



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 March 2003

**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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## INFORMATION FILED WITH THIS REPORT

### Document Index

- 99.1 Press release dated March 18, 2003 (“Flamel Technologies Announces Fourth Quarter and Year-End Results; 2002 Results Show Profit of \$0.18 Per Diluted Share and Improved Cash Position”).
- 99.2 Press release dated March 24, 2003 (“Human Studies show Flamel Technologies’ Medusa® Protein Delivery System BASULIN® Challenges Lantus® for the 24-hour Controlled Release of Insulin”).
- 99.3 Press release dated March 28, 2003 (“GlaxoSmithKline and Flamel Technologies Announce Licence Agreement”).

## 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: April 1, 2003

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

[FLAMEL TECHNOLOGIES LOGO]

**For Immediate Release**

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**Flamel Technologies Announces Fourth Quarter and Year-End  
Results; 2002 Results Show Profit of \$0.18 Per Diluted Share and Improved  
Cash Position**

**2002 Is the Fourth Consecutive Year of Improved Results for Flamel**

**LYON, France— March 18, 2003**—Flamel Technologies (Nasdaq:FLML) today announced its financial results for the fourth quarter and year ended December 31, 2002.

Flamel's Calendar Year 2002 Results

For the calendar year 2002, Flamel reported that its revenues and other income grew to \$21.0 million, compared to revenues of \$13.1 million in 2001. In 2002, license and research revenues totaled \$14.6 million, compared to \$9.9 million in 2001. License and research revenues in 2002 included revenues from Servier and GlaxoSmithKline, as well as from other undisclosed partners.

Product sales and services for 2002 totaled \$2.9 million, compared to \$2.0 million in 2001. This revenue is the combined result of sales of clinical batch materials to our partners and certain contract manufacturing for various parties.

Royalties and other income in 2002 totaled \$3.5 million, compared to \$1.2 million reported in 2001. This largely reflects a payment for the Welcome Trust in connection with the settlement of litigation in respect of Flamel's product Genvir™.

Expenses increased to \$18.6 million for 2002, compared to \$16.2 million in 2001. Research and development expenses increased largely as a result of the change in the exchange rate of the Euro against the U.S. dollar. Slight increases in cost of goods sold and G&A expenses year over year were similarly affected by the exchange rate.

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Net income in 2002 was \$3.0 million, or \$0.18 per diluted share, compared to a net loss of \$2.9 million, or a loss of (\$0.18) per share outstanding, in 2001. Cash on hand at December 31, 2002, was \$14.5 million, compared to \$5.3 million at year-end 2001.

#### Flamel's Fourth Quarter 2002 Results

In the fourth quarter, Flamel reported total revenues of \$5.0 million, compared to \$4.6 million for the same period of 2001. The company's 2001 fourth quarter revenues included \$1.4 million of deferred revenue which was recognized in respect of the termination of Flamel's contract with Novo Nordisk for long-acting insulin.

Product sales and services revenues in the fourth quarter of 2002, consisting largely of contract manufacturing income, were approximately \$0.9 million, compared to \$0.5 million in the fourth quarter of last year.

Other income for the quarter totaled approximately \$0.3 million, compared to \$0.4 million in the fourth quarter of last year. Costs and expenses were \$5.9 million in the quarter, compared to \$4.7 million in the fourth quarter of the prior year.

The company's fourth quarter expenses largely reflect the increase in the value of the Euro against the U.S. dollar and do not reflect a material increase in numbers of employees or external costs.

The net loss was (\$0.3) million for the fourth quarter of 2002, compared to a loss of (\$0.1) million in the fourth quarter of 2001. On a per share basis, the net loss per ordinary share for the quarter was (\$0.02), compared with breakeven results for the fourth quarter of 2001. "Flamel has made substantial strides in 2002, with its first full year of profitability and a dramatic increase in its cash position," noted Stephen Willard, Flamel's Chief Financial Officer. "Revenues and other income in 2002 increased 62%, while increases in our expenses were held relatively constant after giving effect to the increasing value of the Euro against the U.S. dollar. Flamel's profit of \$3.0 million in 2002 is significant and reflects an increase of \$5.9 million over the results a year ago. Our cash increased markedly to \$14.5 million, from \$5.3 million at the end of last year."

"The positive financial performance of 2002 result from the technical and clinical successes of our Micropump® technology, which have triggered the execution of new deals and payment of milestones," reported Dr. Gerard Soula, Flamel's President and Chief Executive Officer. "We have announced two licensing deals, one with Servier and one with GlaxoSmithKline, and have achieved additional technical milestone payments in respect of each project. We have also entered into partnerships with other major pharmaceutical companies which remain undisclosed. Flamel today has a rich portfolio of products based on the Micropump® technology, including its proprietary products Metformin XL, a long-acting metformin, and Genvir™, a long-acting acyclovir, for which Flamel is aggressively seeking partners."

Dr. Soula continued, "With our Medusa® technology for the controlled release of proteins and peptides, we have signed two new feasibility study agreements, and we have launched a second clinical trial in humans with our improved controlled-release formulation of human

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insulin. The results of this trial are expected to be released shortly. In addition, we have obtained particularly promising results with our long-acting formulations of interferon alpha and interleukin-2. We believe that both of our core technologies have wide potential application and are becoming widely recognized among major worldwide pharmaceutical companies, with resulting potential benefits for our company and its stockholders.”

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

Flamel’s expertise in polymer science has also been instrumental in the development of a photochromic eyeglass lens product now marketed by Corning Inc.

*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, 2001.*

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Schedule Attached

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**FLAMEL TECHNOLOGIES S.A.**  
**CONSOLIDATED STATEMENT OF OPERATIONS**  
(Amounts in thousands, except per share data)

|  | Three months ended |                    | Twelve months ended |                    |
|--|--------------------|--------------------|---------------------|--------------------|
|  | <u>December 31</u> | <u>December 31</u> | <u>December 31</u>  | <u>December 31</u> |
|  | 2002<br>US \$      | 2001<br>US \$      | 2002<br>US \$       | 2001<br>US \$      |
| <b>REVENUES</b>  |                    |                    |                     |                    |
| Licence and research revenue                           | 3,792              | 3,639              | 14,593              | 9,858              |
| Product sales and services                             | 898                | 516                | 2,865               | 2,009              |
| Royalties and other income                             | 280                | 406                | 948                 | 1,220              |
| <b>Total Revenues</b>                                  | <b>4,970</b>       | <b>4,561</b>       | <b>18,406</b>       | <b>13,087</b>      |
| <b>COSTS and EXPENSES</b>                              |                    |                    |                     |                    |
| Cost of goods and services sold                        | (835)              | (644)              | (2,373)             | (2,166)            |
| Research and development                               | (3,615)            | (3,055)            | (12,239)            | (10,662)           |
| Selling, general and administrative                    | (1,463)            | (957)              | (3,999)             | (3,391)            |
| Stock compensation expense                             | (5)                | (5)                | (18)                | (23)               |
| <b>Total Costs and Expenses</b>                        | <b>(5,918)</b>     | <b>(4,661)</b>     | <b>(18,629)</b>     | <b>(16,242)</b>    |
| <b>LOSS FROM OPERATIONS</b>                            | <b>(948)</b>       | <b>(100)</b>       | <b>(223)</b>        | <b>(3,155)</b>     |
| Interest income, net                                   | 92                 | 27                 | 248                 | 240                |
| Foreign exchange gain, (loss)                          | (24)               | 8                  | (99)                | 55                 |
| Other income   |                    |                    | 2,526               |                    |
| <b>INCOME, (LOSS) BEFORE INCOME TAXES</b>              | <b>(880)</b>       | <b>(65)</b>        | <b>2,452</b>        | <b>(2,860)</b>     |
| Income tax benefit                                     | 564                | (14)               | 553                 | (14)               |
| <b>NET INCOME, (LOSS)</b>                              | <b>(316)</b>       | <b>(79)</b>        | <b>3,005</b>        | <b>(2,874)</b>     |
| <b>BASIC EARNINGS, (LOSS) PER SHARE</b>                | <b>\$ (0.02)</b>   | <b>\$ (0.00)</b>   | <b>\$ 0.19</b>      | <b>\$ (0.18)</b>   |
| <b>DILUTED EARNINGS PER SHARE</b>                      | <b>\$ (0.02)</b>   | <b>\$ (0.00)</b>   | <b>\$ 0.18</b>      | <b>\$ (0.18)</b>   |
| Weighted average number of ordinary shares outstanding |                    |                    |                     |                    |
| basic  | 16,198             | 16,198             | 16,198              | 16,198             |
| diluted  | 16,198             | 16,198             | 16,711              | 16,198             |

**(UNAUDITED)**



**For Immediate Release**

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**Human Studies show Flamel Technologies' Medusa® Protein  
Delivery System BASULIN® Challenges Lantus®  
for the 24-hour Controlled Release of Insulin**

LYON, France—(Business Wire)—March 24, 2003—Flamel Technologies S.A. (NASDAQ:FLML - news) announced today that the results of its second human clinical trial on BASULIN® have been completed, with excellent results. The trial, which was conducted on 16 healthy volunteers using the clamp technique, showed that BASULIN provided a similar pharmacokinetic profile to the Aventis product, Lantus®, with at least the same efficacy.

Dr Gerard Soula, president and ceo of Flamel explained: 'Our first clinical trial proved the concept of our controlled-release, 24-hour insulin against the Novo Nordisk product, NPH. This new study was designed to compare our optimized formulation of BASULIN with Lantus, a recently introduced product which is increasingly recognized as the best long-acting product to treat Type I and Type II diabetes.' The study was designed to measure the efficacy of BASULIN versus Lantus by infusing glucose over a twenty-four hour period in order to compensate for the hypoglycemic effect of the insulin release by the two formulations.

Dr. Soula continued: 'We are very excited by the results which show that BASULIN released insulin during a twenty-four hour period at a constant rate with good bioavailability and excellent local tolerance. I believe that this is a key technical and clinical milestone for the development of BASULIN.'

'Among BASULIN's many advantages,' continued Dr. Soula, 'the most important is that BASULIN is a controlled release of human insulin, not an artificial insulin like Lantus. It is recognized that the most significant breakthrough for insulin therapy has been the use of human insulin, instead of bovine or porcine insulin, which are different by one or two amino acids in the sequence of the protein. Flamel's goal with BASULIN is to deliver human insulin in order to reduce the risk of potential immune response which can be created by non-human insulin, such as artificial or animal insulins. I believe controlled-release human insulin products are what physicians and patients have been seeking for decades.'

Flamel is preparing a Phase II-a study of Basulin, while actively negotiating with a number of major biopharmaceutical companies for the licensing of this product.

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Dr. Soula also announced that: 'Flamel intends also to do a human clinical study with its Medusa® formulation of interferon alpha, versus pegylated interferon. We expect these studies will show the potential of our Medusa technology.'

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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, 2001. Flamel assumes no obligation to update any forward-looking statements. The name Lanus® is a trademark of Avantis Pharmaceuticals.

## GlaxoSmithKline and Flamel Technologies Announce Licence Agreement

LONDON, England and LYON, France March 28, 2003 GlaxoSmithKline (LSE and NYSE:[GSK](#) - [news](#)) and Flamel Technologies S.A. (NASDAQ:[FLML](#) - [news](#)) announced today that they have entered into an agreement whereby Flamel has licensed its controlled-release Micropump® technology to GlaxoSmithKline ('GSK') to develop a new formulation for an undisclosed existing product. Flamel will receive an upfront payment of \$2M and additional milestone payments upon achievement of certain events, and royalties on sales of the product. Based on the continued successful development and commercialization of this formulation, GSK and Flamel estimate that payments to Flamel could range up to \$45 million by the end of the first year following launch, of which \$25M is attributable to the product reaching certain milestones. Flamel may also participate in the manufacture of product. Additional terms of the agreement have not been disclosed.

Gerard Soula, PhD., president and chief executive officer of Flamel, said "We are very excited about this new development agreement with GSK. We are confident of the potential of Micropump technology for these large, and still growing, markets. This additional agreement further demonstrates the interest of major worldwide pharmaceutical companies in our versatile technology platforms. Moreover, this is our second license agreement with GSK within the past nine months, based on Micropump technology. It confirms the common interest of the two companies to work together. I am very pleased and proud to see GSK, one of the world's premier pharmaceutical companies, expand its relationship with Flamel."

*Lawson Macartney, DVM., PhD., FRCPATH, Head of the Cardiovascular, Metabolic and Urology Therapeutic Areas, GSK, added, "This collaboration will help us to maintain our leadership in product research and development. We are eager to develop with Flamel, leading technologies within our therapeutic areas with the objective of providing the next generation of medicines."*

*GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.*

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