UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K/A

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of September 2014

Commission File Number: 000-28508

Flamel Technologies, S.A.

(Translation of registrant's name into English)

Parc Club du Moulin à Vent
33 avenue du Dr. Georges Levy
69693 Vénissieux Cedex France
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

Indicate by check mark whether registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes o No ☒

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____

Filing of Exhibits

Flamel Technologies, S.A. (the "Company") is filing this amendment No. 1 (this "Amendment No. 1") to its Report on Form 6-K filed September 15, 2014 (the "Original Report") for the sole purpose of amending and re-filing Exhibits 10.1, 10.5 and 10.6. The Company sought confidential treatment under Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended, for portions of Exhibits 10.1, 10.5 and 10.6 filed thereto and, following correspondence with the Staff of the Commission's Division of Corporation Finance, is re-filing Exhibits 10.1, 10.5 and 10.6 with less information redacted. Exhibits 10.1, 10.5 and 10.6 filed herewith supersede in their entirety Exhibits 10.1, 10.5 and 10.6 filed with the Original Report. Except for the revised Exhibits 10.1, 10.5 and 10.6, this Amendment No. 1 does not amend any other information set forth in the Original Report. This Amendment No. 1 does not reflect events occurring after the filing of the Original Report and, other than the filing of new versions of Exhibits 10.1, 10.5 and 10.6, does not modify or update the disclosure in the Original Report in anyway.

Exhibit Index

Exhibit No.	Description
10.1*	License Agreement, dated March 26, 2003, by and between Flamel Technologies, S.A. and SB Pharmco Puerto Rico Inc. (the "2003 License Agreement")
10.5*	License Agreement, dated November 24, 2004, by and between by and between Flamel Technologies, S.A. and SB Pharmco Puerto Rico Inc.
10.6*	Supply Agreement for Commercial Supply, dated September 30, 2011, by and between Flamel Technologies, S.A. and SmithKline Beecham (Cork) Limited

* Confidential treatment has been requested for the redacted portions of this agreement. A complete copy of the agreement, including the redacted portions, has been filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: November 14, 2014

FLAMEL TECHNOLOGIES, S.A.

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: Chief Executive Officer

Exhibit 10.1

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

LICENSE AGREEMENT

dated March 26, 2003

by and between

Flamel Technologies, S.A.

and

SB Pharmco Puerto Rico Inc.

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LICENSE AGREEMENT

This License Agreement (the "Agreement"), dated March 26, 2003 is made by and between SB Pharmco Puerto Rico, Inc., a GlaxoSmithKline company organized and existing under the laws of the territory of Puerto Rico, with its principal place of business at Road 172, KM 9.1/Bo. Certenejas, Cidra, Puerto Rico 00639 (hereinafter, "GSK") and Flamel Technologies, S.A., a corporation organized and existing under the laws of France, with its principal place of business at Parc Club du Moulin a Vent, 33 Avenue du Docteur Georges Levy 69693 Venissieux Cedex, France, (hereinafter, "Flamel") (each a "Party" and collectively, the "Parties").

R E C I T A L S

WHEREAS, Flamel has developed certain proprietary technology related to Flamel Micropump Technology (as defined below);

WHEREAS, GSK and Flamel have undertaken a feasibility study (the "Feasibility Agreement" as defined below) to develop a Formulation (as defined below) by applying the Flamel Micropump Technology to Carvedilol (as defined below and referred to in the Feasibility Agreement the "Molecule");

WHEREAS, Flamel is the owner of all right, title and interest in, or otherwise controls, certain Flamel Patent Rights (as defined below) and Flamel Know-How (as defined below) relating to the use of the Flamel Micropump Technology;

WHEREAS, GSK desires to obtain from Flamel an exclusive license under the Flamel Patent Rights and Flamel Know-How to discover, develop, make, have made, use, market, offer to sell, sell and import the Product (as defined below); and

WHEREAS, Flamel desires to grant to GSK, an exclusive license throughout the world under this Agreement to discover, develop, make, have made, use, market, sell, offer to sell and import the Product throughout the world under the aforesaid Flamel Patent Rights and Flamel Know-How.

NOW, THEREFORE, in consideration of the mutual covenants set forth in this Agreement, GSK and Flamel hereby agree as follows:

ARTICLE 1
DEFINITIONS

1.1. "**Affiliate**" means any legal entity (such as a corporation, partnership, or limited liability company) that directly or indirectly Controls, is Controlled by or is under common Control with a Party to this Agreement. For the purposes of this definition, the term "Control" means: (i) beneficial ownership of at least fifty percent (50%) of the voting securities of a corporation or other business organization with voting securities (or such lesser percentage required under local jurisdiction); (ii) a fifty percent (50%) or greater interest in the net assets or profits of a partnership or other business organization without voting securities; or (iii) the ability to direct the affairs of any such entity.

1.2. "**Calendar Quarter**" means a three (3) month period ending on March 31, June 30, September 30 or December 31.

1.3. "**Carvedilol**" means (1-(9H-carbazol-4-yloxy)-[[2-2(2-methoxyphenoxy)ethyl] amino]-2-propanol), the compound that is known by the generic name of Carvedilol and including all racemates, chelates, complexes, enantiomers, diastereoisomers, salts, bases, esters, hydrates, solvates, polymorphs, crystal forms, crystal habits, prodrugs, isotopic or radiolabeled equivalents, metabolites, or the like, thereof and all mixtures and any of the foregoing, and compositions comprising Carvedilol.

1.4. "**Confidential Information**" means (i) any proprietary or confidential information or material in tangible form disclosed by a Party hereunder that is marked as "Confidential" at the time it is delivered to the receiving Party, and/or (ii) proprietary or confidential information disclosed orally hereunder that is identified as confidential or proprietary when disclosed and such disclosure of confidential information is confirmed in writing within a reasonable period of time thereafter by the disclosing Party.

1.5. "**Control**," "**Controls**," "**Controlled**," or "**Controlling**" means (except with respect to "Affiliate" as defined in Section 1.1) possession of the ability to grant the licenses or sublicenses as provided herein without violating the terms of any license agreement or other arrangement with any Third Party, or any government regulation or statute.

1.6. "**Commercially Reasonable Efforts**" means efforts and resources comparable to those used by GSK and its Affiliates for a compound or product with similar market or commercialization prospects at a similar stage in its product life cycle, taking into account the stage and risk of development or commercialization of Product, the cost-effectiveness of efforts or resources while optimizing profitability, the competitiveness of alternative compounds or products that are or are expected to be in the marketplace, the scope and duration of patent rights or other proprietary rights related to Product, the profitability of Product and alternative products and other relevant commercial factors.

1.7. "**Cost Of Goods Sold**" or "**COGS**" means Flamel's fully allocated cost of manufacturing, comprising all direct costs (including but not limited to, labor, materials, energy, utilities, quality control or other costs incurred directly in the manufacturing of Product that is the active pharmaceutical ingredient thereof) and indirect costs (including but not limited to administrative labor costs, manufacturing facility and equipment maintenance, relevant insurance, and depreciation of manufacturing equipment and manufacturing facilities) specifically allocable to the production and delivery of Product to GSK; such calculation being based upon accepted contract manufacturing industry standards or generally accepted accounting principles.

1.8. "**EMEA**" means the European Agency for the Evaluation of Medicinal Products or any successor agency thereof performing similar functions.

1.9. "**Effective Date**" means the date on which this Agreement is executed.

1.10. "**FDA**" means the Food and Drug Administration of the United States Department of Health and Human Services, or any successor agency thereof performing similar functions.

1.11. "**Feasibility Agreement**" means the Feasibility Study Agreement dated April 8, 2002 between SmithKline Beecham Corporation d/b/a GlaxoSmithKline and Flamel Technologies, S.A., as amended.

1.12. "**First Commercial Sale**" means the first sale of Product to a Third Party by GSK or its Affiliate(s) or sublicensee(s) in a country in the Territory.

1.13. "**Flamel Micropump Technology**" means a multiple-dose system containing a large number of microparticles that may be contained in capsule, tablet, orally dispersible, sachet or suspension formulations. It is expected that the microparticles are released in the stomach and pass into the small intestine, where each microparticle operates as a miniature delivery system, releasing the drug at a controlled rate and over an extended period of time.

1.14. "**Flamel Patent Rights**" means: (i) all patents and patent applications in existence as of the Effective Date or during the Term of this Agreement claiming generically or specifically a product or process using the Flamel Micropump Technology; and (ii) any divisions, continuations, continuations-in-part, reissues, reexaminations, patents of additions, extensions or other governmental actions that extend any of the subject matter of the patent applications or patents in clause (i) above, and any substitutions, confirmations, registrations or revalidations of any of the foregoing, in each case that is owned or Controlled, in whole or part, by license, assignment or otherwise by Flamel as of the Effective Date, or during the Term of the Agreement, to the extent Flamel has the right to license or sublicense such Flamel Patent Rights, and subject to any limitations of any such license or sublicense. The current list of patent applications and patents encompassed within Flamel Patent Rights is set forth in Schedule 1.14, which shall be updated by Flamel on a semi-annual basis during the Term of the Agreement. For the avoidance of doubt, Flamel Patent Rights shall include Flamel-Owned Inventions (as defined in Section 5.1.3).

1.15. "**Flamel Know-How**" means all ideas, non-public inventions, data, instructions, processes, procedures, formulas, expert opinions and information, including, without limitation, biological, chemical, toxicological, pharmacological, physical and analytical, formulation, clinical, analytical, stability, safety, manufacturing and quality control data and information, in each case, that are necessary or useful for the development, testing, use, manufacture or sale of the Formulation or Product and that is in the possession of and owned or Controlled by Flamel as of the Effective Date or during the Term of this Agreement. Flamel Know-How shall include Flamel-Owned Inventions (as defined in Section 5.1.3), but only to the extent that such are not included in Flamel Patent Rights. Flamel Know-How shall be Confidential Information of Flamel as defined in Section 1.4.

1.16. "**Formulation**" means any formulation of Carvedilol developed under the Feasibility Agreement.

1.17. "**Full-Time Equivalent**" or "**FTE**" means the effort equivalent to one (1) full-time employee of Flamel working on a specific project or task assigned by GSK under this Agreement, who is qualified to perform such work, based on a total of one thousand, eight hundred and eighty (1,880) hours of work per year, as further explained in Section 3.8 hereof.

1.18. "**Licensed Technology**" means Flamel Know-How and Flamel Patent Rights.

1.19. "**Joint Development Committee**" means the Joint Development Committee described in Section 4.5.

1.20. "**Major Market**" means any one of the following countries: the United Kingdom; France, Spain; Germany; Italy; Japan; or the United States.

1.21. "**Marketing Authorization Application**" or "**MAA**" means a Marketing Authorization Application submitted to the EMEA for the purpose of obtaining European Commission approval or any other applications for Registration based on mutual recognition procedure by the Committee for Proprietary Medicinal Products ("CPMP") for the marketing of a Product for the countries located within the EU.

1.22. "**Marketing Approval**" means the approval of an NDA in the US, the approval of an MAA in the EU, or any corresponding approvals in any other countries of the Territory, including any pricing and reimbursement approvals in any country of the Territory where such approvals are required for commercially reasonable launch of a Product in such country.

1.23. "**New Drug Application**" or "**NDA**" means a means a New Drug Application submitted to the FDA to obtain FDA approval for the marketing of a Product in the United States.

1.24. "**Net Sales**" means the actual invoiced gross sales of Product to Third Parties by GSK, its Affiliates or sublicensees, as recorded by the selling party in accordance with generally accepted accounting principals, less the following to the extent included in the calculation of invoiced sales:

(i) credited allowances to such Third Party customers for spoiled, damaged, rejected, recalled, outdated and returned Products and for reasonable retroactive price reductions;

(ii) freight, transportation, warehousing, storage, postage and insurance invoiced to such Third Party;

(iii) the amounts of trade and cash discounts actually allowed, to the extent such trade and cash discounts are specifically allowed on account of the purchase of such Product;

(iv) sales taxes, excise taxes, use taxes and import/export duties actually due or incurred in connection with the sales of the Product to any Third Party;

(v) reasonable allowances, adjustments, reimbursements, discounts, chargebacks and rebates granted to Third Parties, including, but not limited to, rebates given to health care organizations or other Third Parties, whether during the actual royalty period or not;

(vi) any bona fide payment made by GSK to government agencies with respect to sales of Product in order to be allowed to tender the sale of the Product in a given country in the Territory, and any bona fide payment made by GSK to any Third Parties for assistance provided to GSK in this process; and

(vii) actual chargeoffs for bad debt.

Sales or transfers of Product among GSK, an Affiliate and/or a sublicensee shall be excluded from the computation of Net Sales, and no royalties will be payable on such sales.

1.25. "**Product**" means any presentation or presentations of Carvedilol that incorporate the Licensed Technology, alone or in combination with other therapeutically active compounds, for the therapeutic or prophylactic treatment of diseases and conditions in humans in any dosage or strength.

1.26. "**Term**" means the term of this Agreement as set forth in Section 9.1.1.

1.27. "**Territory**" [***] provided that, should this Agreement expire as to any country or territory pursuant to Section 9.1, or should GSK terminate this Agreement as to any country or territory pursuant to Section 9.4, such country or territory shall no longer be considered within the Territory. As used in this Agreement, "country" shall refer to country or territory, as appropriate.

1.28. "**Third Party(ies)**" means any party(ies) other than Flamel, GSK, or an Affiliate of either of them.

1.29. "**Valid Claim**" means either: (i) a claim of an issued or unexpired patent within Flamel Patent Rights that has not been held unenforceable, unpatentable or invalid by a governmental agency or a court of competent jurisdiction in any unappealable or unappealed decision within the time allowed for appeal, and that has not been admitted to be unenforceable, unpatentable or invalid through abandonment, reissue, disclaimer or otherwise, or (ii) a claim of a pending patent application within Flamel Patent Rights that has not been abandoned or finally rejected by Flamel without the possibility of appeal or refiling, such that the claim at issue has been under examination for less than three (3) years; provided, however, that such three (3) year time limit shall not apply if Flamel has exercised diligence in pursuing such pending patent application.

1.30. "**Work Plan**" means the plan, as described in Sections 4.3 and 4.5, and as forth in Schedule 1.30 to this Agreement, attached hereto and incorporated herein.

ARTICLE 2
LICENSE GRANTS

2.1. **Statement of Ownership**. The Parties agree that GSK owns the Formulation; provided, however, that such ownership shall not be construed to grant GSK any ownership rights to the Licensed Technology.

2.2. **License Grant from Flamel to GSK**. Subject to the terms and conditions of this Agreement, Flamel hereby grants to GSK an exclusive license, even as to Flamel, with the right to grant sublicenses, under Licensed Technology, to make, have made, use, sell, offer for sale and import the Product in the Territory. Subject to the provisions of Article 3 hereof, such right shall expressly include the right to sublicense all aspects of the development, manufacture and commercialization of the Product without further consent or approval of Flamel.

2.3. **Exclusivity Covenant**. Subject to the terms and conditions of this Agreement, Flamel agrees that Flamel will not develop or grant rights of any kind to any Third Party under the Licensed Technology related to Carvedilol.

ARTICLE 3
PAYMENTS

3.1. **Initial Fee to Flamel**. In partial consideration for the license to Licensed Technology granted to GSK under Section 2.1 of this Agreement, GSK shall pay to [***] on or before March 31, 2003.

3.2. **Milestone Payments to Flamel**. In partial consideration for the license to Licensed Technology granted to GSK under Section 2.1 of this Agreement, GSK shall pay Flamel the following amounts following the first achievement by Flamel, GSK, its Affiliates or sublicensees, as applicable, as the case may be, of each of the following milestone events with respect to the Product ("Milestones"):

	Milestone Event	Amount
1.	[***]	[***]
2.	[***]	[***]
3.	[***]	[***]
4.	[***]	[***]
5.	[***]	[***]
6	[***]	[***]
7.	[***]	[***]

	Milestone Event	Amount
8.	[***]	[***]
9.	[***]	[***]
10.	[***]	[***]

provided that:

(i) No Milestone shall be paid more than one time;

(ii) Payment shall not be owed for a Milestone Event that is not achieved;

(iii) The occurrence of all events leading to Milestones shall be determined by criteria reasonably established by GSK and provided in writing by. GSK to Flamel;

(iv) Milestone payments shall be payable by GSK to Flamel within forty-five (45) business days after achievement of the Milestone; and

(v) Milestone payments shall be payable when achieved, regardless of the order in which they are achieved.

3.3. **Royalties**.

(a) **Royalty Rate**. In partial consideration of the license and rights granted under Section 2.1, GSK shall pay royalties to Flamel on Net Sales of all Products covered by a Valid Claim equal to (i) [***] of annual Net Sales of such Products up to and including [***], (ii) [***] on annual Net Sales of such Products in excess of [***] and up to and including [***], and (iii) [***] on annual Net Sales of such Products in excess of [***].

Example: In the event Net Sales of the Product equal [***], GSK shall pay a royalty [***], calculated as follows: [***] multiplied by [***], plus [***] multiplied by [***], plus [***] multiplied by [***].

(b) **Payment of Royalties**. Payment of royalties shall be made [***] days after the end of each Calendar Quarter on all Net Sales of the Product in the preceding quarter ("Quarterly Payment"). Each Quarterly Payment shall be accompanied by a report detailing the total Net Sales of the Product by country in the Territory for the preceding Calendar Quarter, GSK shall include in the Quarterly Payment for the fourth Calendar Quarter of each calendar year any additional royalties owed for Net Sales in the calendar year to which the last Calendar Quarter relates, based on the annual Net Sales. On or before the end of the first Calendar Quarter following any calendar year, GSK shall reconcile the actual royalties paid to Flamel during the prior calendar year against the amount of royalties that should have been paid to Flamel during that calendar year. In the event that GSK has overpaid the royalties due Flamel, GSK shall be entitled to deduct such overpayment from the royalties determined to be due for the first Calendar Quarter of the calendar year following the calendar year in which the overpayment was made or, if no royalties are due for the first calendar year, in any subsequent Calendar Quarter in which royalties are due to Flamel. The Net Sales calculation includes estimated sales adjustments for Medicare/Medicaid and Managed Care Rebates and chargebacks. Upon verification of actual sales adjustments, actual Net Sales will be reconciled against the estimated Net Sales. Any necessary adjustments, whether in the form of a credit or a debit, will be reflected in the next quarterly report due Flamel.

3.4. **Royalties on Net Sales Where No Valid Claim of Flamel Patent Rights Exists**. In the event that no royalty on certain Net Sales is paid under Section 3.3 because no Valid Claim exists in a country, as further consideration for the licenses granted to GSK under Section 2.2 of this Agreement, GSK shall pay to Flamel [***] of the otherwise applicable royalty rate set forth in Section 3.3 on such Net Sales in such country.

3.5. **Single Royalty; Non-Royalty Sales**. No royalty shall be payable under Section 3.3.1 above with respect to sales of the Product among GSK, its Affiliates and sublicensees for resale to a Third Party. In no event shall more than one such royalty be due Flamel hereunder with respect to the sale of Product, even if such Product is covered by more than one Valid Claim.

3.6. **Compulsory Licenses**. Should a compulsory license be granted by Flamel to a Third Party under the applicable laws of any country in the Territory with respect to Product under the Licensed Technology licensed hereunder to GSK, the royalty rate payable hereunder for sales of Products in such country will be adjusted to match any lower royalty rate granted to such Third Party for such country, with respect to the sales of such Products, and during such periods, for which such Third Parties sell under the compulsory license material quantities of articles that compete with the Products then marketed and sold by GSK in that country comprising the Product identical to the compound contained in such articles.

3.7. **Third Party Fees or Royalties**.

(a) Flamel shall be fully responsible for obtaining a Third Party license and for the payment of any additional royalties, license fees, milestones and any and all other payments due to Third Parties where:

(i) the use, development, manufacture, marketing, selling or importing of Product under Licensed Technology is deemed by a court of competent jurisdiction to infringe a claim of a patent(s) owned or controlled by a Third Party in any given country of the Territory and Flamel or GSK licenses such patent(s) in settlement of such claims; and

(ii) both Parties agree, or it is determined by outside counsel approved by both Parties, that it is necessary for Flamel to take a license to a Third Party and to pay royalties or other fees to such Third Party to obtain a license to practice any Third Party's rights in order to manufacture, use, commercialize or develop a Product under the Licensed Technology in any given country of the Territory.

(b) If GSK and Flamel together have a reasonable belief that a Third Party may assert a claim or right against GSK or Flamel with respect to the Licensed Technology that may result in an infringement claim being brought or asserted by such Third Party with respect to the Licensed Technology, then in such event, GSK may, or may request Flamel to, obtain a license or other settlement with such Third Party, and if GSK obtains such a license, GSK may offset the costs of such royalties or settlement amounts against payments otherwise due Flamel. If Flamel obtains such a license, Flamel will bear all costs associated with such license. If GSK alone has a reasonable belief that a Third Party may assert a claim or right against GSK or Flamel with respect to the Licensed Technology that may result in an infringement claim being brought or asserted by such Third Party with respect to the Licensed Technology, but Flamel does not share such belief, GSK may still obtain a license or other settlement with such Third Party at GSK's sole expense and GSK shall be entitled to submit the matter to arbitration. If the arbitrator determines that the manufacture, use, commercialization or development of Product under the Licensed Technology impinges upon the intellectual property rights of any Third Party such that it is necessary for Flamel and/or GSK to pay royalties or other fees to such Third Party to obtain a license to practice any Third Party's rights in order to manufacture, use, commercialize or develop a Product under the Licensed Technology in any given country of the Territory, then GSK shall be entitled to offset one hundred percent (100%) of the costs of associated with such license or settlement against payments otherwise due Flamel. For the avoidance of doubt, if GSK seeks a license to the Third Party technology that is solely a gastro-retentive technology, then the costs of such license will be borne solely by GSK.

3.8. **Flamel FTE Payments**. As consideration for work conducted by Flamel FTE's as authorized by GSK, GSK shall pay Flamel per year per Flamel FTE at a rate of [***] per hour, which rate shall increase each calendar year upon the anniversary date of the Effective Date by a factor to be agreed between the Parties as reasonably reflecting the prevailing rate of inflation in France in the previous calendar year but no greater than [***], and shall reimburse Flamel for all GSK pre-approved out-of-pocket costs and expenses (including, but not limited to, reasonable travel and hotel costs) as authorized by GSK. GSK shall make payment to Flamel on a quarterly basis for work conducted by Flamel and authorized by GSK within [***] days of receipt of an invoice from Flamel. Each invoice shall describe in detail the work performed by Flamel FTE's and a breakdown of hours of work performed, as is customary for the industry and the type of work being performed. All FTE's shall be deemed employees of Flamel and Flamel shall be responsible for paying all FTE's salaries, benefits, and payroll (or similar) taxes. It is understood that Flamel shall keep weekly records of the FTE costs which shall be sufficient for purposes of this Agreement.

3.9. **Right to Offset**. The Parties agree that in the event that any payment obligation on the part of Flamel to GSK under the terms of this Agreement is not made by Flamel when such payment is due, then in such event and as long as such amount remains unpaid, GSK shall be entitled to offset such unpaid amount against any amounts which may otherwise be due to Flamel from GSK. In the event that GSK is required to pay a license payment in the form of a lump sum payment or an ongoing royalty stream to a Third Party as part of a settlement of a patent infringement claim, suit or proceeding relating to the license granted under Section 2.2 of this Agreement, or in the event that there has been an error in the calculation of 14TE costs or Cost of Goods Sold resulting in an overpayment by GSK to Flamel for such FTE's or Product, GSK shall be entitled to offset such payment(s), or overpayment, as the case may be, from the royalties due Flamel under this Agreement.

3.10. **Currencies**. Payments under this Agreement shall be made in United States Dollars. Revenues and expenses for each country shall be converted into United States Dollars using the applicable exchange rate for converting such local currency to the United States Dollar in accordance with the exchange rates reasonably used by GSK in producing its financial accounts at the time.

3.11. **Manner of Payment**. All sums due to Flamel under this Agreement shall be payable in US dollars by wire transfer in immediately available funds to the designated account below in accordance with the following wire instructions, or such other account and instructions as may from time to time be designated in writing by an officer of Flamel:

Bank:	Citibank F.S.B.
ABA Number:	254070116
Account Name:	Flamel Technologies, S.A.
Account Number:	6678 8404

GSK shall use its reasonable efforts to notify Flamel as to the date and amount of any such wire transfer to Flamel at least two (2) business days prior to such transfer.

3.12. **Tax Withholding**. GSK may withhold taxes in the event that revenue authorities in any country require the withholding of taxes on amounts paid hereunder to Flame. GSK will deduct such taxes from such payment and will be paid by GSK to the proper taxing authority on behalf of Flamel. GSK will procure a tax receipt or provide such other proof of payment for any such withholding evidencing payment of such taxes, which will be forwarded to Flamel. GSK agrees to assist Flamel in claiming exemption from such deductions or withholdings under any applicable double taxation or similar agreement or treaty.

3.13. **Financial Records and Audits**.

(a) Flamel's Right to Audit. Flamel, at its own cost, through an independent auditor reasonably acceptable to GSK, may inspect and audit the records of GSK pertaining to the sale of Product and any estimated or actual royalties due to Flamel under Section 3.3. GSK shall provide such auditors with access to the records during reasonable business hours. Such access need not be given to any such set of records more often than once each calendar year, or more than three (3) years after the date of any report to be audited, and the auditors shall report to Flamel only the amount of royalty due, based on good faith estimates of Net Sales. Flamel shall provide GSK with written notice of its election to inspect and audit the records related to the royalty due hereunder not less than thirty (30) days prior to the proposed date of review of GSK's records by Flamel's auditors. GSK shall maintain sufficient records to permit the inspection and auditing permitted hereunder for three (3) years after the date of each respective reporting period. GSK shall prepare its records and reports according to the generally accepted accounting principles of the United Kingdom. The auditor's review shall be limited to determining whether a good faith estimate was used in the royalty calculation, and shall not be based upon whether such estimate was, in fact subsequently determined to be less than the actual Net Sales. Should the auditor find any underpayment of royalties paid as a result of such quarterly estimates not being conducted in good faith, GSK shall promptly pay Flamel the amount of such underpayment, plus interest at the rate of [***] per month or portion thereof on the amount of any underpayment from the date payment was due, and shall reimburse Flamel for the cost of the audit should such underpayment equal or exceed [***] of royalties paid during the time period audited. Should the auditor find any underpayment of royalties based upon the reconciled annual Net Sales, GSK shall promptly pay Flamel the amount of such underpayment, plus interest at the rate of [***] per month or portion thereof on the amount of any underpayment from the date payment was due, and shall reimburse Flamel for the cost of the audit should such underpayment equal or exceed [***] of royalties paid during the time period audited.

(b) **GSK's Right to Audit**. GSK, at its own cost, through an independent auditor reasonably acceptable to Flamel, may inspect and audit the records of Flamel pertaining to 1i and manufacturing costs, including the calculation of Cost of Goods Sold. Flamel shall provide such auditors with access to the records during reasonable business hours. Such access need not be given to any such set of records more often than once each calendar year, or more than three (3) years after the Effective Date, and the auditors shall report to GSK only as to whether an error was made in the calculation of FIE costs or Cost of Goods Sold. GSK shall provide FLAMEL with written notice of its election to inspect and audit the records related to FTE costs and the Cost of Goods Sold calculation not less than thirty (30) days prior to the proposed date of review of Flamel's records by GSK's auditors. Flamel shall maintain sufficient records to permit the inspection and auditing permitted hereunder for three (3) years after the Effective Date. Should the auditor find any error, GSK shall be entitled to offset such overpayment in accordance with Section 3.9.

ARTICLE 4
DEVELOPMENT, COMMERCIALIZATION AND SUPPLY

4.1. **Responsibility for Product Development and Commercialization by GSK**. GSK shall undertake and resource all development of Product in the Territory so long as it retains full rights thereto under this Agreement, and shall bear all costs it incurs in conducting such development, including, without limitation, expenses incurred in conducting clinical trials. GSK shall be responsible, at its sole expense on a country-by-country basis, for the commercialization and distribution of the Product in the Territory so long as GSK retains rights, on a country-by-country basis, thereto under this Agreement. Notwithstanding the first two sentences of this Section 4.1, GSK has the sole discretion, using its reasonable business judgment, to decide whether to develop or commercialize Product in any country in the Territory.

4.2. **Flamel Technology Transfer**. Within fifteen (15) days of GSK's request, Flamel shall use its commercially reasonable efforts to promptly transfer, or cause to be transferred to GSK, a copy of Flamel Know-How relating to Flamel Micropump Technology, the Formulation and the Product, to enable GSK to develop, manufacture and commercialize Product, at GSK's expense. Such technology shall include, at a minimum, the information set forth in Schedule 1.30 to this Agreement, attached hereto and incorporated herein.

4.3. **Flamel Assistance**. From time to time, GSK may request Flamel's assistance in the development and commercialization, of the Formulation or Product and Flamel shall perform such work as is reasonably requested by GSK in a written statement of work that shall include an estimate of the costs of such work and authorized in writing by the JDC. GSK will compensate Flamel for such authorized work performed in accordance with such statement of work pursuant to Section 3.8.

4.4. **Development and Filing by GSK**. GSK shall use Commercially Reasonable Efforts to file an NDA for a Product in the United States in a timely manner, consistent with the development plan for the Product and taking into consideration the regulatory and commercial climate and scientific and clinical requirements for the development of the Product. GSK shall keep Flamel apprised of its timings for such filing and all progress via the JDC set forth in Section 4.5, including reasons for any changes to such filings. From time to time, GSK may request Flamel's assistance in the preparation of the NDA and/or the MAA, and Flamel shall perform such work as is reasonably requested by GSK. GSK will compensate Flamel for such work pursuant to Section 3.8.

4.5. **Joint Development Committee**. Promptly after the Effective Date, the Parties shall establish a Joint Development Committee ("JDC"). The JDC shall be chaired by GSK and GSK shall be responsible for the issuance of all meeting minutes. The JDC shall have the responsibility to oversee, review, coordinate and expedite the transfer of technology and the development of Product and the progress of work being conducted under the Work Plan, and to update the Work Plan from time to time. The JDC shall be comprised of three (3) GSK representatives and three (3) Flamel representatives. The JDC shall meet quarterly, or as more or less often as otherwise agreed by the Parties, at such locations as the Parties agree. Any decision that cannot be made unanimously by the JDC shall be discussed by the appropriate representatives of the Parties; provided that, in the event of continued disagreement, or otherwise, GSK shall make all final decisions regarding the conduct and progress of the development and commercialization of Product.

4.6. **Completion of Existing Studies initiated by Flamel prior the Effective Date**. The Parties acknowledge that Flamel is conducting additional studies with respect to the Flamel Micropump Technology and Carvedilol. These studies are listed in Schedule 4.6. Flamel agrees to complete these studies pursuant to the terms of the Feasibility Agreement and will provide such necessary quantities and doses of clinical trial materials as listed on Schedule 4.6 of the "small particle micropump" to GSK.

4.7. **Supply**. Within ninety (90) days after the Effective Date, the Parties shall negotiate the terms of supply for Phase II clinical supply of Product, and, if in GSK's reasonable judgement, GSK requires Flamel to supply a portion or all of GSK's requirements of the Formulation or Product for Phase III and/or commercial supply, the Parties will negotiate the terms of such supply in a definitive agreement (the "Supply Agreement"). The Supply Agreement will contain terms and conditions as are customary on the pharmaceutical industry and shall include, but not be limited to terms covering the quality, specifications, yield, quantity, payment, batch failure, change control, regulatory obligations and audits, audit rights for GSK consistent with rights granted herein, information related to manufacture of Product and the Formulation, QA release, testing and shipping requirements. All supply of Product for Phase II or Phase III clinical studies shall be at a price equal to [***]. All supply of Product for commercial sale shall be at a price equal to [***]. Notwithstanding the foregoing, and irrespective of the audit provisions contained in the Supply Agreement, GSK shall be entitled to conduct an audit of Flamel's manufacturing facilities prior to the implementation of the Supply Agreement for the purpose of ascertaining the commercial readiness of Flamel to manufacture Product. Such audit shall occur upon advance reasonable notice, in writing, delivered at least five (5) days' prior such audit and no more than once per annum.

ARTICLE 5
INTELLECTUAL PROPERTY

5.1. **Ownership of Inventions**.

5.1.1. **Inventions under the Feasibility Agreement**. Notwithstanding anything to the contrary herein, all inventions owned by GSK under the Feasibility Agreement shall continue to be the exclusive property of GSK, and all inventions owned by Flamel under the Feasibility Agreement shall continue to be the exclusive property of Flamel.

5.1.2. **GSK Ownership**. Flamel shall promptly disclose to GSK any inventions or improvements made or conceived by Flamel, or any person under Flamel's supervision, either alone or jointly in the course of or as a result of the work under the Feasibility Agreement, or hereunder that pertain to Carvedilol, the Formulation and/or Product (the "GSK-Owned Inventions). All inventions resulting from the Feasibility Agreement or hereunder that relate to Carvedilol, the Formulation and/or Product shall be owned by GSK irrespective of whether the inventor is an employee of Flamel or GSK or whether there are joint inventors, some of whom are employees of Flamel and some of whom are employees of GSK. GSK shall have the right to file patent applications on any such GSK-Owned Inventions and shall receive the cooperation of the employees of Flamel in preparing such patent applications.

5.1.3. **Flamel Ownership**. GSK shall promptly disclose to Flamel any inventions or improvements that pertain solely to the Flamel Micropump Technology made or conceived by GSK, or any person under GSK's supervision, either alone or jointly in the course of or as a result of work under the Feasibility Agreement or hereunder, or as a result of information supplied hereunder that pertain to the Flamel Micropump Technology (the "Flamel-Owned Inventions"). All inventions resulting from the Feasibility Agreement or hereunder relating solely to the Flamel Micropump Technology shall be owned by Flamel irrespective of whether the inventor is an employee of Flamel or GSK or whether there are joint inventors, some whom are employees of Flamel and some of whom are employees of GSK. Flamel shall have the right to file patent applications on any such Flamel-Owned Inventions and shall receive the cooperation of the employees of GSK in preparing such patent applications.

5.2. **Disclosure of Flamel Patent Rights**. Flamel warrants and represents that it has disclosed, or promptly after the Effective Date hereof, will disclose to GSK the complete texts of all Flamel Patent Rights including all patent applications filed by Flamel as of the Effective Date that relate or may reasonably relate to the Formulation and/or Product. Flamel warrants and represents that it has disclosed all information received as of the Effective Date concerning the institution or possible institution of any interference, opposition, re-examination, reissue, revocation, nullification or any official proceeding involving a Flamel Patent Right anywhere in the Territory. Flamel further warrants and represents that it will disclose to GSK the complete texts of all Flamel Patent Rights, including all patent applications filed by Flamel after the Effective Date that relate, or may reasonably relate to the Formulation and/or the Product as well as all information received after the Effective Date concerning the institution or possible institution of any interference, opposition, re-examination, reissue, revocation, nullification or any official proceeding involving a Flamel. Patent Right anywhere in the Territory. GSK shall have the right to review all such pending applications to the extent that they may have a material impact on the Product and other proceedings and make recommendations to Flamel concerning them and their conduct. Flamel agrees to keep GSK promptly and fully informed of the course of patent prosecution or other proceedings by means that include providing GSK with copies of substantive communications, search reports and Third Party observations submitted to or received from patent offices throughout the Territory. GSK shall provide such patent consultation to Flamel at no cost to Flamel and shall treat all information disclosed to it under this Section as confidential and subject to the provisions of this Agreement.

5.3. **Filing, Prosecution, Maintenance**. Each Party shall promptly notify the other on at least a quarterly basis, upon the making, conceiving or reducing to practice of any intellectual property, invention or discovery referred to in Section 5.1. With respect to any such invention:

(a) GSK shall have the first right, using in-house or outside legal counsel selected at GSK's sole discretion, to prepare, file, prosecute, maintain and extend patent applications and patents concerning all such GSK Owned Inventions in countries of GSK's choice throughout the Territory, for which GSK shall bear the costs relating to such activities which occur at GSK's request or direction. GSK shall solicit Flamel's advice and review of the nature and text of any such patent applications to the extent such are related to the Flamel Micropump Technology and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and GSK shall take into account Flamel's reasonable comments related thereto.

(b) Flamel shall have the first right, using in-house or outside legal counsel selected at Flamel's sole discretion, to prepare, file, prosecute, maintain and extend patent applications and patents concerning all such Flamel Owned Inventions in countries of Flamel's choice throughout the Territory, for which Flamel shall bear the costs. Flamel shall solicit GSK's advice and review of the nature and text of such patent applications to the extent such are related to the Product or the Formulation and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and Flamel shall take into account GSK's reasonable comments related thereto.

(c) If Flamel, prior or subsequent to filing patent applications on any Flamel Patent Rights that are owned in whole by Flamel and are necessary or reasonably related to the Formulation and/or the Product and Flamel elects not to file, prosecute or maintain such patent applications or ensuing patents or claims encompassed by such patent applications or ensuing patents in any country of the Territory, Flamel shall give GSK notice thereof within a reasonable period prior to allowing such patent applications or patents or such claims encompassed by such patent applications or patents to lapse or become abandoned or unenforceable, and GSK shall thereafter have the right, at its sole expense and for Flamel's benefit, to prepare, file, prosecute and maintain patent applications and patents or divisional applications related to such claims encompassed by such patent applications or patents concerning all such inventions and discoveries in countries of its choice throughout the world.

(d) Each of Flamel and GSK shall hold all information it presently knows or acquires under this Section that is related to all such patents and patent applications as confidential and subject to the provisions of Article 7 of this Agreement.

(e) Each Party shall cooperate with the other as reasonably requested to effect the provisions of this Section 5.3.

5.4. **Flamel Patent Rights**. In the event that a Party learns that any Flamel Patent Rights necessary for the development, manufacture, use and/or sale of a Product are infringed or misappropriated by activities by a Third Party in any country in the Territory relating to Product, or are subject to a declaratory judgment action arising from such infringement in such country, such Party shall promptly notify the other Party hereto. GSK shall have the initial right (but not the obligation) to enforce such Flamel Patent Rights, or defend any declaratory judgment action with respect thereto, at its expense, and to use Flamel's name in connection therewith; provided that such use without Flamel's written consent may only occur where required by law for GSK to bring such action. In the event that GSK fails to initiate a suit to enforce such Flamel Patent Rights against such a Third Party in any jurisdiction in the Territory within ninety (90) days after notification of such infringement, Flamel may initiate such suit in the name of the Flamel with regard to the applicable Flamel Patent Rights against such infringement, at the expense of Flamel, and to use GSK's name in connection therewith. The Party involved in any such claim, suit or proceeding (the "Enforcing Party"), shall keep the other Party hereto reasonably informed of the progress of any such claim, suit or proceeding. Flamel and GSK shall recover their respective actual out-of-pocket expenses, or equitable proportions thereof, associated with any litigation or settlement thereof from any recovery made by any Party. Any excess amount shall be distributed between the Enforcing Party and the other party in the ratio equivalent to the profit GSK derives from Product in the Territory relative to the royalty Flamel derives from Product in the Territory, with the Enforcing Party receiving the larger proportion of the excess amount.

5.5. **Infringement Claims**. If the manufacture, sale or use of Product in the Territory pursuant to this Agreement results in any claim, suit or proceeding alleging patent infringement against Flamel or GSK, such Party shall promptly notify the other Party hereto. If GSK is not named as a Party in such a claim, suit or proceeding, GSK may, at its own expense and through counsel of its own choice, seek leave to intervene in such claim, suit or proceeding. Flamel agrees not to oppose such intervention. If GSK, and not Flamel, is named as a Party to such claim, suit or proceeding, GSK shall have the right to control the defense and settlement of such claim, suit or proceeding, at its own expense, using counsel of its own choice, however Flamel, at its own expense and through counsel of its own choice, may seek to intervene if the claim, suit or proceeding relates to the commercialization of the Product, and in such event, GSK agrees not to oppose such intervention. If GSK is named as a Party and Flamel shall, at any time, tender its defense to GSK, then GSK shall defend Flamel in such claim, suit or proceeding, at GSK's own expense and through counsel of its own choice, and GSK shall control the defense and settlement of any such claim, suit or proceeding; provided, GSK shall not enter into any agreement which (i) extends or purports to exercise GSK's rights under Licensed Technology beyond the rights granted pursuant to this Agreement, (ii) makes any admission regarding (a) wrongdoing on the part of Flamel, or (b) the invalidity, unenforceability or absence of infringement of any Flamel Patent Rights, without the prior written consent of Flamel, which consent shall not be unreasonably withheld. The Parties shall cooperate with each other in connection with any such claim, suit or proceeding and shall keep each other reasonably informed of all material developments in connection with any such claim, suit or proceeding. Nothing in this Section 5.5 shall limit or modify the provisions of Article 8, which may apply to such infringement claims as discussed herein.

5.6. **Litigation Activities Update**. The Parties shall keep one another informed of the status and of their respective activities regarding any litigation or settlement thereof concerning Product; provided however that no settlement or consent judgment or other voluntary final disposition of any suit defended or action brought by a Party pursuant to this Article 5 may be entered into without the written consent of the other Party, which consent shall not be unreasonably withheld or delayed.

5.7. **Trademarks**. GSK, its Affiliates, and its sublicensees shall have the right to market Product under their own labels, tradenames, and trademark(s) (collectively, the "GSK Marks") and GSK shall solely own such trademarks, labels and tradenames. GSK shall be responsible for the selection of all GSK Marks that it employs in connection with Product in the Territory and shall own and control such GSK Marks and retain ownership upon termination or expiration of this Agreement. GSK shall be responsible for filing, registering and maintaining any GSK Marks throughout the Territory.

ARTICLE 6
REPRESENTATIONS AND WARRANTIES

6.1. **Flamel Representations and Warranties**. As of the Effective Date, Flamel represents and warrants to GSK that:

(a) Flamel has full Control of the Licensed Technology to grant the rights and licenses granted under Section 2.2, and that Flamel otherwise has the full right and authority to enter into this Agreement;

(b) there are no existing or threatened actions, suits or claims pending against Flame' with respect to the Licensed Technology;

(c) there are no existing or threatened actions, suits or claims pending against Flamel with respect to Flamel's right to enter into and perform Flamel's obligations under this Agreement;

(d) Flamel has not granted, nor will Flamel grant during the Term of this Agreement, any right, license or interest in or to the Licensed Technology that is in conflict with the rights or licenses granted under this Agreement, nor as of the Effective Date, has Flamel encumbered any Flamel Know-How and/or Flamel Patent Rights;

(e) to the best of Flamel's knowledge, there is nothing in any Third Party agreement Flamel has entered into that in any way will limit Flamel's ability to perform all of the obligations undertaken by Flamel hereunder, and that Flamel will not enter into any agreement after the Effective Date under which Flamel would incur any such limitations;

(f) Flamel has no knowledge from which Flamel concludes that the Flamel Patent Rights are invalid or that their exercise would infringe patent rights of Third Parties;

(g) Flamel has no knowledge from which Flamel concludes that the use of Flamel Know-How by GSK as contemplated by this Agreement would constitute a misappropriation of a Third Party's trade secrets;

(h) Flamel has not intentionally omitted to furnish GSK with any information requested by GSK, nor intentionally concealed from GSK, any information in its possession concerning the Licensed Technology or Product, or the transactions contemplated by this Agreement, that would be material to GSK's decision to enter into this Agreement and to undertake the commitments and obligations set forth herein;

(i) Flamel has not intentionally concealed from GSK the existence of any data or information concerning the Licensed Technology or the Product that suggests that there may exist quality, toxicity, safety and/or efficacy concerns that may materially impair the utility and/or safety of Product, or anticipated components thereof; and

(j) to the best of Flamel's knowledge, Flamel has obtained, and will continue to obtain, the assignment of all interests and all rights of any and all Third Parties (including employees) which enable Flamel to grant the license under Section 2.2.

6.2. **GSK Representations and Warranties**. GSK represents and warrants to Flamel that, as of the Effective Date:

(a) GSK has the full right and authority to enter into this Agreement;

(b) there are no existing or threatened actions, suits or claims pending against GSK with respect to GSK's right to enter into and perform GSK's obligations under this Agreement, other than as set forth on Schedule 6.2 hereto;

(c) to the best of GSK's knowledge, there is nothing in any Third Party agreement GSK has entered into, other than as set forth on Schedule 6.2 hereto, that, in any way, will limit GSK's ability to perform all of the obligations undertaken by GSK hereunder; and

(d) GSK has not omitted to furnish Flamel with, nor intentionally concealed from Flamel, any information in its possession concerning the transactions contemplated by this Agreement, which would be material to Flames decision to enter into this Agreement and to undertake the commitments and obligations set forth herein.

6.3. **Disclaimer of Warranties**. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT OR MANDATED BY APPLICABLE LAW (WITHOUT THE RIGHT TO WAIVE OR DISCLAIM), NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT, ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS, OR OTHER SUBJECT MA ITE,R OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL WARRANTIES, CONDITIONS OR REPRESENTATIONS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF PERFORMANCE, MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 7
CONFIDENTIALITY AND EXCHANGE OF INFORMATION

7.1. **Confidential Information**. Except as expressly provided herein, the Parties agree that, for the Term of this Agreement and for five (5) years thereafter, the receiving Party shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose except for the purposes contemplated by this Agreement any Confidential Information furnished to it by the disclosing Party hereto pursuant to this Agreement, except that to the extent that it can be established by the receiving Party by competent proof that such Confidential Information:

(i) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(iv) was independently developed by the receiving Party without reference to any information or materials disclosed by the disclosing Party; or

(v) was subsequently disclosed to the receiving Party by a person other than a Party without breach of any legal obligation to the disclosing Party.

7.2. **Permitted Disclosures**. Each Party hereto may disclose the other's Confidential Information to the extent such disclosure is reasonably necessary in connection with the conduct of the development activities to be conducted hereunder, in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations or otherwise submitting information to tax or other governmental authorities, conducting clinical trials, or making a permitted sublicense or otherwise exercising its rights hereunder, provided that if a Party is required to make any such disclosure of another Party's Confidential Information, other than pursuant to a confidentiality agreement, it will give reasonable advance notice to the latter Party of such disclosure and, save to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information prior to its disclosure (whether through protective orders or otherwise).

7.3. **Public Announcements**. No public announcement or any other disclosure, including under a Confidentiality Disclosure Agreement, to Third Parties concerning the existence of, terms, or subject matter or termination of this Agreement shall be made, either directly or indirectly, by any Party to this Agreement, except as may be legally required or as may be required for recording purposes, without first obtaining the written approval of the other Party and agreement upon the nature and text of such announcement or disclosure; provided, however, that in the case of disclosures made by Flamel to a bona fide financial analyst for modeling and valuation purposes under a confidentiality agreement, Flamel shall provide GSK advance written notice of such disclosure (as set forth below), but shall not be obligated to obtain GSK's consent. The Party desiring to make any such public announcement or other disclosure (including those which are legally required or may be required for recording purposes) shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time prior to public release, which shall be at least five (5) business days prior to release of such proposed announcement or disclosure, and shall provide the other Party with a written copy thereof, in order to allow such other Party to comment upon such announcement or disclosure. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either Party included in any such disclosure. Notwithstanding the foregoing, the Parties shall agree upon a press release to announce the execution of this Agreement, substantially in the form attached hereto as Schedule 7.3. Thereafter, Flamel and GSK may each disclose to Third Parties the information contained in such press release without the need for further approval by the other.

7.4. **Third Party Publications**. Nothing herein shall be construed to prevent GSK from disclosing any information received from Flamel hereunder: (i) to a Third Party contract manufacturer of GSK, subject to the consent of Flamel, such consent not to be unreasonably withheld; or (ii) to an Affiliate, sublicensee, distributor, Third Party research or clinical contractor, of GSK, without the consent of Flamel, provided, that in all cases of disclosure under clause (i) or (ii) above, the party to whom such disclosure is made shall have undertaken a similar obligation of confidentiality with respect to the Confidential Information. Neither Party shall submit for written or oral publication any manuscript, abstract or the like which includes data or other information pertaining to Product or Formulation without first obtaining the prior written consent of the other Party, which consent shall not be unreasonably withheld, and shall be given or refused no later than thirty (30) days from the date of receipt by the reviewing Party.

7.5. **Bankruptcy**. All Confidential Information disclosed by one Party to the other shall remain the intellectual property of the disclosing Party. In the event that a court or other legal or administrative tribunal, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a Party to this Agreement based on the insolvency or bankruptcy of such Party, the bankrupt or insolvent Party shall promptly notify the court or other tribunal (i) that Confidential Information received from the other Party under this Agreement remains the property of the other Party, and (ii) of the confidentiality obligations under this Agreement. In addition, the bankrupt or insolvent party shall, to the extent permitted by law, take all steps necessary or desirable to maintain the confidentiality of the other party's Confidential Information and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement.

ARTICLE 8
INDEMNIFICATION

8.1. **Indemnification of GSK**. Flamel shall indemnify and hold harmless GSK and its Affiliates, and their respective directors, officers, employees, agents and counsel, and the successors and assigns of the foregoing (the "GSK Indemnitees"), from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' and professional fees and other expenses of litigation and/or arbitration) resulting from a claim, suit or proceeding brought by a Third Party against a GSK Indemnitee, arising from or occurring as a result of: (i) the infringement of a Third Party's patent rights, trademarks or other intellectual property rights by reason the grant of an exclusive license to GSK, or the manufacture by GSK, an Affiliate, or a Third Party, or the use, sale, offer to sell, or importation by GSK in the Territory, in accordance with Article 2 of this Agreement; or (ii) the development and/or manufacture of Product by Flamel or its Affiliates or sublicensees; or (iii) Flamel's material breach of any representation or warranty set forth in Section 6.1.1, except, in each case, to the extent caused by the negligence or willful misconduct of GSK or to the extent that GSK is obligated to indemnify Flamel under Section 8.2 below.

8.2. **Indemnification of Flamel**. GSK and its Affiliates shall indemnify and hold harmless Flamel and its Affiliates and their respective directors, officers, employees, agents and counsel and the successors and assigns of the foregoing (the "Flamel Indemnitees"), from and against any and all liabilities, damages, costs or expenses (including reasonable attorneys' and professional fees and other expenses of litigation and/or arbitration) resulting from a claim, suit or proceeding brought by a Third Party against a Flamel Indemnitee or a sublicensee, arising from or occurring as a result of: (i) the development, manufacture, marketing and/or commercialization of Product by GSK or its Affiliates or sublicensee; or (iii) GSK's material breach of any representation or warranty set forth in Section 6.1.2 except, in each case, to the extent caused by the negligence or willful misconduct of Flamel or to the extent that Flamel is obligated to indemnify GSK under Section 8.1.

8.3. **Procedure**. A Party (the "Indemnitee") that intends to claim indemnification under this Article 8 shall promptly notify the other Party (the "Indemnitor") in writing of any loss, claim, damage, liability or action in respect of which the Indemnitee or any of its Affiliates, sublicensees or their directors, officers, employees, agents or counsel intend to claim such indemnification, and the Indemnitor shall have the right to participate in, and, to the extent the Indemnitor so desires, to assume the defense thereof with counsel mutually satisfactory to the Parties. The indemnity agreement in this Article 9 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is made without the consent of the Indemnitor, which consent shall not be withheld unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 8. At the Indemnitor's request, the Indemnitee under this Article 8, and its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or liability covered by this indemnification and provide full information with respect thereto.

8.4. **Insurance Provisions**. Immediately upon the first administration of Product to a human in the Territory by GSK, its Affiliates or its sublicensees, and for a period of five (5) years after the expiration of this Agreement or the earlier termination thereof, Flamel shall obtain and/or maintain, respectively, at its sole cost and expense, product liability insurance in amounts set forth on Schedule 8.4. Such product liability insurance shall insure against all liability, including personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of Product in the Territory attributable to Flamel. Flamel shall provide written proof of the existence of such insurance to GSK upon request. Notwithstanding the foregoing, Flamel may satisfy its obligations under this Section 8.4 through self-insurance to the same extent.

8.5. **Consequential Damages**. IN NO EVENT SHALL EITHER PARTY OR THEIR AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, TREBLE OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY; PROVIDED, HOWEVER, THAT THIS LIMITATION SHALL NOT LIMIT THE INDEMNIFICATION OBLIGATION OF SUCH PARTY UNDER THE PROVISIONS OF SECTIONS 8.1 AND 8.2 OF THIS ARTICLE 8 FOR SUCH DAMAGES CLAIMED BY A THIRD PARTY AND NOTHING IN THIS SECTION 8.5 IS INTENDED TO LIMIT GSK'S PAYMENT OBLIGATIONS EXPRESSLY REQUIRED UNDER ARTICLE 3.

ARTICLE 9
TERM AND TERMINATION

9.1. **Term and Termination by GSK**.

9.1.1. **Term**. This Agreement shall commence on the Effective Date, and unless otherwise terminated pursuant to Section 9.2, 9.3 or 9.4, shall continue in full force and effect on a country by country basis until the later of: (1) ten (10) years from the date of the First Commercial Sale of Product in such country, or (2) the expiration of the last to expire Flamel Patent Right in such country.

9.1.2. **Royalty Expiration**. Upon expiration of GSK's royalty obligations under Section 9.1.1, GSK shall have a fully paid up, royalty free, perpetual, irrevocable, non-exclusive, worldwide license, with the right to sublicense and GSK shall be free to make, have made, use and sell Product and to use Flamel Know-How in the Territory, without further royalty payments or any other remuneration to Flamel.

9.2. **Termination for Material Breach**. Either Party may terminate this Agreement in the event the other Party has materially breached or defaulted in the performance of any of its obligations hereunder, and if such default is not corrected within [***] days after receiving written notice from the other Party with respect to such default, such other Party shall have the right to terminate this Agreement by giving written notice to the Party in default, provided the notice of termination is given within one (1) year of when the Party giving notice knew of the default and prior to correction of the default; provided that the time period for providing such notice of termination shall be extended for so long as the Parties are engaged in good faith negotiations to resolve the situation.

9.3. **Termination for Insolvency; Retention of License**. If voluntary or involuntary proceedings by or against a Party are instituted in bankruptcy under any insolvency law, or a receiver or custodian is appointed for such Party, or proceedings are instituted by or against such Party for corporate reorganization or the dissolution of such Party, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing, or if such Party makes an assignment for the benefit of creditors, or substantially all of the assets of such Party are seized or attached and not released within sixty (60) days thereafter, the other Party may immediately terminate this Agreement effective upon notice of such termination. Notwithstanding the bankruptcy of a Party, or the impairment of performance by a Party of its obligations under this Agreement as a result of bankruptcy or insolvency of such Party, and subject to such Party's rights to terminate this Agreement for reasons other than bankruptcy or insolvency as expressly provided in this Agreement, the other Party shall be entitled to retain the licenses under the terms and conditions granted herein.

9.4. **Termination for Convenience by GSK**. GSK may terminate this Agreement in its sole discretion for any reason on a country-by-country basis, or in its entirety, by giving Flamel at least ninety (90) days written notice thereof at any time.

9.5. **General Effect of Termination**.

9.5.1. **Accrued Obligations**. Termination of this Agreement for any reason shall not release any Party hereto from any liability that, at the time of such termination, has already accrued to the other Party or that is attributable to a period prior to such termination, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity that have accrued or are based upon any event occurring prior to such termination.

9.5.2. **Return of Materials**. Upon any termination of this Agreement, GSK and Flamel shall promptly return to the other Party all materials and tangible Confidential Information received from the other Party (except one copy of which may be retained by legal counsel for archival purposes).

9.5.3. **Stock on Hand**. In the event this Agreement is terminated for any reason after commencement of commercial sales of Product by GSK and/or its Affiliates and sublicensees, GSK and its Affiliates and sublicensees shall have the right to sell or otherwise dispose of the stock of any Products then on hand for a period of six (6) months after the date of termination, subject to Article 3 and the other applicable terms of this Agreement, including, but not limited to, royalty obligations.

9.5.4. **Licenses**. In the event of termination by GSK pursuant to Section 9.4 or termination by Flamel under Section 9.2 due to GSK's material breach, the licenses granted to GSK under Section 2.1 shall terminate. In the event of termination by GSK pursuant to Section 9.2 due to Flamel's material breach, all licenses granted by Flamel to GSK under Section 2.1 shall survive and continue in full force, and GSK shall be obligated to continue to make payments under Article 3 to Flamel to the extent GSK continues to develop, use, market, sell or import Product in the Territory.

9.5.5. **Survival of Section 2.3**. In the event of termination by GSK pursuant to Section 9.2, 9.3, or 9.4, the provisions of Section 2.3 shall survive and continue in full force.

9.6. **Bankruptcy Provisions**. All rights and distribution rights granted under or pursuant to the Agreement by Flamel to GSK are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(52) of the U.S. Bankruptcy Code. The Parties agree that GSK, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code, subject to performance by GSK of its preexisting obligations under the Agreement. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Flamel under the U.S. Bankruptcy Code, GSK shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, shall be promptly delivered to GSK (a) upon any such commencement of a bankruptcy proceeding upon written request therefore by GSK, unless Flamel elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of Flamel upon written request therefore by GSK, provided, however, that upon Flamel's (or its successor's) written notification to GSK that it is again willing and able to perform all of its obligations under this Agreement, Flamel shall promptly return all such tangible materials to GSK, but only to the extent that Flamel does not require continued access to such materials to enable GSK to perform its obligations under this Agreement.

9.7. **Survival**. Sections 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8 (all to the extent owed or unpaid); 5.5 (with respect to infringements that occur during the Term); 5.6 (as applied to any matters surviving under Section 5.5), 3.12, and 3.13 (for the time period provided therein); and Sections 2.1, 2.3, 5.1, 5.7 and Articles 1, 6, 7, 8, 9 and 10 shall survive the expiration or termination of this Agreement for any reason. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the observation and performance of the aforementioned surviving portions of this Agreement.

ARTICLE 10
MISCELLANEOUS

10.1. **Governing Law**. This Agreement shall be deemed to have been made in the United States, and its form, execution, validity, construction and effect shall be determined in accordance with, and any dispute arising from the performance or breach hereof shall be governed by and construed in accordance with, the laws of the State of New York, without reference to conflicts of laws principles.

10.2. **Waiver**. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term

10.3. **Assignment**. This Agreement shall not be assignable by either party without the written consent of the other party, except that either Party may assign this Agreement, without such consent, to (i) an Affiliate of such Party; or (ii) an entity that acquires all or substantially all of the business or assets of such Party to which this Agreement pertains, (whether by merger, reorganization, acquisition, sale, or otherwise) and agrees in writing to be bound by the terms and conditions of this Agreement. The terms and conditions of this Agreement shall be binding on and inure to the benefit of the permitted successors and assigns of the Parties. Nothing in this Section 10.3 shall be construed to prevent GSK from sublicensing its rights to develop, manufacture or commercialize Product under this Agreement.

10.4. **Notices**. Any notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by international express delivery service, registered or certified air mail, return receipt requested, postage prepaid, or by facsimile (confirmed by prepaid registered or certified air mail letter or by international express delivery mail) (e.g., FedEx)), and shall be deemed to have been properly served to the addressee upon receipt of such written communication, to the following addresses of the Parties, or such other address as may be specified in writing to the other Parties hereto:

if to GSK:	GlaxoSmithKline 709 Swedeland Road King of Prussia, PA 19406 Attention: Senior Vice President, Business Development Telephone: 610-270-5397 Telecopy: 610-270-5962
with copies to:	GlaxoSmithKline Corporate Legal Department 2301 Renaissance Blvd. Mail Code RN0220 King of Prussia, PA 19406-2772 Attention: Senior Vice President and Assistant General Counsel - R&D Legal Operations Telephone: 610-787-3626 Telecopy: 610-787-7084
if to Flamel:	Flamel Technologies, S.A. Parc Club du Moulin a Vent 33 Avenue du Docteur Georges Levy 69693 Venissieux Cedex France Attention: Dr. Gerard Soula President and Chief Executive Officer Telephone: 334 7278 3434 Telecopy: 334 7278 3435
With a coy to:	Flamel Technologies, S.A. 2121 K Street, Suite 650 Washington, D.C. 20037 Attention: Stephen H. Willard Chief Financial Officer and General Counsel Telephone: 202-862-8400 Telecopy: 202-862-3933

10.5. **Force Majeure**. Neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by earthquake, riot, civil commotion, terrorism, war, hostilities between nations, governmental law, order or regulation, embargo, action by the government or any agency thereof, act of God, storm, fire, accident, labor dispute or strike, sabotage, explosion or other similar or different contingencies, in each case, beyond the reasonable control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use its best endeavors to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If the performance of any obligation under this Agreement is delayed owing to a force majeure for any continuous period of more than six (6) months, the Parties hereto shall consult with respect to an equitable solution including the possible termination of this Agreement.

10.6. **Independent Contractors**. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute GSK or Flame' as partners or joint venturers in the legal sense. No Party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of any other Party or to bind any other Party to any contract, agreement or undertaking with any Third Party.

10.7. **Other Obligations**. Except as expressly provided in this Agreement or as separately agreed upon in writing between Flamel and GSK, each Party shall bear its own costs incurred in connection with the implementation of the obligations under this Agreement.

10.8. **Severability**. If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform with such statute or rule of law. In the event that the terms and conditions of this Agreement are materially altered as a result of the above, the Parties will renegotiate the terms and conditions of this Agreement to resolve any inequities.

10.9. **Further Assurances**. At any time or from time to time on and after the date of this Agreement, either Party shall at the request of the other Party (i) deliver to the requesting Party such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of assignment, transfer or license, and (iii) take or cause to be taken all such actions, as the requesting Party may reasonably deem necessary or desirable in order for the requesting Party to obtain the full benefits of this Agreement and the transactions contemplated hereby.

10.10. **Entire Agreement**. This Agreement constitutes the entire agreement, both written and oral, with respect to the subject matter hereof, and supersedes and terminates all prior or contemporaneous understandings or agreements, whether written or oral, between GSK and Flamel with respect to such subject matter, excluding the Feasibility Agreement. The Exhibits and Schedules to this Agreement, and the terms and conditions incorporated in such Exhibits and Schedules will be deemed integral parts of this Agreement and all references in this Agreement to this Agreement encompass such Exhibits and schedules and the terms and conditions incorporated in such Exhibits and Schedules. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement. To the extent that there is any inconsistency between this Agreement and the Feasibility Agreement, this Agreement shall govern, except to the extent that this Agreement grants rights greater than those granted under the Feasibility Agreement, in which case the Feasibility Agreement shall control.

10.11. **Headings**. The captions to the Articles and Sections hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

10.12. **Rules of Construction**.

10.12.1. **Joint Draftsmanship**. The Agreement will be construed as if both parties drafted the Agreement jointly, and will not be construed against either party as principal drafter.

10.12.2. **Time References**. Unless otherwise provided, all references to months, quarters or years are references to calendar months, calendar quarters or calendar years.

10.12.3. **Laws**. Any reference to any federal, national, state, local or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, unless the context requires otherwise.

10.12.4. **English Language**. The English language version of this Agreement will control and any translations of this Agreement will be for convenience purposes only for the Party making such translation and do not embody any agreement between the Parties.

10.13. **No Third Party Beneficiaries**. All rights, benefits and remedies under this Agreement are solely intended for the benefit of Flamel and GSK, and no Third Party will have any rights whatsoever to (i) enforce any obligation contained in this Agreement, (ii) seek a benefit or remedy for any breach of this Agreement, or (iii) take any other action relating to this Agreement under any legal theory, including but not limited to, actions in contract, tort (including but not limited to negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the Parties.

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

The Remainder of this Page Left Intentionally Blank.

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

FLAMEL TECHNOLOGIES, S.A.		**SB PHARMCO PUERTO RICO, INC.**	
By:		By:	
Name:	Gèrard Soula	Name:	Jean-Pierre Garnier
Title:	President and CEO	Title:	Attorney-in-Fact

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SCHEDULE 1.14
FLAMEL PATENT RIGHTS

Title	Owner	Country	Dèpôt/Filing Date	Filing No	Acceptation/ No of Grant	Date of Grant
Microcapsules General principle	FT	Argentina	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	Brazil	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	Canada	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	Europe	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	France	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	France	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	Germany	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	Great Britain	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	India	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	Israel	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	Italy	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	Japan	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	PCT	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	South Africa	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	Spain	[***]	[***]	[***]	[***]
Microcapsules General principle	FT	USA	[***]	[***]	[***]	[***]
Microencapsulated Aspirin	FT	Europe	[***]	[***]	[***]	[***]
Microencapsulated Aspirin	FT	France	[***]	[***]	[***]	[***]
Microencapsulated Aspirin	FT	Japan	[***]	[***]	[***]	[***]
Microencapsulated Aspirin	FT	USA	[***]	[***]	[***]	[***]
Microencapsulated Aspirin	FT	USA	[***]	[***]	[***]	[***]
Micropump II	FT	France	[***]	[***]	[***]	[***]
Micropump II	FT	PCT	[***]	[***]	[***]	[***]
Mattawan multimicrocapsulaire	FT	France	[***]	[***]	[***]	[***]
Metforrnin multimicrocapsulaire	FT	POT	[***]	[***]		
Metforrnin bitherapie	FT	France	[***]	[***]		
Microcaspsules "delayed release"	FT	France	[***]	[***]		
Micropump surenrobe pour compression	FT	France	[***]	[***]		

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SCHEDULE 1.30
FLAMEL WORK PLAN

TECHNICAL PROJECT

Carvedilol MR

PHASE 2 / Development - Scale-up

1. INTRODUCTION

The goal of this project is to achieve a modified release formulation of Carvedilol (MR) permitting to optimize its efficacy.

FLAMEL has developed two (2) once a day controlled release systems that are tested in a phase I clinical study :

- the first one, using FLAMEL's Micropump I technology, must continuously release the active during five (5) to ten (10) hours,
- the second one, using FLAMEL's Micropump 11 technology, must display a lag time of one (1) to two (2) hours and then release the Carvedilol during five (5) to (8) hours.

One of the formulations tested should display the targeted releasing profile.

2. OBJECTIVES

The main objectives of this project for 2003 are the following:

- to develop an industrial manufacturing process for the selected modified release system,
- to produce batches of Micropump I or Micropump II for the strength range clinical study planned for June 2003,
- to produce the clinical batches with the industrial manufacturing equipment , at the appropriate batch size, for the phase ill clinical study planned for January 2004,
- to carry out a large scale manufacture (qualification) campaign of selected formulations in conjunction with the preparation of Phase al clinical trial supplies to allow GSK to initiate an official stability program for registration,
- to manufacture of phase Di clinical trial supplies will be addressed in the Supply Agreement referenced in Section 4.7 of the Agreement.

3. FLAMEL TECHNOLOGIES PROPOSAL

In 2002, under the terms of the Feasibility Agreement, FLAMEL adapted its Micropump I and II technology to Carvedilol. Initially, Carvedilol free base was used. Subsequently, the Carvedilol phosphate salt was preferred to be tested in a phase I clinical study.

The results of the phase I clinical study will identify a formulation that can be selected for additional clinical and other studies to more fully characterize the pharmacokinetic, pharmacodynamic and pharmaceutical behaviors of the chosen formulation.

In 2003, FLAMEL will conduct additional formulation, development and optimization work in parallel to the phase II clinical studies in order to determine the suitability of the chosen formulation for possible use in phase III clinical studies.

4. PROJECT SPECIFICATIONS AND DEFINITIONS

The specifications of the product corresponding to the formulation chosen will be defined by GSK in collaboration with FLAMEL.

GSK will supply the documentation necessary for the development work.

GSK will supply the Carvedilol phosphate and free base necessary for the development program.

FLAMEL will optimize and validate a manufacturing process to produce a Carvedilol MR formulation at commercial scale.

FLAMEL will develop and validate analytical methodologies to support the selected formulations.

5. WORK PROGRAM

The work program is built around several key issues and predefined dates that imply the list of actions given below:

- choice of the technology and the formulation by mid April 2003;
- completion of manufacturing of the additional phase I clinical batches by May 2003;
- commencement of additional phase II clinical study by June 2003;
- commencement of large-scale manufacture (qualification) campaign for the clinical phase III study supplies on sixty (60) kg batches by July 2003;
- delivery of the selected Micropump formulation for manufacture of the phase al clinical batches, including transfer of blending and encapsulation processes and analytical methods, by September 2003;
- GO/NO-GO decision on the formulation by November 2003;
- commencement of the phase III clinical study by January 2004.

The following program describes the actions to be performed by FLAMEL:

5.1 **Laboratory Development**.

The main objective of this work is to supply the information necessary for an NDA and to establish the basic performance characteristics of the formulation and process.

1. Choice of the excipients.

2. Microcapsules optimization.

3. Optimization of the final formulation according to the dosage defined.

4. Definition of the lots necessary for the in vivo / in vitro (3 profiles) correlation.

5. Screening the dissolution test parameters to prove their suitability to the releasing profile tested (ICH guidelines).

6. Support to the process development and scale-up.

7. Complementary testing on pilot and industrial batches.

5.2 **Process Development and Pilot Scale-Up**.

The objective is to optimize the manufacturing process at the pilot scale (20 kg/batch) in terms of product quality, performance and yield, to be able to facilitate the scale-up of the process to the industrial equipment.

1. Process optimization: microcapsules manufacturing (20 kg/batch)
- Layering
- Carvedilol phosphate yield optimization
- Strength of the deposited layer of active Spray-coating
- Process parameters optimization
- Reproducibility
- Microcapsules characterization
- Active ingredient (A.I.) content.
- SEM characterization of the layer 1 Coating %
- Microcapsules distribution size
- Physical properties (density , flowing)
- Consistency of release rates

2. Capsule filling optimization process
- Microcapsules lubrication with Mg St,
- Capsule filling Characterizations

5.3 **Industrial Scale-Up**.

This Section 5.3 will form the basis of the Supply Agreement and will be superceded by the Supply Agreement. The objective is to precisely define the industrial manufacturing equipment needed, to install it and to optimize the different manufacturing stages to achieve the batch size needed for the clinical phase III batches; provided, however, that FLAMEL shall not be entitled to purchase new equipment at the expense of GSK without the prior written consent of GSK. Moreover, the optimized process will permit to achieve a qualification campaign by July 2003 and to start the ICH stabilities for the NDA.

1. Precise definition of the industrial manufacturing equipment.
- Technical trials
- Definition and installation of the technical options on the industrial equipment

2. Microcapsules Process scale-up and optimization. (60 - 120 kg/batch)
- Layering
- Suspension of A.I. optimization
- Yield optimization.
- Spray-coating
- Process parameters
- Robustness
- Microcapsules characterization.

3. Capsule filling
- Blending with Mg Stearate and characterizations

4. Process validation and manufacturing of 3 Q-batches
- Microcapsules process validation on 3 Q-batches (60 — 120 kg / batch)
- Blending validation : Mg Stearate
- Capsule filling validation
- Packaging
- Starting ICH stabilities

5.4 **Analytical Development**

This Section 5.4 will form the basis of the Supply Agreement and will be superceded by the Supply Agreement.

1. Methods validation

2. Accelerated stabilities on development batches

3. Testing of development and scale-up batches

4. Full testing on the pilot Q-batches according to the validation protocol

5. Testing of the initial industrial scale-up batches.

6. Transfer the analytical methodologies to GSK

6. CLINICAL BATCHES MANUFACTURING

The manufacturing of clinical batches not discussed herein will be discussed between the parties and will be the subject of a separate workplan.

7. QUANTITY OF ACTIVE INGREDIENT NECESSARY

The quantity of Carvedilol phosphate necessary for this project is estimated to about one hundred (100) kg. Half of that amount will be used for the lab and pilot program and the rest for the initial industrial scale-up work. The quantities necessary for the clinical batches will be estimated according to the specific needs. FLAMEL will also supply Carvedilol free base, depending on the formulation selected. The quantities of the Carvedilol free base will be agreed upon between the parties as appropriate.

8. PLANNING AND BUDGET

The development program presented in this document commences January 2003 and ends December 2003.

ANNEX

PLANNING 2003

PERSONNEL ALLOCATED TO THE PROJECT

	2003				
	1st Q	2nd Q	3rd Q	4th Q	TOTAL
Laboratory development	5	5	3	2	3,8
Formulation optimization					
Process development and scale-up support					
Analysis of lab batches and complementary characterizations					
Process development and scale-up (20 kg/batch)	6	4	4	2	4,0
Microcapsules pilot process scale-up (20 kg/batch)					
Blending / Homogeneity					
Capsule filling optimization					
Pilot process validation / Q-batches					
Support to industrial scale-up					
Analytical development	5	5	4	2	4,0
Methods validation					
Accelerated stabilities on development batches					
Testing of development and scale-up batches					
Full testing of the Q-batches : pilot process validation					
ICH stability on Q-batches					
Industrial scale-up : 60 - 120 kg/batch	0	4	5	4	3,3
Technical trails / Precise equipment definition					
Microcapsules process scale-up (150 kg/batch)					
Blending / Homogeneity					
Capsules filling					
TOTAL persons	16	18	16	10	15,0

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SCHEDULE 4.6
Existing Studies and Delivery of Clinical Supplies of Small Particle Micropump

1. Blending studies of Carvedilol Immediate Release and Carvedilol Controlled Release pellets to support manufacture of phase 11 clinical supplies of Micropump 11 as discussed in the GSK/Flamel meeting in Lyon, France on February 3 and 4, 2003.

2. Completion of additional development work and manufacture of clinical supplies to be used in phase I studies on the small size Carvedilol microcapsules as discussed in the GSKJF1amel meeting in Lyon, France on February 3 and 4, 2003.

SCHEDULE 4.7
Key Supply Terms

Volumes and Commitments

- GSK will provide both a three (3) year high level forecast and a fifteen (15) month forecast, the latter being updated at a minimum every six (6) months, with monthly updates to the three (3) months fixed by GSK firm order. These forecasts are not commitments and are for information purposes only; commitments shall be made by GSK firm order.

2. Capacity

- FLAMEL shall ensure it and its GSK approved suppliers have adequate capacity at all times to fulfill **[***]** of GSK's firm order(s) within the agreed lead in period.

3. Term

- **[***]** with the option for GSK to renew in one year increments unless in case of breach or insolvency

4. Notice of Termination and Supply

- In the event of termination, FLAMEL or GSK, as the case may be, shall provide at least [***] notice and FLAMEL shall supply all forecasted Product through the end of the notice of termination period; provided, however, and notwithstanding the foregoing, that in the event of termination by FLAMEL, FLAMEL will continue to supply GSK per the terms of the Supply Agreement until technology transfer from FLAMEL to GSK has been completed and GSK have in place a robust supply alternative to FLAMEL.

5. Cost of goods

A. Clinical Trial Supply

- **[***]**

B Launch stock & commercial supply

- **[***]**

[***]

6. Continuous Improvement Targets

- FLAMEL and GSK shall agree on action plans and continuous improvement targets. **[***]**

7. Alternative Sources of Materials

- In the event that GSK identifies alternative source(s) of supply for constituent elements of the product of equivalent quality from a Third Party on more favorable terms, then FLAMEL shall purchase such materials as GSK shall direct, provided that such materials can be used in accordance with this Agreement.

- **[***]**

8. Approvals

- The manufacturing facility, GSK approved suppliers, materials, specifications, processes, storage facilities and transport utilized by FLAMEL shall be approved in advance by GSK and shall not be modified without GSK's prior approval.

- No capital expenditures will be made by FLAMEL to support the development or manufacture of Product without GSK's prior, written approval.

- The manufacturing facility, processes, storage facility and transport will comply with all relevant and applicable standards, including Current Good Manufacturing Practices (cGMPs41), as defined by the US FDA's Code of Federal Regulations (CFR) parts 210, 211, and 820, as applicable, and to permit FDA (or other regulatory agency) inspections of any facilities in which GSK products are produced.

- FLAMEL shall ensure excipients and all other materials used in the manufacturing meet the agreed specifications.

9. Identity Testing

- Following delivery of GSK active and prior to its use in manufacture, FLAMEL shall conduct identity tests and all other tests required to determine compliance with the corresponding specification.

10. Supply Chain Optimization

- FLAMEL and GSK will work together to identify, develop and implement the optimum robust supply chain for manufacture and supply.

11. Inspection

- GSK shall have the right to undertake all inspections, tests and batch sampling.

12. Yield

- GSK and FLAMEL will agree on the specifications for batch yield along with an acceptable range for batches manufactured by FLAMEL. FLAMEL will be liable all costs, including the cost of Carvedilol, for batches that do not meet the yield criteria.

13. Batch Failures

- GSK shall pay for good in-specification batches only, delivered in accordance with the requirements of the GSK firm order and terms of the Supply Agreement.

14. Contingency Stock Holding

- FLAMEL shall maintain a contingency stock holding at levels agreed with GSK, sufficient to ensure continuous supply of product to GSK

15. Rejection

- GSK shall have the right to reject product that does not comply in quantity or quality with the GSK firm order and the Agreement.

16. Title

- Title shall transfer to GSK upon receipt and acceptance by GSK. The transfer of title shall not release FLAMEL from any of its rights and responsibilities under this agreement.

17. Payment

- GSK shall pay FLAMEL within [***]

18. Key Performance Indicators

- GSK and FLAMEL shall agree performance indicators to measure supply requirements.

19. Insurance

- GSK and FLAMEL shall agree upon insurance provisions that adequately protect the other party against the risk related to the first party's performance under the Agreement.

20. Assignment

- FLAMEL shall not at any time assign or sub-contract any of its rights, or obligations whatsoever in this Agreement to any third party

[***]

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SCHEDULE 6.2
Exceptions To Representations And Warranties

1. COREG® US AGREEMENT BY AND BETWEEN SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM PLC AND HOFFMANN-LA ROCHE LTD., DATED AUGUST 30, 2000 WHEREBY ROCHE HAS GRANTED GSK RIGHTS TO CARVEDILOL IN THE US AND CANADA AND GSK HAS THE OBLIGATION TO OFFER ROCHE A SUBLICENSE TO THE PRODUCT FOR THE ROCHE TERRITORY.

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SCHEDULE 7.3
Press Release

GlaxoSmithKline and Flamel Technologies
Announce License Agreement

LONDON, England and LYON, France March 28, 2003 GlaxoSmithKline (LSE and NYSE:GSK - news) and Flamel Technologies S.A. (NASDAQ:FLML - news) announced today that they have entered into an agreement whereby Flamel has licensed its controlled-release Micropump® technology to GlaxoSmithKline (`GSK') to develop a new formulation for an undisclosed existing product. Flamel will receive an upfront payment of $2M and additional milestone payments upon achievement of certain events, and royalties on sales of the product. Based on the continued successful development and commercialisation of this formulation, GSK and Flamel estimate that payments to Flamel could range up to $45 million by the end of the first year following launch, of which $25M is attributable to the product reaching certain milestones. Flamel may also participate in the manufacture of product. Additional terms of the agreement have not been disclosed.

Gerard Sonia, PhD., president and chief executive officer of Flamel, said "We are very excited about this new development agreement with GSK. We are confident of the potential of Micropump technology for these large, and still growing, markets. This additional agreement further demonstrates the interest of major worldwide pharmaceutical companies in our versatile technology platforms. Moreover, this is our second license agreement with GSK within the past nine months, based on Micropump technology. It confirms the common interest of the two companies to work together. I am very pleased and proud to see GSK, one of the world's premier pharmaceutical companies, expand its relationship with Flamel."

Lawson Macartney, DVM., PhD., FRCPath, Head of the Cardiovascular, Metabolic and Urology Therapeutic Areas, GSK, added, "This collaboration will help us to maintain our leadership in product research and development. We are eager to develop with Flamel leading technologies within our therapeutic areas with the objective of providing the next generation of medicines."

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

Flamel Technologies, S.A. is a biopharmaceutical company principally engaged in the development of two unique polymer-based delivery technologies for medical applications. Flamers Micropump® technology is a controlled release and taste-masking technology for the oral administration of small molecule drugs. Flamel's Medusa® nano-particulate technology is designed to deliver therapeutic proteins. Flamel's expertise in polymer science has also been instrumental in the development of a photochromic eyeglass lens product now marketed by Corning Inc.

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

This document contains a number of matters, particularly as related to the status of various research projects and technology platforms, that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The presentation reflects the current view of management with respect to future events and is subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, uncertainties regarding market acceptance of products in development, the impact of competitive products and pricing, and the risks associated with Flamel's reliance on outside parties and key strategic alliances. These and other risks are described more fully in Flamel's Annual Report on the Securities and Exchange Commission Form 20-F for the year ended December 31, 2000. Flamel assumes no obligation to update any forward-looking statements.

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

SCHEDULE 8.4
Flamel Insurance

SCHEDULE 8.4
FLAMEL INSURANCE

Groupe Lafond & Roullet
Courier d'assurances

GENERAL AND PRODUCTS-PROFESSIONAL LIABILITY INSURANCE
SUMMARY

Insured: FLAMEL TECHNOLOGIES
Insurance company: AXA France
Policy number: 1697334004

COVERAGES	LIMITS OF INDEMNITY (Euro)	DEDUCTIBLE (Euro) Per occurences Excluding bodily Injury
1. **GENERAL LIABILITY**		
• Combined limit for bodily injury, property damage and consequential losses	€ 7,500,000 per occurrence	
with sublimit for:		
• Property damage and consequential losses	€ 3,000,000 per occurrence	€ 760
• Damage to any property in custody, in care	€ 300,000 per occurrence	€ 760
• Non consequential losses	€ 760,000 per occurrence	€ 1,500
2. **PRODUCTS LIABILITY-PROFESSIONAL LIABILITY**		
• Combined limit for bodily injury, property damage and consequential losses	€ 3,000,000 per occurrence and annual aggregate	10% of losses Minimum: € 760 Maximum: € 7,600 USA-Canada: € 30,500
with sublimit for:		
• Non-consequential losses Sublimit for USA-Canada	€ 1,500,000	€ 15,000
• Costs of dismantling and erecting again	€ 300,000 per occurrence	€ 15,000
• Recall costs	€ 300,000	€ 15,000
	€ 300,000	€ 15,000

Geographic scope of coverage: Worldwide

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

LICENSE AGREEMENT

PREAMBLE

THIS LICENSE AGREEMENT (the "Agreement"), dated as of the 24th day of November, 2004 (the "Effective Date"), is made by and between SB Pharmco Puerto Rico, Inc., a GlaxoSmithKline company organized and existing under the laws of the territory of Puerto Rico, with its principal place of business at Road 172, KM 9.1/Bo. Certenejas, Cidra, Puerto Rico 00639 ("GSK") and Flamel Technologies, S.A., a corporation organized and existing under the laws of France, with its principal place of business at Parc Club du Moulin a Vent, 33 Avenue du Docteur Georges Levy 69693 Venissieux Cedex, France, ("Flamel"). GSK and Flamel are sometimes collectively referred to in this Agreement as the "Parties" and separately as a "Party".

WHEREAS, GSK and Flamel are parties to a License Agreement dated March 26, 2003 (the "License Agreement");

WHEREAS, GSK and Flamel have agreed with respect to the Carvedilol MR Patent Rights (as hereinafter defined) and the Micropump Technology Patent Rights (as hereinafter defined) only, that notwithstanding the provisions in Section 5.1 of the License Agreement, the Parties will be joint owners of the Carvedilol MR Patent Rights and the Micropump Technology Patent Rights;

WHEREAS, GSK desires to obtain from Flamel an irrevocable, royalty-free, exclusive license to Flamel's rights under the Carvedilol MR Patent Rights, and Flamel desires to grant GSK an irrevocable, royalty-free, exclusive license to Flamel's rights under the Carvedilol MR Patent Rights, as provided herein; and

WHEREAS, Flamel desires to obtain from GSK an irrevocable, royalty-free, exclusive license to GSK's rights under the Micropump Technology Patent Rights, and GSK desires to grant Flamel an irrevocable, royalty-free, exclusive license to GSK's rights under the Micropump Technology Patent Rights, as provided herein.

NOW, THEREFORE, in consideration of the mutual covenants set forth in this Agreement, GSK and Flamel hereby agree as follows:

Article I. Definitions.

Section 1.1 As used herein, the following capitalized terms will have the meanings set forth below when used in this Agreement, and all terms defined in the singular will have the same meanings when used in the plural (and vice versa), unless otherwise specified:

"Affiliate" means any legal entity (such as a corporation, partnership, or limited liability company) that directly or indirectly Controls, is Controlled by or is under common Control with a Party to this Agreement. For the purposes of this definition, the term "Control" means: (i) beneficial ownership of at least fifty percent (50%) of the voting securities of a corporation or other business organization with voting securities (or such lesser percentage required under local jurisdiction); (ii) a fifty percent (50%) or greater interest in the net assets or profits of a partnership or other business organization without voting securities; or (iii) the ability to direct the affairs of any such entity.

"Carvedilol MR Patent Rights" means (i) the patent application filed by GSK on November 24, 2004, a copy of which is attached hereto as Exhibit A and any patents issuing thereon; (ii) any divisions, continuations, continuations-in-part, reissues, reexaminations, patents of additions, extensions or other governmental actions that extend any of the subject matter of any of the foregoing referenced in (i); (iii) any substitutions, confirmations, registrations or revalidations of any of the foregoing; and (iv) any foreign equivalents of any of the foregoing, including, without limitation any PCTs.

"Confidential Information" means (i) any proprietary or confidential information or material in tangible form disclosed by a Party hereunder that is marked as "Confidential" at the time it is delivered to the receiving Party, and/or (ii) proprietary or confidential information disclosed orally hereunder that is identified as confidential or proprietary when disclosed and such disclosure of confidential information is confirmed in writing within a reasonable period of time thereafter by the disclosing Party.

"Control," "Controls," "Controlled," or "Controlling" means (except with respect to the definition of "Affiliate") possession of the ability to grant the licenses or sublicenses as provided herein without violating the terms of any license agreement or other arrangement with any Third Party, or any government regulation or statute.

"Dispute" will have the meaning set forth in Section 7.1(i).

"Dispute Notice" will have the meaning set forth in Section 7.1(i).

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

"Flamel" will have the meaning set forth in the Preamble.

"Flamel Patent Assignment" means the assignment agreement attached hereto as Exhibit B and incorporated herein.

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

"GSK Patent Assignment" means the assignment agreement attached hereto as Exhibit C and incorporated herein.

"License Agreement" will have the meaning set forth in the Preamble.

"Micropump Technology Patent Rights" means (i) the patent application filed by Flamel on November 24, 2004, a copy of which is attached hereto as Exhibit D and any patents issuing thereon; (ii) any divisions, continuations, continuations-in-part, reissues, reexaminations, patents of additions, extensions or other governmental actions that extend any of the subject matter of any of the foregoing referenced in (i); (iii) any substitutions, confirmations, registrations or revalidations of any of the foregoing; and (iv) any foreign equivalents of any of the foregoing, including, without limitation any PCTs. Flamel will provide GSK with a certified English translation of the patent application attached at Exhibit D within thirty (30) calendar days of the Effective Date.

"Party(ies)" will have the meaning set forth in the Preamble.

"PTO" means the United States Patent and Trademark Office and any successor entity thereto.

"Term" will have the meaning set forth in Section 6.1.

"Territory" means [***]

"Third Party(ies)" means any party(ies) other than Flamel, GSK, or an Affiliate of either of them.

"U.S." or "United States" means the fifty (50) states of the United States of America and the District of Columbia.

Section 1.2 The word "including" or any variation thereof means "including without limitation" and the word "including" or any variation thereof will not be construed to limit any general statement which it follows to the specific or similar items or matters immediately following it.

Article II. License Grants and Assignment.

Section 2.1 Flamel License Grant. Flamel hereby grants to GSK an exclusive (even as to Flamel), royalty-free license, with the right to grant sublicenses, under all of Flamel's rights, title and interest in and to the Carvedilol MR Patent Rights in the Territory.

Section 2.2 GSK License Grant. Subject to Section 3.3, GSK hereby grants to Flamel an exclusive (even as to GSK), royalty-free license, with the right to grant sublicenses, under all of GSK's rights, title and interest in and to the Micropump Technology Patents in the Territory.

Section 2.3 Irrevocable Licenses. The licenses granted under Sections 2.1, 2.2 and 3.3 will be irrevocable for any reason, including termination of this Agreement.

Section 2.4 Assignment of Flamel.

(i) Subject to Section 2.4(ii) below, at any time during the Term after a patent included within Carvedilol MR Patent Rights has issued in a country in the Territory, GSK will have the right, but not the obligation, to send a written request to Flamel that Flamel execute the Flamel Patent Assignment for such patent. Flamel agrees that it will, within ten (10) business days after its receipt of a written request from GSK, execute and deliver to GSK at no cost to GSK, any and all documents provided by GSK to effectuate the assignment of all ofFlamel's ownership interests in such patent, including, without limitation, the Flamel Patent Assignment for such patent, which documents GSK may file with the appropriate national and international patent and other intellectual property authorities. Flamel acknowledges and agrees that GSK will be entitled to injunctive relief in the event that Flamel breaches this Section 2.4(i).

(ii) Notwithstanding anything to the contrary in Section 2.4(i) above, GSK will have the right to request that Flamel execute a Flamel Patent Assignment for any Carvedilol MR Patent Rights in a country and any other documents at any time during the Term if, as provided in Section 7.8, GSK reasonably deems it necessary or desirable to effectuate the assignment of all of Flamel's ownership interest the Carvedilol MR Patent Rights in such country in order for GSK to obtain the full benefits of this Agreement and the transactions contemplated hereby. Flamel agrees that it will, within ten (10) business days after its receipt of a written request from GSK, execute and deliver to GSK at no cost to GSK, any and all documents provided by GSK (including without limitation the Flamel Patent Assignment) to effectuate the assignment of all of Flamel's ownership interests the Carvedilol MR Patent Rights in such country. Flamel acknowledges and agrees that GSK will be entitled to injunctive relief in the event that Flamel breaches this Section 2.4(ii).

(iii) GSK will be responsible for all fees and costs associated with filing the Flamel Patent Assignment with the PTO and the other national and international patent and other intellectual property authorities in the Territory.

(iv) Flamel will cooperate with and reasonably assist GSK in relation to GSK's registration of any assignment of a patent in the Territory as provided in this Section 2.4 with the PTO and with other patent offices in the Territory.

Section 2.5 Assignment of GSK.

(i) Subject to Section 2.5(ii) and Section 3.3 below, at any time during the Term after a patent included within Micropump Technology Patent Rights has issued in a country in the Territory, Flamel will have the right, but not the obligation, to send a written request to GSK that GSK execute the GSK Patent Assignment for such patent. GSK agrees that it will, within ten (10) business days after its receipt of a written request from Flamel, execute and deliver to Flamel at no cost to Flamel, any and all documents provided by Flamel to effectuate the assignment of all of GSK's ownership interests in such patent, including, without limitation, the GSK Patent Assignment for such patent, which documents Flamel may file with the appropriate national and international patent and other intellectual property authorities. GSK acknowledges and agrees that Flamel will be entitled to injunctive relief in the event that GSK breaches this Section 2.5(i).

(ii) Notwithstanding anything to the contrary in Section 2.5(i) above but subject to Section 3.3, Flamel will have the right to request that GSK execute a GSK Patent Assignment for any Micropump Technology Patent Rights in a country and any other documents at any time during the Term if, as provided in Section 7.8, Flamel reasonably deems it necessary or desirable to effectuate the assignment of all of GSK's ownership interest the Micropump Technology Patent Rights in such country in order for Flamel to obtain the full benefits of this Agreement and the transactions contemplated hereby. GSK agrees that it will, within ten (10) business days after its receipt of a written request from Flamel, execute and deliver to Flamel at no cost to Flamel, any and all documents provided by Flamel (including without limitation the GSK Patent Assignment) to effectuate the assignment of all of GSK's ownership interests the Micropump Technology Patent Rights in such country. GSK acknowledges and agrees that Flamel will be entitled to injunctive relief in the event that Flamel breaches this Section 2.5(ii).

(iii) Flamel will be responsible for all fees and costs associated with filing the GSK Patent Assignment with the PTO and the other national and international patent and other intellectual property authorities in the Territory.

(iv) GSK will cooperate with and reasonably assist Flamel in relation to Flamel's registration of any assignment of a patent in the Territory as provided in this Section 2.5 with the PTO and with other patent offices in the Territory.

Article III. Intellectual Property.

Section 3.1 Filing, Prosecution, Maintenance.

(i) GSK will have the sole right, using in-house or outside legal counsel selected at GSK's sole discretion, to prepare, file, prosecute, maintain and extend the Carvedilol MR Patent Rights in countries of GSK's choice throughout the Territory, for which GSK will bear the costs relating to such activities which occur at GSK's request or direction. GSK will solicit Flamel's advice and review of important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and GSK will take into account Flamel's reasonable comments related thereto.

(ii) Subject to Section 3.3, Flamel will have the sole right, using in-house or outside legal counsel selected at Flamel's sole discretion, to prepare, file, prosecute, maintain and extend the Micropump Technology Patent Rights in countries of Flamel's choice throughout the Territory, for which Flamel shall bear the costs. Flamel will solicit GSK's advice and review of important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and Flame' will take into account GSK's reasonable comments related thereto.

(iii) Each of Flamel and GSK will hold all information it presently knows or acquires under this Section that is related to all such patents and patent applications as confidential and subject to the provisions of Article V of this Agreement.

(iv) Each Party will cooperate with the other as reasonably requested to effect the provisions of this Section 3.1.

Section 3.2 Control of Infringement Proceedings.

(i) GSK will have the sole right, but not the obligation, to bring, at its sole discretion and at its own expense, an infringement action against any Third Party relating to the Carvedilol MR Patent Rights, and to use Flamel's name in connection therewith. GSK will have full control over its conduct of such infringement action, including settlement and discontinuance thereof.

(ii) Subject to Section 3.3, Flamel will have the sole right, but not the obligation, to bring, at its sole discretion and its own expense and to use GSK's name in connection therewith, an infringement action against any Third Party relating to the Micropump Technology Patent Rights, and to use GSK's name in connection therewith. Flamel will have full control over its conduct of such infringement action, including settlement and discontinuance thereof.

Section 3.3 Flamel Patent Rights. For the avoidance of doubt, (i) Flamel represents and warrants that the Micropump Technology Patent Rights will not include any claims that cover Carvedilol (as hereinafter defined) and/or any formulation thereof; and (ii) notwithstanding the foregoing but subject in all respects to the License Agreement, to the extent GSK determines in good faith that the Micropump Technology Patent Rights could be interpreted to include a claim that covers Carvedilol and/or any formulation thereof, Flamel hereby agrees that during the Term, GSK will have a perpetual, exclusive (even as to Flamel), royalty-free license, with the right to grant sublicenses, under all of Flamel's rights, title and interest in and to the Micropump Technology Patent Rights with respect to any claims that cover Carvedilol and/or any formulation thereof. For the purposes of this Section 3.3,"Carvedilol" means (1-(9H-carbazol-4-yloxy)-[[2-2(2-methoxyphenoxy)ethyl]amino]-2-propanol), the compound that is known by the generic name of Carvedilol and including all racemates, chelates, complexes, enantiomers, diastereoisomers, anhydrous forms, salts, bases, esters, hydrates, solvates, polymorphs, crystal forms, crystal habits, prodrugs, isotopic or radiolabeled equivalents, metabolites, or the like, thereof and all mixtures and any of the foregoing, and compositions comprising Carvedilol.

Article IV. Re presentations and Warranties.

Section 4.1 Flamel Representations and Warranties. As of the Effective Date, Flamel represents and warrants to GSK that:

(i) Flamel is a corporation duly incorporated, validly existing and in good standing under the law of the jurisdiction of its incorporation, and has the corporate power to grant the licenses and perform its obligations under this Agreement;

(ii) this Agreement has been duly executed and delivered by Flamel, is a legal and valid obligation binding upon Flamel and enforceable against Flamel in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other laws affecting creditors' rights generally or by the availability of equitable remedies;

(iii) Flamel has full Control over its rights, title and interest in and to the Carvedilol MR Patent Rights and Micropump Technology Patent Rights in order for Flamel to grant the licenses under Section 2.1 and Section 3.3, respectively, and Flamel otherwise has the full right and authority to enter into this Agreement;

(iv) there are no existing or threatened actions, suits or claims pending against Flamel with respect to Flamel's right and ability to enter into and perform its obligations under this Agreement;

(v) Flamel has not granted, nor will Flamel grant during the Term, any right, license or interest in or to Flamel's rights, title and interest in and to the Carvedilol MR Patent Rights that is in conflict with the rights or licenses granted to GSK under Section 2.1 and Section 3.3;

(vi) Flamel has not encumbered its rights, title and interest in and to the Carvedilol MR Patent Rights, and Flamel will not encumber its rights, title and interest in and to the Carvedilol MR Patent Rights with liens, mortgages, security interests or otherwise after the Effective Date; and

(vii) to the best of Flamel's knowledge, there is nothing in any Third Party agreement that Flamel has entered into that in any way will limit Flamel's ability to enter into this Agreement and to perform all of the obligations undertaken by Flamel hereunder, and that Flamel will not enter into any such agreement with a Third Party after the Effective Date under which Flamel mould incur any such limitations.

Section 4.2 GSK Representations and Warranties. As of the Effective Date, GSK represents and warrants to Flamel that:

(i) GSK is a corporation duly incorporated, validly existing and in good standing under the law of the jurisdiction of its incorporation, and has the corporate power to grant the licenses and perform its obligations under this Agreement;

(ii) this Agreement has been duly executed and delivered by GSK, is a legal and valid obligation binding upon GSK and enforceable against GSK in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other laws affecting creditors' rights generally or by the availability of equitable remedies;

(iii) GSK has full Control over its rights, title and interest in and to the Micropump Technology Patent Rights in order for GSK to grant the license under Section 2.2, and GSK otherwise has the full right and authority to enter into this Agreement;

(iv) there are no existing or threatened actions, suits or claims pending against GSK with respect to GSK's right and ability to enter into and perform its obligations under this Agreement;

(v) GSK has not granted, nor will GSK grant during the Term, any right, license or interest in or to GSK's rights, title and interest in and to the Micropump Technology Patent Rights that is in conflict with the rights or licenses granted to Flamel under Section 2.2;

(vi) GSK has not encumbered its rights, title and interest in and to the Micropump Technology Patent Rights, and GSK will not encumber its rights, title and interest in and to the Micropump Technology Patent Rights with liens, mortgages, security interests or otherwise after the Effective Date; and

(vii) to the best of GSK's knowledge, there is nothing in any Third Party agreement that GSK has entered into that in any way will limit GSK's ability to enter into this Agreement and to perform all of the obligations undertaken by GSK hereunder, and that GSK will not enter into any such agreement with a Third Party after the Effective Date under which GSK would incur any such limitations.

Section 4.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT OR MANDATED BY APPLICABLE LAW (WITHOUT THE RIGHT TO WAIVE OR DISCLAIM), NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT, ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS, OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL WARRANTIES, CONDITIONS OR REPRESENTATIONS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF PERFORMANCE, MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

Article V. Confidentiality.

Section 5.1 Confidential Information. Except as expressly provided herein, the Parties agree that, during the Term and for a period of five (5) years thereafter, the receiving Party will keep completely confidential and will not publish or otherwise disclose and shall not use for any purpose except for the purposes contemplated by this Agreement any Confidential Information furnished to it by the disclosing Party hereto pursuant to this Agreement, except that to the extent that it can be established by the receiving Party by competent proof that such Confidential Information:

(i) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(iv) was independently developed by the receiving Party without reference to any information or materials disclosed by the disclosing Party; or

(v) was subsequently disclosed to the receiving Party by a person other than a Party without breach of any legal obligation to the disclosing Party.

Section 5.2 Permitted Disclosures. Each Party hereto may disclose the other's Confidential Information to the extent such disclosure is reasonably necessary in connection with the conduct of the development activities to be conducted hereunder, in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations or otherwise submitting information to tax or other governmental authorities, conducting clinical trials, or making a permitted sublicense or otherwise exercising its rights hereunder, provided that if a Party is required to make any such disclosure of another Party's Confidential Information, other than pursuant to a confidentiality agreement, it will give reasonable advance notice to the latter Party of suchdisclosure and, save to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information prior to its disclosure (whether through protective orders or otherwise).

Section 5.3 Public Announcements. No public announcement or any other disclosure, including under a confidentiality agreement, to Third Parties concerning the existence of, terms, or subject matter or termination of this Agreement will be made, either directly or indirectly, by any Party to this Agreement, except as may be legally required or as may be required for recording purposes, without first obtaining the written approval of the other Party and agreement upon the nature and text of such announcement or disclosure; provided, however, that in the case of disclosures made by Flamel to a bona fide financial analyst for modeling and valuation purposes under a confidentiality agreement, Flamel will provide GSK advance written notice of such disclosure (as set forth below), but will not be obligated to obtain GSK's consent. The Party desiring to make any such public announcement or other disclosure (including those which are legally required or may be required for recording purposes) will inform the other Party of the proposed announcement or disclosure in reasonably sufficient time prior to public release, which will be at least five (5) business days prior to release of such proposed announcement or disclosure, and will provide the other Party with a written copy thereof, in order to allow such other Party to comment upon such announcement or disclosure. Each Party agrees that it will cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either Party included in any such disclosure.

Section 5.4 Third Party Publications. Nothing herein shall be construed to prevent GSK from disclosing any information received from Flamel hereunder: (i) to a Third Party contract manufacturer of GSK, subject to the consent of Flamel, such consent not to be unreasonably withheld; or (ii) to an Affiliate, sublicensee, distributor, Third Party research or clinical contractor, of GSK, without the consent of Flamel, provided, that in all cases of disclosure under clause (i) or (ii) above, the Third Party to whom such disclosure is made shall have undertaken a similar obligation of confidentiality with respect to the Confidential Information.

Section 5.5 Bankruptcy. All Confidential Information disclosed by one Party to the other will remain the intellectual property of the disclosing Party. In the event that a court or other legal or administrative tribunal, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a Party to this Agreement based on the insolvency or bankruptcy of such Party, the bankrupt or insolvent Party will promptly notify the court or other tribunal (i) that Confidential Information received from the other Party under this Agreement remains the property of the other Party, and (ii) of the confidentiality obligations under this Agreement. In addition, the bankrupt or insolvent party will, to the extent permitted by law, take all steps necessary or desirable to maintain the confidentiality of the other party's Confidential Information and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement.

Article VI. Term and Termination.

Section 6.1 The term of this Agreement (the "Term") will commence on the Effective Date and, unless earlier terminated as provided in Section 6.3 or Section 6.4, will continue in perpetuity.

Section 6.2 Notwithstanding the bankruptcy of a Party, or the impairment of performance by a Party of its obligations under this Agreement as a result of bankruptcy or insolvency of such Party, and subject to such Party's rights to terminate this Agreement for reasons other than bankruptcy or insolvency as expressly provided in this Agreement, the other Party shall be entitled to retain the licenses under the terms and conditions granted herein.

Section 6.3 Subject to Section 2.3, this Agreement may be terminated at any time during the Term upon the mutual written agreement of the Parties.

Section 6.4 Subject to Section 2.3, either Party may terminate this Agreement in the event the other Party has materially breached or defaulted in the performance of any of its obligations hereunder, and if such default is not corrected within [***] calendar days after receiving written notice from the other Party with respect to such default, such other Party shall have the right to terminate this Agreement by giving written notice to the Party in default, provided the notice of termination is given within one (1) year of when the Party giving notice knew of the default and prior to correction of the default.

Section 6.5 Article V will survive termination of this Agreement by the Parties as provided in Section 6.3 and 6.4. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement will also survive such termination of the Agreement, but only to the extent required for the observation and performance of the aforementioned surviving portions of this Agreement.

Article VII. Miscellaneous Provisions.

Section 7.1 Dispute Resolution; Governing Law.

(i) If a dispute or controversy regarding any right or obligation under this Agreement arises between the Parties which they are unable to resolve, (a "Dispute"), each of the Parties will, within a reasonable amount of time after any such Dispute arises but in no event not more than thirty (30) business days after such Dispute arises (or in the event that there is a cure period as provided in Section 6.4, within thirty (30) business days after the expiration of the applicable cure period), be entitled to submit to the other Party written notice of such Dispute, with such notice setting forth in reasonable detail the nature of the dispute (the "Dispute Notice"). For a period of thirty (30) business days after the date of the receiving Party's receipt of the Dispute Notice, the Parties will seek to resolve such Dispute by good faith negotiation between representatives of the Parties, subject to Section 2.3. If at the end of such thirty (30) business day period the Dispute remains unresolved, such Dispute will be presented to the President of United States Pharmaceuticals business of GlaxoSmithKline or his designee and the CEO of Flamel or his designee, for resolution of such Dispute by good faith negotiations, subject to Section 2.3. If at the end of a subsequent thirty (30) business day period the Dispute remains unresolved, the Parties may only seek relief for such Dispute by referring such Dispute to arbitration under the rules of International Chamber of Commerce (ICC), subject to Sections 2.3, 6.4 and 7.1(ii) The arbitration will be conducted by a panel of three (3) arbitrators, selected in accordance with ICC rules, and any such arbitration will be conducted in the English language and take place in New York, New York. The decision of such arbitration panel will be final and binding upon the Parties. The Parties agree that any pecuniary damages which may be awarded by such arbitration panel will be limited, in the case of GSK, to lost Net Sales (as defined in the License Agreement) and, in the case of Flamel, to lost royalties pursuant to Section 3.3 of the License Agreement. This provisions of this Section7.1 will not restrict in any way the Parties' rights to seek preliminary injunctive or other equitable relief from any court having jurisdiction.

(ii) Subject to Section 2.3, this Agreement will be deemed to have been made in the United States, and its form, execution, validity, construction and effect will be determined in accordance with, and any Dispute will be governed by and construed in accordance with, the laws of the State of New York, without reference to conflicts of laws principles.

Section 7.2 Waiver. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances will be construed as a further or continuing waiver of such condition or term or of another condition or term

Section 7.3 Assignment. This Agreement shall not be assignable by either Party without the written consent of the other Party, except that either Party may assign this Agreement, without such consent, to (i) an Affiliate of such Party; or (ii) an entity that acquires all or substantially all of the business or assets of such Party to which this Agreement pertains, (whether by merger, reorganization, acquisition, sale, or otherwise) and agrees in writing to be bound by the terms and conditions of this Agreement. The terms and conditions of this Agreement shall be binding on and inure to the benefit of the permitted successors and assigns of the Parties.

Section 7.4 Notices. Any notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by international express delivery service, registered or certified air mail, return receipt requested, postage prepaid, or by facsimile (confirmed by prepaid registered or certified air mail letter or by international express delivery mail) (e.g., FedEx)), and shall be deemed to have been properly served to the addressee upon receipt of such written communication, to the following addresses of the Parties, or such other address as may be specified in writing to the other Parties hereto:

if to GSK:

GlaxoSmithKline
709 Swedeland Road
King of Prussia, PA 19406
Attention: Senior Vice President, Business Development
Telephone: 610-270-5397
Telecopy: 610-270-5962

with copies to:

GlaxoSmithKline
Corporate Legal Department
2301 Renaissance Blvd.
Mail Code RN0220
King of Prussia, PA 19406-2772
Attention: Senior Vice President and Assistant General Counsel – R&D Legal Operations
Telephone: 610-787-3626
Telecopy: 610-787-7084

if to Flamel:

Flamel Technologies, S.A.
Parc Club du Moulin a Vent
33 Avenue du Docteur Georges Levy
69693 Venissieux Cedex
France

Attention: Dr. Gerard Soula
President and Chief Executive Officer
Telephone: 334 7278 3434
Telecopy: 334 7278 3435

Flamel Technologies, S.A.
2121 K Street, Suite 650
Washington, D.C. 20037
Attention: Stephen H. Willard
Chief Financial Officer and General Counsel
Telephone: 202-862-8400
Telecopy: 202-862-3933

Section 7.5 Independent Contractors. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute GSK or Flamel as partners or joint venturers in the legal sense. No Party hereto will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of any other Party or to bind any other Party to any contract, agreement or undertaking with any Third Party.

Section 7.6 Other Obligations. Except as expressly provided in this Agreement or as separately agreed upon in writing between Flamel and GSK, each Party will bear its own costs incurred in connection with the implementation of the obligations under this Agreement.

Section 7.7 Severability. If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions will be deemed inoperative to the extent that they may conflict therewith and will be deemed to be modified to conform with such statute or rule of law. In the event that the terms and conditions of this Agreement are materially altered as a result of the above, the Parties will renegotiate the terms and conditions of this Agreement to resolve any inequities.

Section 7.8 Further Assurances. At any time or from time to time on and after the date of this Agreement, either Party will at the request of the other Party (i) deliver to the requesting Party such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of assignment, transfer or license, and (iii) take or cause to be taken all such actions, as the requesting Party may reasonably deem necessary or desirable in order for the requesting Party to obtain the full benefits of this Agreement and the transactions contemplated hereby.

Section 7.9 Entire Agreement. This Agreement constitutes the entire agreement, both written and oral, with respect to the subject matter hereof, and supersedes and terminates all prior or contemporaneous understandings or agreements, whether written or oral, between GSK and Flamel with respect to such subject matter. No terms or provisions of this Agreement will be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement. To the extent that there is any inconsistency between this Agreement and the License Agreement, this Agreement will govern.

Section 7.10 Headings. The captions to the Articles and Sections hereof are not a part of this Agreement, but are included merely for convenience of reference only and will not affect its meaning or interpretation.

Section 7.11 Rules of Construction.

(i) The Agreement will be construed as if both parties drafted the Agreement jointly, and will not be construed against either party as principal drafter.

(ii) Unless otherwise provided, all references to months, quarters or years are references to calendar months, calendar quarters or calendar years.

(iii) Any reference to any federal, national, state, local or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, unless the context requires otherwise.

(iv) The English language version of this Agreement will control and any translations of this Agreement will be for convenience purposes only for the Party making such translation and do not embody any agreement between the Parties.

Section 7.12 No Third Party Beneficiaries. All rights, benefits and remedies under this Agreement are solely intended for the benefit of Flamel and GSK, and no Third Party will have any rights whatsoever to (i) enforce any obligation contained in this Agreement, (ii) seek a benefit or remedy for any breach of this Agreement, or (iii) take any other action relating to this Agreement under any legal theory, including but not limited to, actions in contract, tort (including but not limited to negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the Parties.

Section 7.13 Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument. Facsimile signatures will be binding on the Parties.

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

FLAMEL TECHNOLOGIES, S.A.		**SB PHARMCO PUERTO RICO, INC.**	
By:	_____	By:	_____
Name:	_____	Name:	_____
Title:	_____	Title:	_____

Exhibit 10.6

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

SUPPLY AGREEMENT

FOR

COMMERCIAL SUPPLY

BY AND BETWEEN

SMITHKLINE BEECHAM (CORK) LIMITED

AND

FLAMEL TECHNOLOGIES S.A.

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

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SUPPLY AGREEMENT

This Supply Agreement for Commercial Supply (the "**Agreement**") is made and entered into this 30 day of September 2011 (the "**Signing Date**"), to be effective January 1, 2011 (the "**Effective Date**"), by and between SmithKline Beecham (Cork) Limited, a company organized under the laws of the country of Ireland with a place of business at Curraghbinny, Carrigaline, Country Cork, Ireland, on behalf of itself and its Affiliates ("**GSK**"), and Flamel Technologies S.A., a corporation organized and existing under the laws of France, with its principal place of business at Parc Club du Moulin a Vent, 33 Avenue du Docteur Georges Levy 69693 Venissleux Cedex, France ("**Flamel**") (each a "**Party**" and collectively, the "**Parties**").

RECITALS

WHEREAS, Flamel and GSK have entered into a License Agreement (as defined below) by which GSK has licensed certain proprietary rights from Flamel related to the Flamel Micropump Technology (as defined below);

WHEREAS, Flamel has the facilities and the ability to manufacture and supply to GSK promotional samples supplies and commercial supplies of Intermediate Product;

WHEREAS, Flamel wishes to sell to GSK and its Affiliates such promotional sample supplies and commercial supplies of Intermediate Product;

WHEREAS, it is intended that orders for Intermediate Product to be supplied by Flamel shall be placed by GSK and its Affiliates and that Flamel shall supply GSK or its Affiliates as appropriate with, and invoice them for, the same on the terms of and subject to the conditions in this Agreement.

NOW, THEREFORE, in consideration of the premises and of the mutual promises and undertakings contained herein, the Parties, intending to be legally bound, do hereby agree as follows:

1. DEFINITIONS

"**Affiliate**" shall mean any legal entity (such as a corporation, partnership, or limited liability company) that Controls, is Controlled by, or is under common Control with a Party to this Agreement. For the purposes of this definition, the term "Control" means (i) beneficial ownership of at least fifty percent (50%) of the voting securities of a corporation or other business organization with voting securities (or such lesser percentage which is the maximum allowed by a foreign corporation in a particular jurisdiction); (ii) a fifty percent (50%) or greater interest in the net assets or profits of a partnership or other business organization without voting securities; or (iii) the ability to direct the affairs of any such entity.

"**Agreement**" means this Commercial Supply Agreement together with all its schedules (the "**Schedules**").

"**API**" means the active pharmaceutical ingredient, Carvedilol, which is used in the manufacture of the Intermediate Product.

"**Batch**" means the total Intermediate Product obtained from one Manufacturing run, including purification.

"**Batch Record**" means a record in form and substance satisfactory to GSK signed by a Qualified Person pursuant to Section 15.2.

"**Carvedilol**" means (1-(9H-carbazol-4-yloxy)-[(2-2(2-methoxyphenoxy)ethyljamino]-2-propanol), the compound that is known by the generic name of Carvedilol and including all racemates, chelates, complexes, enantiomers, diastereoisomers, salts, bases, esters, hydrates, solvates, polymorphs, crystal forms, crystal habits, prodrugs, isotopic or radiolabeled equivalents, metabolites, 'or the like, thereof and all mixtures and any of the foregoing, and compositions comprising Carvedilol.

"**Certificate of Analysis**" means a document identified as such and provided by Flamel to GSK that (i) sets forth the analytical test results for a specified lot of Intermediate Products shipped to GSK hereunder, (ii) is in conformance with each applicable Drug Application and (iii) states whether such Intermediate Products are manufactured in accordance with the Specifications and cGMP's.

"**Current Good Manufacturing Practices**" or "**cGMPs**" means all applicable standards relating to manufacturing practices for fine chemicals, intermediates bulk products or finished pharmaceutical products. For purposes of this Agreement, cGMPs shall mean the principles: (1) detailed in the U.S. Current Good Manufacturing Practices, 21 CFR Parts 210 and 211, The Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, and the US Pharmacopoeia and National Formulary, as each may be amended from time to time; (ii) promulgated by any Governmental Body having jurisdiction over the manufacture of pharmaceutical products, in the form of laws or regulations; (iii) promulgated by any Governmental Body having jurisdiction over the manufacture of pharmaceutical products, in the form of guidance documents (including but not limited to advisory opinions, compliance policy guides and guidelines) which guidance documents are being implemented within the pharmaceutical manufacturing industry for such products; or (iv) which Flamel knows or reasonably should have known to be current and shown to be feasible on a commercially reasonable basis and valuable in ensuring drug quality within the pharmaceutical manufacturing industry for such products, in each case as in effect at the Effective Date and as amended, promulgated or accepted from time to time during the term of this Agreement.

"**Confidential Information**" means (i) any proprietary or confidential information or material in tangible form disclosed hereunder that is marked as "Confidential" at the time it is delivered to the receiving Party, and/or (ii) proprietary or confidential information disclosed orally hereunder that is identified as confidential or proprietary when disclosed and such disclosure of confidential information is confirmed in writing within a reasonable period of time thereafter by the disclosing Party.

"**Delivery Terms**" means Ex Works Manufacturing Site (Incoterms 2000)."Drug Application" means any New Drug Application filed with the United States Food & Drug Administration ("**FDA**"), any Abbreviated New Drug Application filed with the FDA, any Supplemental New Drug Application filed with the FDA, any product license or any equivalent drug application or similar pharmaceutical product approval administered by any foreign Governmental Body, or extension or renewal of any of the foregoing.

"**Firm Order**" has the meaning set out in Section 5.1.

"**Flamel Micropump Technology**" means a multiple-dose system containing a large number of microparticles that may be contained in capsule, tablet, orally dispersible, sachet or suspension formulations. It is expected that the microparticles are released in the stomach and pass into the small intestine, where each microparticle operates as a miniature delivery system, releasing the drug at a controlled rate and over an extended period of time.

"**Forecast**" has the meaning set out in Section 5.1.

"**Force Majeure**" means in relation to either Party, any circumstances beyond the reasonable control of that Party (including without limitation earthquakes, riots, civil commotions, terrorism, war, hostilities between nations, governmental laws, orders, or regulations, embargoes, actions by the government or any agency thereof, acts of God, storms, fires, accidents, labor disputes or strikes, sabotage, explosions or other similar or different contingencies).

"**Generic Equivalent Product**" means a pharmaceutical product that has received FDA approval for marketing in the Territory and is directly substitutable for the Product, including any product that is specified under an Abbreviated New Drug Application (ANDA).

"**Good Condition**" means fit for intended purpose, of satisfactory quality, not damaged and capable of any agreed standard of performance.

"**Governmental Body**" means any nation or government, any state, province, or other political subdivision thereof, or any entity with legal authority to exercise executive, legislative, judicial, regulatory or administrative functions or pertaining to government.

"**Improvements**" means any new or improved process, technique, method, formula, invention or know-how relating to the Manufacture of Intermediate Product.

"**Intellectual Property**" means patents, trademarks, service marks, design rights (whether registerable or otherwise), including applications for any of the foregoing, copyright, rights in know-how, trade or business names and other similar rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world whether registerable or not.

"**Intermediate Product**" means any bulk presentation or presentations of Product before encapsulation and final packaging."Intermediate Product License" means each and every product license, marketing authorization or any other authorization(s) (as the case may be) as well as the applications therefore relating to the marketing, sale and/or distribution of the Intermediate Product.

"**Key Performance Indicators**" or "**KPI's**" are those indicators set forth in Schedule A hereto to evaluate the production and supply of Intermediate Product under this Agreement which are used merely as benchmarks to evaluate such production and supply of Intermediate Product and for discussion criteria as to ways Flamel may improve such production and supply.

"**License Agreement**" shall mean the License Agreement entered into by and between the Parties dated March 26, 2003.

"**Level One Maximum Capacity**" means a maximum of [***] Batches per calendar year, "Level Two Maximum Capacity" means a maximum of [***] Batches per calendar year.

"**Manufacture**" means the planning, purchasing, manufacture, processing, compounding, storage, filing, packaging, labelling, testing, sample retention, stability testing, release and shipment of Intermediate Product and such other matters as may be prescribed for each Intermediate Product by GSK.

"**Manufacturing License**" means all licenses necessary for or in connection with the Manufacture of the Intermediate Product at the Manufacturing Site(s).

"**Manufacturing Site**" means the manufacturing facility of Flamel at Pessac, France or such other manufacturing facility of Flamel (or of any duly authorized sub-contractor under Article 37 of this Agreement) as shall have been approved in writing by GSK.

"**Materials**" means the raw materials and components used in the Manufacture of the Intermediate Products.

"**Minimum monthly Fees**" has the meaning set out in Section 9.3.

"**Nominated Contract Manufacturer**" means such of GSK's and its Affiliates' contract manufacturers as shall from time to time be nominated by GSK as being persons to whom supplies of Intermediate Product shall be made pursuant to this Agreement.

"**Order**" has the meaning set out in Section 3.1.

"**Product**" means any presentation or presentations of Carvedilol that incorporate the Flamel Micropump Technology, alone or in combination with other therapeutically active compounds, for the therapeutic or prophylactic treatment of diseases and conditions in humans in any dosage or strength.

"**Qualified Person**" means the person named in this Agreement or any replacement notified by Flamel and agreed by GSK.

"**Reduction Notice**" has the meaning set out in Section 5.9.

"**Regulator**" means any relevant authority which regulates any aspect of the Manufacture of the Intermediate Product and/or the sale or marketing of any product of which an Intermediate Product forms part.

"**Reserve Supply**" has the meaning set out in Section 10.3.

"**Specifications**" means the preliminary specifications for the Intermediate Product as set forth in the Quality Agreement, as such specifications may be amended from time to time in accordance with Section 2.3.

"**Supply Price**" has the meaning set out in Section 8.1.

"**Technical Change Procedure**" means the procedure for changing the manner in which Flamel Manufactures Intermediate Product.

"**Term**" has the meaning set out in Article 29 hereof.

"**Territory**" shall have the meaning set forth in the License Agreement.

"**Third Party Suppliers**" means any such third party suppliers as may be notified to Flamel by GSK and such other supplier(s) of Materials as may be approved by GSK from time to time.

2. FLAMEL'S OBLIGATIONS

2.1 In accordance with the terms of this Agreement, Flame! shall Manufacture, carry out quality control, package and supply GSK's, and GSK's Nominated Contract Manufacturer's operating on behalf of GSK, requirements for the Intermediate Product as ordered from time to time by the same in accordance with Article 5.

2.2 Flamel shall Manufacture the Intermediate Product at the Manufacturing Site in accordance with Good Manufacturing Practice, the Specifications, the Technical Agreement, the Manufacturing License and all laws and regulations relevant to the Manufacture of the Intermediate Product, including not only the country of Manufacture but also, where any of the Intermediate Product is to be supplied to another country, the applicable laws and regulations in such country as reasonably directed by GSK. Without prejudice to the foregoing, Flamel shall not change any Manufacturing Site in which the Intermediate Product is Manufactured, or the Materials, process or plant used in the Manufacture of the Intermediate Products without first obtaining written consent from GSK (or where the Intermediate Product in question are to be supplied to one of GSK's Affiliates, that Affiliate) to such change.

2.3 All of the Intermediate Product supplied by Flamel shall comply with the Specifications and be in Good Condition. The Specifications may, subject to the laws and regulations in force in the relevant territory, only be changed by agreement in writing. Flamel shall not unreasonably withhold its agreement to any change in the Specifications requested by GSK. Any amendment to the Specifications shall be subject to the same rules regarding confidentiality as expressed herein.

3. PLACING OF ORDERS

3.1 GSK (and, if relevant, GSK's Nominated Contract Manufacturers) shall place orders for Intermediate Product by submitting an electronic order to Flamel via GSK's External Supply Chain System ("ESC Collaborate") or in any other written or electronic form, setting out the type and quantity of Intermediate Product required and the date for delivery (an "Order"). Flamel shall supply GSK with details of the anticipated lead times between placing an Order and delivery of Intermediate Product and Flamel shall keep GSK informed of its progress.

3.2 Time shall be of the essence in relation to the performance of any and all of Flannel's obligations pursuant to this Agreement.

4. SUPPLY AND STORAGE OF GSK API, MATERIALS AND INTERMEDIATE PRODUCTS

4.1 Flamel undertakes with GSK not to use any GSK API supplied by GSK or any Affiliate of GSK to Flamel for any purpose whatsoever other than the Manufacture of Intermediate Products for GSK and that until such time as the GSK API has been incorporated into the process of Manufacture of the Intermediate Products, the GSK API will remain the property of GSK or any relevant Affiliate of GSK. Notwithstanding anything to the contrary in this Section 4.1, or in Clauses 12 and 13 of Schedule 4.7 to the License Agreement, if any commercial batches are rejected, Flamel will not be liable for any API loss related to such batches provided, however, that such API loss is not attributable to the negligence of Flamel. Flamel shall use commercially reasonable endeavours to Manufacture Product in accordance with the agreed minimum annual yield limits [***]; provided, however, that in the event Flamel fails to meet such minimum annual yield limits during any calendar quarter, the Parties shall meet to discuss and agree any necessary modifications to the minimum annual yield limits.

4.2 Flamel will report yields of Intermediate Product on a bi-annual basis in writing to GSK.

4.3 Ordering of GSK API and Materials:

4.3.1 Flamel shall be solely responsible for ordering the relevant quantities of API and Materials by reference to the forecasts provided by GSK in accordance with Article 5.

4.3.2 Flamel shall not obtain any supplies of API from any third party except GSK or its Affiliates, unless mutually agreed upon between the Parties. Subject to Section 4.1 above, the cost of API shall be revised annually and GSK will allow Flamel to benefit from any cost reduction.

4.3.3 Any Materials required by Flamel to Manufacture Intermediate Product shall be purchased in accordance with the Technical Agreement. Any purchases from a Third Party Supplier shall be on Flannel's own behalf and not as an agent for GSK and Flamel shall be fully responsible for all purchases from such Third Party Supplier.

4.4 Storage of GSK API, Materials and intermediate Products:

4.4.1 Flamel shall at all times store and warehouse all API , Materials and Intermediate Products manufactured by Flamel pursuant to this Agreement in premises that are secure, clean, compliant with the Manufacturing License and otherwise acceptable to GSK. Flamel shall operate a warehousing system that identifies all API and Intermediate Products according to type and status.

4.4.2 With regard to any API supplied by GSK or its Affiliates and any Intermediate Products, title to which shall in accordance with the terms of this Agreement have passed to GSK or any Affiliates of GSK, Flamel shall ensure that the containers of all such API and any such Intermediate Products are clearly identified to the effect that they are owned by GSK or any relevant Affiliates of GSK or for use only for GSK and its Affiliates (as the case may be).

5. FORECASTS; MANUFACTURING CAPACITY

5.1 GSK shall provide Flamel with a rolling [***] month forecast for commercial supply of Intermediate Product (the "Forecast"), which shall be updated quarterly. The Intermediate Product detailed in the first [***] months of each Forecast will constitute the firm order ("**Firm Order**").

5.2 The amount of Intermediate Product set forth in the Firm Order with regard to any particular month shall not be less than [***], nor more than [***] of the amount of Intermediate Product last forecasted for such particular month. The required delivery or shipment date for each such Firm Order will be specified in the Forecast.

5.3 Flamel shall respond to each Firm Order received from GSK within five (5) business days of receipt of the updated Firm Order within ESC Collaborate. The response shall include confirmation of the delivery dates and quantity as set out in the Firm Order.

5.4 Flamel shall satisfy GSK's and its Affiliates' requirements in respect of Intermediate Product pertaining to each and every Firm Order confirmed by Flamel pursuant to Section 5.3 above and shall use reasonable best endeavours to satisfy any changes in quantity, delivery phasing or dates requested by GSK in respect of such a Firm Order or any additional order, subject to its other manufacturing requirements. In the event that Flamel becomes aware that any Firm Order previously confirmed in accordance with this Section 5.4 will not be satisfied, then Flamel shall inform GSK as soon as reasonably practicable and in any event within one (1) business day. This shall be without prejudice to GSK's rights under this Agreement in respect of failure to meet Firm Orders.

5.5 It is understood that, subject to the requirements of Section 5.2 hereof, the remaining [***] of the Forecast constitutes an estimate of the future Intermediate Product requirement of GSK and its Affiliates and does not comprise any minimum purchase requirement or any binding commitment by GSK or its Affiliates to purchase such Intermediate Product.

5.6 Flamel shall ensure that Flannel and Flamel's GSK-approved suppliers have adequate capacity at all times to fulfill [***] of GSK's Firm Orders within the agreed lead time, to be negotiated in good faith on a case-by-case basis between the Parties. in the event that Flamel is approaching the Level One Maximum Capacity or the Level Two Maximum Capacity and is unable to comply with the provisions of the immediately preceding sentence, then Flamel shall notify GSK immediately of such situation and the Parties shall meet to discuss in good faith the situation and negotiate alternatives.

5.7 No capital expenditures shall be made by Flame! to support the development or manufacture of Intermediate Product without GSK's prior written approval where GSK will fund the expenditure (not unreasonably withheld and delayed). Where capital expenditure shall be made by Flannel to support the development of Intermediate Product which is funded solely by Flamel, Flamel shall notify GSK of this expenditure for GSK accounting purposes.

5.8 During the Term of this Agreement, the maximum amount of Product which may be ordered by GSK in any calendar year beginning from 1st January, 2012 is estimated to be no more than the Level One Maximum Capacity. In case of higher demand, the Parties shall meet to discuss in good faith the situation and shall agree any necessary modifications thereto. Notwithstanding the above, the Parties hereby agree that during the first quarter of 2012 Flamel shall Manufacture up to [***] batches in excess of the Level One Maximum Capacity amount.

5.9 Commencing on October 1, 2012, and quarterly thereafter, GSK may, however, notify Flamel in writing, with three (3) months prior notice, a reduction of the maximum capacity to the Level Two Maximum Capacity (a "**Reduction Notice**"); provided, however, that in the event that GSK shall require an increase from Level Two Maximum Capacity to Level One Maximum Capacity, the Parties shall meet to discuss in good faith the terms and conditions of such request. For the avoidance of any doubt, in the event that the Parties agree to increase the capacity from the Level Two Maximum Capacity to the Level One Maximum Capacity, the payment terms set forth in Section 9.3 above shall apply; provided, however, that Section 5.8 shall apply in the event GSK requires any capacity in excess of the Level One Maximum Capacity.

6. ARRANGEMENT OF ALTERNATIVE SUPPLY

If Flamel is unable to supply the Intermediate Product in accordance with the terms of this Agreement, Flamel shall use its best endeavours to source the same quantity and quality of Intermediate Product from a Third Party Supplier. Flamel shall notify GSK of the identity of the Third Party Supplier and the nature of the Intermediate Product available, (as soon as reasonably possible) prior to the delivery date, and GSK at its sole discretion, which shall not be unreasonably withheld, shall elect whether to authorize the use of Third Party Supplier by Flamel.

7. PASSING OF TITLE AND RISK IN THE INTERMEDIATE PRODUCT

7.1 The title and risk in the Intermediate Product shall remain with Flamel until delivered to the carrier selected by GSK at Flamel's Manufacturing Site, at which point title and risk shall pass to GSK.

7.2 Neither payment by nor passage of title or risk in the intermediate Product to GSK shall be deemed to constitute acceptance of the Intermediate Product.

8. PRICE OF THE INTERMEDIATE PRODUCTS

8.1 Throughout the Term of this Agreement, the prices for the Intermediate Product shall [***] (the "Supply Price"). For the avoidance of doubt, all batches of the intermediate Product already delivered and invoiced to GSK since January 1, 2011 shall be paid at the Supply Price set out above.

8.2 If GSK is able to obtain Intermediate Product of equivalent quality from a Third Party Supplier at a price lower than the prices otherwise payable in accordance with this Agreement, GSK shall so notify Flamel in writing and if so requested by Flamel shall procure that details of the lower price, and verification that such lower price applies to a similar commercial package to that supplied under this Agreement, are provided to Flamel by a mutually acceptable independent Third Party Supplier upon the condition that the identity of the Third Party Supplier is not disclosed to Flamel. With six (6) weeks of Flamel's receipt of such information, Flamel shall use its commercially reasonable endeavors to meet the lower price of the Third Party Supplier; provided, however, that if Flamel does not for any reason wish to, or cannot, meet the lower price for substantially the same quantity of Intermediate Product within that time GSK may exercise its termination right set forth in Section 33.1(b) below.

8.3 Flamel undertakes to submit to GSK within a period of fourteen (14) days of the end of each month or of the termination of this Agreement or such other intervals as may be agreed between the Parties such reports as GSK may require from time to time. Such reports shall include in respect of such month or part thereof or other time period as agreed between the Parties statements of:

(a) the quantity of Materials and API used by Flamel in the Manufacture of Intermediate Product;

(b) the quantity of the Intermediate Product Manufactured by Flamel for GSK and GSK's Nominated Contract Manufacturers (as appropriate);

(c) the quantity of the Intermediate Product delivered to GSK and GSK's Nominated Contract Manufacturers (as appropriate), by Flamel and received in Good Condition and in saleable form; and,

(d) the stock of Intermediate Product broken down by work in process and passed finished Intermediate Product.

9. INVOICE AND PAYMENT

9.1 Upon shipment of Intermediate Product, Flamel shall invoice GSK or GSK's Nominated Contract Manufacturer (as appropriate, depending on who placed the order for the relevant Intermediate Products) for the quantity of Intermediate Product shipped. Intermediate Product shall be invoiced at the Supply Price, as detailed in Section 8.1 above.

9.2 In consideration of this Agreement, taking into account the accommodations necessary to be made by Flannel as a result of GSK's anticipated fluctuations in demand during 2011 and 2012, GSK shall also pay to Flamel the following one time additional payments:

(a) A payment of [***] no later than September 25, 2011; and,

(b) A payment of a further [***] to be paid ten (10) business days after execution of this Agreement, upon invoice by Flamel.

9.3 Notwithstanding the quantity of Intermediate Product, if any, ordered by GSK pursuant to this Agreement, during the Term of this Agreement, GSK shall pay to Flamel "Minimum [***] Fees" to maintain either the Level One Maximum Capacity, or the Level Two Maximum Capacity, as applicable, as follows:

(a) From September 2011 until December 31, 2013, [***], except as may be modified as provided in subsection (c) below by receipt of a Reduction Notice no earlier than January 1, 2013, for Level One Maximum Capacity during such period;

(b) From January 1, 2014 until the end of the Term, [***], except as may be modified as provided in subsection (d) below by receipt of a Reduction Notice, no earlier than January 1, 2013, for Level One Maximum Capacity during such period;

(c) After January 1, 2013, if GSK has given a proper Reduction Notice pursuant to Section 5.9, the Minimum [***] Fees due after the effectiveness of the Reduction Notice shall be [***] for Level Two Maximum Capacity during such period; and,

(d) After January 1, 2014, if GSK has given a proper Reduction Notice pursuant to Section 5.9, the Minimum [***] Fees due after the effectiveness of the Reduction Notice shall be [***] for Level Two Maximum Capacity during such period; and,

(e) All amounts paid [***] pursuant to Section 8.1 shall be fully creditable against the Minimum [***] Fees. If the total amount paid under Section 8.1 for the Intermediate Product supply exceeds the Minimum [***] Fees for a given [***], then the Minimum [***] Fees for such [***] shall not be due from GSK. Conversely, if the total amount paid under Section 8.1 for the Intermediate Product supply is lower than the Minimum [***] Fees for a given [***], then Flamel shall submit an invoice to GSK equal to the complement payment to reach the amount of the applicable Minimum [***] Fees, in addition to the Section 8.1 payment. For example, in 2012 if the total paid for the Intermediate Product supply in any [***] was [***] under Section 8.1, then the Minimum [***] Fees for that [***] would be [***].

(f) The minimum capacity charge will be reconciled quarterly, to allow for aggregation and equal disbursement of the number of batches supplied to GSK over a [***] period of time. Following such reconciliation, GSK shall pay the difference between the amount paid for the number of batches supplied in each [***] and the Minimum [***] Fee due in accordance with Section 9.3 above. For the avoidance of doubt, if after the reconciliation it is determined that the Supply Price multiplied by the number of batches supplied to GSK per [***] exceeds the Minimum [***] Fee for the applicable [***], GSK shall not make be liable for any Minimum [***] Fee in such quarter.

9.4 Each invoice issued by Flamel hereunder shall specify:

(a) FPA (Firm Planed Arrival), customer order reference or purchase order reference;
(b) Local item code and description as per the packing list;
(c) Invoice number and date;
(d) Supplier name and address;
(e) Supplier VAT reg. Number;
(f) Buyer (Trading Partner) name and address (including country);
(g) Consignee (Ship to) name and address (including country);
(h) Currency;
(i) Any direct pass through charges (e.g., freight and insurance charges on a shipment bases); and,
(j) Any Free of Charge products (quantity, item code, batch no).

9.5 Unless otherwise stated in the Order, payment shall be [***] following receipt of the relevant invoice bearing the applicable Order number from Flame!. GSK reserves the right to set off any sums in respect of which Flamel may be in default to GSK.

9.6 Supply Prices are and any other amounts shall be as stated and include delivery and packing taxes and duties but are exclusive of VAT and customs duties. GSK shall only be obliged to pay to Flamel the rate of VAT chargeable in respect of the supply of Intermediate Product upon presentation of a valid VAT invoice. Flamel will supply Intermediate Product in accordance with the Delivery Terms.

10. FAILURE TO SUPPLY

10.1 Without prejudice to Flamel's obligations under this Agreement in the event that Flamel is unable to fulfill its supply obligations under this Agreement, whether it be due to a disruption in the Manufacture of the Intermediate Product at the Manufacturing Site, at periods of peak demand or otherwise, Flamel shall at its own expense use its best endeavours to procure access to capacity at alternative manufacturing plants. Flamel will obtain all necessary approvals and consents therefore at Flamel's cost. Flamel shall use commercially reasonable efforts to comply with all KPI's, as set forth on Schedule A. If any changes to these KPI's are proposed by GSK, they will be reasonably agreed between GSK and Flamel. The mere failure to reach a KPI not be deemed to be a breach of this Agreement; provided however, that the Parties shall meet to determine the cause of such failure and shall work toward resolution in good faith.

10.2 GSK or, if relevant, GSK's Nominated Contract Manufacturer shall notify Flamel as soon as possible if there is an incomplete delivery in accordance with the terms of this Agreement. If Flamel is notified by telephone or in person, then such notification shall be confirmed by GSK or GSK's Nominated Contract Manufacturer (as appropriate) in writing. Flamel shall then be obliged to rectify the incomplete consignment promptly.

10.3 Flamel shall at all times maintain a contingency Materials inventory equivalent to [***] supply of Materials ("Reserve Supply"), subject to GSK's obligation to provide Flamel with API.

10.4 If Flamel is unable, or anticipates that it will be unable, to supply the Intermediate Product in accordance with any Order placed in accordance with Article 3 from its current production or normal stocks of Materials, Flamel shall, as soon as it becomes aware of the fact, and in any event not less than fourteen (14) days before the delivery due date, given written notice to GSK of the reasons for the shortfall and will make up the shortfall, if possible, from the Reserve Supply.

11. QUALITY AND FITNESS FOR PURPOSE

11.1 Flamel shall, prior to their use for Manufacture, analyze or cause to be analyzed against the relevant Specification(s) each delivery of Materials and if in Flamel's opinion such analysis reveals that any delivery of Materials is defective by reference to such Specification, Flamel shall promptly notify GSK or the relevant supplier (as the case may be).

11.2 If Flamel considers that a delivery of Materials which has been supplied by any supplier is defective, Flamel shall reject such delivery, and shall procure that substitute Materials complying with the Specification are promptly supplied by the relevant supplier in substitution.

11.3 GSK shall have the right exercisable within a reasonable time after delivery to reject the Intermediate Product or any part thereof if any such Intermediate Product does not conform in quality with any stipulations in this Agreement or the specific order.

11.4 In the event of an Intermediate Product rejection:

(a) GSK shall notify Flamel in writing;

(b) that is attributable to the negligence or willful misconduct of Flamel, the payment obligation in relation to any such delivery shall be suspended forthwith pending resolution of the dispute in accordance with this Section;

(c) the Parties shall immediately endeavor to agree whether or not the delivery in question complies with the Specification; and,

(d) Flamel shall be entitled at all reasonable times to inspect and/or analyze the delivery in question.

11.5 The Parties shall use their best endeavours to resolve any dispute that may arise pursuant to this Section but if the Parties fail to agree, within thirty (30) days of being notified pursuant to Section 11.4 (a), whether any delivery of Intermediate Product supplied by Flamel to GSK is defective or may be rejected for any other reason set out in Section 11.3, the dispute shall be determined by the independent laboratory and the decision of the independent laboratory shall be final and binding on the Parties. The independent laboratory shall act as an expert and not as an arbitrator and (unless the independent laboratory otherwise determines) its fees shall be borne by the Party against whom the independent laboratory's decision is given.

11.6 If Flamel agrees or the independent laboratory finds that any delivery of the Intermediate Product has not complied with the relevant specification or may be rejected in accordance with this Section 11.6, without prejudice to any other rights that GSK may have against Flamel:

(a) Flamel may elect either to promptly collect at its own expense any rejected Intermediate Product from wheresoever GSK may direct or to reimburse GSK for any costs incurred in its disposal of the rejected Intermediate Product;

(b) Flamel shall in addition promptly reimburse GSK in respect of any cost including but not limited to manufacturing, packaging, freight, clearance, duty and storage charges incurred by GSK in respect of the defective delivery; and,

(c) GSK shall initially give Flamel the opportunity to replace rejected Intermediate Product with the Intermediate Product that complies with the requirements of this Agreement such that Flame] shall supply a replacement delivery to GSK as soon as reasonably practicable and in any event so as to arrive at the specified delivery address.

11.7 If a delivery of the Intermediate Product is found by the independent laboratory to comply with the Specification therefore, GSK shall pay for such consignment in accordance with the payment provisions contained in this Agreement.

11.8 Flamel shall, at GSK's discretion, as soon as reasonably practicable replace Intermediate Product, or refund to GSK the purchase costs of all Intermediate Product that is or becomes defective where such defects are not the result of GSK's actions and occur under proper usage and are due to faulty design, and/or Manufacture, Flamel's erroneous instructions as to use date, or inadequate or faulty Materials (other than Carvedilol) or workmanship, or any breach of Flamel's warranties.

12. SUPPLY AND STORAGE OF MATERIALS AND INTERMEDIATE PRODUCTS

12.1 Flamel shall be solely responsible for ordering the relevant quantities of Materials and for the timely delivery of such Materials. Flame! shall purchase and use only Materials and procedures in the Manufacture of the Intermediate Product which comply with the requirements of the Intermediate Product License and with Good Manufacturing Practice and otherwise are fit for purpose. Flame! shall not obtain any supplies of Materials from any party except a supplier reasonably agreed by GSK, Any such purchase from a supplier shall be on Flamers own behalf and not as an agent for GSK and Flamel hereby agrees to indemnify GSK against any claims which a supplier may make against GSK in respect of any such purchase,

12.2 Flamel shall at all times store and warehouse all Materials and Intermediate Product Manufactured by Flamel pursuant to this Agreement in premises that are secure, clean, compliant with the Manufacturing License and otherwise acceptable to GSK. Flamel shall operate a warehousing system that identifies all Intermediate Product according to type and status.

12.3 Within thirty (30} days of the Effective Date, Flamel shall adopt a risk mitigation program that will secure the supply of Materials.

13. THE INTERMEDIATE PRODUCT LICENSE

13.1 Flamel undertakes with GSK to observe and comply with all requirements from time to time of the Intermediate Product License and any amendments or additions thereto in so far as they apply to the Manufacture of intermediate Product hereunder and have been disclosed by GSK to Flame!.

13.2 GSK undertakes to inform Flamel of any amendments or additions to the Intermediate Product License that are relevant to the performance by Flamel of its obligations under this Agreement at which time the Agreement shall be amended in accordance with the Technical Change Procedure and the amendments or additions implemented by Flamel in the Manufacture of the intermediate Product to the extent required.

13.3 GSK shall be responsible for the registration of the Intermediate Product with all relevant authorities and Flamel shall provide such assistance, at GSK's cost, as GSK may reasonably request in connection therewith.

14. MANUFACTURE OF THE INTERMEDIATE PRODUCT

14.1 Flamel shall at its own cost obtain and throughout the term of this Agreement maintain all necessary Manufacturing Licenses and perform its obligations hereunder in accordance with the Manufacturing Licenses and all applicable laws and legislation in the country in which the Manufacturing Site is situated. Flamel shall supply a copy of each such Manufacturing License to GSK free of charge on request.

14.2 All personnel employed by Flame! in the Manufacture of the Intermediate Product shall be suitably trained, experienced and competent for their respective functions with particular reference to performing their assigned duties in accordance with Good Manufacturing Practice, Flamel shall keep written records of the training provided to such employees, copies of which shall be made available to GSK on request. Flamel covenants with GSK not at any time during the Term of this Agreement to carry out any other activities that prejudice the quality, safety or efficacy of the Intermediate Product.

15. QUALIFIED PERSONS

15.1 Flamel shall at all times:

(a) employ a Qualified Person in accordance with Directive 2001/83/EC who shall be responsible for confirming by his/her signature on the appropriate Batch Record that each batch of the Intermediate Product conforms with the requirements of the Intermediate Product License and the Specification(s) therefore and is Manufactured in accordance with this Agreement and Good Manufacturing Practice;

(b) promptly notify GSK in writing of any change in the identity of the Qualified Person and person or persons responsible for quality assurance in respect of the Intermediate Product; and,

(c) immediately following completion of the Manufacture of each batch of the Intermediate Product supply to GSK or any party nominated by GSK a Batch Record and a Certificate of Analysis duly signed by the Qualified Person.

15.2 The Qualified Person shall be responsible for the release of each batch of the Intermediate Product after the Batch Record and Certificate of Analysis (which shall be signed by the Qualified Person) for each batch of the Intermediate Product has been produced.

16. QUALITY ASSURANCE

16.1 Flamel shall supply to GSK or GSK's Nominated Contract Manufacturers a Certificate of Analysis or similar document for each batch of Intermediate Product supplied to GSK or GSK's Nominated Contract Manufacturer (as appropriate).

16.2 Flamel shall ensure that quality assurance tests agreed by the Parties from time to time are adopted and that representative samples of the Intermediate Product are taken, analyzed and retained in accordance with such terms as may be agreed between the Parties.

16.3 Further, Flamel shall ensure that testing methodology and testing reference standards comply with Good Manufacturing Practice.

16.4 Flamel shall institute and maintain process controls during the Manufacture of the Intermediate Product to ensure continuity of good quality in accordance with Good Manufacturing Practice. Further, Flamel shall maintain full records of such tests which shall upon request be made available to GSK or its nominees together with retained in-process samples, in the event of a complaint or query arising in respect of the Intermediate Product. Such records and samples shall be retained by Flamel in accordance with Section 2.2 of the Technical Agreement.

16.5 Flamel must report any adverse trends to GSK that arise during the testing of the Intermediate Product.

17. MANUFACTURING SITE UTILIZATION AND CONTINUOUS IMPROVEMENT

17.1 During the Term, Flamel shall use its best endeavours, in the ordinary course of its business, to increase utilization at the Manufacturing Site beyond GSK volume and any cost recovery shall be allocated to a reduction in the Minimum Monthly Fee.

17.2 Both Parties will continue to work together on improvement of supply and cost of the Intermediate Product and will equally share resulting benefits out of those improvements.

18. REGULATORY, COMPLIANCE AND ENVIRONMENTAL

18.1 Flamel shall promptly and at its own expense provide to each and every Regulator all such documents and information as may be required by such Regulator with respect to the Manufacture, storage and testing of the Intermediate Product and shall allow inspections of the Manufacturing Site and any other relevant sites and premises as may be requested by such Regulator the findings of which inspections shall promptly be made known in writing to GSK.

18.2 If any Regulator requires any changes to be made with respect to the Manufacture of the Intermediate Product or disposal of effluent relating to such Manufacture, Flamel shall immediately notify GSK and send it copies of any relevant documents delivered to it by the said Regulator within seven (7) days of receipt and will use its reasonable endeavours to defer implementation of any such changes until such time as GSK has been able, in accordance with the Technical Change Procedure, to make any such changes to its Intermediate Product License as may be necessary to accommodate any such changes as may be required by the Regulator.

18.3 Flamel shall respond in an effective and timely manner to any questions of a regulatory nature relating to the Intermediate Product or its Manufacture raised either by GSK, its Affiliates, sub-licensees or distributors or by a Regulator.

19. INTELLECTUAL PROPERTY RIGHTS

All Intellectual Property Rights of each Party shall be governed by the License Agreement dated March 26, 2003 by and between the Parties, including the indemnification rights provided hereunder for infringement of such Intellectual Property Rights.

20. CUSTOMER COMPLAINTS AND INTERMEDIATE PRODUCT RECALL

20.1 Flamel shall ensure that adequate manufacturing, shipping, and analytical records are kept and made available to GSK in order to assess the quality and destination of the Intermediate Product in the event of a Intermediate Product complaint or suspected defect

20.2 In the event that GSK requires access to any records Flamel shall facilitate immediate access to such records.

20.3 Flamel shall use its commercially reasonable efforts notify GSK's Supply and Quality Managers immediately by telephone and in writing promptly upon becoming aware of any issue likely to result in a product recall including but not limited to:

(a) where any Intermediate Product or its labeling may have been mistaken for or applied to another Intermediate Product; or

(b) where any Intermediate Product may be affected by bacteriological or other contamination, significant chemical, physical or other change or deterioration or stability failures; or

(c) where any Intermediate Product is the subject of a complaint by a third party or customer; or

(d) where any Intermediate Product may not comply with the Specifications.

20.4 If any of the circumstances described in Section 20.3 arise whether notified to GSK or not, Flamel shall take at GSK's request and at Flamel's cost, all such acts as GSK may reasonably direct and if GSK deems that a Product recall is required, the recall strategy shall be developed by GSK and fully followed by Flamel including with strict regard to timing requirements. All costs of such recall shall be borne by Flamel in the event that the need for the recall is necessitated by a failure on the part of Flamel to comply with all its obligations under this Agreement solely through negligence on the part of Flamel.

20.5 Complaints in respect of the Intermediate Product will be handled pursuant to Section 27 of the Technical Agreement.

20.6 If GSK deems that recall of a product containing Intermediate Product is required, the recall strategy will be developed by GSK and followed by Flamel including strict regard to timing requirements. All costs of such recall shall be borne by Flame! in the event that the need for the recall is necessitated by a failure on the part of Flamel to comply with all its obligations under this Agreement, solely through negligence on the part of Flamel.

21. DOCUMENTATION AND REPORTS

21.1 Flamel shall:

(a) complete the documentation relative to the Manufacture of each batch of the Intermediate Product in accordance with Good Manufacturing Practice and any other reasonable requirements of GSK and shall retain such documentation in accordance with Section 9 of the Technical Agreement;

(b) supply to GSK one (1) completed copy of the Certificate of Analysis relating to the Intermediate Product which is the subject of any Batch Record at the time that such Intermediate Product is delivered;

(c) permit GSK access to all Manufacturing, regulatory and quality control records in respect of the Intermediate Product and the Materials used in their Manufacture;

(d) supply to GSK a report for the validation batches for each batch of Intermediate Product Manufactured summarizing, but not limited to, the analytical results for each batch Manufactured, the stability results, details of any batch failures, process deviations and any out of specification results as provided for in this Agreement; and

(e) complete and lodge with the appropriate authorities where required all documentation relating to the export of intermediate Product where delivery involves export from the country of Manufacture.

22. CONFIDENTIALITY

22.1 Except as expressly provided herein, the Parties agree that, for the Term of this Agreement and for [***] years thereafter, the receiving Party shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose except for the purposes contemplated by this Agreement any Confidential Information furnished to it by the disclosing Party hereto pursuant to this Agreement, except that to the extent that it can be established by the receiving Party by competent proof that such Confidential Information:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was independently developed by the receiving Party without reference to any information or materials disclosed by the disclosing Party; or

(e) was subsequently disclosed to the receiving Party by a person other than a Party without breach of any legal obligation to the disclosing Party.

22.2 Each Party hereto may disclose the other's Confidential Information to the extent such disclosure is reasonably necessary in connection with the conduct of the development activities to be conducted hereunder, in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations or otherwise submitting information to tax or other governmental authorities, conducting clinical trials, or making a permitted sublicense or otherwise exercising its rights hereunder, provided that if a Party is required to make any such disclosure of another Party's Confidential Information, other than pursuant to a confidentiality agreement, it will give reasonable advance notice to the latter Party of such disclosure and, save to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information prior to its disclosure (whether through protective orders or otherwise).

22.3 No public announcement or any other disclosure, including under a Confidentiality Disclosure Agreement, to Third Parties concerning the existence of, terms, or subject matter or termination of this Agreement shall be made, either directly or indirectly, by any Party to this Agreement, except as may be legally required or as may be required for recording purposes, without first obtaining the written approval of the other Party and agreement upon the nature and text of such announcement or disclosure; provided, however that in the case of disclosures made by Flamel to a bona fide financial analyst for modeling and valuation purposes under a confidentiality agreement, Flamel shall provide GSK advance written notice of such disclosure (as set forth below), but shall not be obligated to obtain GSK's consent. The Party desiring to make any such public announcement or other disclosure (including those which are legally required or may be required for recording purposes) shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time prior to public release, which shall be at least five (5) business days prior to release of such proposed announcement or disclosure, and shall provide the other Party with a written copy thereof, in order to allow such other Party to comment upon such announcement or disclosure. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either Party included in any such disclosure. Notwithstanding the foregoing, within one (1) day of the Signing Date, Flamel shall be permitted to issue a press release, to announce the execution of this Agreement and certain of its terms, such as its duration and general terms; provided, however, that GSK shall have the right to review such press release prior to its issuance.

22.4 Nothing herein shall be construed to prevent GSK from disclosing any information received from Flame! hereunder: (i) to a Third Party contract manufacturer of GSK, subject to the consent of Flamel, such consent not to be unreasonably withheld; or (ii) to an Affiliate, sublicensee, distributor, Third Party research or clinical contractor, of GSK, without the consent of Flamel, provided, that in all cases of disclosure under clause (i) or (ii) above, the party to whom such disclosure is made shall have undertaken a similar obligation of confidentiality with respect to the Confidential Information, Neither Party shall submit for written or oral publication any manuscript, abstract or the like which includes data or other information pertaining to Product or Intermediate Product without first obtaining the prior written consent of the other Party, which consent shall not be unreasonably withheld, and shall be given or refused no later than thirty (30) days from the date of receipt by the reviewing Party.

22.5 All Confidential Information disclosed by one Party to the other shall remain the intellectual property of the disclosing Party. In the event that a court or other legal or administrative tribunal, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a Party to this Agreement based on the insolvency or bankruptcy of such Party, the bankrupt or insolvent Party shall promptly notify the court or other tribunal (1) that Confidential Information received from the other Party under this Agreement remains the property of the other Party, and (ii) of the confidentiality obligations under this Agreement. In addition, the bankrupt or insolvent Party shall, to the extent permitted by law, take all steps necessary or desirable to maintain the confidentiality of the other Party's Confidential Information and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement.

22.6 Flamel shall maintain reasonable security policies at Flamel, to protect the integrity of all Confidential Information and all Intermediate Product at Flamel's facilities, which policies shall be no less stringent than those policies that Flamel has in place to protect the integrity of its own Confidential Information and its own products.

23. RECORDS RETENTION

During the Term of this Agreement and, thereafter, in accordance with any applicable records retention period(s) identified in Schedule C, Flamel shall keep complete and systematic written records of all documentation relating to the manufacture of Intermediate Products by Flamel under this Agreement. Such records shall include any operational documentation pertaining to Flamel's supply of Intermediate Products under this Agreement, including records relevant to any costs or expenses incurred by Flamel on behalf of GSK, any financial records, procedures (including records for compliance with federal, state and local law) and such other documentation pertaining to Flamel's supply of Intermediate Products under this Agreement. All financial records shall be kept in sufficient detail to permit accurate determination of all figures necessary for verification of payment obligations set forth in Sections 8.1 and 9.3 of this Agreement. Flamel shall preserve all such records in accordance with the records retention period(s) specified in Schedule C; provided, however, that in the event a specific retention period is not specified for the particular record, Flamel shall preserve such records for the greater of (a) [***] years, or (b) such other period agreed upon in writing by the Parties.

24. FORCE-MAJEURE

24.1 If any Force Majeure occurs in relation to either Party which affects or may affect the performance of any of its obligations under this Agreement, it shall notify the other Party forthwith as to the nature and extent of the circumstances in question.

24.2 Neither Party shall be deemed to be in breach of this Agreement, or shall be otherwise liable to the other Party, by reason only of any delay in performance, or the nonperformance of any of its obligations hereunder, to the extent that the delay or nonperformance is due to any Force Majeure of which it has duly notified the other Party, and the time for performance of that obligation shall be extended accordingly.

24.3 If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by Force Majeure for a continuous period in excess of five (5) working days, the Parties shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances.

24.4 If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by Force Majeure for [***] or more, consecutively or cumulatively, in anyone year, then the other Party shall in its discretion have the right to terminate the Agreement forthwith upon written notice.

24.5 Notwithstanding the foregoing, GSK may, by notice in writing to Flamel, cancel any deliveries that in GSK's reasonable opinion cannot be made within a reasonable time after the due date without incurring any additional liability on the part of GSK.

25. INSPECTION

25.1 Subject to Flamel's obligation to inspect the Intermediate Product prior to the release of such Intermediate Product and without prejudice to Flamel's obligations under this Agreement, GSK and any third party it appoints on its behalf shall have the right to inspect and carry out any tests, including batch sampling, it wishes at GSK's expense on all Intermediate Product at Flamel's works and the works of any sub-contractors at all reasonable times to ensure Intermediate Product compliance with Specifications and Flamel's compliance with the terms of this Agreement and cGMP. Flamel will provide any or all necessary Certificates of Analysis.

25.2 Any inspections, checking, tests, approval or acceptance given on behalf of GSK by its servants or agents in relation to the Intermediate Product shall not relieve Flamel from its obligations assumed under this Agreement.

25.3 Flamel shall and shall procure that its sub-contractors shall grant a right of reasonable access to GSK and any third party it appoints in order to inspect and test the Intermediate Products.

26. ENVIRONMENTAL, HEALTH AND SAFETY AUDIT OF FLAMEL

GSK shall have the right to conduct, or to nominate a third party to conduct on GSK's behalf, an environmental, health and safety audit of Flamel to ensure that Flamel complies with the GSK's Environmental Health and Safety ("EHS") Requirements for Contract Manufacturers, which are set forth in Schedule B attached hereto and made a part hereof.

27. COMPLIANCE WITH STATUTES AND REGULATIONS

27.1 Flamel must ensure that the Intermediate Product and the delivery thereof comply with the Agreement and any standards specifically stated on it, all relevant statutes, regulations, other legal requirements and applicable guidelines, including without limitation those relevant to the regulation of medicinal products, health, safety, welfare, production, storing, handling and delivery of the Intermediate Product pertaining to the stated country for use of the Intermediate Product. Flamel shall provide evidence of compliance with such legal requirements, for example, permits, inspection reports, Certificates of Analysis, etc. promptly on request and within a reasonable time frame in any event.

27.2 Flamel shall use its best endeavours to ensure that its sub-contractors comply with Section

27.3 Flannel shall use its best endeavours to comply with all reasonable requests of GSK to minimize GSK's compliance costs in respect of applicable health, safety, environmental and producer responsibility obligations.

28. HAZARDS

Flamel will inform and keep GSK informed of all hazards, regulations and guidance (statutory or otherwise) which Flamel knows or believes to be associated with the use, handling, storage labelling, transport, treatment and disposal of the Intermediate Product and Flamel will ensure that relevant consignments are safe, packaged, labeled so as to prevent any health risk to persons, property or the environment and properly marked with the appropriate internationally recognized danger symbols and that prominent hazard warnings appear in English (and/or any other language specified by GSK) on all packages and documents.

29. REPRESENTATIONS AND WARRANTIES

29.1 Flamel represents and warrants that:

(a) Flamel is a validly existing corporation in good standing under the laws of the jurisdiction of its incorporation; the execution, delivery and performance of this Agreement by Flame! (where applicable) has been duly authorized by all requisite corporate action; this Agreement constitutes the legal, valid and binding obligation of Flamel, enforceable against Flamel in accordance with the terms hereof, subject to the effect of bankruptcy, insolvency, reorganization, receivership, moratorium and other similar laws affecting the rights and remedies of creditors generally and the effect of general principles of equity, whether applied by a court of law or equity; and the execution, delivery and performance of this Agreement by Flamel will not violate or conflict with any other agreement or instrument to which Flamel is a party.

(b) To fulfill its obligations under this Agreement, Flamel has allocated and will allocate equipment, production lines, staffing, physical space and other resources sufficient to manufacture the quantities of Intermediate Products required by GSK pursuant to this Agreement.

(c) Flamel has not used, in any capacity associated with or related to the manufacture of the Intermediate Products, the services of any persons who have been, or are in the process of being, debarred under 21 U.S.C. § 335a(a) or (b) or any comparable Regulatory Act. Furthermore, neither Flamel nor any of its officers, employees, or consultants has been convicted of an offense under (i) either a federal or state law that is cited in 21 U.S.C. § 335(a) as a ground for debarment, denial of approval, or suspension, or (ii) any other law cited in any comparable Regulatory Act as a ground for debarment, denial of approval or suspension.

(d) Flamel has all consents necessary or desirable in performance of its obligations hereunder and the manufacture of the Intermediate Products for commercial sale in the Territory.

(e) Flamel will not market the Products produced under this Agreement and will not sell the Products produced under this Agreement except for sales to GSK permitted by this Agreement.

(f) The manufacture, generation, processing, packaging, distribution, transport, treatment, storage, disposal and other handling of any Materials or Intermediate Products by Flamel until delivery to a carrier or freight forwarder shall (i) be in accordance with and conform to the Specifications, cGMPs and GSK Global Quality Policies and Guidelines; (ii) be in accordance with and conform to any applicable standards specified by the United States Pharmacopeia and Pharmacopeia Forum and the European Pharmacopeia and Pharmacopeia! Forum, and (iii) otherwise conform to any provisions of the regulatory acts not reflected in cGMPs, GSK's EHS Requirements and, subject to reliance on GSK's representations and warranties in Section29.1(b), (c), (d) and (e) above, all laws. The Intermediate Products will strictly comply with the Specifications, shall be free from defects in materials and workmanship and shall not be adulterated or misbranded within the meaning of applicable Regulatory Acts or the United States Federal Food, Drug, and Cosmetic Act. THE REPRESENTATIONS AND WARRANTIES PROVIDED IN THIS AGREEMENT DO NOT APPLY TO PRODUCTS TO THE EXTENT THAT, AFTER SHIPMENT BY FLAMEL, OCCURRENCES AFFECTING OR ALTERING THE INTERMEDIATE PRODUCTS AFTER THEY ARE DELIVERED TO THE CARRIER, OR ACTIONS TAKEN OR FAILED TO BE TAKEN AFTER THE INTERMEDIATE PRODUCTS WERE SHIPPED, THE PRODUCTS FAIL TO CONFORM TO SPECIFICATIONS. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 29.1, FLAMEL DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY OF ANY THIRD PARTY.

(g) During the Term of this Agreement, Flame] shall maintain the Manufacturing Site, all personal property, equipment, machinery, systems, intangibles, Intellectual Property Rights (as defined in the License Agreement dated March 26, 2003) in use at the Manufacturing Site in the ordinary course of business, and free of material defects, except for defects attributable to wear and tear consistent with the age and usage of such assets, and except for such defects as do not and will not, in the aggregate, materially impair the ability to use such assets in connection with the manufacture, generation, processing, packaging, distribution, transport, treatment, storage, disposal or other handling of any Materials or Intermediate Products.

(h) Flamel shall not pledge or otherwise transfer, without GSK's prior written consent, Materials or any work-in-process or finished goods inventory of Intermediate Products, other than to GSK or a GSK Affiliate as expressly provided in this Agreement.

(i) Flamel shall maintain reasonable security policies at the Manufacturing Site to protect the integrity of the Intermediate Products and all other GSK assets, tangible and intangible, at the Manufacturing Site.

(j) Flamel may be a participant in the Customs Trade Partnership Against Terrorism (C-TPAT) initiative sponsored by the United States Customs Service (Customs), and Customs has certified Flamel as a C-TPAT member. in the event that Flame! is not currently a participant in C-TPAT, it shall maintain similar security procedures with respect to the supply chain associated with the Products.

(k) The manufacture, generation, processing, distribution, transport, treatment, storage, disposal and other handling of any API by Flamel shall (i) be in accordance with and conform to the API specifications and cGMPs; and (ii) be in accordance with and conform to any standards specified by the United States Pharmacopeia and Pharmacopeia Forum and the European Pharmacopeia and Pharmacopeial Forum applicable to such API. The API shall be free from defects in materials and workmanship and shall not be adulterated or misbranded within the meaning of applicable Regulatory Acts or the U.S. Federal Food, Drug, and Cosmetic Act.

(l) Flamel represents and warrants that to the extent it relies upon materials of foreign origin in its performance of the services or supply of the goods or materials hereunder, Flamel has accurately identified, to the best of its knowledge, the ultimate source of such services, goods or materials, including, but not limited to, information relating to its downstream Flamel's and subcontractors.

30. ETHICAL STANDARDS AND HUMAN RIGHTS

30.1 Unless otherwise required or prohibited by law, Flamel warrants, to the best of its knowledge and belief, that in relation to its performance of this Agreement:

(a) it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;

(b) it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;

(c) it provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by Flamel to its employees is safe for habitation. Flamel provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the Flamel's workplace;

(d) it does not discriminate against any employees on any ground (including race, religion, disability or gender);

(e) it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;

(f) it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;

(g) it complies with the laws on working hours and employment rights in the countries in which it operates;

(h) it is respectful of its employees right to join and form independent trade unions and freedom of association; and

(i) it complies with the GSK Anti-Bribery and Corruption Requirements set out in Schedule D.

(1) Flamel is responsible for controlling its own supply chain and shall encourage compliance with ethical standards and human rights by any subsequent Flamel of goods and services that are used by Flamel when performing its obligations under this Agreement.

(2) Flamel shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies. In the case of any complaints, Flamel shall report the alleged complaint and proposed remedy to GSK.

(3) GSK reserves the right upon reasonable notice (unless inspection is for cause, in which case no notice shall be necessary) to enter upon Flamel's premises to monitor compliance with the provisions of this Section 30, and Flamel shall, subject to compliance with Applicable Laws, provide to GSK any relevant documents requested by GSK in relation thereto.

31. INDEMNIFICATION

31.1 Flamel shall indemnify GSK and hold GSK harmless from and against any and all liability for death, illness or injury to any third party or for loss or damage to any third party's property and against all claims, demands, proceedings and causes of action resulting directly or indirectly therefrom and arising out of any act or default on the part of Flame!, its employees, agents or sub-contractors in the performance of or in compliance with any of their obligations under this Agreement, including without limitation any and all loss in relation to defective Intermediate Products, and any liability arising under any relevant product liability legislation which may apply from time to time due to faulty Intermediate Product, provided that such damage is not due to any negligence on the part of GSK.

31.2 GSK shall indemnify Flamel and hold Flamel harmless from and against any and all liability for death, illness or injury to any third party or for loss or damage to any third party's property and against all claims, demands, proceedings and causes of action resulting directly or indirectly therefrom and arising out of any act or default on the part of GSK, its employees, agents or sub-contractors in the performance of or in compliance with any of their obligations under this Agreement, including without limitation any and all loss in relation to defective API and/or Intermediate Product supplied to GSK by Flamel under this Agreement, and any liability arising under any relevant product liability legislation which may apply from time to time due to faulty API and/or Intermediate Product supplied to GSK by Flamel under this Agreement; provided, however, that such faulty API and/or Intermediate Product supplied to GSK by Flamel under this Agreement is not due to improper handling or storage of such API or Intermediate Product, or due to any negligence on the part of Hamel.

31.3 In the event that either Party receives a claim or demand in respect of a matter which is the subject of an indemnity under this Article 31 it shall give the other Party notice thereof as soon as reasonably practicable and shall permit the other Party to assist in the defense thereof at the other Party's expense. The Parties shall co-operate in such defense by providing reasonable access to evidence available to them and each shall be entitled to participate in the other's defense to the extent that in its judgment it may be prejudiced thereby.

31.4 IN NO EVENT SHALL EITHER PARTY OR THEIR AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, TREBLE OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY; PROVIDED, HOWEVER, THAT THIS LIMITATION SHALL NOT LIMIT THE INDEMNIFICATION OBLIGATION OF SUCH PARTY UNDER THE PROVISIONS OF SECTIONS 31.2 AND 31.3 OF THIS ARTICLE 31 FOR SUCH DAMAGES CLAIMED BY A THIRD PARTY AND NOTHING IN THIS SECTION 31.4 IS INTENDED TO LIMIT GSK'S PAYMENT OBLIGATIONS EXPRESSLY REQUIRED UNDER SECTION 8.1 AND ARTICLE 9.

32. INSURANCE

Flamel shall maintain at its own cost full and sufficient third party, product liability, public and product recall insurance to cover its actual and potential liabilities hereunder within limits reasonably acceptable to GSK and grant GSK the right to inspect the policy which Flamel obtains in support of the indemnity provided by Flame! to GSK.

33. TERM; TERMINATION; REMEDIES

33.1 General:

(a) This Agreement shall commence on the Effective Date and will continue in force for the longer of (i) five (5) years after the Effective Date, or (ii) three (3) years after market entry of a Generic Equivalent Product in the United States, unless earlier terminated in accordance with this Article 33 (collectively, the "**Term**").

(b) No earlier than January 1, 2013, GSK may, in its sole discretion, terminate this Agreement with or without cause by giving six (6) months written notice to Flamel.

(c) In the event that Flamel terminates this Agreement, the Party terminating this Agreement shall provide thirty (30) months written notice prior to the expiration of the Term; provided, however, that in such event, Flamel shall supply all forecasted Intermediate Product until the later of: (i) the end of the notice of termination period; and (ii) (A) until the technology transfer from Flamel to GSK has been completed and (B) GSK shall have a robust supply alternative to Flamel in place.

33.2 Either Party may terminate this Agreement by giving [***] written notice to the other Party if the other Party is in material breach of any term of this Agreement and fails to cure that breach within such [***] period.

33.3 Termination of this Agreement shall not affect the rights and obligations of the Parties that accrued prior to the effective date of termination.

33.4 If voluntary or involuntary proceeding by or against a Party are instituted in bankruptcy under any insolvency law, or a receiver or custodian is appointed for such Party, or proceedings are instituted by or against such Party for corporate reorganization or the dissolution of such Party, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing, or if such Party makes an assignment for the benefit of creditors, or substantially all of the assets of such Party are seized or attached and not released within sixty (60) days thereafter, the other Party may immediately terminate this Agreement effective upon receipt of notice of such termination.

33.5 If GSK ceases to use the Intermediate Product for a significant technical or regulatory reason (and a significant technical or regulatory reason for these purposes is agreed to include, without limitation, any adverse technical or regulatory impact for GSK that is or may be attributable in whole or in significant part to the use by GSK of the Intermediate Product) GSK may terminate this Agreement immediately by notice; provided, however, that GSK shall notify Flamel immediately upon learning of such technical or regulatory impact, and, as appropriate, work together with Flamel to remedy such impact.

33.6 GSK may terminate this Agreement in accordance with Section 24.4.

33.7 If GSK, for any reason, shall terminate this Agreement, GSK shall reimburse Flamel for any inventory of finished Intermediate Product manufactured by Flamel, as well as for any raw material purchased by Flamel for the production of the Intermediate Product; subject, however, to Flamel's obligation to mitigate its damages by using its commercially reasonable efforts to use such raw materials for other purposes, cancel all outstanding and cancellable orders for such raw materials, and return any and all returnable raw materials to the Third Party Supplier. In such event, Flamel shall, at GSK's option, shall either return all such materials to GSK when paid for or dispose of them as Flamel sees fit upon payment.

34. CONSEQUENCES OF TERMINATION

34.1 On termination of the Agreement Flamel shall, not later than seven (7) days after GSK's request but at GSK's cost:

(a) deliver to GSK (or as GSK shall direct) all quantities of the conforming Intermediate Product and API in its possession;

(b) return to GSK all other documents provided to Flamel by GSK;

(c) ensure that all copies of GSK's Confidential Information, know-how and/or any information of a technical nature relating to the Intermediate Product and the Manufacture of the Intermediate Product or of a confidential nature and supplied by GSK to Flamel will be returned to GSK or destroyed by Flamel at GSK's option; and

(d) deliver title to the Equipment, listed in the Side Agreement entered into by the Parties, dated December 3, 2004, and as amended in the Letter Agreement dated July 28, 2006, as provided by the provisions of Section 3 of the Side Agreement, to Flamel.

34.2 Termination of the Agreement shall be without prejudice to the continuation in force of Articles 1, 5, 9 (sections 5 and 9 each with respect to activities up to the date of termination) 11, 13, 18, 19, 20, 21, 22, 25, 26, 27, 29, 30, 31, 32, 33, 45. Furthermore, Flamel agrees to provide GSK with ail reasonable support with respect to any investigation required by GSK or any Regulator with respect to Manufacture of the Intermediate Product carried out prior to such termination or withdrawal even after such termination or withdrawal provided that Flamel's reasonable costs in providing such assistance shall be at GSK's cost.

35. WAIVER

No waiver or forbearance by a Party in enforcing any of its rights under this Agreement shall prejudice or affect the ability of that Party to enforce such rights or any of its other rights at any time in the future. No waiver shall be effective unless in writing and signed by Party granting the waiver. For the avoidance of doubt, it is agreed that a waiver of a right on one occasion shall not constitute a waiver of the same right in the future.

36. NOTICE

In addition to the other specific procedures for notification required herein, all notices, demands, requests and other communications made hereunder shall be in writing and shall be given either by personal delivery, by nationally recognized overnight courier (with charges prepaid), by electronic transmission (provided such transmission shall include information from which it can be determined that it was authorized by a Party hereto and the receipt of such transmission is confirmed by telephone) or by facsimile transmission (with telephone confirmation), and shall be deemed to have been given or made: (i) if personally delivered, on the day of such delivery; (ii) if sent by overnight courier, on the day following the date deposited with such overnight courier service; (iii) if sent by electronic transmission, on the date transmitted on such electronic medium; or (iv) if by facsimile transmission, on the date transmitted to receiving facsimile machine and confirmed by telephone, in each case pending the designation of another address, addressed as follows:

If to GSK:
GlaxoSmithKline
GSK House
Great West Road
Brentford, Middlesex
TW89GS
United Kingdom
Attention: Director, Solid Dose External Supply
Telephone: +44 2080474835
Telecopy: +44 20804721 86

with copy to:
GlaxoSmith Kline
Legal Operations — GMS

Five Moore Drive
Research Triangle Park, NC 27709
Attention: VP and Associate General Counsel, Legal Operations - GMS
Telephone: +1 919 483 2444
Telecopy: +1 919 483 2881

If to Flamel:
Flamel Technologies, S.A.
11, Avenue Gustave-Eiffel
33608 Pessac Cedex
France
Attention: Director of Manufacturing Facility
Telephone: +33 557 260 770
Telecopy: +33 556 367 659

With copy to: Rafael Jorda, Executive Vice President
Chief Operating Officer (jorda@flamel.com)

with copy to:
Flamel Technologies, S.A.
Parc Club du Moulin a Vent
33 Avenue du Docteur Georges Lèvy
69693 Venissieux
France
Fax: +33 472 783 446
Attention: Stephen Willard, Chief Executive Officer
With copy to: Alliance Management (alliance@flamel.com)

37. SURVIVAL OF RIGHTS DUTIES AND OBLIGATIONS

Termination or expiry of this Agreement shall not release either Party hereto from any liability or right of action which at the time of termination has already accrued to either Party hereto or which may thereafter accrue in respect of any act or omission prior to such termination. Such rights shall include but not be limited to the recovery of any monies due hereunder.

38. RELATIONSHIP OF THE PARTIES

In the exercise of its obligations and in respect of its rights and entitlements hereunder or in respect hereof, Flamel is and shall in all respects be treated as an independent contractor of GSK. Neither Party shall be deemed to be a co-venturer or partner of the other. Neither Party is an employee or a legal representative of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party.

39. ASSIGNMENT

39.1 Flamel's rights and obligations under this Agreement may not be assigned in whole or in part to any third party without the prior written consent of GSK (acting in its sole discretion} and any such consent shall not be deemed to relieve Flamel of any of its obligations and liability to GSK pursuant to this Agreement.

39.2 GSK shall be entitled at any time by notice in writing to Flamel to assign the whole or any part of its rights and obligations under this Agreement to any Affiliate or to any successor in title to the whole or part of that part of GSK's business which relates to the Intermediate Product.

39.3 Notwithstanding anything to the contrary in this Agreement, if another entity acquires all or a substantial part of the assets or shares of a Party or merges with a Party hereto, both Parties agree, if appropriate, to re-negotiate the terms of this Agreement. If the Parties are unable to reach subsequent agreement, the Agreement shall terminate forthwith upon notice by the other Party.

40. SUB-CONTRACTORS

Flamel shall not, without the prior written consent of GSK, which shall not unreasonably be withheld, appoint any sub-contractor or any person or persons to carry out its obligations under this Agreement. In the event that Flamel appoints a sub-contractor or other person to perform its obligations it shall remain liable to GSK for the performance of all its obligations and shall ensure that any such sub-contractor or other person reads and understands the implications of this Agreement.

41. ENTIRE AGREEMENT

41.1 This Agreement, including the Schedules hereto and any other document identified herein, represents the entire understanding and agreement between the Parties hereto with respect to the subject matter hereof, and supersedes all prior and contemporaneous agreements an understandings between the Parties with respect to such subject matter, which are hereby expressly terminated.

41.2 The Parties acknowledge that they have expended substantial effort in preparing this Agreement and attempting to describe, in the Schedules hereto, as thoroughly and precisely as possible, Specifications, Intermediate Products, and other information. However, despite these efforts, the Parties acknowledge the possibility of involuntary o inadvertent omissions from the Schedules. The Parties will agree in writing to the changes to be made to the Schedules to add these inadvertent or involuntary omissions and any such written agreement executed by the Parties shall serve as an amendment to this Agreement.

42. AMENDMENTS

Any amendment, modification or supplement of or to any provision of this Agreement, including the Schedules hereto, shall be effective only in writing and signed by a duly authorized officer of suitable title of all Parties hereto. The Parties hereto waive the right to amend the provisions of this Article 42 orally.

43. SEVERABILITY

Each Section of this Agreement is a distinct and severable Section and if any Section is deemed illegal, void or unenforceable, the validity, legality, or enforceability of any other Section or portion of this Agreement shall not be affected thereby.

44. COUNTERPARTS

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

45. RELEASE OF CLAIMS

45.1 For purposes of this Agreement, "Claims" shall mean any and all claims, actions, rights, causes of action, demands, liabilities, debts, contracts, agreements, assignments, assumptions, obligations, losses, and damages of every kind and nature, whether separate, joint, individual, or class claims, counterclaims, cross-claims, third-party claims, or claims for indemnity or contribution, whether asserted or unasserted, anticipated or unanticipated, accrued or unaccrued, direct or indirect, fixed or contingent, known or unknown, under federal, state, or common law or any other law or regulation, at law or in equity, which Flamel did have, may have, or could claim to have against GSK relating to: GSK's submission of the CASPER abstract for publication in August 2007; the securities/shareholder litigation currently pending against Flamel; and/or GSK's decision not to assert its patents against any of the current or future generics who have filed or will file paragraph iv certifications that reference GSK patents listed in the Orange Book.

45.2 As part of the consideration for the execution of this Agreement, and the obligations and agreements of GSK set forth hereunder, Flame!, on its own behalf and on behalf of its principals, affiliates, officers, directors, shareholders, partners (limited and general), employees, agents, representatives, counsel, predecessors, successors, assigns, insurers, parents, subsidiaries, affiliates, divisions, custodians, heirs, executors, trustees, and administrators, hereby releases, remises, quitclaims, and forever discharges GSK and its principals, affiliates, officers, directors, shareholders, partners (limited and general), employees, agents, representatives, counsel, predecessors, successors, assigns, insurers, parents, subsidiaries, affiliates, divisions, custodians, heirs, executors, trustees, and administrators, from all Claims from the beginning of the world through the date of this Agreement. This release does not include and specifically excludes all obligations that either GSK or Flamel has under this Agreement.

46. THIRD PARTY RIGHTS

No person who is not a party to this Agreement shall have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.

47. GOVERNING LAW AND JURISDICTION

This Agreement shall be deemed to have been made in the United States of America (USA), and its form, execution, validity, construction and effect shall be determined in accordance with, and any dispute arising from the performance or breach hereof shall be governed by and construed in accordance with, the laws of the State of New York (USA), without reference to conflicts of laws principles.

48. LIST OF SCHEDULES

Schedule A Key Performance Indicators
Schedule B EHS Requirements for Contract Manufacturers
Schedule C Records Retention
Schedule D GSK Anti-Bribery and Corruption Requirements

IN WITNESS WHEREOF, the Parties have caused this Supply Agreement for Commercial Supply to be duly executed by their authorized representatives as of the Effective Date.

FLAMEL TECHNOLOGIES S.A.	**SMITHKLINE BEECHAM (CORK) LIMITED**
By: _____	By: _____
	Name: _____
	Title: _____
Date: _____	Date: _____

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

EXECUTION VERSION

Schedule A
Key Performance Indicators (KPI's)

A – Quality

Measure	Calculation	Proposed target	To be reported by:
Batches Non Right First Time	Number of batches not released first time (rejected, re-worked or re-processed) ÷ total number of batches produced, reported as percentage	As agreed between the two parties.	Flamel
Number of recalls	Number of Product recalls or Withdrawals		GSK
Complaints	Number of customer complaints		GSK
Overdue Audit CAPAS	Number of audit CAPAS not closed by the agreed due date in the month of reporting		GSK
Overdue PPR	Number of Periodic Product Review not delivered by the date on the agreed schedule		GSK

B - Customer Service

Measure	Calculation	Proposed target	To be reported by:
Perfect Order Fill - Secondary 3rd Party Supplier	Number of customer orders for which all items on the order are filled within +/- 10% and to within minus 3, and plus 0 days of the last agreed due date ÷ Total number of orders due to be delivered	As agreed between the two parties.	Flamel
Stock Out Index	% of days Out of Stock		GSK

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EXECUTION VERSION

Schedule B

EHS Requirements for Contract Manufacturers

EHS Management

Contract manufacturers and key Suppliers shall:

- comply with all applicable Environment Health and Safety (EHS) laws, regulations and codes of practice;
- demonstrate EHS leadership and commitment and establish a management system for making EHS integral to the management of the site's business;
- ensure that there is senior management responsibility for EHS;
- ensure that the site has adequate EHS and employee health advisory resources to enable the effective assessment and control of EHS risks and impacts;
- ensure that EHS risks are identified and assessed, that appropriate measures are in place to manage those risks and that resources are commensurate with level of risk;
- ensure that employees receive adequate training and information and are competent to manage EHS risks within their areas of responsibility;
- provide processes to enable effective communication and liaison with personnel on EHS matters;
- collect, analyse and communicate agreed EHS performance data to GSK;
- ensure that ENS adverse events, including health effects, are investigated so that actions can be taken to prevent recurrence. Report to GSK all confirmed or suspected adverse health effects or adverse events that result in:
- assess the performance of individual EHS programmes and the overall EHS framework to identify opportunities for improvement;
- allow GSK to conduct EHS audits relating to the manufacture, process, storage and disposal of materials and processes related to GSK products on mutually agreed dates at appropriate intervals;
- provide a prompt response to GSK EHS Audit Reports;
- establish and maintain good terms with regulators, neighbours and other stakeholders.

Loss Prevention

Contract manufacturers and key Suppliers shall:

- protect physical assets from loss, damage or prolonged incapacity that might interrupt business- critical activities or seriously affect GSK business;
- provide plans and capabilities in line with the risks to minimise the disruption arising from major fires and other catastrophic events;

- minimise the impact of emergencies on people, the environment and the business;
- provide resources and capabilities to respond to foreseeable emergencies;
- minimise the risks of explosions, fires and large-scale releases of hazardous materials arising from chemical processes, bulk storage facilities or utilities;
- prevent fires from starting and minimise the EHS and loss impacts of any fire that does occur;
- provide adequate measures to detect fires and ensure the safety of life;
- minimise the risks to people, property and the environment from adverse events involving flammable liquids and gases and combustible dusts;
- ensure that buildings, building services and work equipment are maintained in good condition and that the control measures selected through risk assessment are implemented and provide adequate control of EHS risks;
- inspect work areas and supervise work activities to ensure control measures are effective;
- ensure that the EHS implications of new, and changes to existing processes, facilities and equipment are identified, evaluated and addressed. Achieve appropriate standards suggested by GSK via technical and risk management reviews.

Employee Health

Contract manufacturers and key Suppliers shall:

- ensure that risk assessments and controls identify and protect the most susceptible subgroup within the population of workers who are likely to work with it (e.g., pregnant women if cytotoxics are present, asthmatics if respiratory irritants are present);
- carry out health surveillance to:
- ensure that individuals are fit for work under requirements of current Good Manufacturing Practice (cGMP) and Quality Assurance (QA);
  identify and manage appropriately and effectively any individual health factors that may affect people's ability to work safely;
  detect and report the most likely health effects that could be caused by exposure to a given hazard;
- protect the reproductive health of employees from workplace risks;
- optimise tasks, equipment and the work environment to meet the physical capabilities of each individual and reduce ergonomically related disorders;
- provide first aid and emergency medical assistance appropriate to the risks.

Environmental Risks

- Contract manufacturers and key Suppliers shall:
- ensure that wastes, including rejected or returned products declared as wastes, are managed from the point of generation to the point of final disposal in a safe and responsible manner;

- select waste disposal options that represent the best feasible environmental option;
- manage returned and rejected goods to minimise EHS and product security risks and where applicable enable the safe return of GSK products;
- manage site operations in a way that minimises the resources used and the waste generated;
- ensure that any adverse environmental impacts or nuisances associated with air emissions are eliminated or minimised;
- ensure that water is used' efficiently and that wastewater is treated and discharged in a way that minimises adverse impacts to the receiving environment;
- take all prudent measures to prevent contamination of soil and groundwater and address known areas of contamination;
- ensure that effective measures to prevent and contain spillages and fire-water are in place;
- minimise, and ultimately eliminate, the use of Ozone Depleting Substances (ODSs) and their release to the environment.

Hazardous Activities

- Contract manufacturers and key Suppliers shall:
- store and transfer materials securely so that EHS risks are minimised;
- prevent EHS adverse events associated with the operation, cleaning, maintenance and repair of work equipment and systems;
- ensure the appropriate selection, use, cleaning, maintenance and storage of Personal Protective Equipment (PPE);
- ensure that EHS risks are minimised during potentially high-risk activities including construction, maintenance, cleaning and engineering tasks by implementing a permit-to-work system;
- minimise the risks of injuries, damage to property or environmental incidents arising from the use of vehicles and other transport equipment on sites;
- ensure that materials are transported and supplied to the recipient in a way that minimises risks to persons, property and the environment.

Hazardous Agents

- Contract manufacturers and key Suppliers shall:
- ensure that the EHS hazards of materials stored, handled, produced or transported by the site are identified and communicated to all affected persons;
- ensure that occupational and environmental exposure limits or hazard categories are used in risk assessments and in the selection of control measures;
- ensure risks of exposure to GSK substances are controlled to below GSK Occupational Exposure Limits (OELs);
- prevent injury, illness and environmental impact arising from the use, storage and handling of chemical agents;

- prevent employees from becoming sensitised to materials in the workplace and minimise the adverse effects on any employees who do become sensitised;
- control exposures to biological agents and prevent the uncontrolled release of such agents into the environment;
- control exposures to ionising radiation and prevent the uncontrolled release of radioactive materials into the environment;
- minimise the risks associated with the installation, use and maintenance of electrical systems and equipment;
- minimise the risk of noise-related adverse effects on personnel and on the local community.

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EXECUTION VERSION

Schedule C

Records Retention

Record	Retention Period
• Batch Related Records, including all records of laboratory testing, environmental monitoring, production, cleaning and sanitisation, calibration, equipment maintenance, equipment logbooks, process control deviations, out of specification (OOS), complaints, recalls, or other investigations.	• [***]
• Raw material records, including documentation related to active materials, starting materials, intermediates, excipients and packaging components including all laboratory records, deviations, OOS or other investigations.	• [***]
• Master Copies of Operating Instructions and Standard Operating Procedures	• [***]
• Training Records, Job Descriptions and Organisation Charts	• [***]
• Validation Documents, including Validation Master Plans, validation protocols, validation reports and validation batch records), method validation, specifications	• [***]
• Facility Plans, Drawings and Qualification Reports	• [***]
• Product Specifications (Every Version)	• [***]
• Audit Schedules	• [***]
• Audit Reports	• [***]
• Change Control Documentation (Product Specific)	• [***]
• Change Control Documentation (Not Product Specific)	• [***]
• Periodic Product Review Reports	• [***]
• Contract Personnel and Consultant Records, i.e. Curriculum vitae and any associated documentation.	• [***]

- Computer System Documentation — Manufacturing Applications/Systems
- [***]

EXECUTION VERSION

Schedule D

GSK Anti-Bribery and Corruption Requirements

The GSK Anti-Bribery and Corruption Policy (POL-GSK-007) requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which GSK (whether through a third party or otherwise) conducts business. POL-GSK-007 requires all GSK employees and any third party acting for or on behalf of GSK to ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and with the standards of integrity required for all GSK business. GSK values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by GSK employees, officers, or third-parties acting for or on behalf of the GSK.

It is a material term of this Agreement that Supplier (i.e. Flamel for the purpose of this Agreement) shall comply with the following:

1. Supplier shall comply fully at all times with all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territory in which Supplier conducts business with GSK.

2. Supplier agrees that it has not, and covenants and that it will not, in connection with the performance of this Agreement, directly or indirectly, promise, authorise, ratify or offer to make or make any "payments" of "anything of value" (as defined in the glossary section below) to any individual (or at the request of any individual) including a "government official" (as defined in the glossary section below) for the improper purpose of influencing or inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the Supplier or GSK in obtaining or retaining business.

3. Supplier agrees that it has not, and covenants and that it will not, in connection with the performance of this Agreement, directly or indirectly, promise, authorise, ratify or offer to make or make any "facilitating payments" (as defined in the glossary section) to any individual (or at the request of any individual) including a "government official" (as defined in the glossary section).

GLOSSARY

The terms defined herein should be construed broadly to give effect to the letter and spirit of POL-GSK-007.

Anything of Value: this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

Facilitating Payments: otherwise known as "greasing payments" shall mean a payment to an individual to secure or expedite the performance of a routine government action by government officials.

Government Official shall mean: (i) Any officer or employee of a government or any department, agency or instrument of a government; (ii) Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (iii) Any officer or employee of a company or business owned in whole or part by a government; (iv) Any officer or employee of a public international organisation such as the World Bank or United Nations; (v) Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (vi) Any candidate for political office.

Payments: this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.