# Investor Update



Basel, 1 February 2017

### Roche reports good results in 2016

- Group sales increase 4%<sup>1</sup> at constant exchange rates, 5% in Swiss francs
- Pharmaceuticals Division sales up 3%, mainly driven by cancer medicines Perjeta and Herceptin as well as Actemra/RoActemra
- Diagnostics Division sales grow 7%, driven primarily by immunodiagnostic solutions
- Successful launches of four new medicines; five US FDA breakthrough therapy designations granted
- Emicizumab prophylaxis shows positive results in people with haemophilia A in pivotal trial
- Successful launch of new immunochemistry instrument cobas e 801
- Core earnings per share up 5% at constant exchange rates, 8% in Swiss francs
- Board proposes dividend increase to CHF 8.20
- Outlook for 2017: sales expected to grow low- to mid-single digit, at constant exchange rates. Core earnings per share targeted to grow broadly in line with sales, at constant exchange rates. Roche expects to further increase its dividend in Swiss francs.

Key figures 2016	CHF m	nillions	% change		
	2016	2015	CER <sup>1</sup>	CHF	
Group sales	50,576	48,145	+4	+5	
Pharmaceuticals Division	39,103	37,331	+3	+5	
Diagnostics Division	11,473	10,814	+7	+6	
Core operating profit	18,420	17,542	+4	+5	
Core EPS - diluted (CHF)	14.53	13.49	+5	+8	
IFRS net income	9,733	9,056	+7	+7	

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<sup>&</sup>lt;sup>1</sup> Unless otherwise stated, all growth rates in this document are at constant exchange rates (CER: average 2015).

Commenting on the Group's results, Roche CEO Severin Schwan said: «I am pleased that we have again reached all our financial targets while our product portfolio has made significant progress. We brought four new medicines to market in less than a year, including our first cancer immunotherapy Tecentriq. In Diagnostics, we launched an immunodiagnostic instrument, the cobas e 801, which represents a major step forward in realising the connected laboratory. We again look forward to a number of important clinical read-outs and regulatory milestones for Roche medicines this year, reflecting our broad and innovative product pipeline.»

### **Group results**

### Good performance in both divisions

Group sales rose 4% to CHF 50.6 billion. Despite high investments in the launch of new products and product development, core EPS grew faster than sales (+5%). Core EPS growth reflects the good underlying business performance and an impact from changes to the Group's Swiss pension plans. IFRS net income was up 7% at constant exchange rates and in Swiss francs.

Sales in the Pharmaceuticals Division rose 3% to CHF 39.1 billion, driven by growth of Perjeta, Herceptin and Actemra/RoActemra, partially offset by lower sales of Pegasys, Tarceva and Lucentis.

In the US, Pharmaceuticals sales advanced 3%, led by the respiratory medicines Xolair and Esbriet. The recently launched medicines Tecentriq and Alecensa contributed to the growth as well. Sales of eye drug Lucentis and cancer medicines Avastin and Tarceva declined due to growing use of other therapeutic options. In Europe, sales growth of 4% was driven by Perjeta, Actemra/RoActemra and MabThera/Rituxan. In Japan, sales grew 1% despite the biennial price cuts and a special price reduction rule for best-selling medicines. Tamiflu, Alecensa and Actemra/RoActemra were key sales contributors. In the International region, sales gained 4%, driven by the Asia-Pacific and Latin America subregions.

Diagnostics divisional sales increased 7% to CHF 11.5 billion – above market growth. Centralised and Point of Care Solutions<sup>2</sup> was the main contributor, led by its immunodiagnostics business.

In the EMEA<sup>3</sup> (+2%) and North America (+3%) regions, the division's largest markets, the sales increases were led by Centralised and Point of Care Solutions. Sales growth in North America was partially offset by a decline in Diabetes Care business, which faced continued pricing pressure. The sales increase in Asia-Pacific (+16%) was mainly driven by China. In Latin America, sales advanced 18%. Sales growth in Japan (+2%) was also led by the Centralised and Point of Care Solutions business.

<sup>&</sup>lt;sup>2</sup> Formerly Roche Professional Diagnostics

<sup>&</sup>lt;sup>3</sup> EMEA= Europe, Middle East, Africa

#### High number of launches in Pharmaceuticals

Roche recently launched four new medicines: Cotellic (advanced melanoma), Alecensa (lung cancer), Venclexta (chronic lymphocytic leukemia; jointly commercialised with AbbVie) and Tecentriq (bladder and lung cancer). In addition, five FDA breakthrough therapy designations were granted for Roche medicines in 2016. A major highlight was the US launch of Roche's cancer immunotherapy medicine Tecentriq in May. It is the first FDA-approved treatment for people with a specific type of bladder cancer in more than 30 years. Furthermore, in October the FDA cleared Tecentriq for use in previously treated metastatic non-small cell lung cancer (NSCLC). The pivotal Oak trial showed that people with this form of lung cancer who received Tecentriq live significantly longer, regardless of their PD-L1 status, compared with those receiving chemotherapy. Additional data presented at the ECTRIMS<sup>4</sup> congress in September showed that Roche's ocrelizumab increased disease control in both relapsing and primary progressive multiple sclerosis (RMS and PPMS). Roche is seeking regulatory approval for this medicine in RMS and PPMS in the US and the EU. The US FDA's action date for a decision is March 28, 2017.

Roche also presented other important clinical results in 2016. A pivotal study in a group of people with haemophilia A (Haven 1) showed that prophylaxis with emicizumab led to a significant reduction in the number of bleeds over time. A phase III study by Chugai (J-Alex) found that first-line treatment with Alecensa significantly reduced the risk of disease worsening or death compared to crizotinib, the current standard of care, in people with ALK-positive NSCLC. While Gazyva/Gazyvaro showed positive results in a major clinical trial (Gallium) in follicular lymphoma, a separate trial (Goya) of the medicine in diffuse large B-cell lymphoma, did not reach its primary study goal. Also in 2016, Roche presented data from the largest clinical trial ever conducted in giant cell arteritis (GCA), a serious inflammatory disease of blood vessels. Initially combined with a steroid regimen, Actemra/RoActemra more effectively sustained remission compared to a steroid-only regimen in people with newly diagnosed and relapsing GCA.

### Further broadening the Diagnostics portfolio

During 2016, Roche added nine key instruments and tests to its comprehensive portfolio, further improving decision-making in healthcare, and supporting laboratories' efforts to increase efficiency. Among the new instruments are the cobas e 801 immunoassay module, the CoaguChek INRange system to monitor vitamin K antagonist therapy, and the Accu-Chek Guide, a next-generation blood glucose monitoring system.

The US-FDA approved two accompanying diagnostics: the Ventana PD-L1 (SP142) test is a complementary diagnostic which determines PD-L1 status of patients with bladder and lung cancer. The cobas EGFR Mutation test v2 is a companion diagnostic for lung cancer medicine Tarceva. The FDA also granted

<sup>&</sup>lt;sup>4</sup> European Committee for Treatment and Research in Multiple Sclerosis

premarket clearance and a CLIA<sup>5</sup> waiver for the cobas Liat Influenza A/B & RSV test. This is the first pointof-care test that extends molecular testing on the Liat system beyond influenza A/B and *Streptococcus A* to include respiratory syncytial virus (RSV). The FDA also approved Roche tests for the detection of Zika virus.

### Outlook for 2017

In 2017, Roche expects sales to grow low- to mid-single digit, at constant exchange rates. Core earnings per share are targeted to grow broadly in line with sales, at constant exchange rates. Roche expects to further increase its dividend in Swiss francs.

### **Dividend proposal**

The Board of Directors proposes a dividend increase to CHF 8.20 per share and non-voting equity security. Subject to approval by the Annual General Meeting of shareholders on 14 March 2017, this will be Roche's 30th consecutive annual dividend increase.

Key figures 2016	In millions of CHF		As % of sales		% change	
	2016	2015	2016	2015	At CER	In CHF
Pharmaceuticals Division	39,103	37,331	100	100	+3	+5
United States	18,594	17,616	49	47	+3	+6
Europe	9,159	8,734	23	23	+4	+5
Japan	3,711	3,224	9	9	+1	+15
International*	7,639	7,757	19	21	+4	-2

### **Pharmaceuticals Division**

\*Asia–Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, Others

### Key pharmaceutical products in 2016

**Herceptin, Perjeta** and **Kadcyla** (combined +8%). For HER2-positive breast cancer and HER2-positive metastatic gastric cancer (Herceptin only). **Herceptin** sales were up 4%, helped by additional reimbursement approvals in China and continued growth in the US due to longer duration of treatment in combination with Perjeta. **Perjeta** sales (+26%) advanced particularly strongly in Europe and the US, where the medicine was approved for use before surgery in early breast cancer. **Kadcyla** sales (+7%) were fuelled by increasing demand in the International region, due mainly to expanded access in countries in which the medicine was newly launched.

<sup>&</sup>lt;sup>5</sup> CLIA= Clinical Laboratory Improvement Amendments

**MabThera/Rituxan** (+3%). For common forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales continued to rise despite competitive pressure. Increasing demand was mainly seen in China, the US and Europe. Growth in China was supported by expanded regional access, largely in diffuse large B-cell lymphoma.

Avastin (0%). For advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, and relapsed glioblastoma (a type of brain tumour). Sales continued to grow strongly in the International region (+18%), especially China, following the approval of the lung cancer indication in 2015. Sales in the US, where Avastin is already broadly used in its approved indications, declined 5%, largely due to growing use of new immunotherapy agents in the lung cancer setting.

Actemra/RoActemra (+16%). For rheumatoid arthritis and forms of juvenile idiopathic arthritis. Increasing use of Actemra/RoActemra as a single agent and of the subcutaneous formulation remained key growth drivers globally.

**Esbriet** (+34%). For idiopathic pulmonary fibrosis (IPF). Sales continued to expand, mostly due to increasing use in people with moderate and progressive disease. Roche is stepping up its efforts in various markets to improve disease awareness and inform patients and caregivers of the need for early and sustained treatment of IPF.

**Gazyva/Gazyvaro** (+52%). For chronic lymphocytic leukaemia (CLL) and rituximab-refractory follicular lymphoma. Sales expanded in the US and Europe despite increasing competition in CLL. Gazyva/Gazyvaro is now approved for CLL in more than 60 countries. Following US and EU approval of the medicine in previously treated follicular lymphoma in the first half of 2016, early uptake in this indication has been encouraging.

Recently launched medicines showed good sales performance. Alecensa (CHF 182 million) is for people with ALK-positive advanced NSCLC whose disease has progressed on, or who are intolerant to crizotinib. There was very good uptake in the US, driven by strong demand in the previously treated patient population. Sales growth remained strong in Japan, where the medicine was launched in 2014 for a broader patient population, including people who have not received prior treatment with crizotinib. Following FDA approval of **Tecentriq** (CHF 157 million) in bladder and lung cancer, in May and October respectively, market uptake in the US has been strong. **Cotellic** (CHF 45 million) plus Zelboraf for BRAF-mutated metastatic melanoma showed good sales uptake, especially in major markets such as France and the US.

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