



MEMORANDUM

Roche 1Q14 - Worldwide Diabetes Care flat, North America Diabetes Care up a surprising 6%; Accu-Chek Insight launched in the EU - April 15, 2014

Executive Highlights

- Worldwide Diabetes Care totaled 538 million CHF (~\$603 million) in 1Q14, down 0.2% as reported and up 5% operationally.
- Notably, North America sales grew 6% as reported and 13% operationally YOY; international revenue (EMEA and RoW) fell 2% as reported YOY.
- The Accu-Chek Insight insulin pump system (next-gen pump + meter remote) was launched in the EU.

Early this morning, Roche CEO Severin Schwan led the company's 1Q14 financial update. Below, we have for you our top five highlights from the report:

- 1. Worldwide Diabetes Care sales totaled 538 million CHF (~\$603 million), down 0.2% as reported year-over-year (YOY) and up 5% operationally. Sales in North America reached 100 million CHF (~\$112 million), growing a positive 6% as reported YOY and 13% operationally; in a twist from what we've come to expect, international sales actually performed slightly worse, with revenue totaling 438 million CHF (~\$491 million) down 2% as reported. We'd note that only ~20% of Roche's worldwide business comes from the US (per comments in [4Q13](#)), so it is more shielded from competitive bidding than other companies.*
- 2. Commentary from management on how to (cautiously) view this growth, including considering a low 1Q13 base and a change in rebate timing. Said management in Q&A, "We'll continue to see a volatile market and environment."*
- 3. Combined revenue for J&J and Roche - worldwide revenue totaled ~\$1.1 billion, down 6% YOY (driven by J&J's 32% decline in US sales)*
- 4. Roche launched the Accu-Chek Insight insulin pump system (next-gen pump + meter remote) in the EU, consistent with the timing given in the [4Q13 call](#). The company expects to launch the Bluetooth-enabled Accu-Chek Connect meter in the EU before the end of the year.*
- 5. A review of Roche's drug pipeline - no updates on the company's cardiometabolic drugs in development, which include a phase 1 GLP-1/GIP dual agonist and a PCSK9 inhibitor).*

Additionally, we also have for an honorable mention on Roche/Genentech's Lucentis (intravitreal ranibizumab), a drug that continues to be a top driver for Roche. Our report concludes with diabetes-related questions and answers.

TOP FIVE HIGHLIGHTS

1. Roche worldwide Diabetes Care sales totaled 538 million CHF (~\$603 million) in 1Q14, down 0.2% as reported and up 5% operationally. This was an easy comparison, as revenue dropped 4% as reported in 1Q13 (-5% operationally). Sequentially, global Diabetes Care declined 21%; while this drop is steep, revenue has consistently declined in the double-digits between 4Q to 1Q (since we began reporting in 2006). Blood glucose meter (BGM) revenue grew 4% operationally YOY, while "other" Diabetes Care products (insulin delivery) grew 11% operationally, based on a slide presented during the financial call. While it is

difficult to determine the exact revenue from the chart (due to a broad value range), we estimate that Roche's BGM business makes up ~92% of its Diabetes Care business, consistent with previous reports.

- **In North America, Diabetes Care sales reached 100 million CHF (~\$112 million) in 1Q14, up 6% as reported and 13% operationally YOY.** It was notable to see Roche report more positive numbers in a market that has been plagued with competitive bidding and pricing pressures; however, as Roche itself emphasized, this was an easy comparison, since North America revenue fell 21% YOY in 1Q13. As a reminder, Roche does not break out its US Diabetes Care business from North America; however, management did report in 4Q13 that for 2013, the US made up only ~20% of the company's worldwide business. As a result, the smaller decline relative to competitor J&J (see below) is to be expected.
- **Outside of North America, Diabetes Care revenue totaled 438 million CHF (~\$491 million), down 2% as reported.** Roche breaks out its international revenue into two groups: Europe, Middle East, and Africa (EMEA) and Latin America, Asia-Pacific, and Japan (RoW). Sales in EMEA reached 341 million CHF (~\$382 million), down 1% as reported and up 1% operationally; revenue in RoW totaled 97 million CHF (~\$109 million), down 5% as reported but up 10% operationally YOY. However, EMEA faced a more challenging comparison than RoW, with 3% growth and an 8% decline in 1Q13, respectively. Sequentially, revenue outside of North America fell 20%, with EMEA revenue declining 16% and RoW sales declining a steep 30%.
- **Roche presented a slide depicting Diabetes Care as 22% of Roche's Diagnostic Division,** making it the second largest division after Professional Diagnostics (57%). We found it helpful that Roche reported this breakdown of the Diagnostic Division - given management's comments on continued pricing pressures and volatility, this percentage of the Diagnostic Division could be expected to shrink over time.

2. During the company's prepared remarks, management commented on the company's 5% growth in Diabetes Care, pointing out two contributing factors: (i) a low revenue base comparison to 1Q13; and (ii) the change in rebate timing from late 2013 to early 2014. Regarding the latter, management remarked that there was a change in ordering patterns in some of the wholesalers, which increased revenue. Despite this cautious optimism from the company, management did remark that Accu-Chek Aviva and Accu-Chek Performa meters had good uptake in 1Q14, and that the Accu-Chek Mobile saw increased penetration in the market, particularly in the EU; as a reminder, the next-generation Accu-Chek Mobile BGM was launched in the EU in 1H12.

- **The hesitation stemmed from the ongoing extremely challenging reimbursement environment;** during Q&A, management responded to a question on pricing cuts from 2013, commenting that the market will continue to be "volatile." Roche remarked that there will sort of "annualization" of CMS' competitive bidding at the beginning of the third quarter, since that was the first full quarter of competitive bidding. While management does not expect that any reimbursement cuts, the company also emphasized that some countries introduce reimbursement cuts with "relatively short notice."
- **Unlike 4Q13, Roche did not mention the reorganization of its Diabetes Care business,** which the company had commented would continue into 2014. The supplementary materials had highlighted that in September 2013, Roche announced its "Autonomy and Speed" initiative, aimed at focusing on diabetes-specific requirements and speeding up processes and decision making in order to drive efficiencies.

3. Combined 1Q14 worldwide revenue for J&J and Roche totaled ~\$1.1 billion, falling 6% as reported from pooled revenue in 1Q13. Pooled US revenue totaled \$304 million in 1Q14, dropping a marked 21% YOY as reported; this was driven entirely by J&J's BGM business, which fell 32% from 1Q13 to 1Q14. As noted above, for 2013, the US made up only ~20% of Roche's worldwide business. J&J's staggeringly negative performance once again points to the difficulties BGM companies are facing since CMS' competitive bidding initiated at the beginning of 3Q13 (combined revenue for the Big Four - J&J, Roche, Abbott, and Bayer - dropped between 5-10% YOY in 3Q13, between 6-8% YOY in 4Q13, and between 5-7% YOY for the full

year 2013 - as a reminder, we estimate Bayer's Contour revenue, therefore creating a range for the Big Four's pooled revenue). Internationally in 1Q14, J&J and Roche revenue totaled \$811 million, up 2% from 1Q13; for the past six quarters, J&J has consistently fared better in its international business than its US business.

- **Of the combined worldwide revenue for J&J and Roche in 1Q14, Roche held 54%**, up from 49% of the companies' pooled revenues in 1Q13. J&J and Roche held the majority of the BGM market in 2013 (~65%-67%).

Table 2: 1Q14 Roche and J&J Diabetes Care Revenue Comparison

Company	Worldwide		US		International	
	1Q14 Revenue in Millions	Reported (Operational) Growth from 1Q13	1Q14 Revenue in Millions	Reported (Operational) Growth from 1Q13	1Q14 Revenue in Millions	Reported (Operational) Growth from 1Q13
Roche	\$603	-0.2% (5%)	\$112	6.4% (13%)	\$491	-1.6%
J&J	\$512	-14.7 (-13.7%)	\$192	-32.2%	\$320	0.9% (2.9%)

Currency conversion for Roche is based on the average exchange rate on oanda.com (e.g., 1.1200 USD per CHF for January 1 - March 31). Different results are possible with different currency conversion. Roche does not report revenues for an international category, and the international value we report includes the company's EMEA and RoW categories; as such, operational growth is not available. We also note that Roche's US value is slightly inflated, as it includes revenue from Canada ("North America" sales). Reported growth fro Roche is calculated based on CHF.

4. Roche launched the Accu-Chek Insight insulin pump system (next-gen pump + meter remote) in the EU. The company's second goal for 2014 is to launch the Bluetooth-enabled Accu-Chek Connect meter in the EU before the end of the year. For background, we first heard about the Accu-Chek Connect in Roche's [4Q13 financial update](#) - according to the slide deck, the meter will have Bluetooth connectivity to a smartphone app and the cloud. The company is planning to first develop an Android app, followed by apps for addition mobile platforms.

- **We heard no updates on Roche's Accu-Chek Aviva Expert (meter with built-in bolus advisor), the Solo Micropump (Roche's patch pump), or Roche's CGM.** Regarding the latter, we heard accuracy and precision data at [ADA](#) as well as at the [Diabetes Technology Meeting](#) in October (MARD: 8.6% for Roche vs. 10.9% for Dexcom) and ATTD. At [ATTD](#), we also heard that the company is looking to improve the system for the artificial pancreas.

5. Turning to the drug pipeline, Roche also did not mention any of its remaining cardiometabolic drugs in development (which include a phase 1 GLP-1/GIP dual agonist and a PCSK9 inhibitor). According to the company's pipeline, Roche's GLP-1/GIP dual agonist, MAR709/RG7697, remains in a phase 1 study with a primary endpoint of safety and PK (not on ClinicalTrials.gov). Roche's PCSK9 inhibitor RG7652 remains in a phase 2 trial (EQUATOR) for subcutaneous dosing every four weeks with five doses of the drug; internal readouts were expected by the end of 2013, and no data have been released publically yet. We have not heard of a partner for the drug, and Roche has said before that the company will not advance the drug without a partner for the candidate.

- **As a reminder, Roche discontinued its PPAR-alpha/gamma dual agonist aleglitazar** due to lack of efficacy and increased rates of adverse events including fractures, GI bleeding, renal impairment, and heart failure - we recently heard the results from AleCardio (aleglitazar's CVOT that was terminated early for futility) at [ACC 2014](#); in a futility analysis, 55% of planned events accrued predicted 1% chance of success.

HONORABLE MENTION

- **Roche/Genentech's diabetic macular edema (DME) drug Lucentis (intravitreal ranibizumab) revenue totaled 407 million CHF (\$456 million) in 1Q14**, up 4% as reported and 8% operationally YOY. Lucentis has consistently been a driver of growth for Roche, this quarter reaching the eighth spot on Roche's global top 20 products (in 1Q13, the drug came in first, dropping to number 22 in 4Q13). Management commented that it expects to see "additional competition" in the DME setting in 2H14, as well as additional growth for Lucentis - in terms of the competition, Roche is likely referring to two products: (i) [Bayer/Regeneron's](#) anti-VEGF agent, Eylea (afibercept), which had its Biologics License Application for a DME indication accepted by the FDA, placing an approval in August 2014; and (ii) [Alimera's Iluvien](#), which was recently resubmitted to the FDA for a DME indication for the fourth time.

Questions and Answers

Q: Could you give us an update on the outlook for Diabetes Care in 2014? Could the new launch offset the pricing cuts we are going to continue to see in 2014?

A: **We are kind of seeing an annualization from the CMS' competitive bidding that started on July 1, but I would be cautious because many of these cuts have been anticipated. We'll continue to see a volatile market and environment.**

We don't expect any major reimbursement cuts, but, as in the past, some countries move into reimbursement cuts with relatively short notice. Then again, we saw a very soft first quarter last year. This is why we have seen a bit of an uptake here in 1Q14 - this, in addition to the changing pattern we're seeing in which wholesale is responding to rebates in 1Q14 rather than 4Q13.

All of these contributed favorably to the first quarter. I would expect some slowing of growth, of course; however, the uptake in new products are encouraging, as is the ongoing penetration of existing products like the Accu-Chek Mobile in the EU.

Q: There was a fairly generic comment in the presentation about Lucentis and DME; you mentioned Lucentis gaining an increasing amount of the market share in DME - could you be a bit more precise about what you're seeing in these markets relative to off-label use?

A: For DME in particular, we're at about 20% of the share and about a year ago we were at about 14%, so we continue to see very good uptake in the market. Predominately, there is some offset from Avastin and also growth in that market, but there is good, solid uptake in DME.

--by Hannah Martin, Adam Brown, and Kelly Close