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

FORM 20-F

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

OR

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2002

OR

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

For the transition period from _____ to _____

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 à Vent
33, avenue du Docteur Georges Lévy
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 each exchange on which registered
None	None

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

American Depositary Shares (as evidenced by American Depositary Receipts), each representing one Ordinary Share

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None

(Title of Class)

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.

16,197,590 Ordinary Shares, nominal value 0.13 Euros per Ordinary Share

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 _X_ No ___

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

Item 17 ___ Item 18 _X_

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As used herein, references to the Company, 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 0.13 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™, Agsome™, Basulin™, and Genvir™, Micropump®, Medusa®, and ColCys® are registered trademarks of the Company.

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 "€" 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. These translations should not be construed as representations that the Euro amounts actually represent such dollar amounts or could be converted into dollars at the rates indicated or at any other rate. *Euro / U.S. dollar exchange rates based on the Noon Buying Rates, presented as of any date or period on or after to December 31, 1998, have been calculated by applying the fixed exchange rate of 6.55957 French francs per Euro to the Euro / U.S. dollar exchange rate based on the Noon Buying Rate. See "Item 3. Key Information – Exchange Rates" for information regarding the rates of exchange between the franc and the dollar in 1998.*

NOTE: This report contains statements about the intent, belief or current expectation of Flamel or its management, which constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are subject to risks and uncertainties that could cause the actual results and financial position of Flamel to differ materially from the information presented in this report. Factors that could cause actual results to differ materially from those estimated by the forward looking statements in this report, include, but are not limited to, the risk associated with the Company's limited history of operations and historic and future losses, and the risk that products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, uncertainties regarding market acceptance of products in development, the impact of competitive products and pricing, reliance on outside parties and the risks associated with key strategic alliances, and other risks detailed in this report under "Item 3. Key Information – Risk Factors." These forward-looking statements speak only as of the date hereof. Except as required by applicable provisions of the U.S. Securities Exchange Act of 1934 or the rules and regulations thereunder, Flamel does not intend, and does not undertake any obligation, to revise or update any forward-looking statements.

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 for each of the five years in the period ended December 31, 2002 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 auditors. 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.

	1998	1999	2000	2001	2002
			(In thousands except per share data)		
Statement of Operations Data:					
Revenues	**$** 9,522	**$** 11,040	**$** 10,902	**$** 13,087	$ 18,406
Costs and expenses	(18,813)	(18,040)	(16,107)	(16,242)	(18,629)
Loss from operations	(9,291)	(7,000)	(5,205)	(3,155)	(223)
Interest and other expense, net	232	322	375	295	149
Other income					2,526
Income (loss) before income tax and the cumulative effect of a change in accounting principle	(9,059)	(6,678)	(4,834)	(2,860)	2,452
Income tax benefit (charge)	1,247	(16)	(50)	(14)	553
Cumulative effect on prior years (to December 31, 1999) of changing method of revenue recognition	—	—	(4,577)	—	—
Net income (loss)	(7,812)	$ (6,694)	$ (9,461)	$ (2,874)	$ 3,005
Earnings (loss) per share before cumulative effect of change in accounting principle	$ (0.65)	$ (0.52)	$ (0.32)	$ (0.18)	$ 0.19
Basic earnings (loss) per ordinary share	$ (0.65)	$ (0.52)	$ (0.62)	$ (0.18)	$ 0.19
Diluted earnings (loss) per share	(0.65)	(0.52)	(0.62)	(0.18)	0.18
Basic weighted average number of shares outstanding (in thousands)	12,046	12,939	15,331	16,198	16,198
Diluted weighted average number of shares outstanding (in thousands)	12,046	12,939	15,331	16,198	16,711
Dividends per share	—	—	—	—	—

	At December 31,				
	1998	1999	2000	2001	2002
	(In thousands US dollars)				
Balance Sheet Data:					
Cash and cash equivalents	7,277	5,210	10,137	5,309	14,527
Working capital	12,083	4,257	7,948	7,338	12,202
Total assets	25,318	14,920	20,360	18,144	23,076
Long-term liabilities (excluding deferred revenues)	3,180	2,358	1,891	1,299	2,329
Shareholders' equity	17,785	9,067	10,882	7,509	12,286

Exchange Rates

Flamel publishes its financial statements in dollars. However, currently a significant portion of the Company's revenues and 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."

On January 1, 1999, eleven member states of the European Union (Austria, Belgium, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Portugal and Spain) introduced a single currency, the Euro, to replace their national currencies. Pursuant to the Treaty on European Union, fixed exchange rates against the Euro were established for each of the currencies of the participating member states. The rate of conversion for the French franc was fixed at FF6.55957 per Euro.

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 four years and in each of the previous six months. For 1998, the table reflects the average, high and low exchange rates for the French franc, shown after conversion into Euros at the fixed rate of FF 6.55957 per Euro.

Year Ended December 31,	High	Low	Average Rate [(1)]
Euro to U.S. Dollar:			
2002	1.0485	0.8594	0.9495
2001	0.9548	0.8388	0.8958
2000	1.0334	0.8269	0.9207
1999	0.9984	0.8465	0.9443
French Franc to U.S. Dollar:			
1998	6.2130	5.3875	5.9107

(1) *Annual totals represent the average of the noon buying rates for French francs or Euros, as the case may be, on the last business day of each month during the relevant period. Monthly totals represent the average of the noon buying rates for Euros for each business day during the relevant month.*

Previous Six Months	High	Low	Average
March, 2003	1.1080	1.0570	1.0806
February, 2003	1.0875	1.0708	1.0785
January, 2003	1.0861	1.0361	1.0622
December, 2002	1.0485	0.9927	1.0194
November, 2002	1.0139	0.9895	1.0013
October, 2002	0.9881	0.9708	0.9812

The exchange rate for the Euro against the U.S. dollar as at March 31, 2003 was €0.918 to $1.00. The Company makes no representation that French franc 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.

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. You should consider carefully the risks and uncertainties described below, which are not the only ones facing our company. Additional risks and uncertainties also may impair our business operations.

The Loss Of One Of Our Major Customers Could Reduce Our Revenues Significantly.

Revenues from Servier represented approximately 48% of our total revenues for the year ended December 31, 2002. The loss of the licensing agreement with Servier or failure to obtain other significant contracts with other partners who would pay us similar amounts of revenue could cause our revenues to decrease significantly, resulting in losses from our operations. If we cannot broaden our customer base, we will continue to depend on a few customers for the majority of our revenues. We may be unable to negotiate favorable business terms with customers that represent a significant portion of our revenues. If we cannot, our revenues and gross profits may not grow as expected and may be insufficient to allow us to achieve sustained profitability.

We Intend to Rely On Third Parties To Market, Distribute And Sell The Products Incorporating Our Drug Delivery Technologies And Those Third Parties May Not Perform.

Our pharmaceutical company partners are expected to market and sell the products we develop and manufacture. If one or more of our pharmaceutical company partners fails to pursue the marketing of our products as ultimately negotiated, our revenues and gross profits may not reach our expectations, or may decline. We often cannot control the timing and other aspects of the development of products incorporating our technologies because our partners may have priorities that differ from ours. Therefore, our commercialization of products under development may be delayed unexpectedly. Because we incorporate our drug delivery technologies into the dosage forms of products marketed and which are expected to be ultimately sold by our pharmaceutical company partners, we will not have a

direct marketing channel to consumers for our drug delivery technologies. The marketing organizations of our partners may be unsuccessful, or they may assign a low level of priority to the marketing of our products that is different from our priorities. Further, they may discontinue marketing the products that incorporate our technologies. If marketing efforts for our products are not successful, our revenues may fail to grow as expected or may decline.

If We Do Not Enter Into Additional Collaborative Agreements with Pharmaceutical Companies, We May Not Be Able To Achieve Sustained Profitability.

We depend upon collaborative agreements with pharmaceutical companies to develop, test and obtain regulatory approval for, and commercialize forms of active pharmaceutical ingredients using our drug delivery technologies. The number of products that we successfully develop under these collaborative agreements will affect our revenues. If we do not enter into additional agreements in the future, or if our current or future agreements do not result in successful marketing of our products, our revenues and gross profits may be insufficient to allow us to achieve sustained profitability. We currently have collaborative agreements with Servier, GlaxoSmithkline, Merck, Corning, and a number of other undisclosed large pharmaceutical companies.

We face additional risks related to our collaborative agreements, including the risks that:

- any existing or future collaborative agreements may not result in additional commercial products;
- additional commercial products that we may develop may not be successful;
- we may not be able to meet the milestones established in our current or future collaborative agreements; and
- we may not be able to successfully develop new drug delivery technologies that will be attractive in the future to potential pharmaceutical company partners.

If We Cannot Attract And Retain Key Personnel On Which We Depend, We May Not Be Able To Execute Our Business Plan As Anticipated.

During our operating history, we have assigned many key responsibilities within our company to a relatively small number of individuals. If we lose the services of Dr. Gerard Soula, our Chief Executive Officer, Stephen Willard, our Chief Financial Officer and General Counsel, or Raphael Jorda, our Director of Manufacturing, we may have difficulty executing our business plan in the manner we currently anticipate. The competition for qualified personnel is intense and the loss of services of key personnel could adversely affect our business. We do not have employment agreements with these key personnel. We do not maintain key person life insurance for any of our key personnel.

We May Experience Significant Delays In Expected Product Releases While Our Pharmaceutical Company Partners Seek Regulatory Approvals For The Products We Develop And, If They Are Not Successful In Obtaining The Approvals, We May Be Unable To Achieve Our Anticipated Revenues And Profits.

In the United States, the federal government, principally the U.S. Food and Drug Administration (the “FDA”), and state and local government agencies regulate all new pharmaceutical products, including our existing products and those under development. Our pharmaceutical company partners may experience significant delays in expected product releases while attempting to obtain regulatory approval for the products we develop. If they are not successful, our revenues and

profitability may decline. We cannot control, and our pharmaceutical company partners cannot control, the timing of regulatory approval for the products we develop.

Applicants for FDA approval often must submit extensive clinical data and 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. Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new drug application, also may cause delays or rejection of an approval. 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 unforeseen problems follow initial marketing.

Manufacturers of drugs also must comply with applicable good manufacturing practices requirements. If we cannot comply with applicable good manufacturing practices, we may be required to suspend the production and sale of our products, which would reduce our revenues and gross profits. We may not be able to comply with the applicable good manufacturing practices and other FDA regulatory requirements for manufacturing.

If our products are marketed in other jurisdictions, we, and the pharmaceutical company 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.

Our Commercial Products Are Subject To Continuing Regulations And We May Be Subject To Adverse Consequences If We Fail To Comply With Applicable Regulations.

Even if our products receive regulatory approval, either in the United States or internationally, we will continue to be subject to extensive regulatory requirements. These regulations are wide-ranging and govern, among other things:

- adverse drug experience reporting regulations;
- product promotion;
- product manufacturing, including good manufacturing practice requirements; and
- product changes or modifications.

If we fail to comply or maintain compliance with these laws and regulations, we may be fined or barred from selling our products. If the FDA determines that we are not complying with the law, it can:

- 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;
- totally or partially suspend our production;

- withdraw previously approved marketing applications; and
- initiate criminal prosecutions.

If We Cannot Develop Additional Products, Our Ability To Increase Our Revenues Would Be Limited.

We intend to continue to enhance our current technologies and pursue additional proprietary drug delivery technologies. If we are unable to do so, we may be unable to achieve our objectives of revenue growth and sustained profitability. Even if enhanced or additional technologies appear promising during various stages of development, we may not be able to develop commercial applications for them because:

- the potential technologies may fail clinical studies;
- we may not find a pharmaceutical company to adopt the technologies;
- it may be difficult to apply the technologies on a commercial scale; or
- the technologies may be uneconomical to market.

If We Cannot Keep Pace With The Rapid Technological Change And Meet The Intense Competition 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. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical company partners may choose to adopt the drug delivery technologies of our competitors. Companies with oral drug delivery technology that can compete with our Micropump® technology include Eurand, Biovail and Andrx. Our Medusa® technology competes with technologies from companies such as Alkermes and SkyePharma. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of 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 and represent significant competition for us.

Our competitors may succeed in developing competing technologies or obtaining governmental approval for products before us. The products of our competitors may gain market acceptance more rapidly than our products. Developments by competitors may render our products, or potential products, noncompetitive or obsolete.

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 valid or enforceable. They may not protect us against competitors that challenge our patents, 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 May Claim 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 may claim that the manufacture, the use or the sale of our drug delivery technologies infringe on their patent rights. If such claims are asserted, 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.

We enter into collaborative agreements with pharmaceutical 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 companies. Those drugs may be the subject of patents or patent applications and other forms of protection owned by the pharmaceutical 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 company may be restricted or may cease.

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 our polymer technology through our partner Corning in 1999. We have had no commercial sales to date of products incorporating either our Medusa® or Micropump® 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. We are currently making the transition from research and product development operations with limited production to commercial operations with expanding production capabilities in addition to research and product development activities. 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 Do Not Remain Profitable In The Future, The Value Of Our Shares May Fall.

Although we earned an operating profit for the year ended December 31, 2002, we have accumulated aggregate net losses from inception of approximately $56.4 million. If we are unable to remain profitable 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 losses in prior years. Our ability to achieve sustained profitable operations depends on 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; 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 Your 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 develop and possibly to acquire new drug delivery technologies or limit the expansion of our manufacturing capacity. We believe our cash and cash equivalents, and expected revenues from operations will be sufficient to meet our anticipated capital requirements for the foreseeable future. However, we may elect to pursue additional financing at any time to more aggressively pursue development of new drug delivery technologies and expand manufacturing capacity beyond that currently planned.

Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the level of expenditures necessary to develop and, or, acquire new products or technologies;
- the progress of our research and product development programs;
- results of our collaborative efforts with current and potential pharmaceutical company partners; and
- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

If The Marketing Claims Asserted About Our Products Are Not Approved, Our Revenues May Be Limited.

Once a drug product incorporating our technologies is approved by the FDA, the Division of Drug Marketing, Advertising and Communication, the FDA's marketing surveillance department within the Center for Drug Evaluation and Research, must approve marketing claims asserted about it by our pharmaceutical company partners. If our pharmaceutical company partners fail to obtain from the Division of Drug Marketing acceptable marketing claims for a product incorporating our drug technology, our revenues from that product may be limited. Marketing claims are the basis for a product's labeling, advertising and promotion. The claims our pharmaceutical company partners may

assert about our drug delivery technology, or the drug product itself, may not be approved by the Division of Drug Marketing.

We May Face Product Liability Claims Related To Participation In Clinical Trials Or The Use Or Misuse Of Our Products.

The testing, manufacturing and marketing of products using 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 companies conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical 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, which would be reflected as expenses on our statement of operations and reduce our earnings.

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, 2002, the closing sale price for ADRs ranged from $4.85 to $1.22. In the year ended December 31, 2001, the closing sale price of our ADRs ranged from $7.06 to $0.94. 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 company partners relating to the products incorporating our technologies;
- actions by the FDA in connection with submissions related to the products incorporating our technologies; and
- general market conditions.

Our Operating Results May Fluctuate, Causing Our Share Price To Fall.

Fluctuations in our operating results may lead to fluctuations, including declines, in our Share price. Our operating results may fluctuate from quarter to quarter and from year to year depending on:

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

ITEM 4. Information on the Company

General Overview

Flamel Technologies S.A. is a biopharmaceutical company principally engaged in the development of two unique polymer-based delivery technologies for medical applications. Flamel's Micropump® technology is a multiparticulate technology for oral administration of small molecule drugs with applications in controlled release, tastemasking and bioavailability enhancement. Flamel's Medusa nano-particulate technology is designed to deliver therapeutic proteins, peptides and small molecules. Flamel's expertise in polymer science has also been instrumental in the development of a photochromic eyeglass lens product that was launched by Corning in 1999. Additionally, Flamel has developed new herbicide delivery systems and has patented a biomaterial, ColCys.

The Company currently has three major products based on its Micropump technology: Asacard®, a controlled-release formulation of aspirin for the treatment of cardiovascular disease, Metformin XL, a controlled-release form of Metformin currently in development for use for the treatment of Type II diabetes, and Genvir®, a controlled-release acyclovir for the treatment of genital herpes. The Company is in active discussions with a number of potential partners for the further development and registration of its controlled-release Metformin. Flamel intends to file for registration of Genvir in the United States once a partnership is established with a major pharmaceutical company with a substantial sales force. The Company is also in active discussions seeking to obtain a marketing partner for Asacard®.

Flamel's Medusa® technology permits the long-acting controlled release of proteins without the denaturation or other adverse effects on such proteins of certain other delivery systems. The Company's initial application of Medusa is Basulin™, a long-acting insulin for the treatment of diabetes. Since 1999, the Company worked with Novo Nordisk A/S to optimize the Medusa polymer

and the insulin formulation to be delivered using our proprietary technology. As of March 12, 2002, Flamel reacquired all rights to Basulin and is continuing work on the product as it seeks a partner to fund necessary clinical trials for the product. Applications of Medusa to other therapeutic proteins are in an advanced stage of preclinical development; two of which are funded by major pharmaceutical partners and the others are being pursued at Flamel's cost.

Flamel has had a long-standing collaborative relationship with Corning, Inc. to develop advanced polymeric photochromic materials for eyeglass lenses. Flamel has enjoyed more than two years of royalties as a result of sales of this product. This was also the first product containing Flamel technology to be commercialized.

Pursuant to agreements with Monsanto Company, Flamel has collaborated to develop a new herbicide delivery system to enhance the penetration of glyphosate, the world's leading post-emergent herbicide marketed by Monsanto under the brand name, Round-up®. Monsanto's agreement with Flamel in respect of this product has been terminated and Flamel is free to work with other partners in the application of its technology to agricultural uses.

Although ColCys, the biomaterial for the prevention of post-surgical adhesions, has shown promise, the Company has slowed its development until such time as it finds a committed partner or it has sufficient cash to continue.

To date, the Company has entered in licensing or partnership arrangements with six major corporations to commercialize products resulting from its innovative technologies, to fund development work and, in selected cases, co-develop specific products.

The Company was incorporated as a limited liability corporation (*société anonyme*) under the laws of Republic of France in August of 1990, and its shares were listed on EASDAQ and the NASDAQ Stock 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. Flamel's agent in the United States is Flamel Technologies, Inc., 2121 K Street, Suite 650, N.W., Washington, DC 20037.

The Need for Novel Delivery Systems

Flamel's polymer delivery systems are currently focused on the controlled release of therapeutic proteins and the oral administration of pharmaceutical drugs, primarily those which 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. In the United States alone, it is estimated that pharmaceutical product sales utilizing advanced drug delivery technologies amounted to over $13 billion in 2002. In order to leverage their resources, pharmaceutical companies have increasingly sought strategic alliances with companies that have special expertise in delivery systems.

Although significant work has been done on improved drug delivery, little of this knowledge has been applied to the agrochemical industry. The Company believes there is an opportunity of

applying its technologies to develop improved agrochemical compounds that offer higher levels of efficiency and efficacy.

Micropump: Delivery System for the Oral Administration of Drugs

Flamel's other drug delivery platform, Micropump, is an oral multiparticulate technology with applications in sustained release, tastemasking and bioavailability enhancement.

Micropump provides a method of encapsulation microscopic-sized 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.

The Company believes that Micropump particles, which measure 200 to 500 microns in diameter, can provide benefits in controlled release and in the tastemasking of bad tasting active materials. The latter use is particularly important where the microparticles are dosed in sachet or liquid suspension, or as rapid dissolve tablets. In addition, Flamel believes that its Micropump® technology can facilitate improvements in the bioavailability of certain drugs whose low solubility profile restricts both the rate and extent of absorption. The incorporation of certain hydrophilic excipients into the Micropump® particles can lead to marked improvements in drug stability which may, in turn, lead to enhancement of bioavailability. This application of the Micropump® technology is currently being pursued. Many new and effective drug compounds demonstrate poor stability characteristics, which can hamper the ability of these compounds to be successfully developed and commercialized. A drug delivery technology, which has application in stabilizing such compounds, would have significant value.

Micropump technology has several other key attributes including a high loading ratio of active ingredient to polymer coating allowing 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 the tablet or a capsule enhances safety by seeking to avoid 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, the Micropump particle coating is not affected by changes in pH levels that occur in the body and uses a class of material approved for pharmaceutical use by the FDA.

Products Based on Micropump Technology

The Company believes that its Micropump system is most appropriate for delivery of therapeutic compounds for which the small intestine is the optimal site of absorption and for where the extension of mean plasma concentration time is important. The Company is currently developing the following drugs based on the Micropump system:

Asacard 162.5mg: Controlled-release Cardiovascular Aspirin

The first pharmaceutical product utilizing Micropump was Asacard®, a controlled-release formulation of aspirin (acetylsalicylic acid, or ASA) specifically designed for the long-term treatment of cardiovascular diseases with thrombotic origin.

It is estimated that at least 9.5 billion doses of aspirin are consumed worldwide each year for cardiovascular treatment, making it the most rapidly growing segment of the aspirin market. According to a significant body of published medical literature, a majority of people who have suffered a myocardial infarction or stroke are advised to take aspirin daily, and many are expected to do so for the remainder of their lives. However, the long-term use of aspirin may give rise to gastrointestinal (GI) side effects, including stomach bleeding and stomach and intestinal ulcers. It is generally believed that these side effects are the principal obstacle to an even greater use of cost-effective aspirin for this indication.

To avoid the adverse GI side effects of aspirin, two approaches have been proposed to date: enteric coated aspirin and low-dose aspirin. Neither approach provides a satisfactory solution. Enteric coated aspirin formulations attempt to reduce gastric side effects by preventing aspirin from touching the stomach wall, but this solves only a part of the problem. The use of low dose aspirin, 75mg per day, is becoming increasingly popular, particularly in the United States. However, daily use of even low doses can give rise to GI side effects and, more significantly, some published studies suggest that the efficacy of such low doses may not be adequate.

Responding to this need, Flamel developed and patented Asacard, a unique controlled-release, microencapsulated aspirin, based on the Micropump technology. Asacard is designed to provide effective and safe therapy for cardiovascular treatment. Its efficacy for this indication comes from the release of aspirin into the portal circulatory system where it provides cardiovascular benefits similar to conventional aspirin formulations. The Company believes, however, that what differentiates Asacard from conventional aspirin is its improved GI safety profile. Asacard is the only aspirin formulation that significantly controls the rate of release of aspirin in the systemic circulation system, thus avoiding the major cause of GI problems. Additionally, its microparticle coating protects the GI lining from the direct action of aspirin.

Given current U.S. medical practice that favors the lower, 75mg doses of aspirin for cardiovascular disease and the costs of required U.S. clinical testing, the Company has deferred plans to further develop this product. The U.S. patent for Asacard was issued in 1997. Recently, however, increasing interest has been expressed in licensing this product and the Company is engaged in discussions in an effort to seek a partner for this product.

Genvir: Controlled-release Oral Acyclovir

Flamel has also applied its Micropump technology to develop a controlled-release formulation of acyclovir for the treatment of genital herpes.

The Market for Anti-herpes Drugs

The worldwide market for the treatment of herpes infections, primarily genital herpes and zoster, is estimated to be approximately $1.1 billion. Of this, approximately $700 million is estimated for the treatment of genital herpes including $260 million for the treatment of acute infections. Acyclovir, including multiple generic formulations and Glaxo Wellcome's *Zovirax*®, is currently the leading drug for the treatment of herpes infections. Two relatively expensive, second-generation prodrugs of acyclovir – Glaxo Wellcome's *Valtrex*® (valacyclover) and SmithKline Beecham's *Famvir*® (famciclovir) (acquired in 2000 by Novartis) – have recently been gaining market share. These second-generation drugs address a principal weakness of acyclovir: its arduous dosing regimens.

For the acute genital herpes and zoster indications, acyclovir needs to be taken five times per day; for chronic genital herpes indications, acyclovir needs to be taken twice per day. These second generation drugs have reduced the dosing schedule to three times per day for zoster, two times per day for acute genital herpes and one to two times per day for chronic genital herpes. Even though *Valtrex*® and *Famvir*® are priced significantly higher than the generic acyclovir, this improved dosing schedule appears to have contributed to their market gains.

Controlled-release Acyclovir for Acute Genital Herpes

Genvir is an oral drug also offering a twice per day dosing regime for the treatment of acute genital herpes. Using Micropump, the Company has overcome the obstacles presented by the particular absorption characteristics of acyclovir to improve its pharmacokinetic profile and develop an effective, controlled-release formulation of the drug. Genvir, with a dosing schedule equivalent to *Valtrex*® and *Famvir*®, is positioned as a second-generation treatment for acute genital herpes and as an alternative to the acyclovir prodrugs.

As proven in its European Phase III study, Genvir taken twice a day provides the same effective treatment for acute genital herpes as Zovirax® (brand-name acyclovir) taken five times-a-day. The double-blind Phase III clinical study of Genvir was conducted in France and Germany with 596 patients enrolled, 423 of whom were treated for an acute attack of genital herpes. In this study, Genvir 600mg taken twice a day was demonstrated to be therapeutically equivalent to Zovirax® 200mg taken five times-a-day. The principal endpoint in the study was the percentage of patients with healed herpes lesions on the fifth day. Results were: 53.6% of Genvir-treated patients had healed lesions as compared to 45.7% of Zovirax®-treated patients. Additionally, the occurrence of new herpes lesions in the Genvir-treated patients was less than in the Zovirax®-treated patients. The safety profiles of both drugs were excellent and similar.

In addition to this patient compliance advantage over regular acyclovir, the Company believes Genvir will likely be priced significantly below the newer prodrugs when it enters the market. Genvir will also have the added advantages of acyclovir's long-standing record of efficacy and safety, and the well-entrenched prescribing and purchasing behaviors that favor acyclovir.

On April 9, 2003 the Company announced that it had licensed rights to Genvir in the U.S. and Canada to Biovail Corporation. Phase III clinical trials are expected to be conducted by Biovail beginning in 2003. Flamel anticipates using the data from these clinical trials for registration of Genvir outside the U.S. and Canada upon their completion.

Other Products Based on Micropump Technology

From time to time the Company has conducted Micropump feasibility studies on proprietary compounds under limited, confidential agreements with the pharmaceutical companies owning the rights to these compounds. The Company is currently conducting four such confidential studies in partnership with a number of undisclosed pharmaceutical companies. No new products have yet emerged from the research done on these compounds. The Company will seek additional such partnerships in the year 2003.

Medusa: Delivery System for Therapeutic Proteins and Peptides

Therapeutic agents based on biological proteins and peptides are becoming increasingly important. The worldwide market for currently approved biological drugs is over $20 billion; 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*), deliver the protein to the correct site and release the protein at the correct rate over the appropriate time.

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:

(i) that can be metabolized by the human body into harmless substances;

(ii) that is compatible with the protein or peptide;

(iii) that can effectively protect the therapeutic agent during transit and delivery; and

(iv) that will have the required release properties once delivered.

Related processes must overcome very stringent limitations in order to keep the structure of the protein intact.

Responding to these scientific challenges and what it believes is a significant market opportunity, Flamel has developed Medusa, a delivery system designed to encapsulate and deliver proteins and peptides in a controlled manner without denaturation. Flamel's approach utilizes a novel nanoparticulate system, combined with a customized polyaminoacid biopolymer, that meets the above conditions. Flamel has developed a protein-like polyaminoacid composed of only two different amino acids. This polyaminoacid polymer is tailored to spontaneously form nanoparticles 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. Flamel has shown in animal studies that its polyaminoacid polymer is neither immunogenic nor reactogenic.

Basulin: Long-acting Basal Insulin Formulation

Flamel's first application of its 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 baseline, or "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.

The worldwide market for insulin is in excess of $2.5 billion. Of this total, 50% to 55%, or approximately $1.3 billion, is estimated to meet diabetics' long-acting basal insulin requirements. In

Type I diabetics (those with Insulin Dependent Diabetes Mellitus), basal insulin represents 40% of their required treatment. Type II diabetics (those with Non-Insulin Dependent Diabetes Mellitus), significantly out-number Type I diabetics and essentially require only basal insulin. Flamel's Basulin is designed to address the long-acting basal insulin requirements of both of these groups.

The Development of Basulin

Using its Medusa delivery system, Flamel has been able to form nanoparticles of human insulin with its proprietary polyaminoacid polymer to produce a long-acting, injectable insulin formulation, Basulin.

The Company has successfully completed a Phase I clinical study of Basulin in Manchester, England. The randomized, double-blind, placebo controlled study was designed to investigate the pharmacokinetic and pharmacodynamic properties of Basulin using the euglycaemic glucose clamp technique. This protocol determined the duration of efficacy of Basulin in comparison with NPH (Novo Nordisk's commercial long-acting insulin) and with a placebo with favorable results. This study also evaluated the safety of Basulin. Results from the study are expected to be extremely helpful in mapping out the further development of this important drug.

Prior to entering the clinical testing phase of its development, Basulin was extensively evaluated in a series of pharmacokinetic tests on both dogs and pigs. Basulin consistently exhibited its ability to deliver insulin for a longer period of time than the leading long-acting insulin products currently marketed – up to 18-24 hours, compared to 8 to 12 hours for NPH. In these tests, the Basulin formulation also consistently exhibited release profiles significantly flatter than the other long-acting insulin drugs. Theoretically, a profile with minimal peak and trough differences should 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. 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. Minimizing the peaks and valleys of a diabetic's blood glucose level is thought to prevent such serious long-term complications.

If the results of the studies performed to date are confirmed in future clinical trials, Basulin could provide significant benefits in terms of improved control of glucose levels in both Type I and Type II diabetics. It should reduce the frequency of insulin injections and, over the long-term, it could reduce the medical complications associated with sustained elevated glucose levels. There can be no assurance that Basulin will provide any of the benefits described above.

In December 1999, the Company signed a development and licensing agreement with Novo Nordisk, a recognized world leader in insulin and diabetes care. Under the terms of the agreement, Novo Nordisk and Flamel worked together to complete the development of Basulin. As of March 12, 2002, Flamel's agreement with Novo Nordisk has been terminated and the Company does not expect any further revenues from Novo Nordisk for this project. Flamel is working actively to find a new partner for this important project. See – "Strategic Alliances – Novo Nordisk; Basulin."

Other Products Based on the Medusa System

During 2002, Flamel entered into partnerships with a number of major biotechnology and pharmaceutical companies for application of its technology. Confidentiality provisions in each

agreement prevent disclosure of the partner or the product. The Company intends to enter into additional partnerships for the application of its Medusa® technology in 2003.

In a further effort to leverage its knowledge of Basulin and the Medusa® technology, Flamel has sought and received French government funding for research activity related additional applications of its Medusa® technology. These are in the feasibility testing phase.

The Company believes that the Medusa delivery system has the potential to improve formulations of other important biological drugs. During 2002, research efforts were focused on applying Medusa to alpha interferon to develop a long-acting interferon product. The Company believes that the efficacy of alpha interferon, particularly in the treatment of Hepatitis C and cancer, can be improved if its half-life in the body can be extended. Initial in vivo studies have shown promising results. Pharmacokinetic studies in rats using the Sprague Dawley Rat model show a continued concentration of a Medusa-enhanced interferon alpha 2b for up to 96 hours as compared to 8 to 12 hours for the conventional formulation.

The worldwide market for interferon drugs is estimated at $3 billion in 2002 and is expected to grow in 2003 as new indications are sought and approved and as new suppliers emerge. Interferon alpha formulations account for approximately 45% of the worldwide market for interferons. Based on the feasibility test results and the attractiveness of the commercial market, the Company plans to continue the preclinical development of this product and hopes to partner with one or more companies with respect to further work on interferon in the year 2003.

Photochromic Materials

Flamel's expertise in polymer science has led to a long-term collaborative relationship with Corning. Under a contract research arrangement that has existed since 1994, the two companies have worked together to produce two generations of material for photochromic lenses. In 1998, Flamel and Corning entered into a long-term collaboration and development agreement replacing the existing contract research relationship. See "—Strategic Alliances—Corning: Photochromic Materials."

Photochromic lenses automatically darken in the presence of sunlight and then revert to a normal clear when indoors. Such eyeglass lenses 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 a strong and growing demand for photochromic lenses based on polymer (plastic) materials. Corning, by building on its existing franchise and business expertise in the eyeglass lens market, is well positioned to effectively compete in the worldwide market for polymer-based photochromic lens material.

During 1999, Corning launched SunSensor^{TM}, a new, competitive photochromic eyeglass lens product containing Flamel's technology. The Company 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 are dependent on Corning's marketing success.

Under terms of the current agreement, the Company will continue to receive research and development payments for its work performed under the agreement. In the future, the Company will receive royalties on sales of all products that contain intellectual property developed by the collaboration. See "—Strategic Alliances—Corning: Photochromic Materials."

Agsome: Delivery System for Agrochemical Active Ingredients

Several years ago, the Company launched an effort to apply its know-how in the controlled-release of biopharmaceuticals to the delivery of agrochemical products. Agsome, a patented agrochemical active ingredient delivery system, resulted from these efforts.

The Agsome technology nanoencapsulates the agrochemical active ingredients in order to improve their delivery and performance. The resulting increased efficiency of the agrochemical compound reduces the amount of required active ingredient. More efficient delivery, then, could potentially translate into lower material costs for both producer and user. Less agrochemical active ingredients could also have a positive environmental impact.

To advance its Agsome technology, the Company entered into collaboration with one of the worldwide leaders in the agrochemical business, Monsanto. Initially, the Company signed a limited agreement with Monsanto Europe to apply this technology to the leading herbicide, gyphosate, a product commercialized by Monsanto under the brand name Roundup®. Late in 1997, the Company entered into a worldwide agreement with Monsanto that expanded the scope of the collaboration and extended the agreement to all agrochemical active ingredients.

In 1998, the Agsome technology, as applied to glyphosate herbicide, was validated in greenhouse trials by Monsanto. Also in 1998, the collaboration produced seven patent applications related to Agsome technology, particularly as applied to glyphosate herbicide, which are owned by Monsanto. In the event that Monsanto uses any of this technology in its products, it will pay royalties to Flamel for such use.

In August 1999, Monsanto decided to terminate its funding of the joint development efforts for an enhanced formulation of glyphosate herbicide pursuant to its agreement with the Company. Testing of Flamel's formulation by Monsanto is continuing. A two-year non-competition provision of the contract with Monsanto went into effect upon termination of the development funding by Monsanto and expired in August, 2001.

ColCys Biomaterials

Flamel has developed a novel and proprietary family of biomaterials based upon collagen-cystine ("ColCys") that is comprised exclusively of naturally occurring molecules. Collagen materials extracted from various animals are widely used as implantable devices in such fields as plastic and abdominal surgeries.

Collagen is a protein abundantly present in humans and animals and is an excellent building block for designing biocompatible polymers. However, during extraction and purification processes, collagen loses the essential part of its mechanical properties. The Company's proprietary technology grafts cystine molecules onto individual strands of collagen. The molecules are subsequently crosslinked through simple oxidation/reduction reactions to form a network between the collagen chains. This network formation mimics that of keratin, a natural building block found in the body's hair and nails. This unique crosslinking technology provides enhanced mechanical properties and a more controllable rate of biodegradation compared with other crosslinking methods that utilize toxic chemical agents such as gluteraldehyde. By controlling the level of crosslinking, the materials' mechanical properties and their speed of biodegradation can be tailored to meet the needs of different applications. ColCys biomaterials can be prepared as either fluids, hydrogels, molded parts, cast films, or coatings, each of which has the ability to be crosslinked either before implantation or *in vivo*.

ColCys biomaterials' enhanced mechanical properties and more controllable rate of biodegradation make them apparently well suited for medical implantable applications.

ColCys for Post-Surgical Adhesion Prevention

The Company has considered a number of potential applications for ColCys including use in soft tissue surgical adhesives and, most recently, barriers for the prevention of post-surgical adhesions. With a potential worldwide market of $700 million to $1 billion, this latter application for the prevention of post-surgical adhesions has the largest market potential. Therefore, the Company earlier decided to focus its efforts on the development of a ColCys film suitable for preventing the formation of adhesions following certain surgical procedures.

Due to the internal trauma and resulting scarring related to many surgical procedures, unwanted attachments (usually fibrin bands) known as adhesions, form between internal organs and/or surfaces of the body. These adhesions can give rise to excessive and long lasting pain, as well as hinder the organs from functioning properly. Various studies looking at the gynecological and abdominal procedures have shown that adhesions occur in 55% to 100% of the cases examined. These two areas of surgery represent over 4 million procedures per year in the United States alone.

There are a number of different products currently being marketed for adhesion prevention, but they have achieved little success primarily because they do not provide a satisfactory, high level of reliability. The Company believes that for a product to be widely accepted as a preventive for post-surgical adhesion growth it must be consistently effective – effective more than 80% of the time. Without this high level of assurance, surgeons are apparently reluctant to use it and those paying for medical services may have difficulty justifying the related added cost. By tailoring ColCys's mechanical properties and rate of biodegradation, the Company has the potential to produce a film, gel or spray that is better suited for adhesion prevention than other competing products under development.

Further preclinical development efforts and external studies are necessary prior to moving into pivotal clinical studies. Faced with cash and resource constraints, the Company has delayed additional development efforts until partner support and funding is available.

Flamel's Strategy

Flamel's strategy is to focus on the design, development and manufacture of commercially valuable products based on its advanced polymer technologies. The key elements of this strategy are to:

Develop polymer-based technologies that can be applied to multiple product opportunities.

Flamel believes it has state-of-the-art expertise in polymer science and intends to apply this expertise to create and develop innovative technologies that are applicable to multiple products. The Company intends to internally fund and retain full rights to its core technologies while licensing rights to resulting products to corporate partners.

Focus on the development of potentially valuable applications of its proprietary controlled-release technologies.

Using advanced delivery technologies, Flamel aims to establish itself as a provider of innovative drug and chemical formulations. The Company is focusing on developing its Medusa technology for the delivery of therapeutic proteins and peptides and its Micropump technology for the controlled delivery of certain small molecule drugs. The Company seeks to identify existing therapeutic and chemical agents with substantial annual sales whose safety, efficacy, or patient compliance profiles can be enhanced or improved through the application of its technologies.

Focus on research, development and manufacturing.

Flamel believes its main competitive advantages lie in its research and development capabilities and its related know-how in manufacturing key components of its different polymer-based products. The Company intends to continue to invest to maintain its state-of-the-art polymer science expertise and to continue to expand its manufacturing capabilities as its products reach the market. The Company believes the combination of innovation and manufacturing allows it to capture a significant portion of the value-added of each of the products it develops.

Maintain broad state-of-the-art expertise in polymer science.

The Company's expertise in advanced polymer science has led to the development of other commercially valuable technologies. Current examples of such technologies include polymer-based photochromic material, Agsome technology for the controlled delivery of agrochemical active ingredients, and ColCys biomaterials.

Establish collaborative arrangements.

Flamel does not intend to create its own marketing, sales or distribution organizations. To gain access to these functions, as well as funding for non-core technologies, the Company seeks to partner and collaborate with large market-oriented companies possessing strong application skills in selected product areas. Additionally, the Company plans to outsource other services that can be more efficiently provided by third parties. This strategic element should allow the Company to minimize its financing requirements and shorten the time to profitability.

Strategic Alliances

In order to efficiently develop and apply its technologies and effectively commercialize the resulting products, the Company has entered into, and intends to continue to enter into, collaborative arrangements with large corporate partners. Such arrangements typically provide funding for development work and access to target compounds and related know-how and, ultimately, provide distribution capabilities for 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. The Company's existing agreements are outlined below:

Servier

In January 2002, Flamel and Servier Monde announced that they have entered into a licensing agreement for application of Flamel's Micropump technology to an ACE inhibitor which is proprietary to Servier. Flamel received $3 million upon signing of the agreement and total payments of over $10 million during the year 2002. Further terms of the agreement have not been disclosed.

Glaxo SmithKline

In July 2002, Flamel and Glaxo-SmithKline entered into a license agreement for application of Flamel's Micropump technology to a sachet formulation of Augmentin, a blockbuster antibiotic. Flamel received $1.5 million upon signing of the agreement and total payments of more than $4 million during the year 2002. On March 28, 2003, the Company announced an additional license agreement with Glaxo-SmithKine.

Merck & Co.

In October, 2001, Flamel and Merck & Co. entered into a license agreement for an undisclosed class of products. No other terms of the agreement have been disclosed.

Biovail Corporation

In April 2003, Flamel announced that it has entered into an agreement with Biovail Corporation to license its Genvir product for the United States and Canada. Further terms of the agreement have not been disclosed.

Novo Nordisk: Basulin

On December 7, 1999, Flamel and Novo Nordisk entered into a collaborative development and license agreement for Basulin, a once-a-day injectable controlled–release insulin product. Under the agreement, Novo Nordisk was primarily responsible for the development and clinical testing of the product and Flamel is primarily responsible for the optimization, scale-up and manufacturing of its Medusa polyaminoacid polymer. Novo Nordisk is also responsible for seeking and obtaining all necessary regulatory approvals. As of March 12, 2002, Flamel's agreement with Novo Nordisk has been terminated and the Company does not expect any further revenues from Novo Nordisk for this project. Flamel is working actively to find a new partner for this project.

Corning: Photochromic Materials

Corning France, on its own behalf and representing Corning and Corning Europe, entered into an agreement with Flamel 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 the Company's related research and development costs. This agreement also entitled the Company to royalty payments based on Corning's net sales of ophthalmic products that contained materials developed in conjunction with Flamel.

On December 31, 1998, Flamel and Corning S.A. and Corning Incorporated entered into a new, long-term collaboration and development agreement that expanded the scope and applicability of the earlier agreement. Under this new agreement, Corning owns all intellectual property developed with Flamel, however, under certain conditions, Flamel will have the right to use technology developed under the collaboration for applications other than photochromic eyeglass lenses or sunglass lenses. While Flamel previously was entitled to receive royalties on the sales of all products containing intellectual property resulting from the collaboration, the new agreement provides for increased royalties on sales of certain products. The Company received an initial $2.0 million payment and will continue to receive

periodic payments from Corning for its research and development work per an annually agreed work program.

In 1999, Corning launched its first photochromic plastic eyeglass lens product, and Flamel began receiving quarterly royalty payments per the agreement. The year 2002 was the third full year of royalties for Flamel for this product, and Flamel received $0.9 million of royalties. Flamel also received periodic payments for its research and development efforts per the agreement. Also in 2002, as in prior years, Flamel sold Corning quantities of photochromic material needed for the production of the new lens product.

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 2002, and the parties have agreed to extend this manufacturing arrangement for at least another year.

The Pessac facility provides the Company with the capability to manufacture its pharmaceutical products. Since acquiring the facility, the Company has completed certain modifications to the facility, including the addition of a new manufacturing suite with state-of-the-art spray-coating equipment. The Company believes that the facility and its operations are in substantial compliance with "Good Manufacturing Practice ("GMP") requirements, and the facility is approved by 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. In 1999, a new clean room needed for the synthesis of the Basulin biopolymer was added to the Pessac facility, and was further enhanced in the year 2000.

During 2002, the Company's chemical production activities were conducted using highly specialized equipment installed at its pilot plant in a leased facility in Vénissieux, France. In 1999, 2000 and 2001, the Company produced commercial quantities of photochromic material for Corning at this leased facility. The Company sold its interest in this facility and equipment in January 2003 generating a gain of $0.4 million. Corning will obtain its requirements for photochromic polymers from other sources.

In addition to production activities related to its core businesses, Flamel is attempting to build on its capabilities and experience with Smith Kline and other pharmaceutical customers. With its experienced workforce and current GMP operations, the Company can provide clinical batch manufacturing, process scale-up services and toll manufacturing of solid dosage forms, as well as provide analytical services for contract customers.

Patents and Proprietary Technology

Patents and other proprietary rights are important to the Company's business. The policy of the Company is to seek patent protection of its inventions and also to rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain its competitive

position. Generally, the Company files the first patent application covering an invention that it seeks to patent in France and then files counterpart applications for the invention within one year in other countries.

Since inception, the Company has been granted 181 patents (20 in USA and 161 worldwide) patents. Among others, these include French patents that cover microencapsulated aspirin, methods of producing polyaminoacids for use in nanoencapsulating proteins and peptides, and patents on certain ColCys biomaterials. In the case of the French patents, the Company currently has counterpart patents or pending patent applications pending in other European nations, Japan and the United States. The Company has several additional patent applications pending in France, other European nations, Japan, the United States, and some additional countries.

In 2002, the Company was granted 4 new patents (1 in USA and 3 worldwide). Throughout the year, Flamel filed for 13 new patents (10 worldwide and 3 PCT including USA).

There can be no assurance that any patents issued to the Company will provide it 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 the ability of the Company to do business.

The patent position of drug delivery companies generally is highly uncertain and cannot be predicted because there is no clear policy involving the breadth of claims allowed in biotechnology and pharmaceutical patents and the breadth of such claims involves complex legal and factual questions. Consequently, there can be no assurance that the Company will be granted patents in respect of the claims in any of its currently pending or future patent applications, and there can be no assurance that in the event any claims in any of the Company's 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 the Company's 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. For example, French patent authorities do not engage in the kind of pre-issuance review of patent applications that is engaged in by the United States Patent and Trademark Office. Instead, French patent authorities rely on post-issuance litigation proceedings initiated by private third parties to establish the enforceability and scope of issued patents. There can be no assurance, therefore, that the issuance to the Company in one country of a patent covering an invention will be followed by the issuance to the Company 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 the Company's patents are determined to be valid, enforceable and broad in scope, there can be no assurance that competitors will not be able to design around such patents.

The commercial success of the Company will also depend upon avoiding the infringement of patents issued to third parties and upon maintaining any technology licenses upon which any future products of the Company may be based. Any of the Company's competitors may hold, in the future file applications for, or may be issued patents relating to drug delivery and other technologies that block or compete with those of the Company. While the Company believes that it is not infringing any issued patents, pending patent applications in the United States are maintained under conditions of confidentiality and the Company, therefore, cannot determine with certainty that it is not infringing the claims in any pending U.S. patent applications of third parties or, where relevant, that the Company was the first to file patent applications for the same claims as those in any such pending U.S. applications of third parties.

Litigation to establish the validity, enforceability and scope of patents or to assert or to defend against patent infringement claims can be expensive and time consuming, even if the outcome is favorable to the Company. Also, there can be no assurance that the Company's U.S. patent applications will not be challenged by way of interference proceedings to establish the priority of invention or that the Company's non-U.S. patent applications or patents will not be opposed by third parties or that the Company will not be required to provoke such interference proceedings or oppose the patent applications or patents of third parties in order for the Company to protect its patent rights. Interference proceedings and oppositions can be expensive to prosecute and defend. If the outcome of patent prosecution or litigation is not favorable to the Company, the Company could be adversely affected.

The Company also relies on trade secrets, proprietary know-how and continuing technological innovation that it seeks to protect with confidentiality agreements with its collaborators, employees and consultants. There can be no assurance that these agreements will not be breached, that the Company will have adequate remedies for any breach or that the Company's trade secrets and proprietary know-how will not otherwise become known or be independently discovered by competitors. Under certain of the Company's research and development agreements and joint ventures, inventions discovered in certain cases become jointly owned by the Company and the corporate sponsor or partner. Disputes may arise with respect to ownership of these inventions.

Government Regulation

Flamel believes its delivery systems, when used in conjunction with therapeutic pharmaceuticals, will be subject to drug (including biologic) approval requirements. Biological drugs, such as vaccines, generally are subject to the same FDA regulatory requirements as other drugs, although some differences exist. For example, a biologic license application (BLA) is submitted for approval for commercialization instead of the new drug application (NDA) used for other drugs. Also, biological drugs are subject to FDA lot-by-lot release requirements, whereas other drugs are not, and biological drugs cannot be the subject of abbreviated new drug applications (ANDAs). Further in regard to ANDAs, insulin typically has not been the subject of this type of submission, although the FDA is working on a variety of issues pertaining to the possible development of generic versions of insulin. ANDAs likely will not be possible for insulin for an indeterminate period.

Agro-chemical applications of Flamel's Agsome formulation can involve a variety of U.S. state and federal environmental laws. The use of this technology in conjunction with herbicides would be subject to registration and other requirements of the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires pesticides (including herbicides) to be registered by the U.S. Environmental Protection Agency (EPA) and authorizes the EPA to prescribe conditions for their use.

Photochromic eyeglass lenses are regulated by the FDA as medical devices, and Flamel believes certain applications of the Colcys biomaterial also would be subject to regulation as a medical device.

The design, testing, manufacturing and marketing of new or substantially modified drugs or medical devices must be cleared or approved by applicable regulatory agencies, 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. Similar requirements exist in the European Union. There can be no assurance that Flamel or its collaborative partners will be able to obtain such regulatory clearances or approvals on a timely basis, if at all, for any products under development. Delays in receipt or failure to receive such clearances or approvals,

the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations.

Regulation of Drugs

Each pharmaceutical product incorporating one of the Company's drug delivery technologies will be tested in clinical trials designed, to the extent possible, to meet the standards of regulatory authorities in the United States and other countries. However, there can be no assurance that the authorities in any country will be satisfied with the conduct of any particular clinical trials. Phase I trials, carried out on healthy subjects, are designed to demonstrate the essential characteristics of the product and to test basic human safety. Phase II trials, carried out on limited numbers of patients, test dosage levels and involve a detailed evaluation of human efficacy and safety. Phase III trials involve large-scale evaluation of general efficacy and safety and a comparison with existing alternative therapies. These three phases of clinical trials are generally conducted sequentially, but may overlap. Based on the results of these trials, Flamel or one of its collaborative partners files for regulatory approvals of the pharmaceutical products incorporating Flamel's drug delivery technology in each country in which Flamel, or its licensees, intend to sell such products. Regulators in each country may also require post-approval, long-term toxicity studies or other studies relating to product safety or efficacy including Phase IV clinical tests.

There can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant product applications are filed. The data from clinical trials may be susceptible to varying interpretations that could delay, limit, or prevent regulatory approval. After such approvals are obtained, further delays, particularly related to pricing approvals, may be encountered before the products become commercially available. Products are potentially subject to a withdrawal proceeding if new evidence raises significant questions of safety or effectiveness.

Upon approval, a drug may be marketed only for the approved indications in the approved dosages and forms. Further, even if such regulatory approval is obtained, a marketed drug and its manufacturer are subject to continuing review. Discovery of unknown problems with respect to a product or manufacturer may result in restrictions on such product or manufacturer, including withdrawal of the product from the market. Adverse experiences with the product must be reported to regulatory authorities. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems concerning safety or efficacy of the product occur following approval.

United States

The steps required before a new drug product may be marketed in the United States include: (i) preclinical laboratory and animal tests conducted in accordance with the current Good Laboratory Practices; (ii) submission to the FDA of an application for an investigational new drug ("IND"), which must become effective before human clinical trials may commence; (iii) well-controlled Phase I, Phase II, and, usually, Phase III trials; (iv) submission of an NDA, or new drug application, to the FDA; and (v) FDA approval of the NDA prior to any commercial sale or shipment of the drug. FDA approval must be obtained for each product and for each indication to be treated with each product.

In certain cases, an ANDA, an abbreviated NDA , may be filed in lieu of filing an NDA. An ANDA relies on bioequivalency tests that compare the applicant's drug with an already approved reference drug, rather than on clinical studies. Generally, in order to qualify for the use of an ANDA, the formulation of the drug for which approval is being sought must be the same as the formulation of the drug for which approval

has already been granted. An ANDA would be available for a new formulation of an approved drug incorporating Flamel's controlled release technology only in those instances in which bioequivalence is demonstrated with respect to sustained release forms that have already been approved by the FDA. Because the drug formulations embodying the Company's drug delivery technology are not equivalent to conventional formulations previously approved by the FDA, the Company expects that most of its new drug formulations will require NDA filings.

No product for which an NDA or ANDA is required can be marketed or sold in the United States until an NDA or ANDA for the product has been approved by the FDA. The NDA itself is a complicated and detailed document and must include the results of extensive clinical and other testing, the cost of which is substantial. While the FDA is required to review applications within 180 days of their filing, the FDA frequently requests that additional information be submitted during the review process. Typically, the 180-day regulatory review period restarts when the requested additional information is submitted. Until an NDA is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA to justify approval. The packaging and labeling of all drug products are also subject to FDA approval and ongoing regulation. It is impossible to anticipate the amount of time that will be required to obtain approval from the FDA to market any product.

When an applicant obtains FDA approval of an NDA for a new chemical entity or a new dosage form/delivery system, no other entity may obtain FDA approval of an ANDA for a generic version of such product pending the expiration of the applicable exclusivity period (five years for a new chemical entity and three years for other approvals based upon submission of new clinical data that are essential for approval). This regulatory exclusivity does not preclude any other entity from seeking and obtaining FDA approval of a full NDA during such exclusivity period.

Non-U.S. manufacturers of drug products intended for importation into the United States also must comply with current GMPs, referred to as "cGMPs" and are subject to periodic inspection by the FDA or by authorities in other jurisdictions under agreement with the FDA.

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 varies from country to country, can involve additional testing, and the time required may differ from that required for FDA approval. In the European Union, product approval can be obtained 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. All others have the option to use the decentralized procedure, where approval is first obtained in one EU country that then acts as a reporter for obtaining the product's approval in other EU countries. To the extent possible, clinical trials of Flamel's products are designed to develop a regulatory package sufficient for multi-country European Union approval.

Regulatory approval of prices 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. 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. There can be no assurance that, if regulatory authorities establish lower prices for any product incorporating the Company's technology in any one European country, this will not have the

practical effect of requiring the Company's collaborative partner correspondingly to reduce its prices in other European countries. There can be no assurance that the resulting prices would be sufficient to generate an acceptable return on the Company's investment in its products.

Regulation of Medical Devices

Some applications for the ColCys biomaterial (such as use to prevent post-surgical adhesions) would most likely be classified by regulatory authorities as a medical device.

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). The Company believes its ColCys biomaterial for some users will be Class III devices that require premarket approval based on clinical trials. These approvals require proof of the safety and effectiveness of the device to the FDA's satisfaction based upon extensive preclinical and clinical trial data. Even after the FDA permits a device to enter commercial distribution (whether Class I, II or III), many potentially costly and time-consuming post-market regulatory requirements apply, such as compliance with the Quality System Regulation (which imposes cGMP requirements) and adverse event reporting.

Other Countries

For medical devices, since January 1, 1995, EU countries are required to put in effect the 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, all medical devices other than active implants and invitro diagnostic products must qualify for CE Marking by June 14, 1998. All new medical devices put on the market past June 14, 1998 must meet the MDD. Devices are subject to, in addition to existing or future EU 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 devices must be supported by clinical data of a type and to the extent set out by the EU directives and standards as interpreted by regulatory authorities in each member country. Following marketing, a strict vigilance system involving the reporting of incidents and the appropriate measures to deal with these incidents exists in certain EU countries, including France.

Other Regulation

GMP rules apply to the manufacturing of drugs and medical devices. The Company's 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, the Company also is 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. The Company's research and development involves the controlled use of hazardous materials, chemicals, viruses, and various radioactive compounds. Although the Company believes that its 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 the Company's 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 drug store 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 the Company to maintain price levels sufficient to realize an appropriate return on its product development investment. Legislation and regulations affecting the pricing of pharmaceuticals may change before the Company's proposed products are approved for marketing and any such changes could further limit reimbursement for medical products and services.

Competition

Products utilizing the Company's two pharmaceutical controlled delivery systems will primarily compete with traditional formulations of new and existing drugs as well as formulations using alternative delivery systems. In general, the factors upon which the Company's drug delivery products will compete include price, safety, efficacy and patient compliance. For any particular drug formulated with one of the Company's drug delivery technologies, one or more of these factors may be more significant than the others.

Drug delivery is a rapidly evolving field that is expected to undergo significant technological change. Controlled release and alternative drug delivery systems currently under development by others include, without limitation, time-release capsules, liposomes, implantable delivery systems, oral drug delivery systems, passive transdermal systems, electrotransport systems, oral or nasal transmucosal systems, and inhalation systems. There can be no assurance that the development by others of products based on these or other technologies or totally new drugs will not reduce the competitiveness of the Company's products or render them obsolete. The Company is aware of many competitors, including large pharmaceutical companies, drug delivery companies, joint ventures, universities and other research institutions, that are seeking to develop these products. Many of these competitors have substantially greater experience, research and development,

manufacturing, marketing, financial and managerial resources than Flamel. Moreover, there can be no assurance that the Company's competitors will not obtain patent protection or other intellectual property rights that would limit Flamel's or its collaborative partners' ability to use the Company's technology or commercialize products based on the Company's technology. Furthermore, acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance competitors' resources. Accordingly, the Company's competitors may succeed in developing competing technologies and products, obtaining regulatory approval and gaining market share for these products more rapidly than the Company.

ColCys biomaterials will compete with a number of existing and developing biomaterials. The success of these biomaterials will depend upon a number of factors, including mechanical, physical and chemical properties, biocompatibility, biodegradability, ease of handling, cost and the performance in a given application. In the area of post-surgical adhesion prevention, in particular, there are a few, different products currently being marketed and used today. Additionally, a number of other new products are in various stages of development. Many of the companies with or developing new surgical adhesion products have considerably more financial and scientific resources and clinical experience than Flamel. These competitors may be more successful than the Company in developing competing products, obtaining regulatory approval, commercializing such products and gaining market share for such products than the Company. There can be no assurance that any one or all of these new products may not prove to be more effective or, in some way, preferable than the Company's potential product(s).

Market competition for ophthalmic lens materials is intense. In 1997, the market introduction of an initial generation of photochromic material developed by Corning and Flamel was reconsidered after a competing product was introduced to the market first. A second generation product has recently been launched by Corning and a third generation product is under development. No assurance can be given that this product will capture sufficient market share to remain viable. Moreover, competitors of Corning may develop other, more advanced products that may compete effectively, or render obsolete, this newly launched product and the underlying photochromic materials which Corning and Flamel have developed.

Description of Property

The Company's corporate headquarters and the research center are located in Vénissieux, France (a suburb of Lyon) in two adjacent leased facilities totaling 22,000 square feet. One 13,000 square foot building houses the corporate offices and research laboratories, including a clean room equipped for organic synthesis and polymerization, polymer formulation, small scale processing, materials analysis and quality control. The lease on this facility currently expires from 2005 to 2009 and the Company intends to renew it. The other 9,000 square foot facility houses a biological laboratory, certain development functions, and the Company's administrative functions. The lease on this facility currently extends to 2005.

The Company also maintained a 23,000 square foot leased facility at another site in Vénissieux that houses its chemical manufacturing operations. During 2002, these chemical facilities were used for the manufacturing of the photochromic material supplied to Corning. In January 2003, Flamel sold its interest in the facility and its equipment. Corning will obtain its photochromic polymers from a new source as of this date.

In 1996 the Company acquired a 50,000 square foot pharmaceutical production facility located in Pessac, France from SmithKline. The plant is housed on a 470,000 square foot lot in an industrial park not far from Bordeaux airport. Since acquiring the plant, the Company has 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 drug agencies and is cGMP compliant. It is qualified to manufacture pharmaceutical products that can be sold in most countries in Europe. The value of the facility is recorded in the Company's financial

books at the value of the liabilities corresponding to the retirement indemnities of the plant staff that Flamel assumed at the time of the plant purchase, plus the additional investments made by the Company, less the depreciation and appropriate amortization.

In 2002, activities at this facility included contract manufacturing for SmithKline and other major pharmaceutical companies, process and scale-up activities and the production of clinical batches for the Company's own products, and support analytical services for SmithKline and other pharmaceutical laboratories. As the Company's products are commercialized, it is expected that this facility will provide necessary quantities of some portion of the Company's products.

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. Flamel's Medusa® nano-encapsulation technology is designed to deliver therapeutic proteins. The Company's lead product, Basulin®, a long-acting insulin for the treatment of diabetes, is the first application of this patented delivery system. Micropump® is a controlled release technology for the oral administration of small molecules. Asacard®, a controlled-release aspirin, has been approved in the United Kingdom and several other European countries. Genvir, a second product using Micropump®, is a controlled-release acyclovir for the treatment of genital herpes. Flamel's innovative technologies have also been instrumental in the development of a photochromic eyeglass lens product that was launched by Corning in 1999.

In 2002, the Company's internally funded development efforts were focused on the pre-clinical and initial clinical testing of Basulin®, and the application of the Medusa® system to other important therapeutic proteins. Internal funding of other projects was kept to a minimal level in an effort to conserve cash. Activities related to photochromic technologies were fully funded by collaborative partners.

In 2002, the Company recognized revenue from receipt of royalty payments related to the sales of a Corning's photochromic sunglasses lenses containing technology developed by Flamel. Royalty payments are expected to continue, but will fluctuate according to the success of Corning in commercializing these products. As in previous years, in 2002, a major part of Flamel's revenues came from licensing fees and contract research payments paid by corporate partners.

In recent years, revenue from the sale of products and performance of services was a mix of revenue from a contract manufacturing agreement with SmithKline and other major pharmaceutical companies, the sale of photochromic material to Corning, and the performance of various analytical and manufacturing services for other customers. Until its manufacturing capabilities are needed to produce its own proprietary products currently in development, the Company is seeking to utilize its capacity and cover its related costs by building a manufacturing services business and by transferring its chemical production capability from the Venissieux pilot plant to the Pessac site.

In 2002, the majority of the Company's expenses were incurred in Euros. However, a significant portion of the Company's revenues were, and will continue to be, denominated in U.S. dollars. In 2002, 66% of revenues were denominated in U.S. dollars; in 2001, 41% of revenues were denominated in U.S. dollars; and in 2000, 29% of revenues were denominated in U.S. dollars. In each of these years, fluctuations in the value of the Euro relative to the dollar caused dollar-translated amounts to vary from one period to another affecting the Company's reported results. Comparisons in financial statement line items between the years ended December 31, 2002 and December 31, 2001 were affected by a 5% average increase in the value of the Euro relative to the U.S. dollar during the year and a 19% increase in the Euro relative to the U.S. dollar at year-end. 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 does not engage in any hedging activities with respect to the risk of exchange rate fluctuations.

Since its inception, the Company has incurred substantial losses, and through December 31, 2002, had an accumulated deficit of approximately $56.4 million. While Flamel earned a profit in the year ended December 31, 2002, Flamel expects to continue its investment spending in its research and development activities and to maintain its primary facilities and business infrastructure. Thus, there can be no assurance that the Company will not to incur further losses, at least for the next two years, when the growth of revenue may not increase sufficiently to cover expenditures.

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 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."

Critical Accounting Policies

The Company's discussion and analysis of its financial condition and results of operations are based upon the Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to revenue recognition, accounts receivable, bad debts, inventories, warranty obligations, litigation and deferred tax assets. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company believes its more significant judgments and estimates used in the preparation of its Consolidated Financial Statements are made in connection with the following critical accounting policies.

Revenue Recognition

The Company's significant accounting policies are summarized in Note 1 to the Financial Statements. From time to time the Company receives advance payments from strategic partners, usually at the beginning of its alliance with that partner. As described in Note 1.4 to the Financial Statements, these advance payments are recorded as deferred revenue and are recognized on a "systematic and rational basis" to match the revenues with the related costs. The Company's practice, which it expects to continue in the future, has been to recognize these amounts over the term of the related development period. Other than the foregoing, management does not believe that the application of any of these accounting policies requires material estimates or assumptions on its part.

Results of Operations

Years ended December 31, 2002, 2001 and 2000

Operating Revenues

The Company had total revenues of $18.4 million in 2002, $13.1 million in 2001 and $10.9 million in 2000.

In 2002, license and research payments from the Company's various partners totaled $14.6 million. Similar license and research payments in 2001 and 2000 totaled $9.9 million and $6.6 million, respectively. License revenues in 2002 consisted primarily of $6.5 million from Servier and $1.7 million from Glaxo-SmithKline. License revenues in 2001 included $2.8 million from Novo Nordisk, which represented the last portion of the $5.0 million up front fee received in year 1999 which was fully recognized in 2001 due to the termination of the license agreement with Novo Nordisk. License revenues in 2000 included $1.6 million from Novo Nordisk, which represented a portion of the $5.0 million up front fee received in year 1999 but recognized in 2000 due to a change in accounting principle concerning revenue recognition of up front payments. License revenues in 2000 also included a $0.5 million fee from Searle for the contract concerning the Company's Asacard® product license revenues in 1999 included the $5.0 million fee from Novo Nordisk in conjunction with the signing of a development and licensing agreement regarding Basulin, the Company's long-acting insulin product.

In 2002, product sales and services revenues totaled $2.9 million and included $121,000 from SmithKline for the manufacture of cimetidine, $539,000 from Corning for replenishment inventories of photochromic material and $2.2 million from clinical batches and tall manufacturing with various customers. In 2001, product sales and services revenues totaled $2.0 million and included $0.3 million from SmithKline for the manufacture of cimetidine and $1.4 million from Corning for replenishment inventories of photochromic material. In 2000, product sales and services revenues totaled $3.0 million and included $1.2 million from SmithKline for the manufacture of cimetidine and $1.4 million from Corning for replenishment inventories of photochromic material.

Other revenues of $948,000 in 2002 consisted primarily of royalties from Corning related to the sales of photochromic lenses, incorporating Flamel technology. Other revenues of $1,220,000 in 2001 included $961,000 in royalties from Corning related to the sales of photochromic lenses, incorporating Flamel technology, and $219,000 related to the forgiveness of a French government agency loan. Other revenues of $1,249,000 in 2000 included $1,055,000 in royalties from Corning related to sales of photochromic lenses, incorporating Flamel technology, and $115,000 related to the forgiveness of a French government agency loan.

Operating Expenses

The Company had total costs and expenses of $18.6 million in 2002, $16.2 million in 2001, and $16.1 million in 2000.

Research and development costs represent the most significant operating expenses of the Company. These totalled $12.2 million in 2002, $10.7 million in 2001 and $9.8 million in 2000. In 2002, research and development costs increased by approximately $1.5 million over 2001. This increase was primarily due to the increase in the value of the Euro, the currency in which these expenses are paid, against the U.S. dollar. In 2001, research and development costs increased by approximately $0.9 million over 2000. This increase was due to a number of new partnerships obtained during the year and to the active pursuit of self-funded programs.

Costs of goods and services sold were $2.4 million in 2002, $2.2 million in 2001 and $2.9 million in 2000. These costs include the direct and indirect labor, materials, outside services, overhead costs relevant to manufacturing and other services provided to third parties at the Pessac facility and at the Company's Venissieux pilot plant. The fluctuation in costs year-to-year is the result of changes year-to-year in both the mix and volume of products produced and services rendered. The figures show an increase of 10% in 2002 compared to a decline of 24% in 2001.

Selling, general and administrative expenses were increased to $4.0 million in 2002 from $3.4 million in 2001 and $3.4 million in 2000. These increases were largely a result of changes in the Euro/dollar exchange rate and an increase in certain key executive salaries. Stock compensation expenses were $18,000 in 2002, $23,000 in 2001 and $20,000 in 2000.

Non-operating Items

Other income of $2.5 million in 2002 consisted of the amount received from the Wellcome Foundation in settlement of certain litigation with respect to our product, Genvir™ (See Notes to Consolidated Financial Statements No 9).

The French government provides tax credits to companies for annual increased spending for 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. At December 31, 2002, Flamel had total research tax credits receivable of $0.9 million. If these credits are not applied against future income taxes, they will be received as cash payments in 2003 for $0.3 million and in 2007 for $0.6 million. The Company earned a research and development credit in 2002 of $0.6 million and did not have any such credit in 2001 and in 2000. As a result, the Company recognized a tax benefit of $0.6 million in 2002, which resulted primarily from French research and development credits and paid the statutory minimum income tax expense of $14,000 for 2001 and of $50,000 for 2000 including the statutory minimum income tax expense of $16,000, and a $34,000 adjustment from prior years for the fiscal audit concerning research tax credit.

As of December 31, 2002, Flamel had net accumulated French tax loss carryforwards of $30.4 million, which can be credited against future taxes payable. Of this sum, $9.4 million is attributed to the depreciation of capital assets and may be credited against future taxes payable with no time limits. The remaining $21.0 million must be credited against future taxes payable within four years after being incurred. See Note 6 to the Consolidated Financial Statements.

Interest income earned on the Company's cash balance was $297,000 in 2002, $292,000 in 2001 and $373,000 in 2000. The changes in interest earned year-to-year is primarily the result of fluctuating average cash balances invested year-to-year and declining interest rates in 2002. Interest expense was $49,000 in 2002, $52,000 in 2001 and $51,000 in 2000 and is primarily related to the interest applicable to the Company's equipment leases.

Change in accounting principle

The Company has historically recognized non-refundable technology access fees received from its collaboration agreements as revenue when received. In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements". Among other things, SAB No. 101 describes the SEC staff's position on the recognition of certain non-refundable up-front fees received in connection with research collaborations. The Company has evaluated the applicability of SAB No. 101 in conjunction with its existing collaborative agreements. As a result, effective January 1, 2000, the Company changed its method of accounting for the receipt of such fees to recognize revenue over the term of the related development period. The Company recorded the cumulative effect of a change in accounting principle of ($4,577,000) in the results for the year ended December 31, 2000. For the year ended December 31, 2001 and December 31, 2000, the Company has recorded $2,812,000 and $1,565,000 respectively of license and research revenue, which was included in the cumulative effect adjustment recorded on January 1, 2000. There was no effect of this accounting principle in 2002.

Net Profit/Loss

For the year ended December 31, 2002, the Company reported a net profit of $3.0 million, or $0.18 per share on a diluted basis. The net losses reported for the years ended December 31, 2001 and December 31, 2000 were $2.9 million, or $0.18 per share, and $9.5 million, or $0.62 per share, respectively.

Liquidity and Capital Resources

On December 31, 2002 the Company had $14.5 million in cash and cash equivalents.

Net cash provided by (used in) operating activities was $8.8 million in 2002, $(2.9) million in 2001 and $(5.6) million in 2000. In 2002 net cash provided by operating activities reflected a net income of $3.0 million, a $5 million decrease in accounts receivable due to payments of amounts invoiced in 2001, net repayment of $0.9 million related to research tax credits offset by a $1.4 million decrease in accrued expenses.

Net cash used for capital investments was $1.4 million in 2002 and was primarily spent at the Pessac plant to provide the capacity needed for the ongoing development of the Company's products. Net cash used for capital investments amounted to $1.2 million in 2001 and $0.7 million in 2000.

Since its inception in the aggregate, the Company's operations to date have consumed substantial amounts of cash and are expected to continue to do so, at least for the next two years. The Company believes that ongoing research and product development programs are adequately funded for the next year. 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 for the next twelve months.

At December 2002, the Company has loans of $0.9 million from Anvar, an agency of the French government that provides financing to French companies for research and development. These loans do not bear interest and are repayable only in the event that the research is successful technically or commercially. "See Note 4 to the Consolidated Financial Statements".

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

The contractual cash obligations of the Company are as follows:

In thousands of US dollars	Payments due per period				
	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years	Total
Long Term Debt	693	400	991	—	**2,084**
Capital Lease Obligation	249	163	—	—	**412**
Operating Leases	290	496	—	—	**786**
Total Contractual Cash Obligations	**1,232**	**1,059**	**991**		**3,282**

At December 31, 2002, the Company has no other commercial commitments.

NOTE: This "Item 5. Operating and Financial Review and Prospects" contains statements that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform act of 1995. These statements are subject to risks and uncertainties, including but not limited to the risk associated with the Company's limited history of operations and historic and future losses, and the risk that products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, uncertainties regarding market acceptance of products in development, the impact of competitive products and pricing, reliance on outside parties and the risks associated with key strategic alliances, and other risks detailed in Item 3. Key Information – Risk Factors.

ITEM 6. Directors, Senior Management and Employees

Directors and Senior Management

The following table sets forth the name and position of the directors and executive officers of the Registrant.

Name	Position	Year of Initial Appointment
Gerard Soula	*President, Directeur General* (President and Chief Executive Officer), Director of Research and Development, and Director	1990
Stephen H. Willard	*Executive Vice President, Chief Financial Officer, General Counsel, and Director*	2000
Patrick Perrin	Vice President and Controller	1992
Rafael Jorda	Vice President and Director of Manufacturing	1990
Remi Meyrueix	Scientific Director	1990
Emmanuelle Bardet	*Directeur General Délégué* (Vice President), *Pharmacien Responsible* (Chief Pharmacist)	1996
W. George Meredith (1)(2)	Director	2000
Jean-Noël Treilles (1)(2)	Director	2000
Gerard Compain (2)	Director	2002

(1) Member of the Compensation Committee

(2) Member of the Audit Committee

The term of office of each of the directors expires at the year 2003 ordinary shareholders meeting.

In accordance with French law governing a *societe anonyme*, the Company is managed by its Board of Directors and by its *President Directeur General* (President and 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 *President Directeur General* may submit to the Board of Directors the nomination of one or more *Directeurs Generaux Délègués*.

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 24 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. 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, a "permanent representative," who represents such legal entity on the Board. According to an agreement with Alta Partners and its affiliates, a non-voting representative may be designated to attend meetings of the Company's Board of Directors. 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 *statuts*; (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 *statuts* 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 five members. Gérard Soula has been with the Company since 1990; prior to that time he was head of polymer development at Rhone Poulenc. Jean-Noel Treilles has been the President of the Ethical division of E. Merck (the German-based company) since 1999. Prior to this position, he served as Chairman and Chief Executive Officer of the Merck-Lipha France and as Chairman and Chief Executive Officer of LIPHA. W. George Meredith is the retired Executive Vice President of 3M's Life Sciences Sector and a former member of 3M's Board of Directors. Stephen Willard was elected to the Board of Directors. He is the Executive Vice President, Chief Financial Officer and General Counsel of Flamel. Finally, Gerard Compain joined the Board of Directors in 2002. He is the president and general manager of Ingenico, a French company. These directors bring broad experience to Flamel.

Board Practices

Directors of the Company serve without compensation and are reimbursed, upon request, for expenses incurred in attending Board meetings. Mr. Meredith performs consulting services for the Company from time to time and is compensated separately for this service. He performed such services in 2002 and was paid $8,000 for such services during 2002. 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 *Comite d'Entreprise* (Employee Representation Committee) comprised of representative elected from among the personnel. The Employee Representation Committee was formed in 1997. Two of those representatives are entitled to attend certain meetings of the Board of Directors of the Company, but they do not have any voting rights.

The Board has a Compensation Committee currently composed of W. George Meredith and of Jean-Noel Treilles. The Compensation Committee makes recommendations to the Board of Directors on the compensation of the executive officers of the Company, including the President and Chief Executive Officer. The Board of Directors makes final decisions on compensation. The Board has an Audit Committee currently composed of Jean-Noel Treilles and W. George Meredith. The Audit Committee recommends to the Board the selection of Flamel's independent auditors and reviews the findings of the auditors. The Company also has an informal Scientific Advisory Board.

The *President Directeur General* 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 President and 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 President and Chief Executive Officer.

Compensation of Directors and Officers

The aggregate amount set aside or accrued by the Company for the year ended December 31, 2002 to provide pension, retirement or similar benefits for directors and officers of the Company was approximately $17,000.

During 2002, 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 $460,000 for Gerard Soula and $274,000 for Stephen Willard. In addition, Mr. Soula and Mr. Willard were granted options in the amount and on the terms set forth below, in the table showing options and warrants granted in 2002. Internal directors do not receive compensation for their service in that capacity.

Options to Purchase Securities from the Company

On May 10, 1996, the shareholders of the Company authorized the creation of a share option plan (the "1996 Plan"), which authorizes the Board of Directors to issue options to subscribe for up to 1,000,000 Shares. The 1996 Plan is designed to permit the granting of "qualifying stock options" under French tax law principles as well as "incentive stock options" under the U.S. Internal Revenue Code of 1986, as amended. Options granted under the 1996 Plan will have an exercise price of not less than ninety percent (90%) of the fair market value of a Share on the date of grant, based on the closing price of the ADSs on the Nasdaq National Market on that date, after converting the dollar closing price into Euros at the Noon Buying Rate on the date of grant. The options granted under the 1996 Plan are exercisable up to ten years from the date of grant. Under French law, the Company cannot grant options to members of the Board of Directors who are not employees.

On July 19, 2001, the Company issued to each of Messrs. Meredith and Treilles, each a member of the Board of Directors of the Company, 10,000 warrants. Each warrant is exercisable to purchase one Share at a price of 5.94 Euros ($5.24) per share.

On December 19, 2001, the shareholders of the Company authorized the creation of a share option plan (the "2001 Plan"), which authorizes the Board of Directors to issue options to subscribe for up to 750,000 Shares. The 2001 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 2001 Plan will have an exercise price based on the fair market value of a Share on the date of grant, i.e. the closing price of the ADSs on the Nasdaq National Market the day prior the date of the grant, after converting the dollar closing price into Euros at the value published by Banque de France on the day just preceding the date of the grant. The options granted under the 2001 Plan are exercisable up to ten years from the date of grant.

On June 20, 2002, the Company issued to each of Messrs. Meredith and Treilles, each a member of the Board of Directors of the Company, 40,000 warrants. Each warrant is exercisable to purchase one Share at a price of 2.33 Euros ($2.05) per share.

On September 19, 2002, the Company issued to Mr. Compain, a member of the Board of Directors of the Company, 40,000 warrants. Each warrant is exercisable to purchase one Share at a price of 1.36 Euros ($1.35) per share.

OPTIONS AND WARRANTS GRANTED IN 2002

NAME	WARRANTS	OPTIONS	EXERCISE PRICE EUROS	EXERCISE PRICE $	EXPIRATION
G. SOULA		200,000(3)(4)	2.33	2.05	March 2012
MEREDITH	40,000(1)		2.33	2.05	June 2006
TREILLES	40,000(1)		2.33	2.05	June 2006
COMPAIN	40,000(1)		1.36	1.35	June 2006
WILLARD		200,000(3)(4)	2.33	2.05	March 2012
CHAN		40,000(1)(2)	1.36	1.35	June 2012
KRAVTZOFF		50,000(1)(2)	1.36	1.35	June 2012
CHATELLIER		100,000(1)(2)	4.11	4.15	December 2012
BREYNE		20,000(1)(3)	4.11	4.15	December 2012
GUIMBERTEAU		20,000(1)(3)	4.11	4.15	December 2012
NICOLAS		20,000(1)(3)	4.11	4.15	December 2012
O. SOULA		20,000(1)(3)	4.11	4.15	December 2012
YSAC		25,000(1)(3)	4.11	4.15	December 2012

(1) These options vest over a period of four years and are exercisable for ten years from the date of grant.

(2) Granted under the 2000 Plan.

(3) Granted under the 2001 Plan.

(4) These options were pending to the achievement of specific results for the Company, which were realized in the year 2002 . They are exercisable for ten years from the date of grant.

EMPLOYEES

As of December 31, 2002, Flamel had 150 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

YEAR END	VENISSIEUX [1]	PESSAC [2]	USA [3]	TOTAL
2000	78	56	3	**137**
2001	79	57	2	**138**
2002	81	67	2	**150**

[1] Primarily engaged in research activities

[2] Primarily engaged in technical and pharmaceutical development activities

[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 ("*Comité d'Entreprise*") comprised 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 and executive officers as of the date indicated:

OWNERSHIP OF SHARES AS OF MARCH 31, 2003

NAME	SHARES OWNED	%	WARRANTS	NUMBER OF OPTIONS	EXERCISE PRICE EUROS	EXERCISE PRICE $	EXPIRATION	TOTAL	TOTAL %
SOULA	674,248	4.16%		60,000	4.75	5.17	December 2006		
				100,000	4.86	5.29	April 2010		
				50,000	6.40	6.97	December 2010		
				400,000	1.09	1.19	September 2011		
				200,000	2.33	2.54	March 2012		
				200,000	4.32	4.71	March 2013	1,684,248	7.17%
MEREDITH	1	0.00%	40,000		4.88	5.31	June 2005		
			10,000		5.95	6.48	July 2006		
			40,000		2.33	2.54	June 2006	90,001	0.38%
TREILLES	1	0.00%	40,000		4.88	5.31	June 2005		
			10,000		5.95	6.48	July 2006		
			40,000		2.33	2.54	June 2006	90,001	0.38%
COMPAIN		0.00%	40,000		1.36	1.48	September 2006	40,000	0.17%
WILLARD	1	0.00%		160,000	4.58	4.99	September 2010		
				40,000	4.58	4.99	December 2010		
				25,000	6.40	6.97	December 2010		
				100,000	1.09	1.19	September 2011		
				200,000	2.33	2.53	March 2012		
				200,000	4.32	4.71	March 2013	725,001	3.09%
JORDA	24,375	0.15%		30,000	4.75	5.17	December 2006		
				60,000	4.86	5.29	April 2010		
				80,000	2.77	3.01	December 2011	194,375	0.83%
PERRIN	20,497	0.13%		50,000	4.75	5.17	December 2006		
				40,000	4.86	5.29	April 2010		
				10,000	2.77	3.01	December 2011	120,497	0.51%
MEYRUEIX	16,125	0.10%		20,000	4.75	5.17	December 2006		
				40,000	4.86	5.29	April 2010		
				40,000	2.77	3.01	December 2011	116,125	0.49%
KRAVTZOFF		0.00%		50,000	1.36	1.48	June 2012	50,000	0.21%
CHAN				20,000	4.75	5.17	December 2006		
				40,000	4.86	5.29	April 2010		
				40,000	1.36	1.48	June 2012	100,000	0.43
BARDET		0.00%		20,000	6.40	6.97	December 2011	20,000	0.009%

See “Compensation of Directors and Officers” for a description of the Company’s option plans.

ITEM 7. Major Shareholders and Related Party Transactions

Major Shareholders

The table below sets forth certain information with respect to the beneficial ownership of the Shares by the principal shareholders (each person or entity known to the Company to own beneficially five percent or more of the Shares) at March 31, 2003.

Title of Class	Identity of Person or Group	Amount Owned [1]	Percent of Class
Shares	Funds affiliated with Alta Partners [2]	4,050,125	22.05%
Shares	Funds affiliated with Biotechnology Value Fund [3]	2,700,000	15.31%
Shares	Eurazeo	1,619,758	10.00%

(1) Except as otherwise indicated, the persons named in this table have sole voting and investment power with respect to all Shares shown as beneficially owned by them, subject to community property laws where applicable and subject to the information contained in the footnotes to this table. Shares not outstanding but deemed beneficially owned by virtue of the right of a person or group to acquire them within 60 days are treated as outstanding only for purposes of determining the number of and percent owned by such a person or group.

(2) Includes 1,351,954 Shares issuable upon exercise of warrants exercisable within 60 days of March 31, 2003 beneficially owned by Alta BioPharma Partners LP, 772,008 Shares issuable upon exercise of warrants exercisable within 60 days of March 31, 2003 beneficially owned by Flamel Chase Partners (Alta Bio), LLC, and 50,958 Shares issuable upon exercise of warrants exercisable within 60 days of March 31, 2003 beneficially owned by Alta Embarcadero BioPharma, LLC. See “Item 6. Directors, Senior Management and Employees—Options to Purchase Securities from the Company—Other Options.”

(3) Includes 435,000 Shares issuable upon exercise of warrants exercisable within 60 days of March 31, 2003 beneficially owned by Biotechnology Value Fund, L.P., 942,500 Shares issuable upon exercise of warrants exercisable within 60 days of March 31, 2003 beneficially owned by Biotechnology Value Fund II, L.P., and 72,500 Shares issuable upon exercise of warrants exercisable within 60 days of March 31, 2003 beneficially owned by Investment 10 L.L.C. See “Item 6. Directors, Senior Management and Employees—Options to Purchase Securities from the Company—Other Options.”

On April 6, 2000, the Company issued an aggregate of 3,212,500 Ordinary Shares and warrants to purchase up to 3,726,500 Ordinary Shares to certain private investors, including the venture capital funds and affiliates of Biotechnology Value Fund, Alta Partners and Chase Capital Partners, for aggregate consideration of approximately $12.8 million. The Shares and Warrants (as defined below) were issued as units, each unit consisting of one Ordinary Share, 0.56 of a Class A warrant (a “Class A Warrant”), 0.60 of a Class B warrant (a “Class B Warrant”) and 0.60 a Class C warrant (a “Class C Warrant’ and together with the Class A Warrants and Class B Warrants, the “Warrants”). The Warrants have a five-year term. The Class A Warrants are exercisable at 5.96 Euros ($6.00) per share, the Class B Warrants are exercisable at 5.96 Euros ($6.00) per share and the Class C Warrants are exercisable at 0.12 Euros ($0.12) per share. The number of Class B Warrants and Class C Warrants that may be exercised has been determined in relation to the closing price of the Company’s ADSs on the Nasdaq National Market in 2000 and consequently 692,500 Class B Warrants and 1,285,00 Class C Warrants are exercisable. None of these warrants have been exercised as of March 30, 2003 .

Related Party Transactions

George Meredith performs consulting services for the Company from time to time, for which he receives market rate compensation. Mr. Meredith was paid $8,000 for consulting services during 2002.

See also “Major Shareholders” above and “Item 6. Compensation of Directors and Officers — Options to Purchase Securities from the Company.”

ITEM 8. Financial Information

Financial Statements

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

Legal Proceedings

Wellcome Foundation Limited (“Wellcome Foundation”), an affiliate of Glaxo Wellcome, initiated a civil action against the Company in the *Tribunal de Grande Instance* of Paris on September 18, 1997, claiming infringement of its proprietary rights over a drug containing acyclovir. Wellcome Foundation sought damages in an unspecified amount and provisional damages of 3 million francs. Flamel disputed the infringement claim and counterclaimed, alleging that Wellcome Foundation acted in bad faith and used unfair methods of competition. The case was heard by the *Tribunal de Grande Instance* of Paris in November 2000, and a judgment in Flamel’s favor was rendered by the *Tribunal* on February 20, 2001. In January, 2002, the Company and Wellcome Foundation entered into a settlement agreement with respect to this litigation and Flamel received a net payment of $2.5 million in connection therewith.

Flamel is a limited liability company (*société anonyme*), organized and existing under the laws of the Republic of France. Most of Flamel’s officers and directors are residents of France or countries other than the United States and most of its assets are located in France. As a result, it may not be possible for investors to effect service of process upon Flamel or its officers or directors outside of the United States, or to enforce against them judgments obtained in non-French courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or of any State or territory within the United States (collectively, the “U.S. Securities Laws”). Actions for enforcement in France of judgments obtained in non-French courts rendered against these officers and directors would require those persons who are of French nationality to waive their right under Article 15 of the French Civil Code to be sued only in France. Flamel believes that no such French person has waived such right with respect to actions predicated solely upon U.S. Securities Laws. In addition, actions in the United States under the U.S. Securities Laws could be affected under certain circumstances by the French law of July 26, 1968, as amended, which may preclude or restrict the obtaining of evidence in France or from French persons in connection with actions under the U.S. Securities Laws, and awards of punitive damages in actions brought in non-French courts may be unenforceable in France. Moreover, if an original action is brought in France, predicated solely upon the civil liability provisions of the U.S. Securities Laws, French courts may not have the requisite jurisdiction to grant the remedies sought.

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 Ordinary Share, nominal value 0.13 Euros. Each ADS is evidenced by an ADR. The Bank of New York is the Depositary for the ADRs. As of December 31, 2002, there were 10,132,439 ADSs outstanding in the United States. At such date, there were 6 holders of ADSs on record. As of December 31, 2002, there were 16,197,590 Shares outstanding.

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

	Price per ADS (US$)	
Year	High	Low
1998	5.56	2.12
1999	4.63	1.00
2000	11.38	2.00
2001	7.06	0.94
2002	4.85	1.22

	Price per ADS (US$)	
Quarter Ended	High	Low
1st Quarter, 2001	7.06	3.16
2nd Quarter, 2001	3.74	2.34
3rd Quarter, 2001	2.72	1.00
4th Quarter, 2001	2.72	0.94
1st Quarter, 2002	2.95	1.78
2nd Quarter, 2002	2.16	1.23
3rd Quarter, 2002	3.25	1.22
4th Quarter, 2002	4.85	2.21
1st Quarter, 2003	7.15	3.74

	Price per ADS (US$)	
Month Ended	High	Low
March 31,2003	7.15	4.44
February 28, 2003	5.25	4.42
January 31, 2003	4.44	3.74
December 31, 2002	4.85	3.87
November 30, 2002	4.20	2.44
October 31, 2002	4.85	2.21

ITEM 10. Additional Information

Memorandum and Articles of Association

For a general description of these documents, see “Description of Share Capital” in the Company’s registration statement on Form F-1, as filed with the U.S. Securities and Exchange Commission on April 19, 1996, registration number 333-03854, which is incorporated by reference. There have been no changes to these documents.

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 a the ability for such Ministry to oppose the investment during a one-month period. As a result of becoming 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's material contracts are described in "Item 4. Information on the Company" under the heading "Strategic Alliances".

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

French Taxation

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 laws, conventions and treaties in force as of the date of this annual report, all of which are subject to change, possibly with retroactive effect, or different interpretations.

Holders of Flamel Ordinary Shares should consult their own tax advisors about the potential tax effects of owning or disposing of Ordinary Shares in any particular situation.

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 French residents for these purposes.

If a holder of Flamel Ordinary Shares transfers shares using a written agreement, that agreement must generally be registered. The holder will be required to pay a registration duty of 1% of either the purchase price or the market value of the Ordinary Shares transferred, whichever is higher. The maximum duty is #3.049 per transfer. However, if the agreement is executed outside France, the holder of Flamel Ordinary Shares will not be required to pay this duty.

Taxation of Dividends

Withholding Tax and Avoir Fiscal. In France, companies may only pay dividends out of income remaining after tax has been paid. When shareholders resident in France receive dividends from French companies, they are entitled to a tax credit, known as the *avoir fiscal*. The amount of the *avoir fiscal* is generally equal to:

- 50% of the dividend paid for shareholders who are individuals or corporate shareholders that benefit from the participation exemption regime defined in Articles 145 and 216 of the French Tax Code; or

- 15% of the dividend paid for shareholders who are not individuals.

Shareholders resident in France and entitled to the *avoir fiscal* at the rate of 15% may generally be entitled to an additional tax credit equal to 70% of any *prŠcompte* actually paid in cash by a company upon distribution of dividends paid out of specified profits. See “íThe *PrŠcompte*.”

Under French domestic law, shareholders who are not residents of France are not eligible for the *avoir fiscal* unless the double tax treaty between France and the country of residence of the shareholder provides for a transfer of the avoir fiscal.

French companies must generally deduct a 25% 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.

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 arrangements summarized below:

Australia	Germany	Luxembourg	Norway	United Kingdom
Austria	Ghana	Malaysia	Pakistan	United States
Belgium	Iceland	Mali	Senegal	Ukraine
Bolivia	India	Malta	Singapore	Venezuela
Brazil	Israel	Mauritius	South Korea	French Territoires

Burkina Faso	Italy	Mexico	Spain	d'Outre-Mer and Other
Cameroon	Ivory Coast	Namibia	Sweden	Mayotte
Canada	Japan	Netherlands	Switzerland	New Caledonia
Finland	Latvia	New Zealand	Togo	Saint-Pierre et Miquelon
Gabon	Lithuania	Niger	Turkey	

Under these treaties, a shareholder who fulfills specified conditions may generally apply to the French tax authorities for the following:

- lower rate of withholding tax, generally 15%; and
- refund of the *avoir fiscal*, after deduction of withholding tax payable on the *avoir fiscal*.

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

German corporate shareholders and German investment funds, in receipt of French-source dividends, are no longer entitled to the *avoir fiscal* retroactively, as of January 1, 2001, provided they own less than 10% of the share capital of the corporation distributing dividends. German and French authorities are still carrying on discussions as to the suspension of the *avoir fiscal* for individual shareholders.

Some of the countries and territories listed above impose additional conditions for corporate entities wishing to receive the *avoir fiscal*. In other countries and territories, individual residents may receive the *avoir fiscal* but corporate entities may not.

The Précompte. A French company must pay an equalization tax known as the *précompte* to the French tax authorities if it distributes dividends which give rise to avoir fiscal and whenever dividends are distributed out of

- profits which have not been taxed at the ordinary corporate income tax rate; or
- profits which have been earned during a tax year closed more than five years before the distribution.

The amount of the *précompte* is 50% of the net dividends.

A shareholder that is not a French resident for French tax purposes may generally obtain a refund of the amount of any *précompte* Flamel actually pays in cash, net of applicable withholding tax, if the shareholder is entitled to the benefits of a tax treaty and the treaty does not provide for the transfer of the *avoir fiscal*.

Estate and Gift Tax

France imposes estate and gift tax where an individual or entity acquires real and personal property from a non-resident of France by way of inheritance or gift. France has entered into estate and gift tax treaties with a number of countries. Under these treaties, residents of those countries may be exempted from this tax or obtain a tax credit, assuming specified conditions are met. Holders of Flamel Ordinary Shares should consult their own tax advisors about whether French estate and gift tax will apply and whether they may claim an exemption or tax credit.

Wealth Tax

French individual residents are taxable on their worldwide assets. Non-resident individuals are taxable only on their assets which are located in France. However, financial investments made by non-resident individuals, other than in real property companies, are exempt from wealth tax under certain conditions.

If a double tax treaty between France and a holder's country of residence contains more favorable provisions, the holder may not be subject to French wealth tax.

Taxation of U.S. Investors

On August 31, 1994, the United States and France signed a tax treaty, which generally became effective on December 30, 1995. The following is a general summary of the principal tax effects on holders of Flamel Shares for purposes of U.S. federal income tax and French tax, if all of the following five points apply:

- the holder owns, directly or indirectly, less than 10% of Flamel's share capital;
- the holder is any one of (a), (b) or (c) below:

  (a) a citizen or resident of the United States for U.S. federal income tax purposes, or

  (b) a U.S. domestic corporation, or

  (c) otherwise subject to U.S. federal income taxation on a net income basis in respect of its Flamel Shares;
- the holder is entitled to the benefits of the U.S.-France tax treaty under the "limitations on benefits" article of that treaty;
- the holder holds Flamel Shares as capital assets; and
- the holder's functional currency is the U.S. dollar.

For purposes of the U.S.-France tax treaty and U.S. federal income tax, holders of Flamel ADSs will be treated as holders of the Flamel Ordinary Shares which their Flamel ADSs represent.

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 Shares 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 U.S.-France tax treaty, the applicability and effect of state, local, foreign and other tax laws and possible changes in tax law.

Taxation of Dividends

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

Specific provisions apply if the holder is considered an "eligible" U.S. holder of Flamel Shares. A holder is "eligible" if its ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base that the holder has in France and any one of the following four points applies:

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

If a holder is an "eligible" U.S. holder, dividends distributed by Flamel will be subject to a withholding tax at the reduced rate of 15%, provided that the holder has previously established that it is a resident of the United States under the U.S.-France tax treaty in accordance with the following procedures:

- The holder must complete French Treasury Form RF1 A EU-No. 5052 and send it to the paying establishment before the date of payment of the dividend. If the holder is not an individual, the holder must also send the paying establishment an affidavit attesting that the holder is the beneficial owner of all the rights attached to the full ownership of Flamel Shares, including, among other things, the dividend rights.
- If the holder cannot complete Form RF1 A EU-No. 5052 before the date of payment of the dividend, the holder may complete a simplified certificate and send it to the French tax

authorities or the institution which holds the shares on his behalf. This certificate must state all of the following five points:

(a) the holder is a resident of the United States for purposes of the U.S.-France tax treaty;

(b) the holder's ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base in France;

(c) the holder owns all the rights attached to the full ownership of Flamel Shares, including, among other things, the dividend rights;

(d) the holder fulfills all the requirements under the U.S.-France tax treaty to be entitled to the reduced rate of withholding tax and to be entitled to the transfer of the *avoir fiscal*; and

(e) the holder claims the reduced rate of withholding tax and payment of the *avoir fiscal*.

If a holder is not an "eligible" U.S. holder, or if the holder has not completed Form RF1 A EU-No. 5052 or the five-point certificate before the dividend payment date, Flamel will deduct French withholding tax at the rate of 25%. In that case, a holder may claim a refund of the excess withholding tax.

If a holder is an "eligible" U.S. holder, the holder may also claim the *avoir fiscal*, by completing Form RF1 A EU-No. 5052 and sending it to the paying establishment before December 31 of the year following the year during which the dividend is paid. The holder will be entitled to a payment equal to the *avoir fiscal*, less a 15% withholding tax on the *avoir fiscal*. As noted below, the holder will not receive this payment until after the close of the calendar year in which the dividend was paid. To receive the payment, the holder must submit a claim to the French tax authorities and attest that they are subject to U.S. federal income taxes on the payment of the avoir fiscal and the related dividend. For partnerships or trusts, the partners, beneficiaries or grantors must make the attestation.

Specified rules apply to the following:

- tax-exempt U.S. pension funds, which include the exempt pension funds established and managed in order to pay retirement benefits subject to the provisions of Section 401(a) of the Internal Revenue Code (qualified retirement plans), Section 403(b) of the U.S. Internal Revenue Code (tax deferred annuity contracts) or Section 457 of the U.S. Internal Revenue Code (deferred compensation plans); and

- various other tax-exempt entities, including specified state-owned institutions, not-for-profit organizations and individuals for dividends which they beneficially own and which are derived from an investment retirement account.

Entities in these two categories are eligible for the reduced withholding tax rate of 15% on dividends, subject to the same withholding tax filing requirements as "eligible" U.S. holders, except that they may have to supply additional documentation evidencing their entitlement to these benefits. These entities are not entitled to the full *avoir fiscal*. These entities may claim a partial avoir fiscal equal to 30/85 of the gross *avoir fiscal*, provided that they own, directly or indirectly, less than 10% of the company's capital and they satisfy the filing formalities contained in U.S. Internal Revenue Service regulations.

The *avoir fiscal* or partial *avoir fiscal* and any French withholding tax refund are generally expected to be paid within 12 months after the holder of Flamel Shares files Form RF1 A EU-No.

5052. However, they will not be paid before January 15 following the end of the calendar year in which the dividend is paid.

For U.S. federal income tax purposes, the gross amount of a dividend and any *avoir fiscal*, including any French withholding tax, will be included in each holder's gross income as dividend income when payment is received by them (or the custodian, if the 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.

Also for U.S. federal income tax purposes, the amount of any dividend paid in Euro or French francs, including any French withholding taxes, will be equal to the U.S. dollar value of the Euro or French francs on the date the dividend is included in income, regardless of whether the payment is in fact converted into U.S. dollars. A holder will generally be required to recognize U.S. source ordinary income or loss when the holder sells or disposes of the Euros or French francs. A holder may also be required to recognize foreign currency gain or loss if that holder receives a refund under the U.S.-France tax 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 holder's Flamel Shares. This adjustment will increase the amount of gain, or decrease the amount of loss, which a holder will recognize if such 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 holder receives and on any *avoir fiscal* at 15% under the U.S.-France tax treaty is treated as payment of a foreign income tax. A holder may take this amount as a credit against the holder's U.S. federal income tax liability, subject to various conditions and limitations, including minimum holding period requirements.

The Précompte. A French company must pay an equalization tax known as the précompte to the French tax authorities if it distributes dividends which give rise to *avoir fiscal* and whenever dividends are distributed out of:

- profits which have not been taxed at the ordinary corporate income tax rate; or

- profits which have been earned during a tax year closed more than five years before the distribution.

The amount of the précompte is 50% of the net dividends.

If a holder is not entitled to the full *avoir fiscal*, the holder may generally obtain a refund from the French tax authorities of any précompte paid by Flamel with respect to dividends distributed to

them. Under the U.S.-France tax treaty, the amount of the précompte refunded to U.S. residents is reduced by the 15% withholding tax applicable to dividends and by the partial *avoir fiscal*, if any. A holder is entitled to a refund of any précompte which Flamel actually pays in cash, but not to any précompte which Flamel pays by off-setting French and/or foreign tax credits. To apply for a refund of the précompte, a holder should file French Treasury Form RF1 B EU-No. 5053 before December 31 of the year following the year in which the dividend was paid. The form and its instructions are available from the Internal Revenue Service in the United States or from the French Centre des Impots des Non-Residents whose address is 9, rue d'Uzes, 75094 Paris Cedex 2, France.

For U.S. federal income tax purposes, the amount of the précompte will be included in a holder's gross income as dividend income in the year the holder receives it. It will generally constitute foreign source "passive" income for foreign tax credit purposes. For some recipients, it will constitute foreign source "financial services" income for foreign tax credit purposes. The amount of any précompte paid in Euro or French francs, including any French withholding taxes, will be equal to the U.S. dollar value of the Euro or French francs on the date the précompte is included in income, regardless of whether the payment is in fact converted into U.S. dollars. A holder will generally be required to recognize a U.S. source ordinary income or loss when the holder sells or disposes of the Euro or French francs.

Taxation of Capital Gains

If a holder is a resident of the United States for purposes of the U.S.-France tax treaty, the holder will not be subject to French tax on any capital gain if the holder sells or exchanges its Flamel Shares, unless the holder has a permanent establishment or fixed base in France and the Flamel Shares the 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.

In general, for U.S. federal income tax purposes, a holder will recognize capital gain or loss if the holder sells or exchanges its Flamel Shares in the same manner as the holder would if it were to sell or exchange any other shares held as capital assets. Any gain or loss will generally be U.S. source gain or loss. If a holder is an individual, any capital gain will generally be subject to U.S. federal income tax at preferential rates if the 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 fundamentally factual in nature 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 its Shares and any gains a holder realizes when the holder disposes of its Shares may be less favorable to the holder. Each holder should consult its own tax advisors regarding the PFIC rules and their effect on the holder if they purchase Shares.

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 holder transfers their Flamel Shares by gift, or if they are transferred by reason of the holder's death, that transfer will only be subject to French gift or inheritance tax if one of the following applies:

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

French Wealth Tax

The French wealth tax does not generally apply to Flamel Shares if the holder is a "resident" of the United States for purposes of the U.S.-France tax treaty.

United States Information Reporting and Backup Withholding

A holder may be required to report dividend payments and proceeds from the sale or disposal of such holder's Flamel Shares to the Internal Revenue Service. U.S. federal backup withholding generally is a withholding tax imposed at the rate of 30% on some payments to persons that fail to furnish required information. Backup withholding will not apply to a 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 holder's U.S. federal income tax liability. A 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. The information filed with the Commission may be inspected and copied at the Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549 Copies of the materials may be obtained from the Commission's Public Reference Room in Washington, D.C. at prescribed rates. 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.

ITEM 11. Quantitative and Qualitative Disclosures About Market Risk

The Company conducts a significant portion of its business transactions in U.S. dollars. For the year ended December 31, 2002 revenues and expenses denominated in U.S. dollars represented 66% and 10% of total revenues and expenses, respectively. As a result, the Company's financial results could be significantly affected by the fluctuation of the Euro relative to the U.S. dollar. See "Item 5. Operating and Financial Review and Prospects î Overview."

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

Within 90 days prior to the filing date of this annual report on Form 20-F (the "Evaluation Date"), the Company carried out an evaluation, under the supervision and with the participation of management, including the Company's President and Chief Executive Officer, Mr. Gerard Soula, and the Company's Executive Vice President, Chief Financial Officer and General Counsel, Mr. Stephen H. Willard, of the effectiveness of the design and operation of the Company's disclosure controls and procedures, as such term is defined under Rule 13a-14(c) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based on that evaluation, Messrs. Soula and Willard concluded that, as of the Evaluation Date, the disclosure controls and procedures in place at the Company were adequate to ensure that information required to be disclosed by the Company, including its consolidated subsidiaries, in reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported on a timely basis in accordance with applicable rules and regulations.

The Company has not made any significant changes to its internal controls subsequent to the Evaluation Date. The Company has not identified any significant deficiencies or material weaknesses or other factors that could significantly affect these controls, and therefore, no corrective action was taken.

ITEM 16. [Reserved]

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:

Independent Auditors’ Report;

Consolidated Balance Sheets as of December 31, 2001 and 2002;

Consolidated Statement of Operations for the Years Ended December 31, 2000, 2001 and 2002;

Consolidated Statements of Shareholders’ Equity (Deficit) for the Years Ended December 31, 2000, 2001 and 2002; and

Consolidated Statements of Cash Flows for the Years Ended December 31, 2000, 2001 and 2002.

Notes to Consolidated Financial Statements.

See pages F-1 through F-20.

ITEM 19. Exhibits.

Exhibit No.	Description
99.1	Certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 signed by the Company’s Chief Executive Officer and Chief Financial Officer.

FLAMEL TECHNOLOGIES S.A.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

INDEPENDENT AUDITORS' REPORT

The Directors and Shareholders

Flamel Technologies, S.A.

We have audited the accompanying consolidated balance sheets of Flamel Technologies, S.A. (“the Company”) as of December 31, 2001 and 2002 and the related consolidated statements of operations, changes in shareholders’ equity and cash flows for each of the three years in the period ended December 31, 2002. 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 auditing standards generally accepted in the 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 statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company at December 31, 2001 and 2002 and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States.

ERNST & YOUNG Audit

Represented by

Jean-Luc Desplat

April 23, 2003
Villeurbanne, France

FLAMEL TECHNOLOGIES S.A.

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

	December 31,	
	2001	2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,309	$ 14,527
Accounts receivable	7,596	3,462
Inventory	569	375
Prepaid expenses and other current assets	325	347
Total current assets	13,799	18,711
Property and equipment, net	2,672	3,405
Other assets:		
Research and development tax credit receivable	1,623	890
Other long-term assets	50	70
Total other assets	1,673	960
Total assets	$ 18,144	$ 23,076
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 391	$ 693
Current portion of capital lease obligations	390	229
Accounts payable	1,205	1,322
Current portion of deferred revenue	1,072	1,805
Advances from customers	1,191	361
Accrued expenses	1,430	2,028
Other current liabilities	782	71
Total current liabilities	6,461	6,509
Long-term debt, less current portion	779	1,391
Capital lease obligations, less current portion	136	149
Deferred revenue, less current portion	2,875	1,952
Other long-term liabilities	384	789
Total long-term liabilities	4,174	4,281
Commitments and contingencies :	—	—
Shareholders' equity :		
Ordinary shares : 16,197,590 issued and outstanding at December, 31 2001 and 2002	2,366	2,366
Additional paid-in capital	71,177	71,178
Accumulated deficit	(59,386)	(56,381)
Deferred compensation	(32)	(14)
Cumulative other comprehensive loss	(6,616)	(4,863)
Total shareholders' equity	7,509	12,286
Total liabilities and shareholders' equity	$ 18,144	$ 23,076

See notes to consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

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

	Year ended December 31,		
	2000	**2001**	**2002**
Revenue:			
License and research revenue	$ 6,619	$ 9,858	$ 14,593
Product sales and services	3,034	2,009	2,865
Other revenues	1,249	1,220	948
Total revenue	10,902	13,087	18,406
Costs and expenses:			
Cost of goods and services sold	(2,863)	(2,166)	(2,373)
Research and development	(9,789)	(10,662)	(12,239)
Selling, general and administrative	(3,435)	(3,391)	(3,999)
Stock compensation expense	(20)	(23)	(18)
Total	(16,107)	(16,242)	(18,629)
Loss from operations	(5,205)	(3,155)	(223)
Interest expense	(51)	(52)	(49)
Interest income	373	292	297
Foreign exchange gain (loss)	49	55	(99)
Other income	—	—	2,526
Income (loss) before income taxes and the cumulative effect of a change in accounting principle	(4,834)	(2,860)	2,452
Income tax profit, (expense)	(50)	(14)	553
Net income (loss) from operations before cumulative effect of a change in accounting principle	(4,884)	(2,874)	3,005
Cumulative effect on prior years (to December 31,1999) of changing method of revenue recognition.(Note 1.4)	(4,577)	—	—
Net income (loss)	$ (9,461)	$ (2,874)	$ 3,005
Earnings (loss) per share before cumulative effect of a change in accounting principle	$ (0.32)	$ (0.18)	$ 0.19
Cumulative effect per share on prior years (to December 31,1999) of changing method of revenue recognition	$ (0.30)	—	—
Basic earnings (loss) per ordinary share	$ (0.62)	$ (0.18)	$ 0.19
Diluted earnings per share	$ (0.62)	$ (0.18)	$ 0.18
Pro-forma amounts assuming the change in accounting principle had been applied retroactively:			
Net income (loss)	$ (4,884)	$ (2,874)	$ 3,005
Basic Earnings (loss) per ordinary share	$ (0.32)	$ (0.18)	$ 0.19
Diluted earnings per share	$ (0.32)	$ (0.18)	$ 0.18
Weighted average number of shares outstanding (in thousands) :			
Basic	15,331	16,198	16,198
Diluted	15,331	16,198	16,711

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		Deferred	Cumulative Other	
	Shares	Amount	Paid-in Capital	Accumulated Deficit	Compen-sation	Comprehen-sive Loss	Shareholders' Equity
Balance at January 1, 2000	12,939,215	$1,984	$59,306	$(47,051)	$(53)	$(5,119)	$ 9,067
Issuance of ordinary shares at €3.94 ($3.79) per share	3,212,500	377	6,252	—	—	—	6,629
Issuance of 5,654,000 warrants at €0.00 per warrant	—	—	5,544	—	—	—	5,544
Issuance of 120,000 warrants at €0.00 per warrant	—	—	—	—	—	—	—
Exercise of options at €2.82($2.74) per share	20,000	2	53	—	—	—	55
Exercise of warrants at €0.12($0.12) per share	19,250	2	—	—	—	—	2
Exercise of warrants at €0.12($0.11) per share	6,625	1	—	—	—	—	1
Stock compensation	—	—	22	—	(22)	—	—
Amortization of deferred compensation	—	—	—	—	20	—	20
Net loss	—	—	—	(9,461)	—	—	(9,461)
Other comprehensive loss Translation adjustment	—	—	—	—	—	(975)	(975)
Comprehensive loss							(10,436)
Balance at December 31, 2000	16,197,590	$2,366	$71,177	$(56,512)	$(55)	$(6,094)	$ 10,882
Issuance of 70,000 warrants at €0.00 per warrant	—	—	—	—	—	—	—
Amortization of deferred compensation	—	—	—	—	23	—	23
Net loss	—	—	—	(2,874)	—	—	(2,874)
Other comprehensive loss Translation adjustment	—	—	—	—	—	(522)	(522)
Comprehensive loss							(3,396)
Balance at December 31, 2001	16,197,590	$2,366	$71,177	$(59,386)	$(32)	$(6,616)	$ 7,509
Issuance of 80,000 warrants at €0.01 per warrant	—	—	1	—	—	—	1
Issuance of 40,000 warrants at €0.01 per warrant	—	—	—	—	—	—	—
Amortization of deferred compensation	—	—	—	—	18	—	18
Net profit	—	—	—	3,005	—	—	3,005
Other comprehensive income Translation adjustment	—	—	—	—	—	1,753	1,753
Comprehensive income							4,758
Balance at December 31, 2002	16,197,590	$2,366	$71,178	$(56,381)	$(14)	$(4,863)	$ 12,286

See notes to consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

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

	Year ended December 31,		
	2000	**2001**	**2002**
Cash flows from operating activities:			
Net income (loss)	$ (9,461)	$ (2,874)	$ 3,005
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation of property and equipment	1,082	1,270	1,460
Amortization of goodwill and other depreciation	31	—	—
Stock compensation expense	20	23	18
Increase (decrease) in cash from:			
Accounts receivable	(1,139)	(5,184)	5,021
Inventory	(682)	251	271
Prepaid expenses and other current assets	264	78	37
Deferred revenue	3,012	1,089	(845)
Accounts payable	132	(259)	(101)
Accrued expenses	1,050	1,179	(1,429)
Research and development tax credit receivable	36	1,568	938
Other long-term assets and liabilities	33	75	396
Net cash provided by (used in) operating activities	(5,622)	(2,784)	8,771
Cash flows from investing activities:			
Purchases of property and equipment	(737)	(1,178)	(1,435)
Proceeds from disposal of property and equipment	—	3	3
Net cash used in investing activities	(737)	(1,175)	(1,432)
Cash flows from financing activities:			
Repayment of loans or advances	(7)	(110)	—
Proceeds from loans or capital leases	205	330	860
Principal payments on capital lease obligations	(305)	(416)	(459)
Cash proceeds from sale of ordinary shares and warrants	11,728	—	1
Net cash provided by (used in) financing activities	11,621	(196)	402
Effect of exchange rate changes on cash and cash equivalents	(335)	(673)	1,477
Net increase (decrease) in cash and cash equivalents	4,927	(4,828)	9,218
Cash and cash equivalents, beginning of year	5,210	10,137	5,309
Cash and cash equivalents, end of year	$10,137	$ 5,309	$14,527
Supplemental disclosures of cash flow information:			
Capital lease obligations incurred	127	305	236

See notes to consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

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* or limited liability 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 accounting principles generally accepted in the United States (USGAAP).

The preparation of consolidated financial statements in conformity with USGAAP requires management to make estimates and assumptions that effect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the 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

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, 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 and change in accounting principle

Research and laboratory analysis services revenue is recognized on a basis consistent with the performance requirements of the contracts. Certain fees payable to the Company under these contracts are milestone-related and are due in accordance with the terms of each contract when the milestone is achieved. The Company recognizes these milestone-related revenues only when each milestone has been fully performed, as agreed by the parties. 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 on a systematic and rational basis to match the revenues with the related costs.

The Company recognizes revenue from unconditional grants received from governmental agencies in the period granted. Revenue from conditional grants received are recognized when all conditions stated in the grant have been met.

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 has historically recognized non-refundable technology access fees received from its collaboration agreements as revenue when received. In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements". Among other things, SAB No. 101 describes the SEC staff's position on the recognition of certain non-refundable up-front fees received in connection with research collaborations. The Company has evaluated the applicability of SAB No. 101 in conjunction with its existing collaborative agreements. As a result, effective January 1, 2000, the Company changed its method of accounting for the receipt of such fees to recognize revenue over the term of the related development period. The Company recorded the cumulative effect of a change in accounting principle of ($4,577,000) in the results for the year ended December 31, 2000. For the years ended December 31, 2001 and December 31, 2000, the Company has recorded $2,812,000 and $1,508,000 of license and research revenue, which were included in the cumulative effect adjustment recorded on January 1, 2000.

1.5. Research and development costs

Research and development (R&D) expenses are comprised of 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. R&D expenses consist of independent R&D costs and costs associated with collaborative R&D and in-licensing arrangements. Research and development expenditures are charged to operations as incurred.

1.6. Concentration of credit risk

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

The Company's revenues are derived mainly from collaborative research and development contracts with pharmaceutical and chemical 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. At December 31, 2002 and December 31, 2001, there was no allowance for doubtful accounts recorded.

1.7. Net result per share

Basic earnings per share is computed by dividing income available to common shareholders 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.

For the years ended December 31, 2000 and 2001, the effects of dilutive securities were excluded from the calculation of earnings per share as a net loss was reported in those periods.

1.8. Cash and cash equivalents

The Company considers all highly liquid investments purchased with an original maturity date of three months or less to be cash equivalents. Cash and cash equivalents consist of money market funds. All cash equivalents as of December 31, 2001 and 2002 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).

All available-for-sale securities are recorded at fair market value and unrealized gains and losses are included in accumulated other comprehensive income in shareholders’ equity, net of related tax effects. Gross realized gains on sales of these available-for-sale securities amounted to $351,000, $278,000 and $252,000 for the years ended December 31, 2000, 2001 and 2002, respectively. Unrealized gains in each of the three years presented were not material.

1.9. Inventories

Inventories consist principally of raw materials and finished products, which are stated at the lower of cost (first-in, first-out) or market. The components of inventories were as follows :

	December 31,	
(In thousands of U.S. dollars)	2001	2002
Raw materials	249	375
Finished goods	320	—
Inventories, net	569	375

1.10. Property and equipment

Property and equipment is stated at historical cost less accumulated depreciation. Depreciation and amortization are computed using principally the straight-line method over the estimated useful lives of three to twenty years. Assets under capital leases are amortized over the economic life of the asset or the remaining lease term, whichever is shorter. Amortization of capital leases is included in depreciation expense. The components of property and equipment were as follows :

	December 31,	
(In thousands of U.S. dollars)	2001	2002
Land and buildings	78	93
Laboratory equipment	8,210	11,257
Office and computer equipment	771	970
Furniture and fixtures	1,984	2,537
Total property and equipment	11,043	14,857
Less accumulated depreciation and amortization	(8,371)	(11,452)
Property and equipment, net	2,672	3,405

1.11. Impairment of Long-Lived Assets

Property and equipment and other long-lived assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable. If undiscounted expected future cash flows are less than the carrying value of the assets, an impairment loss will be recognized based on the excess of the carrying amount over the fair value of the assets.

1.12. 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.

1.13. Employee stock option plans

At December 31, 2002, the Company has five stock-based employee compensation plans, which are described more fully in Note 5.4. The Company accounts for those plans under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related Interpretations. In accordance with APB 25, the Company recognizes stock-based employee compensation cost over the vesting period when the options granted under those plans have an exercise price lower than the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net income and earnings per share if the company had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	Year Ended December 31		
(In thousands of U.S. dollars except share data)	**2000**	**2001**	**2002**
Net income (loss), as reported	(9,461)	(2,874)	3,005
Add: Stock-based employee compensation expense included in reported net income (loss), net of related tax effects	20	23	18
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(835)	(905)	(1,857)
Pro forma net income (loss)	(10,276)	(3,779)	1,166
Earnings per share:			
Basic, as reported	(0.62)	(0.18)	0.19
Basic, pro forma	(0.67)	(0.23)	0.07
Diluted, as reported	(0.62)	(0.18)	0.18
Diluted, pro forma	(0.67)	(0.23)	0.07

The fair value of each stock option granted during the year is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31		
	2000	2001	2002
Weighted-average expected life (years)	8	8	8
Expected volatility rates	100%	100.6%	91.07%
Expected dividend yield	—	—	—
Risk-free interest rate	5%	5%	4.25%
Weighted-average fair value of options granted during the year (in U.S. dollars)	4.39	1.42	2.15

1.14. Comprehensive Income

Other comprehensive income for the Company consists solely of translation adjustments and is shown separately in the consolidated statements of shareholders' equity.

1.15. New Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board issued SFAS 143, "Accounting for Asset Retirement Obligations" (SFAS 143). SFAS 143 requires the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. An entity shall measure changes in the liability for an asset retirement obligation due to passage of time by applying an interest method of allocation to the amount of the liability at the beginning of the period. That amount shall be recognized as an increase in the carrying amount of the liability and as an expense classified as an operating item in the statement of income. SFAS 143 will become effective for Flamel Technologies beginning on January 1, 2003. Flamel Technologies does not expect that adoption of SFAS 143 will have a material impact on its financial position, results of operations or cash flows.

In June 2002, the Financial Accounting Standards Board issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (SFAS 146). The Statement requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. The Statement replaces EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The Company is required to apply this Statement prospectively to exit or disposal activities initiated after December 31, 2002, with earlier application encouraged. The Company does not expect that adoption of SFAS 146 will have a material impact on its financial position, results of operations or cash flows.

On November 25, 2002, the Financial Accounting Standards Board announced the issuance of Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others", which expands on the accounting guidance of Statements No. 5, 57, and 107 and incorporates without change the provisions of FASB Interpretation No. 34, which has been superseded by this Interpretation. Given observed differences in practice, this Interpretation clarifies the requirements for a

guarantor's accounting and interim and annual financial statement disclosures of certain guarantees issued and outstanding. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. This Interpretation does not prescribe a specific approach for subsequently measuring the guarantor's recognized liability over the term of the related guarantee. The incremental disclosure requirements in this Interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. The initial recognition and initial measurement provisions of this Interpretation are applicable to guarantees issued or modified after December 31, 2002. Flamel Technologies is currently reviewing this interpretation to measure the potential impact on its results of operations and financial position.

In November 2002, the EITF reached a consensus on issue No. 00-21 *Accounting for Revenue Arrangements with Multiple Deliverables* ("EITF 00-21") on a model to be used to determine when a revenue arrangement involving the delivery or performance of multiple products, services and/or rights to use assets should be divided into separate units of accounting. Additionally, EITF 00-21 addresses if separation is appropriate, how the arrangement consideration should be allocated to the identified accounting units. EITF 00-21 will be applicable to agreements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. In addition, companies are permitted to apply EITF 00-21 to all existing arrangements as the cumulative effect of a change in accounting principle in accordance with APB Opinion No. 20, *Accounting Changes*. The Company will adopt EITF 00-21 for revenue arrangements that are initiated after January 1, 2004 and is currently assessing what the impact of EITF 00-21 will be on its financial statements.

In December 2002, the Financial Accounting Standards Board issued FASB Statement No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure* ("SFAS 148"). This Statement amends FASB Statement No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"), to provide alternative methods of transition to SFAS 123's fair value method of accounting for stock-based employee compensation. It also amends the disclosure provisions of SFAS 123 to require prominent disclosure in the summary of significant account policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual financial statements. SFAS 148's amendment of the transition and annual disclosure requirements are effective for fiscal years ending after December 15, 2002. Refer to Note 1.13 for disclosures related to stock based compensation. The Company intends to continue to account for stock-based compensation based on the provisions of APB Opinion No. 25.

2. SUBCONTRACTING AGREEMENT

In accordance with the terms of a subcontracting agreement signed with SmithKline in December 1996, the Company realized, from its pharmaceutical production facility based in Pessac (near Bordeaux, France), sales mainly of Cimetidine formulations to SmithKline for a total amount of $1,167,000 in 2000 and $322,000 in 2001. This agreement was renewed for 2002 and the sales to SmithKline totaled $121,000.

3. LICENSE, RESEARCH AND CONSULTING AGREEMENTS

Novo Nordisk

In December 1999, the Company signed a development and licensing agreement with Novo Nordisk for Flamel's Basulin™ long-acting basal insulin product. Pursuant to the terms of the agreement, Flamel received licensing fees, regular research payments, and potentially milestones and royalties on future

product sales and Novo Nordisk acquired, during the term of the agreement world wide development and marketing rights to Basulin™.

As part of the agreement, the Company received a $5,000,000 licensing fee in December 1999, which was recorded as revenue in 1999. However, effective January 1, 2000, due to the change of the method of accounting for the receipt of such fees, as described in Note 1.5, the Company recorded the cumulative effect of a change in accounting principle of ($4,577,000) in the statement of operations for the year ended December 31, 2000.

In 2000, the Company recognized research and development revenues of $2,760,000 and licensing fees of $1,565,000 in accordance with the new accounting principle.

In December 2001, Novo-Nordisk gave notice of the termination of the license agreement with Flamel, effective as of March 12, 2002. The Company has fulfilled all of its substantive obligations under this contract as of December 31, 2001 and recognized research and development revenues of $2,971,000 and $595,000 in 2001 and 2002, respectively, and licensing fees of $2,812,000 in 2001.

Corning

In December 1998, the Company signed a long-term research and product development agreement with Corning France and Corning Incorporated. This agreement is an expansion of the research agreement that had existed between Flamel and Corning from January 1994 to January 1998 for the co-development of proprietary new material to be incorporated in the manufacturing of ophthalmic and sunglasses lenses. Pursuant to the terms of this agreement, Flamel receives regular research payments and royalties on the sales of Corning products that utilize Flamel's innovations. In relation to this agreement, the Company recognized research revenue and sales of pilot batches of $858,000, $870,000 and $757,000 in 2000, 2001 and 2002, respectively.

The Company realized sales of specialty material for ophthalmic lenses of $1,447,000 in 2000, $651,000 in 2001 and $539,000 in 2002 and recognized royalties on Corning's sales of $1,055,000 in 2000, $961,000 in 2001 and $895,000 in 2002.

G.D. Searle & Co

In January 1996, the Company entered into an agreement with G.D. Searle & Co. ("Searle") giving the latter exclusive rights to market the Company's Asacard™ product in all countries of Western Europe with the exception of Belgium, the Netherlands, Luxembourg, and potentially France. An agreement was signed with Searle in September 2000 to terminate the contract. The Company recognized of revenue of $500,000 in 2000, which represented the fee received for the termination of the contract.

Ministry of Research and Technology

In June 1998, the Company was granted a non-refundable subsidy from the French Ministry of Research and Technology for a research project related to the development of an oral insulin. The Company received payments representing 50% of the total expenses incurred on this project over a three-year period. Total expenses for the project were estimated at $2,287,000. In accordance with the contract and expenses incurred, the Company recognized revenues of $248,000 in 2000 and $200,000 in 2001. This contract expired in December 2001.

Servier

In December 2001, Flamel Technologies and Laboratoires Servier, ("Servier") entered into a license and development agreement whereby the Company agreed to license its Micropump® control release technology to Servier for use with an undisclosed product of Servier. In consideration for the agreement, Servier agreed to make a $3 million initial payment and additional milestone payments upon achievement of certain events. The $3,000,000 initial payment has been recognized on a straight-line basis over the term of the license agreement (i.e. 3 years). The Company recognized licensing fees of $42,000 in 2001 and $955,000 in 2002 with respect to this initial payment. In addition, Flamel recognized two milestone payments of $1.5 million and $4 million as licensing revenue in 2002. Flamel also recognized research and development revenues of $2,339,000 in 2002.

Beecham Pharmaceuticals

In June 2002, Flamel Technologies entered into a license agreement with Beecham Pharmaceuticals (Pte) Limited, ("Beecham") whereby the Company agreed to license its controlled-release Micropump® technology to Beecham in connection with the sachet formulation of its drug Augmentin®. In consideration for the license, Beecham agreed to make an upfront payment of $1.5 million, additional milestone payments upon achievement of certain events and royalty payments on sale of the product. The $1,500,000 upfront payment has been recognized on a straight-line basis over the term of the license agreement (i.e. 3 years).). The Company recognized licensing fees of $168,000 in 2002 with respect to this upfront payment. In 2002, Flamel also recognized a $1.5 million milestone payment as licensing fees, and research and development revenues of $123,000.

Others

The Company recognized research and development revenues on seven feasibility studies with undisclosed partners for an amount of $2,968,000 in 2001 and $2,776,000 in 2002. Such revenues were not material in 2000.

4. LONG-TERM DEBT

Long-term debt comprises:

	December 31,	
(In thousands of U.S. dollars)	**2001**	**2002**
Anvar loans:		
Asacard program	604	719
Other programs	175	208
Grants from Datar and other agencies	391	693
French Ministry of Industry	—	464
Total	1,170	2,084
Current portion	391	693
Long-term portion	779	1,391

Anvar is an agency of the French government that provides financing to French companies for research and development. At December 31, 2001 and 2002, the Company had outstanding loans from Anvar of $779,000 and $927,000, respectively. These loans do not bear interest and are repayable only in the event

the research project is technically or commercially successful. In 2001, the Company renegotiated the timing for the potential repayment of those loans, which was initially scheduled between 2002 and 2005. Potential repayment is now scheduled to occur from 2005 through 2008.

The Company also recorded in 2001 an income of $219,000 related to the abandonment by Anvar of its loan on the Collagene research project due to commercial failure. This abandonment is subject to a clause of return to profitability (see Note 9.3.).

At December 31, 2001 and 2002, the Company had also recorded obligations of $391,000 and $693,000, respectively, related to conditional grants from Datar and other French public agencies. These grants are linked to investments in the development of the Pessac facility from June 1997 to June 2002, under which the Company can receive up to $1,038,000. Future grants and other subsidies are subject to the achievement before the end of June 2002 of the investment and employment objectives described in the development plan of the plant submitted to those public agencies. In the event that those objectives are not realized in the time frame specified, there is the risk of a partial or total reimbursement of the amounts received by the Company. The Company has not received any notification so far.

The payments received between 1999 and 2002 have been accounted for as advances and, accordingly have not been included in revenues.

In 2002, the Company also received a grant 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 will be granted a total amount representing 50% of the total expenses incurred on this project over a three-year period beginning on January 2, 2002. Total expenses for the project are estimated at $3,093,000. This loan will be repaid for one third in July 2008 and for two thirds in July 2011, and is not bearing interest.

Future payments on long-term debt for the years ending December 31 (assuming the underlying project is commercially or technically successful for governmental research loans, but without considering possible success-based payment on the Collagene project, and assuming no reimbursement of grants from Datar and other agencies) are as follows:

(In thousands of U.S. dollars)	December 31,
2005	168
2006	232
2007	287
2008	704
	1,391

5. SHAREHOLDERS' EQUITY

5.1. General

At December 31, 2002, the issued and outstanding share capital of the Company consists of 16,197,590 ordinary shares, nominal value €0.13 per share.

On February 29, 2000, as a result of an exercise of stock options, the Company issued 20,000 ordinary shares at a price of €2.82 ($2.74) per share.

On March 24, 2000, as a result of the exercise of warrants by shareholders, the Company issued 19,250 ordinary shares at a price of €0.13 ($0.12) per share.

On April 6, 2000, the Company issued 3,212,500 ordinary shares at €3.94 (approximately $3.79) to certain private investors, including the venture capital funds and affiliates of Biotechnology Value Fund, Alta Partners and Chase Capital Partners. In addition, the Company issued warrants at a price of €0.00 (FF0.01) per warrant to purchase up to 3,726,750 ordinary shares to these same investors (see Note 5.3). These warrants provide for physical settlement in unregistered shares and convey no other rights. Total proceeds from this issuance amounted to $12.2 million. The proceeds have been allocated to additional paid-in capital on common stock and warrants based on the respective relative fair values at the time of issuance.

On June 4, 2000, as a result of the exercise of warrants by shareholders, the Company issued 6,625 ordinary shares at a price of €0.13 ($0.12).

Shareholders have preemptive rights to subscribe for additional shares issued by the Company for cash on a *pro rata* basis.

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.

5.2. Dividends

The Company has no plans to distribute dividends in the foreseeable future.

5.3. Warrants

On April 6, 2000, the Company issued warrants at a price of €0.00 (FRF0.01) per warrant to purchase up to 3,726,500 ordinary shares to certain private investors, including the venture capital funds and affiliates of Biotechnology Value Fund, Alta Partners and Chase Capital Partners. These warrants provide for physical settlement in unregistered shares and convey no other rights. This issuance included 1,799,000 Class A warrants, 1,927,500 Class B warrants and 1,927,500 Class C warrants. These warrants have a five-year term. The Class A warrants are exercisable at €5.96 (approximately $6.00) per share, the Class B warrants are exercisable at €5.96 (approximately $6.00) per share and the Class C warrants are exercisable at €0.13 (approximately $0.12) per share. The number of Class B Warrants and Class C warrants that may be exercised has been determined in relation to the closing price of the Company's ADSs on the Nasdaq National Market in 2000. Based on the stock closing price during the year 2000, 1,285,000 Class C warrants, and 642,500 Class B warrants are exercisable at December 31, 2001 and expire in March 2005.

On June 14, 2000 the Company issued at a price of €0.00 (FRF0.01) per warrant, 120,000 warrants, giving the right to subscribe for 120,000 ordinary shares at the price of €4.88 ($4.31) per share to certain Directors of the Company. These warrants are issued for a five-year period and will vest over four years from the date of issuance. At December 31, 2002, 80,000 of those warrants remain exercisable, subject to the vesting provisions.

On July 19, 2001 the Company issued at a price of €0.00 (FRF0.01) per warrant, 70,000 warrants, giving the right to subscribe for 70,000 ordinary shares at the price of €5.95 ($5.25) per share to certain Directors of the Company. These warrants are issued for a five-year period and will vest over four years from the date of issuance. At December 31, 2002, 20,000 of those warrants remain exercisable, subject to the vesting provisions.

On June 20, 2002 the Company issued at a price of €0.01 per warrant, 80,000 warrants, giving the right to subscribe for 80,000 ordinary shares at the price of €2.33 per share to certain Directors of the Company. These warrants are issued for a five-year period and will vest over four years from the date of issuance. At December 31, 2002, 80,000 of those warrants remain exercisable, subject to the vesting provisions.

On September 19, 2002 the Company issued at a price of €0.01 per warrant, 40,000 warrants, giving the right to subscribe for 40,000 ordinary shares at the price of €1.36 per share to a Director of the Company. These warrants are issued for a five-year period and will vest over four years from the date of issuance. At December 31, 2002, 40,000 of those warrants remain exercisable, subject to the vesting provisions.

5.4. Stock options

The Company has issued stock options under plans approved by shareholders in 1990, 1993, 1996, 2000 and 2001. Generally, each option vests ratably over a four-year period from the date of grant. The difference between the exercise price and the fair value of the underlying share on the grant date has been recorded as deferred compensation expense and is being amortized over the vesting period. The amounts expensed under these plans in 2000, 2001 and 2002 were $20,000, $23,000 and $18,000, respectively.

The activity under the option plans were as follows:

	Shares Available for Grant	Options Outstanding	Weighted Average Exercise Price
Balance at January 1,2000	430,000	570,000	$4.19
Options Issued	1,000,000	—	—
Granted	(1,025,000)	1,025,000	$5.40
Exercised	—	(20,000)	$2.64
Cancelled or expired	280,000	(280,000)	$3.90
Balance at December 31, 2000	685,000	1,295,000	$5.23
Options Issued	750,000		
Granted	(960,000)	960,000	$1.64
Cancelled or expired	45,000	(245,000)	$4.53
Balance at December 31, 2001	520,000	2,010,000	$3.63
Options Issued	—	—	—
Granted	(695,000)	695,000	$2,73
Cancelled or expired	290,000	(390,000)	$3,64
Balance at December 31, 2001	115,000	2,315,000	$3.36

Stock options outstanding at December 31, 2002, which expire from 2007 to 2012, had exercise prices ranging from €1.09 to €7.58. The weighted average remaining contractual life of all options is 8 years.

The effects of applying the fair value method provided under SFAS No. 123 are shown in Note 1.13 and are not necessarily indicative of future amounts.

In January 1997, the French parliament adopted a law that requires French companies 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 five-year period following the grant of the option. The new 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 grant date if the shares are sold within five years of the option grant. The law applies to all options exercised after January 1, 1997.

The Company has not recorded a liability for social charges which may be assessed for options granted in 2001 and 2002 as the liability, which is dependent on future trading values of the Company’s shares and the timing of employees decisions to exercise options and sell the related shares, cannot be estimated. The Company also does not consider that the liability is probable due to the income tax disincentives to employees of exercising options and selling the shares in less than a five-year period.

6. INCOME TAXES

Income (loss) before income taxes is comprised of the following :

	Year ended December 31,		
(in thousands of dollars)	2000	2001	2002
France	$(9,411)	$(2,860)	$2,452

The Company was not eligible for the research and development tax credit in 2000 and 2001 due to the limited increase of research and development expenses in 2000 and 2001 as compared to 1998, 1999 and 2000, respectively. The income tax benefit in 2002 amounted to $564,000 and was principally related to the research and development tax credit recorded in France.

Research and development credits are recoverable in cash in the fourth year after the credit is earned, if the credit has not been applied against taxes payable. Income tax expense amounted to $50,000 in 2000 and represents the $16,000 minimum income tax payable in France and a $34,000 adjustment to the research and development tax credits from prior years following the conclusions of a tax audit. Income tax expense amounted to $14,000 in 2001 and represents the minimum income tax payable in France.

A reconciliation of income tax benefit computed at the French statutory rate (36.6% in 2000, 35,4% in 2001 and 34.4% in 2002) to the income tax benefit is as follows:

	Year ended December 31,		
(in thousands of dollars)	2000	2001	2002
Income tax benefit (provision) computed at the French statutory rate	3,444	1,010	(843)
Operating losses not utilized	(3,444)	(1,010)	843
Research credits	(34)	—	567
Minimum tax payable	(16)	(14)	(14)
Total	(50)	(14)	553

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

	December 31,	
(In thousands of U.S. dollars)	2001	2002
Deferred tax assets:		
Net operating loss carry-forwards	10,403	10,450
Other deferred tax assets	32	52
Deferred tax liabilities:	—	—
Net deferred tax assets	10,435	10,502
Valuation allowance	(10,435)	(10,502)
Deferred 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, 2002, the Company has $30,381,000 in French net operating loss carry-forwards of which $9,367,000 has no expiration date. The remaining carry-forwards expire as follows:

(In thousands of U.S. dollars)	December 31,
2003	7,515
2004	4,962
2005	6,645
2006	1,892
	21,014

The Company was subject to an income tax audit in 1999 covering various tax items for periods extending from 1995 through April 30, 1999. The Company came to an agreement with Fiscal Administration concerning research tax credit and recorded an adjustment of $34,000 to research tax credit receivables. The research tax credit receivable to the Company is expected to be received in accordance with the following timetable:

(In thousands of U.S. dollars)	December 31,
2003	260
2007	630
	890

7. EMPLOYEE RETIREMENT PLANS

In accordance with French law, post-retirement and post-employment 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 mostly limited to specific payroll deductions. There is no further liability in connection with these plans.

French law also requires payment of a lump sum retirement indemnity to all employees based upon years of service and compensation at retirement. Benefits do not vest prior to retirement. There is no formal plan and no funding of the obligation is required. The provision has been calculated taking into account the estimated payment at retirement (discounted to the current date), turnover and salary increases. As of December 31, 2001 and 2002, the liability for retirement indemnities amounted to $249,000 and $414,000, respectively.

In the United States, the Company sponsors a defined contribution plan. During 2000, 2001 and 2002, the Company made contributions of approximately $52,000, $11,000 and $35,000 to the plan, respectively.

8. FAIR VALUE OF FINANCIAL INSTRUMENTS

At December 31, 2001 and 2002, 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, 2001 and 2002, the fair value of long-term debt with carrying value of $779,000 and $1,391,000, was estimated to be $614,000 and $1,086,000, respectively. Fair value was determined based on expected future cash flows, discounted at market interest rates.

9. COMMITMENTS AND CONTINGENCIES

9.1. Capital leases

The Company leases certain of its equipment under capital leases. Capitalized costs of $2,356,000 and $3,064,000 are included in property and equipment at December 31, 2001 and 2002. Accumulated amortization of these leased assets was approximately $1,714,000 and $2,586,000 at December 31, 2001 and 2002, respectively.

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

(In thousands of U.S. dollars)	December 31,
2003	249
2004	150
2005	13
Total	412
Less amounts representing interest	(34)
Capital lease	378
Less current portion	(229)
Long -term portion	149

Interest paid in the years ended December 31, 2000, 2001 and 2002 was approximately $48,000, $50,000 and $46,000, respectively. Depreciation expense on assets held under capital leases is included in total depreciation expense for the years ended December 31, 2000, 2001 and 2002 and amounted to $298,000, $385,000 and $493,000, respectively.

9.2. Operating leases

The Company leases its facilities and certain equipment under operating leases which expire through 2006. Future minimum lease payments under operating leases due for the fiscal years ending December 31 are as follows:

(In thousands of U.S. dollars)	December 31,
2003	290
2004	268
2005	202
2006	26

Rental expense for the years ended December 31, 2000, 2001 and 2002 was approximately $349,000, $451,000, and $418,000, respectively.

9.3. Other commitments

The Company recorded in 2001 an income of $219,000 related to the abandonment by Anvar of its loan on the Collagene research project due to commercial failure (see Note 5). This abandonment is subject to a clause of return to profitability. Pursuant to the clause, the Company agreed to reimburse the Anvar every year an amount representing 4% of the related products sales, if any, in the limit of $219,000. The clause is effective for a 9-year period beginning as of November 2001.

9.4. Gain contingencies

In 2002, the Company recognized revenue of $2,526,000 as the final result of the litigation with the Wellcome Foundation on Genvir after the signature in January 2002 of a final settlement on that procedure. Such revenue is classified in other income in the statements of operations for the year ended December 31, 2002.

9.5. Litigations

The Company is involved in a number of claims and lawsuits considered normal in its business, including employee litigations. 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, 2002, and for the year then ended.

10. 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.

Operations outside of France consist principally of the operations of the U.S. subsidiary, which had no sales to third parties in 2000, 2001 or 2002.

Revenues generated from customers outside of France (export sales) amounted to $5,265,000, $7,733,000 and $6,358,000 in 2000, 2001 and 2002, respectively.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the Registrant 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)

By: /s/ Gérard Soula

Gérard Soula
President and Chief Executive Officer

Date: April 24, 2003

Exhibit 99.1

CERTIFICATIONS

I, Gérard Soula, certify that:

1. I have reviewed this annual report on Form 20-F of Flamel Technologies S.A.;

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date:

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 24, 2003

/s/ Gérard Soula

Gérard Soula
President and Chief Executive Officer

I, Stephen H. Willard, certify that:

1. I have reviewed this annual report on Form 20-F of Flamel Technologies S.A.;

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date:

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 24, 2003

/s/ Stephen H. Willard

Stephen H. Willard
Executive Vice President, Chief Financial Officer and
General Counsel