



# FORM 6-K

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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**Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

For the month of May 2004

Commission File Number: 000-28508

**Flamel Technologies S.A.**  
(Translation of registrant's name into English)

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

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

Form 20-F

Form 40-F

Indicate by check mark whether registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes

No

Indicate by check mark whether registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes

No

Indicate by check mark whether by furnishing the information contained in this Form the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): Not applicable

This report of Foreign Issuer shall be incorporated by reference into the registration statement on Form S-8 filed with the Securities and Exchange Commission on January 6, 2004 (SEC No. 333-111725) and October 14, 2003 (SEC File No. 333-109693).

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**FLAMEL TECHNOLOGIES S.A.**  
**CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

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**FLAMEL TECHNOLOGIES S.A.**

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**FLAMEL TECHNOLOGIES S.A.**

**Item 1.**

**Financial Statements (Unaudited)**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(unaudited)**  
**(Amounts in thousands of dollars, except per share data )**

	Three months ended	
	2003	2004
Revenue :		
License and research revenue	\$ 1,962	\$ 13,301
Product sales and services	1,037	949
Other revenues	158	103
Total revenue	3,157	14,353
Costs and expenses :		
Cost of goods and services sold	(1,094)	(837)
Research and development	(3,843)	(7,872)
Selling, general and administrative	(1,009)	(1,287)
Stock compensation expense	(4)	(57)
Total costs and expenses	(5,950)	(10,569)
Gain (loss) from operations	(2,793)	3,784
Interest income, net	80	492
Foreign exchange gain (loss)	(83)	(13)
Other income	1,123	57
Income,(loss) before income taxes	(1,673)	4,320
Income tax benefit (expenses)	—	(23)
Net income, (loss)	\$ (1,673)	\$ 4,297
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	\$ (0.10)	\$ 0.20
Diluted earnings (loss) per share	\$ (0.10)	\$ 0.18
Weighted average number of shares outstanding (in thousands):		
Basic	16,198	21,404
Diluted	16,198	23,999

See notes to Unaudited Condensed Consolidated Financial Statements.

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

ASSETS	December 31, 2003	March 31, 2004
<b>Current assets:</b>		
Cash and cash equivalents	\$109,617	\$105,435
Accounts receivable	8,367	7,754
Inventory	1,057	991
Prepaid expenses and other current assets	1,694	3,668
Total current assets	<u>120,735</u>	<u>117,848</u>
Property and equipment, net	5,085	8,331
<b>Other assets:</b>		
Research and development tax credit receivable	1,348	1,304
Other long-term assets	84	107
Total other assets	<u>1,432</u>	<u>1,411</u>
Total assets	<u>\$127,252</u>	<u>\$127,590</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Current portion of long-term debt	\$ —	\$ —
Current portion of capital lease obligations	257	354
Accounts payable	4,397	7,020
Current portion of deferred revenue	9,623	8,970
Advances from customers	344	312
Accrued expenses	3,159	2,444
Other current liabilities	88	276
Total current liabilities	<u>17,868</u>	<u>19,376</u>
Long-term debt, less current portion	1,675	1,622
Capital lease obligations, less current portion	261	116
Deferred revenue, less current portion	14,200	11,755
Other long-term liabilities	1,187	715
Total long-term liabilities	<u>17,323</u>	<u>14,208</u>
Commitments and contingencies:	—	—
<b>Shareholders' equity:</b>		
Ordinary shares: 21,391,590 issued and outstanding at December 31, 2003 and 21,416,590 at March 31, 2004	3,081	3,085
Additional paid-in capital	147,679	147,828
Accumulated deficit	(59,875)	(55,578)
Deferred compensation	(2,388)	(1,859)
Accumulated other comprehensive income (loss)	3,564	530
Total shareholders' equity	<u>92,061</u>	<u>94,006</u>
Total liabilities and shareholders' equity	<u>\$127,252</u>	<u>\$127,590</u>

Note : The balance sheet at December 31, 2003 has been derived from the audited financial statements at that date. See notes to Unaudited Condensed Consolidated Financial Statements.

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(unaudited)

(Amounts in thousands of dollars, except per share data)

	Three months ended	
	March 31,	
	2003	2004
Cash flows from operating activities:		
Net income (loss)	\$ (1,673)	\$ 4,297
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	459	602
Gain on disposal of property and equipment	(362)	—
Grants recognized in other income	(747)	—
Stock compensation expense	4	573
Provision for accounts receivable	—	—
Increase (decrease) in cash from:		
Accounts receivable	92	352
Inventory	(138)	33
Prepaid expenses and other current assets	(497)	(368)
Deferred revenue	1,510	(2,386)
Accounts payable	798	2,828
Accrued expenses	(465)	(557)
Research and development tax credit receivable	(20)	—
Other long-term assets and liabilities	134	(2,234)
Net cash provided by (used in) operating activities	<u>(905)</u>	<u>3,140</u>
Cash flows from investing activities:		
Purchases of property and equipment	(319)	(4,036)
Proceeds from disposal of property and equipment	362	—
Net cash used in investing activities	<u>43</u>	<u>(4,036)</u>
Cash flows from financing activities:		
Repayment of loans or advances	—	—
Proceeds from loans or capital leases	131	149
Principal payments on capital lease obligations	(56)	(24)
Shares issuance costs	—	—
Cash proceeds from issuance of ordinary shares and warrants	—	153
Net cash provided by (used in) financing activities	<u>75</u>	<u>278</u>
Effect of exchange rate changes on cash and cash equivalents.	579	(3,564)
Net increase (decrease) in cash and cash equivalents	(208)	(4,182)
Cash and cash equivalents, beginning of period	<u>14,527</u>	<u>109,617</u>
Cash and cash equivalents, end of period	<u>\$14,319</u>	<u>\$105,435</u>

See notes to Unaudited Condensed Consolidated Financial Statements.

FLAMEL TECHNOLOGIES S.A.

CONDENSED CONSOLIDATED SHAREHOLDERS' EQUITY  
(unaudited)  
(Amounts in thousands of dollars, except per share data)

	Ordinary Shares Share	Amount	Additional Paid-in Capital	Accumulated Deficit	Deferred Compensation	Accumulated Other comprehensive Income	Shareholders Equity
Balance January 1, 2004	21,391,590	\$3,081	\$147,679	\$(59,875)	\$(2,388)	\$ 3,564	\$92,061
Issuance of ordinary shares at €4,75 (\$6,10)	25,000	4	149				153
Amortization of deferred compensation	—	—	—	—	529	—	529
Net income	—	—	—	4,297	—	—	4,297
Other comprehensive income							
Translation adjustment	—	—	—	—	—	(3,034)	(3,034)
Comprehensive income							
Balance March 31, 2004	21,416,590	\$3,085	\$147,828	\$(55,578)	\$(1,859)	\$ 530	\$94,006

## FLAMEL TECHNOLOGIES S.A.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

In the opinion of management, the accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial statements. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States (US GAAP) for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring accruals) considered necessary for a fair presentation have been included.

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

Operating results for the three months ended March 31, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. These condensed consolidated financial statements should be read in conjunction with the Company's audited annual financial statements.

#### 2. REVENUES

##### *2.1 License research and consulting agreements.*

In accordance with a research agreement signed on August 27, 2003 with Bristol-Myers Squibb, the Company recognized revenues of \$10.0 million, including a milestone payment of \$5.1 million and amortization of the up-front payment received in October, 2003 in the amount of \$1.8 million.

The Company recognized license and research revenues of approximately \$3.3 million from multiple partners, including Biovail, Glaxo SmithKline, Merck, Servier, and others which are undisclosed.

##### *2.2 Other revenues.*

In accordance with the long-term research and product development agreement signed with Corning in December 1998, the Company recognized revenue of approximately \$0.2 million corresponding to the royalties for the three month period ended March 31, 2004.

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### 3. INVENTORY

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

<b>(In thousands of U.S. dollars)</b>	<b>March 2004</b>
Raw materials	825
Finished goods	166
Inventories, net	991

### 4. SHAREHOLDERS' EQUITY

Over the three first months of 2004, as a result of exercises of stock options, the Company issued 25,000 ordinary shares, nominal value €0.122 (\$0.138) per share.

### 5. EMPLOYEE STOCK-OPTION PLANS

In March, 2004, 151,000 options were granted to new employees and senior employees with a four year vesting period.

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## FLAMEL TECHNOLOGIES S.A.

### **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

This report on Form 6-K contains forward-looking statements. We may make additional written or oral forward-looking statements from time to time in filings with the SEC or otherwise. The words 'believe,' 'expect,' 'anticipate,' 'project' and similar expressions identify forward-looking statements, which speak only as of the date the statement is made. Such forward-looking statements are within the meaning of that term in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our development and manufacturing activities and our results of operations will not differ materially from our expectations. Factors that could cause actual results to differ from expectations include, among others:

- our product candidates, if approved for marketing, may not produce significant revenues and we rely on our partners to determine the regulatory and marketing strategies;
  - our product candidates, in commercial use, may have unintended side effects, adverse reactions or incidents of misuse;
  - we may enter into a collaboration with a third party to market or fund a proprietary product candidate and the terms of such a collaboration may not meet our expectations;
  - our delivery technologies or product development efforts may not produce safe, effective or commercially viable products;
  - our collaborators could elect to terminate or delay programs at any time and disputes with collaborators or failure to negotiate acceptable new collaborative arrangements for our technologies could occur;
  - we may be unable to manufacture or, if our products are successful, scale-up the manufacturing of our products economically or on a commercial scale;
  - unexpected events could interrupt manufacturing operations at our facilities, which could be the sole source of supply for these products;
  - after the completion of clinical trials of products incorporating our technologies and the submission to the FDA of a New Drug Application, or NDA, for marketing approval and to other health authorities as a marketing authorization application, the FDA or other health authorities could refuse to accept such filings or could request additional pre-clinical or clinical studies be conducted, each of which could result in significant delays, or such authorities could refuse to approve the product at all;
  - our product candidates could be ineffective or unsafe during pre-clinical studies and clinical trials and we and our collaborators may not be permitted by regulatory authorities to undertake new or additional clinical trials for product candidates incorporating our technologies, or clinical trials could be delayed;
  - we may experience significant delays in clinical trials on our products;
  - we may not realize any revenue from milestone or royalty payments under our license agreements with our partners, including Bristol-Myers;
  - even if our product candidates appear promising at an early stage of development, product candidates could fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance, be precluded from commercialization by proprietary rights of third parties or experience substantial competition in the marketplace;
  - technological changes in the biotechnology or pharmaceutical industries could render our product candidates obsolete or noncompetitive;
  - we may face difficulties or set-backs in obtaining and enforcing our patents or defending claims of patent infringement by others; and
  - we may need to raise substantial additional funding to continue research and development programs and clinical trials and could incur difficulties or setbacks in raising such funds.
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Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by or underlying the forward-looking statements. Statements in this report on Form 6-K and in our annual report on Form 20-F for the fiscal year ended December 31, 2003 including those set forth in 'Risk Factors' in that report, describe factors, among others, that could contribute to or cause such differences.

#### Results of Operations

For the first quarter, Flamel reported total revenues of \$14.4 million, compared to \$3.1 million in the first quarter of 2003.

License and research revenues totaled \$13.3 million, which included a \$5 million milestone payment from Bristol-Myers Squibb (BMS), as well as amortization of the \$20 million up-front payment the Company received from BMS in October, 2003 and a further \$3.0 million in research and development work performed during the quarter. License and research revenues during the quarter also included approximately \$1.5 million from Glaxo SmithKline, \$0.5 million from Biovail as well as revenues from multiple other partners. License and research revenues in the first quarter of 2003 totaled \$2.0 million and consisted primarily of revenues received from Glaxo SmithKline, Servier, and various undisclosed partners.

Revenues from product sales and services during the quarter declined to \$0.9 million, compared to \$1.0 million in the first quarter of 2003, reflecting diminished services to Corning and the planned transition away from contract manufacturing activities. Other revenues declined from \$0.2 million in the year-ago period to \$0.1 million.

Costs and expenses of Flamel's research and development increased to \$7.9 million, from \$3.8 million in the year-ago quarter. This increase was largely as a result of increased clinical and preclinical study work, related to projects developed internally and also with our partners, as well as the increase of 16% in the value of the Euro against the U.S. dollar versus the year-ago period. Cost of goods and services sold decreased to \$0.8 million, compared to \$1.1 million a year ago, largely in conjunction with decreasing revenues in this category. SG&A increased to \$1.3 million from \$1.0 million, mainly due to increase of the Euro against the U.S. dollar.

As a result of fluctuations in the amount of quarterly revenues, which may arise from the signing of research collaborations, license agreements or other extraordinary transactions, interim results are not necessarily indicative of the operating results for the full year.

#### Liquidity and Capital Resources

Cash on hand at the end of the first quarter was \$105.4 million, versus \$14.3 million at the end of the first quarter a year ago.

Net decreases in cash and cash equivalents amounted to a decline of \$4.2 million for the first three months of 2004, primarily due to increased purchase of equipment and materials used in our research and development activities, as well as to the decline in value of the US dollar.

#### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

None

#### **Item 4. Purchases of Equity Securities By the Issuer and Affiliated Purchasers**

None

#### **Item 5. Exhibits**

Not Applicable

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### **Flamel Technologies S.A.**

Dated: May 28, 2004

By: /s/ Stephen Willard \_\_\_\_\_

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