
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): **June 7, 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 7.01 Regulation FD Disclosure.

On June 7, 2016, Flamel Technologies S.A. (the “Company”) intends to make a presentation at the Jefferies 2016 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 June 7, 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: June 7, 2016

Exhibit Index

99.1	Form of Slide Presentation of Flamel Technologies S.A. as of June 7, 2016.
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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® 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.

Investment Highlights

Strong Financial Position

- Profitable; strong cash flow & balance sheet – NO DEBT
- \$84.3 million cash flow from operations generated in 2015
- \$160 million in cash and marketable securities as of March 31, 2016

Phase III Trial

- Trial using Micropump® applied to sodium oxybate to begin mid 2016
- Current market size in excess of \$900 million

Expanding Product Portfolio

- 3 branded anesthetic products with little competition
- 4 products added through acquisition of FSC Pediatrics in Q1 2016

Robust Pipeline

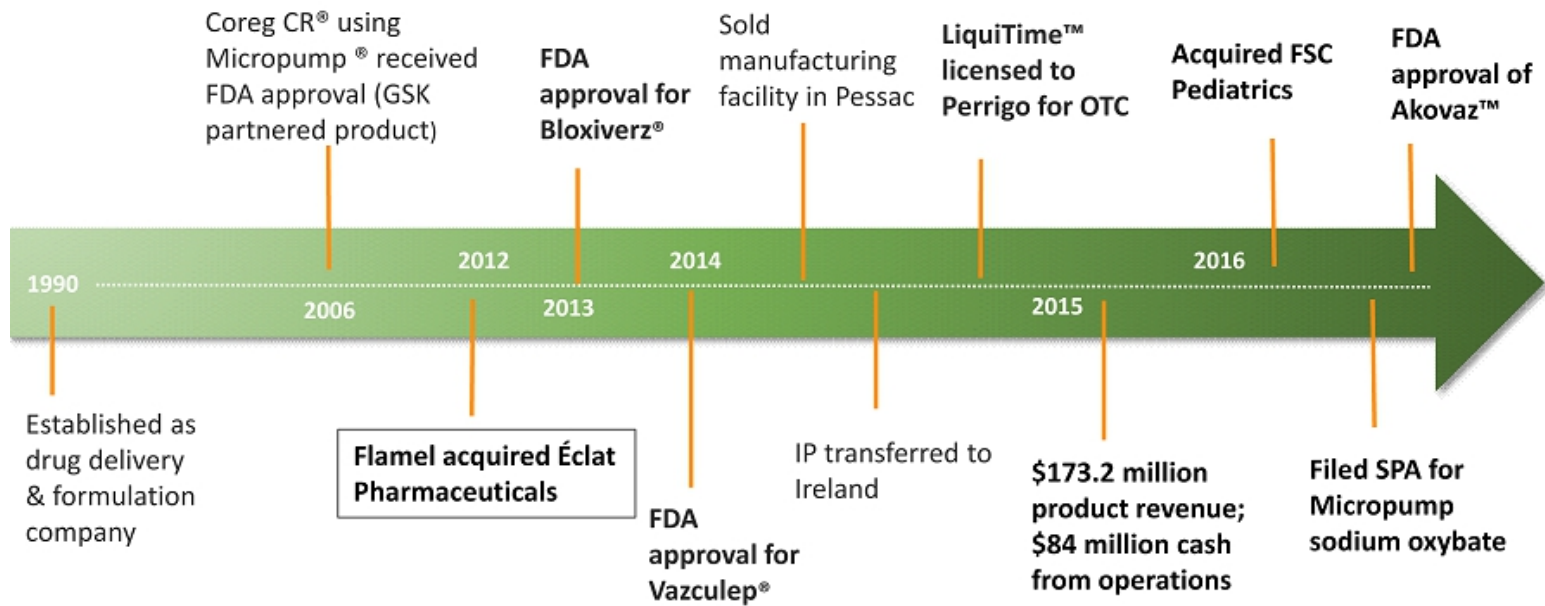
- Micropump® sodium oxybate
- LiquiTime® for OTC and Rx
- Trigger Lock™ hydromorphone
- Medusa™exenatide

Extensive IP

- Technology patent life extends to a minimum of 2025
- Product specific IP

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

Corporate Transformation



In past 3 years, received 3 NDA approvals, validated its LiquiTime technology & transformed into a profitable, cash flow positive specialty pharma company

2016 Expectations

Launch Akovaz™
(Approved on 4/29/16)

Integrate FSC Pediatrics:
\$10 - \$15 million in
product revenues

Begin development of
UMD #4¹

Commence registration & dosing for pivotal study
of Micropump® sodium oxybate by mid year


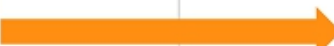


Begin licensing
discussions for Trigger
Lock™ & Medusa
platforms



Complete cross-border merger from France to Ireland

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

¹ 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.

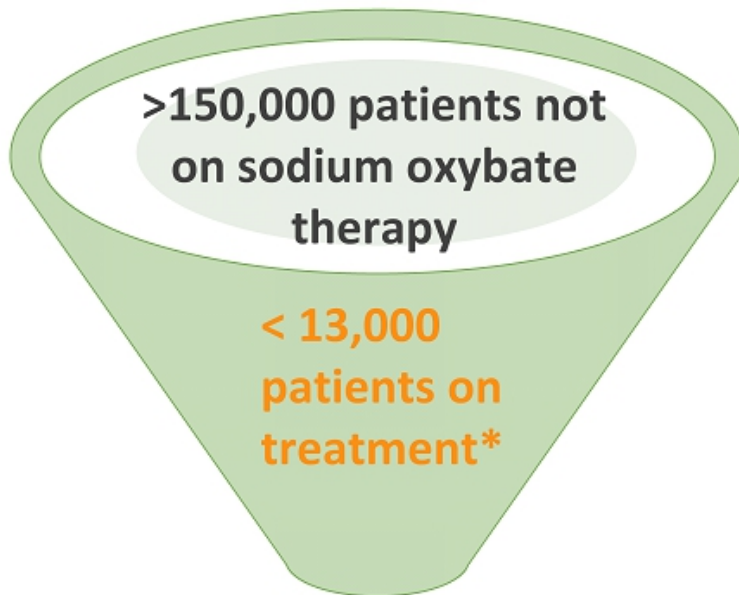
Current Pipeline

Drug/ Technology	Indication	Proof of Concept	Pilot	Phase III	Under Review	Approved
Unapproved Marketed Drug #4	Undisclosed					
Sodium oxybate/ Micropump®	Narcolepsy					
Hydromorphone / Trigger Lock™	Pain					
Exenatide/Medusa™	Diabetes					

Partnered Products						
Ibuprofen / LiquiTime®	Pain / Fever					
Guaifenesin / LiquiTime®	Respiratory					

Sodium Oxybate Market Opportunity

>~178,000 narcoleptic patients in U.S.*



Large untapped opportunity exists in narcolepsy patient population

Xyrem® FY 2016 sales expected to be \$1.095 - \$1.130 billion

* GlobalData & JAZZ's 4Q'15 earnings call

Micropump[®] Sodium Oxybate (FT218)

Micropump sodium oxybate studied in 40 healthy volunteers at 4.5 grams, 6 grams and 7.5 grams

Results showed:

Similar onset of action as Xyrem
Slightly lower Cmax than
Similar blood levels at hours 7 - 8

Sodium Oxybate: Standard of care for treatment of excessive daytime sleepiness (EDS) & cataplexy for patients suffering from narcolepsy

Dosed twice nightly*

3 - 4.5 grams at bedtime
3 - 4.5 grams at 2.5 – 4 hrs later

Potential to eliminate 2nd dose & provide other patient benefits

Pivotal trial to begin mid year 2016



Micropump[®] Overview

Robust platform technology utilizing microparticles for the extended/delayed release of drugs in GI tract

Tailored release profile solves dosing problems related to PK profiles and drugs with short half lives

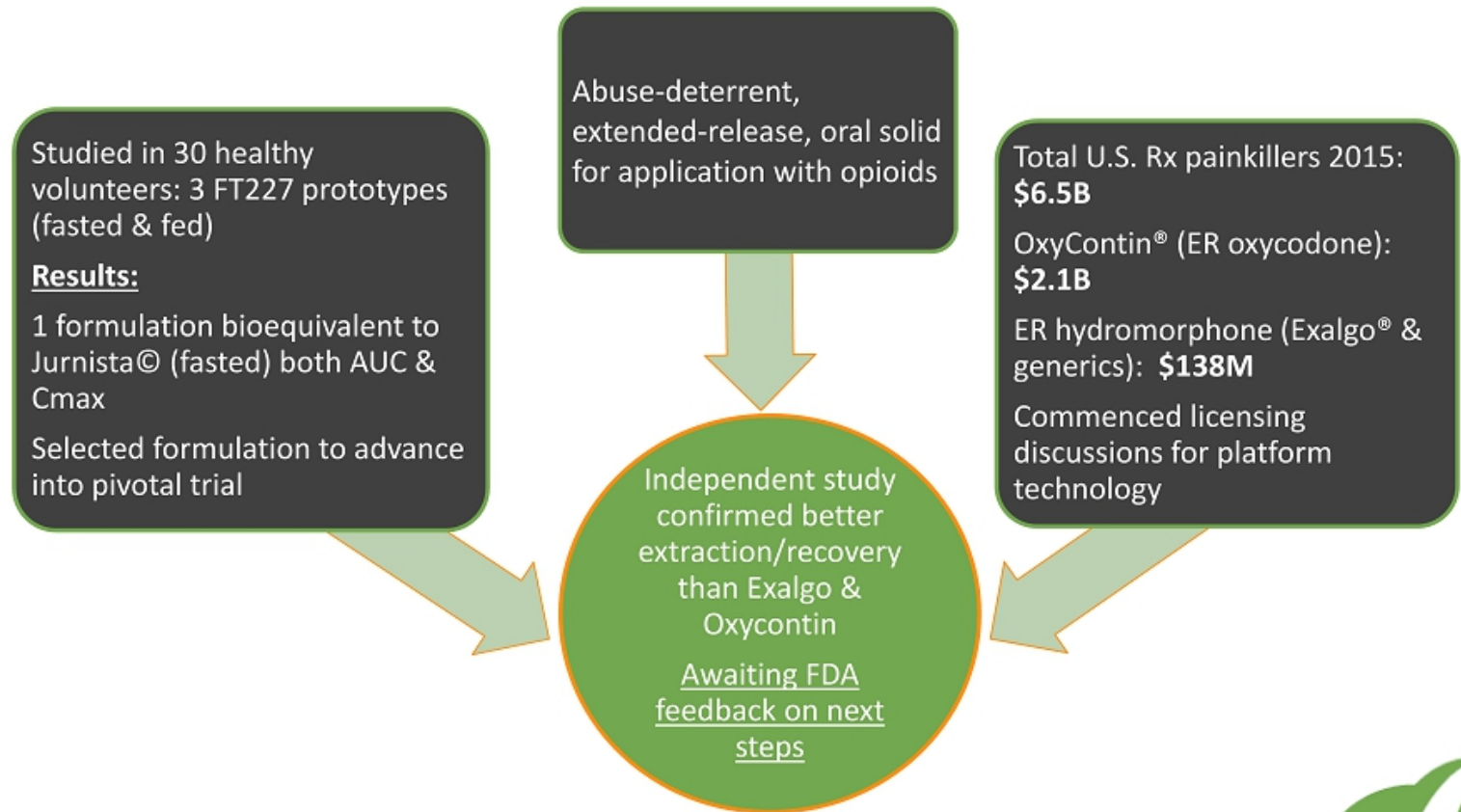
Micropump 1st approved in 2006 in Coreg CR (carvedilol)

10 years – no generics

Applicable to wide variety of molecules

Patented through 2027 with product specific patents to extend protection

Trigger Lock™ Hydromorphone (FT227)



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**¹
- Additional products to be announced throughout 2016
- Potential for liquid prescription products is largely untapped

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
- Data for phase 1b study in 1H 2016

Market Opportunity

GLP-1 products recorded **\$3.9 billion*** of sales:

- **\$2.5 billion** 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)

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

Pediatric Products

Karbinal^{ER}
(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. ~ \$110M

CEFACLOR

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[®]
Sprinkle[™]**
(rabeprazole sodium)

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

flexichamber[®]
Anti-static Valved Collapsible Holding Chamber ^{Rx 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

Product specific IP utilizing platforms will extend patent life

Seasoned Senior Management

Name	Title	Experience
Michael S. Anderson	Chief Executive Officer	40+ years Pharma
Mike Kanan	Senior Vice President and Chief Financial Officer	30+ years Financial
Phillandas T. Thompson	Senior Vice President, General Counsel	16+ years Legal
Sandy Hatten	Senior Vice President, Quality and Regulatory Affairs	30+ years Pharma
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:

Income Statement Metrics	Three months ended March 31,	
	2016	2015
Revenue	\$ 36.2	\$32.9
COGS	(4.4)	(3.6)
R&D	(5.4)	(6.0)
SG&A	(9.5)	(4.5)
Acquisition Earn-Out Payments/Accruals	(5.4)	(6.0)
Adj Op. Profit (Loss) *	11.5	12.8
Adj. Net Income (Loss) *	1.6	4.7
Adjusted Diluted EPS *	0.04	0.11

Balance Sheet Metrics	March 31,	Dec 31,
	2016	2015
Cash & Marketable Securities	\$ 160.0	\$144.8
Goodwill & Intangible Assets	57.0	34.3
Long-term Contingent Consideration Liability	131.0	122.7

Cash Flow Metrics	Three months ended March 31,	
	2016	2015
Free Cash Flow *	\$ 13.0	\$ 24.7

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

Flamel Technologies Transformed

- 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

Appendix

Reconciliation of Non GAAP to GAAP Results

Operating Income and EBITDA:

Reported Operating Income	\$ 5,542	\$ 10,214
<i>Exclude:</i> Contingent consideration - Acquisition-related fair value remeasurements - Inc./Dec.)	7,916	5,254
Intangible asset amortization	3,514	3,143
Purchase accounting adjustments - FSC	763	-
<i>Include:</i> Contingent consideration - Acquisition-related paid/accrued	(6,217)	(5,796)
Total adjustments	5,976	2,601
Adjusted Operating Income	\$ 11,518	\$ 12,815
<i>Exclude:</i> Depreciation Expense	240	117
Adjusted EBITDA	\$ 11,758	\$ 12,932

Net income (loss)

Reported	\$ (6,376)	\$ 11,647
<i>Exclude:</i> Contingent consideration - Acquisition-related fair value remeasurements - Inc./Dec.)	7,916	5,254
Contingent consideration - Financing-related fair value remeasurements - Inc./Dec.)	1,861	259
Intangible asset amortization	3,514	3,143
Purchase accounting adjustments - FSC	763	-
Foreign exchange (gain)/loss	2,941	(11,501)
<i>Include:</i> Contingent consideration - Acquisition-related paid/accrued	(6,217)	(5,796)
Contingent consideration - Financing-related paid/accrued	(1,023)	(845)
Income tax expense (benefit) related to all above adjustments	(1,829)	2,555
Total adjustments	7,926	(6,931)
Adjusted	\$ 1,550	\$ 4,716

Reconciliation of Non GAAP to GAAP Results

Net income (loss) per share - Diluted

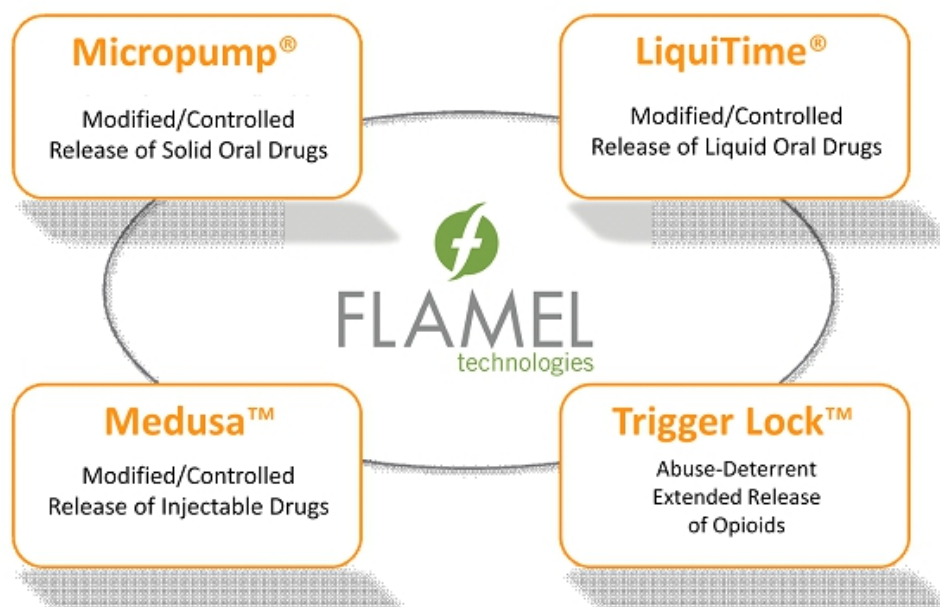
Reported	\$	(0.15)	\$	0.27
<i>Exclude:</i> Contingent consideration - Acquisition-related fair value remeasurements - Inc./Dec.)		0.17		0.13
Contingent consideration - Financing-related fair value remeasurements - Inc./Dec.)		0.05		0.01
Intangible asset amortization		0.09		0.07
Purchase accounting adjustments - FSC		0.02		-
Foreign exchange (gain)/loss		0.07		(0.27)
<i>Include:</i> Contingent consideration - Acquisition-related paid/accrued		(0.15)		(0.14)
Contingent consideration - Financing-related paid/accrued		(0.02)		(0.02)
Income tax expense (benefit) related to all above adjustments		(0.04)		0.06
Total adjustments		<u>0.19</u>		<u>(0.16)</u>
Adjusted	<u>\$</u>	<u>0.04</u>	<u>\$</u>	<u>0.11</u>

Free Cash Flow

Net cash provided by operating activities	\$	22,498	\$	25,275
<i>Less:</i> Purchases of property and equipment		(460)		(234)
Contingent consideration - Acquisition-related payments		(8,014)		(325)
Contingent consideration - Financing-related payments		(1,092)		-
Free Cash Flow	<u>\$</u>	<u>12,932</u>	<u>\$</u>	<u>24,716</u>

Diversified and Proven Drug Delivery Platforms

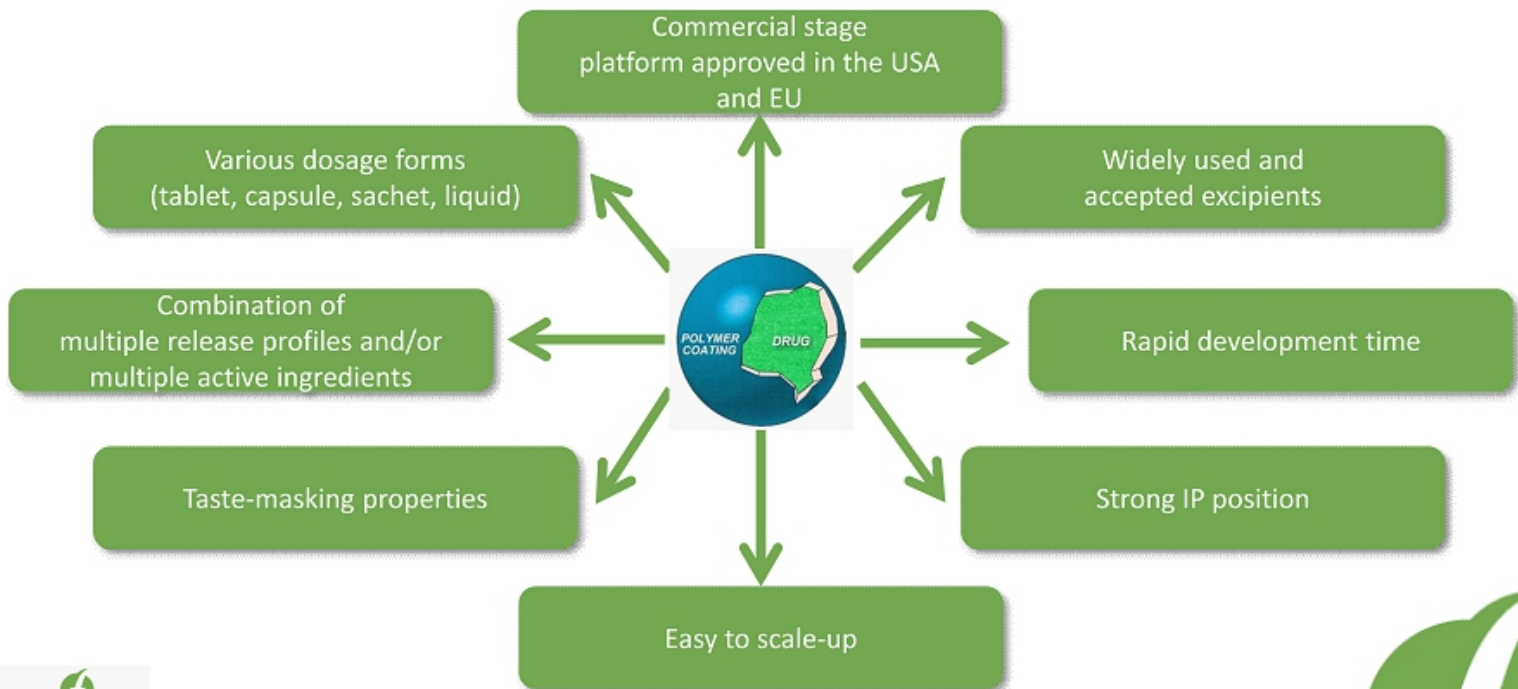
- Outstanding drug delivery platforms to tackle key challenges in the formulation, in **various dosage forms** (e.g. capsules, tablets, sachets or **oral** liquid suspensions; or **injectable** for subcutaneous administration) of a broad range of drugs (already-marketed, off-patent or novel)



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

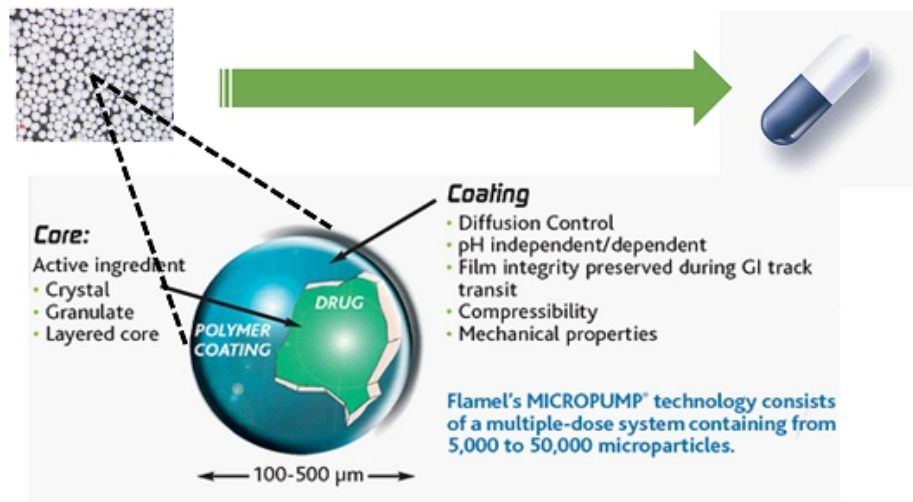
Micropump® Platform at a Glance

- 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

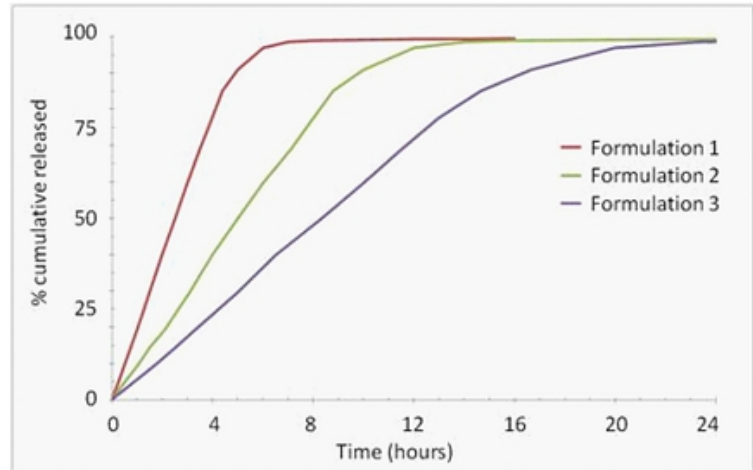


- Microparticles are dispersed in the stomach and pass into the small intestine, after which each microparticle releases the drug at an adjustable rate and over an extended period of time (up to 24 hours)
- Drug released at an adjustable rate controlled and/or delayed
- Micropump® microparticles can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

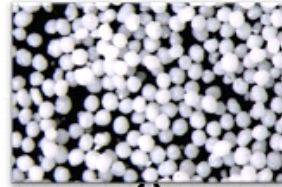


This graph illustrates the different near zero-order release profiles which can be tailored for the same drug

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

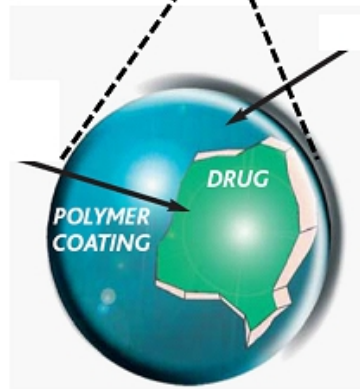
LiquiTime® for Extended-Release Liquid Suspension

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

← 150-500 μm →

Trigger Lock™ Platform at a Glance

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

- ✓ The sustained release Micropump®-based microparticles are virtually **impervious to crushing**
- ✓ Trigger Lock™ **resists extraction attempts** to prevent injection, even in boiling liquids and with alcohol
- ✓ Trigger Lock™ **preserves the bioavailability** of the opioid analgesics
- ✓ Trigger Lock™ is compatible with different dosage forms (capsules, tablets)



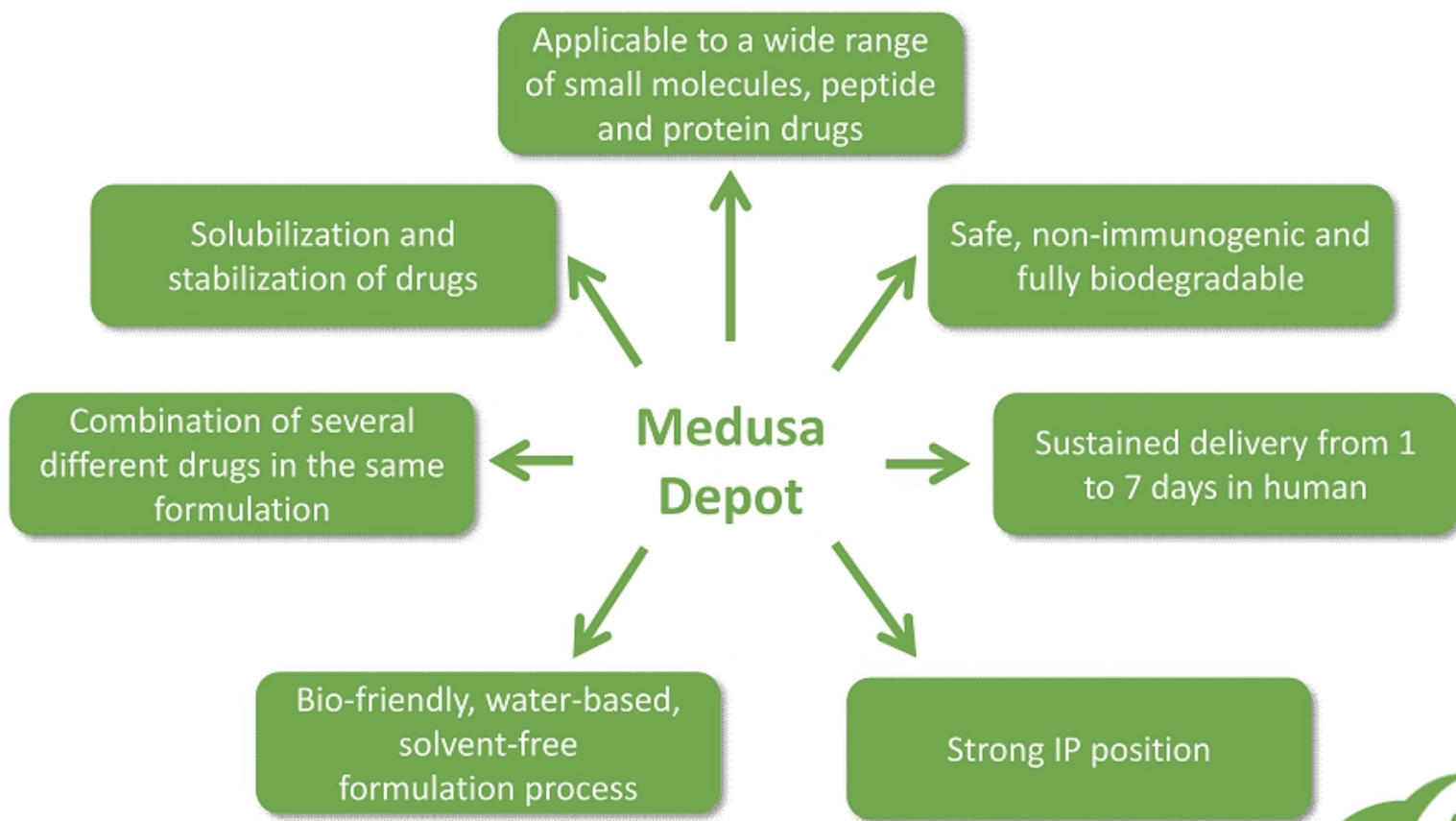
Trigger Lock™ For Abuse Deterrence

- 1. Drug loaded Micropump® microparticles**
Sustained Release (SR) microparticles individually polymer coated 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 (forming a complex with the opioid preventing its solubilization in aqueous/alcoholic medium)

→ Each microparticle retains its polymer coating

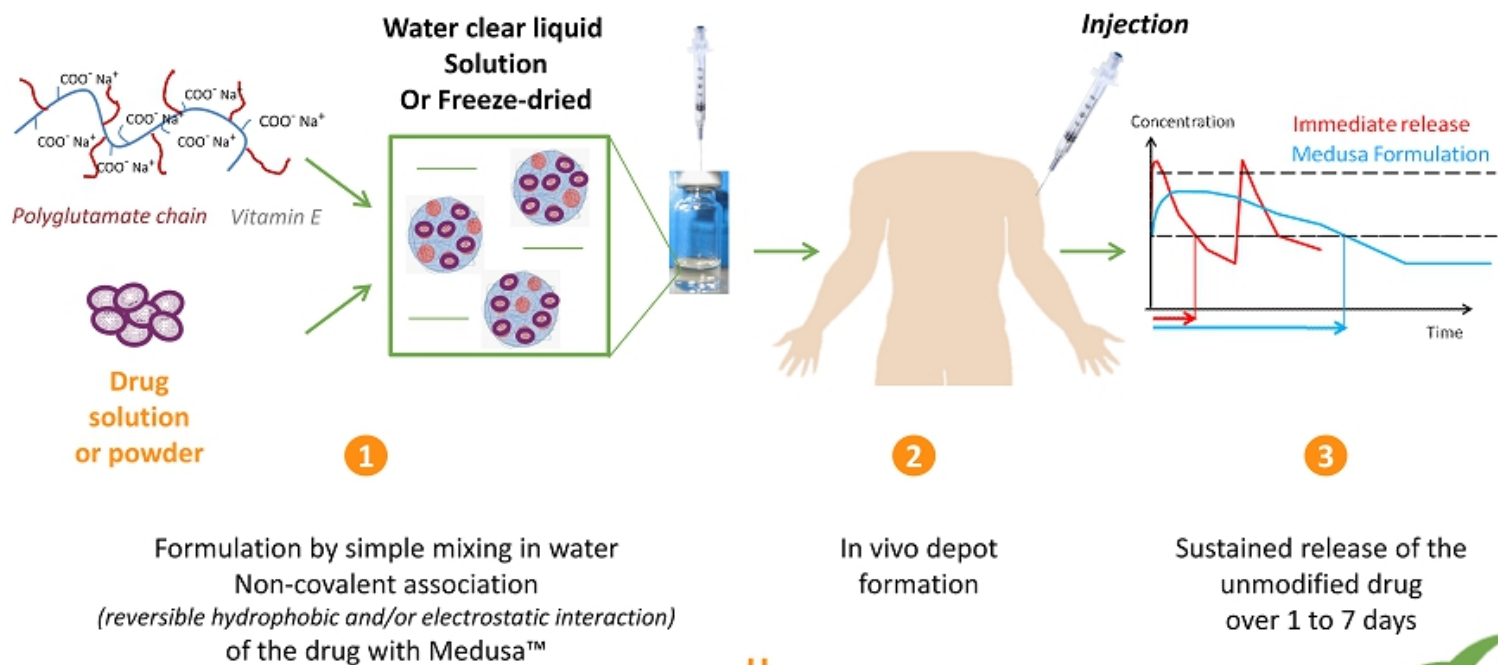
→ Trigger Lock™ is virtually impervious to crushing

Medusa™ Platform at a Glance



Medusa™ Depot for Injection

- Made of polyglutamic acid and Vitamin E
- Amphiphilic and spontaneous association in water
- Complexes are stable over a wide range of pH



In Vitro

In Vivo