

Group and Divisional Results |

Roche achieves excellent sales and profit growth while moving swiftly to integrate Genentech.

Double-digit increase in Core EPS. Above-market sales growth expected for full year in both divisions. Core EPS outlook raised for 2009 and 2010. Genentech integration to yield significant synergies.

Roche Group

Strong operating results

In the first half of 2009 the Roche Group continued the strong performance of recent years. Group sales grew 10% in local currencies (9% in Swiss francs; 1% in US dollars) to 24.0 billion Swiss francs. The Pharmaceuticals Division's sales increased 11% in local currencies (11% in Swiss francs; 3% in US dollars) to 19.1 billion Swiss francs – this is twice the global market growth rate. Demand for the oncology drugs Avastin, Herceptin, MabThera/Rituxan, Xeloda and Tarceva continued to increase strongly, with dynamic growth seen in a number of emerging markets. In addition, Tamiflu and Pegasys in virology and Lucentis in ophthalmology contributed significantly to growth. The Diagnostics Division also continued to grow well ahead of the market, with sales up 7% in local currencies (3% in Swiss francs; –4% in US dollars) to 4.9 billion Swiss francs. Professional Diagnostics and Tissue Diagnostics made the strongest contributions to growth. Diabetes Care's sales rose 3% in local currencies, driven primarily by its new generation of blood glucose monitoring products.

The Group's operating profit before exceptional items increased 20% in local currencies, significantly faster than sales. The Pharmaceuticals Division increased its operating profit before exceptional items by 19% in local currencies (13% in Swiss francs) to 7.5 billion Swiss francs, driven by strong sales growth, which more than compensated for higher research and development costs and a moderate increase in marketing and distribution costs. Operating profit in the Diagnostics Division rose 28% in local currencies (11% in Swiss francs) to 644 million Swiss francs.

The Group's operating free cash flow increased 52% in local currencies to 6.8 billion Swiss francs. This strong cash flow will enable the Group to repay its net debt quickly.

Core Earnings per Share – a key metric for assessing corporate performance – advanced 20% in local currencies (10% in Swiss francs), driven by the Group's strong operating results and the positive impact of the Genentech transaction.

Integration of Genentech and changes in Group organisation

Effective 26 March 2009, the Group obtained full ownership of Genentech. Since then, business-critical decisions have been taken regarding management appointments, organisational structure and alignment of processes. The integration will be largely completed by the end of this year.

The new Group structure is designed to maintain a diversity of promising approaches to research and early development and strengthen cross-fertilisation between the companies, thus enhancing overall innovation within the Group. Today, the combined R & D pipeline is already one of the strongest in the industry, with ten new molecular entities in ongoing or planned late-stage clinical trials.

While Genentech Research and Early Development will continue to operate as an independent unit, we expect to achieve significant productivity gains by reshaping the Group's global supply network and combining administrative and support functions.

During the first half of 2009 exceptional operating expenses of 2.4 billion Swiss francs were incurred, 2 billion in connection with the Genentech transaction and integration and 0.4 billion in increased provisions for pending legal cases. Total integration costs are expected to amount to approximately 3 billion Swiss francs, mainly in connection with the partial closure of the manufacturing site in Vacaville (California) and the discontinuation of manufacturing in Nutley (New Jersey). These closures are part of a global initiative to align capacity requirements and improve the operational efficiency of our global manufacturing network. In addition, administrative functions are being streamlined following the transfer of research operations from Palo Alto (California) to Nutley and San Francisco and the consolidation of our US Pharmaceuticals headquarters in San Francisco. Approximately 1.6 billion Swiss francs of the exceptional operating expenses incurred in the first half of 2009 are non-cash items. Roche expects to realise yearly synergies of approximately 1 billion Swiss francs by 2011.

Financing costs increased significantly due to the Genentech transaction. As a consequence, net financial income before exceptional items declined 788 million Swiss francs to minus 551 million,

compared with a net contribution of 237 million in the first half of 2008.

Net income decreased by 29% in Swiss francs to 4.1 billion Swiss francs in the first half-year, driven mainly by the exceptional operating expenses related to the Genentech transaction and integration. Excluding exceptional items, net income attributable to Roche shareholders was up 11% in Swiss francs.

Significant increase in debt to finance

Genentech transaction

To finance the Genentech transaction, the Group issued bonds and notes worth 41 billion US dollars (48 billion Swiss francs), resulting in a net debt position for the Group of 32 billion Swiss francs. The purchase of the outstanding non-controlling interests in Genentech was accounted for in full as an equity transaction. As a consequence the consolidated equity of the Group was reduced by 47 billion US dollars (52 billion Swiss francs) to 5 billion Swiss francs. This accounting effect has no impact on the Group's business or its dividend guidance.

Outlook

We expect 2009 full-year sales in both divisions to grow well ahead of the market. In the Pharmaceuticals Division we expect full-year sales growth in the high single-digit range. We are aiming for double-digit Core EPS growth in both 2009 and 2010 (at constant exchange rates). Given the rapid progress in integrating Genentech, we expect to see further significant productivity gains next year. By 2011 we aim to capture annual synergies of approximately 1 billion Swiss francs. Based on our strong operating free cash flow, we expect to reduce our debt progressively and to return to a net cash position by 2015 while maintaining our dividend guidance.

Key figures: Pharmaceuticals Division

	In millions of CHF	% change in CHF	% change in local currencies	As % of sales
Sales	19,104	11	11	100
– Europe/Rest of World ¹	9,404	2	11	49
– United States	7,516	14	6	39
– Japan	2,184	50	27	12
Operating profit ²	7,463	13	19	39.1
Operating free cash flow	6,497	39	48	34.0

¹ Roche defines Europe/Rest of World as covering Europe and all other countries except Japan and the United States.

² Before exceptional items.

Pharmaceuticals

The Pharmaceuticals Division recorded double-digit sales growth and a further improvement in profitability. In addition, the division passed significant regulatory and development milestones with key marketed products, including MabThera/Rituxan, Avastin and Herceptin, and with promising development compounds such as T-DM1 and R7204 for cancer and aleglitazar for type 2 diabetes.

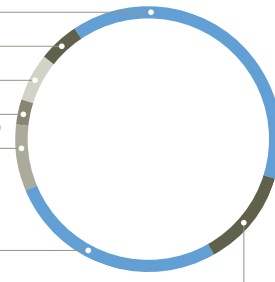
Results and main business developments

In the first half of 2009 sales by the Pharmaceuticals Division grew 11% in local currencies and in Swiss francs (3% in US dollars) to 19.1 billion Swiss francs, around twice the growth rate of the global pharmaceuticals market (5%).¹ Excluding Tamiflu, the division's sales were up 7%, or almost two percentage points higher than global market growth, driven by strong demand for key products, primarily Avastin, Herceptin, MabThera/Rituxan, Lucentis and Pegasys.² Demand for Tamiflu increased markedly in the second quarter, following the worldwide spread of a new strain of influenza A/H1N1.

Sales continued to grow in all regions. In the United States solid growth of key oncology products and Lucentis more than compensated for the negative impact of the loss of CellCept patent protection from May onwards. Sales by Chugai in Japan increased strongly due to demand for Tamiflu, key anticancer medicines, Actemra and Pegasys. Sales in Europe/Rest of World³ were driven by demand in Europe and in emerging markets for our anticancer medicines, Tamiflu, Mircera, Bonviva/Boniva and Pegasys.

Sales by region

United States	39% (+6%)
Asia-Pacific	5% (+14%)
Latin America	6% (+11%)
Others	3% (+23%)
CEMAI	8% (+17%)
Western Europe	27% (+8%)
Japan	12% (+27%)



Italics = growth rates.

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

In the first half of 2009 the Pharmaceuticals Division's operating profit before exceptional items continued to advance faster than sales, growing 19% in local currencies (13% in Swiss francs) to 7.5 billion Swiss francs. This strong increase was driven mainly by the performance of our key pharmaceutical products and ongoing measures to improve efficiency. The operating profit margin rose 0.9 percentage points to 39.1%.

The division generated an operating free cash flow of 6.5 billion Swiss francs in the first half-year, an increase of 48% in local currencies (39% in Swiss francs) over the year-earlier period.

¹ Market growth according to IMS (to end of March 2009).

² Unless otherwise stated, all growth rates are in local currencies.

³ Roche defines Europe/Rest of World as covering Europe and all other countries except Japan and the United States.

Key products drive first-half sales growth, encouraging market response to Actemra/RoActemra

Overall sales (oncology and autoimmune diseases) of **MabThera/Rituxan** (rituximab), for non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL) and rheumatoid arthritis (RA), rose 8% to 3.1 billion Swiss francs. While uptake continues to increase in the first-line NHL setting, high adoption rates for this indication have already been achieved in most markets. The European rollout of MabThera for CLL and further uptake in the NHL maintenance setting and in RA are contributing additional sales growth. Sales in the RA segment are being driven by increased prescribing of the product after a single inadequate response to anti-tumour necrosis factor therapy.

In the first half of 2009 **Avastin** (bevacizumab), for advanced colorectal, breast, lung and kidney cancer, and relapsed glioblastoma (a type of brain tumour), continued to record strong sales growth in all regions, with global sales increasing 29% to 3.1 billion Swiss francs. Sales are being driven by use of Avastin for colorectal, breast and lung cancer. Very strong sales growth in Japan reflects increasing acceptance of Avastin for the treatment of advanced colorectal cancer since the results of a compulsory post-marketing surveillance study were announced last October.

Sales of **Herceptin** (trastuzumab), for HER2-positive breast cancer, increased 10% to 2.6 billion Swiss francs for the half-year, driven by continued uptake in early breast cancer in Japan and increasing market penetration in Eastern Europe and emerging markets.

Sales of **Tarceva** (erlotinib), for advanced lung and pancreatic cancer, rose 10% to 643 million Swiss francs in the first half, with the main contributions coming from Western Europe, Japan and China. Encouraging growth is also being recorded in countries of the CEMAI⁴ region.

Solid first-half sales of **Xeloda** (capecitabine), for colorectal, stomach and breast cancer, which grew 11% to 626 million Swiss francs, were driven primarily by double-digit gains in the United States, Japan and certain CEMAI region countries. Xeloda continues to generate particularly strong sales growth in China following its launch in 2008 for advanced stomach cancer.

Global sales of the antiinfluenza medicine **Tamiflu** (oseltamivir) rose 203% to 1.0 billion Swiss francs in the first half-year, following the rapid worldwide spread of a new strain of influenza A/H1N1 ('swine flu'). Of this, sales to governments and corporations for pandemic stockpiling amounted to 653 million francs. Additional government stockpiling orders and increased demand in the retail pharmacy market contributed to the particularly strong sales recorded in the second quarter (609 million francs overall, compared with 49 million francs in the second quarter of 2008).

US sales of **Lucentis** (ranibizumab), for wet age-related macular degeneration, increased 21% to 573 million Swiss francs. Solid growth through the first and second quarters was driven primarily by an increase in the number of Lucentis injections administered to patients in their first and second years of treatment, as well as continued improvement in market conditions compared with the first half of 2008.

Sales of **Pegasys** (peginterferon alfa-2a), for hepatitis B and C, rose 10% to 842 million Swiss francs in the first half-year. Growth was driven by continuing strong demand in certain emerging markets, solid sales increases in the US and Japan, and steady market-share gains worldwide.

Following EU marketing approval in January of the novel rheumatoid arthritis (RA) medicine **RoActemra** (tocilizumab, known as **Actemra** outside Europe), the product has been launched in seven EU countries, including Germany. Actemra was also introduced in India and Brazil, with launches in additional countries worldwide planned for the second half-year as marketing and reimbursement approvals are gained. The response from physicians in the initial launch markets is very encouraging. In Japan, where Actemra was approved for RA in adults and related pediatric indications in April 2008, adoption continues to develop well, with doctors already using the medicine as a first-line biologic treatment in many patients.

Sales of **CellCept** (mycophenolate mofetil), for the prevention of solid organ transplant rejection, decreased 8% to 927 million Swiss francs in the first

⁴ Central and Eastern Europe, Middle East, Africa, Central Asia, Indian Subcontinent.

Top-selling pharmaceutical products – Roche Group

Product	Active substance	Indication	Sales in millions of CHF	% change in local currencies
MabThera/Rituxan	rituximab	non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis	3,098	8
Avastin	bevacizumab	advanced colorectal, non-small cell lung, and breast cancer, renal cell carcinoma, relapsed glioblastoma	3,090	29
Herceptin	trastuzumab	HER2-positive breast cancer	2,645	10
Tamiflu	oseltamivir	treatment and prevention of influenza A and B	1,010	203
CellCept	mycophenolate mofetil	transplantation	927	-8
Pegasys	peginterferon alfa-2a	hepatitis B and C	842	10
NeoRecormon, Epogin	epoetin beta	anemia	789	-10
Tarceva	erlotinib	non-small cell lung cancer, pancreatic cancer	643	10
Xeloda	capecitabine	colorectal cancer, breast cancer, stomach cancer	626	11
Lucentis ¹	ranibizumab	wet age-related macular degeneration	573	21

¹ US sales; Lucentis is marketed by Novartis outside the United States.

six months of 2009. As expected, following solid single-digit sales growth in the first quarter, sales fell sharply in the second quarter (-21% year on year) after the product's US patent expired in May, allowing generic competitors to enter the market. The erosion of US sales was partly offset by continued solid growth elsewhere, especially in China, Mexico, Western Europe and Japan.

Combined sales of Roche's **NeoRecormon** and Chugai's **Epogin** (epoetin beta), for anemia, declined 10% to 789 million Swiss francs in a highly competitive market. Combined second-quarter sales were down 8% compared with the year-earlier period. NeoRecormon maintained its market share in a declining market, while Epogin remains Japan's leading medication for renal anemia.

At the beginning of April Roche and Genentech announced a phased voluntary withdrawal of the psoriasis drug **Raptiva** (efalizumab) from the US market. The decision was based on the association of Raptiva with an increased risk of progressive multifocal leukoencephalopathy (PML), a rare and usually fatal disease of the central nervous system. As part of the measures agreed between the US Food and Drug

Administration (FDA) and Genentech, the Raptiva marketing licence was revoked as of 8 July. Genentech will continue to monitor patient safety.

Product development highlights

In the first six months of 2009 the Pharmaceuticals Division filed ten major new marketing applications and gained four major regulatory approvals (see table, p. 15).

In February Roche received EU approval for **MabThera** in combination with chemotherapy for previously untreated chronic lymphocytic leukemia (CLL), the most common form of adult leukemia. Roche filed an application in January for EU approval of MabThera for relapsed or refractory CLL, based on results of the REACH trial. In May Genentech and Biogen Idec submitted two supplemental Biologics License Applications (sBLAs) to the FDA for approval of **Rituxan** plus standard chemotherapy in previously untreated or treated CLL. The FDA has designated the first of these (treatment of patients with previously untreated CLL) for priority review.

Also in May, the FDA approved **Avastin** for use in patients with previously treated (relapsed)

glioblastoma, the most aggressive form of brain tumour. The new indication was granted under the FDA's accelerated approval programme and followed a unanimous vote by the agency's Oncologic Drugs Advisory Committee in March. In June the EU's Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion supporting the use of Avastin in combination with docetaxel in the first-line treatment of metastatic breast cancer. The filing was based on the results of the AVADO study.

In March Roche and OSI Pharmaceuticals submitted applications to the European Medicines Agency (EMA) and the FDA, respectively, for approval of **Tarceva** as maintenance therapy in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed following first-line chemotherapy. Both filings were based on data from the phase III SATURN trial. In July Roche, Genentech and OSI announced that SATURN had met an important secondary endpoint of extending overall survival in patients with advanced NSCLC who received Tarceva immediately after initial chemotherapy. A statistically significant improvement in overall survival was seen in the pre-planned final analysis of all patients in the study. These additional data will be submitted to the FDA and the EMA to support the March filings.

In June Roche submitted a combined filing to the EU health authorities to extend the marketing approval for **MabThera** as a first-line biologic therapy for rheumatoid arthritis (RA). The new indications being sought are for patients who have not been treated with methotrexate (MTX), the current standard treatment option, for patients who have had an inadequate response to MTX, and for the prevention of joint damage across all RA patient populations. The combined filing follows positive results from the IMAGE, SERENE and MIRROR trials, which showed that MabThera, when used as the first biologic in combination with MTX, improves the signs and symptoms of RA, compared with MTX alone. In addition, IMAGE demonstrated that treatment with MabThera combined with MTX can significantly reduce the progression of joint damage.

Roche Group presents strong clinical trials data at major medical conferences

The company presented results from more than 550 studies in over 20 types of cancer at the annual American Society of Clinical Oncology (ASCO) meeting from 29 May to 2 June. This was well over ten percent of the abstracts presented at the world's foremost oncology conference.

Among the presentations were the full results of the first phase III trial of **Avastin** in early-stage colon cancer (NSABP C-08). Although the study did not meet its primary endpoint of improving disease-free survival, the data suggest that Avastin is active in patients with early-stage colon cancer. Further insights will be provided by AVANT, another trial with Avastin in the adjuvant (early-stage) colon cancer setting, which is expected to report in 2010. We remain committed to the ongoing adjuvant programme with Avastin in colon, breast and lung cancer, which involves over 26,000 patients.

Positive phase III results from the SATURN and ATLAS studies presented at ASCO showed that effective maintenance treatment using **Tarceva**, following either Avastin based therapy or chemotherapy alone, can help lung cancer patients continue to fight their disease without the need for continued chemotherapy. The SATURN trial demonstrated that treatment with Tarceva benefited patients with squamous-cell and non-squamous non-small cell lung cancer (NSCLC). In addition, patients with mutations of the epidermal growth factor receptor (EGFR) showed a dramatic improvement in progression-free survival (the time patients live without their cancer getting worse).

The ATLAS results showed that combined first-line maintenance treatment with **Avastin** and **Tarceva** following Avastin based chemotherapy extends progression-free survival in patients with advanced NSCLC. The trial was stopped early because of the significance of the data. Roche plans to discuss the results with the regulatory authorities to determine requirements for potential regulatory filings.

Roche and Genentech also presented data from an international phase III trial (ToGA) which showed that combining **Herceptin** (trastuzumab) with standard chemotherapy (Xeloda or intravenous 5-FU and cisplatin) extends the lives of patients with advanced

Major regulatory filings in the first half of 2009¹

Product	Active substance	Indication and/or dosage form	Country
Avastin	bevacizumab	relapsed glioblastoma multiforme	Switzerland
MabThera/Rituxan	rituximab	rheumatoid arthritis – patients with an inadequate response to a disease-modifying antirheumatic drug; patients not previously treated with methotrexate; prevention of joint damage	EU, Switzerland
		first-line chronic lymphocytic leukemia	USA
		relapsed/refractory chronic lymphocytic leukemia	EU, USA, Switzerland
Tarceva	erlotinib	non-small cell lung cancer, first-line maintenance after chemotherapy	EU, USA, Switzerland

Major regulatory approvals in the first half of 2009¹

Product	Active substance	Indication and/or dosage form	Country
Avastin	bevacizumab	relapsed glioblastoma multiforme ²	USA
MabThera	rituximab	first-line chronic lymphocytic leukemia	EU
		relapsed/refractory chronic lymphocytic leukemia	Switzerland
RoActemra	tocilizumab	rheumatoid arthritis signs and symptoms	EU

¹ Includes supplemental indications; updated to 30 June 2009.

² Accelerated approval (FDA).

HER2-positive stomach cancer on average by nearly three months to 13.8 months. Patients with tumours exhibiting high levels of HER2 experienced even greater benefit from the addition of Herceptin: their lives were extended to 16 months on average.

Final results from a phase II study presented at ASCO show that treatment with **trastuzumab-DM1** (T-DM1, R3502), the first antibody-drug conjugate for breast cancer, produced a remarkable rate of tumour shrinkage in patients whose advanced HER2-positive disease had progressed following previous therapy. EMILIA, a phase III trial with T-DM1 in the second-line treatment of patients with HER2-positive metastatic breast cancer, commenced in February.

Also presented were highly promising data from a phase I trial investigating **R7204** (PLX4032) in patients with B-Raf mutation-positive malignant melanoma, the deadliest form of skin cancer. Roche and its partner Plexikon plan to evaluate R7204 in larger trials to support a potential registration programme beginning later this year. The companies are also codeveloping a diagnostic test to select

patients with B-Raf mutation-positive tumours for clinical trials and ultimately for treatment with R7204.

Findings from clinical trials with Roche Group medicines for autoimmune and metabolic disorders were also presented at major medical conferences in the first half of 2009. New data confirming the benefits of MabThera/Rituxan and Actemra/RoActemra in rheumatoid arthritis were presented at the European League Against Rheumatism (EULAR) annual congress in June. Results from the IMAGE trial demonstrated the ability of **MabThera/Rituxan** to reduce the progression of joint damage when used as a first-line biologic treatment in RA. Inhibiting the structural damage to joints is a critical measure of treatment effectiveness.

New long-term treatment data presented at EULAR show that rheumatoid arthritis patients treated with **Actemra/RoActemra** achieve consistently high remission rates that increase over time. In addition, one-year results from the LITHE study show that Actemra/RoActemra is effective in preventing the progression of joint destruction.

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

Compound	Lead indication	Status	Market potential
ocrelizumab	rheumatoid arthritis	phase III enrolment completed	best in class
T-DM1	HER2-positive metastatic breast cancer	phase III started Q1 2009 (2nd-line treatment)	first in class
pertuzumab	HER2-positive metastatic breast cancer	phase III started Q1 2008	first in class
R7159 (GA101)	non-Hodgkin's lymphoma	phase III to start in 2nd half of 2009	best in class
R7204 (PLX4032)	malignant melanoma	registration studies to start in 2nd half of 2009	first in class
hedgehog pathway inhibitor	advanced basal cell carcinoma	pivotal phase II started Q1 2009	first in class
ABT-263	chronic lymphocytic leukemia	phase II ongoing	first in class
aleglitazar	cardiovascular high risk in type 2 diabetes	phase III decision announced	first in class
tasoglutide	type 2 diabetes	first phase III results expected Q4 2009	best in class
dalcetrapib	dyslipidemia, cardiovascular high risk	phase III enrolment ongoing	first in class

Following the decision to advance **aleglitazar** (R1439) into phase III clinical testing, Roche expects the first trial to start in the first quarter of 2010. Aleglitazar is a novel PPAR co-agonist with unique properties and the potential to reduce cardiovascular disease and death in high-risk patients with type 2 diabetes. The results of the phase II SYNCHRONY study, presented at the annual American Diabetes Association Scientific Sessions in June, showed that the compound has positive effects on both blood fats and glucose control and a good safety and tolerability profile in patients with type 2 diabetes. Cardiovascular disease is the leading cause of death in people with type 2 diabetes, accounting for half of all fatalities in this patient population.

In July Roche and Genentech announced the results of a phase III study (BRAVO) which showed that **Lucentis** improved vision in patients with macular edema due to branch retinal vein occlusion. Retinal vein occlusion is a common cause of vision loss that occurs when blood flow through a retinal vein becomes blocked, such as by a blood clot.

Combination of Roche and Genentech creates industry-leading R & D pipeline

Combining Roche and Genentech has created one of the strongest R&D pipelines in the industry. The Group's late-stage pipeline now comprises ten new molecular entities (NMEs) in ongoing or planned late-stage clinical trials (see table, above). All of these agents have demonstrated promising activity and safety in early clinical trials.

As of 30 June 2009 the Pharmaceuticals Division's research and development pipeline (phase I to III/ registration) included 65 NMEs and 60 additional indications (AIs). During the first half-year six projects entered phase I, seven entered phase II and three entered phase III development. Portfolio prioritisations led to the discontinuation of three phase I and three phase II projects. Two phase III projects were discontinued.

In the first quarter of 2009 Roche announced new licensing agreements with Plexikon for PLX5568 (R7376), a novel kinase inhibitor for polycystic kidney disease, and with Evotec for phase II development of EVT 101 for treatment-resistant depression. The acquisition of US-based Memory Pharmaceuticals

was completed in January. In May Roche and Tekmira Pharmaceuticals entered into a product development agreement to advance Roche's first two RNA interference (RNAi) product candidates into human clinical testing. Both product candidates will be based on Tekmira's stable nucleic acid-lipid particle (SNALP) technology.

Reshaping the global supply network

Roche and Genentech are working closely to integrate and optimise the combined supply network. The division is reshaping its manufacturing network to concentrate activities, align capacity requirements and ultimately improve operational efficiency. As part of the realignment, the second bulk drug production unit at Genentech's Vacaville (USA) facility will be closed and a new unit at Roche's Penzberg (Germany) plant will not be completed.

Roche continues to invest in its manufacturing network to ensure continuous supply of medicines to patients worldwide. In January the foundation stone was laid for a technical research and development building in Basel (Switzerland). The new facility will house a centre for the development of production methods and the manufacture of clinical trials samples. In June Roche inaugurated a new production centre in Kaiseraugst (Switzerland), for the manufacture of medicines in sterile forms, including liquid and lyophilised vials and prefilled syringes.

Key figures: Diagnostics Division

	In millions of CHF	% change in CHF	% change in local currencies	As % of sales
Sales	4,902	3	7	100
– Professional Diagnostics	2,238	4	9	46
– Diabetes Care	1,438	–3	3	29
– Molecular Diagnostics	594	5	6	12
– Applied Science	403	8	8	8
– Tissue Diagnostics	229	40	33	5
Operating profit	644	11	28	13.1
Operating free cash flow	507	102	131	10.3

Diagnostics

Roche's Diagnostics Division performed strongly in the first half of 2009. Divisional sales again grew significantly faster than the market, with strong uptake of new products contributing to market share gains in key segments such as immunoassays. All five business areas launched major new products. The operating profit and operating margin increased, helped by strong sales growth and ongoing improvements in operational efficiency.

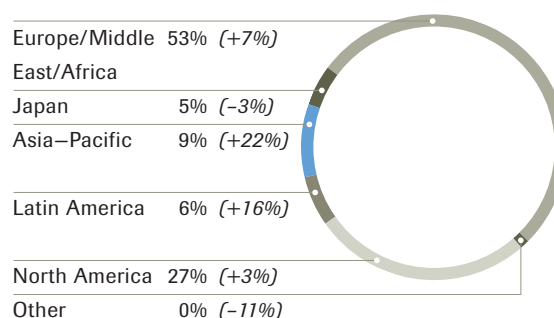
Results and main business developments

In the first half of 2009 the Diagnostics Division recorded sales of 4.9 billion Swiss francs, an increase of 7% in local currencies (3% in Swiss francs; –4% in US dollars) over the first six months of 2008.¹ This was more than twice the estimated growth of the *in vitro* diagnostics market (3%). Second-quarter sales totalled 2.5 billion Swiss francs, up 7% from the year-earlier period.

All five business areas increased their half-year sales, led by Professional Diagnostics and Tissue Diagnostics. Regionally, the strongest growth occurred in Asia–Pacific and Latin America, with all business areas contributing. Tissue Diagnostics was the primary sales driver in North America. In Japan Professional Diagnostics and Tissue Diagnostics achieved good growth, but overall sales were down slightly.

The division's operating profit for the half-year increased 28% to 644 million Swiss francs. The operating margin in local currencies advanced 2.3 percentage points despite higher cost of sales.

Sales by region



Italics = growth rates.

The increase reflects sales growth, tight cost management and significant one-time expenses in the first half of 2008, particularly in relation to the Ventana acquisition. In Swiss francs the margin increased only 0.9 percentage points to 13.1%, due particularly to the unfavourable impact of currency movements. For more information on the divisional operating results, see the Financial Review on page 23.

In April Roche acquired innovatis AG, a leader in automated cell analysis solutions; integration activities are already well underway. Integration of Swisslab GmbH, a leading European supplier of laboratory information systems, acquired in December 2008, has been completed. The acquisitions expand and strengthen the portfolios of the Applied Science and Professional Diagnostics businesses, respectively.

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

Roche's top-selling diagnostics

Product lines	Market segment	Business area	Sales in millions of CHF	% change in local currencies
Accu-Chek meters	Blood glucose monitoring	Diabetes Care	1,333	3
cobas e modules, Modular Analytics, Elecsys	Immunoassays	Professional Diagnostics	789	18
cobas c modules, Modular Analytics, Cobas Integra	Clinical chemistry	Professional Diagnostics	638	3
cobas AmpliPrep/ cobas TaqMan	Virology	Molecular Diagnostics	283	4
cobas AmpliScreen, cobas TaqScreen	Blood screening	Molecular Diagnostics	158	10
CoaguChek	Coagulation monitoring	Professional Diagnostics	140	24
Immunohistochemistry reagents	Advanced tissue staining	Tissue Diagnostics	138	39
MagNA Pure/LightCycler	Gene expression research	Applied Science	103	11

Focus on operational efficiency

The division is taking decisive steps to improve operational efficiency. Initiatives to simplify core processes, consolidate services, streamline product portfolios and reduce time to market without increasing development costs are in place at several major sites. In the first half of 2009 such initiatives contributed to a 10% decrease in administration costs and helped the division limit headcount growth despite the Swisslab and innovatis acquisitions. As existing programmes are expanded to more sites and further initiatives are launched, they are expected to enhance productivity and yield additional savings in all areas.

Business area highlights – All business areas continue to grow sales while stepping up stream of new products

Roche Professional Diagnostics' half-year sales outpaced the market, advancing 9% to 2,238 million Swiss francs. Second-quarter sales increased 9% over the year-earlier period. Immunoassays and clinical chemistry, the unit's two largest segments by sales, remained the biggest contributors to growth, with half-year sales up 18% and 3%, respectively.

Recent additions to the immunoassay menu such as the Elecsys anti-CCP assay (diagnosis of rheumatoid arthritis) were among the important growth drivers. Sales of products for decentralised testing rose 5%, led by strong double-digit growth from coagulation

monitoring products like the CoaguChek XS for health professionals and patients.

Professional Diagnostics launched four new immunoassays in the EU and other markets recognising CE Mark certification. These include a highly sensitive test for cardiac troponin T that can detect even minor myocardial injury in acute heart attack patients and patients with chronic heart disease.

In August the business area will begin rolling out the cobas 8000 series of modular analysers for high-throughput laboratories in Europe. The response when this new flagship cobas platform was unveiled at the Euromedlab Conference in June was overwhelmingly positive.

Roche Diabetes Care maintained its global market leadership with sales up 3% to 1,438 million Swiss francs for the half-year. Second-quarter sales increased 2% from the year-earlier period. The economic downturn has impacted some markets like the US where a number of patients pay or co-pay for their medical supplies. Half-year sales in North America showed low single-digit growth despite a declining market.

The Accu-Chek Aviva and Accu-Chek Performa blood glucose (BG) monitoring systems remained the main growth drivers, more than offsetting declining sales of

older Accu-Chek systems. Accu-Chek Aviva, Diabetes Care's top-selling BG meter, posted half-year sales growth of over 22%.

The launch of four major BG monitoring systems, including Accu-Chek Mobile (featuring strip-free technology) and the compact Accu-Chek Aviva Nano and Performa Nano monitors (for young, frequent testers), got off to a strong start in Europe. Accu-Chek Combo, Europe's first interactive diabetes management system combining an insulin pump and a BG meter/remote control, was successfully launched in its first markets.

Roche Molecular Diagnostics' half-year sales advanced 6% to 594 million Swiss francs. Growth was led by the core blood screening portfolio, which gained market share on 10% sales growth. The business area maintained its leading share of the increasingly competitive virology market with low single-digit sales growth. The business area's second-quarter sales increased 4% over the year-earlier period.

The fully automated cobas TaqScreen MPX multiplex blood screening test, available in Europe since 2006 and launched last year in the US, was a major contributor to growth. In virology, the business area captured competitive share in the US with its suite of automated viral load monitoring tests, which includes hepatitis B and hepatitis C tests launched in the US in the second half of 2008.

Very strong uptake of the TheraScreen K-RAS Mutation Test, which Roche began distributing in December 2008, was also a major growth driver. Used with other clinically relevant information, the test can aid doctors in determining patients' suitability for certain cancer treatments. It is the first clinically validated, CE Mark-certified companion diagnostic for tumour-specific mutations in patients with colorectal cancer.

The LightCycler MRSA Advanced Test for improved screening for methicillin-resistant *Staphylococcus aureus* – a potentially deadly microbe that is a growing public health concern worldwide – was launched in Europe in April. A filing for US marketing clearance of the test was submitted to the Food and Drug Administration in May.

Roche Applied Science's half-year sales rose 8% to 403 million Swiss francs despite competitive price erosion and the impact of the economic downturn on government research spending. Second-quarter sales grew 11% compared with last year.

DNA sequencing systems and microarrays continued to drive growth, delivering robust double-digit sales increases. Placements of the xCELLigence cell analysis systems launched worldwide last year also contributed significantly to growth.

In the second quarter Applied Science launched the LightCycler 1536 system for high-throughput DNA/RNA analysis using real-time quantitative PCR (polymerase chain reaction) technology. The system's miniaturised 1536 well format enables scientists to extract more data from precious biological samples.

Roche Tissue Diagnostics' half-year sales totalled 229 million Swiss francs, a 33% rise over the five months' sales consolidated in the first half of 2008, following the Ventana acquisition in February. On a comparable basis, half-year sales advanced 17%, well ahead of the market. Second-quarter sales grew 18% versus the prior-year period.

Advanced tissue staining (immunohistochemistry and *in situ* hybridisation) was again the main growth driver, reflecting a robust double-digit rise in immunohistochemistry reagent sales and excellent uptake of the BenchMark Ultra system, launched in the US and EU in 2008. Half-year sales of the Symphony slide staining instrument and reagents for the high-volume primary staining market grew at double-digit rates.

In the first half of 2009 Tissue Diagnostics launched further immunohistochemistry probes and antibodies to detect various cancers, including lung and gastric cancer, leukemia and lymphoma. In June the labelling of two HER2 testing products used to predict treatment response to Herceptin in breast cancer was expanded to include analytical claims for use with gastric tissue samples.

Tissue Diagnostics continues to expand its business into new geographic markets, including major emerging markets in Asia-Pacific and Latin America.

Major product launches in the first half of 2009

Business area	Product	Quarter
Professional Diagnostics	High-sensitivity Elecsys Troponin T immunoassay for the diagnosis of heart attack and cardiac risk stratification (EU)	Q1
	Elecsys immunoassays for PIGF (placenta growth factor) and sFlt1 (soluble fms-like tyrosine kinase 1) for the diagnosis of preeclampsia (EU)	Q1
	Elecsys IL-6 (interleukin-6) immunoassay to aid the management of critically ill patients (EU)	Q1
	Elecsys Troponin I Assay: test for cardiac-specific troponin I levels to predict mortality risk in patients with acute coronary syndrome (EU)	Q2
	Sysmex XT-4000i: new-generation automated hematology analyser with test capabilities for whole blood and other body fluids (contractual territory in EMEA)	Q2
	Diabetes Care	Accu-Chek Mobile: integrated lancing and blood glucose monitoring device employing a unique 'no strip' technology that replaces test strips with a continuous tape of 50 tests (EU)
	Accu-Chek Aviva Nano and Accu-Chek Performa Nano: sleeker versions of the Accu-Chek Aviva and Accu-Chek Performa meters offering an enhanced feature set (EU)	Q1
	Accu-Chek Active: new version of an existing meter, featuring an extended test memory and a number of fail-safe capabilities (EU)	Q1
	Accu-Chek Combo: diabetes management system combining an insulin pump with a glucose meter that also functions as a pump remote control (EU)	Q1
Molecular Diagnostics	MRSA Advanced Test: automated real-time test for methicillin-resistant <i>Staphylococcus aureus</i> . The test can identify MRSA carriers in under two hours (EU)	Q2
Applied Science	xCELLigence RTCA DP (dual plate) system: highly flexible medium-throughput system for real-time non-invasive cell analysis (worldwide)	Q2
	LightCycler 1536 system for high-throughput quantitative PCR analysis (worldwide)	Q2
	NimbleGen MS 200: fully automated high-resolution microarray scanner for use with all NimbleGen DNA microarrays (worldwide)	Q2
Tissue Diagnostics	INFORM EGFR DNA Probe: detects extra copies of the epidermal growth factor receptor (EGFR) gene, an abnormality associated with non-small cell lung cancer (EMEA, APAC)	Q1
	Intended use of CONFIRM anti HER2/neu Primary Antibody and INFORM HER2 DNA Probe expanded to include analytical claims regarding performance with gastric as well as breast tissue samples (EMEA, APAC)	Q2

EU = European Union; EMEA = Europe, Middle East and Africa; APAC = Asia-Pacific.