

FORM 6-K
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 December 2003

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.

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

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)

	Nine months ended September 30,	
	2002	2003
Revenue:		
License and research revenue	\$ 10,801	\$ 10,504
Product sales and services	1,967	2,800
Other income	718	594
Total revenue	13,486	13,898
Costs and expenses:		
Cost of goods and services sold	(1,538)	(2,694)
Research and development	(8,624)	(13,514)
Selling, general and administrative	(2,536)	(3,818)
Stock compensation expense	(13)	(14)
Total costs and expenses	(12,711)	(20,040)
Profit (loss) from operations	775	(6,142)
Other income	2,476	999
Interest income, net	156	207
Foreign exchange gain (loss)	(75)	(236)
Income tax expense	—	(20)
Net profit, (loss)	\$ 3,332	\$ (5,192)
Earnings (loss) per ordinary share		
Basic	\$ 0.21	\$ (0.27)
Diluted	\$ 0.19	\$ (0.27)
Weighted average number of ordinary shares outstanding (in thousands)		
Basic	16,198	19,292
Diluted	16,711	19,292

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)

	Three months ended September 30,	
	2002	2003
Revenue:		
License and research revenue	\$ 5,441	\$ 4,245
Product sales and services	653	899
Other income	183	222
Total revenue	6,277	5,366
Costs and expenses :		
Cost of goods and services sold	(457)	(883)
Research and development	(2,929)	(4,989)
Selling, general and administrative	(745)	(1,467)
Stock compensation expense	(3)	(10)
Total costs and expenses	(4,134)	(7,349)
Profit (loss) from operations	2,143	(1,983)
Other income	80	(8)
Interest income, net	78	65
Foreign exchange gain (loss)	72	57
Income tax expense	—	—
Net profit, (loss)	\$ 2,373	\$ (1,869)
Earnings (loss) per ordinary share		
Basic	\$ 0.15	\$ (0.11)
Diluted	\$ 0.14	\$ (0.11)
Weighted average number of ordinary shares outstanding (in thousands)		
Basic	16,198	19,292
Diluted	16,711	19,292

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, 2002 (Note)	September 30, 2003 (Unaudited)
Current assets:		
Cash and cash equivalents	\$ 14,527	\$ 22,076
Accounts receivable	3,462	4,347
Inventory	375	545
Prepaid expenses and other current assets	347	1,620
Total current assets	18,711	28,588
Property and equipment, net	3,405	3,658
Other assets:		
Research and development tax credit receivable	890	699
Other long-term assets	70	77
Total other assets	960	776
Total assets	\$ 23,076	\$ 33,022
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 693	\$ —
Current portion of capital lease obligations	229	241
Accounts payable	1,322	2,357
Current portion of deferred revenue	1,805	2,269
Accrued expenses	2,028	2,404
Advances from customers	361	290
Other current liabilities	71	307
Total current liabilities	6,509	7,868
Long-term debt, less current portion	1,391	1,546
Other long-term liabilities	789	1,063
Deferred revenue, less current portion	1,952	2,025
Capital lease obligation, less current portion	149	41
Total long-term liabilities	4,281	4,675
Shareholders' equity:		
Ordinary shares	2,366	2,779
Additional paid-in capital	71,178	82,209
Accumulated deficit	(56,381)	(61,573)
Deferred compensation	(14)	(10)
Cumulative other comprehensive income	(4,863)	(2,926)
Total shareholders' equity	12,286	20,479
Total liabilities and shareholders' equity	\$ 23,076	\$ 33,022

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 STATEMENTS OF CASH FLOWS

(unaudited)

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

	Nine months ended September 30,	
	2002	2003
Cash flows from operating activities:		
Net profit (loss)	\$ 3,332	\$ (5,192)
Adjustments to reconcile net profit (loss) to net cash provided by operating activities:		
Depreciation and amortization	967	1,239
Gain (loss) on disposal of property and equipment		(373)
(Gain) loss on recognition of grants		(870)
Stock compensation expense	13	4
Increase (decrease) in cash from:		
Accounts receivable	5,218	(478)
Inventory	268	(122)
Prepaid expenses and other current assets	19	(1,178)
Deferred revenue	(425)	114
Accounts payable	(266)	847
Accrued expenses	(1,635)	255
Research and development tax credit receivable	1,461	276
Other	130	178
Net cash provided (used) by operating activities	9,082	(5,300)
Cash flows from investing activities:		
Purchases of property and equipment	(1,074)	(800)
Disposal of short-term investments	—	375
Net cash provided (used) for investing activities	(1,074)	(425)
Cash flows from financing activities:		
Cash proceeds from sale of ordinary shares	1	11,698
Cash proceeds from new loans	471	136
Principal payments on loans and capital lease obligations	(328)	(164)
Net cash provided (used) by financing activities	144	11,670
Effect of exchange rate changes on cash and cash equivalents	1,162	1,604
Net increase (decrease) in cash and cash equivalents	9,314	7,549
Cash and cash equivalents, beginning of period	5,309	14,527
Cash and cash equivalents, end of period	\$14,623	\$22,076

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)

	Share	Amount	Additional Paid-in Capital	Accumulated Deficit	Deferred Compensation	Cumulative Translation Adjustment	Shareholders Equity
Balance January 1, 2003	16,197,590	\$2,366	\$71,178	\$(56,381)	\$ (14)	\$(4,863)	\$12,286
Issuance of ordinary shares at €4,75 (\$5,37)	225,000	32	1,177				1,209
Issuance of ordinary shares at €2,78 (\$3,21)	2,500	0	8				8
Issuance of ordinary shares at €4,88 (\$5,76)	30,000	4	169				173
Issuance of ordinary shares at €5,95 (\$7,02)	10,000	1	66				67
Issuance of ordinary shares at €2,33 (\$2,75)	10,000	1	26				27
Issuance of ordinary shares at €4,88 (\$5,28)	30,000	4	155				159
Issuance of ordinary shares at €2,33 (\$2,52)	10,000	1	24				25
Issuance of ordinary shares at €5,96 (\$6,44)	1,491,500	197	9,406				9,603
Issuance of ordinary shares at €0,12 (\$0,13)	1,285,000	173	—				173
Amortization of deferred compensation	—	—	—	—	4	—	4
Net loss	—	—	—	(5,192)	—	—	(5,192)
Other comprehensive income							
Translation adjustment	—	—	—	—	—	1,937	1,937
Comprehensive income							(3,255)
Balance September 30, 2003	<u>19,291,590</u>	<u>\$2,779</u>	<u>\$82,209</u>	<u>\$(61,573)</u>	<u>\$ (10)</u>	<u>\$(2,926)</u>	<u>\$20,479</u>

FLAMEL TECHNOLOGIES S.A.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

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

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 nine months ended September 30, 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.

2. REVENUES

2.1 License research and consulting agreements.

In accordance with the long-term research and product development agreement signed with Corning in December 1998, the Company recognized research and development revenues of \$290,000 for the first nine months of 2003.

In accordance with the license agreement signed with Servier in December 2001, the Company recognized research and development revenues of \$1,358,000 and licensing fees of \$1,423,000 for the first nine months of 2003. The licensing fees include a milestone payment of \$475,000 related to results achieved in June 2003.

In accordance with the license agreement signed with Beecham Pharmaceuticals (Pte) Limited in June 2002, the Company recognized licensing fees of \$423,000 for the first three quarters 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 \$2,750,000 and licensing fees of \$1,293,000 for the first nine months of 2003. The licensing fees include a milestone payment for \$950,000 for results achieved in June 2003. The remaining \$343,000 relates to the \$2,000,000 upfront payment received in March 2003 and recognized as revenue on a straight-line basis over the term of the development period.

In accordance with the license agreement signed with Biovail in February 2003, the Company recognized revenue of \$104,000 during the nine-month period ended September 2003 relating to the \$500,000 upfront payment received in February 2003.

In accordance with a research agreement signed on August 27, 2003 with Bristol-Myers Squibb, the Company recognized revenues of \$744,000.

The Company recognized research and development revenues on three feasibility studies with undisclosed partners of \$2,077,000 for the first nine months of 2003.

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 \$552,000 corresponding to the royalties for the nine-month period ended September 30, 2003.

3. OTHER INCOME

In February 2003, the Company recognized a gain of \$378,000 from the sale of the equipment of its pilot plant of Vénissieux.

In March 2003, the Company recognized revenues of \$772,000 from conditional grants received from French public agencies. The grants required the Company to maintain certain levels of employment, which were achieved in 2003.

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)	Sept. 2003
Raw materials	385
Finished goods	160
	—
Inventories, net	545
	—

5. SHAREHOLDERS' EQUITY

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

Over the same period, as a result of some Directors exercising warrants, the Company issued 90,000 ordinary shares, nominal value €0.122 (\$0.138) per share. As a result of the exercise of 1,099,000 Class A options, 392,500 Class B options and 1,285,000 Class C options, the Company issued 2,776,500 ordinary shares, nominal value €0.122 (\$0.138) per share.

As of September 30, 2003, the issued and outstanding share capital of the Company consisted of 19,291,590 ordinary shares, nominal value of €0.122 per share.

6. SUBSEQUENT EVENTS

6.1 Shareholders' equity

On October 8, 2003, the Company sold 2,000,000 ordinary shares, at a price of € 26.7319 (\$ 31.255) per share in a public offering.

As of October 8, 2003, the issued and outstanding share capital of the Company consisted of 21,291,590 ordinary shares, nominal value of €0.122 (\$0.138) per share.

6.2 Business update

On October 20, 2003, the Company announced that the license agreement with Beecham Pharmaceuticals (Pte) Limited (GlaxoSmithKline) for the sachet formulation of Augmentin would be terminated as of January 14, 2004.

FLAMEL TECHNOLOGIES S.A.

Item 2.

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

Results of Operations

Revenues for the nine months ended September 30, 2003 increased to \$13.8 million, compared to \$13.5 million for the first three quarters of 2002.

Licence and research revenue for the nine months ended September 30, 2003 was \$10.5 million which included \$4.3 million from GlaxoSmithKline, \$2.8 million revenue from Servier, \$0.8million from Bristol-Meyers Squibb and \$2.6 million from feasibility studies with other partners. License and research revenue for the first nine months of 2002 largely consisted of revenues from Servier (\$7.8 million), Novo-Nordisk, Corning and various undisclosed partners.

Other revenues for the nine months ended September 30, 2003 consisted of royalties from Corning.

Other income included the sale of equipment from the Company's pilot plant in Vénissieux, and \$0.7 million in French government grants. Other income in 2002 included \$2.3 million received in settlement of litigation with the Welcome Foundation regarding Flamel's long acting acyclovir product Genvir.

Revenues from product sales and services were \$2.8 million in the nine months ended September 30, 2003, compared to \$1.9 million in the first nine months of 2002, largely as a result of increased contract manufacturing.

Total costs and expenses for the nine months ended September 30, 2003 amounted to \$20.0 million, up from \$12.7 million in the comparable 2002 period, largely as a result of increasing clinical and preclinical study work primarily related to projects developed internally and an increase of 20% in the value of the Euro against the U.S. dollar during the nine month period.

Sales, General and Administrative costs increased to \$3.8 million for the nine months ended September 30, 2003 as compared to \$2.5 million in 2002, largely as a result of additional expenses related to the secondary offering completed in October 2003.

Overall, the Company had a loss of \$5.2 million for the nine months ended September 30, 2003 as compared to a gain of \$3.3 million in the comparable period 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 September 30, 2003, the Company had \$22.1 million in cash, compared to \$14.6 million in cash at the end of the first nine months 2002.

Net cash from operating activities amounted to a decline of \$5.3 million for the first nine months of 2003, primarily due to the net loss for the period and prepaid expenses and other current assets.

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: December 31, 2003

By: /s/ Stephen Willard
Stephen Willard
Executive Vice President,
Chief Financial Officer and General
Counsel