
Roche 3Q15 - Record lows for Global, North America, and International segments; Pooled J&J, Abbott, Roche sales fall 17% YOY; Lucentis down 18% - October 29, 2015

Executive Highlights

- Roche's 3Q15 update set record revenue lows (in our model) for the Global, North America, and International segments. Global sales declined 18% as reported and 9% operationally to 476 million CHF (~\$494 million). International sales fell 14% to 407 million CHF (~\$422 million), while North American sales fell a striking 37% to 69 million CHF (~\$72 million).
- Pooled global revenue for J&J, Roche, and Abbott totaled ~\$1.2 billion in 3Q15, falling a sizable 17% relative to pooled revenue in [3Q14](#) (~\$1.5 billion). The weakness stems from currency headwinds, pricing pressure, and presumably ever-increasing low-cost competition and better type 2 oral therapies.
- There were no pipeline updates on Roche's novel CGM or the Solo MicroPump.

Roche CEO Mr. Severin Schwan recently led the company's [3Q15 financial update](#). Below, we have for you our top ten highlights from the update. There was no diabetes relevant Q&A.

Financial Highlights

1. Global Diabetes Care revenue totaled 476 million CHF (~\$494 million) in 3Q15, declining 18% as reported and 9% operationally year-over-year (YOY). This marks the lowest global revenue ever recorded in our Roche model, stretching back over a decade. The silver lining continues to be Insulin Delivery systems, which has grown 8% operationally in 2015.

2. In North America, Diabetes Care revenue totaled a record-low 69 million CHF (~\$72 million), falling a striking 37% against an easy comparison to [3Q14](#) (sales fell 2%). YOY revenue has come in under 100 million CHF for three consecutive quarters - the first time we have seen this pattern in our Roche model.

3. Outside North America, Diabetes Care sales totaled a record-low 407 million CHF (~\$422 million), falling 14% as reported YOY against an easy comparison (down 2%) in 3Q14. This was split into: (i) sales in EMEA, which totaled 294 million CHF (~\$305 million), down 15% as reported after growing 2% in 3Q14, and; (ii) sales in RoW, which totaled 113 million CHF (~\$117 million), down 9% as reported after growing 1% a year ago.

Pooled BGM Financial Highlights

4. Pooled global revenue for J&J, Roche, and Abbott totaled ~\$1.2 billion in 3Q15, falling 17% relative to pooled revenue in [3Q14](#) (~\$1.5 billion). We attribute the weakness to a combination of currency headwinds, pricing pressure, and presumably ever-increasing low-cost competition and better type 2 oral therapies.

Device Pipeline Highlights

5. Roche did not share any major pipeline updates. The call did not reference the development of the company's novel CGM or the Solo MicroPump (Roche's patch pump).

6. Roche rolled out its next-gen cobas c 513 A1c analyzer in the EU in [3Q15](#), calling the launch a "key" pipeline development. [Roche's slide deck](#) puts the market potential for A1c testing at ~520 million CHF (we're not sure what it totals now).

7. Though not mentioned during the update, Roche launched its Accu-Chek Connect BGM and paired smartphone app (with a bolus calculator) in the US in early August - see [our full coverage](#) and [read the diaTribe test drive](#).

8. As in [2Q15](#), Roche's [supplementary materials](#) (slide 165) also highlighted the 2015 worldwide launch of the Accu-Chek Active BGM. This is a new meter platform, and though few details are available, we believe it has relatively basic features (e.g., no smartphone/cloud-connectivity).

Drug Pipeline Highlights

9. US sales of Lucentis (intravitreal ranibizumab) declined a striking 24% YOY as reported and 18% in constant currencies to 327 million CHF (~\$339 million) in 3Q15. Management acknowledged increased competition for Lucentis in diabetic macular edema, in line with previous updates.

10. Q&A commentary predicted that increased pricing pressure will force pharmaceutical companies to double down on either highly innovative or low-cost products, with those in the middle getting squeezed out.

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Financial Highlights

1. Global Diabetes Care revenue totaled 476 million CHF (~\$494 million) in 3Q15, declining 18% as reported and 9% operationally year-over-year (YOY). The performance marks the lowest global revenue ever recorded in our Roche model - which stretches back to 2004 - and comes against a relatively easy comparison to sales growth of 1% as reported and 4% operationally YOY in [3Q14](#). It's hard to know how real the "record low" is given the way currency headwinds are diluting reported performance, though the 9% operational decline is not encouraging. Management attributed the weakness to continued pricing spillover from Medicare's competitive bidding coupled with unexpected volume declines in the retail market. Roche's accompanying slides noted that the Accu-Chek Aviva/Performa franchise has declined 1% through 2015 (1Q - 3Q). We had hoped the [August US launch](#) of the Accu-Chek Connect system (standalone meter + smartphone app + web portal) might provide a boost, though there is certainly a stickiness factor to switching BGMs.

- **Sales declined 14% sequentially against a low base in 2Q15 (when sales of 550 million CHF marked an all-time low in 2Q for the global business).** The weakness is not particularly surprising, given that we typically see declining sequential growth between 2Q and 3Q, including in each of the past nine years.
- **The silver lining for the Global Diabetes Care business continues to be the positive growth for Insulin Delivery systems (up 8% operationally thus far in 2015).** Pumps were similarly characterized as drivers of growth at recent updates ([2Q15](#); [1Q15](#); [4Q14](#)). We assume the modest growth reflects uptake of the Accu-Chek Insight (next generation insulin pump and BGM system), which [launched in the EU](#) in January 2014. Management did not comment on this franchise during its prepared remarks or Q&A. We wonder how the company is thinking about closed-loop.

2. In North America, Diabetes Care revenue totaled a record-low 69 million CHF (~\$72 million), falling a striking 37% against an easy comparison to 3Q14 (sales fell 2%). North America has been tremendously challenging for Roche - YOY North America sales have now declined for six straight quarters, and Roche has recorded only four quarters of positive YOY reported growth in North America in the past 29 quarters (since 1Q08). The 3Q15 performance also marks three consecutive quarters in which YOY revenue has come in under 100 million CHF - the first time we have seen this pattern in our Roche model.

- **There was more discouraging news on the sequential front where sales fell 30% in 3Q15.** This came against a low base, too, as sales of 99 million CHF in 1Q15 were the second lowest-ever in the business since 2009.
- **The US business is by no means rebounding, as pricing pressures stemming from competitive bidding continue to adversely impact the business.** That said, the seasonality of the BGM business means sales tend to pick up in 4Q (positive/flat sequential growth every year since 2006). We would not be surprised if this is the case next quarter, too, given the easy comparison to 4Q14 (when sales fell 8%).

3. International sales were similarly disappointing, with revenue falling 14% as reported YOY to a record-low 407 million CHF (~\$422 million) in our model. The decline comes against a modest comparison as sales grew 2% in 3Q14 and marks three consecutive quarters of YOY declines following a string of two straight quarters of YOY growth for the business. Though this is not promising, we assume much of this weakness is currency driven. It is tough to say for sure since Roche does not report operational sales for the overall international business. Sales fell 10% sequentially, consistent with the seasonality of the business.

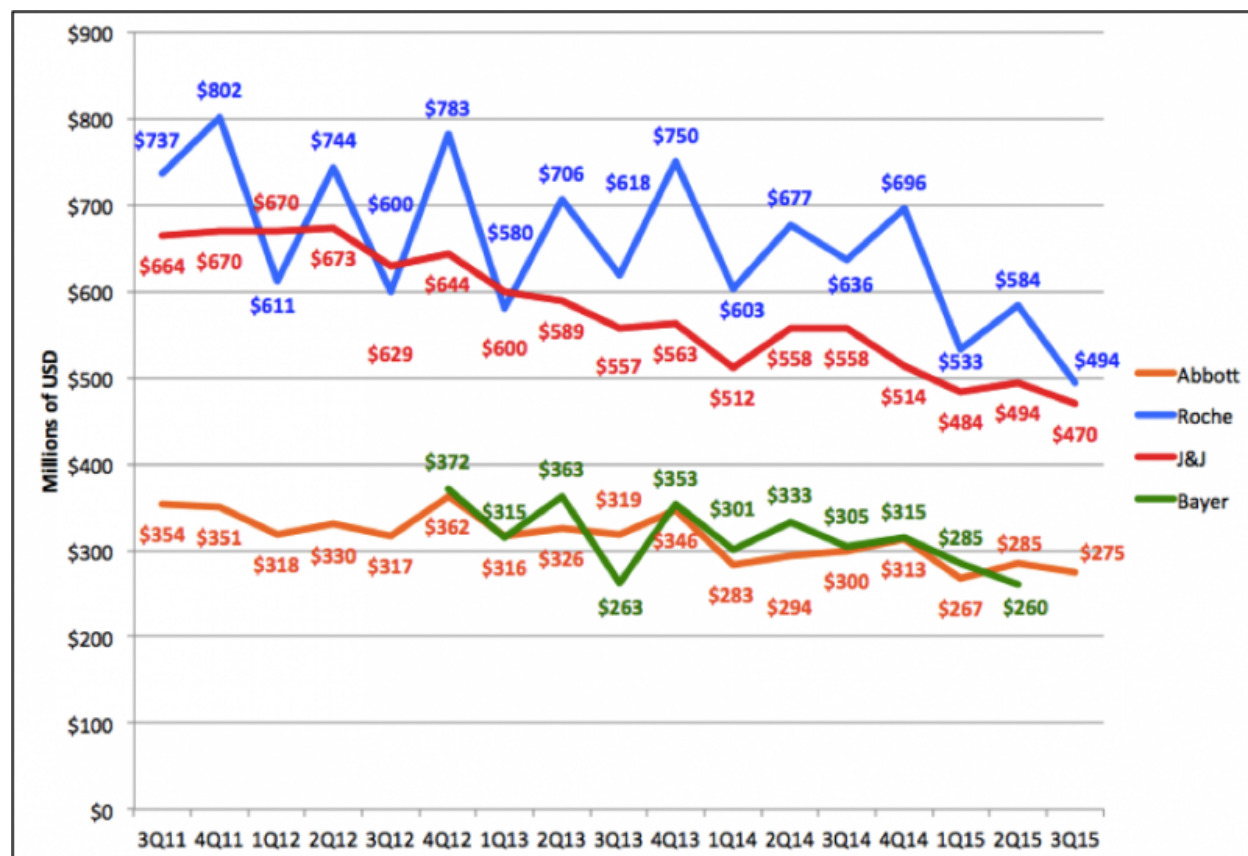
- **Sales in EMEA totaled 294 million CHF (~\$305 million), down 15% as reported after growing 2% in 3Q14.** We believe much of this is currency driven, as year-to-date operational sales declines were just 1% YOY (Roche does not report quarterly operational performance.) Still, three consecutive quarters of double-digit YOY reported declines (1Q: down 11%; 2Q: down 13%) do not bring much reason for optimism. Sequentially, sales declined 11% on a low base (2Q15 sales of 330 million CHF marked the third lowest ever recorded in our EMEA model that stretches back to 2010).
- **Sales in RoW totaled 113 million CHF (~\$117 million), down 9% as reported after growing 1% a year ago.** Much of this is probably currency driven, as Roche actually disclosed year-to-date operational sales growth of 9% YOY. Management did not comment on the RoW Diabetes franchise performance in the call, though presumably the positive movement reflects growth in an underpenetrated market. In 4Q14, management suggested that these underpenetrated regions are seeing strong BGM and insulin delivery uptake - Roche's 3Q15 slide deck indicated year-to-date 13% Diagnostic segment growth in Latin American and 15% growth in Asia Pacific (not diabetes specific). Sales declined 7% sequentially.

Pooled Financial Highlights

4. Pooled global revenue for J&J, Roche, and Abbott totaled ~\$1.2 billion in 3Q15, falling 17% relative to pooled revenue in 3Q14 (~\$1.5 billion). We attribute the weakness to a combination of currency headwinds, pricing pressure, and ever-increasing low-cost competition. For context, Roche and J&J are largely responsible for the decline as the companies' sales fell \$142 million and \$88 million, respectively vs. Abbott, whose sales fell a smaller \$25 million (albeit on a much smaller base). Pooled sales fell 9% sequentially.

- **As a note, it is difficult to make direct comparisons between J&J, Abbott, and Roche, given that each company's Diabetes Care business includes a fraction of non-BGM revenue.** J&J and Roche have global insulin delivery and Abbott has CGM and FreeStyle Libre outside of the US. We look forward to adding the last of the Big Four - Bayer - to this comparison when the company reports on October 29 (Thursday).

FIGURE 2: POOLED GLOBAL ABBOTT, J&J, AND ROCHE SALES (3Q11 - 3Q15)



- **A comparison of Abbott/J&J/Roche quarterly global sales illustrates unique revenue trends for each company.** Roche is the most cyclical of the three with sales that vary distinctly with quarters (high in 2Q and 4Q; low in 1Q and 3Q). Roche has seen the largest drop in sales since 3Q15 (-\$243 million), followed by J&J (-\$194 million). Abbott sales have been steadier over the past few years (two-thirds of its sales are outside the US).
- **Pooled declines were driven in large part by US weakness, where combined sales of ~\$375 million fell 20% YOY against an easy comparison to pooled revenue in 3Q14 (down 3%).** Depressed revenues seem to be the new normal in this region, and the big question is when the market will bottom out (or if it already has). Sequentially, pooled sales declined 7% relative to 2Q15.
- **International pooled sales were not much better, as combined sales of ~\$864 million fell ~16% YOY against an easy comparison to pooled sales in 3Q14 (\$1.0 billion).** Pooled sales fell 9% sequentially.

Device Pipeline Highlights

5. Roche did not share any major pipeline updates nor did the call reference the development of the company's novel CGM. As of the [company's 2Q15 analyst day event](#) in July, the plan was to launch the CGM in the next 18 months. We assume launch will occur in Europe first. There were no updates on commercialization, accuracy, or form factor in [Roche's DTM presentation](#) over the weekend. We think Roche has an uphill battle ahead given the greater experience and next-gen innovation happening at Abbott (FreeStyle Libre), Dexcom (G5), and Medtronic (Enlite 3).

- **Similarly, there were no updates on the Solo MicroPump (Roche's patch pump).** We heard a couple quarters ago that the company is still working on this internally. The patch pump business model is challenging, and the slow progress on this product is not confidence

inspiring. The main competitors in full-featured patch pumps are Insulet (slower recent sales in the US and internationally, but Ypsomed just reported a 19% increase in the patient base in 1H15) and Cellnovo in Europe (very small early sales of \$194,000 in [3Q15](#) on 62 systems shipped).

- **In the simple patch device category**, Valeritas' V-Go device is already on the US market through a small regional rollout. The landscape is bound to get more competitive next year, with J&J slating a launch of its Calibra Finesse insulin delivery device in 2016 ([J&J 3Q15](#)), and CeQur planning an EU launch of its [PaQ device](#) in 2016 (potential US launch in 2017).

6. Roche called out the [EU launch](#) of its next-gen cobas c 513 A1c analyzer as a "key" pipeline development in 3Q15. We first heard about this anticipated launch at 4Q14, and were glad to see Roche hit its timeline. We believe the product would be used in a laboratory setting and is designed to replace Roche's existing dedicated HbA1c analyzer, the COBAS INTEGRA 800 CTS. The next-gen, "market leading" product boasts increased efficiency by doubling the throughput from 200 to 400 patients per hour that Roche's slide deck states is "five times faster than its closest competition." [The competition in this market is harder to track... Alere's portfolio does feature a similar product though we assume there are others.] Roche's slide deck puts the target market for A1c testing at ~520 million CHF, which grew 5% in 2014.

7. Though it was not mentioned during the update, Roche launched its Accu-Chek Connect BGM and paired smartphone app (with a bolus calculator) in the US in early August - see [our full coverage](#) and [diaTribe's test drive](#). We see the Connect as an important move toward more seamless, automatic, and hassle-free transfer of blood glucose data and believe the first-to-market status with a mobile bolus calculator could benefit Roche. The meter has been priced reasonably at \$29.99, roughly the same as the cost of [LifeScan's OneTouch Verio Sync](#) (the only other Big Four smartphone-connected BGM) and the app is already available for free on [Apple](#) and [Android](#) devices. Management has yet to provide sales/trajectory and we assume these figures will stay under wraps unless the product sees strong uptake. Connected meters still have very low penetration in the diabetes market research company dQ&A patient panel; for more information, please [contact CEO Richard Wood](#).

8. As in 2Q15, Roche's [supplementary materials](#) (slide 165) also highlighted the 2015 worldwide launch of the Accu-Chek Active BGM. This is a new meter platform, and though few details are available, we believe it has relatively basic features (e.g., no smartphone/cloud-connectivity). This quarter's slide deck provided no updates on timeline or meter features (as is standard nowadays, the strips are no-coding). For context, the [4Q14](#) call marked the first time we had heard of the next-gen Active BGM. The first-gen Active BGM was launched in the EU in 2Q13 but never made it to the US market. Our search of the FDA database seemed to indicate that the meter has yet to be filed with the Agency; this would have to happen soon if a US launch is to be included in the 2015 "worldwide" launch.

Drug Pipeline Highlights

9. US sales of Lucentis (intravitreal ranibizumab) declined a striking 24% YOY as reported and 18% in constant currencies to 327 million CHF (~\$339 million) in 3Q15. Sequentially, sales declined 22%. The drug did retain its position at #4 on Roche's "Top 20" Pharma Division products list - a testament to the relatively high base. As in previous updates, management attributed weakness to increased competition for Lucentis in diabetic macular edema (DME) and age-related macular degeneration. While it was not explicitly mentioned during prepared remarks, Roche's presentation slides highlighted the ongoing launch of Lucentis in diabetic retinopathy (in patients with DME) following [FDA approval](#) in February. The FDA also approved Bayer/Regeneron's Eylea (intravitreal aflibercept) for diabetic retinopathy in patients with DME [earlier this year](#). We wonder whether sales have been negatively impacted by the results of a recent [comparative effectiveness study](#) showing greater gains in visual acuity with Eylea vs. Lucentis in patients with worse than ~20/50 vision at baseline. Off-label use of Genentech's Avastin (bevacizumab), which offers a significant price discount compared to the two approved options, is also likely cutting into sales for both Lucentis and Eylea. As a reminder, Genentech markets Lucentis in the US and Novartis markets it ex-US - see our [Novartis 3Q15 report](#) for an update on the drug's international performance, which was also sluggish.

- **We believe expanded indications for Lucentis in ophthalmology will help sales long term, though they are still a ways down the line.** Roche has begun a phase 2 port delivery system study for Lucentis for the treatment of ocular disease while a study investigating Lucentis in wet age-related macular degeneration has been moved into phase 2.

10. During Q&A, management predicted that increased pricing pressure will force pharmaceutical companies to double down on either highly innovative or low-cost products, with those in the middle getting squeezed out. The comment came in response to a question about how the increased scrutiny on prescription drug prices in the US would impact Roche and the broader industry going forward. Investors are clearly paying attention to the recent public outcry over pharmaceutical prices, as the topic has come up in almost every earnings call for a major drug company so far this quarter - to a much greater extent than in the recent past. Management suggested that as pricing pressure rises, "either you are highly innovative with clinical differentiation or you go into low-cost generics, but there is nothing between anymore." Roche believes this trend has already become apparent in Europe and may be on its way in the US. The company placed itself squarely in the "highly innovative" camp and expressed confidence that even cost-conscious societies will be willing to pay for new products that make a difference for patients. If true, this trend will likely pose challenges for the type 2 diabetes drug arena, where most innovation in recent years has been incremental. While we imagine there will certainly be room for new type 2 diabetes drugs that are highly differentiated (e.g., a safe and effective insulin sensitizer or a new cardioprotective drug), the opportunity may be narrower for products that offer only minimal advantages over existing options.

Honorable Mention: As a reminder, Roche's GLP-1/GIP dual agonist RG7697 for type 2 diabetes was removed from the phase 2 pipeline in 2Q15. Considering the crowded market and high development costs (presumably including a CVOT), some may not find the news that surprising though given the investment, we were certainly disappointed to hear this.

Questions and Answers

Q: What's your view on the pricing environment for Roche in the US going into 2016? Are there any categories where you anticipate significant price pressure? And do you really expect any components of the broader US drug pricing environment to change over the next two years given the heightened scrutiny on drug pricing?

A: Obviously, we at Roche are clearly focused on highly innovative medicines, differentiated medicines, medicines that provide significant value for patients. And I believe as such, we are less exposed to price pressure not only in the US but worldwide. And we see that in the numbers. So I wouldn't see a major impact for us over the coming years.

In general terms, if price pressure goes up - and we are certainly seeing that in Europe already and we can speculate what is going to happen in the US - what I think is you will see more segmentation of the market. We will see a clear segmentation of companies on the one hand who bet on true innovation, clinically relevant innovation that makes a difference for patients, and societies will continue to reward this kind of innovation. On the other hand, you will see generics companies who have their role, who focus on cost, on economies of scale, etc. But the part in the middle will definitely disappear and it will get tougher and tougher for those companies to survive. **Either you are highly innovative with clinical differentiation or you go into low-cost generics, but there is nothing in between anymore.**

We have seen this in Europe very clearly. We see this already happening to a big degree in the international markets. If you look into China, for example, the price pressure is on the older medicines, on branded generics, and less so on the innovative medicines. And if the price pressure should increase in the US as well, I would expect a similar development. And I think with our focus on innovation, we should be well positioned.

-- by Varun Iyengar, Adam Brown, Emily Regier, and Kelly Close