



## **Roche** *First quarter 2004*

**Presentation to analysts** *Basle, April 21, 2004* 



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- 10. Loss of key executives or other employees; and...
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## Group

**Dr. Erich Hunziker** *Chief Financial Officer* 

# Q1 '04: Major progress on operational and strategic level



- Sales growth well above market in both divisions
- Calling of outstanding debt instruments, one time gain of CHF 613 million after taxes from LYONs IV
- AGM: further steps for improved corporate governance approved
  - lead director appointed (Bruno Gehrig)
  - majority of the Board consists now of independent non-executive members
  - new group and statutory auditors (KPMG)
- Igen acquisition closed
- Decision on the future of the OTC business expected in H2 '04

# **Q1 '04: Sales growth above market** *...in both divisions*

	Q1 '03 CHF billion	Q1 '04 CHF billion	% change in CHF local	
Pharmaceuticals	4.9	5.6	16	17
Prescription	4.5	5.2	16	18
OTC	0.4	0.4	7	5
Diagnostics	1.7	1.9	11	10
Sales of core businesses (continuing businesses)	6.6	7.6	14	15
Vitamins & Fine Chemicals <sup>1</sup> (discontinuing businesses)	0.7		-100	-100
Roche Group	7.4	7.6	3	3

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# **Q1 '04: Finance and Treasury** (Roche *Towards the goal of a balanced financial income*

#### • LYONs IV called

- reduced group debt by CHF 1.36 billion
- one-time gain after taxes of CHF 613 million
- current shareholding in Genentech: 55.3 % (majority stake did not and will not change)
- LYONs III called
  - will reduce group debt by around CHF 2.2 billion
  - will reduce interest expenses with currently around 7 % effective interest rate

#### **Outlook** *Guidance reiterated*



- Pharmaceuticals and Diagnostics division sales growth above market (in local currencies)
- Pharma operating profit margin<sup>1</sup> towards 26 % by end of 2004
- By the end of 2004 conditions in place for a balanced financial income
- Tax rate around 29 %
- Exceptional income from bond conversion and redemption in 2004 and significant increase in net income

#### ... and after

- Operating profit margin<sup>1</sup> of the Group above 22 % in 2005
- Diagnostics operating profit margin<sup>1</sup> around 23 % in 2006







## Pharmaceuticals Division

**William M. Burns** *Head of Pharmaceuticals Division* 

#### Q1 '04: Highlights



- Prescription sales growth (+18 %<sup>1</sup>) above world market
- Strong growth of the oncology franchise (+27 %<sup>1</sup>) with MabThera and Herceptin as major contributors, also fuelled by US launch of Avastin
- Pegasys now world-wide market leader in the pegylated interferon market, franchise on the way to become Pharmaceutical's sixth billion CHF selling product
- Transplantation franchise continues to outperform market

#### **Pharmaceuticals sales**



	Q1 '04 CHF m	Growth vs. Q1 '03 in CHF	Growth vs. Q1 '03 in Local Currencies
Roche World Wide Prescription Group <sup>1</sup>	5,217	16 %	18 %
OTC <sup>1</sup>	429	7%	5%
Pharmaceuticals <sup>1</sup>	5,646	16%	17%

<sup>1</sup> Roche, Genentech and Chugai



## **Operational Performance**

#### **Key Products**

### **Strong growth in US, Japan and EU** ...and in key franchises

	% of prescr. sales	growth (local)
North America	37 %	22 %
Japan	14 %	12 %
Western Europe	31 %	15 %
Total	82 %	
Oncology	32 %	27 %
Transplantation	9 %	24 %
Virology	12 %	85 %
Anemia	8 %	2 %
Total	61 %	31 %

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#### **Prescription - key brands driving growth** ~*CHF 0.65 billion additional sales*<sup>1</sup>





<sup>1</sup> at constant fx: 0.69 billion additional sales, Xeloda performance included



### **Operational Performance**

**Key Products** 

### MabThera / Rituxan Continuing growth path



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- Sales of CHF 782 million
- EU marketing application for 1st line iNHL filed in Jan '04
- EORTC 20981 in relapsed iNHL patients met primary endpoints two years earlier than expected
  - third study in iNHL to confirm benefits of MabThera maintenance
- Data to be presented at ASCO
  - MInT data (aNHL 1st line, <60 yrs)</li>
  - ECOG 1496 (iNHL maintenance)

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### MabThera / Rituxan Increased penetration in Europe



#### **EU** first line penetration

- Sales in Europe and RoW increased by 56 %<sup>1</sup> in Q1
- Drivers for aNHL 1<sup>st</sup> line
  - EU approval based on GELA data (Mar '02)
  - MInT trial result (full data expected at ASCO '04)
  - NICE approval obtained in UK (Sep '03 )
- Drivers for iHNL 1st line
  - R-CVP data (ASH '03); filed for EU 1<sup>st</sup> line approval
  - R-CHOP (EORTC 20981)

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### **Herceptin** Sales and trials firmly progressing



- Sales of CHF 328 million
- 12-month update of *Taxotere* +/-Herceptin combination study
  - improved life expectancy by more than one-third<sup>2</sup>
  - presented at EBCC (Mar '04)
  - EU marketing application filed (Sep '03)
- Ongoing clinical development
  - Recruitment for Herceptin +/- Arimidex (hormonal combination) almost complete
    - ➢ filing now anticipated for 2005
  - HERA recruitment going well
    - filing still anticipated for 2007

<sup>1</sup> local growth

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<sup>2</sup> About half the patients treated with the combination therapy survived, on average, at least 31 months compared to 22 months for patients treated with Taxotere alone

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## Xeloda Strong growth in Europe

#### CHF m





- Sales of CHF 115 million (-11 %<sup>1</sup>)
- Strong growth of 34 % in Europe, Latin America and Asia
- US sales (-49 %) y-o-y, same sales level as Q4 '03, mainly due to changes in wholesalers buying pattern
  - US prescription up 19 %<sup>2</sup>
  - correction anticipated by year-end
- Next data expected
  - X-ACT<sup>3</sup> results mid '04



<sup>1</sup> local growth; <sup>2</sup> Source: IMS <sup>3</sup> Xeloda vs. bolus IV 5-FU/LV in adjuvant CRC

## Avastin First anti-angiogenesis treatment approved for treating cancer

- Approved in the US end Feb '04 in first-line mCRC, initial sales of CHF 48 million
- Filed in Europe in Dec '03
- Priority review in Switzerland, Canada and Australia
- Ongoing clinical development in various cancers
  - renal cell cancer
  - NSCLC
  - adjuvant colon cancer
  - metastatic breast cancer
  - pancreatic cancer
  - other solid tumors

#### **Pegasys / Copegus** *Global market leadership achieved*



#### 450 -Copegus RoW 400 Copegus US Pegasys J 350 Pegasys US 300 Pegasys RoW 250 200 150 100 50 0 **Q2 Q3 Q2 Q**3 **Q4 Q1 Q4 Q1** 01 '02 '03 '03 '03 '03 04 '02

**CHF** m

- Sales of CHF 391 million (+236 %<sup>1</sup>)
- US market share increased to 57 %<sup>2</sup>
- Important results in 2004
  - APRICOT trial in co-infected patients (HIV / HCV)<sup>3</sup>
  - Hep B HBeAg positive patients
    data to be presented in H2 '04

# **Pegasys** >50 % in major markets



Sources: IMS or local affiliate market research, March 2004 (\*Feb 04,\*\* Jan 04, \*\*\* Dec 03), <sup>1</sup> Pegylated Interferon market, <sup>2</sup> Interferon market share (includes Conventional Interferons).

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#### **Fuzeon** *Corrective measures taken*

- Sales of CHF 31 million
- Switch from single distributor to traditional multi-channel distribution in USA
- Launches in Spain and Italy started
- Reimbursement negotiations ongoing in several EU countries
- Programs to improve acceptance of injection regime put in place

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### **Transplantation franchise** *Growing above market*





- Global sales of CellCept CHF 369 million (+23 %<sup>1</sup>)
  - growing steadily in all regions
  - US: +18 %<sup>1</sup> (~50 % w/w market)
  - RoW: +29 %<sup>1</sup> (~40 % w/w market)
- Valcyte / Cymevene up 38 %<sup>1</sup> due to new indication in prevention of CMV in highrisk kidney, kidney-pancreas and heart transplant patients<sup>2.</sup>
  - Some pipeline filling following new approved indication
- Isotechnika agreement restructured

### **Anemia Management** *NeoRecormon/Epogin and CERA*



- Sales<sup>2</sup> of CHF 489 million (+5 %<sup>1,2</sup>)
- Moderate growth due to high base in Q1 '03, price competition and slower growth of oncology segment
- NeoRecormon 30.000 PFS onceweekly in oncology may further fuel growth (CPMP approval Feb '04)
- CERA
  - phase III in renal started in Q1 '04
  - phase III in oncology to start end 2004



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#### **Roche R&D pipeline today** *Total of 63 NME's including 6 opt-in opportunities*

#### phase 0

R547	solid tumors
R873	MED
R1454	solid tumors
R1496	obesity
R1497	depression
R1498	type II diabetes
R1499	type II diabetes
R1541	IBD
R1559	solid tumors
R1576	depression
R1577	Alzheimer's
R1593	dislipidemia
R1603	Alzheimer's
R1628	rheumatoid arthritis
R1630	solid tumors
Gen	wound healing
Gen	basal cell carcinoma
Gen	cancer therapy
	HIV (Me)

#### phase I

R448	COPD
R1204	depression/anxiety
R1295	rheumatoid arthritis
R1438	type II diabetes
R1439	type II diabetes
R1440	type II diabetes
R1484	SUI
R1485	Alzheimer's
R1500	Alzheimer's
R1503	rheumatoid arthritis
R1516	anemia
R1533	Alzheimer's
R1550	breast cancer
R1558	bact. infections
R1594	rheumatoid arthritis
Chu	multiple myeloma
Chu	breast cancer
	antifungal (Bs)
	type II diabetes (Ip)
	solid tumors (At)
	transplantation (Is)

#### phase II

R411	asthma
R483	(insulin sensitizer) type II diabetes
R667	emphysema
R673	(NK1) depression/anxiety
R1273	(Omnitarg) solid tumors
R1492	solid tumors
R1536	solid tumors
-	
R1569	rheumatoid arthritis
Chu	bone metastases
	<b>_</b>
Chu	bone metastases
Chu Chu	bone metastases osteoporosis
Chu Chu Chu	bone metastases osteoporosis osteoporosis
Chu Chu Chu Chu Chu	bone metastases osteoporosis osteoporosis gastroparesis

## phase III / registration

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R435	(Avastin) oncology
R484	(Boniva/Bonviva) osteoporosis
R744	(next generation anaemia treatment)
R1415	(Tarceva) oncology
R1549	(Pemtumomab) ovarian cancer
Gen	macular degeneration
Gen	acute heart failure
Chu	(Antevas) subarach. haemorrhage

Roche managed
participation through Genentech
participation through Chugai
opt-in opportunities Antisoma (At) Basilea (Bs) Ipsen (Ip) Isotechnika (Is) Medivir (Me)

#### Major development in Q1 '04, outlook Q2 '04



Major news	•	R483 Insulin sensitizer R744 (CERA) MabThera (RA, 1 <sup>st</sup> line)	phase IIb completed phase III in renal started phase IIb last patient recruited
Major changes in pipeline	•	R450 (SUI) R1524 (ISA)	dropped agreement restructured
Major results available	•	R411 (asthma) Omnitarg (solid tumors) Tarceva (NSCLC) Pemtumomab (ovarian c.) X-Act (Xeloda adj.)	phase II, data available phase II, data available phase III, data available phase III, data available phase III, data available

## **Projected filings over the next 5 years** (Roche New molecular entities and significant line extensions



# **Our growth objectives for 2004 and beyond** (Roche) *Pharmaceuticals*

#### 2004

- Local sales growth above the market
- Operating profit margin (before exceptional items) towards 26 % by end of 2004



## **Diagnostics Division**

Heino von Prondzynski Head of Diagnostics Division

#### **Roche Diagnostics** *Key achievements*

#### **Sales**

More than double IVD industry growth

#### **Product launches**

#### • 7 product launches

*Elecsys P1NP, Elecsys S100, HCV linear array, Accu-Chek Go, STA CephaScreen, HPV (CE mark), BSE approved (US)* 

#### Deals

- Igen transaction closed
- Disetronic integration completed
- Two license deals performed (NT-proBNP, hsCRP)



## **Operational Performance**

**Key Areas** 

## **Roche continues to grow faster than competitors**



#### market share<sup>1</sup>

sales growth<sup>2</sup>



<sup>1</sup> source: company reports, Boston Biomedical Consultants, Roche analysis <sup>2</sup> in local currencies, excludes Life Science research market

\* based on 2003 results

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### **Roche growing faster than IVD market** Overall and in high growth segments



**Roche growing double the market** - now in 6th year





\* excludes Industrial Business; including +13 % \*\* including Disetronic; excluding +10 %



source: Roche analysis, Boston Biomedical Consultants, company reports



### **2004: Off to a great start** *Above market growth in core IVD business*

	<b>2003</b> CHF m	<b>2004</b> CHF m	growth local	CHF
Diabetes Care	617	710	15 %	15 %
Molecular Diagnostics (ex. ind. bus)	203	231	14 %	14 %
Centralized Diagnostics	622	671	5 %	8 %
Near Patient Testing	137	137	-1 %	0 %
Roche <i>in vitro</i> Diagnostics	1,579	1,749	10 %	11 %
Applied Science	127	139	10 %	9 %
Molecular Diag - industrial business	19	20	14 %	5 %
Life Science business	146	159	10 %	9 %
Roche Diagnostics	1,725	1,908	10 %	11 %

#### **Above local market growth in all regions** *January to March 2004*



#### CHF 1,908 million

#### local sales growth Jan to Mar 2004 vs. 2003





\* US: underlying growth + 13.1%


# **Operational Performance**

**Key Areas** 

## **Diabetes Care** *Accu-Chek: head to head in the US*





- Accu-Chek Compact success-story continues in US and Europe
- Launch of Accu-Chek Advantage III strengthening leading position of Advantage product line
- Global roll out Accu-Chek Go progressing as planned

\* local growth Infusion Systems vs former Disetronic: -12 % (YTD Q1 '04)

# **Diabetes Care highlights Q1 '04** New systems designed for individual needs



# **Molecular Diagnostics** *Blood screening continues strong growth*



Molecular Diagnostics: Q1 '04: CHF 251 million (+14 % local growth, +13 % CHF)

- Growth driven by blood screening and women's health
- AmpliChip CYP450 on track for CE mark Q3 '04
- Linear Array HCV genotyping test
  - launched Q1 as RUO in US
  - CE mark planned for Q3 '04
- Clinical genomics program well underway (details R&D day)

# **Molecular Diagnostics highlights Q1 '04** *Expanding into new markets*



#### **Women's Health**

#### HPV

- microwell plate product (MWP)
  - -in clinical studies in Nth America
  - -CE mark achieved
- Linear array test
  - -on track for CE mark Q4 '04

#### CT/ NG

 market share grew by approximately 4 %

#### **Blood Screening**

- Expanded indication
  - 1st FDA approval for in-house NAT source plasma screening using COBAS AmpliScreen HIV-1 Test
- Expanded market
  - Korean Red Cross deal (70 % of NAT screening) expands
    Roche market share in Asia
    Pacific/ Japan to 77 %

#### **Centralized Diagnostics** *New markers growing Elecsys menu*



#### **Q1 '04: CHF 671 million** (+5 % local growth) (+2%) **Clinical chemistry** (+24 %) Immunochemistry (+8%) Coagulation (-49%) Hematology (+1%)Urinalysis (-4%) Other/ service 150 200 250 300 350 400 50 100 0 Q1 '03

- Igen acquisition secures access to ECL technology and entry into physician office labs
- Increased Elecsys penetration in the US
- Granted license agreement to Diagnostic Products Corporation (DPC) for nonexclusive rights to NT-proBNP
- Acquired non-exclusive sublicense from Dade Behring for high sensitive C-Reactive Protein (assay for cardiovascular risk assessment)

#### **Centralized Diagnostics highlights Q1 '04** *Two novel markers launched on Elecsys*





- novel marker for therapy monitoring of malignant melanoma
- potential utility for brain damage
- novel bone formation marker
- aid in therapy management of osteoporosis
- 4th generation Immunoassay for determination of HIV antigen & antibodies
- semi-automated urinalysis instrument for mid/ low volume workloads

# **Our growth objectives for 2004 and beyond** *Diagnostics*



#### 2004 and beyond

- 2004: sales growth significantly above the market in local currency
- More than 20 product launches in 2004
- Further improvement in operating profit (before exceptional items), around 23 % by 2006



# Appendix



## **Pharmaceuticals sales** Sales outperform world market





## **Pharmaceuticals sales** *Quarterly local sales growth in %*



## **Top 20 Prescription products** *Sales Q1 '04 (vs. Q1 '03)*



# **Big brands driving growth** Sales Q1 '04 (vs. Q1 '03)



#### **Growth in main regions and therapeutic areas** Sales Q1 '04 (vs. Q1 '03)





all growth figures are in local currencies

\* including Eastern Europe

# Q1 2004: Western Europe growing above market



## **Pegasys / Copegus** *Performance has exceeded expectations*



#### US market share total scripts (TRx)<sup>1</sup>



Sources: <sup>1</sup> IMS Dec 03, <sup>2</sup> Interferon market share (includes conventional interferons). <sup>3</sup> Ribavirin market share

# **Oncology - Roche the no. 1 company** (Roche *Expected to further increase to CHF7-10 billion*



## **Rocephin** *Demand still strong in the US*



- Sales of CHF 369 million
  - strong demand in Italy and the US
  - generic competition impacting especially in France and Germany

• US

- sales increase in Q1 '04 in connection with winter flu season
- patent protected until July 2005
- EU sales expected to further decline due to patents expiry in Italy

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#### **Our main primary care products**





• Dilatrend

- growth driven also by COMET
- off patent in major European markets during 2004
- Tamiflu
  - strong sales in Japan (+6 %) and RoW (+191 %<sup>1</sup>)
  - future sales dependent on flu season
- Xenical
  - sales stabilized at CHF 146 million
  - CPMP approved label extension and inclusion of XENDOS study

# **Roche managed R&D pipeline –overview** *By therapy area*



Research





New Molecular Entities prior to regulatory approval As of March 31, 2004

## **Roche managed R&D pipeline** *Development discontinued in the past 12 months*



#### phase 0

R1067	depression
R1315	Alzheimer's
R1554	OAB

#### phase I

R701	OAB
R944	HIV
R1068	emesis
R1479	HCV
R1487	RA
R1518	HCV



R1124	emesis
R1270	HCV
R724	(T-1249) HIV
R1461	HPV
R450	(alpha 1 agonist) SUI

## phase III / registration

#### **Roche R&D managed pipeline (NME's)** *Changes over 12 months (March 2003 - 2004)*



#### 16 in, 6 up, 4\* out \*of which 1 back to opt-in

= New from in-house or moved to next phase

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= New from external partner

 $\rightarrow$ 

#### phase I

R701	OAB		
R1295	rheumatoid arthritis		
R1438	type II diabetes		
R1439	type II diabetes		
R944	HIV		
R1440	type II diabetes		
R1500	Alzheimer's		
R1503	rheumatoid arthritis		
R1533	Alzheimer's		
R1068	emesis		
R1485	Alzheimer's		
R1594	rheumatoid arthritis		
R1204	depression/anxiety		
$\frown$			
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R1479	HCV		
R1484	R1484 stress incontinence		
R1487	RA		
R1518	HCV		
R1516	anaemia		
R1516 R1550	anaemia breast cancer		
R1550	breast cancer		

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#### phase II

R411	asthma	
R450	(alpha 1 antagonist) SUI	
R483	(insulin sensitizer) type II diabetes	
R667	emphysema	
R673	(NK1) depression/anxiety	
	)	
R724	(T-1249) HIV	
R1124	emesis	
R1273	solid tumors	
R1461	HPV	
R1524 renal transplant (now opt-in)		
R1536	solid tumors	
R1569 rheumatoid arthritis		
R1270	нсу	
R1492	solid tumors	

2 in, 1 up, 6 out\* \*of which 1 back to opt-in

#### phase III / registration

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2 in, 1 launched, 0 out

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## **Projected news flow for world wide prescription** *First half 2004*

Pending approvals	Region
Avastin 1 <sup>st</sup> line mCRC	US 🗸
Bonviva / Boniva 2.5 mg oral daily tablet	EU 🖌
Herceptin, Taxotere combo	EU
NeoRecormon 30,000 PFS, once-weekly, cancer	EU 🗸
Nutropin / Nutropin AQ for idiopathic short stature	US
Viracept 625 mg formulation HIV disease	EU
Xenical in treatment and prevention of type II diabetes	EU 🗸
Projected filings	
Bonviva / Boniva once-monthly oral	US / EU
MabThera / Rituxan 1 <sup>st</sup> line iNHL	US 🗸

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#### **Projected news flow for world wide prescription** *First half 2004*

#### Key phase III data

Bonviva / Boniva, once-monthly oral Pegasys HIV co-infected patients Pegasys HBV treatment of HBeAg positive patients Pemtumomab ovarian cancer Tarceva BR21, monotherapy NSCLC, relapsed

#### Key phase II data

CERA (renal / oncology) R450 (stress urinary incontinence) R483 (Insulin sensitizer) Omnitarg (solid tumors) R411 (asthma)

#### **Near Patient Testing**



#### Q1 '04: CHF 137 million (-1 % local growth/ adjusted local growth\* +3 %)



\* impacted by OPTI & DAT divestiture (underlying growth +3 %)

#### **Applied Science**



#### Q1 '04: CHF 139 million (+10 % local growth)



## **Diagnostic innovations for 2004**



