



Hovione

CPhI Russia

St. Petersburg, Russia - 17 April 2014



Agenda

Hovione - the beginning

Who we are

Hovione worldwide

Hovione - sales & people

What we do

Generics for Inhalation and other applications

Quality & Compliance

The beginning



- ✓ Founded in April of 1959 by Ivan Villax, chemical engineer and researcher
- ✓ Industrial operations started in 1969, Loures - Portugal



Who we are (1/2)

- Hovione is a global company 50+ years of experience in the development and manufacture of Active Pharmaceutical Ingredients (APIs) and Drug product intermediates.
- Our Clients range from small biotechs to large pharmaceutical groups.



Who we are (2/2)



- Hovione effectively bridges between chemistry and drug products by offering:
 - Tailored API
 - Particle Engineering
 - Formulation development
 - Dry Powder Inhalers
- Hovione developed and successfully submitted *Quality by Design* (QbD) innovative products that are now commercial

Hovione Worldwide



New Jersey, USA

Technology transfer center.
R&D Labs, Kilo and pilot plant.
Sales and marketing for North America
FDA Sep 2013 - no 483



Loures, Portugal

430 m³ manufacturing facilities
including R&D Labs, kilo and pilot plants



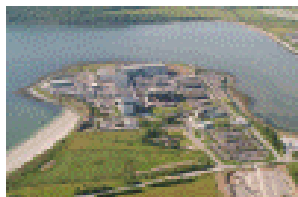
Macau, China

100 m³ manufacturing facilities
FDA Jan 2013 - no 483



Cork, Ireland

427 m³ manufacturing facilities
FDA Mar 2012



Taizhou, China

350 m³ manufacturing facilities



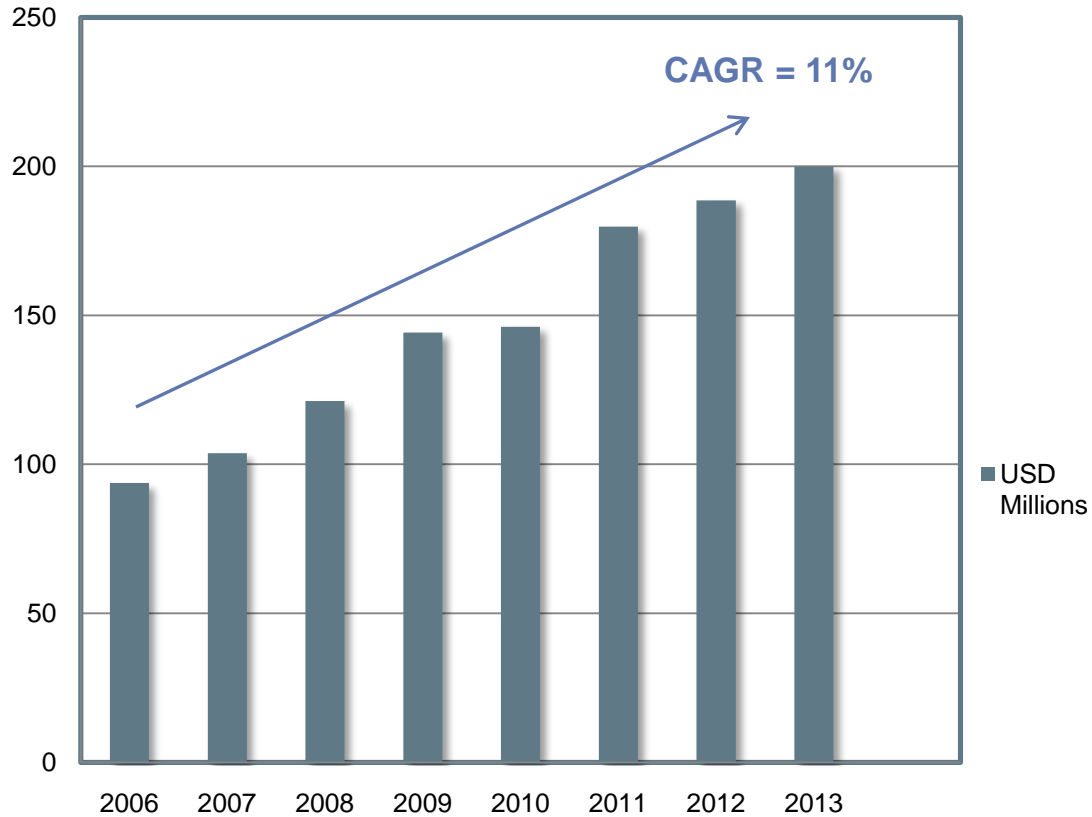
Shanghai, China

Process chemistry
R&D Center

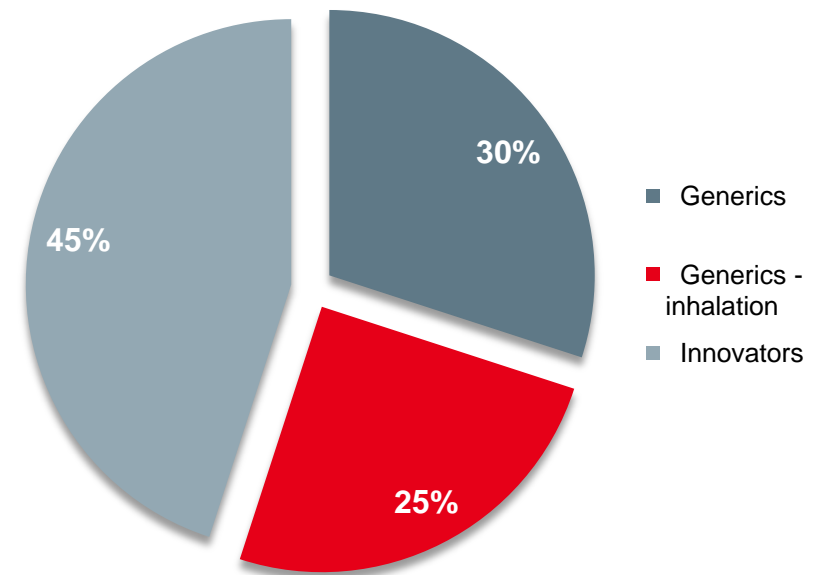


A growing Company ...

Sales 2006 - 2013

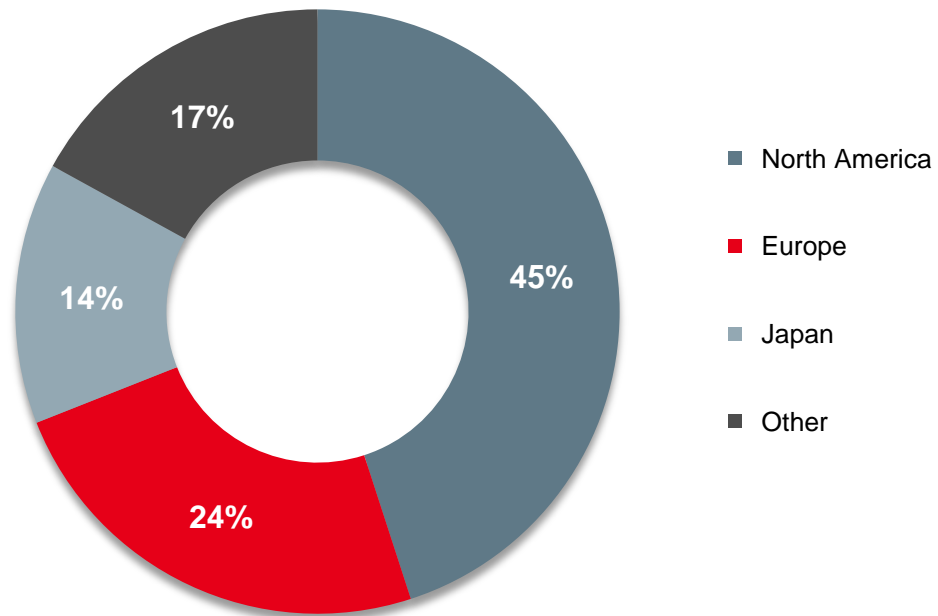


Split by business segments

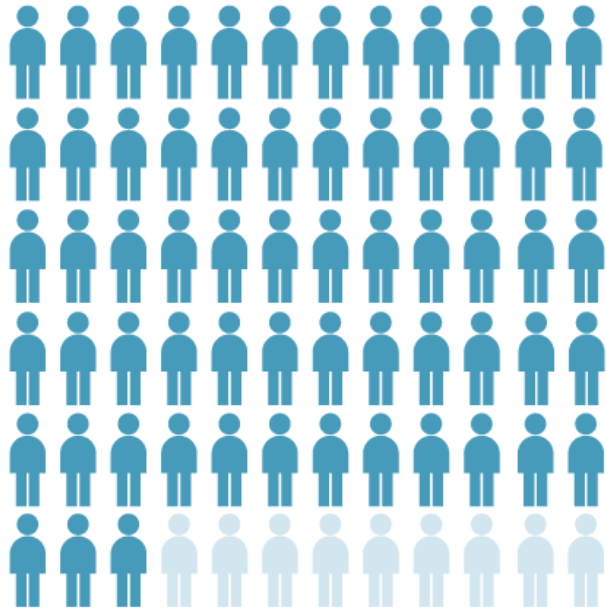


... across all business areas

Sales by Territory

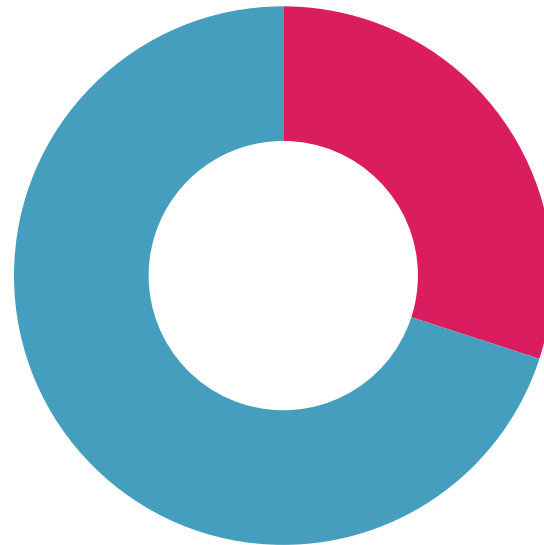


People...



Worldwide

1,260



 30%

 70%



51%

University degree
or above

What we do ... from API to Drug Product



API Synthesis

- 1300 m3 reaction capacity
- Reactors from 20 to 16,000 liters
- High pressure Hydrogenations up to 100 bar
- Cryogenic reactions down to -90°C
- Clean Rooms (class D - ISO 8)



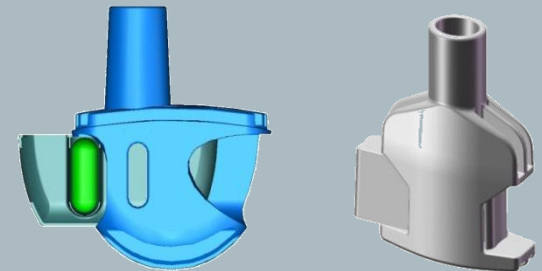
Particle Design

- Spray Drying
- Hot Melt Extrusion
- Spray Congealing
- Wet Polishing
- Jet Milling



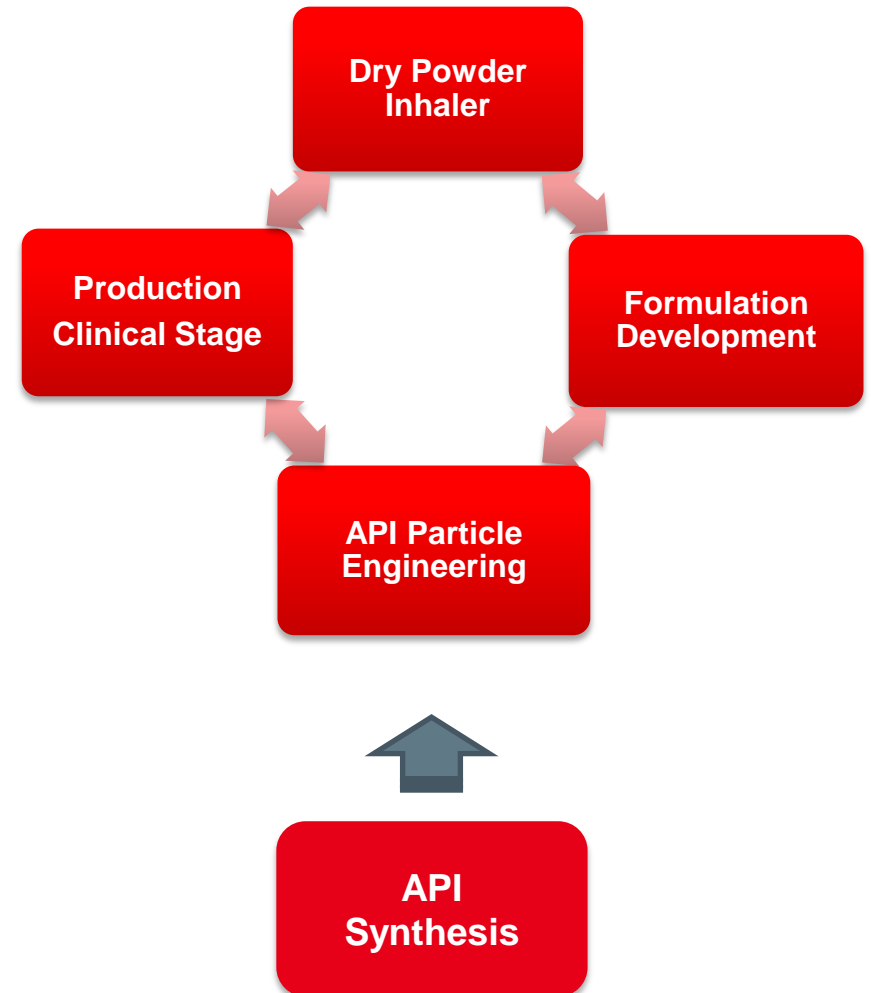
Drug Product & Dry Powder Inhalers

- Formulation development
- Capsule Filling
- DPI - Licensing and sale



An Integrated Approach ...

- API Synthesis
- APIs tailor-made for Inhalation:
 - Highly customizable PSD
 - Particle Size: 2-3 μm
 - Low span
 - Virtually zero amorphous content
 - Optimizing
 - Density, Cohesiveness & Adhesion
- Formulation Development:
 - Extensive Particle Design experience
 - Stability Studies
 - Analytical Methods development & validation
- Production capacity for all development stages, from clinical to PIII to commercial
- Dry Powder Inhalers: licensing and sales



Our off-patent APIs - Inhalation

Commercial

- Fluticasone propionate
- Mometasone furoate anhydrous
- Mometasone furoate monohydrate
- Beclomethasone dipropionate anhydrous
- Beclomethasone dipropionate monohydrate

Development:

- Fluticasone furoate
- Salmeterol xinafoate
- Tiotropium bromide monohydrate
- Tiotropium bromide anhydrous



Our off-patent APIs – other Applications

Antibiotics

- Doxycycline hyclate
- Doxycycline monohydrate
- Minocycline hydrochloride
- Minocycline base
- Roxithromycin



Anti-parasitics

- Ivermectin



Contrast Media

X-Ray

- Iopamidol
- Iohexol
- Iodixanol

MRI

- Gadopentetate monomeglumine



Excellent Track Record (1/2)

We are regularly inspected by worldwide Health Authorities:

- FDA – USA
 - 25 inspections since 1982
 - 2011: FDA approved 24 products of which 2 were developed by Hovione
 - 13 last inspections were “pre-approval”, i.e., specific for a new Product
 - First ever PAI for a NDA entirely developed under *Quality by Design* (3 inspectors on site)
- INFARMED – Portugal
 - 16 inspections since 1994
- PMDA – Japan
 - 3 inspections since 2008
- KFDA – Korea
 - 1 inspections in 2013



Excellent Track Record (2/2)

- Average rate of 40 audits per year between Health Authorities and Customers
- Quality driven work environment in a strict regulatory framework
- Supply chain continuity
- No product produced at Hovione was ever subject to a market recall.



Thank you !

Nuno Mineiro

+ 351 21 98 29 411

nmineiro@hovione.com

www.hovione.com