

Ad hoc announcement pursuant to Art. 53 LR

Basel, 20 October 2021

Roche reports strong growth in the first nine months – outlook for 2021 raised

- **Group sales** up 8%¹ at constant exchange rates (CER); 6% in Swiss francs
- **Pharmaceuticals Division sales** grow 5% in the third quarter and are now in line with the prior year for the first nine months; continued strong growth of newly launched medicines
- **Diagnostics Division sales** grow 18% in the third quarter and 39% in the first nine months due to high demand for COVID-19 tests, a strong recovery in the base business and the newly launched diagnostics platforms
- **Highlights in the third quarter:**
 - FDA approves cancer immunotherapy Tecentriq (early-stage lung cancer) and grants Priority Review for eye medicine faricimab
 - Positive study results for Polivy (blood cancer) and Ronapreve (COVID-19)
 - FDA grants Breakthrough Therapy Designation to gantenerumab (Alzheimer's disease); final study results expected in second half of 2022
 - Share purchase agreement with long-term partner TIB Molbiol to expand molecular diagnostics portfolio
- **Outlook** raised

Sales January–September 2021	CHF millions		As % of sales		% change	
	2021	2020	2021	2020	CER	CHF
Group sales	46,684	43,979	100.0	100.0	8	6
Pharmaceuticals Division	33,379	34,317	71.5	78.0	0	-3
United States	16,707	18,389	35.8	41.8	-5	-9
Europe	6,610	6,268	14.2	14.3	3	5
Japan	3,186	2,802	6.8	6.4	20	14
International*	6,876	6,858	14.7	15.5	2	0
Diagnostics Division	13,305	9,662	28.5	22.0	39	38

*Asia-Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, others

CEO Severin Schwan on the results: “The demand for coronavirus tests remained high in the third quarter due to the Delta variant. Together with the recently launched medicines and diagnostics platforms they contributed to the strong sales growth. We also made significant progress in our product pipeline in the third quarter, including with Polivy, the first medicine in 20 years to significantly improve outcomes in a form of aggressive blood cancer. Based on the results achieved so far, we are raising our outlook for the full year.”

Outlook raised for 2021

Sales are now expected to grow in the mid-single digit range, at constant exchange rates (before: in the low to mid-single digit range). Core earnings per share are targeted to grow broadly in line with sales, at constant exchange rates. Roche expects to increase its dividend in Swiss francs further.

Group results

Group sales increased by 8% (6% in CHF) to CHF 46.7 billion in the first nine months of the year.

Pharmaceuticals Division sales remained stable at CHF 33.4 billion. Since summer there have been signs of recovery from the COVID-19 pandemic and the biosimilar impact is slowing down as expected (Pharma sales: -9% in the first quarter, +4% in the second quarter and +5% in the third quarter).

In the **United States**, sales declined by 5% over the first nine months, with stable year-on-year sales since the summer.

Competition from biosimilars for the established cancer medicines MabThera/Rituxan, Avastin and Herceptin led to an overall decline, partly offset by sales of Actemra/RoActemra, Hemlibra, Ocrevus and Tecentriq, as well as for Evrysdi (spinal muscular atrophy) and Phesgo (breast cancer), which were launched only last year.

Sales in **Europe** increased by 3%. Sales growth of new medicines (Ronapreve, Ocrevus, Hemlibra and Kadcyła) more than offset the impact of biosimilars.

In **Japan**, sales increased by 20%. Growth was driven by the new medicines Ronapreve, Tecentriq, Enspryng and Hemlibra. This more than offset the impact of biosimilars and government price cuts.

Sales in the **International** region grew 2%, driven by strong demand for Perjeta and Ronapreve. Sales growth in China (+2%) resulted from continued strong uptake of Perjeta, Alecensa and other innovative cancer medicines.

The **Diagnostics Division** achieved strong sales growth of 39% to CHF 13.3 billion in the first nine months. Growth was 18% in the third quarter compared to the already very strong third quarter last year. Demand for COVID-19 testing remained high in the third quarter, driven primarily by the Delta variant. As a result, Roche's industry-leading portfolio of COVID-19 tests again contributed significantly to the division's overall sales growth.

The base business, still heavily impacted by the pandemic in 2020, showed strong growth in the first nine months of 2021: after a significant recovery in the first half of the year (+17% in the first quarter, 31% in the second quarter), strong growth of 11% was also achieved in the third quarter.

Sales grew strongly in all regions: **Europe, Middle East and Africa** +54%, **Asia-Pacific** +35%, **North America** +18% and **Latin America** +63%.

In September Roche signed a definitive share purchase agreement with **TIB Molbiol**. Roche and TIB Molbiol have been working together for more than 20 years on tests and reagents for pathogens such as SARS, anthrax, MERS, the novel H1N1 swine flu virus and, most recently, the SARS-CoV-2 virus and its variants. This acquisition will add a range of infectious disease tests to Roche's broad portfolio of molecular diagnostic solutions.

Pharmaceuticals: strong pipeline

Roche now has 17 new compounds in late-stage development or registration, which is a new all-time high, and almost an 80% increase over the last decade. Thanks to innovative new approaches, Roche was able to reduce the drug filing process from on average 26 to just 13 weeks.

In the third quarter, Roche achieved a number of **regulatory milestones**:

After the FDA granted Priority Review to **Tecentriq** in August, approval was already granted in October: Tecentriq is now the first and only cancer immunotherapy available for adjuvant treatment of certain people with early-stage non-small cell lung cancer (NSCLC). It has the potential to significantly reduce risk of cancer recurrence, after more than a decade with limited treatment advances in this setting.

In September, Roche was granted another Priority Review by the FDA: for its eye medicine **faricimab** for the treatment of neovascular or "wet" age-related macular degeneration (nAMD) and diabetic macular edema (DME). If approved, faricimab would be the first in a new class of eye medicines targeting two key pathways that drive retinal disorders, with the potential to offer durable vision outcomes with fewer eye injections than the current standard of care.

Also in September, the European Medicines Agency (EMA) recommended the approval of RET inhibitor **Gavreto** as monotherapy for patients with advanced RET-fusion positive NSCLC. RET alterations are key disease drivers in many cancer types, including NSCLC and multiple types of thyroid cancer.

In October, the EMA approved a new, shorter 90-minute **Gazyva/Gazyvaro** infusion, administered in combination with chemotherapy in patients with previously treated or untreated advanced follicular lymphoma; the regular rate of infusion can take three to four hours.

Furthermore, the FDA granted two additional Breakthrough Therapy Designations (BTD):

- for **Venclexta/Venclyxto** combination therapy for the treatment of adult patients with myelodysplastic syndromes, a rare form of blood cancer. This marks the sixth BTD for Venclexta/Venclyxto.
- for **gantenerumab** for the treatment of people with Alzheimer's disease (AD). Gantenerumab would be the first subcutaneous drug for AD treatment that could also be administered at home. The pivotal trials are expected to be completed in the second half of 2022. This is the 39th BTD for Roche.

In the third quarter, Roche also announced several **key development milestones** in neuroscience, ophthalmology, oncology and COVID-19:

Neuroscience is a major research focus at Roche. The company is investigating more than a dozen medicines for neurological disorders, including rare neuromuscular disorders, such as spinal muscular atrophy (SMA) and Duchenne muscular dystrophy (DMD).

SMA is the leading genetic cause of death in babies. In September, new data showed that pre-symptomatic babies with SMA treated with **Evrysdi** maintained the ability to swallow. Evrysdi thus demonstrated consistent clinically meaningful efficacy in adults, children, and babies two months and older.

DMD is a rare progressive neuromuscular disease caused by mutations in the DMD gene. Longevity is limited due to cardiac and/or respiratory failure. Also in September, new data supported the efficacy, safety and durability of gene therapy **SRP-9001** in the treatment of DMD.

In October, Roche presented new data for **Ocrevus** (multiple sclerosis; MS) and **Enspryng** (neuromyelitis optica spectrum disorder; NMOSD). The longer-term efficacy and safety data for both medicines reinforce the impact of Ocrevus in significantly slowing disease progression in MS and of Enspryng in significantly reducing relapses in NMOSD.

Among the highlights in **oncology** were the highly promising phase III study results for first-line **Polivy** combination therapy in an aggressive form of blood cancer (previously untreated diffuse large B-cell lymphoma, DLBCL). This Polivy regimen is the first therapy in two decades to improve progression-free survival in DLBCL compared to the standard of care. Since 40% of people with DLBCL relapse after initial therapy, achieving meaningful treatment effects in the front-line setting has the potential to be transformative.

Another highlight were the new encouraging phase II data from an interim analysis on **giredestrant** in hormone receptor (HR)-positive and HER2-negative early breast cancer. Giredestrant is a next-generation selective oestrogen receptor degrader (SERD). Because it is taken orally, it has the potential to transform the treatment experience for patients by offering greater convenience and a less painful option compared to therapies administered via intramuscular injection.

Cancer of unknown origin (CUP) is still a devastating diagnosis. In CUPs, doctors are unable to identify the location of the primary tumour and can only find metastases, which makes treatment difficult. In September, Roche published initial results of a phase II study (CUPISCO), which emphasised the importance of **genomic profiling** for patients with CUP and how it may help to inform a more personalised treatment plan in the future.

COVID-19 has now led to almost 4.9 million deaths, mostly involving hospitalised patients. While vaccines are mostly effective in preventing hospitalisation, there is still a high medical need for all those who have not or could not receive a vaccination so far.

In September, Roche published positive data from a phase II/III study on **Ronapreve** in patients hospitalised with COVID-19. The trial showed that the antibody combination (co-developed with Regeneron) significantly reduced viral load within seven days of treatment in patients who had not mounted a natural antibody response of their own. These data add to previous findings that support the potential of Ronapreve in hospitalised patients, which may also help to ease pressure on healthcare systems.

In addition, the World Health Organization recently issued guidance regarding the use of Ronapreve for the treatment of certain patients with COVID-19. So far, Ronapreve has been made available to patients in more than 40 countries via bilateral purchase agreements across many geographies and economies, including lower middle-income countries.

The study on **AT-527** did not meet its primary endpoint. Final data from the full phase II study will be submitted to a peer-reviewed publication. Roche and its partner Atea will continue to analyse available and

incoming data from the trial to generate evidence and provide a more complete picture of AT-527 in COVID-19.

Pharmaceuticals: major clinical studies and regulatory milestones up to mid-October 2021

	Compound	Indication	Milestone
Regulatory	Xofluza	Influenza: healthy people; high-risk people; post exposure	EU approval
	Evrysdi	Spinal muscular atrophy (SMA) type 1/2/3	EU approval
	faricimab	Diabetic macular oedema/neovascular age-related macular degeneration (nAMD)	US/EU joint filing
	Tecentriq	First-line PD-L1+ non-small cell lung cancer (NSCLC)	EU approval
	Venclexta/Venclyxto + azacitidine	Acute myeloid leukaemia	EU approval
	Venclexta/Venclyxto combination therapy	Myelodysplastic syndromes	Breakthrough Therapy Designation (BTD)
	gantenerumab	Alzheimer's disease	BTD
Phase III / pivotal readouts	faricimab	nAMD	Phase III TENAYA/LUCERNE
	Ronapreve	SARS-CoV-2 outpatient	Phase III study 2067
	Ronapreve	SARS-CoV-2 post-exposure prophylaxis	Phase III study 2069
	Tecentriq	Adjuvant NSCLC	Phase III IMpower010
	Evrysdi	SMA type 1/2/3 switching study	Phase II JEWELFISH
	Polivy + R-CHP	First-line diffuse large B-cell lymphoma (DLBCL)	Phase III POLARIX

Diagnostics: key launches in virology and oncology

Whether for infectious diseases (such as COVID-19), cancer or other serious health threats, prevention and early detection are key and depend on high-quality diagnostics. The division launched several innovative solutions in the third quarter.

One of the highlights was the launch of **three molecular PCR diagnostic test panels** to simultaneously detect and differentiate common respiratory pathogens such as influenza, out of one patient sample. Syndromic panels are a flexible testing option to look at 15 or more pathogens. It enables clear diagnosis in one test and ability to pair to the right antibiotic without exposing patients to antibiotics they may not respond to. With this multimodal testing infrastructure offering, Roche allows for fit-for-purpose diagnostic testing needs for the patient and avoids antibiotic misuse.

Roche is also investing heavily in the digitalisation of healthcare data. To enhance collaboration, Roche has opened access to its pathology imaging tools. The **Roche Digital Pathology Open Environment** allows software developers globally to distribute their digital products through Roche's uPath software, offering a broader set of diagnostics tools for pathologists and ultimately, benefiting patients.

In addition, the **Elecsys GAAD Algorithm** received the CE mark. This algorithm is used to aid in the diagnosis of early stage hepatocellular carcinoma (HCC) and is an important step towards clinical algorithms supporting clinicians to make earlier treatment decisions to facilitate better clinical outcomes for patients.

Pharmaceuticals sales

Sales January- September 2021	CHF millions		As % of sales		% change	
	2021	2020	2021	2020	CER	CHF
Pharmaceuticals Division	33,379	34,317	100.0	100.0	0	-3
United States	16,707	18,389	50.1	53.6	-5	-9
Europe	6,610	6,268	20.0	18.3	3	5
Japan	3,186	2,802	9.5	8.2	20	14
International*	6,876	6,858	20.4	19.9	2	0

*Asia-Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, others

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Ocrevus	3,721	17	2,779	11	689	37	-	-	253	50
Perjeta	2,974	4	1,079	-1	847	-3	200	-4	848	24
Actemra/RoActemra	2,690	30	1,300	44	663	14	285	12	442	29
Tecentriq	2,477	27	1,272	14	520	17	387	81	298	66
Avastin	2,390	-39	745	-48	346	-69	502	-1	797	-12
Hemlibra	2,172	42	1,317	35	440	65	260	21	155	138
Herceptin	2,061	-32	501	-55	407	-24	63	-39	1,090	-15
MabThera/Rituxan	1,968	-41	1,197	-47	203	-35	31	-34	537	-26
Kadcyla	1,460	16	613	4	508	23	94	57	245	26
Xolair	1,416	2	1,416	2	-	-	-	-	-	-

* Asia-Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, others

Pharmaceuticals: established products

Actemra/RoActemra (CHF 2.7 billion, +30%). Rheumatoid arthritis, forms of juvenile idiopathic arthritis and giant cell arteritis as well as CAR T cell-induced severe or life-threatening cytokine release syndrome. Growth was driven by the inclusion in a number of countries of this medicine in treatment guidelines for severe COVID-19-associated pneumonia. The US and the International region were the major contributors to this sales increase.

Avastin (CHF 2.4 billion, -39%). 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 strongly impacted by the launch of biosimilars, mainly in Europe and the US.

Herceptin (CHF 2.1 billion, -32%). HER2-positive breast cancer and HER2-positive metastatic gastric cancer. Sales decrease was mainly due to biosimilar launches in the US and Europe.

MabThera/Rituxan (CHF 2.0 billion, -41%). Forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales were lower due to the biosimilar erosion as well as COVID-19 pandemic restrictions.

Xolair (CHF 1.4 billion, +2%, US only). Chronic idiopathic urticaria and allergic asthma. Sales growth in the chronic idiopathic urticaria indication was offset by competition in the allergic asthma indication. Xolair remains the market leader in the larger allergic asthma indication.

Pharmaceuticals: medicines launched since 2012

Ocrevus (first approved in 2017; CHF 3.7 billion, +17%). Relapsing and primary progressive forms of multiple sclerosis; 2-hour only infusion. The demand for this treatment in both indications remained strong, while the pandemic still had a certain negative impact. Growth was driven both by new and returning patients, with a higher proportion of sales generated by returning patients.

Perjeta (first approved in 2012; CHF 3.0 billion, +4%). HER2-positive breast cancer. Sales increased mostly due to high demand in the International region (China, Argentina and Brazil) in both early and metastatic breast cancer settings.

Tecentriq (first approved in 2016; CHF 2.5 billion, +27%). Cancer immunotherapy for various types of cancer (either alone or in combinations), e.g. certain types of lung, bladder, breast and liver cancer. Sales increased in all regions, most notably in Japan, primarily due to the growth in the treatment of hepatocellular carcinoma (HCC). US sales were higher, driven by the new indications for first-line non-small cell lung cancer (NSCLC) and HCC.

Hemlibra (first approved in 2017; CHF 2.2 billion, +42%). 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 a strong uptake, especially in the US and Europe.

Kadcyla (first approved in 2013; CHF 1.5 billion, +16%). 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 the new standard of treatment.

Ronapreve (first approved in 2021; CHF 1.1 billion*). Antibody combination for the treatment of recently diagnosed high-risk patients with mild to moderate COVID-19. Roche and Regeneron are collaborating on developing and manufacturing the medicine; Roche is responsible for distribution in Europe and other countries outside the US. The uptake has been strong, mainly in Europe and Japan.

Alecensa (first approved in 2015; CHF 1.0 billion, +19%). ALK-positive non-small-cell lung cancer. The global uptake continued with sales growth across all regions.

Esbriet (first approved in 2014; CHF 789 million, -4%). Idiopathic pulmonary fibrosis (IPF).

Gazyva/Gazyvaro (first approved in 2013; CHF 501 million, +8%). Chronic lymphocytic leukaemia, rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma.

Evrysdi (first approved in 2020; CHF 396 million*). Spinal muscular atrophy (SMA) in adults and children two months of age and older. Evrysdi helps infants to survive without permanent ventilation; the first and only medicine for SMA that can be administered at home. The new SMA medicine continued to show a strong uptake, mainly in the US, Russia and Germany.

Phesgo (first approved in 2020; CHF 213 million*). 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.

Erivedge (first approved in 2012; CHF 196 million, -3%). Advanced basal cell carcinoma.

Polivy (first approved in 2019; CHF 167 million, +35%). 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 69 million*). 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. The medicine has continued to show a good uptake, including newly diagnosed and previously treated patients. It is now approved in 58 countries.

Rozlytrek (first approved in 2019; CHF 35 million, +137%). Specific form of non-small cell lung cancer (NSCLC); solid tumours expressing a specific gene fusion; ROS1-positive, advanced NSCLC.

* recently approved; no growth figures available

Diagnosics sales

Sales January–September 2021	CHF millions		As % of sales		% change	
	2021	2020	2021	2020	CER	CHF
Diagnosics Division	13,305	9,662	100.0	100.0	39	38
Customer Areas						
Core Lab	5,610	4,487	42.1	46.4	26	25
Molecular Lab	3,454	2,578	26.0	26.7	36	34
Point of Care	2,058	541	15.5	5.6	279	280

Diabetes Care	1,294	1,261	9.7	13.1	4	3
Pathology Lab	889	795	6.7	8.2	14	12
Regions						
Europe, Middle East, Africa	5,715	3,686	43.0	38.4	54	55
North America	3,139	2,768	23.6	28.4	18	13
Asia-Pacific	3,611	2,654	27.1	27.5	35	36
Latin America	840	554	6.3	5.7	63	52

Core Lab. Focuses on central labs; provides diagnostics solutions in the areas of immunoassays, clinical chemistry and custom biotech. Sales increased by 26% due to its immunodiagnosics business, with infectious and cardiac tests as main contributors. Sales grew across all regions, mainly in Asia-Pacific and EMEA.

Molecular Lab. Focuses on molecular labs; provides diagnostics solutions for the detection and monitoring of pathogens, donor screening, sexual health and genomics. Sales grew 36%, led by the virology business. COVID-19 testing, such as with the high-throughput PCR tests, continued to grow due to the Delta variant. Sales grew double-digit in all regions, led by Asia-Pacific and North America.

Point of Care. Focuses on diagnostics solutions at the point of care, e.g. 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 279%; the SARS-CoV-2 Rapid Antigen test was the main growth driver, especially in the EMEA region.

Diabetes Care. Focuses on integrated personalised diabetes management for people with diabetes and healthcare professionals. Sales increased 4%, driven by the blood glucose monitoring business (such as the Accu-Chek Guide system).

Pathology Lab. Focuses on pathology labs; provides diagnostics solutions for tissue biopsies and companion diagnostics. Sales increased 14%. This was mainly due to growth in the advanced staining business.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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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 Annual Report, 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 for 2020 or any subsequent period will necessarily match or exceed the historical published earnings or earnings per share of Roche

References

[1] Unless otherwise stated, all growth rates and comparisons to prior year in this document are at constant exchange rates (CER: average 2020) and all total figures quoted are reported in CHF.

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