



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F/A

(Amendment No. 2)

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

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2003

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 a Vent  
33, avenue du Docteur Georges Levy  
69693 Venissieux 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.

21,391,590 Ordinary Shares, nominal value 0.122 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  No

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

Item 17  Item 18

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## EXPLANATORY NOTE

This Amendment No. 2 to the Annual Report on Form 20-F/A (“Amendment No. 2”) for Flamel Technologies S.A. (the “Company”) for the fiscal year ended December 31, 2003, is being filed to amend and restate the items described below contained in the Company’s Annual Report on Form 20-F originally filed with the Securities and Exchange Commission (“SEC”) on April 26, 2004, as amended by Amendment No. 1 on Form 20-F/A (“Amendment No. 1”) filed with the SEC on April 22, 2005.

This Amendment No. 2 makes changes to Item 3, Key Information, Item 5, Operating and Financial Review and Prospects, Item 18, Financial Statements and Item 19 Exhibits to reflect the accounting treatment of the Company’s investments in monetary SICAV’s (Société d’Investissement à Capital Variable). Monetary SICAVs are highly liquid investments with financial institutions and represent units of ownership in a portfolio of investments. The underlying investments of monetary SICAVs are comprised of low risk investments with a short-term fixed maturity date such as government bonds, certificates of deposit, and Euro Commercial paper. The Company historically accounted for these as cash and cash equivalents. Our investments in SICAVs are equity securities and therefore do not have specific maturity dates even though there is a high degree of liquidity. Consequently, we have determined that the SICAVs we hold should be classified as marketable securities and, thus, are subject to the Statement of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities. According to our accounting policy, such investments should be accounted for as “Available for Sale” and therefore unrealized holding gains relating to the SICAVs is excluded from earnings and reported in a separate component of shareholders’ equity, other comprehensive income, until realized.

We have therefore restated the financial results we had previously released for FY 2003. Unrealized holding gains relating to the SICAV’s is excluded from earnings and reported in a separate component of shareholders’ equity, other comprehensive income, until realized. The restated balance sheet now reflects cash and cash equivalents totaling \$1.199 million (previously reported as \$109.617 million) as well as marketable securities totaling \$108.418 million. Similarly the cash flow statement for 2003 has been updated to reflect purchases and sales of marketable securities as cash flows from investing activities.

As a result of the foregoing, the Company’s net loss related to the fiscal year 2003 is increased by \$430,000. The restated loss in 2003 totaled (\$3,924) million or (\$0.22) per share compared to (\$3.494) million or (\$0.20) per share as reported in the original Form 20-F filed on April 26, 2004

### ITEM 3. Key Information

#### Selected Financial Data

The selected consolidated financial data for each of the five years in the period ended December 31, 2003 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, an independent registered public accounting firm. 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.

<b>Statement of Operations Data: *</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003 (restated)**</b>
Revenues	\$ 11,040	\$ 10,902	\$ 13,087	\$ 18,406	\$ 25,167
Cost and Expenses	(18,040)	(16,107)	(16,242)	(18,629)	(29,866)
Loss from Operations	(7,000)	(5,205)	(3,155)	(223)	(4,699)
Interest and other expenses, net	322	375	295	149	(856)
Other income				2,525	1,128
Income (loss) before income tax and the cumulative effect of a change in accounting principle	6,678	(4,834)	(2,860)	2,452	(4,427)
Income tax benefit (charge)	(16)	(50)	(14)	553	503
Cumulative effect on prior years (to December 31,1999) of changing method of revenue recognition ***	—	(4,577)	—	—	—
Net income (loss)	\$ (6,694)	\$ (9,461)	\$ (2,874)	\$ 3,005	\$ (3,924)
Earning (loss) per share before cumulative effect of change in accounting principle	\$ (0.52)	\$ (0.32)	\$ (0.18)	\$ 0.19	\$ (0.22)
Basic earnings (loss) per ordinary share	\$ (0.52)	\$ (0.62)	\$ (0.18)	\$ 0.19	\$ (0.22)
Diluted earnings (loss) per ordinary share	\$ (0.52)	\$ (0.62)	\$ (0.18)	\$ 0.18	\$ (0.22)
Basic weighted average number of shares outstanding (in thousands)	12,939	15,331	16,198	16,198	17,762
Diluted weighted average number of shares outstanding (in thousands)	12,939	15,331	16,198	16,711	17,762
Dividends per share	—	—	—	—	—

\* (in thousands of US dollars, except per share data)

<b>Balance Sheet Data:*</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003 (as restated)</b>
Cash , Cash equivalents and Marketable securities **	\$ 5,210	\$ 10,137	\$ 5,309	\$ 14,527	\$ 109,617
Working capital****	4,257	7,948	7,338	12,202	102,867
Total assets	14,920	20,360	18,144	23,076	127,252
Long term liabilities (excluding deferred revenues)	2,358	1,891	1,299	2,329	3,123
Shareholders equity	9,067	10,882	7,509	12,286	92,061

\* (in thousands of US dollars)

\*\* The Company has historically accounted for certain investments, known as monetary SICAV's (Société d'Investissement à Capital Variable), as cash and cash equivalents. Monetary SICAVs are highly liquid investments with financial institutions and represent unit of ownership in a portfolio of investments. The underlying investments of monetary SICAVs are comprised of low risk investments with a short-term fixed maturity date such as government bonds, certificates of deposit and Euro Commercial paper. Our investments in SICAVs are equity securities and therefore do not have specific maturity dates even though there is a high degree of liquidity. Consequently, we have determined that the SICAVs we hold should be classified as marketable securities and, thus, are subject to the Statement of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities. According to our accounting policy, such investments should be accounted for as "Available for Sale" and therefore unrealized holding gains relating to the SICAVs is excluded from earnings and reported in a separate component of shareholders' equity, other comprehensive income, until realized.

The restated balance sheet now reflects cash and cash equivalents totaling \$1.199 million (previously reported as \$109.617 million) as well as marketable securities totaling \$108.418 million. Similarly the cash flow statement for 2003 has been updated to reflect purchases and sales of marketable securities as cash-flows from investing activities.

As a result of the correction of the 2003 financial statements, the Company's net loss related to the fiscal year 2003 is increased by \$430,000. The restated loss in 2003 totaled (\$3,924) million or (\$0.22) per share compared to (\$3.494) million or (\$0.20) per share as reported in the original 2003 Form 20-F (See Note 2 of the Financial Statements).

\*\*\* 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) 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.

\*\*\*\* (current assets - current liabilities)

## Exchange Rates

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

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 five years and in each of the previous six months.

Year Ended December 31, Euro to U.S. Dollar:	High	Low	Average Rate <sup>1</sup>
2003	1.246	1.036	1.132
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
<b>Previous Six Months, Euro to U.S. Dollar:</b>	<b>High</b>	<b>Low</b>	<b>Average</b>
March, 2004	1.229	1.214	1.221
February, 2004	1.285	1.243	1.264
January, 2004	1.285	1.239	1.264
December, 2003	1.260	1.196	1.230
November, 2003	1.200	1.142	1.171
October, 2003	1.183	1.160	1.171

<sup>1</sup> Annual totals represent the average of the noon buying rates for Euros 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.

The exchange rate for the Euro against the U.S. dollar as of March 31, 2004 was € 1.2292 to \$1.00. The Company makes no representation that Euro amounts have been, could have been or could be converted into dollars at any of the exchange rates referred to herein as of a given date.

## ITEM 5. Operating and Financial Review and Prospects

The following should be read in conjunction with the restated financial statements set forth in this Form 20-F/A.

### 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. The Company recently licensed Basulin® to Bristol Myers. Micropump® is a controlled-release technology for the oral administration of small molecules. Genvir, our lead product using our Micropump® technology, is a controlled-release formulation of acyclovir for the treatment of genital herpes. We have licensed Genvir™ to Biovail. 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 2003, the Company's internally funded development efforts were focused on the pre-clinical and initial clinical testing of one formulation of Basulin®, and the application of the Medusa® system to other important therapeutic proteins, including interferon alpha, interleukin-2, human growth hormone and erythropoietin (EPO). Activities related to photochromic technologies were fully funded by collaborative partners. Asacard™, a controlled release aspirin, has been approved for sale in the United Kingdom and several other European countries.

In 2003, the Company recognized revenue from receipt of royalty payments related to the sales of 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 2003, a major part of Flamel's revenues came from licensing fees and contract research payments paid by corporate partners.

Our core technologies are focused on improving delivery properties of existing products. We have established long-term development and commercialization partnerships with leading biopharmaceutical companies to maximize the breadth of our technology and leverage the capabilities of our partners.

As in previous years, in 2003, a major part of our revenue came from licensing fees and contract research payments received from our biotechnology and pharmaceutical company partners. In recent years, revenue from the sale of products and performance of services included a mix of revenue from a contract manufacturing agreement with GlaxoSmithKline 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 our manufacturing capabilities are needed to produce the proprietary products currently in development, we will seek to utilize our manufacturing capacity and to cover our related costs by building a manufacturing services business and by transferring our manufacturing chemical production capability from the Venissieux pilot plant to the Pessac site.

In the future, we expect that our costs of goods sold may increase as a result of an increase in manufacturing costs. We also expect that research and development may decrease as a percentage of revenues.

In 2003, 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 2003, 81% of revenues were denominated in U.S. dollars; in 2002, 66% of revenues were denominated in U.S. dollars; and in 2001, 41% 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, 2003 and December 31, 2002 were affected by a 19.72% average increase in the value of the Euro relative to the U.S. dollar during the year and a 20.43% 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.

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The Company has incurred substantial losses since its inception, and through December 31, 2003, had an accumulated deficit of approximately \$60.3 million. For the year ended December 31, 2003, the Company reported a net loss of \$3.9 million. 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 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**

### ***Revenue Recognition***

The Company recognizes revenue from contracts arrangements, products sales and royalties earned. Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered elements. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

Contract revenue generally includes upfront licensing fees, milestone payments and reimbursements of research and development costs. Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period. The Company recognizes milestone-related revenues only when performance of the milestone under the terms of the collaboration is achieved and there are no further performance obligations. Research and laboratory analysis services revenue is recognized as the research and development work is performed. Costs incurred under these contracts are considered costs in the period incurred. Payments received in advance of performance are recorded as deferred revenue and recognized in revenue as services are rendered.

The Company receives financial support for various research and investment projects from governmental agencies. The Company recognizes proceeds from unconditional grants related to investment projects as a reduction of the carrying amount of the assets subsidized. Revenue from conditional grants received is recognized in other income when all conditions stated in the grant have been met and the funding has been received.

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

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

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## Results of Operations

Years Ended December 31, 2003, 2002 and 2001

### Operating Revenues

The Company had total revenues of \$25.2 million in 2003, \$18.4 million in 2002, and \$13.1 million in 2001.

		2001	2002	2003
<b>License and Research Revenues</b>		<b>9.9</b>	<b>14.6</b>	<b>21</b>
<b>Research</b>		<b>7.0</b>	<b>6.5</b>	<b>13</b>
Research	Servier		2.3	1.4
	GSK other			4.4
	GSK Augmentin		0.1	
	BMS			3.8
	Corning	0.9	0.8	0.4
	MRT	0.2		
	Novo	3.0	0.6	
	undisclosed partners	2.9	2.7	3.0
<b>Licenses</b>		<b>2.9</b>	<b>8.1</b>	<b>8.0</b>
Up front payment	Servier	0.1	1.0	1.3
	GSK other			0.5
	GSK Augmentin		0.2	1.4
	BMS			1.3
	Novo	2.8		
	Undisclosed partners			0.2
Milestones	Servier		5.4	0.5
	GSK other			2.8
	GSK Augmentin		1.5	
<b>Total</b>		<b>9.9</b>	<b>14.6</b>	<b>21</b>
	Servier	0.1	8.7	3.2
	GSK other			7.7
	GSK Augmentin		1.8	1.4
	Corning	0.9	0.8	0.4
	MRT	0.2		
	BMS			5.1
	Novo	5.8	0.6	
	Undisclosed partners	2.9	2.7	3.2

In 2003, license and research payments from the Company's various partners totalled \$21 million. Similar license and research payments in 2002 and 2001 totalled \$14.6 million and \$9.9 million, respectively. In 2003, license payments totalled \$8.0 million; research and development revenue totalled \$13 million. In 2002, license payments totalled \$8.1 million and research and development revenue totalled \$6.5 million. In 2001, license payments totalled \$2.9 million and research and development revenue totalled \$7.0 million.

License revenues in 2003 consisted primarily of \$4.7 million from GlaxoSmithKline (of which \$1.9 million represents amortization of initial up-front payments), \$1.8 million from Servier (of which \$1.3 million represents up-front payment amortization) and \$1.3 million from Bristol-Myers Squibb which represents the amortized portion of the \$20 million upfront payment. License revenues in 2002 consisted primarily of \$6.4 million from Servier and \$1.7 million from GlaxoSmithKline. License revenues in 2001 included \$2.8 million from Novo Nordisk.

Research and development revenues in 2003 consisted primarily of \$3.8 million from Bristol-Myers Squibb, \$4.4 million from GlaxoSmithKline, and \$1.4 million from Servier. Research and development revenues in 2002 consisted primarily of \$2.3 million from Servier, \$0.6 million from Novo Nordisk, and \$0.1 from Beecham Pharmaceuticals. In 2001, research and development revenue consisted primarily of \$3.0 million from Novo Nordisk.

In 2003, product sales and services revenues totaled \$3.4 million and included \$115,000 from GlaxoSmithKline for the manufacture of cimetidine and Tagamet, \$396,000 from Corning for research and development and the sale of pilot batches, and \$2.8 million from clinical batches and tall manufacturing with various customers. In 2002, product sales and services revenues totaled \$2.9 million and included \$121,000 from GlaxoSmithKline 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 GlaxoSmithKline for the manufacture of cimetidine and \$1.4 million from Corning for replenishment inventories of photochromic material. Product sales and service revenues have grown over the past three years due to increased demand, primarily for clinical batches, consistent with the increased number of partnerships into which the Company has entered.

Other revenues of \$778,000 in 2003 consisted primarily of royalties from Corning related to the sale of photochromic lenses, incorporating Flamel's technology. Other revenues of \$948,000 in 2002 consisted primarily of royalties from Corning related to the sale 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. It appears to us that Corning has de-emphasized its sales of photochromic eyeglass lenses in order to focus greater attention on other areas of their business.

#### *Operating Expenses*

The Company had total costs and expenses of \$29.9 million in 2003, \$18.6 million in 2002, and \$16.2 million in 2001.

In 2003, research and development costs represent the most significant operating expenses of the Company. These totaled \$20.2 million in 2003 (or 80% of recognized revenues), \$12.2 million in 2002 (or 66% of recognized revenues) and \$10.7 million in 2001 (or 81% of recognized revenues). Research and Development costs have increased broadly in keeping with the Company's license and other revenues. Because the Company's base of operations is in France, these costs are denominated in Euros. Consequently, the increase in the value of the Euro during the last three years has contributed to higher dollar-denominated costs. Beyond that, increased interest in the Company's technology platforms have resulted in more projects being undertaken in conjunction with partners. The Company has also undertaken several projects on its own initiative.

In 2002, research and development costs increased by approximately \$1.5 million over 2001 (or 14%). To the extent that the increase was not attributable to the 5.66% increase in the average exchange rate between the US dollar and the Euro, the increase was due to a number of new partnerships obtained during the year and particularly to the active pursuit of self-funded programs, especially Basulin®.

Costs of goods and services sold were \$3.7 million in 2003, \$2.4 million in 2002, and \$2.2 million in 2001, of which services sold represented \$578,000, \$319,000, and \$378,000, respectively. These costs include the direct and indirect labor, materials, outside services, overhead costs relevant to contract 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 30% at a comparable exchange rate in 2003 compared to an increase of 10% in 2002. While gross margins for contract manufacturing and services were negative in 2003 (largely due to exchange rate fluctuations), these activities have been useful to the Company in that they enabled us to maintain our facilities and make use of idle capacity, as well as to maintain scientific expertise. As the Company ramps up the work to develop the Medusa® and Micropump® platforms, in conjunction with our partners and on its own, we intend to de-emphasize contract manufacturing and services.

Selling, general and administrative expenses increased to \$5.6 million in 2003 from \$4.0 million in 2002 and \$3.4 million in 2001. During 2003, salaries increased approximately 20%; fees increased nearly \$150,000; tax increased by over \$100,000; insurance expenses increased by over \$50,000. These increases were exacerbated as a result of changes in the Euro/dollar exchange rate, which increased by 18%. Increases in 2002 over 2001 SG&A expenses were largely attributable to salary increases (approximately 20%); and increased taxes (approximately \$100,000). Stock compensation expenses were \$355,000 in 2003, \$18,000 in 2002 and \$23,000 in 2001.

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### *Non-Operating Items*

Other income of \$1.1 million in 2003 consisted mainly of recognition of \$823,000 from conditional grants received from French public agencies. The requirements related to the grants consisted principally in maintaining certain levels of employment, which were achieved in 2003. The remaining \$0.3 million resulted from the sale of the equipment of its pilot plant of Vénissieux. 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™.

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. As of December 31, 2003, Flamel had total research tax credits receivable of \$1.35 million. If these credits are not applied against future income taxes, they will be received as cash payments in the fourth year after the credit is earned, i.e. \$0.76 million in 2006 and \$0.59 million in 2007. The Company earned a research and development credit in 2003 of \$0.5 million and of \$0.6 million in 2002 and did not have any such credit in 2001. As a result, the Company recognized a tax benefit of \$0.5 million in 2003, which resulted primarily from French research and development credits and paid the statutory minimum income tax expense of \$24,500 for 2003.

As of December 31, 2003, the Company had \$22,498,000 in French net operating loss carry-forwards. Due to a change in French tax law in 2003, we have been informed that the above carry-forwards no longer have an expiration date. See Note 15 to the Consolidated Financial Statements.

Interest income earned on the Company's cash balance was \$192,000 in 2003, \$297,000 in 2002 and \$292,000 in 2001. The changes in interest earned year-to-year are primarily the result of fluctuating average cash balances invested year-to-year and declining interest rates in 2003. Interest expense was \$29,000 in 2003 \$49,000 in 2002 and \$52,000 in 2001 and is primarily related to the interest applicable to the Company's equipment leases.

### *Net Profit/Loss*

For the year ended December 31, 2003, the Company reported a net loss of \$3.9 million, or \$(0.22) per share. The net profit reported for the year ended December 31, 2002 was \$3.0 million, or \$0.18 per share on a diluted basis, and the net loss reported for the year ended December 31, 2001 was \$2.9 million or \$(0.18) per share.

### **Liquidity and Capital Resources**

On December 31, 2003 the Company had \$1.2 million in cash and cash equivalents as compared to \$0.3 million on December 31, 2002.

Net cash provided by (used in) operating activities was \$11.4 in 2003, \$8.5 million in 2002 and \$(2.9) million in 2001. In 2003 net cash provided by operating activities reflected a net loss of \$3.9 million, a \$17.3 million increase in deferred revenues reflecting the BMS up-front payment, a \$4.0 million increase in accounts receivable due to payments of amounts invoiced in 2003 and a \$2.5 million increase in accounts payable.

Net cash used in investing activities was \$82.8 million in 2003 and was primarily spent on marketable securities operations (net difference between the proceeds and the purchase), and also at the Pessac plant to provide the capacity needed for the ongoing development of the Company's products. Net cash used in investing activities amounted to \$10.1 million in 2002 and \$1.2 million in 2001.

As of December 2003, the Company held marketable securities classified as available-for-sale and recorded at fair value. Total marketable securities amounted \$108.4 million in 2003 and \$14.3 million in 2002.

Net cash provided by financing activities was \$74.4 million in 2003, \$0.4 million in 2002, and not material for 2001. In 2003, the financing activities show an increase in cash of \$75 million resulting in large part from 2,000,000 shares sold within the public offering in October (\$62.2 million), the exercise of warrants from investors and directors (\$10.2 million) and the exercise of options from employees (\$2.1 million).

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Since its inception, 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 at least the next two years.

As in previous years, in 2003, a major part of our revenue came from licensing fees and contract research payments received from our biotechnology and pharmaceutical company partners. In recent years, revenue from the sale of products and performance of services included a mix of revenue from a contract manufacturing agreement with GlaxoSmithKline 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 our manufacturing capabilities are needed to produce the proprietary products currently in development, we will seek to utilize our manufacturing capacity and to cover our related costs by building a manufacturing services business and by transferring our manufacturing chemical production capability from the Venissieux pilot plant to the Pessac site.

In the future, we expect that our costs of goods sold may increase as a result of an increase in manufacturing costs. We also expect that research and development may decrease as a percentage of revenues.

As of December 2003, the Company had loans of \$1.1 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 9 to the Consolidated Financial Statements. Further, the Company received a loan from the French Ministry of Industry for a 'Proteozome research project' in 2002 which was valued at \$559,000 as of December 31, 2003.

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)	Payments Due Per Period				Total
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	
Long-Term Debt	\$ —	\$ 827	\$ 848	\$ —	\$ 1,675
Capital Lease Obligation	257	261	—	—	518
Operating Leases	366	298	—	—	664
Total Contractual Cash Obligations	\$ 623	\$ 1,386	\$ 848		\$ 2,857

As of December 31, 2003, the Company has no other commercial commitments. As of December 31, 2003, the Company has no off-balance sheet arrangements.

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of 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, 2002 and 2003 (as restated) and the (as restated) related consolidated statements of operations, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial 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 consolidated financial position of the Company at December 31, 2002 and 2003 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States.

As more fully described in Note 2 to the financial statements, the Company restated its 2003 financial statements.

ERNST & YOUNG Audit

/s/ JEAN-LUC DESPLAT

Represented by  
Jean-Luc Desplat

Lyon, France  
April 7, 2004  
except for Note 2, as to which the date is June 14, 2005

**FLAMEL TECHNOLOGIES S.A.**  
**CONSOLIDATED BALANCE SHEETS**  
(Amounts in thousands of dollars except share data)

	December 31,	
	2002	2003 (restated – See Note 2)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 276	\$ 1,199
Marketable securities	14,251	108,418
Accounts receivable	3,462	8,367
Inventory	375	1,057
Prepaid expenses and other current assets	347	1,694
Total current assets	<u>18,711</u>	<u>120,735</u>
Property and equipment, net	3,405	5,085
Other assets:		
Research and development tax credit receivable	890	1,348
Other long-term assets	70	84
Total other assets	<u>960</u>	<u>1,432</u>
Total assets	<u>\$ 23,076</u>	<u>\$ 127,252</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 693	\$ —
Current portion of capital lease obligations	229	257
Accounts payable	1,322	4,397
Current portion of deferred revenue	1,805	9,623
Advances from customers	361	344
Accrued expenses	2,028	3,159
Other current liabilities	71	88
Total current liabilities	<u>6,509</u>	<u>17,868</u>
Long-term debt, less current portion	1,391	1,675
Capital lease obligations, less current portion	149	261
Deferred revenue, less current portion	1,952	14,200
Other long-term liabilities	789	1,187
Total long-term liabilities	<u>4,281</u>	<u>17,323</u>
Commitments and contingencies:		
	—	—
Shareholders' equity:		
Ordinary shares: 16,197,590 issued and outstanding at December 31, 2002 and 21,391,000 at December 31, 2003	2,366	3,081
Additional paid-in capital	71,178	147,679
Accumulated deficit	(56,381)	(60,305)
Deferred compensation	(14)	(2,388)
Accumulated other comprehensive income (loss)	(4,863)	3,994
Total shareholders' equity	<u>12,286</u>	<u>92,061</u>
Total liabilities and shareholders' equity	<u>\$ 23,076</u>	<u>\$ 127,252</u>

See notes to consolidated financial statements

**FLAMEL TECHNOLOGIES S.A.**  
**CONSOLIDATED INCOME STATEMENTS**  
**(Amounts in thousands of dollars except share data)**

	Year ended December 31,		
	2001	2002	2003 (Restated – See Note 2)
<b>Revenue:</b>			
License and research revenue	\$ 9,858	\$ 14,593	\$ 20,978
Product sales and services	2,009	2,865	3,411
Other revenues	1,220	948	778
<b>Total revenue</b>	<b>13,087</b>	<b>18,406</b>	<b>25,167</b>
<b>Costs and expenses:</b>			
Cost of goods and services sold	(2,166)	(2,373)	(3,676)
Research and development	(10,662)	(12,239)	(20,223)
Selling, general and administrative	(3,414)	(4,017)	(5,967)
<b>Total</b>	<b>(16,242)</b>	<b>(18,629)</b>	<b>(29,866)</b>
<b>Loss from operations</b>	<b>(3,155)</b>	<b>(223)</b>	<b>(4,699)</b>
Interest expense	(52)	(49)	(29)
Interest income	292	297	192
Foreign exchange gain (loss)	55	(99)	(1,019)
Other income	—	2,526	1,128
<b>Income (loss) before income taxes</b>	<b>(2,860)</b>	<b>2,452</b>	<b>(4,427)</b>
Income tax benefit (expense)	(14)	553	503
<b>Net income (loss)</b>	<b>\$ (2,874)</b>	<b>\$ 3,005</b>	<b>\$ (3,924)</b>
<b>Earnings (loss) per share</b>			
Basic earnings (loss) per ordinary share	\$ (0.18)	\$ 0.19	\$ (0.22)
Diluted earnings (loss) per share	\$ (0.18)	\$ 0.18	\$ (0.22)
<b>Weighted average number of shares outstanding (in thousands):</b>			
Basic	16,198	16,198	17,762
Diluted	16,198	16,711	17,762

See notes to consolidated financial statements



FLAMEL TECHNOLOGIES S.A.

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

	Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Deferred Compen- Sation	Accumulated Other Comprehen- sive Income (Loss)	Shareholders' Equity
	Shares	Amount					
Balance at January 1, 2001	<u>16,197,590</u>	<u>\$ 2,366</u>	<u>\$ 71,177</u>	<u>\$ (56,512)</u>	<u>\$ (55)</u>	<u>\$ (6,094)</u>	<u>\$ 10,882</u>
Issuance of 70,000 warrants at €0.00 per warrant	—	—	—	—	—	—	—
Amort. 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	<u>16,197,590</u>	<u>\$ 2,366</u>	<u>\$ 71,177</u>	<u>\$ (59,386)</u>	<u>\$ (32)</u>	<u>\$ (6,616)</u>	<u>\$ 7,509</u>
Issuance of 80,000 warrants at €0.01 per warrant	—	—	1	—	—	—	1
Issuance of 40,000 warrants at €0.01 per warrant	—	—	—	—	—	—	—
Amort. deferred compensation	—	—	—	—	18	—	18
Net income	—	—	—	3,005	—	—	3,005
Other comprehensive income							
Translation adjustment	—	—	—	—	—	1,753	1,753
Comprehensive income							4,758
Balance at December 31, 2002	<u>16,197,590</u>	<u>\$ 2,366</u>	<u>\$ 71,178</u>	<u>\$ (56,381)</u>	<u>\$ (14)</u>	<u>\$ (4,863)</u>	<u>\$ 12,286</u>
Issuance of ordinary shares on exercise of stock-options	327,500	45	2,048	—	—	—	2,093
Issuance of ordinary shares on exercise of warrants	2,866,500	382	9,846	—	—	—	10,228
Issuance of ordinary shares at €26,73 (\$31,58)	2,000,000	288	62,874	—	—	—	63,162
Shares issuance costs			(996)	—	—	—	(996)
Deferred stock compensation			2,729	—	(2,729)	—	0
Amort. deferred compensation			—	—	355	—	355
Net loss	—	—	—	(3,924)	—	—	(3,924)
Unrealized gains on securities available-for-sale						479	479
Translation adjustment	—	—	—	—	—	8,378	8,378
Comprehensive income							4,933
Balance December 31, 2003 (Restated – See Note 2)	<u>21,391,590</u>	<u>\$ 3,081</u>	<u>\$ 147,679</u>	<u>\$ (60,305)</u>	<u>\$ (2,388)</u>	<u>\$ 3,994</u>	<u>\$ 92,061</u>

See notes to consolidated financial statements

**FLAMEL TECHNOLOGIES S.A.**

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

	Year ended December 31,		
	2001	2002	2003 (Restated - see note 2)
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ (2,874)	\$ 3,005	\$ (3,924)
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>			
Depreciation of property and equipment	1,270	1,460	1,712
Gain on disposal of property and equipment	—	—	(380)
Gain on sales of marketable securities	(102)	(252)	(322)
Grants recognized in other income	—	—	(823)
Stock compensation expense	23	18	355
Provision for accounts receivable	—	—	273
Increase (decrease) in cash from:			
Accounts receivable	(5,184)	5,021	(4,032)
Inventory	251	271	(569)
Prepaid expenses and other current assets	78	37	(1,143)
Deferred revenue	1,089	(845)	17,280
Accounts payable	(259)	(101)	2,511
Accrued expenses	1,179	(1,429)	468
Research and development tax credit receivable	1,568	938	(247)
Other long-term assets and liabilities	75	396	316
Net cash provided by (used in) operating activities	<u>(2,886)</u>	<u>8,519</u>	<u>11,475</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(1,178)	(1,435)	(2,841)
Proceeds from disposal of property and equipment	3	3	918
Proceeds from sales of marketable securities	6,371	12,636	24,367
Purchase of marketable securities	(6,374)	(21,275)	(105,293)
Net cash used in investing activities	<u>(1,178)</u>	<u>(10,071)</u>	<u>(82,849)</u>
<b>Cash flows from financing activities:</b>			
Repayment of loans or advances	(110)	—	(99)
Proceeds from loans or capital leases	330	860	175
Principal payments on capital lease obligations	(416)	(459)	(230)
Shares issuance costs	—	—	(898)
Cash proceeds from issuance of ordinary shares and warrants	—	1	75,482
Net cash provided by (used in) financing activities	<u>(196)</u>	<u>(402)</u>	<u>74,430</u>
Effect of exchange rate changes on cash and cash equivalents	(458)	53	(2,133)
Net increase (decrease) in cash and cash equivalents	(4,718)	(1,097)	923
Cash and cash equivalents, beginning of year	<u>6,091</u>	<u>1,373</u>	<u>276</u>
Cash and cash equivalents, end of year	<u>\$ 1,373</u>	<u>\$ 276</u>	<u>\$ 1,199</u>
<b>Supplemental disclosures of cash flow information</b>			
Non cash transactions:			
Capital lease obligations incurred	305	236	341

See notes to consolidated financial statements

## FLAMEL TECHNOLOGIES S.A.

### NOTE 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 affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of 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, except those of the U.S. subsidiary whose functional currency is the U.S. dollar, are translated into U.S. dollar equivalents at exchange rates as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity.

Transaction gains and losses are reflected in the statement of operations. The Company has not undertaken hedging transactions to cover its currency translation exposure.

##### 1.4. Revenue recognition

In December 2003, the SEC issued Staff Accounting Bulletin No. 104, *Revenue Recognition* ("SAB 104"), which updates the previously issued revenue recognition guidance in SAB 101, based on the Emerging Issues Task Force Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. EITF 00-21 is applicable to agreements entered into in fiscal periods beginning after June 15, 2003. The Company adopted EITF 00-21 on July 1, 2003. The issuance of SAB 104 and EITF 00-21 has not had any impact on the Company's results of operations, its financial position or its cash flows.

## FLAMEL TECHNOLOGIES S.A.

### NOTE TO CONSOLIDATED FINANCIAL STATEMENTS

Contract revenue generally includes upfront licensing fees, milestone payments and reimbursements of research and development costs. Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period. The Company recognizes milestone-related revenues only when performance of the milestone under the terms of the collaboration is achieved and there are no further performance obligations. Research and laboratory analysis services revenue is recognized as the research and development work is performed. Costs incurred under these contracts are considered costs in the period incurred. Payments received in advance of performance are recorded as deferred revenue and recognized in revenue as services rendered.

The Company receives financial support for various research and investment projects from governmental agencies. The Company recognizes proceeds from unconditional grants related to investment projects as a reduction of the carrying amount of the assets subsidized. Revenue from conditional grants received is recognized in other income when all conditions stated in the grant have been met and the funding has been received.

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

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

#### *1.5. Research and development costs*

Research and development (R&D) expenses comprise the following types of costs incurred in performing R&D activities: salaries, allocated overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract and other outside service fees. 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 Cr dit Commercial de France (CCF, member of HBSC), Cr dit Lyonnais and Cr dit 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, 2001 and December 31, 2002, there was no allowance for doubtful accounts recorded. In 2003, a total amount of \$304,000 has been recorded for doubtful accounts.

#### *1.7. Earnings 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

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

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 effect 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.

*1.8. Cash and cash equivalents*

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

*1.9 Marketable securities*

Marketable securities consist of highly liquid investments in money market mutual funds. As of December 2003, Flamel Technologies's marketable securities are classified as available-for-sale securities in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities" (SFAS 115). These investments are recorded at fair value, which is based on quoted market prices. Accordingly, unrealized gains and losses are included in accumulated other comprehensive income until realized.

*1.10. Accounts Receivable*

Accounts receivable are stated at cost net of allowances for doubtful accounts. The Company makes judgments as to its ability to collect outstanding receivables and provide allowances for the portion of receivables when collection becomes doubtful. Provision is made based upon a specific review of all significant outstanding invoices.

*1.11. Inventories*

Inventories consist principally of raw materials and finished products, which are stated at the lower of cost (first-in, first-out) or market.

*1.12. Property and equipment*

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

Land and buildings	20 years
Laboratory equipment	4 - 5 years
Office and computer equipment	3 years
Furniture and fixture	5-10 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.

*1.13. Impairment of Long-Lived Assets*

Property and equipment and other long-lived assets to be held and used are reviewed for impairment whenever events or circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. If undiscounted

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

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. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

*1.14. 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.

*1.15. Employee stock options and warrants*

The company accounts for stock options granted to employees and warrants granted to non-employee board members 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 or the warrants granted 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.

(In thousands of U.S. dollars except share data)	Year Ended December 31		
	2001	2002	2003
Net income (loss), as reported	(2,874)	3,005	(3,924)
Add: Stock-based employee compensation expense included in reported net income (loss), net of related tax effects	23	18	355
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,021)	(1,748)	(3,277)
Pro forma net income (loss)	(3,872)	1,275	(6,846)
<b>Earnings per share:</b>			
Basic, as reported	(0.18)	0.19	(0.22)
Basic, pro forma	(0.24)	0.08	(0.39)
Diluted, as reported	(0.18)	0.18	(0.22)
Diluted, pro forma	(0.24)	0.08	(0.39)

The fair value of each stock option and warrant 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		
	2001	2002	2003
Weighted-average expected life (years)	7.7	7.4	4.9
Expected volatility rates	100.6%	91.07%	115.08%
Expected dividend yield	—	—	—
Risk-free interest rate	5%	4.25%	3.50%

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

The weighted-average fair value and the weighted average exercise price of options and warrants granted during 2001, 2002 and 2003 were as follows:

(In U.S. dollars)	Year Ended December 31					
	2001		2002		2003	
	Weighted avg. Fair value <sup>2</sup>	Weighted avg. Exer. Price <sup>1</sup>	Weighted avg. Fair value <sup>1</sup>	Weighted avg. Exer. Price <sup>1</sup>	Weighted avg. Fair value <sup>1</sup>	Weighted avg. Exer. Price <sup>1</sup>
Options or warrants whose price equaled market price of the underlying shares on the date of grant	1.58	1.88	2.03	2.49	13.89	16.78
Options or warrants whose price was less than the market price of the underlying shares on the date of grant	—	—	—	—	21.21	11.29

*1.16. Comprehensive Income*

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

*1.17. New Accounting Pronouncements*

In January 2003, the FASB issued FASB Interpretation ("FIN") No. 46, *Consolidation of Variable Interest Entities*. FIN No. 46 sets forth the criteria used in determining whether an investment in a variable interest entity ("VIE") should be consolidated and is based on the general premise that a company that controls another entity through interests other than voting interests should consolidate the controlled entity. In December 2003, the FASB published a revision to FIN No. 46 ("FIN46R") to clarify some of the provisions of the interpretation and defer the effective date of implementation for certain entities. Under the guidance of FIN46R, entities that do not have interests in structures that are commonly referred to as special purpose entities are required to apply the provisions of the interpretation in financial statements for periods ending after March 14, 2004. The Company does not have an interest in any structure that would be considered a special-purpose entity. Adoption of this interpretation is not expected to have a material impact on the Company's results of operations or financial position.

**2. RESTATEMENT OF FINANCIAL STATEMENTS**

The Company has historically accounted for certain investments, known as monetary SICAVs (Société d'Investissement à Capital Variable), as cash and cash equivalents. Monetary SICAVs are highly liquid investments with financial institutions and represent units of ownership in a portfolio of investments. The underlying investments of monetary SICAVs are comprised of low risk investments with a short-term fixed maturity date such as government bonds, certificates of deposit and Euro Commercial paper. Our investments in SICAVs are equity securities and therefore do not have specific maturity dates even though there is a high degree of liquidity. Consequently, we have determined that the SICAVs we hold should be classified as marketable securities and, thus, are subject to the Statement of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities. According to our accounting policy, such investments

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<sup>2</sup> Historical exchange rate

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

should be accounted for as “Available for Sale” and therefore unrealized holding gains relating to the SICAVs is excluded from earnings and reported in a separate component of shareholders’ equity, other comprehensive income, until realized.

The restated balance sheet now reflects cash and cash equivalents totaling \$1.199 million (previously reported as \$109.617 million) as well as marketable securities totaling \$108.418 million. Similarly the cash flow statement for 2003 has been updated to reflect purchases and sales of marketable securities as cash-flows from investing activities.

As a result of the correction, the Company’s net loss related to the fiscal year 2003 is increased by \$430,000. The restated loss in 2003 totaled (\$3,924) million or (\$0.22) per share compared to (\$3.494) million or (\$0.20) per share as reported in the original 2003 Form 20-F.

	<b>Fiscal Year Ended December 31,</b>		
	<b>2003 (as previously reported)</b>	<b>Adjustments</b>	<b>2003 (as restated)</b>
<b>Consolidated balance Sheet</b>			
Current assets:			
Cash and cash equivalents	\$ 109,617	(\$108,418)	\$ 1,199
Marketable securities	—	108,418	108,418
Shareholder’s equity			
Accumulated deficit	(59,875)	(430)	(60,305)
Accumulated other comprehensive income (loss)	3,564	430	3,994
<b>Consolidated Statement of Operations</b>			
Interest income	622	(430)	192
Loss before income taxes	(3,997)	(430)	(4,427)
Net loss	(3,494)	(430)	(3,924)
Basic loss per share	(\$0.20)	(\$0.02)	(\$0.22)
<b>Consolidated Statement of Cash Flow</b>			
Cash provided by operating activities	12,227	(752)	11,475
Cash used in investing activities	(1,923)	(80,926)	(82,849)
Cash provided by financing activities	74,430	—	74,430
Cash and cash equivalents end of the year	109,617	(108,418)	1,199

**3. SUBCONTRACTING AGREEMENT**

In accordance with the terms of a subcontracting agreement signed with SmithKline in December 1996, the Company recognized product sales consisting mainly of Cimetidine formulations for a total amount of \$322,000 in 2001 and \$121,000 in 2002. This agreement was renewed for 2003 and the sales to SmithKline totaled \$115,000.

**4. LICENSE, RESEARCH AND CONSULTING AGREEMENTS**

Bristol-Myers Squibb

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



## FLAMEL TECHNOLOGIES S.A.

### NOTE TO CONSOLIDATED FINANCIAL STATEMENTS

In consideration for the agreement, BMS made a \$20 million initial payment and agreed to make additional milestone payments upon achievement of certain events. The \$20,000,000 initial payment is being recognized on a straight-line basis over the term of the development period of three years. The Company recognized licensing fees of \$1,315,000 in 2003 with respect to this initial payment. In addition, Flamel also recognized research and development revenues of \$3,811,000 in 2003 under this agreement.

#### SB Pharma Puerto Rico Inc.

In March 2003, Flamel Technologies and SB Pharma Puerto Rico Inc (“SB Pharma”) entered into a license agreement whereby the Company agreed to license its controlled-release Micropump® in order to develop a new formulation for an undisclosed existing product. In accordance with this license agreement, the Company recognized research and development revenues of \$4,379,000 and licensing fees of \$3,311,000. These licensing fees include two milestones payments of \$967,000 and \$1,822,000. The remaining \$522,000 relates to the \$2,000,000 upfront payment received in March 2003, which is being recognized as revenue on a straight-line basis over the term of the development period.

#### Biovail

In February 2003, Flamel Technologies entered into a license agreement with Biovail whereby the Company agreed to license to Biovail the exclusive North America rights to Flamel’s oral solid controlled release formulation of acyclovir.

In consideration for this license, the Company received \$500,000, which is being recognized on a straight-line basis over the development period. The Company recognized \$104,000 under this arrangement during the year ended December 31, 2003.

#### 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 was being recognized on a straight-line basis over the term of anticipated development of the product (i.e. 3 years). The Company recognized licensing fees of \$168,000 in 2002 with respect to this upfront payment and recognized a \$1.5 million milestone payment as a milestone was achieved and research and development revenues of \$123,000 related to the performance of agreed upon research and development.

In September 2003, Beecham gave notice of the termination of the license agreement with Flamel. As the Company had fulfilled all of its substantive obligations under this contract as of December 31, 2003, the remaining amount of the up-front payment of \$1,418,000 was recognized as licensing fees in 2003.

#### 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

## FLAMEL TECHNOLOGIES S.A.

### NOTE TO CONSOLIDATED FINANCIAL STATEMENTS

payment has been recognized on a straight-line basis over the term of anticipated development of the product (i.e. 3 years). The Company recognized licensing fees of \$42,000 in 2001, \$955,000 in 2002 and \$1,283,000 in 2003 with respect to this initial payment. In addition, Flamel recognized one milestone payment of \$484,000 as licensing revenue in 2003. Flamel also recognized research and development revenues of \$1,381,000 in 2003.

#### 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 is eligible to receive milestone payments and royalties on future product sales. Novo Nordisk acquired, during the term of the agreement, world wide development and marketing rights to Basulin™.

In December 2001, Novo Nordisk gave notice of the termination of the license agreement with Flamel. As the Company has fulfilled all of its substantive obligations under this contract as of December 31, 2001, it accelerated the recognition of the remainder of the upfront license fee. The Company 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. The Company did not recognize any revenues from Novo Nordisk in 2003.

#### Corning

In December 1998, the Company signed a long-term research and product development agreement with Corning France and Corning Incorporated. Pursuant to the terms of this agreement, Flamel receives regular research payments and royalties on the sales of Corning products that utilize Flamel's innovations. The Company recognized research revenue and sales of pilot batches of \$870,000, \$757,000 and \$396,000 in 2001, 2002 and 2003, respectively.

The Company recognized sales of specialty material for ophthalmic lenses of \$651,000 in 2001, \$539,000 in 2002 and \$0 in 2003 and recognized royalties on Corning's sales of \$961,000 in 2001, \$895,000 in 2002 and \$719,000 in 2003.

#### Ministry of Research and Technology

In June 1998, the Company entered into an agreement with 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. In accordance with the contract, the Company recognized revenues \$378,000 in 2001, which represented the final installment due under the arrangement. This contract expired in December 2001. No revenue was recorded in 2002 and 2003. The \$198,000 remaining balance of the grant receivable was paid in 2003. The contract is closed.

#### Others

The Company recognized research and development revenues on several feasibility studies with undisclosed partners for an amount of \$2,968,000 in 2001, \$2,776,000 in 2002 and \$2,970,000 in 2003.

### 5. OTHER INCOME

Other income of \$1.1 million in 2003 consisted mainly of recognition of \$823,000 from conditional grants received from French public agencies. The requirements related to the grants consisted principally in maintaining certain levels of employment, which were achieved in 2003.

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

The remaining \$0.3 million resulted from the sale of the equipment of its pilot plant in Vénissieux.

In 2002, the Company recognized revenue of \$2,526,000 related to the settlement of litigation with the Wellcome Foundation concerning Genvir®. This settlement is classified as other income in the statements of operations for the year ended December 31, 2002.

**6. CASH AND CASH EQUIVALENTS**

Cash consist of cash on deposit held in several major banks and cash on hand.

Cash and cash equivalents, includes:

<b>(In thousands of U.S. dollars)</b>	<b>December,</b>	
	<b>2002</b>	<b>2003</b>
Cash on deposit	\$ 276	\$ 1,199
Total cash and cash equivalents	\$ 276	\$ 1,199

**7. MARKETABLE SECURITIES**

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

<b>(In thousands of U.S. dollars)</b>	<b>December,</b>	
	<b>2002</b>	<b>2003</b>
Marketable securities	\$ 14,251	\$ 108,418
Total Marketable securities	\$ 14,251	\$ 108,418

Gross realized gains on sales of these available-for-sale securities amounted to \$278,000, \$252,000 and \$322,000 for the years ended December 31, 2001, 2002 and 2003, respectively. Unrealized gains amounted to \$479,000 for the year ended December 31, 2003. Unrealized gains were not material for the years ended December 31, 2001 and 2002.

**8. INVENTORY**

The components of inventories were as follows:

<b>(In thousands of U.S. dollars)</b>	<b>December 31,</b>	
	<b>2002</b>	<b>2003</b>
Raw materials	375	828
Finished goods	—	229
Inventories, net	375	1,057

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

**9. PROPERTY AND EQUIPMENT**

The components of property and equipment were as follows:

(In thousands of U.S. dollars)	December 31,	
	2002	2003
Land and buildings	93	113
Laboratory equipment	11,257	14,038
Office and computer equipment	970	1,148
Furniture and fixtures	2,537	3,451
Total property and equipment	14,857	18,750
Less accumulated depreciation and amortization	(11,452)	(13,665)
Property and equipment, net	3,405	5,085

Depreciation expense related to property and equipment amounted to \$1,270,000, \$1,460,000 and \$1,712,000 for the years ended December 31, 2001, 2002 and 2003, respectively.

Capitalized costs of \$3,064,000 and \$4,037,000 are included in property and equipment at December 31, 2002 and 2003. Accumulated amortization of these leased assets was approximately \$2,586,000 and \$3,547,000 at December 31, 2002 and 2003, respectively. Depreciation expense on assets held under capital leases is included in total depreciation expense for the years ended December 31, 2001, 2002 and 2003 and amounted to \$385,000, \$493,000 and \$386,000, respectively.

**10. ACCRUED EXPENSES**

Accrued expenses comprise the following:

(In thousands of U.S. dollars)	December 31,	
	2002	2003
Accrued compensation	816	1,812
Accrued social charges	1,055	1,220
Other	157	127
Total accrued expenses	2,028	3,159

**11. LONG-TERM DEBT**

Long-term debt comprises:

(In thousands of U.S. dollars)	December 31,	
	2002	2003
Anvar loans:		
Asacard program	719	866
Other programs	208	250
Grants from Datar and other agencies	693	—
French Ministry of Industry	464	559
Total	2,084	1,675
Current portion	693	—
Long-term portion	1,391	1,675

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

Anvar is an agency of the French government that provides financing to French companies for research and development. At December 31, 2002 and 2003, the Company had outstanding loans from Anvar of \$927,000 and \$1,116,000, 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.

In 2001, the Company recognized \$219,000 in other income related to the forgiveness by Anvar of its loan on the Collagene research project due to the commercial failure of the project.

Grants from Datar and other French public agencies are linked to investments in the development of the Pessac facility from June 1997 to June 2002, under which the Company received \$693,000. In 2003, the Company received an additional grant of \$195,000 following the achievement of the investment and employment objectives described in the development plan of the plant submitted to those public agencies. As a result of the achievement of the grants' objectives in 2003, revenue of \$823,000 has been recognized in other income in 2003. One grant of \$110,000 was repaid to Datar as there was only partial achievement of the objectives.

In 2002, the Company received a loan of \$464,000 from the French Ministry of Industry on a research project (the "Proteozome" project) related to the development of new Medusa applications. Pursuant to the agreement, the Company 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. One third of this loan is due for repayment in July 2008 with the remainder due on July 2011. The loan is non-interest bearing. No additional amount was received in 2003. The difference between the 2002 and 2003 balance is due to fluctuation in foreign exchange rates.

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 other agencies) are as follows:

(In thousands of U.S. dollars)	<b>December 31,</b>
2005	202
2006	279
2007	346
2008	848
	1,675

**12. CAPITAL LEASE OBLIGATIONS**

The Company leases certain of its equipment under capital leases. Future payments on capital lease for the years ending December 31 are as follows:

(In thousands of U.S. dollars)	<b>December 31,</b>
2004	272
2005	114
2006	90
2007	73
Total	549
Less amounts representing interest	(32)
Capital lease	517
Less current portion	(257)
Long-term portion	261

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

Interest paid in the years ended December 31, 2001, 2002 and 2003 was approximately \$50,000, \$46,000 and \$27,000, respectively.

**13. EARNINGS PER SHARE**

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

	Year ended December 31,		
	2001	2002	2003
(In thousands, except per share amounts)			
<b>Numerator:</b>			
Net income (loss)	\$ (2,874)	\$ 3,005	\$ (3,924)
<b>Denominator:</b>			
Weighted average shares outstanding used for basic earnings (loss) per share	16,197,590	16,197,590	17,762,050
<b>Effect of dilutive securities:</b>			
Stock-options and warrants	—	513,410	—
Weighted average shares outstanding and dilutive securities used for diluted earnings (loss) per share	<u>16,197,590</u>	<u>16,711,000</u>	<u>17,762,050</u>
Basic earnings (loss) per share	<u>\$ (0,18)</u>	<u>\$ 0,19</u>	<u>\$ (0,22)</u>
Diluted earnings (loss) per share	<u>\$ (0,18)</u>	<u>\$ 0,18</u>	<u>\$ (0,22)</u>

For the years ended December 31, 2001 and 2003, the effects of dilutive securities were excluded from the calculation of earnings per share as a net loss was reported in those periods.

**14. SHAREHOLDERS' EQUITY**

*14.1. General*

At December 31, 2003 and 2002, the issued and outstanding share capital of the Company consisted of 21,391,590 and 16,197,590 ordinary shares, respectively, with a nominal value of €0.122 per share.

Over the first nine months of 2003, as a result of exercises of stock options, the Company issued 227,500 ordinary shares, with a nominal value of €0.122 (\$0.138) per share.

Over the same period, as a result of exercises of warrants by Directors, the Company issued 90,000 ordinary shares, with a nominal value of €0,122 (\$0.138) per share. In September 2003, as a result of the exercise of 1,099,000 Class A, 392,500 Class B and 1,285,000 Class C warrants, the Company issued 2,776,500 ordinary shares, with a nominal value of €0,122 (\$0.133) per share.

On October 2, 2003, as a result of the public offering described in the Registration Statement filed with the SEC, the Company issued 2,000,000 ordinary shares, at a price of € 26.7319 (\$ 31.58) per share.

## FLAMEL TECHNOLOGIES S.A.

### NOTE TO CONSOLIDATED FINANCIAL STATEMENTS

On October 23, 2003, as a result of exercises of stock options, the Company issued 32,500 ordinary shares, with a nominal value of €0.122 (\$0.138) per share.

On November 6, 2003, as a result of exercises of stock options, the Company issued 67,500 ordinary shares, with a nominal value of €0.122 (\$0.138) per share.

#### 14.2. Preemptive subscription rights

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.

#### 14.3. Dividends

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception. The accumulated deficit for statutory purposes totaled approximately \$38.1 million at December 31, 2003. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

#### 14.4. 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 642,500 Class B warrants and 1,285,000 Class C warrants. These warrants have a five-year term. The Class A and Class B warrants are exercisable at €5.96 per share and the Class C warrants are exercisable at €0.122 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.

In September 2003, the Company issued 1,285,000 shares as a result of the exercise of Class C warrants by Biotechnology Value Fund (500,000), Alta Partners (750,000) and Chase Capital Partners (35,000).

On September 3, 2003, the Company issued 1,425,000 shares as a result of the exercise by Alta Partners of 1,050,000 Class A warrants and 375,000 of Class B warrants.

On September 12, 2003, the Company issued 66,500 shares as a result of the exercise by Chase Capital Partners of 49,000 Class A warrants and 17,500 of Class B warrants.

At December 31, 2003, 700,000 Class A and 250,000 Class B warrants remained exercisable, subject to the vesting provisions.

On June 14, 2000 the Company issued, at a price of €0.00 per warrant, 120,000 warrants to certain Directors of the Company giving them the right to subscribe to 120,000 ordinary shares at the price of €4.88 per share. These warrants are issued for a five-year period and vest ratably over four years from the date of issuance. During 2003, 60,000 warrants were exercised and 10,000 warrants were cancelled due to the departure of certain Directors. As of December 31, 2003, 10,000 warrants remained exercisable, subject to the vesting provisions.

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

On July 19, 2001, the Company issued, at a price of €0.00 (FRF0.01) per warrant, 70,000 warrants to certain Directors of the Company giving them the right to subscribe to 70,000 ordinary shares at the price of €5.95 per share. These warrants are issued for a five-year period and will vest ratably over four years from the date of issuance. During 2003, 10,000 warrants were exercised and 5,000 were cancelled. As of December 31, 2003, 5,000 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 to certain Directors of the Company giving them the right to subscribe to 80,000 ordinary shares at the price of €2.33 per share. These warrants were issued for a five-year period and will vest ratably over four years from the date of issuance. During 2003, 20,000 warrants were exercised and 30,000 warrants were cancelled. As of December 31, 2003, 30,000 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 to a Director of the Company giving him the right to subscribe to 40,000 ordinary shares at the price of €1.36 per share. These warrants are issued for a five-year period and will vest ratably over four years from the date of issuance. During 2003, the 40,000 warrants were cancelled.

On November 7, 2003, the Company issued, at a price of €0.01 per warrant, 200,000 warrants to certain Directors of the Company giving them the right to subscribe to 200,000 ordinary shares at the price of € 9.88 (\$11.29) per share. Out of these 200,000 warrants, 120,000 are issued for a five-year period and will vest ratably over four years from the date of issuance, whereas the remaining 80,000 warrants will vest with the next General Shareholders meeting on June, 22 2004. At December 31, 2003, the 200,000 warrants remain exercisable, subject to the vesting provisions. The Company accounted for these warrants granted to non-employee directors for their services as directors under APB 25. Under APB 25, when the exercise price of the Company's warrants is less than the market price of the underlying shares at the date of grant, the Company records deferred compensation expense, which is being amortized on a straight-line basis over the vesting period. The deferred compensation related to these warrants amounted to \$2,729,000 at the date of grant. In 2003, the Company recorded compensation expense related to these 200,000 warrants of \$346,000.

The summary of warrants activity is as follows:

	<b>Warrants Outstanding</b>	<b>Weighted Average Exercise Price in U.S. dollars<sup>3</sup></b>
Balance at January 1, 2001	3,846,500	\$ 3.81
Warrants granted	70,000	\$ 5.17
Warrants cancelled	90,000	\$ 4.95
Balance at December 31, 2001	3,826,500	\$ 3.81
Warrants granted	120,000	\$ 1.94
Balance at December 31, 2002	3,946,500	\$ 3.75
Warrants granted	200,000	\$ 11.29
Warrants exercised	2,866,500	\$ 3.16
Warrants cancelled	85,000	\$ 2.28
Balance at December 31, 2003	1,195,000	\$ 6.55

<sup>3</sup> Historical exchange rate



FLAMEL TECHNOLOGIES S.A.

NOTE TO CONSOLIDATED FINANCIAL STATEMENTS

Exercise prices for warrants outstanding as of December 31, 2003 were as follows:

Range of exercise prices in euros	Warrants Outstanding			Warrants Exercisable	
	Number of shares	Weighted average remaining contractual life	Weighted average exercise price in euros	Number of shares	Weighted average exercise price in euros
0 to 2.33	30 000	3.47	2.33	0.00	—
2.33 to 5.96	965 000	1.27	5.95	0.00	—
5.96 to 9.88	200 000	4.86	9.88	0.00	—
	<u>1195 000</u>	<u>1.93</u>	<u>6.52</u>	<u>0.00</u>	<u>—</u>

14.5. Stock options

The Company has issued stock options under plans approved by shareholders in 1990, 1993, 1996, 2000, 2001 and 2003. Generally, each option vests four years from the date of grant. In accordance with APB 25, 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 on a straight-line basis over the vesting period. The amounts expensed under these plans in 2001, 2002 and 2003 were \$23,000, \$18,000 and \$9,000, respectively.

The activity under the option plans were as follows:

	Shares Available for Grant	Options Outstanding	Weighted Average Exercise Price <sup>4</sup>
Balance at January 1, 2001			
Options Authorized	685,000	1,295,000	\$ 5.23
Granted	750,000		
Cancelled or expired	(960,000)	960,000	\$ 1.64
Balance at December 31, 2001	45,000	(245,000)	\$ 4.53
Options authorized	520,000	2,010,000	\$ 3.63
Granted	—	—	—
Cancelled or expired	(695,000)	695,000	\$ 2.73
Balance at December 31, 2002	290,000	(390,000)	\$ 3.64
Options authorized	115,000	2,315,000	\$ 3.36
Granted	1,900,000		
Exercised	(1,350,000)	1,350,000	\$ 16.66
Cancelled or expired		(327,500)	\$ 5.33
Balance at December 31, 2003	107,500	(117,500)	\$ 4.09
	<u>772,500</u>	<u>3,220,000</u>	<u>\$ 8.65</u>

Stock options outstanding at December 31, 2003, which expire from 2007 to 2013, had exercise prices ranging from €1.09 to € 20.81. The weighted average remaining contractual life of all options is 8 years. At December 31, 2003, there were 3,220,000 outstanding options at a weighted average exercise price of €7.68, of which 1,301,250 were exercisable at a weighted average price of € 3.79.

<sup>4</sup> Historical exchange rate

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

Exercise prices for options outstanding as of December 31, 2003 were as follows:

<i>Range of exercise prices in euros</i>	<b>Stock Options Outstanding</b>			<b>Stock Options Exercisable</b>	
	<b>Number of shares</b>	<b>Weighted average remaining contractual life</b>	<b>Weighted average exercise price in euros</b>	<b>Number of shares</b>	<b>Weighted average exercise price in euros</b>
0 to 1.36	640,000	7.9	1.13	285,000	1.11
2.33 to 2.77	520,000	8.1	2.43	460,000	2.39
4.11 to 4.86	890,000	8.1	4.47	246,250	4.77
6.40	260,000	6.9	6.4	195,000	6.40
7.58 to 9.88	155,000	8.4	8.99	115,000	9.48
20.81	755,000	9.9	20.81	—	—
	<u>3,220,000</u>	<u>8.4</u>	<u>7.68</u>	<u>1,301,250</u>	<u>3.79</u>

In March 2002, 400,000 options were granted to certain executives, the vesting of which could accelerate upon the achievement of certain targets in 2002. If these targets are not attained, the options would continue to vest over four years in accordance with the terms of the 2001 plan agreement. No deferred compensation expense has been recognized under APB 25 as the exercise price equals the stock price at the date of grant. The targets were achieved during 2002.

In March 2003, 400,000 options were granted to certain executives, the vesting of which would accelerate upon the achievement of certain targets in 2003. If these targets were not attained, the options would continue to vest over four years in accordance with the terms of the 2003 plan agreement. No deferred compensation expense has been recognized under APB 25 as the exercise price equals the stock price at the date of grant. The achievement of the targets was recognized during 2003.

The effects of applying the fair value method provided under SFAS No. 123 are shown in Note 1.12 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, 2002, and 2003 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. The Company has instituted a new rule that options may not be exercised if social charges could be made against the Company. As a result, we do not expect any liability for such social charges.

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

**15. INCOME TAXES**

Income (loss) before income taxes comprises the following:

(in thousands of dollars) France	Year ended December 31,		
	2001	2002	2003
	\$ (2,860)	\$ 2,452	\$ (4,427)

A reconciliation of income tax benefit computed at the French statutory rate (35.4% in 2001, 34.4% in 2002 and 34.4% in 2003) to the income tax benefit is as follows:

(in thousands of dollars)	Year ended December 31,		
	2001	2002	2003
Income tax benefit (provision) computed at the French statutory rate	1,010	(843)	1,524
Operating losses not utilized	(1,010)	843	(1,524)
Research credits	—	567	527
Minimum tax payable	(14)	(14)	(24)
Total	(14)	553	503

The Company was not eligible for research and development tax credit in 2001 due to the limited increase in research and development expenses in 2001 as compared to 1998, 1999 and 2000, respectively. Income tax benefits amounted to \$553,000 in 2002 and \$503,000 in 2003 and was principally related to the research and development tax credit recorded in France.

Income tax expense amounted to \$14,000 in 2001 and represented the minimum income tax payable in France. In 2002, the minimum income tax payable in France was equal to \$14,173. Minimum income tax payable in France amounted to \$24,500 in 2003.

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

(In thousands of U.S. dollars)	December 31,	
	2002	2003
Deferred tax assets:		
Net operating loss carry-forwards	10,450	7,739
Other deferred tax assets	1,502	8,624
Deferred tax liabilities	35	—
Net deferred tax assets	11,917	16,363
Valuation allowance	(11,917)	(16,363)
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, 2003, the Company had \$22,498,000 in French net operating losses carry-forwards. Due to a change in French tax law in 2003, we have been informed that the above carry-forwards no longer have an expiration date. The reduction in available net operating losses carry-forwards in 2003 is attributable to the use of \$9,051 and \$5,042 of net operating losses carry-forwards respectively related to 1998 and 1999.

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. As of December 31, 2003, Flamel had total research tax credits receivable of \$1,348,000. If these credits are not applied against future income

FLAMEL TECHNOLOGIES S.A.

NOTE TO CONSOLIDATED FINANCIAL STATEMENTS

taxes, they will be received as cash payments in the fourth year after the credit is earned in accordance with the following timetable:

<b>(In thousands of U.S. dollars)</b>	<b>December 31,</b>
2006	758
2007	590
	<u>1,348</u>

**16. 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, 2002 and 2003, the liability for retirement indemnities amounted to \$414,000 and \$457,000, respectively.

In the United States, the Company sponsors a retirement plan. The company made contributions of approximately \$11,000 in 2001, \$35,000 in 2002 and \$23,000 in 2003.

**17. FAIR VALUE OF FINANCIAL INSTRUMENTS**

At December 31, 2002 and 2003, 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, 2002 and 2003, the fair value of long-term debt with carrying value of \$1,391,000 and \$1,675,000, was estimated to be \$1,086,000 and \$1,179,000, respectively. Fair value was determined based on expected future cash flows, discounted at market interest rates.

**18. COMMITMENTS AND CONTINGENCIES**

*18.1. Capital leases*

The Company currently has commitments regarding capital leases as described in Note 12.

*18.2. 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:

<b>(In thousands of U.S. dollars)</b>	<b>December 31,</b>
2004	366
2005	201
2006	98

**FLAMEL TECHNOLOGIES S.A.**

**NOTE TO CONSOLIDATED FINANCIAL STATEMENTS**

Rental expense for the years ended December 31, 2001, 2002 and 2003 was approximately \$451,000, \$418,000, and \$587,000, respectively.

*18.3. Litigation*

The Company is involved in a number of claims and lawsuits considered normal in its business, including employee litigation. While it is not possible to predict the outcome of legal actions brought against the Company, the Company believes that the liability resulting from the pending claims and suits would not have a material adverse effect on the results of its operations, cash flows, or financial position as of December 31, 2003, and for the year then ended.

**19. 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 2001, 2002 or 2003.

Revenues generated from customers outside of France (export sales) amounted to \$7,733,000, \$6,358,000 and \$18,926,000 in 2001, 2002 and 2003, respectively.

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

	<u>As of December 30,</u>	
	<u>2002</u>	<u>2003</u>
	<u>(in thousands)</u>	
Long-lived assets:		
North America	\$ 35	\$ 39
France	4,330	6,478
Total long-lived assets	<u>\$ 4,365</u>	<u>\$ 6,517</u>

## SIGNATURES

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

FLAMEL TECHNOLOGIES S.A.  
(Registrant)

By: /s/ Gerard Soula  
Gérard Soula  
President and Chief Executive Officer

Date: June 15, 2005

**ITEM 19. Exhibits**

**Exhibit 12.1. Certification Pursuant to Sec Rule 13a-14(a)/15d-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Gerard Soula, President and Chief Executive Officer of Flamel Technologies S.A. (the “**Company**”), certify that:

1. I have reviewed this amended annual report on Form 20-F/A of the Company;
2. Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

Date: June 15, 2005

/s/ Gerard Soula

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Gerard Soula  
President and  
Chief Executive Officer

**Exhibit 12.2. Certification Pursuant to Sec Rule 13a-14(a)/15d-14(a) as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Stephen H. Willard, Executive Vice President and Chief Financial Officer of Flamel Technologies S.A. (the “**Company**”), certify that:

1. I have reviewed this amended annual report on Form 20-F/A of the Company;
2. Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

Date: June 15, 2005

/s/ Stephen H. Willard

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Stephen H. Willard  
Executive Vice President and  
Chief Financial Officer



**Exhibit 13.1. Certification Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Amended Annual Report of Flamel Technologies S.A. (the “**Company**”) on Form 20-F/A for the fiscal year ended December 31, 2003, filed with the Securities and Exchange Commission on the date hereof (the “**Report**”), I, Gerard Soula, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Gerard Soula

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President and  
Chief Executive Officer  
June 15, 2005

**Exhibit 13.2. Certification Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Amended Annual Report of Flamel Technologies S.A. (the “**Company**”) on Form 20-F/A for the fiscal year ended December 31, 2003, filed with the Securities and Exchange Commission on the date hereof (the “**Report**”), I, Stephen H. Willard, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen H. Willard

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Executive Vice President and  
Chief Financial Officer  
June 15, 2005

[Ernst & Young Letterhead]

**CONSENT OF INDEPENDENT AUDITORS**

We consent to the incorporation in the Registration Statements on Form 20-F/A (000-28508), pertaining to the consolidated financial statements of Flamel Technologies S.A. for the year ended December 31, 2003, filed with the Securities and Exchange Commission, of our report dated June 14, 2005.

Lyon, France  
June 14, 2005

Ernst & Young Audit

/s/ JEAN-LUC DESPLAT

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Jean-Luc Desplat