Media & Investor Release

Ad hoc announcement pursuant to Art. 53 LR

Basel, 23 October 2024

Roche's strong sales growth of 9% (CER) continues in the third quarter of 2024; Group sales increase 6% in the first nine months

- **Group sales** grew by 6%[1] at constant exchange rates (CER) (2% in CHF) in the first nine months, driven by the high demand for both our medicines and diagnostics; excluding COVID-19-related products, sales increased by 8%
- In the third quarter, Group sales rose by 9% (6% in CHF), as they did in the second quarter
- **Pharmaceuticals Division** sales rose by 7% in the first nine months; the strong growth of 9% in the **base business**[2] was driven by continued high demand for our newer medicines to treat severe diseases; Vabysmo (serious eye diseases), Phesgo (breast cancer) and Ocrevus (multiple sclerosis) were major growth drivers
- **Diagnostics Division** sales increased by 5% in the first nine months, while the **base business**[2] grew by 8% due to higher demand for immunodiagnostic, pathology and molecular solutions
- **Highlights:**
    - US approval for **Itovebi** (inavolisib) for breast cancer, **Ocrevus Zunovo** subcutaneous injection for multiple sclerosis and **Tecentriq Hybreza** subcutaneous formulation for various types of cancer
    - EU approval for **Vabysmo** for retinal vein occlusion (RVO), a serious eye disease, and **PiaSky** for paroxysmal nocturnal haemoglobinuria (PNH), a rare life-threatening blood condition
    - Positive phase III data for **Gazyva/Gazyvaro** (lupus nephritis, a kidney disease), **Xofluza** (influenza) and **Tecentriq** (lung cancer). New positive phase II data for **fenebrutinib** (multiple sclerosis), and new positive long-term data for **Evrysdi** (spinal muscular atrophy)
    - Acquired **AntlerA Therapeutics** for a novel target in ophthalmology, and signed agreement for the acquisition of two next-generation CDK inhibitor drugs targeting breast cancer from **Regor Pharmaceuticals**
    - Closing of acquisition of **LumiraDx's point-of-care technology** to expand access to diagnostic testing in primary care and low- and middle-income countries
    - Launch of the **cobas Respiratory flex test**, the first to use our new Temperature-Activated Generation of Signal (TAGS) technology
    - WHO endorsement for **CINtec PLUS** testing for cervical cancer prevention
- **Outlook for 2024 confirmed**

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Roche CEO **Thomas Schinecker**: “Our strong growth momentum continued in the third quarter, reflecting the high demand for our innovative medicines and diagnostic solutions and their positive impact on patients’ lives around the world.

We made significant progress in our pharmaceuticals portfolio in the last quarter with five important regulatory approvals for our medicines, three positive phase III read-outs, and two acquisitions to strengthen our oncology and ophthalmology pipelines.

Itovebi (inavolisib) recently received US approval based on clinical data demonstrating a reduction of more than 50% in the risk of death or worsening disease for people suffering from a form of advanced, hard-to-treat breast cancer. In addition, we had positive phase III results for Gazyva/Gazyvaro in lupus nephritis, a potentially life-threatening kidney disease for which limited treatment options are available today.

We confirm our outlook for 2024.”

Sales	**CHF millions**		**As % of sales**		**% change**	
January–September	**2024**	**2023**	**2024**	**2023**	**At CER**	**In CHF**
Group	44,984	44,053	100.0	100.0	6	2
Pharmaceuticals Division	34,257	33,372	76.2	75.8	7	3
United States	18,166	17,430	40.4	39.6	7	4
Europe	6,613	6,259	14.7	14.2	7	6
Japan	2,083	2,937	4.6	6.7	-21	-29
International*	7,395	6,746	16.5	15.3	19	10
Diagnostics Division	10,727	10,681	23.8	24.2	5	0

All figures shown in the table were restated to reflect the shift of the Foundation Medicine (FMI) business from the Pharmaceuticals Division to the Diagnostics Division.
*Asia-Pacific, CEETRIS (Central Eastern Europe, Türkiye, Russia and Indian subcontinent), Latin America, Middle East, Africa, Canada, others

Outlook for 2024 confirmed

Roche expects an increase in Group sales in the mid single digit range (CER).

Core earnings per share are targeted to grow in the high single digit range (CER), excluding the impact from the resolution of tax disputes in 2023.

Roche expects to further increase its dividend in Swiss francs.

Group sales

In the first nine months of 2024, **Group sales** increased by 6% at CER (2% in CHF) to CHF 45.0 billion as strong demand for our novel medicines as well as diagnostic products including immunodiagnostic, pathology and molecular solutions more than offset the anticipated decline in COVID-19-related sales and the impact of biosimilar/generic erosion.

The appreciation of the Swiss franc against most currencies had an adverse impact on the sales reported in Swiss francs compared to constant exchange rates.

The **Pharmaceuticals Division sales** increased by 7% to CHF 34.3 billion, while the **base business** (excluding COVID-19) grew by 9%, driven primarily by higher sales of Vabysmo (severe eye diseases), Phesgo (breast cancer), Ocrevus (multiple sclerosis), Hemlibra (haemophilia) and Polivy (blood cancer).

These five medicines together generated total sales of CHF 13.2 billion, an increase of CHF 2.7 billion (CER) from the first nine months of 2023.

The eye medicine Vabysmo, launched in early 2022, continues to be a major growth driver, generating sales of CHF 2.8 billion on growing demand in all regions.

Sales of Avastin (various types of cancer), Herceptin (breast and gastric cancer) and MabThera/Rituxan (blood cancer, rheumatoid arthritis) decreased by a combined CHF 0.5 billion as the impact of biosimilar competition slowed further. Sales of the COVID-19 medicine Ronapreve were negligible compared with CHF 0.5 billion in the first nine months of 2023.

In the **United States**, sales grew by 7% as strong sales of Vabysmo, Ocrevus, Polivy and Xolair (food allergies) were partially offset by the continued decline in sales of medicines for which patent protection has expired. Vabysmo achieved CHF 2.1 billion in sales, showing a high uptake in both new patients and patients switching from other medications.

In **Europe**, sales rose by 7%, driven by demand for Vabysmo as well as by the continued uptake of Phesgo, Ocrevus, Evrysdi (spinal muscular atrophy) and Hemlibra. This was partially offset by lower sales of medicines for which patent protection has expired and of Perjeta (breast cancer) due to the ongoing conversion of patients to Phesgo.

Sales in **Japan** were down 21%, mainly due to the base effect of the supply of Ronapreve (COVID-19) to the government in the first quarter of 2023. Excluding this effect, sales in Japan were 3% lower as strong demand for Phesgo and Vabysmo was more than offset by the impact of government price cuts and lower sales of medicines for which patent protection has expired.

Sales in the **International region** surged by 19%, led by demand for Perjeta, Hemlibra, Tecentriq (cancer immunotherapy), Phesgo and Ocrevus as well as the launch of Elevydis (gene therapy, Duchenne muscular dystrophy). Sales in China increased by 8%, driven by Xofluza, Perjeta, Polivy and Avastin.

The **Diagnostics Division sales** increased by 5% to CHF 10.7 billion, while the **base business** (excluding COVID-19) grew by 8%. Immunodiagnostic products, which include cardiac, oncology and thyroid tests, were the main growth drivers (10%). Additional growth came from pathology and molecular solutions. Sales of COVID-19 tests were CHF 0.1 billion in the first nine months of 2024 compared with CHF 0.4 billion in the corresponding period last year.

Sales growth was reported across regions, with the **Europe**, **Middle East and Africa** (EMEA) region growing by 5%, **North America** by 6%, **Asia-Pacific** by 2% and **Latin America** by 18%.

Pharmaceuticals: key developments

Compound	Milestone
Regulatory	
Itovebi (inavolisib) Breast cancer	**FDA approves Itovebi, a targeted treatment for advanced hormone receptor (HR)-positive, HER2-negative breast cancer with a PIK3CA mutation** ● Approval is based on phase III INAVO120 results, showing the regimen based on Itovebi (inavolisib) more than doubled progression-free survival compared with palbociclib and fulvestrant alone in the first-line setting ● This approval helps address an urgent unmet need in breast cancer for people with a mutated PIK3CA gene, one of the most commonly mutated genes in HR-positive disease and which is associated with poor prognosis ● Itovebi is Roche's first targeted therapy approved for people with HR-positive disease, the most prevalent breast cancer subtype, marking an important step in our ambition to continue bringing innovative medicines to more people with breast cancer More information: Media Release, 11 October 2024
Ocrevus Zunovo Multiple sclerosis	**FDA approves Ocrevus Zunovo as the first and only twice-a-year 10-minute subcutaneous injection for people with relapsing and progressive multiple sclerosis** ● Ocrevus Zunovo has the potential to expand treatment options to centres without intravenous (IV) infrastructure or with IV constraints, like at a doctor's office ● This approval is backed by a decade of proven safety and efficacy data of Ocrevus IV, with over 350,000 people treated globally

	• Ocrevus Zunovo offers people with multiple sclerosis more options to access treatment based on their individual needs More information: Media Release, 16 September 2024
Tecentriq Hybreza Various types of cancer	**FDA approves Tecentriq Hybreza, the first and only subcutaneous anti-PD-(L)1 cancer immunotherapy** • Tecentriq Hybreza provides patients and physicians with greater flexibility of treatment options while showing safety and efficacy consistent with intravenous (IV) Tecentriq • New subcutaneous option reduces treatment time to approximately seven minutes, compared with 30–60 minutes for IV infusion More information: Media Release, 13 September 2024
PiaSky Rare blood disease	**PiaSky approved in the EU as the first monthly subcutaneous treatment for people with paroxysmal nocturnal haemoglobinuria (PNH)** • With the option of self-administration, PiaSky (crovalimab) has the potential to reduce treatment burden for people with PNH and their caregivers in Europe • Approval is based on COMMODORE 2, where subcutaneous (SC) PiaSky once a month was equivalent to intravenous eculizumab every two weeks • PiaSky advances C5 inhibition through innovative recycling technology, which enables its monthly SC administration More information: Media Release, 27 August 2024
Vabysmo Severe eye diseases	**European Commission approves Vabysmo for treatment of retinal vein occlusion (RVO)** • Approval is based on data from two phase III studies in branch and central retinal vein occlusion (RVO) showing early and sustained vision improvements non-inferior to aflibercept, and robust retinal drying with Vabysmo • Additional submitted data shows that up to 60% of people receiving Vabysmo were able to extend treatment intervals to three or four months • Vabysmo is already approved in several countries, including the US and Japan, for RVO and in nearly 100 countries for people with neovascular or 'wet' age-related macular degeneration (nAMD) and diabetic macular edema (DME) More information: Media Release, 30 July 2024
Phase III, pivotal and other key readouts	
Evrysdi Spinal muscular atrophy	**Majority of children with spinal muscular atrophy (SMA) treated with Evrysdi are able to sit, stand and walk independently, two-year data demonstrate** • Positive data confirm Evrysdi efficacy and safety in children first treated pre-symptomatically before six weeks of age, with most achieving motor milestones similar to children without SMA • All children were able to swallow and feed orally, with none requiring permanent ventilation • Evrysdi is the only non-invasive SMA therapy and is approved in over 100 countries, with more than 16,000 people with SMA treated globally More information: Media Release, 14 October 2024

Gazyva/ Gazyvaro Kidney disease	**Positive phase III results for Gazyva/Gazyvaro show superiority to standard therapy alone in people with lupus nephritis** ● The REGENCY study met its primary endpoint, demonstrating statistically significant and clinically meaningful treatment benefits in people with active lupus nephritis ● Gazyva/Gazyvaro is designed to target an underlying cause of lupus nephritis, aiming to prevent or delay progression to end-stage kidney disease ● Lupus nephritis is a potentially life-threatening manifestation of an autoimmune disease affecting 1.7 million people worldwide, primarily women; up to one-third of people on current treatments will progress to end-stage kidney disease within 10 years More information: Media Release, 26 September 2024
Xofluza Influenza	**Positive phase III results show Xofluza significantly reduces the transmission of influenza viruses** ● Data from the CENTERSTONE study shows single-dose Xofluza reduces transmission of influenza from an infected person to household members ● This is the first time that any antiviral used in the treatment of a respiratory viral illness has demonstrated a transmission reduction benefit in a global phase III study ● Reducing the spread of infection in the household could help limit transmission within communities and societies, easing the burden of both seasonal and pandemic influenza on healthcare systems More information: Media Release, 19 September 2024
Fenebrutinib Multiple sclerosis	**Fenebrutinib demonstrated near-complete suppression of disease activity and disability progression for up to 48 weeks in patients with relapsing multiple sclerosis** ● New phase II data show vast majority of patients experiencing no relapses or disability progression ● Fenebrutinib suppressed acute and chronic MRI lesions ● Fenebrutinib's safety profile was consistent with previous and ongoing clinical trials across multiple diseases including more than 2,700 people to date More information: Media Release, 4 September 2024
Susvimo Severe eye disease	**New data for Susvimo demonstrates sustained efficacy in two serious diabetic eye conditions** ● Two-year phase III data presented at ASRS 2024 show Susvimo's potential as an alternative to eye injections to treat diabetic macular edema (DME) and diabetic retinopathy (DR) ● Safety data were consistent with the known safety profile for Susvimo in people with DME and DR ● Additionally, the US FDA has accepted the filing application for Susvimo in DME and DR based on one-year Pagoda and Pavilion study data More information: Media Release, 18 July 2024
Other	
Pharma Research and	**Roche opens Pharma Research and Early Development Center in Basel to accelerate scientific innovation**

Early Development Center	• Switzerland's most innovative research and development centre underscores Roche's long-term investment in scientific advancement to meet patient needs • The new centre will simplify and increase collaboration, thereby accelerating scientific innovation More information: Media Release, 10 September 2024

Pharmaceuticals sales

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January–September	**2024**	**2023**	**2024**	**2023**	**At CER**	**In CHF**
Pharmaceuticals Division	34,257	33,372	100.0	100.0	7	3
United States	18,166	17,430	53.0	52.2	7	4
Europe	6,613	6,259	19.3	18.8	7	6
Japan	2,083	2,937	6.1	8.8	-21	-29
International*	7,395	6,746	21.6	20.2	19	10

All figures shown in the table were restated to reflect the shift of the Foundation Medicine (FMI) business from the Pharmaceuticals Division to the Diagnostics Division.
* 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	5,056	9	3,640	7	961	11	-	-	455	26
Hemlibra Haemophilia A	3,280	10	1,906	5	690	10	259	4	425	42
Vabysmo Eye diseases (nAMD, DME, RVO)	2,816	79	2,146	67	454	148	86	37	130	256

Perjeta[3] Breast cancer	2,809	-1	1,029	-4	502	-17	92	-36	1,186	17
Tecentriq Cancer immunotherapy	2,703	1	1,325	-8	649	5	277	-1	452	32
Actemra/RoActemra[3] RA, COVID-19	1,948	5	949	11	508	-11	225	9	266	17
Xolair[3] Asthma	1,737	11	1,737	11	-	-	-	-	-	-
Kadcyla[3] Breast cancer	1,494	6	574	4	428	-2	71	4	421	22
Evrysdi Spinal muscular atrophy	1,246	21	429	15	435	18	66	10	316	35
Phesgo Breast cancer	1,244	58	404	29	543	44	88	-	209	104
Alecensa Lung cancer	1,151	7	372	12	217	1	144	3	418	8
Herceptin[3] Breast and gastric cancer	1,063	-11	201	-20	227	-15	11	-48	624	-5
MabThera/Rituxan[3] Blood cancer, RA	1,023	-16	615	-17	109	-21	12	-26	287	-10
Avastin[3] Various cancer types	943	-17	289	-20	63	-17	149	-33	442	-8
Activase/TNKase[3] Cardiac diseases	895	2	850	1	-	-	-	-	45	5
Polivy Blood cancer	817	41	410	83	142	6	143	-4	122	79
Gazyva/Gazyvaro[3] Blood cancer	670	13	333	15	185	8	21	-16	131	21
Pulmozyme[3] Cystic fibrosis	329	0	213	-5	55	-3	1	17	60	23
Mircera[3] Anaemia related to kidney disease	304	-1	-	-	31	-6	28	-23	245	4
CellCept[3] Immunosuppressant	283	1	17	-21	81	-13	27	-9	158	17

DME: diabetic macular edema / nAMD: neovascular or 'wet' age-related macular degeneration / RVO: retinal vein occlusion / RA: rheumatoid arthritis

Diagnostics: key developments

Product	Milestone
VENTANA CLDN18 assay Gastric or gastro-oesophageal junction cancer	**Roche obtains CE certification for the first companion diagnostic to identify patients with gastric and gastro-oesophageal junction cancer eligible for targeted treatment with VYLOY** ● The new VENTANA CLDN18 (43-14A) RxDx assay helps fulfil an unmet medical need by enabling clinicians to identify patients with gastric or gastro-oesophageal junction (GOJ) cancer who may benefit from a targeted treatment option ● CLDN18.2 is an emerging biomarker in gastric and GOJ cancers and helps predict the likelihood of response to targeted therapy ● As the leader in companion diagnostics, Roche continues to build on its commitment to improve personalised healthcare to enable better patient outcomes More information: Media Release, 10 October 2024
cobas Respiratory flex test Respiratory illnesses	**Roche launches the first test to use its breakthrough TAGS technology for high-throughput, simultaneous detection of 12 respiratory viruses** ● The new Temperature-Activated Generation of Signal (TAGS) technology enables up to 15 targets to be detected simultaneously in a single patient sample on the high-throughput molecular diagnostic analysers cobas 5800, 6800 and 8800 ● TAGS has the potential to revolutionise testing for other infectious diseases in the future, by bringing high-throughput customised syndromic panel testing to the routine clinical laboratory ● The first TAGS-based test to be made available, the cobas Respiratory flex, offers fast, efficient detection of up to 12 of the most common respiratory viruses with the flexibility for targeted testing, expediting accurate diagnosis, optimising antimicrobial use and saving time in the lab More information: Media Release, 24 September 2024
CINtec PLUS Cervical cancer	**WHO endorses dual-stain cytology (CINtec PLUS) testing in its cervical cancer prevention guidelines, advancing patient care and underlining Roche's role in pioneering cervical cancer solutions** ● CINtec PLUS Cytology is the only FDA-approved and CE-marked dual-stain test to triage human papillomavirus (HPV)-positive cervical cancer screening test results ● Dual-stain biomarkers aid in detection of cervical precancer and may reduce the number of women who undergo unnecessary colposcopy procedures while allowing earlier intervention for those who are at higher risk of developing cervical cancer ● This recognition follows the American Society for Colposcopy and Cervical Pathology (ASCCP)'s recent inclusion of dual-stain testing in cervical cancer screening guidelines, as well as other WHO prequalifications of Roche's cobas HPV test More information: Media Release, 23 September 2024
cobas MPXV test, LightMix Mpox	**Roche responds to WHO's declaration of a global health emergency due to the ongoing mpox outbreak** ● Roche is committed to supporting all those working to overcome the mpox outbreak by providing access to high-quality polymerase chain reaction (PCR) testing

	• Roche confirms that its cobas MPXV test and the LightMix research-use-only kits detect the latest mpox virus variants • We are actively working to enhance laboratory testing capacity for mpox worldwide More information: Media Release, 20 August 2024
LumiraDx	**Roche closes acquisition of LumiraDx's point-of-care technology to expand access to diagnostic testing in primary care** • The acquisition of LumiraDx's point-of-care technology received all required antitrust and regulatory clearances • LumiraDx's transformative point-of-care solution will complement Roche's diagnostics portfolio across clinical chemistry, immunochemistry, coagulation and molecular, and across multiple disease areas • By integrating LumiraDx, Roche will further its ambition to deliver decentralised solutions that expand global access to testing in primary care settings worldwide More information: Media Release, 29 July 2024

Diagnostics sales

Sales	**CHF millions**		**As % of sales**		**% change**	
January–September	**2024**	**2023**	**2024**	**2023**	**At CER**	**In CHF**
Diagnostics Division	10,727	10,681	100.0	100.0	5	0
Customer Areas[4]						
Core Lab	6,052	5,836	56.4	54.6	9	4
Molecular Lab[5]	1,903	1,897	17.7	17.8	4	0
Near Patient Care[6]	1,616	1,902	15.1	17.8	-10	-15
Pathology Lab	1,156	1,046	10.8	9.8	15	11
Regions						
Europe, Middle East and Africa	3,589	3,569	33.5	33.4	5	1

North America[5]	3,222	3,103	30.0	29.1	6	4
Asia-Pacific	3,146	3,263	29.3	30.5	2	-4
Latin America	770	746	7.2	7.0	18	3

More information on Roche sales in the first nine months of 2024:

- Q3 2024 presentation
- Appendix with tables

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 pharmaceuticals with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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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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 2023) and all total figures quoted are reported in CHF.
[2] Pharmaceuticals Division base business: excluding COVID-19 medicine Ronapreve.
Diagnostics Division base business: excluding COVID-19-related products.
[3] Products launched before 2015.
[4] Core Lab: diagnostics solutions in the areas of immunoassays, clinical chemistry and CustomBiotech.
Molecular Lab: diagnostics solutions for pathogen detection and monitoring, donor screening, sexual health and genomics, genomic tumour profiling.
Near Patient Care: diagnostics solutions in emergency rooms, medical practices and directly with patients, including integrated personalised diabetes management.
Pathology Lab: diagnostics solutions for tissue biopsies and companion diagnostics.
[5] Sales in the Molecular Lab customer area include sales from the Foundation Medicine business, which moved under the responsibility of the Diagnostics Division from the Pharmaceuticals Division effective 1 January 2024. The comparative information for 2023 has been restated accordingly.
[6] Sales in the new Near Patient Care customer area include sales from Diabetes Care and the Point of Care business, both previously shown as separate customer areas. The comparative information for 2023 has been restated accordingly.

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 for this or any subsequent period will necessarily match or exceed the historical published earnings or earnings per share of Roche.

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