



Ad hoc announcement pursuant to Art. 53 LR

Basel, 25 April 2022

Roche reports good sales growth in the first quarter of 2022

- **Group sales** increase 11%¹ at constant exchange rates (CER) and 10% in Swiss francs
- **Pharmaceuticals Division sales** up 6%; continued strong sales of new medicines for severe diseases. Impact of biosimilars decreases as expected.
- **Diagnostics Division sales** grow 24% due to good momentum in base business and continued high demand for COVID-19 tests. After a strong first quarter, significant decline in COVID-19-related testing expected.
- **Highlights** in the first quarter:
 - FDA approval of Vabysmo (severe eye diseases); CHMP recommends EU approval of Polivy combination (aggressive form of blood cancer), Tecentriq (early-stage non-small cell lung cancer) and mosunetuzumab (follicular lymphoma)
 - Positive long-term data for Evrysdi (spinal muscular atrophy) and for Vabysmo and Susvimo (severe eye diseases)
 - Roche provides molecular testing solutions to identify and differentiate SARS-CoV-2 Omicron variants
- Outlook for 2022 confirmed

Commenting on the Group's sales, Roche CEO Severin Schwan said: "As expected, we started the year with strong demand for our diagnostics base business, our broad portfolio of COVID-19 tests and our new medicines. I am particularly pleased about the progress we are making in developing our product pipeline, including positive new data in neurology as well as in severe eye diseases. Based on our current assessment of the development of the COVID-19 pandemic, we confirm the outlook for the full year."



Sales	CHF m	illions	As % o	fsales	% change		
January - March 2022	2022	2021	2022	2021	At CER	In CHF	
Group sales	16,445	14,930	100.0	100.0	11	10	
Pharmaceuticals Division	11,159	10,600	67.9	71.0	6	5	
United States	5,489	5,292	33.4	35.4	2	4	
Europe	2,072	2,175	12.6	14.6	-1	-5	
Japan	1,337	852	8.1	5.7	69	57	
International*	2,261	2,281	13.8	15.3	0	-1	
Diagnostics Division	5,286	4,330	32.1	29.0	24	22	

*Asia-Pacific, CEETRIS (Central Eastern Europe, Turkey, Russia and Indian subcontinent), Latin America, Middle East, Africa, Canada, others

Outlook confirmed for 2022

Sales are expected to be stable or grow in the low-single digits (at constant exchange rates). Core earnings per share are targeted to grow in the low- to mid-single digit range (at constant exchange rates), including the accretive effect of the 2021 share repurchase. Roche expects to increase its dividend in Swiss francs further.

Roche anticipates sales of COVID-19 medicines and diagnostics to decrease by approximately CHF 2 billion to around CHF 5 billion, and sales losses to biosimilars in the current year to be roughly CHF 2.5 billion. Excluding those effects, Group sales are expected to grow in the high-single digit range.

Group results

In the first quarter of the year, **Group** sales rose by 11% (10% in CHF) to CHF 16.4 billion.

Pharmaceuticals Division sales increased by 6% to CHF 11.2 billion. Newly launched medicines to treat severe diseases continued their strong growth, including Ronapreve (COVID-19; mainly in Japan), Ocrevus (multiple sclerosis), Hemlibra (haemophilia), Evrysdi (spinal muscular atrophy) and Phesgo (breast cancer).

The impact of competition from biosimilars for the established cancer medicines Avastin, MabThera/Rituxan and Herceptin has further slowed down as expected (combined CHF 568 million of sales reduction).

In the **United States**, sales increased by 2%. Ocrevus, Hemlibra, Actemra/RoActemra, Tecentriq and Phesgo were the main growth drivers. This was partly offset by the expected impact of biosimilars.

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In **Europe**, sales decreased by 1%. Growth of Ocrevus, Phesgo and Evrysdi and other innovative medicines was offset by the biosimilars impact and lower Ronapreve sales.

Sales in **Japan** significantly increased (+69%), driven by the high demand for Ronapreve and other innovative medicines, such as Polivy and Evrysdi.

Sales in the **International region** were stable. Sales growth of Perjeta, Ronapreve, Alecensa, Evrysdi, Hemlibra and Ocrevus was neutralised by the impact of biosimilars. In China, sales declined by 9% due to strong biosimilars competition; excluding China, sales increased by 5%.

The **Diagnostics Division** reported strong sales growth of 24% to CHF 5.3 billion. The division's base business showed good momentum (+10%), especially in the immunodiagnostics business, with cardiac tests as key contributor.

Roche's leading portfolio of COVID-19 tests remained a major sales driver, with increased demand for point-of-care and PCR tests. The portfolio contributed significantly to the division's overall sales growth with a total of CHF 1.9 billion (CHF 1.2 billion in the first quarter of 2021).

Sales grew across all regions, driven by **North America** (59%) and **Asia-Pacific** (34%). **Latin America** reported a plus of 9%; **Europe, Middle East and Africa** (EMEA) grew 2%.

Pharmaceuticals: key development milestones in the first quarter of 2022

Ophthalmology

In January 2022, the FDA approved **Vabysmo** for the treatment of neovascular or 'wet' agerelated macular degeneration (nAMD) and diabetic macular oedema (DME). In March, approval was granted in Japan. Neovascular AMD and DME are two leading causes of vision loss, together affecting around 40 million people worldwide.

In February, Roche presented promising longer-term data from its phase III studies of **Vabysmo** and **Susvimo** (nAMD). These results further reinforce the potential of both eye medicines to offer durable vision outcomes with fewer eye injections than the current standard of care, thus reducing the treatment burden for people with these conditions.

Oncology

In March, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended the approval of **Polivy** combination therapy for the treatment of previously untreated diffuse large B-cell lymphoma (DLBCL). This is the most common form of non-Hodgkin lymphoma. The Polivy regimen is the first therapy in more than 20 years to significantly improve outcomes in this aggressive form of blood cancer.

Also in March, Roche announced that the phase III SKYSCRAPER-02 study, evaluating the investigational anti-TIGIT immunotherapy **tiragolumab** plus Tecentriq and chemotherapy as

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an initial treatment for people with extensive-stage small cell lung cancer (ES-SCLC), did not meet its co-primary endpoint of progression-free survival. The broad tiragolumab programme in other cancer types will be continued with high priority.

In April, the phase II acelERA trial on **giredestrant** did not meet its primary endpoint of progression-free survival in people with a certain form of advanced breast cancer. However, efficacy data were encouraging with a more pronounced benefit in patients with higher dependence on estrogen receptor activity. Overall survival data are still immature. The acelERA trial is the second randomized trial following the phase II coopERA trial in the neoadjuvant setting where giredestrant demonstrated improved efficacy and good safety. Giredestrant is being investigated in further clinical trials for patients with 1st line metastatic breast cancer and early breast cancer. Results from the acelERA trial will be presented at a medical meeting later this year.

Also in April, the CHMP recommended EU approvals of **Tecentriq** as adjuvant treatment for certain people with early-stage non-small cell lung cancer (eNSCLC) and of **mosunetuzumab** for the treatment of relapsed or refractory follicular lymphoma (FL).

If approved, Tecentriq will be the first and only cancer immunotherapy available for certain people with early-stage NSCLC in Europe, and mosunetuzumab will be the first CD20xCD3 T-cell engaging bispecific antibody available to treat FL offering a new, off-the-shelf, fixed-duration treatment option.

Neurosciences

At two neurology conferences (the *Muscular Dystrophy Association Clinical and Scientific Conference* and the *American Academy of Neurology Annual Meeting*), Roche presented new data from its growing neuroscience portfolio, including multiple sclerosis (MS), spinal muscular atrophy (SMA), neuromyelitis optica spectrum disorder (NMOSD), Alzheimer's disease (AD) and Duchenne muscular dystrophy (DMD).

The new data underlined the longer-term efficacy and safety for Roche's new medicines **Ocrevus** (MS), **Evrysdi** (SMA) and **Enspryng** (NMOSD).

- New data for **Ocrevus** showed benefit in disability progression and cognitive decline in both secondary progressive and primary progressive MS. Roche is also focusing on making its clinical trials more inclusive: A separate analysis included findings from underrepresented populations, such as Black and Hispanic/Latino-American MS patients.
- New data for **Evrysdi** (pivotal SUNFISH study) confirmed that increases in motor function were sustained at three years while adverse events decreased over the same period.



In addition, Roche and its partner Sarepta announced details of the phase III pivotal study (EMBARK) of **delandistrogene moxeparvovec (SRP-9001)**, an investigational gene therapy for boys living with DMD.

Roche also presented baseline characteristics of its Alzheimer's disease (AD) clinical programme with **gantenerumab**, a late-stage investigational subcutaneously administered monoclonal antibody. Data from the pivotal GRADUATE trials are expected in the fourth quarter of 2022.

COVID-19

The high rate of unvaccinated people will continue to put a strain on hospitals and healthcare systems around the world, furthering the need for effective COVID-19 treatments.

In April, the FDA granted priority review to **Actemra/RoActemra** for the treatment of COVID-19 in hospitalised adults. More than one million people with severe or critical COVID-19 have already been treated with Actemra/RoActemra worldwide, demonstrating the important role of this medicine in the fight against the pandemic. Roche has established a comprehensive access approach to improve the availability of its COVID-19 medicines around the world, such as implementing an international differential pricing strategy, specifically designed to address the needs during this pandemic.

	Compound	Indication	Milestone		
Regulatory Polivy combination Actemra/RoActemra		Previously untreated diffuse large B-cell lymphoma	CHMP recommendation of EU approval		
		COVID-19 in hospitalised adults	FDA priority review; EU filing; WHO prequalification		
	Vabysmo	Neovascular age-related macular degeneration (nAMD) and diabetic macular oedema (DME)	US and Japan approval; EU filing		
Tecentriq		Adjuvant treatment for certain people with early-stage non-small cell lung cancer (eNSCLC)	CHMP recommendation of EU approval		
	mosunetuzumab	Relapsed or refractory follicular lymphoma (FL)	CHMP recommendation of EU approval		
Phase III / pivotal and other key	Vabysmo	Diabetic macular oedema (DME)	Phase III YOSEMITE and RHINE (2-year data)		
readouts Susvimo		Neovascular or 'wet' age-related macular degeneration (nAMD)	Phase III Archway (2-year data)		

Pharmaceuticals: Key development milestones in the first quarter of 2022



Ocrevus	Complete spectrum multiple sclerosis (MS): SPMS and PPMS	Phase III CONSONANCE (1-year data)
Evrysdi	SMA type 2 or 3: Long-term efficacy and safety in people aged 2–25 years	Phase III SUNFISH part 1 and 2 (3-year data)
Evrysdi	Presymptomatic infants with SMA	Phase II RAINBOWFISH ad interim data
Enspryng	Neuromyelitis optica spectrum disorder (NMOSD): Long-term efficacy and safety	Phase III SAkuraSky and SAkuraStar
tiragolumab + Tecentriq + chemotherapy	First-line treatment of extensive-stage small cell lung cancer (ES-SCLC)	Phase III SKYSCRAPER-02: co- primary endpoint not met
delandistrogene moxeparvovec (SRP- 9001) gene therapy	Duchenne muscular dystrophy (DMD)	Phase III study design, EMBARK
giredestrant	ER-positive, HER2-negative locally advanced or metastatic breast cancer	Phase II acelERA: primary endpoint not met

Diagnostics: key milestones in the first quarter 2022

In March, Roche and its subsidiary, TIB Molbiol, confirmed that they have molecular testing solutions to identify and differentiate **SARS-CoV-2 Omicron variants** of concern. It is critical to quickly and accurately identify variants to inform ongoing research and development of therapeutics and vaccines. This can potentially stop or slow down the advancement of the disease. In addition, differentiated testing helps public health professionals to plan and implement the necessary measures.

Also in March, Roche announced a collaboration with Bristol Myers Squibb to advance personalised healthcare through **digital pathology solutions**. This collaboration is among the first examples where artificial intelligence (AI) technology and digital pathology applications are playing a role in developing treatments for patients.



Pharmaceuticals sales

Sales	CHF millions		As % o	f sales	% change		
January – March 2022	2022 2021		2022	2022 2021		In CHF	
Pharmaceuticals Division	11,159	10,600	100.0	100.0	6	5	
United States	5,489	5,292	49.2	49.9	2	4	
Europe	2,072	2,175	18.7	20.4	-1	-5	
Japan	1,337	852	12.0	8.0	69	57	
International*	2,261	2,281	20.1	21.7	0	-1	

*Asia-Pacific, CEETRIS (Central Eastern Europe, Turkey, Russia and Indian subcontinent), Latin America, Middle East, Africa, Canada, others

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHF m	%
Ocrevus	1,449	18	1,050	12	280	34	-	-	119	29
Perjeta	993	1	362	-1	228	-21	59	-1	344	32
Hemlibra	853	30	520	28	170	31	84	15	79	63
Tecentriq	825	8	446	10	183	14	107	-5	89	-
Actemra/RoActemra	792	3	380	22	220	-4	87	12	105	-30
Herceptin	607	-19	144	-26	122	-13	15	-30	326	-18
Ronapreve	587	272	-	-	62	-61	483	-	42	-
Avastin	581	-32	178	-39	58	-56	131	-12	214	-23
MabThera/Rituxan	564	-21	347	-20	54	-19	8	-15	155	-23
Kadcyla	511	9	204	-	172	8	32	28	103	26

*Asia-Pacific, CEETRIS (Central Eastern Europe, Turkey, Russia and Indian subcontinent), Latin America, Middle East, Africa, Canada, others

Pharmaceuticals sales: Selected top-selling and new medicines

Ocrevus (first approved in 2017; CHF 1.4 billion, +18%). Relapsing and primary progressive forms of multiple sclerosis; two-hour only infusion. The demand for this treatment in both indications remained strong, mainly in the United States, while the pandemic still had a certain negative impact. Sales growth in Europe across most countries, notably in Germany, Italy and UK.

Perjeta (first approved in 2012; CHF 993 million, +1%). HER2-positive breast cancer. Sales increased mostly due to high demand in China in both early and metastatic breast cancer settings. Sales growth in the International region (mainly China) was partly offset by sales decline in Europe due to the launch of Phesgo in 2020.

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Hemlibra (first approved in 2017; CHF 853 million, +30%). Haemophilia A with and without factor VIII inhibitors; only prophylactic treatment that can be administered subcutaneously once weekly, every two or every four weeks. Sales continued to show an impressive uptake, especially in the United States and Europe.

Tecentriq (first approved in 2016; CHF 825 million, +8%). Cancer immunotherapy (either alone or in combinations) for various types of cancer, e.g. lung, bladder, breast and liver cancer. Sales increased mostly due to high demand in the United States and Europe. Sales in Japan decreased, primarily due to governmental price cuts.

Actemra/RoActemra² (CHF 792 million, +3%). Rheumatoid arthritis, forms of juvenile idiopathic arthritis and giant cell arteritis, CAR T cell-induced severe or life-threatening cytokine release syndrome and COVID-19 pneumonia. The inclusion of this medicine in treatment guidelines for severe COVID-19-associated pneumonia by a number of countries drove sales growth, with the United States as a major contributor.

Herceptin² (CHF 607 million, -19%). HER2-positive breast cancer and HER2-positive metastatic gastric cancer. The sales decrease was mainly due to biosimilar uptake in various countries.

Ronapreve (first approved in 2021; CHF 587 million, +272%). Antibody combination for the prevention and treatment of recently diagnosed high-risk patients with mild to moderate COVID-19. Roche is responsible for distribution in Europe and other countries outside the United States, its partner Regeneron is responsible for the United States. The sales growth in Japan was partly offset by the sales decline in Europe.

Avastin² (CHF 581 million, -32%). Advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, relapsed glioblastoma (a type of brain tumour) and liver cancer in combination with Tecentriq. Sales were heavily impacted by the uptake of biosimilars, mainly in the United States.

MabThera/Rituxan² (CHF 564 million, -21%). Forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales further decreased due to the biosimilar erosion, notably in the United States.

Kadcyla (first approved in 2013; CHF 511 million, +9%). HER2-positive breast cancer. Sales growth was driven by the usage of Kadcyla in the early breast cancer setting. Sales benefited from patients switching to this new standard of treatment.

Xolair² (CHF 456 million, +9%, United States only). Chronic spontaneous urticaria and allergic asthma. Steady sales growth in the chronic spontaneous urticaria indication. Xolair remains the market leader in the larger allergic asthma indication.

Alecensa (first approved in 2015; CHF 361 million, +23%). ALK-positive non-small-cell lung cancer. The global uptake continued with sales growth across all regions.

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Lucentis² (CHF 256 million, -26%, United States only). Eye conditions, including 'wet' agerelated macular degeneration.

TNKase/Activase² (CHF 247 million, -20%). Acute myocardial infarction (AMI).

Esbriet (first approved in 2014; CHF 241 million, -6%). Idiopathic pulmonary fibrosis (IPF).

Evrysdi (first approved in 2020; CHF 226 million, +189%). Spinal muscular atrophy (SMA) in adults and children two months of age and older. Evrysdi helps infants to survive without permanent ventilation. It is the first and only medicine for SMA that can be administered at home. Evrysdi continued to show a strong uptake across all regions, mainly in Europe.

Gazyva/Gazyvaro (first approved in 2013; CHF 165 million, +7%). Chronic lymphocytic leukaemia, rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma. Approved as a shorter duration infusion time of 90 minutes, compared to the standard infusion of 3-4 hours.

Phesgo (first approved in 2020; CHF 146 million, +410%). Early and metastatic HER2-positive breast cancer (fixed-dose combination of Perjeta and Herceptin for subcutaneous injection). Offers faster administration in just minutes, compared to hours with standard intravenous administration. Sales continued to show a considerable uptake, especially in Europe and the United States.

Polivy (first approved in 2019; CHF 81 million, +89%). Relapsed or refractory diffuse large B-cell lymphoma; part of combination therapy; a fixed-duration treatment option for people with this aggressive form of blood cancer.

Enspryng (first approved in 2020; CHF 41 million, +216%). Rare autoimmune disease of the central nervous system (neuromyelitis optica spectrum disorder; NMOSD); first subcutaneous NMOSD treatment that can be self- or carer-administered at home. Enspryng has continued to show a very good uptake, with over 1,000 people with this rare disease treated to date (including newly diagnosed and previously treated patients).

Vabysmo (first approved in 2022; CHF 21 million³). Neovascular or 'wet' age-related macular degeneration (nAMD) and diabetic macular oedema (DME), two leading causes of vision loss. Sales of this new eye medicine showed a good uptake.

Rozlytrek (first approved in 2019; CHF 16 million, +78%). Specific form of non-small cell lung cancer (NSCLC); solid tumours expressing a specific gene fusion; ROS1-positive, advanced NSCLC.

Susvimo (first approved in 2021; CHF 1 million³). Eye implant with continuous drug delivery for neovascular or 'wet' age-related macular degeneration (nAMD) treatment.

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Diagnostics sales

Sales	CHF r	nillions	As % o	fsales	% change		
January – March 2022	2022	2021	2022	2021	At CER	In CHF	
Diagnostics Division	5,286	4,330	100.0	100.0	24	22	
Customer Areas							
Core Lab ⁴	1,896	1,786	35.9	41.3	8	6	
Point of Care ⁴	1,466	806	27.7	18.6	84	82	
Molecular Lab ⁴	1,189	996	22.5	23.0	21	19	
Diabetes Care	417	460	7.9	10.6	-7	-9	
Pathology Lab	318	282	6.0	6.5	14	13	
Regions							
Europe, Middle East, Africa (EMEA)	1,902	1,967	35.9	45.5	2	-3	
North America	1,705	1,051	32.2	24.2	59	62	
Asia-Pacific	1,395	1,045	26.5	24.1	34	33	
Latin America	284	267	5.4	6.2	9	6	

Core Lab. Focuses on central labs; provides diagnostics solutions in the areas of immunoassays, clinical chemistry and custom biotech. Sales increased by 8% due to its immunodiagnostics business, with cardiac tests as main contributors. Sales grew across all regions, mostly in Asia-Pacific and EMEA. The US Core Lab business (excluding custom biotech) grew 10%.

Point of Care. Focuses on diagnostics solutions in emergency rooms, medical practices or directly with patients; includes SARS-CoV-2 rapid tests, blood gas and electrolyte tests. Continued significant sales growth of 84%. The SARS-CoV-2 Rapid Antigen test was the main growth driver, especially in North America.

Molecular Lab. Focuses on molecular labs; provides diagnostics solutions for pathogen detection and monitoring, donor screening, sexual health and genomics. Sales grew 21%, led by the virology business, mainly in EMEA and Asia-Pacific.

Diabetes Care. Focuses on integrated personalised diabetes management for people with diabetes and healthcare professionals. Sales decreased by 7%, as a result of the continued contraction of the blood glucose monitoring market due to people switching to continuous glucose monitoring systems. This was partly offset by higher demand in emerging markets. Excluding the base effect of the resolution of a rebate dispute in the first quarter of 2021, sales increased by 1%.

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Pathology Lab. Focuses on pathology labs; provides diagnostics solutions for tissue biopsies and companion diagnostics. These targeted diagnostics support the specific therapy decisions for each patient. Sales increased by 14%, especially in North America and Asia-Pacific. This was mainly due to growth in the advanced staining business.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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For more information, please visit <u>www.roche.com</u>.

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References

[1] Unless otherwise stated, all growth rates and comparisons to the previous year in this document are at constant exchange rates (CER: average 2021) and all total figures quoted are reported in CHF.
[2] Established products (launched before 2012), including Actemra/RoActemra, Avastin, Herceptin, MabThera/Rituxan, Xolair, Lucentis, Activase/TNKase, Pulmozyme and CellCept.
[3] Recently approved; no growth figures available.
[4] Sales in the Point of Care customer area include sales from the Liat business (POC molecular), and sales in the

Core Lab customer area include sales from the Life Science Alliances, both previously shown as part of the Molecular Lab customer area. The comparative information for 2021 has been updated accordingly. POC molecular sales: Q1/21 = 90mCHF, Q2/21 = 92mCHF, Q3/21 = 175mCHF, Q4/21 = 194mCHF. Life Science Alliances sales: Q1/21 = 21mCHF, Q2/21 = 23mCHF, Q3/21 = 23mCHF, Q4/21 = 20mCHF.

Cautionary statement regarding forward-looking statements

This document contains certain forward-looking statements. These forward-looking statements may be identified by words such as 'believes', 'expects', 'anticipates', 'projects', 'intends', 'should', 'seeks', 'estimates', 'future' or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this document, such as: (1) pricing and product initiatives of competitors; (2) legislative and regulatory developments and economic conditions; (3) delay or inability in obtaining regulatory approvals or bringing products to market; (4) fluctuations in currency exchange rates and general financial market conditions; (5) uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side effects of pipeline or marketed products; (6) increased government pricing pressures; (7) interruptions in production; (8) loss of or inability to obtain adequate protection for intellectual property rights; (9) litigation; (10) loss of key executives or other employees; and (11) adverse publicity and news coverage. The statement regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche's earnings or earnings per share of Roche.

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