UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): October 25, 2016

FLAMEL TECHNOLOGIES S.A.

(Exact name of registrant as specified in its charter)

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

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)
\square 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))

Item 8.01 Other Events.

On October 25, 2016, Flamel Technologies S.A. issued a press release, a copy of which is furnished as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release of Flamel Technologies S.A. dated as of October 25, 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: <u>/s/ Phillandas T. Thompson</u>
Phillandas T. Thompson
Senior Vice President, General Counsel and Corporate Secretary

Date: October 27, 2016

Exhibit Index

99.1 Press release of Flamel Technologies S.A. dated as of October 25, 2016.



Flamel Technologies to Report Third Quarter 2016 Results

Lyon, France – October 25, 2016 - Flamel Technologies SA (NASDAQ: FLML) today announced that the Company will report its financial results for the third quarter ended September 30, 2016 on Monday, November 7, 2016, before the market open. A conference call to discuss these results has been scheduled for Monday, November 7, 2016 at 10:00 a.m. ET. A question and answer period will follow management's prepared remarks.

To participate in the conference call, investors are invited to dial 800-765-0709 (U.S. and Canada) or 913-312-0726 (international). The conference ID number is 9865797. A live audio webcast and accompanying slides can be accessed by visiting the Events & Presentations page of the Company's Investor website at http://www.flamel.com/investors. A replay of the webcast will be archived on Flamel's website for 90 days following the event.

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 markets three previously Unapproved Marketed Drugs ("UMDs") in the United States, Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection), and Akovaz[™] (ephedrine sulfate injection). The Company also develops products utilizing its proprietary drug delivery platforms, Micropump® (oral sustained release microparticles platform), along with its tangent technologies, LiquiTime® (a Micropumpderivative platform for liquid oral products) and Trigger Lock™ (a Micropump-derivative platform for abuse-resistant opioids). Additionally, the Company has developed a long acting injectable platform, MedusaTM, a hydrogel depot technology, particularly suited to the development of subcutaneously administered formulations. Current applications of Flamel's drug delivery products include sodium oxybate (Micropump®), extended-release of liquid medicines such as ibuprofen and guaifenesin (LiquiTime®, through a license arrangement with Elan Pharma International Limited for the U.S. Over-the-Counter market) and a current study of the delivery of exenatide utilizing the Medusa™ technology. In February 2016, Flamel acquired FSC Pediatrics, a company that markets three pediatric pharmaceutical products - Cefaclor for oral suspension, indicated for infection, Karbinal™ ER, indicated for allergic rhinitis and AcipHex® SprinkleTM (rabeprazole sodium) indicated for the treatment of gastroesophageal disease (GERD). FSC also received 510(k) clearance from the FDA in October 2014 for Flexichamber™, a collapsible holding chamber for used in the administration of aerosolized medication using pressurized Metered Dose Inhalers (pMDIs) for the treatment of



asthma. The Company is headquartered in Lyon, France and has operations in Dublin, Ireland and in St. Louis, Missouri. Additional information may be found at 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 forwardlooking 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®, Vazculep® and Akovaz™ 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 pipeline product 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 product and apply for FDA approval of such product 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 10-K for the year ended December 31, 2015, 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.

Contacts: Michael F. Kanan



Chief Financial Officer

Phone: (636) 449-1844 E-mail: kanan@flamel.com

Lauren Stival

Sr. Director, Investor Relations and Corporate Communications

Phone: (636) 449-5866 Email: stival@flamel.com