UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

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

For the month of September 2003

Commission File Number 0-28508

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 Form 20-F or Form 40-F.

Form 20-F x Form 40-F o

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 x

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

INFORMATION FILED WITH THIS REPORT

On August 27, 2003, Flamel Technologies S.A. (the "Company") announced that it had licensed its controlled-release long-acting human insulin product, Basulin™, to Bristol-Myers Squibb Company. The License Agreement is attached hereto as Exhibit 10.1 and incorporated herein by reference.[1]

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[1] Confidential portions of this Exhibit have been omitted in reliance on Rule 24b-2 of the Securities Exchange Act of 1934. The confidential portions have been submitted separately to 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.

Flamel Technologies

Dated: September 17, 2003

By: /s/ Stephen H. Willard

Name: Stephen Willard
Title: Executive Vice President,
Chief Financial Officer and General Counsel

LICENSE AGREEMENT

Dated August 26, 2003

by and between

Flamel Technologies, S.A.

and

Bristol-Myers Squibb Company

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LICENSE AGREEMENT

This License Agreement is made by and Bristol-Myers Squibb Company, a corporation organized under the laws of the State of Delaware, USA **("BMS")**, and Flamel Technologies, S.A. **("Flamel")**, a corporation organized under the laws of France (each a "Party" and collectively, the "Parties").

R E C I T A L S

WHEREAS, Flamel is the owner of, and is beneficially entitled to, a number of patents and patent applications in relation to the development and production of an injectable sustained release drug delivery system based on polyaminoacid polymers, known as the MEDUSA® Technology (all terms as hereinafter defined);

WHEREAS, Flamel has applied the MEDUSA® Technology to develop a controlled-release formulation of recombinant human insulin incorporating the MEDUSA® Technology, currently known as Basulin®; and

WHEREAS, BMS wishes to enter into a development and license agreement with Flamel to complete development of, and to license from Flamel its Patent Rights and Know-How in respect of, controlled release formulations of recombinant human insulin incorporating the MEDUSA Technology upon the terms and conditions set forth herein, and Flamel desires to enter into such development agreement and to grant such a license;

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

ARTICLE 1
DEFINITIONS

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

1.1 **"Affiliate"** shall mean (i) any corporation or business entity of which fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership or membership interest are owned, controlled or held, directly or indirectly, by BMS or Flamel; or (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership or membership interest, of BMS or Flamel; or (iii) any corporation or business entity of which fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership or membership interest are owned, controlled or held, directly or indirectly, by a corporation or business entity described in (i) or (ii).

1.2 **"Agreement"** shall mean this agreement, as it may be amended or supplemented from time to time hereafter in accordance with Section 10.9 hereof.

1.3 **"Application for Regulatory Approval"** shall mean an application made to a Regulatory Authority in any country for permission to market a pharmaceutical product in that country, and shall include a New Drug Application (an "NDA") and an Abbreviated New Drug Application (an "ANDA").

1.4 **"Calendar Quarter"** shall mean any period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31.

1.5 **"Calendar Year"** shall mean a period of twelve consecutive (12) months commencing on January 1 and ending on December 31.

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1.6 **"Clinical Studies"** shall mean all of the tests and studies required for an Application for Regulatory Approval of the Product in the Territory.

1.7 **"Compound"** shall mean human insulin and its analogues and derivatives thereof.

1.8 **"Confidential Information"** means (i) any proprietary or confidential information or material in tangible form (including in writing or electronically) 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 which 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.

1.9 **"Developed Product"** shall mean the controlled release formulation of the Compound incorporating the MEDUSA® Technology as developed by Flamel prior to the Effective Date.

1.10 **"Development Plan"** shall mean the pre-clinical and clinical development plan required to file an Application for Regulatory Approval for the Product in the Territory. The Development Plan for the Product shall be determined by the JDC as soon as practicable following the Effective Date and updated periodically thereafter by the JDC as appropriate.

1.11 **"Effective Date"** means the date set forth in Section 6.2.

1.12 **"Execution Date"** means the date that this Agreement is signed by the last Party to sign below.

1.13 **"EU Major Market"** means any of France, Germany, Italy, Spain or the United Kingdom.

1.14 **"FDA"** shall mean the United States Food and Drug Administration or any successor regulatory agency.

1.15 **"Field"** shall mean the treatment and prevention of all human and animal diseases and conditions.

1.16 **"First Commercial Sale"** shall mean the first sale for end use or consumption of the Product in any country in the Territory following receipt of Regulatory Approval in such country.

1.17 **"Flamel Facility"** shall mean any Flamel manufacturing or research facility at which all or part of any clinical or commercial supplies are to be manufactured by Flamel.

1.18 **"Flamel Know-How"** shall mean all information and materials including but not limited to, discoveries, improvements, processes, formulas, data, inventions, know-how and trade secrets, patentable or otherwise, relating to the Product, or any other controlled release formulation of the Compound, which at the Execution Date or during the term of this Agreement (i) are in the possession or control of Flamel or any of its Affiliates, (ii) are not generally known and (iii) are necessary or useful to BMS in connection with the research, development, manufacture, marketing, sale, or use of the Product in the Territory.

1.19 **"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 BMS under this Agreement, who is qualified to perform such work.

1.20 **"FTE Rate"** shall be * U.S. dollars ($ *) per year.

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1.21 **"cGMP Standards"** shall mean all current good manufacturing practices applicable to the manufacturing of any Product for Marketing in the Territory, including those required by the FDA, and any other good manufacturing practices that are applicable to that Product, and **"cGMP"** shall have a similar meaning.

1.22 **"Information"** shall mean any and all information and data relating to the Product, communicated in writing or orally or by any other method by one Party to the other Party in connection with this Agreement, including without limitation all scientific, preclinical, clinical, regulatory, manufacturing, marketing, financial and commercial information and data.

1.23 **"Licensed Technology"** shall mean all of the following: (i) the Patent Rights; and (ii) any Flamel Know-How (including any patents or patent applications filed after the date hereof which include any Flamel Know-How), each as currently owned or licensed by Flamel (or any of its Affiliates) or acquired, licensed or developed by Flamel (or any of its Affiliates) after the date hereof which may be licensed or sublicensed without breaking any Third Party agreement.

1.24 **"Manufacturing Cost"** means (i) where and to the extent the Product (or any component thereof) is manufactured, finished or packaged by BMS, the direct costs and a reasonable allocation of indirect costs (such as materials, labor and charges in the nature of depreciation, and variable and fixed overhead) that are necessary for the normal operation of a production facility that are incurred by BMS and its Affiliates in connection with the manufacturing, finishing and packaging of the Product at any BMS facility where the Product (or such component) is so manufactured, finished and packaged, as determined in accordance with U.S. GAAP, consistently applied from period to period, plus (ii) where and to the extent the Product (or any component thereof) is manufactured, finished or packaged by a Third Party, the actual cost charged to BMS by such Third Party. Manufacturing overhead (including any idle capacity charges) required to operate the facility will be allocated based on the amount of capacity that BMS is reasonably required to reserve to meet expected demand for the Product. Annual adjustments to variable overhead charges will be based on actual costs, while fixed overhead will be adjusted annually based on changes from the previous year to the Producer Price Index-Commodities Index for Drugs and Pharmaceuticals, as published by U.S. Department of Labor, Bureau of Statistics (or successor Governmental Authority). As an example of idle capacity charges, if BMS reserves a capacity of five million vials and actual demand is three million vials, then the idle plant for the balance of two million vials will be included in the Manufacturing Cost; however, if BMS needs five million vial capacity and BMS were to build a new plant for ten million vial capacity, then the extra five million vial idle plant will not be part of the Manufacturing Cost.

1.25 **"MEDUSA Core Technology"** means the polyaminoacid technology described on *Appendix B* hereto. For sake of clarity, the Core Technology does not include techniques, know-how or methods for formulating a product using polyaminoacids and the active ingredient in a product.

1.26 **"MEDUSA® Technology"** means the Licensed Technology as it relates to the MEDUSA® Core Technology, to an injectable sustained release drug delivery system based on or using the MEDUSA® Core Technology, and to the manufacture of the Product using the MEDUSA Core Technology.

1.27 **"Net Sales"** means, for any time period, the total of all invoiced gross sales in that time period by BMS or by an Affiliate of BMS, in respect of Product sold by BMS, an Affiliate of BMS, or a sub-licensee of BMS to arm's length purchasers (but excluding sales by BMS to an Affiliate for resale to such purchasers), net of, where applicable:

(i) discounts, credits, allowances and adjustments granted to non-sublicensee Third Parties consistent with BMS' usual course of dealing for its products other than the Product (including, without limitation, government mandated and managed healthcare negotiated rebates and distributors', wholesalers' or trade discounts or rebates, and rebates for distribution services);

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(ii) price adjustments to customers' inventories;

(iii) charge-backs or rebates actually allowed and taken on such sales in such amounts as are customary in the trade and are specifically related to the Product (excluding cash discounts, except for normal trade discounts for early payment of invoices);

(iv) free goods;

(v) import and customs duties and taxes (including sales, excise, turnover, inventory, value-added, and similar taxes assessed on the sale of the Product (but excluding income taxes) to the extent separately included in the amount billed;

(vi) transportation charges and insurance separately itemized;

(vii) credits or allowances for Product returns and rejected Product;

(viii) amounts repaid, credited or written off by reason of uncollectible debt, rejections, recalls, billing errors and returns; and

(ix) other allowances actually given by BMS or an Affiliate of BMS to such Third Parties.

For sake of clarity, (x) the distribution of Product samples, and the disposition of the Product or the use of the Product in clinical studies, compassionate, named patient, test marketing, or any nonregistrational studies where the Product is supplied without charge shall not result in any Net Sales, and (y) sales by BMS and its Affiliates to non-Affiliated distributors and wholesalers shall be considered sales to Third Parties.

If a Combination Product is developed under the Agreement (the term **"Combination Product"** meaning any product which comprises the Product and any pharmacologically active ingredients, whether in a single formulation or as a packaged product), then for purposes of determining royalties on Net Sales of such Combination Products, Net Sales of such Combination Product will be calculated as follows:

1) If the Combination Product involves two products that are co-packaged, then the Net Sales allocable to the Product shall be determined by multiplying the total Net Sales of the Combination Product by the fraction A/(A+B), where A is the average invoice price of the Product in finished form in the applicable country in the Territory if sold separately, and B is the sum of the average invoice prices of all other active ingredients or products in the Combination Product in the applicable country if sold separately in finished form during the applicable calendar quarter. If no such separate prices are available for the Product or the other active ingredients in such country for the applicable period, the Parties shall negotiate in an equitable allocation of the Net Sales of the Product in the Combination Product; provided, that if the Parties cannot agree upon a determination, then such matter shall be referred for resolution by an arbitrator jointly selected by the Parties; and

2) if the Combination Product involves insulin manufactured using the Licensed Technology coupled with short-acting insulin, and the two are premixed or self-mixed, then the Net Sales of the Product for royalty purposes hereunder shall equal the Net Sales of the Combination Product, less any additional Manufacturing Costs incurred by BMS for the Combination Product over what it would have incurred in manufacturing only the Product using the same amount of Compound that is included in the Combination Product and formulated using the Licensed Technology; and

3) if the Combination Product involves any other combination of active ingredients other than as set forth in (1) and (2), then the Parties will meet and confer to determine how much of the Net Sales of the

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Combination Product should equitably be allocated to the Product for royalty determination purposes. If the Parties cannot mutually agree on such allocation, then the matter shall be referred to an arbitrator mutually acceptable to both Parties whose determination shall be binding upon the Parties.

1.28 **"Other Exclusivity"** shall mean exclusivity within a country for a Product substantially equivalent to composition of matter patent protection under a Patent Right.

1.29 **"Party"** means Flamel or BMS, as the case may be. **"Parties"** means both BMS and Flamel.

1.30 **"Patent Claim"** shall mean a claim of an issued and unexpired patent included within the Patent Rights, which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which is not appealable or has not been appealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

1.31 **"Patent Rights"** shall mean any and all patents and patent applications in the Territory (which for the purposes of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention, as well as confirmation patents, registration patents, or patents of addition based on any such patent) that are reasonably related to or required for the manufacturing, use or sale of the Product and which during the term of this Agreement are owned by Flamel (or any of its Affiliates) or to which Flamel (or any of its Affiliates), through license or otherwise, acquires rights, and which: (i) claim or cover the MEDUSA Technology; or (ii) claim or cover the Flamel Know-How; or (iii) claim or cover the composition of the Product (including any polyaminoacids used in the Product), or the manufacture, sale or use of the Product, or (iv) are divisions, continuations, continuations-in-part, reissues, renewals, extensions, supplementary protection certificates, and the like of any of the foregoing patents and patent applications in (i), (ii) and (iii) and foreign equivalents thereof, including, but not limited to, those listed on *Appendix A hereto*. Extensions of patents shall include (a) extensions under the U.S. Patent Term Restoration Act; (b) extension of patents under the Japanese Patent Law; and (c) Supplemental Protection Certificates **("SPCs")** for members of the European Patent Convention and other countries in the European Economic Area.

1.32 **"Phase IIb Study"** shall mean a controlled clinical trial which utilizes the pharmacokinetic and pharmacodynamic information obtained in the phase IIa trial(s) to confirm the optimal manner of use of the Product (dose and dose regimen) prior to initiation of the pivotal phase III trials. The period of dosing in phase IIb trials will be more than 2 weeks (the duration of dosing in phase IIa trials) and less than 26 weeks (the duration of dosing expected in the phase III trials).

1.33 **"Product"** shall mean any product incorporating the Compound and that is manufactured or formulated through the use of the MEDUSA® Technology, either alone or in combination with on or more other therapeutically active substances, for sale by prescription or any other method.

1.34 **"Regulatory Approval"** shall mean the permission or consent granted by any relevant Regulatory Authority for the Marketing of a Product in any portion of the Territory.

1.35 **"Regulatory Authority"** shall mean any applicable government regulatory authority involved in granting approvals for the Manufacture, Marketing, and/or pricing of the Product in the Territory, including without limitation, in the United States, the Food and Drug Administration **("FDA")**, and any successor government authority having substantially the same function, and foreign equivalents thereof.

1.36 **"Territory"** shall mean worldwide.

1.37 **"Third Party"** means any person or entity other than BMS, Flamel and their respective Affiliates.

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1.38 **"Valid Claim"** means either: (i) a claim of an issued patent within Flamel Patent Rights that has not been held unenforceable or invalid by an agency or a court of competent jurisdiction which is not appealable or has not been appealed within the time allowed for appeal or (ii) a claim of a pending patent application within Flamel Patent Rights that has not been abandoned or finally rejected without the possibility of appeal or refiling (but only where such application has been pending not more than five (5) years from the earliest priority date claimed for such patent application).

1.39 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

Definition	Section
BMS Indemnitee	8.1
BMS-Owned Invention	5.1.1
BMS Marks	5.9
Flamel Indemnitee	8.2
HSR Act	6.2.1
Indemnitee	8.3
Indemnitor	8.3
JCC	4.6
JDC	4.6
Milestones	3.2
Notice Period	9.23
Quarterly Payment	3.3(b)
Royalty Rates	3.3(a)
SPCs	5.7

ARTICLE 2
LICENSE GRANTS; RIGHT OF FIRST REFUSAL

2.1. **License Grant from Flamel to BMS.** Subject to the terms and conditions of this Agreement, Flamel hereby grants to BMS an exclusive license, even as to Flamel, with the right to grant sublicenses, under the Licensed Technology, to make, have made, use, sell, offer for sale and import the Product within the Field 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 with the consent of Flamel, which shall not unreasonably be withheld; provided, that such consent shall not be required for BMS to sublicense rights to BMS Affiliates (with BMS remaining responsible for the performance by such Affiliate with the terms of the sublicense). Flamel acknowledges and agrees that BMS shall have the right to appoint distributor(s), co-promoter(s) or co-marketer(s) under this Agreement. Any sublicensee shall be bound by the same terms and conditions of this Agreement, including royalties, as BMS.

2.2 **Prohibition Against Option Grant.** During the term of this Agreement, Flamel covenants and warrants that it will not grant to any Third Party any option right (including any right of first negotiation or right of first refusal) for any product developed by Flamel for the treatment of Type I or Type II diabetes which utilizes the MEDUSA® Technology; provided, that the foregoing restriction shall only apply to a product where the active ingredient in such product is not proprietary to any Third Party. Nothing in the foregoing shall preclude Flamel from negotiating and/or entering into any agreement with a Third Party for the grant of a license to any such product or the acquisition of rights to any such product by such Third Party.

2.3 **Animal Rights.** Flamel covenants and warrants that as of the Execution Date it has not granted, and that during the term of this Agreement it will not grant, any rights under the MEDUSA® Technology to any

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Third Party for the development or commercialization of any product for use in animals that uses any human or animal insulin (or their analogs or derivatives) in any country where BMS retains rights under this Agreement. The foregoing shall not preclude Flamel from finishing studies it has commenced as of the Execution Date with a Third Party.

ARTICLE 3
PAYMENTS

3.1. **Initial Fee to Flamel.** In partial consideration for the license to Licensed Technology granted to BMS under Section 2.1 of this Agreement, BMS shall pay to Flamel twenty million U.S. dollars (U.S. $20,000,000) within fifteen (15) days after the Effective Date.

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

	Milestone	Amounts		
1.	Delivery of sufficient, spec-compliant clinical batches of Product for first Phase II(b) clinical study	U.S. $	*	1
2.	First patient enrolled in a Phase IIb study	U.S. $	*	1
3.	Delivery of sufficient, spec-compliant clinical batches of Product for first Phase III clinical study	U.S. $	*	
4.	First patient enrolled in first Phase III clinical trial	U.S. $	*	2
5.	NDA Acceptance (U.S.)	U.S. $	*	
6.	MAA acceptance (EU)	U.S. $	*	
7.	JNDA acceptance (Japan)	U.S. $	*	
8.	Regulatory approval by FDA	U.S. $	*	
9.	Regulatory Approval in first EU Major Market country	U.S. $	*	
10.	Launch in Japan	U.S. $	*	

1 If BMS takes delivery of spec-compliant supplies for a Phase III study or commences a Phase III study without initiating a Phase IIb study, then this milestone shall be paid upon delivery of the spec-compliant supplies for the Phase III study or initiation of the Phase III study, as the case may be.

2 If FDA requires BMS to conduct long-term carcinogenicity studies, this milestone shall be reduced to $ * . BMS will then pay an additional milestone of $ * to Flamel upon the earlier of: (x) BMS' determination in its sole discretion that the long-term carcinogenicity studies are successful and will support an NDA filing in the U.S. or (y) upon NDA Acceptance in the U.S.

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11.	Regulatory Approval for both the Product and the use of the Basulin® Trademark with the Product in:	U.S. — $ * First of any Major EU Market or Japan to grant both such approvals — $ *

provided that:

(i) No Milestone shall be paid more than one time on the Product, regardless of the number of indications obtained for the Product.

(ii) In the event BMS develops additional products using an analog or derivative of recombinant human insulin using the MEDUSA® Technology, then BMS will pay to Flamel milestones to be mutually agreed upon in writing prior to the initiation of Phase II clinical studies, but which milestones will not, in any event, exceed the milestones set forth above, whether individually or in the aggregate. The Parties will meet and confer with a view to agreeing upon such milestones within ninety (90) days after Flamel receives written notice from BMS with respect to same.

(iii) Payment shall not be owed for a Milestone that is not achieved, and achievement of any Milestone shall be subject to payment under this Section 3.2 whenever achieved;

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

(v) Milestone payments shall be payable by BMS to Flamel within forty-five (45) business days after achievement of the Milestone.

3.3 **Royalty Rates and Payment.**

3.3.1 **Royalty Rates.** Subject to Section 3.3.3, in partial consideration of the license and rights granted under Section 2.1, BMS shall pay royalties to Flamel on Net Sales of all Products equal to the following:

(i) * percent (* %) of annual Net Sales of such Products up to $ * of Net Sales;

(ii) * percent (* %) of annual Net Sales in excess of $ * up to $ * of Net Sales; and

(iii) * percent (* %) of annual Net Sales in excess of $ *

(the "Royalty Rates"). Such Royalty Rates shall be reduced in a given country to (i) * percent (* %) of the Royalty Rates once competition for the Product using technology substantially similar to the MEDUSA Technology (whether generic, based on 505(b)(2), or otherwise in a given country) has entered such country's markets, (ii) * percent (* %) of the Royalty Rates in a given country once such competition exceeds * % of the Product's sales in such country (based on total prescription Rxs for the Product sold by BMS and for such other forms of the Product), and to * percent (* %) of the Royalty Rates in a given country once such competition has reached * % of the Product's sales (based on total prescription Rxs for the Product sold by BMS and for such other forms of the Product) in such country.

3.3.2 **Payment of Royalties.** Payment of royalties shall be made forty-five (45) days after the end of each Calendar Quarter (60 days after the end of a Calendar Year) on all Net Sales in such quarter ("Quarterly

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Payment"). Each Quarterly Payment shall be accompanied by a report detailing the total Net Sales by country in the Territory for the preceding Calendar Quarter, BMS 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, BMS 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 BMS has overpaid the royalties due Flamel, BMS 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 in such calendar year, in any subsequent Calendar Quarter in which royalties are due to Flamel (or if the Agreement has terminated, BMS shall be entitled to a refund from Flamel of the overpayment).

3.3.3 **Adjustment for Excess Cost of Goods.** If BMS' Manufacturing Costs for a given calendar year following first Product launch anywhere in the world should exceed * percent (* %) of Net Sales for such year, then the royalty rate for such period (and only such period) shall be reduced as follows:

(i) if the excess costs are incurred in any year during the period beginning on such first Product launch and ending on December 31 of the third full calendar year following such Product launch, then the excess percentage shall reduce the * % Royalty Rate (but not the Rates for the two higher tiers) by the amount of the excess percentage, up to a maximum reduction of * percent (* %) in such Royalty Rate; and

(ii) if the excess costs are incurred in any year during the period beginning with the fourth full calendar year following such Product Launch, then * percent (* %) of the percentage by which BMS' Manufacturing Costs for such year exceed * percent (* %) of Net Sales shall reduce the * % Royalty Rate (but not the Rates for the two higher tiers), up to a maximum reduction of * percent in such Royalty Rate. For example, if BMS' Manufacturing Costs for the fifth calendar year post-Product launch are * percent (* %) of Net Sales, the Royalty Rate for the first tier for such year shall be * % (* % .*(* %)).

3.3.4 **Flamel Audit Rights With Respect to Manufacturing.** Flamel will be entitled to audit BMS' Manufacturing Costs pursuant to Section 3.10 with respect to any year in which BMS a royalty reduction pursuant to Section 3.3.3.

3.4. **Single Royalty; Non-Royalty Sales.** No royalty shall be payable under Section 3.3 above with respect to sales of the Product among BMS, 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.

3.5. **Third Party Fees or Royalties.** Flamel shall be fully responsible for the payment of any additional royalties, license fees, milestones and any and all other payments due to Third Parties that are required for BMS or its licensees to develop, manufacture, use, market, sell or import Product using the MEDUSA Technology.

3.6. **Flamel FTE Payments.** As consideration for work conducted by Flamel FTEs as authorized by BMS, BMS shall pay Flamel per year per Flamel FTE at a rate of * U.S. dollars (U.S. $ *) per year, 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 * percent (* %), and shall reimburse Flamel for all pre-approved out-of-pocket costs and expenses (including, but not limited to, reasonable travel and hotel costs) as authorized by BMS. BMS shall make payment to Flamel on a quarterly basis for work conducted by Flamel and authorized by BMS within thirty

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(30) days of receipt of an invoice from Flamel. Each invoice shall describe in detail the work performed by Flamel FTEs.

3.7. **Currencies.** Payments under this Agreement shall be made in United States Dollars. Revenues and expenses for each country shall be converted monthly 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 used by BMS in producing its financial accounts for its annual report to its shareholders.

3.8. **Manner of Payments.** All sums due to Flamel under this Agreement shall be payable in United States Dollars by bank wire transfer in immediately available funds to such bank account as Flamel shall designate. BMS shall 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.

3.9. **Tax Withholding.** Any tax, duty or other levy paid or required to be withheld by BMS or its sublicensees on account of royalties or other payments payable to Flamel under this Agreement shall be deducted from the amount of royalties or payments otherwise due, provided that BMS shall make such deductions only to the minimum extent required by the relevant jurisdiction. BMS shall secure and send to Flamel proof of any such taxes, duties or other levies withheld and paid by BMS or its sublicensees for the benefit of Flamel, and cooperate at Flamel's reasonable request to ensure that amounts withheld are reduced to the fullest extent permitted by the relevant jurisdiction.

3.10. **Financial Records and Audits; Flamel's Right to Audit.** Flamel, at its own cost, through an independent auditor reasonably acceptable to BMS (and who has executed an appropriate confidentiality agreement reasonably acceptable to BMS that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to Flamel), may inspect and audit the relevant records of BMS pertaining to the calculation of any royalties due to Flamel under Section 3.3. BMS 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 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. Flamel shall provide BMS 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 BMS' records by Flamel's auditors. BMS shall maintain sufficient records to permit the inspection and auditing permitted hereunder for three (3) years after the date of each respective reporting period. BMS shall prepare its records and reports in accordance with its customary business practices. Should the auditor find any underpayment of royalties by BMS, BMS shall promptly pay Flamel the amount of such underpayment, plus interest at the rate of one percent (1.0%) 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 four percent (4%) of royalties paid during the time period audited. If the auditor finds overpayment by BMS, then BMS shall have the right to deduct the overpayment from any future royalties due Flamel by BMS (or if no such future royalties are payable by reason of termination of the Agreement, then Flamel shall refund the overpayment to BMS without interest). BMS may designate competitively sensitive information which such auditor may see and review but which it may not disclose to Flamel; provided, however, that such designation shall not restrict the auditor's investigation or conclusions.

ARTICLE 4
DEVELOPMENT AND COMMERCIALIZATION

4.1. **Product Development by BMS.** Subject to the completion of Technology Transfer pursuant to Section 4.2 below, BMS shall use its commercially reasonable efforts to undertake and resource all development of Product in the Territory, and shall, subject to Sections 3.5 and 8.1, bear all costs it incurs in conducting such development, including, without limitation, expenses incurred in conducting clinical trials. Subject to Sections 3.5

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and 8.1, BMS 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 BMS retains rights thereto under this Agreement. Subject to its obligations in this Section 4.1, BMS has the sole discretion, using its reasonable business judgment, to decide whether to commercialize Product in a country in the Territory and whether to manufacture the Product itself or, subject to Section 2.1, have the Product manufactured for it by a Third Party in whole or in part. Notwithstanding the foregoing, Flamel shall sponsor and supervise those Phase IIa studies for the Product set forth on *Schedule 4.1* to this Agreement, and BMS will reimburse Flamel for its out-of-pocket costs incurred in connection therewith. Further, to the extent Flamel has made any regulatory filings for the Product anywhere in the world as of the Effective Date, Flamel shall assign such filings to BMS promptly after the Effective Date.

4.2. **Flamel Data/Technology Transfer.**

4.2.1 Immediately after the Effective Date, Flamel shall use its reasonable commercial efforts to promptly transfer, or cause to be transferred to BMS, all Flamel Know-How relating to the formulation of the Product using the MEDUSA® Technology, with polyaminoacid polymers to be supplied by Flamel. The Parties will also establish a supply agreement covering the terms and conditions of such supply by Flamel, which polymers shall be supplied at Flamel's fully-absorbed cost.

4.2.2 Upon completion of the scale-up optimization work contemplated by Section 4.3, Flamel shall use its reasonable commercial efforts to promptly transfer, or cause to be transferred to BMS, all Flamel Know-How relating to the manufacture of those polyaminoacid polymers that the Parties have mutually agreed upon for use in the Product, so that BMS can manufacture the Product in its entirety using the MEDUSA® Technology for all development and commercialization requirements.

4.2.3 Flamel will provide BMS with such documentation, drawings, charts, manuals, assays, formulae, specimens, designs and other tangible information as will enable BMS to fully understand and be able to use the MEDUSA® Technology and Flamel Know-How in connection with the transfer of the technology provided in Section 4.2.1 and 4.2.2. Flamel will provide BMS at Flamel's expense with a reasonable amount of on-site, as well as telephonic, assistance at pertinent BMS facilities in connection with any such technology transfer, and BMS will reimburse Flamel for any out-of-pocket costs incurred by Flamel at BMS' expense in connection therewith.

4.3. **Flamel Assistance.** From time to time, BMS may request Flamel's assistance in writing in the development of the Product and Flamel shall perform such work as is reasonably requested by BMS. BMS will compensate Flamel for such work pursuant to Section 3.6. Prior to the performance by Flamel of any such development work, the Parties will agree in writing on a detailed description of the tasks to be performed by Flamel, the deliverables and documentation to be produced, acceptance criteria (if any), schedule of performance, schedule of payments, and any other relevant work specifications and compensation terms as may be mutually determined. If any provisions of any such writing conflict with any provisions set forth in this Agreement, the provisions of this Agreement shall take precedence. In particular, the Parties shall promptly develop such a work plan after the Effective Date to address the joint development of the optimal scale-up technology necessary for the production of the necessary polymers in sufficient commercial quantities for use in the Product. BMS shall fund the development costs of such work at the Flamel FTE rate for one year for those Flamel FTEs required by and as set forth in the work plan, together with reasonable out of pocket expenses, equipment and supplies; provided, that if the work plan requires more than ten (10) Flamel FTES, then Flamel will bear the cost of any Flamel FTEs required by the work plan in excess of ten (10) Flamel FTEs; and provided, further, that Flamel's consent (not to be unreasonably withheld) shall be required for any use of Flamel FTEs greater than ten FTEs. BMS shall bear the cost of its own FTEs under the work plan. The Parties shall promptly upon execution of this agreement identify and make available appropriate personnel for the necessary development efforts. The Parties shall work cooperatively together so that such development can be completed within one year.

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4.4. **Development and Filing by BMS.** BMS shall use its reasonable commercial efforts to file an NDA for a Product in the United States and regulatory filings in other Major Markets 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. "Reasonable commercial efforts" under this Section 4.4 shall mean at least those typically used by BMS to develop compounds at comparable stages of development, and to commercialize products, with similar market potential. BMS shall keep Flamel apprised of its timings for such filing and all progress at least quarterly, including reasons for any changes to such filings. Not later than the filing of the JNDA for the Product, BMS agrees to seek a marketing partner to assist it in actively exploiting the Japanese market (and to consult with Flamel with regarding same), unless Flamel provides its consent (not to be unreasonably withheld) that BMS is capable of diligently exploiting the Japanese market itself without the need of a Third Party marketing partner.

4.5. **Sourcing of Recombinant Human Insulin.** BMS shall use commercially reasonable efforts to obtain supplies of insulin of sufficient quality and quantity for the performance of its obligations under this Agreement

4.6. **Establishment of Joint Committees.** Promptly after execution of this Agreement, a joint development committee ("JDC") will be established to agree on a definitive development plan for the Product. Such committee shall be responsible for all development activities under this Agreement. A joint commercialization committee ("JCC") shall be formed upon the commencement of Phase III clinical trials. All launch plans and other material commercialization activities will be presented, with sufficient notice, to the JCC prior to their implementation. Each committee will have five (5) members, with BMS having three members and Flamel two members on each of the JDC and JCC. Each Party shall appoint its members to the JDC or JCC, provided that such individuals are full-time employees of such Party or its Affiliates and that such individuals are appropriately qualified to sit on the pertinent committee. Each individual appointed by a Party to the JDC or JCC shall have one vote on any matters coming before the JDC or JCC, and each committee shall decide matters coming before it by majority vote. A BMS appointee shall chair each Committee. Each of the JCC and JDC shall hold meetings at such times as it shall determine, but in no event shall such meetings be held less frequently than once every quarter. Meetings shall be held at BMS facilities in the U.S. or Europe (as selected by BMS) or at such other locations as the Parties may otherwise agree. Each Party may, at its discretion, invite employees who are not members of the JCC or JDC to a meeting, and, with the consent of the other Party (not to be unreasonably withheld), consultants, representatives, or advisors (provided they are engaged under obligations of confidentiality) involved in the development, manufacture or commercialization of the Product to attend meetings of the JCC or JDC as nonvoting observers. Meetings of the JCC and JDC may be held by audio or video teleconference with the consent of each Party. Each Party shall be responsible for all of its own expenses of participating in the JCC and JDC. No action taken at a meeting of the JSC or JDC shall be effective unless a representative of each Party is present or participating, and no action may modify the terms of this Agreement.

4.6.1 The JDC will promptly formulate a Development Plan for the Product following the Effective Date. BMS will keep Flamel fully informed on not less than a quarterly basis of its progress against the Development Plan and the results of the studies conducted thereunder through the JDC. All development activities proposed by BMS that materially alter or are in addition to the Development Plan will be submitted to Flamel through the JDC for a reasonable period of review and comments. Any material amendments to the Development Plan for registrational trials will require the approval of the JDC.

4.6.2 No later than the time of filing the U.S. NDA, BMS will provide to the JCC its launch plan for the Licensed Product in reasonable detail. While the launch plan and subsequent commercialization plans will not require the approval of the JCC, BMS will discuss all material sales and marketing activities with Flamel through the JCC.

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ARTICLE 5
INTELLECTUAL PROPERTY

5.1. **Ownership of Inventions.** Except as provided in Sections 5.1.1, 5.1.2 and 5.1.3 below, each Party shall exclusively own all inventions made solely by such Party, its employees, agents and consultants, and the Parties shall jointly own all inventions made jointly by employees, agents and consultants of BMS and employees, agents and consultants of Flamel, on the basis of each Party having an undivided interest in the whole. For purposes of determining whether an invention is a BMS sole invention, a Flamel sole invention or a joint invention, questions of inventorship shall be resolved in accordance with United States patent laws. Subject to the terms of this Agreement, each Party shall be entitled to exercise its interest in any joint invention without obligation or accounting to the other Party.

5.1.1. **BMS Ownership.** Flamel shall promptly disclose to BMS any inventions or improvements made or conceived after the Effective Date by any employee, agent or other person acting under the authority of Flamel or any of its Affiliates (and who is obligated by law or contract to assign such invention or improvement to Flamel), either alone or jointly, that pertain to the MEDUSA® Technology, Compound and/or Product. Subject to Section 5.1.2, all inventions made by employees, agents or other person acting under the authority of Flamel or BMS (and who are obligated by law or contract to assign such inventions to Flamel or BMS) during the term of this Agreement that relate to the Compound and/or Product shall be owned by BMS, and Flamel shall assign to BMS its entire right, title and interest in any such invention (the "BMS-Owned Inventions); provided, that Flamel shall remain the sole owner (or joint owner, where it is the joint inventor) of all inventions that are made by Flamel (and any Patent Rights obtained thereon) that (i) pertain to the Compound and/or Product and that were made by Flamel prior to the Effective Date or (ii) that relate specifically to the MEDUSA® Core Technology or formulation of the Product using the MEDUSA® Core Technology. BMS shall have the right to file and prosecute patent applications on any such BMS-Owned Inventions at its expense and shall receive the reasonable cooperation of the employees of Flamel in preparing such patent applications (including execution of documents assigning such inventions as BMS may reasonably request).

5.1.2. **BMS Unblocking License Grants.** BMS shall promptly disclose to Flamel any inventions or improvements that could not be used or practiced without infringing a Valid Claim of an issued Flamel Patent Right and:

(i) that relate specifically to the MEDUSA® Core Technology, or

(ii) that relate to, and are used by BMS in, the formulation or manufacture of the Product for commercial purposes, and that can only be exclusively used or practiced with the MEDUSA® Core Technology,

and that are made or conceived after the Effective Date by any employee, agent or other person acting under the authority of BMS or any of its Affiliates (and who is obligated by law or contract to assign such invention or improvement to BMS), either alone or jointly. Subject to Section 5.1.4, BMS shall grant to Flamel a non-exclusive, royalty-free, worldwide, perpetual, irrevocable, and sublicensable right and license to use any such invention (and any patent rights obtained by BMS thereon under (i) and (ii) of this section 5.1.2) and improvement for any purpose. In the event that BMS elects not to file for or maintain any patent application or patent on any such invention, BMS shall give Flamel thirty (30) days written notice of same so that Flamel may undertake to do so thereafter at its expense and in BMS' name.

5.1.3 **BMS Option Grant.** If BMS or any of its Affiliates should during the term of this Agreement make any improvement, whether patentable or not, to the MEDUSA® Technology that (x)(i) does not relate specifically and exclusively to the MEDUSA® Core Technology or (ii) relates to (and is used in) the

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formulation or manufacture of the Product for commercial purposes but can be used or practiced with the technologies other than the MEDUSA® Core Technology (e.g., a spray drying technique or invention for polymer isolation or for commercial manufacturing) and (y) is used by BMS in the manufacture or formulation of the Product for commercial purposes, BMS shall disclose same to Flamel and grant to Flamel an option to acquire a non-exclusive, worldwide right and license to use such improvement or invention (and any patent rights obtained by BMS thereon) in connection with the practice of the MEDUSA® Core Technology by Flamel, on such terms as the Parties may mutually agreed upon (which may include license fees and/or royalties).

5.1.4 **Third Party Restrictions.** For sake of clarity, BMS shall not be obligated to assign any inventions or improvements made by Third Parties that are useful in connection with the MEDUSA® Technology and that are licensed to BMS, but will in good faith consider the grant of a sublicense to Flamel where (x) the Third Party license agreement permits BMS to so sublicense, and (y) BMS and Flamel are able to mutually agree on the terms of such sublicense.

5.2. **Disclosure of Flamel Patent Rights.** Flamel warrants and represents that it has disclosed to BMS the complete texts of all Flamel Patent Rights including all patent applications filed by Flamel as of the Execution Date that relate or may reasonably relate to the Compound and/or Product. Flamel warrants and represents that it has disclosed all information received as of the Execution 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 BMS the complete texts of all Flamel Patent Rights, including all patent applications filed by Flamel after the Execution Date that relate, or may reasonably relate to the MEDUSA Technology and/or the Product as well as all information received after the Execution 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. BMS 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 BMS promptly and fully informed of the course of patent prosecution or other proceedings by means that include providing BMS with copies of substantive communications, search reports and Third Party observations submitted to or received from patent offices throughout the Territory. BMS 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 Sections 5.1.1, 5.1.2, or 5.1.3. With respect to any such invention:

(a) BMS shall have the first right, using in-house or outside legal counsel selected at BMS' sole discretion, to prepare, file, prosecute, maintain and extend patent applications and patents concerning all such BMS Owned Inventions in countries of BMS' choice throughout the Territory, for which BMS shall bear the costs relating to such activities which occur at BMS' request or direction. BMS 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 MEDUSA® Technology and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and BMS shall take into account Flamel' reasonable comments related thereto. Flamel shall provide such patent consultation to BMS at no cost to BMS and shall treat all information disclosed to it under this Section 5.2(a) as confidential and subject to the provisions of this Agreement.

(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 inventions owned solely by Flamel in countries of Flamel's choice throughout the Territory, for which Flamel shall bear the costs. Flamel shall solicit BMS' advice and review of the nature and text of such patent applications to the extent such are related to Product and important prosecution matters related thereto in reasonably

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sufficient time prior to filing thereof, and Flamel shall take into account BMS' reasonable comments related thereto. BMS 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.

(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 MEDUSA® Technology and/or the Product, and if 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 BMS 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 BMS shall thereafter have the right, at its sole expense and in the name of BMS, 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 BMS 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 and to ensure that filings are made in a manner that maximizes the Parties' ability to file for and obtain patent rights in all relevant markets.

(f) Subject to Sections 5.1.1 and 5.1.2, for jointly owned inventions, the Parties shall meet and confer for the purpose of determining which Party shall take the lead on filing patent applications covering the cost thereof. The Parties shall, unless otherwise mutually agreed, evenly share any out-of-pocket costs incurred to file and prosecute patent applications on any such joint inventions and maintain any patents obtained thereon. If a Party does not wish to pay for its share of any such costs in a given country, it may decline to do so, in which event it shall execute an assignment of all its right, title and interest in such joint patent or joint invention to the other Party in such country.

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 of a Third Party in any country in the Territory, or are subject to a declaratory judgment action arising from such infringement in such country, such Party shall promptly notify the other Party hereto. BMS 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 BMS to bring such action, and provided that BMS shall not have the initial right, and Flamel shall have the initial right, to enforce any such Flamel Patent Rights that pertain to the MEDUSA® Core Technology. In the event that BMS 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 or declaratory judgment action, and if such Flamel patent Rights relate to the MEDUSA® Technology, 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 BMS' name in connection therewith. In the event that Flamel fails to initiate a suit to enforce such Flamel Patent Rights relating to the MEDUSA Core Technology against such a Third Party in any jurisdiction in the Territory within ninety (90) days after notification of such infringement or declaratory judgment action, BMS 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 BMS, and to use Flamel'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 BMS shall recover their respective actual out-of-pocket expenses, or equitable proportions thereof, associated with any

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litigation or settlement thereof from any recovery made by any Party. Any remaining amounts shall be distributed between the Enforcing Party, with the Enforcing Party receiving ¾ of any such net recovery and the other Party ¼.

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 BMS, such Party shall promptly notify the other Party hereto. If BMS is not named as a Party in such a claim, suit or proceeding, BMS 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 BMS, and not Flamel, is named as a Party to such claim, suit or proceeding, BMS 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, BMS agrees not to oppose such intervention. If BMS is named as a Party and Flamel shall, at any time, tender its defense to BMS, then BMS shall defend Flamel in such claim, suit or proceeding, at BMS' own expense (subject to Section 3.5 hereof) and through counsel of its own choice, and BMS shall control the defense and settlement of any such claim, suit or proceeding; provided, BMS shall not enter into any agreement which (i) extends or purports to exercise BMS' 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.

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. **BMS Extensions of Flamel Patent Rights, Pipeline Protection and Supplementary Patent Certificates ("SPCs").**

5.7.1. **Patent Extensions.** BMS shall have the right but not the obligation to seek extensions of the terms of Flamel Patent Rights. At BMS' request, Flamel shall either authorize BMS to act as Flamel's agent for the purpose of making any application for any extensions of the term of Flamel Patent Rights and provide reasonable assistance therefor to BMS or shall diligently seek to obtain such extensions.

5.7.2. **SPCs.** At BMS' request, Flamel shall seek to obtain SPCs based on Flamel Patent Rights or authorize BMS to obtain SPCs based on Flamel Patent Rights on Flamel's behalf. Where BMS holds a relevant Marketing Authorization, BMS shall at its sole discretion provide to Flamel a copy of said Marketing Authorization and any information necessary for the purpose of obtaining an SPC based on a Flamel Patent Right.

5.7.3 **Expenses.** Each Party shall bear its own internal expenses in fulfilling its obligations under Sections 5.7.1 and 5.7.2. Flamel shall bear any out-of-pocket costs (including filing fees and reasonable attorneys fees) incurred to the extent that the Patent Extension or SPC relates to the MEDUSA® Technology; BMS shall bear any out-of-pocket costs (including filing fees and reasonable attorneys fees) incurred to the extent that the Patent Extension or SPC relates to the Compound or Product (but not the MEDUSA® Technology).

5.8. **Flamel's Additional Patent Protection.** Notwithstanding Sections 5.7.1 and 5.7.2, Flamel shall have the right, but not the obligation, to seek extensions of the terms of Flamel Patent Rights and to seek to obtain SPCs based on Flamel Patent Rights at its own expense. At Flamel's request, BMS shall provide to Flamel a copy

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of any requested Marketing Authorization where BMS holds such Marketing Authorization, and any information necessary for the purpose of seeking such extensions of Flamel Patent Rights and obtaining SPCs.

5.9. **Trademarks.** BMS, its Affiliates, and its sublicensees shall have the right to market Product under their own labels, tradenames, and trademark(s) (collectively, the "BMS Marks") and BMS shall solely own such trademarks, labels and tradenames. BMS shall be responsible for the selection of all BMS Marks that it employs in connection with Product in the Territory and shall own and control such BMS Marks and retain ownership upon termination or expiration of this Agreement. BMS shall be responsible for filing, registering and maintaining all BMS Marks throughout the Territory. Concurrently with the execution of this Agreement, Flamel and BMS will execute the Trademark Assignment attached as *Schedule 5.9* hereto, pursuant to which Flamel will assign to BMS its entire right, title and interest in and to the Basulin® trademark. In the event that BMS elects not to use the Basulin® trademark in the United States or fails to receive all necessary Regulatory Approvals for the use of this trademark with the Product in the United States, then BMS shall assign the trademark back to Flamel without charge for use in the United States. In the event that BMS elects not to use the Basulin® trademark in an EU Major Market country or Japan or fails to receive all necessary Regulatory Approvals for the use of this trademark with the Product any such country, then BMS shall assign the trademark back to Flamel without charge for use in such country. In the event that BMS uses the Basulin® trademark in the U.S., in all EU Major Markets and in Japan, then BMS need not assign back to Flamel rights to the Basulin® trademark for any other country where BMS elects not to use the trademark.

ARTICLE 6

REPRESENTATIONS AND WARRANTIES; EFFECTIVENESS CONDITIONS

6.1. **Representations and Warranties.**

6.1.1. **Flamel.** Flamel warrants and represents to BMS that:

(i) as of the Execution Date, and except as otherwise disclosed to BMS on *Schedule 6.1.1*, it has full Control of the Licensed Technology, is entitled to grant the rights and licenses granted under Section 2.1, and is not currently subject to any Third Party agreement or to any outstanding order, judgment or decree of any court or administrative agency that restricts it in any way from using the Licensed Technology or from licensing or sublicensing to BMS, either as of the Execution Date or in the future, any know-how or patent rights that would otherwise be useful for the manufacture, formulation, use or sale of the Product;

(ii) as of the Execution Date, there are no existing or threatened actions, suits or claims pending against it with respect to (x) the Licensed Technology which, if adversely determined, would have an adverse effect upon its ability to grant rights to BMS relating to, or upon the ability of BMS to fully utilize or exercise, the Licensed Technology or (y) its right to enter into and perform its obligations under this Agreement;

(iii) as of the Execution Date, it has not granted, and will not 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 Execution Date, has it encumbered any Flamel Know-How and/or Flamel Patent Rights;

(iv) as of the Execution Date, it has no knowledge from which it would have reason to conclude that the Flamel Patent Rights are invalid or that their exercise would infringe patent rights of Third Parties;

(v) The Licensed Technology licensed or sublicensed to BMS pursuant to this Agreement have not been obtained by Flamel or its Affiliates (or its predecessors-in-interest) in violation of any contractual or fiduciary obligation owed by any of them to a Third Party or by misappropriation of the trade secrets of any Third Party;

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(vi) The Patent Rights listed on *Appendix A* list all Patent Rights owned or Controlled by Flamel relating to the Licensed Technology as of the Execution Date, and such Appendix specifies the jurisdiction(s) by or in which each such right has been issued or registered or in which an application for such issuance or registration has been filed, including respective registration or application numbers. All fees required to maintain such Patent Rights have been paid to date. To the best of Flamel's knowledge, the issued claims under any issued Patent Rights are valid and in full force and effect as of the Execution Date; and

(vii) Flamel has no knowledge of any infringement by any Third Party of any of the Licensed Technology as of the Execution Date.

6.1.2. **Mutual.** Each Party warrants and represents to the other that:

(i) as of the Execution Date**,** it has the full right and authority to enter into this Agreement;

(ii) as of the Execution Date, there are no existing or threatened actions, suits or claims pending against it with respect to its right to enter into and perform its obligations under this Agreement;

(iii) to the best of a Party's knowledge, there is nothing in any Third Party agreement or understanding, written or oral, entered into or agreed to by such Party as of the Execution Date, that, in any way, will limit such Party's ability to perform all of the obligations undertaken by it hereunder, and that it will not enter into any agreement after the Execution Date under which it would incur any such limitations; and

(iv) it is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction agreement (including any outstanding order, judgment or decree of any court or administrative agency) which in any way limits or conflicts with its ability to fulfill any of its obligations under this Agreement, and

(v) this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by such Party do not violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

6.2. **Conditions to Each Party's Obligations.** The respective obligation of each Party to effect the transactions contemplated by this Agreement shall be subject to the satisfaction or waiver of the following conditions, and this Agreement shall not take effect unless and until such conditions have been waived or satisfied:

6.2.1 **HSR Act.** The waiting period (including any extensions thereof) applicable to the consummation of the transactions contemplated by this Agreement required pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act") shall have expired or been terminated. The Parties will use all reasonable efforts to make all necessary filings under the HSR Act as promptly as practicable.

6.2.2 **No Order.** There shall not be in effect any statute, regulation, order, decree or judgment of any Governmental Entity which makes illegal, enjoins or prevents the consummation of the transactions contemplated by this Agreement prior to the satisfaction of the conditions set forth in Section 6.2.1.

6.2.3 **Termination; Effective Date.** If all conditions set forth in Section 6.2.1 and 6.2.2 shall not have been waived or satisfied by not later than November 30, 2003, then this Agreement shall terminate. The date that the conditions set forth in section 6.2.1 and 6.2.2 shall have been waived or satisfied is referred to as the *"Effective Date"* for purposes of this Agreement.

* The asterisk denotes that confidential portions of this exhibit have been omitted in reliance on Rule 24b-2 of the Securities Exchange Act of 1934. The confidential portions have been submitted separately to the Securities and Exchange Commission.

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 use commercially reasonable efforts to keep completely confidential and not to disclose, shall not publish, 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:

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

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

(3) 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;

(4) was independently developed by the receiving Party or any of its Affiliates without reference to any information or materials disclosed by the disclosing Party; or

(5) was subsequently disclosed to the receiving Party or any of its Affiliates 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).

Each Party further reserves the right to make reasonable disclosures (including the material financial terms of this Agreement) under strictures of confidentiality to any actual or potential acquirer, bona fide potential strategic partner or collaborator, merger partner, bank, venture capital firm, or financial institution, as well as to accountants, attorneys and other professional advisors on a need-to-know basis. Further, notwithstanding anything herein to the contrary, any Party to this Agreement (and any employee, representative, or other agent of any Party to this Agreement) may disclose to any and all persons, without limitation of any kind, the tax treatment and tax structure of the transactions contemplated by this Agreement and all materials of any kind (including opinions or other tax analyses) that are provided to it relating to such tax treatment and tax structure. However, any such information relating to the tax treatment or tax structure is required to be kept confidential to the extent necessary to comply with any applicable federal or state securities laws.

7.3. **Public Announcements.** No public announcement or other disclosure to Third Parties concerning the existence of, terms, or subject matter 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 purposed, without first

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obtaining the approval of the other Party (not to be unreasonably withheld) and agreement upon the nature and text of such announcement or disclosure. 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; thereafter, Flamel and BMS may each disclose to Third Parties the information contained in such press release without the need for further approval by the other.

7.4. **Publications.** Nothing herein shall be construed to prevent BMS from disclosing any information received from Flamel hereunder to an Affiliate, sublicensee, distributor, Third Party research or clinical contractor of BMS, provided, in the case of a sublicensee, distributor or Third Party research or clinical contractor of BMS, such sublicensee, distributor, or Third Party research or clinical contractor of BMS has 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 without first obtaining the prior written consent of the other Party, which consent shall not be unreasonably withheld, and shall be promptly given or refused; provided, that the foregoing shall not apply to publications by academic institutions conducting pre-clinical or clinical research pertaining to the Product.

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 BMS.** Flamel shall indemnify and hold harmless BMS and its Affiliates, and their respective directors, officers, employees, agents and counsel, and the successors and assigns of the foregoing (the "BMS 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) payable to a Third Party resulting from a claim, suit or proceeding brought by a Third Party against a BMS Indemnitee, arising from or occurring as a result of: (i) the failure by Flamel to obtain or maintain rights under Flamel Patent Rights sufficient to grant BMS an exclusive license in accordance with Article 2 of this Agreement; or (ii) 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 BMS or to the extent that BMS is obligated to indemnify Flamel under Section 8.2 below.

8.2. **Indemnification of Flamel.** Subject to Section 3.5, BMS and its Affiliates and sublicensees 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

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litigation and/or arbitration) payable to a Third Party resulting from a claim, suit or proceeding brought by a Third Party against a Flamel Indemnitee, arising from or occurring as a result of: (i) the development, manufacture, marketing and/or commercialization of Product by BMS or its Affiliates or sublicensees; or (iii) BMS' 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 BMS under Section 8.1.

8.3. **Procedure.** Subject to Sections 5.4 and 5.5, 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 agreements of an Indemnitor in this Article 8 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is made by the Indemnitee 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 **Limitation of Liability.** SUBJECT TO SECTIONS 3.5, 8.1 AND 8.2, NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, INDIRECT OR PUNITIVE DAMAGES (INCLUDING WITHOUT LIMITATION, LOST PROFITS, LOST REVENUES AND/OR FUTURE ROYALTIES PAYABLE TO, OR THAT MAY BE EARNED BY, A PARTY HEREUNDER) ARISING OUT OF ANY BREACH OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 9
TERM AND TERMINATION

9.1. **Term and Termination by BMS.**

9.1.1. **Term.** This Agreement shall commence on the Execution Date, and unless otherwise terminated pursuant to Section 6.2, 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 BMS' royalty obligations under Section 9.1.1 in a given country, BMS shall have a fully paid up, royalty free, perpetual, irrevocable, non-exclusive, world wide license under the Flamel Know-How in such country, with the right to sublicense and BMS shall be free to make, have made, use and sell Product and to use Flamel Know-How in the such country, 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 sixty (60) 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 or should have known of the default and prior to correction of the default; provided that the time period for providing

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such notice of termination shall be extended for so long as the Parties are engaged in good faith negotiations to resolve the situation. Any such termination shall be limited in force and effect to the country or countries to which such material breach relates.

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 by BMS.** BMS may terminate this Agreement in its sole discretion on a country-by-country basis, or in its entirety, by giving Flamel at least ninety (90) days written notice thereof (the "Notice Period") at any time for scientific, technical, medical, regulatory or commercial reasons.

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 which, at the time of such termination, has already accrued to the other Party or which 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 which accrued or are based upon any event occurring prior to such termination; provided, that BMS shall not be obligated to pay any milestone payment under Section 3.2 that may become due following delivery of notice of termination. In the event of a termination pursuant to Section 9.4, all development work which had been agreed prior to termination shall continue to be performed during the Notice Period and for 90 days thereafter and shall be subject to all terms of this Agreement.

9.5.2. **Return of Materials.** Upon any termination of this Agreement, BMS 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 BMS and/or its Affiliates and sublicensees, BMS 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 BMS pursuant to Section 9.4 or termination by Flamel under Section 9.2 due to BMS' material breach, the licenses granted to BMS under Section 2.1 shall terminate. In the event of termination by BMS pursuant to Section 9.2 due to Flamel's material breach, all licenses granted by Flamel to BMS under Section 2.1 shall survive and continue in full force, all licenses granted by BMS to Flamel under Section 5.1 shall terminate, and BMS shall be obligated to continue to make payments under Article 3 to Flamel to the extent BMS continues to develop, use, market, sell or import Product in the Territory. Furthermore, in the event that BMS terminates this Agreement after the initiation of any Phase III study but prior to NDA Approval in the U.S, BMS shall pay to Flamel the additional sum of * dollars (US$ *); provided, that such sum shall not be payable if BMS terminates the Agreement pursuant to Section 9.2 or pursuant to Section 9.4 for reasons of Product safety or because the Product failed to meet the clinical endpoints of any

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pivotal clinical trial. In the event of termination by either Party pursuant to Section 6.2, all licenses granted by either Party to the other under this Agreement shall terminate.

9.6. **Bankruptcy Provisions.** All rights and distribution rights granted under or pursuant to the Agreement by Flamel to BMS 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 BMS, 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 BMS 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, BMS 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 BMS (a) upon any such commencement of a bankruptcy proceeding upon written request therefore by BMS, 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 BMS, provided, however, that upon Flamel's (or its successor's) written notification to BMS 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 BMS, but only to the extent that Flamel does not require continued access to such materials to enable BMS to perform its obligations under this Agreement.

9.7. **Survival.** Sections 3.2, 3.3, 3.4, 3.6, 3.7 (all to the extent owed or unpaid), 3.8, 3.9, 3.10, 5.1, 5.4 (with respect to actions commenced prior to the termination date), 5.5 (with respect to infringements that occur during the Term); 5.6 (as applied to any matters surviving under Section 5.5), 6.1 and 7.1 (for the time period provided therein); 7.2, 7.3, 7.5 and Articles 1, 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; Jurisdiction.**

10.1.1. **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, OTHER THAN SECTION 5-1401 OF THE NEW YORK GENERAL OBLIGATIONS LAW.

10.1.2. **Consent to Jurisdiction.** Each Party irrevocably submits to the exclusive jurisdiction of (a) the Supreme Court of the State of New York, New York County, and (b) the United States District Court for the Southern District of New York, for the purposes of any suit, action or other proceeding arising out of this Agreement or out of any transaction contemplated hereby. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the Southern District of New York or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York, New York County. Each Party further agrees that service of any process, summons, notice or document personal delivery, by registered mail, or by a recognized international express delivery service to such Party's respective address set forth above shall be effective service of process for any action, suit or proceeding in New York with respect to any matters to which it has submitted to jurisdiction in this Section 10.1. Each Party

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irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in (i) the Supreme Court of the State of New York, New York County or (ii) the United States District Court for the Southern District of New York, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

10.1.3. **Waiver of Jury Trial.** Each Party hereto hereby waives to the fullest extent permitted by applicable law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of, under or in connection with this Agreement. Each Party hereto (a) certifies that no representative, agent or attorney of any other Party has represented, expressly or otherwise, that such other Party would not, in the event of litigation, seek to enforce that foregoing waiver and (b) acknowledges that it and the other Party hereto have been induced to enter into this Agreement, as applicable, by, among other things, the mutual waivers and certifications in this Section 10.1.3.

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.

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 BMS:	Bristol-Myers Squibb Pharmaceutical Group Route 206 at Province Line Road Princeton, New Jersey 08543-4000 USA Attention: Tamar D. Howson Senior Vice President – Corporate Development Telephone: 609-252-4128 Telecopy: 609-252-7128
with copies to:	Bristol-Myers Squibb Pharmaceutical Group Route 206 at Province Line Road Princeton, New Jersey 08543-4000 USA Attention: Charles Linzner VP and Senior Counsel for Corporate Development Telephone: 609-252-4311 Telecopy: 609-252-4232

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and

Bristol-Myers Squibb Pharmaceutical Group
Route 206 at Province Line Road
Princeton, New Jersey 08543-4000 USA
Attention: Michael Levy
Vice President – Alliance Management
Telephone: 609-252-6818
Telecopy: 609-252-7235

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: 33 (0)4 72 78 34 34
Telecopy: 334 7278 3435

with copy to:

Flamel Technologies, Inc.
2121 K Street, Suite 650
Washington, D.C. 20037 USA
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 BMS or Flamel 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. **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. Neither this Agreement nor any

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provision of this Agreement shall be construed for or against any Party because the Agreement as a whole, or any portion of it, was requested or drafted by such Party.

10.8 **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.

10.9 **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 BMS and Flamel with respect to such subject matter (including all prior confidentiality agreements between the Parties relating to the Product or the MEDUSA® Technology with respect to disclosures following the Effective Date). 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.

10.10. **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 shall not affect its meaning or interpretation.

10.11. **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.

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

FLAMEL TECHNOLOGIES, S.A.		**BRISTOL-MYERS SQUIBB COMPANY**	
By:	_____	By:	_____
Name:	_____	Name:	_____
Date:	_____	Date:	_____
Title:	_____	Title:	_____

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APPENDIX A

LIST OF FLAMEL PATENTS PERTAINING TO THE PRODUCT AND THE JURISDICTIONS IN WHICH FILED

{four pages attached}

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APPENDIX B

DESCRIPTION OF MEDUSA CORE TECHNOLOGY

Particles (including microparticles or nanoparticles) comprising a plurality of chains of polyaminoacid block copolymers for delivery of compounds or active ingredients and methods for making the polyaminoacids and particles. The polyaminoacid block copolymers comprising amino acids, particularly, hydrophobic neutral amino acids (such as leucine) and amino acids having an ionizable side chain (such as glutamate), wherein the polyaminoacids assemble into a particle in water or other aqueous solution (without the use of an organic solvent) and wherein the particle is capable of having an active ingredient or compound associate with the hydrophobic amino acid residues of the polyaminoacids and the active ingredient or compound is competitively displaced from the particle by another protein or compound. The MEDUSA® Core Technology does not include an active ingredient or compound associated with, adsorbed to, or loaded on the polyaminoacids, or techniques, know-how, methods of formulating a product using polyaminoacids and an active ingredient or compound in a product. The MEDUSA® Core Technology is further delineated and encompassed within the Valid Claims of any Flamel Patent Rights.

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SCHEDULE 4.1

PHASE IIa STUDIES TO BE SPONSORED BY FLAMEL

AN OPEN LABEL, SINGLE WAY STUDY TO INVESTIGATE THE TOLERANCE, PHARMACOKINETICS AND EFFICACY OF A REPEATED DOSE OF A NEW LONG-ACTING INSULIN (BASULIN®) IN 30 TYPE 1 DIABETIC PATIENTS.

BACKGROUND

Basulin® Xe is a complex of soluble insulin and a synthetic polymer, MEDUSA® Xe.

The polymer retards the absorption of injected insulin but does not alter its intrinsic action. The delayed absorption makes it potentially useful as a once daily injection for providing long acting basal insulin for diabetics.

Preclinical studies have confirmed its slow absorption and prolonged action and lack of systemic toxicity. Adverse reactions appear to be limited to injection site reactions which are generally mild and which disappear spontaneously.

The first human study compared the tolerability, insulin pharmacokinetics and pharmacodynamics (assessed by euglycaemic glucose clamping) of three formulations of Basulin® Xe and Lantus®. Single doses were given to healthy male volunteers. Basulin® Xe was locally well tolerated at the injection site and systemically. The insulin profile demonstrated a smooth, flat, sustained profile extending beyond 24 hours, with action confirmed by glucose clamping.

It now proposed to investigate the safety and describe the pharmacokinetics and pharmacodynamics of the selected formulation of Basulin® in Type 1 diabetic patients following repeated administration.

OBJECTIVES

1. To investigate the tolerability and safety of repeated dosing with Basulin®.

2. To describe the plasma insulin PK profiles of products containing insulin: Basulin® combined with licensed short acting insulin administered by subcutaneous route.

3. To describe glucose control of products containing insulin: Basulin® with a licensed short acting insulin administered by subcutaneous route.

STUDY DESIGN

This is an open label, single-way, multiple dose study in Type 1 diabetic patients.

One treatment will be investigated Basulin® (direct equivalent in IU for patients Lantus® dose) administered once daily in the evening over a 14 days period. Treatment will be administered by subcutaneous injection by appropriately trained medical staff at Clinical Unit.

Patients will continue to use variable doses of short acting pre-prandial insulins their usual manner throughout the duration of the study.

*The asterisk denotes that confidential portions of this exhibit have been omitted in reliance on Rule 24b-2 of the Securities Exchange Act of 1934. The confidential portions have been submitted separately to the Securities and Exchange Commission.

STUDY POPULATION

The study population will consist of Type 1 diabetic patients aged between 18 and 65 years inclusive. Thirty patients will be entered into the study.

TEST PRODUCT AND DOSAGE

One treatment will be investigated:

Basulin® (direct equivalent in IU for patients Lantus® dose) administered once daily in the evening over a 14 days period. Treatment will be administered by subcutaneous injection by appropriately trained medical staff at Clinical Unit.

Patients will continue to use variable doses of short acting pre-prandial insulins their usual manner throughout the duration of the study. However, the patient will be strongly asked to record the dose used in diary.

ASSESSMENTS

1. General safety assessments including recording adverse events, adherence to study restrictions and use of concomitant medications.

2. Physical examination: patients will undergo a complete physical examination at screening, admission on Days 1, 7 and 14 and at the post-study medical.

3. Vital signs (heart rate, supine blood pressure, temperature and respiratory rate) will be measured and recorded at screening, at intervals throughout the study period and at the post-study medical.

4. Routine safety laboratory tests performed at screening, at intervals throughout the study period and at the post-study medical.

5. Blood glucose measurements will be recorded using a memory meter by patients. Reading will be taken during the study at 8 timepoints during the day (fasting, before each meal, 90 min after each meal, at 1500, at bedtime)

6. Blood fasting glucose will be recorded using memory meter by patient on a daily base. In addition BFG will be analysed by beckman glucose analyser on screening, and D15 as a part of glycaemia profile.

7. Blood glucose measurements (analysed by the Beckman Glucose Analyser) will be taken over the 24h residential sampling sessions on Day -1/1 (baseline) and 14/15.

8. Urinary ketone levels will be collected by the patient during the study and recorded in a diary card.

9. Plasma concentrations of insulin, C-peptide during the residential sampling period on Days -1/1 (baseline) and 14/15.

10. Plasma concentrations of insulin pre dose on Days 1, 4, and 11.

11. Plasma HBA1c and C-peptide at screening, Day1, 8 and post study.

12. Insulin antibody levels at screening and post study (Day 28)

13. Polymer antibodies at screening and post study (Day 28)

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14. Safety monitoring – patients will be provided with the following advice for safety monitoring of blood glucose:

If pre-meal blood glucose is less than 4 mmol/litre decrease short acting insulin by 2 units.

If pre-meal blood glucose is between 12-16 mmol/litre, increase short acting insulin by 2 units.

If pre-meal blood glucose is greater than 16 mmol/litre, increase short acting insulin by 4 units.

In addition, in case of hypoglycaemic events, when reduction of short acting insulin is not sufficient and at the investigator judgements the dose of Basulin may decrease by 2-4 IU.

15. Assessing adverse events at adequate time points

DATA ANALYSIS

All clinical and safety data will be listed for each subject. Demographic information and past medical history will be summarised and tabulated. Physical examination findings will be tabulated. Coded adverse events will be summarised and tabulated for each treatment. Vital signs data will be tabulated and summarised descriptively for each treatment and measurement time. Individual clinical laboratory values will be listed for each treatment and values outside normal ranges will be flagged and tabulated. Individual virology data will be listed. Drugs of abuse and alcohol breath test results will be listed. Memory meter blood glucose levels will be listed. Pre-study medications and concomitant medications used during the study will be listed.

Short acting insulin daily dose will be plotted for each subject and mean plots will be constructed.

Glucose, insulin and C-peptide levels will be listed for each subject and treatment and summarised descriptively. Individual glucose, insulin and C-peptide profiles will be plotted for each subject and mean plots will be constructed.

The following insulin pharmacokinetic parameters will be derived by standard model-independent methods using WinNonlin Professional following drug administration at Day 14: C_{max}, t_{max}, $AUC_{0-\tau}$. C_{max} and $AUC_{0-\tau}$.

Individual subject measurements, as well as summary statistics will be reported.

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SCHEDULE 5.9

FORM OF TRADEMARK ASSIGNMENT

THIS ASSIGNMENT OF TRADEMARKS (this "Assignment") is made as of the 26th day of August, 2003, by and between Bristol-Myers Squibb Company, a Delaware corporation ("Assignee"), and Flamel Technologies, S.A., a corporation organized under the laws of France ("Assignor").

W I T N E S S E T H

WHEREAS, Assignor is engaged in developing a product under the trademark Basulin® (the "Product"); and

WHEREAS, Assignor and Assignee have entered into a License Agreement for Basulin® dated as of the 26th day of August, 2003 (the "License Agreement"), pursuant to which Assignor is exclusively licensing to Assignee rights under certain patent rights and know-how controlled by Assignor for the purpose of enabling Assignee to develop and commercialize a controlled-release formulation of human insulin using the Assignor's MEDUSA® technology; and

WHEREAS, Assignee desires to explore the use of the Basulin trademark with the Product.

NOW, THEREFORE, for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Assignor does hereby sell, assign, transfer, set over, and deliver to Assignee all right, title and interest in and to:

(i) the trademark registrations and/or applications set forth on such Schedule I annexed hereto (collectively, the "Trademark");

(ii) the goodwill of Assignor's business connected with the use of the Trademark throughout the world (the "Territory");

(iii) all rights of enforcement and the right to damages for past infringement, unfair competition or other conflicts relating to the Trademark in the Territory; and

(iv) all other rights, including common law rights, relating to the Trademark in the Territory to the extent such rights exist.

2. Assignor will, at the expense of Assignee, (i) execute and deliver such further instruments including, without limitation, further instruments of assignment, and (ii) take such further actions as Assignee may reasonably request in order to register this Assignment at the appropriate registries and to demonstrate Assignee's title to the Trademark or in order to prosecute any of the pending applications included in the Trademark.

3. For avoidance of doubt, Assignee acknowledges and agrees that Assignor makes no representations or warranties whatsoever with respect to the Trademark and the other assets and rights described in clauses (ii), (iii) and (iv) above (including any representations and warranties with respect to the existence, validity, enforceability, use or ownership of any such common law rights).

4. This Assignment shall be governed by and construed in accordance with the laws of the State of New York, without regard to any applicable principles of conflicts of law. Each of the Parties hereto hereby

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irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the courts of the State of New York and of the United States of America in each case located in the County of New York for any litigation arising out of or relating to this Assignment (and agrees not to commence any litigation relating thereto except in such courts).

IN WITNESS WHEREOF, the Parties hereto have executed this Assignment as of the date first written above in multiple counterparts by their duly authorized representatives.

BRISTOL-MYERS SQUIBB COMPANY

By: _____
Name:
Title:

FLAMEL TECHNOLOGIES, S.A.

By: _____
Name:
Title:

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SCHEDULE I
ASSIGNED TRADEMARK

BASULIN® Trademark:

Registration No. and Country	Registration Date	Registered Owner
U.S. No. 2,292,086	11/16/1999	Flamel Technologies, S.A
France No. 97/687226	1/22/1998	Flamel Technologies, S.A.
EU: No. 000724278	1/22/2001	Flamel Technologies, S.A.
Japan: No. 4339029	11/26/1999	Furameru Technologies

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SCHEDULE 6.1.1

EXCEPTIONS TO FLAMEL REPRESENTATIONS AND WARRANTIES

None

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