

FORM 6-K

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**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 2004
Commission File Number 000-28508

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): Not Applicable

INDEX

FLAMEL TECHNOLOGIES S.A.

	Page
<u>Item 1.</u> <u>Financial Statements (Unaudited)</u>	
(a) <u>Condensed Consolidated Statements of Operations</u> <u>Six months ended June 30, 2004 and 2003.</u>	1
(b) <u>Condensed Consolidated Statements of Operations</u> <u>Three months ended June 30, 2004 and 2003.</u>	2
(c) <u>Condensed Consolidated Balance Sheets</u> <u>June 30, 2004 and December 31, 2003.</u>	3
(d) <u>Condensed Consolidated Statements of Cash Flows</u> <u>Six months ended June 30, 2004 and 2003.</u>	4
(e) <u>Consolidated Statement of Shareholders' Equity.</u>	5
(f) <u>Notes to Condensed Consolidated Financial Statements.</u>	6
<u>Item 2.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of</u> <u>Operations</u>	8
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	9
<u>Item 4.</u> <u>Purchases of Equity Securities By the Issuer and Affiliated Purchasers</u>	10
<u>Item 5.</u> <u>Exhibits</u>	10

FLAMEL TECHNOLOGIES S.A.

Item 1.

Financial Statements (Unaudited)

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

	Six months ended June 30,	
	2003	2004
Revenue:		
License and research revenue	\$ 6,259	\$ 20,838
Product sales and services	1,901	2,118
Other revenues	372	388
Total revenue	<u>8,532</u>	<u>23,344</u>
Costs and expenses:		
Cost of goods and services sold	(1,811)	(1,715)
Research and development	(8,525)	(15,891)
Selling, general and administrative	(2,351)	(2,914)
Stock compensation expense	(4)	(1,125)
Total costs and expenses	<u>(12,691)</u>	<u>(21,645)</u>
Profit (loss) from operations	(4,159)	1,699
Interest income, net	142	967
Foreign exchange gain (loss)	(293)	18
Other income	1,007	81
Income,(loss) before income taxes	(3,303)	2,765
Income tax benefit (expenses)	(21)	(23)
Net income, (loss)	<u>\$ (3,324)</u>	<u>\$ 2,742</u>
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	\$ (0.20)	\$ 0.13
Diluted earnings (loss) per share	<u>\$ (0.20)</u>	<u>\$ 0.11</u>
Weighted average number of shares outstanding (in thousands):		
Basic	16,327	21,415
Diluted	<u>16,327</u>	<u>24,120</u>

See notes to unaudited condensed consolidated financial statements

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

	Three months ended June 30,	
	2003	2004
Revenue:		
License and research revenue	\$ 4,297	\$ 7,537
Product sales and services	864	1,169
Other revenues	(162)	285
Total revenue	<u>4,999</u>	<u>8,991</u>
Costs and expenses :		
Cost of goods and services sold	(717)	(878)
Research and development	(4,682)	(8,019)
Selling, general and administrative	(1,341)	(1,627)
Stock compensation expense	—	(552)
Total costs and expenses	<u>(6,740)</u>	<u>(11,076)</u>
Profit (loss) from operations	(1,741)	(2,085)
Interest income, net	62	475
Foreign exchange gain (loss)	(210)	31
Other income	260	24
Income,(loss) before income taxes	(1,629)	(1,555)
Income tax benefit (expenses)	(21)	—
Net income, (loss)	<u>\$ (1,650)</u>	<u>\$ (1,555)</u>
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	<u>\$ (0.10)</u>	<u>\$ (0.07)</u>
Diluted earnings (loss) per share	<u>\$ (0.10)</u>	<u>\$ (0.07)</u>
Weighted average number of shares outstanding (in thousands):		
Basic	16,327	21,415
Diluted	<u>16,327</u>	<u>21,415</u>

See notes to unaudited condensed consolidated financial statements

FLAMEL TECHNOLOGIES, S.A.

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

ASSETS	December 31, 2003	June 30, 2004
Current assets:		
Cash and cash equivalents	\$ 109,617	\$ 100,850
Accounts receivable	8,367	5,212
Inventory	1,057	1,310
Prepaid expenses and other current assets	1,694	3,694
Total current assets	<u>120,735</u>	<u>111,066</u>
Property and equipment, net	5,085	11,747
Other assets:		
Research and development tax credit receivable	1,348	1,297
Other long-term assets	84	120
Total other assets	<u>1,432</u>	<u>1,417</u>
Total assets	<u>\$ 127,252</u>	<u>\$ 124,230</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ —	\$ —
Current portion of capital lease obligations	257	231
Accounts payable	4,397	6,961
Current portion of deferred revenue	9,623	8,577
Advances from customers	344	311
Accrued expenses	3,159	2,831
Other current liabilities	88	69
Total current liabilities	<u>17,868</u>	<u>18,980</u>
Long-term debt, less current portion	1,675	1,613
Capital lease obligations, less current portion	261	380
Deferred revenue, less current portion	14,200	9,714
Other long-term liabilities	1,187	770
Total long-term liabilities	<u>17,323</u>	<u>12,477</u>
Commitments and contingencies:	—	—
Shareholders' equity:		
Ordinary shares: 21,391,590 issued and outstanding at December 31, 2003 and 21,446,590 at June 30, 2004	3,081	3,088
Additional paid-in capital	147,679	148,019
Accumulated deficit	(59,875)	(57,133)
Deferred compensation	(2,388)	(1,342)
Accumulated other comprehensive income (loss)	3,564	141
Total shareholders' equity	<u>92,061</u>	<u>92,773</u>
Total liabilities and shareholders' equity	<u>\$ 127,252</u>	<u>\$ 124,230</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

FLAMEL TECHNOLOGIES S.A.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(Amounts in thousands of dollars, except per share data)

	Six months ended June 30,	
	2003	2004
Cash flows from operating activities:		
Net income (loss)	\$ (3,323)	\$ 2,742
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	604	967
Gain on disposal of property and equipment	(362)	(27)
Grants recognized in other income	(769)	—
Stock compensation expense	4	1,124
Provision for accounts receivables and others	—	87
Increase (decrease) in cash from:		
Accounts receivable	(2,162)	2,745
Inventory	(638)	(296)
Prepaid expenses and other current assets	(542)	(2,084)
Deferred revenue	1,363	(4,683)
Accounts payable	916	2,756
Accrued expenses	(375)	(247)
Research and development tax credit receivable	274	—
Other long-term assets and liabilities	138	(377)
Net cash provided by (used in) in operating activities	(4,872)	2,707
Cash flows from investing activities:		
Purchases of property and equipment	(368)	(7,654)
Proceeds from disposal of property and equipment	372	119
Net cash provided by (used in) in investing activities	4	(7,535)
Cash flows from financing activities:		
Repayment of loans or advances	—	—
Proceeds from loans or capital leases	135	(131)
Principal payments on capital lease obligations	694	246
Cash proceeds from sale of ordinary shares	(126)	—
Cash proceeds from issuance of ordinary shares and warrants	—	348
Net cash provided by financing activities	703	463
Effect of exchange rate changes on cash and cash equivalents	1,294	(4,403)
Net increase (decrease) in cash and cash equivalents	(2,871)	(8,768)
Cash and cash equivalents, beginning of period	14,527	109,617
Cash and cash equivalents, end of period	\$ 11,649	\$ 100,850

See notes to unaudited condensed consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

CONDENSED CONSOLIDATED SHAREHOLDER'S EQUITY (UNAUDITED)
(Amounts in thousands of dollars, except per share data)

	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 €5.11 (\$6.33) (*)	55,000	7	340				347
Amortization of deferred compensation	—	—	—	—	1,046	—	1,046
Net income	—	—	—	2,742	—	—	2,742
Other comprehensive income							
Translation adjustment	—	—	—	—	—	(3,423)	(3,423)
Comprehensive income							
Balance March 2004	<u>21,446,590</u>	<u>\$ 3,088</u>	<u>\$ 148,019</u>	<u>\$ (57,133)</u>	<u>\$ (1,342)</u>	<u>\$ 141</u>	<u>\$ 92,773</u>

(*) Average issuance price

See notes to unaudited 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 effect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Operating results for the six months ended June 30, 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. License research and consulting agreements.

In accordance with the license agreement signed with Servier in December 2001, the Company recognized research and development revenues of approximately \$0.23 million and licensing fees of approximately \$0.67 million for the first six months of 2004.

In accordance with the license agreement signed with SB Pharma Puerto Rico Inc. in March 2003, the Company recognized research and development revenues of approximately \$3.04 million and licensing fees of approximately \$0.38 million for the first six months of 2004.

In accordance with the license agreement signed with Biovail in February 2003, the Company recognized research and development revenues of approximately \$0.60 million and licensing fees of approximately \$0.10 million for the first six months of 2004.

In accordance with the license agreement signed with Bristol-Myers Squibb (BMS) in August 27, 2003, the Company recognized research and development revenues of approximately \$5.6 million and licensing fees of approximately \$8.5 million for the first six months of 2004. The licensing fees include a milestone payment of approximately \$5.0 million related to results achieved in March 2004.

The Company recognized research and development revenues on feasibility studies with undisclosed partners for an amount of approximately \$1.6 million for the first six months of 2004.

See notes to unaudited condensed consolidated financial statements

[Table of Contents](#)

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 \$0.40 million corresponding to the royalties for the six-month period ended June 30, 2004.

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 :

(In thousands of U.S. dollars)	June, 2004
Raw materials.	890
Finished goods	420
Inventories, net	1,310

5. SHAREHOLDERS' EQUITY

Over the 2004 first quarter, as a result of exercises of stock options, the Company issued 55,000 ordinary shares, nominal value €0.122 (\$0.149) per share.

6. EMPLOYEE STOCK-OPTION PLANS

During the 2004 six-month period, 280,000 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;

See notes to unaudited condensed consolidated financial statements

Table of Contents

- 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.

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.

See notes to unaudited condensed consolidated financial statements

Table of Contents

Results of Operations

Revenues for the first six months ended June 30, 2004 increased to \$23.3 million, compared to \$8.5 million for the first six months of 2003.

License and research revenue for the six months ended June 30, 2004 was \$20.8 million, which includes \$14.2 million from Bristol-Myers Squibb, \$3.4 million from GlaxoSmithKline, \$0.9 million from Servier, \$0.7 revenue from Biovail and \$1.7 million from feasibility studies with other partners.

License and research revenue for the first six months of 2003 largely consisted of revenues from GlaxoSmithKline (\$3 million), Servier (\$2 million), Corning and undisclosed partners.

Other revenues for the six months ended June 30, 2004 consisted of royalties from Corning.

No significant other income has been recorded in the first six months of 2004.

Other income in 2003 included the sale of equipment from the Company's pilot plant in Vénissieux, and \$0.7 million in French government grants.

Revenues from product sales and services were \$2.1 million in the first six months of 2004, compared to \$1.9 million for the same period in 2003, reflecting concentration of the production on the first eight months of 2004. Starting with the third quarter 2004, the Company plans to transition away from contract manufacturing activities.

Total operating costs for the six months ended June 30, 2004 amounted to \$21.6 million, up from \$12.7 million in the comparable 2003 period. This is largely the result of increasing clinical and preclinical study work, primarily related to projects developed internally and also with our partners, as well as the increase of 10% in the value of the Euro against the U.S. dollar as compared to the same period in 2003.

Overall, the Company recorded a profit of \$2.7 million for the six months ended June 30, 2004 compared to a loss of \$(3.3) million in the comparable period in 2003.

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 June 30, 2004 the Company had \$100.9 million in cash, compared to \$11.6 million in cash at the end of the first six months 2003.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

See notes to unaudited condensed consolidated financial statements

[Table of Contents](#)

Item 4. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 5. Exhibits

None.

See notes to unaudited condensed consolidated financial statements

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

Dated: September 1, 2004

By: /s/ Stephen Willard

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

See notes to unaudited condensed consolidated financial statements