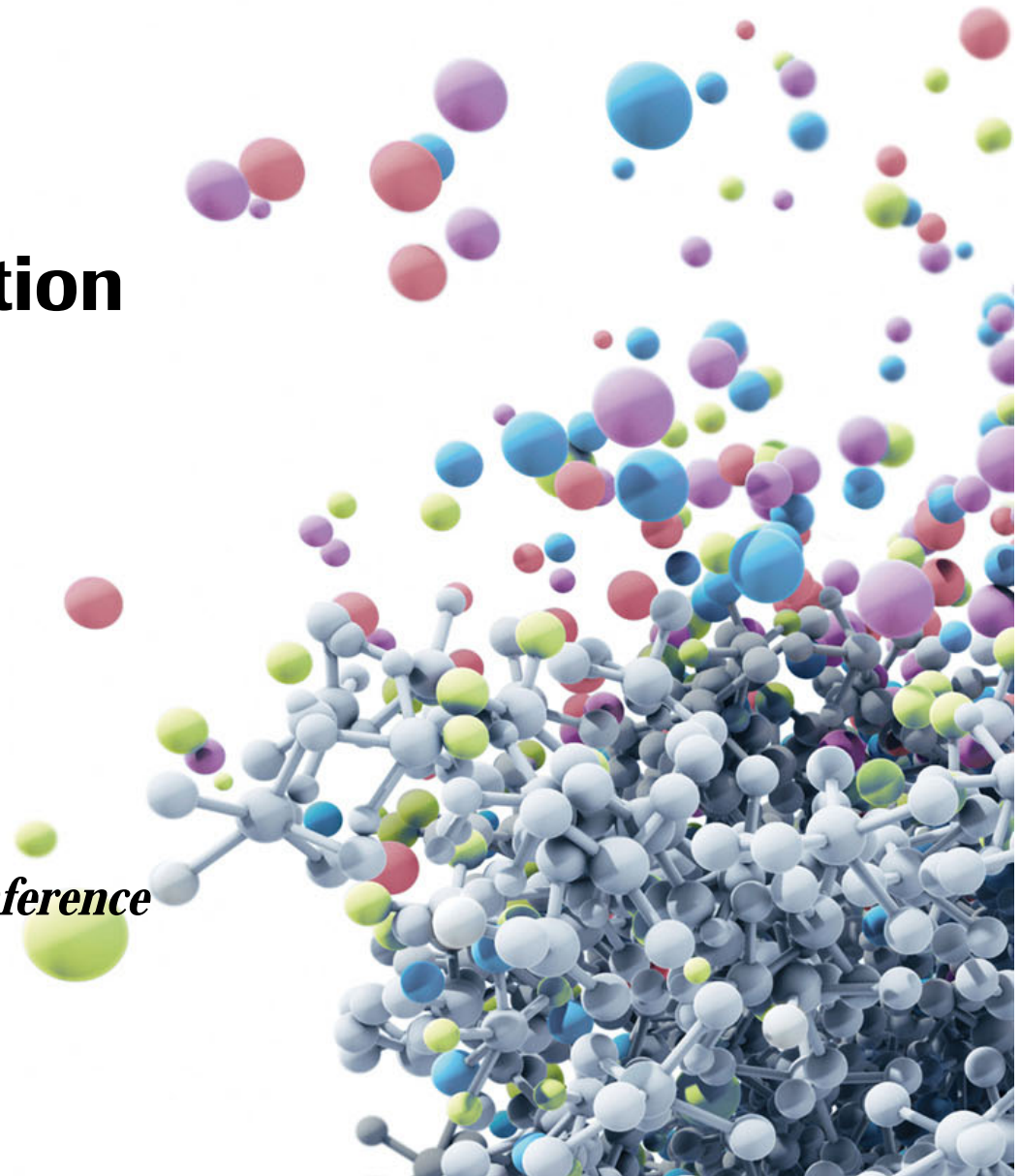




# Committed to innovation and growth

*Roland Diggelmann,  
COO Roche Diagnostics*

*Goldman Sachs  
Medtech & Healthcare Services Conference  
September 4, 2013*





# **HY 2013 Group Results**

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## **Diagnostics**

**Overview & Strategy**

**HY 2013**

**Companion Diagnostics**

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## **Outlook**

# HY 2013: Roche Group highlights

## *HY 2013 performance*

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- Strong Pharma performance, driven by US; solid growth for Diagnostics
- 12% core EPS growth<sup>1</sup>, driven largely by strong underlying business
- Solid operating free cash flow (+4%<sup>1</sup>)

## *Innovation*

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- Move into phase III: Bcl2 inhibitor and anti-PDL1
- Data read-outs for potential phase III decisions: etrolizumab and anti-factor D
- Positive CHMP recommendation for Herceptin SC
- Discontinued: aleglitazar and GA201

<sup>1</sup> CER=Constant Exchange Rates

# HY 2013: Strong sales momentum continues



	<b>HY 2013 CHF bn</b>	<b>HY 2012 CHF bn</b>	<b>Change in % CHF</b>	<b>Change in % CER</b>
<b>Pharmaceuticals Division</b>	<b>18.2</b>	17.4	<b>4</b>	<b>6</b>
<b>Diagnostics Division</b>	<b>5.1</b>	5.0	<b>2</b>	<b>3</b>
<b>Roche Group</b>	<b>23.3</b>	22.4	<b>4</b>	<b>5</b>



# **HY 2013 Group Results**

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## **Diagnostics**

**Overview & Strategy**

**HY 2013**

**Companion Diagnostics**

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## **Outlook**

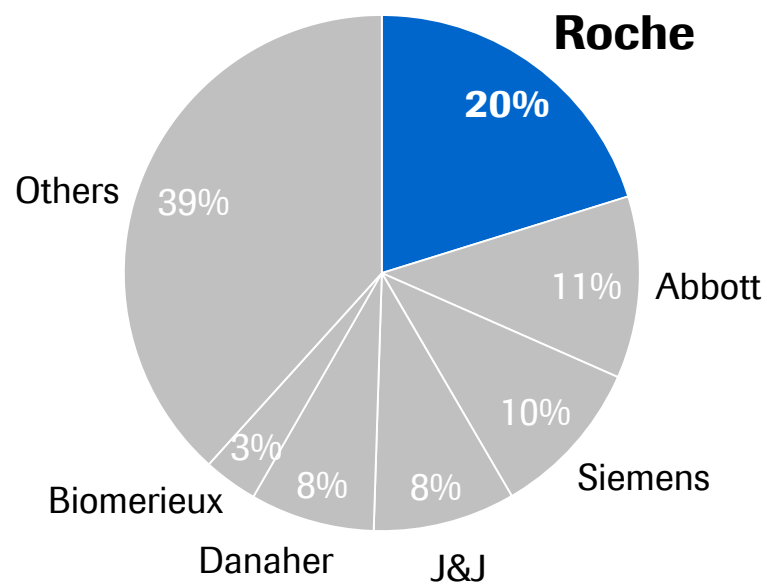


# In-Vitro Diagnostics market overview

## *Large and growing market; Roche is market leader*

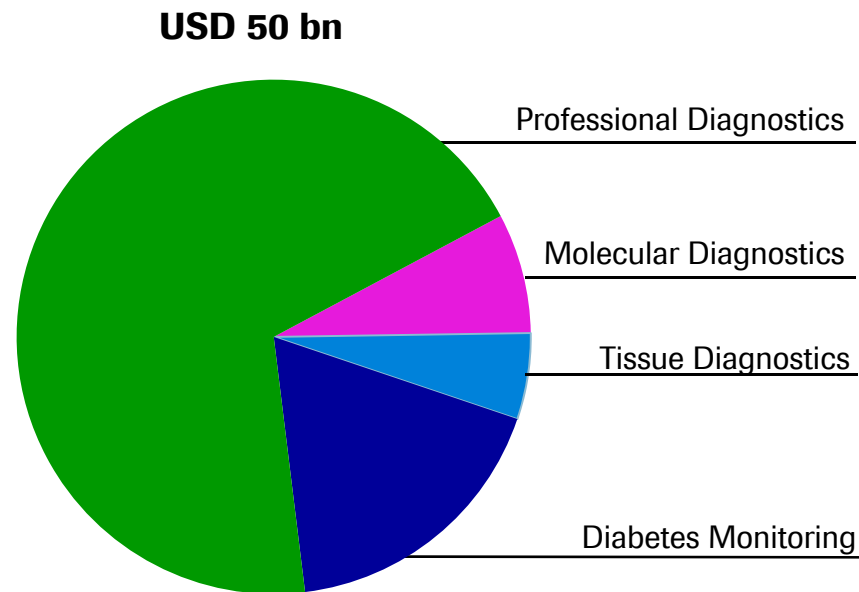
### Market share

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### Market size

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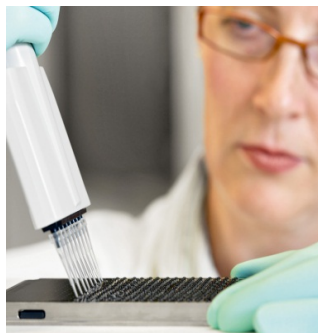


# Overview of Roche Diagnostics

## *New reporting structure*

### In Vitro Diagnostics & Life Sciences

**Professional  
Diagnostics  
(RPD)**



**Molecular  
Diagnostics  
(RMD)**



**Tissue  
Diagnostics  
(RTD)**

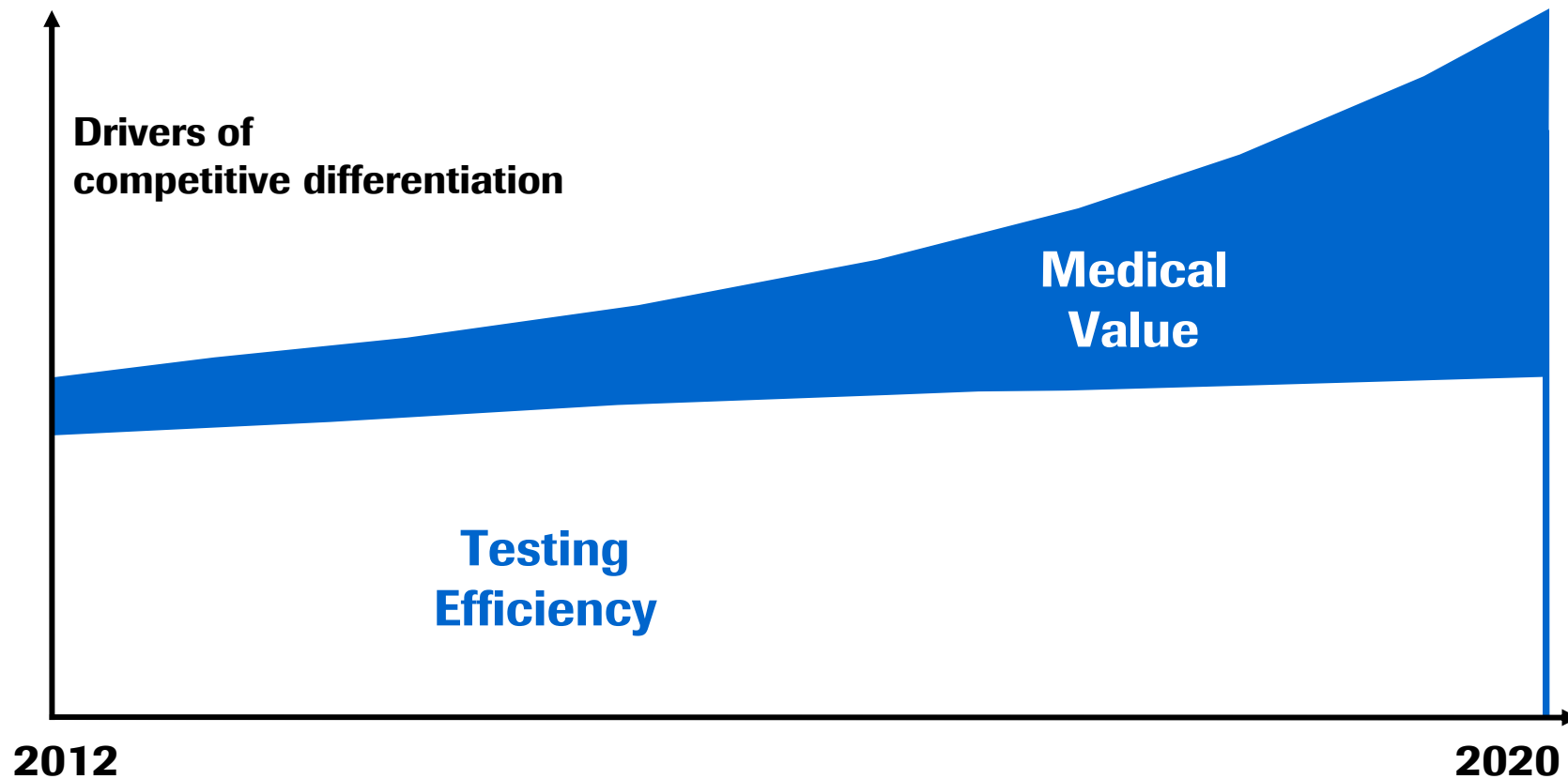


**Diabetes Care  
(RDC)**



# Roche Diagnostics' strategy

*Differentiation through innovation in testing efficiency and medical value*





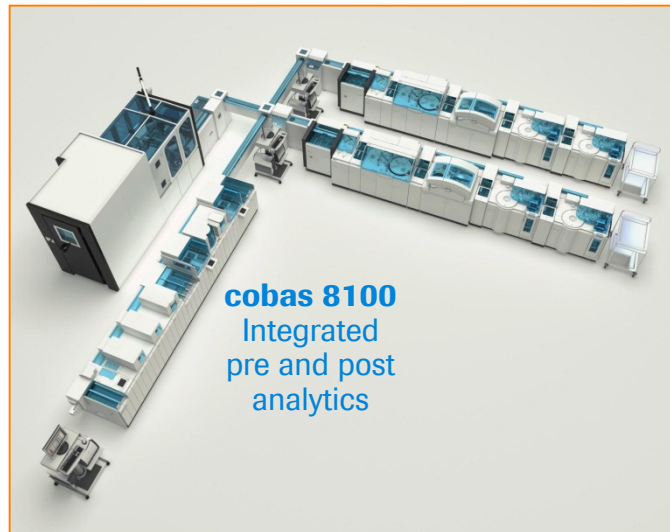
# RPD: Differentiated strategy driving strong growth

## *Delivering patient and customer benefits*



### Increase testing efficiency

- **cobas 8100 preview at Euromedlab<sup>1</sup>**
  - Provides total lab automation



### Provide medical value

#### Q2 launches

- **proGRP test for SCLC<sup>2</sup>**
  - aids in early differential diagnosis for SCLC
  - expands tumor marker offering<sup>3</sup>
- **Cyclosporine and Tacrolimus tests for transplant patients**
  - monitoring and optimal dosing for efficacy vs side effects
  - personalised patient treatment

<sup>1</sup>Expected launch in autumn 2013;

<sup>2</sup> Small cell lung cancer;

<sup>3</sup> >CHF 500m revenues with 14% growth in HY13

# RMD: cobas 6800/8800/4800

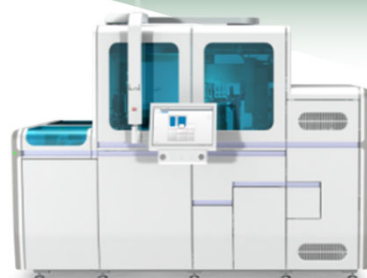
## *Setting new standards for molecular testing*

	Blood Screening	Virology	HPV & CT/NG	Microbiology	Genomics & Oncology
<b>RMD Assays</b>	<ul style="list-style-type: none"> <li>▪ Multiplex HIV, HCV, HBV</li> <li>▪ West Nile Virus</li> <li>▪ B19 and HAV</li> </ul>	<ul style="list-style-type: none"> <li>▪ HIV</li> <li>▪ Hepatitis B, C</li> <li>▪ HSV</li> <li>▪ CMV</li> </ul>	<ul style="list-style-type: none"> <li>▪ Human Papillomavirus</li> <li>▪ Chlamydia &amp; Gonorrhea</li> </ul>	<ul style="list-style-type: none"> <li>▪ MTBMAI</li> <li>▪ MRSA</li> </ul>	<ul style="list-style-type: none"> <li>▪ BRAF</li> <li>▪ K-RAS</li> <li>▪ EGFR</li> <li>▪ PIK3CA</li> </ul>

**RMD Platform Strategy**

**cobas® 6800/8800 Systems**

**cobas® 4800 System**



- Advanced PCR automation
- High throughput:
  - 3 x above closest competitor
  - up to 1'000 samples in 8 hours
- Broadest menu



# **HY 2013: Diagnostics sales**

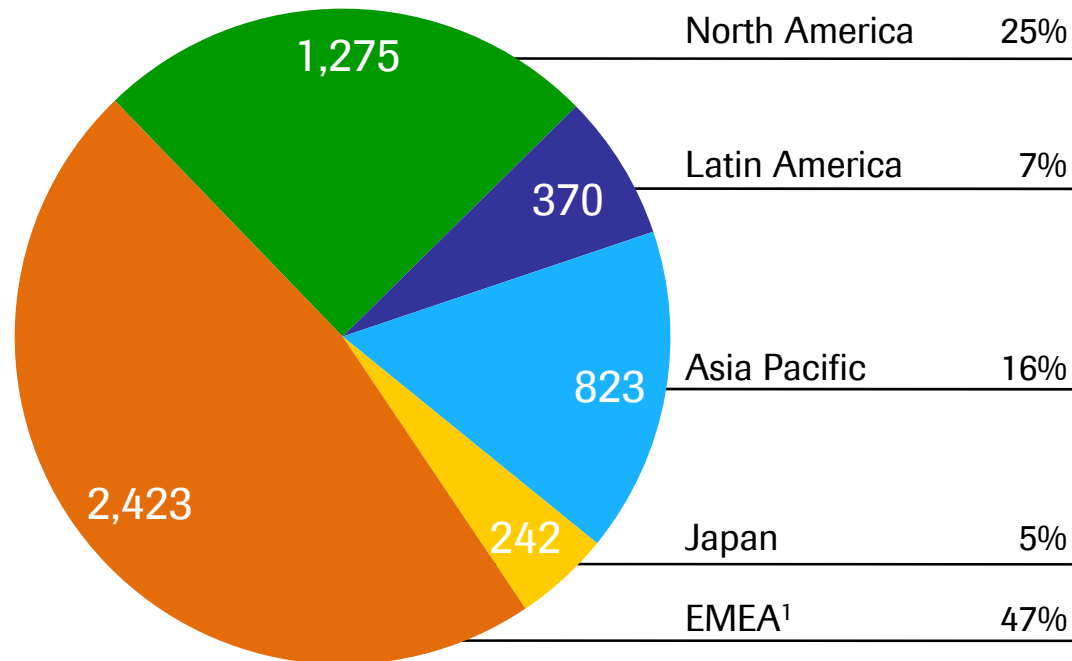
## *Growth driven by Professional Diagnostics*

	<b>HY 2013</b>	<b>HY 2012</b>	<b>change in %</b>	
	<b>CHF m</b>	<b>CHF m</b>	<b>CHF</b>	<b>CER</b>
<b>Diagnostics Division*</b>	<b>5,133</b>	<b>5,014</b>	<b>+2</b>	<b>+3</b>
Professional Diagnostics	2,809	2,653	+6	+6
Diabetes Care	1,205	1,260	-4	-5
Molecular Diagnostics	797	796	0	+1
Tissue Diagnostics	322	305	+6	+6

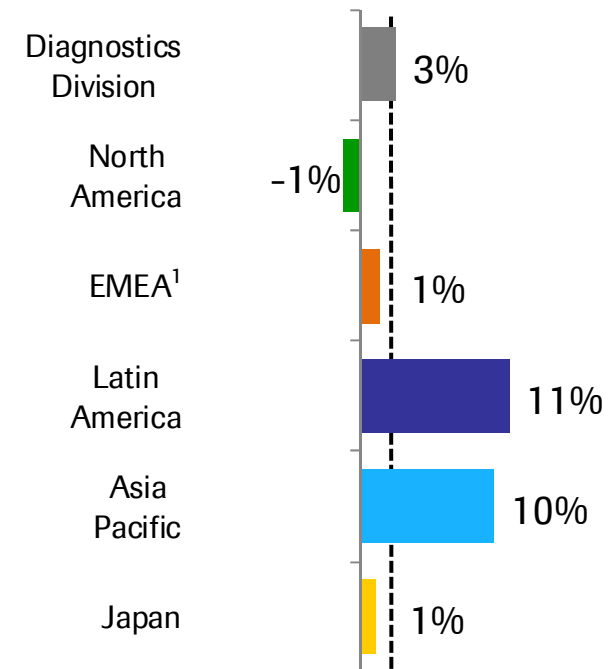
# HY 2013: Diagnostics sales

## *Growth driven by emerging markets*

CHF 5,133 m



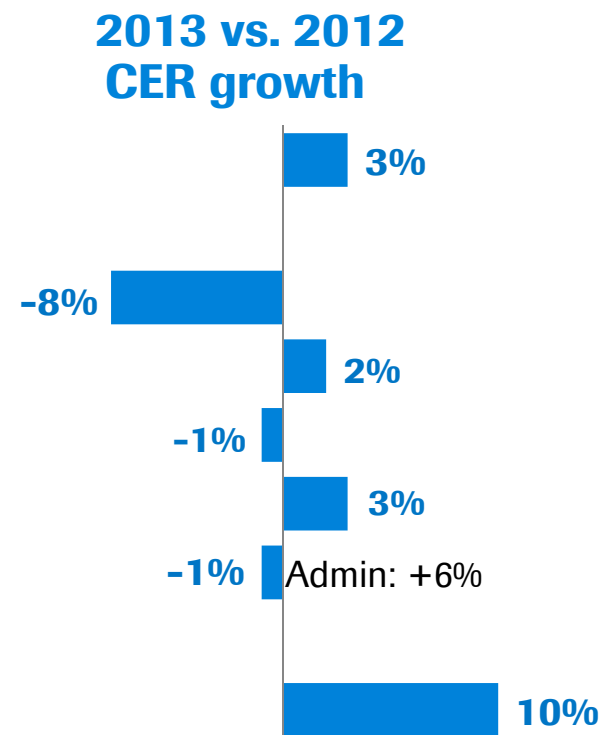
CER sales growth



# HY 2013: Diagnostics

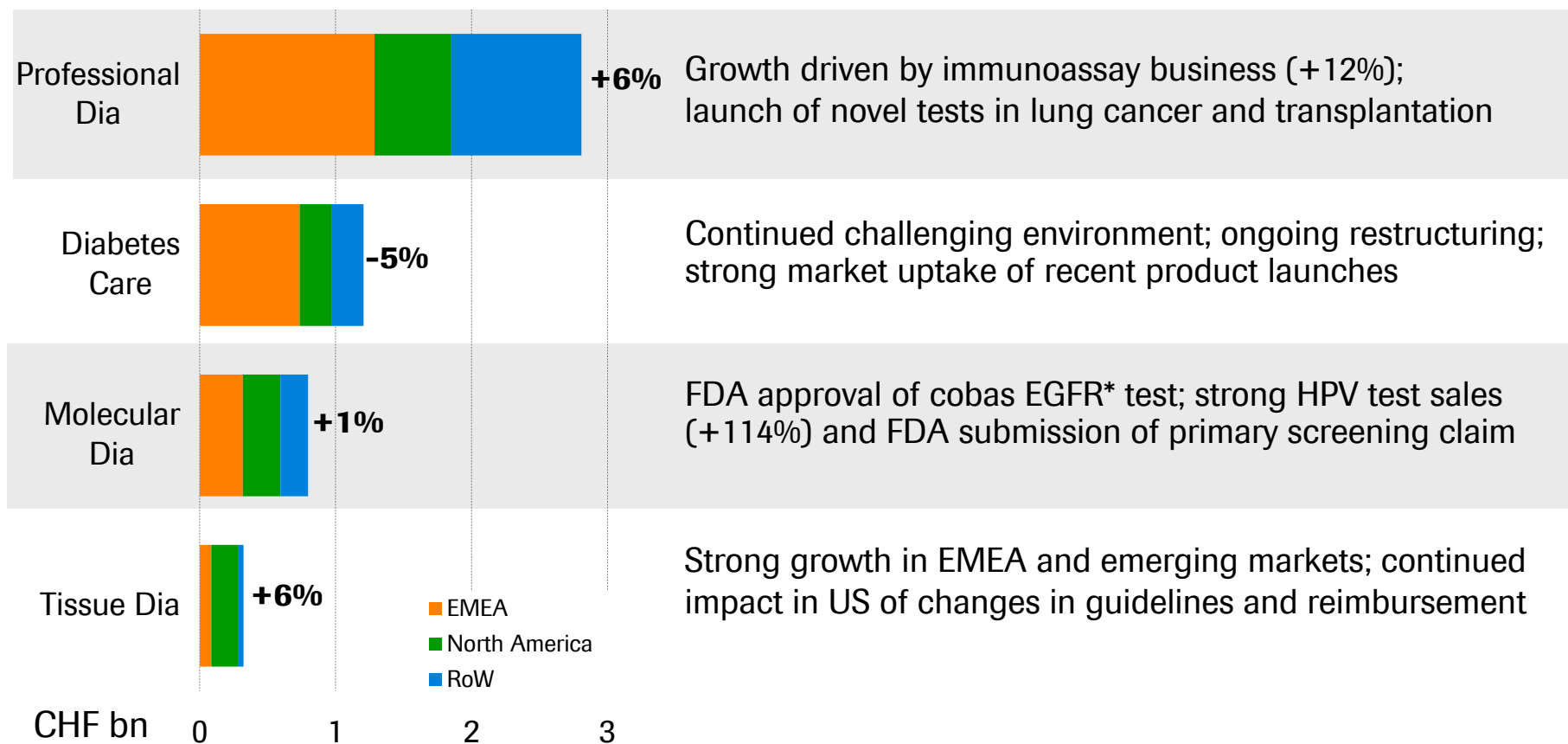
*Profit growth and margin increase due to lower operating expenses*

	HY 2013	
	CHF m	% sales
<b>Sales</b>	<b>5,133</b>	<b>100.0</b>
Royalties & other op inc	73	1.4
Cost of sales <sup>1</sup>	-2,213	-43.1
M & D	-1,233	-24.0
R & D	-473	-9.2
G & A	-204	-4.0
<b>Core operating profit</b>	<b>1,083</b>	<b>21.1</b>



# HY 2013: Diagnostics highlights

## CER growth



# RPD: Acquisition of Constitution Medical Inc.

## *Strengthen our commitment to hematology testing*

### Integrated hematology system<sup>1</sup>

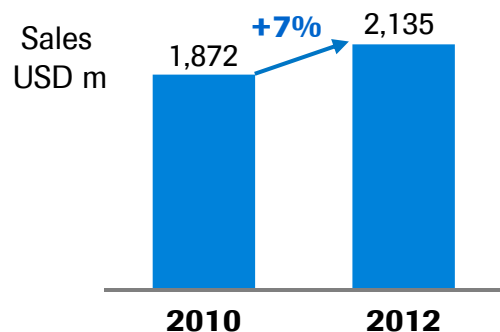


- Innovative technology
- Software algorithms recognise and classify digitalised blood cells printed on slides

### Addresses key customer needs

- Fully automated system
- Saves lab space, consumables and manual processes
- Provides fast and accurate results

### Hematology market<sup>2</sup>



### Strengthens product portfolio

- New hematology capability to reinforce IVD leadership
- Expands core lab offering

<sup>1</sup>In development, not yet cleared by FDA. Not available for sale within or outside the United States

<sup>2</sup> 2012 figures from Independent Industry Analysis;

# Diabetes Care: Adapting to a changing environment

## *Reimbursement cuts and increased competition from low price providers*

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- Implementation of Medicare cut for bGM<sup>1</sup> strips as of July 1, 2013
- Increased pricing pressures in emerging markets, especially Asia

## *Ongoing restructuring measures to adapt to current environment*

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- Consolidation of R&D and containment of marketing and admin. costs
- Profitability protection as a result of restructuring

## *Innovation remains the key for differentiation, success and better patient outcomes*

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- Good uptake of premium products in the market
- Clinical data supports increased patient benefit from innovative products:
  - Accu-Chek Aviva Expert automatic bolus advisor for insulin dosing<sup>2</sup>
  - Accu-Chek Mobile strip-free bGM system<sup>3</sup>



**Accu-Chek  
Aviva Expert**

<sup>1</sup>Blood glucose monitoring;  
<sup>3</sup> ExAcT study at ATTD 2013

<sup>2</sup> ABACUS study at American Diabetes Association 2013;



# Key launches 2013



	<i>Area</i>	<i>Product</i>	<i>Market</i>	<i>BA<sup>1</sup></i>
<i>Instruments / Devices</i>	<b>Labs</b>	cobas 8100 – Next generation modular pre-analytics	EU	RPD
	<b>Life Sciences</b>	GS FLX+ long amplicons- Software for long read targeted sequencing	WW	✓ RMD
	<b>Diabetes Care</b>	Accu-Chek Insight- Next generation insulin pump & bGM <sup>2</sup> system	EU	RDC
Accu-Chek Active LCM- Next-generation bGM <sup>1</sup> meter with maltose independent test strips		EU	✓ RDC	
<i>Tests/ Assays</i>	<b>Oncology</b>	Calcitonin – Medullary thyroid cancer	EU	✓ RPD
		proGRP- Small cell lung cancer	EU	✓ RPD
		CINtec PLUS Cytology- Cervical pre-cancer	EU	RTD
		ER- Breast cancer	US	✓ RTD
		EGFR- Lung cancer	US	✓ RMD
	<b>Infectious Diseases</b>	MPX 2.0 – Next generation blood screening multiplex test for HIV, HCV & HBV	US	RMD
		CAP/CTM HCV 2.0 – Next generation HCV viral load test	US	✓ RMD
	<b>Transplant</b>	Cyclosporin, Tacrolimus – immunosuppressive drug monitoring	EU	✓ RPD
	<b>Sequencing</b>	SeqCap EZ Reagent Kits – Targeted next gen. sequencing	WW	✓ RMD

<sup>1</sup> Business Areas. RPD: Roche Professional Diagnostics; RDC: Roche Diabetes Care; RMD: Roche Molecular Diagnostics, RTD: Roche Tissue Diagnostics;

<sup>2</sup> blood glucose monitoring



# **HY 2013 Group Results**

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## **Diagnostics**

**Overview & Strategy**

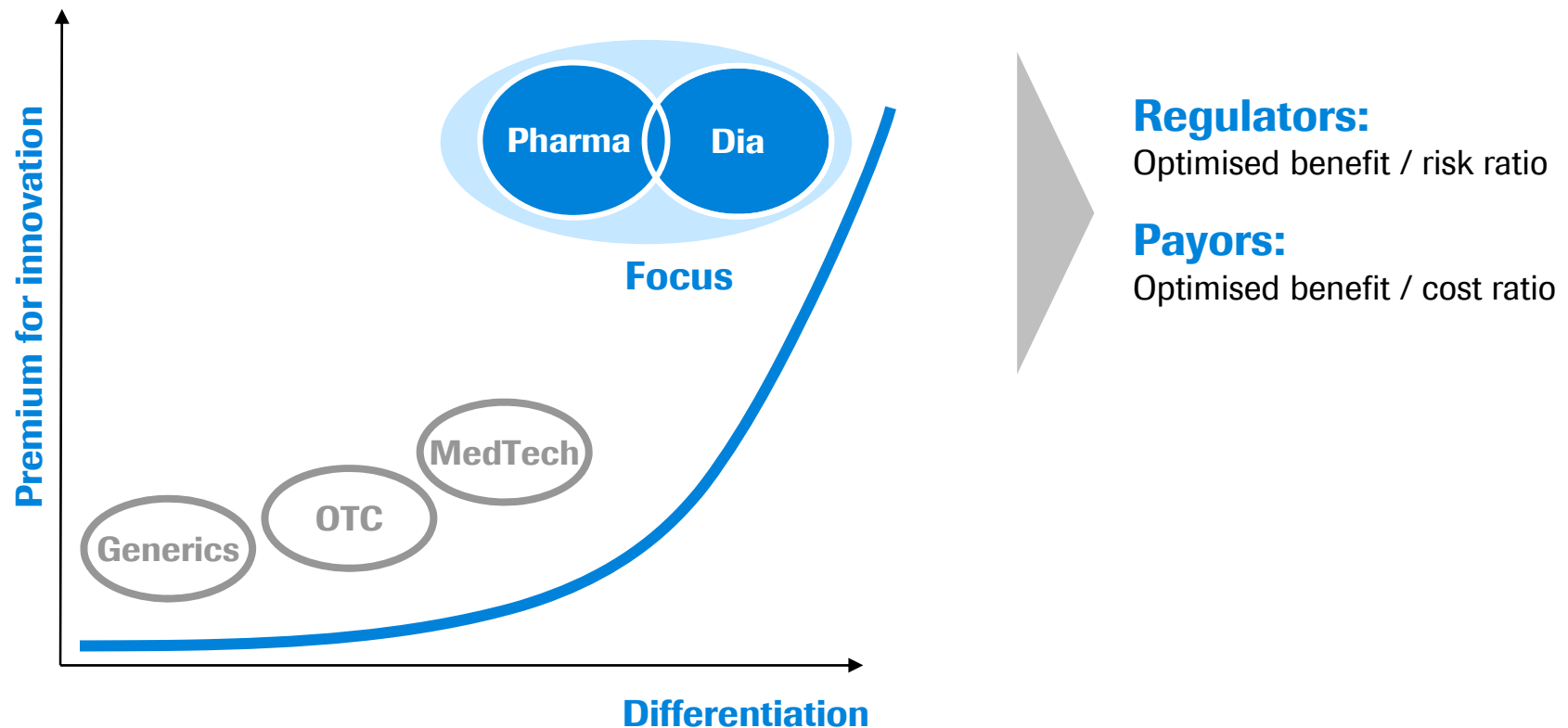
**HY 2013**

**Companion Diagnostics**

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## **Outlook**

# Roche strategy: Focused on medically differentiated therapies and personalised healthcare



# RMD: FDA approval and launch of cobas EGFR test

## *Companion diagnostic for Tarceva*



**cobas 4800 System**  
Fully automated PCR platform



Expansion of cobas 4800 menu  
- BRAF, EGFR, KRAS<sup>1</sup>, PIK3CA<sup>2</sup>, HPV, CT/NG



Approved for EGFR mutated NSCLC



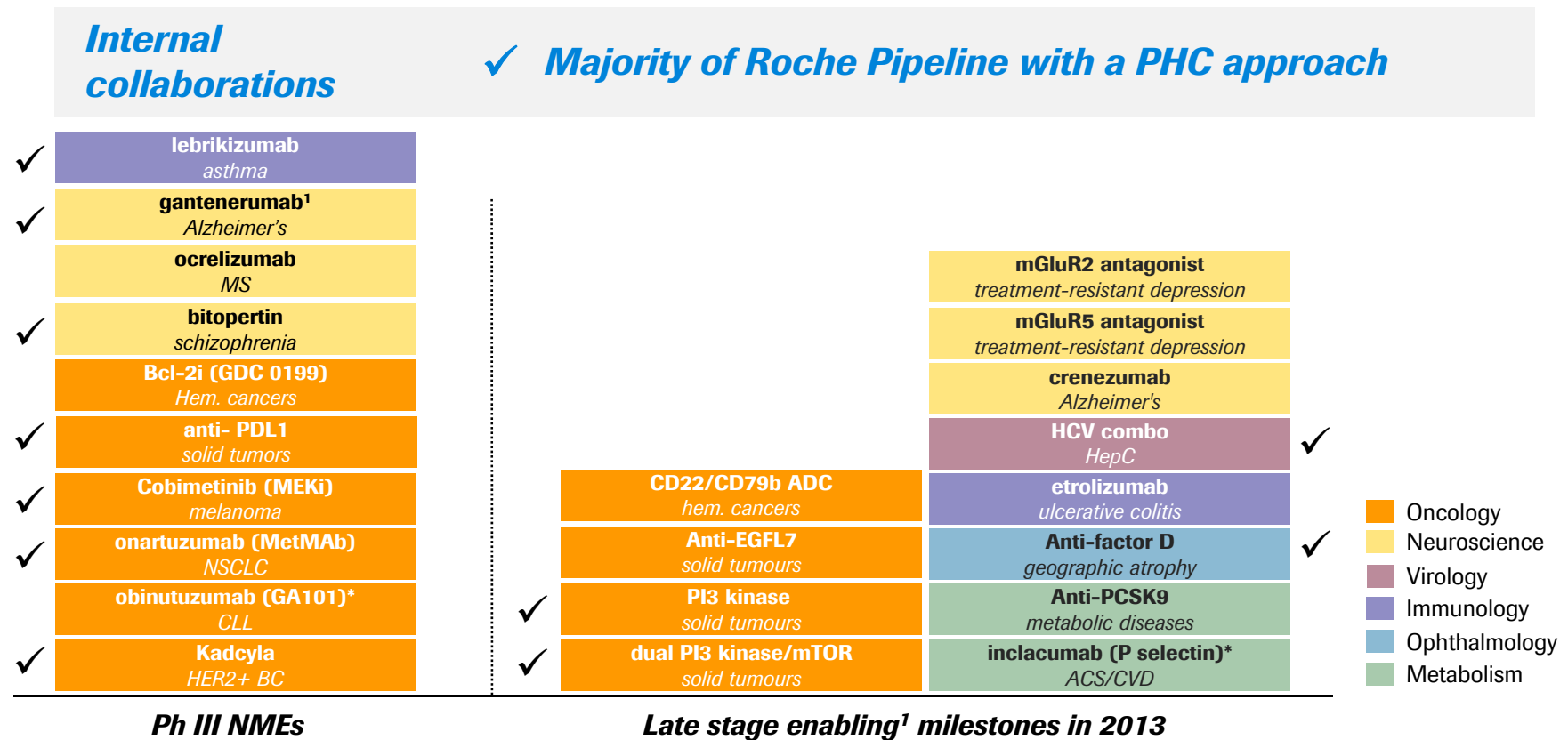
**cobas EGFR test**

- Identifies patients with EGFR mutations
- Provides consistent and reliable results

<sup>1</sup>Available with CE mark

<sup>2</sup>Available for Research Use Only

# Roche Diagnostics' commitment to PHC



**External collaborations** • PHC collaborations<sup>2</sup> with more than 40 pharma & biotech companies

<sup>1</sup>Phase II/III label enabling; <sup>2</sup> Including R&D collaborations and CDx projects



# **HY 2013 Group Results**

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## **Diagnostics**

**Overview & Strategy**

**HY 2013**

**Companion Diagnostics**

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## **Outlook**

# **Outlook: Roche Diagnostics**

## ***Sustained sales growth driven by leading IVD business***

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### ***Drivers***

- Further growth of installed base
  - Expansion of test menu
  - Emerging markets
  - Stabilise Diabetes Care
  - Increasing CDx collaborations
-

# 2013 Outlook: Roche Group



<b>Group sales growth<sup>1</sup></b>	In line with sales growth recorded in 2012
<b>Core EPS growth<sup>1</sup></b>	Ahead of sales growth
<b>Dividend outlook</b>	Further increase dividend

<sup>1</sup>At constant exchange rates; Excluding one-off Past Service Income impact of CHF 196 m on core net income



*Doing now what patients need next*