
Roche 4Q15 - Diabetes Care sees record low annual sales worldwide; EU launch of Accu-Chek Insight CGM in 2016 - February 3, 2016

Executive Highlights

- Global Diabetes Care revenue totaled 595 million CHF (~\$601 million) in 4Q15, declining 11% as reported and 3% operationally year-over-year (YOY); full year sales reached 2.1 billion CHF (~\$2.2 billion), declining 11% as reported and 3% operationally YOY. Management characterized the business a "tale of two cities," alluding to some positive indicators (5% BGM volume growth in the US) despite the broader negative picture. Overall this result was more positive than many would have expected.
- Pooled global revenue for J&J, Roche, and Abbott totaled ~\$1.4 billion, falling 10% relative to pooled revenue in 4Q14 (~\$1.5 billion). Abbott had the strongest operational performance in the quarter (up 2% YOY) vs. J&J (down 2%) and Roche (down 3%).
- Roche confirmed the 2016 EU launch timeline for its novel CGM, though there were no updates on commercialization, accuracy, or form factor. Management also projected a 2016 EU launch for the new Accu-Chek Guide, a new smartphone/cloud-connected BGM system. There were no updates on the Solo MicroPump (Roche's patch pump).

Roche CEO Mr. Severin Schwan recently led the company's [4Q15 financial update](#). We've show the call's top ten highlights below. There was no (none!) Q&A related to diabetes.

Financial Highlights

1. Global Diabetes Care revenue totaled 595 million CHF (~\$601 million) in 4Q15, declining 11% as reported and 3% operationally year-over-year (YOY); 4Q sales did not break 600 million CHF for the first time this decade. Remarkably, management optimistically characterized the business as a "tale of two cities," alluding to some positive indicators despite the broader negative picture: 5% BGM volume growth in the US, 8% operational growth in insulin delivery.
2. In North America, Diabetes Care revenue totaled 121 million CHF (~\$122 million) in 4Q15, with flat growth YOY against an easy comparison to [4Q14](#) (sales fell 8% YOY). Full-year sales fell 13% to an all-time low of 383 million CHF (~\$398 million).
3. Outside North America, Diabetes Care sales totaled 474 million CHF (~\$479 million) in 4Q15, falling 14% as reported; FY 15 sales totaled 1.7 billion CHF (~\$1.8 billion), down 11% as reported. We assume some of this weakness is currency driven, though Roche does not report the operational numbers.

Pooled Financial Highlights

4. Pooled global revenue for J&J, Roche, and Abbott totaled ~\$1.4 billion, falling 10% relative to pooled revenue in 4Q14 (~\$1.5 billion). Abbott had the strongest operational performance in the quarter (up 2% YOY) vs. J&J (down 2%) and Roche (down 3%). YOY pooled sales for the three companies have now fallen for 15 (!) consecutive quarters.

Device Pipeline Highlights

5. Roche confirmed the 2016 EU launch timeline for its novel CGM - now called the "Accu-Chek Insight CGM" - though there were no updates on commercialization, accuracy, or form factor. We love the name. The new name does make us wonder whether it will actually be a sensor-integrated pump, since Roche already markets the "Accu-Check Insight" pump system. The competition is fierce in glucose sensors in

Europe, with Abbott's FreeStyle Libre, Dexcom's G5, and Medtronic's MiniMed 640G but the penetration remains low and we expect a good product will add to and hopefully help create a thriving commercial market - penetration remains very low due to reimbursement. How will Roche's device stand out?

6. Roche's supplementary materials projected a 2016 EU launch for a new smartphone/cloud-connected BGM, the Accu-Chek Guide. This is the first we have heard of this new BGM, which will pair with the bolus advisor on the Accu-Chek Connect app.

7. There were no updates on the Solo MicroPump (Roche's patch pump). At this point, we assume this product is not likely coming to market, though the company was working on it as of a few quarters ago.

8. Supplementary materials also called out the 2015 EU launch of Roche's next-gen cobas c 513 A1c analyzer, characterizing it as a key pipeline development in 2015. This is great from our view - A1c has helped substantially with better diagnosis rates and we're happy to see progress on this front as early diagnosis is so key to patients getting in optimal control and staying there.

Drug Pipeline Highlights

9. US sales of Lucentis (intravitreal ranibizumab) declined 14% YOY as reported and 17% in constant currencies to 378 million CHF (~\$382 million) in 4Q15, while full-year 2015 sales declined 15% operationally to 1.5 billion CHF (~\$1.6 billion).

10. Roche's [presentation slides](#) noted that the company expects a moderate decline in Lucentis sales in 2016.

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Financial Highlights

1. Global Diabetes Care revenue totaled 595 million CHF (~\$601 million) in 4Q15, declining 11% as reported and 3% operationally year-over-year (YOY). The performance comes against a relatively easy comparison to 4Q14 when sales fell 1% as reported and grew 1% operationally. The performance does mark the highest quarterly revenue in 2015 and a striking sequential increase of 25% vs. 3Q15, though we would position this "silver lining" very conservatively since it's been such a tough market. Sequential gains between 3Q-4Q have been in the ~16-26% range over the past four years and the numbers are not surprising when considering the very low base in 3Q15 (when sales of 476 million CHF marked an all-time low). Indeed, a closer look at the numbers tells the true story as this is the first year in our Roche model (which goes back to 2004) that 4Q sales have not broken 600 million CHF - a testament to just how challenging this business has been. [For context, 4Q sales peaked at 904 million CHF in 2007.]

- **For the 2015 fiscal year, global revenue reached 2.1 billion CHF (~\$2.2 billion), declining 11% as reported and 3% operationally YOY.** This came against a relatively easy comparison as revenue fell 3% as reported and grew 1% operationally in FY14. We note that full-year revenue for the global business has been flat or declining since 2008 - in fact, sales for FY15 are the lowest fiscal year total since we began reporting in 2004.
- **Roche COO Mr. Diggelmann characterized Diabetes Care as "a tale of two stories," referring to simultaneous pricing pressure and a 5% "volume increase" in the US - presumably, he was talking about the BGM market.** Indeed, supplementary materials indicated that BGM sales fell "just" 4% in FY15 - relative, of course, to how challenging this market

has been! Meanwhile, sales of "other" Diabetes Care products grew 9% driven by positive growth in Insulin Delivery systems (up 8% operationally in FY15). Pumps have been characterized as a driver of growth in nearly all recent quarterly updates ([3Q15](#); [2Q15](#); [1Q15](#)), and we assume the modest growth reflects uptake of the Accu-Chek Insight (next generation insulin pump and BGM system) that [launched in the EU](#) in January 2014. Management believes it can sustain this growth momentum moving forward, labeling it one of a handful of "opportunities" in Diabetes Care in 2016.

- **In other news, Roche continues to implement [global restructuring plans](#) aimed at enhancing the long-term profitability of the global business.** As a reminder, Roche announced the "Autonomy and Speed" initiative in September 2013. We assume that the program reflects a mix of cost cutting and strategies originally designed to respond to CMS' competitive bidding program. This has been ongoing for over two years now and we're not sure what concrete changes have been made - even the language in the Finance Report has remained nearly identical over the past year. The Report does note that the company incurred 175 million CHF (~\$177 million) in various costs associated with the initiative in 2015 (IT-related, consultancy, etc.) vs. 118 million CHF (~\$129 million) in 2014. Judging from the language ("ongoing"), it appears that reorganization efforts will continue into 2016. The company has not provided a timeline for completion nor has it provided details on specific strategy.

2. In North America, Diabetes Care revenue totaled 121 million CHF (~\$122 million) in 4Q15, with flat growth YOY against an easy comparison to 4Q14 (sales fell 8% YOY). Management did not comment on the North American business though supplementary materials did allude to a "challenging US market" due to spillover effect of Medicare prices on private sector. This was no surprise though - on a positive note - we would point out that 4Q15 does mark the first non-negative YOY performance since 1Q14. That said, it's far too early to forget how tough this region has been for Roche - especially in light of the full year numbers (see below). For context, in the past eight years (since 1Q08), Roche has recorded only four quarters of positive YOY reported growth in North America. Sequentially, revenue was up a whopping 75% from a very, very low base in [3Q15](#) (sales of 69 CHF million marked an all-time low). The seasonality of the BGM business means that sales pretty much always pick up in 4Q (positive/flat sequential growth every year since 2006).

- **For the full year, Diabetes Care sales in North America reached just 383 million CHF (~\$398 million), declining 13% as reported. This marks the lowest total revenue in our North America model (which reaches back to 2004).** The performance comes against an easy comparison to FY14 that - at the time - marked the lowest annual revenue when sales fell 8%. For perspective, the US business peaked in 2004 when sales were more than double (983 million CHF) what they were in 2015.
- **As a reminder, CMS [announced in December 2014](#) the bidding timeline for the next round of its Competitive Bidding Program (that includes diabetes testing supplies) and we're not sure how this will play a role in upcoming earnings.** It appears that the competitive bidding process is the same as the first time around - meaning non-binding bids that could drive the reimbursed price to ridiculously low levels; that unknown suppliers can enter the market; and that off-shore strips and meters will dilute the pool. We remain extremely concerned about the degree to which responsible manufacturers are "doing the right thing" and the one-off manufacturers have quality that is very questionable - but they manufacture so far away and are so under the radar screen that the under-resourced FDA won't visit them due to lack of funding and lack of human and financial resources. The implementation of new contracts and prices will occur in July 2016, so Roche does have ~two quarters to prepare for the implementation though management did not allude to any changes in the 4Q call. We would love for CMS to think about how it could contribute to better diabetes care for those that are not at their glycemic target - nearly half of all people with diabetes in the United States!

3. Outside North America, Diabetes Care sales totaled 474 million CHF (~\$479 million) in 4Q15, falling 14% as reported YOY against growth of 1% YOY in 4Q14. The performance marks four 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 some 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. Sequentially, sales grew 16% against a very low base in [3Q15](#) (407 million CHF). As a reminder, Roche breaks out its non-North America revenue into two groups - Europe, Middle East, and Africa (EMEA) and Latin America, Asia-Pacific, and Japan (RoW):

- **Sales in EMEA totaled 357 million CHF (~\$360 million) in 4Q15, falling 13% as reported after growing 1% in 4Q14.** We believe much of this is currency driven, as year-to-date operational sales decline was just 2% YOY (Roche does not report quarterly operational performance.) Still, four consecutive quarters of double-digit YOY reported declines (1Q: down 11%; 2Q: down 13%; 3Q: down 15%) do not bring much reason for optimism. Sequentially, sales grew 21% on a low base from 3Q15.
- **Sales in RoW totaled 117 million CHF (~\$118 million) in 4Q15, falling 16% as reported after growing 1% in 4Q14.** Again, we believe much of this is probably currency driven, as Roche actually disclosed year-to-date operational sales growth of 5% YOY. Management did not comment on the RoW Diabetes franchise performance in the call though presumably the positive movement reflects growth in underpenetrated markets. Roche's 4Q15 slide deck indicated year-to-date 11% Diagnostic segment growth in Latin American and 15% growth in Asia Pacific (not diabetes specific). Sales grew 4% sequentially.
- **For the full year, Diabetes Care sales outside North America totaled 1.7 billion CHF (~\$1.8 billion), down 11% as reported against an easy comparison to a 1% sales decline in 2014.** This performance marks the lowest total revenue outside North America since 2004 (similar to 2015 global and North American sales).
 - **In EMEA, revenue reached 1.3 billion CHF (~\$1.4 billion), falling 13% as reported and 2% operationally.** The comparison was an easy one as sales in FY14 fell 1% as reported but grew 2% operationally. Looking back, this year saw four consecutive quarters of YOY reported declines and though this should make for easy comparisons in 2016, it's hard to expect more than moderate growth in the near future.
 - **In RoW, revenue reached 460 million CHF (~\$470 million), down 3% as reported and up 5% operationally.** This performance came against a modest comparison as sales grew 6% operationally in 2014 (though fell 4% as reported).

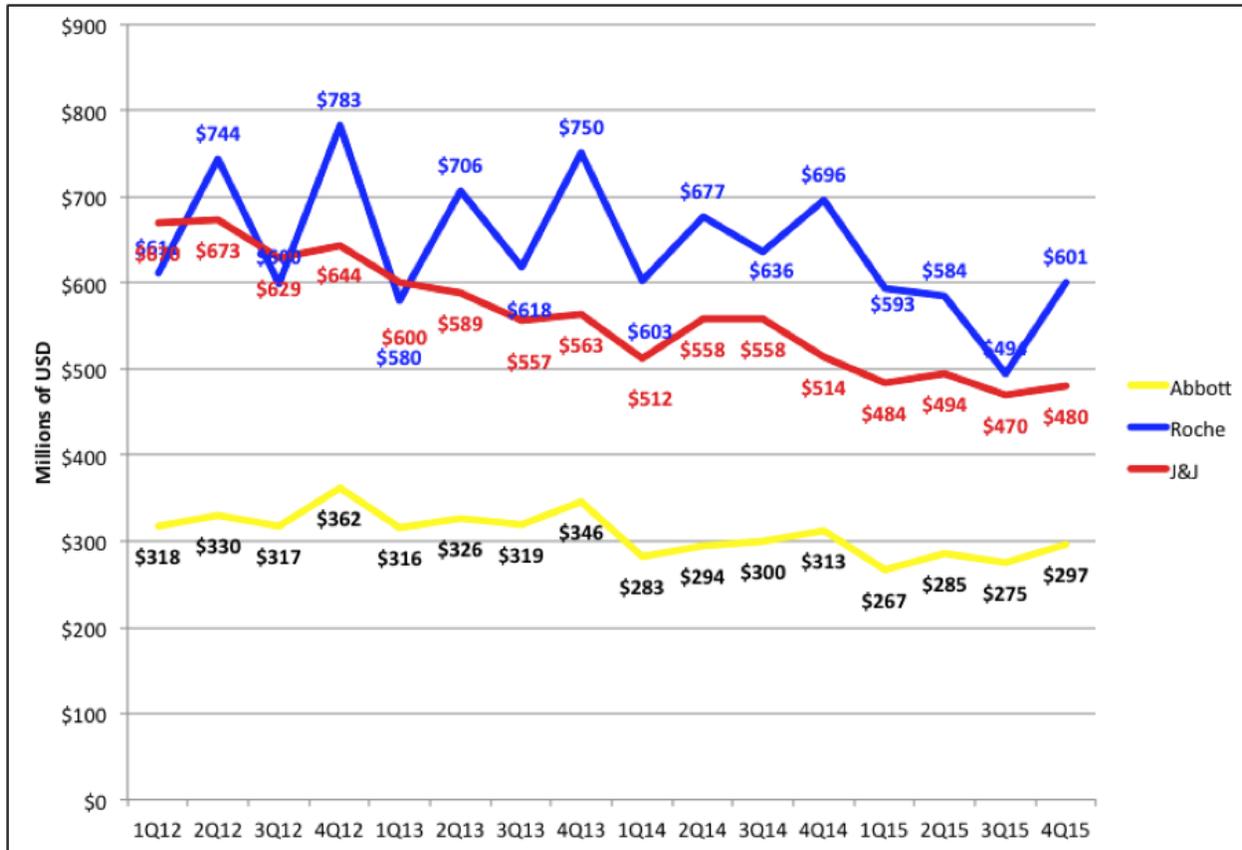
Pooled Financial Highlights

4. Pooled global revenue for J&J, Roche, and Abbott totaled ~\$1.4 billion, falling 10% relative to pooled revenue in 4Q14 (~\$1.5 billion). This comes against an easy comparison, as combined revenue declined 8% a year ago. While some of the weakness comes from currency headwinds, it cannot explain the entire drop - YOY pooled sales for the three companies have now fallen for 15 (!) consecutive quarters, going far beyond the recent strengthening of the dollar. Pooled sales broken out by region (see below) support this explanation, as both US and international markets have seen declines. On a sequential basis, pooled sales grew 11%, though this growth is a regular cyclical pattern between 3Q and 4Q.

- **Pooled declines in 4Q15 were driven in large part by international weakness, where combined sales of ~\$953 million fell ~12% YOY against an easy comparison to pooled sales in 4Q14 (\$1.1 billion).** Depressed revenues as a result of foreign exchange have characterized the business for several quarters now, and the big question is when the market will bottom out. Pooled sales grew 10% sequentially (again, this growth is cyclical).
- **US sales were not much better as combined sales of ~\$425 million fell 3% YOY against an easy comparison to pooled revenue in 4Q14 (down 11%).** Sequentially, pooled sales grew 13% relative to 3Q15 (again, this growth is cyclical).
- **Abbott had the strongest operational performance in the quarter (up 2% YOY) vs. J&J (down 2%) and Roche (down 3%).** 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 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/Panasonic [Ascensia]- to this comparison when the company reports (Date TBD - we are in conversations with management).

FIGURE 3: POOLED ABBOTT, J&J, AND ROCHE QUARTERLY SALES (1Q12 - 4Q15)



Device Pipeline Highlights

5. Management confirmed the 2016 EU launch timeline for its novel CGM - now being called the "Accu-Chek Insight CGM" - though there were no updates on commercialization, accuracy, or form factor. We found it encouraging to see supplementary materials characterize the CGM as a "key" 2016 launch and even more promising to hear Mr. Diggelman express enthusiasm for the product in his prepared remarks - the transparency seems to speak to significant internal confidence in the timeline. That said, we still think that Roche has an uphill battle ahead given the greater experience and next-gen innovation happening at Abbott (FreeStyle Libre), Dexcom (G5, G6), and Medtronic (Enlite 3). What will set Roche's CGM apart?

- The new name - Accu-Chek Insight CGM - makes us wonder whether Roche's coming offering will actually be a sensor-integrated pump.** As a reminder, Roche currently markets the "Accu-Chek Insight" in the EU as an insulin pump system alone (launched in January 2014). Skipping the standalone CGM offering and pairing its first-gen CGM with a pump would also be a smart competitive move to stay competitive with J&J (Vibe integrated with Dexcom G4), Tandem (t:slim integrated with the Dexcom G4), and Medtronic (MiniMed 640G). The accuracy of Roche's offering remains a big question mark (MARD<15%? MARD<10%?), as does the number of required calibrations, on-body size, length of wear, connectivity, and pricing strategy.

- **At JPM 2016, we learned that Roche will not submit its CGM to regulatory authorities in the US in 2016.** Management alluded to a more stringent regulatory process slowing things down.

6. Roche's supplementary materials projected a 2016 EU launch for the Accu-Chek Guide (a next-gen BGM system with smartphone connectivity). This is the first we have heard of this new BGM. The slide deck provided few details on the specific timeline or meter features though management has informed us that the device will talk to the Accu-Chek Connect app (Android and iOS). In addition to the FDA-approved bolus advisor built into the current Accu-Chek Connect app, the next-gen app will contain a 3-day profile (from the STEP study) to facilitate patient motivation. The new system will also work with the online platform to enable intuitive data sharing with caregivers and healthcare providers. Further, the new system will feature on-board pattern detection and an entirely new, more accurate test strip that performs on a wide temperature and hematocrit range.

- **The 2015 launch of the Accu-Chek Connect BGM and paired smartphone app (with a bolus calculator) in the US was briefly mentioned in accompanying materials - 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 available for free on Apple and Android devices. Management has not provided sales or growth figures but we'd love to see them and are working on it.

7. There were no updates on the Solo MicroPump (Roche's patch pump). We heard several quarters ago that the company is still working on the Solo MicroPump internally, though we're not sure if this is still the case - we can't imagine this is the place it most wants to put resources as this pump was sort of behind Insulet awhile back and Insulet is moving ahead. The patch pump business model is challenging (even though overall they have traditionally collected more funds than the traditional pump players over four years), and the slow movement on this product is not surprising. The main competitors in full-featured patch pumps are Insulet (total revenue reached a record high \$87 million in [3Q15](#)) and Cellnovo in Europe (early days, as [4Q15](#) saw 102 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 this year, with J&J slating a launch of its Calibra Finesse insulin delivery device in 2016 (though no updates [this quarter](#)), and CeQur planning an EU launch of its PaQ device in 2016 (potential US launch in 2017). Patients seem to love the V-Go once they can get it and this is a product that has clearly helped patients enormously - the clinical results are spectacular but it's not easy to get reimbursement for pumps for type 2 patients.

8. Supplementary materials also called out the [2015 EU launch](#) of its next-gen cobas c 513 A1c analyzer as a key pipeline development in 2015. The next-gen, "market leading" product boasts increased efficiency by doubling the throughput from 200 to 400 patients per hour that Roche's 3Q15 slide deck stated is "five times faster than its closest competition." [The competition in the point-of-care A1c market is harder to track ... Alere and Abbott both have A1c analyzers, and we assume there are others.] Roche has previously estimated the target market for A1c testing at ~520 million CHF. We think this is great news since so much more work needs to be done on diagnosing patients earlier, across the globe, and this helps enable that.

Drug Pipeline Updates

9. US sales of Lucentis (intravitreal ranibizumab) declined 14% YOY as reported and 17% in constant currencies to 378 million CHF (~\$382 million) in 4Q15, while full-year 2015 sales declined 15% operationally to 1.5 billion CHF (~\$1.6 billion). 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. Sequentially, sales grew 16% against a very low base in [3Q15](#) (sales of 327 million CHF, \$339 million).

- **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](#)**, noting that an [NIH-funded study demonstrated](#) that Lucentis is a safe alternative to laser therapy against proliferative diabetic retinopathy. The FDA also approved Bayer/Regeneron's Eylea (intravitreal aflibercept) for diabetic retinopathy in patients with DME [earlier this year](#). As a reminder, Genentech markets Lucentis in the US and Novartis markets it ex-US - see our Novartis [4Q15](#) report for an update on the drug's international performance, which was also sluggish.
- **As noted in the [presentation slides](#), Roche continues two phase 2 studies for Lucentis.** One is a phase 2 port delivery system study for Lucentis for the treatment of ocular disease (LADDER), while the other is a study investigating Lucentis in wet age-related macular degeneration (AVENUE). Expanded indications for Lucentis in ophthalmology will help sales long term, though they are still a ways down the line.

10. Roche's [presentation slides](#) noted that the company expects a moderate decline in Lucentis sales in 2016. We wonder whether sales will continue to be 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.

-- by Ava Runge, Varun Iyengar, Adam Brown, and Kelly Close