

Basel, 4 February 2009

Strong operating results for Roche in 2008

Double-digit sales growth * – Core Earnings per share at constant exchange rates above 2007 level
– Dividend increase by 9% to 5.00 Swiss francs proposed

Group

- Roche reports strong results in a challenging market environment: Group sales up significantly, increasing by 10% in local currencies excluding Tamiflu pandemic sales.
- Strong organic growth of key products more than outweighs lower Tamiflu pandemic sales. Including Tamiflu pandemic sales, Group sales in local currency rise 6%.
- Operating profit exceeds last year's record by 4% in local currencies, reaching 13.9 billion Swiss francs despite increased level of R&D investment.
- Net income down by 5% in Swiss francs to 10.8 billion Swiss francs, primarily due to the strong Swiss franc, but also to lower net financial income.
- Core Earnings per share at constant exchange rates 2% above previous year's record level.

Pharmaceuticals

- Pharmaceuticals sales advance 10% * — twice the global market growth rate. This is the sixth double-digit increase in as many years.
- Oncology product sales grow by 15% to 19.7 billion Swiss francs. For the first time, three cancer products achieve sales of over 5 billion Swiss francs.
- Operating profit margin increases by 0.7 percentage points to 36.2% despite significantly lower Tamiflu pandemic sales and increased investments in the development pipeline.
- Avastin receives accelerated approval for breast cancer in US; applications for approval in brain cancer filed in US and EU.
- Actemra/RoActemra approved for rheumatoid arthritis in Japan, EU and Switzerland; additional data will be submitted to US FDA in 2009.
- Twelve major phase III programmes initiated.
- Acquisitions of Piramed, Mirus and ARIUS significantly strengthen R&D pipeline with new compounds and technology platforms.

Diagnostics

- Divisional sales show double-digit growth, rising 10%.
- Operating profit margin declines 5.3 percentage points to 12.3%, mostly due to acquisition impacts and strong competition in the US diabetes care market.
- Integration of Tissue Diagnostics (Ventana) completed; the new business's performance exceeds expectations.

Outlook

- Above-market sales growth in both divisions.
- Mid-single-digit sales growth for both divisions and Group.
- Core Earnings per share target to remain at the high level of 2008 in spite of increased investments in research and development and expected lower net financial result.**

Barring unforeseen events.

Unless otherwise stated, all growth rates are in local currencies.

*Excluding Tamiflu pandemic sales.

**Core Earnings per share target is based on constant exchange rates.

Severin Schwan, CEO of Roche, on the Group's 2008 results: "Roche continued the positive trend of recent years. Once more sales by both the Pharmaceuticals and Diagnostics Divisions grew considerably faster than the market. Core Earnings per share in local currencies also rose again." Speaking of Roche's future strategic direction, Schwan said: "In these times of economic upheaval it is more important than ever that we adhere rigorously to our strategy. We will continue to focus on our core pharmaceuticals and diagnostics businesses. Our aim remains to offer patients ever better treatments that are tailored to their condition."

Roche Group

Marked sales increase in a challenging market environment

Key figures	In millions of CHF		% change		As % of sales	
	2008	2007	In CHF	In local currencies	2008	2007
Sales	45,617	46,133	-1	+6	100.0	100.0
Research and development	8,845	8,385	+5	+13	19.4	18.2
Operating profit	13,924	14,468	-4	+4	30.5	31.4
Net income	10,844	11,437	-5		23.8	24.8

	2008	2007	% change
Equity ratio (in %)	70.7	68.2	
Core Earnings per share (in CHF)	11.04	11.85	-7 (CHF) +2 (local currencies)
Dividend per share * (in CHF)	5.00	4.60	+9
Number of employees (at 31 Dec.)	80,080	78,604	+2

* 2008: As proposed by the Board of Directors

In 2008, the Group continued its strong sales performance. Total sales grew by 6% in local currencies (-1% in Swiss francs; 10% in US dollars) to 45.6 billion Swiss francs, with the Pharmaceuticals Division representing 79% of Group sales and the Diagnostics Division contributing 21%. The sales increase in the underlying business more than compensated for the anticipated decline in Tamiflu pandemic sales of 1.6 billion Swiss francs. Local currency sales growth excluding Tamiflu pandemic sales was 10%. Both

the Pharmaceuticals and Diagnostics Divisions grew well ahead of their respective markets.

Demand for the Group's oncology drugs Avastin, MabThera/Rituxan, Herceptin, Tarceva and Xeloda continued to be strong. Additional growth drivers in the Pharmaceuticals Division were Bonviva/Boniva in metabolism/bone and CellCept in transplantation. In the Diagnostics Division the main growth areas were Professional Diagnostics and Applied Science, with both business areas growing well ahead of their respective markets. Following the acquisition of Ventana at the beginning of February 2008, sales in the Tissue Diagnostics business grew significantly faster than the market, contributing 4 percentage points to local currency sales growth of the Diagnostics Division.

Significant increase in operating free cash flow

The Group's operating profit increased by 4% in local currencies to 13.9 billion Swiss francs. The operating profit margin declined slightly by 0.9 percentage points to 30.5% due to a margin reduction in the Diagnostics Division of 5.3 percentage points. The main reason being the impact of recent acquisitions, strong competition in the US diabetes care market and portfolio mix effects. The Pharmaceuticals margin improved by 0.7 percentage points to 36.2% despite significantly lower Tamiflu pandemic sales and increased investments in the strong development pipeline. Operating free cash flow increased by 16% to 12.4 billion Swiss francs despite significant currency translation effects.

Strong balance sheet

The financial crisis had only a minimal adverse effect on net financial income due to the conservative investment approach with limited exposure to equity securities. In 2008, net financial income reached 0.2 billion Swiss francs. The reduction of 0.6 billion Swiss francs compared with 2007 is primarily due to lower interest income resulting from lower liquid funds and reductions in interest rates. Due to the strong Swiss franc and the lower net financial income, group net income decreased by 5% to 10.8 billion Swiss francs. Core EPS increased by 2% in local currencies to 11.04 Swiss francs. The Group continues to have a strong balance sheet, also when compared internationally, with equity (including non-controlling interests) representing 71% of total assets and 84% of total assets financed long-term.

Outlook

Barring unforeseen events, the Roche Group expects to continue to perform strongly in 2009. Full-year sales in both the Pharmaceuticals and the Diagnostics Division are expected to grow ahead of the market, with increases in the mid-single-digit range in local currencies. Roche will continue to invest in the large-scale confirmatory clinical trials that are vital to the Group's long-term success. Despite the higher research and development costs involved and the expected lower net financial result, the Group is aiming for Core Earnings per share (Core EPS) at constant exchange rates to remain at the same high level as in

2008. Following the proposed purchase of the outstanding Genentech shares, Roche expects that the transaction will have a positive impact on Core EPS within the first year after closing. Roche will update its targets once the transaction has been closed.

22nd dividend increase in a row

In view of Roche's latest excellent results, the Board of Directors will propose that the dividend for 2008 be increased by 9% to 5.00 Swiss francs per share and non-voting equity security (up from 4.60 Swiss francs for 2007). Subject to approval at the next Annual General Meeting of Shareholders, this will be Roche's 22nd consecutive annual dividend increase.

Pharmaceuticals Division

Significant sales growth driven primarily by key products

Key figures	In millions of CHF	% change in CHF	% change in local currencies	As % of sales
Sales	35,961	-2	+5	100
- Roche Pharmaceuticals	22,164	-4	+3	62
- Genentech	10,461	0	+11	29
- Chugai	3,336	-2	-4	9
Operating profit	13,002	0	+8	36.2
Operating free cash flow	12,053	+20	+31	33.5
Research and development	7,904	+4	+11	22.0

The Pharmaceuticals Division maintained its strong performance throughout 2008, with solid growth of the underlying business more than compensating for the expected sharp decline in pandemic sales of Tamiflu to governments and corporations. Divisional sales increased 5% in local currencies (-2% in Swiss francs; 8% in US dollars) to 36.0 billion Swiss francs.¹ Excluding pandemic sales of Tamiflu, pharmaceutical sales grew 10% in local currencies, or around twice the global market growth rate – the sixth double-digit increase in as many years. Growth was driven primarily by key products in the division's oncology, inflammation and transplant, virology and metabolism/bone portfolios. On the same basis, the division recorded above-market growth in all key regions. The division's sales performance is broadly based: in 2008 nine products generated annual turnover of more than 1 billion Swiss francs each, three of which achieved sales of over 5 billion francs each.

In 2008, the Pharmaceuticals Division's operating profit advanced even faster than sales, rising 8% in local currencies (0% in Swiss francs) to 13.0 billion Swiss francs. The corresponding margin increased 0.7

¹ Unless otherwise stated, all growth rates are in local currencies

percentage points to 36.2% compared with 2007 despite significantly lower Tamiflu pandemic sales and increased investments in research and development.

Oncology – key medicines post sustained double-digit growth

In 2008 Roche continued to strengthen its position as the world's leading supplier of medicines to treat cancer. Sales of the Pharmaceuticals Division's oncology portfolio rose 15% to 19.7 billion Swiss francs for the year, or 55% of total pharmaceutical sales, with all key brands contributing double-digit growth. Just as importantly, the Group advanced key development programmes and filed marketing applications aimed at making more effective treatment options available to doctors and cancer patients or expanding the range of conditions for which innovative medicines such as MabThera/Rituxan, Avastin, Herceptin, Tarceva and Xeloda can be prescribed.

In 2008 combined sales of **MabThera/Rituxan** (rituximab) in the oncology and inflammation/autoimmune segments grew 16% versus the prior-year period to 5.9 billion Swiss francs. Strong to solid growth was recorded in Europe/Rest of World (RoW)² (19%), the US (14%) and Japan (10%). Growth in oncology is being driven by sustained expansion in the use of MabThera/Rituxan for induction and maintenance therapy of non-Hodgkin's lymphoma and improved access in emerging markets for all approved indications.

During the year Roche and its partners, Genentech and Biogen Idec, achieved important milestones in the ongoing development of MabThera/Rituxan. In January Roche announced results of a major phase III trial (CLL8) of MabThera as first-line treatment for chronic lymphocytic leukemia (CLL). The study showed that combined treatment with MabThera and the current standard chemotherapy achieved significantly better outcomes than chemotherapy alone. Roche used these data to support an application, filed in July, to add this new indication to the medicine's EU marketing authorisation. In January 2009 the EU's Committee for Medicinal Products for Human Use (CHMP) recommended approval of MabThera in this indication. In December Roche received approval in Switzerland for MabThera as initial (first-line) treatment in certain patients with CLL.

In October a study of MabThera/Rituxan in patients with relapsed or refractory CLL (REACH) met its primary endpoint, demonstrating that patients treated with MabThera combined with the current standard chemotherapy showed a significant improvement in progression-free survival (the time patients live without their cancer getting worse) compared with those who received chemotherapy alone. These data formed the basis for a regulatory filing in the EU for this indication, submitted by Roche in

² Roche defines Europe/Rest of World as covering Europe and all other countries except Japan and the United States.

January 2009. The results of CLL8 and REACH were presented at the American Society of Hematology annual meeting in December. Genentech and Biogen Idec are evaluating the data from both trials and expect to submit supplementary Biologic License Applications for these indications in the US by the third quarter of 2009.

Global sales of **Avastin** (bevacizumab) rose strongly throughout 2008, advancing 37% to 5.2 billion Swiss francs, with all key regions contributing. Dynamic sales growth in Europe/RoW (67%) was driven primarily by increased use of the medicine for metastatic colorectal and breast cancer. Sales in Europe also benefited from the rollout of new indications and increasing uptake for non-small cell lung cancer (NSCLC) and renal cell carcinoma. In the United States solid double-digit growth continued (17%), driven primarily by increased use in metastatic non-small cell lung and metastatic breast cancer following accelerated approval by the US Food and Drug Administration (FDA). In Japan, where Avastin is approved for metastatic colorectal cancer, sales continue to grow strongly.

Avastin received additional regulatory approvals in key markets during the year. In January, the EU authorities approved an extension of the product's metastatic colorectal cancer indication, permitting the combination of Avastin with the most commonly used chemotherapy regimens in all lines of treatment. As a result, virtually all patients with metastatic colorectal cancer can now have access to the proven survival benefits of Avastin. In February, Genentech received accelerated approval from the FDA for Avastin, in combination with paclitaxel chemotherapy, for the first-line treatment of patients with HER2-negative metastatic breast cancer.

In July Roche filed an application to expand and update the current EU approval for Avastin in metastatic breast cancer with final data from the AVADO study, which were also presented at the 2008 meeting of the American Society of Clinical Oncology (ASCO) in June. This phase III clinical study confirmed the results of an earlier trial (E2100), showing that Avastin combined with taxane chemotherapy significantly improves progression-free survival in this setting. In September, Genentech filed a supplementary application with the FDA for approval of Avastin in combination with interferon alfa to treat advanced renal cell carcinoma. In November, Genentech also applied for US approval of the medicine as monotherapy for people with previously treated (relapsed) glioblastoma, the most aggressive form of brain tumour, based on positive results from a phase II clinical trial (BRAIN). Roche applied for EU approval of Avastin alone and combined with chemotherapy for the same indication in December. In November, Chugai filed a supplementary application in Japan for expansion of the product's marketing approval to include non-small cell lung cancer.

Other important clinical data on the benefits of Avastin in breast and lung cancer were published during the year. In November, Roche announced that a phase III trial (RIBBON-1) investigating Avastin in first-line metastatic HER2-negative breast cancer in combination with commonly used chemotherapies, met its primary endpoint of increasing the time women with breast cancer lived without their disease advancing (progression-free survival) compared with chemotherapy alone. After AVADO and E2100, RIBBON-1 is the third study to confirm the benefit of Avastin combined with chemotherapy for women with metastatic breast cancer. In October Roche announced the first results from a phase III study (BeTa Lung) investigating the use of Avastin plus Tarceva for the second-line treatment of patients with advanced NSCLC. While the combination did not meet the primary endpoint of overall survival, there was clear evidence of clinical activity, with improvements in the secondary endpoints of progression-free survival and response rate when Tarceva was added to Avastin.

Herceptin (trastuzumab) posted solid double-digit sales growth (12%) throughout 2008, for a total of 5.1 billion Swiss francs. Growth was especially strong in Japan (47%) due to continuing uptake after approval of Herceptin for early breast cancer in February. Solid single-digit growth was recorded in the United States (7%), while double-digit gains were achieved in Europe/RoW (13%). The main contributions to growth in the latter region came from the CEMAI³ countries and key emerging markets. More modest growth in the US and Western Europe reflects the product's high market penetration in these regions, particularly in the early breast cancer setting. Adoption of Herceptin for metastatic breast cancer remained stable. In January, the FDA approved the use of Herceptin as a single agent for the adjuvant treatment of HER2-positive breast cancer following multimodality anthracycline-based therapy. In May, Genentech received FDA approval for a supplemental regimen for adjuvant HER2-positive breast cancer combining Herceptin with docetaxel and carboplatin chemotherapy. This combination has been shown to reduce the rate of heart problems observed when Herceptin is given with anthracycline-containing regimens, thereby potentially allowing more patients to benefit from Herceptin.

The final analysis of a phase III trial (GBG-26), presented at ASCO 2008 in June, confirmed that Herceptin helps women with metastatic HER2-positive breast cancer live longer without their cancer progressing (progression-free survival). The results also showed that Herceptin continued to be effective in women who needed additional treatment after their cancer progressed during previous Herceptin treatment. Results of the GeparQuattro and NOAH trials presented at medical conferences in April and December respectively, showed that Herceptin, given in combination with standard chemotherapy before surgery (known as neoadjuvant therapy), helps shrink locally advanced tumours, enabling breast-

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

conserving surgery and improving long-term outcomes. Final analysis of the NOAH data showed that adding Herceptin to chemotherapy eradicated the tumour in nearly twice as many patients as treatment with chemotherapy alone.

Sales of Tarceva (erlotinib) continued to increase strongly in 2008, growing 23% to 1.2 billion Swiss francs overall, with the main contributions coming from Western Europe and the Asia–Pacific region. Market uptake is particularly strong in Japan and China. Market penetration in Western Europe also continued to expand strongly, while double-digit sales growth was maintained in the United States. Expanding uptake in all regions reflects doctors' growing experience with and confidence in the product. In November the UK's National Institute for Health and Clinical Excellence (NICE) issued final guidance for Tarceva as an alternative to docetaxel chemotherapy for the second-line treatment of NSCLC, opening the way for reimbursement by the National Health Service.

New data from the phase II FAST-ACT trial, presented at the 2008 ASCO and European Society for Medical Oncology meetings, showed that first-line treatment with Tarceva alternating with chemotherapy and followed by Tarceva maintenance therapy significantly improved progression-free survival in Asian patients with advanced NSCLC compared with chemotherapy alone, irrespective of tumour type or mutation status. In November, Roche announced that the phase III SATURN study had met its primary endpoint, demonstrating that first-line maintenance treatment with Tarceva (given immediately following initial treatment with platinum-based chemotherapy) significantly extended progression-free survival for patients with advanced NSCLC. The results show for the first time that earlier treatment with Tarceva delays lung cancer progression. Roche will discuss the data with regulatory agencies and plans to submit a marketing application for this new indication. OSI Pharmaceuticals, in collaboration with Genentech and Roche, expects to submit a supplemental New Drug Application to the US FDA in the first half of 2009 based on the SATURN data.

Xeloda (capecitabine) recorded sustained double-digit sales growth throughout 2008 with sales increasing 13% to 1.2 billion Swiss francs. Growth in Japan was particularly strong (74%), and solid increases were also achieved in the United States (9%) and Europe/RoW (14%). Sales were driven by expanded indications approved in 2007 and 2008, notably stomach cancer and advanced colorectal cancer, along with continued uptake in breast cancer. Growth is also being helped by new clinical data and reimbursement approvals, as combination regimens with Xeloda gain acceptance as standard therapy in these indications. Xeloda is generating strong double-digit sales growth in China following approval there in September for advanced stomach cancer. In February, the EU authorities approved Xeloda for the treatment of metastatic colorectal cancer in combination with any chemotherapy in all lines of treatment, with or without Avastin. This approval provides new treatment options for the large

number of patients with metastatic disease. Also in February, Chugai filed an application in Japan to expand the product's approval to allow its combination with oxaliplatin chemotherapy, with or without Avastin, for the treatment of metastatic colorectal cancer.

Transplantation – CellCept continues to expand market share

CellCept (mycophenolate mofetil) again recorded a double-digit increase in sales in 2008, advancing 13% to 2.1 billion Swiss francs. Growth was driven primarily by strong demand in the US and Japan.

Anemia – Overall sales decline in a competitive, cost sensitive market

Combined sales of NeoRecormon and Epogin (epoetin beta) declined 13% to 1.8 billion Swiss francs in 2008, in an increasingly competitive, highly cost-sensitive market, characterised by heavily discounted contract tenders and group purchasing. New guidelines on the use of ESAs in cancer and renal patients issued during the year by the European Medicines Agency (EMA) and other regulators also contributed to the overall contraction of the global anemia market. In Europe/RoW erosion of NeoRecormon sales has been moderate (-10%) despite the entry of several biosimilar versions of epoetin alfa since late 2007. In Japan, where Epogin remains the market leader, an 18% decline in sales of the medicine was due primarily to sustained pricing pressure and government-mandated price cuts that came into effect in April. As of January 2009 Mircera (methoxy polyethylene glycol-epoetin beta) has been approved in 72 countries worldwide and launched in 56, including the major EU markets. Physician feedback in the early launch markets is positive. Sales are modest but are progressing as the product's global rollout continues.

Virology – Pegasys maintains clear market leadership, expands market share

In 2008 Pegasys (peginterferon alfa-2a) maintained its clear leadership of the global pegylated interferon market and continued to gain market share worldwide. Global sales advanced 6% to 1.6 billion Swiss francs, driven by strong growth in Japan and key emerging markets, combined with solid market-share growth in the United States, where Pegasys now accounts for 70% of new prescriptions for hepatitis C. In June, the EU authorities approved a shortened course of treatment with Pegasys plus Copegus (ribavirin) for patients with genotype 2 or 3 HCV infection who have very low virus levels and show a rapid virological response. The approval personalises therapy for these patients, offering a chance for cure with only four months' treatment. This new approach is made possible by Roche Diagnostics' highly sensitive, real-time cobas PCR diagnostic tests. In November, Roche also received EU approval for the retreatment of patients whose chronic HCV infection did not respond to previous treatment with interferon alfa (pegylated or non-pegylated), alone or in combination with ribavirin. Pegasys is the first and only pegylated interferon to be indicated for retreatment of up to 72 weeks, allowing therapy to be personalised and optimised. The recommended retreatment period depends on the HCV genotype, the

type of previous treatment and the patient's virological response during retreatment.

As forecast, total sales of the anti-influenza medicine **Tamiflu** (oseltamivir) continued to decline in 2008, with the fall of 68% to 609 million Swiss francs due to substantially reduced pandemic stockpiling orders from governments and corporations. The expected sharp fall-off in pandemic sales, down 1.6 billion Swiss francs compared with 2007, more than outweighed a significant increase in seasonal sales, which rose 76% to 372 million Swiss francs. The main contributions to seasonal sales came from the United States, where the 2007/2008 flu season was particularly severe. As part of its policy to help ensure pandemic readiness, Roche continued to work with governments worldwide on appropriate Tamiflu stockpiles, in line with WHO recommendations. Based on data provided by Roche and Chugai, the authorities in the United States, Japan, Canada, Australia and elsewhere have increased the shelf-life of government stockpiles of Tamiflu to seven years. Roche has filed data to support similar shelf-life extensions in other countries.

Combined sales of **Valcyte** (valgancyclovir) and **Cymevene** (ganciclovir) rose 10% to 553 million Swiss francs in 2008. Robust growth throughout the year was driven mainly by demand in Europe/RoW, with very strong gains recorded in Germany and Spain. In July, the FDA granted pediatric exclusivity for Valcyte in the United States. This extends the medicine's patent protection for six months, to September 2015.

In the third quarter of 2008, following extensive toxicology studies by Roche, both the EU and the Swiss authorities confirmed that the presence of a chemical impurity in some batches of the HIV medicine **Viracept** (nelfinavir) last year did not present a risk to patients. The authorities have determined that there is now no need to follow patients in registries. The discovery of the impurity led to a global recall of Viracept in June 2007. Since then, Viracept has been reintroduced in the EU, Switzerland and other markets where Roche supplies the product.

Inflammatory and autoimmune diseases – Actemra/RoActemra approved for rheumatoid arthritis in Japan, EU and Switzerland

Estimated sales⁴ of **MabThera/Rituxan** (rituximab) in the inflammation/autoimmune segment amounted to approximately 800 million Swiss francs in 2008, driven by strong worldwide uptake of the product for the treatment of severe rheumatoid arthritis (RA). The first and only selective B cell therapy approved in this indication, MabThera/Rituxan has rapidly established itself as a proven choice for RA patients with inadequate response to tumour necrosis factor (TNF) inhibitor therapy and is now the

⁴ Based on data from Genentech and from Roche territories.

market leader in this indication outside the US. 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 move patients to MabThera/Rituxan following inadequate response to their first TNF inhibitor. The use of MabThera/Rituxan in this setting is supported by a growing body of evidence, including new clinical trial data presented at medical conferences in 2008 showing sustained or improved reduction of disease activity with repeated treatment courses and sustained inhibition of the progression of joint damage.

Roche, Genentech and Biogen Idec continued development programmes evaluating additional RA settings in which MabThera/Rituxan may provide benefit to patients. Two major trials in a phase III programme investigating the medicine for use in RA patients with less advanced disease met their primary endpoints in 2008. In January, results from the SERENE study in patients with an inadequate response to previous therapy with disease-modifying antirheumatic drugs (DMARDs) showed that significantly more patients treated with MabThera/Rituxan plus methotrexate (MTX) achieved an improvement in disease signs and symptoms compared with those who received MTX alone. In December Roche announced that IMAGE, a radiographic study assessing the ability of MabThera/Rituxan to inhibit structural joint damage in patients not previously treated with MTX, had also met its primary endpoint. Roche plans to use the signs and symptoms data in conjunction with the radiographic data to support a combined EU regulatory filing for additional RA indications in 2009. In September, based on the SERENE data, Genentech filed a supplementary marketing application in the US seeking approval for Rituxan in RA patients with inadequate response to DMARD therapy.

Actemra/RoActemra (tocilizumab) is a first-in-class therapy based on IL-6 inhibition, representing a novel approach to the treatment of patients with moderate to severe RA. Following approval in April of Actemra for RA in adults and for related pediatric disorders and the subsequent rollout by Chugai, sales uptake in Japan has been very encouraging. In December, the Swiss authorities approved RoActemra for the treatment of moderately severe to severe, active rheumatoid arthritis in adult patients who have not responded adequately to treatment with DMARDs or TNF inhibitors. Roche received EU marketing approval for RoActemra in the same indication in January 2009. In September, in a complete response letter to Roche's US marketing application for Actemra, the FDA requested additional documentation. Following further discussions and as a result of the FDA's evolving Risk Evaluation and Mitigation Strategy (REMS) requirements for medications, in December, the agency asked Roche to prepare a REMS plan for Actemra. In addition, based on the evolving requirements for approval of new biologics, the FDA has asked Roche for non-clinical animal model data, beyond that which was included in the original marketing application. Roche is performing the requested preclinical studies and expects to submit the complete response for Actemra to the FDA in the third quarter of 2009. The FDA has not

requested additional clinical studies prior to approval.

Metabolic disorders – Bonviva/Boniva maintains robust growth in a competitive market

In an increasingly competitive market environment **Bonviva/Boniva** (ibandronic acid) recorded solid overall sales performance in 2008, with sales increasing 35% to 1.1 billion Swiss francs. Further market-share gains supported robust growth in Europe/RoW and the United States despite the entry of generic versions of competitor products in the US and Europe. New data from a retrospective observational study in over 64,000 postmenopausal women (VIBE) presented at a major European rheumatology congress in June provided additional evidence for the effectiveness of once-monthly Bonviva compared with weekly bisphosphonates in preventing vertebral, non-vertebral and hip fractures. In November, the FDA expanded the existing marketing approval for once-monthly Boniva to include prevention of postmenopausal osteoporosis.

Research and development – research and development portfolio making significant progress

In 2008 the Pharmaceuticals Division filed 11 major new marketing applications and gained 13 major regulatory approvals. At the beginning of 2009, the division's R&D pipeline comprised 120 clinical projects, including 62 new molecular entities (NMEs) and 58 additional indications. Forty NMEs are currently in phase I, 16 in phase II and six in phase III or filed for regulatory review.

Roche Pharmaceuticals currently has 100 projects in preclinical research across five therapeutic areas and 84 development projects in five therapeutic areas, including five in phase 0 (transition from preclinical to clinical development).

In 2008 twelve Roche-managed projects were terminated: six in phase I, four in phase II and two in phase III. Two of these projects reverted to our R&D partners, and decisions were taken to outlicense another two.

The global development programme for **Avastin** currently includes more than 450 clinical trials with around 40,000 patients in over 30 different tumour types. Phase III studies in diseases such as ovarian, prostate and gastric (stomach) cancer are scheduled to report over the next two years. Final results from a key clinical trial of Avastin in the early colon cancer setting (NSABP C-08) are expected in 2009, with the results of another trial in the same setting (AVANT) due in 2010. Important milestones were passed in several Avastin programmes in 2008: BETH, a global phase III trial of Avastin combined with Herceptin in adjuvant HER2-positive breast cancer, started in May; patient recruitment for the phase III AVAGAST trial in first-line advanced gastric cancer was completed in December; and BERNIE, a phase II trial to assess Avastin in combination with standard chemotherapy in children and adolescents with sarcoma, commenced in July. In October, the EU authorities approved a pediatric investigation plan for

Avastin; the studies included will eventually provide physicians with new data on dosing and safety that can improve clinical outcomes specifically for children.

In collaboration with OSI Pharmaceuticals and Genentech, Roche is conducting an extensive development programme of more than 130 clinical studies with Tarceva at earlier stages of lung cancer and in combination with other treatments, including Avastin, to further evaluate the life-extending benefits of Tarceva for patients with NSCLC. Ongoing and planned phase III studies in the Tarceva development programme include a randomised phase III trial (ATLAS) in advanced non-small cell lung cancer. Interim results showed that Tarceva plus Avastin given as first line maintenance treatment following initial therapy with Avastin plus chemotherapy extended the time patients live without their disease getting worse compared to maintenance therapy with Avastin plus placebo.

Several studies are currently evaluating **Herceptin** in combination with Avastin or pertuzumab in patients with HER2-positive breast cancer. In addition to BETH (see above, Avastin), CLEOPATRA and NEOSPHERE (see below, pertuzumab), Herceptin is also being studied in a global phase III study (AVEREL) in combination with Avastin in the first-line treatment of advanced breast cancer. Herceptin is also being investigated in HER2-positive advanced gastric cancer in the phase III ToGA study. Around 20% of patients with gastric cancer have HER2-positive disease.

Pertuzumab (R1273), currently being studied in combination with Herceptin and standard chemotherapy in HER2-positive breast cancer, entered phase III development in 2008. Pertuzumab inhibits the pairing of HER2 with other HER receptors, a key mechanism of tumour growth. CLEOPATRA, a phase III study evaluating the addition of pertuzumab to Herceptin and chemotherapy in first-line treatment of patients with advanced disease commenced in the first quarter of 2008. In addition, NEOSPHERE, a phase II trial investigating neoadjuvant (presurgical) treatment with pertuzumab, started in the first half of the year. Data from a phase II trial (17929) presented at ASCO 2008 showed that half of the patients with advanced HER2-positive breast cancer whose disease had progressed during previous treatment with a regimen including Herceptin benefited from a combination of Herceptin and pertuzumab.

Ocrelizumab (R1594) is a humanised anti-CD20 monoclonal antibody being developed by Roche, Genentech and Chugai for the treatment of autoimmune diseases. Like MabThera/Rituxan, ocrelizumab also targets B cells. As a humanised antibody, it has the potential to be less immunogenic, better tolerated and more convenient to administer. An extensive phase III programme involving more than 2,700 patients with rheumatoid arthritis is ongoing, and recruitment for a phase III trial in lupus nephritis is continuing as planned. In May a phase III trial of ocrelizumab in systemic lupus erythematosus was

discontinued due to the negative results of a trial with MabThera/Rituxan in a similar patient population.

Dalcetrapib (R1658, JTT-705, licensed from Japan Tobacco) increases levels of HDLC by blocking the action of the cholesteryl ester transfer protein (CETP), thereby potentially reducing the risk of cardiovascular disease and death in high-risk patients. A phase III morbidity and mortality study of dalcetrapib (dal-OUTCOMES) started in April, and patient recruitment is proceeding well. Phase II data presented at the American Congress of Cardiology in March show that dalcetrapib is well tolerated and has a good general and cardiovascular safety profile when given alone or in combination with statins. Additional data presented at the American Heart Association meeting in November showed that dalcetrapib has a unique chemical structure and, unlike certain other CETP inhibitors, does not activate enzymes or genes involved in blood-pressure regulation.

Taspoglutide (R1583, BIM 51077, licensed from Ipsen), the first once-weekly human glucagon-like peptide-1 (GLP-1) hormone analogue, is being developed by Roche for type 2 diabetes. The structure of the molecule is similar to that of the natural human hormone. In clinical trials to date, taspoglutide was generally well tolerated and significantly improved glucose control and weight loss after only eight weeks of treatment. Roche initiated an extensive phase III clinical development programme with taspoglutide in July. In late 2008, the FDA issued new guidance on the clinical testing of new treatments for type 2 diabetes. Roche is reviewing the taspoglutide programme to comply with these recommendations.

Diagnostics Division

Growth well above the market average

Key figures	In millions of CHF	% change in CHF	% change in local currencies	As % of sales
Sales	9,656	+3	+10	100
- Professional Diagnostics	4,422	+3	+9	46
- Diabetes Care	2,971	-8	-1	31
- Molecular Diagnostics	1,122	-2	+5	11
- Applied Science	765	+11	+19	8
- Tissue Diagnostics	376	n/a	n/a	4
Operating profit	1,187	-28	-22	12.3
Operating free cash flow	600	-44	-33	6.2
Research and development	941	+20	+26	9.7

In 2008, Roche's Diagnostics Division recorded sales of 9.7 billion Swiss francs, an increase of 10% in local currencies (3% in Swiss francs; 15% in US dollars) over the previous year.⁵ Once again, this was faster than global *in vitro* diagnostics (IVD) market growth, which is estimated at approximately 5%. Despite recent sector consolidation, the division maintained its leading market position. Divisional sales continued to grow ahead of or in line with the market in all regions, with double-digit gains in North America (including the positive impact of the Ventana acquisition), Asia-Pacific and Latin America and strong mid-single-digit growth in the EMEA region (Europe, Middle East and Africa) and Japan.

Four of the five divisional business areas posted rising sales, with the biggest contributions to growth coming from the Professional Diagnostics, Applied Science and Tissue Diagnostics units. Within these businesses, immunoassay systems, DNA sequencing products and advanced staining remained the major growth drivers, respectively. Roche Diabetes Care posted a modest sales decline overall in a highly competitive market, but achieved strong growth with its new products. Roche Molecular Diagnostics' growth continued to be driven by sales of automated real-time PCR virology and blood screening systems. Roche Tissue Diagnostics (Ventana), the US-based leader in automated tissue staining acquired in February, posted sales of 376 million Swiss francs in the 11 months to 31 December 2008, accounting for 4% of the division's full-year sales.

The division continues to invest heavily in innovation. In 2008, research and development (R&D) costs increased 26% to 941 million Swiss francs, reflecting investments in the sequencing business, new immunoassays, molecular diagnostic tests and platforms for infectious diseases and cancer, new products for diabetes care, advanced staining systems and laboratory information management solutions. These areas will continue to be R&D priorities in 2009. R&D spending as a percentage of sales increased to 9.7%, up from 8.4% in 2007.

Operating profit in the Diagnostics Division decreased 22% to 1,187 million Swiss francs in 2008, and the operating margin decreased 5.3 percentage points to 12.3%. More than half of the margin decline resulted from the impact of recent acquisitions, including amortisation of acquired intangible assets and investments to develop the acquired businesses. The rest was mainly due to strong competition in the US diabetes care market and portfolio mix effects.

Professional Diagnostics – new tests help fuel eighth year of double-digit immunoassay sales growth

In 2008, Roche Professional Diagnostics' sales rose 9% to 4,422 million Swiss francs, compared with estimated market growth of 6%. Sales in Asia-Pacific and Latin America showed strong double-digit

⁵ Unless otherwise stated, all growth rates are in local currencies.

growth; gains in other regions were in the high single-digit range.

Sales of **Serum Work Area solutions** (clinical chemistry and immunoassay systems), Professional Diagnostics' largest business segment, grew significantly faster than the market, increasing 10%, compared with estimated market growth of 5%. Immunoassay sales (instruments and tests) were up 19% for the year. 2008 was the eighth consecutive year of double-digit sales growth for Roche's immunoassay portfolio. New placements of cobas 6000 instruments helped drive growth, as did strong uptake of the anti-HCV assay (diagnosis of hepatitis C virus infection) launched in the EMEA region and other markets in the first half of 2008. The Elecsys cardiac assays for NT proBNP and troponin T also remained major growth drivers. Clinical chemistry sales advanced 3% amid continuing price erosion in the market.

Roche continues to be the leading supplier of clinical chemistry and immunoassay systems in all markets except the United States, with a global market share of approximately 19%.

Demand for the cobas 6000 analyser series for medium-workload laboratories (up to about 5000 tests per day) remains very strong. Introduced in 2006, it was the first of several modular Roche platforms designed to integrate and improve the efficiency of immunoassay and clinical chemistry testing in different-sized laboratories. Two new configurations were launched in 2008, completing the series and increasing its competitiveness. The rollout of the smaller cobas 4000 series of instruments for small- to medium-workload laboratories continued with the successful July launch of the cobas c 311 clinical chemistry analyser in all markets except the United States. A US launch is scheduled for the first quarter of 2009.

Roche Professional Diagnostics supplies one of the most comprehensive menus of clinical chemistry and immunoassay tests in the industry. Twelve new fully automated Serum Work Area assays launched in late 2007 or 2008 were rolled out during the year across Europe and in other markets. Major new assays included the Elecsys anti-TSH receptor antibody assay for the diagnosis of Graves' disease (the most common autoimmune thyroid disease), the Elecsys anti-CCP antibody assay, a highly specific test to aid the diagnosis of rheumatoid arthritis and the Roche Cystatin C clinical chemistry test for early detection of impaired kidney function. In the fourth quarter Roche Professional Diagnostics launched anti-CMV IgG and anti-CMV IgM immunoassays for the diagnosis of cytomegalovirus infection. Almost half of the assays rolled out in Europe during the year were also launched in the United States.

Roche's **laboratory coagulation portfolio** generated solid 6% growth in 2008, with placements of all instrument types up significantly from the previous year. Sales grew particularly strongly in Europe and

Latin America. High-volume analysers and the Coasys Plus C, a fully automated low-volume coagulation analyser launched in the third quarter of 2008, were important growth drivers.

Hematology sales also showed solid mid-single-digit growth, with placements of new instruments up more strongly than expected. Growth was seen across all regions covered by Roche's exclusive distribution agreement with Sysmex Corporation (Japan). Growth continued to be driven mainly by the Sysmex XS 1000i, one of a line of compact, fully automated analysers launched in 2007. In **urinalysis**, Roche maintained its number two position despite strong pressure from low-price competitors. Full commercial launch of the cobas u 411, a stand-alone urinalysis system for small- to medium-workload laboratories, was successfully completed outside the United States. Uptake of this system has significantly exceeded expectations.

Sales of **decentralised testing** products rose 10%, helped by the continued trend towards diagnostic testing at the point of care.

Point-of-care cardiac assays posted strong double-digit growth, fuelled by increased uptake of the Roche Cardiac proBNP assay (diagnosis and assessment of heart failure) and the cobas h 232 portable cardiac testing device, launched in 2007. The cobas h 232 provides highly reliable results in just 8 to 10 minutes and has a test menu that includes most of the major blood markers for heart attack, heart failure and assessing a patient's risk of future cardiovascular events.

Overall sales of ambulatory care/monitoring solutions showed solid double-digit growth. Coagulation monitoring (instruments and test strips) continued to post strong double-digit sales increases, driven mainly by the CoaguChek XS monitor for professional use and patient self-testing. Accutrend Plus, a handheld device that measures important indicators of cardiac risk (cholesterol, glucose, triglycerides) and tissue hypoxia (lactate) contributed to high single-digit sales growth across several ambulatory care segments. Launched in its first markets in November 2007, this device for professional and self-testing environments is now available worldwide.

Uptake of the Accu-Chek Inform II, the first and only wireless system for hospital glucose testing and monitoring, particularly in intensive care settings, has been very strong since the device was launched outside the United States in June. US approval and launch are expected in March 2009.

Diabetes Care – new products deliver strong growth

Roche Diabetes Care remains the global market leader. In 2008 its sales reached 2,971 million Swiss francs, a 1% decline from 2007. Single-digit sales increases in the EMEA region, Asia-Pacific and Japan

and a double-digit increase in Latin America did not quite offset lower US sales. Following a strong second quarter, US sales fell in the third and fourth quarters as a result of an accelerating decline in sales of older monitoring products, strong competition and continued pricing pressures. The older products that are being phased out of the portfolio now account for less than 30% of Roche Diabetes Care's sales.

The new generation of Accu-Chek **blood glucose monitoring** systems delivered robust growth. Accu-Chek Aviva, Roche Diabetes Care's largest-selling glucose monitoring system, posted a strong double-digit sales increase over 2007. The Accu-Chek Performa, launched in most markets during the first half of 2008, has experienced a strong uptake; the global rollout continued with the December launch in China and is now almost complete.

The global rollout of the Accu-Chek Compact Plus system was completed in November. Combined sales of Accu-Chek Compact Plus test strips grew at a double-digit rate in countries where this device was launched in late 2007.

In the coming months Roche Diabetes Care will be launching four important new diabetes monitoring products. The Accu-Chek Aviva Nano and Accu-Chek Performa Nano blood glucose meters will be available in the European Union, their first market, starting in the first quarter of 2009. Offering the same functionality as the Accu-Chek Aviva and Accu-Chek Performa systems in a sleeker, more discreet design, the Nano meters are aimed especially at young high-frequency testers. The new Accu-Chek Active, targeted particularly at emerging markets, will also begin rolling out in the first quarter of 2009.

The fourth new offering, Accu-Chek Mobile, is expected to strengthen Roche Diabetes Care's lead in the market segment for integrated blood glucose monitoring systems. Accu-Chek Mobile offers complete integration of testing and lancing in a single device and features a unique strip-free technology that employs a continuous tape of 50 tests instead of single-use test strips.

In the first quarter of 2009 Roche Diabetes Care will start updating its glucose monitoring systems to a new testing method that avoids the risk of maltose interference. This will offer additional safety to certain dialysis patients who also monitor their blood glucose.

The innovative Accu-Chek Combo system, scheduled for launch in the European Union in the first quarter of 2009, will be a strong addition to Roche Diabetes Care's **insulin delivery portfolio**. Accu-Chek Combo combines an Accu-Chek Spirit insulin pump and a high-end glucose meter with remote-control and bolus calculator capabilities. Users can deliver a bolus insulin dose anytime, anywhere, without having to touch their pump. The Accu-Chek Combo also offers small dose increments for optimised

insulin dosing and fine-tuned glucose control. Premarketing activities have already started to secure the current customer base in preparation for the launch of this new system.

Molecular Diagnostics – a year of major assay launches

Roche Molecular Diagnostics remains the industry leader, with a 33% share of a fast-growing but increasingly competitive market. Sales totalled 1,122 million Swiss francs in 2008, an increase of 5% from a year earlier. Sales showed double-digit growth in Asia–Pacific and Latin America, with single-digit growth in North America and the EMEA region.

Virology testing, Roche Molecular Diagnostics' largest segment by sales, remained the most significant contributor to growth. Virology sales grew 4%, led by demand for automated real-time PCR platforms and tests for HIV-1 (the most common form of the virus that causes AIDS in humans) and hepatitis C and hepatitis B virus (HCV, HBV). Roche Molecular Diagnostics' virology portfolio includes systems for automated sample preparation and real-time PCR analysis. The combined Cobas AmpliPrep/Cobas TaqMan (CAP/CTM) system is the only platform available worldwide that offers customers fully automated real-time PCR testing for clinical diagnostic use.

In October, the US Food and Drug Administration (FDA) approved the CAP/CTM HCV Test, which quantifies the amount of hepatitis C virus (viral load) in a patient's blood. A month earlier, in September, the Cobas TaqMan HBV Test became the first hepatitis B viral load test to receive FDA approval. This, along with the fully automated CAP/CTM HIV-1 Test approved in 2007, completed initial automation of Roche's major virology products in the US market. Physicians use these tests to establish baseline levels of infection prior to treatment and to monitor patients' responses to therapy by tracking changes in their virus levels during treatment. Numerous US laboratories have already signed contracts for the HCV and HBV tests, including one of the nation's largest reference laboratories, which converted to the Roche HBV test just weeks after it was approved.

Second-generation versions of the CAP/CTM HIV-1 and HBV tests received CE Mark certification in December, allowing them to be sold for clinical use in the European Union. The new HIV test has a unique dual-target design enabling simultaneous detection of two separate regions of the HIV genome. This provides greater test reliability when viral mutations are present. In addition, both new tests have even broader dynamic ranges (ability to quantify very low and very high viral loads) than earlier-generation tests. This is a critical advantage, since very high or very low levels of virus can indicate the need for more or less aggressive therapy. Regulatory filings for the new CAP/CTM HIV-1 and HBV tests are currently under review in Japan.

Sales of **blood screening** products, Molecular Diagnostics' second-largest segment by sales, advanced 2% for the year, as additional blood centres in Europe, Asia–Pacific and Latin America began routine screening with the multiplex cobas TaqScreen MPX Test on the fully automated cobas s 201 platform. The decline seen in this segment earlier in the year, which resulted from price pressure and the ongoing effect of accounts lost in 2007, is levelling off, and further growth is expected in 2009.

In December, the FDA approved the cobas TaqScreen MPX Test for use on the cobas s 201 system. This test is the most comprehensive nucleic acid test of its kind available today, offering the unique ability to detect HIV-1 groups M and O, HIV-2, HCV and HBV in a single automated assay. Originally launched in Europe in 2006, the cobas TaqScreen MPX Test has already been widely adopted by and demonstrated excellent performance in blood centres worldwide. In Japan the test has been used since September on the fully integrated cobas s 401 system to screen 100% of the Japanese blood supply.

The Cobas TaqMan CT Test v2.0, for improved detection of *Chlamydia trachomatis* (CT), was launched for clinical use in Europe, Asia–Pacific and Latin America in the second half of 2008. The transition to this new test, which runs on the automated Cobas TaqMan 48 real-time PCR analyser, has been completed in the majority of the markets where it is available. The Cobas TaqMan CT Test v2.0 simultaneously detects two targets within the *Chlamydia* cryptic plasmid and genome target DNA. As a result, it is able to detect infections caused by all known strains of CT, even if there are unexpected changes to the bacterial genome, as in the case of the recently discovered Swedish variant. Chlamydial infection is one of the most commonly reported sexually transmitted diseases. If left untreated, it can lead to serious complications such as pelvic inflammatory disease and infertility in women.

The Amplicor and Linear Array tests for detecting and identifying low- and high-risk strains of human papillomavirus (HPV) showed double-digit growth. Persistent infection with certain high-risk strains of HPV can progress to pre-cancerous conditions or cervical cancer. The Amplicor HPV test was approved and launched in Japan in September.

In June, Roche signed an exclusive deal with DxS Ltd. (UK) for distribution of the TheraScreen K-RAS Mutation Test, which Roche began distributing in December, and the TheraScreen EGFR 29 Mutation Test. Both tests are real-time PCR assays and have CE Mark certification. Used in conjunction with other clinically relevant information, K-RAS and EGFR mutation testing can aid doctors in determining patients' suitability for certain cancer therapies.

Applied Science – sequencing, quantitative PCR and arrays drive very strong growth in genomics

In 2008, Roche Applied Science recorded sales of 765 million Swiss francs. This was an increase of 19%

for the year, more than three times the estimated market growth rate (6%). Sales of DNA sequencing products, led once again by the ultra-fast Genome Sequencer FLX (GS FLX), nearly doubled, despite increased pressure from competitors. Roche Applied Science is the market leader in placements of next-generation sequencing systems. Products for real-time quantitative PCR (qPCR) analysis, particularly the LightCycler 480 instruments and reagents, delivered robust double-digit growth, with strong sales increases in North America and China. Total instrument placements roughly doubled in 2008. Microarray systems made a significant contribution to full-year sales; sequential quarterly sales growth for these products has been steady and strong since Roche acquired NimbleGen in August 2007.

Biochemical and industrial reagents, which account for a major part of Roche Applied Science's revenues, showed moderate growth overall in a market impacted by flat government funding for life science research.

In late September, Roche Applied Science launched its GS FLX Titanium series of next-generation sequencing products (including new reagents and software). Compared with standard GS FLX sequencing, Titanium increases throughput by a factor of five. Roche NimbleGen's SeqCap (sequence capture) arrays, which help laboratories to take full advantage of this sequencing capacity, were introduced in initial markets in March and are now available worldwide. These high-density arrays produce targeted, sequencing-ready samples much faster and more cost-effectively than conventional methods of sample preparation, thus easing a major bottleneck in genomic research.

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. The RealTime assays will make the LightCycler systems even more competitive and are expected to be an important sales driver. The LightCycler series was also strengthened by the launch of the LightCycler 480 II in the first half of 2008. The new LightCycler instrument features enhanced analysis software for greater efficiency over a range of applications.

In the second half of 2008 Roche Applied Science successfully launched single- and multi-plate versions of the xCELLigence cell analyser, a system co-developed with ACEA Biosciences Inc. The analyser uses a technology that eliminates the need for labour- and cost-intensive steps like cell labelling and cell fixation and measures changes in cell morphology, cell proliferation and cell death in real time. Very importantly, it could significantly reduce the use of animal testing in pharmaceutical research and toxicology, among other areas. Initial placements have already occurred in all regions.

Tissue Diagnostics — strong year-on-year growth and the launch of two major new systems

Roche's consolidated full-year results for 2008 include Roche Tissue Diagnostics sales of 376 million Swiss francs, representing sales from the date of acquisition in February to 31 December 2008. These additional sales contributed four percentage points to the Diagnostics Division's local-currency sales growth. On a stand-alone basis, Roche Tissue Diagnostics' sales for the entire year reached 369 million US dollars, an increase of 23% in local currencies (26% in US dollars) over 2007. This was significantly faster than the estimated market growth rate of 14%. Sales increased at above-market rates in North America, EMEA and Asia-Pacific, helped by new products for advanced and primary staining and workflow management.

Advanced tissue staining (immunohistochemistry and in situ hybridisation) remained the business area's biggest growth driver, delivering robust reagent sales and an even stronger increase in instrument sales. Sales of the fully automated BenchMark XT and BenchMark LT instruments and immunohistochemistry reagents all increased at high double-digit growth rates.

BenchMark Ultra, a new system that performs immunohistochemistry and in situ hybridisation testing simultaneously on a single continuous and random access platform was launched in the United States and Canada in August and in Europe in November. The BenchMark Ultra has 30 individual staining chambers, each of which can be accessed at any time without interrupting workflow. As a result, test turnaround times are reduced significantly, and STAT samples (those requiring rush testing) can be added at any time for expedited patient diagnosis. The market response to the BenchMark Ultra has been very positive, with a significant number of placements in 2008 and substantial sales acceleration expected in 2009.

In 2008, Roche Tissue Diagnostics expanded its immunohistochemistry menu with a total of ten new CONFIRM antibodies for various cancers, including thyroid, lung, prostate and breast cancers and lymphoma.

US placements of the Symphony instrument for **hematoxylin and eosin staining** accelerated in the second half of 2008, following upgrades that further enhance system reliability and staining interpretation. Symphony's commercial performance in the high-volume primary staining market is expected to improve further in 2009; launches in Europe and Australia are planned for the second and third quarters of the year. Overall, sales of primary staining instruments and reagents were up 27% for the year.

Uptake of the Vantage **workflow solution** launched in the United States in April 2008 was even stronger

than expected, with orders well over forecast for 2008. Vantage is a 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. The product will be rolled out in Europe and Australia starting in the third quarter of 2009.

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 2008 sales by the Pharmaceuticals Division totalled 36.0 billion Swiss francs, and the Diagnostics Division posted sales of 9.7 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested nearly 9 billion Swiss francs in R&D in 2008. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at www.roche.com.

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Additional information

- Media release including a full set of tables: www.roche.com//med-cor-2009-02-04
- Annual Report 2008: http://www.roche.com/annual_reports.htm
- Presentations / live media conference broadcast (starting at 10:00 am CET):
<http://www.roche.com/media/events/bmk2009.htm>
- Photographs of the media conference (as from 2:00 pm CET):
<http://www.roche.com/media/events/bmk2009.htm>
- Roche Pharmaceuticals pipeline: www.roche.com/pipeline.htm
- Roche Finance Info System: rofis.roche.com/dynasight/rofis.html

Next events

- Annual General Meeting: 10 March
- First quarter sales 2009: 16 April (tentative date)

- Half-year results 2009: 23 July (tentative date)
- Nine-month sales 2009: 15 October (tentative date)

Roche Group Media Relations

Telephone: +41 61 688 8888 / Email: basel.mediaoffice@roche.com

- Daniel Piller (Head)
- Alexander Klauser
- Valeria Passoni
- Martina Rupp
- Claudia Schmitt

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1. Sales January to December 2008 and 2007

	2008	2007	% change	
	CHF m	CHF m	In CHF	In local currencies
January – December				
Pharmaceuticals Division	35,961	36,783	-2	+5
Roche Pharmaceuticals	22,164	22,970	-4	+3
Genentech	10,461	10,414	0	+11
Chugai	3,336	3,399	-2	-4
Diagnostics Division	9,656	9,350	+3	+10
Roche Group	45,617	46,133	-1	+6

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

	2008	2007	% change	
	CHF m	CHF m	In CHF	In local currencies
January – December				
Pharmaceuticals Division	35,724	34,927	+2	+10
Roche Pharmaceuticals	21,941	21,404	+3	+9
Genentech	10,461	10,414	0	+11
Chugai	3,322	3,109	+7	+4
Diagnostics Division	9,656	9,350	+3	+10
Roche Group	45,380	44,277	+2	+10

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

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

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

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

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

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

5. Quarterly sales by Division in 2007 and 2008

CHF millions	Q4 2007	Q1 2008	Q2 2008	Q3 2008	Q4 2008
Pharmaceuticals Division	9,659	8,568	8,689	8,936	9,768
Roche Pharmaceuticals	6,178	5,498	5,440	5,485	5,741
Genentech	2,564	2,399	2,468	2,669	2,925
Chugai	917	671	781	782	1,102
Diagnostics Division	2,527	2,287	2,460	2,365	2,544
Roche Group	12,186	10,855	11,149	11,301	12,312

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

CHF millions	Q4 2007	Q1 2008	Q2 2008	Q3 2008	Q4 2008
Pharmaceuticals Division	9,201	8,523	8,639	8,900	9,662
Roche Pharmaceuticals	5,736	5,455	5,390	5,449	5,647
Genentech	2,564	2,399	2,468	2,669	2,925
Chugai	901	669	781	782	1,090
Diagnostics Division	2,527	2,287	2,460	2,365	2,544
Roche Group	11,728	10,810	11,099	11,265	12,206

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

7. Top 20 Pharmaceuticals Division product sales¹ and local growth² in YTD December 2008: US, Japan and Europe/Rest of World

	Total		US		Japan		Europe/RoW	
	CHF m	%	CHF m	%	CHF m	%	CHF m	%
MabThera/Rituxan	5,923	16%	2,930	14%	214	10%	2,779	19%
Avastin	5,207	37%	2,908	17%	210	476%	2,089	67%
Herceptin	5,092	12%	1,496	7%	249	47%	3,347	13%
CellCept	2,099	13%	1,026	15%	41	15%	1,032	11%
NeoRecormon/Epogin	1,774	-13%	-	-	470	-18%	1,304	-10%
Pegasys	1,635	6%	395	10%	102	54%	1,138	2%
Tarceva	1,215	23%	495	10%	47	2562%	673	27%
Xeloda	1,211	13%	428	9%	50	74%	733	14%
Bonviva/Boniva	1,108	35%	675	26%	-	-	433	55%
Lucentis	960	7%	960	7%	-	-	-	-
Tamiflu	609	-68%	430	-50%	88	-78%	91	-86%
Xolair	560	10%	560	10%	-	-	-	-
Valcyte/Cymevene	553	10%	258	7%	-	-	295	14%
Xenical	502	-13%	43	-40%	-	-	459	-9%
Pulmozyme	496	12%	278	15%	-	-	218	7%
Nutropin	413	-2%	401	-2%	-	-	12	-6%
Neutrogen	404	-3%	-	-	404	-3%	-	-
Rocephin	344	-10%	5	-74%	61	3%	278	-8%
Activase/TNKase	342	-1%	298	-2%	-	-	44	9%
Madopar	311	4%	-	-	20	4%	291	4%

¹ Roche Pharmaceuticals, Genentech and Chugai combined ² versus YTD December 2007

8. Top 20 Pharmaceuticals Division quarterly local product sales growth¹ in 2007 and 2008

	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007	Q4 2008 vs. Q4 2007
MabThera/Rituxan	17%	16%	15%	16%
Avastin	35%	38%	37%	36%
Herceptin	11%	12%	14%	12%
CellCept	11%	16%	14%	11%
NeoRecormon/Epogin	-13%	-14%	-15%	-8%
Pegasys	-3%	10%	12%	5%
Tarceva	28%	27%	18%	19%
Xeloda	13%	14%	14%	12%
Bonviva/Boniva	56%	47%	26%	23%
Lucentis	-5%	2%	15%	19%
Tamiflu	-64%	-86%	-56%	-65%
Xolair	6%	7%	12%	13%
Valcyte/Cymevene	9%	10%	13%	9%
Xenical	-11%	-21%	-9%	-11%
Pulmozyme	15%	11%	6%	14%
Nutropin	-5%	-5%	1%	-1%
Neutrogen	1%	1%	0%	-13%
Rocephin	-4%	-13%	-16%	-6%
Activase/TNKase	-3%	-11%	-2%	13%
Madopar	0%	9%	4%	3%

¹ Roche Pharmaceuticals, Genentech and Chugai combined

9. Pharmaceuticals Division quarterly local product sales growth¹ US in 2007 and 2008

	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007	Q4 2008 vs. Q4 2007
MabThera/Rituxan	14%	13%	14%	15%
Avastin	13%	15%	18%	21%
Herceptin	9%	3%	15%	3%
CellCept	14%	15%	20%	12%
NeoRecormon/Epogin	-	-	-	-
Pegasys	-10%	5%	45%	9%
Tarceva	10%	17%	9%	5%
Xeloda	16%	5%	9%	8%
Bonviva/Boniva	47%	39%	16%	12%
Lucentis	-5%	2%	15%	19%
Tamiflu	83%	-87%	6%	-83%
Xolair	6%	7%	12%	13%
Valcyte/Cymevene	11%	5%	7%	5%
Xenical	-35%	-46%	-33%	-48%
Pulmozyme	10%	14%	13%	24%
Nutropin	-6%	-4%	1%	-1%
Neutrogin	-	-	-	-
Rocephin	-34%	-85%	-	-89%
Activase/TNKase	-6%	-12%	-2%	13%
Madopar	-	-	-	-

¹ Roche Pharmaceuticals and Genentech combined

10. Pharmaceuticals Division quarterly local product sales growth Japan¹ in 2007 and 2008

	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007	Q4 2008 vs. Q4 2007
MabThera/Rituxan	13%	11%	8%	9%
Avastin	-	1567%	442%	236%
Herceptin	16%	29%	69%	73%
CellCept	13%	21%	15%	10%
NeoRecormon/Epogin	-16%	-29%	-9%	-16%
Pegasys	98%	53%	49%	39%
Tarceva	-	-	-	699%
Xeloda	48%	73%	88%	81%
Bonviva/Boniva	-	-	-	-
Lucentis	-	-	-	-
Tamiflu	-93%	-78%	-98%	-2%
Xolair	-	-	-	-
Valcyte/Cymevene	-	-	-	-
Xenical	-	-	-	-
Pulmozyme	-	-	-	-
Nutropin	-	-	-	-
Neutrogen	1%	1%	0%	-13%
Rocephin	9%	-2%	-1%	5%
Activase/TNKase	-	-	-	-
Madopar	5%	5%	6%	0%

¹ Chugai

11. Pharmaceuticals Division quarterly local product sales growth Europe/Rest of World¹ in 2007 and 2008

	Q1 2008 vs. Q1 2007	Q2 2008 vs. Q2 2007	Q3 2008 vs. Q3 2007	Q4 2008 vs. Q4 2007
MabThera/Rituxan	21%	21%	17%	18%
Avastin	78%	78%	67%	52%
Herceptin	12%	15%	11%	13%
CellCept	8%	16%	9%	9%
NeoRecormon/Epogin	-13%	-7%	-17%	-4%
Pegasys	-4%	9%	1%	1%
Tarceva	40%	28%	17%	24%
Xeloda	11%	18%	14%	12%
Bonviva/Boniva	77%	61%	45%	47%
Lucentis	-	-	-	-
Tamiflu	-94%	-83%	-93%	6%
Xolair	-	-	-	-
Valcyte/Cymevene	8%	16%	19%	14%
Xenical	-7%	-17%	-6%	-7%
Pulmozyme	22%	8%	-3%	2%
Nutropin	-1%	-12%	-10%	-2%
Neutrogen	-	-	-	-
Rocephin	-3%	-9%	-13%	-6%
Activase/TNKase	30%	1%	1%	11%
Madopar	0%	9%	4%	4%

¹ Roche Pharmaceuticals

12. Top 20 Pharmaceuticals Division quarterly product sales¹ in 2007 and 2008

CHF millions	Q4 2007	Q1 2008	Q2 2008	Q3 2008	Q4 2008
MabThera/Rituxan	1,432	1,407	1,460	1,472	1,584
Avastin	1,135	1,131	1,220	1,351	1,505
Herceptin	1,261	1,225	1,249	1,295	1,323
CellCept	548	487	523	513	576
NeoRecormon/Epogin	510	442	450	427	455
Pegasys	447	369	416	405	445
Tarceva	288	286	301	298	330
Xeloda	312	281	292	307	331
Bonviva/Boniva	283	241	266	268	333
Lucentis	228	215	225	246	274
Tamiflu	512	278	49	101	181
Xolair	138	125	134	145	156
Valcyte/Cymevene	144	125	136	143	149
Xenical	142	136	128	126	112
Pulmozyme	128	117	120	120	139
Nutropin	113	97	98	106	112
Neutrogen	110	95	97	98	114
Rocephin	100	91	85	76	92
Activase/TNKase	88	83	81	81	97
Madopar	83	74	80	77	80

¹ Roche Pharmaceuticals, Genentech and Chugai combined

13. Pharmaceuticals Division quarterly product sales¹ in US in 2007 and 2008

CHF millions	Q4 2007	Q1 2008	Q2 2008	Q3 2008	Q4 2008
MabThera/Rituxan	709	675	706	732	817
Avastin	693	642	671	754	841
Herceptin	375	363	349	394	390
CellCept	290	215	243	247	321
NeoRecormon/Epogin	-	-	-	-	-
Pegasys	111	81	95	99	120
Tarceva	129	119	123	117	136
Xeloda	123	89	97	111	131
Bonviva/Boniva	190	153	159	155	208
Lucentis	228	215	225	246	274
Tamiflu	398	234	30	96	70
Xolair	138	125	134	145	156
Valcyte/Cymevene	73	54	62	66	76
Xenical	13	14	12	9	8
Pulmozyme	67	61	65	69	83
Nutropin	108	94	94	104	109
Neutrogen	-	-	-	-	-
Rocephin	1	3	1	0	1
Activase/TNKase	76	71	71	70	86
Madopar	-	-	-	-	-

¹ Roche Pharmaceuticals and Genentech combined

14. Pharmaceuticals Division quarterly product sales¹ in Japan in 2007 and 2008

CHF millions	Q4 2007	Q1 2008	Q2 2008	Q3 2008	Q4 2008
MabThera/Rituxan	55	43	52	51	68
Avastin	23	28	43	57	82
Herceptin	44	42	56	64	87
CellCept	10	8	11	9	13
NeoRecormon/Epogin	146	103	114	111	142
Pegasys	23	19	22	26	35
Tarceva	2	8	12	11	16
Xeloda	8	8	12	13	17
Bonviva/Boniva	-	-	-	-	-
Lucentis	-	-	-	-	-
Tamiflu	69	16	0	1	71
Xolair	-	-	-	-	-
Valcyte/Cymevene	-	-	-	-	-
Xenical	-	-	-	-	-
Pulmozyme	-	-	-	-	-
Nutropin	-	-	-	-	-
Neutrogen	110	95	97	98	114
Rocephin	16	13	15	14	19
Activase/TNKase	-	-	-	-	-
Madopar	6	4	5	5	6

¹ Chugai

15. Pharmaceuticals Division quarterly product sales in Europe/Rest of World¹ in 2007 and 2008

CHF millions	Q4 2007	Q1 2008	Q2 2008	Q3 2008	Q4 2008
MabThera/Rituxan	668	689	702	689	699
Avastin	419	461	506	540	582
Herceptin	842	820	844	837	846
CellCept	248	264	269	257	242
NeoRecormon/Epogin	364	339	336	316	313
Pegasys	313	269	299	280	290
Tarceva	157	159	166	170	178
Xeloda	181	184	183	183	183
Bonviva/Boniva	93	88	107	113	125
Lucentis	-	-	-	-	-
Tamiflu	45	28	19	4	40
Xolair	-	-	-	-	-
Valcyte/Cymevene	71	71	74	77	73
Xenical	129	122	116	117	104
Pulmozyme	61	56	55	51	56
Nutropin	5	3	4	2	3
Neutrogen	-	-	-	-	-
Rocephin	83	75	69	62	72
Activase/TNKase	12	12	10	11	11
Madopar	77	70	75	72	74

¹ Roche Pharmaceuticals