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**Roche Diagnostics**  
*Daniel O'Day*  
*COO Roche Diagnostics*



# 2010 Summary for Roche Group

## Financial guidance fully met

## Operational Excellence on track

- Most of the concerned employees individually notified
- R&D prioritised
- Divestitures of factories initiated

## Major progress in Personalised Healthcare

- Strong late-stage pipeline of 12 NMEs out of which 6 tailored to specific patient groups

# 2010: Group sales

*Solid underlying growth in line with guidance*

	2009 CHF m	2010 CHF m	change in % CHF	local	Excluding Tamiflu*
<b>Pharmaceuticals Division</b>	<b>38,996</b>	<b>37,058</b>	<b>-5</b>	<b>-2</b>	<b>+5</b>
<b>Diagnostics Division</b>	<b>10,055</b>	<b>10,415</b>	<b>+4</b>	<b>+8</b>	<b>+8</b>
<b>Roche Group</b>	<b>49,051</b>	<b>47,473</b>	<b>-3</b>	<b>0</b>	<b>+5</b>

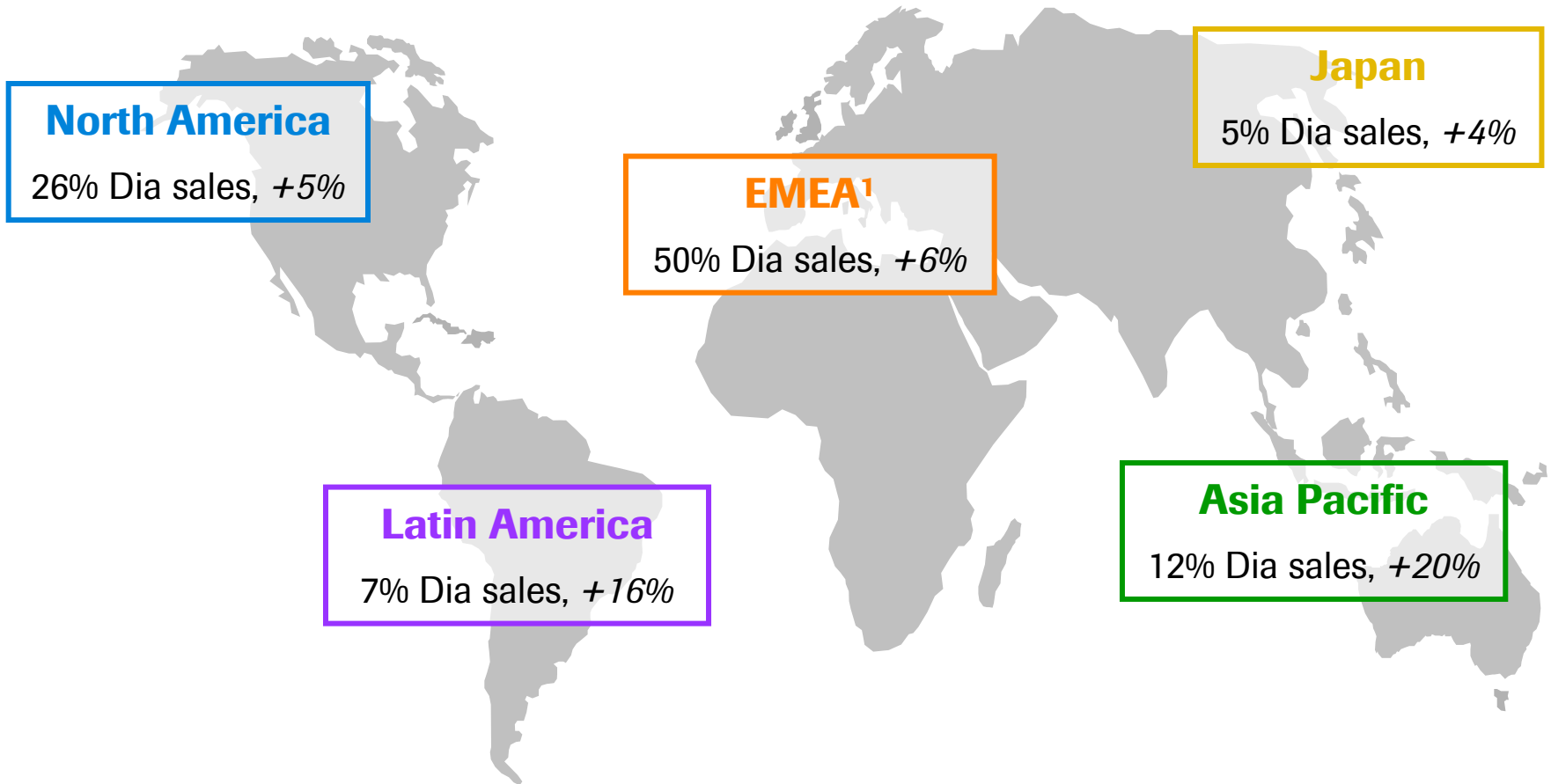
# 2010: Diagnostics Division sales

## *Sustained high growth above the market*

	2009 CHF m	2010 CHF m	CHF growth	local growth
Professional Diagnostics	4,553	4,858	7%	11%
Diabetes Care	2,969	2,959	0%	4%
Molecular Diagnostics	1,183	1,189	1%	4%
Applied Science	870	868	0%	4%
Tissue Diagnostics	480	541	13%	17%
<b>Diagnostics Division</b>	<b>10,055</b>	<b>10,415</b>	<b>4%</b>	<b>8%</b>

# 2010: Diagnostics Division sales

## *Growth above market in all regions*



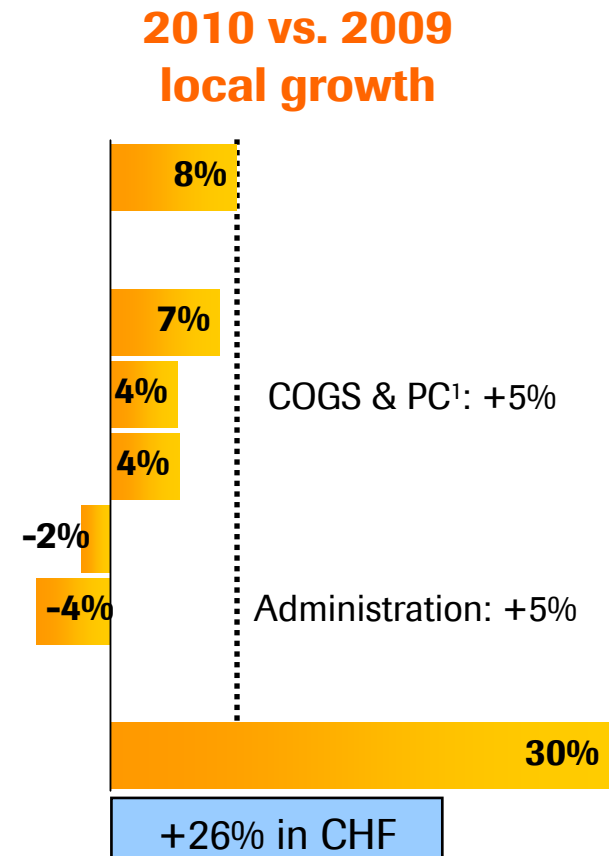
<sup>1</sup> Europe, Middle East and Africa  
All growth in local currency

IVD market growth estimated 4-5%

# 2010: Diagnostics profit improvement on track

*Significant profit and margin increase driven by strong sales and tight management of operating expenses*

	2010	
	CHF m	% sales
<b>Sales</b>	<b>10,415</b>	<b>100.0</b>
Royalties & other op inc	157	1.5
Cost of sales	-4,564	-43.8
M & D	-2,515	-24.1
R & D	-890	-8.6
G & A	-401	-3.9
<b>Core operating profit</b>	<b>2,202</b>	<b>21.1</b>

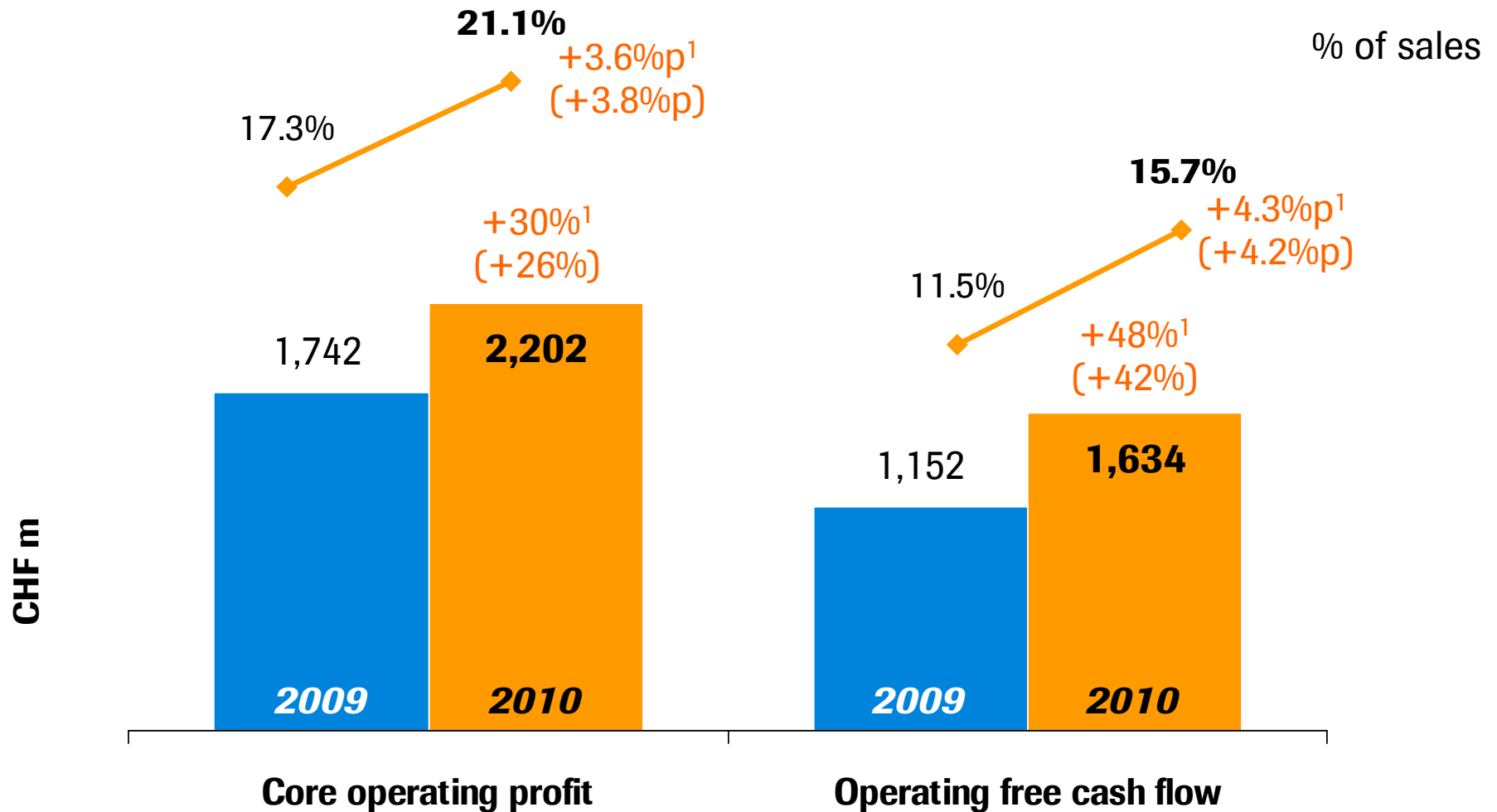


<sup>1</sup> Cost of goods sold & period costs



# 2010: Diagnostics performance

## *Operating free cash flow increase driven by profit growth*



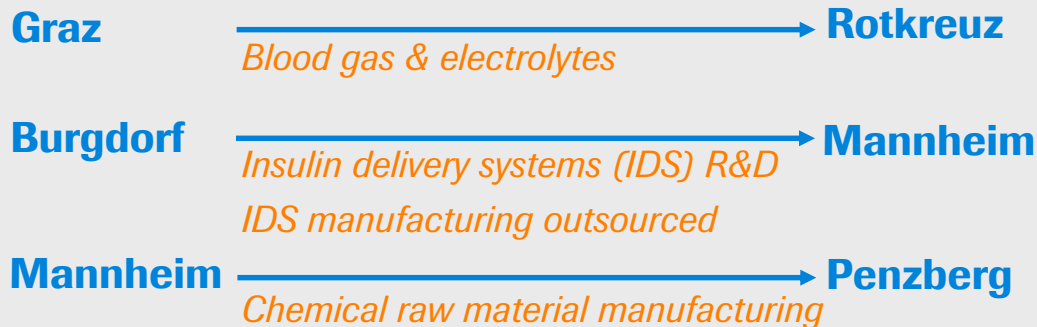
<sup>1</sup> at constant exchange rates

# Accelerated delivery of ongoing initiatives for sustainable margin improvement

## Ongoing operational efficiency programmes

- manufacturing excellence (COGs)
- consolidation of services (regional call centres, shared services)
- active portfolio management

## Further streamlining of sites *(site closures 2013-2014)*

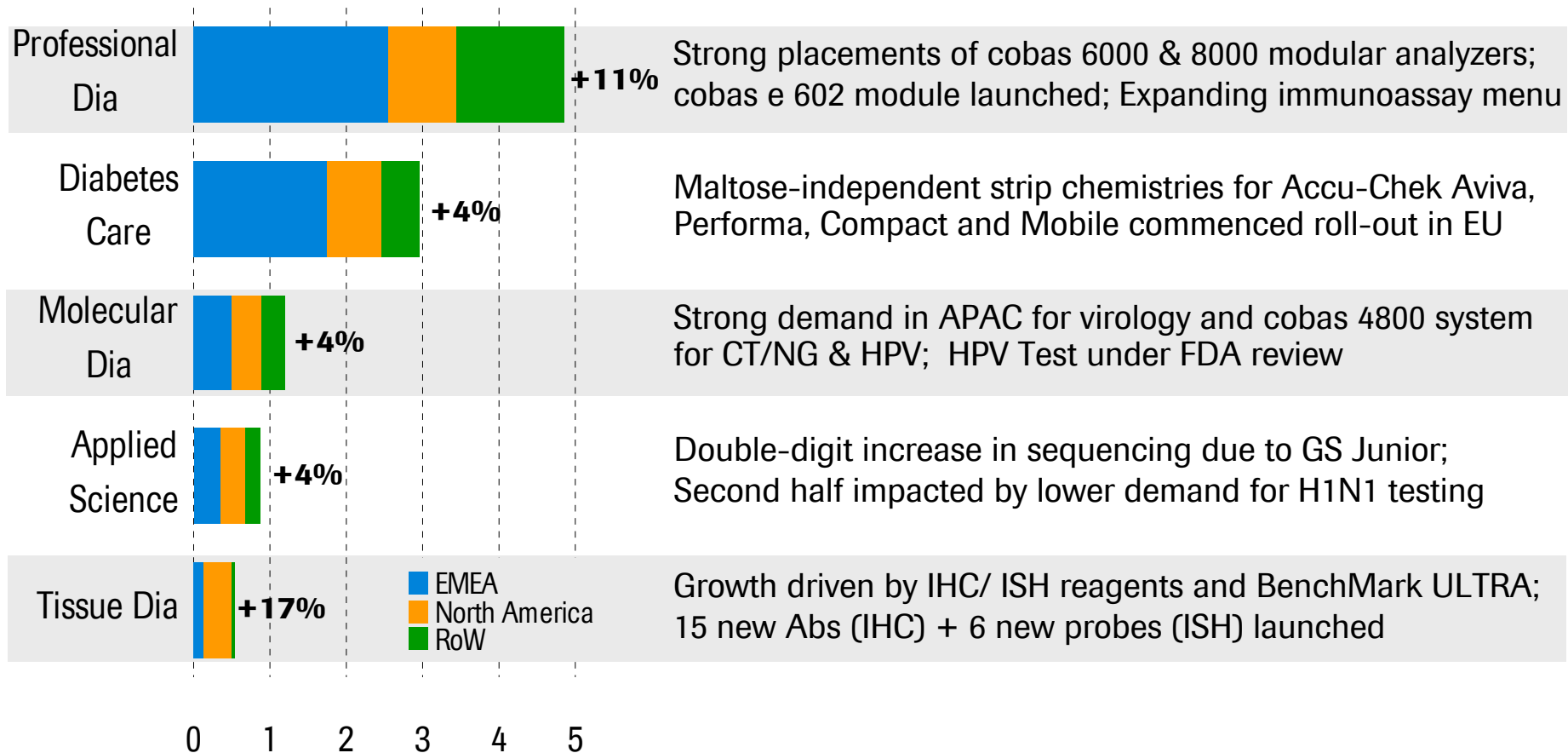


Enhancing system integration  
Leveraging existing capacities  
Reducing infrastructure costs

# Growth driven by Professional Diagnostics and Diabetes Care

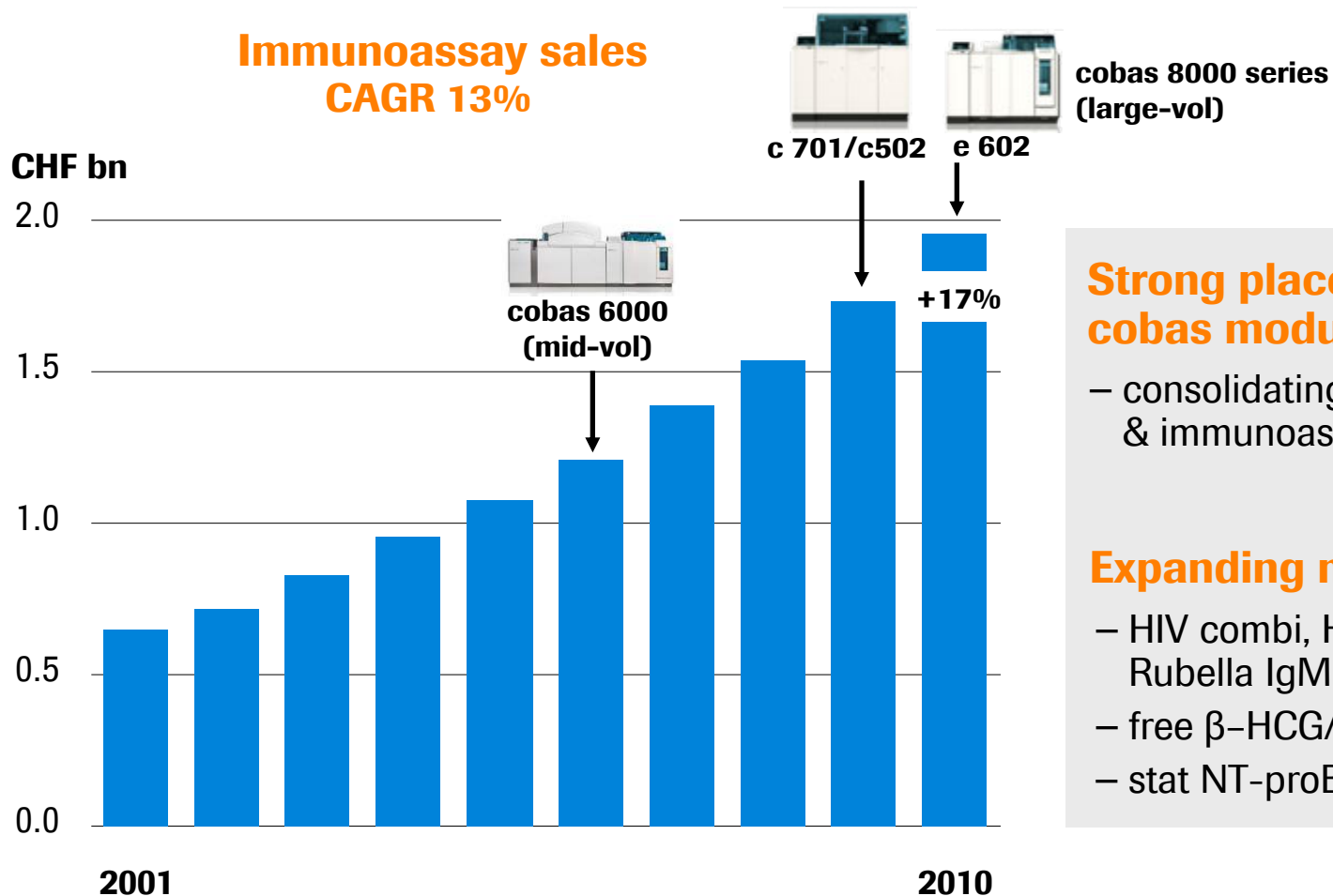
**2010 vs. 2009  
local growth**

**CHF bn**



# Immunoassays driving sales

## *Ten consecutive years of double-digit growth*



### Strong placements of cobas modular platforms

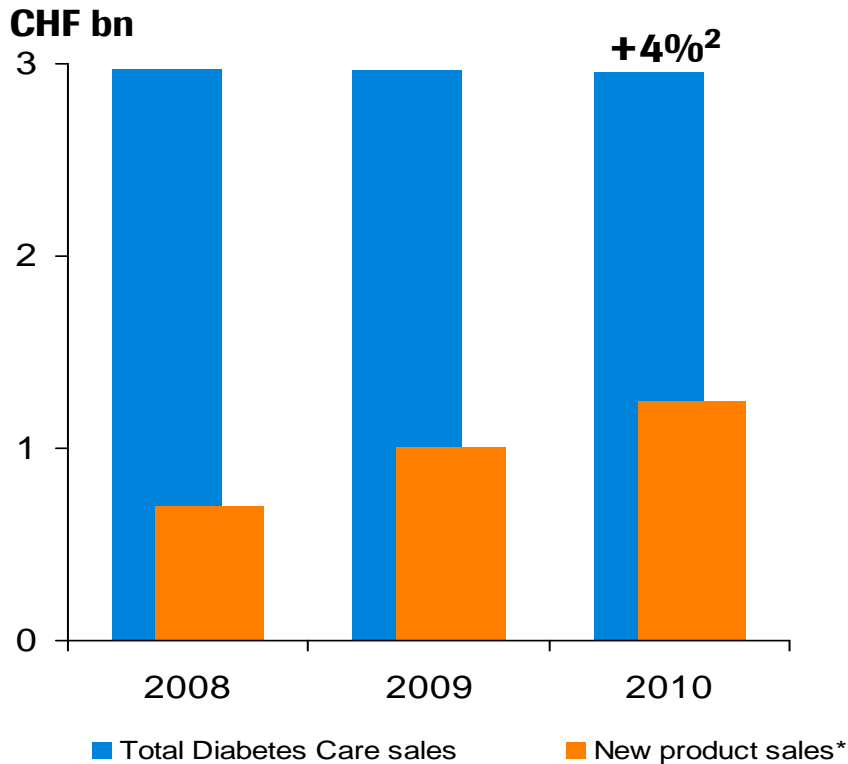
- consolidating clinical chemistry & immunoassays

### Expanding menu

- HIV combi, HSV-1, HSV-2, Rubella IgM, HAV, HCV
- free  $\beta$ -HCG/ PAPP-A
- stat NT-proBNP

# New Accu-Chek products driving above-market<sup>1</sup> growth in Diabetes Care

## Diabetes Care sales



## New product launches<sup>3</sup> (2008-2009)

### Accu-Chek Aviva Nano & Performa Nano



- Small, sleek design developed for young, high-frequency testers

### Accu-Chek Mobile



- Only “strip-free” system enabling less steps for greater ease of use

### Accu-Chek Combo



- First interactive insulin pump in EU allowing patients to operate pump by meter

<sup>1</sup> BG market growth estimated 2%

<sup>2</sup> local currency

<sup>3</sup> Not available in the US

\* New product sales includes: Accu-Chek Aviva/ Nano, Accu-Chek Performa/ Nano, Accu-Chek Mobile, Accu-Chek Combo

# Creating medical value and improving patient care

## *Three trials demonstrating the value of diagnostics*

*Diagnostics*

*Companion  
Diagnostics*

### ATHENA



#### HPV (cervical cancer)

- 47,000 women screened by cobas 4800 HPV Test with 16/18 genotyping
- 1/10 women<sup>1</sup> positive for HPV 16/18 had cervical precancer although their PAP test was normal<sup>2</sup>

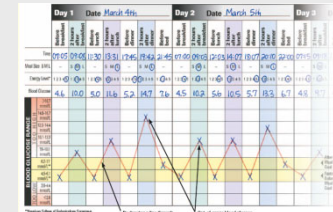
### PROTECT



#### NT-proBNP (heart failure)

- NT-proBNP levels used to guide heart failure (HF) therapy
- Patients experienced significant reduction in total cardiovascular events and HF-related hospitalisations<sup>3</sup>

### STeP



#### Glucose monitoring (diabetes)

- Patients created 7-point BG profiles over 3 consecutive days
- Therapy decisions based on pattern analysis
- Patients showed significantly better HbA1c and glycemic control<sup>4</sup>

<sup>1</sup> >30 years old

<sup>3</sup> Januzzi, J., AHA Chicago, November 2010

<sup>2</sup> Wright TC, et al, IPV Montreal, July 2010

<sup>4</sup> Polonsky et al, Diabetes Care, 34, 2011

# ATHENA Clinical Trial

## *HPV 16/18 genotype status identifies cervical pre-cancer missed by PAP*

### ATHENA proved:

#### 1 PAP testing insufficient:

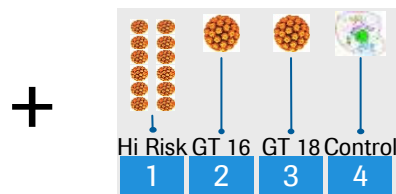
- Testing for HPV genotypes 16/18 identified cervical pre-cancer in one of ten women<sup>1</sup> although their PAP test was normal<sup>2</sup>

% Absolute Risk for CIN2 <sup>2</sup>		
	PAP + <sup>3</sup>	PAP -
Pooled HR HPV +	14.0	6.1
Today's follow up	Colposcopy	Retest ~1y
HPV 16/18 +	24.4	11.4
Suggested follow up	Colposcopy	Colposcopy

#### 2 Roche cobas 4800 HPV test setting new standard

≥CIN2 <sup>4</sup> in ASC-US	cobas 4800 HPV	Qiagen hc2
Sensitivity (%)	90.0	87.2
Specificity (%)	70.5	71.1

Equivalent performance



GT 16/18 & 12 HR HPV in one test



Fully automated throughput up to 388/12hr

<sup>1</sup> >30 years old

<sup>2</sup> Wright TC, et al, IPV Montreal, July 2010;

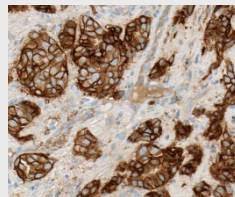
<sup>3</sup> ASC-US <sup>4</sup> Stoler M, et al, IPV Montreal, July 2010;

CIN=cervical intraepithelial neoplasia; ASC-US = atypical squamous cells of undetermined significance

# Creating medical value and improving patient care

## *Six NMEs in late-stage development have PHC approach*

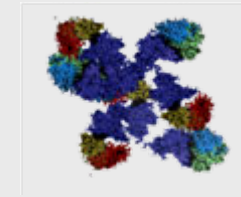
*Diagnostics*



HER2/3  
(Pertuzumab)

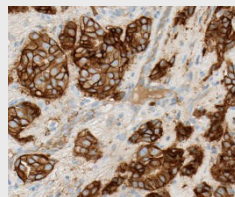


Met  
(MetMAb)

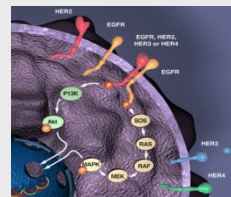


Periostin  
(Ibrikizumab)

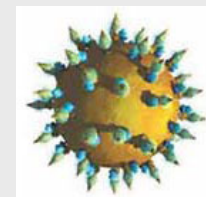
*Companion  
Diagnostics*



HER2  
(T-DM1)



BRAF V600  
(BRAFinh)



HCV load, genotype  
(HCV pol inh)

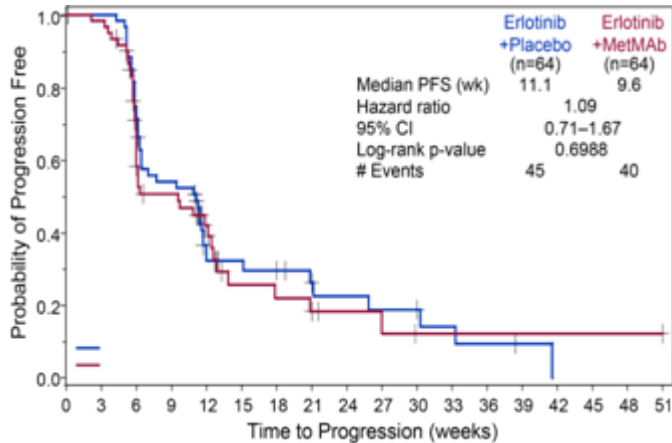


# MetMAb + Tarceva in 2<sup>nd</sup>/3<sup>rd</sup> line mNSCLC

## *Met IHC Companion Diagnostic collaboration with*

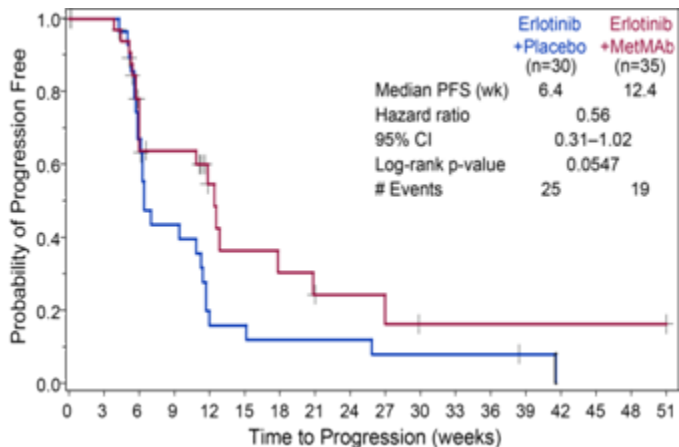
### *RTD*

All patients: PFS<sup>2</sup>, HR<sup>3</sup>=1.09



- Met-high patients lived **nearly twice as long** without their disease getting worse when treated with MetMAb and Tarceva compared to placebo and Tarceva
- Met receptor over-expressed or mutated in variety of tumors and associated with poor prognosis

Met-high patients: PFS<sup>2</sup>, HR<sup>3</sup>=0.56



Results demonstrated the importance of selecting NSCLC patients based on Met status

<sup>1</sup> metastatic non-small cell lung cancer; <sup>2</sup> progression free survival; <sup>3</sup> hazard ratio  
Source: Spigel D., *et al.*, LBA No. 5146, ESMO 2010

# Acquisitions, collaborations and licensing of IP to strengthen businesses

## Acquisitions

**MEDINGO**  
Medical Solutions



Semi-disposable micropump for insulin delivery

**bio**magene  
innovative.digital.pathology



High resolution, whole-slide scanning of tissue samples & algorithms

## Research & technology collaborations

- IBM and DNA electronics (sequencing)
- German Cancer Research Centre (HPV)
- InterComponentWare (Diabetes Care)

## Intellectual Property

- EGFR
- PI3K
- p63

# Key launches for 2011\*

<b>Professional Diagnostics</b>	<ul style="list-style-type: none"> <li>▪ Vitamin D total and HE4 immunoassays (EU)</li> <li>▪ cobas 8000 modular analyzer series, cobas c 702 module (EU, US)</li> <li>▪ cobas b 123 POC system for bloodgas &amp; electrolytes (US)</li> </ul>
<b>Diabetes Care</b>	<ul style="list-style-type: none"> <li>▪ Accu-Chek Mobile LCM (EU)</li> <li>▪ Accu-Chek Combo (US)</li> <li>▪ Accu-Chek Nano (US)</li> </ul>
<b>Molecular Diagnostics</b>	<ul style="list-style-type: none"> <li>▪ cobas 4800 HPV Test (US)</li> <li>▪ cobas 4800 EGFR Mutation Test (EU)</li> <li>▪ cobas 4800 KRAS Mutation Test (EU)</li> <li>▪ cobas 4800 BRAF V600 Mutation Test (EU, US)</li> </ul>
<b>Applied Science</b>	<ul style="list-style-type: none"> <li>▪ HLA genotyping on GS Junior &amp; FLX sequencing systems (global)</li> <li>▪ GS FLX Titanium-XL system (global)</li> <li>▪ Ultra-high resolution CGH arrays (global)</li> </ul>
<b>Tissue Diagnostics</b>	<ul style="list-style-type: none"> <li>▪ ER/PR antibody for IHC (US)</li> <li>▪ HER2 dual colour ISH probe (US)</li> <li>▪ <i>FutureView</i> detection system (US, EU)</li> </ul>

**Diagnostics Division Outlook: Sales growth significantly above the market**

# Priorities in 2011

- **Drive above-market growth**
- **Deliver key product launches**
- **Drive Personalised Healthcare with Pharma**
- **Continue strong growth in emerging markets**
- **Further improve profitability**



*We Innovate Healthcare*