Media Release

Ad hoc announcement pursuant to Art. 53 LR

Basel, 19 October 2023

Roche reports good sales growth despite decline in demand for COVID-19 products

- **Group sales** grow by 1%[1] at constant exchange rates (CER) in the first nine months, showing a strong increase of 7% in the third quarter
- Excluding COVID-19 products, **Group sales** increase by 9%
- **Pharmaceuticals Division sales** grow by 9%, driven by continued high demand for newer medicines
- **Diagnostics Division's base business** increases by 7%; **overall divisional sales** are down 18% due to a surge in demand for COVID-19 tests in 2022
- **Highlights** in the third quarter of 2023:
    - EU approval of **Evrysdi** for babies under two months old with spinal muscular atrophy
    - First approval of subcutaneous form of cancer immunotherapy **Tecentriq**
    - Positive phase III data for **Alecensa** (early-stage lung cancer) and **Ocrevus** (subcutaneous injection; multiple sclerosis)
    - Positive phase II data for **zilebesiran** (hypertension in patients at high risk of cardiovascular disease) and additional positive phase II data for **fenebrutinib** (multiple sclerosis)
    - Positive longer-term efficacy and safety data for **Ocrevus** (multiple sclerosis) and **Vabysmo** (retinal vein occlusion, a severe eye disease)
    - Launch of first validated test for earlier **diagnosis of neonatal sepsis** and new module to **improve laboratory efficiency**
- **Outlook for 2023 confirmed**

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Roche CEO Thomas Schinecker: “We achieved good results in the first nine months of 2023, more than compensating for the expected decline in demand for COVID-19 products. Our Group sales excluding COVID-19 products continued to grow strongly by +9% at constant exchange rates. Additionally, we made significant progress in our product pipeline with numerous positive clinical studies. I am particularly pleased about the phase III data for Alecensa in early-stage lung cancer. Treating cancer at an early stage may give patients a chance for a cure. We confirm our outlook for 2023.”

Sales January–September 2023	**CHF millions**		**As % of sales**		**% change**	
	2023	**2022**	**2023**	**2022**	**At CER**	**In CHF**
Group	44,053	47,037	100.0	100.0	1	-6
Pharmaceuticals Division	33,622	33,189	76.3	70.6	9	1
United States	17,680	17,199	40.1	36.6	8	3
Europe	6,259	6,100	14.2	13.0	7	3
Japan	2,937	3,029	6.7	6.4	10	-3
International*	6,746	6,861	15.3	14.6	12	-2
Diagnostics Division	10,431	13,848	23.7	29.4	-18	-25

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

Outlook for 2023 confirmed

Due to the sharp decline in sales of COVID-19 products of roughly CHF 4.5 billion, Roche expects a decrease in Group sales in the low single digit range (at constant exchange rates). Excluding this COVID-19 sales decline, Roche anticipates strong sales growth in both divisions’ base business.

Core earnings per share are targeted to develop broadly in line with the sales decline (at constant exchange rates). Roche expects to further increase its dividend in Swiss francs.

Group sales

In the first nine months of 2023, **Group sales** increased by 1% (-6% in CHF) to CHF 44.1 billion, even though the company had to compensate for the significant drop in sales of COVID-19 products and the biosimilar erosion[2] (a total of CHF 4.0 billion or 9% of sales).

Excluding COVID-19 products, **Group sales** grew by 9%.

The appreciation of the Swiss franc against most currencies had a significant adverse impact on the results presented in Swiss francs compared to constant exchange rates.

Continued high demand for newer medicines to treat severe diseases led to a 9% increase in **Pharmaceuticals Division** sales, reaching CHF 33.6 billion.

Roche's top five growth drivers – Vabysmo (severe eye diseases), Ocrevus (multiple sclerosis), Hemlibra (haemophilia), Polivy (blood cancer) and Evrysdi (spinal muscular atrophy) – collectively generated total sales of CHF 11.2 billion, marking a CHF 3.3 billion increase compared to the first nine months of 2022.

In the **United States**, sales increased by 8%. This notable growth was primarily driven by Vabysmo, Ocrevus and Hemlibra, in contrast to declining sales of medicines with expired patent protection.

Sales in **Europe** grew 7%, mainly driven by Germany, UK and France. Sales growth of Vabysmo, Phesgo, Evrysdi and Hemlibra was partially offset by the impact of biosimilars and the absence of sales for Ronapreve (COVID-19).

Sales in **Japan** experienced a 10% increase, primarily driven by Ronapreve, Polivy, Vabysmo, Hemlibra, Enspryng and Tamiflu (influenza). This sales growth more than offset the impact of biosimilars.

In the **International region**, sales grew by 12%. This encouraging trend was evident in all major markets, with Brazil and Canada leading the way. China recorded a 6% increase in sales, mainly fuelled by Tamiflu, Xeloda, Polivy and Perjeta. This more than outweighed the impact of biosimilars.

Sales of the **Diagnostics Division's base business** grew strongly (+7%) across all major markets. The primary drivers of growth were immunodiagnostics, particularly cardiac tests, and diagnostic solutions for clinical chemistry.

Overall, the **Diagnostics Division** achieved sales of CHF 10.4 billion. The 18% decrease was in line with the anticipated significant drop in demand for COVID-19 tests (CHF 0.4 billion in the first nine months of 2023, in contrast to CHF 3.6 billion in the same period last year).

Sales in the **North America, Asia-Pacific** and **Europe, Middle East and Africa (EMEA)** regions were down by 23%, 19% and 17%, respectively. The decline in sales across regions is primarily due to the sharp decline in demand for COVID-19 tests.

Pharmaceuticals: key development milestones in the third quarter of 2023

Compound	Milestone
Regulatory	
Tecentriq SC Subcutaneous cancer immunotherapy	**Tecentriq becomes the first subcutaneous anti-PD-(L)1 cancer immunotherapy available to patients in Great Britain, reducing treatment time to just minutes** • Tecentriq subcutaneous (SC) is now approved in Great Britain for all indications of intravenous Tecentriq, including certain types of lung, bladder, breast and liver cancer, offering a faster, more convenient option to receive treatment • Administered under the skin within approx. seven minutes, Tecentriq SC saves time for patients and helps conserve resources in healthcare systems • Evaluations by other health authorities globally are ongoing More information: Media Release, 29 August 2023
Evrysdi Spinal muscular atrophy	**European Commission approves Evrysdi for babies under two months old with spinal muscular atrophy (SMA)** • Evrysdi now available to treat people of all ages with SMA in the European Union, including babies from birth • Approval is based on interim data from ongoing RAINBOWFISH trial showing majority of babies treated with Evrysdi were able to stand and walk within timeframes typical of healthy babies by 12 months' treatment • Evrysdi is the only non-invasive SMA therapy and is approved in more than 100 countries with more than 11,000 patients treated globally More information: Media Release, 29 August 2023
Phase III, pivotal and other key readouts; data presentations	
Alecensa Lung cancer	**Alecensa reduces the risk of disease recurrence or death by an unprecedented 76% in people with ALK-positive early-stage non-small cell lung cancer (NSCLC)** • These phase III data are the first and only to show an improvement in disease-free survival in early-stage resected ALK-positive NSCLC • With about one in two people with early-stage NSCLC experiencing disease recurrence following surgery, despite adjuvant chemotherapy, more effective treatment options are urgently needed to provide the best chance for cure • Data are being presented as a late-breaking oral during the ESMO 2023 Presidential Symposium More information: Media Release, 18 October 2023

Fenebrutinib Multiple sclerosis	**Late-breaking data for BTK inhibitor fenebrutinib show brain penetration and significant reduction in lesions in patients with relapsing multiple sclerosis (MS)** ● New data from phase II FENopta study in relapsing multiple sclerosis (RMS) show fenebrutinib crosses the blood-brain barrier with the potential to act directly on the chronic inflammation related to multiple sclerosis ● More than 90% relative reduction in new/enlarging T2 lesions and new T1 gadolinium-enhancing (Gd+) lesions with fenebrutinib beginning at eight weeks ● The safety profile of fenebrutinib was consistent with previous and ongoing clinical trials across more than 2,500 people to date More information: Media Release, 13 October 2023
Ocrevus subcutaneous injection Multiple sclerosis	**Ocrevus twice-yearly, 10-minute subcutaneous injection is non-inferior to intravenous infusion and provided near-complete suppression of brain lesions** ● Late-breaking phase III results show subcutaneous injection was non-inferior to intravenous (IV) infusion based on Ocrevus levels in the blood over 12 weeks ● Ocrevus subcutaneous injection was comparable to IV infusion in providing rapid and sustained depletion of B cells and near-complete suppression of MRI lesion activity in the brain over 24 weeks ● The safety profile of Ocrevus subcutaneous injection was consistent with the well-established safety profile of Ocrevus IV infusion ● The 10-minute subcutaneous injection has potential to improve the treatment experience for people with multiple sclerosis (MS) and expand usage in centres with IV capacity limitations More information: Media Release, 11 October 2023
Vabysmo Retinal vein occlusion	**Vabysmo maintains vision improvements with extended treatment intervals for up to four months for people with retinal vein occlusion (RVO) in phase III studies** ● Vabysmo showed robust and sustained retinal drying for up to 72 weeks and a safety profile consistent with previous studies ● Regulatory applications for Vabysmo in RVO are under review by health authorities around the world; if approved, RVO would be the third indication in addition to neovascular or 'wet' age-related macular degeneration (nAMD) and diabetic macular edema (DME) ● Vabysmo is the first and only treatment that targets and inhibits two signalling pathways linked to a number of vision-threatening retinal conditions More information: Media Release, 10 October 2023
Evrysdi Spinal muscular atrophy	**Majority of newborn babies with spinal muscular atrophy (SMA) treated with Evrysdi are able to sit independently after one year of treatment** ● RAINBOWFISH study met its primary endpoint with 80% of babies sitting without support for at least five seconds after one year of Evrysdi treatment – without treatment these babies would never be able to sit ● All babies were able to swallow and feed orally and none required permanent ventilation ● Evrysdi is the only non-invasive SMA therapy and is approved in over 100 countries with more than 11,000 patients treated globally More information: Media Release, 4 October 2023

Ocrevus subcutaneous injection Multiple sclerosis **Fenebrutinib** Multiple sclerosis **Enspryng** Neuromyelitis optica spectrum disorder	**Roche to present new key clinical and real-world data at ECTRIMS-ACTRIMS 2023 showcasing strength of long-term outcomes in MS and NMOSD** ● Late-breaking results from phase III trial of Ocrevus subcutaneous injection and phase II trial of BTK inhibitor fenebrutinib in multiple sclerosis (MS) will be presented ● Ten-year Ocrevus efficacy and safety data show significant benefit in slowing long-term disability progression and consistent long-term safety profile in MS ● Additional Ocrevus real-world and clinical data show impact for underrepresented populations including more than 3,200 pregnant women and Black and Hispanic/Latinx patients with MS ● Longer-term safety data and late-breaking efficacy data from phase III trial of Enspryng in neuromyelitis optica spectrum disorder (NMOSD) will be presented More information: Media Release, 2 October 2023
Zilebesiran Hypertension	**Roche and Alnylam report positive topline results from phase II study KARDIA-1 of zilebesiran, an investigational RNAi therapeutic in development to treat hypertension in patients at high risk of cardiovascular disease** ● Zilebesiran met primary endpoint demonstrating a clinically significant reduction in 24-hour mean systolic blood pressure measured by Ambulatory Blood Pressure Monitoring (ABPM) at three months of treatment, achieving a placebo-subtracted reduction greater than 15 mmHg ● Study met key secondary endpoints showing consistent reductions of systolic blood pressure at six months ● Early results indicate the potential for zilebesiran to achieve sustained blood pressure reduction with quarterly or half-yearly dosing More information: Media Release, 7 September 2023
Alecensa Lung cancer	**Alecensa delivers unprecedented phase III results for people with ALK-positive early-stage lung cancer (NSCLC)** ● ALINA data demonstrate Alecensa reduces disease recurrence in the early setting for people with ALK-positive non-small cell lung cancer, building on its long-established benefit in the advanced setting ● About half of people with NSCLC experience disease recurrence following surgery, despite adjuvant chemotherapy, therefore new treatments are urgently needed to provide the best chance for cure ● These data will be submitted to health authorities globally and presented at an upcoming medical meeting More information: Media Release, 1 September 2023
Tiragolumab Non-small cell lung cancer	**Roche provides update on phase III SKYSCRAPER-01 study in PD-L1-high metastatic non-small cell lung cancer (NSCLC)** ● Inadvertent disclosure of the second interim analysis of the phase III SKYSCRAPER-01 study, evaluating anti-TIGIT immunotherapy tiragolumab plus Tecentriq versus Tecentriq alone as an initial (first-line) treatment for people with PD-L1-high locally advanced or metastatic non-small cell lung cancer ● SKYSCRAPER-01 is ongoing as planned until the final analysis of overall survival, the primary endpoint of the study, and remains blinded to patients and investigators; the interim results for the primary endpoint of overall survival were not mature at the time of the second interim analysis More information: Media Release, 23 August 2023

Pharmaceuticals sales

Sales	CHF millions		As % of sales		% change	
January–September 2023	**2023**	**2022**	**2023**	**2022**	**At CER**	**In CHF**
Pharmaceuticals Division	33,622	33,189	100.0	100.0	9	1
United States	17,680	17,199	52.6	51.8	8	3
Europe	6,259	6,100	18.4	18.4	7	3
Japan	2,937	3,029	8.7	9.1	10	-3
International*	6,746	6,861	20.3	20.7	12	-2

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

Top-selling medicines	Total		United States		Europe		Japan		International	
	CHF m	%	CHF m	%	CHF m	%	CHF m	%	CHF m	%
Ocrevus Multiple sclerosis	4,767	14	3,492	12	877	12	-	-	398	35
Hemlibra Haemophilia A	3,112	19	1,862	17	637	22	281	15	332	36
Perjeta[3] Breast cancer	2,995	6	1,101	2	615	-4	161	4	1,118	15
Tecentriq Cancer immunotherapy	2,791	11	1,476	7	628	14	313	9	374	24
Actemra/RoActemra[3] RA, COVID-19	1,943	2	877	1	583	1	232	3	251	6
Vabysmo Eye diseases (nAMD, DME)	1,613	**	1,320	449	185	**	70	236	38	**
Xolair[3] Asthma	1,601	4	1,601	4	-	-	-	-	-	-

Kadcyla[3] Breast cancer	1,486	2	568	-3	446	-9	77	-14	395	29
Herceptin[3] Breast and gastric cancer	1,261	-17	258	-28	271	-15	24	-33	708	-13
MabThera/Rituxan[3] Blood cancer, RA	1,260	-15	761	-20	140	-7	19	-13	340	-8
Avastin[3] Various cancer types	1,210	-20	370	-22	78	-48	250	-25	512	-8
Alecensa Lung cancer	1,126	9	340	8	220	5	157	6	409	12
Evrysdi Spinal muscular atrophy	1,065	45	381	15	374	54	67	29	243	115
Activase/TNKase Cardiac diseases	903	8	859	8	-	-	-	-	44	7
Phesgo Breast cancer	817	66	320	56	384	53	-	-	113	186
Gazyva/Gazyvaro[3] Blood cancer	615	22	297	25	174	25	28	-17	116	24
Polivy Blood cancer	605	126	230	100	136	70	167	181	72	372
Ronapreve COVID-19	532	-5	-	-	-	-100	531	33	1	-99

** Over 500%

DME: diabetic macular oedema / nAMD: neovascular or 'wet' age-related macular degeneration / RA: rheumatoid arthritis

Diagnostics: key milestones in the third quarter of 2023

Product	Milestone
Elecsys IL-6 claim extension Neonatal sepsis	**Roche IL-6 is the first immunoassay approved to aid sepsis diagnosis in newborns** • Neonatal sepsis is a leading cause of death for newborns • Testing IL-6 can indicate a neonatal sepsis infection earlier than other biomarkers • Earlier diagnosis of neonatal sepsis can lead to improved outcomes and a reduction of long-term complications from sepsis More information: Media Release, 18 October 2023
CCM Vertical Laboratory module	**Roche launches a new addition to the cobas connection modules, the CCM Vertical, helping to improve laboratory efficiency** • The cobas connection modules (CCM) sample conveyors system has been extended with newly developed elevator and overhead conveyor modules enabling more flexibility in lab design • CCM Vertical optimises the use of laboratory space without compromising on sample throughput of CCM up to 2,500 samples per hour • The fully modular system allows connection of different work areas in the laboratory without blocking walkways and enabling transport of samples to adjacent floors or rooms More information: Media Statement, 17 August 2023

Diagnostics sales

Sales	CHF millions		As % of sales		% change	
January–September 2023	**2023**	**2022**	**2023**	**2022**	**At CER**	**In CHF**
Diagnostics Division	10,431	13,848	100.0	100.0	-18	-25
Customer Areas[4]						
Core Lab	5,836	5,833	56.0	42.1	9	0
Molecular Lab	1,647	2,735	15.8	19.8	-35	-40
Pathology Lab	1,046	975	10.0	7.0	15	7
Diabetes Care	1,037	1,219	9.9	8.8	-6	-15
Point of Care	865	3,086	8.3	22.3	-70	-72
Regions						
Europe, Middle East and Africa	3,569	4,595	34.2	33.2	-17	-22
North America	2,853	3,923	27.5	28.3	-23	-27
Asia-Pacific	3,263	4,522	31.3	32.7	-19	-28
Latin America	746	808	7.0	5.8	6	-8

More information on Roche sales in the first nine months of 2023:

- Investor presentation Q3 2023
- Appendix with Tables Q3 2023

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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 endeavour 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.

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.

References

[1] Unless otherwise stated, all growth rates and comparisons to the previous year in this document are at constant exchange rates (CER: average rates 2022) and all total figures quoted are reported in CHF.
[2] Biosimilar erosion to Avastin, Herceptin and Mabthera/Rituxan.
[3] Products launched before 2015.
[4] Core Lab: diagnostics solutions in the areas of immunoassays, clinical chemistry and CustomBiotech.
Point of Care: diagnostics solutions in emergency rooms, medical practices or directly with patients.
Molecular Lab: diagnostics solutions for pathogen detection and monitoring, donor screening, sexual health and genomics.
Diabetes Care: integrated personalised diabetes management.
Pathology Lab: diagnostics solutions for tissue biopsies and companion diagnostics.

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