



MEMORANDUM

Roche 2Q15: Global sales flat operationally; 10% decline in North America; No mention of Accu-Chek Connect - July 23, 2015

Executive Highlights

- Global Diabetes Care revenue totaled 550 million CHF (~\$584 million) in 2Q15, declining 9% as reported and remaining flat operationally year-over-year (YOY). North America sales reached just 99 million CHF (~\$105 million), declining 10% against a very easy comparison.
- Combined global revenue for J&J, Roche, and Abbott totaled ~\$1.4 billion in 2Q15, falling 11% relative to pooled revenue in 2Q14 (~\$1.5 billion). Pooled declines were driven by both the US - where combined sales of ~\$412 million fell 7% YOY - and international markets - where combined sales of ~\$944 million declined 13% YOY.
- There were no additional pipeline updates. Roche did not mention the US launch of its Accu-Chek Connect system (standalone meter + smartphone app + web portal) planned for August 7. The meter will be priced at \$29.99.

Early this morning, Roche CEO Mr. Severin Schwan led the company's [2Q15 financial update](#). Below, we have for you our top ten happenings and highlights from the update. There was no diabetes relevant Q&A.

Financial Highlights

1. Global Diabetes Care revenue totaled 550 million CHF (~\$584 million) in 2Q15, declining 9% as reported and remaining flat operationally year-over-year (YOY). This is the lowest global revenue ever recorded in 2Q in our Roche model, which stretches back to 2004. Performance was carried by positive growth for the Accu-Chek Aviva/Performa franchise and Insulin Delivery systems (up 4% and 2% operationally in 2Q15, respectively).

2. In North America, Diabetes Care revenue totaled 99 million CHF (~\$105 million) in 2Q15, declining 10% against a very easy comparison (sales fell 24% in [2Q14](#)). The performance now marks two 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. Sales had never fallen sub-100 million CHF before 1Q14 (94 million CHF). This result was still better in the US than Abbott, which had below \$100 million - BGM sales at Abbott, to add some context, have now come in under \$100 million in three of the past six quarters; prior to 1Q14, sales had never fallen sub-\$100 million in the past decade.

3. Outside North America, Diabetes Care sales totaled 451 million CHF (~\$479 million) in 2Q15, falling 8% as reported YOY against an easy comparison (down 6%) in [2Q14](#). This was split into: (i) sales in EMEA, which totaled 330 million CHF (~\$350 million), down 13% as reported after falling 4% in [2Q14](#), and; (ii) sales in RoW, which totaled 121 million CHF (~\$128 million), up 5% as reported against an easy comparison as sales fell 12% [a year ago](#).

Pooled Financial Analysis

4. Combined global revenue for J&J, Roche, and Abbott totaled ~\$1.4 billion in 2Q15, falling 11% relative to pooled revenue in 2Q14 (~\$1.5 billion). Pooled declines were driven by both the US (where combined sales of ~\$412 million fell 7% YOY) and even more by international markets (where combined sales of ~\$944 million declined 13% YOY).

Device Pipeline Highlights

5. Roche [recently announced](#) plans to launch its Accu-Chek Connect BGM and paired smartphone app (with a bolus calculator!) in the US on August 7 through an exclusive distribution agreement with Walgreens. The meter will be priced at \$29.99 - like at Abbott, we're very glad to see companies reaching out and doing so much for patients who need the most help.

6. Roche's supplementary materials (slide 181) again 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) at present.

7. Management's prepared remarks again called out the EU launch of the cobas c 513 A1c analyzer as one of two particularly anticipated launches in 2015. A more specific timeline has not been provided.

8. There were no additional pipeline updates. Management did not comment on the development of Roche's novel CGM or on the Solo MicroPump (Roche's patch pump).

Drug Pipeline Highlights

9. US sales of Lucentis (intravitreal ranibizumab) declined 11% YOY as reported and 16% in constant currencies to 421 million CHF (~\$447 million) in 2Q15. Sequentially, sales were up 7% from a low base in [1Q15](#). Management acknowledged increased competition for Lucentis in diabetic macular edema, in line with previous updates.

10. Roche's GLP-1/GIP dual agonist RG7696 for type 2 diabetes has been removed from the phase 2 pipeline, representing another example of the increasingly high bar for new glucose-lowering drugs. This was from Marcadia - Roche paid just over \$250 million for Marcadia some years back, largely on the promise of this compound.

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Introduction of the Accu-Chek Connect System

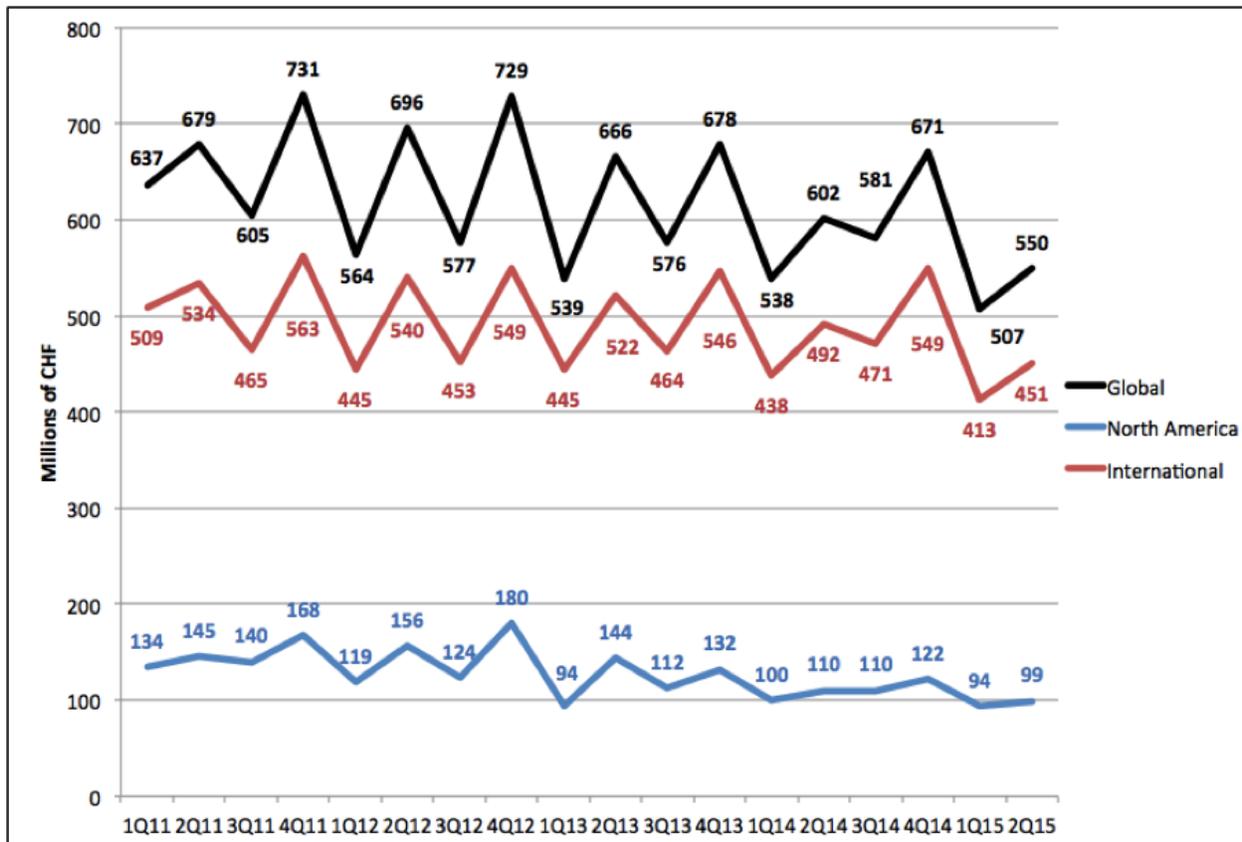
Financial Highlights

1. Global Diabetes Care revenue totaled 550 million CHF (~\$584 million) in 2Q15, declining 9% as reported and remaining flat operationally year-over-year (YOY). This marks the lowest global revenue ever recorded in 2Q in our Roche model - which stretches back to 2004 - and though we attribute the decline at least partially to the challenging currency impact, it is challenging to discuss the quarter optimistically. The 9% reported decline in [1Q15](#) came against a very easy comparison to [2Q14](#) (reported sales down 10%); operationally, the comparison was also relatively easy (sales fell 4%). This did mark the sixth consecutive quarter in which operational growth has been neutral or positive, indicating that the underlying business is growing very slightly. As a reminder, Roche was 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. A breakout quarter

seems unlikely going forward, though we wonder whether the [coming launch](#) of the Accu-Chek Connect system (standalone meter + smartphone app + web portal) might buck the trend in a positive way - more on this below.

- **Sequentially, sales grew 8% against a very low base in 1Q15 (when sales of 507 million CHF marked an all-time low for the global business).** The single-digit sequential growth is actually somewhat disappointing, given that we typically see double-digit sequential growth between 1Q and 2Q, including in five of the past six years (7% sequential growth in 2Q11 was the only exception).
- **Roche's subdued commentary on Diabetes Care - not wholly dissimilar to [Abbott and J&J's 2Q15 discussion of BGM](#) - was quite apparent to us.** That said, at [J&J's 2Q15 call](#), we heard confidence in the launch of the Animas Vibe and huge enthusiasm for the potential of the OneTouch Verio BGM. J&J management suggested that the BGM business, in particular, is well positioned to deliver profitable growth in the future despite negative price dynamics. Meanwhile, [Abbott](#) continues to express significant optimism on FreeStyle Libre and enthusiasm for the product continues to grow internationally as well as domestically (where some patients have managed to get their hands on one). In contrast, Roche offered only one sentence of commentary on the health of the business in its prepared remarks - "Solid growth in diabetes care despite the challenging environment." Roche's performance has long been described in the context of a "challenging" market, and certainly, the broader silence does not bring much reason for optimism.

FIGURE 1: GLOBAL, NORTH AMERICA, INTERNATIONAL QUARTERLY SALES (1Q11 - 2Q15)



- **Global Diabetes Care performance continues to be carried by positive growth for the Accu-Chek Aviva/Performa franchise and Insulin Delivery systems (up 4% and 2% operationally in 2Q15, respectively).** These products were similarly characterized as drivers of

growth at recent updates ([1Q15](#); [4Q14](#)). On pumps, we assume that the modest growth in Insulin Delivery reflects uptake of Roche's Accu-Chek Insight (next generation insulin pump and BGM system), which [launched in the EU](#) in January 2014. Management did not comment on either franchise during its prepared remarks or Q&A.

2. In North America, Diabetes Care revenue totaled 99 million CHF (~\$105 million) in 2Q15, declining 10% against a very easy comparison (sales fell 24% in 2Q14, the second-greatest drop in North America since 2009). In the past 28 quarters (since 1Q08), Roche has recorded only four quarters of positive YOY reported growth in the region. Sequential sales grew 5% in 2Q15, though this came against an incredibly easy comparison as sales of \$94 million in [1Q15](#) were tied for the lowest-ever in the business's history.

- **North America continues to be a very challenging region for Roche.** The 2Q15 performance now marks two 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. As a reminder, sales had never fallen sub-100 million CHF before 1Q14 (94 million CHF).

3. Outside North America, Diabetes Care sales totaled 451 million CHF (~\$479 million) in 2Q15, falling 8% as reported YOY against an easy comparison (down 6%) in 2Q14. The performance marks two consecutive quarters of YOY declines following a string of two straight quarters of YOY growth for the business. Sequentially, sales grew 9% though this was not surprising given the low base (revenue tied in [1Q15](#) marked an all-time low for the segment [413 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 67/33 between the two for sales outside of North America.

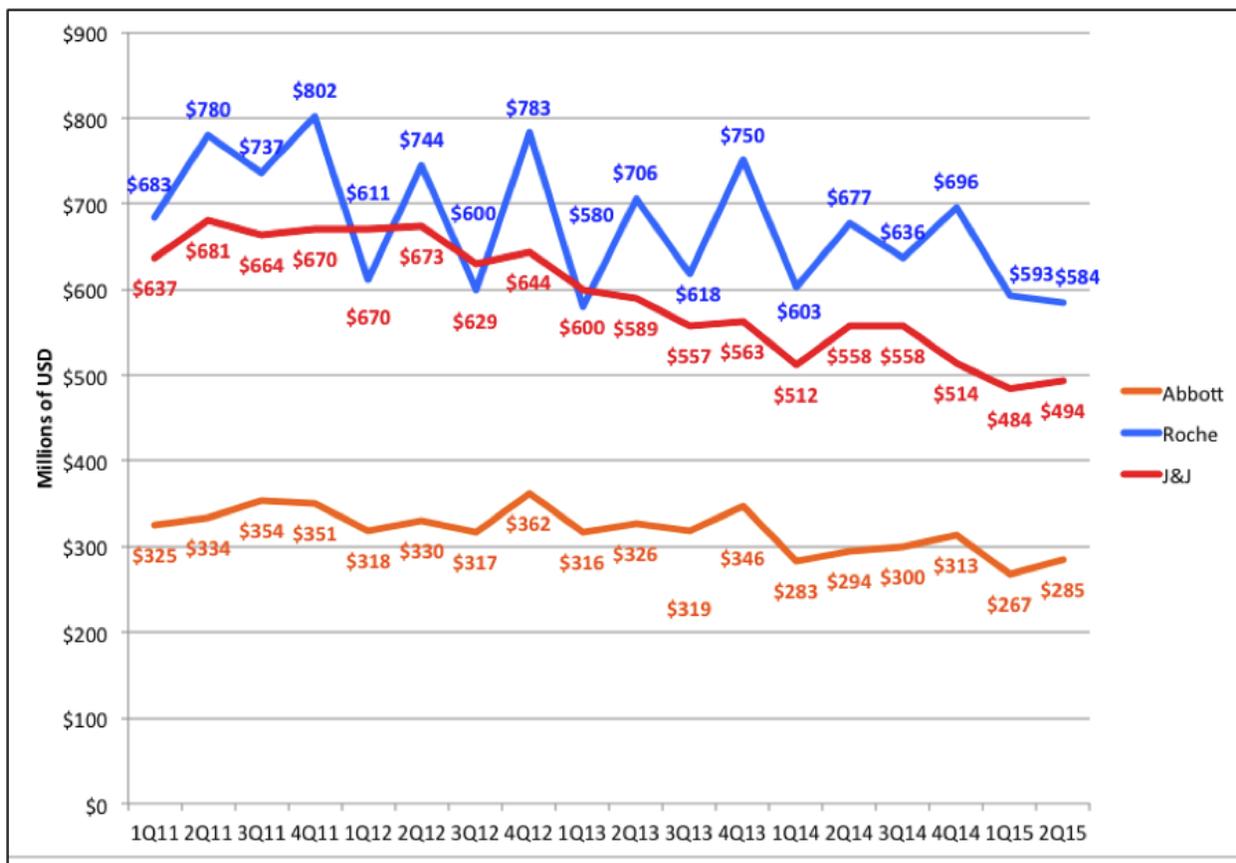
- **Sales in EMEA totaled 330 million CHF (~\$350 million), down 13% as reported after falling 4% in 2Q14.** The indicators in this region are not particularly promising: sales of 330 million CHF mark the third lowest ever recorded in the region in our EMEA model (which stretches back to 2010). Of even more concern, two consecutive quarters of double-digit YOY declines (against two easy comparisons) do not bode well for the remainder of the year. Based on the performance, it seems that the [September international launch](#) of the Accu-Chek Connect (standalone meter + smartphone app + web portal) in South Africa, Italy, and Germany did not drive significant growth during the quarter. Sequentially, sales grew 9% against a low base (sales of 304 CHF million in [1Q15](#) were the lowest recorded in the past five years).
- **Sales in RoW totaled 121 million CHF (~\$128 million), up 5% as reported against a very easy comparison as sales were down 12% a year ago.** While Roche did not comment on the RoW Diabetes franchise performance, presumably the positive (relatively) movement reflects growth of a very undeveloped market. In [4Q14](#), management suggested that the strength reflects BGM and insulin delivery uptake in relatively underpenetrated regions where Roche has a growing presence - Roche's 2Q15 slide deck indicated 14% Diagnostic segment growth in Latin American and 15% growth in Asia Pacific (not diabetes specific). Sequentially, sales grew 11% against a low base.

Pooled Financial Analysis

4. Combined global revenue for J&J, Roche, and Abbott totaled ~\$1.4 billion in 2Q15, falling 11% relative to pooled revenue in 2Q14 (~\$1.5 billion). We were hoping this would be a bit better, though the significant strengthening of the US dollar has contributed to the decline - more on this below. The performance does come against an easy comparison as combined revenue declined 6% a year ago. Sequentially, global pooled revenues grew 5% relative to 1Q15 (when sales reached ~\$1.3 billion). The weakness is not surprising considering that all three BGM businesses saw global declines in reported revenue in 2Q15. For context, [J&J's](#) business declined 12% in 2Q15, while [Abbott's](#) declined 5% and Roche's declined 9%. On an operational basis, Abbott (up 5% YOY) outperformed J&J (down 2% YOY) and Roche (flat YOY). 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

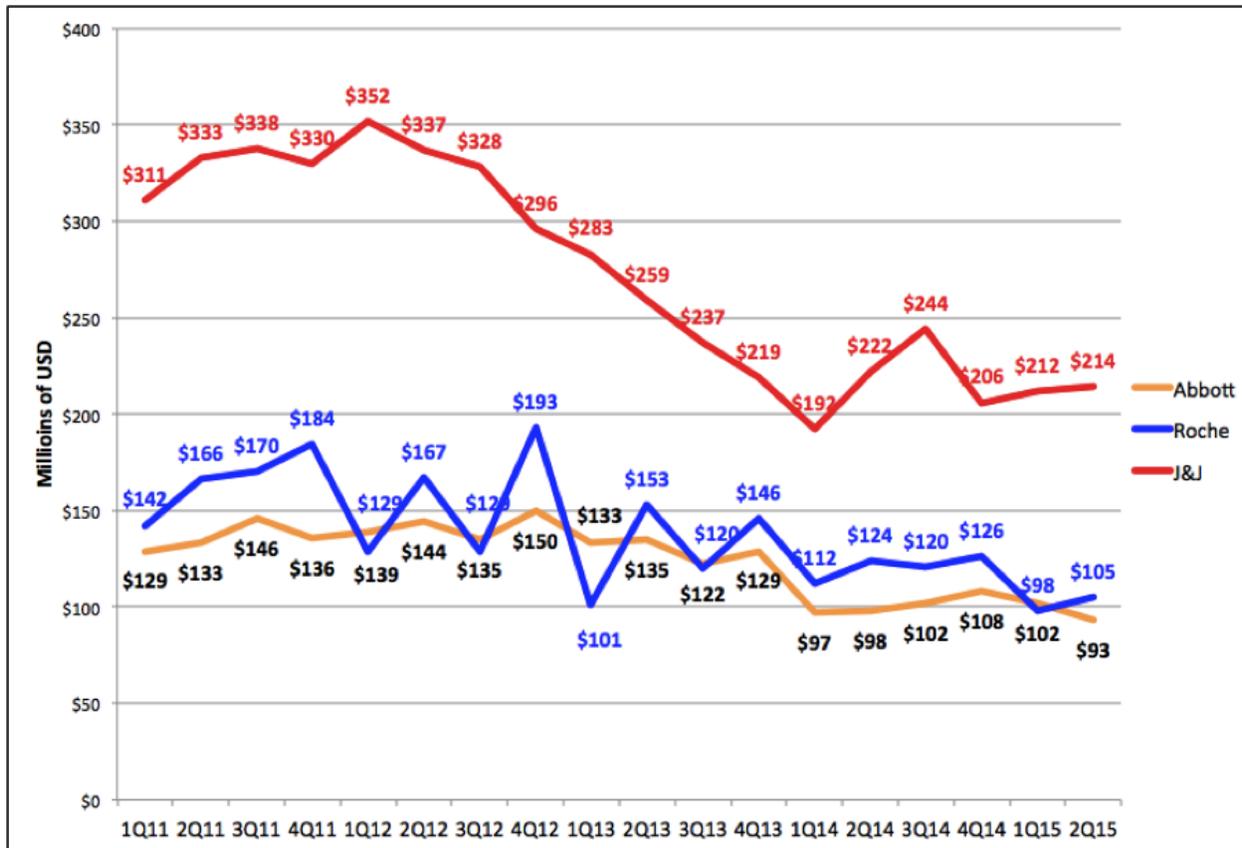
insulin delivery and Abbott has CGM and FGM outside of the US). We look forward to adding the last of the Big Four - Bayer - to this comparison when the company reports on July 29.

FIGURE 2: POOLED GLOBAL ABBOTT, J&J, AND ROCHE SALES (1Q11 - 2Q15)



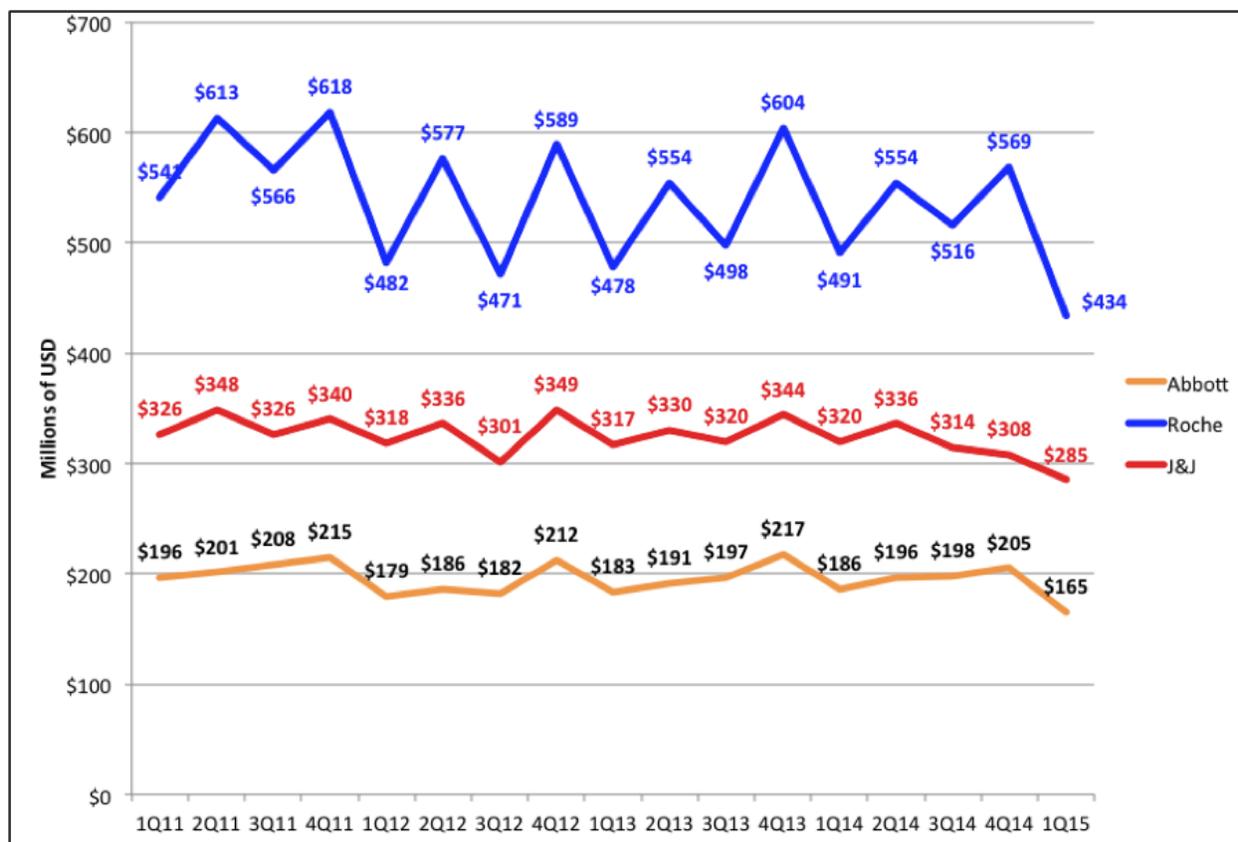
- **A comparison of Abbott/J&J/Roche quarterly global sales illustrates unique revenue trends for each company.** Roche is the most cyclical of the three with sales that vary distinctly with quarters (high in 2Q and 4Q; low in 1Q and 3Q). J&J revenue has declined substantially since 2011 (more of its 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).
- **Pooled declines were driven in part by US weakness, where combined sales of ~\$412 million fell 7% YOY against a strikingly easy comparison to pooled revenue in 2Q14 (down 19%).** 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 were flat relative to 1Q15.

FIGURE 3: POOLED US ABBOTT, J&J, AND ROCHE SALES (1Q11 - 2Q15)



- **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 - however, looking at the past year, perhaps some might say that we could be seeing signs of stabilization.** Declines began, of course, even before the implementation of competitive bidding, when pricing pressure was much less benign. Year to date, Abbott and Roche have suffered more modest declines.
- **Pooled declines were driven in a bigger way by international weakness, where combined sales of ~\$944 million declined 13% YOY.** This came against a modest comparison (for the BGM industry) as sales grew 1% in 2Q14. Sequentially, pooled international revenues grew 7% relative to 2Q14 (~\$876 million). These negative trends seem to reflect the significant strengthening of the US dollar as opposed to underlying weakness in any of the business' fundamentals. J&J, Roche, and Abbott have announced steep YOY reported declines in 2Q15 offset by stronger operational performance: for context, J&J sales were down 12% as reported and down 2% operationally YOY in 2Q15 while Abbott sales were down 5% as reported and up ~5% operationally.

FIGURE 4: POOLED INTERNATIONAL ABBOTT, J&J, AND ROCHE SALES (1Q11 - 2Q15)



- **A comparison of Abbott/J&J/Roche quarterly international sales illustrates how much more stable this environment has been relative to the US/North America businesses.** The seasonality of Roche's business is again apparent here (high in 2Q and 4Q; low in 1Q and 3Q). Broadly speaking, quarterly sales across all three businesses have dropped slightly (~\$50 million) over the past four years.
- **Roche's global revenues accounted for the majority (43%) of the three companies' pooled revenues; this held steady relative to Roche's share in 2Q14 (44%).** Abbott and J&J revenues also held relatively constant at 21% (vs. 19%) and 36% (vs. 37%), respectively. Regionally, J&J holds the greatest percentage of revenue in the US at 52% (vs. 50% in 2Q14), while Roche holds the greatest share of international revenue at 51% (vs. 51% in 2Q14). Overall, we are impressed with how steady market share has been.

Device Pipeline Highlights

5. Though it was not mentioned during the update, Roche [recently announced](#) plans to launch its Accu-Chek Connect BGM and paired smartphone app (with a bolus calculator!) in the US on August 7 - see our full coverage in the Appendix below. The nationwide launch during AADE will come to market through an exclusive distribution agreement with Walgreens. We see the Connect as an important move toward more seamless, automatic, and hassle-free transfer of blood glucose data. Roche's laudable aim is to reduce the patient and provider hassle in the downloading process by removing the need for manual data entry. The biggest highlight of the system is undoubtedly the app, which provides the convenience of insulin bolus advice on a smartphone based on blood glucose results and entered carbohydrates - we think this will be a very big deal in terms of convenience in particular and we are very excited about it for Roche. The meter will be 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.

- **The launch of the system represents a big win for Roche - first-to-market status with a mobile bolus calculator.** There are many US insulin users on MDI (the vast majority of type 1s and 2s) who do not have access to bolus calculators on an insulin pump, so we believe there is a big available market here. We'll have to wait for specifics on revenue/trajectory in coming updates, though are hopeful the launch can provide a boost to the struggling North American business. Roche confirmed that the insulin bolus feature will only be available to patients who purchase the Connect meter. We were disappointed to hear this, though not surprised as it makes a lot of sense from a competitive advantage point of view.

6. Roche's [supplementary materials](#) (slide 181) 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.

7. Management's prepared remarks again called out the EU launch of the cobas c 513 A1c analyzer as one of two particularly anticipated launches in 2015. We first heard about this upcoming launch at [4Q14](#). We're still unsure if this would be used in a laboratory setting or in the clinic, and a more specific timeline for the launch has not been provided. We are unclear on the market potential, though the need for accurate A1c testing is of course critical for diagnosing and managing diabetes.

8. There were no additional pipeline updates. 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 at JPM 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 main comparator in the space is Insulet, who still expects to submit an FDA 510(k) filing for its next-gen PDM by the end of this year. The landscape is bound to get more competitive, as well, with J&J slating a launch of its Calibra Finesse insulin delivery device in 2016 - read our [J&J 2Q15](#) report for additional details. The V-Go is already on the market through a small regional rollout, and CeQur has [EU and US launches](#) of its PaQ device planned for 2016.

Drug Pipeline Highlights

9. US sales of Lucentis (intravitreal ranibizumab) declined 11% YOY as reported and 16% in constant currencies to 421 million CHF (~\$447 million) in 2Q15. Sequentially, sales were up 7% from a low base in [1Q15](#). Despite the weakness, the drug was #4 on Roche's "Top 20" Pharma Division products list. Management acknowledged increased competition for Lucentis in diabetic macular edema (DME), which has been characteristic of recent updates, particularly since the FDA [approved](#) Bayer/Regeneron's Eylea (intravitreal aflibercept) for diabetic retinopathy in patients with diabetic macular edema (DME) earlier this year. As we understand it, the [rollout for Lucentis](#) in patients with diabetic retinopathy in DME is still ongoing, and we hope the new indication will have a positive impact on sales moving forward. On the other hand, sales could 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. As a reminder, Lucentis is marketed by Genentech in the US and by Novartis ex-US - see our [Novartis 2Q15 report](#) for an update on the drug's international performance.

10. Roche's GLP-1/GIP dual agonist RG7697 for type 2 diabetes has been removed from the phase 2 pipeline. The trial (n=105) has not yet been updated on ClinicalTrials.gov (Identifier: [NCT02205528](#)), and the announcement was tucked away in the [supplementary slide deck](#) (slide 69 - we pointed this out to you in our report last night about an hour after the company reported). While this drug had been progressing slowly, we assumed the novel dual agonist had been moving ahead - though it is not so surprising given the competition and the very challenging regulatory landscape. This decision, along with Lilly's announcement in its 2Q15 update this morning that it had discontinued its phase 2 glucagon receptor antagonist and two undisclosed phase 1 candidates in diabetes, illustrates just how high the bar has risen for new glucose-lowering drugs. Facing a fairly crowded market and such high development costs (presumably including a CVOT), it is unfortunately not surprising to us that Roche concluded this product was not worth the investment.

Appendix - Keystone 2015 Coverage of Accu-Chek Connect

INTRODUCTION OF THE ACCU-CHEK CONNECT SYSTEM

Jeremy Mangelson (Area Business Manager, Roche Diabetes Care, Indianapolis, US)

Roche's hands-on workshop debuted the [Accu-Chek Connect](#) BGM and paired smartphone app (with a bolus calculator!) in the US, sharing the planned August 7 launch date and reasonable \$29.99 pricing. Regional Business Manager Jeremy Mangelson ran us through the system, highlighting that the nationwide launch during AADE will come to market through an exclusive distribution agreement with Walgreens - a bold move indeed! The meter is 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 [though you cannot do much with it without the meter]. The next-generation system is based on the Aviva Plus strip platform and features wireless Bluetooth compatibility with the paired apps. Most notably, the Connect app is the first FDA-approved mobile platform that offers insulin-dosing recommendations - a tremendous win for MDI users (who do not have access to bolus calculators on an insulin pump) and for Roche (first-to-market status with a bolus calculator mobile app). Roche confirmed that the insulin bolus feature will only be available to patients who purchase the Connect meter; those with other meters will be able to enter glucose values, but will be unable to use the Bolus Advisor function. We understand this from a competitive perspective, though it would be an amazing win for patients (and tremendous legacy for Roche) if the app was available to all meter users. Though the app is a free download, it is a "prescription" product (not the meter, just the app!), as patients must receive an HCP code to activate the Bolus Advisor software. The Connect also sends readings automatically to the cloud and can notify caregivers of values, a nice feature for parents. Our full report below features our first in-depth look at the meter, app, and web portal including pictures and an overview of the smartphone/cloud-connected market.

- **The Accu-Chek Connect is an important move toward more seamless, automatic, and hassle-free transfer of blood glucose data.** Roche's laudable aim is to reduce the patient and provider hassle in the downloading process by removing the need for manual data entry. The Connect builds on a trend of smartphone/cloud-connected meters - see below for a competitive landscape of the industry. Notably, the launch of the Connect marks the second smartphone-connected BGM commercialized by a Big Four company ([LifeScan's OneTouch VerioSync](#)). We believe much of the diabetes device industry is moving in this direction, and it will only be a matter of time before most devices (BGM, CGM, pumps) are cloud/smartphone app connected. ([Google's 2Q15](#) earnings call reminded us of the power of mobile: More Google searches now take place on mobile devices than on computers in 10 countries, including the US and Japan.)
- **The biggest highlight of the Connect system is undoubtedly the app - see pictures below - which provides the convenience of insulin bolus advice on a smartphone based on blood glucose results and entered carbohydrates.** The FDA clearance marks the software as the first mobile platform cleared for insulin-dosing recommendations. The app is a "prescription" product, as patients must consult with a provider to receive an HCP code that activates the Bolus Advisor software. It's interesting that this is required, since there are many free bolus calculator

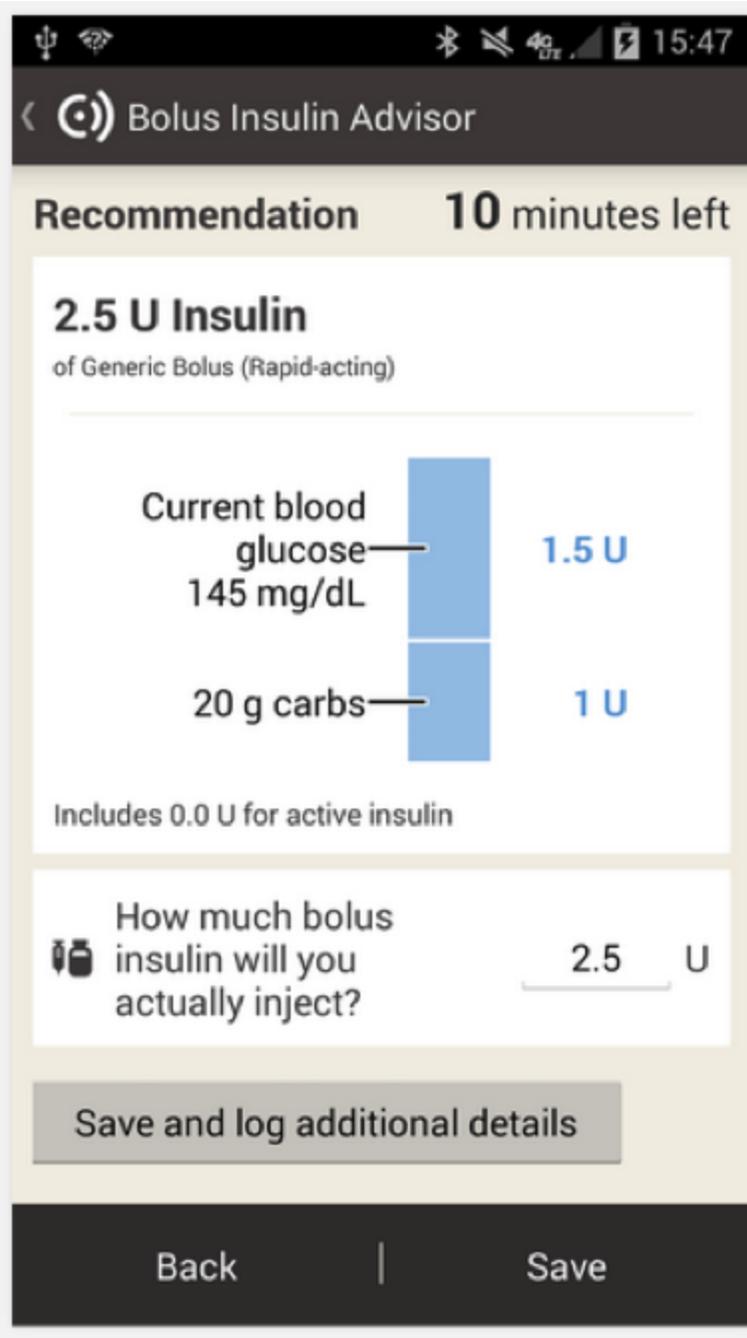
apps on the app store right now that are unapproved by the FDA. There's certainly a danger in the wrong settings, but there's also a danger in not using a bolus calculator app at all. We wonder if Roche proposed the HCP code, or if the Agency required this. HCP involvement is of course critical for proper bolus calculator setup, so the requirement is understandable.

- **The app stands as big win for US insulin users on MDI (the vast majority of type 1s and 2s) who do not have access to bolus calculators on an insulin pump, and a big win for Roche (first-to-market status with a mobile bolus calculator).** We have yet to see rigorous data that such an advisor can improve glycemic control, though anecdotally this seems like a no-brainer (and Roche is reportedly working to get these data published). Dosing insulin - even with the best technology today - is still a guessing game at best, and the math is hard even with ratios that end in "0" and "5." Down the road, perhaps Roche and others will build algorithms to better optimize bolus calculator settings - certainly, Medtronic is thinking about this with the [IBM Watson partnership](#).
 - **Roche confirmed that the insulin bolus feature will *only* be available to patients who purchase the Connect meter.** Those with other meters will be able to enter glucose values, but will be unable to use the Bolus Advisor function. We were disappointed to hear this, though not surprised as it makes a lot of sense from a competitive advantage point of view. We wonder if patients on other meters would be interested in using the app, and whether Roche would reconsider this stance - certainly, it would be an amazing legacy for the company. Bolus calculators are tremendous tools and MDIs only have access to unapproved - and frankly not very good - free versions on the app store.
- **Glucose readings can automatically be sent (via text) to up to ten additional mobile devices** - a huge patient and caregiver convenience that enables remote monitoring and peace of mind. Roche is coming out with strong marketing towards the pediatric population, positioning the monitoring as a way to reduce the burden of pediatric diabetes management and to enable kids to live a more normal life (e.g., attending sleepovers).
 - **Additional tabs within the mobile app offer insight into time-in-range, average number of tests per day as well as pages for viewing results.** Among these is a convenient page to summarize paired points (e.g., before vs. after breakfast) that offers a great way for patients to connect the dots between behavior change and clinical results (e.g., a 15-minute walk *actually* reduces blood sugar!). Roche has done some outstanding work on the BGM education front, and we salute the company for going beyond simply display of glucose values.
- **Upon testing, the Connect app also prompts users to enter the bolus advisor page.** This tab offers the chance to log carbs and take a picture of the meal. We are particular fans of this latter feature, which can create "teachable moments" - after all, carb counting is hard and this enables providers/caregivers to compare the carbs logged with a picture of the actual meal. The following tab provides the patient with the bolus advice, showing graphically the amount of insulin on board and amount of insulin to be injected. Data is automatically sent to the online portal.
- **We were also provided a short demo of the online web portal, which comes in both provider- and patient-facing versions.** The provider-facing side enables population management in a notable way, showing all of a provider's patients on one screen including a symbol to indicate hypoglycemia risk (we like this being front and center!). Following pages in the portal enable providers to see the number of times patients are overriding bolus advice, to change a patient's insulin factors and ratios, to view a color-coded logbook, or to view a graphical display of a patients' average blood glucose over time.
- **It's not clear how Roche is thinking about interoperability (e.g., Apple's Health Kit, Glooko, Tidepool, diasend).** Ideally, the glucose results should flow freely between apps, enabling the ecosystem that many in diabetes technology hope for. Our test drive of Meal Memory

and the Dexcom Share receiver has given us a lot of optimism over targeted apps that leverage passively collected data to drive meaningful therapeutic change - [let us know](#) if you are interested in a sneak preview of this article. We hope Roche is strongly considering data interoperability with these growing platforms.

- **We were also intrigued to learn more about the timeline over which various functionalities of the Accu-Chek Connect System received clearance:** (i) the Connect BGM [was cleared](#) in March 2015; (ii) the Connect app for Android platforms was cleared in late March; and (iii) the Connect app for iOS systems was cleared in early June. Notably though, the Android version of the app was recalled in April (before being launched in the US) after clearance due to problems with inaccurate bolus advice associated with changes of the screen orientation (e.g., from portrait to landscape or vice versa) during calculations. The app [had been downloaded](#) a total of 644 times (Italy: 219, South Africa: 24, Germany: 401). As we understand it, the software bug was fixed "within a few days." Both the Apple and Android apps are currently available on the [Apple](#) and [Android](#) stores.

The Accu-Chek Connect App - Bolus Advisor



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