# 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 March 2005

# 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 

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 o 

No 

No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_

## INFORMATION FILED WITH THIS REPORT

## Document Index

| 99.1 | Press release dated March 3, 2005 relating to the termination of a licensing agreement with Biovail for Genvir®.   |
|------|--|
| 99.2 | Press release dated March 7, 2005 relating to the announcement of results of meeting of shareholders and the setting of the fourth quarter earnings release date and announcing conference call. |
| 99.3 | Press release dated March 11, 2005 relating to the fourth quarter and year-end results.  |

## **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: March 14, 2005

Flamel Technologies S.A.

By: /s/ Stephen H. Willard

Name: Stephen H. Willard

Title: Executive Vice President, Chief Financial Officer

and General Counsel

#### FLAMEL TECHNOLOGIES S.A.

EXHIBIT 99.1

## Flamel Technologies Announces Termination of Licensing Agreement for Genvir® and Recovery of Rights

**Lyon, France, March 3, 2005** Flamel Technologies (<u>NASDAQ:FLML</u>) announced today that it has terminated the License Agreement with Biovail Laboratories Inc. ("Biovail") for Flamel's long-acting acyclovir formulation, Genvir®.

The License Agreement, which was signed in February 2003, granted a license to Biovail in the U.S. and Canada, subject to initiation by Biovail of certain clinical trials in the United States. The License Agreement provided for termination by Flamel in the event the clinical trials were not initiated by a date set out in the License Agreement.

Gerard Soula, PhD., founder, president and chief executive officer of Flamel, said, "Despite having granted additional time to Biovail, we regret that so much time has passed without initiation of U.S. clinical trials. We believe that now is the time to work actively to find another partner to conduct these trials and to handle registration and marketing of Genvir®".

A conference call to discuss this matter has been scheduled for Friday morning, March 4th at 8:30 am EST. The dial-in number for the conference call is 800 374-1498 in the United States and Canada. International callers should dial 706-634-7261.

This document contains a number of matters, particularly as related to financial projections and 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.

 $CONTACT: Flamel\ Technologies,\ S.A.$ 

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### FLAMEL TECHNOLOGIES S.A.

EXHIBIT 99.2

## Flamel Technologies Announces Results of Meeting of Shareholders; Sets Projected Release Date for 2004 Results and Conference Call

**Lyon, France, March 7, 2005** Flamel Technologies (**NASDAQ: FLML**) announced today the results of its extraordinary meeting of shareholders held on March 4, 2005. All management-recommended proposals presented to the shareholders by the Board of Directors, including the granting of warrants to the members of the Scientific Advisory Board of Flamel, were approved with the support of approximately 90% or more of those voting.

Dr. Gerard Soula, president and chief executive of Flamel Technologies, S.A. said: "Since our company's founding, our scientific advisory board has been an important part of our development. We are pleased that our shareholders gave their support to our Scientific Advisory Board and to the Company's effort to attract and keep talented employees."

### Q4 and Year-end 2004 Conference Call

The Company anticipates release of its 2004 financial results after the market close on Friday, March 11th. A conference call to discuss the results has been scheduled for Monday morning, March 14th at 8:30 am EST. The dial-in number for the conference call is 800 374-1498 in the United States and Canada. International callers should dial 706-634-7261.

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.

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#### FLAMEL TECHNOLOGIES S.A.



## Flamel Technologies Announces Fourth Quarter and Year-End Results; Fourth Quarter Results Show Profit of \$0.28 per Diluted Share on License and Research Revenue Growth

**Lyon, France, March 11, 2005** Flamel Technologies (<u>NASDAQ: FLML</u>) today announced its financial results for the fourth quarter and year ended December 31, 2004.

### Flamel's Fourth Quarter Results

Flamel reported net income of \$6.5 million (\$0.28 per diluted share) for the fourth quarter of 2004, versus a gain of \$1.7 million (\$0.07 per diluted share) in the fourth quarter a year ago.

Total revenues for the fourth quarter 2004 were \$18.7 million versus \$11.3 million in the year ago period. License and research revenue totaled \$17.8 million during the quarter, compared to \$10.5 million in 2003. License and research revenue recognized during the quarter included revenues from GlaxoSmithKline and TAP Pharmaceuticals, as well as the accelerated amortization of the upfront payment received from Bristol-Myers Squibb for the Basulin® license. Product sales and services during the fourth quarter of 2004 were \$0.8 million versus \$0.6 million last year.

Expenses during the quarter grew to approximately \$13.7 million in the period, up from \$9.8 million in the fourth quarter of 2003. Expenses increased as a result of initiation of clinical trials on Flamel's formulations of Interferon alpha and Interleukin-2, as well as formulation and development activities applying Flamel's technology platforms to additional drugs. Reported expenses also increased due to the increase in value of the Euro versus the US dollar in the twelve-month period. The fourth quarter results include charges which respect to withholding tax and interest income which have application across all four quarters.

### Flamel's 2004 Annual Results

For the calendar year 2004, Flamel reported that its operating revenue grew to \$55.4 million, compared to \$25.2 million in 2003. License and research revenue grew by 143%, increasing to \$50.9 million in 2004 from approximately \$21 million in 2003. License and research revenue in 2004 included revenues from TAP, Bristol Myers, Biovail, GlaxoSmithKline, Merck, and Servier as well as from others. The agreements with Bristol-Myers and Biovail are now terminated. A portion of the increase in license and research revenue resulted from the accelerated amortization of \$12.8 million, beginning September 16th 2004, of the \$20 million upfront payment made to Flamel by Bristol-Myers Squibb in October 2003. Product sales and services for the year 2004 increased to \$3.8 million versus approximately \$3.4 million in the year 2003.



Expenses in 2004 increased to \$46.6 million from \$29.9 million in 2003. The increase was largely in research and development expenses concerning the formulation of additional drugs using our technologies, particularly Interferon-alpha and Interleukin-2.

The company reported a net gain for the year 2004 of \$12.0 million, or \$0.51 per diluted share, as compared with a loss of approximately (\$3.5 million), or (\$0.20) per share for the year 2003.

Flamel's cash on hand at year-end 2004 was \$105 million, compared to \$109 million at the end of 2003.

Stephen Willard, chief financial officer of Flamel Technologies, noted: "Flamel has maintained its strong balance sheet in 2004, while making significant progress in the development of products. Our results in the fourth quarter of 2004 were largely the result of accelerated amortization of the remaining portion of the \$20 million upfront licensing fee received from Bristol Myers in 2003. More importantly, we were able to develop our internal pipeline throughout the year and make significant investment in people, plant and equipment, while maintaining over \$100 million in cash on the balance sheet."

Dr. Gerard Soula, founder, president and CEO of Flamel, said: "The year 2004 was a very positive one for Flamel and its team. We initiated two new clinical trials for the Medusa®-enabled formulations of Interferon-alpha and Interleukin-2 in Hepatitis C and renal cancer, respectively. Both of these formulations could have even wider applicability if we are successful in lowering their side-effect profiles. Our ongoing work with TAP Pharmaceuticals on an improved formulation of lansoprazole continues to progress smoothly. We are excited about the prospects for the partnership we have with GlaxoSmithKline in the development of an improved formulation of one of their already-marketed products. In December of last year, we signed a supply agreement with GSK whereby we will be provided with equipment to produce this formulation at no cost to us. This equipment is being installed at our plant in Pessac. I am pleased to enter 2005 with a strong financial position, excellent partners and a rich pipeline. Our strategy remains to work aggressively to obtain partnerships for the other products in our pipeline."

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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.

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Schedule Attached



# Condensed Consolidated Statement of Operations (unaudited)

# Amounts in thousands of dollars (except share data)

|   |           | Three months ended Dec 31, |            | Twelve months ended Dec 31, |  |
|---|-----------|----------------------------|------------|-----------------------------|--|
|   | 2003      | 2004                       | 2003       | 2004                        |  |
| Revenue:  |           |                            |            |                             |  |
| License and research revenue                                  | \$ 10,474 | \$ 17,794                  | \$ 20,978  | \$ 50,893                   |  |
| Product sales and services                                    | 611       | 762                        | 3,411      | 3,755                       |  |
| Other revenue   | 184       | 162                        | 778        | 762                         |  |
| Total revenue   | 11,269    | 18,718                     | 25,167     | 55,410                      |  |
| Costs and expenses:   |           |                            |            |                             |  |
| Cost of goods and services sold                               | (982)     | (973)                      | (3,676)    | (3,602)                     |  |
| Research and development                                      | (6,709)   | (10,913)                   | (20,223)   | (35,359)                    |  |
| Selling, general and administrative                           | (1,796)   | (1,676)                    | (5,614)    | (5,996)                     |  |
| Stock compensation expense                                    | (339)     | (137)                      | (353)      | (1,618)                     |  |
| Total costs and expenses                                      | (9,826)   | (13,699)                   | (29,866)   | (46,575)                    |  |
| Profit (loss) from operations                                 | 1,443     | 5,019                      | (4,699)    | 8,835                       |  |
| Other income  | 129       | (1,290)                    | 1,128      | (982)                       |  |
| Interest income (expense), net                                | 386       | (1,278)                    | 593        | 133                         |  |
| Foreign exchange gain (loss)                                  | (783)     | (273)                      | (1,019)    | (243)                       |  |
| Income, (loss) before income taxes                            | 1,175     | 2,178                      | (3,997)    | 7,743                       |  |
| Income tax benefit  | 524       | 4,306                      | 503        | 4,283                       |  |
| Net gain (loss)   | \$ 1,699  | \$ 6,484                   | \$ (3,494) | \$ 12,026                   |  |
| Earnings (loss) per share:                                    |           |                            |            |                             |  |
| Basic earnings (loss) per ordinary share                      | \$ 0.08   | \$ 0.30                    | \$ (0.20)  | \$ 0.56                     |  |
| Diluted earnings (loss) per share                             | \$ 0.07   | \$ 0.28                    | \$ (0.20)  | \$ 0.51                     |  |
| Weighted average number of shares outstanding (in thousands): |           |                            |            |                             |  |
| Basic   | 21,204    | 21,752                     | 17,762     | 21,513                      |  |
| Diluted   | 23,370    | 23,531                     | 17,762     | 23,559                      |  |