



MEMORANDUM

Roche 4Q14 - Global sales up 1% in 4Q14 despite US challenge; 2014 sales decline 1% operationally; two BGM launches in 2015 - January 29, 2015

Executive Highlights

- Global Diabetes Care revenue totaled 671 million CHF (~\$696 million) in 4Q14, declining 1% as reported and growing 1% operationally year-over-year (YOY). North America sales fell 8% as reported YOY against a very easy comparison.
- For the full year 2014, global sales totaled 2.4 billion CHF (~\$2.6 billion), falling 3% as reported and growing 1% operationally; revenue in North America totaled just 442 million CHF (~\$483 million), the lowest fiscal year revenue in the past decade.
- In 2015, Roche plans to launch the Accu-Check Active (next-gen BGM) worldwide and the Accu-Chek Connect System (standalone meter + smartphone app + web portal) in the US.

Early yesterday morning, Roche CEO Mr. Severin Schwan led the company's 4Q14 and full-year financial update. Overall, the global Diabetes Care business showed some signs of stability despite "continuous challenges" - of course, this was relative to an easy comparison when sales declined 7% in 4Q13. It is notable to see two products planned for 2015 despite financial challenges as Roche sees "innovation potential" in the BGM landscape. Below, we bring you the top financial and R&D highlights from the call; there was no relevant Q&A.

Financial Highlights

1. Global Diabetes Care revenue totaled 671 million CHF (~\$696 million) in 4Q14, declining 1% as reported and growing 1% operationally year-over-year (YOY). We'd note that the more stable performance was against an easy YOY comparison (revenue fell 7% in 4Q13). For the full year, revenue totaled 2.4 billion CHF (~\$2.6 billion), down 3% as reported and up 1% operationally YOY.
2. In North America, Diabetes Care revenue totaled 122 million CHF (~\$126 million) in 4Q14, declining 8% against an extremely easy comparison (sales fell 27% in 4Q13). On the plus side, the business did see positive/flat sequential growth for a third consecutive quarter. For the full year, North America revenue totaled 442 million CHF (~\$483 million), down 8% as reported and 6% operationally YOY. This was Roche's lowest US fiscal year revenue in the past decade.
3. Outside North America, Diabetes Care sales totaled 549 million CHF (~\$569 million) in 4Q14, growing 1% as reported YOY against flat growth in 4Q13. For 2014, revenue outside North America fell 1% as reported, reaching 2.0 billion CHF (~\$2.1 billion).
4. Combined global revenue for J&J, Roche, and Abbott fell 8% relative to pooled revenue in 4Q13 (pooled revenue declined 7%). Abbott had the weakest 4Q14 performance (down 10% YOY) compared to J&J (down 9%) and Roche (down 1%). J&J's US business has been the hardest hit in the past few years, while Roche and Abbott have seen more moderate declines.
5. Roche is engaged in [global restructuring plans](#) aimed at enhancing the long-term profitability of the business. Reorganization costs totaled a fairly significant 118 million CHF (~\$129 million) in 2014.

Device Pipeline Highlights

6. In 2015, Roche plans to launch the Accu-Check Active (next-gen BGM) worldwide and the Accu-Chek Connect System (standalone meter + smartphone app + web portal) in the US.

7. Despite the many challenges in the market, management shared optimism for its Diabetes Care division, and noted, in reference to its BGM products - "Indeed, there's still innovation potential in this business."

8. The call provided no commentary on Roche's novel CGM or Solo MicroPump. Prepared remarks highlighted the 2015 EU launch of the cobas c 513 A1c analyzer.

Drug Pipeline Highlights

9. US sales of Lucentis (intravitreal ranibizumab) declined 5% YOY in constant currencies to 441 million CHF (~\$457 million) in 4Q14, while full-year 2014 sales rose 2% YOY in constant currencies to 1.7 billion CHF (~\$1.9 billion). Management commented that 2014 growth was largely driven by the DME indication and offered a more conservative outlook for 2015 due to "increased competition" (both Eylea and Iluvien received FDA approval for DME in 2014).

10. Roche's GLP-1/GIP dual agonist RG7697 remains in phase 2 for type 2 diabetes.

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Financial Highlights

1. Worldwide Diabetes Care revenue totaled 671 million CHF (~\$696 million) in 4Q14, declining 1% as reported and growing 1% operationally year-over-year (YOY). This marks the fourth consecutive quarter in which operational growth has been neutral or positive, though we'd note that the performance came against an easy comparison to [4Q13](#), when sales declined 4% operationally. Additionally, while revenue fell only 1% as reported in 4Q13, this was against a 7% reported decline in [4Q13](#). Notably, Roche is the only one of the Big Four BGM companies (J&J, Abbott, Bayer) that did not experience a double-digit YOY decline during some quarter in 2014. On the other hand, the company has not had a quarter with YOY growth above 3% since 1Q10, so a breakout quarter seems unlikely going forward. Sequentially, worldwide sales grew 16% from [3Q14](#), a bit lower than the ~18-26% sequential gains from 3Q to 4Q we've seen in the past three years.

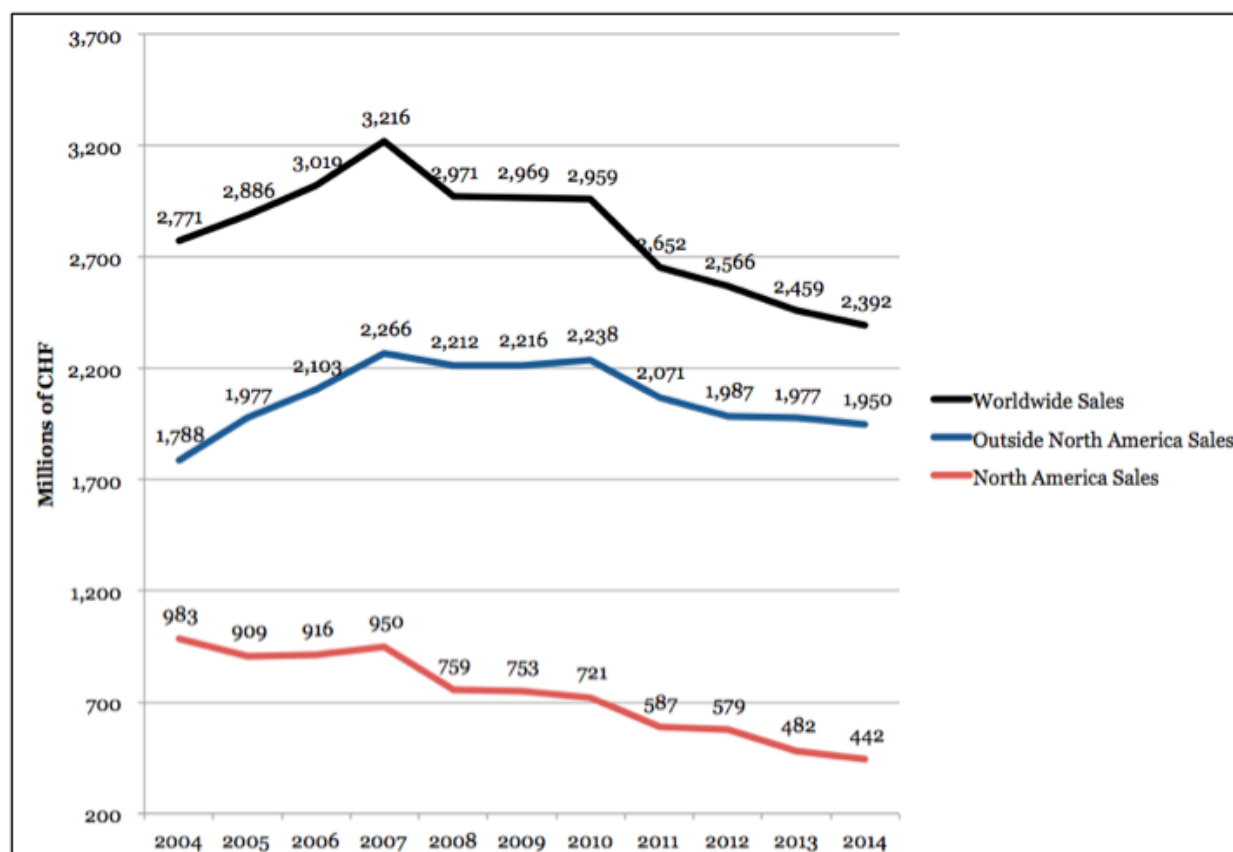
- **For the fiscal year, global Diabetes Care revenue reached 2.4 billion CHF (~\$2.6 billion), declining 3% as reported and growing 1% operationally YOY;** this came against an easy comparison as revenue declined 4% in [FY2013](#). We also note that full-year revenue for the global business has been flat or declining since 2008 - in fact, sales for FY2014 are the lowest fiscal year total since we began reporting in 2004.
- **Despite these declines, management was strikingly positive on the Diabetes Care business, noting that the business is "clearly outpacing the market."** (Management estimated that the market as a whole declined ~4% for the first nine months of 2014.) Roche's performance was described in the context of a "continuously challenging market," particularly in the US - such commentary has been consistent in Big Four quarterly updates for over a year since competitive bidding "anniversaried" in July 2014.
- **The weakness was offset by growth in the sales of the Accu-Chek Mobile BGM** (up 19% operationally for the full-year 2014) and Accu-Chek Aviva/Performa BGM (up 7% operationally for the full-year 2014). We assume this refers to sales of meters (and not strips), where the margins and volume are much lower.
- **Based on the [supplementary slide deck](#) (slide 176), we continue to estimate that Roche's BGM business makes up ~92% of its Diabetes Care business,** with the remaining ~8% attributable to Insulin Delivery.

Table 1: Roche Diabetes Care revenue by region in 4Q14 and 2014

	4Q14 Revenue in Millions (CHF [USD])	Reported (Operational) Growth from 4Q13	2014 Revenue in Millions (CHF [USD])	Reported (Operational) Growth from 2013
Roche Diabetes Care	671 (\$696)	-1% (1%)	2,392 (\$2,611)	-3% (1%)
<i>North America</i>	122 (\$126)	-8%	442 (\$483)	-8% (-6%)
<i>EMEA</i>	410 (\$425)	1%	1,475 (\$1,614)	1% (2%)
<i>RoW</i>	139 (\$144)	1%	475 (\$520)	-4% (6%)

EMEA = Europe, Middle East, and Africa. RoW = Latin America, Asia-Pacific, and Japan. Currency conversion based on average exchange rate from October 1 - December 31 (for 4Q14) and from January 1 - December 31 (for FY14) on oanda.com: 1.037 USD per CHF and 1.094 USD per CHF, respectively. Roche does not provide operational growth for its regional breakdown in the quarter.

Figure 1: Full-Year Worldwide, North America, Ex-North America Sales (2004-2014)



2. In North America, Diabetes Care revenue totaled 122 million CHF (~\$126 million) in 4Q14, declining 8% against a very easy comparison (sales fell 27% in 4Q13, the greatest drop for North American revenue since we began reporting in 2006). In prepared remarks, management did not comment at all on the North American business, and to no surprise, given the consistent challenges - in the past 28 quarters (since 1Q08), Roche has recorded only four quarters of positive YOY reported growth in North America. There is a glimmer of hope as the business did see positive/flat sequential revenue for the third

consecutive quarter in the US in 4Q14, a pattern we have not seen since 2008 (2Q - 4Q). That said, the seasonality of the BGM business means sales 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 442 million CHF (~\$483 million), declining 8% as reported and 6% operationally YOY; this marks the lowest total revenue we have reported in the past decade** (we began recording in 2004). For perspective, the US business peaked in 2004 and 2007 when sales were more than double (983 and 950 million CHF) what they were in 2014. Discouragingly, the decline came on a very easy comparison, as well, with sales declining 17% in [2013](#).
- **The big question is whether the US business is turning a corner.** Pricing pressures stemming from competitive bidding continue to exert their impact on the Big Four. For now, it appears that even at these lower revenue numbers, the business is still profitable and cash-generating, suggesting that the "new normal" may be viable. However, the impact on R&D moving forward is certainly not positive.
- **As a reminder, CMS [announced in December](#) the bidding timeline for the next round of its Competitive Bidding Program that includes diabetes testing supplies.** 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; unknown suppliers; and off-shore strips and meters. The price of strips may increase some as suppliers take stock of profits/losses since July 2013 - as noted at [DTM 2014 from Dr. James Scott](#). Of course, the implementation of new contracts and prices will only occur in July 2016, and so, for now, has only medium-term relevance.

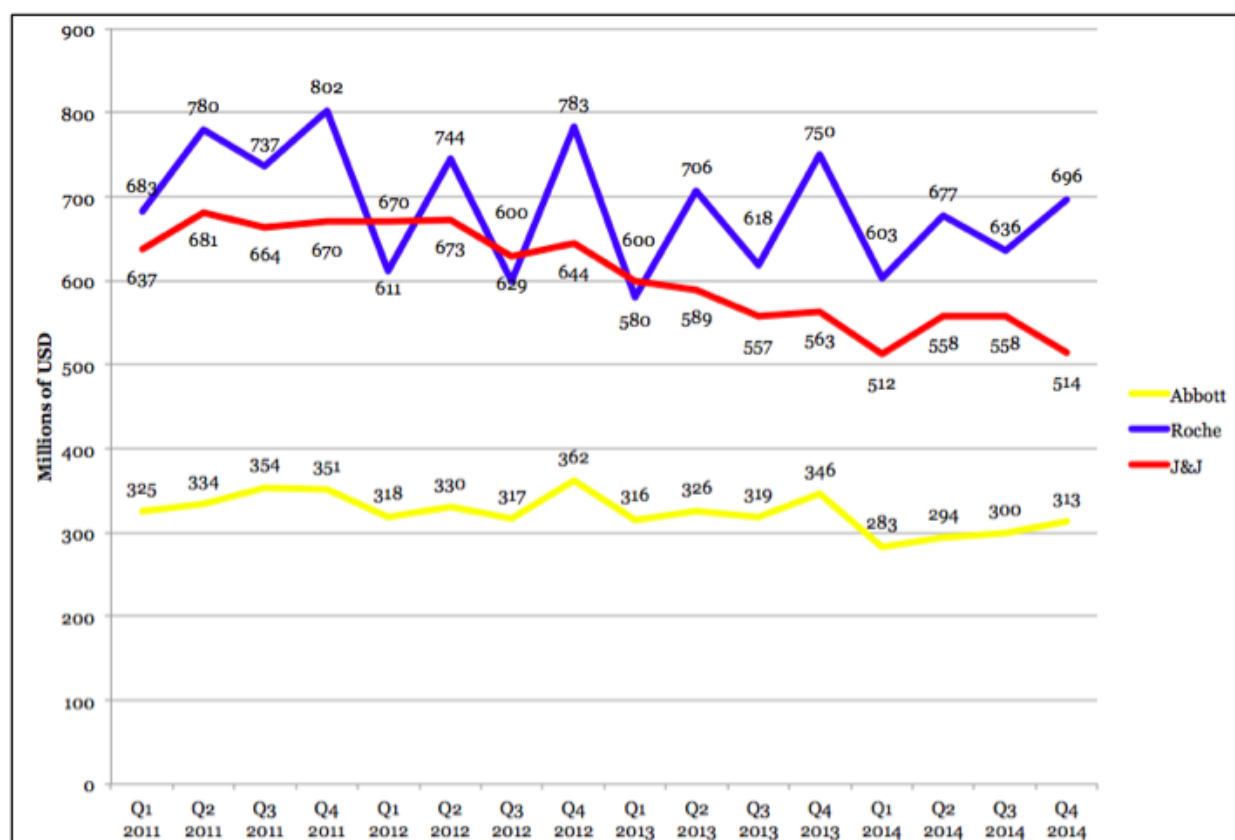
3. Outside North America, Diabetes Care sales totaled 549 million CHF (~\$569 million) in 4Q14, growing 1% as reported YOY against flat growth in 4Q13. Notably, this marks two consecutive quarters of YOY growth for the business outside of North America for the first time since 2010 (1Q - 2Q) and the highest non-North America sales for a quarter since 4Q12 (also 549 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 were split roughly 75/25 between the two for sales outside of North America.

- **Sales in EMEA totaled 410 million CHF (~\$425 million), up a modest 1% as reported** after falling 2% in [4Q13](#). We assume this performance can be at least partially attributed to the [launch of the Accu-Chek Connect System](#) in South Africa, Italy, and Germany in September.
- **Sales in RoW totaled 139 million CHF (~\$144 million), also up 1%** against a more challenging comparison (sales were up 3% a year ago) - notably, 4Q14 marks the third-highest revenue total for the region since Roche began reporting the figure in 2010 (behind only 4Q11 [142 million CHF] and 2Q12 [144 million CHF]).
- **For the full year, Diabetes Care sales outside North America totaled 2.0 billion CHF (~\$2.1 billion), falling 1% as reported against flat growth in 2013.** Sales were split roughly 75/25 between the EMEA and RoW for sales outside of North America, respectively.
 - **In EMEA, revenue reached 1.5 billion CHF (~\$1.6 billion) growing 2% operationally but declining 1% as reported YOY** against a relatively flat comparison (sales grew 1% operationally YOY in [2013](#)).
 - **Sales in RoW performed better, up 6% operationally and down 1% as reported to total 475 million CHF (~\$520 million)** against a more challenging comparison (revenue grew 3% in [2013](#)).
 - **Both regions struggled at the beginning of the year (declines in 1Q and 2Q), but recovered in the second half (growth in 3Q and 4Q)** - while the pattern will make for easier comparisons in early 2015, we do not expect more than moderate (i.e., single-digit) growth in the near future.

4. Combined global revenue for J&J, Roche, and Abbott totaled ~\$1.5 billion, falling 8% relative to pooled revenue in 4Q13 (~\$1.7 billion). This comes against an easy comparison as combined revenue declined 7% a year ago. Abbott had the weakest growth (down 10% YOY) for the third consecutive quarter vs. J&J (down 9%) and Roche (down 1%). 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 outside of the US). We look forward to adding the last of the Big Four - Bayer - to this comparison when the company reports on February 26.

- **Unsurprisingly, pooled declines were driven largely by US weakness where combined sales of ~\$440 million fell 11% YOY - and this is after a staggering 23% pooled decline in 4Q13.** Clearly, the US continues to be a challenging region for growth despite the fact that we are well past the annualization of competitive bidding -depressed revenues seem to be the new normal, and the big question is when the market will bottom out (or if it already has).
- **Roche's global revenues accounted for the majority (46%) of the three companies' pooled revenues;** this held steady relative to Roche's share in 4Q13 (45%). Abbott and J&J revenues also held constant at 21% and 34%, respectively. (We note that the numbers do not add to 100% due to rounding.) Regionally, J&J holds the greatest percentage of revenue in the US at 47% (vs. 44% in 4Q13), while Roche holds the greatest share of international revenue at 53% (vs. 52% in 4Q13). Overall, we are impressed with how steady market share has been.

Figure 2: Abbott/J&J/Roche Quarterly Global Revenue Comparison (1Q11 - 4Q14)



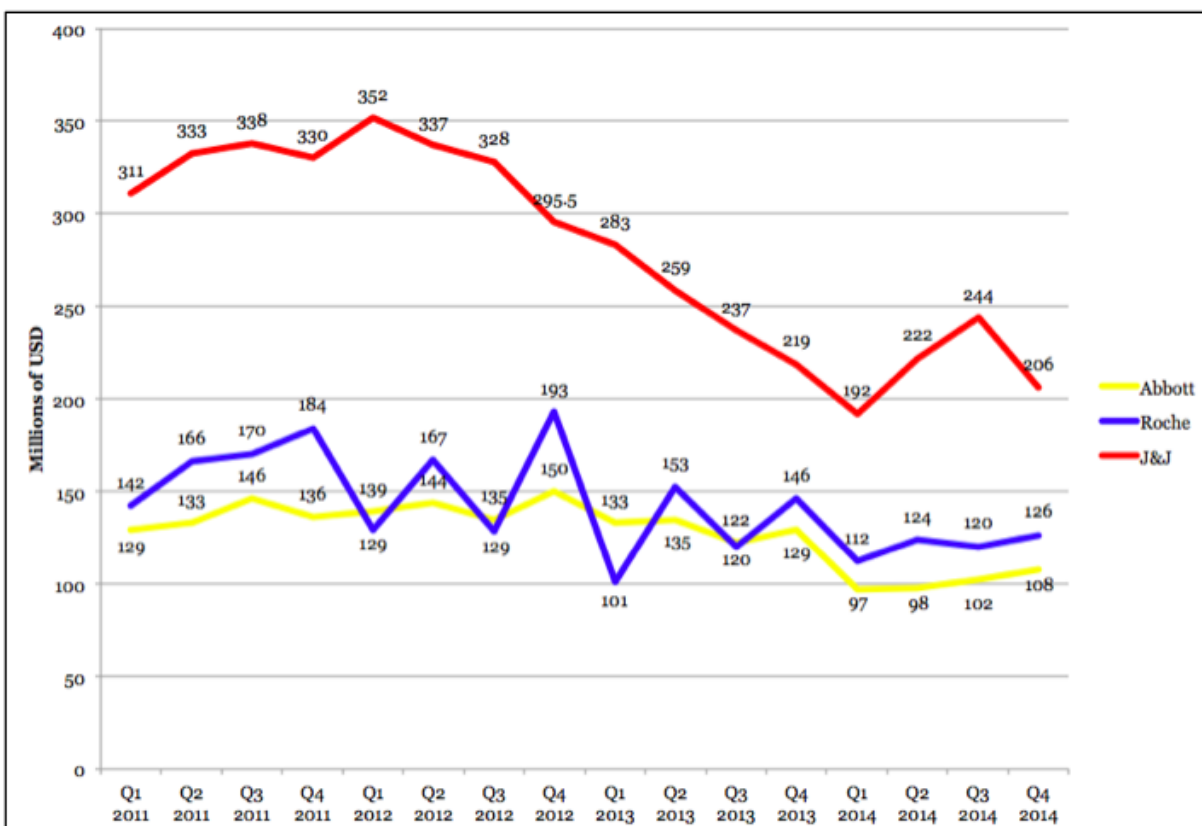
- **A comparison of Abbott/J&J/Roche quarterly global sales illustrates unique revenue trends for each company.** Roche is the most cyclical of the three with sales that vary distinctly with quarters (high in 2Q and 4Q; low in 1Q and 3Q). J&J revenue has declined substantial since 2011 (more of its business is from the US, and its stateside business has been harder hit), while Abbott sales have been surprisingly steady (two-thirds of its sales are OUS).

Table 1: J&J, Roche, and Abbott Worldwide Quarterly Performance (YOY)

	1Q13	2Q13	3Q13	4Q13	1Q14	2Q14	3Q14	4Q14
J&J	-10%	-13%	-11%	-13%	-15%	-5%	0%	-9%
Roche	-4%	-4%	0%	-7%	0%	-7%	1%	-1%
Abbott	-1%	-1%	1%	4%	-10%	-10%	-6%	-10%

- We would note that Abbott outperformed J&J and Roche in each quarter of 2013, but has experienced much weaker growth in 2014.

Figure 3: Abbott/J&J/Roche Quarterly US Revenue Comparison (1Q11 - 4Q14)



- A comparison of Abbott/J&J/Roche quarterly US sales illustrates how significantly J&J's US business has suffered in the past four years; we would note that declines began even before the implementation of competitive bidding. Abbott and Roche have suffered more modest declines.

5. 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. According to Roche's Finance Report, the company incurred 118 million CHF (~\$129 million) in various costs associated with the initiative (IT-related, consultancy, etc.) in 2014. Judging from the language ("ongoing structural adjustments"), it appears that reorganization efforts will continue into 2015. The company has not provided a timeline for completion nor has it provided details on specific strategy.

Device Pipeline Highlights

6. Roche's supplementary materials highlighted two planned device launches in 2015: the Accu-Check Active BGM (worldwide) and the Accu-Chek Connect (US). This is the first we have heard of the next-gen Active BGM. The [slide deck](#) provided few details on timeline or meter features (as is standard nowadays, the strips are no-coding). The first-gen Active BGM was [launched in the EU](#) in 2Q13 but never made it to the US market. A search of the FDA database revealed 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 the 2015 "worldwide" launch.

- **The Accu-Chek Connect system (standalone meter + smartphone app + web portal) appears on track for a 2015 US launch;** the system was [originally launched](#) in South Africa, Italy, and Germany in September 2014. At [JPM 2015](#) last month, the company did not provide a timeline for an FDA 510(k) submission. We have seen the length of FDA reviews vary from four months ([iHealth Smart-Gluco Monitoring System](#)) to 15 months ([Philosys Gmate Smart](#)) for similar smartphone/cloud-connected BGM, meaning a submission in the near-term is likely necessary to ensure a 2015 launch.

7. Despite the financial challenges of the BGM market, Roche seems committed to continued R&D - "Indeed, there's still innovation potential in this business," said management. This was a breath of fresh optimism in an environment that has been so devastated by competitive bidding. In 2014, Roche launched three new devices: the Accu-Chek Insight (next gen insulin pump with BGM remote), [Accu-Chek Connect](#) (in the EU), and [Accu-Chek Expert](#) (BGM with built-in bolus advisor). Of course, not all members of the Big Four have continued to push BGM innovation in the same manner. Bayer, for example, has not brought a new product to market in the past two years. J&J has straddled the middle ground, launching two devices in the US in the past 12 months (the [OneTouch VerioSync](#) last January and the [OneTouch Verio](#) this January) but none outside the States that we are aware of. On the opposite end of the spectrum is Abbott's bold attempt to disrupt the field with the [FreeStyle Libre](#) system in the EU.

8. Management did not comment on the development of Roche's novel CGM, though at [JPM 2015](#), acknowledged that the project is moving forward ("we feel we are in the race"). While hesitant to provide a strict timeline, we heard confirmation that commercialization is more than 12 months away. Roche plans to file the device in the EU before bringing it stateside (~18 months later), so we assume US commercialization would not occur before late-2017 at the earliest.

- **Similarly, there were no updates on the Solo MicroPump (Roche's patch pump).** We have heard that there continues to be work at Roche on this front - it's just not public. The patch pump business model is challenging, and we applaud Roche for persevering in the business; the landscape is bound to get more competitive, as well, with J&J slating a launch of its Calibra Finesse insulin delivery device in mid/late 2016 (read our [J&J 4Q14 report](#) for additional details)
- **Management's prepared remarks and slide deck (slide 57) highlighted the 2015 EU launch of the cobas c 513 A1c analyzer.** We're unsure if this would be used in a laboratory setting or in the clinic. A timeline for the launch was not provided. We are unclear on the market potential, though the need for accurate A1c testing is of course critical for diagnosing and managing diabetes. Roche mentioned the product in its prepared remarks, perhaps hinting at internal optimism.

Drug Pipeline Highlights

9. US sales of the ophthalmologic drug Lucentis (intravitreal ranbizumab) declined 5% YOY in constant currencies to 441 million CHF (~\$457 million) in 4Q14, while full-year 2014 sales rose 2% YOY in constant currencies to 1.7 billion CHF (~\$1.9 billion). Management commented that growth in 2014 was primarily driven by the diabetic macular edema (DME) indication as well as continued overall market expansion (including both new patients and patients switching from Avastin).

- **The outlook for Lucentis in 2015 is much more conservative - management guided for flat sales or even a slight decline due to increased competition in DME.** We expect this is

from both Bayer/Regeneron's Eylea (intravitreal aflibercept; [approved](#) in July) and Alimera Sciences/pSivida's Iluvien (intravitreal fluocinolone acetonide; [approved](#) in September), which both received FDA approval for a DME indication in 2014. As a reminder, Lucentis is marketed by Roche's Genentech division in the US and by Novartis ex-US - see our [Novartis 4Q14 report](#) for an update on the drug's international performance.

- **Management also highlighted the upcoming FDA decision (PDUFA date on February 6) on a diabetic retinopathy indication for Lucentis.** The drug, which [received Priority Review status](#) from the FDA for this indication, would be the first treatment available to patients with existing diabetic retinopathy. This expanded indication would be a huge win for patients, and we assume it could also significantly bolster Lucentis sales and at least partially blunt the impact of the increased competition in DME.

10. Roche's GLP-1/GIP dual agonist RG7697 remains in phase 2 for type 2 diabetes. A phase 2 trial (ClinicalTrials.gov Identifier: [NCT02205528](#)) of the compound is currently recruiting participants and is expected to complete in September. The 12-week study aims to enroll 105 patients with type 2 diabetes on background metformin who will be randomized to receive daily injections of RG7697, Novo Nordisk's Victoza (liraglutide), or placebo. The RG7697 and placebo groups are double-blinded while the Victoza group is open-label. The trial has a primary endpoint of change in A1c from baseline at eight weeks; secondary endpoints include change in A1c, body weight, and fasting and post-prandial glucose at 12 weeks.

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