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

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FORM 8-K

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CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **April 15, 2016**

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**FLAMEL TECHNOLOGIES S.A.**

(Exact name of registrant as specified in its charter)

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**Republic of France**  
(State or Other Jurisdiction  
of Incorporation)

**000-28508**  
(Commission File Number)

**98-0639540**  
(I.R.S. Employer  
Identification No.)

**Parc Club du Moulin à Vent**  
**33, avenue du Docteur Georges Levy**  
**69200 Vénissieux France**  
(Address of Principal Executive Offices)

**Not Applicable**  
(Zip Code)

Registrant's telephone number, including area code: **011 +33 472 78 34 34**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- £ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - £ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - £ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - £ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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#### Item 4.01 Change in Registrant's Certifying Accountant.

On April 15, 2016, PricewaterhouseCoopers Audit ("PwC-France") informed Flamel Technologies S.A. (the "Company" or "we") that PwC-France declined to stand for reappointment as the Company's independent registered public accounting firm for SEC reporting purposes. Also, on April 15, 2016, the Company engaged PricewaterhouseCoopers ("PwC-U.S.") as its independent registered public accounting firm for the fiscal year ending December 31, 2016. The decision to engage PwC-U.S. as the Company's independent registered public accounting firm was approved by both the Company's Audit Committee and the Company's Board of Directors.

The reports of PwC-France on the consolidated financial statements of the Company for the fiscal years ended December 31, 2015 and 2014 contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principle.

During the Company's fiscal years ended December 31, 2015 and 2014, and the subsequent interim period through April 15, 2016, there were no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K) with PwC-France on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of PwC-France, would have caused PwC-France to make reference thereto in their reports on the consolidated financial statements for such fiscal years.

During the Company's fiscal years ended December 31, 2015 and 2014, and the subsequent interim period through April 15, 2016, there have been no reportable events (as defined in Item 304(a)(1)(v) of Regulation S-K), except as follows. The Company reported, in its annual report on Form 10-K for the fiscal year ended December 31, 2015 (the "2015 10-K"), that management had identified certain control deficiencies that constituted material weaknesses in the Company's internal control over financial reporting as of December 31, 2015. The control deficiencies were:

- **Lack of sufficient personnel:** 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.
- **Segregation of duties:** As a consequence of the above weakness we have not designed or maintained effective controls over segregation of duties and restricted access for processes, including an assessment of incompatible management responsibilities relating to the following:
  - o Journal entries: We have not designed or maintained effective controls over the review, approval and documentation related to journal entries recorded in the US.
  - o Third party vendors and third party payments: We have not designed or maintained effective controls in the US over the review, approval, ongoing maintenance of third party vendor contracts and vendor payments.
  - o Cash payment process: We have not designed or maintained effective controls over the cash payment process in the US. We do not have an adequate process to ensure the safeguarding of the Company's assets to support the proper functioning of internal controls.
  - o Payroll and related accounts: We have not designed or maintained effective controls over the US payroll process.

- **Revenue:** We have not designed or maintained effective controls over the revenue process. Specifically, we have not designed or maintained effective controls over the review and approval of product prices and subsequent changes to customer prices, the authorization, review and accounting for rebate arrangements included in customer contracts and the company's use of service providers in the revenue process.
- **Income taxes:** We have not designed or maintained effective controls over the income tax process. Specifically, we have not designed or maintained effective controls related to the income tax process on a quarterly or year-end basis, including deferred tax reconciliations, valuation allowances, review of state income taxes and related apportionment, review of tax returns and return to provision differences, review of information provided to and received from the outsourced tax provider, review of effective income tax rates and any uncertain tax positions.
- **Information technology general controls and key spreadsheets:** We have not designed or maintained effective controls over information technology general controls and key spreadsheets used within certain processes and management's controls to support account balances or in the preparation of the financial statements.
- **Financial close process:** We have not designed or maintained effective controls over the financial close process.
- **Monitoring controls:** We did not design and maintain effective monitoring controls related to the design and operational effectiveness of our internal controls. Specifically, we did not maintain an internal audit function sufficient to monitor control activities.

Because of these material weaknesses, management concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2015, based on criteria in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

The audit report of PwC-France included in the 2015 10-K with respect to the Company's internal control over financial reporting opined that the Company did not maintain effective internal control over financial reporting as of December 31, 2015.

The material weaknesses identified by management and described in the 2015 10-K were discussed by the Company's management and the Audit Committee with PwC-France. The Audit Committee has authorized PwC-France to respond fully to the inquiries of the successor independent registered public accounting firm concerning all matters related to the audits performed by PwC-France, including the material weaknesses referred to above.

The Company provided PwC-France with a copy of the disclosures in this current report on Form 8-K prior to the time this Form 8-K was filed with the Securities and Exchange Commission (the "SEC"). The Company requested that PwC-France furnish a letter addressed to the SEC stating whether they agree with the above statements and, if not, stating the respects in which they do not agree. A copy of that letter from PwC-France, dated April 19, 2016, is filed as Exhibit 16.1 to this current report on Form 8-K.

As noted above, on April 15, 2016, the Company engaged PwC-U.S. as the Company's independent registered public accounting firm for SEC reporting purposes. During the fiscal years ended December 31, 2015 and 2014 and the subsequent interim period through April 15, 2016, PwC-U.S. performed work in support of PwC-France's audit of the financial statements included in the Company's SEC filings or PwC-France's work in connection with the Company's French statutory audit requirements. During the Company's fiscal years ended December 31, 2015 and 2014, and subsequent interim period through April 15, 2016, except in the ordinary course of the work performed in support of the audit as described above, neither the Company nor anyone on its behalf consulted with PwC-U.S. regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and no written report or oral advice was provided by PwC-U.S. to the Company that PwC-U.S. concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to such Item 304, or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

#### **Item 9.01 Financial Statements and Exhibits.**

##### **(d) Exhibits**

16.1 Letter from PricewaterhouseCoopers Audit dated as of April 19, 2016

**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 hereunto duly authorized.

**FLAMEL TECHNOLOGIES S.A.**

By: /s/ Michael F. Kanan  
Michael F. Kanan  
Chief Financial Officer

Date: April 19, 2016

16.1 Letter from PricewaterhouseCoopers Audit dated as of April 19, 2016

April 19, 2016

Securities and Exchange Commission  
100 F Street, N.E.  
Washington, DC 20549

Commissioners:

We have read the statements made by Flamel Technologies S.A. (copy attached), which we understand will be filed with the Securities and Exchange Commission, pursuant to Item 4.01 of Form 8-K, as part of the Form 8-K of Flamel Technologies S.A. dated April 15, 2016. We agree with the statements concerning our Firm in such Form 8-K.

Very truly yours,

PricewaterhouseCoopers Audit  
Represented by

/s/ Frederic Charcosset  
Frederic Charcosset

**Attachment**

**Change in Registrant's Certifying Accountant.**

On April 15, 2016, PricewaterhouseCoopers Audit ("PwC-France") informed Flamel Technologies S.A. (the "Company" or "we") that PwC-France declined to stand for reappointment as the Company's independent registered public accounting firm for SEC reporting purposes. Also, on April 15, 2016, the Company engaged PricewaterhouseCoopers ("PwC-U.S.") as its independent registered public accounting firm for the fiscal year ending December 31, 2016. The decision to engage PwC-U.S. as the Company's independent registered public accounting firm was approved by both the Company's Audit Committee and the Company's Board of Directors.

The reports of PwC-France on the consolidated financial statements of the Company for the fiscal years ended December 31, 2015 and 2014 contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principle.

During the Company's fiscal years ended December 31, 2015 and 2014, and the subsequent interim period through April 15, 2016, there were no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K) with PwC-France on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of PwC-France, would have caused PwC-France to make reference thereto in their reports on the consolidated financial statements for such fiscal years.

During the Company's fiscal years ended December 31, 2015 and 2014, and the subsequent interim period through April 15, 2016, there have been no reportable events (as defined in Item 304(a)(1)(v) of Regulation S-K), except as follows. The Company reported, in its annual report on Form 10-K for the fiscal year ended December 31, 2015 (the "2015 10-K"), that management had identified certain control deficiencies that constituted material weaknesses in the Company's internal control over financial reporting as of December 31, 2015. The control deficiencies were:

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- **Information technology general controls and key spreadsheets:** We have not designed or maintained effective controls over information technology general controls and key spreadsheets used within certain processes and management's controls to support account balances or in the preparation of the financial statements.
- **Financial close process:** We have not designed or maintained effective controls over the financial close process.
- **Monitoring controls:** We did not design and maintain effective monitoring controls related to the design and operational effectiveness of our internal controls. Specifically, we did not maintain an internal audit function sufficient to monitor control activities.

Because of these material weaknesses, management concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2015, based on criteria in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

The audit report of PwC-France included in the 2015 10-K with respect to the Company's internal control over financial reporting opined that the Company did not maintain effective internal control over financial reporting as of December 31, 2015.

The material weaknesses identified by management and described in the 2015 10-K were discussed by the Company's management and the Audit Committee with PwC-France. The Audit Committee has authorized PwC-France to respond fully to the inquiries of the successor independent registered public accounting firm concerning all matters related to the audits performed by PwC-France, including the material weaknesses referred to above.