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March 2, 2011

## CORRESPONDENCE FILED VIA EDGAR AND OVERNIGHT DELIVERY

Keira Nakada Division of Corporation Finance United States Securities and Exchange Commission 100 F Street NE Washington, DC 20549

> Re: Flamel Technologies S.A. Form 20-F for the Year Ended December 31, 2009 File No. 000-28508

Dear Ms. Nakada:

On behalf of Flamel Technologies S.A. ("Flamel" or the "Company"), set forth below are Flamel's responses to the comment letter from the staff of the Securities and Exchange Commission (the "Staff"), dated February 15, 2011, relating to Flamel's Annual Report on Form 20-F for the fiscal year ended December 31, 2009 (the "2009 Form 20-F"). The February 15, 2011 comment letter followed the Company's January 21, 2011 response to the Staff's initial December 20, 2010 comment letter. For ease of reference, the Staff's comments are set forth below in italic type immediately before the Company's response.

# <u>Risk Factors</u> <u>"We depend on a limited number of suppliers for certain raw materials..." page 5.</u>

1. We note your response to comment two. Please expand the risk factor disclosure to address how long your current inventory of key ingredients from the sole supplier are anticipated to last.

The Company acknowledges the Staff's comment. In future filings, the Company will address the anticipated inventory coverage of key ingredients from sole suppliers. The Company currently intends to include in its next Annual Report on Form 20-F the following revised disclosure, or substantially similar disclosure. Portions of the disclosure that reflect proposed additional disclosure from the 2009 Form 20-F have been underlined for convenience.

# We depend on a limited number of suppliers for certain raw materials used in our products, and any failure to deliver sufficient supplies could interrupt our production process and could have a material adverse affect on our business.

We purchase a number of raw materials used in our products from a limited number of suppliers, including a single supplier for certain key ingredients. These raw materials include excipients such as celpheres and cellets and active ingredients such as carvedilol phosphate used for the production of Coreg CR microparticles and polyglutamate used in the production of our Medusa polymers. The Company generally has contracts in place with the suppliers of these materials, which are reviewed based on future forecast requirements. The Company determines minimum inventory levels of these raw materials based on the Company's goal of holding at least three months of future requirements in inventory. If the supplies of these materials were interrupted for any reason, our manufacturing and marketing of certain products could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required regulatory approval. For example, an alternative supplier may be required to pass an inspection by the FDA for compliance with current Good Manufacturing Practices (cGMP) requirements before we may incorporate that supplier's ingredients into our manufacturing. We expect to continue relying on our current suppliers for the foreseeable future. Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

#### Strategic Alliances, page 25

2. We note your response to comment six and reissue the comment in part. As previously requested, please provide draft disclosure of the aggregate milestone payments, the range of royalty rates, and the term and termination provisions of the agreements with Baxter International, Merck Serono, and Pfizer. In this regard, we note your statement that historical revenues are not indicative of future payments nor of a consistent or predictable future revenue stream and the specificity of the information requested by the staff could create a false impression of the likelihood of receipt of such payments. The materiality of an agreement is not necessarily determined retrospectively. In this instance, we note the company has highlighted the agreements in the discussion and notes to the financial statements and the company has described the significant advance payments.

The Company acknowledges the Staff's comment and intends to expand the disclosure on the Merck Serono, Baxter and Pfizer agreements in its next Annual Report on Form 20-F. Taking into account the factual differences among the Company's agreements, the Company intends to provide more expansive disclosure for agreements involving projects in clinical development, such as Merck Serono, but more limited disclosure for agreements involving pre-clinical projects, such as Baxter and Pfizer. Consequently, certain disclosure requested by the Staff may not be relevant to certain agreements, such as milestone payments under the Pfizer agreement that the Company believes are too speculative to disclose given the relative progress of development under that agreement or milestone payments that do not exist under the Baxter feasibility study agreement. The Company intends to include in its next Annual Report on Form 20-F the revised disclosure below, or substantially similar disclosure. Portions of the disclosure that reflect proposed additional disclosure from the 2009 Form 20-F have been underlined for convenience. In addition, as suggested by the Staff, the Company will add disclosure, where appropriate, to temper the discussion of payments under these agreements with cautionary language describing the extent, limitations or duration of possible future payments.

#### **Strategic Alliances**

In order to develop and apply our technologies efficiently and effectively commercialize the resulting products, we have entered into, and intend to continue to enter into, <u>various types of</u> collaborative arrangements with large biotechnology and pharmaceutical company partners. Such arrangements typically provide funding for development work and access to target compounds and related know-how and <u>in many cases ultimately</u> provide distribution capabilities for any resulting products <u>either directly or by providing for the option to enter into future license agreements</u>. Such arrangements generally include termination provisions in the event either party decides that, for strategic or other reasons, it does not wish to pursue the alliance. In many of our agreements, particularly feasibility studies, we are precluded from disclosing the identity of the partner and/or of the molecule(s) with which we are collaborating. <u>A summary of</u> the major existing agreements we are able to disclose <u>is provided below</u>. Where <u>agreements provide for the possibility of future payments, there can be no assurance that the payments contemplated under these agreements will be paid, either at all or in part. Future payments are contingent upon a number of factors, such as clinical, regulatory and market success, that are <u>subject to numerous risks and uncertainties</u>. Due to the uncertainties associated with development and commercialization activities in the pharmaceutical industry generally and our business in particular, contemplated payments are neither indicative of the likelihood of receipt of such payments nor of a consistent or predictable future revenue stream.</u>

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#### Merck Serono

In December 2007, we entered into a relationship with Merck Serono to develop a controlled release formulation of an already-marketed Merck Serono product using our Medusa technology platform. In February 2009, Merck Serono exercised its option to <u>enter into</u> a development and license agreement for this program and paid an upfront fee of € 5.0 million (\$6.5 million). <u>Under the terms of the agreement, we are eligible to receive up to €41 million in milestone payments and royalties ranging from the mid- to high- single digits as a percentage of product sales, upon certain agreed-upon development events. The program is in a Phase I clinical trial, and under the agreement Merck Serono will pay all future development costs for the program. The term of the agreement continues on a country-by-country basis until there is no remaining royalty or other payment obligation in a particular country, unless terminated earlier by Merck Serono for convenience or by either party in the event of an uncured material breach.</u>

#### Baxter International, Inc.

In June 2009, we entered into <u>a feasibility study agreement</u> with Baxter <u>Healthcare</u> to create controlled release applications of blood clotting factor replacement therapies using our Medusa technology. This collaboration includes work on intravenous formulations. <u>The feasibility studies</u> <u>are being conducted to determine whether to enter into a further collaboration and licensing agreement</u>. To date, <u>the program is in pre-clinical</u> <u>development</u>. Baxter <u>has</u> paid technology access fees totaling €2.5 million (or \$3.6 million), will pay development costs for the program and has an exclusive right to negotiate a license to the Medusa platform for these applications. <u>Under the agreement</u>, we are not entitled to any additional <u>technology access or other fees beyond the amounts previously paid and there are no milestone payments or royalties</u>. The term of the agreement <u>continues until the execution of a license agreement</u>, <u>unless earlier terminated by Baxter for convenience or terminated by either party in the event of an uncured material breach</u>.

#### Pfizer

In September 2007, we entered into an evaluation, option and license agreement with Wyeth Pharmaceuticals, which was later acquired by <u>Pfizer in October 2009, to</u> assess the applicability of the Medusa platform to certain molecules in development. In November 2009, Pfizer exercised its option to license the Medusa technology for the development of a controlled release formulation of an already-marketed protein. The <u>exercise of the option</u> triggered an initial license payment to us of \$1 million. Under the agreement, Pfizer also will pay all development costs of the program, and may in the future be responsible for milestone payments on development objectives and royalties to the extent there are commercial sales. <u>This program is currently in pre-clinical development.</u>

### Item 5. Operating and Financial Review and Prospects, page 37

3. We acknowledge your response to comment nine. As previously requested, please provide us proposed draft disclosure for inclusion in future periodic reports that specifically indicates that you do not maintain research and development costs by project. In addition, please include in this proposed disclosure an explanation regarding why you do not maintain research and development cost by project and clarify how you manage the research and development function in terms of scientific progress and resource and allocation, including the level of effort expended, the costs incurred and how you determine whether it is economical to continue to develop an individual project. As previously requested, also include in your proposed revised disclosure other quantitative or qualitative information that indicates the amount of your resources being used on each project.

In response to the Staff's comment, the Company currently intends to expand the disclosure in its next Annual Report on Form 20-F. As explained in the draft disclosure below, research and development expenditures are not tracked by project but across the organization as a whole and, to a limited extent, by technological platform. The Company has adopted this approach because of the crossover applicability of its research and development to both internal and partner-sponsored research programs and because the cost of internal support functions would generally need to be allocated across all projects and the Company does not see a benefit in doing so. The Company monitors the research and development function based on the allocation of human resources to each project in terms of days worked by research and development staff (and does not convert that information into monetary terms) and the cost of outside services for pre-clinical and clinical activities. The Company intends to include in its next Annual Report on Form 20-F the revised disclosure below, or substantially similar disclosure. Portions of the disclosure that reflect proposed revisions from the 2009 Form 20-F have been underlined for convenience.

**Critical Accounting Policies:** 

#### Research and Development Costs

Research and development (R&D) expenses comprise the following types of costs incurred in performing R&D activities: salaries, allocated overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract and other outside service fees. Research and development expenditures are charged to operations as incurred.

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> The Company does not maintain or track total research and development costs by project. Generally, the Company's research and development efforts are either funded internally or by third-party partners. The Company's research and development efforts are organized to allow internal services to support both internal research programs and a variety of partner-sponsored research programs simultaneously, reflecting the Company's approach and belief that internal projects can benefit from the research and development efforts funded by partners and vice versa. Due to this approach, the Company views research and development costs as a whole across the organization and by technological platform. The Company monitors progress on the basis of the actual number of hours/days worked and the cost of outside services for pre-clinical and clinical activities.

# **Operating** Expenses

Our total research and development expenditures can be disaggregated in the following significant type of expenses (\$USD in millions):

	2008	2009	2010
Salaries and employee benefits			
Materials and Supplies			
Pre-clinical and Clinical outside services			
Grants			
Depreciation of facilities and equipment			
Other Expenses & Taxes			
Total			

#### The resources allocated to each technological platform over the past three years are as follows:

<u>Full Time Equivalents</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>
<u>Medusa</u>			
Micropump			

The cost of outside services for pre-clinical and clinical activities by technological platform over the past three years are as follows (\$USD in millions):

		<u>2008</u>	<u>2009</u>	<u>2010</u>
Pre-Clinical	<u>Medusa</u>			
	<u>Micropump</u>			
<u>Clinical</u>	<u>Medusa</u>			
	<u>Micropump</u>			

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Please feel free to contact me at 212-918-8270 if you have questions about these responses.

Sincerely,

/s/ Amy Bowerman Freed

Amy Bowerman Freed Hogan Lovells US LLP

cc: Mr. Stephen Willard, Flamel Technologies Ms. Sian Crouzet, Flamel Technologies Mr. William I. Intner, Hogan Lovells US LLP Mr. G. Allen Hicks, Hogan Lovells US LLP