

# Media Release

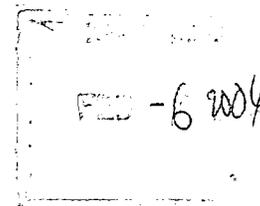


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Basel, 2 February 2004

## Roche's Corporate Sustainability website launched

New annual Sustainability Report to be released in combination with annual results

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Roche announces the launch of a new section on its internet website detailing Roche's many activities towards sustainable development. As a global company Roche contributes daily to improving the quality of life of people around the world and is directly involved in community service projects, makes donations to charitable causes and works in partnership with a wide range of non-profit organizations. Based on the triple bottom line approach of social and environmental responsibility, combined with economic viability, the new section on Corporate Sustainability is designed to provide a detailed overview on the many achievements made and initiatives launched by the company towards sustainable development and improved corporate governance.

"Sustainability as a term is relatively new, but the principle it expresses has long been a part of Roche's culture and activities" says Franz B. Humer, Chairman and CEO of Roche. "Since the foundation of Roche more than 100 years ago, sustainability has guided our activities by uniting entrepreneurial responsibility with innovation for health." Humer continues "Innovation is central to Roche's pharmaceutical and diagnostic business. But we are also breaking new ground to resolve healthcare challenges in the developing world and we put great emphasis on state of the art environmental protection technologies as well as on programs for our employees. Now access to detailed information concerning these activities, along with Roche's policies and guidelines has been facilitated through this new site."

Strong corporate responsibility has always featured highly within Roche, as exemplified by programs initiated or sponsored by the Swiss company since many years, such as the "Phelophepa train" (since 1994), "Sight and Life" (since 1986) and "Blue Sky" (since 1998) initiatives, and these values have continued to inform its corporate culture to this day. Roche is

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committed to a system of corporate governance that conforms to the latest standards and is continuously benchmarking its principles and achievements against the industry and best practice.

In addition to its internet publication, Roche will launch its first Corporate Sustainability report in conjunction with the annual report on February 4<sup>th</sup> 2004. Since 1992 Roche has been producing a detailed Safety and Environmental Protection report, which will be expanded to include information on social responsibility, as well as number of indicators as recommended by the Global Reporting Initiative (GRI). This report will provide a vehicle for summarizing key figures and activities, and will compliment the Sustainability website.

#### Sustainable Development and Roche

Roche regards safety and environmental protection as crucial issues and believes that sustainable business practices are the key to success for a forward-looking, innovative company. Sustainable development means conserving resources in order not to restrict the options available for future generations. In 2003 Roche revised its Corporate Principles, first published in 1990, and adapted them accordingly. The main objective was to bring them into line with Roche's strategic realignment as a healthcare company built on the twin pillars of pharmaceuticals and diagnostics. At the same time Roche wanted to give more emphasis to good corporate citizenship, environmental stewardship and corporate governance. The Roche Corporate Sustainability Committee was set up in 2003 with the task of assessing and coordinating the Group's policies and activities as they relate to sustainable development.

Details on the wide range of Roche's contributions including its transparent price and patent policies, assistance with infrastructure, training, education, sponsorships and numerous other programs may be found on the Internet ([www.roche.com/home/sustain.htm](http://www.roche.com/home/sustain.htm)).

#### Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 65,000 people in 150 countries. The Group has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai. Roche's Diagnostics

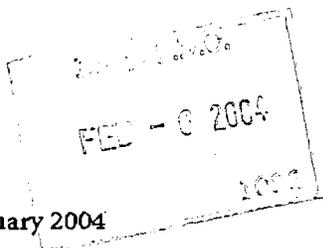
Division, the world leader in in-vitro diagnostics with a uniquely broad product portfolio, supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide.

**Additional information**

- Roche's commitment to Sustainable Development: [www.roche.com/home/sustain.htm](http://www.roche.com/home/sustain.htm)

- Roche's commitment to Access to Healthcare:

[www.roche.com/pages/downloads/sustain/pdf/comm\\_diff\\_rep.pdf](http://www.roche.com/pages/downloads/sustain/pdf/comm_diff_rep.pdf)



Basel, 2 February 2004

## Roche scientists identify small molecules that activate a key tumour suppressor pathway

New insights into a key cancer pathway – known as p53 – have been uncovered by scientists at Roche. In a paper published in the February 6 issue of *Science* and *Scienceexpress* on January 2, for the first time, researchers have identified a small molecule that activates the p53 pathway by preventing the binding between p53 and its inhibitor, MDM2. Long a target of interest to cancer researchers, it was believed that it would not be possible to create a potent small molecule p53-MDM2 binding inhibitor. The new research shows that this is now possible.

The tumour suppressor p53 is a potent transcription factor controlling a major pathway, which protects cells from becoming malignant. This makes it the most frequently inactivated protein in human cancer and therefore an important pathway to target for cancer therapy. Approximately 50 percent of all human tumours have dysfunctional p53. It is believed that in the rest of the human malignancies the tumour suppressor is disabled by other mechanisms. One such mechanism is the overproduction of its natural inhibitor MDM2. "By inhibiting MDM2 we can stabilize and activate p53, which leads to growth arrest and apoptosis (cell death) in tumour cells," noted Lyubomir Vassilev, Ph.D., research leader at Roche, and lead author on the paper. "Therefore, this new research may offer a novel strategy for cancer therapy and allow us to develop a small-molecule drug, which could be administered orally."

Protein-protein interactions have historically posed a challenge in drug development. To identify the small molecule, Roche scientists screened a diverse library of chemicals via high throughput screening and identified a class of compounds, termed Nutlins, which inhibit tumour growth in mice by 90 percent, without producing harmful side effects. "Although MDM2 antagonists are likely to be most effective against those tumours that have abnormally high levels of MDM2, many of the 50 percent of all patients with cancers harbouring wild-type p53 may also benefit from p53-activating therapy" added Dr. Vassilev.

"While many more studies are needed to assess the full therapeutic potential of Nutlins, this research has provided us with valuable tools for the discovery process, as well as increased our knowledge and understanding of the p53 pathway in many ways," stated David Heimbrook, Ph.D., vice president, Nutley Oncology Research and global therapeutic area head, Oncology at Roche.

#### About p53

The p53 protein and its corresponding gene were discovered in 1979 but its role as a major tumor suppressor was elucidated in the early 90's. P53 controls cellular response to stress, including DNA damage, by inducing cell cycle arrest or programmed cell death (apoptosis) thus protecting cells from malignant transformation. The gene coding for the p53 protein is the most commonly mutated gene in all human cancers, with 50 percent of tumors found to have lesions in the p53 gene. That number rises to 60-70 percent in certain lung and colon cancers.

#### Roche in Oncology

Within the last five years Roche has become the world's leading provider of anti-cancer treatments, supportive care products and diagnostics. Its oncology business includes an unprecedented three marketed products with survival benefit; Herceptin, MabThera and Xeloda, treating a range of malignancies - breast cancer, non-Hodgkin's lymphoma and colorectal cancer. Other key products include NeoRecormon (anaemia in various cancer settings), Bondronat (prevention of skeletal events in breast cancer and bone metastases patients, hypercalcemia of malignancy), Kytril (chemotherapy and radiotherapy-induced nausea and vomiting) and Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma). Roche's cancer medicines generated sales of 4.5 billion Swiss francs in the first nine months of 2003.

The goal of Roche oncology research is to provide more effective cancer therapies through the discovery and development of novel therapeutics. The company's research focus is on four major approaches to cancer treatment: tumor suppression, molecular-targeted therapies, inhibition of blood vessel growth and supportive care. A variety of tumor types are being investigated, including five common and deadly forms: lung, breast, colon and prostate cancer and lymphoma.

Roche is developing new tests which will have a significant impact on disease management for cancer patients in the future. With a broad portfolio of tumour markers for prostate, colorectal, liver, ovarian, breast, stomach, pancreas and lung cancer, as well as a range of molecular oncology tests, we will continue to be the leaders in providing cancer focused treatments and diagnostics. Roche Oncology has four research sites (two in the US, Germany and Japan) and four Headquarter Development sites (two in the US, UK and Switzerland).

### About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 65,000 people in 150 countries. The Group has alliances and R&D agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

### Further information

Gene p53 - A Paradigm for Drug Discovery." *The Pharmaceutical Journal*. 2000; Volume 265, No 7116: p486

<http://www.roche.com/home/science/science-events/science-roundtablep.htm>

<http://www.gene.com/gene/index.jsp>

<http://www.sciencemag.org>

# Media Release



Basel, 4 February 2004

## **Roche in 2003: growth significantly outpaces global market — strong operating performance — net income of 3.1 billion Swiss francs**

### **Roche Group in 2003**

- Roche posts double-digit sales gains in core businesses, up 19% in local currencies (11% in CHF) to 29.0 billion CHF — sustained strong growth in Q4 2003
- Operating profit of core businesses before exceptional items rises 25% in local currencies (17% in CHF) to 6.1 billion CHF, operating profit margin up from 20.0% to 21.1%
- Very robust gross cash flow (EBITDA) of 8.4 billion CHF from core businesses, financial position strengthened further
- Net income totals 3.1 billion CHF (following previous year's net loss of 4.0 billion CHF) — seventeenth dividend increase in as many years
- Further improvements to corporate governance, appointment of independent lead director planned
- Group publishes first separate Sustainability Report
- Roche expects to outpace global market growth again in 2004, operating profit margin of above 22% anticipated in 2005

### **Roche Pharmaceuticals in 2003**

- Thanks to organic growth and integration of Chugai, Pharmaceuticals Division posts sales growth of 23% in local currencies (14% in CHF), gains market share in all major regions worldwide
- Operating profit margin before exceptional items up 1.1 percentage points to 23.0%
- Hepatitis C combination treatment Pegasys plus Copegus exceeds expectations with sales of nearly 1 billion CHF

### **Roche Diagnostics in 2003**

- Diagnostics Division substantially ahead of world market as sales grow by 8% in local currencies (3% in CHF)
- Operating profit margin before exceptional items up 0.5 percentage points to 19.0%
- Strategic boost from acquisitions of Disetronic and Igen

Commenting on the full-year results for 2003, Roche Chairman and CEO Franz B. Humer said, "We are pleased to report that we achieved our ambitious goals in 2003. Together, our core pharmaceuticals and diagnostics businesses posted double-digit sales growth of 19% in local currencies, and both grew faster than their respective markets. Operating profit before exceptional items again grew faster than sales. It rose by 25% in local currencies to 6.1 billion Swiss francs. In addition, we strengthened Roche's financial position further and continued to enhance corporate governance. The good results achieved in 2003 confirm that our clear strategy of focus and innovation is on track and being successfully implemented. We firmly believe that long-term business success is possible only through economically, socially and environmentally sustainable value creation. Our new sustainability report underlines this commitment."

**Key figures** *in millions of CHF*

			Roche Group % change		Continuing businesses <sup>a)</sup> % change			
	2003	2002	in CHF	in local cur.	2003	2002	in CHF	in local cur.
Sales	31,220	29,453	6	13	28,960	26,066	11	19
EBITDA <sup>b)</sup>	8,609	7,993	8	16	8,390	7,532	11	20
Operating profit before exceptional items	6,268	5,448	15	24	6,104	5,223	17	25
Operating profit	5,592	1,335	319	350	5,823	4,532	28	37
Net income	3,069	-4,026	-	-	3,292	-1,052	-	-
Research and development	4,766	4,257	12	21	4,671	4,132	13	22
Additions to property, plant and equipment	2,265	2,044	11	17	2,093	1,746	20	28
Earnings per share and non-voting equity security, diluted (in CHF)	3.61	-4.80	-	-	3.87	-1.25	-	-
Dividend per share and non-voting equity security (in CHF) <sup>c)</sup>	1.65	1.45	14	-	-	-	-	-
Employees	65,357	69,659		-6	65,357	62,398		5

a) Continuing businesses includes the core pharmaceuticals and diagnostics businesses, together with treasury and other corporate activities. The Vitamins and Fine Chemicals Division is reported as a discontinuing business.

b) EBITDA: Earnings before exceptional items and before interest and other financial income, tax, depreciation and amortisation, including impairment. This corresponds to operating profit before exceptional items and before depreciation and amortisation, including impairment.

c) 2003 dividend as proposed by the Board of Directors.

## Roche Group

In 2003 combined sales by Roche's core pharmaceuticals and diagnostics businesses totalled 29.0 billion Swiss francs, a year-on-year increase of 19% in local currencies (11% in CHF), with new and established Roche products contributing gains of around 12% and the integration of Chugai some 7%. Both divisions posted above-market growth, with pharmaceutical sales up 23% in local currencies (14% in CHF) and diagnostics sales up 8% in local currencies (3% in CHF).

### **Core businesses: substantial increases in operating profit and margin**

Thanks to the strong sales growth and a reduction in other operating expenses, operating profit before exceptional items rose 25% in local currencies. Operating profit after exceptional items increased by an even stronger 37% in local currencies. The operating profit margin before exceptional items rose by 1.1 percentage points to 21.1% and after exceptional items by 2.7 percentage points to 20.1%.

### **Strong cash flow, major progress in finance**

The Group's financial position was also strengthened in 2003, helped in particular by strong cash flow from operating activities and the proceeds from the sale of the Vitamins and Fine Chemicals Division to DSM. Roche's core pharmaceuticals and diagnostics businesses generated an impressive gross cash flow (EBITDA) of 8.4 billion Swiss francs. Group debt was substantially reduced and bank loans replaced by capital market bonds. The Group's net liquidity increased from 0.6 billion to 5.9 billion Swiss francs, while the equity ratio (including minority interests) improved from 40% to 49%.

### **Return to healthy net income level**

In 2003 the Roche Group posted net income of 3.1 billion Swiss francs, or 3.3 billion francs for its core businesses, following the net loss recorded in 2002 under the impact of one-time charges. The consolidated financial statements for 2003 include Chugai's full-year results (versus three months for the year-earlier period) and the Vitamins and Fine Chemicals Division in the first nine months of the year, including the closing entries relating to the sale of the division.

### **Outlook optimistic**

Roche expects both its pharmaceuticals and diagnostics businesses to grow faster than the global market in 2004. The Pharmaceuticals Division remains committed to achieving an operating profit margin approaching 26% before exceptional items by the end of 2004 (equivalent to the previously announced goal of an adjusted margin approaching 25%). The Diagnostics Division is expected to achieve its objective of an operating profit margin of around 23% before exceptional items in 2006 (equivalent to the previously announced goal of an adjusted margin of 20%). The Group anticipates an operating profit margin of above 22% in 2005.

### **Seventeenth dividend increase in as many years — changes on the Board of Directors**

Based on the strong gains in operating result and net income, the Board of Directors will ask the Annual General Meeting on 6 April 2004 to approve a dividend increase of 14%, to 1.65 Swiss francs per share and non-voting equity security.

As previously announced, Fritz Gerber, Andres F. Leuenberger and Henri B. Meier will be stepping down

from the Board of Directors at this year's AGM. The Board will nominate Bruno Gehrig and Lodewijk J.R. de Vink as new members for election by the AGM. Subject to his election, Bruno Gehrig will assume the newly created function of Independent Lead Director. Before taking up his current position as chairman of the board of directors of Swiss Life Holding, Bruno Gehrig was vice-chairman of the governing board of the Swiss National Bank, which he joined in 1996. From 1992 to 1996 he was Professor of Business Economics at the University of St. Gallen. Lodewijk J.R. de Vink is a founding member and consultant of Blackstone Healthcare Partners. A past president of Schering International and former chairman, president and CEO of Warner-Lambert, Mr de Vink has very solid experience spanning many years in the pharmaceutical industry.

The Board will also propose that the General Meeting elect KPMG as the new Group auditors and statutory auditors of Roche Holding Ltd.

#### **Further improvements to corporate governance**

The proposed changes to the Board of Directors mean that the majority of its members will be independent directors who can contribute substantial international experience and expertise. Other improvements to corporate governance at Roche include changes that facilitate comparison of the Group's results with those of other healthcare companies. As announced at the end of 2003, Roche is changing the presentation of its consolidated financial statements for the current and year-earlier periods to distinguish between continuing and discontinuing businesses. The expanded information in Roche's latest Annual Report includes details of the compensation paid to the Board of Directors and to each member of the Executive Committee.

#### **Roche publishes first separate Sustainability Report**

As a good corporate citizen, Roche has long accepted its responsibilities towards the environment and society. Its new Sustainability Report, which from now on will be published each year with the Annual Report, underscores this commitment. The Sustainability Report includes the Group's safety and environmental protection report, which used to be published separately each year. The new report details the main activities Roche is undertaking to promote sustainable development. In doing so, the company is observing the guidelines of the Global Reporting Initiative --- a body that unites the interests of various dialogue groups and works closely with agencies of the United Nations.

## Pharmaceuticals Division

Double-digit growth in prescription drugs business

Key figures	in millions of CHF	% change in CHF	% change in local currencies	as % of sales
Sales	21,551	14	23	100
- Roche worldwide prescription group	19,781	14	23	92
- Non-prescription medicines (OTC)	1,770	12	17	8
EBITDA	6,542	13	21	30.4
Operating profit*	4,965	20	28	23.0
Research and development	3,946	14	25	18.3
Employees	46,625	4	-	-

\*Before exceptional items

Sales by the Pharmaceuticals Division increased 23% in local currencies (14% in CHF) to 21,551 million Swiss francs. Even without the newly integrated Chugai, sales grew faster than the global market, with new and established Roche products accounting for over half of the gains (+14% in local currencies). Operating profit before exceptional items rose even faster than sales, advancing 28% in local currencies (20% in CHF) to 4,965 million Swiss francs. Despite substantially higher expenditures on new drug launches and on the many highly promising projects in its development pipeline, the Pharmaceuticals Division posted another significant increase in profitability, recording an operating profit margin before exceptional items of 23.0%, a gain of 1.1 percentage points. EBITDA was up 21% in local currencies (13% in CHF) to 6,542 million Swiss francs. The EBITDA margin was comparable to that of 2002.

### Prescription medicines continue to post strong growth

Sales of prescription medicines in 2003 totalled 19,781 million Swiss francs, a rise of 23% in local currencies (14% in CHF). Operating profit before exceptional items reached 4,698 million Swiss francs, and the operating profit margin, at 23.8%, was also up again for the year. EBITDA increased to 6,234 million Swiss francs, or 31.5% of sales. The division's oncology portfolio<sup>1</sup> continued to be a major contributor to growth, with sales rising 30%<sup>2</sup> to 6,078 million Swiss francs. Sales and market penetration of Pegasys and Copegus, a new combination treatment for hepatitis C, surpassed the division's high expectations. Fuzeon, Roche's novel HIV/AIDS therapy, has now been launched in 12 markets worldwide. CellCept and NeoRecormon posted accelerated growth, with both products experiencing double-digit gains in their respective indications. As expected, Roaccutan/Accutane experienced sales erosion due to generic competition.

<sup>1</sup> Oncology portfolio: MabThera/Rituxan, Herceptin, Xeloda, Bondronat, Kytril, Furtulon, Neupogen, NeoRecormon (25%), Roferon-A (60%), Neutrogen, Picibanil.

<sup>2</sup> All growth rates are based on local currencies.

### **Above-market growth in all regions**

Roche's prescription medicines posted above-market sales growth in all key regions. Thanks to strong sales by both Genentech and Roche, sales in North America increased by 20%, significantly outpacing the market. In Europe prescription drug sales accelerated in the double-digit range. The very strong sales increase recorded in the relatively sluggish Japanese market can be ascribed mainly to the consolidation of Chugai since 1 October 2002 and to above-average underlying organic growth. In Latin America sales returned to growth in a still-declining market. In rapidly developing markets from Eastern Europe to China, Roche has been growing very quickly and is strongly positioned as an industry leader.

### **Oncology — Roche extends its market lead**

In 2003 Roche strengthened its position as the world's number-one oncology company, with more than 6 billion Swiss francs in sales and a 30% growth rate. MabThera/Rituxan, for non-Hodgkin's lymphoma (NHL), achieved sales of 2.8 billion Swiss francs (+34%). Trial data announced in December showed that MabThera/Rituxan in combination with chemotherapy also represents a major clinical advance in the first-line treatment of indolent lymphoma. These data are expected to result in an expanded indication, potentially doubling the number of patients with indolent NHL who could benefit from treatment with MabThera/Rituxan. A regulatory filing for the combination was submitted to the EU authorities in January 2004. Herceptin sales rose 27%. A recent study has shown that the combination of Herceptin and Taxotere significantly improves patient survival compared with Taxotere alone. Based on these positive results, Roche has filed a marketing application for the Herceptin-Taxotere combination in the European Union. Roche expects the filing to be approved in 2004. Xeloda sales continued their strong upward trend, growing by 29%. This tumour-activated oral chemotherapeutic agent is used to treat breast and colorectal cancers. Xeloda was approved for the treatment of breast cancer in Japan. Sales of Kytril, an anti-emetic used in patients who are receiving chemotherapy or radiation therapy or who have undergone surgery, were up 7%. Thanks to its highly competitive profile, it recaptured market share in a fiercely contested segment.

### **Anemia — strong growth**

Combined sales of NeoRecormon and Epogin — the leading products for the treatment of renal anemia in Europe and Japan, respectively — rose 77%. NeoRecormon alone posted an impressive 30% increase in sales and achieved significant market share gains in Europe, where the regulatory authorities approved a new regimen in April for dialysis patients with stable hemoglobin levels. The use of this medicine in oncology continues to rise. A marketing application for a new, easy-to-use NeoRecormon formulation for once-weekly treatment of anemic patients with lymphoid malignancies was recently submitted to the EU authorities.

### **Transplantation — sales of leading immunosuppressant in the US accelerate**

Sales growth for Roche's immunosuppressive agent CellCept, the top-selling branded product in the United States for preventing organ rejection, accelerated to a rate of 27%. Combined sales of Valcyte and Cymevene grew 6%. Because of its potency and simple dosing schedule, Valcyte is increasingly the medicine of choice for preventing and treating cytomegalovirus infections (e.g. CMV retinitis). Initially approved for use in HIV-infected patients co-infected with CMV, the product gained important approvals last year in the European Union and the United States for use in solid organ transplant patients with CMV infections.

### **Virology — exceptional gains in hepatitis C segment**

Sales of Pegasys and Copegus, Roche's new drug combination for hepatitis C, totalled 942 million Swiss francs. In December Pegasys accounted for over 50% of total US interferon prescriptions for hepatitis C. Pegasys and Copegus are available for the treatment of hepatitis C in more than 80 countries. In October Pegasys monotherapy was approved in Japan, completing the regulatory approval process in all major markets worldwide. Fuzeon, the world's first fusion inhibitor, is being rolled out for HIV. The product belongs to the first new class of anti-HIV treatments in seven years and is the first and only drug that blocks the virus before it enters host cells. Fuzeon is currently available in 12 countries, and further important launches are expected in the near future. Sales totalled 49 million Swiss francs. Roche and its partner Trimeris are actively working to accelerate the uptake of Fuzeon in the US market. Combined sales of the protease inhibitors Viracept, Invirase and Fortovase declined by 11%. Viracept remains under pressure from competitor products and was also affected last year by additional price reductions in important markets. Sales of Tamiflu were up sharply, increasing by 184%, due to the severe 2002/2003 flu season in Japan and an early start to the 2003/2004 flu season in the United States.

### **Other major products — Rocephin sales remain stable**

While Xenical remained the leading weight management medicine in 2003, sales declined by 13% in line with market trends. In December 2003 the US Food and Drug Administration (FDA) approved labelling for the use of Xenical in the management of obesity in patients aged 12 to 16 years. Sales of Dilatrend, a beta blocking agent for hypertension, chronic heart failure and coronary artery disease, continued to rise, advancing 19% for the year. Well established in hypertension and coronary heart disease, Dilatrend benefited in late 2003 from new clinical data from the COMET study. Roche expects sales to decline in 2004, as Dilatrend will be going off patent in several major European markets at the beginning of April. Roche's new bisphosphonate, Bonviva/Boniva (ibandronate), was approved by the FDA in May 2003 for the treatment and prevention of osteoporosis in postmenopausal women and received a positive opinion for use in the same indication from the European Union's Committee for Proprietary Medicinal Products (CPMP) in October. Based on very encouraging phase III trial data, a supplemental filing for a

simpler, more convenient dosage regimen will be submitted in 2004. Overall sales of Rocephin remained stable. Because of the early flu season in the United States and Japan sales in these markets rose by a substantial 7% and 14%, respectively, compensating for continued generic erosion in Europe, especially in France and Germany. Demand is expected to remain strong in the United States, where the product will continue to be protected by patent until 2005. Sales of Roaccutan/Accutane, for severe acne, fell 37%. The decline was largely due to the market entry of competing generics in the United States and Europe.

#### **Research and development — substantial number of new products expected**

Roche's research and development pipeline is currently very strong, with 61 new molecular entities (NMEs), including five opt-in opportunities. The quality of the portfolio has steadily improved over the past three years. Roche is currently pursuing 125 research projects spanning seven therapeutic areas and 60 development projects in ten therapeutic areas. Results from a phase III trial with the late-stage cancer drug Avastin showed a 30% increase in survival duration in patients who received Avastin plus chemotherapy as first-line treatment for metastatic colorectal cancer. An application for approval of Avastin was filed in the United States in September and has been designated for priority review by the FDA; approval is expected in the first quarter of 2004. An EU filing was submitted in December. A monotherapy trial with Tarceva in pre-treated lung cancer patients is proceeding as planned, with results expected in the first quarter of 2004. Development of the innovative anemia treatment CERA for worldwide use in anemic patients with cancer or renal disease is moving ahead as planned. Phase III studies in renal patients are scheduled to start early in 2004, and phase III trials in cancer patients are due to start by the end of the year.

#### **Roche Consumer Health — strong organic growth**

In 2003 sales of non-prescription (OTC) medicines, including sales by Chugai in Japan, grew 17% in local currencies (12% in CHF) to 1,770 million Swiss francs. Roche Consumer Health (RCH) achieved strong organic growth; excluding Chugai, sales increased by 5%. Solid sales growth was reported in almost all markets, but especially in the Asia-Pacific region and Eastern Europe. RCH's ten top-selling brands posted growth of 10%, with the strongest contributions coming from Bepanthen, Redoxon and Aleve. Chugai's OTC sales were in line with expectations. Operating profit from the OTC business totalled 267 million Swiss francs before exceptional items, a gain of 12% in local currencies (9% in CHF) over the previous year. The operating profit margin decreased slightly, to 15.1% before exceptional items, due to the lower profitability of Chugai's OTC business and investments to develop Xenical (orlistat) as an OTC product.

## **Diagnostics Division**

## Market leadership extended

Key figures	in millions of CHF	% change in CHF	% change in local currencies	as % of sales
Sales	7,409	3	8	100
- Diabetes Care	2,695	9	15	36
- Near Patient Testing	548	-7	-2	7
- Centralized Diagnostics	2,634	2	6	36
- Molecular Diagnostics	1,024	5	13	14
- Applied Science	508	-11	-6	7
EBITDA	2,111	6	12	28.5
Operating profit*	1,405	6	13	19.0
Research and development	724	7	11	9.8
Employees	18,302	7	-	-

\*Before exceptional items

Sales by the Diagnostics Division in 2003 totalled 7,409 million Swiss francs, a year-on-year increase of 8% in local currencies (3% in CHF). Roche Diagnostics thus grew twice as fast as the global *in-vitro* diagnostics market. Profitability measures also continued to improve. Operating profit before exceptional items was up 13% in local currencies (6% in CHF) to 1,405 million Swiss francs, with EBITDA rising 12% in local currencies (6% in CHF) to 2,111 million Swiss francs. The operating profit margin was up 0.5 percentage points to 19.0%, and the EBITDA margin advanced 0.9 percentage points to 28.5%. The division's most profitable and fastest-growing businesses — Diabetes Care, Molecular Diagnostics and immunochemistry — were the main contributors to this strong performance. Further growth was generated by a large number of attractive new products.

### Regions — above-average growth worldwide

Roche Diagnostics recorded significant sales gains in all regions, despite weak or negative growth in the world's major diagnostics markets. Sales in North America were up 7%, double the market average. In Europe, a market characterised by healthcare budget restrictions, sales growth was 10%. Sales in Japan rose 3%, despite a decline in the market as a whole. In Asia-Pacific and Iberia/Latin America Roche Diagnostics expanded its market share with double-digit sales growth.

### Diabetes Care — integration of Disetronic on track

Roche Diabetes Care grew 15%, outpacing the market by a substantial margin as it further extended its leading position in blood glucose monitoring. In 2003 Diabetes Care expanded and optimised its portfolio of blood glucose monitoring systems. New versions of the proven Accu-Chek Advantage and Accu-Chek Active glucose meters posted good sales right from the start, as did a new test strip for Accu-Chek Compact; the new strip gives faster results from less blood. In addition, the roll-out of Accu-Chek Go, a novel and especially user-friendly glucose meter, started at the end of 2003. The acquisition of Disetronic, the world's second-largest supplier of insulin pumps, is an important strategic move. As a

result of this transaction, which was finalised in May 2003, Roche now offers a comprehensive range of products for people with diabetes, from glucose monitoring and data management to insulin delivery. The integration of Disetronic's facilities is proceeding according to plan and has already been completed in most countries. Roche is working closely with the FDA to address the agency's concerns about Disetronic's production processes and documentation. The Group aims to resume pump sales in the US in the second half of 2004; reinspection by the FDA is expected to take place around the middle of the year.

#### **Near Patient Testing — steady market share gains in a variety of segments**

Total sales by Roche Near Patient Testing decreased by 2% in 2003 due to streamlining of the product range early in the year (divestment of the OPTI systems and drugs-of-abuse testing businesses). On a comparable basis Near Patient Testing sales rose 6%. Worldwide sales of coagulation monitoring products increased by over 20%, with demand fuelled largely by the continuing trend to patient self-monitoring. Coagulation monitoring is another segment in which Roche Diagnostics is the clear market leader, with a market share of 95%. Roche is also steadily improving its market share in the Hospital Point of Care segment. Key factors behind the high growth in this segment in 2003 were the decision to refocus activities on the core business and strong sales of cardiac assays and OMNI blood gas analysers. In the Primary Care segment (compact systems for doctors' offices) the multiparameter systems of the Reflotron product line and Accutrend cholesterol testing products posted above-average growth. The rollout of a new generation of instruments offering standardised urinalysis met with a good market response.

#### **Centralized Diagnostics — acquisition of Igen gives Roche access to high-growth market**

Sales by Roche Centralized Diagnostics rose 6%, fuelled by high demand for modular high-tech systems for diagnostic laboratories. Once again, the Elecsys immunochemistry product line posted double-digit gains. In 2003 Roche transferred its US hematology business back to its partner, Sysmex. Roche's agreements with Sysmex outside the US are unaffected by this move. Roche expects to complete its acquisition of US-based Igen, announced in July 2003, in mid-February 2004. This strategic move secures Roche's rights to the use of electrochemiluminescence (ECL) technology and also allows it to tap into new markets in one of the division's largest growth areas, immunochemistry. Since the acquisition was announced, Centralized Diagnostics has signed contracts for several large orders.

#### **Molecular Diagnostics — first pharmacogenomic DNA microarray launched**

Sales of *in-vitro* diagnostic products by Roche Molecular Diagnostics grew by 21%, while sales of enzymes to industrial customers, which account for a relatively small percentage of revenues, declined. Growth in sales of blood screening tests and tests for sexually transmitted diseases was in the high

double-digit range. In just eight weeks Molecular Diagnostics developed the first PCR-based research test to detect the virus that causes the respiratory disease SARS. In addition, it developed a highly automated test for screening donated blood for West Nile virus and other pathogens belonging to the Japanese encephalitis virus group. June saw the US launch, for research use, of AmpliChip CYP450, the world's first pharmacogenomic microarray. In future the new DNA chip-based test will help physicians select the appropriate medication and dosage. Roche is working to obtain approval in the United States and Europe for a clinical diagnostic version of the test in 2004. At the end of 2003 in the United States Roche launched a product that enables qualitative testing for human papilloma virus, initially for use by certain specialist laboratories. It plans to launch a clinical diagnostic version in early 2004. Cobas TaqMan 48 was launched in the United States in June and received EU marketing approval shortly thereafter. The system puts real-time PCR technology within the reach of small and medium-sized laboratories for the first time.

#### **Applied Science — numerous product launches**

Sales by Roche Applied Science declined 6% due to the sluggish economic climate and a weak biotech market, especially in the United States. A number of important products for use in genomics were launched in 2003, including an updated version of the LightCycler system that offers greater versatility in research applications; MagNA Pure Compact, a compact benchtop instrument for fast, easy nucleic acid purification; and the new LightTyper, for single nucleotide polymorphism (SNP) analysis. In addition, Prionics Check LIA, a new, fully automated test that enables detection of BSE in slaughtered cattle, received marketing approval in Europe.

This media release with all tables may be found at

[www.roche.com/med-corp-detail-2004?jd=1129&media-language=c](http://www.roche.com/med-corp-detail-2004?jd=1129&media-language=c)

Roche's 2003 Annual Report and — for the first time — the Sustainability Report 2003 as well as the presentations for the media conference will be available at [www.roche.com](http://www.roche.com) from 7:00 am CET and 10:00 am CET, respectively. The media conference in Basel will be webcast on the Internet in English and German, starting at 10:00 am CET.

#### **Planned dates in 2004**

- 6 April: Annual General Meeting
- 21 April (tentative): first-quarter sales
- 21 July (tentative): half-year results

#### **Disclaimer**

This release contains certain forward-looking statements. These forward-looking statements may be identified by words such as "believes", "expects", "anticipates", "projects", "intends", "should", "seeks", "estimates", "future" or similar expressions or by discussion of strategy, goals, plans or intentions.

Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation among others: (1) pricing and product initiatives of competitors; (2) legislative and regulatory developments and economic conditions; (3) delay or inability in obtaining regulatory approvals or bringing products to market; (4) fluctuations in currency exchange rates and general financial market conditions; (5) uncertainties in the discovery, development or marketing of new products or new uses of existing products; (6) increased government pricing pressures; (7) interruptions in production; (8) loss of or inability to obtain adequate protection for intellectual property rights; (9) litigation; (10) loss of key executives or other employees; and (11) adverse publicity or news coverage.