

# **Roche: adapting to the changing environment**

### Severin Schwan, CEO Roche Group Tokyo, 8 October 2010





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- 2 legislative and regulatory developments and economic conditions;
- 3 delay or inability in obtaining regulatory approvals or bringing products to market;
- 4 fluctuations in currency exchange rates and general financial market conditions;
- 5 uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
- 6 increased government pricing pressures;
- 7 interruptions in production;
- 8 loss of or inability to obtain adequate protection for intellectual property rights;
- 9 litigation;
- 10 loss of key executives or other employees; and
- 11 adverse publicity and news coverage.

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### A position of strength

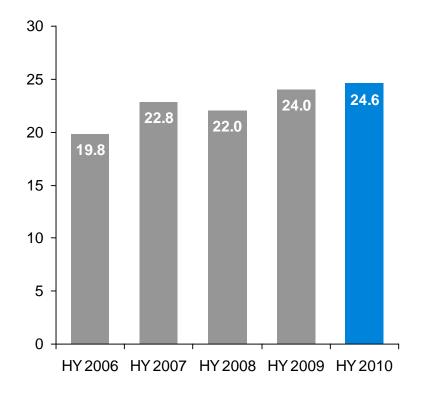
### **Operational Excellence – adapting to a changing environment**

**Continued focus on innovation** 

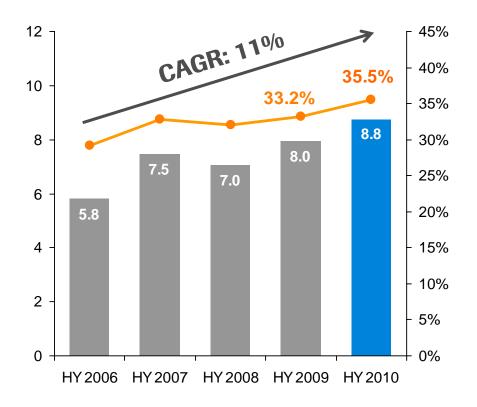
### **Continuous growth in sales and margin**



Group sales (CHF bn)

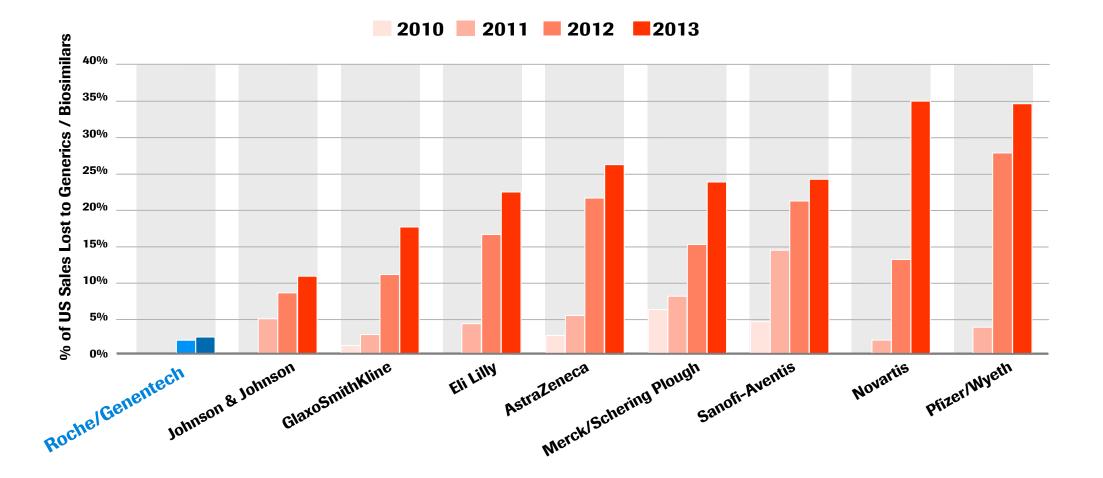


#### **Operating profit<sup>1</sup> (CHF bn) and margin**



### Limited exposure to patent expiries

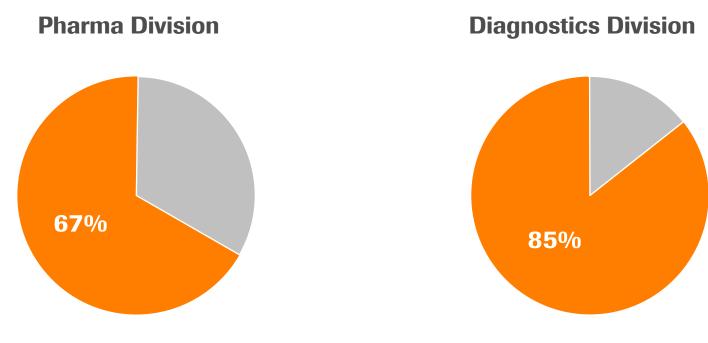




% Sales Lost calculated by subtracting given year sales ('10, '11, '12, '13) from full year sales from year prior to LOE. Data excludes sales lost impact of products with LOE prior to 2010. Source: Evaluate Pharma



### **Biotech products drive growth in both divisions**



**Biotech products as % of sales** 

# Long patent protection Biosimilars facing high hurdles

# Long primary patent protection of our key biologics

US	EU ROW/EM
2019	similar
2019	marketed by Novartis
2018	earlier
2019	earlier
2018	similar
	2019 2019 2018 2018 2019



#### **Biosimilars outlook**

**US:** recent healthcare legislation opens pathway for biosimilars

FDA in the process of developing guidelines

Data exclusivity for biologics 12 years

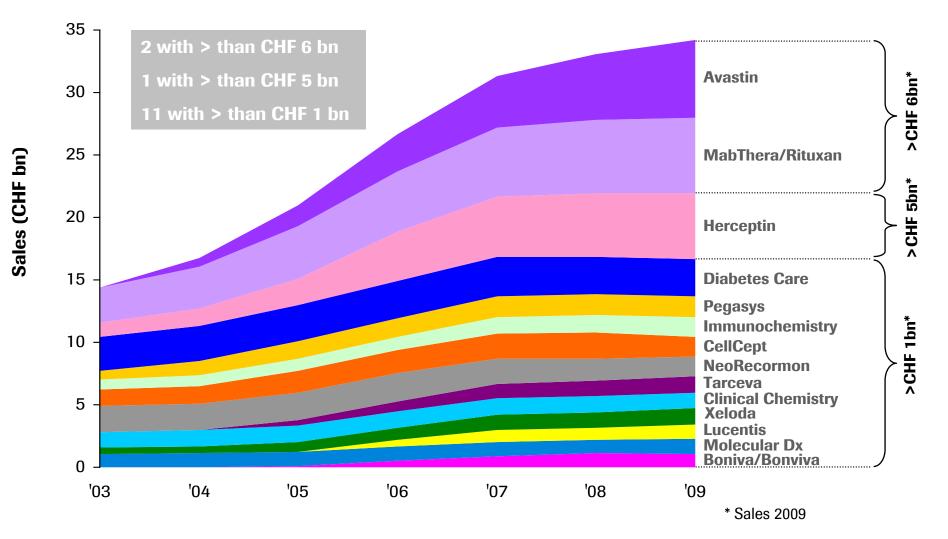
**EU:** legal and regulatory hurdles likely to remain high for biosimilars

**ROW/EM:** investment in countries with strong IP regulations (China)

Brand awareness important



# Key Pharmaceuticals & Diagnostics products A risk-diversified portfolio of drugs and BUs



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# **Avastin: Portfolio within a portfolio Key treatment option in multiple tumor types**

 Superior PFS front line Ovarian 20%-25% Superior PFS in multiple 1<sup>st</sup> **Metastatic** line trials **Breast** - Superior PFS in 2<sup>nd</sup> line Superior PFS in 1<sup>st</sup> line Renal Unsurpassed Recurrent **PFS and OS** 75%-80% Glioblastoma **Advanced**  Superior OS 1<sup>st</sup> line **Non-Small Cell** - Superior PFS 1st and 2nd line Lung Cancer Superior OS 1<sup>st</sup> and 2<sup>nd</sup> line **Metastatic**  Superior PFS 1<sup>st</sup> and 2<sup>nd</sup> line **Colorectal** 

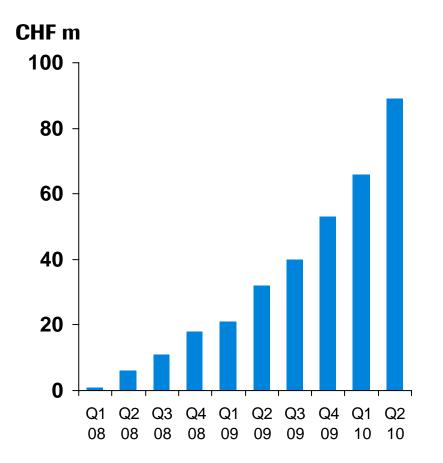
**2009 Sales** 

# Actemra/RoActemra *Building new pillar*

- Launched in ~50 countries so far
- Uptake in Japan remains strong
- In US after only 5 months, Actemra already prescribed by more than 50% of rheumatologists
- US patient share constantly increasing (currently 3-6% following anti-TNFs)

Actemra vs Humira H2H trial Enrolling patients

#### Actemra/RoActemra quarterly sales

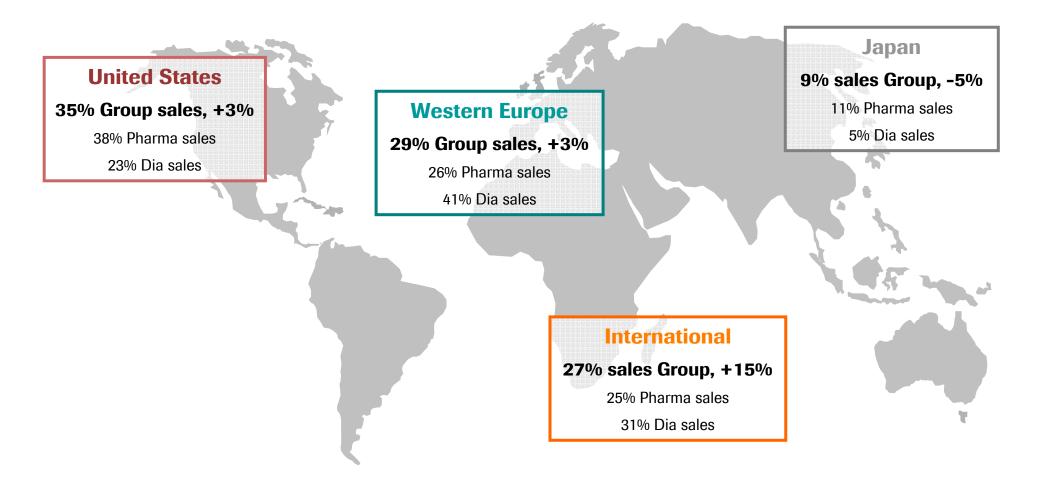




Roche



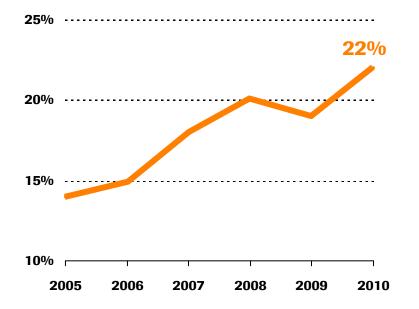
# Roche in Emerging Markets Gaining in significance

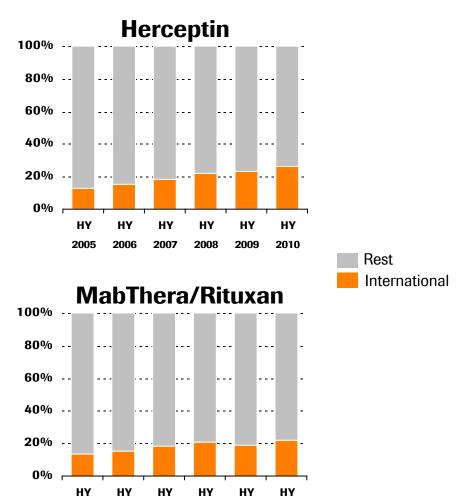




# Roche in Emerging Markets Oncology leading the trend

#### International region as % of Oncology sales







# Roche Acting from a position of strength

- Protection of current portfolio:
  - long patent protection
  - hurdles for biosimilars
- Diversified portfolio; 14 franchises with>CHF 1 bn sales
- Significant opportunities for Avastin based on approved indications
- Growth in emerging markets



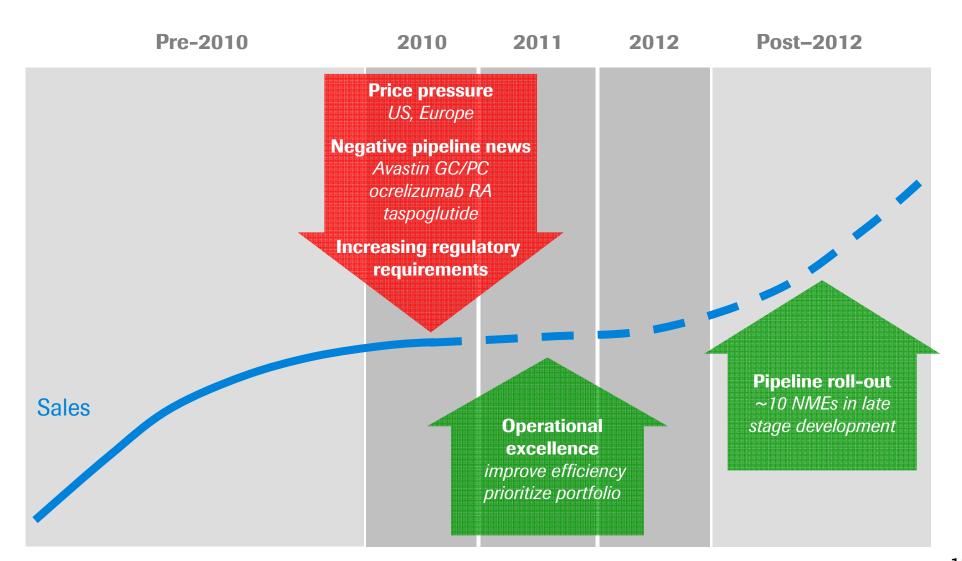
### A position of strength

### **Operational Excellence – adapting to a changing environment**

**Continued focus on innovation** 

### **Roche's response to new environment**





Illustrative



# Roche's response to new environment *Operational excellence initiative*

### **Objectives**

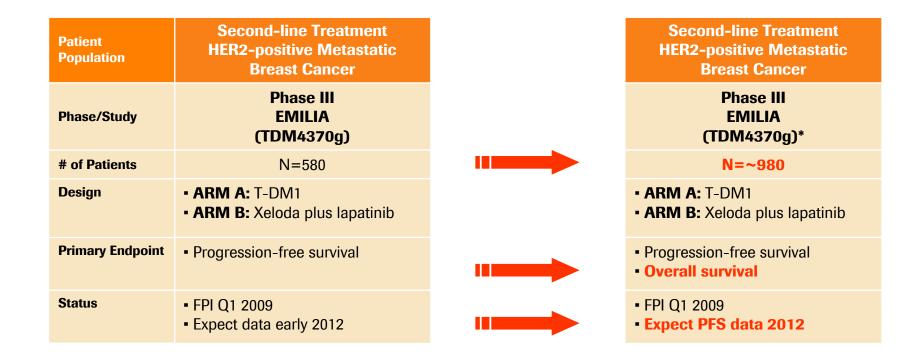
- protect our profitability and safeguard financial flexibility
- adapt cost structure while sustaining innovation leadership
- focus our resources towards investments that will drive innovation

### **Scope and timeline**

- Group-wide
- measures decided before end of the year
- implementation in 2011 and 2012



# Roche's response to new environment Adapting to evolving regulatory environment (T-DM1 trial)



Trial recruiting well. Filing for accelerated approval expected in mid-2012, with mature PFS data. OS data to be provided within 3 years thereafter.



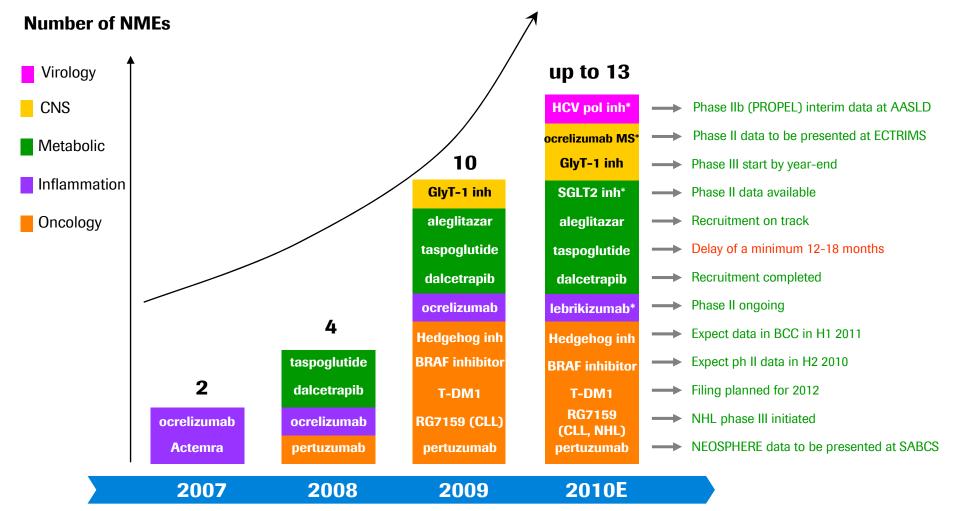
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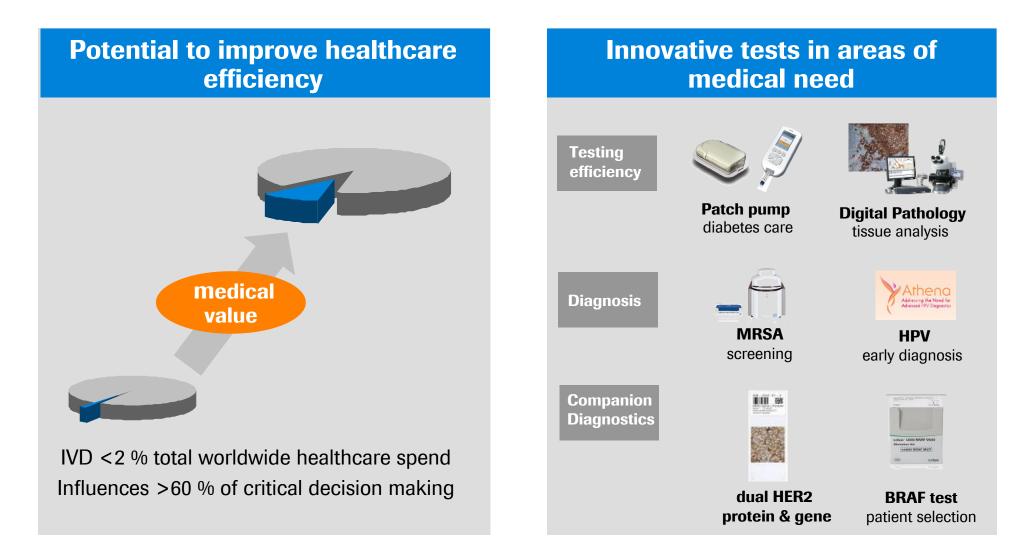
### Late-stage pipeline continues to build up *Expanding into new therapeutic areas*



\* LIP or phase III decision pending

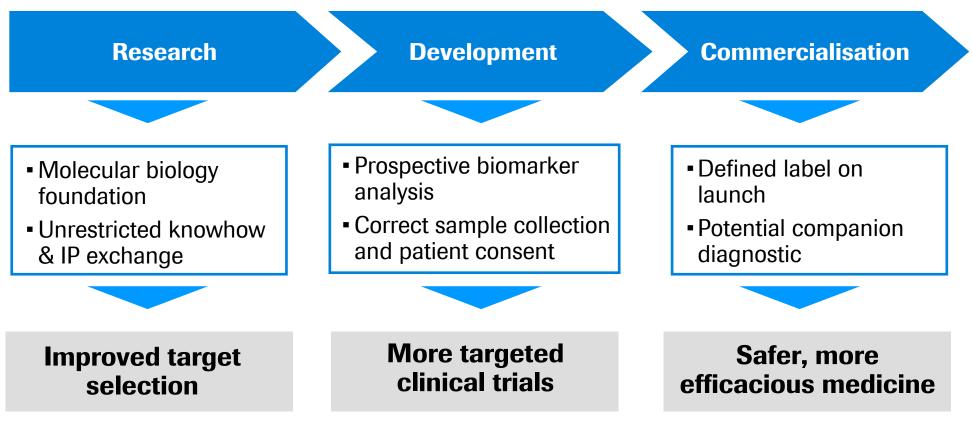


# Diagnostics *Continued high growth driven by need for medical value*





# Personalised Healthcare to deliver medical value Leveraging Pharma & Diagnostics from discovery to commercialisation





# We Innovate Healthcare