



# **SANDOZ**

## **CEO panel: which way forward for the generics medicines industry?**

**Dr. Andreas Rummelt, CEO Sandoz**

13th EGA Annual Conference

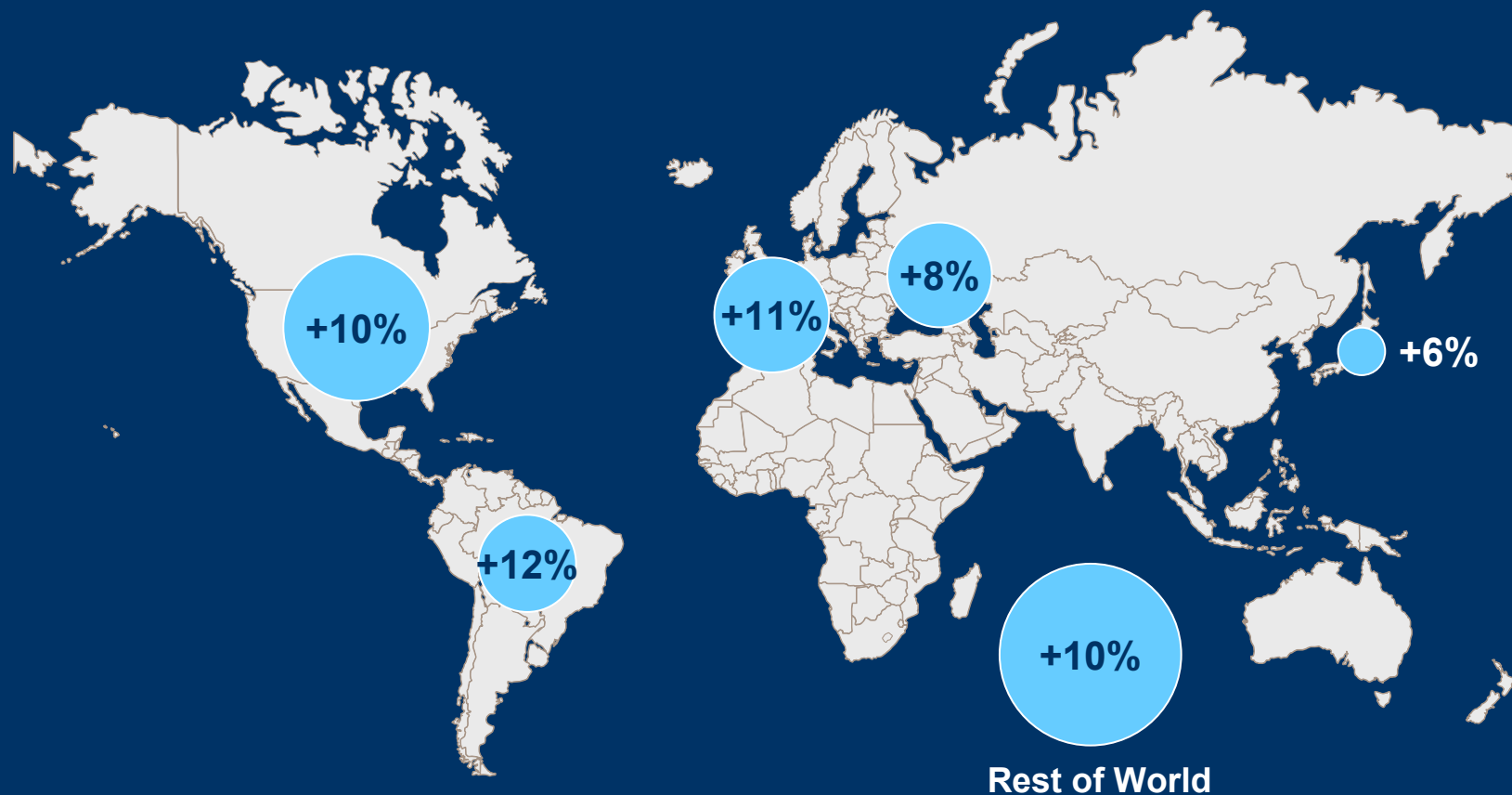
Istanbul, June 15, 2007

**a Novartis company**

# Generics market of USD 77 bn with expected annual net growth of 10%

Net market growth<sup>1</sup> by region, 2006-2011

● Regional market size



<sup>1</sup> CAGR – Compound Annual Growth Rate

<sup>2</sup> 13th EGA Annual Conference / Andreas Rummelt / June 15, 2007

# Generics market still dynamic

## Consolidation

- >25 major M&A transactions
- Merck KGaA acquired by Mylan
- CVS-Caremark merger

## Regulatory pathways

- Established biosimilar pathway in EU, slowly emerging in US
- Omnitrope approval

## Increasing penetration

- Growing acceptance
- Cost containment

## Legislation

- AVWG<sup>1</sup> & WSG<sup>2</sup> (Germany), Dutreil law (France)
- Price cuts in Italy & Spain

<sup>1</sup> Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz; <sup>2</sup> Wettbewerbsstärkungsgesetz

# Looking into the future: opportunities & challenges ahead

## Challenges

- **Pressure on prices** from governments/payors, key customers, and Asian players
- Several markets shifting to **INN**
- **Defense strategies** by originators
- Regulation on **biosimilars in the US** not expected soon
- **Wholesalers/chains** moving into generics production or partnerships, increased leverage of **private label**

## Opportunities

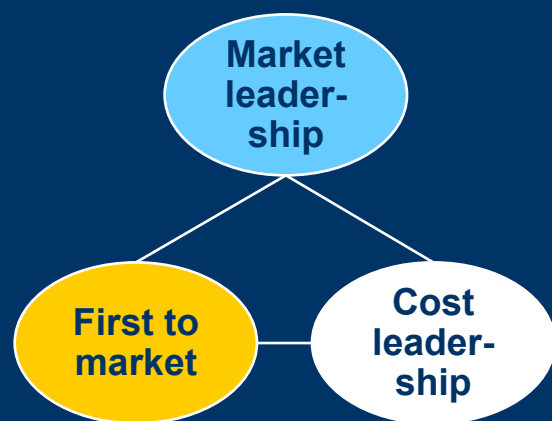
- **Stable flow of patent expiries** with increasing share of **biopharmaceuticals**
- Increasing **generics penetration**
- Strong **GDP growth** in emerging markets
- Government **cost containment** efforts favoring generics
- **Special technologies** offering upside potential

# Strategic imperatives in generics will lead to accelerated consolidation

## Strategic success factors



# Sandoz strategy = market & cost leadership and first to market



- 1 Leadership in key markets
- 2 Investment in growth and acquisitions
- 3 Difficult-to-make generics & biosimilars
- 4 Competence centers in development
- 5 Leverage of scale in production
- 6 In-house API development & production

# Difficult-to-make generics: opportunity for differentiation and higher margins

**Bio-similars**



**Omnitrope®**: first bio-similar in EU and US

**Patches**



**Fentanyl**: leading position in US and Germany

**Differentiation from competition and higher margins**

**Inhalation**



**Budesonid**: strong position in Germany

**Oral solids**

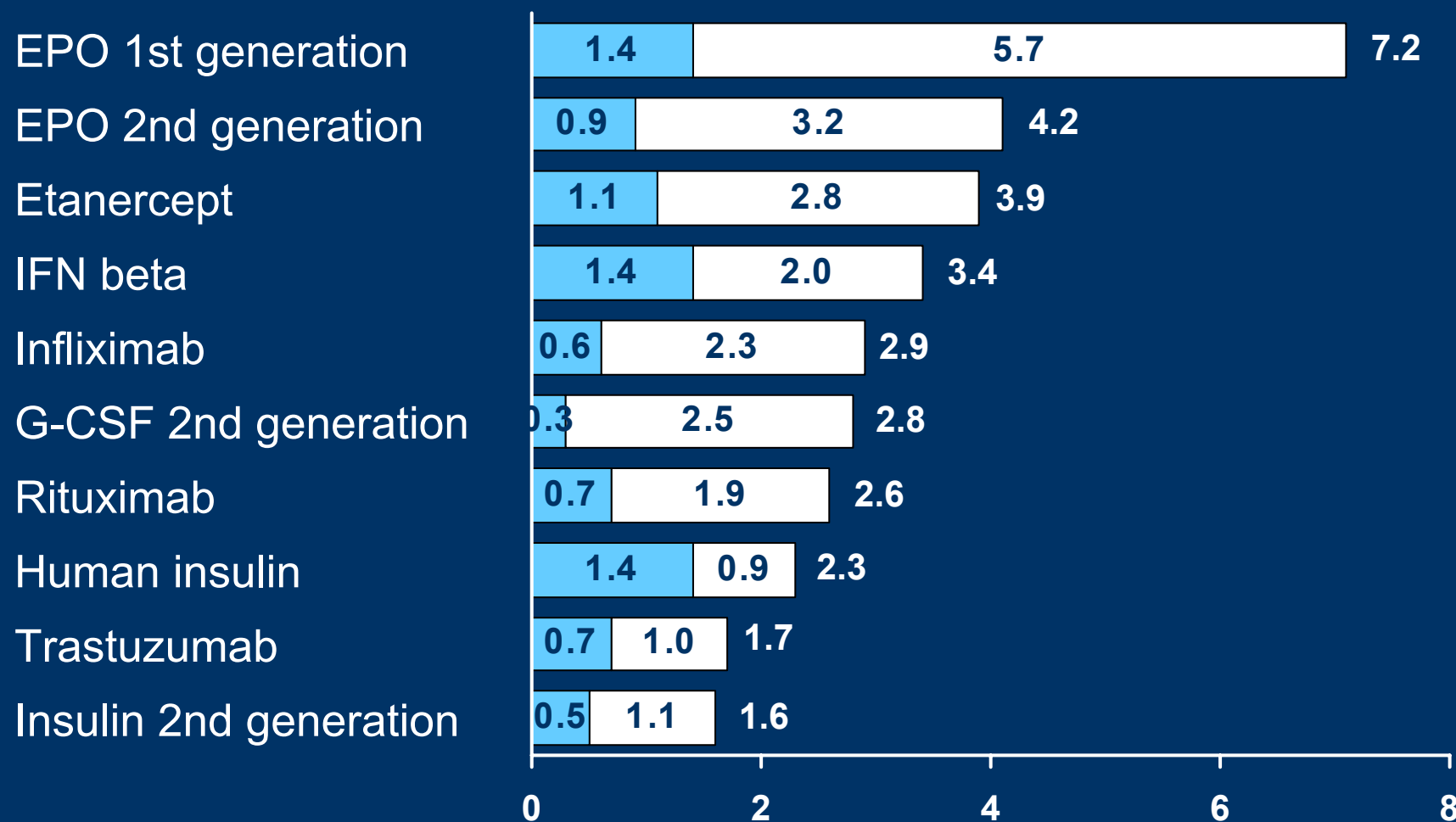


**Metoprolol succinate**: sustained release

# Biopharmaceuticals with significant market potential

Top 10 biopharmaceutical products, in USD bn (2006)

■ EU  
■ US



Source: IMS PADSS (MAT Q2 2006)

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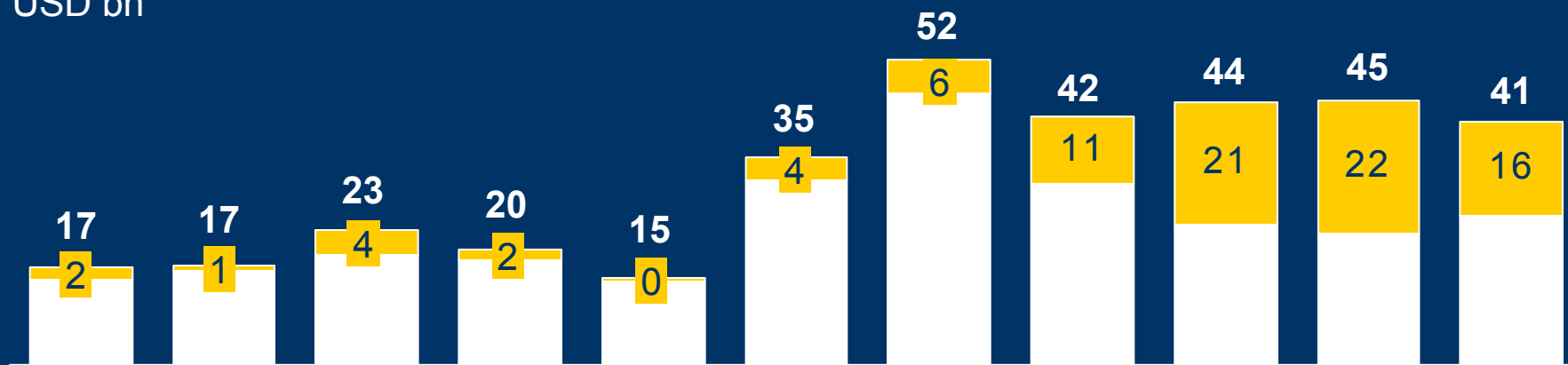
# Value of products going off patent expected to increase from 2010

US patent expiries<sup>1</sup> 2005-15

■ Biotech products  
■ Conventional products

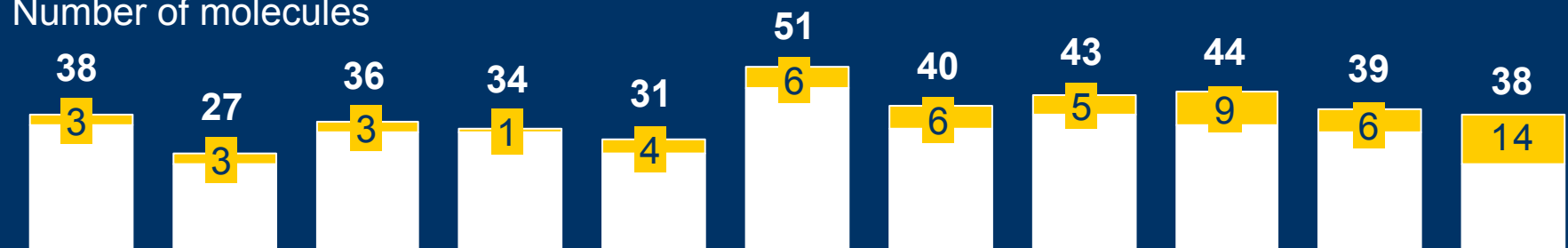
Worldwide sales of expiring products in year of US patent expiry

USD bn



Molecules coming off-patent<sup>2</sup>

Number of molecules



2005

2010

2015

<sup>1</sup> Nominal patent expiries not corrected for supplementary patents, litigation probability

<sup>2</sup> Only molecules with associated sales were counted, a combination of two molecules is considered to be a separate molecule

Source: Internal estimates

# Biosimilars require a different approach than small molecule generics

## Development

### Success factors

- Regulatory/patent know-how
- Protein analytics
- Quality-by-design
- Manage (pre)clinical trials and PMS<sup>1</sup>

## Production

- In-house production (low COGS)
- State-of-the-art technologies and devices

## New business model

- Access to key opinion leaders
- Patient flow dynamics
- Product positioning
- Excellent sales force (scientific arguments)

### Prerequisites

- Resources for clinical studies and production capacity
- Relatively high investments associated with risk with late return
- Mindset and business model different than for small molecules

<sup>1</sup> Post-marketing surveillance  
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# Conclusions

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- Difficult-to-make generics/biosimilars offer opportunities for differentiation and higher margins.
- Biosimilars are a must for market leaders, but generics companies need to establish a different business model to be successful.
- Sandoz is well positioned: regional/local market leadership, first to market, cost leadership.
- The generics industry remains attractive offering significant growth opportunities.