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**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 September 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 of 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.**

**ITEM. 1 Financial Statements (Unaudited)**

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

	Six months ended June 30, 2004 (restated)*	2005
Revenue:		
License and research revenue	\$ 20,838	\$ 12,803
Product sales and services	2,118	950
Other revenues	388	496
Total revenue	<u>23,344</u>	<u>14,249</u>
Costs and expenses:		
Cost of goods and services sold	(1,715)	(1,242)
Research and development	(15,891)	(26,042)
Selling, general and administrative	(4,039)	(4,462)
Total	<u>(21,645)</u>	<u>(31,746)</u>
Profit (loss) from operations	1,699	(17,497)
Interest income net	200	2,779
Foreign exchange gain (loss)	18	405
Other income (loss)	81	5,366
Income (loss) before income taxes	<u>1,998</u>	<u>(8,947)</u>
Income tax benefit (expense)	(23)	(98)
Net income (loss)	<u>\$ 1,975</u>	<u>(\$ 9,045)</u>
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	<u>\$ 0.09</u>	<u>(\$ 0.40)</u>
Diluted earnings (loss) per share	<u>\$ 0.08</u>	<u>(\$ 0.40)</u>
Weighted average number of shares outstanding (in thousands) :		
Basic	21,415	22,351
Diluted	24,120	22,351

\* Unrealized gains related to the marketable securities held by the Company as of June 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)

	Three months ended June 30, 2004 (restated)*	2005
Revenue:		
License and research revenue	\$ 7,537	\$ 5,354
Product sales and services	1,169	542
Other revenues	285	248
Total revenue	<u>8,991</u>	<u>6,144</u>
Costs and expenses:		
Cost of goods and services sold	(878)	(905)
Research and development	(8,019)	(12,587)
Selling, general and administrative	(2,179)	(2,568)
Total	<u>(11,076)</u>	<u>(16,060)</u>
Profit (loss) from operations	(2,085)	(9,916)
Interest income net	89	469
Foreign exchange gain (loss)	31	23
Other income (loss)	24	99
Income (loss) before income taxes	<u>(1,941)</u>	<u>(9,325)</u>
Income tax benefit (expense)	0	95
Net income (loss)	<u>(\$ 1,941)</u>	<u>(\$ 9,230)</u>
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	<u>(\$ 0.09)</u>	<u>(\$ 0.41)</u>
Diluted earnings (loss) per share	<u>(\$ 0.09)</u>	<u>(\$ 0.41)</u>
Weighted average number of shares outstanding (in thousands) :		
Basic	21,415	22,351
Diluted	21,415	22,351

\* Unrealized gains related to the marketable securities held by the Company as of June 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, except share data)**

	<u>December 31,</u> <u>2004</u>	<u>June 30,</u> <u>2005</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,591	\$ 914
Marketable securities	100,783	101,680
Accounts receivable	8,203	7,255
Inventory	1,597	966
Prepaid expenses and other current assets	5,598	5,971
Total current assets	<u>120,772</u>	<u>116,786</u>
Property and equipment, net	18,162	19,863
Other assets	—	—
Research and development tax credit receivable	6,533	5,800
Other long-term assets	141	136
Total other assets	6,674	5,936
Total assets	<u>\$ 145,608</u>	<u>\$ 142,585</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 218	\$ 0
Current portion of capital lease obligations	334	369
Accounts payable	9,660	15,486
Current portion of deferred revenue	2,528	795
Advances from customers	368	2,247
Accrued expenses	4,329	3,493
Other current liabilities	5,889	8,100
Total current liabilities	<u>23,326</u>	<u>30,490</u>
Long-term debt, less current portion	1,589	1,604
Capital lease obligations, less current portion	789	840
Deferred revenue, less current portion	860	487
Other long-term liabilities	2,287	4,057
Total long-term liabilities	<u>5,525</u>	<u>6,988</u>
Commitments and contingencies:	—	—
Shareholders' equity:		
Ordinary shares: 21,751,590 issued and outstanding at December 31, 2004 and 23,436,595 at June 30, 2005	3,135	3,398
Additional paid-in capital	148,389	159,364
Accumulated deficit	(47,806)	(56,851)
Deferred compensation	(1,122)	—
Accumulated other comprehensive income (loss)	14,161	(804)
Total shareholders' equity	<u>116,757</u>	<u>105,107</u>
Total liabilities and shareholders' equity	<u>\$ 145,608</u>	<u>\$ 142,585</u>

See notes to unaudited consolidated financial statements

**FLAMEL TECHNOLOGIES S.A.**

**Condensed Consolidated Statement of Cash Flows**  
**(Unaudited)**  
**(Amounts in thousands of dollars)**

	Six months ended June 30,	
	2004 (restated)*	2005
Cash flows from operating activities:		
Net income (loss)	\$ 1,975	(\$ 9,045)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	967	2,277
Gain (loss) on disposal of property and equipment	(27)	(192)
Gains on sales of marketable securities	(213)	(2,809)
Stock compensation expense	1,124	341
Increase (decrease) in cash from:		
Accounts receivable	2,832	29
Inventory	(296)	480
Prepaid expenses and other current assets	(2,084)	(1,065)
Research and development tax credit receivable	—	—
Accounts payable	2,756	6,984
Deferred revenue	(4,683)	(1,836)
Accrued expenses	(247)	1,943
Other current liabilities	—	(3,524)
Other long-term assets and liabilities	(377)	2,143
Net cash provided by (used in) operating activities	<u>1,727</u>	<u>(4,274)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(7,654)	(5,834)
Proceeds from disposal of property and equipment	119	192
Purchase of marketable securities	(8,082)	(244,350)
Proceeds from sales of marketable securities	<u>17,692</u>	<u>234,179</u>
Net cash provided by (used in) investing activities	<u>2,075</u>	<u>(15,813)</u>
Cash flows from financing activities:		
Funding from partner GSK	—	11,570
Repayment of loans or advances	—	(7,122)
Proceeds from loans or capital leases	246	450
Principal payments on capital lease obligations	(131)	(261)
Cash proceeds from issuance of ordinary shares and warrants	348	12,058
Net cash provided by financing activities	<u>463</u>	<u>16,695</u>
Effect of exchange rate changes on cash and cash equivalents	(70)	(285)
Net increase (decrease) in cash and cash equivalents	(126)	(3,677)
Cash and cash equivalents, beginning of the period	<u>1,199</u>	<u>4,591</u>
Cash and cash equivalents, end of the period	<u>\$ 1,073</u>	<u>\$ 914</u>

\* Unrealized gains related to the marketable securities held by the Company as of June 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 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	3,135.10	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	560,005	83	2,599				2,682
Amort. deferred compensation			(820)		1,122		302
Net income				(9,045)			(9,045)
Unrealized gains on available-for-sale securities						(1,885)	(1,885)
Translation adjustment						(13,080)	(13,080)
Comprehensive income							(\$ 24,010)
Balance at June 30, 2005	<u>23,436,595</u>	<u>\$ 3,398</u>	<u>\$ 159,364</u>	<u>(\$ 56,851)</u>	<u>\$ 0</u>	<u>(\$ 804)</u>	<u>\$ 105,107</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 six months ended June 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 \$3,482,000 and licensing fees of \$396,000 for the first six months of 2005.

In accordance with the supply agreement signed with GlaxoSmithKline in December 2004, the Company recognized research and development revenues of \$200,000 for the first six months of 2005.

In accordance with the license agreement signed with TAP in January 2004, the Company recognized research and development revenues of \$6,844,000 and licensing fees of \$1,660,000 for the first six months of 2005.

*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 \$496,000 corresponding to the royalties for the six-month period ended June 30, 2005.

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### 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	June 30, 2005
Raw materials	1,445	952
Finished goods	361	233
Provision for inventory obsolescence	(209)	(219)
Inventories, net	<u>1,597</u>	<u>966</u>

### 4. SHAREHOLDERS' EQUITY

During the first six months of 2005, as a result of exercises of warrants and stock options, the Company issued 1,685,005 ordinary shares, nominal value € 0.122 (\$0.162) per share.

### 5. EMPLOYEE STOCK OPTION PLANS

During the 2005 six-month period ending June 30, 2005, 292,500 options were granted to new employees and senior employees with a four year vesting period.

## FLAMEL TECHNOLOGIES S.A.

### 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

## FLAMEL TECHNOLOGIES S.A.

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 six months of 2005, Flamel reported total revenues of \$14.2 million, compared to \$23.3 million in the first half of 2004.

Flamel's 2005 first half license and research revenues of \$12.8 million included \$8.5 million from TAP Pharmaceuticals, Inc. and \$4.1 million from GSK. License and research revenues in the first half of 2004 were \$20.8 million. Revenues from product sales and services during the first half of 2005 declined to \$0.9 million compared to \$2.1 million in the year-ago period, reflecting our decision to de-emphasize contract manufacturing activities.

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

Expenses increased to \$31.7 million from \$21.6 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 expenses includes additional development work and preparations for supply of product to be made by Flamel for GlaxoSmithKline ("GSK") pursuant to the supply agreement signed with GSK in December 2004. Flamel employed 241 employees over the first six months of 2005, of whom 162 (or 70%) were scientists involved in research and development. Comparable numbers in 2004 were 197 employees, including 132 scientists.

Other income of \$5.4 million is mainly composed of the \$5.0 million termination fee received in February 2005 from Bristol-Myers Squibb in full settlement of all amounts due to Flamel. During the first half of 2004, other income totaled \$0.1 million.

Costs and expenses of Flamel's research and development in the first six months of 2006 increased to \$26.0 million, from \$15.9 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 facilities in which for them to work, and the increase of 4.7% in the value of the Euro against the U.S. dollar versus the year-ago period.

Costs of goods and services sold decreased to \$1.2 million, compared to \$1.7 million in the first half of 2004, largely in conjunction with decreased revenues in this category. SG&A grew to \$4.5 million, from \$4.0 million,

**FLAMEL TECHNOLOGIES S.A.**

due mostly to the costs associated with the Company's activities in connection with the annual shareholder's meeting.

Liquidity and Capital Resources

On June 30, 2005 the Company had \$102.6 million in cash, cash equivalents and marketable securities, compared to \$100.9 million on June 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.

Flamel Technologies S.A.

Dated: September 9, 2005

By: /S/ Stephen Willard

Name: Stephen Willard

Title: Chief Executive Officer