


# Flamel Technologies

Corporate Presentation  
March 2012

# Forward Looking Statements

*This document contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including certain plans, expectations, goals and projections regarding financial results, product developments and technology platforms. All statements that are not clearly historical in nature are forward-looking, and the words “anticipate,” “assume,” “believe,” “expect,” “estimate,” “plan,” “will,” and similar expressions are generally intended to identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond our control, that could cause actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that the acquisition of Éclat Pharmaceuticals will not be successful, clinical trial results will not be positive or that our partners may decide not to move forward, management transition to a new chief executive officer may be disruptive or not succeed as planned, products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, products in development may not achieve market acceptance, competitive products and pricing may hinder our commercial opportunities, and the risks associated with Flamel's reliance on outside parties and key strategic alliances. These and other risks are described more fully in Flamel's Annual Report on the Securities and Exchange Commission Form 20-F for the year ended December 31, 2010. All forward-looking statements included in this presentation are based on information available at the time of the presentation. We undertake no obligation to update or alter our forward-looking statements as a result of new information, future events or otherwise.*

# Our Value Proposition

- Two complementary drug delivery platforms validated by leading pharma and biotech partnerships
- A diversified portfolio of partnered products addressing large markets
- Late-stage pipeline of wholly-owned products
- FDA-approved manufacturing facility provides a plug-and-play option for our partners
- Strong cash position
- Significant corporate profitability can be achieved with a modest number of projects continuing further in the clinic and to market

# Acquisition of Éclat Pharmaceuticals

- Éclat is a specialty pharmaceutical company focused on the development, approval, and commercialization of niche brands and generic products
- Five products in development
- Favorable success-based terms for FLML shareholders
  - \$12 million, 7.5% note
  - Six-year Warrants for the purchase of a total of 3.3 million Flamel shares: 2.2 million at \$7.44, 1.1 million warrants at \$11 per share
  - Warrants subject to 20% limit on equity control
- The note will be forgiven after the sixth anniversary of the deal closing unless:
  - Two or more Éclat launch products are approved by the U.S. FDA; or
  - One Éclat product is approved by the FDA and \$40 million in cumulative net revenues have been achieved
- The Éclat shareholders will also be entitled to a 20% earn out of gross profit from the Éclat launch products

# Creating a More Vertically Integrated Company

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- Flamel now has its own marketed product and a late-stage product pipeline
- Greater development and commercial expertise
- Best in class drug delivery platforms
- Ability to capture greater upside from Flamel-generated IP
- More near-term and mid-term potential value creating catalysts
- Improved control of our product pipeline and news flow
- Expanded management team of pharmaceutical veterans
  - Mike Anderson, Éclat's CEO, will head the combined company

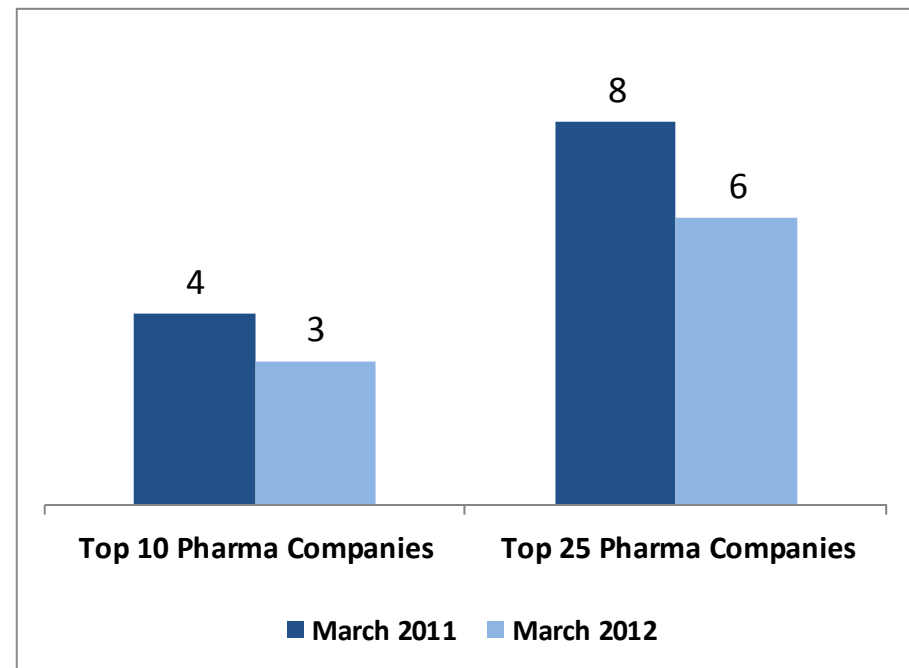
# Partnerships Drive Our Growth

- Flamel works with leading companies to provide the best drug delivery solutions to improve existing products and bringing new products to market
- We currently work with 6 of the top 25 pharmaceutical companies in the world
- Leverage partner's expertise to develop our platforms

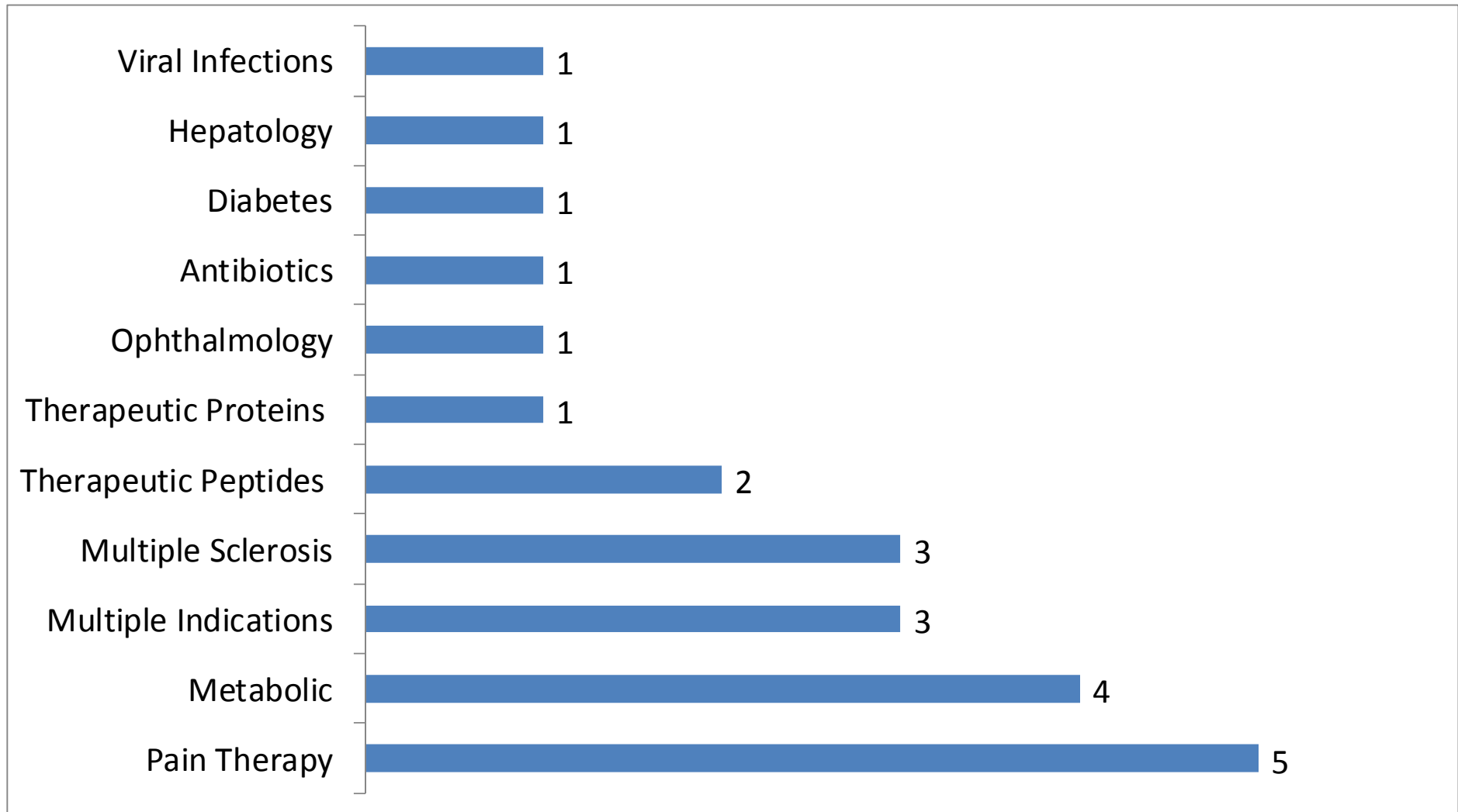
- Pharmacos partners:



- Biotech partners:



# Partnership Portfolio (as of March 2012)



# Recent Joint Development Partnerships

- Working with development stage companies which have exceptional potential in early stage molecules
- Flamel benefits from joint ownership
  - Greater economic participation
  - Limited out-of-pocket expense limits potential risk
  - Access to novel molecules addressing large markets with high unmet medical needs
- Two programs have been announced thus far:
  - Theralpha SAS (May 9, 2011): Acid Sensing Ion Channel Inhibitor
  - Digna Biotech SL (June 27, 2011): Multiple programs

 Theralpha

 DIGNA BIOTECH

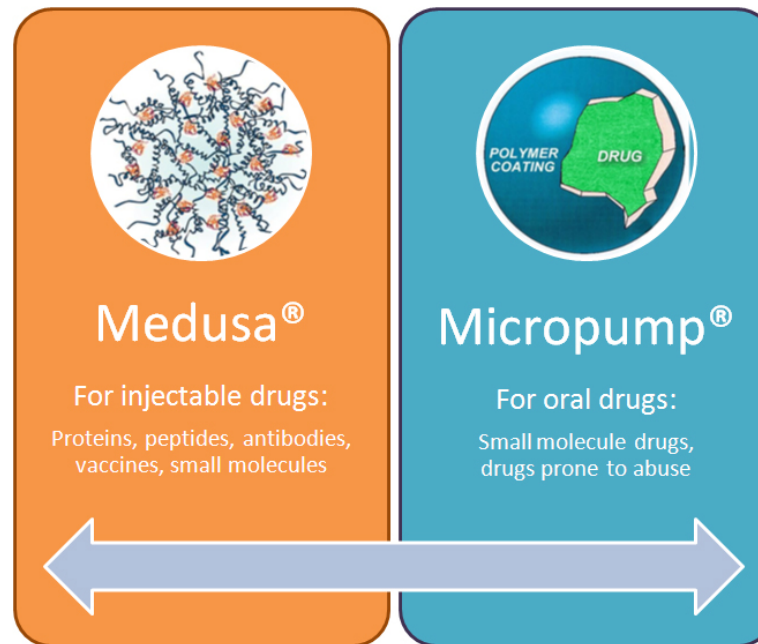
# Theralpha Joint Development Partnership Update

- Medusa-based hydrogel depot controlled-release formulation of THA902 (THA902 XL)
  - Natural peptide, potent and highly specific ASIC3 inhibitor
  - Groundbreaking IP covering Acid Sensing Ion Channels (ASIC's)
  - Targeted indications include:
    - Post-Operative Pain;
    - Osteoarthritis; and
    - Fybromyalgia
- Chronic pain market currently valued at \$30B and still significant therapeutic gap in current pain management
- Continued need across inflammatory pain syndromes for novel agents like THA902
- **Status update:** THA902 XL is expected to enter into non-clinical pharmacokinetic and pharmacodynamic studies in March 2012

- Digna Biotech SL, largest private biomedical research center in Spain
- Multiple Products development relationship covering:
  - Medusa-based hydrogel depot controlled-release formulations of TGF-beta1 inhibitors P144 (Disitertide) and P17
    - Promising activities for potential application in the treatment of pulmonary fibrosis, cirrhosis, angiogenesis and metastasis prevention
    - Primary targeted indication: Idiopathic pulmonary fibrosis, orphan designation to be envisaged
    - **Status update:** expected to enter into non-clinical pharmacokinetic and pharmacodynamic studies in March 2012
  - Micropump formulation of Methylthiadenosine (MTA)
    - Potent immunomodulator with neuroprotective properties to be evaluated in treatment of Multiple Sclerosis and other CNS disorders
    - **Status update:** expected to enter into non-clinical pharmacokinetic and pharmacodynamic studies in Q2 2012

- Medusa-based hydrogel depot formulation of small molecule antibiotic tigecycline
- Development & License agreement (October 13, 2011); all development expenses are the sole responsibility of Eagle Pharmaceuticals
  - Switch from twice-a-day intravenous to once-a-day subcutaneous administration, reducing Cmax and consequently the side effects associated with tigecycline
- Competitive advantages:
  - Reduced costs to hospitals
  - Improved convenience for patients
- Market potential for such IV to SC switch:
  - > \$1B for antibacterial drugs
  - > \$4B for anti-cancer treatments
- **Status update:** expected to enter into non-clinical pharmacokinetic and pharmacodynamic studies in Q2 2012

# Advanced Formulation and Delivery Platforms



**Deliver fully active biological or chemical drugs  
in the right place, during the right time, and at the right dose**

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# Medusa<sup>®</sup> Drug Delivery Platform

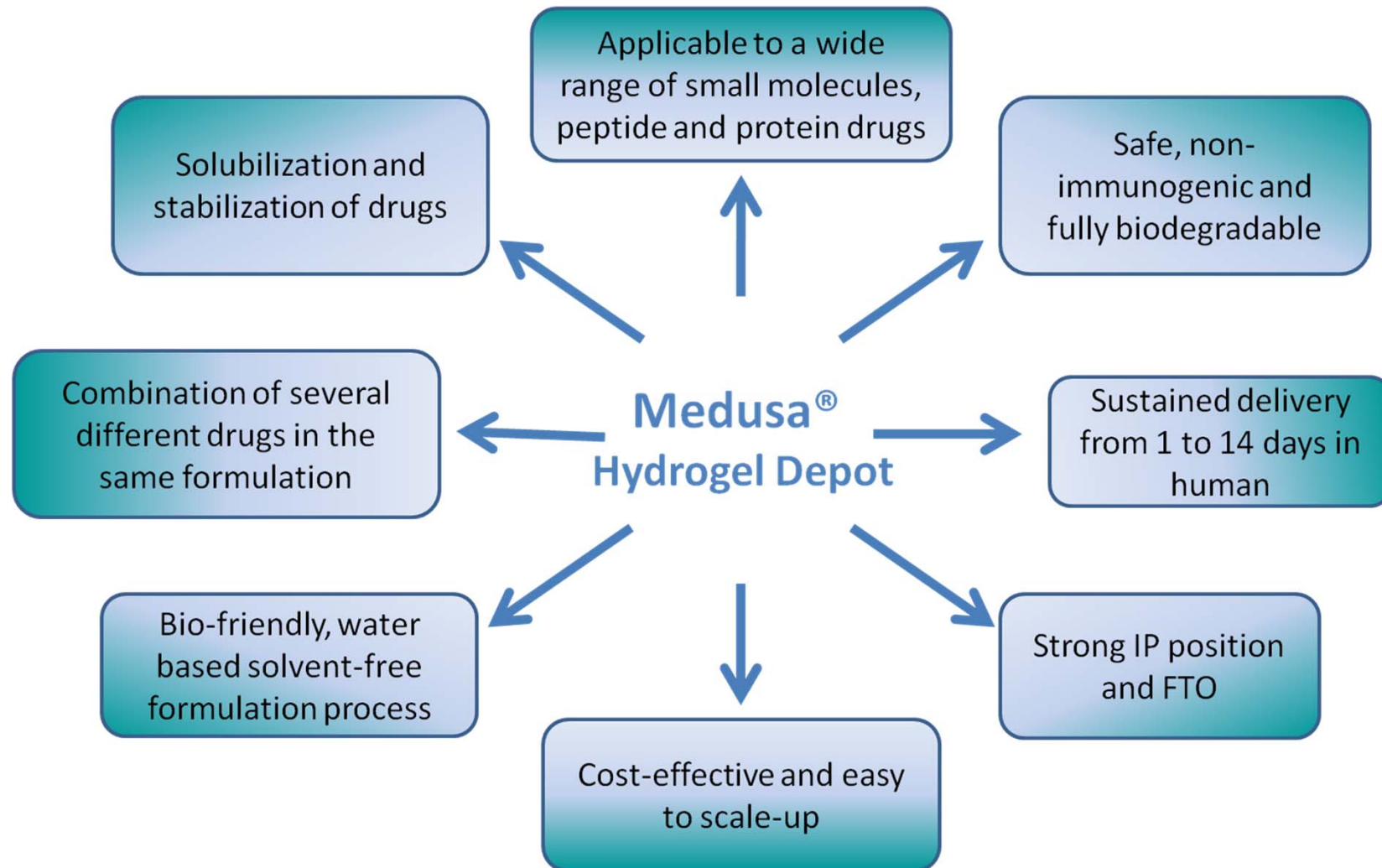
An Innovative Safe and Biodegradable  
Hydrogel Depot Formulation  
For the delivery of a Broad Range of  
Biological and Chemical Drugs

Medusa is a trademark of Flamel Technologies S.A.

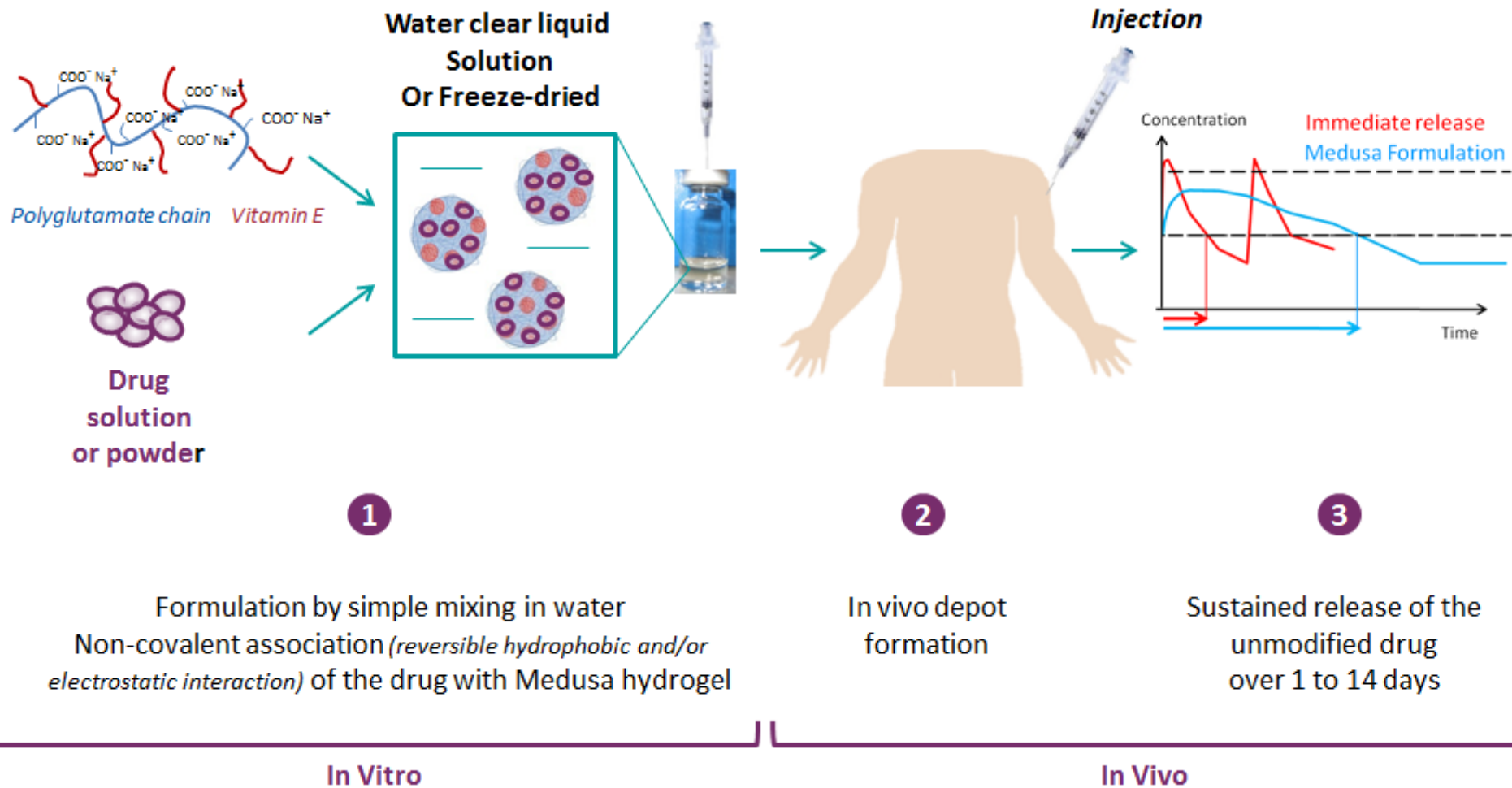
[Medusa: an Innovative Formulation Approach to Improve Pharmacokinetic & Safety Profiles of Biotherapeutics](#)

Chan Y.-P., Meyrueix R., Rivail C. and Chatellier J. (2011) **ONdrugDelivery**, August 2011: 4-6.

# Medusa Drug Delivery Platform at a Glance



# Medusa Hydrogel Depot



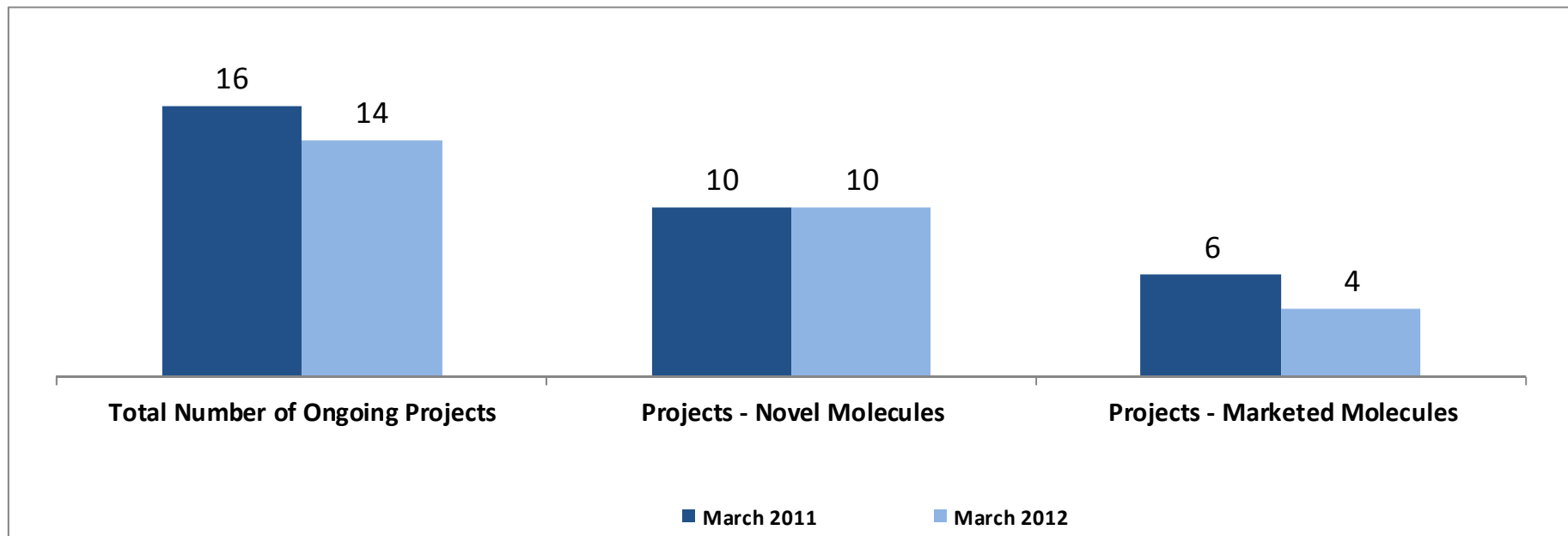
# Medusa-Based Products Pipeline

## Industry Endorsed Platform

	Preclinical	Phase 1	Phase 2	Phase 3	Partnerships
<b>IFN-<math>\alpha</math> XL, Long-acting Interferon Alpha 2b - Hepatitis C</b>					
<b>IFN-<math>\beta</math> XL, Long-acting Interferon Beta 1a - Multiple Sclerosis</b>					
<b>FT-105, Long-acting Basal Insulin Diabetes Type I and II</b>					
<b>IL-2 XL, Long-acting Human IL-2 Renal Cell Carcinoma</b>					
<b>hGH XL, Long-acting hGH Growth Disorders</b>					
<b>GLP-1 XL, Long-acting GLP-1 analog Diabetes Type II</b>					
<b>Tigecycline XL Pneumonia</b>					
<b>Other ongoing projects (i.e. proteins, peptides, small molecules)</b>					  & other undisclosed companies

# Medusa Project Portfolio

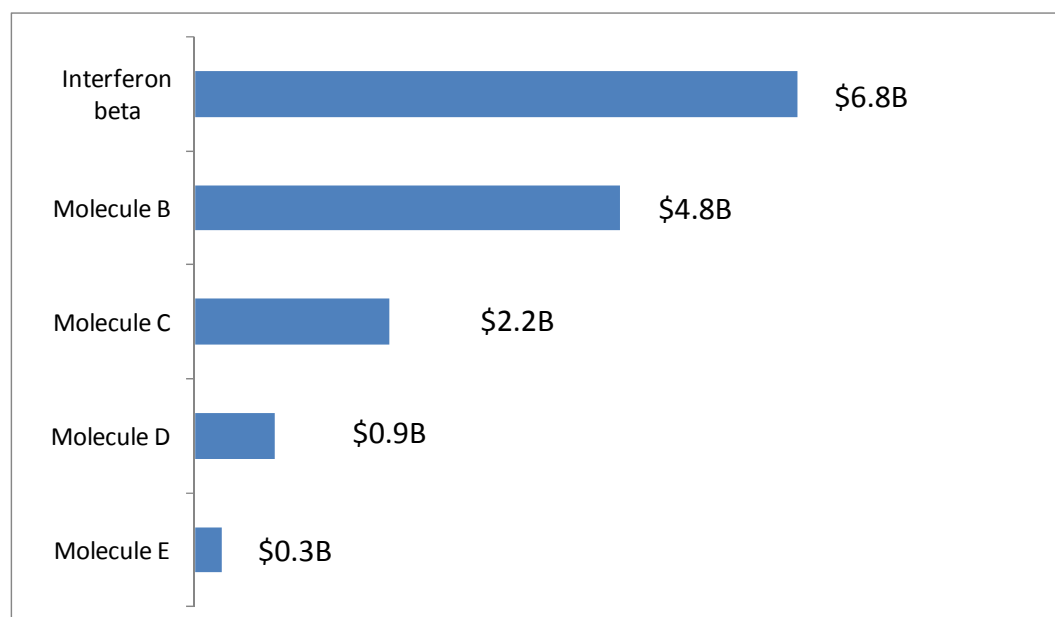
- Our portfolio of projects is well diversified
- Balance between lower-risk reformulations and higher-risk NMEs
- Successful non clinical feasibility studies feed our pipeline, most of them reaching in vivo confirmatory pharmacokinetic studies



# Medusa Large Addressable Markets

- Medusa platform is applicable to a wide variety of molecule types and therapeutic areas
- Clinical development studies are funded by partners
- Clinical development studies addressing a total \$15 billion in market opportunities

*Global 2011 market value for selected Medusa-based compounds  
(in \$ billion)*

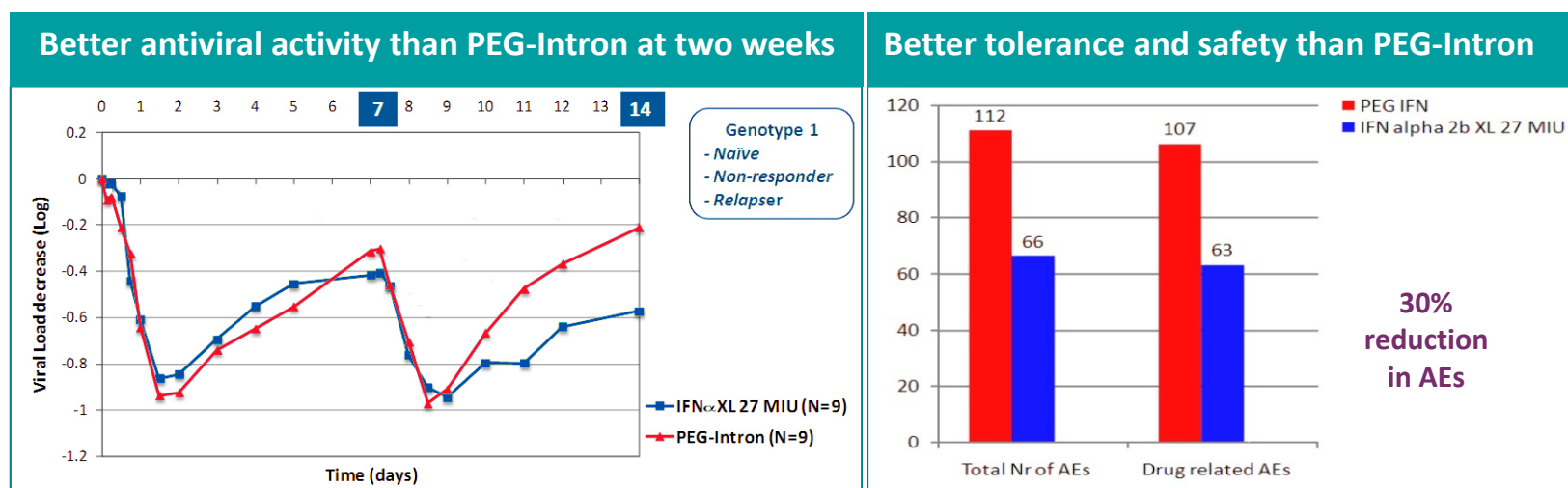


# Medusa News

- Recent Completion of Phase 1 study of Medusa-based long-acting formulation of interferon beta-1a by our partner Merck Serono
  - The Phase 1 results are currently being analyzed and discussed with our partner
- Ongoing Phase 2 study of Medusa-based long-acting interferon alpha-2b
  - Intermediate analysis presented in November 2011 at the AASLD annual meeting (San Francisco, USA)
  - Interim efficacy results to be presented at a major scientific congress this Spring
- Signature in Q4.11 of two new feasibility study agreements for Medusa-based hydrogel depot controlled-release formulation of:
  - A metabolic peptide drug with a top-10 leading pharmaceutical company
  - A protein drug for ocular applications with a leading biotechnology company

# Focus on IFN- $\alpha$ XL, a Better Interferon

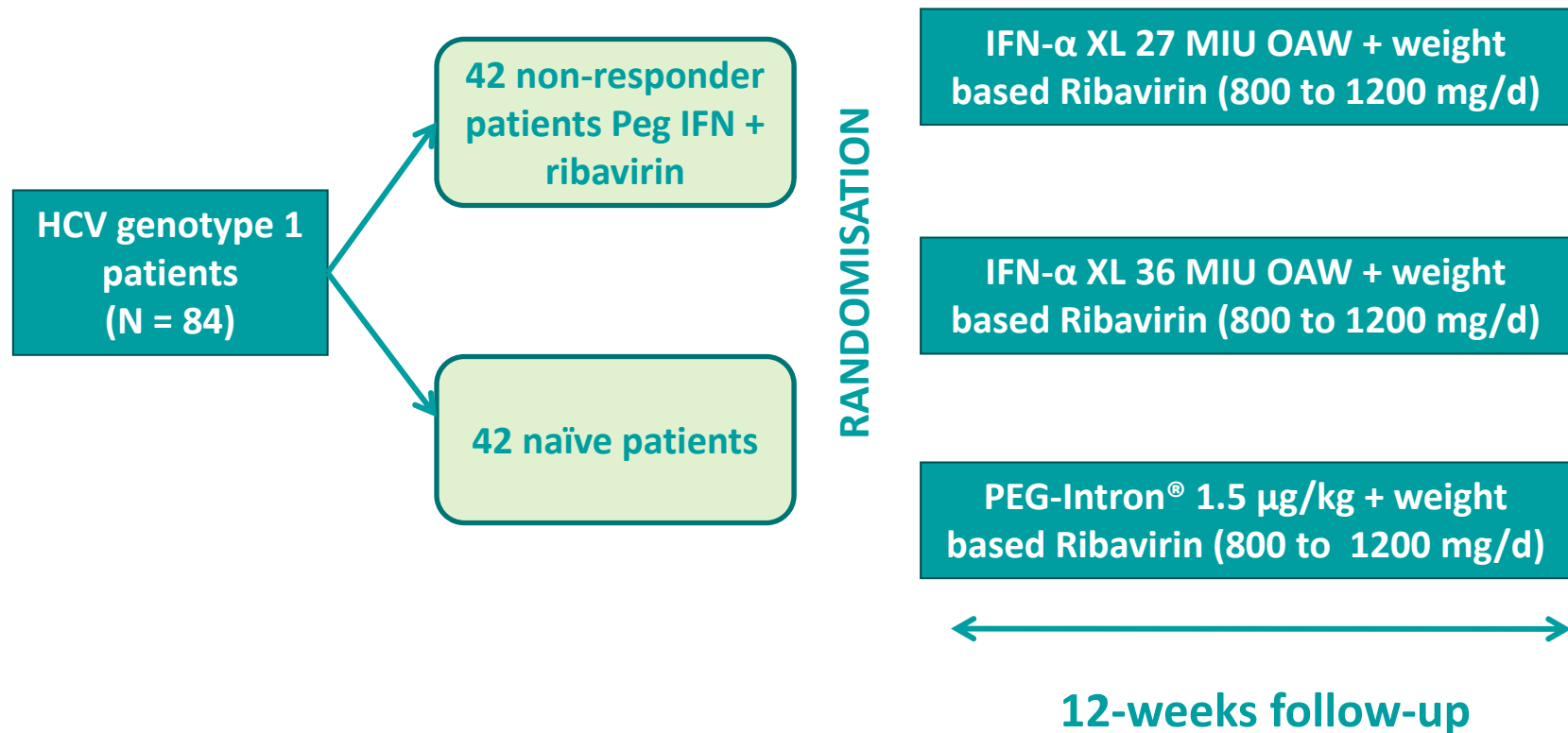
- Unlike current HCV market standards (Roche's Pegasys and Merck & Co's Peg-Intron), IFN- $\alpha$  XL releases **unmodified, fully active interferon alpha-2b**, allowing a greater reduction in viral load and a better safety profile (IFN- $\alpha$  XL has been safely administered to 123 HCV patients in 3 clinical trials)



- **With much better safety and tolerability and potentially higher efficacy than conventional marketed interferon therapies, IFN- $\alpha$  XL is well positioned to become a major advance in hepatitis C treatment**
- A 12-week Phase 2 study is ongoing in genotype 1 and 4 patients; interim results were presented at AASLD Nov. 2011 (see next slide)

# Ongoing Phase 2 Study

Confirmation Of Antiviral activity and Tolerability of IFN- $\alpha$  XL (ANRS HC 23 COAT-IFN)\*



Interim results presented at AASLD Annual Meeting on November 7, 2011, in San Francisco, USA (*see next slide*)

\* <http://clinicaltrials.gov/ct2/show/NCT01010646>

Event	N	IFN $\alpha$ -2b XL 27 (n=7) (%)	N	Peg IFN $\alpha$ -2b (n=7) (%)
Flu-like syndrom	4	57.1	7	100.0
Headache	2	28.6	5	71.4
Fever	1	14.3	2	28.6
Myalgia	1	14.3	2	28.6
Asthenia	5	71.4	6	85.7
Diarrhoea	2	28.6	3	42.9
Injection site induration	2	28.6	0	0.0
Injection site erythema	2	28.6	5	71.4
Dry skin	0	0.0	3	42.9
Irritability-depression	1	14.3	3	42.9

**Reduced mean number of treatment-related AEs/patient: 4.6 (IFN  $\alpha$ -2b XL 27) vs 6.9 (Peg IFN  $\alpha$ -2b)**

Total Nr of events / patient: 5.7 (IFN  $\alpha$ -2b XL 27) vs 7.1 (Peg IFN  $\alpha$ -2b )

**Improved hematological safety: two-fold less decrease in platelet count (-26.2 vs -52.4 G/L)**

Consistency with findings from previous studies:

1st phase 1 study: 3.8 AEs (IFN  $\alpha$ -2b XL 27) vs 5.2 AEs (IFN  $\alpha$ -2b XL 3/w) /patient

2nd phase 1b study: 5.2 AEs (IFN  $\alpha$ -2b XL 27) vs 7.6 AEs (Peg IFN  $\alpha$ -2b) /patient

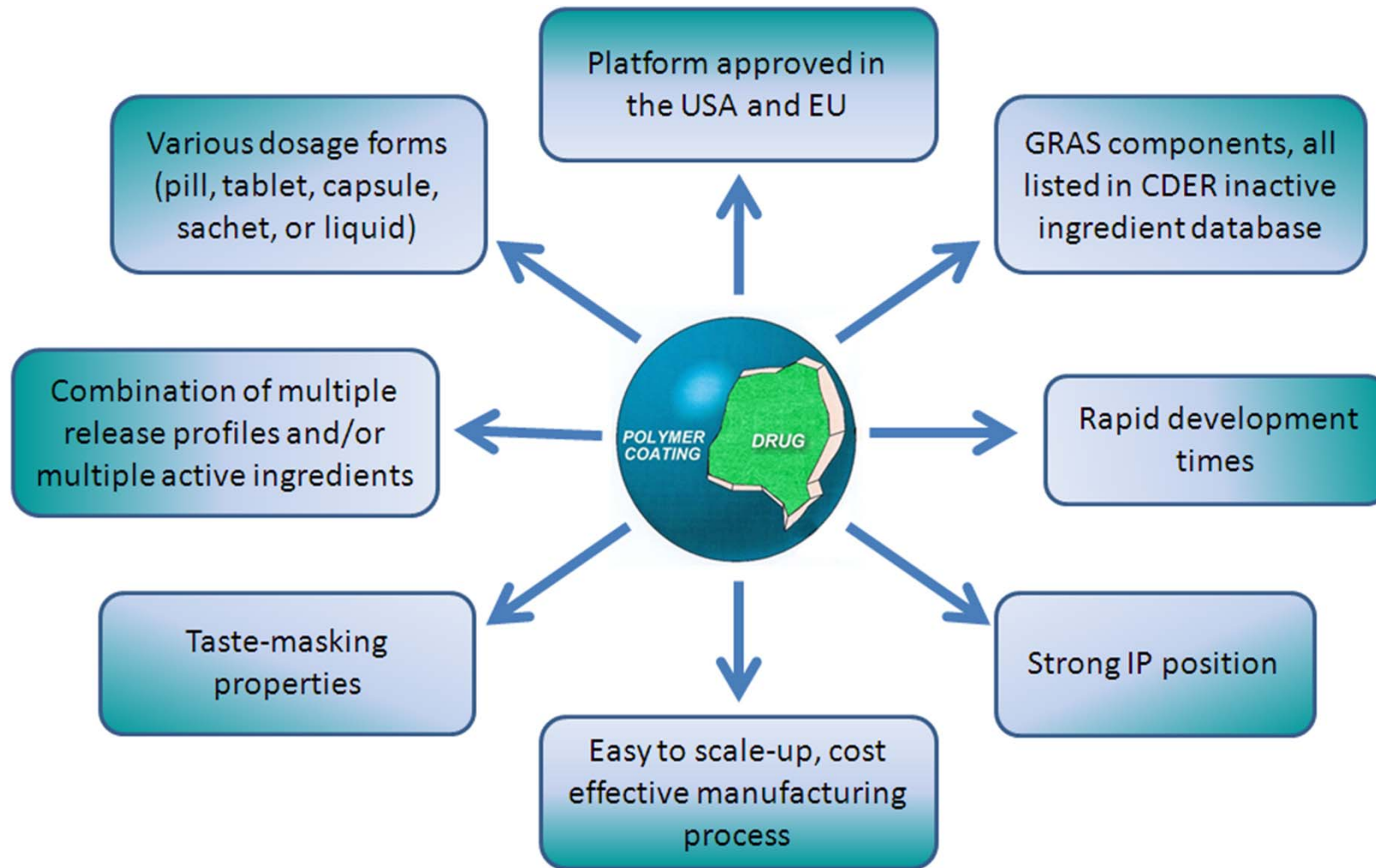
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# Micropump<sup>®</sup> Drug Delivery Platform

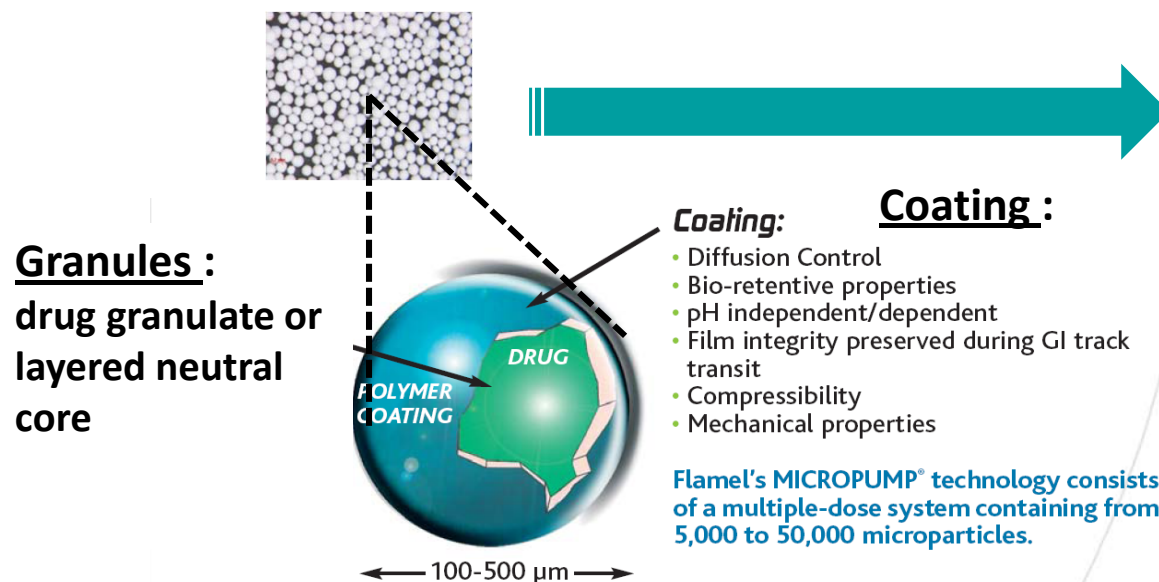
**A High-Performance, Flexible Technology  
for the Controlled-Release of Small Molecule Drugs**

- **LiquiTime<sup>®</sup>** oral liquid platform for pediatric and geriatric applications
- **Trigger Lock<sup>™</sup>** oral platform for narcotic / opioid analgesics abuse deterrence

# Micropump Drug Delivery Platform at a Glance



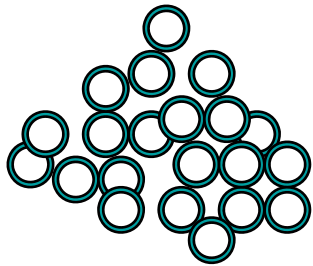
# Micropump Drug Delivery Platform for Oral Drugs



- Microparticles are dispersed in the stomach and pass into the small intestine, where 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 for Micropump I
  - Delayed for Micropump II
- Both types of Micropump particles can be used separately or together to provide highly specialized delivery profiles

# Micropump Permits Various Dosage Forms And Combinations

Coated  
microparticles



+

GRAS Excipients



✓ Capsule

✓ Tablet

✓ Sachet

✓ Liquid suspension /  
Syrup (LiquiTime®)

- One unique microparticle formulation used for different dose strengths and forms
- Easy mixing of
  - Same drug with different release profiles, or
  - Two or more drugs for combination therapy

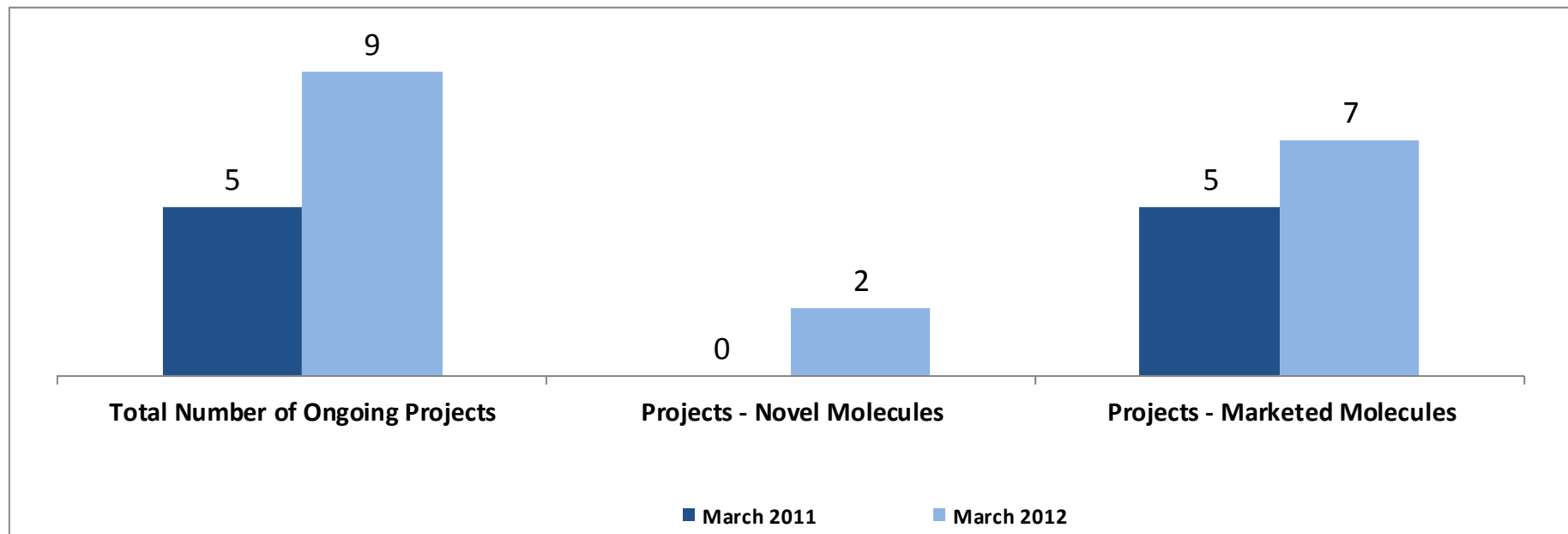
# Micropump is Clinically Proven and Approved in the USA and in Europe

- Micropump extends the release of drugs best absorbed in the small intestine (75% of all drugs)
- Numerous Micropump-based products were successfully tested in human clinical trials
  - Coreg CR® (Carvedilol CR)
  - NHP-554 (Micropump aspirin)
  - Genvir™ (acyclovir SR)
  - Metformin XL
  - Lansoprazole SR
  - Omeprazole XL
  - Co-amoxyclov XR
  - Others drugs (cardiovascular, pain, etc.) undisclosed

	Phase 1	Phase 2	Phase 3	Approved	Marketed	Partnerships
<b>COREG CR, controlled-release carvedilol</b> Hypertension						
<b>NHP-554, long-acting aspirin</b> Cardiovascular diseases						
<b>Several ongoing projects</b>				<i>Undisclosed</i>		

# Micropump Project Portfolio

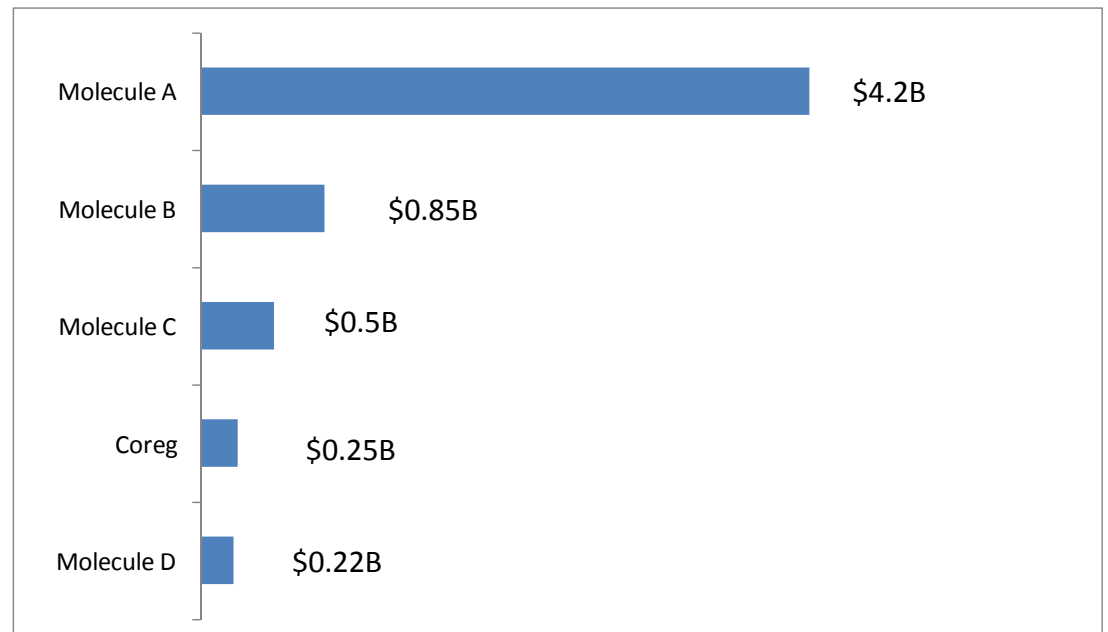
- Ongoing projects have almost doubled compared to last year
- Introduction of NMEs formulation: Higher risk but higher reward
- Successful feasibility studies feed our pipeline, most of them reaching clinical development



# Micropump Large Addressable Markets

- Micropump platform is applicable to a wide variety of molecule types and therapeutic areas
- Clinical development studies are funded by partners
- Clinical development studies addressing a total greater than \$6 billion in market opportunities

*Global 2011 market value for selected Micropump-based compounds (in \$ billion)*



# Micropump News

- Issuance of the US 209' patent (No. 8,101,209) covering Micropump
  - Registration in the Orange Book by our partner GSK
- Signature in Q4.11 of two new feasibility study agreements with undisclosed top-10 pharmaceutical companies on each of our two most recently developed drug delivery platforms:
  - Trigger Lock™ - abuse deterrent oral delivery platform
  - LiquiTime® - controlled release stable liquid formulation
- Multi-year supply agreement signed with GlaxoSmithKline for Coreg CR microparticles
  - Additional payments of €2.6 million (in Q3 & Q4.11)
  - Increased manufacturing margins

# Coreg CR<sup>®</sup> Update

- Partnered with GlaxoSmithKline plc
  - Milestones; Royalties on Net Sales; and Supply agreement for production of microparticles
  - Total net sales of Coreg CR & Coreg as reported by GSK were \$250 MM in 2011
- Hatch-Waxman expired April 2010
- Flamel filed a Citizen's Petition with the FDA in April 2010
  - FDA Response Received and available at [www.flamel.com](http://www.flamel.com)
- Three ANDA filings submitted to date, from URL Pharma, Lupin Pharmaceuticals and Anchen Pharmaceuticals
  - To date, no generic formulation of Coreg CR has yet been approved
- New Supply Agreement completed October 2011 includes guaranteed minimums and expanded margins



## Financials (as of December 2011)

(\$ MM, except per share)	3 months ended	12 months ended
	<u>December 31, 2011</u>	<u>December 31, 2011</u>
Total Revenue	8.65	32.60
Total Costs and Expenses	(10.93)	(42.18)
Loss from Operations	(2.28)	(9.58)
Net Loss	(2.09)	(8.77)
Diluted EPS	(\$ 0.08)	(\$ 0.36)
Diluted Shares Outstanding	24.74 MM	24.67 MM

### Strong cash position

- As of December 31, 2011, cash and equivalents amounted to \$24.5 MM



# Flamel Technologies

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**Flamel Technologies SA** (NASDAQ: FLML; or “the Company”) is a leading drug delivery company focused on the development of safe, efficacious and compliant formulations of drugs tackling unmet medical needs. Its product development pipeline includes chemical and biological drugs formulated with its proprietary platforms, **Medusa**<sup>®</sup> and **Micropump**<sup>®</sup>. Several **Medusa-based products** are at various clinical stages of development; Medusa’s lead product candidate IFN- $\alpha$  XL is currently the subject of a Phase 2 trial in HCV patients. The Company's has developed **products approved in the US and the EU** and manufactures Micropump-based microparticles. Flamel Technologies has collaborations with a number of leading pharmaceutical and biotechnology companies.

Additional information can be found at <http://www.flamel.com>

