



### Roche

## 2015 results

Basel, 28 January 2016

Roche

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- 6 increased government pricing pressures;
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- 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.

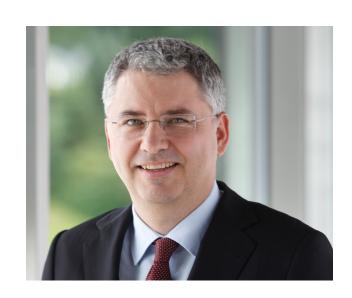
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Group
Severin Schwan
Chief Executive Officer





## 2015 performance

### **Outlook**





Targets for 2015		FY 2015	
Group sales growth <sup>1</sup> Mid-single digit		+5%	$\checkmark$
Core EPS growth <sup>1</sup> Ahead of sales growth <sup>2</sup>		<b>+7</b> %	✓
Dividend outlook	Further increase dividend in Swiss francs <sup>3</sup> (Payout ratio increased to 60% from 56%)	CHF 8.10	✓

<sup>&</sup>lt;sup>1</sup> At constant exchange rates (CER); <sup>2</sup> Excluding sale of filgrastim rights in 2014; <sup>3</sup> 2015 dividend as proposed by the Board of Directors



## 2015: Strong sales growth in both divisions

	2015	2014	Change in %	
	CHFbn	CHFbn	CHF	CER
Pharmaceuticals Division	37.3	36.7	2	5
Diagnostics Division	10.8	10.8	0	6
Roche Group	48.1	47.5	1	5



## Roche: Significantly advancing patient care Recognition for innovation 2013-present

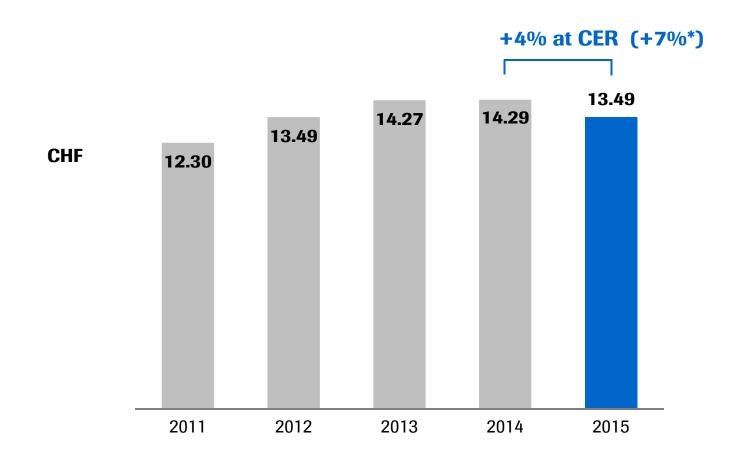
## Breakthrough Therapy Designations

Rank	Company	#
1	Roche	11
2	BMS	8
3	Novartis	6
3	Merck	6
3	Pfizer	6
4	GSK	5

Molecule		
Venetoclax (AML)		
Venetoclax + Rituxan (R/R CLL)		
Actemra (Systemic sclerosis)		
Atezolizumab (NSCLC)		
Venetoclax (R/R CLL 17p del)		
Emicizumab/ACE 910 (Hemophilia A)		
Esbriet (IPF)		
Lucentis (DR)		
Atezolizumab (Bladder)		
Alectinib (2L ALK+ NSCLC)		
<b>Gazyva</b> (1L CLL)		



## 2015: Strong underlying Core EPS growth



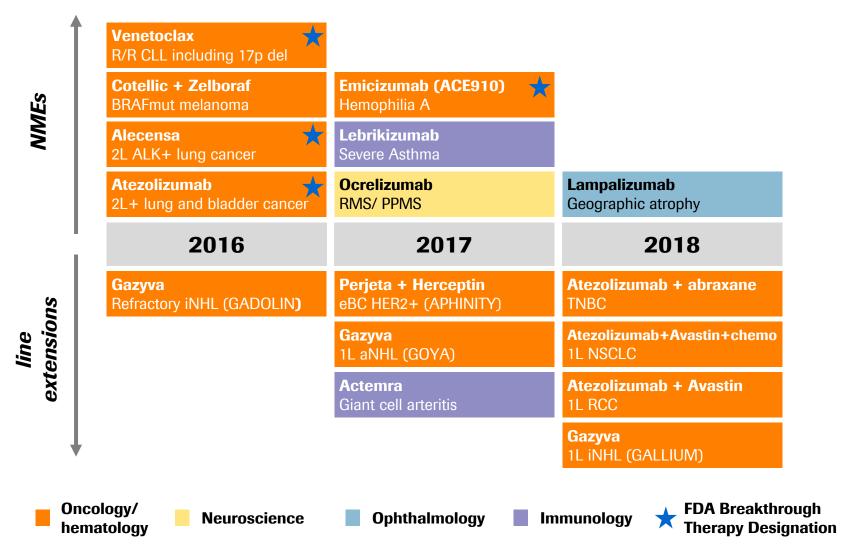


## performance

## **Outlook**



### 2016 onwards: Significant launch activities



### 2016 outlook



**Group sales growth**<sup>1</sup>

Low to mid-single digit

Core EPS growth<sup>1</sup>

Ahead of sales growth

**Dividend outlook** 

Further increase dividend in Swiss francs



Pharmaceuticals Division

Daniel O'Day

COO Roche Pharmaceuticals





### 2015 results

**Innovation** 

**Outlook** 

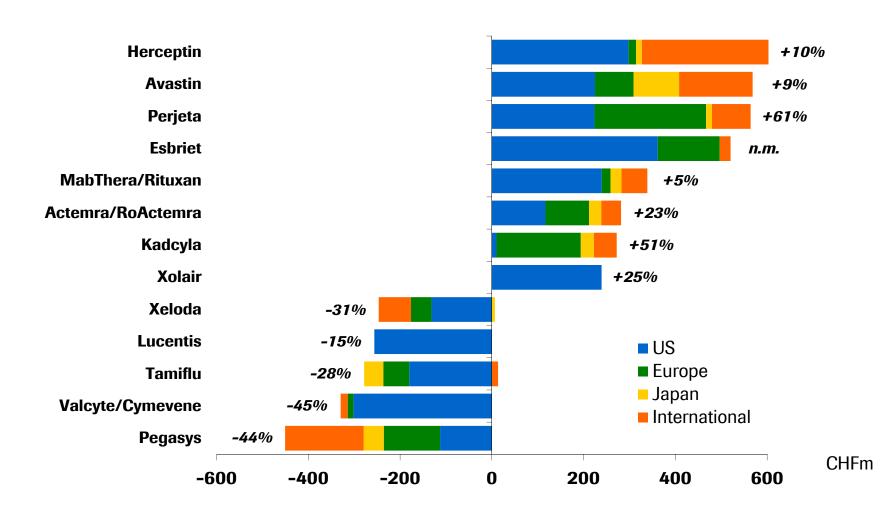


# **2015: Pharma sales** *Strong growth driven by all regions*

	2015	2015 2014		Change in %	
	CHFm	CHFm	CHF	CER	
Pharmaceuticals Division	37,331	36,696	2	5	
United States	17,616	15,822	11	6	
Europe	8,734	9,422	-7	4	
Japan	3,224	3,301	-2	6	
International	7,757	8,151	-5	5	



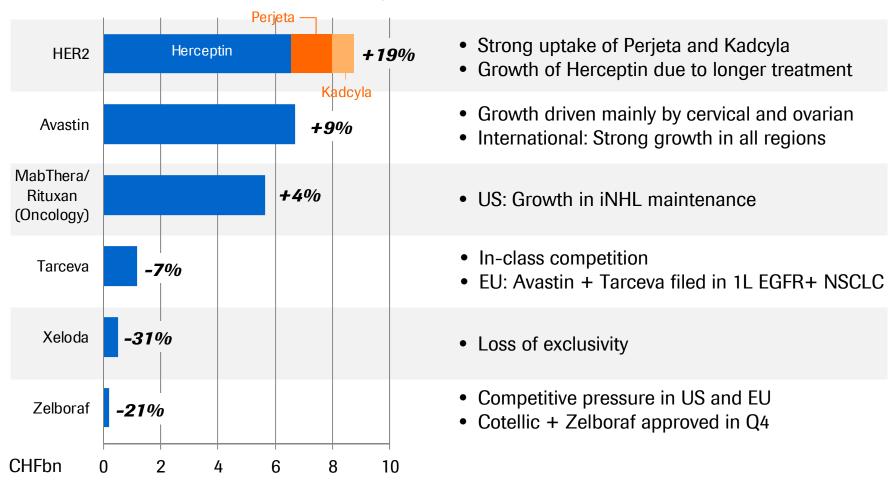
## 2015: Strong performance from oncology and immunology franchises





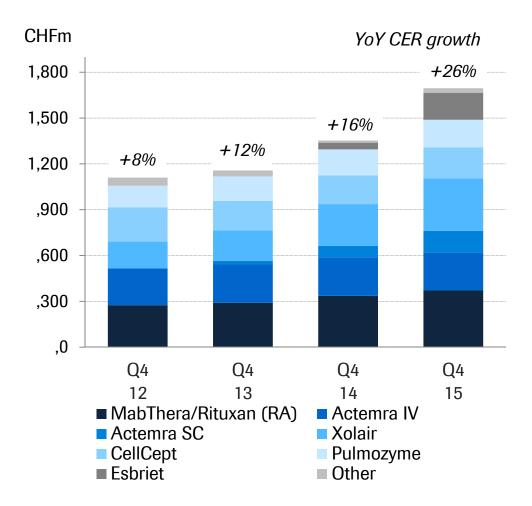


### YoY CER growth





### **Immunology: Continued strong performance**



### **Immunology Q4 2015**

#### **Xolair** (+22%)

Allergic asthma and strong growth in chronic idiopathic urticaria

#### **Actemra** (+25%)

- SC formulation driving growth
- Increasing 1L monotherapy leadership focusing on MTX intolerant patients

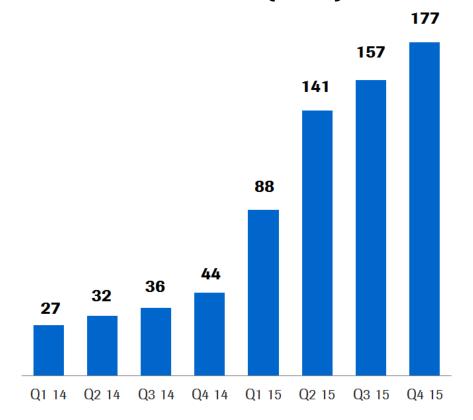
#### MabThera/Rituxan (+14%)

 Continues to grow in rheumatoid arthritis and vasculitis (GPA and MPA)



### **Esbriet: Market leadership in IPF established**

### **Esbriet sales (CHFm)**



#### US

- Strong underlying growth
- Around 100,000 IPF patients in the US with high unmet need

#### EU

 Increasing differentiation due to strengthened label including the pooled 1 Yr mortality data

#### Outlook 2016

 Continued growth due to increased penetration and longer treatment



### 2015 results

### **Innovation**

### **Outlook**



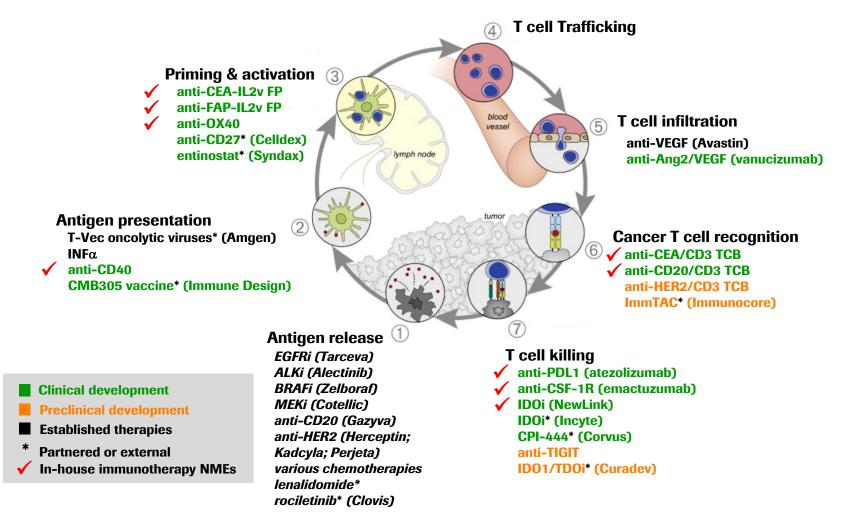
## 2015: Key late-stage news flow

	Compound	Indication	Milestone	
Regulatory	Avastin	Cervical cancer	EU approval	✓
	Lucentis	Diabetic retinopathy	US approval	$\checkmark$
	Alecensa	2L ALK+ NSCLC	US/EU filing/approval	$\checkmark$
	Cotellic + Zelboraf	1L Melanoma	US/EU approval	$\checkmark$
	Gazyva	MabThera/Rituxan-refractory iNHL	Ph III GADOLIN	✓
	Gazyva	Front-line aNHL	Ph III GOYA (interim)	2016
D	ocrelizumab	Relapsing forms of MS (RMS)	Ph III OPERA I/II	$\checkmark$
Phase III readouts*	ocrelizumab	Primary progressive MS (PPMS)	Ph III ORATORIO	$\checkmark$
	Perjeta	2L HER2+ mBC	Ph III PHEREXA	Data in-hous
	Kadcyla	2L HER2+ gastric cancer	Ph II/III GATSBY	×
	atezolizumab**	2/3L Bladder cancer	Ph III	✓
	atezolizumab**	1L TNBC	Ph III	✓
	atezolizumab**	1L RCC	Ph III	✓
Phase III starts	atezolizumab**	Adjuvant bladder	Ph III	$\checkmark$
	etrolizumab	Crohn's disease	Ph III	$\checkmark$
	emicizumab (ACE910)	Hemophilia A	Ph III	$\checkmark$
	taselisib (PI3K inhib)	HR+/PI3Kmut BC	Ph III SANDPIPER	✓
Phase II readouts*	atezolizumab	2/3L NSCLC	Ph II FIR, POPLAR, BIRCH	✓
	atezolizumab	Bladder cancer	Ph II	✓
	ipatasertib (AKT inhib)	Gastric/prostate cancers	Ph II MARTIN, JAGUAR	Data in-house

<sup>\*</sup> Outcome studies are event driven, timelines may change; \*\* For atezolizumab (aPDL1) only P3 trials in new indications are listed (1L NSCLC starts not shown)

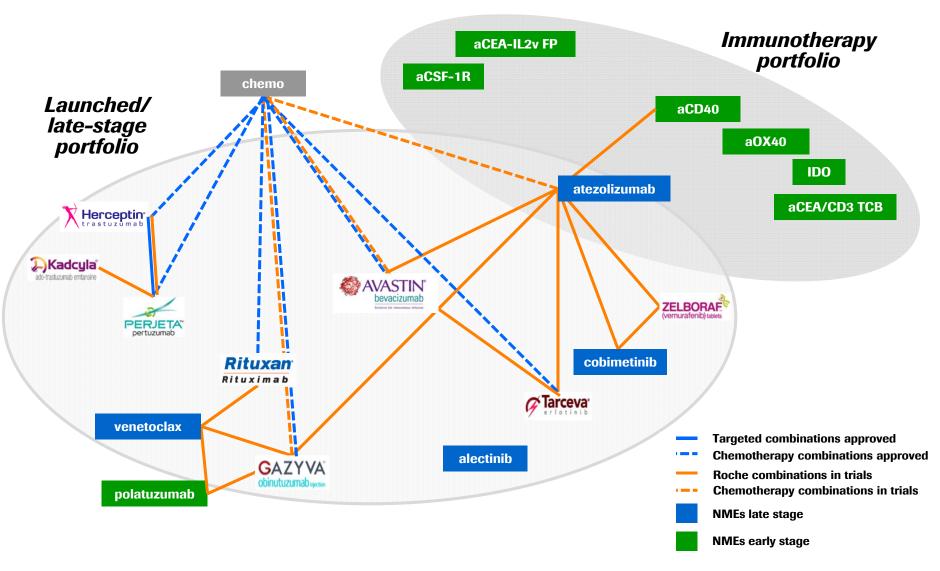
## Unlocking the full value of cancer immunotherapy Nine in-house immunotherapy NMEs in the clinic





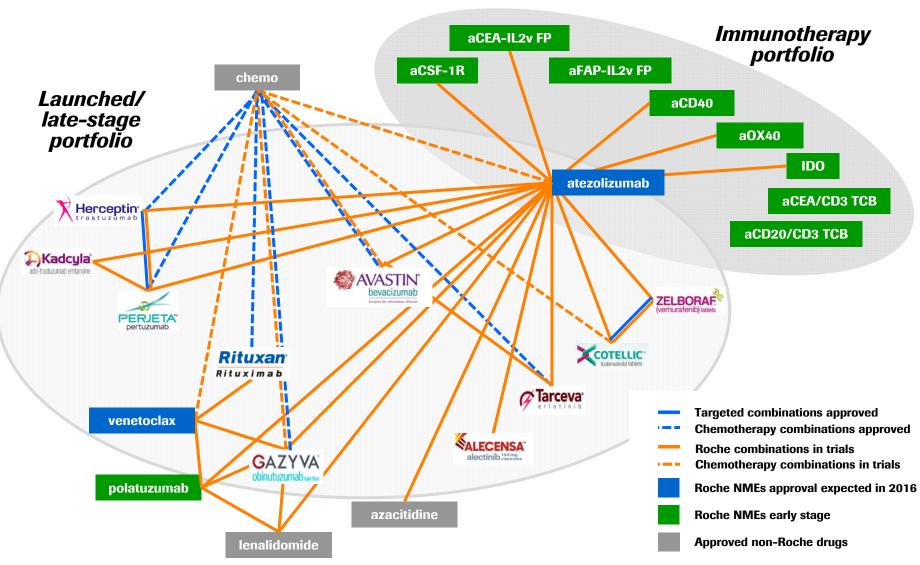


### **Combination trials as of beginning 2015...**





### ...and combination trials as of today





## Ocrelizumab in multiple sclerosis First drug active in both RMS and PPMS

#### Phase III OPERA I/II Studies (RMS)

	Study Endpoint	Relative Risk Reduction versus Rebif®			
		OPERA I	OPERA II	POOLED	
1 EP	ARR	-46%	-47%	NA	
Key 2 EP	CDP (12 wks)	-43%	-37%	-40%	
	CDP (24 wks)	-43%	-37%	-40%	
	T1 <u>Gd</u> -enhancing lesions	-94%	-95%	NA	
	New and/or enlarging T2 lesions	-77%	-83%	NA	

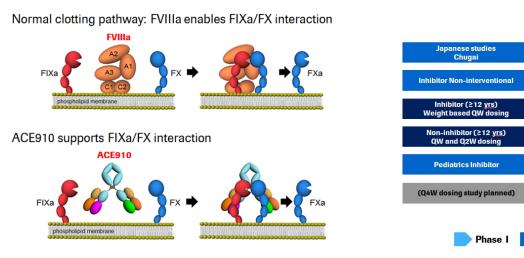
#### **Phase III ORATORIO Study (PPMS)**

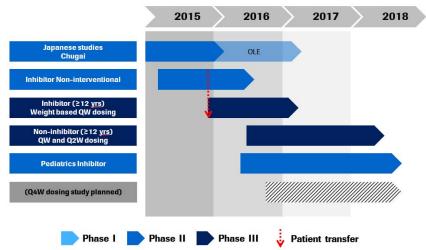
Study Endpoint		Relative Risk Reduction versus placebo	
		ORATORIO	
1 EP	CDP (12 wks)	24%	
	CDP (24 wks)	25%	
Kou	Timed 25-foot walk (baseline to wk 120)	29%	
Key 2 EP	T2 lesion volume (baseline to wk 120)	3.4%	
	Whole brain volume (wk 24 to wk 120)	17.5%	

- First and only investigational medicine to suppress disease progression in both RMS and PPMS
- Results confirm B cells play a central role in MS
- US/EU filing for RMS and PPMS on track for H1 2016



## Emicizumab (ACE910) in hemophilia A First-patient-in achieved in inhibitor study

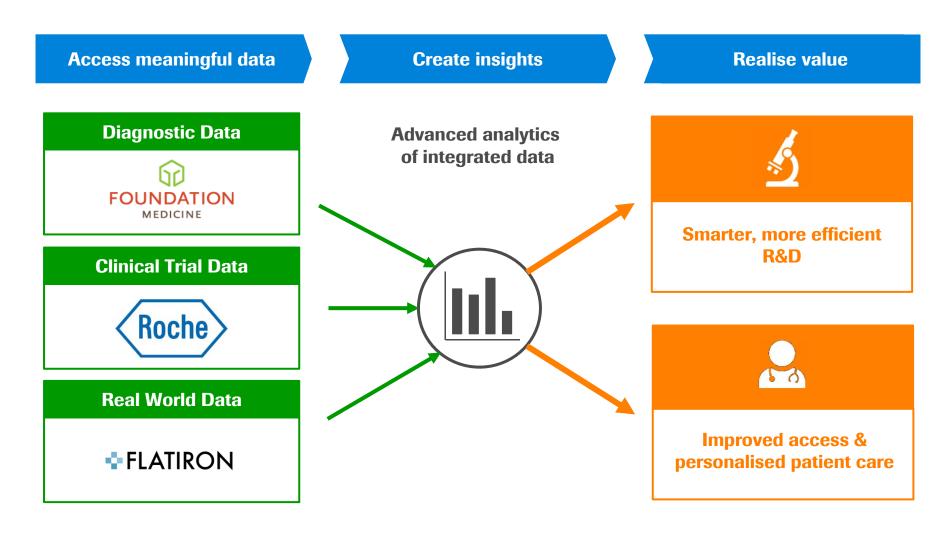




- First-patient-in in the inhibitor phase III study achieved
- Inhibitor non-interventional study has recruited >90 patients and will be expanded to non-inhibitors
- Non-inhibitor and pediatrics studies expected to start in 2016
- New data at ASH 2015: Patient underwent surgery without need for any Factor VIII replacement therapy



## Strengthening Pharma through collaborations Data analysis driving innovation and efficiencies





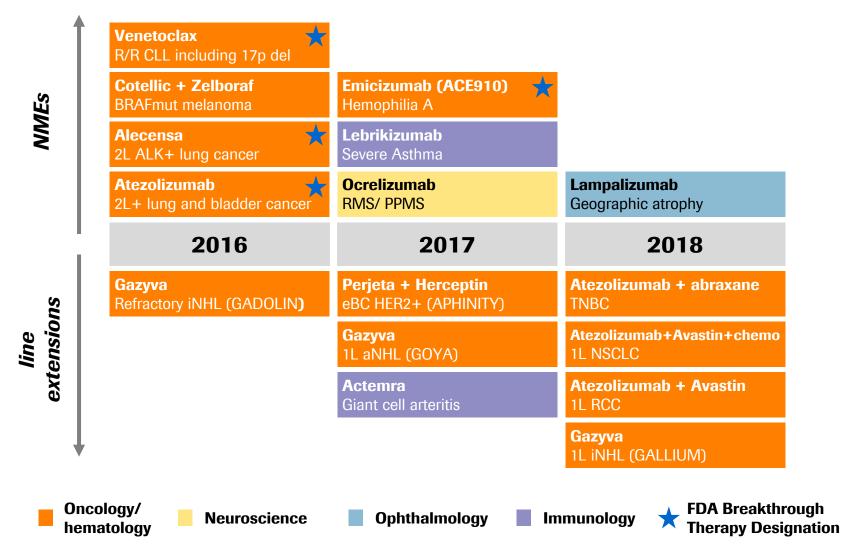
### 2015 results

### **Innovation**

## **Outlook**



### 2016 onwards: Significant launch activities





## 2016: Key late-stage news flow

	Compound	Indication	Milestone
Danielatani	Gazyva	MabThera/Rituxan-refractory iNHL	US/EU approval
	venetoclax	R/R CLL	US approval
	ocrelizumab	RMS/PPMS	US/EU filing
Regulatory	atezolizumab	Bladder cancer	US approval
	atezolizumab	2/3L NSCLC	US approval
	Alecensa	2L ALK+ NSCLC	EU approval
	lebrikizumab	Severe asthma	Ph III LAVOLTA I/II
	atezolizumab	2/3L NSCLC	Ph III OAK
Phase III readouts*	Gazyva	Front-line aNHL	Ph III GOYA
Phase III Teauouts	Perjeta + Herceptin	Adjuvant HER2+ BC	Ph III APHINITY
	Actemra	Giant cell arthritis	Ph III GiACTA
	Alecensa	1L ALK+ NSCLC	Ph III ALEX
	lebrikizumab	Atopic dermatitis	Ph II TREBLE, ARBAN
	atezolizumab	Bladder cancer	Ph II IMvigor 210 (1L cohort)
Phase II readouts*	atezolizumab + Avastin	1L Renal cancer	Ph II Immotion 150
	venetoclax	R/R FL (iNHL)	Ph II CAVALLI
	venetoclax	1L aNHL	Ph II CONTRALTO

<sup>\*</sup> Outcome studies are event driven, timelines may change



Diagnostics Division
Roland Diggelmann
COO Roche Diagnostics





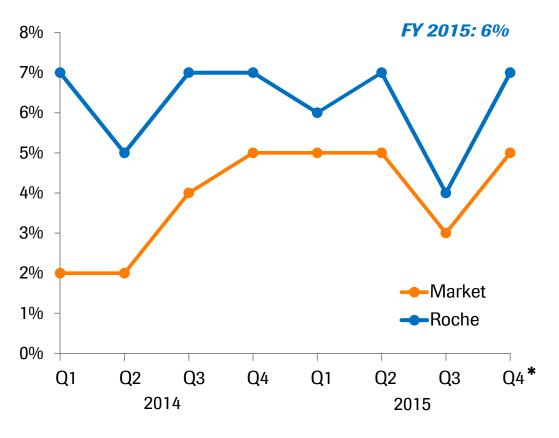
# **2015: Diagnostics sales** *Strong sales performance*

	2015	2014	Change	Change in %	
	CHFm	CHFm	CHF	CER	
<b>Diagnostics Division</b>	10,814	10,766	0	6	
Professional Diagnostics	6,175	6,045	2	8	
Diabetes Care	2,128	2,392	-11	-3	
Molecular Diagnostics	1,719	1,613	7	10	
Tissue Diagnostics	792	716	11	12	



## Roche outgrowing the market in a challenging environment

### **Quarterly growth (%)**



- Worldwide IVD market leader
- Strong commercial presence
- Broadest test menu



## **2015: Diagnostics regional sales** *Growth driven by APAC and EMEA*



+3%

26% of divisional sales

### EMEA<sup>1</sup>

+4%

42% of divisional sales

### Japan

0%

4% of divisional sales

### **Latin America**

+11%

7% of divisional sales

### **Asia Pacific**

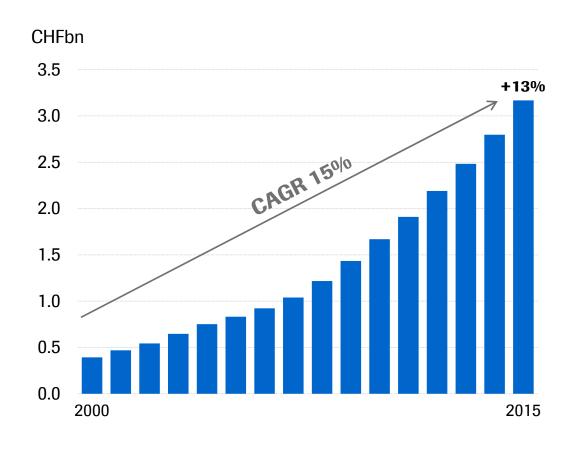
+15%

21% of divisional sales

### 14% growth in E7 countries<sup>2</sup>



## Immunodiagnostics: 15 years of consecutive double digit growth



#### **Continuous extension**

- 100+ assays
- Largest installed instrument base
- Mfc capacity expansion in 2015

#### Outlook

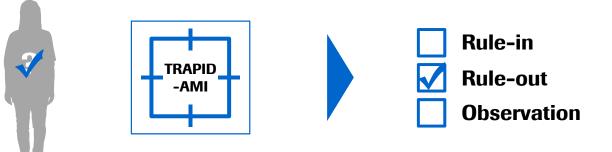
- Launch of cobas e801 instrument: Double throughput with same footprint
- New reagent plant in China



## **Elecsys Troponin T high sensitive (TnT-hs)**

Safe and effective AMI\* rule-in and rule-out in 1

hour\*\*



Reduces diagnosis time to 1h in 76-78% of acute chest pain patients



**Enables faster treatment decisions and reduced ER waiting times** 

<sup>\*</sup> AMI: acute myocardial infarction; \*\* 1 hour refers to time for analysis between two samples



## Molecular Diagnostics: cobas 6800/8800 US launch of instruments and viral load tests\*

**cobas** 6800

# Blood Screening Wirology Menu Expansion MPX (HIV, HCV, HBV) West Nile Virus DPX (B19 & HAV) Hepatitis B Hepatitis C HIV 1/2 Qualitative MTB/MAI & RIF/INH

- Fully automated PCR systems
- Highest throughput (3x above closest competitor)
- Highest walk-away time to increase lab efficiency

**cobas 8800** 

<sup>\*</sup> US approved tests for cobas 6800/8800: HBV, HCV and HIV-1



# Tissue Diagnostics: Launch of VENTANA HE 600 Potential to change standard of care in H&E\* staining



- Latest platform with individual slide staining technology, avoids sample cross contamination
- Platform features:
  - Highest result quality and reproducibility
  - Highest test capacity and most efficient workflow
  - Easy and safe to operate



## Diabetes Care: Challenging US market Launch of innovative products in 2016

#### **Challenges in 2015:**

US: Spillover effect of Medicare prices to private sector

#### **Opportunities in 2016:**

- Product launches
  - Accu-Chek Guide: New blood glucose monitoring device with universal test strip for improved accuracy
  - Accu-Chek Insight CGM\*: New sensor technology
- Growth prospect
  - Insulin Delivery Systems: Sustaining current growth momentum





#### **Key launches 2016**



	Area	Product	Market
Instruments / Devices	Central Laboratory	cobas 8000 <e 801=""> - high throughput immunochemistry analyzer cobas c 513 - high throughput dedicated HbA1c analyzer</e>	EU US
	Point of Care	CoaguChek INRange (Zenith) – modified analyzer for intuitive self testing with full blue tooth connectivity	EU
	Sequencing	Roche SMRT Sequencer – single molecule sequencer for clinical research (in collaboration with Pacific Biosciences)	WW
	Diabetes Care	Accu-Chek Guide – next-generation blood glucose monitoring system  Accu-Chek Insight CGM – new high-performance continuous glucose monitoring system	EU EU
Tests / Assays	Virology	cobas 6800/8800 HIV Qual - early Infant Diagnosis and Confirmatory HIV Test	EU
	HPV / Microbiology	cobas 6800/8800 CT/NG - fully automated solution for screening and diagnosis of Chlamydia trachomatis and Neisseria gonorrhoeae in symptomatic & asymptomatic patients	' EU
	Point of Care	cobas Liat Influenza A/B plus RSV (CLIA) – automated multiplex real time RT-PCR assay for qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV)	US
	Sequencing	ctDNA oncology panels - liquid biopsy for circulating tumor DNA for cancer therapy selection	US
	Companion Diagnostics	PD-L1 (SP142) for Bladder Cancer* - companion diagnostic for atezolizumab PD-L1 (SP142) for NSCLC* - companion diagnostic for atezolizumab	US US

<sup>\*</sup> achieve commercial readiness, dependent on Pharma label and approval



# Finance Alan Hippe Chief Financial Officer



#### **2015: Highlights**



#### **Business**

- Strong sales growth of +5%1 and Core EPS growth +7%1 excluding filgrastim2
- Core operating profit up +5%<sup>1</sup>, excluding filgrastim<sup>2</sup> +7%<sup>1</sup>
- Dividend in Swiss franc and payout ratio further increased

#### **Cash flow**

- Cash generation remains strong (Op. FCF of CHF 14.9bn) despite expanding manufacturing network and investments in intangible assets
- Accounts receivable in Southern Europe further decreased

#### **Debt restructuring**

- Attractive financing conditions in capital markets used for major debt restructuring
  - Total major restructuring of USD 0.9bn and EUR 0.4bn in 2015
- Lower interest expenses of CHF 61m despite average gross debt of CHF 24bn in 2015 vs.
   CHF 21bn in 2014



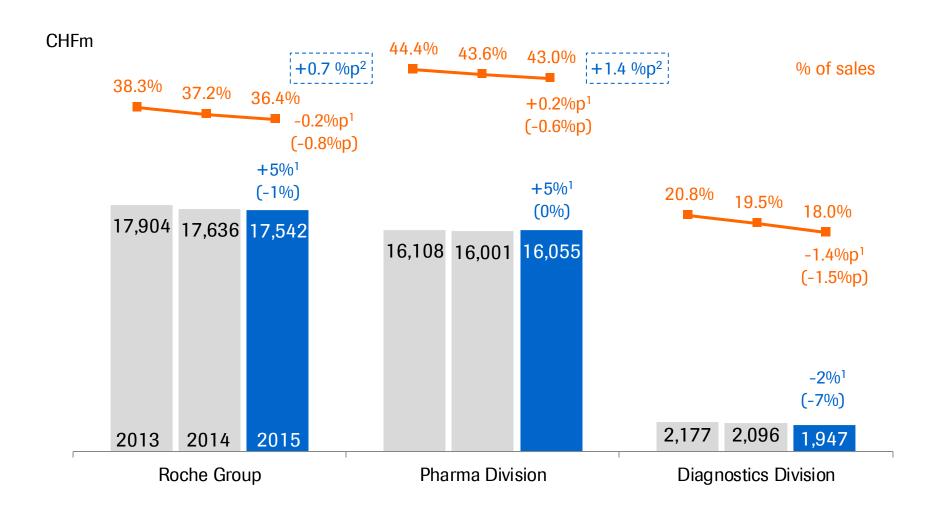
#### **2015: Group performance**

#### Core EPS growth +4%, +7% excluding filgrastim\*

	2015	2014	Change in %		Excl.	
	CHFm	CHFm	CHF	CER	filgrastim	
Sales	48,145	47,462	1	5		
Core operating profit as % of sales	<b>17,542</b> 36.4	<b>17,636</b> <i>37.2</i>	-1	5	7	
Core net income as % of sales	<b>11,837</b> 24.6	<b>12,533</b> <i>26.4</i>	-6	1	4	
Core EPS (CHF)	13.49	14.29	-6	4	7	
IFRS net income	9,056	9,535	-5	4		
Operating free cash flow as % of sales	<b>14,872</b> 30.9	<b>15,778</b> <i>33.2</i>	-6	-7		
Free cash flow as % of sales	<b>3,352</b> 7.0	<b>5,322</b> <i>11.2</i>	-37	-41		



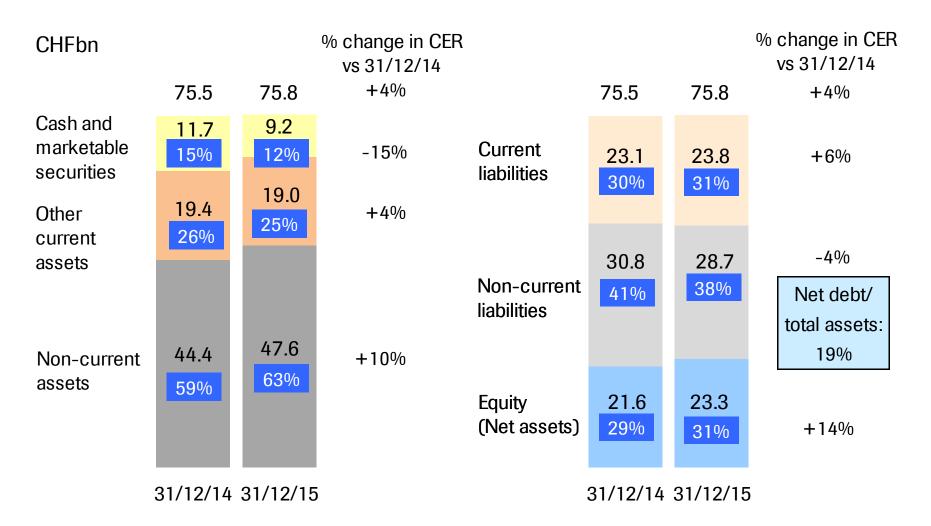
#### 2015: Strong Core operating profit and margin



<sup>&</sup>lt;sup>1</sup> At CER=Constant Exchange Rates; <sup>2</sup> Excluding sale of filgrastim rights in 2014

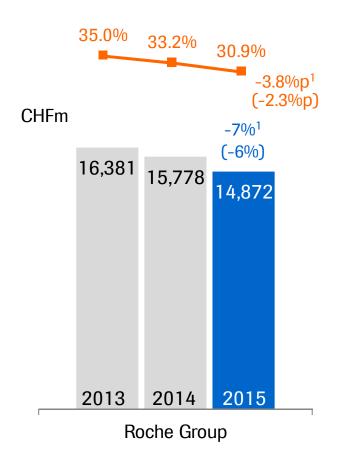
#### **Balance sheet 31 December 2015**







#### 2015: Operating free cash flow and margin

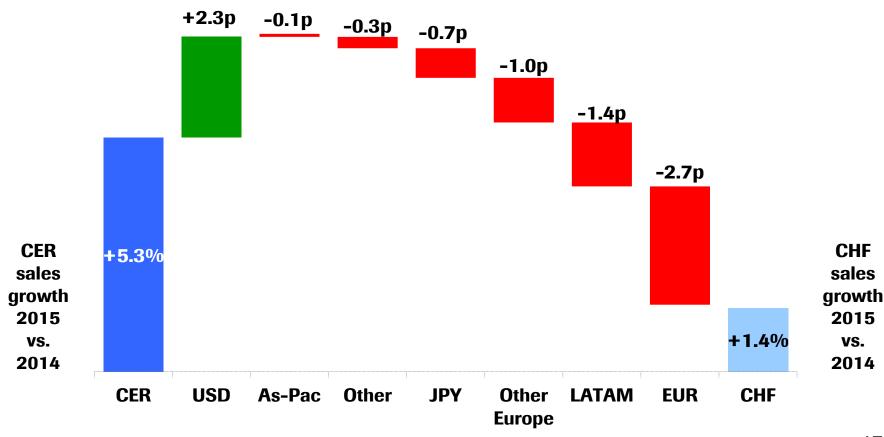


- Capex driven by expanding manufacturing network
- Investments in intangible assets

<sup>1</sup> At CER=Constant Exchange Rates 46

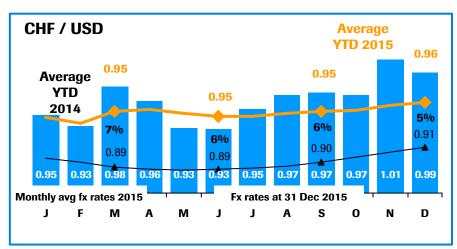


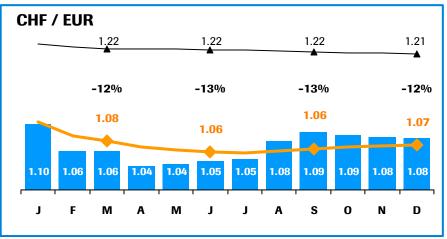
# Exchange rate impact on sales growth Negative impact from EUR, LATAM and Europe more than offsetting positive impact of USD



#### **Currency impact in 2015/2016**







#### In 2015 impact<sup>1</sup> is (%p):

	Q1	НҮ	Sep YTD	FY
Sales	-2	-3	-4	-4
Core operating profit		-4		-6
Core EPS		-7		-10

In 2016 currency impact<sup>1</sup> expected is (based on **31 Dec 2015** FX rates):

- No FX impact on sales
- -2%p on Core OP and up to -5%p on Core EPS

<sup>&</sup>lt;sup>1</sup> On Group growth rates

#### 2016 outlook



**Group sales growth**<sup>1</sup>

Low to mid-single digit

Core EPS growth<sup>1</sup>

Ahead of sales growth

**Dividend outlook** 

Further increase dividend in Swiss francs



### Doing now what patients need next