# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# 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 July 2005

# **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)

Form 40-F o

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 ☑

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 o

No ☑

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_\_

See notes to unaudited condensed consolidated financial statements

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# ITEM. 1 Financial Statements (Unaudited)

# CONDENSED STATEMENT OF OPERATIONS

(Amounts in thousands of dollars)

		ree months end (restated)	ded March 31 2005
Revenue:			
License and research revenue	\$	13,301	\$ 7,449
Product sales and services		949	408
Other revenues		103	248
Total revenue		14,353	8,105
Costs and expenses:			
Cost of goods and services sold		(837)	(337)
Research and development		(7,872)	(13,454)
Selling, general and administrative		(1,860)	(1,894)
Total		(10,569)	(15,685)
Profit (loss) from operations		3,784	(7,580)
Interest income net		111	2,310
Foreign exchange gain (loss)		(13)	381
Other income (loss)		57	5,267
Income (loss) before income taxes	_	3,939	378
Income tax benefit (expense)		(23)	(193)
· • ·	\$		
Net income (loss)	<u> </u>	3,916	\$ 185
Earnings (loss) per share			
Basic earnings (loss) per ordinary share	\$	0.18	\$ 0.01
Diluted earnings (loss) per share	\$	0.16	\$ 0.01
Weighted average number of shares outstanding (in thousands):			
weighted average number of shares outstanding (in thousands).			
Basic		21,404	21,548
Diluted		23,999	23,200
See notes to unaudited consolidated financial statements			
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# CONDENSED CONSOLIDATED BALANCE SHEET (Unaudited)

(Amounts in thousands of dollars )

	December 31, 2004	March 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,591	\$ 1,332
Marketable securities	100,783	107,497
Accounts receivable	8,203	8,458
Inventory	1,597	1,129
Prepaid expenses and other current assets	5,598	5,005
Total current assets	120,772	123,421
Property and equipment, net	18,162	16,108
Other assets:	C = 22	6.0.40
Research and development tax credit receivable	6,533	6,242
Other long-term assets	141	179
Total other assets	6,674	6,421
Total assets	\$ 145,608	\$145,950
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 218	\$ 208
Current portion of capital lease obligations	334	385
Accounts payable	9,660	7,811
Current portion of deferred revenue	2,528	1,002
Advances from customers	368	323
Accrued expenses	4,329	3,173
Other current liabilities	5,889	10,547
Total current liabilities	23,326	23,449
Long-term debt, less current portion	2,732	1,512
Capital lease obligations, less current portion	789	1,013
Deferred revenue, less current portion	860	660
Other long-term liabilities	1,144	2,363
Total long-term liabilities	5,525	5,548
Commitments and contingencies:	_	_
Shareholders' equity:		
Ordinary shares: 21,751,590 issued and outstanding at December 31, 2004 and 22,701,595 at March 31, 2005	3,135	3,290
Additional paid-in capital	148,389	155,817
Accumulated deficit	(47,806)	(47,663)
Deferred compensation	(1,122)	(1,008)
Accumulated other comprehensive income (loss)	14,161	6,517
Total shareholders' equity	116,757	116,953
Total liabilities and shareholders' equity	\$ 145,608	\$ 145,950
Total Information and Materioration equity	Ψ 110,000	ψ 1 10,000

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

# (Amounts in thousands of dollars)

	<u>March</u> 2004 (restated)	31, 2005
Cash flows from operating activities:	2004 (restateu)	2005
Net income (loss)	\$ 3,915	\$ 185
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:	_	
Depreciation of property and equipment	602	872
Gain (loss) on disposal of property and equipment	_	(157)
Gains on sales of marketable securities	(121)	(2,330)
Stock compensation expense	573	131
Increase (decrease) in cash from:		
Accounts receivable	352	(658)
Inventory	33	360
Prepaid expenses and other current assets	(368)	327
Research and development tax credit receivable	_	(25)
Accounts payable	2,828	(1,398)
Deferred revenue	(2,386)	(1,581)
Accrued expenses	(557)	(1,888)
Other current liabilities	_	962
Other long-term assets and liabilities	(2,234)	(70)
Net cash provided by (used in) operating activities	2,637	(5,270)
		<u> </u>
Cash flows from investing activities:		
Purchases of property and equipment	(4,036)	(1,029)
Proceeds from disposal of property and equipment	_	157
Purchase of marketable securities	(1,865)	(127,489)
Proceeds from sales of marketable securities	10,456	118,107
Net cash provided by (used in) investing activities	4,555	(10,254)
	·	
Cash flows from financing activities:		
Funding from partner GSK	_	4,899
Repayment of loans or advances	_	(214)
Proceeds from loans or capital leases	149	459
Principal payments on capital lease obligations	(24)	(132)
Shares issuance costs	_	_
Cash proceeds from issuance of ordinary shares and warrants	153	7,583
Net cash provided by financing activities	278	12,595
Effect of exchange rate changes on cash and cash equivalents	(263)	(330)
	,	` /
Net increase (decrease) in cash and cash equivalents	7,207	(3,259)
	,	,
Cash and cash equivalents, beginning of the period	1,199	4,591
Cash and cash equivalents, end of the period	\$ 8,406	\$ 1,332
	·	

See notes to unaudited consolidated financial statements

# CONDENSED CONSOLIDATED SHAREHOLDER'S EQUITY (Unaudited)

(Amounts in thousands of dollars except share data)

				Additional		Deferred	Co	cumulated Other omprehen-		
	Ordinary Shares		nount	Paid-in Capital	Accumulat Deficit	ed Compen- sation	siv	ve Income (Loss)	Sh	areholders' Equity
Balance at December 31, 2004	21,751,590	\$3,1	35.10	\$148,389	(\$47,8		\$	14,161	\$	116,757
Issuance of ordinary shares on exercise of										
warrants	950,005		154	7,429						7,583
Amort. deferred compensation						114				114
Net income					18	35				185
Unrealized gains on available-for-										
sale securities								(1,881)		(1,881)
Translation adjustment								(5,806)		(5,806)
Comprehensive income										(7,502)
Balance at March 31, 2005	22,701,595	\$	3,289	\$ 155,818	(\$47,6)	21) (\$1,008)	\$	6,474	\$	116,952

See notes to unaudited consolidated financial statements

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

### 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, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. 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 the license agreement signed with SB Pharma Puerto Rico Inc. (Glaxo SmithKline) in March 2003, the Company recognized research and development revenues of \$1,669,000 and licensing fees of \$202,000 for the first three months of 2005.

In accordance with the supply agreement signed with Glaxo SmithKline in December 2004, the Company recognized research and development revenues of \$98,000 for the first three months of 2005.

In accordance with the license agreement signed with TAP in January 2004, the Company recognized research and development revenues of \$3,651,000 and licensing fees of \$1,604,000,000 for the first three months of 2005. The licensing fees include a milestone payment of \$1,515,000 related to results achieved in March 2005.

On March 3, 2005 the Company announced the termination of the license agreement with Biovail. Accordingly, the Company recognized \$224,000 as the full amortization of the up-front payment received in 2003 and initially amortized over three years.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

### 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 \$248,000 corresponding to the royalties for the three-month period ended March 31, 2005.

### 4. 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:

	Decemb	oer 31,
(In thousands of U.S. dollars)	December 31, 2004	March 31, 2005
Raw materials	1,445	1,076
Finished goods	361	288
Provision for inventory obsolescence	(209)	(234)
Inventories, net	1,597	1,129

# 5. SHAREHOLDERS' EQUITY

During the first three months of 2005, as a result of exercises of warrants and stock options, the Company issued 950,005 ordinary shares, nominal value €0.122 (\$0.162) per share.

### 6. EMPLOYEE STOCK-OPTION PLANS

During the first three months of 2005, 242,500 options were granted to new employees and senior employees with a four year vesting period.

### 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 GlaxoSmithKline and TAP Pharmaceutical Products, Inc "TAP";
- even if our product candidates appear promising at an early stage of development, product candidates could fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance, be precluded from commercialization by proprietary rights of third parties or experience substantial competition in the marketplace;

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

Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by or underlying the forward-looking statements. Statements in this report on Form 6-K and in our annual report on Form 20-F for the fiscal year ended December 31, 2004 including those set forth in 'Risk Factors' in this report, describe factors, among others, that could contribute to or cause such differences.

### **Results of Operations**

For the first quarter of 2005, Flamel reported total revenues of \$8.1 million, compared to \$14.4 million in the first quarter of 2004.

In the first quarter of 2005, Flamel received a \$1.5 million milestone payment from TAP Pharmaceutical Products Inc. In the first quarter of 2004, Flamel received a \$5 million milestone payment from Bristol-Myers Squibb Company.

Flamel's 2005 first quarter revenues included license and research revenues of \$7.5 million. License and research revenues in the first quarter of 2004 were \$13.3 million. Revenues from product sales and services during the quarter declined to \$0.4 million compared to \$0.9 million in the first quarter of 2004, reflecting our decision to de-emphasize contract manufacturing activities.

Other revenues were \$0.2 million, compared to \$0.1 million in the year-ago period.

Expenses increased to \$15.7 million from \$10.6 million in the year-ago quarter. This increase results from ongoing clinical trials for Interferon alpha and Interleukin-2, as well as additional trials which have not been disclosed, and an increase in personnel. The increase in personnel includes additional development work and preparations for supply of product to be made by Flamel to GlaxoSmithKline ("GSK") pursuant to the supply agreement signed with GSK in December 2004. Flamel employed 230 employees over the first three months of 2005, of whom 162 (or 70%) were scientists involved in research and development. Comparable numbers in 2004 were 189 employees, including 132 scientists.

Other income of \$5.3M is mainly composed of the termination fees received in February 2005 from Bristol-Myers Squibb in full settlement of all amounts due to Flamel.

Costs and expenses of Flamel's research and development increased to \$13.5 million, from \$7.9 million in the year-ago quarter. This was largely as a result of increased clinical and preclinical study work, related to projects developed internally and also with our partners, the increase in employees and costs related to establishing facilities in which for them to work, as well as the increase of 4.8% in the value of the Euro against the U.S. dollar versus the year-ago period.

Costs of goods and services sold decreased to \$0.3 million, compared to \$0.8 million a year ago, largely in conjunction with decreased revenues in this category. SG&A was relatively flat at \$1.9 million, resulting from a decline in stock compensation expense, offset by increases in costs for professional staff.

### Liquidity and Capital Resources

On March 31, 2005 the Company had \$108.8 million in cash, cash equivalents and marketable securities, compared to \$105.4 million at the end of the first three months of 2004.

### **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: July 22, 2005

Flamel Technologies S.A.
Ву:
Name: Stephen Willard
Title: Chief Executive Officer

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