

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

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**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 December 2009

Commission File Number 000-28508

**Flamel Technologies S.A.**

(Translation of registrant's name into English)

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

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

Form 20-F  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-\_\_\_\_\_

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**INFORMATION FILED WITH THIS REPORT**

Document Index

99.1 Press release regarding initiation of clinical trial of IFN-Alpha-2b XL in patients with hepatitis C, dated December 18, 2009.

## 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 S.A.

Dated: December 18, 2009

/s/ Stephen H. Willard

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Stephen H. Willard  
Chief Executive Officer

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press release regarding initiation of clinical trial of IFN-Alpha-2b XL in patients with hepatitis C, dated December 18, 2009.



FLAMEL TECHNOLOGIES

**For Immediate Release**

**Flamel Technologies Announces the Initiation of a Phase 2a  
Clinical Trial of Flamel's IFN-Alpha-2b XL in Patients with Chronic  
Hepatitis C Virus Infection**

**Lyon, France – December 18, 2009** - Flamel Technologies (NASDAQ:FLML) today announced the initiation of a Phase 2a clinical trial of Flamel's Interferon alpha-2b XL (IFN-alpha-2b XL), which is based on Flamel's Medusa<sup>®</sup> platform for controlled release of biologics. IFN-alpha-2b XL is being developed as a controlled release of unmodified interferon alpha-2b for the treatment of chronic hepatitis C virus (HCV). This Phase 2a randomized study, known as ANRS HC 23 COAT-IFN (C**O**nfirmation of **A**nti-viral activity and **T**olerance of Interferon alpha-2b XL), is sponsored by the *Agence Nationale de Recherche sur le SIDA et les Hépatites Virales* (ANRS). The Phase 2a study is designed to evaluate IFN-alpha-2b XL in combination with ribavirin in genotype-1 chronic hepatitis C patients who are either naïve to treatment or previous non-responders to standard interferon therapy (PEGylated interferon plus ribavirin).

The study will evaluate two doses of Interferon-alpha-2b XL (27 and 36 MIU) administered once a week for 12 weeks in combination with weight-based ribavirin in treatment-naïve and non-responder hepatitis C patients with genotype-1 HCV. The comparator arm of patients also comprises sub-groups of either treatment naïve or non-responder genotype-1 patients, each of which will be administered with PegIntron<sup>®</sup> (1.5µg/kg) once a week for 12 weeks in combination with weight-based ribavirin. A total of 84 patients (28 patients by arm which will be equally split into naïve and non-responder patients) is expected to be enrolled in the trial. The study will assess viral response: the primary endpoint will be viral load reduction at week 4 and week 12. Investigators will also be looking at the percentage of patients achieving Rapid Virological Response, or RVR, defined as an undetectable viral load at week 4, and Early Virological Response, or EVR, defined as a viral load reduction greater than 2 log at week 12. Another endpoint that investigators will be assessing closely is the safety and tolerability data for both doses of Interferon-alpha-2b XL versus PegIntron. Results from the study will be used to select the doses of Interferon-alpha 2b XL for the pivotal confirmatory clinical trial.

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Roger Kravtsoff, Flamel's Director of Preclinical and Clinical Development commented: "We are very pleased to pursue the clinical development of this very promising product. Better safety and efficacy will be important outcomes for the next generation of interferon products, which we believe will continue to be part of the standard of care for HCV treatment, even with the advent of new small molecule drugs currently in clinical development. The potential benefits of IFN-alpha-2b XL have been highlighted by the results of the Phase 1b trial which indicated:

- Better tolerance, characterized by a marked reduction in side effects for patients given IFN-alpha-2b XL compared to those who received PegIntron; and
- Better antiviral activity, characterized by:
  - A statistically significant reduction in viral load for genotype-1 patients compared to similar patients who received PegIntron.
  - A marked reduction in viral load for "non-responder" patients compared to similar patients who received PegIntron.

If these results are confirmed in the COAT-IFN study using longer treatment, we believe that IFN-alpha-2b XL provides a better therapeutic option to treat patients."

The principal investigator of the study, Professor Christian Trepo (Hôtel Dieu Hospital - Lyon), remarked: "The results of the prior phase 1b study were encouraging in that the most difficult to treat patients, namely genotype-1 non-responders, experienced a greater reduction in viral load when given 27 MIU of IFN-alpha-2b XL than patients administered the standard dose of PegIntron. Moreover, the trend we observed in the study suggests that the advantages of Interferon-alpha-2b XL with respect to viral load reduction are cumulative and may become more pronounced during the longer treatment regimens used in the COAT-IFN study."

"This is especially positive, I believe, as these patients also experienced significantly fewer adverse events than patients in the comparator PEGinterferon group. Side effects associated with interferon treatment are debilitating and treatment limiting. Therapeutic outcomes are often negatively affected by the adverse events experienced by HCV carrier patients to the extent that dose reductions become necessary. Many patients may even choose to discontinue therapy. The previous Phase 1b results suggest that IFN-alpha-2b XL potentially provides at least equivalent and possibly better therapeutic benefits with fewer side effects in comparison to existing interferon-alpha based therapies. Indeed, entering the age of new anti-HCV molecules, what is most urgently wanted is the improvement of tolerance of the still needed interferon-alpha which is the number one hurdle of therapy. The confirmation of improved efficacy in the most hard to treat, genotype-1 non-responder patients will be most useful, especially in the future context of multiple therapies involving protease and polymerase inhibitors."

#### **About IFN-alpha-2b XL**

IFN-alpha-2b XL is a new formulation of recombinant Interferon alpha-2b based on Flamel's proprietary Medusa nanoparticle delivery system. Medusa is a versatile biologics carrier for the development of a wide range of novel and second-generation long-acting native protein and peptide products. IFN-alpha-2b XL is designed to provide patients with a longer acting and more tolerable approach to interferon therapy compared with approved interferon regimens.

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## About Hepatitis C

Hepatitis C virus is a blood-borne pathogen that causes inflammation of the liver. According to the U.S. Centers for Disease Control and Prevention (CDC), more than 75 percent of people infected with HCV will develop chronic infections, and 60 to 70 percent of these people will subsequently develop chronic hepatitis. HCV infection is the most common blood-borne viral infection in the United States. Approximately 4 million people in the United States are infected with HCV and the World Health Organization estimates that 170 million people worldwide – 3 percent of the world's population – are infected with HCV.

*Flamel Technologies, S.A. is a biopharmaceutical company principally engaged in the development of two unique polymer-based delivery technologies for medical applications. Micropump<sup>®</sup> is a controlled release and taste- masking technology for the oral administration of small molecule drugs. Flamel's Medusa<sup>®</sup> technology is designed to deliver controlled-release formulations of therapeutic proteins, peptides and other biologics.*

*This document contains a number of matters, particularly as related to the status of various research projects and technology platforms, that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.*

*This document reflects the current view of management with respect to future events and is subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements.*

*These risks include risks that products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, uncertainties regarding market acceptance of products in development, the impact of competitive products and pricing, and the risks associated with Flamel's reliance on outside parties and key strategic alliances.*

*These and other risks are described more fully in Flamel's Annual Report on the Securities and Exchange Commission Form 20-F for the year ended December 31, 2008.*

PegIntron is a registered trademark of Schering-Plough Corporation.

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