

**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): **November 15, 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 Other Events.**

On November 16, 2016, Flamel Technologies S.A. (the “Company”) intends to make a presentation at Jefferies 2016 Healthcare Conference in London, England. 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 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Form of Slide Presentation of Flamel Technologies S.A. as of November 15, 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: November 15, 2016

Exhibit Index

99.1 Form of Slide Presentation of Flamel Technologies S.A. as of November 15, 2016.



# Company Highlights

## Strong Financial Position

- Cash flow positive & strong balance sheet – NO DEBT
- \$149.7 million in cash & marketable securities at September 30, 2016

## Phase III Trial

- Data for Micropump® applied to sodium oxybate expected 1H 2018
- Current market size in excess of \$1 billion

## Expanding Product Portfolio

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

## Platform Technologies

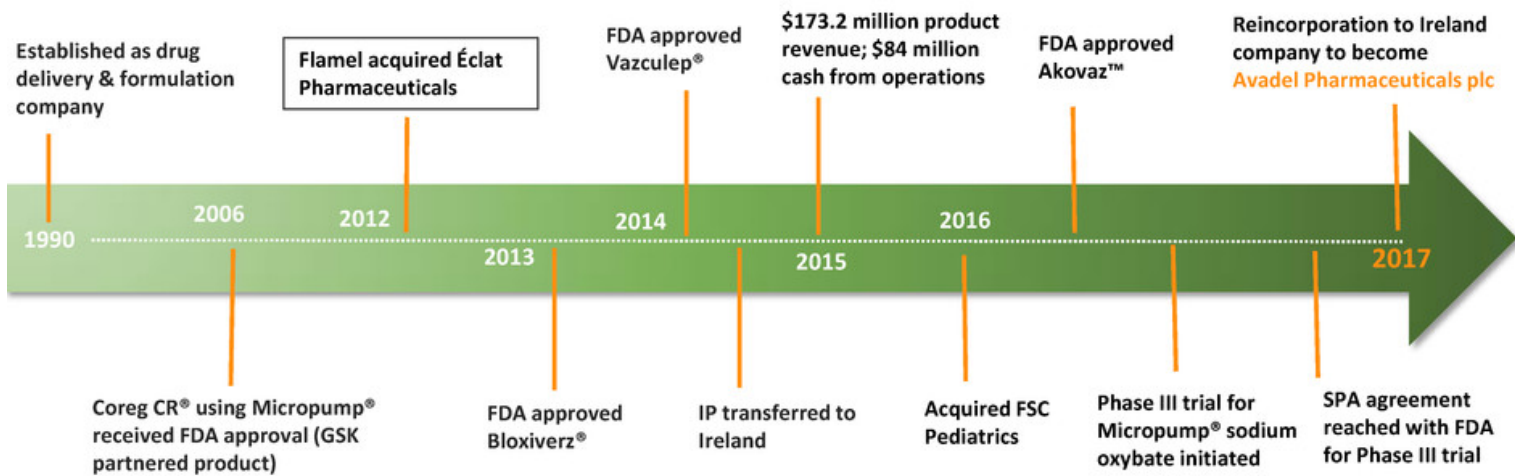
- Micropump® sodium oxybate
- LiquiTime® for OTC and Rx
- Trigger Lock™ hydromorphone
- Medusa™ exenatide

## Extensive IP

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

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

# Corporate Transformation



Since 2013 Flamel received three NDA approvals, initiated Phase III trial for Micropump<sup>®</sup> sodium oxybate & transformed into a cash flow positive company

# Becoming Avadel Pharmaceuticals plc

---

- *Avadel Pharmaceuticals plc* (NASDAQ: AVDL)
- “AdVAnced DELivery”
- Cross-border merger from France to Ireland effective January 1, 2017
- No changes to capital structure or share count



# 2016 Expectations

✓ Launch Akovaz™ (Approved on 4/29/16)

✓ Integrate FSC Pediatrics and optimize sales territories

✓ Begin licensing discussions for Trigger Lock™ & Medusa™ platforms





✓ Commence registration & dosing for Phase III trial of Micropump® sodium oxybate by 2H 2016

**Initiate development of UMD #4**

**Generate total revenue of \$133 - \$143 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	Phase III	Under Review	Approved
Unapproved Marketed Drug #4	Undisclosed				
Sodium oxybate/ Micropump®	Narcolepsy				
Hydromorphone / Trigger Lock™	Pain				
Exenatide/Medusa™	Diabetes				

## Partnered Products

LiquiTime®	Cough/Cold				
------------	------------	---	--	--	--

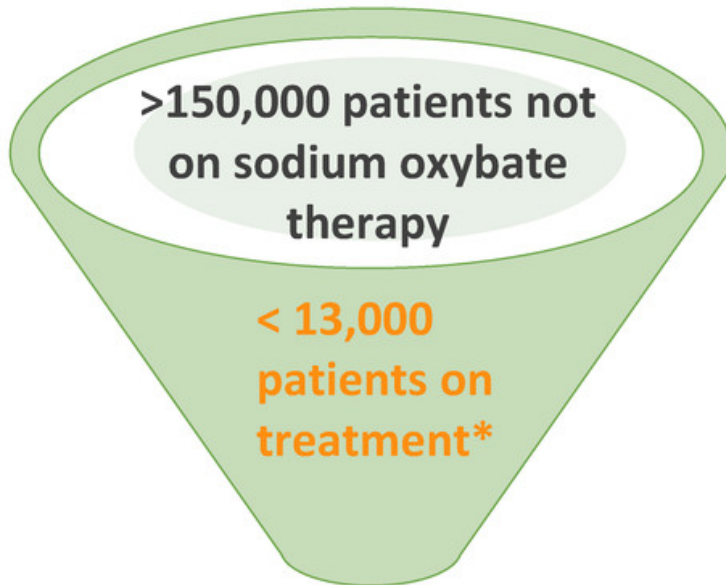
Phase III trial for Micropump® sodium oxybate initiated September 2016

 No IP Protection     IP Protection



# 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 \$1.2 - \$1.25 billion

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

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 C<sub>max</sub> than Xyrem  
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

FT218 has potential to eliminate 2<sup>nd</sup> dose & provide other patient benefits

# Phase III Pivotal Trial - FT218

- Randomized, double-blind, placebo controlled efficacy study
- **264** patients
- **~50-60** clinical sites across U.S., Canada & Eastern Europe



- Patients will undergo screening period then be titrated to daily doses of **4.5 g, 6.0 g, 7.5 g and 9.0 g** FT218 or placebo
- **Patients on drug or placebo for 13 weeks**
- Overall timeline to complete enrollment: **~ 1 year**

# Micropump<sup>®</sup> 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**

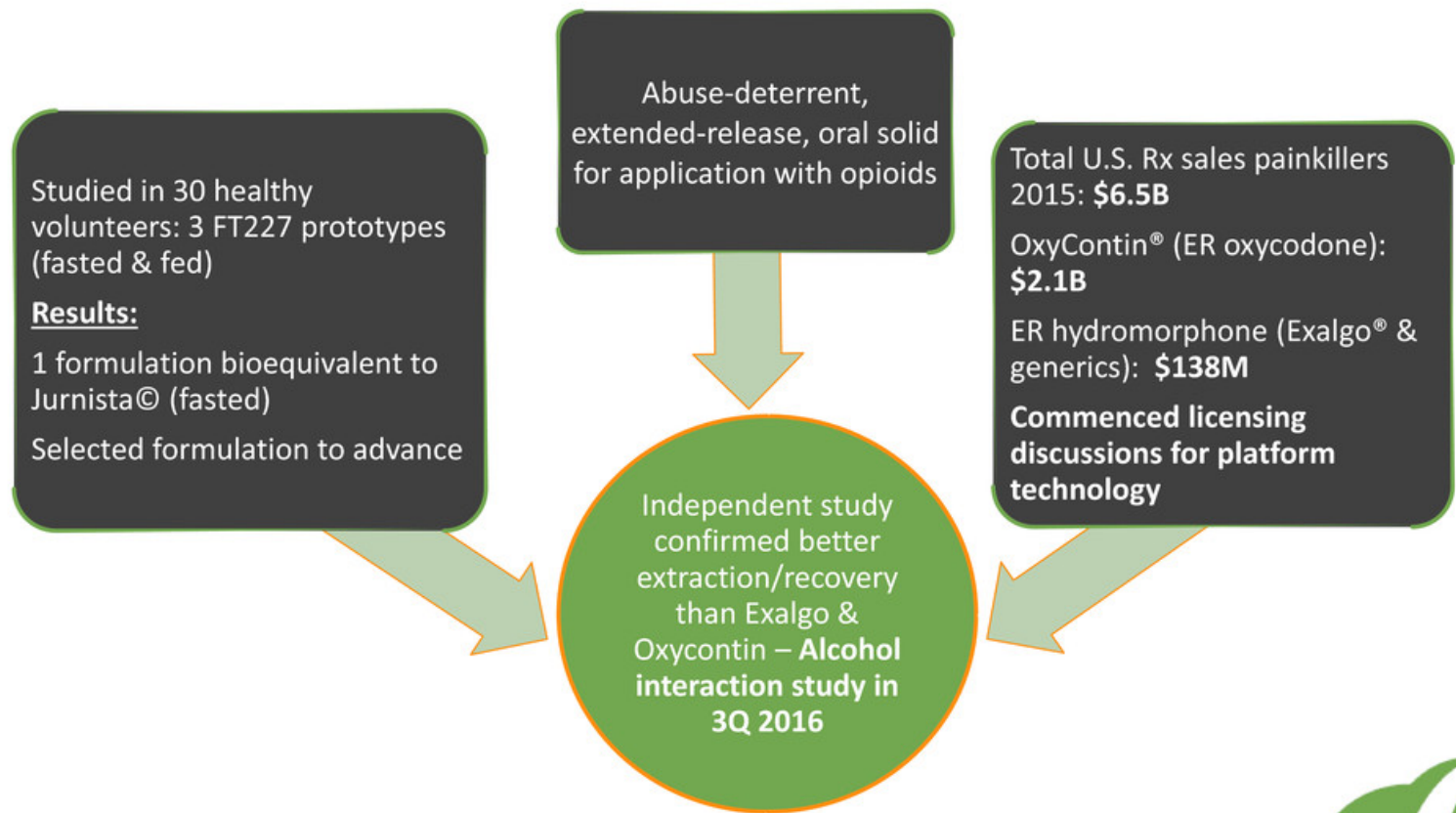
**Micropump 1<sup>st</sup> approved in 2006 in Coreg CR (carvedilol)**

**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® Overview

---

Licensed OTC rights to Perrigo in October 2015 – first two products:

- Ibuprofen
  - 12 hour profile developed for pain/fever
  - Regulatory pathway deemed high risk and high cost
- Guaifenesin
  - Successful pilot PK study reported in March 2015
  - Second PK study ongoing
  - Update anticipated in early 2017

LiquiTime for prescription products currently under feasibility

# Medusa™ Exenatide (FT228)

Subcutaneous injection formulation of exenatide, a GLP-1 (glucagon-like peptide – 1) for treatment of Type 2 diabetes

## Phase Ib Results

- 1 dose FT228 (140mcg) / week for 4 weeks in 12 type 2 diabetes mellitus patients
- PK data showed continuous release of exenatide over period of up to 14 days & RBA close to 100%
- PD data comparable to current marketed products Bydureon® & Victoza®
- Low incidence of prolonged GI side effects and mild injection site reactions
- **Actively seeking partnership / licensing deal for Medusa**

## 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)

---

# 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)

- Indication: Treatment of clinically important hypotension occurring in the setting of anesthesia
- ~ 7 million vials sold annually in the U.S.

# Pediatric 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. ~ \$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<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  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
Flexichamber®	March 2028

Product specific IP combined with platform IP 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

# Non-GAAP Financial Results

(in \$000s)

\*Reconciliations from GAAP to Non-GAAP can be found in the appendix

	Q3 2016	Q2 2016	Q3 2015
<b>Revenue</b>	<b>\$ 32,087</b>	<b>\$ 38,858</b>	<b>\$ 47,313</b>
Cost of products and services sold	2,844	3,145	2,087
Research and development expenses	8,143	7,604	7,221
Selling, general and admin expenses	12,740	11,290	4,568
Intangible asset amortization	-	-	-
Fair value adjustments of contingent consideration	5,884	6,992	9,027
Operating Expenses	<u>29,611</u>	<u>29,031</u>	<u>22,903</u>
<b>Operating income (loss)</b>	<b>2,476</b>	<b>9,827</b>	<b>24,410</b>
Interest & Other Expense (net)	<u>(559)</u>	<u>(814)</u>	<u>(1,014)</u>
<b>Income (loss) before income taxes</b>	<b>1,917</b>	<b>9,013</b>	<b>23,397</b>
Income tax provision	5,416	9,998	10,255
<b>Net loss</b>	<u><b>\$ (3,499)</b></u>	<u><b>\$ (985)</b></u>	<u><b>\$ 13,142</b></u>
<b>Diluted loss per share</b>	<b>\$ (0.08)</b>	<b>\$ (0.02)</b>	<b>\$ 0.32</b>

Difference - Inc./ (Dec.)	
Q3 2016 vs. Q2 2016	Q3 2016 vs. Q3 2015
\$ (6,771)	\$ (15,226)
(301)	757
539	922
1,450	8,172
-	-
(1,108)	(3,143)
580	6,708
(7,351)	(21,934)
255	455
(7,096)	(21,480)
(4,581)	(4,839)
<u>\$ (2,515)</u>	<u>\$ (16,641)</u>
<u>\$ (0.06)</u>	<u>\$ (0.40)</u>

# Cash Flow Summary

(in \$000s)

	<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
<b><u>TOTAL Cash and Marketable Securities</u></b>		
<b>Beginning Balance</b>	<b>\$ 144,802</b>	<b>\$ 92,834</b>
Operating Cash Flows (excluding tax and earnout/royalty payments)	49,639	92,277
Tax Payments	(22,200)	(34,382)
Earnout/Royalty Payments	(24,229)	(17,655)
Repayment of Debt	-	(4,904)
Issuance of Ordinary Shares and Warrants	-	6,990
FX & Other, net	1,655	(6,788)
<b><i>Change in Total</i></b>	<b><u>4,865</u></b>	<b><u>35,538</u></b>
<b>Ending Balance</b>	<b><u>\$ 149,667</u></b>	<b><u>\$ 128,372</u></b>

Balance sheet remains strong with no bank debt and \$149.7 million in cash and marketable securities

# Company Highlights

## Strong Financial Position

- Cash flow positive & strong balance sheet – NO DEBT
- \$154.9 million in cash and marketable securities as of June 30, 2016

## Phase III Trial

- Data for Micropump® applied to sodium oxybate expected 1H 2018
- Current market size in excess of \$1 billion

## Expanding Product Portfolio

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

## Platform Technologies

- 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 will extend patent life

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

---

# Appendix



# GAAP to Non-GAAP Reconciliations

## Three Months Ended September 30, 2016:

(in thousands - US\$)

	GAAP	Adjustments				Total Adjustments	NON-GAAP
		Exclude		Include			
		Intangible asset amortization	Foreign exchange (gain)/loss	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued		
Product sales and services	\$ 31,340	\$ -	\$ -	\$ -	\$ -	\$ 31,340	
License and research revenue	747	-	-	-	-	747	
<b>Total revenue</b>	<b>32,087</b>	-	-	-	-	<b>32,087</b>	
Cost of products and services sold (3rd Party)	2,844	-	-	-	-	2,844	
Intercompany cost of products sold	-	-	-	-	-	-	
Cost of products and services sold	2,844	-	-	-	-	2,844	
Research and development expenses	8,143	-	-	-	-	8,143	
Selling, general and administrative expenses	12,740	-	-	-	-	12,740	
Intangible asset amortization	3,702	(3,702)	-	-	(3,702)	-	
Changes in fair value of related party contingent consideration	20,848	-	-	(20,848)	5,884	5,884	
<b>Total operating expenses</b>	<b>48,277</b>	<b>(3,702)</b>	<b>-</b>	<b>(20,848)</b>	<b>5,884</b>	<b>29,611</b>	
<b>Operating income (loss)</b>	<b>(16,190)</b>	<b>3,702</b>	<b>-</b>	<b>20,848</b>	<b>(5,884)</b>	<b>2,476</b>	
Investment Income	490	-	-	-	-	490	
Interest Expense	(264)	-	-	-	-	(264)	
Other Expense - changes in fair value of related party payable	(1,828)	-	-	1,828	(785)	(785)	
Foreign exchange gain (loss)	1,249	-	(1,249)	-	(1,249)	-	
<b>Income (loss) before income taxes</b>	<b>(16,543)</b>	<b>3,702</b>	<b>(1,249)</b>	<b>22,676</b>	<b>(6,669)</b>	<b>1,917</b>	
Income tax provision	3,451	1,329	-	1,021	(385)	5,416	
Income Tax Rate	(21%)	36%	-	5%	6%	283%	
<b>Net Loss</b>	<b>\$ (19,994)</b>	<b>\$ 2,373</b>	<b>\$ (1,249)</b>	<b>\$ 21,655</b>	<b>\$ (6,284)</b>	<b>\$ (3,499)</b>	
<b>Net loss per share - Diluted</b>	<b>\$ (0.48)</b>	<b>\$ 0.06</b>	<b>\$ (0.03)</b>	<b>\$ 0.52</b>	<b>\$ (0.15)</b>	<b>\$ (0.08)</b>	
Weighted average number of shares outstanding - Diluted	41,241	41,241	41,241	41,241	41,241	41,241	

# GAAP to Non-GAAP Reconciliations

## Three Months Ended June 30, 2016:

(in thousands - USD\$)

	GAAP	Adjustments						Total Adjustments	NON-GAAP
		Exclude				Include			
		Intangible asset amortization	Foreign exchange (gain)/loss	Purchase accounting adjustments - FSC	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued			
Product sales and services	\$ 38,165	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 38,165	
License and research revenue	693	-	-	-	-	-	-	693	
<b>Total revenue</b>	<b>38,858</b>	-	-	-	-	-	-	<b>38,858</b>	
Cost of products and services sold	3,907	-	-	(762)	-	-	(762)	3,145	
Research and development expenses	7,604	-	-	-	-	-	-	7,604	
Selling, general and administrative expenses	11,290	-	-	-	-	-	-	11,290	
Intangible asset amortization	3,702	(3,702)	-	-	-	-	(3,702)	-	
Changes in fair value of related party contingent consideration	23,898	-	-	-	(23,898)	6,992	(16,906)	6,992	
<b>Total operating expenses</b>	<b>50,401</b>	<b>(3,702)</b>	-	<b>(762)</b>	<b>(23,898)</b>	<b>6,992</b>	<b>(21,370)</b>	<b>29,031</b>	
<b>Operating income (loss)</b>	<b>(11,543)</b>	<b>3,702</b>	-	<b>762</b>	<b>23,898</b>	<b>(6,992)</b>	<b>21,370</b>	<b>9,827</b>	
Investment Income	390	-	-	-	-	-	-	390	
Interest Expense	(263)	-	-	-	-	-	-	(263)	
Other Expense - changes in fair value of related party payable	(2,773)	-	-	-	2,773	(941)	1,832	(941)	
Foreign exchange gain (loss)	1,680	-	(1,680)	-	-	-	(1,680)	-	
<b>Income (loss) before income taxes</b>	<b>(12,509)</b>	<b>3,702</b>	<b>(1,680)</b>	<b>762</b>	<b>26,671</b>	<b>(7,933)</b>	<b>21,522</b>	<b>9,013</b>	
Income tax provision	7,449	1,329	-	266	1,414	(460)	2,549	9,998	
Income Tax Rate	(60%)	36%	-	35%	5%	6%	12%	111%	
<b>Net Loss</b>	<b>\$ (19,958)</b>	<b>\$ 2,373</b>	<b>\$ (1,680)</b>	<b>\$ 496</b>	<b>\$ 25,257</b>	<b>\$ (7,473)</b>	<b>\$ 18,973</b>	<b>\$ (985)</b>	
Net loss per share - Diluted	\$ (0.48)	\$ 0.06	\$ (0.04)	\$ 0.01	\$ 0.60	\$ (0.18)	\$ 0.46	\$ (0.02)	
Weighted average number of shares outstanding - Diluted	41,241	41,241	41,241	41,241	41,241	41,241	41,241	41,241	

# GAAP to Non-GAAP Reconciliations

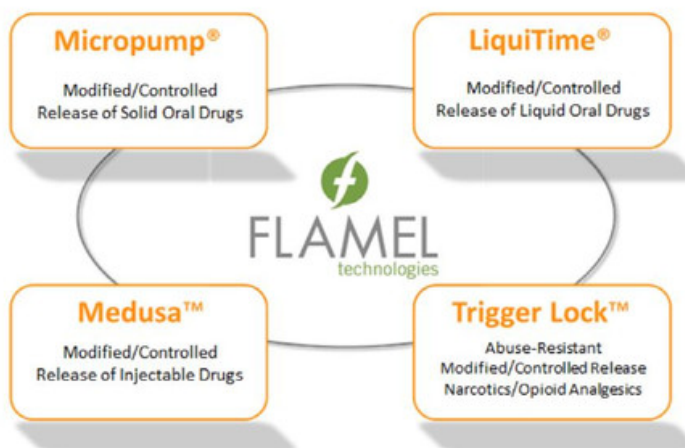
## Three Months Ended September 30, 2015:

(in thousands - US\$)

	GAAP	Adjustments				Total Adjustments	NON-GAAP
		Exclude		Include			
		Intangible asset amortization	Foreign exchange (gain)/loss	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued		
Product sales and services	\$ 47,313	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 47,313
License and research revenue	-	-	-	-	-	-	-
<b>Total revenue</b>	<b>47,313</b>	-	-	-	-	-	<b>47,313</b>
Cost of products and services sold	2,087	-	-	-	-	-	2,087
Research and development expenses	7,221	-	-	-	-	-	7,221
Selling, general and administrative expenses	4,568	-	-	-	-	-	4,568
Intangible asset amortization	3,141	(3,141)	-	-	-	(3,141)	-
Changes in fair value of related party contingent consideration	44,782	-	-	(44,782)	9,027	(35,755)	9,027
<b>Total operating expenses</b>	<b>61,799</b>	<b>(3,141)</b>	<b>-</b>	<b>(44,782)</b>	<b>9,027</b>	<b>(38,896)</b>	<b>22,903</b>
<b>Operating income (loss)</b>	<b>(14,486)</b>	<b>3,141</b>	<b>-</b>	<b>44,782</b>	<b>(9,027)</b>	<b>38,896</b>	<b>24,410</b>
Investment Income	197	-	-	-	-	-	197
Interest Expense	-	-	-	-	-	-	-
Other Expense - changes in fair value of related party payable	(6,644)	-	-	6,644	(1,211)	5,433	(1,211)
Foreign exchange gain (loss)	160	-	(160)	-	-	(160)	-
<b>Income (loss) before income taxes</b>	<b>(20,773)</b>	<b>3,141</b>	<b>(160)</b>	<b>51,426</b>	<b>(10,237)</b>	<b>44,170</b>	<b>23,397</b>
Income tax provision	7,302	1,099	(48)	2,325	(424)	2,953	10,255
<i>Income Tax Rate</i>	<i>(35%)</i>	<i>35%</i>	<i>30%</i>	<i>5%</i>	<i>4%</i>	<i>7%</i>	<i>44%</i>
<b>Net Loss</b>	<b>\$ (28,075)</b>	<b>\$ 2,042</b>	<b>\$ (112)</b>	<b>\$ 49,101</b>	<b>\$ (9,814)</b>	<b>\$ 41,217</b>	<b>\$ 13,142</b>
<b>Net loss per share - Diluted</b>	<b>\$ (0.69)</b>	<b>\$ 0.05</b>	<b>\$ -</b>	<b>\$ 1.20</b>	<b>\$ (0.24)</b>	<b>\$ 1.01</b>	<b>\$ 0.32</b>
<i>Weighted average number of shares outstanding - Diluted</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>

# Flamel's Proprietary Drug Delivery Platforms

Advanced Formulation and Delivery Platforms for Better and Safer Drugs





**Micropump<sup>®</sup>**  
**Drug Delivery Platform**

## **Modified/Controlled Release of Solid Oral Drugs**

# Micropump®

**Micropump®** allows development of modified and/or controlled release of solid, oral dosage formulations of drugs

- Derivative **LiquiTime®** allows development of modified/controlled release of liquid formulations
- Derivative **Trigger Lock™** allows development of tamper-resistant modified/controlled release formulations of narcotic/opioid analgesics

**Versatility of Micropump®** allows development of differentiated product profiles (SR / DR formulations) under various dosage forms:

- Capsules, tablets, sachets (sodium oxybate)
- Oral liquid suspensions (LiquiTime®)

**Unique formulation** used for different dose strengths and forms

- Same drug with different release profiles or
- Two or more drugs with tailored release profiles for combination therapy

Coated microparticles

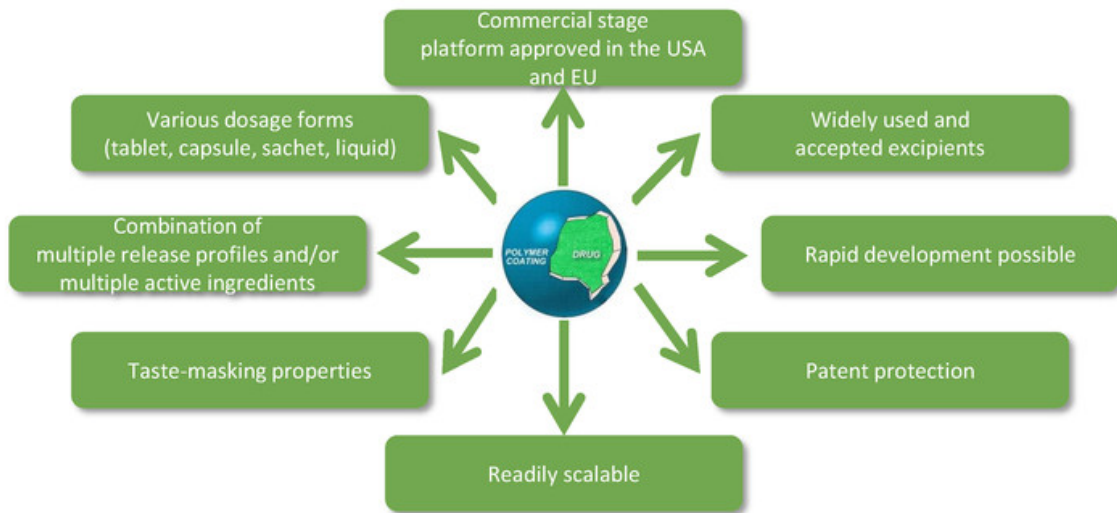


+  
Widely used and  
accepted excipients

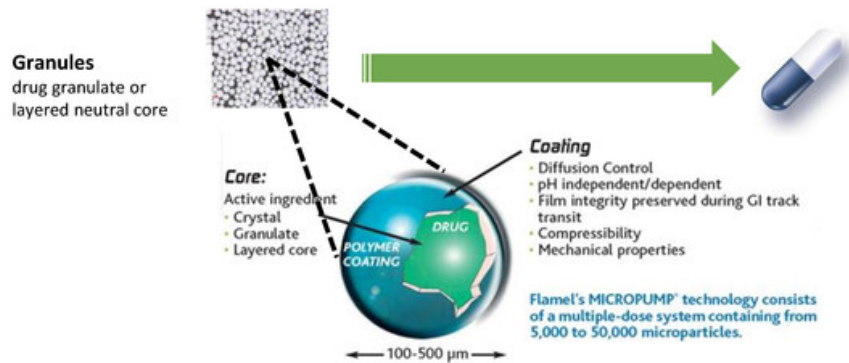


# Micropump® Platform at a Glance

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



# Microparticles for Controlled/Modified Release



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





LiquiTime®  
Drug Delivery Platform

**Modified/Controlled Release  
of Liquid Oral Drugs**

# LiquiTime®

- Allows development of modified/controlled release liquid formulations for patients having issues swallowing tablets/capsules
- **Not limited to working solely with ionic drugs as with resin-complex based technologies**
- Readily scalable to commercial quantities
- Easy to swallow, good mouth feel, taste masked - dose flexibility while maintaining accuracy and safety

## Applicable to:

### Pediatric<sup>1</sup>

- US population younger than 18 years old = 76 million in 2019
- 75% of households with children under 12 purchased an OTC pain reliever over the past 12 months
- Sales of OTC pediatric product in the US = \$1.6 B in 2013 (\$1.9 B estimated in 2018)

### Geriatric

- 810 million people > 60 years in 2012 2 billion expected in 2050<sup>2</sup>
- In 2010 approximately 45-50% of the prescriptions were written for people aged 60 and above and one in three patients took at least 5 drugs or more on a daily basis in the United States<sup>3</sup>

<sup>1</sup> "OTC Pediatrics – US" (March 2014, Mintel)  
Health Organization

<sup>2</sup> World

<sup>3</sup> "Geriatric Medicine Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2013 – 2019"  
(Transparency Market Research)

---



# Trigger Lock™ Platform

## Abuse Deterrent Extended Release of Opioids

# Trigger Lock™ for Abuse Deterrence

---

- **Drug loaded Micropump® microparticles:** Sustained Release (SR) microparticles individually polymer coated which are resistant to crushing
- **Viscosifying ingredient(s):** To prevent abuse by injection after extraction in a small volume of solvent
- **Quenching ingredient(s):** To prevent extraction in large volumes of liquid (forming a complex with the opioid preventing its solubilization in aqueous/alcoholic media)

→ Each microparticle retains its polymer coating

→ Trigger Lock™ is virtually impervious to crushing



## Medusa™ Drug Delivery Platform

### Modified/Controlled Release of Injectable Drugs

# In Vivo Drug Release from Medusa™ Depot

