

# PharmEste s.r.l.

# Developing best-in-class TRP channel therapeutics

"LO SMALL BUSINESS ACT E IL VENTURE CAPITAL COME SOSTEGNO ALLA CRESCITA DELLE PICCOLE E MEDIE IMPRESE EMILIANO-ROMAGNOLE"

Bologna, 13 Dicembre 2010

### PharmEste Overview



- Founded as a spin-off of the University of Ferrara
- Committed management team with extensive industrial expertise and dedicated staff with strong multidisciplinary experience (total 12 people)
- First class Scientific Advisory Board
- Business Unit in Milan & Labs in Ferrara (Italy)
- Strong IP position fully owned by the company
- PHE377, a TRPV1 antagonist in Phase I clinical studies.
- New Drug Candidate from Second generation TRPV1 antagonist under selection
- Discovery program for new TRPs antagonists
- Two round financing for an overall amount of €11 million with a panel of Investors (Corporate Industrial Ventures and Professional Venture Capitals)
- Partnership planned in 2011

### Company mission, strategy and goals



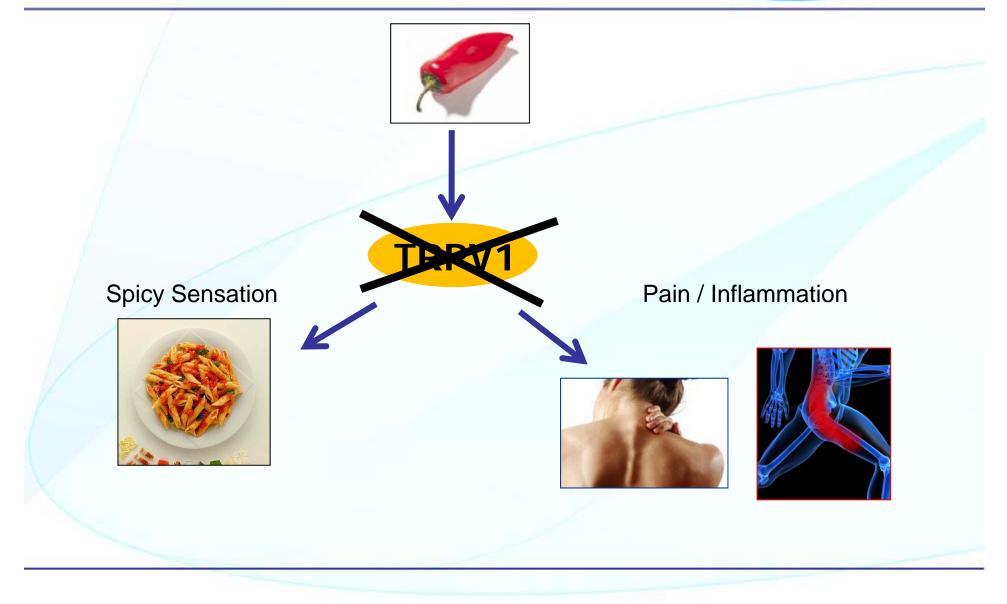
- To play a leading role in the discovery and development of small molecule TRP channel therapeutics for the treatment of pain, overactive bladder and other TRPmediated diseases
- The Company intends to strategically pursue the development of TRPs antagonists to address:
  - Neuropathic pain of different origins
  - Other TRPs related diseases such as Overactive Bladder, Cough, Itch and Gastrointestinal Disorder
- First compound PHE377 will be developed up to completion of all **Phase I** clinical studies by PharmEste.

**Phase IIa** studies will be conducted in partnership in the following clinical conditions:

- Painful diabetic neuropathy (PDN)
- Post-herpetic neuralgia (PHN)

### TRPV1: the Capsaicin Receptor





## *Neuropathic Pain: an unmet medical need*



- Chronic pain syndrome results from damage to the nervous system induced by different processes
- Includes a group of disorders such as:



Painful diabetic neuropathy: the most common complication of diabetes mellitus

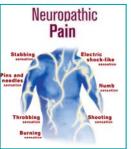


Post-herpetic neuralgia: a complication of shingles, the second outbreak of the varicella zoster virus



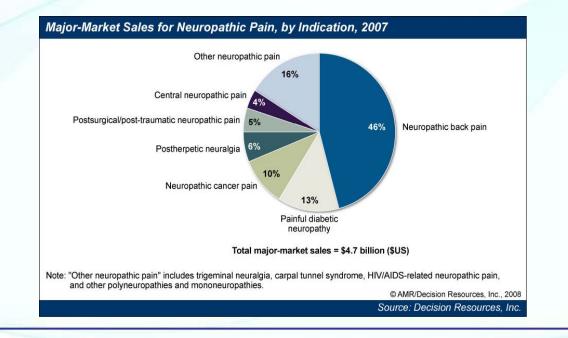
Low back pain: one of the most common pain syndromes and among the most frequent causes of loss of working days and disability

- These disorders share several critical features, including:
  - poor response to conventional analgesics
  - chronic course of the symptomatology



Neuropathic Pain: a market opportunity PharmEste

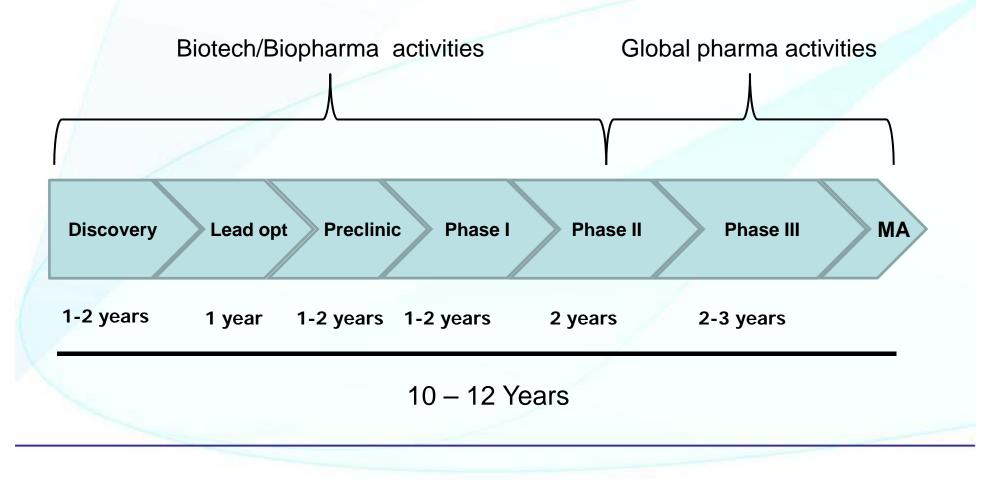
- It is estimated that ~1% of the population is affected
- About € 4.7 billion in the top seven countries in 2007
- Growth estimated to accelerate in the next 10 years (€ 7.9 billion in 2017) due to aging population, emerging geographical markets and availability of better tolerated and more effective drugs



### From bench research to the market

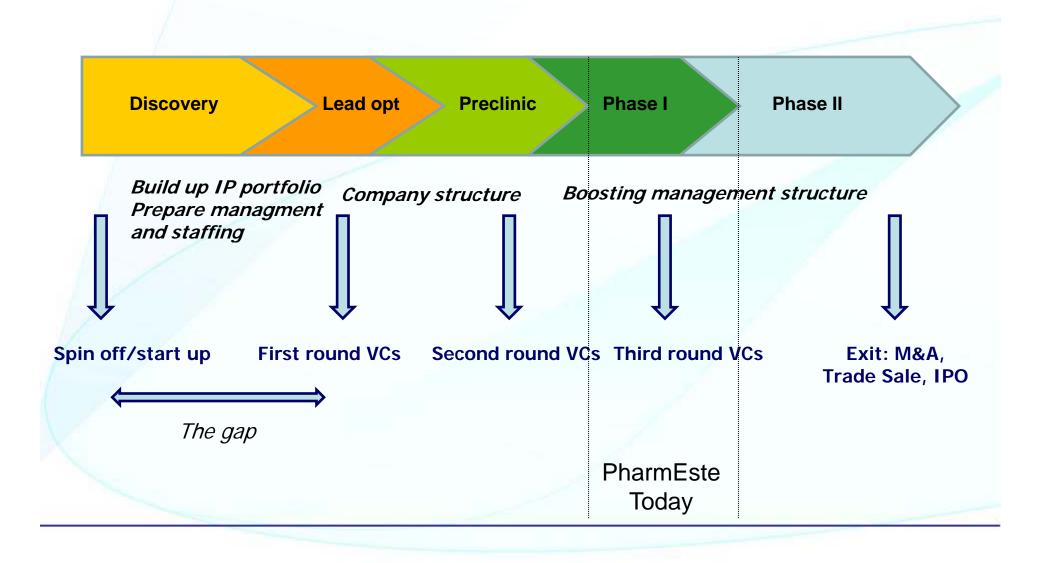


From discovery to the market a NCE will take more than 10 years with high risk of failure and high investment needed.



### From bench research to the exit

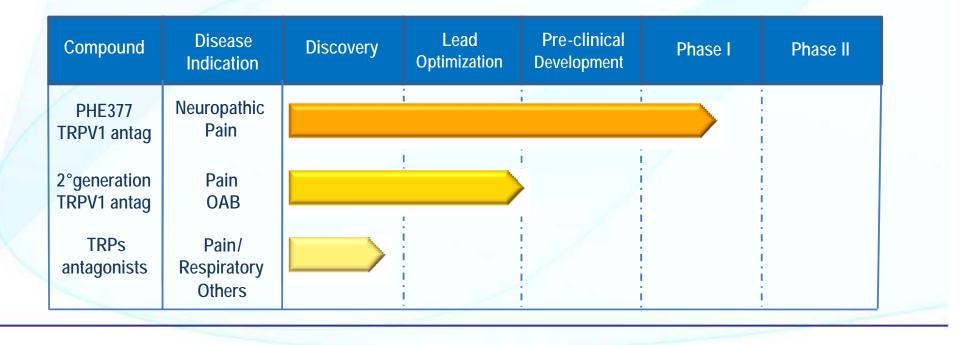




### PharmEste current portfolio



- Six fully owned patents all related to small molecules covering 5 different chemical classes
- **PHE377** for the treatment of **neuropathic pain** in Phase I studies
- 2° generation TRPV1 antagonists under final optimization phase
- Evaluation of TRP modulators potential in other related clinical indications also through external research collaborations



### PharmEste Key events



- 2003 : founded as <u>University Spin off</u> by University professors P. Baraldi; P.Borea; P.Geppetti around an innovative and high potential project as <u>TRPV1 antagonist</u> for the treatment of neuropathic pain
- 2004 : agreement with <u>Z-Cube</u> corporate venture <u>Zambon Company</u> providing seed, managerial activities and scientific support.

### 2004-2006 : -discovery activities

- -filing the first IPs
- -identification of most relevant chemical structures
- -identification of initial management and staffing
- January 2007 : first financial round closing <u>€3,2 million</u> (<u>Zernike MetaVenture</u>; <u>Fondamenta SGR</u>; <u>Quantica SGR</u>; <u>Z-Cube srl</u>) -Set up the first independent managerial and staffing team -Set up an outstanding scientific international advisory board
- October 2007 : PHE377 selected for the preclinical development New drug discovery program for 2nd generation TRPV1 antagonist

### PharmEste Key events



October 2008	<ul> <li>Second financial round of €6million (MPS Venture; MP Healthcare Venture Management; Quantica SGR; Z-Cube srl)</li> </ul>
2008-2009	- Implementation of company management and staffing.
	- Established new location as Business office in Bresso and new laboratories in Ferrara
July 2009	<ul> <li>Enter into PhaseI clinical development after approval from EC/Swiss Medic</li> </ul>
October 2010	- Additional financing and commitment from internal investors to further support Company development
	<ul> <li>Selection of second drug candidate from 2nd generation TRPV1 antagonist for the preclinical development</li> </ul>
	- New discovery program for a new target as TRPs antagonists
1Q 2011	- Initiation of PhaseIb clinical study to demonstrate PoP in HV.
2011	- Open discussion for partnership with international pharmaceutical companies.

# Key based for the success



#### From the science:

✓ An oustanding research project which should meet the unmet medical need.
✓ A relevant market potential

### From the managment and staffing

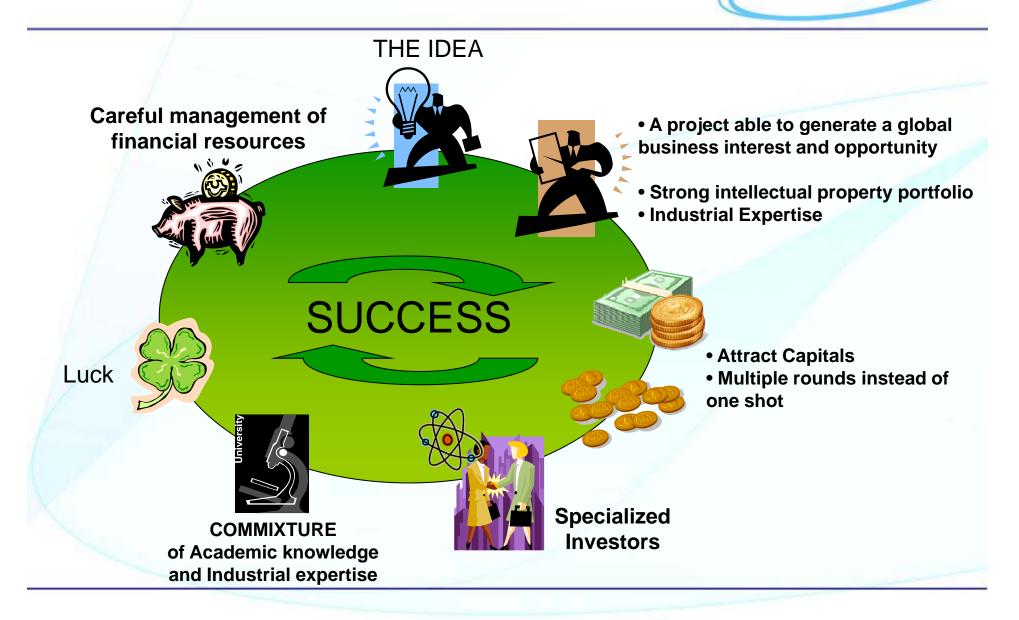
An experinced industrial team able to transform the scientific project in a real drug Potential and able to attract investors for their manageral capability

#### **From investors**

A group of professional investors able to support the company in different round of financing

The final costumer of the biotech/biopharmaceutical company is the global pharamaceutical one who has to buy the product or the company

### Our Success has required multiple aspects PharmEste





- January 2007: Series A round closed at €3.2 M (Z-Cube, Quantica, Zernike MetaVenture and Fondamenta)
- September 2008: Series B round closed at €6 M
   (Z-Cube, Quantica, MPS Venture, MP Healthcare Venture Management)
- October 2010: first extension Series B round closed at € 1.8M
- By 2011 PharmEste expects to have:

   completed all phase I clinical studies for PHE377
   initiated IND package with a second generation TRPV1 antagonist
   selected of a new TRPs antagonist
   generated partnerships with Pharma Companies

# Contact us



#### PharmEste Management and Staff

Claudio Semeraro CEO Paolo Indennitate CFO and Business Officer Mauro Napoletano Research Manager Gabriele Morazzoni Development Manager Marcello Trevisani Head of Pharmacology Francesca Fruttarolo Senior Researcher Maria Giovanna Pavani Senior Researcher Raffaele Gatti Senior Researcher Matilde Mallardi Researcher Serena Bencivenni Researcher Lara Fullin Assistant

### Scientific Advisory Board

Prof. Troels Staehelin Jensen (Denmark) Prof. Clive Page (United Kingdom) Dr. Ennio Ongini (Italy) Prof. Arpad Szallasi (USA)





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