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

FORM 20-F

o **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, 2007

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

o **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.

24 051 590 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 o No ☑

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 o 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 o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer ☑	Non-accelerated filer o	Smaller reporting company o
		(Do not check if a smaller reporting company)	

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 o
Other o

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

Item 17 o 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 o No ☑

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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®, Genvir™ , 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’ 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.

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 'believe,' 'expect,' 'anticipate,' '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:

- our products and product candidates, if approved for marketing, may not produce significant revenues and we rely on our partners to determine the regulatory and marketing strategies;
- our products and product candidates, in commercial use, may have unintended side effects, adverse reactions or incidents of misuse;
- we may enter into a collaboration with a third party to market or fund a proprietary product candidate and the terms of such a collaboration may not meet our expectations;
- our delivery technologies or product development efforts may not produce safe, effective or commercially viable products;
- our collaborators could elect to terminate or delay programs at any time and disputes with collaborators or failure to negotiate acceptable new collaborative arrangements for our technologies could occur;
- we may be unable to manufacture or, if our products are successful, scale-up the manufacturing of our products economically or on a commercial scale;
- unexpected events could interrupt manufacturing operations at our facilities, which could be the sole source of supply for these products;
- after the completion of clinical trials of products incorporating our technologies and the submission to the U.S. Food and Drug Administration (FDA) of a New Drug Application, or NDA, for marketing approval and to other health authorities as a marketing authorization application, the FDA or other health authorities could refuse to accept such filings or could request additional pre-clinical or clinical studies be conducted, each of which could result in significant delays, or such authorities could refuse to approve the product at all;
- our product candidates could be ineffective or unsafe during pre-clinical studies and clinical trials and we and our collaborators may not be permitted by regulatory authorities to undertake new or additional clinical trials for product candidates incorporating our technologies, or clinical trials could be delayed;
- we may experience significant delays in clinical trials on our products;
- we may not realize any revenue from milestone or royalty payments under our license agreements with our partners, including GlaxoSmithKline;
- even if our product candidates appear promising at an early stage of development, product candidates could fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance, be precluded from commercialization by proprietary rights of third parties or experience substantial competition in the marketplace;

- technological changes in the biotechnology or pharmaceutical industries could render our product candidates obsolete or noncompetitive;
- we may face difficulties or set-backs in obtaining and enforcing our patents or defending claims of patent infringement by others; and
- we may need to raise substantial additional funding to continue research and development programs and clinical trials and could incur difficulties or setbacks in raising such funds.

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.

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, 2007 are derived from the Consolidated Financial Statements of the Company, which have been prepared in accordance with U.S. GAAP and audited by Ernst & Young Audit, 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*:

	2003	2004	2005	2006	2007
Revenues	$ 25,167	$ 55,410	$ 23,598	$ 23,020	$ 36,654
Cost and Expenses	(29,866)	(46,575)	(64,367)	(61,858)	(77,503)
Income (Loss) from Operations	(4,699)	8,835	(40,769)	(38,838)	(40,849)
Interest and foreign exchange gain (loss), net	(856)	363	4,103	1,388	1,221
Other income	1,128	100	5,003	131	197
Income (loss) before income tax	(4,427)	9,298	(31,663)	(37,319)	(39,431)
Income tax benefit (expense)	503	3,201	4,286	2,118	1,694
Net income (loss)	$ (3,924)	$ 12,499	$(27,377)	$(35,201)	$(37,737)
Income (Loss) from Operations per ordinary share	$ (0.26)	$ 0.41	$ (1.77)	$ (1.63)	$ (1.70)
Basic earnings (loss) per ordinary share	$ (0.22)	$ 0.58	$ (1.19)	$ (1.48)	$ (1.57)
Diluted earnings (loss) per ordinary share	$ (0.22)	$ 0.53	$ (1.19)	$ (1.48)	$ (1.57)
Basic weighted average number of shares outstanding (in thousands)	17,762	21,514	22,999	23,812	24,024
Diluted weighted average number of shares outstanding (in thousands)	17,762	23,559	22,999	23,812	24,024
Dividends per share	—	—	—		

(* in thousands of U.S. dollars, except share and per share data)

Balance Sheet Data*:

	2003	2004	2005	2006	2007
Cash, Cash equivalents & Marketable securities	$109,617	$105,374	$ 83,774	$ 62,771	$ 41,062
Working capital**	102,867	97,446	67,092	55,465	31,155
Total assets	127,252	145,608	124,351	114,894	101,401
Long term liabilities (excluding deferred revenues)	3,123	4,665	12,801	20,504	21,483
Shareholders equity	92,061	116,757	86,654	73,026	54,627

* (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,	High	Low	Average Rate[1]
Euro to U.S. Dollar:			
2007	1.4874	1.2893	1.37064
2006	1.3331	1.1826	1.25567
2005	1.3507	1.1667	1.24478
2004	1.367	1.176	1.248
2003	1.246	1.036	1.132

Previous Six Months,	High	Low	Average Rate[1]
Euro to U.S. Dollar:			
March, 2008	1.5812	1.5196	1.552653
February, 2008	1.5167	1.4513	1.474838
January, 2008	1.4895	1.4482	1.471791
December, 2007	1.4741	1.4349	1.457037
November, 2007	1.4874	1.4423	1.468364
October, 2007	1.4447	1.4037	1.422748

The exchange rate for the Euro against the U.S. dollar as of May 5, 2008 was $1.546 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.*

Risk Factors:

Certain statements made in this annual report on Form 20-F are forward-looking statements based on our current expectations, assumptions, estimates and projections about our business and our industry. These forward-looking statements involve risks and uncertainties. Our business, financial condition and results of operations could differ materially from those anticipated in these forward-looking statements as a result of certain factors, as more fully described below and elsewhere in this annual report. The risks and uncertainties described below are not the only ones we face.

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. 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 allow us to enjoy profitability.

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, Wyeth, Servier, and other unnamed pharmaceutical and biotechnology companies.

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. 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 and adverse impact on our revenues and profits. 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; and
- our collaborative partners may terminate their relationships with us.

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. Accordingly, it is possible that products that incorporate our technologies may never reach the commercial market for any number of reasons. 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, and we may be unable to increase our revenue.

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

- the FDA or an institutional review board may delay or stop the conduct of clinical trials;
- our pharmaceutical or biotechnology partners may face slower than expected rate of patient recruitment and enrollment;
- they may be found to be ineffective or cause harmful side effects, or they may fail during 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 cannot be manufactured on a commercial scale and, therefore, may not be economical to produce; or
- products that use our technologies also could fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties.

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.

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 they 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 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. The FDA has substantial discretion in the approval process and may disagree with our or our partners' interpretations of such data and information 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, or may 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 also must comply with applicable current Good Manufacturing Practices (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 or our pharmaceutical and biotechnology company partners 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.

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 and quality. If approvals to market our products are delayed, if we fail to receive these approvals or if we lose previously received approvals, our revenues would be reduced. We may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals.

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 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 impact 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.

Our commercial products are subject to continuing regulation and we may be subject to adverse consequences if we fail to comply with applicable regulations.

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

- adverse drug experience 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;
- 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, or other regulatory organizations, may take actions that could significantly restrict or prohibit commercial distribution of products that incorporate our technologies. If the FDA determines that we are not complying with the law, it 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;
- suspend or limit our production;
- withdraw approval of marketing applications; and
- initiate criminal prosecutions.

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

From time to time, Congress adopts changes to the statutes that FDA enforces in ways that could significant affects our business. In addition, the FDA often issues new regulations or guidances, or revises or reinterprets its current regulations and guidances in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of any such changes may be.

Recently, for example, the Food and Drug Administration Amendments Act of 2007 (the "FDA Amendments") was enacted. This legislation contains a number of provisions that strengthen 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. These and other changes in the law (and the subsequent changes in FDA regulation and guidances) may have a significant impact on the path to approval and our obligations after products are approved.

Moreover under current U.S. law and FDA policy, generic versions of conventional chemical drug compounds, sometimes referred to as small molecule compounds, may be approved through an abbreviated approval process under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act. There is no such process under current law for biological products approved under a biologic license application (BLA), such as growth factors, interferons and certain other proteins. The FDA generally has asserted that it lacks statutory authority to implement an abbreviated approval pathway for generic or "follow-on" biological products. Some have disagreed with this assessment, suggesting that the FDA has the necessary authority. In addition, there have been legislative proposals in Congress to explicitly grant the FDA such authority. If the law is changed or if the FDA otherwise concludes that it has authority to approve follow-on biologics, such an abbreviated approval process could adversely affect biological products that incorporate our technologies.

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 reduced 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, 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.

Certain companies to which we have licensed our technology are subject to extensive regulation by the U.S. Food and Drug Administration. 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 and equivalent foreign regulatory authorities. Those regulatory agencies may conduct periodic audits or inspections of the companies' facilities to monitor compliance with applicable regulatory standards. With respect to Corning, the manufacturer of products containing Photochromic eyeglass lenses, these regulations include the Quality System Regulation (which requires manufacturers, including third-party manufacturers, to follow stringent testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process), labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off-label" uses, regulations governing the recall of products, and the Medical Device Reporting regulation, which requires that a manufacturer report to the FDA if its device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. If the FDA finds that a facility has failed to comply with applicable regulations, the agency can institute a wide variety of enforcement actions, ranging from warning letters or untitled letters; fines and civil penalties; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, products; withdrawal or suspension of approval of products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; 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 impair those companies' ability to produce and market their products and thus could significantly impact the royalties that we receive from them.

If we cannot keep pace with the rapid technological change in our industry, we may lose business.

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.

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.

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. 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 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. Further, we may not have the necessary financial resources to enforce our patents.

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.

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, U.S. 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 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 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 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. We currently do maintain insurance coverage for environmental liabilities. 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.

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

Our ability to successfully commercialize our products and technologies may depend in part 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. 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. Adequate third party reimbursement may not be available for our 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 ability to commercialize that particular drug. We cannot predict the effect that changes in the healthcare system, especially cost containment efforts, may have on our business. Any such changes may adversely affect our business.

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, including decreases, 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, therefore, 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 accumulated aggregate net loss from inception of approximately $148.1 million through December 31, 2007. 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 2007, 2006, 2005, 2003, and 2001. 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 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.

We may require additional financing, which may not be available on favorable terms or at all, 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. 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 also may elect to pursue additional financing at any time to more aggressively pursue development of new drug delivery technologies. 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.

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, 2007, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $8.17 to $36.97. In the year ended December 31, 2006, the closing sale price for our ADSs as reported on the NASDAQ National Market ranged from $16.70 to $34.88. 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;
- 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;
- litigation;

- decisions by our pharmaceutical and biotechnology company partners relating to the products incorporating our technologies;
- actions by the FDA 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.

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.

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

For the year ended December 31, 2007 we derived 44% of our total revenues from transactions in U.S. dollars, but have 98.9% 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 57 for more information on the impact of currency exchange rate fluctuations

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 for the improvement of medical applications. Our Medusa nanoparticulate technology is designed to deliver therapeutic proteins, peptides and other large and small molecules injected subcutaneously. Our Micropump technology is a multiparticulate 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 prevent the misuse of medications subject to abuse and to avoid dose dumping in the presence of alcohol. Our expertise in polymer science has also been instrumental in the development of a photochromic eyeglass lens product that was launched by Corning in 1999.

Our Medusa technology permits the long-acting controlled-release of proteins peptides and other molecules without the denaturation or other adverse effects of certain other delivery systems. Our lead application of Medusa is Interferon-Alpha XL ,a long-acting interferon-alpha 2b for the treatment of hepatitis C virus and certain oncology applications.

In October 2007, we announced top-line results of a two-week trial we conducted to compare Medusa-enabled Interferon-Alpha XL with Viraferon™ (marketed in the U.S. as Peg-Intron™). Top line results showed a statistically significant reduction in viral load in those patients given the highest dose of IFN-Alpha XL after two weeks in the group comprising genotype-1 naïve patients, and non-responder/relapsed patients to pegylated interferon plus ribavirin. Patients receiving the highest dose of Interferon-Alpha XL also reported fewer adverse events than patients receiving Peg-Intron. We presented the full data set in an oral presentation at the Annual Meeting for the European Association for the Study of the Liver in Milan, on April 25, 2008. Interferon-Alpha XL is available for licensing.

Another lead product using the Medusa technology is FT-105 basal insulin. FT-105 is the result of efforts we made to re-formulate Basulin®, a product that we originally developed in 2003, to extend its duration of action using a new polymer (the ubiquitous polymer) in a new microparticulate formulation. We believe that the new formulation potentially may provide true once-daily dosing for all patients who require basal insulin, while maintaining the other advantages offered by Basulin compared to existing products on the market. These advantages include the fact that it is a recombinant human insulin with full bioactivity, both with respect to glucose control as well as insulin's role as a modulator of growth factors, especially vascular endothelial growth factor (VEGF). VEGF plays an essential role in maintaining vascular health.

In October 2007, we announced top-line results of the Phase I three-way crossover trial comparing two doses of FT-105 with Lantus®, the current standard of care. The trial was conducted in 18 healthy volunteers, and used the euglycemic clamp technique, whereby patients are requested to fast for 36 hours and their levels of insulin and glycemia are monitored. Pharamacodynamics were monitored for 48 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. 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. Competing technologies such as pegylation have thus far not been shown effective when applied to many smaller proteins and peptides.

On December 8, 2004, we announced the initiation of a Phase I/II trial for Medusa-enabled long-acting interleukin-2 (IL-2) for the treatment of end-stage renal cancer. We reported the results of this Phase I/II trial at the May 2006 annual meeting of the American Society of Clinical Oncologists (ASCO). The results showed 7 day duration of action and improved immunostimulation of CD-4, CD-8, and CD-25 as compared to Proleukin®. We believe that these results represent the first time that interleukin-2 has been administered in a controlled release formulation. The Medusa-enabled formulation of IL-2 is available for licensing.

In September 2007, we signed a license for the application of the Medusa platform with Wyeth Pharmaceuticals for the controlled release of an already marketed therapeutic protein. The license agreement included an upfront payment and potential development fees, milestones and royalty payments, the terms of which are not disclosed. The program is in the feasibility stage.

In December 2007, we announced that we had engaged with Merck Serono for the development of a controlled release formulation of a therapeutic protein belonging to Merck Serono. We received an upfront payment of €2 million for investigating the therapeutic protein and Merck Serono will be responsible for all costs associated with the development of the program, which is in the late pre-clinical stage.

Applications of Medusa to other therapeutic proteins, including human growth hormone have shown promise in late pre-clinical studies. In addition, during 2007, we signed eight other feasibility agreements with eight other pharmaceutical and biotechnology partners for the development of controlled release formulations of marketed or novel proteins and peptides.

Our Micropump technology platform allows us to specifically tailor the pharmacokinetics of small molecule drugs best absorbed in the small intestine. Advantages of the Micropump platform include the ability to specifically design certain pharmacokinetic properties for targeted indications, the minimization of inter-patient and intra-patient pharmacokinetic variability, taste masking, and the ability to design a wide variety of formulations, including tablets, capsules, sachets, and syrups or suspensions. Our lead product using Micropump technology is Coreg CR, which we developed with GlaxoSmithKline (GSK).

We licensed Coreg CR to GSK in March 2003. In September 2004, we announced that GSK had initiated a Phase III trial for the formulation. In December, 2004, we announced that we had entered into a supply agreement with GSK for the production of Coreg CR microparticles at our plant in Pessac, France. The provisions of the agreement included payments such that Flamel did not incur cash outlays in connection with equipment to be used. The FDA has audited and approved our Pessac facility. This supply agreement was supplemented in July 2006 when we announced that GSK had agreed to partially fund an expansion of the Pessac facility from two lines to three, in anticipation of expected increased demand for the product. The NDA for Coreg CR was submitted in December 2005 and the FDA approved the product for all requested indications (moderate to severe congestive heart failure; left ventricular dysfunction following myocardial infarction; and hypertension) on October 20, 2006. GSK launched the product in the U.S. in March 2007.

GSK has announced that they plan to file a New Drug Application in 2008 for the combination of Coreg CR and lisinopril, an ACE inhibitor indicated for the treatment of hypertension and congestive heart failure. A number of Phase III studies sponsored by GSK evaluating the combination product are listed on www.clinicaltrials.gov.

Flamel is also engaged in two pre-clinical relationships using Micropump. One of these is addressing the applicability of the Trigger-Lock® application of Micropump to multiple molecules used in the treatment of moderate to severe pain. Trigger-Lock is designed to effect the controlled release of small molecules while defeating commonly used methods to immediately liberate the active ingredient. This is a common problem affecting controlled release formulations of opioid analgesics, such as Oxycontin®, as well as other small molecules subject to abuse. Flamel believes that Trigger-Lock offers potential advantages to interested partners in its ability to potentially offer the same degree of pharmacokinetic controlled release while simultaneously protecting against these commonly used means of liberating the active ingredient.

There are a number of Micropump-enabled formulations that were developed internally in which we will not invest further funds in the absence of a licensed partnership: omeprazole-XL, for control of gastric-reflux disease (GERD); Genvir, a controlled-release acyclovir for the treatment of genital herpes; Metformin XL, a controlled-release form of Metformin currently in development for use in the treatment of Type II diabetes; and co-amoxiclav, our Micropump-enabled formulation of the active ingredients in Augmentin® for pediatric and geriatric use. A sixth product, Asacard, a controlled-release formulation of aspirin for the treatment of cardiovascular disease, was licensed in May 2006 to RHEI Pharmaceuticals for the greater China territory. As of March 31, 2008 we had feasibility relationships with four of the top ten and 6 of the top 20 pharmaceutical companies in the world. These relationships focus on potential improvements to a variety of small and large molecule drugs, some of which are novel molecules and others of which are already-marketed products.

We have had a long-standing collaborative relationship with Corning to develop advanced polymeric photochromic materials for eyeglass lenses. We have enjoyed eight years of royalties as a result of sales of this product. This is also the first product containing our technology to have been commercialized.

The Company was incorporated as a societe anonyme, a form of corporation under the laws of the Republic of France in August 1990, 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 a Vent, 33, avenue du Docteur Georges Levy, 69693 Venissieux Cedex France, telephone number 011 33 (4) 72 78 3434. A list of the Company's significant subsidiaries can be found in Exhibit 8.1.

The Need for Novel Delivery Systems

Our polymer delivery systems currently focus on the controlled release of therapeutic proteins and peptides 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 U.S. market for drug delivery formulations is expected to grow at an annual rate of 10% and could reach $132 billion by 2012.

Business Strategy

We aim to build on our core strength as a science based, market focused innovator of controlled release drug delivery systems. The key elements of our strategy that will enable us to build upon our strengths are as follows:

- 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.

For the reasons set forth below in this Item 4, 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 remain committed to focusing on our strengths. We will continue to partner our proprietary formulations with pharmaceutical companies with 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 that 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 and Peptides

Therapeutic agents based on biological proteins and peptides are becoming increasingly important. According to our internal estimates, the worldwide market for currently approved therapeutic proteins was over $75 billion in 2007 and the growth of this market is expected to be significant as new products are commercialized. In developing these products, a principal challenge is finding a suitable delivery system that can transport the protein or peptide to its site of action, release it at the optimal therapeutic rate, and protect it from being unduly degraded without denaturing it (i.e., causing a structural change that results in a loss of the properties that are linked to its precise structure).

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:

- can be metabolized by the human body into harmless substances;
- is compatible with the protein or peptide;
- keeps the structure of the protein intact;

- protects the therapeutic agent during transit and delivery; and
- has the required release properties once delivered.

Responding to these scientific challenges and to what we believe is a significant market opportunity, we have developed Medusa, a delivery system designed to deliver proteins and peptides in a controlled manner without denaturation. Our approach utilizes a novel nanoparticulate system, combined with a polyaminoacid biopolymer, that meets the above conditions. We have developed a protein-like polyaminoacid composed of only one or two different amino acids. We have tailored this polyaminoacid polymer to form nano-sized particles spontaneously in water that entrap proteins without the use of solvents or any surfactants. This 'self-assembly' process is critical in avoiding the denaturing of the proteins. The "ubiquitous" polymer is potentially applicable across substantially all therapeutic proteins and peptides. One advantage of this approach is that we do not anticipate the necessity to conduct individual toxicity and carcinogenicity tests for each product that we develop using the technology. That is because the bond created in the self-assembly process is a physical bond and not a chemical one. We have shown in animal studies that our polyaminoacid polymer is neither immunogenic nor reactogenic. Nevertheless, further testing is necessary in each application of Medusa to a drug to demonstrate that each product does not pose a potential risk for human subjects.

Products Based on the Medusa Technology

1. Interferon

We believe that the Medusa delivery system has the potential to improve formulations of other important biological drugs. In December 2004, we initiated a Phase I/II clinical trial of Medusa enabled long-acting interferon-alpha (IFN-alpha XL). We presented the data from this study at the XII Annual International Symposium on Viral Hepatitis and Liver Disease in July 2006. The results strengthen our belief that the therapeutic profile of interferon alpha, particularly in the treatment of hepatitis C and cancer, can be improved if its peak concentration in the blood (Cmax) is reduced. One key advantage of the Medusa-enabled formulation of interferon-alpha is its improved safety profile. IFN-alpha XL allows for the possibility of lesser side-effects at constant dosing, the potential for administering higher doses for greater efficacy, or some combination of the two.

In October 2007, we announced top-line results of a two-week trial we conducted to compare Medusa-enabled Interferon-Alpha XL with Viraferon™ (marketed in the U.S. as Peg-Intron™). We presented the full data set in an oral presentation at the Annual Meeting for the European Association for the Study of the Liver in Milan on April 25, 2008. Top line 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 lower in those patients administered Interferon-Alpha XL than in those patients administered Peg-Intron.

We estimate that the worldwide market for interferon drugs to have been $7.9 billion in 2007, 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 2007, we estimate that interferon alpha formulations accounted for approximately 35% of the worldwide market for interferons. We are in discussions regarding a licensing agreement 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 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. The body also produces a small quantity of insulin every 15 minutes to ensure that a basal level of insulin is maintained throughout the day. To maintain similar control over their glucose levels, diabetics who need insulin also require two different types: a fast-acting insulin to be taken at meal times, and a long-acting insulin to maintain a constant minimum level of needed insulin, particularly throughout the night when patients do not inject insulin.

We estimate that the worldwide market for insulin is estimated to have been approximately $10.5 billion in 2007. Of this total, long-acting basal insulin constitutes nearly $6.9 billion in annual sales. 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 long-acting basal insulin requirements of both of these groups.

The Development of FT-105 basal insulin

Using our the microparticulate adaptation of our Medusa delivery system, we have been able to form nanoparticles of human insulin with our proprietary polyaminoacid polymer and aggregate these to produce a long-acting, injectable insulin formulation, FT-105.

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. Optimizing the insulin uptake implies a better control of the diabetic's blood glucose level which prevents such serious long-term complications. 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'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 insulin's role as a modulator of growth factors, especially VEGF. VEGF plays an essential role in maintaining vascular health.

On August 27, 2003, we announced that we had entered into a license agreement with Bristol-Myers Squibb (BMS) for Basulin, the predecessor product to FT-105. The license agreement provided for an initial payment to us of $20 million and additional milestone payments that could have reached $145 million plus royalties on the sale of the product. BMS also would assume all costs of future clinical trials, development, registration and marketing of the product. On September 16, 2004, we received a letter notifying us of BMS's intention to cancel the partnership. On December 15, 2004, ninety days after receipt of the cancellation letter, we re-obtained the rights to Basulin. On January 31, 2005, Flamel Technologies and BMS entered into a termination agreement, with respect to the former licensing agreement. Under the terms of the January 31, 2005 agreement, we received a cash payment of $5,850,000. We held discussions with potential pharmaceutical partners during the second half of 2005 regarding the potential licensing of the Basulin, after it had been reformulated to provide lower viscosity.

In 2006, we further re-formulated FT-105 to extend its duration of action using a new polymer (the ubiquitous polymer) in a new microparticulate formulation. We believe that the new formulation potentially may provide true once-daily dosing for all patients who require basal insulin, while maintaining the other advantages offered by FT-105 compared to existing products on the market.

In October 2007, we announced top-line results of the Phase I three-way crossover trial of FT-105 conducted in 18 healthy volunteers. The trial used the euglycemic clamp technique, whereby patients are requested to fast for 36 hours and their levels of insulin and glycemia are monitored. Pharamacodynamics were monitored for 48 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.

3. Interleukin

In December 2004, we initiated a Phase I/II clinical trial of Medusa-enabled long-acting interleukin-2 (IL-2 XL) for the treatment of renal cancer. We believe that the use of IL-2 as a treatment for renal cancer as well as in other indications has been limited due to its extreme toxicity. Pre-clinical studies of our long-acting interleukin-2 versus Proleukin® in monkeys showed an increase in the duration of action of the drug, with a lower blood concentration of drug after injection (Cmax). Flamel's formulation resulted in measurable increases in levels of lymphocyte CD4 and CD8, and the soluble fraction of CD25 in the monkeys studied, which are considered surrogate markers for stimulation of the body's immune system. These results were confirmed in the Phase I/II clinical trial, the results of which we presented at the 2006 general meeting of the American Society

for Clinical Oncology (ASCO). In addition to its application for advanced kidney cancer, IL-2 XL could be used in further oncology indications where immune response plays a significant role because of its potentially improved safety profile. IL-2 XL could also become an important adjuvant for vaccines as well as in the treatment of HIV. We have held discussions with interested parties regarding clinical studies of IL-2 XL for use in treating HIV. Specifically, IL-2 XL could be used to allow patients who have undertaken combination therapy to suspend such therapy, to reduce the load on the liver. Further, with respect to patients with severely compromised immune systems, as evidenced by suppressed CD-4 counts, it is possible that IL-2 could serve to greatly boost their immune system.

Other Products Based on the Medusa Technology

The success in development of the ubiquitous polymer has generated ten new feasibility study relationships with biotechnology and pharmaceutical partners in 2007. These include the relationships with Wyeth and Merck Serono, as well as several relationships with some of the top five biopharmaceutical companies in the world. These relationships range from work on marketed therapeutic proteins to peptides, and other novel large molecules. We believe that the strategy of engaging in feasibility work with a wide range of partners strengthens the Company as it allows us to diversify our development risks, improve our understanding of many cutting edge fields of research, and, importantly, to engage in projects designed to extend the Medusa platform to different indications and methods of delivery.

Micropump: Delivery System for the Oral Administration of Drugs

Our first drug delivery platform, Micropump, is an oral multiparticulate technology with applications in sustained release, tastemasking and bioavailability enhancement.

Micropump provides a method of encapsulating microscopic-sized particles or granulates of a pharmaceutical compound with carefully selected polymers designed to achieve a desired pharmacokinetic profile. These microparticles have dimensions that are intended to control the absorption rate of the drug. Each microparticle acts as an independent drug delivery vehicle that slowly releases particles, since they can be ‘programmed’ for each drug and each therapeutic indication by modifying the thickness and composition of the polymer coatings and the excipients encapsulated with the drug.

We believe that Micropump particles, which measure approximately 200 to 500 microns in diameter, can provide benefits in controlled-release and in the taste-masking of bad-tasting active materials. The latter use is particularly important where the microparticles are dosed in sachet or liquid suspension, or as rapidly dissolving tablets. In addition, we believe that our Micropump technology can facilitate improvements in the bioavailability of certain drugs whose low solubility profile restricts both the rate and extent of absorption. We have demonstrated that the incorporation of certain hydrophilic excipients into the Micropump particles leads to marked improvements in drug stability, which may, in turn, lead to enhancement of bioavailability. We are currently pursuing this application for the Micropump technology. Many new and effective drug compounds demonstrate poor stability characteristics, which can hamper the ability of these compounds to be successfully developed and commercialized. We believe that a drug delivery technology which has application in stabilizing such compounds would have significant value. The reformulation of existing compounds to incorporate such advantages may also potentially extend the patent life of such compounds.

Micropump technology has several other key attributes, including a high loading ratio of active ingredient to its polymer coating, allowing for conventional size tablets or capsules. This is important for some products, such as acyclovir, where large daily doses are required. The large number of microparticles contained in a tablet or capsule also enhances safety by avoiding the problem of dose-dumping (releasing all of the dose at one time/one place). Dose-dumping can give rise to side effects such as ulceration. In addition, changes in pH levels within a patient’s body have been shown not to affect the Micropump particle coating, unless so designed. This coating uses a class of material approved for pharmaceutical use by the FDA, which may accelerate testing and approval.

Our Trigger-Lock™ technology is an adaptation of the Micropump platform designed to prevent misuse of drugs subject to abuse, such as narcotic analgesics like Oxycontin. Such drugs are designed as controlled release formulations for the treatment of moderate to severe pain. When abused by recreational drug users, the controlled release mechanism is circumvented in such a way as to achieve the immediate release of the active ingredient. It is a significant medical and societal problem which has garnered a high level of attention from local, state, and federal officials in the U.S., as well as public health officers in the rest of the world. Because of their size, Micropump particles cannot be crushed, meaning that the platform is resistant to the most common method of misuse. Further modifications to the platform have been tailored to prevent other

less publicized methods of foiling currently-marketed controlled release systems. We believe that our Trigger-Lock technology is at least as good as competing technologies with respect to the prevention of potential abuse while also providing substantially better pharmacokinetic to patients when taken as directed. This combination of safety and pharmacokinetic efficacy could potentially enable us to create a best in class platform for the controlled release of drugs subject to abuse.

Moreover, we believe that there is potential wide applicability of the Trigger-Lock technology with respect to the prevention of alcohol-related dose-dumping in the presence of alcohol. Recently, greater attention has been paid to the problem of controlled release formulations that are compromised when taken in conjunction with alcohol. This scrutiny extends beyond commonly abused controlled substances that are particularly subject to abuse; it also concerns those drugs that are titrated until a patient begins to feel side-effects, such as cardiovascular drugs and anti-depressants. The expertise that we have gained in the development of our Trigger-Lock platform has benefits that extend beyond controlled substances and are applicable to the entire Micropump platform.

Products Based on the Micropump Technology

We believe that our Micropump system is most appropriate for delivery of therapeutic compounds for which the small intestine is the optimal site of absorption and where the extension of mean plasma concentration time is important. Our first approved product using the Micropump platform is Coreg CR, which we have developed with GSK.

1. Coreg CR

Beginning in 2003, we have worked with GSK to develop Coreg CR, an extended release formulation of carvedilol phosphate. Coreg CR is a next generation formulation of Coreg, 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. Under the terms of our license agreement with GSK, signed in 2003, we will receive milestones totaling $25 million, of which $19 million have been received as of December 31, 2007, as well as royalties on the sale of the product. GSK also agreed to pay all of the costs of research and development for the product. Under the supply agreement with GSK that we signed in December 2004, we expanded our capacity for the production of microparticles at our plant in Pessac, France at no cost to us. Pursuant to the supply agreement with GSK, we produce Coreg CR microparticles on a cost plus basis. In July 2006, we announced that GSK had agreed to partially sponsor the expansion of our plant in Pessac, from two lines to three, in anticipation of increased demand for the product. 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. The product was launched in March 2007.

The Market for Beta Blockers

Beta blockers are indicated for the treatment of Congestive Heart Failure (CHF) as well as to treat hypertension. Additionally, Coreg and Coreg CR are indicated for the treatment of left ventricular dysfunction following myocardial infarction. For some years, Coreg (carvedilol) has been the market leader in the treatment of CHF; it is the only beta blocker approved for the treatment of moderate to severe CHF. Coreg attained this leadership position despite the fact that it was not available in a once-daily formulation, unlike the rest 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. In August 2007, however, the CASPER study was published, in which investigators failed to prove a compliance advantage in patients prescribed Coreg CR versus those prescribed immediate release Coreg, according to the criteria that they pre-defined.

Earlier generations of beta blockers have not been widely used in the treatment of hypertension because of perceived drawbacks. The greatest of these drawbacks, perhaps, was the fact that many other beta blockers, have been associated with increased glycemia levels in Type II diabetic patients. Carvedilol has been clinically proven not to cause increased glycemia levels in diabetic patients. Many hypertension patients in the U.S. suffer from Type II diabetes; there are over 13 million Type II diabetic hypertensives in the U.S. According to the Centers for Disease Control, many more hypertensive patients suffer from what is referred to as metabolic syndrome, meaning that they have a combination of factors that affect their health in an interrelated fashion, and these patients are considered to be at-risk for Type II diabetes. They may even have what is known as pre-diabetes, meaning that their blood sugar levels are above average but do not yet reflect the level insulin insensitivity that defines Type II diabetes.

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.

2. Asacard162.5mg: Controlled-Release Cardiovascular Aspirin

Asacard is a controlled release formulation of aspirin, designed to provide effective and safe therapy for cardiovascular treatment. Aspirin is a highly effective prophylactic treatment that promotes cardiovascular health. For many users, however, aspirin causes gastro-intestinal damage because it inhibits the Cox-1 enzyme. Asacard's advantage is that the release of aspirin is controlled such that substantially all of the aspirin is metabolized in the liver before reaching the circulatory system. This allows the aspirin to maintain all of its benefits while drastically reducing the potential gastro-intestinal side-effects associated with Cox-1 inhibition.

In May of 2006, we announced that we had entered into a licensing contract with RHEI Pharmaceuticals, Inc. The agreement grants RHEI the exclusive right to market Asacard in the Greater China region (including China, Taiwan, Hong Kong and Macau). Flamel will manufacture commercial supply of the product at its facilities in Pessac, France.

Other Products 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. Such contracts provide us with the possibility for expanded relationships. Moreover, these relationships are invaluable insofar as our potential partners are often able to identify opportunities for the Micropump platform from their internal pipeline, opportunities which we would not otherwise know.

Photochromic Materials

Our expertise in polymer science has led to a long-term collaborative relationship with Corning. Under a contract research arrangement that has 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.

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(TM), 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.'

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. Our existing agreements are as follows:

GlaxoSmithKline

On March 28, 2003, we announced that we licensed our Micropump technology to GlaxoSmithKline for the development of Coreg CR. We announced in September 2004 that GlaxoSmithKline had begun a Phase III clinical trial of the product. We received a $2 million milestone payment as a consequence of the Phase III trial initiation. In December 2004, we announced that we signed an agreement whereby Flamel will supply GlaxoSmithKline with commercial supplies of the drug. The provisions of the agreement include payments such that we will not have cash outlays in connection with equipment to be used. On October 26, 2005, we announced that GSK had determined that successful Phase III results had been obtained on this product. The determination triggered a $2 million milestone payment. On December 21, 2005, we announced that GSK had submitted a New Drug Application to the FDA for the product. In February, 2006, we received a $2 million milestone payment following the submission of a NDA for Coreg CR. This supply agreement was supplemented in July 2006 when we announced that GSK had agreed to fund an expansion of the Pessac facility from two lines to three, in anticipation of expected increased demand for the product. Coreg CR received an approval letter from the FDA on October 20, 2006, triggering the receipt of a $3 million milestone payment. In March 2007, GSK launched Coreg CR and we received a further $1 million milestone. Turnover of Coreg CR through to December 31, 2007 amounted to $176 million on which we recognized royalty revenue of $5.9 million.

Merck Serono

On December 20, 2007, we announced that we had entered into a relationship with Merck Serono for the development of a controlled release formulation of a Merck Serono product using our Medusa technology platform. We received € 2 million to engage in the project and have negotiated terms including development reimbursement, milestones and royalties that will be due to us if and as the project advances.

Wyeth

We announced on September 12, 2007 that we had entered into a license agreement with Wyeth Pharmaceuticals for the development of an already-marketed Wyeth protein. We received an upfront fee and may receive potential development fees, milestones, and royalties on the product.

TAP

On September 16, 2004, we announced that we had entered into a licensing agreement with TAP Pharmaceuticals, Ltd. for an extended release formulation of lansoprazole, the active ingredient in Prevacid®. The license agreement provides for milestone payments of up to $100 million as well as royalties on the sale of the product TAP Pharmaceuticals, Ltd. also assumed all costs of future clinical trials, development, and marketing of the product. On September 5, 2005, we announced that we had received a letter from TAP Pharmaceuticals, Ltd. notifying us of their intent to terminate the agreement. The termination became effective in December 2005.

Bristol-Myers Squibb

On August 27, 2003, we announced that we had entered into a licensing agreement with Bristol-Myers Squibb for Basulin®. The license agreement provided for an initial payment to us of $20 million, and additional milestone payments that could have reached $145 million plus royalties on the sale of the product. In March 2004, we announced that we had received a $5 million milestone payment for the delivery of the phase II-b trial batch. On September 16, 2004, we announced that we had received a letter of termination from Bristol-Myers Squibb. On December 15, 2004, ninety days after receipt of the cancellation letter, we re-acquired the rights to Basulin. On January 31, 2005, Flamel Technologies and BMS entered into a termination agreement, with respect to the former licensing agreement.

Biovail

On April 9, 2003, we announced that we entered into an agreement with Biovail to license our Genvir™ product for the United States and Canada. We retained the rights to the product in the rest of the world. Under the agreement, Biovail was responsible for all development, clinical and regulatory costs associated with the filing and approval of the product in the U.S. and Canada. Biovail was also responsible for all expenses associated with the marketing, sales, advertising and promotion of the product in these markets. On March 3, 2005, Flamel sent a termination letter to Biovail. The agreement was terminated effective upon receipt of the letter by Biovail.

Servier

On January 11, 2002, we announced that we entered into a licensing agreement with Servier for application of our Micropump technology to an ACE inhibitor that is proprietary to Servier. We received $3 million upon signing of the agreement and total payments of over $10 million during 2002. In 2003, we received an additional $1,283,000 in research and development revenues and we recognized one milestone payment of $484,000 as licensing revenue. We had additional development income from them in 2007.

Merck & Co.

Effective September 30, 2001, we entered into a licensing agreement with Merck for an undisclosed class of products.

Corning: Photochromic Materials

Corning France, on its own behalf and representing Corning Incorporated and Corning Europe Inc., 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. Under this agreement, from March 1994 to February 1998, Corning financed our related research and development costs. This agreement also entitled us to royalty payments based on Corning's net sales, if any, of ophthalmic products that contained materials developed in conjunction with us.

On December 31, 1998, we entered into a new, long-term collaboration and development agreement with Corning S.A. and Corning Incorporated that expanded the scope and applicability of the earlier agreement. Under this new agreement, Corning owns all intellectual property developed with us. However, under specified conditions, we will have the right to use technology developed under the collaboration for applications other than photochromic eyeglass lenses or sunglass lenses. While we previously were entitled to receive royalties on the sales of all products containing intellectual property resulting from the collaboration, the new agreement provides for an increase in royalties on sales of certain products.

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. The year 2007 was the eighth full year of royalties for us for this product, and we received approximately $633,000 in royalties.

Manufacturing

On December 31, 1996, the Company 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 and entered into a three-year toll manufacturing agreement with SmithKline for cimetidine formulations. The Company has consistently met SmithKline's production requirements. The agreement was extended through the year 2005.

Up until 2005, activities at this facility included contract manufacturing for GlaxoSmithKline and other major pharmaceutical companies, process and scale-up activities and the production of clinical batches for our own products, as well as support analytical services for SmithKline and other pharmaceutical laboratories. As our products are commercialized, we expect that this facility will provide necessary quantities of some portion of our products other than Coreg CR.

In 2004, we built a new facility of 16,000 square feet 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 will support the production of polymer to meet the needs from projects such as FT-105, interferon-alpha, and interleukin-2. 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 pages F-13 of our consolidated financial statements.

The Pessac facility provides the Company with the capability to manufacture its pharmaceutical products. The Company believes that the facility and its operations are in substantial compliance with current 'Good Manufacturing Practice' (cGMP) requirements, and the facility is approved by U.S. and European drug agencies for production of certain pharmaceutical products, including commercial quantities of the Company's microencapsulated drugs. Such approval qualifies the Company 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 its core businesses, Flamel was able to build on its capabilities and experience with GlaxoSmithKline and other pharmaceutical customers to engage in toll manufacturing for pharmaceutical partners. With its experienced workforce and cGMP operations, the Company provided clinical batch manufacturing, process scale-up services and toll manufacturing of solid dosage forms, and also provided analytical services for contract customers up until the last quarter of 2005. Our production site at Pessac was in full-scale production of Coreg CR microparticles during the majority of 2007.

At the end of 2006 we began the construction of a new facility, dedicated to Micropump process development. 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 has been partially funded by our partner, GSK.

Patents and Proprietary Technology

Patents and other proprietary rights are important to our business. As a matter of policy we seek patent protection of our inventions and trademarks and we 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 counterpart patent applications in other countries.

Since inception, we have been granted 311 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 (BASULIN®), interferon and interleukins.

In the case of the French patents, we currently have counterpart patents or patent applications pending in other European nations, Japan and the United States.

Throughout 2007, we were granted 22 new patents (including 2 in the United States); we filed for 3 new patent applications with the French Patent Office and for corresponding U.S. provisional patent applications. We have also filed 6 Patent Cooperation Treaty (PCT) extensions of cases first filed in 2006 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.

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, drug products 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 permanently emerging 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.

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. Violations of these 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. The intended clinical trial must be authorized by the regulatory authority(ies) of each country where the trial is intended to be run and will be based on the favorable attitude of the Ethics Committee(s) of each country (EU equivalent to IRBs) before trial authorization will be given by the agency(ies) concerned.

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. This latter 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.

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 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 NDAs and BLAs submitted 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 "not-approvable" letter, communicating the agency's refusal 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. 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.

Other Countries

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable 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 regulations, product approval can be obtained for a period of five years, renewable subject to certain procedures through either a centralized or decentralized procedure depending on the nature and type of drug. Certain designated drugs are required to use the centralized procedure (mandatory: biologics, biotech and certain indications such as cancer, AIDS, diabetes and CNS; optional for various types of innovations). All others have the option to use the mutual recognition procedure, where approval is first obtained in one European Union country that then acts as a reporter for extending the product's approval in other European Union countries, or the new decentralized procedure where submission is concomitant in all desired countries, one of them 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 most other countries outside the United States. In particular, certain European countries will condition the reimbursement of a product by the countries' medical regulatory authorities on the agreement of the seller not to sell the product for more than a certain price in that country or by unilateral decision of the medical regulatory authorities and to the inscription of a 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. 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.

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 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” are 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 would likely be subject to device and/or drug regulations, 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, phase IV post-marketing 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 record keeping 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 record keeping 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, 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.

The recently enacted 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 collect adverse reactions and other eventual supplementary information, report to authorities at regular intervals and take adequate safety measures agreed with regulatory agencies as necessary.

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.

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. There is no such process under current law for biological products approved under a BLA, such as growth factors, interferons and certain other proteins. The FDA generally has asserted that it lacks statutory authority to implement an abbreviated approval pathway for generic or "follow-on" biological products. Some have disagreed with this assessment, suggesting that FDA has the necessary authority. In addition, there have been legislative proposals in Congress to explicitly grant FDA such authority. If the law is changed or if the FDA otherwise concludes that it has authority to approve follow-on biologics, 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

For medical devices, since January 1, 1995, European Union countries are required to put in effect certain Medical Devices Directives (MDD). This legislation includes, among others, requirements with respect to the design, safety, performance and manufacture of products. Under the system established by the MDD, medical devices must qualify for CE Marking by June 14, 1998. All new medical devices put on the market after June 14, 1998 must meet the MDD requirements. Devices are subject to, in addition to existing or future European Union or other countries' legislation, continued national regulation on pricing and reimbursement that may vary from country to country.

In order to qualify for CE Marking, the manufacturer must comply with the safety and performance requirements of the MDD. In order to demonstrate compliance, the manufacturer must undergo conformity assessment that depends on the class of the product. Once all the necessary conformity assessment tasks have been completed, CE Marking may be affixed on the products concerned. Although member countries 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 MDD can restrict, prohibit and recall CE Marked products if they are unsafe. Member countries can impose additional requirements as long as they do not violate the MDD 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 and applicable member country regulations. Following marketing, a strict vigilance system involving the reporting of incidents and the appropriate measures to deal with these incidents exists in certain European Union countries, including France.

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. Its 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 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, 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.

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 currently expires in 2009. We intend to renew it. A second facility comprising approximately 13,000 square feet houses equipment dedicated to our Micropump technology. We have renewed the lease on this facility which expires in 2015. The third and fourth facilities of approximately 11,000 square feet house our administrative offices. The leases on these facilities expire from 2010 to 2013. The fifth facility of approximately 6,800 square feet houses analytical laboratories and quality control, with a lease expiring at the end of 2012. 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 end of 2014.

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 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.

In 2006, we completed the expansion of 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 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 new Micropump facility was constructed at a cost of $8.2 million and has been manufacturing commercial quantities of the product on a 24 hour a day 7 days a week basis during a portion of 2007.

In the last quarter of 2006, we commenced the expansion of our Micropump Pilot Development facilities increasing the available area by 14,300 square feet and renovating a further 4,500 square feet. This facility has been completed in early 2008. 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.

ITEM 4A. Unresolved Staff Comments

N/A.

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.

2007 has been another key year for the Company with the launch of Coreg CR in the U.S. market at the end of the first quarter by our partner GlaxoSmithKline (GSK). The commercial phase of this partnership has driven the increase in revenues through royalty revenue, as well as product sales on the supply of commercial quantities of Coreg CR microparticles to GSK.

The Company has continued to achieve scientific success and the results of the phase 1 clinical trials conducted in 2007 for IFN Alpha XL and FT 105, Long Acting Insulin, which drive the increase in Research and Devlopment expenditures, are highly encouraging. A further twelve new relationships across both technology platforms have been established in 2007 and the Company's R&D teams have been committed to their execution in 2007 and will continue to do so in 2008. In particular, the engagements signed with Merck-Serono and Wyeth Pharmaceuticals have generated new sources of revenues in 2007 and are expected to continue to do so in 2008.

Investments have been pursued in 2007 in order to meet demands of key partners and in particular the renovation and extension of existing Micropump Development facilities at Pessac, part of which was financed by GSK.

As in previous years, the majority of the Company's expenses were incurred in Euros. 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 conversion of the Company's financial accounts to U.S. dollars is calculated in accordance with the value of the Euro to the U.S. dollar. See 'Item 3. Key Information — Exchange Rates. The Company's base of operations being in France, its costs are denominated primarily in Euros, but are translated for reporting purposes into U.S. dollars. The strengthening of the Euro relative to the U.S. dollar has resulted in an 9.2% increase in the average value of the Euro relative to the US dollar between 2006 and 2007. Consequently Euro denominated expenses have increased by an equivalent amount year on year simply as a result of the translation from Euros to U.S. dollars for reporting purposes. Similarly, the closing

value of the Euro relative to the U.S. dollar has increased by 11.8% resulting in a corresponding increase in amounts represented in the Balance Sheet as of December 31, 2007, compared with December 31 2006. 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, 2007.

In certain instances we compare expenses from one period to another in this Annual Report on Form 20-F using comparable currency exchange rates. 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 €13.8 million in each of fiscal year 2007 and fiscal year 2006, we would report $18.9 million of SG&A expenses in fiscal year 2007 (based on an exchange rate of 1€ = $1.37064, which was the average exchange rate in fiscal year 2007) and $17.3 million in fiscal year 2006 (based on an exchange rate of 1€ = $1.25567, which was the average exchange rate in fiscal year 2006). The comparable currency presentation would translate the fiscal 2006 expenses using the fiscal 2007 exchange rates and indicate that underlying expenses were flat rather than increasing by $1.6 million, as would be reported in the financial statements under U.S. GAAP. We present this comparable currency information in order to assess our underlying performance before taking into account exchange fluctuations. 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.

The Company has continued its strategy to tightly control expenses ensuring efficient and effective use of funds for the long term benefit of the Company. Operating expenses, excluding Costs of Goods Sold, have increased primarily as a result of the translation into U.S. dollars for reporting purposes. At comparable exchange rates operating expenses, excluding Costs of Goods Sold, have marginally decreased, despite the financing the two phase 1 clinical trials. Non-cash expenses relative to FAS 123R — Stock Based Compensation, amounted to $12.0 million in 2007 compared with $10.0 in 2006.

The Company continues to benefit from a solid cash position which has enabled it to continue to invest both in internal research programs and in the infrastructure required to execute these programs and those of its partners.

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, 2007, had an accumulated deficit of approximately $148.1 million. Flamel expects to continue maintain its investment in its research and development activities and in its facilities and business infrastructure whilst 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. In the future, revenues royalties are expected to increase since, in 2008, the Company will benefit from a full year of sales of Coreg CR. Equally the Company is committed to strict control over expenses and investments, by prioritizing expenditure on core activities critical to the Company's future success.

Critical Accounting Policies

Revenue Recognition

The Company recognizes revenue from contract arrangements, product sales and royalties earned.

Contract revenue generally includes upfront licensing fees, milestone payments and reimbursements of research and development costs. 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. The Company recognizes milestone-related revenues based on performance only when performance criteria are met under the terms of the collaboration and there are no further performance obligations. Where agreements have more than one milestone, a determination is made as to whether the milestones should be recognized separately or combined into a single unit of account in accordance with Emerging Issues Task Force Issue 00-21, Revenue Arrangements with Multiple Deliverables. In general milestones which 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) are recognized as separate units of account. 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 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 as 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 Corning, which 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 agreement provides for the payment of royalties to the Company based on sales of the licensed product. The Company records these royalty revenues based on actual sales to third parties that occurred during the relevant period.

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

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 received to finance certain research and development projects are repayable on commercial success of the project. In the absence of commercial success the Company is release of its obligation to repay the funds and they 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.

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.

Results of Operations

Years Ended December 31, 2007, 2006 and 2005

Operating Revenues

The Company had total revenues of $36.7 million in 2007, $23.0 million in 2006 and $ 23.6 million in 2005.

		2005	2006	2007
LICENSE AND RESEARCH REVENUES		**20.8**	**20.3**	**10.3**
RESEARCH		**15.4**	**13.4**	**5.5**
Research	GSK Coreg CR	8.6	9.6	1.9
	TAP Lansoprazole	6.8		
	Wyeth Pharmaceuticals			0.3
	RHEI Pharmaceuticals			0.1
	Undisclosed Partners		3.8	3.2
LICENSES		**5.4**	**6.9**	**4.8**
Up Front Payment	GSK Coreg CR	0.8	0.2	
	TAP Lansoprazole	0.9		
	Biovail Genvir	0.2		
	Wyeth Pharmaceuticals			0.2
	RHEI Pharmaceuticals			0.2
	Undisclosed Partners		0.7	0.4
Milestones	GSK Coreg CR	2.0	6.0	4.0
	TAP Lansoprazole	1.5		
TOTAL		**20.8**	**20.3**	**10.3**
	GSK Coreg CR	11.4	15.8	5.9
	TAP Lansoprazole	9.2		
	Biovail Genvir	0.2		
	Wyeth Pharmaceuticals			0.5
	RHEI Pharmaceuticals			0.3
	Undisclosed Partners		4.5	3.6

Amounts in millions of U.S. Dollars

In 2007, license and research revenue from the Company's various partners totalled $10.3 million. License and research revenue in 2006 and 2005 totalled $20.3 million and $20.8 million, respectively. In 2007, research and development revenue totalled $5.5 million; license revenue totalled $4.8 million. In 2006, research and development revenue totalled $13.4 million; license revenue totalled $6.9 million. In 2005, research and development revenue totalled $15.4 million; license revenue totalled $5.4 million. License and research revenues in 2007 are significantly lower than 2006 primarily as a result of the conclusion of research efforts on CoregCR following the commercial launch of the product in March 2007. Nevertheless, additional research and licence revenues have been recognised with new partners in addition to a substantial volume of revenues from undisclosed partners.

Research and development revenues in 2007 consisted primarily of $1.9 million from GSK, and $3.2 million from undisclosed partners. Research and development revenues in 2006 consisted primarily of $ 9.6 million from GSK, and $ 3.8 million from undisclosed partners. Research and development revenues in 2005 consisted primarily of $ 8.6 million from GSK, and $ 6.8 million from TAP.

License revenues in 2007 consisted primarily of $4.0 million from GSK following the achievement of specific milestones. License revenue in 2006 consisted primarily of $6.2 million from GSK (of which $0.2 million represents amortization of up-front payments). Recognition of the amortization of up-front payments is calculated according to the average exchange rate during the period of recognition. License revenues in 2005 consisted primarily of $2.8 million from GSK (of which $0.8 million represents amortization of up-front payments) and $2.4 million from TAP.

In 2007, product sales and services revenues totaled $19.8 million and in 2006 totaled $2.1 million, 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. In 2005, product sales and services revenues totaled $ 1.8 million, of which $0.1 million related to the manufacture of Cimetidine and Tagamet for GlaxoSmithKline and $1.7 million from clinical batches and toll manufacturing with various customers.

Other revenues of $6.6 million 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. Other revenues of $0.7 million in 2006 and $ 1.0 million in 2005 consisted primarily of royalties from Corning.

Operating Expenses

The Company had total costs and expenses of $77.5 million in 2007, $61.9 million in 2006 and $64.4 million in 2005.

In 2007, research and development costs represented the most significant operating expenses of the Company. These totaled $43.6 million in 2007, $38.2 million in 2006 and $47.3 million in 2005. The increase in research and development expenses compared with 2006 is largely as a result of the adverse impact of the €/$ exchange rate. At comparable exchange rates research and development costs increased by $1.7 million in 2007 compared with 2006. The Company continued to fund key research programs through 2007 and pursued two phase 1 clinical studies on Interferon Alpha XL and FT105 Long-acting insulin. The funding of these clinical study programs, partially offset by tight control of other expenses, has driven the marginal increase in research and development expenses year on year. Nevertheless, the funding of these programs was critical in order to place both projects on a better standing for attracting potential partners to license these projects. The Company continued to pursue its activities on early phase projects and new projects and initiatives in order to ensure that its technologies are at the forefront of scientific research. Research and Development costs include FAS 123R Stock based compensation expense of $5.7 million in 2007 and $3.9 million in 2006.

The increase in research and development costs in 2005 compared to 2006 and 2007 was due to the active pursuit of ongoing partnerships and the conclusion of activities on Basulin® following the termination of the agreement in late 2004 by BMS.

The number of employees dedicated to research and development activities has remained stable over the last three years and the Company invested $6.4 million on pre-clinical and clinical studies in 2007, representing an increase of $2.2 million compared with 2006 and $1.8 million at comparable exchange rates.

Costs of products and services sold were $17.3 million in 2007, $6.3 million in 2006 and $2.5 million in 2005. These costs include direct and indirect labor, materials, outside services and overhead costs relevant to contract manufacturing provided to third parties at the Pessac facility and since late 2006 all costs incurred for the supply of commercial quantities of microparticles of CoregCR to GSK and for the availability of production capacity. The fluctuation in costs year-to-year is the result of the de-emphasizing of contract manufacturing in 2005 and a focus of our production capabilities in 2006 towards the manufacture of commercial quantities of Coreg CR microparticles. In 2007 the costs are related solely to the manufacture of commercial quantities of Coreg CR microparticles. In 2006 costs represent both the costs of preparation and qualification of our facilities plus the cost of producing commercial quantities of the product for GSK.

Selling, general and administrative (SG&A) expenses, amounted to $16.6 million in 2007, $17.4 million in 2006 and $14.5 million in 2005. SG&A expenses included FAS 123R Stock based compensation expense of $5.8 million in 2007 and $5.9 million in 2006. In 2005 SG&A expenses included a provision of $4.3 million resulting primarily from the consequences of the departure of the former Chairman and Chief Executive Officer. SG&A expenses in 2007 are adversely impacted by the strengthening of the Euro against the U.S. dollar and at comparable exchange rates SG&A expenses have decreased by $2.2 million compared with 2006. This reduction is driven by ongoing efforts to tightly control expenses on non-core activities and a reduction in costs associated with Sarbanes-Oxley 404 which was implemented in 2006, thus generating additional one-off costs in that year. SG&A costs in 2006, excluding the impact of FAS 123R stock based compensation expense, increased by $1.3 million compared with 2005 as a result of costs on patent registrations and execution of diligence on the implementation of Sarbanes Oxley 404.

Non-Operating Items

Interest income and realized gains on the sale of monetary SICAVs (*Societes d'Investissement à Capital Variable*) were $1.7 million in 2007, $ 2.0 million in 2006 and $3.7 million in 2005. The decrease in interest income in 2007 is a direct impact of the reduction in average cash balances invested year-to-year. The significant decrease in interest income in 2006 is due to the realized gain on sale of monetary SICAVs in 2005 which had accumulated since 2003. Interest expense was $16,000 in 2007, $35,000 in 2006 and $68,000 in 2005 and is primarily related to the interest applicable to the Company's equipment leases.

Foreign exchange loss for 2007 amounted to $0.5 million in 2007 compared with $0.6 million in 2006 and a gain of $0.5 million in 2005. These amounts are the consequence of having a significant volume of revenues denominated in USD and the corresponding variation in exchange rates during the year.

Other income in 2007 consisted of a number of miscellaneous items as is the case in 2006. In 2005 other income consisted primarily of the termination fee from Bristol-Myers Squibb totaling $4.9 million executed in January 2005 relative to the licensing and commercialization agreement to develop and market Basulin®.

The French government provides tax credits to companies both for annual increased spending and annual volume of 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, 2007, Flamel had total research tax credits receivables of $15.4 million. 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, i.e. $5.4 million in 2008, $5.0million in 2009 , $2.5 million in 2010 and $2.5 million in 2011. The Company earned a research and development credit in 2007 of $2.3 million in 2007, 2006 of $2.1 million and $4.2 million in 2005. The relative stability of the credit earned in 2007 is a direct result of the stability of research and development costs in 2007 compared with 2006 and 2005. The reduction in credit earned in 2006 is a direct result of the decrease in research and development costs compared to 2005 and 2004.

In 2007 the research tax credit was offset by withholding tax of $0.6 million incurred on royalty revenues received from GSK in accordance with the license agreement.

As of December 31, 2007, the Company had $126.2 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, 2007 the Company reported a net loss of $37.7 million or ($1.57) per share. For the year ended December 31, 2006 the Company reported a net loss of $35.2 million or ($1.48) per share. For the year ended December 31, 2005, the Company reported a net loss of $27.4 million, or ($1.19) per share.

Liquidity and Capital Resources

On December 31, 2007, the Company had $26.3 million in cash and cash equivalents and $14.7 million in marketable securities, as compared to $51.8 million and $10.9 million on December 31, 2006 and $ 1.0 million and $82.8 million on December 31, 2005. The reduction in the level of cash and cash equivalents is a direct result of cash used during the year to finance operating activities. The significant increase in cash and cash equivalents between December 31, 2005 and December 31, 2006 is as a result of the transfer of a significant volume of the Company's resources to Short Term Fixed Deposits rather than marketable security investments in order to benefit from a higher return on investments.

Net cash used in operating activities was ($19.2) million as of December 31, 2007, ($30.3) million as of December 31, 2006 and ($19.4) million as of December 31, 2005. As of December 31, 2007, net cash used in operating activities reflected a net loss of $37.7 million offset by non-cash expenses totaling $18.2 million, including $6.2 million from depreciation of property and equipment and $12.0 million relative to stock compensation expense. The decrease in net cash used for operating activities compared with the period ended December 31, 2006 is principally the result of the variation in working capital year on year resulting in cash provided of $1.9 million compared with a cash utilization of $8.7 million in 2006. In 2006 the variation in working capital, in particular the increase in inventory and accounts receivable was as a direct result of of the commencement of manufacturing to meet demand for launch of commercial quantities of Coreg CR microparticles on behalf of GSK in the last quarter of 2006. In 2007 the level of inventory has fallen in order to meet ongoing demand for the product and the Company has ensured prompt payment of accounts receivable balances and as such decreased working capital requirements. In addition, the Company received in December 2007 an upfront payment of $2.7 million from Merck-Serono, subsequent to the relationship entered into to investigate the applicability of Flamel's Medusa technology for the extended release of a therapeutic protein of Merck-Serono's portfolio, which is being amortized to income over the development period to which the payment relates.

Net cash used by investing activities was ($13.2) million in 2007 and included proceeds from the sale of marketable securities for $94.7 million and purchase of marketable securities for $96.7 million. The Company has invested a total of $11.2 million in the purchase of property and equipment in 2007 relative to the expansion of facilities at Pessac and the increase in capacity from two production lines to three. This facility was completed and qualified in early 2008. Net cash provided by investing activities amounted to $72.7 million in 2006 and net cash used by investing activities amounted to ($4.5) million in 2005. The increase in net cash provided by investing activities in 2006 is as a result of the transfer of certain of investments from marketable securities to Short Term Fixed Deposits as discussed above.

Net cash provided by financing activities was $3.0 million in 2007, which included $2.1 million received from GSK to sponsor part of the extension of existing facilities increasing production capacity from two lines to three and $0.8 million of conditional and unconditional grants received from government agencies. In 2006 and 2005, financing activities provided $5.5 million and $21.1 million, respectively. In 2006, net cash provided by financing activities included $5.0 million received from GSK to sponsor part of the extension of existing facilities increasing production capacity from two lines to three, less $2.1 million used to invest in equipment on behalf of GSK, and $2.6 million resulting from the exercise of warrants by directors and the exercise of options by employees. In 2005, net cash provided by financing activities included $12.3 million received from GSK for the funding of investments less $7.9 million used to invest in equipment on behalf of GSK, plus $3.5 million of conditional grants received from government agencies and $13.6 million resulting from the exercise of warrants by investors and directors which yielded $9.4 million, and the exercise of options by employees which yielded $4.2 million.

Since its inception, the Company's operations have consumed substantial amounts of cash and are expected to 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.

As of December 31, 2007, the Company held marketable securities classified as available-for-sale and recorded at fair value. Total marketable securities totaled $14.7 million at December 31, 2007 and $10.9 million at December 31, 2006.

As of December 31, 2007, the Company had loans of $0.9 million from Anvar, an agency of the French government that provides financing to French companies for research and development and $2.2 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.

As of December 31, 2006, Flamel had received all amounts payable by GSK under the agreement as detailed above. 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 $0.9 million and as a long term liability for $7.1 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.

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 and are classified as a current liability for $0.9 million and as a long term liability for $7.2 million. The liability will be 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. and reflected as an offset of the depreciation of the related assets.

The Company does not maintain any credit lines with financial institutions.

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 (see note 14)	$3,124	$ 724	$ 157	$1,964	$ 279
Capital Lease Obligation (see note 15)	$ 304	$ 260	$ 44		
Operating Leases (see note 21.2)	$5,071	$1,187	$1,587	$1,324	$ 973
Total Contractual Cash Obligations	$8,499	$2,171	$1,788	$3,288	$1,252

As of December 31, 2007, the Company has no off-balance sheet arrangements.

Directors and Senior Management

The following table sets forth the name and position of the directors of the Registrant as of December 31, 2007.

Name	Position	Year of Initial Appointment
Elie Vannier (1) (2)	Non-Executive Chairman of the Board of Directors	2005
Cor Boonstra (2) (4)	Director	2005
Frédéric Lemoine (2) (3)	Director	2005
Lodewijk J.R. de Vink (1) (3)	Director	2006
John L. Vogelstein(1) (3)	Director	2005
Dr; Frank J.T Fildes (5)	Director	2008
Stephen H. Willard (6)	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) Retired on February 29, 2008

(5) Nominated on February 29, 2008 in replacement of Cor Boonstra

(6) 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 as of December 31, 2007.

Name	Position	Year of Initial Appointment
Michel Finance (6)	Executive Vice President and Chief Financial Officer	2005
Rafael Jorda	Executive Vice President and Chief Operating Officer	1991
Christian Kalita	Directeur Général Délégué Pharmacien Responsable (Chief Pharmacist)	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
Siân Crouzet (7)	Financial Controller	2005
Katherine Hanras	Intellectual Property Director	1998
Roger Kravtzoff	Preclinical and Early Clinical Development Director	2002
Nigel McWilliam	Director of Business Development	2005
Remi 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

(6) On March 3, 2008 the Company announced the departure of Michel Finance.

(7) On March 3, 2008 the Company announced the nomination of Siân Crouzet as ‘Principal Financial Officer’.

The term of office of each of the directors expires at the year 2008 ordinary shareholders meeting.

In accordance with French law governing a *societe 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* 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 and former COO of GrandVision SA, Director of Ingénico, Famar, Visilab, GrandVision, Conbipel and Compagnie Européenne de Téléphonie,
- Cor Boonstra who retired in February 2008, former chairman and chief executive officer of Philips Electronics NV and Director of Hunton Douglas, and replaced by Dr. Frank J.T Fildes, the former Senior Vice President: Head of Global Development for AstraZeneca, PLC, Director of ProStrakan Group PLC and Piramed, Ltd, member of the Scientific Advisory Board of UCB Pharmaceuticals; and a member of the New Agents Development Committee for Cancer Research UK,
- Frédéric Lemoine, Chairman of the Supervisory Board of AREVA, former Deputy General Secretary of Economic Affairs to President Jacques Chirac of France, Director of Groupama SA and member of the Censor to the Supervisory Board of Générale de Santé,
- 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, Stiefel and member of the International Advisory Board of Sotheby's and Member of the European Advisory Council of Rothschild,
- John L. Vogelstein, who is Senior Advisor of Warburg Pincus, former Vice Chairman of Warburg Pincus and Director of Mattel, Inc.

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.

All directors are elected by the shareholders at each ordinary shareholders' 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 currently composed of Lodewijk J.R. de Vink (Chairman of the Committee), John L. Vogelstein and Elie Vannier. The Compensation Committee makes recommendations to the Board of Directors on the compensation of the executive officers of the Company, including the Chief Executive Officer. The Board of Directors makes the final decisions on compensation. The Board has an Audit Committee currently composed of Frédéric Lemoine (Chairman of the Committee), Cor Boonstra, recently replaced by 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. The Company has a Nominating and Corporate Governance Committee, currently composed of John L.Vogelstein (Chairman of the Committee), Frédéric Lemoine and Lodewijk J.R. de Vink. 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.

Compensation of Directors and Officers

During 2007, 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 $507,281 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 May 15, 2007, a shareholders' meeting approved a total amount of annual attendance fees to be allocated to the Board of 400,000 Euros, of which 380,000 Euros was subsequently distributed. For the financial year 2007 a total amount of 422,500 Euros ($579,095) 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. 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.

Michel Finance was our Chief Financial Officer and Executive Vice-President up until the Company's announcement, on March 3, 2008, of his departure. He previously served as the Senior Vice President and Corporate Controller for Aventis Group, where he reported to the Vice-Chairman of the Board. He also worked as the Chief Financial Officer of Pasteur Mérieux Connaught (currently Sanofi Pasteur) from 1995 to 1999. He held before that various financial executive positions at Rhône Poulenc subsidiaries after having worked as an auditor at Coopers & Lybrand for five years. He is a graduate of EM Lyon and a French CPA.

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.

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.

Yves Bourboulou is our Technical Director and Pessac Plant Deputy Manager. He worked previously as Plant manager at Pharmacia and Fresenius Kabi. He held before various senior pharmaceutical positions as Quality assurance Director; 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 this as Human Relations manager responsible for a couple of automobile plants. She is a graduate of Lyon Human Sciences University.

Catherine Castan is our Galenic Department 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 R&D in the field of biocompatible polymers for drug delivery and heads the analytical research group.

Siân Crouzet is our Controller and nominated Principal Financial Officer on March 3, 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.

Katherine Hanras is our Intellectual Property Director and joined Flamel in 1998. Mrs. Hanras spent two years at the Lipid Institut (ITERG) working on Cell membranes and Biovector interactions and after joined Sarget Pharma as manager in the R&D analytical Department. In 1998, she obtained her PhD in pharmaceutical science/option Analytical Chemistry with a dissertation on natural polyphenolic plant extracts: structure-property relationships with skinhealing and cell apoptose.

Roger Kravtzoff is our Pharmaceutical Development Director. Mr. Kravtzoff received his Doctorat-es Sciences in Biochemistry from Tours University (France) in 1988 and 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 one of the subsidiaries 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 regulatory affairs with regard to our pre-clinical and clinical developments.

Nigel McWilliam is our Director of Business Development. Nigel 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, who 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.

Remi 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 10 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 May 15, 2007 the shareholders of the Company authorized the issuance of up to 150,000 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 125,000 have been subscribed for.

On May 15, 2007 the Board of Directors authorized the Directors of the Company, Mssrs., Boonstra, de Vink, Lemoine, Vannier and Vogelstein, to subscribe to 25,000 warrants each for a subscription price of 2.16 Euros per warrant ($2.92)[2]. Each warrant is exercisable to purchase one Share at a price of 20.54 Euros ($27.83)[2].

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 beneficiaries are required to retain the shares for a further two years.

On May 15, 2007 the shareholders of the Company authorized the creation of a share option plan (the ‘2007 Plan’), which authorizes the Board of Directors to issue options to subscribe for up to 500,000 Shares. The 2007 Plan is designed to permit the granting of ‘qualifying stock options’ under French tax law principles as well as ‘incentive stock options’ under the Internal Revenue Code of 1986, as amended. Options granted under the 2007 Plan will have an exercise price based on the market price of the share, in the form of ADS, on NASDAQ, on the day preceding the date of the Board meeting, provided however, that such price is not less than 80% of the average market price for the shares on the NASDAQ, in the form of ADSs, during the last twenty trading days preceding said meeting. In this case, the price of the shares should be equal or superior to 80% of the average market price for the share on NASDAQ, in the form of ADS, during the last twenty trading days preceding such meeting. Such minimum price is the price applicable to companies, the shares of which are admitted to negotiation on a regulated market. The options granted under the 2007 Plan are exercisable up to ten years from the date of grant.

Free of Charge Share Awards Granted and Warrants Subscribed from January 1, 2007 to 31 March 2008

	Warrants	Exercise Price in Euros €	Exercise Price in USD $2	Expiration	Free of Charge Share Awards
Vannier	25,000	20.54	27.83	May 2010	
Boonstra	25,000	20.54	27.83	May 2010	
De Vink	25,000	20.54	27.83	May 2010	
Lemoine	25,000	20.54	27.83	May 2010	
Vogelstein	25,000	20.54	27.83	May 2010	
Autant					3,000
Bardet					2,000
Bourboulou					5,000
Borel					2,000
Boutherin-Falson					1,500
Capelle					4,000
Castan					4,500
Chan					6,000
Commaret					3,000
Constancis					4,000
Crouzet					4,000
Fernandez					3,000
Franoux					2,000
Gorria					4,000
Guimberteau					2,000
Hanras					2,500
Kalita					4,500
Kravtzoff					6,000
Lemercier					3,000
Marlio					3,500
McWilliam					5,000
Meyrueix					4,500
Nicolas					3,000
Portella					3,000
Prevot					2,500
Vialas					3,000
Weber					3,000

Employees

As of December 31, 2007, 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)	USA (3)	Total
Year End				
2005	123	131	5	259
2006	128	174	4	306
2007	130	168	4	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 MARCH 31, 2008

Name	Shares Owned	% of Ordinary Shares Outstanding	Warrants	Number of Options	Exercise Price in Euros €	Exercise Price in USD (2) $	Expiration	Total	Total %
Vannier	1	0,00%		75 000	13,72	16,68	September 2008		
			25 000		14,6	18,48	June 2009		
			25 000		20,54	27,83	May 2010	125 001	0,43%
De Vink	1	0,00%	63 084		20,07	23,99	March 2009		
			25 000		14,6	18,48	June 2009		
			25 000		20,54	27,83	May 2010	113 085	0,39%
Fildes	1	0,00%						1	0,00%
Lemoine	1	0,00%	30 750		14,91	17,88	November 2008		
			25 000		14,6	18,48	June 2009		
			25 000		20,54	27,83	May 2010	80 751	0,28%
Vogelstein	100 001	0,34%	60 000		14,91	17,88	November 2008		
			3 083		20,07	23,99	March 2009		
			25 000		14,6	18,48	June 2009		
			25 000		20,54	27,83	May 2010	213 084	0,73%
Willard	40 001	0,14%		40 000	7,58	4,99	September 2010		
				40 000	6,4	5,73	December 2010		
				25 000	6,4	5,73	December 2010		
				50 000	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	1 040 001	3,66%

OWNERSHIP OF SHARES AS OF MARCH 31, 2008 continued

Name	Shares Owned	% of Ordinary Shares Outstanding	Warrants	Number of Options	Exercise Price in Euros €	Exercise Price in USD (2) $	Expiration	Free of Charge Share Awards	Total	Total %
Bourboulou		0,00%		50 000	13,08	17,49	May 2015			
				20 000	12,86	15,83	September 2015			
				6 500	25,39	33,46	December 2016	10 000	86 500	0,30%
Capelle		0,00%		25 000	13,97	17,65	June 2016			
				3 750	25,39	33,46	December 2016	6 800	35 550	0,13%
Castan		0,00%		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	9 000	103 000	0,36%
Chan		0,00%		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	9 300	58 800	0,21%
Crouzet		0,00%		50 000	12,86	15,83	September 2015			
				5 000	16,23	19,35	December 2015			
				3 750	25,39	33,46	December 2016	6 800	65 550	0,23%
Finance				200 000	12,86	15,83	September 2015			
				20 000	16,23	19,35	December 2015			
				30 000	25,39	33,46	December 2016	2 500	252 500	0,89%
Hanras		0,00%		5 000	9,88	11,66	June 2013			
				40 000	20,81	25,27	December 2013	2 500	47 500	0,17%
Jorda	369	0,00%		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	5 000	330 369	1,16%
Kalita		0,00%		50 000	16,23	19,35	December 2015			
				6 500	25,39	33,46	December 2016	9 500	66 000	0,23%
Kravtzoff	0	0,00%		20 000	1,36	1,34	June 2012			
				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	9 300	88 800	0,31%
McWilliam				100 000	12,86	15,83	September 2015			
				5 000	16,23	19,35	December 2015			
				10 000	25,39	33,46	December 2016	5 000	120 000	0,42%
Meyrueix	125	0,00%		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	9 900	192 275	0,68%
Mosseri-Marlio		0,00%		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	5 200	72 450	0,26%
Portella		0,00%		2 750	25,39	33,46	December 2016	5 000	7 750	0,03%
Weber		0,00%		50 000	12,02	14,81	September 2014			
				2 750	25,39	33,46	December 2016	5 000	57 750	0,20%

ITEM 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth as of April 25, 2008, the percentage of Ordinary Shares owned by O.S.S. Capital Management LP, Knoll Capital Management, LP, Greenlight Capital Management, BVF, Inc., and Silver Point Capital 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, 2008: 24,066,590

Identity of Person or Group	Amount of Ordinary Shares Owned	Percentage of Class
O.S.S. Capital Management LP	6,346,047(1)	26.37%
BVF, Inc.	2,435,172(2)	10.12%
Knoll Capital Management LP	2,230,463(3)	9.27%
Greenlight Capital Management	1,887,008(4)	7.84%
Silver Point Capital L.P	1,500,000(5)	6.23%

(1) Based solely on a review of a Schedule 13D/A filed on August 31, 2007, O.S.S. Capital Management LP, shares beneficial ownership over the Ordinary Shares it owns with Schafer Brothers LLC and Oscar S. Schafer; in respect of 13.3% of the Ordinary Shares with O.S.S. Overseas Fund Ltd.; in respect of 12.1% of the Ordinary Shares with O.S.S. Advisors Ltd; and in respect of 11.1% of the Ordinary Shares with Oscar S. Schafer & Partners II LP.

(2) Based solely on a review of a Schedule 13G filed on January 24, 2008, BVF Inc. shares beneficial ownership over the Ordinary Shares it owns with BVF partners.

(3) Based solely on a review of a Schedule 13G/A filed on February 11, 2008, Knoll Capital Management, LP shares beneficial ownership over the Ordinary Shares it owns with Fred Knoll.

(4) Based solely on a review of a Schedule 13G/A filed on February 14, 2008, Greenlight Capital, LLC shares beneficial ownership over the Ordinary Shares it owns with David Einhorn.

(5) Based solely on a review of a Schedule 13G filed on February 14, 2008, Silver Point Capital L.P shares beneficial ownership over the Ordinary Shares it owns.

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. The Company has twenty-eight Ordinary shareholders of record including the Bank of New York. Approximately 99.60% of the Company's outstanding shares are represented by American Depositary Shares (ADS).

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	Date	Ownership Percentage
O.S.S. Capital Management LP	February 11, 2005	7.80%
Schafer Brothers LLC	April 18, 2005	9.70%
Oscar S. Schafer	May 11, 2005	11.9%
	May 12, 2005	12.3%
	June 23, 2005	11.7%
	September 9, 2006	13.0%
	January 13, 2006	15.4%
	February 14, 2007	17.6%
	August 31, 2007	26.37%
BVF, Inc.	February 14, 2005	10.31%
BVF Partners L.P.	April 21, 2005	11.41%
	July 22, 2005	9.5%
	January 13, 2006	8.1%
	April 25, 2006	6.7%
	September 18, 2006	5.5%
	October 16, 2006	4.9%
	January 24, 2008	10.12%
Knoll Capital Management L.P.	April 20, 2005	7.8%
Fred Knoll	February 9, 2006	8.5%
	February 11, 2008	9.27%
	July, 18, 2005	6.44%
Greenlight Capital Management	February 14, 2008	7.84%
Silver Point Capital L.P.	October 29, 2007	5.2%
	February 14, 2008	6.23%

B. Related Party Transactions

During 2007, and as of March 31, 2008, there is no related party transaction known to the Company to identify in 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.

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. The Company believes the claim to have no merit and is vigorously contesting the suit.

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, 2007, there were 23,956,339 ADSs outstanding in the United States. At such date, there were 33 holders of ADSs on record. As of December 31, 2007, there were 24,051,590 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**
2003	42.85	3.74
2004	31.73	14.67
2005	21.37	12.25
2006	34.88	16.7
2007	36.97	8.17

	Price Per ADS (U.S.$)	
Quarter Ended	**High**	**Low**
1st Quarter, 2005	19.65	12.82
2nd Quarter, 2005	21.37	12.25
3rd Quarter, 2005	20.45	14.90
4th Quarter, 2005	19.77	17.22
1st Quarter, 2006	24.40	18.50
2nd Quarter, 2006	21.37	17.37
3rd Quarter, 2006	18.75	16.7
4th Quarter, 2006	34.88	18.37
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

Month Ended	Price Per ADS (U.S.$) High	Low
October 31, 2007	12.03	8.34
November 30, 2007	9.00	8.25
December 31, 2007	10.70	8.17
January 31, 2008	10.65	9.305
February 28, 2008	9.57	8.38
March 31,2008	9.48	8.40

ITEM 10. Additional Information

Exemptions from certain NASDAQ Corporate Governance Rules

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 25% (in case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 33.3% (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 25% 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 NASDAQ Marketplace Rule 4350(g) requiring each issuer to solicit proxies and to provide proxy statements for all meetings of shareholders. 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 requirement to solicit proxies and provide proxy statements for shareholder meetings would be contrary to accepted business practice in France.

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.

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

Tax Consequences to Non-U.S. Holders

The following is a description of the French tax consequences of owning and disposing of Flamel Ordinary Shares. This description may only be relevant to holders of Flamel Ordinary Shares 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. 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 (the "*Treaty*") 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.

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. This summary does not address all potential tax implications that may be relevant as a holder, in light of particular circumstances.

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; and
- the holder has held not more than 25% of Flamel's dividend rights, known as *droits aux benefices sociaux*, at any time during the preceding five years, either directly or indirectly.

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.

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 1.10% on the higher of either the purchase price or the market value of the transferred shares would be due, with a maximum duty of €4,000 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 (*réfaction de 40%)* and to (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 as well as to(iii) a tax credit (*credit d'impôt*) 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.

b) Non-Residents

As from January 1, 2008, French companies must, in principle, deduct an 18% French withholding tax from dividends paid to non-residents. 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 *credit 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.

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

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 18%, 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.

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 or indirectly, less than 10% of Flamel's share capital;
- the U.S. Holder is entitled to the benefits of the Treaty under the 'limitations on benefits' article of that 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 Shares should consult their own tax advisers as to the particular tax consequences to them of owning Flamel Shares, including their eligibility for the benefits of the Treaty, the applicability and effect of 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 18% French withholding tax. Under the U.S.-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% and then reduced at a later date to 18%, 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 filling requirements as the U.S. Holders except that they may have 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 and is also available from the U.S. Internal Revenue Service. 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.

U.S. individual holders, who are residents of the United States for purposes of the Treaty, may also claim the *credit 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 withholding tax, 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 some recipients, they will constitute foreign source 'financial services' income for foreign tax credit purposes.

Under current guidance by the U.S. Internal Revenue Service, amounts distributed as dividends by Flamel with respect to Flamel Shares or ADSs will constitute "qualified dividend income" and will be subject to a U.S. Federal income tax at the same preferential rates as long-term capital gains, provided that certain holding period and other requirements are met and Flamel is not treated as a PFIC (as defined below under "Taxation of Capital Gains").

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 Shares. 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 Shares.
- 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 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.

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 Shares, unless the U.S. Holder has a permanent establishment or fixed base in France and the Flamel Shares the U.S. Holder sold or exchanged were part of the business property of 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 ADSs. Any such gain or loss will generally 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 the minimum holding periods.

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 applicable to distributions on Flamel Ordinary Shares and ADSs, and any gains a U.S. Holder realizes when the U.S. Holder disposes of such Flamel Ordinary Shares or ADSs, may be less favorable to the U.S. Holder. 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 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 reaty, "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".

United States Information Reporting and Backup Withholding

A U.S. Holder may be required to report dividend payments and proceeds from the sale or disposal of such U.S. Holder's Flamel Shares to the Internal Revenue Service. U.S. federal backup withholding generally is a withholding tax imposed at current 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. Finalized Treasury regulations, which are applicable to payments made after December 31, 2000, have generally expanded the circumstances under which information reporting and backup withholding may apply.

Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability. A U.S. Holder 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.

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.

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, 2007 revenues denominated in U.S. dollars represented 44% 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, 98.9% of the Company's cash and cash equivalents, totalling $26.3 million as of December 31, 2007, and all of the Company's marketable securities, totalling $14.7 million, as of December 31, 2007, 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 $3.7 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 $4.5 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

Not applicable.

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.

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, 2007. 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, 2007.

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young Audit, independent registered accounting firm, as stated in their report on the Company's internal control over reporting as of December 31, 2007, which is included herein. See report of Ernst & Young Audit, independent registered accounting firm, included under this item on page 60.

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, 2007 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).

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 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.

The Company's management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2007. 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, 2007, 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.

Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting

The Board of Directors and Shareholders,

We have audited Flamel Technologies, S.A.'s internal control over financial reporting as of December 31, 2007 based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Flamel Technologies, S.A.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying management report on internal control over financial reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides 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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

In our opinion, Flamel Technologies, S.A. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2007 consolidated financial statements of Flamel Technologies, S.A. and our report dated May 7, 2008 expressed an unqualified opinion thereon.

Lyon, France, May 7, 2008

The Independent Registered Public Accounting Firm
ERNST & YOUNG Audit

Represented by
Jean-Luc Desplat

ITEM 16. [Reserved]

ITEM 16A. Audit Committee Financial Expert

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

ITEM 16B. Code of Ethics

The Board adopted a written Code of Ethics. 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. This 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 Ernst &Young Audit for professional services rendered for the fiscal years ended December 31, 2007 and December 31, 2006:

Fee Category	Fiscal 2007 Fees (Euros)	Fiscal 2006 Fees (Euros)
Audit	333,275	158,300
Audit-Related Fees	15,000	133,525
Tax Fees	47,413	38,090
All Other Fees	0	0
Total Fees	**395,688**	**329,915**

All fees were billed in Euros. Using the average exchange rate of 1.37064 U.S dollars per Euro for 2007 and 1.25567 U.S dollars per Euro for 2006, audit fees equaled $542,346 for Fiscal 2007 and $414,264 for Fiscal 2006.

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.

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 and internal controls over Financial Reporting.

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 2007 and 2006 that are not included in one of the above categories.

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**.**

PART III

ITEM 17. Financial Statements

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

ITEM 18. Financial Statements

The following financial statements, together with the report of Ernst & Young Audit thereon, are filed as part of this Annual Report:

See pages F-1 through F-33

ITEM 19. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
1.1	Revised *Statuts* or charter of the Company.
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	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 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.

FLAMEL TECHNOLOGIES S.A.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders,

We have audited the accompanying consolidated balance sheets of Flamel Technologies S.A. as of December 31, 2006 and 2007, and the related consolidated statements of operations, shareholders' equity and cash-flows for each of the three years in the period 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 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 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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Flamel Technologies S.A. at December 31, 2006 and 2007, and the consolidated results of its operations and its cash-flows for the each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, the company adopted, as of January 1, 2006, the method of accounting share based payments in accordance with Statement of Financial Accounting Standards No. 123 (Revised 2004).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Flamel Technologies S.A.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated May 7, 2008 expressed an unqualified opinion thereon.

Lyon, France, May 7, 2008

The Independent Registered Public Accounting Firm
ERNST & YOUNG Audit

Represented by
Jean-Luc Desplat

FLAMEL TECHNOLOGIES S.A.

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

	Note	December 31, 2006	2007
ASSETS			
Current assets:			
Cash and cash equivalents	6	$ 51,827	$ 26,313
Marketable securities	7	10,944	14,749
Accounts receivable (net of allowance of $113 and $126 at December 31, 2006 and 2007 respectively)		5,583	4,987
Inventory	8	3,332	1,771
Research and development tax credit receivable current portion	18	615	5,490
Prepaid expenses and other current assets	9	4,478	2,800
Total current assets		76,779	56,110
Property and equipment, net	10	25,705	35,140
Other assets:			
Research and development tax credit receivable less current portion	18	11,599	9,932
Other long-term assets		811	219
Total assets		$ 114,894	$ 101,401
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Current portion of long-term debt	14	—	724
Current portion of capital lease obligations	15	420	256
Accounts payable		9,702	8,568
Current portion of deferred revenue	13	562	2,948
Advances from customers		394	1,215
Accrued expenses	11	5,505	5,369
Other current liabilities	12	4,731	5,875
Total current liabilities		21,314	24,955
Long-term debt, less current portion	14	2,795	2,400
Capital lease obligations, less current portion	15	272	44
Deferred revenue, less current portion	13	50	336
Other long-term liabilities	12 - 19	17,437	19,039
Total long-term liabilities		20,554	21,819
Commitments and contingencies:		—	—
Shareholders' equity :	17		
Ordinary shares: 23,990,590 issued and outstanding at December 31, 2006 and 24,051,590 at December 31, 2007 (nominal value 0.122 euro)		3,480	3,490
Additional paid-in capital		173,479	185,173
Accumulated deficit		(110,384)	(148,121)
Accumulated other comprehensive income		6,451	14,085
Total shareholders' equity		73,026	54,627
Total liabilities and shareholders' equity		$ 114,894	$ 101,401

See notes to consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

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

	Note	Year ended December 31, 2005	2006	2007
Revenue:				
License and research revenue	3	$ 20,825	$ 20,263	$ 10,307
Product sales and services	2	1,757	2,083	19,768
Other revenues		1,016	674	6,579
Total revenue		23,598	23,020	36,654
Costs and expenses:				
Cost of products and services sold		(2,525)	(6,250)	(17,320)
Research and development		(47,301)	(38,233)	(43,557)
Selling, general and administrative		(14,541)	(17,375)	(16,626)
Total		(64,367)	(61,858)	(77,503)
Income (loss) from operations		(40,769)	(38,838)	(40,849)
Interest expense		(68)	(35)	(16)
Interest income		3,671	2,022	1,691
Foreign exchange gain (loss)		500	(599)	(454)
Other income	5	5,003	131	197
Income (loss) before income taxes		(31,663)	(37,319)	(39,431)
Income tax benefit	18	4,286	2,118	1,694
Net income (loss)		$ (27,377)	$ (35,201)	$ (37,737)
Earnings (loss) per share				
Basic earnings (loss) per share		$ (1.19)	$ (1.48)	$ (1.57)
Diluted earnings (loss) per share	16	$ (1.19)	$ (1.48)	$ (1.57)
Weighted average number of shares outstanding (in thousands) :				
Basic		22,999	23,812	24,024
Diluted		22,999	23,812	24,024

See notes to consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

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

	Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Deferred Compen-sation	Accumulated Other Comprehen-sive Income (Loss)	Shareholders' Equity
	Shares	Amount					
Balance at January 1, 2005	21,751,590	$ 3,135	$ 148,389	$ (47,806)	$ (1,122)	$ 14,161	$ 116,757
Issuance of ordinary shares on exercise of warrants	1,125,000	180	9,196				9,376
Issuance of ordinary shares on exercise of stock -options	830,000	121	4,148				4,269
Compensation on warrants granted to non employees			207				207
Amort. deferred compensation			(820)		1,122		302
Net loss				(27,377)			(27,377)
Unrealized gains (loss) on available-for-sale securities						(1,887)	(1,887)
Foreign currency translation adjustment						(14,993)	(14,993)
Comprehensive loss							$ (44,257)
Balance at December 31, 2005	23,706,590	$ 3,436	$ 161,120	$ (75,183)	$ 0	$ (2,719)	$ 86,654
Subscription of warrants			706				706
Issuance of ordinary shares on exercise of stock -options	257,000	40	1,366				1,406
Issuance of ordinary shares on exercise of warrants	27,000	4	500				504
Stock-based compensation expense			9,787				9,787
Net loss				(35,201)			(35,201)
Unrealized losses on available-for-sale securities						(17)	(17)
Foreign currency translation adjustment						9,187	9,187
Comprehensive loss							$ (26,031)
Balance at December 31, 2006	23,990,590	$ 3,480	$ 173,479	$ (110,384)	$ 0	$ 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)	$ 0	$ 14,085	$ 54,627

See notes to consolidated financial statements

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

	Year ended December 31,		
	2005	2006	2007
Cash flows from operating activities:			
Net income (loss)	$ (27,377)	$ (35,201)	$ (37,737)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation of property and equipment	4,743	5,639	6,198
Loss (gain) on disposal of property and equipment	(93)	(92)	(39)
Gains on sales of marketable securities	(3,650)	(1,336)	(318)
Grants recognized in other income and income from operations	—	(183)	(1,216)
Stock compensation expense	546	9,989	12,004
Provision for losses on accounts receivable	—	15	—
Increase (decrease) in cash from:			
Accounts receivable	4,771	(2,589)	1,167
Inventory	351	(2,059)	1,818
Prepaid expenses and other current assets	1,029	(146)	2,054
Research and development tax credit receivable	(4,221)	(1,365)	(1,648)
Accounts payable	3,303	(2,987)	(3,023)
Deferred revenue	(2,905)	390	2,421
Accrued expenses	813	387	(9)
Other current liabilities	3,411	(1,466)	547
Other long-term assets and liabilities	(110)	1,178	(1,460)
Net cash provided by (used in) operating activities	(19,389)	(29,826)	(19,241)
Cash flows from investing activities:			
Purchases of property and equipment	(11,326)	(6,394)	(11,272)
Proceeds from disposal of property and equipment	154	92	47
Proceeds from sales of marketable securities	431,055	262,584	94,707
Purchase of marketable securities	(424,383)	(183,614)	(96,713)
Net cash provided by (used in) investing activities	(4,500)	72,668	(13,231)
Cash flows from financing activities:			
Funding from partner GSK	12,311	5,023	2,056
Use of funds received from partners (GSK) or relating to conditional grants	(7,951)	(2,087)	—
Proceeds from loans or conditional grants	3,470	347	839
Principal payments on capital lease obligations	(397)	(419)	(441)
Cash proceeds from issuance of ordinary shares and warrants	13,646	2,617	569
Net cash provided by (used in) financing activities	21,079	5,481	3,023
Effect of exchange rate changes on cash and cash equivalents	(763)	2,486	3,934
Net increase (decrease) in cash and cash equivalents	(3,573)	50,809	(25,515)
Cash and cash equivalents, beginning of year	4,591	1,018	51,827
Cash and cash equivalents, end of year	$ 1,018	$ 51,827	$ 26,312
Supplemental disclosures of cash flow information:			
Income tax paid	23	—	—
Interest paid	68	35	16
Non cash transactions:			
Capital lease obligations incurred	339	—	—

See notes to consolidated financial statements

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. 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. 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.

1.4. Revenue recognition:

Revenue includes upfront licensing fees, milestone payments and reimbursements of research and development costs. 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. Milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations. Where agreements have more than one milestone, a determination is made as to whether the milestones should be recognized separately or combined into a single unit of account in accordance with Emerging Issues Task Force Issue 00-21, Revenue Arrangements with Multiple Deliverables. In general milestones which 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) are recognized as separate units of account. 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.

1.5. 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'.

1.6. 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.

1.7. Concentration of credit risk:

The Company's cash and cash equivalents are deposited with HSBC, Barclays Bank, 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 $489,000 $113,000 and $126,000 at December 31, 2005, 2006 and 2007, respectively.

1.8. 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.

1.9. Cash and cash equivalents:

Cash and cash equivalents consist 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.

1.10.Marketable securities:

Marketable securities consist of highly liquid investments in money market mutual funds. As of December 2007, Flamel Technologies' marketable securities are classified as available-for-sale securities in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities" (SFAS 115). 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.

1.11. 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.

1.12. 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.

1.13. 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 - 5 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 or the remaining lease terms, whichever are shorter. Amortization of the carrying value of assets under capital leases is included in depreciation expense.

1.14. 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.

1.15. Income taxes:

The Company accounts for income taxes in accordance with SFAS No. 109, “Accounting for Income Taxes” (SFAS 109). Under SFAS 109, 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.

In June 2006, the Financial Accounting Standards Board (“FASB”) issued FASB Interpretation No. (“FIN”) 48, “Accounting for Uncertainty in Income Taxes,” effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing rules for recognition, measurement, classification and disclosure in our financial statements of uncertain tax positions taken or expected to be taken in a tax return. FIN 48 is effective to the Company as of January 1, 2007 and did not have a material impact on our consolidated financial statements.

1.16 . Employee stock options and warrants:

Prior to January 1, 2006, the Company accounted for stock-based compensation in accordance with APB No. 25, “Accounting for Stock Issued to Employees” and related interpretations. Accordingly, no compensation expense was recorded for options issued to employees in fixed amounts and with a fixed exercise price at least equal to the fair market value of the Company’s common stock at the date of grant. Conversely, when the exercise price for accounting purposes was below fair market value of the Company’s common stock at the date of grant, a non-cash charge to compensation expense was recorded ratably over the term of the option vesting period, in an amount equal to the difference between exercise price and the fair market value. These grants resulted in the recording of deferred compensation.

Effective January 1, 2006, the Company adopted FAS 123R, “Accounting for Stock-based Compensation” using the modified prospective method. Under the transition method, compensation cost in 2006 includes: (i) compensation cost for all share-based payments granted prior to but not vested as of January 1, 2006, based on the original provisions of FAS 123, and (ii) compensation cost for all share-based payments granted in 2006, based on grant-date fair value estimated in accordance with the provisions of FAS 123R.

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 in accordance with SAB 107 regardless of whether the company has sufficient information to make more defined estimates of the expected term. On December 21, 2007 the Security and Exchange Commission issued SAB 110 which expresses the view that “the use of a simplified method is not allowed if the Company may have sufficient historical exercise data for some of its share options grants. SAB 110 accepts therefore the use of simplified method for only some grants but not all share options grants”. The Company will adopt SAB 110 as of January 1, 2008 for the calculation of expected term should sufficient historical data exist. The impact of adoption of SAB110 will depend on the grant of stock based compensation in the future and the existence of available historical data, although we do not expect any material effect on our consolidated financial statements.

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

1.17. 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.

1.18. Recent Accounting Pronouncements:

In December 2007, the FASB ratified EITF No. 07-1, "*Accounting for Collaborative Agreements*" ("EITF 07-1"). EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes arrangements the Company has entered into regarding development and commercialization of products and product candidates. EITF 07-1 is effective for the Company as of January 1, 2009, and its adoption is not expected to have a material impact on our consolidated results of operations or financial position.

In June 2007, the FASB ratified EITF No. 07-3, *"Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" (* "EITF 07-3"), which requires that nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities pursuant to executory contractual arrangements be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. EITF No. 07-3 became effective as of January 1, 2008 and it did not have a material impact on our consolidated results of operations or financial position upon adoption.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities*" ("SFAS 159"). SFAS 159 became effective as of January 1, 2008 and will have no impact on our consolidated results of operations of financial position.

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurement*" ("SFAS 157"). SFAS 157 defines fair value, provides guidance for measuring fair value in U.S. generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 became effective as of January 1, 2008 and it did not have a material impact on our consolidated results of operations or financial position.

2. Subcontracting agreement:

In accordance with the terms of a subcontracting agreement signed with Smithkline in December 1996, the Company recognized as revenues from product sales a total amount of $102,000 in 2005. This agreement ceased in 2005 as the Company de-emphasized this activity.

In accordance with the terms of a supply agreement signed with GlaxoSmithKline in December 2004 for the manufacture of Coreg CR microparticles on a cost plus basis, the Company recognized as revenues from product sales a total amount of $2,083,000 in 2006 and $19,768,000 in 2007. 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. No sales of this product were made in 2005.

3. License, research and consulting agreements:

TAP Pharmaceutical Products Inc.

On January 30, 2004, Flamel Technologies and TAP Pharmaceutical Products Inc, ("TAP") entered into a licensing agreement whereby the Company agreed to license its controlled release Micropump® in order to develop a new formulation of Prevacid®, a proton pump inhibitor. The agreement was subject to FDA approval received on September 10, 2004.

In consideration of this agreement, TAP made an initial payment of $1,000,000 and agreed to make additional milestones payments upon achievement of certain events. The $1,000,000 initial payment was being recognized on a straight line basis over the three-year term of the development period. In 2004, the Company recognized licensing fees of $611,000 representing a milestone payment of $508,000 and amortization of the up-front payment for $103,000. In addition Flamel recognized research and development revenues of $4,862,000.

On September 2, 2005 TAP gave notice of the termination of the license agreement to Flamel. As the Company has fulfilled all of its obligations under this contract as of December 31, 2005, the remaining amount of the up-front payment of $913,000 was recognized as licensing fees in 2005. The Company also recognized in 2005 research and development revenues of $6,757,000 and a milestone payment of $1,462,000.

The Company did not recognize any revenues under this contract in 2006 and 2007.

Bristol-Myers Squibb

On August 27, 2003, Flamel Technologies and Bristol-Myers Squibb ("BMS") entered into a licensing and commercialization agreement to develop and market Basulin®, a controlled release unmodified human insulin. The agreement was subject to antitrust clearance, which was obtained on October 17, 2003.

In consideration of the agreement, BMS made a $20 million initial payment and agreed to make additional milestone payments upon achievement of certain events. The initial payment was being recognized on a straight-line basis over the term of the development period of three years.

On September 16, 2004, BMS gave notice of the termination of the license agreement to Flamel. As the Company had fulfilled all of its obligations under this contract as of December 31, 2004, the remaining amount of the up-front payment of $18,649,000 was recognized as licensing fees in 2004.

On January 31, 2005 Flamel Technologies and BMS entered into a termination agreement, with respect to the former licensing agreement. Under the terms of the January 31, 2005 agreement, the Company recognized $4,875,000 as other income (see note 5).

The Company did not recognize any revenues from BMS in 2006 and 2007.

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 2005, the Company recognized research and development revenues of $6,882,000. The Company also recognized $2,046,000 of milestone payments and $766,000 of amortization of the initial up-front payment.

In 2006, the Company recognized research and development revenues of $9,574,000. The Company also recognized $6,000,000 of milestone payments and $193,000 of amortization of the initial up-front payment.

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 CoregCR.

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.

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.

The Company received all installments due under the agreement by December 31, 2006.

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, 2007, the funds received from GSK to finance the acquisition of assets owned by Flamel are classified in other current liabilities for $904,000 and in other long term liabilities for $7,112,000. 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 to be provided by GSK amounted to $8.1M to finance the acquisition of equipments, buildings and fixtures. As of December 31, 2007 all installments due under the agreement were received and classified in other current liabilities for $902,000 and long term liabilities for $7,194,000. 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).

Biovail

In February 2003, Flamel Technologies entered into a license agreement with Biovail whereby the Company agreed to license to Biovail the exclusive North America rights to Flamel's oral solid controlled release formulation of acyclovir. In consideration for this license, the Company received $500,000, which we recognized on a straight-line basis over the development period of 3 years.

On March 3, 2005 Flamel announced the termination of the licensing agreement with Biovail. As the Company has fulfilled all of its obligations under this contract as of December 31, 2005, the remaining amount of the up-front payment of $213,000 was recognized as licensing fees in 2005.

The Company did not recognize any revenues under this contract in 2006 and 2007.

Wyeth Pharmaceuticals

On September 12, 2007 the Company entered into a development and license agreement with Wyeth Pharmaceuticals,('Wyeth') 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. 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.

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. Terms have been negotiated to include development reimbursement, milestones and royalties that will be due to the Company if and as the project advances.

In consideration of this agreement, Merck-Serono made an upfront payment of $2.7 million for investigating the therapeutic protein, which is being amortized over the development period .The Company recognized research and development revenues of $78,000 in 2007 being amortization of the initial up-front payment.

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 $1,016,000 in 2005, $674,000 in 2006 and $636,000 in 2007.

Others

The Company recognized license and research and development revenues on several feasibility studies with undisclosed partners for an amount of $4,427,000 in 2006, $3,705,000 in 2007 and no significant revenues in 2005.

4. Stock based compensation :

4.1 Adoption of SFAS 123R

With effect on January 1st, 2006 the Company has applied the provisions of FAS 123R 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:

	2006	2007
Weighted-average expected life (years)	4.36	1.71
Expected volatility rate	52.5%	52.7%
Expected dividend yield	—	—
Risk-free interest rate	4.66%	4.83%
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. The expected life is computed using the "simplified method" as provided by the Securities and Exchange Commission ("SEC") Staff Accounting Bulletin No. 107. Under this method, the expected life equals the arithmetic average of the vesting term and the original contractual life of the options. As of January 1, 2008, the Company will adopt SAB 110 for all new grants and will use the simplified method only in the absence of sufficient historical statistics.

Stock based compensation expense recognized under SFAS123R was as follows:

(In thousands of U.S dollars except per share data)	Options		Free of charge share awards		Warrants		Total	
	2006	2007	2006	2007	2006	2007	2006	2007
Research and development	3,662	4,598	56	1,220	203	(88)	3,921	5,730
Cost of goods sold	144	234	10	223	—	—	154	457
Selling, general and administrative	3,581	4,542	13	317	2,319	958	5,914	5,817
Total stock-based compensation expense	7,387	9,374	79	1,760	2,522	870	9,989	12,004
Effect on earnings per share								
Basic	0.31	0.39	0.00	0.07	0.11	0.04	0.42	0.50
Diluted	0.31	0.39	0.00	0.07	0.11	0.04	0.42	0.50

As of December 31, 2006, the projected compensation expense related to non vested options or warrants amounted to $22,873,000 and was expected to be recognized over a weighted average period of 2.27 years.

As of December 31, 2007, the projected compensation expense related to non vested options or warrants amounted to $11,861,000 and is expected to be recognized over a weighted average period of 1.62 years.

4.2 Proforma information for periods prior to adoption of SFAS 123R

The following pro forma income and EPS were determined as if we had accounted for stock-based compensation under the fair value method prescribed by SFAS123.

(In thousands of U.S. dollars except share data)	Year Ended December 31, 2005
Net income (loss), as reported	(27,377)
Add: Stock-based employee compensation expense included in reported net income (loss), net of related tax effects	335
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(2,220)
Pro forma net income (loss)	(29,262)

(In thousands of U.S. dollars except share data)	Year Ended December 31, 2005
Earnings per share:	
Basic, as reported	(1.19)
Basic, pro forma	(1.27)
Diluted, as reported	(1.19)
Diluted, pro forma	(1.27)

The weighted-average fair value and the weighted-average exercise price of options and warrants granted during 2005, 2006 and 2007 were as follows:

(In U.S. dollars)	Year Ended December 31					
	2005		2006		2007	
	Weighted avg. Fair value[1]	Weighted avg. Exer. Price[1]	Weighted avg. Fair value[1]	Weighted avg. Exer. Price[1]	Weighted avg. Fair value[1]	Weighted avg. Exer. Price[1]
	9.61	16.82	14.39	25.67	6.41	27.83

[1] Historical exchange rate at date of grant

4.3 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, 2005	1,275,000	$ 7.79	€ 7.47
Warrants granted	40,000	$16.18	€12.34
Warrants exercised	1,125,000	$ 6.34	€ 6.37
Warrants cancelled	150,000	$18.68	€15.70
Balance at December 31, 2005	40,000	$16.18	€12.34
Warrants granted	365,000	$19.25	€15.78
Warrants exercised	27,000	$17.44	€14.24
Balance at December 31, 2006	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

[1] Historical exchange rate at date of grant

The total intrinsic value of warrants exercised during 2006 amounted to €193,000 or $254,000 (historical exchange rate at date of exercise). No warrants were exercised during 2007.

Exercise prices and intrinsic value for warrants outstanding as of December 31, 2007 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 12.34	30 500	2,01	12,34	—	23 000	12,34	—
14.60 to 14.91	275 750	1,12	14,77	—	275 750	14,77	—
20.07 to 20.54	194 250	2,00	20,37	—	69 250	20,07	—
	500 500	**1,51**	**16,80**	**—**	**368 000**	**15,62**	**—**

The total fair value of warrants vested during 2006 amounted to €1,422,000 or $1,786,000 (average exchange rate of the year).

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

Intrinsic value represents the variance between the share price and the exercise price. As of December 31, 2007 the share price was less than the exercise prices of the warrants, accordingly intrinsic value was zero for each warrant outstanding or exercisable.

4.4 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, 2005	49,000	3,583,500	$ 11.55	€ 9.72
Options authorized	1,500,000	—	—	—
Granted	(1,545,500)	1,545,500	$ 16.83	€ 13.64
Exercised	—	(830,000)	$ 4.12	€ 4.26
Forfeited	794,000	(874,000)	$ 19.60	€ 15.69
Balance at December 31, 2005	797,500	3,425,000	$ 13.69	€ 11.31
Options authorized	—	—	—	—
Granted	(483,750)	483,750	$ 28.81	€ 22.33
Exercised	—	(257,000)	$ 4.74	€ 4.39
Forfeited	32,500	(122,500)	$ 18.82	€ 14.95
Balance at December 31, 2006	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

[1] Historical exchange rate at date of grant

The total intrinsic value of options exercised during 2006 amounted to €3,891,000 or $4,936,000 (historical exchange rate at date of exercise).

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

Stock options outstanding at December 31, 2007, which expire from 2010 to 2016 had exercise prices ranging from €1.09 to € 25.39. The weighted average remaining contractual life of all options is 6.71 years. As of December 31, 2007, there were 3,212,750 outstanding options at a weighted average exercise price of €13.31, of which 2,169,938 were exercisable at a weighted average price of €11.64.

Exercise prices and intrinsic value for options outstanding as of December 31, 2007 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	88,000	4.03	1.20	5.58	88,000	1.20	5.58
2.33 to 2.77	255,000	4.13	2.43	4.34	255,000	2.43	4.34
4.11 to 4.86	294,000	4.76	4.36	2.42	294,000	4.36	2.42
6.40 to 7.58	125,000	2.89	6.78	0.38	125,000	6.78	0.38
9.88 to 12.02	224,000	6.55	11.08	—	157,500	10.88	—
12.86 to 16.23	1,531,000	7.66	14.18	—	846,250	14.20	—
19.2 to 25.39	695,750	7.46	22.62	—	404,188	21.48	—
	3,212,750	**6.71**	**13.31**	**3.25**	**2,169,938**	**11.64**	**3.25**

The total fair value of options vested during 2006 amounted to €5,317,000 or $6,676,000 (average exchange rate of the year).

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 aggregate intrinsic value of options outstanding or exercisable amounted to €2,344,000 or $3,451,000 (exchange rate at date of balance sheet).

4.4 Free of charge share award

The activity under the free of charge 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

[1] Historical exchange rate at date of grant

As of December 31, 2006, the total fair value (or intrinsic value) of Free of Charge Share Award outstanding amounted to €2,691,000 or $3,546,000 (historical exchange rate at date of grant).

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

5. Other Income:

Other income of $5 million in 2005 consisted mainly of $4,875,000 termination fee received from BMS under the terms of the termination agreement signed on January 31, 2005. For the years ended December 31, 2006 and December 31, 2007 other income was not material.

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:

	December 31,	
(In thousands of U.S. dollars)	2006	2007
HSBC	$ 26,605	$ 13,968
Credit Lyonnais	61	17
Credit Agricole	24,883	4,796
Barclays Bank	—	7,438
Other	278	94
Total cash and cash equivalents	$ 51,827	$ 26,313

For the year ended December 31, 2007 cash and cash equivalents included fixed term deposits for $17,665,000 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, 2006 marketable securities amounted to $10,944,000. For the year ended December 31, 2007 marketable securities amounted to $14,749,000.

As of December 31, 2005, December 31, 2006 and December 31, 2007unrealized gains or losses were not material.

	Fair value		Value at cost		Unrealized Gains (Losses)	
(in thousands of U.S dollars)	2006	2007	2006	2007	2006	2007
Credit Agricole securities	1,520	4,739	1,520	4,739	—	—
Credit Lyonnais securities	102	79	102	79	—	—
HSBC securities	2,779	9,931	2,779	9,931	—	—
Barclays securities	6,543	—	6,560	—	(17)	—
Total	10,944	14,749	10,961	14,749	(17)	—

Gross realized gains on sales of these available-for-sale securities amounted to $3,650,000, $1,337,000 and $318,000 for the years ended December 31, 2005, 2006 and 2007 respectively.

(In thousands of U.S dollars)	Proceeds from sales		Purchase of securities		Gross gains (Losses)	
	2006	2007	2006	2007	2006	2007
Credit Agricole securities	104,280	40,034	69,494	42,753	500	111
Credit Lyonnais securities	1,615	327	1,288	292	7	2
HSBC securities	144,147	40,635	94,125	46,818	740	171
Barclays securities	12,542	13,711	18,707	6,851	90	34
Total	250,042	94,707	183,614	96,714	1,247	318

8. Inventory:

The components of inventories were as follows:

(In thousands of U.S. dollars)	December 31,	
	2006	2007
Raw materials	1,752	2,676
Finished goods	1,752	535
Provision for inventory obsolescence	(172)	(1,439)
Inventories, net	3,332	1,771

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,	
	2006	2007
Prepaid expenses	1,427	845
Valued-added tax recoverable	2,790	1,662
Advance to suppliers	261	293
Total Prepaid expenses and other current assets	4,478	2,800

10. Property and Equipment:

The components of property and equipment were as follows:

(In thousands of U.S. dollars)	December 31, 2006	2007
Land and buildings	5,930	6,627
Laboratory equipment	22,231	26,101
Office and computer equipment	3,051	3,852
Furniture, fixtures and fittings	13,971	16,053
Construction in progress	4,312	15,731
Total property and equipment	49,495	68,366
Less accumulated depreciation and amortization	(23,790)	(33,225)
Property and equipment, net	25,705	35,140

Depreciation expense related to property and equipment amounted to $4,743,000, $5,639,000 and $6,198,000 for the years ended December 31, 2005, 2006 and 2007, respectively.

Property and Equipment include costs of $1,650,000 and $1,844,000 at December 31, 2006 and 2007 that are related to capitalized lease assets. Accumulated amortization of these leased assets was approximately $1,324,000 and $1,818,000 at December 31, 2006 and 2007, respectively. Depreciation expense on assets held under capital leases is included in total depreciation expense for the years ended December 31, 2005, 2006 and 2007 and amounted to $580,000, $499,000and $315,000 respectively.

Construction in progress of $4,312,000 and $15,731,000 at December 31, 2006 and 2007 is mainly related to our ongoing expansion of production and development facilities at our site in Pessac.

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, 2006	2007
Accrued compensation	2,364	1,703
Accrued social charges	3,128	3,666
Other	13	—
Total accrued expenses	5,505	5,369

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, 2006	2007
Funding from partner GSK short term	925	1,805
Provision for costs	2,256	2,091
Conditional grants short term	—	1,362
Withholding tax	—	236
Employee service award provision short term	549	129
Valued-added tax payable	1,001	252
Total Other current liabilities	4,731	5,875

In connection with the supply agreement with GSK (see note 3), the Company received funds to finance facilities related assets. As of December 2006 the Company had received all installments due under the agreement. 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. The funds received from GSK to finance the acquisition of assets owned by Flamel are classified as a current liability for $904,000 and as a long term liability for $7,111,000. 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). As of December 31, 2007, the Company received all the installments for an amount of $8,097,000 of which $901,000 is classified as current liability and $7,196,000 recorded as long term liability. (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).

The provision for costs of $2.3 million in 2006 results from the consequence of the departure of the Chairman, CEO and founder of Flamel Technologies and related parties. These costs include French social security contributions associated with the exercise of stock options and, as of December 31, 2007 amounted to $2.0 million.

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, 2006 the provision for service award amounted to $1,525,000 of which $549,000 is short term. For the year ended December 31, 2007 the provision amounted to $1,541,000 of which $129,000 is short term.

12.2. Other long term liabilities

Other long term liabilities are composed of the following:

(In thousands of U.S. dollars)	December 31, 2006	2007
Funding from partner GSK long term	12,375	14,307
Conditional grants	2,675	1,372
Provision for retirement indemnity (see note 19)	914	1,450
Employee service award provision long term	976	1,412
Other	497	498
Total Other long term liabilities	17,437	19,039

Funding from partner GSK long term amounted to $7,111,000 in connection with the supply agreement signed in December 2004 and relates to the acquisition of buildings and fixtures (see note 12.1) and $7,196,000 in connection with the side agreement to the original agreement, signed in July 2006.

Conditional grants of $2.7 million in 2006 and $1.4 million in 2007 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, 2007 the Company recognized such grants for an amount of $1,216,000.

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, 2006 deferred revenues amounted to $612,000 and for the year ended December 31, 2007 $3,284,000.

14. Long-term Debt:

Long-term debt comprises:

(In thousands of U.S. dollars)	December 31, 2006	2007
Anvar loans (a) :		
Asacard program	853	953
French Ministry of Industry (b)	1,942	2,171
Total	2,795	3,124
Current portion	—	724
Long-term portion	2,795	2,400

(a) Anvar is an agency of the French government that provides financing to French companies for research and development. At December 31, 2006 and 2007, the Company had outstanding loans from Anvar of $853,000 and $953,000, respectively. These loans do not bear interest and are repayable only in the event the research project is technically or commercially successful. In 2006, Anvar agreed to recognize the commercial failure of one of the programs and authorized a further postponement of the scheduled repayments under the Asacard program. Potential repayment is now scheduled to occur from 2010 through 2013.

(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 in July 2008 with the remainder due on July 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,
2008	724
2009	—
2010	157
2011	1,672
2012	292
2013	279
	3,124

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 of one Euro. 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,
2008	261
2009	44
Total	304
Less amounts representing interest	(4)
Future payments on capital leases	300
Less current portion	256
Long term portion	44

Interest paid in the years ended December 31, 2005, 2006 and 2007 was approximately $50,000, $31,000 and $16,000, 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, 2005	2006	2007
Numerator:			
Net income (loss)	($27,377)	($35,201)	($37,737)
Denominator:			
Weighted average shares outstanding used for basic earnings (loss) per share	22,998,504	23,811,624	24,024,131
Effect of dilutive securities:			
Stock-options and warrants	—	—	—
Weighted average shares outstanding and dilutive securities used for diluted earnings (loss) per share	22,998,504	23,811,624	24,024,131
Basic earnings (loss) per share	($1.19)	($1.48)	($1.57)
Diluted earnings (loss) per share	($1.19)	($1.48)	($1.57)

For the years ended December 31, 2005, 2006 and 2007, the effects of dilutive securities were excluded from the calculation of earnings per share as a net loss was reported in these periods.

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 $135.4 million at December 31, 2007. 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, 2007, 7,000 warrants were exercised and 2,500 were forfeited.

The related compensation expense is computed under EITF 96-18 prescriptions.

On November 3, 2005, the Company authorized the Directors of the Company, to subscribe to 240,000 warrants for a subscription price of 1.49 Euros per warrant ($1.79). Each warrant is exercisable to purchase one Share at price of 14.91 Euros ($17.88). These warrants are issued for a three-year period and will vest over one year from the date of issuance. As of December 31, 2007 170,750 warrants were subscribed, 69,250 were cancelled and 20,000 warrants were exercised.

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

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 Euros per warrant ($1.84). Each warrant is exercisable to purchase one Share at a price of 14.6 Euros ($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.

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 Euros per warrant ($2.93). Each warrant is exercisable to purchase one Share at a price of 20.54 Euros ($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.

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

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

The effects of applying the fair value method provided in accordance with SFAS 123R are shown in Note 4.

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 recorded a liability in 2005 for social charges arising from exercise of stock options by employees having left the Company and for which the underlying shares have been sold within four years of the option being granted (see note 12.1). The Company has instituted a 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 of Charge Share Awards

On October 24, 2005 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 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.

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 of charge share awards to officers and employees.

On December 11, 2007 the Company granted 130,000 free of charge share awards to officers and employees.

17.6. Accumulated other comprehensive income:

The components of accumulated other comprehensive income are as follows:

	December 31,	
(In thousands of U.S. dollars)	2006	2007
Unrealized gains (loss) on available-for-sale securities	(17)	—
Foreign currency translation	6,468	14,085
Total	6,451	14,085

18. Income taxes :

Income (loss) before income taxes comprises the following:

	Year ended December 31,		
(in thousands of U.S. dollars)	2005	2006	2007
France	$(31,663)	$(37,319)	$(39,431)

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A reconciliation of income tax benefit (provision) computed at the French statutory rate (33.83% in 2005, 33.33% in 2006 and 2007) to the income tax benefit is as follows:

(in thousands of U.S. dollars)	Year ended December 31, 2005	2006	2007
Income tax benefit (provision) computed at the French statutory rate	10,712	12,438	13,142
Operating losses (not utilized)	(10,712)	(12,438)	(13,142)
Withholding tax	89	—	(594)
Research tax credits	4,220	2,118	2,288
Minimum tax payable	(23)	—	—
Total	4,286	2,118	1,694

Income tax benefits amounted to $4,286,000 in 2005 and were principally related to the research and development tax credit recorded in France for $4,220,000. In 2006, the research tax credit amounted to $2,118,000 and $2,288,000 in 2007.

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, 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.

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

(In thousands of U.S. dollars)	December 31, 2006	2007
Deferred income tax assets:		
Net french taxable operating loss carry-forwards (not utilized)	29,866	42,056
Other deferred income tax assets	2,656	3,684
Valuation allowance	(32,522)	(45,740)
Net deferred income tax assets	97	166
Deferred income tax liabilities	(97)	(166)
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, 2007, the Company had $126,181,000 in French net operating losses carry-forwards which have no expiration date.

The increase in available net operating losses carry-forwards in 2007 is due to a tax loss of $24,230,000. 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, 2007, Flamel had total research tax credits receivable of $15,422,000. 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 in accordance with the following timetable:

(In thousands of U.S. dollars)	December 31,
2008	5,490
Total current portion	**5,490**
2009	4,992
2010	2,483
2011	2,457
Total long term portion	**9,932**
Total	**15,422**

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 $1,609,000 in 2007, $1,538,000 in 2006 and $1,060,000 in 2005.

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 $1,450,000, $914,000, $664,000 as of December 31, 2007, 2006 and 2005, 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.

In 2007, the French Parliament adopted a new tax which represents 50% of the retirement indemnity. 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:

	2005	2006	2007
Average increase of salaries	3%	3%	3%
Discounted interest rate	4%	4.5%	5.5%
Turn over	average of the last 4 years	average of the last 4 years	average of the last 4 years
Age of retirement	65 years	65 years	65 years

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

In thousands of U.S. dollars	December 31, 2006	2007
Benefit obligations at beginning of year	664	913
Service cost	55	97
Interest cost	31	43
Benefits paids	(59)	(39)
Actuarial loss (gain)	137	299
Exchange rate changes	86	137
Benefit obligations at end of year	914	1,450

Change in plan assets	December 31, 2006	2007
Fair value of plan assets at beginning of year	—	—
Employer contributions	59	39
Benefits paid	(59)	(39)
Fair value of plan assets at end of year	—	—

Reconciliation of funded status	December 31, 2006	2007
Fair value of plan assets	—	—
Benefit obligations	914	1,450
Funded status (plan assets less benefit obligations)	(914)	(1,450)

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

In thousands of U.S. dollars	Year Ending:	
	12/31/2008	—
	12/31/2009	—
	12/31/2010	—
	12/31/2011	47
	12/31/2012	—
	Next 5 Years	1,624

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 $45,000 in 2007. The Company made contributions of approximately $79,000 in 2007, $40,000 in 2006 and $56,000 in 2005.

20. Fair value of financial instruments:

At December 31, 2006 and 2007, 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.

At December 31, 2006 and 2007, the fair value of long-term debt with carrying value of $2,795,000 and $3,124,000 was estimated to be $2,348,000 and $1,995,000, 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, 2007 are as follows:

(In thousands of U.S. dollars)	December 31,
2008	1,187
2009	821
2010	766
2011	703
2012	621
Thereafter	973
TOTAL	5,071

Rental expense for the years ended December 31, 2005, 2006 and 2007 was approximately, $1,089,000, $1,300,000 and $1,388,000 respectively.

21.3. Litigation

The Company is involved in a number of claims and lawsuits considered normal in its business, including employee litigation. While it is not possible to predict the outcome of legal actions brought against the Company, the Company believes that the liability resulting from the pending claims and suits would not have a material adverse effect on the results of its operations, cash flows, or financial position as of December 31, 2007, and for the year then ended.

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 86% of total revenues in 2007.

Operations outside of France consist principally of the operations of the U.S. subsidiary, which had no sales to third parties in 2005, 2006 or 2007.

Revenues by geographic location of customers are as follows:

	As of December 31,		
(in thousands of U.S. dollars)	**2005**	**2006**	**2007**
Revenues USA	$ 18 972	$ 16 385	$ 15 278
France	$ 2 773	$ 699	$ 1 234
Other	$ 1 853	$ 5 936	$ 20 142
Total Revenues	$ 23 598	$ 23 020	$ 36 654

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

	As of December 31,	
(in thousands of U.S. dollars)	**2006**	**2007**
Long-lived assets:		
USA	$ 55	$ 53
France	$ 38 060	$ 45 238
Total long-lived assets	$ 38 115	$ 45 291

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, 2008

Exhibit 1.1

-Translated from French-

FLAMEL TECHNOLOGIES

A joint stock company with a share capital of € 2,933,195
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 April 3, 2008

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 thirty three thousand one hundred and ninety five euros (€2,933,195), divided into 24,051,590 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 form 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.

-Translated from French-

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.

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.

-Translated from French-

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.	(Virginia)

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, 2008

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

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, 2008

/s/ Siân Crouzet
Siân Crouzet
Principal Financial Officer

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, 2007, 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, 2008

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, 2007, 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, 2008

Exhibit 23

CONSENT OF
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 of Flamel Technologies S.A., dated October 5, 2006 (No. 333-137844), May 31, 2006 (No. 333-134638), January 6, 2004 (No. 333-111725), October 14, 2003 (No. 333-109693) and September 15, 2000 (No. 333-12542), of our report dated May 7, 2008, with respect to the consolidated financial statements of Flamel Technologies S.A. and the effectiveness of internal control over Financial Reporting of Flamel Technologies S.A., included in this Annual Report under Form 20-F for the year ended December 31, 2007.

Lyon, France, May 7, 2008

The Independent Registered Public Accounting Firm
ERNST & YOUNG Audit

Represented by
Jean-Luc Desplat