

**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): **February 8, 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)
  - £ 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 8.01 Other Events.**

On February 8, 2016, the registrant issued a press release with respect to the completion of an acquisition transaction. A copy of the press release is furnished as Exhibit 99.1 to this current report 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 February 8, 2016

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## 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/ Phillandas T. Thompson  
Phillandas T. Thompson  
Senior Vice President, General Counsel and Corporate Secretary

Date: February 8, 2016

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## Flamel Technologies Acquires FSC

*Diversifies product portfolio and brings established commercial infrastructure  
Revised full year 2016 revenue guidance of \$110 to \$130 million  
Conference call today at 5:30 pm ET to discuss the transaction*

**Lyon, France – February 8, 2016** - Flamel Technologies (NASDAQ: FLML) today announced the acquisition of FSC Holdings, LLC, together with its wholly owned subsidiaries FSC Pediatrics, Inc., FSC Therapeutics, LLC, and FSC Laboratories, Inc.. FSC is a Charlotte, NC-based specialty pharmaceutical company dedicated to providing innovative solutions to unmet medical needs for pediatric patients. Leveraging its 45 person sales force, FSC markets three pediatric pharmaceutical products indicated for infection, allergy, gastroesophageal disease (GERD), and a medical device for the administration of aerosolized medication using pressurized Metered Dose Inhalers (pMDIs) for the treatment of asthma. Prior to the acquisition, FSC was an affiliate of Deerfield CSF, LLC, a Deerfield Management company..

Mike Anderson, Chief Executive Officer of Flamel, stated, "FSC provides Flamel a commercial footprint into the US prescription pharmaceutical market with patent protected or exclusive products that offer innovative solutions to physicians and patients. We intend to leverage FSC's marketing and distribution expertise for our Micropump® and LiquiTime® projects, and reduce our dependence on Bloxiverz®, Vazculep® and Éclat #3 in the short term by adding new revenue streams. This acquisition marks the continued execution of our growth strategy as FSC provides an important platform around which to establish Flamel's commercial infrastructure."

He added, "Our intention will be to expand sales of the commercialized products of the combined Flamel and FSC portfolios, in addition to selectively acquiring value-added opportunities in the future. We will continue to develop Flamel's pipeline products and ultimately, our objective is to use our drug delivery technology platforms to create solutions for patients."

Peter Steelman, President and CEO of FSC Pediatrics, commented, "During the last twelve years, we have built our team and commercialized four exclusive products that provide innovative solutions to address the needs of pediatric primary care. The FSC team, commercial platform, and product portfolio comprise a strong and sound base for Flamel within the United States. We expect the combined company to fulfill Flamel's mission to become a premier specialty pharmaceutical company."

### **Strategic and Financial Benefits**

- Leverage established commercial footprint for Flamel's future prescription products, including LiquiTime and Micropump.
- Diversifies product portfolio with a mix of patent-protected products and exclusive licenses, one patent-protected medical device and one sole source antibiotic; thereby lessening short-term dependence on Bloxiverz, Vazculep and Éclat #3, which are subject to generic competition
- Establishes Flamel as a more attractive business partner for pediatric and other assets
- Expected combined full year 2016 revenue guidance of \$110 to \$130 million, inclusive of \$10 to \$15 million in estimated revenues from FSC

FSC has an established commercial infrastructure that is comprised of a 45 person sales team, combined with marketing and distribution capabilities. FSC currently markets the following three pharmaceutical products and one medical device in the pediatric market:

- AcipHex® Sprinkle™ (rabeprazole sodium) is a delayed-release capsule, in dosages of 5 mg and 10 mg, indicated for the treatment of GERD in children 1 to 11 years of age for up to 12 weeks. AcipHex Sprinkle can be sprinkled on a small amount of soft food (e.g., applesauce, fruit or vegetable based baby food, or yogurt) or the capsule granules can be emptied into a small amount of liquid (e.g., infant formula, apple juice, or pediatric electrolyte solution). The U.S. marketing rights for this product were acquired from Eisai Inc.
- Karbinal™ ER, an H1 receptor antagonist (antihistamine) indicated for children two years of age and older, is the only first generation extended release oral suspension antihistamine available in U.S. Karbinal ER provides physicians with a new, effective and easy to use treatment option for children with seasonal and perennial allergic rhinitis that need symptomatic relief for runny nose, sneezing, itchy nose or throat and itchy and watery eyes. Karbinal ER is exclusively licensed from Tris Pharma.
- Cefaclor for Oral Suspension, 125 mg/5 mL, 250 mg/5 mL and 375 mg/5 mL, is indicated for the treatment of otitis media, lower respiratory infections, pharyngitis and tonsillitis, urinary tract infections, and skin and skin structure infections, caused by susceptible organisms. It is a second-generation cephalosporin antibiotic used to treat certain infections, caused by susceptible bacteria.
- Flexichamber™, a collapsible holding chamber for use by patients under the care or treatment of a licensed healthcare professional to administer aerosolized medication from most pressurized Metered Dose Inhalers (MDI), is a prescription medical device. Flexichamber is comprised of anti-static materials to help improve delivery of medication from MDIs to the patient, while minimizing the adherence of the medication to the walls of the chamber. Flexichamber can be used with or without a mask. FSC received FDA 510(k) clearance for Flexichamber in October 2014.

### **Terms of Transaction**

Under the terms of the acquisition, Flamel will pay \$20.25 million over a five year period to Deerfield for all of its equity interests in FSC Holdings. Whereby, Flamel will pay \$1.05 million annually for five years and will make a final payment in January 2021 of \$15.0 million. Flamel will also pay Deerfield a 15% royalty per annum on net sales of the current FSC products, up to \$12.5 million for a period not exceeding ten years.

***Conference Call***

A conference call to discuss this acquisition is scheduled for 5:30 p.m. ET on Monday, February 8, 2016. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 800-835-9927 (U.S. and Canada) or 913-312-0699 (international). The conference ID number is 5085654. 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 FSC Pediatrics:**

FSC Pediatrics, Inc., a subsidiary of FSC Holdings, Inc., based in Charlotte, NC, is a specialty pharmaceutical and medical device company founded in 2004, solely dedicated to providing innovative solutions to unmet medical needs for pediatric patients. FSC Pediatrics provides products that meet pediatric primary care and specialist needs in the following therapeutic categories: Gastrointestinal, Infection and Allergy/Asthma.

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### **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, which have been licensed to Elan Pharma International Limited for the U.S. Over-the-Counter market) 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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