
Roche

Roche

2013 results

London, 30 January 2014

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1 pricing and product initiatives of competitors;
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;
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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

2013 performance

Outlook

2013: Targets fully achieved

Targets for 2013		*FY 2013*	
Group sales	In line with sales growth recorded in 2012[1]	**+6%**	✓
Core EPS	Ahead of sales growth[1]	**+10%**	✓
Dividend	Further increase dividend	**CHF 7.80 +6%**	✓

[1]At constant exchange rates
Excluding one-off Past Service Income impact of CHF 236m on core net income and excluding 340B reserve release impact of CHF 182m on sales and CHF 94m on core net income
2013 dividend as proposed by the Board of Directors

2013 Highlights

Innovation

- HER2 franchise secured through Kadcyla, Perjeta and Herceptin SC
- Haematology franchise strengthened through Gazyva in CLL
- 15 compounds in late-stage development, strong emerging portfolio in immunology/ophthalmology
- Cobas 8100 next generation automation system launched

Growth

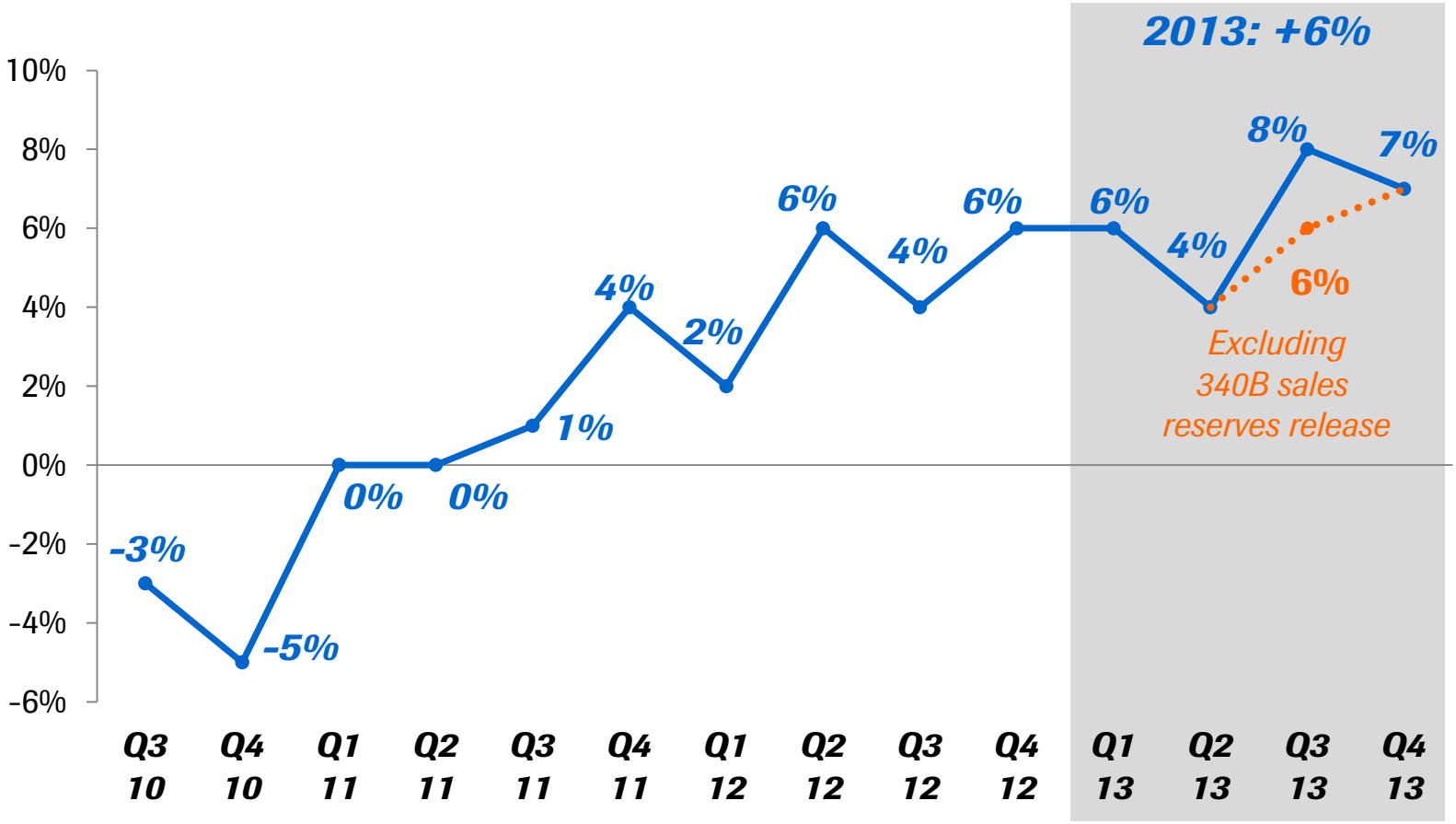
- 3 major new medicine launches: Perjeta in EU, Kadcyla in US and EU, Gazyva in US
- Strong growth for oncology franchise, Actemra and Lucentis
- Further financial deleverage contributing to EPS momentum

2013: Strong sales growth

	2013 CHFbn	2012 CHFbn	Change in % CHF	Change in % CER
Pharmaceuticals Division	**36.3**	35.2	**3**	**7**
Diagnostics Division	**10.5**	10.3	**2**	**4**
Roche Group	**46.8**	45.5	**3**	**6**

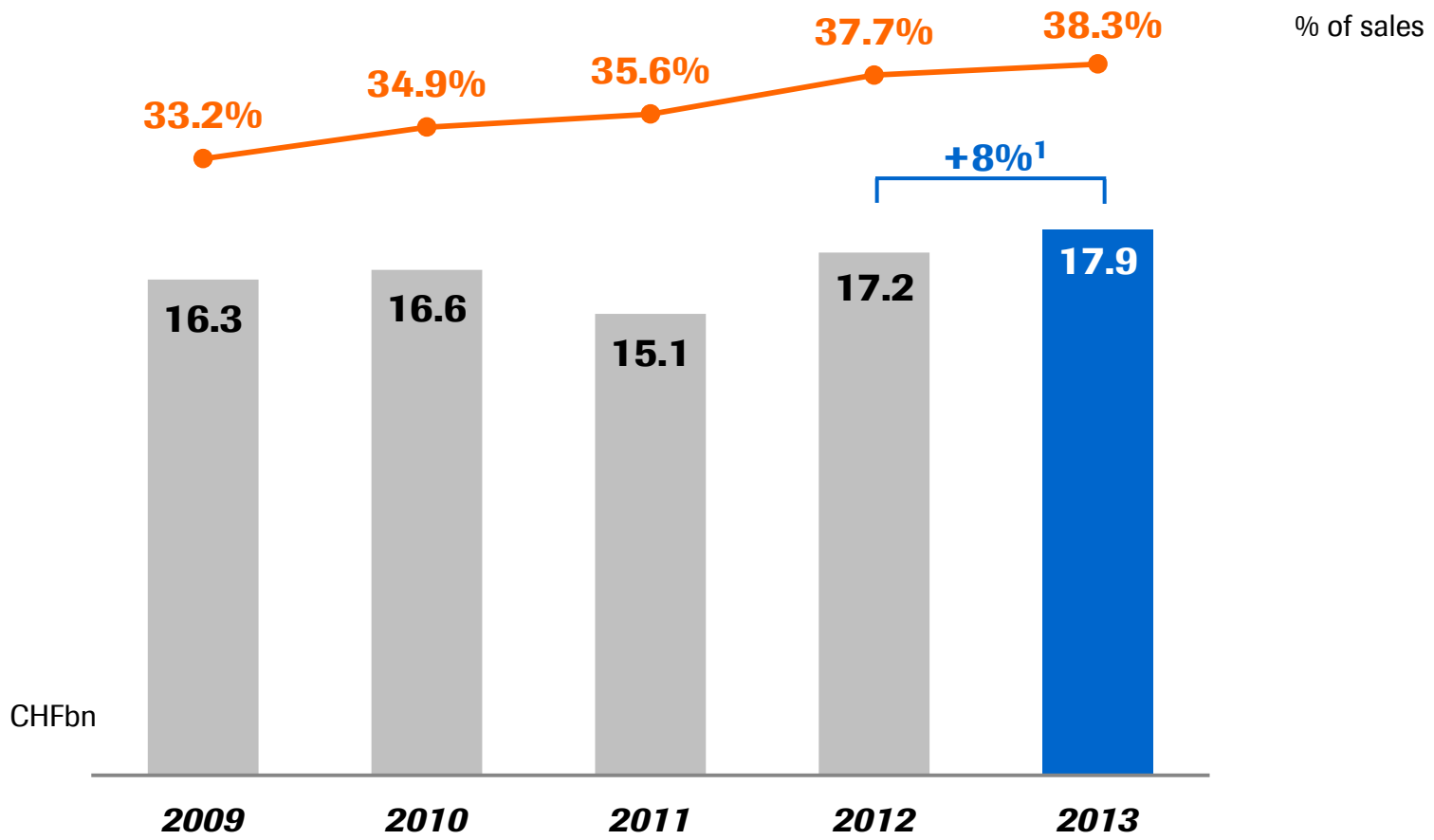
CER=Constant Exchange Rates

Group: Strong sales growth sustained



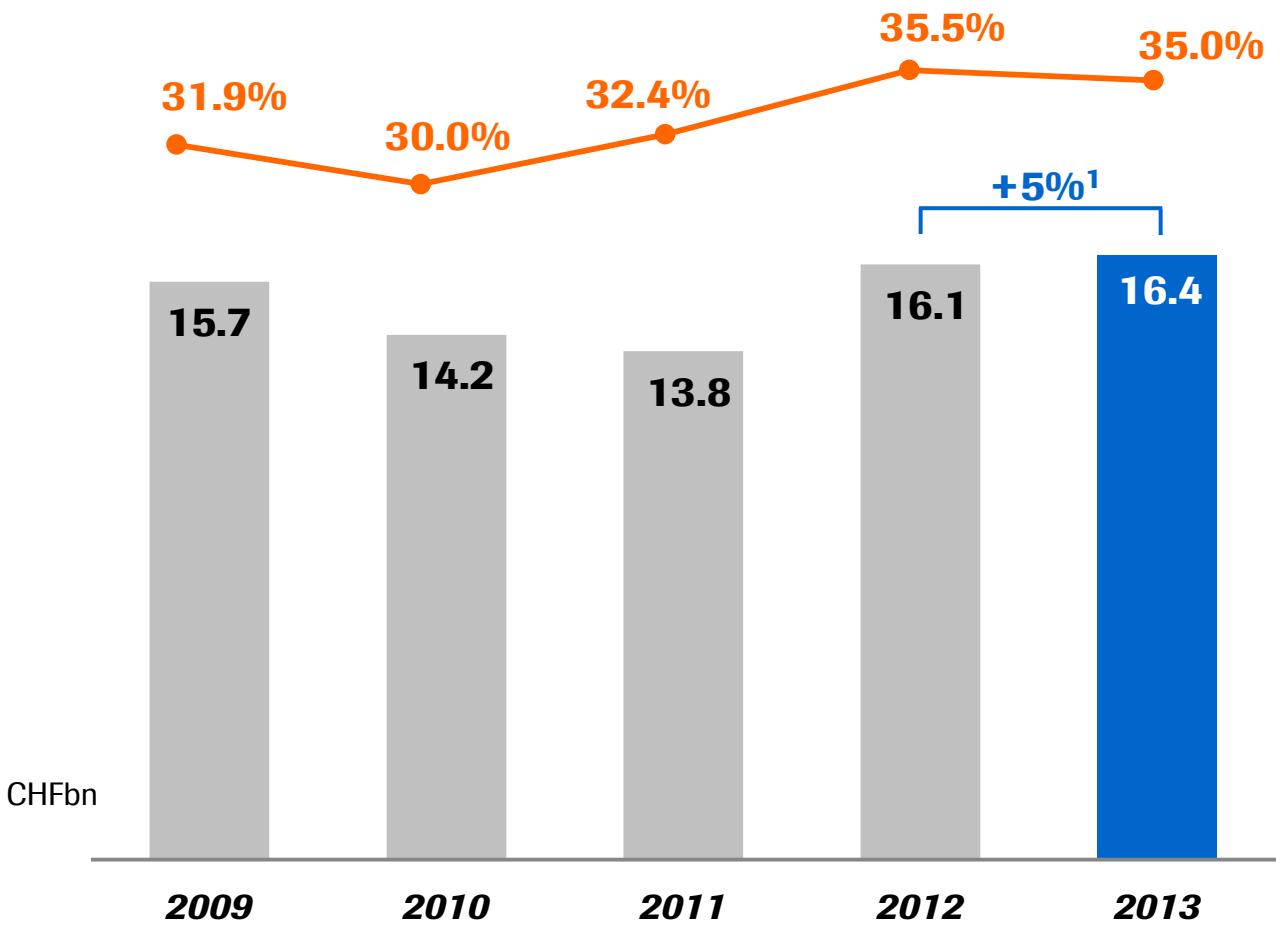
All values at constant exchange rates

Group operating profit and margin



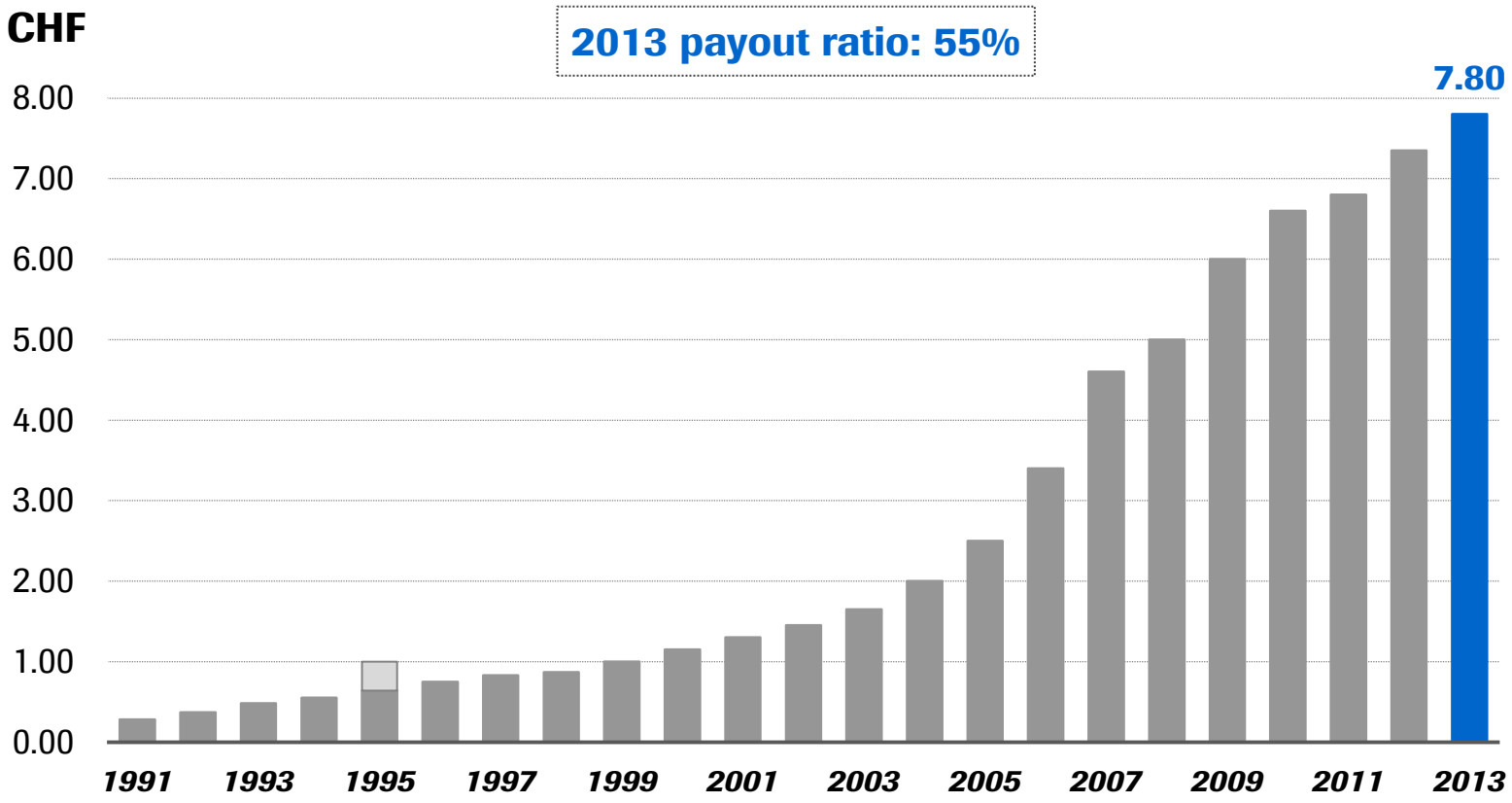
[1] At constant exchange rates

Strong operating free cash flow



[1] At constant exchange rates

2013: Dividend further increased

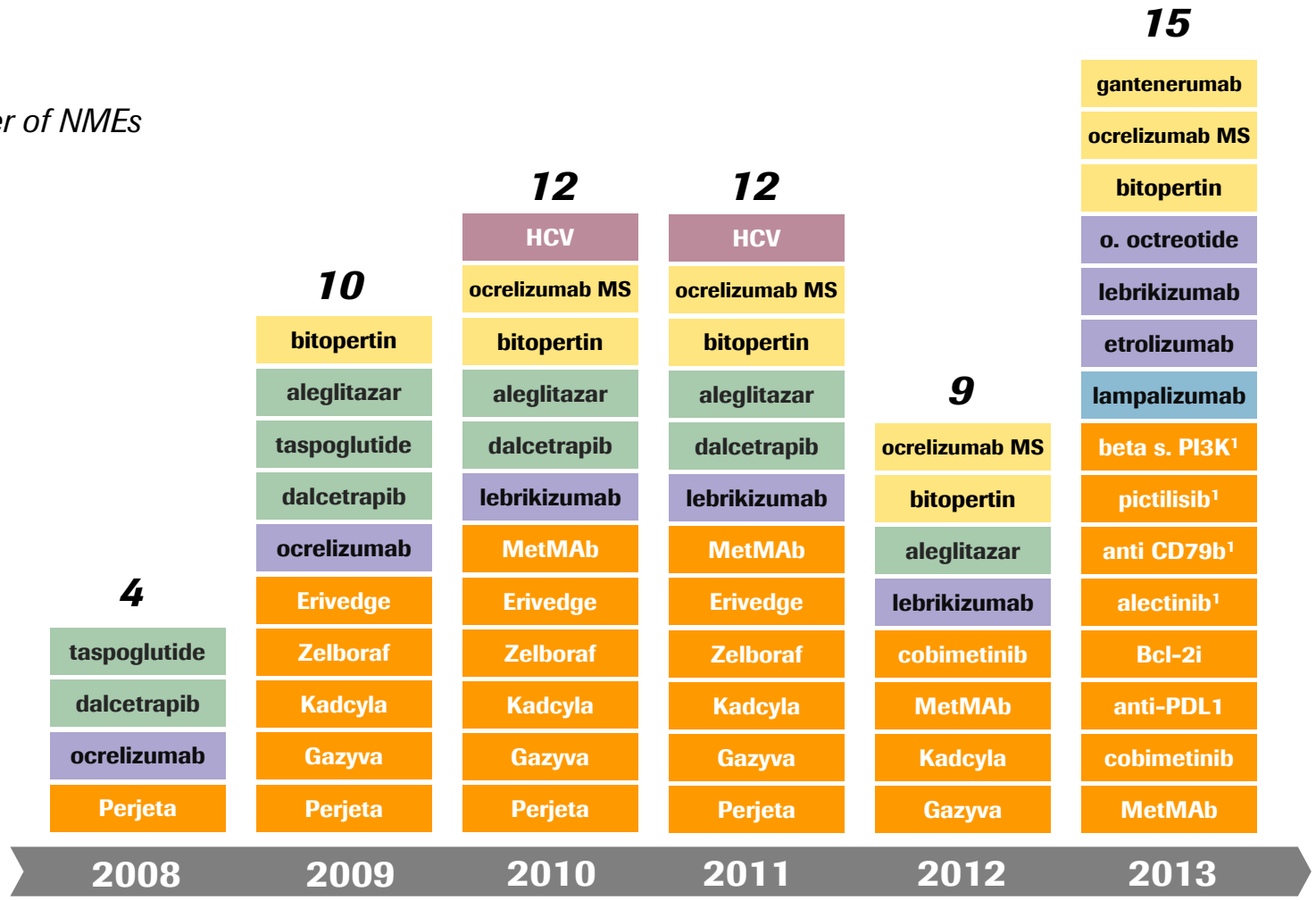


Pay-out ratio calculated as dividend per share divided by core earnings per share (diluted); 2013 as proposed by the Board of Directors

A leading pipeline

15 NMEs in late-stage development

Number of NMEs



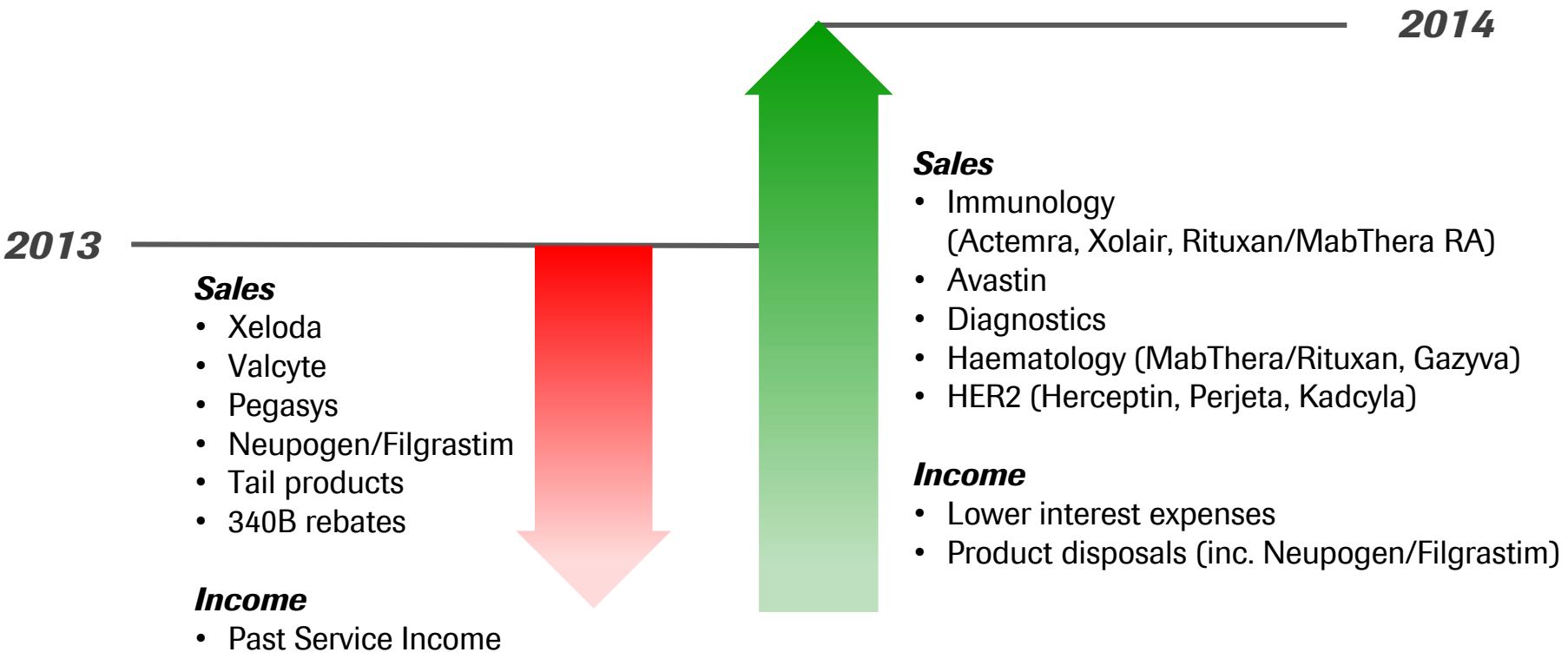
Oncology
Neuroscience
Ophthalmology
Immunology
CardioMetabolism

[1] Phase III decision pending

2013 performance

Outlook

2014 outlook: New and established products enable growth despite patent losses



2014 Outlook

Group sales growth[1]	Low- to mid-single digit
Core EPS growth[1]	Ahead of sales growth
Dividend outlook	Further increase dividend

[1]At constant exchange rates

Pharmaceuticals Division

Daniel O'Day

COO Roche Pharmaceuticals

2013 results

Innovation

Outlook

2013: Pharma sales

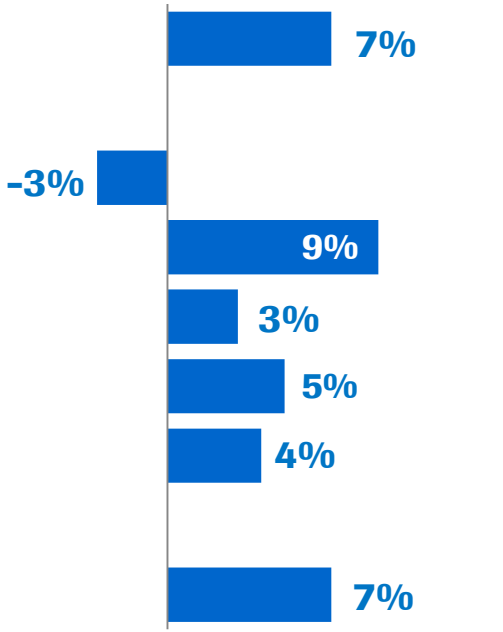
Strong growth in US and International

	2013 CHFm	2012 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**36,304**	**35,232**	**+3**	**+7**
United States	15,097	13,856	+9	+10
Europe	9,254	8,952	+3	+2
Japan	3,405	4,108	-17	+2
International	8,548	8,316	+3	+8

CER=Constant Exchange Rates

2013: Pharma Division
Profit driven by higher sales

	2013 CHFm	2013 % sales
Sales	**36,304**	**100.0**
Royalties & other op inc	1,702	4.7
Cost of sales	-7,353	-20.2
M & D	-5,795	-16.0
R & D	-7,683	-21.2
G & A	-1,067	-2.9
Core operating profit	**16,108**	**44.4**



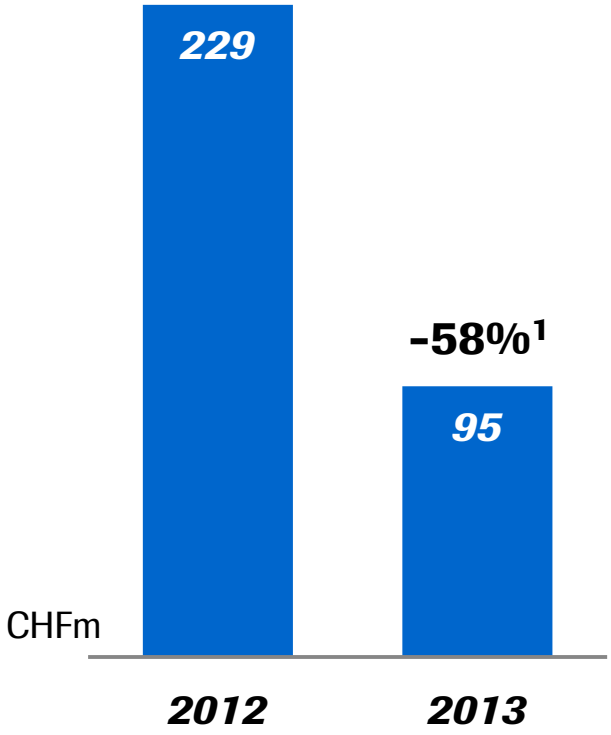
+4% in CHF

CER=Constant Exchange Rates

2012–2013 product disposals

Impact on Royalties and other operating income

Income from disposals and other

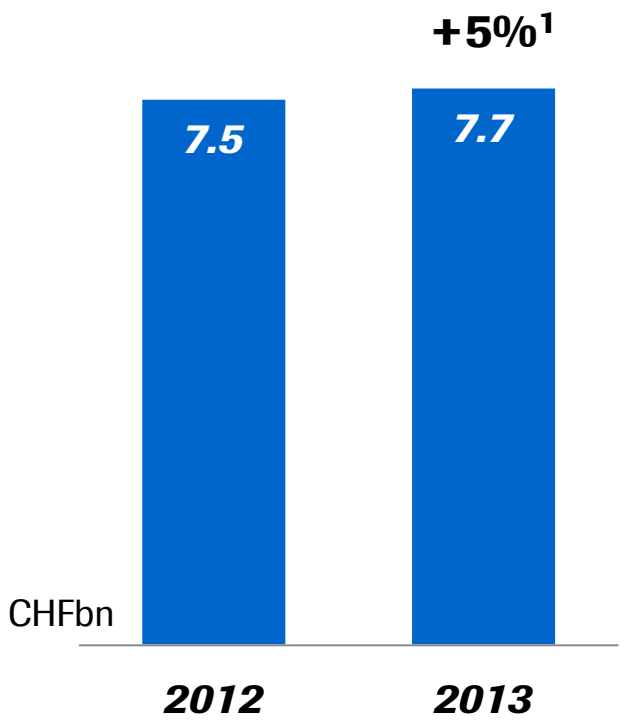


- Ostac, Rocaltrol, Vesanoid, Rohypnol divested in 2012
- CHF ~132m lower income from disposals in 2013

[1] At constant exchange rates

Research and development

Pharma R&D investment

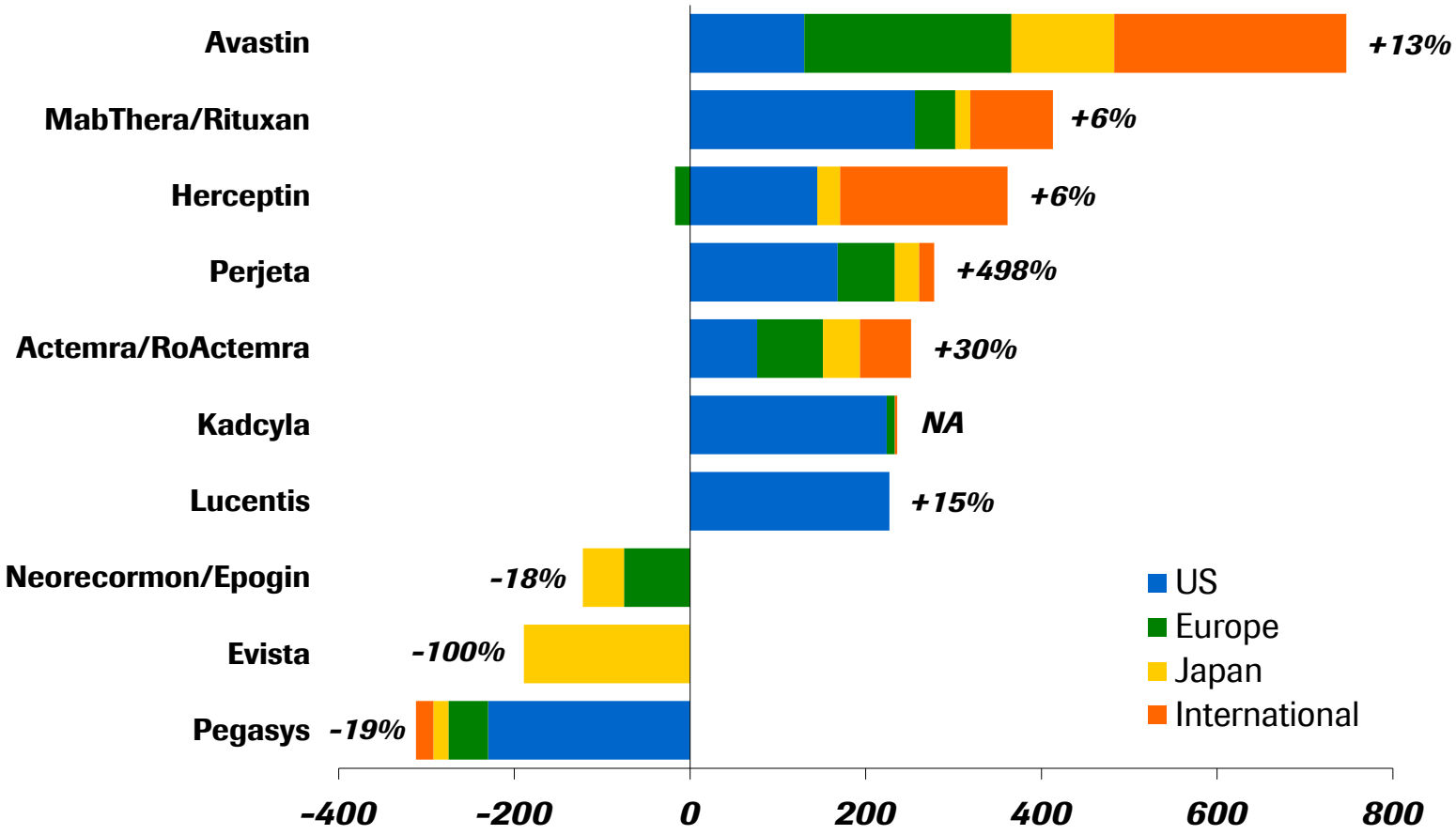


- Higher number of projects in late-stage clinical development
- Increased technical development investment in early-stage projects
- Investment in post-approval studies (Ph IV) after recent launches of new medicines and meeting increasing compliance requirements

[1] At constant exchange rates

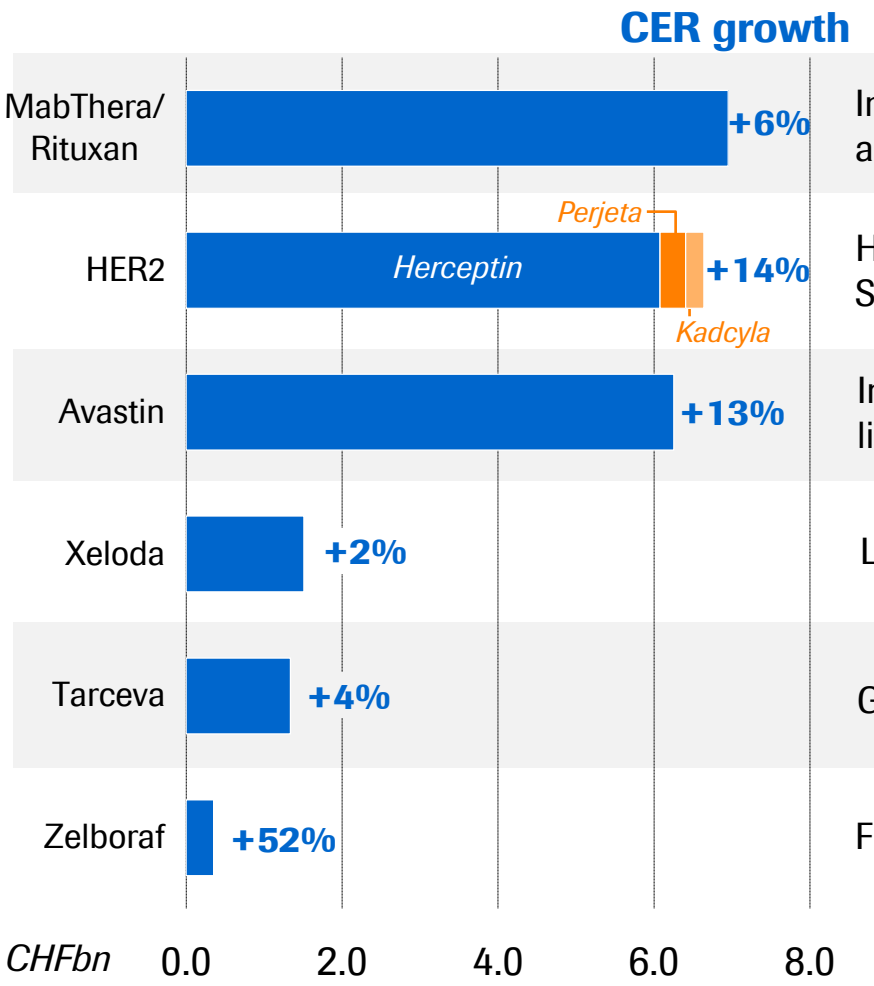
2013: Pharma sales

Oncology, Actemra and Lucentis main growth drivers



Absolute amounts and growth rates at constant exchange rates (2012)

2013 sales: Oncology franchise up 10%

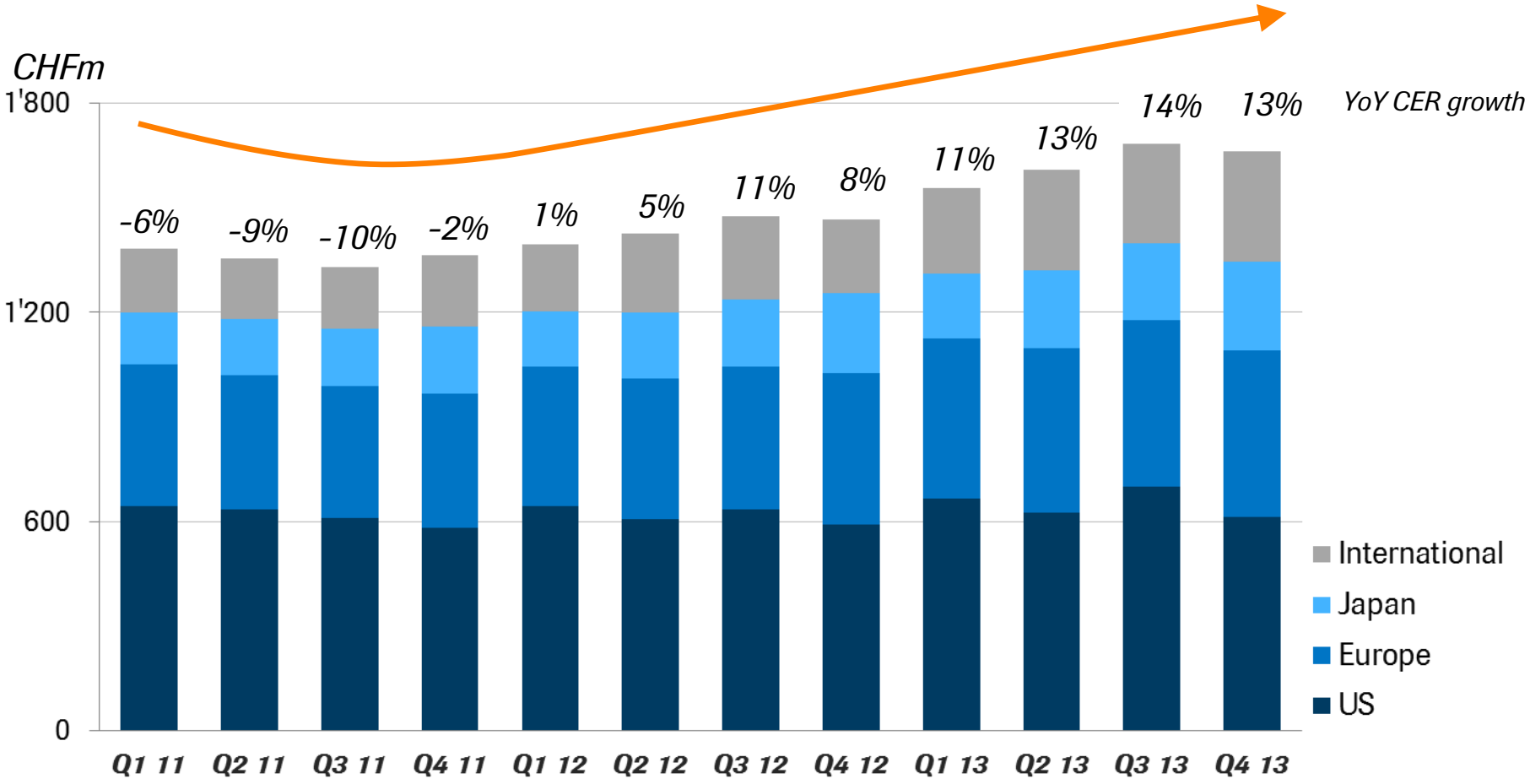


MabThera/ Rituxan	Increased usage across a variety of indications in Europe and growing use in DLBCL patients in China
HER2	Herceptin volume growth driven by Asia and LatAm. Strong uptake of Perjeta and Kadcyla
Avastin	Increased use in mCRC due to treatment through multiple lines label, continued uptake in ovarian cancer (EU)
Xeloda	Loss of exclusivity in EU (Dec 2013) and US (Feb 2014)
Tarceva	Good uptake in 1st line EGFR mut+ NSCLC
Zelboraf	Fully penetrated in US, strong growth in Europe

CER=Constant Exchange Rates

Oncology 2013 sales: CHF 22.5bn

Avastin: Continued uptake in ovarian cancer and treatment through multiple lines in mCRC



Absolute amounts and growth rates at constant exchange rates (2012)

HER2 franchise: Innovative therapies define new standard of care

PERJETA™

- Sales growth driven by metastatic BC
- Continued increase in 1L HER2+ mBC
- US approval of neo-adjuvant HER2+ BC
- Encouraging rollout in Europe

Kadcyla
trastuzumab emtansine

- Strong US uptake in HER2+ mBC 2nd line and beyond
- Continued increase in patient share
- Launched in some European countries

Herceptin SC
trastuzumab
subcutaneous

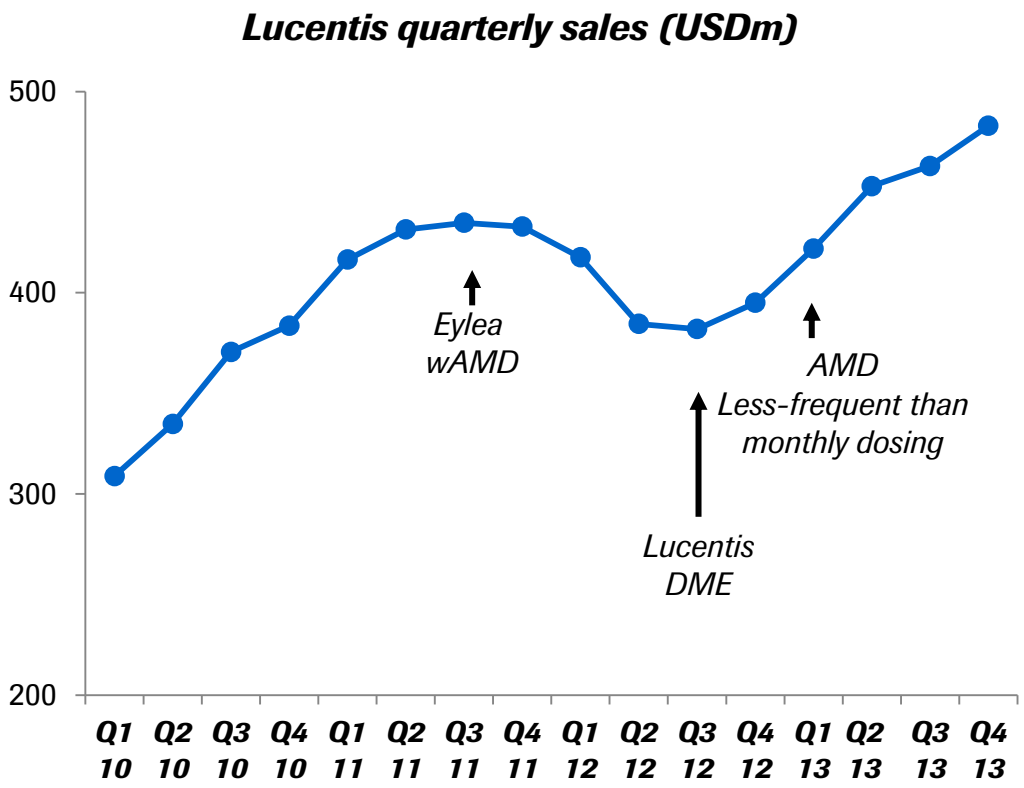
- Approval in Europe; positive feedback in centers where available

HER2 franchise: +14% growth[1] in 2013

[1] At constant exchange rates

Lucentis: Strong growth in 2013

Medical benefit and long-term safety proven in 27 clinical trials



AMD

- Benefit from label change in AMD

DME and RVO

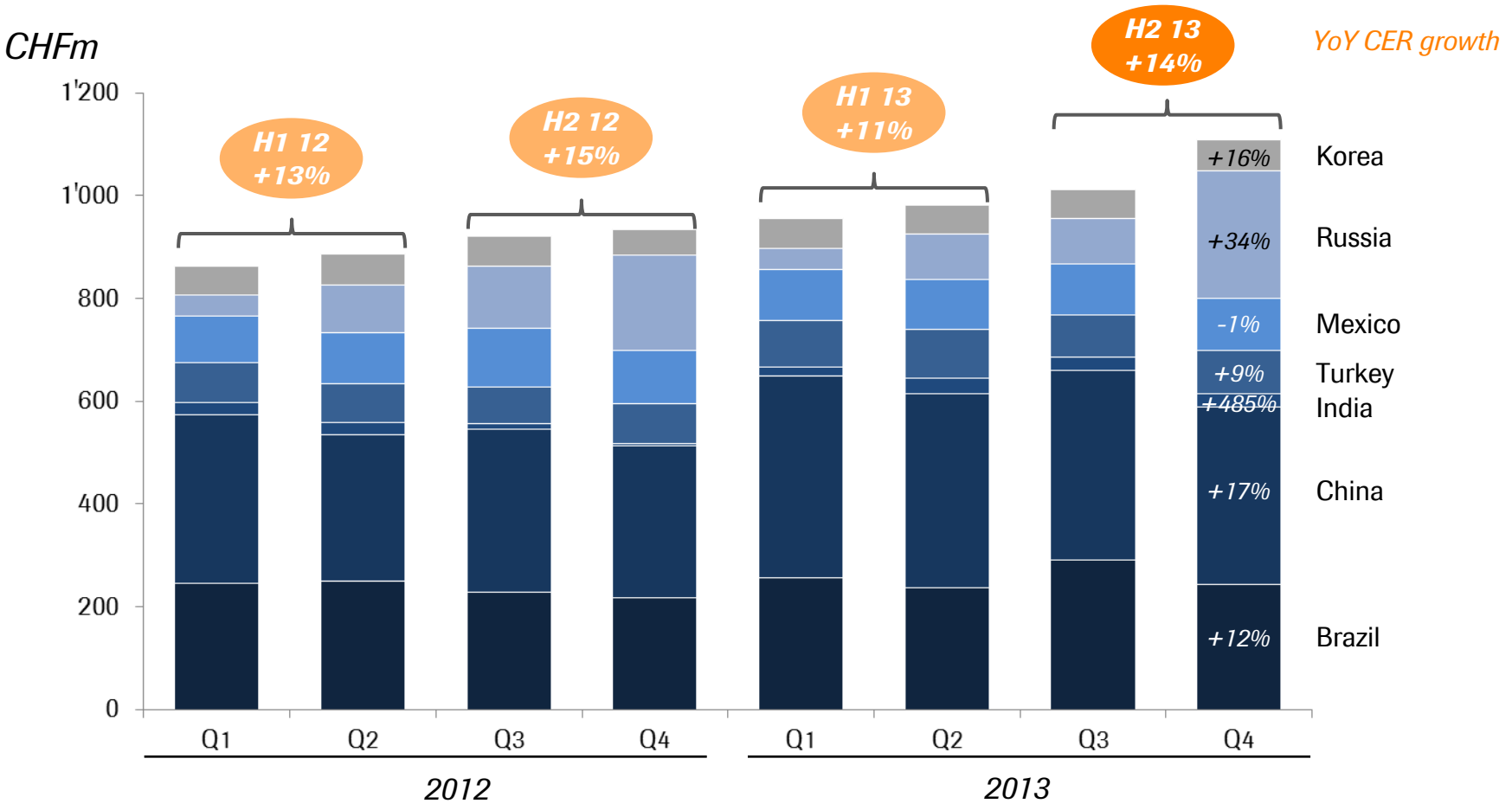
- Further increase in patient share

2014 Outlook

- Benefit from the overall AMD market growth
- Potential competition in DME (~15% Lucentis sales)

AMD=wet age-related macular degeneration; RVO=retinal vein occlusion; DME=diabetic macular edema

E7 Pharma sales: Emerging markets remain strong



CER=Constant Exchange Rates

2013 results

Innovation

Outlook

2013: Major clinical and regulatory news flow

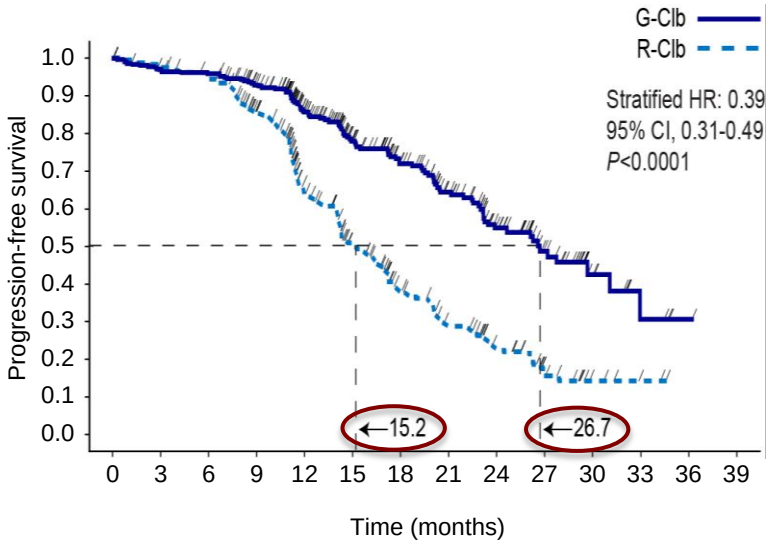
	Compound	Indication	Milestone
Regulatory	***Avastin***	mCRC (TML)	US ✓ EU ✓ approval
	Avastin	Newly diagnosed glioblastoma	EU filing ✓
	Actemra subcutaneous	RA	US approval ✓
	Erivedge	Advanced BCC	EU approval ✓
	Herceptin subcutaneous	HER2-positive BC	EU approval ✓
	Lucentis	wAMD (HARBOR)	US approval ✓
	Perjeta	1st line HER2-positive mBC	EU approval ✓
	Perjeta	Neoadjuvant HER2+ BC	US filing ✓ US approval ✓
	Tarceva	EGFR mut+ 1st line NSCLC	US approval ✓
	Kadcyla	2nd line HER2-positive mBC	US ✓ EU ✓ approval
	Gazyva (GA101)	Front line CLL	US approval ✓
Phase III	***aleglitazar***	Metabolic diseases	Ph III ✗
	Gazyva (GA101)	Front line CLL	Ph III ✓
	Tarceva	Adjuvant NSCLC	Ph III RADIANT ✗
	Xolair	Chronic idiopathic urticaria	Ph III ✓ US filing ✓

Milestones previously expected later than 2013

Outcome studies are event driven, timelines may change

Haematology franchise
Establishing a new standard of care

Gazyva vs. MabThera/Rituxan in CLL
(combo with chlorambucil)



US approval Nov 2013
Included in NCCN guidelines

Bcl-2 inhibitor (ABT/GDC-199)

- Ph II in CLL patients with 17p deletion: expect data 2014/15
- TLS mitigation program on track: final measures to be decided mid-2014
- Ph III in combination with Gazyva in front-line CLL expected to start Q4 2014

- Gazyva: Several combination studies with new promising agents in preparation (Investigator sponsored studies and studies sponsored by other companies)

Bcl-2 inhibitor ABT/GDC-199 in collaboration with AbbVie

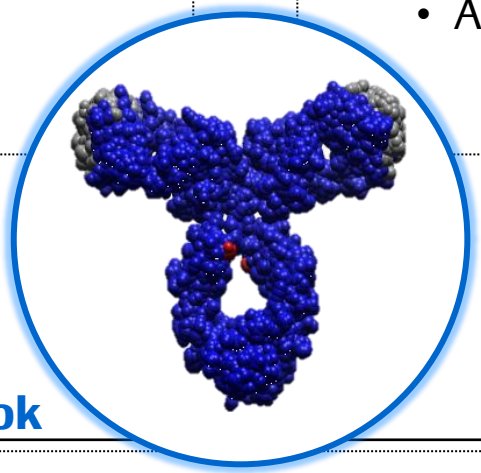
Anti-PDL1

NSCLC & RCC

- Ph II FIR: expect data 2014/15
- Ph II POPLAR: expect data 2015
- Ph II BIRCH: expect data 2015
- Ph III OAK: expect data 2016
- Ph II in 1L RCC (±Avastin vs. sunitinib)

Ongoing combination studies

- Anti-PDL1+Avastin (±chemo) (solid tumours)
- Anti-PDL1+Tarceva (NSCLC)
- Anti-PDL1+Zelboraf (melanoma)
- Anti-PDL1+cobimetinib (solid tumours)

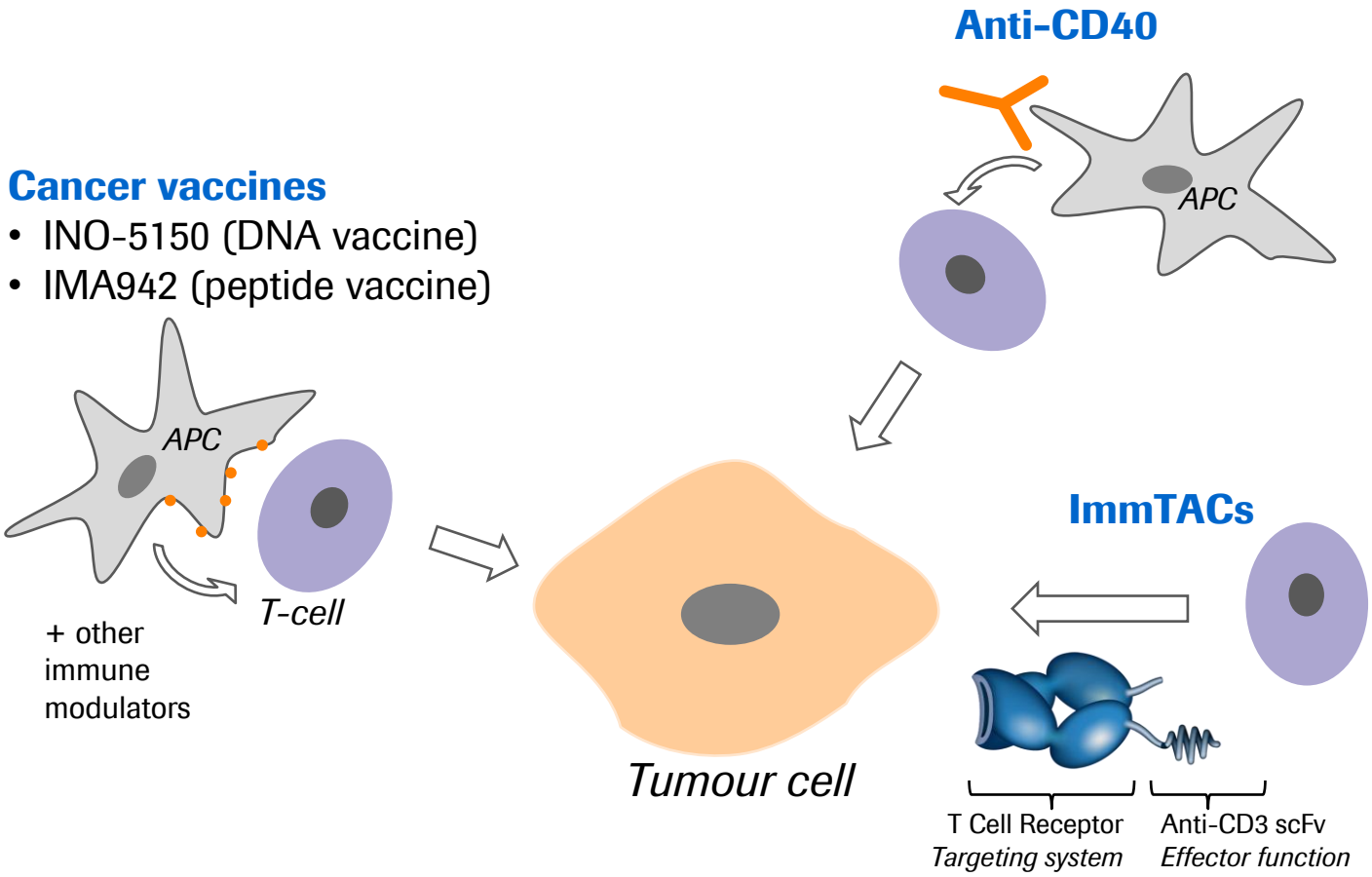


2014 outlook

- 1H: data in new tumour type
- Additional combinations, including immune doublets, starting throughout 2014

Immuno-oncology: Collaboration deals in 2013

Major focus areas

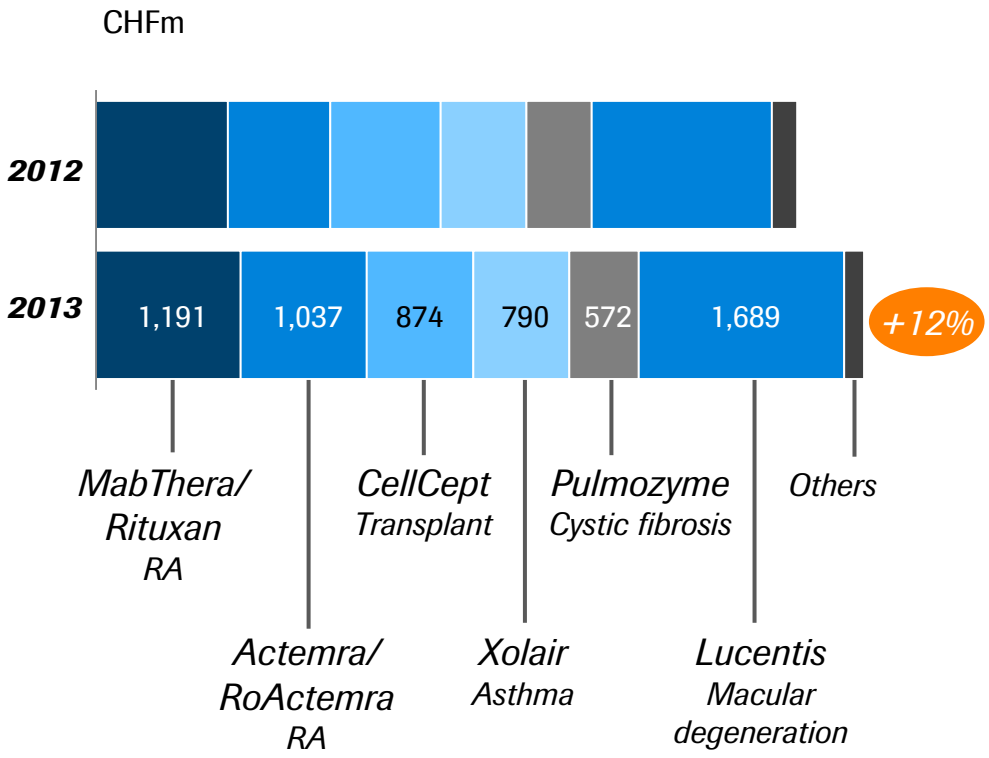


INO-5150 licenced from Inovio; IMA942 licenced from immatics; Anti-CD40 acquired from VLST; ImmTACs in collaboration with Immunocore; APC=Antigen Presenting Cell

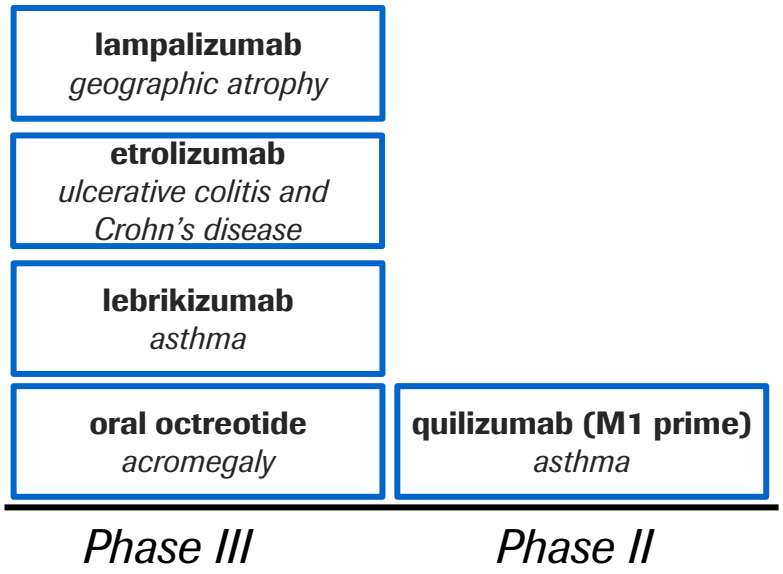
Immunology and Ophthalmology

New late-stage compounds in a well-established franchise

Growing existing franchise (CHF 6.3bn)



Developing pipeline



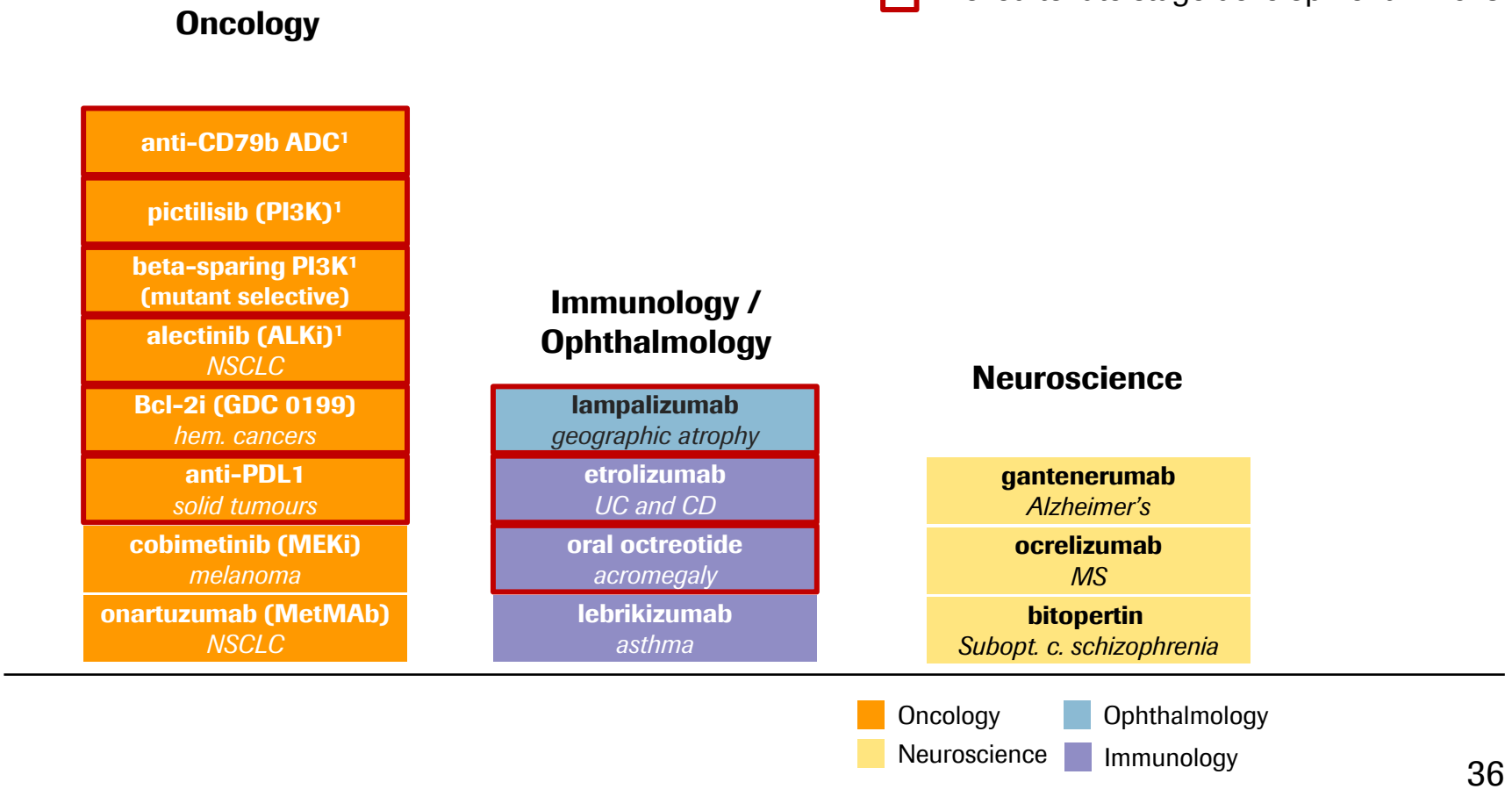
2013 results

Innovation

Outlook

2013: 15 new compounds in late stage development

Moved to late stage development in 2013



[1] Phase III decision pending

2014: Key late stage news flow – I

Regulatory milestones

Compound	Indication	Milestone
Actemra subcutaneous	Rheumatoid arthritis	EU approval
Avastin	Glioblastoma	EU approval
Avastin	Cervical cancer	US, EU filing
Avastin	Pt-resistant ovarian cancer	EU approval
MabThera subcutaneous	NHL	EU approval
obinutuzumab (GA101)	Front line CLL	EU approval
Xolair	Chronic idiopathic urticaria	US approval

Outcome studies are event driven, timelines may change

2014: Key late stage news flow – II

Major readouts

Compound	Indication	Milestone
bitopertin	Negative symptoms schizophrenia	Ph III ✘
cobimetinib (MEKi)	Met. melanoma	Ph III (combo w Zelboraf)
Kadcyla & Perjeta	HER2+ mBC (1 Line)	Ph III MARIANNE
onartuzumab (MetMAb)	Lung cancer (2/3L)	Ph III (combo w Tarceva)
oral octreotide	Acromegaly	Ph III
alectinib (ALKi)	NSCLC	Ph II
anti-HER3 EGFR DAF	Head and neck, colorectal cancer	Ph II (MEHGAN, DARECK)
anti-PDL1	Solid tumours	Ph I/II
crenezumab	Alzheimer's	Ph II
mGlu2/5	Neuroscience	Ph II
quilizumab (M1 prime)	Asthma	Ph II (COSTA)

Outcome studies are event driven, timelines may change

Diagnostics Division

Roland Diggelmann

COO Roche Diagnostics

2013 results and performance

Q4 highlights

Strategy & outlook

2013: Diagnostics sales

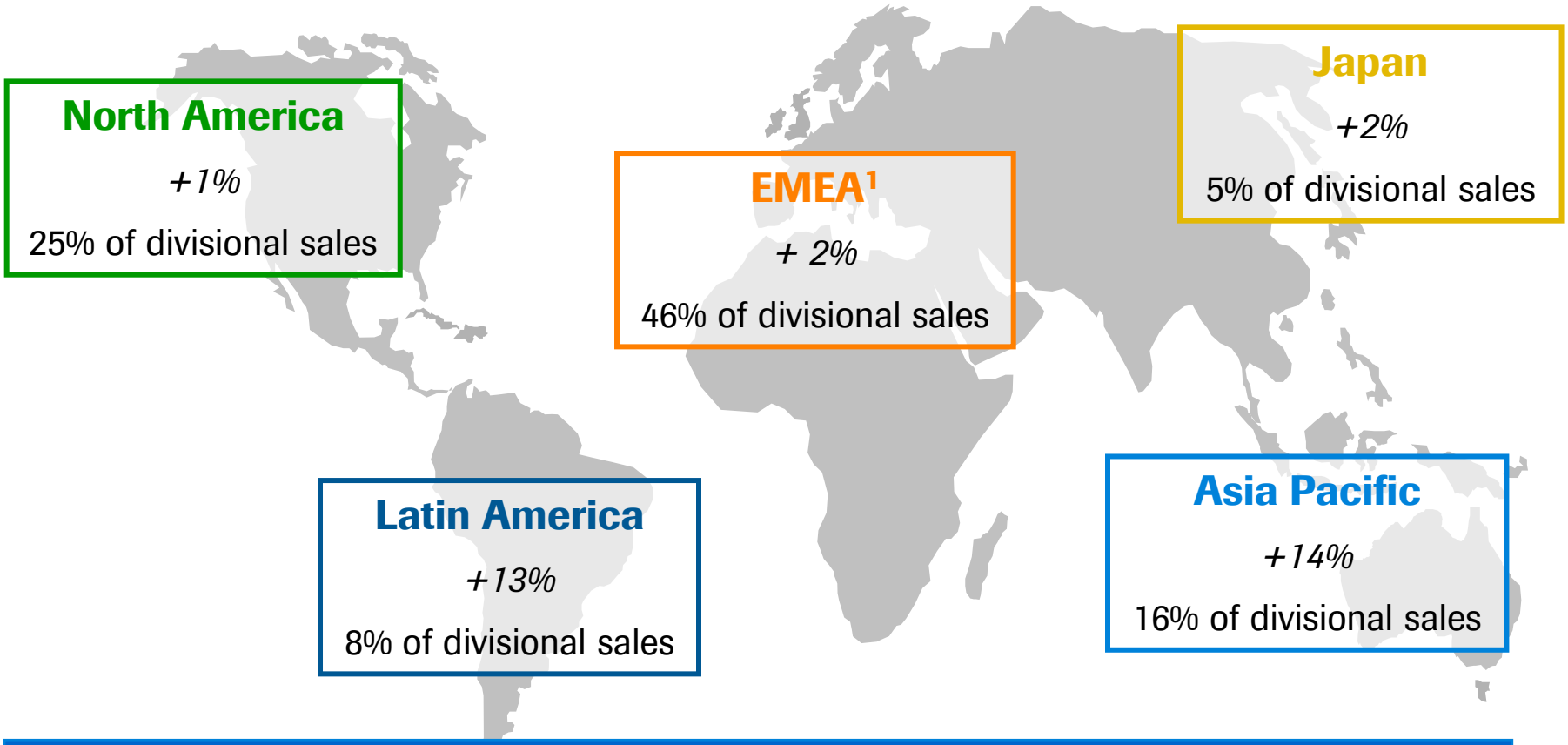
*Sustained growth above the market**

	2013 CHFm	2012 CHFm	change in % CHF	change in % CER
Diagnostics Division	**10,476**	**10,267**	**+2**	**+4**
Professional Diagnostics[1]	5,740	5,443	+5	+8
Diabetes Care	2,459	2,556	-4	-3
Molecular Diagnostics[1]	1,612	1,627	-1	+2
Tissue Diagnostics	665	631	+5	+7

*Estimates from independent IVD consultancy as of end Q3 2013
[1]2012 sales restated for Applied Science integration into Professional Diagnostics and Molecular Diagnostics.
Underlying growth of Molecular Diagnostics excluding Sequencing Solutions: +6%
CER=Constant Exchange Rates

2013: Diagnostics regional sales

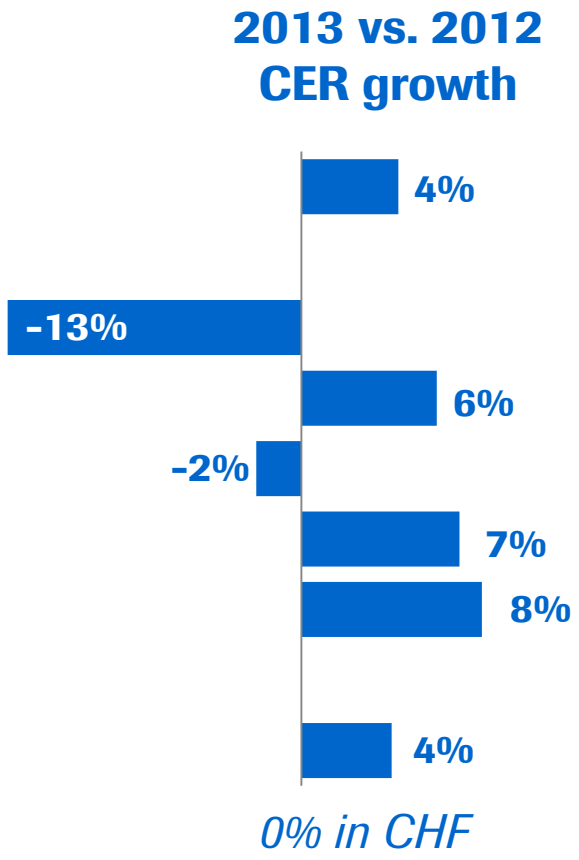
Growth driven by emerging markets



[1]Europe, Middle East and Africa; [2]Brazil, China, India, Mexico, Russia, South Korea, Turkey
All growth rates at constant exchange rates

2013: Diagnostics Division

	2013 CHFm	2013 % sales
Sales	**10,476**	**100.0**
Royalties & other op income	130	1.2
Cost of sales	-4,539	-43.3
M & D	-2,446	-23.3
R & D	-1,017	-9.7
G & A	-427	-4.1
Core operating profit	**2,177**	**20.8**



CER=Constant Exchange Rates

Key launches 2013

	Area	Product	Market	BA[1]
Instruments / Devices	Labs	cobas 8100 – Next generation modular pre-analytics	EU ✓	RPD
	Life Sciences	GS FLX+ long amplicons- Software for long read targeted sequencing	WW ✓	RMD
	Diabetes Care	Accu-Chek Insight- Next generation insulin pump & bGM[2] system	EU	RDC
		Accu-Chek Active LCM- Next-generation bGM[2] meter with maltose independent test strips	EU ✓	RDC
Tests/ Assays	Oncology	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
	Infectious Diseases	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
	Transplant	Cyclosporin, Tacrolimus – immunosuppressive drug monitoring	EU ✓	RPD
	Sequencing	SeqCap EZ Reagent Kits – Targeted next gen. sequencing	WW ✓	RMD

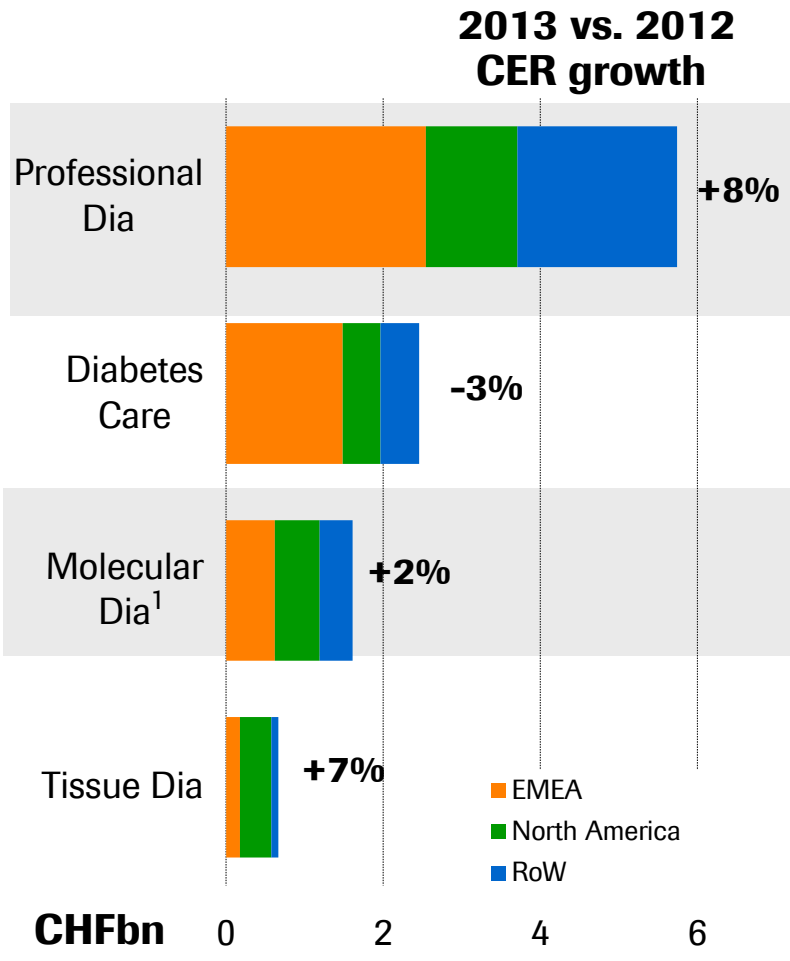
[1] Business Areas. RPD: Roche Professional Diagnostics; RDC: Roche Diabetes Care; RMD: Roche Molecular Diagnostics, RTD: Roche Tissue Diagnostics; [2] blood glucose monitoring

2013 results and performance

Q4 highlights

Strategy & outlook

2013: Growth driven by Professional Diagnostics



Q4 highlights

Professional Dia	Strong sales growth in immunoassays (14%) accompanied by expanded menu; Roll out of cobas 8100 automation system
Diabetes Care	Continued challenging environment especially in the US; Accu Chek Mobile sales growth +41%; FDA clearance of Accu-Chek Aviva Expert in U.S
Molecular Dia[1]	Strong sales growth in qPCR/NAP(+6%) and HPV (+90%), offering complemented by CT/NG test with expanded US label
Tissue Dia	Growth driven by advanced staining outside the US (17%); Launch of CINtec PLUS Cytology in Europe

[1] Underlying growth of Molecular Diagnostics excluding Sequencing Solutions: +6%
CER=Constant Exchange Rates; EMEA=Europe, Middle East and Africa

RPD*: Launch of cobas Infinity IT solutions

Providing full connectivity and automation

Pre-analytics sample prep

Analyzer

cobas Infinity

Next generation IT system

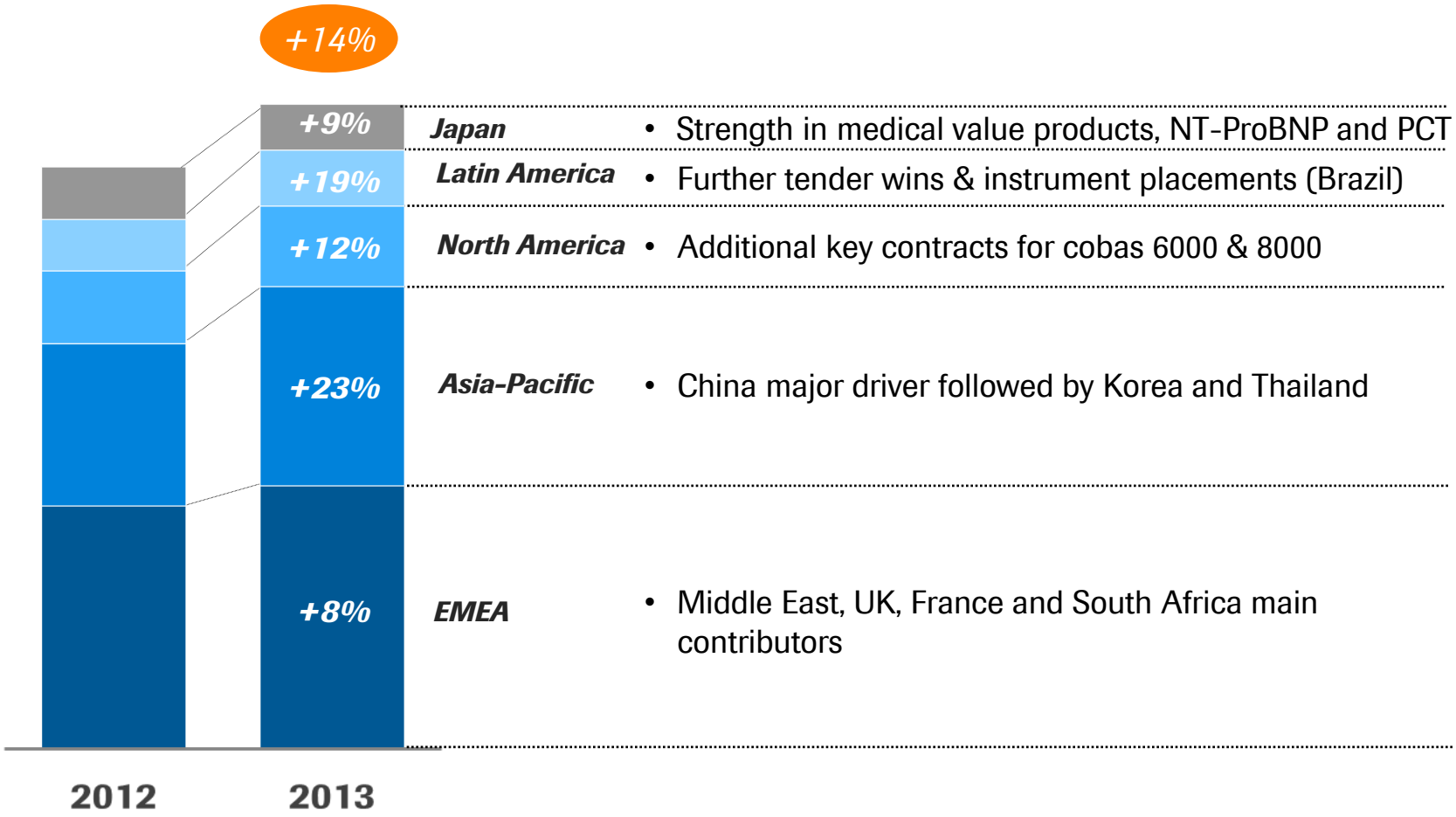
Lab/Hospital Information System

Post-analytics storage

* Roche Professional Diagnostics

Immunoassays*: 25% of Diagnostics sales

Strong growth in all regions



*Tests that detect molecules using antibody binding. Immunoassays business is a part of Roche Professional Diagnostics

RMD*: CE Mark[1] for MRSA/SA and HSV

Expansion of test menu on cobas 4800 platform

cobas 4800 system

Fully automated PCR platform for low to mid volumes

Microbiology

MRSA/SA, C-difficile[2]

MRSA[3] *(cobas MRSA/SA)* New

- Leading cause of hospital acquired infections
- 9m tests per year (39% market growth)

Sexually transmitted diseases

HPV, CT/NG, HSV-1&2

HSV[4] *(cobas HSV-1&2 test)* New

- Diagnosis of genital herpes
- Superior and faster detection

Oncology

BRAF, EGFR, KRAS, PIK3CA[5]

*Roche Molecular Diagnostics

[1]January 2014; [2]To be launched in Q1 2014; [3]Methicilin Resistant Staphylococus Aureus; [4]Herpes Simplex Virus; [5]Research use only

2013 results and performance

Q4 highlights

Strategy & outlook

Outlook
Sustain sales growth and profitability

Drivers

- Further expand installed base and test menu
- Launch next generation platforms and drive lab efficiency
- Continue to strengthen leading presence in emerging markets
- Ongoing adjustments in Diabetes Care to adapt to market environment
- Grow PHC* and companion diagnostics collaborations

* Personalised healthcare

Key launches 2014

	Area	Product	Market	BA[1]
Instruments / Devices	***Labs***	cobas 6800/8800 – Next generation molecular (PCR) system	WW*	RMD
		cobas m 511 – Fully integrated and automated hematology system	EU	RPD
		cobas 6500 – automated urinalysis work area platform	EU	RPD
		Connect-V – Middleware providing connectivity to LIS[2]	WW	RTD
	Diabetes Care	Accu-Chek Insight- Next generation insulin pump & bGm[3] system	EU	RDC
		Accu-Chek Connect – bG meter with connectivity to smart phones, mobile app and cloud	EU	RDC
Tests/ Assays	***Infectious Diseases / Blood Screening***	MPX 2.0 – Next generation blood screening multiplex test	US	RMD
		MPX (HIV, HCV, HBV), HEV, DPX[4], WNV[5] – Full NAT blood screening menu for cobas 6800/8800	WW*	RMD
		HIV, HCV, HBV – Virology tests for cobas 6800/8800	WW*	RMD
		HSV- Detection of Herpes Simplex Virus on cobas 4800	EU ✓	RMD
		Syphillis– Immunoassay for the detection of *Treponema pallidum*	EU	RPD
	Microbiology	MRSA/SA – Next generation assay on cobas 4800	EU ✓	RMD
		C-difficile – Diagnosis of infections and associated diarrhea	EU	RMD
	Women's Health	PE Prognosis- Claim extension for short-term prediction of Preeclampsia in pregnancy	EU	RPD
		AMH- Assessment of ovarion reserve for fertility	EU	RPD

*Excluding US;
[1]Business Areas: RPD: Roche Professional Diagnostics; RDC: Roche Diabetes Care; RMD: Roche Molecular Diagnostics, RTD: Roche Tissue Diagnostics; [2] hospital information systems; [3] blood glucose monitoring; [4] parvovirus B19 and hepatitis A virus; [5] west nile virus

Finance

Alan Hippe

Chief Financial Officer

2013: Finance highlights

Business

- Strong Core EPS growth: +10%[1]
- Solid operating free cash flow +5%[1] and free cash flow +6%[1]

Improved financial result

- Positive development of Core net financial result: +11%[1] lower expense
- Early bond recall of USD 1.0bn with CHF 168m costs

Net debt down by CHF 3.9bn

- Net debt / total assets now 11% (down from 16% in 2012)

[1] At constant exchange rates

2013 performance

Focus on cash

2013: Group performance

Core EPS growth +10%[1]

CHFm	2013	2012	% Change CHF	% Change CER	Excl. PSI & 340B
Sales	**46,780**	**45,499**	**+3**	**+6**	+6
Core operating profit	**17,904**	**17,160**	**+4**	**+8**	+5
as % of sales	*38.3*	*37.7*			*37.5*
Core net income	**12,526**	**11,765**	**+6**	**+10**	+7
as % of sales	*26.8*	*25.9*			*26.2*
Attributable to Roche shareholders	12,316	11,531	+7	+10	+7
Core EPS (CHF)	**14.27**	**13.49**	**+6**	**+10**	+7
Operating free cash flow	**16,381**	**16,135**	**+2**	**+5**	
% of sales	*35.0*	*35.5*			
Free cash flow	**5,403**	**5,376**	**+1**	**+6**	
% of sales	*11.5*	*11.8*			

[1] CER=Constant Exchange Rates

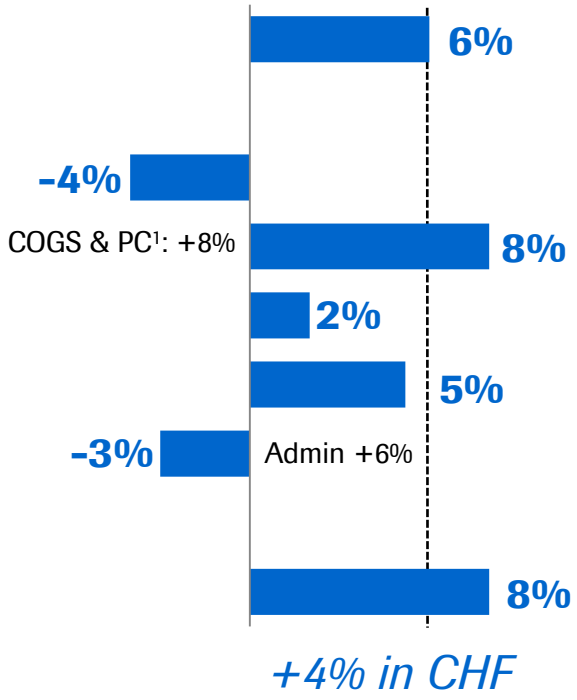
2013: Impact of past service income (PSI) and 340B sales reserves release

in CHFm	Group	Pharma	Diagnostics	Corporate	
Sales	182	182			***340B***
Cost of sales	-37	-37			
General & administration	302	131	67	104	***PSI***
Operating profit	**447**	**276**	**67**	**104**	
Deferred taxes	-117				
Net income	**330**				

2013: Group operating performance

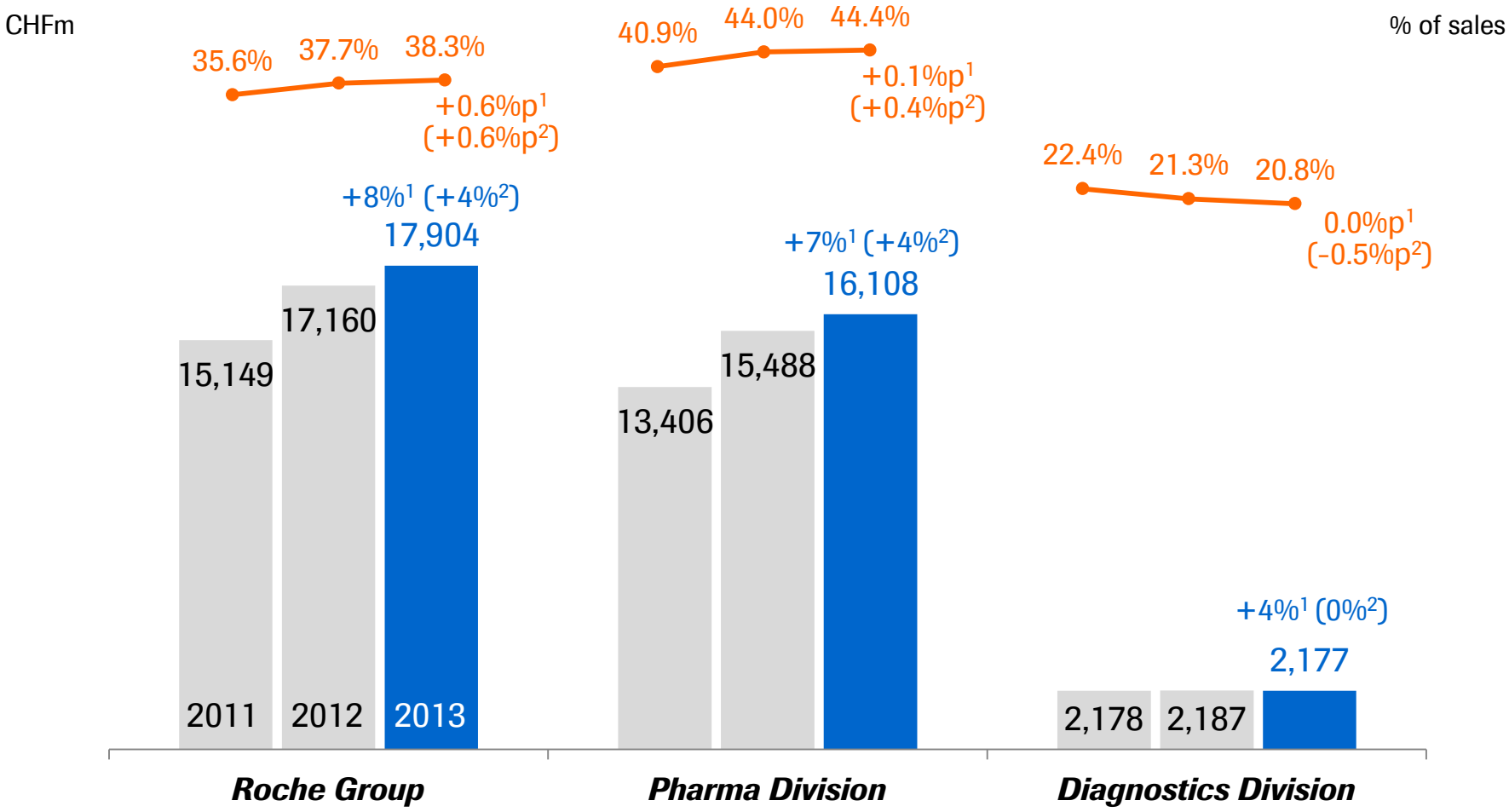
Good sales momentum translated into profit increase

	2013 CHFm	2013 % sales
Sales	**46,780**	**100.0**
Royalties & other op inc	1,832	3.9
Cost of sales	-11,892	-25.4
M & D	-8,241	-17.6
R & D	-8,700	-18.6
G & A	-1,875	-4.0
Core operating profit	**17,904**	**38.3**



CER=Constant Exchange Rates [1] Cost of goods sold & period cost

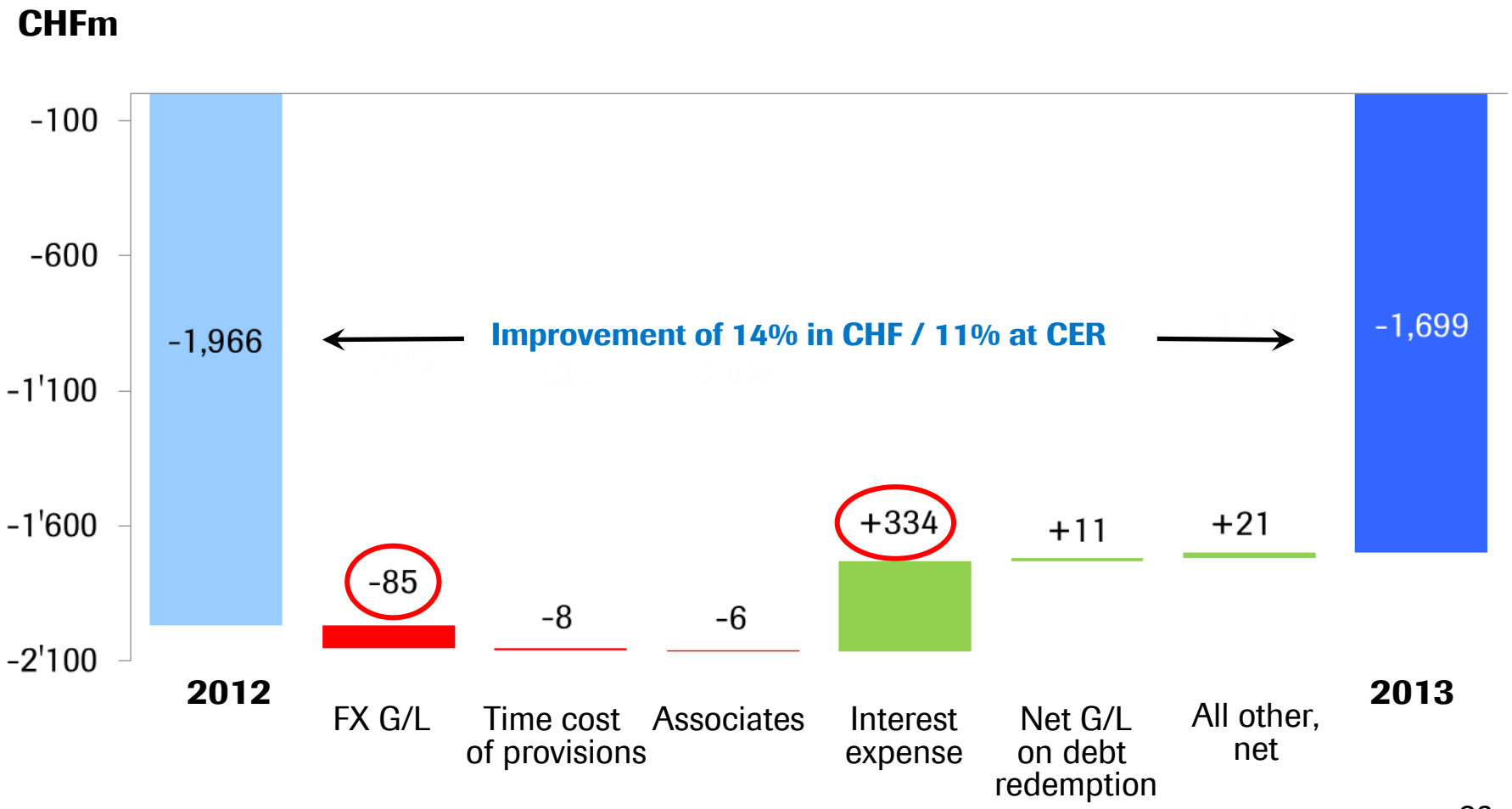
2013: Core operating profit and margin



[1] At constant exchange rates; [2] As reported in CHF

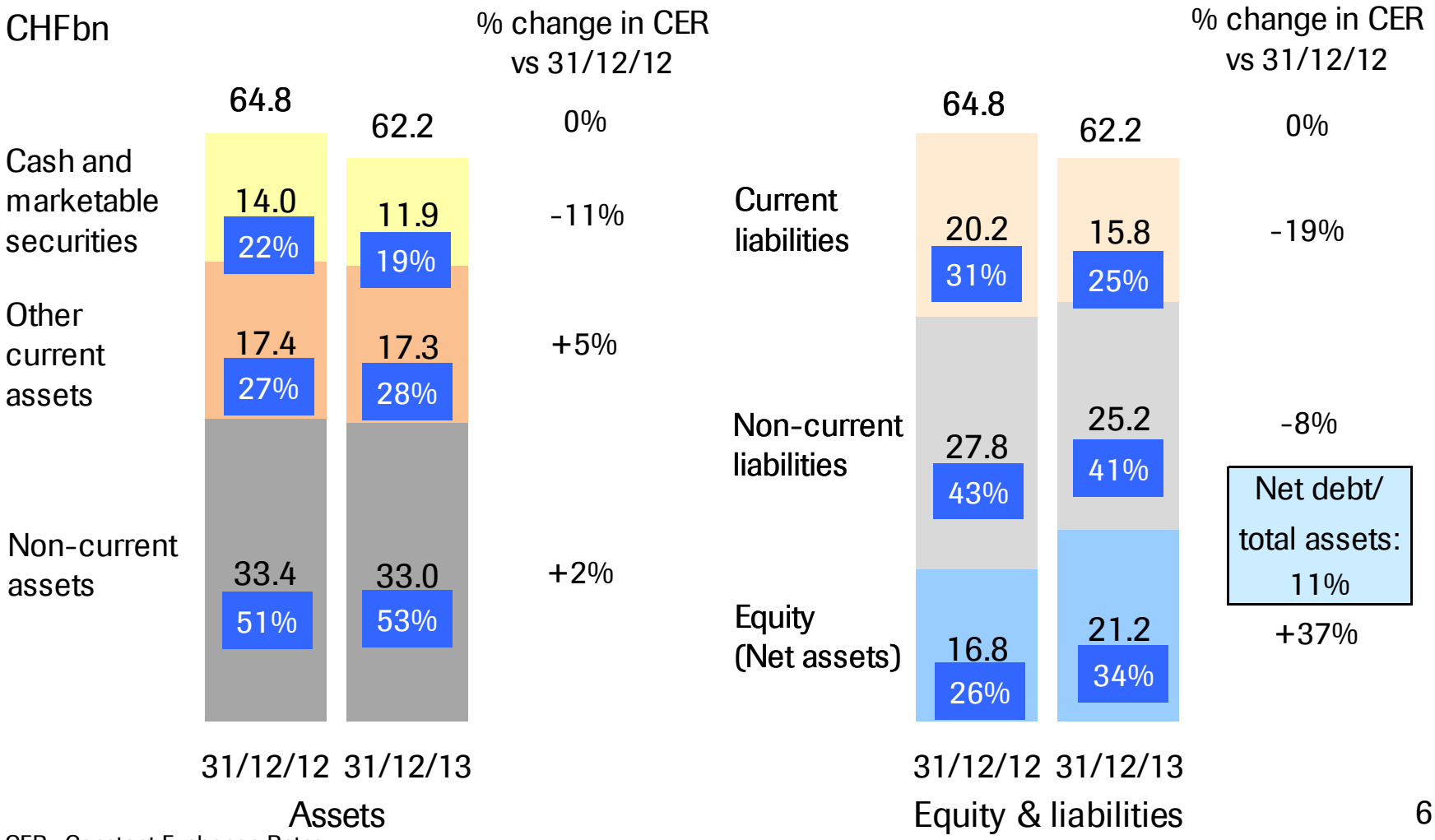
2013: Core net financial result

Lower interest expenses partly offset by fx losses



CER=Constant Exchange Rates

Balance sheet: Equity ratio at 34%



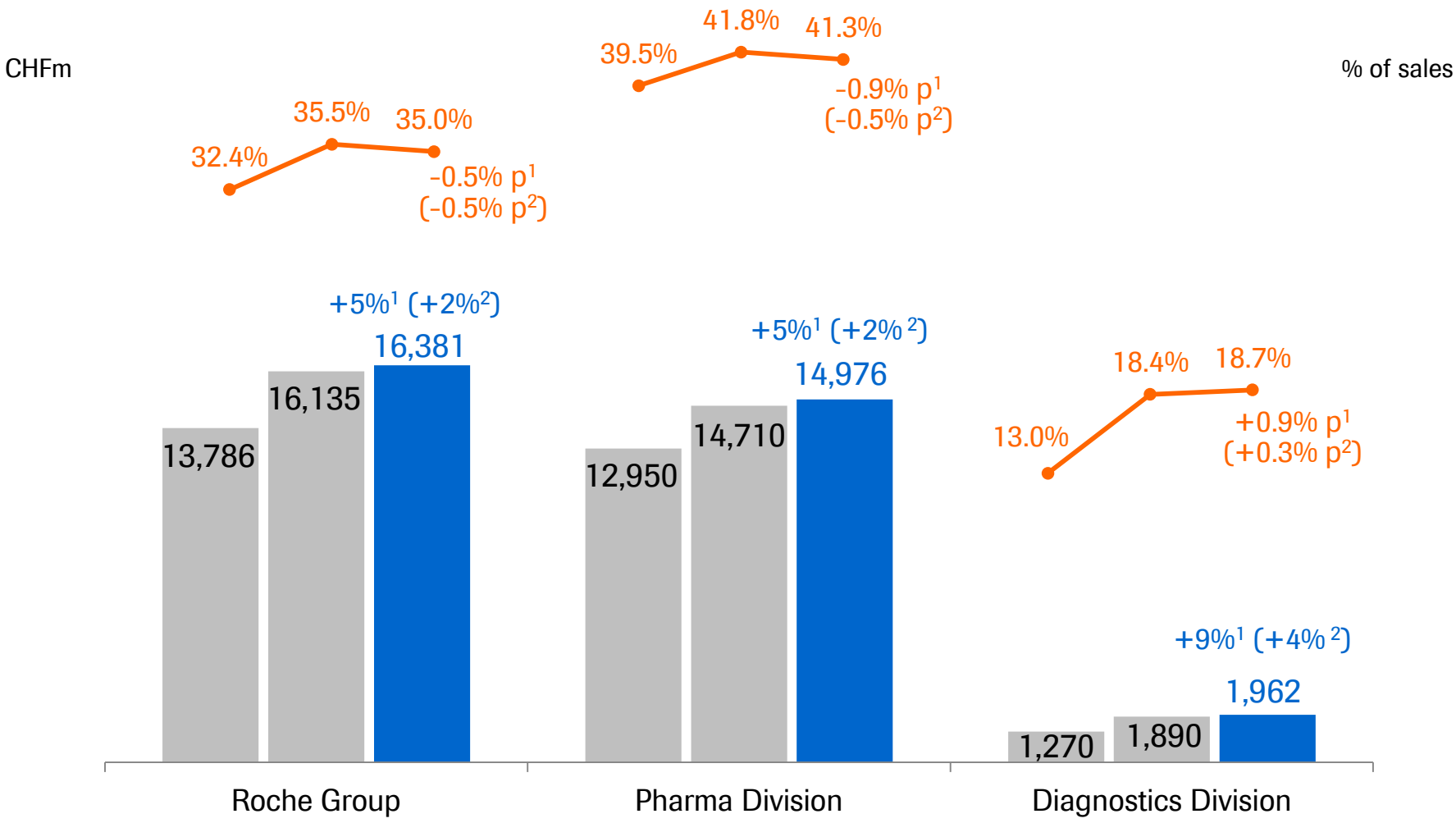
CER=Constant Exchange Rates

2013 Results and Performance

Focus on cash

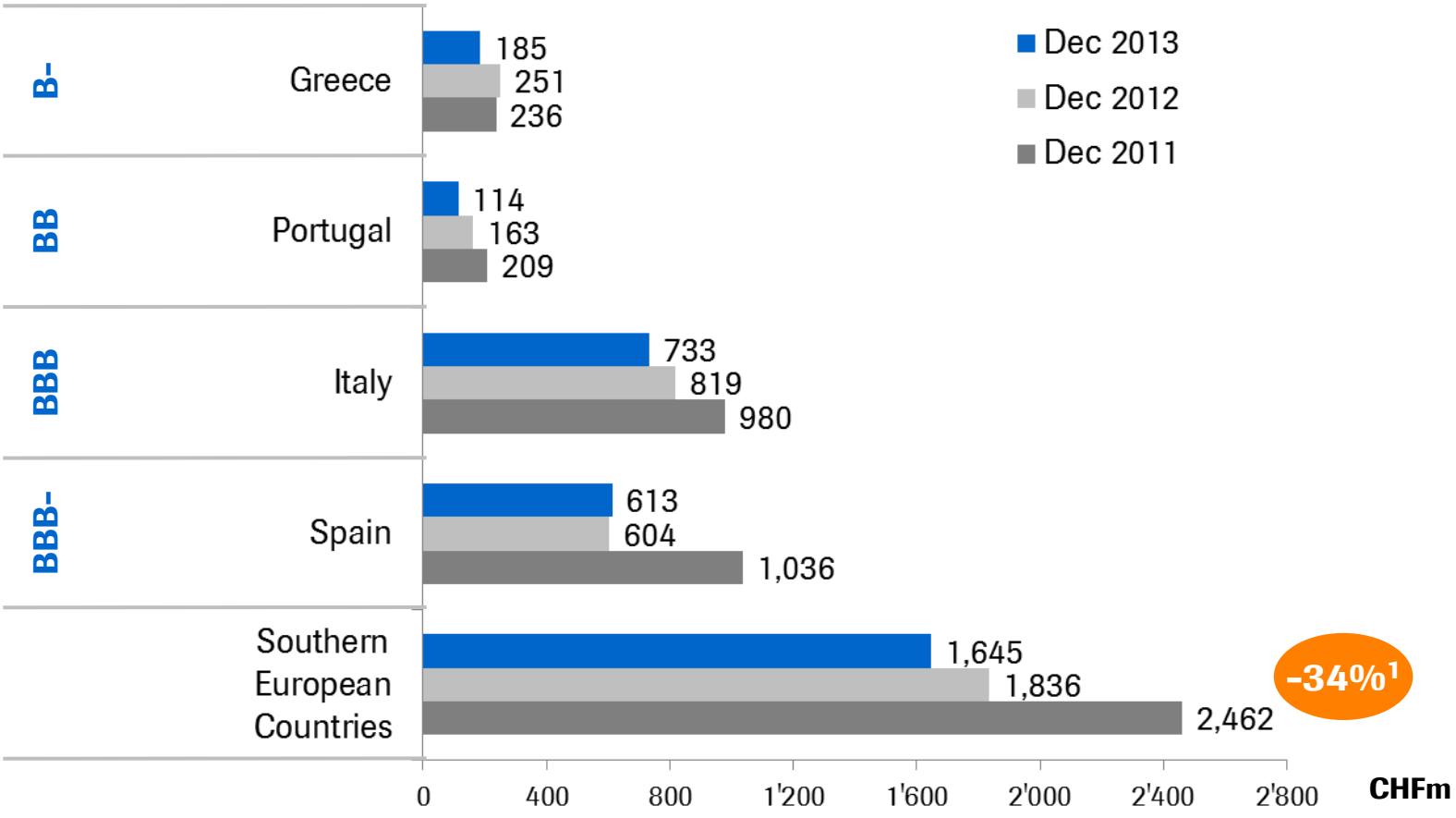
2013: Operating free cash flow and margin

5% increase[1]



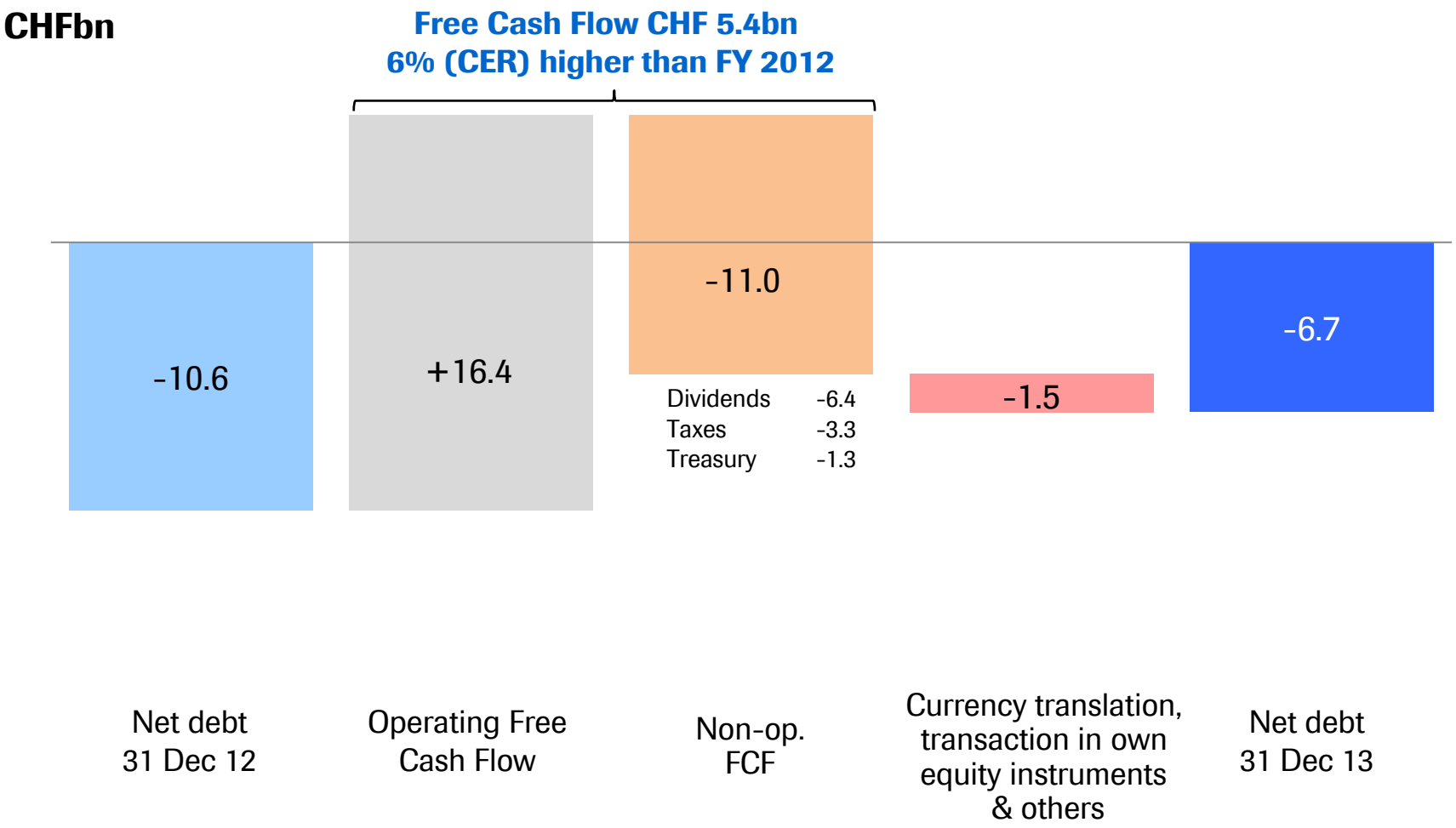
[1] At constant exchange rates; [2] As reported in CHF

2013: Accounts receivable in Southern Europe further reduced despite CHF 0.7bn benefit in 2012



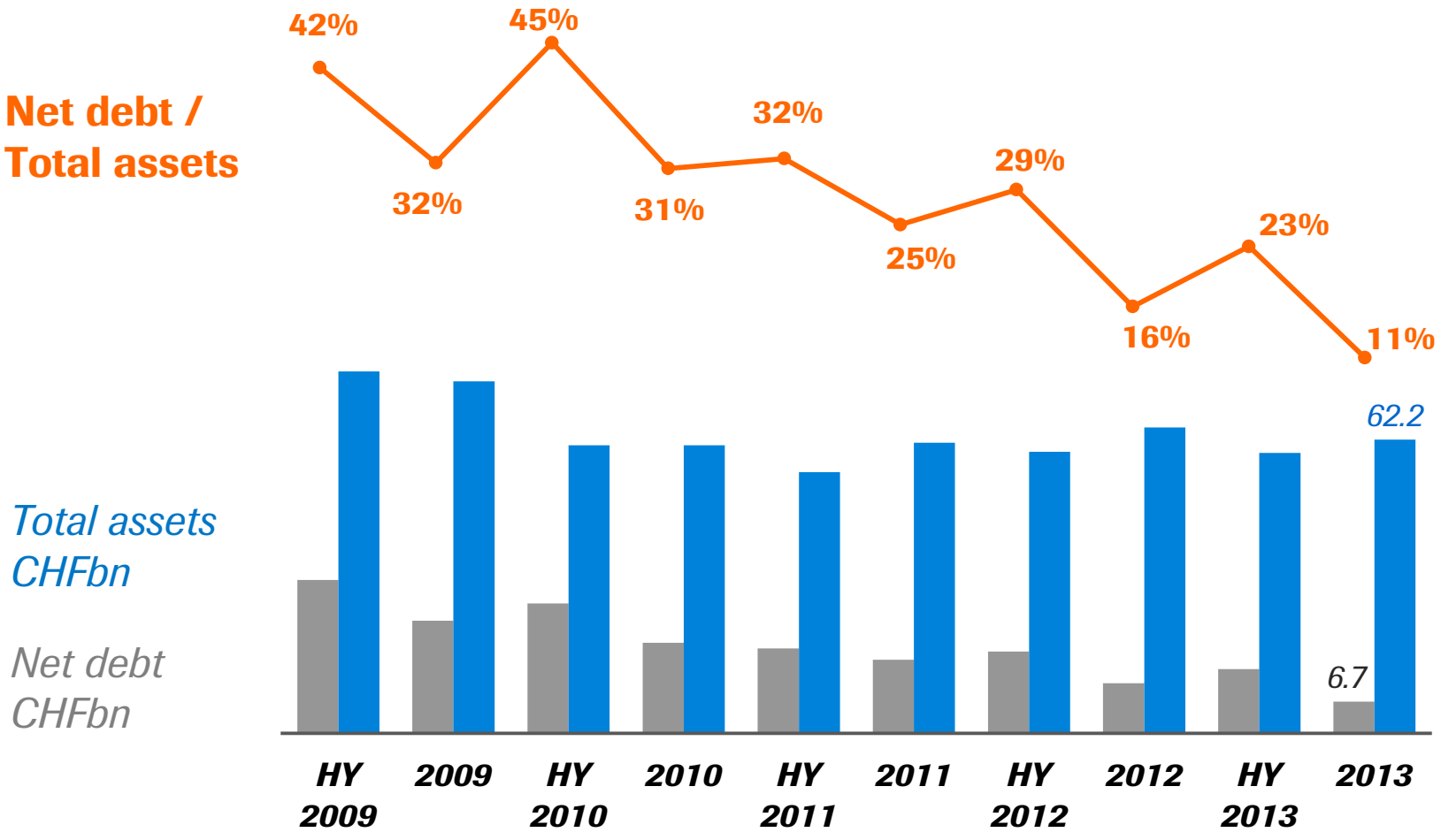
Sovereign country ratings from Standard & Poor's, as of 7 Jan 2014; [1] At constant exchange rates

2013: Group net debt substantially lower



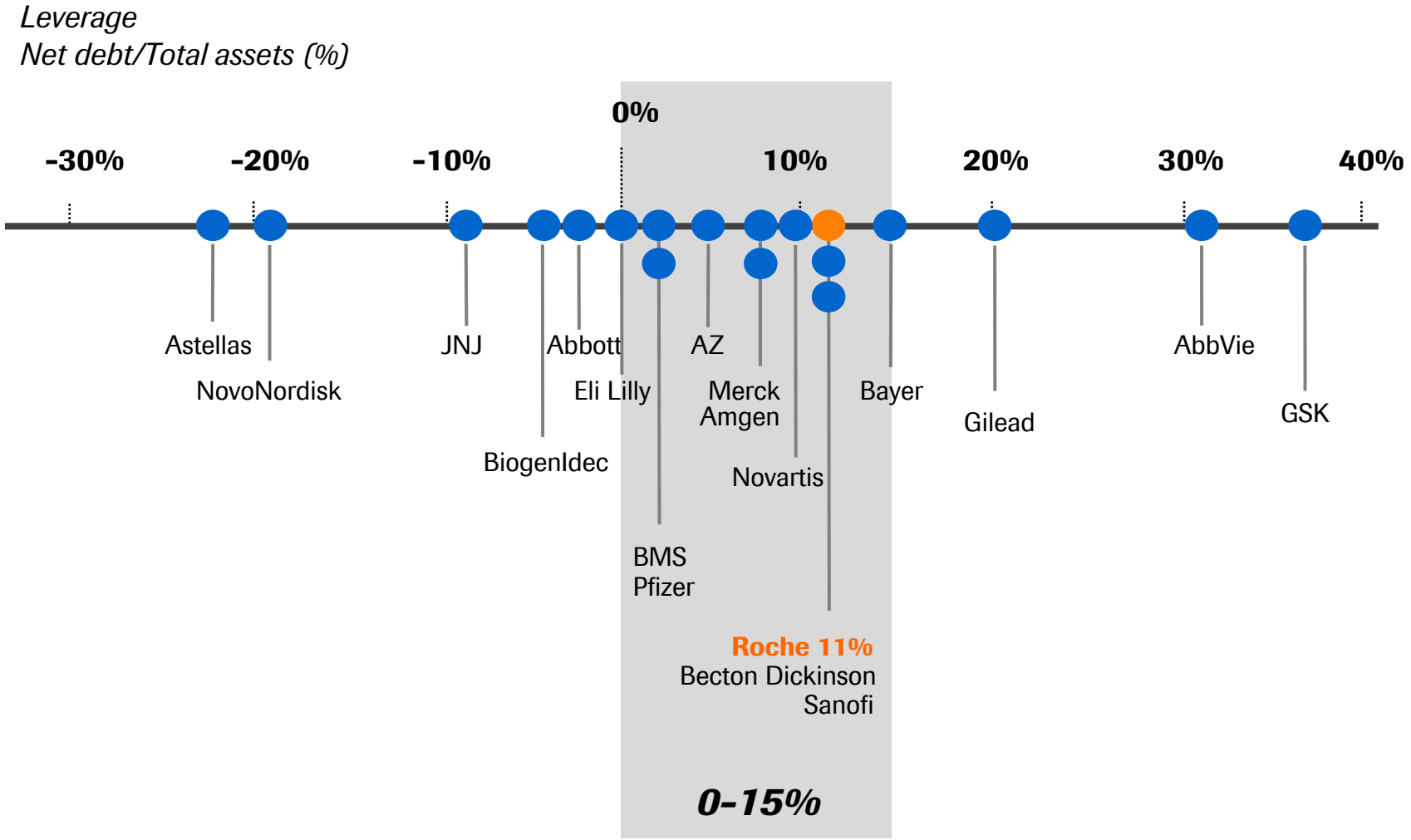
CER=Constant Exchange Rates

Strong earnings capacity reflected in sustained net debt reduction



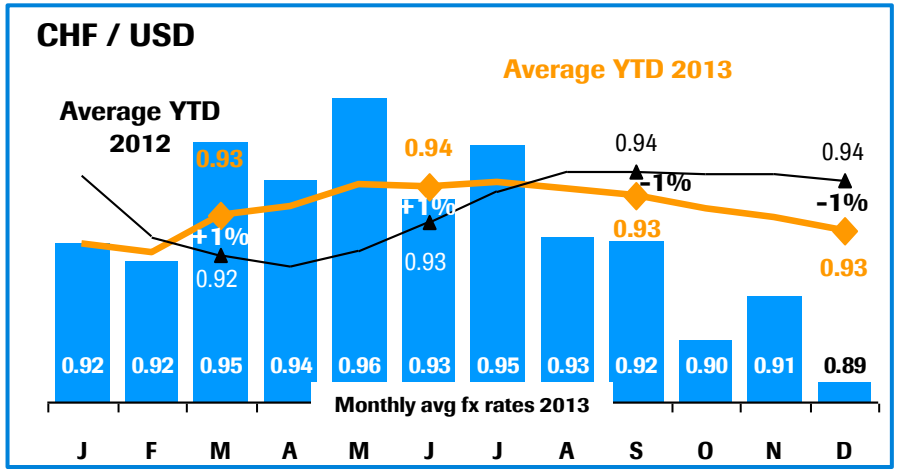
Industry balance sheet leverage

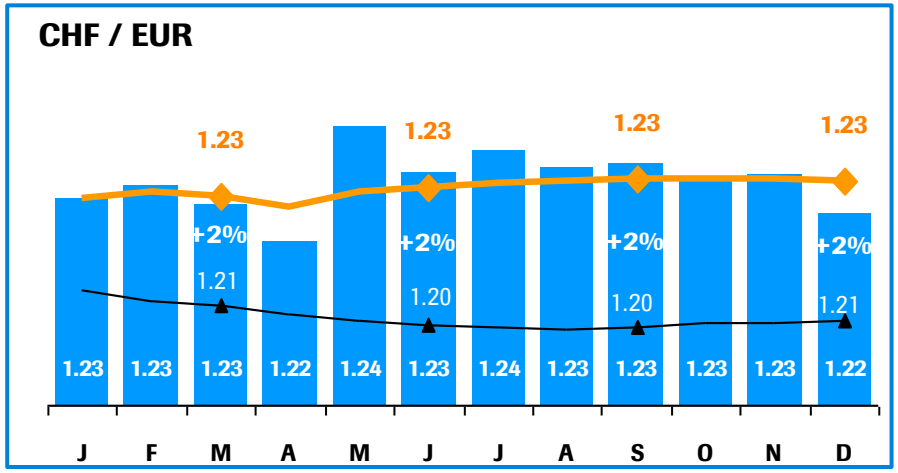
Roche still above the industry average



Source: Bloomberg January 2014, based on the most recent reported data

Negative currency impact in 2014 expected





Assuming the 31 Dec 2013 exchange rates remain stable until end of 2014, 2014 impact is expected to be (%p):

	Q1	HY	Sep YTD	FY
Sales	-5	-6	-5	-4
Core operating profit		-7		-5
Core EPS		-8		-6

2014 Outlook

Group sales growth[1]	Low- to mid-single digit
Core EPS growth[1]	Ahead of sales growth
Dividend outlook	Further increase dividend

[1]At constant exchange rates

Doing now what patients need next

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development

Genentech research and early development

Roche Group 2013 results

Diagnostics

Foreign exchange rate information

Changes to the development pipeline
Q4 2013 update

New to Phase I	New to Phase II	New to Phase III	New to Registration
5 NMEs **RG7641** - kidney disease **RG7716** - wAMD **RG7800** SMN2 splicing modifier - spinal muscular atrophy **RG7813** CEA IL2v - solid tumors **RG7845** - hematological tumors **2 AIs** **RG7446** PD-L1 MAb combination with cobimetinib - solid tumors **RG7601** Bcl-2 inh combination with Gazyva - CLL	**1NME** **RG7745** FluA MAb - influenza **1 NME in-licensed from Polyphor** **RG7929** LptD Antibiotic - antibacterial **2 NMEs Chugai** **IL-31R MAb** - atopic dermatitis **FIXa/FX** bispecific MAb - hemophilia A **2 AIs** **RG3637** lebrikizumab idiopathic pulmonary fibrosis **RG7446** PD-L1 MAb combination with Avastin - RCC	**2 NMEs** **RG1450** gantenerumab - AD **RG7601** Bcl-2 inh - CLL rel/refractory **2 AIs** **RG3638** onartuzumab - NSCLC 1L EGFR mutation-positive **RG3502** Kadcyla - Her2-positive gastric cancer	
Removed from Phase I	**Removed from Phase II**	**Removed from Phase III**	**Removed from Registration**
3 NMEs **RG7212** Tweak MAb - oncology **RG7356** CD44MAb - solid tumors **RG7602** ChK1 inh(2) - solid tumors & lymphoma	**1NME** **RG7422** apitolisib (PI3K/mTOR) - solid & hematological tumors **2 AIs** **RG7204** Zelboraf - papillary thyroid cancer **RG3638** onartuzumab - glioblastoma 1st line	**2AIs** **RG435** Avastin - Her2-positive BC adjuvant **RG1415** Tarceva - NSCLC adjuvant	**1 NME EU approval** **RG3502** Kadcyla - HER2-positive pretreated mBC

Status as of December 31, 2013

Roche Group development pipeline

Phase I
(30 NMEs + 8 AIs)

Oncology

RG3638	onartuzumab	liver cancer
RG7116	HER3 MAb	solid tumors
RG7155	CSF-1R MAb	solid tumors
RG7167	MEK inh	solid tumors
RG7221	Ang2-VEGF MAb	oncology
RG7304	Raf & MEK dual inh	solid tumors
RG7388	MDM2 ant	solid & hem tumors
RG7446	PD-L1 MAb+Zelboraf	m. melanoma
RG7446	PD-L1 MAb+Avastin	solid tumors
RG7446	PD-L1 MAb+cobimetinib	solid tumors
RG7446	PD-L1 MAb	solid tumors
RG7450	Steap 1 ADC	prostate ca.
RG7458	MUC16 ADC	ovarian & pancreatic ca.
RG7598	ADC	multiple myeloma
RG7599	NaPi2b ADC	oncology
RG7600	ADC	oncology
RG7601	Bcl-2 inh + Gazyva	CLL
RG7601	Bcl-2 inh	heme indications
RG7604	PI3K inh beta sparing	solid tumors
RG7636	ETBR ADC	metastatic melanoma
RG7666	PI3k inh	glioblastoma 2L
RG7741	ChK1 inh	solid tum & lymphoma
RG7813	CEA IL2v	solid tumors
RG7842	-	solid tumors
RG7845	-	heme tumors
CHU	PI3K inh	solid tumors

Other disease areas

RG7624	IL-17 MAb	autoimmune diseases
CHU	IL-6R MAb	RA
RG7795	TLR7 agonist	HBV
RG7863	TLR7 agonist (2)	HBV
RG7641	-	kidney disease
RG7697	GIP/GLP-1 dual ago	type 2 diabetes
RG1662	GABRA5 NAM	cognitive disorders
RG7203	PDE10A inh	schizophrenia
RG7410	-	schizophrenia
RG7800	SMN2 splicer	spinal muscular atrophy
RG3645	Lucentis sust. deliv.	AMD/RVO/DME
RG7716	-	wAMD

New Molecular Entity (NME)
Additional Indication (AI)

Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other

RG-No **Roche Genentech managed**
CHU **Chugai managed**

Status as of December 31, 2013

Roche Group development pipeline

Phase II
(27 NMEs + 11 AIs)

RG1273	Perjeta	HER2+ mBC 2nd line
RG3616	Erivedge	AML
RG3616	Erivedge	operable BCC
RG3638	onartuzumab	mCRC 1st line
RG3638	onartuzumab	NSCLC non squamous 1st l
RG3638	onartuzumab	NSCLC squamous 1st line
RG7321	pictilisib (PI3K inh)	solid tumors
RG7440	ipatasertib (AKT inh)	solid tumors
RG7446	PD-L1 MAb	NSCLC 2nd/3rd line
RG7446	PD-L1 MAb + Avastin	RCC
RG7593	pinatuzumab vedotin (CD22 ADC)	hem tumors
RG7596	polatuzumab vedotin (CD79bADC)	hem tumors
RG7597	HER3/EGFR MAb	m. epithelial tumors
RG7601	Bcl-2 inh	CLL rel/refract 17pdel
RG7853	alectinib (ALK inhibitor)	NSCLC
RG7686	glypican-3 MAb	liver cancer
RG1569	Actemra	systemic sclerosis
RG3637	lebrikizumab	idiopathic pulmonary fibrosis
RG7413	etrolizumab	ulcerative colitis
RG7415	rontalizumab	systemic lupus erythem
RG7449	quilizumab	asthma
CHU	IL-31R MAb	atopic dermatitis
RG7128	mericitabine	HCV
RG7227	danoprevir	HCV
RG7667	-	CMV
RG7745	Flu A MAb	influenza
RG7790	setrobuvir	HCV
RG7929	LptD antibiotic	antibacterial
RG1512	inclacumab	ACS/CVD
RG7652	PCSK9 MAb	metabolic diseases
RG1577	MAO-B inh	Alzheimer's
RG1578	mGlu2 NAM	depression
RG1678	bitopertin	obsessive compulsive dis.
RG7090	mGlu5 NAM	tx.resistant depression
RG7314	V1 receptor antag	autism
RG7412	crenezumab	Alzheimer's
RG7417	lampalizumab (factor D)	geo. atrophy
CHU	FIXa /FX bispecific MAb	hemophilia A

Phase III
(8NMEs + 21 AIs)

RG435	Avastin	HER2-neg. BC adj
RG435	Avastin	NSCLC adj
RG435	Avastin	high risk carcinoid
RG435[1]	Avastin	ovarian cancer 1st line
RG435[1]	Avastin	rel. ovarian ca. Pt-sensitive
RG435	Avastin	cervical cancer recurrent
RG1273	Perjeta	HER2+ early BC
RG1273	Perjeta	HER2+ gastric cancer
RG3502	Kadcyla	HER2+ gastric cancer
RG3502	Kadcyla +/- Perjeta	HER2+ mBC 1st l
RG3502	Kadcyla	HER2+ early BC
RG3638	onartuzumab	NSCLC 2nd/3rd line
RG3638	onartuzumab	gastric cancer
RG3638	onartuzumab	NSCLC 1L EGFR mut+
RG7159	Gazyva (obinutuzumab)	DLBCL
RG7159	Gazyva (obinutuzumab)	iNHL relapsed
RG7159	Gazyva (obinutuzumab)	iNHL front-line
RG7204	Zelboraf	m. melanoma adj
RG7421	cobimetinib + Zelboraf	m. melanoma
RG7601	Bcl-2 inh	CLL rel/refract
RG1569	Actemra	giant cell arteritis
RG3637	lebrikizumab	severe asthma
RG3806	oral octreotide	acromegaly
CHU	Suvenyl	enthesopathy
RG1450	gantenerumab	Alzheimer's
RG1594	ocrelizumab	RMS
RG1594	ocrelizumab	PPMS
RG1678	bitopertin	schiz neg symptoms
RG1678	bitopertin	schiz subopt control

Registration
(1 NME + 6 AIs)

RG105[2]	MabThera	NHL sc formulation
RG435[3]	Avastin	rel. ovarian ca. Pt-resistant
RG435[3]	Avastin	glioblastoma 1st line
RG7159[4]	obinutuzumab (GA 101)	CLL
RG1569[2]	Actemra	early RA
RG1569[4]	Actemra	RA sc formulation
RG3648[5]	Xolair	chronic idiopathic urticaria

1 US only: FDA submission pending
2 Submitted in EU
3 Submitted in EU, US filing pending
4 Approved in US, submitted in EU
5 Submitted in US

New Molecular Entity (NME)
Additional Indication (AI)

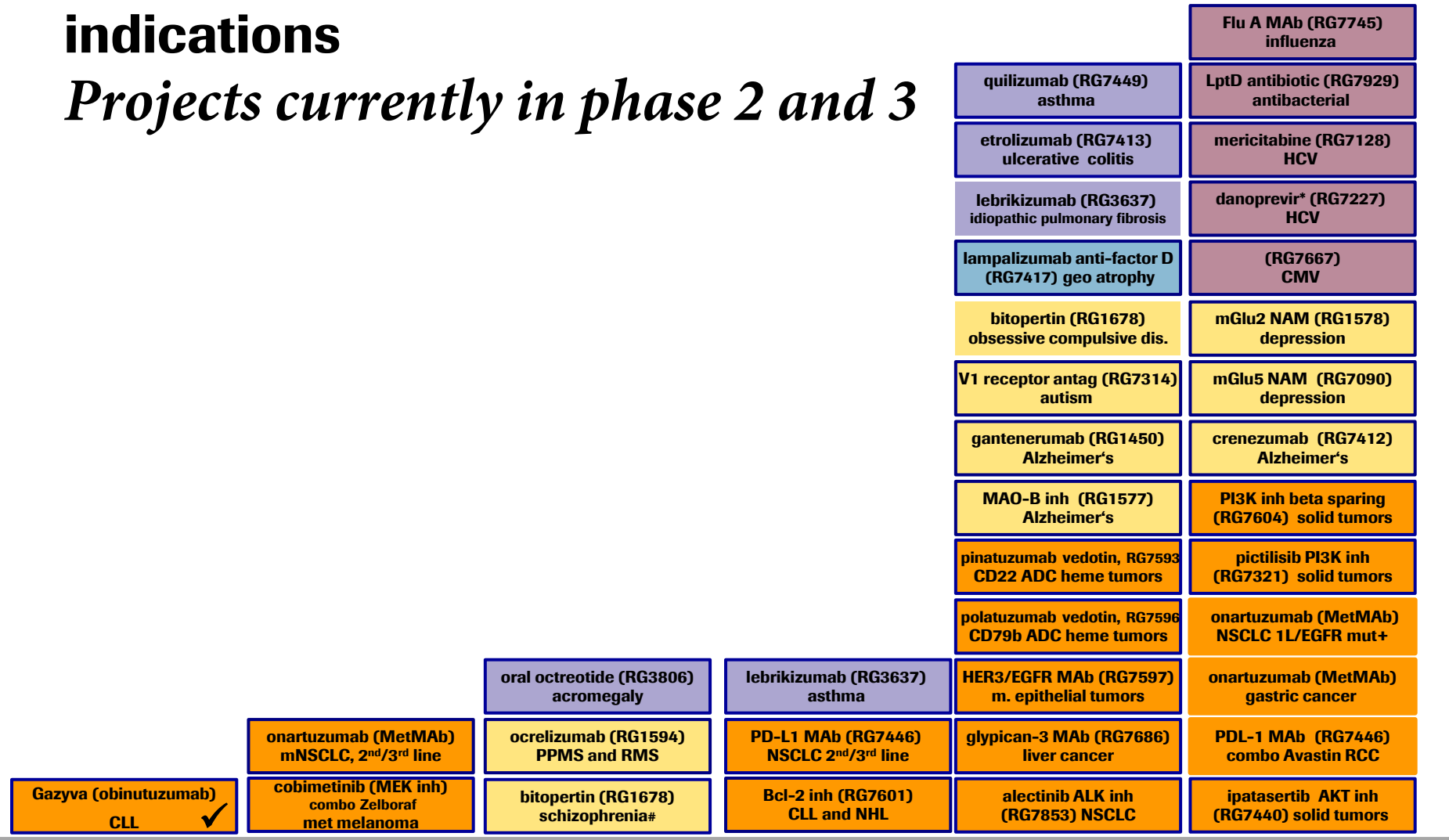
Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology

RG-No Roche Genentech managed
CHU Chugai managed
RG105 MabThera is branded as Rituxan in US and Japan
RG1569 Actemra is branded as RoActemra in EU

Status as of December 31, 2013

NME submissions and their additional indications

Projects currently in phase 2 and 3



Unless stated otherwise, submissions are planned to occur in US and EU

✓ Indicates submission to health authorities has occurred

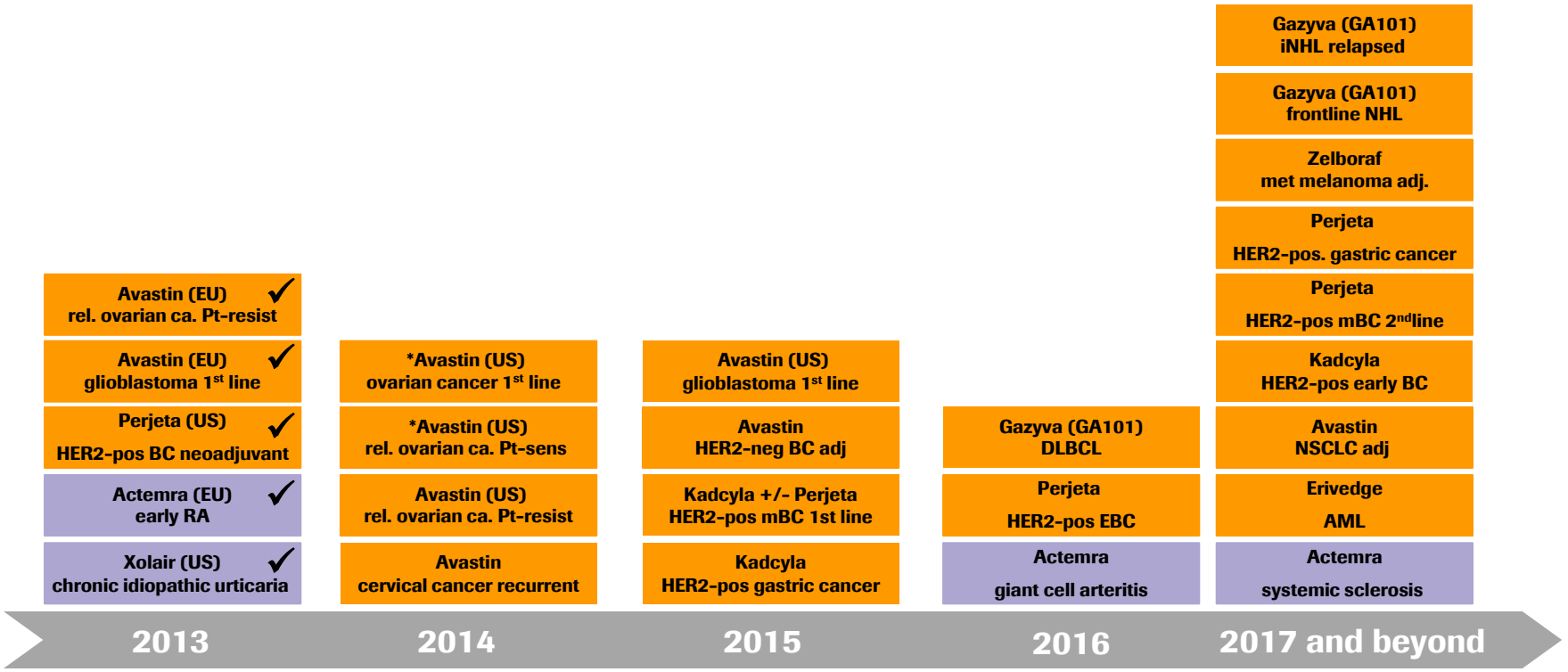
* lead market China

\# sub-optimally controlled symptoms

Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
NME

Submissions of additional indications for existing products

Projects currently in phase 2 and 3



✓ Indicates submission to health authorities has occurred.

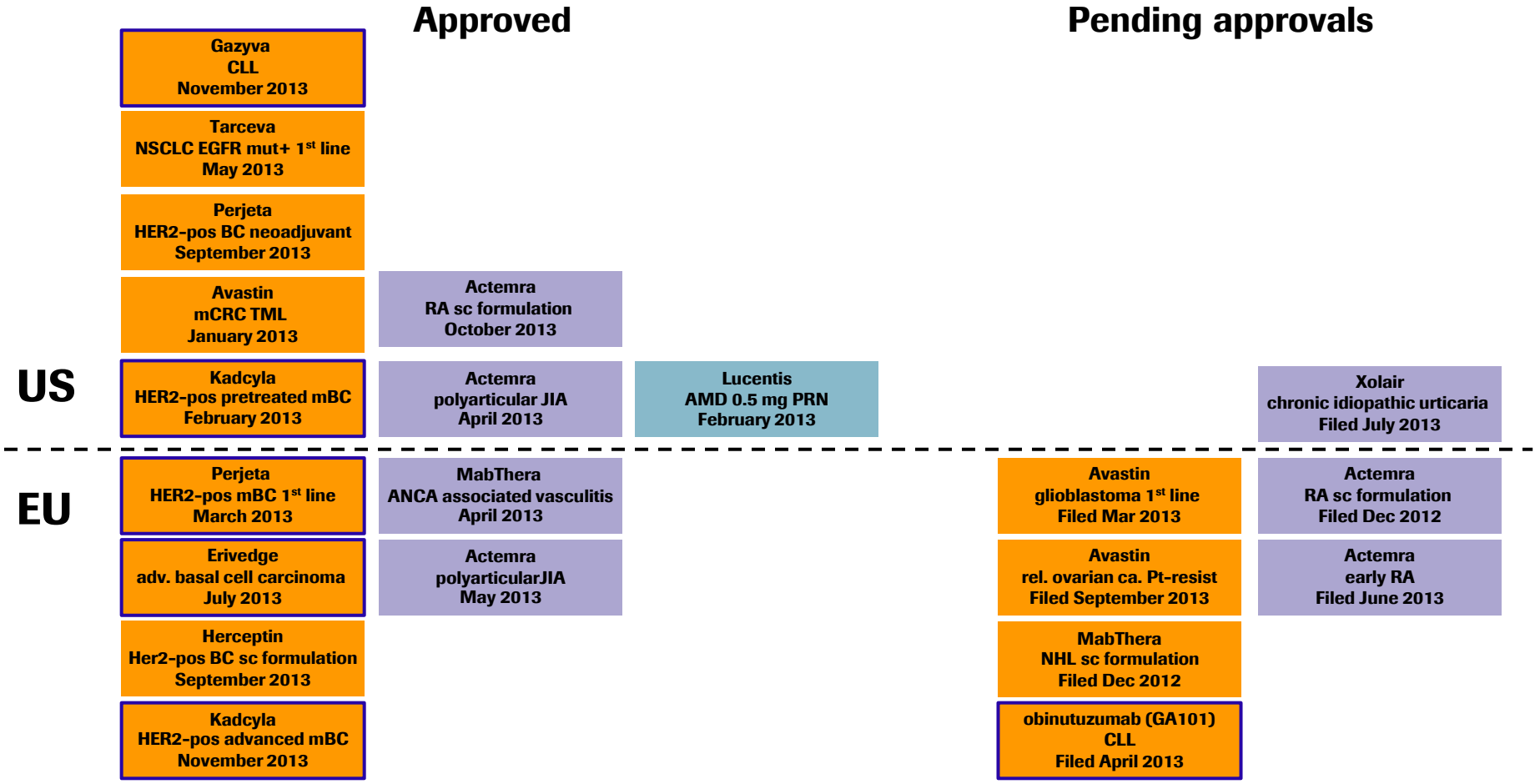
* Approved in the EU

Unless stated otherwise, submissions are planned to occur in US and EU.

Oncology
Immunology
Infectious diseases
CardioMetabolism
Neuroscience
Ophthalmology

Status as of December 31, 2013

Major granted and pending approvals 2013



Status as of December 31, 2013

Major Chugai granted and pending approvals 2013

Approved

- Avastin malignant glioma June 2013
- Tarceva NSCLC EGFR mut+ 1st line June 2013
- Perjeta HER2-pos mBC June 2013
- Kadcyla HER2-pos mBC September 2013
- Avastin ovarian cancer November 2013
- Actemra sc formulation March 2013
- Bonviva iv. osteoporosis June 2013

Pending approvals

- alectinib ALK-pos rec/adv NSCLC Filed October 2013

Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
NME

Status as of December 31, 2013

Doing now what patients need next

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group 2013 results

Diagnostics

Foreign exchange rate information

Avastin

Ovarian cancer clinical development programme

Patient population	Front-line metastatic ovarian cancer	
Phase/study	**Phase III GOG-0218**	**Phase III ICON7**
# of patients	N=1,873	N=1,528
Design	▪ **ARM A:** Paclitaxel and carboplatin for 6 cycles plus 5 cycles of concurrent placebo followed by placebo alone for up to 22 cycles (15 months) ▪ **ARM B:** Paclitaxel and carboplatin for 6 cycles plus 5 cycles of concurrent Avastin followed by placebo alone for up to 22 cycles (15 months) ▪ **ARM C:** Paclitaxel and carboplatin for 6 cycles plus 5 cycles of concurrent Avastin followed by Avastin alone for up to 22 cycles (15 months)	▪ **ARM A:** Paclitaxel and carboplatin for 6 cycles ▪ **ARM B:** Paclitaxel and carboplatin plus concurrent Avastin for 6 cycles followed by Avastin alone for up to 18 cycles (12 months)
Avastin dose	▪ 15 mg/kg q3 weeks	▪ 7.5 mg/kg q3 weeks
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival
Status	▪ Study met its primary endpoint in Q1 2010 ▪ Data presented at ASCO 2010 and 2011 ▪ Results: NEJM 2011 Dec 29;365(26):2484-96	▪ Study met its primary endpoint Q3 2010 ▪ Data presented at ESMO 2010 and ASCO 2011 ▪ Results: NEJM 2011 Dec 29;365(26):2473-83 ▪ OS data presented at ECC 2013
	▪ EMA approval Q4 2011 ▪ Re-evaluate FDA submission in 2014	

ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology

Avastin

Ovarian cancer clinical development programme

Patient population	Relapsed Platinum-sensitive ovarian cancer	Relapsed Platinum-resistant ovarian cancer
Phase/study	**Phase III OCEANS**	**Phase III AURELIA**
# of patients	N=484	N=361
Design	▪ **ARM A:** Carboplatin, gemcitabine, and concurrent placebo for 6-10 cycles, followed by placebo alone until disease progression ▪ **ARM B:** Carboplatin, gemcitabine, and concurrent Avastin for 6-10 cycles, followed by Avastin alone until disease progression.	▪ **ARM A:** Paclitaxel, topotecan or liposomal doxorubicin ▪ **ARM B:** Paclitaxel, topotecan or liposomal doxorubicin plus Avastin
Avastin dose	▪ 15 mg/kg q3 weeks	▪ 10 mg/kg q2 weeks or 15 mg/kg q3 weeks
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival
Status	▪ Study met its primary endpoint Q1 2011 ▪ Data presented at ASCO 2011 ▪ EMA approval received Q4 2012 ▪ Re-evaluate FDA submission in 2014	▪ Study met its primary endpoint Q2 2012 ▪ Data presented at ASCO 2012 ▪ Filed in EU Q3 2013 ▪ OS data presented at ECC 2013 ▪ US filing in 2014

ASCO=American Society of Clinical Oncology; ; ECC=European Cancer Congress

Avastin

Cervical cancer clinical development programme

Patient population	Stage IVB, recurrent or persistent cervical cancer
Phase/study	**Phase III** **GOG-240**
# of patients	N=452
Design	▪ **ARM A:** Paclitaxel, cisplatin ▪ **ARM B:** Paclitaxel, cisplatin plus Avastin ▪ **ARM C:** Paclitaxel, topotecan ▪ **ARM D:** Paclitaxel, topotecan plus Avastin
Avastin dose	▪ 15 mg/kg q3 weeks
Primary endpoint	▪ Progression-free survival
Status	▪ Study met its primary endpoint Q1 2013 ▪ Data presented at ASCO 2013 ▪ To be filed globally 2014

ASCO=American Society of Clinical Oncology.

Avastin

High risk carcinoid, brain and breast cancer development programmes

Patient population	High risk carcinoid	Newly diagnosed glioblastoma	First-line HER2-negative metastatic breast cancer
Phase/study	**Phase III** **SWOG SO518**	**Phase III** **AVAglio**	**Phase III** **MERiDiAN**
# of patients	N=424	N=920	N=480
Design	▪ **ARM A:** Depot octreotide plus interferon alpha ▪ **ARM B:** Depot octreotide plus Avastin	▪ **ARM A:** Concurrent radiation and temozolomide plus placebo; followed by maintenance TMZ plus placebo for 6 cycles; then placebo until disease progression ▪ **ARM B:** Concurrent radiation and TMZ plus Avastin; followed by maintenance TMZ plus Avastin for 6 cycles; then Avastin (15mg/kg q3 weeks) monotherapy until disease progression	▪ **ARM A:** Paclitaxel + Avastin ▪ **ARM B:** Paclitaxel + Placebo
Avastin dose	▪ 15 mg/kg q3 weeks	▪ 10 mg/kg q2 weeks or 15 mg/kg q3 weeks	▪ 10 mg/kg q2 weeks
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival ▪ Overall survival	▪ PFS in ITT ▪ PFS in patients with high plasma VEGF-A
Status	▪ Recruitment completed ▪ Expect data 2015	▪ Co-primary endpoint of PFS met Q3 2012 ▪ Overall survival data presented at ASCO 2013 ▪ Filed in EU Q1 2013	▪ FPI Q3 2012

TMZ=temozolomide; ASCO=American Society of Clinical Oncology

Avastin

Adjuvant clinical development programme

Patient population	Adjuvant lung cancer	Adjuvant breast cancer	
Phase/study	**Phase III** **ECOG 1505**	**Phase III** **ECOG 5103** HER2-negative	**Phase III** **BETH** HER2-positive
# of patients	N=1,500	N=4,950	N=3,600
Design	▪ **ARM A:** Cisplatin plus vinorelbine, docetaxel, gemcitabine or pemetrexed ▪ **ARM B:** Cisplatin plus vinorelbine, docetaxel, gemcitabine or pemetrexed plus Avastin up to 12 months	▪ **ARM A:** Anthracycline plus cyclophosphamide (AC) followed by paclitaxel ▪ **ARM B:** AC plus Avastin followed by paclitaxel plus Avastin ▪ **ARM C:** AC plus Avastin followed by paclitaxel plus Avastin, followed by Avastin up to 12 months	▪ **COHORT 1:** Docetaxel/ carboplatin plus Herceptin ± Avastin ▪ **COHORT 2:** Docetaxel plus Herceptin ± Avastin, followed by 5-fluorouracil, epirubicin, cyclophosphamide For both cohorts, patients receive Herceptin ± Avastin to complete one year of targeted therapy
Avastin dose	▪ 15 mg/kg q3 weeks	▪ 15 mg/kg q3 weeks	▪ 15 mg/kg q3 weeks
Primary endpoint	▪ Overall survival	▪ Disease-free survival	▪ Disease-free survival
Status	▪ Recruitment completed Q4 2013 ▪ Expect data in 2016	▪ Enrolment completed Q2 2011 ▪ Expect data 2014	▪ Primary endpoint not met Q4 2013 ▪ Data presented at SABCS 2013

Erivedge

A novel small molecule inhibitor of the hedgehog signaling pathway

Patient population	Operable basal cell carcinoma	Locally advanced or metastatic basal cell carcinoma	Acute myelogenous leukemia and relapsed refractory high-risk myelodysplastic syndrome
Phase/study	**Phase II**	**Phase II STEVIE**	**Phase II**
# of patients	N=74	N=1,200	N=60
Design	▪ **Single ARM:** 150 mg Erivedge orally once daily	▪ **Single ARM:** 150 mg Erivedge orally once daily	▪ **ARM A**: 150mg Erivedge orally once daily ▪ **ARM B**: Cytarabine
Primary endpoint	▪ COHORT 1: Complete clearance (12 weeks Erivedge) ▪ COHORT 2: Durable complete clearance (12 weeks Erivedge) ▪ COHORT 3: Complete clearance (16 weeks Erivedge)	▪ Safety: Incidence of adverse events	▪ Overall response rate
Status	▪ Recruitment completed Q3 2013 ▪ Cohort 1 data presented at Society for Investigative Dermatology (May 2012) ▪ Data accepted for presentation at AAD 2014	▪ FPI Q2 2011	▪ FPI Q3 2013

In collaboration with Curis
AAD=American Academy of Dermatology

Gazyva

Type II, glycoengineered anti-CD20 monoclonal antibody

Patient population	Front-line chronic lymphocytic leukaemia Patients with comorbidities	Previously untreated chronic lymphocytic leukaemia (CLL)	Previously untreated or relapsed/refractory chronic lymphocytic CLL
Phase/study	**Phase III CLL11**	**Phase I GALTON**	**Phase III GREEN**
# of patients	N=781	N=41	N=800
Design	▪ **ARM A:** Gazyva 1000mg iv plus chlorambucil ▪ **ARM B:** MabThera/Rituxan plus chlorambucil ▪ **ARM C:** Chlorambucil alone	▪ **Cohort A**: Gazyva plus bendamustine ▪ **Cohort B:** Gazyva plus fludarabine plus cyclophosphamide	▪ Single-arm cohort study: Gazyva alone or in combination with different chemotherapy regimens (FC, Bendamustin or Clb)
Primary endpoint	▪ Progression-free survival	▪ Safety	▪ Safety in combination with different chemotherapy regimens
Status	▪ Stage 1 analysis (ARM A/B vs. ARM C) positive ▪ Stage 1 analysis presented at ASCO 2013 ▪ Breakthrough status and priority review granted by the FDA Q2 2013 ▪ Filed globally Q2 2013 ▪ FDA approval granted Q4 2013 ▪ Positive stage 2 analysis (ARM A vs. ARM B) presented at ASH 2013 ▪ Full data published NEJM Jan 8 2014	▪ Recruitment completed ▪ Data presented at ASH 2013	▪ FPI Q4 2013

In collaboration with Biogen Idec

ASCO = American Society of Clinical Oncology, ASH=American Society of Hematology

Gazyva

Type II, glycoengineered anti-CD20 monoclonal antibody

Patient population	Indolent non-Hodgkin's lymphoma MabThera/Rituxan refractory	Diffuse large B-cell lymphoma (DLBCL)	Front-line indolent non-Hodgkin's lymphoma
Phase/study	**Phase III GADOLIN**	**Phase III GOYA**	**Phase III GALLIUM**
# of patients	N=410	N=1,400	N=1,400
Design	▪ **ARM A:** Gazyva 1000mg iv plus bendamustine ▪ **ARM B:** bendamustine	▪ **ARM A:** Gazyva 1000mg iv plus CHOP ▪ **ARM B:** MabThera/Rituxan plus CHOP	▪ **ARM A:** Gazyva 1000mg iv plus chemotherapy followed by Gazyva maintenance ▪ **ARM B:** MabThera/Rituxan plus chemotherapy followed by MabThera/Rituxan maintenance Chemotherapy: ▪ For follicular lymphoma: CHOP, CVP or bendamustine ▪ For non-follicular lymphoma: physician's choice
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Progression-free survival
Status	▪ FPI Q2 2010 ▪ Expect data 2017	▪ FPI Q3 2011 ▪ Expect data 2015	▪ FPI Q3 2011 ▪ Expect data 2017

In collaboration with Biogen Idec

CHOP=Cyclophosphamide, Doxorubicin, Vincristine and Prednisone; CVP=Cyclophosphamide, Vincristine and Prednisolone

Kadcyla

Evaluating new treatment options in HER2-positive breast cancer

Patient population	Pretreated HER2 pos. metastatic breast cancer[1]	Previously untreated HER2 pos. metastatic breast cancer
Phase/study	**Phase III EMILIA**	**Phase III MARIANNE**
# of patients	N=991	N=1,092
Design	▪ **ARM A:** Kadcyla 3.6mg/kg q3w ▪ **ARM B:** Xeloda plus lapatinib	▪ **ARM A:** Herceptin plus taxane ▪ **ARM B:** Kadcyla 3.6mg/kg q3w plus Perjeta ▪ **ARM C:** Kadcyla 3.6 mg/kg q3w plus placebo
Primary endpoint	Co-primary endpoints: ▪ Progression-free survival (PFS) ▪ Overall survival	▪ Progression-free survival assessed by IRF
Status	▪ PFS data presented at ASCO 2012 ▪ OS data presented at ESMO 2012 ▪ Submitted for FDA and EMA approval Q3 2012 ▪ FDA approval granted Q1 2013 ▪ EU approval granted Q4 2013	▪ Recruitment completed Q2 2012 ▪ Expect data in 2014

In collaboration with ImmunoGen, Inc.

[1] Patients must have received prior treatment which included both: a taxane, alone or in combination with another agent, and Herceptin in the adjuvant, locally advanced, or metastatic setting.

ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology

Kadcyla

Evaluating new treatment options in HER2-positive breast and gastric cancer

Patient population	HER2-positive early breast cancer high-risk patients	Operable HER2-positive early breast cancer	Previously Treated Locally Advanced Or Metastatic Her2-Positive Gastric Cancer
Phase/study	**Phase III KATHERINE**	**Phase III KAITLIN**	**Phase II/III GATSBY**
# of patients	N=1,484	N=2,500	N=412
Design	▪ **ARM A:** Kadcyla 3.6mg/kg q3w ▪ **ARM B:** Herceptin	Following surgery and antracycline-based therapy: ▪ **ARM A:** Kadcyla 3.6mg/kg q3w plus Perjeta 420mg/kg q3w plus taxane ▪ **ARM B:** Herceptin 6mg/kg q3w plus Perjeta 420 mg/kg q3w plus taxane	▪ **ARM A**: Kadcyla 3.6mg/kg q3w ▪ **ARM B**: Kadcyla 2.4mg/kg weekly ▪ **ARM C**: Docetaxel or paclitaxel
Primary endpoint	▪ Invasive disease-free survival (IDFS)	▪ Invasive disease-free survival (IDFS)	▪ Phase II: Dose-finding ▪ Phase III: Overall survival
Status	▪ FPI Q1 2013	▪ Expect FPI Q1 2014	▪ FPI Q3 2012

In collaboration with ImmunoGen, Inc.

MabThera/Rituxan

Oncology development programme

Patient population	Front-line follicular non-Hodgkin's lymphoma	Previously untreated chronic lymphocytic leukemia
Phase/study	**Phase III** **SABRINA** Subcutaneous study *Study being conducted ex-US*	**Phase Ib** **SAWYER** Subcutaneous study *Study being conducted ex-US*
# of patients	N=405	N=225
Design	▪ **ARM A:** MabThera iv plus chemotherapy (CHOP or CVP) ▪ **ARM B:** MabThera 1400mg SC plus chemotherapy (CHOP or CVP) *Two-stage design:* ○ Stage 1 (dose confirmation, N=127): PK primary endpoint ○ Stage 2 (N=280): Efficacy primary endpoint (ORR) *Responders will continue on maintenance every 8 weeks over 24 months*	▪ Two-stage design: - Stage 1 (dose-finding, N=55) - Stage 2 (N=170): CLL dose confirmation: ▪ **ARM A**: MabThera iv plus chemotherapy (fludarabine and cyclophosphamide) ▪ **ARM B**: MabThera 1600mg sc plus chemotherapy (fludarabine and cyclophosphamide)
Primary endpoint	▪ Pharmacokinetics, safety and efficacy	▪ Part 1: PK (dose selection) ▪ Part 2: PK of MabThera iv versus MabThera sc (arm A vs arm B)
Status	▪ Stage 1 primary endpoint (PK noninferiority) met ▪ Presented at ASH 2012 ▪ CHMP positive opinion January 2014	▪ FPI (stage 2) Q3 2012 ▪ Stage 1 data presented at ASH 2012

Subcutaneous MabThera : applies Enhanze technology, partnered with Halozyme
CHOP=Cyclophosphamide, Doxorubicin, Vincristine and Prednisolone; CVP=Cyclophosphamide, Vincristine and Prednisolone
ASH=American Society of Hematology.

Perjeta

First in a new class of HER dimerization inhibitors

Patient population	Neoadjuvant HER2-positive breast cancer		Adjuvant HER2-positive breast cancer
Phase/ study	**Phase II NEOSPHERE**	**Phase II TRYPHAENA**	**Phase III APHINITY**
# of patients	N=417	N=225	N=4,800
Design	▪ **ARM A:** Herceptin plus docetaxel ▪ **ARM B:** Perjeta (840mg loading, 420mg q3w) plus Herceptin and docetaxel ▪ **ARM C:** Perjeta plus Herceptin ▪ **ARM D:** Perjeta plus docetaxel	▪ **ARM A:** FEC followed by Taxane with Herceptin and pertuzumab (H+P given concurrently) ▪ **ARM B:** FEC followed by Taxane with Herceptin + pertuzumab (H+P given sequentially) ▪ **ARM C:** TCH + pertuzumab (H+P given concurrently)	▪ **ARM A:** Perjeta (840mg loading, 420 q3w) plus Herceptin for 52 weeks plus chemotherapy (6-8 cycles) ▪ **ARM B**: Placebo plus Herceptin (52 weeks) plus chemotherapy (6-8 cycles)
Primary endpoint	▪ Pathologic complete response (pCR)	▪ Safety	▪ Invasive disease-free survival (IDFS)
Status	▪ Positive data presented at SABCS 2010 ▪ Biomarker data presented SABCS 2011	▪ Positive safety and efficacy data presented at SABCS 2011	▪ Recruitment completed Q3 2013 ▪ Expect data in 2016
	▪ Filed in US Q2 2013 ▪ FDA approval granted Q3 2013 ▪ EU submission under evaluation		

FEC = Fluorouracil, Epirubicin, and Cyclophosphamide; TCH = Docetaxel, Carboplatin, Herceptin; SABCS=San Antonio Breast Cancer Symposium.

Perjeta

First in a new class of HER dimerization inhibitors

Patient population	Second-line HER2-positive metastatic breast cancer	Advanced HER2-positive gastric cancer
Phase/ study	**Phase II** **PHEREXA**	**Phase III** **JACOB**
# of patients	N=450	N=780
Design	▪ **ARM A:** Herceptin plus Xeloda ▪ **ARM B:** Perjeta plus Herceptin and Xeloda	▪ **ARM A:** Perjeta (840mg loading, 420mg q3w) plus Herceptin and chemotherapy ▪ **ARM B:** Placebo plus Herceptin and chemotherapy
Primary endpoint	▪ Progression-free survival	▪ Overall survival
Status	▪ Recruitment completed Q3 2013 ▪ Expect data in 2014	▪ FPI Q2 2013

Tarceva

Reversible tyrosine kinase inhibitor

Patient population	Adjuvant non-small cell lung cancer
Phase/study	**Phase III** **RADIANT**
# of patients	N=974 (2:1 randomisation)
Design	▪ Following surgical resection ± adjuvant chemotherapy: • **ARM A:** Tarceva up to 2 years • **ARM B:** Placebo up to 2 years
Primary endpoint	▪ Disease-free survival • EGFR IHC and/or FISH-positive
Status	▪ Enrolment completed Q3 2010 ▪ Primary endpoint not met Q4 2013

Zelboraf

A selective novel small molecule that inhibits mutant BRAF

Patient population	Adjuvant therapy in patients with resected cutaneous BRAF mutation positive melanoma	Melanoma patients with brain metastases BRAF mutation positive
Phase/study	**Phase III BRIM8**	**Phase II**
# of patients	N=725	N=132
Design	52-week treatment ▪ **ARM A:** Zelboraf 960mg bid ▪ **ARM B:** Placebo	▪ **Single ARM:** Zelboraf
Primary endpoint	▪ Disease-free survival	▪ Overall response rate in the brain
Status	▪ FPI Q3 2012	▪ Recruitment completed Q3 2013 ▪ Presented at SMR 2013

In collaboration with Plexxikon, a member of Daiichi Sankyo Group
SMR=Society for Melanoma Research
See also combinations with: cobimetinib (MEK inhibitor) and anti-PDL1 (RG7446)

Actemra/RoActemra

Interleukin 6 receptor inhibitor

Patient population	Early moderate-to-severe rheumatoid arthritis	Moderate-to-severe rheumatoid arthritis	Moderate-to-severe rheumatoid arthritis
Phase/study	**Phase III** **FUNCTION**	**Phase III** **SUMMACTA** Subcutaneous study	**Pivotal Phase III** **BREVACTA** Subcutaneous study
# of patients	N=1,162	N=1,262	N=656
Design	104 week treatment ▪**ARM A**: Actemra IV 8 mg/kg q4w plus placebo MTX ▪**ARM B:** Actemra IV 8 mg/kg q4w plus MTX ▪**ARM C:** Actemra IV 4 mg/kg q4w plus MTX ▪**ARM D:** MTX alone	▪ Add-on to DMARD therapy ▪ Weekly dosing for 104 weeks ▪ **ARM A:** Actemra SC 162mg weekly plus placebo IV q4w ▪ **ARM B:** Actemra IV 8mg/kg q4w plus placebo SC weekly	▪ Add-on to DMARD therapy ▪ Dosing every two weeks for 104 weeks ▪ **ARM A:** Actemra SC 162mg q2w ▪ **ARM B:** Placebo SC q2w
Primary endpoint	▪ DAS28 remission at 24 weeks, 1 year and 2 years	▪ ACR 20 at week 24	▪ ACR 20 at week 24
Status	▪ Primary endpoint met Q3 2012 ▪ Data presented at EULAR 2013 ▪ Filed in EU Q3 2013	▪ Primary endpoint met Q2 2012 ▪ Presented at ACR 2012 ▪ Filed in US and EU in Q4 2012	▪ Primary endpoint met Q3 2012 ▪ Presented at ACR 2012 ▪ Filed in US and EU in Q4 2012
		▪ FDA approval received Q4 2013 ▪ CHMP positive opinion Q4 2013	

In collaboration with Chugai
MTX=methotrexate; DMARD=Disease-Modifying Anti-Rheumatic Drugs
EULAR=The European League Against Rheumatism, ACR=American College of Rheumatology

Actemra/RoActemra

Interleukin 6 receptor inhibitor

Patient population	Systemic sclerosis	Giant Cell Arteritis
Phase/study	**Phase II** **faSScinate** Proof-of-concept study	**Phase III** **GiACTA**
# of patients	N=86	N=250
Design	Blinded 48-week treatment with weekly dosing: ▪**ARM A:** Actemra SC 162mg ▪**ARM B:** Placebo SC Open-label weekly dosing at weeks 49 to 96: ▪Actemra SC 162mg	Part 1: 52-week blinded period ▪ **ARM A:** Actemra SC 162mg qw + 26 weeks prednisone taper ▪ **ARM B:** Actemra SC 162mg q2w + 26 weeks prednisone taper ▪ **ARM C:** Placebo+ 26 weeks prednisone taper ▪ **ARM D:** Placebo+ 52 weeks prednisone taper Part II: ▪ 104-weel open label extension – patients in remission followed off of the study drug; Patients with active disease receive open label Actemra SC 162mg qw
Primary endpoint	▪ Change in modified Rodnan skin score (mRSS) at week 24 ▪ Safety	▪ Proportion of patients in sustained remission at week 52
Status	▪ Recruitment completed Q2 2013 ▪ Expect data H1 2014	▪ FPI Q3 2013

In collaboration with Chugai

Xolair

Evaluating potential in chronic idiopathic urticaria, an IgE related disease

Patient population	**Chronic idiopathic urticaria** Patients who remain symptomatic despite treatment*		
Phase/study	**Phase III** **ASTERIA I**	**Phase III** **ASTERIA II**	**Phase III** **GLACIAL**
# of patients	N=328	N=322	N=335
Design	Add-on therapy to approved doses of H1 anti-histamines 24 week treatment period (q4-week) • **ARM A:** Xolair 300 mg • **ARM B:** Xolair 150 mg • **ARM C:** Xolair 75 mg • **ARM D:** Placebo	Add-on therapy to approved doses of H1 anti-histamines 12 week treatment period (q4-week) ▪**ARM A:** Xolair 300 mg ▪**ARM B:** Xolair 150 mg ▪**ARM C:** Xolair 75 mg ▪**ARM D:** Placebo	Add-on therapy to 4 times approved doses of H1 anti-histamines, H2 blockers, and/or LTRA 24 week treatment period (q4-week) ▪**ARM A:** Xolair 300 mg ▪**ARM B:** Placebo
Primary endpoint	▪ Change from baseline to week 12 in weekly itch severity score (ISS)	▪ Change from baseline to week 12 in weekly itch severity score (ISS)	▪ Safety
Status	▪ Enrolment completed Q1 2012 ▪ Presented at EADV 2013	▪ Enrolment completed Q4 2011 ▪ Presented at AAAAI 2013	▪ Enrolment completed Q1 2012 ▪ Data presented at EAACI-WAO 2013
	▪ Filed in US Q3 2013		

In collaboration with Novartis

*Refractory to H1 anti-histamines, H2 blockers, and/or leukotriene receptor antagonists (LTRAs) at the time of randomization.

AAAAI=American Academy of Allergy, Asthma and Immunology

EAACI-WAO=European Academy of Allergy and Clinical Immunology – World Allergy Organization

EADV=European Academy of Dermatology and Venereology

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group 2013 results

Diagnostics

Foreign exchange rate information

Alectinib (ALK inhibitor, RG7853, AF802)

New potent inhibitor of anaplastic lymphoma kinase

Patient population	Non-small cell lung cancer	
Phase	**Phase I**	**Phase II**
# of patients	N=90-100	N=215
Design	• Dose escalation to MTD	Patients with ALK mutation that failed crizotinib •**Part 1**: Dose escalation monotherapy •**Part 2**: Monotherapy, dose selected based on the results of Part 1
Primary endpoint	• Safety and efficacy	• Safety and efficacy
Status	▪ Study in crizotinib-naïve patients in Japan completed; crizotinib-failure patients in US ongoing ▪ Data presented at ECC 2013 ▪ Japan study results: Lancet Oncology 2013 Jun;14(7):590-8 ▪ Filed in Japan October 2013	▪ FPI Q3 2013
	▪ Breakthrough designation granted by the FDA in Q2 2013	

In collaboration with Chugai
ECC=European Cancer Congress

Anti-PDL1 (MPDL3280A, RG7446)

Novel approach in cancer immunotherapy

Patient population	Metastatic NSCLC 2nd line	Locally advanced or metastatic NSCLC PD-L1 positive	Locally advanced or metastatic NSCLC (2nd/3rd line)	Solid tumors	Solid tumors
Phase/study	**Phase III OAK**	**Phase II FIR**	**Phase II POPLAR**	**Phase I**	**Phase I**
# of patients	N=850	N=100	N=180	N=344	N=68
Design	▪ RG7446 1200mg q3w ▪ docetaxel	Single arm study ▪ 1200mg of Anti-PDL1 q3w for maximum of 16 cycles	▪ **ARM A**: RG7446 1200mg IV q3w, up to 16 cycles ▪ **ARM A**: Docetaxel IV q3w	▪ Dose escalation study	▪ **ARM A**: Anti-PDL1+Avastin ▪ **ARM B**: Anti-PDL1+Avastin+ chemotherapy
Primary endpoint	▪ Overall survival	▪ Efficacy and safety	▪ Overall survival	▪ Safety/PK	▪ Safety/PK
Status	▪ Expect FPI Q1 2014	▪ FPI Q2 2013	▪ FPI Q3 2013	▪ FPI Q2 2011 ▪ Initial efficacy data presented at ASCO 2013 ▪ Updated data presented at ECC 2013	▪ FPI Q2 2012

ASCO=American Society of Clinical Oncology; ECC=European Cancer Congress

Anti-PDL1 (MPDL3280A, RG7446)

Novel approach in cancer immunotherapy

Patient population	Previously untreated metastatic melanoma BRAF mutation positive	Untreated advanced renal cell carcinoma	Non-small cell lung cancer	Locally advanced or metastatic tumors
Phase/study	**Phase I**	**Phase II**	**Phase I**	**Phase I**
# of patients	N=44	N=150	N=32	N=90
Design	▪ Three-arm study with different doses of anti-PDL1-Zelboraf[1] combination	▪ **ARM A**: RG7446 plus Avastin ▪ **ARM B**: RG7446; following PD: RG7446 plus Avastin ▪ **ARM C**: sunitinib; following PD: RG7446 plus Avastin	▪ RG7446 plus Tarceva[2]	▪ **ARM A:** Dose-finding – RG7446 plus cobimetinib[3] ▪ **ARM B:** Dose-expansion - RG7446 plus cobimetinib
Primary endpoint	▪ Safety/PK	▪ Progression free survival	▪ Safety	▪ Safety
Status	▪ FPI Q3 2012	▪ Expect FPI Q1 2014	▪ Expect FPI Q1 2014	▪ FPI Q4 2013

[1]Zelboraf in collaboration with Plexxikon, a member of Daiichi Sankyo Group;
[2]Tarceva is a registered trademark of OSI Pharmaceuticals, LLC, a subsidiary of Astellas US, LLC; [3]Cobimetinib in collaboration with Exelixis

Bcl-2 inhibitor (RG7601, ABT/GDC-199)

Novel small molecule Bcl-2 selective inhibitor

Patient population	Relapsed/Refractory CLL with 17p deletion	Relapsed or Refractory CLL	Relapsed CLL and SLL	Relapsed/Refractory CLL and NHL
Phase/study	**Phase II**	**Phase III**	**Phase Ib**	**Phase I**
# of patients	N=100	N=370	N=50	N=130
Design	▪ Single-agent RG7601	▪ **ARM A**: RG7601 plus Rituxan ▪ **ARM B**: Rituxan plus bendamustine	▪ Dose-escalation study in combination with MabThera/Rituxan	▪ Dose-escalation study
Primary endpoint	▪ Safety/MTD	▪ Safety/MTD	▪ Safety/MTD	▪ Safety/PK/Response rate
Status	▪ FPI Q3 2013	▪ Expect FPI Q1 2014	▪ FPI Q3 2012	▪ FPI Q2 2011 ▪ CLL and NHL data presented at ASCO 2013 ▪ Updated CLL and SLL data presented at ASH 2013

Joint project with AbbVie in collaboration with WEHI (The Walter and Eliza Hall Institute)
CLL=Chronic Lymphocytic Leukemia; NHL=Non-Hodgkin's Lymphoma; SLL=Small Lymphocytic Lymphoma
ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

Bcl-2 inhibitor (RG7601, ABT/GDC-199)

Novel small molecule Bcl-2 selective inhibitor

Patient population	Relapsed/Refractory or previously untreated CLL	Relapsed/Refractory or previously untreated CLL	Relapsed or Refractory NHL	Acute Myelogenous Leukemia (AML)
Phase/study	**Phase I**	**Phase I**	**Phase I**	**Phase II**
# of patients	N=70	N=74	N=40	N=54
Design	▪ RG7601 in combination with MabThera/Rituxan and bendamustine	▪ RG7601 in combination with Gazyva	▪ Dose escalation of RG7601 in combination with Rituxan and bendamustine	▪ Dose escalation of RD7601
Primary endpoint	▪ Safety/MTD	▪ Safety/MTD	▪ Safety/MTD	▪ Overall response rate
Status	▪ FPI Q2 2013	▪ FPI Q1 2014	▪ FPI Q2 2012 ▪ Study resumed Q3 2013	▪ FPI Q4 2013

Joint project with AbbVie in collaboration with WEHI (The Walter and Eliza Hall Institute)

Bcl-2 inhibitor (RG7601, ABT/GDC-199)

Novel small molecule Bcl-2 selective inhibitor

Patient population	Relapsed/Refractory multiple myeloma	Relapsed/Refractory multiple myeloma
Phase/study	**Phase I**	**Phase I**
# of patients	N=30	N=30
Design	Patients receiving Bortezomib and Dexamethasone as standard therapy: ▪ Dose escalation cohort: RG7601+bortezomib+dexamethasone ▪ Safety expansion cohort: RG7601+bortezomib+dexamethasone	▪ Dose escalation cohort ▪ Safety expansion cohort
Primary endpoint	▪ Safety/MTD	▪ Safety/MTD
Status	▪ FPI Q4 2012	▪ FPI Q4 2012

Joint project with AbbVie in collaboration with WEHI (The Walter and Eliza Hall Institute)

Cobimetinib (RG7421, GDC-0973)

Selective small molecule inhibitor of mitogen-activated protein kinase kinase

Patient population	Previously untreated metastatic melanoma BRAF mutation positive	Metastatic melanoma BRAF mutation positive	Solid tumors	Solid tumors
Phase/study	**Phase III coBRIM**	**Phase Ib BRIM7**	**Phase Ib**	**Phase Ib**
# of patients	N=500	N=~100	N=212	N=108
Design	▪ **ARM A:** Zelboraf[1] plus cobimetinib ▪ **ARM B:** Zelboraf[1] plus placebo	▪ Dose escalation study evaluating Zelboraf[1] plus cobimetinib	▪ Dose escalation study evaluating cobimetinib plus pictilisib (PI3 kinase inhibitor)	▪ Dose escalation study of cobimetinib in combination with ipatasertib[2] (AKT inhibitor)
Primary endpoint	▪ Progression-free survival	▪ Safety/PK	▪ Safety/PK	▪ Safety/PK
Status	▪ FPI Q1 2013 ▪ Expect data 2014	▪ FPI Q1 2011 ▪ Data presented at ESMO 2012 ▪ Updated data presentation at EADO and ECC 2013	▪ FPI Q4 2009 ▪ Updated data presented at ASCO 2012	▪ FPI Q2 2012

In collaboration with Exelixis

[1]Zelboraf In collaboration with Plexxikon, a member of Daiichi Sankyo Group; [2]ipatasertib in collaboration with Array BioPharma

ESMO=European Society for Medical Oncology; ECC=European Cancer Congress; EADO=European Association of Dermato-Oncology

Cobimetinib (RG7421, GDC-0973)

Selective small molecule inhibitor of mitogen-activated protein kinase

Patient population	Locally advanced or metastatic tumors	Locally advanced or metastatic tumors with mutant KRAS	Advanced solid tumors
Phase/study	**Phase I**	**Phase I**	**Phase I**
# of patients	N=90	N=50	N=96
Design	▪ **ARM A:** Dose-finding - cobimetinib plus RG7446 (anti-PDL1) ▪ **ARM B:** Dose-expansion - cobimetinib plus RG7446 (anti-PDL1)	▪ Dose finding of cobimetinib plus RG7597 (anti-HER3/EGFR DAF)	▪ Dose finding study of cobimetinib plus onartuzumab with or without Zelboraf[1]
Primary endpoint	▪ Safety	▪ Safety	▪ Safety
Status	▪ Expect FPI Q1 2014	▪ FPI Q4 2013	▪ FPI Q4 2013

In collaboration with Exelixis

[1]Zelboraf In collaboration with Plexxikon, a member of Daiichi Sankyo Group

Onartuzumab (MetMAb, RG3638)

Anti-Met monovalent antibody that inhibits HGF-mediated activation

Patient population	2nd- and 3rd-line Met-positive metastatic NSCLC	Advanced NSCLC Met-positive with EGFR activating mutation
Phase/study	**Phase III MetLung**	**Phase III**
# of patients	N=490	N=300
Design	▪ **ARM A:** Tarceva plus onartuzumab ▪ **ARM B:** Tarceva plus placebo	▪ **Arm A**: Onartuzumab + Tarceva ▪ **Arm B**: Placebo + Tarceva
Primary endpoint	▪ Overall survival	▪ Progression-Free Survival
Status	▪ Recruitment completed Q3 2013	▪ FPI Q4 2013

Onartuzumab (MetMAb, RG3638)

Anti-Met monovalent antibody that inhibits HGF-mediated activation

Patient population	1st line non-squamous NSCLC	1st line squamous NSCLC
Phase/study	**Phase II**	**Phase II**
# of patients	N=260	N=110
Design	**Cohort 1** ▪**Arm A**: Onartuzumab + Avastin + paclitaxel + platinum-based chemo (cisplatin or carboplatin) ▪**Arm B**: Placebo + Avastin + paclitaxel + platinum-based chemo (cisplatin or carboplatin) **Cohort 2** ▪**Arm A**: Onartuzumab + pemetrexed + platinum-based chemo (cisplatin or carboplatin) ▪**Arm B**: Placebo + pemetrexed + platinum-based chemo (cisplatin or carboplatin)	▪ **Arm A**: Onartuzumab + paclitaxel + platinum-based chemo (cisplatin or carboplatin) ▪ **Arm B**: Placebo + paclitaxel + platinum-based chemo (cisplatin or carboplatin)
Primary endpoint	▪ Progression-Free Survival in the ITT population ▪ Progression-Free Survival in Met-positive patients	▪ Progression-Free Survival in the ITT population ▪ Progression-Free Survival in Met-positive patients
Status	▪ FPI Q2 2012	▪ FPI Q3 2012

Onartuzumab (MetMAb, RG3638)

Anti-Met monovalent antibody that inhibits HGF-mediated activation

Patient population	Metastatic HER2-negative gastroesophageal cancer	Metastatic HER2-negative gastroesophageal cancer	Advanced solid tumors
Phase/study	**Phase III MetGastric**	**Phase II**	**Phase I**
# of patients	N=800	N=120	N=96
Design	▪ **ARM A:** Onartuzumab plus mFOLFOX6 ▪ **ARM B:** Placebo plus mFOLFOX6	▪ **ARM A:** Onartuzumab plus mFOLFOX ▪ **ARM B:** Placebo plus mFOLFOX	▪ Dose finding study of onartuzumab plus cobimetinib[1] with or without Zelboraf[2]
Primary endpoint	▪ Overall survival in Met-positive patients	▪ Progression–free survival in ITT ▪ Progression-free survival in pre-specified Met-positive patients	▪ Safety
Status	▪ FPI Q4 2012	▪ FPI Q3 2012	▪ FPI Q4 2013

[1]Cobimetinib in collaboration with Exelixis; [2]Zelboraf In collaboration with Plexxikon, a member of Daiichi Sankyo Group
mFOLFOX6=modified FOLFOX (Folinic acid, Fluorouracil, Oxaliplatin)

Onartuzumab (MetMAb, RG3638)

Anti-Met monovalent antibody that inhibits HGF-mediated activation

Patient population	1st-line metastatic colorectal cancer	Avastin-naïve recurrent glioblastoma	Hepatocellular carcinoma
Phase	**Phase II**	**Phase II**	**Phase I**
# of patients	N=188	N=120	N=54
Design	▪ **ARM A:** FOLFOX plus Avastin plus onartuzumab ▪ **ARM B:** FOLFOX plus Avastin plus placebo	▪ **Arm A**: Onartuzumab + Avastin ▪ **Arm B**: Placebo + Avastin ▪ **Arm C:** Onartuzumab +Placebo (enrolment to arm C suspended)	▪ Single-agent onartuzumab in combination with sorafenib
Primary endpoint	▪ Progression–free survival in ITT ▪ Progression-free survival in pre-specified Met-positive patients	▪ Progression-Free Survival in the ITT population ▪ Progression-Free Survival in Met-positive population	▪ Safety
Status	▪ Enrolment completed Q4 2012 ▪ Expect data 2014	▪ Primary endpoint not met January 2014	▪ FPI Q3 2013

FOLFOX=Folinic acid, Fluorouracil, Oxaliplatin

PI3 kinase inhibitor (RG7604, GDC-0032)

Beta isoform sparing PI3 kinase inhibitor targeting commonly mutated oncogene

Molecule	**PI3 Kinase inhibitor** (GDC-0032, RG7604)	
Patient population	**Solid tumors and HER2-negative HR-positive breast cancer**	**HER2-negative locally recurrent or metastatic breast cancer**
Phase	**Phase I/II**	**Phase I**
# of patients	N=260	N=65
Design	**Phase I** ▪ RG7604 ▪ RG7604 plus letrozole or fulvestrant **Phase II** ▪ RG7604 plus fulvestrant	▪ RG7604 plus docetaxel ▪ RG7604 plus paclitaxel
Primary endpoint	▪ Safety/PK/efficacy	▪ Safety
Status	▪ FPI Q1 2011 ▪ Data presented at SABCS 2013	▪ FPI Q2 2013

SABCS=San Antonio Breast Cancer Symposium

Pictilisib (RG7321, GDC-0941)

Pan-PI3 kinase inhibitor with potential activity in multiple cancers

Patient population	2L ER-positive metastatic breast cancer	Previously untreated advanced or recurrent NSCLC	Locally recurrent or metastatic HER2-negative HR-positive breast cancer
Phase	**Phase II** **FERGI**	**Phase II** **FIGARO**	**Phase II** **PEGGY**
# of patients	N=340	N=302	N=180
Design	▪ **ARM A:** pictilisib plus hormonal therapy ▪ **ARM B:** apitolisib plus hormonal therapy (ARM B discontinued) ▪ **ARM C:** Hormonal therapy + placebo	▪ **ARM A:** Pictilisib + carboplatin + paclitaxel ▪ **ARM B:** Placebo + carboplatin + paclitaxel ▪ **ARM C:** Pictilisib+ carboplatin + paclitaxel + bevacizumab ▪ **ARM D:** Pictilisib+ carboplatin + paclitaxel + bevacizumab	▪ **ARM A**: Pictilisib+ paclitaxel ▪ **ARM B**: Placebo + paclitaxel
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Progression-free survival
Status	▪ Recruitment completed January 2014	▪ FPI Q1 2012	▪ FPI Q1 2013

Polatuzumab vedotin (RG7596)

Antibody drug conjugate targeting CD79b for the treatment of B-cell malignancies

Patient population	Hematologic malignancies	Non-Hodgkin's Lymphoma
Phase	**Phase I**	**Phase II ROMULUS**
# of patients	N=99	N=120
Design	▪ Dose escalation study	▪ **ARM A:** RG7593 plus Rituxan ▪ **ARM B:** RG7596 plus Rituxan
Primary endpoint	▪ Safety	▪ Safety and anti-tumor activity
Status	▪ Final data presented at ASH 2013	▪ Recruitment completed Jan 2014 ▪ Data to be presented in 2014

In collaboration with Seattle Genetics
ASH=American Society of Hematology

Bitopertin (GlyT-1, RG1678)

A small molecule first-in-class glycin reuptake inhibitor (GRI)

Patient population	Persistent, predominant negative symptoms of schizophrenia			Obsessive-compulsive disorder
Phase/study	**Phase III SUNLYTE**	**Phase III DAYLYTE**	**Phase III FLASHLYTE**	**Phase II SKYLITE**
# of patients	N=630	N=630	N=630	N=99
Design	▪ Add-on therapy to anti-psychotics ▪ 52-week treatment period ▪ **ARM A:** bitopertin (10 mg) ▪ **ARM B:** bitopertin (20 mg) ▪ **ARM C:** Placebo	▪ Add-on therapy to anti-psychotics ▪ 52-week treatment period ▪ **ARM A:** bitopertin (5 mg) ▪ **ARM B:** bitopertin (10 mg) ▪ **ARM C:** Placebo	▪ Add-on therapy to anti-psychotics ▪ 52-week treatment period ▪ **ARM A:** bitopertin (10 mg) ▪ **ARM B:** bitopertin (20 mg) ▪ **ARM C**: Placebo	▪ 16-week treatment period ▪ Background therapy of selective serotonin reuptake inhibitors (SSRI) ▪ **ARM A**: bitopertin daily (30 mg) ▪ **ARM B**: bitopertin daily (10 mg) ▪ **ARM C**: Placebo
Primary endpoint	▪ PANSS negative symptom factor at week 24	▪ PANSS negative symptom factor at week 24	▪ PANSS negative symptom factor at week 24	▪ Change in total score on Yale-Brown Obsessive Compulsive Scale
Status	▪ FPI Q4 2010	▪ Enrolment completed Q2 2013 ▪ Primary endpoint not met January 2014	▪ Enrolment completed Q2 2013	▪ FPI Q4 2012

PANSS=Positive and Negative Syndrome Scale

Bitopertin (GlyT-1, RG1678)

A small molecule first-in-class glycin reuptake inhibitor (GRI)

Patient population	Sub-optimally controlled symptoms of schizophrenia		
Phase/study	**Phase III NIGHTLYTE**	**Phase III MOONLYTE**	**Phase III TWILYTE**
# of patients	N=600	N=600	N=600
Design	▪ Add-on therapy to anti-psychotics ▪ 52-week treatment period ▪ **ARM A:** bitopertin daily (10 mg) ▪ **ARM B:** bitopertin daily (20 mg) ▪ **ARM C:** Placebo	▪ Add-on therapy to anti-psychotics ▪ 52-week treatment period ▪ **ARM A:** bitopertin daily (10 mg) ▪ **ARM B:** bitopertin daily (20 mg) ▪ **ARM C:** Placebo	▪ Add-on therapy to anti-psychotics ▪ 52-week treatment period ▪ **ARM A:** bitopertin daily (5 mg) ▪ **ARM B:** bitopertin daily (10 mg) ▪ **ARM C:** Placebo
Primary endpoint	▪ PANSS positive symptom factor at week 12	▪ PANSS positive symptom factor at week 12	▪ PANSS positive symptom factor at week 12
Status	▪ FPI Q4 2010	▪ FPI Q4 2010	▪ Recruitment completed Q3 2013

PANSS=Positive and Negative Syndrome Scale

Gantenerumab (RG1450)

Fully human monoclonal antibody against amyloid-beta

Patient population	Prodromal Alzheimer's Disease	Mild Alzheimer's Disease
Phase/study	**Phase II/III** **SCarlet RoAD**	**Phase III** **Marguerite Road**
# of patients	N=799	N=1,000
Design	104-week subcutaneous treatment period ▪**ARM A:** Gantenerumab (225 mg) ▪**ARM B:** Gantenerumab (105 mg) ▪**ARM C:** Placebo	104-week subcutaneous treatment period ▪**ARM A:** Gantenerumab ▪**ARM B:** Placebo
Primary endpoint	▪Change in CDR-SOB at 2 years ▪Sub-study: change in brain amyloid by PET at 2 years	▪Change in ADAS-Cog and ADCS-ADL at 2 years (co-primary)
Status	▪Phase I PET data: Archives of Neurology 2012 Feb;69(2):198-207 ▪Enrollment completed Q4 2013 ▪Data expected in 2016	▪Expect FPI Q2 2014

In collaboration with Morphosys
CDR-SOB=Clinical Dementia Rating scale Sum of Boxes

Lampalizumab (RG7417)

Antibody fragment to selectively block activation of alternative complement pathway

Patient population	Geographic atrophy (GA) secondary to age-related macular degeneration
Phase/study	**Phase Ib/II** **MAHALO**
# of patients	N=143

Design	▪ **Part 1: Open-label**
	  ▪ Multiple dosing
	▪ **Part 2: Randomized**
	  ▪ **ARM A:** Lampalizumab injection
	  ▪ **ARM B:** Sham injection

Primary endpoint	▪ Part 1: Safety ▪ Part 2: Growth rate of GA lesions at month 18
Status	▪ Primary endpoint met Q3 2013 ▪ Efficacy data including biomarker presented at AAO 2013

AAO=American Academy of Ophthalmology

Lebrikizumab (RG3637)

A humanized monoclonal antibody designed to bind specifically to IL-13

	Severe uncontrolled adult asthma	
Patient population	**Adult patients whose asthma is uncontrolled with inhaled corticosteroids and a second controller medication**	
Phase/study	**Phase III LAVOLTA I**	**Phase III LAVOLTA II**
# of patients	N=1050	N=1050
Design	Subcutaneous lebrikizumab q4w on top of SOC for 52 weeks safety follow-up ▪**ARM A:** Lebrikizumab high dose ▪**ARM B:** Lebrikizumab low dose ▪**ARM C:** Placebo Patients will be tested for periostin level	Subcutaneous lebrikizumab q4w on top of SOC for 52 weeks safety follow-up ▪**ARM A:** Lebrikizumab high dose ▪**ARM B:** Lebrikizumab low dose ▪**ARM C:** Placebo Patients will be tested for periostin level
Primary endpoint	▪ Rate of asthma exacerbations during the 52-week placebo-controlled period	▪ Rate of asthma exacerbations during the 52-week placebo-controlled period
Status	▪ FPI Q3 2013	▪ FPI Q3 2013

Lebrikizumab (RG3637)

A humanized monoclonal antibody designed to bind specifically to IL-13

	Severe uncontrolled adult asthma	
Patient population	**Adult patients whose asthma is uncontrolled with inhaled corticosteroids and a second controller medication**	
Phase/study	**Phase IIb LUTE**	**Phase IIb VERSE**
# of patients	N=258	N=205
Design	Subcutaneous lebrikizumab q4w on top of SOC for 28 to 52 weeks with a 24 week safety follow-up ▪**ARM A:** Lebrikizumab highest dose ▪**ARM B:** Lebrikizumab middle dose ▪**ARM C:** Lebrikizumab lowest dose ▪**ARM D:** Placebo Patients will be tested for periostin level	Subcutaneous lebrikizumab q4w on top of SOC for 28 to 52 weeks with a 24 week safety follow-up ▪**ARM A:** Lebrikizumab highest dose ▪**ARM B:** Lebrikizumab middle dose ▪**ARM C:** Lebrikizumab lowest dose ▪**ARM D:** Placebo Patients will be tested for periostin level
Primary endpoint	▪ Rate of asthma exacerbations during the 52-week placebo-controlled period	▪ Rate of asthma exacerbations during the 52-week placebo-controlled period
Status	▪ Recruitment completed Q4 2012 ▪ Data publication in 2014	▪ Recruitment completed Q4 2012 ▪ Data publication in 2014

Lebrikizumab (RG3637)

A humanized monoclonal antibody designed to bind specifically to IL-13

Patient population	Adolescent patients whose asthma is uncontrolled with inhaled corticosteroids and a second controller medication	Idiopathic pulmonary fibrosis
Phase/study	**Phase III** **ACOUSTICS**	**Phase II** **RIFF**
# of patients	N=375	N=250
Design	Subcutaneous lebrikizumab q4w on top of SOC for 52 weeks with 52 week double-blind active treatment extension ▪**ARM A:** Lebrikizumab high dose, week 1-104 or week 52-104 ▪**ARM B:** Lebrikizumab low dose, week 1-104 or week 52-104 ▪**ARM C:** Placebo, week 1-52	▪**ARM A:** Lebrikizumab SC q4w ▪**ARM B:** Placebo
Primary endpoint	▪ Rate of asthma exacerbations during the 52-week placebo-controlled period	▪ Progression-free survival
Status	▪ FPI Q3 2013	▪ FPI Q4 2013

Ocrelizumab (RG1594)

2nd generation anti-CD20 monoclonal antibody

Patient population	Relapsing multiple sclerosis (RMS)		Primary progressive multiple sclerosis (PPMS)
Phase/study	**Phase III OPERA I**	**Phase III OPERA II**	**Phase III ORATORIO**
# of patients	N=800	N=800	N=630
Design	• 96-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	• 96-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	• 120-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv every 24 weeks ▪ **ARM B:** Placebo
Primary endpoint	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Sustained disability progression versus placebo by Expanded Disability Status Scale (EDSS)
Status	▪ Enrolment completed Q1 2013 ▪ Expect data in 2015	▪ Enrolment completed Q1 2013 ▪ Expect data in 2015	▪ Enrolment completed Q1 2013 ▪ Expect data in 2015

Mericitabine (RG7128)

Nucleoside NS5B polymerase inhibitor added to approved protease inhibitors in prior null responders to IFN/RBV

Patient population	Treatment-naive and failure chronic hepatitis C Genotype 1 and 4	Treatment-naive and failure chronic hepatitis C Genotype 1 and 4
Phase/study	**Phase IIb DYNAMO 1***	**Phase IIb DYNAMO 2** Longer duration study
# of patients	N=120	N= 120
Design	• **ARM A:** Boceprevir + mericitabine (1000 mg BID) + Pegasys and Copegus for 24 weeks • **ARM B:** Boceprevir + mericitabine (1000 mg BID) + Pegasys and Copegus for 24 weeks followed by boceprevir+Pegasys and Copegus for 24 weeks • **ARM C :** Boceprevir+Pegasys and Copegus for 48 weeks	• **ARM A:** Telaprevir + mericitabine (1000 mg BID) + Pegasys and Copegus for 12 weeks, followed by + mericitabine (1000 mg BID) + Pegasys and Copegus for 12 weeks • **ARM B:** Telaprevir + mericitabine (1000 mg BID) + Pegasys and Copegus for 12 weeks, followed by + mericitabine (1000 mg BID) + Pegasys and Copegus for 12 weeks, followed by Pegasys and Copegus for 24 weeks • **ARM C :** Telaprevir + mericitabine (1000 mg BID) + Pegasys and Copegus for 12 weeks, followed by Pegasys and Copegus for 36 weeks • **ARM D:** Telaprevir + Pegasys and Copegus for 12 weeks, followed by Pegasys and Copegus for 36 weeks
Primary endpoint	▪ Sustained virological response (SVR)	▪ Sustained virological response (SVR)
Status	▪ Recruitment completed Q3 2012 ▪ Data presented at AASLD 2013	▪ Recruitment completed Q3 2012 ▪ Data presented at AASLD 2013

Mericitabine (RG7128) licensed from Pharmasset, now part of Gilead
* In collaboration with Merck

Mericitabine, danoprevir, setrobuvir

IFN-free combination of different direct-acting antivirals in treatment naïve patients

Patient population	Hepatitis C patients Treatment-naïve or null-responders to interferon-based treatment
Phase/study	**Phase II** **ANNAPURNA**
# of patients	N=110
Design	• **ARM A:** GT1a including setrobuvir, danoprevir, ritonavir, ribavirin and mericitabine • **ARM B:** GT1a including setrobuvir, danoprevir, ritonavir, ribavirin and mericitabine • **ARM C:** GT1a including setrobuvir, danoprevir, ritonavir and ribavirin • **ARM D:** GT1b including setrobuvir, danoprevir, ritonavir, ribavirin and mericitabine • **ARM E:** GT1b including setrobuvir, danoprevir, ritonavir and ribavirin
Primary endpoint	▪ Sustained virological response at week 12 after the end of the study treatment
Status	▪ FPI Q2 2012 ▪ Recruitment Part 1 completed in Q4 2012 ▪ Interim data presented at AASLD 2013

Mericitabine (RG7128) licensed from Pharmasset, now part of Gilead; Danoprevir=RG7227; Setrobuvir=RG7790
AASLD=American Association for the Study of Liver Diseases

Danoprevir, mericitabine

Comparing IFN-free, IFN-based triple and IFN-based quad regimens in patients who failed IFN/RBV

Patient population	Treatment-experienced chronic hepatitis C patients
Phase	**Phase IIb** **Matterhorn** Boosted Danoprevir in Triple, Quad and Interferon-free combinations
# of patients	N=381
Design	Danoprevir boosted by low dose ritonavir in IFN-free, triple and QUAD **Cohort A: partial responders:** ▪**ARM A1**: Danoprevir 100 mg bid+ Ritonavir 100mg bid+ mericitabine 1000 mg bid + Copegus for 24 weeks ▪**ARM A2:** Danoprevir 100 mg bid + Ritonavir 100mg bid+ Pegasys + Copegus for 24 weeks ▪**ARM A3:** Danoprevir 100 mg bid + Ritonavir 100mg bid + mericitabine 1000 mg bid + Pegasys + Copegus for 24 weeks **Cohort B: null responders:** ▪**ARM B1**: Danoprevir 100 mg bid + Ritonavir 100mg bid + mericitabine 1000 mg bid + Copegus for 24 weeks ▪**ARM B2:** Danoprevir 100 mg bid + Ritonavir 100mg bid+ mericitabine 1000 mg bid + Pegasys + Copegus for 24 weeks ▪**ARM B3:** Danoprevir 100 mg bid+ Ritonavir 100mg bid + mericitabine 1000 mg bid + Pegasys + Copegus for 24 weeks, followed by 24 weeks Pegasys + Copegus
Primary endpoint	▪ Sustained virological response 24 weeks after the end of study treatment
Status	▪ Recruitment completed Q3 2011 ▪ Preliminary data presented at AASLD 2012

Mericitabine (RG7128) licensed from Pharmasset, now part of Gilead; Danoprevir=RG7227
AASLD=American Association for the Study of Liver Diseases

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group 2013 results

Diagnostics

Foreign exchange rate information

Oncology development programmes

Small molecules

Molecule	MDM2 (4) antagonist (RG7388)		MEK inhibitor (CIF, RG7167)	Raf/MEK inhibitor (CKI27, RG7304)
Patient population	**Solid tumors**	**Acute myeloid leukemia**	**Solid tumors**	**Solid tumors**
Phase	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=100	N=100	N=144	N=52
Design	• Multiple ascending dose-escalation study	• Multiple ascending dose-escalation study	• Dose-escalation, followed by expansion into 4 cohorts in specific indications	• Dose-escalation to MTD
Primary endpoint	• MTD	• MTD	• MTD and tumor assessment	• MTD and tumor assessment
Status	▪ Completed Q2 2013	▪ FPI Q1 2013	▪ Recruitment into expansion cohorts completed Q4 2011 ▪ Data presented at EORTC-NCI-AACR 2012	▪ Initiated Q4 2008 ▪ Enrolment stopped in Q4 2010
Collaborator			Chugai	

Oncology development programmes
Monoclonal antibodies

Molecule	Anti-glypican-3 MAb (GC33, RG7686)	
Patient population	**Metastatic liver cancer (hepatocellular carcinoma)**	**2L metastatic liver cancer (hepatocellular carcinoma)**
Phase	**Phase Ib**	**Phase II**
# of patients	N= 40-50	N=171
Design	▪ Study US monotherapy ▪ Study Japan monotherapy ▪ Dose escalation study in combo with SoC	Adaptive design study Double blind randomized 2:1 RG7686 : placebo Patients are stratified according to the level of GPC-3 expression in tumor
Primary endpoint	▪ Safety and tolerability	▪ Progression-free survival
Status	▪ Recruitment completed Q4 2013 ▪ Dose escalation completed for US and Japan monotherapy and combination therapy studies ▪ Patients continuing on combination treatment with SoC on study	▪ Recruitment completed Q1 2013 ▪ Results under internal review
Collaborator	Chugai	

SoC=standard of care

Oncology development programmes
Monoclonal antibodies (continued)

Roche pRED

Molecule	GE-huMAb HER3 (RG7116)	
Patient population	Solid tumors	HER2-low and HER3-positive metastatic breast cancer
Phase	Phase I	Phase I
# of patients	N=105	N=40
Design	▪ Multiple ascending dose study with extension cohorts and imaging sub-study ▪ Combination arms with HER1-targeted therapies (erlotinib, cetuximab)	▪ Multiple ascending dose of RG7116 in combination with Perjeta and paclitaxel
Primary endpoint	▪ Safety, PK	▪ Safety
Status	▪ FPI Q4 2011	▪ FPI Q3 2013

Oncology development programmes
Monoclonal antibodies (continued)

Roche pRED

Molecule	CSF-1R huMAb (RG7155)	Ang2-VEGF MAb (RG7221)	CEA-IL2v (RG7813)
Patient population	Solid tumors	Solid tumors	Solid tumors
Phase	Phase I	Phase I	Phase I
# of patients	N≈95	N≈80	N~110
Design	▪ Multiple ascending dose study +/- paclitaxel with extension cohorts	▪ Multiple ascending dose study with extension cohorts in solid tumors to assess the PD effects and platinum resistant ovarian cancer	▪ Single and multiple dose escalation study with extension cohorts
Primary endpoint	▪ Safety, PK, PD & preliminary clinical activity	▪ Safety, PK	▪ Safety, PK, PD
Status	▪ FPI Q4 2011 ▪ Biomarker data presented at AACR 2013	▪ FPI Q4 2012	▪ FPI Q4 2013

AACR=American Association for Cancer Research

Metabolic development programmes

Roche pRED

Molecule	**Inclacumab** (P-selectin huMAb, RG1512)	
Patient population	**Prevention of saphenous vein graft disease** Patients undergoing coronary artery bypass graft (CABG) surgery	**Acute Coronary Syndrome (ACS)** Patients undergoing percutaneous coronary intervention (PCI)
Phase/study	**Phase II** **SELECT-CABG**	**Phase II** **SELECT-ACS**
# of patients	N=384	N=516
Design	32-week treatment period ▪**ARM A:** Inclacumab (20 mg/kg) ▪**ARM B:** Placebo	Single infusion ▪**ARM A:** Inclacumab (5 mg/kg) ▪**ARM B**: Inclacumab (20 mg/kg) ▪**ARM C:** Placebo
Primary Endpoint	▪Sapheneous vein graft re-occlusion	▪Procedural damage (troponin)
Status	▪ Recruitment completed Q2 2012 ▪ Data to be published in 2014	▪ Recruitment completed ▪ Data presented at ACC 2013
	▪ Candidate for partnering-out	
Collaborator	Genmab	

ACC=American College of Cardiology

Metabolic development programmes

Molecule	GLP-1/GIP dual agonist (MAR709, RG7697)	NME (RG7641)
Patient population	Type 2 diabetes	Metabolic diseases
Phase/study	**Phase I**	**Phase I**
# of patients	N=60	N=96
Design	▪**ARM A:** RG7697 SC ▪**AMR B:** placebo	▪**ARM A:** RG7641 single dose ▪**ARM B:** Placebo
Primary Endpoint	▪ Safety, PK	▪ Safety
Status	▪ MAD study ongoing	▪ FPI Q4 2013
Collaborator	Marcadia Biotech, Inc. acquisition	

FSI=First Subject In

Neuroscience development programmes

Roche pRED

	Metabolic glutamate receptor pathway			
Molecule	**mGlu2 Negative Allosteric Modulator (NAM)** (RG1578)	**mGlu5 Negative Allosteric Modulator (NAM)** (RG7090)		
Patient population	**Adjunctive Treatment of Major Depressive Disorder**	**Adjunctive Treatment of Major Depressive Disorder**	**Fragile X Syndrome**	
Phase/study	**Phase II ArtDeCo**	**Phase II Marigold**	**Phase II Fragxis**	**Phase II FoXtail**
# of patients	N=480	N=300	N=180	N=45 Pediatric patients
Design	▪**ARM A:** RG1578 5 mg ▪**ARM B:** RG1578 15 mg ▪**ARM C:** RG1578 30 mg ▪**ARM D:** Matching Placebo	▪**ARM A:** RG7090 0.5 mg ▪**ARM B:** RG7090 1.5 mg ▪**ARM C:** Matching Placebo	▪**ARM A:** RG7090 0.5 mg ▪**ARM B:** RG7090 1.5 mg ▪**ARM C :** Matching Placebo	▪**ARM A:** RG7090 Dose A ▪**ARM B:** RG7090 Dose B ▪**ARM C :** Matching Placebo
Primary Endpoint	▪ Efficacy - Montgomery Asberg Depression Rating Scale	▪ Efficacy - Montgomery Asberg Depression Rating Scale	▪ Efficacy, safety and tolerability	▪ Safety ▪ Exploratory efficacy and tolerability
Status	▪ Recruitment ongoing	▪ Study completed ▪ Data in-house under review	▪ Recruitment completed	▪ Recruitment completed

Neuroscience development programmes

Roche pRED

Molecule	PDE10A inhibitor (RG7203)		TAAR1 agonist (RG7410)
Patient population	Schizophrenia		Schizophrenia
Phase	Phase I	Phase I	Phase I
# of patients	N=49	N=48	N=24
Design	▪ Double-blind, multiple-ascending dose, placebo controlled study in healthy volunteers ▪ Open-label single-dose PET study in healthy volunteers	▪ **ARM A**: RG7203 plus prednisone ▪ **ARM A**: placebo plus prednisone	▪ **ARM A:** RG7410 single dose ▪ **ARM B:** Placebo
Primary endpoint	▪ Safety, PK ▪ Target engagement	▪ Safety	▪ Safety
Status	▪ SAD completed ▪ SD PET completed ▪ MAD FPI Q2 2013	▪ Expect FPI Q1 2014	▪ Study completed Q4 2013

Neuroscience development programmes

Roche pRED

Molecule	Monoamine oxidase type B (MAO-B) inhibitor (RG1577, EVT-302)	V1 receptor antagonist (RG7314)	SMN2 splicing modifier (RG7800)
Patient population	Alzheimer's Disease	Autism	Spinal muscular atrophy
Phase	**Phase IIb MAyflOwer RoAD**	**Phase II VANILLA**	**Phase I**
# of patients	N=495	N=150	N=48
Design	▪52-week oral treatment ▪**ARM A:** RG1577 (dose 1) ▪**ARM B:** RG1577 (dose 2) ▪**ARM C:** placebo	▪Multi-center, randomized, double-blind, placebo-controlled proof-of-concept study in individuals with Autism Spectrum Disorder (ASD)	Healthy volunteer study ▪**ARM A:** RG7800 Single ascending dose ▪**ARM B:** Placebo
Primary endpoint	▪ Changes in ADAS-Cog at 52 weeks	▪ Safety and efficacy	▪ Safety, PK
Status	▪ FPI Q4 2012	▪ FPI Q3 2013	▪ FPI Q1 2014
Collaborator	Evotec		▪ PTC Therapeutics/ SMA Foundation

Neuroscience development programmes

Roche pRED

Molecule	GABRA5 negative allosteric modulator (NAM) (RG1662)		
Patient population	**Down Syndrome**		
Phase	**Phase I**	**Phase Ib**	**Phase IIB CLEMATIS**
# of patients	N=17	N=33	N=180
Design	▪ Molecular and functional imaging study in individuals with Down Syndrome and healthy volunteers	▪ Multi-center, randomized, double-blind, placebo-controlled, multiple dose study in individuals with Down Syndrome	For 26 weeks patients will receive: ▪ **ARM A**: RG1662 120mg twice daily ▪ **ARM B**: RG1662 120mg twice daily ▪ **ARM C**: Placebo
Primary endpoint	▪ GABAA alpha5 receptor expression, occupancy and functional connectivity	▪ Safety, tolerability	▪ Cognition and adaptive behavior
Status	▪ FPI Q3 2012	▪ Recruitment completed Q3 2013	▪ Expect FPI Q1 2014

Ophthalmology and infectious diseases programmes

Molecule	TLR7 agonist (RG7863)	NME (RG7716)
Patient population	Chronic hepatitis B	Wet age-related macular degeneration
Phase	**Phase I**	**Phase I**
# of patients	N=60	N=30
Design	• Healthy volunteer study • **ARM A**: Single ascending dose of RG7863 • **ARM B**: Placebo	• Healthy volunteer study • Single ascending dose of RG7716
Primary endpoint	▪ Safety	▪ Safety
Status	▪ FPI Q3 2013	▪ FPI Q4 2013

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group 2013 results

Diagnostics

Foreign exchange rate information

Oncology development programmes
Monoclonal antibodies

Genentech Research & Early Development

	Growth factor signaling			
Molecule	**Anti-HER3 EGFR DAF MAb** (RG7597)			
Patient population	**Metastatic/recurrent SCCHN**	**KRAS wild-type metastatic colorectal cancer**	**1L recurrent/metastatic squamous cell carcinoma of head and neck**	**Locally advanced or metastatic tumors with mutant KRAS**
Phase/study	**Phase II MEHGAN**	**Phase II DARECK**	**Phase Ib**	**Phase I**
# of patients	N=110	N=130	N=120	N=50
Design	▪ **ARM A:** RG7597 ▪ **ARM B**: Cetuximab	▪ **ARM A:** RG7597+FOLFIRI ▪ **ARM B**: Cetuximab+FOLFIRI	Evaluating safety/tolerability with two chemo backbones ▪ **Arm A**: Cisplatin/5-FU ▪ **Arm B**: Carboplatin/Paclitaxel	▪ Dose finding of RG7597 plus cobimetinib[1]
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Safety, DLT, PK	▪ Safety
Status	▪ Recruitment completed Q2 2013	▪ Recruitment completed Q4 2013	▪ FPI Q3 2013	▪ FPI Q4 2013

[1]cobimetinib in collaboration with Exelixis
SCCHN=Squamous Cell Carcinoma of the Head and Neck; AACR=American Association for Cancer Research
FOLFOX=Folinic acid, Fluorouracil, Oxaliplatin; FOLFIRI=Folinic acid, Fluorouracil, Irinotecan

Oncology development programmes
Antibody drug conjugates

gRED Genentech Research & Early Development

	Antibody drug conjugates (ADCs)		
Molecule	**Anti-STEAP1 ADC** (RG7450)	**Anti-MUC16 ADC** (RG7458)	**NME ADC** (RG7598)
Patient population	**Prostate cancer**	**Ovarian and pancreatic cancer**	**Multiple myeloma**
Phase	**Phase I**	**Phase I**	**Phase I**
# of patients	N=49	N=57	N=30-45
Design	▪ Dose escalation study	▪ Dose escalation study	▪ Dose escalation study
Primary endpoint	▪ Safety	▪ Safety/PK	▪ Safety
Status	▪ FPI Q1 2011 ▪ Data presented at ASCO 2013	▪ FPI Q2 2011 ▪ Safety and PK data presented at AACR 2013	▪ FPI Q3 2011
Collaborator	Seattle Genetics and Agensys	Seattle Genetics	

ASCO=American Society of Clinical Oncology; AACR=American Association for Cancer Research

Oncology development programmes
Antibody drug conjugates (continued)

Genentech Research & Early Development

	Antibody drug conjugates (ADCs)		
Molecule	**Anti-NaPi2b ADC** (RG7599)		
Patient population	**NSCLC and ovarian cancer**	**Platinum-sensitive ovarian cancer**	**Platinum-resistant ovarian cancer**
Phase	**Phase I**	**Phase Ib**	**Phase II**
# of patients	N=96	N=42	N=92
Design	▪ Dose escalation study	▪ Dose escalation of RG7599in combination with carboplatin, with or without Avastin	▪ **ARM A**: RG7599 ▪ **ARM B**: Pegylated liposomal doxorubicin
Primary endpoint	▪ Safety	▪ Safety, PK	▪ Progression-free survival
Status	▪ FPI Q2 2011 ▪ Safety and efficacy data presented at ASCO 2013	▪ FPI Q4 2013	▪ Expect FPI Q1 2014
Collaborator	Seattle Genetics		

ASCO=American Society of Clinical Oncology

Oncology development programmes
Antibody drug conjugates (continued)

Genentech Research & Early Development

	Antibody drug conjugates (ADCs)			
Molecule	**NME ADC** (RG7600)	**Anti-ETBR ADC** (RG7636)	**Pinatuzumab vedotin (Anti-CD22, RG7593)**	**Pinatuzumab vedotin (RG7593) vs. polatuzumab vedotin (RG7596)**
Patient population	**Pancreatic and ovarian cancer**	**Metastatic or unresectable melanoma**	**Hematologic malignancies**	**Non-Hodgkin's Lymphoma**
Phase	**Phase I**	**Phase I**	**Phase I**	**Phase II ROMULUS**
# of patients	N=66-96	N=44-64	N=76	N=120
Design	▪ Dose escalation study	▪ Dose escalation study	▪ Dose escalation study	▪ RG7593 plus Rituxan ▪ RG7596 plus Rituxan
Primary endpoint	▪ Safety	▪ Safety	▪ Safety	▪ Safety and anti-tumor activity
Status	▪ FPI Q4 2011	▪ FPI Q1 2012	▪ Final data presented at ASH 2013	▪ Recruitment completed Jan 2014 ▪ Data to be presented in 2014
Collaborator	Seattle Genetics			

Oncology development programmes
Small molecules (continued)

Genentech Research & Early Development

Molecule	**Ipatasertib** (AKT inhibitor, GDC-0068, RG7440)			
Patient population	**Solid tumors**	**2L Castration-resistant prostate cancer**	**Solid tumors**	**1L metastatic gastric or gastroesophageal junction adenocarcinoma**
Phase	**Phase Ib**	**Phase II A.MARTIN**	**Phase Ib**	**Phase II JAGUAR**
# of patients	N=90	N=262	N=62	N=120
Design	Dose escalation with: ▪ **ARM A:** Docetaxel ▪ **ARM B:** Fluoropyrimidine plus oxaliplatin ▪ **ARM C:** Paclitaxel ▪ **ARM D:** Enzalutamide	▪ **ARM A**: Ipatasertib (400mg) + abiraterone ▪ **ARM B**: Ipatasertib (200mg) + abiraterone ▪ **ARM C**: Placebo + abiraterone	▪ Dose escalations study of ipatasertib in combination with cobimetinib*	▪ **ARM A: I**patasertib + mFOLFOX6 ▪ **ARM B:** Placebo + mFOLFOX6
Primary endpoint	▪ Safety	▪ Progression-free survival	▪ Safety/PK	▪ Progression-free survival
Status	▪ FPI Q3 2011 ▪ Data presented at ASCO and ESMO 2012	▪ FPI Q3 2013	▪ FPI Q2 2012	▪ FPI Q3 2013
Collaborator	Array BioPharma			

*cobimetinib in collaboration with Exelixis
ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology
mFOLFOX6=modified FOLFOX (Folinic acid, Fluorouracil, Oxaliplatin)

Oncology development programmes

Small molecules (continued)

gRED Genentech Research & Early Development

Molecule	ChK1 inhibitor (GDC-0575, RG7741)	NME (RG7842, GDC-0994)	NME (RG7845, GDC-0853)	PI3 Kinase inhibitor (GDC-0084, RG7666)
Patient population	**Solid tumors or lymphoma**	**Solid tumors**	**B-cell lymphoma and chronic lymphocytic leukemia**	**Progressive or recurrent high-grade glioma**
Phase I	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=45	N=78	N=121	N=68
Design	▪ Dose escalation study	▪ Stage 1: Dose escalation ▪ Stage 2: Cohort expansion	▪ Stage 1: Dose escalation ▪ Stage 2: Cohort expansion	▪ Dose escalation study
Primary endpoint	▪ Safety/PK	▪ Safety, MTD, PK	▪ Safety/PK, MTD	▪ Safety/PK
Status	▪ FPI Q2 2012	▪ FPI Q2 2013	▪ FPI Q4 2013	▪ FPI Q2 2012
Collaborator	Array BioPharma			

Immunology development programmes

gRED Genentech Research & Early Development

Molecule	Quilizumab (Anti-M1 prime, RG7449)		Rontalizumab (Anti-INFalpha, RG7415)	anti-IL17 (RG7624)
Patient population	**Allergic asthma - inadequately controlled**	**Chronic spontaneous urticaria**	**Systemic lupus erythematosus**	**Autoimmune diseases**
Phase/study	**Phase IIb COSTA**	**Phase II QUAIL**	**Phase II ROSE**	**Phase Ib**
# of patients	N=560	N=30	N=238	N=21
Design	SC administration on top of SoC ▪**ARM A**: Quilizumab 300mg ▪**ARM B**: Quilizumab 150mg ▪**ARM C**: Quilizumab 450mg ▪**ARM D**: Placebo	▪**ARM A**: Quilizumab sc ▪**ARM B**: Placebo sc	▪ **ARM A**: Placebo • Part 1 – iv • Part 2 - sc ▪ **ARM B**: Rontalizumab • Part 1 – iv • Part 2 – sc	▪ Randomized, double-blind, placebo-controlled, multiple ascending dose escalation study
Primary endpoint	▪ Rate of protocol-defined exacerbations from baseline to week 36	▪ Efficacy and safety	▪ Proportion of responders at Week 24	▪ Safety and tolerability
Status	▪ Recruitment completed Q3 2013	▪ FPI Q4 2013	▪ Enrolment completed Q3 2010 ▪ Data presented at ACR 2012 ▪ Candidate for partnering-out	▪ Enrolment completed Q2 2012
Collaborator				NovImmune

SoC=Standard of Care

Neuroscience development programmes

gRED Genentech Research & Early Development

Molecule	**Crenezumab** (Anti-Aβ, RG7412)		
Patient population	**Alzheimer's Disease**		**Alzheimer's Prevention initiative (API) Colombia**
Phase/study	**Phase II** **ABBY** Cognition study	**Phase II** **BLAZE** Biomarker study	**Phase II** Cognition study
# of patients	N=360	N=72	N=300
Design	▪ **ARM A**: Crenezumab sc ▪ **ARM B**: Crenezumab iv ▪ **ARM C:** Placebo	▪ **ARM A**: Crenezumab sc ▪ **ARM B**: Crenezumab iv ▪ **ARM C:** Placebo	▪ **ARM A**: 100 carriers receive crenezumab sc ▪ **ARM B**: 100 carriers receive placebo ▪ **ARM C:** 100 non-carriers receive placebo
Primary endpoint	▪ Change in cognition (ADAS-cog) and Clinical Dementia Rating, Sum of Boxes (CDR-SOB) score from baseline to week 73	▪ Change in brain amyloid load from baseline to week 69	▪ Change on Alzheimer's Prevention Initiative (API) Composite Cognitive Test total score
Status	▪ Enrolment completed Q3 2012	▪ Enrolment completed Q3 2012	▪ FPI Q4 2013
Collaborator	AC Immune		

Metabolism and infectious diseases development programmes

gRED Genentech Research & Early Development

Molecule	Anti-PCSK9 (RG7652)	NME targeting CMV (RG7667)	Anti-Flu A (RG7745)
Patient population	**Metabolic diseases**	**Prevention of cytomegalovirus disease in kidney transplant recipients**	**Influenza**
Phase/study	**Phase II EQUATOR**	**Phase II**	**Phase IIa**
# of patients	N=224	N=120	N=100
Design	SC dosing every 4 weeks ▪ Experimental: five different doses of RG7652 ▪ Placebo	• **ARM A:** RG7667 • **ARM B:** Placebo	Healthy volunteers in an influenza challenge model ▪ ARM A: RG7745 ▪ ARM B: Placebo ▪ ARM C: Tamiflu
Primary endpoint	▪ Absolute change from baseline in LDL-c concentration	▪ Safety, clinical activity	▪ Reduction in viral activity
Status	▪ Phase I data presented at ESC 2013 ▪ Phase II data readout in 2013 ▪ Candidate for partnering-out	▪ FPI Q4 2012	▪ FPI Q4 2013

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group 2013 results

Diagnostics

Foreign exchange rate information

Geographical sales split by divisions and Group*

CHFm	2012	2013	% change CER
Pharmaceuticals Division	**35,232**	**36,304**	**+7**
United States	13,856	15,097	+10
Europe	8,952	9,254	+2
Japan	4,108	3,405	+2
International	8,316	8,548	+8
Diagnostics Division	**10,267**	**10,476**	**+4**
United States	2,346	2,331	+1
Europe	3,964	4,045	+1
Japan	593	492	+2
International	3,364	3,608	+12
Group	**45,499**	**46,780**	**+6**
United States	16,202	17,428	+9
Europe	12,916	13,299	+1
Japan	4,701	3,897	+2
International	11,680	12,156	+9

* Geographical sales split shown here does not represent operational organization; CER=Constant Exchange Rates

Pharma Division sales 2013 (vs. 2012)

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
MabThera/Rituxan	6,951	6	3,329	8	1,918	3	249	6	1,455	6
Avastin	6,254	13	2,575	5	1,919	14	717	15	1,043	30
Herceptin	6,079	6	1,787	9	2,191	-1	294	8	1,807	11
Lucentis	1,689	15	1,689	15	-	-	-	-	-	-
Xeloda	1,509	2	616	0	315	-4	107	4	471	8
Tarceva	1,339	4	604	7	343	-5	99	10	293	8
Pegasys	1,312	-19	307	-43	356	-11	52	-21	597	-3
Actemra/RoActemra	1,037	30	314	32	360	27	197	21	166	49
CellCept	874	-2	204	21	238	-12	68	10	364	-7
Xolair	790	13	790	13	-	-	-	-	-	-
Valcyte/Cymevene	693	10	358	12	174	-1	-	-	161	19
Activase/TNKase	683	19	635	20	-	-	-	-	48	0
Tamiflu	635	19	428	24	18	110	105	-8	84	41
Pulmozyme	572	8	355	12	124	2	0	73	93	5
NeoRec./Epogin	520	-18	-	-	218	-26	100	-28	202	0
Mircera	425	24	-	-	104	25	214	27	107	19
Zelboraf	354	52	123	11	194	65	-	-	37	*
Perjeta	326	498	219	311	68	*	23	-	16	*
Madopar	313	4	-	-	112	-1	19	5	182	7
Nutropin	274	-9	268	-8	-	-	-	-	6	-14

CER=Constant Exchange Rates; * over +500%

Pharma Division sales 2013 (vs. 2012)

Recently launched products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Kadcyla	234	-	222	-	9	-	-	-	3	-
Erivedge	75	161	66	132	8	-	-	-	1	-
Gazyva	3	-	3	-	-	-	-	-	-	-

CER=Constant Exchange Rates

Pharma Division CER sales growth[1] in %
Global top 20 products

	Q4/12	Q1/13	Q2/13	Q3/13	Q4/13
MabThera/Rituxan	7	6	0	12	7
Avastin	8	11	13	14	13
Herceptin	8	11	0	7	7
Lucentis	-9	1	18	21	22
Xeloda	5	1	3	6	-3
Tarceva	-3	0	9	5	4
Pegasys	-5	-15	-24	-16	-20
Actemra/RoActemra	30	32	33	33	23
CellCept	1	4	1	-2	-10
Xolair	10	12	10	14	17
Valcyte/Cymevene	9	8	8	0	26
Activase/TNKase	17	35	3	18	19
Tamiflu	449	84	44	115	-27
Pulmozyme	4	9	7	0	18
NeoRec./Epogin	-25	-22	-20	-16	-14
Mircera	2	12	35	29	23
Zelboraf	271	154	46	38	26
Perjeta	-	-	*	262	394
Madopar	5	9	-4	3	9
Nutropin	-5	-6	-8	-8	-12

CER=Constant Exchange Rates; [1] Q4/12 vs. Q4/11, Q1-Q4/13 vs. Q1-Q4/12; * over +500%

Pharma Division CER sales growth in %

Top 20 products by region

	US				Europe				Japan				International			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
MabThera/Rituxan	12	-1	20	2	2	3	6	0	0	6	8	8	-2	-3	3	26
Avastin	3	3	10	4	15	17	17	9	18	18	15	12	26	29	19	49
Herceptin	17	1	14	3	1	-2	-1	-2	6	7	7	11	19	-1	8	21
Lucentis	1	18	21	22	-	-	-	-	-	-	-	-	-	-	-	-
Xeloda	0	-3	8	-8	-4	-2	1	-9	8	5	3	0	3	13	10	9
Tarceva	14	18	5	-8	-12	-4	0	-3	8	-2	8	25	-12	12	13	27
Pegasys	-30	-40	-51	-55	-10	-8	-14	-14	-16	-18	-22	-28	-4	-21	18	1
Actemra/RoActemra	45	33	33	20	29	31	26	21	8	23	26	24	53	57	59	31
CellCept	60	17	13	5	-13	-18	-11	-5	8	13	13	8	-4	6	-5	-24
Xolair	12	10	14	17	-	-	-	-	-	-	-	-	-	-	-	-
Valcyte/Cymevene	4	14	10	19	-1	-5	-22	28	-	-	-	-	27	9	3	38
Activase/TNKase	36	3	19	22	-	-	-	-	-	-	-	-	27	-5	-1	-13
Tamiflu	171	-41	*	-24	54	-58	-76	-	6	121	-73	-47	132	161	-17	-72
Pulmozyme	17	8	6	16	-3	4	6	1	-	308	29	12	-6	5	-25	41
NeoRec./Epogin	-	-	-	-	-25	-31	-26	-19	-37	-29	-22	-22	-3	2	3	-2
Mircera	-	-	-	-	-32	142	74	29	46	21	26	21	28	19	11	20
Zelboraf	19	15	12	-1	*	51	36	17	-	-	-	-	*	*	489	425
Perjeta	-	*	129	201	-	-	*	*	-	-	-	-	-	-	-	*
Madopar	-	-	-	-	-3	-2	2	-1	8	3	5	3	17	-6	3	18
Nutropin	-6	-8	-7	-13	-	-	-	-	-	-	-	-	-13	-12	-25	-7

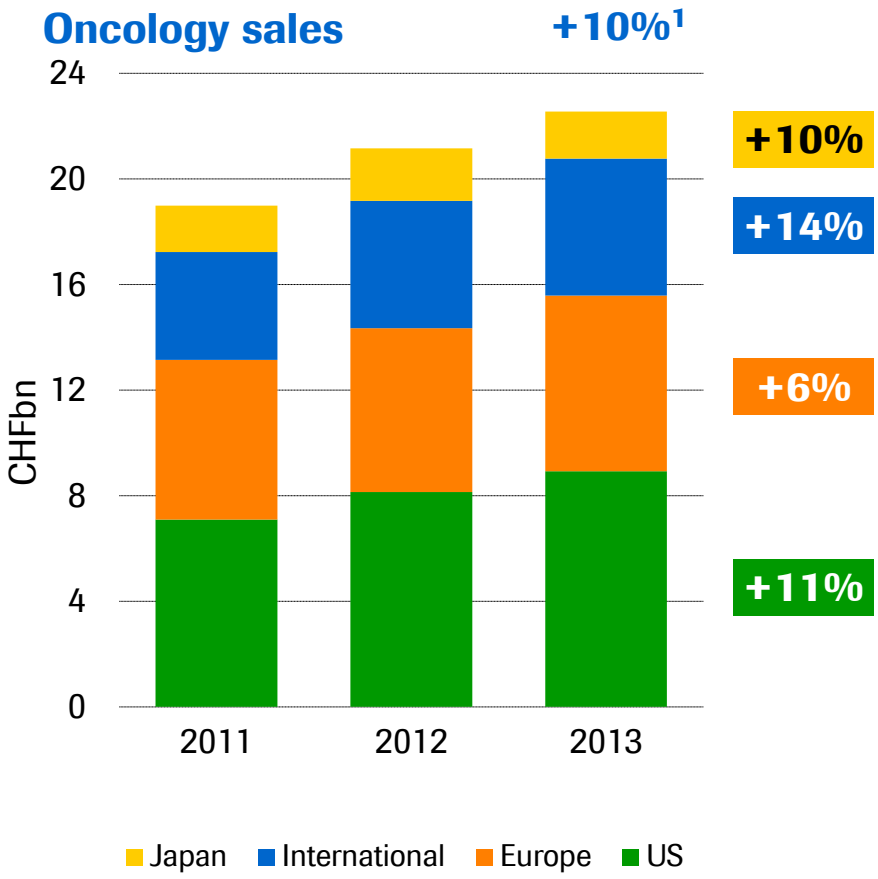
CER=Constant Exchange Rates; * over +500%

CER sales growth (%)
Quarterly development

	2012 vs. 2011				2013 vs. 2012			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmaceuticals Division	**2**	**6**	**4**	**7**	**7**	**4**	**9**	**7**
United States	6	6	5	13	13	7	16	5
Europe	-3	-1	-2	0	1	2	3	2
Japan	1	0	1	5	2	2	4	2
International	3	16	12	6	8	2	5	18
Diagnostics Division	**4**	**6**	**1**	**4**	**1**	**4**	**7**	**5**
Roche Group	**2**	**6**	**4**	**6**	**6**	**4**	**8**	**7**

CER=Constant Exchange Rates

2013: Oncology franchise



US

- Sales growth driven by Rituxan, Kadcyla, Perjeta and Herceptin, partially due to 340B reserves release

Europe

- Major drivers Avastin and Zelboraf

International

- Strong growth for Avastin and Herceptin

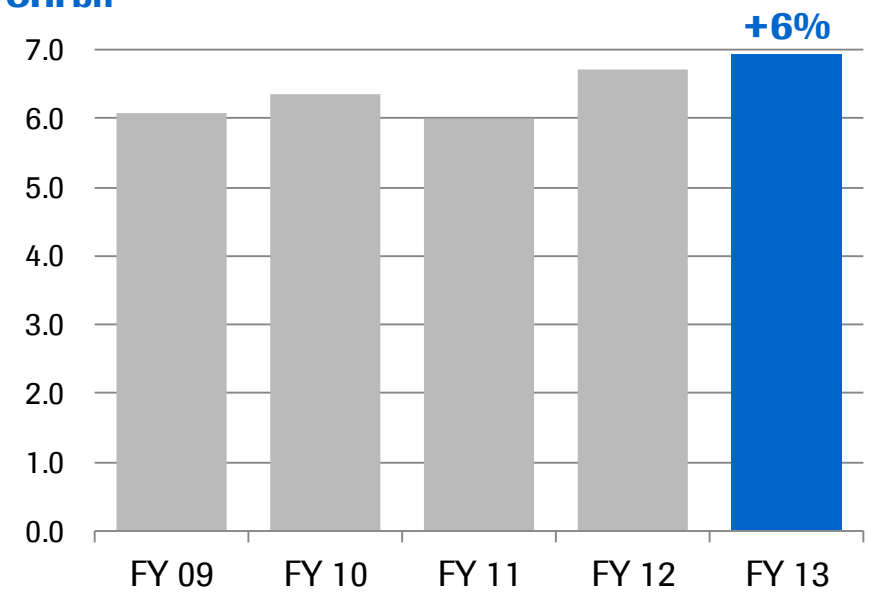
Japan

- Growth driven largely by Avastin

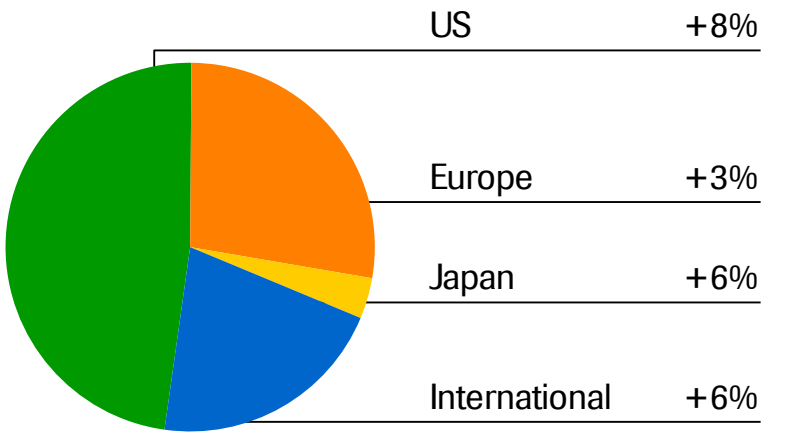
[1] CER=Constant Exchange Rates; Oncology sales CHF 22.5bn

MabThera/Rituxan

Global sales



Regional sales



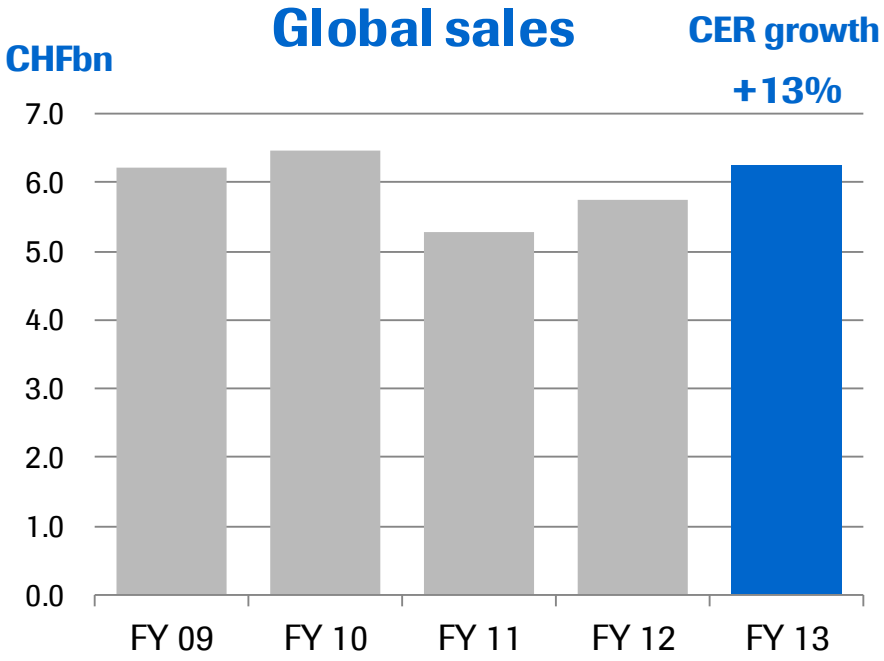
2013 sales of CHF 6.951bn

- US/Europe: Growth driven primarily by population growth
- Developing market growth largely due to increased share and duration of treatment in DLBCL

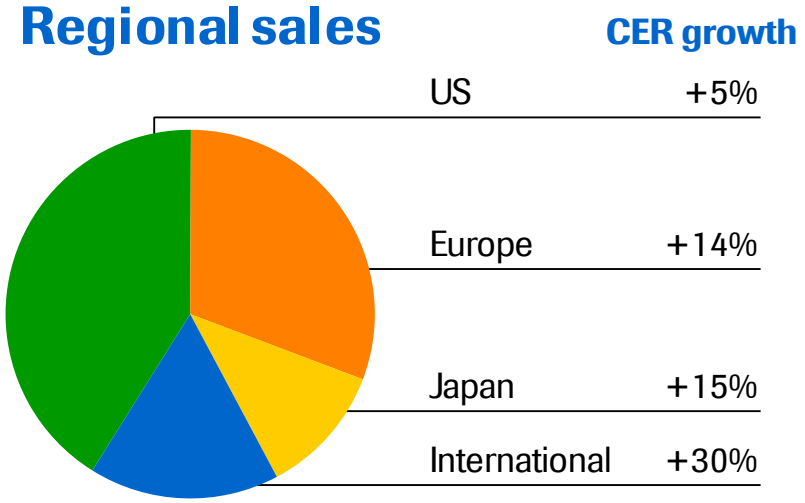
CER=Constant Exchange Rates

Avastin

Global sales



Regional sales



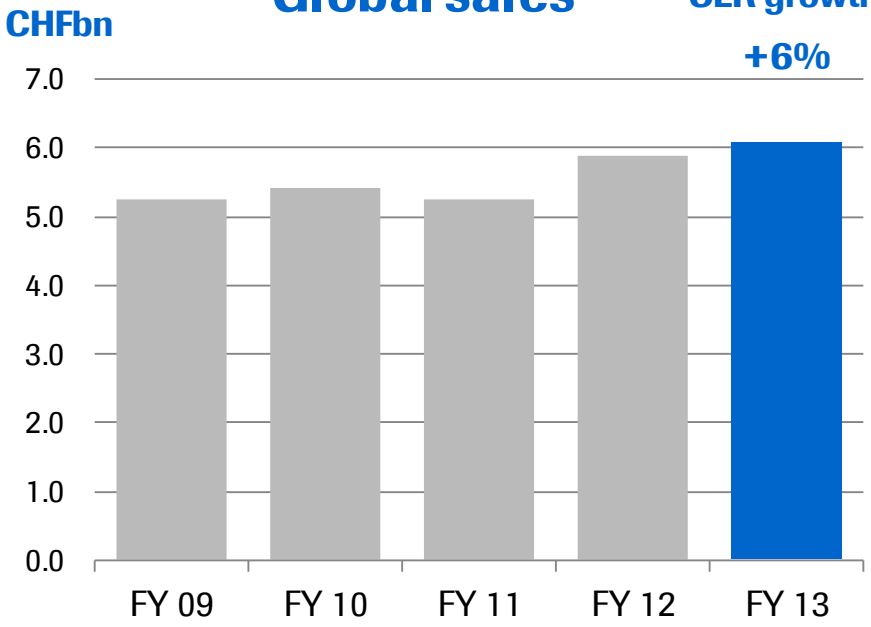
2013 sales of CHF 6.254bn

- Europe: strong growth driven by further uptake in ovarian and colorectal cancer (Treatment through multiple lines)
- US: increase in mCRC use associated with TML awareness
- Japan: steady growth in CRC, BC, NSCLC

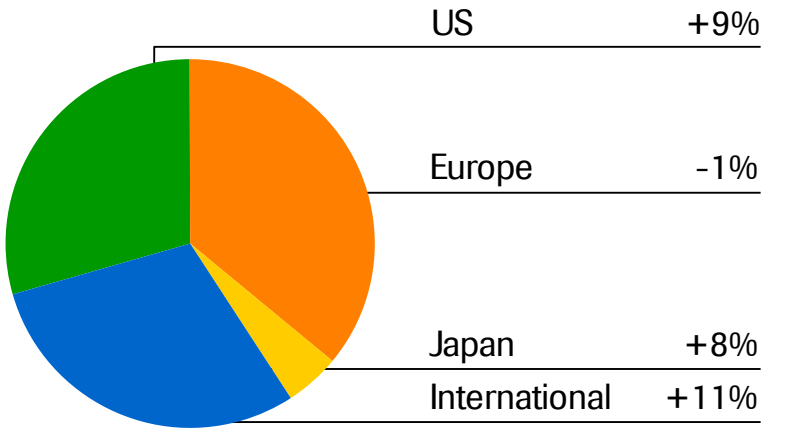
CER=Constant Exchange Rates

Herceptin

Global sales



Regional sales



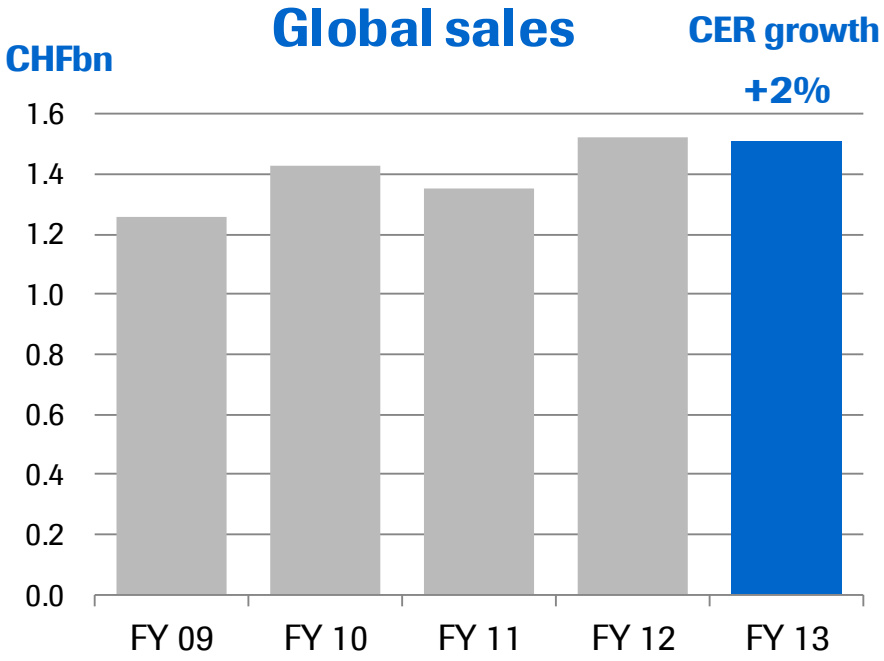
2013 sales of CHF 6.079bn

- Volume growth driven by International region
- Emerging markets: driven by access in public markets in key countries, patient access program in China and longer duration of use in early breast cancer

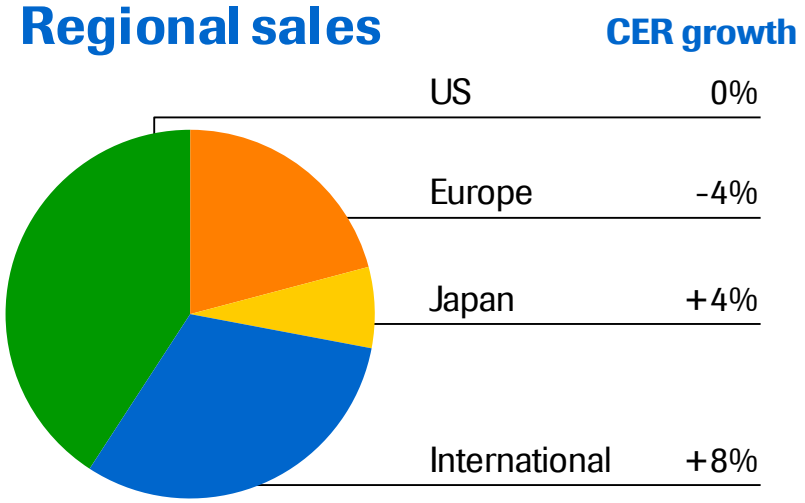
CER=Constant Exchange Rates

Xeloda

Global sales



Regional sales



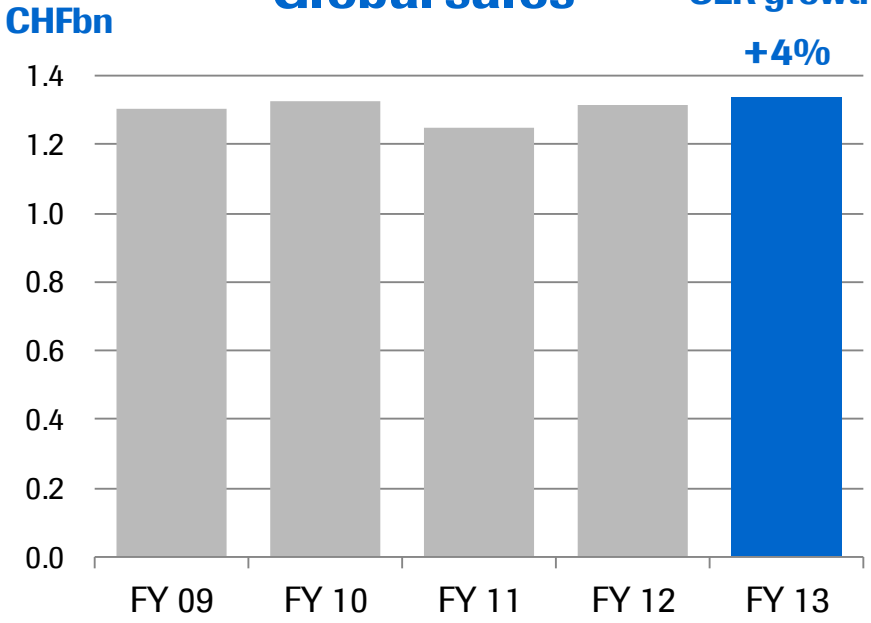
2013 sales of CHF 1.509bn

- US: supply of IV 5FU normalised. Brand approaching end of lifecycle; loss of exclusivity Feb 2014
- Europe: Loss of exclusivity Dec 2013
- Sales growth in the International region driven by China

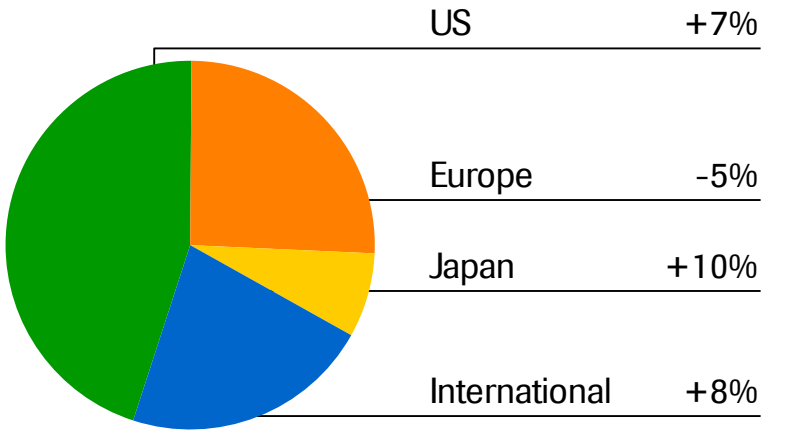
CER=Constant Exchange Rates

Tarceva

Global sales



Regional sales



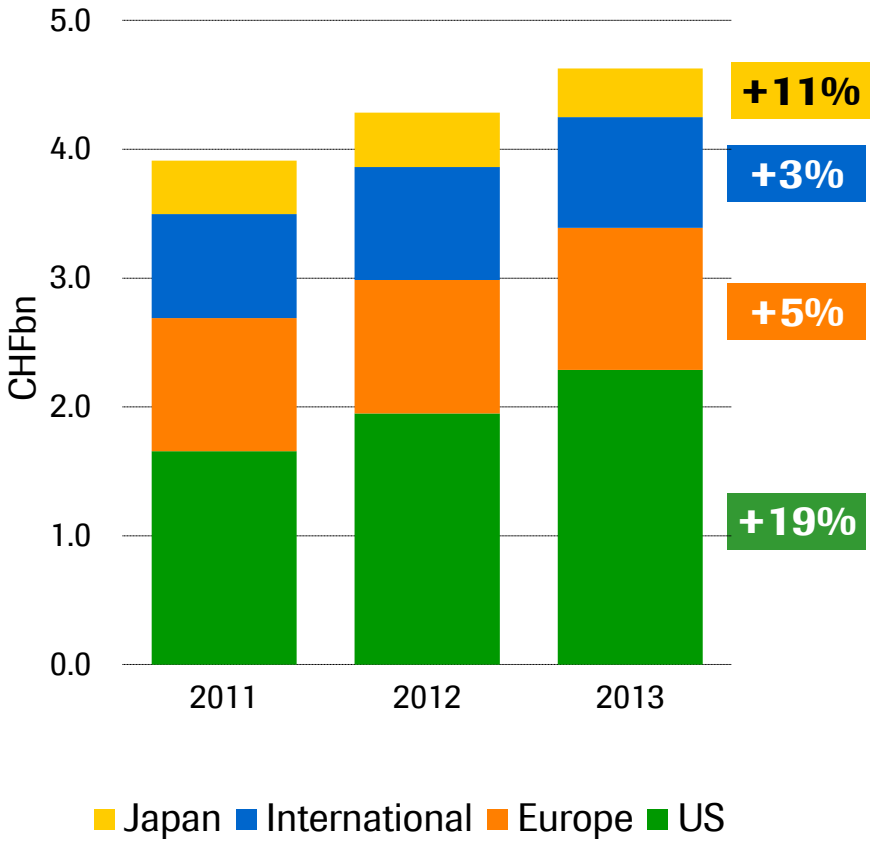
2013 sales of CHF 1.339bn

- US: strong EGFR testing rates, 1L treatment rates for Mut+ve patients and increase in 1L maintenance use for squamous patients
- EU: stabilization ahead of further reimbursement approvals for 1LMut+ indication; competitive challenges remain

CER=Constant Exchange Rates

Immunology

Immunology sales +11%[1]



2013 sales: CHF 4.628bn

- Strong growth of Actemra/RoActemra and MabThera/Rituxan, CellCept stabilising

Actemra/RoActemra

Sales: CHF 1,037m (+30%)

- Growth driven by monotherapy use; US biggest growth contributor, good uptake of subcutaneous formulation in Japan

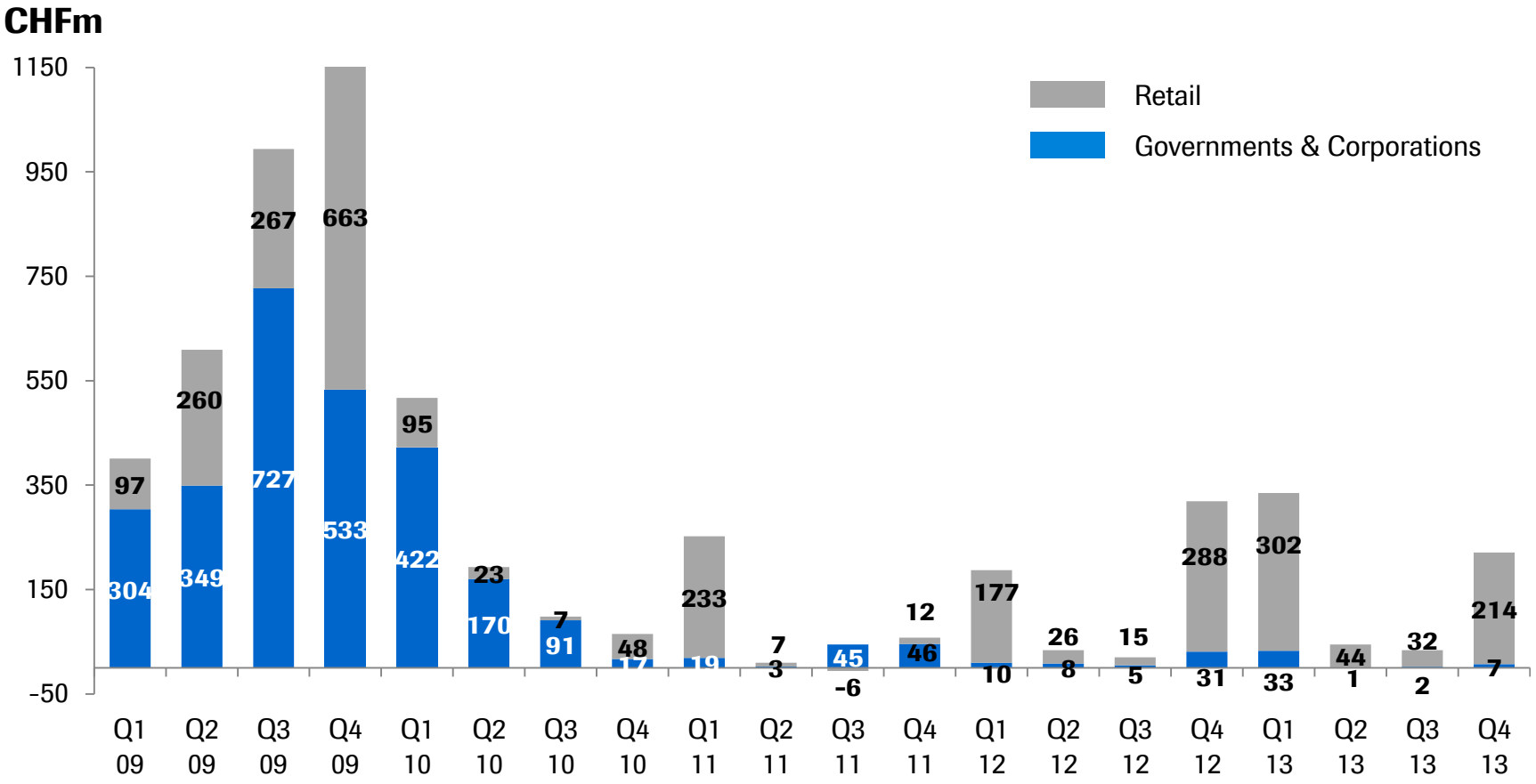
CellCept

Sales: CHF 874m (-2%)

- Patent expiry key EU countries end 2010

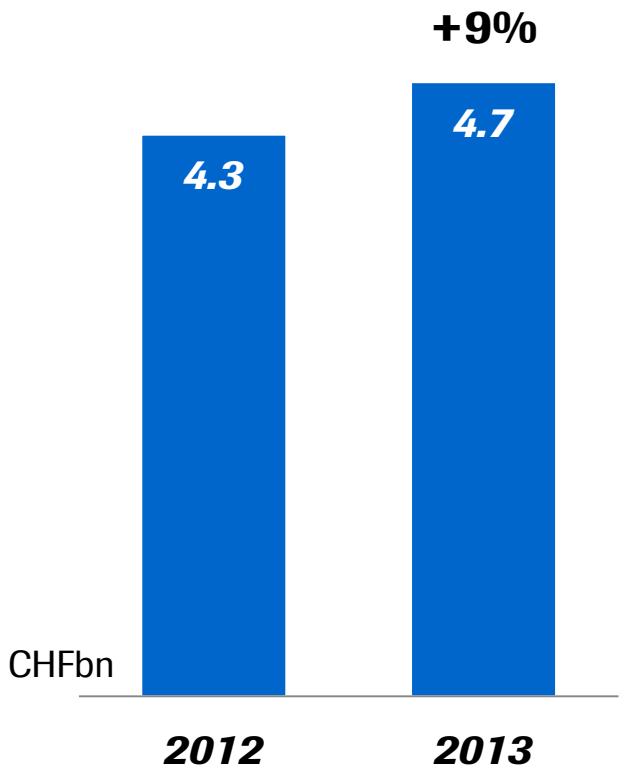
[1] CER=Constant Exchange Rates

Tamiflu quarterly sales 2009 – 2013
Retail and Governments/Corporations



Securing supply and fostering compliance

Costs of goods sold[1]



- Higher sales volumes
- Currency exchange variations (Chugai)
- Expansion of manufacturing network
- Reconfiguration of existing production network to increase supply reliability
- Compliance costs in increasingly stringent environment

Absolute amounts and growth rate at constant exchange rates (2012); [1] incl. Period costs

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group 2013 results

Diagnostics

Foreign exchange rate information

Diagnostics Division CER growth
By Region and Business Area (vs. 2012)

	Global		North America		EMEA[1]		RoW	
	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth
Professional Diagnostics	5,740	8	1,162	7	2,545	3	2,033	15
Diabetes Care	2,459	-3	482	-15	1,484	0	493	3
Molecular Diagnostics	1,612	2	567	4	622	0	423	3
Tissue Diagnostics	665	7	400	1	174	14	91	27
Diagnostics Division	**10,476**	**4**	**2,611**	**1**	**4,825**	**2**	**3,040**	**11**

CER=Constant Exchange Rates
[1] Europe, Middle East and Africa

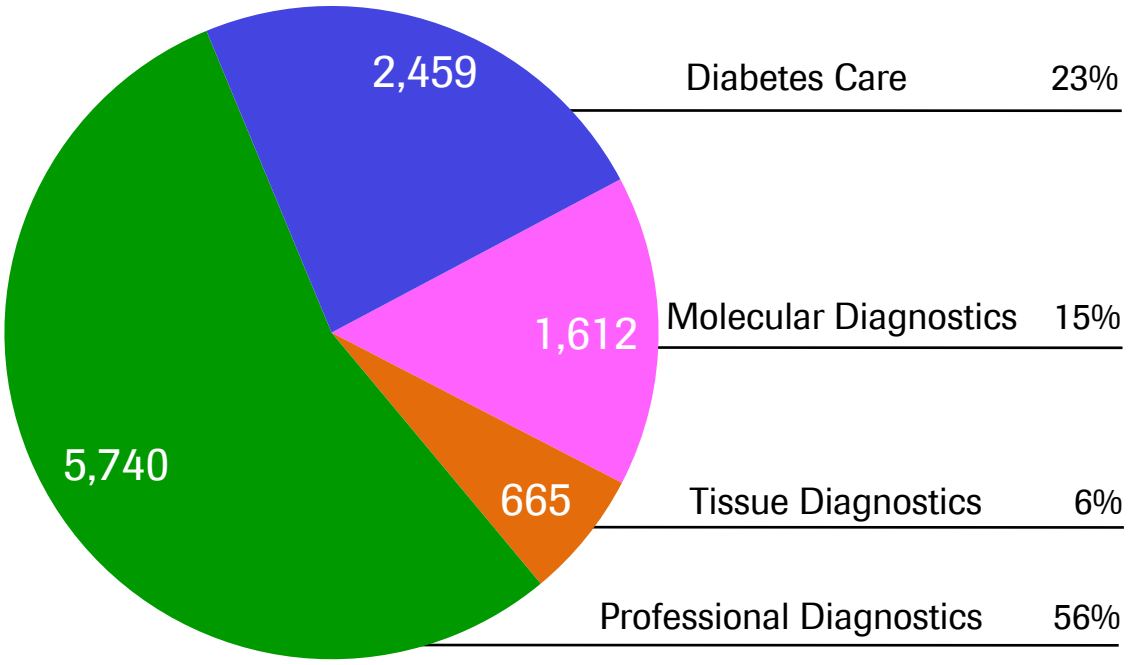
Diagnostics Division quarterly sales and CER growth[1]

	Q3 12		Q4 12		Q1 13		Q2 13		Q3 13		Q4 13	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Professional Diagnostics	1,357	8	1,433	7	1,337	4	1,472	8	1,418	9	1,513	10
Diabetes Care	577	-12	729	-1	539	-5	666	-4	576	3	678	-4
Molecular Diagnostics	395	-2	436	2	386	-3	411	6	391	4	424	3
Tissue Diagnostics	153	10	173	7	157	7	165	4	159	8	184	10
Dia Division	**2,482**	**1**	**2,771**	**4**	**2,419**	**1**	**2,714**	**4**	**2,544**	**7**	**2,799**	**5**

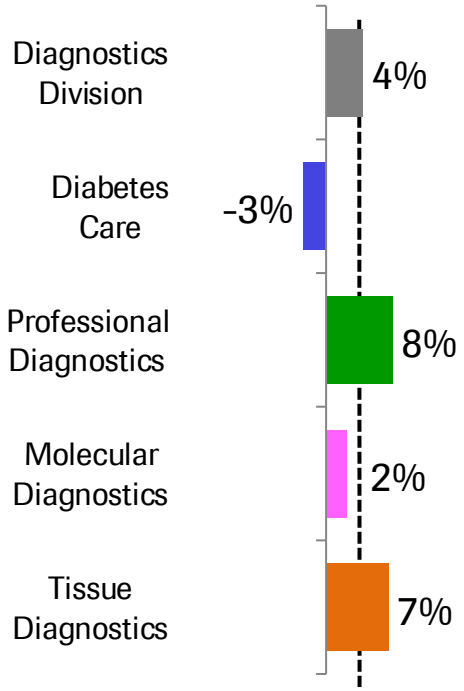
CER=Constant Exchange Rates
[1] versus same period of prior year

2013: Diagnostics Division sales
Growth driven by Professional Diagnostics

CHF 10,476 m



CER sales growth

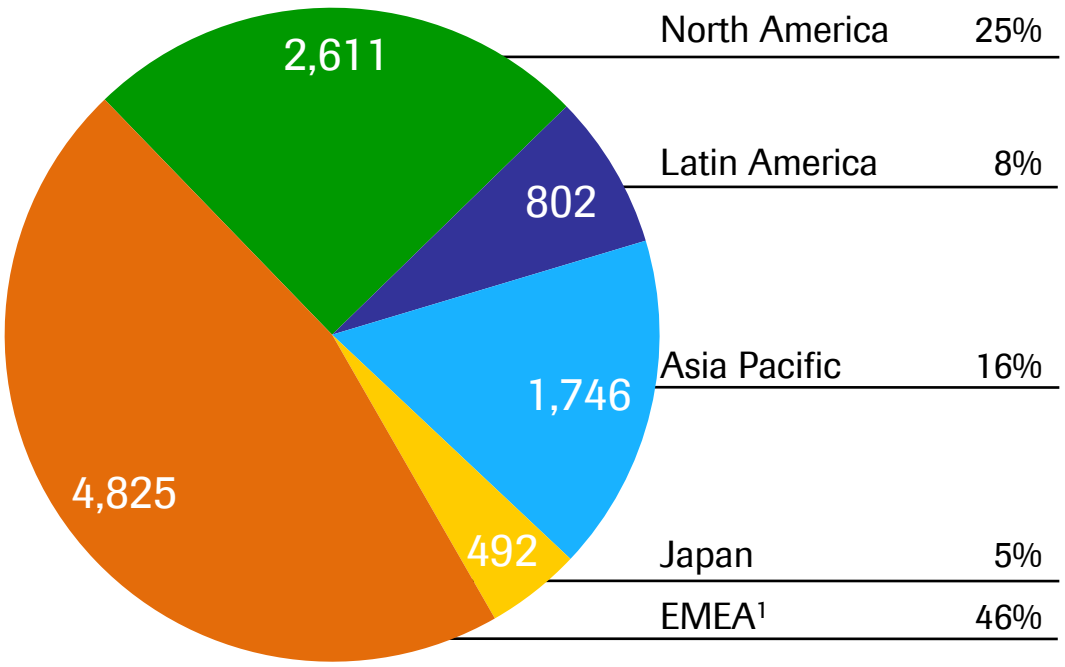


CER=Constant Exchange Rates

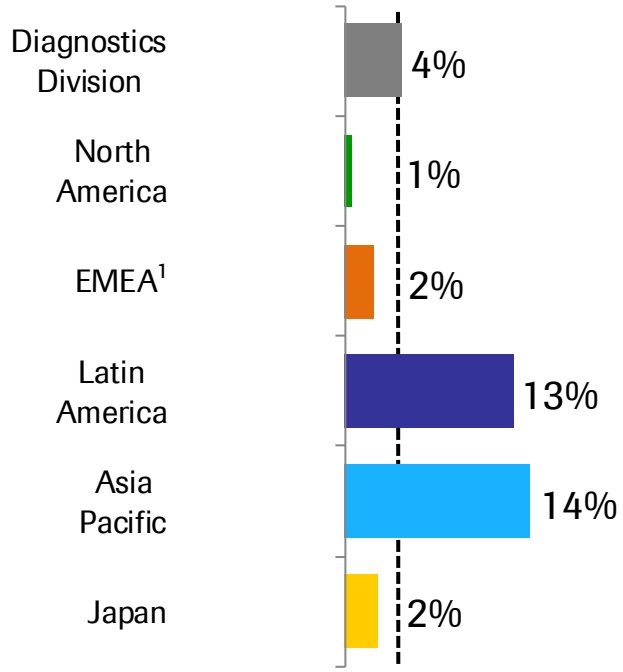
2013: Diagnostics Division sales

Growth driven by Asia Pacific, EMEA and Latin America

CHF 10,476 m



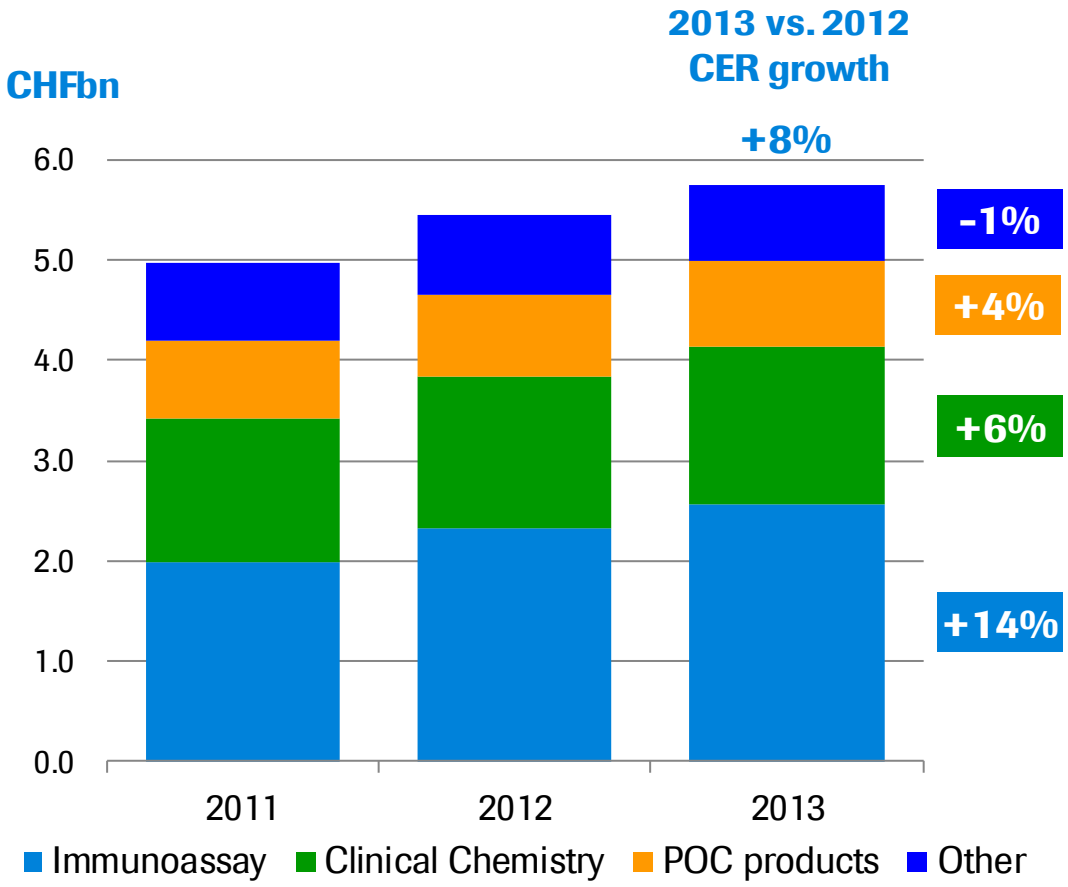
CER sales growth



CER=Constant Exchange Rates
[1] Europe, Middle East and Africa

Professional Diagnostics

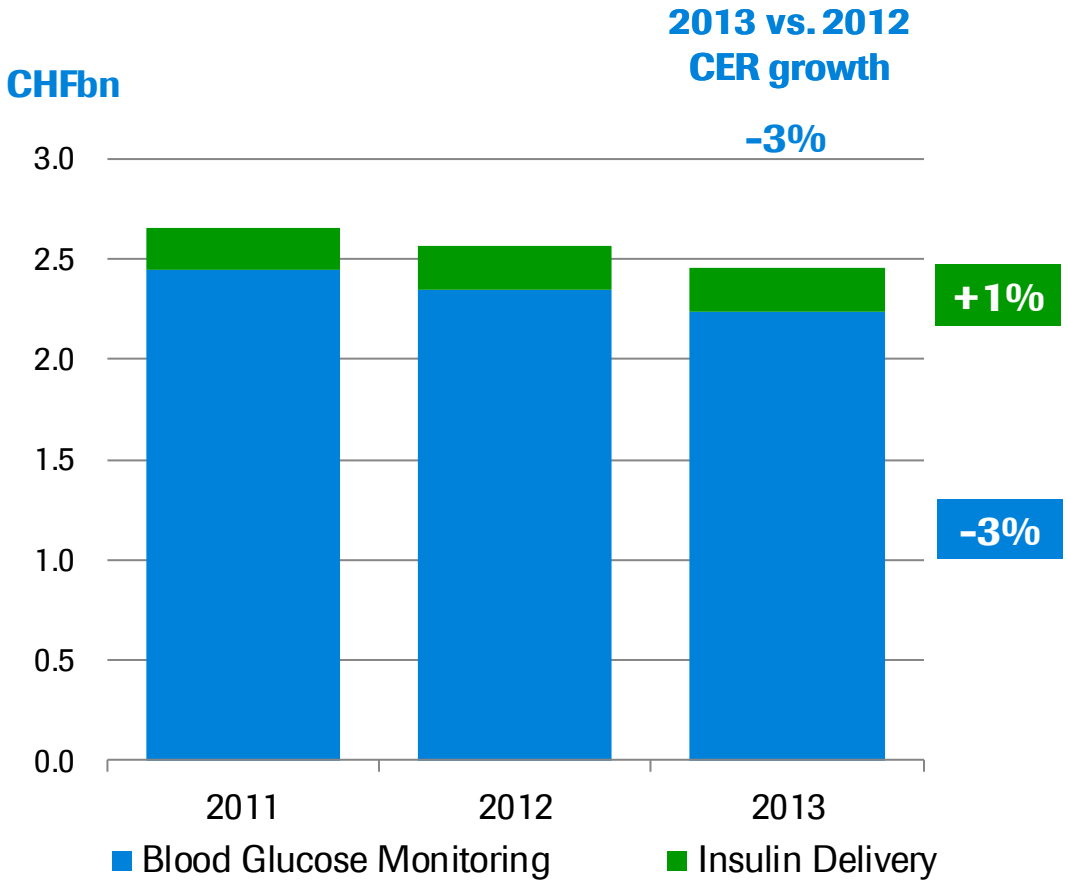
Strong growth driven by immunoassays



CER=Constant Exchange Rates

Diabetes Care

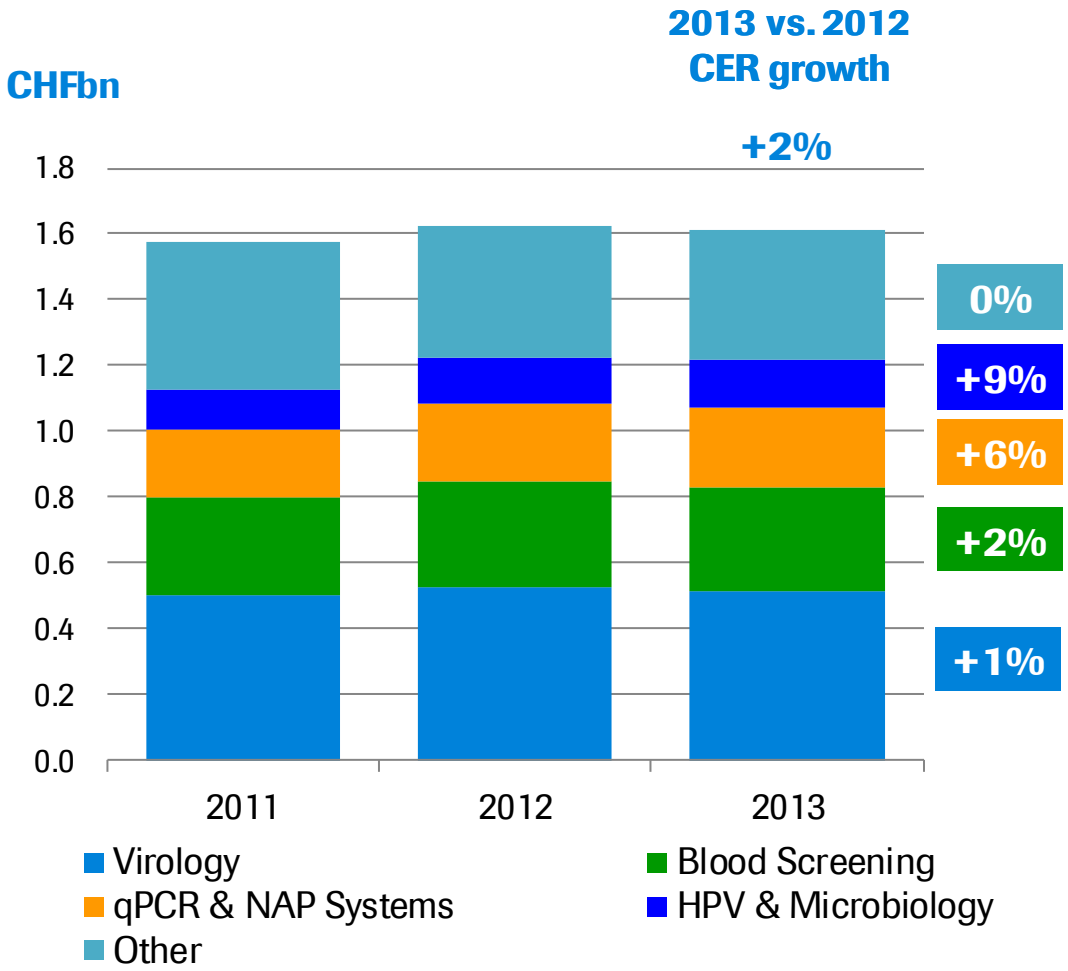
Defending global market leadership in a challenging environment



CER=Constant Exchange Rates

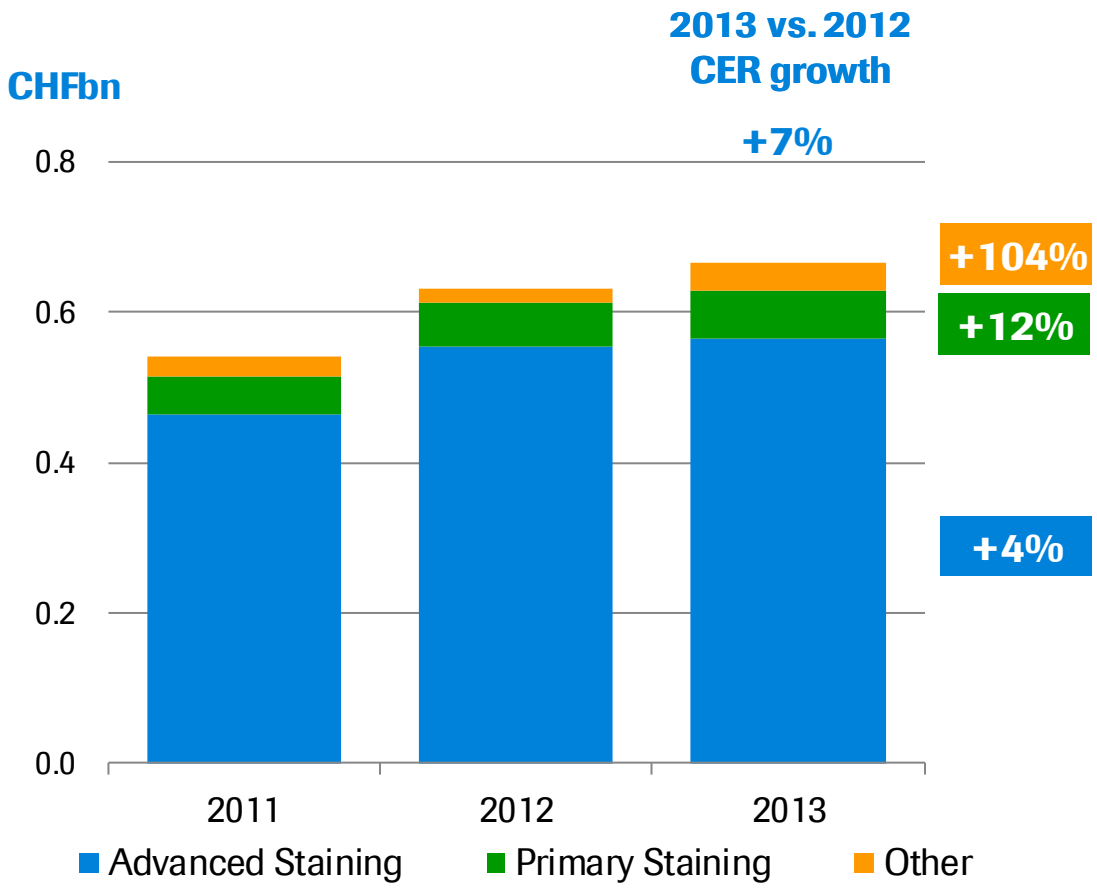
Molecular Diagnostics

Growth driven by HPV and qPCR for life sciences



[1] 2012 sales restated for Applied Science integration into Professional Diagnostics and Molecular Diagnostics.
Underlying growth of Molecular Diagnostics excluding Sequencing Solutions: +6%
CER=Constant Exchange Rates

Tissue Diagnostics
Strong growth ex-US



CER=Constant Exchange Rates

2014: Key planned product launches
Professional Diagnostics

Product	Description	Region
cobas m 511	Fully integrated and automated hematology system	EU
cobas 6500 (u 701)	Automated urinalysis work area platform including u701 microscopy analyzer	EU
Syphillis	Immunoassay for the detection of *Treponema pallidum*	EU
PE Prognosis	Claim extension for short-term prediction, rule in/out of Preeclampsia in pregnancy	EU
Anti Mullerian Hormone	Fully automated test for the assessment of ovarion reserve for fertility	EU

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2014: Key planned product launches
Diabetes Care

Product	Description	Region
Accu-Chek Connect	bG meter that connects wirelessly via Bluetooth to a smartphone app and cloud to transmit bG values	EU
Accu-Chek Insight	Next generation insulin delivery system combining an insulin pump and a blood glucose meter that functions as a pump remote control	EU

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2014: Key planned product launches
Molecular Diagnostics

Product	Description	Region
cobas 6800/8800	Next generation PCR platform for molecular testing in virology and blood screening, serving mid to high volumes	WW*
MPX 2.0	Next generation multiplex test for blood screening for HIV, HCV and HBV	US
HSV 1 and 2 test	Detection of Herpes Simplex Virus on cobas 4800 platform	EU ✓
MRSA/SA test	Detection of MRSA/SA on cobas 4800	EU ✓
C-difficile test	Detection of C-difficile on cobas 4800	US

* excluding US

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2014: Key planned product launches
Tissue Diagnostics

Product	Description	Region
Connect-V	Middleware providing connectivity for RTD instruments to simplify interfacing and connectivity to laboratory and hospital information systems	WW

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

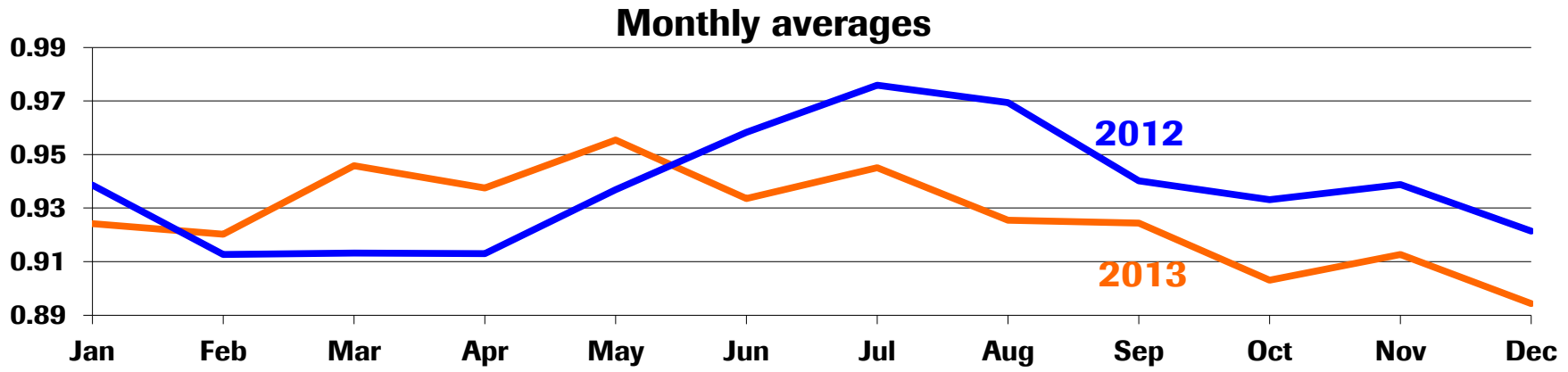
gRED (Genentech Research & Early Development)

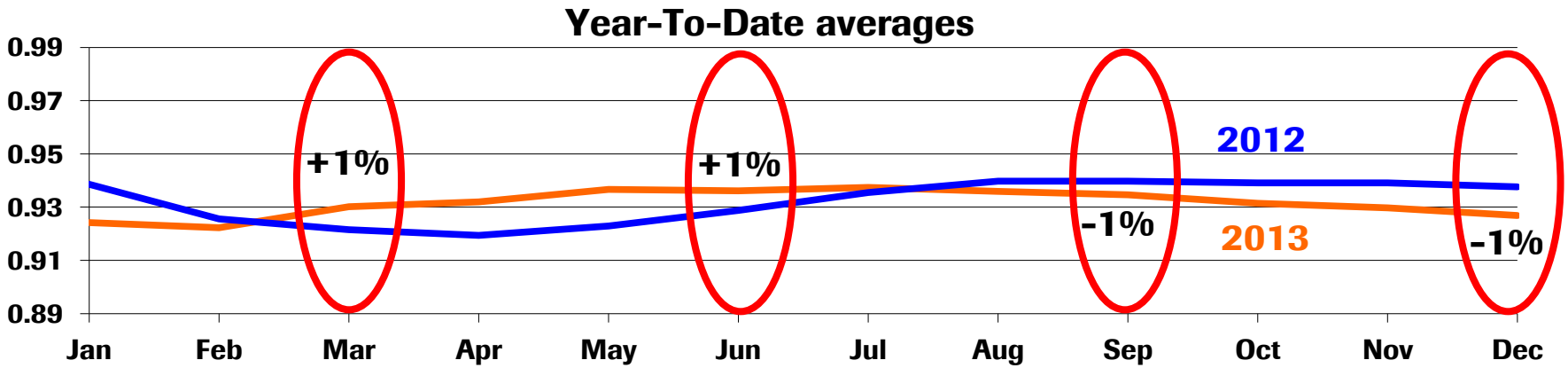
Roche Group 2013 results

Diagnostics

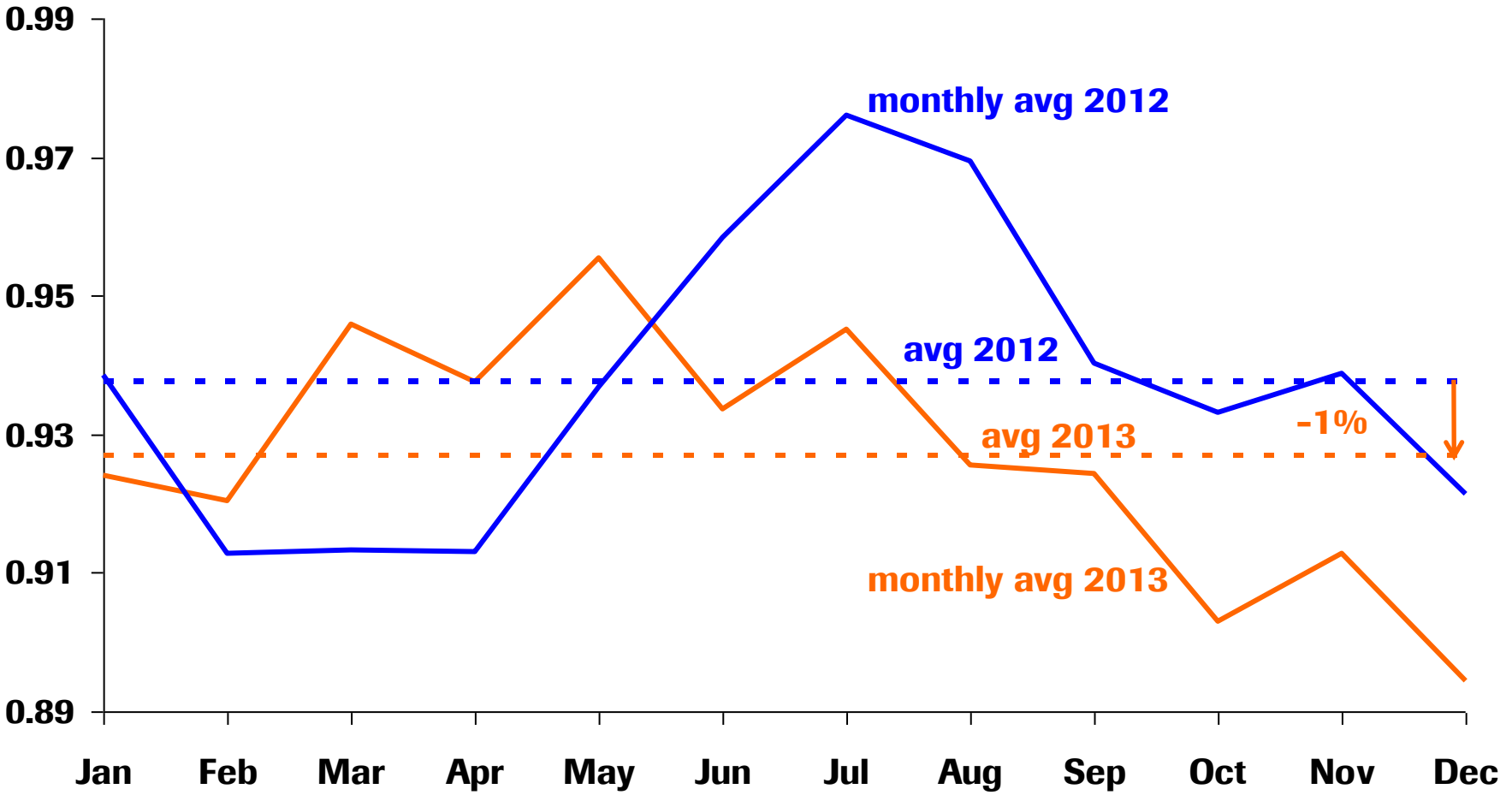
Foreign exchange rate information

CHF / USD

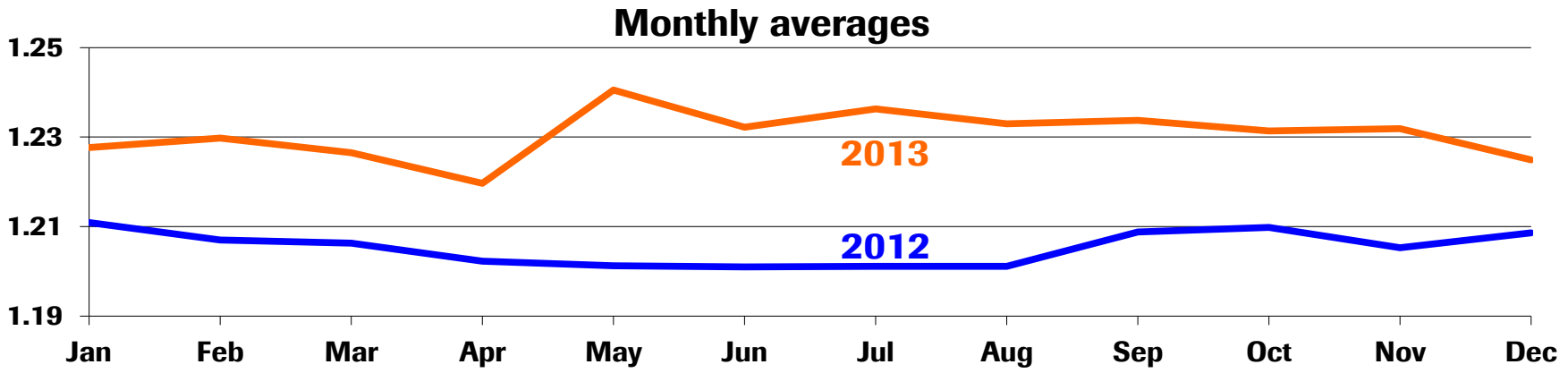

Monthly averages
0.99
0.97
0.95
0.93
0.91
0.89
2012
2013
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

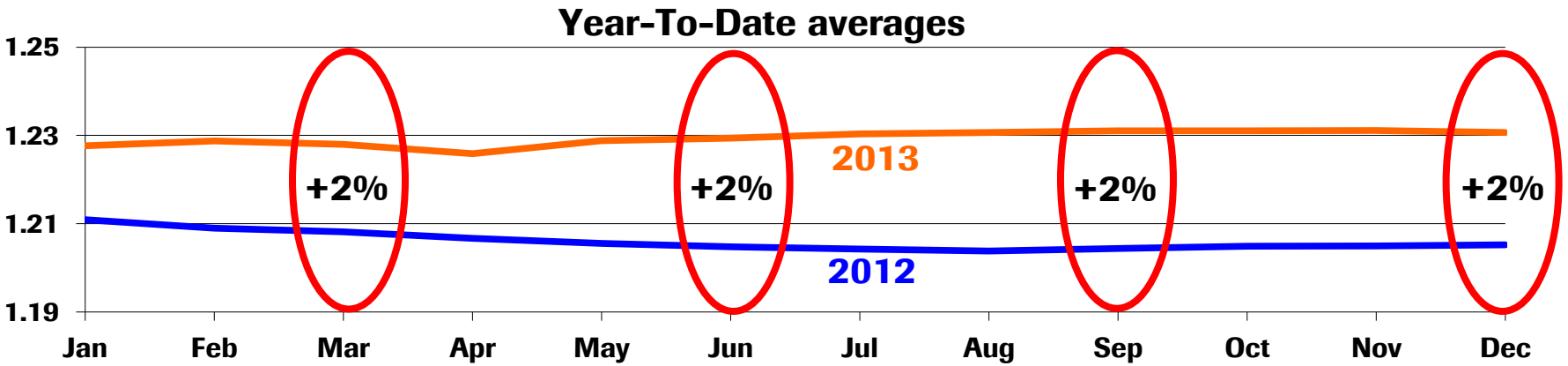

Year-To-Date averages
0.99
0.97
0.95
0.93
0.91
0.89
+1%
+1%
-1%
-1%
2012
2013
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / USD

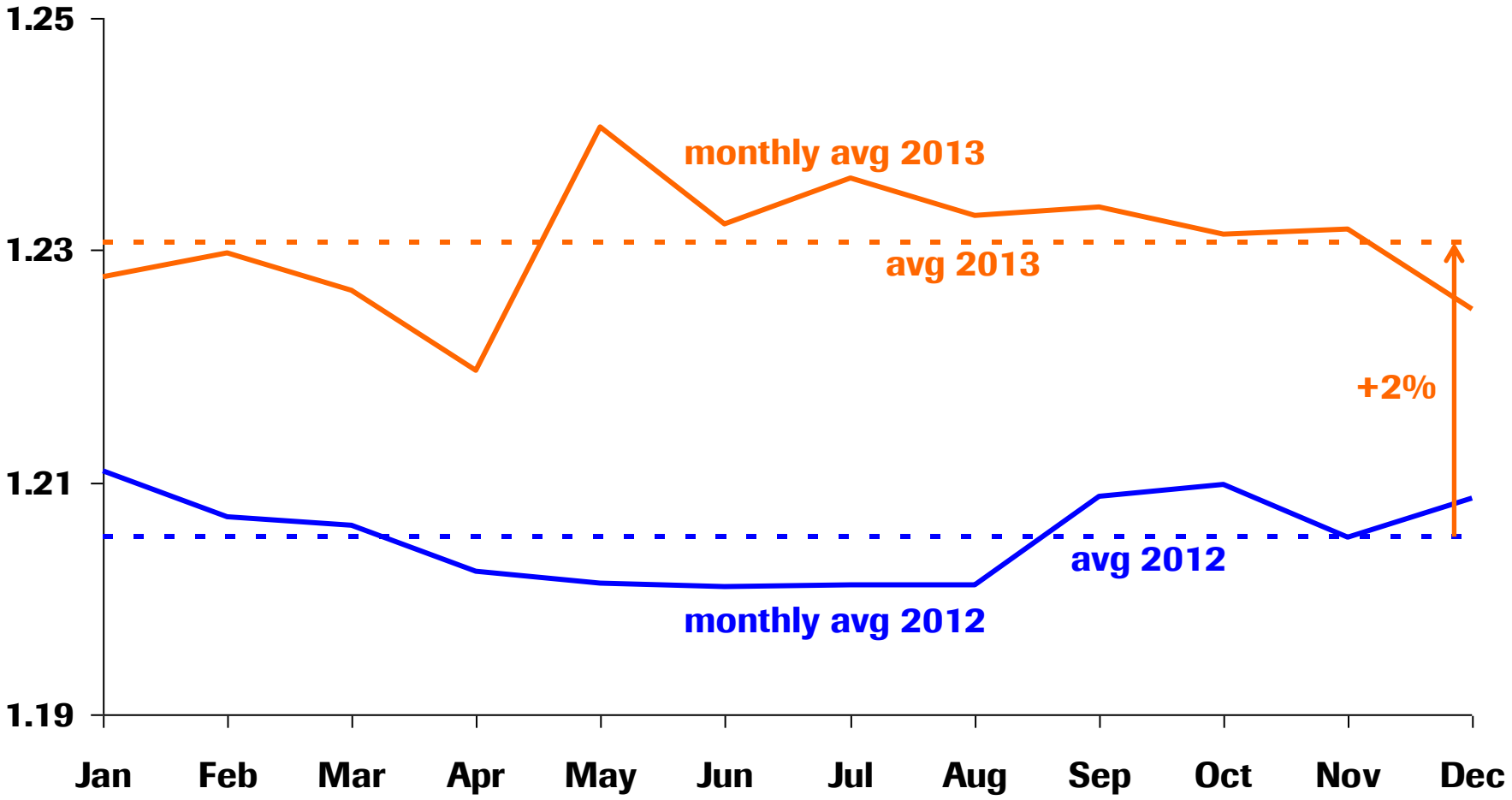

0.99
0.97
0.95
0.93
0.91
0.89
monthly avg 2012
avg 2012
avg 2013
-1%
monthly avg 2013
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / EUR


Monthly averages
1.25
1.23
1.21
1.19
2013
2012
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec


Year-To-Date averages
1.25
1.23
1.21
1.19
+2%
+2%
+2%
+2%
2013
2012
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / EUR


1.25
1.23
1.21
1.19
monthly avg 2013
avg 2013
+2%
avg 2012
monthly avg 2012
Jan
Feb
Mar
Apr
May
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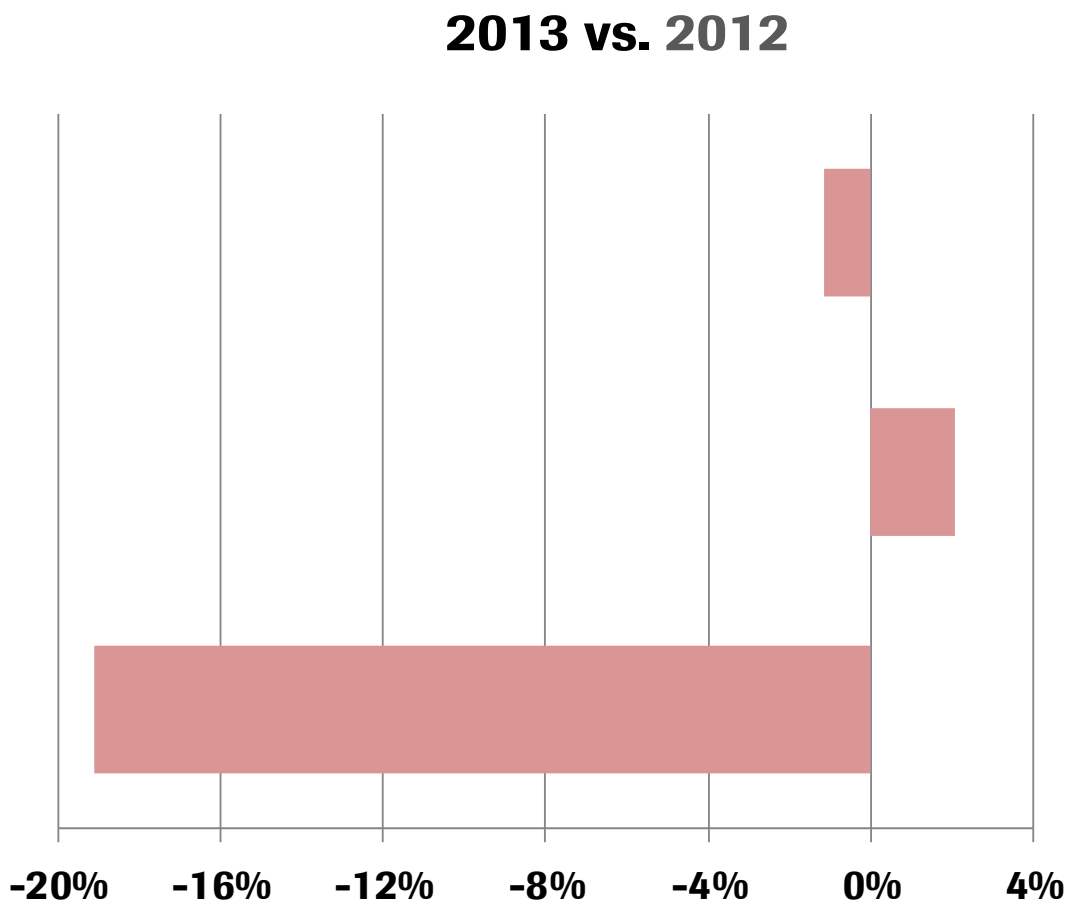
Oct
Nov
Dec

Average exchange rates

	2013	2012
USD	0.93	0.94
EUR	1.23	1.21
JPY	0.95	1.17

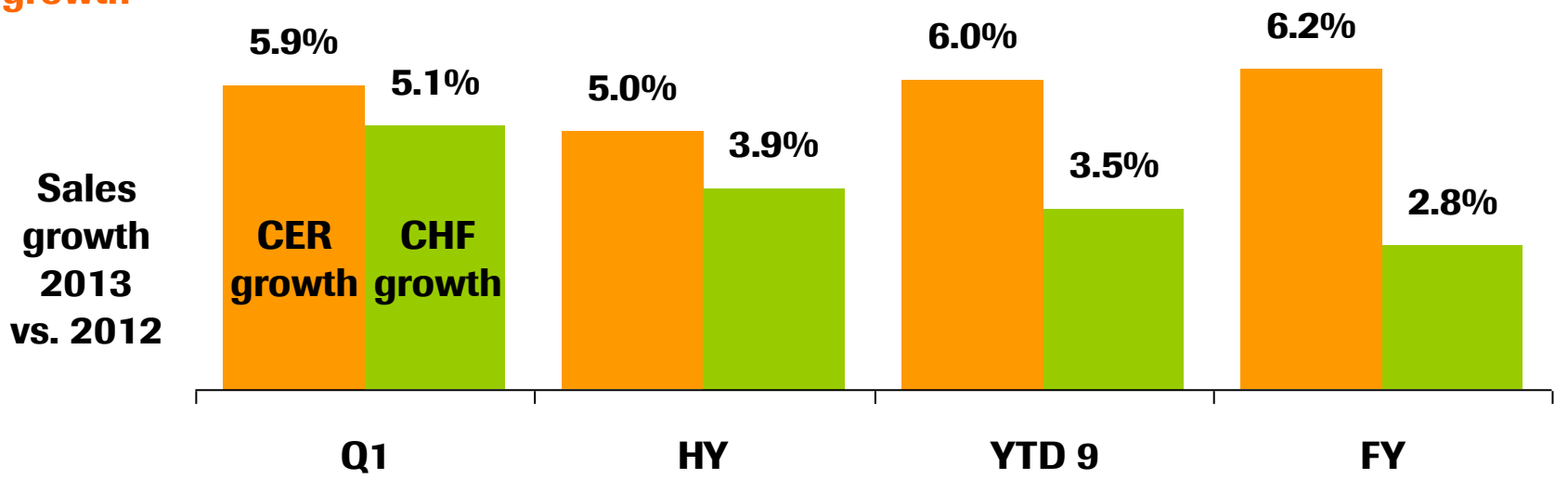


Exchange rate impact on sales growth

In 2013 negative impact from JPY and USD partially offset by positive impact from EUR

Development of average exchange rates versus prior year period

CHF / EUR	+1.6%	+2.0%	+2.2%	+2.1%
CHF / USD	+0.9%	+0.8%	-0.5%	-1.2%
CHF / JPY	-13.3%	-15.8%	-18.3%	-19.1%
Difference in CHF / CER growth	-0.8%p	-1.1%p	-2.5%p	-3.4%p



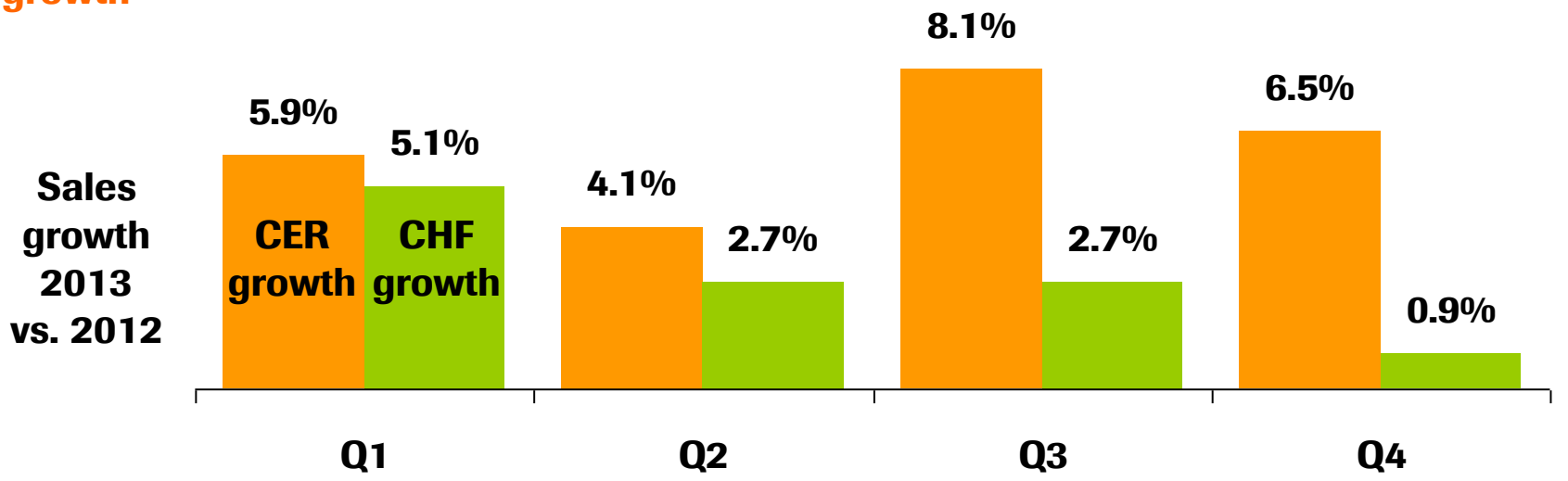
CER=Constant Exchange Rates

Exchange rate impact on sales growth

In Q4 negative impact from JPY and USD partially offset by positive impact from EUR

Development of average exchange rates versus prior year period

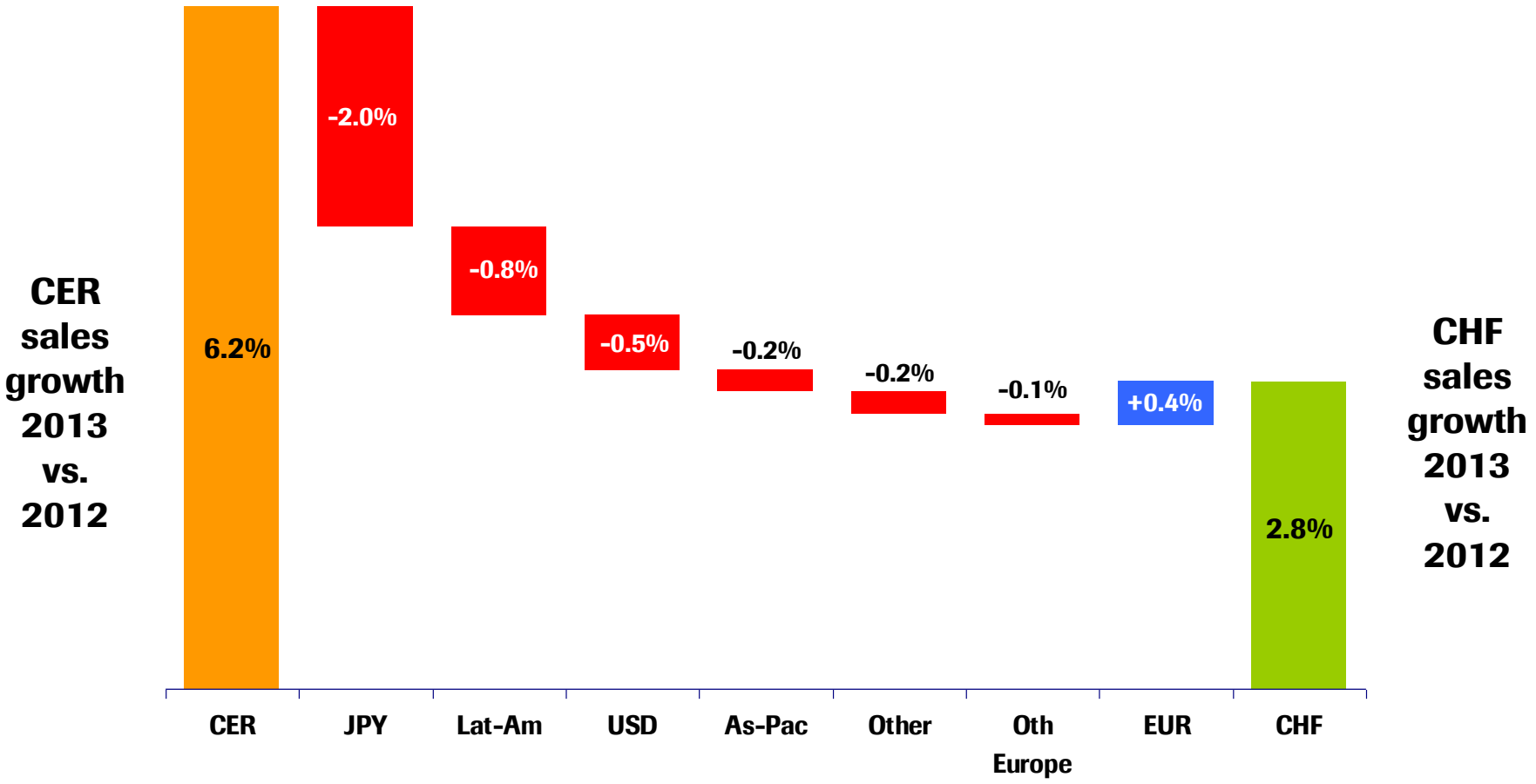
CHF / EUR	+1.6%	+2.4%	+2.5%	+1.8%
CHF / USD	+0.9%	+0.7%	-3.1%	-3.0%
CHF / JPY	-13.3%	-18.2%	-23.0%	-21.6%
Difference in CHF / CER growth	-0.8%p	-1.4%p	-5.4%p	-5.6%p



CER=Constant Exchange Rates

Exchange rate impact on sales growth

Negative impact from JPY and Latin American currencies



CER=Constant Exchange Rates

Doing now what patients need next