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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 December 2004

**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-\_\_\_\_\_

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**FLAMEL TECHNOLOGIES S.A.**

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

**CONDENSED STATEMENTS OF OPERATIONS**

(Amounts in thousands of dollars)

	Nine months ended Sept 30,	
	2003	2004
<b>Revenue:</b>		
License and research revenue	\$ 10,504	\$ 33,099
Product sales and services	2,800	2,993
Other revenues	594	600
Total revenue	13,898	36,692
<b>Costs and expenses:</b>		
Cost of goods and services sold	(2,694)	(2,629)
Research and development	(13,514)	(24,446)
Selling, general and administrative	(3,818)	(4,320)
Stock compensation expense	(14)	(1,481)
Total costs and expenses	(20,040)	(32,876)
Profit (loss) from operations	(6,142)	3,816
Interest income, net	207	1,411
Foreign exchange gain (loss)	(236)	30
Other income	999	308
Income, (loss) before income taxes	(5,172)	5,565
Income tax benefit (expenses)	(21)	(23)
Net income, (loss)	\$ (5,192)	\$ 5,542
<b>Earnings (loss) per share</b>		
Basic earnings (loss) per ordinary share	\$ (0.27)	\$ 0.26
Diluted earnings (loss) per share	\$ (0.27)	\$ 0.23
<b>Weighted average number of shares outstanding (in thousands):</b>		
Basic	19,292	21,434
Diluted	19,292	24,182

See notes to unaudited consolidated financial statements.

**FLAMEL TECHNOLOGIES S.A.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**  
**(Amounts in thousands of dollars )**

	Three months ended September 30,	
	2003	2004
<b>Revenue:</b>		
License and research revenue	\$ 4,245	\$ 12,261
Product sales and services	899	875
Other revenues	222	212
<b>Total revenue</b>	<u>5,366</u>	<u>13,348</u>
<b>Costs and expenses:</b>		
Cost of goods and services sold	(883)	(914)
Research and development	(4,989)	(8,555)
Selling, general and administrative	(1,467)	(1,406)
Stock compensation expense	(10)	(356)
<b>Total costs and expenses</b>	<u>(7,349)</u>	<u>(11,231)</u>
Profit (loss) from operations	(1,983)	2,117
Interest income, net	65	444
Foreign exchange gain (loss)	57	12
Other income	(8)	227
Income, (loss) before income taxes	(1,869)	2,800
Income tax benefit (expenses)	—	—
Net income, (loss)	<u>\$ (1,869)</u>	<u>\$ 2,800</u>
<b>Earnings (loss) per share</b>		
Basic earnings (loss) per ordinary share	\$ (0.11)	\$ 0.13
Diluted earnings (loss) per share	<u>\$ (0.11)</u>	<u>\$ 0.12</u>
<b>Weighted average number of shares outstanding (in thousands):</b>		
Basic	19,292	21,434
Diluted	<u>19,292</u>	<u>24,182</u>

See notes to unaudited consolidated financial statements.

**FLAMEL TECHNOLOGIES S.A.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**  
**(Amounts in thousands of dollars)**

	December 31, 2003	September 30, 2004
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 109,617	\$ 95,697
Accounts receivable	8,367	7,737
Inventory	1,057	1,301
Prepaid expenses and other current assets	1,694	3,378
Total current assets	<u>120,735</u>	<u>108,113</u>
Property and equipment, net	5,085	16,007
Other assets:		
Research and development tax credit receivable	1,348	1,324
Other long-term assets	84	130
Total other assets	<u>1,432</u>	<u>1,454</u>
Total assets	<u>\$ 127,252</u>	<u>\$ 125,574</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ —	\$ —
Current portion of capital lease obligations	257	281
Accounts payable	4,397	4,879
Current portion of deferred revenue	9,623	14,092
Advances from customers	344	309
Accrued expenses	3,159	3,259
Other current liabilities	88	281
Total current liabilities	<u>17,868</u>	<u>23,101</u>
Long-term debt, less current portion	1,675	1,645
Capital lease obligations, less current portion	261	665
Deferred revenue, less current portion	14,200	1,125
Other long-term liabilities	1,187	952
Total long-term liabilities	<u>17,323</u>	<u>4,387</u>
Commitments and contingencies:	—	—
Shareholders' equity:		
Ordinary shares: 21,391,590 issued and outstanding at December 31, 2003 and 21,651,590 at September 30, 2004	3,081	3,120
Additional paid-in capital	147,679	148,269
Accumulated deficit	(59,875)	(54,333)
Deferred compensation	(2,388)	(1,126)
Accumulated other comprehensive income (loss)	3,564	2,156
Total shareholders' equity	<u>92,061</u>	<u>98,086</u>
Total liabilities and shareholders' equity	<u>\$ 127,252</u>	<u>\$ 125,574</u>

Note: The balance sheet at December 31, 2003 has been derived from the audited financial statements at that date.

See notes to unaudited consolidated financial statements.

FLAMEL TECHNOLOGIES S.A.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)

(Amounts in thousands of dollars )

	Nine months ended September 30,	
	2003	2004
Cash flows from operating activities:		
Net income (loss)	\$ (5,192)	\$ 5,542
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	1,239	1,667
Gain on disposal of property and equipment	(373)	—
Grants recognized in other income	(870)	—
Stock compensation expense	4	1,482
Provision for accounts receivables and others	—	200
Increase (decrease) in cash from:		
Accounts receivable	(478)	355
Inventory	(122)	(259)
Prepaid expenses and other current assets	(1,178)	(1,694)
Deferred revenue	114	(8,089)
Accounts payable	847	552
Accrued expenses	255	317
Research and development tax credit receivable	276	—
Other long-term assets and liabilities	178	(48)
Net cash provided by (used in) in operating activities.	<u>(5,300)</u>	<u>25</u>
Cash flows from investing activities:		
Purchases of property and equipment	(800)	(12,624)
Proceeds from disposal of property and equipment	375	223
Net cash provided by (used in) in investing activities.	<u>(425)</u>	<u>(12,401)</u>
Cash flows from financing activities:		
Repayment of loans or advances	—	—
Proceeds from loans or capital leases	136	662
Principal payments on capital lease obligations	(164)	(257)
Cash proceeds from sale of ordinary shares	11,698	—
Cash proceeds from issuance of ordinary shares and warrants	—	629
Net cash provided by financing activities	<u>11,670</u>	<u>1,034</u>
Effect of exchange rate changes on cash and cash equivalents.	1,604	(2,578)
Net increase (decrease) in cash and cash equivalents	7,549	(13,920)
Cash and cash equivalents, beginning of period	14,527	109,617
Cash and cash equivalents, end of period	<u>\$ 22,076</u>	<u>\$ 95,697</u>

See notes to unaudited consolidated financial statements.

FLAMEL TECHNOLOGIES S.A.

CONDENSED CONSOLIDATED SHAREHOLDER'S EQUITY  
(Unaudited)

(Amounts in thousands of dollars except share data)

	<u>Share</u>	<u>Amount</u>	<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Deferred Compensation</u>	<u>Accumulated Other Com- prehensive Income</u>	<u>Shareholders Equity</u>
Balance January 1, 2004	21,391,590	\$ 3,081	\$ 147,679	\$ (59,875)	\$ (2,388)	\$ 3,564	\$ 92,061
Issuance of ordinary shares at €1,96(\$2,42)(*)	260,000	39	590				629
Amortization of deferred compensation	—	—	—	—	1,262	—	1,262
Net income	—	—	—	5,542	—	—	5,542
Other comprehensive income							
Translation adjustment	—	—	—	—	—	(1,408)	(1,408)
Comprehensive income							
Balance September 2004	<u>21,651,590</u>	<u>\$ 3,120</u>	<u>\$ 148,269</u>	<u>\$ (54,333)</u>	<u>\$ (1,126)</u>	<u>\$ 2,156</u>	<u>\$ 98,086</u>

(\*) Average issuance price

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 USGAAP 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, 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**

*2.1 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 \$225,000 and licensing fees of \$1,040,000 for the first nine months of 2004.

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 \$4,777,000 and licensing fees of \$2,590,000 for the first nine months of 2004. The licensing fees include a milestone payment of \$2,024,000 related to results achieved in September 2004.

In accordance with the license agreement signed with Biovail in February 2003, the Company recognized research and development revenues of \$596,000 and licensing fees of \$142,000 for the first nine 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 \$8,300,000 and licensing fees of \$12,349,000 for the first nine months of 2004. The licensing fees include a milestone payment of \$5,021,000 related to results achieved in March 2004. Due to the termination of the licensing agreement with Bristol Myers Squibb dated September 16<sup>th</sup>, 2004, the licensing fees includes \$7,328,000 of amortization of the initial up-front payment received in November 2003 (of which \$2,332,000 relates to quicker amortization starting with September 17<sup>th</sup>).

**FLAMEL TECHNOLOGIES S.A.**

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

In accordance with the license agreement signed with TAP, the Company recognized research and development revenues of \$1,995,000 and licensing fees of \$583,000 for the first nine months of 2004. The licensing fees include a milestone payment of \$520,000 related to results achieved in September 2004.

The Company recognized research and development revenues on feasibility studies with undisclosed partners for an amount of \$625,000 for the first nine months of 2004.

*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 \$600,000 corresponding to the royalties for the nine-month period ended September 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 :

<b>( In thousands of U.S. dollars)</b>	<b>Sept, 2004</b>
Raw materials	946
Finished goods	355
Inventories, net	<u>1,301</u>

**5. SHAREHOLDERS' EQUITY**

Over the 2004 first nine months, as a result of exercises of stock options, the Company issued 260,000 ordinary shares, nominal value €0,122 (\$0,149) per share.

**6. EMPLOYEE STOCK-OPTION PLANS**

During the 2004 nine-month period, 333,000 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

#### Results of Operations

Revenues for the first nine months ended September 30, 2004 increased to \$36.7 million, compared to \$13.9 million for the same 2003 period.

License and research revenue for the nine months ended September 30, 2004 of \$33.1 million included \$20.6 million from Bristol-Myers Squibb, \$7.4 million from GlaxoSmithKline, \$2.5 million revenue from TAP, \$1.2 million revenue from Servier, \$0.7 revenue from Biovail and \$0.7 million from feasibility studies with other partners.

License and research revenue for the first nine months of 2003 of \$10.5 million largely consisted of revenues from GlaxoSmithKline (\$4.4 million), Servier (\$2.8 million), BMS (\$0.8 million), Corning (\$0.3 million) and undisclosed partners.

Other revenues for the nine months ended September 30, 2004 consisted of royalties from Corning.

No significant other income have been recorded in the first nine months of 2004.

Other income in 2003 included the sale of equipment from the Company's pilot plant in Vénissieux for \$378,000, and \$772,000 in French government grants.

Revenues from product sales and services were \$3 million in the first nine months of 2004, compared to 2.8 million for the same period in 2003, reflecting concentration of the production on the first months of 2004. Starting with third quarter 2004, a transition away from contract manufacturing activities is planned.

Total operating costs for the nine months ended September 30, 2004 amounted to \$32.9 million, up from \$20 million in the comparable 2003 period, largely as a 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 versus the year ago period.

Overall, the Company has a profit of \$5.5 million for the nine months ended September 30, 2004 compared to a loss of \$(5.2) 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 September 30, 2004 the Company had \$95.7 million in cash, compared to \$22.1 million in cash at the end of the first nine months 2003.

**FLAMEL TECHNOLOGIES S.A.**

**ITEM. 6 Exhibits**

99.1 Press Release dated September 16, 2004 (Flamel Technologies Announces Termination of License Agreement for Long-Acting Insulin)

99.2 Press Release dated September 16, 2004 (Flamel Technologies Announces Initiation of Phase III trial for Micropump Formulation of a GlaxoSmithKline Product)

99.3 Press Release dated September 16, 2004 (Flamel Technologies Announces the License of Flamel's Micropump Technology to TAP Pharmaceutical Products Inc. for Lansoprazole)

**FLAMEL TECHNOLOGIES S.A.**

**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: December 30, 2004

By: /s/ Stephen Willard \_\_\_\_\_

Name: Stephen Willard

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

## FLAMEL TECHNOLOGIES S.A.

### EXHIBIT 99.1

#### **Flamel Technologies Announces Termination of License Agreement for Long-Acting Insulin**

**Lyon, France, September 16, 2004** Flamel Technologies (**NASDAQ:FLML**) announced today termination of the license agreement dated August 26, 2003 between the Flamel and Bristol-Myers Squibb Company ("BMS") for Flamel's formulation of long-acting human insulin (the "License Agreement").

BMS informed Flamel in a letter dated today that it has decided not to progress with Flamel to develop long-acting insulin. BMS said in the letter that it had made this decision for commercial and other reasons, including reallocation of resources behind other pipeline projects.

Gerard Soula, founder, president and chief executive officer of Flamel Technologies, said: "We are disappointed by the decision of BMS to terminate this partnership, but we respect their commercial decision. We will look actively for a new partner for this highly promising product."

Pursuant to the License Agreement, the termination will take effect in December, 2004. Various payments will be made by BMS to Flamel pursuant to the License Agreement. As a result of the termination, Flamel will recognize the balance of the initial upfront payment from BMS (approximately 13 million Euros) as income from this payment in the remaining two quarters of 2004.

Concurrently with this release, Flamel is also announcing today by separate releases two additional matters: the initiation of Phase III clinical trials by GSK of a Flamel Micropump® formulation of a major drug; and execution of a new license agreement with TAP Pharmaceutical Products Inc. for a long-acting Micropump® formulation of lansoprazole, the active ingredient in Tap's product, Prevacid®.

A conference call will be held at 8:00 a.m. Eastern Time on September 17, 2004 to discuss the matters contained in the three press releases. The dial-in number is 800-374-1498 (706-634-7261 from outside the USA and Canada). The pass code is 9986675.

*Flamel Technologies, S.A. is a biopharmaceutical company principally engaged in the development of two unique polymer-based delivery technologies for medical applications. Micropump® is a controlled release and taste- masking technology for the oral administration of small molecule drugs. Flamel's Medusa® technology is designed to deliver controlled-release formulations of therapeutic proteins.*

This document contains a number of matters, particularly as related to the status of various research projects and technology platforms, that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The presentation reflects the current view of management with respect to future events and is subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, uncertainties regarding market acceptance of products in development, the impact of competitive products and pricing, and the risks associated with Flamel's reliance on outside parties and key strategic alliances. These and other risks are described more fully in Flamel's Annual Report on the Securities and Exchange Commission Form 20-F for the year ended December 31, 2003.

**FLAMEL TECHNOLOGIES S.A.**

EXHIBIT 99.2

**Flamel Technologies Announces Initiation of Phase III trial for Micropump Formulation of a GlaxoSmithKline Product**

**Lyon, France, September 16, 2004** Flamel Technologies (**NASDAQ:FLML**) announced today that GSK has initiated Phase III clinical trials of a major, currently-marketed, GSK drug utilizing Flamel's Micropump® formulation.

Gerard Soula, PhD., founder, president and chief executive officer of Flamel, said, "We are very excited to be moving forward on this important project with GSK. The initiation of Phase III trials is an important indication of the success we have achieved with this product, and with our Micropump® technology generally. We hope that the results of these trials will further demonstrate the potential of our Micropump® technology."

Flamel's Micropump® technology was licensed to GSK for this drug in March, 2003.

Pursuant to the license, Flamel will receive a milestone of \$2 million, which will be recognized in the third quarter of 2004.

Concurrently with this release, Flamel is also announcing today by separate releases two additional matters; the termination of its license agreement for Flamel's Medusa® formulation of long-acting insulin with Bristol-Myers Squibb Company; and the execution of a new license agreement with Tap Pharmaceutical Products Inc. for a long-acting Micropump® formulation of lansoprazole, the active ingredient in Tap's product Prevacid®.

A conference call will be held at 8:00 a.m. Eastern Time on September 17, 2004 to discuss the matters contained in the three press releases. The dial-in number is 800-374-1498 (706-634-7261 from outside the USA and Canada). The pass code is 9986675.

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## FLAMEL TECHNOLOGIES S.A.

EXHIBIT 99.3

### **Flamel Technologies Announces the License of Flamel's Micropump Technology to TAP Pharmaceutical Products Inc. for Lansoprazole**

**Lyon, France, September 16, 2004** Flamel Technologies (**NASDAQ:FLML**) announced today that TAP Pharmaceutical Products Inc. ("TAP") has licensed the worldwide rights for Flamel's Micropump® technology, a controlled release technology for the oral administration of small molecule drugs, for potential use in the delivery of lansoprazole, the active ingredient in TAP's product Prevacid®.

Prevacid is the seventh largest selling drug in the United States, with 2003 sales of nearly \$3.2 billion in the United States. Prevacid works by helping prevent the creation of acid in the stomach, which may cause heartburn and can lead to a condition known as acid-reflux disease, caused when stomach acid backs up into the esophagus.

Under the terms of the license agreement, TAP will pay all costs of further development, testing, regulatory approval and marketing of the new formulation. Flamel also has the potential to earn more than \$100 million of milestones and will receive royalties on sales of the product.

Gerard Soula, PhD., founder, president and chief executive officer of Flamel, said, "We are very pleased to develop with TAP an extended release formulation of lansoprazole using our Micropump technology. This improved formulation will be investigated for providing better efficacy for patients. This is a new key opportunity for Flamel to apply its unique Micropump® technology."

"This collaboration represents an opportunity to potentially expand the Prevacid franchise beyond our current formulations, including Prevacid SoluTab and Prevacid IV for injection," said Xavier Frapaise, MD, vice president of research and development for TAP Pharmaceutical Products Inc.

The License Agreement also contemplates potential further arrangements between TAP and Flamel with respect to other proton pump inhibitors.

Concurrently with this release, Flamel is also announcing today by separate releases two additional matters: the termination of a licensing agreement for Flamel's Medusa® formulation of long-acting insulin with Bristol-Myers Squibb Company; and the initiation of Phase III clinical trials by GSK of a Flamel Micropump® formulation of a major drug.

A conference call will be held at 8:00 a.m. Eastern Time on September 17, 2004 to discuss the matters contained in the three press releases. The dial-in number is 800-374-1498 (706-634-7261 from outside the USA and Canada). The pass code is 9986675.

#### **Webcast**

*Flamel Technologies, S.A. is a biopharmaceutical company principally engaged in the development of two unique polymer-based delivery technologies for medical applications. Micropump® is a controlled release and taste- masking technology for the oral administration of small molecule drugs. Flamel's Medusa® technology is designed to deliver controlled-release formulations of therapeutic proteins.*

*TAP Pharmaceutical Products Inc., located in Lake Forest, Ill., is a joint venture between Abbott Laboratories, headquartered in Abbott Park, Ill., and Takeda Pharmaceutical Company Limited of Osaka, Japan. TAP markets Prevacid® (lansoprazole) and Lupron Depot® (leuprolide acetate for depot suspension). For more information about TAP Pharmaceutical Products Inc. and its products, visit the company's Web site at [www.tap.com](http://www.tap.com).*

This document contains a number of matters, particularly as related to the status of various research projects and technology platforms, that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The presentation reflects the current view of management with respect to future events and is subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, uncertainties regarding market acceptance of products in development, the impact of competitive products and pricing, and the risks associated with Flamel's reliance on outside parties and key strategic alliances. These and other risks are described more fully in Flamel's Annual Report on the Securities and Exchange Commission Form 20-F for the year ended December 31, 2003.