



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

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**FORM 6-K**

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

For the month of April 2003

**Flamel Technologies**

(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 by furnishing the information contained in this Form 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): 82-

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**FLAMEL TECHNOLOGIES S.A.**

**CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**  
**(Amounts in thousands of dollars except share data)**

**STATEMENTS OF OPERATIONS**

	Three months ended March 31,	
	2002	2003
Revenue :		
License and research revenue	\$ 2,366	\$ 1,962
Product sales and services	220	1,037
Other revenue	267	534
	2,853	3,533
Costs and expenses :		
Cost of goods and services sold	(300)	(1,094)
Research and development	(2,954)	(3,843)
Selling, general and administrative	(931)	(1,009)
Stock compensation expense	(5)	(4)
	(4,190)	(5,950)
Loss from operations	(1,337)	(2,417)
Other income	2,342	747
Interest income, net	17	80
Foreign exchange gain (loss)	5	(83)
	1,027	(1,673)
Income tax benefit	—	—
	\$ 1,027	\$ (1,673)
Net profit, (loss)	\$ 1,027	\$ (1,673)
Basic profit, (loss) per ordinary share	\$ 0.07	\$ (0.10)
Diluted profit, (loss) per ordinary share	\$ 0.07	\$ (0.10)
Weighted average number of ordinary shares outstanding	16,198	16,198

See notes to unaudited condensed consolidated financial statements

**FLAMEL TECHNOLOGIES S.A.**

**CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**  
**(Amounts in thousands of dollars except share data)**

**BALANCE SHEETS**

**ASSETS**

	December 31, 2002 (Note)	March 31, 2003 (Unaudited)
<b>Current assets :</b>		
Cash and cash equivalents	\$ 14,527	\$ 14,319
Accounts receivable	3,462	3,503
Inventory	375	531
Prepaid expenses and other current assets	347	865
Total current assets	18,711	19,218
Property and equipment, net	3,405	3,342
<b>Other assets :</b>		
Research and development tax credit receivable	890	945
Other long-term assets	70	75
Total other assets	960	1,020
Total assets	\$ 23,076	\$ 23,580
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities :</b>		
Current portion of long-term debt	\$ 693	\$ 95
Current portion of capital lease obligations	229	195
Accounts payable	1,322	2,184
Current portion of deferred revenue	1,805	2,532
Accrued expenses	2,028	1,644
Advances from customers	361	271
Other current liabilities	71	240
Total current liabilities	6,509	7,161
Long-term debt, less current portion	1,391	1,445
Other long-term liabilities	789	884
Deferred revenue, less current portion	1,952	2,905
Capital lease obligation, less current portion	149	116
Total long-term liabilities	4,281	5,350
<b>Shareholders' equity :</b>		
Ordinary shares	2,366	2,366
Additional paid-in capital	71,178	71,178
Accumulated deficit	(56,381)	(58,054)
Deferred compensation	(14)	(10)
Cumulative other comprehensive income	(4,863)	(4,411)
Total shareholders' equity	12,286	11,069
Total liabilities and shareholders' equity	\$ 23,076	\$ 23,580

Note : The balance sheet at December 31, 2002 has been derived from the audited financial statements at that date.

See notes to unaudited condensed consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
(Amounts in thousands of dollars except share data)

CASH FLOWS

	Three months ended March 31,	
	2002	2003
Cash flows from operating activities :		
Net profit, (loss)	\$ 1,027	\$ (1,673)
Adjustments to reconcile net loss to net cash provided by operating activities :		
Depreciation and amortization	310	459
Stock compensation expense	5	4
(Gain) loss on disposal of property and equipment	—	(362)
(Gain) loss on recognition of grants	—	(747)
Increase (decrease) in cash from :		
Accounts receivable	3,533	92
Inventory	(114)	(138)
Prepaid expenses and other current assets	(61)	(497)
Deferred revenue	(1,083)	1,510
Accounts payable	14	798
Accrued expenses	(1,375)	(465)
Research and development tax credit receivable	1,383	(20)
Other	480	134
Net cash from, (used by) operating activities	4,119	(905)
Cash flows from investing activities :		
Purchases of property and equipment	(89)	(319)
Disposal of property and equipment	—	362
Net cash from (used for) investing activities	(89)	43
Cash flows from financing activities :		
Proceeds of loans	—	131
Principal payments on capital lease obligations	(104)	(56)
Net cash provided, (used by) financing activities	(104)	75
Effect of exchange rate changes on cash and cash equivalents	(539)	579
Net increase (decrease) in cash and cash equivalents	3,387	(208)
Cash and cash equivalents, beginning of period	5,309	14,527
Cash and cash equivalents, end of period	\$ 8,696	\$14,319

See notes to unaudited condensed consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
(Amounts in thousands of dollars except share data)

SHAREHOLDERS' EQUITY

	Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Deferred Compensation	Cumulative Translation Adjustment	Shareholders' Equity
	Shares	Amount					
Balance January 1, 2003	16,197,590	\$2,366	\$71,178	\$(56,381)	\$ (14)	\$(4,863)	\$12,286
Amortization of deferred compensation	—	—	—	—	4	—	5
Net loss	—	—	—	(1,673)	—	—	(1,673)
Other comprehensive income							
Translation adjustment	—	—	—	—	—	452	452
Comprehensive income							(1,221)
Balance March 31, 2003	16,197,590	\$2,366	\$71,178	\$(58,054)	\$ (10)	\$(4,411)	\$11,069

See notes to unaudited condensed consolidated financial statements

**FLAMEL TECHNOLOGIES S.A.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**1. ACCOUNTING POLICIES**

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

The reporting currency of the Company is the U.S. dollar. The financial statements of the Company, whose functional currency is the Euro, have been translated into U.S. dollar equivalents using the period-end rate for asset and liability accounts, the weighted average rate for income and expense accounts, and historical rates for shareholders' equity accounts. Corresponding translation gains or losses are recorded in shareholders' equity.

Operating results for the three months ended March 31, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. These condensed consolidated financial statements should be read in conjunction with the Company's audited annual financial statements.

**1. REVENUES**

**1.1 LICENSE RESEARCH AND CONSULTING AGREEMENTS**

In accordance with the long-term research and product development agreement signed with Corning in December 1998, the Company received research and development payment of \$93,000 for the first three months of 2003.

In accordance with the license agreement signed with Servier in December 2001, the Company recognized research and development revenues of \$441,000 and licensing fees of \$303,000 for the first three months of 2003. In accordance with the license agreement signed with Beecham Pharmaceuticals (Pte) Limited in June 2002, the Company recognized licensing fees of \$136,000 for the first three months of 2003.

In accordance with the license agreement signed with SB Pharma Puerto Rico Inc. in March 2003, the Company recognized research and development revenues of \$731,000 and licensing fees of \$8,000 for the first three months of 2003.

The Company received research and development payments on three feasibility studies with undisclosed partners for an amount of \$275,000 for the first three months of 2003.



**FLAMEL TECHNOLOGIES S.A.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**1.2 OTHER REVENUES**

In accordance with the long-term research and product development agreement signed with Corning in December 1998, the Company recognized revenue of \$137,000 corresponding to the royalties for the three months period ended March 31, 2003.

The Company recognized in February 2003 a revenue of \$362,000 from the sale of the equipments of its pilot plant of Vénissieux.

**2. OTHER INCOME**

The Company recognized in March 2003 a revenue of \$747,000 from grants of French public agencies linked to investments in the development of the Pessac facility, following to the achievement of the conditions of those grants.

## Item. 2

### Management's Discussion and Analysis of Financial Condition and Results of Operations

#### Results of Operations

Revenues for the quarter ended March 31, 2003 increased to \$3.5 million, compared to \$2.9 million for the first quarter of 2002.

License and research revenue for the quarter ended March 31, 2003 of \$2.0 million included \$0.9 million revenue from GlaxoSmithKline, \$0.7 million from Servier, \$0.3 million from feasibility studies with other partners and \$0.1 million from the on going research collaboration with Corning. License and research revenue for the first quarter of 2002 largely consisted of revenues from Novo-Nordisk, Corning, and various undisclosed partners.

Other revenues for the quarter ended March 31, 2002 consisted of royalties from Corning and the sale of equipment from the Company's pilot plant in Venissieux. Other income included \$0.7 million in French government grants. Other revenue in the first quarter of 2002 included \$2.3 million received in settlement of litigation with the Wellcome Foundation regarding Flamel's long acting acyclovir product Genvir. Revenues from product sales and services were \$1.0 million in the quarter ended March 31, 2003, compared to \$0.2 million in the first quarter of 2002, largely as a result of increased toll manufacturing.

Total operating costs for the quarter ended March 31, 2003 amounted to \$6.0 million, up from \$4.2 million in the comparable quarter in 2002, largely as a result of the increased value of the Euro to the dollar. Research and Development costs for the first quarter of 2003 increased to \$3.8 million from \$3.0 million in the first quarter 2002, largely as a result of the exchange rate. Sales, General and Administrative costs increased slightly to \$1.0 million from \$0.0 million in the first quarter of 2002.

Overall, the Company had a loss of \$1.7 million for the quarter, compared to a gain of \$1.0 million in the comparable quarter in 2002.

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**

On March 31, 2003, the Company had \$14.3 million in cash, compared to \$8.7 million in cash at the end of the first quarter 2002.

Net cash from operating activities amounted to a decline of \$0.2 million for the first three months of 2003 which is due primarily to the loss for the period, offset by increases in deferred revenue from the recent licensing agreement with GlaxoSmithKline.

Cash used for capital investments was \$0.3 million for the first three months of 2003, an increase from \$0.1 million for the comparable period in 2002.

**INFORMATION FILED WITH THIS REPORT**

Document Index

- 99.1 Press release dated April 9, 2003 (“Biovail Acquires Rights to Controlled Release Acyclovir (Genvir) from Flamel Technologies”).
- 99.2 Press release dated April 30, 2003 (“Flamel Technologies Announces First Quarter Results, Showing Maintained Level of Cash and loss per share of (\$0.10)”).

## 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.

Dated: May 9, 2003

Flamel Technologies

By: /s/ Stephen H. Willard

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

FLAMEL TECHNOLOGIES

CONTACT: Biovail Corporation  
Ken Howling  
Vice President Finance  
(905) 286-3000

Flamel Technologies  
Steve Willard  
Chief Financial Officer  
(202) 862-3993

FOR IMMEDIATE RELEASE:

**BIOVAIL ACQUIRES RIGHTS TO CONTROLLED RELEASE ACYCLOVIR (GENVIR)  
FROM FLAMEL TECHNOLOGIES**

\* Phase III clinical trials set to begin in the U.S. in the second half of 2003 \*

TORONTO, Canada, and LYON, France, April 9, 2003 — Biovail Corporation (NYSE, TSX: BVF) and Flamel Technologies S.A. (NASDAQ: FLML) announced today that they have entered into an agreement whereby Flamel has licensed to Biovail the exclusive North American rights to Flamel's oral solid controlled release formulation of acyclovir for the treatment of episodic and recurrent genital herpes infections. Biovail intends to manufacture this novel form of the well-known and highly prescribed herpes treatment utilizing Flamel's proprietary controlled release "Micropump Technology".

Through this multi-million dollar agreement, Biovail acquires the exclusive North American rights to develop, register, promote, market and manufacture the oral solid controlled release form of acyclovir. The agreement includes an upfront payment as well as documented milestone payments and a royalty on sales of the product when commercialized. Under the agreement, Biovail is responsible for all development, clinical and regulatory costs associated with the filing and approval of the product in the U.S. and Canada. Biovail is also responsible for all expenses associated with the marketing, sales, advertising and promotion of the product in the North American market.

Biovail anticipates the start of Phase III clinical trials in the second half of 2003. Plans include two Phase III trials in two separate genital herpes indications. The first pivotal trial will focus on the use of this controlled release version of acyclovir in the treatment of recurrent episodes of genital herpes infections while the second study will focus on the suppression of genital herpes infections.

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“The market for genital herpes medication in North America is large and growing,” commented Eugene Melnyk, Chairman and Chief Executive Officer of Biovail Corporation. “Oral acyclovir has been a trusted, safe and effective therapy for the treatment of herpes infections since its introduction as Zovirax in 1985. Currently marketed acyclovir products have arduous daily multi-dosing requirements for the treatment of recurrent episodes of genital herpes. Flamel’s oral controlled release formulation presents an opportunity to offer a more convenient twice daily (BID) dosing for acute therapy, as well as offering the first acyclovir once daily dosing for suppressive therapy. The acquisition of this product allows us to expand our anti-viral franchise by offering this novel formulation of acyclovir to complement the topical Zovirax herpes treatments we already have on the market.”

Gerard Soula, president and chief executive officer of Flamel said: “We are very excited to extend development of Genvir™, our controlled release formulation of acyclovir using our Micropump® technology, to North America. We believe Biovail is an excellent partner for this product, in light of their existing presence in the market for herpes products and their substantial sales force. This agreement is another example of the progress we are achieving in bringing our Micropump technology to market.”

#### Market size

The North American market for oral antiviral herpes treatment achieved sales of \$723 million in 2002, representing an annual growth rate of 14.6% over the previous year. Over the same period, 11 million prescriptions were written for this class of products, with oral acyclovir accounting for 4.4 million or 40% of the total prescriptions.

#### About Genital Herpes

Genital herpes is a sexually transmitted disease (STD) caused by the herpes simplex viruses type 1 (HSV-1) and type 2 (HSV-2). HSV type 2 is the more common cause of genital herpes and it can produce sores or lesions in and around the genital area and on the buttocks and thighs. HSV remains dormant in the dorsal root ganglion nerve tissue, making genital herpes a recurrent, life-long chronic viral infection. Episodes of genital herpes lesions can recur a number of times per year in a patient, as the virus becomes reactivated under certain conditions. It is estimated that approximately 50 million Americans, or 20% of the total adolescent and adult population, is infected with the HSV-2 virus. In the United States, an estimated 1 million new cases of genital herpes occur each year.

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Biovail Corporation is an international full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture, sale and promotion of pharmaceutical products utilizing advanced drug delivery technologies.

Flamel Technologies, S.A. is a biopharmaceutical company principally engaged in the development of two unique polymer-based delivery technologies for medical applications. Flamel's Micropump® technology is a controlled release and taste-masking technology for the oral administration of small molecule drugs. Flamel's Medusa® nano-particulate technology is designed to deliver therapeutic proteins. Flamel's expertise in polymer science has also been instrumental in the development of a photochromic eyeglass lens product now marketed by Corning Inc.

For further information at Biovail, please contact Ken Howling at 905-286-3000 or send inquiries to [ir@biovail.com](mailto:ir@biovail.com). For further information at Flamel, please contact Steve Willard at 202-862-3993 or send inquiries to [Willard@flamel.com](mailto:Willard@flamel.com).

*“Safe Harbor” statement under the Private Securities Litigation Reform Act of 1995.*

*To the extent any statements made in this release contain information that is not historical, these statements are essentially forward looking and are subject to risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials, the regulatory environment, fluctuations in operating results and other risks detailed from time to time in each company's filings with the Securities and Exchange Commission.*



For Immediate Release

Contact:	G�rard Soula, C.E.O	Stephen H. Willard, Chief Financial Officer
	Fr�d�rick Simonin, Marketing Assistant	Tel: (202) 862-3993
Tel.:	(33) 4-72-78-34-34	Fax: (202) 862-3933
Fax:	(33) 4-72-78-34-35	E-Mail: Willard@flamel.com
E-Mail:	Soula@flamel.com	
	Simonin@flamel.com	

**Flamel Technologies Announces First Quarter Results,  
Showing Maintained Level of Cash and loss per share of (\$0.10)**

**LYON, France—April 30, 2003**—Flamel Technologies (Nasdaq:FLML) today announced its financial results for the first quarter of 2003.

For the first quarter, Flamel reported operating revenues of \$3.5 million, compared to \$2.9 million in the first quarter of 2002. Expenses increased to \$6.0 million, from \$4.2 million in the first quarter of 2002. Operating net loss in the first quarter of 2003 was \$2.4 million, compared to a loss of \$1.3 million in the first quarter of last year. Other income was \$0.7 million in the first quarter of 2003, compared to \$2.3 million in the first quarter of 2002, which resulted from a settlement of litigation in Flamel's favor in early 2002. Net loss for the first quarter of 2003 was \$1.7 million (\$0.10 per share), compared to a net profit per share in the first quarter of 2002 of \$1.0 million (\$0.07 per share). Cash on hand at the end of the quarter was \$14.2 million, compared to \$8.7 million a year ago.

Flamel's first quarter revenues included license and research revenues of \$2.0 million, compared to \$2.4 million in the same quarter of last year. Product sales and services increased to \$1.0 million, compared to \$0.2 million for the year-ago period, reflecting production of clinical batches for our clinical partners. Royalties to Flamel on sales of Corning's Sunsensor® products increased slightly (\$0.1 million) compared to the first quarter of last year. Others revenues recorded in first quarter included a \$0.4 million revenue due to the sale of equipment of the pilot plant of V nissieux.

Costs and expenses of Flamel's research and development increased to \$3.8 million, from \$3.0 million in the first quarter of 2002, largely as a result of increases in the rate of exchange between the Euro and the U.S. dollar (unfavorable 22% increase due to the conversion rate) and increased costs of product sales and services. SG&A increased slightly to \$1.0 million from \$0.9 million, reflecting the same unfavorable exchange rates impact.

"Our financial results this quarter show that we are continuing to be able to maintain our cash position, in part due to our newest license agreement with GlaxoSmithKline," commented Gerard Soula, president and chief executive officer of Flamel. "Our loss per share reflects the fact that our major transactional payment this quarter is amortized over three years and is not directly taken into income. While we received a payment in settlement of litigation in the first quarter of 2002, resulting in a net profit, I believe that payments in respect of new licensing deals, like the one received this past quarter from GlaxoSmithKline, represent a stream of future opportunities and income for Flamel which are far more significant than settlement of past litigation. We expect to return to a pattern of breakeven or positive net income with the second quarter of 2003 and are working actively to add a number of new deals to those we have announced thus far this year."

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Flamel Technologies, S.A. is a biopharmaceutical company principally engaged in the development of two unique polymer-based delivery technologies for medical applications. Micropump® is a controlled release and taste-masking technology for the oral administration of small molecule drugs. Flamel's Medusa® technology is designed to deliver controlled-release formulations of therapeutic proteins.

Flamel's expertise in polymer science has also been instrumental in the development of a photochromic eyeglass lens product now marketed by Corning Inc.

*This document contains a number of matters, particularly as related to financial projections and the status of various research projects and technology platforms, that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The presentation reflects the current view of management with respect to future events and is subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, uncertainties regarding market acceptance of products in development, the impact of competitive products and pricing, and the risks associated with Flamel's reliance on outside parties and key strategic alliances. These and other risks are described more fully in Flamel's Annual Report on the Securities and Exchange Commission Form 20-F for the year ended December 31, 2001.*

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Schedule Attached

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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 share data)**

	Three months ended	
	March 31,	
	2002	2003
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Foreign exchange gain (loss)	5	(83)
Profit (loss) before income taxes	1,027	(1,673)
Income tax benefit	—	—
Net profit, (loss)	\$ 1,027	\$ (1,673)
Basic profit, (loss) per ordinary share	\$ 0.07	\$ (0.10)
Diluted profit, (loss) per ordinary share	\$ 0.07	\$ (0.10)
Weighted average number of ordinary shares outstanding	16,198	16,198