
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 November 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)

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-_____

FLAMEL TECHNOLOGIES S.A.

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FLAMEL TECHNOLOGIES S.A.

Item. 1 Financial Statements (Unaudited)

CONDENSED STATEMENT OF OPERATIONS
(Amounts in thousands of dollars, except share data)

	Nine months ended September 30,	
	2004 (restated) *	2005
Revenue:		
License and research revenue	\$ 33,099	\$ 15,141
Product sales and services	2,993	1,408
Other revenues	600	788
Total revenue	<u>36,692</u>	<u>17,337</u>
Costs and expenses:		
Cost of goods and services sold	(2,629)	(2,000)
Research and development	(24,446)	(37,582)
Selling, general and administrative	(5,801)	(7,433)
Total	<u>(32,876)</u>	<u>(47,015)</u>
Profit (loss) from operations	3,816	(29,678)
Interest income net	442	3,214
Foreign exchange gain (loss)	30	335
Other income (loss)	308	5,300
Income (loss) before income taxes	<u>4,596</u>	<u>(20,829)</u>
Income tax benefit (expense)	(23)	(100)
Net income (loss)	<u>\$ 4,573</u>	<u>(\$ 20,929)</u>
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	<u>\$ 0.21</u>	<u>(\$ 0.89)</u>
Diluted earnings (loss) per share	<u>\$ 0.19</u>	<u>(\$ 0.89)</u>
Weighted average number of shares outstanding (in thousands):		
Basic	21,434	23,640
Diluted	24,182	23,640

* Unrealized gains related to the marketable securities held by the Company as of September 30, 2004 have been recorded in other comprehensive income instead of earnings.

See notes to unaudited consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

Item. 1 Financial Statements (Unaudited)

CONDENSED STATEMENT OF OPERATIONS
(Amounts in thousands of dollars, except share data)

	<u>Three months ended September 30,</u>	
	<u>2004 (restated)</u>	<u>2005</u>
	<u>*</u>	
Revenue:		
License and research revenue	\$ 12,261	\$ 2,338
Product sales and services	875	458
Other revenues	212	292
Total revenue	<u>13,348</u>	<u>3,088</u>
Costs and expenses:		
Cost of goods and services sold	(914)	(758)
Research and development	(8,555)	(11,540)
Selling, general and administrative	(1,762)	(2,971)
Total	<u>(11,231)</u>	<u>(15,269)</u>
Profit (loss) from operations	2,117	(12,181)
Interest income net	242	435
Foreign exchange gain (loss)	12	(70)
Other income (loss)	227	(66)
Income (loss) before income taxes	<u>2,598</u>	<u>(11,882)</u>
Income tax benefit (expense)	—	(2)
Net income (loss)	<u>\$ 2,598</u>	<u>(\$ 11,884)</u>
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	<u>\$ 0.12</u>	<u>(\$ 0.50)</u>
Diluted earnings (loss) per share	<u>\$ 0.11</u>	<u>(\$ 0.50)</u>
Weighted average number of shares outstanding (in thousands) :		
Basic	21,434	23,640
Diluted	24,182	23,640

* Unrealized gains related to the marketable securities held by the Company as of September 30, 2004 have been recorded in other comprehensive income instead of earnings.

See notes to unaudited consolidated financial statements

FLAMEL TECHNOLOGIES S.A.
CONDENSED CONSOLIDATED BALANCE SHEET
(Unaudited)
(Amounts in thousands of dollars)

	December 31, 2004	September 30, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,591	\$ 1,606
Marketable securities	100,783	87,812
Accounts receivable	8,203	6,238
Inventory	1,597	1,171
Prepaid expenses and other current assets	5,598	4,777
Total current assets	<u>120,772</u>	<u>101,604</u>
Property and equipment, net	18,162	20,460
Other assets:		
Research and development tax credit receivable	6,533	5,773
Other long-term assets	141	135
Total other assets	<u>6,674</u>	<u>5,908</u>
Total assets	<u>\$ 145,608</u>	<u>\$ 127,972</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 218	\$ 193
Current portion of capital lease obligations	334	378
Accounts payable	9,660	11,069
Current portion of deferred revenue	2,528	1,826
Advances from customers	368	300
Accrued expenses	4,329	4,693
Other current liabilities	5,889	3,121
Total current liabilities	<u>23,326</u>	<u>21,580</u>
Long-term debt, less current portion	1,589	3,153
Capital lease obligations, less current portion	789	740
Deferred revenue, less current portion	860	—
Other long-term liabilities	2,287	7,974
Total long-term liabilities	<u>5,525</u>	<u>11,867</u>
Commitments and contingencies:	—	—
Shareholders' equity:		
Ordinary shares: 21,751,590 issued and outstanding at December 31, 2004 and 23,639,590 at September 30, 2005	3,135	3,427
Additional paid-in capital	148,389	160,667
Accumulated deficit	(47,806)	(68,735)
Deferred compensation	(1,122)	—
Accumulated other comprehensive income (loss)	14,161	(834)
Total shareholders' equity	<u>116,757</u>	<u>94,525</u>
Total liabilities and shareholders' equity	<u>\$ 145,608</u>	<u>\$ 127,972</u>

See notes to unaudited consolidated financial statements

FLAMEL TECHNOLOGIES S.A.
Condensed Consolidated Statement of Cash Flows
(Unaudited)
(Amounts in thousands of dollars)

	Nine Months ended September 30,	
	2004 (restated)	2005
Cash flows from operating activities:		
Net income (loss)	\$ 4,594	(\$20,929)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	1,667	3,537
Gain (loss) on disposal of property and equipment	—	(74)
Gains on sales of marketable securities	(462)	(3,251)
Stock compensation expense	1,482	337
Increase (decrease) in cash from:		
Accounts receivable	555	621
Inventory	(259)	252
Prepaid expenses and other current assets	(1,694)	181
Research and development tax credit receivable	—	3
Accounts payable	552	2,653
Deferred revenue	(8,089)	(1,227)
Accrued expenses	317	1,375
Other current liabilities	—	105
Other long-term assets and liabilities	(48)	6,234
Net cash provided by (used in) operating activities	<u>(1,385)</u>	<u>(10,183)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(12,624)	(7,699)
Proceeds from disposal of property and equipment	223	102
Purchase of marketable securities	(14,569)	341,036
Proceeds from sales of marketable securities	29,402	(338,219)
Net cash provided by (used in) investing activities	<u>2,432</u>	<u>(4,780)</u>
Cash flows from financing activities:		
Funding from partner GSK	—	11,372
Repayment of loans or advances	—	(14,159)
Proceeds from loans or capital leases	662	2,277
Principal payments on capital lease obligations	(257)	(387)
Cash proceeds from issuance of ordinary shares and warrants	629	13,391
Net cash provided by financing activities	<u>1,034</u>	<u>12,494</u>
Effect of exchange rate changes on cash and cash equivalents	(537)	(516)
Net increase (decrease) in cash and cash equivalents	1,544	(2,985)
Cash and cash equivalents, beginning of the period	1,199	4,591
Cash and cash equivalents, end of the period	<u>\$ 2,743</u>	<u>\$ 1,606</u>

* Unrealized gains related to the marketable securities held by the Company as of September 30, 2004 have been recorded in other comprehensive income instead of earnings.

See notes to unaudited consolidated financial statements

FLAMEL TECHNOLOGIES S.A.
Consolidated Statement of Shareholders' Equity
(Unaudited)
(Amounts in thousands of dollars, except share data)

	<u>Ordinary Shares</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Deferred Compensation</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Shareholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>					
Balance at December 31, 2004	21,751,590	3,135	148,389	(47,806)	(1,122)	14,161	116,757
Issuance of ordinary shares on exercise of warrants	1,125,000	180	9,196				9,376
Issuance of ordinary shares on exercise of stock options	763,000	112	3,902				4,014
Amort. deferred compensation			(820)		1,122		302
Net income				(20,929)			(20,929)
Unrealized gains on available- for-sale securities						(1,885)	(1,885)
Translation adjustment						(13,110)	(13,110)
Comprehensive income							(\$ 35,924)
Balance at September 30, 2005	<u>23,639,590</u>	<u>\$ 3,427</u>	<u>\$ 160,667</u>	<u>(\$68,735)</u>	<u>\$ 0</u>	<u>(\$ 834)</u>	<u>\$ 94,525</u>

See notes to unaudited consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

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 nine months ended September 30, 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. (GlaxoSmithKline) in March 2003, the Company recognized research and development revenues of \$5,107,000 and licensing fees of \$580,000 for the first nine months of 2005.

In accordance with the supply agreement signed with GlaxoSmithKline in December 2004, the Company recognized research and development revenues of \$401,000 for the first nine months of 2005.

In accordance with the license agreement signed with TAP Pharmaceuticals ("TAP") in January 2004, the Company recognized research and development revenues of \$6,878,000 and licensing fees of \$1,905,000, for the first nine months of 2005. Due to the termination of the licensing agreement with TAP dated September 2nd, 2005, the licensing fees include \$446,000 of amortization of initial up-front payment received in September 2004 (of which \$182,000 relates to acceleration of amortization for the period of termination notice).

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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 \$788,000 corresponding to the royalties for the nine-month period ended September 30, 2005.

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 :

(In thousands of U.S. dollars)	December 31, 2004	September 30, 2005
Raw materials	1,445	1,079
Finished goods	361	189
Provision for inventory obsolescence	(209)	(97)
Inventories, net	<u>1,597</u>	<u>1,171</u>

4. SHAREHOLDERS' EQUITY

During the nine-month period ended September 30, 2005, as a result of exercises of warrants and stock options, the Company issued 1,888,000 ordinary shares, nominal value €0.122 (\$0.162) per share.

5. EMPLOYEE STOCK-OPTION PLANS

During the 2005 nine-month period ending September 30, 2005, 1,058,000 options were granted to new employees and senior employees with a four year vesting period.

FLAMEL TECHNOLOGIES S.A.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

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;

FLAMEL TECHNOLOGIES S.A.

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

- 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

During the first nine months of 2005, Flamel reported total revenues of \$17.3 million, compared to \$36.7 million in the first nine months of 2004.

License and research revenues for the nine months ended September 30, 2005 of \$15.1 million included \$8.8 million from TAP Pharmaceuticals, Inc. and \$6.1 million from GSK. License and research revenues in the first nine months of 2004 of \$33.1 million largely consisted of revenues from Bristol-Myers Squibb (\$20.6 million), GlaxoSmithKline (\$7.4 million), TAP Pharmaceuticals (\$2.5 million), Servier (\$1.2 million), Biovail (\$0.7 million) and feasibility studies with other partners.

Revenues from product sales and services during the first nine months of 2005 declined to \$1.4 million compared to \$3 million in the year-ago period, reflecting our decision to de-emphasize contract manufacturing activities.

Other revenues for the nine months ended September 30, 2005 consisted of royalties from Corning.

On September 2, 2005, the Company received notification from TAP Pharmaceutical Products, Inc. ("TAP") of TAP's intention to terminate the contract for development of a Micropump® enabled formulation of lansoprazole. Under the terms of the contract between the Company and TAP, the decision is effective following 90 days after receipt of the termination letter.

Expenses increased to \$47 million from \$32.9 million in the year-ago period. This increase results from ongoing clinical trials for interferon and interleukin, an additional trial on a formulation of Basulin with an improved viscosity profile, and an increase in personnel. The increase in personnel stems in part from 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 252 employees over the first nine months of 2005, of whom 175 (or 70%) were scientists involved in research and development. Comparable numbers in 2004 were 214 employees, including 146 scientists.

Other income of \$5.3 million is mainly composed of the \$5.0 million termination fee (net) received in February 2005 from Bristol-Myers Squibb in full settlement of all amounts due to the Company.

Costs and expenses of Flamel's research and development in the first nine months of 2005 increased to \$37.6 million, from \$24.4 million in the year-ago period. This was largely as a result of increased clinical and preclinical study work, related to projects developed internally but also with our partners, the increase in employees and costs related to establishing additional facilities, and the increase of 3% in the value of the Euro against the U.S. dollar versus the year-ago period.

Costs of goods and services sold decreased to \$2 million, compared to \$2.6 million in the first nine months of 2004, largely in conjunction with decreased revenues in this category. SG&A grew to \$7.4 million, from \$5.8 million, due mostly to the expenses incurred by the Company in connection with the annual shareholders' meeting in the first half of the financial year and increases in personnel in Business Development and Marketing department.

Liquidity and Capital Resources

On September 30, 2005, the Company had \$89.4 million in cash, cash equivalents and marketable securities, compared to \$95.7 million on September 30, 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: November 22, 2005

Flamel Technologies S.A.

By: /s/ Stephen Willard

Name: Stephen Willard

Title: Chief Executive Officer