18-04621-E

Julia Justusson
ktMINE
940 West Adams
Suite 100
Chicago, IL 60607

6/7/2018

U.S. Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE
Mail Stop 2465
Washington, DC 20549-5100

Dear Sir or Madam:

Under the Freedom of Information Act (FOIA), please send the confidential portions (i.e. unredacted documents) corresponding to the expiration of the Confidential Treatment Order submitted under Rule 24b-2 of the following company:

Exhibit 4.67 to the form 20-F filed by Amarin Corporation plc\UK on May 19, 2008.

We authorize $0 for search and review fees, as these documents have been previously requested. Please contact me if search will require additional fees beyond the above mentioned. I can be reached via email at julia.justusson@ktmine.com.

Sincerely,

Julia Justusson

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

Office of FOIA Services

July 5, 2018

Ms. Julia Justusson
ktMINE
940 West Adams
Suite 100
Chicago, IL 60607

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-04621-E

Dear Ms. Justusson:

This letter is in response to your request, dated and received in this office on June 7, 2018, for a copy of Exhibit 4.67 to the Form 20-F filed by Amarin Corporation plc\UK on May 19, 2008.

The search for responsive records has resulted in the retrieval of the enclosed 59 pages which are being released in their entirety. Because this exhibit was released in response to a previous FOIA request, no chargeable processing fees were incurred.

If you have any questions, please contact me at morrowa@sec.gov or (202) 551-8376. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Jeffery Ovall 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,

Alysia Morrow

Alysia Morrow
FOIA Research Specialist

4.67

Execution Copy

ELAN PHARMA INTERNATIONAL LIMITED

AND

AMARIN PHARMACEUTICALS IRELAND LIMITED

DEVELOPMENT AND LICENSE AGREEMENT

INDEX

THIS AGREEMENT is dated March 6, 2007

PARTIES:

(1) **ELAN PHARMA INTERNATIONAL LIMITED,** a limited liability company incorporated under the laws of Ireland, having its registered office at Monksland, Athlone, Co. Westmeath, Ireland ("**Elan**"); and

(2) **AMARIN PHARMACEUTICALS IRELAND LIMTED**, a limited liability company incorporated under the laws of Ireland, having its principal place of business at First Floor, Block 3, the Oval, Shelbourne Road, Ballsbridge, Dublin 4, Ireland ("**Amarin**").

BACKGROUND:

(A) Elan possesses certain proprietary small particle technology as well as proprietary know-how and confidential information used or useful in the manufacture and use of products containing nanoparticles.

(B) Amarin has certain expertise relating to the Compound (as defined below).

(C) Amarin wishes to enter into this Agreement to obtain the right to utilize the Elan Intellectual Property (as defined below) to import, use, offer for sale and sell the Product in the Field in the Territory, and to have Elan develop the Product Intermediate for Amarin, in accordance with the terms and conditions set out below.

TERMS:

The parties agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1. Definitions. In this Agreement:

"**Affiliate**" means any corporation or entity controlling, controlled or under common control with Elan or Amarin, as the case may be. For the purposes of this Agreement, "control" means the direct or indirect ownership of more than 50% of the issued voting shares or other voting rights of the subject entity to elect directors, or if not meeting the preceding criteria, any entity owned or controlled by or owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

"**Agreement**" means this development and license agreement (which expression shall be deemed to include its Recitals and Schedules).

"**Amarin Compound Data**" means data relating to the Compound, Product Intermediate or Product generated pursuant to this Agreement as follows: (i) all data from any Phase I, Phase II, Phase III and/or Phase IV study conducted by Amarin in relation to the Compound, Product Intermediate or Product during the Term; (ii) all data from any pre-clinical study conducted by Amarin in relation to the Compound, Product Intermediate or Product during the Term; and (iii) all data generated by Amarin arising out of the incorporation of the Product Intermediate into the Product. For the avoidance of doubt, Amarin Compound Data does not include any

data generated from formulation development activities related to the Compound, Product Intermediate or Product using Elan Intellectual Property.

"**Amarin Improvements**" means (i) any and all rights in respect of improvements or inventions pertaining to the Compound, of which, as of the Effective Date, there are none, that may be conceived, created, developed and/or otherwise invented solely by Amarin outside the R&D Program pursuant to this Agreement; (ii) any and all rights in respect of improvements or inventions pertaining to a Device and which, as of the Effective Date, there are none, that may be conceived, created, developed and/or otherwise solely invented by Amarin or on behalf of Amarin and (iii) Amarin's interest in the [[Joint Compound Improvements]].

"**Amarin Intellectual Property**" means the Amarin Know-How, Amarin Improvements and the Amarin Patents, of which, as of the Effective Date, there are none.

"**Amarin Know-How**" means any and all rights, of which, as of the Effective Date, there is none, which Amarin may own, license or control (otherwise than pursuant to this Agreement) to any scientific, pharmaceutical or technical information, data, discovery, invention (whether patentable or not), know-how, substances, techniques, processes, systems, formulations and designs and expertise relating to the Compound or Device used to administer the Product which is not generally known to the public.

"**Amarin Patents**" means any and all Patent Rights, of which, as of the Effective Date, there are none, which Amarin may hereafter file or acquire or license relating to the Compound, the Device used to administer the Product or the Product (other than the Elan Patents or Elan Improvements licensed under this Agreement or any patents arising out of [[Joint Compound Improvements]]).

"**Amarin Trademark**" means Amarin's rights to use such trademark(s) as Amarin may from time to time reasonably specify.

"**Buccal Formulation**" means formulations of Product Intermediate for administration by placing in the mouth for absorption through the cheek, the gum or the upper or lower inside lip without swallowing, achieved by means of a muco adhesive, including but not limited to any specific formulation that may be selected for commercialization.

"**Business Days**" means Monday to Friday inclusive, excluding any days on which the clearing banks are generally closed in Dublin and/or New York.

"**cGMP**", "**cGLP**" and "**cGCP**" respectively mean current Good Manufacturing Practice, current Good Laboratory Practice and current Good Clinical Practice, as defined in the US Federal Food, Drug and Cosmetic Act of 1934, and the regulations promulgated thereunder, as may be amended from time to time, and, where applicable, the equivalent regulations and requirements imposed by other Governmental Authorities in the Territory.

"**Claims**" means all and any claims (whether successful or otherwise), loss, liability, damages and expenses, including reasonable attorneys' fees and expenses and legal costs.

"**CMC Section**" means the chemistry, manufacturing, and controls section of the Regulatory Application in the United States as defined in 21 Code of Federal Regulations Section 314.50 (1), as may be amended from time to time, and/or its equivalent in other Regulatory Applications.

"**Compound**" means the active drug substance lorazepam (7-chloro-5-(2-chlorophenyl)-3-hydroxy-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one) including all salts, esters, complexes, chelates, hydrates, isomers, stereoisomers, crystalline forms, amorphous forms, prodrugs

(including all compounds that are metabolized or dissolve into the same active moiety in the body), solvates, metabolites/metabolic precursors, and pegylated form thereof.

"**Device**" shall mean any instrument, apparatus, appliance, material or other article (including software) that will be used to administer or that otherwise utilizes or applies the Product, Product Intermediate or a derivative thereof.

"**DMF**" means the Drug Master File, as defined in the United States in 21 Code of Federal Regulations, Section 314.420 and/or its equivalent in the other countries of the Territory, which Elan may file in respect of the Elan Technology and (at Elan's sole option) the application of the Elan Technology as regards the Product.

"**EEA**" means the Member States of the European Economic Area, as same may change from time to time in terms of Member States.

"**Effective Date**" means the date of this Agreement.

"**Elan Compound Data**" means data relating to the Compound, Product Intermediate, or Product generated by Elan pursuant to this Agreement (which includes but is not limited to the R&D Program) or the Manufacturing Agreement, including but not limited to data relating to chemistry, manufacturing and controls in support of any Compound formulation(s) generated during the R&D Program, including the Product Intermediate, but excluding the Amarin Compound Data.

"**Elan's Facility**" shall mean Elan facility for manufacture of commercial supplies of Product Intermediate, as such will be defined in the Manufacturing Agreement.

"**Elan Improvements**" means (i) the Product Patents and any and all improvements to the Elan Patents, the Elan Know-How and/or the Elan Technology and/or the Product and/or the Product Intermediate that have been conceived, created, developed and/or otherwise invented by Elan and/or Amarin under the R&D Program, or otherwise pursuant to this Agreement, (ii) any and all rights in respect of improvements or inventions pertaining to the Device and which, as of the Effective Date, there are none, that may be conceived, created, developed and/or otherwise solely invented by Elan pursuant this Agreement and (iii) any and all rights in respect of improvements or inventions pertaining to the Compound conceived, created, developed and/or otherwise invented solely by Elan under the R&D Program (excluding [[Joint Compound Improvements]]) or otherwise.

"**Elan Intellectual Property**" means the Elan Know-How, the Elan Patents, the Elan Improvements and Elan's interest in the [[Joint Compound Improvements]].

"**Elan Know-How**" means any and all rights owned by Elan as of the Effective Date to any scientific, pharmaceutical or technical information, data, discovery, invention (whether patentable or not), know-how, substances, techniques, processes, systems, formulations, designs and expertise relating to the Elan Technology which is not generally known to the public.

"**Elan Patents**" means any and all Patent Rights, now existing, currently pending or hereafter filed by Elan relating to the Elan Technology and the Product Intermediate (other than [[Joint Compound Improvements]]), as set forth in Schedule 1, together with any other patents that may be filed by Elan in relation to the Product Intermediate (other than [[Joint Compound Improvements]]) and any additional Elan Patents that may need to be licensed to Amarin in the event that Amarin exercises the option set out in Clause 2.4.

"**Elan Technology**" means Elan's proprietary technology directed to nanoparticulate dispersions of compounds stabilized against agglomeration of the nanoparticles and methods and equipment used for making such dispersions and characterizing such dispersions, as more fully described in the Elan Patents and applied in the Elan Know-How.

"**Elan Trademark**" means Elan's trademark "NanoCrystal®", or such other trade marks as Elan may from time to time reasonably specify.

"**EU**" means the Member States of the European Union, as same may change from time to time in terms of Member States.

"**EU Major Markets**" means the United Kingdom, France, Germany, Italy and Spain, and an "**EU Major Market**" means any of them.

"**EXW**" (ex works) has the same meaning as in the ICC Incoterms 2000, International Rules for the Interpretation of Trade terms, ICC Publication No. 560.

"**Ex-US Net Revenues**" means:

(i) all royalties received by Amarin or an Affiliate of Amarin pursuant to a Sub-License Agreement in respect of sales of the Product by a sub-licensee made outside the United States;

(ii) all upfront payments and milestone payments received by Amarin or an Affiliate of Amarin in respect of the Product pursuant to a Sub-License Agreement which upfront payments and milestone payments relate to countries or territories outside the United States.

(iii) any other consideration received by Amarin and/or any Amarin Affiliate in respect of the Product arising from a Sub-License Agreement that applies outside the United States, provided that this shall not include any bona fide consideration which Amarin or an Amarin Affiliate receives for any pre-clinical, clinical or regulatory work undertaken by Amarin for the purpose of regulatory approval or marketing purposes in the country/countries to which the Sub-License Agreement applies.

"**FDA**" means the United States Food and Drug Administration or any other successor agency whose approval is necessary to market the Product in the United States.

"**Field**" means the use as a prescription or over-the-counter pharmaceutical product in humans, specifically excluding diagnostic use.

"**Force Majeure**" means any cause or condition beyond the reasonable control of the party obliged to perform, including acts of God, acts of government (in particular with respect to the refusal to issue necessary import or export licenses), fire, flood, earthquake, war, riots or embargoes or strikes affecting a party, or the failure of the Compound, other materials or Product Intermediate to meet applicable specifications for reasons that cannot be determined or rectified and that are not attributable to the negligent acts or omissions of the party obliged to perform under this Agreement or to a breach of an obligation by the performing party under this Agreement.

"**Generic Competition**" means the commercial sale by a third party of a product which is AB-Rateable to the Product in the applicable country.

"**Governmental Authority**" means all governmental and regulatory bodies, agencies, departments or entities, whether or not located in the Territory, which regulate, direct or control commercial and other related activities in or with the Territory.

"**IND**" means Investigational New Drug Application in the United States as set forth in the 21 Code of Federal Regulations Section 312 and/or its equivalent in the other countries of the Territory.

"**Infringement Claim Fees**" means the following court ordered costs or court ordered settlements incurred in defending or otherwise managing an Infringement Claim: (i) a party's reasonable costs and expenses (including attorneys' fees), (ii) damages or costs awarded against either party, and (iii) other payments that a party may be ordered to pay a third party in order to secure the right to continue the commercialization of the Product.

"**In Market**" means the sale of the Product in the Territory by Amarin, or where applicable, by an Amarin Affiliate, a permitted sub-licensee or a distributor, to an unaffiliated third party, such as a wholesaler, managed care organisation, hospital or pharmacy which effects the final commercial sale to the end user of the Product and shall exclude the transfer pricing of the Product by one Amarin Affiliate to another Amarin Affiliate, a permitted sub-licensee or a distributor.

"[**[Joint Compound Improvements]**" means and any and all rights, including Patent Rights, in respect of improvements or inventions solely applicable to the Compound jointly conceived, created, developed and/or otherwise invented by Elan and Amarin under the R&D Program.]

"**Manufacturing Agreement**" means the future agreement referred to in Clause 9.

"**Manufacturing Cost**" shall mean the costs described in Schedule 4.

"**Manufacturing Royalty**" shall mean a royalty of 8% of Worldwide Net Sales, which shall be payable by Amarin to Elan under Clause 10.4 during any period when Elan manufactures the Product Intermediate under the terms of this Agreement.

"**NDA**" means a New Drug Application filed with the FDA, including any supplements or amendments thereto which may be filed.

"**Net Sales**" shall, subject to the provisions of Clause 10.6, mean in the case of Product sold by Amarin, an Affiliate of Amarin, a permitted sub-licensee or a distributor in the circumstances set out in Clauses 10.4.1 and 10.4.2 only, the aggregate gross In Market sales proceeds billed for the Product by Amarin, an Affiliate of Amarin, a permitted sub-licensee or a distributor in the circumstances set forth in Clauses 10.4.1 and 10.4.2 only, in accordance with generally accepted accounting principles as adopted by Amarin, less the following deductions:

(i) trade, cash or quantity discounts, allowances, adjustments and rejections;

(ii) rebates, recalls (other than where the Product is replaced without charge) and returns;

(iii) price reductions or rebates imposed by Governmental Authorities;

(iv) sales, excise, turnover, inventory, value-added and similar taxes assessed on the royalty-bearing sale of such Product, but not including any taxes on income paid by or assessed against Amarin or a permitted sub-licensee;

(v) transportation, importation, shipping, insurance and other handling expenses directly chargeable to the royalty-bearing sale of the Product, but only to the extent that such expenses are separately delineated in the applicable invoices; and

(vi) credits, chargebacks, prime vendor rebates, reimbursements and similar payments granted to drug wholesalers or their customers in cases where there are not direct shipments to such customers by Amarin or its permitted sublicense.

Any discretionary rebates, discounts or adjustments shall be commercially reasonable and consistent with standard industry practices.

"**Notional NSP**" shall mean the estimated NSP of Product at the applicable time, which shall on a country by country basis be provided by Amarin to Elan within ninety (90) days prior to commencement of each calendar year (or, for the launch year in any country, within ninety (90) days prior to the estimated date of first commercial sale in such country); provided that:

(a) for (i) the launch year and (ii) if no Statement is due to be produced prior to ninety (90) days of the estimated first commercial sale in such country, the Notional NSP shall be estimated in good faith; and

(b) in each subsequent year, Notional NSP shall be calculated by reference to the average NSP in that country as evidenced by the last four Statements (or such lesser number of Statements as have actually been produced in relation to that country);

"**NSP**" shall mean the Worldwide Net Sales divided the number of units of Product sold for the given period.

"**Other Compound**" means diazepam (7-chloro-1-methyl-5-phenyl-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one). including all salts, esters, complexes, chelates, hydrates, isomers, stereoisomers, crystalline forms, amorphous forms, prodrugs (including all compounds that are metabolized or dissolve into the same active moiety in the body), solvates, metabolites/metabolic precursors, and pegylated form thereof.

"**Patent Rights**" means any and all rights under any and all patent applications and/or issued or granted patents, now existing, currently pending or hereafter filed, including, but not limited to, provisional applications, substitutions, divisionals, continuations, continuations-in-part, renewals and any foreign counterparts thereof or equivalents thereto, including the right to claim priority from any of the foregoing under the Paris Convention, and all patents issuing or granted on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, re-examinations, supplemental protection certificates, or extensions thereof, and any foreign counterparts thereof, or any other government-issued rights substantially equivalent to the foregoing.

"**Phase I**" means a human clinical trial of a Product, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, including the trials referred to in 21 Code of Federal Regulations. §312.21(a), as amended.

"**Phase II**" means a human clinical trial of a Product, the principal purpose of which is a determination of safety and efficacy in the target patient population or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, including the trials referred to in 21 Code of Federal Regulations §312.21(b), as amended.

"**Phase III Studies**" means a human clinical trial of the Product that is designed to establish that such Product is safe and efficacious for its intended use, and which trial is intended to support marketing approval of such Product in any country or countries, and "**Phase III Study**" means any one such study.

"**Phase IV**" means a human clinical trial of a Product that is not included in the original NDA submission for such Product, but is required to obtain or maintain the approval by the FDA of the NDA for such Product, including studies conducted to fulfill commitments made as a condition of NDA approval or any subsequent human clinical trials requested or required by the FDA as a condition of maintaining such approval or which are desirable for the purposes of marketing or otherwise.

"**Primary Territory**" means the United States, Canada, Mexico, Japan, the countries of the European Union, Australia and New Zealand.

"**Product**" means, subject to Clause 2.4, the nasal formulation of Product Intermediate incorporated or filled into a Device.

"**Product Intermediate**" shall mean non-sterile formulations of the Compound (or Other Compound, if applicable and subject to Clause 2.4) as the sole active ingredient that incorporates Elan Technology, including but not limited to the specific formulation that is selected for use in the Product.

"**Product Patents**" means any and all Patent Rights relating to any formulation of the Compound (or Other Compound, if applicable and subject to Clause 2.4) incorporating the Elan Technology, including the composition of any formulations and methods of formulating the Compound using the Elan Technology.

"**Prosecute**" means in relation to a class of intellectual property:

(a) to secure the grant of any patent application within such class;

(b) to file and prosecute patent applications on patentable inventions and discoveries relating to that class;

(c) to defend all such applications against third party oppositions; and

(d) to maintain in force any issued letters patent relating to the same

and "**Prosecution**" has a corresponding meaning.

"**R&D Program**" means the research and development program set forth in Schedule 2, as it may be amended by agreement of the parties from time to time, including but not limited to any work agreed by the parties under the R&D Program pursuant to a workplan.

"**Regulatory Application**" means any regulatory application or any other application for marketing approval for the Product, which Amarin will file in the Territory hereunder, including any supplements or amendments thereto which Amarin may file.

"**Regulatory Approval**" means the final approval to market the Product hereunder in any country of the Territory, including pricing and reimbursement approval and any other approval which is required to launch the Product in the normal course of business.

"**Secondary Territory**" means the Territory other than the Primary Territory.

"**Sub-License Agreement**" means any sub-license agreement or distribution agreement entered into by Amarin with a third party sub-licensee or distributor in reference to this Agreement whereby the third party is granted the right to offer for sale and sell the Product in the Territory.

"**Sublingual Formulation**" means formulations of Product Intermediate for administration by placing in the mouth under the tongue without swallowing, including but not limited to any specific formulation that may be selected for commercialization.

"**Technological Competitor**" means a person or entity listed in Schedule 3, and divisions, subsidiaries and successors thereof, or any additional broad-based technological competitor of Elan added to such Schedule from time to time by Elan.

PROVIDED THAT Elan may only add to Schedule 3 companies that are "competitors" to Elan and Elan shall remove from such list companies which cease to be competitors. For this definition "competitors" shall mean companies who have or use, other than through a license from Elan, technology that is directed to and / or suitable for providing substantially similar or comparable enhancements to the solubility characteristics of active pharmaceutical ingredients as those provided by the Elan Technology, via any particle size reduction technology approaches, as opposed to chemical solubilization or other approaches. In so far as a third party company is a licensee of Elan Technology they shall only cease to be a Technology Competitor to the extent of the licence. In particular, holding a licence to Elan Technology shall not preclude a company from being a Technological Competitor where that company has or uses other technology that is directed to and / or suitable for providing substantially similar or comparable enhancements to the solubility characteristics of active pharmaceutical ingredients as those provided by the Elan Technology, via any particle size reduction technology approaches, as opposed to chemical solubilization or other approaches.

"**Term**" means the Initial Term and any continuations under Clause 12.2.

"**Territory**" means all of the countries of the world.

"**Third Party Royalties**" means license fees, milestone payments and royalties paid to a Third Party arising from an Infringement Claim that relates to the use of the Elan Patents, Elan Know-How or the Elan Improvements in the Product and Product Intermediate.

"**Valid Patent Claim**" means any claim of an issued (or granted) and unexpired patent included within the Elan Intellectual Property, which has not been held permanently revoked, unenforceable, unpatentable or invalid by a decision of a court or government agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal, and which has not been abandoned, disclaimed, denied or expressly admitted by the holder of the patent or supplementary protection certificate to any person to be invalid or unenforceable through reissue or disclaimer or otherwise.

"**Worldwide Net Sales**" shall, subject to the provisions of Clause 10.6, mean in the case of Product sold by Amarin, an Affiliate of Amarin, any permitted sub-licensee or any distributor, the aggregate gross In Market sales proceeds billed for the Product by Amarin, an Affiliate of Amarin, a permitted sub-licensee or a distributor, in accordance with generally accepted accounting principles as adopted by Amarin, less the following deductions:

(vii) trade, cash or quantity discounts, allowances, adjustments and rejections;

(viii) rebates, recalls (other than where the Product is replaced without charge) and returns;

(ix) price reductions or rebates imposed by Governmental Authorities;

(x) sales, excise, turnover, inventory, value-added and similar taxes assessed on the royalty-bearing sale of such Product, but not including any taxes on income paid by or assessed against Amarin or a permitted sub-licensee;

(xi) transportation, importation, shipping, insurance and other handling expenses directly chargeable to the royalty-bearing sale of the Product, but only to the extent that such expenses are separately delineated in the applicable invoices; and

(xii) credits, chargebacks, prime vendor rebates, reimbursements and similar payments granted to drug wholesalers or their customers in cases where there are not direct shipments to such customers by Amarin or its permitted sublicense.

Any discretionary rebates, discounts or adjustments shall be commercially reasonable and consistent with standard industry practices.

"**$**" and "**US$**" mean United States Dollars.

1.2. Further Definitions. In addition, the following definitions have the meanings in the Clauses corresponding thereto, as set forth below:

Definition	**Clause**
"Acquiring/Successor Entity"	15.15
"Confidential Information"	15.1
"Combination Formulation"	2.4
"Disclosing Party"	15.12
"Due Date"	11.9
"Elan License"	2.1
"Expanded Formulation"	2.4.1
"Infringement Claim"	3.4.1
"Initial Term"	12.1
"License Milestone Payments"	10.1
"Notice"	16.11.1
"Project Team"	6.1
"Relevant Marks"	3.7.4
"Statement"	11.1
"Third Party Site"	9.6
"Trademark Owner"	3.7.4
"Trademark User"	3.7.4

1.3. Interpretation. In this Agreement:

1.3.1 the singular includes the plural and vice versa, and unless the context or subject otherwise requires, references to words in one gender include references to the other genders;

1.3.2 unless the context otherwise requires, reference to a recital, article, paragraph, provision, clause or schedule is to a recital, article, paragraph, provision, clause or schedule of or to this Agreement;

1.3.3 the headings in this Agreement are inserted for convenience only and do not affect its construction; and

1.3.4 the expressions "include", "includes", "including", "in particular" and similar expressions shall be construed without limitation.

2. THE LICENSE

2.1. Elan License to Amarin. Subject to the terms of this Agreement, Elan hereby grants to Amarin for the Term an exclusive license (the "**Elan License**") to the Elan Intellectual Property to import, export, use (other than for formulation development activities), offer for sale and sell the Product in the Field in the Territory. For the avoidance of doubt, nothing in this license grant permits Amarin to make or have made Product Intermediate or to carry out, directly or indirectly (other than through Elan which retains these rights), any formulation development activities with regard to the Compound using the Elan Intellectual Property.

2.2. Elan acknowledges that Amarin may contract with a third party (who is not a Technological Competitor) to further carry out any activities required to fill the Product Intermediate into a Device. Elan agrees to provide such third party with a royalty-free, non-exclusive license to any Elan Intellectual Property limited to the extent necessary for the third party to conduct such activities, subject to the formulation development restrictions set out in Clause 2.1.

2.3. Sub-licensing. Amarin shall be entitled, subject to [the prior written consent of Elan,] to grant sub-licenses in respect of the Elan Intellectual Property to import, export, have imported, have exported, use (other than formulation development activities), offer for sale and sell the Product in the Field in one or more countries of the Territory. Any grant of sub-license shall also be subject to the following conditions:

2.3.1 Amarin shall grant one sub-license only per country except as required by law;

2.3.2 Amarin shall not grant a sub-license to a Technological Competitor, nor in circumstances which cause a material adverse tax consequence to Elan which is not fully compensated for by Amarin;

2.3.3 Amarin shall remain responsible for all payments due to Elan under this Agreement;

2.3.4 Any sub-license granted shall be in the same terms as the terms of this Agreement insofar as they are applicable, mutatis mutandis, but excluding the right to grant a sub-license; provided that the sub-licence need not contain obligations with respect to diligence in marketing and promotion efforts, provided further that nothing herein shall prejudice Amarin's obligations in respect thereof (including in that part of the territory sub-licensed);

2.3.5 Amarin shall use reasonable efforts to obtain for Elan the same rights of audit and inspection vis-à-vis a sub-licensee as Elan has vis-à-vis Amarin pursuant to this Agreement; provided, however, if Amarin does not obtain such rights for Elan with respect to a sub-licensee, Amarin shall obtain such rights for itself with respect to such sub-licensee and shall promptly exercise such rights upon written request of Elan.

2.3.6 Amarin shall be liable to Elan for all acts and omissions of any sub-licensee as though such acts and omissions were by Amarin.

2.3.7 Amarin shall undertake to protect the confidentiality of Elan's formulation, engineering and manufacturing processes for the Product Intermediate and the Product in its dealings with permitted sub-licensees and shall not disclose any information from the CMC Section to any third party, including a permitted sub-licensee, without the prior written consent of Elan.

2.4. Option. In the event that, within 3 (three) years of the commencement of the R&D Program, it is determined by the parties that the Product is not feasible, then Amarin shall have an option, which shall become effective on the date that the parties agree that the Product is not feasible and shall expire sixty (60) days thereafter if the option is not exercised in writing by Amarin before that time, to expand the Elan License to include (i) a Buccal Formulation or a Sublingual Formulation of the Compound in combination with the Elan Technology or, alternatively, (ii) one of any of a nasal formulation or a Buccal Formulation or a Sublingual Formulation of the Other Compound, by written notice to Elan. Upon exercise of such option:

2.4.1 Amarin shall promptly articulate the precise option it wishes to exercise, namely the exact compound and the route of delivery that is to be developed ("**Expanded Formulation**");

2.4.2 this Agreement shall expand and apply as necessary (including but not limited to the expansion of the terms "Compound", "Product Intermediate" and "Product" throughout this Agreement) to include the exact compound and the exact route of delivery of the Expanded Formulation;

2.4.3 subject to the provisions of Clause 10.1, the provisions of this Agreement regarding milestones and royalties shall additionally apply to such Expanded Formulation;

2.4.4 a new Expanded Formulation R&D Program will be determined by the parties through good faith negotiations within 90 days from the date that Amarin notifies Elan that it intends to exercise the option granted under this Clause 2.4;

2.4.5 pricing for development services and for commercial supply of such Expanded Formulation will be determined by the parties through good faith negotiations;

2.4.6 such other changes as shall be agreed by the parties in good faith. For the avoidance of doubt, the parties acknowledge and agree that Elan shall not be required under any circumstances to fund any further aspect of the R&D Program unless it so agrees; and

2.4.7 the parties shall be released from of any further obligation to pursue the development and marketing of a Product Intermediate or Product for nasal use containing the Compound.

Amarin shall also be entitled to service notice on Elan at any time after the Effective Date and prior to the end of the three (3) year option period that it wishes to terminate its option right hereunder. Said notice, once served, shall automatically terminate all parties' rights and obligations in reference to the option set out in this Clause 2.4.

2.5. Secondary Territory. Prior to marketing the Product in any country of the Secondary Territory, Amarin shall notify Elan of its intention to do so, and thereafter Elan may if it considers it necessary to protect its Confidential Information, remove such country from the Territory and the Secondary Territory.

3. INTELLECTUAL PROPERTY

3.1. Ownership of Intellectual Property.

3.1.1 Elan shall remain the owner of the Elan Intellectual Property.

3.1.2 Amarin shall remain the owner of the Amarin Intellectual Property.

3.1.3 Elan and Amarin shall jointly own the [Joint Compound Improvements] and each party shall have an undivided interest in such [Joint Compound Improvements] and may exercise its interests in such [Joint Compound Improvements] (including, subject to Clause 2.1, the right to grant licences) without accounting to the other party except as otherwise specifically provided for herein. To the extent either party or its Affiliates would be deemed to be the sole owner of such [Joint Compound Improvements] under the intellectual property laws of any jurisdiction, such party hereby irrevocably assigns, and shall cause such Affiliate to assign, to the other party an equal undivided interest in such [Joint Compound Improvements].

3.1.4 Elan owns Elan Compound Data.

3.1.5 Amarin owns Amarin Compound Data.

3.1.6 Amarin grants Elan the right to use Amarin Compound Data to Prosecute Elan Patents or Elan Improvements and/or [Joint Compound Improvements].

3.2. Patent Prosecution and Maintenance.

3.2.1 Elan, at its sole discretion and expense, may Prosecute the Elan Intellectual Property in the Territory. Elan and Amarin shall discuss any filing strategy in the Territory for any proposed patent applications (s) relating to the Product, the Product Intermediate and/or [Joint Compound Improvements]. Elan shall inform Amarin of any patent applications relating to the Product, the Product Intermediate and/or [Joint Compound Improvements] filed in the Territory. Elan shall have the first right to Prosecute Product Patents and [Joint Compound Improvements]. Elan shall keep Amarin reasonably informed regarding the prosecution of Product Patents and [Joint Compound Improvements]. Amarin shall treat such information as Confidential Information. Where Elan chooses not to Prosecute any Product Patents or [Joint Compound Improvements] Patent Rights, Elan shall provide written notice to this effect to Amarin. Upon receipt of such notice, Amarin shall have the right at its sole expense to Prosecute the Product Patents or [Joint Compound Improvements] referred to in this notice.

3.2.2 Amarin, at its sole discretion and expense, may Prosecute the Amarin Intellectual Property in the Territory.

3.2.3 Elan shall promptly notify Amarin of any developments that fall within the Amarin Intellectual Property. Amarin shall promptly notify Elan of any developments that fall within the Elan Intellectual Property.

3.2.4 Each party shall provide the other with reasonable support in the Prosecution of the Elan Intellectual Property and the Amarin Intellectual Property in respect of any inventions that were developed under this Agreement and shall provide all information and/or data in its possession that is necessary to support any relevant patent application in the Territory.

3.2.5 Amarin and Elan shall discuss the filing strategy for any proposed patent application(s) in the Territory and shall co-ordinate the filing of such patent application(s) between the two parties in order to protect the intellectual property rights of both parties in the Territory.

3.3. Enforcement.

With respect to any unauthorized use of the Elan Intellectual Property or the Amarin Intellectual Property by a third party, including but not limited to any permitted sub-licensee, as such relates to the Product and Product Intermediate the parties agree as follows:

3.3.1 Elan and Amarin shall promptly inform each other in writing of any actual or alleged unauthorized use of the Elan Intellectual Property or the Amarin Intellectual Property by a third party of which it becomes aware and provide the other party with any available evidence of such unauthorized use.

3.3.2 Elan shall have the right to enforce for Elan's own benefit (including by agreement or by litigation) Elan Intellectual Property at its own instigation and expense. Amarin shall reasonably cooperate with Elan to enforce such rights, provided that Amarin is indemnified for any out-of-pocket expenses incurred in providing such cooperation. Amarin shall be kept advised at all times of such suit or proceedings brought by Elan.

3.3.3 In the event that Elan does not wish to enforce its rights in respect of Product Patents within sixty (60) days of notification under Clause 3.3.1, then insofar as the alleged infringement occurred after the Effective Date, Amarin may instead at its own instigation and expense enforce for its own benefit (including by agreement or by litigation) such Product Patents, subject to the following provisions:

3.3.3.1 Elan shall reasonably cooperate with Amarin to enforce such rights, provided that Elan is indemnified for out-of-pocket expenses incurred in providing such cooperation;

3.3.3.2 Such proceedings shall be conducted at Amarin's expense;

3.3.3.3 Elan shall be kept advised at all times of such suit or proceedings brought by Amarin;

3.3.3.4 Elan shall have the right to review and comment on settlement agreement proposals and any pleadings or other documents to be filed with the court in any such litigation and shall do so promptly. Amarin shall consider such comments and take them into account as is necessary and reasonable;

3.3.3.5 Without prejudice to Clause 12.6.1.1, prior to knowingly making any statements, that would render any Product Patents unenforceable, invalid or unpatentable, Amarin shall notify Elan of such statement and discuss reasonable alternatives with Elan (except as prohibited by applicable law); however in no circumstances shall Amarin make any such statement without the prior written consent of Elan, except to the extent required by applicable law; and

3.3.3.6 Under no circumstances shall Amarin, without Elan's prior written consent, purport to grant, or otherwise

suggest or offer the grant of, any license to Product Patents as a part of any settlement proposal.

3.3.4 Amarin shall have the right to enforce for Amarin's own benefit (including by agreement or through litigation) Amarin Intellectual Property at its own instigation and expense. Elan shall reasonably cooperate with Amarin to enforce such rights, provided that Elan is indemnified for out-of-pocket expenses incurred in providing such cooperation. Elan shall be kept advised at all times of such suit or proceedings brought by Amarin.

3.4. Defense of and Liability for Infringement Claims.

3.4.1 Each of the parties shall promptly notify the other party in writing of any Claim made or brought against either of them alleging infringement or other unauthorised use of the proprietary rights of a third party arising from the manufacture, importation, use, offer for sale, sale or other commercialization of the Product or Product Intermediate in the Territory ("**Infringement Claim**").

3.4.2 Notwithstanding any term or provision to the contrary contained in this Agreement, Amarin shall indemnify and hold harmless Elan against all Infringement Claims arising from the use or sale of Product or Product Intermediate by Amarin, its Affiliates, permitted sub-licensees, distributors or other Amarin subcontractors except to the extent such claims arise from a breach by Elan of its representations and warranties set forth in Clause 14.1 herein or except as provided in Clause 3.4.3. Amarin shall indemnify and hold harmless Elan against all Infringement Claims arising from but not limited to:

3.4.2.1 the handling or storage of the Product Intermediate or Product by or on behalf of Amarin, its Affiliates, permitted sub-licensees, distributors or other Amarin subcontractors;

3.4.2.2 the further processing of the Product Intermediate by or on behalf of Amarin, its Affiliates, permitted sub-licensees, distributors or other Amarin subcontractors;

3.4.2.3 the handling or use of any Device in relation to the Product by or on behalf of Amarin, its Affiliates, permitted sub-licensees, distributors or other Amarin subcontractors, including any use of a Device to administer the Product; or

3.4.2.4 the method by which the Product is administered to any patient as directed by or on behalf of Amarin, its Affiliates, permitted sub-licensees, distributors or other Amarin subcontractors.

3.4.3 Elan will provide reasonable assistance to Amarin in its defence of Infringement Claims. In respect of those Infringement Claims related to the Elan Patents, Elan Know-How or the Elan Improvements, the Infringement Claim Fees and/or Third Party Royalties arising from the use or sale of Product or Product Intermediate by Amarin, its Affiliates, permitted sub-licensees, distributors or other Amarin subcontractors shall be apportioned as follows subject to the terms and conditions as set forth in Clause 3.5 herein:

3.4.3.1 Elan shall be responsible for [fifty percent (50%)] of Infringement Claim Fees arising from any Infringement Claims related to Elan Patents, Elan Know-How or Elan Improvements and/or Third Party

Royalties payable up to [fifty percent (50%)] of the royalties otherwise payable to Elan under this Agreement;

3.4.3.2 Amarin shall be responsible for any excess Infringement Claim Fees and/or Third Party Royalties over and above the amount as set forth in Clause 3.4.3.1;

3.4.3.3 Amarin will be entitled to recover Infringement Claim Fees and/or Third Party Royalties due by Elan as set forth in Clause 3.4.3.1 as a credit against up to [fifty percent (50%)] of the royalties otherwise payable to Elan under this Agreement in a calendar quarter, subject to Clause 3.5 below;

3.4.3.4 Any deficit remaining in Amarin's recovery of amounts due by Elan to Amarin under Clause 3.4.3.1 may be carried over to subsequent calendar quarters until exhausted. Such carry-over shall remain subject to the limit of up to [fifty percent (50%)] of the royalties otherwise payable to Elan under this Agreement in such calendar quarter (subject to Clause 3.5).

3.4.4 In its defence of Infringement Claims, Amarin shall:

3.4.4.1 keep Elan informed with respect to any developments in such proceedings that are reasonably likely to have a material adverse effect on sales of the Product;

3.4.4.2 provide Elan with the right to review and comment, as practical, on any pleadings or other documents to be filed with the court in any such litigation (including at the option of Elan through separately appointed counsel); and

3.4.4.3 except to the extent required by applicable law, not make any reference to Elan Intellectual Property in any proceedings, without the prior written consent of Elan, such consent not to be unreasonably withheld, conditioned or delayed.

3.4.5 Save as specifically provided otherwise in this Clause 3.4, the provisions of Clause 14.6 shall apply as regards the conduct of any Infringement Claim.

3.5. For the avoidance of doubt, Elan's maximum aggregate liability for all Third Party Royalties and all Infringement Claim Fees under Clause 3.4.3.1 in any calendar quarter shall be limited to up to [fifty percent (50%)] of the royalties otherwise payable to Elan under Clause 10.4 in that calendar quarter, *provided that* any sums paid by Amarin to Elan pursuant to Clauses 9 and 10 or under the Manufacturing Agreement for the supply of Product Intermediate shall not be treated as royalty payments for the purposes of this Clause 3.5.

3.6. With reference to the provisions of this Clause 3, Elan and Amarin shall consult as regards any actions Elan or Amarin proposes to take in order to mitigate any loss or liability in respect of any Infringement Claim, such as for example Amarin ceasing to sell the Product, the parties agreeing to modify the Product, or either or both of the parties entering into a licensing or settlement negotiation with the third party. In the event that the parties are unable to agree on such action, Elan shall be entitled to take and direct such action as it may reasonably consider expedient, including requiring the withdrawal of the Product within a reasonable time frame. In the event that Amarin fails to promptly take such action, Amarin

shall indemnify and hold Elan harmless against all Infringement Claims to the extent that they relate to the period after the date by which Amarin was required to take such action.

3.7. Trademarks.

3.7.1 Amarin shall market the Product in the Territory under the Amarin Trademark.

3.7.2 Amarin shall prominently display the Elan Trademark on the packaging of the Product and on all promotional materials in relation to the Product to acknowledge that the Elan Technology has been applied in developing and manufacturing the Product.

3.7.3 For this purpose:

3.7.3.1 Amarin grants to Elan and its Affiliates for the Term a royalty free, worldwide, non-exclusive license to the Amarin Trademark and, if different, trademarks showing Amarin's corporate logo, solely for the purpose of Elan's promotion of its activities in relation to this Agreement and of the Elan Technology in relation to this Agreement; and

3.7.3.2 Elan grants to Amarin for the Term a paid-up, worldwide, non-exclusive license to the Elan Trademark, solely for the purpose of fulfilling Amarin's obligations in relation to this Agreement, and for the purpose of Amarin's promotion of its activities in relation to this Agreement.

3.7.4 The following provisions shall apply to the use by one party ("**Trademark User**") of the trademark(s) ("**Relevant Marks**") of the other ("**Trademark Owner**"):

3.7.4.1 Trademark User shall ensure that each reference to and use of the Relevant Marks by Trademark User is in a manner from time to time approved by Trademark Owner and accompanied by an acknowledgement, in a form approved by Trademark Owner, that the same is a trademark (or registered trademark) of Trademark Owner.

3.7.4.2 Trademark User shall not use the Relevant Mark in any way which might materially prejudice its distinctiveness or validity or the goodwill of Trademark Owner therein.

3.7.4.3 Trademark User shall not use in the Territory any trademarks or trade names so resembling the Relevant Marks or any of them as to be likely to cause confusion or deception.

3.7.4.4 Trademark Owner shall, at its sole discretion and expense, file and prosecute applications to register and maintain registrations of Relevant Marks in the Territory.

3.7.4.5 Trademark Owner will be entitled to conduct all enforcement proceedings relating to the Relevant Marks and shall at its sole discretion decide what action, if any, to take in respect of any infringement or alleged infringement of the Relevant Marks or passing-off or any other claim or counter-claim brought or threatened in respect

of the use or registration of the Relevant Marks. Any such proceedings shall be conducted at Trademark Owner's expense and for its own benefit.

4. NON-COMPETITION

4.1. Product and Product Intermediate. During the Term, Amarin shall not, and shall procure that its Affiliates do not, either directly or indirectly:

4.1.1 market, sell or distribute the Product or Product Intermediate in a country outside the EEA (other than in those countries outside the EEA which are part of the Territory), or sell the Product to any person who it believes or ought reasonably to know intends to sell the Product in such a country; or

4.1.2 actively sell the Product or Product Intermediate into a territory in the EEA reserved on an exclusive basis to Elan or a territory allocated by Elan on an exclusive basis to its other licensees and/or distributors. For this purpose, the parties acknowledge that each territory which is not exclusively allocated by Elan to other licensees and/or distributors and in respect of which this Agreement has been terminated is reserved to Elan.

4.2. Competing Products (Amarin). Amarin shall not, and shall procure that its Affiliates do not market or sell:

4.2.1 any nasal formulation containing the Compound (but not including the Other Compound in any circumstances as formulations of Other Compound are regulated by Clause 4.2.2) as its sole active ingredient, other than the Product: (i) in the EEA for a period of five years beginning on the date of the first In Market sale of the Product in the EEA, or (ii) elsewhere in the Territory during the Initial Term;

4.2.2 any formulation containing the Compound as its sole active ingredient for use in buccal or sublingual administration or any formulation containing the Other Compound as its sole active ingredient for use in nasal, buccal or sublingual administration, as from the Effective Date until the soonest of:

(a) the end of the Initial Term; or

(b) where Amarin exercises its option under Clause 2.4, the restriction imposed by this Clause 4.2 shall immediately terminate in relation to any option formulation that Amarin does not chose to be the Expanded Formulation; or

(c) service of notice by Amarin on Elan that it wishes to terminate its option rights under Clause 2.4 prior to the expiry of the time period referred to in Clause 2.4; or

(d) expiry of the period referred to in Clause 2.4 without the exercise of an option in respect of an Expanded Formulation.

For the avoidance of doubt, in the event that the Elan License is extended to include an Expanded Formulation, then Amarin shall not market or sell any formulation containing the same compound (Compound or Other Compound, as applicable) as its sole active ingredient in the Expanded Formulation and using the same route of administration as the Expanded Formulation, other than the Product: (i) in the EEA for a period of five years beginning on the date of the first In Market sale of the

Expanded Formulation in the EEA or (ii) elsewhere in the Territory during the Initial Term.

4.3. Competing Products (Elan). Elan shall not, and shall procure that its Affiliates do not, use or license the Elan Technology to market or sell:

4.3.1 any nasal formulation containing the Compound (not including the Other Compound in any circumstances as formulations of Other Compound are regulated by Clause 4.3.2) as its sole active ingredient, other than the Product in circumstances and in countries where Elan is entitled under this Agreement to market Product: (i) in the EEA for a period of five years beginning on the date of the first In Market sale of the Product in the EEA or (ii) elsewhere in the Territory during the Initial Term;

4.3.2 any formulation containing the Compound as its sole active ingredient for use in buccal or sublingual administration or any formulation containing the Other Compound as its sole active ingredient for use in nasal, buccal, or sublingual administration as from the Effective Date until the soonest of:

(a) the end of the Initial Term; or

(b) where Amarin exercises its option under Clause 2.4, the restriction imposed by this Clause 4.3 shall immediately terminate in relation to any option formulation that Amarin does not chose to be the Expanded Formulation; or

(c) service of notice by Amarin on Elan that it wishes to terminate its option to expand the license under Clause 2.4 prior to the expiry of the time period referred to in Clause 2.4; or

(d) expiry of the period referred to in Clause 2.4 without the exercise of an option having been made under Clause 2.4 in respect of an Extended Formulation.

4.4 Competing Combination Products. Clauses 4.2 and 4.3 shall apply mutatis mutandis to such formulations in which the Compound is an active ingredient but not the sole active ingredient (**"Combination Formulation"**), provided that such Combination Formulation does not require human clinical trials comparing the efficacy of such Combination Formulation to both the Compound and the other active ingredient individually.

5. DEVELOPMENT OF THE PRODUCT INTERMEDIATE

5.1. Development. Elan shall use commercially reasonable efforts to develop the Product Intermediate in accordance with the R&D Program:

5.1.1 in particular, Elan agrees that it shall:

5.1.1.1 be responsible for obtaining and maintaining the necessary licenses and permits for the development, manufacturing, testing and storage of the Product Intermediate by Elan as may be required under the R&D Program.

5.1.1.2 provide Product Intermediate as agreed in the R&D Program and shall manufacture such Product Intermediate in accordance with prevailing cGLP, cGCP and cGMP and, in all material respects, in accordance

with all applicable Governmental Authority standards and guidelines, as appropriate for the phase or stage under which such Product Intermediate is produced during the R&D Program.

5.2. Compound Supply. Elan shall supply Compound for its activities under the R&D Program up until the completion of the initial animal pharmacokinetic. Thereafter, Amarin shall reimburse Elan for any Compound purchased by Elan for use in the R&D Program.

5.3. Other Materials, Third Party Costs and Services. Following the completion of the initial animal pharmacokinetic study, Amarin shall reimburse Elan for all materials (including but not limited to the Compound as set out in Clause 5.2), other out-of-pocket expenses, third party costs and development services provided by Elan under the R&D Program in accordance with Clause 10.3.

5.4. Changes and Additional Work. Any changes to the R&D Program shall be agreed in advance with Elan, and Amarin shall bear the cost of any resulting additional work. The Parties also agreed that additional work will be conducted under additional workplans, which if agreed and undertaken, will be appended and controlled by the terms of this Agreement.

6. PROJECT TEAM AND PROJECT MANAGEMENT

6.1. Establishment. Within sixty (60) days of the Effective Date, the parties will establish a project team ("**Project Team**"), which shall consist of development personnel from each party who are appropriately skilled and knowledgeable in relation to the R&D Program and who are deemed necessary to accomplish the work of the R&D Program.

The Project Team shall have an equal number of members from each of the parties and the total size of the Project Team shall not exceed six (6) people.

6.2. Conduct. Unless otherwise agreed by the parties:

6.2.1 the Project Team shall meet at least once each calendar quarter, such meetings to continue until the time of launch or such later time as may be agreed, alternatively at the offices of Elan and Amarin;

6.2.2 meetings shall be chaired by an Elan representative;

6.2.3 each party shall be responsible for its own costs in respect of travel and accommodation expenses in attending meetings of the Project Team;

6.2.4 at and between meetings of the Project Team, each party shall keep the other fully and regularly informed as to its progress with its respective tasks and obligations under the R&D Program;

6.2.5 the Project Team shall also monitor the progress of the R&D Program against the timeframe set for it and shall report on delays in the conduct of the R&D Program which would materially affect Elan's ability to successfully complete the R&D Program within the timeframe set out for it and recommend whether corrective action is required under the provisions of Clause 6.3.

6.3. Co-operation. Elan and Amarin shall undertake their respective obligations under the R&D Program on a collaborative basis. Accordingly, the parties shall co-operate in good faith particularly with respect to unknown problems or contingencies and shall perform their respective obligations in a commercially reasonable, diligent and workmanlike manner.

6.4. The parties hereby confirm that the parties first and primary objective (under the R&D Program and under this Agreement generally) is to generate an NDA and to secure an NDA Approval for the Product in the United States. While it is the parties desire and expectation that where possible the body of data generated by them for NDA filing and NDA Approval may also be used to support other regulatory filings and approvals, the parties' initial focus and efforts during the development program will be intended to generate an NDA and secure NDA Approval.

7. REGULATORY MATTERS

7.1. Elan. Elan shall own, and shall be responsible for, filing for and maintaining:

7.1.1 regulatory approvals in respect of the Elan Technology;

7.1.2 the DMF and any equivalent; and

7.1.3 all necessary manufacturing approvals for the manufacture of the Product Intermediate.

Amarin shall reimburse Elan forthwith for any filing fees incurred by Elan in connection therewith. Amarin shall additionally reimburse Elan at Elan's then-current full time equivalent rate, currently [US$250] per person-hour, for all services provided by Elan and for any out-of-pocket expenses and any Third Party costs associated with preparing, filing, obtaining and maintaining Regulatory Approvals for the Product.

7.2. Amarin. Except as provided in Clause 7.1, Amarin shall own and shall be responsible for filing for and maintaining the Amarin Compound Data and all necessary Regulatory Approvals, including any necessary export or import licenses in relation to the Compound (where applicable), Product Intermediate and/or the Product. For the avoidance of doubt, all of the data, filings and other information provided by Elan to Amarin or any such Affiliate to support Amarin regulatory filings shall be treated as Confidential Information belonging to Elan and its Affiliates in accordance with the provisions of Clause 15.

7.3. Disclosure. Without prejudice to any other right of Elan under this Agreement, Amarin shall pursue a strategy of minimum disclosure of information relating to the manufacturing process of the Product. The parties shall discuss the implementation of this strategy in good faith on a case by case basis.

7.4. Review. Elan shall be given a reasonable opportunity to review and comment upon all regulatory submissions prior to their submission.

7.5. Co-operation. Elan and Amarin will provide all reasonable co-operation with respect to the other's regulatory filings.

7.6. Keep Advised. Amarin shall keep Elan promptly and fully advised of all Amarin's regulatory activities in respect of the Product and the Compound. Without prejudice to the generality of the foregoing, Amarin shall:

7.6.1 notify Elan upon the date of submission of any Regulatory Application in the Territory;

7.6.2 notify Elan upon the date of issue of a Regulatory Approval or related regulatory action letters; and

7.6.3 submit to Elan a quarterly report, for every calendar quarter prior to the marketing of the Product within 14 days of the end of the relevant quarter fully outlining the regulatory status of the Product throughout the Territory.

7.7. Right of Reference to DMF. Elan will authorise Amarin to reference Elan's DMF with the Governmental Authorities to the extent necessary to enable Amarin to file Regulatory Applications and to maintain Regulatory Approvals in connection with the Product. In the event that a Governmental Authority raises any queries in relation to Elan's DMF which can only be resolved by Elan (and not by Amarin), Elan shall use commercially reasonable efforts to resolve any such queries with said Governmental Authority in an expeditious manner.

7.8. Retention of Samples. Unless the parties agree otherwise, Elan will maintain raw material, clinical supply and analytical samples in storage for a time period based upon Elan's sample retention policy, or such longer period of time as Amarin may reasonably request. Elan agrees to maintain Product Intermediate batch production and control records and associated test results until the marketing application is approved by the FDA or until Amarin notifies FDA of discontinuation of the IND.

7.9. Access. Upon Elan's prior written notice, Amarin shall permit Elan to have access to the Regulatory Applications and Regulatory Approvals and to take photocopies of same, as required by Elan to fulfil reporting requirements or as otherwise may reasonably be required by Elan in connection with this Agreement.

7.10. Governmental Inspection. Each party shall notify the other as soon as possible of any notification received by that party from a Governmental Authority to conduct an inspection of its manufacturing or other facilities specific to the development, manufacturing, packaging, storage or handling of the Compound, Product Intermediate and/or the Product. Copies of all correspondence with the Governmental Authority solely related to the Compound, Product Intermediate or the Product and material to that party's activities under this Agreement will be provided to that other party.

7.11. Right to Inspect. Each party shall make that portion of its facility where the Compound, Product Intermediate or the Product is manufactured, tested or stored, including all record and reference samples, available for inspection upon reasonable notice and not more than once per annum:

7.11.1 by the other party's duly qualified employee or, with the consent of the party being inspected, by the other party's duly qualified agent or contractor; or

7.11.2 by the relevant Governmental Authority.

An inspection under this Clause 7.11 shall be limited to determining whether there is compliance with cGMP and other requirements of applicable law.

Any consent required under this Clause 7.11 shall not be unreasonably withheld or delayed.

8. CLINICAL DEVELOPMENT, REGISTRATION, MARKETING AND THE PROMOTION OF THE PRODUCT

8.1. Diligent Efforts. Amarin shall be responsible for (at its own cost) and shall use commercially reasonable efforts to (i) conduct all stage I activities set out in Schedule 5; (ii) conduct any further development activities and any further clinical trials with respect to the Product Intermediate, the Product or any relevant Device to commercialize Product in the Primary Territory and (iii) register, market and promote the Product in the Primary Territory:

8.1.1 in particular in respect of the Primary Territory, Amarin agrees that it, its Affiliates and permitted sub-licensees shall:

8.1.1.1 conduct in an expeditious manner all necessary pre-clinical and clinical studies in respect of the Product Intermediate, the Product and any Device that may be used to administer the Product or Product Intermediate and to conduct such activities in accordance with prevailing cGLP, cGCP and cGMP and, in all material respects, in accordance with all applicable Governmental Authority standards and guidelines;

8.1.1.2 obtain Regulatory Approvals for the Product and all necessary governmental approvals that may need to be obtained for the Device in order to market the Product in the Primary Territory;

8.1.1.3 promote the Product as the flagship brand under Amarin's prevailing trademark(s) for use in an outpatient setting in repetitive epileptic seizures and for any other indications in a country for which the Product is approved for use in that country and to otherwise use the same level of effort as used by Amarin with other similar products of similar sales potential;

8.1.1.4 market and promote the Product with a view to achieving maximum market impact and concentration throughout the Primary Territory and at least the same level of effort as with other similar products of similar sales potential which it markets; and in the event that Amarin elects to market the Product in any part of the Secondary Territory, the same obligation shall apply to such territory; and

8.1.1.5 comply with all applicable rules and regulations, in all material respects, in regard to the storage, handling, development and commercialization of Product and Product Intermediate and otherwise conduct all storage, handling, development and commercialization activities relating to the Product and Product Intermediate with due care in accordance with normal standards in the pharmaceutical industry.

8.2. Promotional Campaign. Amarin shall:

8.2.1 control and be responsible for the content and format of each promotional campaign to be submitted to the relevant Governmental Authority, but shall inform Elan thereof and, upon reasonable request by Elan, provide to Elan a copy of such submissions;

8.2.2 within ninety (90) days after the filing of the first Regulatory Application in the Territory, if requested in writing by Elan, outline to Elan the structure of the promotional activities to be carried out by Amarin for the period up to the first launch of the Product and for a period of 1 year thereafter; and

8.2.3 both prior to and subsequent to the launch of the Product, communicate with Elan regarding its objectives for and performance of the Product in the Territory.

8.3. Packaging and Labels. Amarin shall submit to Elan for Elan's information copies of all trade packaging and labels and other printed materials which Amarin proposes at any time to use in relation to the sale of the Product. For the avoidance of doubt, nothing in this Clause 8.3

affects any other obligation of Amarin, and Amarin shall indemnify and hold harmless Elan against all Claims which may arise relating to the activities described in this Clause 8.

8.4. Changes. Amarin shall be entitled to change such trade packaging and labels and other printed materials only as often as is commercially reasonable and in compliance with applicable laws and regulations. Such changes shall be at Amarin's sole expense and for the avoidance of doubt shall not constitute allowable deductions from Net Sales.

8.5. Required Markings. All trade packaging and marketing materials shall:

8.5.1 to the extent permitted by law, include due acknowledgement that the Product Intermediate is developed and manufactured by Elan; and

8.5.2 have marked representative patent number(s) including that of the formulation patent in respect of the Elan Patents on all Product, or otherwise reasonably communicate to the trade the existence of any Elan Patents for the countries within the Territory in such a manner as to ensure compliance with, and enforceability under, applicable laws.

8.6. Launch. Amarin shall effect the first full scale national commercial launch of the Product:

8.6.1 in the United States within 180 days of the Regulatory Approval in the United States, provided that Amarin shall have received the agreed quantities of Launch Stocks ordered pursuant to firm purchase orders under this Agreement at least 60 days in advance of the launch date; and

8.6.2 in each of the other countries of the Territory, within 270 days after the relevant Regulatory Approval.

8.7. Reporting. Following first Regulatory Approval of the Product, the parties shall meet as often as reasonably requested by the other (not more than once per calendar quarter). At such meetings, Amarin shall report on the ongoing sales performance of the Product in each country of the Territory, including marketing approaches, promotional and educational campaigns, performance against competitors, its ongoing objectives for the Product and its plans for promotion of the Product for the next quarterly period. Such meetings may be held by telephone. If held in person, each party shall be responsible for its own costs in respect of travel and accommodation expenses in attending such meetings.

9. COMMERCIAL MANUFACTURE

The parties shall negotiate in good faith a manufacturing agreement relating to the commercial supply of Product Intermediate ("**Manufacturing Agreement**") containing the following terms, and such other terms as may be agreed:

9.1. Elan shall maintain the exclusive right and obligation to manufacture or have manufactured and to supply or have supplied Amarin's entire requirement of commercial supplies of Product Intermediate in the Field in the Territory, subject to Clause 9.6 and 9.7. Elan shall be entitled to subcontract or delegate these obligations (subject to Amarin's prior written consent which shall not be unreasonably withheld, conditioned or delayed), but shall remain liable to Amarin for all acts or omissions of any Affiliate or subcontractor under the Manufacturing Agreement as though such acts or omissions were by Elan.

9.2. Elan shall be responsible for the cost and sourcing of the Compound for the commercial supply of Product Intermediate referred to in Clause 9.1.

9.3. The Product Intermediate supplied shall be manufactured in accordance with cGMP and all applicable laws and regulations. The manner in which Amarin shall notify Elan of any failure by Elan to supply Product Intermediate to Amarin that conforms to such requirements and the methods by which Elan may rectify such problems and other consequences for failing to provide Product Intermediate in accordance with these requirements shall be negotiated in good faith and set out in the Manufacturing Agreement.

9.4. The price of Product Intermediate manufactured by Elan under the Manufacturing Agreement shall be equivalent to [eight per cent (8%)] of Notional NSP (the "**Supply Price**") and upon delivery Elan will render to Amarin an invoice for Product Intermediate supplied EXW Elan's Facility packaged and labelled in a form to be agreed between the parties.

9.5. For the avoidance of doubt the parties agree that if for whatever reason the Product Intermediate supplied by Elan to Amarin, which meets agreed Product Intermediate specifications and applicable law and regulatory requirements, is not sold by Amarin, payment for such Product Intermediate shall nonetheless be effected and the price of the Product Intermediate shall be the Supply Price.

9.6. In the event that either party is of the opinion that [140%] of Manufacturing Cost for one unit of Product Intermediate would exceed the Supply Price, then it shall promptly notify the other in writing. In such event the parties shall meet within thirty (30) days of such notification to discuss, *inter alia*, the manner in which Manufacturing Cost is calculated by Elan and also Amarin's commercialisation plans. Thereafter, the parties shall re-negotiate in good faith (i) the Supply Price or, alternatively, (ii) whether Elan shall use commercially reasonable efforts to locate a third party site ("**Third Party Site**") of Elan's choosing (but subject to Amarin's prior written consent which shall not be unreasonably withheld, conditioned or delayed) to supply the Product Intermediate and to arrange for a technology transfer between Elan and that third party at Elan's cost. The parties further agree that during the course of such good faith discussions and during any period prior to the time at which the Third Party Site is ready to commence manufacture of the Product Intermediate, Elan shall continue to supply Product Intermediate to Amarin at a price of not less than [140%] of Manufacturing Cost.

9.7. In the event that the parties cannot agree on a Supply Price or on the technology transfer as provided in Clause 9.6, then Elan shall continue to supply the Product Intermediate to Amarin but at a price not less than [140%] of Manufacturing Cost.

9.8. Forecasting and ordering provisions will be agreed in good faith, taking into account the practical requirements involved in manufacturing the Product Intermediate including, *inter alia,* the fact that the Compound is a controlled substance;

9.9. Amarin will be responsible for the purchase of (and shall own) any capital equipment specifically required for the manufacture of the Product Intermediate which is unique and/or dedicated to the manufacture of Product Intermediate. Elan will be responsible for all other capital equipment used in manufacture;

9.10. In circumstances where the gross sales of the Product exceed US$50,000,000, Elan shall establish a second site of manufacture. In such circumstance, Amarin shall bear its own and all third-party costs related to any regulatory filing fees and any regulatory maintenance fees or any license fees related to the registration of such second site, to the extent related to the manufacture of Product Intermediate.

10. FINANCIAL PROVISIONS

10.1. Milestone Payments. In consideration of the grant of the Elan License, Amarin shall pay to Elan the following non-refundable amounts:

10.1.1 A milestone of [US$150,000 (one hundred and fifty thousand dollars)] upon the earlier of: (i) the commencement of Stage 1 of the R&D Program or (ii) the commencement of the second animal pharmacokinetic study that may be conducted on Product Intermediate;

10.1.2 a milestone payment of [US$500,000 (five hundred thousand dollars)] upon the commencement of the first Phase III Study of the Product;

10.1.3 a milestone payment of [US$1,000,000 (one million dollars)] upon the filing of the first Regulatory Application in the United States or in any other country in the Primary Territory;

10.1.4 a milestone payment of [US$2,000,000 (two million dollars)] upon Regulatory Approval in the United States;

10.1.5 a milestone payment of [US$1,500,000 (one million five hundred thousand dollars)] upon first Regulatory Approval in any country other than the United States in the Primary Territory.

the payments described in Clauses 10.1.1 to 10.1.5 being **"License Milestone Payments"**, and for the avoidance of doubt each being payable once only, save where Amarin exercises its option under Clause 2.4 to develop an Expanded Formulation that includes Other Compound, in which case the milestones described in Clause 10.1.2 to 10.1.5 (but excluding the milestone described in Clause 10.1.1) shall be payable more than once.

If an event in respect of which a License Milestone Payment would be payable does not occur, but another such event occurs which would ordinarily occur only after the first such event, then the amount of the first relevant License Milestone Payment shall be added to the second.

10.2. Not Subject to Future Performance Obligations. The License Milestone Payments shall not be subject to future performance obligations of Elan to Amarin and shall not be applicable against future services provided by Elan to Amarin.

The terms of Clause 10.1 relating to the License Milestone Payments are independent and distinct from the other terms of this Agreement.

10.3. Development Fees. Following the completion of the initial animal pharmacokinetic study that is conducted on the Product or Product Intermediate in accordance with the R&D Program, Amarin shall reimburse Elan for all materials (including the Compound), other reasonable out-of-pocket expenses and third party costs incurred by Elan during the R&D Program. Amarin shall also reimburse Elan for all services provided by Elan after the completion of the initial animal pharmacokinetic study that is conducted on the Product or Product Intermediate during the R&D Program at Elan's prevailing full time equivalent rate ("FTE"), currently US$250/hour.

10.4. Royalties. In consideration of the grant of the Elan License, Amarin shall pay to Elan non-refundable royalties as follows:

10.4.1 If Amarin or an Amarin Affiliate sells the Product In Market in any country in the Territory, then subject to Clause 10.5, a non-refundable royalty, calculated by reference to the table set out below, being the sum of the royalties payable to Elan within the bands of Net Sales generated by Amarin or an Amarin Affiliate in the Territory at the corresponding royalty percentage below:

Annual Worldwide Net Sales Bands	Applicable Royalty Rate
First[US$100,000,000] of Worldwide Net Sales	[16%] of Net Sales generated by Amarin or an Amarin Affiliate in the Territory
Increments above [US$100,000,000] of Worldwide Net Sales	[18%] of Net Sales generated by Amarin or an Amarin Affiliate in the Territory.

The above royalty includes the Manufacturing Royalty which shall be payable by Amarin to Elan for the commercial manufacture and supply by Elan of the Product Intermediate to Amarin.

10.4.2 If Amarin enters into a Sub-License Agreement or other agreement whereby a third party is granted rights to sell the Product in the United States, then subject to Clause 10.5, a non-refundable royalty calculated by reference to the table set out below, being the sum of royalties payable to Elan with the bands of Net Sales generated by the third party sub-licensee at the corresponding royalty percentage below:

Annual Worldwide Net Sales Bands	Applicable Royalty Rate
First [US$100,000,000] of Worldwide Net Sales	[16%] of Net Sales generated in the US.
Increments above [US$100,000,000] of Worldwide Net Sales	[18%] of Net Sales generated in the US.

The above royalty includes the Manufacturing Royalty which shall be payable by Amarin to Elan for the commercial manufacture and supply of the Product Intermediate by Elan to Amarin for Product that is sold by third parties in the United States.

10.4.3 If Amarin enters into a Sub-License Agreement or other agreement whereby a third party is granted rights to sell the Product outside the United States, then subject to Clause 10.5:

10.4.3.1 a non-refundable royalty of [12%] of the Ex-US Net Revenues; and

10.4.3.2 the Manufacturing Royalty, which shall be payable by Amarin to Elan for the commercial manufacture and supply of the Product Intermediate by Elan to Amarin for Product that is sold by a third party outside the United States.

The parties also agree that upon provision of any Statement, Amarin will pay Elan the difference between the sums previously paid to Elan for the supply of Product Intermediate for the quarter in question pursuant to Clause 9 and the royalty sums due hereunder by reference to the Statement for that quarter.

10.5. Generic Competition. In the event of Generic Competition in a given country, the parties agree that Elan shall at all times continue to receive the Manufacturing Royalty for all Product Intermediate supplied by or on behalf of Elan pursuant to this Agreement and the Manufacturing Agreement but that the remaining royalties due to Elan pursuant to Clause 10.4 shall be [halved] as from the date of commencement of such Generic Competition in that country.

10.6. Bundling. In the event that Amarin, an Amarin Affiliate, permitted sub-licensee and a third party distributor or any permitted sub-licensee shall sell the Product together with other products of Amarin, an Amarin Affiliate, a permitted sub-licensee and third party distributor to third parties (by the method commonly known in the pharmaceutical industry as "bundling") and the price attributable to the Product is less than the average price of "arms length" sales to similar customers for the reporting period in which sales occur (such sales to be excluded from the calculation of the average price of "arms length" sales), Net Sales for any such sales shall be the average price of "arms length" sales by Amarin or sub permitted sub-licensee to similar customers in the country where such bundling occurs during the reporting period in which such sales occur.

10.7. Method of calculation of fees. The parties acknowledge and agree that the methods for calculating the royalties and fees under this Agreement are for the purposes of the convenience of the parties, are freely chosen and not coerced.

11. PAYMENTS, REPORTS AND AUDITS

11.1. Records. Amarin shall keep true and accurate records of gross sales of the Product, the items deducted from the gross amount in calculating the Net Sales, the Net Sales and the royalties payable to Elan under Clause 10.4. Amarin shall deliver to Elan a written statement (the "**Statement**") thereof within 45 days following the end of each calendar quarter, (or any part thereof in the first or last calendar quarter of this Agreement) for such calendar quarter. The Statement shall outline on a country-by-country basis, the calculation of the Net Sales from gross revenues during that calendar quarter, the applicable percentage rate, and a computation of the sums due to Elan. The parties' financial officers shall agree upon the precise format of the Statement.

11.2. Foreign Currency. Payments due on Net Sales of the Product based on sales amounts in a currency other than US$ shall first be calculated in the foreign currency and then converted to US$ on the basis of the exchange rate in effect for the purchase of US$ with such foreign currency quoted in the Wall Street Journal (or comparable publication if not quoted in the Wall Street Journal) on the last day of the relevant calendar quarter.

11.3. VAT. All payments to Elan are exclusive of any applicable value added or any other sales tax, for which Amarin will be additionally liable if applicable.

11.4. Taxes. If Amarin is required by law to pay or withhold any income or other taxes on behalf of Elan with respect to any monies payable to Elan under this Agreement:

11.4.1 Amarin shall deduct them from the amount of such monies due;

11.4.2 any such tax required to be paid or withheld shall be an expense of and borne solely by Elan;

11.4.3 Amarin shall promptly provide Elan with a certificate or other documentary evidence to enable Elan to support a claim for a refund or a foreign tax credit.

11.5. Withholding Notice. In the event that Amarin is required by law to withhold any income or other taxes on behalf of Elan from any payment to Elan under the terms of this Agreement, Amarin shall use commercially reasonable efforts to notify Elan at least thirty (30) days in advance of making any such payment.

11.6. Double Tax Co-operation. Elan and Amarin agree to co-operate in all respects necessary to take advantage of any double taxation agreements or similar agreements as may, from time to time, be available in order to enable Amarin to make such payments to Elan without any deduction or withholding.

11.7. Timing. Payments to Elan shall be made as follows:

11.7.1 each of the License Milestone Payments shall be paid within 45 days of the achievement of the relevant event to which they relate;

11.7.2 payment for all Product supplied shall be made within 30 days of receipt of the relevant invoice; and

11.7.3 payment of royalties shall be made upon provision of the Statement.

11.8. Manner of Payment. All payments due hereunder shall be made in US$ to the designated bank account of Elan in accordance with such timely written instructions as Elan shall from time to time provide.

11.9. Interest. Without prejudice to Elan's other remedies hereunder, Amarin shall pay interest to Elan on sums not paid to Elan on the date on which payment should have been made pursuant to the applicable provisions of this Agreement ("**Due Date**") over the period from the Due Date until the date of actual payment (both before and after judgement) at the Prime Rate publicly announced by Morgan Guaranty Trust Company of New York at its principal office on the Due Date (or next to occur business day, if such date is not a business day) plus [5%], such interest to payable on demand from time to time and compounded monthly. Interest shall be payable both before and after judgment.

11.10. Audit. For the 180 day period following the close of each calendar year of the Agreement, Elan and Amarin will, in the event that the other party reasonably requests such access, provide each other's independent certified accountants (reasonably acceptable to the other party) with access, during regular business hours and subject to the confidentiality provisions as contained in this Agreement, to such party's books and records relating to the Product, solely for the purpose of verifying the accuracy and reasonable composition of the calculations under this Agreement for the calendar year then ended.

11.11. Correction of Discrepancies. In the event of a discovery of a discrepancy, a correcting payment shall be made forthwith by Amarin to Elan or Elan to Amarin, as the case may be, together with interest at the rate specified in Clause 11.9. If the discrepancy exceeds 5% of

the amount due or charged by a party for any period and provided that the amount of the discrepancy exceeds US$5,000, then additionally the cost of such accountants shall be borne by the audited party.

12. DURATION AND TERMINATION

12.1. Initial Term. This Agreement shall be deemed to have come into force on the Effective Date and, subject to the rights of termination outlined in this Clause 12 and the provisions of applicable laws, will expire on a country by country basis:-

12.1.1 on the 15th anniversary of the date of the first In Market sale of the Product in the country concerned; or

12.1.2 in any country upon expiry of the last Valid Patent Claim –

whichever date is later to occur (the "**Initial Term**").

12.2. Continuation. At the end of the Initial Term, the Agreement shall continue automatically for rolling 3 year periods thereafter, unless the Agreement has been terminated by either of the parties by serving 2 years' written notice on the other party immediately prior to the end of the Initial Term or any such additional 3 year period.

12.3. Breach / Insolvency. In addition to the rights of termination provided for elsewhere in this Agreement, either party will be entitled forthwith to terminate this Agreement by written notice to the other party if:

12.3.1 that other party commits a material breach of any of the provisions of this Agreement or the Manufacturing Agreement, and fails to cure the same within 60 days after receipt of a written notice from another party hereto giving full particulars of the breach and requiring it to be remedied; provided, that if the breaching party has proposed a course of action to cure the breach and is acting in good faith to cure same but has not cured the breach by the 60th day, such period shall be extended by such period as is reasonably necessary to permit the breach to be cured, provided that such period shall not be extended by more than 90 days, unless otherwise agreed in writing by the parties;

12.3.2 that other party goes into liquidation under the laws of any applicable jurisdiction (except for the purposes of amalgamation or reconstruction and in such manner that the company resulting therefrom effectively agrees to be bound by or assume the obligations imposed on that other party under this Agreement);

12.3.3 a receiver, administrator, examiner, trustee or similar officer is appointed over all or substantially all of assets of that other party under the laws of any applicable jurisdiction; or

12.3.4 any proceedings are filed or commenced by that other party under bankruptcy, insolvency or debtor relief laws, or anything analogous to any of the foregoing under the laws of any applicable jurisdiction occurs in relation to that other party.

12.4. Free Termination by Amarin. Amarin may terminate this Agreement upon thirty (30) days' written notice to Elan:

12.4.1 at any time up to the initiation of a Phase III Study of the Product; or

12.4.2 at any time following the failure of a Phase III Study; or

12.4.3 at any time after the fifth anniversary of the first In Market sale of the Product; or

12.4.4 if Elan is in breach of Clause 4.3, provided that if such breach results solely from the acquisition of Elan by a third party, Amarin shall not terminate this Agreement if the acquirer completes the divestiture of the competing products or the Product Intermediate within six (6) months. Save with respect to the provision in the previous sentence, this Clause shall not prejudice any other remedy Amarin may have in respect of such breach.

12.5. Other Termination by Amarin. Amarin may terminate this Agreement on a country-by-country basis at any time upon thirty (30) days' written notice to Elan where:

12.5.1 the sale of the Product becomes prohibited by a Governmental Authority in that country; or

12.5.2 despite having used commercially reasonable efforts, Amarin is unable to obtain Regulatory Approval for the Product in such country so as to permit a reasonable commercial return for Amarin.

12.6. Additional Elan Termination Rights. In further addition to the rights and termination provided for elsewhere in this Agreement, Elan shall be entitled to terminate this Agreement upon thirty (30) days written notice to Amarin:

12.6.1 in its entirety in the event that:

12.6.1.1 Amarin, its Affiliates or a permitted sub-licensee knowingly challenges the validity and/or ownership of any of the Elan Patents and/or the scope of any claims therein in a formal proceeding, mediation or binding arbitration; or

12.6.1.2 Amarin is in breach of Clause 4.2, provided that if such breach results solely from the acquisition of Amarin by a third party, Elan shall not terminate this Agreement if the acquiror completes the divestiture of the competing product(s) or the Product (without prejudice to any right of Elan to withhold consent to such divestiture) within six (6) months. Save with respect to the proviso in the previous sentence, this Clause shall not prejudice any other remedy Elan may have in respect of such breach.

12.6.2 for any country or countries of the Territory in the event that Amarin fails to file a Regulatory Application:

12.6.2.1 in the United States within [seven (7) years] after the completion of first human pharmacokenetics study that enables entry into efficacy studies ("**PK Date**");

12.6.2.2 in an EU Major Market (through either a local or EU procedure which would result in the immediate approval of the Product in a EU Major Market) [within 8 years] from the PK Date; or

12.6.2.3 in Japan [within 9 years] from the PK Date.

Recognizing that Amarin's ability to move forward relies on Elan's (and its Affiliates') performance, the dates listed above shall be extended to take account of any unreasonable delay or failure on Elan's part to perform, and any evaluation of

Amarin's diligence must take account of these delays and failures. Similarly, Elan's unreasonable delays (including unreasonable delay in supplying required clinical supplies) will extend the 7, 8 and 9 year deadlines.

13. CONSEQUENCES OF TERMINATION

13.1. General Consequence. Upon exercise of those rights of termination specified in Clause 12 or elsewhere in this Agreement, this Agreement shall, subject to Clauses 13.2 and 13.3, automatically terminate forthwith and be of no further legal force or effect.

13.2. Specific Consequences. Upon termination of the Agreement, or upon termination of a license for a particular country under Clause 12.6, the following shall be the consequences relating to the Territory or the particular country, as applicable:

13.2.1 any sums that were due from Amarin to Elan under the provisions of this Agreement prior to its termination or expiry shall be paid in full within 30 days of termination of this Agreement and Elan shall not be liable to repay to Amarin any amount of money paid or payable by Amarin to Elan up to the date of the termination of this Agreement;

13.2.2 the provisions of this Agreement regarding with respect to confidentiality and non-use of Confidential Information shall remain in effect for a further period of 7 (seven) years.

13.2.3 Clauses 1, 3.1, 3.4, 3.5, 3.6, 11, 13 (in accordance with its terms), 14.1 through 14.10, 14.11 (in accordance with its terms), and 16 shall survive termination;

13.2.4 any sub-license granted under Clause 2.3 shall automatically terminate, although Elan agrees that it will negotiate in good faith with sub-licensees to renew such sub-license agreements after the date of such termination provided that Elan is satisfied that renewing said agreements will produce a reasonable economic return for Elan and the sub-licensee is not a Technological Competitor. In the event that such negotiations do not result in the renewal of the relevant license rights, the sub-licensee shall be provided with a certain period of time in which to deplete stock and to return or destroy all Elan Confidential Information in its possession;

13.2.5 where Elan terminates under Clause 12.3, 12.6 or where Amarin terminates this License on a country-by-country basis or for reasons other than a breach of this Agreement by Elan, [Elan shall be entitled to research, develop and commercialise the Product for its own benefit in the Territory or in the relevant country or countries of the Territory] in accordance with the provisions of Clause 13.3;

13.2.6 where Elan terminates under Clause 12.3, 12.6 or where Amarin terminates this License on a country-by-country basis or for reasons other than a breach of this Agreement by Elan, [Elan shall be entitled to file for Regulatory Approval for the Product in any country which ceases to be a part of the Territory, or in any country of the Territory in the event of termination hereof, in circumstances where Elan exercises its rights under Clause 13.2.5 to research, develop and commercialise the Product];

13.2.7 for the avoidance of doubt, the parties further agree that the termination of this Agreement for any reason shall not relieve the parties of any obligation accruing prior thereto and shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of the provisions of this Agreement.

13.2.8 If following the date of termination of this Agreement Amarin is required to indemnify Elan under the provisions of [Clause 3.4 due to the survival of Clause 3.4 pursuant to Clause 13.2.3 (for example, an Infringement Claim arises following the date of termination but relates to a claim for damages in relation to (a) the period prior to the date of termination and/or (b) sales post termination by a permitted sub-licensee pursuant to Clause 13.2.4) then the parties shall negotiate in good faith to agree a mechanism pursuant to which Elan bears responsibility for such Infringement Claim to the extent provided for pursuant to Clause 3.4.3.1 (subject to the remaining provisions of Clause 3.4 and Clause 3.5) solely to the extent that there are no royalties against which Amarin may credit such amount pursuant to Clause 3.4.3.3 or Clause 3.4.3.4].

13.3. Ancillary Rights. [If Elan should require a license of the Amarin Intellectual Property in order to research, develop and commercialise the Product under Clause 13.2.5:

13.3.1 Amarin shall grant Elan a non-exclusive license in respect to the Amarin Intellectual Property to make and have made and use the Compound in the Territory for the sole purposes of importing, using, making, having made, offering for sale, selling and having sold the Product in the Territory for so long as any part of the Amarin Intellectual Property remains legally protected or protectable (unless sooner terminated by Elan by 30 days' prior notice in writing to Amarin).

13.3.2 The license described in Clause 13.3.1 will be subject to payment of a fee to be agreed between the parties, which shall not exceed the costs incurred by Amarin in the development of the Product (including Amarin pre-clinical and clinical activities), properly vouched for.

13.3.3 Elan and Amarin shall be entitled to grant sub-licenses of the Amarin Intellectual Property to import, use, make, have made, offer for sale and sell the Product in the Territory.

13.3.4 Amarin shall permit Elan or Elan's designee without charge to conduct sufficient cross-referencing to, and have sufficient access to, any and all Regulatory Applications or Regulatory Approvals for the relevant country or countries of the Territory, and shall permit Elan to have a right of access to any pre-clinical or clinical Amarin Compound Data that does not form part of Regulatory Applications or Regulatory Approvals provided that for the avoidance of doubt it is acknowledged by the parties that Amarin will continue to own Amarin Compound Data.

13.3.5 The parties shall negotiate in good faith a further written license agreement(s) which shall incorporate the foregoing provisions of this Clause 13.3 and which shall include such customary and reasonable terms which unless otherwise agreed by the parties, shall be substantially similar to those in this Agreement with respect to commercialisation of the Product by Amarin. The parties shall also discuss in good faith taking into account, amongst other matters, the commercial value of this new license agreement given its non-exclusive nature and the extent to which Elan shall indemnify Amarin in respect of liability arising from third party Infringement Claims that have arisen and been settled pursuant to this Agreement in respect of which Amarin may incur additional liability due to Elan's sale (or sale by Elan's Affiliates, sub-licensees or other Elan subcontractors) of the Product under this Clause 13.3.]

14. WARRANTIES, INDEMNIFICATION AND LIABILITY

14.1. Elan Warranties. Elan represents and warrants to Amarin as of the Effective Date, as follows:

14.1.1 Elan owns, beneficially or otherwise, the Elan Patents has the right to enter into this Agreement and grant the Elan License.

14.1.2 There are no agreements between Elan and any third party that conflict with this Agreement.

14.1.3 Except for the oppositions in the European Patent Office of EP-B-499299 and EP-1185371, Elan has not been notified of and, to the best of Elan's knowledge, information and belief with no special search (i) there are no infringement proceedings, actions, suits or complaints pending against nor any outstanding injunctions, judgments, orders, decrees, rulings or other charges against Elan or any Affiliate of Elan in connection with the Elan Patents or the Elan Know How in the Territory that may affect the making, using, or selling of the Product, (ii) there are no claims or litigation brought or threatened by any third party alleging that the Elan Patents are invalid or unenforceable, in whole or in part and (iii) Elan or any Affiliate has not received notice from a third party indicating that the use of the Elan Patents or Elan Know-How infringes any third party patent rights which would adversely affect the commercialization of the Product in the Territory.

14.1.4 Elan has not been notified and to the best of its knowledge without any special search no allegation has been made that the application of the Elan Technology ot the Product Intermediate infringes the patent rights of any third party.

14.2. Amarin Warranties. Amarin represents and warrants to Elan as of the Effective Date, as follows:

14.2.1 Amarin has the right to enter into this Agreement.

14.2.2 There are no agreements between Amarin and any third party that conflict with this Agreement.

14.2.3 As of the Effective Date of this Agreement, there is no Amarin Intellectual Property in existence.

14.2.4 Amarin has not been notified and has no actual knowledge that application of the Elan Technology to the Product Intermediate infringes the patent rights of any third party.

14.3. Mutual Indemnification. Each of the parties ("Indemnifying Party") shall indemnify and hold harmless the other party ("Indemnified Party") against all Claims insofar as they arise out of any breach by the Indemnifying Party of any of its obligations or warranties under this Agreement or from the Indemnifying Party's fraud or wilful misconduct.

14.4. Infringement Claims. The parties acknowledge that Clause 3.4 contains the parties' full agreement as regards liability for Infringement Claims, save to the extent that Clause 3.4 incorporates other provisions of this Agreement by specific cross-reference.

14.5. Indemnification (Medical Claims). Except to the relative extent that Elan is obliged to indemnify Amarin under this Agreement, Amarin shall indemnify Elan against all any Claims made or brought against Elan seeking damages for personal injury (including death) and/or

for the cost of medical treatment, caused by or attributed to the Product Intermediate or Product.

For the avoidance of doubt, this Clause shall require Amarin to indemnify Elan for any Claim arising out of or in connection with Amarin's, it's Affiliates', permitted sub-licensees or third party subcontractors' obligations and activities under this Agreement or otherwise, including but not limited to:

14.5.1 the use, sale, promotion, distribution, storage of Product or Product Intermediate in the Territory;

14.5.2 the application and use of any Device with the Product or Product Intermediate

14.5.3 the storage of and any further processing, packaging or other activities performed by, or on behalf of Amarin, its Affiliates, its permitted sub-licensees or its permitted subcontractors of the Product Intermediate;

14.5.4 any clinical trial programs conducted by, on behalf of, or at the request of Amarin, its Affiliates, its permitted sub-licensees or permitted third party subcontractors with respect to the development of the Product and Product Intermediate and in respect of all regulatory activities conducted in connection with the Product or Product Intermediate.

14.6. Conduct of Claims. The party seeking an indemnity shall:

14.6.1 fully and promptly notify the other party of any claim or proceedings, or threatened claim or proceedings;

14.6.2 permit the indemnifying party to take full control of such claim or proceedings, with counsel of the indemnifying party's choice, provided that the indemnifying party shall reasonably and regularly consult with the indemnified party in relation to the progress and status of such claim or proceedings;

14.6.3 co-operate in the investigation and defense of such claim or proceedings; and

14.6.4 take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceedings.

The indemnifying party may settle a Claim on terms which provide only for monetary relief and do not include any admission of liability. Save as aforesaid, neither the indemnifying party nor Indemnified Party shall acknowledge the validity of, compromise or otherwise settle any Claim without the prior written consent of the other, which shall not be unreasonably withheld.

14.7. Exclusion of Implied Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, AMARIN ACKNOWLEDGES THAT THE ELAN LICENSE IS GRANTED AND THE PRODUCT INTERMEDIATE SUPPLIED ON AN "AS IS" BASIS, WITHOUT REPRESENTATION OR WARRANTY WHETHER EXPRESS OR IMPLIED INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF THIRD PARTY RIGHTS, AND ALL SUCH WARRANTIES ARE EXPRESSLY DISCLAIMED TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAWS.

14.8. Exclusion of Consequential Loss. WITHOUT PREJUDICE TO THE OBLIGATION OF EITHER PARTY TO INDEMNIFY THE OTHER IN RESPECT OF CLAIMS BY A THIRD

PARTY, NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, ELAN AND AMARIN SHALL NOT BE LIABLE TO THE OTHER BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF COMMON LAW, OR UNDER THE EXPRESS TERMS OF THIS AGREEMENT, FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, INCIDENTAL OR PUNITIVE LOSS OR DAMAGE (WHETHER FOR LOSS OF CURRENT OR FUTURE PROFITS, LOSS OF ENTERPRISE VALUE OR OTHERWISE) AND WHETHER OCCASIONED BY THE NEGLIGENCE OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE.

14.9. Extension of Indemnification. Where this Agreement provides for the indemnification of a party to this Agreement or for the limitation of a party's liability, such indemnification and/or limitation (as the case may be) shall also apply for the benefit of such party's Affiliates and the employees, officers, directors and agents of any of them, acting in such capacity.

14.10. Inherent Risk. It is hereby acknowledged that there are inherent uncertainties involved in the development and registration of pharmaceutical products and such uncertainties form part of the business risk involved in undertaking the form of commercial collaboration outlined in this Agreement. Accordingly, Amarin shall have no liability to Elan as a result of the failure of the Product to obtain Regulatory Approval in one or more countries in the Territory provided that Amarin has satisfied its diligence efforts under Clause 8.1 to conduct pre-clinical and clinical studies in respect of the Product Intermediate and Product and Elan will have no liability to Amarin as a result of any failure or delay of the Product Intermediate to achieve the Product Intermediate Specifications or one or more of the milestones set out in the R&D Program and/or to obtain the Regulatory Approval in one or more of the countries of the Territory provided that Elan uses commercially reasonable efforts under Clause 5.1 to develop the Product Intermediate in accordance with the R&D Program.

14.11. Insurance. Amarin shall maintain clinical trial insurance and comprehensive general liability insurance including product liability insurance on the Product, the Product Intermediate and Compound in such prudent amount as the parties may agree for the duration of this Agreement and for such period thereafter as necessary to cover the insured risks.

Amarin shall provide Elan with a certificate from the insurance company verifying the above and shall notify Elan in writing at least 30 days prior to the expiration or termination of such coverage.

15. CONFIDENTIALITY

15.1. Confidential Information: The parties agree that it will be necessary, from time to time, to disclose to each other confidential and proprietary materials and information, including without limitation, inventions, trade secrets, specifications, designs, data, know-how and other proprietary information relating to the Product, processes, services and business of the disclosing party.

The foregoing shall be referred to collectively as "**Confidential Information**".

15.2. Exclusion. Confidential Information shall be deemed not to include:

15.2.1 information which is in the public domain;

15.2.2 information which is made public through no breach of this Agreement;

15.2.3 information which is independently developed by a party, as evidenced by such party's records; or

15.2.4 information that becomes available to a receiving party on a non-confidential basis, whether directly or indirectly, from a source other than the other party hereto, which source did not acquire this information on a confidential basis.

15.3. Use of Confidential Information. Any Confidential Information disclosed by the disclosing party shall be used by the receiving party exclusively for the purposes of fulfilling the receiving party's obligations under this Agreement and for no other purpose.

15.4. Non-Disclosure. Except as otherwise specifically provided in this Agreement, each party shall disclose Confidential Information of the other party only to those employees, representatives and agents requiring knowledge thereof in connection with fulfilling the party's obligations under this Agreement, and not to any other third party.

15.5. Obligation to Inform. Each party further agrees to inform all such employees, representatives and agents of the terms and provisions of this Agreement relating to Confidential Information and to obtain their agreement hereto as a condition of receiving Confidential Information.

15.6. Care. Each party shall exercise the same standard of care as it would itself exercise in relation to its own confidential information (but in no event less than a reasonable standard of care) to protect and preserve the proprietary and confidential nature of the Confidential Information disclosed to it by the other party.

15.7. Return of Information. Upon termination or expiration of this Agreement, each party shall promptly, upon request of the other party, return all documents and any copies thereof containing Confidential Information belonging to, or disclosed by, such other party, save that it may retain one copy of the same solely for the purposes of ensuring compliance with this Clause 15.

15.8. Attribution. Any breach of this Clause 15 by any person informed by one of the parties is considered a breach by the party itself.

15.9. Acknowledgment. The parties agree that the obligations of this Clause 15 are necessary and reasonable in order to protect the parties' respective businesses. The parties further agree that monetary damages may be inadequate to compensate a party for any breach by the other party of its covenants and agreements with respect to confidentiality, and that each party shall be entitled to seek injunctive or other equitable relief against the threatened or continued breach of those provisions, in addition to with any other remedy which may be available.

15.10. Compound Data. For the purpose of demonstrating to third parties the benefits of the Elan Technology, Elan shall be entitled, with the prior written consent of Amarin, to disclose to third parties the numerical values underlying the Amarin Compound Data provided that Elan does not disclose Amarin's name or the name of the Compound.

15.11. Announcements. No announcement or public statement concerning the existence, subject matter or any term of this Agreement, or its performance, shall be made by or on behalf of any party without the prior written approval of the other, such approval not to be unreasonably withheld or delayed. Any such statement by Amarin shall contain suitable reference to the fact that the Product is developed using the Elan Technology, and that Elan is the owner of such technology.

15.12. Required Disclosures. A party (the "**Disclosing Party**") will be entitled to make an announcement or public statement concerning the existence, subject matter or any term of this Agreement, or to disclose Confidential Information that the Disclosing Party is required to make or disclose pursuant to:

15.12.1 a valid order of a court or Governmental Authority; or

15.12.2 any other requirement of law or any securities or stock exchange;

provided that if the Disclosing Party becomes legally required to make such announcement, public statement or disclosure hereunder, the Disclosing Party shall give the other party prompt notice of such fact to enable the other party to seek a protective order or other appropriate remedy concerning any such announcement, public statement or disclosure, including confidential treatment and/or appropriate redactions.

The Disclosing Party shall fully co-operate with the other party in connection with that other party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude announcement, public statement or disclosure, the Disclosing Party shall make such announcement, public statement or disclosure only to the extent that the same is legally required.

15.13. Disclosures to Regulatory Authorities. Notwithstanding Clause 15.12, Amarin (and its distributors and permitted sub-licensees) shall not be permitted to include Elan's Confidential Information in any Regulatory Application or other regulatory filings, without Elan's prior written consent. For the avoidance of doubt, such consent shall not be taken to permit Amarin, its distributors and/or permitted sub-licensees to claim ownership rights to the information provided and/or to use the information for any purpose other than the specific use and in such manner as that for which consent was obtained.

15.14. Other Disclosures. Each of the parties shall be entitled to provide a redacted copy of this Agreement, to be agreed by the parties, to any potential distributor or sub-licensees without the prior written consent of the other party on the condition that such potential sub-licensees agree to be bound by confidentiality obligations no less onerous than those contained in this Agreement.

15.15. Technological Competitors. [In circumstances where Amarin or any entity that may be a successor-in-interest to Amarin becomes a Technological Competitor ("**Acquiring/Successor Entity**"), said Acquiring/Successor Entity shall contain this Agreement and the Manufacturing Agreement within a ring fence. For the purposes of this Clause 15.15, "contained within a ring fence" means that (i) the Acquiring/Successor Entity's employees who perform activities and obligations under this Agreement and the Manufacturing Agreement must be identified by name and location by the Acquiring/Successor Entity and must sign a confidentiality agreement, to be approved by Elan, prohibiting the disclosure of any Elan Intellectual Property and/or related Elan Confidential Information to the Acquiring/Successor Entity's employees who do not work on activities directly related to this Agreement and the Manufacturing Agreement (with the exception and to the extent required of internal auditors, the legal department and other non-operational centralized services) and (ii) to the extent permitted by applicable laws and regulations, any of the Acquiring/Successor Entity's employees who may be transferred to work on the activities and have access to and knowledge of Elan Intellectual Property and/or related Confidential Information may not subsequently be transferred to work on the Acquiring/Successor Entity's other technologies which compete with Elan Technology for a period of eighteen (18) months as from the date on which they cease to work on such activities under this Agreement and the Manufacturing Agreement without the prior consent of Elan, which shall not be unreasonably withheld. Elan shall also be entitled to reasonable site inspections and audits by Elan or its designee to ensure strict compliance with these terms and conditions.]

16. MISCELLANEOUS PROVISIONS

16.1. Force Majeure. Neither party shall be liable for failure or delay in the performance of any of its obligations under this Agreement if such failure or delay results from Force Majeure, but any such failure or delay shall be remedied by such party as soon as practicable.

16.2. Assignment.

16.2.1 Each party be entitled without the consent of the other:

16.2.1.1 to subcontract or delegate the whole or any part of its duties hereunder to its Affiliate(s); and/or

16.2.1.2 to assign this Agreement to its Affiliate, provided that such assignment has no material adverse tax implications for the other party.

16.2.2 Amarin may assign this Agreement to any person to whom it would be permitted to grant a sub-license under the Elan License, subject to any conditions which would attach thereto. For the avoidance of doubt, Amarin shall under no circumstances assign this Agreement to a Technological Competitor.

16.2.3 Each party shall be entitled to assign this Agreement to any acquiror of all or substantially all of its assets related to this Agreement, regardless of the form of such transaction provided that Amarin shall under no circumstances assign this Agreement to a Technological Competitor and shall make Elan whole for any tax consequence.

16.2.4 Except as provided for in Clauses 16.2.1 to 16.2.3 inclusive, this Agreement may not be assigned by a party nor any duties hereunder subcontracted or delegated by a party without the prior written consent of the other, which shall not be unreasonably withheld or delayed.

16.2.5 In the event that an Affiliate of Amarin to whom this Agreement has been assigned ceases to be an Affiliate of Amarin, this Agreement shall be deemed automatically reassigned to Amarin (or such Affiliate as it may specify, subject to the condition set out in Clause 16.2.1.2).

16.2.6 Any assignee shall assume the obligations of the assignor under this Agreement.

16.2.7 Each party is entering into this Agreement on its own behalf and not on behalf of any other person or entity.

16.3. Parties Bound. This Agreement shall be binding upon and run for the benefit of the parties, their successors and permitted assigns.

16.4. Relationship of the Parties. In this Agreement, nothing shall be deemed to constitute a partnership between the parties or make either party an agent for the other, for any purpose whatsoever.

16.5. Entire Agreement. This Agreement constitutes the entire agreement and understanding between the parties with respect to its subject matter, and except as expressly provided, supersedes all prior representations, writings, negotiations or understandings with respect to that subject matter.

Nothing in this Clause 16.5 shall exclude any liability which any party would otherwise have to the other party or any right which either of them may have to rescind this Agreement in respect of any statements made fraudulently by the other prior to the execution of this Agreement or any rights which either of them may have in respect of fraudulent concealment by the other.

16.6. Severability. If any provision in this Agreement is deemed to be, or becomes invalid, illegal, void or unenforceable under applicable laws, such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable, or if it cannot be so amended without materially altering the intention of the parties, it will be deleted, but the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

16.7. Further Assurance. Each party shall do and execute, or arrange for the doing and executing of, each necessary act, document and thing reasonably within its power to implement this Agreement.

16.8. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

16.9. Waivers. A failure to exercise or delay in exercising a right or remedy provided by this Agreement or by law does not constitute a waiver of the right or remedy or a waiver of other rights or remedies. No single or partial exercise of a right or remedy provided by this Agreement or by law prevents further exercise of the right or remedy or the exercise of another right or remedy.

16.10. Variations. No variation of this Agreement shall be effective unless it is made in writing and signed by each of the parties.

16.11. Notices.

16.11.1 A notice under or in connection with this Agreement (a "**Notice**"):

16.11.1.1 shall be in writing; and

16.11.1.2 may be delivered personally or sent by first class post (and air mail if overseas) or by fax to the party due to receive the Notice at its address set out below:

16.11.2 The address referred to in Clause 16.11.1.2 is:

(a) in the case of Elan:

Address: Elan Pharma International Limited
Monksland
Athlone
Co. Westmeath
Ireland

Attention: Vice President & Legal Counsel
Fax: + 353 9064 95402

(b) in the case of Amarin:

Address: Amarin Pharmaceuticals Ireland Limited
First Floor
Block 3
The Oval
Shelbourne Road
Ballsbridge
Dublin 4
Ireland
Fax: +353 1 669 9028
Marked for the attention of : General Counsel

16.11.3 Notice is deemed given:

16.11.3.1 if delivered personally, when the person delivering the notice obtains the signature of a person at the address referred to in Clause 16.11.1.2;

16.11.3.2 if sent by post, except air mail, two Business Days after posting it;

16.11.3.3 if sent by air mail, six Business Days after posting it;

16.11.3.4 if sent by fax, when confirmation of its transmission has been recorded by the sender's fax machine.

16.12. Set-off. Each of the parties will be entitled but not obliged to set-off against any amount of money payable to it by the other party under this Agreement, any amount of money payable by it to the other party under this Agreement.

16.13. Disputes. Any disputes between the parties which cannot be amicably resolved shall first be referred to the Chief Operations Officer of Elan Drug Technologies and the Chief Executive Office of Amarin, who shall attempt to resolve the matter in good faith.

16.14. Governing Law and Jurisdiction: This Agreement shall be governed by and construed in accordance with the laws of Ireland, without regard to its conflict of laws rules, and shall be subject to the exclusive jurisdiction of Irish Courts.

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SCHEDULE 1 ELAN PATENTS

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Patent Family Title	*Territory*	*Application No.*	*Patent / Publication No.*
Surface modified drug nanoparticles	US		5,145,684
	Argentina		AR255241
	Australia	10147/92	654836
	Austria	92200153.2	0 499 299 B1
	Belguim	92200153.2	0 499 299 B1
	Canada		2,059,432
	Chile	92/074	
	Columbia	354003	24635
	Denmark	92200153.2	0 499 299 B1
	European Patent Office	92200153.2	0 499 299 B1
	Finland		108333
	France	92200153.2	0 499 299 B1
	Germany	92200153.2	0 499 299 B1
	Greece	92200153.2	0 499 299 B1
	Hungary	P9200226	221,586
	Ireland	1992/0217	83410
	Israel		100754
	Italy	92200153.2	0 499 299 B1
	Japan	4-011226	3602546B2
	Liechtenstein	92200153.2	0 499 299 B1
	Luxembourg	92200153.2	0 499 299 B1
	Malaysia	PI9200109	MY-108134-A
	Mexico	9200291	176345
	Monaco	92200153.2	0 499 299 B1
	Netherlands	92200153.2	0 499 299 B1
	New Zealand		241362
	Norway	920334	303668
	Phillipines		29069
	Portugal	92200153.2	0 499 299 B1
	Russia	5010891	2066553
	Singapore	9606361-5	55104
	South Korea	1077/92	200061
	Spain	92200153.2	0 499 299 B1
	Sweden	92200153.2	0 499 299 B1
	Switzerland	92200153.2	0 499 299 B1
	Taiwan	81100510	NI-071312
	United Kingdom	92200153.2	0 499 299 B1

Method to reduce particle size growth during lyophilization	US		5,302,401

Use of charged phospholipids to reduce particle aggregation	US		5,470,583

The use of Tyloxapol as a nanoparticle stabilizer and dispersant	US		5,429,824
	Canada	2108192	
	European Patent Office	93203365.7	0602702
	France	93203365.7	0602702
	Germany	93203365.7	69324456.9
	Israel		107874
	Italy	93203365.7	0602702
	Japan	280799/93	
	Philippines		29957
	South Korea	22700/93	320390
	United Kingdom	93203365.7	0602702

Process of preparing thereputic compositions containing nanoparticles	US		5,510,118

Method of grinding pharmaceutical substances	US		5,518,187
	Argentina		251,001
	Australia		660,852
	Canada	2,107,400	
	Czech Republic	284802	CZ284802 B6
	Austria	93202795.6	0600528 B1
	Belguim	93202795.6	0600528 B1
	Denmark	93202795.6	0600528 B1
	European Patent Office	93202795.6	0600528 B1
	Finland		108399
	France	93202795.6	0600528 B1
	Germany	93202795.6	0600528 B1
	Greece	93202795.6	0600528 B1
	Hungary		210928
	Ireland	93202795.6	0600528 B1
	Italy	93202795.6	0600528 B1
	Japan	250972/02	
	Liechtenstein	93202795.6	0600528 B1
	Luxembourg	93202795.6	0600528 B1
	Malaysia		MY-109,419-A
	Mexico		189779
	Monaco	93202795.6	0600528 B1
	Netherlands	93202795.6	0600528 B1
	New Zealand		248813
	Phillipines		31118
	Portugal	93202795.6	0600528 B1
	Slovak Republic	PV1301/93	281078
	South Korea		312798

	Spain	93202795.6	0600528 B1
	Switzerland	93202795.6	0600528 B1
	Sweden	93202795.6	0600528 B1
	Taiwan		NI-69476
	Ukraine	93/3406	
	United Kingdom	93202795.6	0600528 B1
	Venezuela	1484-93	

Method of preparing stable drug nanoparticles	US		5,534,270

Butylene oxide-ethylene oxide block copolymer surfactants as stabilizer coatings for nanoparticle compositions	US		5,587,143
	Canada	2193503	
	European Patent Office		0804162B
	Germany		0804162B
	Italy		0804162B
	Israel		114,354
	Japan		3,710,811
	United Kingdom		0804162B

Sugar based surfactant for nanocrystals	US		5,622,938

Continuous method of grinding pharmaceutical substances	US		5,718,388
	Austria	95919062.0	0 804 161 B1
	Argentina	331937	AR 253558 V1
	Canada	2190134	2,190,134
	Belguim	95919062.0	0 804 161 B1
	Denmark	95919062.0	0 804 161 B1
	European Patent Office	95919062.0	0 804 161 B1
	France	95919062.0	0 804 161 B1
	Germany	95919062.0	0 804 161 B1
	Ireland	95919062.0	0 804 161 B1
	Israel	113851	113851
	Italy	95919062.0	0 804 161 B1
	Japan	530317/1995	3607294
	Luxembourg	95919062.0	0 804 161 B1
	Lichtenstein	95919062.0	0 804 161 B1
	Malaysia	PI95001375	MY-113, 569-A
	Monaco	95919062.0	0 804 161 B1
	Netherlands	95919062.0	0 804 161 B1
	Phillipines	50574	31497
	Portugal	95919062.0	0 804 161 B1
	Spain	95919062.0	0 804 161 B1
	Sweden	95919062.0	0 804 161 B1
	Switzerland	95919062.0	0 804 161 B1
	Taiwan	84103642	NI-122518
	United Kingdom	95919062.0	0 804 161 B1
	Venezuela	0854-95	

Method of grinding	US		5,682,999

pharmaceutical substances	Argentina	331,938	AR 254497 V1
	Canada	2190966	2,190,966
	Austria	95919828.4	0760653 B1
	Belguim	95919828.4	0760653 B1
	Denmark	95919828.4	0760653 B1
	European Patent Office	95919828.4	0760653 B1
	France	95919828.4	0760653 B1
	Germany	95919828.4	0760653 B1
	Greece	95919828.4	0760653 B1
	Israel	113852	113852
	Italy	95919828.4	0760653 B1
	Japan	530352/95	
	Lichtenstein	95919828.4	0760653 B1
	Luxembourg	95919828.4	0760653 B1
	Malaysia		MY-112, 458-A
	Monaco	95919828.4	0760653 B1
	Netherlands	95919828.4	0760653 B1
	Phillipines	1-1995-50573	
	Portugal	95919828.4	0760653 B1
	Spain	95919828.4	0760653 B1
	Sweden	95919828.4	0760653 B1
	Switzerland	95919828.4	0760653 B1
	Taiwan	84104440	NI-112433
	United Kingdom	95919828.4	0760653 B1
	Venezuela	0853-95	57612

Nebulized aerosols containing nanoparticle dispersions	US		6,264,922
	Canada		2,213,638
	European Patent Office	96906566.3	0 810 853 B1
	France	96906566.3	0 810 853 B1
	Germany	96906566.3	0 810 853 B1
	Italy	96906566.3	0 810 853 B1
	Japan	8-525798	
	Luxembourg	96906566.3	0 810 853 B1
	United Kingdom	96906566.3	0 810 853 B1

Methods for preventing crystal growth and particle aggregation in nanoparticle compositions	US		6,267,989
	US		6,745,962
	US		6,991,191
	Canada	2367096	2367096
	European Patent Office	00910167.6	1161229 B1
	France	00910167.6	1161229 B1
	Germany	00910167.6	1161229 B1
	Italy	00910167.6	1161229 B1
	Japan	2000-603653	
	United Kingdom	00910167.6	1161229 B1

Use of PEG-derivatized Lipids as surface stabilizers for nanoparticule compositions	US		6,270,806
	Canada	2362508	2362508
	European Patent Office	00913448.7	1156788 B1
	France	00913448.7	1156788 B1
	Italy	00913448.7	1156788 B1

	Japan	2000-602040	
	United Kingdom	00913448.7	1156788 B1

Solid dose nanoparticulate compositions comprising a synergistc combination of a ppolymeric surface stabilizer and dioctyl sodium sulfosuccinate	US		6,375,986
	Canada	2416109	
	European Patent Office	01975724.4	1318788
	Japan	2002-528199	

Nanoparticulate compositions comprising a synergistic combination of a polymeric surface stabilizer and dioctyl sodium sulfosuccinate	US		6,592,903
	Canada	2416109	
	European Patent Office	01975724.4	1318788 A1
	Japan	2002-528199	

Nanoparticulate compositions comprising copolymers of vinyl pyrrolidone and vinyl acetate as surface stabilizers	US		6,969,529
	Canada	2428785	
	European Patent Office	01274072.6	1341521 A2
	Japan	2002-590934	

Aerosol comprising nanoparticle drugs	US	09/190,138	2002102294
	US		6,811,767
	Australia	1346900	
	Canada	2350074	
	European Patent Office	99956981.7	1128814
	Japan	2000-580594	

Stabilization of chemical compounds using nanoparticulate technology	US	09/952,032	
	European Patent Office	02775709.5	1427395 A1
	Japan	2003-528521	

Low viscosity liquid dosage forms	US	10/420,927	
	Canada	2508301	
	European Patent Office	03724196.5	1613276 A1
	Japan	2004-570751	

Liquid dosage compositions of stable nanoparticulate active agents	US	10/619,539	2004258757
	Australia	200361167	
	Canada	2492488	
	European Patent Office	03764723.7	1551457 A1
	Japan	2004-521891	

Aerosol and injectible formulations of nanoparticulate benzodiazepines	US	11/354,249	
	PCT	PCT/US06/05224	

]

SCHEDULE 2 R&D PROGRAM

[NanoCrystal® Colloidal Disperson ("NCD") Lorazepam Nasal Spray (4mg/100μl) Amarin

1. OBJECTIVE

This document outlines Elan's proposal for the development of a nasal formulation of lorazepam and progression through an initial animal pharmacokinetic study (herein referred to as Proof-of-Concept or POC Study) through to a Phase I pharmacokinetic study in man.

2. EXECUTIVE SUMMARY

Lorazepam is currently available as tablet and parenteral (intravenous or intramuscular injection) products and is routinely used for the treatment of anxiety and as a sedative. The injectable form also finds common application in the treatment of fitting in patients where a rapid onset of action is required. Due to the very low drug solubility, cosolvents including polyethylene glycol and benzyl alcohol are used to solubilise the drug substance in the injectable formulation. It has been proposed that the nasal route could provide a more convenient route of administration than the current parenteral therapies. The current injectable formulation is not suitable for nasal therapy as the cosolvents it contains would be highly irritating to the nasal mucosa.

Elan propose to develop a liquid nasal formulation of lorazepam based on NanoCrystal® dispersion (NCD) technology for use in POC studies. Due the fine particle size and large surface area available, it is anticipated that such a formulation could provide a rapid onset of action when applied to the nasal mucosa to provide an effective therapy for the treatment of fitting. Ultimately, Amarin would develop a final formulation in a nasal delivery in a suitable (single dose unit) nasal spray.

The goal of the first stage of the program is to develop a suitable nasal Product Intermediate based on NCD technology and conduct a Proof-of-Concept study in an animal model to compare the pharmacokinetic profile (with particular emphasis on speed of onset) against an injectable formulation. On completion of a successful POC study the formulation would be further refined and placed in a suitable nasal delivery device. Elan will develop a formulation and process for a NCD bulk intermediate and conduct appropriate analytical and stability testing and develop a suitable manufacturing process.

Elan proposes to conduct the project in the stages outlined below:

Stage 0: Preclinical Development (Proof of Concept)

- NCD candidate development to identify suitable milling techniques and stabilisers to provide a physically stable dispersion of the required particle size distribution.
- Conducting a short-term stability study to confirm the chemical and physical stability of the product.
- Manufacture a batch of product for use in an animal POC study.
- Perform required activities to assist in the identification of a suitable nasal delivery device.

Stage 1: Clinical development (Phase I & Human Pharmacokinetic)

- API testing and the generation of an API specification.
- Analytical method development and validation.
- Investigation of other formulation attributes to support development of a final nasal delivery device/formulation combination (scope to be fully assessed).
- Development of a final stable NCD bulk intermediate dispersion.
- Development & validation of cleaning methods.
- Scale-up of the NCD bulk dispersion process (to support Phase I)
- Stability assessment of NCD bulk dispersion.
- Preparation of bulk NCD dispersion for Phase I (pharmacokinetic) supplies.
- Testing and release of NCD dispersion.

3. ASSUMPTIONS

- The product will be a liquid NCD dispersion in single unit nasal spray.
- It is anticipated that the formulation will contain 4mg lorazepam per 100μL dose unit although this may change depending on various factors including pharmacokinetic parameters, study designs, technical issues and business requirements.
- Pending selection of the final nasal delivery device, it is assumed that the formulation will contain an antimicrobial preservative.
- Elan will develop and manufacture a simple non-preserved formulation for conducting a Proof-of-Concept study in animals.
- For subsequent stages, Elan will be responsible for development and manufacture of a preserved NCD dispersion intermediate.
- Amarin will be responsible for selecting the device and the overall activities required to develop and select the final formulation and device combination for Phase I (including for example device selection and performance, compatibility and stability).
- Milling of the NanoCrystal® dispersion for the POC study will be carried out on a laboratory scale NanoMill®. Subject to the scale and types of clinical studies envisaged, milling will be carried out on the laboratory scale mill (anticipated yield up to 1000 dose units).
- It is anticipated that the final nasal product will be stored at ambient temperature and stability assessments will be carried out at 25 and 40°C. Refrigerated

samples will also be placed on stability. These storage conditions will be applied to the NanoCrystal® bulk intermediate.

R&D PROGRAM

4. SCOPE

4.1 STAGE O: Preclinical Development (Proof-of-Concept)

4.1.1 NCD Candidate Assessments

A NCD formulation containing lorazepam (anticipated dose 4mg/100μL) will be developed based on Elan's NanoCrystal® Dispersion (NCD) Technology. The aim of the studies will be to develop a product with a suitable sub-micron particle size that demonstrates a high degree of physical and chemical stability which can form the basis of a marketed formulation with shelf life of two years or more. Further assessments of milling parameters and stabilisers will be carried out to build on the studies conducted to date. At this stage it is anticipated that the formulations used for early POC studies will not be preserved although the impact of ionic surfactants on the formulation and milling parameters will be briefly assessed. The physical stability of the dispersions will be continually assessed using standard Elan methodology (e.g. pH, laser diffraction and microscopy).

4.1.2 NCD Prototype Stability Assessment

Two formulations (primary and back-up) will be selected from the candidate assessment and placed on a short term stability study. These will be stored at 25°C, 40°C (ICH conditions) and 5°C and the stability assessed (assay, impurities, pH, particle size distribution and microscopy) at 2 week and 4 week time-points. Contingent on the stability of the formulation and timings of the study the product may be shipped to the study site after the 2 week test point.

Following a review of the stability data, one formulation will be selected for use in the animal studies.

4.1.3 Proof-of-Concept Studies

One nasal formulation option will be selected. This will be manufactured and supplied to the contract house to conduct a POC study (species and study design to be confirmed) against intravenous Ativan®. Prior to despatch, analytical testing will be carried out on the formulation and a test certificate prepared. The nasal formulation will be administered using suitable devices provided by the contract house.

Pending a satisfactory outcome of the POC study the formulation will be progressed to the Stage 1 (Clinical Development).

4.2 STAGE 1 (Phase I Clinical Development) – Elan Activities

Elan will be primarily responsible for the development of a NanoCrystal® Dispersion intermediate (also referred to as Product Intermediate) for use in a nasal drug delivery system. The required activities are as follows:

4.2.1 Receipt and Testing of Drug Substance

Sufficient API will be ordered to support the development of the NCD bulk intermediate and will be tested and released according to a suitable test specification. Analytical methods for testing the drug substance will be validated to the appropriate stage of development.

4.2.2 Development and Validation of Analytical Methods.

Analytical methods for the NCD bulk intermediate will be developed and validated to the appropriate stage of development. Tests would include for example assay, impurities/related substances, particle size distribution, pH and viscosity.

4.2.3 Formulation and Process Development

A final NCD bulk intermediate formulation will be developed and the milling process optimised. Aspects investigated during the studies will include an assessment of antimicrobial preservatives and viscosifiers. Physical characteristics of the formulation such as particle size distribution, potential for crystal growth, viscosity and redispersibility will be assessed.

It is anticipated that these studies will be conducted on a laboratory scale mill (NanoMill® 01). Dependent on the size of the Phase I pharmacokinetic studies the Nanomill® 01 may subsequently be used for preparation of study.

4.2.4 Cleaning Validation Methods

Development of cleaning methods will be carried out and the methods validated. The study will confirm that the drug can be removed from contact surfaces of manufacturing equipment and that a procedure with adequate detection limits is available.

4.2.5 Process Development & Scale-up

The manufacturing process will be scale-up up to a larger mill (e.g. Nanomill® 1) to enable supplies of required quantities of material for larger phase I studies.

4.2.6 Stability Assessment

The NCD bulk intermediate product will be filled into suitable containers and placed on a stability study at 5°C, 25°C and 40°C and samples tested at 1, 3 and 6 month time-points. Analysis will include appearance, assay, impurities,

preservative levels, pH, viscosity, particle size distribution and microscopy assessments).

4.2.7 Clinical manufacture. Testing and release (NCD Bulk Intermediate)

Following acquisition of adequate stability data and a successful clinical trial application, a batch of NCD bulk intermediate for lorazepam nasal spray will be manufactured according to GMP procedures (batch size to be determined). The bulk intermediate would be tested and released according to a predefined specification.

5. Cost Estimates

For clarity all costings set out below are Elan estimates and are subject to the provision of the license agreement. All Stage 1 costs below shall be invoiced by Elan to Amarin on a time and material basis at Elan's prevailing FTE rate together with any third party costs. Note the costs provided below for Stage 1 are estimates only and are not to be considered binding. Note also that any work in any further lorazepam program (whether a further nasal program or any other agreed route) on the compound that may be conducted by Elan on behalf of Amarin shall be invoiced by Elan to Amarin as set out above.

STAGE 0: PRECLINICAL DEVELOPMENT (PROOF OF CONCEPT)

Stage	Cost (USD)
NCD Candidate Assessments	147,000
NCD Prototype Stability Assessment	
• Formulation preparation	12,000
• Analytical Testing	30,000
Proof of Concept Studies	
• Formulation manufacture	12,000
• Analytical testing and Release	8,000
SUBTOTAL	209,000

Proof of Concept Study	**est.**	75,000
TOTAL		284,000

cont .....

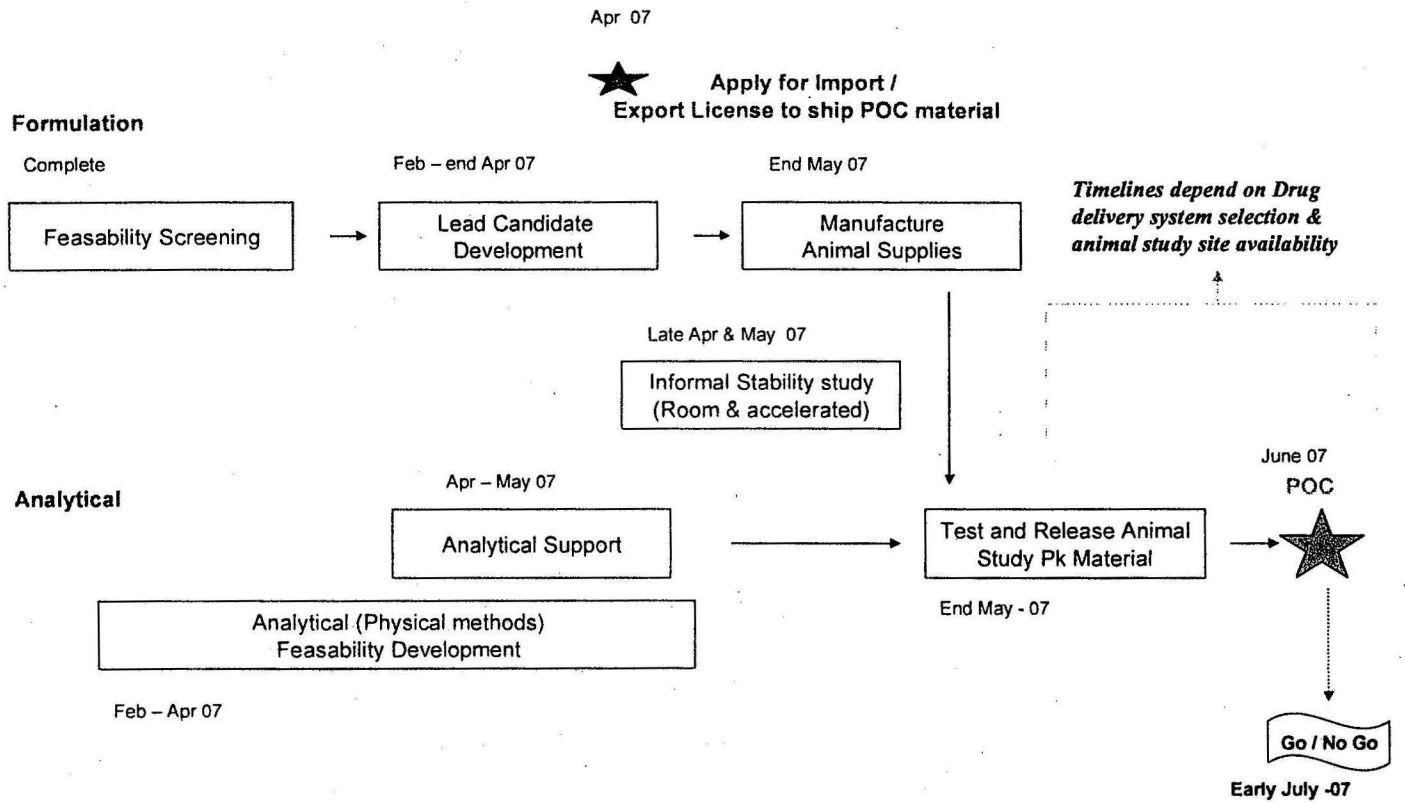
STAGE 1: PHASE I CLINICAL (PK STUDIES)

Receipt, Validation & Testing of GMP API	
• API Cost	16,000
• Method Development & Validation	24,000
• API Testing & release	22,000
Receipt, Validation & Testing of Excipients (x4)	
• Method Development & Validation	40,000
• Testing & Release	76,000
Development & Validation of Analytical Methods for NCD	
• Method Development	34,000
• Method Validation	96,000
Formulation & Process Development	
• Formulation Studies	120,000
• Analytical Support	22,000
• External Analysis (e.g. Micro & Preservative Efficacy)	10,000
Cleaning Method Development & Validation	47,000
Process Development & Scale-up	
• Processing Studies	88,000
• Analytical Support	20,000
Stability Assessment	
• Manufacture of Supplies	20,000
• Analytical testing	32,000
Clinical manufacture (NCD Bulk Intermediate)	
• Documentation	12,000
• Manufacturing	20,000
• Analytical testing & Release	24,000
Stability Study on Phase I Supplies	32,000
Project Management & Technical Meetings	75,500
TOTAL	830,500

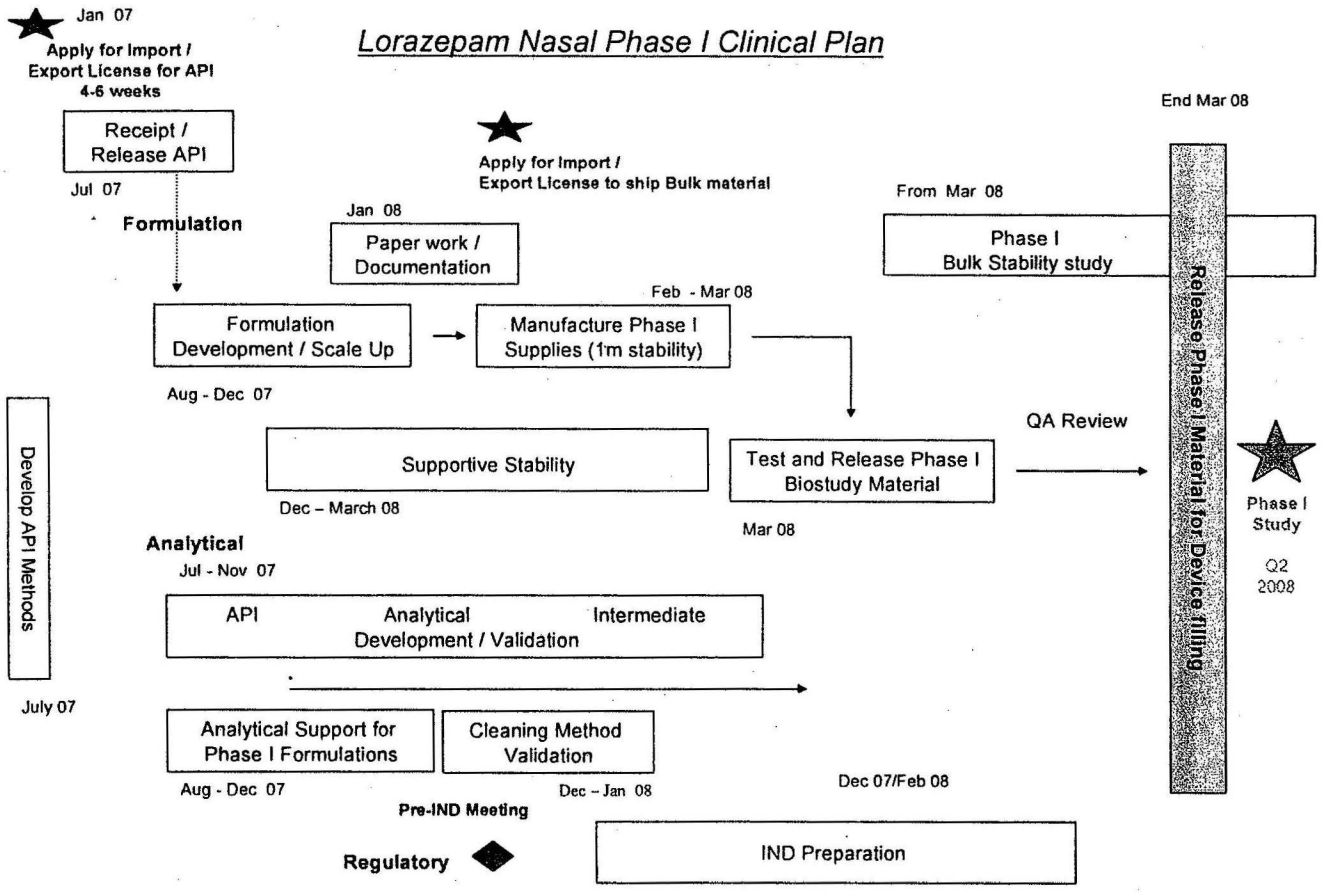
Costs of Clinical Studies to be established

APPENDIX 1 OF SCHEUDLE 2

Lorazepam Nasal Pre-Clinical Plan



APPENDIX II of Schedule 2



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SCHEDULE 3 TECHNOLOGICAL COMPETITORS OF ELAN

[
Abbott Laboratories (Soliqs and Knoll)
Alkermes, Inc.
Abraxis Pharmaceutical Products, Inc.
Andrx Corporation
BASF
Baxter International Inc.
Bespak Plc
Biovail Corporation International
Boehringer Ingelheim
Cardinal Health
Chrysalis Technologies
CyDex Inc
Dow Chemical Company
Dabur Pharma
E.I. DuPont de Nemours & Co.
Ethypharm
Eurand
Flamel Technologies
FMC
Gattefossé Group
GlaxoSmithKline plc.
ISP Pharma
K-V Pharmaceutical Company
Labopharm
Nektar Therapeutics
Penwest Pharmaceuticals Co.
SkyePharma plc]

SCHEDULE 4 MANUFACTURING COSTS

"Manufacturing Cost" means the fully absorbed cost of manufacture which shall be determined on the basis of the following elements:

(a) Direct material, labour and overhead cost; and

(b) Such indirect labour, factory, laboratory and other overhead costs properly allocable. Overhead allocations shall include expenses of plant maintenance and engineering, plant management, receiving and warehousing, disposal and treatment of waste, building occupancy, quality control, costs of services provided to manufacturing, insurance provided to manufacturing, and depreciation/amortisation of applicable capital.

Such allocations shall be in a manner consistent with US generally accepted accounting principles from time to time and in a manner consistent with expenses and overhead allocated to other products manufactured by Elan or its Affiliates.

Where some parts of the manufacture are conducted by unaffiliated third party(ies), Product Manufacturing Cost shall be the amount paid to such third party(ies) plus any of the aforementioned costs incurred by Elan or its Affiliates in completing the manufacture, or delivery of the Product Intermediate.

SCHEDULE 5 AMARIN STAGE I ACTIVITIES

[STAGE 1 (Phase I Clinical Development) – Amarin Activities

Amarin will be responsible for the following activities that will need to be completed to develop a final nasal product for use in Phase I clinical studies:

- Identification of a suitable nasal device.
- Development of final nasal spray formulation for device filling.
- Preservative efficacy testing of final nasal formulation.
- Device performance studies (e.g. droplet size and spray patterns).
- Device-formulation compatibility studies (e.g. adsorption and extractables).
- Identification of a third party for preparation filling of nasal devices.
- Stability studies on the final nasal formulation including chemical, physical formulation parameters and device performance.
- Development of test specifications for the nasal device and final formulation-device combination.
- Preparation of CTD and other documentation to support clinical trial applications.
- Manufacture, testing and release of clinical batches for Phase I clinical studies.
- Stability assessment on clinical batches.]

SIGNED

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Duly authorised for and on behalf of:
ELAN PHARMA INTERNATIONAL LIMITED

SIGNED

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Duly authorised for and on behalf of:
AMARIN PHARMACEUTICALS IRELAND LIMITED