

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 12B-25

NOTIFICATION OF LATE FILING

SEC File No. 0-21467  
CUSIP No. 69423U 10 7

(Check One):  Form 10-K  Form 20-F  Form 11-K  Form 10-Q  Form 10-D  Form N-SAR  Form N-CSR

For Period Ended: December 31, 2015

- Transition Report on Form 10-K  
 Transition Report on Form 20-F  
 Transition Report on Form 11-K  
 Transition Report on Form 10-Q  
 Transition Report on Form N-SAR

For the Transition Period Ended: \_\_\_\_\_

Read Instruction (on back page) Before Preparing Form. Please Print or Type.  
**Nothing in this form shall be construed to imply that the Commission has verified any information contained herein.**

If the notification relates to a portion of the filing checked above, identify the Item(s) to which the notification relates:

**PART I - REGISTRANT INFORMATION**

**Flamel Technologies S.A.**

Full Name of Registrant

Former Name if Applicable

**Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Levy**

Address of Principal Executive Office (Street and Number)

**69200 Venissieux, France**

City, State, Zip Code

**PART II - RULES 12b-25 (b) AND (c)**

If the subject report could not be filed without unreasonable effort or expense and the registrant seeks relief pursuant to Rule 12b-25(b), the following should be completed. (Check box if appropriate)

- (a) The reasons described in reasonable detail in Part III of this form could not be eliminated without unreasonable effort or expense;
- (b) The subject annual report, semi-annual report, transition report on Form 10-K, Form 20-F, 11-K Form N-SAR or Form N-CSR, or portion thereof, will be filed on or before the fifteenth calendar day following the prescribed due date; or the subject quarterly report of transition report on Form 10-Q or subject distribution report on Form 10-D, or portion thereof, will be filed on or before the fifth calendar day following the prescribed due date; and
- (c) The accountant's statement or other exhibit required by Rule 12b-25(c) has been attached if applicable.

**PART III - NARRATIVE**

State below in reasonable detail the reasons why Forms 10-K, 20-F, 11-K, 10-Q, 10-D, N-SAR, N-CSR or the transition report or portion thereof could not be filed within the prescribed time period.

Flamel Technologies S.A. (the "Company") has determined that it is not able to file its Annual Report on Form 10-K for the year ended December 31, 2015 (the "Form 10-K") within the prescribed time period without unreasonable effort or expense for the reasons described below.

Prior to 2016, the Company was a foreign private issuer under applicable rules of the Securities and Exchange Commission (the "SEC"). As a foreign private issuer, the Company filed its annual reports on Form 20-F, which must be filed within four months of the end of the applicable registrant's fiscal year; in the case of the Company, with a fiscal year ending December 31, its Form 20-F was due by April 30 of each following year. Commencing with 2016, the Company is filing its periodic reports as a "domestic issuer" and the prescribed date for filing its Annual Report on Form 10-K for the fiscal year ended December 31, 2015 is February 29, 2016. Because of this accelerated prescribed filing date of February 29, 2016, the Company's management and finance and accounting personnel have had substantially less time – 60 days instead of 120 days – to prepare and record final accounting entries and adjustments for 2015, prepare financial statements as of and for the year ended December 31, 2015 and the accompanying notes, and prepare and finalize the other disclosures required by Form 10-K. In anticipation of the need to file its Annual Report on Form 10-K by February 29, 2016, the Company has increased its finance and accounting staff, and the Company's management and finance and accounting personnel have worked diligently to complete the Annual Report on Form 10-K. Despite these efforts, additional time is needed to complete the Annual Report on Form 10-K.

In addition, predominately as a result of the rapid growth of the Company in 2015, management has identified certain control deficiencies that constituted material weaknesses in our internal control over financial reporting as of December 31, 2015. These material weaknesses primarily result from a lack of sufficient personnel, where we did not maintain a sufficient number of personnel with an appropriate level of knowledge, experience and training in internal control over financial reporting commensurate with our financial reporting requirements. As a consequence of the above weaknesses, we have not designed or maintained effective controls over segregation of duties and restricted access for processes, including an assessment of incompatible management responsibilities, in areas such as journal entries, third party payments, cash payment processes, and payroll processing. In the process of preparing the Company's Annual Report on Form 10-K, the Company required additional time to evaluate, develop and implement a plan to remediate, and prepare required disclosures in the Annual Report on Form 10-K with respect to, such weaknesses.

The Company expects to file its Annual Report on Form 10-K within the extension period of 15 calendar days as provided under Rule 12b-25.

The Company's expectation regarding the timing of the filing of its Annual Report on Form 10-K and the description of anticipated material changes from the results of operation from the corresponding period of the last fiscal year are forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, and actual events may differ from those contemplated by these forward-looking statements. These forward-looking statements are subject to certain risks and uncertainties, including the inability of the Company or its independent registered public accounting firm to complete the work necessary in order to file such Annual Report on Form 10-K in the time frame that is anticipated or unanticipated changes being reported in the Company's operating results as reported in the Annual Report on Form 10-K as filed. The Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

**PART IV - OTHER INFORMATION**

(1) Name and telephone number of person to contact in regard to this notification:

<u>Michael F. Kanan</u>	<u>(636)</u>	<u>449-1844</u>
(Name)	(Area Code)	(Telephone Number)

(2) Have all other periodic reports required under Section 13 or 15(d) of the Securities Exchange Act of 1934 or Section 30 of the Investment Company Act of 1940 during the preceding 12 months or for such shorter period that the registrant was required to file such report(s) been filed? If answer is no, identify report(s).

Yes  No

(3) Is it anticipated that any significant change in results of operations from the corresponding period for the last fiscal year will be reflected by the earnings statements to be included in the subject report or portion thereof?

Yes  No

If so: attach an explanation of the anticipated change, both narratively and quantitatively, and, if appropriate, state the reasons why a reasonable estimate of the results cannot be made.

**Although the Company has not completed its financial statements for the year ended December 31, 2015, we anticipate that the changes in the Company's results of operation for 2015 will be materially different from the Company's results of operation for 2014, and that the Company's press release dated November 12, 2015 (a copy of which is attached hereto as Exhibit 99.1), discussing the results of operations for the nine-month period ended September 30, 2015, is illustrative of the nature and general magnitude of the changes anticipated between the full-year results of 2015 as compared with 2014. In particular, as previously announced, we expect 2015 revenue to be at the lower end of our 2015 guidance of \$170 to \$185 million. The primary factors contributing to our improved revenue results during 2015 as compared with 2014 sales of approximately \$15 million, were (i) substantially higher sales of an existing product, Bloxiverz, resulting from market share gains and higher net selling prices, and (ii) sales contributions from the launch of a new product, Vazculep.**

**Flamel Technologies S.A.**

(Name of Registrant as Specified in Charter)

has caused this notification to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 29, 2016 By: /s/ Michael F. Kanan  
Michael F. Kanan, Chief Financial Officer

INSTRUCTION: The form may be signed by an executive officer of the registrant or by any other duly authorized representative. The name and title of the person signing the form shall be typed or printed beneath the signature. If the statement is signed on behalf of the registrant by an authorized representative (other than an executive officer), evidence of the representative's authority to sign on behalf of the registrant shall be filed with the form.

ATTENTION

Intentional misstatements or omissions of fact constitute Federal Criminal Violations (See 18 U.S.C. 1001).

GENERAL INSTRUCTIONS

1. This form is required by Rule 12b-25 (17 CRF 240.12b-25) of the General Rules and Regulations under the Securities Exchange Act of 1934.
2. One signed original and four conformed copies of this form and amendments thereto must be completed and filed with the Securities and Exchange Commission, Washington, D.C. 20549, in accordance with Rule 0-3 of the General Rules and Regulations under the Act. The information contained in or filed with the form will be made a matter of public record in the Commission files.
3. A manually signed copy of the form and amendments thereto shall be filed with each national securities exchange on which any class of securities of the registrant is registered.
4. Amendments to the notifications must also be filed on form 12b-25 but need not restate information that has been correctly furnished. The form shall be clearly identified as an amended notification.
5. ELECTRONIC FILERS. This form shall not be used by electronic filers unable to timely file a report solely due to electronic difficulties. Filers unable to submit a report within the time period prescribed due to difficulties in electronic filing should comply with either Rule 201 or Rule 202 of Regulation S-T (Section 232.201 or Section 232.202 of this chapter) or apply for an adjustment in filing date pursuant to Rule 13(b) of Regulation S-T (Section 232.13(b) of this chapter).



## Flamel Technologies Reports Third Quarter 2015 Results

*Reaffirmed product revenue guidance for 2015 of \$170-\$185 million*

*Licensed LiquiTime® to Perrigo for the U.S. OTC market*

**Lyon, France – November 12, 2015** - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the third quarter of fiscal year 2015. Highlights included:

- Total revenue for third quarter was \$47.3 million, compared to \$2.9 million during the same period last year.
- GAAP net loss was (\$29.7) million, or (\$0.73) per diluted share, compared to (\$10.0) million, or (\$0.26) per diluted share, during the same period last year. Adjusted net income, which excludes certain items described below, was \$11.5 million, or \$0.28 per diluted share, compared to an adjusted net loss of (\$6.0) million, or (\$0.16) per diluted share, during the same period last year.
- Cash on hand at September 30, 2015 was \$128.4 million, compared to \$116.1 million at June 30, 2015.
- Received acceptance of a New Drug Application (NDA) for the Company's third Unapproved Marketed Drug (UMD), Éclat #3, by the U.S. Food and Drug Administration (FDA).
- Licensed exclusive rights for the Company's LiquiTime® drug delivery platform to Perrigo for the U.S. Over-the-Counter (OTC) drug market.

Michael Anderson, Chief Executive Officer of Flamel, commented, "The third quarter of 2015 marked another consecutive period of strong revenues and cash flow generated by Flamel's marketed products, Bloxiverz® and Vazculep®, allowing the Company to reiterate its yearly revenue guidance of \$170-\$185 million. As expected, Bloxiverz maintained its market share during the quarter averaging approximately 60%. In addition to strong revenue generation, the Company received acceptance from the FDA for its third NDA for Éclat #3 and a PDUFA date of April 30, 2016."

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Mr. Anderson continued, “Near the end of the third quarter, Flamel licensed its proprietary LiquiTime drug delivery platform to Perrigo for the U.S. Over-the-Counter (OTC) drug market. Flamel received an upfront payment of \$6 million and will be eligible for a minimum of \$50 million in approval and launch milestone payments for at least seven products, in addition to receiving mid-single digit royalties on net sales of these products. The OTC cough/cold market is estimated to be in the range of \$6.5 billion per year, and we believe the need for extended release liquid oral therapies is widely recognized. Both Flamel and Perrigo believe that the commercial potential for mono and combination therapies using our LiquiTime drug delivery platform is robust. This agreement with Perrigo is a significant milestone for Flamel as we successfully out-licensed our technology to a leading OTC player and believe Perrigo is well positioned to maximize the commercial potential of LiquiTime.”

### **Third Quarter Results**

Flamel reported total revenues during the third quarter of 2015 of \$47.3 million, an increase of \$44.4 million compared to the prior year period. Total revenues included revenue from Bloxiverz of \$41.2 million and from Vazculep of \$5.6 million.

Adjusted net income for the third quarter of 2015 was \$11.5 million, compared to adjusted net loss of (\$6.0) million in the third quarter of 2014. Adjusted earnings per diluted share was \$0.28 in the third quarter of 2015, versus adjusted loss per diluted share of (\$0.16) in the prior year period. The Bloxiverz and Vazculep revenue streams drove the increase in adjusted net income enabling continued investment and spending for the Company’s opportunistic UMD strategy and further development of its proprietary pipeline of pharmaceutical products, which will contribute to its product portfolio in the medium term.

Net loss from Continuing Operations for the third quarter of 2015 was (\$29.7) million, versus net loss of (\$10.0) million in the year-ago period. Loss per diluted share from Continuing Operations was (\$0.73) in the third quarter of 2015, versus loss per diluted share from Continuing Operations of (\$0.26) in the third quarter of 2014. The increase in net loss from continuing operations when compared to the same period last year primarily resulted from higher charges associated with fair value remeasurements of certain acquisition and royalty liabilities which increased by \$36.9 million and \$5.2 million, respectively, and a decrease in foreign exchange gain of \$7.9 million from the third quarter of 2014 that did not repeat in the third quarter of 2015. These items were partially offset by higher net income resulting from greater revenue levels in the third quarter of 2015, compared to the third quarter of 2014.

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Flamel discloses certain non-GAAP financial measures, including adjusted net income and loss and adjusted net income and loss per diluted share, as management believes that a comparison of its current and historical results would be difficult if the disclosures were limited to financial measures prepared only in accordance with generally accepted accounting principles (GAAP) in the U.S. In addition to reporting its financial results in accordance with GAAP, Flamel reports certain non-GAAP results that exclude fair value remeasurements, impairment of intangible assets, amortization expense of intangible assets, effects of accelerated reimbursement of certain debt instruments, and unrealized foreign exchange gains and losses on assets and liabilities denominated in foreign currency, but includes the operating cash flows associated with the acquisition liabilities and Royalty Agreements, in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance. The Company's management uses these non-GAAP measures internally for forecasting, budgeting and measuring its operating performance. Investors and other readers are encouraged to review the related GAAP financial measures and the reconciliation of non-GAAP measures to their most closely applicable GAAP measure set forth below and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP. The following table reconciles GAAP net income and loss and diluted earnings or loss per share to the corresponding adjusted amounts.

	<b>Three months ended September 30,</b>				<b>Nine months ended September 30,</b>			
	<b>2014</b>		<b>2015</b>		<b>2014</b>		<b>2015</b>	
GAAP Net income (loss) and diluted earnings (loss) per share	\$ (10,046)	\$ (0.26)	\$ (29,685)	\$ (0.73)	\$ (57,757)	\$ (1.64)	\$ (35,438)	\$ (0.88)
Fair value remeasurement of acquisition liabilities	7,865		44,782		35,098		82,036	
Fair value remeasurement of royalty agreement	1,486		6,644		2,721		9,629	
Amortization of Intangible R&D Assets	2,937		3,141		8,812		9,423	
Accelerated reimbursement of acquisition note	-		-		3,013		-	
Accelerated reimbursement of facility agreements	-		-		4,741		-	
Earn-out acquisition payment payable	(361)		(9,028)		(1,356)		(24,203)	
Royalty payable	(58)		(1,211)		(204)		(3,326)	
Unrealized foreign exchange (gain)/loss	(7,856)		(32)		(8,337)		(4,814)	
Tax effects of the above items	-		(3,089)		(2,338)		(4,080)	
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share,	<u>\$ (6,033)</u>	<u>\$ (0.16)</u>	<u>\$ 11,522</u>	<u>\$ 0.28</u>	<u>\$ (15,607)</u>	<u>\$ (0.44)</u>	<u>\$ 29,227</u>	<u>\$ 0.72</u>



A conference call to discuss these results and other updates is scheduled for 10:00 a.m. ET on Thursday, November 12, 2015. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-811-5408 (U.S. and Canada) or +1-913-312-1486 (international). The conference ID number is 776094. Interested parties may access a live audio webcast of the conference call via the investor section of the Company website, [www.flamel.com](http://www.flamel.com). The archived webcast of the conference call will be available for 90 days on Flamel's website.

**About Flamel Technologies:** Flamel Technologies SA (NASDAQ: FLML) is a specialty pharmaceutical company utilizing its core competencies in formulation development and drug delivery to develop safer and more efficacious pharmaceutical products, addressing unmet medical needs and/or reducing overall healthcare costs. Flamel currently has approvals for and markets two previously Unapproved Marketed Drugs ("UMDs") in the USA, Bloxiverz® (neostigmine methylsulfate injection) and Vazculep® (phenylephrine hydrochloride injection). The Company intends to add to this branded business by creating additional products, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms, and recently announced FDA acceptance of its third NDA filing with an FDA-assigned PDUFA date of April 30, 2016. Flamel also has several products in development utilizing Micropump® (oral sustained release microparticles platform) along with its tangent technologies, LiquiTime® and Trigger Lock™. The lead project for Micropump® is sodium oxybate. LiquiTime® allows for the extended-release of liquid medicines (such as ibuprofen and guaifenesin) and Trigger Lock™ is an abuse-resistant iteration of Micropump®, designed specifically for long-acting opioids (such as hydromorphone). Additionally, the Company has developed a long acting injectable platform, Medusa™, a hydrogel depot technology currently being studied with exenatide. Flamel's products are targeting high-value molecules and will utilize either the 505(b)(2) approval process for NDAs or biosimilar pathways ultimately approved by FDA and other regulatory authorities. The Company is headquartered in Lyon, France and has operations in St. Louis, Missouri, USA, and Dublin, Ireland. Additional information may be found at [www.flamel.com](http://www.flamel.com).

**Safe Harbor:** *This release may include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements herein that are not clearly historical in nature are forward-looking, and the words "anticipate," "assume," "believe," "expect," "estimate," "plan," "will," "may," and the negative of these and similar expressions generally identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond Flamel's control and could cause actual results to differ materially from the results contemplated in such forward-looking statements. These risks, uncertainties and contingencies include the risks relating to: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz® and Vazculep® products, which are not patent protected, could face substantial competition resulting in a loss of market share or forcing us to reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for the two pipeline products we are evaluating for potential application to the FDA pursuant to our "unapproved-to-approved" strategy, or that competitors could complete the development of such products and apply for FDA approval of such products before us; our dependence on the performance of third parties in partnerships or strategic alliances for the commercialization of some of our products; the possibility that our products may not reach the commercial market or gain market acceptance; our need to invest substantial sums in research and development in order to remain competitive; our dependence on certain single providers for development of several of our drug delivery platforms and products; our dependence on a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products; the possibility that our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do; the challenges in protecting the intellectual property underlying our drug delivery platforms and other products; our dependence on key personnel to execute our business plan; the amount of additional costs we will incur to comply with U.S. securities laws as a result of our ceasing to qualify as a foreign private issuer; and the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 20-F for the year ended December 31, 2014, all of which filings are also available on the Company's website. Flamel undertakes no obligation to update its forward-looking statements as a result of new information, future events or otherwise, except as required by law.*

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**Contact:**     **Michael S. Anderson**  
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                  E-mail: anderson@flamel.com

**Investor Relations**  
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**Condensed Consolidated Statements of Operations**  
(Amounts in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2015	2014	2015
<b>Revenue:</b>				
License and research revenue	\$ 335	-	\$ 2,752	-
Product sales and services	2,570	47,314	9,013	\$ 129,790
Other revenues	8	6	44	51
<b>Total revenue</b>	<b>2,913</b>	<b>47,320</b>	<b>11,809</b>	<b>129,841</b>
<b>Costs and expenses:</b>				
Cost of goods and services sold	(707)	(2,087)	(1,987)	(8,473)
Research and development	(4,118)	(7,221)	(11,662)	(20,447)
Selling, general and administrative	(4,025)	(4,568)	(11,606)	(14,904)
Fair value remeasurement of acquisition liabilities, incl. related parties	(7,865)	(44,782)	(35,098)	(82,036)
Amortisation of intangible R&D assets	(2,937)	(3,141)	(8,812)	(9,423)
Acquisition note expenses, incl. related parties	-	-	(3,013)	-
<b>Total</b>	<b>(19,652)</b>	<b>(61,799)</b>	<b>(72,178)</b>	<b>(135,283)</b>
<b>Operating profit (loss) from continuing operations</b>	<b>(16,739)</b>	<b>(14,479)</b>	<b>(60,369)</b>	<b>(5,442)</b>
Interest income	86	407	225	1,858
Interest expense	-	(237)	(5,552)	(719)
Interest expense on debt related to the royalty agreement with related parties	(1,486)	(6,644)	(2,721)	(9,629)
Foreign exchange gain (loss)	8,074	160	8,545	8,096
Other income (loss)	71	27	152	32
<b>Income (loss) before income taxes from continuing operations</b>	<b>(9,994)</b>	<b>(20,766)</b>	<b>(59,720)</b>	<b>(5,804)</b>
Income tax benefit (expense)	14	(8,919)	2,679	(29,634)
<b>Net income (loss) from continuing operations</b>	<b>\$ (9,980)</b>	<b>\$ (29,685)</b>	<b>\$ (57,041)</b>	<b>\$ (35,438)</b>
<b>Net income from discontinued operations</b>	<b>\$ (66)</b>	<b>\$ 0</b>	<b>\$ (716)</b>	<b>\$ 0</b>
<b>Net income (loss)</b>	<b>\$ (10,046)</b>	<b>\$ (29,685)</b>	<b>\$ (57,757)</b>	<b>\$ (35,438)</b>
<b>Earnings (loss) per ordinary share (Basic):</b>				
Continuing operations	\$ (0.26)	\$ (0.73)	\$ (1.62)	\$ (0.88)
Discontinued operations	\$ (0.00)	\$ 0.00	\$ (0.02)	\$ 0.00
<b>Net income (loss)</b>	<b>\$ (0.26)</b>	<b>\$ (0.73)</b>	<b>\$ (1.64)</b>	<b>\$ (0.88)</b>
<b>Earnings (loss) per share (Diluted):</b>				
Continuing operations	\$ (0.26)	\$ (0.73)	\$ (1.62)	\$ (0.88)
Discontinued operations	\$ 0.00	\$ 0.00	\$ (0.02)	\$ 0.00
<b>Net income (loss)</b>	<b>\$ (0.26)</b>	<b>\$ (0.73)</b>	<b>\$ (1.64)</b>	<b>\$ (0.88)</b>
<b>Weighted average number of shares outstanding (in thousands) :</b>				
Basic	38,767	40,625	35,201	40,397
Diluted	38,767	40,625	35,201	40,397