (a) infringe the Braeburn IP, (b) [***], and (c) directly or indirectly initiate or prosecute any lawsuit or any other civil or administrative proceeding, or make any claim or counterclaim, of any kind in any court, tribunal, agency or governmental entity anywhere in the world challenging the validity or enforceability of the Braeburn IP.

ARTICLE 7

CONFIDENTIALITY; PUBLICITY

7.1 <u>Confidentiality; Exceptions.</u>

(a) <u>Confidential Information</u>. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, including the long-term Mutual Non-Disclosure Agreement (LZ#48464) with an effective date of September 1, 2015, the Parties agree that the receiving Party (the "Receiving Party") will keep confidential and will not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise), which are disclosed to it by the other Party (the "Disclosing Party") or otherwise received or accessed by a Receiving Party in the course

14

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

of performing its obligations or exercising its rights under this Agreement (collectively, "Confidential Information"), except to the extent that it can be established by the Receiving Party that such Confidential Information:

- (i) was in the lawful knowledge and possession of the Receiving Party prior to the time it was disclosed to, or learned by, the Receiving Party, or was otherwise developed independently by or for the Receiving Party, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual knowledge by the Receiving Party;
 - (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party:
- (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; or
- (iv) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others.
- (b) <u>Authorized Disclosure</u>. Except as otherwise provided in this Agreement, a Receiving Party may use and disclose Confidential Information of the Disclosing Party as follows:
 - (i) under appropriate confidentiality provisions substantially equivalent to those in this Agreement, in connection with the performance of its obligations or exercise of rights granted or reserved in this Agreement;
 - (ii) to the extent such disclosure is reasonably necessary in filing or prosecuting patent, copyright and trademark applications, prosecuting or defending litigation, complying with applicable governmental regulations, obtaining Regulatory Approval, conducting pre-clinical activities or clinical trials, in the case of Braeburn marketing IDDS Products, or otherwise required by Applicable Laws; provided, that if a Receiving Party is required by Applicable Laws to make any such disclosure of a Disclosing Party's Confidential Information it will, to the extent legally permissible, (1) except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure requirement, (2) upon the request of the Disclosing Party, use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed, and (3) only disclose that portion of the Confidential Information required to be disclosed by Applicable Laws;
 - (iii) to existing or prospective investors, advisors, collaborators, (sub)licensees, partners or joint venturers, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement; and

15

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(iv) as reasonably required under the circumstances, to a Third Party in connection with (1) a Change in Control, or (2) to the extent mutually agreed in writing by the Parties.

In each of the above authorized disclosures, the Receiving Party shall remain responsible for any failure by any Person who receives the Confidential Information from the Receiving Party pursuant to this Section 7.1(b) to treat such Confidential Information as required under this Article 7.

- 7.2 <u>Prior Secrecy Agreement.</u> As of the Effective Date, this Agreement supersedes the Secrecy Agreement, executed as of June 3,2010, between Lubrizol and Endo Pharmaceuticals Inc., which agreement was assigned by Endo Pharmaceuticals, Inc. to Braeburn. All information exchanged between the Parties prior to the Effective Date and/or under such Secrecy Agreement will be deemed Confidential Information hereunder and will be subject to the terms of this <u>Article 7</u>.
 - 7.3 Survival of Obligations. The obligations set forth in this Article 7 shall survive the termination of this Agreement for a period of [***] years.
- 7.4 Return of Confidential Information. Within [***] days after the termination of this Agreement, the Receiving Party shall (and shall cause its employees, agents and Affiliates to) return to the Disclosing Party or destroy all documents and tangible items then in its possession which it has received from the Disclosing Party or any Affiliate or representative thereof that include or incorporate or contain any of the Disclosing Party's Confidential Information, as well as all copies, summaries, records, descriptions, modifications, and duplications that it, or any of its Affiliates employees or agents, has made from the documents or tangible items received from the Disclosing Party or any Affiliate or representative thereof; provided, however, that the Receiving Party may retain one copy of Confidential

Information in its legal files solely to permit the Receiving Party to continue to comply with its obligations hereunder and, in addition, may upon notice to the Disclosing Party, retain in its legal files or in the office of outside legal counsel one copy of any document solely for use in any pending legal proceeding to which such document relates.

7.5 <u>Publicity.</u> Except as required by Applicable Law, neither Party shall use the other's name or refer to it directly or indirectly in an advertisement, news release or release to any professional or trade publication without written approval from such Party, which approval may not be unreasonably withheld or delayed.

ARTICLE 8

REPRESENTATIONS AND WARRANTIES

8.1 Representations and Warranties of the Parties. Each Party represents and warrants to the other Party as of the Effective Date as follows:

(a) such Party is (i) duly organized and validly existing under the laws of its jurisdiction of organization or formation, (ii) has all necessary corporate power and authority to

16

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

carry on its business as presently being conducted, and (iii) has all necessary power and authority to execute, deliver and perform this Agreement;

- (b) the execution, delivery and performance of this Agreement by such Party has been duly and validly authorized by all necessary action by such Party and this Agreement constitutes the legal, valid and binding obligation of such Party, enforceable against it in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization and other similar laws and equitable principles relating to or limiting creditors' rights generally; and
- (c) the execution, delivery and performance of this Agreement by such Party will not conflict with, result in the breach of, violate the provisions of, or constitute a default under Applicable Law or any agreement to which such Party, its officers, director, agents or employees are parties, or by which such Party, its officers, directors, agents or employees is, or may be, bound.
 - 8.2 <u>Representations of Lubrizol</u>. Lubrizol represents to Braeburn as follows:
- (a) As of the Effective Date and during the Term, Lubrizol represents that it owns or Controls all of the rights, title and interest in and to the intellectual property covering or claiming the Product and has the right to manufacture the Product and supply the Product to Braeburn in accordance with this Agreement without violating the terms of any agreement or arrangement with any Third Party.
- (b) As of the Effective Date, Lubrizol represents that, to Lubrizol's knowledge, there are no settled, pending or threatened claims, lawsuits or legal proceedings of a Third Party against Lubrizol alleging that the intellectual property covering or claiming the Product misappropriates or infringes, in part or in whole, the intellectual property or intellectual property rights of such Third Party.
- (c) As of the Effective Date and during the term, Lubrizol represents that, to Lubrizol's knowledge, it has not granted and will not grant any right to any Third Party relating to the Product that would conflict or interfere with any of the rights granted to Braeburn hereunder.
- (d) As of the Effective Date, Lubrizol represents that, to Lubrizol's knowledge, no actions are pending before any court or governmental agency or other tribunal relating to the Product;
- (e) As of the Effective Date and during the Term, Lubrizol represents that the manufacturing facilities owned or operated by Lubrizol and the processes utilized by Lubrizol for the manufacture of the Product, and, to the knowledge of Lubrizol, the manufacturing facilities owned or operated by Lubrizol's subcontractors and the processes utilized by Lubrizol's subcontractors for the manufacture of the Product, comply with all Applicable Laws including, without limitation, applicable GMP, and Lubrizol will manufacture the Product in conformance with the Product Requirements;
- (f) As of the Effective Date and during the Term, except for the DMF and the Module 3 Information, Lubrizol has obtained all approvals, authorizations, registrations,

17

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

licenses, permits and certificates from governmental authorities necessary to manufacture, transport, import, store, handle and sell the Product in accordance with this Agreement;

- (g) As of the Effective Date and during the Term, Lubrizol represents that it possesses the requisite specialization, expertise, personnel, facilities and supplies to manufacture and supply the Product in accordance with this Agreement.
- (h) As of the Effective Date and during the Term, Lubrizol represents that Lubrizol has not and will not, in connection with manufacturing of Product, employ or contract for the services of any person who is (1) excluded, debarred, disqualified or suspended from participation in any foreign or U.S. federal health care program or under any FDA laws and equivalent foreign laws; or (2) under investigation by the FDA or any other Regulatory Authority for exclusion, debarment, disqualification or suspension. Lubrizol will immediately notify Braeburn if, during the Term, Lubrizol learns that it or any of its employees come under investigation by the FDA or any other Regulatory Authority for exclusion, debarment, disqualification or suspension, or becomes excluded, debarred, disqualified or suspended.
- 8.3 WARRANTY DISCLAIMERS. Notwithstanding the warranty set forth in Section 3.3(a), Lubrizol shall have no obligation hereunder if the Products become defective as a result of improper storage, contamination, adulteration, improper use or misapplication after delivery thereof to Braeburn. For avoidance of doubt, the Product warranty extends only to Braeburn; an IDDS Commercial Partner may receive Product warranty under a separate agreement with Lubrizol. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, NOR OTHER WARRANTY, EXPRESS, IMPLIED OR STATUTORY, BY LUBRIZOL. BRAEBURN ACKNOWLEDGES THAT IT IS PURCHASING THE PRODUCTS SOLELY ON THE BASIS OF THE

COMMITMENTS OF LUBRIZOL EXPRESSLY SET FORTH HEREIN. LUBRIZOL MAKES NO WARRANTIES WHATSOEVER FOR THE USE OF PRODUCTS PROVIDED BY LUBRIZOL IN ANY IDDS PRODUCT OR OTHER MEDICAL, PHARMACOLOGICAL, OR FOOD APPLICATIONS.

- 8.4 LIMITATION OF LIABILITY. LUBRIZOL'S LIABILITY FOR ANY CLAIM OF ANY KIND, FOR ANY LOSS OR DAMAGE ARISING OUT OF, CONNECTED WITH OR RESULTING FROM THIS AGREEMENT, OR FROM THE PERFORMANCE OR BREACH THEREOF, [***]. LUBRIZOL SHALL NOT BE LIABLE FOR PENALTY CLAUSES OF ANY DESCRIPTION, ANY ACTION RESULTING FROM ANY CLAIM ARISING UNDER THIS AGREEMENT WHICH IS BROUGHT BY BRAEBURN AGAINST LUBRIZOL MUST BE COMMENCED WITHIN [***] AFTER THE CAUSE OF ACTION HAS ACCRUED.
- 8.5 <u>Representations and Warranties of Braeburn</u>. Braeburn represents and warrants to Lubrizol as of the Effective Date and during the Term that Braeburn will only use GMP Product and not use Non-GMP Product for use in any IDDS Product that is intended for use in any human clinical trial or for commercial sale to be administered for human use.
- 8.6 <u>Mutual Covenant</u>. Each Party shall notify the other Party in writing promptly in the event that it has actual knowledge of the material breach of any representation or warranty provided by either Party under <u>Section 8.1</u> or by Lubrizol under <u>Section 8.2</u>. In addition, if a subsequent event occurs (or if Lubrizol becomes aware that a subsequent event has occurred)

18

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

following the Effective Date that would be in contravention of the representations, warranties and covenants in Section 8.2, Lubrizol shall promptly notify Braeburn in writing within [***] days.

ARTICLE 9

REMEDIES; INDEMNIFICATION

- 9.1 <u>Indemnification by Lubrizol</u>. The Parties acknowledge that Lubrizol limits its liability to meeting Product Specifications. Lubrizol shall therefore only indemnify and hold harmless Braeburn [***].
- 9.2 <u>Indemnification by Braeburn</u>. The Parties acknowledge that Braeburn, rather than Lubrizol, shall solely bear all liability arising from or related to using the Product as an Excipient in Braeburn's IDDS Products. Braeburn shall therefore indemnify, defend and hold harmless Lubrizol [***].
- 9.3 <u>Procedure; Defense.</u> In the event that any Person (an "**Indemnitee**") entitled to indemnification under <u>Section 9.1</u> or <u>9.2</u> is seeking such indemnification, such Indemnitee shall [***].
- 9.4 <u>Limitations of Damages.</u> NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES (EXCEPT WITH RESPECT TO BREACH OF ITS OBLIGATIONS OF CONFIDENTIALITY UNDER <u>ARTICLE 7</u>, OR INDEMNIFICATION OBLIGATIONS UNDER THIS <u>ARTICLE 9</u>) FOR ANY INDIRECT, SPECIAL, INCIDENTAL (INCLUDING, WITHOUT LIMITATION, LOST PROFITS) OR PUNITIVE DAMAGES OF THE OTHER PARTY OR ITS AFFILIATES FROM ANY BREACH OR DEFAULT OF A PARTY'S OBLIGATIONS HEREUNDER OR THE BREACH OF ANY REPRESENTATION OR WARRANTY MADE HEREUNDER OR FOR ANY ACTION OR CLAIM ARISING OUT OF OR RELATED TO THIS AGREEMENT, WHETHER THE ACTION IN WHICH RECOVERY OF DAMAGES IS SOUGHT IS BASED UPON AGREEMENT, TORT, STATUTE OR OTHERWISE EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 10

TERM; TERMINATION

10.1 Term. Unless earlier terminated in accordance with this Article 10, the term of this Agreement shall commence on the Effective Date and continue for 20 years (the "Term"); provided, that Braeburn may extend the Term for additional 5-year extension terms (each, an Extension Term") if Braeburn provides Lubrizol with at least six (6) months written notice prior to the termination of the Term or any Extension Term. During any Extension Term, the price paid by Braeburn for the Product may be adjusted in accordance with Section 4.2. If Braeburn objects to the price adjustment for any Extension Term, then the last price of the Product reflected on Exhibit A (if and as amended) shall be [***]% of the then-current price for a period not to exceed one year as requested by Braeburn to identify an alternative manufacturing site.

19

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

10.2 <u>Termination for Material Breach</u>. Either Party may terminate this Agreement in the event the other Party commits a material breach of this Agreement, including, without limitation, a Supply Failure, and has not cured such breach within 30 days' written notice thereof from the non-breaching Party.

10.3 <u>Termination Without Cause</u>.

- (a) Braeburn may terminate this Agreement upon 60 days' written notice to Lubrizol in the event of a Change in Control of Lubrizol; provided, that Braeburn shall have no right to terminate the Agreement if, during such 60 day period, Lubrizol undertakes to provide an alternative arrangement that provides Braeburn with a supply of the Product on terms and conditions that are consistent in all material respects with the terms and conditions of this Agreement.
- (b) Braeburn may terminate this Agreement upon 180 days' written notice if Braeburn discontinues development and commercialization of all IDDS Products.
- (c) Lubrizol may, subsequent to submission by Braeburn of the first Royalty Report, terminate this Agreement if Braeburn does not make a Royalty Payment for two consecutive calendar quarters.

10.4 <u>Termination for Insolvency</u>. Either Party may terminate this Agreement if the other Party files, or has filed against it, a petition for voluntary or involuntary bankruptcy or pursuant to any other insolvency law, or the other Party makes or seeks to make a general assignment for the benefit of its creditors or applies for or consents to the appointment of a trustee, receiver or custodian for it or a substantial part of its property, and such situation is not cured within 30 days from its occurrence, such termination to take effect upon delivery of notice of termination to the other Party.

10.5 Effect of Expiration or Termination.

- (a) Expiration or termination of this Agreement shall not relieve the Parties of their respective confidentiality obligations hereunder. Upon termination or expiration of this Agreement, (i) except for termination with cause by Braeburn in accordance with Section 10.2. Braeburn shall take delivery of and pay for all Product under any POs, along with any Safety Stock, Backup Supply, and Backup Resin, outstanding as of the date of termination or expiration in accordance with the terms of this Agreement, and (ii) except for termination with cause by Lubrizol in accordance with Section 10.2, Lubrizol shall fulfill all POs outstanding as of the date of termination or expiration in accordance with the terms of this Agreement. Notwithstanding the foregoing, Braeburn shall not be obligated to pay for quantities of Safety Stock, Backup Supply, and Backup Resin maintained by Lubrizol in excess of the quantities required to be maintained under this Agreement.
- (b) If (i) Braeburn terminates this Agreement in accordance with Section 10.3(a), or (ii) Braeburn terminates this Agreement in accordance with Section 10.2, then Lubrizol shall allow Braeburn to purchase its pro rata allocation of the existing inventory of the Product based on all other orders of the Product among similarly situated customers of Lubrizol.

20

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

- (c) If Lubrizol terminates this Agreement in accordance with Section 10.3(c), Lubrizol will deliver, at the request of Braeburn, prior to the effective date of termination, and at Braeburn's expense, a quantity of GMP Product that the parties reasonably agree represents a two (2) year supply for Braeburn's use as a component in IDDS Products in the Field of Use. Braeburn's obligations under this Agreement to make Royalty Payments to Lubrizol for IDDS Product manufactured using such GMP Product delivered prior to the effective date of termination shall continue regardless of termination.
- 10.6 <u>Survival</u>. All of the representations, warranties, and indemnifications made in this Agreement, and all terms and provisions hereof intended to be observed and performed by the parties after the termination hereof, including <u>Article 7</u>, shall survive such termination and continue thereafter in full force and effect, subject to applicable statutes of limitations.

ARTICLE 11

MISCELLANEOUS

- 11.1 <u>Assignment; Binding Effect.</u> This Agreement shall not be assignable or otherwise transferable by either party without the prior written consent of the assigning party and shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Notwithstanding anything in this Agreement, the Parties acknowledge and agree that either Party may assign its rights to, or perform its obligations under this Agreement through, an Affiliate.
- 11.2 Notices. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Braeburn, addressed to:

Braeburn Pharmaceuticals, Inc. 47 Hulfish Street Princeton, New Jersey 08542 United States of America Attn: Chief Executive Officer

with a copy (which shall not constitute notice) to: notices@Braeburnphanna.com.

If to Lubrizol, addressed to:

Lubrizol Advanced Materials, Inc. 9911 Brecksville Road Cleveland, Ohio 44141 Attention: Deb Langer

with a copy (which shall not constitute notice) to:

21

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

The Lubrizol Corporation 29400 Lakeland Boulevard Wickliffe, Ohio 44092 Attention: General Counsel

or to such other address for such Party as it shall have specified by like notice to the other Parties; provided, that notices of a change of address shall be effective only upon receipt thereof. If delivered personally, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third Business Day after such notice or request was deposited with the U.S. Postal Service.

11.3 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction or other authority to be

invalid, void, unenforceable or against its regulatory policy such determination shall not affect the enforceability of any others or of the remainder of this Agreement; and in connection with such term, provision, covenant or restriction of this Agreement which is held invalid, void, unenforceable or against regulatory policy, the Parties shall negotiate in good faith with a view to the substitution therefor of a suitable and equitable solution in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid term, provision, covenant or restriction and, absent any agreement by the Parties, such court of competent jurisdiction or other authority shall substitute therefore such term, provision, covenant or restriction as is legal, valid and enforceable but otherwise similar to the invalid term, provision, covenant or restriction.

- 11.4 No Third-Party Beneficiaries. This Agreement is solely for the benefit of the Parties hereto and their respective Affiliates and no provision of this Agreement shall be deemed to confer upon any Third Parties any remedy, claim, liability, reimbursement, claim of action or other right in excess of those existing without reference to this Agreement.
- 11.5 <u>Waiver</u>. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term.
- 11.6 Governing Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the laws of the State of Delaware without reference to conflicts of laws principles which would direct the application of the laws of another jurisdiction.
 - 11.7 <u>Injunctive Relief.</u> [***]

22

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

- 11.8 Construction. The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement.
- 11.9 <u>Headings: Interpretation</u>. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. Further, in this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable.
- 11.10 <u>Further Assurances.</u> Braeburn and Lubrizol covenant and agree that subsequent to the execution and delivery of this Agreement and without any additional consideration, each of Braeburn and Lubrizol shall execute and deliver any further legal instruments and perform such acts which are or may become necessary to effectuate the purposes of this Agreement.
- 11.11 <u>Relationship</u>. Lubrizol is an independent contractor engaged by Braeburn for the provision of the Product. Nothing in this Agreement shall constitute either Party as an employee, agent or general representative of the other, nor shall Braeburn or Lubrizol have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against, or in the name of or on behalf of, the other.
- 11.12 <u>Counterparts.</u> This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.
- 11.13 Entire Agreement. This Agreement, the Exhibits hereto, the long-term Mutual Non-Disclosure Agreement (LZ No. 48464) with an effective date of September 1, 2015 and the Quality Agreement set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties on the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties. In the event that a Regulatory Authority in the

23

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

European Union determines that the Product is not an excipient but rather the device element of a drug delivery system, then the Parties shall promptly negotiate in good faith an amendment to this Agreement including any revisions required to address such determination.

24

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934. AS AMENDED.

IN WITNESS WHEREOF, the Parties hereto have caused this Supply Agreement to be executed by their respective duly authorized officers as of the date first above written.

By:			
Name: Behshad Shel	don		
Title: President and O	CEO		
LUBRIZOL ADVA	NCED MATERIAI	LS, INC.	
Dr			
By:			
Name: Deb Langer			
Title: Vice President	& General Manager		

EXHIBIT A

PRICING

	Price per Foot of Product
Product Description	Purchased
[***]	[***]
[***]	[***]

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT B

GMP PRODUCT AND NON-GMP PRODUCT SPECIFICATIONS

GMP Products

	Tubing: P100001					
	Characteristics	Product Spo	ecification			
		Measurement	Tolerance			
[***]	[***]					
[***]	[***]	[***]	[***]			
[***]	[***]	[***]				
[***]	[***]	[***]	[***]			
[***]	[***]	[***]	` 1			

		Tubing: P100002	
	Characteristics	Product Spo	ecification
		Measurement	Tolerance
[***]	[***]		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	
[***]	[***]	[***]	[***]
[***]	[***]	[***]	•

Non-GMP Products

	Characteristics	Product Spo	ecification
		Measurement	Tolerance
[***]	[***]	<u> </u>	
	[***]		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	
[***]	[***]	[***]	[***]
[***]	[***]	[***]	

	Characteristics	Product Sp	ecification
,		Measurement	Tolerance
[***]	[***]		
	[***]		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	
[***]	[***]	[***]	[***]
[***]	[***]	[***]	

EXHIBIT C

BRAEBURN IP

Country Name	Serial #	Filed Date	Patent #	Issue Date
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	t j	L J
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	,	, ,
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	. ,	L J
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		

Country Name	Serial #	Filed Date	Patent #	Issue Date
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		

[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
		C-2		
		C-2		

Country Name	Serial #	Filed Date	Patent #	Issue Date
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
***	[***]	[***]		
***	[***]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
***]		. ,		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
***	[***]	[***]		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		
]	[]	[***]	[***]	[***]
]	[]	[***]	[***]	[***]
]	[*]	[***]	. 1	L J
]	[]	[***]		
]	[]	[***]		
]	[]	[***]		

Country Name	Serial #	Filed Date	Patent #	Issue Date
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
		C-4		

EXHIBIT D

SIGNIFICANT CHANGES PROTOCOL

Excipient and Medical Grade Notification of Change

Type Change Cystem Cys		Notify Medical & Excipient Customers
EAR		(via prod. Mgr.)
RAB	Plant (Production and Packaging)	5.4.4.4.3
[***] [**] [***] [**]		[***]
*** *** **** ***** **** **** ***** ***** **** **** ****		Eduta 2
[***]	[***]	[***]
*** ***	[***]	
[***] [**] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***	[***]
*** ***		
[***] [***]		
***	[***]	[***]
[***]		
[***] *** ***	[***]	[***]
[***] *** ***	[***]	
[***] *** ***	[***]	
[***] [***]	[***]	
[***] *** ***	[***]	
[***] *** ***	[***]	
[***] [***]	[***]	
[***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***]	[***]	
[***] [***]	***	
[***] [***]	[***]	[***]
[***] [***]	[***]	·
[***] [***]	[***]	[***]
[***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***]		, ,
[***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***]	[***]	
[***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***]	[***]	[***]
[***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***]	[***]	
[***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***]		Ļ J
[***] [***] [***] [***] [***] [***] [***] [***] [***]	[***]	[***]
[***] [***] [***] [***] [***] [***] [***]	[***]	[***]
[***] [***] [***] [***] [***] [***]	[***]	l J
[***] [***] [***] [***] [***]	[***]	[***]
[***] [***] [***]	[***]	[***]
[***] [***]	[***]	L J
[***]		[***]
[***]		L J
[***]	[***]	[***]
	L J	$\mathfrak{l}_{\ldots}\mathfrak{l}$

Notify Medical & **Excipient Customers**

Type of Change	(via prod. Mgr.)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	
[***]	[***]
[***]	
[***]	
D	-2

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT E

GMP AND NON-GMP RESIN SPECIFICATIONS

GMP Products					
	Characteristics		Product Speci	fication	
-		Resin: [***]	Min	Max	
[***]	[***]	[***]	[***]		
[***]		[***]	[***]	[***]	
[***]	[***]	[***]	• •	[***]	
[***]	. ,	. ,			
[***]	[***]		[***]		
[***]	. ,				
[***]			[***]		
[***]			[***]		
	Characteristics		Product Speci	Product Specification	
	Ondi determines	Resin: [***]	Min	Max	
[***]	[***]	[***]	[***]		
[***]	. ,	[***]	[***]	[***]	
[***]	[***]	[***]	, ,	[***]	
[***]	. ,	. ,		. ,	
[***]	[***]		[***]		
[***]	, ,				
[***]			[***]		
[***]			[***]		
Non-GMP Produ	ucts				
	Characteristics		Product Specification		
		Resin: [***]	Min	Max	
[***]	[***]	[***]	[***]		
[***]		[***]	[***]	[***]	
[***]	[***]	[***]	[***]	[***]	
[***]					
[***]			[***]		
[***]			[***]		
	Characteristics		Product Speci	Product Specification	
		Resin: [***]	Min	Max	
[***]	[***]	[***]	[***]		

	Characteristics		Product Specification		
		Resin: [***]	Min	Max	
[***]		[***]	[***]	[***]	
[***]	[***]	[***]	[***]	[***]	
[***]					
[***]			[***]		
[***]			[***]		
		E 2			