
Roche

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# Roche

# 2022 results

*Basel, 2 February 2023*

# Group

***Severin Schwan***
***Chief Executive Officer***

# 2022 performance

## Outlook

# 2022: Good Group results

## Group sales +2% driven by good performance in both divisions

- Pharma portfolio rejuvenation ongoing, key products offsetting LOE impact
- Diagnostics with good growth momentum driven by strong base business (+7%)
- Decline of roughly CHF 1 bn in COVID-19 sales

## Profit and Cash Flow

- Core EPS growth +5%, Operating Free Cash Flow remains strong (CHF 17.7bn)

## Growth supported by key products and strong launches

- Pharma key products Ocrevus, Hemlibra, Vabysmo, Evrysdi, Tecentriq, Phesgo and Polivy continuing to grow strongly
- Key approvals achieved: Vabysmo in nAMD/DME in US/EU; Polivy in 1L DLBCL in EU/Japan/China; Tecentriq in adjuvant NSCLC in EU; Lunsumio in 3L+ FL in US/EU
- Launches of next generation of SARS-CoV-2 rapid antigen test 2.0, cobas® HCV DUO, Elecsys® pTau/AB42 ratio Gen2 CSF (FDA), Benchmark Ultraplus, Digital LightCyler, cobas® pure and 5800 (FDA)

## Significant newsflow in 2023

- Pharma: 16 late-stage read-outs incl. 3 NMEs (tiragolumab, crovalimab, SRP-9001) and important line extensions for Tecentriq, Venclexta, Alecensa, Ocrevus, Lunsumio and TNKase; positive results for Tecentriq in adjuvant HCC and Susvimo in DME/DR achieved
- Diagnostics: CCM Vertical, LightCycler Pro, Anti-HEV IgG/IgM, HBeAg Quant, IL-6 Neonatal sepsis



Growth rates at CER (Constant exchange Rates); LOE=loss-of-exclusivity

# 2022: Guidance achieved

| *Targets for 2022* | | *FY 2022* | |
|---|---|---|---|
| **Group sales growth[1]** | **Stable- to low-single digit** | **+2%** | ✓ |
| **Core EPS growth[1]** | **Low- to mid-single digit** | **+5%** | ✓ |
| **Dividend outlook** | **Further increase dividend in Swiss francs[2]** | **CHF 9.50** | ✓ |

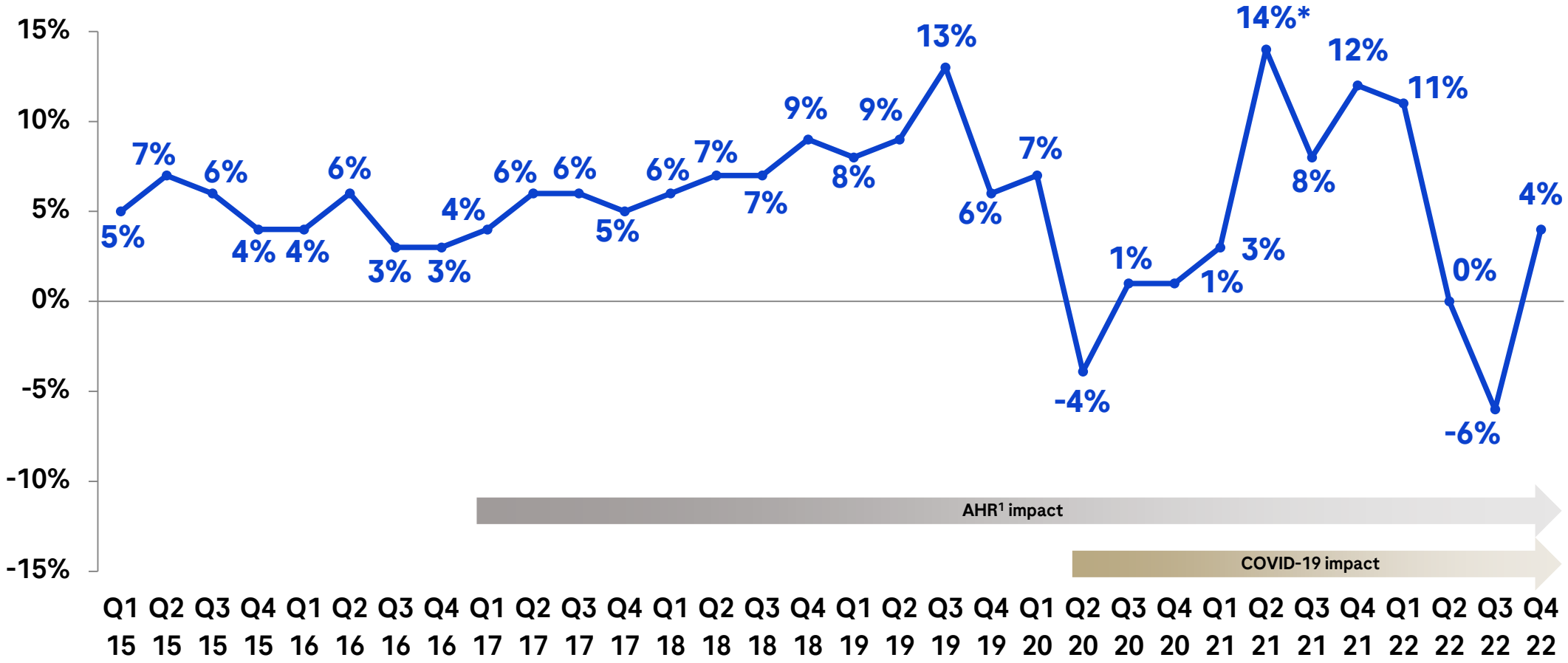
[1] At constant exchange rates (CER); [2] 2022 dividend as proposed by the Board of Directors

# 2022: Good sales growth in both divisions despite COVID-19 headwinds

| | 2022 CHFbn | 2021 CHFbn | Change in % CHF | Change in % CER |
|---|---|---|---|---|
| **Pharmaceuticals Division** | **45.6** | 45.0 | 1 | 2 |
| **Diagnostics Division** | **17.7** | 17.8 | 0 | 3 |
| **Roche Group** | **63.3** | 62.8 | 1 | 2 |

CER=Constant Exchange Rates; totals may include differences due to rounding

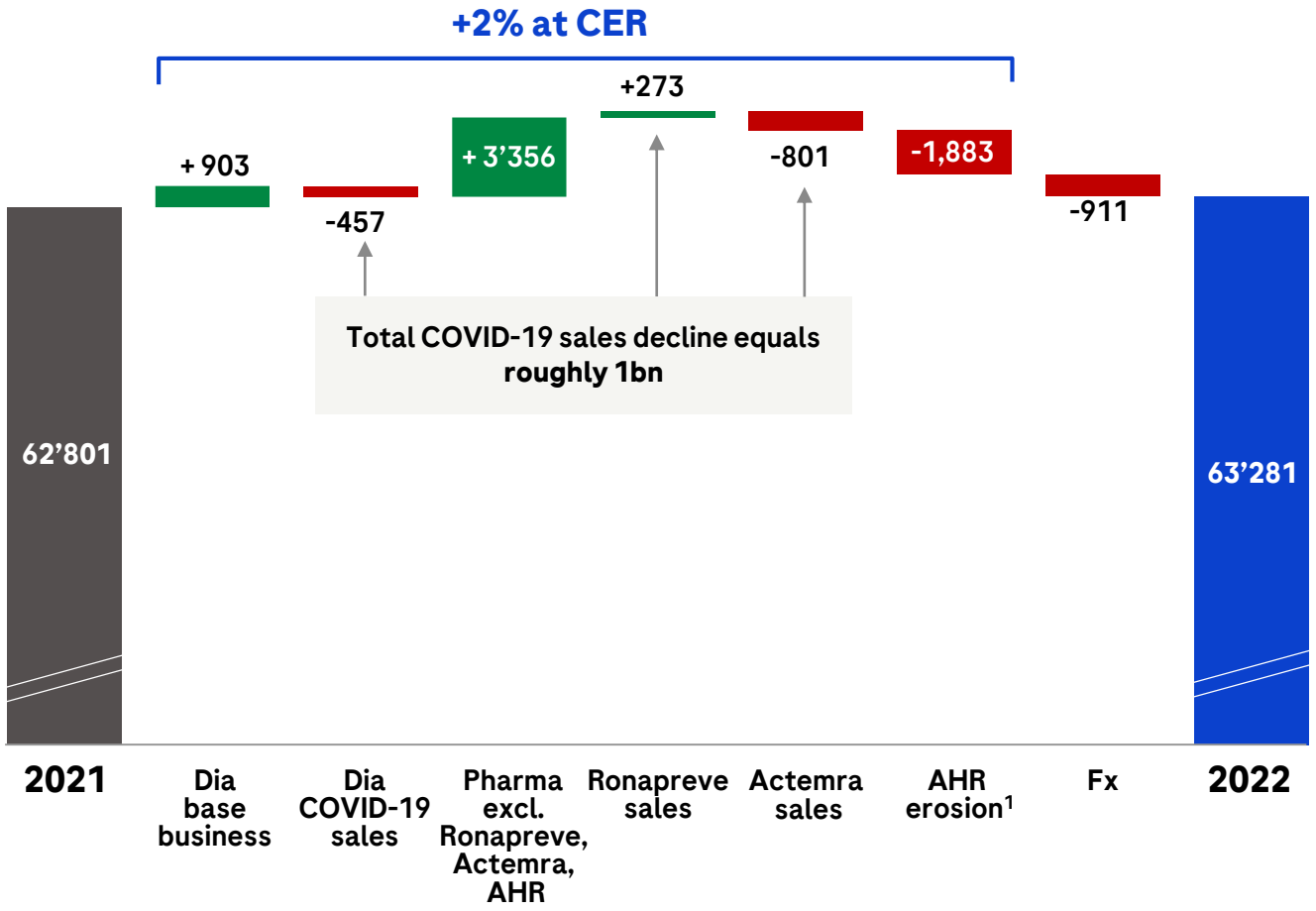
# Quarterly sales performance: COVID-19 sales declining



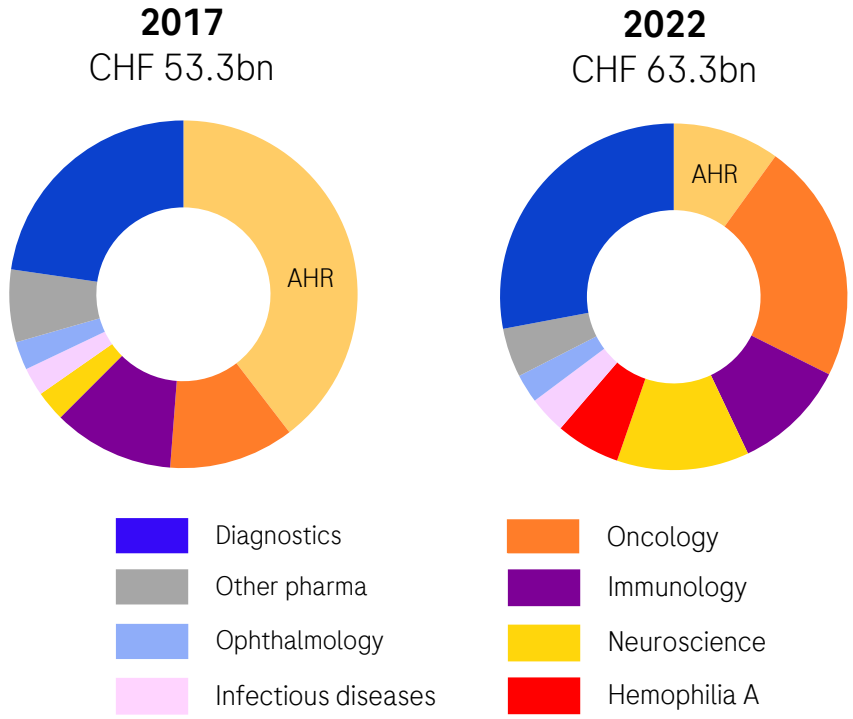

Growth rates at CER (Constant Exchange Rates); * Q2 2020 sales severely impacted by COVID-19 pandemic onset; [1] AHR: Avastin, Herceptin, Rituxan/MabThera

# 2022: Pharma and Diagnostics underlying business driving growth

CHFm



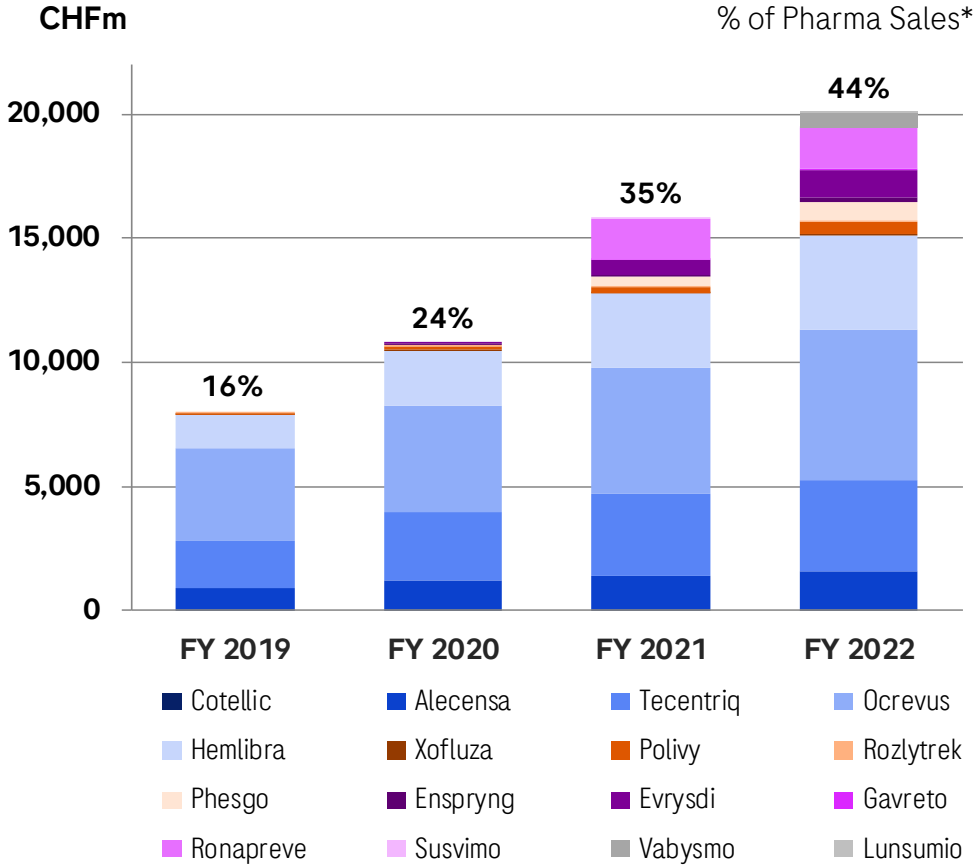

## Diversification of Roche business




2022 values in reported CHFm, variances in CERm; [1] AHR: Avastin, Herceptin, Rituxan/MabThera sales erosion

# Pharma portfolio rejuvenation ongoing

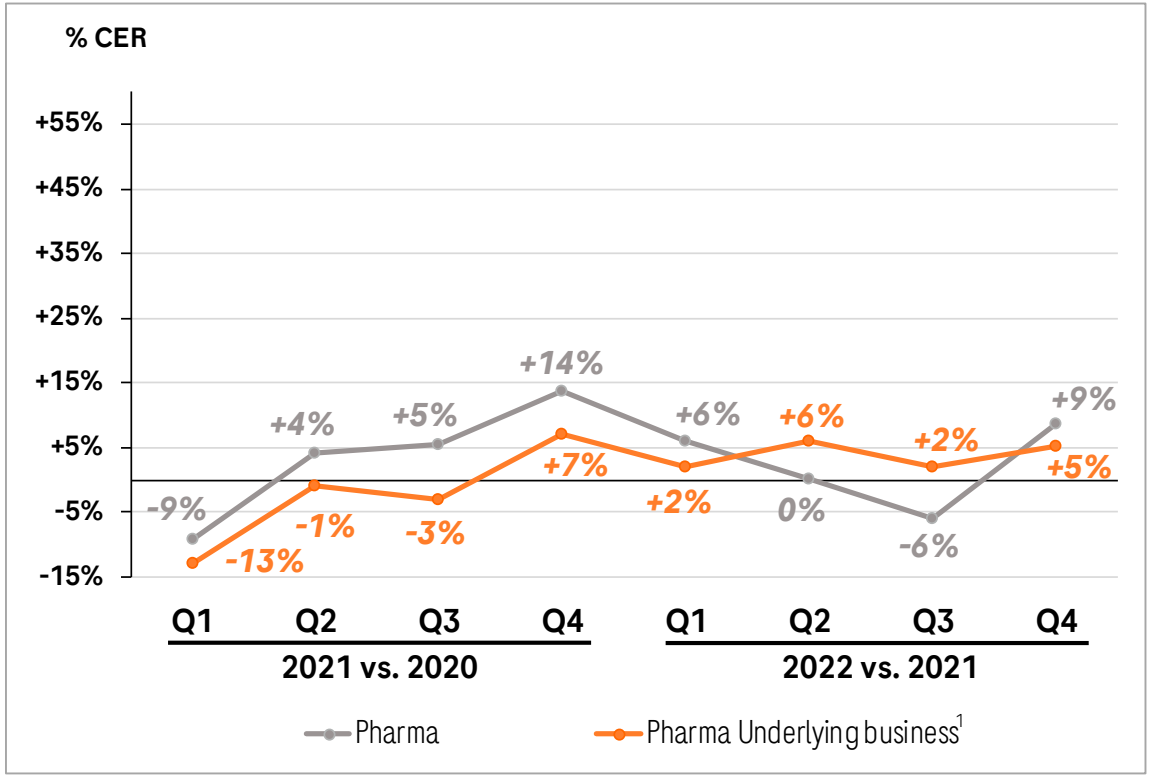
*16 blockbusters at the end of 2022, compared to 8 in 2015*

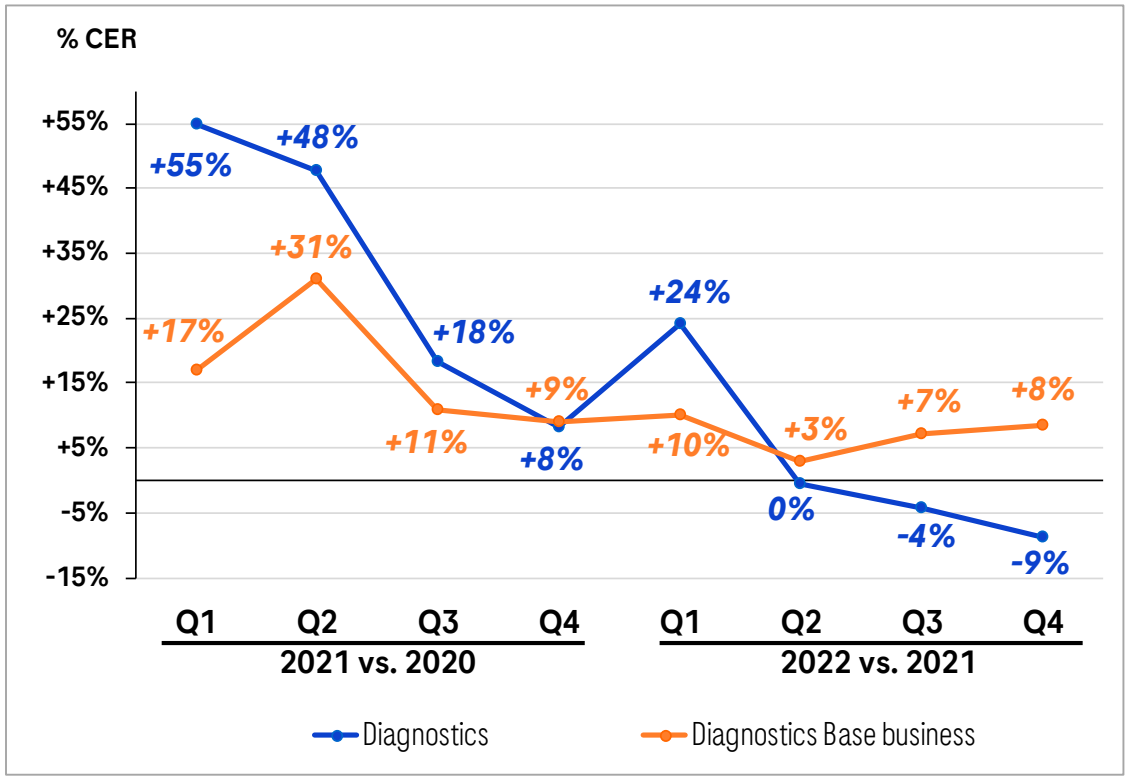

* Venclexta sales booked by AbbVie and therefore not included, ** SRP-9001: Accelerated US-filing by partner company Sarepta; crovalimab: First filing in China

# 2022: Underlying business with strong momentum at year-end

## Pharma
### Quarterly sales evolution 2021-2022



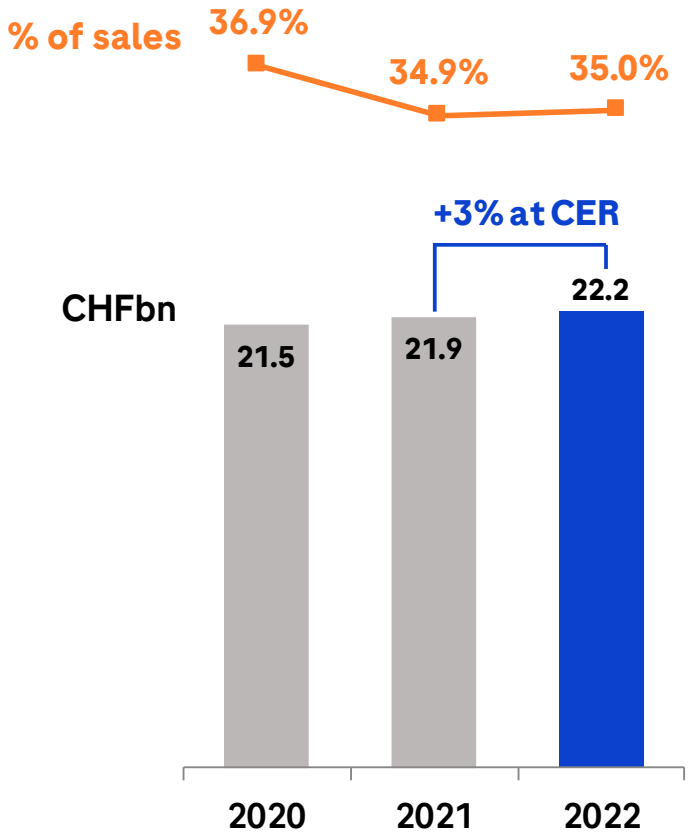

## Diagnostics
### Quarterly sales evolution 2021-2022



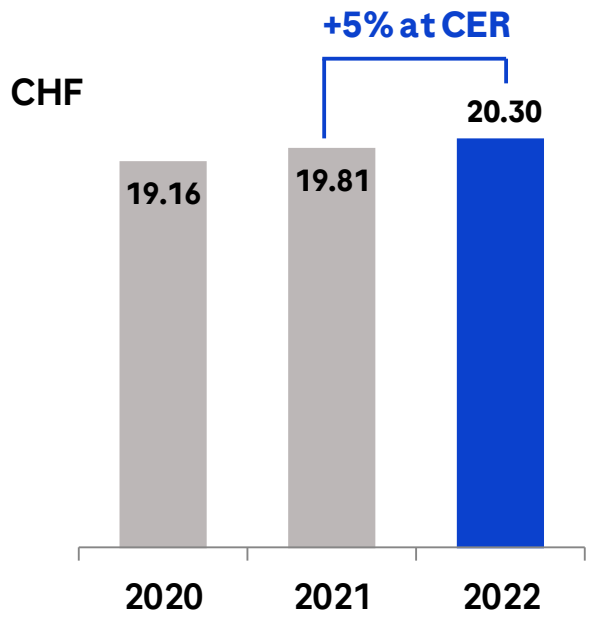

Growth rates at CER (Constant Exchange Rates); [1] Excl. Ronapreve and total Actemra

# 2022: EPS growth +5%, operating cash flow remains strong

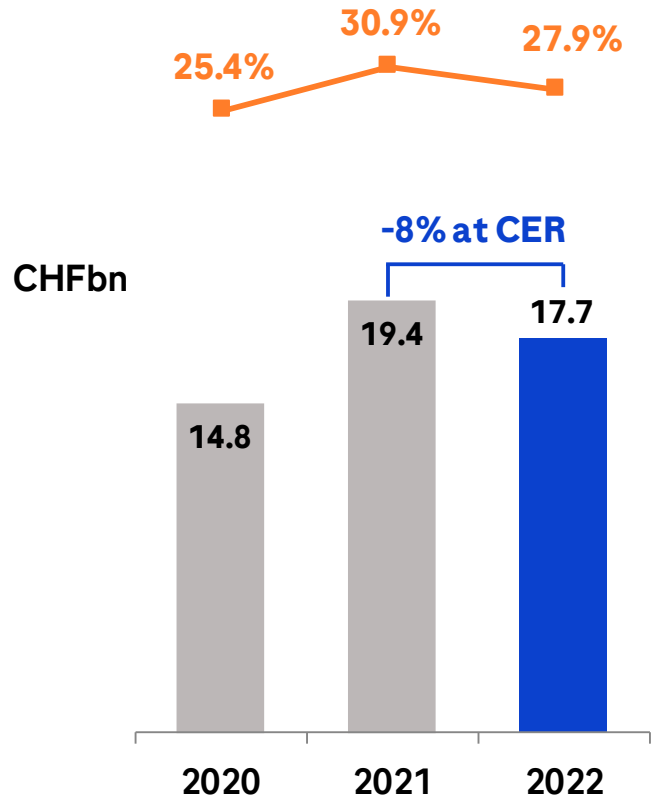
## Core operating profit




## Core EPS

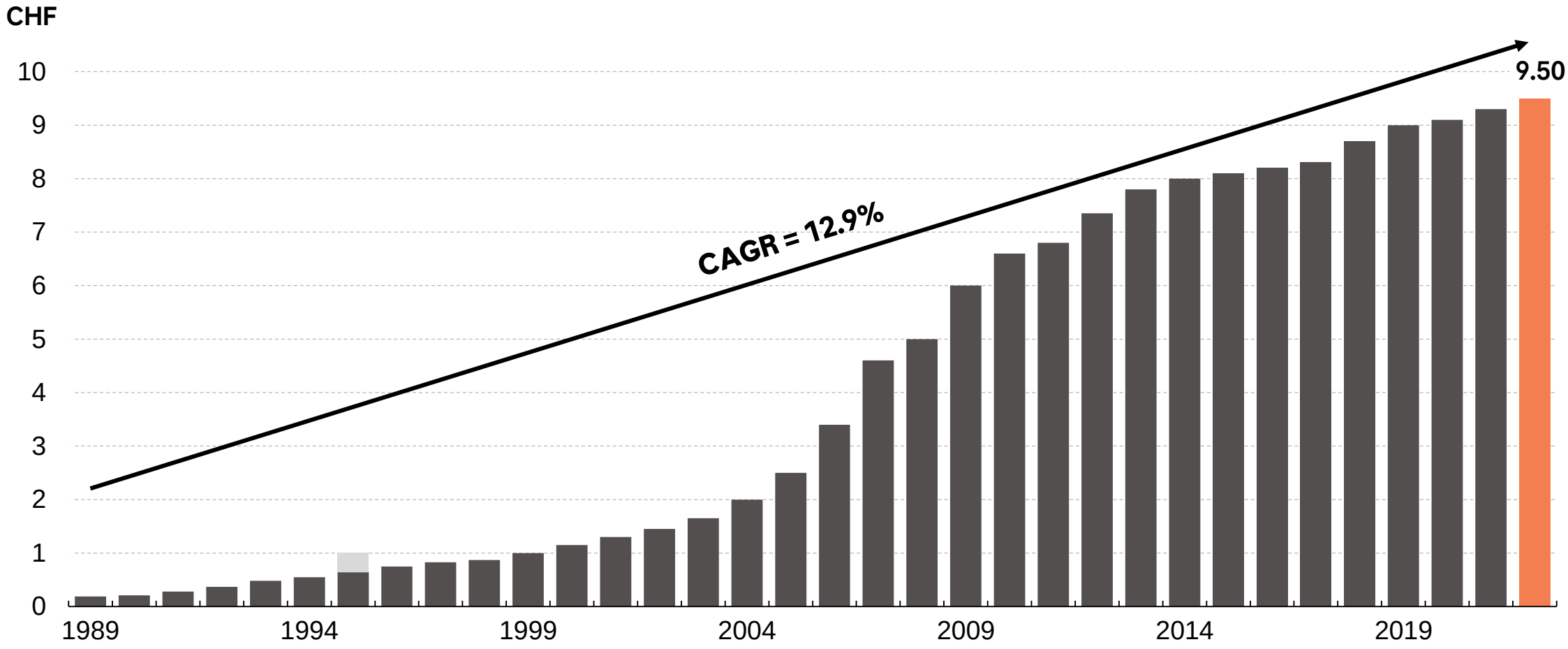



## Operating free cash flow




CER=Constant Exchange Rates

# 2022: 36th consecutive annual dividend increase




2022 dividend as proposed by the Board of Directors; Note: For 1995, a special dividend was paid out to mark F. Hoffmann-La Roche's 100th anniversary in 1996

# 2022 performance

## Outlook

# 2023: Upcoming newsflow

## Pharma

| | |
|---|---|
| **Tiragolumab + Tecentriq** in 1L PDL1+ NSCLC | **Glofitamab + GemOx** in 2L+ DLBCL |
| **Tiragolumab + Tecentriq + chemo** in 1L Esophageal | **Lunsumio + Polivy** in 2L+ DLBCL* |
| **Tecentriq + Avastin** in adjuvant HCC ✓ | **Crovalimab** in PNH |
| **Tecentriq** in adjuvant SCCHN | **Delandistrogene moxeparvovec (SRP-9001)** in DMD |
| **Tecentriq + chemo** in adjuvant TNBC | **Ocrevus 6m SC** in RMS / PPMS |
| **Tecentriq** neoadjuvant/adjuvant TNBC | **TNKase** in Stroke |
| **Phesgo OBI** in HER2+ BC | **Susvimo** in DME ✓ |
| **Alecensa** in adjuvant ALK+ NSCLC | **Susvimo** in DR ✓ |
| **Venclexta + azacitidine** in 1L high risk MDS | **Xolair** in Food allergy |
| **Venclexta + dexamethasone** in R/R MM (t11;14) | |

## Diagnostics

| | |
|---|---|
| **CCM Vertical** | Modular transportation system, integrated into existing cobas connection modules |
| **LightCycler Pro** | Flexible real-time PCR instrument with dual IVD and Research mode |
| **Anti-HEV IgG and Anti-HEV IgM** | Anti-HEV IgM: Immunoassay aiding in diagnosis of acute HEV infection in clinic. Anti-HEV IgG: Immunoassay aiding in detection of a recent or past HEV infection |
| **HBeAg Quant** | Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B |
| **IL-6 Neonatal sepsis (claim extension)** | Immunoassay with dedicated claim aiding in diagnosis of sepsis in neonates |

Neuroscience
Oncology/Hematology
Diagnostics
Ophthalmology
Immunology

DME=diabetic macular edema; DLBCL=diffuse large B-cell lymphoma; NSCLC=non-small cell lung cancer; HCC=hepatocellular carcinoma; MM=multiple myeloma; RVO=retinal vein occlusion; CSF=cerebrospinal fluid; PCR=polymerase chain reaction; SC=subcutaneous; DR=diabetic retinopathy; RMS=relapsing MS; PPMS=primary progressive MS; PNH=Paroxysmal nocturnal hemoglobinuria; TNBC=triple negative breast cancer; SCCHN=squamous cell carcinoma of head and neck; DMD=Duchenne muscular dystrophy; *Results are event-driven, read-outs expected 2023/24; OBI=on-body injector

# 2023 sales outlook

## Sales drivers[1]

**Pharma: Key products with strong growth and momentum from ongoing launches**

**Diagnostics: Base business with solid growth**

**COVID-19 sales for Diagnostics and Pharma expected to decline by roughly CHF 5bn**

**AHR[2] sales expected to erode by roughly CHF 1.6bn**

| | |
|---|---|
| **Group sales growth[1]** | Low single digit decline |

[1] At Constant Exchange Rates (CER); [2] AHR=Avastin, Herceptin, Rituxan/MabThera

# 2023 outlook

| | |
|---|---|
| **Group sales growth[1]** | • Low single digit decline |
| **Core EPS growth[1]** | • Broadly in line with sales decline |
| **Dividend outlook** | • Further increase dividend in Swiss francs |

[1] At Constant Exchange Rates (CER)

# Pharmaceuticals Division

*Thomas Schinecker*
*CEO Roche Pharmaceuticals*

# 2022: Pharmaceuticals Division sales growth

*New products compensate for loss-of-exclusivity and COVID-19 sales decline*

| | 2022 CHFm | 2021 CHFm | Change in % CHF | Change in % CER |
|---|---|---|---|---|
| **Pharmaceuticals Division** | **45,551** | **45,041** | **1** | **2** |
| United States | 23,322 | 22,505 | 4 | -1 |
| Europe | 8,143 | 8,876 | -8 | -2 |
| Japan | 4,949 | 4,506 | 10 | 26 |
| International | 9,137 | 9,154 | 0 | 1 |

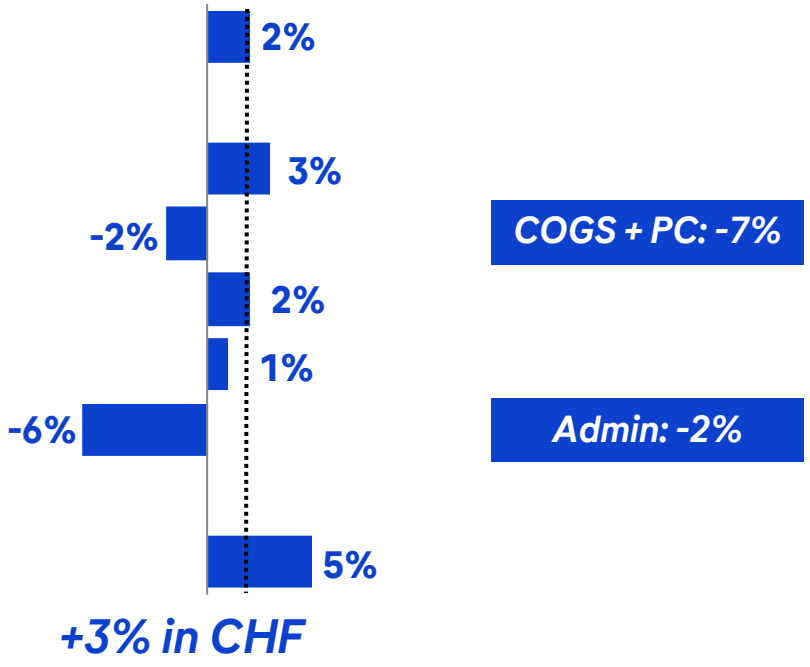
CER=Constant Exchange Rates

# 2022: Pharmaceuticals Division

*Core OP growth driven by higher gross profit, higher ROOI and lower G&A*

| | 2022 CHFm | 2022 % sales |
|---|---|---|
| **Sales** | **45,551** | **100.0** |
| Royalties & other op. inc. | 3,077 | 6.8 |
| Cost of sales | -9,262 | -20.3 |
| M & D | -6,657 | -14.6 |
| R & D | -12,096 | -26.6 |
| G & A | -1,441 | -3.2 |
| **Core operating profit** | **19,172** | **42.1** |

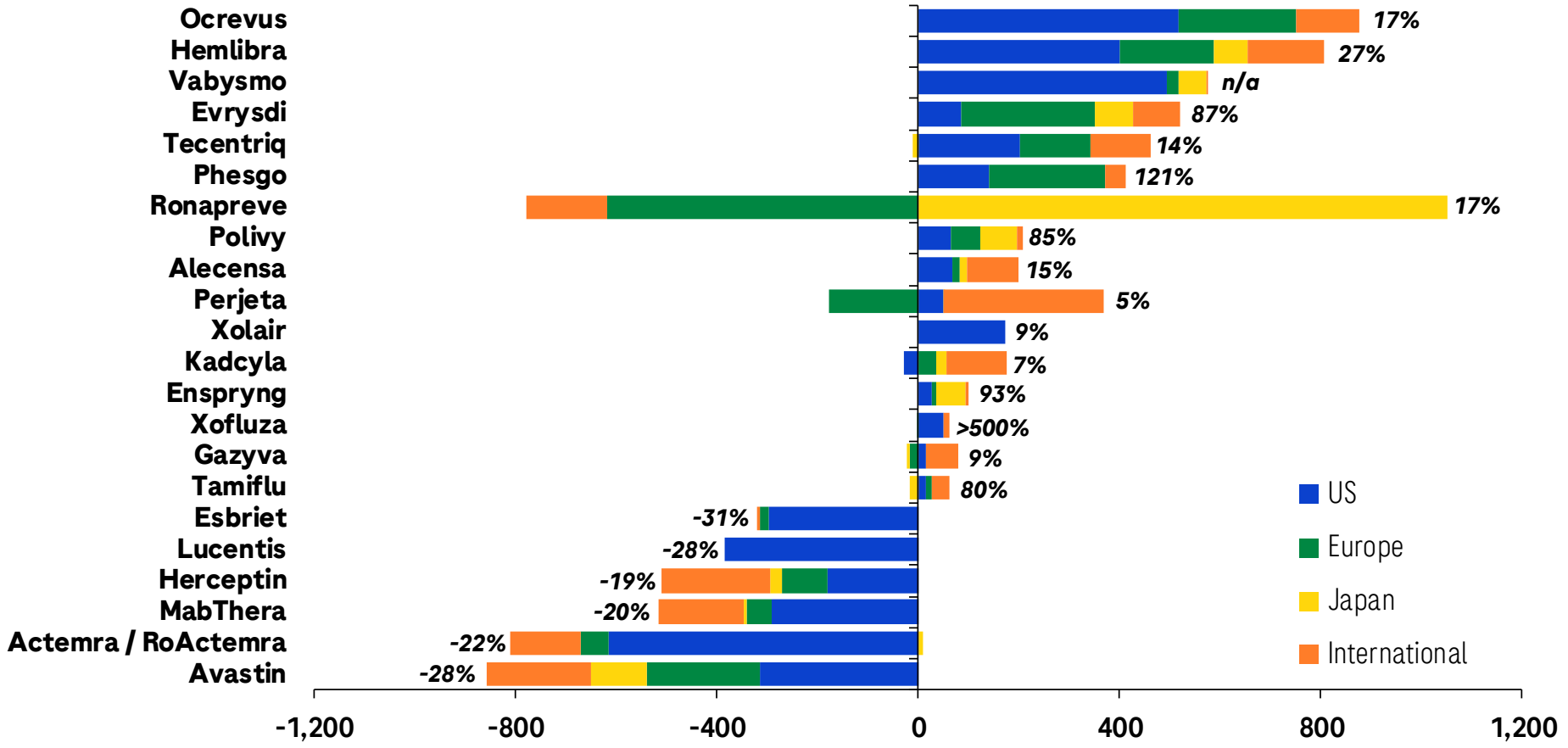
**2022 vs. 2021 CER growth**




CER=Constant Exchange Rates; ROOI=royalties and other operating income; COGS=costs of goods sold; PC=period costs

# 2022: Portfolio diversification accelerating

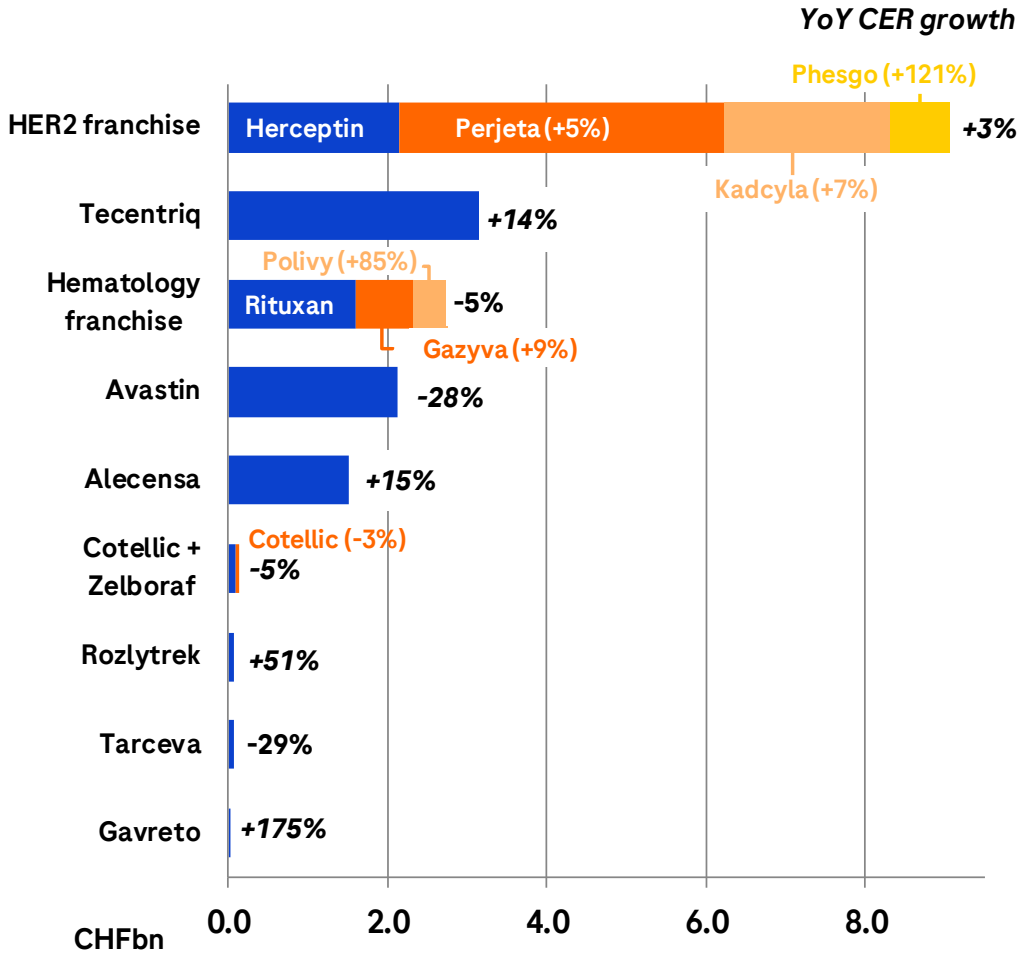
*Currently 16 blockbusters, with Vabysmo and Phesgo emerging*




Absolute values and growth rates at Constant Exchange Rates (CER)

# 2022: Oncology portfolio

*Full year sales stable as portfolio rejuvenation progresses*




## HER2 franchise

- Kadcyla (+7%) with growth ex-US due to adjuvant BC
- Perjeta (+5%) driven by International; decline in EU due to conversion
- Phesgo (CHF 740m): 33% conversion in early launch countries*

## Tecentriq

- Growth (+14%) driven by adjuvant NSCLC, 1L HCC and 1L SCLC

## Hematology franchise

- Venclexta**: Expanding patient share in 1L AML & 1L / R/R CLL
- Gazyva (+9%): Growth driven by 1L FL and in 1L CLL
- Polivy (+85%): Strong 1L DLBCL uptake in early launch countries; NCCN guideline inclusion as category 1 granted in Q1 2023
- Lunsumio: EU launch in 3L+ FL ongoing; US approval granted in Dec***; NCCN guideline inclusion as category 2A granted in Q1 2023

## Alecensa

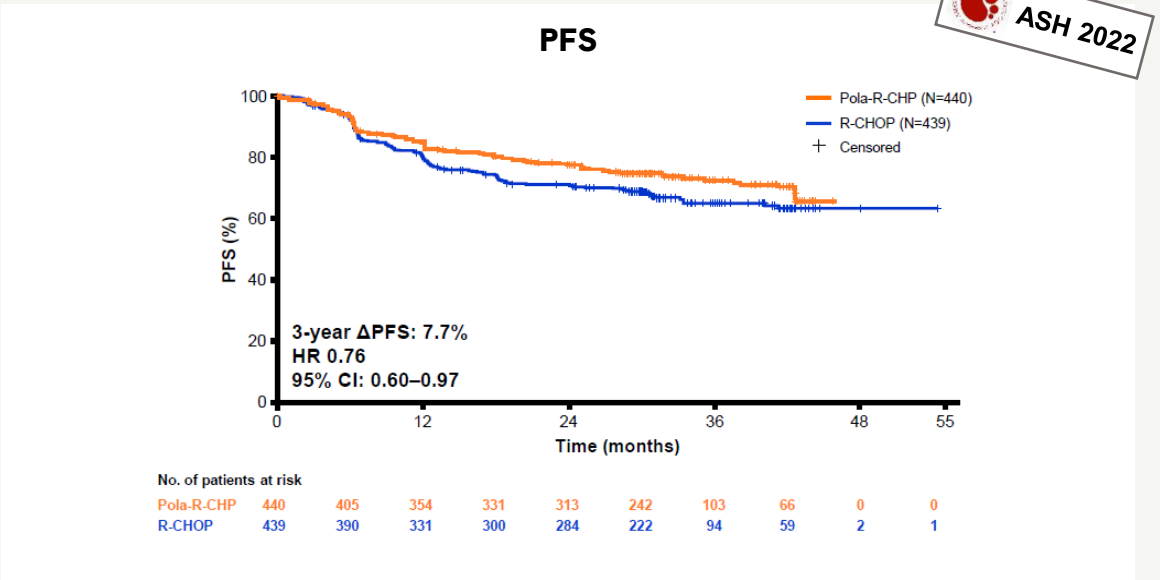
- Strong growth (+15%) and 1L ALK+ NSCLC leadership in major markets
- Ph III (ALINA) in adjuvant ALK+ NSCLC expected in 2023

2022 Oncology sales: CHF 20.0bn; CER growth -1%; CER=Constant Exchange Rates; * Phesgo conversion rate is based on volumes (vials) and includes all launch countries after the 2nd quarter after the launch (30 countries); ** Venclexta sales booked by AbbVie and therefore not included; ***Lunsumio launched in the US in Jan 2023; Polivy in collaboration with Seagen; BC=breast cancer; HCC=hepatocellular carcinoma; NSCLC=non-small cell lung cancer; SCLC=small cell lung cancer; AML=acute myeloid leukemia; R/R CLL=relapsed/refractory chronic lymphocytic leukemia; FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; NCCN=national comprehensive cancer network; ALK=anaplastic lymphoma kinase

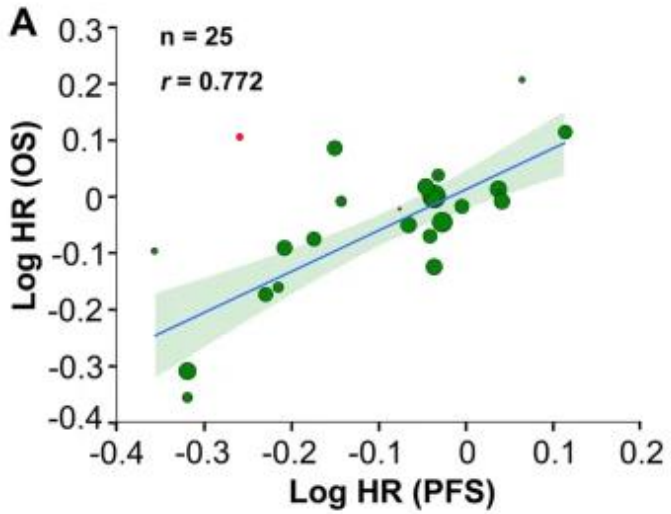
# Polivy in 1L DLBCL: First new treatment in >20 years

*Included in NCCN guideline as category 1*; NICE reimbursement obtained***

## Ph III (POLARIX) results




## PFS strongly predicts OS outcomes[1]




- Updated Ph III (POLARIX) results: median follow-up 39.7 months demonstrated sustained PFS benefit in Pola-R-CHP (HR 0.76) vs. R-CHOP
- PFS is a valid endpoint recognized by all major health authorities to demonstrate efficacy benefit in 1L DLBCL
- Polivy in 1L DLBCL has significant potential to decrease cost for progressive disease, due to fewer patients progressing
- Approved in EU/UK/Japan/China/Canada, overall >50 countries; US filing: ODAC on Mar 9th and PDUFA date set for Apr 2nd

Polivy in collaboration with Seagen; *NCCN guidelines for B-Cell Lymphomas (V1.2023); **NICE: Polatuzumab vedotin in combination for untreated diffuse large B-cell lymphoma [ID3901]; [1] Shi Q, Schmitz N, Ou FS, et al. Progression free survival as a surrogate end point for overall survival in first line diffuse large B cell lymphoma: An individual patient level analysis of multiple randomized tr ials (SEAL). J Clin Oncol.2018;36(25):2593 2602; DLBCL=diffuse large B-cell lymphoma; PFS=progression free survival; OS=overall survival; R-CH(O)P=Rituxan + cyclophosphamide + doxorubicin + (vincristine) + prednisone; HR=hazard ratio; NCCN=national comprehensive cancer network; NICE=national institute for health and care excellence

# Lunsumio & glofitamab: Expanding into earlier lines of treatment

*Off-the-shelf, fixed duration with durable responses and manageable safety*

## Product profile

**Lunsumio**

- High CR rate and durable responses
- Favorable tolerability with low grade CRS
- No required hospitalization

**For outpatient setting, indolent disease (FL) and elderly/unfit patients**

**Glofitamab**

- Best in class efficacy potential, high CR rates and durable responses comparable to CAR-Ts
- Well tolerated with low rate of discontinuations and ICANS; low grade, predictable CRS
- Minimal CRS in 1L DLBCL combined with R + chemo

**For aggressive disease (1L DLBCL, R/R DLBCL, MCL)**

## Key clinical trials

| Regimen | Indication | Ph I / Ph II / Ph III | |
|---|---|---|---|
| Lunsumio | 3L+ FL | | ✓ US/EU approved |
| Lunsumio + Polivy | 2L+ DLBCL (SCT-ineligible) | SUNMO | Readout 2023/24 |
| Lunsumio + lenalidomide | 2L+ FL | CELESTIMO | IA 2024 |
| Lunsumio | r/r CLL | | |
| Lunsumio | 1L DLBCL (elderly/unfit) | | |
| Lunsumio + Polivy | 1L DLBCL (elderly/unfit) | | |

ASH 2022

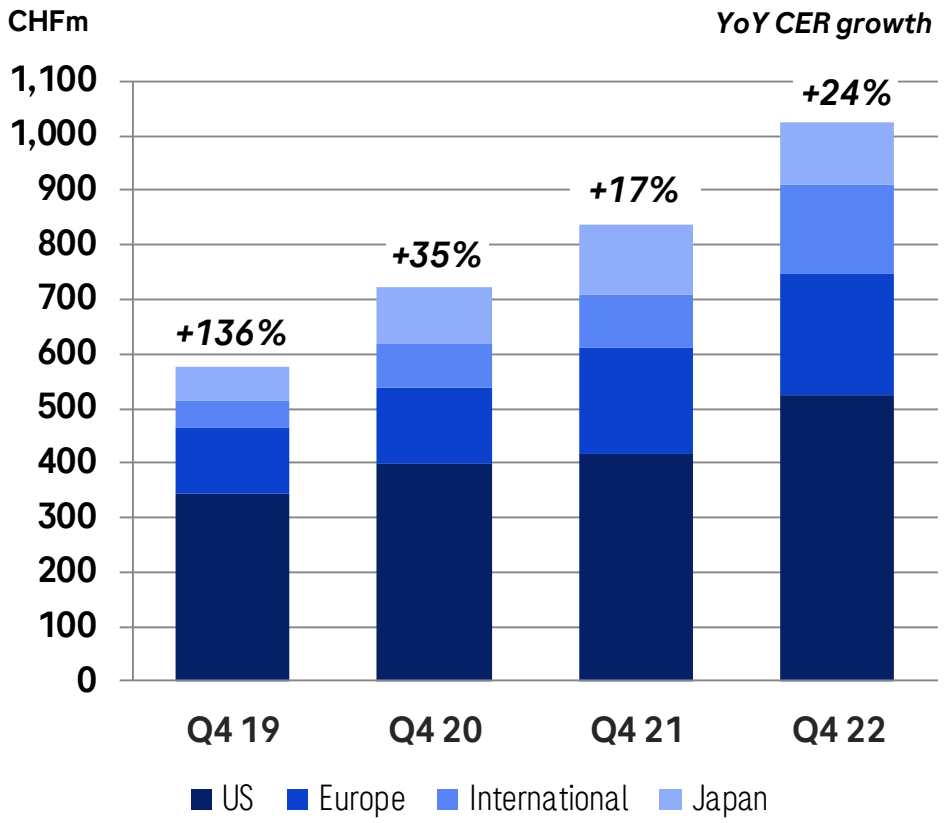
| Regimen | Indication | Ph I / Ph II / Ph III | |
|---|---|---|---|
| glofitamab | 3L+ DLBCL | | Filed in US (PDUFA 1st July)<br>Filed in EU |
| glofitamab + GemOx | 2L+ DLBCL (SCT-ineligible) | STARGLO | Readout 2023 |
| glofitamab + CD19x4-1BBL | r/r NHL | | |
| glofitamab + CD19xCD28 | r/r NHL | | |
| Glofitamab + Polivy + R-CHP | 1L DLBCL | | Ph III to initiate in 2023 |

ASH 2022

R/R=relapsed refractory; CRS=cytokine release syndrome; FL=follicular lymphoma; DLBCL=diffuse large B-cell lymphoma; CR=complete response; MCL=mantle cell lymphoma; CAR-T=chimeric antigen receptor T cells; ICANS=immune effector cell-associated neurotoxicity syndrome; IA=interim analysis; CLL=chronic lymphocytic leukemia; SCT=stem cell transplantation; NHL=non-Hodgkin's lymphoma; GemOx=gemcitabine oxaliplatin; PDUFA=prescription drug user fee act; R-CHP=rituxan + cyclophosphamide + hydroxydaunorubicin + prednisone

# Tecentriq: Further adjuvant read-outs in 2023

*First positive read-out in adjuvant HCC; first PD-(L)1 with pivotal SC results filed*




## Q4 update

- SC: EU and US filing (PDUFA date set for Sep 15th)

## Lung franchise (NSCLC, SCLC)

- EU: 1L SCLC with continued growth
- US: Continued strong launch in adjuvant NSCLC

## GI franchise (HCC)

- US/EU/Japan: Further growth in 1L HCC
- Ph III (IMbrave050) in adjuvant HCC met RFS primary endpoint; OS immature

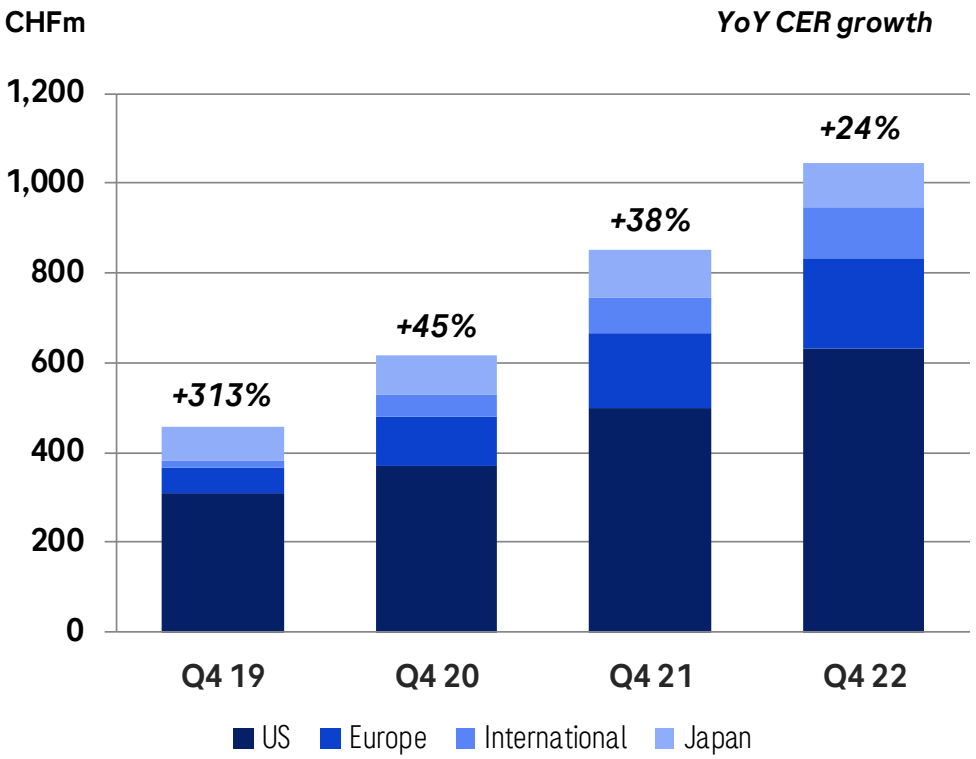
## Outlook 2023

- Ph III results in adjuvant SCCHN and TNBC expected; Ph III (IMpower030) in periadjuvant NSCLC continues to 2024
- Ph III (SKYSCRAPER-01) Tecentriq + tiragolumab in 1L NSCLC

CER=Constant Exchange Rates; SC=subcutaneous; NSCLC=non-small cell lung cancer; HCC=hepatocellular cancer; RFS=recurrence-free survival; SCLC=small cell lung cancer; TNBC=triple-negative breast cancer; SCCHN=squamous cell carcinoma of head and neck; PDUFA=prescription drug user fee act; OS=overall survival

# Hemophilia A: Hemlibra, new global standard of care

*36% US/EU-5 patient share reached*




## Q4 update

- >19,000 patients treated globally
- Hemlibra continues to penetrate across all approved patient segments
- Ph III (HAVEN 7) in infants (0-1 year) interim data presented at ASH 2022
- SPK 8011 (hem A gene therapy) 5-year data with stable Factor VIII levels presented at ASH 2022

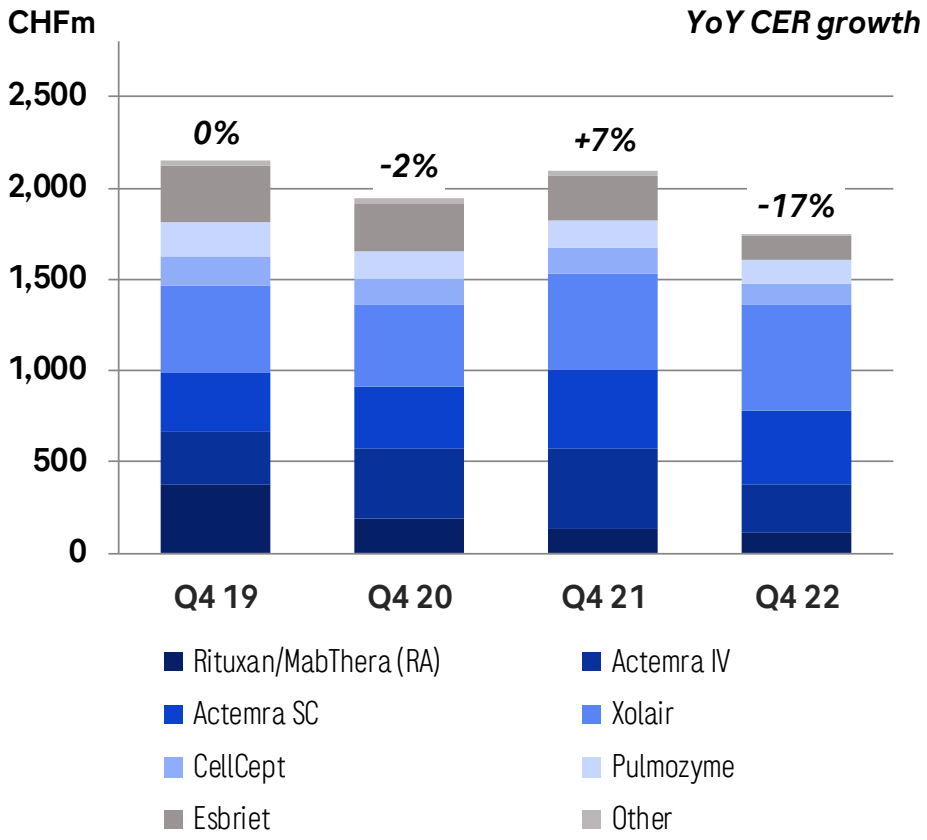
## Outlook 2023

- EU: Label extension to include moderate patients (HAVEN 6) granted in Q1
- US/EU: Further patient share gains in non-inhibitors
- SPK 8011 pivotal Ph III to be initiated

CER=Constant Exchange Rates

# Immunology: Actemra COVID-19 sales declining and Esbriet LOE

*Xolair autoinjector approval and Ph III food allergy readout expected in 2023*




## Q4 updates

### Actemra (-22%)

- COVID-19 related sales declining
- Shift from IV to SC ongoing, SC share reaches 60%

### Xolair (+6%)

- Market leader in asthma biologics and strong growth in CSU

### Esbriet (-48%)

- US: Generic competition

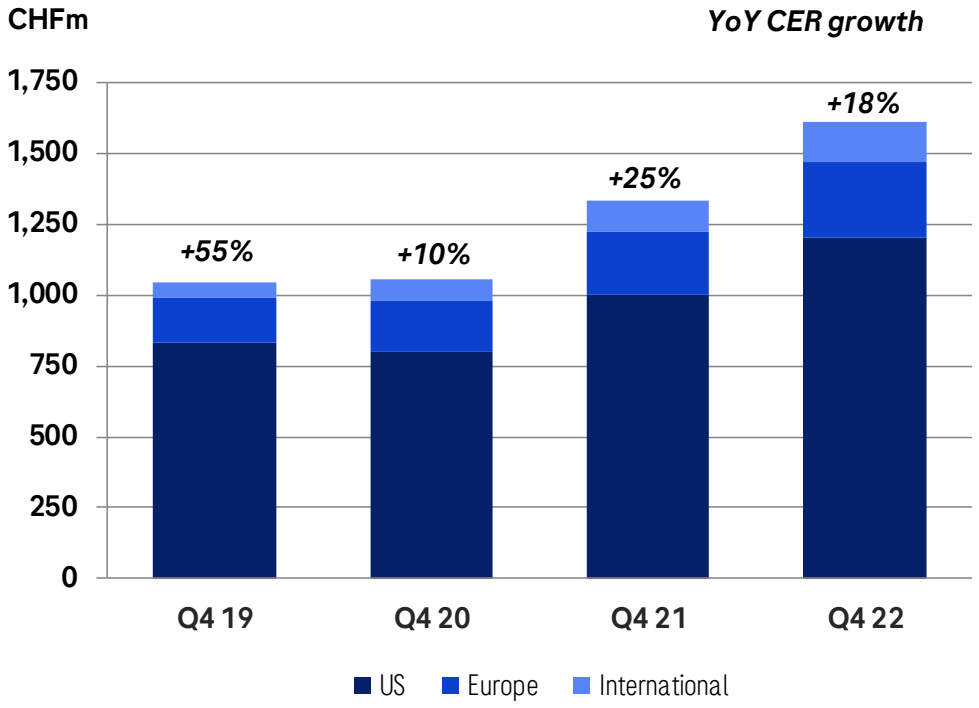
### Outlook 2023

- US approval of Xolair autoinjector expected; Ph III (OUtMATCH) in food allergy to read out
- Ph III ASO factor B in IgAN to be initiated
- Ph III (INShore) Gazyva in PNS to be initiated

CER=Constant Exchange Rates; LOE=loss of exclusivity; RA=rheumatoid arthritis; IV=intravenous; SC=subcutaneous; CSU=chronic spontaneous urticaria; ASO=antisense oligonucleotide; IgAN=immunoglobulin A nephropathy; PNS=pediatric nephrotic syndrome

# Multiple Sclerosis: Global leader, reaching 21% patient share

*Ph III results for 6M SC Ocrevus expected in 2023*




## Q4 update

- #1 treatment in US and EU-5, both in total share and new to brand share
- Higher retention rate than other MS medicines

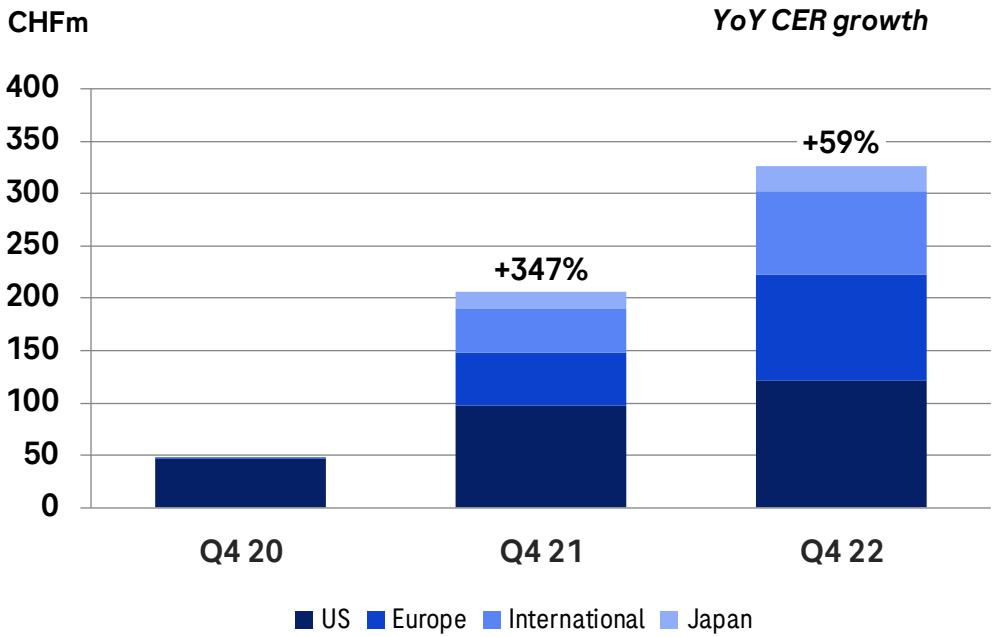
## Outlook 2023

- US/EU: Further market share gains expected
- Ph III (OCARINA II) Ocrevus SC with Q6M dosing in RMS & PPMS data read out expected
- Ph III (GAVOTTE/MUSETTE) high-dose Ocrevus nearing recruitment completion in Q1

CER=Constant Exchange Rates; MS=multiple sclerosis; SC=subcutaneous; Q6M=every 6 months; RMS=relapsing MS; PPMS=primary progressive MS

# Spinal Muscular Atrophy: Evrysdi market leader in US and Japan

*Switches remain a key source of new patient starts*




## Q4 update

- >7,000 patients treated worldwide; retention rate in first 12 months of ~90% globally
- US: Growth driven by switch and naive patient starts including patients <2 months old
- Ex-US: Continued strong growth and share gains in all major markets

## Outlook 2023

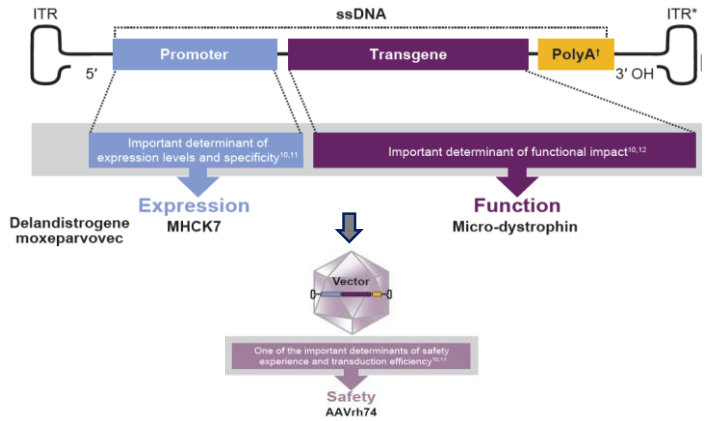
- Continued growth and market share gains
- EU: Label extension (<2 months old) based on Ph II (RAINBOWFISH) expected

CER=Constant Exchange Rates; SMA=spinal muscular atrophy

# SRP-9001 in DMD: Pivotal Ph III results expected at year-end

*First and potential best-in-class gene therapy*

## Delandistrogene moxeparvovec




- Targeted delivery of functional shortened dystrophin transgene to muscle tissue
- Vector and promotor specifically designed for skeletal & cardiac muscles
- Transgene can enable meaningful and durable response

## Clinical trial program overview

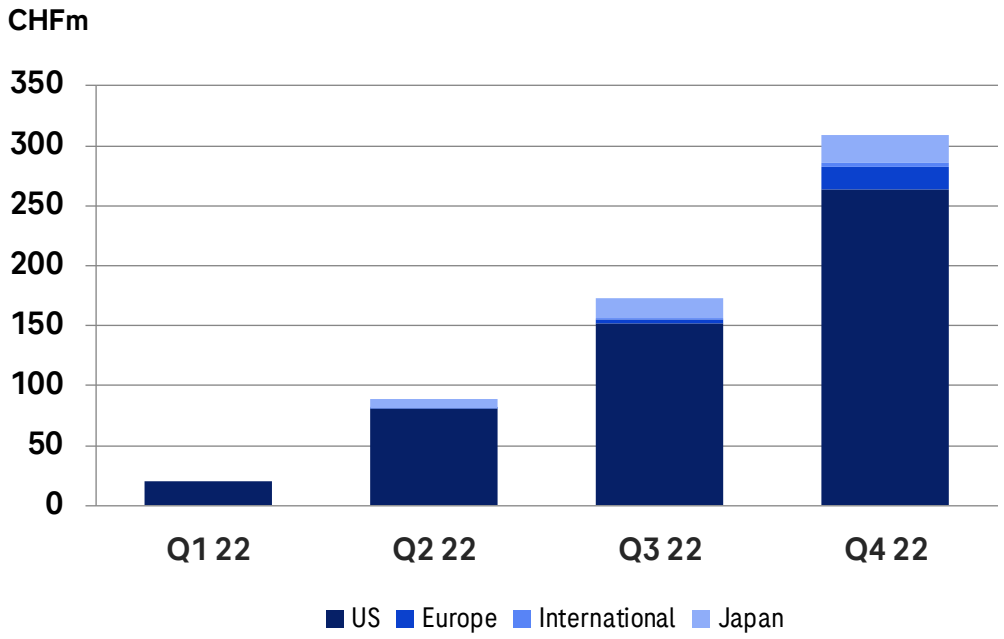
| Study | DMD subgroup | Ph I / Ph II / Ph III | Comment |
|---|---|---|---|
| 101 | Ambulatory, 4-7 yrs. | | US filing by Sarepta |
| 102 | Ambulatory, 4-7 yrs. | | US filing by Sarepta |
| 103 (ENDEAVOR) | Ambulatory, 3-18 yrs<br>Non-ambulatory, all ages | | US filing by Sarepta* |
| 301 (EMBARK) | Ambulatory, 4-7 yrs. | | Data read out expected Q4 2023 |
| 302 (ENVOL) | Ambulatory, 0-3 yrs. | | Ph II to initiate in 2023 |
| 303 (ENVISION) | Ambulatory, 8-18 yrs<br>Non-ambulatory, all ages | | Ph III to initiate in 2023 |

- Positive functional and clinically meaningful results at multiple time points (including 1, 2, 4 years after treatment) with consistent safety profile shown for >80 patients
- US filing by partner Sarepta accepted and priority review granted with PDUFA date set for 29th May
- Ph III (EMBARK) read out expected in Q4; results will form the basis for EU filing

DMD=Duchenne muscular dystrophy; PDUFA=prescription drug user fee act; Delandistrogene moxeparvovec in collaboration with Sarepta Therapeutics; *Cohort 1 only

# Ophthalmology: Excellent Vabysmo launch

*More than 450k vials shipped globally in first 11 months of launch*




## Q4 update

### Vabysmo

- US: Strong uptake with switches primarily from aflibercept; use in naive patients further accelerating
- Rapid launch uptake in UK & Japan
- Positive Ph III (BALATON/COMINO) results for Vabysmo in RVO achieved

### Susvimo

- Positive Ph III (PAGODA/PAVILLION) results for Susvimo in DME/DR achieved

### Outlook 2023

- Vabysmo: Continued growth and market share gains in nAMD & DME
- Ph III (MEERKAT/SANDCAT) anti IL-6 mAb in UME started
- Ph III results for Vabysmo in RVO and Susvimo in DME/DR to be presented at Angiogenesis (Feb 10-11)

DME=diabetic macular edema; RVO=retinal vein occlusion; DR=diabetic retinopathy; UME=uveitic macular edema; mAb=monoclonal antibody; Eylea (aflibercept) is a registered trademark/product of Regeneron

# Vabysmo: Chosen disease criteria impacts dosing interval

*Vabysmo nAMD trials use vision or anatomical disease activity criteria, reflecting clinical practice*[1]

## Different ≥Q12W disease criteria as applied to TENAYA/LUCERNE patients

**Stringent criteria (as actually applied in TENAYA/LUCERNE)****

*Treatment change if **ANY** criteria are met (based on criteria used in pivotal trials)*

**≥ 5 letters BCVA loss** vs avg. BCVA over previous 2 scheduled visits, due to nAMD* **OR** **≥ 10 letters BCVA loss** vs highest BCVA recorded over previous 2 scheduled visits, due to nAMD* **OR** **> 50 µm CST increase** vs avg. CST over previous 2 scheduled visits **OR** **≥ 75 µm CST increase** vs lowest CST recorded at either of previous 2 scheduled visits **OR** **Presence of new macular hemorrhage***, due to nAMD activity

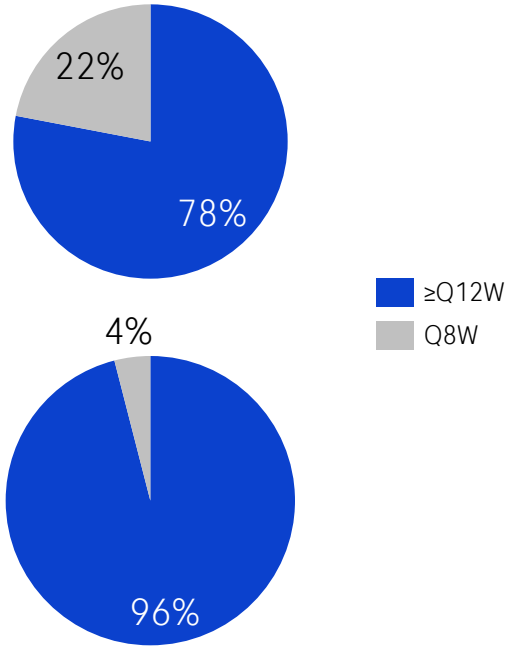
**Less stringent criteria (post hoc analysis)**

*Treatment change if **ALL** criteria are met*

**>5 letters BCVA loss** vs week 16 BCVA **AND** **> 25 µm CST increase** vs week 16 CST or new macular hemorrhage

**Share of patients assigned to ≥Q12W dosing**

*Assessment done at week 20*




- Ph III TENAYA/LUCERNE trial with stringent patient-centric criteria resulted in 22% of patients being allocated to Q8W dosing
- Using less stringent criteria, only 4% of patients would have been assigned to Q8W dosing (post hoc analysis)

[1] Heier et al. Lancet. 2022;399(10326):729-40; TENAYA (NCT03823287) & LUCERNE (NCT03823300); *per the investigator; **Additional patients with a missing Week 20 assessment were considered to have met disease activity criteria and were treated Q8W; Q8W=every 8 weeks; BCVA=best-corrected visual acuity; nAMD=neovascular age-related macular degeneration; CST=central subfield thickness; Note: This analysis is not intended as a cross-trial comparison; This analysis cannot predict whether faricimab-treated patients in TENAYA & LUCERNE would have achieved non-inferiority vs aflibercept 2mg if the treatment regimen had been modified; This analysis is not intended to state or imply long term efficacy or safety

# Ophthalmology: Adding new indications

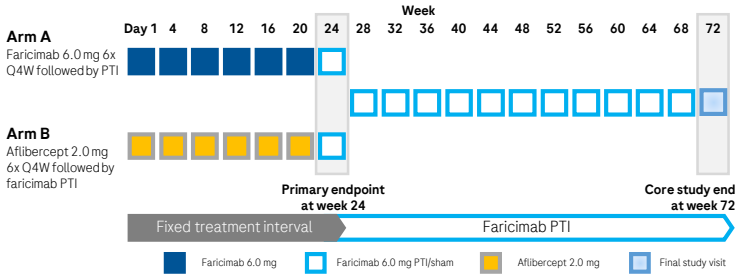
*Positive Ph III results to be presented at Angiogenesis*

IR virtual event February 13th

Angiogenesis Feb 10-11

## Vabysmo in RVO

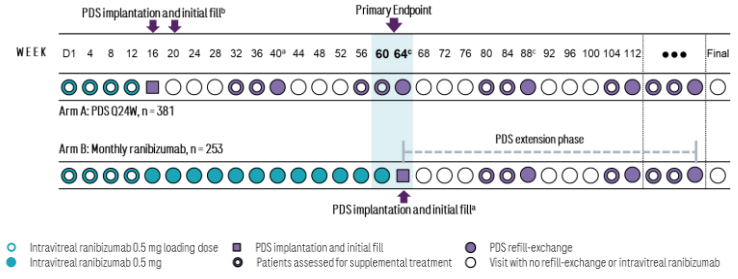
### Ph III (BALATON/COMINO)




**Primary endpoint**: Change from baseline in BCVA at week 24

## Susvimo in DME

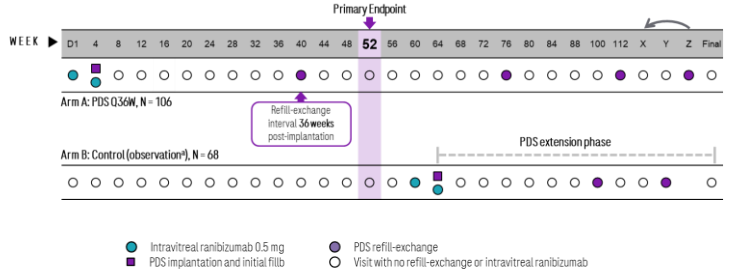
### Ph III (PAGODA)




**Primary endpoint**: BCVA score change from baseline averaged over weeks 60 and 64 as measured via ETDRS chart

## Susvimo in DR

### Ph III (PAVILION)




**Primary endpoint**: Percentage of patients with a ≥2-step improvement from baseline on the ETDRS-DRSS at week 52

- All studies met their respective primary endpoints; safety profiles were consistent with previous trials
- Results to be presented at the Angiogenesis virtual medical meeting (Feb 10-11)
- IR virtual event planned for Feb 13th (4:30 - 5:30pm CET/7:30 - 8:30am PST); clinical results to be presented by Veeral Sheth, MD (retinal specialist and clinical investigator)

(B/C)RVO=(branch/central) retinal vein occlusion; BCVA=best-corrected visual acuity; HRVO=hemiretinal vein occlusion; CST=central subfield thickness; PTI=personalized treatment interval; QXW=every X weeks; PDS=port delivery system; DME=diabetic macular edema; nAMD=neovascular age-related macular degeneration; DR=diabetic retinopathy; EDTRS(-DRSS)=early treatment diabetic retinopathy study (-diabetic retinopathy severity scale); Eylea (aflibercept) is a registered trademark/product of Regeneron

# 2023: Key late-stage news flow*

| | Compound | Indication | Milestone | |
|---|---|---|---|---|
| Regulatory | **Hemlibra** | Moderate hemophilia A | EU approval | ✓ |
| | **Polivy + R-CHP** | 1L DLBCL | US approval | |
| | **Vabysmo** | RVO | US approval/EU filing | |
| | **Tecentriq** | Subcutaneous administration | US approval/EU filing | |
| | **Glofitamab** | 3L+ DLBCL | US/EU approval | |
| | **Xofluza** | Influenza (paediatric 1+ yrs.) | EU approval | ✓ |
| Phase III / pivotal readouts | **Tecentriq + Avastin** | Adjuvant HCC | Ph III IMbrave050 | ✓ |
| | **Tecentriq + chemo** | Neoadjuvant / adjuvant TNBC | Ph III GeparDouze/NSABP B-59 | |
| | **Tecentriq** | Adjuvant SCCHN | Ph III IMvoke010 | |
| | **Tecentriq + chemo** | Adjuvant TNBC | Ph III IMpassion030 | |
| | **Tiragolumab + Tecentriq** | 1L PDL1+ NSCLC | Ph III SKYSCRAPER-01 | |
| | **Tiragolumab + Tecentriq + chemo** | 1L esophageal cancer | Ph III SKYSCRAPER-08 (China only) | |
| | **Venclexta + dexamethasone** | t(11;14) R/R MM | Ph III CANOVA | |
| | **Venclexta + azacitidine** | 1L high risk MDS | Ph III VERONA | |
| | **Alecensa** | Adjuvant ALK+ NSCLC | Ph III ALINA | |
| | **Phesgo OBI (on body injector)** | HER2+ BC | Ph I *(pivotal)* | |
| | **Crovalimab** | PNH | Ph III COMMODORE 1/2 | |
| | **Glofitamab + GemOx** | 2L+ DLBCL | Ph III STARGLO | |
| | **Lunsumio + Polivy** | 2L+ DLBCL | Ph III SUNMO** | |
| | **Delandistrogene moxeparvovec (SRP-9001)** | DMD | Ph III EMBARK | |
| | **Ocrevus 6m SC** | RMS / PPMS | Ph III OCARINA II | |
| | **TNKase** | Stroke patients 4.5-24h | Ph III TIMELESS | |
| | **Susvimo** | DME | Ph III PAGODA | ✓ |
| | **Susvimo** | DR | Ph III PAVILION | ✓ |
| | **Xolair** | Food allergy | Ph III OUtMATCH | |

* Outcome studies are event-driven: timelines may change; ** Results are event-driven; read-outs expected in 2023/24

# Diagnostics Division

***Matt Sause***
***CEO Roche Diagnostics***

# 2022: Diagnostics Division sales

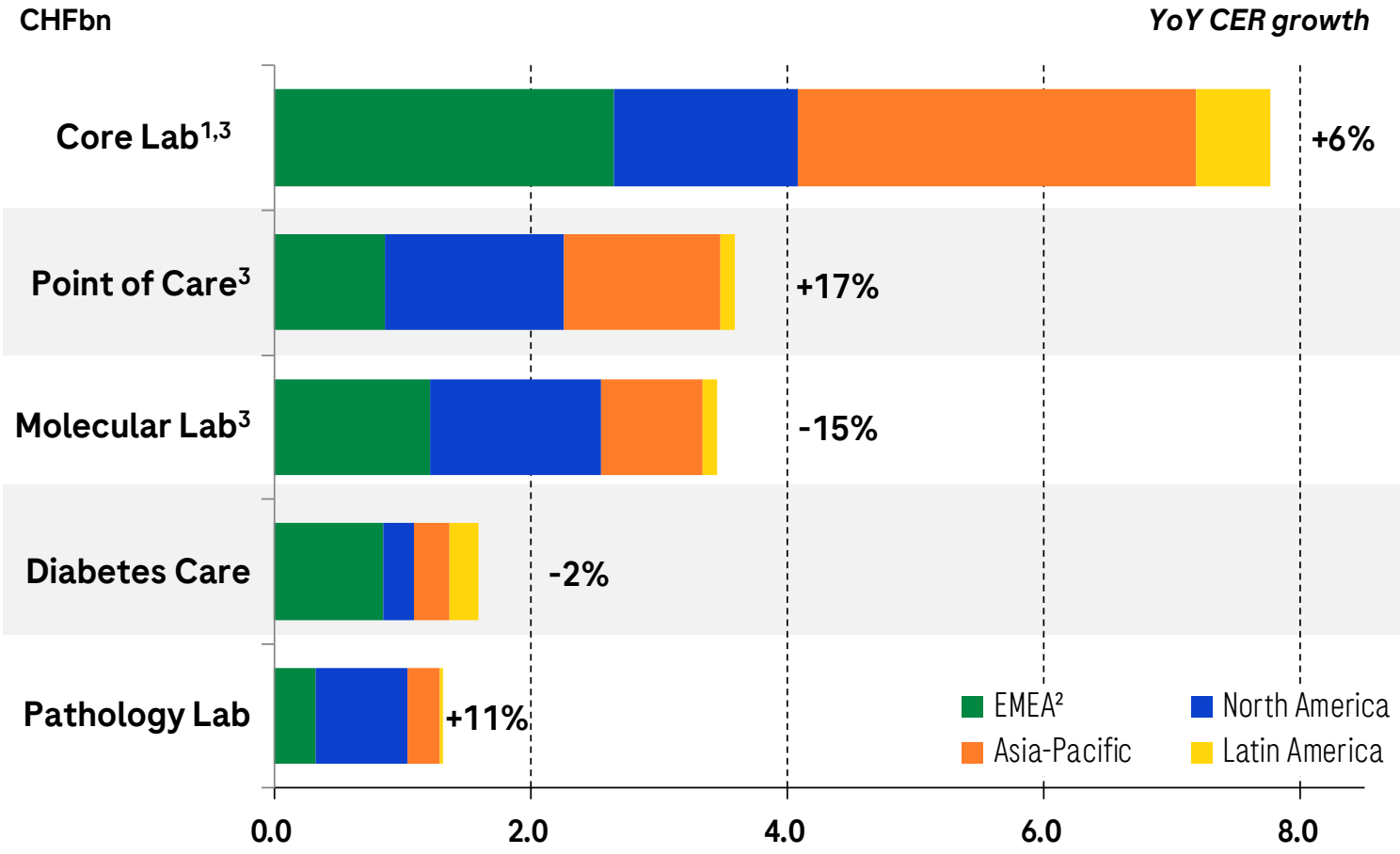
*Sales increase of +3% driven by base business offsetting COVID-19 testing decline*

| | 2022 CHFm | 2021 CHFm | Change in % CHF | Change in % CER |
|---|---|---|---|---|
| **Diagnostics Division** | **17,730** | **17,760** | **0** | **3** |
| Core Lab[1] | 7,775 | 7,560 | 3 | 6 |
| Point of Care[1] | 3,589 | 3,134 | 15 | 17 |
| Molecular Lab[1] | 3,450 | 4,174 | -17 | -15 |
| Diabetes Care | 1,598 | 1,690 | -5 | -2 |
| Pathology Lab | 1,318 | 1,202 | 10 | 11 |

CER=Constant Exchange Rates; underlying growth of Core Lab excluding Roche Information Solutions: +6%; [1]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 Molecular Lab customer area. The comparative information for 2021 has been updated accordingly. In Q1 21 POC molecular sales = 90mCHF, Q2 21=92mCHF, Q3 21=175mCHF, Q4 21=194mCHF. In Q1 21 LS Alliances = 21mCHF, Q2 21=23mCHF, Q3 21=23m CHF, Q4 21=20mCHF.

# 2022: Diagnostics Division highlights

*Strong growth despite a high base in 2021*




- Immunodiagnostics (+7%)
- Clinical Chemistry (+9%)
- Custom biotech (-7%)

- POC Immunodiagnostics (+22%)
- POC Molecular[3] (+22%)

- Virology (-20%)
- qPCR&NAP (-31%)

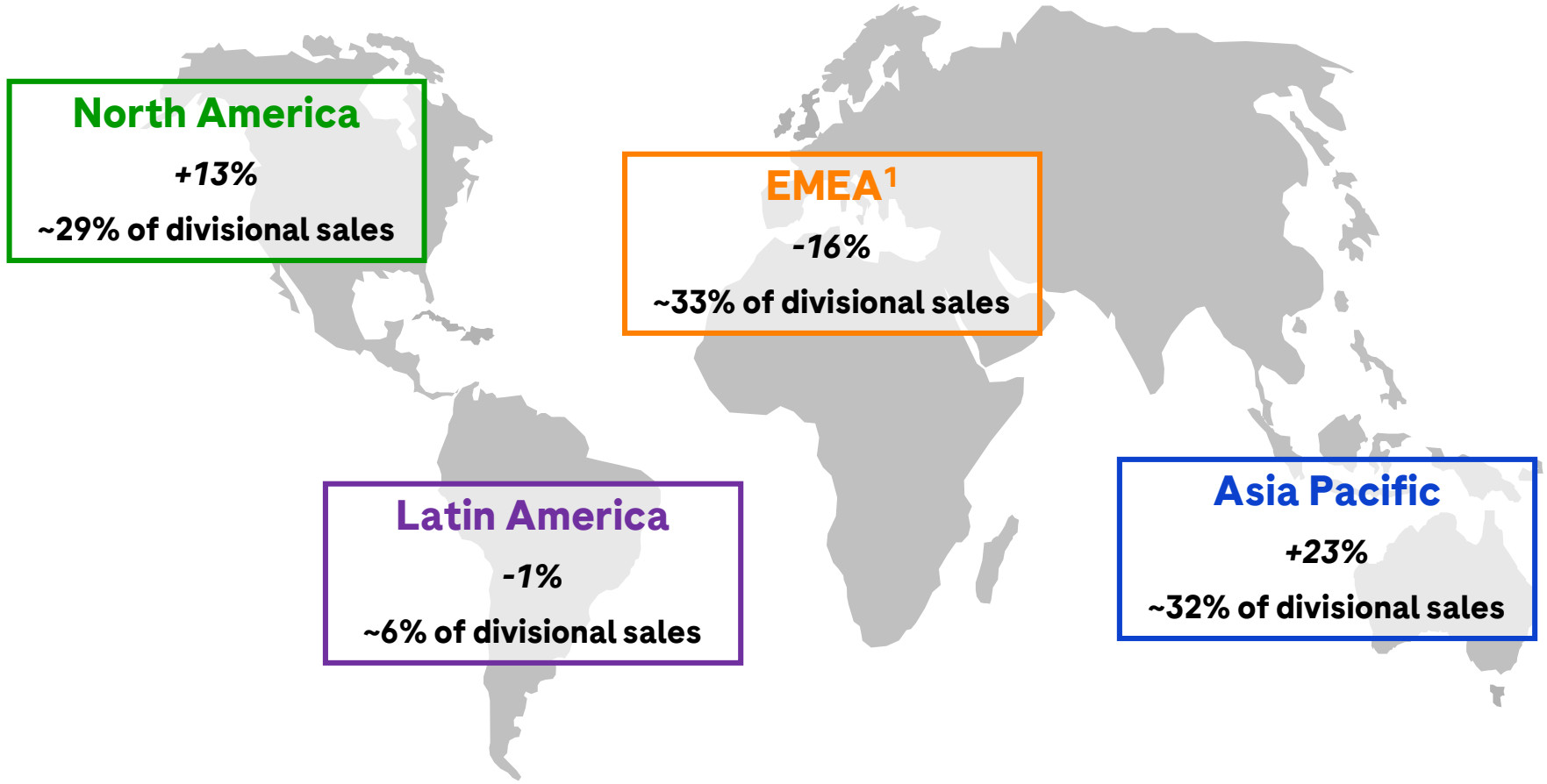
- Blood glucose monitoring (-3%)
- Insulin delivery systems (+5%)

- Advanced staining (+9%)
- Companion diagnostics (+25%)

CER=Constant Exchange Rates; POC=point of care; [1] Underlying growth of Core Lab excluding Roche Information Solutions: +6%; [2] EMEA=Europe, Middle East and Africa; [3] Sales in 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 Molecular Lab customer area. The comparative information for 2021 has been updated accordingly. In Q1 21 POC molecular sales = 90mCHF, Q2 21=92mCHF, Q3 21=175mCHF, Q4 21=194mCHF. In Q1 21 LS Alliances = 21mCHF, Q2 21=23mCHF, Q3 21=23mCHF, Q4 21=20mCHF.

# 2022: Diagnostics Division regional sales

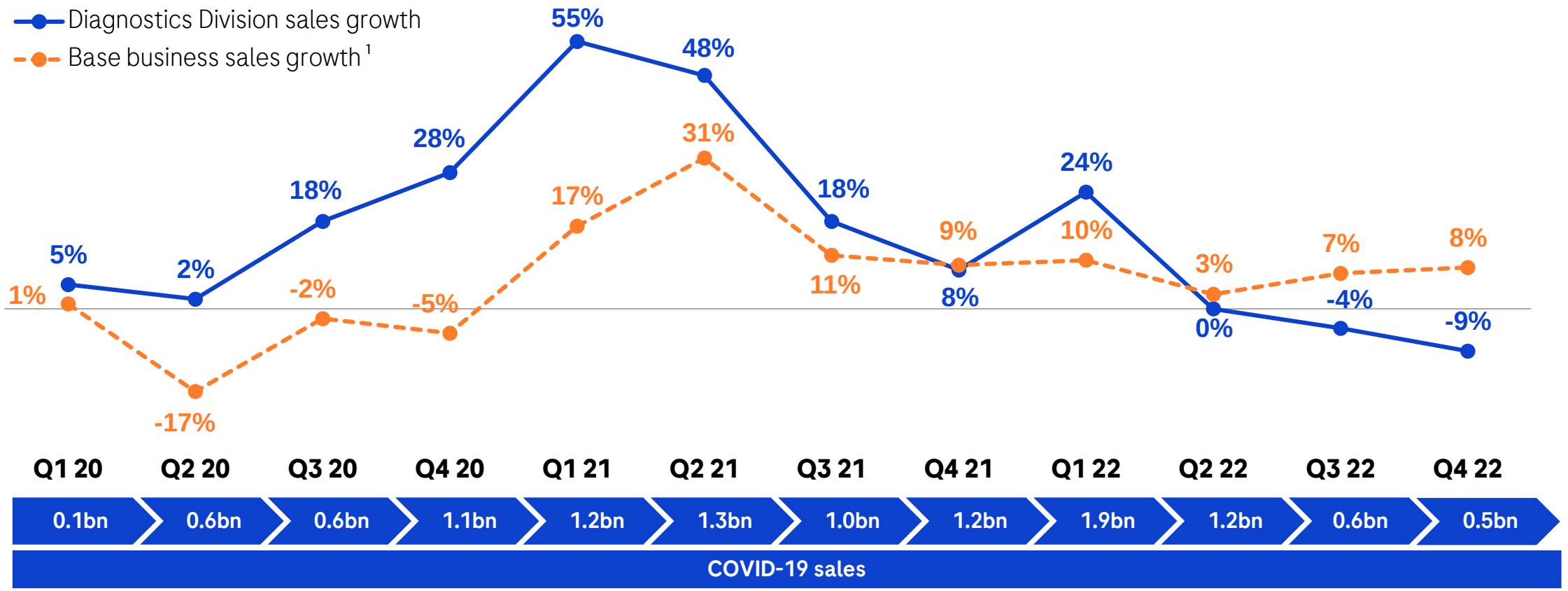
*Strong base business growth across all regions*




Growth rates at CER (Constant exchange Rates); [1] Europe, Middle East and Africa

# Diagnostics Division sales growth by quarter

*Strong base business growth*

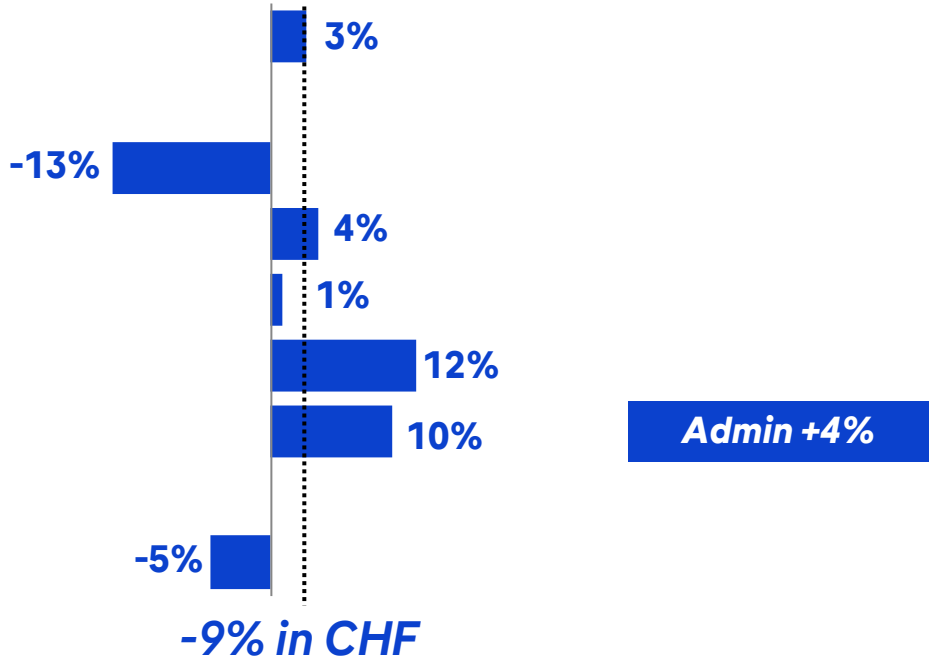



Growth rates and absolute values at CER (Constant exchange Rates); [1] Quarterly sales growth excluding COVID-19 sales

# 2022: Diagnostics Division

*Core operating profit decline of -5%*

| | 2022 CHFm | 2022 % sales |
|---|---|---|
| **Sales** | **17,730** | **100.0** |
| Royalties & other op. inc. | 68 | 0.4 |
| Cost of sales | -8,813 | -49.7 |
| M & D | -2,889 | -16.3 |
| R & D | -1,957 | -11.0 |
| G & A | -583 | -3.3 |
| **Core operating profit** | **3,556** | **20.1** |

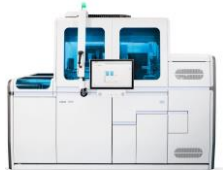



CER=Constant Exchange Rates

# New system launches in US

*Enabling comparable results in different size laboratories*

Throughput

| | | | |
|---|---|---|---|
| Serum Work Area solutions | cobas® pure<br>US Launch[1]<br>  | cobas® pro ✓<br>  | cobas® pro (high throughput) ✓<br>  |
| Molecular solutions | cobas® 5800<br>US Launch[2]<br>  | cobas® 6800 ✓<br>  | cobas® 8800 ✓<br>  |

**Increasing access**
Family concept addressing needs of all lab sizes. Beyond US, will increase access in low and middle income countries

**Reducing cost**
Automation and tailored throughput help laboratories and health care systems

**More sustainable**
Up to 80% less plastic waste per test

[1] Launched in Q3 2022; [2] Launched in Q4 2022

# FDA emergency use authorization for the mpox assay

*Running on cobas® 6800/8800 high throughput platforms*


- **May 2022:** Launch of LightMix® modular virus kits for the detection of the mpox virus (on LightCycler instruments)
- **November 2022:** Received FDA EUA for the mpox assay run on cobas 6800/8800 within two months of regulatory pathway opening in September
- **Roche fast response** to the public health emergency contributed to fortifying its position and reputation in addressing outbreaks

EUA: Emergency Use Authorization

# STRONG-HF[1] trial stopped early due to superior efficacy[2]

*Significant reduction of hospitalizations or mortality in heart failure*

***Evaluate the efficacy and safety of rapid up-titration of oral HF therapy, supported by NT-proBNP monitoring[2,3,4]***

## Disease burden

**> 64m patients** diagnosed with heart failure annually[5]

**>50% mortality after 5 years** of patients under current site of care treatment regimen[5]

STRONG-HF
CONTEMPORARY POST-DISCHARGE MANAGEMENT IN HEART-FAILURE

## Study set up[6]

**6 tests per patient** of NT-proBNP are needed for safety monitoring (on label)

**Serial measurements** of NT-proBNP during uptitration of 4 evidence based HF drugs[7]

**N=1078 Pts[8], 1oEP**: composite all-cause death + HF hospitalization at day 180

**Outcome: 34% decrease in hospitalization and deaths, p<0.05 (NNT=12)[2,9]**

[1] Safety, Tolerability and Efficacy of Rapid Optimization, Helped by NT-proBNP testinG, of Heart Failure Therapies; [2] Mebazza-A et al. Lancet 2022. 400:1938-1952; [3] Kimmoun-A et al. Eur J Heart Fail 2019. 21: 1459–1467; [4] Gotter-G et al. Eur J Heart Fail 2021. 23:1981-1982; [5] Groenewegen-A et al. Eur J Heart Fail 2020. 22:1342-1356; [6] multicenter, randomized, parallel group strategy-based trial; [7] Source: https://clinicaltrials.gov/ct2/show/NCT03412201, Drugs: beta-blockers; angiotensin converting enzyme inhibitors (ACEi), angiotensin receptor blocker (ARB) or angiotensin receptor neprolysin inhibitor (ARNi); and mineralocorticoid receptor antagonist (MRAs); [8] Initially planned study setup of n=1,800 which wasn't reached due to termination for superior efficacy; [9] NNT = Number Needed to Treat

# Elecsys® Amyloid Plasma Panel clinical results

*Received FDA approval for Elecsys ® CSF AD assays pTau /Abeta 42*

**1 Triage**
Patients undergoing initial evaluation for non-specific cognitive decline[1]

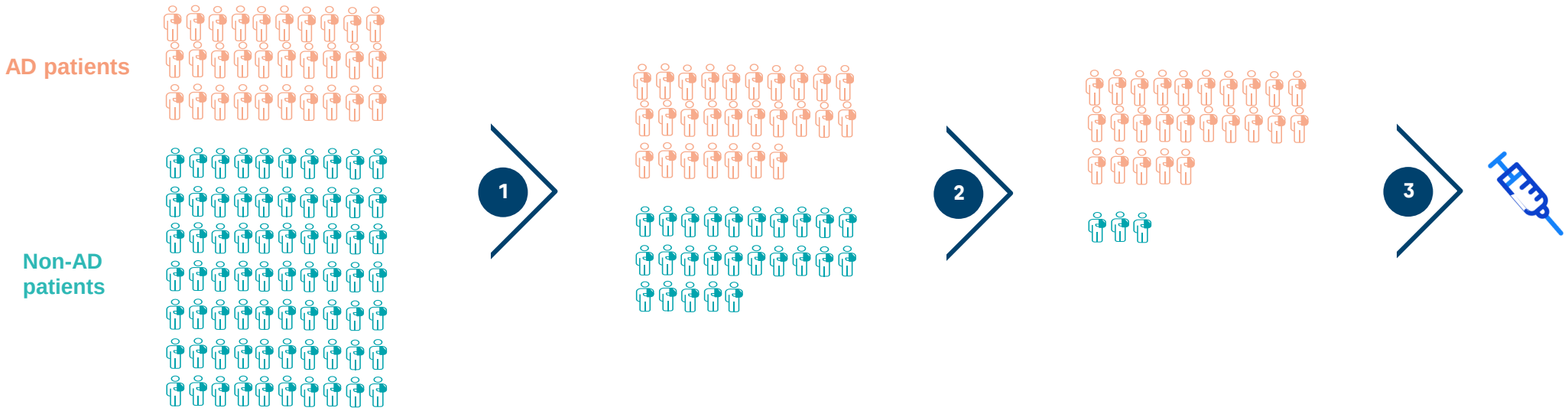
Elecsys® Amyloid Plasma Panel[2]
*pTau181 + APOE4*
FDA BDD
sensitivity > 85%
specificity > 65%

**2 Confirmation**
Patients referred for amyloid confirmatory testing[3]

Elecsys® CSF AD assays
*pTau /Abeta 42*
FDA
sensitivity > 90%
specificity > 90%

**3 Therapy**
Patients identified for future therapies

Anti-amyloid antibodies




= 10 patients

[1] Assumed prevalence of AD 30% in symptomatic patients; [2] Mean of clinical performance data from retrospective cohorts measured with Elecsys Amyloid Plasma Panel; Blennow K et al. Clinical performance and robustness of blood-based biomarkers for early detection of amyloid pathology associated with Alzheimer's disease . Alzheimer's Dement. 2022,18(6):e069052 [3] Alternative to PET scan

# Diagnostics key launches 2023

| | Area | Product | Description | Markets |
|---|---|---|---|---|
| Instruments Automation | Core Lab | CCM Vertical | Modular transportation system, integrated into the existing cobas connection modules, allowing for overhead sample transportation over different work areas or different floors enabling effective use of lab space | Global |
| | | cobas pro integrated solutions | Scalable and modular serum work area analyzer for mid to high volume clinical chemistry and immunochemistry testing | China |
| | | cobas pure integrated solutions | Serum work area analyzer for low to mid volume clinical chemistry and immunochemistry testing on a footprint of two square meters | China |
| | Molecular Lab | LightCycler Pro | Flexible real-time PCR instrument with dual IVD and research mode as well as enhanced system features | US & CE |
| | Point of Care | cobas pulse | Handheld device combining professional glucose meter and a digital platform to host digital clinical decision support applications (from Roche and third parties) | US |
| Tests | Pathology Lab | IDH1 R132H (IDH Glioma) | Neuropathology Immunohistochemistry (IHC) solution supporting the detection of tumor cells with the IDH1 R132H mutation aiding pathologists to render a diagnosis of gliomas | US |
| | Core Lab | Anti-HEV IgG and Anti-HEV IgM | Anti-HEV IgM: Immunoassay aiding in the diagnosis of acute HEV infection in clinical settings; Anti-HEV IgG: Immunoassay aiding in the detection of a recent or past HEV infection and enabling accurate seroprevalence determinations. The two assays expand the hepatitis panel (HAV, HBV, HCV, HEV) on the same analytical platform | CE |
| | | HBeAg Quant | Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B viral infection | CE |
| | | IL-6 Neonatal sepsis (claim extension) | Only immunoassay available on the market with dedicated claim and supporting evidence aiding in diagnosis of sepsis in neonates, with potential to reduce newborn mortality | CE |
| | | RUO Amyloid Plasma Assays (pTau181 & ApoE4) | Two qualitative immunoassays measuring the phosphorylated Tau 181 protein and apolipoprotein E4 in human plasma for research use only | US |
| Digital Solutions | Pathology Lab | RUO Digital Pathology Algorithm: PD-L1 SP142 | Digital pathology algorithm aiding pathologists in scoring PD-L1 (SP142) breast samples, ensuring a standardized approach and an adjunctive tool to augment diagnostic confidence for research use only | Global |
| | Lab Insights | navify Algorithm Suite | Digital solution providing access to an open library of certified IVD-based clinical algorithms | Selected markets[1] |
| | | Menu for navify Algorithm Suite | Certified clinical algorithms for oncology applications such as colon and liver cancers | Selected markets[1] |
| | | cobas infinity lab 3.05 | Next-generation lab middleware enabling ecosystem of cloud-based solutions for quality control and instrument maintenance | Global |
| | | navify Marketplace | Digital marketplace offering lab customers full range of innovative applications (from Roche and third parties) | Selected markets[1] |
| | | navify Sample Tracking | Open digital solution offering sample tracking beyond the lab setting (from IVD-sample creation to lab reception) to improve testing traceability and quality | Selected markets[1] |

[1] Selected markets: 14 countries with first releases // CE: European conformity; RUO: Research use only; PCR: Polymerase chain reaction; IVD: In vitro diagnostic; IDH: Isocitrate dehydrogenase; HEV: Hepatitis E virus; HAV: Hepatitis A virus; HBV: Hepatitis B virus; HCV: Hepatitis C virus

# Finance

***Alan Hippe***
***Chief Financial Officer***

# 2022 results

## Focus on cash and balance sheet

## Outlook

## New Income Statement Representation in 2023

# 2022: Highlights

## Business

- Group sales growth of +2% due to strong underlying business in both divisions
- Core operating profit up by +3% and Core EPS growth +5% (incl. accretion of 4.8%)
- Proposal to further increase dividend in Swiss francs

## Cash flow

- Strong Operating Free Cash Flow of CHF 17.7bn, -8% lower due to increased net working capital
- Net debt decreased by CHF 2.6bn vs. YE 2021

## Net financial results

- Core net financial result worsened by -475m driven by higher interest expenses

## IFRS

- Net income -6% driven by higher Intangible Assets impairment, partially offset by lower Intangible Assets amortization

Growth rates and variances at CER (Constant exchange Rates)

# 2022: Group performance

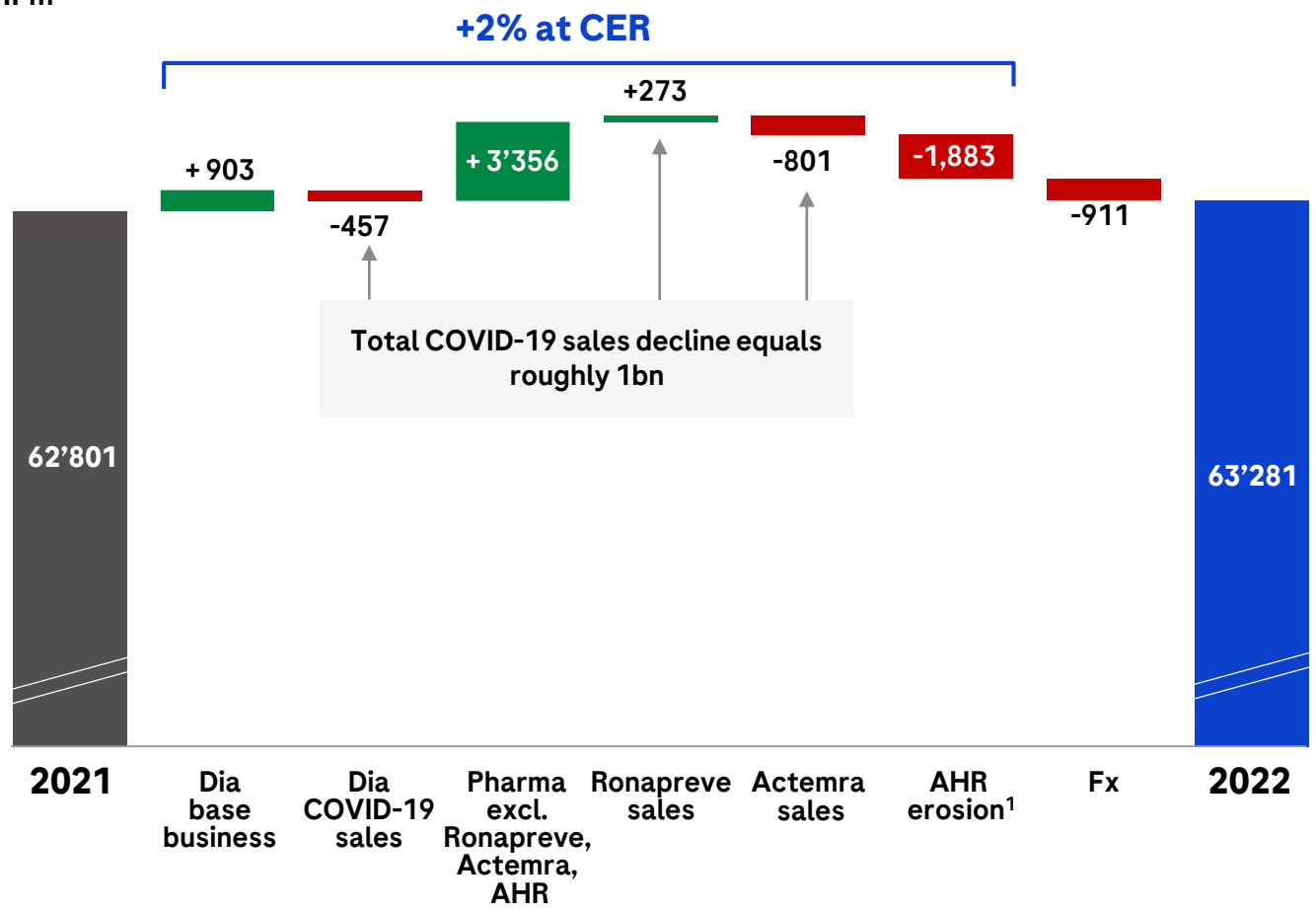
*Sales growth of +2%, Core Operating profit up +3%, Core EPS growth of +5%*

| | 2022 CHFm | 2021 CHFm | Change in % CHF | Change in % CER |
|---|---|---|---|---|
| **Sales** | **63,281** | **62,801** | **1** | **2** |
| **Core operating profit** | **22,173** | **21,897** | **1** | **3** |
| *as % of sales* | *35.0* | *34.9* | | |
| **Core net income** | **17,530** | **18,071** | **-3** | **-1** |
| *as % of sales* | *27.7* | *28.8* | | |
| **Core EPS (CHF)** | **20.30** | **19.81** | **2** | **5** |
| **IFRS net income** | **13,531** | **14,935** | **-9** | **-6** |
| *as % of sales* | *21.4* | *23.8* | | |
| **Operating free cash flow** | **17,673** | **19,411** | **-9** | **-8** |
| *as % of sales* | *27.9* | *30.9* | | |
| **Free cash flow** | **13,041** | **15,691** | **-17** | **-16** |
| *as % of sales* | *20.6* | *25.0* | | |

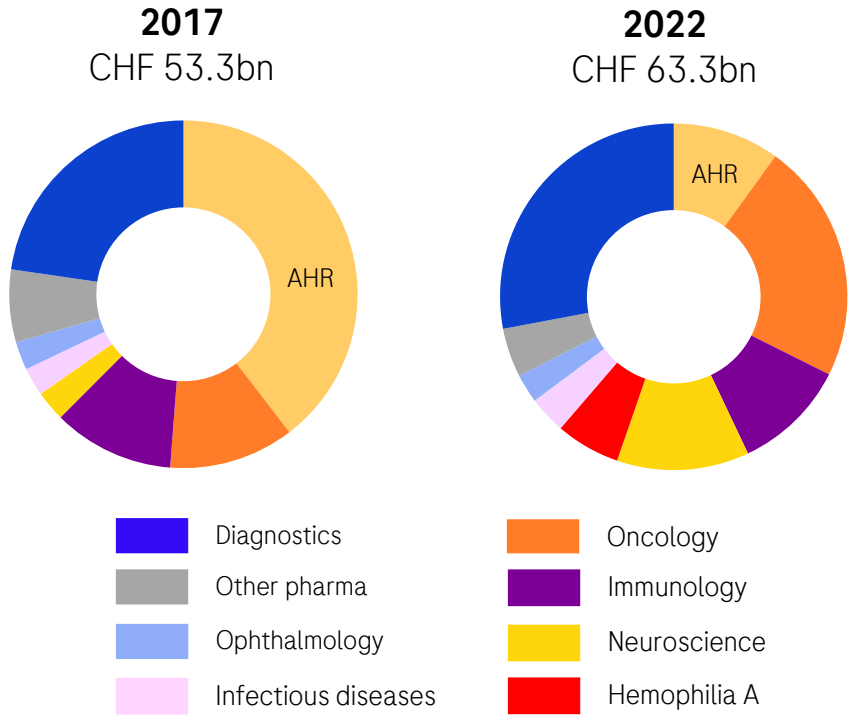
CER=Constant Exchange Rates

# 2022: Pharma and Diagnostics underlying business driving growth

CHFm




## Diversification of Roche business




2022 values in reported CHFm, variances in CERm; [1] AHR: Avastin, Herceptin, Rituxan/MabThera sales erosion

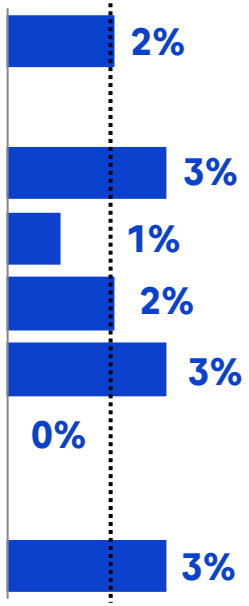
# 2022: Group operating performance

*Core operating profit growth of +3%*

| | 2022 | |
|---|---|---|
| | CHFm | abs. CER |
| **Sales** | **63,281** | **+1,391** |
| Royalties & other op. inc. | 3,145 | +83 |
| Cost of sales | -18,075 | -204 |
| M & D | -9,546 | -159 |
| R & D | -14,053 | -367 |
| G & A | -2,579 | -4 |
| **Core operating profit** | **22,173** | **+740** |

**2022 vs. 2021**

**CER growth**

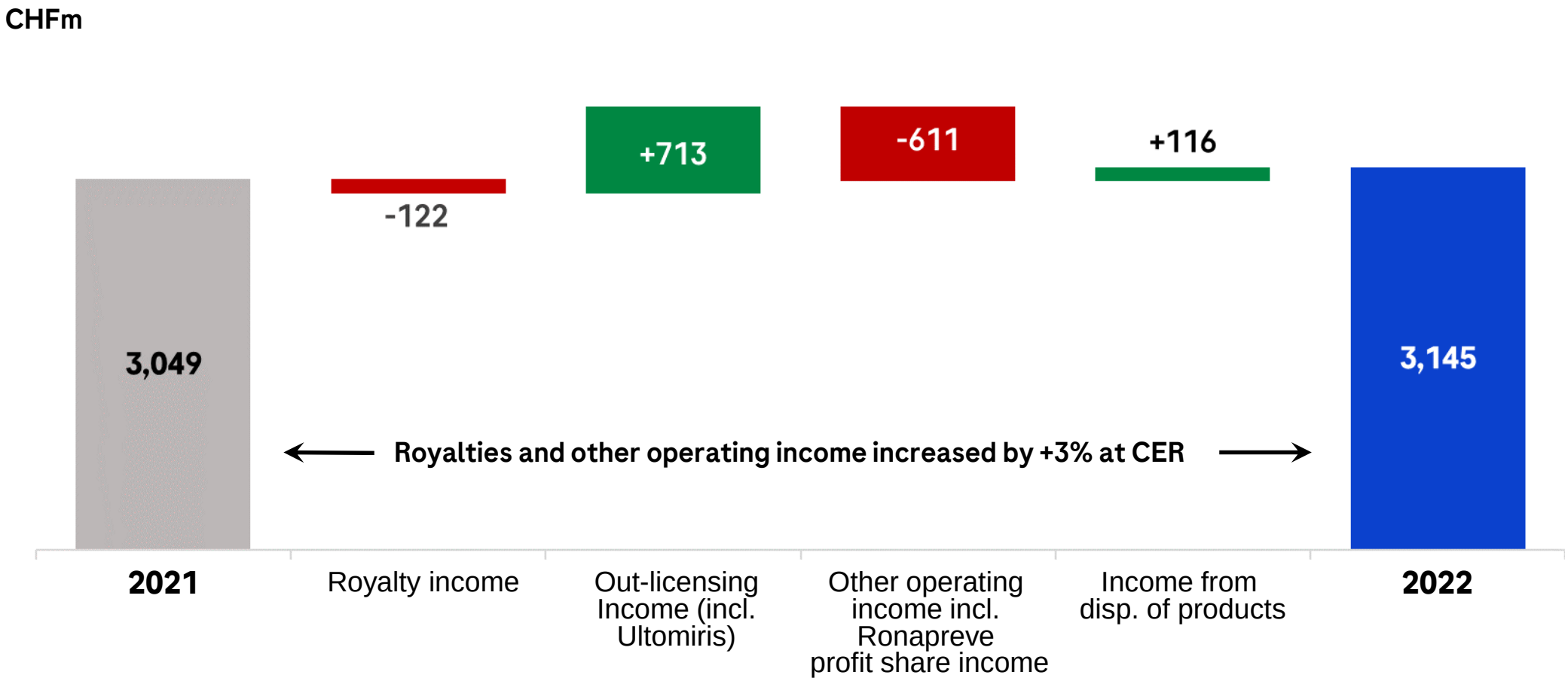



*+1% in CHF*

CER=Constant Exchange Rates

# 2022: Royalties and other operating income

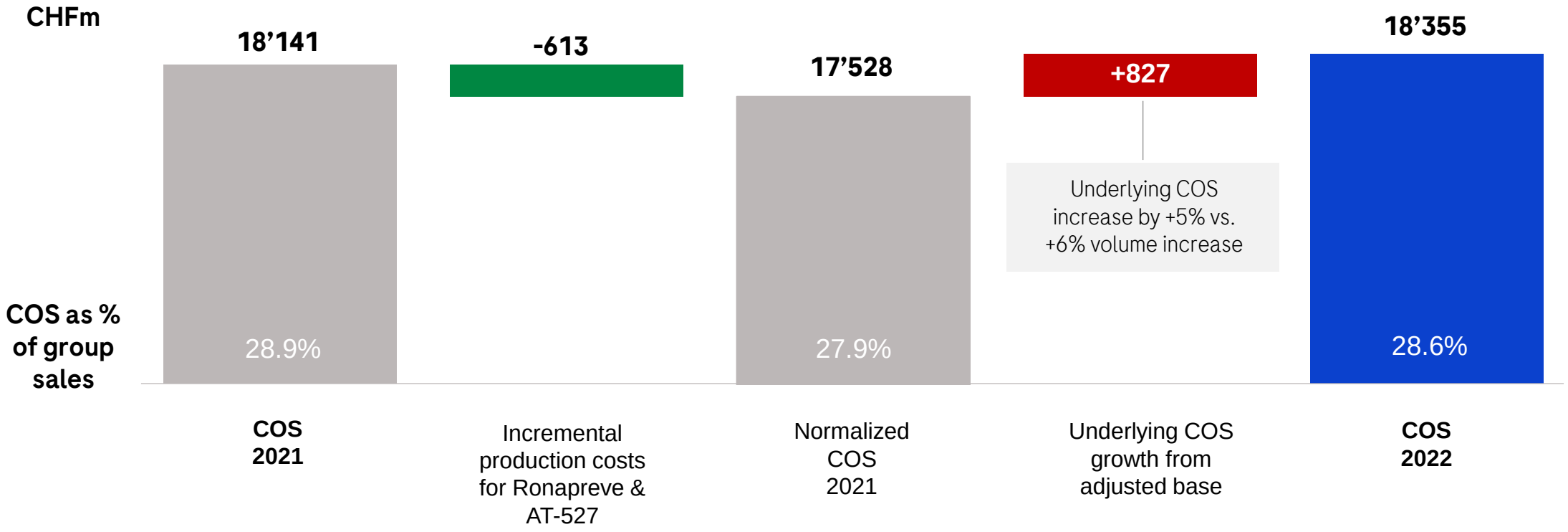
*Higher income driven by one-time Ultomiris patent settlement gains*




CER = Constant Exchange Rates

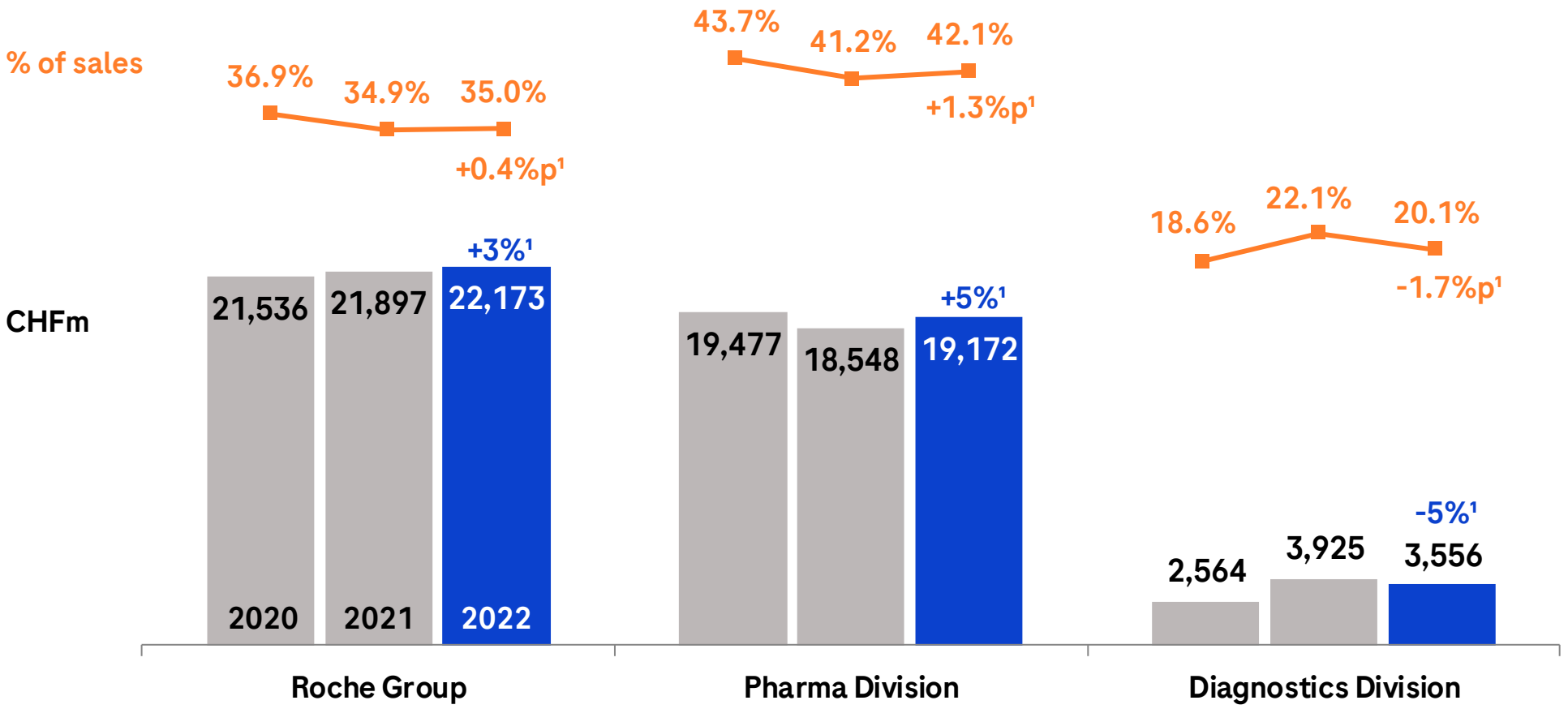
# 2022: Group Core cost of sales (COS)

*Increase due to volume growth, partially offset by the base effect of the 2021 incremental production costs for Ronapreve & AT-527*




All at CER=Constant Exchange Rates; COS=Cost of Sales

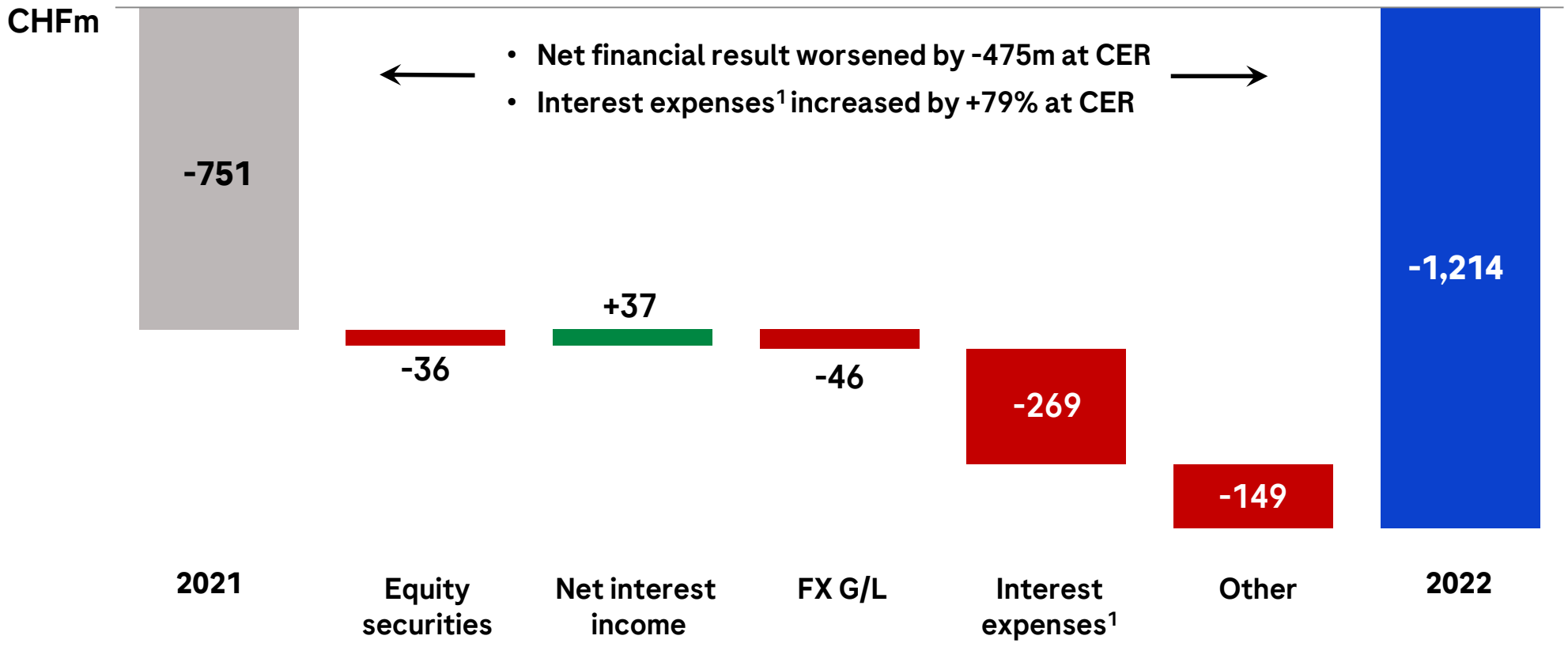
# 2022: Core operating profit and margin




[1] At CER=Constant Exchange Rates

# 2022: Core net financial result

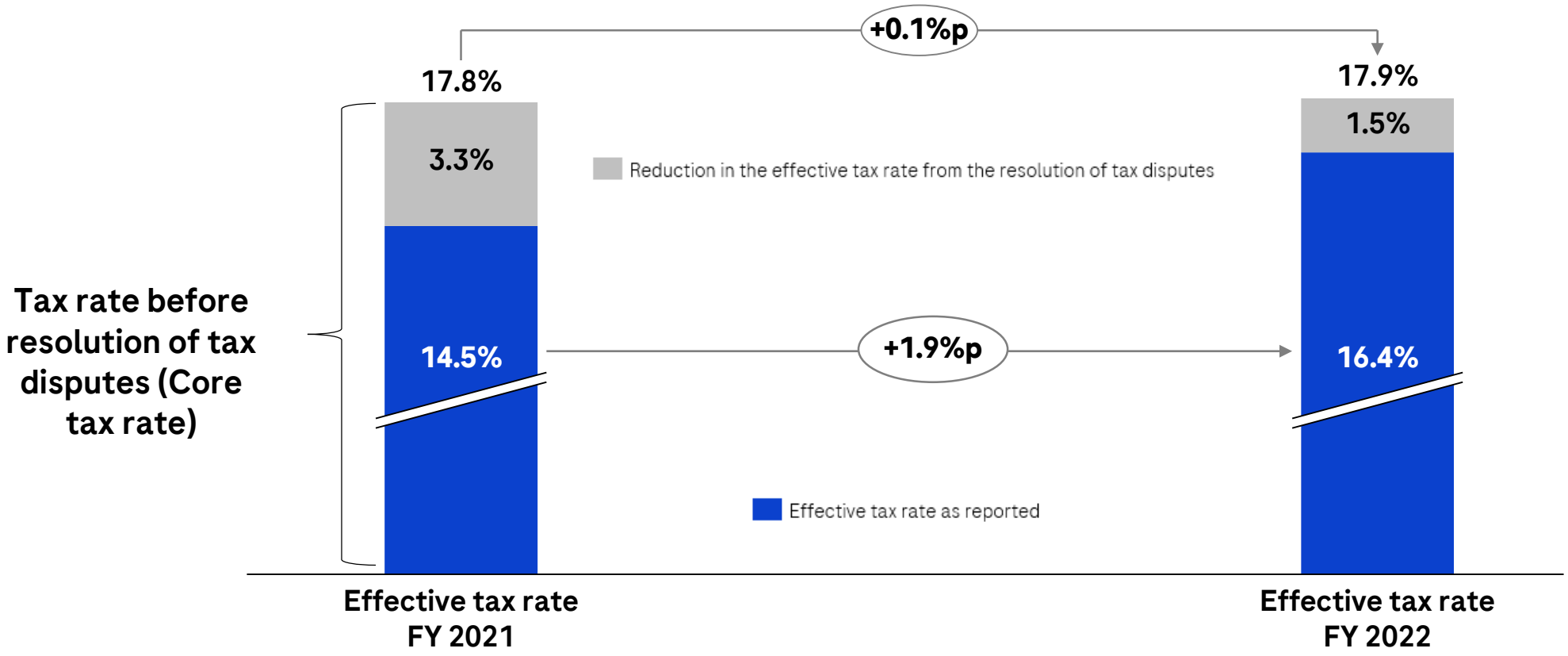
*Net financial result worsened due to higher interest expenses*




CER=Constant Exchange Rates; [1] incl. amortization of debt discount and net gains on interest rate derivatives

# 2022: Group Core tax rate

*Increase in core tax rate mainly due to the relative lower impact from the resolution of tax disputes in 2022 compared to 2021*



# 2022: Core EPS development

*Operations growth and accretion effect from share repurchase are main drivers for higher Core EPS*


At Constant Exchange Rates (CER); [1] Core operating profit excluding impacts from Ultomiris patent settlement and Profit Sharing Income from Regeneron; [2] Net impact from the Ultomiris patent settlement: gross income, net of income tax and non-controlling interests and Profit Sharing Income from Regeneron, net of tax; [3] Impact of lower number of shares partially offset by increase in interest expense; [4] Other (net) include effects from changes in effective tax rate, gains/losses on equity securities, other financial income and expenses and non-controlling interests

# 2022: Non-core and IFRS income

*Non-core operating expenses above PY driven by higher impairment of intangible assets, partially offset by lower amortization of intangible assets due to Esbriet*

| | 2021 | 2022 | | Change in % | |
|---|---|---|---|---|---|
| | CHFm | CHFm | CHFm | CHF | CER |
| **Core operating profit** | **21,897** | **22,173** | **277** | **+1** | **+3** |
| Global restructuring plans | -1,362 | -969 | 393 | | |
| Amortisation of intangible assets | -1,556 | -933 | 623 | | |
| Impairment of intangible assets[1] | -651 | -2,837 | -2,186 | | |
| M&A and alliance transactions | -55 | 20 | 75 | | |
| Legal & Environmental[2] | -118 | 22 | 140 | | |
| *Total non-core operating items* | -3,742 | -4,697 | -955 | | |
| **IFRS Operating profit** | **18,155** | **17,476** | **-680** | **-4** | **-1** |
| *Total financial result & taxes* | -3,220 | -3,944 | -724 | | |
| **IFRS net income** | **14,935** | **13,531** | **-1,405** | **-9** | **-6** |

CER = Constant Exchange Rates; IA=intangible assets; [1] incl. goodwill; [2] incl. pension plan settlements

2022 results

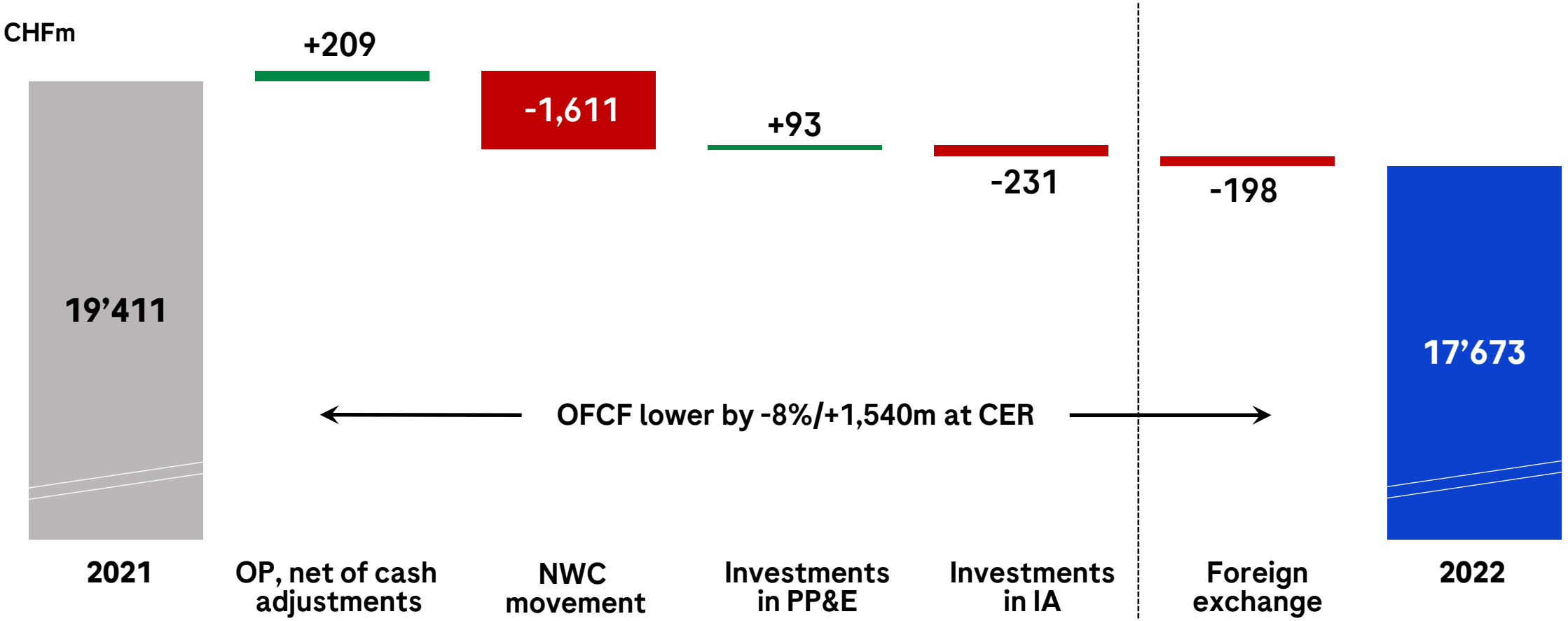
Focus on cash and balance sheet

Outlook

New Income Statement Representation in 2023

# 2022: Group Operating Free Cash Flow

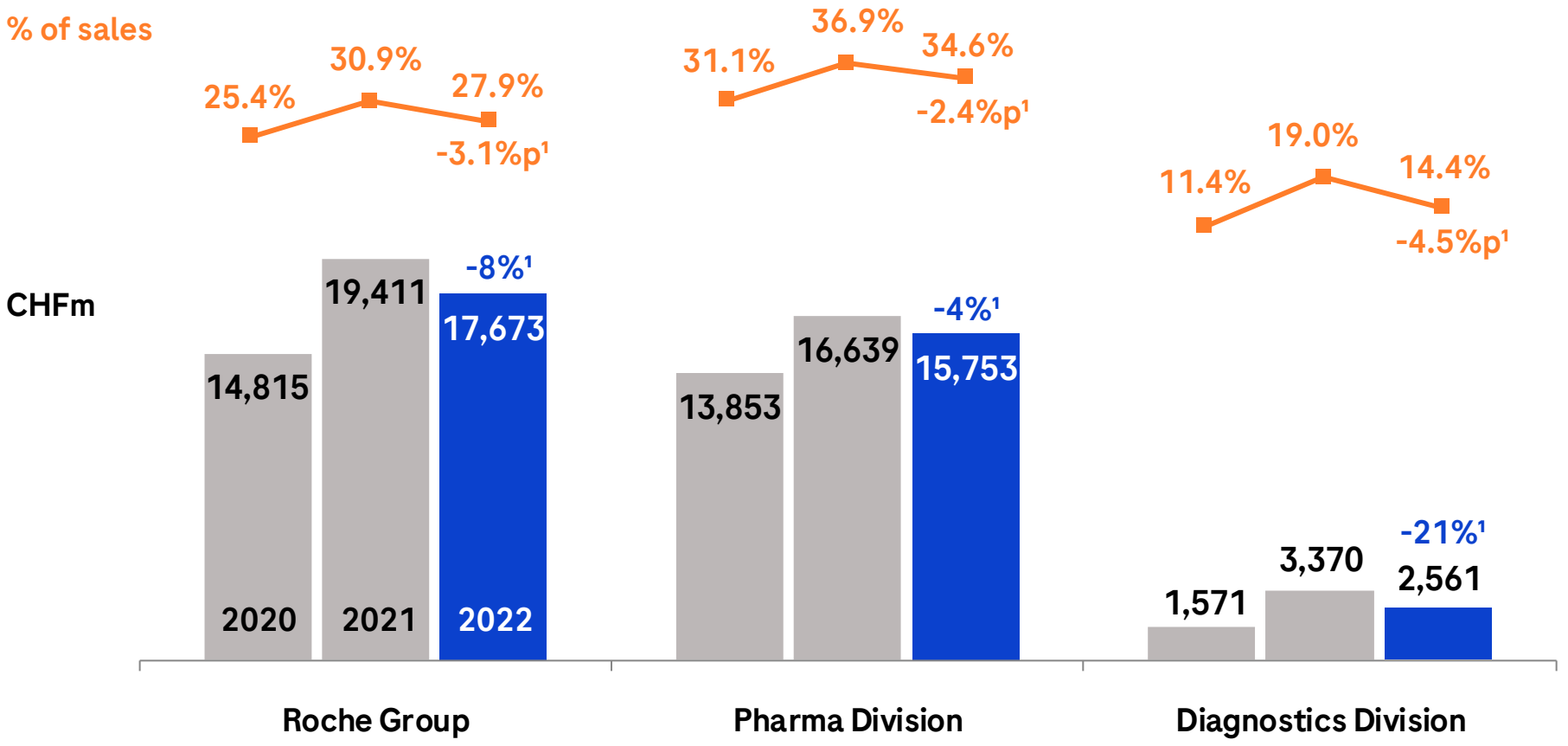
*OFCF -8% driven by movements in NWC and higher investments in IA*




CER = Constant Exchange Rates; OP = Operating Profit; NWC: Net Working Capital; PP&E = Property, Plant & Equipment incl. increase of lease liability paid; IA = Intangible Assets

# 2022: Operating free cash flow and margin

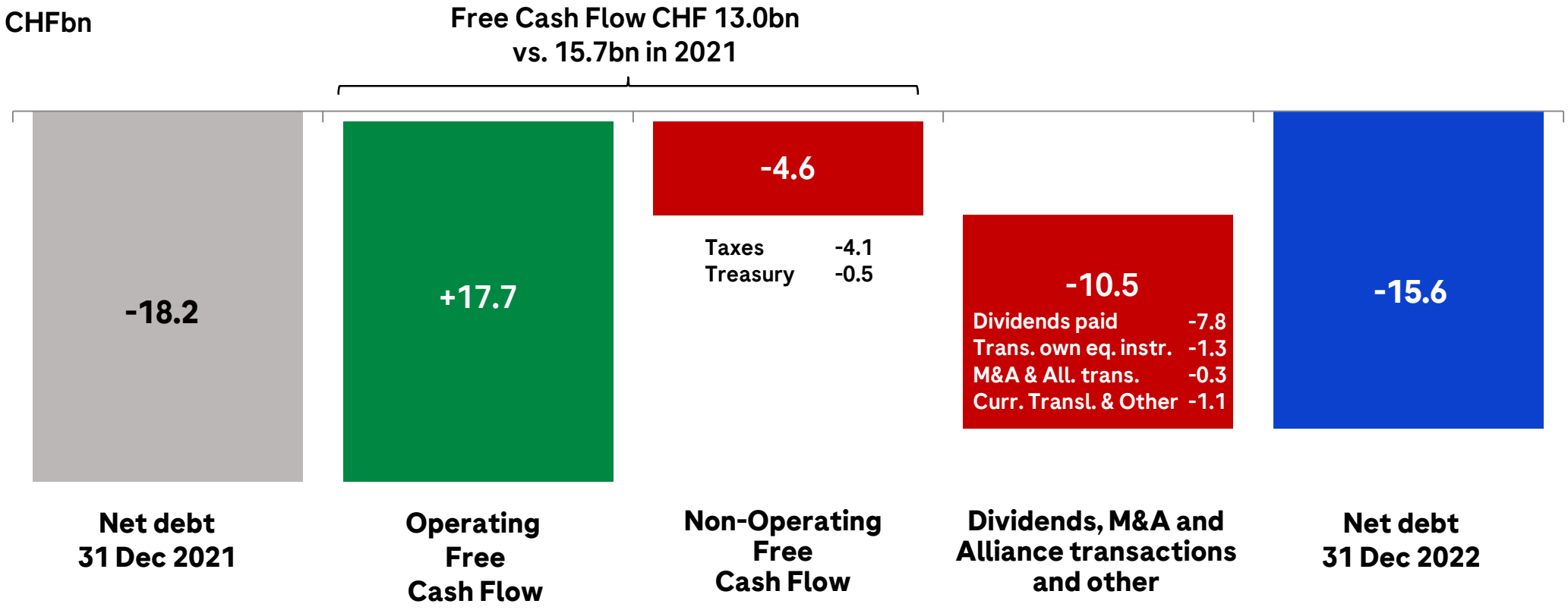
*OFCF -8% driven by movements in NWC and higher investments in IA*




[1] At CER=Constant Exchange Rates

# 2022: Group net debt development

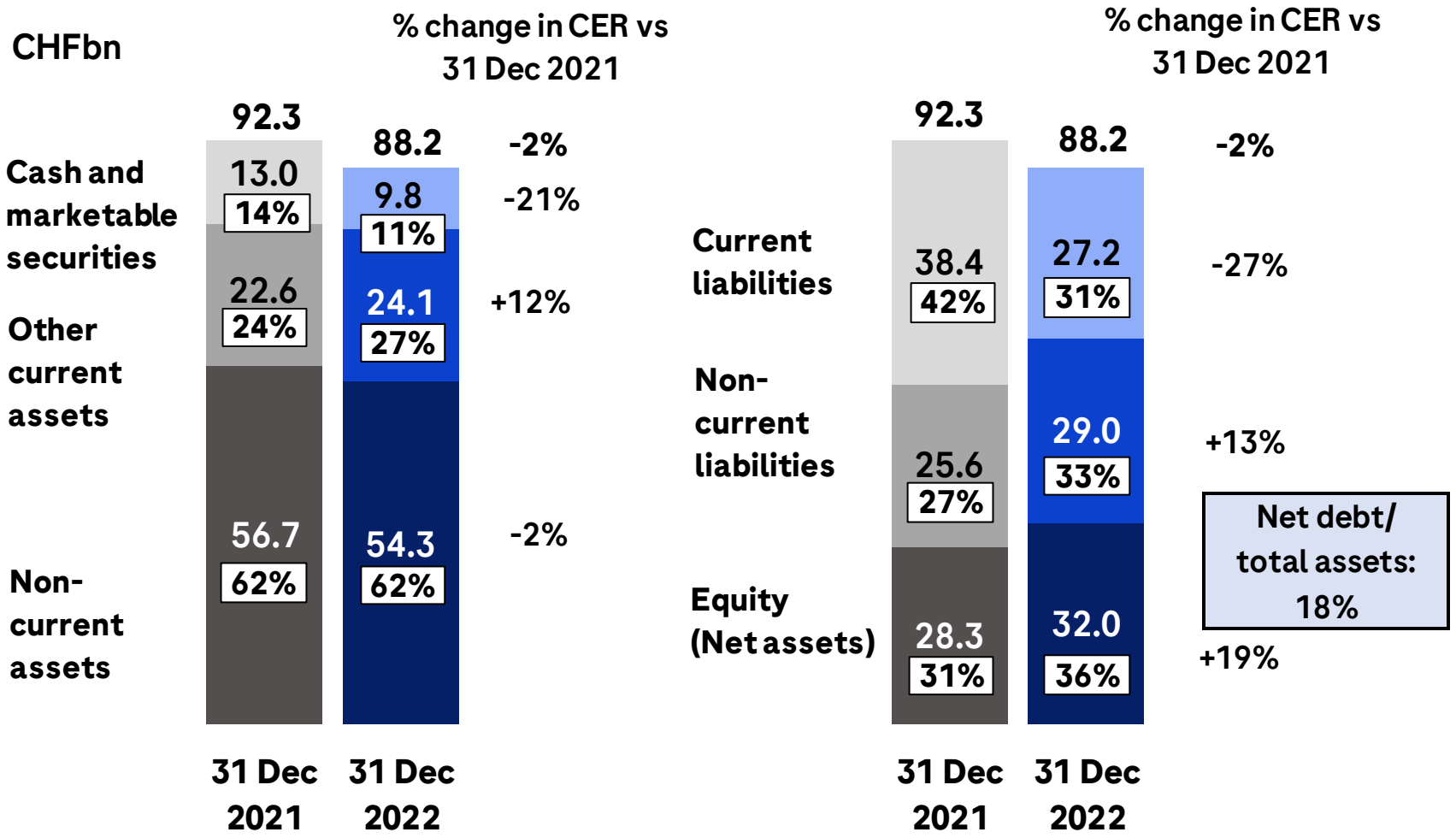
*Net debt lower by CHF +2.6bn vs. year end 2021*




| Thereof investments in innovation: | | Intangible Asset | Equity | M&A | Total |
|---|---|---|---|---|---|
| | 2022 | -1.1 | 0.0 | -0.3 | -1.4 |
| | 2021 | -0.9 | -0.3 | -2.4 | -3.6 |

# Balance sheet 31 December 2022

*Equity ratio at 36% (31 Dec 2021: 31%) and net debt to assets at 18% (31 Dec 2021: 20%)*




CER = Constant Exchange Rates

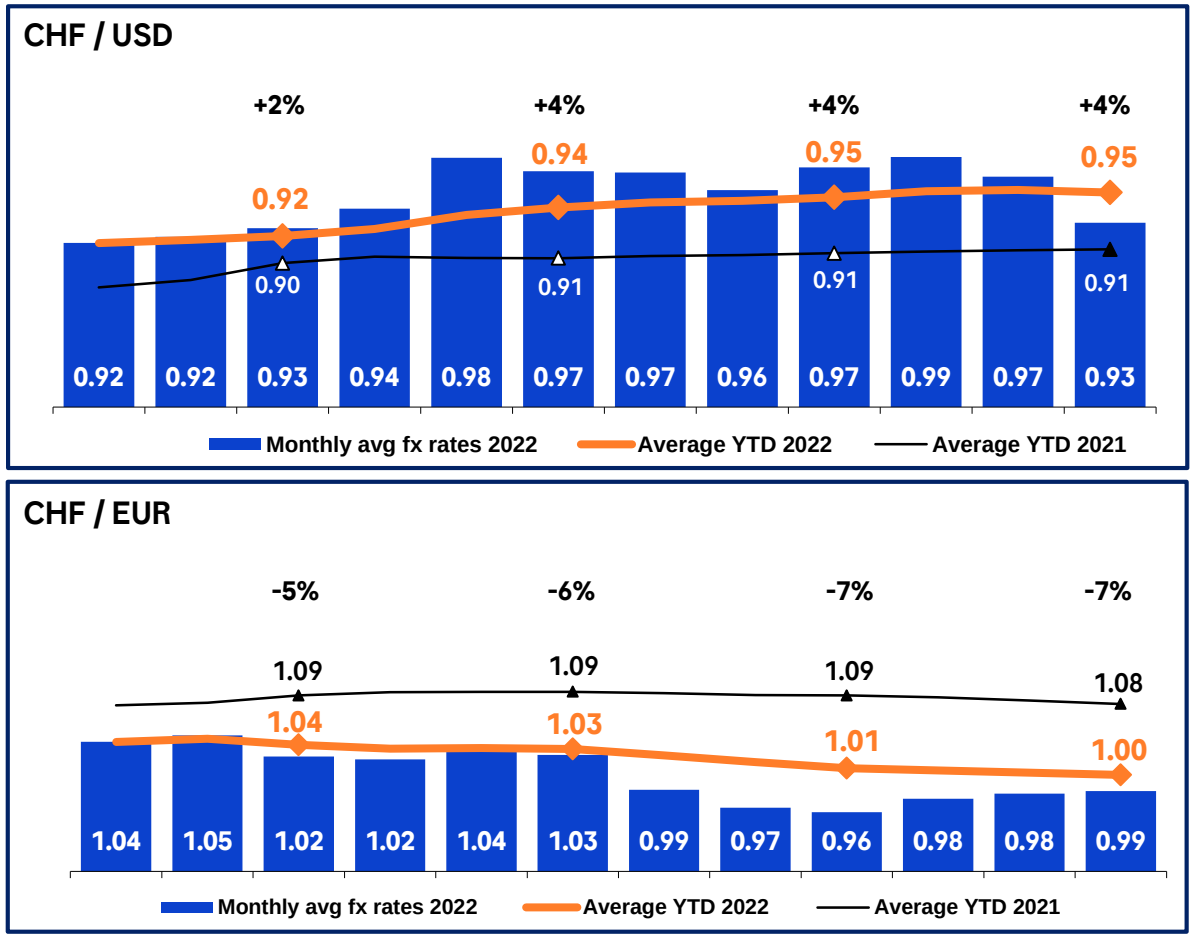
2022 results

Focus on cash and balance sheet

Outlook

New Income Statement Representation in 2023

# Currency impact 2022




*In 2022 impact[1] is (%p):*

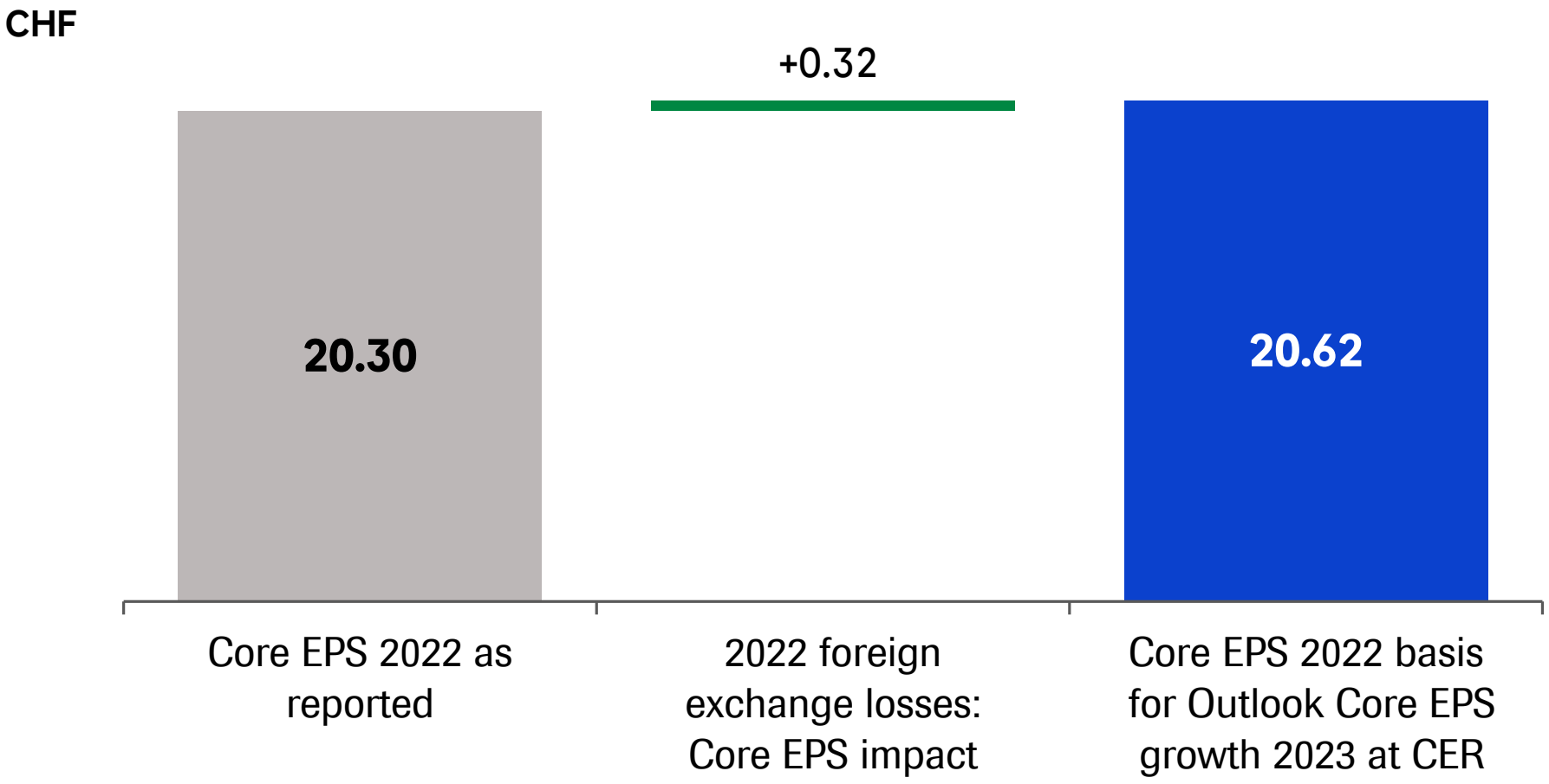
| | Q1 | HY | Sep YTD | FY |
|---|---|---|---|---|
| Sales | -1 | 0 | -1 | -1 |
| Core operating profit | | 0 | | -2 |
| Core EPS | | 0 | | -3 |

***2023 currency impact[1] expected (based on 30 December 2022 FX rates):***
***Around -4%p to -6%p on Sales, Core OP & Core EPS***

[1] On group growth rates

# 2022: Core EPS

*Core EPS 2022 of CHF 20.62 is basis for Core EPS outlook 2023 at CER*




CER = Constant Exchange Rates

# 2023 outlook

| | |
|---|---|
| **Group sales growth[1]** | • Low single digit decline |
| **Core EPS growth[1]** | • Broadly in line with sales decline |
| **Dividend outlook** | • Further increase dividend in Swiss francs |

[1] At Constant Exchange Rates (CER)

2022 results

Focus on cash and balance sheet

Outlook

New Income Statement Representation in 2023

# Income Statement Presentation 2023

*Improving comparability, reducing complexity, reinforcing alignment*

## Changes in Income Statement presentation

- Improve external comparability and simplify messaging by using **“Selling, General & Administration”** costs, from merging “Marketing & Distribution” and “General & Administration”.
- Reinforcing alignment with latest developments on *Revenue* by using **“Other revenues”**, instead of “Royalties and Other Operating Income”. Introducing a line **“Other operating income / expense**” for non-revenue income and expenses that do not fall into the regular functional costs.
- Simplify and standardise reporting by **removing allocations** from Corporate to the Divisions and various reporting lines for functions with global accountability such as informatics, human resources, and finance.

## Consequences

- Sales, Group Operating Profit and EPS **metrics are unaffected**.
- No change to Core Reporting Concept.
- Allocation changes will reduce costs allocated to Divisions and **increase Divisional margins** (around 4.0-5.0 %points).

## Timeline

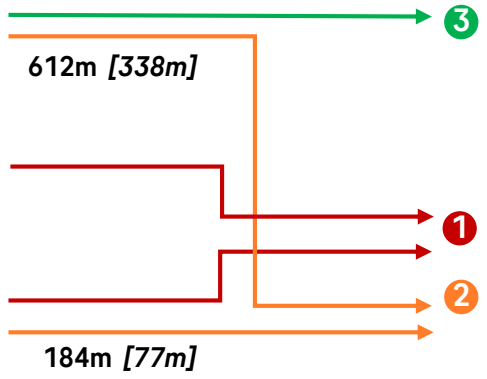
- Implementation effective 1 January 2023. Comparative 2022 information will be restated.

# Changes to income statement presentation (1)

## As published income statement (core)

| Core basis CHFm | 30 June 2022 | 31 Dec 2022 |
|---|---|---|
| **Sales** | **32,295** | **63,281** |
| Royalties & Other Operating Income | 1,943 | 3,145 |
| Cost of Sales | (9,305) | (18,075) |
| Marketing & Distribution | (4,459) | (9,546) |
| Research & Development | (6,628) | (14,053) |
| General & Administration | (1,178) | (2,579) |
| **Core Operating Profit** | **12,668** | **22,173** |

**Reclassifications FY 2022 *[HY 2022]***




## Revised, prior to Group allocation changes

| Core basis CHFm | 30 June 2022 | 31 Dec 2022 |
|---|---|---|
| **Sales** | **32,295** | **63,281** |
| Other Revenue | 1,605 | 2,533 |
| Cost of Sales | (9,305) | (18,075) |
| Research & Development | (6,628) | (14,053) |
| Selling, General & Administration | (5,714) | (12,309) |
| Other Operating Income (Expense) | 415 | 796 |
| **Core Operating Profit** | **12,668** | **22,173** |

1. **Selling, General & Administration:** Merging of M&D and G&A to improve comparability vs. peers
2. **Other Operating Income (Expense):** Reinforces alignment with latest developments on revenue. OOIE will include non-revenue items currently in ROOI, such as “Income from disposal of product rights”, as well as “Gains/losses on divestments”, as well as expenses that do not fall into the regular functional costs, such as “Pension -past service costs” and “Impairment of goodwill” (non-core).
3. **Rename:** Former ROOI to **Other Revenue** including royalty income, profit share income and other out-licensing income

# Changes to income statement presentation (2)

## Revised, prior to Group allocation changes

| Core basis CHFm | 30 June 2022 | 31 Dec 2022 |
|---|---|---|
| **Sales** | **32,295** | **63,281** |
| Royalties & Other Operating Income | 1,605 | 2,533 |
| Cost of Sales | (9,305) | (18,075) |
| Research & Development | (6,628) | (14,053) |
| Selling, General & Administration | (5,714) | (12,309) |
| Other Operating Income (Expense) | 415 | 796 |
| **Core Operating Profit** | **12,668** | **22,173** |

**Reclassifications**
**FY 2022** ***[HY 2022]***

**660m** ***[319m]*** ❶

❷ **798m** ***[383m]***

**1,458m** ***[702m]***

## Restated

| Core basis CHFm | 30 June 2022 | 31 Dec 2022 |
|---|---|---|
| **Sales** | **32,295** | **63,281** |
| Other Revenue | 1,605 | 2,533 |
| Cost of Sales | (8,986) | (17,415) |
| Research & Development | (6,245) | (13,255) |
| Selling, General & Administration | (6,416) | (13,767) |
| Other Operating Income (Expense) | 415 | 796 |
| **Core Operating Profit** | **12,668** | **22,173** |

❶ **Cost of Sales:** Reclassification of globally managed informatics, human resources and finance to SG&A.

❷ **Research & Development:** Reclassification of globally managed informatics, human resources and finance to SG&A.

# Removing allocations of Group Functions

*Increase in Divisional Margins of 4-5 % points, no change in Group Margins*

| *CHFm* | As published | 30 June 2022 Group Functions shift | Restated | As published | 31 December 2022 Group Functions shift | Restated |
|---|---|---|---|---|---|---|
| **Core Operating Profit** | | | | | | |
| **Roche Group** | **12,668** | | **12,668** | **22,173** | | **22,173** |
| Pharmaceuticals Division | 10,318 | 971 | 11,289 | 19,172 | 1,959 | 21,131 |
| Diagnostics Division | 2,560 | 393 | 2,953 | 3,556 | 825 | 4,381 |
| Corporate | (210) | | (1,574) | (555) | | (3,339) |
| | | | | | | |
| **Core Operating Profit as % of Sales 3rd** | | | | | | |
| **Roche Group** | **39.2%** | | **39.2%** | **35.0%** | | **35.0%** |
| Pharmaceuticals Division | 46.2% | | 50.5% | 42.1% | | 46.4% |
| Diagnostics Division | 25.7% | | 29.7% | 20.1% | | 24.7% |

# Doing now what patients need next

# Roche Group development pipeline

**Marketed products development programmes**

**Roche Pharma global development programmes**

**Roche Pharma research and early development (pRED)**

**Genentech research and early development (gRED)**

**Spark**

**Pharma sales appendix**

**Diagnostics sales appendix**

**Foreign exchange rates information**

# Changes to the development pipeline

*Q4 2022 update*

## New to phase I

**6 NMEs:**
**RG6209** NME – retinal disease
**RG6421** TMEM16A potentiator – cystic fibrosis
**RG6524** NME – solid tumors
**RG6411** NME – solid tumors
**CHU** anti-HLA-DQ2.5 x gluten peptides – celiac disease
**CHU** RAY121 – immunology

## New to phase II

**1 NME:**
**RG1662** basmisanil – Dup15q syndrome

**1 NME (moved from phase III):**
**RG6042** tominersen – Huntington's

## New to phase III

**2 NMEs:**
**RG6179** anti-IL-6 – UME
**RG6330** KRAS G12C – 2L NSCLC

## New to registration

**1 NME (US):**
**RG6026** glofitamab – 3L+ DLBCL

**1 AI (US & EU):**
**RG7446** Tecentriq SC – subcutaneous formulation, all approved indications

## Removed from phase I

**1 NME:**
**RG7880** efmarodocokin alfa – aGVHD

## Removed from phase II

## Removed from phase III

**2 NMEs:**
**RG1450** gantenerumab – prodromal to mild Alzheimer's
**RG7440** ipatasertib + abiraterone - 1L CRPC

**5 AIs:**
**RG7446** Tecentriq + chemo – 1L mUC
**RG7446** Tecentriq + cabozantinib – 2L NSCLC
**RG3502** Kadcyla + Tecentriq – 2L+ HER-2+ PD-L1+ mBC
**RG1450** gantenerumab – preclinical Alzheimer's
**RG6354** zinpentraxin alfa (PRM-151 ) – IPF

## Approvals

**1 NME (US):**
**RG7828** Lunsumio – 3L+ FL

**3 AIs (US):**
**RG7446** Tecentriq – ASPS
**RG1569** Actemra – COVID-19 pneumonia
**RG7421** Cotellic – histiocytosis

**2 AIs (EU):**
**RG6152** Xofluza – influenza pediatric
**RG6013** Hemlibra – moderate hemophilia A

Status as of February 2, 2023

# Roche Group development pipeline

## Phase I (55 NMEs + 12 AIs)

| | | |
|---|---|---|
| RG6007 | HLA-A2-WT1 x CD3 | AML |
| RG6026 | glofitamab monotherapy + combos | heme tumors |
| RG6058 | tiragolumab combos | heme & solid tumors |
| RG6076 | CD19-4-1BBL combos | heme tumors |
| RG6129 | HLA-A2-MAGE-A4 x CD3 | solid tumors |
| RG6160 | cevostamab (FcRH5 x CD3) | r/r multiple myeloma |
| RG6171 | giredestrant (SERD) | solid tumors |
| RG6114 | inavolisib (mPI3K alpha inh) | solid tumors |
| RG6156 | EGFRvIII x CD3 | glioblastoma |
| RG6180 | autogene cevumeran ± T | solid tumors |
| RG6185 | belvarafenib (pan-RAF inh) + Cotellic ± T | solid tumors |
| RG6189 | FAP-CD40 ± T | solid tumors |
| RG6194 | runimotamab (HER2 x CD3) | BC |
| RG6234 | forimtamig (GPRC5D x CD3) | multiple myeloma |
| RG6264 | Phesgo OBI | HER2+ BC |
| RG6279 | PD1-IL2v ± T | solid tumors |
| RG6286 | - | colorectal cancer |
| RG6290 | MAGE-A4 ImmTAC ± T | solid tumors |
| RG6292 | CD25 MAb combos | heme & solid tumors |
| RG6323 | IL15/IL15Ra-Fc ± T | solid tumors |
| RG6330 | KRAS G12C | solid tumors |
| RG6333 | CD19 x CD28 + glofitamab | r/r NHL |
| RG6344 | BRAF inhibitor (3) | solid tumors |
| RG6392 | - | oncology |
| RG6411 | - | solid tumors |
| RG6433 | SHP2i combos | solid tumors |
| RG6440 | TGFβ (SOF10) | solid tumors |
| RG6512 | FIXa x FX | hemophilia |
| RG6524 | - | solid tumors |
| RG6526[1] | camonsertib | solid tumors |
| RG6538[2] | P-BCMA-ALLO1 | multiple myeloma |
| RG7446 | Morpheus platform | solid tumors |
| RG7601 | Venclexta ± azacitidine | r/r MDS |
| RG7802 | cibisatamab ± T | solid tumors |
| RG7827 | FAP-4-1BBL monotherapy + combos | solid tumors |
| RG7828 | Lunsumio monotheraphy + combos | heme tumors |
| CHU | glypican-3 x CD3 | solid tumors |
| CHU | codrituzumab | HCC |
| CHU | CD137 switch antibody | solid tumors |
| CHU | RAS inhibitor | solid tumors |
| CHU | SPYK04 | solid tumors |
| SQZ | PBMC vaccine | solid tumors |
| RG6287 | - | IBD |
| RG6315 | - | immunologic disorders |
| RG6341 | - | asthma |
| RG6421 | TMEM16A potentiator | cystic fibrosis |
| RG6536[3] | vixarelimab | immunology |
| RG7828 | Lunsumio | SLE |
| CHU | anti-HLA-DQ2.5 x gluten peptides | celiac disease |
| CHU | RAY121 | immunology |
| RG6006 | Abx MCP | bacterial infections |
| RG6319 | LepB inhibitor | complicated urinary tract infection |
| RG6035 | BS-CD20 MAb | multiple sclerosis |
| RG6091 | rugonersen (UBE3A LNA) | Angelman syndrome |
| RG6163 | - | psychiatric disorders |
| RG6182 | - | neurodegenerative diseases |
| RG6237 | latent myostatin | neuromuscular disorders |
| RG6289 | - | Alzheimer´s |
| RG6418* | selnoflast | inflammation |
| RG7637 | - | psychiatric disorders |
| RG6120 | VEGF-Ang2 DutaFab | nAMD |
| RG6209 | - | retinal disease |
| RG6312 | - | geographic atrophy |
| RG6351 | - | retinal disease |
| RG6501[4] | OpRegen | geographic atrophy |
| RG7921 | - | RVO |
| CHU | anti-IL-8 recycling antibody | endometriosis |

## Phase II (23 NMEs + 8 AIs)

| | | |
|---|---|---|
| RG6026 | glofitamab + chemo | 1L ctDNA high risk DLBCL |
| RG6058 | tiragolumab + T | NSCLC |
| | tiragolumab + T + chemo | NSCLC neoadj-adj |
| | tiragolumab + T | cervical cancer |
| | tiragolumab + T | 1L PD-L1+ mSCCHN |
| RG6107 | crovalimab | sickle cell disease |
| RG6139 | PD1 x LAG3 | solid tumors |
| RG6180 | autogene cevumeran + pembrolizumab | 1L melanoma |
| RG6354 | zinpentraxin alfa (PRM-151) | myelofibrosis |
| RG6357 | SPK-8011 | hemophilia A |
| RG6358 | SPK-8016 | hemophilia A with inhibitors to factor VIII |
| RG6149 | astegolimab (Anti-ST2) | COPD |
| RG6299[5] | ASO factor B | IgA nephropathy |
| RG7854/ RG6346/ RG6084** | ruzotolimod (TLR7 ago[3])/ xalnesiran (siRNA)/ PDL1 LNA | HBV |
| RG6359 | SPK-3006 | Pompe disease |
| RG1662 | basmisanil | Dup15q syndrome |
| RG6042 | tominersen | Huntington's |
| RG6100 | semorinemab | Alzheimer's |
| RG6102 | trontinemab | Alzheimer's |
| RG6237 | latent myostatin + Evrysdi | SMA |
| RG6416 | bepranemab | Alzheimer's |
| RG7314 | balovaptan | post-traumatic stress disorder |
| RG7412 | crenezumab | familial Alzheimer's healthy pts |
| RG7816 | alogabat (GABA Aa5 PAM) | ASD |
| RG7906 | ralmitaront | schizophrenia |
| RG7935 | prasinezumab | Parkinson's |
| RG6179 | anti-IL-6 | DME |
| RG7774 | vicasinabin (CB2 receptor agonist) | DR |
| RG6299[5] | ASO factor B | geographic atrophy |

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Metabolism
Neuroscience
Ophthalmology
Other

Status as of February 2, 2023

RG-No - Roche/Genentech; CHU - Chugai managed; SQZ - SQZ Biotechnology managed; [1]Repare Therapeutics managed; [2]Poseida Therapeutics managed; [3]Kiniksa Pharmaceuticals managed; [4]Lineage Cell Therapeutics managed; [5]IONIS managed; T=Tecentriq; BS=Brain Shuttle; OBI=On-Body Delivery System; *also developed in Immunology; **combination platform

# Roche Group development pipeline

## Phase III (8 NMEs + 41 AIs)

| | | |
|---|---|---|
| RG3502 | Kadcyla + T | HER-2+ eBC high-risk |
| RG6026 | glofitamab + chemo | 2L+ DLBCL |
| RG6058 | tiragolumab + T | 1L PD-L1+ NSCLC |
| | tiragolumab + T | 1L esophageal cancer |
| | tiragolumab + T | locally advanced esophageal cancer |
| | tiragolumab + T | stage III unresectable 1L NSCLC |
| | tiragolumab + T | 1L non-squamous NSCLC |
| RG6107 | crovalimab* | PNH |
| | crovalimab | aHUS |
| RG6114 | inavolisib (mPI3K alpha inh) | 1L HR+ mBC |
| RG6171 | giredestrant (SERD) | 1L ER+/HER2- mBC |
| | giredestrant (SERD) | ER+ BC adj |
| | giredestrant (SERD) + Phesgo | 1L ER+/HER2+ BC |
| RG6330 | KRAS G12C | 2L NSCLC |
| RG7446 | Tecentriq + platinum chemo | NSCLC periadj |
| | Tecentriq | NMIBC, high-risk |
| | Tecentriq + cabozantinib | RCC adv |
| | T ± chemo | SCCHN adj |
| | T + capecitabine or carbo/gem | 1L TNBC |
| | T + paclitaxel | TNBC adj |
| | T + Avastin | HCC adj |
| | Tecentriq | ctDNA+ high-risk MIBC |
| | T+ lurbinectedin | 1L maintenance SCLC |
| RG7601 | Venclexta | r/r MM t(11:14) |
| | Venclexta + azacitidine | 1L MDS |
| RG7828 | Lunsumio + lenalidomide | 2L+ FL |
| | Lunsumio + Polivy | 2L+ DLBCL |
| RG7853 | Alecensa | ALK+ NSCLC adj |
| RG3648 | Xolair | food allergy |
| RG7159 | Gazyva | lupus nephritis |
| | Gazyva | membranous nephropathy |
| | Gazyva | systemic lupus erythematosus |
| RG6152 | Xofluza | influenza, pediatric (0-1 year) |
| | Xofluza | influenza direct transmission |
| RG1594 | Ocrevus higher dose | RMS & PPMS |
| | Ocrevus SC | RMS & PPMS |
| RG3625 | TNKase | stroke |
| RG6168 | Enspryng | myasthenia gravis |
| RG6168 | Enspryng | MOG-AD |
| RG6168 | Enspryng | autoimmune encephalitis |
| RG6356 | delandistrogene moxeparvovec (SRP-9001) | DMD |
| RG7845 | fenebrutinib | RMS |
| RG7845 | fenebrutinib | PPMS |
| RG6179 | anti-IL-6 | UME |
| RG6321 | Susvimo (PDS) | DME |
| | Susvimo (PDS) | DR |
| | Susvimo (PDS) | wAMD, 36-week |
| RG7716 | Vabysmo (faricimab) | BRVO |
| | Vabysmo (faricimab) | CRVO |

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Metabolism
Neuroscience
Ophthalmology
Other

## Registration US & EU (1 NME + 4 AIs)

| | | |
|---|---|---|
| RG6026 | glofitamab | 3L+ DLBCL |
| RG7446 | Tecentriq SC | all approved indications |
| RG7596 | Polivy[1] | 1L DLBCL |
| RG6413+ RG6412 | Ronapreve[2] | SARS-CoV-2 hospitalised |
| RG7916 | Evrysdi[3] | SMA pediatric <2months |

[1]Approved in EU, filed in US
[2]Filed in EU
[3]Approved in US, filed in EU

T=Tecentriq
PDS=Port Delivery System with ranibizumab
*First filed in China in Q3 2022

Status as of February 2, 2023

# NME submissions and their additional indications

## *Projects in phase II and III*

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Metabolism
Neuroscience
Ophthalmology
Other

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
PDS=Port Delivery System with ranibizumab
Mosun=mosunetuzumab
*First filed in China
[1]IONIS managed

### 2022

| | |
|---|---|
| RG6026 | **glofitamab** 3L+ DLBCL ✓ |
| RG6107 | **crovalimab*** PNH (CN) ✓ |

### 2023

| | |
|---|---|
| RG6058 | **tiragolumab + T** 1L PD-L1+ NSCLC |
| RG6058 | **tiragolumab + T** 1L esophageal cancer (CN) |
| RG6107 | **crovalimab*** PNH (EU, US) |
| RG6321 | **Susvimo (PDS)** DME (US) |
| RG6321 | **Susvimo (PDS)** DR (US) |
| RG7716 | **Vabysmo (faricimab)** BRVO/CRVO |

### 2024

| | |
|---|---|
| RG6026 | **glofitamab + chemo** 2L DLBCL |
| RG6058 | **tiragolumab + T** Stage III unresectable 1L NSCLC |
| RG6107 | **crovalimab** aHUS |
| RG6114 | **inavolisib (mPI3K alpha inh)** 1L HR+ BC |
| RG6356 | **delandistrogene moxeparvovec (SRP-9001)** DMD (EU) |

### 2025 and beyond

| | |
|---|---|
| RG6026 | **glofitamab + chemo** 1L ctDNA+ high risk DLBCL |
| RG6058 | **tiragolumab + T** 1L PD-L1+ cervical cancer |
| RG6058 | **tiragolumab + T** locally adv esophageal cancer |
| RG6058 | **tiragolumab + T** 1L non-sq NSCLC |
| RG6058 | **tiragolumab + T** 1L PD-L1+ mSCCHN |
| RG6058 | **tiragolumab+T+/- chemo** NSCLC neoadj/adj |
| RG6107 | **crovalimab** sickle cell disease |
| RG6139 | **PD1xLAG3** solid tumors |
| RG6171 | **giredestrant (SERD)** 1L ER+/HER2- mBC |
| RG6171 | **giredestrant (SERD)** ER+ BC adj |
| RG6171 | **giredestrant (SERD) + Phesgo** 1L ER+/HER2+ BC |
| RG6180 | **autogene cevumeran** 1L melanoma |
| RG6330 | **KRAS G12 C** 2L NSCLC |
| RG6354 | **zinpentraxin alfa (PRM-151)** myelofibrosis |
| RG7828 | **Lunsumio (mosun) + lenalidomide** 2L FL |
| RG7828 | **Lunsumio (mosun) + Polivy** 2L+ DLBCL (US) |
| RG6149 | **astegolimab (anti-ST2)** COPD |
| RG6299[1] | **ASO factor B** IgA nephropathy |
| RG7854/ RG6346/ RG6084 | **ruzotolimod (TLR7 ago [3])/ xalnesiran (siRNA)/ PDL1 LNA** HBV |
| RG1662 | **basmisanil** Dup15q syndrome |
| RG6042 | **tominersen** Huntington's |
| RG6100 | **semorinemab** Alzheimer's |
| RG6102 | **trontinemab** Alzheimer's |
| RG6237 | **latent myostatin + Evrysdi** SMA |
| RG6416 | **bepranemab** Alzheimer's |
| RG7314 | **balovaptan** post-traumatic stress disorder |
| RG7816 | **alogabat (GABA Aa5 PAM)** ASD |
| RG7845 | **fenebrutinib** RMS |
| RG7845 | **fenebrutinib** PPMS |
| RG7906 | **ralmitaront** schizophrenia |
| RG7935 | **prasinezumab** Parkinson's |
| RG6179 | **anti-IL-6** UME |
| RG6179 | **anti-IL-6** DME |
| RG6299[1] | **ASO factor B** geographic atrophy |
| RG6321 | **Susvimo (PDS)** wAMD, 36-week refill |
| RG7774 | **vicasinabin (CB2 receptor agonist)** DR |

Status as of February 2, 2023

# AI submissions for existing products

*Projects in phase II and III*

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases

Metabolism
Neuroscience
Ophthalmology
Other

| 2022 | | 2023 | | 2023 | | 2024 | | 2025 and beyond | |
|---|---|---|---|---|---|---|---|---|---|
| RG6413+ RG6412 | **Ronapreve**** SARS-CoV-2 hospitalized (EU) ✓ | RG6264 | **Phesgo OBI** HER2+ BC | | | RG7446 | **Tecentriq**[1] NSCLC periadj | RG3502 | **Kadcyla + Tecentriq** HER-2+ eBC high-risk |
| | | RG6396 | **Gavreto** Tumor agnostic (US) | | | RG7446 | **Tecentriq** SCCHN adj | RG7446 | **Tecentriq** High-risk NMIBC |
| | | RG7446 | **Tecentriq + cabozantinib** RCC adv | RG1594 | **Ocrevus SC** RMS & PPMS | RG7446 | **Tecentriq + paclitaxel** TNBC adj | RG7446 | **Tecentriq+ lurbinectedin** 1l maintenance SCLC |
| RG1569 | **Actemra** COVID-19 pneumonia ✓ | RG7446 | **Tecentriq + Avastin** HCC adj | RG3625 | **TNKase** stroke | RG7446 | **Tecentriq** ctDNA+ high-risk MIBC | RG7159 | **Gazyva** membranous nephropathy |
| RG7446 | **Tecentriq SC** all approved indications ✓ | RG7601 | **Venclexta** r/r MM t(11:14) | RG3648 | **Xolair** food allergy | RG7601 | **Venclexta + azacitidine** 1L MDS | RG7159 | **Gazyva** systemic lupus erythematosus |
| RG7596 | **Polivy** 1L DLBCL (US) ✓ | RG7446 | **Tecentriq + capecitabine or carbo/gem** TNBC | RG6152 | **Xofluza** direct transmission | RG7159 | **Gazyva** lupus nephritis | RG1594 | **Ocrevus higher dose** RMS & PPMS |
| | | RG7853 | **Alecensa** ALK+ NSCLC adj | RG6152 | **Xofluza** influenza, pediatric (0-1 year) | RG6168 | **Enspryng** myasthenia gravis | RG6168 | **Enspryng** MOG-AD |
| | | | | | | | | RG6168 | **Enspryng** autoimmune encephalitis |

Status as of February 2, 2023

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
[1]filing timeline based on data from interim analysis

OBI=On-Body Delivery System
**Ronapreve (casirivimab+imdevimab also known as REGEN-COV in the US) developed in collaboration with Regeneron Pharmaceuticals

# Major pending approvals 2022

| US | | EU | | China | | Japan-Chugai | |
|---|---|---|---|---|---|---|---|
| RG7596 | **Polivy**<br>1L DLBCL (US)<br>Filed Aug 2022 | RG7916 | **Evrysdi**<br>SMA presymptomatic pediatric <2mo<br>Filed Nov 2021 | RG7916 | **Evrysdi**<br>SMA presymptomatic pediatric <2mo<br>Filed June 2022 | RG6264 | **Phesgo**<br>HER-2+ BC/CC<br>Filed Sept 2022 |
| RG7446 | **Tecentriq SC**<br>all approved indications<br>Filed Nov 2022 | RG6413+ RG6412 | **Ronapreve***<br>SARS-CoV-2 hospitalized<br>Filed Jan 2022 | RG6264 | **Phesgo**<br>HER-2+ BC<br>Filed July 2022 | | |
| RG6026 | **glofitamab**<br>3L+ DLBCL<br>Filed Dec 2022 | RG6026 | **glofitamab**<br>3L+ DLBCL<br>Filed April 2022 | RG6107 | **crovalimab**<br>PNH<br>Filed Aug 2022 | | |
| | | RG1569 | **Actemra**<br>SS-ILD<br>Filed Aug 2022 | RG6026 | **glofitamab**<br>3L+ DLBCL<br>Filed Dec 2022 | | |
| | | RG7446 | **Tecentriq SC**<br>all approved indications<br>Filed Nov 2022 | | | | |

Status as of February 2, 2023

New Molecular Entity (NME)
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Ophthalmology
Other

PDS=Port Delivery System with ranibizumab
SC=Subcutaneous
*Ronapreve (casirivimab+imdevimab also known as REGEN-COV in the US) developed in collaboration with Regeneron Pharmaceuticals

# Major granted approvals 2022 and 2023 YTD

| US | |
|---|---|
| RG7716 | **Vabysmo (faricimab)**<br>DME<br>Jan 2022 |
| RG7716 | **Vabysmo (faricimab)**<br>wAMD<br>Jan 2022 |
| RG1569 | **Actemra**<br>GCA IV<br>Feb 2022 |
| RG7916 | **Evrysdi**<br>SMA presymptomatic pediatric <2mo<br>May 2022 |
| RG6152 | **Xofluza**<br>influenza pediatric<br>Aug 2022 |
| RG7421 | **Cotellic**<br>histiocytosis<br>Oct 2022 |
| RG7446 | **Tecentriq**<br>ASPS<br>Dec 2022 |
| RG7828 | **Lunsumio (mosunetuzumab)**<br>3L+ FL<br>Dec 2022 |
| RG1569 | **Actemra**<br>COVID-19 pneumonia<br>Dec 2022 |

| EU | |
|---|---|
| RG7596 | **Polivy**<br>1L DLBCL<br>May 2022 |
| RG7446 | **Tecentriq**<br>NSCLC adj<br>June 2022 |
| RG7828 | **Lunsumio (mosunetuzumab)**<br>3L+ FL<br>June 2022 |
| RG7716 | **Vabysmo (faricimab)**<br>DME<br>Sept 2022 |
| RG7716 | **Vabysmo (faricimab)**<br>wAMD<br>Sept 2022 |
| RG6152 | **Xofluza**<br>influenza pediatric<br>Jan 2023 |
| RG6013 | **Hemlibra**<br>moderate hemophilia A<br>Jan 2023 |

| China | |
|---|---|
| RG7446 | **Tecentriq**<br>NSCLC adj<br>March 2022 |
| RG1569 | **Actemra**<br>RA SC<br>April 2022 |
| RG6268 | **Rozlytrek**<br>NTRK+ solid tumors<br>July 2022 |
| RG6268 | **Rozlytrek**<br>ROS1+ NSCLC<br>Aug 2022 |
| RG7596 | **Polivy**<br>1L DLBCL<br>Jan 2023 |
| RG7596 | **Polivy**<br>r/r DLBCL<br>Jan 2023 |

| Japan-Chugai | |
|---|---|
| RG1569 | **Actemra**<br>COVID-19 pneumonia<br>Jan 2022 |
| RG7716 | **Vabysmo (faricimab)**<br>DME<br>March 2022 |
| RG7716 | **Vabysmo (faricimab)**<br>wAMD<br>March 2022 |
| RG1273 | **Perjeta + Herceptin**<br>HER-2+ CRC<br>March 2022 |
| RG7446 | **Tecentriq**<br>NSCLC adj<br>May 2022 |
| RG6013 | **Hemlibra**<br>acquired Hemophilia A<br>June 2022 |
| RG105 | **Rituxan**<br>NMOSD<br>June 2022 |
| RG7596 | **Polivy**<br>1L DLBCL<br>Aug 2022 |
| RG7159 | **Gazyva**<br>1L CLL<br>Dec 2022 |

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# Doing now what patients need next