



 **Chiesi**
People and ideas for innovation in healthcare

Chiesi Group profile

Andrea Chiesi

Parma, 9 novembre 2011

Our Mission

Our aim is to be recognised **as a research-focused international** Group, able to develop and commercialise **innovative pharmaceutical solutions** to improve the quality of human life.

We want to maintain a **high quality entrepreneurial** team characterised by self confidence and a collaborative spirit.

Our goal is to combine commitment to results with **integrity**, operating in a socially and environmentally responsible manner.

Chiesi Group: our Values

RELIABLE COMPANY

- Ethics
- Transparent

FOCUS ON PEOPLE

- Listening
- Development

FOCUS ON CUSTOMERS

- Excellence
- Devotion

TEAM SPIRIT

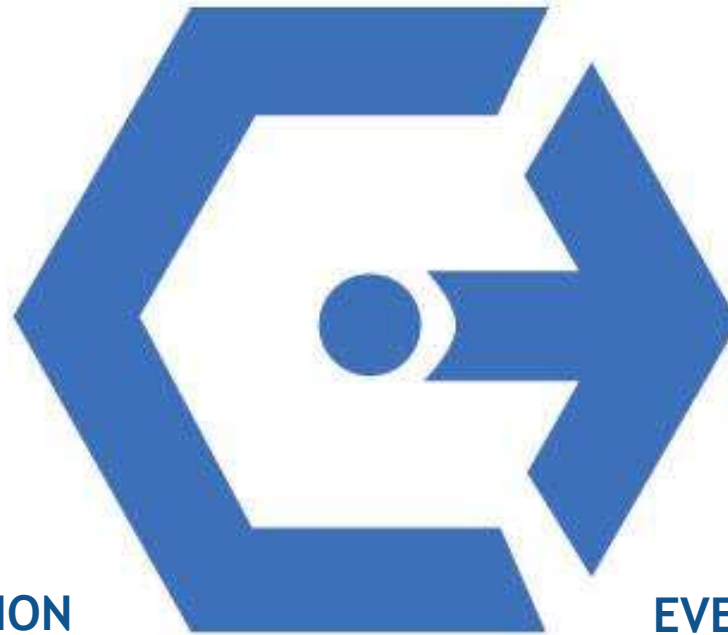
- Cohesion
- Collaboration

VALUE GENERATION

- Innovation
- Entrepreneurship

EVERY ONE OF US IS CHIESI

- Sense of belonging
- Responsibility



Chiesi Group: - Facts & Figures

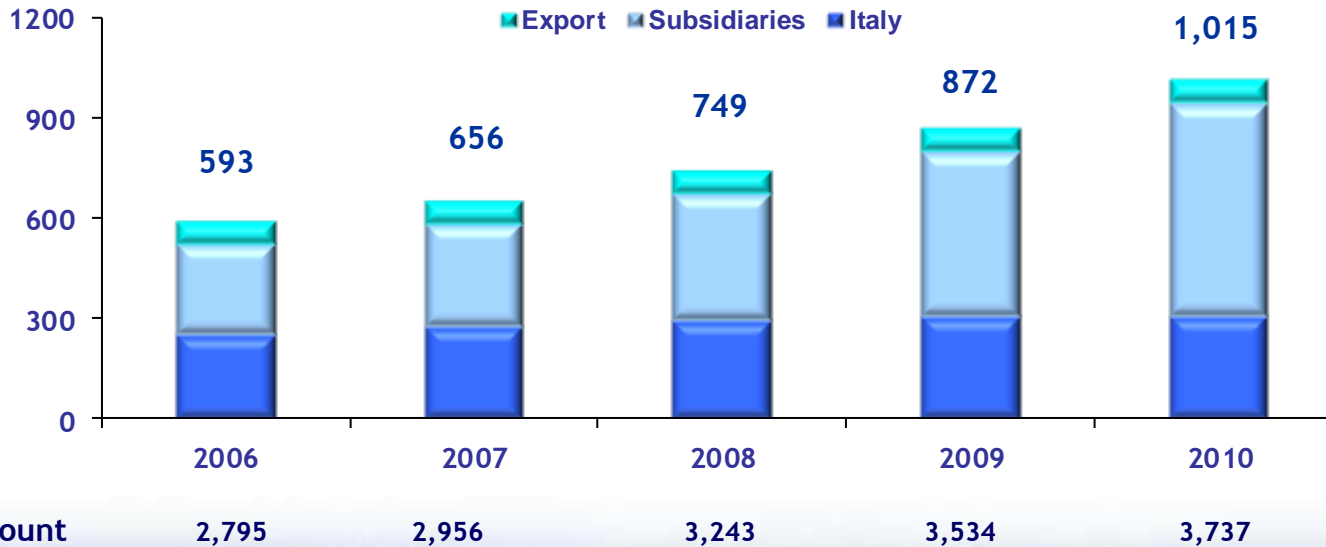
2010 Key facts

- Founded in 1935/ Privately owned
- Employees: 3,737; 1,507 in Italy
- Revenues: 1,015 M €
- R&D investments: 150.3 M €
- Direct Affiliates: 24
- Geographic focus: Europe

Therapeutic focus:

- Respiratory diseases
- Cardiovascular & metabolic disorders
- Neonatology & Special Care Diseases

Corporate Sales (millions €)



The Strategic View



Focus

Due to the high level of necessary investments, focus in R&D is essential

Respiratory

Experience and expertise in the development of respiratory products are a core asset for the growth of the Group

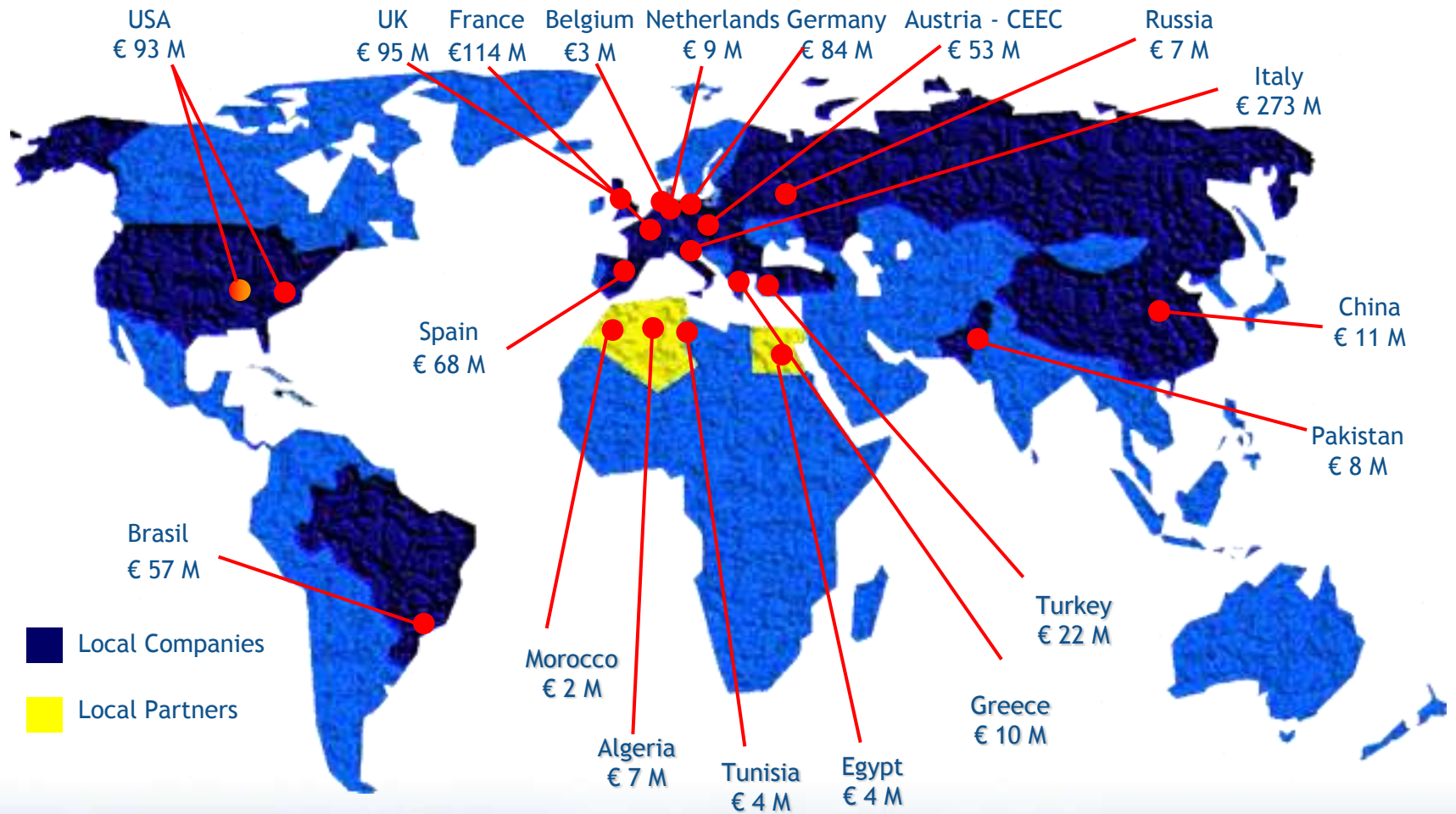
Rare diseases

The therapeutic unmet needs and the social impact of rare diseases are at the origin of the Group's effort in this area

World-wide

Development of key respiratory products based on Modulite® technology

Chiesi worldwide: 2010 sales



Chiesi Partnerships

Licensing-in

- Takeda Pharmaceuticals
- Tanabe Seiyaku
- Astra Zeneca
- 3M

Licensing-out

- Abbott
- GSK
- Novartis
- Nycomed
- Pierre Fabre
- Johnson & Johnson
- Pfizer
- UCB

Commercial Capabilities

- Direct European presence, marketing expertise and OL networking

Development Capabilities

- Technical, clinical, regulatory and manufacturing expertise and experience

Partnership Management

- Accurate evaluation and rapid decision-making process

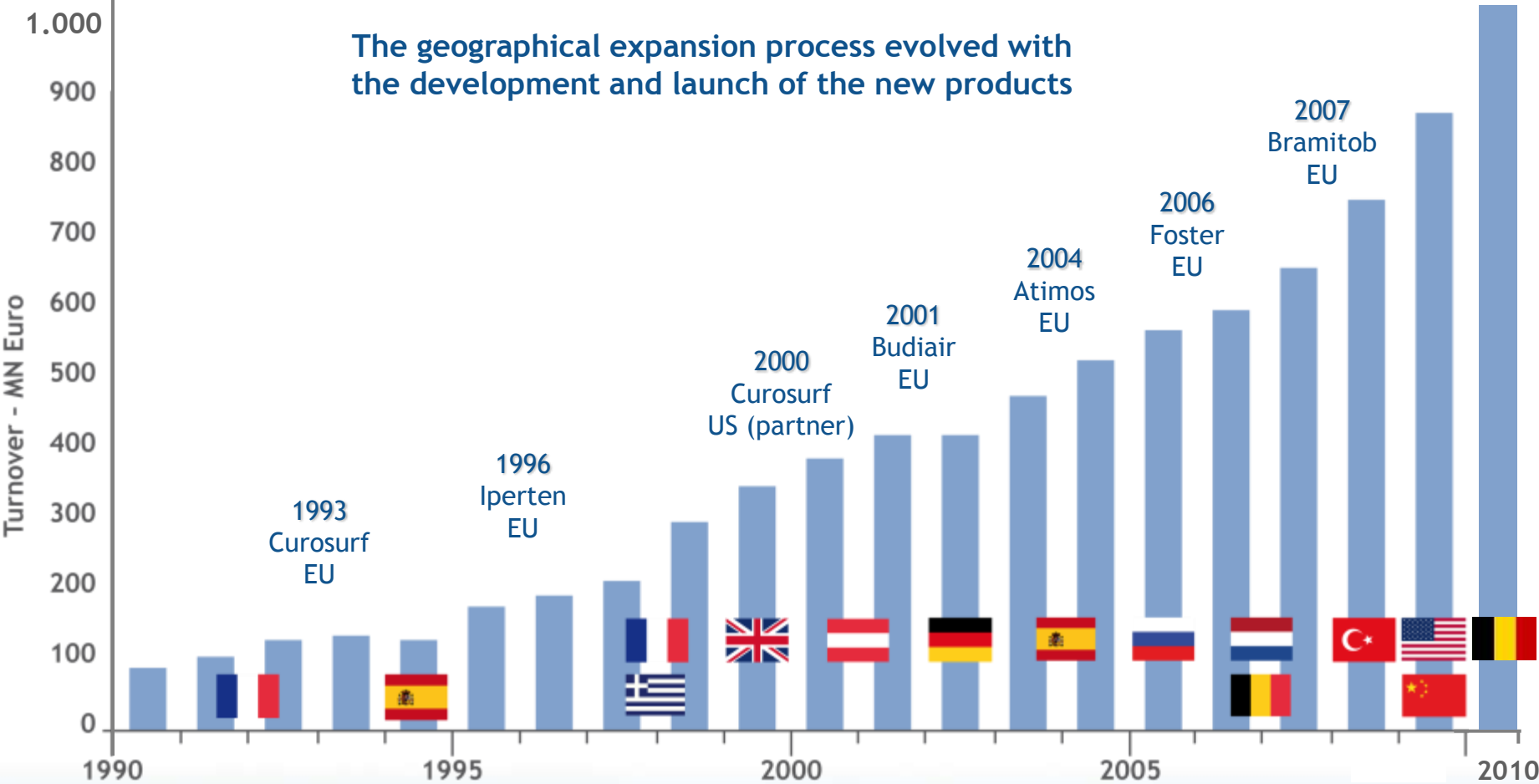
Chiesi ranking

2009 RANK (2008 RANK)	COMPANY	2009 PHARMA SALES (\$ MILLION)	% CHANGE 09 Vs 08
56 (66)	Hisamitsu	1389	14,9
57 (76)	Warner Chilcott	1385	50,7
58 (NR)	Meiji Holdings	1366	N/A
59 (63)	Galderma	1364	8,6
60 (55)	Gedeon Richter	1335	-3,8
61 (60)	Ferring	1325	4,1
62 (67)	Esteve	1316	11,2
63 (56)	Almirall	1291	-2,8
64 (61)	Grünenthal	1229	-3,3
65 (71)	Chiesi	1216	10,4
66 (68)	Asahi Kasei Pharma	1211	4,4

SOURCE: IMS - World's Top 100 Pharma Companies 2009

International Growth & Corporate Products

The geographical expansion process evolved with the development and launch of the new products



Our main products



A passion for breathing

The European Respiratory Society Congress is the most important European Event for respiratory pathologies and new therapies

During the last 5 years we have constantly been increasing visibility and quality of our presence through:

- the quantity & quality of the data presented (4 papers in 2007, 3 in 2008, 9 in 2009, 15 in 2010)
- the relevance of the presenters
- the quality of the relations
- the passion of the Chiesi people





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Industrial operations

Parma Facilities



Parma, Italy

- Regularly and successfully inspected by the U.S. F.D.A.
- ISO 9001: 2008 Certified
- OHSAS 18001 Certified
- Total Production Area 15,650 m²
- Registered into over 65 Countries

Production capacity

- 23 million packs in real solids
- 12 million packs in Unit-Dose Vials (UDV)
- 24 million packs in Metered-Dose Inhalers
- 375,000 vials in sterile suspensions

Saturation rate 2010

54%

100%

80%

89%

Other Facilities



Blois, France

- Manufacturing capacity: 13 million finished packages per year
- Specialised in blister packaging for capsules and tablets, and final stages of the MDI assembly
- Ample refrigerated stores for the products
- Equipped to supply Group's Affiliates and distribute directly to clients in the French and export markets.



Santana de Parnaiba, Brazil

- Manufacturing capacity: 30 million finished packages per year
- Solid formulations, pressurised solutions and suspensions for inhalant therapy (MDI)
- Santana supplies both the domestic market and the Group's Affiliates and exports to licensees and distributors.



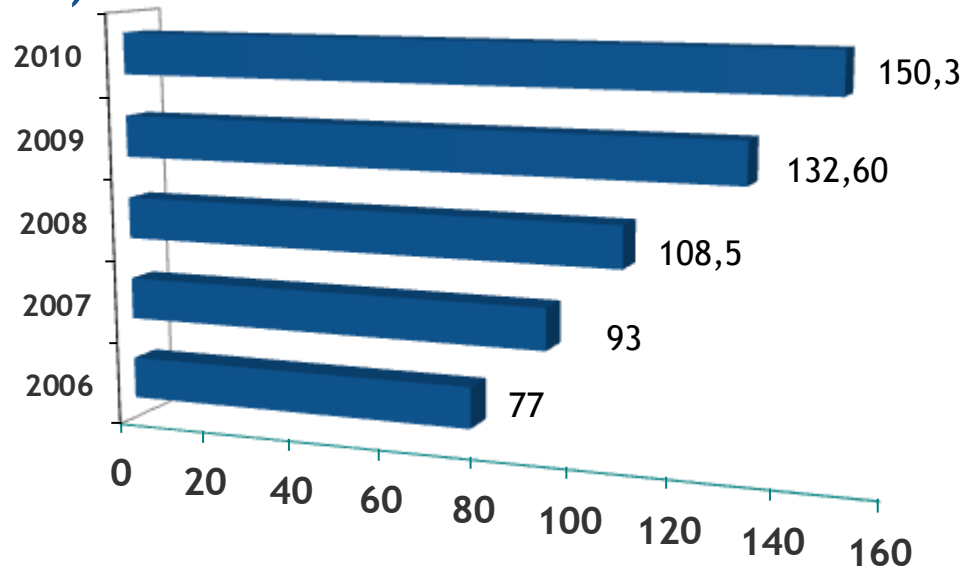
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Research & Development

Chiesi R&D at a glance

Headcount: 402 - Investments in 2010: 150,3 M € (15 % on turnover)



- 4 sites: Parma - Italy; Paris - France; Rockville - USA; Chippenham - UK
- 8° R&D investor in Italy*
- 1° among the Italian pharmaceutical companies*
- 14° among the European pharmaceutical companies*

* European Commission - 2009 EU Industrial R&D Investment Scoreboard

The Pharma R&D activities: The 'Research' Phase

Aimed at pharmacological innovation:

- Define the target we want to hit
- Identify/synthesise molecules able to interact with the target
- Evaluate therapeutic efficacy in *in vitro* and *in vivo* experimental models
- Deliver candidate drugs (CD)



The Pharma R&D activities : The 'Learn' Phase

The 'Learn' phase establishes the so called 'proof of concept'

- Identify an appropriate pharmaceutical formulation
- Conduct toxicology studies in various animal species
- Study the drug metabolism in the animals and humans
- Establish safety and active doses
- Identify up to two effective doses in the desired indication to progress into full development (pivotal studies)



The Pharma R&D activities : the ‘Confirmation, launch, and growth’ Phase

The completed clinical development

- Demonstrate efficacy and safety in patients with a rigorous comparison with “standard of care” in a larger number of patients (health economics)
- Expand the use with studies in all indications and patients populations of interest

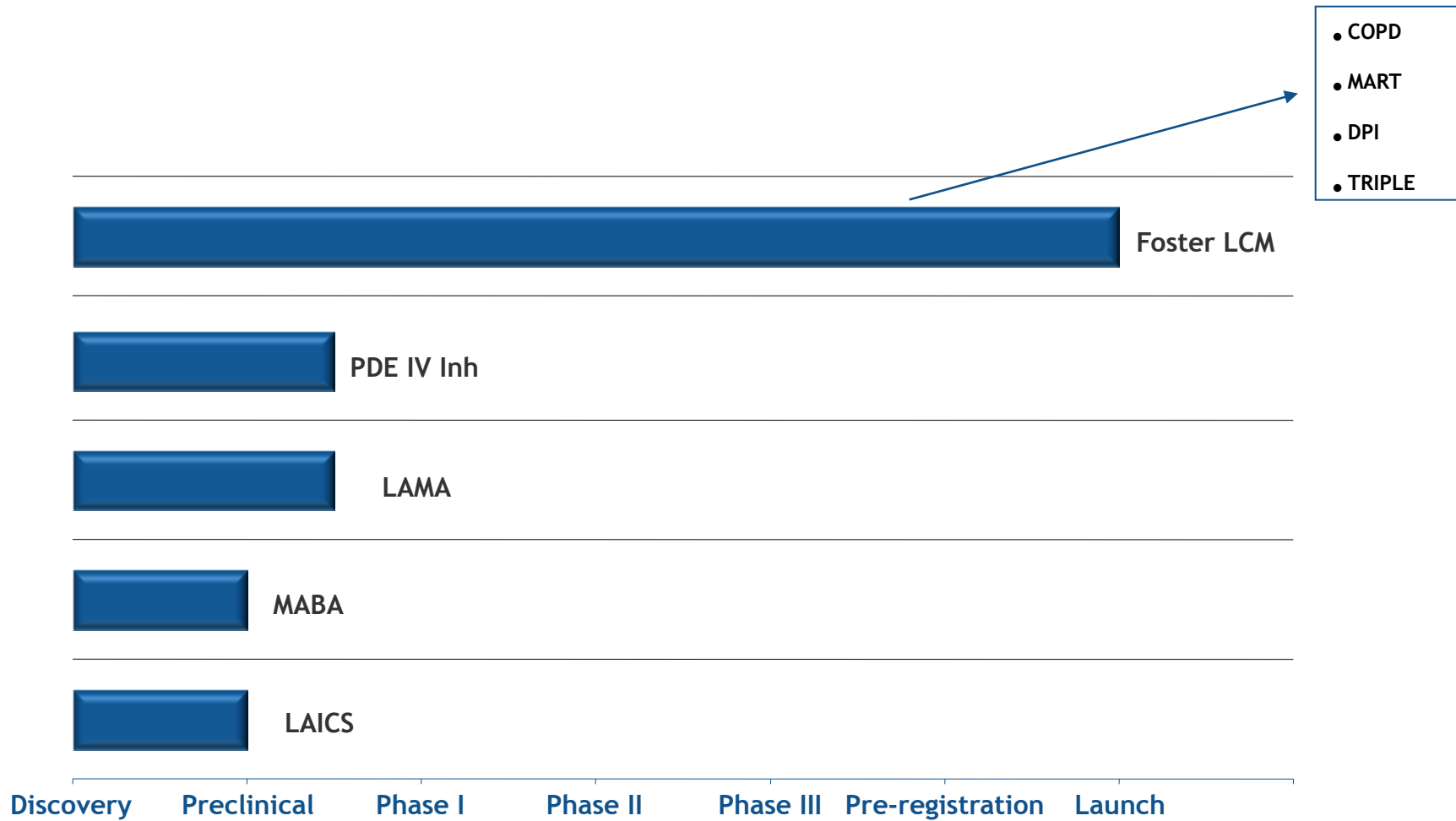
Request for MA (regulatory dossier) submitted to Regulatory Authorities (EMA, FDA et al.), launch and post -marketing activities



Proprietary Innovation @ 360°

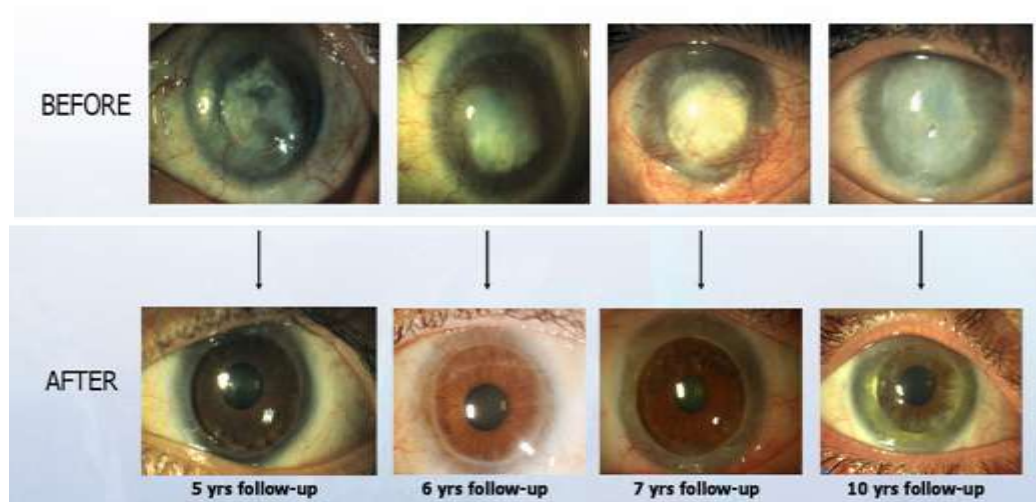
- 8 new patented compounds and 3 COMBOs for asthma and COPD

Pipeline: Respiratory

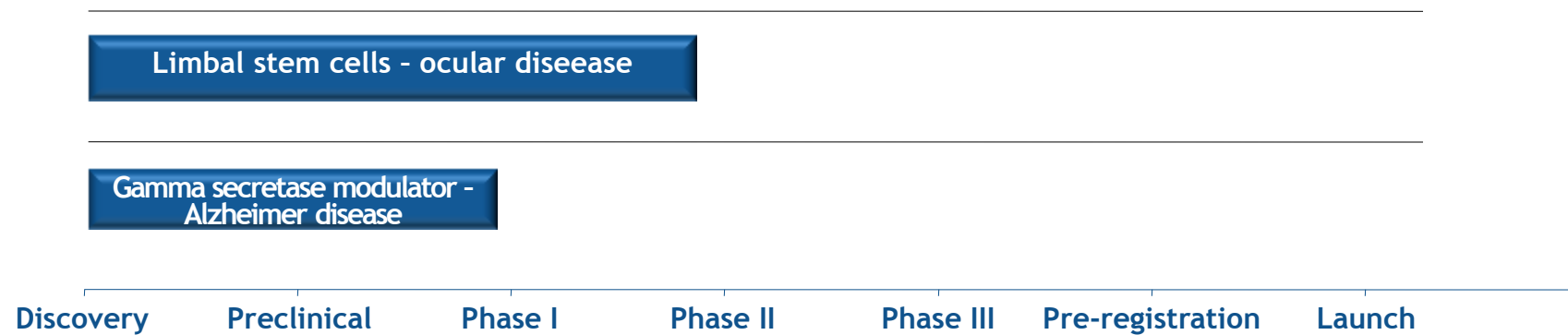


Proprietary Innovation @ 360°

- 8 new patented compounds and 3 COMBOs for asthma and COPD
- New personalised therapies: regenerative stem cells for the blind



Pipeline: Metabolics, Rigenerative Medicine, CNS



Proprietary Innovation @ 360°

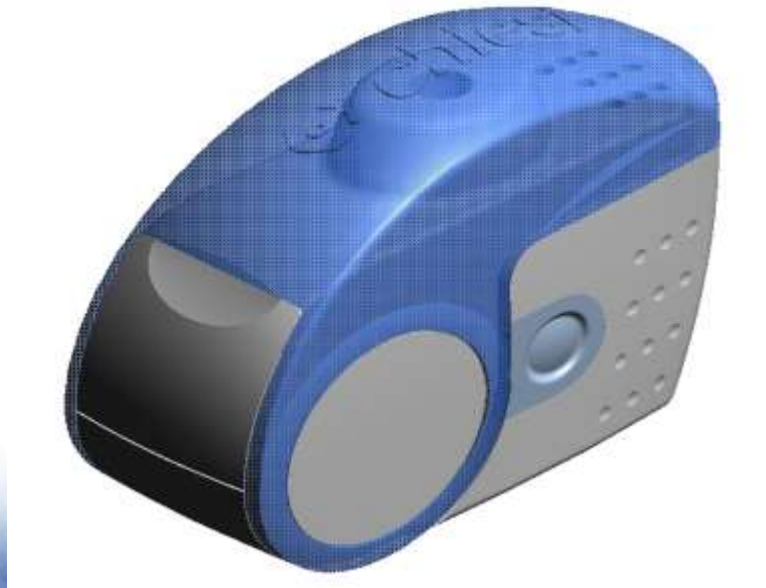
- 8 new patented compounds and 3 COMBOs for asthma and COPD
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- New environment-friendly formulations for our respiratory drugs

Proprietary Innovation @ 360°

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- New best-in-class specific delivery systems

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Proprietary Innovation @ 360°

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- New personalised therapies: regenerative stem cells for the blind
- New environment-friendly formulations for our respiratory drugs
- New best-in-class specific delivery systems
- New tools & technologies for physicians and patients



Innovation through partnerships

- The PUMA opportunity: Paediatric Use Marketing Authorization
 - Applies to off-patent products
 - Covers paediatric indication and formulation
 - Application must include documents to support QUALITY, SAFETY and EFFICACY in accordance with an agreed paediatric investigation plan (PIP)
 - 10 year data protection/exclusivity with EU funding

Chiesi is leading two major workpackages of the IMI project:

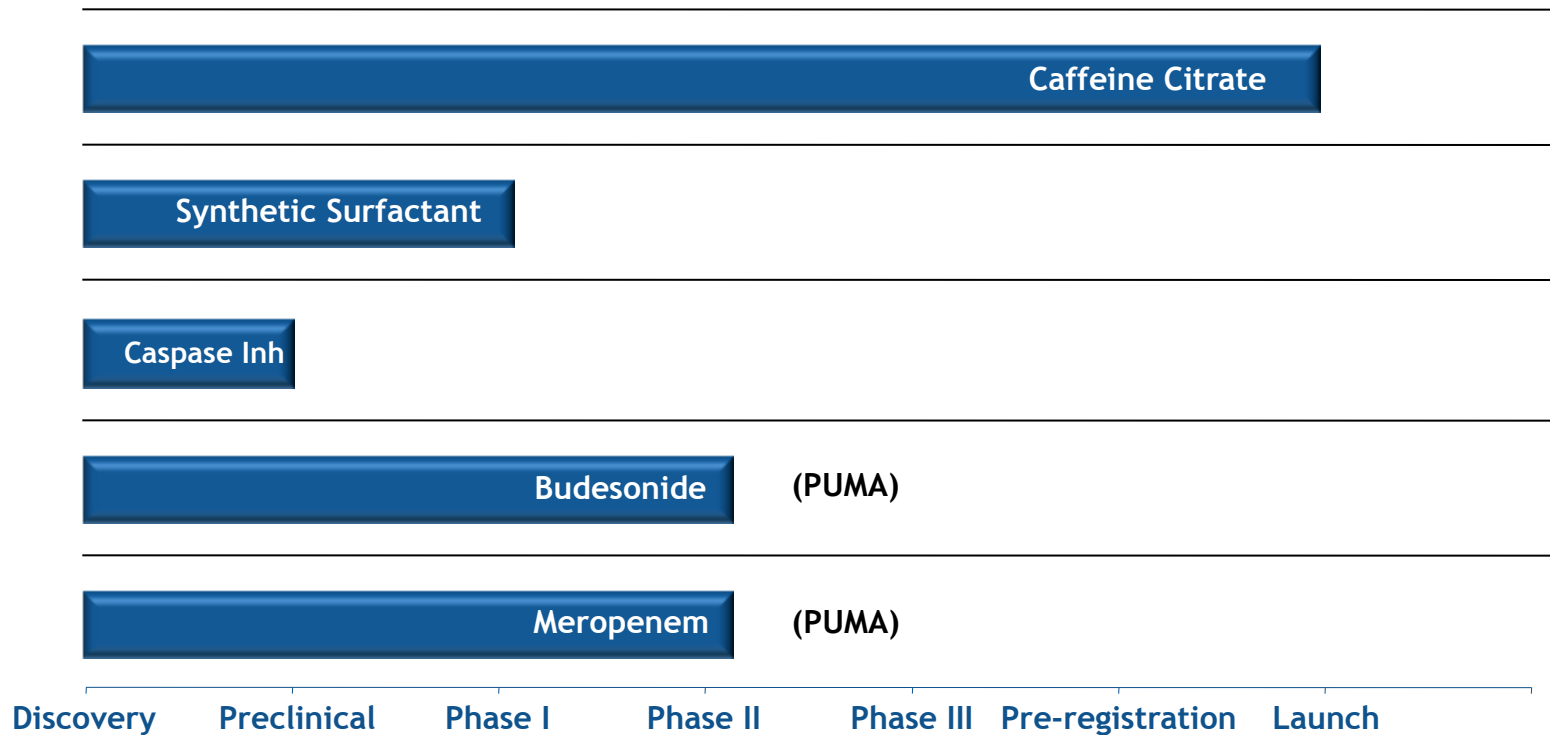
- Severe asthma (U-bioPRED)
- Active-PRO in COPD

Spiromics:

- Partners on board: Boehringer-Ingelheim, Chiesi Farmaceutici, GlaxoSmithKline, Novartis, Nycomed, Talecris Biotherapeutics
- Major Scientific Goals
 - Divide the heterogeneous population of COPD patients into meaningful subpopulations
 - Identify intermediate outcome measures that will allow increased efficiency in clinical trials of COPD



Pipeline: Neonatology



The new R&D Center

In 2012, after the completion of the new Parma R&D Centre, more than 300 researchers are foreseen to work within the compound

Sustainability, automation, flexibility, openness and communication are the keywords of this new, state-of-the-art facility



The Research Center: key figures

Total Investment Cost	> 90 M€
Total Gross Area	60.000 Sqm
Total Building Area	22.000 Sqm
Total Capacity	450 People
Total Construction Hours	600.000 H
Total Involved Contractors	200

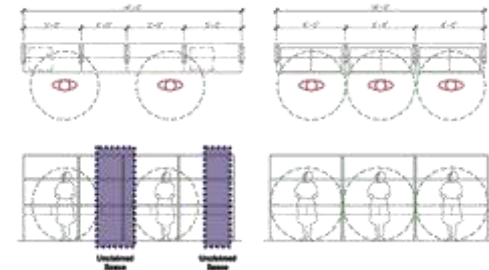
The innovative technologies

Creating flexible utilities supply and casework that encourage research teams to alter their spaces to meet their needs



Creating all the space necessary for research team members to operate properly near each other

Bench Size and Usage



FLEXI LAB
CONCEPT

Establishing clearly defined circulation patterns



Provide interior glazing to allow people to see one another



The innovative technologies

Energy waste reduction and sustainability

- Air warming, ventilation, and conditioning with energy recovery
- VAV (Variable Air Volume) System for the reduction of air conditioning volumes
- Renewable energy sources

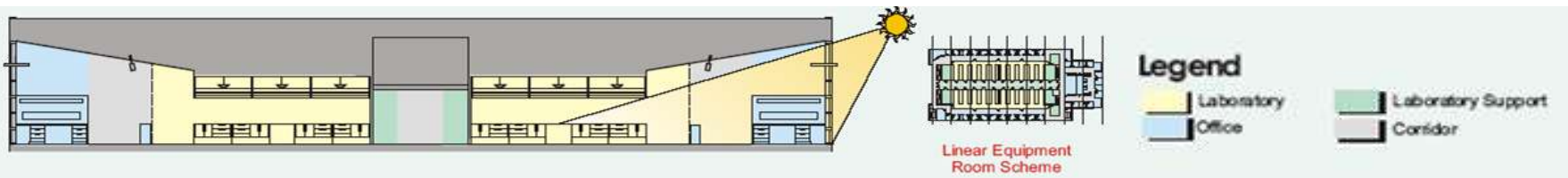


Ergonomics and comfort

- The cooled air gently descends to occupant level, providing a pleasant cooling effect with minimal air movement



Natural light for increased comfort

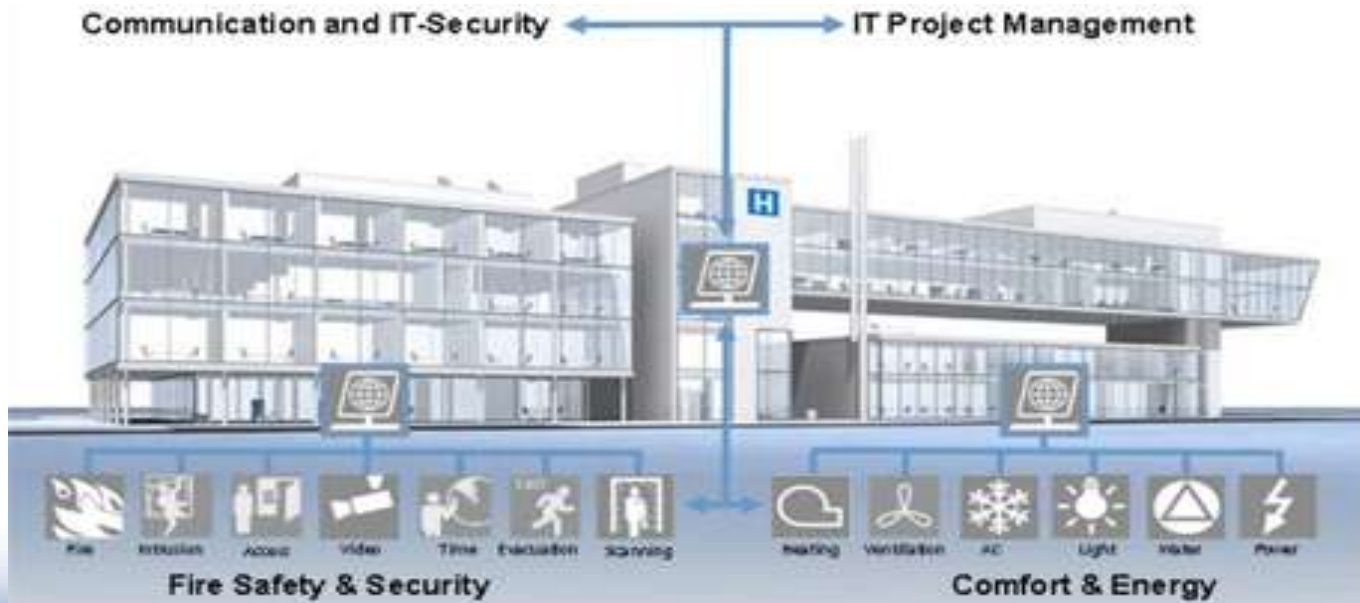


The innovative technologies

Automation - TOTAL BUILDING MANAGEMENT SYSTEM: synergies and cost reduction

Availability of all required
information at a unique
Control Room

Increased comfort and safety,
and sustained energy
optimization



Projects in the context of the organization & strategy

New Product Development (NPD) projects are a key enabler of growth, bringing innovation to the market

Successful delivery of new ideas to the market requires integrated multi-functional activities, achieved via project teams

The **soft infrastructure** - people, processes and problem solving - is **more important** to sustainable innovation than the **hard** - feature, functions, technology: **“Soft is the new Hard”**

Technical uncertainties and risks are inherent in Development: this require

- **Flexibility** and **Personal Openness** to the change
- New perspective: **Problem solving** and **Decision making**
- **Communication skill & Active listening**

Our expectations

- ▶ **New technologies:**
 - Production line for inhalation suspension formulation
 - Improved logistics for better efficiency
 - Workflow and ergonomics optimized to increase efficiency, quality and safety
- ▶ **Increased capacity:**
 - Larger working spaces
 - Increased number of projects
 - Specific suites for different product lines
- ▶ **New way of working:**
 - All R&D people under the same shelter
 - A space designed for interpersonal relations



Ability to sustain the Company growth

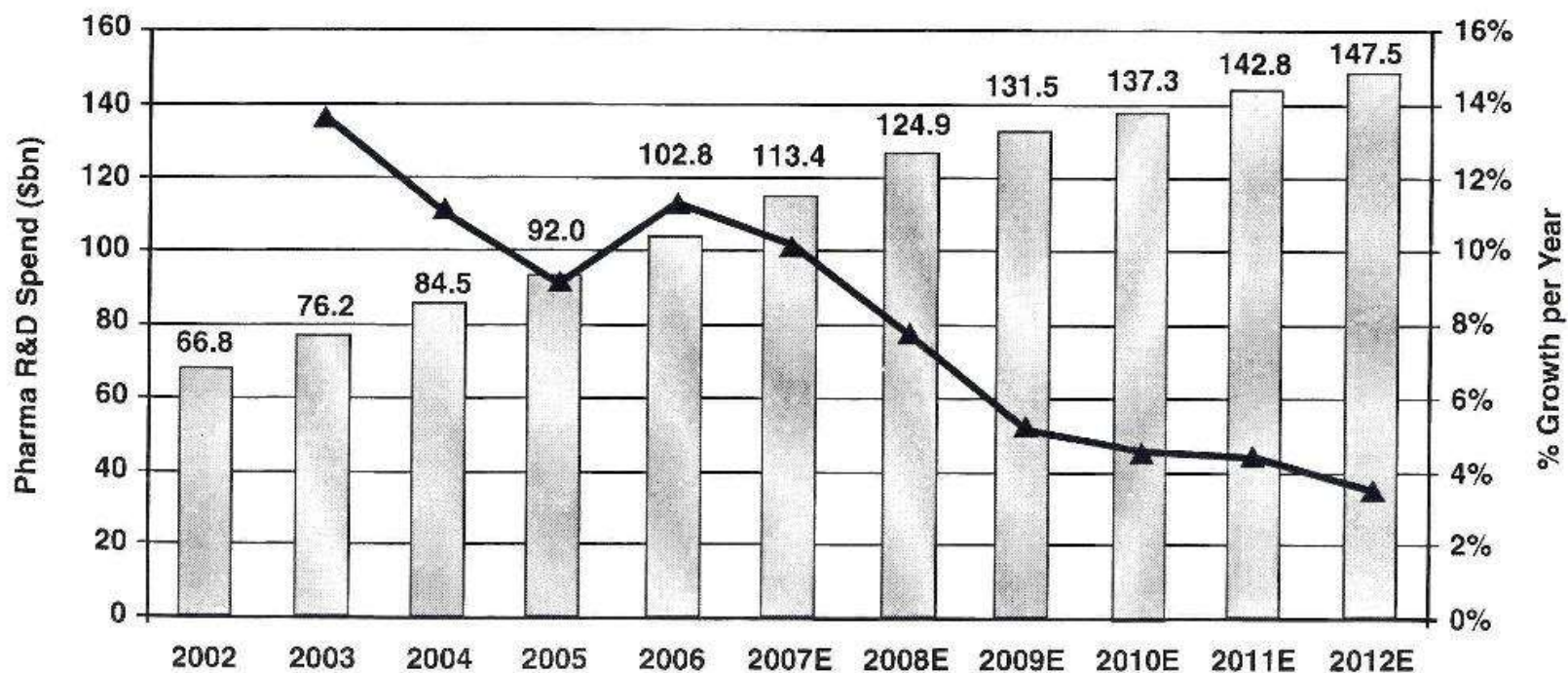


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The strategy

Lo sviluppo di nuovi farmaci ha raggiunto costi elevatissimi

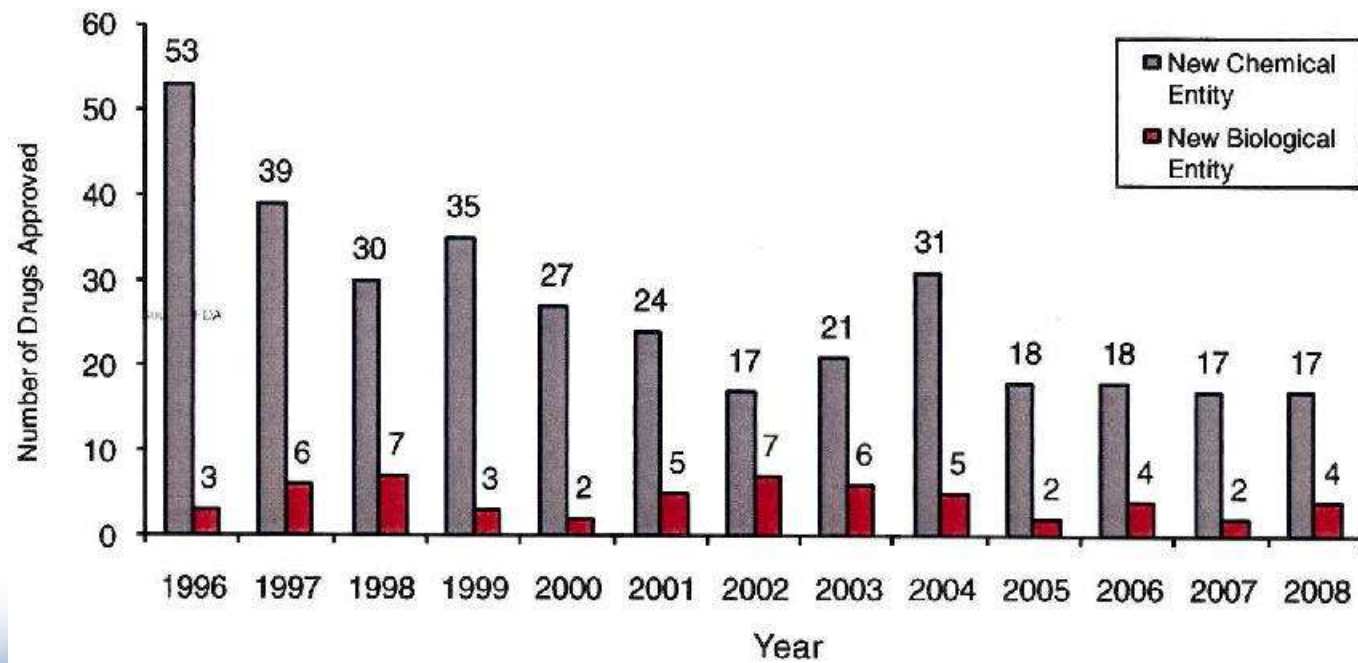
*Global R&D Spending by World's Top 400 Pharma & Biotech Companies
(2002-2012)*



Source: Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2008/2009








A fronte di un forte aumento degli investimenti in R&D, il numero di nuovi prodotti approvati é diminuito

- Aumento delle esigenze “regolatorie” di efficacia e safety
- Incremento della numerosità e della durata degli studi
- Aumento del tasso di fallimento dei progetti nella fase finale di sviluppo

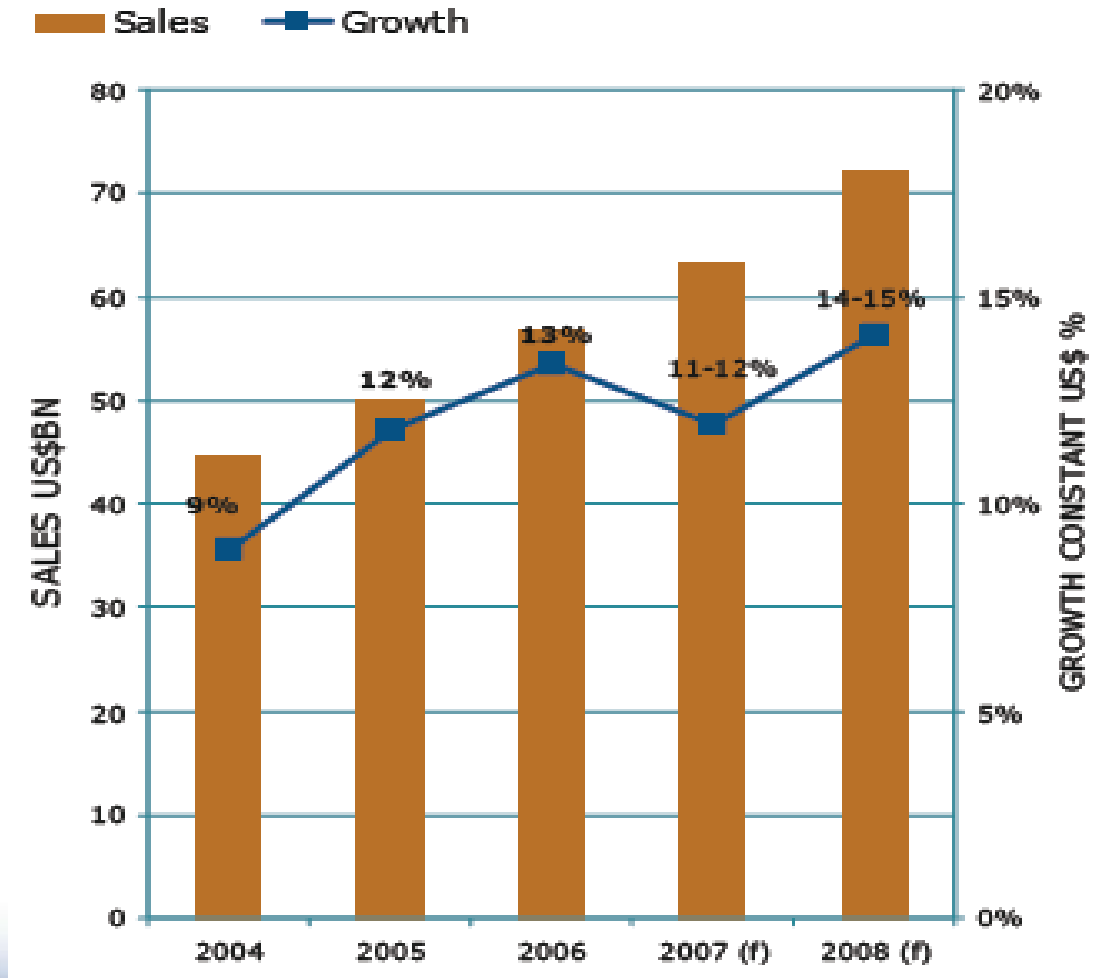


Source: CMR International – Global Annual Strategy Workshop (data from FDA website)

Le misure di contenimento della spesa si susseguono, aumentando il rischio paese

	<i>Past</i>	<i>Current</i>	<i>Future</i> 
	National level negotiations ASMR	De-listing of products with low SMR value Volume controls DRGs to fee-per-procedure	Reference pricing and therapeutic substitution Volume controls
	Physician budgets Reference pricing Negative/positive list	Reference pricing NICE-like institute DRGs	Reference pricing HTAs
	National level price negotiations Regionalisation	Access controls – Nota Regionalisation	Therapeutic referencing pricing International reference pricing
	National level price negotiations Regionalisation	Volume controls (Visado) Regionalisation	Volume controls Generics
	Physician budgets NICE Primary Care Trusts	PPRS price cut NICE evaluations	HTAs Primary Care Trusts
	Price ceiling for reimbursement	Reference Pricing Price Cuts on Imports	Rationalisation (E-Rx) Centralised tendering

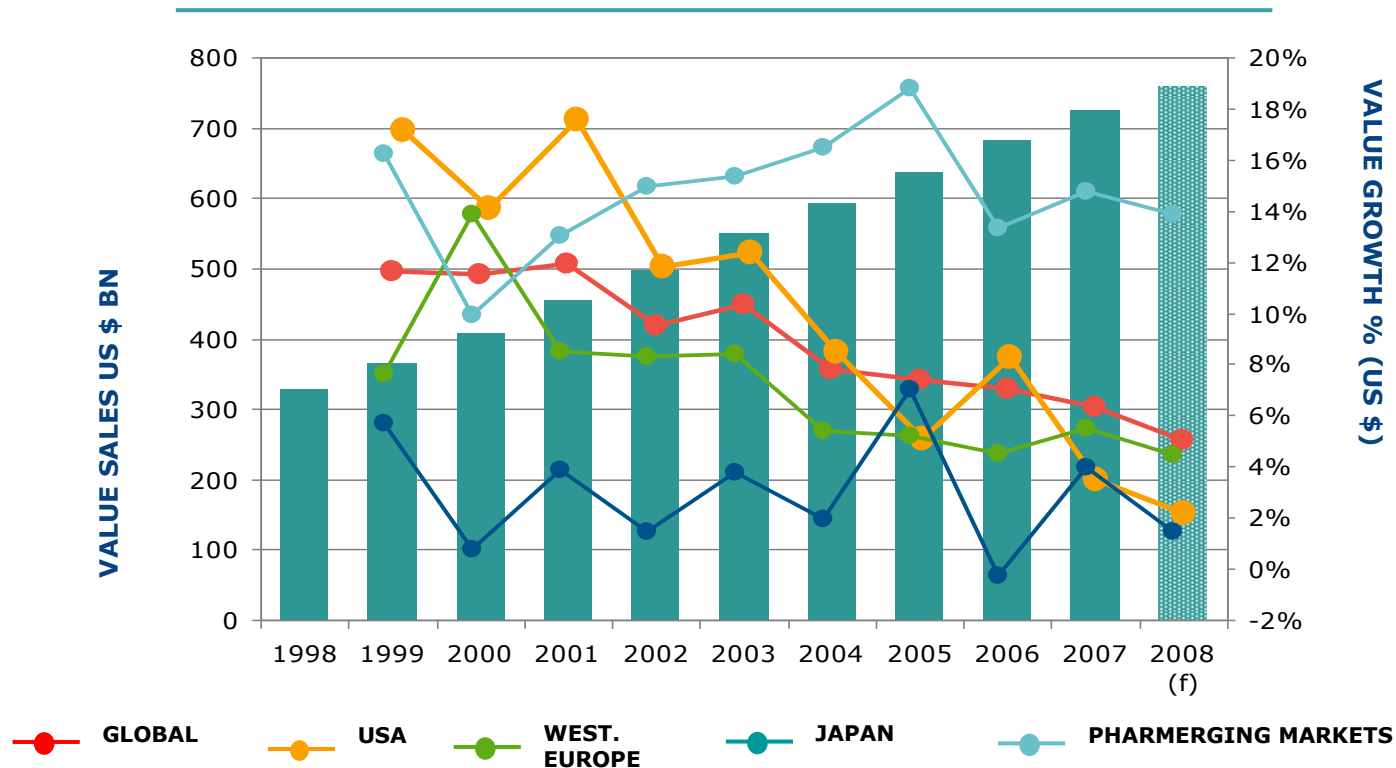
A fronte di un incremento degli investimenti di sviluppo necessari, si riduce la vita protetta e aumenta la competizione dei generici



Source: IMS Health, Generics Market Prognosis, Sep 2007

Competizione crescente in un mondo a due velocità

Global Pharmaceutical Sales and Market Growth



2007

USA, Top 5 EU,
Giappone

+ 4,5 %

VS

Mercati emergenti

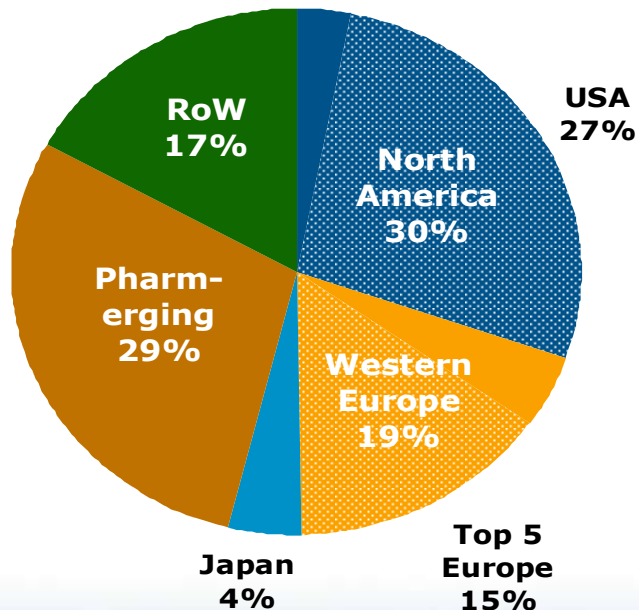
+ 14,5 %

É necessario puntare anche sui “nuovi paesi”

Nei prossimi anni i mercati emergenti contribuiranno alla crescita piú degli USA

Contribution to Global Growth (US\$)

2007-2012



Mature Markets CAGR 2007-2012

USA	3-6%
Japan	1-4%
France	3-6%
Germany	3-6%
Italy	2-5%
UK	2-5%
Spain	5-8%
Canada	5-8%

Pharmerging Markets CAGR 2007-12

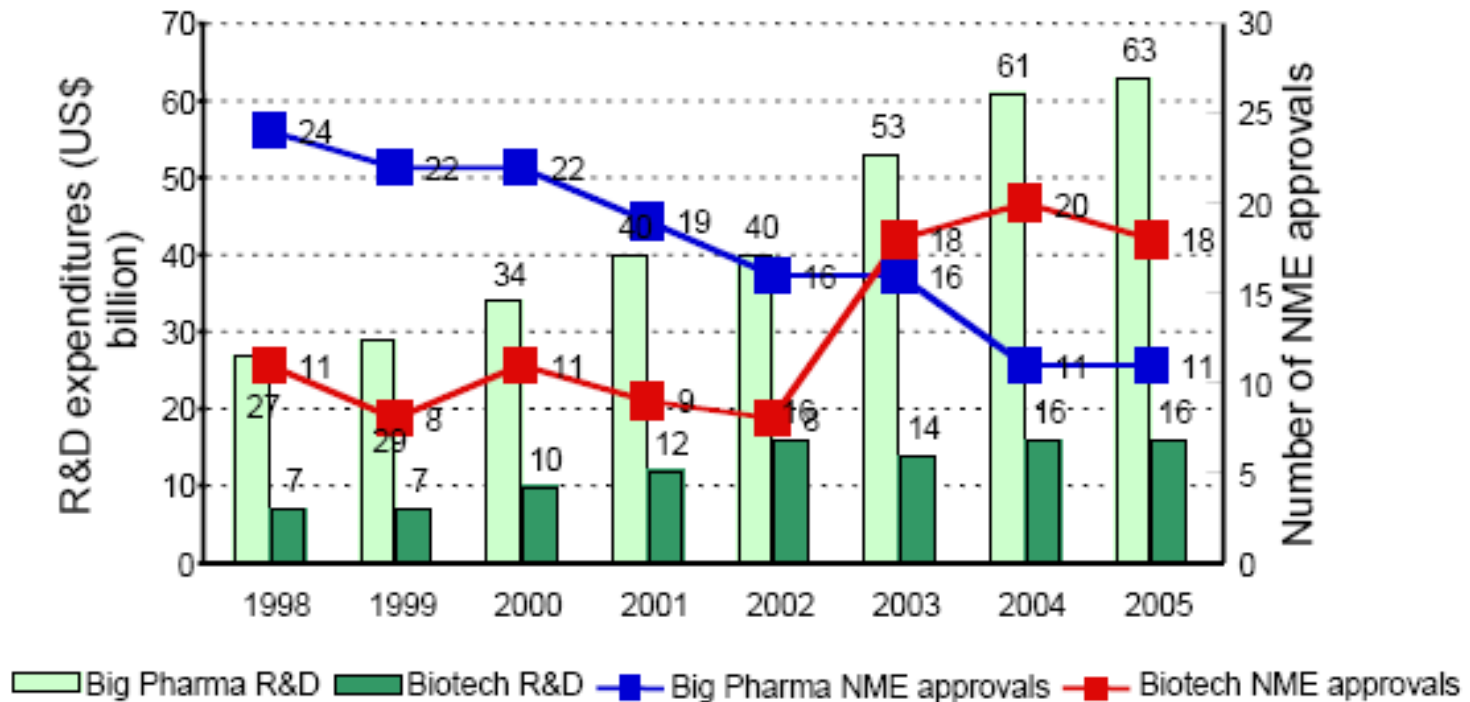
China	18-21%
Brazil	8-11%
Turkey	13-16%
Russia	16-19%
India	11-14%
Korea	8-11%
Mexico	6-9%

Crescere é necessario per...

- Assicurare la massa critica necessaria per sostenere gli investimenti di R&D
- Ridurre il rischio paese
- Massimizzare e velocizzare il ritorno commerciale dei prodotti
 - Presenza geografica allargata all'Europa
 - Massa critica per paese

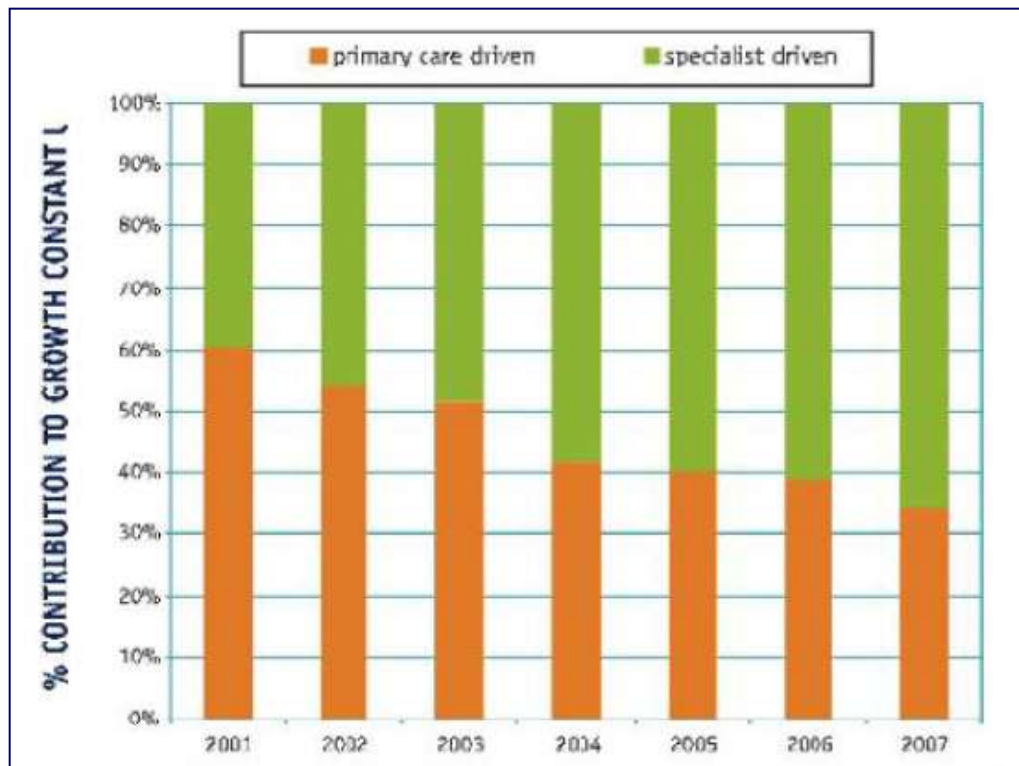
Cambia il modello di successo nella ricerca e sviluppo

Big Pharma & Biotech Productivity



From: Nature Biotechnology 2007.

Terapie piú specifiche e sempre piú in mano allo specialista



2007
% Share of Sales

Specialist Driven

60%

Primary Care Driven

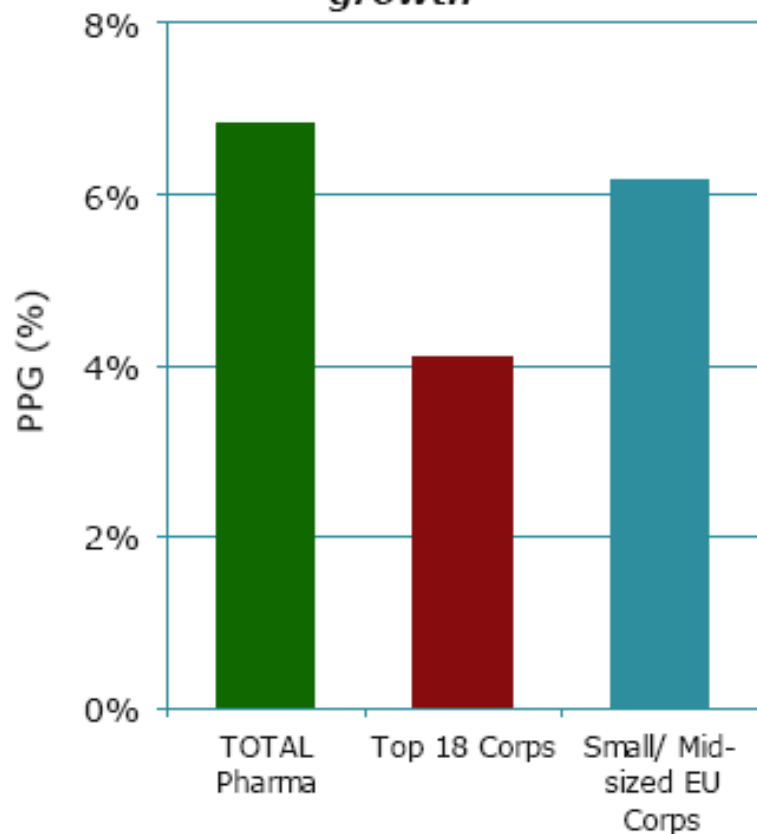
40%

Source: IMS Health, MIDAS, MAT Dec

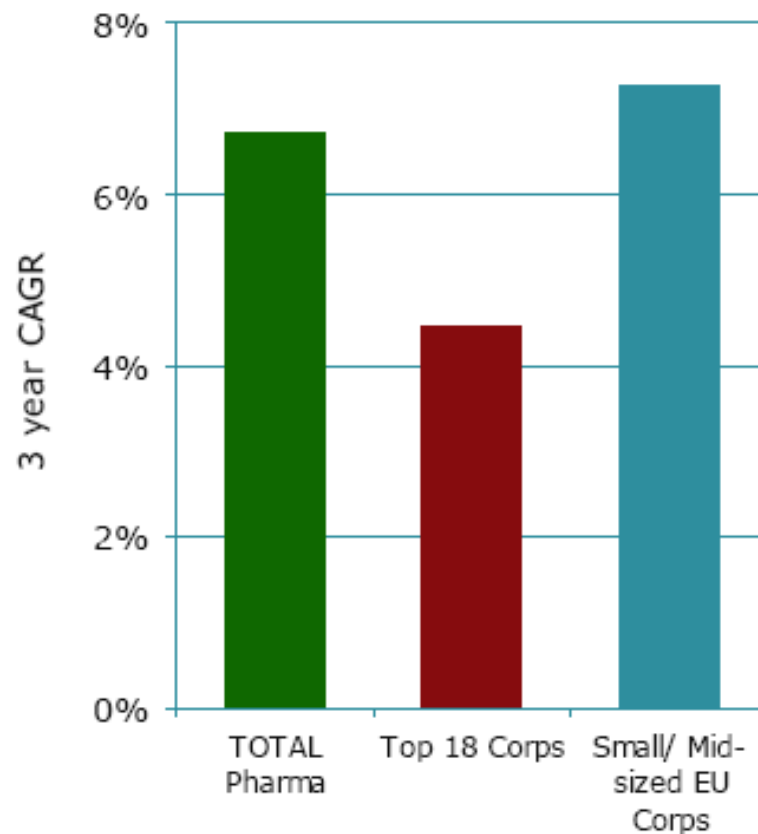
2007

Le medie aziende, piú specializzate, sono piú efficaci

Short term growth: Previous period growth



Long term growth: 3 year CAGR



Source: IMS Health MIDAS MAT June 2007