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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): **May 2, 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 7.01 Regulation FD Disclosure.**

On May 4, 2016, Flamel Technologies S.A. (the “Company”) intends to make a presentation at Deutsche Bank’s 41st Annual Health Care Conference in Boston, Massachusetts. A copy of the Company’s complete slide presentation to be used at the Conference is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company’s presentation will be webcast live and can be accessed by visiting the Investor section of the Company’s website at <http://www.flamel.com/investors>. A replay of the presentation, together with the complete slide presentation, will also be available and archived for at least 30 days on the website following the event.

The information responsive to Item 7.01 of this Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as may be expressly set forth by specific reference in such a filing.

**Item 8.01 Other Events.**

On May 2, 2016, the Company issued a press release, a copy of which is furnished as Exhibit 99.2 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	Form of Slide Presentation of Flamel Technologies S.A. as of May 4, 2016.
99.2	Press release of Flamel Technologies S.A. dated as of May 2, 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/ Phillandas T. Thompson  
Phillandas T. Thompson  
Senior Vice President, General Counsel and Corporate Secretary

Date: May 4, 2016

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Exhibit Index

99.1	Form of Slide Presentation of Flamel Technologies S.A. as of May 4, 2016.
99.2	Press release of Flamel Technologies S.A. dated as of May 2, 2016.

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May 2016



# Forward Looking Statements

*This presentation 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<sup>®</sup> and Vazculep<sup>®</sup> 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 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.*

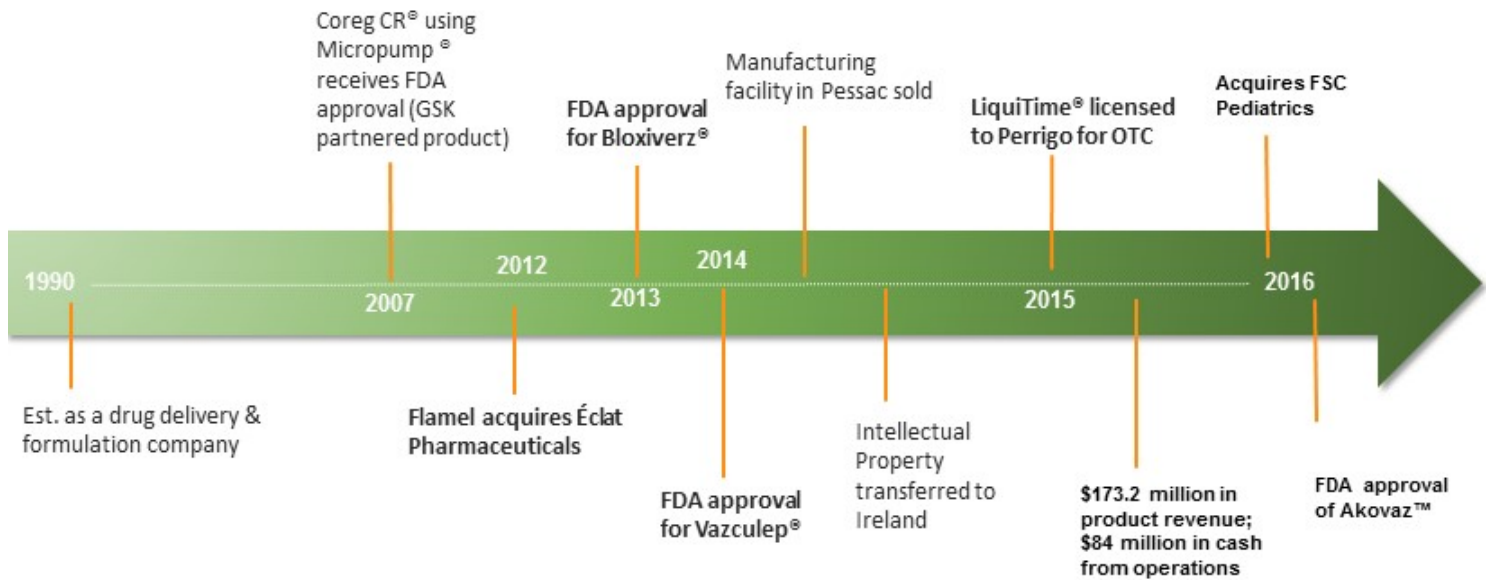
# Investment Highlights

- **Strong financial position – profitable with strong cash flow & balance sheet**
  - \$173.2 million in product revenues in 2015
  - \$84.3 million cash flow from operations generated in 2015; no debt
- **Initiating Phase III pivotal trial using Micropump® sodium oxybate in 2016**
  - Current market size in excess of \$900 million
- **Expanding commercial product portfolio:**
  - 7 FDA approved products from Éclat Portfolio & FSC Pediatrics acquisition
- **Robust pipeline with strong IP protection – ongoing projects include:**
  - LiquiTime® for OTC and Rx
  - Trigger Lock™ hydromorphone
  - Medusa™ exenatide

**Mission: To build a diversified specialty pharmaceutical company that controls 100% of its drug development and future**



# Flamel Technologies Transformed



**Transition from an unprofitable stand alone drug delivery company to a diversified specialty pharma company that is profitable and cash flow positive**

# 2016 Expectations

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- Commence patient registration & dosing for pivotal study of Micropump<sup>®</sup> sodium oxybate by mid year
- Complete cross border merger to Ireland
- Launch Akovaz<sup>™</sup> (Approved on April 29, 2016)
- Integrate & market newly acquired FSC Pediatrics' products
- Begin licensing discussions for Trigger Lock<sup>™</sup> platform
- Report data from Phase 1b study with Medusa<sup>™</sup> exenatide in patients
- Begin development of UMD #4<sup>1</sup>

**Achieve total product sales of \$110-130 million**

<sup>1</sup> UMD is Flamel's Unapproved Marketed Drugs Strategy, which takes unapproved drugs through the FDA approval process. These products are not protected by IP and are subject to generic filers.



# Current Pipeline

Drug/ Technology	Indication	Proof of Concept	Pilot	Pivotal	Under Review	Approved
UMD #4	Undisclosed					
Sodium oxybate/ Micropump <sup>®</sup>	Narcolepsy					
Ibuprofen / LiquiTime <sup>®</sup>	Pain / Fever					
Guaifenesin / LiquiTime <sup>®</sup>	Respiratory					
Hydromorphone / Trigger Lock <sup>™</sup>	Pain					
Exenatide/Medusa <sup>™</sup>	Diabetes					

# Micropump<sup>®</sup> Sodium Oxybate (FT218)

## FT218 Overview

- Extended release oral solid formulation of sodium oxybate using Micropump<sup>®</sup>
- Studied in 40 healthy volunteers across 2 studies
- **Standard of care:** Jazz's Xyrem<sup>®</sup> dosed 2x nightly
  - **Improved formulation needed:** Micropump<sup>®</sup> profile consistent with target of 1x dose before bedtime
- Announced submission of SPA and IND on March 31, 2016
- **Next step:** Initiate patient registration and begin pivotal study

## Market Opportunity

- Jazz's Xyrem<sup>®</sup> FY 2015 sales **were \$955.2 million\***
- >~178,000 narcoleptic patients in the U.S.\*
- Jazz reports < **13,000 patients on treatment\***
- Limited competition to date



# Trigger Lock™ Hydromorphone (FT227)

## FT227 Overview

- Abuse-deterrent, extended-release, oral hydromorphone product for treatment of pain – technology is applicable to all opioids
- Positive results from two pilot PK studies in healthy volunteers announced in June 2015
- **Next step:** Continue dialogue with FDA regarding pivotal study in 1H 2016; begin partnering discussions

## Market Opportunity

- U.S. market for prescription painkillers (all forms) in 2015: **\$6.5 billion**<sup>1</sup>
  - OxyContin® (extended-release oxycodone, Purdue): **\$2.1 billion**<sup>1</sup>
  - ER hydromorphone (Exalgo® & generics) **\$138 million**<sup>1</sup>
- Opioid prescriptions grew from ~76 million in 1991 to ~207 million in 2013<sup>2</sup>
- ~2.1 million people suffered from substance use disorders related to prescription opioids<sup>2</sup>

<sup>1</sup> IMS data <sup>2</sup> "America's Addiction to Opioids: Heroin and Prescription Drug Abuse" (National Institute on Drug Abuse, May 14, 2014)



# Medusa™ Exenatide (FT228)

## FT228 Overview

- Subcutaneous injection formulation of exenatide, a GLP-1 (glucagon-like peptide – 1) for treatment of Type 2 diabetes
- Interim Phase I human clinical data reported in December 2015
- PK profile compatible with a release over one week in humans
- **Next step:** Complete Phase 1b study in 1H 2016

## Market Opportunity

- Market opportunity: GLP-1 products recorded **\$3.9 billion\*** of sales:
  - **\$2.5 million** for Victoza® (once a day liraglutide, Novo Nordisk)
  - **\$736 million** for Bydureon® (once-a-week exenatide, AstraZeneca)
  - **\$319 million** for Byetta® (twice-a-day exenatide, AstraZeneca)



# LiquiTime® Platform Overview

## Overview

- Extended release liquid oral suspension for more convenient and improved dosing with a focus on pediatric and geriatric markets
- **Exclusive U.S. rights licensed to Perrigo for the OTC drug market: development ongoing**
- Flexible capability allows for the combination of multiple active ingredients

## Market Opportunity

- Cough and cold U.S. market is estimated at **\$6.5 billion annually**<sup>1</sup>
- **Potential for liquid prescription products is largely untapped**

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# Marketed Products

# Éclat Portfolio Products



## Bloxiverz® (neostigmine methylsulfate injection)

- Indication: Reverses neuromuscular blockades used in surgical procedures
- 1 of 3 approved versions; ~ 4 million vials sold annually in the U.S.\*

## Vazculep® (phenylephrine hydrochloride injection)

- Indication: Treatment of hypotension resulting primarily from vasodilation in the setting of anesthesia
- Form: 1 mL single use vials, 5 mL and 10 mL
  - 1mL vial – **5.7 million**      5mL vial – **1.2 M**      10mL vial – **0.2 million**



**Akovaz™**  
(Ephedrine Sulfate Injection, USP)  
(50 mg/mL)

## Akovaz™ (ephedrine sulfate injection)

- Indication: Treatment of hypotension clinically important hypotension occurring in the setting of anesthesia
- ~ 5 million vials sold annually in the U.S.

In line with Company's strategy to become a fully integrated global specialty pharmaceutical company

- Commercial stage specialty pharmaceuticals company headquartered Charlotte, NC
- Provides 4 commercial stage assets to be marketed by 45 person salesforce
- Positions Flamel as a more attractive business partner for potential pediatric and geriatric assets
- Fixed acquisition price totals \$20.25 million paid over a five year period
  - \$1 million annually for five years
  - Final payment in January 2021 of \$15.0 million
- Expected 2016 revenues to approximate \$10-\$15 million



# FSC Products

## **Karbinal<sup>ER</sup>** (carbinoxamine maleate) extended-release oral suspension | 4mg/5mL

- Indication: Perennial allergic rhinitis in children 2 years of age and older
- Patent protection through March 2029
- Rx antihistamine market size in U.S. ~ \$11M

## **CEFACTOR**

For Oral Suspension, USP  
125 mg/5 mL • 250 mg/5 mL • 375 mg/5 mL

- Indication: 2nd generation Cephalosporin covering a variety of common pathogens
- For children as young as 1 year
- U.S. Market for Cephalosporin ~ \$300M

## **AcipHex<sup>®</sup> Sprinkle<sup>™</sup>** (rabeprazole sodium)

- Indication: Treatment of GERD in pediatric patients aged 1-11 years
- Proton Pump Inhibitor (PPI)
- Market size in U.S. ~ \$110M

## **flexichamber<sup>®</sup>** Anti-static Valved Collapsible Holding Chamber <sup>Rx</sup> Only



- Indication: Collapsible asthma spacer for use with metered dose inhalers (MDIs)
- Patent protection through March 2028
- Market size in U.S. ~ \$50M

# Strong Intellectual Property

	Patent Protection Through..	
Platform	US	Europe
Micropump®	July 2027	July 2023
LiquiTime®	September 2025	April 2023
Trigger Lock™	April 2027	May 2026 (pending)
Medusa™	June 2031	June 2027 (pending)
Product	US	
Karbinal™ ER	March 2029	
AcipHex® Sprinkle™	September 2016	
Flexichamber®	March 2028	

# Seasoned Senior Management

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Name	Title	Experience
Michael S. Anderson	Chief Executive Officer	40+ years Pharma
Sandy Hatten	Senior Vice President, Quality and Regulatory Affairs	30+ years Pharma
Phillandas T. Thompson, J.D., M.B.A.	Senior Vice President, General Counsel	16+ years Legal
Mike Kanan	Senior Vice President and Chief Financial Officer	30+ years Financial
Gregory J. Davis	Vice President, Corporate and Business Development	20+ years Pharma
David Monteith, Ph.D.	Vice President, Research and Development	25+ years Pharma
Dhiren D'Silva	Vice President of Irish and European Operations	19+ years Business

# Key Financial Metrics (Unaudited)

In Millions USD, Except Per Share Data:

<i>Income Statement Metrics</i>	Twelve months ended December 31,	
	2015	2014
Revenue	\$ 173.2	\$14.8
COGS	(10.9)	(3.4)
R&D	(25.6)	(17.3)
SG&A	(21.7)	(15.7)
Acquisition Earn-Out Payments/Accruals	(32.2)	(1.7)
Adj Op. Profit (Loss) *	82.8	(23.3)
Adj. Net Income (Loss) *	43.1	(24.6)
Adjusted Diluted EPS *	0.99	(0.68)

<i>Balance Sheet Metrics</i>	At December 31,	
	2015	2014
Cash & Marketable Securities	\$ 144.8	\$92.8
Goodwill & Intangible Assets	34.3	46.9
Long-term Contingent Consideration Liability	122.7	114.8

<i>Cash Flow Metrics</i>	Twelve months ended December 31,	
	2015	2014
Free Cash Flow *	\$ 58.1	(\$13.7)

\* = Non-GAAP. See Reconciliation of Non GAAP to GAAP in Appendix

# Flamel Technologies Transformed

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- **Strong financial condition - profitable with strong cash flow and balance sheet**
- **Seven FDA approved products**
- **Experienced management team**
- **Robust pipeline with extensive IP protection**

**Mission: To build a diversified specialty pharmaceutical company that controls 100% of its drug development and future**

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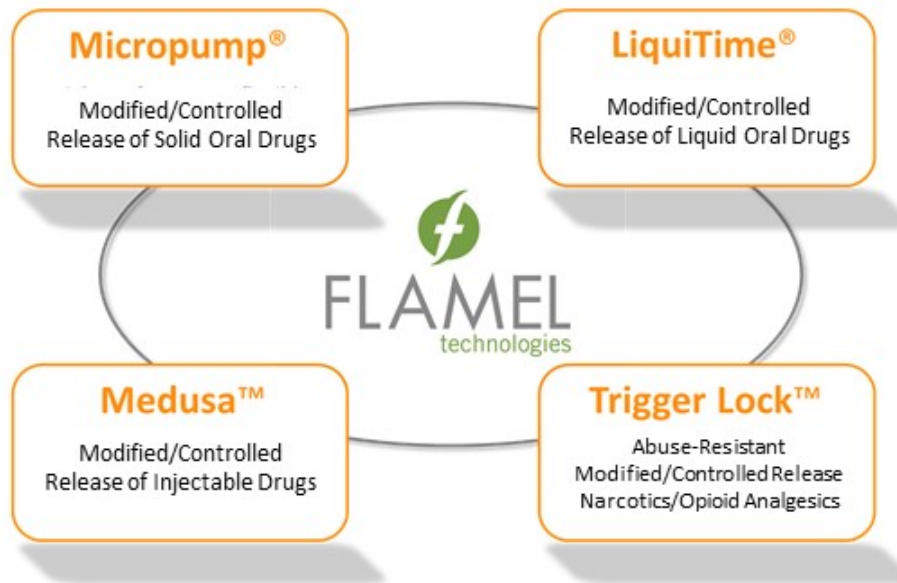
# Appendix

# Reconciliation of Non GAAP to GAAP Results

	Operating Income (Loss)		Net Income (Loss)		Diluted Earnings (Loss) per share	
	2015	2014	2015	2014	2015	2014
<b>Reported</b>	\$ 71.4	\$ (93.9)	\$ 40.7	\$ (84.9)	\$ 0.93	\$ (2.34)
<i>Exclude:</i> Contingent consideration - Acquisition-related fair value remeasurements - Inc. (Dec.)	31.0	57.5	31.0	57.5	0.71	1.59
Contingent consideration - Financing-related fair value remeasurements - Inc. (Dec.)	<i>n/a</i>	<i>n/a</i>	4.8	3.5	0.11	0.10
Intangible asset amortization	12.6	11.8	12.6	11.8	0.29	0.32
Unrealized foreign exchange (gain) loss	<i>n/a</i>	<i>n/a</i>	(6.8)	(11.7)	(0.15)	(0.32)
Loss on early repayment of related party acquisition-related note	-	3.0	-	3.0	-	0.08
Loss on early repayment of related party facility agreement notes	<i>n/a</i>	<i>n/a</i>	-	4.7	-	0.13
Net income from discontinued operations	<i>n/a</i>	<i>n/a</i>	-	(4.0)	-	(0.11)
<i>Include:</i> Contingent consideration - Acquisition-related paid/accrued	(32.2)	(1.7)	(32.2)	(1.7)	(0.74)	(0.05)
Contingent consideration - Financing-related paid/accrued	<i>n/a</i>	<i>n/a</i>	(4.4)	(0.2)	(0.10)	(0.01)
Income tax expense (benefit) related to all above adjustments	<i>n/a</i>	<i>n/a</i>	(2.6)	(2.6)	(0.06)	(0.07)
Total adjustments	11.4	70.6	2.4	60.3	0.06	1.66
<b>Adjusted</b>	<b>\$ 82.8</b>	<b>\$ (23.3)</b>	<b>\$ 43.1</b>	<b>\$ (24.6)</b>	<b>\$ 0.99</b>	<b>\$ (0.68)</b>
<b>Free Cash Flow:</b>	<b>2015</b>	<b>2014</b>				
Net cash provided by (used in) operating activities	\$ 84.3	\$ (10.6)				
Less: Purchases of property and equipment	(1.6)	(1.7)				
Earn-out payments for related party acquisition-related contingent consideration	(24.6)	(1.4)				
<b>Free Cash Flow</b>	<b>\$ 58.1</b>	<b>\$ (13.7)</b>				

# Diversified and Proven Drug Delivery Platforms

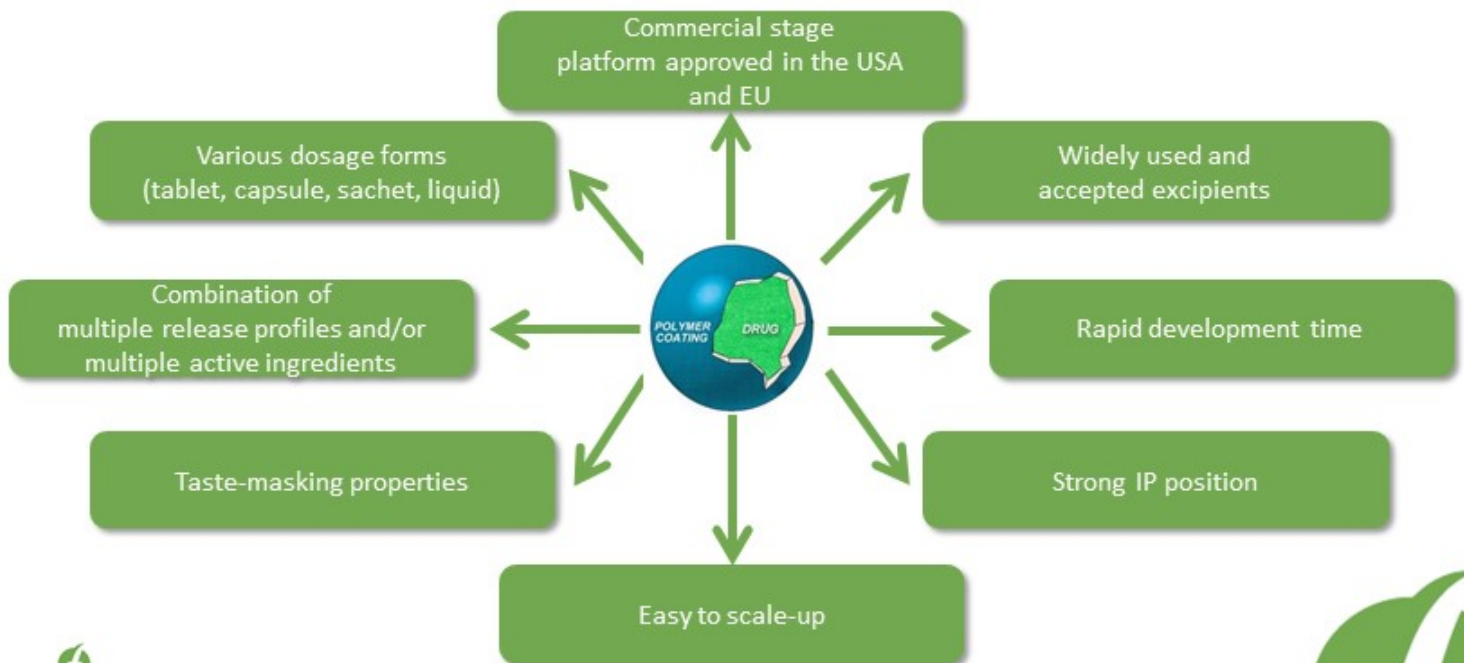
- Outstanding drug delivery platforms to tackle key challenges in the formulation, in **various dosage forms** (e.g. capsules, tablets, sachets or **oral** liquid suspensions; or **injectable** for subcutaneous administration) of a broad range of drugs (already-marketed, off-patent or novel)





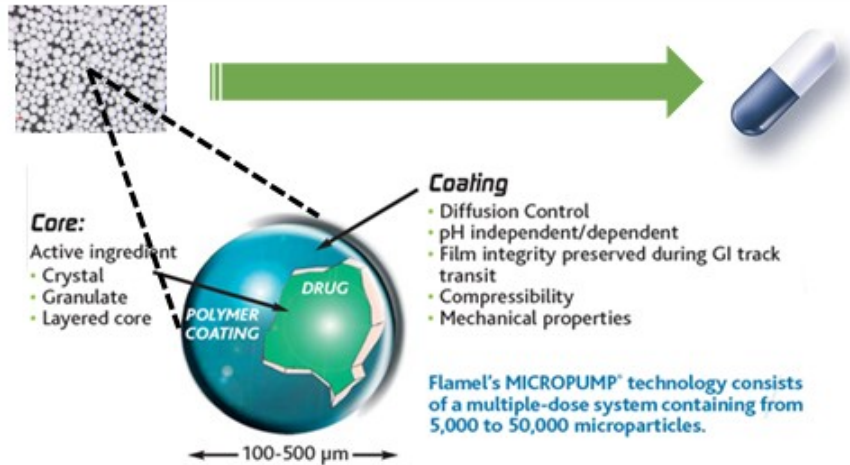
# Micropump® Platform at a Glance

- Extended/delayed-release of drugs in the GI tract
- Precise pharmacokinetics of single or combination of drugs in various formats
- Numerous Micropump®-based products successfully tested in human clinical trials



# Micropump Microparticles for Controlled/Modified Release

**Granules**  
drug granulate or  
layered neutral core

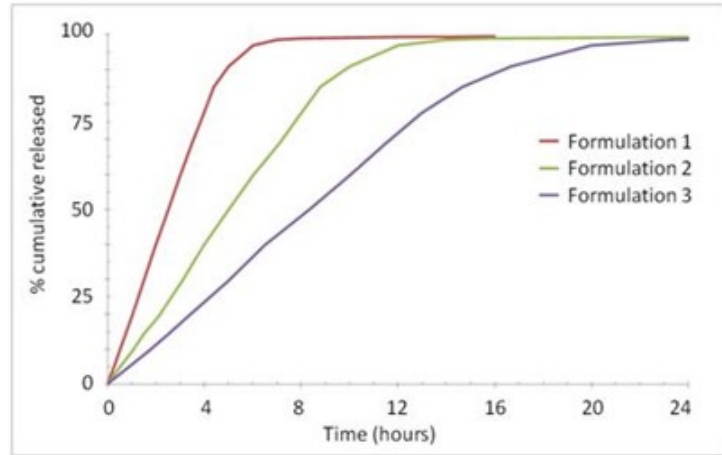


- Microparticles are dispersed in the stomach and pass into the small intestine, after which each microparticle releases the drug at an adjustable rate and over an extended period of time (up to 24 hours)
- Drug released at an adjustable rate controlled and/or delayed
- Micropump® microparticles can be used separately or together to provide highly specialized delivery profiles

# LiquiTime® Platform at a Glance

LiquiTime® is a novel, proprietary and innovative delivery platform allowing the stable **Liquid** and **controlled release** formulation of one or several combined drugs over **Time**

LiquiTime® meets challenges faced in the treatment of pediatric and geriatric patients and patient populations who have difficulty swallowing tablets or capsules, and may provide better patient compliance

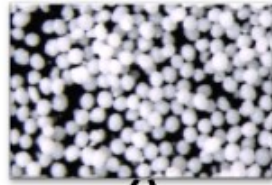


*This graph illustrates the different near zero-order release profiles which can be tailored for the same drug*

LiquiTime's versatility allows **once- or twice-daily liquid formulations** of a wide variety of drugs

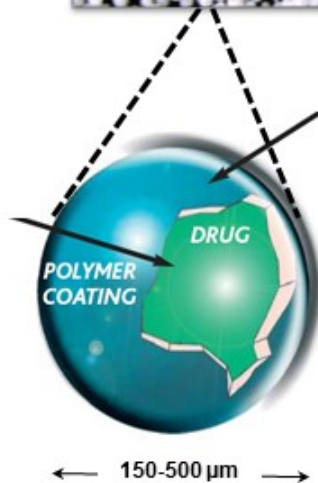
# LiquiTime® for Extended-Release Liquid Suspension

Liquid suspension contains small coated drug microparticles  
A dose typically contains 5,000 to 50,000 particles



ER microparticles are suspended in the liquid medium

**Granules**  
drug granulate or layered neutral core



### Coating

- controls diffusion
- keeps its integrity
- offers good resistance to stress

Each microparticle is individually coated and behaves as an independent micro reservoir

# Trigger Lock™ Platform at a Glance

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Trigger Lock™ is a proprietary and innovative delivery platform that enables the **controlled release of narcotic and opioid analgesics while deterring their abuse**

Trigger Lock™ successfully addresses the issues of narcotic/opioid analgesics tampering:

- ✓ The sustained release Micropump®-based microparticles are resistant to crushing: each microparticle retains its polymer coating which is virtually impervious to further crushing
- ✓ Trigger Lock™ resists extraction attempts (even in boiling liquids) with beverages (alcoholic or not) preventing injection
- ✓ Trigger Lock™ preserves the bioavailability of the narcotic/opioid analgesics
- ✓ Trigger Lock™ is compatible with different dosage forms (capsules, tablets)

# Trigger Lock™ SR Microparticles for Abuse Resistance

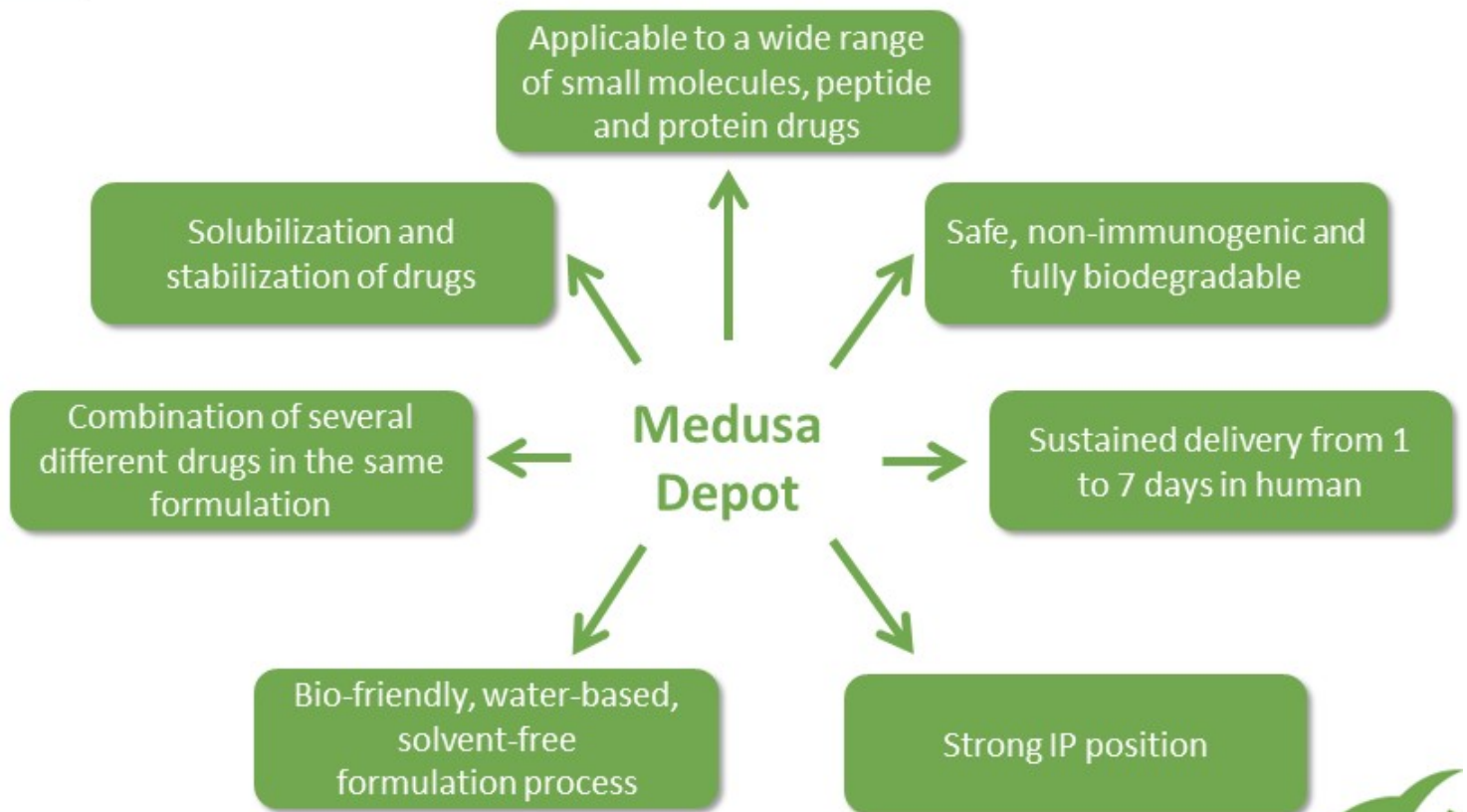
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- 1. Drug loaded Micropump® microparticles**  
Sustained Release (SR) microparticles which are resistant to crushing
- 2. Viscosifying ingredient(s)**  
To prevent abuse by injection after extraction in a small volume of solvent
- 3. Quenching ingredient(s)**  
To prevent extraction in large volumes of liquid

- **Each microparticle retains its polymer coating which is virtually impervious to further crushing**

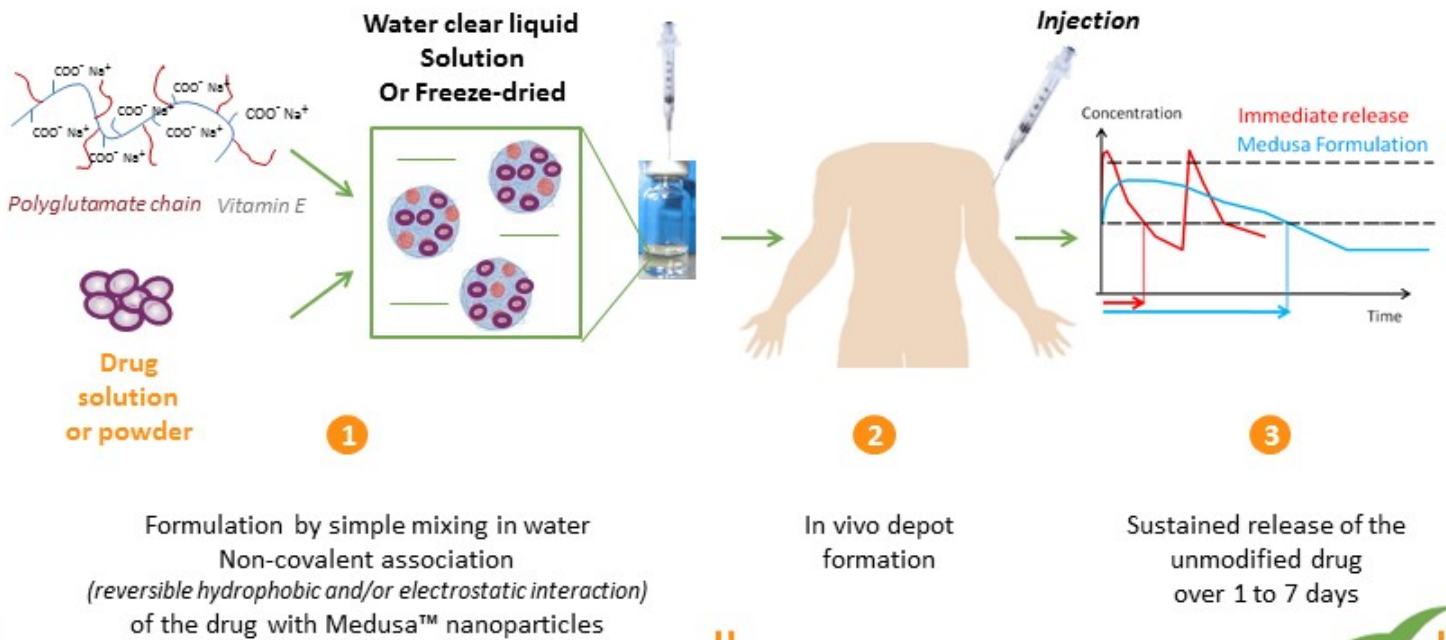


# Medusa™ Platform at a Glance



# Medusa™ Depot for Injection

- Made of polyglutamic acid and Vitamin E
- Amphiphilic and spontaneously forms stable nanoparticles in water
- Complexes are stable over a wide range of pH





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*Specialty Pharmaceutical Company with  
Proprietary Drug Delivery Platforms Focused on  
Improved or Cost-Effective Products*

**Headquarters**

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69200 Vénissieux (Lyon)  
France

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E-mail: [licensing@flamel.com](mailto:licensing@flamel.com)

**U.S. Commercial Operations**

16640 Chesterfield Grove Road, Suite 200  
Chesterfield, MO  
Phone: 636 449 1830  
Fax: 636 449 1850



## Flamel Technologies to Report First Quarter 2016 Results

**Lyon, France – May 2, 2016** - Flamel Technologies (NASDAQ: FLML) today announced that the Company will report its financial results for the first quarter ended March 31, 2016 on Monday, May 9, 2016, before the market open. A conference call to discuss these results has been scheduled for Monday, May 9, 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 800-753-0420 (U.S. and Canada) or 913-312-0645 (international). The conference ID number is 3821495. A live audio webcast can be accessed by visiting the Investor section of the Company's 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 two previously Unapproved Marketed Drugs ("UMDs") in the United States, Bloxiverz® (neostigmine methylsulfate injection) and Vazculep® (phenylephrine hydrochloride 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 Micropump-derivative 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, Medusa™, a hydrogel depot technology. 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 Charlotte, North Carolina-based company that markets three pediatric pharmaceutical products - Cefaclor for oral suspension, indicated for infection, Karbinal™ ER, indicated for allergic rhinitis and AcipHex® Sprinkle™ (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 the USA in both St. Louis, Missouri and Charlotte, North Carolina. Additional information may be found at [www.flamel.com](http://www.flamel.com).

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**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 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.

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