

# Hovione Product Development & Licensing

**Courtney R Smith** Bio Europe Conference: Delivery Track Wednesday, November 5, 2014



#### **Hovione overview**

**Product Development & Licensing** 

Integrated approach to pulmonary delivery



# A leader in Active Pharmaceutical Development and Manufacturing since 1959...



#### New Jersey, USA

Technology transfer center. R&D Labs,Kilo and pilot plant. Sales and marketing for North America

> Cork, Ireland 427 m<sup>3</sup> manufacturing facilities





Loures, Portugal 430 m<sup>3</sup> manufacturing facilities including R&D Labs, kilo and pilot plants



Macau, China 100 m<sup>3</sup> manufacturing facilities





Taizhou, China 350 m<sup>3</sup> manufacturing facilities



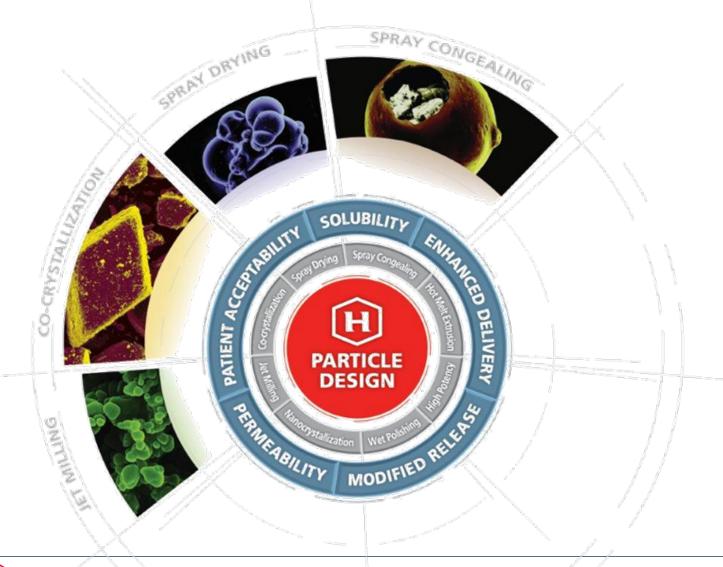
Shanghai, China Process chemistry R&D Center

### **Overview of Hovione**

- Privately-held; stable management
- 1200 Team members world-wide
- Our customers:
  - Biotech
  - Medium, specialty and large pharma
  - 50% innovators, 50% generics
- Revenues (2013) USD 201 m
- Sales: World-wide reach
  - 40% USA, 25% EU, 25% Japan



### Growth fueled by particle technology platforms



### Particle Engineering Technologies

	SOLUTIONS				
TECHNOLOGIES	Solubility	Enhanced Delivery*	Patient Acceptability	Modified Release	Permeability
Spray Drying	Ĥ	H	Ĥ	H	Ĥ
Hot Melt Extrusion	H		Ĥ	H	H
Nanocrystallization **	H	H			
Wet Polishing	H	H	Ĥ		H
Jet Milling	H	H			
Co-crystallization **	H			H	
Spray Congealing	Ĥ		Ĥ	H	Ĥ
Controlled Crystallization**	Ĥ	Ĥ			
Emulsification **	Ĥ	Ĥ	Ĥ	Ĥ	Ĥ
Fluidized Spray Drying	Ĥ	H	Ĥ	H	Ĥ
Inclusion Complexes	Ĥ	H	Ĥ		

\*Enhanced delivery by non-oral routes of administration including lung delivery

\*\* New offer/ coming soon

Hovione then and now

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### Product Development and Licensing



### Build a balanced drug product portfolio

- Reformulated products from known APIs (505b2)
- High value Generics (DPI)



Leverage on our technology strengths

- Particle Engineering expertise
- Inhalation know-how
- Dry Powder Inhalation Devices Design



### Develop partnering opportunities

- Licensees
- Co-development with synergetic technologies
- Investors to pay for clinical development

### **PDL Product Pipeline**

Produc	t	Indication	Formulation Development	Pre-clinical	Clinical	Marketed	Partner
HX02	Generic	Contrast agent					Imax Diagnostic Imaging Available for licensing
HY01	New product	Skin inflammation (acne, rosacea)		IND filed			Available for licensing
НХ20	New product	GI tract imaging					Under development
IH01	Generic	COPD		UNDISC	LOSED		Available for licensing
HD20	Generic						Under development

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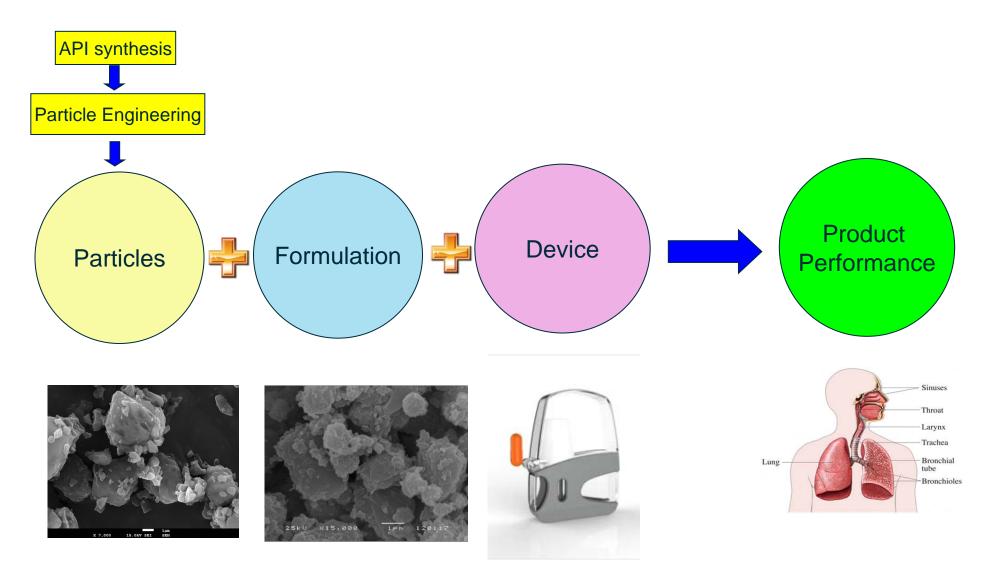
Hovione then and now

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### Integrated Approach to Inhalation



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### Dry Powder Device Portfolio

Product	Prototype	<b>Clinical trials</b>	Marketed	Regulatory framework
<b>TwinCaps</b> disposable inhaler + INAVIR				Combination
<b>TwinCaps</b> disposable inhaler + other API				product
<b>XCaps</b> capsule based DPI				Medical device

#### Ночопе 🔃 вю Еч

### Hovione Dry Powder Inhalers

#### **Key Advantages**



- Cavity-based, high efficiency single-use, disposable inhaler
- Market-leader in Japan– combination product regulatory path
- Acute diseases
- Patent life until 2027
- Partnering opportunities vaccines, antibiotics, anti-viral, others

#### • XCaps



- Capsule based high efficiency re-usable inhaler
- Generic or NCE delivered as a stable powder
- Patent life until 2033
- Partnering opportunities asthma, COPD, CF, others

### Benefits of Hovione inhalers

Dose Loading	<ul> <li>Large doses for mAbs. Antibiotics</li> <li>Small doses for asthma, COPD (corticosteroids)</li> </ul>
Efficient delivery	More accessible to patients with reduced lung function
Easy to use	Designed from human use factor feedback
Patent protected devices	Extended patent life and protected product sales
Global reach	Cost conscious on a global scale

#### Hovione 🔀





## Thank you for your attention.

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