## 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 January 2009

## **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- 🗹 Form 40- o

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 🗹

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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## PART 1. FINANCIAL INFORMATION

## Item 1. Condensed Consolidated Financial Statements – Unaudited

## **Condensed Consolidated Statement of Operations**

(Unaudited)

(Amounts in thousands of dollars, except per share data)

	Three months en	
	2007	2008
Revenue:		
License and research revenue	\$ 1,973	\$ 3,140
Product sales and services	4,824	3,023
Other revenues	2,222	2,972
Total revenue	9,019	9,135
Costs and expenses:		
Cost of goods and services sold	(4,251)	(2,613)
Research and development	(9,908)	(8,239)
Selling, general and administrative	(4,124)	(2,899)
Total	(18,283)	(13,751)
Profit (loss) from operations	(9,264)	(4,616)
Interest income net	411	377
Foreign exchange gain (loss)	(229)	220
Other income (loss)	16	58
Income (loss) before income taxes	(9,066)	(3,961)
Income tax benefit (expense)	(40)	1,657
Net income (loss)	<u>\$ (9,106</u> )	\$ (2,304)
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	\$ (0.38)	\$ (0.10)
Diluted earnings (loss) per share	<u>\$ (0.38)</u>	\$ (0.10)
Weighted average number of shares outstanding (in thousands) :		
	24.042	24.077
Basic	24,042	24,077
Diluted	24,042	24,077

See notes to condensed consolidated financial statements

# Condensed Consolidated Statement of Operations (Unaudited)

(Amounts in thousands of dollars, except per share data)

	Nine months ended	l September 30,
	2007	2008
Revenue:		
License and research revenue	\$ 6,891	\$ 9,841
Product sales and services	15,042	10,918
Other revenues	4,160	8,394
Total revenue	26,093	29,153
Costs and expenses:		
Cost of goods and services sold	(12,430)	(7,263)
Research and development	(33,666)	(26,476)
Selling, general and administrative	(12,787)	(10,659)
Total	(58,883)	(44,398)
		/
Profit (loss) from operations	(32,790)	(15,245)
Interest income net	1,305	1,127
Foreign exchange gain (loss)	(311)	76
Other income (loss)	54	159
Income (loss) before income taxes	(31,742)	(13,883)
Income tax benefit (expense)	(58)	4,525
Net income (loss)	\$ (31,800)	\$ (9,358)
		· (
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	\$ (1.32)	\$ (0.39)
Diluted earnings (loss) per share	\$ (1.32)	\$ (0.39)
Diluced curnings (1000) per share		ф <u>(0.55</u> )
Weighted average number of shares outstanding (in thousands) :		
Basic	24 017	24.000
Diluted	24,017	24,066
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See notes to condensed consolidated financial statements

#### Condensed Consolidated Balance Sheet (Unaudited) (Amounts in thousands of dollars, except share data)

	December 31, 2007	September 30, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 26,313	\$ 28,405
Marketable securities	14,749	4,414
Accounts receivable	4,987	7,131
Inventory	1,771	1,683
Research and development tax credit receivable current portion	5,490	5,334
Prepaid expenses and other current assets	2,800	2,634
Total current assets	56,110	49,601
Property and equipment, net	35,140	29,890
Other assets:		
Research and development tax credit receivable less current portion	9,932	9,055
Other long-term assets	219	221
Total other assets	10,151	9,276
Total assets	\$ 101,401	\$ 88,767

LIABILITIES

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Current liabilities:		
Current portion of long-term debt	724	703
Current portion of capital lease obligations	256	102
Accounts payable	8,568	4,912
Current portion of deferred revenue	2,948	1,419
Advances from customers	1,215	1,586
Accrued expenses	5,369	5,086
Other current liabilities	5,875	4,740
Total current liabilities	24,955	18,548
Long-term debt, less current portion	2,400	2,332
Capital lease obligations, less current portion	44	105
Deferred revenue, less current portion	336	_
Other long-term liabilities	19,039	17,119
Total long-term liabilities	21,819	19,556

## Commitments and contingencies:

Shareholders' equity:

Ordinary shares: 24,051,590 issued and outstanding at December 31, 2007 and 24,106,600 at September 30,		
2008 (nominal value 0.122 euro)	3,490	3,500
Additional paid-in capital	185,173	191,086
Accumulated deficit	(148,121)	(157,479)
Accumulated other comprehensive income (loss)	14,085	13,556
Total shareholders' equity	54,627	50,663
Total liabilities and shareholders' equity	\$ 101,401	\$ 88,767

See notes to condensed consolidated financial statements



## Condensed Consolidated Statement of Cashflows

(Unaudited)

(Amounts in thousands of dollars, except share data)

	Nine mon Septem	
	2007	2008
Cash flows from operating activities:		
Net income (loss)	\$ (31,800)	\$ (9,358
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	4,532	5,535
Loss (gain) on disposal of property and equipment	(11)	
Gains on sales of marketable securities	(217)	(274
Grants recognized in other income and income from operations	—	(1,408
Stock compensation expense	9,267	6,246
Increase (decrease) in cash from:		
Accounts receivable	(1,662)	(2,432
Inventory		41
Prepaid expenses and other current assets	579	91
Research and development tax credit receivable	614	633
Accounts payable	2,828	(1,206
Deferred revenue	(71)	(1,885
Accrued expenses	125	292
Other current liabilities	1,546	376
Other long-term assets and liabilities	(3,336)	(1,476
Net cash provided by (used in) operating activities	(17,606)	(4,825
Cash flows from investing activities: Purchases of property and equipment Proceeds from disposal of property and equipment	(11,198) 14	(3,436
Proceeds from sales of marketable securities	(69,935)	(47,280
Purchase of marketable securities	70,704	58,105
Net cash provided by (used in) investing activities	(10,415)	7,389
Net cash provided by (used in) investing activities	(10,413)	/,309
Cash flows from financing activities:		
Funding from partner GSK	2,776	
Proceeds from loans or conditional grants	134	
Principal payments on capital lease obligations	(321)	(89
Cash proceeds from issuance of ordinary shares and warrants	528	540
Net cash provided by (used in) financing activities	3,117	451
Effect of exchange rate changes on cash and cash equivalents	2,616	(923
Net increase (decrease) in cash and cash equivalents	(22,288)	2,092
Cash and cash equivalents, beginning of year	51,827	26,313
Cash and cash equivalents, end of year	\$ 29,539	\$ 28,405

See notes to condensed consolidated financial statements

# Consolidated Statement of Shareholders' Equity (Unaudited) (Amounts in thousands of dollars)

		-	Additional		Accumulated Other Comprehen-	
	Ordinary : Shares	Shares Amount	Paid-in Capital	Accumulated Deficit	sive Income (Loss)	Shareholders' Equity
Balance at January 1, 2008	24,051,590	\$ 3,490	\$185,173	\$ (148,121)	\$ 14,085	\$ 54,627
Subscription of warrants			354			354
Issuance of ordinary shares on exercise of						
stock-options	55,010	10	176			186
Stock-based compensation expense			5,383			5,383
Net loss				(9,358)		(9,358)
Foreign currency translation adjustment					(529)	(529)
Comprehensive loss						\$ (9,887)
Balance at September 30, 2008	24,106,600	3,500	191,086	\$ (157,479)	13,556	\$ 50,663

See notes to condensed consolidated financial statements 6

#### Notes to Condensed Consolidated Financial Statements (Unaudited)

## 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

In the opinion of the management of Flamel Technologies S.A. (the "Company"), 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, these Financial Statements do not include all of the information and footnotes required for complete annual financial statements, since certain footnotes and other financial information required by generally accepted accounting principles in the United States (US GAAP) can be condensed or omitted for interim reporting requirements. In the opinion of management, all adjustments (consisting of only normal recurring accruals) considered necessary for a fair presentation of our financial position and operating results 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 consolidated 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, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. These condensed consolidated financial statements should be read in conjunction with the Company's audited annual financial statements.

The reporting currency of the Company and its wholly-owned subsidiary is the U.S. dollar. All assets and liabilities in the balance sheets of the Company, whose functional currency is the Euro, except those of the U.S. subsidiary whose functional currency is the U.S. dollar, are translated into U.S. dollar equivalents at exchange rates as follows: (1) asset and liability accounts at period-end rates, (2) income statement accounts at weighted average exchange rates for the period, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity as Currency Translation Adjustments.

#### 2. REVENUES

#### 2.1 License and research revenue

The Company recognized research and development revenues of \$6,650,000 for the first nine months of 2008. Research and Development revenues include \$1,565,000 in accordance with the agreement signed with Merck-Serono on December 20, 2007 and \$1,125,000 pursuant to the agreement signed with Wyeth Pharmaceuticals on September 12, 2007.

Licensing fees of \$3,191,000 were recognized in the first nine months of 2008 and included one milestone of €500,000 (\$765,000) from Merck-Serono .

2.2 Product sales and services.

In accordance with the supply agreement signed with GlaxoSmithline (GSK) in December 2004, the Company recognized revenues of \$ 10,918,000.

#### Notes to Condensed Consolidated Financial Statements (Unaudited)

#### 2.3 Other revenues.

The Company recognized other revenues of \$8,394,000 for the nine month period ended September 30, 2008 which includes primarily royalties from the License Agreement with GSK with respect to Coreg CR.

#### **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, 2007	September 30, 2008
Raw materials	2,676	2,311
Finished goods	535	492
Provision for inventory obsolescence	(1,439)	(1,120)
Inventories, net	1,771	1,683

#### 4. RESEARCH TAX CREDIT

The French government provides tax credits to companies for spending on innovative research and development. Income tax benefits correspond to these French research tax credits, which are credited against income taxes payable in each of the four years after being incurred or, if not so utilized, are recoverable in cash.

Effective January 1, 2008 French tax legislation has changed to the extent that the tax credit is due solely on the volume of expenditure for research and development in the period. Prior to January 1, 2008 the tax credit was calculated based on both the annual volume of research and development expenditure and on the increase in research and expenditure compared with the average of the previous two years. Up until December 31, 2007, the Company recorded the tax credit at the end of the fiscal year. As of January 1, 2008, the tax credit is accrued quarterly based on qualifying research and development expenditures during the quarter.

For the first nine months period ended September 30, 2008, the credit amounted to \$5,042,000.

#### 5. SHAREHOLDERS' EQUITY

During the nine-month period ending September 30, 2008, as a result of exercise of stock options, the Company issued 55,010 ordinary shares, nominal value €0.122 per share.



## Notes to Condensed Consolidated Financial Statements (Unaudited)

## 6. STOCK COMPENSATION EXPENSE

During the three-month period ending September 30, 2008, no stock options, free of charge share awards or warrants were granted by the Company.

Net income before and after stock-based compensation is as follows :

	Three mont	hs ended	Nine mont	ths ended
(in thousands except per share data)	September 30, 2007	September 30, 2008	September 30, 2007	September 30, 2008
Net loss	\$ (9,106)	\$ (2,304)	\$(31,800)	\$ (9,358)
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Net loss per share				
Basic	\$ (0.38)	\$ (0.10)	\$ (1.32)	\$ (0.39)
Diluted	\$ (0.38)	\$ (0.10)	\$ (1.32)	\$ (0.39)
Number of shares used for computing				
Basic	24,042	24,077	24,017	24,066
Diluted	24,042	24,077	24,017	24,066
Stock-based compensation (FAS123R)				
Cost of products and services sold	112	82	337	338
Research and development	1,303	573	4,410	3,137
Selling, General and administrative	1,348	507	4,520	2,771
Total	2,763	1,162	9,267	6,246
Net income (loss) before stock-based compensation	(6,343)	(1,142)	(22,533)	(3,112)
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Net income (loss) before stock-based compensation per share				
Basic	\$ (0.26)	\$ (0.05)	\$ (0.94)	\$ (0.13)
Diluted	\$ (0.26)	\$ (0.05)	\$ (0.94)	\$ (0.13)
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#### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

#### FORWARD-LOOKING STATEMENTS

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 Securities and Exchange Commission 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 those listed in Part II, Item 1A, Risk Factors.

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. We undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise. You should not place undue reliance on these 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, 2007, including those set forth in 'Risk Factors,' describe factors, among others, that could contribute to or cause such differences.

#### **RESULTS OF OPERATIONS**

For the first nine months of 2008, Flamel reported total revenues of \$29.2 million compared to \$26.1 million for the first nine months of 2007.

License and research revenues for the nine months ended September 30, 2008 were \$9.8 million compared to \$6.9 million for the first nine months of 2007, and included one milestone payment for a total amount of €0.5 million (\$0.76 million) received from Merck-Serono.

Product sales and services, pursuant to the company's supply contract with GSK totaled \$10.9 million for the first nine months of 2008 compared to \$15.0 million for the first nine months of 2007. The reduction in revenues during the period coincided with lower demand for Coreg CR. In 2007, product sales and services represented volume required to ensure sufficient product was available for launch and expected uptake of the product.

Other revenues were \$8.4 million for the nine months ended September 30, 2008 compared to \$4.2 million for the first nine months of 2007 and included royalties on sales of Coreg CR. The increase results from the timing of launch of the product in 2007. In 2008 the Company benefits from nine months of sales of Coreg CR.

Operational expenses decreased to \$44.4 million during the first nine months of 2008 from \$58.9 million for the first nine months of 2007. This decrease was due primarily to efforts to contain operating costs and prioritize our expenditures and the recognition in the second quarter, as an offset to operating expenses, of local government grants amounting to \$1.4 million.

Costs of goods and services sold were \$7.3 million, as compared to \$12.4 million in the first nine months of 2007. This decrease was due primarily to reductions in expenditures in 2008 to correspond with lower demand for Coreg CR while our 2007 expenditures were higher as we focused on ensuring sufficient product in the pipeline for the product launch.

Research and development expenditures were \$26.5 million, compared to \$33.7 million in the first nine months of 2007. Research and development expenses before non-cash stock compensation cost were \$23.3 million, compared to \$29.3 million in the first nine months of 2007. The reduction in research and development expenditures results from our focus on early-stage and pre-clinical research compared with the clinical study program conducted in 2007 which included three phase 1 clinical studies. In addition, the expansion of the number of active projects enables an increasing volume of external costs to be borne by our partners.

SG&A expenses during the quarter were \$10.7 million compared to \$12.8 million in the year-ago period due primarily to efforts to contain and prioritize expenditures and reduced stock compensation expense.

Net loss for the first nine months was (\$9.4) million, compared to a net loss of (\$31.8) million in the first nine months of 2007. Net loss per share (basic) for the first nine months of 2008 was (\$0.39), compared to net loss per share in the year-ago period of (\$1.32).

#### LIQUIDITY AND CAPITAL RESOURCES

On September 30, 2008 the Company had \$32.8 million in cash, cash equivalents and marketable securities, compared to \$41.1 million on December 31, 2007. We believe the Company to have sufficient funds to finance operations and cash requirements for at least the next twelve months.



#### PART II. OTHER INFORMATION

#### **Item 1. Legal Proceedings**

GlaxoSmithKline (GSK), the company with which we developed Coreg CR, is currently involved in litigation challenging the validity of its patent on the active form carvedilol phosphate. This is one of several patents by which Coreg CR is protected. The litigation arose out of Mutual Pharmaceuticals' attempt to seek approval of a generic formulation of Coreg CR. GSK has filed a motion to dismiss claims that it had pursued versus Mutual Pharmaceuticals. GSK also filed a motion to stay discovery pending resolution of GSK's motion to dismiss all claims. Flamel is not party to the litigation, which is being handled solely by GSK. It is too soon to reasonably determine what impact, if any, the litigation may have on Coreg CR. If GSK's motion to dismiss is granted, it is likely that GSK's composition of matter patent will not serve as a barrier to Mutual Pharmaceuticals in its efforts to develop a generic product that is competitive with Coreg CR. There are other separate and unrelated defenses for Coreg CR, such as the Hatch-Waxman exclusivity period, which lasts until April 2010, during which time applications from generic competitors, including Mutual Pharmaceuticals, cannot be approved by the FDA.

#### Item 1A. Risk Factors

Set forth below and in our Annual Report on Form 20-F for the year ended December 31, 2007 is a discussion of risks related to our industry and our business. In addition to the other information in our SEC filings, you should consider carefully the following risk factors. The occurrence of any one or more of the risks or uncertainties described below could have a material adverse effect on business, financial condition and results of operations:

- We depend on a few customers for the majority of our revenues, and the loss of any one of these customers could reduce our revenues significantly.
- Our revenues depend on pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery technologies.
- Although products that incorporate our drug delivery technologies may appear promising at their early stages of development and in clinical trials, none of these potential products may reach the commercial market for a number of reasons.
- We depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.
- Products that incorporate our drug delivery technologies are subject to regulatory approval. If our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.
- We may face product liability claims related to participation in clinical trials or the use or misuse of our products or products that incorporate our technologies.

- Our commercial products are subject to continuing regulation, and we may be subject to adverse consequences if we fail to comply with applicable regulations.
- Regulatory reforms may adversely affect our ability to sell our products profitably.
- If our competitors develop and market drug delivery technologies or related products that are more effective than ours, or obtain regulatory approval and market such technology or products before we do, our commercial opportunity will be reduced or eliminated.
- Certain companies to which we have licensed our technology are subject to extensive regulation by the U.S. Food and Drug Administration. Their failure to meet strict regulatory requirements could adversely affect our business.
- If we cannot keep pace with the rapid technological change in our industry, we may lose business.
- Our products and technologies may not gain market acceptance.
- If we cannot adequately protect our technology and proprietary information, we may be unable to sustain a competitive advantage.
- Third parties have claimed, and may claim in the future, that our technologies, or the products in which they are used, infringe on their rights and we may incur significant costs resolving these claims.
- If the patents or other forms of protection owned by our collaborating pharmaceutical partners or other third parties expire, are challenged or become ineffective, sales of products by our collaborating partners may be restricted or may cease.
- If we or our collaborative partners are required to obtain licenses from third parties, our revenues and royalties on any commercialized products could be reduced.
- If we use biological and hazardous materials in a manner that causes injury, we may be liable for significant damages.
- Healthcare reform and restrictions on reimbursements may limit our financial returns.
- Because we have a limited operating history, investors in our shares may have difficulty evaluating our prospects.
- If we are not profitable in the future, the value of our shares may fall.
- We may require additional financing to continue research and development programs and clinical trials, which may not be available on favorable terms, if at all, particularly in light of the global economic recession and its negative impact on the capital markets;
- Our share price has been volatile and may continue to be volatile.

- Our operating results may fluctuate and may be impacted by the uncertainties of the global economy, which may adversely affect our share price.
- Fluctuations in foreign currency exchange rates may cause fluctuations in our financial 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.

Flamel Technologies, S.A.

Dated: January 9, 2009

/s/ Stephen H. Willard Chief Executive Officer