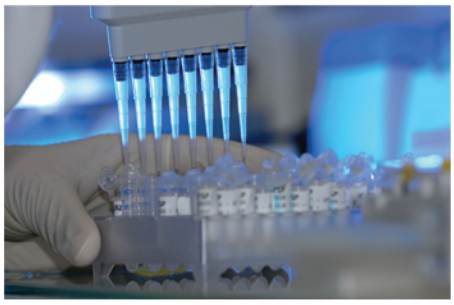
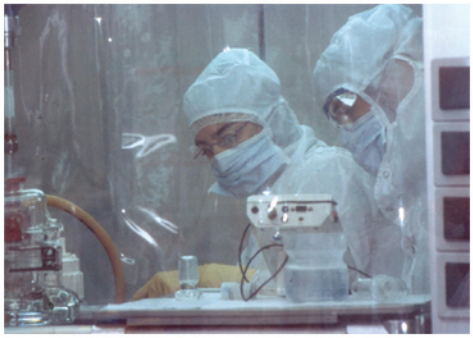




FLAMEL TECHNOLOGIES

2009 Annual Report

Stephen H. Willard
Chief Executive Officer
Flamel Technologies

First, let me begin by thanking you, our shareholders, for your continued support.

Overall, 2009 was a successful year for Flamel Technologies, both operationally and financially. We attracted important new pharmaceutical partners during the year while advancing projects in development and extending our comparative advantage in drug delivery. We now work with five of the top ten pharmaceutical companies in the world, as well as eight of the top twenty. We know of no other drug delivery company that enjoys the same breadth and the depth of the relationships Flamel has with top biotechnology and pharmaceutical companies. The strength of these relationships provides a strong foundation for the future growth of the Company, which we expect to accelerate in the years to come.

During 2009, we entered into eight new projects with six different companies. Among these, we signed an agreement in June 2009 with Baxter to assess the applicability of the Medusa platform for the development of controlled release formulations of certain blood factors. Baxter engaged to pay the full costs of the program and also paid us a technology access fee of € 2.5 million, the first technology access fee from a pharmaceutical company in the company's history. We believe that our ability to develop controlled release intravenous formulations using the Medusa platform is an important new competitive advantage that promises to create significant potential value for patients and caregivers, as well as Flamel shareholders.

Other programs signed during 2009 involved a mix of novel and existing molecules with both established large biotechnology companies and emerging companies developing new classes of molecules to address unmet medical needs. We are pleased to be working with such a variety of companies and diversified mix of projects. Our projects now address most every large market indication in healthcare, using both the Medusa and Micropump platforms to benefit an unparalleled variety of molecules.

Given our progress in 2009, and including our efforts to date in 2010, the Company is now working on 25 projects. Of these, twenty projects involve the Medusa platform for subcutaneous and intravenous controlled release and five involve the Micropump platform for controlled release of molecules taken orally. In total, these projects comprise 13 already-marketed molecules and 12 novel molecules. 2009 revenues for the already-marketed molecules totaled well over $17 billion.

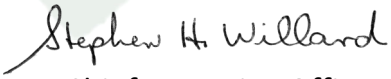
In addition to completing new partnerships, we maintained focus on the continued execution regarding existing partnerships. During 2009, we made important progress on our existing projects with both Merck Serono and Pfizer. In February, Merck Serono exercised the option to license the Medusa platform they had acquired in our original agreement from 2007. As a result, we received a €5 million license fee. Following exercise of the option, we continue to be paid for the full development costs of the program, which involves a undisclosed therapeutic protein in Merck Serono's portfolio. Our expectation is that we will receive at least one milestone payment from Merck Serono during 2010 based on continued progress of the program. Additionally, we enjoy a strong, productive relationship with Merck Serono and are involved in additional projects with them.

In November 2009, we announced that Pfizer had exercised the option to license the Medusa platform for an already-marketed therapeutic protein that was originally part of the Wyeth portfolio. As a result, Pfizer paid us a license fee of $1 million. The project with Pfizer involves the controlled release of an intravenously administered molecule. Prior to the announcement of the Pfizer and Wyeth merger in January, 2009, we had previously announced an existing collaboration with Pfizer on other projects. We are pleased Pfizer decided to exercise the option based on the ongoing work with Wyeth so soon after the completion of the merger, especially given the numerous cuts made to other programs in development. We enjoy a strong and wide-ranging relationship with Pfizer and look forward to continued progress with the company over the remainder of 2010 and next year.

Regarding internal programs, in December, the *Agence Nationale de Recherche sur le SIDA et les Hépatites Virales* (ANRS) announced that they had commenced a Phase IIa twelve week study that they are sponsoring for our formulation of Interferon-alpha 2b XL. The study is designed to evaluate two doses of Interferon-alpha-2b XL (27 MIU and 36 MIU) administered once a week for twelve weeks in combination with weight-based ribavirin in treatment-naïve and non-responder hepatitis C patients with genotype-1 HCV. Both arms are being evaluated versus a comparator arm of weight-based Peg-Intron® plus ribavirin. PegIntron is a pegylated formulation of interferon alpha 2b marketed by Merck. This ongoing study is important for several reasons. We believe that Interferon-alpha 2b XL may offer important efficacy and safety benefits to patients with genotype 1 HCV. In terms of HCV treatment, this study will offer important insights as to what these benefits may be and, as such, is important for the development of the product on a stand-alone basis. In terms of Medusa platform validation, the publication of twelve week data comparing a Medusa formulation to a pegylated equivalent will offer an important set of data with respect to the advantages of the Medusa platform as a whole versus pegylation, the currently marketed standard. Finally, because we believe Medusa is far more widely applicable than pegylation, and potentially may be administered in the clinic without new and costly pre-clinical toxicology and safety studies, we believe that the study may benefit the application of Medusa for new molecular targets as well.

With respect to Micropump, we have made some important progress. Last year we completed proof of concept work for our controlled release liquid suspension application using the Micropump platform. Controlled release liquid formulations remain challenging to develop. There is at least one competing technology that has been applied to a certain select molecules; however this technology does not appear to be applicable to the vast majority of molecules that might benefit from controlled release liquid technology. Based on our efforts to date, we continue to believe that Micropump is applicable in many of these instances, providing a substantial market opportunity for the Company – both with respect to the molecule on which we have been working but on other molecules as well.

Flamel continues to grow in a prudent and well disciplined manner. The Company has furthered existing relationships in 2009 and developed new ones that we believe will prove potentially quite profitable over the coming years. Based on our demonstrated progress, we anticipate an acceleration of data releases and other announcements to share with you over the coming quarters. We look forward to the year ahead.



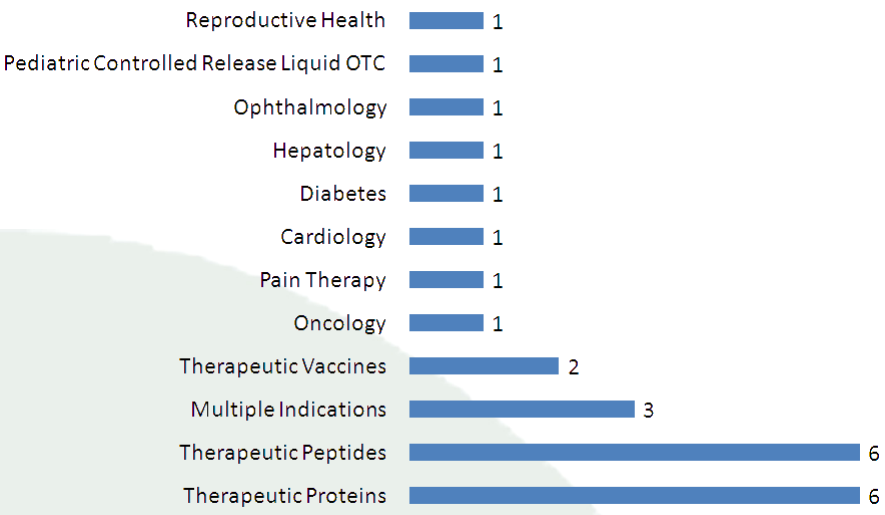
Chief Executive Officer

Flamel Technologies is a Strong and Recognized Drug Delivery Company

Flamel Technologies provides solutions for the delivery of existing pharmaceutical therapies with potentially better safety and efficacy or for drugs that cannot currently be delivered effectively.

Flamel owns an FDA-approved manufacturing site that provides a plug-and-play option for our partners.

Flamel has attracted major pharmaceutical partners: 8 of the top 25 pharmaceutical companies (including Baxter, GlaxoSmithKline, Merck Serono and Pfizer) are currently working with us.



We are developing a diversified portfolio of 25 partnered projects addressing large markets.

Flamel Technologies Develops Innovative and Proven Drug Delivery Technologies

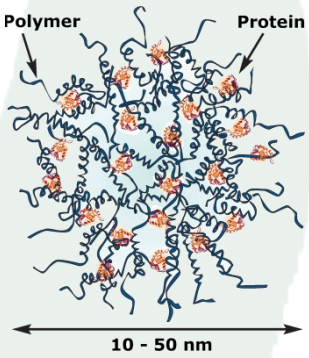
Flamel Technologies has created two drug delivery systems, MEDUSA and MICROPUMP, which enable the controlled delivery of small and large molecules.

MEDUSA, Platform for the Controlled Release of Large and Small Molecules by Injection

Flamel Technologies has developed a technology for the delivery of biological entities (proteins, peptides, therapeutic vaccines, antibodies and other large molecules).

***Description of the Technology*:**

The MEDUSA platform consists of a stable polymer nanogel (comprising polyglutamate and vitamin E) that is amphiphilic and forms spontaneously in water. Medusa biologics complexes are robust over a wide range of pH values and can be stored as either stable liquid or stable dry forms that can be easily reconstituted in water. The MEDUSA ubiquitous polymer has unfilled hydrophobic bonding sites on which biologics self-associate to form a stable delivery vehicle.



***Advantages of MEDUSA*:**

The technology enables the controlled and extended (up to one or two weeks) release of active ingredients with improved properties: full bioactivity (the biologics are not covalently bound, which ensures no alteration of activity), better pharmacokinetics and pharmacodynamics (lower C_{max}; no burst effect; higher sustained concentrations; enhanced solubility and stability; prevention of aggregation; and fewer side effects).

MEDUSA allows combination of several molecules. The polymer on which the system is based benefits from a full safety and toxicology package, which limits the risk of development failure. The technology enables the development of injectable dosage forms that improve patient and caregiver convenience, with potential pharmaco-economic advantages.

***Applications of MEDUSA*:**

MEDUSA can be applied to a variety of molecules: proteins and peptides, which can be delivered by intravenous or subcutaneous antigens for vaccines, “biobetters” (improvement of already marketed biologics), and new chemical entities (the technology is being applied to unstable, insoluble molecules that might otherwise be shelved).

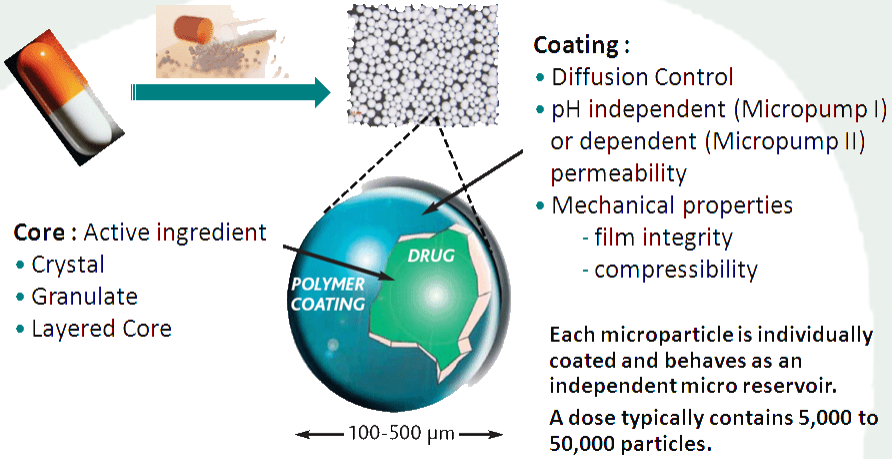
As of May 2010, Flamel Technologies has 20 ongoing projects based on MEDUSA, 12 of which relate to novel molecules, ensuring a balance between lower-risk reformulations and higher-risk new molecular entities.
Our most advanced internal program is IFN alpha-2b XL, a fully-owned project on interferon alpha, the standard of care for hepatitis C infection. The product demonstrated reduced side effects in phase I clinical trial. A phase IIb study, fully funded by French Government agency specializing in hepatitis, was initiated in December 2009.

MICROPUMP, Powerful Oral Platform for the Controlled Release of Small Molecules

Flamel Technologies has developed a technology for the delivery of small large molecules and scheduled drugs.

Description of the Technology:

MICROPUMP is a multiple-dose system containing 5,000 to 50,000 microparticles per capsule or tablet.
These microparticles are released in the stomach and pass into the small intestine, where each of them acts as an individual drug delivery device.
The drug is released at an adjustable rate, either controlled (MICROPUMP I), or delayed (MICROPUMP II).



Advantages of MICROPUMP:

The technology is a best-in class oral delivery solution for small molecule formulations that enables the formulation of controlled release drugs as solid or liquid forms suitable for all patient populations containing either a single molecule or a combination of molecules. The microparticles control the absorption rate, mask the taste of the compound, allow limitation of inter- and intra-patient variability and peak : trough ratio, enable gains in terms of solubility (leading to plasma levels increase), and avoid dose-dumping. Each microparticle delivers an active ingredient separately: combination of different microparticles offers precise control of absorption. The high loading ratio of active to polymer coating is important for products with large daily dosing.

TRIGGER-LOCK is an adaptation of MICROPUMP designed to prevent tampering with scheduled drugs.

Advantages of TRIGGER-LOCK:

The system prevents misuse of scheduled drugs such as narcotic analgesics, as the microparticles cannot be crushed, and additional modifications can be tailored to prevent other less publicized methods of foiling controlled release systems.
TRIGGER-LOCK demonstrated bioequivalent or improved pharmacokinetics, and is applicable to novel, already-marketed or off-patent molecules.

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FORM 20-F

FLAMEL TECHNOLOGIES SA - FLML

Filed: May 10, 2010 (period: December 31, 2009)

Annual and transition report of foreign private issuers pursuant to sections 13 or 15(d)

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

FORM 20-F

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2009

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from_____ to _____

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of event requiring this shell company report_____

Commission file number: 000-28508

Flamel Technologies S.A.

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Republic of France

(Jurisdiction of incorporation or organization)

Parc Club du Moulin a Vent
33, avenue du Docteur Georges Levy
69693 Vénissieux Cedex France

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Name of Exchange on which Registered
Ordinary Shares, nominal value 0.122 Euros per share, represented by American Depositary Shares (as evidenced by American Depositary Receipts), each representing one Ordinary Share	**NASDAQ Global Market**

Securities registered or to be registered pursuant to Section 12(g) of the Act. None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

24 342 600 Ordinary Shares, nominal value 0.122 Euros per Ordinary Share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

US GAAP ☒
International Accounting Standards as Issued by the International Accounting Standards Board ☐
Other ☐

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☒

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

TABLE OF CONTENTS

PART I	**1**
ITEM 1. Identity of Directors, Senior Management and Advisers	*1*
ITEM 2. Offer Statistics and Expected Timetable	*1*
ITEM 3. Key Information	*1*
ITEM 4. Information on the Company	*15*
ITEM 4A. Unresolved Staff Comments	*37*
ITEM 5. Operating and Financial Review and Prospects	*37*
ITEM 6. Directors, Senior Management and Employees	*46*
ITEM 7. Major Shareholders and Related Party Transactions	*54*
ITEM 8. Financial Information	*55*
ITEM 9. The Offer and Listing	*56*
ITEM 10. Additional Information	*57*
ITEM 11. Quantitative and Qualitative Disclosures About Market Risk	*65*
ITEM 12. Description of Securities Other Than Equity Securities	*65*
ITEM 12.A Debt Securities	*65*
ITEM 12.B Warrants and Rights	*65*
ITEM 12.C Other Securities	*65*
ITEM 12.D American Depositary Shares	*65*
PART II	**66**
ITEM 13. Defaults, Dividend Arrearages and Delinquencies	*66*
ITEM 14. Material Modifications to the Rights of Security Holders and Use of Proceeds	*66*
ITEM 15. Controls and Procedures	*67*
ITEM 16. [Reserved]	*68*
ITEM 16A. Audit Committee Financial Expert	*68*
ITEM 16B. Code of Ethics	*68*
ITEM 16C. Principal Accountant Fees and Services	*68*
ITEM 16D. Exemptions from the Listing Standards for Audit Committees	*69*
ITEM 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers	*69*
ITEM 16F. Change in Registrant's Certifying Accountant	*69*
ITEM 16G. Corporate Governance	*69*
PART III	**71**
ITEM 17. Financial Statements	*71*
ITEM 18. Financial Statements	*71*
ITEM 19. Exhibits	*71*

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As used herein, references to the Company, 'we,' 'us,' 'our,' the Registrant and Flamel refer to Flamel Technologies S.A. and its consolidated subsidiary, Flamel Technologies, Inc., unless the context indicates otherwise. References to Shares herein refer to (i) the Ordinary Shares of Flamel, nominal value 0.122 Euros per Ordinary Share (the 'Ordinary Shares') and (ii) Flamel's American Depositary Shares, each of which represents one Ordinary Share ('ADSs'). The ADSs are evidenced by American Depositary Receipts ('ADRs'). Ordinary Shares and ADSs are referred to herein as 'Shares.'

The following product or technology designations are trademarks of the Company: Asacard®, Basulin®, Flamel Technologies®, Micropump®, Medusa®, Trigger-Lock™.

Flamel publishes its financial statements in U.S. dollars. In this annual report, references to 'dollars' or '$' are to U.S. dollars and references to 'Euros' or 'EUR' or '€' are to the currency of the European Union as used in the Republic of France. Except as otherwise stated herein, all monetary amounts in this annual report have been presented in dollars. Solely for the convenience of the reader, this annual report contains translations of certain Euro amounts into dollars at specified rates. See 'Item 3. Key Information - Exchange Rates' for information regarding the rates of exchange between the Euro and the dollar in each of the previous five years.

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SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This annual report contains forward-looking statements. We may make additional written or oral forward-looking statements from time to time in filings with the Securities and Exchange Commission or otherwise. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions identify forward-looking statements, which speak only as of the date the statement is made. Such forward-looking statements are within the meaning of that term in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our development and manufacturing activities and our results of operations will not differ materially from our expectations. Factors that could cause actual results to differ from expectations include, among others, those specified in "Risk Factors" beginning on page 3, some of which are highlighted below:

- we depend on a few customers for the majority of our revenues, and the loss of any one of these customers could reduce our revenues significantly.
- our revenues depend on pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery technologies.
- although products that incorporate our drug delivery technologies may appear promising at their early stages of development and in clinical trials, none of these potential products may reach the commercial market for a number of reasons.
- we must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments.
- we depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.
- if we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery systems could become obsolete or noncompetitive.
- if we cannot adequately protect our technology and proprietary information, we may be unable to sustain a competitive advantage.
- our products and technologies may not gain market acceptance.
- if our third party collaborative partners face generic competition for their products, our revenues and royalties from such products may be adversely affected.
- healthcare reform and restrictions on reimbursements may limit our financial returns.
- products that incorporate our drug delivery technologies are subject to regulatory approval. If our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.
- we may face product liability claims related to participation in clinical trials or the use or misuse of our products or products that incorporate our technologies.
- third parties have claimed, and may claim in the future, that our technologies, or the products in which they are used, infringe on their rights and we may incur significant costs resolving these claims.
- if we use biological and hazardous materials in a manner that causes injury, we may be liable for significant damages.
- our share price has been volatile and may continue to be volatile.

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- because we have a limited operating history, investors in our shares may have difficulty evaluating our prospects.
- if we are not profitable in the future, the value of our shares may fall.
- our operating results may fluctuate, which may adversely affect our share price.
- we currently do not intend to pay dividends, and cannot assure shareholders that we will make dividend payments in the future.
- our largest shareholders own a significant percentage of the share capital and voting rights of the Company.

Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by or underlying the forward-looking statements. We undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise. You should not place undue reliance on these forward-looking statements. Statements in this annual report including those set forth in 'Risk Factors' in this report, describe factors, among others, that could contribute to or cause such differences.

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PART I

ITEM 1. Identity of Directors, Senior Management and Advisers

Not applicable.

ITEM 2. Offer Statistics and Expected Timetable

Not applicable.

ITEM 3. Key Information

Selected Financial Data

The selected consolidated financial data as of and for each of the five years ended December 31, 2009 are derived from the Consolidated Financial Statements of the Company, which have been prepared in accordance with U.S. GAAP and audited by an independent registered accounting firm with the Public Company Accounting Oversight Board (United States). The selected consolidated financial data of the Company set forth below are qualified by reference to, and should be read in conjunction with, 'Item 5. Operating and Financial Review and Prospects' and the Consolidated Financial Statements and the Notes related thereto appearing elsewhere in this annual report.

Statement of Operations Data*:

	2005	2006	2007	2008	2009
Revenues	$ 23,598	$ 23,020	$ 36,654	$ 38,619	$ 42,118
Cost and Expenses	(60,147)	(59,740)	(75,215)	(51,801)	(53,871)
Income (Loss) from Operations	(36,549)	(36,720)	(38,561)	(13,182)	(11,753)
Interest and foreign exchange gain (loss), net	4,103	1,388	1,221	1,417	342
Other income	5,003	131	197	181	(28)
Income (loss) before income tax	(27,443)	(35,201)	(37,143)	(11,584)	(11,439)
Income tax benefit (expense)¤	66	-	(594)	(500)	-
Net income (loss)	$ (27,377)	$ (35,201)	$ (37,737)	$ (12,084)	$ (11,439)
Income (Loss) from Operations per ordinary share	$ (1.59)	$ (1.54)	$ (1.61)	$ (0.55)	$ (0.49)
Basic earnings (loss) per ordinary share	$ (1.19)	$ (1.48)	$ (1.57)	$ (0.50)	$ (0.47)
Diluted earnings (loss) per ordinary share	$ (1.19)	$ (1.48)	$ (1.57)	$ (0.50)	$ (0.47
Basic weighted average number of shares outstanding (in thousands)	22,999	23,812	24,024	24,082	24,225
Diluted weighted average number of shares outstanding (in thousands)	22,999	23,812	24,024	24,082	24,225
Dividends per share	—				

* in thousands of U.S. dollars, except share and per share data
¤ Research and Development tax credit reclassified from Income tax benefit to Cost and Expenses for all periods presented (see Note 4 to the Consolidated Financial Statements).

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Balance Sheet Data*:

	2005	2006	2007	2008	2009
Cash, Cash equivalents & Marketable securities	$ 83,774	$ 62,771	$ 41,062	$ 37,078	$ 44,068
Working capital**	67,092	55,465	31,155	38,934	44,185
Total assets	124,351	114,894	101,401	91,861	94,296
Long term liabilities (excluding deferred revenues)	12,801	20,504	21,483	22,859	20,744
Shareholders' equity	86,654	73,026	54,627	48,546	44,863

*(in thousands of U.S. dollars)
** (current assets - current liabilities)

Exchange Rates:

Flamel publishes its financial statements in dollars. However, currently a significant portion of the Company's expenses are denominated in Euros. For information regarding the effects of currency fluctuations on the Company's results, see 'Item 5. Operating and Financial Review and Prospects.'

The following table sets forth the high, low and average exchange rates for the Euro against the U.S. dollar in each of the last five years and in each of the previous six months.

Year Ended December 31, Euro to U.S. Dollar:	High	Low	Average Rate[1]
2009	1.512	1.2555	1.3933
2008	1.599	1.246	1.4706
2007	1.4874	1.2893	1.37064
2006	1.3331	1.1826	1.25567
2005	1.3507	1.1667	1.24478

Previous Six Months, Euro to U.S. Dollar:	High	Low	Average Rate[1]
April 2010	1.3615	1.3245	1.3406
March 2010	1.3765	1.3338	1.3569
February 2010	1.3984	1.3489	1.3686
January 2010	1.4563	1.3966	1.4272
December 2009	1.512	1.4276	1.4614
November 2009	1.5083	1.4658	1.4914

The exchange rate for the Euro against the U.S. dollar as of April 30, was $1.3315 to € 1.00. The Company makes no representation that Euro amounts have been, could have been or could be converted into dollars at any of the exchange rates referred to herein as of a given date.

[1] *Annual totals represent the average of the noon buying rates for Euros of each business day during the relevant period. Monthly totals represent the average of the noon buying rates for Euros for each business day during the relevant month.*

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Risk Factors

Our business faces many risks. The risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occur, our business, financial condition or results of operations could suffer, and the trading price of our securities could decline. As a result, you should consider all of the following risks, together with all of the other information in this Annual Report on Form 20-F, before deciding to invest in our securities.

Risks Relating to Our Business and Industry

We depend on a few customers for the majority of our revenues, and the loss of any one of these customers could reduce our revenues significantly.

We depend on a few customers and partners for the majority of our revenues, particularly GlaxoSmithKline but also Merck Serono, Pfizer and Baxter. The termination of our relationship with any of these major customers or partners and our failure to broaden our customer base could cause our revenues to decrease significantly and result in losses from our operations. Further, we may be unable to negotiate favorable business terms with customers and partners that represent a significant portion of our revenues. If so, our revenues and gross profits, if any, may not grow as expected or may not grow at a rate sufficient to make us profitable.

Our revenues depend on pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery technologies.

We market and sell our technologies to third parties who incorporate our technologies into their products. We depend upon collaborative agreements with pharmaceutical and biotechnology companies to develop, test, obtain regulatory approval for and commercialize products that incorporate our drug delivery technologies. We currently have collaborative agreements or relationships with GlaxoSmithKline, Merck Serono, Pfizer, Baxter and other pharmaceutical and biotechnology companies whose identities remain confidential.

The number of products that our partners successfully develop under these collaborative agreements will affect our revenues. We cannot control the timing and other aspects of the development or marketing by our pharmaceutical and biotechnology company partners of their products that incorporate our technologies and may not be informed by our partners concerning the timing and other aspects of their development or marketing efforts. The failure of one or more of our partners to develop successful products that incorporate our technologies or to perform as we expect under our agreements with them could have a material adverse effect on our business, financial condition and results of operations. We face risks relating to our collaborative agreements, including risks that:

- our collaborative agreements may not result in any new commercial products;
- the existing commercial products developed under our collaborative agreements may not be successful;
- our pharmaceutical and biotechnology company partners may not successfully market any commercial products;
- we may not be able to meet the milestones established in our current or future collaborative agreements;
- we may not be able to successfully develop new drug delivery technologies that would be attractive to potential pharmaceutical or biotechnology company partners;
- our collaborative partners may terminate their relationships with us; and
- our collaborative partners may enter bankruptcy or otherwise dissolve.

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Although products that incorporate our drug delivery technologies may appear promising at their early stages of development and in clinical trials, none of these potential products may reach the commercial market for a number of reasons.

Successful research and development of pharmaceutical products is difficult, expensive, and time consuming. Many product candidates fail to reach the market. We intend to continue to enhance our current technologies and pursue additional proprietary drug delivery technologies. Our success will depend on the discovery and the successful commercialization of products that can utilize our drug delivery technologies. If products using our technologies fail to reach the commercial market, our revenues would be adversely affected.

Even if our technologies appear promising during various stages of development, there may not be successful commercial applications developed for them for a number of reasons, including:

- the FDA (Food and Drug Administration) the European Medicines Agency (EMA) or an institutional review board, or our pharmaceutical or biotechnology partners may delay or halt clinical trials;
- our pharmaceutical or biotechnology partners may face slower than expected rate of patient recruitment and enrollment in clinical trials;
- our technologies or our pharmaceutical and biotechnology company partners' products may be found to be ineffective or cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;
- we may not find pharmaceutical or biotechnology companies to adopt the technologies or, if partnered, the business strategy of our partner may change;
- our pharmaceutical and biotechnology company partners may find that certain products using our technologies cannot be manufactured on a commercial scale and, therefore, may not be economical to produce;
- our pharmaceutical and biotechnology company partners may determine that managed care providers are unwilling or unable to reimburse patients at an economically attractive level for products under development; or
- products that use our technologies could fail to obtain approval or, if approved, fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties.

We must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments.

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products. In 2009, we spent $ 30.4 million on research and development. Our ongoing investments in research and development for future products could result in higher costs without a proportionate increase in revenues. The research and development process is lengthy and carries a substantial risk of product failure. If our research and development does not yield sufficient new products that achieve commercial success, our future operating results may be adversely affected.

We depend upon a single site to manufacture our products, and any interruption of operations could have a material adverse effect on our business.

All of our manufacturing currently takes place in our production facilities located in Pessac, France. A significant interruption of operations at this facility for any reason, such as fire, flood or other manmade or natural disaster or a failure to obtain or maintain required regulatory approvals, could have a material adverse effect on our business, financial condition and results of operations. In case of a disruption, we may need to establish alternative manufacturing sources for our products, and this would likely lead to substantial production delays as we build or locate replacement facilities and seek to satisfy necessary regulatory obligations, including obtaining a successful inspection by the FDA . If this occurs, we may be unable to satisfy contractual obligations with our pharmaceutical or biotechnology partners in a timely manner.

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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. 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.

We depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.

Our success depends in large part upon our ability to attract and retain highly qualified personnel. During our operating history, we have assigned many key responsibilities within our Company to a relatively small number of individuals, each of whom has played key roles in executing various important components of our business. We do not maintain material key person life insurance for any of our key personnel. If we lose the services of Stephen H. Willard our Chief Executive Officer, or Rafael Jorda, our Chief Operating Officer, we may have difficulty executing our business plan in the manner we currently anticipate. Further, because each of our key personnel plays more than one role in respect of numerous components of our business, the loss of any one or more of such individuals could have an adverse effect on our business.

If our competitors develop and market drug delivery technologies or related products that are more effective than ours, or obtain regulatory approval and market such technology or products before we do, our commercial opportunity will be diminished or eliminated.

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing drug delivery systems. Our Medusa technology competes with technologies from companies such as Alkermes, Inc., Enzon Pharmaceuticals, Human Genome Sciences, Nektar Therapeutics, and SkyePharma, plc. Companies with oral drug delivery technology that can compete with our Micropump technology include Durect, Depomed, Biovail and Andrx Corporation. We also compete generally with other drug delivery, biotechnology and pharmaceutical and biotechnology companies that develop alternative drug delivery technologies or new drug research and testing.

Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do. Furthermore, acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval and gaining market share for these products more rapidly than we do.

Additionally, new chemical entities could be developed that, if successful, could compete against our technologies or products. Among the many experimental therapies being tested in the United States and in Europe, there may be some that we do not now know of that may compete with our drug delivery systems or products in the future. These chemical entities and new products may be safer or may work better than our technologies or products. Our collaborators could choose a competing drug delivery system to use with their drugs instead of one of our drug delivery systems.

If we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery systems could become obsolete or noncompetitive.

Our success depends, in part, on maintaining a competitive position in the development of products and technologies in a rapidly evolving field. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical and biotechnology company partners may choose to adopt the drug delivery technologies of our competitors. Our competitors may succeed in developing competing technologies or obtaining governmental approval for products before us, and the products of our competitors may gain market acceptance more rapidly than our products. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our drug delivery systems obsolete or noncompetitive.

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If we cannot adequately protect our technology and proprietary information, we may be unable to sustain a competitive advantage.

Our success depends, in part, on our ability to obtain and enforce patents for our products, processes and technologies and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments.

Any patent applications we may have made or may make relating to our potential products, processes and technologies may not result in patents being issued. Patent law relating to the scope of claims in the pharmaceutical field in which we operate is continually evolving and can be the subject of some uncertainty. The laws providing patent protection may change in a way that would limit protection. Our current patents may not be exclusive, valid or enforceable. They may not protect us against competitors that challenge our patents, such as companies that submit drug marketing applications to the FDA, the EMA, or the competent authorities of EU Member States that rely, at least in part, on safety and efficacy data from our products or our business partners' products (e.g., abbreviated new drug applications), obtain patents that may have an adverse effect on our ability to conduct business or are able to circumvent our patents. The scope of any patent protection may not be sufficiently broad to exclude competing products. Our collaborations with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented technology confidential.

We may not have the necessary financial resources to enforce our patents. Further, patent protection once obtained is limited in time, after which competitors may use the covered technology without obtaining a license from us. Because of the time required to obtain regulatory marketing approval, the period of effective patent protection for a marketed product is frequently substantially shorter.

To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with our employees, consultants and advisors. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information. If these agreements are breached, we cannot be certain that we will have adequate remedies.

Our products and technologies may not gain market acceptance.

The competitive nature of our industry could adversely affect market acceptance of our products or the use of our drug delivery technologies. Our products, technologies and product candidates, even if we and our pharmaceutical and biotechnology company partners obtain the necessary regulatory approval to market our products and products that incorporate our technologies, may not gain market acceptance among physicians, patients, healthcare payers and the medical community.

The degree of market acceptance of any product, technology or product candidate will depend on a number of factors, including:

- the effectiveness of our marketing strategy;
- demonstration of the clinical efficacy and safety of the product or technology;
- no evidence of undesirable side effects which delay or extend trials;
- no regulatory delays or other regulatory actions;
- its cost-effectiveness;
- its potential advantage over alternative treatment methods; and
- the marketing and distribution support it receives.

If any of our products or technologies fail to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business.

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If we or our collaborative partners are required to obtain licenses from third parties, our revenues and royalties on any commercialized products could be reduced.

The development of some of our products may require the use of technology developed by third parties. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which we or our collaborative partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our collaborative partners must obtain licenses from third parties, fees must be paid for such licenses. These fees would reduce the revenues and royalties we may receive on commercialized products that incorporate our technologies.

If our third party collaborative partners face generic competition for their products, our revenues and royalties from such products may be adversely affected.

Some of our third party collaborative partners may utilize our drug delivery technologies in products with exclusive rights secured by patents or other means. These rights are limited in time and do not always provide effective protection for their products. If our collaborative partners are unable to protect their products' exclusivity, generic competition may erode their market share, undermine the profitability of their products and limit the royalties we could collect from product sales. In the near term, the expiration of Hatch-Waxman exclusivity for Coreg CR in April 2010 could open Coreg CR to generic competition, which may negatively affect the royalties we could collect in the future. To date, we have generated more revenues from Coreg CR than any other product sold using our drug delivery technology.

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability to successfully commercialize our products and technologies may depend on the extent to which the government health administration authorities, private health insurers and other third party payers will reimburse consumers for the cost of these products, which affects the volume of drug products sold by pharmaceutical and biotechnology companies that incorporate our technology into their products. Third party payers are increasingly challenging both the need for, and the price of, novel therapeutic drugs and uncertainty exists as to the reimbursement status of newly approved therapeutics. The commercial success of our products depends in part on the conditions under which products incorporating our technology are reimbursed. Adequate third party reimbursement may not be available for such drug products to enable us to maintain price levels sufficient to realize an appropriate return on our investments in research and product development, which could materially and adversely affect our business. We cannot predict the effect that changes in the healthcare system, especially cost containment efforts, may have on our business. In particular, it is difficult to predict the effect of the recently enacted health care reform legislation in the United States, which is still subject to legislative change. Any such changes may adversely affect our business.

Ongoing current credit and financial market conditions may exacerbate certain risks affecting our business

We rely on third parties for several important aspects of our business. For example, we depend upon collaborators for both manufacturing and royalty revenue and the clinical development of collaboration products and we may rely upon several single source providers of raw materials for the manufacture of our products. Due to the ongoing limited availability of global credit and the disruption in the financial markets, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. If such third parties are unable to satisfy their commitments to us, our business would be adversely affected.

Fluctuations in foreign currency exchange rates may cause fluctuations in our financial results.

For the year ended December 31, 2009 we derived 36.0% of our total revenues from transactions in U.S. dollars, but have 85.7 % of our cash and cash equivalents, all of our marketable securities, and the majority of our expenses denominated in Euros. As a result, our financial results could be significantly affected by fluctuations of the euro relative to the U.S. dollar. The Company does not engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, although it does, from time to time, purchase Euros against invoiced dollar receivables. Any strengthening in the U.S. dollar relative to the euro would have a negative effect on our balance sheet while a weakening in the U.S. dollar relative to the euro would have a positive effect. See 'Quantitative and Qualitative Disclosures About Market Risk' on page 65 for more information on the impact of currency exchange rate fluctuations.

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Risks Relating to Regulatory and Legal Matters

Products that incorporate our drug delivery technologies are subject to regulatory approval. If our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.

In the United States, the federal government, principally the FDA, and state and local government agencies regulate all pharmaceutical products, including existing products and those under development. Our pharmaceutical and biotechnology company partners may experience significant delays in expected product releases while attempting to obtain regulatory approval for products incorporating our technologies. If our partners are not successful, our revenues and profitability may decline. We cannot control, and our pharmaceutical and biotechnology company partners cannot control, the timing of regulatory approval for any of these products, or if approval is obtained at all.

Applicants for FDA approval often must submit extensive clinical and pre-clinical data as well as information about product manufacturing processes and facilities and other supporting information to the FDA. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us or our partners to conduct additional pre-clinical studies or clinical trials. For instance, we do not anticipate the necessity to conduct individual toxicity and carcinogenicity tests for each product that we develop using the Medusa nano-particulate technology. Due to their special properties, however, nanoparticle formulations may pose different issues of safety or effectiveness than non-nanoscale products. With that in mind, the FDA may require additional toxicology tests and clinical trials to confirm the safety and effectiveness of product candidates using the Medusa technology, which would impact development plans for product candidates.

Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new product application, also may delay an approval or rejection of an application. For instance, under the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), our partners may be required to develop risk evaluations and mitigation strategies, or REMS, to ensure the safe use of their product candidates. If the FDA disagrees with our partners' REMS proposals, it may be more difficult and costly for our partners to obtain regulatory approval for their product candidates. Similarly, FDAAA provisions may make it more likely that the FDA will refer a marketing application for a new product to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. This review can add to the time to approval and, although the FDA is not bound by the recommendation of an advisory committee, objections or concerns expressed by an advisory committee may cause the FDA to delay or deny approval.

The FDA has substantial discretion in the approval process and may disagree with our or our partners' interpretations of data and information submitted in an application, which also could cause delays of an approval or rejection of an application. Even if the FDA approves a product, the approval may limit the uses or indications for which a product may be marketed, restrict distribution of the product, or require further studies.

The FDA also can withdraw product clearances and approvals for failure to comply with regulatory requirements or if problems follow initial marketing.

Manufacturers of drugs, including the active pharmaceutical ingredients, also must comply with applicable current cGMP requirements, both as a condition of approval and for continued authority to manufacture and distribute products. Our manufacturing facilities and those of our pharmaceutical and biotechnology company partners may be required to pass a pre-approval inspection by the FDA, and will be subject to periodic inspection after that, all intended to ensure compliance with cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures, and we and our pharmaceutical and biotechnology company partners will need to ensure that all of our processes, methods, and equipment are compliant with cGMP. We will be obligated to expend time, money, and effort in production, record keeping, and quality control to assure that the product meets applicable specifications and other requirements. If we, our pharmaceutical and biotechnology company partners or suppliers of key ingredients, cannot comply with these practices, the sale of our products or products developed by our partners that incorporate our technologies may be suspended. This would reduce our revenues and gross profits.

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If our products or products that incorporate our technologies are marketed in other jurisdictions, we and the partners with whom we are developing our technologies must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety, quality and efficacy. The related obligations are as demanding as those imposed by the FDA. If approvals to market our products or our partners' products are delayed, if we or our partners fail to receive these approvals or previously received approvals are withdrawn, our revenues would be reduced. We may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals.

Commercial products incorporating our technologies are subject to continuing regulation, and we and our pharmaceutical and biotechnology company partners may be subject to adverse consequences if we or they fail to comply with applicable regulations.

We and our partners will continue to be subject to extensive regulatory requirements for products and product candidates that incorporate our technologies, even if they receive regulatory approval. These regulations are wide-ranging and govern, among other things:

- adverse drug experiences and other reporting requirements;
- product promotion and marketing;
- product manufacturing, including cGMP compliance;
- record keeping;
- distribution of drug samples;
- required post-marketing studies or clinical trials;
- authorization renewal procedures
- compliance with any required REMS;
- updating safety and efficacy information;
- use of electronic records and signatures; and
- changes to product manufacturing or labeling.

If we or our partners fail to comply with these laws and regulations, the FDA, the European Commission, competent authorities of EU Member States, or other regulatory organizations, may take actions that could significantly restrict or prohibit commercial distribution of products that incorporate our technologies. If the FDA, the European Commission, competent authorities of EU Member States determine that we are not in compliance with these laws and regulations, they can, among other things:

- issue warning letters;
- impose fines;
- seize products or order recalls;
- issue injunctions to stop future sales of products;
- refuse to permit products to be imported into, or exported out of, the United States or the European Union;
- suspend or limit our production;
- withdraw approval of marketing applications;

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- order the competent authorities of EU Member States to withdraw national authorization; and
- initiate criminal prosecutions.

Regulatory reforms may adversely affect our ability to sell our products profitably.

From time to time, the United States Congress and the Council of the European Union and the European Parliament adopt changes to the statutes that the FDA and the European Commission enforce in ways that could significantly affect our business. In addition, the FDA and the European Commission often issue new regulations or guidance, or revises or reinterprets its current regulations and guidance in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA or EU regulations, guidance or interpretations changed, and what the impact of any such changes may be.

It is possible, however, that such changes could have a significant impact on the path to approval of products incorporating our technologies or of competing products, and to our obligations and those of our partner pharmaceutical and biotechnology companies. For example, the FDAAA contains a number of provisions that strengthen the FDA's regulatory authority in various areas, including clinical trial registration and results reporting; pharmacovigilance and other safety-related issues; and post-approval clinical study requirements. More recently, the Patient Protection and Affordable Care Act became law. Among other things, this statute creates an abbreviated pathway to FDA approval of "biosimilar" biological products that can include a determination that a product is interchangeable with a previously approved biological product.

Certain companies to which we have licensed our technology are subject to extensive regulation by the FDA and other regulatory authorities. Their failure to meet strict regulatory requirements could adversely affect our business.

Companies to which we have licensed our technology are subject to extensive regulation by the FDA, other domestic regulatory authorities, and equivalent foreign regulatory authorities, particularly the European Commission. Those regulatory authorities may conduct periodic audits or inspections of the companies' facilities to monitor compliance with applicable regulatory standards. If the FDA or another regulatory authority finds that a company has failed to comply with applicable regulations, the authority can institute a wide variety of enforcement actions, including warning letters or untitled letters; fines and civil penalties; delays in clearing or approving, or refusal to clear or approve, products; withdrawal or suspension of approval of products; product recall or seizure; order the competent authorities of EU Member States to withdraw national authorization; orders for physician notification or device repair, replacement or refund; interruption of production; operating restrictions; injunctions; and criminal prosecution. Any adverse action by an applicable regulatory agency could lead to unanticipated expenditures to address or defend such action, and may impair those companies' ability to produce and market their products, which could significantly impact the royalties that we receive from them.

We may face product liability claims related to participation in clinical trials or the use or misuse of our products or products that incorporate our technologies.

The testing, manufacturing and marketing of our products or products that incorporate our drug delivery technologies may expose us to potential product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical and biotechnology companies or hospitals conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. Although we currently maintain product liability and recall insurance in amounts we believe to be commercially reasonable, we cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost, a product liability claim or recall could adversely affect our financial condition. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical and biotechnology companies with whom we are developing our drug delivery technologies may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or be sufficient to reimburse us, for any expenses or losses we may suffer. A successful product liability claim against us, if not covered by, or if in excess of, our product liability insurance, may require us to make significant compensation payments. These payments would be reflected as expenses on our statement of operations and reduce our earnings.

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Third parties have claimed, and may claim in the future, that our technologies, or the products in which they are used, infringe on their rights and we may incur significant costs resolving these claims.

Third parties have claimed, and may claim in the future, that the manufacture, use or sale of our drug delivery technologies infringes on their patent rights. In response to such claims, we may have to seek licenses, defend infringement actions or challenge the validity of those patents in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by the patents of others. We may not have identified, or be able to identify in the future, United States and foreign patents that pose a risk of potential infringement claims.

Any claims that our products infringe or may infringe proprietary rights of third parties, with or without merit, could be time-consuming, result in costly litigation or divert the efforts of our technical and management personnel, any of which could disrupt our relationships with our partners and could significantly harm our operating results.

We enter into collaborative agreements with pharmaceutical and biotechnology companies to apply our drug delivery technologies to drugs developed by others. Ultimately, we receive license revenues and product development fees, as well as revenues from the sale of products incorporating our technology and royalties. The drugs to which our drug delivery technologies are applied are generally the property of the pharmaceutical and biotechnology companies. Those drugs may be the subject of patents or patent applications and other forms of protection owned by the pharmaceutical and biotechnology companies or third parties. If those patents or other forms of protection expire, are challenged or become ineffective, sales of the drugs by the collaborating pharmaceutical and biotechnology company may be restricted or may cease.

If we use biological and hazardous materials in a manner that causes injury, we may be liable for significant damages.

Our research and development activities involve the controlled use of potentially harmful biological materials, hazardous materials and chemicals, and are subject to federal, state, EU, national and local laws and regulations governing the use, storage, handling and disposal of those materials and specified waste products. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials, including fires and/or explosions, storage tank leaks and ruptures; and discharges or releases of toxic or hazardous substances. These operating risks can cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and the imposition of civil or criminal penalties. The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

We currently maintain environmental liability, property, business interruption and casualty insurance. If we fail to comply with environmental regulations, we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any such liability could be significant.

Risks Relating to Ownership of Our Securities

Our share price has been volatile and may continue to be volatile.

The trading price of our shares has been, and is likely to continue to be, highly volatile. The market value of an investment in our shares may fall sharply at any time due to this volatility. In the year ended December 31, 2009, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $3.99 to $9.67. In the year ended December 31, 2008, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $3.68 to $10.72. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include:

- fluctuations in our operating results;
- announcements of technological collaborations, innovations or new products by us or our competitors;
- governmental regulations;

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- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drugs developed by us or others;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to our products;
- lack of efficacy of our products;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to the products incorporating our technologies;
- actions by the FDA, the EMA or national authorities of EU Member States in connection with submissions related to the products incorporating our technologies;
- the perception by the market of biotechnology and high technology companies generally; and
- general market conditions, including the impact of the current financial environment.

Because we have a limited operating history, investors in our shares may have difficulty evaluating our prospects.

We recorded the first commercial sales of products using one of our polymer technologies through our partner, Corning, in 1999. Our first commercial sales of a pharmaceutical compound incorporating our Micropump technology occurred in March 2007 with the launch of Coreg CR. We have had no commercial sales to date of products incorporating our Medusa technology. Accordingly, we have only a limited operating history, which may make it difficult to evaluate our prospects. The difficulty investors may have in evaluating our prospects may cause volatile fluctuations in the market price of our shares as investors react to information about our prospects. Since 1995, we have generated revenues from product development fees and licensing arrangements and royalties. Our business and prospects must be evaluated in light of the risks and uncertainties of a company with a limited operating history and, in particular, one in the pharmaceutical industry.

If we are not profitable in the future, the value of our shares may fall.

We have a history of operating losses and have accumulated aggregate net loss from inception of approximately $171.6 million through December 31, 2009. If we are unable to earn a profit in future periods, the market price of our stock may fall. The costs for research and product development of our drug delivery technologies and general and administrative expenses have been the principal causes of our net losses in over recent years. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- the demand for our technologies and products;
- the level of product and price competition;
- our ability to develop new collaborative partnerships and additional commercial applications for our products;
- our ability to control our costs;
- our ability to broaden our customer base;
- the effectiveness of our marketing strategy;
- the effectiveness of our partners' marketing strategy for products which use our technology; and
- general economic conditions.

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We may require additional financing, which may not be available on favorable terms or at all, particularly in light of the slow global economic recovery and its negative effect on the capital markets, and which may result in dilution of our shareholders' equity interest.

We may require additional financing to fund the development and possible acquisition of new drug delivery technologies and to increase our production capacity beyond what is currently anticipated. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail our plans to continue to develop drug delivery technologies. We may also elect to pursue additional financing at any time to more aggressively pursue development of new drug delivery technologies. Obtaining additional financing may be difficult in light of the slow global economic recovery and extremely tight capital markets. Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the development and acquisition of new products and technologies;
- the progress of our research and product development programs;
- results of our collaborative efforts with current and potential pharmaceutical and biotechnology company partners; and
- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs, and reduced revenues.

Our operating results may fluctuate, which may adversely affect our share price.

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results may fluctuate from period to period due to a variety of factors, including:

- demand by consumers for the products we produce;
- new product introductions;
- pharmaceutical and biotechnology company ordering patterns;
- the number of new collaborative agreements into which we enter;
- the number and timing of product development milestones that we achieve under collaborative agreements;
- the level of our development activity conducted for, and at the direction of, pharmaceutical and biotechnology companies under collaborative agreements; and
- the level of our spending on new drug delivery technology development and technology acquisition, and internal product development.

Variations in the timing of our revenue and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses.

We are subject to different corporate disclosure standards that may limit the information available to holders of our ADSs.

As a foreign private issuer, we are not required to comply with the notice and disclosure requirements under the Securities Exchange Act of 1934, as amended, or the Exchange Act, relating to the solicitation of proxies for shareholder meetings. Although we are subject to the periodic reporting requirements of the Exchange Act, the periodic disclosure required of non-United States issuers under the Exchange Act is more limited than the periodic disclosure required of United States issuers. Therefore, there may be less publicly available information about us than is regularly published by or about other public companies in the United States.

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We currently do not intend to pay dividends, and cannot assure shareholders that we will make dividend payments in the future.

The Company has never declared or paid a cash dividend on any of its capital stock and does not anticipate declaring cash dividends in the foreseeable future. Declaration of dividends on our shares will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant.

Judgments of United States courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, may not be enforceable in French courts.

An investor in the United States may find it difficult to:

- effect service of process within the United States against us and our non-United States resident directors and officers;
- enforce United States court judgments based upon the civil liability provisions of the United States federal securities laws against us and our non-United States resident directors and officers in France; or
  bring an original action in a French court to enforce liabilities based upon the United States federal securities laws against us and our non-United States resident directors and officers.

Holders of ADSs have fewer rights than shareholders and have to act through the Depositary to exercise those rights.

Holders of ADSs do not have the same rights as shareholders and accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as depositary (the "***Depositary***"), is the registered shareholder of the deposited shares underlying the ADSs, and therefore holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We will use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by it for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

Preferential subscription rights may not be available for United States persons.

Under French law, shareholders have preferential rights to subscribe for cash issuances of new shares or other securities giving rights to acquire additional shares on a pro rata basis. United States holders of our securities (which might not be shares but ADRs) may not be able to exercise preferential subscription rights for their securities unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. We may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, United States holders of our securities will be unable to exercise any preferential rights and their interests will be diluted. We are under no obligation to file any registration statement in connection with any issuance of new shares or other securities.

For holders of our shares in the form of ADSs, the Depositary may make these rights or other distributions available to holders after we instruct it to do in the United States. If we fail to do this and the Depositary determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case the holders will receive no value for them.

Our largest shareholders own a significant percentage of the share capital and voting rights of the Company.

At December 31, 2009, O.S.S. Capital Management LP and BVF, Inc., our two largest shareholders, held approximately 13.1% and 14.5% of our issued share capital. See "Item 7. Major Shareholders and Related Party Transactions — A. Major Shareholders." To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, they will remain in a position to exert heightened influence in the election of the directors [and officers] of the Company and in other corporate actions that require shareholders' approval.

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ITEM 4. Information on the Company

General Overview

We are a biopharmaceutical company principally engaged in the development of two unique polymer-based drug delivery technologies. Our nanoparticle Medusa technology is designed to provide controlled release following injection of therapeutic proteins, peptides and other large and small molecules. We also have developed a microparticule adaptation of the Medusa platform which we believe offers important advantages in the delivery of smaller proteins and peptides. Our Micropump technology is a multiparticle technology for oral administration of small molecule drugs with applications in controlled-release, taste-masking and bioavailability enhancement. Our Trigger-Lock® technology is an adaptation of Micropump designed to minimize the misuse and abuse of medications subject to abuse.

Our Business Model

We develop specific applications of our controlled release technologies in partnership with biotechnology and pharmaceutical companies. Our business model enables us to focus on our comparative advantages in polymer chemistry and drug delivery while leveraging the expertise of partner companies in specific indications, clinical and regulatory development, marketing, and sales. We generate revenues through license payments from our partners to develop products using our drug delivery technologies, milestone payments for achieving certain objectives in getting products to market and royalty payments based on product sales. Currently we are working with eight of the top twenty five pharmaceutical companies in the world, based on annual healthcare revenue, and on twenty five feasibility and license and development projects. These projects are being conducted across a wide range of indications and with both novel and already-marketed molecules. Twenty of these concern the Medusa platform and four are for Micropump applications. The remaining project with a leading pain therapy company is an application of the Trigger Lock platform using multiple molecules.

Recent Developments

In June 2009 we entered into collaboration with Baxter International Inc. to create controlled release applications of blood clotting factor replacement therapies using our Medusa technology. This collaboration includes work on intravenous formulations. Baxter paid technology access fees totaling € 2.5 million (or $3.6 million), will pay all development costs for the program and has an exclusive right to negotiate a license to the Medusa platform for these applications. Based on sales, Baxter is the world leader in the field of blood clotting factor replacement therapies.

In February 2009, Merck Serono, a partner since 2007, exercised its option to license the Medusa platform for the continued development of an already-marketed therapeutic protein proprietary Pursuant to the license Merck Serono will pay all future development costs for the program as well as make payments upon achievement of certain clinical and regulatory milestones and pay royalties upon any sales of the product.

In November 2009, Pfizer, who acquired Wyeth in October 2009, exercised its option to license the Medusa technology. In September 2007, Wyeth Pharmaceuticals became a partner when we signed a license for the application of the Medusa platform for the controlled release of an already marketed therapeutic protein. . This election triggered a $1 million payment to Flamel and Pfizer will pay all development costs of the program, including milestone payments and royalties on any worldwide commercial sales.

The lead product using our Micropump technology is Coreg CR, which we developed with GlaxoSmithKline (GSK) and which is approved, marketed and sold in the United States of America. We began work with GSK in 2003, the product was approved by FDA in October 2006 and launched in March 2007. Pursuant to the supply agreement with GSK, we produce Coreg CR microparticles on a cost plus basis. $23 million in milestone payments have been received from GSK to date and Flamel still is eligible to receive an additional $2 million if certain milestones are achieved. Turnover of Coreg CR through December 31, 2009 amounted to $251 million on which we recognized royalty revenue of $8.8 million. The Hatch-Waxman exclusivity period for Coreg CR ended on April 20, 2010. It is possible that Coreg CR may experience generic competition from one or more competitors following approval of an Abbreviated New Drug Application (ANDA). To date only one ANDA had been submitted to the U.S. FDA, URL Pharma in March 2008 and it has not yet been reviewed. A Citizen Petition has been submitted to the FDA that respectfully requests that the FDA require any proposed generic formulations of Coreg CR to meet the same requirements that the FDA required for the approval of Coreg CR, which is a higher standard than is otherwise required under the minimum bioequivalence regulations.

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Applications Under Development

Flamel also has several important programs for which we do not currently have a partner. An example of the potential of the Medusa platform to improve the safety and efficacy of therapeutic proteins is our formulation of Interferon-Alpha XL, a long acting formulation of Interferon-Alpha. In December 2009 the *Agence Nationale de Recherche sur le SIDA* (AIDS) *et les Hépatites Virales* (*ANRS*) initiated a twelve week Phase 2 study comparing two dosage forms of our IFN-alpha XL plus ribavirin versus Peg-Intron® plus ribavirin in genotype 1 hepatitis C patients. This builds on two previous studies we conducted that demonstrated promising results of the formulation as compared to Intron-A® (immediate release interferon-alpha 2b, marketed by Schering Plough, since acquired by Merck) and Peg-Intron® (pegylated interferon-alpha 2b, also marketed by Schering Plough [now owned by Merck]). In both studies patients receiving our drug experienced fewer adverse events than those receiving the comparator treatment. Furthermore in a study presented at the Annual Meeting for the European Association for the Study of the Liver in Milan in April, 2008, the results showed a statistically significant reduction in viral load after two weeks in the group comprising genotype-1 naïve patients, and non-responder/relapsed patients, relative to comparator treatment.

Our FT-105 program uses a microparticle adaptation of our Medusa technology to meet the long-acting, 'basal' insulin requirements of diabetic patients as opposed to the requirement for insulin associated with meals. In diabetics, large variations in blood glucose levels over time can lead to serious, long-term complications including vision impairment, foot ulcerations and kidney failure. Theoretically, the need for basal insulin implies a profile with minimal peak and trough differences to minimize a diabetic's hypoglycemia and hyperglycemia (low and elevated blood glucose levels) episodes, particularly during the first hours after insulin injections and during the sleeping hours. FT-105 has been shown to provide a controlled-release of fully human insulin over at least 48 hours with good bioavailablity and excellent local tolerance.

Long-acting "basal" insulins already are available and have generated significant sales. Leading long-acting basal insulins, Lantus® (insulin glargine, Sanofi-Aventis) and Levemir® (insulin detemir, Novo Nordisk), had sales of $4.3 billion and $980 million respectively in 2009. In Type I diabetics, basal insulin is projected to represent 40% of their required treatment. Type II diabetics significantly out-number Type I diabetics and often require only basal insulin. Our FT-105 basal insulin is designed to address the requirements of both these groups. In October 2007, we announced top-line results of the Phase I three-way crossover trial of FT-105 conducted in eighteen healthy volunteers. The results showed a 48-hour controlled release of recombinant human insulin, with a very flat curve as compared to Lantus, the current standard of care.

Corporate Information

The Company was incorporated as a *société anonyme*, a form of corporation under the laws of the Republic of France, in August 1990 as Flamel Technologies S.A. and its shares were quoted on the NASDAQ National Market in 1996. Flamel's principal place of business is located at Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Lévy, 69693 Venissieux Cedex, France, telephone number +33 472 78 34 34. A list of the Company's significant subsidiaries can be found in Exhibit 8.1.

Market Opportunity: The Need for Novel Drug Delivery Systems

Our polymer delivery systems focus on the controlled release of therapeutic proteins and peptides following injection and the oral administration of pharmaceutical drugs, primarily those that are best absorbed in the small intestine. The pharmaceutical industry utilizes drug delivery technologies as a tool to improve existing products as well as to overcome certain problems encountered in the development of new products. Drug delivery technologies enable pharmaceutical companies to improve the safety and efficacy profiles of innovative new therapeutic compounds, to improve patient compliance and acceptance of existing drugs, to expand therapeutic indications of an existing drug, and to gain competitive advantages for drugs facing patent expirations. The global market for advanced drug delivery systems was projected to reach $139 billion in 2009 and grow at a compound rate of over 7% thereafter, according to BCC Research.

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Business Strengths and Strategies

Our core strength is as a science-based, market-focused innovator of controlled release drug delivery systems. The key elements of our strategy that enable us to build upon our strengths are:

- to maximize the potential of our existing drug delivery systems;
- to develop additional drug delivery technologies;
- to develop new formulations of proprietary compounds that we receive from additional partners;
- to leverage capabilities of pharmaceutical partners for clinical development and commercialization; and
- to identify additional compounds for unmet medical needs.

We believe that we have a competitive advantage in developing controlled-release formulations of proteins, peptides, and small molecules that improve dosing, compliance and efficacy, while potentially reducing side-effects. We will continue to partner our proprietary formulations with pharmaceutical companies which have the clinical, regulatory and marketing resources to secure regulatory approval and to commercialize these pharmaceuticals successfully. We are increasingly focused on working with pharmaceutical and biotechnology partners at an earlier stage of development as we believe this removes the market-related risk that has negatively affected our ability to partner internally-developed products in the past.

Under our partner agreements, our pharmaceutical company partners typically assume responsibility for all clinical, regulatory and marketing costs and make payments to us at the time the agreement is signed and upon the achievement of significant technical, clinical and regulatory milestones. We also typically are entitled to receive ongoing royalty payments on the sales of pharmaceuticals that incorporate our technologies.

Medusa Delivery System for Therapeutic Proteins, Peptides and Other Large Molecules

The use of therapeutic agents based on biological proteins and peptides is projected to grow significantly in the near future. According to IMS, sales of biologics were approximately $120 billion in 2008, nearly 17% of total pharmaceutical turnover, and are expected to grow 11-12% annually, a growth rate roughly double that of the overall pharmaceutical marketplace. In the same year five of the top fifteen best selling drugs were biologics, accounting for 26% of sales of these top fifteen. With over 600 biotechnology drugs in development, biologics are expected to continue to increase in significance.

However, biologics pose particular challenges for drug delivery, which we believe Medusa is able to address. Nearly all biologics need to be injected, and are fragile entities relative to traditional small molecule drugs. In developing these products, a principal challenge is finding a suitable system that can release the protein, peptide, or other large molecule at the optimal therapeutic rate, and protect it from being unduly degraded without denaturing it (i.e., causing a structural change that result in a loss of bioactivity).

The scientific challenges to developing such a controlled-release process for protein-based drugs are significant. For a polymer-based delivery system, these constraints require a polymer that:

- has the required release properties once delivered;
- is compatible with the protein or peptide;
- keeps the structure of the protein intact;
- protects the therapeutic agent during transit and delivery; and
- can be metabolized by the human body into harmless substances.

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Responding to these scientific challenges and to what we believe is a significant market opportunity, we have developed Medusa, a system designed to optimize delivery of proteins, peptides and other large molecules in a controlled manner following subcutaneous or intravenous injection. Our approach utilizes a proprietary system consisting of a polyaminoacid biopolymer comprised of only one or two different amino acids grafted with vitamin E. We have engineered this polyaminoacid polymer to form nano-sized particles spontaneously in water which then entrap the protein or peptide; all without the use of solvents, surfactants, extreme temperatures or pH, or other conditions that might damage the biologic. This 'self-assembly' process is thermodynamically driven and until the polymer reaches saturation essentially all the drug is entrapped.

Once injected, Medusa forms a reservoir from which the drug is released over time as a result of exchange with endogenous proteins. The timing of this release can be engineered to be short or as long as one to two weeks following a single injection.

We have found that the same polymer is potentially applicable across substantially all therapeutic proteins and peptides, as well as other large molecules and even small molecules. One advantage of this "ubiquitous polymer" approach is that we do not anticipate a need to conduct extensive individual toxicity and carcinogenicity tests for each product that we develop using the technology. This is because the same polymer is used across multiple products and the association between polymer and drug is a physical interaction and not a chemical bond. We have shown in animal studies that our polyaminoacid polymer is neither immunogenic nor reactogenic. Nevertheless, further testing is necessary in each specific application of Medusa to a drug to demonstrate that the product does not pose a potential risk for human subjects.

Additionally, we have demonstrated in recent years that the Medusa polymer may serve to address certain issues that would otherwise limit development of potentially promising large molecules. Particularly, we have demonstrated that Medusa formulations of certain large and small molecules with poor solubility have solubility levels up to several thousand times greater than the native molecules themselves. These gains in solubility may offer our partners the potential to develop molecules which they otherwise would discontinue.

Medusa also has demonstrated the ability to reduce protein aggregation. Protein aggregation is another threshold issue in drug development that often is associated with greater immunological response in the body. We believe the ability to address both of these problems, poor solubility and protein aggregation, is an important advantage to our partners.

Products Under Development Based on the Medusa Technology

1. Interferon Alpha

We believe that the Medusa delivery system has the potential to improve formulations of many important biological drugs. An example of the potential of the Medusa platform to improve the safety and efficacy of therapeutic proteins is our formulation of Interferon-Alpha XL. Interferon-alpha is a naturally occurring protein that the body uses as part of its immune response and which is part of the current standard of care for the treatment of Hepatitis C virus. In December 2009 the *Agence Nationale de Recherche sur le SIDA et les Hépatites Virales* (*ANRS*) initiated a twelve week Phase 2 study comparing two dosage forms of our IFN-alpha XL plus ribavirin versus Peg-Intron® plus ribavirin in genotype 1 hepatitis C patients. We have conducted two previous studies that demonstrated promising results of the formulation as compared to Intron-A® (immediate release interferon-alpha 2b, marketed by Schering Plough, since acquired by Merck) and Peg-Intron (pegylated interferon-alpha 2b, also marketed by Schering Plough (Merck)).

Our first study compared Interferon-Alpha XL with Intron-A. The dose-escalating study was conducted in 53 subjects with chronic hepatitis C. Thirty-nine participants were assigned to receive a single subcutaneous injection of one of three escalating doses of IFN-alpha-XL (12 - 14 patients per dose). The three IFN-alpha-XL groups received an injection of 9 million international units (MIU), 18 MIU, and 27 MIU, respectively. A cohort of 14 patients received three subcutaneous injections of a standard dose of Intron-A (3 MIU) over one week as a comparator. All patients completed the study, and no serious adverse events were reported.

Adverse events were similar to what has been reported in other studies of interferon therapy and were transient in duration and mild to moderate in severity. Patients receiving IFN-alpha-XL experienced fewer adverse events than patients receiving Intron A, even when the weekly dosage of IFN-alpha-XL was at its highest level. Pharmacokinetic data demonstrate that the Medusa formulation provides sustained release of IFN-alpha-XL over one week.

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The second trial we completed compared our Interferon-Alpha XL with Peg-Intron. The full data set was presented at the Annual Meeting for the European Association for the Study of the Liver in Milan in April, 2008. Results showed a statistically significant reduction in viral load after two weeks in the group comprising genotype-1 naïve patients, and non-responder/relapsed patients to pegylated interferon plus ribavirin. Importantly, these patients also benefitted with respect to tolerance of the treatment, as reported adverse events were fewer in those patients administered Interferon-Alpha XL than in those patients administered Peg-Intron.

The worldwide market for leading interferon (alpha, beta and gamma) products amounted to approximately $8.6 billion in 2009, and we expect this market to grow in the future as researchers identify additional indications that may be treated effectively using interferon drugs, as such proposed treatments gain approval and as new suppliers emerge. In 2009, interferon alpha formulations accounted for approximately 30% of the worldwide market for interferons. We are in discussions regarding licensing agreements with interested parties for the further development of the Medusa platform with respect to interferon-alpha.

2. FT-105 Long-acting Basal Insulin Formulation

Our first application of our proprietary Medusa technology microparticulate application is a depot delivery formulation of insulin targeted to meet the long-acting, 'basal' insulin requirements of diabetic patients.

Insulin Market

Insulin serves to regulate the glucose level in the blood. In a non-diabetic person, the body produces insulin in large quantities after each meal to reduce the resulting high glucose level. In non-diabetics the body also produces a small quantity of insulin every 15 minutes to ensure that a protective basal level of insulin is maintained throughout the day. To maintain similar control over their glucose levels, diabetics who need insulin injections require two different types of release profiles: a fast-acting insulin to be taken at meal times, and a long-acting insulin to maintain a constant minimum ("basal") level of insulin, particularly throughout the night when patients do not inject insulin.

Global sales of leading insulin drugs were approximately $13.6 billion in 2009. Leading long-acting basal insulins, Lantus® (insulin glargine, Sanofi-Aventis) and Levemir® (insulin detemir, Novo Nordisk), are among the fastest growing insulins, with sales of $4.3 billion and $980 million respectively in 2009 (together nearly 39% of the global insulin market). In Type I diabetics (those with Insulin Dependent Diabetes Mellitus), basal insulin is projected to represent 40% of their required treatment. Type II diabetics (those with Non-Insulin Dependent Diabetes Mellitus) significantly out-number Type I diabetics and often require only basal insulin. Our FT-105 basal insulin is designed to address the requirements of both these groups.

The Development of FT-105 basal insulin

Using a microparticulate adaptation of our Medusa delivery system, we have been able to form nanoparticles of human insulin and aggregate them to produce a long-acting, injectable insulin formulation known as FT-105. The microparticulate formulation of Medusa polymer has a longer release profile than the nanoparticles themselves. We believe this is because following injection the much larger microparticles sequester the insulin and protect it from being susceptible to exchange with endogenous proteins. These microparticles then slowly disaggregate into nanoparticles which in turn release the insulin as a result of exchange with endogenous protein.

In diabetics, large variations in blood glucose levels over time can lead to serious, long-term complications including vision impairment, foot ulcerations and kidney failure. Theoretically, the need for basal insulin implies a profile with minimal peak and trough differences to minimize a diabetic's hypoglycemia and hyperglycemia (low and elevated blood glucose levels) episodes, particularly during the first hours after insulin injections and during the sleeping hours. FT-105 has been shown to provide a controlled-release of fully human insulin over at least 48 hours with good bioavailablity and excellent local tolerance. Among FT-105's potential advantages is the fact that it is a recombinant human insulin with full bioactivity, both with respect to glucose control as well as with respect to insulin's role as a modulator of growth factors, especially VEGF. VEGF plays an essential role in maintaining vascular health.

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In October 2007, we announced top-line results of the Phase I three-way crossover trial of FT-105 conducted in eighteen healthy volunteers. The trial used the euglycemic clamp technique, whereby patients are requested to fast for thirty-six hours and their levels of insulin and glycemia are monitored. Pharamacodynamics were monitored for forty-eight hours through immunological analysis. The results showed a 48-hour controlled release of recombinant human insulin, with a very flat curve as compared to Lantus, the current standard of care. These results are promising insofar as they support the Company's thesis that Medusa can be used to enable a basal insulin formulation that may be administered to 100% of patients with true 24-hour glucose control and with a lesser risk of hypoglycemia. The results also provide a proof of concept for the microparticulate approach, which is an essential component of much of the work that the company is undertaking in feasibility studies with partners who are interested in controlling the release of smaller proteins and peptides.

Other Products Under Development Based on the Medusa Technology

Our success in development of the "ubiquitous" Medusa polymer has generated numerous feasibility study relationships with biotechnology and pharmaceutical partners in the past two years. Currently we are working on twenty Medusa projects with various pharmaceutical partners. These projects involve both novel and already-marketed molecules. Flamel expects some of these projects to evolve into license agreements as a function of many factors. These include the promise of the molecule itself (particularly with respect to novel molecules there is a high rate of attrition); the success of formulation work that we conduct for our partners; the evolving strategy and marketing focus of our partners; and the pharmaco-economics associated with the eventual product and the indication(s) for which it is being developed.

The twenty Medusa projects currently under development include those in our relationships with Merck Serono, Pfizer, Baxter and several other top twenty-five pharmaceutical companies. These relationships range from work on marketed therapeutic proteins to novel proteins and peptides, and other novel large molecules. We believe that our strategy of engaging in feasibility work with a wide range of partners strengthens the Company, by diversifying our development risks, improving our understanding of many cutting edge fields of research, and engaging us in projects designed to extend the Medusa platform into different indications and methods of delivery.

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Micropump: Delivery System for the Oral Administration of Drugs

Historically Flamel's first drug delivery platform, Micropump is aflexible technology for the controlled release of small molecule drugs following oral administration. Micropump differs from competing technologies in several important ways and offers a distinctive set of features and benefits to patients and to our pharmaceutical partners. Micropump provides:

- Extended drug absorption,
- Extended and controlled release,
- Delayed release profile is possible if desired,
- Ability to target delivery to specific regions of the intestine if desired,
- Lower peak drug concentration, which can result in a reduced level of undesirable side effects,
- Reduced inter- and intra-subject variability,
- Perfect dose proportionality,
- Ability to "fine tune" pharmacokinetic behavior by combining multiple release profiles if desired,
- Ability to combine multiple active ingredients but still keep them physically separate because they are in different microparticle formulations which are then mixed,
- Ability to develop easily multiple dose strengths based on one microparticle formulation,
- Possibility of release profile that is not accelerated in humans in the presence of alcohol,
- Taste masking which is useful for bitter or distasteful drugs,
- Multiple dosage forms including tablets, capsules, sachets, suspensions, and rapidly dissolving tablets,
- Stable liquid formulations are possible as well as dry suspensions that can be easily reconstituted with water creating liquid dosage forms,
- Components considered by regulatory authorities, including the US FDA, to be "GRAS" – Generally Regarded as Safe - and are listed on the FDA's Center for Drug Evaluation and Research (CDER) database of inactive, acceptable pharmaceutical excipients,
- Commercial production capabilities,
- Rapid time to first testing in humans – approximately one year or less for known active pharmaceutical ingredients,
- Rapid development times: for example Coreg CR took 3.5 years from project inception to NDA filing and required only a 10 month review by the US FDA.

A Micropump tablet, capsule, sachet, liquid formulation, or any other presentation form, contains 5,000 to 50,000 discrete microparticles which disassociate from one another in the intestine, and each of which then acts as a miniature "drug pump", releasing its drug independently from all of the other individual microparticles. Because of the statistics of large numbers, the large number of independently releasing microparticles results in Micropump's reduced inter- and intra-subject variability relative to many competing technologies. It also enhances safety by avoiding the problem of "dose dumping" (releasing all the drug at one time and place) which can sometimes be experienced with competing systems that rely on one or a small number of releasing vehicles.

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The size range of Micropump microparticles typically is between 100 and 500 micrometers. Each independent microparticle comprises an inert core surrounded by the active drug, and coated with a polymer which defines the controlled release properties. The composition and thickness of the polymer coating, as well as the excipients used, can be adjusted to regulate precisely the release profile, and therefore pharmacokinetics, for that drug and therapeutic application. For most Micropump applications we use a polymer coating which behaves and releases the same irrespective of pH changes within the patient's body. However, for certain applications we also can utilize a special coating which does not allow appreciable drug release at the low, acidic pH of the stomach, but only upon experiencing the higher pH found in the intestine, and in fact we can regulate this release to target the drug to different regions of the intestine when desired. For certain other applications we can utilize a special coating which provides a time delayed release if desired.

Because each dose consists of thousands of discrete microparticles, the release kinetics are independent of dose, and it is simple to produce multiple dose strengths. Micropump exhibits perfect dose proportionality, and to double the dose, we simply double the number of particles used. Also because of the discrete microparticle nature of the product, we can produce different microparticle formulations of the same drug with different release characteristics, including delayed release if desirable, and then mix those formulations to precisely "fine tune" the desired release and pharmacokinetic properties of the drug. This allows us extreme control to achieve the optimum profile for a specific drug and therapeutic target.

Also by virtue of the multi-microparticle nature of Micropump, we easily can create "combination products" which contain two or more discrete active pharmaceutical ingredients, each of which is physically separate from the other drug based on the independent polymer coating surrounding each microparticle, and each of which will release with its own optimized, independent controlled release profile.

It is possible to create a Micropump formulation whose release profile is not accelerated in humans or biostudies by the presence of alcohol. Also, the polymer coating on each microparticle results in a "taste masking" effect which can be important for bitter or otherwise distasteful drugs. This can be particularly important when developing ready-to-use, stable liquid controlled-release formulations, an application for which Micropump is one of the only systems in the world we are aware of suitable for developing such formulations. We are exploring the use of such stable liquid formulations particularly for pediatric and geriatric markets, but also for CNS drugs where patient compliance is an issue.

The materials we use to formulate and produce our Micropump products all are listed on the US FDA Center for Drug Evaluation and Research database of inactive, acceptable excipients and are "Generally Regarded as Safe" (GRAS) which means that we are not required to test and demonstrate the safety of these materials, we simply can use them in our products and reference the appropriate excipient master files at the regulatory authorities.

This use of only GRAS components also results in advantages of rapid development time. For most known (already approved) active pharmaceutical ingredients, we can simulate reliably the optimum release profile on our computers, quickly create those formulations, and bring them directly into human clinical studies without ever having to perform animal safety and efficacy studies. As a result, the time to first testing in humans typically is less than a year from program inception for known APIs. And overall development times also are rapid; for Coreg CR it only took approximately 3.5 years from program inception to complete all the necessary formulation work and clinical testing and to file the New Drug Application, which itself only required a 10 month review by FDA, which is rapid by industry standards.

Trigger Lock™ is a special application based on our Micropump technology designed to provide a technical solution to the serious societal problems of intentional and unintentional abuse and misuse of narcotics and other dangerous, but pharmaceutically important, drugs. This problem increasingly is receiving FDA and Congressional attention in the United States and we believe our Trigger Lock technology is ideally positioned to make it more difficult to abuse, misuse or tamper with these drugs.

One problem with some controlled-release technologies, which can present serious problems with narcotic formulations even among patients not intentionally trying to abuse or misuse the drug, is drug dumping in the presence of alcohol. Because our Trigger Lock technology uses our Micropump approach, there is no drug dumping seen in humans or biostudies.

Because they are designed to provide effective drug levels for a prolonged period of time, controlled-release narcotic formulations typically contain large amounts of the active substance relative to immediate release forms. Controlled-release narcotics therefore attract the attention of recreational drug users who typically might grind a controlled-release formulation up into a powder, dissolve it in water, filter and inject it to provide immediate availability of the entire dose and the subsequent "rush" sought.

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If a Trigger Lock tablet or capsule is ground between spoons, with a commercial pill pulverizer or even with a mortar and pestle, which is the most effective technology typically used, the capsule or tablet will be successfully broken down to the individual microparticles which are what make up the overall tablet. However, each microparticle retains its polymer coating which is virtually impervious to further crushing and so the narcotic remains sequestered and unobtainable and the powder exhibits identical release characteristics as the intact, overall tablet or capsule.

To provide additional margins of safety and enhance the deterrents to misuse, we add viscosifying agents such that if the microparticle powder obtained by grinding is dissolved in a small volume of water it forms a gel and the recreational drug user will be unable to pass it through a cotton ball or other filter into a syringe for injection. Even with solvents other than water, such as ethanol or ethanol/water mixtures, the mixtures obtained are highly viscous and heterogeneous and less than 5% of the liquid can be recovered. Our testing has shown that even if many tablets are crushed and extracted, less than 0.1% of the narcotic is recovered.

Another approach typically used by recreational drug users is to dissolve the controlled release drug powder, obtained by crushing or grinding, into a large volume, typically 50 to 100 ml, of water or alcohol and then drink the resulting mixture, again providing a way to obtain most or all of the dose of narcotic in an immediate release. We defeat this possibility by adding a "quenching" or "sequestering" agent that absorbs the narcotic as it comes out if the microparticle powder is dissolved in a large volume of water or alcohol, and so most of the drug is not immediately available even if a long time is allowed for dissolution.

Nonetheless, if the Trigger Lock capsule or tablet is taken by a patient as intended, the drug is fully available to the patient over the time course and in the levels intended. Furthermore, we can duplicate almost any existing controlled-release narcotic formulation to produce a product which is as effective as the original product, but much more resistant to intentional or unintentional misuse or abuse.

Products Based on the Micropump Technology

Our first approved product using the Micropump platform is Coreg CR, which we have developed with GSK.

Coreg CR

Coreg CR is an extended-release formulation of Coreg (carvedilol phosphate), a beta blocker that is considered the standard of care for the treatment of moderate to severe heart failure and left ventricular dysfunction following myocardial infarction. Coreg CR was approved by the FDA on October 20, 2006 for use in the treatment of moderate to severe congestive heart failure; left ventricular dysfunction following myocardial infarction; and hypertension. We began work with GSK on this program in 2003 and the product was launched in March 2007. Pursuant to the supply agreement with GSK, we produce Coreg CR microparticles on a cost plus basis. To date, we have received $23 million in milestone payments from GSK and are eligible to receive an additional $2 million if certain milestones are achieved. We also received royalties on Coreg CR in 2009 of $8.8 million based on net sales of $251 million as reported by GSK.

The Hatch-Waxman exclusivity period for Coreg CR ended on April 20, 2010. It is possible that Coreg CR may experience generic competition from one or more competitors following approval of an Abbreviated New Drug Application (ANDA). To date, only one ANDA has been submitted to the U.S. FDA, URL Pharma in March 2008, and it has not yet been reviewed. A Citizen Petition has been submitted to the FDA that respectfully requests that the FDA require any proposed generic formulations of Coreg CR to meet the same requirements that the FDA required for the approval of Coreg CR, which is a higher standard than is otherwise required under the minimum bioequivalence regulations.

Coreg CR and the Market for Beta Blockers

Coreg and Coreg CR are indicated for the treatment of congestive heart failure (CHF) as well as for the treatment of left ventricular dysfunction following myocardial infarction. Coreg and Coreg CR additionally are indicated for the treatment of hypertension. Coreg is part of the standard of care for the treatment of heart failure. Coreg and Coreg CR are the only beta blockers indicated for the severe form of heart failure. Coreg initially attained this leadership position despite the fact that it was not available in a once-daily formulation, unlike many others of the beta blocker class. In general, many physicians prefer once-daily formulations for their patients due to the compliance advantages that they may offer, even though the CASPER study (Compliance and Quality of Life Study Comparing Once-Daily Carvedilol CR and Twice-Daily Carvedilol IR in Patients with Heart Failure) published in 2007 failed to prove a compliance advantage in patients prescribed Coreg CR versus those prescribed immediate release Coreg, according to the pre-defined criteria.

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Earlier generations of beta blockers were not widely used in the treatment of hypertension because of perceived drawbacks. Perhaps the greatest of these drawbacks was the fact that many other beta blockers, have been associated with increased glycemia levels in Type II diabetic patients. By contrast, Coreg has been proven clinically not to cause increased glycemia levels in diabetic patients, of which there are over thirteen million Type II diabetic hypertensives in the Unites States. Type II diabetics who suffer from hypertension are defined by the American Diabetes Association as suffering from complicated hypertension, meaning that they are recommended to reduce their blood pressure to a level of 130/80 (as opposed to 140/90 for essential hypertension). Sixty-five percent of those suffering from Type II diabetes, it is estimated, will require two or more anti-hypertensive agents.

Carvedilol is a non-selective antagonist of Beta 1, Beta 2 andrenergic receptors and a selective antagonist of Alpha 1 andrenergic receptors. It has been demonstrated to have notable anti-inflammatory properties, in distinction to most other beta blockers. Research further suggests that carvedilol possesses significant anti-oxidative effects, which are beneficial to vascular health.

Other Products Under Development Based on Micropump Technology

From time to time we have conducted Micropump feasibility studies on other proprietary therapeutic compounds under limited, confidential agreements with the pharmaceutical companies owning the rights to these compounds. We currently are engaged in two such projects, one for a liquid formulation of an already-marketed over-the-counter product and a second for a combination product in the cardiovascular setting. Such contracts provide us with the possibility for expanded relationships. Moreover, these relationships are invaluable insofar as our potential partners often are able to identify opportunities for the Micropump platform from their internal pipeline, opportunities which we would not otherwise know.

Photochromic Materials

Our broad expertise in polymer science led to a long-term commercial relationship with Corning. Under a contract research arrangement that existed since 1994, we have worked with Corning to produce two generations of material for photochromic lenses. The research and development activities ended in 2003 and we no longer are focusing strategically on this market.

Photochromic lenses automatically darken in the presence of sunlight and then revert to clear when indoors. These eyeglass lenses, which are based on mineral material, have been available for over 20 years, and Corning has been the dominant worldwide supplier of these lenses since their introduction. However, as eyeglass lenses have been increasingly made with plastic materials, there is an increasing demand for photochromic lenses based on polymer (plastic) materials.

During 1999, Corning launched SunSensor, a new, competitive photochromic eyeglass lens product containing our technology. We began receiving royalties on the sales of this product late in 1999. The amount of future royalties related to this and other potential products resulting from this collaboration is dependent on Corning’s marketing success.

Under the terms of our current agreement with Corning, we continue to receive royalties on sales of all products that contain intellectual property developed by the collaboration. See ‘— Strategic Alliances — Corning: Photochromic Materials.

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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, 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, ultimately, provide distribution capabilities for any resulting products. 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. The major existing agreements we are able to disclose are as follows:

Baxter International, Inc.

In June 2009 we entered into collaboration with Baxter International Inc. to create controlled release applications of blood clotting factor replacement therapies using our Medusa technology. This collaboration includes work on intravenous formulations. Baxter paid technology access fees totaling € 2.5 million (or $3.6 million), will pay all development costs for the program and has an exclusive right to negotiate a license to the Medusa platform for these applications. Baxter is the world leader, based on sales, in the field of blood clotting factor replacement therapies.

GlaxoSmithKline

We began work with GSK on a Micropump formulation of Coreg in 2003, the product was approved by FDA on October 2006 and launched in March 2007. Pursuant to the supply agreement with GSK, we produce Coreg CR microparticles on a cost plus basis. To date, we have received $23 million in milestone payments from GSK and are eligible to receive an additional $2 million if certain milestones are achieved. Turnover of Coreg CR through December 31, 2009 amounted to $251 million on which we recognized royalty revenue of $8.8 million.

The Hatch-Waxman exclusivity period for Coreg CR ended on April 20, 2010. It is possible that Coreg CR may experience generic competition from one or more competitors following approval of an Abbreviated New Drug Application (ANDA). To date, only one ANDA has been submitted to the U.S. FDA, URL Pharma in March 2008, and it has not yet been reviewed. A Citizen Petition has been submitted to the FDA that respectfully requests that the FDA require any proposed generic formulations of Coreg CR to meet the same requirements that the FDA required for the approval of Coreg CR, which is a higher standard than is otherwise required under the minimum bioequivalence regulations.

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 a development and license agreement for this program and paid an upfront fee of € 5.0 million ($6.5 million). Pursuant to the license, Merck Serono will pay all future development costs for the program as well as payments upon achievement of certain clinical and regulatory milestones and royalties upon any eventual sales of the product.

Pfizer

Since December 2008, we have been engaged in work with Pfizer to assess the applicability of the Medusa platform to certain molecules in development. Additionally, 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. This election triggered a $1 million payment to us and Pfizer will pay all development costs of the program, including milestone payments and royalties on any worldwide commercial sales. The program was begun in 2007 with Wyeth, which was acquired by Pfizer in October 2009.

Corning: Photochromic Materials

Corning S.A and Corning Incorporated (Corning) entered into an agreement with us in March 1994 for the co-development of proprietary, polymer-based photochromic eyeglass lens material to be sold by Corning to manufacturers of ophthalmic lenses worldwide. The research and development activities ended in 2003. In 1999, Corning launched its first photochromic plastic eyeglass lens product developed in collaboration with us, and we began receiving quarterly royalty payments under this agreement. In 2009 we received approximately $370,000 in royalties, the tenth full year of royalties for us for this product.

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Manufacturing

On December 31, 1996, we acquired a 50,000-square foot pharmaceutical production facility located in Pessac, France from SmithKline. See 'Item 4. Key Information — Description of Property.' As part of the acquisition, Flamel employed forty-two experienced plant personnel.

In 2004, we built a new facility of 16,000 square feet adjacent to the existing facility in Pessac for a total purchase price of $10.3 million. This new building included 8,600 square feet for the Medusa technology with a new cGMP pilot plant, extended synthesis capacity and increased capacity to manufacture qualification and phase III batches at 10% of the commercial batch size. This facility supports the production of polymer to meet the needs from projects such as FT-105, interferon-alpha, and other projects based on our Medusa technology. A further building of 2,900 square feet houses utilities and a warehouse.

In 2005, we expanded our facilities in preparation for the manufacture of Coreg CR microparticles for GlaxoSmithKline as well as other Micropump-enabled formulations. The new facility comprises 6,800 square feet and includes the 4,600 remaining square feet from the 2004 expansion. The new Micropump facility was constructed at a cost of $8.2 million. See page F-12 of our consolidated financial statements.

The Pessac facility provides us with the capability to manufacture its pharmaceutical products. We believe that the facility and its operations are in substantial compliance with current cGMP requirements, and the facility is approved by U.S. and European drug agencies for production of certain pharmaceutical products, including commercial quantities of our microencapsulated drugs. Such approval qualifies us to manufacture certain approved pharmaceutical products for sale in most countries in Europe and the U.S.

In the past, in addition to production activities related to our core businesses, we were able to build on our capabilities and experience with GlaxoSmithKline and other pharmaceutical customers to engage in toll manufacturing for pharmaceutical partners. With its experienced workforce and cGMP operations, we perform clinical batch manufacturing and process scale-up services at the facilities and, up until the last quarter of 2005, performed toll manufacturing of solid dosage forms, and analytical services for contract customers. Our production site at Pessac has now been producing Coreg CR microparticles since the fourth quarter of 2006.

We completed construction of a new 14,300 square foot facility, dedicated to Micropump process development in 2008. This new area can either be used for development or manufacturing work and was qualified in early 2008, increasing our capacity from two lines to three. This facility has been partially funded by our partner, GSK.

Patents and Proprietary Technology

Patents and other proprietary rights are essential to our business. All of our contracts are dependent on our technology being patent protected. As a matter of policy we seek patent protection of our inventions and trademarks and also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

Generally, we first file a patent application covering an invention in France and in the United States (provisional application). Within one year, we file a U.S. non provisional patent application for that invention together with an international patent application pursuant to the Patent Cooperation Treaty (PCT).

In addition to seeking patent protection in the United States and France, to further protect the inventions that we consider important to the development of our business, from the PCT we will generally prosecute patent applications in Europe, Japan, Canada, and key foreign markets on a selective basis: therefore, in addition to the above-named countries, we also have patents granted or patent applications pending in a number of other countries, including Mexico, Brazil, China, India and South Korea.

In selected cases, an invention developed jointly by Flamel Technologies and a partner may be assigned to the partner. The information provided herein does not include such patent applications.

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The Orange book lists patent number 6,022,562 pertaining to the method of micro-encapsulation that is the basis for the Micropump platform, as covering Coreg CR. This patent is held by Flamel Technologies and has an expiration date of October 17, 2015. A second patent covering advances in the platform, specifically concerning techniques to delay the release of active ingredient after ingestion, has been filed with the U.S. PTO. This patent would expire in 2023 or later and is the subject of a notice of allowance in the European Union.

Since inception, we have been granted 464 patents. Among others, these include patents that relate to microencapsulated aspirin (Asacard), microencapsulated active principles (Micropump), methods of producing polyaminoacids for use in delivering proteins and peptides, nanoparticles of polyaminoacids (Medusa) for delivering proteins and peptides such as insulin, interferon and interleukins.

During 2009, we were granted one hundred and twenty-six (126) new patents and filed for five new patent applications with the French Patent Office and for corresponding U.S. provisional patent applications. We have also filed three Patent Cooperation Treaty (PCT) extensions of cases first filed in 2008 and also filed for the corresponding direct U.S. non provisional patent applications.

We can offer no assurance that any patents issued to us will provide us with competitive advantages or will not be infringed, challenged, invalidated or circumvented by others, or that the patents or proprietary rights of others will not have an adverse effect on our ability to do business.

There can be no assurance that we will be granted patents in respect of the claims in any of our currently pending or future patent applications, and we can offer no assurance that in the event any claims in any of our issued patents are challenged by one or more third parties, that any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable or sufficiently broad in scope to protect our proprietary rights. Also, the nature of the process for obtaining patents and the extent of protection provided by patent laws varies from country to country. We can offer no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance to us in other countries of patents covering the same invention or that any judicial interpretation of such patents will be uniform in multiple jurisdictions. Furthermore, even if our patents are determined to be valid, enforceable and broad in scope, we can offer no assurance that competitors will not be able to design around such patents.

Government Regulation

The design, testing, manufacturing and marketing of certain new or substantially modified drugs, biological products or medical devices must be approved or cleared by regulatory agencies under applicable laws and regulations, the requirements of which may vary from country to country. This regulatory process is lengthy, expensive and uncertain. In the United States, the FDA regulates such products under various federal statutes, including the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act. Similar requirements exist in the Member States of the European Union. There can be no assurance that we or our collaborative partners will be able to obtain such regulatory approvals or clearances on a timely basis, if at all, for any products under development. Delays in receipt or failure to receive such approvals or clearances, the revocation of previously received approvals or clearances, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

We believe our delivery systems, when used in conjunction with therapeutic pharmaceuticals, will be subject to drug and biological product approval requirements. In the United States, biological products, such as therapeutic proteins and peptides, generally are subject to the same FDA regulatory requirements as other drugs, although some differences exist. For example, for some biological products a biologic license application (BLA) is submitted for approval for commercialization instead of the new drug application (NDA) used for other drugs. Also, unlike drug products, some biological products are subject to FDA lot-by-lot release requirements and those approved under a BLA currently cannot be the subject of abbreviated new drug applications (ANDAs). Insulin, which is regulated as a drug product, typically has not been the subject of ANDAs. However, the FDA is working on a variety of issues pertaining to the possible development of generic versions of insulin and there can be no assurance that this type of submission will continue to be unavailable for insulin. Additionally, our delivery systems likely will be regulated by the FDA as ‘combination products’ if they are used together with a biologic or medical device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of both components.

Photochromic eyeglass lenses are regulated by the FDA as medical devices.

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New Drug and Biological Product Development and Approval Process

United States

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture, and marketing of biological and drug products and in ongoing research and product development activities. The products of all of our pharmaceutical and biotechnology partners will require regulatory approval by governmental agencies prior to commercialization. In particular, these products are subject to manufacturing according to stringent cGMP quality principles, and rigorous, pre-clinical and clinical testing and other pre-market approval requirements by the FDA and regulatory authorities in other countries. In the United States, various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical and biological products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources.

The FDA's statutes, regulations, or policies may change and additional statutes or government regulations may be enacted which could prevent or delay regulatory approvals of biological or drug products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Regulatory approval, when and if obtained, may be limited in scope. In particular, regulatory approvals will restrict the marketing of a product to specific uses. Approved biological and other drugs, as well as their manufacturers, are subject to ongoing review (including requirements and restrictions related to record keeping and reporting, FDA approval of certain changes in manufacturing processes or product labeling, product promotion and advertising, and pharmacovigilance, which includes monitoring and reporting adverse reactions, maintaining safety measures, and conducting dossier reviews for marketing authorization renewal). Discovery of previously unknown problems with these products may result in restrictions on their manufacture, sale or use, or in their withdrawal from the market. Failure to comply with regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other actions affecting the commercial prospects of our pharmaceutical and biotechnology partners' potential products or uses or products that incorporate our technologies. Any failure by our pharmaceutical and biotechnology partners to comply with current or new and changing regulatory obligations, and any failure to obtain and maintain, or any delay in obtaining, regulatory approvals, could materially adversely affect our business.

The process for new drug and biological product development and approval has many steps, including:

Chemical and Formulation Development

Pharmaceutical formulation taking into account the chemistry and physical characteristics of the drug or biological substance is the beginning of a new product. If initial laboratory experiments reveal that the concept for a new drug or biological product looks promising, then, a variety of further development steps and tests complying with internationally recognized guidance documents will have to be continued, in order to provide for a product ready for testing in animals and, after sufficient animal test results, also in humans.

Concurrent with pre-clinical studies and clinical trials, companies must continue to develop information about the properties of the drug product and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product, and the manufacturer must develop and validate methods for testing the quality, purity and potency of the final products. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

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Pre-Clinical Testing

Once a biological or drug candidate is identified for development, the candidate enters the pre-clinical testing stage. This includes laboratory evaluation of product chemistry and formulation, as well as animal studies of pharmacology (mechanism of action, pharmacokinetics) and toxicology which may have to be conducted over lengthy periods of time, to assess the potential safety and efficacy of the product as formulated. Pre-clinical tests must be conducted in compliance with good laboratory practice regulations and the Animal Welfare Act and its regulations. Violations of these laws and regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be replicated. In some cases, long-term pre-clinical studies are conducted while clinical studies are ongoing.

Investigational New Drug Application

USA: The entire body of chemical or biochemical, pharmaceutical and pre-clinical development work necessary to administer investigational drugs to human volunteers or patients is summarized in an investigational new drug (IND) application to the FDA. The IND becomes effective if not rejected by the FDA within 30 days after filing. There is no assurance that the submission of an IND will eventually allow a company to commence clinical trials. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations to ensure the quality and integrity of clinical trial results and data. These regulations include the requirement that, with limited exceptions, all subjects provide informed consent. In addition, an institutional review board (IRB), composed primarily of physicians and other qualified experts at the hospital or clinic where the proposed studies will be conducted, must review and approve each human study. The IRB also continues to monitor the study and must be kept aware of the study's progress, particularly as to adverse events and changes in the research. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events occur. Failure to adhere to good clinical practices and the protocols, and failure to obtain IRB approval and informed consent, may result in FDA rejection of clinical trial results and data, and may delay or prevent the FDA from approving the drug for commercial use.

European Union: The European equivalent to the IND is the Investigational Medicinal Product Dossier (IMPD) which likewise has to contain pharmaceutical, pre-clinical and, if existing, previous clinical information on the drug substance and product. An overall risk-benefit assessment critically analyzing the non-clinical and clinical data in relation to the potential risks and benefits of the proposed trial must also be included. The intended clinical trial must be submitted for authorization by the regulatory authority(ies) of each EU Member States in which the trial is intended to be conducted prior to its commencement. The trial shall be conducted on the basis of the proposal as approved by an Ethics Committee(s) in each EU Member State (EU equivalent to IRBs) before the trial commences. Before submitting an application to the competent authority, the sponsor must register the trial in the EudraCT database where it will be provided with a unique EudraCT number from the EudraCT database.

Clinical Trials

Typically, clinical testing involves the administration of the drug or biological product first to healthy human volunteers and then to patients with conditions needing treatment under the supervision of a qualified principal investigator, usually a physician, pursuant to an FDA-reviewed (via the IND submission) 'protocol,' or clinical plan. The protocol details matters such as a description of the condition to be treated, the objectives of the study, a description of the patient population eligible for the study and the parameters to be used to monitor safety and efficacy.

Clinical trials are time-consuming and costly, and typically are conducted in three sequential phases, which sometimes may overlap. Phase I trials consist of testing the product in a small number of patients or normal volunteers, primarily for safety, in one or more dosages, as well as characterization of a drug's pharmacokinetic and/or pharmacodynamic profile. In phase II, in addition to safety, the product is studied in a patient population to evaluate the product's efficacy for the specific, targeted indications and to determine dosage tolerance and optimal dosage. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded patient population at geographically dispersed sites. With limited exceptions, all patients involved in a clinical trial must provide informed consent prior to their participation. Meeting clinical endpoints in early stage clinical trials does not assure success in later stage clinical trials. Phase I, II, and III testing may not be completed successfully within any specified time period, if at all.

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The FDA monitors the progress of each clinical trial phase conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate clinical trials at any point in this process for various reasons, including a finding that patients are being exposed to an unacceptable health risk or a determination that it is unethical to continue the study. The FDA can also request additional clinical trials be conducted as a condition to product approval. The IRB and sponsor also may order the temporary or permanent discontinuance of a clinical trial at any time for a variety of reasons, particularly if safety concerns arise. Such holds can cause substantial delay and in some cases may require abandonment of product development. These clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations and/or internationally recognized guidance (such as ICH, or International Conference on Harmonization).

New Drug Application or Biological License Application

After the completion of the clinical trial phases of development, if the sponsor concludes that there is substantial evidence that the drug or biological candidate is effective and that the drug is safe for its intended use, an NDA or BLA may be submitted to the FDA. The application must contain all of the information on the drug or biological candidate gathered to that date, including data from the pre-clinical and clinical trials, information pertaining to the preparation of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability (shelf-life). NDAs and BLAs are often over 100,000 pages in length. If FDA determines that a risk evaluation and mitigation strategy (REMS) is necessary to ensure that the benefits of the drug outweigh the risks, a sponsor may be required to include as part of the application a proposed REMS, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide better information to consumers about the drug's risks and benefits. Submission of an NDA or BLA does not assure FDA approval for marketing.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing (the U.S. prerequisite for dossier review). It may refuse to file the application and request additional information rather than accepting an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA to determine, among other things, whether a product is safe and effective for its intended use. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. Recent changes to the FDCA create a strong presumption for advisory committee review for any drug containing an active ingredient not previously approved. The FDA is not bound by the recommendation of an advisory committee. Under the Prescription Drug User Fee Act (PDUFA), submission of an NDA or BLA with clinical data requires payment of a fee. In return, the FDA assigns a goal of 10 months from acceptance of the application to return of a first 'complete response,' in which the FDA may approve the product or request additional information. (Although PDUFA also provides for a six-month "priority review" process, we do not anticipate it applying to any of our products or our partners' products.) There can be no assurance that an application will be approved within the performance goal timeframe established under PDUFA, if at all. If the FDA's evaluation of the NDA or BLA is not favorable, the FDA usually will outline the deficiencies in the submission and request additional testing or information. Notwithstanding the submission of any requested additional information, or even in lieu of asking for additional information, the FDA may decide that the marketing application does not satisfy the regulatory criteria for approval and issue a complete response letter, communicating the agency's decision not to approve the application.

FDA approval of an NDA or BLA will be based, among other factors, on the agency's review of the pre-clinical and clinical data submitted, a risk/benefit analysis of the product, and an evaluation of the manufacturing processes and facilities. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA or BLA. Among the conditions for NDA or BLA approval is the requirement that each prospective manufacturer's quality control and manufacturing procedures conform to cGMP standards and requirements. Manufacturing establishments often are subject to inspections prior to NDA or BLA approval to assure compliance with cGMPs and with manufacturing commitments made in the relevant marketing application.

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Other Countries

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by regulatory authorities must be obtained in any other country prior to the commencement of marketing of the product in that country. The approval procedure may vary from country to country, can involve additional testing, and the time required may differ from that required for FDA approval. Under European Union legislation, product authorization is granted for an initial period of five years. The authorization may subsequently be renewed for an unlimited period on the basis of a re-evaluation of the risk-benefit balance by the competent authorizing authority. In the EU, marketing authorization of drugs is according to either a centralized or decentralized procedure, generally depending on the nature and type of drug. Certain designated drugs may be authorized only in accordance with the centralized procedure by the European Commission following an opinion by the European Medicines Agency (EMA). The centralized procedure is mandatory for pharmaceutical products developed by means of biotechnological processes (recombinant DNA, controlled expression of genes coding, hybridoma and monoclonal antibody methods), products containing new actives substances indicated for the treatment of AIDS, cancer, diabetes and neuro-degenerative diseases, orphan designated medicinal products and advanced therapy products. Other pharmaceutical products may be authorized in accordance with the centralized procedure where it is demonstrated that they contain new active substances or are demonstrated to have a significant therapeutic benefit, or where they constitute a scientific or technical innovation, or are in the interest of patients or animal health at Community level. Where authorization is in accordance with the decentralized procedure, approval is either by "mutual recognition," whereby the authorization granted by the competent authorities of one Member States are recognized by the authorities of other Member States, or where the competent authorities of each Member State authorize a product on the basis of an identical dossier, with, one national authority taking care of the dossier intensively and coordinating activities. To the extent possible, clinical trials of our products are designed to develop a regulatory package sufficient for multi-country European Union approval.

Regulatory approval of prices for certain drugs is required in France and in manyother countries outside the United States. In particular, many European countries make the reimbursement of a product within the national social security system conditional on the agreement by the seller not to sell the product above a fixed price in that country. Also common is the unilateral establishment of a reimbursement price by the national authorities, often accompanied by the inclusion of the product on a list of reimbursable products. Related pricing discussions and ultimate governmental approvals can take several months to years. Some countries require periodic pricing updates and renewals at intervals ranging from two to five years. Some countries also impose price freezes or obligatory price reductions. We cannot assure you that, if regulatory authorities establish lower prices for any product incorporating our technology in any one European country, this will not have the practical effect of requiring our collaborative partner correspondingly to reduce its prices in other European countries. We can offer no assurance that the resulting prices would be sufficient to generate an acceptable return on our investment in our products.

Regulation of Combination Drugs

Medical products containing a combination of drugs, biological products or medical devices may be regulated as 'combination products' in the United States. A combination product generally is defined as a product comprising components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device.

To determine which FDA center or centers will review a combination product submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation.

In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of both components. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. It is possible that our delivery technologies, when coupled with a drug, biologic or medical device component, could be considered and regulated by the FDA as a combination product.

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If the primary mode of action is determined to be a drug, the product will be reviewed by the Center for Drug Evaluation and Research (CDER) either in consultation with another center or independently. If the primary mode of action is determined to be a medical device, the product would be reviewed by Center for Devices and Radiological Health (CDRH) either in consultation with another center, such as CDER, or independently. In addition, FDA could determine that the product is a biologic and subject to the jurisdiction of the Center for Biologic Evaluation and Research (CBER). In the European Union, drug combinations, that is, drug products containing 2 or more drug substances each of which has to contribute a proven advantage of therapy (e.g., synergism, less adverse reactions) and are subject to drug regulations like all others. Products combining drug substances or drugs with a device may be subject to device and/or drug regulations, or may be classified as medical devices, depending on the individual case.

Marketing Approval and Reporting Requirements

If the FDA approves an NDA or BLA, the product becomes available for physicians to prescribe. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval to develop additional information regarding the safety of a product. These studies may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side effects associated with long-term use. After approval, the FDA may require post-marketing studies or clinical trials, as well as periodic status reports, if new safety information develops. These post-marketing studies may include clinical trials to investigate known serious risks or signals of serious risks or identify unexpected serious risks. Failure to conduct these studies in a timely manner may result in substantial civil fines.

In addition, the FDA may require distribution to patients of a medication guide for prescription products that the agency determines pose a serious and significant health concern in order to provide information necessary to patients' safe and effective use of such products.

In the European Union, the marketing authorization of a medicinal product may be made conditional on the conduct of phase IV post-marketing studies. Failure to conduct these studies can lead to the imposition of substantial fines. Moreover, phase IV studies are often run by companies in order to obtain further information on product efficacy and positioning on the market in view of competitors.

Post-Marketing Obligations

Any products manufactured and/or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences with the product, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, submitting periodic reports to the FDA, maintaining and providing updated safety and efficacy information to the FDA, and complying with FDA promotion and advertising requirements.

Drug and biologics manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and to list their products with the FDA. The FDA periodically inspects manufacturing facilities in the United States and abroad in order to assure compliance with the applicable cGMP regulations and other requirements. Facilities also are subject to inspections by other federal, foreign, state or local agencies. In complying with the cGMP regulations, manufacturers must continue to expend time, money and effort in recordkeeping and quality control to assure that the product meets applicable specifications and other post-marketing requirements. Failure of the Company or our licensees to comply with FDA's cGMP regulations or other requirements could have a significant adverse effect on the Company's business, financial condition and results of operations.

Also, newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, additional pre-clinical or clinical studies, or even in some instances, revocation or withdrawal of the approval. Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's delay in approving or refusal to approve a product, withdrawal or recall of an approved product from the market, other voluntary or FDA-initiated action that could delay or restrict further marketing, and the imposition of civil fines and criminal penalties against the manufacturer and NDA or BLA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product, manufacturer or NDA or BLA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development, or affect the conditions under which approved products are marketed.

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The Food and Drug Administration Amendments Act of 2007 provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA's authority with respect to post-marketing safety surveillance, including, among other things, the authority to require additional post-marketing studies or clinical trials, labeling changes as a result of safety findings, registering clinical trials, and making clinical trial results publicly available.

In the European Union, stringent pharmacovigilance regulations oblige companies to appoint a suitably qualified and experienced Qualified Person resident in the European Economic Area, prepare and submit to the competent authorities adverse event reports within specific time lines, prepare Periodic Safety Update Reports (PSURs) and provide other eventual supplementary information, report to authorities at regular intervals and take adequate safety measures agreed with regulatory agencies as necessary. Failure to undertake these obligations can lead to the imposition of substantial fines.

Patent Restoration and Exclusivity

Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, a portion of a product's patent term that is lost during a product's clinical development and application review by the FDA may be restored. Patent term restoration can return up to five years of patent term for a patent that covers a new product or its use. The patent term restoration period is generally one-half the time between the effective date of the IND and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The maximum period of restoration cannot exceed 5 years, or restore the total remaining term of the patent to greater than 14 years from the date of FDA approval of the product. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office (USPTO), in conjunction with the FDA. It usually takes at least six months to obtain approval of the application for patent term extension, and there can be no guarantee that the application will be granted.

The Hatch-Waxman Act also created an abbreviated FDA review process for generic and modified versions of pioneer (brand name) drug products, along with a period of statutory protection, known as exclusivity, for new drugs approved under an NDA by the FDA. After approval of a 'new chemical entity,' the FDA may not, for a period of five years, accept an ANDA for a generic version of the drug, or an NDA for a drug that is a modification of the innovator and seeks to rely, to some degree, on FDA's finding that the innovator is safe and effective. This latter type of submission is known as a "505(b)(2) NDA." After the period of exclusivity has expired, the ANDA process permits a competitor to obtain marketing approval for a generic version of the innovator by showing that the generic product is bioequivalent to the innovator, and without submitting data demonstrating the product's safety and effectiveness. Similarly, a 505(b)(2) NDA can also then be submitted for a drug that reflects a modification of the innovator product, but seeks to rely on FDA's previous findings as part of the data demonstrating the new product's safety and efficacy.

Hatch-Waxman also provides three years of exclusivity for NDAs that, although not for a new chemical entity, rely on the results of new clinical investigations (other than bioavailability studies) that were essential to the FDA's approval of the application. Often, this applies to NDAs and NDA supplements seeking approval for new indications, dosage forms, strengths, or conditions of use of previously approved products. As a general proposition, the Hatch-Waxman exclusivities do not bar the approval of full NDAs – that is, NDAs containing all the clinical and other data necessary for FDA's finding of safety and efficacy – for the same active ingredient. In addition, the three-year exclusivity for new clinical trials only bars applications for a product with the same characteristic as what required the new clinical trials. For example, Coreg CR received three-year exclusivity for the clinical trials that demonstrated the safety and efficacy of the new, controlled-release dosage form; that exclusivity blocks other controlled-release products.

When an innovator product is approved, the applicant must identify for the FDA certain patents related to the drug that is the subject of the approval. When an ANDA or 505(b)(2) NDA is submitted, the sponsor must notify the holder of the NDA for the innovator drug that is the reference product and the holder of patents listed with that innovator product, and make certifications regarding the patents. If the sponsor asserts that the patents are invalid or not infringed by the manufacture, sale or use of the new product (this is known as a "Paragraph IV certification"), the ANDA or 505(b)(2) NDA can be submitted four years into the five-year exclusivity. In addition, such a certification allows the NDA or patent holder to bring a patent infringement suit, and that suit imposes a 30-month stay on approval of the ANDA or 505(b)(2) NDA. The discovery, trial and appeals process in such suits can take several years. If the litigation is resolved in favor of the generic applicant or the challenged patent expires during the 30-month period, the stay is lifted and the FDA's review of the application may proceed. If a court finds the patent valid and infringed, the ANDA or 505(b)(2) application may not be made approved until the expiration of the patent. In addition, if the NDA holder or patent owner chooses not to sue such an applicant within the 45-day window, the FDA may approve the ANDA or 505(b)(2) application whenever all of the other requirements for approval are met.

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The protection provided by listed patents and Hatch-Waxman exclusivities can be extended by six months if a company studies the drug in a pediatric population in response to a written request from the FDA. The trial results do not need to show efficacy in the pediatric population studied; rather, if the trial is deemed to fairly respond to the request, the additional protection is granted. Coreg CR has received such pediatric exclusivity, which extends the three-year new clinical trial exclusivity it previously obtained, as well as the protection of the listed patents. The statutory provision permitting the award of pediatric exclusivity expires on October 1, 2012, and there can be no guarantee that Congress will reauthorize this provision, or do so without significant changes.

The Hatch-Waxman construct applies only to conventional chemical drug compounds, sometimes referred to as small molecule compounds approved under an NDA. On March 23, 2010, however, the Patient Protection and Affordable Care Act became law. Among other things, it creates an abbreviated pathway to FDA approval of "biosimilar" biological products approved under a BLA, such as growth factors, interferons and certain other that includes the possibility of FDA designating a biological product as interchangeable with a previously approved product. The statute also provides innovator biological products with a 12-year exclusivity period during which no "biosimilar" products may be approved. The impact of this new law will be seen as it is implemented, by promulgation of regulations and other administrative and judicial actions, but such an abbreviated approval process could adversely affect biological products that incorporate our technologies.

Regulation of Medical Devices

United States

In the United States, medical devices are classified into Class I, II or III on the basis of the controls deemed by the FDA to be reasonably necessary to ensure their safety and effectiveness. Class I devices are subject to general controls (e.g., labeling, and adherence to cGMPs) and Class II devices are subject to special controls (e.g., performance standards, postmarket surveillance, patient registries, and FDA guidelines). Generally, Class III devices are those which must require premarket approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices or those found not to be substantially equivalent to legally marketed devices).

Other Countries

The marketing of medical devices in the EU is governed by a variety of EU legislative provisions, the application of which depends on the intended use and the classification of the device. Although medical devices are not subject to authorization by the national authorities of EU Member States, manufacturers must ensure that the device complies with requirements with respect to design, safety, performance and manufacture. Devices are, in addition, often subject to existing or future national regulation on pricing and reimbursement, which varies from country to country.

The manufacturer of a medical device cannot add a CE mark, which is a mandatory mark for certain products sold in the EU, to the device unless it is demonstrated to comply with the obligations concerning safety and performance requirements of the EU medical device legislation. In order to demonstrate compliance, the manufacturing facility and the medical device must undergo conformity assessment by a notified body. The nature of this assessment will depend on the class of the product. Once all the necessary conformity assessment tasks have been completed, the CE Mark may be affixed on the products concerned. Although Member States must accept for marketing medical devices bearing a CE Marking without imposing further requirements related to product safety and performance, national regulatory authorities who are required to enforce compliance with requirements of the EU medical device legislation may restrict, prohibit and recall CE Marked medical devices if they consider, on the basis of available information that they are unsafe. Member countries can impose additional requirements as long as they do not exceed the obligations provided for in EU medical device legislation or constitute technical barriers to trade. Within the European Union, premarket compliance for certain devices must be supported by clinical data of a type and to the extent set out by the European Union directives. When the CE mark has been placed on a medical device its manufacturer must comply with a strict vigilance system. This includes establishment of a vigilance reporting system in accordance with the Guidance provided by the European Commission, which is intended to ensure that reportable adverse events are reported to the competent authority, that information is collected and maintained and that regular reporting obligations are fulfilled.

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Other Regulation

Controlled Substances Act. Our Trigger-Lock technology is designed to control the release of narcotics and other active ingredients subject to abuse. Narcotics are "controlled substances" under the Controlled Substances Act. The federal Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, regulates the manufacture and distribution of narcotics and other controlled substances, including stimulants, depressants and hallucinogens. The CSA is administered by the Drug Enforcement Administration (DEA), a division of the U.S. Department of Justice, and is intended to prevent the abuse or diversion of controlled substances into illicit channels of commerce.

Any person or firm that manufactures, distributes, dispenses, imports, or exports any controlled substance (or proposes to do so) must register with the DEA. The applicant must register for a specific business activity related to controlled substances, including manufacturing or distributing, and may engage in only the activity or activities for which it is registered. The DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to comply with relevant DEA regulations, particularly as manifested in the loss or diversion of controlled substances, can result in regulatory action including civil penalties, refusal to renew necessary registrations, or proceedings to revoke those registrations. In certain circumstances, violations can lead to criminal prosecution. In addition to these federal statutory and regulatory obligations, there may be state and local laws and regulations relevant to the handling of controlled substances or listed chemicals.

cGMP. Current Good Manufacturing Practices (cGMP) rules apply to the manufacturing of drugs and medical devices. Our manufacturing facilities and laboratories are subject to inspection and regulation by French regulatory authorities in accordance with applicable EU provisions governing cGMP and may also be subject to the United States' and other countries' regulatory agencies. Mutual recognition agreements for government inspections exist between the United States, the European Union, Canada, Australia and New Zealand.

In addition to regulations enforced by the FDA, we are also subject to French, U.S. and other countries' rules and regulations governing permissible laboratory activities, waste disposal, handling of toxic, dangerous or radioactive materials and other matters. Our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by French, U.S. and other foreign rules and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated.

Healthcare Reimbursement

In both U.S. and foreign markets, sales of our potential products as well as products of pharmaceutical and biotechnology companies that incorporate our technology into their products, if any, will depend in part on the availability of reimbursement by third-party payers, such as government health administration authorities, private health insurers and other organizations. The U.S. market for pharmaceutical products is increasingly being shaped by managed care organizations, pharmacy benefit managers, cooperative buying organizations and large drugstore chains. Third-party payers are challenging the price and cost effectiveness of medical products and services. Uncertainty particularly exists as to the reimbursement status of newly approved healthcare products. There can be no assurance reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our product development investment. Legislation and regulations affecting the pricing of pharmaceuticals may change before our proposed products are approved for marketing and any such changes could further limit reimbursement for medical products and services.

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Competition

We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing drug delivery systems. Some of these competitors are also our business partners.

There are other companies developing sustained release drug delivery systems and oral delivery systems. There could be new chemical entities that are being developed that, if successful, could compete against our technologies or products. Among the many experimental therapies being tested in the United States and in Europe, there may be some that we do not now know of that may compete with our drug delivery systems or products in the future. These chemical entities and new products may turn out to be safer or may work better than our technologies or products. Our collaborators could choose a competing drug delivery system to use with their drugs instead of one of our drug delivery systems.

Many of our competitors have substantially greater experience and research and development, manufacturing, marketing, financial and managerial resources than we do. Moreover, there can be no assurance that our competitors will not obtain patent protection or other intellectual property rights that would make it difficult or impossible for us to compete with their products. Furthermore, acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval and gaining market share for these products more rapidly than we do.

Further, major technological changes can happen quickly in the biotechnology and pharmaceutical industries. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our drug delivery systems obsolete or noncompetitive.

Additionally, the competitive nature of our industry could adversely affect market acceptance of our products or the use of our drug delivery technologies. Our products and technologies may not gain market acceptance among physicians, patients, healthcare payers and the medical community. The degree of market acceptance of any product candidate that we develop will depend on a number of factors, including:

- demonstration of its clinical efficacy and safety;
- its cost-effectiveness;
- its potential advantage over alternative treatment methods; and
- the marketing and distribution support it receives.

Description of Property

Our corporate headquarters and the research center are located in Venissieux, France (a suburb of Lyon) in six adjacent leased facilities totaling approximately 60,000 square feet. One building of approximately 13,000 square feet houses research laboratories, including equipment dedicated to polymer characterization and analytical research. The lease on this facility will expire in 2013. A second facility comprising approximately 13,000 square feet houses equipment dedicated to our Micropump technology which expires in 2015. The third and fourth facilities of approximately 10,000 square feet combined house our administrative offices. The leases on these facilities expire in 2010 and 2013 and we expect to renew the lease that expires in 2010. The fifth facility of approximately 6,800 square feet houses analytical laboratories and quality control, with a lease expiring at the end of 2013. The sixth facility of approximately 20,000 square feet houses a biological laboratory and research laboratories with equipment for organic synthesis and polymerization, polymer formulation and small scale processing. The lease on this facility expires at the end of 2014.

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In 1996, we acquired a pharmaceutical production facility from SmithKline, which now comprises approximately 103,900 square feet of facilities located in Pessac, France. The plant is housed on a 470,000 square foot lot in an industrial park not far from the Bordeaux airport. Since acquiring the plant, we have added a new manufacturing site with spray-coating equipment and a clean room for the synthesis of biopolymers. The facility has been audited by European and U.S. drug agencies and is, we believe, cGMP compliant. It is qualified to manufacture pharmaceutical products that can be sold in most countries in Europe and the U.S. The value of the facility is recorded in our financial books at the value of the liabilities corresponding to the retirement indemnities of the plant staff that we assumed at the time of the plant purchase, plus the additional investments made by us, less the depreciation and appropriate amortization.

In 2004, we built a new facility of 16,000 square feet on our existing site in Pessac for a total purchase price of $10.3 million. This new building included 8,600 square feet for the Medusa technology with a new cGMP pilot plant, extended synthesis capacity and increased capacity to manufacture qualification and phase III lots at 10% of the commercial batch size. This facility was successfully inspected by the French Agency (AFSAPPS) in June 2008 and recorded officially as a GMP excipient manufacturing facility. We directly own this facility.

In 2006, we completed the expansion of our facilities at our site in Pessac in preparation for the manufacture of Coreg CR microparticles for GlaxoSmithKline as well as other Micropump enabled formulations. The new facility comprises 6,800 square feet and houses two suites of equipment, as well as a dedicated warehouse, analytical control laboratory and a technical area with air compressor units, refrigeration units for solvents, and heat boiler. The buildings associated with the new Micropump facility, which we own directly, were constructed at a cost of $8.2 million and has been manufacturing commercial quantities of the product since the fourth quarter of 2006. The facility is approved by U.S. and European drug agencies for production of certain pharmaceutical products, including commercial quantities of our microencapsulated drugs. Such approval qualifies us to manufacture certain approved pharmaceutical products for sale in most countries in Europe and the U.S.

In the fourth quarter of 2006, we commenced the expansion of our Micropump Pilot Development facilities at our site in Pessac, increasing the available area by 14,300 square feet and renovating a further 4,500 square feet. This expansion was completed in early 2008 for a total purchase price of $14.7 million of which a significant proportion was funded by our partner, GSK. The new facility houses administrative offices and process development areas which can be utilized for the production of both clinical and commercial batches, thus increasing our production capacity from two lines to three. We own the facility directly.

ITEM 4A. Unresolved Staff Comments

Not applicable

ITEM 5. Operating and Financial Review and Prospects

The following should be read in conjunction with 'Item 3. Key Information' and the Company's Financial Statements and the Notes related thereto appearing elsewhere in this Annual Report. See also 'Item 11. Quantitative and Qualitative Disclosures About Market Risk.'

Overview

Flamel is a biopharmaceutical company principally engaged in the development of two unique polymer based delivery systems for medical applications. Our core technologies are focused on improving delivery properties of existing products. We have established long-term development and commercialization partnerships with leading biopharmaceutical companies to maximize the breadth of our technology and leverage the capabilities of our partners.

Over the course of 2008 and 2009 we have sought to diversify our revenue stream, through additional agreements with the top pharmaceutical companies across a diverse number of domains and on both new and marketed molecules. This diversification complements the activity and revenues generated by Coreg CR and commercialized by our partner GlaxoSmithKline (GSK). The diversification of the product, project and customer portfolio is critical to our ongoing success and our goal is to maintain a fairly steady number of externally funded feasibility programs in our pipeline to replace the programs that may be licensed or which do not move forward for further development. As of 2009, revenues generated by our partner GSK amounted to 60% compared with 68% in 2008.

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Throughout 2009, our scientists have been dedicated to executing the research programs signed with our partners and fundamental research programs on which we have obtained government funding. The majority of these programs are early stage and pre-clinical programs. In 2009 Merck Serono exercised an option in a development and license agreement for a controlled release formulation of an already-marketed Merck Serono product using our Medusa technology platform and Pfizer equally executed an option to license the Medusa technology for the development of a controlled release formulation of an already-marketed protein. In addition, we have signed a number of new feasibility agreements during 2009 such that we are currently working with eight of the top twenty five pharmaceutical companies in the world, based on annual healthcare revenue, and on twenty feasibility and license and development projects across both our Medusa and Micropump technology platforms. The development and addition of a number of projects over 2009 have contributed to the increase in research and development revenues. We have had to increase our research and development expenditure in order to execute these projects in a timely manner. We expect to maintain this strategy in the future and support programs that partners decide to pursue for development, while continuing to invest in internal research programs to develop our next generation technology platforms.

Operating expenses have increased marginally in 2009. This increase was driven predominantly by an increase in research and development, which we refer to as R&D in this Form 20-F, expenditures in order to support our growing portfolio. We continue to maintain an aggressive approach to cost controls and are committed to challenging our costs on non-core activities. As projects advance to later stage development we would expect to see an ongoing increase in R&D expenditure, in line with a corresponding increase in associated revenues. Non-cash expenses relative to stock based compensation, amounted to $5.6 million in 2009 compared with $8.3 million in 2008.

As in 2008, investment in property and equipment in 2009 has been limited to small equipment required to support our research and development activities.

As in previous years, the majority of the Company’s expenses were incurred in Euros, since the Company’s base of operations is in France. However, a portion of revenues were, and will continue to be, denominated in U.S. dollars, see ‘Item 11. Quantitative and Qualitative Disclosures about Market Risk’. The Company’s functional currency is the Euro, whereas the reporting currency is the U.S. dollar. Conversion of the Company’s financial accounts to U.S. dollars for reporting purposes is calculated in accordance with the value of the Euro to the U.S. dollar. See ‘Item 3. Key Information – Exchange Rates. As such, the Financial Statements are translated as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at quarterly weighted average exchange rates for the year (3) cash flow statement quarterly weighted average exchange rates for the year, and (4) shareholders' equity accounts at historical rates. Consequently, the variation in the Euro relative to the U.S. dollar has an impact on the interpretation of the financial statements, which may differ from the underlying variations in the functional currency. For example, the weakening of the Euro relative to the U.S. dollar has resulted in a 5.3% decrease in the average value of the Euro relative to the US dollar between 2008 and 2009. However, the closing value of the Euro relative to the U.S. dollar has increased by 3.5% resulting in a corresponding increase in amounts represented in the balance sheet as of December 31, 2009, compared with December 31, 2008. The Company does not engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, although it does, from time to time, purchase Euros against invoiced dollar receivables. There is no outstanding hedging agreement as of December 31, 2009.

In certain instances we may compare expenses from one period to another in this Annual Report on Form 20-F using comparable currency exchange rates in order to assess our underlying performance before taking into account exchange fluctuations. To present this information, prior period expenses are converted into U.S. dollars at current year average exchange rates rather than exchange rates for the prior fiscal year. For example, if SG&A expenses were €9.6 million in each of fiscal year 2009 and fiscal year 2008, we would report $13.3 million of SG&A expenses in fiscal year 2009 (based on the quarterly weighted average exchange rates during 2009) and $14.1 million in fiscal year 2008. The comparable currency presentation would translate the fiscal 2008 expenses using the fiscal 2009 exchange rates and indicate that underlying expenses were flat rather than decreasing by $0.7 million, as would be reported in the financial statements under U.S. GAAP. We use figures prepared on a comparable currency basis for internal analysis and communicate similarly externally, since we believe this appropriate in order to analyze variations in expenditure from one period to another. However, figures provided on a comparable currency basis are unaudited and are not measurements under U.S. GAAP.

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Flamel's business is subject to substantial risks, including the uncertainties associated with the research and development of new products or technologies, the length and uncertainty linked to the results of clinical trials and regulatory procedures, uncertainties relating to collaborative arrangements with large companies, difficulties in the scale-up and manufacturing of its products, and the uncertainty relating to the market acceptance of new products based on its technologies. The time required for the Company to achieve sustained profitability, and consequently, the amount of future losses, is highly uncertain. Operating losses may also fluctuate from quarter to quarter as a result of differences in timing of revenues recognized or expenses incurred. See 'Item 3. Key Information - Risk Factors.'

The Company has incurred substantial losses since its inception, and through December 31, 2009, had an accumulated deficit of approximately $171.6 million. Flamel expects to maintain its investment in its research and development activities while being vigilant in ensuring that investments are limited in non-core activities. Thus, there can be no assurance that the Company will not continue to incur losses in the short term. The Company intends to pursue the strategy adopted over the last two years to maintain the pipeline of feasibility agreements. The pursuit of these agreements into full license and development agreements is dependent on decisions of our partners, which is subject to much uncertainty. We will continue to tightly control expenses and investments in non-critical areas, but as and when projects advance beyond the feasibility stage our research and development costs are expected to increase. However, our intention is for such increase to be largely financed either by our partners or either by government grants that are available to us to fund our own internal research.

Critical Accounting Policies

Revenue Recognition

Revenue includes upfront licensing fees, milestone payments for R&D achievements, and reimbursements of research and development costs. Where agreements have more than one deliverable, a determination is made as to whether the license and R&D elements should be recognized separately or combined into a single unit of account in accordance with Accounting Standards Codification 605-25 Revenue Arrangements with Multiple Deliverables. In general, the different elements of these arrangements are recognized as one unit of accounting, as the Company does not have objective and verifiable evidence of the fair value of the undelivered items in the arrangement and because of the interrelated nature of license and R&D activities.

The Company uses a Multiple Attribution Model, referred to as the milestone-based method:

- As milestones relate to discrete development steps (i.e. can be used by the co-development partners to decide whether to continue the development under the agreement), the Company views that milestone events have substance and represent the achievement of defined goals worthy of the payments. Therefore, milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations.
- Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period.
- Research and development work is compensated at a non-refundable hourly rate for a projected number of hours. Revenue on such agreements is recognized at the hourly rate for the number of hours worked as the research and development work is performed. Costs incurred under these contracts are considered costs in the period incurred. Payments received in advance of performance are recorded as deferred revenue and recognized in revenue as services are rendered.

The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured.

The Company receives royalty revenues under a license agreement with a third party that sells products based on technology developed by the Company. There are no future performance obligations on the part of the Company under this license agreement. The license agreements provide for the payment of royalties to the Company based on sales of the licensed product. The Company records these revenues based on actual sales that occurred during the relevant period and classified these revenues in 'Other Revenues'.

The Company signs feasibility study agreements. Revenue is recognized over the term of the agreement as services are performed.

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The Company receives financial support for various research and investment projects from governmental agencies. Revenue from conditional grants related to specific development projects is recognized as an offset to operating expenses when all conditions stated in the grant have been met and the funding has been received. Revenue from unconditional grants for research and development projects are recognized as an offset to research and development expense on a pro-rata basis over the duration of the program. Funding can be received to finance certain research and development projects which are repayable on commercial success of the project. In the absence of commercial success, the Company is released of its obligation to repay the funds and the funds are recognized in the Income Statement as 'Other Income'.

The Company receives financial support for capital investment programs from partners. Revenue from these operations is amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets in the consolidated statement of operations.

The Company benefits from tax credits on a percentage of eligible research and development costs. These tax credits can be refundable in cash and are not contingent upon future taxable income. As explained in note 4 to the Consolidated Financial Statements, the company determined that the research tax credit should be classified as a research and development grant and the tax credit is recognized as an offset to research and development expense.

Translation of Financial Statements

The reporting currency of the Company is the U.S. dollar and the functional currency of the Company is the Euro. As such, the Financial Statements are translated for reporting purposes as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity.

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Results of Operations

Years Ended December 31, 2009, 2008 and 2007

Operating Revenues

The Company had total revenues of $42.1million in 2009, $38.6 million in 2008 and $36.7 million in 2007.

Amounts in millions of U.S. Dollars

		2009	2008	2007
LICENSE AND RESEARCH REVENUES		**20.8**	**13.2**	**10.3**
RESEARCH		**13.6**	**9.4**	**5.5**
Research	GSK Coreg CR		1.1	1.9
	Merck Serono	5.9	2.9	
	Baxter International	0.3		
	Pfizer	0.8		
	Wyeth Pharmaceuticals	0.9	1.5	0.3
	RHEI Pharmaceuticals		0.1	0.1
	Undisclosed Partners	5.7	3.8	3.2
LICENSES		**7.2**	**3.8**	**4.8**
Up Front Payment	GSK Coreg CR			
	Merck-Serono	1.5	2.5	
	Baxter International	1.0		
	Wyeth Pharmaceuticals	0.4	0.6	0.2
	RHEI Pharmaceuticals			0.2
	Undisclosed Partners	0.2		0.4
Milestones	GSK Coreg CR	3.9		4.0
	Merck Serono		0.7	
	Undisclosed Partners	0.2		
TOTAL		**20.8**	**13.2**	**10.3**
	GSK Coreg CR	3.9	1.1	5.9
	Merck Serono	7.4	6.1	
	Baxter International	1.3		
	Pfizer	0.8		
	Wyeth Pharmaceuticals	1.3	2.1	0.5
	RHEI Pharmaceuticals		0.1	0.3
	Undisclosed Partners	6.1	3.8	3.6

In 2009, license and research revenue from the Company's various partners totalled $20.8 million. License and research revenue in 2008 and 2007 totalled $13.2 million and $10.3 million, respectively. In 2008, research and development revenue totalled $9.4 million and license revenue totalled $3.8 million. In 2007, research and development revenue totalled $5.5 million and license revenue totalled $4.8 million. License and research revenues in 2009 have grown significantly compared with 2008 as a result of the execution of additional feasibility agreements and the pursuit of our programs signed with Merck Serono, Pfizer, Baxter International and Wyeth Pharmaceuticals.

Research and development revenues in 2009 consisted primarily of $5.9 million from MerckSerono, $0.9 million from Wyeth Pharmaceuticals, $0.8 million from Pfizer and $5.7 from undisclosed partners. Research and development revenues in 2008 consisted primarily of $2.9 million from Merck Serono, $1.5 million from Wyeth Pharmaceuticals, $1.1 million from GSK and $3.8 million from undisclosed partners. Research and development revenues in 2007 consisted primarily of $1.9 million from GSK, and $3.2 million from undisclosed partners.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

License revenues in 2009 consisted primarily of a $3.9 million milestone payment from GSK, $1.5 million from Merck Serono (amortization of up-front payment) and $1 million from Baxter International (amortization of up-font payment). License revenues in 2008 consisted primarily of $3.2 million from Merck Serono (of which $2.5 million represents amortization of up-front payments) and $0.6 million from Wyeth Pharmaceuticals (amortization of up-font payment). License revenues in 2007 consisted primarily of $4.0 million from GSK following the achievement of specific milestones.

In 2009, product sales and services revenues totaled $11.9 million, $13.5 million in 2008 and $19.8 million in 2007, all of which relate to the sale of Coreg CR microparticles to GSK. Revenues from the sale of Coreg CR microparticles are determined on a cost plus basis, in accordance with the supply agreement and product requirements from GSK.

Other revenues of $9.4 million in 2009, $11.8 million in 2008 and $6.6 million in 2007 consisted primarily of royalties from GSK related to the sale of Coreg CR and to a lesser extent royalties from Corning related to the sale of photochromic lenses, incorporating Flamel's technology.

Operating Expenses

The Company had total costs and expenses of $53.9 million in 2009, $51.8 million in 2008 and $75.2 million in 2007.

As in previous years, in 2009 the majority of costs were incurred on research and development. R&D costs totaled $30.4 million in 2009, $29.3 million in 2008 and $41.3 million in 2007. At comparable exchange rates research and development costs increased by $2.6 million in 2009 compared with 2008. The increase in R&D expenses is a direct result of the pursuit of a number of projects into development phase and preparation of human trials, while maintaining a steady portfolio of feasibility projects. In order to maintain these projects and meet timelines and objectives agreed with our partners we have had to increase the number of personnel dedicated to our research activities. Research and development costs include stock based compensation expense of $2.1 million in 2009, $4.1 million in 2008 and $5.7 million in 2007.

As of December 31, 2009, Flamel had total research tax credits receivable of $11.9 million. In 2008, the Company obtained an advance secured against the tax credits generated in 2005, 2006 and 2007 for a total of $8.0 million. This advance would normally have been received as cash payments of $5.1 million in 2009, $2.5 million in 2010 and $2.4 million in 2011. In 2009, the Company received reimbursement of the 2005 tax credit for a total amount of $4.4 million and reimbursed the advance of $4.0 million. In the second quarter of 2009, subsequent to a temporary modification of the tax legislation enabling immediate reimbursement of the prior year tax credit, the Company received reimbursement of the 2008 tax credit for a total of $5.8 million. The Company earned a research and development credit of $6.6 million in 2009, $7.0 million in 2008 and $2.3 million in 2007. The Company expects to receive reimbursement of the 2009 tax credit in the first half of 2010 due to the prolongation of tax regulation enabling immediate reimbursement of the asset.

The Company has increased the number of employees dedicated to research and development activities over the course of 2009 in order to resource both license and development projects signed in 2009 and the increasing number of feasibility projects. The Company has spent almost $4.0 million on pre-clinical and clinical studies in 2009 compared with $2.4 million in 2008. This increase has been financed predominantly by partners and funding from government sources. The increase in clinical and pre-clinical costs is driven by development work related to the ongoing project with Merck Serono and cost of clinical study batches required to conduct the 12 week phase 2 clinical study on Interferon Alpha, which was initiated in December, 2009.

Costs of products and services sold were $10.1 million in 2009, $9.6 million in 2008 and $17.3 million in 2007. These costs relate solely to the supply of commercial quantities of microparticles of CoregCR to GSK and the availability of relevant production capacity. The fluctuation in costs year-to-year is the result of the variation in production requirements with 2007 representing costs associated for the supply of product in line with expected uptake of the product on launch. In 2008 and 2009, costs have declined in line with ongoing demand for the product.

Selling, general and administrative (SG&A) expenses, amounted to $13.3 million in 2009, $12.9 million in 2008 and $16.6 million in 2007. SG&A expenses included stock based compensation expense of $3.3 million in 2009, $3.7 million in 2008 and $5.8 million in 2007. SG&A expenses in 2009 have increased by $1.1million over 2008 expenses at comparable exchange rates. In 2008, SG&A costs were offset by the reversal of a provision for risk on social charges on stock options in 2008, effectively reducing SG&A by $2.0 million. On a comparable basis SG&A costs have decreased by $0.9 million in 2009 compared to 2008 as a result of continued efforts to tightly control expenses.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Non-Operating Items

Interest income and realized gains on the sale of monetary SICAVs (*Sociétés d'Investissement à Capital Variable*) were $0.4 million in 2009, $1.4 million in 2008 and $1.7 million in 2007. The decrease in interest income in 2009 is a direct result of the significant reduction in interest rates year over year despite the increase in average cash balances. Interest expense was $100,000 in 2009, $18,000 in 2008 and $16,000 in 2007 and is primarily related to the interest applicable to the Company's equipment leases and, for 2009, interest incurred on the advance received from Oseo, a French government agency, and secured against future research tax credits (see Note 12.1 to the Consolidated Financial Statements).

Foreign exchange loss for 2009 was $83,000 compared with a gain of $3,000 in 2008 and a loss of $0.5 million in 2007. These exchange gains and losses are generated by transactions denominated in foreign currency and in particular revenues denominated in USD. The variation in foreign exchange gain/loss results from the volume of operations in foreign currency and the variation in exchange rates over the year.

Other income in 2009 consisted of a number of miscellaneous items as is the case in 2008 and 2007.

Given the generation of tax losses in 2009 no income tax expense was incurred. In 2008 and 2007 withholding tax was incurred on royalty revenues received from GSK in accordance with the license agreement for a total of $0.5 million in 2008 and $0.6 million in 2007.

As of December 31, 2009, the Company had $144.0 million in French net operating loss carry-forwards. The above carry-forwards can be utilized against future operating income indefinitely.

Net Income/Loss

For the year ended December 31, 2009, the Company reported a net loss of $11.4 million or ($0.47) per share. For the year ended December 31, 2008, the Company reported a net loss of $12.1 million or ($0.50) per share. For the year ended December 31, 2007, the Company reported a net loss of $37.7 million or ($1.57) per share.

Liquidity and Capital Resources

On December 31, 2009 the Company had $8.7 million in cash and cash equivalents and $35.4 million in marketable securities as compared with $27.0 million in cash and cash equivalents and $10.1 million in marketable securities on December 31, 2008 and $26.3 million in cash and cash equivalents and $14.7 million in marketable securities on December 31, 2007. The increase in the level of cash and cash equivalents and marketable securities is a direct result of the increase in the project portfolio generating significant upfront payments including €5.0 million ($6.5 million) from Merck Serono and €2.5 million ($3.6 million) from Baxter International.

Net cash provided from operating activities was $8.2 million as of December 31, 2009 compared with net cash used in operating activities of ($7.5) million as of December 31, 2008 and ($19.2) million as of December 31, 2007. As of December 31, 2009 net cash generated in operating activities reflected a net loss of $11.4 million offset by non-cash movements of $8.9 million, including $5.9 million of depreciation on property and equipment, $5.5 million relative to stock compensation expense and $2.5 million of grants recognized to the income statement. The significant increase in cash provided from operating activities is driven by the increase in deferred revenue subsequent to upfront payments from Merck Serono for €5 million ($6.5 million) and from Baxter International for €2.5 million ($3.6 million) and the rapid reimbursement of the 2009 research tax credit for $5.8 million effectively reducing the research and tax credit receivables. The decrease in net cash used for operating activities as of December 31, 2008 compared with the period ended December 31, 2007 is principally as a result of the significant improvement in net loss, offset by the variation in working capital, this latter generating cash utilization of $9.3 million in 2008 compared with cash provided of $1.9 million in 2007.

Net cash used by investing activities was ($24.3) million in 2009 compared with net cash provided by investing activities of $0.9 million in 2008. Investing activities included proceeds from the sale of marketable securities for $161.0 million and purchase of marketable securities for $138.5 million. The increase in proceeds from sales of marketable securities results from the Company's efforts to maximize returns on available funds and as such has transferred certain investments into marketable securities rather than short term fixed deposits. A total of $1.8 million has been investment in property and equipment in 2009, for the purchase of small equipment to support ongoing research and development activities. Net cash provided by investing activities in 2008 amounted to $0.9 million and the Company invested $3.5 million in the purchase of property and equipment. Net cash used by investing activities in 2007 amounted to ($13.2) million and the Company invested $11.3 million in the purchase of property and equipment to increase production capacity from two production lines to three.

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Net cash used by financing activities was $1.6 million in 2009 and included reimbursement of the advance from Oseo of ($4.0) million, secured against the 2005 research tax credit. In 2009 grants were received from different government agencies for a total of$2.2 million. These funds were dedicated principally to investment in various research activities. Net cash provided by financing activities was $8.9 million in 2008 and included an advance of $8.5 million from Oseo secured against future research and development tax credits. In 2007, net cash provided by financing activities amounted to $3.0 million in 2007 and included $2.1 million received from GSK to sponsor part of the extension of facilities to increase production capacity from two lines to three and $0.8 million of conditional and unconditional grants received from government agencies.

Since its inception, the Company's operations have consumed substantial amounts of cash and may continue to do so in the short term. The Company believes that ongoing research and product development programs are adequately funded for the next year and believe current working capital to be sufficient for the Company's present requirements. The Company also believes current financial resources and cash from various grants, royalty payments and licenses will be sufficient to meet the Company's cash requirements in the near future. We believe the Company to have sufficient funds to finance operations and cash requirements for at least the next twelve months.

As of December 31, 2009, the Company held marketable securities classified as available-for-sale and recorded at fair value. Total marketable securities totaled $35.4 million at December 31, 2009 and $10.0 million at December 31, 2008.

As of December 31, 2009, the Company had loans of $1.70 million from Oseo, an agency of the French government that provides financing to French companies for research and development, and $2.1 million advance from the French Ministry of Industry for a 'Proteozome' research project. These loans do not bear interest and are repayable only in the event that the research is successful technically or commercially. (See Note 14 to the Consolidated Financial Statements).

In addition, in 2004, Flamel and GlaxoSmithKline entered into a four year supply agreement whereby Flamel agreed to supply GlaxoSmithKline with commercial supplies of product. The provisions of the agreement include payments to Flamel of $20.7 million to support the costs and capital expenditure relative to the creation of a manufacturing area for the production of commercial supply of the product. The capital expenditure consists of both buildings and fixtures, and production equipment. Flamel will have immediate title to the building and fixtures and title to production equipment vests with GlaxoSmithKline for the duration of the supply agreement.

If the Company breaches the supply agreement through gross negligence, GlaxoSmithKline can choose to terminate the supply agreement. The occurrence of this event is deemed remote given the Company's ability to perform under supply arrangements based on our historical experience. In the event of a breach and a decision to terminate the agreement, all payments received become repayable to GlaxoSmithKline and Flamel will receive immediate title to all production equipment.

Upon cessation of the supply agreement, in the normal course, GSK will pass title to all production equipment to Flamel without cost of any kind. The supply agreement has been extended until the end of 2010.

A total of $8.2 million has been spent on the acquisition of buildings and fixtures and a total of $11.1 million has been spent on behalf of GSK for the purchase of production equipment. All funds received for completion of the manufacturing area have been used to purchase both equipment and facilities prior to December 31, 2006. The funds received from GSK to finance the acquisition of assets owned by Flamel are classified as a current liability for $0.8 million and as a long term liability for $5.4 million. The total liability is being amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets.

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In July 2006, the supply agreement was supplemented by an agreement with GSK to partly sponsor the expansion of facilities at Pessac from two lines to three in anticipation of an expected increase in demand for the product. The provisions of the agreement include payments to Flamel of $8.1 million to partially support the acquisition of equipment, building and fixtures on which Flamel will have immediate title. GSK will have exclusive use of part of the facilities in order to meet demand requirements for a period of time. As of December 31, 2007, all installments due under the agreement were received. As of December 31, 2009 these funds are classified as a current liability for $1.3 million and as a long term liability for $4.3 million. The liability is being amortized on a pro-rata basis over the expected life of the assets and proportionally based on funding received compared with the total value of the related assets. The amortization of the liability is reflected as an offset of the depreciation of the related assets.

In December 2008, the Company obtained an advance from OSEO, a French governmental agency supporting innovation, for $8.0 million secured against research tax credits due to the Company by the tax authorities for expenditure incurred in 2005, 2006 and 2007. Two advances were obtained. The first amount of $4.3 million, and secured against the 2005 research tax credit of $5.1 million, was reimbursed in 2009. The second amounts to $3,741,000 and is secured against the research credit tax from 2006 and 2007 totaling $4,880,000. This advance matures in 2010, with a possibility to renew the financing. The interest rate applied is the monthly average of the Euro Interbank Offered Rate (EURIBOR) plus 0.8%. As of December 31, 2009 the total liability amounted to $3,872,000 of which $1,944,000 is classified as short term.

The contractual cash obligations of the Company are as follows:

	Payments Due Per Period				
(in thousands of U.S.)	**Total**	**Less than 1 year**	**1 to 3 years**	**3 to 5 years**	**More than 5 years**
Long-Term Debt Obligations (see Note 14)	$ 3,806	$ 862	$ 1,922	$ 483	$ 539
Capital Lease Obligations (see Note 15)	$ 113	$ 43	$ 70	-	-
Operating Leases Obligations (see Note 21.2)	$ 4,119	$ 1,297	$ 2,016	$ 628	$ 178
Other Long-Term Liabilities reflected on the Registrant's Balance Sheet under GAAP (see Note 19)	$ 2,208	$ 54	$ 405	$ 588	$ 1,161
Total Contractual Cash Obligations	$ 10,246	$ 2,256	$ 4,413	$ 1,699	$ 1,878

Future interest payments included in capital lease obligations amount to a total of $14,000.

Off-Balance Sheet Arrangements

As of December 31, 2009, the Company has no off-balance sheet arrangements.

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Directors and Senior Management

The following table sets forth the name and position of the directors of the Registrant as of December 31, 2009.

Name	Position	Year of Initial Appointment
Elie Vannier (1) (2)	Non-Executive Chairman of the Board of Directors	2005
Dr. Frank J.T Fildes (2) (4)	Director	2008
Frédéric Lemoine (2) (3)	Director	2005
Lodewijk J.R. de Vink (1) (3)	Director	2006
John L. Vogelstein(1) (3)	Director	2005
Stephen H. Willard (5)	Chief Executive Officer and Director	2000

(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) Member of the Nominating and Corporate Governance Committee
(4) Nominated in February 2008 in replacement of Cor Boonstra
(5) Appointed as a Director in 2001

The following table sets forth the name and position of the executive officers and senior managers of the Registrant for the year ended December 31, 2009.

Name	Position	Year of Initial Appointment
Rafael Jorda	Executive Vice President and Chief Operating Officer	1991
Jeffery S. Vick	Chief Business Officer	2009
Christian Kalita	Directeur Général Délégué Pharmacien Responsable (Chief Pharmacist)	2005
Siân Crouzet	Principal Financial Officer	2005
Yves Bourboulou	Industrial Director	2005
Martine Capelle	Human Resources Director	2006
Catherine Castan	Director of R&D Micropump	1992
You Ping Chan	Director of Chemistry Department	1992
Roger Kravtzoff	Preclinical and Early Clinical Development Director	2002
Nigel McWilliam	Director of Business Development	2005
Rémi Meyrueix	Director of Physico-Chemistry	1990
Charles Mosseri-Marlio	Director of Strategic Planning and Investor Relations	2004
Raphaëlle Portella	Legal Counsel, France	2006
David Weber	Supply Chain Director	2004

The term of office of each of the directors expires at the year 2009 ordinary shareholders meeting. With the exception of Mr. Willard, our Chief Executive Officer, all of the directors are independent as defined in NASDAQ Marketplace Rule 5605 (a)(2).

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In accordance with French law governing a *société anonyme*, the Company is managed by its Board of Directors and by its *Directeur Général* (Chief Executive Officer), who has full executive authority to manage the affairs of the Company, subject to the prior authorization of the Board of Directors or of the Company's shareholders for certain decisions expressly specified by law. In addition, the *Directeur Général* may submit to the Board of Directors the nomination of one or more, but not more than five (5) *Directeurs Généraux Délégués*.

The Board of Directors reviews and monitors Flamel's economic, financial and technical strategies. In addition, under French law, the Board of Directors prepares and presents the year-end French statutory accounts of the Company to the shareholders and convenes shareholders' meetings. French law provides that the Board of Directors be composed of no fewer than three and not more than 18 members, each of whom must be a shareholder of the Company. The actual number of directors must be within such limits and may be provided for in the *statuts, our bylaws,* or determined by the shareholders at the annual general meeting of shareholders. The number of directors may be increased or decreased only by decision of the shareholders. No more than a third of directors may be over the age of seventy.

Under French law, a director may be an individual or a legal entity. A legal entity that serves as a director must appoint an individual, as a 'permanent representative,' who represents such legal entity on the Board. There is no limitation, other than applicable age limits, on the number of terms that a director may serve. Directors are elected by the shareholders and serve until the expiration of their respective terms, or until their resignation, death or removal, with or without cause, by the shareholders. Vacancies which exist on the Board of Directors: (i) because of the resignation or death of a director, may be filled by the Board of Directors pending the next shareholders' meeting, if the number of remaining directors after such resignation or death exceeds the minimum number of directors set forth in the Articles of Association; (ii) for whatever reason, must be filled by the Board of Directors within three months of such vacancy, if the number of remaining directors after such vacancy is less than the minimum number of directors set forth in the Articles of Association but exceeds the minimum legal requirement; and (iii) for whatever reason, must be filled immediately at a shareholders' meeting if the number of directors after such vacancy is less than the minimum legal requirement.

The Company's Board of Directors currently consists of six members, five of whom are outside directors and whom we believe bring broad experience to Flamel:

- Elie Vannier, Chairman of the Board of Directors of the Company, former Group Managing Director of WALLY and former Chief Operating Officer of GrandVision SA, Director of Ingénico, Famar, Conbipel and Deputy Chairman of the Supervisory Board Groupe Loret,

- Frank Fildes, former Senior Vice President: Head of Global Development for AstraZeneca, PLC, Director of ProStrakan Group PLC and Fildes Partners Ltd, and a Fellow of the Royal Society of Medicine and the Royal Society of Chemistry.

- Frédéric Lemoine, Chairman of Executive Board of Wendel and former Chairman of the Supervisory Board of Areva; Director of Groupama, Vice-Chairman and Director of Bureau Veritas, Director of Legrand and Compagnie Saint Gobain,

- Lodewijk J.R. de Vink, former President of Schering Plough International, former Chairman and Chief Executive Officer of Warner Lambert, Inc., Director of Alcon, Roche, and member of the International Advisory Board of Sotheby's and Member of the European Advisory Council of Rothschild; and,

- John L. Vogelstein, who is former President of Warburg Pincus and a Senior Advisor of Warburg Pincus and Chairman of New Providence Asset Management; Chairman of the New York City Ballet, Chairman of Prep for Prep, Vice Chairman of the Overseers Board of The Leonard N. Stern School of Business at New York University, Chairman of Third Way, Director of the Jewish Museum.

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Board Practices

Non-executive Directors of the Company receive fees for their services and are entitled to subscribe for warrants (as described in Note 17.3 to our Consolidated Financial Statements). Directors' fees and warrants are proposed by the Board of Directors and are submitted for the approval of shareholders at the annual general shareholders' meeting. Non-executive directors are reimbursed, upon request, for expenses incurred in attending Board meetings. Upon termination, no benefits are provided to non-executive directors.

All directors are elected by the shareholders at each ordinary shareholder's meeting approving the annual French statutory accounts of the Company. A quorum of the Board consists of one-half of the members of the Board of Directors, and actions are generally approved by a vote of the majority of the members present or represented by other members of the Board of Directors. The Chairman of the Board does not have the ability to cast a deciding vote in the event of a tie vote. A director may give a proxy to another director, but a director cannot represent more than one other director at any particular meeting. Members of the Board of Directors represented by another member at meetings do not count for purposes of determining the existence of a quorum.

Directors are required to comply with applicable law and Flamel's *statuts*. Under French law, directors are liable for violations of French legal or regulatory requirements applicable to '*societes anonymes'*, violation of the Company's *statuts* or mismanagement. Directors may be held liable for such actions both individually and jointly with the other directors.

French law requires that companies having at least 50 employees for a period of 12 consecutive months have a *Comité d'Entreprise* (Employee Representation Committee) composed of representatives elected from among the personnel. The Employee Representation Committee was formed in 1997. Two of those representatives are entitled to attend all meetings of the Board of Directors of the Company and shareholder's meeting, but they do not have any voting rights.

The Board has a Compensation Committee comprised of solely independent directors, namely Lodewijk J.R. de Vink (Chairman of the Committee), John L. Vogelstein and Elie Vannier. The Compensation Committee makes recommendations to the Board on the compensation of the executive officers of the Company, including the Chief Executive Officer. The Board makes the final decisions on compensation. The Board has an Audit Committee comprised of solely independent directors, namely Frédéric Lemoine (Chairman of the Committee), Frank J.T.Fildes and Elie Vannier. The Audit Committee recommends to the Board the selection of Flamel's independent auditors and reviews the findings of the auditors and operates in accordance with the Audit Committee Charter, which is reviewed annually. The Board has a Nominating and Corporate Governance Committee, composed of solely independent directors, namely John L.Vogelstein (Chairman of the Committee), Frédéric Lemoine and Lodewijk J.R. de Vink. Each of the Compensation Committee, Audit Committee, and Nominating and Corporate Governance Committee has a written charter. The Audit Committee Charter outlines the roles and responsibilities of the Audit Committee which includes appointment, compensation and oversight of the work of any registered public accounting firm employed by the Company and review of all related party transactions. The Audit Committee also assists the Board in oversight of: (1) the integrity of the financial statements of the Company; (2) the adequacy of the Company's system of internal controls; (3) compliance by the Company with legal and regulatory requirements; (4) the qualifications and independence of the Company's independent auditors; and (5) the performance of the Company's independent and internal auditors. The Company also has an informal Scientific Advisory Board.

The Chief Executive Officer of Flamel has full executive authority to manage the affairs of Flamel and has broad powers to act on behalf of Flamel and to represent Flamel in dealings with third parties, subject only to those powers expressly reserved by law or corporate resolutions of the Board of Directors or the shareholders. The Chief Executive Officer determines, and is responsible for the implementation of the goals, strategies and budgets of Flamel, which are reviewed and monitored by the Board of Directors. The Board of Directors has the power to appoint and remove, at any time, the Chief Executive Officer.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Compensation of Directors and Officers

During 2009, the amount of compensation paid or accrued for the benefit of executive officers of the Company and its subsidiaries for services in all capacities was $893,837 for Stephen H. Willard. In the event of termination of employment of Mr Willard by the Company, other than for gross misconduct, Mr. Willard is entitled to receive an amount of $500,000. Executive directors do not receive compensation for their service in that capacity.

On June 24, 2009, a shareholders' meeting approved a total amount of annual attendance fees to be allocated to the Board of 325,000 Euros, all of which was subsequently distributed. For the fiscal year 2009 a total amount of 297,917 Euros ($415,077) was paid or accrued for the benefit of non-executives for their services in that capacity.

Senior Management and Executive Officers

The Company's senior management includes the following individuals:

Stephen H. Willard is our Chief Executive Officer and also serves on our Board of Directors. Prior to being asked to serve in his present capacity by the Board of Directors in June of 2005, Mr. Willard was Flamel's Chief Financial Officer and General Counsel. Immediately prior to joining us in August, 2000, Mr. Willard was employed as a vice president of Biovail, a pharmaceutical company. He also worked as an investment banker at Credit Suisse First Boston and as an attorney with Gibson, Dunn & Crutcher LLP and Shearman & Sterling LLP. He is a graduate of Yale Law School (1985) and Williams College (1982). He is a Director of E-Trade Financial Corporation.

Rafael Jorda is our Chief Operating Officer and Executive Vice President. Mr. Jorda joined us in 1991 and specializes in chemical engineering and in the structure-property relationships of materials. From 1986 to 1990, he worked as a research and development scientist on controlled-released and biopolymers at Rhone-Poulenc.

Jeffery S. Vick is our Chief Business Officer. Mr. Vick joined us in February 2009 and has more than 20 years experience in the business and research side of the biotechnology industry in both Europe and the US. Prior to joining Flamel, Mr. Vick was Chief Executive Officer of Silence Therapeutics. Mr. Vick previously held senior management positions with Centelion SAS, a wholly-owned subsidiary of Sanofi-Aventis; Genset SA; Cytovia, Inc; and DepoTech Corporation and worked with Sanderling Venture Capital for two years. Mr. Vick holds an MBA from Stanford, an MS Chemistry from the University of California, San Diego, and a BS Chemistry from the University of Virginia.

Christian Kalita is our Chief Pharmacist and Director of Quality Assurance and Regulatory Affairs . Mr Kalita worked previously at Skye Pharma as Director of Quality for Europe. He also worked from 1990 to 2000 for Merck Lipha and Merck generics in different roles as Chief Pharmacist, head of quality control management and Head of Industrial Affairs.

Siân Crouzet became our Principal Financial Officer in March 2008. Mrs. Crouzet previously worked as Financial Controller France for McCormick & Company Inc. She also worked five years as an external auditor with Ernst and Young. She is a UK Chartered Accountant and a graduate of Bradford University.

Yves Bourboulou is our Technical Director and Pessac Plant Director. He worked previously as Plant manager at Pharmacia and Fresenius Kabi. He previously held various senior pharmaceutical positions including as Quality assurance Director and Chief Pharmacist. He has more than 20 years experience in pharmaceutical production; quality and development.

Martine Capelle is our Human Resources Director and joined us in 2006. She previously worked for the Danone group for 15 years in different Human Resource functions and roles and prior to that she worked as Human Relations manager for two automobile plants. She is a graduate of Lyon Human Sciences University.

Catherine Castan is our R&D Oral Dosage Forms Director. Mrs. Castan joined us in 1992 after having spent four years at Sanofi Recherche. She is a graduate of Ecole Nationale Supérieure de Chimie de Montpellier and has a PHD in polymer chemistry, applied in drug delivery.

You-Ping Chan is our Chemistry Department Director. Mr. Chan received his Ph. D in Chemistry from Université Louis Pasteur, Strasbourg in 1990. After spending a year as a post-doctoral associate at the Massachusetts Institute of Technology, he joined us in 1992 as a researcher in polymer science. He currently manages research and development in the field of biocompatible polymers for drug delivery and heads the analytical research group.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Roger Kravtzoff is our Pharmaceutical Development Director. Mr. Kravtzoff received his Doctorat-es Sciences in Biochemistry from Tours University (France) in 1988 and has a broad expertise in drug delivery system. In 1985, he joined Centre Regional de Transfusion Sanguine as a research engineer, and in 1991, he became a scientist associate director in a subsidiary of the French National Blood Center, Novacell. He joined Biovector Therapeutics in 1993 and worked as a Project Director. He joined us in June 2002 and is currently managing our pre-clinical and clinical development regulatory affairs.

Nigel McWilliam is our Director of Business Development. Mr. McWilliam has a Bachelors degree in Science from the University of Dundee. He spent almost 20 years with Dow Corning Corporation's Health Care Businesses in commercial positions in Europe and the U.S. In 1993 he became President of Leiras Inc., the U.S. subsidiary of a Finnish pharmaceutical company (now part of Bayer-Schering, AG). In 1996 he was appointed CEO of Veos Ltd., then a privately held female health company, which he helped to take public on London's AIM market in 1999. Nigel moved back to the U.S. to take the position of Senior V.P. Business Development at SkyePharma in 2000. Nigel joined Flamel as Director of Business Development in Flamel's Washington office in August 2005.

Rémi Meyrueix is our Director of Physico-Chemistry. Mr. Meyrueix holds the degree of engineer in physics and a doctoral thesis in physics, which he received from the Polytechnic Institute of Grenoble in 1977 and 1980, respectively. He worked at Rhone Poulenc from 1982 to 1990 and joined us in early 1991 as a research engineer. He is now managing the Nanotechnology platform in Venissieux, France.

Charles Mosseri-Marlio is our Director of Strategic Planning and Investor Relations, having previously served as Associate General Counsel. Mr. Mosseri-Marlio joined us in 2004 after working as a portfolio manager of Baldwin Brothers, Inc, a U.S. Investment Advisory firm. Mr. Mosseri-Marlio received his JD in 1994 from the University of Colorado.

Raphaëlle Portella is our French Legal in-house Counsel and joined us in April 2006. Mrs. Portella previously worked as Head of the Corporate and Business Law Department for ADIA (Adecco Group) for almost 10 years. She graduated from Lyon University with a master (DESS) in Business Law.

David Weber is our Supply Chain Director. He has more than ten years experience in purchasing and operations management at various international companies including Garrett (Honeywell group) and Isringhausen. Before joining us he was Vice President and Cofounder of Pertinence Data Intelligence.

Options to Purchase Securities from the Company

On June 24, 2009 the shareholders of the Company authorized the issuance of up to 250,000 warrants reserved to a category of beneficiaries comprising the Directors of the Company who are not officers and/or employees of the Company, including the Chairman, of which 250,000 have been subscribed for.

On June 24, 2009 the Board of Directors authorized the Directors of the Company, Mssrs., de Vink, Fildes, Lemoine, Vannier and Vogelstein, to subscribe to 50,000 warrants each for a subscription price of 0.74 Euros per warrant ($1.03) [2]. Each warrant is exercisable to purchase one Share at a price of 4.50 Euros ($6.29)[2].

On June 24, 2009 the shareholders of the Company authorized the issuance of new shares which authorizes the Board of Directors to award and issue up to 200,000 shares free to officers and employees of the company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by the beneficiaries two years following their allocation and the beneficiaries are required to retain the shares for a further two years.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Free Share Awards Granted and Warrants Subscribed from January 1, 2009 to April 30, 2010

	Warrants	Stock Options	Exercise Price in Euros €	Exercise Price in USD $2	Expiration	Free Share Awards
Vannier	50,000		4.50	6.29	June 2013	
De Vink	50,000		4.50	6.29	June 2013	
Fildes	50,000		4.50	6.29	June 2013	
Lemoine	50,000		4.50	6.29	June 2013	
Vogelstein	50,000		4.50	6.29	June 2013	
Autant						3,000
Bardet						2,500
Bonnet-Gonnet						3,000
Borel						2,500
Bourboulou		5,000	5.06	7.46	December 2019	10,000
Boutherin-Falson						3,000
Capelle						6,000
Castan		5,000	5.06	7.46	December 2019	6,000
Chan		5,000	5.06	7.46	December 2019	8,000
Commaret						3,000
Constancis						4,000
Crouzet		10,000	5.06	7.46	December 2019	12,000
Fernandez						6,000
Franoux						3,000
Gorria						4,000
Guest						3,000
Jorda		75,000	5.06	7.46	December 2019	25,000
Kalita		5,000	5.06	7.46	December 2019	8,000
Kravtzoff		10,000	5.06	7.46	December 2019	10,000
Lemercier						3,000
Marlio						6,000
McWilliam		10,000	5.06	7.46	December 2019	10,000
Meyrueix		5,000	5.06	7.46	December 2019	9,000
Nicolas						4,000
Portella						6,000
Prevot						2,500
Pouliquen						3,000
Vialas						4,500
Vick		100,000	4.03	5.17	December 2018	25,000
						10,000
Weber						6,000
Willard		100,000	5.06	7.46	December 2019	45,000

(2) Historical value at date of grant

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Employees

As of December 31, 2009, Flamel had 302 full-time employees. The following table sets forth the number of employees for each of the last three years based in their principal geographic locations.

Employees

	Venissieux (1)	Pessac (2)	U.S. (3)	Total
Year End				
2007	130	168	4	302
2008	130	151	3	284
2009	150	149	3	302

(1) Primarily engaged in research activities
(2) Primarily engaged in technical and pharmaceutical development activities and manufacturing
(3) Primarily engaged in administrative and marketing activities

The Company's future will depend on its ability to attract and retain highly qualified personnel. The Company believes that its employee relations are good. As required by French law, the Company has created an Employee Representation Committee ('*Comite d'Entreprise'*) composed of representatives elected from among the personnel. Two of these representatives are entitled to attend certain meetings of the Board of Directors of the Company, but they do not have any voting rights.

Share Ownership

The following table sets forth the share ownership of directors, executive officers and senior managers as of the date indicated:

OWNERSHIP OF SHARES AS OF APRIL 30, 2010

Name	Shares Owned	% of Ordinary Shares Outstanding	Warrants	Number of Options	Exercise Price in Euros €	Exercise Price in USD (2) $	Expiration	Free Share Awards	Total	Total %
Vannier	1	0.00%	25,000		20.54	27.83	May 2010			
			50,000		6.57	10.20	June 2012			
			50,000		4.5	6.29	June 2013		125,001	0.44%
De Vink	1	0.00%	25,000		20.54	27.83	May 2010			
			50,000		6.57	10.20	June 2012			
			50,000		4.5	6.29	June 2013		125,001	0.44%
Fildes	1	0.00%	50,000		6.57	10.20	June 2012			
			50,000		4.5	6.29	June 2013		100,001	0.35%
Lemoine	1	0.00%	25,000		20.54	27.83	May 2010			
			50,000		6.57	10.20	June 2012			
			50,000		4.5	6.29	June 2013		125,001	0.44%
Vogelstein	100,001	0.41%	25,000		20.54	27.83	May 2010			
			50,000		6.57	10.20	June 2012			
			50,000		4.5	6.29	June 2013		225,001	0.79%
Willard	125,001	0.51%		40,000	6.4	4.99	December 2010			
				25,000	6.4	5.73	December 2010			
				30,000	1.09	0.99	September 2011			
				195,000	2.33	2.04	March 2012			
				200,000	4.32	4.62	March 2013			
				100,000	20.81	25.27	December 2013			
				150,000	14.81	19.70	December 2014			
				100,000	16.23	19.35	December 2015			
				100,000	25.39	33.46	December 2016			
				75,000	4.03	5.17	December 2018			
				100,000	5.06	7.46	December 2019	85,000	1,325,001	4.63%

(2) Historical value at date of grant

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Name	Shares Owned	% of Ordinary Shares Outstanding	Warrants	Number of Options	Exercise Price in Euros €	Exercise Price in USD (2) $	Expiration	Free Share Awards	Total	Total %
Bourboulou	10,000	0.04%		50,000	13.08	17.49	May 2015			
				20,000	12.86	15.83	September 2015			
				6,500	25.39	33.46	December 2016			
				5,000	5.06	7.46	December 2019	17,000	108,500	0.38%
Capelle	6,800	0.03%		25,000	13.97	17.65	June 2016			
				3,750	25.39	33.46	December 2016	11,000	46,550	0.16%
Castan	9,000	0.04%		3,000	1.09	0.99	September 2011			
				5,000	9.88	11.66	June 2013			
				40,000	20.81	25.27	December 2013			
				20,000	12.86	15.83	September 2015			
				20,000	16.23	19.35	December 2015			
				6,000	25.39	33.46	December 2016			
				5,000	5.06	7.46	December 2019	11,000	119,000	0.42%
Chan	9,300	0.04%		5,000	9.88	11.66	June 2013			
				20,000	12.86	15.83	September 2015			
				20,000	16.23	19.35	December 2015			
				4,500	25.39	33.46	December 2016			
				5,000	5.06	7.46	December 2019	13,000	76,800	0.27%
Crouzet	6,810	0.03%		49,990	12.86	15.83	September 2015			
				5,000	16.23	19.35	December 2015			
				3,750	25.39	33.46	December 2016			
				10,000	5.06	7.46	December 2019	19,750	95,300	0.33%
Fernandez	2,800	0.01%		25,000	4.11	4.15	December 2012			
				5,000	9.88	11.66	June 2013			
				20,000	12.86	15.83	September 2015			
				5,000	16.23	19.35	December 2015			
				3,750	25.39	33.46	December 2016	11,000	72,550	0.25%
Jorda	20,369	0.08%		20,000	2.78	2.49	December 2011			
				5,000	9.88	11.66	June 2013			
				60,000	14.81	19.70	December 2014			
				105,000	12.86	15.83	September 2015			
				75,000	16.23	19.35	December 2015			
				60,000	25.39	33.46	December 2016			
				50,000	4.03	5.17	December 2018			
				75,000	5.06	7.46	December 2019	45,000	515,369	1.80%
Kalita	5,000	0.02%		50,000	16.23	19.35	December 2015			
				6,500	25.39	33.46	December 2016			
				5,000	5.06	7.46	December 2019	15,000	81,500	0.28%
Kravtzoff	3,300	0.01%		5,000	9.88	11.66	June 2013			
				30,000	12.86	15.83	September 2015			
				20,000	16.23	19.35	December 2015			
				4,500	25.39	33.46	December 2016			
Lundstrom		0.00%		100,000	16.56	20.40	June 2016		100,000	0.35%
McWilliam		0.00%		100,000	12.86	15.83	September 2015			
				5,000	16.23	19.35	December 2015			
				10,000	25.39	33.46	December 2016			
				10,000	5.06	7.46	December 2019	20,000	145,000	0.51%
Meyrueix	5,525	0.02%		40,000	4.87	4.65	April 2010			
				40,000	2.78	2.49	December 2011			
				5,000	9.88	11.66	June 2013			
				40,000	14.81	19.70	December 2014			
				30,000	12.86	15.83	September 2015			
				20,000	16.23	19.35	December 2015			
				7,250	25.39	33.46	December 2016			
				5,000	5.06	7.46	December 2019	14,000	206,775	0.72%
Marlio	1,700	0.01%		50,000	19.2	23.61	March 2014			
				10,000	12.86	15.83	September 2015			
				5,000	16.23	19.35	December 2015			
				2,250	25.39	33.46	December 2016	11,000	79,950	0.28%
Portella	2,000	0.01%		2,750	25.39	33.46	December 2016	9,000	13,750	0.05%
Weber	2,000	0.01%		50,000	12.02	14.81	September 2014			
				2,750	25.39	33.46	December 2016	9,000	63,750	0.22%

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

ITEM 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth as of April 30, 2010, the percentage of Ordinary Shares owned by O.S.S. Capital Management LP, BVF, Inc.and Visium Asset Management LP, the persons each known to beneficially own more than 5% of the Company's Ordinary Shares. The table set forth below is based on information contained in Schedule 13/Ds or 13/Gs on file with the SEC. Percentages are calculated based on the total number of shares outstanding as of April 30, 2010: 24,422,600.

Identity of Person or Group	Amount of Ordinary Shares Owned	Percentage of Class
BVF, Inc.	3,538,774(1)	14.49%
O.S.S. Capital Management LP	3,200,000(2)	13.10%
Visium Asset Management LP	1,850,516(3)	7.58%

(1) Information as to the amount and nature of beneficial ownership was obtained from the Schedule 13G/A filed with the SEC on February 10, 2010 by Biotechnology Value Fund, L.P. ("BVF"). As of the close of business on December 31, 2009, (i) BVF beneficially owned 775,319 ADRs, (ii) Biotechnology Value Fund II, L.P. ("BVF2") beneficially owned 537,935 ADRs, (iii) BVF Investments, L.L.C. ("BVLLC") beneficially owned 2,011,308 ADRs and (iv) Investment 10, L.L.C. ("ILL10") beneficially owned 214,212 ADRs. BVF Partners L.P. ("Partners"), as the general partner of BVF and BVF2, the manager of BVLLC and the investment adviser of ILL10, may be deemed to beneficially own the 3,538,774 ADRs beneficially owned in the aggregate by BVF, BVF2, BVLLC and ILL10. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the 3,538,774 ADRs beneficially owned by Partners. Mr. Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 3,538,774 ADRs beneficially owned by BVF Inc. The address of BVF is 900 N. Michigan Avenue, Suite 1100, Chicago, IL 60611.

(2) Information as to the amount and nature of beneficial ownership was obtained from the Schedule 13G filed with the SEC on March 31, 2010 by O.S.S. Capital Management LP ("OCM"). OCM shares beneficial ownership with Oscar S. Schafer & Partners I LP in respect of 209,827 Ordinary Shares, Oscar S. Schafer & Partners II LP in respect of 1,796,744 Ordinary Shares, O.S.S. Overseas Fund Ltd. in respect of 1,111,348 Ordinary Shares, O.S.S. Advisors LLC in respect of 2,006,571 Ordinary Shares and Schafer Brothers LLC and Oscar S. Schafer in respect of all 3,200,000 Ordinary Shares. Additionally, Mr. Oscar S. Schafer beneficially owns 50,000 shares over which he has sole voting and dispositive power. The address of OCM is 605 Third Ave, New York NY 10158.

(3) Information as to the amount and nature of beneficial ownership was obtained from the Schedule 13G filed with the SEC on April 9, 2010 by Visium Asset Management, LP ("VAM"), which reports dispositive power over 1,850,516 Ordinary Shares. Visium Balanced Master Fund, LTD, JG Asset, LLC and Jacob Gottlieb share dispositive power over the 1,850,516 Ordinary Shares held by VAM. The address for VAM is 950 Third Avenue, 29th Floor, New York, New York 10022.

The Company's major shareholders do not have different voting rights. To the best of our knowledge, Flamel Technologies is not directly or indirectly owned or controlled by another corporation, by any government, or by any other natural or legal person. We are not aware of any arrangement that may at a subsequent date result in a change of control. As of April 30, 2010, the Company has 183 Ordinary shareholders of record including the Bank of New York. Approximately 98.7% of the Company's outstanding shares are represented by American Depositary Shares (ADS). 1.24% of the Ordinary Shares are held in France. One record holder resides in France.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Significant changes in the percentage ownership held of record by any of our major shareholders in the last three years, as reported to the SEC, were as follows:

Major Shareholder	Filing Date	Ownership Percentage
BVF, Inc.	January 24, 2008	10.12%
BVF Partners L.P.	October 17, 2008	18.99%
	February 2, 2009	15.88%
	February 10, 2010	14.49%
O.S.S. Capital Management LP	February 14, 2007	17.60%
Schafer Brothers LLC	August 31, 2007	26.12%
Oscar S. Schafer	February 22, 2010	23.52%
	March 31, 2010	13.10%
Visium Asset Management L.P.	April 9, 2010	7.58%
Knoll Capital Management L.P.	February 11, 2008	9.27%
Fred Knoll	February 17, 2009	5.22%
	January 29, 2010	3.61%
Greenlight Capital Management	February 14, 2008	7.84%
	February 13, 2009	0.00%
Silver Point Capital L.P.	October 29, 2007	5.20%
	February 14, 2008	6.23%
	February 17, 2009	0.00%

B. Related Party Transactions

For the year ended December 31, 2009, and as of April 30, 2010, the Company is not aware of any related party transaction requiring disclosure pursuant to this section.

C. Interests of Experts and Counsel

Not applicable

ITEM 8. Financial Information

Financial Statements

The financial statements contained in this Annual Report begin on page F-1.

Legal Proceedings

While we may be engaged in various claims and legal proceedings in the ordinary course of business, we are not involved (whether as a defendant or otherwise) in and we have no knowledge of any threat of, any litigation, arbitration or administrative or other proceeding which management believes will have a material adverse effect on our consolidated financial position or results of operations.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

On November 9, 2007 a putative class action was filed in the United States District Court for the Southern District of New York against the Company and certain of its current and former officers entitled *Billhofer v. Flamel Technologies, et al*. The complaint purports to allege claims arising under the Securities Exchange Act of 1934 based on certain public statements by the Company concerning, among other things, a clinical trial involving Coreg CR and seeks the award of damages in an unspecified amount. By Order dated February 11, 2008, the Court appointed a lead plaintiff and lead counsel in the action. On March 27, 2008, the lead plaintiff filed an amended complaint which continued to name as defendants the Company and two previously named officers and asserted the same claims based on the same events as alleged in the initial complaint. On May 12, 2008, the Company filed a motion to dismiss the action, which the Court denied by Order dated October 1, 2009. The action is now in the discovery phase pursuant to a schedule approved by the Court in a Case Management Order, signed December 9, 2009. The Company intends to vigorously defend itself in the action. Neither of the two individual defendants named in the amended complaint have been served in the action.

On August 27, 2007, a New York court denied Flamel U.S. jurisdiction in a lawsuit filed against Gérard Soula by the Company. This decision has not had and is not expected to have a materially adverse effect upon the Company.

Dividend Policy

The Company has never declared or paid a cash dividend on any of its capital stock and does not anticipate declaring cash dividends in the foreseeable future.

ITEM 9. The Offer and Listing

The principal trading market for the Company's securities in ADSs is the NASDAQ National Market. Each ADS represents one Share, nominal value 0.122 Euros. Each ADS is evidenced by an ADR. The Bank of New York is the Depositary for the ADRs. As of December 31, 2009, there were 24,021,939 ADSs outstanding in the United States. At such date, there were 34 holders of ADSs on record. As of December 31, 2009, there were 24,342,600 Shares outstanding.

The following table shows the high and low closing sales prices of the ADSs on the NASDAQ Market for the periods indicated.

	Price Per ADS (U.S.$)	
Year	**High**	**Low**
2005	21.37	12.25
2006	34.88	16.7
2007	36.97	8.17
2008	10.80	3.68
2009	9.67	3.99

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Quarter Ended	Price Per ADS (U.S.$) High	Low
1st Quarter, 2007	36.97	25.60
2nd Quarter, 2007	29.87	20.97
3rd Quarter, 2007	24.39	8.99
4th Quarter, 2007	12.03	8.17
1st Quarter, 2008	10.65	8.38
2nd Quarter, 2008	10.80	9.18
3rd Quarter, 2008	10.06	7.20
4th Quarter, 2008	7.25	3.68
1st Quarter, 2009	6.77	3.99
2nd Quarter, 2009	7.00	5.84
3rd Quarter, 2009	9.67	7.00
4th Quarter, 2009	9.49	7.00
1st Quarter, 2010		

Month Ended	Price Per ADS (U.S.$) High	Low
November 30, 2009	9.01	7.05
December 31, 2009	8.04	7.00
January 31, 2010	8.85	7.515
February 28, 2010	8.6	7.58
March 31, 2010	7.58	9.60
April 30, 2010	9.06	8.52

ITEM 10. Additional Information

Memorandum and Articles of Association

For a general description of these documents, see 'Description of Share Capital' in the Company's registration statement on Form F-1, as filed with the U.S. Securities and Exchange Commission on April 19, 1996, registration number 333-03854, which is incorporated by reference. There have been no changes to these documents. No more than a third of Directors may serve over the age of seventy.

Ownership of Shares by Non-European Union Persons

A 'declaration administrative' or administrative declaration is required in The Republic of France to be filed with the French Ministry of the Economy, Finance and the Budget at the time of the acquisition of a controlling interest in Flamel by any non-EU resident or group of non-EU residents acting in concert or by any EU resident controlled by a non-EU resident. With respect to the acquisition (by a EU resident or a non-EU resident) of a controlling interest in a company that could affect 'public health,' the administrative declaration is replaced by a procedure that requires prior declaration of the acquisition to the French Ministry of Economy, Finance and the Budget with the ability for such Ministry to oppose the investment during a one-month period. As it is a pharmaceutical company, the acquisition of a controlling interest in Flamel could be deemed to affect 'public health.'

Under existing administrative rulings, ownership of 20% or more of a listed company's share capital is regarded as a controlling interest, but a lower percentage may be held to be a controlling interest in certain circumstances (such as when the shareholder has the ability to elect members of the board of directors). No administrative declaration is required where an EU resident or group of EU residents acts in concert to acquire a controlling interest in Flamel provided that the acquiring party or parties satisfy the requirements of EU residency.

Under French law, there is no limitation on the right of non-resident or foreign shareholders to vote securities of a French company.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Material Contracts

The Company has no material contracts on file with the SEC.

Exchange Controls

The payment of any dividends to foreign shareholders must be effected through an authorized intermediary bank. All registered banks and credit establishments in the Republic of France are authorized intermediaries. Under current French exchange control regulations, there are no limitations on the amount of cash payments that may be remitted by Flamel to residents of the United States. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an authorized intermediary bank.

Taxation

The following is a description of certain French and U.S. federal tax consequences of owning and disposing of Flamel Ordinary Shares or Flamel ADSs. This description may only be relevant to holders of Flamel Ordinary Shares or Flamel ADSs who are not residents of France and do not hold their shares in connection with a permanent establishment or a fixed base in France through which the holders carry on a business or perform personal services.

This description may not address all aspects of French tax laws that may be relevant in light of the particular circumstances of individual holders of Flamel Ordinary Shares or Flamel ADSs. It is based on the applicable tax laws, regulations and judicial decisions as of the date of this annual report, and on the Convention between the United States of America and the Republic of France for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income and Capital dated as of August 31, 1994 entered into force on December 30, 1995, and the 2004 Protocol amending the Treaty which entered into force on December 21, 2006, all of which are subject to change, possibly with retroactive effect, or different interpretations. On January 13, 2009, the United States and France signed an additional Protocol (the "*New Protocol*") amending the Treaty. This discussion also takes into account the New Protocol entered into force on December 23, 2009. The New Protocol enters into force with respect to taxes withheld at source on January 1, 2009 and with respect to all other taxes on January 1, 2010. This discussion refers to the treaty between the United States and France described above, the Protocol, and the New Protocol together as the 'Treaty'.

The following description of tax consequences should be considered only as a summary and does not purport to be a complete analysis of all potential tax effects of the purchase or ownership of the Flamel Ordinary Shares or Flamel ADSs. This summary does not address all potential tax implications that may be relevant as a holder, in light of particular circumstances.

Tax Consequences to Non-U.S. Holders The following discussion applies to holders of Flamel Ordinary Shares that are not 'U.S. Holders,' as defined below. Holders of Flamel Ordinary Shares should consult their tax advisor concerning the French tax consequences.

Taxation on Sale or Disposal of Flamel Ordinary Shares

Generally, a holder of Flamel Ordinary Shares will not be subject to any French income tax or capital gains tax when the holder sells or disposes of Flamel Ordinary Shares if both of the following apply:

- the holder is not a French resident for French tax purposes;
- the holder has held not more than 25% of Flamel's dividend rights, known as droits aux bénéfices sociaux, at any time during the preceding five years, either directly or indirectly; and
- Flamel is not considered as a real estate company

If a double tax treaty between France and the country of residence of a holder of Flamel Ordinary Shares contains more favorable provisions, a holder may not be subject to any French income tax or capital gains tax when the holder sells or disposes of any Flamel Ordinary Shares, even if one or both of the above statements does not apply to the holder.

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Subject to various conditions, foreign states, international organizations and a number of foreign public bodies are not considered as French residents for these purposes.

Transfers of a listed company's shares will not be subject to French registration or transfer taxes, unless the transfer is effected by means of a written agreement that is executed within France. Should such written agreement be executed within France, a registration duty of 3% on the higher of either the purchase price or the market value of the transferred shares would be due, with a maximum duty of €5,000 per transaction.

Taxation of Dividends

In France, companies may only pay dividends out of income remaining after tax has been paid.

a) French Resident Individuals

French resident individuals receiving dividends are entitled to (i) a 40% rebate applied to the gross amount of the dividends received meaning that dividends are assessed to income tax at progressive rate (with a maximum rate of 40%) but only for 60% of their amount and (ii) an additional annual tax allowance *(abattement fixe annuel)* equal to €1,525 for single individuals or married persons subject to separate taxation and €3,050 for married couples and members of a union agreement subject to joint taxation[2], and (iii) a tax credit (*crédit d'impôt*)[3] equal to 50% of the dividends received, but with an overall annual cap of €230 for married couples and members of a union agreement subject to joint taxation or, €115 for single individuals or married persons subject to separate taxation.

As from January 1 2008, there is also an option to subject dividends to a final levy at a rate of 18% (in practice, 30.1% after taking into account the 12.1% social taxes including the newly enacted contribution *Revenu de Solidarité Active* applicable since January 1st, 2009).

b) Non-Residents

French companies must, in principle, deduct a 25% withholding tax from dividends paid to non-residents. As from January 1, 2008, the rate of this withholding tax has been reduced to 18% for dividends paid to EU, Norway and Iceland residents.

In addition, the French Amended Finance Bill for 2009 provides for new anti-avoidance rules regarding transactions concluded with non-cooperative jurisdictions. As a consequence, dividends distributed to non-cooperative jurisdictions residents as of March 1, 2010, as per the criteria defined by the French tax code, would be subject to a 50% withholding tax.

Under most tax treaties between France and other countries, the rate of this withholding tax may be reduced or eliminated in some circumstances. Generally, if dividends are subject to a French withholding tax, a holder who is a non-French resident is subsequently entitled to a tax credit in that holder's country of residence for the amount of tax actually withheld.

However, France has entered into tax treaties with various countries under which qualifying residents are entitled to obtain from the French tax authorities a reduction (generally to 15% or 5%) or an elimination of the French withholding tax.

According to the French tax guidelines 5 I-2-06 dated January 12, 2006, non-French resident individual shareholders who are currently benefiting from a treaty providing for the transfer of the abolished *avoir fiscal* will benefit from the above-mentioned *crédit d'impôt* capped at €230 or €115 depending on the marital status of this shareholder in respect of dividends paid as from January 1, 2005.

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[2] This annual tax allowance would be applied after the 40% rebate.
[3] This tax credit should be applied after the above mentioned 40% rebate and annual allowance.

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The following countries, French overseas territories, known as Territoires d'Outre-Mer, and other territories have entered into income tax treaties with France that provide for the transfer of the *crédit d'impôt* (referred to in the tax treaties as *avoir fiscal*):

Australia	Ghana	Malaysia	Niger	Togo
Austria	Iceland	Mali	Norway	Turkey
Belgium	India	Malta	Pakistan	Ukraine
Bolivia	Israel	Mauritius	Saint-Pierre et Miquelon	United Kingdom
Brazil	Italy	Mayotte	Senegal	United States
Burkina Faso	Ivory Coast	Mexico	Singapore	Venezuela
Canada	Japan	Namibia	South Korea	
Estonia	Latvia	Netherlands	Spain	
Finland	Lithuania	New Caledonia	Sweden	
Gabon	Luxembourg	New Zealand	Switzerland	

Except for the United States, none of the countries or territories listed above has a Treaty granting benefits to holders of Flamel ADSs, as opposed to Ordinary Shares. Accordingly, this discussion of treaty benefits does not apply to Flamel ADS holders. If these arrangements apply to a shareholder, Flamel will withhold tax from the dividend at the lower rate, provided that the shareholder has established, before the date of payment of the dividend, that the shareholder is entitled to the lower rate and has complied with the filing formalities. Otherwise, Flamel must withhold tax at the full rate of 25% (for other than European Union, Iceland, or Norway residents) or 18% (for European Union, Iceland, or Norway residents), and the shareholder may subsequently claim the excess tax paid.

Estate and Gift Tax

France imposes estate and gift tax on shares of a French company that are acquired by inheritance or gift, this tax applying without regards to the residence of the transferor. However, France has entered into estate and gift tax treaties with certain countries pursuant to which, provided that certain conditions are met, residents of the treaty country may be exempt from such tax or obtain a tax credit.

Non-residents should consult their own tax advisors whether French estate and gift tax would apply to them and whether they might be able to claim an exemption or tax credit pursuant to an applicable tax treaty.

Wealth Tax

French individual residents are taxable on their worldwide assets. Non-resident individuals may be subject to French wealth tax (*impôt de solidarité sur la fortune*) only on their assets which are located in France. However, financial investments made by non-resident individuals, other than in real estate companies, are exempt from wealth taxes as long as the individuals own less than 10% of the French company's capital stock, either directly or indirectly, provided that their shares do not enable them to exercise influence on the French company.

Even if these conditions are not satisfied, a non-French resident holder may be exempt from French wealth tax if such holder is entitled to more favourable provisions pursuant to a double tax treaty between France and the holder's country of residence.

Tax Consequences to U.S. Holders

The following is a summary of the principal U.S. federal income tax considerations that are likely to be material to the ownership and disposition of Flamel Ordinary Shares or Flamel ADSs by a U.S. Holder. A "U.S. Holder" is a beneficial owner of the Flamel Ordinary Shares or Flamel ADSs who is (i) an individual citizen or resident of the United States; (ii) a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof; (iii) an estate whose income is includible in gross income for United States federal income tax purposes regardless of its source; or (iv) a trust whose administration is subject to the primary supervision of a United States court and over which one or more United States persons have the authority to control all substantial decisions of the trust. If an entity that is treated as a partnership for United States federal income tax purposes holds Flamel Ordinary Shares or Flamel ADSs, the tax treatment of a partner of such partnership will generally depend on the status of the partner and upon the activities and organization of the partnership. If you are a partner of such a partnership you are urged to consult your tax advisor. This discussion does not apply to a U.S. Holder who is also a resident of France for French tax purposes.

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This summary is based in part upon the representations of the custodian and the assumption that each obligation in the Depositary Agreement with the Bank of New York relating to our ADRs and any related agreement will be performed in accordance with its terms.

The following is a general summary of the principal tax effects on U.S. Holders for purposes of U.S. federal income tax and French tax, if all of the following four points apply:

- the U.S. Holder owns, directly, indirectly, or constructively, less than 10% of Flamel's share capital;
- the U.S. Holder is entitled to the benefits of the Treaty (including under the 'limitations on benefits article of the Treaty);
- the U.S. Holder holds Flamel Shares as capital assets; and
- the U.S. Holder's functional currency is the U.S. dollar.

For purposes of the Treaty and the U.S. Internal Revenue Code of 1986, Holders of Flamel ADSs will be treated as the owner of the Flamel Ordinary Shares represented by such ADSs.

Special rules may apply to United States expatriates, insurance companies, pass-through entities and investors in such entities, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, securities broker-dealers and persons holding their Flamel Ordinary Shares or Flamel ADSs as part of a conversion transaction, among others. Those special rules are not discussed in this annual report.

Holders of Flamel Ordinary Shares or Flamel ADSs should consult their own tax advisers as to the particular tax consequences to them of owning Flamel Ordinary Shares or Flamel ADSs, including their eligibility for benefits under the Treaty, the applicability and effect of U.S. federal, state, local, foreign and other tax laws and possible changes in tax law.

Taxation of Dividends

Withholding Tax Dividends paid to non-residents by French companies are subject to an 25% French withholding tax. Under the Treaty, this withholding tax is reduced to 15% if a U.S. Holder's ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base that the U.S. Holder has in France.

Dividends paid to a U.S. Holder by French companies are immediately subject to a reduced rate of 15%, provided that such U.S. Holder establishes before the date of payment that he is a U.S. resident under the Treaty by completing and providing the depositary with a simplified certificate (the "*Certificate*") in accordance with the French tax guidelines (4 J–1-05 released on February 25, 2005). Dividends paid to a U.S. Holder that has not filed the Certificate before the dividend payment date will be subject to French withholding tax at the rate of 25%. The tax withheld in excess of 15% can be reclaimed, provided that such U.S. Holder duly completes and provides the French tax authorities with the relevant form described in the tax guidelines mentioned above (the "*Form*") before December 31 of the second calendar year following the year during which the dividend is paid. U.S. Pension Funds and other Tax-Exempt Entities are subject to the same general filing requirements as the U.S. Holders except that they may be required to supply additional documentation evidencing their entitlement to these benefits.

The Certificate and the Form, together with instructions, will be provided by the depositary to all U.S. Holders registered with the depositary. The depositary will arrange for the filing with the French Tax authorities of all Certificates properly completed and executed by U.S. Holders of Shares and returned to the depositary in sufficient time that they may be filed with French Tax authorities before the distribution so as to obtain an immediate reduced withholding tax rate.

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U.S. individual holders, who are residents of the United States for purposes of the Treaty, may also claim the *crédit d'impôt* capped at €230 or €115 depending on the marital status of this taxpayer, after application of the 15% withholding tax. This specific provision applies to any of the following U.S. Holders (if the ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base that the U.S. Holder has in France):

- the U.S. Holder is an individual or other non-corporate holder that is a resident of the United States for purposes of the Treaty;
- the U.S. Holder is a U.S. corporation, other than a regulated investment company;
- the U.S. Holder is a U.S. corporation which is a regulated investment company, provided that less than 20% of the U.S. Holder's shares are beneficially owned by persons who are neither citizens nor residents of the United States; or
- the U.S. Holder is a partnership or trust that is a resident of the United States for purposes of the Treaty, but only to the extent that the U.S. Holder's partners, beneficiaries or grantors would qualify as 'eligible' under one of the first two points in this list.

U.S. Income Tax. For U.S. federal income tax purposes, the gross amount of a dividend and any *crédit d'impôt* (referred to in the Treaty as *avoir fiscal*), including any French tax withheld, will be included in each U.S. Holder's gross income as dividend income when payment is received by them (or the custodian, if the U.S. Holder owns Flamel ADSs), to the extent they are paid or deemed paid out of Flamel's current or accumulated earnings and profits as calculated for U.S. federal income tax purposes. Dividends paid by Flamel will not give rise to any dividends received deduction. They will generally constitute foreign source 'passive' income for foreign tax credit purposes. For certain recipients, as a general matter, dividends will constitute foreign source 'general' income with respect to dividends received after December 31, 2006, or 'financial services' income with respect to dividends received before January 1, 2007, in either case for foreign tax credit purposes.

Under current U.S. federal tax law, amounts distributed as dividends by Flamel with respect to Flamel Shares or Flamel ADSs paid to you in taxable years beginning before January 1, 2011will be eligible to be treated as "qualified dividend income" that is subject to a U.S. federal income tax at the same preferential rates as long-term capital gains, provided that certain minimum holding period and other requirements are met and Flamel is not treated as a PFIC (as defined below under the section titled "*PFIC Status*").

Also for U.S. federal income tax purposes, the amount of any dividend paid in Euros, including any French withholding taxes, will be equal to the U.S. dollar value of the Euro on the date the dividend is included in income, regardless of whether the payment is in fact converted into U.S. dollars. A U.S. Holder will generally be required to recognize U.S. source ordinary income or loss when the U.S. Holder sells or disposes of the Euros. A U.S. Holder may also be required to recognize foreign currency gain or loss if that U.S. Holder receives a refund under the Treaty of tax withheld in excess of the Treaty rate. This foreign currency gain or loss will generally be U.S. source ordinary income or loss.

To the extent that any dividends paid exceed Flamel's current and accumulated earnings and profits as calculated for U.S. federal income tax purposes, the distribution will be treated as follows:

- First, as a tax-free return of capital, which will cause a reduction in the adjusted basis of a U.S. Holder's Flamel Ordinary Shares or Flamel ADSs. This adjustment will increase the amount of gain, or decrease the amount of loss, which a U.S. Holder will recognize if such U.S. Holder later disposes of those Flamel Ordinary Shares or Flamel ADSs, as the case may be.
- Second, the balance of the dividend in excess of the adjusted basis will be taxed as capital gain recognized on a sale or exchange.

French withholding tax imposed on the dividends a U.S. Holder receives and on any *crédit d'impôt* (referred to in the Treaty as *avoir fiscal*) at 15% under the Treaty generally is treated as payment of a foreign income tax. A U.S. Holder may take this amount as a credit or deduction against the U.S. Holder's U.S. federal income tax liability. The foreign tax credit is subject to various conditions and limitations, including minimum holding period requirements. Special rules apply in determining the foreign tax credit limitation with respect to dividends that are subject to the maximum 15% tax rate.

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To the extent a refund of French tax withheld with respect to dividends (including *crédit d'impôt* (referred to in the Treaty as *avoir fiscal*)) is available under the Treaty or under French law, the amount of tax withheld that is refundable will not be eligible for credit against your U.S. federal income tax liability.

Taxation of Capital Gains

French Tax. A U.S. Holder who is a resident of the United States for purposes of the Treaty will not be subject to French tax on any capital gain if such U.S. Holder sells or exchanges its Flamel Ordinary Shares or Flamel ADSs, unless the U.S. Holder has a permanent establishment or fixed base in France and the Flamel Ordinary Shares or Flamel ADSs the U.S. Holder sold or exchanged were attributable to that permanent establishment or fixed base. Special rules apply to individuals who are residents of more than one country.

U.S. Income Tax. In general, for U.S. federal income tax purposes, a U.S. Holder will recognize capital gain or loss if the U.S. Holder sells or exchanges its Flamel Ordinary Shares or Flamel ADSs. Any such gain or loss generally will be U.S. source gain or loss. If a U.S. Holder is an individual, any capital gain will generally be subject to U.S. federal income tax at preferential rates if the U.S. Holder meets applicable minimum holding period requirements.

PFIC Status. Flamel believes that it will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes, for the current taxable year or for future taxable years. However, an actual determination of PFIC status is factual and cannot be made until the close of the applicable taxable year. Flamel will be a PFIC for any taxable year in which either:

- 75% or more of its gross income is passive income; or
- its assets which produce passive income or which are held for the production of passive income amount to at least 50% of the value of its total assets on average.

If Flamel were to become a PFIC, the tax consequences applicable to distributions on Flamel Ordinary Shares and Flamel ADSs, and any gains a U.S. Holder realizes when the U.S. Holder disposes of such Flamel Ordinary Shares or Flamel ADSs, may be less favorable to the U.S. Holder. In addition, a U.S. Holder would be required to file Form 8621 with respect to its interest in Flamel. Each U.S. Holder should consult its own tax advisors regarding the PFIC rules and their effect on the U.S. Holder if they purchase Flamel Ordinary Shares or Flamel ADSs.

French Estate and Gift Taxes

Under 'The Convention Between the United States of America and the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritance and Gifts of November 24, 1978,' if a U.S. Holder transfers their Flamel Shares by gift, or if they are transferred by reason of the U.S. Holder's death, that transfer will only be subject to French gift or inheritance tax if one of the following applies:

- the U.S. Holder is domiciled in France at the time of making the gift, or at the time of the U.S. Holder's death; or
- the U.S. Holder used the Flamel Shares in conducting a business through a permanent establishment or fixed base in France, or the U.S. Holder held the Flamel Shares for that use.

French Wealth Tax

The French wealth tax does not generally apply to Flamel Shares if the U.S. Holder is a 'resident' of the United States for purposes of the Treaty. It will be the case if the Flamel U.S. Holder does not own a substantial interest (*participation substantielle)*. Pursuant to article 23 §2 of the Treaty, "an individual is considered to have a substantial interest if he or she owns, alone or with related persons, directly or indirectly, shares, rights, or interests the total of which gives right to at least 25% of the corporate earnings".

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Health Care and Reconciliation Act of 2010

The Health Care and Reconciliation Act of 2010 requires that, in certain circumstances, certain U.S. Shareholders that are individuals, estates, and trusts pay a 3.8% tax on "net investment income," which includes, among other things, dividends on and gains from the sale or other disposition of stock, effective for taxable years beginning after December 31, 2012. Prospective investors should consult their own tax advisors regarding this new legislation.

United States Information Reporting and Backup Withholding

Dividend payments made by us to a U.S. Holder in respect of Flamel Ordinary Shares or Flamel ADSs and proceeds from the sale or disposal of a U.S. Holder's Flamel Ordinary Shares or Flamel ADSs may be subject to information reporting to the Internal Revenue Service.

U.S. federal backup withholding generally is a withholding tax (currently imposed at a rate of 28%) on some payments to persons that fail to furnish required information. Backup withholding will not apply to a U.S. Holder who furnishes a correct taxpayer identification number or certificate of foreign status and makes any other required certification, or who is otherwise exempt from backup withholding. Any U.S. persons required to establish their exempt status generally must file Internal Revenue Service Form W-9, entitled Request for Taxpayer Identification Number and Certification. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability. A U.S. Holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information within the appropriate amount of time.

Recently Enacted Legislation Related to Disclosure of Information with Respect to Foreign Financial Assets

Recently enacted legislation in the U.S. requires a U.S. Holder that holds an interest in "specified foreign financial assets" to disclose information to the IRS related to these holdings. These new disclosure requirements are effective for taxable years beginning after March 18, 2010, and apply for any year in which the aggregate value of all such holdings is greater than $50,000. For these purposes, "specified foreign financial assets" may include (i) depository or custodial account maintained by foreign financial institutions and foreign investment vehicles, (ii) interests in, or securities issued by, non-U.S. persons, and (iii) other financial instruments or contracts held for investment where the issuer or counterparty is a non-U.S. person. In addition, a U.S. Holder may be required to furnish information to avoid a presumption that the aggregate value of the U.S. Holder's holdings of specified foreign financial assets is in excess of $50,000. A U.S. Holder who fails to comply with these requirements may be subject to penalties. As is common with new legislation, the application of these requirements in any particular circumstance may not be entirely clear. Investors should consult their own tax advisors regarding the effect of this legislation in their particular circumstances.

Documents on Display

Flamel is subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and, in accordance with those requirements, files reports and other information with the U.S. Securities and Exchange Commission. Copies of reports and other information, when so filed, may be inspected free of charge and may be obtained at prescribed rates at the public reference facility maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. You may also access documents filed with the SEC at its website www.sec.gov. Certain of the reports that the Company files with the Commission may be available from time to time on the Company's internet website, at www.flamel.com. Flamel is not incorporating the contents of its or the SEC's websites or the website of any other person into this document.

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ITEM 11. Quantitative and Qualitative Disclosures About Market Risk

The Company conducts a portion of its business transactions in U.S. dollars. For the year ended December 31, 2009 revenues denominated in U.S. dollars represented 36.0% of total revenues. As a result, the Company's financial results could be significantly affected by the fluctuation of the Euro relative to the U.S. dollar. Specifically, 27.8% of the Company's cash and cash equivalents, totalling $2.4 million as of December 31, 2009, and all of the Company's marketable securities, totalling $35.4 million, as of December 31, 2009, are denominated in Euros, as are the vast majority of the Company's expenses. If the dollar were to strengthen by 10% versus the Euro, there would be a corresponding negative effect on these items of $3.4 million in our balance sheet. Conversely, if the dollar were to weaken by 10% versus the Euro, there would be a positive effect on these items of $4.2 million in our balance sheet. See 'Item 5. Operating and Financial Review and Prospects - Overview.'

The Company is not exposed to interest rate risk.

ITEM 12. Description of Securities Other Than Equity Securities

ITEM 12.A Debt Securities

Not applicable.

ITEM 12.B Warrants and Rights

Not applicable.

ITEM 12.C Other Securities

Not applicable.

ITEM 12.D American Depositary Shares

Charges of Depositary

The Company will pay fees, reasonable expenses and out-of-pocket charges of the depositary and those of any registrar only in accordance with agreements in writing entered into between the Depositary and the Company from time to time. The following charges shall be incurred by any party depositing or withdrawing shares or by any party surrendering receipts or to whom receipts are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by the Company or an exchange of stock regarding the receipts or deposited securities or a distribution of receipts pursuant to the terms of the deposit agreement):

- taxes and other governmental charges
- any applicable registration or transfer fees
- any cable, telex and facsimile transmission charges as provided in the deposit agreement
- any expenses incurred in the conversion of foreign currency
- $5.00 (or less) per 100 ADSs (or portion thereof) for the execution and delivery of Receipts and surrender of receipts
- $0.02 or less per ADS (or portion thereof) for any cash distribution pursuant to the deposit agreement
- $1.50 or less per certificate for a receipt or transfer of a receipt
- A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

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PART II

ITEM 13. Defaults, Dividend Arrearages and Delinquencies

There has not been any material default with respect to any indebtedness of the Company.

ITEM 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

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ITEM 15. Controls and Procedures

Disclosure Controls and Procedures

The Company's Chief Executive Officer and Principal Financial Officer have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2009. Based on this evaluation, the Chief Executive Officer and Principal Financial Officer of the Company concluded that the Company's disclosure controls and procedures were effective as of December 31, 2009.

Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting that occurred during the Company's fiscal year ended December 31, 2009 that has materially affected, or is reasonable likely to materially affect, the Company's internal control over financial reporting.

Management Report on Internal Control over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) of the Company.

The internal control over financial reporting at the Company was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America;
- provide reasonable assurance that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2009. Management based this assessment on criteria for effective internal control over financial reporting described in "Internal Control – Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management determined that, as of December 31, 2009, the Company maintained effective internal control over financial reporting. Management reviewed the results of its assessment with the Audit Committee of the Board of Directors.

Attestation report of registered public accounting firm

The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers, an independent registered accounting firm, as stated in their report on the Company's internal control over reporting as of December 31, 2009, which is included herein.
See report of PricewaterhouseCoopers, an independent registered accounting firm, included within the financial statements on page F-2.

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ITEM 16. [Reserved]

ITEM 16A. Audit Committee Financial Expert

The Board has determined that Elie Vannier and Frédéric Lemoine are 'audit committee financial experts,' as defined by the rules of the SEC. Messrs Vannier and Lemoine are 'independent' as defined by the NASDAQ Marketplace Rules.

ITEM 16B. Code of Ethics

The Board adopted a written Code of Ethics which applies to the Chief Executive Officer, Chief Operating Officer and senior financial officers. The principles set forth in our Code of Ethics are intended to promote the honest and ethical conduct of our principal executive officer, the principal financial officer, the principal accounting officer or controller, or persons performing similar functions. The Code of Ethics was filed as exhibit 11.1 to our annual report on Form 20-F for the year ended December 31, 2003, on April 26, 2004.

ITEM 16C. Principal Accountant Fees and Services

The following is a summary of the fees billed to Flamel by PricewaterhouseCoopers for professional services rendered for the fiscal years ended December 31, 2009 and 2008:

Fee Category	Fiscal 2009 Fees (Euros)	Fiscal 2008 Fees (Euros)
Audit Fees	198,000	199,800
Audit-Related Fees	10,500	9,500
Tax Fees	-	
All Other Fees	-	0
Total Fees	**208,500**	**209,300**

All fees were billed in Euros. Using the average exchange rate of 1.393265 U.S dollars per Euro for 2009 and 1.47059 U.S dollars per Euro for 2008, audit fees equaled $290,496 for Fiscal 2009 and $307,794 for Fiscal 2008.

Audit Fees. Consists of fees billed for professional services rendered for the audit of the Company's consolidated financial statements, review of the interim consolidated financial statements included in quarterly reports and review of internal controls over Financial Reporting.

Audit-Related Fees. Consists of fees billed for assurance and related services by the principal accountant that are reasonably related to the performance of the audit or review of Flamel's consolidated financial statements.

Tax Fees. Consists of fees billed for professional services for tax compliance, tax advice and tax planning.

All Other Fees. There were no fees billed for professional services in fiscal years 2009 and 2008 that are not included in one of the above categories.

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Audit Committee's Pre-Approval Policies and Procedures

Our Audit Committee nominates and engages our independent auditors to audit our financial statements. See also 'Item 6. Directors, Senior Management and Employees – Board Practices – Committees of the Board of Directors.' In 2005, our Audit Committee adopted a revised policy requiring management to obtain the Committee's approval before engaging our independent auditors to provide any other audit or permitted non-audit services to us or our subsidiaries. Pursuant to this policy, which is designed to assure that such engagements do not impair the independence of our auditors, the Audit Committee annually pre-approves, in accordance with an audit plan, specific audit and non-audit services in the categories Audit Service, Audit-Related Services, Tax Consulting Services, and Other Services that may be performed by our auditors. All of the fees to the principal accountants were approved by the Audit Committee pursuant to paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X in 2005. Our Principal Financial Officer reviews all individual management requests to engage our auditors as a service provider in accordance with this policy and, if the requested services are permitted pursuant to the audit plan approved by the Audit Committee and are less than €10,000, approves the request accordingly. In the event of a request for services pursuant to the audit plan in excess of €10,000 and less than €20,000, the Chairman of the Audit Committee approves the request. Any services in excess of €20,000 are to be pre-approved by the Audit Committee. We inform the Audit Committee about all approvals made by the Principal Financial Officer or Chairman of the Audit Committee at the following Audit Committee meeting. The chairman of our Audit Committee is not permitted to approve any engagement of our auditors if the services to be performed either fall into a category of services that are not permitted by applicable law or the services would be inconsistent with maintaining the auditors' independence.

ITEM 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

ITEM 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable**.**

ITEM 16F. Change in Registrant's Certifying Accountant

Not applicable**.**

ITEM 16G. Corporate Governance

The Company is exempt from NASDAQ's quorum requirements applicable to meetings of shareholders. In keeping with French law and generally accepted business practices in France, the presence in person or by proxy of shareholders having not less than 20% (in case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 25% (in the case of an extraordinary general meeting) of the Shares is necessary for a quorum. If a quorum is not present at any meeting, the meeting is adjourned. Upon recommencement of an adjourned meeting, there is no quorum requirement in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves. The presence in person or by proxy of shareholders having not less than 20% of the Shares is necessary for a quorum in the case of any other type of extraordinary general meeting.

The Company also has been granted an exemption from former NASDAQ Marketplace Rule 4350(g), now Rule 5620 (b). The French Commercial Code does not require that we solicit or provide proxy statements for meetings of shareholders. In accordance with the French Commercial Code and our *statuts,* we inform shareholders of all meetings in a public notice, which notice states the requirements for admission to the meeting. Meeting the Nasdaq requirement to solicit proxies and provide proxy statements for shareholder meetings would be contrary to accepted business practice in France.

All Related Party Transactions are reviewed by the Board of Directors as part of French Legal requirements and documented, audited and approved by the shareholders at each ordinary shareholder's meeting approving the annual French statutory accounts of the Company.

Under French law, the committees of our Board of Directors are advisory only, and where the Nasdaq requirements would vest certain decision-making powers with specific committees by delegation (e.g., nominating or audit committees), our Board of Directors remains under French law the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the shareholder meeting of the Company that is competent to appoint our auditors upon the proposal of our Board of Directors.

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In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option plans or other share capital increases, whether for the benefit of top management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As a 'foreign private issuer' under the U.S. securities laws, our Chief Executive Officer and our Principal Financial Officer issue the certifications required by §302 and §906 of the Sarbanes Oxley Act of 2002 on an annual basis (with the filing of our annual report on U.S. Form 20-F) rather than on a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on U.S. Form 10-Q.

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PART III

ITEM 17. Financial Statements

Not applicable. See 'Item 18. Financial Statements.'

ITEM 18. Financial Statements

The following financial statements, together with the reports of Independent registered accounting firm thereon, are filed as part of this Annual Report:

Reports of independent registered public accounting firms	F-2
Consolidated Balance Sheets as of December 31, 2008 and 2009	F-4
Consolidated Statement of Operations for the Years Ended December 31, 2007, 2008 and 2009	F-5
Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2007, 2008 and 2009	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2007, 2008 and 2009	F-7
Notes to Consolidated Financial Statements	F-8

See pages F-1 through F-31 incorporated herein by reference

The registrant undertakes to provide to each shareholder requesting the same a copy of each exhibit referred to herein upon payment of a reasonable fee limited to the registrant's reasonable expenses in furnishing such exhibit.

ITEM 19. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
1.1	Revised *Statuts* or bylaws of the Company (Filed herewith)
2.1	Deposit Agreement among Flamel, The Bank of New York, as Depositary, and holders from time to time of American Depositary Shares issued thereunder (including as an exhibit the form of American Depositary Receipt) (1)
8.1	List of Subsidiaries (Filed herewith)
11.1	Code of Ethics for CEO (Directeur Général), Delegated Managing Directors (Directeurs Generaux Delegues) and Senior Financial Officers (2)
12.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
12.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
13.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
13.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
23.1	Consent of PricewaterhouseCoopers Audit (Filed herewith)
23.2	Consent of Ernst & Young Audit (Filed herewith)

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(1) Incorporated by reference to Post-Effective Amendment No. 1 to the Company's registration statement on Form F-6 filed July 26, 2001, as amended (No. 333-12790).
(2) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2003, filed on April 26, 2004.

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FLAMEL TECHNOLOGIES S.A.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm, PricewaterhouseCoopers Audit	F-2
Report of Independent Registered Public Accounting Firm, Ernst & Young Audit	F-3
Consolidated Balance Sheets as of December 31, 2008 and 2009	F-4
Consolidated Statements of Operations for the Years Ended December 31, 2007, 2008 and 2009	F-5
Consolidated Statements of Shareholders' Equity for the years Ended December 31, 2007, 2008 and 2009	F-6
Consolidated Statements of Cash flows for the Years Ended December 31, 2007, 2008 and 2009	F-7
Notes to Consolidated Financial Statements	F-8

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Flamel Technologies SA and its subsidiary at December 31, 2009 and 2008, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2009 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting, appearing on page 67 of the 2009 Annual Report to Shareholders. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation.

Our audits of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Lyon, France, May 7, 2010

PricewaterhouseCoopers Audit

Represented by
Bernard Rascle

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders,

We have audited the accompanying consolidated statements of operations, shareholders' equity and cash-flows of Flamel Technologies S.A. for the year ended December 31, 2007. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statements presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows of Flamel Technologies S.A. for the year ended December 31, 2007 in conformity with U.S. generally accepted accounting principles.

Lyon, France

May 7, 2008

ERNST & YOUNG Audit

Represented by
Jean-Luc Desplat

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FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of dollars except share data)

	Note	December 31, 2008	December 31, 2009
ASSETS			
Current assets:			
Cash and cash equivalents	6	$ 27,021	$ 8,716
Marketable securities	7	10,057	35,352
Accounts receivable (net of allowance of $147 and $152 at December 31, 2008 and 2009 respectively)		6,979	8,675
Inventory	8	1,837	1,072
Research and development tax credit receivable current portion	18	11,114	9,400
Prepaid expenses and other current assets	9	2,181	3,626
Total current assets		59,189	66,841
Property and equipment, net	10	27,601	24,759
Other assets:			
Research and development tax credit receivable less current portion	18	4,880	2,484
Other long-term assets		191	212
Total assets		$ 91,861	$ 94,296
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Current portion of long-term debt	14	684	862
Current portion of capital lease obligations	15	69	33
Accounts payable		5,760	6,366
Current portion of deferred revenue	13	798	3,862
Advances from customers		587	851
Accrued expenses	11	5,905	6,318
Other current liabilities	12	6,452	4,604
Total current liabilities		20,255	22,896
Long-term debt, less current portion	14	2,269	2,944
Capital lease obligations, less current portion	15	96	66
Deferred revenue, less current portion	13	201	6,033
Other long-term liabilities	12 - 19	20,494	17,494
Total long-term liabilities		23,060	26,537
Commitments and contingencies:		-	-
Shareholders' equity :	17		
Ordinary shares: 24,205,350 issued and outstanding at December 31, 2008 and 24,342,600 at December 31, 2009 (shares authorised 28,713,090) at nominal value of 0.122 euro		3,516	3,540
Additional paid-in capital		193,085	198,498
Accumulated deficit		(160,205)	(171,644)
Accumulated other comprehensive income		12,150	14,469
Total shareholders' equity		48,546	44,863
Total liabilities and shareholders' equity		$ 91,861	$ 94,296

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FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands of dollars except share data)

	Note	Year ended December 31, 2007	2008	2009
Revenue:				
License and research revenue	3	$ 10,307	$ 13,247	$ 20,815
Product sales and services	2	19,768	13,549	11,871
Other revenues		6,579	11,823	9,432
Total revenue		36,654	38,619	42,118
Costs and expenses:				
Cost of products and services sold		(17,320)	(9,621)	(10,118)
Research and development		(41,269)	(29,269)	(30,416)
Selling, general and administrative		(16,626)	(12,911)	(13,337)
Total		(75,215)	(51,801)	(53,871)
Income (loss) from operations		(38,561)	(13,182)	(11,753)
Interest expense		(16)	(18)	(100)
Interest income		1,691	1,432	525
Foreign exchange gain (loss)		(454)	3	(83)
Other income		197	181	(28)
Income (loss) before income taxes		(37,143)	(11,584)	(11,439)
Income tax	18	(594)	(500)	
Net income (loss)		$ (37,737)	$ (12,084)	$ (11,439)
Earnings (loss) per share				
Basic earnings (loss) per share		$ (1.57)	$ (0.50)	$ (0.47)
Diluted earnings (loss) per share	16	$ (1.57)	$ (0.50)	$ (0.47)
Weighted average number of shares outstanding (in thousands) :				
Basic		24,024	24,082	24,225
Diluted		24,024	24,082	24,225

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FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(Amounts in thousands of dollars except share data)

	Ordinary Shares		Additional Paid-in	Accumulated	Accumulated Other Comprehen-sive Income	Shareholders'
	Shares	Amount	Capital	Deficit	(Loss)	Equity
Balance at January 1, 2007	23,990,590	$ 3,480	$ 173,479	$ (110,384)	$ 6,451	$ 73,026
Subscription of warrants			362			362
Issuance of ordinary shares on exercise of stock -options	61,000	10	197			207
Stock-based compensation expense			11,135			11,135
Net loss				(37,737)		(37,737)
Unrealized losses on available- for-sale securities					17	17
Foreign currency translation adjustment					7,617	7,617
Comprehensive loss						$ (30,103)
Balance at December 31, 2007	24,051,590	$ 3,490	$ 185,173	$ (148,121)	$ 14,085	$ 54,627
Subscription of warrants			354			354
Issuance of ordinary shares on exercise of stock -options	55,010	10	176			186
Issuance of ordinary shares on vesting of free shares (note 17.5)	98,750	16	(16)			-
Stock-based compensation expense			7,398			7,398
Net loss				(12,084)		(12,084)
Foreign currency translation adjustment					(1,935)	(1,935)
Comprehensive loss						$ (14,019)
Balance at December 31, 2008	24,205,350	$ 3,516	$ 193,085	$ (160,205)	$ 12,150	$ 48,546
Subscription of warrants			262			262
Issuance of ordinary shares on exercise of stock -options	20,000	3	26			29
Issuance of ordinary shares on vesting of free shares (note 17.5)	117,250	21	(21)			-
Stock-based compensation expense			5,146			5,146
Net loss				(11,439)		(11,439)
Foreign currency translation adjustment					2,319	2,319
Comprehensive loss						$ (9,120)
Balance at December 31, 2009	24,342,600	$ 3,540	$ 198,498	$ (171,644)	$ 14,469	$ 44,863

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FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of dollars except share data)

	Year ended December 31,		
	2007	2008	2009
Cash flows from operating activities:			
Net income (loss)	$ (37,737)	$ (12,084)	$ (11,439)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation of property and equipment	6,198.0	7,249	5,917
Loss (gain) on disposal of property and equipment	(39.0)	-	-
Gains on sales of marketable securities	(318.0)	(327)	(153)
Grants recognized in other income and income from operations	(1,216.0)	(1,360)	(2,522)
Stock compensation expense	12,004.0	8,286	5,499
Provision for losses on accounts receivable	-	-	-
Increase (decrease) in cash from:			
Accounts receivable	1,167.0	(2,392)	(1,257)
Inventory	1,818.0	(171)	909
Prepaid expenses and other current assets	2,054.0	492	(1,722)
Research and development tax credit receivable	(1,648.0)	(1,494)	4,064
Accounts payable	(3,023.0)	(258)	32
Deferred revenue	2,421.0	(2,226)	8,251
Accrued expenses	(9.0)	282	453
Other current liabilities	547.0	(1,644)	2,251
Other long-term assets and liabilities	(1,460.0)	(1,861)	(2,088)
Net cash used in operating activities	(19,241)	(7,508)	8,195
Cash flows from investing activities:			
Purchases of property and equipment	(11,272)	(3,523)	(1,770)
Proceeds from disposal of property and equipment	47	-	-
Proceeds from sales of marketable securities	94,707	75,216	138,476
Purchase of marketable securities	(96,713)	(70,782)	(160,968)
Net cash provided by (used in) investing activities	(13,231)	911	(24,262)
Cash flows from financing activities:			
Funding from partner GSK	2,056	-	-
Reimbursment of loans or conditional grants	-	-	(3,999)
Proceeds from loans or conditional grants	839	8,467	2,191
Principal payments on capital lease obligations	(441)	(272)	(67)
New capital lease obligation	-	147	-
Cash proceeds from issuance of ordinary shares and warrants	569	540	291
Net cash provided by financing activities	3,023	8,882	(1,584)
Effect of exchange rate changes on cash and cash equivalents	3,935	(1,577)	(654)
Net increase (decrease) in cash and cash equivalents	(25,515)	708	(18,305)
Cash and cash equivalents, beginning of year	51,827	26,313	27,021
Cash and cash equivalents, end of year	$ 26,312	$ 27,021	$ 8,716
Supplemental disclosures of cash flow information:			
Income tax paid	-	-	-
Interest paid	16	18	100
Non cash transactions:			
Capital lease obligations incurred	-	124	-

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1. Nature of business and summary of significant accounting policies:

1.1. Nature of business:

Flamel Technologies, S.A. (the "Company") is organized as a *société anonyme*, a form of corporation under the laws of The Republic of France. The Company was founded in 1990. The Company is engaged in the development of advanced polymer technologies for unique life science applications. The Company operates primarily in France.

1.2. Principles of consolidation:

The accompanying consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP).

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The accompanying consolidated financial statements include the Company and its wholly-owned subsidiary in the United States. All inter-company accounts and transactions have been eliminated.

1.3. Financial Accounting Standards Board Accounting Standards Codification:

Effective July 1, 2009, the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) became the authoritative source of GAAP. All existing FASB accounting standards and guidance were superseded by the ASC. Instead of issuing new accounting standards in the form of statements, staff positions and Emerging Issues Task Force abstracts, the FASB now issues Accounting Standards. Updates that update the Codification Rules and interpretive releases of the Securities and Exchange Commission (“SEC”) under authority of federal securities laws continue to be additional sources of authoritative GAAP for SEC registrants.

1.4. Translation of financial statements of foreign entities and foreign currency transactions:

The reporting currency of the Company and its wholly-owned subsidiary is the U.S. dollar as permitted by the SEC for a foreign private issuer (S-X Rule 3-20(a)). All assets and liabilities in the balance sheets of the Company, whose functional currency is the Euro, except those of the U.S. subsidiary whose functional currency is the U.S. dollar, are translated into U.S. dollar equivalents at exchange rates as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity.

Transaction gains and losses are reflected in the statement of operations.

The Company has not undertaken hedging transactions to cover its currency translation exposure.

1.5. Revenue recognition:

Revenue includes upfront licensing fees, milestone payments for R&D achievements, and reimbursements of research and development costs. Where agreements have more than one deliverable, a determination is made as to whether the license and R&D elements should be recognized separately or combined into a single unit of account in accordance with Accounting Standards Codification 605-25, Revenue Arrangements with Multiple Deliverables. In general, the different elements of these arrangements are recognized as one unit of accounting, as the Company does not have objective and verifiable evidence of the fair value of the undelivered items in the arrangement and because of the interrelated nature of license and R&D activities.

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The Company uses a multiple attribution model, referred to as the milestone-based method:

- As milestones relate to discrete development steps (i.e. can be used by the co-development partners to decide whether to continue the development under the agreement), the Company views that milestone events have substance and represent the achievement of defined goals worthy of the payments. Therefore, milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations.
- Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period.
- Research and development work is compensated at a non-refundable hourly rate for a projected number of hours. Revenue on such agreements is recognized at the hourly rate for the number of hours worked as the research and development work is performed. Costs incurred under these contracts are considered costs in the period incurred. Payments received in advance of performance are recorded as deferred revenue and recognized in revenue as services are rendered.

The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured.

The Company receives royalty revenues under a license agreement with a third party that sells products based on technology developed by the Company. There are no future performance obligations on the part of the Company under this license agreement. The license agreements provide for the payment of royalties to the Company based on sales of the licensed product. The Company records these revenues based on actual sales that occurred during the relevant period and classified these revenues in ‘Other Revenues’.

The Company signs feasibility study agreements. Revenue is recognized over the term of the agreement as services are performed.

1.6. Governmental Grants:

The Company receives financial support for various research or investment projects from governmental agencies.

The Company recognizes conditional grants related to specific development projects conditioned on completion of investment program and ongoing employment at the facilities as an offset to operating expenses once all conditions stated in the grant have been met.

The Company recognizes unconditional grants for research and development (R&D) projects requiring the collaboration of both private and public research partners as an offset to R&D expense on a pro-rate basis over the duration of the program.

The Company receives funds to finance R&D projects. These funds are repayable on commercial success of the project. In the absence of commercial success, the Company is released of its obligation to repay the funds and as such the funds are recognized in the Income Statement as ‘Other Income’.

1.7. 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.

The Company does not disclose research development costs per partner funded contract and does not believe such disclosure would be material to investors.

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1.8. Concentration of credit risk:

The Company's cash and cash equivalents are deposited with HSBC, Crédit Lyonnais and Crédit Agricole, major banks.

The marketable securities are issued by institutions with strong credit ratings.

The Company's revenues are derived mainly from collaborative research and development contracts and supply agreements with pharmaceutical companies based in Europe and the United States. All significant customers are discussed in Note 3.

The Company performs ongoing credit evaluations of its customers and maintains provisions for potential credit losses as considered necessary. The Company generally does not require collateral. Historically, the Company has not experienced significant credit losses on its customer accounts. The allowance for doubtful accounts was $126,000 $147,000 and $152,000 at December 31, 2007, 2008 and 2009, respectively.

1.9. Earnings per share:

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted earnings per share reflects potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company. The dilutive effects of the Company's common stock options and warrants is determined using the treasury stock method to measure the number of shares that are assumed to have been repurchased using the average market price during the period, which is converted from U.S. dollars at the average exchange rate for the period. Such securities are not considered in computing diluted loss per share as their effects would be anti-dilutive.

1.10. Cash and cash equivalents:

Cash and cash equivalents consist of cash on hand, cash on deposit and fixed term deposit being highly liquid investments with a maturity of three months or less at the date of purchase.

1.11. Marketable securities:

Marketable securities consist of highly liquid investments in money market mutual funds. Marketable securities are classified as available-for-sale securities in accordance with ASC 320-10, "Accounting for Certain Investments in Debt and Equity Securities" These investments are recorded at fair value, which is based on quoted market prices. Accordingly, unrealized gains and losses are included in accumulated other comprehensive income until realized.

1.12. Accounts Receivable:

Accounts receivable are stated at amounts invoiced net of allowances for doubtful accounts**.** The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for the portion of receivables deemed uncollectible. Provision is made based upon a specific review of all significant outstanding invoices.

1.13. Inventories:

Inventories consist principally of raw materials and finished products, which are stated at the lower of cost or market value with cost determined under the first-in, first-out ("FIFO") method. Raw materials used in the production of pre-clinical and clinical products are expensed as research and development costs when consumed. The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow-moving on a case by case basis, equal to the difference between the cost of inventory and estimated market value based upon assumptions about future demand, technology and market conditions.

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1.14. Property and equipment:

Property and equipment is stated at historical cost less accumulated depreciation. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Land and buildings	20 years
Laboratory equipment	4 - 8 years
Office and computer equipment	3 years
Furniture, fixtures and fittings	5-10 years

Assets under capital leases are amortized over the economic lives of the assets. Amortization of the carrying value of assets under capital leases is included in depreciation expense.

1.15. Impairment of Long-Lived Assets:

The Company reviews the carrying value of its long-lived assets, including fixed assets and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. Recoverability of long-lived assets is assessed by a comparison of the carrying amount of the asset (or the group of assets, including the asset in question, that represents the lowest level of separately-identifiable cash flows) to the total estimated undiscounted future cash flows expected to be generated by the asset or group of assets. If the future net undiscounted cash flows is less than the carrying amount of the asset or group of assets, the asset or group of assets is considered impaired and an expense is recognized equal to the amount required to reduce the carrying amount of the asset or group of assets to its then fair value. Fair value is determined by discounting the cash flows expected to be generated by the asset, when the quoted market prices are not available for the long-lived assets. Estimated future cash flows are based on management assumptions and are subject to risk and uncertainty.

1.16. Income taxes:

The Company accounts for income taxes in accordance with ASC 740. Under ASC 740, deferred tax assets are determined based on the difference between the financial reporting and tax basis of assets and liabilities, applying enacted statutory tax rates in effect for the year in which the tax differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in the tax laws and rates on the date of enactment.

1.17. Employee stock options and warrants:

The Company accounts for Stock based compensation based on grant-date fair value estimated in accordance with SAB 107, SAB 110 (ASC 505, ASC 718)
The Company estimated the fair value of stock options and warrants using a Black-Scholes option-pricing valuation model ("Black-Scholes model").
The Company uses a simplified method to estimate the maturity. The Company considered historical data was insufficient and irrelevant relative to the grant of stock-options and warrants to a limited population and the simplified method was used to determine the expected term for stock-options and warrants granted.

The Company recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

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1.18. Comprehensive Income:

Other comprehensive income for the Company consists both of foreign currency translation adjustments and the recognition of the unrealized gains (losses) related to available-for-sale securities. Each item is shown separately in the consolidated statements of shareholders' equity.

1.19. Recent Accounting Pronouncements:

In October 2009, the FASB issued a new accounting standard which amends guidance on accounting for revenue arrangements involving the delivery of more than one element of goods and/or services. This standard addresses the unit of accounting for arrangements involving multiple deliverables and removes the previous separation criteria that objective and reliable evidence of fair value of any undelivered item must exist for the delivered item to be considered a separate unit of accounting. This standard also addresses how the arrangement consideration should be allocated to each deliverable. Finally, this standard expands disclosures related to multiple element revenue arrangements. This standard is effective for us beginning January 1, 2011. The Company is currently evaluating the impact of this on the consolidated results of operations, financial position or cash flows.

2. Subcontracting agreement:

In accordance with the terms of a supply agreement signed with GlaxoSmithKline in December 2004 and renewed in May 2008 for the manufacture of Coreg CR microparticles on a cost plus basis, the Company recognized as revenues from product sales a total amount of $19,768,000 in 2007 , $13,549,000 in 2008 and $11,871,000 in 2009. Costs include all amounts attributable to the availability of production capacity for the manufacture of Coreg CR microparticles such as direct and indirect labor, materials, outside services and overhead.

3. License, research and consulting agreements:

SB Pharma Puerto Rico Inc. (GSK)

In March 2003, Flamel Technologies and SB Pharma Puerto Rico Inc (GSK) entered into a license agreement whereby the Company agreed to license its controlled-release Micropump® in order to develop a new formulation for an undisclosed existing product. This product was disclosed by GlaxoSmithKline, in March 2006, to be carvedilol, which is marketed by GlaxoSmithKline as Coreg.

In 2007, the Company recognized research and development revenues of $1,864,000. The Company also recognized $4,000,000 of milestone payments and $5,943,000 of royalties on GSK sales of Coreg CR.

In 2008, the Company recognized research and development revenues of $1,070,000. The Company also recognized $11,204,000 of royalties on GSK sales of Coreg CR.

In 2009, the Company recognized $ 3,857,000 of milestone payments and $8,808,000 of royalties of Coreg sales.

In December 2004, Flamel and GlaxoSmithKline (GSK) entered into a four year supply agreement whereby Flamel agreed to supply GSK with commercial supplies of product. The provisions of the agreement include payments to Flamel of $20,717,000 to support the costs and capital expenditure relative to the creation of a manufacturing area for the production of commercial supply of the product. The capital expenditures consist of both buildings and fixtures, and production equipment. Flamel will have immediate title to buildings and fixtures; however title to production equipment remains with GSK for the duration of the supply agreement.

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If the Company breaches the supply agreement through gross negligence, GSK can choose to terminate the supply agreement. The likely occurrence of this event is deemed remote given the Company's ability to perform under supply arrangements based on its historical experience. In the event of a breach and a decision to terminate the agreement, all payments received become repayable to GSK and Flamel will receive immediate title to all production equipment

Upon cessation of the supply agreement, in the normal course of business, GSK will pass title to all production equipment to Flamel without cost of any kind.

A total of $8,188,000 has been incurred on the acquisition of buildings and fixtures and a total of $11,138,000 has been incurred on behalf of GSK for the purchase of production equipment and associated costs. As of December 31, 2009, the funds received from GSK to finance the acquisition of assets owned by Flamel are classified in other current liabilities for $728,000 and in other long term liabilities for $5,366,000. The liability is amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets.

In July 2006, Flamel and GSK entered into a further agreement as a supplement to the original supply agreement whereby GSK will partly sponsor the extension of the existing facilities at Pessac from two lines to three. GSK will have exclusive use of part of this equipment, in order to increase the production capacity of Coreg CR microparticles. The total funding provided by GSK amounted to $8.1million to finance the acquisition of equipments, buildings and fixtures. The Company received all installments due under the agreement by December 31, 2007. As of December 31, 2009 the funds received from GSK to finance the extension were classified in other current liabilities for $1,285,000 and long term liabilities for $4,282,000. The liability is amortized on a pro-rata basis over the expected life of the assets and proportionally based on funding received compared with the total value of the related assets. This amortization is reflected as an offset of the depreciation of the related assets (see Note 12).

In May 2008, Flamel and GSK signed an amendment to the original supply agreement, extending the supply of commercial supplies of the product through to end of 2010.

Wyeth Pharmaceuticals

On September 12, 2007 the Company entered into a development and license agreement with Wyeth Pharmaceuticals, ('Wyeth') now part of Pfizer Inc, whereby the Company agreed to license its Medusa technology for the development and licensing of a marketed protein. The Company received an upfront fee and may receive development fees, milestones and royalties on the product. On September 2, 2008 Wyeth confirmed their intention to pursue the development and license agreement triggering a $500,000 payment. On November 4, 2009 Wyeth exercised the option for the licensing of Flamel technology and paid $1,000,000.

In consideration of this agreement, the Company recognized research and development revenues of $349,000 and $153,000 of amortization of the initial up-front payment in 2007.

In 2008, the Company recognized research and development revenues of $1,479,000. The Company also recognized $528,000 of amortization of the up-front payment.

In 2009, the Company recognized research and development revenues of $863,000. The Company also recognized $378,000 of amortization of up-front payment and option payment.

Merck-Serono

On December 20, 2007 Flamel Technologies entered into a relationship with Merck-Serono, a division of Merck KGaA, to investigate the applicability of Flamel's Medusa technology for the extended release of a therapeutic protein of Merck-Serono's portfolio.

In consideration of the agreement signed in 2007, Merck-Serono made an upfront payment of $2.7 million for investigating the therapeutic protein, which has been amortized over the initial feasibility period. In February 2009 Merck-Serono exercised the option to license our technology triggering a payment of $ 6,500,000 (€5,000,000).

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In 2007, the Company recognized research and development revenues of $78,000 as amortization of the initial up-front payment.

In 2008, the Company recognized research and development revenues of $2,957,000. The Company also recognized $735,000 of milestone payment and $2,521,000 of amortization of the initial up-front payment.

In 2009, the Company recognized research and development revenues of $5,905,000. The Company also recognized $1,529,000 of amortization of the initial up-front and option payments.

Baxter Healthcare Inc

On June 19, 2009 the Company entered into agreement with Baxter Healthcare Inc, to formulate controlled release applications of blood clotting factor replacement therapies using Flamel's Medusa® Technology. In consideration of this agreement the Company received an access fee of $3,600,000 (€2,500,000). The company recognized research and development revenues of $291,000 and $968,000 of amortization of the initial up-front fee.

Pfizer Inc

The company has entered into a research collaboration with Pfizer Inc to assess the applicability of the Medusa platform to certain molecules in development. Under this collaboration, the Company recognized research and development revenues of $1,401,000 in 2008 and $836,000 in 2009.

Corning

In December 1998, the Company signed a long-term research and product development agreement with Corning France and Corning Incorporated. Pursuant to the terms of this agreement, Flamel receives royalties on the sales of Corning products that utilize Flamel's innovations.

The Company also recognized royalties on Corning's sales of $636,000 in 2007, $581,000 in 2008and $370,000 in 2009.

Others

The Company recognized license and research and development revenues on several feasibility studies with undisclosed partners for an amount of $3,705,000 in 2007, $2,556,000 in 2008 and $6,191,000 in 2009. The increase in revenues from undisclosed partners results from the increase in the number of feasibility agreements executed year on year.

4. Research and Development expenses

Due to a worldwide increase in government tax incentives and recent developments and changes in the calculation of the French research tax credit, the company reviewed its analysis and presentation of the research tax credit. The company determined in 2009 that the research tax credit should be classified as a research and development grant as the tax credit is calculated based on a percentage of eligible research and development costs, the tax credit can be refundable in cash and it is not contingent upon future taxable income. As a result, the research tax credit, amounting to $ 6,498,000 in 2009, has been classified in research and development expense instead of income tax. The presentation for the 2008 and 2007 research tax credits amounting to $6,978,000 and to $2,288,000, respectively, has also been reclassified from income tax to research and development expense for comparable presentation.

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The table hereafter shows the effect of this reclassification:

	2007		2008		2009	
	Before	After	Before	After	Before	After
Research and development expenses	(43,557)	(41,269)	(36,247)	(29,269)	(36,913)	(30,416)
Income (loss) from operations	(40,849)	(38,561)	(20,160)	(13,182)	(18,250)	(11,753)
Income tax	1,694	(594)	6,478	(500)	6,497	-
Net income (loss)	(37,737)	(37,737)	(12,084)	(12,084)	(11,439)	(11,439)

5. Stock based compensation :

5.1 ASC 718

The Company applies the provisions of ASC 718, Securities and Exchange Commission ("SEC") Staff Accounting Bulletin n°107, Securities and Exchange Commission ("SEC") Staff Accounting Bulletin n°110 (ASC 505,), in accounting for its stock based compensation. The fair value of each option and warrant granted during the year is estimated on the date of grant using the Black-Scholes option pricing model. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The weighted-average assumptions on grants made in each of the following years were:

	Year Ended December 31		
	2007	2008	2009
Weighted-average expected life (years)	1.71	3.73	4.30
Expected volatility rate	52.70%	61.5%	63.6%
Expected dividend yield	-	-	-
Risk-free interest rate	4.83%	2.57%	2.02%
Forfeiture rate	5%	5%	-

Since no stock options were granted in 2007, the weighted-average expected life for 2007 results solely from the grant of warrants, whose expected life is shorter than that of stock options in accordance with conditions for vesting and exercise as defined at time of grant, see Note 17.3 and 17.4.

We base our determination of expected volatility predominantly on the implied volatility of our traded options with consideration of our historical volatilities. Given the limited historical data and the grant of stock options and warrants to a limited population, the simplified method has been used to calculate the expected life.

Stock based compensation expense recognized was as follows:

(In thousands of U.S dollars except per share data)	Options			Free of charge share awards			Warrants			Total		
	2007	2008	2009	2007	2008	2009	2007	2008	2009	2007	2008	2009
Research and development	4,598	2,691	1,532	1,220	1,454	668	(88)	(5)	-	5,730	4,141	2,199
Cost of goods sold	234	150	87	223	285	119	-	-	-	457	434	206
Selling, general and administrative	4,542	2,412	1,969	317	642	532	958	657	592	5,817	3,711	3,093
Total stock-based compensation expense	9,374	5,253	3,588	1,760	2,381	1,319	870	652	592	12,004	8,286	5,499
Effect on earnings per share												
Basic	0.39	0.22	0.15	0.07	0.10	0.05	0.04	0.03	0.02	0.50	0.34	0.23
Diluted	0.39	0.22	0.15	0.07	0.10	0.05	0.04	0.03	0.02	0.50	0.34	0.23

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As of December 31, 2009, the projected compensation expense related to non vested options or warrants amounted to $4,445,000 and is expected to be recognized over a weighted average period of 1.42 years.

5.2 Warrants

The summary of warrants activity is as follows:

	Warrants Outstanding	Weighted Average Exercise Price in U.S dollars [1]	Weighted Average Exercise Price in Euros
Balance at January 1, 2007	378,000	$ 19.05	€ 15.53
Warrants granted	125,000	$ 27.83	€ 20.54
Warrants cancelled	2,500	$ 16.18	€ 12.34
Balance at December 31, 2007	500,500	$ 21.26	€ 16.80
Warrants granted	250,000	$ 10.20	€ 6.57
Warrants cancelled	203,833	$ 19.27	€ 15.64
Balance at December 31, 2008	546,667	$ 16.94	€ 12.55
Warrants granted	250,000	$ 6.29	€ 4.50
Warrants cancelled	166,167	$ 20.67	€ 16.78
Balance at December 31, 2009	630,500	$ 11.73	€ 8.24

[1] Historical exchange rate at date of grant

No warrants were exercised in 2007, 2008 and 2009.

Exercise prices and intrinsic value for warrants outstanding as of December 31, 2009 were as follows:

	Warrants Outstanding				Warrants Exercisable		
Range of exercise prices in euros	Number of shares	Weighted average remaining contractual life	Weighted average exercise price in euros	Weighted average intrinsic value in euros	Number of shares	Weighted average exercise price in euros	Weighted average intrinsic value in euros
0 to 6.57	500,000	2.95	5.54	0.64	250,000	6.57	-
12.34 to 20.54	130,500	0.28	18.62	-	130,500	18.62	-
	630,500	**2.40**	**8.24**	**0.25**	**380,500**	**10.70**	-

The total fair value of warrants vested during 2007 amounted to €878,000 or $1,204,000 (average exchange rate of the year).

The total fair value of warrants vested during 2008 amounted to €492,000 or $724,000 (average exchange rate of the year).

The total fair value of warrants vested during 2009 amounted to €651,000 or $908,000 (average exchange rate of the year).

Intrinsic value represents the variance between the share price and the exercise price. As of December 31, 2009 the aggregate intrinsic value of warrants outstanding amounted to €159,000 or $229,000 (exchange rate at date of balance sheet).

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5.3 Stock Options

The activity under the option plans is as follows:

	Shares Available for Grant	Options Granted and Outstanding	Weighted Average Exercise Price in U.S dollars[1]	Weighted Average Exercise Price in Euros
Balance at January 1, 2007	346,250	3,529,250	$ 16.23	€ 13.18
Options authorized	500,000	-	-	-
Granted	-	-	-	-
Exercised	-	(61,000)	$ 2.33	€ 2.48
Forfeited	219,500	(255,500)	$ 17.73	€ 14.06
Balance at December 31, 2007	1,065,750	3,212,750	$ 16.37	€ 13.31
Options authorized		-	-	-
Granted	(125,000)	125,000	$ 5.17	€ 4.03
Exercised	-	(55,010)	$ 2.36	€ 2.36
Forfeited	(565,750)	(477,750)	$ 18.18	€ 14.68
Balance at December 31, 2008	375,000	2,804,990	$ 15.84	€ 12.88
Options authorized		-	-	-
Granted	(330,000)	330,000	$ 6.76	€ 4.75
Exercised	-	(20,000)	$ 0.99	€ 1.09
Forfeited		(4,000)	$ 25.27	€ 20.81
Balance at December 31, 2009	45,000	3,110,990	$ 14.96	€ 12.08

[1] Historical exchange rate at date of grant

The total intrinsic value of options exercised during 2007 amounted to €951,000 or $1,285,000 (historical exchange rate at date of exercise).
The total intrinsic value of options exercised during 2008 amounted to €181,000 or $267,000 (historical exchange rate at date of exercise).
The total intrinsic value of options exercised during 2009 amounted to €68,000 or $99,000 (historical exchange rate at date of exercise).

Stock options outstanding at December 31, 2009, which expire from 2010 to 2019 had exercise prices ranging from €1.09 to € 25.39. The weighted average remaining contractual life of all options is 5.33 years. As of December 31, 2009, there were 3,110,990 outstanding options at a weighted average exercise price of €12.08, of which 2,597,740 were exercisable at a weighted average price of €12.91. Exercise prices and intrinsic value for options outstanding as of December 31, 2009 were as follows:

	Stock Options Outstanding				Stock Options Exercisable		
Range of exercise prices in euros	Number of shares	Weighted average remaining contractual life	Weighted average exercise price in euros	Weighted average intrinsic value in euros	Number of shares	Weighted average exercise price in euros	Weighted average intrinsic value in euros
0 to 1.36	33,000	1.73	1.09	4.05	33,000	1.09	4.05
2.33 to 2.77	255,000	2.13	2.43	2.70	255,000	2.43	2.70
4.03 to 5.06	729,000	6.95	4.48	0.65	305,250	4.34	0.80
6.40 to 7.58	125,000	0.89	6.78	-	125,000	6.78	-
9.88 to 12.02	193,500	4.53	11.10	-	193,500	11.10	-
12.86 to 16.23	1,163,990	5.63	14.47	-	1,154,740	14.47	-
19.2 to 25.39	611,500	5.49	22.61	-	531,250	22.32	-
	3,110,990	**5.33**	**12.08**	**0.42**	**2,597,740**	**12.91**	**0.41**

The total fair value of options vested during 2007 amounted to €6,782,000 or $9,296,000 (average exchange rate of the year).

The total fair value of options vested during 2008 amounted to €4,027,000 or $5,922,000 (average exchange rate of the year).
The total fair value of options vested during 2009 amounted to €3,197,000 or $4,454,000 (average exchange rate of the year).

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The aggregate intrinsic value of options outstanding amounted to €1,298,000 or $1,870,000. The aggregate intrinsic value of options exercisable amounted to €1,066,000 or $1,536,000 (exchange rate at date of balance sheet).

5.4 Free share award

The activity under the free share award plans is as follows:

	Free of Charge Share Award Available for Grant	Free of Charge Share Award Granted and Outstanding	Weighted Average Fair Value in U.S dollars[1]	Weighted Average Fair Value in Euros
Balance at January 1, 2007	94,000	106,000	$ 33.46	€ 25.39
Authorized	200,000			
Granted	(130,000)	130,000	$ 8.54	€ 5.80
Forfeited	1,450	(1,450)	$ 33.46	€ 25.39
Balance at December 31, 2007	165,450	234,550	$ 19.64	€ 14.53
Options authorized	200,000			
Granted	(250,000)	250,000	$ 5.88	€ 4.37
Exercised	-	(98,750)	$ 33.46	€ 25.39
Forfeited	12,100	(12,100)	$ 20.48	€ 15.19
Balance at December 31, 2008	127,550	373,700	$ 6.76	€ 4.85
Options authorized	200,000			
Granted	(320,000)	320,000	$ 7.27	€ 4.98
Exercised		(117,250)	$ 8.54	€ 5.80
Forfeited	3,100	(3,100)	$ 6.75	€ 4.86
Balance at December 31, 2009	10,650	573,350	$ 6.68	€ 4.73

[1] Historical exchange rate at date of grant

As of December 31, 2007 the total fair value (or intrinsic value) of Free Share Award outstanding amounted to €3,409,000 or $4,608,000 (historical exchange rate at date of grant).

As of December 31, 2008 the total fair value (or intrinsic value) of Free Share Award outstanding amounted to €1,753,000 or $2,399,000 (historical exchange rate at date of grant).

As of December 31, 2009 the total fair value (or intrinsic value) of Free Share Award outstanding amounted to €2,710,000 or $3,830,000 (historical exchange rate at date of grant).

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6. Cash and Cash Equivalents:

Cash consists of cash on deposit and fixed term investments held in several major banks, and cash on hand. The components of cash and cash equivalents were as follows:

(In thousands of U.S . dollars)	December 31, 2008	December 31, 2009
HSBC	$ 7,573	$ 7,044
Credit Lyonnais	38	27
Credit Agricole	19,217	1,458
Other	192	187
Total cash and cash equivalents	$ 27,021	$ 8,716

For the year ended December 31, 2008 cash and cash equivalents included fixed term deposits for $18,100,000 with maturities of less than ninety days.

7. Marketable securities:

Marketable securities are classified as available-for-sale securities and are recorded at fair market value. Unrealized gains and losses are recorded as other comprehensive income in shareholder's equity, net of income tax effects.

For the year ended December 31, 2007, 2008 and 2009 marketable securities amounted respectively to $14,749,000, $10,058,000 and $35,353,000.

As of December 31, 2007, December 31, 2008 and December 31, 2009 there were no unrealized gains or losses.

(in thousands of U.S dollars)	Fair value		Value at cost		Unrealized Gains (Losses)	
	2008	2009	2008	2009	2008	2009
Credit Agricole securities	3,359	7,710	3,359	7,710	-	-
Credit Lyonnais securities	47	49	47	49	-	-
HSBC securities	6,651	27,593	6,651	27,593	-	-
Total	10,057	35,352	10,057	35,352	-	-

Gross realized gains on sales of these available-for-sale securities amounted to $318,000, $329,000 and $153,000 for the years ended December 31, 2007, 2008 and 2009 respectively.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

(in thousands of U.S dollars)	Proceeds from sales		Purchase of securities		Gross gains (Losses)	
	2008	2009	2008	2009	2008	2009
Credit Agricole securities	27,295	33,932	25,962	37,624	149	45
Credit Lyonnais securities	413	188	380	188	3	-
HSBC securities	47,508	104,356	44,440	123,156	175	108
Barclays securities	-	-	-	-	-	-
Total	75,216	138,476	70,782	160,968	327	153

8. Inventory:

The components of inventories were as follows:

(In thousands of U.S . dollars)	December 31,	
	2008	2009
Raw materials	1,272	1,072
Finished goods	565	-
Inventories, net	1,837	1,072

9. Prepaid expenses and other current assets

The components of prepaid expenses and other current assets were as follows:

(In thousands of U.S . dollars)	December 31,	
	2008	2009
Prepaid expenses	664	945
Grants recoverable	-	1,039
Valued-added tax recoverable	1,226	1,143
Advance to suppliers	291	498
Total Prepaid expenses and other current assets	2,181	3,625

10. Property and Equipment:

The components of property and equipment were as follows:

(In thousands of U.S . dollars)	December 31,	
	2008	2009
Land and buildings	10,895	11,281
Laboratory equipment	30,542	31,713
Office and computer equipment	3,856	4,249
Furniture, fixtures and fittings	20,218	21,353
Total property and equipment	65,511	68,596
Less accumulated depreciation and amortization	(37,910)	(43,837)
Property and equipment, net	27,601	24,759

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Depreciation expense related to property and equipment amounted to $6,198,000, $7,249,000 and $5,917,000 for the years ended December 31, 2007, 2008 and 2009, respectively.

Property and Equipment include costs of $1,559,000 and $144,000 at December 31, 2008 and 2009 that are related to capitalized lease assets. Accumulated amortization of these leased assets was approximately $1,453,000 and $83,000 at December 31, 2008 and 2009, respectively. Depreciation expense on assets held under capital leases is included in total depreciation expense for the years ended December 31, 2007, 2008 and 2009 and amounted to $315,000, $65,000 and $46,000 respectively.

11. Accrued Expenses:

Accrued expenses consist mainly of expenses related to bonuses, paid vacations, compensatory leaves and related social charges.

Accrued expenses comprises of the following:

(In thousands of U.S . dollars)	December 31, 2008	2009
Accrued compensation	2,499	2,543
Accrued social charges	3,406	3,775
Total accrued expenses	5,905	6,318

12. Other current and Long Term liabilities:

12.1. Other current liabilities:

Other current liabilities comprise the following:

(In thousands of U.S . dollars)	December 31, 2008	2009
Funding from partner GSK short term	1,813	2,013
R&D credit tax financing short term	4,272	1,957
Provision for costs	11	-
Employee service award provision short term	284	375
Valued-added tax payable	72	272
Total Other current liabilities	6,452	4,617

In connection with the supply agreement with GSK (see Note 3), the Company received funds to finance facilities related assets. A total of $8,188,000 has been spent on the acquisition of buildings and fixtures and a total of $11,138,000 has been spent on behalf of GSK for the purchase of production equipment. As of December 31, 2009 the funds received from GSK to finance the acquisition of assets owned by Flamel are classified as a current liability for $728,000 and as a long term liability for $5,366,000. In July 2006, Flamel and GSK entered into a side agreement to the original agreement whereby GSK will partially sponsor the extension of the Micropump development facility (see Note 3). This facility was completed in March 2008. As of December 31, 2007, the Company had received all installments from GSK for financing of this project. The total installments amounted to $8,097,000. As of December 31, 2009, the funds received from GSK are classified as a current liability for $1,285,000 and as a long term liability for $4,282,000 (see Note 12.2).

The liability is amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets (see Note 3).

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

The Service award provision is accrued over the respective service period (5, 10 and 15 years) using actuarial assumptions and calculations as for the lump sum retirement indemnity (see Note 19).

For the year ended December 31, 2008 the provision for service award amounted to $1,627,000 of which $284,000 is short term. For the year ended December 31, 2009 the provision amounted to $2,296,000 of which $375,000 is short term.

In December 2008, the Company obtained an advance from OSEO, a governmental agency supporting innovation, for $8,013,000 secured against the research tax credits due to the company by the tax authorities for expenditure incurred in 2005, 2006 and 2007 (see Note 18). Two advances were obtained. The first amount for $4,272,000 and secured against the research tax credit from 2005 amounting to $5,114,000 was reimbursed in 2009. The second amounts to $3,741,000 and is secured against the research credit tax from 2006 and 2007 totaling $4,880,000. This advance matures in 2010, with a possibility to renew the financing. The interest rate applied is the monthly average of the Euro Interbank Offered Rate (EURIBOR) plus 0.8%. As of December 31, 2008 the funding was classified as a short term liability for $4,272,000 and as a long term liability for $3,741,000. As of December 31, 2009 the total liability amounted to $3,872,000 of which $1,944,000 is short term.

12.2. Other long term liabilities

Other long term liabilities are composed of the following:

	December 31,	
(In thousands of U.S . dollars)	**2008**	**2009**
Funding from partner GSK long term	11,494	9,648
Conditional grants	1,819	1,765
Provision for retirement indemnity (see note 19)	1,649	2,208
R&D credit tax financing long term (see note 12.1)	3,741	1,916
Employee service award provision long term	1,343	1,921
Other	448	23
Total Other long term liabilities	20,494	17,481

Funding from partner GSK long term amounted to $5,366,000 in connection with the supply agreement signed in December 2004 and relates to the acquisition of buildings and fixtures (see Note 12.1) and $4,282,000 in connection with the side agreement to the original agreement, signed in July 2006.

Conditional grants of $1.8 million in 2008 and 2009 were received from local authorities to partly finance investments at Pessac. The grants are conditional on completion of the total investment programme and ongoing employment at the facilities for a period of three to five years. The Company recognizes conditional grants as an offset to operating expenses once all conditions stated in the grant have been met. As of December 31, 2009 the Company recognized to the income statement conditional grants for $782,000 and unconditional grants for a total of $1,740,000..

13. Deferred Revenue:

Current portion of deferred revenue comprises of upfront licensing fees which are recognized over the development period of the contract. For the year ended December 31, 2008 deferred revenues amounted to $999,000 and $9,895,000 for the year ended December 31, 2009. The significant increase in deferred revenues results from the upfront license fees received in 2009 of €5 million from Merck Serono, €2.5 million from Baxter International and $1 million from Wyeth Pharmaceuticals.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

14. Long-term Debt:

Long-term debt comprises:

(In thousands of U.S . dollars)	December 31, 2008	December 31, 2009
Oseo Anvar loans (a)	901	1,682
French Ministry of Industry (b)	2,052	2,124
Total	2,953	3,806
Current portion	684	862
Long-term portion	2,269	2,944

(a) OSEO Anvar is an agency of the French government that provides financing to French companies for research and development. At December 31, 2008 and 2009, the Company had outstanding loans from Anvar of $901,000 and $1,682,000, respectively for various programs. In 2009, the Company received $749,000 for a new project These loans do not bear interest and are repayable only in the event the research project is technically or commercially successful. Potential repayment is scheduled to occur from 2010 through 2017.

(b) In 2002, the Company received a loan of $464,000 from the French Ministry of Industry on a research project (the “Proteozome” project) related to the development of new Medusa applications. Pursuant to the agreement, the Company is granted a loan equal to 50% of the total expenses incurred on this project over a three-year period beginning on January 2, 2002. The remainder of the advance of $1,707,000 was received in 2005. One third of this loan is due for repayment 2010 with the remainder due in 2011. The loan is non-interest bearing and is repayable only in the event the research project is technically or commercially successful.

Total future payments on long-term debt for the years ending December 31 (assuming the underlying projects are commercially or technically successful for governmental research loans) are as follows:

(In thousands of U.S . dollars)	December 31,
2010	862
2011	1,636
2012	286
2013	339
2014	144
2015	180
2016	209
2017	150
	3,806

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

15. Capital lease obligations:

The Company leases certain of its equipment under capital leases. Each lease contract generally has a term of four years with a purchase option. No specific restrictions or guarantee provisions are included in the arrangement.

Future payments on capital leases for the years ending December 31 are as follows:

(In thousands of U.S . dollars)	**December 31,**
2010	43
2011	43
2012	27
Total	113
Less amounts representing interest	(14)
Future payments on capital leases	99
Less current portion	33
Long term portion	66

Interest paid in the years ended December 31, 2007, 2008 and 2009 was approximately $16,000, $16,000 and $14,000, respectively.

16. Earnings Per Share:

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per share computations:

(In thousands, except per share amounts)	**Year ended December 31,**		
	2007	**2008**	**2009**
Numerator:			
Net income (loss)	$ (37,737)	$ (12,084)	$ (11,439)
Denominator:			
Weighted average shares outstanding used for basic earnings (loss) per share	24,024,131	24,081,723	24,225,261
Effect of dilutive securities:			
Stock-options and warrants	-	-	-
Weighted average shares outstanding and dilutive securities used for diluted earnings (loss) per share	24,024,131	24,081,723	24,225,261
Basic earnings (loss) per share	$ (1.57)	$ (0.50)	$ (0.47)
Diluted earnings (loss) per share	$ (1.57)	$ (0.50)	$ (0.47)

For the years ended December 31, 2007, 2008 and 2009, the effects of dilutive securities were excluded from the calculation of earnings per share as a net loss was reported in these periods.

Options to purchase 2,978,000 shares of common stock at an average of €13 per share were outstanding during 2009, but were not included in the computation of diluted EPS because the exercise price was greater than the average market price of common shares. The options, which expire in December 2018, were still outstanding at the end of year 2009.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

17. Shareholders' Equity:

17.1. Preemptive subscription rights:

Shareholders have preemptive rights to subscribe for additional shares issued by the Company for cash on a *pro rata* basis when the Company makes a share offering. Shareholders may waive such preemptive subscription rights at an extraordinary general meeting of shareholders under certain circumstances. Preemptive subscription rights, if not previously waived, are transferable during the subscription period relating to a particular offer of shares.

17.2. Dividends:

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception, as the result of an accumulated statutory deficit of approximately $138.2 million at December 31, 2009. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

17.3. Warrants:

On March 4, 2005, the Company issued, at a price of €0.01 per warrant, 40,000 warrants to the scientific advisors of the Company giving them the right to subscribe to 40,000 ordinary shares at the price of €12.34 per share. These warrants are subject to vesting for 25% at the subscription and the remainder vest ratably over a three year period. The exercise of these warrants should occur before January 3, 2010. As of December 31, 2009, 7,000 warrants were exercised and 2,500 were forfeited.

The related compensation expense is computed under prescriptions ASC 505-50.

The effects of applying the fair value method provided in accordance with ASC 505 and ASC 718 are shown in Note 5.

On March 2, 2006, the Company authorized the Directors, to subscribe to 69,250 warrants for a subscription price of €2.0 per warrant ($2.40). Each warrant is exercisable to purchase one Share at price of €20.07 ($23.99). These warrants were subscribed in April 2006. As of December 31, 2009, all the warrants were cancelled.

On June 12, 2006, the Company authorized the Directors of the Company, to subscribe to 125,000 warrants for a subscription price of €1.46 per warrant ($1.84). Each warrant is exercisable to purchase one Share at a price of €14.6 ($18.48). These warrants are issued for a three-year period and will vest over one year from the date of issuance. These warrants were subscribed in July and August 2006. As of December 31, 2009, all the warrants were cancelled.

On May 15, 2007, the Company authorized the Directors of the Company, to subscribe to 125,000 warrants for a subscription price of €2.16 per warrant ($2.93). Each warrant is exercisable to purchase one Share at a price of €20.54 ($27.83). These warrants are issued for a three-year period and will vest over one year from the date of issuance. These warrants were subscribed in June 2007. As of December 31, 2009, 25,000 warrants were cancelled.

On June 3, 2008 the Company authorized the Directors of the Company, to subscribe to 250,000 warrants for a subscription price of €0.91 per warrant ($1.42). Each warrant is exercisable to purchase one Share at a price of €6.57 ($10.20). These warrants are issued for a four-year period and will vest over one year from the date of issuance. These warrants were subscribed in June 2008.

On June 24, 2009 the Company authorized the Directors of the Company, to subscribe to 250,000 warrants for a subscription price of €0.74 per warrant ($1.03). Each warrant is exercisable to purchase one Share at a price of €4.50 ($6.29). These warrants are issued for a four-year period and will vest over one year from the date of issuance. These warrants were subscribed in July 2009.

On exercise of warrants by beneficiaries, the Company issues new shares.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

17.4. Stock options:

The Company issued stock options under plans approved by shareholders in 1990, 1993, 1996, 2000, 2001, 2003, 2004, 2005, and 2007. The option terms provide for exercise within a maximum 10-year term as from the date of grant. Generally, each option vests no more than four years from the date of grant.

In January 1997, the French parliament adopted a law that requires French companies and beneficiaries to pay social contributions, which generally represent 45% of the taxable salary, on the difference between the exercise price of a stock option and the fair market value of the underlying shares on the exercise date if the beneficiary sells the stock before a four-year period following the grant of the option (five years for options granted before 2000). This law is consistent with personal income tax law that requires individuals to pay income tax on the difference between the option exercise price and the fair value of the shares at the sale date if the shares are sold within four years of the option grant. The law applies to all options exercised after January 1, 1997. The Company has instituted an internal rule whereby, whilst remaining an employee of the Company, an individual may not sell the underlying share within four years of the option being granted.

In December 2007, the French parliament adopted a law that requires French companies to pay an additional social security contribution of 10% for each option granted, based on either the fair value of the option or 25% of share price at date of grant. This is applicable on all options granted since October 16, 2007.

On exercise of stock options by beneficiaries, the Company issues new shares.

17.5. Free Share Awards

On May 15, 2007, the shareholders of the Company authorized the issue of new shares which authorizes the Board of Directors to award and issue up to 200,000 shares free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by the beneficiaries two years following their allocation and the Company issues new shares. The beneficiaries are required to retain the shares for two additional years.

On June 3, 2008, the shareholders of the Company authorized the issue of new shares which authorizes the Board of Directors to award and issue up to 200,000 shares free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by the beneficiaries two years following their allocation and the Company issues new shares. The beneficiaries are required to retain the shares for two additional years.

On June 24, 2009, the shareholders of the Company authorized the issue of new shares which authorizes the Board of Directors to award and issue up to 200,000 shares free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by the beneficiaries two years following their allocation and the Company issues new shares. The beneficiaries are required to retain the shares for two additional years.

In December 2007, the French parliament adopted a law that requires French companies to pay an additional social contribution of 10% for each share granted, based on the share price at date of grant.

On December 12, 2006 the Company granted 106,000 free share awards to officers and employees. On December 13, 2008, the Company issued 98,750 new shares related to this grant.

On December 11, 2007 the Company granted 130,000 free share awards to officers and employees. On December 11, 2009 the Company issued 117,250 new shares related to this grant.

On December 10, 2008 the Company granted 250,000 free share awards to officers and employees.

On February 1, 2009 the Company granted 25,000 free shares to officers.

On December 11, 2009 the Company granted 295,000 free share awards to officers and employees.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

17.6. Accumulated other comprehensive income:

The components of accumulated other comprehensive income are as follows:

(In thousands of U.S. dollars)	December 31, 2008	2009
Foreign currency translation	12,150	14,469
Total	12,150	14,469

18. Income taxes :

Income (loss) before income taxes comprises the following:

(in thousands of U.S. dollars)	Year ended December 31, 2007	2008	2009
France	$ (37,143)	$ (11,584)	$ (11,439)

A reconciliation of income tax benefit (provision) computed at the French statutory rate (33.33%) to the income tax benefit is as follows:

(in thousands of U.S. dollars)	Year ended December 31, 2007	2008	2009
Income tax benefit (provision) computed at the French statutory rate	12,380	3,861	3,813
Deferred Tax Allowance	(12,380)	(3,861)	(3,813)
Withholding tax	(594)	(500)	-
Total	(594)	(500)	-

License fees, milestone and royalties payments may be subject to a withholding tax depending on the tax rules of the country in which the licensee is located. In 2007 and 2008, withholding tax relates to royalties received from GSK in accordance with the license agreement.

Since our subsidiary realizes no taxable income, the Company does not incur any income taxes under United States jurisdiction.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Significant components of the Company's deferred taxes consist of the following:

(In thousands of U.S. dollars)	December 31, 2008	2009
Deferred income tax assets:		
Net French taxable operating loss carry-forwards (not utilized)	45,266	48,007
Other deferred income tax assets	3,528	6,779
Valuation allowance	(48,593)	(54,447)
Net deferred income tax assets	201	339
Deferred income tax liabilities	(201)	(339)
Deferred income taxes, net	-	-

The Company has provided valuation allowances covering 100% of net deferred tax assets due to the Company's history of losses.

As of December 31, 2009, the Company had $144,034,000 in French net operating losses carry-forwards which have no expiration date.

The increase in available net operating losses carry-forwards in 2009 is due to a tax loss of $3,338,000. The French government provides tax credits to companies for spending on innovative research and development. Income tax benefits correspond to these French research tax credits, which are credited against income taxes payable in each of the four years after being incurred or, if not so utilized, are recoverable in cash. As of December 31, 2009, Flamel had total research tax credits receivable of $11,884,000. In December 2008, the Company obtained an advance from OSEO, a governmental agency supporting innovation, secured against the Research tax credits generated in fiscal years 2005, 2006 and 2007 (see Note 12.1) Generally, if these credits are not applied against future income taxes, they will be received as cash payments in the fourth year after the credit is earned: At the beginning of 2009, the French government introduced a temporary measure consisting in early reimbursement of the research credit tax for fiscal year 2008. The company received reimbursement of the research tax credit for fiscal 2008 in May 2009. The measure was renewed by the French government for the fiscal year 2009 and the Company expects to apply for early reimbursement in the first half of 2010.

The scheduled payments are shown in the following table

(In thousands of U.S . dollars)	December 31,
2010	9,400
Total current portion	**9,400**
2011	2,484
Total long term portion	**2,484**
Total	**11,884**

19. Employee Retirement plans:

In accordance with French law, post-retirement benefits for most of the Company’s employees are sponsored by the relevant government agencies in France. The Company’s liability with respect to these plans is generally limited to specific monthly payroll deductions. Consequently, there is no additional liability in connection with these plans. Expenses recognized for these plans were $1,713,000 in 2009, $1,690,000 in 2008 and $1,609,000 in 2007.

French law requires the Company to provide for the payment of a lump sum retirement indemnity to French employees based upon years of service and compensation at retirement. Benefits do not vest prior to retirement. The Company’s benefit obligation was $2,208,000, $1,649,000, $1,450,000 as of December 31, 2009, 2008 and 2007, respectively. The increase in the balance is the result of increases to the obligation for service and interest cost, adjusted by the actuarial valuation and the overall impact of the translation of this euro-denominated obligation to U.S. dollars. Any actuarial gains or losses are recognized in the period when they occur.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

In 2008, the French Government reinforced legislation regarding an employer's ability to make employees retire. As such the retirement indemnity has been calculated on the assumption of voluntary retirement and the impact on the benefit obligation was recognized as an actuarial loss.

The benefit obligation is calculated as the present value of estimated future benefits to be paid, using the following assumptions:

	2007	2008	2009
Average increase of salaries	3%	3%	3%
Discounted interest rate	5.5%	5.5%	5.0%
Turn over	average of the last 4 years	actuarial standard and average of the last 5 years	actuarial standard and average of the last 5 years
Age of retirement	65 years	60 to 65 years actuarial standard based on age and professional status	60 to 65 years actuarial standard based on age and professional status

Changes in the funded status of the benefit plans were as follows:

	December 31,	
In thousands of U.S . dollars	**2008**	**2009**
Benefit obligations at beginning of year	1,450	1,649
Service cost	131	137
Interest cost	80	90
Plan amendments	-	136
Benefits paids	(143)	-
Actuarial loss (gain)	226	122
Exchange rate changes	(95)	74
Benefit obligations at end of year	1,649	2,208

	December 31,	
Change in plan assets	**2008**	**2009**
Fair value of plan assets at beginning of year	-	-
Employer contributions	143	-
Benefits paid	(143)	-
Fair value of plan assets at end of year	-	-

The Company does not have a funded benefit plan and the lump sum retirement indemnity is accrued on the balance sheet as a liability.

The future expected benefits to be paid over the next five years and for the five years thereafter is as follows:

Future expected payment of benefits: Year Ending: **In thousands of U.S . dollars**	
12/31/2010	54
12/31/2011	84
12/31/2012	321
12/31/2013	56
12/31/2014	532
Next 5 Years	586

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

In the United States, the Company sponsors a defined contribution retirement plan for its employees located in the United States. The contribution is the lesser of 25% of an employee's wages or $49,000 in 2009. The Company made contributions of approximately $68,000 in 2009, $82,000 in 2008 and $79,000 in 2007.

20. Fair value of financial instruments:

At December 31, 2008 and 2009, the carrying values of financial instruments such as cash and cash equivalents, trade receivables and payables, other receivables and accrued liabilities and the current portion of long-term debt approximated their market values, based on the short-term maturities of these instruments.

As noted in Note 7, the company calculates fair value for its marketable securities based on quoted market prices for identical assets and liabilities which represents Level 1 of SFAS 157 (ASC 820-10) fair value hierarchy.
At December 31, 2008 and 2009, the fair value of long-term debt with carrying value of $2,953,000 and $3,806,000 was estimated to be $2,892,000 and $3,726,000, respectively. Fair value was determined based on expected future cash flows, discounted at market interest rates.

21. Commitments and Contingencies:

21.1. Capital leases

The Company currently has commitments regarding capital leases as described in Note 15.

21.2. Operating leases

The Company leases its facilities and certain equipment under non cancelable operating leases, which expire through 2015. Future minimum lease payments under operating leases due for the fiscal years ending December 31, 2009 are as follows:

(In thousands of U.S. dollars)	December 31,
2010	1,297
2011	1,076
2012	940
2013	427
2014	201
Thereafter	178
TOTAL	4,119

Rental expense for the years ended December 31, 2007, 2008 and 2009 was approximately, $1,388,000, $1,381,000 and $1,418,000 respectively.

21.3. Litigation

While the Company may be engaged in various claims and legal proceedings in the ordinary course of business, the Company is not involved (whether as a defendant or otherwise) in and has no knowledge of any threat of, any litigation, arbitration or administrative or other proceeding which would have a material adverse effect on on the results of its operations, cash flows, or financial position as of December 31, 2009, and for the year then ended.

On November 9, 2007 a putative class action was filed in the United States District Court for the Southern District of New York against the Company and certain of its current and former officers entitled *Billhofer v. Flamel Technologies, et al*. The complaint purports to allege claims arising under the Securities Exchange Act of 1934 based on certain public statements by the Company concerning, among other things, a clinical trial involving Coreg CR and seeks the award of damages in an unspecified amount. By Order dated February 11, 2008, the Court appointed a lead plaintiff and lead counsel in the action. On March 27, 2008, the lead plaintiff filed an amended complaint which continued to name as defendants the Company and two previously named officers and asserted the same claims based on the same events as alleged in the initial complaint. On May 12, 2008, the Company filed a motion to dismiss the action, which the Court denied by Order dated October 1, 2009. The action is now in the discovery phase pursuant to a schedule approved by the Court in a Case Management Order, signed December 9, 2009. The Company intends to vigorously defend itself in the action. Neither of the two individual defendants named in the amended complaint have been served in the action.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

On August 27, 2007, a New York court denied Flamel U.S. jurisdiction in a lawsuit filed against Gérard Soula by the Company. This decision has not had and is not expected to have a materially adverse effect upon the Company.

22. Industry and geographic information:

The Company operates in one segment, the development and commercialization of controlled-release therapeutic products based on its proprietary polymer based technology.

Revenues from GSK represented 68% of total revenues in 2008 and 60% in 2009.

Operations outside of France consist principally of the operations of the U.S. subsidiary, which had no sales to third parties in 2007, 2008 or 2009.

Revenues by geographic location of customers are as follows:

(in thousands of U.S. dollars)	As of December 31,		
	2007	2008	2009
Revenues			
United Kingdom & Ireland	20,064	21,336	24,792
USA	15,278	9,219	4,021
France	1,234	1,472	2,691
Europe	78	6,592	10,614
Total Revenues	36,654	38,619	42,118

The following is a summary of long-lived assets by geographic location:

(in thousands of U.S. dollars)	As of December 31,	
	2008	2009
Long-lived assets:		
USA	$ 20	$ 38
France	$ 32,652	$ 27,417
Total long-lived assets	$ 32,672	$ 27,455

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

FLAMEL TECHNOLOGIES S.A.
(Registrant)

/s/ Stephen H. Willard
Stephen H. Willard
Chief Executive Officer

Date: May 7, 2010

EXHIBIT INDEX

Exhibit Number	Description
1.1	Revised *Statuts* or bylaws of the Company (Filed herewith)
2.1	Deposit Agreement among Flamel, The Bank of New York, as Depositary, and holders from time to time of American Depositary Shares issued thereunder (including as an exhibit the form of American Depositary Receipt) (1)
8.1	List of Subsidiaries (Filed herewith)
11.1	Code of Ethics for CEO (Directeur Général), Delegated Managing Directors (Directeurs Generaux Delegues) and Senior Financial Officers (2)
12.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
12.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
13.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
13.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
23.1	Consent of PricewaterhouseCoopers Audit (Filed herewith)
23.2	Consent of Ernst & Young Audit (Filed herewith)

(1) Incorporated by reference to Post-Effective Amendment No. 1 to the Company's registration statement on Form F-6 filed July 26, 2001, as amended (No. 333-12790).
(2) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2003, filed on April 26, 2004.

The registrant undertakes to provide to each shareholder requesting the same a copy of each exhibit referred to herein upon payment of a reasonable fee limited to the registrant's reasonable expenses in furnishing such exhibit.

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

-Translated from French-

FLAMEL TECHNOLOGIES

A joint stock company with a share capital of € 2,968,823
Registered office located at VENISSIEUX (Rhône) Parc Club du Moulin à Vent
33, avenue du Docteur Georges Lévy

R.C.S. LYON B 379.001.530

BY LAWS

Updated as of March 4, 2010

ARTICLE 1 – FORM

The Company is a joint stock company governed by applicable laws and regulations and by these by-laws.

ARTICLE 2 – CORPORATE NAME

The corporate name is **FLAMEL TECHNOLOGIES.**

All the decisions and documents of the Company addressed to third parties, including but not limited to, letters, invoices, announcements and releases must indicate the name of the Company, immediately preceded or followed by, in legible form, the words « *société anonyme* » or of the initials "S.A.", the indication of the amount of the share capital and the SIREN number followed by the mention "R.C.S.", followed by the name of the city where is located the court with which the Company is registered.

ARTICLE 3 – COMPANY PURPOSE

The purpose of the Company is, in France or abroad:

- on the one hand :

  - design, realization of new materials for the chemical industry as well as for other industries, specifically in the field of pharmacy, health (biomaterials), cars, aerospace, telecommunications, motorists (turbines), packing and conditioning (specifically in the field of bio-destruction) ;

  - research and development of polymer and ceramic materials corresponding to identified needs ;

  - filing, study, acquisition, operation and concession of patents, licenses, processes, trademarks and specialized knowledge linked with, or relating to, in any way, to the above mentioned technological fields ;

  - production and sale of designed materials ;

- on the other hand:

  - design, development, manufacture, distribution, import, export of drugs, pharmaceutical specialities and other health products, as well as the exploitation of pharmaceutical specialities, drugs and other health products,

  - and generally, all operations, of any kind, economic or legal, financial, civil or commercial that can be directly or indirectly linked, on its own behalf of on the behalf of third parties, either alone or with third parties, with this corporate purpose or with any similar, related or complementary purpose, as well as the direct or indirect participation of the Company to all activities or industrial operations on any kind, if such activities or operation can be directly or indirectly linked to the company purpose or to any similar, related or complementary purpose.

ARTICLE 4 – REGISTERED OFFICE

The registered office is at VENISSIEUX (Rhône) 33, avenue du Docteur G. Lévy - Parc Club du Moulin à vent.

Notwithstanding the power granted to the shareholders by law and these by-laws in this respect, the registered office may be transferred to any other site in the same *département* or an adjoining *département* upon a decision of the board of directors, subject to ratification at the subsequent ordinary general shareholders meeting, or any other locality by virtue of a decision of an extraordinary general shareholders meeting.

ARTICLE 5 - DURATION

The duration of the Company has started to run as of August 10, 1999 and shall expire on August 9, 2099, except in cases of early dissolution or extension.

ARTICLE 6 – SHARE CAPITAL

The share capital is set at an amount of two million nine hundred and sixty eight thousand eight hundred and twenty three Euros €2 968 823, divided into 24 342 600 shares each with a value of 0.12196 Euros, fully subscribed to and paid up.

ARTICLE 7 – FISCAL YEAR

Each fiscal year shall last one year starting January first of each year and ending on December 31 of the same year.

By exception, the first fiscal year shall end on December 31, 1991.

ARTICLE 8 - ALLOCATION OF THE PROFITS

If the results of the fiscal year, as approved by the general shareholders meeting, show the existence of a distributable profit, the general shareholders meeting shall decide to allocate such profit to one or several reserve accounts of which the general shareholders meeting decides the attribution or use, to carry it forward or to distribute it.

After acknowledging the existence of reserves, the general shareholders meeting may decide the distribution of the amounts taken from the reserves. In this case, the decision expressly mentions the reserve accounts from which the amounts are taken. The general shareholders meeting may also grant to each shareholder, an option between the payment in cash or in shares of all or part of the paid dividend.

ARTICLE 9 - TYPE OF THE SHARES

The shares are registered.

They shall be registered on an account opened by the Company in the name of the shareholder under the conditions set forth in applicable law and regulations. An affidavit of inscription on the account can be granted to the shareholder on shareholder's request.

ARTICLE 10 – SALE AND ASSIGNMENT OF SHARES

Shares are freely negotiable under the conditions and limitations set forth by applicable law and regulations.

Any transfer of shares takes place, as far as both the Company and third parties are concerned, by way of transfer order signed by the assignor or its representative and the assignee if the shares have not yet been paid-up. The transfer order is registered on the day of its receipt on a numbered and initialized register called "*registre des mouvements*" (share transfer ledger).

The Company may require that the signatures on the transfer orders be certified by a public officer or a mayor, without prejudice to any legal rules to the contrary.

Shares transfer fees are borne by the assignee, except agreement to the contrary between the parties.

Transfer orders concerning shares not paid up to amounts due and payable shall be rejected.

The Company updates, at least on a six-month basis, the list of shareholders with the indication of the domicile declared by the shareholders.

Title to the shares results from their inscription in the name of the holder(s) on the registers or accounts held to that end by the Company or its representative.

ARTICLE 11 – RIGHTS AND DUTIES ATTACHED TO THE SHARES

Each share gives the right to title in the Company's assets, a share in profit and in the liquidation surplus, proportional to the value of the existing shares.

The same treatment shall be applied to all the shares that make up or that shall re make up the share capital, as far as the fiscal expenses are concerned.

As a consequence, all taxes that, for any reason, due to the repayment of the capital of these shares, could become due with respect to certain of them only, either during the life of the Company or upon liquidation thereof, shall be allocated among all the shares composing the capital at the moment of this repayment or these repayments, such that all existing or future shares grant to their holder, for the paid-up but not redeemed amount, the same real benefits and give them the right to receive the same net proceeds.

Each time it is necessary to hold several shares to exercise any right, the isolated shares or shares in an number less than the one required number, shall give no right to their holders against the Company; the shareholders shall, in this case, be personally responsible for the gathering of the necessary number of shares.

ARTICLE 12 – PAYMENT OF THE SHARE CAPITAL

The amounts that remain to be paid on the shares to be paid in cash are requested by the board of directors.

The shareholders are informed of the amounts requested and of the date when the corresponding amounts must be paid, either by a newspapers notice inserted fifteen days in advance in a journal authorized to publish legal notices in the *département* where the registered office is located, or by registered letter sent to each of the shareholders within the same time period.

A shareholder that does not proceed on time with the requested payments on the shares he holds, shall automatically and without prior notice owe a late payment interest calculated day by day, as of the date the amount was due, at the legal rate applicable in commercial matters plus tree points and without prejudice to enforcement measures set forth by law.

ARTICLE 13 – BOARD OF DIRECTORS

The Company is managed by a Board of Directors composed of at least three members and a maximum of eighteen members.

Subject to the decisions for which French law requires the physical presence of the Directors, the Board of Directors may provide for in its internal regulation that Directors who participate in the board meeting via videoconferencing or telecommunications means allowing for their identification and guaranteeing their effective participation in the Board meeting, in accordance with the provisions of a *Conseil d'Etat* decree, are deemed present for calculation of the quorum and the majority.

During the term of the Company, the members of the Board of Directors are appointed and removed, in the conditions provided by applicable laws and regulations.

Each member of the Board of Directors must own at least one share during the whole term of his/her office.

The term of office of the members of the Board of Directors is one year. It expires at the end of the shareholders' meeting called on to rule on the financial statements for the last financial year.

The number of Directors being over the age of 70 years may not, at any time, exceed one third of the total number of Directors in office.

ARTICLE 14 - DELIBERATIONS OF THE BOARD OF DIRECTORS

Board Meetings are convened by the Chairman, as frequently as the interests of the Company so require, either at the registered office, or in any other place indicated in the convening notice.

The members of the Board are convened to meetings by any means, even verbally.

When the Board of Directors has not met for more than two months, at least one third of the members of the Board may request the Chairman to convene a meeting for a defined agenda.

The Managing Director may also request the Chairman to convene a meeting for a defined agenda.

The Chairman is bound by the requests that are addressed to him pursuant to these last two paragraphs.

For sake of validity of deliberations, the effective attendance of at least half of the members in office is required.

Decisions are made with the majority of members present or duly represented: each member holds one vote, and each member may only hold one proxy. The Chairman has no tie-breaking vote.

Deliberations of the Board are recorded in minutes drawn-up, signed and recorded in accordance with applicable laws and regulations.

Copies and excerpts of the minutes for producing in court or elsewhere shall be validly certified either in accordance with applicable laws and regulations.

ARTICLE 15 – POWERS OF THE BOARD OF DIRECTORS

The Board determines the orientation of the Company's activity and ensures that they are implemented. Subject to the powers expressly granted to the Shareholders Meetings and within the corporate purpose, the Board may address any issue relating to the good operation of the Company and settles Company business through its deliberations.

In its relations to third parties, the Company is bound even by the actions of the Board of Directors that are unrelated to the corporate purpose, unless it can prove that the third party knew that the action exceeded the purpose or could not ignore it under the circumstances, it being excluded that the publication of the by-laws alone is sufficient to constitute such proof.

The Board of Directors undertakes the checks and verifications that it considers to be appropriate. Each Director receives all the information necessary to accomplish his mission and has access to all documents that he considers useful.

ARTICLE 16 – CHAIRMAN OF THE BOARD OF DIRECTORS

The Board of Directors elects from amongst its members a Chairman, who must be an individual. The Board determines the Chairman's term of office, which may not exceed his term of office as a Director.

The Chairman of the Board of Directors represents the Board vis-à-vis shareholders and third parties. He organizes and manages the work of the Board and reports thereon to the meeting of the shareholders. He oversees the good operation of the Company bodies, in accordance with applicable laws and regulations.

The Chairman of the Board may simultaneously hold offices of managing directors, member of a Board of Directors, of sole managing director, or member of a supervisory Board of stock corporations (sociétés anonymes) having their registered office in the French territory, only to the extent permitted by applicable laws and regulations

The Chairman of the Board is re-eligible. The Board of Directors may remove him/her at any time.

ARTICLE 17 – GENERAL MANAGEMENT

The general management of the Company is carried out, under his responsibility, either by the Chairman of the Board of Directors or by any other individual appointed by the Board, whether or not chosen from amongst its members, and having the title of Managing Director (*Directeur Général*).

The Board of Directors chooses between these two ways of exercising the General Management by a simple majority vote. Absent a vote to that effect, general management is undertaken by the Chairman of the Board of Directors, until a contrary decision is adopted by the Board of Directors.

When the general management of the Company is undertaken by the Chairman of the Board of Directors, the provisions of these by-laws relating to the Managing Director apply to the Chairman of the Board.

The Managing Director is appointed for a term of one year, expiring at the end of the general shareholders' meeting called on to rule on the approval of the financial statements for the last financial year.

The Managing Director has the most extensive powers to act under all circumstances in the name of the Company. He exercises these powers within the limit of the corporate purpose and subject to the powers expressly granted by law to Board and Shareholder meetings.

He represents the Company in its relations with third parties. The Company is even bound by the actions of the Managing Director that are not within the scope of the corporate purpose, unless it can prove that the third party knew that the action exceeded this purpose or could not ignore this fact under the circumstances, it being excluded that the publication of the by-laws alone is sufficient to constitute such proof.

The provisions of these by-laws and the decisions of the Board of Directors limiting the powers of the Managing Director may not be invoked against third parties.
Upon a proposal by the Managing Director, the Board of Directors may appoint one or several individuals with the title of Executive Managing Director, responsible for assisting the Managing Director. The Board of Directors may not appoint more than five Executive Managing Directors.

Executive Managing Directors have the same powers as the Managing Director in respect of third parties. With the Managing Director's approval, the Board of Directors determines the extent and duration of the powers assigned to the Executive Managing Directors.

The Board of Directors may remove the Managing Director at any time. The Executive Managing Directors may also be removed, upon a proposal of the Managing Director. If the removal is without just cause, it may give rise to damages, unless the Managing Director also assumes the functions of the Chairman of the Board of Directors.

Whenever the Managing Director ceases to carry or is prevented from carrying out his duties, the Executive Managing Directors retain their duties and attributions, subject to a contrary decision by the Board, until a new Managing Director is appointed.
An individual may not hold more than one office of Managing Director of stock corporations (sociétés anonymes) having their registered office on the French territory.

The remuneration of the Chairman, and that of the Managing Director and Executive Managing Directors, is determined by the Board of Directors; it may be fixed or proportional or both.

ARTICLE 18 – STATUTORY AUDITORS

The control of the Company's financial statements is carried out by one or several statutory auditors, appointed and exercising their duties, in the conditions provided by law.

The statutory auditor(s) may be assisted with one or several controllers appointed by the Board of Directors and chosen either from amongst its members, or from outside them. The controllers may be invited by the Chairman to attend to meetings of the Board of Directors. In this case, they have a consultative vote.

ARTICLE 19 – GENERAL MEETINGS OF SHAREHOLDERS

Shareholders' meetings are called in the conditions provided by applicable laws and regulations.

Meetings take place at the registered office or at any other place indicated in the calling notice.

The right to participate in shareholders' meetings is subject to:

- the registration of the shareholder in the Company's share accounts for owners of registered shares,

- the deposit, at the place indicated in the calling notice, of a certificate of account registration issued by the bank, the financial establishment or the stockbroker, depositary of the shares, as the case may be, for the owners of bearer shares.

The time period during which these formalities must be completed expires a day before the date of the meeting.

General meetings of shareholders are chaired by the Chairman of the Board of Directors, or, in his/her absence, by a director specially delegated to this end by the Board, failing which the shareholders' meeting elects its chairman.

The duties of scrutineers are fulfilled by two members of the meeting present and accepting, who hold the higher number of shares.

The meeting officials appoint the secretary of the meeting, who may choose from outside the shareholders.

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An attendance sheet is drawn up in the conditions provided by applicable laws and regulations.

Are deemed to be present for purposes of calculating the quorum and majority, the shareholders who participate in the meeting by videoconference or by means of telecommunication, the nature and conditions of which are determined by a Decree issued by the *Conseil d'Etat* .

The copies and excerpts of the minutes of the shareholders' meeting are validly certified in accordance with the conditions provided by applicable laws and regulations.

ARTICLE 20 – POWERS AND RESOLUTIONS OF THE SHAREHOLDERS' MEETINGS

The ordinary and extraordinary shareholders' meetings, ruling under the conditions of quorum and majority prescribed by provisions respectively governing them, exercise the powers granted to them by applicable laws and regulations.

ARTICLE 21 - DISSOLUTION - LIQUIDATION

Upon expiration of the term of the Company or in the event of earlier dissolution, the shareholders' meeting determines the method of liquidation and appoints one or several liquidators, of whom it determines their powers, and who exercise their duties in accordance with applicable laws and regulations.

ARTICLE 22 - DISPUTES

Any dispute that may arise during the existence or liquidation of the Company, either between the shareholders or between the Company and the shareholders, regarding the interpretation or the enforceability of these by-laws or regarding, generally, any corporate matter, will be submitted to the relevant courts having jurisdiction where the registered office is located.

To that effect, in the event of a dispute, every shareholder must elect domicile in a place where the courts have jurisdiction over the registered office and all summons or services of process are validly delivered to this domicile.

CERTIFIED TRUE COPY

Exhibit 8.1

Subsidiaries of Flamel Technologies S.A.

Flamel Technologies, Inc.	Incorporated in the Commonwealth of Virginia, U.S.	Wholly owned subsidiary

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Exhibit 12.1

CERTIFICATION PURSUANT TO
SEC RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen H. Willard, certify that:

1. I have reviewed this annual report on Form 20-F of Flamel Technologies S.A. (the "**Company**");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
   c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the Audit Committee of the Company's Board of Directors (or persons performing the equivalent functions):
   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: May 7, 2010

/s/ Stephen H. Willard
Stephen H. Willard
Chief Executive Officer

Source: FLAMEL TECHNOLOGIES SA, 20-F, May 10, 2010 Powered by Morningstar® Document Research℠

Exhibit 12.2

CERTIFICATION PURSUANT TO
SEC RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Siân Crouzet, certify that:

1. I have reviewed this annual report on Form 20-F of Flamel Technologies S.A. (the "**Company**");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
   c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the Audit Committee of the Company's Board of Directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: May 7, 2010

/s/ Siân Crouzet
Siân Crouzet
Principal Financial Officer

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Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Flamel Technologies S.A. (the "**Company**") on Form 20-F for the fiscal year ended December 31, 2009, filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, Stephen H. Willard, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen H. Willard
Stephen H. Willard
Chief Executive Officer
May 7, 2010

Exhibit 13.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Flamel Technologies S.A. (the "**Company**") on Form 20-F for the fiscal year ended December 31, 2009, filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, Siân Crouzet, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Siân Crouzet
Siân Crouzet
Principal Financial Officer
May 7, 2010

Exhibit 23.1

CONSENT OF
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 of Flamel Technologies S.A., Nos. 333-137844, 333-134638, 333-111725, 333-109693 and 333-12542, of our report dated May 7, 2010, relating to the financial statement and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

Lyon, France, May 7, 2010

PricewaterhouseCoopers Audit

Represented by
Bernard Rascle

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Exhibit 23.2

CONSENT OF
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use of our report dated May 7, 2008, with respect to the consolidated financial statements of Flamel Technologies S.A. for the year ended December 31, 2007 included in the Annual Report on Form 20-F of Flamel Technologies S.A. for the year ended December 31, 2009.

Lyon, France

May 7, 2010

ERNST & YOUNG Audit

Represented by
Jean-Luc Desplat

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