18-03640-E

Madison, Wilton

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, March 30, 2018 8:42 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 4.18 to the 12/31/07 Form 20-F, filed by Eurand N.V. on 3/31/2008. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to $61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

April 27, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-03640-E

Dear Mr. Edwards:

This letter is in response to your request, dated March 30, 2018 and received in this office on April 2, 2018, for Exhibit Exhibit 4.18 to the December 31, 2007 Form 20-F, filed by Eurand N.V. on March 31, 2008.

The search for responsive records has resulted in the retrieval of 96 pages of records that may be responsive to your request. They are being provided to you with this letter.

No fees have been assessed for the processing of this request. If you have any questions, please contact me at andersonc@sec.gov or (202) 551-8315. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Clarissa Anderson

Clarissa Anderson
FOIA Research Specialist

Enclosure

4.18

DEVELOPMENT
AND
LICENSE AGREEMENT

between

Eurand, Inc.

And

SmithKline Beecham Corporation d/b/a GlaxoSmithKline

For a

Lamotrigine ODT

CONFIDENTIAL

DEVELOPMENT AND LICENSE AGREEMENT

PREAMBLE

THIS DEVELOPMENT AND LICENSE AGREEMENT dated as of the 21st day of April 2006, (the "Effective Date") is by and between Eurand, Inc., a Nevada corporation with its principal offices at 845 Center Drive, Vandalia, Ohio 45377 ("Eurand") and SmithKline Beecham Corporation d/b/a GlaxoSmithKline, a Pennsylvania corporation with its principal offices at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania 19102 ("GSK"). Eurand and GSK are sometimes collectively referred to herein as the "Parties" and separately as a "Party".

A. Eurand is the owner or licensee of the Eurand Intellectual Property Rights (as hereinafter defined), and has the right to grant certain licenses or sublicenses thereunder.

B. GSK desires that Eurand undertake a project to develop Product (as hereinafter defined) that is covered under the Eurand Intellectual Property Rights.

C. GSK also desires to obtain an exclusive license from Eurand under the Eurand Intellectual Property Rights to use, package, sell, offer for sale and import Product in the Field (as hereinafter defined) in the Territory (as hereinafter defined) on the terms and conditions set forth in this Agreement (as hereinafter defined).

D. Eurand is willing to undertake such a development project relating to Product and to grant such a license on the terms and conditions set forth in this Agreement.

E. Eurand and GSK will enter into supply agreements pursuant to which Eurand will manufacture and supply GSK's total clinical and commercial requirements for bulk tablets of Product.

NOW, THEREFORE, in consideration of the agreements and covenants hereinafter set forth and intending to be legally bound hereby, Eurand and GSK hereto covenant and agree as follows:

1 DEFINITIONS: The following capitalized terms shall have the following meanings when used in this Agreement and all terms defined in the singular will have the same meanings when used in the plural (and vice versa), unless otherwise specified. Further, the word "including" or any variation thereof means "including without limitation" and the word "including" or any variation thereof will not be construed to limit any general statement which it follows to the specific or similar items or matters immediately following it.

1.1 "AAA" will have the meaning set forth in Section 14.14.1.

1.2 "Abandoned Eurand Patent Rights" will have the meaning set forth in Section 9.4.2.

1.3 "Abandoned GSK Invention Patent Rights" will have the meaning set forth in Section 9.4.1.

1.4 "Act" means the United States Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder from time to time.

1.5 "Action" will have the meaning set forth in Section 9.7.2.

1.6 An "Affiliate" of an Entity means any other Entity, directly or indirectly controlling, controlled by or under common control with such Entity and, for purposes of this Section 1.6 only, "control" means (i) direct or indirect beneficial ownership of fifty percent (50%) or more (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting stock or shares entitled to vote on or direct the affairs of such Entity, or (ii) the possession, directly or indirectly, of the right or power to direct or cause the direction of the policies or management of such Entity, whether by ownership of stock, by contract or otherwise.

1.7 "Agreement" means this Development and License Agreement, together with all exhibits annexed hereto.

1.8 "Applicable Laws" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, ordinances, judgments, decrees, directives, injunctions, orders, permits (including the Regulatory Approvals) of or from any court, arbitrator or governmental agency or authority having jurisdiction over or related to the subject item.

1.9 "Business Day" means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in Ohio, Pennsylvania, Italy or the United Kingdom.

1.10 "Calendar Quarter" means each of the consecutive three (3) month periods ending March 31, June 30, September 30, and December 31; provided, however, that the first (1st) Calendar Quarter under this Agreement will be the period beginning on the Effective Date and ending on the end of the Calendar Quarter in which the Effective Date is encompassed.

1.11 "Calendar Year" means, for the first Calendar Year, the period beginning on the Effective Date and ending December 31, 2006, and for each Calendar Year thereafter, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31; provided, however, that the last Calendar Year of the Term will be the period beginning on January 1 and ending on the effective date of expiration or termination of the Term.

1.12 "cGMP" or "GMP" means current Good Manufacturing Practices as determined at any given time by the FDA, based on the authority and regulations set forth in Parts 210 and 211 of the United States Code of Federal Regulations and based on all applicable FDA rules, regulations, guides and guidances, as amended from time to time and in effect during the Term.

1.13 "Clinical Studies" means any testing, use or administration of the Product in humans in preparation for obtaining Regulatory Approvals to commercialize Product in the Field in the Territory, including, but not limited to, bioequivalence studies, pharmacokinetic studies, organoleptic evaluation studies, and/or clinical efficacy studies.

1.14 "Clinical Supply Agreement" will have the meaning set forth in Section 6.2.

1.15 "Commercially Reasonable" or "Commercially Reasonable Efforts" means efforts and resources normally used by a Party to accomplish a similar objective for a pharmaceutical product owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of patent coverage, safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or

product, the regulatory structure involved, the profitability of the applicable product, and other relevant factors.

1.16 "Commercial Supply Agreement" will have the meaning set forth in Section 6.3.

1.17 "Competing Business Entity" will have the meaning set forth in Section 10.6.3.

1.18 "Competitive Product" means any immediate-release (i.e., lacking any substantial sustained, modified or controlled release component to the drug release) orally disintegrating, dispersing or dissolving dosage labeled as containing any amount of the Compound, whether or not as the sole active pharmaceutical ingredient, other than Product. For the avoidance of doubt, the term "Competitive Product" will in no event include, or be deemed to include, any substantial sustained, modified or controlled release pharmaceutical formulation or composition containing the Compound, GSK's Lamictal® (lamotrigine) tablets approved under GSK's NDA No. 20-241, GSK's Lamictal® (lamotrigine) chewable dispersable approved under GSK's NDA No. 20-764 or any Generic Equivalent.

1.19 "Compound" means 3,5-diamino-6-(2,3-dichlorophenyl)-1,2,4-triazine, the compound that is known by the generic name lamotrigine, and its prodrugs, metabolites, isomers, esters, salts, hydrates, solvates and polymorphs.

1.20 "Confidential Information" means any and all information disclosed to or obtained by Recipient pursuant to or in connection with the negotiation, execution, delivery and performance of this Agreement or the consummation of the transactions contemplated hereby and any and all information regarding, related to, or associated with any or all elements of this Agreement, including the development, manufacture and/or commercialization of Product in the Field in and outside of the Territory or any aspect thereof, or each Party's operations that is disclosed by the Disclosing Party to the Recipient; provided, however, that Confidential Information will not include information which: (i) at the time of disclosure is in the public domain; (ii) after disclosure becomes part of the public domain, except through breach of this Agreement; (iii) the Recipient can demonstrate by reasonable proof was in its possession prior to the time of disclosure by the Disclosing Party hereunder, and was not acquired directly or indirectly from the Disclosing Party; (iv) the Recipient can demonstrate by reasonable proof was developed by or on behalf of Recipient independent of and without reference to the Disclosing Party's Confidential Information; or (v) becomes available to Recipient from a Third Party who did not acquire such information directly or indirectly from the Disclosing Party and who is not otherwise prohibited from disclosing such information.

1.21 "Confidentiality Agreements" will have the meaning set forth in Section 13.1.9.

1.22 "Control" means, with respect to the subject item, the ability and authority of a Party or its Affiliate, whether arising by ownership, possession or pursuant to a license or sublicense, to grant licenses or sublicenses to the other Party under or to the subject item as specified in this Agreement, without breaching the terms of any agreement with any Third Party and/or its Affiliates.

1.23 "CTM" (i.e., "clinical trial material") means presentations of Product manufactured by Eurand pursuant to the Clinical Supply Agreement for use by or on behalf of GSK in Clinical Studies.

1.24 "CTM Specifications" means with respect to any CTM, all specifications for materials, approved suppliers, formula, manufacturing, analytical and testing procedures, release and other processes relating to the manufacture of the CTM, which have been mutually agreed by the Parties and made part of the Clinical Supply Agreement.

1.25 "Cure Period" will have the meaning set forth in Section 11.2.2.

1.26 "Data" means all data and information generated by or on behalf of either Party during the performance of their respective activities under the Program, including any data generated by or on behalf of GSK during the conduct of any Clinical Studies.

1.27 "Disclosing Party" will have the meaning set forth in Section 13.1.1.

1.28 "DMF" means the Drug Master File developed and filed with Regulatory Authorities by Eurand which relates to and describes the composition and manufacture of the Product.

1.29 "Drug Substance" means Compound which is manufactured by or on behalf of GSK and which is used by Eurand in the manufacture of Product, including CTM.

1.30 "Drug Substance Specifications" means the GSK provided United States specifications for the Drug Substance.

1.31 "Effective Date" will have the meaning set forth in the Preamble.

1.32 "Entity" means any individual, partnership, association, joint venture, limited liability company, corporation or other business entity, or any government or regulatory, administrative or political subdivision or agency, department or instrumentality thereof.

1.33 "Eurand" will have the meaning set forth in the Preamble.

1.34 "Eurand Auditor" will have the meaning set forth in Section 8.4.3(i).

1.35 "Eurand Data" means Data relating solely to (i) the ODT Technology and (ii) the DMF as it relates solely to the ODT Technology.

1.36 "Eurand Development Activities" means those activities to be carried out by Eurand in connection with the Program, which activities are conducted in accordance with the Proposal and the terms of this Agreement, and as directed by the Steering Committee.

1.37 "Eurand Intellectual Property Rights" means Intellectual Property Rights Controlled by Eurand and/or its Affiliates or a Third Party on behalf of Eurand or its Affiliates on the Effective Date and at any time during the Term relating to the ODT Technology, including, without limitation, the Eurand Patent Rights, Eurand Know-How, and Eurand Trademarks relating to the ODT Technology, but excluding any GSK Intellectual Property Rights.

1.38 "Eurand Inventions" will have the meaning set forth in Section 9.3.4.

1.39 "Eurand Know-How" means any and all Know-How that is Controlled by Eurand or its Affiliates or a Third Party on behalf of Eurand or its Affiliates on the Effective Date or at any time during the Term (including, without limitation, any Know-How to which Eurand and/or its Affiliate

obtained rights under the Kyowa Agreement), which is used in the making, having made, use, sale, offering for sale and/or import of the Formulation and/or Product, but excluding any GSK Know-How.

1.40 "Eurand Patent Rights" means any and all Patent Rights Controlled by Eurand and/or its Affiliates on the Effective Date or at any time during the Term (including, without limitation, any Patent Rights to which Eurand and/or its Affiliate obtained rights under the Kyowa Agreement), which include one or more claims that, but for this Agreement, would be infringed by the making, having made, use, sale, offering for sale or import of the Formulation and/or Product, including patent applications filed by or on behalf of Eurand or its Affiliates pursuant to Section 9.3.4 or assumed by Eurand pursuant to Section 9.4.1, but excluding the GSK Patent Rights. A list of the Patent Rights included within the Eurand Patent Rights as of the Effective Date is attached hereto as Exhibit A, and Eurand will update such Exhibit at least once each Calendar Year during the Term, or promptly after GSK's reasonable written request.

1.41 "Eurand Publication" will have the meaning set forth in Section 13.3.1.

1.42 "Eurand Trademarks" means all Trademarks Controlled by Eurand and/or its Affiliates or a Third Party on behalf of Eurand or its Affiliates on the Effective Date or at any time during the Term, which are used in connection with the ODT Technology. A list of the Eurand Trademarks as of the Effective Date is attached hereto as Exhibit B, and Eurand will update such Exhibit at least once each Calendar Year during the Term, or promptly after GSK's reasonable written request.

1.43 "Existing Eurand Patent Rights" will have the meaning set forth in Section 9.1.

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

1.45 "Field" means the treatment, palliation and/or treatment of all human disease.

1.46 "First Commercial Sale" means the date of the first commercial sale of Product in the Field in the Territory by GSK and/or its Affiliates or sublicensees to distributors, wholesalers or other customers in a quantity sufficient for the distribution of such Product to pharmacies or other commercial distribution channels for sale in the Field in the Territory. Sales of Product for compassionate use, named patient use, clinical trial purposes or other similar uses, including, without limitation, for any Clinical Studies, will not constitute a First Commercial Sale.

1.47 "Force Majeure Event" means any cause or causes which wholly or partially prevent or delay the performance of obligations arising under this Agreement and which are not reasonably within the control of the non-performing Party and cannot be prevented by the non-performing Party through the use of Commercially Reasonable Efforts, including fire, floods, epidemics, explosions, embargoes, war, acts of war (whether war is declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority (including any Regulatory Authority).

1.48 "Formulation" means the formulation developed pursuant to the Program which (i) identifies and selects the ingredients (including the Drug Substance) for inclusion in the Product, (ii) sets forth the quantities of such ingredients, and (iii) sets forth the test methods, prototype

formulations, manufacturing processes, and operating procedures for combining and forming such ingredients with the ODT Technology to form the Product.

1.49 "GSK" will have the meaning set forth in the Preamble.

1.50 "GSK Auditor" shall have the meaning set forth in Section 8.4.3(ii).

1.51 "GSK Data" means any and all Data other than Eurand Data.

1.52 "GSK Development Activities" will have the meaning set forth in Section 3.2.

1.53 "Generic Equivalent" means on a product by product basis, any (i) FDA approved prescription generic lamotrigine tablet product for human use that is supplied or manufactured by or for GSK or any GSK licensee (or any of their respective Affiliates) under NDA No. 20-241 for sale in the Territory as a generic equivalent to any strength (including, without limitation, the 25mg, 100mg, 150mg, or 200mg strengths) of GSK's Lamictal® (lamotrigine) tablets approved under GSK's NDA No. 20-241, and (ii) FDA approved prescription generic lamotrigine chewable dispersible tablet product for human use that is supplied or manufactured by or for GSK or any GSK licensee (or any of their respective Affiliates) under NDA No. 20-764 for sale in the Territory as a generic equivalent to any strength (including, without limitation, the 5mg or 25mg strengths) of GSK's Lamictal® (lamotrigine) chewable dispersible tablets approved under GSK's NDA No. 20-764.

1.54 "GSK Intellectual Property Rights" means Intellectual Property Rights Controlled by GSK and/or its Affiliates or a Third Party on behalf of GSK or its Affiliates on the Effective Date or at any time during the Term, including the GSK Patent Rights, GSK Know-How, GSK Trademarks and GSK Program Rights, but excluding the Eurand Intellectual Property Rights.

1.55 "GSK Inventions" will have the meaning set forth in Section 9.3.3.

1.56 "GSK Invention Patent Rights" will have the meaning set forth in Section 9.3.3. GSK will provide Eurand with a list of any GSK Invention Patent Rights, which GSK will update at least once each Calendar Year during the Term or promptly after Eurand's reasonable written request.

1.57 "GSK Know-How" means any and all Know-How that is Controlled by GSK or its Affiliates or a Third Party on behalf of GSK or its Affiliates on the Effective Date or at any time during the Term which is directly related to or used in the making, having made, use, sale, offering for sale and import of the Compound, Drug Substance, the Formulation and/or the Product, including the GSK Data and Know-How included in the GSK Program Rights, but excluding any Eurand Know-How.

1.58 "GSK Patent Rights" means any and all Patents Rights Controlled by GSK and/or its Affiliates as of the Effective Date or during the Term, which include one or more claims that, but for this Agreement, would be infringed by the making, having made, use, sale, offering for sale and import of the Compound, Drug Substance, the Formulation and/or Product, including any GSK Invention Patent Rights filed by or on behalf of GSK or its Affiliates pursuant to Section 9.3.3 or assumed by GSK under Section 9.4.2 but excluding the Eurand Patent Rights. A list of the Patent

Rights included within the GSK Patent Rights as of the Effective Date is attached hereto as Exhibit C.

1.59 "GSK Program Rights" means any and all Intellectual Property Rights and GSK Data developed or generated by or on behalf of either Party after the Effective Date and in the performance of its respective obligations under the Program and this Agreement, including (i) Intellectual Property Rights relating to the Compound, Drug Substance, Formulation, and/or Product, (ii) the GSK Data, and (iii) the GSK Invention Patent Rights and the patent applications assumed by GSK under Section 9.4.2, but in each case specifically excluding the ODT Technology.

1.60 "GSK Publication" will have the meaning set forth in Section 13.3.2.

1.61 "GSK Trademarks" will have the meaning set forth in Section 4.3.

1.62 "Intellectual Property Rights" means Patent Rights, Know How, Trademarks and any and all other forms of intellectual property rights whatsoever.

1.63 "Inventions" will have the meaning set forth in Section 9.3.2.

1.64 "Know-How" means trade secrets and inventions (patentable or otherwise), and proprietary data, formulations, methods, technology and information directly related to or used in the subject item but which are not disclosed in any published Patent Rights claiming the subject item, including ideas, designs, processes, techniques, innovations, discoveries, improvements, and/or analytical methodology used in development, testing, analysis, manufacture and/or medical, clinical, toxicological testing as well as other scientific data.

1.65 "Kyowa" means Kyowa Hakko Kogyo Co. Ltd. For the avoidance of doubt, Kyowa is not an Affiliate of Eurand.

1.66 "Kyowa Agreement" means the License Agreement dated as of December 19, 2002, by and between Kyowa and Eurand Pharmaceuticals Limited, an Affiliate of Eurand.

1.67 "Lamotrigine Patent" means U.S. Patent 4,602,017 and any reissues, reexaminations or extensions thereof.

1.68 "Lamotrigine Patent Expiration Date" means January 22, 2009, or if GSK or its Affiliates shall not have received Pediatric Exclusivity, then July 22, 2008. For the purposes of this definition, the term "Pediatric Exclusivity" means the marketing exclusivity rights granted to GSK (or its Affiliate) by the FDA for Pediatric Exclusivity under Section 505A of the Act related to Product as applied to NDA No. 20-241 and NDA No. 20-764.

1.69 "Materials Safety Data Sheet" means a document which sets forth the handling and use standards for hazardous materials.

1.70 "Merger" or "Merging" will have the meaning set forth in Section 10.6.2.

1.71 "Milestone Events" will have the meaning set forth in Section 8.2.

1.72 "Milestone Payments" will have the meaning set forth in Section 8.2.

1.73 "NDA" means a New Drug Application or a Supplemental New Drug Application, as applicable, which is filed with the FDA in accordance with the Act in order to gain the FDA's approval to market a pharmaceutical product in the Territory for the indications set forth in the New Drug Application or Supplemental New Drug Application, as applicable.

1.74 "NDA No. 20-241" means NDA No. 20-241, including all amendments and supplements thereto.

1.75 "NDA No. 20-764" means NDA No. 20-764, including all amendments and supplements thereto.

1.76 "New Country License Agreement" will have the meaning set forth in Section 9.5.4.

1.77 "Net Sales" means the gross invoiced sales of Product in the Field in the Territory by GSK, its Affiliates or any of its sublicensees to Third Parties on an arms-length basis less any of the following charges or expenses that are incurred in connection with such gross sales:

1.77.1 transportation charges relating to Product, including handling charges and insurance premiums relating thereto;

1.77.2 sales taxes, excise taxes and duties paid by GSK, its Affiliates or sublicensees in relation to Product and any other equivalent governmental charges imposed upon the importation, use or sale of Product;

1.77.3 government-mandated and other rebates (such as those in respect of any state or federal Medicare, Medicaid or similar programs);

1.77.4 customary trade, quantity and cash discounts allowed on Product;

1.77.5 allowances or credits to customers on account of retrospective price reductions affecting Product;

1.77.6 customary Product rebates and Product charge backs including those granted to managed care entities; and

1.77.7 the lesser of (i) two percent (2%) of the aggregate gross amount billed or invoiced on sales of Product or (ii) the actual amount of any write-offs for bad debt relating to such sales of Product.

In the event that non-monetary consideration is received for any Product, Net Sales will be calculated based on the average price charged for such Product during the preceding Calendar Quarter, or in the absence of such sales, the fair market value of the Product, as determined by the Parties in good faith.

Net Sales will be calculated in accordance with the International Financial Reporting Standards consistently applied. The Parties acknowledge and agree that this Net Sales definition will be amended as appropriate to reflect changes to GSK's accounting rules brought about by merger or take-over of GSK, its Affiliate or sublicensee or changes in Applicable Laws.

1.78 "Non-Participating Party" will have the meaning set forth in Section 9.7.2.

1.79 "Non-Competing Business Entity" will have the meaning set forth in Section 10.6.3.

1.80 "ODT Technology" means the proprietary oral dissolve drug delivery and related technology Controlled by Eurand and/or its Affiliates as of the Effective Date or during the Term, including, without limitation, the Microcaps® taste masking microencapsulation technology and the AdvaTab® oral disintegrating tablet technology and, in each case, any manufacturing processes relating thereto.

1.81 "Participating Party" will have the meaning set forth in Section 9.7.2.

1.82 "Party" or "Parties" will have the meaning set forth in the Preamble.

1.83 "Patent Rights" means patents and patent applications including continuations, continuations-in-part, divisions, patents of addition, patents issuing from reissue, re-examination, renewal or extension proceedings, utility models, all Supplemental Protection Certificates and any foreign counterparts thereof, including PCTs.

1.84 "Potential Contaminants" will have the meaning set forth in Section 3.3.2(vii).

1.85 "Pre-Registration Activities" means those activities that are necessary prerequisites to the preparation and filing of the NDA with the FDA, which activities include: (i) filing the DMF, (ii) conducting stability studies on Product, and (iii) conducting the Clinical Studies deemed necessary by GSK for filing of the NDA for Product.

1.86 "Product" means an immediate-release (i.e., lacking any substantial sustained or controlled release component to the drug release) pharmaceutical composition containing the Compound, as the sole active ingredient and regardless of presentation or dosage, which is developed by or on behalf of the Parties pursuant to this Agreement, and which uses the Formulation and incorporates the ODT Technology.

1.87 "Product Specifications" means, with respect to any Product, all specifications for materials, approved suppliers, formula, manufacturing, analytical and testing procedures, release, packaging, labeling, artwork and other processes relating to the manufacture of Product other than CTM, which have been mutually agreed by the Parties and made part of the Commercial Supply Agreement.

1.88 "Program" means the development work conducted by the Parties under this Agreement as specified in the Proposal and such other work relating to the Formulation and/or Product as mutually agreed upon by the Parties from time to time during the Term.

1.89 "Program Initiation Date" will have the meaning set forth in Section 3.1.

1.90 "Proposal" will have the meaning set forth in Section 3.1.

1.91 "Recipient" will have the meaning set forth in Section 13.1.1.

1.92 "Regulatory Approval" means an approval, license, registration, and/or authorization necessary for the development, manufacture and/or commercialization of a prescription pharmaceutical or other product in any country, including the NDA.

1.93 "Regulatory Authority" means any or all national, supranational, regional, state, or local regulatory agency, department, bureau, commission, council, or other government entity involved in the granting of Regulatory Approval for a prescription pharmaceutical or other product in any country.

1.94 "Right of Negotiation" will have the meaning set forth in Section 9.5.1.

1.95 "Right of Negotiation Notice" will have the meaning set forth in Section 9.5.2.

1.96 "Right of Negotiation Period" will have the meaning set forth in Section 9.5.4.

1.97 "Royalties" will have the meaning set forth in Section 8.3.1.

1.98 "Steering Committee" will have the meaning set forth in Section 5.1.

1.99 "Term" will have the meaning set forth in Section 11.1.

1.100 "Territory" means the fifty (50) states of the United States of America, the District of Columbia, and all of its territories and possessions (including Puerto Rico).

1.101 "Third Party" means any Entity other than Eurand GSK or their respective Affiliates.

1.102 "Third Party Infringement" will have the meaning set forth in Section 9.7.1.

1.103 "Third Party Payments" will have the meaning set forth in Section 8.3.5.

1.104 "Trademarks" means trademarks, trade names, brand names, copyrights, logo types, symbols, service marks, designs, domain names and URLs, including, without limitation, registrations and applications for registrations thereof and all renewals, modifications and extensions thereof.

2 LICENSES:

2.1 Eurand's License Grants to GSK. Subject to the terms and conditions of this Agreement, Eurand hereby grants to GSK the following:

2.1.1 an exclusive license (or sublicense as the case may be with respect to Know-How and Patent Rights arising under the Kyowa Agreement), with the right to grant sublicenses as provided in Section 2.4, under the Eurand Intellectual Property Rights (excluding the Eurand Trademarks) to use, sell, offer for sale, package, and import Product in the Field in the Territory;

2.1.2 a worldwide, exclusive license (or sublicense as the case may with respect to Know-How and Patent Rights arising under the Kyowa Agreement), with the right to grant sublicenses as provided in Section 2.4 under the Eurand Intellectual Property Rights (excluding the Eurand Trademarks) in the Field to make and have made Product solely to the extent that GSK is permitted to make or have made Product under the Clinical Supply Agreement and Commercial Supply Agreement; and

2.1.3 a worldwide, exclusive license (or sublicense as the case may be with respect to Know-How and Patent Rights arising under the Kyowa Agreement), with the right to grant sublicenses as provided in Section 2.4, under the Eurand Intellectual Property Rights (excluding the Eurand Trademarks) to package Product in any country outside of the Territory and to use Product for the purpose of conducting Clinical Studies in any country outside of the Territory.

2.2 GSK's License Grants to Eurand. Subject to the terms and conditions of this Agreement, GSK hereby grants to Eurand the following:

2.2.1 a worldwide, non-exclusive, royalty-free license, with the right to grant sublicenses as provided in Section 2.4, under the GSK Intellectual Property Rights (excluding the GSK Trademarks) to use Drug Substance for the sole purpose of conducting the Eurand Development Activities as provided herein;

2.2.2 a worldwide, non-exclusive, royalty-free license, with the right to grant sublicenses as provided in Section 2.4, under the GSK Intellectual Property Rights (excluding the GSK Trademarks) to make Product solely as set forth under the Clinical Supply Agreement and Commercial Supply Agreement.

2.3 Trademark License.

2.3.1 Subject to the terms and conditions of this Agreement, Eurand hereby grants to GSK:

(i) an exclusive right, with the right to grant sublicenses as provided in Section 2.4, to use the Eurand Trademarks in connection with the using, selling, offering for sale and importing of Product in the Field in the Territory;

(ii) a worldwide, exclusive right to use the Eurand Trademarks in connection with the making and having made of Product solely to the extent that GSK is permitted to make or have made Product under the Clinical Supply Agreement and Commercial Supply Agreement; and

(iii) a worldwide, exclusive right to use the Eurand Trademarks in connection with the packaging of Product outside of the Territory and the use of Product for the purpose of conducting Clinical Studies in any country outside of the Territory.

2.3.2 Except where prohibited by Applicable Laws, GSK will refer to the Eurand Trademarks on the final packaging for, and internal leaflets used with, Product and on promotional materials used in connection with Product. Prior to printing any materials containing the Eurand Trademark, GSK will use Commercially Reasonable Efforts to send to Eurand, not less than fifteen (15) Business Days prior to their distribution, a sample of such materials (in final or substantially final form) for Eurand's prior review and approval solely with respect to GSK's use of the Eurand Trademark, which approval will not be unreasonably withheld or delayed. In the event that Eurand does not provide any comment to GSK during such fifteen (15) Business Day period, Eurand will be deemed to have consented to GSK's use of the Eurand Trademarks on such materials. GSK may make any subsequent changes to materials bearing an approved Eurand Trademark other than changes to the Eurand Trademark, without the subsequent approval from Eurand. GSK covenants that its use of the Eurand Trademark will be in accordance with the terms of this Agreement and that

all rights to and ownership of the Eurand Trademark will remain with Eurand. GSK may use the Eurand Trademark solely with respect to CTM and Product manufactured under the Clinical Supply Agreement and Commercial Supply Agreement, respectively, and no other product. For the avoidance of doubt, CTM and Product manufactured under an agreement with a Third Party manufacturer is deemed to be manufactured under the Clinical Supply Agreement or Commercial Supply Agreement, respectively, provided that the manufacturer is authorized under those agreements.

2.4 Right to Grant Sublicenses.

2.4.1 Except as set forth in Section 10.6 with respect to any Competing Business Entity, GSK will have the right to sublicense any or all of its rights under the Eurand Intellectual Property Rights as provided in Section 2.1 and under the Eurand Trademarks as provided in Section 2.3 to its Affiliates without the consent of Eurand. Except as set forth in Section 10.6 with respect to any Competing Business Entity, Eurand will have the right to sublicense any or all of its rights under the GSK Intellectual Property Rights as provided in Section 2.2 to its Affiliates without the consent of GSK.

2.4.2 GSK will have the right to sublicense its rights under the Eurand Intellectual Property Rights as provided in Section 2.1.2 to Third Parties to make and have made Product without the consent of Eurand, and solely in connection with any such sublicense, GSK will have the right to sublicense its rights under the Eurand Trademarks as provided in Section 2.3 to Third Parties solely to make and have made Product without the consent of Eurand. Notwithstanding the foregoing GSK will only be permitted to grant sublicenses under this Section 2.4.2 to the extent that the manufacture of CTM or Product by Third Parties is permitted under the Clinical Supply Agreement or the Commercial Supply Agreement, respectively.

2.4.3 GSK will have the right to sublicense its rights under the Eurand Intellectual Property Rights as provided in Section 2.1 to any Third Parties who GSK may engage to provide services to or on behalf of GSK relating to this Agreement or to perform any GSK Development Activities under this Agreement (including a Clinical Research Organization (CRO), Third Party packagers and Third Party distributors), in each case without the consent of Eurand, and solely in connection with any such sublicense, GSK will have the right to sublicense its rights under the Eurand Trademarks as provided in Section 2.3 to Third Parties without the consent of Eurand.

2.4.4 For all instances other than as provided in Sections 2.4.1, 2.4.2 and 2.4.3, GSK will have the right to sublicense its rights under the Eurand Intellectual Property Rights as provided in Section 2.1 and under the Eurand Trademarks as provided in Section 2.3 to any Third Party upon the prior written consent of Eurand, which consent will not be unreasonably withheld or delayed. Eurand will have the right to sublicense its rights under the GSK Intellectual Property Rights as provided in Section 2.2 to any Third Party upon the prior written consent of GSK.

2.4.5 The Parties acknowledge and agree that any sublicense agreement with a sublicensee will provide that the sublicensee is bound by all the terms and obligations of this Agreement. In addition, each Party will guarantee the performance of its sublicensee.

2.5 Affiliates. Notwithstanding anything in this Agreement to the contrary, either Party may contract or agree with one or more of its Affiliates to have such Affiliate perform any of such Party's obligations herein. In no event will such use of an Affiliate be deemed to relieve a Party of

its liabilities or obligations to the other Party under this Agreement; provided, that performance of an obligation hereunder by an Affiliate of a Party will be attributed to such Party. Each Party expressly acknowledges and agrees that it will remain fully and unconditionally obligated and responsible for the full and complete performance of all of its obligations under the terms and conditions of this Agreement, whether or not such performance is carried out by such Party or any of its Affiliates.

2.6 Kyowa Agreement.

2.6.1 Eurand will not, and will cause its Affiliates not to: (i) on its or their own or in agreement with Kyowa, terminate the Kyowa Agreement or supplement, amend or modify the Kyowa Agreement in any way that materially and adversely affects GSK's rights under the Eurand Intellectual Property Rights or in this Agreement without the prior written consent of GSK; or, (ii) send written notice to Kyowa of any monetary or non-monetary breach by Kyowa of the Kyowa Agreement without providing at least ten (10) calendar days' prior written notice to GSK.

2.6.2 Within five (5) Business Days of receiving written notice of a monetary breach or non-monetary material breach from Kyowa pursuant to Section 10.2 of the Kyowa Agreement, Eurand will, subject to its obligations to protect the confidential information of Kyowa or Eurand's Third Party licensees, consult with GSK concerning the nature of any problem or occurrence that is related to the receipt of such notification from Kyowa and shall inform GSK of the actions it plans to take to redress any problems and ensure that Eurand's rights to the Kyowa Agreement, and GSK's rights under the Know-How and Patent Rights arising under the Kyowa Agreement pursuant to this Agreement, remain in effect and undiminished. Eurand will use Commercially Reasonable Efforts to obtain permission from Kyowa to disclose to GSK any confidential information pertinent to any such notification received from Kyowa and pertinent to the nature of the problem.

2.6.3 Eurand will, within five (5) Business Days, inform GSK in the event that Eurand and/or any of its Affiliates becomes aware that Kyowa will, directly or indirectly, exercise its reserved rights pursuant to Section 2.3 under the Kyowa Agreement with respect to Compound in the Territory.

2.7 Reservation of Rights. No right or license under any Intellectual Property Rights Controlled by either Party is granted or implied except as expressly granted in this Agreement. Except for the rights specifically granted in this Agreement, each Party expressly reserves all rights Controlled by it or its Affiliates to all its products and intellectual property, and reserves the right to utilize or allow its Affiliates or Third Parties to utilize such products and Intellectual Property Rights in any manner not inconsistent with the terms of this Agreement.

3 PROGRAM:

3.1 Eurand Development Activities.

Eurand will be solely responsible for, using Commercially Reasonable Efforts, conducting the Eurand Development Activities in accordance with the terms and conditions of this Agreement and as directed by the Steering Committee, which Eurand Development Activities are initially set forth in Exhibit D, attached hereto and incorporated herein (the "Proposal"). Eurand will initiate the Eurand

Development Activities on the first (1st) Business Day after the Effective Date (the "Program Initiation Date"). Further, Eurand will assign professionally qualified personnel to perform the Eurand Development Activities and Eurand will, and will cause its Affiliates and personnel to, perform the Eurand Development Activities in compliance with the requirements of Applicable Laws, including cGMPs when appropriate.

3.2 GSK Development Activities. GSK, at its sole discretion and expense, will be solely responsible for, using Commercially Reasonable Efforts, conducting all aspects of the development of the Program other than the Eurand Development Activities (the "GSK Development Activities"), including, without limitation, determining the clinical, regulatory and manufacturing strategy (in accordance with the terms of the Clinical Supply Agreement and Commercial Supply Agreement) for the Product, the conduct of any and all Clinical Studies, and liaising and managing all interactions with Regulatory Authorities, with the exception of the filing and maintenance of the DMF.

3.3 Supply of Drug Substance for use in Eurand Development Activities. The Parties acknowledge and agree that in order for Eurand to commence performing the Eurand Development Activities upon the first Business Day after the Effective Date, GSK has provided Eurand with thirty (30) kilograms of Drug Substance prior to the Effective Date at no cost. In addition to Drug Substance transferred by GSK to Eurand prior to the Effective Date, GSK may transfer additional reasonable quantities of Drug Substance to Eurand at no cost except as set forth in Section 3.3.2(iv), which Eurand may reasonably request in connection with conducting the Eurand Development Activities and which request will be agreed to by GSK provided that it is consistent with the Proposal or in accordance with Section 3.5.

3.3.1 Prior to receipt by Eurand of Drug Substance before the Effective Date, GSK shall have provided Eurand with available information pertaining to procedures and warnings for the safe handling and use of the Drug Substance through the issuance to Eurand of Material Safety Data Sheets for the Drug Substance, and GSK shall provide Eurand with such additional available information pertinent to procedures and warnings for the safe handling and use of the Drug Substance and update the same during the course of the Program. Further, GSK shall have delivered to Eurand with such shipment of Drug Substance prior to the Effective Date a certificate of analysis stating that the Drug Substance meets the Drug Substance Specifications and has been manufactured in accordance with cGMP. Prior to receipt by Eurand of any additional quantities of Drug Substance after the Effective Date pursuant to this Section 3.3, GSK shall provide Eurand with available information pertaining to procedures and warnings for the safe handling and use of the Drug Substance through the issuance to Eurand of Material Safety Data Sheets for the Drug Substance, and GSK shall provide Eurand with such additional available information pertinent to procedures and warnings for the safe handling and use of the Drug Substance and update the same during the course of the Program. All Drug Substance provided after the Effective Date as provided in this Section 3.3 shall meet the Drug Substance Specifications. Further, GSK shall deliver to Eurand with each such shipment of Drug Substance after the Effective Date a certificate of analysis stating that the Drug Substance meets the Drug Substance Specifications and has been manufactured in accordance with cGMP.

3.3.2 Eurand agrees to use Drug Substance supplied to it by GSK pursuant to this Section 3.3, whether supplied prior to or after the Effective Date, in accordance with the following terms:

(i) Upon receipt, Eurand will sample and analyze each shipment of Drug Substance to determine if such shipment meets the Drug Substance Specifications. Eurand shall notify GSK within ten (10) Business Days after delivery of such shipment of Drug Substance if there are shortages, if the shipment of Drug Substance does not meet the Drug Substance Specifications or if the shipment of Drug Substance is considered to be adulterated or misbranded within the meaning of the Act. Unless Eurand advises GSK that a shipment is unsatisfactory within such ten (10) Business Day period, such shipment shall be deemed to have been accepted by Eurand.

(ii) Eurand will ensure that all quantities of Drug Substance received from GSK pursuant to this Section 3.3, whether received prior to or after the Effective Date, are used for the sole purpose of completing the Eurand Development Activities under this Agreement and as specified in the Proposal.

(iii) Eurand will not make Drug Substance available to any Entity not under the direct supervision of Eurand without the prior written consent of GSK.

(iv) Eurand will use Commercially Reasonable Efforts to ensure its use of the Drug Substance provided to it by GSK pursuant to this Section 3.3, whether provided prior to or after the Effective Date, minimizes or eliminates any loss or waste of such Drug Substance. Eurand acknowledges and agrees that the Drug Substance is available from GSK in limited quantities and excessive loss or waste of the Drug Substance (but excluding process-related yield losses normally encountered in developing a product) may result in charges to Eurand for receipt of additional quantities of Drug Substance pursuant to this Section 3.3.

(v) All Drug Substance provided to Eurand by GSK pursuant to this Section 3.3, whether provided prior to or after the Effective Date, will remain the property of GSK; however, risk of loss and damage to the Drug Substance shall remain with Eurand while the Drug Substance is under Eurand's care and control.

(vi) Eurand will ensure that all Drug Substance received from GSK pursuant to this Section 3.3, whether received prior to or after the Effective Date, is stored in accordance with cGMP and Applicable Laws, and is kept separate from other materials belonging to Eurand or Third Parties.

(vii) Eurand will not store or process any Drug Substance in the same building in which Eurand manufactures, stores or processes cytotoxics, penicillin, genetically modified organisms, cephalosporins, sex hormones, anabolic steroids, and infectious agents (e.g., spore-bearing and live viruses), (collectively, "Potential Contaminants") unless the Potential Contaminants are stored or manufactured in contained environments and in compliance with cleaning, validation and changeover standards of all cGMPs, and all Applicable Laws. Eurand will promptly notify GSK if any of the Potential Contaminants are manufactured, processed or stored in any portion of the facility which may result in the introduction of Potential Contaminants into the areas of the facility where Eurand stores the Drug Substance. Eurand will notify GSK by not later than the earlier to occur of (A) one hundred twenty (120) calendar days prior to such event or (B) Eurand's knowledge of such event, if Eurand intends to change the nature or use of any portion of the Eurand facility or any module to include the use of any of the Potential Contaminants. Eurand will not make such changes if the change could reasonably be expected to result in a material adverse effect on Eurand's ability to fully perform its obligations under this Agreement and Eurand has not

demonstrated to GSK's reasonable satisfaction that such Potential Contaminants shall be completely segregated from the Drug Substance at all times in the Eurand facility.

(viii) Upon termination of this Agreement for any reason or upon GSK's request, Eurand will at GSK's sole option and expense either (A) certify destruction of all Drug Substance provided to it by GSK pursuant to this Section 3.3, whether provided prior to or after the Effective Date, and account for any used Drug Substance or (B) return the remaining Drug Substance provided to it by GSK pursuant to this Section 3.3, whether provided prior to or after the Effective Date, and account for any used Drug Substance.

3.4 Each Party will use Commercially Reasonable Efforts to cooperate with the other Party in carrying out the Program. Each Party will make available such of its scientific, engineering, manufacturing and other personnel necessary to perform its respective responsibilities under the Program in accordance with the terms of this Agreement. The Parties shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Drug Substance and any Product resulting from the Program. The Parties agree that the Drug Substance and Product will be used in compliance with all Applicable Laws, including without limitation those governing disposal of hazardous materials.

3.5 Program Changes. The Parties acknowledge that the nature of the development process is such that modifications to the Program (including modifications relating to the acquisition of additional equipment and materials) may be desirable or reasonably necessary at certain times for regulatory, legal, commercial or other reasons. Accordingly, in the event that either Party believes that a change to the Program is required, that Party will immediately notify the Steering Committee in writing of the exact nature of any desired change and the specific reasons therefor. The Steering Committee will then meet promptly to discuss the changes that may be needed. If the Steering Committee agrees that changes in the Program are required, the Parties will amend the Proposal to reflect the necessary changes, and also set out any cost increases or additional time that is required to fulfill the Program. All cost increases relating to any changes in the Program will be borne wholly by GSK unless such changes to the Program were necessary due to any act or omission of Eurand, in which case the cost increases relating to the changes in the Program due partially or solely to an act or omission of Eurand will be borne either partially or wholly by Eurand, as applicable.

4 COMMERCIALIZATION:

4.1 GSK will have full control, authority and responsibility for the commercialization of Product in the Field in the Territory. GSK will exercise its Commercially Reasonable Efforts in commercializing Product in the Territory once it has obtained all required Regulatory Approvals. GSK will have final decision-making authority, in its sole discretion, relating to all aspects of the marketing and commercialization of Product in the Field in the Territory, including pricing and reimbursement for Product, Product advertising and promotional materials, Product packaging, sales force training and all interactions with Regulatory Authorities regarding the commercialization of Product in the Field.

4.2 GSK will book all sales of Product in the Field in the Territory and will warehouse and distribute the Product in the Field in the Territory; provided, however, that GSK will be

permitted to warehouse Product in the Field outside of the Territory if such Product has been packaged by or on behalf of GSK outside of the Territory or manufactured by or on behalf of GSK outside of the Territory to the extent permitted under the Clinical Supply Agreement or the Commercial Supply Agreement.

4.3 Subject to Applicable Law and Section 2.3.2, GSK will, in its sole discretion, determine and select all Trademarks used in connection with Product in the Field (the "GSK Trademarks"). For the avoidance of doubt, the term "GSK Trademarks" means all Trademarks Controlled by GSK and/or its Affiliates or a Third Party on behalf of GSK or its Affiliates on the Effective Date or at any time during the Term; provided, however, that the term "GSK Trademarks" will in no way be deemed to include the Eurand Trademarks.

4.4 Except if GSK terminates this Agreement pursuant to Sections 11.2.2 or 11.2.4, GSK agrees that it will not, and it will prevent its Affiliates and contractually mandate that its sublicensees will refrain from, making, using, selling, offering for sale or importing Product upon the termination (but not the expiration) of this Agreement.

5 STEERING COMMITTEE:

5.1 Within ten (10) Business Days after the Effective Date, the Parties will form a committee (the "Steering Committee"), which will oversee each Party's conduct of its respective obligations under the Program and to serve as a forum for the Parties to discuss any issues that may arise under this Agreement during the Term.

5.2 Each Party will designate at least two (2) representatives for membership on the Steering Committee. Each Party may change one or more of its representatives to the Steering Committee at any time. In addition, each Party may from time to time and in its sole discretion include non-voting ad-hoc representatives to participate in Steering Committee meetings to address specific issues. A GSK member will chair the Steering Committee. Each Party will have one (1) vote on each matter brought before the Steering Committee.

5.3 The first meeting of the Steering Committee will be face to face at a location agreed to by the Parties and will occur within thirty (30) Business Days after the Effective Date. Thereafter, the meetings will be held at least once every Calendar Quarter or more or less frequently as the Steering Committee members may agree. The location of such meetings will alternate between sites selected by Eurand and GSK, unless otherwise agreed upon by the Parties. Steering Committee meetings need not necessarily be face to face but, upon the agreement of the Parties, can be via other methods of communication such as teleconferences and/or videoconferences. Each Party will bear all expenses it incurs in regard to participating in all Steering Committee meetings, including, without limitation, traveling and living expenses.

5.4 Minutes of the Steering Committee will be prepared by the chair or his/her designee. Draft minutes shall be sent to all members of the Steering Committee within ten (10) Business Days after each meeting. The draft minutes shall be edited by the chair based on comments from the members of the Steering Committee and shall be distributed to the members prior to the next meeting of the Steering Committee. All records of the Steering Committee shall at all times be available to both Parties.

5.5 The Steering Committee may delegate its responsibilities to any one or more subcommittees, each of which shall have an equal number of members from GSK and Eurand. Any disputes between the members of any subcommittees will be submitted to the Steering Committee for resolution in accordance with Section 5.6.

5.6 Resolution of Disputes. All decisions of the Steering Committee will be by unanimous vote, which decisions will be final and binding on the Parties. Should the members of the Steering Committee become deadlocked on an issue after good faith but unsuccessful effort to break such deadlock, the issue will be resolved in accordance with the following procedures:

5.6.1 the disputed matter will be presented to the President of Eurand or to his/her respective designee and as to the senior executives of GSK as follows: (i) to the Chairman of Research and Development of GSK, or to his/her respective designee for disputes relating to development issues, (ii) to the President of U.S. Pharmaceuticals of GSK, or to his/her respective designee for disputes relating to commercial issues; and (iii) to either of the foregoing senior executives of GSK, as determined by GSK, for all other disputes.

5.6.2 such executives shall meet or discuss in a telephone or video conference each Party's view and explain the basis for such disagreement; and

5.6.3 if such executives cannot promptly resolve such disagreement under Section 5.6.1(i), (ii)or (iii), as applicable, within ten (10) calendar days after such issue has been referred to them, then GSK will in good faith and using Commercially Reasonable business judgment make the final and binding decision regarding the matter unless such decision would have a material and detrimental impact on Eurand, in which case Eurand may refer the decision to the dispute resolution process set forth in Section 14.14. For the avoidance of doubt, if such executives are unable to resolve a dispute regarding whether a Milestone Event has been achieved as set forth in Section 8.2, GSK will have no right to make the final and binding decision regarding such matter, but rather such matter will be resolved through the dispute resolution process set forth in Section 14.14.

5.7 The Steering Committee will have only such powers as are specifically delegated to it in this Agreement, and will have no power to amend this Agreement or waive a Party's rights or obligations under this Agreement.

6 SUPPLY OF CLINICAL AND COMMERCIAL MATERIAL:

6.1 Generally. Notwithstanding anything set forth in Section 2, the Parties acknowledge and agree that GSK hereby engages Eurand to exclusively (even as to GSK except as set forth in the Clinical Supply Agreement and Commercial Supply Agreement): (i) manufacture CTM which GSK will use in Clinical Studies, and (ii) manufacture bulk tablet forms of Product which GSK will commercialize and sell in the Territory. The terms pursuant to which Eurand will supply such CTM and Product are set forth in Sections 6.2 and 6.3, respectively.

6.2 Clinical Supply Agreement. Within sixty (60) calendar days after the Effective Date, the Parties will execute a supply agreement (the "Clinical Supply Agreement") and quality agreement, which will set forth the terms and conditions pursuant to which Eurand will supply CTM to GSK. Such Clinical Supply Agreement will include the terms set forth on Exhibit E, attached

hereto and incorporated herein. If the Parties do not enter into a Clinical Supply Agreement within sixty (60) calendar days after the Effective Date, the Parties acknowledge and agree that the terms set forth on Exhibit E will serve as the binding terms pursuant to which Eurand will supply CTM requested by GSK for use in Clinical Studies until a Clinical Supply Agreement is executed, and the terms and conditions of this Agreement shall apply to such supply relationship to the extent that they are not inconsistent with the terms set forth in Exhibit E, excluding any limitations of liability contained in this Agreement.

6.3 Commercial Supply Agreement. Prior to NDA Acceptance (as such term is defined in 8.2.1(vi), the Parties will execute a supply agreement (the "Commercial Supply Agreement") and quality agreement, which will set forth the terms and conditions pursuant to which Eurand will supply Product to GSK for sale in the Territory. Such Commercial Supply Agreement will include the terms set forth on Exhibit F, attached hereto and incorporated herein. If the Parties do not enter into a Commercial Supply Agreement prior to NDA Acceptance, the Parties acknowledge and agree that the terms set forth on Exhibit F will serve as the binding terms pursuant to which Eurand will supply Product requested by GSK for sale in the Field in the Territory until a Commercial Supply Agreement is executed and the terms and conditions of this Agreement shall apply to such supply relationship to the extent that they are not inconsistent with the terms set forth in Exhibit F, excluding any limitations of liability contained in this Agreement.

6.4 For the avoidance of doubt, GSK will be responsible for conducting, or arranging for the conducting of, commercial packaging, commercial stability testing and commercial labeling of all Product.

7 REGULATORY:

7.1 Regulatory Affairs.

7.1.1 During the Program, to the extent required by the FDA or any other Regulatory Authority to conduct Clinical Studies in humans or in order for GSK to receive Regulatory Approvals for Product, Eurand shall prepare a DMF and submit the DMF to the FDA; provided, however, that GSK will have the right, and will be provided a reasonable amount of time, to fully review and comment on the DMF prior to each such submission by Eurand, which comments of GSK will be considered in good faith by Eurand for inclusion in each DMF submission. Eurand shall notify GSK of the submission date for the DMF at least ten (10) Business Days prior to each such submission, and notify GSK promptly regarding any material issues with respect to the filing or maintenance of the DMF. Further, Eurand will allow GSK to review all correspondence between Regulatory Agencies and Eurand regarding each DMF submission and permit GSK to comment on such correspondence, which comments of GSK will be considered in good faith by Eurand for inclusion in any correspondence to Regulatory Agencies regarding each DMF submission. During the Term and for twelve (12) consecutive months after the expiration thereof, Eurand will provide GSK with unrestricted, full access to the DMF, copies of which will be provided by Eurand to a location identified by GSK, so that GSK may review and reference the DMF as appropriate to prepare the CMC portion of the NDA for the Product and to prepare any other applications to obtain Regulatory Approvals for the Product during the Term. GSK will treat all information reviewed in the DMF as Eurand's Confidential Information and to the extent possible, GSK will limit the review of the DMF to certain named individuals at GSK.

7.1.2 The Parties will use Commercially Reasonable Efforts to complete, and to cooperate with the other Party in its completion of, the Pre-Registration Activities. Any disagreement as to whether the Pre-Registration Activities are completed shall be resolved in accordance with Section 5.6.

7.1.3 GSK will use Commercially Reasonable Efforts to prepare and submit all necessary applications to obtain Regulatory Approvals to use, market and sell the Product in the Territory as provided in this Agreement. Eurand shall have the right to review and comment upon the portions of proposed protocols and investigator brochures and informed consent forms as far as they relate to the ODT Technology or Eurand's Confidential Information, and GSK will consider in good faith, but will in no way be obligated to adopt in such protocols and investigator brochures, any changes suggested by Eurand. With the exception of the DMF as set forth in Section 7.1.1, and except to the extent that Eurand is exclusively using, marketing or selling Product in a country as set forth in Section 9.5, it is understood that GSK will prepare and make all other necessary filings for Regulatory Approvals with the appropriate Regulatory Authorities which are required to secure approval to use, market and sell the Product in the Field as provided in this Agreement. Eurand agrees, upon request from GSK, to promptly provide GSK with such information as GSK may reasonably require to complete any and all such filings and submissions for Regulatory Approvals, unless such information is contained in the DMF in which case the information will be filed with the DMF. Eurand will, on a timely basis and as requested by GSK from time to time during the Term, fully co-operate with GSK by providing such people and resources as reasonably necessary to respond to questions from, and attend meetings with, Regulatory Authorities relating to filings for Regulatory Approvals made by GSK relating to the Product. GSK shall own all Regulatory Approvals for Product.

7.1.4 GSK shall notify Eurand of the submission date of each application for Regulatory Approvals for the Product in the Territory at least five (5) Business Days prior to such submission, and notify Eurand of the effective dates of any such Regulatory Approvals or NDA Acceptance not later than five (5) Business Days after each such date. During the Term, GSK shall provide Eurand with a report on the status of progress of all filings for Regulatory Approval in the Territory every three (3) months following completion of the Pre-Registration Activities until such filings are approved by the appropriate Regulatory Authorities and thereafter, on the status of its progress toward making the First Commercial Sale of Product in the Territory. GSK shall notify Eurand of the date of First Commercial Sale within three (3) Business Days after its occurrence.

7.1.5 Eurand shall use Commercially Reasonable Efforts to give GSK reasonable notice of any impending governmental or other Third Party audit of Eurand as it relates to the manufacture or testing of the Product or CTM supplied to GSK pursuant to the Commercial Supply Agreement and the Clinical Supply Agreement, respectively, and shall provide GSK with any documentation provided to it relating to such audit. In the event that any such audit involves an inspection of a Eurand facility, then Eurand shall use Commercially Reasonable Efforts to promptly notify GSK of any such inspection and provide GSK the opportunity to be present at that part of such inspection as it relates solely to the Product or CTM, provided that GSK acknowledges that Eurand does not control the timing of such inspections and, as such, cannot guarantee timing that will permit GSK's attendance. GSK acknowledges that should representatives of GSK be present during an audit, their function is restricted to that of being an observer and that Eurand is solely responsible for the manner and conduct of any and all audits. Eurand shall also use Commercially Reasonable Efforts to provide GSK with a reasonable opportunity to review, prior to submission, any documentation prepared in response to such governmental or other Third Party audit and shall

immediately provide GSK with the results of such audit following its conclusion; however, Eurand shall have sole discretion in responding to any such audit. Eurand agrees that GSK shall have the right from time to time during the Term to carry out an audit of Eurand for conformance with cGMPs, but not more than once per Calendar Year, unless an audit results in adverse findings in which case GSK shall be entitled to re-audit Eurand with respect to such adverse findings pursuant to this Section 7.1.5 without reference to the once per Calendar Year limitation. GSK must provide advanced written notice at least fifteen (15) Business Days prior to such audits and audits may only be scheduled with the consent and approval of Eurand, such approval not to be unreasonably withheld.

7.1.6 Eurand shall provide GSK with reasonable notification of its receipt of any of the following related to the manufacture or testing of the Product: a copy of any list of observations (Form FDA 483), warning letter, information letter, regulatory letter or the like issued by the FDA as well as provide GSK an opportunity to review any written response prior to submission to the issuing agency. However, Eurand shall have sole discretion regarding the resolution of any matter pertaining to such notifications.

8 COMPENSATION:

8.1 Development Fees.

8.1.1 Eurand shall invoice GSK at the end of each month for its personnel costs and expenses incurred in Eurand's performance of the Eurand Development Activities. Each invoice shall be accompanied by a detailed accounting of the personnel time spent, and costs and expenses incurred, by Eurand in performing the Eurand Development Activities. Eurand shall also invoice GSK for all out-of-pocket expenses actually incurred by Eurand which are directly associated with Eurand's performance of the Eurand Development Activities in accordance with the Proposal and this Agreement, provided, however that such costs and expenses are pre-approved by GSK in writing. Such invoices shall be sent to:

Lamictal ODT Project Leader
Greenford Road
Greenford
Middlesex, England
UB6 OHE

With a copy to:

Alliance Director for Lamictal ODT
New Frontiers Science Park
Third Avenue
Harlow
Essex, England
CM19 SAW

8.1.2 Eurand's monthly invoices as provided above shall reflect an hourly rate of One Hundred Forty Seven U.S. Dollars and Fifty Cents (U.S. $147.50) per person; such rate may be adjusted by not more than the percentage change for the immediately preceding twelve (12) months in the Employment Cost Index as published by the Bureau of Labor Statistics of US Department of Labor once each consecutive twelve (12) month period after the Effective Date by Eurand to reflect reasonable and customary changes to its billing rates. Eurand's personnel time for performing the Eurand Development Activities shall not exceed the estimated amounts set forth in Exhibit D by more than ten percent (10%) for each stage of Eurand Development Activities under the Proposal, unless such Eurand Development Activities are changed as set forth in Section 3.5, or as otherwise agreed to in advance and in writing by GSK.

8.1.3 *Additional Expenses.* In addition to the cost estimates set forth in Exhibit D hereto, GSK shall be responsible for the following additional, costs and/or expenses:

(i) the cost of any additional Eurand Development Activities performed by Eurand as a result of changes made to the Program, subject to Section 3.5;

(ii) the cost of any external contract research, which is agreed to by GSK in writing prior to such costs being incurred; and

(iii) the cost of any Program specific tooling and dedicated equipment, which is agreed to by GSK in writing prior to such costs being incurred, and which tooling and dedicated equipment will be the exclusive property of GSK.

All such permitted additional costs and expenses will be invoiced by Eurand on a monthly basis in accordance with Sections 8.1.1 and 8.1.2 above.

8.1.4 Payments. Subject to Section 8.4, GSK shall make payments to Eurand for all uncontested amounts due under this Section 8.1 within thirty (30) Business Days of receipt of an invoice from Eurand as provided in this Section 8.1. In the event GSK fails to pay any uncontested amounts set forth in any invoice as provided in this Section 8.1.4, Eurand may at its discretion impose a late payment fee on GSK equivalent to one-half percent (0.5%) of the outstanding uncontested amount due per month. In the event of a late payment by Eurand to GSK of any overpayment received by Eurand under this Section 8.1, as provided in Section 8.4.3(ii), GSK may at its discretion impose a late payment fee on Eurand equivalent to one-half percent (0.5%) of the overdue payment from the date such payment was due to the date such payment is received by GSK.

8.2 Milestone Payments. In consideration for Eurand's performance of the Eurand Development Activities, subject to Sections 8.2.1 and 8.2.2, GSK will make the following non-refundable payments (the "Milestone Payments") to Eurand in the incremental amounts and in the manner set forth below, which Milestone Payments will not exceed Forty Two Million U.S. Dollars (U.S. $42,000,000), upon achieving the Milestone Payment events set forth below (the "Milestone Events"):

	Milestone Event	Milestone Payment
(i)	Program Initiation Date	U.S. $3,000,000
(ii)	Successful Completion of Stage I	U.S. $1,000,000

(iii)	Successful Completion of Stage II	U.S. $500,000
(iv)	Submission of DMF to the FDA	U.S. $500,000
(v)	Initiation of Bioequivalence Study	U.S. $1,000,000
(vi)	Successful Demonstration of Bioequivalence	U.S. $1,500,000
(vii)	NDA Acceptance	U.S. $2,000,000
(viii)	NDA Approval	U.S. $2,500,000
(ix)	Net Sales Equal to U.S. $120,000,000	U.S. $8,000,000
(x)	Net Sales Equal to U.S. $240,000,000	U.S. $10,000,000
(xi)	Net Sales Equal to U.S. $360,000,000	U.S. $12,000,000

8.2.1 *Milestone Payment Definitions.*

(i) The phrase "Successful Completion of Stage I", as used in Section 8.2(ii) above and Section 9.6 below, means that Eurand has delivered to GSK five (5) prototypes of Product within ninety (90) calendar days after the Program Initiation Date as follows:

Prototype 1: using granulation approach (100mg, cherry flavor);

Prototype 2: using granulation approach (200mg, mint flavor);

Prototype 3: using granulation approach (200mg, cherry flavor);

Prototype 4: using coacervation approach (100mg, cherry flavor); and

Prototype 5: using coacervation approach (200mg, cherry flavor);

or such other smaller combination of the same five (5) prototypes listed above as determined by the Steering Committee. GSK may in no event request more than five (5) prototypes of Product from Eurand pursuant to this Section 8.2.1(i). In the event that the Steering Committee requires a material change to the requirements for any of the prototypes described in this Section 8.2.1(i), then the Steering Committee shall agree on an appropriate time extension for Successful Completion of Stage I.

(ii) The phrase "Successful Completion of Stage II", as used in Section 8.2(iii) above and Section 9.6 below, means that Eurand has delivered to GSK, within one hundred ninety five (195) calendar days after the Program Initiation Date and in accordance with the terms and conditions of the Clinical Supply Agreement, four (4) batches of CTM for use by or on behalf of GSK in a pilot pharmacokinetic study relating to Product as follows:

CTM 1: using coacervation approach (25mg, cherry flavor);

CTM 2: using coacervation approach (200mg, cherry flavor);

CTM 3: using granulation approach (25mg, mint flavor); and

CTM 4: using granulation approach (200mg, cherry flavor);

or such other smaller combination of CTM batches as determined by the Steering Committee. In the event that the Steering Committee requires a material change to the requirements for any of the CTM batches described in this Section 8.2.1(ii), then the Steering Committee shall agree on an appropriate time extension for Successful Completion of Stage II.

(iii) The phrase "Submission of DMF to the FDA", as used in Section 8.2(iv) above, means the date on which Eurand submits the DMF to the FDA in accordance with the Applicable Laws.

(iv) The phrase "Initiation of Bioequivalence Study", as used in Section 8.2(v) above, means the date on which the first subject is dosed in a pivotal pharmacokinetic study conducted by or on behalf of GSK to determine whether CTM supplied by Eurand to GSK (pursuant to the Clinical Supply Agreement) is bioequivalent to GSK's Lamictal® (lamotrigine) tablets, *provided, however,* that such date is not later than three hundred forty five (345) calendar days after the Project Initiation Date.

(v) The phrase "Successful Demonstration of Bioequivalence", as used in Section 8.2(vi) above, means the date on which GSK determines in its sole discretion that the results of a pivotal pharmacokinetic study, which study and its statistical analysis must have been completed prior to August 10, 2007, demonstrates that CTM provided by Eurand to GSK pursuant to the Clinical Supply Agreement is bioequivalent to GSK's Lamictal® (lamotrigine) tablets.

(vi) The phrase "NDA Acceptance", as used in Section 8.2(vii) above, means the date on which GSK receives written notice from the FDA of acceptance for substantive review of a NDA filed by or on behalf of GSK for the purpose of obtaining Regulatory Approval to commercialize Product in the Field in the Territory, which date must be prior to December 31, 2007.

(vii) The phrase "NDA Approval" as used in Section 8.2(viii) above, means the date on which GSK receives written notice from the FDA that it has approved the NDA filed by or on behalf of GSK to commercialize Product in the Territory in the Field, which date must be prior to October 1, 2008.

(viii) The phrase "Net Sales Equal to U.S. $120,000,000", as used in Section 8.2(ix) above, means the first time Net Sales reach One Hundred Twenty Million U.S. Dollars (U.S. $120,000,000) in any Calendar Year during the Term.

(ix) The phrase "Net Sales Equal to U.S. $240,000,000", as used in Section 8.2(x) above, means the first time Net Sales reach Two Hundred Forty Million U.S. Dollars (U.S. $240,000,000) in any Calendar Year during the Term.

(x) The phrase "Net Sales Equal to U.S. $360,000,000", as used in Section 8.2(xi) above, means the first time Net Sales reach Three Hundred Sixty Million U.S. Dollars (U.S. $360,000,000) in any Calendar Year during the Term.

8.2.2 *Milestone Payment Provisions.*

(i) Each Milestone Payment will be made only one time and only for the first time that the corresponding Milestone Event is achieved, regardless of how many times such Milestone Event is achieved, and no Milestone Payments will be owed for a Milestone Event which is not achieved; provided however, that in the event that GSK achieves the First Commercial Sale of Product in the Territory, the Milestone Payments set forth in Sections 8.2(ii)-(viii) which have not been paid by GSK will be deemed to have been achieved as of the date of such First Commercial Sale and will be payable as provided herein.

(ii) Subject to Section 8.4, GSK will remit payment to Eurand of each Milestone Payment within thirty (30) Business Days after receipt of an invoice from Eurand following the earlier of (i) agreement by the Steering Committee, or (ii) notification by GSK, of the achievement of the Milestone Event.

8.3 Royalties.

8.3.1 *Full Royalty.* In consideration for the licenses and sublicenses granted to GSK by Eurand in this Agreement, and subject to Sections 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.4, 10.4.3 and 10.6.3, GSK will pay to Eurand a percentage of Net Sales in each Calendar Year (the "Royalties"), as follows:

	Aggregate Net Sales in the Territory in a Calendar Year	**Incremental Royalty Rate on Aggregate Net Sales in the Territory in a Calendar Year**
(i)	0 to U.S. $40,000,000	3.5%
(ii)	U.S. $40,000,001 to U.S. $80,000,000	5%
(iii)	U.S. $80,000,001 to U.S. $120,000,000	6.5%
(iv)	U.S. $120,000,001 and above	8%

8.3.2 *Reduced Royalty.*

(i) In the event that Competitive Products are marketed by a Third Party(ies) in the Territory, GSK shall promptly notify Eurand of such event providing information regarding the Competitive Product(s) and Third Party(ies). In the event that such Competitive Products in the aggregate, achieve prescription market share equal to fifteen percent (15%) or greater in the aggregate of total prescriptions for Product (assessed on a moving quarterly basis ending on the same date as the Calendar Quarter using reference data published by IMS Health, or another industry accepted source, provided that such other source is agreed upon by the Steering Committee), then beginning in the following Calendar Quarter and continuing thereafter (subject to Section 8.3.3), the Royalties set forth in Sections 8.3.1(ii), 8.3.1(iii), and 8.3.1(iv) will be reduced to four percent (4%), five percent (5%) and six percent (6%), respectively.

(ii) In the event that Competitive Products are marketed by a Third Party(ies) in the Territory which, in the aggregate, achieve prescription market share equal to fifty

percent (50%) or greater in the aggregate of total prescriptions for Product (assessed on a moving quarterly basis ending on the same date as the Calendar Quarter using reference data published by IMS Health, or another industry accepted source, provided that such other source is agreed upon by the Steering Committee), then beginning in the following Calendar Quarter and continuing thereafter (subject to Section 8.3.3), the Royalties set forth in Sections 8.3.1(ii), 8.3.1(iii) and 8.3.1(iv) will be reduced to four percent (4%).

(iii) GSK shall provide the Steering Committee with such reference data described in Section 8.3.2(i) and 8.3.2(ii) detailing the prescriptions for Product and Competitive Products for such Calendar Quarters for which GSK seeks a royalty rate reduction in the corresponding following Calendar Quarters.

8.3.3 *Commencement and Expiration of Royalty Obligations.* GSK's obligation to pay the Royalties as provided in Section 8.3.1 and 8.3.2 will commence upon the First Commercial Sale in the Territory and expire on the date that is ten (10) years from the date of the First Commercial Sale in the Territory. During the period that is equal to or more than eleven (11) years from the date of the First Commercial Sale in the Territory but in no event more than fifteen (15) years after the First Commercial Sale in the Territory, the Royalties set forth in Sections 8.3.1 and 8.3.2, as applicable, will be reduced to the lesser of (i) three and one half percent (3.5%), or (ii) the royalty rate owed by Eurand to Kyowa under the Kyowa Agreement on sales of Product in the Territory plus three quarters of one percent (0.75%).

8.3.4 *Royalty to Kyowa.* For the avoidance of doubt, the Parties acknowledge and agree that the Royalties payable by GSK to Eurand on Net Sales as provided in this Section 8.3 are inclusive of any royalties or consideration of any kind owed by Eurand to Kyowa under the Kyowa Agreement on sales of Product in the Territory, and that GSK will not owe any additional consideration to Eurand and/or Kyowa on Net Sales in the Territory in any period during the Term or thereafter.

8.3.5 *Third Party Payments.* Although as of the Effective Date, they have no actual knowledge of such a requirement, the Parties acknowledge that, during the Term, one (1) or more royalty-bearing licenses may be required from one (1) or more Third Parties in order for GSK and its Affiliates to use, sell, offer for sale and import Product in the Field without infringing the Intellectual Property Rights of one or more Third Parties. Subject first to Eurand's rights and obligations under Section 9.6.1, GSK will have the right but not the obligation, to use Commercially Reasonable Efforts to obtain and maintain such Third Party licenses. If Eurand is unable to effect any of the actions described in Section 9.6.1, and as a result of GSK subsequently obtaining and maintaining such Third Party licenses, it is necessary for GSK to make royalty payments and/or license fee payments to such Third Party (collectively, the "Third Party Payments") solely in order for GSK to practice the Eurand Intellectual Property Rights granted in Sections 2.1 and 2.3 without infringing such Third Party's rights, GSK will be entitled to offset all such Third Party Payments against any Royalties owed to Eurand pursuant to this Section 8.3 during the Term; provided, however, that GSK will not be permitted to reduce any Royalties owed to Eurand in any Calendar Quarter pursuant to this Section 8.3 by more than fifty percent (50%); and provided, further that any Third Party Payments that cannot be offset against Royalties in any Calendar Quarter may be carried over to offset against Royalties in future Calendar Quarters, subject to this Section 8.3.5. Specifically, GSK shall be entitled to offset such Third Party Payments: (i) only against Royalties earned by Eurand after GSK pays such Third Party Payments, and (ii) only with respect to Third Party Payments for licenses that are required to practice the Eurand Intellectual Property Rights. For

the avoidance of doubt, Eurand will have no obligation to make any payments to either GSK or to such Third Party under this Section 8.3.5 in order for GSK to practice its rights under the Eurand Intellectual Property Rights.

8.3.6 *Royalty Payment Terms.*

(i) Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge and agree that Royalties will only be payable on Net Sales occurring on and after the First Commercial Sale by GSK, its Affiliates and their respective sublicensees to a Third Party.

(ii) No later than fifteen (15) Business Days after the end of each month, GSK shall use Commercially Reasonable Efforts to report to Eurand the Net Sales in the Territory for the previous month.

(iii) Subject to Section 8.4, within thirty (30) Business Days after the last day of each Calendar Quarter, GSK will report the Net Sales in the immediately preceding Calendar Quarter and the Royalty owed on such Net Sales and will pay to Eurand all Royalties due and payable on Net Sales in the immediately preceding Calendar Quarter, or portion thereof if applicable.

(iv) Any and all Royalty payments made by GSK to Eurand pursuant to this Agreement will be accompanied by a written statement setting forth the calculation of Royalties due.

(v) In the event of a late payment of Royalties, GSK will pay to Eurand interest calculated on a daily basis on the overdue payment from the date such payment was due to the date such payment is received by Eurand at a rate of one-half percent (0.5%) per calendar month. In the event of a late payment of any overpaid Royalties by Eurand to GSK as provided in Section 8.4.3(i), Eurand will pay to GSK interest calculated on a daily basis on the overdue payment from the date such payment was due to the date such payment is received by GSK at a rate of one-half percent (0.5%) per calendar month.

8.4 General Payment Terms. Notwithstanding anything to the contrary in this Section 8, all payments made by GSK to Eurand under this Agreement will be subject to the following:

8.4.1 All payments made under this Agreement will be made in U.S. dollars. All payments will be made by wire transfer in immediately available funds to one or more bank accounts to be designated in writing by Eurand.

8.4.2 If taxes, assessments, fees or other charges are required to be withheld from payments to Eurand, GSK will make such payments to the applicable taxing authority as required to fulfill such requirement and pay to Eurand the net amount of the Milestone Payments, Royalties or other payments due. Receipts, if available, for all such withholdings will be provided to Eurand. GSK will assist Eurand in claiming exemption from such deductions or withholdings under any applicable double taxation or similar agreement or treaty.

8.4.3 *Audit Rights.*

(i) After the first (1st) anniversary of the date of First Commercial Sale and upon the provision of not less than sixty (60) calendar days' prior written notice, Eurand will

have the right, during normal business hours not more than once in each Calendar Year during the Term and for one (1) Calendar Year thereafter, using an independent public accountant designated by Eurand and reasonably acceptable to GSK (the "Eurand Auditor"), to inspect GSK's books of account, records, documents and instruments for up to the previous two (2) Calendar Years during the Term (or such lesser period if Product has been commercialized for less than two (2) Calendar Years), to ascertain the accuracy of GSK's Net Sales and the Royalty payments made by GSK to Eurand pursuant to this Agreement. If such examination by the Eurand Auditor results in a determination that GSK's Net Sales or Royalty payments owed to Eurand by GSK have been understated, unpaid amounts due will be paid by GSK to Eurand within thirty (30) calendar days after such Eurand Auditor notifies the Parties of such discrepancy. If such examination results in a determination that GSK's Net Sales or Royalty payments owed to Eurand by GSK have been overstated, overpaid amounts due will be re-paid by Eurand to GSK within thirty (30) calendar days after such Eurand Auditor notifies the Parties of such discrepancy. The expense of such audit shall be Eurand's unless the audit shall demonstrate an underpayment of Royalties greater than five percent (5%) between Royalties reported and paid and those which were actually due, in which event the reasonable expenses of Eurand Auditor shall be borne by GSK. The Eurand Auditor will report to the Parties only its conclusions as to whether GSK is in compliance with its Royalty obligations and the amount of any underpayment or overpayment, and such report and the conclusions contained therein will constitute GSK Confidential Information.

(ii) After the first (1st) anniversary of the Effective Date and upon the provision of not less than sixty (60) calendar days' prior written notice, GSK will have the right, during normal business hours not more than once in each Calendar Year during the Term and for one (1) Calendar Year thereafter, using an independent public accountant designated by GSK and reasonably acceptable to Eurand (the "GSK Auditor"), to inspect Eurand's books of account, records, documents and instruments for up to the previous two (2) Calendar Years during the Term (or such lesser period if this Agreement has been effective for less than two (2) Calendar Years), to ascertain the accuracy of the invoices provided by Eurand pursuant to Section 8.1 and of the personnel time and all costs and expenses incurred by Eurand in performing the Eurand Development Activities pursuant to this Agreement. If such examination by the GSK Auditor results in a determination that amounts invoiced by Eurand pursuant to Section 8.1 have been overstated, such amounts overpaid by GSK will be paid by Eurand to GSK within thirty (30) calendar days after such GSK Auditor notifies the Parties of such discrepancy. If such examination results in a determination that amounts invoiced by Eurand have been understated, any underpaid amounts due will be re-paid by GSK to Eurand within thirty (30) calendar days after such GSK Auditor notifies the Parties of such discrepancy. The expense of such audit shall be GSK's unless the audit shall demonstrate an overpayment by GSK of any amounts pursuant to Section 8.1 greater than five percent (5%) of what was actually owed to Eurand, in which event the reasonable expenses of GSK Auditor shall be borne by Eurand. The GSK Auditor will report to the Parties only its conclusions as to whether Eurand has accurately invoiced GSK for amounts due pursuant to Section 8.1 and the conclusions contained therein will constitute Eurand Confidential Information.

9 INTELLECTUAL PROPERTY:

9.1 Responsibility for Eurand Patent Rights Existing as of the Effective Date. Eurand will have sole responsibility for and control over, subject to Sections 9.4 and 9.5 of the Kyowa Agreement, and will use its Commercially Reasonable Efforts with regard to, the preparation, filing,

prosecution and maintenance of the Eurand Patent Rights existing as of the Effective Date (the "Existing Eurand Patent Rights") and Eurand will bear all the costs and expenses associated therewith. Notwithstanding the foregoing, GSK will have the right to review all pending patent applications included within the Existing Eurand Patent Rights, significant filings and other significant proceedings which relate materially to the Program and/or GSK's commercialization of Product in the Field in the Territory (but only to the extent that Eurand (as opposed to Kyowa) conducts the applications and filings; provided, however, that Eurand will provide GSK with copies of any applications or filings made by Kyowa with respect to any Existing Eurand Patent Rights), and make recommendations to Eurand concerning them and their conduct, which recommendations Eurand will consider in good faith. GSK will provide any such patent consultation to Eurand at no cost to Eurand. Notwithstanding the foregoing, Eurand shall not be required to make any disclosure that would violate its confidentiality obligations to Kyowa under the Kyowa Agreement, although Eurand will use Commercially Reasonable Efforts to request Kyowa's consent to such disclosures to GSK.

9.2 Responsibility for GSK Patent Rights Existing as of the Effective Date. GSK will have sole responsibility for and control over, and will use its Commercially Reasonable Efforts with regard to, the preparation, filing, prosecution and maintenance of the GSK Patent Rights existing as of the Effective Date and GSK will bear all the costs and expenses associated therewith.

9.3 Ownership of Inventions.

9.3.1 At all times during the Term and thereafter, GSK will own the GSK Program Rights. Eurand will at all times during the Term and thereafter own any and all inventions relating solely to the ODT Technology.

9.3.2 Each Party will promptly disclose to the Steering Committee any inventions or improvements made or conceived by such Party, its Affiliates or any person or Entity under such Party's or its Affiliate's supervision, either alone or jointly in the course of or as a result of the activities under the Program (the "Inventions"); provided, however for the avoidance of doubt, the term "Inventions" will not include or be deemed to include any improvements or inventions made or conceived by GSK or its Affiliates relating to primary and/or secondary packaging for Product. The Steering Committee will determine the strategy for protecting all such Inventions, including, without limitation, the filing of patent applications on any Inventions, in a manner consistent with this Section 9.3 and in accordance with Section 5.6; provided, however, the Steering Committee shall not prevent Eurand from filing patent applications that do not disclose or claim any GSK Inventions or prevent GSK from filing any application that does not disclose or claim any Eurand Inventions.

9.3.3 GSK will solely own Inventions which relate to the Compound, Drug Substance, Formulation and/or Product, but excluding Inventions relating solely to the ODT Technology (collectively, the "GSK Inventions"), irrespective of whether the inventor is an employee of Eurand or its Affiliates or GSK or whether there are joint inventors, some of whom are employees of Eurand (or its Affiliates) and some of whom are employees of GSK. As determined by the Steering Committee, GSK will have the right, at its sole expense using in-house or outside legal counsel selected at GSK's sole discretion, to prepare, file, prosecute, maintain and extend any and all Patent Rights inside and/or outside of the Territory on GSK Inventions (the "GSK Invention Patent Rights"). Notwithstanding the foregoing, Eurand will have the right to review all pending patent applications included within the GSK Invention Patent Rights, significant filings and other significant proceedings which materially relate to the ODT Technology, and make recommendations

to GSK concerning them and their conduct, which recommendations GSK will consider in good faith. Eurand will provide any such patent consultation to GSK at no cost to GSK. Further, Eurand will, and will cause its Affiliates and its and their respective employees to, cooperate with GSK in preparing patent applications on GSK Inventions to the extent such are related to the ODT Technology and will provide GSK with appropriate assignment of Intellectual Property Rights to the GSK Inventions. Any GSK Invention Patent Rights, except as set forth in Section 9.4.1, will be deemed to be included within the GSK Patent Rights and any Know-How related to such GSK Inventions will be deemed to be included within GSK Know-How.

9.3.4 Eurand will solely own Inventions which relate solely to the ODT Technology (the "Eurand Inventions"), irrespective of whether the inventor is an employee of GSK or its Affiliates or Eurand or whether there are joint inventors, some of whom are employees of GSK (or its Affiliates) and some of whom are employees of Eurand. As determined by the Steering Committee Eurand will have the right at its sole expense using in-house or outside legal counsel selected at Eurand's sole discretion to prepare, file, prosecute, maintain and extend any and all Patent Rights inside and/or outside of the Territory on Eurand Inventions. GSK will, and will cause its Affiliates and its and their respective employees to, cooperate with Eurand in preparing patent applications on Eurand Inventions and to provide Eurand with appropriate assignment of Intellectual Property Rights to the Eurand Inventions. Any patent applications and patents filed by or on behalf of Eurand on Eurand Inventions, except as set forth in Section 9.4.2, will be deemed to be included within the Eurand Patent Rights and any Know-How related to such Eurand Inventions will be deemed to be included within Eurand Know-How.

9.3.5 GSK will exclusively own the GSK Data and such GSK Data will be deemed to be GSK Know-How and GSK Confidential Information, and will constitute part of the GSK Program Rights. Eurand will exclusively own the Eurand Data and such Eurand Data will be deemed to be Eurand Know-How and Eurand Confidential Information, and will constitute part of the Eurand Intellectual Property Rights.

9.3.6 Any information contained in a patent filing by a Party under this Agreement will be subject to the confidentiality provisions of Section 13, unless and until such patent filing is published by an applicable Patent Office, and the Confidential Information of a Party may not be used by the other Party in a patent filing without the express written consent of such first Party.

9.4 Abandoned Patent Rights.

9.4.1 Should GSK elect to abandon any Patent Right contained in the GSK Invention Patent Rights relating to the Formulation and/or Product, including, without limitation, any Patent Rights on any GSK Invention relating to the Formulation and/or Product (the "Abandoned GSK Invention Patent Rights"), it will (i) provide Eurand with written notice as soon as reasonably possible after making such election but in any event no later than sixty (60) calendar days after making such election but in any event before a possible loss of rights, and Eurand will have the right to file, prosecute and maintain any Abandoned Invention GSK Patent Rights in its sole discretion, at its sole expense and in Eurand's name, and such Abandoned Invention GSK Patent Rights will be deemed to be included in the Eurand Patent Rights. For the avoidance of doubt, the Abandoned Invention GSK Patent Rights will not include any Patent Rights contained in the GSK Invention Patent Rights that may be abandoned by GSK which relate to the Compound and/or Drug Substance.

9.4.2 Should Eurand elect to abandon any Patent Right contained in the Eurand Patent Rights including, without limitation, any Patent Rights on any Eurand Invention (the "Abandoned Eurand Patent Rights"), it will (i) provide GSK with written notice as soon as reasonably possible after making such election but in any event no later than sixty (60) calendar days after making such election but in any event before a possible loss of rights, and GSK will have the right to file, prosecute and maintain any Abandoned Eurand Patent Rights in its sole discretion, at its sole expense and in Eurand's name, GSK's name or the name of both GSK and Eurand, as determined by GSK in its sole discretion, and such Abandoned Eurand Patent Rights will be deemed to be included in the GSK Patent Rights.

9.5 Commercialization of Product and Competitive Product:

9.5.1 Eurand acknowledges and agrees that during the Term: (i) Eurand will not, and will cause its Affiliates not to, except pursuant to this Section 9.5, the Clinical Supply Agreement and Commercial Supply Agreement make, have made, use, sell, offer for sale and/or import Product in the Field in any country in the world or assist any Third Party in making, having made, using, selling, offering for sale and/or importing Product in the Field in any country in the world; and (ii) Eurand will not, and will cause its Affiliates not to, except as set forth in this Section 9.5 and in Section 10.6, make, have made, use, sell, offer for sale and/or import Competitive Product in any country in the world. If, after the date of the First Commercial Sale of Product in the Territory provided that the date of the First Commercial Sale is after the Lamotrigine Patent Expiration Date or if the First Commercial Sale has not occurred then the date that is six (6) months after the Lamotrigine Patent Expiration Date, whichever date is earlier, Eurand, on its own or through any of its Affiliates or any Third Party, desires to commercialize Product and/or Competitive Product in the Field in a country outside of the Territory, Eurand will provide prior written notice to GSK and thereby grant to GSK an exclusive right to negotiate with Eurand for an exclusive license under the Eurand Intellectual Property Rights to make, have made, use, sell, offer for sale and import such Product and/or Competitive Product in the Field in such country (each such notice referred to as a "Right of Negotiation"). GSK shall have only one (1) Right of Negotiation with respect to each country outside of the Territory.

9.5.2 GSK must exercise a Right of Negotiation by providing written notice to Eurand (each such notice referred to as a "Right of Negotiation Notice") within sixty (60) calendar days after receiving written notice from Eurand as provided in Section 9.5.1 of such Right of Negotiation.

9.5.3 If GSK does not submit a Right of Negotiation Notice to Eurand as provided in Section 9.5.2 prior to the expiration of the sixty (60) calendar day period referenced in Section 9.5.2, the corresponding Right of Negotiation will immediately terminate at 12:01 a.m. Eastern Standard Time on the calendar day that is immediately after the last calendar day of such sixty (60) calendar day period and Eurand will have no further obligation to GSK with respect to such Right of Negotiation for Product and/or Competitive Product (as applicable) in such country except as provided below in Section 9.5.6.

9.5.4 If GSK exercises a Right of Negotiation by providing a Right of Negotiation Notice as provided in Section 9.5.2, the Parties will in good faith negotiate during the Right of Negotiation Period a license and supply agreement pursuant to which GSK would obtain an exclusive license under the Eurand Intellectual Property Rights to make, have made, package, use, sell, offer for sale and import Product and/or Competitive Product in the Field in such country, and

Eurand will supply GSK's total requirements for clinical and commercial supply of bulk tablets of Product in such country (the "New Country License Agreement"). The "Right of Negotiation Period" will be the period that commences on the date on which GSK provides Eurand with a Right of Negotiation Notice as provided in Section 9.5.2 (for the purposes of this Section 9.5.4 only, the "commencement date") and expires at 12:01 a.m. Eastern Standard Time on the day immediately following the sixtieth (60^{th}) day after the commencement date. Each such Right of Negotiation Period may be extended upon the mutual written agreement of the Parties prior to the expiration thereof as provided in Section 9.5.5 or earlier terminated by the termination of this Agreement. Notwithstanding the foregoing, GSK will have the right, at any time and for any reason during a Right of Negotiation Period, to terminate in writing such Right of Negotiation Period which would terminate the corresponding Right of Negotiation.

9.5.5 In the event the Parties have not executed the New Country License Agreement during the Right of Negotiation Period, after starting to negotiate the terms and conditions thereof in good faith: (i) then at GSK's request, the Parties will extend such Right of Negotiation Period for one successive additional period of twenty (20) Business Days; or (ii) if not extended by GSK as provided in (i), such Right of Negotiation Period will expire as provided in Section 9.5.4 and Eurand will have no further obligation to GSK with respect to such Right of Negotiation or Product and/or Competitive Product (as applicable) in such country except as provided in Section 9.5.6; provided, however, that in the making, having made, use, sale, offering for sale and import of Product and/or Competitive Product in such country, Eurand covenants and agrees it will not, and will cause its Affiliates and any Third Party not to, knowingly, materially and adversely affect the profitability of Product in the Territory or GSK's right and ability to make, have made (only pursuant to the Clinical Supply Agreement and the Commercial Supply Agreement), use, sell, offer for sale and import Product in the Field in the Territory.

9.5.6 In the event that the Parties do not enter into a New Country License Agreement as provided in this Section 9.5, then subject to Section 11.3.5(v) GSK will enter into a license agreement which will include the following:

(i) GSK will grant to Eurand an exclusive license with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale and import Product (if applicable) in the Field in such country, subject to GSK's retained rights to package Product and conduct Clinical Studies as provided in Section 2.1 and GSK's retained rights (if any) to make and have made Product in such country to the extent permitted under the Clinical Supply Agreement and the Commercial Supply Agreement.

(ii) GSK will grant to Eurand a non-exclusive license with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale and import Competitive Product (if applicable) in the Field in such country, subject to GSK's retained rights to package Product and conduct Clinical Studies as provided in Section 2.1 and GSK's retained rights (if any) to make and have made Product in such country to the extent permitted under the Clinical Supply Agreement and the Commercial Supply Agreement.

(iii) In consideration for such license, but subject to Section 11.3.5(iii) Eurand will pay to GSK royalties on net sales of Product and/or Competitive Product by Eurand, its Affiliates or sublicensees in such country for a period of fifteen (15) years after the first commercial sale of such Product and/or Competitive Product, at a rate equal to three percent (3%) of net sales of Product or Competitive Product (as applicable). For the purposes of the license, "net sales" of

Product and/or Competitive Product by Eurand, its Affiliates and sublicensees will be calculated similarly to Net Sales under this Agreement. Further such royalty will be payable by Eurand to GSK in the same manner in which Royalties are payable by GSK to Eurand pursuant to Sections 8.3.6.

9.6 Infringement. Eurand agrees that it will provide GSK with the Formulation within five (5) Business Days after the following: the Successful Completion of Stage I (as defined in Section 8.2.1(i) above), the Successful Completion of Stage II (as defined in Section 8.2.1(ii) above), and thereafter whenever the Formulation is modified, in each case so that GSK may monitor the freedom to use Product as contemplated under this Agreement without infringing a Third Party's Intellectual Property Rights. In the event that a claim of infringement of a Third Party's Intellectual Property Rights is made or brought against either Party or grounds for a claim of infringement of a Third Party's Intellectual Property Rights becomes known to either Party, as a result of the activities under the Program or otherwise under the Agreement, the Party receiving such claim or becoming aware of grounds for such claim shall promptly inform the other Party, and the Parties shall consult with each other in order to develop a strategy for addressing the alleged infringement. Each Party shall reasonably cooperate with the other in any investigations undertaken to determine any potential infringement.

9.6.1 To the extent the alleged infringement relates primarily to the use of the Eurand Intellectual Property Rights, Eurand shall take one or more of the following actions at its sole cost and expense (simultaneously or sequentially):

(i) defend the infringement claim and indemnify and hold harmless GSK with respect to any such alleged infringement claim under this Section 9.6.1 pursuant to Section 12.1, or

(ii) obtain a license with the right to grant sublicenses, at its sole cost and expense, to utilize the technology upon which the Third Party claim of infringement was based, or

(iii) with the approval of the Steering Committee, attempt to address the alleged infringement by modifying the Formulation and/or the Product.

9.6.2 If Eurand is unable to effect any of the actions described in Section 9.6.1, after explaining to the Steering Committee in reasonable detail what actions Eurand has taken, then GSK may exercise its rights under Section 8.3.5 with respect to alleged infringement related primarily to the use of the ODT Technology.

9.6.3 In the event that the alleged infringement relates to the use of the ODT Technology but also relates to an aspect of the Product other than ODT Technology, Eurand and GSK will work in good faith to jointly address the alleged infringement. To the extent the alleged infringement does not relate to the use of the ODT Technology, GSK may, at its sole discretion, cost and expense, defend the claim or obtain a license to use the technology upon which the Third Party Claim is based, but, in any case, GSK shall indemnify and hold harmless Eurand with respect to any such alleged infringement claim under this Section 9.6.3 pursuant to Section 12.2.

9.7 Third Party Infringement of Patents

9.7.1 Each Party shall promptly report in writing to the other Party during the Term any (i) known infringement or suspected infringement of any Patent Rights included in the Eurand Intellectual Property Rights or the GSK Invention Property Rights, (ii) unauthorized use or misappropriation of Confidential Information, Eurand Intellectual Property Rights or GSK Program Rights by a Third Party, or (iii) known infringement or suspected infringement relating to either the Formulation or Product (in each case, "Third Party Infringement") of which it becomes aware (including infringement under 35 U.S.C. Section 271(e)(2)), and which relate to a Product or a Competitive Product, and shall provide the other Party with all available evidence indicative of said infringement, suspected infringement or unauthorized use or misappropriation.

9.7.2 In the event of a report of a Third Party Infringement under Section 9.7.1, Eurand and GSK shall consult with each other in order to develop a strategy for addressing the Third Party Infringement. In the event that the Parties agree to take legal action to stop the Third Party Infringement (the "Action"), they shall agree upon legal counsel and unless they agree upon a different formula for sharing the expenses (including attorney and expert fees) of such action and for sharing any award or settlement, they shall share them equally. In the event that a Party (the "Nonparticipating Party") does not desire to participate in the Action, the other Party shall be free (at its sole discretion) to bring the action (the "Participating Party") based on the Participating Party's own Intellectual Property Rights in its own name, at its own expense and retain any award or settlement in its entirety. The Participating Party may, only with the written consent of the Nonparticipating Party, bring an Action based on the Nonparticipating Party's Intellectual Property Rights (i.e., the Eurand Intellectual Property Rights if Eurand is the Nonparticipating Party and the GSK Program Rights if GSK is the Nonparticipating Party), in its Participating Party's own name, and own expense, and retain any award or settlement in its entirety. The Nonparticipating Party will in no event be obligated and may decline to join or participate in the Action, or to provide assistance to the Participating Party if the Nonparticipating Party believes in good faith that such joinder, participation, or assistance could expose the Nonparticipating Party to legal or regulatory harm. Otherwise, the Nonparticipating Party shall join as a party to the suit but shall be under no obligation to participate except to the extent that such participation is required as the result of being a named party to the suit, and shall offer reasonable assistance in connection therewith at no charge to the other Party except for reimbursement of reasonable out-of-pocket expenses. If either Party desires to retain counsel independently, at its own expense, the Party may do so, but it shall not relieve the Party of its obligations under this section.

10 REPRESENTATIONS AND WARRANTIES:

10.1 Mutual Representations and Warranties. Eurand and GSK each hereby represent and warrant to the other as follows, as of the Effective Date:

10.1.1 It is a corporation duly organized, validly existing and is in good standing under the laws of its jurisdiction of formation, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement, the Clinical Supply Agreement (and related quality agreement) and the Commercial Supply Agreement (and related quality agreement);

10.1.2 The execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action and do not and will not (i) require any consent or approval of its stockholders, (ii) violate any provision of any Applicable Law or any provision of its

certificate of incorporation, by-laws or other founding document, or (iii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license, permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected;

10.1.3 It is not currently debarred, suspended or otherwise excluded by any government agency from receiving government contracts that would adversely affect its ability to perform its obligations hereunder;

10.1.4 It is not under any obligation to any Entity, contractual or otherwise, that is conflicting or inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder; and

10.1.5 This Agreement is a legal, valid and binding obligation enforceable against it in accordance with its terms and conditions, except as such enforceability may be limited by applicable bankruptcy, insolvency, moratorium, reorganization or similar laws, from time to time in effect, affecting creditor's rights generally.

10.2 Eurand Representations and Warranties. Eurand represents and warrants to GSK that as of the Effective Date:

10.2.1 It owns the entire right, title and interest in and to, or otherwise has the right to grant the license or sublicense rights outlined in Section 2 under the Eurand Intellectual Property Rights, all of which are, to Eurand's actual knowledge, free and clear of any liens, mortgages, security interests, charges, encumbrances or otherwise;

10.2.2 It has not, up through and including the Effective Date, knowingly withheld any material information in Eurand's possession from GSK in response to GSK's reasonable inquiries in connection with GSK's due diligence relating to the ODT Technology, this Agreement and the underlying transaction, and to the best of its knowledge, the information related to the ODT Technology that Eurand has provided to GSK prior to the Effective Date is up-to-date and accurate in all material respects;

10.2.3 Except as set forth on Exhibit G, to the best of its knowledge, the Patent Rights included in the Eurand Patent Rights are valid and enforceable and there are no pending or threatened claims or legal actions asserting that the Patent Rights included in the Eurand Patent Rights are invalid or unenforceable;

10.2.4 To the best of its knowledge, except with respect to Kyowa, the ODT Technology will not constitute an infringement of any patents, trade secrets, or other industrial or Intellectual Property Rights of any Third Party;

10.2.5 To the best of its knowledge, the Eurand Trademarks are valid and enforceable and that there are no pending or threatened claims or legal actions asserting that such Eurand Trademarks are invalid or unenforceable in the Territory; and

10.2.6 Eurand has provided GSK with a redacted copy of the Kyowa Agreement, including, without limitation, any and all amendments made thereto as of the Effective Date. To the

best of Eurand's knowledge, the Kyowa Agreement remains in full force and effect and Eurand is in compliance in all material respects with the terms of the Kyowa Agreement.

10.3 GSK's Representations and Warranties. GSK represents and warrants to Eurand that as of the Effective Date:

10.3.1 It owns the entire right, title and interest in and to, or otherwise has the right to grant the license or sublicense rights outlined in Section 2 under the GSK Intellectual Property Rights, all of which are, to GSK's actual knowledge, free and clear of any liens, mortgages, security interests, charges, encumbrances or otherwise; and

10.3.2 To the best of GSK's knowledge, the Drug Substance will not constitute and infringement of any patents, trade secrets, or other industrial or Intellectual Property Rights of any Third Party.

10.4 Covenants of Eurand and GSK.

10.4.1 Eurand covenants to GSK that Eurand will not at any time during the Term, encumber any of its Confidential Information or the Eurand Intellectual Property Rights with liens, mortgages, security interests, charges, or otherwise in any manner that could reasonably be believed to have a material adverse effect on GSK's rights under the Eurand Intellectual Property Rights to make and have made (only to the extent provided in the Clinical Supply Agreement or Commercial Supply Agreement), package, use, sell, offer for sale and import Product in the Field.

10.4.2 Eurand covenants to GSK that Eurand will not knowingly take or omit to take any actions that would constitute a material breach of the Kyowa Agreement, which breach would be reasonably likely to have a material adverse effect on GSK's rights under the Eurand Intellectual Property Rights as set forth in Section 2.1.

10.4.3 Eurand covenants to GSK that, at all times during the Term, Eurand will use its best efforts and take all actions reasonably available to it to keep in full force and effect the Kyowa Agreement and any of its rights thereunder, the loss or restriction of which would in any material way adversely affect or interfere with the exercise of any of GSK's rights under this Agreement. Notwithstanding any other provision hereof, in the event Eurand is in default of the Kyowa Agreement or becomes aware of any set of facts or circumstances that make a default of the Kyowa Agreement imminent or reasonably likely, and such default presents a reasonable likelihood of material interference with, curtailment of or adverse effect upon the exercise or scope of any of GSK's rights under this Agreement (or under any agreement entered into in connection herewith, including the Clinical Supply Agreement and Commercial Supply Agreement), Eurand shall, upon GSK's request, use its best efforts to assist GSK, on or before the effective date of any termination or material restriction of the Kyowa Agreement, to obtain rights under the Kyowa Agreement with respect to the Product that are equivalent to those granted to GSK herein under Section 2.1. Further, Eurand acknowledges and agrees that upon termination of the Kyowa Agreement, this Agreement will immediately terminate without the application of any Cure Period as set forth in Section 11.2.2 and GSK will, as of the effective date of the termination of this Agreement, have an irrevocable, worldwide, exclusive, royalty-free license, with the right to grant sublicenses, under the Eurand Intellectual Property Rights to make, have made, use, sell, offer for sale and import Formulation and/or Product in the Field.

10.4.4 Eurand covenants to GSK that Eurand will only use Drug Substance in its performance of the Eurand Development Activities, and manufacture of CTM and Product for GSK pursuant to the Clinical Supply Agreement and Commercial Supply Agreement, respectively.

10.4.5 Eurand covenants to GSK that during the Term and for five (5) years thereafter Eurand will not, and will cause its Affiliates not to during the Term and for five (5) years thereafter, use any GSK Know How or GSK Data in the making, have made, use, sale, offering for sale and/or import of, or directly or indirectly assist any Third Party during the Term and for five (5) years therafter in using any GSK Know-How or GSK Data in the making, having made, use, sale, offering for sale and/or import of, any product other than as set forth in this Agreement, including not for any product which has any sustained, modified or controlled release component to the drug release and which contains any amount of the Compound, whether or not as the sole active ingredient.

10.4.6 GSK covenants to Eurand that GSK will not and will cause its Affiliates not to analyze any of the prototypes of the Formulation or CTM provided hereunder to determine their composition or the manner in which they have been manufactured unless and until required under the Program.

10.5 Compliance with Laws. Each Party covenants and agrees that it will comply, and will cause its respective Affiliates to and contractually mandate that its sublicensees will comply, with all Applicable Laws in the performance of its respective obligations under this Agreement.

10.6 Non-Competition.

10.6.1 Eurand represents and warrants to GSK that Eurand will not, and will cause its Affiliates not to, make, have made, use, sell, offer for sale and/or import, or directly or indirectly assist any Third Party in making, having made, using, offering for sale and/or importing a Competitive Product in the Field in the Territory during the Term. GSK represents and warrants to Eurand that GSK will not, and will cause its Affiliates not to, make, have made, use, sell, offer for sale and/or import, or directly or indirectly assist any Third Party in the making, having made, use, sale, offering for sale and/or import of, a Competitive Product in the Field in the Territory during the Term.

10.6.2 Notwithstanding anything contained in this Section 10.6 to the contrary, nothing herein will, expressly or impliedly, preclude or restrict either Party (or its respective Affiliates) in any way from (i) acquiring a majority of the voting stock, or all or substantially all of the assets of, a Competing Business Entity or a Non-Competing Business Entity (as both such terms are defined in Section 10.6.3 below); (ii) being acquired by a Competing Business Entity or a Non-Competing Business Entity; or (iii) merging, amalgamating, taking over, or consolidating (or engaging in any similar transaction) with a Competing Business Entity or Non-Competing Business Entity (hereinafter, the actions referred to in (i), (ii) and (iii) of this Section 10.6.2 are collectively referred to as "Merger" or "Merging" as of the date that any such action becomes effectively complete).

10.6.3 The term "Competing Business Entity" as used in Section 10.6.2 means an Entity that markets a Competitive Product in the Field in the Territory during the Term. A "Non-Competing Business Entity" means any other Entity other than a Competing Business Entity. In the

event that a Party or any of its Affiliates Merges with a Competing Business Entity during the Term (the "Merging Party"), such Merging Party will inform the other Party in writing, within three (3) Business Days after the date of the public announcement of the consummation or closing of such Merger ("Merger Date"), as to whether such Merging Party will divest or cause the divestiture of the Competitive Product marketed by the Competing Business Entity. If the Merging Party notifies the other Party that it plans to so divest, then the other Party may not terminate this Agreement for breach of Section 10.6.1 any earlier than one (1) month after the Merger Date. The sale, promotion or marketing of any such Competitive Product by the Merging Party or any of its Affiliates during such one (1) month period following the Merger Date is expressly permitted hereunder and will not be grounds for termination by the other Party so long as: (i) the Merging Party or its Affiliate is using Commercially Reasonable Efforts to divest itself of the Competing Product as promptly as reasonably practicable during such one (1) month period, and (ii) the Merging Party continues to comply with the terms of this Agreement in all respects; provided, however, that during the period in which Eurand is marketing a Competing Product in the Territory pursuant to this Section 10.6.3, GSK will have no obligation to pay, and Eurand will have no right to receive, any Royalties on Net Sales during such period. If the Merging Party notifies the other Party that the Merging Party does not plan to so divest, then the other Party may immediately terminate this Agreement upon prior written notice to the Merging Party; provided, however that in the event GSK terminates this Agreement as provided in this Section 10.6.3, then effective as of the date of the termination of this Agreement GSK will have an irrevocable, exclusive, royalty-free license, with the right to grant sublicenses, under the Eurand Intellectual Property Rights to make, have made use, sell, offer for sale and import Product in the Field, except with respect to any countries in which Eurand has obtained an exclusive license under the GSK Program Rights pursuant to Section 9.5.6 to make, have made, use, sell, offer for sale and import Product.

10.7 Limitation of Warranty. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 10 NEITHER PARTY MAKES ANY OTHER REPRESENTATION OR WARRANTY, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, WITH RESPECT TO ANY PRODUCT, MATERIALS, INFORMATION, SERVICES OR LICENSES PROVIDED TO THE OTHER PARTY PURSUANT TO THIS AGREEMENT.

11 TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "Term") will commence on the Effective Date, and unless sooner terminated as provided in this Sections 10.4.3, 10.6.3, or 11, will expire on the date GSK's obligations to pay Royalties as provided in Section 8.3 expire. Upon the expiration of this Agreement, GSK will be permitted to make, have made, use, sell, offer for sale and import Product in the Field in the Territory, and use the Eurand Know-How in the Territory, without any further payments or other remuneration to Eurand.

11.2 Termination.

11.2.1 *By GSK.* GSK may terminate this Agreement at any time during the Term with sixty (60) calendar days' prior written notice to Eurand if such termination is prior to the First Commercial Sale and with one hundred twenty (120) calendar days' prior written notice to Eurand if

such termination is after the First Commercial Sale, in each case if based upon a reasonable determination by GSK, using the same standards GSK would use in assessing whether or not to continue development of a product of its own making, that the medical/scientific, technical, safety, regulatory or commercial profile of the Product does not justify continued development or commercialization in the Territory.

11.2.2 *By Either Party for Material Breach.* Either Party may terminate this Agreement in its entirety upon written notice to the other Party in the event that the other Party is in material default or breach of any of its material obligations hereunder, and fails to remedy any such default or breach within sixty (60) calendar days without (i) providing a written explanation reasonably satisfactory to the non-defaulting Party that a default has not occurred or (ii) commencing to cure the default within thirty (30) days of such notice and thereafter curing such default within ninety (90) days of such notice; or in the case of failure to pay any uncontested amounts due hereunder, thirty (30) calendar days (in each case, the "Cure Period") after notice thereof by the non-defaulting/non-breaching Party. If such default or breach is not corrected within the applicable Cure Period, the non-defaulting/non-breaching Party will have the right to immediately terminate this Agreement by giving written notice to the Party in default or breach. However, in the event that the Party in default provides a written explanation to the non-defaulting Party and there is a dispute regarding whether the explanation is reasonably satisfactory, the dispute shall be resolved in accordance with Section 14.14 and the Cure Period shall be extended during the pendency of the resolution of the dispute.

11.2.3 *By Mutual Consent.* The Parties may terminate this Agreement in its entirety at any time and for any reason during the Term upon their mutual written agreement.

11.2.4 *By Either Party for Bankruptcy.* Either Party may terminate this Agreement in its entirety at any time during the Term by giving written notice to the other Party if the other Party files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition will not be dismissed with sixty (60) calendar days after the filing thereof, or if the other Party makes a general assignment for the benefit of creditors. Notwithstanding the bankruptcy of Eurand, or the impairment of performance by Eurand of its obligations under this Agreement as a result of bankruptcy or insolvency of Eurand, GSK will be entitled to retain all rights and licenses granted to GSK by Eurand under this Agreement. All rights and licenses granted under or pursuant to this Agreement by Eurand to GSK are, and will otherwise be deemed to be, for purposes of Article 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Article 101(52) of the Bankruptcy Code. The Parties agree that GSK, as a licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Eurand under the Bankruptcy Code, GSK will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to GSK (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by GSK, unless Eurand elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of Eurand upon written request therefor by GSK.

11.2.5 Eurand may terminate this Agreement in the event that: (i) GSK, prior to the First Commercial Sale, suspends conducting any GSK Development Activities for six (6) continuous months, or (ii) GSK fails to make the First Commercial Sale in the Territory within one (1) year of the NDA approval, or (iii) GSK discontinues selling the Product in the Territory, unless in each case above, such failure is due to a Force Majeure Event, Product supply disruption, regulatory or other legal issues outside of GSK's reasonable control, or Eurand's breach of this Agreement or the Commercial Supply Agreement or some other reason which GSK is using Commercially Reasonable Efforts to address. The provisions of this paragraph shall operate independently of the cure provisions in Section 11.2.2.

11.3 Effects of Termination.

11.3.1 Upon termination of this Agreement, Eurand will have the right to retain any sums already paid by GSK hereunder.

11.3.2 The expiration or termination of this Agreement for any reason shall not relieve the Parties of any obligation (including any payments) that accrued prior to such expiration or termination. Further, neither Party will be precluded from pursuing all rights and remedies that it may have hereunder at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

11.3.3 Upon termination of this Agreement by GSK pursuant to Section 11.2.2, GSK will immediately have an irrevocable, exclusive, royalty-free license, with the right to grant sublicenses, under the Eurand Intellectual Property Rights to make, have made use, sell, offer for sale and import Product in the Field.

11.3.4 If the First Commercial Sale has occurred at the time of termination of this Agreement pursuant to Section 11.2.3, by GSK pursuant to Section 11.2.1 or by Eurand pursuant to Sections 11.2.2, 11.2.4 or 11.2.5, GSK will have the right to sell-through its existing inventory of the Product, and such sales will be subject to the Royalty provisions contained herein.

11.3.5 Post-*Termination Rights of Eurand Under the GSK Program Rights.*

(i) *Prior to First Commercial Sale and Prior to the Lamotrigine Patent Expiration Date.*

(A) If this Agreement is terminated prior to the First Commercial Sale and prior to the Lamotrigine Patent Expiration Date by the Parties pursuant to Section 11.2.3 or by GSK pursuant to Section 11.2.1, then (1) GSK will grant to Eurand a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made and use Product in the Field for the sole purpose of seeking Regulatory Approvals for Product in the Field, and (2) after the Lamotrigine Patent Expiration Date, GSK will grant to Eurand a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale and import Product in the Field, provided, that Eurand pays a royalty to GSK of one and one half percent (1.5%). Such royalty will be payable by Eurand to GSK in the same manner in which Royalties are payable by GSK to Eurand pursuant to Sections 8.3.6.

(B) If this Agreement is terminated prior to the First Commercial Sale and prior to the Lamotrigine Patent Expiration Date by Eurand pursuant to Sections 11.2.2,

11.2.4 or 11.2.5, then (1) upon the effective date of the termination of this Agreement, Eurand will have a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made and use Product in the Field for the sole purpose of seeking Regulatory Approvals for Product in the Field, and (2) after the Lamotrigine Patent Expiration Date, Eurand will have a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale and import Product in the Field. The license rights of Eurand under the GSK Program Rights pursuant to this Section 11.3.5(i)(B) will be royalty free.

(ii) *Prior to the First Commercial Sale and After the Lamotrigine Patent Expiration Date*.

(A) If this Agreement is terminated prior to the First Commercial Sale and after the Lamotrigine Patent Expiration Date by the Parties pursuant to Section 11.2.3 or by GSK pursuant to Section 11.2.1, then GSK will grant to Eurand a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale, import and seek Regulatory Approvals for the Product in the Field, provided that Eurand pays a royalty to GSK of one and one half percent (1.5%). Such royalty will be payable by Eurand to GSK in the same manner in which Royalties are payable by GSK to Eurand pursuant to Sections 8.3.6.

(B) If this Agreement is terminated prior to the First Commercial Sale and after the Lamotrigine Patent Expiration Date by Eurand pursuant to Section 11.2.2, 11.2.4 or 11.2.5, then upon the effective date of the termination of this Agreement, Eurand will have a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale, import and seek Regulatory Approvals for the Product in the Field. The license rights of Eurand under the GSK Program Rights pursuant to this Section 11.3.5(ii)(B) will be royalty free.

(iii) *After First Commercial Sale and Prior to the Lamotrigine Patent Expiration Date*.

(A) If this Agreement is terminated after the First Commercial Sale and prior to the Lamotrigine Patent Expiration Date by Eurand pursuant to Sections 10.6.3, 11.2.2 or 11.2.4, then (1) upon the effective date of the termination of this Agreement, except as to those countries in which Eurand is already commercializing Product pursuant to Section 9.5, Eurand will have a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made and use Product in the Field for the sole purpose of seeking Regulatory Approvals for the Product in the Field, and (2) after the Lamotrigine Patent Expiration Date, Eurand will have a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale, import, and seek Regulatory Approval for the Product in the Field. The license granted by GSK to Eurand under this Section 11.3.5(iii)(A) will be royalty free.

(B) If this Agreement is terminated after the First Commercial Sale but prior to the Lamotrigine Patent Expiration Date by the Parties pursuant to Section 11.2.3, by GSK pursuant to Section 11.2.1 or by Eurand pursuant to Section 11.2.5, then (1) except as to those countries in which Eurand is already commercializing Product pursuant to Section 9.5, GSK will grant to Eurand a worldwide, non-exclusive license, with the right to grant sublicenses, under the

GSK Program Rights to make, have made and use Product in the Field for the sole purpose of seeking Regulatory Approvals for the Product in the Field, and (2) after the Lamotrigine Patent Expiration Date, GSK will grant to Eurand a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale, import, and seek Regulatory Approval for the Product in the Field, provided that Eurand pays to GSK a royalty of three percent (3%). Such royalty will be payable by Eurand to GSK in the same manner in which Royalties are payable by GSK to Eurand pursuant to Sections 8.3.6.

(iv) *After the First Commercial Sale and After the Lamotrigine Patent Expiration Date.*

(A) If this Agreement is terminated after the First Commercial Sale and after the Lamotrigine Patent Expiration Date by Eurand pursuant to Sections 10.6.3, 11.2.2 or 11.2.4, then upon the effective date of the termination of this Agreement, Eurand will have a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale, import and seek Regulatory Approvals for the Product in the Field. The license granted by GSK to Eurand under this Section 11.3.5(iii)(B) will be royalty free.

(B) If this Agreement is terminated after the First Commercial Sale and after the Lamotrigine Patent Expiration Date by the Parties pursuant to Section 11.2.3, by GSK pursuant to Section 11.2.1 or by Eurand pursuant to Section 11.2.5, then GSK will grant to Eurand a worldwide, non-exclusive license, with the right to grant sublicenses, under the GSK Program Rights to make, have made, use, sell, offer for sale, import, and seek Regulatory Approval for the Product in the Field, provided that Eurand pays to GSK a royalty of three percent (3%). Such royalty will be payable by Eurand to GSK in the same manner in which Royalties are payable by GSK to Eurand pursuant to Sections 8.3.6.

(v) *For Cause by GSK.* If this Agreement is terminated before or after the First Commercial Sale pursuant to Section 10.4.3 or by GSK pursuant to Sections 10.6.3, 11.2.2 or 11.24, Eurand will have no rights of any kind whatsoever under the GSK Program Rights and as to those countries in which Eurand is already commercializing Product pursuant to Section 9.5, such licenses (and any sublicenses granted by Eurand) under the GSK Program Rights in such countries will terminate as of the effective date of the termination of this Agreement.

(vi) Notwithstanding anything to the contrary in this Section 11.3.5 or in this Agreement, the Parties acknowledge and agree that the term "GSK Program Rights " included in this Section 11.3.5 will not include and will not be deemed to include the GSK Data, the Lamotrigine Patent and any GSK Intellectual Property Rights relating to the primary and/or secondary packaging of Product. Further, the Parties acknowledge and agree that the licenses and rights that may be granted to Eurand pursuant to this Section 11.3.5 will in no way include any licenses or rights to or under the GSK Data, the Lamotrigine Patent and/or any GSK Intellectual Property Rights relating to the primary and/or secondary packaging of Product.

11.4 Survival. The following provisions will survive any expiration or termination of this Agreement:

11.4.1 Sections 2.1, 2.3, 2.4, 2.6, 4.1, 4.2, 4.3, 8.3 and 8.4, all with regard to GSK's post-termination/expiration sales of Product pursuant to Section 11.3.4;

11.4.2 Sections 3.3.2(viii), 4.4, 5.6, 8.1 (solely with respect to payments which have accrued prior to the expiration or termination of this Agreement), 8.3.6 (solely with respect to payments which have accrued prior to the expiration or termination of this Agreement), 8.4.3, 9.3.1, 9.3.3, 9.3.4, 9.3.5, 10.4.3 (last sentence only), 10.4.5, 10.6.3 (last sentence only), 11.3, 11.4, 12, 13, 14.4 and 14.14; and

11.4.3 Section 1 for the sole purposes of interpreting the obligations and liabilities between the Parties surviving termination of this Agreement;

which will survive termination or expiration of this Agreement for the time period specified in such Sections or if no such time period is specified, indefinitely.

12 INDEMNIFICATION AND INSURANCE: SUBLICENSEES

12.1 Indemnification of GSK. Eurand shall indemnify and hold GSK harmless from and against all damages, losses, expenses, claims (including wrongful death), demands, suits, penalties, judgments or administrative and judicial orders and liabilities (including, but not limited to, reasonable counsel fees and expenses) incurred, assessed or sustained by GSK, its Affiliates, or any of their respective officers, directors, and employees resulting from or arising out of a claim or proceeding brought by a Third Party with respect to or involving or arising out of (i) Eurand's negligence or willful misconduct, (ii) Eurand's breach of any representation, warranty, obligation or covenant of this Agreement; (iii) resulting from or arising out of Eurand's sublicensee's breach of any representation, warranty, obligation or covenant of this Agreement; (iv) Eurand's defense of any claim of infringement of a Third Party's Intellectual Property Rights as set forth in Section 9.6.1; and/or (v) Eurand's participation in any Action as set forth in Section 9.7.2 provided that GSK is a Nonparticipating Party in such Action; except however in each of (i) through (v) to the extent such claim arises from an event for which GSK has an obligation to indemnify Eurand under Section 12.2 or pursuant to the Clinical Supply Agreement Commercial Supply Agreement.

12.2 Indemnification of Eurand. GSK shall indemnify and hold Eurand and its Affiliates harmless from and against all damages, losses, expenses, claims (including wrongful death and product liability), demands, suits, penalties, judgments or administrative and judicial orders and liabilities (including, but not limited to, reasonable counsel fees and expenses) incurred, assessed or sustained by Eurand, its Affiliates, or any of their respective officers, directors, and employees resulting from or arising out of a claim or proceeding brought by a Third Party with respect to or involving or arising out of (i) GSK's negligence or willful misconduct; (ii) GSK's breach of any representation, warranty, obligation or covenant of this Agreement; (iii) Eurand's use of the Drug Substance in conducting the Eurand Development Activities to the extent the claim arises from or relates to GSK's failure to provide up to date information procedures and warnings regarding the safe handling and use of the Drug Substance; (iv) the sale, packaging, labeling, advertising, distribution, design, consumption or use of any CTM or Product; (v) resulting from or arising out of GSK's sublicensee's breach of any representation, warranty, obligation or covenant of this Agreement; (vi) GSK's defense of any claim of infringement of a Third Party's Intellectual Property Rights as set forth in Section 9.6.3; and/or (vii) GSK's participation in any Action as set forth in Section 9.7.2 provided that Eurand is a Nonparticipating Party in such Action; except however in each of (i) through (vii) to the extent such claim arises from an event for which Eurand has an obligation to indemnify GSK under Section 12.1 or pursuant to the Clinical Supply Agreement or Commercial Supply Agreement.

12.3 Notice and Legal Defense. Promptly after receipt by a Party seeking indemnification under Section 12.1 or 12.2 (the "Indemnified Party") of any claim, suit or proceeding brought by a Third Party or notice of the commencement of any action, administrative or legal proceeding, or investigation as to which the indemnity provided for in Section 12.1 and 12.2 hereof may apply, the Party seeking indemnification shall notify the indemnifying Party of such fact (i) within fifteen (15) calendar days after receipt of services of process of the commencement of a suit or (ii) for non-litigated matters, within thirty (30) calendar days after receipt of notice thereof; provided, however, that in each case, the failure to give such notice will not relieve the Indemnifying Party of its obligation to provide indemnification hereunder except if, and to the extent that, such failure materially and adversely affects the ability of the Indemnifying Party to defend the applicable claim, suit or proceeding. The Indemnified Party will permit the Indemnifying Party to assume sole control over the defense of any such claim, suit or proceeding at the Indemnifying Party's own cost and expense; and, at the Indemnifying Party's expense, the Indemnified Party will co-operate as reasonably requested in the defense of the claim, suit or proceeding. The Indemnified Party will have the right to retain its own counsel at its own expense, provided, however, that if the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have material conflicting interests with respect to such claim, suit or proceeding, the Indemnifying Party will be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith. The Indemnifying Party may not settle such action or claim, or otherwise consent to an adverse judgment in such action or claim, which would subject the Indemnified Party to an injunction or if such settlement or judgment would materially diminish or limit or otherwise adversely affect the rights, activities or financial interests of the Indemnified Party, without the express written consent of the Indemnified Party.

12.4 Consequential Damages IN NO EVENT, SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES ARISING OUT OF, OR AS THE RESULT OF, THE SALE, DELIVERY, NON-DELIVERY, SERVICING, USE OR LOSS OF USE OF ANY CTM OR PRODUCT, REGARDLESS OF WHETHER SUCH CLAIM IS BASED UPON BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER LEGAL THEORY.

12.5 Insurance Eurand will, at its sole cost and expense, carry commercial general liability insurance, including clinical trial and product liability insurance, which coverage shall have limits of liability which are commercially reasonable but shall not be less than $5,000,000 per loss occurrence. Such coverage shall be maintained during the Term and for not less than three (3) years following the expiration or earlier termination of this Agreement or if such coverage is of the "claims made" type, for five (5) years following termination of this Agreement. GSK agrees that during the Term and for five (5) years following the expiration or earlier termination of this Agreement, it will self-insure for the same amounts and types of coverage set forth above.

13 CONFIDENTIALITY:

13.1 Confidential Information. Eurand and GSK each hereby recognize and acknowledge that the other Party's Confidential Information constitutes valuable and confidential information. Subject to other express provisions of this Agreement, Eurand and GSK each agree that during the

Term, and for a period of five (5) years after the effective date of the expiration or earlier termination of this Agreement for any reason:

13.1.1 The Parties will not disclose, directly or indirectly, in any manner whatsoever to any Third Parties any Confidential Information received from the other Party (the "Disclosing Party") without first obtaining the written consent of the Disclosing Party, and the other Party ("Recipient") will keep confidential, all of the Disclosing Party's Confidential Information that is disclosed to Recipient. Recipient agrees to use the same level of care in safeguarding the Disclosing Party's Confidential Information that Recipient uses with its own confidential information of a similar nature, but in no event less than reasonable care. Recipient will restrict disclosure of the Disclosing Party's Confidential Information solely to those of its (or its Affiliate's) employees or representatives having a need to know such Confidential Information in order to exercise a right granted or fulfill an obligation under, this Agreement.

13.1.2 Both Parties shall ensure that each of their respective employees and representatives who will have access to the Confidential Information of the Disclosing Party are bound by an obligation to maintain such Confidential Information in accordance with the confidentiality obligations set forth in this Section 13.

13.1.3 Recipient will not use the Disclosing Party's Confidential Information in any manner whatsoever other than solely in connection with the performance of its obligations, or exercise of its rights, under this Agreement.

13.1.4 Except as permitted by this Section 13, or as otherwise required by Applicable Law, and subject to the Kyowa Agreement, Eurand and GSK each agree not to disclose any terms or conditions of this Agreement or the existence of this Agreement to any Third Party without the prior written consent of the other Party, *provided, that* each Party will be entitled to disclose the terms of this Agreement without such consent to its advisors and potential investors or other financing sources, to bona fide potential investors, lenders and acquirors/acquirees, and to such Party's consultants and advisors, and to its permitted licensees and sublicensees on the condition that such Entities agree to keep such Confidential Information in accordance with the obligations set forth in this Section 13.

13.1.5 In the event Recipient is requested pursuant to, or required by, Applicable Law to disclose any of the Disclosing Party's Confidential Information, it will notify the Disclosing Party promptly so that the Disclosing Party may seek a protective order or other appropriate remedy or, in the Disclosing Party's sole discretion, waive compliance with the confidentiality provisions of this Agreement. At the Disclosing Party's expense, Recipient will co-operate in all reasonable respects, in connection with any reasonable actions to be taken for the foregoing purpose. In the event that no such protective order or other remedy is obtained, or that the Disclosing Party waives compliance with the confidentiality provisions of this Agreement, Recipient will, without liability hereunder, furnish only that portion of the Confidential Information which Recipient is advised by its counsel is legally required, and Recipient will exercise reasonable efforts to obtain reliable assurances that confidential treatment will be accorded the Disclosing Party's Confidential Information.

13.1.6 Upon the effective date of the termination of this Agreement for any reason, either Party may request in writing, and the other Party will either: (i) promptly destroy all copies of the requesting Party's Confidential Information in the possession of the other Party and confirm such

destruction in writing to the requesting Party; or (ii) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party, *provided, however,* the other Party will be permitted to retain one (1) copy of the requesting Party's Confidential Information for the sole purpose of determining any continuing obligations hereunder. Additionally, upon termination of this Agreement for any reason, both Parties will immediately cease all use of the other Party's Confidential Information including, to the extent reasonably possible, removing all references to such Confidential Information from its internal analyses, memoranda, compilations, studies or other documents; provided however, that: (a) GSK will be permitted to continue using Eurand's Confidential Information after termination of this Agreement in the exercise of its rights under Sections 11.3.3 and Eurand will be permitted to continue using GSK's Confidential Information after termination of this Agreement in the event that Eurand obtains a license under the GSK Program Rights as set forth in Section 11.3.5. For the avoidance of doubt, each Party will be permitted to use the other Party's Confidential Information after the expiration of this Agreement and will not be obligated to return such Confidential Information of the other Party in accordance with this Section 13.1.6. All Confidential Information will continue to be subject to the terms of this Agreement for the period set forth in Section 13.1.

13.1.7 Each Party represents and warrants to the other Party that it has all right, title and ownership interest in and to its Confidential Information and/or it has the right to disclose its Confidential Information to the other Party. Each Party may seek to enforce all rights and legal remedies available under this Section 13 or by law, including injunctive relief, specific performance and other equitable remedies in the event of a breach of the provisions of this Section 13 by the other Party.

13.1.8 Notwithstanding the provisions of this Section 13, the Parties agree that nothing contained in this Section 13 will prevent GSK, in any way whatsoever from disclosing any Eurand Confidential Information, without obtaining Eurand's prior consent, to any Affiliate of GSK or to any Third Party for the purposes of engaging in the development (including the Clinical Studies and filing of Regulatory Approvals for Product) and commercialization of Product in the Field in the Territory, provided such Affiliate or Third Party is under an obligation of confidentiality at least as restrictive as the obligations contained in Section 13 herein with respect to the Confidential Information.

13.1.9 The confidentiality obligations set forth in this Section 13 will supersede the Confidential Disclosure Agreements dated as of October 10, 2005 and November 30, 2005, between the Parties ("Confidentiality Agreements"), and will govern any and all information disclosed by either Party to the other pursuant thereto, and will be retroactively effective to the date of the Confidentiality Agreement.

13.2 Publicity. Any announcements or publicity regarding the existence of this Agreement or any terms or subject matter of this Agreement by either Eurand and/or GSK will be agreed to by Eurand and GSK in writing in advance of any such announcement or publicity. The Party preparing any such announcement, publicity or press release will provide the other Party with a draft thereof reasonably in advance of disclosure so as to permit the other Party to review and comment on such announcement, publicity or press release, unless Applicable Law otherwise requires immediate public disclosure. The foregoing notwithstanding, the Parties will agree on a press release to announce the execution of this Agreement, together with a corresponding question/answer outline for use in responding to inquiries about this Agreement. Thereafter, Eurand

and GSK may each disclose to Third Parties the information contained in such press release and question/answer outline without the need for further approval by the other Party. Each Party agrees that it will co-operate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either Party included in any such disclosure. Further, Eurand acknowledges and agrees that it will not have a right to disclose the Compound and/or Drug Substance, as it relates solely to this Agreement, in any announcement, publicity or press release prior to the First Commercial Sale unless agreed to by GSK.

13.3 Publication.

13.3.1 Eurand will not submit for written, electronic or oral publication any document, manuscript, abstract or the like (a "Eurand Publication") which includes any GSK Data or any other information regarding, related to, Product in the Field without first providing GSK with a copy of such Eurand Publication for GSK's review. GSK will review and provide its comments and changes, if any, to such Eurand Publication which is an abstract, within fifteen (15) Business Days after receipt of the Eurand Publication from Eurand and to such Eurand Publication which is a manuscript or any other document, within thirty (30) Business Days after receipt of the Eurand Publication from Eurand, or in each of foregoing cases, such longer period of time as agreed to by the Parties in order to afford GSK a reasonable opportunity to protect its rights under any GSK Intellectual Property Rights. Eurand will incorporate any comments and changes received from GSK as provided herein with respect to such Eurand Publication. Any GSK contributions will be acknowledged in any such Eurand Publication.

13.3.2 GSK will not submit for written, electronic or oral publication any document, manuscript, abstract or the like (a "GSK Publication") which includes any Eurand Data or any other information regarding, related to, Product in the Field without first providing Eurand with a copy of such GSK Publication for Eurand's review. Eurand will review and provide its comments and changes, if any, to such GSK Publication which is an abstract, within fifteen (15) Business Days after receipt of the GSK Publication from GSK and to such GSK Publication which is a manuscript or any other document, within thirty (30) Business Days after receipt of the GSK Publication from GSK, or in each of the foregoing cases, such longer period of time as agreed to by the Parties in order to afford Eurand a reasonable opportunity to protect its rights under any Eurand Intellectual Property Rights. GSK will consider in good faith any comments and changes received from GSK as provided herein with respect to such GSK Publication. Any Eurand contributions will be acknowledged in any such GSK Publication.

13.4 Clinical Trial Registries. The Parties acknowledge and agree that notwithstanding anything to the contrary contained in this Section 13, GSK may publish the protocols, results and/or summaries of any clinical trials relating to Compound and/or Product, including without limitation the Data, on a clinical trial register maintained by GSK or its Affiliate and the protocols of clinical trials relating to Compound and/or Product on www.ClinicalTrials.gov (and/or in each case publish the results, summaries and/or protocols of clinical trials on such other websites and/or repositories as required by Applicable Law or such GSK's or its Affiliate's standard operating procedures), and that each such publication will not be a breach of the confidentiality obligations provided in this Section 13.

14 MISCELLANEOUS:

14.1 Assignment Neither this Agreement nor any interest herein may be assigned, in whole or in part, by either Party hereto without the prior written consent of the other Party hereto, provided that either Party shall have the right to assign all or part of its rights, interest and obligations to an Affiliate, a successor to a controlling or majority share of such Party, or to a successor to substantially all the assets of the business to which this Agreement relates. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective permitted successors and assigns. Eurand acknowledges and agrees that in the event that it assigns in whole or in part any of its rights, interests and/or obligations under this Agreement as provided in this Section 14.1 to a Competing Business Entity, and elects not to divest or cause the divestiture of the Competitive Product marketed by the Competing Business Entity, as part of a Merger as defined in Section 10.6, GSK will have an irrevocable option of assuming sole responsibility for the manufacture of Product, in which case Eurand shall be responsible for all technology transfer costs incurred by Eurand.

14.2 Safety Data Exchange Agreement. The procedures for sharing and reporting of Adverse Events and Serious Adverse Events encountered by each Party relating to or associated in any way with the development, use, manufacture and/or commercialization of Compound, Drug Substance and/or Product as contemplated under this Agreement, which procedures will be no less stringent that those set forth in the applicable guidelines of the ICH and will be sufficient to allow each Party to satisfy both expedited and periodic regulatory reporting requirements, will be as set forth in a Safety Data Exchange Agreement to be finalized and exchanged by the Parties within ninety (90) days after the Effective Date, or such other date as agreed upon by the Steering Committee. For the purposes of this Agreement, the terms "Adverse Event" and "Serious Adverse Event" will have the meanings ascribed to them in the Safety Data Exchange Agreement. For the purposes of this Section 14.2, "ICH" means the International Committee on Harmonization developed through a collaboration between the FDA and regulatory agencies in the European Union and Japan to harmonize regulatory requirements to produce marketing applications acceptable to the countries of the European Union, Japan and the United States.

14.3 No Implied Waiver. Failure by either Party hereto on one or more occasions to avail itself of a right conferred by this Agreement shall in no event be construed as a waiver of such Party's right to enforce said right in the future.

14.4 Choice of Law. This Agreement and all rights and obligations hereunder, including matters of construction, validity and performance, shall be exclusively governed by and construed in accordance with the laws of the state of New York, without regard to the choice-of-law provisions thereof. The Parties hereby consent to service of process by mailing or delivering such service to the Party at its respective principal business address. The Parties hereby submit to the jurisdiction of the federal courts in the State of New York for the resolution of any disputes through any judicial mechanism.

14.5 No Third Party Beneficiaries. No Third Party, including any employee of any Party to this Agreement, will have or acquire any rights by reason of this Agreement.

14.6 Notices. Any notice and other communication required or permitted to be given hereunder shall be in writing and shall be deemed given when delivered personally, telecopied or received by registered mail, return receipt requested, to the Parties at the following addresses:

If to Eurand, to:

Eurand, Inc.
845 Center Drive
Vandalia, OH 45377
Attention: Office of Business Development
Facsimile: (937) 898-1093

If to GSK, to:

GlaxoSmithKline R&D Limited
Greenford Road
Greenford, Middlesex
UB6 0HE
UK
Attention: Vice President, Worldwide Business Development Transactions
Facsimile: +44 208 966 5371

with a copy to:

Smith Kline Beecham Corporation d/b/a GlaxoSmithKline
2301 Renaissance Boulevard
King of Prussia, PA 19406-2772
Attention: Vice President and Associate General Counsel, R&D Legal Operations, Business Development Transactions Team
Facsimile: 610-787-7084

or at such other addresses as the Parties may designate by notice sent in accordance with this Section 14.6.

14.7 Execution of Additional Documents. Each Party hereto agrees to execute such further documents or agreements, and do all such other commercially reasonable acts, as may be reasonably necessary or desirable to effect the purpose of this Agreement and carry out its provisions.

14.8 Severability. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, such provision shall be considered severed from this Agreement, and it is the intention of the Parties that the remainder of the Agreement will not be affected. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

14.9 Captions/Headings. The article and section captions or headings in this Agreement have been inserted as a matter of convenience and are not part of this Agreement.

14.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original of this Agreement and all of which together shall constitute one and the same instrument.

14.11 Independent Relationship. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other or to bind the other Party in any respect whatsoever. All activities undertaken by Eurand hereunder shall be that of an independent contractor.

14.12 Entire Agreement. This Agreement, together with the Safety Data Exchange Agreement, Clinical Supply Agreement (and related quality agreement) and Commercial Supply Agreement (and related quality agreement), contains the entire agreement between the Parties related to subject matter hereof, and this Agreement cannot be amended, varied or abridged in any manner except by amendment in writing duly signed by the Parties. This Agreement takes the place of any existing agreement, arrangements or discussions between the Parties relating to the subject matter hereof, whether oral or written, including, without limitation, the Confidentiality Agreements.

14.13 Force Majeure. Neither Eurand nor GSK will be liable for failure of or delay in performing obligations set forth in this Agreement (other than the payment of amounts owed), and neither will be deemed in breach of its obligations, if such failure or delay is due to a Force Majeure Event. When a Force Majeure Event arises, the Parties will discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

14.14 Resolution of Disputes.

14.14.1 If the dispute cannot be resolved by the senior executives as set forth in Section 5.6, then either Party may submit the matter to arbitration conducted in New York, New York in accordance with the rules of the American Arbitration Association ("AAA"). The award of such arbitration shall be final, binding and non-appealable, except to the extent provided for in the rules of the AAA. The arbitrator(s) will have the discretion to impose the cost of the arbitration upon the losing Party or divide it between the Parties upon any terms which he/they deem appropriate; provided, however, that each Party shall bear its own legal fees and costs. A judgment upon an award rendered by the arbitrator(s) may be entered in any court of competent jurisdiction, or application may be made to such court for confirmation of such award or a judicial acceptance of such award, and for an order of enforcement or other legal remedy.

14.14.2 If the total aggregate amount at issue in a dispute to be arbitrated is equal to or less than Two Million US Dollars ($2,000,000), the number of arbitrators shall be one (1). The arbitrator shall be selected by the AAA. If the total aggregate amount at issue in a dispute to be arbitrated is equal to or greater than Two Million Dollars ($2,000,000), the number of arbitrators shall be three (3). Each Party shall select one (1) arbitrator from among a list of qualified arbitrators compiled by the AAA. The two arbitrators so selected shall select a third qualified arbitrator, who shall act as president of the tribunal. If the two arbitrators selected by the Parties fail to agree on the third arbitrator within thirty (30) calendar days of the selection of the second arbitrator, the third qualified arbitrator shall be designated in accordance with the rules of the AAA. In addition to the qualification criteria for arbitrators established by the rules of the AAA, each arbitrator shall meet the

following additional criteria: (i) the arbitrator shall be experienced in resolving the type of dispute(s) at issue; and (ii) the arbitrator shall have technical or intellectual property related background and/or knowledge if relevant to the dispute.

14.14.3 Notwithstanding the foregoing, either Party may, without waiving any remedy under this Agreement, seek, from any court having jurisdiction, any interim relief or provisional relief (including, without limitation, injunctive relief) that is necessary to protect the rights or property of that Party pending the establishment of the arbitral tribunal set forth in this Section 14.14.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Development and License Agreement to be executed by their duly authorized representatives as of the Effective Date.

EURAND, INC.	SMITH KLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE
By: /s/ John Fraher	By: /s/ Donald F. Parman
Name: John Fraher	Name: Donald F. Parman
Title: President, Eurand North America	Title: Vice President & Secretary

EXHIBIT A

EURAND PATENT RIGHTS

Title	US Status	US Application No./ Filing Date	US Publication No./ Publication Date	US Patent No. Issue Date	Foreign Counterparts
PULSATING VIBRATION AIR GENERATION MEANS	Granted	08/713,128 9/16/1996		6,062,826 5/16/2000	JP Pat. 2811057-Active EP Patent 0787935-Confirmed Active in Germany and Great Britain
SPRAY FOR SPRAYING POWDERED MATERIAL ACTIVATED BY PULSATING VIBRATION AIR AND METHOD	Granted	08/878,944 6/19/1997		5,996,902 12/07/1999	JP App. 158825/97-Active EP Pat. 0815931
ROTARY-TYPE TABLETTING MACHINE WITH LUBRICANT SPRAYING MEANS	Granted	08/332,533 10/31/1994		5,700,492 12/23/1997	JP Pat. 2681601-Active EP Pat. 0650826
TASTE-MASKED MICROCAPSULE COMPOSITIONS AND METHODS OF MANUFACTURE	Granted	08/942,094 10/01/1997		6,139,865 10/31/2000	AU Pat. 722289 BR App. PI9711585-1 CA Pat. 2266629 EP App. 97945437.8 IL App. 129242 JP App. 516859/1998 MX Pat. 214521 NZ Pat. 334914
ORALLY DISINTEGRATING TABLETS AND METHODS OF MANUFACTURE	Pending	10/827,106 4/19/2004	2005/0232988 10/20/2005		PCT App. PCT/US2005/010901

Title	US Status	US Application No./ Filing Date	US Publication No./ Publication Date	US Patent No. Issue Date	Foreign Counterparts
TASTE-MASKED PHARMACEUTICAL COMPOSITIONS PREPARED BY COACERVATON	Pending	11/213,266 8/26/2005			PCT App. PCT/US2005/037084
INTRABUCALLY RAPIDLY DISINTEGRATING TABLET AND A PRODUCTION METHOD OF THE TABLETS	Pending	10/356,641 6/20/2003	2003/0215500 11/20/2003		AU Pat. 733032-Active RU Pat. 001898-Active JP App. 501448/98-Active EP Pat. 0914818
TABLETS QUICKLY DISINTEGRATING IN ORAL CAVITY	Pending	10/506,349 3/06/2003	2005/0147666 7/07/2005		
WETTABLE MICROCAPSULES HAVING HYDROPHOBIC POLYMER COATED CORES	Granted	09/673,178 4/09/1999		6,509,034 1/21/2003	AU Pat. 742009 CA App. 2328080 EP Pat. 1069891 JP App. 2000-543120 NZ Pat. 507951
METHOD FOR PRODUCTION OF MICROCAPSULES	Granted	10/019,363 10/25/2001		6,716,456 4/06/2004	CA App. 2371200 EP Pat. 1189690 JP App. 2000-613559
CONTROLLED RELEASE POTASSIUM CHLORIDE TABLET	Granted	07/925,717 8/14/1992		5,422,122 6/06/1995	CA Pat. 2101697

Title	US Status	US Application No./ Filing Date	US Publication No./ Publication Date	US Patent No. Issue Date	Foreign Counterparts
PHARMACEUTICAL FORMULATIONS	Granted	07/776,329 12/11/1991		5,409,711 4/25/1995	AU Pat. 635133 CA Pat. 2058946 EG App. 1263/98 EP Pat. 0477333 HK Pat. 0950124 IE Pat. 64274 JM Pat. 3438 JO Pat. 2087 JP Pat. 3193041 KR Pat. 164863 NZ 237824 PT Pat. 97369 RU Pat. 2085190 SG Pat. 9790653-1 TW Pat. NI56345 ZA Pat. 91/2793
POWERED MATERIAL SPRAYING DEVICE	Granted	10/019,936 7/05/2000		6,776,361 8/17/04	JP App. 509312/01 EP App. 00944259.1
TABLET PRODUCTION METHOD AND TABLET	Pending	09/647,777 4/09/1999			JP App. 543105/00 EP App. 99913634.4
TABLET PRODUCTION METHOD AND TABLET	Granted	09/647,786 4/07/1999		6,964,779 11/15/2005	JP App. 543104/00 EP App. 99913582.5
TABLET PRODUCTION METHOD AND TABLET	Granted	09/806,761 10/05/1999		6,764,695 7/20/2004	JP App. 573345/00 EP App. 99969950.7
EFFERVESCENT TABLET, EFFERVESCENT BATH TABLET, EFFERVESCENT WASH TABLET, AND EFFERVESCENT ORAL DOSAGE	Pending	10/181,346 10/02/2002	2003/0194434 10/02/2002		JP App. 552868/00

Title	US Status	US Application No./ Filing Date	US Publication No./ Publication Date	US Patent No. Issue Date	Foreign Counterparts
TABLET					

EXHIBIT B

EURAND TRADEMARKS – United States

Application No./ Filing Date	Registration No./ Registration Date	Status	Mark	Class/Goods
74/272,755 5/05/1992	1,880,251 2/21/1995	Registered	MICROCAPS	Class 5: decongestants, stimulant capsules and caplets, anti-inflammatory preparations, pharmaceutical preparations for the treatment of cardiovascular disorders
74/272,730 5/05/1992	1,901,350 6/20/1995	Registered	MICROCAPS	Class 5: oral analgesics and potassium supplements
76/212,896 2/16/2001	2,612,075 08/27/2002	Registered	MICROCAPS	Class 5: oral analgesics and potassium supplements
76/212,897 2/16/2001	2,587,934 7/02/2002	Registered	MICROCAPS	Class 5: decongestants, stimulant capsules and caplets, anti-inflammatory preparations, pharmaceutical preparations for the treatment of cardiovascular disorders
78/252,564 5/21/2003		Allowed	ADVATAB	Class 5: Orally disintegrating pharmaceutical tablets for use in chemotherapy; Orally disintegrating pharmaceutical tablets for use in the prevention, treatment or relief of gout, heart rhythm disorders, infectious diseases, viral diseases, immunologic diseases, neurological diseases and disorders, central nervous system diseases and disorders, gastro-intestinal diseases, genitourinary diseases, prostate disease, hemotological disorders, cardiovascular diseases, allergic rhinitis, asthma, respiratory diseases, diabetes, psychiatric diseases, skin disorders, erectile dysfunction, bone diseases,

Application No./ Filing Date	Registration No./ Registration Date	Status	Mark	Class/Goods
				cancer, iron deficiency, inflammatory diseases, osteo and rheumatoid arthritis and glaucoma; Orally disintegrating pharmaceutical tablets acting on the central nervous system; Antibacterial, anti-diabetic, cardiovascular, antihelmintics and dermatological pharmaceuticals in orally disintegrating tablets form; Orally disintegrating pharmaceutical tablets for the treatment of obesity, nephropathy, atherothrombosis, thrombosis, arrhythmia, angina, insomnia, epilepsy, schizophrenia, hormonal disorders; Orally disintegrating pharmaceutical tablets for the prevention and treatment of osteoporosis; Orally disintegrating pharmaceutical tablets for use in dermatology; Orally disintegrating pharmaceutical tablets for chloasma; Orally disintegrating pharmaceutical tablets to prevent swelling in the legs; Orally disintegrating pharmaceutical tablets for ophthalmological use; Orally disintegrating pharmaceutical tablets, namely, absorbents, lipid lowering agents, psychotropics, adrenocorticals, acne medication, alteratives, allergenics, analeptics, analgesics, aphrodisiacs, anaphrodisiacs, androgenics, anesthetics, anhidrotics, antagonists, anthelmintics, anodynes, antacids, anthelmintics, antiarrhythmics, anti-anginals, anti-arthritics, antibiotics, anticoagulants,

Application No./ Filing Date	Registration No./ Registration Date	Status	Mark	Class/Goods
				anticonvulsants, antidepressants, antichlorotics, antidotes, antiedemics, antiemetics, antiepileptics, antiflatulants, antigalactagogues, antihypertensives, anti-infectives, anti-inflammatories, antigonorrheics, antihidrotics, antihistamines, antilithics, antineoplastics, antineuralgics, antiparasitics, antiperiodics, antiphlogistics, antipyretics, antirheumatics, antiserotonins, antithyroid preparations, antisyphylitics, antisialagogues, antivirals, antimicrobial, antispasmodics, antipsychotics, antipyretics, antisymotics aperients aphrodisiacs, antitussives, antivenins, aromatics, anxiolytics, beta-adrenergic blockers, appetite suppressants; calcium channel blockers, cardiac sedatives, cardiac stimulants, carminatives, cathartics, cerebral depressants and stimulants, central nervous system depressants and stimulants, cholagogues, choleretics, counter-irritants, demulcents, deoxidizers, diaphoretics, digestives, discutients, diuretics, ecbolics, emetics, emmenagogues, ciliary excitants, deliriants, diluents, expectorants, febrifuges, galactagogues, gastric tonics, emostatics, hepatic stimulants, hormones, hypnotics, laxatives, metabolic agents, motor depressants, motor excitants, mydriatics, myotics, narcotics, nervines, nutriants, nutrients, oxytocics,

Application No./ Filing Date	Registration No./ Registration Date	Status	Mark	Class/Goods
				ptyalagogues, purgatives, pustulants, refrigerants (medicinal), resolvents, rubefacients, sedatives, sialagogues, soporifics, sternutatories, stimulants, stomachics, sulfonamides, teniafuges, tonics, ureteritics, vaso-constrictors, vasodilators, vasotherapeutics, vascular sedatives, diarrhetics, fungicides, laxatives, cortisones, hydrocortisones vermicides, and vesicants; prenatal tablets and capsules; pharmaceutical tablets and capsules for pain management and relief; Orally disintegrating pharmaceutical tablets, namely, chelating agents, decongestants, expectorants, sustained-release medications for treating heart rhythm disorders, and synthetic anticholinergics; Orally disintegrating pharmaceutical tablets for treating cardiology conditions, gasteroenterology conditions, neurology conditions, urological conditions, gynecologic conditions, obstetric conditions, and internal medicine disorders; Orally disintegrating pharmaceutical tablets, namely, diarrhea medication, stomach remedies, motion sickness remedies, and sleep aids; Orally disintegrating birth control pills; Orally disintegrating pharmaceutical tablets for the treatment of pain, congestion, cough, urinary tract disorders, psychotic conditions, gastrointestinal disorders,

Application No./ Filing Date	Registration No./ Registration Date	Status	Mark	Class/Goods
				spasms, urinary incontinence, and histamine production; Orally disintegrating pharmaceutical tablets for the treatment of coughs, colds, influenza, headaches, and allergies; Orally disintegrating pharmaceutical tablets, namely, endocrinology medications, gastrointestinal medications, anti-hematosis medications, fungal medications, ophthalmic medications, lactation inhibitors, measles prophylactics, pneumococcal prophylactics, and muscle relaxants; Orally disintegrating pharmaceutical tablets for the treatment of central nervous system, cardiovascular, endocrinological, gastroenterological, hematological, respiratory, circulatory, hormonal, diabetic, stomach, digestive, muscular, rheumatic, immune system, metabolic and ocular disorders; Orally disintegrating pharmaceutical tablets for use in oncology; Orally disintegrating pharmaceutical tablets for smoking cessation; Orally disintegrating vitamins and food supplements; Orally disintegrating nutraceuticals for use as a dietary supplement; Orally disintegrating veterinary pharmaceuticals for use in the treatment of gastrointestinal diseases, cardiovascular diseases, circulatory disorders, neurological diseases, urological diseases, hormonal disorders, blood diseases, and muscle disorders; Orally disintegrating anti-infective,

Application No./ Filing Date	Registration No./ Registration Date	Status	Mark	Class/Goods
				bacterial, and bacteriological pharmaceuticals for veterinary purposes; Orally disintegrating veterinary pharmaceuticals for treatment of intestinal bacteria; Orally disintegrating pain relief medication for veterinary purposes; and Orally disintegrating veterinary vaccines and anthelmintics

EXHIBIT C

GSK PATENT RIGHTS

Application No./Filing Date	Publication No./Publication Date	Patent No. Issue Date	Status	Title
583286 27 February 1984		4602017 22 July 1986	Granted	SUBSTITUTED AROMATIC COMPOUNDS

EXHIBIT D

PROPOSAL

Product Development Proposal

Lamotrigine IR Orally Disintegrating Tablets

(25, 50, 100 & 200 mg)

Formulation Development and Clinical Trial Materials

I. Summary

This proposal describes the development of an immediate-release (IR) orally disintegrating tablet (ODT) formulation of lamotrigine based on Eurand's proprietary Microcaps® and AdvaTab® technologies. Lamotrigine is the active ingredient in GSK's marketed product, Lamictal®, an antiepileptic drug of the phenyltriazine class. Lamotrigine has favorable pharmacological properties, both in efficacy and safety. Lamictal swallowable tablets are marketed for oral administration in 25, 100, 150, and 200 mg strengths, while Lamictal Chewable Dispersible tablets contain 2, 5, or 25 mg of lamotrigine (see Fig. 1). GSK is interested in developing Lamictal Orally Disintegrating Tablets in strengths of 25, 50, 100 and 200 mg as part of its life cycle management strategy

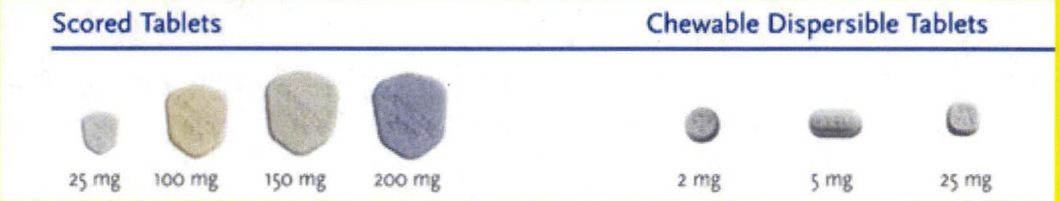

Figure 1: Currently marketed Lamictal solid oral dosage forms

Eurand will formulate an ODT dosage form of lamotrigine using both microencapsulated cores of granulated lamotrigine and non-encapsulated lamotrigine. Upon contact with saliva in the oral cavity, the ODTs rapidly disintegrate into small, coated particles which are swallowed whole. Rapid and complete release of the drug occurs in the stomach, thus there is a high probability of achieving bioequivalence to the reference listed drug (RLD) products (Lamictal IR or the 25 mg Chewable/Dispersible tablet). Eurand will develop dose-proportional formulations for all four strengths (based on lab book batch records in GMP facilities), with approximate tablet weights and dimensions shown in Tables 1 and 2. Eurand will then develop, test and provide to GSK 5 (five) ODT formulations (two 100 mg and three 200 mg tablet formulations), based on both granulated lamotrigine, and microencapsulated lamotrigine process approaches. Based on the results, Eurand and GSK may decide on minor compositional changes in the prototypes which Eurand will implement and then produce as GMP clinical trial material (CTM) consisting of both 25mg and 200mg strength tablets from both process approaches in order for GSK to conduct pilot PK studies. Following shipment of the GMP CTM to support the pilot PK study, Eurand will perform scale-up to commercial scale (i.e., approximately 750 kg) and optimize the manufacturing processes. Eurand will then manufacture, release, and initiate stability monitoring on pivotal BE / registration stability ODT batches packaged in commercial configurations to support product registration and will collect sufficient in-process data to enable these batches to serve as pre-validation batches. Eurand will initiate manufacture of the validation and commercial batches approximately three months after NDA filing to support product launch.

Strength (mg)	Tablet Weight (mg)	Color/Sweetener	Flavor
200	1,000 - 1,200	White/Sucralose	Cherry (or mint)
100	500 – 600	White/Sucralose	Cherry (or mint)
50	250 – 300	White/Sucralose	Cherry (or mint)
25	125 – 150	White/Sucralose	Cherry (or mint)

Table 1: Estimated tablet weights for dose-proportional formulation

The anticipated tablet size for each of the four strengths is summarized below:

Strength:	200 mg	100 mg	50 mg	25 mg
Diameter:	~13-14 mm	~ 11-12 mm	~ 9-10 mm	~ 8-9 mm
Tablet Weight:	~1000-1200mg	~500-600 mg	~250-300 mg	~125-150 mg

Table 2: Approximate tablet size

II. Lamotrigine Drug Substance

Lamotrigine is 3,5-diamino-6-(2,3-dichlorophenyl)-*as*-triazine. It has an empirical formula of $C_9H_7N_5Cl_2$, a molecular weight of 256.09 and the structural formula shown below. It is a white to pale cream-colored crystalline powder, with a melting point of 216-218 °C, and a pKa of 5.7. Lamotrigine is very slightly soluble in water (~0.17 mg/ml at 25 °C; ~0.57 mg/ml at 37 °C), but is significantly more soluble in 0.01N HCl (~3 mg/ml at 25°C) and 0.1N HCl (~4 mg/ml at 25°C). It is reported to be mildly bitter, but masking with flavoring agents (black currant) has been successfully achieved for the Chewable Dispersable tablet. Eurand has determined that lamotrigine has a very low solubility in cyclohexane (46 µg/ml at 25°C, and 34 µg/ml 80°C). The API that GSK will provide has a D_{90} particle size of 8.3 – 17.2 µm, and there is only one polymorphic form. The API is stable in its solid state and is compatible with mannitol.

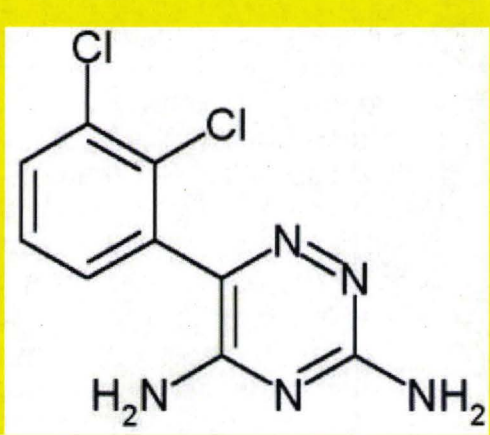

Figure 2: Chemical structure of lamotrigine

Clinical Pharmacology

Following oral administration, lamotrigine is rapidly and completely absorbed with negligible first-pass metabolism (absolute bioavailability is 98%). The lamotrigine chewable/dispersible tablets were found to be bioequivalent to the lamotrigine IR tablets in terms of C_{max} and AUC whether administered as dispersed in water, chewed or swallowed intact.

III. Eurand Technology

Eurand is a recognized leader in the oral drug delivery field, providing integrated formulation development and manufacturing solutions to meet the requirements of its pharmaceutical partners worldwide. The company operates facilities both in Vandalia, Ohio and Pessano, Italy. The company was established over thirty years ago, and has taken part in the successful commercialization of over 50 products worldwide. These products are based on one of Eurand's three technology platforms – Customized Release (Diffucaps®/ Diffutab®/ Minitabs®/ Orbexa®), Taste-masking and Orally Disintegrating Tablets (Microcaps®/ AdvaTab®), and Solubility Enhancement (Biorise®).

Microcaps® – Taste-Masking and Sustained Release Technologies

Eurand's Microcaps microencapsulation technology can be utilized to develop novel taste-masked or sustained-release dosage forms. The Microcaps process is based on coacervation - a versatile and precise coating technique used to encapsulate individual drug particles and achieve superior taste masking properties (Fig. 3). The coacervation process places a complete and uniform polymer coating directly on the drug crystals or granules (Fig. 4). Microcaps particles can be incorporated into many different dosage forms including dispersible tablets, orally disintegrating tablets, sachets, and suspensions where taste-masking is critical. Eurand can apply this technology to both soluble and poorly-soluble drug substances, as well as the development of high dose products. Eurand's technology is used for a wide range of poor tasting drugs including theophylline, ibuprofen, acetaminophen, pseudoephedrine, H_2 antagonists, and macrolide antibiotics. Eurand's taste masked actives are incorporated into products such as Children's Chewable Advil®, the Triaminic® line of products, Bronchoretard® (*theophylline*), Rulid® (*roxithromycin*), Children's Chewable Benadryl® and Children's Softchew Tylenol®, among others.

The Microcaps technology has also enabled Eurand to develop sustained-release (SR) products of active pharmaceutical ingredients for absorption throughout the GI tract. For example, the drug cores, coated with functional polymers by Eurand's proprietary coacervation and fluid-bed coating processes, permit development of orally disintegrating tablet formulations exhibiting SR profiles (over a period of 1-12 hours). The approach is quite flexible in this regard, by altering the composition and thickness of the coating polymers various dissolution profiles can be achieved. The Microcaps of potassium chloride crystals shown in Figure 4 were formulated as part of an effort to create a disintegrating tablet product bioequivalent to the K-Dur® 20 brand which exhibits an 8 hour release profile (US patent application 2005/0013860 A1). Figure 5 shows the *in vitro* drug release profiles of Eurand's pivotal biobatch compared to the reference product. In the pivotal bioavailability study, Eurand's product proved to be bioequivalent to K-Dur, and is marketed by Par Pharmaceuticals.

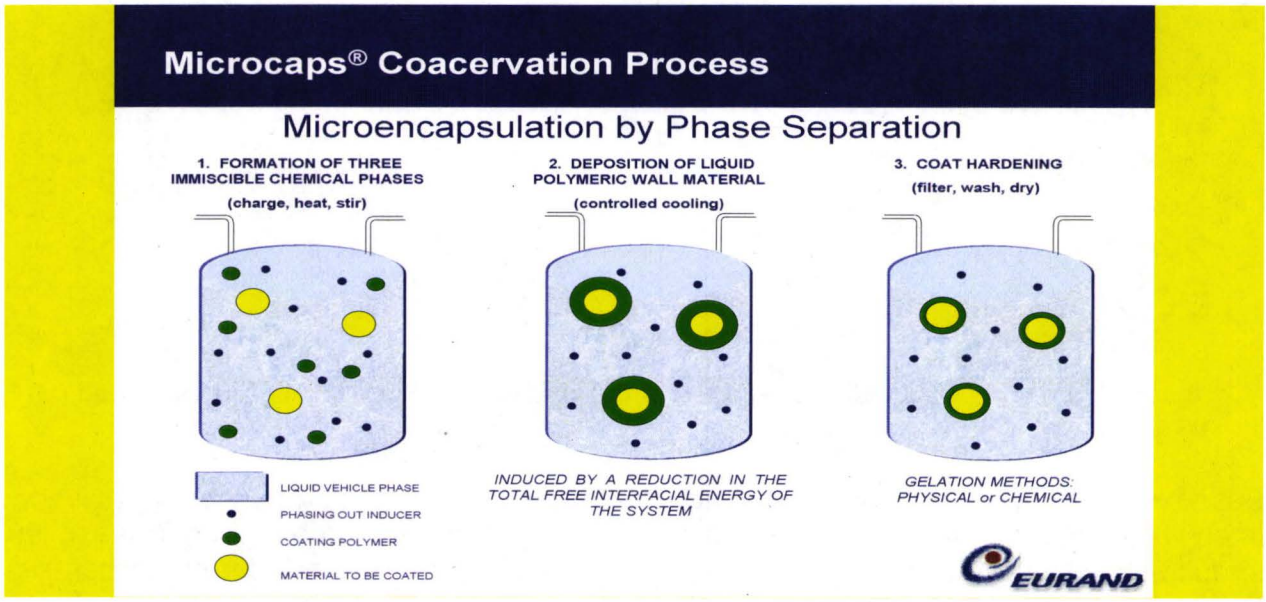

Figure 3: Microencapsulation

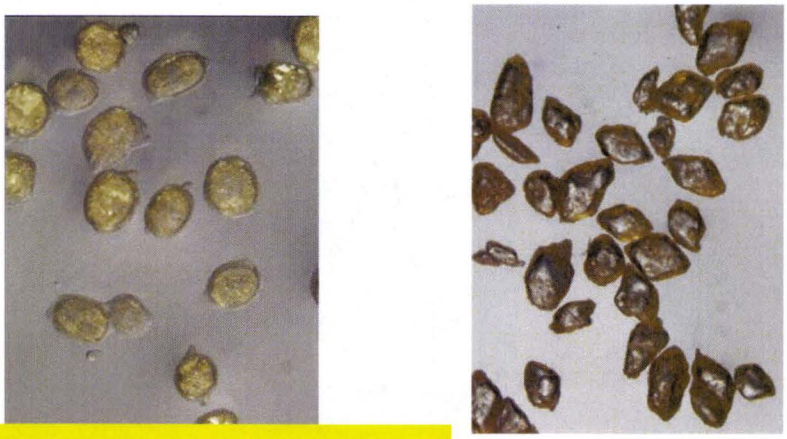

Figure 4: Microencapsulated acetaminophen (left) and potassium chloride (right)

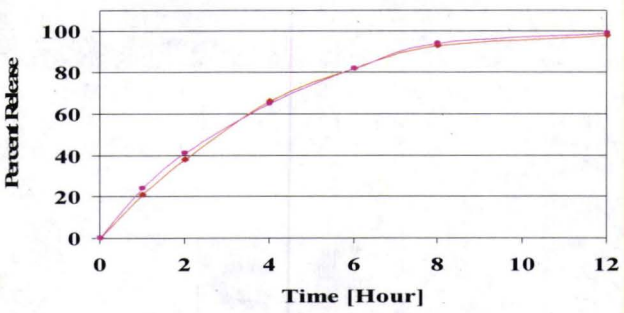

Figure 5: Eurand's KCl ER tablet (pink) compared to K-Dur 20 reference (red)

Based on preliminary work conducted by Eurand on lamotrigine, it appears very likely to achieve both (i) effective taste-masking (i.e., negligible drug release in simulated saliva fluid over 3 minutes) and (ii) fast dissolution in simulated gastric fluid. Fig. 6 demonstrates a slow, SR release profile of lamotrigine in phosphate buffer at pH 6.8 for a microencapsulated formulation; however, the formulation rapidly dissolves (e.g., 100% in 10 minutes) when dissolution tested in 0.1N HCl.

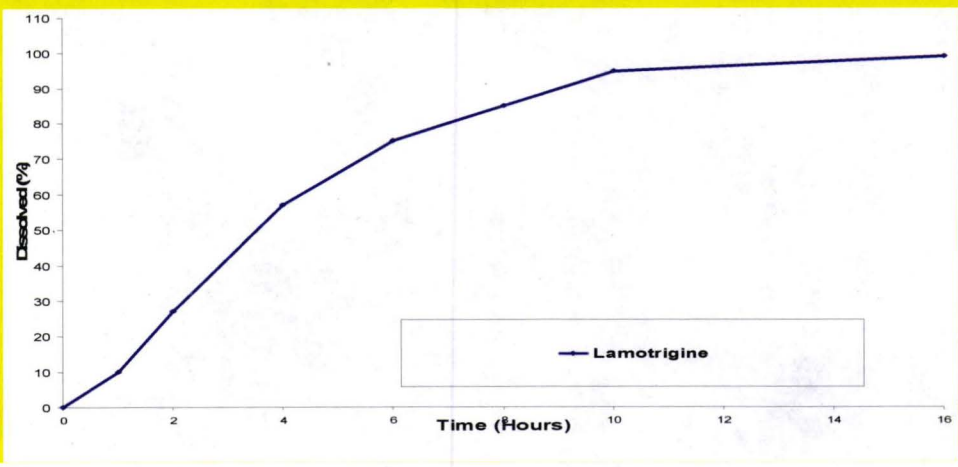

Figure 6: Dissolution of coated lamotrigine at pH = 6.8

AdvaTab® - Orally Disintegrating Tablet Technology

AdvaTab is an orally disintegrating tablet technology that incorporates drug granules into a tablet formulation that disperses quickly in the mouth without water or chewing. Using the proprietary rapidly dispersing microgranules (protected by EP patent allowed and US patent pending) and patented external lubrication system (USP 5,700,492, USP 5,996,902, and USP 6,062,826), dosage forms with excellent physical robustness, mouth-feel and disintegration properties can be achieved. Key attributes of Eurand's orally disintegrating technology include:

- excellent mouth-feel;
- hard tablets that can be packaged in bottles or blisters (e.g., friability <1%, typically < 0.5%);
- rapid disintegration;
- ability to incorporate microencapsulated drug if necessary (e.g., for taste-masking purposes);
- ability to incorporate larger drug doses than conventional ODT technologies
- utilization of standard production processes;
- ability to emboss tablets on either one or both sides; and
- ability to formulate modified release products.

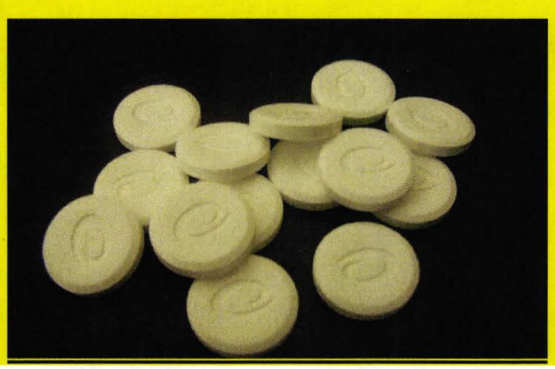

Figure 7: AdvaTab Tablets

The AdvaTab technology is comprised of two complementary elements: i) a proprietary tablet composition and ii) a patented direct compression tabletting system that does not compromise the disintegration characteristics offered by the tablet composition.

Proprietary Tablet Composition

Eurand has developed a proprietary process for the development and manufacture of a quick disintegrating tablet. This technology (US patent pending; patent allowed in Europe) is based on the use of small, micronized porous particles that will rapidly disintegrate into a suspension in the buccal cavity. The characteristics of the suspension are instrumental in reducing the grittiness associated with drug particles as they are swallowed. Unlike microcrystalline cellulose or calcium phosphate, which are chalky and do not mask particle grittiness particularly well, the AdvaTab system can easily mask the grittiness of particles as large as 600µm in diameter. The AdvaTab formulation utilizes low moisture processing and typically has <1% residual water content – thus it is ideal for moisture sensitive compounds. The tablet does not contain any excipients that are traditionally used to improve powder flow properties or provide for tablet lubrication. These conventional excipients can adversely affect disintegration and dissolution rates of fast dissolving tablet systems.

Patented Direct Compression Process

Eurand uses a proprietary direct compression process to produce the final ODT dosage form comprising both the taste-masked active ingredient and micronized granules of the AdvaTab formulation. This patented process technology employs direct, external lubrication of the tabletting punches. Via a reduction, by approximately 30-fold, of the amount of hydrophobic lubricants contained in a conventional tablet formulation (the sole function of which is to allow for effective high speed tabletting) water uptake into the AdvaTab tablet core is rapid when the tablet is placed in the mouth. The AdvaTab tablet then can disperse quickly in the mouth with a very smooth mouth-feel as the AdvaTab formulation is very soluble. In addition, AdvaTab tablets are robust enough to be packaged in either bottles or push-through blisters. It is the combination of the tablet composition and tabletting technology that confer the product attributes that make Eurand's AdvaTab system one of the most effective orally disintegrating tablet systems available to the pharmaceutical industry today.

Content Uniformity

Eurand uses a conventional blending process to combine the microencapsulated active with the AdvaTab granulation and other tablet excipients. For example, Eurand has developed an AdvaTab Acetaminophen product with a formulation containing approximately 40% Microcaps® APAP combined with AdvaTab® base granules, a disintegrant, a sweetener, and strawberry flavor. This formulation was blended in a 10 cu-ft blender at a batch size of 150 kg for 5, 10, & 15 minutes and the samples (see Figure 8 for locations) pulled at each time point were assayed for content uniformity. The table below shows the results (theoretical assay = 35%).

Time Point (minutes)	Location of Sample						
	A	B	C	D	E	F	**Mean (%RSD)**
10	37.1%	36.8%	33.3%	36.3%	37.8%	34.9%	**36.0 (4.6)**
15	34.4%	35.0%	35.8%	35.3%	35.9%	35.6%	**35.3 (1.5)**
20	37.3%	37.4%	36.2%	37.1%	36.7%	36.0%	**36.8 (1.6)**

Table 3: Content Uniformity Results for AdvaTab Acetaminophen

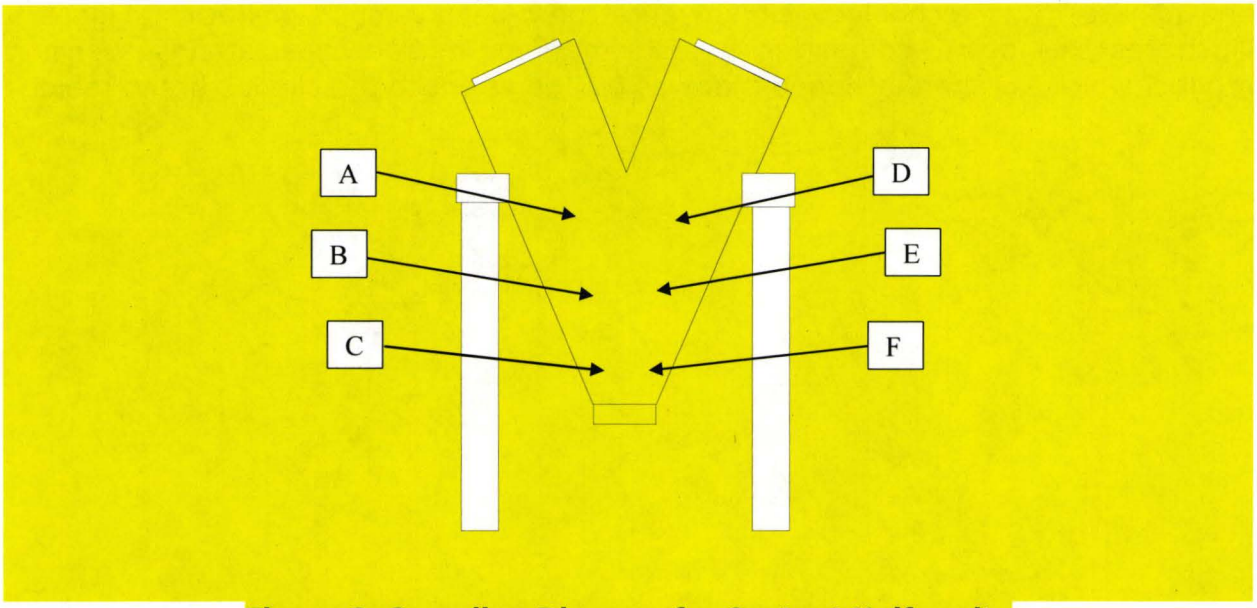

Figure 8: Sampling Diagram for Content Uniformity

Developing Bioequivalent Products

Eurand has significant experience developing bioequivalent products for its clients. When taste-masking is not required, the challenge of establishing bioequivalence is even further reduced. The active can be directly blending into the AdvaTab formulation and is available for immediate dissolution upon disintegration of the ODT, similar to the disintegration of a standard tablet or capsule presentation. For example, Eurand is currently developing an ODT for a proprietary client program where the reference drug (poorly water soluble) is a capsule dosed at 30 mg. The table below shows comparative dissolution results.

Time (min)	% Dissolved	
	30 mg capsule (RLD)	30 mg ODT
5	84	99
15	105	102
30	106	101

Table 4: Dissolution Results for AdvaTab vs. Client Reference Product

Often, microencapsulation of the active is necessary to mask the taste of the active, and the microencapsulation polymers have the potential to delay dissolution and thus create a challenge with demonstrating bioequivalence. Eurand has developed microencapsulation technology that restricts dissolution of the active in the mouth, but allows rapid dissolution at gastric pH. As the residence time in the mouth of an ODT, chewable tablet, or suspension dosage form is very brief (typically less than

one minute), this technology circumvents the bioequivalence obstacle. Figure 9 illustrates this point, comparing a taste-masked, microencapsulated suspension product which Eurand developed that was bioequivalent to the client's brand tablet.

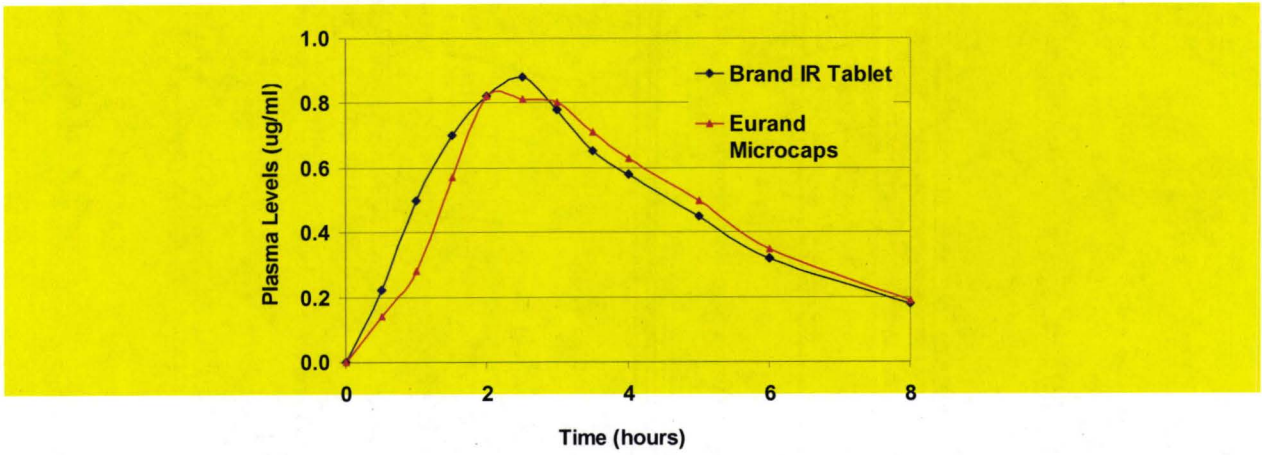

Figure 9: Eurand development program demonstrating bioequivalence

In another example, Fig. 10 below shows data from a pilot biostudy study conducted by Eurand in sixteen subjects for its AdvaTab cetirizine product. AdvaTab cetirizine was shown to be bioequivalent to the reference product (Zyrtec IR and Zyrtec chewable tablets) when taken either with or without water.

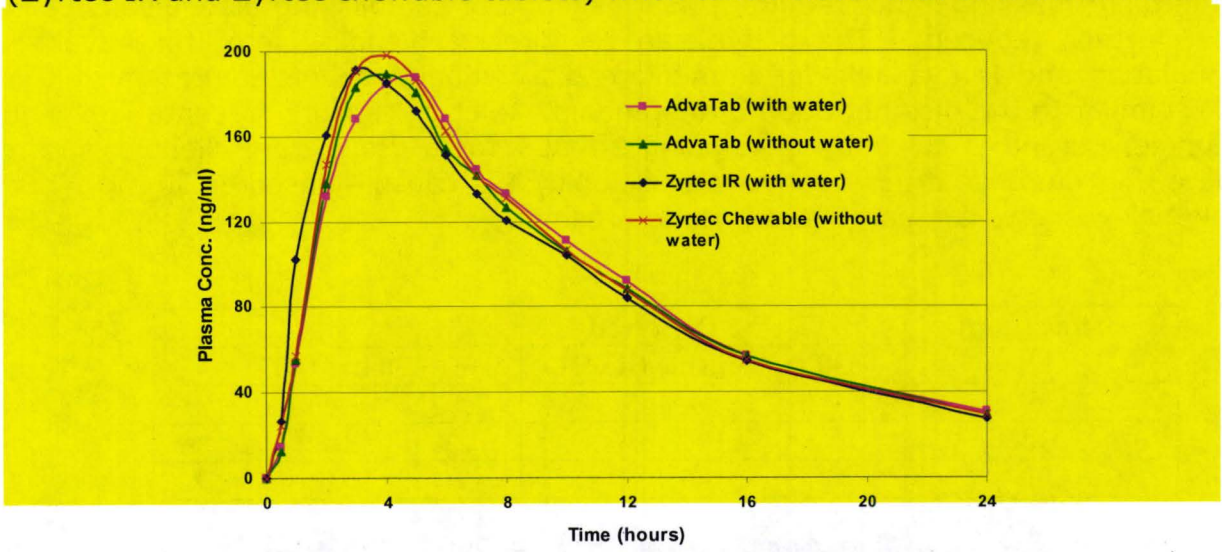

Figure 10: AdvaTab Cetirizine Bioequivalence Study Results

IV. Product Development Proposal

Objectives

- The first objective of this proposal is to develop an ODT formulation of lamotrigine with superior stability, disintegration time, taste and mouthfeel.

- The second objective is to produce, release, and supply GMP prototype ODT formulations to support organoleptic testing, and to demonstrate bioequivalence in a pilot PK study to be performed by GSK.

- The third objective is to produce, release, and supply clinical trial materials (CTM) at full commercial scale to GSK to support a pivotal bioequivalence study, and to package the CTM in commercial configurations (e.g., push-through blisters and HDPE bottles) in order to generate registration stability data to support an NDA filing by GSK.

Product Development Timeline

Extrapolating from the time required for completion of the proposed formulation development and CTM supply, the estimate below details the expected timing for the program to complete scale-up and development of the AdvaTab lamotrigine products.

Activity	Start Date *	End Date	Responsible Party
Program Initiation Date	15 April 2006	NA	Eurand & GSK
Stage I (deliverable = 5 prototypes)	15 April 2006	15 July 2006	Eurand
Conduct stability testing on Stage I prototypes (deliverable = data summary sheets)	15 July 2006	30 Oct. 2006	Eurand
Evaluate and approve Stage I prototypes	15 July 2006	01 Aug. 2006	GSK
One month stability on Stage 1 prototypes available	15 July 2006	31 Aug. 2006	Eurand
Formulation iteration (if required, to take place during Stage II)	N/A	N/A	GSK
Stage II (deliverable = 4 pilot CTM batches at small commercial scale)	01 Aug. 2006	30 Oct.2006	Eurand
Provision of data for IND/CTA filing (minimum 1 month on prototypes plus batch analysis for pilot)	30 Oct. 2006	15 Dec. 2006	Eurand/GSK
Conduct stability on pilot CTM batches	30 Oct. 2006	Ongoing	Eurand
Evaluate and approve Stage II CTM	30 Oct. 2006	15 Nov. 2006	GSK
Submit IND/CTA	N/A	15 Nov. 2006	GSK
Conduct Pilot PK Trial (CTM stability conducted concurrently)	15 Dec. 2006	Feb. 07**	GSK
Stage III (deliverable = pivotal CTM at commercial scale)	15 Nov. 2006	01 Feb. 2007	Eurand
All registration Batches manufactured	15 Nov. 2006	01 Mar. 2007	Eurand
Evaluate and approve Stage III CTM and	01 Feb. 2007	01 April 2007	GSK

registration batch manufacture			
Package registration batches	01 Feb. 2007	01 April 2007	Eurand
Conduct Pivotal PK Trial	01 April 2007	10 Aug. 2007	GSK
Conduct Registration Stability Testing	01 April 2007	31 Oct. 2007	Eurand
File NDA	15 Nov. 2007	NA	GSK
Validation & Launch Production	01 Mar. 2008	30 June 2008	Eurand
PAI	TBD	TBD	Eurand
NDA Approval	30 Sept. 2008	NA	GSK
First Commercial Sale	15 Oct. 2008	NA	GSK

* all start and end dates are based on an assumed Program Initiation Date of 15 April 2006, the actual start and end dates will be dependent on the actual Program Initiation Date

** interim PK/Stats results of preferred formulation to provide assurance of in vivo characteristics to ensure a reasonable probability of a successful BE (25 mg and 200 mg dose strengths) will be available by this time.

NOTE: In order to meet the above timelines, Eurand will be conducting many activities "at-risk" and in parallel.

Stage 1. Formulation Feasibility

Scope

To establish a Eurand/GSK project team, develop prototype formulations, develop analytical methods and determine stability of prototypes.

Project Initiation

- Identify project development team, establish process for working relationship, and establish project management contacts.
- Initiate team meeting to confirm objectives, initial product specifications, timelines, and deliverables.
-

Preformulation

- Selection of globally acceptable excipients;
- Eurand will perform preformulation and compatibility studies of drug and excipients;
- Analysis of API to determine pertinent physical characteristics.

- Formulation Development

After establishing compatibility between lamotrigine and the excipients to be used in the formulations, the granulation, coacervation, and tabletting processes will be developed and optimized. Granulation of the micronized API will be conducted in order to improve taste and to develop an appropriate particle size for optimal

mouthfeel. Further enhancement in taste-masking will be explored via coacervation microencapsulation of lamotrigine, or of granulation containing lamotrigine.

The tasks include:

- develop a granulation process to produce resilient granules, and establish the need for further taste-masking;
- develop/optimize solvent coacervation process; and
- develop/optimize tabletting process.

- Analytical Development

Analytical methods development will include a stability indicating assay, determination of impurities, dissolution methodology, residual solvent, and moisture analysis of dosage forms to support formulation development. Analytical methods to support equipment cleaning procedures will be developed. The tasks include:

- modify, as needed, the analytical methods received from GSK to support equipment cleaning procedures
- modify, as needed, the analytical methods received from GSK for testing of prototype formulations
- conduct dissolution testing on prototype formulations (at both 0.1N HCl and 0.01N HCl) and comparative testing of RLD products; and
- initiate and monitor stability of prototypes in push-through blisters and in induction-sealed HDPE bottles which are representative of the intended commercial packaging configurations

- Stability Study on Selected Prototypes

Eurand maintains stability chambers according to ICH guidelines. Eurand will conduct stability evaluation to include assay, dissolution, chemical degradation, moisture, and physical properties. Packaging of stability samples will be conducted by Eurand. The proposed stability protocol is:

Storage Conditions	*Time (months)*		
	1	2	3
40°C / 75%RH	X	X	X
30°C / 65%RH	X	X	X
25°C / 60%RH	X	X	X

GSK will provide to Eurand information on commercial configurations, such as HDPE bottle and closure type, size and material composition, and blister material, with a pocket size and pocket separation distance, representative of the intended commercial pack. Eurand will commence screening of potential blister materials (i.e., PVC, PVC/PVDC, etc) to facilitate the decision on packaging materials selected

for pivotal stability testing. Packaging material grades and DFM requirements should be agreed with GSK prior to initiation. Eurand will also initiate the following activities during Stage I:

- evaluate tablet friability for distribution chain (e.g., ASTM D4169);
- evaluate robustness of tablets during removal from blister packaging;
- evaluate tablet friability in bottle packaging;
- optimise desiccant levels to bottle fill counts;
- evaluate stability in blister packaging; and
- establish embossing ability for the commercial product

Timing

Approximately three (3) months (not including the stability testing)

Deliverables

- Report summarizing the manufacture of five (5) prototype orally disintegrating tablet formulations exhibiting desired properties (rapid dissolution, robust tablets, quick oral disintegration, good taste, and smooth mouth-feel)
  - Prototype 1 = granulation approach, 100 mg strength, cherry flavor
  - Prototype 2 = granulation approach, 200 mg strength, mint flavor
  - Prototype 3 = granulation approach, 200 mg strength, cherry flavor
  - Prototype 4 = coacervation approach, 100 mg strength, cherry flavor
  - Prototype 5 = coacervation approach, 200 mg strength, cherry flavor
- Report summarizing stability study for formulations (1-month data in HDPE bottles) approximately 6 weeks following initiation of stability monitoring to facilitate prototype selection.

Stage 2. Pilot Clinical Trial Materials

Based upon the organoleptic testing results provided by GSK, Eurand and GSK will determine and agree if adjustments are required for any of the formulations. Eurand will optimize the formulations to reflect such agreed changes. It is envisaged that samples of the adjusted formulations will be provided to GSK prior to the manufacture of CTM material, however this activity will not be a rate limiting step in the production of the CTM. Pilot CTM representing two orally disintegrating tablet (ODT) formulations (25 mg and 200 mg (or 100 mg) strengths for each formulation) will be manufactured under GMP conditions. CTM will be tested, packaged and released by Eurand using qualified methods.

Purpose

Produce pilot CTM, including analytical methods development, and provide stability data.

Formulation Development

Eurand will conduct the following formulation development activities:

- Implement minor formulation changes in selected formulations as agreed and select formulations for CTM;
- scale-up to one-tenth of the commercial scale and optimize granulation and microencapsulation processes;
- Set specifications in consultation with GSK for the manufacture of CTM
- prepare and review master batch records; and
- manufacture, package, and release CTM to GSK.

Analytical Development

- complete methods qualification as necessary;
- test and release of raw materials;
- test and release CTM using qualified analytical methods;
- initiate and monitor stability of CTM in induction-sealed HDPE bottles per ICH guidelines
- Prepare DMF to support regulatory filing (if required)

Stability Conditions & Testing of CTM

The proposed stability protocol is:

Storage Conditions	*Time (months)*						
	1	2	3	6	12	18	24
40°C / 75%RH	X	X	X	X			
30°C / 65%RH			X	X	X	X	X
25°C / 60%RH*	X		X	X	X	X	X

** only if unacceptable results are obtained for the 30°C / 65%RH condition*

Timing

Approximately three (3) months from the date of initiation of Stage II (not including stability testing)

Deliverables

- Ideally, four GMP pilot CTM batches:
  - CTM 1 = coacervation process, 25 mg strength, cherry flavor
  - CTM 2 = coacervation process, 200 mg strength, cherry flavor
  - CTM 3 = granulation process, 25 mg strength, mint flavor
  - CTM 4 = granulation process, 200 mg strength, cherry flavor

- Certificate of analysis for the pilot CTM
- Report summarizing stability study for pilot CTM formulations (to follow)
- Provide data for GSK Investigational Medicinal Product Dossier (IMPD) for regulatory filing at least 45 days prior to filing date

Stage III – Clinical Trial Materials (CTM) & Registration Stability Batches

While the pilot clinical testing is ongoing, Eurand will start scale-up and optimization work. Eurand will also manufacture pivotal CTM and registration stability batches - three ODT batches (one from each of three different lots of lamotrigine) of each strength – then generate stability on registration stability batches in commercial packaging to support product registration (NDA).

Table 5: Manufacturing Strategy For Pivotal and Registration Stability Batches

A compression blend batch size of approximately 750 kg will produce:
- 750,000 ODTs of 200 mg strength (target tablet weight:1,000 mg); or
- 1,500,000 ODTs of 100 mg strength (target tablet weight:500 mg); or
- 3 million ODTs of 50 mg strength (target tablet weight:250 mg); or
- 6 million ODTs of 25 mg strength (target tablet weight:125 mg).

Compression Blend	API Lot#	Quantity of ODTs Produced			
		200 mg	100 mg	50 mg	25 mg
Pivotal CTM	Lot# X	600,000			1.2 million
Registration Batch 1	Lot# X	250,000	250,000	350,000	800,000
Registration Batch 2	Lot# Y	250,000	250,000	350,000	800,000
Registration Batch 3	Lot# Z	250,000	250,000	350,000	800,000

Formulation Development

Eurand will conduct the following formulation development activities:

- scale-up to full commercial scale (i.e., fluid-bed granulation and/or microencapsulation in appropriate large-scale systems, compression blending in the 50 cu-ft blender (batch size: approximately 750 kg) and compression at a scale as indicated in Table 5 above) and optimize manufacturing processes;
- review with GSK current in-process data collection practice, and agree on the extent of DFM/PAT data collection practices, in order to attempt to meet GSK/FDA requirements during scale up;
- conduct a shipping study on tablets in bulk;

- get scaled-up tablets packaged in commercial configurations (e.g., push-through blisters and bottles) by Eurand contract packer, and conduct stability testing for registration purposes;
- set product specifications;
- finalize batch records for granulation/microencapsulation, blending and tabletting operations;
- produce pivotal BE and registration stability batches of 25, 50, 100 and 200 mg orally disintegrating tablets;
- bottle-pack pivotal CTM and ship to GSK;
- evaluate tablet friability for distribution chain (e.g., ASTM D4169);
- evaluate robustness of tablets during removal from blister packaging;
- evaluate tablet friability in bottle packaging;
- optimise desiccant levels to bottle fill counts;
- evaluate stability in blister packaging; and
- establish embossing ability for the commercial product.

Analytical Development

Analytical methods will be validated prior to manufacturing the pivotal BE batch.

- complete methods validation as necessary;
- test and release the pivotal BE / Registration stability batches;
- initiate and monitor stability of the pivotal BE batches in clinical packaging configurations and Registration stability batches in push-through blisters and induction-sealed HDPE bottles per relevant ICH Guidelines for stability matrixing or bracketing (to be pre-approved by GSK/FDA).

Storage Conditions *Time (months)*

	1	3	6	9	12	18	24	36
40°C / 75%RH	X	X	X					
30°C / 65%RH	X	X	X	X	X	X	X	X
25°C / 60%RH*		X	X	X	X	X	X	X
5°C / ambient %RH			X					
50°C / ambient %RH	X							

** only if unacceptable results are obtained for the 30°C / 65%RH condition*

Light testing to meet ICH standard conditions will be included

Timing

Approximately 3-4 months to ship Pivotal CTM and all registration batches for packaging (not including stability testing)

Deliverables

- Certificate of analysis for the GMP pivotal BE / Registration stability batches
- Report summarizing stability data for pivotal BE / Registration stability batches (to follow)
- Update DMF to support NDA filing by GSK

V. Cost Estimate

Below is an estimate of the hours required to complete the Eurand Development Activities as outlined in this Proposal (hours for the stability monitoring of the registration stability batches are not included, and this will be provided upon approval of a registration stability matrixing protocol by GSK). Actual hours required to complete the work may be higher or lower based on issues or delays that are difficult to anticipate at this time. Eurand will provide monthly invoices for the actual hours utilized on the program. Additional costs will be incurred for project specific raw materials, consumables, equipment and/or tooling.

Stage	Hour Estimate
1. Formulation Feasibility (5 prototypes)	2,600
2. Pilot CTM Supply (4 batches)	3,000
3. Pivotal CTM and Registration batches (4 compression blends)	2,200
Total	**7,800**

Table 6: Estimated Development Costs

VI. Items Requested from GSK

- Analytical methods including the method for equipment cleaning and cleaning verification, preformulation report, and forced degradation study report, if available
- API:
  - 50 kg for feasibility formulation development and manufacture of prototypes (from three different lots of lamotrigine)
  - Approximately 400-500 kg for pilot CTM manufacture
  - Approximately 1,000-1,200 kg for pivotal CTM and manufacture of registration batches
  - Packaging material/configuration recommendations

EXHIBIT E

KEY TERMS FOR CLINICAL SUPPLY AGREEMENT

1. Provisioning and Use of Drug Substance:

For the purposes of manufacturing the CTM supplies under stage II of the Proposal, GSK shall provide Eurand with four hundred to five hundred (400-500) kg of Drug Substance. For the purposes of manufacturing the CTM supplies under stage III of the Proposal, GSK shall provide Eurand with one thousand to twelve hundred (1,000-1,200) kg of Drug Substance. As Drug Substance quantities from GSK are limited, the Parties shall agree to GSK's provisioning of additional quantities of Drug Substance to Eurand on an as needed basis.

Eurand shall store all Drug Substance in accordance with cGMP and all Applicable Laws. Eurand shall closely monitor and report its use of the Drug Substance and have responsibility for any excessive loss or waste while such Drug Substance is in its possession with the exception of Commercially Reasonable process-related yield losses.

2. Testing and Rejection of CTM:

Each shipment of CTM shall be sampled and analyzed by Eurand to determine if the shipment meets the CTM Specifications. Eurand shall deliver to GSK with each such shipment of the CTM a certificate of analysis stating that the CTM, when shipped, meets the CTM Specifications and has been manufactured in accordance with cGMP.

GSK may conduct its own analyses on each shipment of the CTM. GSK shall notify Eurand within ten (10) Business Days after delivery of such CTM if there are shortages, or within thirty (30) days if the same does not meet the Specifications or terms and conditions of this Agreement, or is considered to be adulterated or misbranded within the meaning of the Act. Unless GSK advises Eurand that a shipment of CTM is unsatisfactory within thirty (30) Business Days of its receipt, such shipment shall be deemed to have been accepted by GSK.

Any lawsuit or other action based upon breach of this Clinical Supply Agreement or upon any other claim arising out of an order or acceptance must be commenced within one year from the date of the tender of delivery by Eurand or, in the case of a cause of action based upon an alleged breach of warranty, within one year from the date within the warranty period on which the defect is or should have been discovered by GSK. This limitation shall not apply to latent bulk Product defects.

3. Rejection of CTM:

Any dispute arising between Eurand and GSK concerning the acceptability of any shipment of CTM shall be settled in accordance with Section 5.6 of the Agreement.

Eurand shall replace, at Eurand's expense, any CTM delivered hereunder that is rejected in good faith as unsatisfactory by GSK and agreed to by Eurand.

4. Release of CTM:

Eurand shall retain sole responsibility for releasing the CTM to GSK, or to the clinical sites if required by GSK. GSK will also retain rights to release CTM to clinical sites rather than request that such release be done by Eurand.

5. Shipment and Delivery:

All CTM shall be shipped EXW (as such term is defined in INCOTERMS, 2000) from Eurand's manufacturing facility currently located in Vandalia, Ohio, at GSK's expense via a carrier identified by GSK. Delivery of any CTM shall occur when the CTM is delivered to a carrier identified by GSK. Title and risk of loss of such quantities of the CTM shall pass to GSK upon delivery of such material to such common carrier. GSK shall be responsible for freight and insurance charges.

6. Pricing:

All CTM shall be provided to GSK at no cost. The Parties acknowledge and agree that the cost of any CTM is included in the rate set forth in Section 8.1.2.

7. Capacity

Eurand shall ensure that it and its suppliers have adequate capacity at all times to fulfill GSK's CTM requirements within the agreed lead time.

8. Approvals:

The manufacturing facility, materials, specifications, processes, storage facilities and transport utilized by Eurand for the CTM shall be approved in advance by GSK, such approval to not be unreasonably withheld and any such delay shall not be the basis for a delay in achievement of any applicable Milestone Payment under Section 8.2 of the Agreement and Eurand shall not make any material changes that directly relate to the CTM without GSK's prior approval via a change control procedure set forth in the quality agreement to be entered into by the Parties.

No capital expenditures for which GSK has financial responsibility or which will form any portion of the CTM costs will be made by Eurand to support the development or manufacture of CTM without GSK's prior, written approval.

The manufacturing facility, processes, storage facility and transport will comply with all relevant and applicable standards, including cGMPs, and Applicable Laws; and Eurand will permit FDA (or other regulatory agency) and appropriate GSK inspections of any facilities in which CTM is produced.

9. Inspection:

GSK shall have the right to undertake all Commercially Reasonable inspections, tests and batch sampling relating to CTM, and subject to Commercially Reasonable notice to Eurand.

10. Quality Agreement:

As an appendix to the Clinical Supply Agreement, the Parties will ensure that a quality agreement, which will govern any quality and regulatory issues, is in place between GSK and Eurand.

11. Force Majeure:

The Force Majeure provisions of Section 14.13 of the Agreement shall apply to the Clinical Supply Agreement. However, for the avoidance of doubt, any failure by Eurand to deliver CTM or to meet any obligation under the Clinical Supply Agreement due to an order, injunction or other action by a Regulatory Authority which is specific to Eurand and not an industry wide requirement change will not constitute a Force Majeure Event.

12. Certain Limitations:

EXCLUDING A PARTY'S INDEMNIFICATION OBLIGATIONS TO THIRD PARTIES, IN NO EVENT, SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES ARISING OUT OF, OR AS THE RESULT OF, THE SALE, DELIVERY, NON-DELIVERY, SERVICING, USE OR LOSS OF USE OF ANY CTM OR PRODUCT, REGARDLESS OF WHETHER SUCH CLAIM IS BASED UPON BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER LEGAL THEORY.

EXHIBIT F

KEY TERMS FOR COMMERCIAL SUPPLY AGREEMENT

1. Scope:

- GSK will engage Eurand to exclusively manufacture GSK's total requirement for bulk tablets of Product in the Territory.

- The Parties shall negotiate the circumstances under which Eurand shall lose such exclusive manufacturing rights and such rights shall be returned to GSK for its use or the use of GSK's Third Party contract manufacturer. Those circumstances include:
  - insolvency or bankruptcy of Eurand;
  - failure of Eurand to supply Product which shall be defined as per Section 22 below;
  - repeated quality failures of Product provided by Eurand; and
  - Merger of Eurand (to a Competing Business Entity, and Eurand elects not to divest or cause the divestiture of the Competitive Product marketed by the Competing Business Entity)

- Upon termination of Eurand's right to manufacture Product, Eurand shall assist GSK in completing a non-exclusive technology transfer to GSK or its Third Party contract manufacturer the cost of which shall be negotiated by the Parties, with the exception of a Merger of Eurand in which case the cost shall be at at Eurand's sole cost and expense. Eurand will continue to supply Product until such technology transfer is, in GSK's reasonable judgment, complete. Such technology transfer shall be performed under appropriate confidentiality agreements which protect Eurand's Intellectual Property Rights. GSK or its Third Party contract manufacturer will be provided an exclusive, worldwide, royalty free, paid up license under the Eurand Intellectual Property to make and have made Product to the extent that Eurand is unable to perform its supply obligations.

2. Volumes and Commitments:

- GSK will provide both a two (2) year high level forecast and a twelve (12) month rolling forecast. This twelve (12) month forecast will be updated on a monthly basis. The first three (3) months of the twelve (12) month forecast will be binding and fixed by a GSK firm order schedule. Except for the first three (3) months of each twelve (12) month forecast, the forecasts are not commitments and are for information purposes only; commitments shall be made by GSK pursuant to the firm order schedule. Nevertheless, GSK shall use Commercially Reasonable Efforts to make such forecasts as accurate as possible.

3. Capacity:

- Eurand shall ensure that it (and its GSK approved suppliers) have adequate capacity at all times to fulfill one hundred and twenty five percent (125%) of GSK's firm order(s) within the agreed lead time. Eurand shall make Commercially Reasonable Efforts to accept that portion of GSK's firm orders that exceed the one hundred and twenty five percent (125%) limit.

4. Risk Mitigation Plan:

- Eurand agrees to develop in conjunction with GSK a risk mitigation plan to ensure its ability to provide GSK's total requirements for Product. Such plans may include but not be limited to:
    - Identification and regulatory qualification of at least one alternative manufacturing site; and
    - Identification and regulatory qualification of alternative sources of any necessary Product materials suppliers.

5. Term:

- The term of the Commercial Supply Agreement shall be for the same period of time as the Term of the Development and License Agreement.

6. Notice of Termination and Supply:

- In the event of termination, Eurand shall supply all forecasted Product through the end of the notice of termination period; provided, however, and notwithstanding the foregoing, in the event of termination by Eurand, Eurand will continue to supply Product to GSK pursuant to the terms of the Commercial Supply Agreement and to perform a technology transfer from Eurand to GSK until such time as GSK has in place a robust supply alternative to Eurand.

7. Cost of Goods:

- Launch stock and commercial supply of bulk tablets of Product shall be provided to GSK at a negotiated, volume-based, fixed transfer price.
- Such initial fixed transfer price shall not exceed $0.16 per unit of bulk tablet of Product (not including the cost of the Drug Substance).
- Any adjustments to the transfer price shall be mutually agreed by the Parties and shall only reflect actual changes in Eurand's direct manufacturing cost.

8. Approvals:

All manufacturing facilities, suppliers, materials, specifications, processes, storage facilities and transport utilized by Eurand will comply with all relevant and applicable standards, including cGMPs, Applicable Laws, and the NDA for the Product and any modifications shall be approved in advance by GSK and shall not be modified without GSK's prior approval via a change control procedure set forth in the quality agreement to be entered into by the Parties, which approvals shall not be unreasonably withheld or delayed.

- No capital expenditures for which GSK has any financial responsibility or which will form any portion of the Product costs will be made by Eurand to support the development or manufacture of Product without GSK's prior written approval.
- Eurand will permit FDA (or other regulatory agency) and appropriate GSK inspections of any facilities in which the bulk Product is produced. GSK inspections may also include testing and batch sampling.
- Eurand will permit a 'for cause' audit outside any per calendar year limitation of scheduled audits. Where the audit request arises from regulatory action, any notice period notification requirement shall be waived if this is necessary to provide a timely response to proposed regulatory action.
- Eurand shall ensure excipients and all other materials used in the manufacturing meet the agreed specifications.

9. Identity Testing:

- Following delivery of Drug Substance and prior to its use in manufacture, Eurand shall conduct identity tests and all other tests required to determine compliance with the Drug Substance Specification.

10. Supply Chain Optimization:

- Eurand and GSK will work together to identify, develop and implement a commercially effective supply chain for manufacture and supply of Product.

11. Yield For Drug Substance:

- Using development, full scale and validation batches, GSK and Eurand will agree on the specifications for batch yield along with an acceptable annual yield for batches manufactured by Eurand. GSK shall provide Eurand with its direct cost per kilogram for the Drug Substance. Additionally, after Eurand has supplied the Product to GSK for the earlier of (i) a period of twelve (12) months, or (ii) for such time as GSK has received a defined number of batches of Product, the Parties shall mutually agree upon an acceptable yield loss for the Drug Substance used in manufacturing the Product, and Eurand shall be responsible for the cost of Drug Substance used in excess of that required to meet the agreed upon maximum yield loss, in the event that such yields are not met thereafter on an annual basis.

12. Batch Failures:

- GSK shall pay for batches of Product for which final disposition has been determined that they meet the Product Specifications, have been manufactured in accordance with cGMP, registered manufacturing process and controls, and other Applicable Laws, delivered in accordance with the requirements of the GSK firm order and terms of the Commercial Supply Agreement.

13. Contingency Stock Holding:

- Eurand shall maintain a contingency stock holding at levels of Product agreed with GSK, sufficient to ensure continuous supply of Product to GSK. GSK shall pay Eurand the agreed upon transfer price for the contingency stock upon shipment of the stock to GSK. However, GSK payment for a specific level of contingency stock shall not relieve Eurand of its obligation to supply agreed levels of Product in accordance with the binding forecast period.

14. Rejection:

- GSK shall have the right to reject Product for which final disposition has been determined that they do not meet the Product Specifications, has not been manufactured in accordance with cGMP, registered manufacturing process and controls and does not comply in quantity or quality with the GSK firm order or other terms of the Commercial Supply Agreement.
- Replacement Product shall be provided from contingency stock holding within forty-eight (48) hours of GSK's rejection.
- Any lawsuit or other action based upon breach of this Commercial Supply Agreement or upon any other claim arising out of an order or acceptance must be commenced within one year from the date of the tender of delivery by Eurand or, in the case of a cause of action based upon an alleged breach of warranty, within one year from the date within the warranty period on which the defect is or should have been discovered by GSK. This limitation shall not apply to any latent defects.

15 Title:

- Delivery shall be complete and title to the Product shall transfer to GSK EXW (as such term is defined in INCOTERMS 2000) Eurand's manufacturing facility to a carrier identified by GSK. The transfer of title shall not release Eurand from any of its rights and responsibilities under the Commercial Supply Agreement.

16. Payment:

- GSK shall pay Eurand within thirty (30) Business Days from receipt in full of the order, subject to all specifications in the firm order, and a corresponding invoice.

17. Key Performance Indicators:

- GSK and Eurand shall agree upon performance indicators to ensure its compliance with the terms of the Commercial Supply Agreement and its commitment to continuity of supply for GSK Product.

18. Insurance:

- GSK and Eurand shall agree upon Commercially Reasonable insurance provisions that adequately protect the other Party against risks related to the first Party's performance under the Commercial Supply Agreement.

19. Assignment:

- Eurand shall not at any time assign or sub-contract any of its rights, or obligations whatsoever in the Commercial Supply Agreement to any Third Party without the prior written consent of GSK, such consent to not be unreasonably withheld.

20. Quality Agreement:

- As an appendix to the Commercial Supply Agreement, the Parties will ensure that a quality agreement, which will govern any quality and regulatory issues, is in place between GSK and Eurand.

21. Continuous Improvement Program:

- Eurand shall be responsible for continuous improvement for commercial supply of Product. The allocation of benefits from any cost reduction shall be the subject of negotiation between the Parties.

22. Failure to Supply Provisions:

- Eurand's failure to supply shall be defined in the Commercial Supply Agreement to be a failure on Eurand's part to deliver at least seventy five percent (75%) of GSK's order volume (based on GSK ordering no more than one hundred percent (100%) of the volumes set forth in a binding forecast period) over a three (3) month period provided that GSK has provided sufficient Drug Substance to Eurand.

- Eurand and GSK agree to include additional failure to supply provisions in the Commercial Supply Agreement which include but are not limited to specific payment remedies for failure to supply and allocation of costs penalties for late deliveries.

23. Provisioning of Drug Substance:

- GSK shall provide Drug Substance to Eurand to allow manufacture of GSK's Product requirements. The Parties shall agree on a forecast process where GSK provides a Product forecast to Eurand. Upon receipt Eurand shall within a reasonable period provide a Drug Substance forecast to GSK setting forth the amount of Drug Substance required to fulfill the Product forecast.

- GSK shall retain title to the Drug Substance, however, Eurand shall assume risk of loss and damage for all Drug Substance in its possession. All Drug Substance shall be stored in accordance with cGMP and other regulatory requirements.

- Drug Substance may only be used by Eurand for the manufacturing of Product.

24. Environmental Health and Safety:

- Eurand shall comply with all EHS Applicable Laws, obtain and maintain all licenses and permits required by EHS Applicable Laws.

- Eurand agrees to be responsible for:

    - ensuring that all EHS and loss prevention issues are handled by qualified EHS Professionals;

    - providing safe plant and equipment and managing the work in a safe and environmentally conscious manner (taking into account all EHS and loss prevention risks);

    - making appropriate provisions to minimize risk of explosions, fires, and large scale releases of hazardous materials arising from chemical processes, bulk storage facilities or utilities;

    - ensuring safety of all persons involved in the handling of and exposure to GSK products, (including visitors); ensuring that all appropriate information/instruction/specific training (as required by a hazard risk assessment) is received by all affected employees before starting work on the bulk Product; and ensuring all appropriate controls are in place; and

    - ensuring all waste generated in the manufacture or packing of the bulk Product is disposed of in accordance with applicable laws and GSK requirements for waste disposal.

25. Force Majeure:

The Force Majeure provisions of Section 14.13 of the Agreement shall apply to the Commercial Supply Agreement. However for the avoidance of doubt, any failure by Eurand to deliver Product or to meet any obligation under the Commercial Supply Agreement due to an order, injunction or other action by a Regulatory Authority which is specific to Eurand and not an industry wide requirement change will not constitute a Force Majeure Event.

26. Certain Limitations:

EXCLUDING A PARTY'S INDEMNIFICATION OBLIGATIONS TO THIRD PARTIES OR RECALL EVENTS, IN NO EVENT, SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES ARISING OUT OF, OR AS THE RESULT OF, THE SALE, DELIVERY, NON-DELIVERY, SERVICING, USE OR LOSS OF USE OF ANY CTM OR PRODUCT, REGARDLESS OF WHETHER SUCH CLAIM IS BASED UPON BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER LEGAL THEORY.

EXHIBIT G

1. Opposition by Teijin Pharma of March 9, 2006 against Kyowa's European Patent 0914818B1.

2. Opposition by Unidentified Opposed of March 7, 2006 against Kyowa's European Patent 0914818B1.