

**Hughes  
Hubbard**

Hughes Hubbard & Reed LLP  
One Battery Park Plaza  
New York, New York 10004-1482  
Telephone: 212-837-6000  
Fax: 212-422-4726  
hugheshubbard.com

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Ellen S. Friedenberg  
Direct Dial: 212-837-6465  
frieden@hugheshubbard.com

January 7, 2009

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Securities and Exchange Commission  
Office of International Corporate Finance  
100 F Street N.E.  
Washington, DC 20549

Re: Chugai Pharmaceutical Co., Ltd. – File Number 82-34668

Dear Sirs:

On behalf of Chugai Pharmaceutical Co., Ltd. (the “Company”), I enclose the Company’s letter submitting materials pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934, together with the attachments thereto.

I would be grateful if you could stamp one copy of the enclosed letter in order to acknowledge receipt thereof and return it to me in the enclosed envelope.

Please direct any communications regarding this filing to me at the above address. I can also be reached at 212-837-6465 (telephone), 212-422-4726 (fax) or [frieden@hugheshubbard.com](mailto:frieden@hugheshubbard.com).

Very truly yours,

ESF:bam

Enclosure

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CHUGAI PHARMACEUTICAL CO., LTD.  
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku  
Tokyo 103 8324, Japan



January 5, 2009

Securities and Exchange Commission  
Office of International Corporate Finance  
Division of Corporation Finance  
100 F Street, N.E.  
Washington, D.C. 20549

RECEIVED  
2009 JAN -8 A 8:57  
SECURITIES AND EXCHANGE COMMISSION  
OFFICE OF INTERNATIONAL CORPORATE FINANCE

Re: Chugai Pharmaceutical Co., Ltd.  
Rule 12g3-2(b) Exemption: File Number 82-34668

Dear Sir / Madam:

Pursuant to Rule 12g3-2(b) promulgated under the Securities Exchange Act of 1934, as amended, Chugai Pharmaceutical Co., Ltd., a company incorporated under the laws of Japan (the "Company"), is submitting the enclosed documents as identified on Exhibit A hereto. With respect to Japanese language documents listed in Exhibit A for which no English language version has been prepared, brief descriptions are set forth in Exhibit B hereto.

In the event of any questions or requests for additional information, please do not hesitate to contact our United States counsel in connection with this submission, Ellen Friedenberg of Hughes Hubbard & Reed LLP, One Battery Park Plaza, New York, New York 10004, telephone (212) 837-6465, fax number (212) 422-4726.

Very truly yours,

Chugai Pharmaceutical Co., Ltd.

By: 

Name: Toshihiko Tsuchiya  
Title: General Manager of  
General Affairs Department

Enclosure

**Additional Rule 12g3-2(b) Documents**

**A. English Language Documents**

None

**B. Japanese Language Documents**

1. Overview of Consolidated Company Performance (unaudited) (for the third quarter of fiscal year 2008), dated October 21, 2008 (English translation as Attachment 1)
2. Correction of Consolidated Company Performance (for the third quarter of fiscal year 2008.12 ended September 30, 2008), dated October 21, 2008 (English translation as Attachment 2)
3. Documents concerning material information concerning the Company which may have a material influence on an investor's decision (which have been filed by the Company with Tokyo Stock Exchange on which the common stock of the Company is listed and which are made public by Tokyo Stock Exchange)
  - a. Document titled "F. Hoffmann-La Roche Announces Third Quarter Sales 2008" dated October 21, 2008 (English translation as Attachment 3)
  - b. Document titled "RoACTEMRA®, a Humanized Anti-Human IL-6 Receptor Monoclonal Antibody, Receives Positive Opinion in Europe for the Treatment of Rheumatoid Arthritis" dated November 25, 2008 (English translation as Attachment 4)
  - c. Document titled "Anti-malignancy agent / anti-VEGF humanised monoclonal antibody, Avastin® Application for Approval of Additional Indication of NSCLC" dated November 26, 2008 (English translation as Attachment 5)
  - d. Document titled "Update on FDA Registration of Actemra®, a Humanized Anti-Human IL-6 Receptor Monoclonal Antibody for Rheumatoid Arthritis" dated December 4, 2008 (English translation as Attachment 6)
  - e. Document titled "Eldecalcitol, An Active Vitamin D<sub>3</sub> Derivative, Reduces Incidence of New Vertebral Fractures in Osteoporosis Patients in Phase III Clinical Trial" dated December 16, 2008 (English translation as Attachment 7)
4. Commercial Register (brief description of which is set forth in Exhibit B)

[End]



**CHUGAI PHARMACEUTICAL CO., LTD.**

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 A member of the Roche group

## OVERVIEW OF CONSOLIDATED COMPANY PERFORMANCE (Unaudited) (for the third quarter of fiscal year 2008)

Name of Company: **Chugai Pharmaceutical Co., Ltd.** October 21, 2008  
 Stock Listings: Tokyo Stock Exchange, First Section  
 Security Code No.: 4519  
 (URL <http://www.chugai-pharm.co.jp/english>)  
 Representative: Mr. Osamu Nagayama, President and CEO, Chairman of the Board of Directors  
 Contact: Mr. Toshiaki Itagaki, General Manager of Finance and Accounting Department  
 Phone: +81-(0) 3-3281-6611

### 1. Consolidated Operating Results for the Third Quarter of FY 2008 (January 1 - September 30)

#### (1) Results of operations (Consolidated)

*Note: Amounts of less than one million yen are omitted.*

	Revenues	% change	Operating Income	% change	Recurring Profit	% change
3 <sup>rd</sup> quarter of FY 2008 (Jan.-Sep.)	¥229,680 million	(8.3)	¥39,823 million	(18.8)	¥42,707 million	(16.2)
3 <sup>rd</sup> quarter of FY 2007 (Jan.-Sep.)	¥250,451 million	10.3	¥49,024 million	24.2	¥50,959 million	20.8
FY 2007 (Jan.-Dec.)	¥344,808 million	—	¥66,702 million	—	¥67,687 million	—

	Net Income	% change	Net Income per Share (Basic)	Net Income per Share (Fully Diluted)
3 <sup>rd</sup> quarter of FY 2008 (Jan.-Sep.)	¥30,141 million	(0.3)	¥55.32	¥55.32
3 <sup>rd</sup> quarter of FY 2007 (Jan.-Sep.)	¥30,220 million	11.1	¥55.17	¥55.11
FY 2007 (Jan.-Dec.)	¥40,060 million	—	¥73.23	¥73.16

*Note: Percentages represent changes compared with the same period of the previous fiscal year.*

#### (2) Financial conditions (Consolidated)

	Total Assets	Net Assets	Equity Ratio	Net Assets per Share
As of Sep. 30, 2008	¥461,862 million	¥394,476 million	85.0%	¥720.66
As of Sep. 30, 2007	¥440,576 million	¥376,447 million	85.0%	¥687.54
As of Dec. 31, 2007	¥458,942 million	¥385,797 million	83.5%	¥703.80

#### (3) Results of cash flows (Consolidated)

	Cash Flows from Operating Activities	Cash Flows from Investing Activities	Cash Flows from Financing Activities	Balance of Cash and Cash Equivalents
3 <sup>rd</sup> quarter of FY 2008 (Jan.-Sep.)	¥32,579 million	¥(19,097) million	¥(18,360) million	¥65,405 million
3 <sup>rd</sup> quarter of FY 2007 (Jan.-Sep.)	¥44,140 million	¥4,924 million	¥(45,682) million	¥72,329 million
FY 2007 (Jan.-Dec.)	¥60,364 million	¥(7,509) million	¥(47,173) million	¥73,723 million

## Qualitative Information

### 1. Qualitative Information Regarding Operating Results Financial Condition (Consolidated)

Consolidated net revenue for the fiscal period under review totaled ¥229,680 million, down 8.3% from the same period last year. The main reasons for this decline were the drop in sales of anti-influenza agent Tamiflu and the termination of the marketing agreement with sanofi-aventis K.K. at the end of last year. However, excluding these special factors, revenues were ¥18.1 billion higher compared to the same period last year. Other factors accounting for the decline in revenues were the change in the price for recombinant human erythropoietin Epogin and the decline in royalties and other operating income (mainly milestone income). On the other hand, anti-cancer agents Avastin, anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody, and Tarceva, human epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, launched respectively in June and December 2007, as well as Actemra, humanized anti-human IL-6 receptor monoclonal antibody; and anti-cancer agents Herceptin, anti-HER2 monoclonal antibody, and Xeloda which were approved for additional indications, booked much higher sales on an year on year basis.

Overseas revenues totaled ¥25,046 million (10.9% of consolidated net revenue), which was down 5.2% compared to the same period last year, mainly reflecting the decline in royalties and other operating income which principally consist of milestone income, while ¥1.6 billion for export sales of Actemra was included in overseas revenues.

At the profit level, in addition to the decrease in net revenue, cost related to the activities to promote appropriate usage of newly launched drugs and indications and post-marketing surveillances resulted in lower profit level than in the same period last year. The operating income and recurring profit totaled ¥39,823 million, down 18.8%, and ¥42,707 million, down 16.2%, respectively, from the same period last year. Net income was ¥30,141 million, a 0.3% decrease from the same period last year.

R&D expenses for the period under review amounted to ¥36,315 million.

### 2. Qualitative Information Regarding Financial Condition (Consolidated)

#### (1) Changes in the Company's Financial Condition

Total assets at the end of the fiscal period under review were ¥461,862 million, up ¥2,920 million from the previous fiscal year-end, mainly due to the increase in inventories and tangible fixed assets, offsetting decrease in cash and deposits and trade notes and accounts receivable. Total liabilities were ¥67,386 million, which was ¥5,757 million lower than at the previous fiscal year-end, mainly due to a decrease in accrued income tax that was more than the increase in notes and accounts payable. Net working capital (current assets less current liabilities) was ¥263,346 million, the current ratio was 509.6%, reflecting the Company's continuing sound financial position.

Net assets amounted to ¥394,476 million, increasing by ¥8,678 million compared to the previous fiscal year-end. The equity ratio was 85.0% (83.5% as of the previous fiscal year-end).

#### (2) Cash Flows

Cash and cash equivalents at the end of the fiscal period under review amounted to ¥65,405 million, down ¥8,317 million from the previous fiscal year-end.

Net cash provided by operating activities amounted to ¥32,579 million, a decrease of ¥11,561 million compared with the same period of the previous fiscal year, mainly because of an increase in income taxes paid.

Net cash used in investing activities amounted to ¥19,097 million, a decrease of ¥24,021 million compared with the same period of the previous fiscal year, mainly due to a decrease in sale of securities.

Net cash used in financing activities amounted to ¥18,360 million, an increase of ¥27,322 million compared with the same period of the previous fiscal year, mainly due to a decrease in the acquisition of treasury stock.

### 3. Others

(1) Changes in the state of material subsidiaries during the period (changes regarding specific subsidiaries attendant with change in scope of consolidation): None

(2) Adoption of simplified method: None

(3) Change in accounting policies: None

Accounts	As of September 30, 2007 (A)		As of September 30, 2008 (B)		Change (B)-(A)	As of December 31, 2007	
	Millions of Yen	%	Millions of Yen	%		Millions of Yen	%
<b>Liabilities</b>							
<b>I Current liabilities:</b>							
Trade notes and accounts Payable	16,708		24,606		7,898	17,325	
Bonds with warrants due within one year	300		—		(300)	300	
Convertible bonds due within one year	42		—		(42)	42	
Other payables	9,145		9,099		(45)	5,201	
Accrued tax liabilities	8,294		5,061		(3,233)	16,325	
Accrued consumption taxes	982		53		(929)	1,164	
Accrued expenses	9,435		12,332		2,896	17,635	
Reserve for bonuses to employees	9,213		8,391		(822)	4,534	
Reserve for bonuses to directors	148		154		6	198	
Reserve for sales rebates and other items	2,945		2,470		(474)	4,090	
Other	3,232		2,116		(1,115)	2,979	
Total current liabilities	60,449	13.7	64,287	13.9	3,837	69,797	15.2
<b>II Fixed liabilities:</b>							
Deferred tax liabilities	3		1		(2)	2	
Reserve for employees' retirement benefits	2,981		2,248		(732)	2,604	
Reserve for directors' retirement benefits	610		742		132	633	
Other	84		106		22	106	
Total fixed liabilities	3,679	0.9	3,099	0.7	(580)	3,346	0.7
Total liabilities	64,129	14.6	67,386	14.6	3,256	73,144	15.9

## (2) Consolidated Statements of Income

Accounts	Third quarter of FY 2007 (Jan. 1, 2007-Sep. 30, 2007) (A)		Third quarter of FY 2008 (Jan. 1, 2008-Sep. 30, 2008) (B)		Change (B)-(A)	FY 2007 (Jan. 1, 2007-Dec. 31, 2007)	
	Millions of Yen	%	Millions of Yen	%		Millions of Yen	%
I Revenues	<u>250,451</u>	100.0	<u>229,680</u>	100.0	<u>(20,771)</u>	<u>344,808</u>	100.0
Sales	242,838		224,876		(17,961)	332,943	
Royalties and other operating income	7,613		4,803		(2,810)	11,864	
II Cost of sales	100,959	40.3	87,614	38.1	(13,345)	137,293	39.8
Gross profit	149,492	59.7	142,065	61.9	(7,426)	207,514	60.2
III Selling, general and administrative expenses	<u>100,467</u>	40.1	<u>102,241</u>	44.5	<u>1,774</u>	<u>140,812</u>	40.8
Sales promotion expenses	7,570		9,979		2,408	13,066	
Salaries and benefits	17,389		18,894		1,504	27,264	
Reserve for bonuses	5,563		5,136		(427)	2,700	
R&D Expenses	38,842		36,315		(2,527)	54,243	
Other	31,101		31,916		815	43,537	
Operating income	49,024	19.6	39,823	17.3	(9,201)	66,702	19.3
IV Non-operating income:	<u>2,996</u>	1.2	<u>4,314</u>	1.9	<u>1,317</u>	<u>4,312</u>	1.3
Interest income	945		1,245		299	1,345	
Dividend income	56		64		7	98	
Life insurance dividends Received	314		332		18	314	
Gain on foreign exchanges	32		1,647		1,614	575	
Gain on derivatives	356		—		(356)	368	
Insurance income received	334		—		(334)	—	
Other	956		1,024		67	1,610	
V Non-operating expenses:	<u>1,062</u>	0.4	<u>1,431</u>	0.6	<u>368</u>	<u>3,327</u>	1.0
Interest expenses	136		98		(37)	176	
Loss on disposal of fixed Assets	153		193		40	326	
Loss on inventories	299		843		544	2,236	
Other	474		295		(179)	587	
Recurring profit	50,959	20.3	42,707	18.6	(8,252)	67,687	19.6
VI Extraordinary gain:	<u>293</u>	0.1	<u>7,256</u>	3.2	<u>6,962</u>	<u>293</u>	0.1
Gain on disposal of fixed Assets	—		415		415	—	
Gain on the liquidation of affiliates	293		—		(293)	293	
Gain on settlement of co-development costs	—		6,340		6,340	—	
Subsidies received	—		500		500	—	
VII Extraordinary loss:	<u>1,177</u>	0.5	<u>363</u>	0.2	<u>(814)</u>	<u>1,553</u>	0.5
Loss on disposal of fixed Assets	—		5		5	—	
Impairment loss	13		31		18	32	
Loss on office realignment costs	1,164		199		(965)	1,520	
Retirement benefit expenses	—		107		107	—	
Loss on revaluation of investment securities	—		19		19	—	
Income before income taxes and minority interests	50,075	20.0	49,600	21.6	(474)	66,427	19.3
Income taxes	18,423	7.4	18,138	7.9	(284)	24,537	7.1
Minority interests	1,431	0.6	1,319	0.6	(112)	1,829	0.5
Net income	30,220	12.1	30,141	13.1	(78)	40,060	11.6

The third quarter of FY 2008 (Jan. 1, 2008–Sep. 30, 2008)

(Millions of Yen)

	Shareholders' equity				
	Common stock	Additional paid-in capital	Retained earnings	Treasury stock, at cost	Total shareholders' equity
Balance as of Dec. 31, 2007	72,947	92,796	248,098	(35,108)	378,733
Changes:					
New stock issuance	19	18			37
Dividends paid			(16,344)		(16,344)
Third quarter net income			30,141		30,141
Purchase of treasury stocks				(62)	(62)
Disposition of treasury stocks			(2)	8	5
Net changes except for shareholders' equity					
Net changes	19	18	13,794	(54)	13,778
Balance as of Sep. 30, 2008	72,966	92,815	261,892	(35,162)	392,512

(Millions of Yen)

	Valuation and translation adjustments			New share warrants	Minority interests	Total net assets
	Net unrealized gain on securities	Foreign currency translation adjustments	Total valuation and translation adjustments			
Balance as of Dec. 31, 2007	2,757	1,944	4,701	139	2,222	385,797
Changes:						
New stock issuance						37
Dividends paid						(16,344)
Third quarter net income						30,141
Purchase of treasury stocks						(62)
Disposition of treasury stocks						5
Net changes except for shareholders' equity	(1,035)	(3,547)	(4,582)	139	(657)	(5,099)
Net changes	(1,035)	(3,547)	(4,582)	139	(657)	8,678
Balance as of Sep. 30, 2008	1,722	(1,602)	119	279	1,565	394,476

## (4) Consolidated Statements of Cash Flow

	Third quarter of FY 2007 (Jan. 1, 2007-Sep. 30, 2007)	Third quarter of FY 2008 (Jan. 1, 2008-Sep. 30, 2008)	FY 2007 (Jan. 1, 2007-Dec. 31, 2007)
Accounts	Millions of Yen	Millions of Yen	Millions of Yen
<b>I Cash flows from operating activities:</b>			
Income before income taxes and minority interests	50,075	49,600	66,427
Depreciation and amortization	10,013	14,270	14,913
Impairment loss	13	31	32
Increase (decrease) in reserve for employees' retirement benefits	(1,160)	(348)	(1,534)
Interest and dividend income	(1,002)	(1,310)	(1,444)
Interest expense	136	98	176
Loss on disposal of fixed assets	153	193	326
Loss (gain) on sales of fixed assets	31	(410)	34
Loss (gain) on sales and revaluation of investment securities	20	19	21
Decrease (increase) in notes and accounts receivable	14,114	13,269	(1,257)
Decrease (increase) in inventories	1,799	(18,274)	6,174
Increase (decrease) in notes and accounts payable	(11,418)	7,640	(10,709)
Increase (decrease) in accrued consumption tax	946	(2,445)	1,128
Other	(437)	(964)	5,639
Subtotal	63,284	61,370	79,929
Interest and dividends received	970	1,182	1,365
Interest paid	(136)	(99)	(176)
Income taxes paid	(19,977)	(29,873)	(20,754)
Net cash provided by (used in) operating activities	44,140	32,579	60,364
<b>II Cash flows from investing activities:</b>			
Purchase of marketable securities	(160,891)	(152,614)	(225,852)
Proceeds from sales of marketable securities	181,900	154,500	242,900
Purchase of investment securities	(3,004)	(4,003)	(3,504)
Proceeds from sales of investment securities	1,335	—	1,335
Purchases of fixed assets	(14,451)	(17,502)	(22,596)
Proceeds from sales of fixed assets	35	503	191
Net decrease (increase) in short-term loans	(1)	5	2
Net decrease (increase) in long-term loans	1	13	14
Net cash provided by (used in) investing activities	4,924	(19,097)	(7,509)
<b>III Cash flows from financing activities:</b>			
Redemption of bonds	(0)	(304)	(0)
Net decrease (increase) in treasury stock	(27,533)	(57)	(27,517)
Cash dividends paid	(18,149)	(16,347)	(18,136)
Cash dividends paid to minority interests	—	(1,651)	(1,519)
Net cash provided by (used in) financing activities	(45,682)	(18,360)	(47,173)
<b>IV Effect of exchange rate changes on cash and cash equivalents</b>	<b>614</b>	<b>(3,439)</b>	<b>(291)</b>
<b>V Net increase (decrease) in cash and cash equivalents</b>	<b>3,996</b>	<b>(8,317)</b>	<b>5,390</b>
<b>VI Cash and cash equivalents at beginning of period</b>	<b>68,332</b>	<b>73,723</b>	<b>68,332</b>
<b>VII Cash and cash equivalents at end of period</b>	<b>72,329</b>	<b>65,405</b>	<b>73,723</b>

[Reference]

Statements of Revenues

(Millions of Yen)\*1

	Consolidated					
	Third quarter of FY2007 (Jan.-Sep.)	Third quarter of FY2008 (Jan.-Sep.)	Change (%)	Third quarter of FY2007 (Jul.-Sep.)	Third quarter of FY2008 (Jul.-Sep.)	Change (%)
Epogin	40,400	32,800	(18.8)	12,200	11,100	(9.0)
Neutrogen	28,600	28,700	0.3	9,900	9,900	0.0
Herceptin	11,700	16,200	38.5	3,800	6,400	68.4
Rituxan	13,200	14,600	10.6	4,700	5,100	8.5
Avastin	1,300	12,800	884.6	1,000	5,600	460.0
Sigmart	12,800	12,500	(2.3)	4,200	4,000	(4.8)
Evista	11,100	11,700	5.4	3,900	4,100	5.1
Alfarol	10,300	10,000	(2.9)	3,500	3,300	(5.7)
Suvenyl	7,800	8,700	11.5	2,800	3,000	7.1
Kytril	9,700	8,100	(16.5)	3,400	2,700	(20.6)
Oxarol	6,100	7,300	19.7	2,200	2,500	13.6
Pegasys	4,100	6,700	63.4	1,700	2,600	52.9
Rocephin	4,100	4,200	2.4	1,400	1,400	0.0
Renagel	4,000	4,200	5.0	1,400	1,400	0.0
Actemra	300	3,500	1,066.7	100	2,600	2,500.0
Xeloda	1,900	3,300	73.7	700	1,300	85.7
Tarceva	—	3,200	—	—	1,200	—
Copegus	1,100	2,900	163.6	600	1,100	83.3
CellCept	2,400	2,800	16.7	800	1,000	25.0
Tamiflu	31,800	1,700	(94.7)	8,000	100	(98.8)
Femara	700	1,200	71.4	300	400	33.3
Other *2, 3	46,900	32,900	(29.9)	13,000	12,800	(1.5)
Total	250,500	229,700	(8.3)	79,600	83,800	5.3

Notes: 1. Figures are rounded to the nearest 100 million. The percentages are calculated based on the rounded numbers.

2. Royalties and other operating income are included in the "Other" (7,600 million yen for Jan.-Sep. 2007, 100 million yen for Jul.-Sep. 2007, 4,800 million yen for Jan.-Sep. 2008, 3,800 million yen for Jul.-Sep. 2008)

3. Sales of the products for which the marketing agreement in Japan with sanofi-aventis K.K. ended on December 31, 2007, are included in the "Other" (8,800 million yen for Jan.-Sep. 2007, 2,900 million yen for Jul.-Sep. 2007)

## Development pipeline (as of October 21, 2008)

Development code	Indication # Additional indication	Stage (date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
<b><i>Oncology</i></b>					
R340	Colorectal cancer #	Filed Feb.08	capecitabine Xeloda	Roche Xeloda	Antimetabolite, 5-FU derivative
	Gastric cancer #	Phase III	Oral		
R435	Colon cancer (adjuvant) #	Phase III Multinational study	bevacizumab Avastin Injection	Roche /Genentech Avastin	Anti-VEGF(Vascular Endothelial Growth Factor) humanized monoclonal antibody
	Gastric cancer #	Phase III Multinational study			
	Breast cancer (adjuvant) #	Phase III Multinational study			
	Non-small cell lung cancer #	Phase II			
	Breast cancer #	Phase II			
R597	Gastric cancer #	Phase III Multinational study	trastuzumab Herceptin Injection	Roche /Genentech Herceptin	Anti-HER2 humanized monoclonal antibody
EPOCH	Chemotherapy-induced anemia #	Phase III	epoetin beta Epogin Injection	In-house	Recombinant human erythropoietin
R1415	Pancreatic cancer #	Phase II	erlotinib Tarceva Oral	OSI/Genentech/ Roche Tarceva	EGFR tyrosine kinase inhibitor
R744	Chemotherapy-induced anemia	Phase II	Injection	Roche Mircera	Continuous erythropoietin receptor activator
MRA	Multiple myeloma	Phase II Overseas	tocilizumab Actemra Injection	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody
R1273	Breast cancer, etc	Phase I	pertuzumab Injection	Roche /Genentech	HER dimerization inhibitory humanized monoclonal antibody
TP300	Colorectal cancer, etc	Phase I Overseas	Injection	In-house	Topoisomerase I inhibitor
CIF (R7167)	Solid tumors	Phase I Overseas	Oral	In-house (Roche)	-
GC33	Liver cancer	Phase I Overseas	Injection	In-house	-
R7159 (GA101)	Non-Hodgkin's lymphoma	Phase I	Injection	Roche/GlycArt	Humanized anti-CD20 monoclonal antibody

Development code	Indication # Additional Indication	Stage (date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
<b><u>Other diseases</u></b>					
EPOCH	Predeposit of autologous blood transfusion #	Filed Mar.02	epoetin beta Epogin Injection	In-house	Recombinant human erythropoietin
R1678	Schizophrenia	Phase II Multinational study	Oral	Roche	GLYT1 inhibitor
GM-611	Diabetic gastroparesis	Phase I Completed Japan	mitomcinal Oral	In-house	Motilin agonist Recovery of gastrointestinal motility
	Irritable bowel syndrome (IBS)	Phase II Overseas			
R1583 (ITM-077)	Type II diabetes	Phase I	tasoglutide Injection	Roche / Ipsen (Teijin)	GLP-I analogue
CSG452 (R7201)	Type II diabetes	Phase I	Oral	In-house (Roche)	-
R1579	Type II diabetes	Phase I	Oral	Roche	DPP-IV inhibitor

Changes from the last announcement on July 31, 2008

Oncology

- GC33 Started Phase I (liver cancer)
- R7159(GA101) Started Phase I (Non-Hodgkin's lymphoma)

Cardio/Cerebro-vascular diseases

- NA808 Started Phase I (chronic hepatitis C / Japan)

R&D Activities (Aug.1, 2008 – Oct. 21, 2008)

As for clinical development activities in Japan, the Company saw progress as described below:

Oncology

- In October, we started Phase I clinical trials for R7159(GA101) (expected indication: Non-Hodgkin's lymphoma).
- In September, we obtained the approval for modification of manufacturing process for drug substance (to use porcine derived material) for humanized anti-HER2 monoclonal antibody R597 (product name: Herceptin).

Cardio/Cerebro-vascular diseases

- In October, we started Phase I clinical trials for NA808 in Japan (expected indication: chronic hepatitis C).

At present, we are awaiting the approval of applications (new molecular entities or additions of indications) filed for 2 development themes, including R340 (expected indication: colorectal cancer).

Also, as for clinical development activities overseas, the Company saw progress as described below.

- In October, we started Phase I clinical trials for GC33 (expected indication: liver cancer).

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Name of listed company: Chugai Pharmaceutical Co., Ltd.  
Code number: 4519 (1<sup>st</sup> Section of Tokyo Stock Exchange)  
Head office: 1-1, Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo  
President & CEO: Osamu Nagayama  
Inquiries to: Mamoru Togashi, General Manager,  
Corporate Communications Dept.  
Tel: +81-(0)3-3273-0881

**Correction of Consolidated Company Performance  
(for the third quarter of fiscal year 2008.12 ended September 30, 2008)**

Chugai Pharmaceutical Co., Ltd. (Head office: Chuo-ku, Tokyo / President & CEO: Osamu Nagayama) announced corrections of the third quarter Consolidated Financial Statements (for the third quarter of fiscal year 2008.12 ended September 30, 2008) as described below. Correction is shown underlined.

Correction: Page 3, Qualitative Information

(Before correction)

***1. Qualitative Information Regarding Operating Results Financial Condition (Consolidated)***

"... excluding these special factors, revenues were ¥17.8 billion higher compared to the same period last year."

(After correction)

***1. Qualitative Information Regarding Operating Results Financial Condition (Consolidated)***

"... excluding these special factors, revenues were ¥18.1 billion higher compared to the same period last year."

Name of listed company: Chugai Pharmaceutical Co., Ltd.  
Code number: 4519 (1<sup>st</sup> Section of Tokyo Stock Exchange)  
Head office: 1-1, Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo  
President & CEO: Osamu Nagayama  
Inquiries to: Mamoru Togashi, General Manager,  
Corporate Communications Dept.  
Tel: +81-(0)3-3273-0881

## F. Hoffmann-La Roche Announces Third Quarter Sales 2008

F. Hoffmann-La Roche Ltd. (hereafter "Roche") [Head Office: Basel, Switzerland. CEO: Severin Schwan] announced today, its third quarter sales 2008(January 1 – September 30, 2008). Roche owns 59.9% of Chugai's outstanding shares (61.5% of voting rights) as of end of September 2008. Its press release and presentation materials can be found on its Website (<http://www.roche.com>).

Media Release

Presentation[PDF]

Chugai's sales for the period of January 1 to September 30, 2008 are included in the announced Roche Group's sales. These results are based on Roche's accounting policies which conform to International Financial Reporting Standards, which differ from generally accepted accounting standards in Japan.

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Basel, 21 October 2008

## Roche posts sustained double-digit sales growth for the first nine months of 2008 Full-year outlook confirmed

### Roche Group

- Group sales up 10% in local currencies to 33.2 billion Swiss francs, excluding Tamiflu pandemic sales
- Including Tamiflu pandemic sales, Group sales total 33.3 billion francs, an increase of 6% in local currencies and 13% in US dollars, and a decline of 2% in Swiss francs
- Roche confirms full-year outlook
- Roche reaffirms commitment to Genentech offer

### Pharmaceuticals Division

- Sales advance 10% in local currencies\* — twice the global market growth rate
- Growth driven by key products in oncology, autoimmune, virology, metabolism/bone and transplantation portfolios
- Promising launch of Actemra for rheumatoid arthritis in Japan, Roche continuing to work with FDA following receipt of complete response letter in September

### Diagnostics Division

- Divisional sales again outpace the market, increasing 11% in local currencies
- Professional Diagnostics and Applied Science continue to drive growth
- Diabetes Care posts solid growth in Latin America, Asia-Pacific and Japan, more than offsetting lower US sales
- Ventana continues to exceed expectations as integration nears successful completion

Unless otherwise stated, all growth rates are in local currencies

\* Excluding Tamiflu pandemic sales

Commenting on the Group's sales performance in the first nine months of 2008, Roche CEO Severin Schwan said: 'The Roche Group maintained its strong growth in the third quarter. Sales by both the Pharmaceuticals and Diagnostics divisions<sup>1</sup> advanced at double-digit rates in local currencies, clearly outgrowing their respective markets. Based on this performance, we again expect a good full-year result and confirm our outlook for 2008. We are also pleased that the newly acquired Ventana business continues to exceed expectations and that the integration process is well advanced.'

## Roche Group

### Excluding Tamiflu pandemic sales

Sales from January to September	2008	2007	% Change		
	mCHF	mCHF	in CHF	in local currencies	in US dollars
Pharmaceuticals Division	26,062	25,726	+1	+10	+17
Roche Pharmaceuticals	16,294	15,668	+4	+10	+20
Genentech	7,536	7,850	-4	+11	+11
Chugai	2,232	2,208	+1	+3	+16
Diagnostics Division	7,112	6,823	+4	+11	+20
Roche Group	33,174	32,549	+2	+10	+17

### Including Tamiflu pandemic sales

Sales from January to September	2008	2007	% Change		
	mCHF	mCHF	in CHF	in local currencies	in US dollars
Pharmaceuticals Division	26,193	27,124	-3	+4	+11
Roche Pharmaceuticals	16,423	16,792	-2	+3	+13
Genentech	7,536	7,850	-4	+11	+11
Chugai	2,234	2,482	-10	-8	+4
Diagnostics Division	7,112	6,823	+4	+11	+20
Roche Group	33,305	33,947	-2	+6	+13

See attachment to this release for details of quarterly sales growth

Sales by the Roche Group in the first nine months of 2008 increased by 6% in local currencies (-2% in Swiss francs; 13% in US dollars)<sup>2</sup> to 33.3 billion Swiss francs. Excluding Tamiflu pandemic sales to governments

<sup>1</sup> Excluding Tamiflu pandemic sales

<sup>2</sup> Unless otherwise stated, all growth rates are in local currencies

and corporations, sales rose 10% (2% in Swiss francs; 17% in US dollars). The rise in the Swiss franc against most currencies, particularly against the US dollar, resulted in Swiss franc growth being eight percentage points lower than growth in local currencies.

#### **2008 full-year outlook confirmed**

Barring unforeseen events, based on the sustained strong sales growth over the first nine months, Roche confirms its targets for full-year 2008. Excluding Tamiflu pandemic sales to governments and corporations, Roche anticipates a high single-digit increase in Group sales, with above-market sales growth in both divisions. Despite considerably lower Tamiflu pandemic sales and significantly higher R&D spending, Roche is aiming for 2008 Core EPS at constant exchange rates to remain at least in line with the record level achieved in 2007.

## **Pharmaceuticals Division**

### **Strong underlying sales growth maintained**

Despite the predicted sharp decline in Tamiflu pandemic sales versus the same period last year, Pharmaceuticals Division sales increased 4% in local currencies (-3% in Swiss francs; 11% in US dollars) to 26.2 billion Swiss francs. Excluding pandemic sales of Tamiflu, sales by the Pharmaceuticals Division grew 10% in local currencies — or twice the global market growth rate — driven primarily by the division's oncology, autoimmune disease, virology, metabolism/bone and transplant portfolios. Excluding pandemic Tamiflu, the division's growth rate in the third quarter was 10%. On the same basis, nine-month sales advanced 11% in North America (compared with 1% market growth)<sup>3</sup>, 9% in Western Europe (vs 5% market growth), 11% in the CEMAI<sup>4</sup> countries (vs 11% market growth) and 3% in Japan (vs 3% market growth).

### **Oncology – all key products post solid double-digit growth**

Oncology continues to be a key driver of growth for Roche. Combined sales of the division's oncology medicines advanced 15% to over 14 billion Swiss francs in the first nine months, with key products Avastin, MabThera/Rituxan, Herceptin, Tarceva and Xeloda recording sustained double-digit growth in all three quarters.

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<sup>3</sup> Market growth here and elsewhere according to IMS (to end of June 2008)

<sup>4</sup> Central and Eastern Europe, Middle East, Africa, Central Asia, Indian Subcontinent

In the first nine months of 2008 overall sales (oncology and autoimmune diseases) of MabThera/Rituxan (rituximab), the leading treatment for patients with non-Hodgkin's lymphoma, grew 16% versus the prior-year period to 4.3 billion Swiss francs, with third-quarter sales advancing 15%. Sales of the product for cancer indications increased strongly. Growth in oncology is being driven by increasing use of MabThera/Rituxan for maintenance therapy of relapsed follicular lymphoma, increased adoption of optimal dosing regimens, and improved access in key emerging markets for all approved indications. In July Roche filed an application with the EU authorities for approval of MabThera as a first-line treatment of chronic lymphocytic leukemia (CLL), the most common form of adult leukemia. The filing was based on results from a major phase III trial (CLL8), which showed that combined treatment with MabThera and the current standard chemotherapy achieved significantly better outcomes than chemotherapy alone. In October Roche announced that a separate clinical trial of MabThera/Rituxan in patients with relapsed or refractory CLL (REACH) has met its primary end-point; patients treated with MabThera combined with the current standard chemotherapy showed a significant improvement in progression-free survival compared with patients who received chemotherapy alone. Full results of the study will be submitted for presentation at an upcoming medical meeting.

Sales of Herceptin (trastuzumab), for early and advanced HER2-positive breast cancer, increased 12% to 3.8 billion francs in the first nine months, with double-digit growth continuing in the third quarter (+14%). Growth is particularly strong in Japan due to continuing uptake of Herceptin for early breast cancer, an indication approved last February. Solid sales growth was also seen in Europe/Rest of World (RoW)<sup>5</sup>, with strong gains recorded in key emerging markets.

Worldwide sales of Avastin (bevacizumab), for advanced colorectal, lung, breast and kidney cancer, grew 37% to 3.7 billion francs overall (+37% in the third quarter). The main growth is coming from Western Europe, driven primarily by increased use of the product for metastatic colorectal and breast cancer. Sales in Europe are also benefitting from the rollout of new indications and increasing uptake for non-small cell lung cancer and renal cell carcinoma. Genentech's rollout of the metastatic breast cancer indication in the US has further strengthened the product's position in that market. Sales in Japan continue to progress well. In September Genentech filed a supplementary application with the US Food and Drug Administration (FDA) for approval of Avastin in combination with interferon alfa to treat advanced renal cell carcinoma.

Data presented at the Congress of the European Society for Medical Oncology (ESMO) in September

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<sup>5</sup> Roche defines Europe/Rest of World as covering Europe and all other countries except Japan and the United States

confirmed that Avastin in combination with chemotherapy is the only biologic that provides a statistically significant overall survival benefit to patients receiving first-line or second-line treatment for metastatic colorectal cancer. In addition, Avastin remains the only biologic offering a progression-free survival benefit in metastatic colorectal cancer, regardless of mutations in the K-Ras gene, and also the only biologic with a statistically significant overall survival benefit in K-Ras wild-type patients.

In October Roche announced topline results from a phase III study (BeTa Lung) investigating the addition of Avastin to Tarceva for the second-line treatment of patients with advanced non-small cell lung cancer. The data showed that, while the primary overall survival endpoint for the combination was not met, there was clear evidence of clinical activity, with improvements in the secondary endpoints of progression-free survival and response rate when Avastin was added to Tarceva. Further analyses, including post-progression therapy, are being conducted to explore the potential impact on the overall survival endpoint. No new safety signals for Avastin or Tarceva were reported, and the results do not affect the approved indications for Avastin and Tarceva. At the beginning of October the EU authorities approved a pediatric investigation plan for Avastin. The studies included in the plan will eventually provide physicians with new data on dosing and safety that can improve clinical outcomes specifically for children.

Sales of Tarceva (erlotinib), the only epidermal growth factor receptor (EGFR) inhibitor with proven survival benefits in the treatment of patients with advanced non-small cell lung cancer and pancreatic cancer, increased 24% to 885 million francs. Growth is being driven primarily by Western Europe, particularly France, Germany and Spain, and uptake is also strong in Japan and China. Increased volume and market penetration resulted in steady growth in the US. Expanding uptake in all regions reflects doctors' growing experience with the product.

Worldwide sales of Xeloda (capecitabine), an oral chemotherapy medicine for gastrointestinal and breast cancer, were up 14% to 880 million francs. Growth in Japan remained particularly strong for the third successive quarter, with solid gains also recorded in Europe/RoW and the United States. Xeloda is generating consistent double-digit sales growth in China following its approval there earlier this year for advanced stomach cancer.

#### **Anemia – NeoRecormon holding up well in a highly competitive market**

Combined sales of Roche's NeoRecormon and Chugai's Epogin (epoetin beta), for anemia, declined 14% to 1.3 billion Swiss francs, reflecting the highly competitive market environment. In Europe, despite the market

entry of several biosimilar versions of epoetin alfa in the past 12 months, the market share of NeoRecormon has dropped only slightly, with sales down 12% in the first nine months. In Japan, where Epogin remains the market leader, sales declined 19% due primarily to sustained pricing pressure.

Mircera (methoxy polyethylene glycol-epoetin beta), for the treatment of symptomatic anemia associated with chronic kidney disease, is now approved in 66 countries worldwide and has been launched in 28 so far, including several major EU markets. Physician feedback from the early launch markets is positive, and sales are progressing as Roche wins more contracts.

#### **Transplantation – CellCept continues to record double-digit growth**

CellCept (mycophenolate mofetil), the world's most widely used immunosuppressant medication, recorded worldwide sales of 1.5 billion Swiss francs in the nine months to 30 September, an increase of 14% over the year-earlier period.

#### **Virology – Pegasys continues to expand market share in major markets**

Sales of Pegasys (peginterferon alfa-2a), the world's leading pegylated interferon, for the treatment of hepatitis B and C, totalled 1.2 billion francs in the first nine months of 2008, a rise of 6% over the same period last year. Sales were driven by strong growth in Japan (+62%) and key emerging markets. Pegasys continues to expand its market share in all mature markets, including the US and major EU countries.

Global sales of Tamiflu (oseltamivir), for the treatment and prevention of influenza, declined 69% to 428 million Swiss francs in the first nine months of 2008. The decline is due to the expected sharp fall-off in pandemic stockpiling sales of the product (down 1.3 billion francs for the period versus 2007), which substantially outweighed the increase in seasonal sales recorded earlier in the year. No significant additional pandemic orders were received in the first nine months. The US, Canadian, South Korean and Hong Kong authorities have extended the shelf life of government stockpiles of Tamiflu to seven years, and data have been filed to support similar extensions in other countries.

Combined sales of Valcyte (valgancyclovir) and Cymevene (ganciclovir), the standard of care for the treatment of cytomegalovirus disease in transplant patients and people with HIV/AIDS, maintained their robust growth into the third quarter and advanced 11% to 404 million Swiss francs overall in the first nine months of 2008. In July the FDA granted pediatric exclusivity for Valcyte in the United States until September 2015.

#### **Autoimmune diseases – MabThera/Rituxan continues to gain ground in rheumatoid arthritis**

Worldwide uptake of MabThera/Rituxan (rituximab) for the treatment of rheumatoid arthritis (RA) was strong throughout the first nine months of 2008. MabThera/Rituxan, the first and only selective B cell therapy approved for RA, is now established as a proven choice for patients with inadequate response to tumour necrosis factor (TNF) inhibitor therapy. Observational data showing the superiority of MabThera/Rituxan over sequential use of TNF inhibitors and the product's increasingly positive long-term efficacy and safety profile are convincing more and more rheumatologists to switch patients to MabThera/Rituxan following inadequate response to their first TNF inhibitor.

Actemra (tocilizumab) represents a new approach to the treatment of rheumatoid arthritis. Following the medicine's approval in Japan for RA and related pediatric indications earlier this year, uptake has been very encouraging. In September, in a complete response letter to Roche's US marketing application for Actemra, the Food and Drug Administration (FDA) requested additional documentation related to the product's manufacturing and certain other components such as final labelling. The FDA has not requested any additional clinical studies. Roche is continuing to work with the FDA to promptly address the agency's requests.

#### **Metabolic Diseases – Bonviva/Boniva posts strong sales growth**

Global sales of Bonviva/Boniva (ibandronic acid), for the treatment of postmenopausal osteoporosis, grew 41% to 775 million Swiss francs in the first nine months of 2008. Market-share gains are supporting robust growth in Europe/RoW and the United States despite the entry of generic versions of competitor products in the US and Europe.

#### **Development – major projects on track**

As of 30 September 2008, the Pharmaceuticals Division's R&D pipeline (phase I to III/registration) included 65 new molecular entities (NMEs) and 54 additional indications (AIs). During the third quarter four projects entered phase I and another entered phase III development. One phase II project was discontinued; no phase III projects were discontinued. Since the beginning of 2008 the division has initiated ten major phase III clinical programmes.

Pertuzumab, a HER dimerisation inhibitor, is being developed by Roche and Genentech as a potential treatment for breast cancer. Recruitment of patients for a phase III study of pertuzumab combined with Herceptin and docetaxel in HER2-positive metastatic breast cancer (CLEOPATRA) is proceeding according

to plan. Patients are also being enrolled in a phase II study of neoadjuvant (presurgical) treatment with pertuzumab plus Herceptin in early HER2-positive breast cancer (NEOSPHERE).

Ocrelizumab is a humanised anti-CD20 monoclonal antibody being developed by Roche, Genentech and Chugai for the treatment of autoimmune diseases. An extensive phase III programme involving 3000 patients with rheumatoid arthritis is ongoing, while recruitment for a phase III trial in lupus nephritis is continuing as planned. In addition, a phase IIb trial of the drug in relapsing-remitting multiple sclerosis started in July 2008 and is currently enrolling patients.

Recruitment of patients for a phase III clinical trial of the cholesteryl ester transfer protein (CETP) inhibitor dalcetrapib (R1658, JTT-705) is proceeding according to plan. Dalcetrapib increases levels of high-density lipoprotein cholesterol (HDL, or 'good' cholesterol), thereby potentially reducing the risk of cardiovascular disease and death in high-risk patients.

Phase III testing of taspoglutide (R1583, BIM 51077), a long-acting glucagon-like peptide-1 (GLP-1) analogue being developed for the treatment of type 2 diabetes, commenced in July.

Development of R1626, a polymerase inhibitor being investigated as a treatment for infection with hepatitis C virus (HCV), was terminated in the third quarter due to new and unexpected safety findings from a phase IIb study. Roche's pipeline of direct antiviral agents for HCV remains robust, with another polymerase inhibitor, R7128 (collaboration with Pharmasset), and a protease inhibitor, R7227 (collaboration with InterMune) in clinical development. Both agents are being investigated in combination with Pegasys and Copegus (ribavirin).

## **Diagnostics Division**

### **Professional Diagnostics and Applied Science continue to drive sales growth**

In the first nine months of 2008 Roche's Diagnostics Division recorded sales of 7.1 billion Swiss francs, an increase of 11% in local currencies (4% in Swiss francs, 20% in US dollars). Divisional sales again grew ahead of or in line with the market in all regions, making especially strong gains in Latin America, Asia-Pacific and Japan. All five business areas increased their sales for the period, with the biggest contributions to growth again coming from the Professional Diagnostics and Applied Science units. Ventana, the tissue diagnostics business acquired in February, posted sales of 261 million Swiss francs in the eight months to 30 September 2008, accounting for 4% of the division's nine-month revenues.

### **Professional Diagnostics — further market share gains for immunodiagnostics**

Roche Professional Diagnostics' nine-month sales rose 9% to 3,270 million Swiss francs. Sales of serum work area (clinical chemistry and immunochemistry) systems grew 10% for the period, well above the estimated market growth rate (4%).<sup>6</sup> Immunochemistry gained further market share on sales growth of 19%. New placements of cobas 6000 instruments helped drive this growth, as did strong uptake of the anti-HCV assay (diagnosis of hepatitis C) launched for all cobas and Elecsys systems in the first half of 2008. Clinical chemistry sales grew 2% amid continuing price erosion in this more established market.

The US Food and Drug Administration (FDA) approved three new immunoassays for the cobas, Elecsys and Modular Analytics platforms, including a fully automated anti-TSH receptor assay (diagnosis of Grave's disease) and an assay for anti-CCP antibodies (highly specific test for the diagnosis of rheumatoid arthritis), both launched in ex-US markets earlier this year. An assay for Toxo IgG (determination of toxoplasmosis status) was also approved. The launch (ex US) in July of the cobas c 311 — a stand-alone clinical chemistry analyser — rounds out Roche's offerings for the low-volume testing segment.

Hematology sales were up strongly in the EMEA region (Europe, Middle East and Africa), Asia-Pacific and Latin America. Growth was driven mainly by placements of the Sysmex XS 1000i, one of a new line of compact, fully automated analysers.

Point-of-care cardiac assays posted solid double-digit sales growth, fuelled by increased uptake of the Roche Cardiac proBNP assay and the cobas h 232 portable cardiac testing device. Placements of Accu-Chek Inform

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<sup>6</sup> Diagnostics market growth according to company estimates and various industry reports

II, the first wireless-enabled hospital blood glucose meter, were also a growth driver. Coagulation monitoring sales again showed strong double-digit growth, driven mainly by the CoaguChek XS monitor for professional use and patient self-testing.

#### **Diabetes Care — strong growth of new product sales continues**

Roche Diabetes Care's sales rose 2% to 2,207 million Swiss francs in the first nine months of 2008. Solid mid-single-digit growth in Japan and double-digit gains in Asia-Pacific, Latin America and the agency business more than offset lower nine-month US sales. Following a strong second quarter, US sales fell in the third quarter as a result of a significant decrease in sales of older monitoring products, strong competition in insulin delivery systems and price declines.

Sales of the Accu-Chek Aviva, now Roche Diabetes Care's top-selling blood glucose monitoring system, showed strong double-digit growth for the period. The rollout of the Accu-Chek Performa system also continues to drive growth, particularly in emerging markets. Uptake of the new Accu-Chek Compact Plus meter has been very strong, helping to revitalise Accu-Chek Compact strip sales, which grew at a combined double-digit rate in those countries where the device was launched in the fourth quarter of 2007. The global rollout of the Accu-Chek Compact Plus will be completed in November.

#### **Molecular Diagnostics — growth in core business continues, preparing for new markets**

Roche Molecular Diagnostics' nine-month sales advanced 4% to 828 million Swiss francs. Virology sales grew 4%, driven by continued placements of automated platforms for HIV and hepatitis B and C (HBV, HCV) testing in Asia-Pacific, EMEA and the US. Blood screening sales declined 2% for the period, with new contracts offset by pricing pressures and the ongoing effect of accounts lost in 2007.

In September the FDA approved the Cobas TaqMan HBV Test. This is the first quantitative test for hepatitis B DNA to be approved in the US, offering a significantly wider dynamic range than any other HBV monitoring test currently on the US market. The hepatitis C viral load test for the automated Cobas AmpliPrep/Cobas TaqMan platform is currently under FDA review. These tests, which complement the automated HIV-1 viral load test launched in 2007, are expected to play an important role in meeting US needs for automated hepatitis testing. Roche's automated viral load tests are also available in ex-US markets.

The cobas TaqScreen MPX Test, a multiplex blood screening assay for simultaneous detection of HIV-1 (groups M&O), HIV-2, HCV and HBV, is in the final stages of FDA review. The test will run in the US on the

fully automated cobas s 201 system. Since September the Japanese Red Cross has been using the MPX Test on the fully integrated cobas s 401 system to screen 100% of the Japanese blood supply.

Most European markets have completed the transition to the Cobas TaqMan CT Test v2.0, which received CE Mark certification in June. This dual target test, now launched in Europe, Asia-Pacific and Latin America, enables reliable screening of all known strains of *Chlamydia trachomatis*, the cause of the most commonly reported bacterial sexually transmitted disease.

Recruitment continues for the study initiated earlier this year to support US filings for Roche's HPV (human papillomavirus) detection and genotyping tests. These tests are designed to support improved cervical cancer screening.

#### **Applied Science — further strong growth in genomics**

Roche Applied Science posted nine-month sales of 546 million Swiss francs. This was an increase of 19% for the period, or roughly three times the estimated market growth rate. Sales of sequencing products, led once again by the ultra-fast Genome Sequencer FLX, nearly doubled despite increased pressure from competitors. Products for real-time quantitative PCR (qPCR) analysis, particularly the LightCycler 480 instruments, delivered strong double-digit growth. Roche NimbleGen microarrays also contributed to sales.

In late September RAS launched its GS FLX Titanium series of next-generation sequencing products (including new reagents and software). Compared with standard FLX sequencing, Titanium increases throughput by a factor of five. Roche NimbleGen's SeqCap arrays are now available worldwide. Other major launches included MagNa Pure 2.0, a redesigned and improved instrument for automated qPCR sample preparation, and the first of a new family of pre-plated, ready-to-use qPCR assays called RealTime *ready*.

#### **Tissue Diagnostics — strong double-digit growth continues**

Ventana, the US-based leader in tissue diagnostics acquired in February, continues to perform even more strongly than expected during the post-merger integration phase. Commercial operations outside North America have now largely been integrated into Roche, and efforts are well under way to expand the business into new markets in Europe and Latin America.

Roche's consolidated nine-month results include Ventana sales totalling 261 million Swiss francs, representing sales from the date of acquisition to 30 September 2008. These additional sales contributed four

percentage points to the Diagnostics Division's local-currency sales growth. On a stand-alone basis, Ventana's sales for the entire nine-month period reached 270 million US dollars, an increase of 24% in local currencies (27% in US dollars) over the same period in 2007. This was well above market growth.

Advanced staining (immunohistochemistry and *in situ* hybridisation) remained the biggest growth driver, delivering robust reagent sales and an even stronger than expected rise in instrument sales. BenchMark Ultra, enabling continuous and random access for expedited diagnosis, was launched in the US in early September. It is expected to have a significant positive impact on sales and market share for Ventana's core advanced staining business. US placements of the Symphony primary (hematoxylin and eosin) staining instrument accelerated in the third quarter, helped by the July launch of enhancements further improving system reliability and staining interpretation. The Vantage workflow solution, launched in the US in May 2008, also contributed to sales growth. Vantage is the first complete workflow information management system for the anatomical pathology laboratory, providing tracking capabilities that streamline and integrate lab work and information flows for greater productivity and patient safety.

#### About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at [www.roche.com](http://www.roche.com).

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#### Additional information

- Media release including a full set of tables: [www.roche.com/med-cor-2008-10-21](http://www.roche.com/med-cor-2008-10-21)
- Roche Pharma pipeline: [www.roche.com/pipeline.htm](http://www.roche.com/pipeline.htm)
- Roche Diagnostics pipeline: [www.roche.com/diagnostics\\_portfolio](http://www.roche.com/diagnostics_portfolio)
- Roche Finance Info System: [rofis.roche.com/dynasight/rofis.html](http://rofis.roche.com/dynasight/rofis.html)

#### Next events

- Full-year results 2008: 4 February 2009 (tentative date)

#### Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)

- Daniel Piller (Head)
- Alexander Klausner
- Martina Rupp
- Claudia Schmitt
- Elina Ämmälä

#### Disclaimer: Cautionary statement regarding forward-looking statements

This document contains certain forward-looking statements. These forward-looking statements may be identified by words such as 'believes', 'expects', 'anticipates', 'projects', 'intends', 'should', 'seeks', 'estimates', 'future' or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this document, among others: (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; (8) loss of or inability to obtain adequate protection for intellectual property rights; (9) litigation; (10) loss of key executives or other employees; and (11) adverse publicity and news coverage. The statement regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche's earnings or earnings per share for any current or future period will necessarily match or exceed the historical published earnings or earnings per share of Roche.

1. Sales January to September 2008 and 2007

January – September	2008	2007	% change	
	CHF m	CHF m	In CHF	In local currencies
Pharmaceuticals Division	26,193	27,124	-3	+4
Roche Pharmaceuticals	16,423	16,792	-2	+3
Genentech	7,536	7,850	-4	+11
Chugai	2,234	2,482	-10	-8
Diagnosics Division	7,112	6,823	+4	+11
Roche Group	33,305	33,947	-2	+6

2. Sales January to September 2008 and 2007 excluding Pandemic Tamiflu\*

January – September	2008	2007	% change	
	CHF m	CHF m	In CHF	In local currencies
Pharmaceuticals Division	26,062	25,726	+1	+10
Roche Pharmaceuticals	16,294	15,668	+4	+10
Genentech	7,536	7,850	-4	+11
Chugai	2,232	2,208	+1	+3
Diagnosics Division	7,112	6,823	+4	+11
Roche Group	33,174	32,549	+2	+10

\* excluding government & corporate pandemic Tamiflu sales; including seasonal Tamiflu sales

3. Quarterly local sales growth by Division in 2007 and 2008

	Q4 2007 vs. Q4 2006	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007
<b>Pharmaceuticals Division</b>	+5	+1	+5	+8
Roche Pharmaceuticals	+7	+1	+3	+6
Genentech	+6	+9	+9	+14
Chugai	-8	-23	+2	-1
<b>Diagnostics Division</b>	+8	+9	+13	+11
<b>Roche Group</b>	+6	+2	+7	+9

4. Quarterly local sales growth by Division in 2007 and 2008 excluding Pandemic Tamiflu\*

	Q4 2007 vs. Q4 2006	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007
<b>Pharmaceuticals Division</b>	+11	+9	+10	+10
Roche Pharmaceuticals	+14	+11	+11	+8
Genentech	+6	+9	+9	+14
Chugai	+4	-2	+2	+10
<b>Diagnostics Division</b>	+8	+9	+13	+11
<b>Roche Group</b>	+10	+9	+10	+10

\* excluding government & corporate pandemic Tamiflu sales; including seasonal Tamiflu sales

5. Quarterly sales by Division in 2007 and 2008

CHF millions	Q3 2007	Q4 2007	Q1 2008	Q2 2008	Q3 2008
<b>Pharmaceuticals Division</b>	8,856	9,659	8,568	8,689	8,936
Roche Pharmaceuticals	5,425	6,178	5,498	5,440	5,485
Genentech	2,623	2,564	2,399	2,468	2,669
Chugai	808	917	671	781	782
<b>Diagnostics Division</b>	2,264	2,527	2,287	2,460	2,365
<b>Roche Group</b>	11,120	12,186	10,855	11,149	11,301

6. Quarterly sales by Division in 2007 and 2008 excluding Pandemic Tamiflu\*

CHF millions	Q3 2007	Q4 2007	Q1 2008	Q2 2008	Q3 2008
<b>Pharmaceuticals Division</b>	8,664	9,201	8,523	8,639	8,900
Roche Pharmaceuticals	5,314	5,736	5,455	5,390	5,449
Genentech	2,623	2,564	2,399	2,468	2,669
Chugai	727	901	669	781	782
<b>Diagnostics Division</b>	2,264	2,527	2,287	2,460	2,365
<b>Roche Group</b>	10,928	11,728	10,810	11,099	11,265

\* excluding government & corporate pandemic Tamiflu sales; including seasonal Tamiflu sales

7. Top 20 Pharmaceuticals Division product sales<sup>1</sup> and local growth<sup>2</sup> in YTD September 2008: US, Japan and Europe/Rest of World

	Total		US		Japan		Europe/RoW	
	CHF m	%	CHF m	%	CHF m	%	CHF m	%
MabThera/Rituxan	4,339	16%	2,113	14%	146	11%	2,080	20%
Herceptin	3,769	12%	1,106	9%	162	38%	2,501	13%
Avastin	3,702	37%	2,067	15%	128	878%	1,507	74%
CellCept	1,523	14%	705	16%	28	16%	790	11%
NeoRecormon/Epogin	1,319	-14%	-	-	328	-19%	991	-12%
Pegasys	1,190	6%	275	11%	67	62%	848	2%
Tarceva	885	24%	359	12%	31	-	495	28%
Xeloda	880	14%	297	9%	33	71%	550	14%
Bonviva/Boniva	775	41%	467	33%	-	-	308	59%
Lucentis	686	4%	686	4%	-	-	-	-
Tamiflu	428	-69%	360	-27%	17	-95%	51	-92%
Valcyte/Cymevene	404	11%	182	8%	-	-	222	14%
Xolair	404	9%	404	9%	-	-	-	-
Xenical	390	-14%	35	-39%	-	-	355	-10%
Pulmozyme	357	11%	195	12%	-	-	162	8%
Nutropin	301	-3%	292	-3%	-	-	9	-8%
Neutrogen	290	1%	-	-	290	1%	-	-
Rocephin	252	-11%	4	-73%	42	2%	206	-9%
Activase/TNKase	245	-5%	212	-7%	-	-	33	9%
Madopar	231	4%	-	-	14	5%	217	4%

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

<sup>2</sup> versus YTD September 2007

8. Top 20 Pharmaceuticals Division quarterly local product sales growth<sup>1</sup> in 2007 and 2008

	Q4 2007 vs. Q4 2006	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007
MabThera/Rituxan	12%	17%	16%	15%
Herceptin	14%	11%	12%	14%
Avastin	41%	35%	38%	37%
CellCept	16%	11%	16%	14%
NeoRecormon/Epogin	-15%	-13%	-14%	-15%
Pegasys	14%	-3%	10%	12%
Tarceva	24%	28%	27%	18%
Xeloda	22%	13%	14%	14%
Bonviva/Boniva	63%	56%	47%	26%
Lucentis	-9%	-5%	2%	15%
Tamiflu	-46%	-64%	-86%	-56%
Valcyte/Cymevene	7%	9%	10%	13%
Xolair	2%	6%	7%	12%
Xenical	-17%	-11%	-21%	-9%
Pulmozyme	13%	15%	11%	6%
Nutropin	-8%	-5%	-5%	1%
Neutrogen	14%	1%	1%	0%
Rocephin	-4%	-4%	-13%	-16%
Activase/TNKase	-2%	-3%	-11%	-2%
Madopar	14%	0%	9%	4%

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

9. Pharmaceuticals Division quarterly local product sales growth<sup>1</sup> US in 2007 and 2008

	Q4 2007 vs. Q4 2006	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007
MabThera/Rituxan	4%	14%	13%	14%
Herceptin	1%	9%	3%	15%
Avastin	23%	13%	15%	18%
CellCept	17%	14%	15%	20%
NeoRecormon/Epogin	-	-	-	-
Pegasys	-3%	-10%	5%	45%
Tarceva	5%	10%	17%	9%
Xeloda	19%	16%	5%	9%
Bonviva/Boniva	40%	47%	39%	16%
Lucentis	-9%	-5%	2%	15%
Tamiflu	52%	83%	-87%	6%
Valcyte/Cymevene	3%	11%	5%	7%
Xolair	2%	6%	7%	12%
Xenical	-46%	-35%	-46%	-33%
Pulmozyme	10%	10%	14%	13%
Nutropin	-8%	-6%	-4%	1%
Neutrogin	-	-	-	-
Rocephin	-32%	-34%	-85%	-
Activase/TNKase	0%	-6%	-12%	-2%
Madopar	-	-	-	-

<sup>1</sup> Roche Pharmaceuticals and Genentech combined

10. Pharmaceuticals Division quarterly local product sales growth Japan<sup>1</sup> in 2007 and 2008

	Q4 2007 vs. Q4 2006	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007
MabThera/Rituxan	2%	13%	11%	8%
Herceptin	0%	16%	29%	69%
Avastin	-	-	1567%	442%
CellCept	18%	13%	21%	15%
NeoRecormon/Epogin	-22%	-16%	-29%	-9%
Pegasys	53%	98%	53%	49%
Tarceva	-	-	-	-
Xeloda	14%	48%	73%	88%
Bonviva/Boniva	-	-	-	-
Lucentis	-	-	-	-
Tamiflu	-58%	-93%	-78%	-98%
Valcyte/Cymevene	-	-	-	-
Xolair	-	-	-	-
Xenical	-	-	-	-
Pulmozyme	-	-	-	-
Nutropin	-	-	-	-
Neutrogen	14%	1%	1%	0%
Rocephin	-1%	9%	-2%	-1%
Activase/TNKase	-	-	-	-
Madopar	3%	5%	5%	6%

<sup>1</sup> Chugai

11. Pharmaceuticals Division quarterly local product sales growth Europe/Rest of World<sup>1</sup> in 2007 and 2008

	Q4 2007 vs. Q4 2006	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007
MabThera/Rituxan	25%	21%	21%	17%
Herceptin	23%	12%	15%	11%
Avastin	80%	78%	78%	67%
CellCept	14%	8%	16%	9%
NeoRecormon/Epogin	-11%	-13%	-7%	-17%
Pegasys	20%	-4%	9%	1%
Tarceva	47%	40%	28%	17%
Xeloda	25%	11%	18%	14%
Bonviva/Boniva	160%	77%	61%	45%
Lucentis	-	-	-	-
Tamiflu	-92%	-94%	-83%	-93%
Valcyte/Cymevene	11%	8%	16%	19%
Xolair	-	-	-	-
Xenical	-11%	-7%	-17%	-6%
Pulmozyme	17%	22%	8%	-3%
Nutropin	-10%	-1%	-12%	-10%
Neutrogin	-	-	-	-
Rocephin	-3%	-3%	-9%	-13%
Activase/TNKase	-16%	30%	1%	1%
Madopar	15%	0%	9%	4%

<sup>1</sup> Roche Pharmaceuticals

12. Top 20 Pharmaceuticals Division quarterly product sales<sup>1</sup> in 2007 and 2008

CHF millions	Q3 2007	Q4 2007	Q1 2008	Q2 2008	Q3 2008
MabThera/Rituxan	1,380	1,432	1,407	1,460	1,472
Herceptin	1,209	1,261	1,225	1,249	1,295
Avastin	1,062	1,135	1,131	1,220	1,351
CellCept	485	548	487	523	513
NeoRecormon/Epogin	518	510	442	450	427
Pegasys	383	447	369	416	405
Tarceva	271	288	286	301	298
Xeloda	290	312	281	292	307
Bonviva/Boniva	230	283	241	266	268
Lucentis	239	228	215	225	246
Tamiflu	257	512	278	49	101
Valcyte/Cymevene	137	144	125	136	143
Xolair	145	138	125	134	145
Xenical	151	142	136	128	126
Pulmozyme	124	128	117	120	120
Nutropin	118	113	97	98	106
Neutrogen	100	110	95	97	98
Rocephin	95	100	91	85	76
Activase/TNKase	92	88	83	81	81
Madopar	76	83	74	80	77

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

13. Pharmaceuticals Division quarterly product sales<sup>1</sup> in US in 2007 and 2008

CHF millions	Q3 2007	Q4 2007	Q1 2008	Q2 2008	Q3 2008
MabThera/Rituxan	718	709	675	706	732
Herceptin	384	375	363	349	394
Avastin	718	693	642	671	754
CellCept	232	290	215	243	247
NeoRecormon/Epogin	-	-	-	-	-
Pegasys	75	111	81	95	99
Tarceva	121	129	119	123	117
Xeloda	114	123	89	97	111
Boniva/Boniva	150	190	153	159	155
Lucentis	239	228	215	225	246
Tamiflu	98	398	234	30	96
Valcyte/Cymevene	69	73	54	62	66
Xolair	145	138	125	134	145
Xenical	17	13	14	12	9
Pulmozyme	68	67	61	65	69
Nutropin	115	108	94	94	104
Neutrogen	-	-	-	-	-
Rocephin	5	1	3	1	0
Activase/TNKase	80	76	71	71	70
Madopar	-	-	-	-	-

<sup>1</sup> Roche Pharmaceuticals and Genentech combined

14. Pharmaceuticals Division quarterly product sales<sup>1</sup> in Japan in 2007 and 2008

CHF millions	Q3 2007	Q4 2007	Q1 2008	Q2 2008	Q3 2008
MabThera/Rituxan	49	55	43	52	51
Herceptin	39	44	42	56	64
Avastin	10	23	28	43	57
CellCept	9	10	8	11	9
NeoRecormon/Epogin	124	146	103	114	111
Pegasys	17	23	19	22	26
Tarceva	-	2	8	12	11
Xeloda	7	8	8	12	13
Bonviva/Boniva	-	-	-	-	-
Lucentis	-	-	-	-	-
Tamiflu	81	69	16	0	1
Valcyte/Cymevene	-	-	-	-	-
Xolair	-	-	-	-	-
Xenical	-	-	-	-	-
Pulmozyme	-	-	-	-	-
Nutropin	-	-	-	-	-
Neutrogen	100	110	95	97	98
Rocephin	14	16	13	15	14
Activase/TNKase	-	-	-	-	-
Madopar	4	6	4	5	5

<sup>1</sup> Chugai

15. Pharmaceuticals Division quarterly product sales in Europe/Rest of World<sup>1</sup> in 2007 and 2008

CHF millions	Q3 2007	Q4 2007	Q1 2008	Q2 2008	Q3 2008
MabThera/Rituxan	613	668	689	702	689
Herceptin	786	842	820	844	837
Avastin	334	419	461	506	540
CellCept	244	248	264	269	257
NeoRecormon/Epogin	394	364	339	336	316
Pegasys	291	313	269	299	280
Tarceva	150	157	159	166	170
Xeloda	169	181	184	183	183
Bonviva/Boniva	80	93	88	107	113
Lucentis	-	-	-	-	-
Tamiflu	78	45	28	19	4
Valcyte/Cymevene	68	71	71	74	77
Xolair	-	-	-	-	-
Xenical	134	129	122	116	117
Pulmozyme	56	61	56	55	51
Nutropin	3	5	3	4	2
Neutrogen	-	-	-	-	-
Rocephin	76	83	75	69	62
Activase/TNKase	12	12	12	10	11
Madopar	72	77	70	75	72

<sup>1</sup> Roche Pharmaceuticals

## Roche: Building on strength

*Q3 '08: Analyst call*

*October 21, 2008*



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- 9 litigation;
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## **Group**

*Severin Schwan*

*Chief Executive Officer*



## **Our business model works - also in the current environment**

### **Short term**

- Acting from a position of stability and strength: ~CHF 3 bn organic sales growth<sup>1</sup>
- Products serving high medical needs - less exposed to economic climate

### **Long term**

- Demand will remain for products with clear medical value
- Progress in science will lead to more targeted treatment options
- Well positioned with an innovation-focused business model leveraging Pharma & Diagnostics

### **Genentech minority buy-out**

- Roche reaffirms commitment to Genentech offer and a negotiated agreement

<sup>1</sup> YTD Sept 2008, excluding Tamiflu government and corporate pandemic sales

## Continued strong growth in both divisions

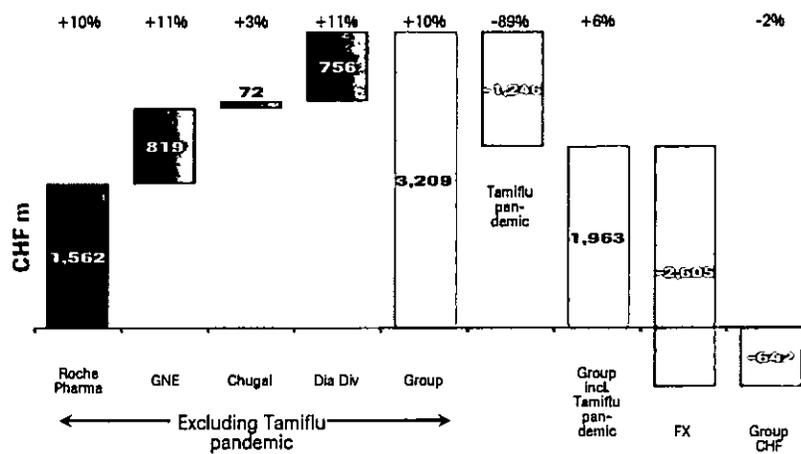


CHF bn	YTD 9'07		YTD 9'08		% change in		USD growth
	YTD 9'07	YTD 9'08	CHF	local	CHF	local	
<b>Pharmaceuticals</b>	<b>27.1</b>	<b>26.2</b>	<b>-3</b>	<b>4</b>	<b>11</b>	<b>17</b>	
<b>excl. Tamiflu pandemic</b>	<b>25.7</b>	<b>26.1</b>	<b>1</b>	<b>10</b>	<b>17</b>	<b>17</b>	
<b>Diagnostics</b>	<b>6.8</b>	<b>7.1</b>	<b>4</b>	<b>11</b>	<b>20</b>	<b>20</b>	
<b>Roche Group</b>	<b>33.9</b>	<b>33.3</b>	<b>-2</b>	<b>6</b>	<b>13</b>	<b>17</b>	
<b>excl. Tamiflu pandemic</b>	<b>32.5</b>	<b>33.2</b>	<b>2</b>	<b>10</b>	<b>17</b>	<b>17</b>	

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## YTD Sept '08: ~CHF 3 bn organic growth

*Strong underlying growth impacted by currency and Tamiflu effect*



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## Reconfirming objectives for 2008

### Sales

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- High single-digit local currency sales increase for Roche Group (excl. Tamiflu pandemic<sup>1</sup>)
- Above-market sales growth<sup>1</sup> in both divisions

### Core EPS

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- Core earnings per share target<sup>2</sup> at least at record 2007 level despite significant increase in R&D investment and considerably lower Tamiflu pandemic sales

### Shareholder return

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- Continuous increase in dividend pay-out ratio over the next 3 years

<sup>1</sup> Excluding government and corporate stockpiling orders of Tamiflu for pandemic use  
<sup>2</sup> At constant exchange rates

## Pharmaceuticals Division

*William M. Burns*

*CEO Roche Pharmaceuticals*



## Q3 '08: Highlights in Pharma

### Short, medium and long-term opportunities on track

#### Very solid current business momentum

- All businesses outgrow their markets

#### Medium-term growth opportunities on track

- *New clinical data:* MabThera in relapsed CLL<sup>1</sup>: topline data phase III announced
- *Two major filings:* Avastin with docetaxel in 1<sup>st</sup> line mBC (EU) and MabThera in 1st line CLL (EU)
- *Regulatory up-date:* Actemra in RA - positive FDA Advisory Committee recommendation; Complete response letter received, working with FDA to address outstanding matters, CHMP review on track

#### Long-term growth projects initiated

- YTD 10 major new phase III projects started
- GLP-1 (diabetes): phase III recruitment started in Q3
- T-DM1 (breast cancer): phase III "go" decision taken

<sup>1</sup>CLL=Chronic Lymphocytic Leukemia

## Pharma: Strong underlying momentum

Sales CHF m	YTD 9'07	YTD 9'08	% change in		USD growth
			CHF	local	
Roche Pharma	16,792	16,423	-2	3	13
excl. Tamiflu pandemic	15,668	16,294	4	10	20
Genentech	7,850	7,536	-4	11	11
Chugai	2,482	2,234	-10	-8	4
excl. Tamiflu pandemic	2,208	2,232	1	3	16
<b>Pharmaceuticals</b>	<b>27,124</b>	<b>26,193</b>	<b>-3</b>	<b>4</b>	<b>11</b>
<b>excl. Tamiflu pandemic</b>	<b>25,726</b>	<b>26,062</b>	<b>1</b>	<b>10</b>	<b>17</b>

## Growth momentum maintained



	2007 vs. 2006 <sup>1</sup>				2008 vs. 2007 <sup>1</sup>			USD growth		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q1	Q2	Q3
<b>Pharmaceuticals Division</b>	<b>20</b>	<b>16</b>	<b>6</b>	<b>5</b>	<b>1</b>	<b>5</b>	<b>8</b>	<b>8</b>	<b>13</b>	<b>13</b>
<b>excl. Tamifu pandemic<sup>2</sup></b>	<b>16</b>	<b>14</b>	<b>12</b>	<b>11</b>	<b>9</b>	<b>10</b>	<b>10</b>	<b>17</b>	<b>18</b>	<b>15</b>
Roche Pharma	18	13	1	7	1	3	6	11	14	13
Genentech	30	26	18	6	9	9	14	9	9	14
Chugai	11	2	8	-8	-23	2	-1	-13	18	8

<sup>1</sup> Local Currency

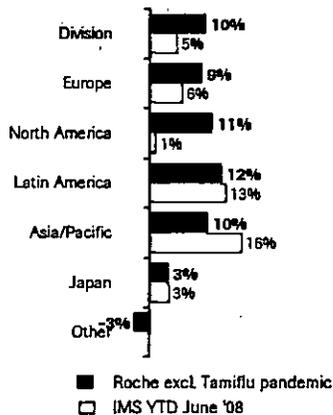
<sup>2</sup> Tamifu corporate and government pandemic sales; all figures in %

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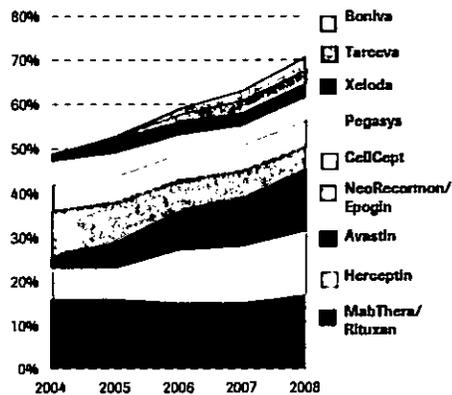
## YTD Sept '08: Risk-diversified business continues to outperform the market



### Local sales growth



### Key products account for >70% of business

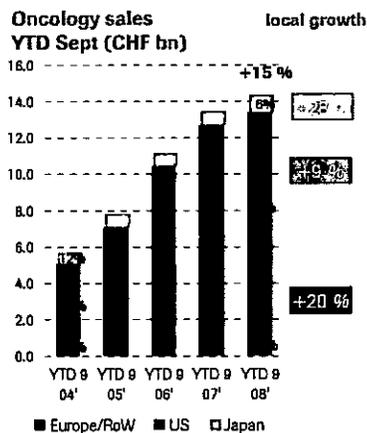


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## Therapeutic areas: quarter review

### Pipeline summary

## Oncology: Europe/RoW continues impressive growth



### Double-digit growth outside the US

#### Europe/RoW

- Continued strong increase in Avastin utilization across four approved tumor types
- Emerging markets contributing to continued MabThera, Herceptin, Tarceva growth - Avastin still untapped potential

#### Japan

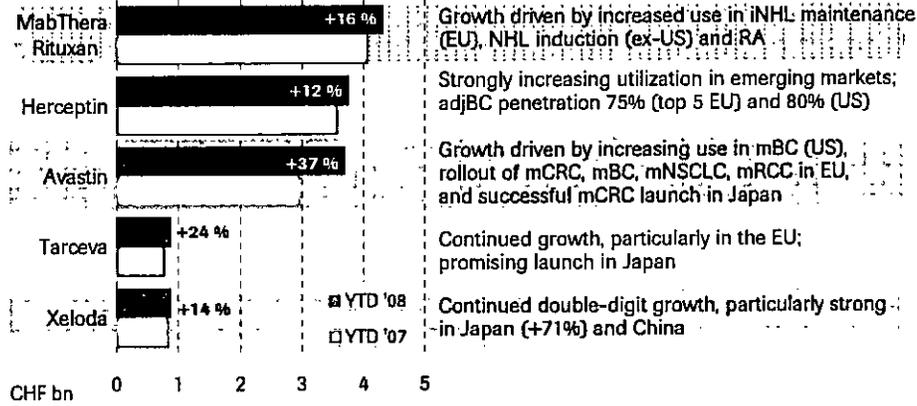
- Important progress made in portfolio roll-out
  - Avastin, Tarceva, Herceptin (adjuvant) launches

## Oncology: All products grow double digit



### Major brands

YTD Sept '08 vs. YTD '07  
local growth



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## Oncology: Q3 '08 pipeline update

*Significant newsflow before end of year*



### MabThera in relapsed CLL: REACH ✓

Randomized ph. III, 552 patients  
Fludarabine+cyclophosphamide  
+/-MabThera  
met primary endpoint (PFS)

**Filing 2009**

### Tarceva+Avastin in 2nd line NSCLC: BETA lung ✓

Tarceva+/-Avastin  
improvement in PFS / RR benefit  
OS not significant

**EU filing under evaluation**

### Avastin in 1st line mBC: RIBBON-1

Phase III study, 1238 patients,  
2 primary analyses:  
Anthracycline-/taxane-based +/- Avastin,  
and Xeloda +/- Avastin

**Expect topline data Q4 '08**

### Tarceva 1st line maintenance NSCLC: SATURN

4 chemo cycles followed by T vs. placebo  
Enrollment completed Q2 '08  
Potentially label-enabling for Tarceva

**Expect topline data Q4 '08**

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## MabThera in CLL: an important opportunity in EU/RoW



Treatable CLL patients per year (top 5 EU): ~17'000  
 (~50% of the number of treatable patients with indolent NHL)

1st line Treatment choice ~8,500 patients	current	<b>Chemotherapy</b> ~80% of patients	Immuno-chemotherapy ~20% of patients
	future	MabThera + chemotherapy	

Relapsed Treatment choice ~8,500 patients	current	<b>Chemotherapy</b> ~57% of patients	Immuno-chemotherapy ~29% of patients	<b>alemtuzumab</b> ~14% of patients
	future	MabThera + chemotherapy		

Current main treatment paradigm     Future main treatment paradigm

Conference call from ASH 2008 in December

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Source: Genacis Top 5 EU Q4 2007 (all CLL patients); values are rounded

## Maintaining leadership in oncology Building on our key areas of expertise

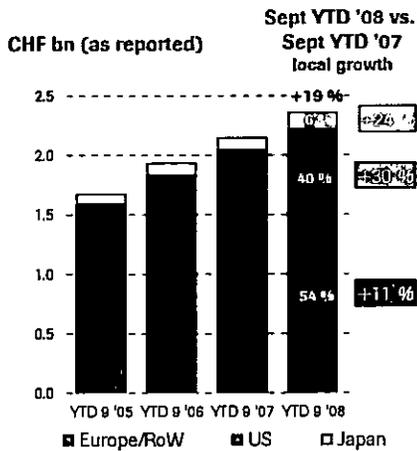


New molecular entities	Key features	Potential patient benefit	Stage of development
<b>Anti-CD 20 (building on MabThera)</b>			
R7159/GA101 (3rd generation)	Glyco-engineered type II antibody, fully humanized; ADCC↑, CDC↓ direct cell death↑	Significantly improved efficacy	ph. I / II NHL, CLL
<b>Anti-HER2 (building on Herceptin)</b>			
Pertuzumab	Inhibition of HER2 dimerisation	Improved efficacy in combo with Herceptin	ph. III mBC ph. II mNSCLC
Trastuzumab-DM1	Anti-microtubule linked to Herceptin	Reduced side effects, superior efficacy	ph. II mBC ph. III 'go'
<b>Angiogenesis (building on Avastin)</b>			
R7334 / TB-403 Anti-PlGF mAb	mAb against placental growth factor (PlGF); blocks a pro-angiogenic factor	Adding efficacy to Avastin in combo or sequentially	ph. I



## Inflammation/Autoimmune/Transplantation

### Growing in rheumatoid arthritis



<sup>1</sup> Complete Response Letter

### Q3 2008

#### CellCept

- Double-digit growth continues

#### MabThera/Rituxan in RA

- Market penetration in RA continues to increase strongly

#### Actemra

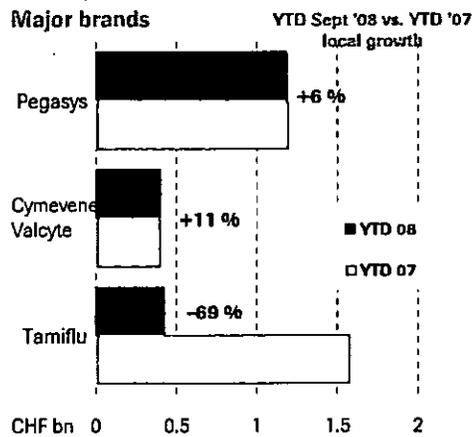
- Good initial uptake in Japan
- LITHE (X-ray study) met 1 yr primary end point, data at ACR
- Positive FDA panel on July 29<sup>th</sup> 2008; CRL<sup>1</sup> received; working with FDA to address outstanding matters, EU review on track

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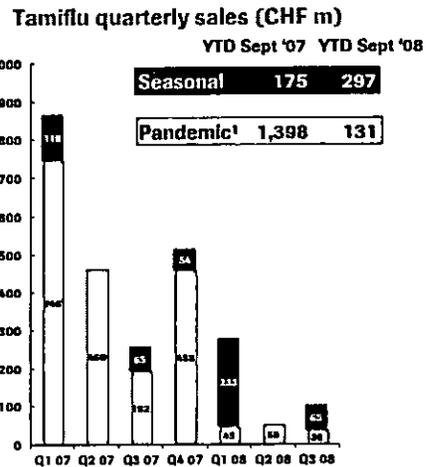


## Virology: Pegasys back to growth

### Tamiflu in line with expectations



<sup>1</sup> Governmental & Corporate



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## Therapeutic areas: quarter review

### Pipeline summary

## Major progress in late-stage development

*Pipeline movements since YE 2007 and in Q3 2008*

### Phase 3

#### Ten Initiations since YE 2007 (+ 2 in Q3 '08)

R1658	dalcetrapib (CETP) in dyslipidemia
R1569	Actemra in sJIA
R435	Avastin combo Herceptin in HER2+ adj BC
R1273	pertuzumab combo Herceptin in 1st line Her2+ mBC
GEN	Avastin in 2nd line platinum-sensitive ovarian cancer
R1594	ocrelizumab in lupus nephritis
R435	Avastin combo Herceptin in 1st line HER2+ mBC (2nd study, E1105)
GEN	Avastin in high-risk carcinoid
R1583	tasoglutide (GLP-1) in T2D
R435	Avastin in GIST

#### Three major submissions since YE 2007 (all in Q3 '08)

R105	MabThera in CLL 1st line
R435	Avastin combo docetaxel in HER2- mBC
R435	Avastin in 1st line mRCC (US)

## Pharmaceuticals objectives for 2008

Major clinical data	Compound	Phase	Indication / data	Timing	Status Q3
	Avastin	III	mBC (AVADO)	H1 2008	✓
	Avastin	III	mBC (RIBBON-1)	Q4 2008	
	Avastin+Tarceva	III	2nd line NSCLC (BETA lung) interim	Event-driven	✓ PEP <sup>1</sup> not met
	Tarceva	III	1st line NSCLC (SATURN)	Q4 2008	
	MabThera	III	RA, DMARD-IR	Q1 2008	✓
	MabThera	III	SLE (EXPLORER)	Q2 2008	-
	MabThera	III	PPMS (OLYPMUS)	Q2 2008	-
	MabThera	III	CLL 1 <sup>st</sup> line ph. III data interim	Q1 2008	✓
	MabThera	III	CLL relapsed ph. III data Interim	Event-driven	✓
	Xeloda	III	Adjuvant CC (NO16968) interim	Event-driven	
	Actemra	III	RA (AMBITION, RADIATE) full data	H1 2008	✓
	GLP-1	IIb	Type 2 diabetes full data	H1 2008	✓
DPP-IV	II	Type 2 diabetes	H2 2008	✓	

Filings	Compound	Indication	Status
	Avastin	mBC (AVADO)	✓
	Avastin+Tarceva	NSCLC 2nd line (BETA lung)	Under evaluation
	MabThera	CLL (1st line)	✓
	MabThera	RA, DMARD IR	To be filed in 2009
Avastin	Glioblastoma 2nd line	To be filed Q4 2008	

### Divisional sales growth

Above-market excluding pandemic Tamifu

barring unforeseen events 23

<sup>1</sup>PEP—Primary Endpoint

## Diagnostics Division

*Jürgen Schwiezer*  
CEO Roche Diagnostics





## Q3 '08: Diagnostics Division continues to outpace the market

### Solid current business momentum

- Sales growth in-line or above the market in all regions
- Ventana integration nears successful completion; strong double-digit growth continues

### Strong series of launches providing future growth

- Three new systems launched in Professional Diagnostics and Tissue Diagnostics
  - cobas c 311 (clin. chem.) & Accu-Chek Inform II (POC) ex-US
  - BenchMark ULTRA (advanced tissue staining)
- Four FDA approvals received
  - CTM HBV viral load test (mol. dia.)
  - anti-CCP, anti.TSH receptor & Toxo IgG immunoassays
- GS FLX Titanium series released; further improving sequencing offering

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## YTD Sept '08: Growth driven by Professional Diagnostics, Applied Science and Tissue Diagnostics

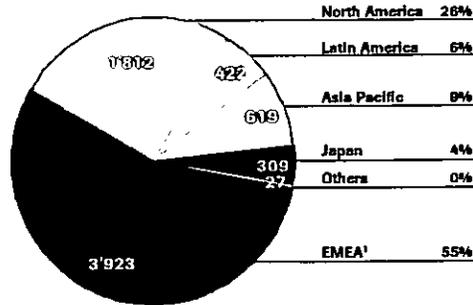
Sales CHF m	YTD Sept 2007	YTD Sept 2008	% change in CHF local		USD growth
Professional Diagnostics	3,157	3,270	4	9	19 %
Diabetes Care	2,312	2,207	-5	2	10 %
Molecular Diagnostics	856	828	-3	4	12 %
Applied Science	498	546	10	19	26 %
Tissue Diagnostics <sup>1</sup>	-	261	-	-	-
<b>Diagnostics Division</b>	<b>6,823</b>	<b>7,112</b>	<b>4</b>	<b>11</b>	<b>20 %</b>

<sup>1</sup> Sales from beginning of February 2008

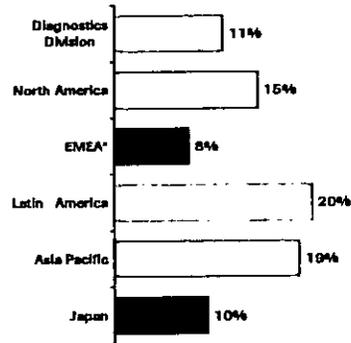
26

## YTD Sept '08: Above-market growth, particularly in Japan and emerging markets

CHF 7,112 m



local sales growth



<sup>1</sup> Europe, Middle East and Africa

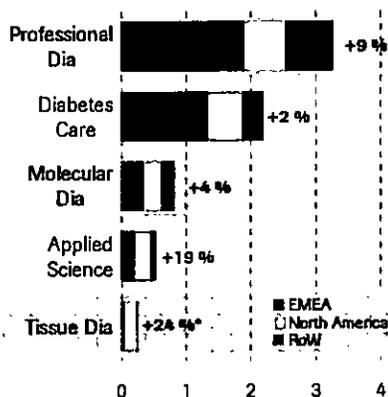
Tissue Diagnostics sales consolidated since beginning of February 2008

27

## YTD Sept '08: New products and instrument placements driving growth

CHF bn

YTD Sept '08 vs. YTD Sept '07  
local growth



Three new immunoassays received FDA approval  
Launched cobas c 311 (clin chem) ex-US;

Solid growth in all regions except North America;  
Accu-Chek Aviva now top selling system

FDA approval received CTM HBV Test; EU & APAC  
transitioned to TaqMan CT; HPV test approved in Japan

Released GS FLX Titanium series, strengthening  
sequencing business; SeqCap arrays now available w.w.

Launched BenchMark ULTRA (IHC/ISH); Symphony (H&E)  
and VANTAGE systems contributing strongly to growth

\* 9 month sales on a stand-alone basis

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## Key growth drivers in 2008

*Commercialise current assets; prepare market for new drivers*

### Key 2007 Launches

### Key 2008 Launches\*

<b>Professional Diagnostics</b>	<ul style="list-style-type: none"> <li>cobas 4000 analyser series               <ul style="list-style-type: none"> <li>cobas e 411 analyser</li> <li>cobas IT 3000 &amp; 1000</li> <li>cobas h 232</li> <li>cobas h 152 (Accutrend Plus)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>cobas 4000 analyser series               <ul style="list-style-type: none"> <li>cobas c 311 analyzer (ex-US) ✓</li> <li>Accu-Chek Inform II (ex-US) ✓</li> <li>menu: HCV, RA, sepsis, CMV (ex-US) ✓✓✓</li> </ul> </li> </ul>
<b>Diabetes Care</b>	<ul style="list-style-type: none"> <li>Accu-Chek Performa</li> <li>Accu-Chek Compact Plus (new)</li> <li>Accu-Chek 360°</li> </ul>	<ul style="list-style-type: none"> <li>Accu-Chek Aviva Nano</li> </ul>
<b>Molecular Diagnostics</b>	<ul style="list-style-type: none"> <li>cobas s 201 system &amp; WNV Test (US)</li> <li>Cobas AmpliPrep/Cobas TaqMan HIV Test (US)</li> </ul>	<ul style="list-style-type: none"> <li>CAP/CTM HCV Test (US)</li> <li>cobas TaqScreen MPX (US) (J) ✓</li> <li>cobas TaqMan 48 HBV Test (US) ✓</li> <li>cobas TaqMan 48 CT Test (EU) ✓</li> </ul>
<b>Tissue Diagnostics</b>	<ul style="list-style-type: none"> <li>PATHWAY HER-2 Primary Antibody</li> <li>INFORM HER2 DNA Probe Assay SISH (EU)</li> </ul>	<ul style="list-style-type: none"> <li>BenchMark ULTRA IHC/ISH staining system (US) ✓</li> <li>VANTAGE Workflow Management Solution (US) ✓</li> <li>VIAS: Imaging application for HER-2 SISH (EU) ✓</li> </ul>
<b>Applied Science</b>	<ul style="list-style-type: none"> <li>Genome Sequencer FLX</li> </ul>	<ul style="list-style-type: none"> <li>Real-Time Cell Analyser xCELLigence ✓</li> <li>GS FLX Titanium for DNA sequencing (454) ✓</li> <li>Comprehensive menu of NimbleGen microarrays ✓</li> </ul>

**Divisional sales growth outlook**

**Above market growth in local currencies**

\* Subject to appropriate regulatory approvals; US launch may be later

barring unforeseen events

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**Group**

*Erich Hunziker*

*Chief Financial Officer*



## Roche's strong position in the current market environment

### Short-term stability

- Risk-averse liquid funds management strategy paying off
- High equity ratio of over 70%<sup>1</sup>
- Net cash of more than CHF 10 bn<sup>1</sup>

### Long-term stability

- Young and growing product portfolio and low generic exposure
- Strong cash-generating ability; 2007 operating free cash flow - CHF 11 bn

<sup>1</sup>As reported as part of HY 2008 results

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## Exchange rate impact on sales growth

*Improved USD situation in Q3, but still significant negative impact YTD*

### Development of

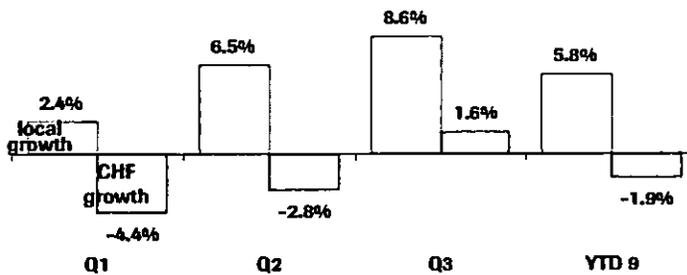
average exchange rates versus prior year period

CHF / EUR	-0.9%	-2.2%	-2.2%	-1.8%
<b>CHF / USD</b>	<b>-13.3%</b>	<b>-15.7%</b>	<b>-10.6%</b>	<b>-13.2%</b>
CHF / JPY	-1.8%	-2.6%	-2.1%	-2.1%

Difference  
in CHF / local  
growth

-6.8 %pt      -9.3 %pt      -7.0 %pt      -7.7 %pt

Sales  
growth  
2008  
vs. 2007



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## Reconfirming objectives for 2008



### Sales

---

- High single-digit local currency sales increase for Roche Group (excl. Tamiflu pandemic<sup>1</sup>)
- Above-market sales growth<sup>1</sup> in both divisions

### Core EPS

---

- Core earnings per share target<sup>2</sup> at least at record 2007 level despite significant increase in R&D investment and considerably lower Tamiflu pandemic sales

### Shareholder return

---

- Continuous increase in dividend pay-out ratio over the next 3 years

<sup>1</sup> Excluding government and corporate stockpiling orders of Tamiflu for pandemic use  
<sup>2</sup> At constant exchange rates

Barring unforeseen events



## Pharma sales YTD September 2008 (vs. 2007)

### Top 20 products

	Global		US		Japan		Europe/RoW	
	CHF m	% loc	CHF m	% loc	CHF m	% loc	CHF m	% loc
MabThera/Rituxan	4,339	16	2,113	14	146	11	2,080	20
Herceptin	3,769	12	1,106	9	162	38	2,501	13
Avastin	3,702	37	2,067	15	128	878	1,507	74
CellCept	1,523	14	705	16	28	16	790	11
NeoRecorm/Epogin	1,319	-14	-	-	328	-19	991	-12
Pegasys	1,190	6	275	11	67	62	848	2
Tarceva	885	24	359	12	31	-	495	28
Xeloda	880	14	297	9	33	71	550	14
Bonviva/Boniva	775	41	467	33	-	-	308	59
Lucentis	686	4	686	4	-	-	-	-
Tamiflu	428	-69	360	-27	17	-95	51	-92
Valcyte/Cymevene	404	11	182	8	-	-	222	14
Xolair	404	9	404	9	-	-	-	-
Xenical	390	-14	35	-39	-	-	355	-10
Pulmozyme	357	11	195	12	-	-	162	8
Nutropin	301	-3	292	-3	-	-	9	-8
Neutrogen	290	1	-	-	290	1	-	-
Rocephin	252	-11	4	-73	42	2	206	-9
Activase/TNKase	245	-5	212	-7	-	-	33	9
Madopar	231	4	-	-	14	5	217	4

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## Pharma sales YTD September 2008 (vs. 2007)

### Other launches since January 2003<sup>1</sup>

	Global		US		Japan		Europe/RoW	
	CHF m	% loc	CHF m	% loc	CHF m	% loc	CHF m	% loc
Copegus	176	14	3	-	29	153	144	-3
Fuzeon	133	-41	48	-48	-	-	85	-35
Evista	117	5	-	-	117	5	-	-
Raptiva	100	12	100	12	-	-	-	-
Renagel	47	5	-	-	47	5	-	-
Mircera	34	-	-	-	-	-	34	-
Actemra	18	461	-	-	18	461	-	-
Femara	12	79	-	-	12	79	-	-

<sup>1</sup> other than launches already covered in Top 20



**Pharma local sales growth<sup>1</sup> in %**  
*Global top 20 products*

	Q3/07	Q4/07	Q1/08	Q2/08	Q3/08
MabThera/Rituxan	17	12	17	16	15
Herceptin	18	14	11	12	14
Avastin	45	41	35	38	37
CellCept	4	16	11	16	14
NeoRecormon/Epogin	-5	-15	-13	-14	-15
Pegasy	7	14	-3	10	12
Tarceva	28	24	28	27	18
Xeloda	20	22	13	14	14
Bonviva/Boniva	62	63	56	47	26
Lucentis	31	-9	-5	2	15
Tamiflu	-60	-46	-64	-86	-56
Valcyte/Cymevene	9	7	9	10	13
Xolair	11	2	6	7	12
Xenical	-9	-17	-11	-21	-9
Pulmozyme	14	13	15	11	6
Nutropin	3	-8	-5	-5	1
Neutrogin	15	14	1	1	0
Rocephin	-2	-4	-4	-13	-16
Activase/TNKase	6	-2	-3	-11	-2
Madopar	5	14	0	9	4

<sup>1</sup> versus previous year

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**Pharma local sales growth in %**  
*Top 20 products by region*

	US				Japan				Europe/RoW			
	Q4 <sup>1</sup>	Q1 <sup>2</sup>	Q2 <sup>2</sup>	Q3 <sup>2</sup>	Q4 <sup>1</sup>	Q1 <sup>2</sup>	Q2 <sup>2</sup>	Q3 <sup>2</sup>	Q4 <sup>1</sup>	Q1 <sup>2</sup>	Q2 <sup>2</sup>	Q3 <sup>2</sup>
MabThera/Rituxan	4	14	13	14	2	13	11	8	25	21	21	17
Herceptin	1	9	3	15	0	16	29	69	23	12	15	11
Avastin	23	13	15	18	-	-	1567	442	80	78	78	67
CellCept	17	14	15	20	18	13	21	15	14	8	16	9
NeoRecormon/Epogin	-	-	-	-	-22	-16	-29	-9	-11	-13	-7	-17
Pegasy	-3	-10	5	45	53	98	53	49	20	-4	8	1
Tarceva	5	10	17	9	-	-	-	-	47	40	28	17
Xeloda	19	16	5	9	14	48	73	88	25	11	18	14
Bonviva/Boniva	40	47	39	18	-	-	-	-	160	77	61	45
Lucentis	-9	-5	2	15	-	-	-	-	-	-	-	-
Tamiflu	52	83	-87	8	-58	-83	-78	-88	-92	-84	-83	-83
Valcyte/Cymevene	3	11	5	7	-	-	-	-	11	8	16	19
Xolair	2	6	7	12	-	-	-	-	-	-	-	-
Xenical	-46	-35	-46	-33	-	-	-	-	-11	-7	-17	-6
Pulmozyme	10	10	14	13	-	-	-	-	17	22	8	-3
Nutropin	-8	-8	-4	1	-	-	-	-	-10	-1	-12	-10
Neutrogin	-	-	-	-	14	1	1	0	-	-	-	-
Rocephin	-32	-34	-85	-	-1	9	-2	-1	-3	-3	-8	-13
Activase/TNKase	0	-6	-12	-2	-	-	-	-	-16	30	1	1
Madopar	-	-	-	-	3	5	5	6	15	0	8	4

<sup>1</sup> 2007 vs. 2006

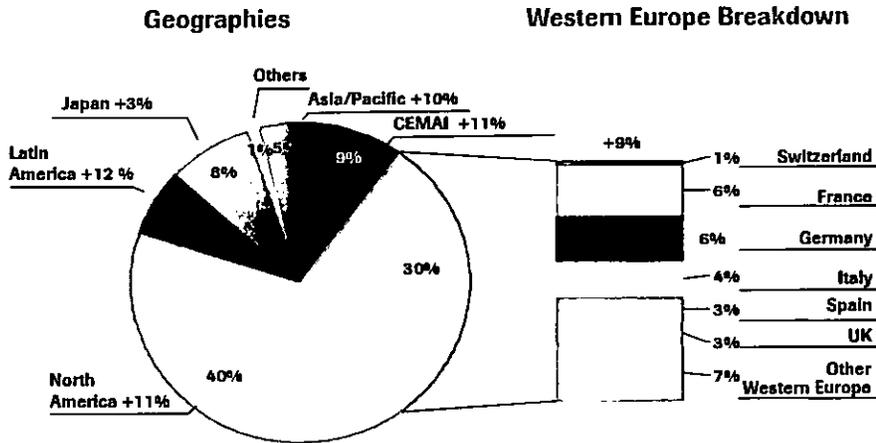
<sup>2</sup> 2008 vs. 2007

38



## YTD Sept '08: Pharmaceuticals Division

*Regional sales distribution & growth excl. Tamiflu pandemic*



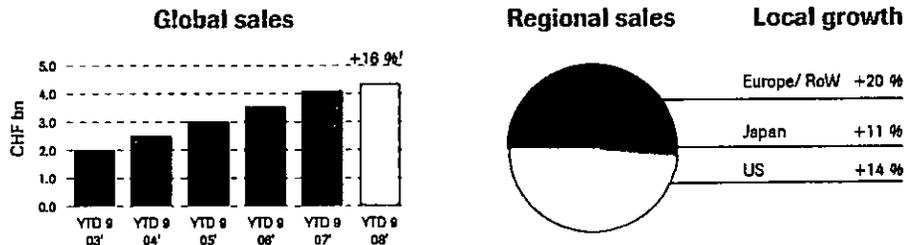
■ growth figures are in local currencies

CEMAI: Central and Eastern Europe, Middle East, Africa, Indian Subcontinent 39



## MabThera/Rituxan: Strong growth over a decade

*Penetration in oncology & RA continues to increase*



- YTD sales of CHF 4.339 bn
- Continued growth in 1st line aNHL and iNHL in EU/RoW
- Growth from increased use in iNHL following 1st line (including maintenance therapy)
- Strong growth in RA in US and Europe/ ROW

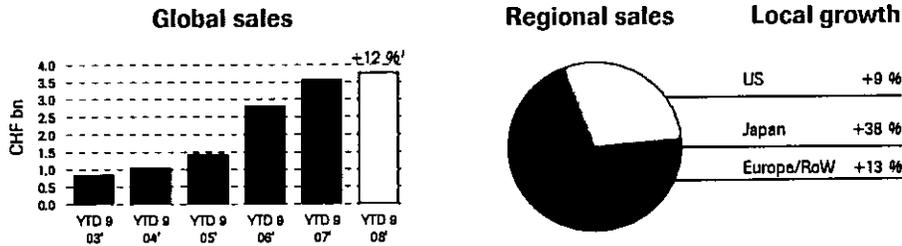
<sup>1</sup> local growth

40



## Herceptin: double-digit growth maintained

### Adjuvant usage continues to drive growth



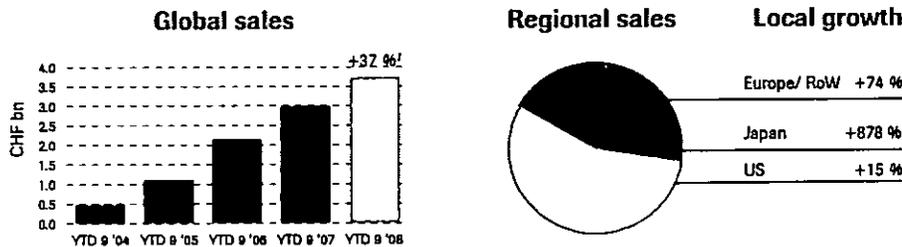
- YTD sales of CHF 3.769 bn
  - US market penetration
    - adjuvant: approximately 80% (Q3 '08)
    - 1st line metastatic: approx. 75% (Q3' 08)
  - Top 5 EU market penetration (Q2 '08)
    - adjuvant: approx. 75%
    - 1st line metastatic: approx. 80%, stable
  - Penetration rates in other markets remain well below US/Top 5 EU levels
- <sup>1</sup> local growth

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## Avastin: very strong growth in EU/RoW continues

### Growth driven by multiple new indications



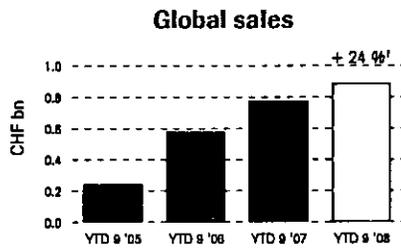
- YTD sales of CHF 3.702 bn
  - US:
    - growth primarily from increased use in 1st line mBC (penetration rate: approx. 40%)
  - EU/RoW:
    - strong growth in mCRC continues; 1st line mCRC penetration has grown by almost 25% (year on year) in the top 4 EU markets, driven by the expanded label; with a penetration of almost 40% in the leading market. In the irinotecan segment average penetration is 50% across the top 4 EU markets.
    - Market penetration in 1st line mBC continues to increase; mNSCLC and mRCC launches promising
- <sup>1</sup> local growth.

42



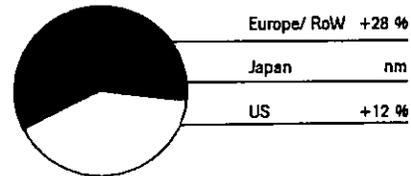
## Tarceva

### Strong double-digit growth continues



### Regional sales

### Local growth



- YTD sales of CHF 885 million
- Market penetration in NSCLC, top 5 EU (Q2'08):
  - 2nd line: approx. 30%
  - 3rd line: approx. 45%

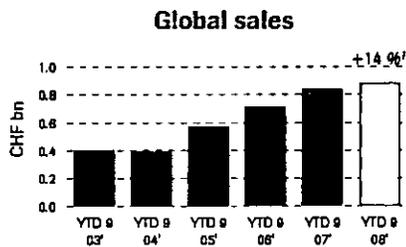
<sup>1</sup> local growth. n.m. = not meaningful

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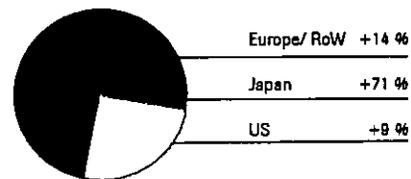
## Xeloda

### Label expansions driving growth



### Regional sales

### Local growth



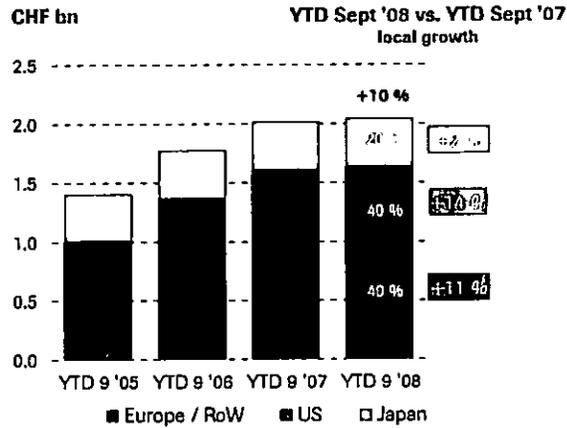
- YTD sales of CHF 880 million
- Xeloda mCRC broad label extension approval in EU in Q1 2008
- Strong growth in Japan driven by new indications (adjuvant CC and new dosage strength in mBC)

<sup>1</sup> local growth

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## Metabolism/Bone

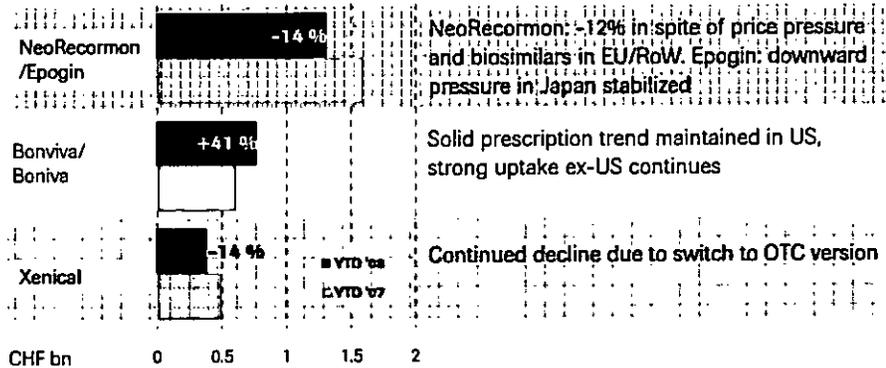
*Franchise growth driven by Boniva*



## Metabolism/Bone/Anemia

### Major brands

YTD Sept '08 vs. YTD '07  
local growth





## Avastin – maximising a key asset

### Gastrointestinal cancers & renal cell carcinoma

Main Indication		Study name	Status
<b>mCRC</b>	Treatment through multiple lines (after progression on 1st line chemo+Avastin)	ML18147/AIO0504	Initiated Q1'06
<b>Adjuvant colon cancer</b>	Stage II / stage III	NSABP C-08	Final analysis will likely occur in mid-2009
	Stage II high risk / stage III	AVANT	Recruitment completed Q2'07
<b>Met. gastric cancer</b>	1st line	AVAGAST	Initiated Q3 2007
<b>Gastrointestinal Stromal Tumors</b>	GIST	SWOG S0502	Initiated Q3 2008
<b>High risk carcinoid</b>		SWOG S0518	Initiated in Q1'08
<b>Renal cell carcinoma</b>	1st line	AVOREN	Approved in EU; filed in US Q3'08
	1st line	CALGB 90206	Topline PFS and safety results submitted to FDA in support of AVOREN sBLA 47



## Avastin – maximising a key asset

### Lung and breast cancer

Main Indication		Study name	Status
<b>NSCLC</b>	1st line (with Tarceva)	ATLAS	Expect data H1 2009
	2nd line (with Tarceva)	BETA Lung	Primary endpoint not met
	1st line squamous	BRIDGE (pilot study)	Expect results Q4'08
	1st or 2nd line non-squamous previously treated CNS mets	PASSPORT (ph. II)	Expect results late '08/early '09
<b>Adjuvant NSCLC</b>	Stage IB-IIIa, sq. + non-sq.	ECOG 1505	Initiated Q3'07
<b>mBC</b>	1st line HER2-negative	AVADO	Filed EU Q3 2008
	1st line HER2-negative	RIBBON-1	Top-line data expected Q4'08
	ER/PR-positive 1st l. mBC, with hormonal therapy	CALGB-40503	To start Q4 2008
	1st line HER2-positive (with Herceptin)	AVEREL	Initiated Q3'06
	1st line HER2-positive (with Herceptin)	E1105	Initiated Q1'08
	2nd line HER2-negative	RIBBON-2	Expect results 2009
<b>Adjuvant BC</b>	HER2-negative	E5103	Initiated Q4'07
	HER2-negative, ER-/PR-neg.	BEATRICE	Initiated Q4'07
	HER2-positive (with Herceptin)	BETH	Initiated Q2'08



## Avastin – maximising a key asset

### Brain, ovarian, prostate cancer and NHL

Main Indication		Study name	Status
Glioblastoma multiforme	relapsed	BRAIN (ph. II)	To be submitted in Q4'08
	Newly diagnosed	Phase III in preparation	To be initiated H1 2009
Ovarian Cancer	1st line	GOG-0218	Initiated Q3'05
	1st line	ICON-7	Initiat. Q4'06, expect to complete enrollment in H1 '09
	Relapsed, platinum-sensitive	GOG-0213	Initiated Q4'07
	Relapsed, platinum-sensitive	OCEANS	Initiated Q2'07-expanded to phase III study in Q2 '08
Prostate Cancer	1st line, hormone refractory	CALGB 90401	Expect data in 2010
NHL aggressive	1st line (with MabThera)	MAIN	Initiated in Q3'07

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## Herceptin, pertuzumab and T-DM1

### Improving the standard of care in HER2-positive breast cancer

Main Indication		Study name	Status
HERCEPTIN	Gastric cancer	Combo with chemotherapy	ToGA
		1 year vs. 2 years treatment	HERA
			Initiated Q3'05, final analysis 2009, event-driven
			Potentially results from event-driven interim analysis end '08 / early '09 comparing 2-years vs. 1-year Herceptin treatment; final analysis expected 2011
PERTUZUMAB	mBC HER2+ 1st line	Herceptin+docetaxel+/- pertuzumab	CLEOPATRA (ph. III)
		Combo with Herceptin	NEOSPHERE (ph. II)
		Combo with Herceptin	BO17929 (ph. II)
			Initiated Q1'08
			Initiated Q1'08
			Full efficacy data presented at ASCO '08

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## Herceptin, pertuzumab and T-DM1

### *Improving the standard of care in HER2-positive breast cancer*

Main Indication	Study name	Status
<b>TRASTUZUMAB-DM1 (T-DM1)</b>		
<b>mBC, HER2+, 1st line</b> T-DM1 vs Herceptin+ docetaxel	<b>Phase II</b>	Initiated Q3 2008
<b>mBC, HER2+, 2nd line</b> monotherapy	<b>Phase II</b>	Completed enrollment Q2 2008 data at SABCs 2008
<b>mBC, HER2+, 2nd line</b> T-DM1 vs Xeloda+lapatinib	<b>Phase III in preparation</b>	'go' decision, expect to initiate H1'09
<b>mBC, HER2+, 3rd line</b> monotherapy	<b>Phase II</b>	Expect to initiate Q3 2008
<b>mBC, HER2+ patients who have progressed on Herceptin-based treatment</b> T-DM1+pertuzumab	<b>Phase I b</b>	Expect to initiate H1 2009

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## Xeloda / Tarceva / MabThera

### *Expanding through new indications and combinations*

Main Indication	Study name	Status
<b>XELODA</b>		
<b>Adjuvant BC</b> Combo with Avastin XELOX vs. 5FU/LV	<b>AVANT NO16968</b>	Recruitment completed Q2'07 Recruitment completed, final analysis event driven (2009)
<b>Adjuvant BC</b> AC -> T vs. AC -> TX	<b>NO17629</b>	Recruitment completed in Jan '06, final analysis event driven
<b>TARCEVA</b>		
<b>NSCLC 1st line meta</b> Combo with chemotherapy	<b>SATURN</b>	Expect results Q4'08
Combo with Avastin	<b>ATLAS</b>	Completed enrollment Q2'08
<b>NSCLC 2nd line</b> Combo with Avastin	<b>BETA Lung</b>	Primary endpoint not met
<b>Adjuvant NSCLC</b>	<b>RADIANT</b>	Expect to complete enrollment 2009/2010
<b>MABTHERA</b>		
<b>NSCLC 1st line meta</b> After MabThera induction	<b>PRIMA</b>	Recruitment completed Q1'07, Final analysis expected 2010
<b>CLL 1st line</b> Combo with chemotherapy	<b>CLL-8</b>	Filed for EU approval Q3'08; data at ASH 2008
<b>CLL relapsed</b> Combo with chemotherapy	<b>REACH</b>	Study met primary endpoint

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## Actemra

### Strong data in all RA patient segments

Main Indication	Study name	Status
<b>Rheumatoid Arthritis</b> MTX-IR	<b>OPTION</b>	Presented at EULAR 2007
DMARD-IR	<b>TOWARD</b>	Presented at ACR 2007
MTX-naïve (monotherapy)	<b>AMBITION</b>	Presented at EULAR 2008
Anti-TNF IR	<b>RADIATE</b>	Presented at EULAR 2008
MTX-IR Prevention of structural damage (X-ray study)	<b>LITHE</b>	2 years study - 1 year data at ACR '08

IR = inadequate responders

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## RA/autoimmune anti-CD20 pipeline

### Major rheumatoid arthritis programs on track

Main Indication	Study name	Status
<b>Rheumatoid Arthritis</b> <b>MABTHERA</b>		
MTX-IR	<b>SERENE</b> (ph. III)	Met primary endpoint- to be presented at ACR '08
MTX-IR dose escalation retreatment	<b>MIRROR</b> (ph. III)	Recruitment completed, to be presented at ACR '08
Anti-TNF-IR	<b>SUNRISE</b> (ph. III)	Met primary endpoint- to be presented at ACR '08
MTX-naïve, X-ray study	<b>IMAGE</b> (ph. III)	Expect data late '08/early '09
Combo with Enbrel	<b>TAME</b> (ph. II, Biogen IDEC)	Initiated Q2'08
<b>OCRELIZUMAB</b>		
MTX-IR	<b>STAGE</b> (ph. III)	Initiated Q4'08
Anti-TNF IR	<b>SCRIPT</b> (ph. III)	Initiated Q2'07
MTX-naïve; X-ray study	<b>FILM</b> (ph. III)	Initiated Q2'07

IR = inadequate responders

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**RA/autoimmune anti-CD20 pipeline**  
*Ocrelizumab multiple sclerosis phase II recruiting*

Main Indication		Study name	Status
<b>ANCA associated vasculitis</b>			
MABTHERA		RAVE	Initiated Q4'04
<b>Lupus nephritis</b>			
MABTHERA		LUNAR (ph. III)	Expect data H1'09
OCRELIZUMAB		BELONG (ph. III)	Initiated Q1'08
<b>Multiple Sclerosis</b>			
MABTHERA	RRMS	HERMES (ph. II)	Met primary endpoint, data presented at AAN 2007
OCRELIZUMAB	RRMS	Phase II dose-finding study	Initiated Q3'08



**Metabolism/type 2 diabetes late-stage pipeline**  
*Two major phase III projects running (CETPi and GLP-1)*

Main Indication		Status
<b>Type 2 Diabetes</b>		
R1583 (GLP-1)	Phase III recruiting	Phase II data presented at ADA 2008
R1439 (PPAR $\alpha$ )	Phase II	Phase III decision expected by early 2009
R1579 (DPP IV-3)	Phase II	Outlicensing planned
<b>Dyslipidemia</b>		
R1658 (JTT-705)	Phase III recruiting	Phase II safety data presented at ACC 2008

# Important achievements in phase II projects

## Pipeline movements since YE 2007 and in Q3 2008



### Phase 2

#### Initiations since YE 2007 (+ 1 in Q3 '08, + 4 total)

- R1678 GlyT1 inhibitor Schizophrenia
- GEN Mabthera/Rituxan+/-Apomab for NHL
- GEN Systemic Hedgehog antagonist for cancer
- R3502 T-DM1 1st and 3rd line mBC - "go" decision taken for phase III

#### Exits

- R3421 PNP inhibitor (Biocryst) - AI/Transplant (reverted to partner)
- R1626 HCV polymerase inhibitor (terminated)

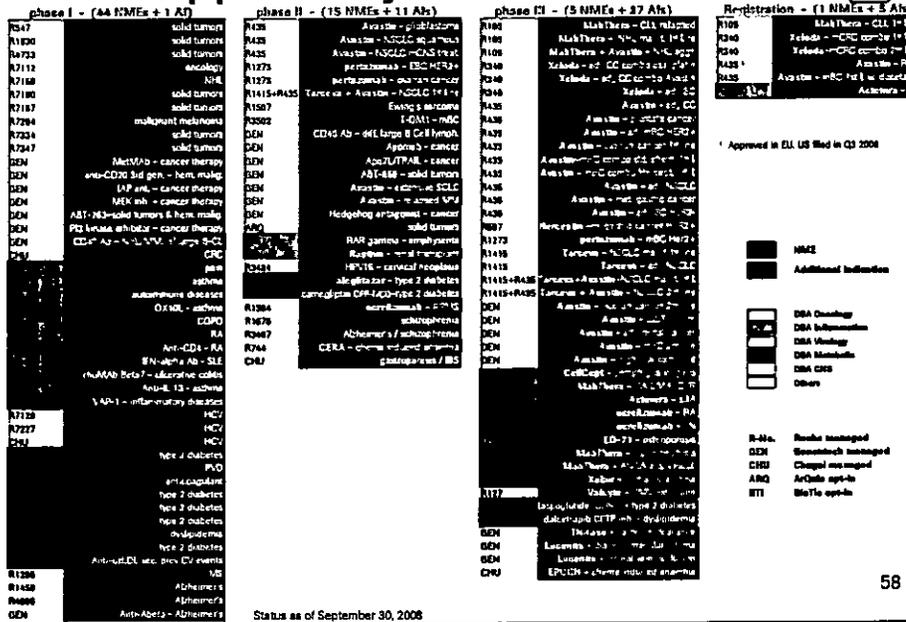
#### Opt-in from partner

- R3487 alpha 7 nicotinic acid (Memory) in AD/Schizophrenia

#### Moved to phase III (+ 1 in Q3 '08, + 3 total)

- R1273 pertuzumab combo Herceptin in 1st line HER2+ mBC
- R1658 dalcetrapib (CETPI) in dyslipidemia
- R1583 taspoglutide (GLP-1) in T2D

# Roche R&D pipeline today



# 48 projects in late stage development (phase III/reg.)



## Low-risk line extensions and innovative NMEs

### Key phase III projects

Oncology (1 NME + 25 AIs)	Inflammation (2 NMEs + 7 AIs)	Metabolism (2 NMEs)	
<b>R105</b> MabThera - CLL relapsed <b>R105</b> MabThera - NHL mixed T1/T2 <b>R106</b> MabThera + Avastin - NHL opp <b>R346</b> Xeloda - adj. CC combo escalation <b>R346</b> Xeloda - adj. CC combo Avastin <b>R346</b> Xeloda - adj. CC <b>R436</b> Avastin - adj. CC <b>R435</b> Avastin - prostate cancer <b>R435</b> Avastin - adj. mCRC HER2 <b>R436</b> Avastin - oral ch cancer 1st line <b>R435</b> Avastin-mCRC combo oral chemo 1st line <b>R435</b> Avastin - mCRC combo Herceptin 1st line <b>R435</b> Avastin - adj. NSCLC <b>R435</b> Avastin - met. gastric cancer <b>R436</b> Avastin - adj. mCRC HER2 <b>R467</b> Herceptin - met. gastric cancer HER2+ <b>R1278</b> pertuzumab - mCRC HER2+ <b>R1415</b> Tarceva - NSCLC maint 1st line <b>R1415</b> Tarceva - adj. NSCLC <b>R1418+R435</b> Tarceva + Avastin - NSCLC maint 1st line <b>R1418+R435</b> Tarceva + Avastin - NSCLC met. line <b>DEN</b> Avastin - ovarian cancer 2nd line <b>DEN</b> Avastin - GSI recast <b>DEN</b> Avastin - ad. rectal cancer <b>DEN</b> Avastin - mCRC 2nd line <b>DEN</b> Avastin - N. chima. carcinoma	<b>CellCept</b> - periphidic vulgaris <b>MabThera</b> - RA DMARD in <b>Acetamin</b> - sHJ <b>metformin</b> - RA Sars & smpat <b>metformin</b> - LH <b>LD-71</b> - osteoporosis <b>MabThera</b> - acute hepatitis <b>MabThera</b> - HIV-1 p24 viral load <b>Yelaris</b> - pediatric asthma	<b>CTP (m)</b> - dyslipidemia <b>GLP-1</b> - type 2 diabetes	<b>NME</b> <b>Additional Indication</b> <b>DSA Oncology</b> <b>DSA Inflammation</b> <b>DSA Metabolic</b> <b>R-Na</b> Roche managed <b>GM</b> Genentech managed <b>CHU</b> Chugai managed

### Registration

<b>R346</b> Xeloda - mCRC combo 1st line <b>R435</b> Xeloda - mCRC combo 2nd line <b>R435</b> Avastin - RCC <b>R435</b> Avastin - mCRC 1st line (coastal) <b>R105</b> MabThera - CLL 1st line	<b>Avastin</b> - RA	Approved in EU US filed in CD 2008
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Status as of September 30, 2008

# Phase II projects on track to strengthen portfolio



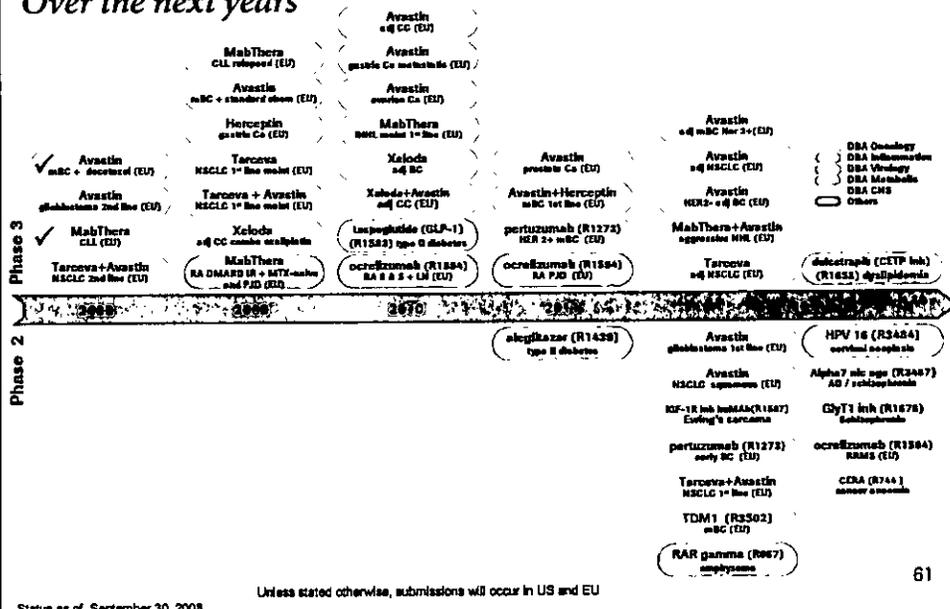
## Focusing on our five key therapeutic areas

### Key phase II projects

Oncology (8 NMEs + 8 AIs)	Inflammation (1 NME + 1 AI)	Metabolic, CNS & Urology (5 NMEs + 1 AI)	
<b>R435</b> Avastin - p. carcinoma <b>R435</b> Avastin - NSCLC maint 1st line <b>R435</b> Avastin - NSCLC met. line <b>R1278</b> pertuzumab - ESC HER2+ <b>R1278</b> pertuzumab - oral ch cancer <b>R1418+R435</b> Tarceva + Avastin - NSCLC 1st line <b>R1507</b> Ewing's sarcoma <b>R2602</b> CDV1 - mCRC <b>DEN</b> CD40 Ab - det. large B cell lymphoma <b>DEN</b> Apremilast - cancer <b>DEN</b> ApoLUTRAL - cancer <b>DEN</b> AGI-489 - solid tumors <b>DEN</b> Avastin - extensive CC/CJ <b>DEN</b> Avastin - mCRC 2nd line <b>DEN</b> Hedgehog antagonists - cancer <b>ARC</b> solid tumors	<b>RAJ</b> generic - emphysema <b>Raxson</b> - oral contraceptives	<b>alogliptin</b> - type 2 diabetes <b>DFP (D)</b> - type 2 diabetes <b>metformin</b> - PMS <b>schizosiphen</b> <b>Abkema</b> / schizosiphen <b>NPV16</b> - cervical neoplasia	<b>NME</b> <b>Additional Indication</b> <b>DSA Oncology</b> <b>DSA Inflammation</b> <b>DSA Metabolic</b> <b>DSA CNS</b> <b>R-Na</b> Roche managed <b>GM</b> Genentech managed <b>CHU</b> Chugai managed <b>ARC</b> ArQule spp-ly

# Major Roche managed projected submissions

Over the next years

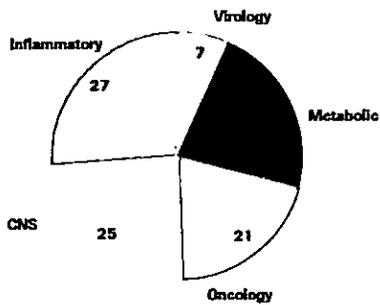


# Roche managed R&D pipeline - overview

Projects by Disease Biology Area (DBA)

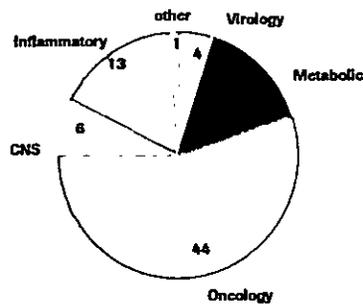


## Research



103 Projects

## Development



82 Projects  
Including 2 in phase 0



## YTD Sept '08: Diagnostics Division local sales By Region and Business Area (vs. 2007)

Sales CHF m	Global		North Am.		EMEA		RoW	
	% loc growth		% loc growth		% loc growth		% loc growth	
Professional Diag.	3,270	9	620	6	1,922	7	728	19
Diabetes Care	2,207	2	523	-8	1,358	4	326	12
Molecular Diagnostics	828	4	261	3	355	4	212	6
Applied Science	546	19	223	26	228	12	95	19
Tissue Diagnostics <sup>1</sup>	261	-	185	-	60	-	16	-
<b>Diagnostics Division</b>	<b>7,112</b>	<b>11</b>	<b>1,812</b>	<b>15</b>	<b>3,923</b>	<b>8</b>	<b>1,377</b>	<b>16</b>

<sup>1</sup> sales from beginning of February 2008

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## Diagnostics Division quarterly sales and local growth<sup>1</sup>

Sales CHF m	Q2 '07		Q3 '07		Q4 '07		Q1 '08		Q2 '08		Q3 '08	
	% loc		% loc		% loc		% loc		% loc		% loc	
Professional Diagnostics	1,093	8%	1,047	7%	1,137	10%	1,070	10%	1,113	9%	1,087	10%
Diabetes Care	789	3%	768	0%	904	7%	699	-3%	783	7%	725	0%
Molecular Diagnostics	296	-3%	282	-3%	292	1%	270	4%	281	3%	277	5%
Applied Science	165	12%	167	11%	194	15%	183	19%	184	23%	179	16%
Tissue Diagnostics							65	n.a.	99	n.a.	97	n.a.
<b>DIA Division</b>	<b>2,343</b>	<b>5%</b>	<b>2,264</b>	<b>4%</b>	<b>2,527</b>	<b>8%</b>	<b>2,287</b>	<b>8%</b>	<b>2,460</b>	<b>13%</b>	<b>2,365</b>	<b>11%</b>

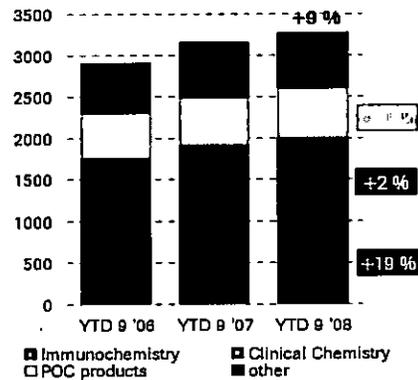
<sup>1</sup> 2007 vs. 2008 for Q2 to Q4 '07, 2008 vs. 2007 for Q1 to Q3 '08

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## Professional Diagnostics

*Immunochemistry continues driving the growth*

CHF m YTD Sept '08 vs. YTD Sept '07  
local growth



all growth in local currencies

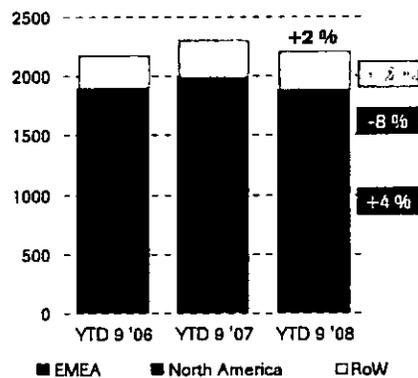
- cobas c 311 launched ex-US
  - Stand-alone clin. chem. analyser small labs (cobas 4000 series)
- Six new immunoassays continue roll-out in Europe
- Three assays received FDA approval:
  - anti-TSH receptor antibodies
  - Toxo IgG
  - anti-CCP immunoassay (RA)
- Accu-Chek Inform II launched ex-US
  - first wireless enable hospital blood glucose meter

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## Diabetes Care

*Strong growth in new products*

CHF m YTD Sept '08 vs. YTD Sept '07  
local growth



all growth in local currencies

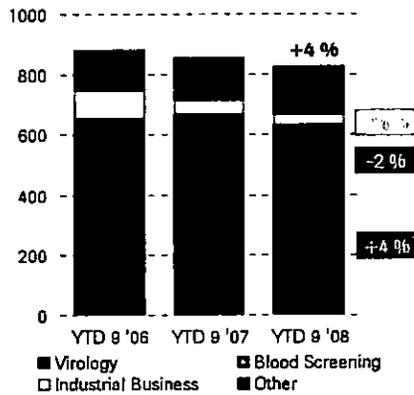
- Solid growth in Eastern Europe, Latin America and Japan
- Accu-Chek Aviva now top selling system with strong double-digit growth
- Roll-out of Accu-Chek Performa system and Accu-Chek Compact Plus meter continues in additional markets

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## Molecular Diagnostics

*Virology continues as mainstay of business*

CHF m YTD Sept '08 vs. YTD Sept '07  
local growth



all growth in local currencies

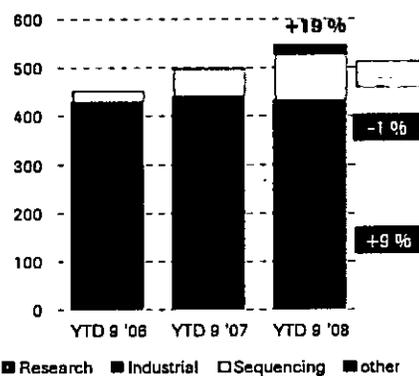
- Automated HBV viral load test received FDA approval
  - fully automated HCV viral load test & multiplex HIV/HCV/HBV blood screening test pending FDA review
- European & APAC countries transitioned to new COBAS TaqMan CT Test
- Amplicor HPV test received approval in Japan
  - recruitment on track for trial to support US registration of HPV tests

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## Applied Science

*Genomic portfolio driving growth*

CHF m YTD Sept '08 vs. YTD Sept '07  
local growth



all growth in local currencies

- Launch of GS FLX Titanium series, next generation sequencing products
  - increases read length 5 times
- NimbleGen SeqCap microarrays now available worldwide

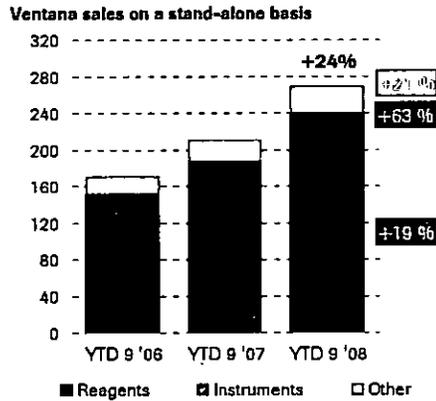
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## Tissue Diagnostics

### Integration on plan; maintained market out-performance

USD m YTD Sept '08 vs. YTD Sept '07 local growth



- BenchMark ULTRA launched globally
  - first continuous, random access system for both IHC & ISH
- System enhancements on Symphony staining platform accelerating placements, driving primary staining revenues
- VANTAGE workflow information solution roll-out continuing, entering new area of workflow solutions

all growth in local currencies

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## 2008: Key planned product launches\* (1)

Product	BA <sup>1</sup>	Indication	Region
<b>cobas 4000 analyzer series</b> - cobas c 311 analyzer	PD	Next generation system consolidating clinical chemistry and immunochemistry testing for small to medium workload laboratories; software links stand-alone cobas c 311 analyzer (clinical chemistry) & cobas e 411 analyzer (immunochemistry) modules with cobas p 242 data manager	Ex-US
<b>Accu-Chek Inform II system</b>	PD	First wireless enabled hospital blood glucose meter	Ex-US
<b>Immunochemistry menu</b>	PD	New assays for a number of important diagnostic uses: <ul style="list-style-type: none"> <li>• Elecsys Anti-HCV: Assay for the detection of hepatitis C infection</li> <li>• Elecsys anti-CCP (anti-cyclic citrullinated peptide antibody): Assay for the diagnosis of rheumatoid arthritis</li> <li>• IL-6 (Interleukin-6): Immunoassay to aid in management of critically ill patients as early indicator for acute inflammation and to monitor course of disease</li> <li>• Procalcitonin: immunoassay to aid in early detection and monitoring of sepsis</li> <li>• Elecsys Anti-CMV IgG and Anti-CMV IgM: For the detection of cytomegalovirus infection</li> </ul>	Global/ EU

<sup>1</sup> Business Areas: Professional Diagnostics (PD)

\* Subject to appropriate regulatory approvals; US launches may be later than indicated

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## 2008: Key planned product launches\* (2)

Product	BA <sup>1</sup>	Indication	Region
Cobas TaqMan 48 HBV Test	MD	Automated, real-time PCR test for monitoring hepatitis B viral load	US
Cobas AmpliPrep/ Cobas TaqMan HCV Test	MD	Real-time PCR quantification of HCV viral levels on fully automated Cobas AmpliPrep/Cobas TaqMan systems	US
cobas TaqScreen MPX Test	MD	Screens donated blood for major viruses (HIV-1, HIV-2, hepatitis B, and hepatitis C) in a single assay. Will run on automated cobas s 201 system in US and on automated, fully integrated cobas s 401 system in Japan	US, Japan
Cobas TaqMan 48 CT Test	MD	New version of an automated, real-time PCR test for Chlamydia trachomatis; also detects the new Swedish CT strain	EU
Accu-Chek Aviva Nano	DC	Enhanced portability by reduced size, combined with an attractive design and improved features	Global
GS FLX Titanium	AS	DNA sequencing kit enabling increased read lengths and higher throughputs per plate (454)	Global
xCELLigence	AS	Real time, label free cell analysis system	Global

<sup>1</sup> Business Areas: Applied Science (AS), Molecular Diagnostics (MD), Diabetes Care (DC)  
\* Subject to appropriate regulatory approvals; US launches may be later than indicated

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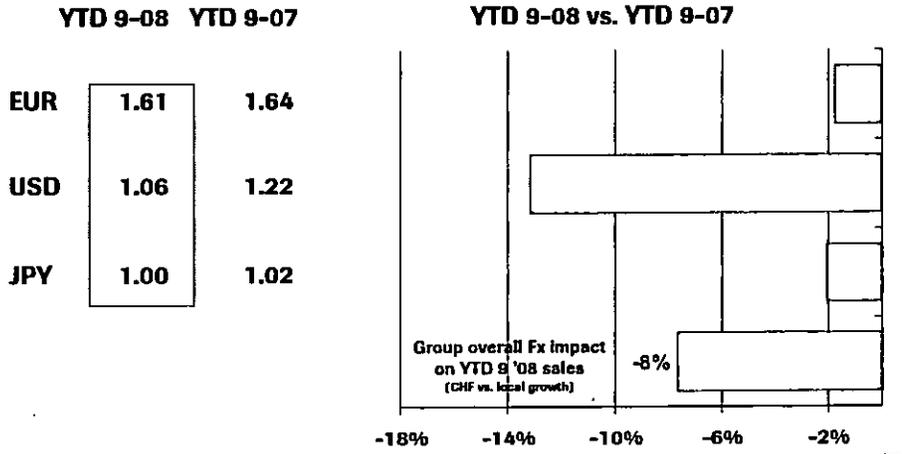
## 2008: Key planned product launches\* (3)

Product	BA <sup>1</sup>	Indication	Region
BenchMark™ ULTRA	TD	Continuous access, patient case-centric IHC/ISH staining system to enhance laboratory workflow	Global
CONFIRM® anti-EGFR (5B7) Primary Antibody	TD	Proprietary rabbit monoclonal antibody with potential applications as a Prognostic or Companion Diagnostic	Global
ultraVIEW™ Red ISH for two color Detection Kit	TD	Companion to the ultraVIEW™ SISH detection kit to provide single slide, two parameter detection	Global
VANTAGE™ Information Solution	TD	Workflow solution for productivity improvement through lean processes and positive sample tracking throughout the laboratory	US

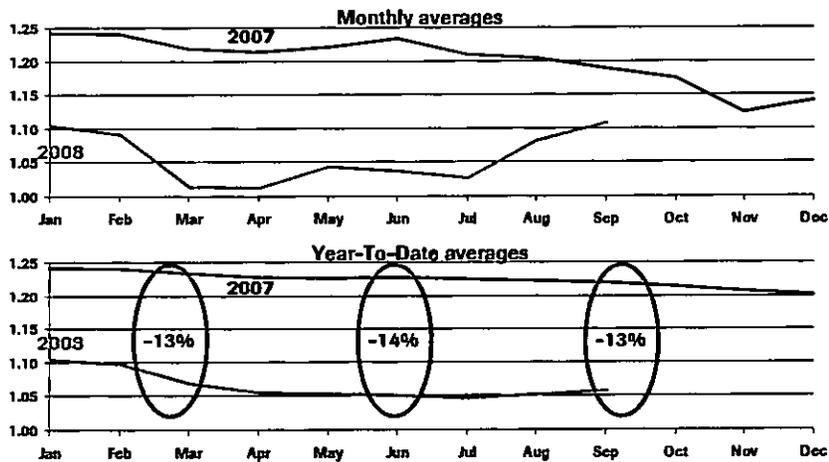
<sup>1</sup> Business Areas: Tissue Diagnostics (TD)  
\* Subject to appropriate regulatory approvals; US launches may be later than indicated

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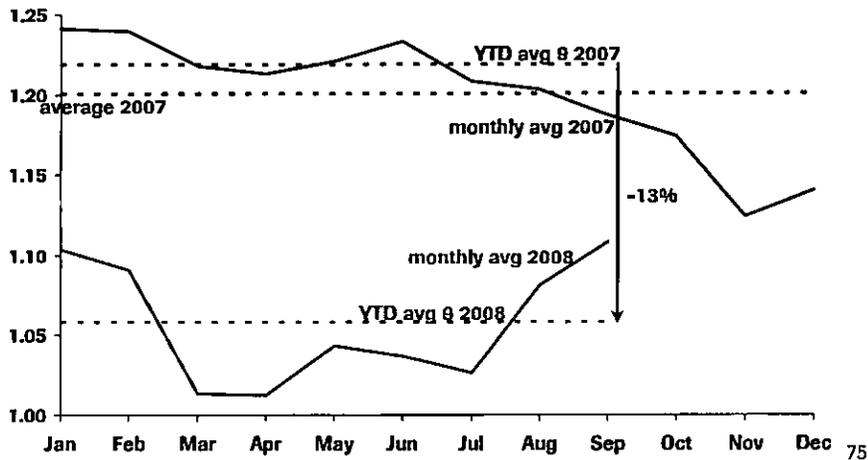
## 2008 vs. 2007: Substantial weakening of USD



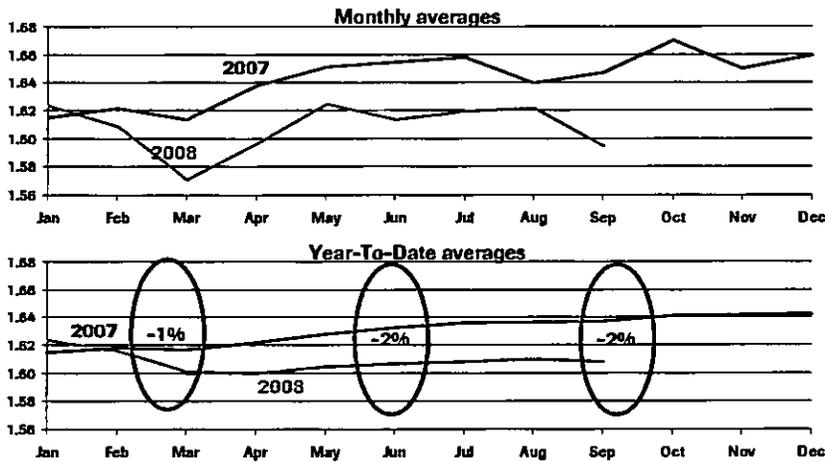
## 2008 and 2007 CHF / USD



### 2008 and 2007 Average monthly CHF / USD

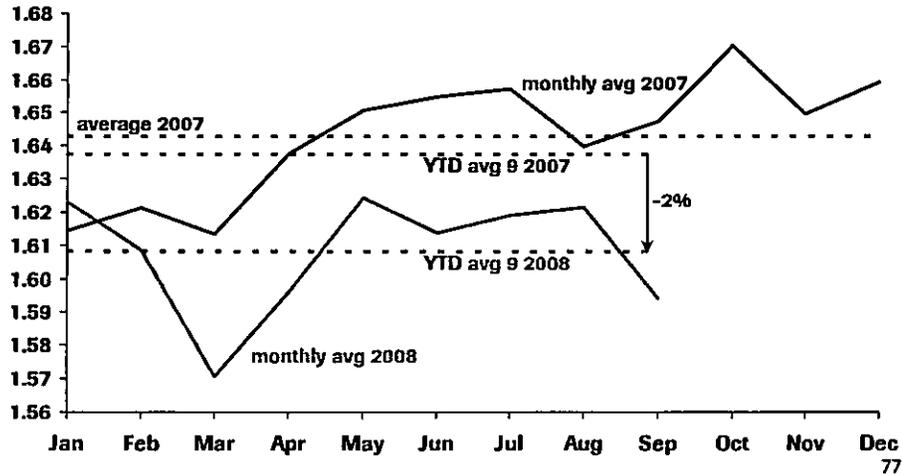


### 2008 and 2007 CHF / EUR





**2008 and 2007**  
Average monthly CHF / EUR

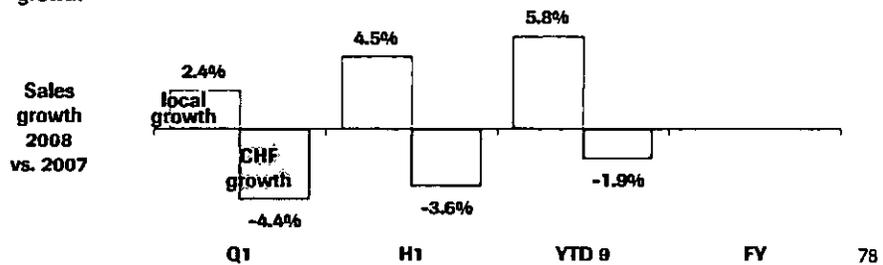


**Exchange rate impact on sales growth**  
*Significant negative impact from weaker USD*

Development of average exchange rates versus prior year period

CHF / EUR	-0.9%	-1.6%	-1.8%
CHF / USD	-13.3%	-14.5%	-13.2%
CHF / JPY	-1.8%	-2.2%	-2.1%

Difference in CHF / local growth	-6.8 %pt	-8.1 %pt	-7.7 %pt
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## Exchange rate impact on sales growth

*Significant negative impact from weaker USD*

### Development of

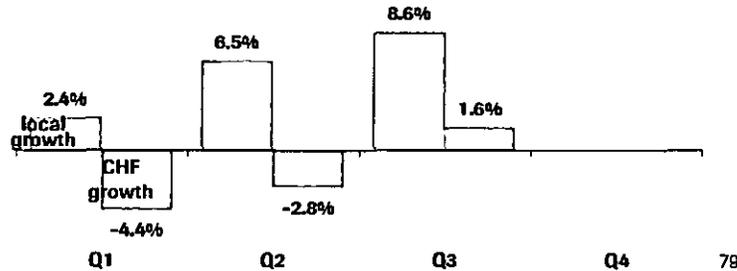
average exchange rates versus prior year period

CHF / EUR	-0.9%	-2.2%	-2.2%
CHF / USD	-13.3%	-15.7%	-10.6%
CHF / JPY	-1.8%	-2.6%	-2.1%

Difference  
in CHF / local  
growth

	-6.8 %pt	-9.3 %pt	-7.0 %pt
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Sales  
growth  
2008  
vs. 2007



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Name of listed company: Chugai Pharmaceutical Co., Ltd.  
Code number: 4519 (1<sup>st</sup> Section of Tokyo Stock Exchange)  
Head office: 1-1, Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo  
President & CEO: Osamu Nagayama  
Inquiries to: Mamoru Togashi, General Manager,  
Corporate Communications Dept.  
Tel: +81-(0)3-3273-0881

**RoACTEMRA<sup>®</sup>,  
a Humanized Anti-Human IL-6 Receptor Monoclonal Antibody,  
Receives Positive Opinion in Europe  
for the Treatment of Rheumatoid Arthritis**

November 25, 2008 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President Osamu Nagayama (hereafter, "Chugai")] and F. Hoffmann-La Roche Ltd. [Head Office: Basel, Switzerland. CEO: Severin Schwan (hereafter, "Roche")] announced that European Committee on Human Medicinal Products (CHMP) has given a positive recommendation for RoACTEMRA<sup>®</sup>, the humanized anti-human IL-6 (interleukin-6) receptor monoclonal antibody, filed with the European Medicines Evaluation Agency (EMA) in November 2007 as a treatment for moderate to severe rheumatoid arthritis (RA).

RoACTEMRA<sup>®</sup>, the first antibody drug (humanized monoclonal antibody) originating from Japan, was created by Chugai in collaboration with Osaka University, utilizing genetic recombinant technology to produce a monoclonal antibody against the anti-IL6 receptor. It works by inhibiting biological activity of IL-6 through competitively blocking the binding of IL-6 to its receptor.

Outside of Japan, five phase III clinical trials, including extension studies in RA are going on in 40 countries involving more than 4,000 patients worldwide under co-development between Chugai and Roche. The submissions were made to the EMA, based on results and extension studies from four out of five of these trials, and the interim analysis of the remaining ongoing trial. Upon approval in Europe, Chugai will co-promote with Roche in U.K., France and Germany, where Chugai already has its own sales bases.

In Japan, 200mg preparation of Actemra<sup>®</sup> was launched in June 2005 by Chugai, as the world's first treatment for Castleman's disease, following approval in April, the same year. Subsequently, it was approved for the additional indications of RA (including prevention of structural damage of joints), polyarticular-course juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis in April 2008. 80mg and 400mg preparations were launched additionally in June 2008.

RA is a systemic inflammatory disease in which the cause is unknown. The main symptoms are multiple joint inflammation and progressive joint damage. Millions of patients are suffering from the pain and debilitating effects of the disease in Europe. Chugai focuses on bone and joint diseases area as one of the strategic domains, and is committed to contribute to the treatment by providing new therapeutic options for medical professionals and patients.

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**Anti-malignancy agent / anti-VEGF  
humanised monoclonal antibody, Avastin<sup>®</sup>  
Application for Approval of Additional Indication of NSCLC**

November 26, 2008 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President Osamu Nagayama (hereafter, Chugai)] announced today that the company filed an application with the Japanese Ministry of Health, Labour and Welfare for the approval of an additional indication of non-small cell lung cancer (NSCLC) for the anti-malignancy agent / anti-VEGF\*<sup>1</sup> humanised monoclonal antibody, "AVASTIN I.V. Infusion 100mg/4mL and 400mg/16mL" [generic name: bevacizumab (Recombinant) for Infusion] (hereafter, Avastin<sup>®</sup>). Avastin<sup>®</sup> has been approved in Japan for the treatment of unresectable advanced or recurrent colorectal cancer. Avastin<sup>®</sup> is a novel drug that inhibits the growth of a network of blood vessels that supply nutrients and oxygen to cancerous tissue.

In pivotal phase III clinical trials conducted overseas in patients with previously untreated advanced or recurrent non-squamous NSCLC (E4599 and AVAiL), overall and/or progression-free survival of patients who received Avastin<sup>®</sup> in combination with standard platinum-based chemotherapy were significantly prolonged compared to patients given only chemotherapy. Based on these data, the drug has been approved for the first-line treatment of patients with advanced or recurrent non-squamous NSCLC outside Japan.

In Japan, NSCLC is the most frequent cause of deaths from cancer (ranked no.1 in male, no.2 in female) and the number of patients is increasing year by year. Chugai positions Oncology as one of its key therapeutic areas, and will work for the approval to offer medical practitioners and patients a new treatment option as soon as possible.

It is estimated that there will be approximately 99,000 patients with lung cancer in Japan in 2010\*<sup>2</sup>.

\*1: Vascular Endothelial Growth Factor

\*2: A. Oshima, T. Kuroishi, K. Tajima, Cancer White Paper - Incidence / Death / Prognosis - 2004, Shinoharashinsha Inc.

**About Avastin<sup>®</sup>**

Avastin<sup>®</sup> received approval for the treatment of metastatic colorectal cancer in the U.S. in February 2004 and is recommended as standard treatment in guidelines. Avastin<sup>®</sup> was approved as a first-line therapy for advanced non-squamous NSCLC in the U.S. in October 2006 and in Europe in August 2007.

In Japan, it received approval for unresectable advanced or recurrent colorectal cancer in April 2007. Chugai has promoted the proper use of Avastin<sup>®</sup> since launch by conducting a special drug-use results survey.

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President & CEO: Osamu Nagayama  
Inquiries to: Mamoru Togashi, General Manager,  
Corporate Communications Dept.  
Tel: +81-(0)3-3273-0881

## **Update on FDA Registration of Actemra<sup>®</sup>, a Humanized Anti-Human IL-6 Receptor Monoclonal Antibody for Rheumatoid Arthritis**

December 4, 2008 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President Osamu Nagayama (hereafter, "Chugai")] and F. Hoffmann-La Roche Ltd. [Head Office: Basel, Switzerland. CEO: Severin Schwan (hereafter "Roche")] announced today that the U.S. Food and Drug Administration (FDA) has provided further guidance on requirements for the Biologics License Application (BLA) for Actemra<sup>®</sup>, the humanized anti-human IL-6 (interleukin-6) receptor monoclonal antibody as a treatment for moderately to severely active rheumatoid arthritis (RA).

As a result of the FDA's evolving Risk Evaluation and Mitigation Strategy (REMS) requirements for medications, the Agency has clarified that a REMS plan is required to help ensure that health care professionals prescribe and administer Actemra<sup>®</sup> correctly, and that patients understand the potential benefits and risks associated with this medication. Additionally, based on the evolving requirements for approval of new biologics, the FDA has asked Roche for non-clinical animal model data, beyond what was included in the Actemra BLA. Roche is performing the requested pre-clinical studies to confirm the published literature suggesting that Actemra<sup>®</sup> does not affect peri- and post-natal development, and fertility. The FDA has not requested additional clinical studies prior to approval. The FDA Office of Compliance has also completed its evaluation of the manufacturing facility in Japan, and has indicated that it is acceptable to manufacture Actemra<sup>®</sup>.

The BLA was filed with the FDA in November 2007, and the FDA issued a Complete Response Letter in September, 2008. Since then, Roche has been engaged in productive discussions with the FDA and recently met with Agency representatives to receive clarification on the outstanding components of the Actemra BLA. The resubmission is anticipated to be made in the third quarter of 2009.

In EU, it is under review by the European Medicines Evaluation Agency (EMA), and the Committee on Human Medicinal Products (CHMP) has given a positive recommendation in November 2008. In Switzerland, the authorities approved RoACTEMRA<sup>®</sup> for the treatment of moderately severe to severe, active rheumatoid arthritis on December 3, 2008.

Name of listed company: **Chugai Pharmaceutical Co., Ltd.**  
Code number: 4519 (1<sup>st</sup> Section of Tokyo Stock Exchange)  
Head office: 1-1, Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo  
President: Osamu Nagayama  
Inquiries to: Mamoru Togashi, General Manager,  
Corporate Communications Dept.  
Tel: +81-(0)3-3273-0881

Name of listed company: **Taisho Pharmaceutical Co., Ltd.**  
Code number: 4535 (1<sup>st</sup> Section of Tokyo Stock Exchange)  
Head office: 24-1, Takada 3-Chome, Toshima-ku, Tokyo  
President: Akira Uehara  
Inquiries to: Masaki Tsuboi, General Manager,  
Public Relations Section  
Tel: +81-(0)3-3985-1115

### **Eldecalcitol, An Active Vitamin D<sub>3</sub> Derivative, Reduces Incidence of New Vertebral Fractures in Osteoporosis Patients in Phase III Clinical Trial**

December 16, 2008 (Tokyo) - Chugai Pharmaceutical Co., Ltd. ("Chugai") [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama] and Taisho Pharmaceutical Co., Ltd. ("Taisho") [Head Office: Toshima-ku, Tokyo; President: Akira Uehara], announced today that the active vitamin D<sub>3</sub> derivative being co-developed by the two companies for treatment of osteoporosis (generic name: eldecalcitol; Chugai development code: ED-71, Taisho development code: CT-081) significantly reduced the incidence of new vertebral fractures in osteoporosis patients in a randomized, double-blind, comparative trial. Detailed study results will be published in a medical journal and announced at a medical conference.

Eldecalcitol is an active vitamin D<sub>3</sub> derivative synthesized by Chugai. It is an agent with superior effect on bone compared to the existing active vitamin D<sub>3</sub> agent widely used in Japan. This phase III clinical trial, begun in 2004, was a randomized, double-blind, comparative study to compare the efficacy and safety of eldecalcitol with that of alfacalcidol\* in osteoporosis patients. A total of 1,087 patients were randomly allocated to receive a once-daily oral dose of either eldecalcitol or alfacalcidol, and the incidence of new vertebral fractures in both groups was monitored for a period of three years. As a result, patients receiving eldecalcitol showed a significantly lower incidence of bone fractures compared to those receiving alfacalcidol, indicating that eldecalcitol is superior in preventing fractures. The safety profile was similar to that of alfacalcidol, and nothing irregular was observed.

There are an estimated 12 million patients with osteoporosis in Japan. Treatments to increase bone density and quality and thus reduce the incidence of fractures are necessary since osteoporosis-related fractures reduce quality of life, rendering patients bedridden for example, and increase the risk of death. Chugai and Taisho hope that the new drug eldecalcitol will help as many patients with osteoporosis as possible.

Regulatory filing for eldecalcitol is planned for 2009 after the results of the trial have been collated.

\* Alfacalcidol is an active vitamin D<sub>3</sub> prodrug (Chugai brand name: Alfarol<sup>®</sup>) used in Japan to treat osteoporosis.

**Brief Description of Japanese Language Documents**  
**Designated in Exhibit A**

1. Commercial Register

A Commercial Register is administered by the Legal Affairs Bureau and containing information such as trade name, business purposes, number of authorized shares, location of head office, number of issued shares, amount of capital and names of representative directors, directors and statutory auditors.

[End]

END