Media Release

Basel, 2 February 2011

Solid overall results

Mid-single digit sales growth in local currencies excluding Tamiflu
Strong profit growth
Promising late stage pharmaceutical pipeline of twelve new molecular entities

Group

- Group sales increase 5% in local currencies, excluding Tamiflu; including Tamiflu, Group sales remain stable in local currencies at 47.5 billion Swiss francs.
- Growth momentum maintained throughout 4th quarter due to continued uptake for Actemra, Herceptin, MabThera and immunoassays.
- Core operating profit increases 7% in local currencies to 16.6 billion Swiss francs, core operating profit margin up by 1.7 percentage points to 34.9%; operating free cash flow of 14.1 billion Swiss francs underscores financial strength.
- Net income increases 4% to 8.9 billion Swiss francs despite significant costs in connection with the 'Operational Excellence' initiative.
- Core Earnings per Share 10% higher at constant exchange rates and 4% higher in Swiss francs.
- Implementation of Operational Excellence on track; Group-wide review of structures and processes aims to accelerate productivity improvements and strengthen innovation capacity; cost savings of 2.4 billion Swiss francs from 2012 onwards; restructuring charges of 2.7 billion Swiss francs, of which 1.3 billion Swiss francs were included in the 2010 operating results.
- Board proposes a dividend increase of 10% to 6.60 Swiss francs, the 24th consecutive year of dividend growth; this would increase the payout ratio to 52%.

Key figures	**In millions of CHF**		**% change**		**As % of sales**	
	2010	**2009**	**In CHF**	**In LC[1]**	**2010**	**2009**
Sales	47,473	49,051	-3	0		
Research and development	9,050	9,509	-5	-2	19.1	19.4
Core operating profit	16,591	16,272	+2	+7	34.9	33.2
Operating free cash flow	14,149	15,722	-10	-6	29.8	32.1
Net income attributable to Roche shareholders	8,666	7,784	+11			
Net income	8,891	8,510	+4		18.7	17.3
Core Earnings per share (CHF)	12.78	12.34	+4	+10		
Dividend per share[2] (CHF)	6.60	6.00	+10			

[1] LC= local currencies

[2] Dividend 2010 as proposed by the Board of Directors

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Pharmaceuticals

- Pharmaceuticals sales up 5% in local currencies, excluding Tamiflu, above the global market. Major growth drivers are key products for cancer, Actemra/RoActemra for rheumatoid arthritis and Lucentis in ophthalmology.
- Core operating profit margin increases significantly, by 1.9 percentage points to 39.9%.
- Late-stage development pipeline with twelve innovative new molecular entities, including six potential personalised healthcare medicines with planned companion diagnostic tests.
- Roche personalized investigational medicine RG7204 shows survival benefit in advanced skin cancer.
- Four new molecular entities moved into late-stage clinical development: lebrikizumab (asthma), MetMAb (lung cancer), RG 7128 (hepatitis C) and ocrelizumab (multiple sclerosis).
- Roche has made the decision to stop the development of taspoglutide for type 2 diabetes and to return the product to Ipsen.

Diagnostics

- Diagnostics sales increase 8% in local currencies to 10.4 billion Swiss francs, significantly ahead of the market, driven by Professional Diagnostics and Diabetes Care.
- Core operating profit margin up substantially, 3.8 percentage points to 21.1%.
- Fifty tests and instruments launched in key markets.
- cobas 8000 modular analyser series rolled out in US; new immunoassay module enables consolidation of serum work area for high-volume laboratories.
- ATHENA clinical trial demonstrates high medical value of cobas 4800 HPV test, which detects high-risk genotypes 16 and 18, in screening for cervical cancer.

Outlook

- Full-year 2011 sales for Pharmaceutical and the Group expected to grow at low single-digit rates in local currencies (excluding Tamiflu), in line with expected market growth.
- Diagnostics sales expected to grow significantly ahead of the market.
- Target of high single-digit Core Earnings per Share growth in 2011 at constant exchange rates.
- Planned dividend increase in line with Core Earnings per Share growth.
- Based on the strong operating free cash flow, Roche expects to reduce debt progressively and to return to a net cash position by 2015.

Barring unforeseen events.

Commenting on the Group's 2010 performance, Roche CEO Severin Schwan said: 'The Group results are solid despite an increasingly challenging market environment. Excluding Tamiflu the Pharma Division grew above the market. Diagnostics kept its strong momentum and grew significantly ahead of the market. The twelve innovative new molecular entities in our late-stage pharmaceutical pipeline form a strong basis for the company's future success. Six of these drug candidates are being developed for specific patient subpopulations with the aim to advance personalised healthcare in key therapeutic areas such as cancer and asthma.'

Group Results and Outlook

Overall results

The Roche Group posted solid overall results in 2010. Group sales were stable in local currencies at 47.5 billion Swiss francs (–3% in Swiss francs; 1% in US dollars). The good underlying growth of both divisions compensated for the expected decline in Tamiflu sales and the impacts of healthcare reforms and austerity measures. Excluding Tamiflu, sales increased by 5% in local currencies. The Pharmaceuticals Division represented 78% of Group sales and the Diagnostics Division contributed 22%.

Sales in the Pharmaceuticals Division declined by 2% in local currencies to 37.1 billion Swiss francs. Excluding Tamiflu, local growth was 5%, above market growth. Demand for the oncology drugs Avastin, MabThera/Rituxan, Herceptin, Xeloda and Tarceva continued to grow strongly. Additional major growth drivers were Actemra/RoActemra in rheumatoid arthritis, Mircera in anemia and Lucentis in ophthalmology. Actemra, which is now launched in some 50 countries including the United States, the EU and Japan, reached sales of 397 million Swiss francs in 2010. These positive factors compensated for most of the expected strong decline in Tamiflu sales, the reduction in CellCept sales due to US patent expiry in May 2009 and the impacts of the US healthcare reforms, European austerity measures and price cuts in Japan.

The Diagnostics Division increased sales to 10.4 billion Swiss francs in 2010, growing 8% in local currencies (4% in Swiss francs; 8% in US dollars), thereby strengthening its leading market position. Major drivers were Professional Diagnostics with 11% sales growth and Diabetes Care with 4% sales growth.

The Group's core operating profit increased by 7% in local currencies (2% in Swiss francs). The Pharmaceuticals Division increased its core operating profit by 4% in local currencies, driven primarily by cost synergies from the Genentech integration and productivity improvements. Core operating profit

growth in the Diagnostics Division was 30% in local currencies, mainly resulting from sales growth due to new product launches and the ongoing operational efficiency programmes. The Group's core operating profit margin increased by 1.7 percentage points to 34.9%, with the Pharmaceuticals Division improving by 1.9 percentage points to 39.9% and the Diagnostics Division by 3.8 percentage points to 21.1%.

In 2010 the Group's net income increased by 4% to 8.9 billion Swiss francs compared to 2009. Net income attributable to Roche shareholders rose 11% to 8.7 billion Swiss francs.

The Group's operating free cash flow remained strong at 14.1 billion Swiss francs. A free cash flow of 4.7 billion Swiss francs was achieved in 2010 despite higher interest, tax and dividend payments.

Of the debt raised in early 2009 to finance the Genentech transaction, 33% had already been repaid by 31 December 2010. In addition, the Group exercised its option to call for redemption a portion of the US dollar notes due 1 March 2014. Of the total principal amount of 2.75 billion US dollars, 1.0 billion US dollars will be redeemed in March 2011. The net debt position of the Group is 19.2 billion Swiss francs, a decrease of 4.7 billion Swiss francs from 31 December 2009.

Financial implications of Operational Excellence

On 17 November 2010 the Group announced implementation plans for its Operational Excellence programme, which is aimed at adapting cost structures to an increasingly challenging market environment and achieving significant efficiency and productivity gains. The initiative is expected to generate savings of 1.8 billion Swiss francs in 2011, with projected savings of 2.4 billion Swiss francs from 2012 onwards. Implementation is scheduled to be substantially completed by the end of 2012. During the period from 2010 through 2012 Roche expects to incur restructuring costs totalling 2.7 billion Swiss francs.

As a consequence of implementing the respective restructuring measures, significant costs were already incurred in 2010. The costs in 2010 of 1.3 billion Swiss francs mainly relate to severance payments and impairments of intangible assets. The Pharmaceuticals Division accounts for 1.2 billion Swiss francs of these costs, and 0.1 billion Swiss francs relate to the Diagnostics Division. Roughly 40% of the charges are non-cash, being mainly impairments of property, plant and equipment and intangible assets.

Outlook 2011

In 2011, Group and Pharmaceuticals sales (excluding Tamiflu) are expected to grow at low single-digit rates in local currencies, reflecting the impact of US healthcare reform and European austerity measures. Pharmaceuticals sales are thus expected to grow in line with the market.

In 2011, Diagnostics sales are again expected to grow significantly ahead of the market, driven by further rollout of new products in all business areas.

In spite of a more challenging environment and the introduction of an excise tax in the United States, Roche aims for Core Earnings per Share to grow at a high single-digit rate at constant exchange rates in 2011.

Roche aims to increase the dividend in line with Core Earnings per Share.

Based on the strong operating free cash flow, Roche expects to reduce debt progressively and to return to a net cash position by 2015.

Proposals to the Annual General Meeting 2011

The Board of Directors is proposing an increase of 10% in the dividend for 2010 to 6.60 Swiss francs per share and non-voting equity security (2009: 6.00 Swiss francs) for approval at the Annual General Meeting. This would be the 24th consecutive increase of the dividend and corresponds to an increase in payout ratio from 49% in 2009 to 52% for 2010.

Roche announced in December 2010 that Walter Frey and Wolfgang Ruttenstorfer will not stand for re-election to the Board of Directors. Paul Bulcke (CEO of Nestlé), Christoph Franz (chairman and CEO of Deutsche Lufthansa AG) and Peter Voser (CEO of Royal Dutch Shell plc) will be proposed for election to the Board of Directors at the 2011 Annual General Meeting.

Furthermore Roche will propose that the term of Board members will be reduced from three to two years.

Pharmaceuticals Division

Key figures				
	In millions of CHF	**% change in CHF**	**% change in local currencies**	**% of sales**
Sales	37,058	-5	-2	100
— United States	14,071	-5	-1	38
— Western Europe	9,467	-13	-5	25
— Japan	4,319	-9	-12	12
— International (Asia-Pacific, CEMAI[1], Latin America, Canada, Others)	9,201	7	8	25
Core operating profit	14,776	0	4	39.9
Operating free cash flow	12,933	-13	-9	34.9
Research and development (core basis)	8,160	-5	-2	22.0

1 CEMAI: Central and Eastern Europe, Middle East, Africa, Central Asia, Indian Subcontinent.

Sales by the Pharmaceuticals Division in 2010 declined 2% in local currencies (-5% in Swiss francs, -1% in US dollars) compared with 2009 to 37.1 billion Swiss francs. Excluding Tamiflu, the division's local-currency sales grew 5%, above the global market. In addition to the Group's five main cancer medicines, the primary sales drivers were Lucentis, Actemra/RoActemra and Mircera. Growth from these and other pharmaceuticals largely compensated for lower sales of Tamiflu, CellCept and NeoRecormon/ Epogin. Together, the top six sales drivers — Avastin, MabThera/Rituxan, Herceptin, Lucentis, Actemra/ RoActemra and Xeloda — contributed over 1.3 billion Swiss francs in additional sales in 2010. Due to the passing of the influenza A (H1N1) pandemic, a relatively mild influenza season and the completion of most government stockpiling orders, sales of Tamiflu declined strongly, to 873 million Swiss francs (2.3 billion francs lower than in 2009).

Sales expanded fastest in the International region (8%, or 11% excluding Tamiflu), driven by demand for MabThera, Herceptin, Avastin and other key medicines in emerging markets. Particularly strong growth was recorded in Latin America (20%), led by Brazil and Venezuela. Solid growth in the Asia–Pacific region (8%) was led by China and Taiwan. A slight decrease in the United States (-1%) reflects significantly lower sales of Tamiflu and CellCept, as well as healthcare reform impacts affecting all major products. A 5% decline in sales in Western Europe was due primarily to markedly lower sales of Tamiflu and NeoRecormon

and the effects of government austerity measures introduced in a number of countries, including Greece and Spain in the second quarter and Germany in the third quarter. Together, healthcare reforms in the United States and austerity measures in Europe had a negative impact on total sales of approximately 530 million Swiss francs or 1.5 percentage points. Excluding Tamiflu, sales in the US and Western Europe increased 4% and 2%, respectively, compared with market growth[1] of 3% and 2%. A decline in sales of 12% in Japan reflects both significantly lower demand for Tamiflu and the impact of revised National Health Insurance reimbursement prices that came into effect in April. Excluding Tamiflu, Japanese sales grew 3% in a virtually flat market.

Core operating profit grew 4% in local currencies and was stable in Swiss francs at 14.8 billion Swiss francs. The corresponding margin increased 1.9 percentage points to 39.9%, driven by synergies from the merger with Genentech and productivity improvements. This was achieved despite the expected sharp decline in Tamiflu sales and the impact of healthcare reforms and austerity measures. A reduction of 1% in marketing expenses was achieved through tight cost management, which more than covered an increase in allowances for bad debts in Southern Europe. Research and development expenses declined 2% versus 2009 thanks to resource prioritisation while securing long-term growth through the rich R&D pipeline. In addition to investments in phase III initiations, the metabolism franchise and the earlier-stage neurology portfolio, research and development expenses included costs associated with the discontinuation of the ocrelizumab rheumatoid arthritis programme and project termination costs associated with the Operational Excellence programme.

The division's full-year operating free cash flow remained strong at 12.9 billion Swiss francs. The decrease of 9% compared with 2009 primarily reflects the payment in 2010 of certain large 2009 year-end accruals, including employee retention and severance payments, and high royalty payments relating to strong Tamiflu sales in the second half of 2009. The Pharmaceuticals Division is on track to achieve its goal of pre-tax annual synergies from the Genentech merger of approximately 1 billion Swiss francs by 2011. Synergies of over 800 million Swiss francs were achieved in 2010.

1 Pharmaceutical market growth according to IMS (to end of September 2010)

Sales review - selected key products

	Total		United States		Western Europe		Japan		International	
	CHF m	%	CHF m	%	CHF m	%	CHF m	%	CHF m	%
Avastin	6,461	9%	3,190	0%	1,762	7%	625	51%	884	31%
MabThera/ Rituxan	6,356	9%	3,026	4%	1,639	8%	273	9%	1,418	20%
Herceptin	5,429	7%	1,591	6%	2,075	6%	300	-15%	1,463	18%
Pegasys	1,645	2%	389	0%	352	-4%	124	-6%	780	9%
Lucentis	1,458	27%	1,458	27%	-	-	-	-	-	-
Xeloda	1,426	17%	530	17%	305	6%	128	62%	463	17%
Tarceva	1,325	6%	523	5%	432	-1%	94	37%	276	16%
CellCept	1,290	-15%	275	-48%	451	-2%	61	16%	503	5%
NeoRecormon/ Epogin	1,285	-15%	-	-	474	-24%	476	-10%	335	-4%
Bonviva/Boniva	1,013	1%	526	-4%	293	5%	-	-	194	10%

Growth rates in local currencies.

Oncology

Global sales of **Avastin** (bevacizumab), for advanced colorectal, breast, lung and kidney cancer, and for relapsed glioblastoma (a type of brain tumour), rose 9% to 6.5 billion Swiss francs, reflecting continued positive uptake of the product overall. Sales growth in Western Europe (7%) was driven primarily by continued uptake for breast cancer and improved uptake for colorectal and lung cancer. Austerity measures introduced during the year in Greece, Spain, Germany and other markets resulted in a progressive flattening of growth in the region as a whole that was particularly noticeable in the fourth quarter. Sales in the US were flat for the year, reflecting reserve adjustments due to the healthcare reforms enacted in 2010 and regulatory and reimbursement uncertainty regarding the metastatic breast cancer indication; together these factors led to a decline in sales in the second half-year, especially the fourth quarter. Avastin maintained its high US market share in its metastatic colorectal and lung cancer indications. Very strong sales growth in Japan (51%) was driven by continued good uptake in colorectal and non-small cell lung cancer. Very strong growth was also recorded in Latin America (42%). In the third quarter Avastin was launched in China in its first indication, first-line treatment of metastatic colorectal cancer; initial uptake has been very encouraging.

In December the European and US health authorities announced decisions that are pivotal in determining

whether Avastin remains available as a treatment for metastatic breast cancer. Roche believes strongly that patients should have this option and are pleased that the European authorities continue to support the use of Avastin in this indication. It is disappointing that the US Food and Drug Administration (FDA) has come to a different conclusion after reviewing the same set of data. Roche believes that women with HER2-negative metastatic breast cancer living in the US should also have Avastin as a treatment option, and has requested a hearing with the FDA accordingly.

Full-year sales (oncology and autoimmune diseases) of **MabThera/Rituxan** (rituximab), for non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL) and rheumatoid arthritis (RA), totalled 6.4 billion Swiss francs in 2010, an increase of 9% versus 2009. Sustained growth in the oncology segment was driven by uptake in CLL and continued strong use in NHL in Western Europe and the US. Solid double-digit growth in the International region, including strong gains in key emerging markets, reflects uptake of the medicine in its NHL indications. The European rollout of MabThera in a new indication, first-line maintenance treatment of patients with follicular lymphoma, commenced in the fourth quarter. Estimated sales of MabThera/Rituxan in the RA segment reached the 1 billion Swiss franc mark in 2010 (16% of the product's total sales), 17% higher than in 2009. Growth is being driven by increased use in patients with an inadequate response to one or more tumour necrosis factor inhibitors and by growing acceptance of six-month repeat treatment intervals.

Global sales of **Herceptin** (trastuzumab), for HER2-positive breast cancer and HER2-positive metastatic stomach cancer, rose 7% to 5.4 billion Swiss francs on sustained, solid single-digit growth in the United States and Western Europe, and double-digit gains in the International region. Herceptin maintained its high market penetration in breast cancer, with sales also benefitting from initial uptake for stomach cancer in EU countries and other markets. In addition, improvements in the quality of HER2 testing are expanding the population of patients eligible for treatment with Herceptin. In Japan, where Herceptin has a market share of approximately 90% in its breast cancer indications, a stable sales volume and revised reimbursement prices from April resulted in a significant decline in sales revenue compared with 2009.

Xeloda (capecitabine), for colorectal, stomach and breast cancer, generated total sales of 1.4 billion Swiss francs, an increase of 17% compared with 2009. Growth was driven primarily by strong gains in the United States, Japan and China, the product's three largest markets. Global sales of Xeloda are benefitting from a number of new indications, including stomach cancer in China, an expanded metastatic colorectal cancer indication in Japan, and adjuvant[2] colon cancer in Europe, as well as increased patient share in metastatic breast cancer in the US and EU.

2 Adjuvant treatment is given after surgical removal of the tumour to lower the risk of relapse.

Sales of **Tarceva** (erlotinib), for advanced lung and pancreatic cancer, increased 6% to 1.3 billion Swiss francs, driven mainly by increased use in the second-line non-small cell lung cancer setting. The main contributions to growth came from the International region, Japan and the US. Mid-single-digit growth in the US reflects steady demand in the lung and pancreatic cancer indications and the impact of government healthcare reforms. Against a background of stable demand, sales in Western Europe declined slightly, mainly as a result of government-mandated price reductions and rebates in several major markets. Sustained strong sales growth in Japan (37%) reflects continued market penetration and oncologists' increasing confidence in the benefits of treatment with Tarceva.

Virology

Worldwide sales of **Pegasys** (peginterferon alfa-2a), for hepatitis B and C, increased 2% to 1.6 billion Swiss francs in 2010. Flat sales in the United States and sales decreases in Western Europe, Japan and certain other mature markets were offset by growth in the International region, especially Asia–Pacific and CEMAI[3] countries. The product's market share continued to expand in the main European markets, the US and Japan. Global sales continued to benefit from clinical data reinforcing the superiority of Pegasys over other treatment options and increased use in hepatitis B. The hepatitis C market is poised for major expansion, with the introduction of a new generation of direct-acting antiviral agents expected from 2011 onwards. Because Pegasys — the leading pegylated interferon — is used in most hepatitis treatment development programmes today, it is expected to become the backbone of future combination therapies with the new antivirals.

Following exceptional demand in 2009 due to the influenza A (H1N1) pandemic, sales of **Tamiflu** (oseltamivir), for influenza A and B, totalled 873 million Swiss francs in 2010, 73% (2.3 billion francs) lower than in 2009. With government stockpiling orders largely completed by early 2010 and the influenza A (H1N1) pandemic passing its peak, sales fell sharply in the last three quarters. Sales were also affected by relatively mild influenza seasons in both hemispheres during 2010. Roche remains ready to address potential threats posed by influenza and is maintaining production capacity in cooperation with external manufacturing partners to enable a rapid response to future significant outbreaks or government stockpiling orders.

3 CEMAI: Central and Eastern Europe, Middle East, Africa, Central Asia, Indian Subcontinent.

Ophthalmology

US sales of **Lucentis** (ranibizumab), for wet age-related macular degeneration and macular edema following retinal vein occlusion, rose 27% to 1.5 billion Swiss francs. Strong growth throughout 2010 was driven primarily by increases in the total number of patients receiving Lucentis and the time patients are on treatment. The US launch of Lucentis for the treatment of macular edema (swelling in the retina) following retinal vein occlusion began in late June, and initial uptake is encouraging.

Inflammation and autoimmune disorders

As the global rollout of the novel rheumatoid arthritis medicine **Actemra** (tocilizumab, known as RoActemra in the EU) continued, sales in 2010 totalled 397 million Swiss francs, a rise of 177% over 2009. Uptake of Actemra/RoActemra in the EU, the United States and other launch markets remains very encouraging. Around 60% of US rheumatologists have already prescribed the medicine. Continued strong sales growth in Japan reflects increasing use of Actemra as a first-line biologic. Chugai announced in August that the Japanese health authorities had removed the approval conditions for Actemra for the rheumatoid arthritis and polyarticular-course juvenile idiopathic arthritis indications. The decision gives more patients access to Actemra and follows positive results from a routine post-marketing surveillance programme. Actemra/RoActemra is now available in some 50 countries worldwide.

Anemia and transplantation

Sales of the renal anemia medication **Mircera** (methoxy polyethylene glycol-epoetin beta) rose 51% to 255 million Swiss francs. Demand for Mircera, which is now available in over 100 countries worldwide, is coming mainly from the predialysis segment and new patient commencements. Combined sales of the Group's established anemia medicines, Roche's **NeoRecormon** and Chugai's **Epogin** (epoetin beta), declined 15% to 1.3 billion Swiss francs. Roche Pharmaceuticals' overall share of the European anemia market remained stable despite increasing biosimilar competition, due mainly to the strong performance of Mircera in the major EU countries and a robust market share by volume for NeoRecormon in the renal indication. A 10% decline in sales of Epogin in Japan was due mainly to competition in the dialysis market and a lower National Health Insurance reimbursement price, factors which outweighed increased demand for the medicine in the predialysis segment.

At 1.3 billion Swiss francs for the full year, sales revenue from **CellCept** (mycophenolate mofetil), for the prevention of solid organ transplant rejection, remained significant. The sales decrease of 15% was due primarily to the loss of patent exclusivity in the United States in 2009. The resulting losses to competition

from generic versions were partly offset by sales growth in Japan and the International region.

Development highlights — key marketed products

Roche achieved important product development successes in 2010, including expanded marketing approvals for Actemra/RoActemra for rheumatoid arthritis in the US and the EU, Herceptin for stomach cancer (EU and US), MabThera/Rituxan for chronic lymphocytic leukemia (US) and maintenance treatment of follicular lymphoma (EU and, in January 2011, US), and Lucentis for macular edema following retinal vein occlusion (US). Key regulatory filings included marketing applications for Actemra/RoActemra for juvenile idiopathic arthritis in the EU and US, Herceptin for stomach cancer in Japan and Avastin for advanced ovarian cancer in the EU.

In 2010 the Pharmaceuticals Division filed 20 major new marketing applications and gained 18 major regulatory approvals. The following summaries present approvals, filings and major clinical trial results for key marketed products, by indication.

Major regulatory filings in 2010[1]

Product	Clinical data supporting filing	Indication and/or dosage form	Country
Actemra/ RoActemra	LITHE (2-year data)	rheumatoid arthritis, reduction or inhibition of progression of joint damage and improvement of physical function	USA
	ML21753	rheumatoid arthritis signs and symptoms, progressive joint damage	China (refiled)
	TENDER	systemic onset juvenile idiopathic arthritis	EU, USA
Avastin	RIBBON-2	metastatic breast cancer, second-line treatment	USA
	ICON-7, GOG 218	metastatic ovarian cancer	EU
Herceptin	ToGA	advanced HER2-positive gastric cancer	USA, China
Herceptin + Xeloda	ToGA	advanced HER2-positive gastric cancer	Japan
MabThera/ Rituxan	PRIMA	advanced follicular lymphoma, first-line maintenance following induction treatment with MabThera/Rituxan plus chemotherapy	EU, USA, Switzerland
	RAVE	ANCA-associated vasculitis	USA

Mircera	ML20680	renal anemia	China
	CORDATUS (NH20052)	correction of symptomatic anemia in adults with chronic kidney disease who do not yet need dialysis, once-monthly administration	EU, Switzerland
Tarceva	emerging data from clinical trials, ongoing clinical experience	metastatic non-small cell lung cancer with EGFR-activating mutations, first-line treatment	EU
Xeloda	NO16968 (XELOXA)	adjuvant colon cancer, combination with oxaliplatin	Switzerland
	data in the public domain	advanced or refractory gastric cancer in patients who are not candidates for curative surgery	Japan
	XELOX (NO16966)	metastatic colorectal cancer, combination with oxaliplatin	China (refiled)

Major regulatory approvals in 2010[1]

Product	**Clinical data supporting filing**	**Indication and/or dosage form**	**Country**
Actemra/ RoActemra	OPTION, TOWARD, RADIATE, AMBITION, LITHE (6-month data)	rheumatoid arthritis signs and symptoms	USA
	LITHE (2-year data)	rheumatoid arthritis, reduction or inhibition of progression of joint damage and improvement of physical function	EU, Switzerland, USA[2]
Avastin	AVF 2107, E3200, NO16966 (global); ARTIST (China)	metastatic colorectal cancer	China
Herceptin	ToGA	advanced HER2-positive gastric cancer	EU, USA, Switzerland
Lucentis	CRUISE, BRAVO	macular edema following retinal vein occlusion	USA
MabThera/Rituxan	CLL-8	first-line chronic lymphocytic leukemia	USA
	REACH	relapsed or refractory chronic	USA

		lymphocytic leukemia	
	PRIMA	advanced follicular lymphoma, first-line maintenance following induction treatment with MabThera/Rituxan plus chemotherapy	EU, Switzerland, USA[2]
	REFLEX	rheumatoid arthritis, inhibition of progression of joint damage and improvement of physical function	EU
Mircera	CORDATUS (NH20052)	correction of symptomatic anemia in adults with chronic kidney disease who do not yet need dialysis, once-monthly administration	EU, Switzerland
Tarceva	SATURN	non-small cell lung cancer, first-line maintenance after chemotherapy	USA, EU
Xeloda	NO16968 (XELOXA)	adjuvant colon cancer, combination with oxaliplatin	EU

1 Includes supplemental indications.
2 January 2011

Research and development

During the year Roche made decisions to move several projects into late-stage development, including ocrelizumab for multiple sclerosis, RG7128 for hepatitis C, lebrikizumab for asthma and RG3638 (MetMAb) for lung cancer. Positive results from clinical trials with other late-stage compounds such as RG7204 (BRAF inhibitor) for melanoma, RG7159 (GA101) for non-Hodgkin's lymphoma and chronic lymphocytic leukemia, and T–DM1 and pertuzumab for HER2-positive breast cancer were published or presented at major medical conferences during 2010. These targeted compounds are designed to move the standard of care for these diseases and improve patient survival. Roche's pharmaceutical pipeline currently includes 12 new molecular entities in late-stage development.

Two recent examples of the progress that Roche is making towards PHC in the development of therapies for difficult-to-treat diseases are RG3638 (MetMAb) for lung cancer and RG7204 (BRAF inhibitor) for malignant melanoma. Roche Diagnostics is developing diagnostic tests designed to guide appropriate use of both compounds in their target patient populations. Roche's research on antibody–drug conjugates as a means of treating cancer is another example of a highly targeted approach with the potential of improving outcomes while reducing the side effects of treatment. T–DM1, for HER2-positive breast cancer, is the most advanced of these projects.

At the beginning of 2011 the division's R&D pipeline included 102 projects in clinical development (phase I to III and filed for regulatory review). Of these, 62 involved new molecular entities (NMEs) and 40 involved additional indications. Twelve NMEs are in late-stage development. Twenty-two projects investigating additional indications for existing products are in phase III.

Twelve new molecular entities in ongoing or planned late-stage studies

Compound	Indication	Status	Expected first filing
RG7204 (BRAF inhibitor)	metastatic melanoma	phase III trial in first-line treatment met primary endpoints in January 2011	2011
RG3616 (hedgehog pathway inhibitor)	advanced basal cell carcinoma	pivotal phase II started in first quarter 2009	2011
pertuzumab	HER2-positive metastatic breast cancer, first line	phase III started in 2008	2011
trastuzumab–DM1	HER2-positive metastatic breast cancer, first and second line	phase III started in first quarter 2009	2012
RG7159 (GA101)	chronic lymphocytic leukemia, non-Hodgkin's lymphoma	phase III started in fourth quarter 2009 (chronic lymphocytic leukemia)	2013
dalcetrapib	dyslipidemia, cardiovascular high risk	phase III enrolment completed in second quarter 2010	2013
RG1678 (glycine reuptake inhibitor)	negative symptoms of schizophrenia, suboptimally controlled positive symptoms of schizophrenia	phase III started November 2010	2013
RG7128 (HCV polymerase inhibitor)	hepatitis C	LIP[1] decision made, preparing for phase III	2013
ocrelizumab	multiple sclerosis	phase III planned to start in first	post-2013

	(RRMS and PPMS)	quarter (PPMS) and second quarter (RRMS) 2011	
RG3638 (MetMAb)	solid tumours	LIP[1] decision made, preparing for phase III	post-2013
lebrikizumab	asthma	LIP[1] decision made, preparing for phase III	post-2013
aleglitazar	cardiovascular risk reduction in type 2 diabetes	phase III initiated in first quarter 2010	post-2013

1 Lifecycle investment point (decision to commence late-stage development leading to submission of marketing applications).

Discontinuation of taspoglutide programme

A decision to stop dosing of patients in the taspoglutide Phase III trials was taken in September 2010. This was based on higher than expected patient discontinuation rates, mainly due to gastrointestinal (GI) tolerability, observed in the T-emerge programme, and also resulting from the previously communicated risk mitigation plan to address serious hypersensitivity reactions.

After further extensive analysis, Roche has now made the decision to stop the development of taspoglutide and to return the product to Ipsen.

Diagnostics Division

Key figures				
	In millions of CHF	**% change in CHF**	**% change in local currencies**	**% of sales**
Sales	10,415	4	8	100
— Professional Diagnostics	4,858	7	11	47
— Diabetes Care	2,959	0	4	28
— Molecular Diagnostics	1,189	1	4	12
— Applied Science	868	0	4	8
— Tissue Diagnostics	541	13	17	5
Core operating profit	2,202	26	30	21.1
Operating free cash flow	1,634	42	48	15.7
Research and development (core basis)	890	-6	-2	8.6

In 2010 the Diagnostics Division recorded sales of 10.4 billion Swiss francs, an increase of 8% in local currencies over 2009[1] (4% in Swiss francs; 8% in US dollars). This was significantly above the estimated IVD market growth rate (5%)[2]. All five divisional business areas contributed to sales growth, led by Professional Diagnostics and Diabetes Care. Immunoassays and blood glucose monitoring systems remained these businesses' primary growth drivers. Strong demand for advanced tissue staining products continued to fuel above-market growth in Tissue Diagnostics. Virology was the main contributor to sustained sales growth in Molecular Diagnostics. Strong sales of cell analysis and genomics systems were Applied Science's main growth drivers. Instrument placements were again up significantly for the division as a whole and were a major growth driver in all segments.

1 Unless otherwise stated, all growth rates are in local currencies.
2 In-vitro-diagnostic (IVD) market growth based on company and independent reports (to end of September 2010).

Sales again outpaced the market in all regions. Growth was very strong in Asia-Pacific (20%) — particularly in China and South Korea — driven mainly by Professional Diagnostics. Despite pricing challenges, sales outperformed the market in both mature and emerging EMEA[3] economies (6%), helped by strong performances by Professional Diagnostics and Diabetes Care. Professional Diagnostics and Tissue Diagnostics were the primary growth drivers in North America (5%). In Japan (4%) overall divisional sales grew faster than the market with Professional Diagnostics' strong performance offsetting continuing challenges in Diabetes Care. Increased investment and strong demand for immunoassays and other leading-edge Roche products contributed to robust above-market growth in the E7 markets (21%)[4], which in 2010 accounted for almost 13% of total divisional revenues.

On a Swiss franc basis, the division's core operating profit for 2010 increased 26% (30% in local currencies) to 2,202 million Swiss francs, while the core operating profit margin advanced 3.8 percentage points to 21.1%. These increases largely reflect the strong performance of Roche's key diagnostic products as well as ongoing initiatives to improve operational excellence.

The division launched a total of 39 tests, which expanded the immunoassay menu in infectious diseases, extended the molecular test panel in virology and further strengthened the tissue assay portfolio in oncology. In addition, 11 instruments were launched in key markets facilitating maximum efficiency in state-of-the-art testing in clinical laboratories, research centres and point-of-care units. In 2011 the division plans to launch 18 key products, including the US introduction of Accu-Chek Combo for the management of blood glucose in diabetes, the cobas 4800 HPV Test for cervical cancer screening and the cobas 4800 BRAF Mutation Test in melanoma.

In 2010 Roche completed major acquisitions in Diabetes Care (Medingo Ltd.) and Tissue Diagnostics (BioImagene Inc.) and entered into a number of research and technology collaborations in Diabetes Care (with InterComponentWare), Molecular Diagnostics (with the German Cancer Research Centre) and Applied Science (with IBM and DNA Electronics). Moreover, the division signed over 80 licensing agreements, approximately half of them in-licensing IP to broaden Roche's innovation base.

3 EMEA = Europe, Middle East, Africa.
4 E7 countries = Brazil, Russia, India, China, South Korea, Mexico and Turkey

Professional Diagnostics

Professional Diagnostics' full-year sales grew about twice as fast as the global market, rising 11% to 4,858 million Swiss francs and outpacing market growth in all regions. Immunoassays were a key growth driver, with sales up 17% in 2010. For a decade this segment has consistently grown at double-digit rates, thanks to a strong installed base and an ever-expanding test menu. Sales of clinical chemistry and coagulation monitoring products grew 5% and 19%, respectively.

Diabetes Care

In 2010 Diabetes Care's sales rose 4% to 2,959 million Swiss francs. This was well above the global market growth rate in an environment that remains challenging due to the uncertain economic recovery and general price pressure. Sales of blood glucose monitoring systems (4%) were driven by Accu-Chek Aviva and Accu-Chek Performa, which showed strong double-digit growth, supported by strong market uptake of the sleek versions Accu-Chek Aviva Nano and Accu-Chek Performa Nano. The Accu-Chek Mobile also posted significant sales growth. In the EU maltose-independent strip chemistries for the Accu-Chek Aviva, Accu-Chek Performa, Accu-Chek Compact and Accu-Chek Mobile product lines received regulatory approval in June and were immediately rolled out. Insulin delivery systems posted double digit sales growth, driven mainly by continued strong uptake of the new interactive insulin pump system Accu-Chek Combo.

Molecular Diagnostics

Molecular Diagnostics continued its steady performance in 2010, with sales advancing 4% to 1,189 million Swiss francs. Growth was led by virology (2%), which currently accounts for about half of the business area's sales. Demand for the cobas 4800 system, launched in late 2009, was strong with the system now installed in 25 countries in Europe, Asia-Pacific, Latin America and Canada. Regionally, North America sales showed good growth, while sales held steady in the EU. Latin America and Asia-Pacific posted excellent double-digit growth. Strong contribution from the E7 markets was led by Russia and Mexico. Supported by the ATHENA results, Roche filed the HPV test in the US in June, with approval expected in the second half of 2011. This test received CE Mark certification in late 2009 and experienced a strong market uptake in CE markets throughout 2010.

Applied Science

Applied Science posted 4% growth on sales totalling 868 million Swiss francs. Growth drivers were the cell analysis segment (thanks to increased demand for solutions in oncology and stem cell research), genomics (formerly reported as sequencing and microarray businesses) and custom biotech (due to recovery of the global economy). Sales of the MagNA Pure and LightCycler product lines for sample preparation and quantitative PCR analysis declined due to dramatically lower demand for influenza A (H1N1) virus testing. All regions showed sales increases except Latin America, where the negative effect of decreased H1N1 testing was particularly pronounced. Sales in Asia-Pacific were exceptionally strong (15%), led by China and India.

Tissue Diagnostics

Tissue Diagnostics significantly outpaced the market in 2010, recording sales of 541 million Swiss francs, an increase of 17% compared to the year-earlier period. Advanced tissue staining — immunohistochemistry (IHC) and *in situ* hybridisation (ISH) — was the main growth driver (17%), reflecting strong reagent sales and robust uptake of the fully automated BenchMark ULTRA system for simultaneous IHC and ISH testing on a single platform. The business area performed strongly worldwide, growing two to four times as fast as the market in Europe, Latin America and Asia-Pacific. Sales in these regions benefited from intensified commercialisation efforts outside the US, synergies with Roche Pharmaceuticals in HER2 testing in breast and gastric cancer and the introduction of BenchMark GX at an economic price in emerging markets.

Research and development

Data from three clinical studies were presented at major scientific congresses: ATHENA, a large registration trial investigating the benefits of HPV testing in screening for cervical cancer, PROTECT, a randomised trial studying the NT-proBNP biomarker-guided approach in treatment of heart failure, and the STeP trial aiming at improvement of diabetes management through structured testing. All three trials demonstrated the high medical value of Roche diagnostic products.

In addition to the medical value of IVD tests applied in the clinic, diagnostics today play a number of critical roles in drug development, from identifying new therapeutic targets and screening out unpromising drug candidates to selecting appropriate patient populations for clinical trials. Some may also become companion diagnostics for patient selection, response prediction or therapeutic monitoring. Every drug under development at Roche has its own associated biomarker programme, and Diagnostics expertise and advice are made available for each of these programmes. In 2010 the Diagnostics and Pharmaceuticals

Divisions, including pRED, gRED, Pharma Medicines and Chugai, collaborated on more than 160 projects across all disease areas of interest at Roche. More than half of these projects were in oncology, followed by inflammation, CNS, virology and metabolic diseases. In addition, the Diagnostics Division collaborated with several other pharmaceutical companies to develop companion diagnostics for key biomarkers, particularly in oncology.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2010, Roche had over 80,000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

Additional information

- Media release including a full set of tables: www.roche.com/med-cor-2011-02-02
- Annual Report 2010: www.roche.com/annual_reports.htm
- Roche Pharmaceuticals pipeline: www.roche.com/pipeline.htm
- Roche Finance Info System: rofis.roche.com/dynasight/rofis.html
- Photographs of the media conference (as from 4:00 pm CET): http://download.roche.com/selection/20110202/

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Roche Group consolidated income statement for the year ended 31 December 2010 | in millions of CHF

	Pharma-ceuticals	Diagnostics	Corporate	Group
Sales	**37,058**	**10,415**		**47,473**
Royalties and other operating income	1,537	157		1,694
Cost of sales	(8,169)	(5,124)		(13,293)
Marketing and distribution	(6,964)	(2,524)		(9,488)
Research and development	(9,090)	(936)		(10,026)
General and administration	(2,071)	(409)	(394)	(2,874)
Operating profit	**12,301**	**1,579**	**(394)**	**13,486**
Associates				(3)
Financial income				557
Financing costs				(2,829)
Profit before taxes				**11,211**
Income taxes				(2,320)
Net income				**8,891**
Attributable to				
- Roche shareholders				8,666
- Non-controlling interests				225
Earnings per share and non-voting equity security				
Basic (CHF)				10.14
Diluted (CHF)				10.11

Core results reconciliation - 2010 | in millions of CHF

	IFRS	Global restructuring	Intangibles - amortisation	Intangibles - impairment	Alliances & Business combinations	Legal & environmental	Normalisation of ECP tax benefit	Core
Sales	47,473	-	-	-	-	-	-	47,473
Royalties and other operating income	1,694	-	-	-	-	-	-	1,694
Cost of sales	(13,293)	157	592	33	-	-	-	(12,511)
Marketing and distribution	(9,488)	317	4	-	-	-	-	(9,167)
Research and development	(10,026)	319	23	634	-	-	-	(9,050)
General and administration	(2,874)	722	-	-	5	299	-	(1,848)
Operating profit	13,486	1,515	619	667	5	299	-	16,591
Associates	(3)	-	-	-	-	-	-	(3)
Financial income	557	-	-	-	-	-	-	557
Financing costs	(2,829)	-	-	-	-	-	-	(2,829)
Profit before taxes	11,211	1,515	619	667	5	299	-	14,316
Income taxes	(2,320)	(398)	(207)	(185)	(1)	(107)	83	(3,135)
Net income	8,891	1,117	412	482	4	192	83	11,181
Attributable to								
- Roche shareholders	8,666	1,117	412	482	4	191	83	10,955
- Non-controlling interests	225	-	-	-	-	1	-	226
EPS	10.11	1.30	0.48	0.56	0.01	0.22	0.10	12.78

Divisional core results reconciliation - 2010 | in millions of CHF

	IFRS	Global restructuring	Intangibles - amortisation	Intangibles - impairment	Alliances & Business combinations	Legal & environmental	Core
Pharmaceuticals							
Sales	37,058	-	-	-	-	-	37,058
Royalties and other operating income	1,537	-	-	-	-	-	1,537
Cost of sales	(8,169)	66	156	-	-	-	(7,947)
Marketing and distribution	(6,964)	312	-	-	-	-	(6,652)
Research and development	(9,090)	277	19	634	-	-	(8,160)
General and administration	(2,071)	709	-	-	1	301	(1,060)
Operating profit	12,301	1,364	175	634	1	301	14,776
Diagnostics							
Sales	10,415	-	-	-	-	-	10,415
Royalties and other operating income	157	-	-	-	-	-	157
Cost of sales	(5,124)	91	436	33	-	-	(4,564)
Marketing and distribution	(2,524)	5	4	-	-	-	(2,515)
Research and development	(936)	42	4	-	-	-	(890)
General and administration	(409)	6	-	-	4	(2)	(401)
Operating profit	1,579	144	444	33	4	(2)	2,202
Corporate							
General and administration	(394)	7	-	-	-	-	(387)
Operating profit	(394)	7	-	-	-	-	(387)

Roche Group consolidated balance sheet | in millions of CHF

	31 December 2010	31 December 2009	31 December 2008
Non-current assets			
Property, plant and equipment	16,729	17,697	18,190
Goodwill	7,722	8,261	8,353
Intangible assets	5,133	6,005	7,121
Associates	13	16	9
Financial long-term assets	428	481	940
Other long-term assets	456	452	451
Deferred income tax assets	2,368	2,573	1,829
Post-employment benefit assets	559	601	592
Total non-current assets	33,408	36,086	37,485
Current assets			
Inventories	4,972	5,648	5,830
Accounts receivable	9,403	10,461	9,755
Current income tax assets	168	244	268
Other current assets	2,168	3,577	1,980
Marketable securities	9,060	16,107	15,856
Cash and cash equivalents	1,841	2,442	4,915
Total current assets	27,612	38,479	38,604
Total assets	61,020	74,565	76,089
Non-current liabilities			
Long-term debt	(27,857)	(36,143)	(2,972)
Deferred income tax liabilities	(885)	(1,099)	(1,409)
Post-employment benefit liabilities	(4,367)	(4,726)	(4,669)
Provisions	(934)	(700)	(654)
Other non-current liabilities	(337)	(416)	(459)
Total non-current liabilities	(34,380)	(43,084)	(10,163)
Current liabilities			
Short-term debt	(2,201)	(6,273)	(1,117)
Current income tax liabilities	(2,037)	(2,478)	(2,193)
Provisions	(2,146)	(1,618)	(804)
Accounts payable	(2,068)	(2,300)	(2,017)
Accrued and other current liabilities	(6,526)	(9,398)	(5,973)
Total current liabilities	(14,978)	(22,067)	(12,104)
Total liabilities	(49,358)	(65,151)	(22,267)
Total net assets	11,662	9,414	53,822
Equity			
Capital and reserves attributable to Roche shareholders	9,469	7,366	44,479
Equity attributable to non-controlling interests	2,193	2,048	9,343
Total equity	11,662	9,414	53,822

Roche Group consolidated statement of cash flows | in millions of CHF

	Year ended 31 December	
	2010	**2009**
Cash flows from operating activities		
Cash generated from operations	19,436	19,304
(Increase) decrease in working capital	(1,266)	349
Payments made for defined benefit post-employment plans	(334)	(467)
Utilisation of provisions	(729)	(709)
Disposal of products	30	169
Other operating cash flows	(6)	167
Cash flows from operating activities, before income taxes paid	17,131	18,813
Income taxes paid	(2,789)	(1,767)
Total cash flows from operating activities	14,342	17,046
Cash flows from investing activities		
Purchase of property, plant and equipment	(2,671)	(2,984)
Purchase of intangible assets	(339)	(235)
Disposal of property, plant and equipment	112	113
Disposal of intangible assets	-	3
Business combinations	(504)	(98)
Divestments of subsidiaries	-	15
Interest and dividends received	59	306
Sales of marketable securities	43,057	14,968
Purchases of marketable securities	(36,345)	(15,171)
Other investing cash flows	165	5
Total cash flows from investing activities	3,534	(3,078)
Cash flows from financing activities		
Proceeds from issue of bonds and notes	-	48,197
Redemption and repurchase of bonds and notes	(8,625)	(7,421)
Increase (decrease) in commercial paper	(86)	(261)
Increase (decrease) in other debt	(51)	(133)
Hedging and collateral arrangements	(1,717)	3,264
Change in ownership interest in subsidiaries		
- Genentech	-	(52,708)
- Memory	-	(6)
Equity contribution by non-controlling interests	14	-
Interest paid	(1,931)	(748)
Dividends paid	(5,265)	(4,395)
Genentech equity compensation plans	-	108
Equity-settled equity compensation plans, net of transactions in own equity instruments	(773)	(651)
Chugai share repurchases	-	(14)
Other financing cash flows	-	-

Total cash flows from financing activities	(18,434)	(14,768)
Net effect of currency translation on cash and cash equivalents	(43)	(1,673)
Increase (decrease) in cash and cash equivalents	(601)	(2,473)
Cash and cash equivalents at 1 January	**2,442**	4,915
Cash and cash equivalents at 31 December	**1,841**	2,442