

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 23, 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))

Item 7.01 Regulation FD Disclosure.

On February 23, 2016, Flamel Technologies S.A. (the “Company”) intends to make a presentation at the RBC Capital Markets Global Healthcare Conference in New York, New York. 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. As previously announced, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Form of Slide Presentation of Flamel Technologies S.A. as of February 23, 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 23, 2016

Exhibit Index

99.1		Form of Slide Presentation of Flamel Technologies S.A. as of February 23, 2016.
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Forward Looking Statements

This document includes statements concerning our operating results (including product sales), financial condition and product development milestones, which are “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 possibility that we may cease to qualify as a foreign private issuer, which would increase the costs and expenses we incur to comply with U.S. securities laws; 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.

Flamel Technologies Transformed

- **Strong financial condition - profitable with strong cash flow and balance sheet**
- **Two FDA approved products - a third expected in 2016**
- **New and experienced management team**
- **Robust pipeline**

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



Key Milestones Achieved in 2015

- ✓ Generated over \$170M of revenues
- ✓ Profitable and cash flow positive for first time in company's history
- ✓ Had successful meeting with FDA on Micropump® Sodium Oxybate
- ✓ Presented positive clinical data
 - **LiquiTime® guaifenesin**
 - **Trigger Lock™ hydromorphone**
 - **Medusa™ exenatide**
 - Licensed exclusive U.S. rights to the LiquiTime® drug delivery platform to Perrigo for the Over-The-Counter (OTC) drug market
- ✓ Made key senior management team hires

2016 Expectations

- Achieve total product sales of \$110-130 million, inclusive of FSC Pediatrics
- Launch UMD#3
- Integrate and market newly acquired FSC Pediatrics' products
- Start patient registration and dosing for pivotal study of Micropump® sodium oxybate
- Begin licensing discussions for Trigger Lock™ platform
- Complete and report data from Phase 1b study with Medusa™ exenatide in patients
- Begin development of UMD #4*
- Corporate restructuring to geographically align business with location of intellectual property



Acquisition of FSC



This acquisition compliments our strategy to become a fully integrated global specialty pharmaceutical company

FSC Pediatrics

- Commercial stage specialty pharmaceuticals company headquartered Charlotte, NC
- Provides commercial infrastructure to leverage for future products
- Provides new revenue streams and lessens dependence on Éclat products
- Become a more attractive business partner for potential pediatric, geriatric and other assets

Commercial Products

- **Karbinol** – Carbinoxamine extended release for the treatment of seasonal and perennial allergic rhinitis in children ages 2 and up
- **AcipHex Sprinkle** – Rabeprazol for the treatment of GERD in pediatric patients aged 1-11 years
- **Ceflacor** – Cephalosporin for the treatment of certain infections
- **Flexichamber** – collapsible asthma spacer

Terms of the Transaction

- Fixed acquisition price totals \$20.25 million paid over a five year period
 - \$1 million annually for five years
 - And a final payment in January 2021 of \$15.0 million
- Variable consideration:
 - Royalties of 15% per annum on net sales of the current FSC products, up to \$12.5 million for a period not exceeding ten years
- Expected 2015 revenues to approximate \$10-\$15 million
- Adjusted operating profit and cash flow neutral

Terms of the Transaction are Very Cash Friendly

FSC Territory Map

- - WEST
- - SOUTH CENTRAL
- - MIDWEST
- - SOUTHEAST
- - NORTHEAST



Marketed Products Portfolio

- Flamel's Products
- Acquired FSC Products

BLOXIVERZ® & VAZCULEP® Overview

Bloxiverz®

- Indication: Reverses neuromuscular blockades used in surgical procedures
- 1 of 3 approved versions of neostigmine methylsulfate injection
- Approximately 4 million vials sold annually in the United States*
- More details can be found at www.bloxiverz.com



Vazculep®



- Indication: Treatment of hypotension resulting primarily from vasodilation in the setting of anesthesia
- Form: 1 mL single use vials, 5 mL and 10 mL
- Market potential at end 2015*
 - 1mL vial – **5.7 million** 5mL vial – **1.2 million** 10mL vial – **0.2 million**
- More details can be found at www.vazculep.com



Karbinal ER & Cefaclor Overview

Karbinal^{ER}
(carbinoxamine maleate) extended-release
oral suspension | 4mg/5mL

- Licensed from Tris Pharma in August 2013
- Used for the treatment of seasonal and perennial allergic rhinitis in children 2 years of age and older
- Orange book patent protection through March 2029
- Market size for liquids in US estimated at \$110 million

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

- Licensed from Yung Shin in March 2015
- 2nd generation Cephalosporin
- Market size approximates \$300 million
- FDA-approved as therapeutically equivalent to Ceclor (significant brand recognition)
- Broad indication for children as young as 1 month of age; covers common pathogens

AcipHex Sprinkle Overview

- Licensed from Eisai in June 2014
- FDA approved AcipHex Sprinkle in March, 2013 for the treatment of GERD in pediatric patients aged 1-11 years
- Launched promotional efforts in August 2014
- Market size for liquids in US estimated at \$110 million
- Proton Pump Inhibitor (PPI) market is large and stable



> 2.0MM annual prescriptions for patients aged 10-19 years
Market opportunity in this age group in excess of \$750MM

>1.1MM annual prescriptions for patients aged 0-9 years
Market opportunity for this age group exceeds \$400MM

TRANSFORMING THE TRADITIONAL CHAMBER TO MOVE WITH THE LIFE OF A CHILD

- Collapsible asthma spacer
- Internally developed with a 510 (K) approval
- Market size estimated at \$50 million
- Patents through 2028
- Patient benefits:
 - ✓ Dynamic Portability
 - ✓ Optimal Performance
 - ✓ Simple Assembly
 - ✓ Enhanced Patient Care



Flamel's R&D Pipeline

- Micropump[®] sodium oxybate
- LiquiTime[®]
- Trigger Lock[™] hydromorphone
- Medusa[™] exenatide

Current Pipeline

Drug/ Technology	Indication	Proof of Concept	Pilot	Pivotal	Under Review	Approved	Sales Force
UD/UMD ¹ #3	Undisclosed						Flamel
UD/UMD ¹ #4	Undisclosed						Flamel
Sodium oxybate/ Micropump [®]	Narcolepsy						Flamel
Ibuprofen / LiquiTime [®]	Pain / Fever						Perrigo
Guaifenesin / LiquiTime [®]	Respiratory						Perrigo
Hydromorphone / Trigger Lock [™]	Pain						TBD
Exenatide/Medusa [™]	Diabetes						TBD

¹ UMD is Flamel's Unapproved Marketed Drugs Strategy that does not involve patented technology
UD = undisclosed

Micropump[®] Sodium Oxybate (FT218)

FT218 Overview

- Extended release oral solid formulation of sodium oxybate using Micropump[®]
- Studied in **40 healthy volunteers** across 2 studies
- **Profile is consistent** with the target of single dose before bedtime
- **Met with FDA mid 2015** and will submit IND and SPA during 1H 2016
- **Next step:** Phase III clinical trial application submission and initiation of pivotal study

Market Opportunity

- Jazz's Xyrem[®] FY2015 sales **could exceed \$900 million***
- >~178,000 narcoleptic patients in the U.S.*
- Jazz reports **< 13,000 patients on treatment***
- Limited competition to date
- Micropump[®] sodium oxybate could benefit from improved formulation

LiquiTime® OTC

Overview

- Extended release liquid oral suspension for treatment of pain and fever
- Ibuprofen & Guaifenesin oral suspension twice-daily dosing confirmed

Next Step:

- **Ibuprofen** – IND/CTA filing and pivotal trial initiation in 2H 2016
- **Guaifenesin** – Confirmatory PK study in 1H 2016

Market Opportunity

- Cough and cold U.S. market is estimated at **\$6.5b annually**¹
 - OTC ibuprofen-containing products recorded over **\$490 million**² of sales
 - OTC guaifenesin-containing products recorded over **\$440 million**² of sales
- LiquiTime® allows for combination of active ingredients
- **Exclusive U.S. rights licensed to Perrigo for the OTC drug market**

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:** Meet with the FDA in 1H 2016; begin partnering discussions

Market Opportunity

- U.S. market for prescription painkillers (all forms) in 2015: **\$6.5b¹**
 - OxyContin® (extended-release oxycodone, Purdue): **\$2.1b¹**
 - ER hydromorphone (Exalgo® & generics) **\$138m¹**
- Opioid prescriptions grew from ~76 million in 1991 to ~207 million in 2013²
- ~2.1 million people suffered from substance use disorders related to prescription opioids²



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 over **\$3.2 billion***:
 - **\$2.1b** for Victoza® (once a day liraglutide, Novo Nordisk)
 - **\$600m** for Bydureon® (once-a-week exenatide, AstraZeneca)
 - **\$266m** for Byetta® (twice-a-day exenatide, AstraZeneca)

Flamel's Strengths

- Strong intellectual property
- Seasoned senior management
- Healthy financial situation

Strong Intellectual Property

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)

- New patents may be issued targeting each individual product in development where a Flamel drug delivery platform is applied to a specific molecule

Seasoned Senior Management

Name	Title	Appointed	Experience
Michael S. Anderson	Chief Executive Officer	2012	40+ years Pharma
Sandy Hatten	Senior Vice President, Quality and Regulatory Affairs	2015	30+ years Pharma
Phillandas T. Thompson, J.D., M.B.A.	Senior Vice President, General Counsel	2013	16+ years Legal
Mike Kanan	Senior Vice President and Chief Financial Officer	2015	30+ years Financial
Gregory J. Davis	Vice President, Corporate and Business Development	2015	20+ years Pharma
David Monteith, Ph.D.	Vice President, Research and Development	2014	25+ years Pharma
Dhiren D'Silva	Vice President of Irish and European Operations	2015	19+ years Business

Condensed Consolidated Statement of Operations

(Unaudited)

<i>In USD million, except EPS and shares data (million)</i>	Nine months ended	
	September 30, 2015	September 30, 2014
Revenue	\$ 130	\$12
COGS	(8)	(2)
R&D	(20)	(12)
SG&A	(15)	(12)
Acquisition Royalty Payments	(24)	(1)
Adj Op. Profit (Loss) (non-GAAP)	62	(15)
Adj. Net Income (Loss) (non-GAAP)	29	(16)
Adjusted Diluted EPS	0.72	(0.44)

See Reconciliation of Non GAAP to GAAP in Appendix

Flamel Technologies Transformed

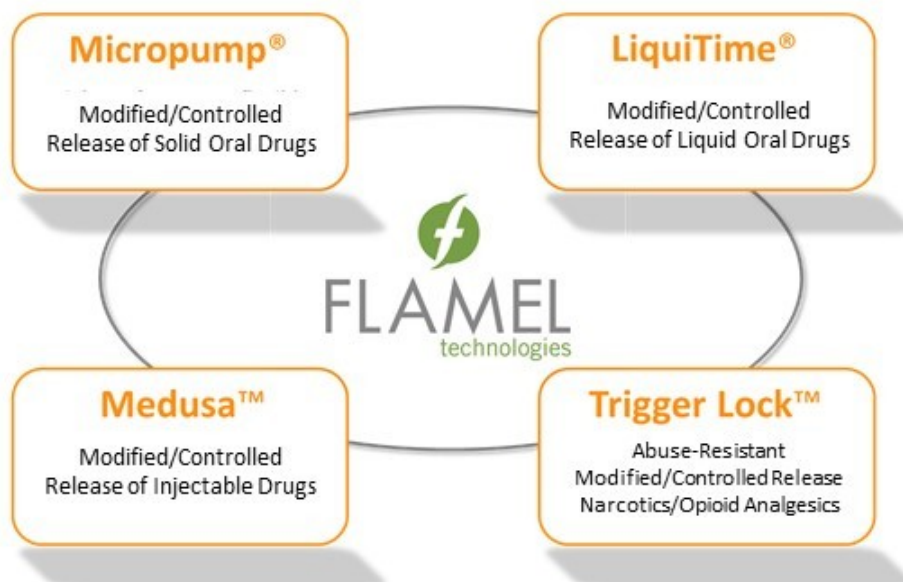
- **Strong financial condition - Profitable with strong cash flow and balance sheet**
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Appendix

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, LiquiTime, Trigger Lock and Medusa are trademarks of Flamel Ireland Ltd.

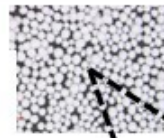
Micropump® Platform at a Glance

- 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



Core:

- Active ingredient
- Crystal
- Granulate
- Layered core



Coating

- Diffusion Control
- pH independent/dependent
- Film integrity preserved during GI track transit
- Compressibility
- Mechanical properties

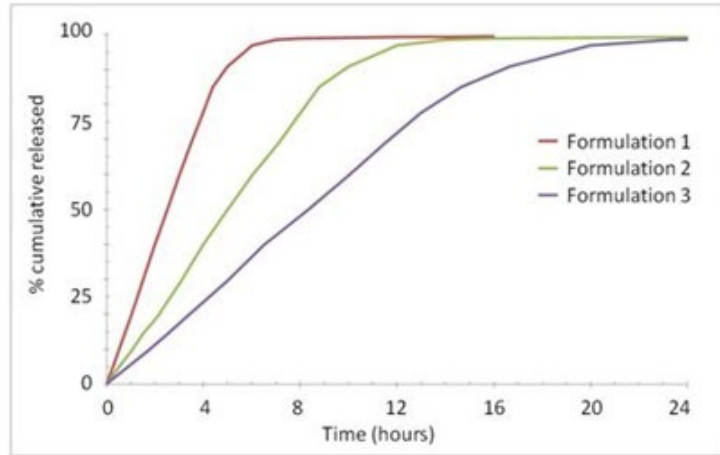
Flamel's MICROPUMP® technology consists of a multiple-dose system containing from 5,000 to 50,000 microparticles.

- 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

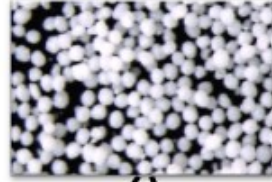


This graph illustrates the different near zero-order release profiles which can be tailored for the same drug

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

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)

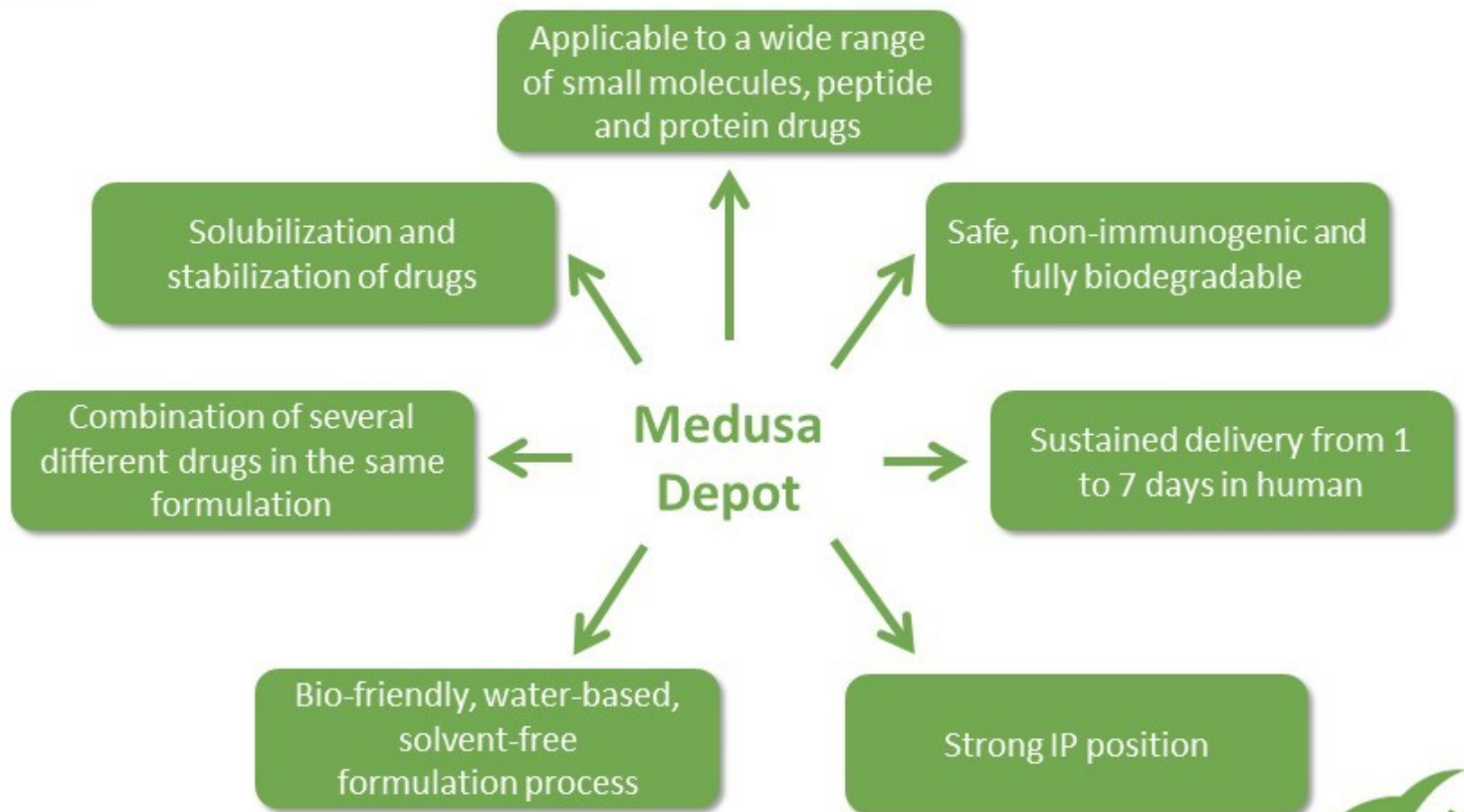
Trigger Lock™ SR Microparticles for Abuse Resistance

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**

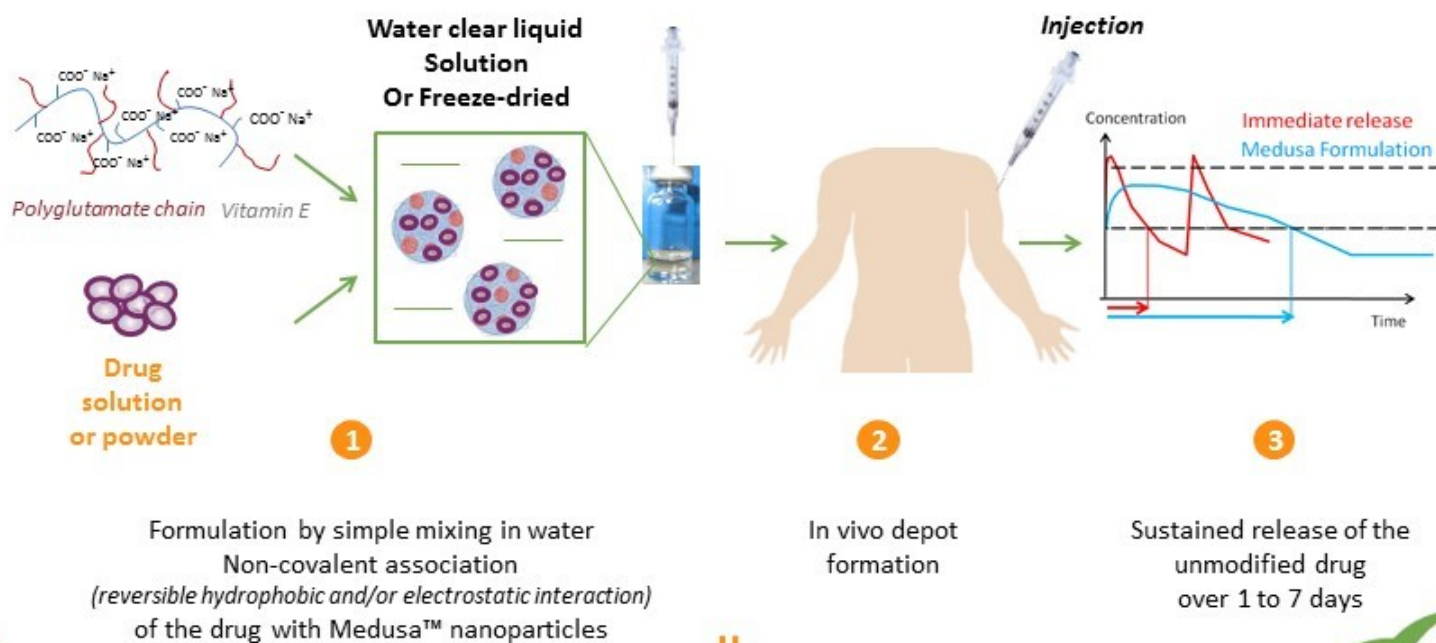


Medusa™ Platform at a Glance



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



Reconciliation of Non GAAP to GAAP Results

Flamel Technologies

Reconciliation of GAAP to Non GAAP

	<u>Nine months ended Sept 30, 2015</u>	<u>Nine months ended Sept 30, 2014</u>
Non GAAP Operating Profit (Loss)	\$ 62	\$ (15)
Contingent Consideration - Cash Payments	24	2
Contingent Consideration - Fair Value Remeasurement	(82)	(35)
Amortization of R&D Intangibles	(9)	(9)
Acquisition Note Expenses	-	(3)
Total Adjustments to arrive at GAAP Operating Profit	<u>(67)</u>	<u>(45)</u>
GAAP Operating Profit	<u>\$ (5)</u>	<u>\$ (60)</u>

	<u>Net</u>	<u>Diluted</u>	<u>Net</u>	<u>Diluted</u>
	<u>Income (loss)</u>	<u>EPS</u>	<u>Income (loss)</u>	<u>EPS</u>
Non GAAP Net Income (Loss)	\$ 29	0.72	\$ (16)	\$ (0.44)
Non GAAP Adjustments above	(67)	(1.66)	(45)	(1.28)
Other, net	(1)	(0.04)	1	0.03
Taxes	4	0.09	2	0.05
GAAP Net Income	<u>\$ (35)</u>	<u>\$ (0.88)</u>	<u>\$ (58)</u>	<u>\$ (1.64)</u>

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

Headquarters

33 avenue du Dr. Georges Levy
69200 Vénissieux (Lyon)
France

Corporate Contact

Phone: +33 472 783 434
Fax: +33 472 783 435
E-mail: licensing@flamel.com

U.S. Commercial Operations

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