
Roche 3Q17 - Global Diabetes Care sales rise 3% YOY; BGM down 1%, pumps down 7% YTD; Pooled Roche, Abbott, J&J sales grow 6% YOY; Lucentis up 7% YOY - October 19, 2017

Executive Highlights

- Global Diabetes Care revenue totaled 503 million CHF (~\$521 million), growing 3% YOY as reported against modest 2% growth in 3Q16. This is actually the biggest YOY growth for the business since 1Q10! Year-to-date BGM sales fell 1% YOY operationally, while the other product lines of the Diabetes Unit declined 7% YOY (mainly insulin pumps).
- The North American business saw sales of 73 million CHF (\$76 million) grow 4% YOY after falling a staggering 27% YOY during 2Q17, while sales in the rest of the world grew 3% YOY to 429 million CHF (~\$446 million). Sequential sales rose 6%.
- Pooled "Big Three" revenue (Roche, [J&J](#), and [Abbott](#)) totaled ~\$1.3 billion for the quarter, rising 6% YOY. Unsurprisingly, US weakness drove the pooled declines (-9%), while pooled revenue shot up 11% internationally thanks to remarkable uptake of Abbott's FreeStyle Libre overseas (+34% operational growth for Abbott in 3Q17). Excluding a rough estimate of global Libre sales (~\$130 million) translates to a pooled decline of 4%.
- Notably, we've heard more from management teams on 3Q17 Q&A than ever before; the diagnostics head Mr. Roland Diggelman pointed to opportunities in CGM, pumps, and a focus on the "entire holistic management" of diabetes patients, surely referring to the "integrated diabetes ecosystem," featuring Senseonics' Eversense and mySugr, that we heard about at EASD. This seems like a "long view" comment confirming Roche's investment plans.
- Lucentis (intravitreal ranibizumab) US sales grew 7% YOY to 399 million CHF (~\$415 million) - the highest total since 2Q15 - and against a tough comparison to 14% growth in [3Q16](#).

Roche CEO Dr. Severin Schwan led the company's [3Q17 financial update](#) this morning (see the [slide deck](#) here). The Diabetes business saw modest growth in the face of reimbursement cuts and the US discontinuation of new pump sales, along with strong competitive headwinds in pumps outside of the US. Roche is in a transition period and hopes to shift its focus from a device-based hardware approach to an ecosystem/service-based approach with a wider emphasis on glucose sensing, digital health, and a "holistic management." Below, we bring you our top financial, pipeline, and therapy highlights from the call, as well as pooled "Big Three" (Abbott, J&J, Roche) analysis and selected Q&A.

Financial Highlights

1. Global Diabetes Care revenue grew 3% YOY to 502 million CHF (~\$521 million) in 3Q17 against 2% growth in [3Q16](#) (one of the better quarters of late). For the challenged diabetes segment, this is the biggest YOY growth since 1Q10 (!) - albeit from a low base - and just the ninth quarter of YOY gains in four years. Year-to-date (YTD) BGM sales fell 1% YOY operationally, while the other product lines of the Diabetes Unit declined 7% YOY (mainly insulin pumps).

2. In North America, Diabetes Care revenue climbed 4% YOY to 73 million CHF (~\$76 million) against a modest comparison to 1% YOY growth in [3Q16](#). Sequentially, sales rose 6% against the backdrop of a marked 41% sequential gain in [2Q17](#) (from a very weak [1Q17](#)). We wonder if Accu-Chek Guide is finally picking up steam in the US - the [Simple Pay co-pay program](#) is a strong cash-pay offering in our view.

3. Outside of North America, sales of 429 million CHF (~\$446 million) rose 3% YOY against a modest YOY comparison (2% growth in [3Q16](#)). The alternating up-down sequential pattern that has characterized the international business for some time now (see [Figure 1](#)) continued this past quarter.

Pooled Financial Highlights

4. Pooled global revenue for the "Big Three" (Roche, J&J, and Abbott) totaled ~\$1.3 billion, rising 6% YOY on an easy pooled comparison to [3Q16](#) (down 1% to ~\$1.23 billion). US pooled revenue fell 9%, while international pooled revenue grew 11%. Abbott again [carried the quarter](#), with global sales up 19% on the international strength of FreeStyle Libre.

Device Pipeline Highlights

5. In Q&A, Mr. Diggelman confirmed plans to focus on the "entire holistic management" of diabetes patients, referring to the "integrated diabetes ecosystem" (e.g., Senseonics Eversense implantable CGM and [recently-acquired mySugr](#)) that we heard about at EASD. Per the symposia, it will "hopefully" be available before next year's EASD - we're impressed with the approach and excited to see Roche's movement here.

6. There was no mention of Roche's own Accu-Chek Insight CGM, which launched in a controlled fashion in the EU toward the end of 2016. We learned at EASD that the company will deprioritize the sensor in favor of Senseonics' Eversense implantable CGM - this seems like a smart move, assuming Senseonics can scale, drive to factory calibration, and maintain 180-day reliability. We saw a number of patients at EASD recently on Senseonics and believe with about 1% global penetration of CGM, it will be possible for a number of companies to be successful - no doubt Senseonics was ahead of the Roche internal system so this decision made lots of sense.

7. The [slide deck](#) noted again that the Accu-Chek bG Instant System launched in the EU. We're not sure what the US plans are for the Instant, but Roche told us the initial launch countries are Greece, Romania, and South Africa. The Accu-Chek Guide, which launched in the US [in May](#) and has expanded into at least five more countries, was not mentioned today.

8. On the Senseonics 2Q17 call, we learned that the [Senseonics/Roche/TypeZero long-term closed loop system](#) (180-day sensor) iDCL pivotal trial should begin enrolling in early 2018 and wrap up later in 2018 to support a CE mark. We hope to hear an update when NIH's Dr. Guillermo Arreaza-Rubin speaks about the NIH AP Consortium at [DTM next month](#). The [US main phase](#) (Tandem/Dexcom/TypeZero) was slated to start on October 15, though is still "not yet recruiting" so we're not positive on the timing.

Drug Pipeline Highlights

9. US sales of Lucentis (intravitreal ranibizumab) rose 7% YOY to 399 million CHF (~\$415 million) - the highest total since 2Q15 - and against a tough comparison to 14% growth in [3Q16](#). In Q&A, management declined to comment on Novartis' RTH258, which will be competition for Lucentis down the line. As a reminder, Novartis licenses Lucentis for ex-US sale.

10. Enrollment for the phase 2 Lucentis port delivery study - [LADDER](#) (n=220) - has completed ahead of schedule, and results are expected in 2018 (September, per CT.gov). Slides also noted phase 2 results in 2018 for the anti-VEGF/Ang2 bispecific antibody with dual mechanism of action (RG7716).

11. There were no updates on Roche's FGF21 candidate, though the company's presentation slides highlighted two phase 1 clinical trials: One [study in obesity](#) (n=79 adults with overweight/obesity and no type 2 diabetes, but suspected insulin resistance) was completed in March 2017, while another is ongoing in [type 2 diabetes](#) (n=120) and is expected to complete in June 2018.

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Financial Highlights

1. GLOBAL DIABETES CARE UP 3% YOY; YTD, BGM DOWN 1% & PUMPS DOWN 7%

Global Diabetes Care revenue grew 3% YOY to 502 million CHF (~\$521 million) in 3Q17 against modest 2% growth in 3Q16. For the challenged diabetes segment, this is the biggest YOY growth since 1Q10 (!) - albeit from a low base - and just the ninth quarter of YOY gains in four years. Despite the quarterly growth, the [slide deck](#) (which shows -2% nine-month year-to-date revenue) pointed to continued US pricing and reimbursement pressures as a major source of recent strains. In accordance with the pronounced seasonality of the diabetes business - sequential growth in Q2 and Q4, with sequential declines in Q1 and Q3 - worldwide sales fell 3% sequentially from [2Q17](#). Diagnostics Division CEO Mr. Roland Diggelmann acknowledged these swings are in part related to reimbursement cuts in the US. It's been over three years since the business topped 600 million CHF, something it used to do routinely prior to a 24% sequential plummet in [1Q15](#).

- **Year-to-date (YTD) BGM sales fell 1% YOY operationally, while the other product lines of the Diabetes Unit dropped 7% YOY (mainly insulin pumps).** The 1% BGM decline in the first nine months of 2017 actually indicates a positive third quarter for the segment, as BGM fell 3% in the [first six months](#) (the company doesn't breakdown segments sales on a single-quarter basis). This can likely be chalked up to the Accu-Chek Guide BGM beginning to ramp in major US and German markets, as well as the continued Accu-Chek Instant bG EU rollout in more price-sensitive markets (called out in the [slide deck](#)). It is no surprise that the pump business fell so markedly, as the company discontinued new pump sales in the US as of the [beginning of 2017](#) and ceased US pump supply sales at the [end of August](#), and strong competitive pressures loom around the world (largely from Medtronic's MiniMed 640G and Insulet's OmniPod outside the US). Based on the new [move into automated insulin delivery](#) with TypeZero/Senseonics, it's possible Roche may re-enter

the US pump market at a later date; for now, the focus seems to be on Europe with this collaboration.

- **Mr. Diggelmann added, at two separate points, "I just want to remind you" that there were "obviously" 20% reimbursement cuts (he mistakenly cited 25% in one instance) in the US public sector, which are continuing to spill over into the private sector.** He was of course referring to the second round of CMS' competitive bidding, a program which by all accounts has had devastating unintended consequences for patients ([increase in mortality, inpatient admissions, + higher costs; 37.5% \(n=90,923\) of insulin-treated beneficiaries calculating insulin dose with partial/no SMBG](#)). The irony is profound in our view that CGM is being reimbursed at Medicare but SMBG is now at such an incredibly low level. That said, if all goes as we suspect, better outcomes will continue to be seen with CGM, which should propel Medicare investment. Spillover into the private sector will certainly put even more pressure on the BGM field, and we're not sure what implications this has for the [~65% of Americans under 65 with private insurance](#) - will only lower quality BGMs be covered (with factories that FDA can't afford to visit)? As for Roche, it's good to see the company placing parallel hedged bets in "holistic diabetes management," CGM (Senseonics Eversense), digital health (mySugr), automated insulin delivery (Senseonics/TypeZero), and perhaps even moving beyond hardware to more population health and risk-based contracting - we certainly hope to see the latter. Roche's investment in CGM is particularly opportune: According to our [1H17 industry roundup](#), CGM drove 18% of the Diabetes industry's growth in Q1 and 20% in Q2 (and there is *plenty* of runway), whereas BGM and pump/insulin delivery, by our estimates, fell. That said, large-scale, market-expanding adoption of Senseonics' implantable Eversense is still a major question mark - but the market is certainly healthy and the management team strong. Early signs point to a majority (~80%) of current Eversense users coming from other CGMs.

FIGURE 1: GLOBAL, NORTH AMERICA, INTERNATIONAL QUARTERLY SALES (1Q11 - 3Q17)

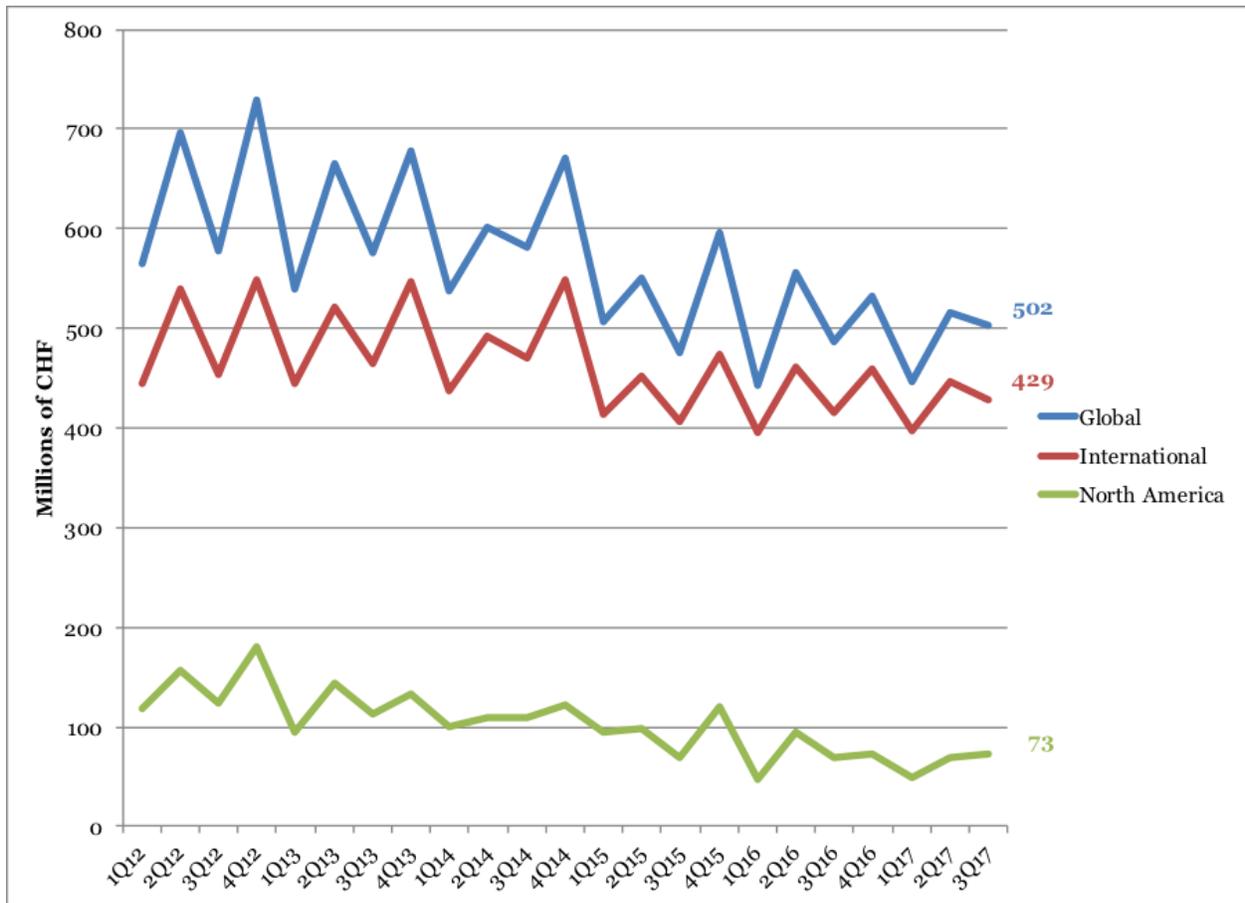
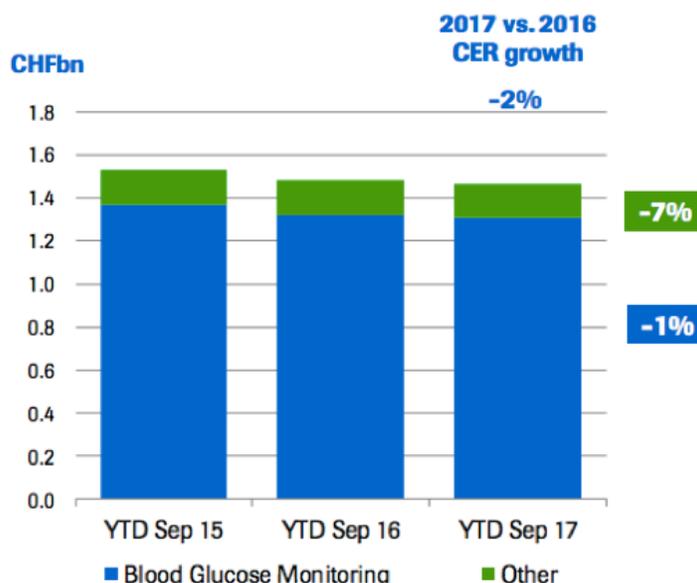


FIGURE 2: YEAR-TO-DATE BGM AND "OTHER" (MOSTLY PUMPS) SALES

Diabetes Care



CER=Constant Exchange Rates

180

2. NORTH AMERICAN REVENUE GROWS 4% ON MODEST COMPARISON (+1% IN 3Q16)

In North America, Diabetes Care revenue climbed 4% YOY to 73 million CHF (~\$76 million) against a modest comparison to 1% YOY growth in 3Q16. Sequentially, sales rose 6% against the backdrop of a marked 41% sequential gain in 2Q17 (from a very weak 1Q17). This is the sixth quarter in a row with North American revenues under 100 million CH. Notably, the international business is running ~six times the size of the US business; in 2012, it was more like ~three times! As with previous quarters, the [slide deck](#) pointed to pricing and reimbursement pressures stateside - 20% reimbursement cuts in the second round of competitive bidding - for the challenging environment (despite 4% growth this quarter, North American sales have fallen 11% YTD, driven by a striking 27% YOY decline last quarter). We wonder how the Accu-Chek Guide, complete with highly accurate and affordable strips, is faring in the US since its [official May launch](#) (it's also in Germany, Denmark, Switzerland, Australia, and possibly Italy by now per rep comments in [February](#)). Roche [stopped selling new pumps in the US](#) as of January 1, which could have partially contributed to the drop-in revenue.

3. REVENUE OUTSIDE OF NORTH AMERICA RISES 3% YOY

Outside of North America, sales of 429 million CHF (~\$446 million) rose 3% YOY against a modest YOY comparison (2% growth in 3Q16). The alternating up-down sequential pattern that has characterized the international business for some time now (see [Figure 1](#) above) continued this past quarter (falling 4% from 2Q17 following 12% sequential growth in the previous quarter). For the past seven quarters, despite quarter-to-quarter fluctuations, the international business has remained remarkably flat - for the bulk

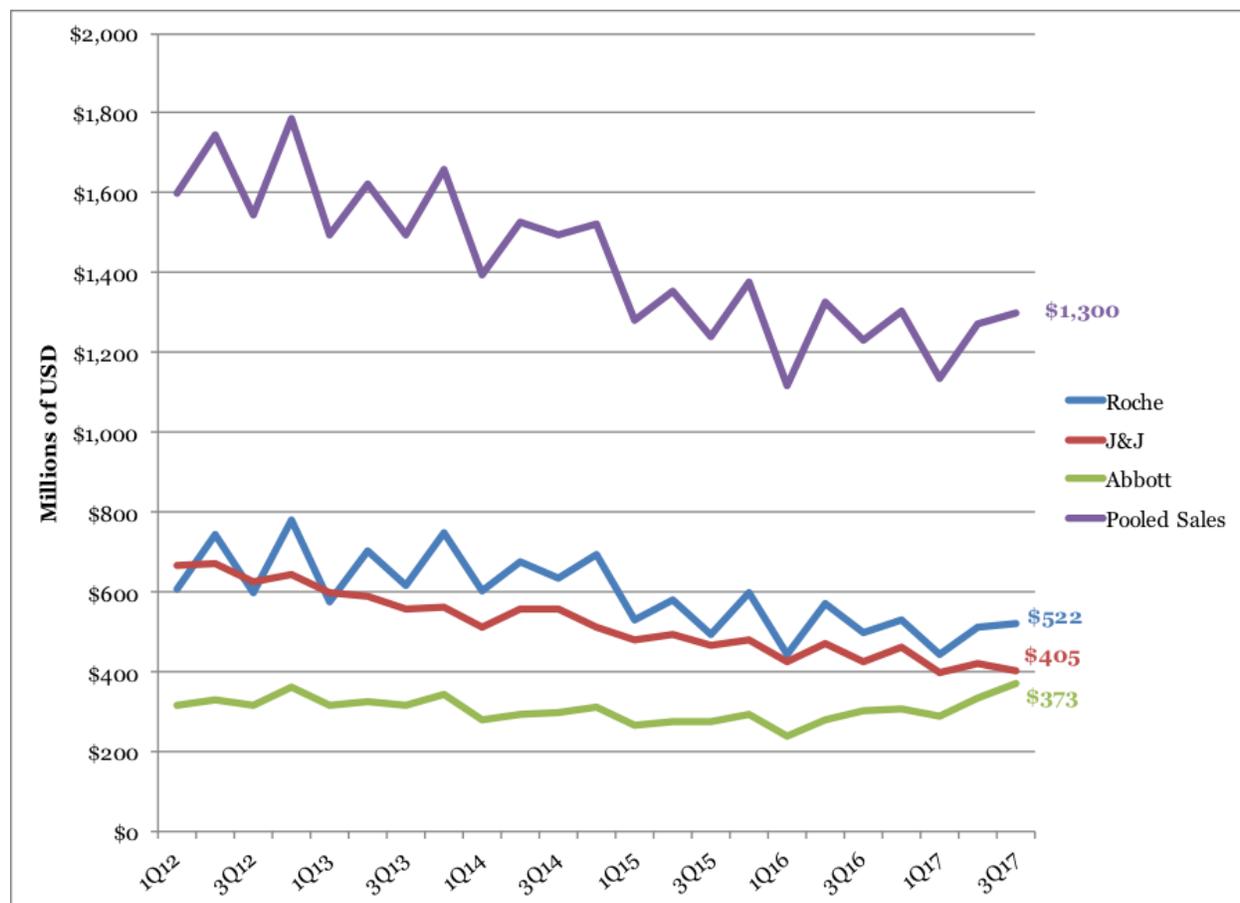
of the business to be holding relatively steady during this period of strategic transition is a positive. For the first nine months of 2017 at a geographic level, total Diabetes Care sales again expanded in Latin America (+8%) and Asia-Pacific (+5%), but declined in EMEA (-2%) and Japan (-4%).

Pooled Financial Highlights

4. POOLED "BIG THREE" REVENUE FOR THE QUARTER RISES 6% TO \$1.3B - FLAT YOY EXCLUDING ABBOTT

Pooled global revenue for the "Big Three" (Roche, J&J, and Abbott) totaled ~\$1.3 billion, rising 6% YOY on an easy pooled comparison to 3Q16 (down 1% to ~\$1.23 billion). The companies don't break out BGM revenue and each has other revenue streams, so pooled revenue isn't as informative about the health of the BGM field as it used to be. That said, it is very telling that J&J is considering strategic options for LifeScan following [Animas' exit](#), Abbott is going all in on FreeStyle Libre (including an [automated insulin delivery partnership with Bigfoot](#)), and Roche is focused on partnerships and holistic diabetes management (including Senseonics, mySugr, and the [automated insulin delivery partnership with Senseonics/TypeZero](#)). Abbott is separating itself from Roche and J&J in a meaningful way at this stage. Though from a lower base, in 3Q17, Abbott Diabetes Care sales grew 19% YOY globally, buoyed by remarkable 34% YOY operational international growth to record-high revenue of \$289 million. FreeStyle Libre continues to shine. With FDA approval and expanding reimbursement (+ Japan and UK in the past quarter), Abbott anticipates more double-digit growth moving forward. Meanwhile, J&J has seen 12 straight quarters with YOY declines (down 7% YOY in [3Q17](#)) and Roche matched its seven-year-high of 3% growth this quarter. **Excluding Abbott sales from the pooled calculation paints a different picture, as global J&J + Roche sales were flat YOY in 3Q17. Pooled US sales fell 7% YOY, while international sales grew 3%.**

FIGURE 3: WORLDWIDE POOLED ROCHE, ABBOTT, AND J&J QUARTERLY SALES (1Q12 - 3Q17)



- In the US market, pooled revenue fell 9% to \$328 million on an easy comparison (-4% in 3Q16).** J&J LifeScan and Roche both pointed to pricing pressures as a headwind, though we imagine Abbott was also negatively impacted - we can't remember the last time we heard Abbott CEO Miles White publicly discuss the company's legacy BGM business (perhaps not since 2Q15, based on our writing!). It was a weak US quarter for Abbott and J&J, who saw 13% and 12% respective declines, but Roche's North American Diabetes Care segment actually grew 4% on a modest comparison. Roche sales do encompass all of North America, but we have included the figure in our US calculation because individual country revenues are not reported (and presumably the US dominates this geography for Roche). Abbott's US sales will see a dramatic uptick in the coming quarters, as Mr. White generally endorsed analyst Mike Weinstein's estimate of "\$50 million? \$100 million?" for US Libre revenue in 2018. The sensor will launch by end of year.
- Internationally, "Big Three" revenue of \$962 million grew a notable 11%, carried by Abbott's FreeStyle Libre.** The growth came against a modest comparison, as sales grew 1% in 3Q16. Sequentially, pooled revenue grew 1%. J&J's international revenue fell 3% YOY, Roche's grew 3%, and Abbott's grew 34% to a record-high (for the second quarter in a row). There are now over 400,000 FreeStyle Libre users in the world - excluding roughly-estimated Libre 3Q17 sales of ~\$130 million and 3Q16 sales of ~\$65 million (~\$120 per month; 90% utilization), then pooled revenue for the three companies was actually up 4% YOY in 3Q17. Pooling just J&J and Roche international sales also translates to 3% YOY growth.

Device Pipeline Highlights

5. FOCUS ON "ENTIRE HOLISTIC MANAGEMENT OF DIABETES PATIENTS" - A LOT ON THIS AT EASD, BUT NO SPECIFICS

Notably, in Q&A, Mr. Diggelman confirmed that Roche wants to focus on the "entire holistic management" of diabetes patients, no doubt referring to the "integrated diabetes ecosystem" (including Senseonics Eversense implantable CGM and [recently-acquired mySugr](#)) that we heard so much about at EASD. This seems like a "long view" comment confirming Roche's investment plans. Per the [exhibit hall](#), the ecosystem, which will leverage Accu-Chek BGMs, the mySugr app, GoCarb (an AI carb quantification app), Accu-Chek Connect app, Eversense CGM, Accu-Chek View (a digital diary with HCP data sharing portal for prediabetes), the connected Pendiq pen, and other pieces, will "hopefully" be available before next year's EASD. We look forward to learning about the business model and how Roche will make the diabetes care experience more connected and seamless - integrating this many pieces into a unified, digital user experience is quite a tall order, particularly given the pace at which apps move and must be maintained. One rep told us that the ecosystem platform - whatever business model it is based upon - will be device agnostic in 1.5-2 years. Individual pieces are rolling out, of course - mySugr has been available for years and has 1+ million users, and has recently expanded with a Pro bundle reimbursed by a large payer in Germany and launching direct-to-consumer in the US. It's encouraging to see the Roche diabetes business pursuing a broader strategy, a refreshing change from the (believable) [rumors of divestment](#) just seven months ago. The transition to more of a service/digital health-based diabetes tech business will not be automatic for a large company like Roche, but it does align with the market's prevailing trends. Can Roche fit the puzzle together and make a compelling case to payers? See our coverage of Roche's [corporate symposium](#) at EASD for more detail and an exciting day-in-the-life use case/demo.

6. PER EASD, ROCHE DEPRIORITIZING ACCU-CHEK INSIGHT CGM IN FAVOR OF SENSEONICS

There was no mention in prepared remarks, Q&A, or the slide of Roche's own Accu-Chek Insight CGM, which launched in a controlled fashion in the Netherlands, Norway, Denmark, and Sweden toward the end of 2016. As EASD, we learned that the company will deprioritize the sensor in favor of partner Senseonics' Eversense implantable CGM. In one of the few tech updates EASD, Roche told us it does not plan to launch further versions of Insight, though we confirmed the sensor will stay in existing limited launch markets ("specialized diabetes centers"). Reps weren't sure if Roche would expand the offering to other countries. It's hard to imagine Roche doubling down on this sensor, given the partnership with Senseonics and not enough differentiation or new features relative to Dexcom and Abbott. Roche management shared the same hesitation at EASD, noting that while Insight performs up to par with the competition, it doesn't add anything novel, unlike the implantable 90-180-day Eversense. As a reminder, Roche currently [distributes Eversense widely](#), invested ~\$30 million in the company [in May](#), and is supplying the Accu-Chek Insight pump for the [development of an automated insulin delivery system with Senseonics and TypeZero](#). Will Roche eventually acquire Senseonics? Can Senseonics scale and expand the market, or will use be limited to early adopters? Will HCPs be willing to do the procedure?

- **Notably, 80% of patients who have gone on Eversense are experienced CGM/Libre users** - ~50% are "experienced [Abbott FreeStyle] Libre users" and 30% were previously on Dexcom or Medtronic. The other 20% are CGM naïve. This one metric represents a major concern and a nice opportunity. On one hand, Senseonics (and all companies) need to expand the market, but this early stat suggests it is stealing share. On the other hand, the fact that ~80% of users are from other CGMs suggests Senseonics has something quite competitive and is filling a niche. Previous sensor users reported a desire to move to Eversense because of the freedom, convenience, extended wear, and alarms. This will be a critical metric to watch for Senseonics and the ecosystem - will the company mostly steal share or expand the market? It will take time to see what happens, since most early users are likely to be "in the know" and on CGM already.

7. NO COMMENTS ON ACCU-CHEK INSTANT BG AND GUIDE ROLLING OUT WORLDWIDE

The [slide deck](#) noted again that the Accu-Chek bG Instant System launched in the EU. We're not sure what the US plans are for the Instant, but Roche told us the initial launch countries are Greece, Romania, and South Africa. Roche is positioning the meter as an "effortless, accurate and affordable bG system for price-sensitive markets." We got to see it in person at ATTD 2017, where a rep told us the device has a streamlined feature set including a target range indicator, Bluetooth connectivity, and just a single button, and that it may be better for patients who don't need all of the whistles and bells offered by the Guide, but just a quick indication of blood sugar. We appreciate that the company is making more options available, especially with price point in mind.

- **The Accu-Chek Guide, which launched in the US [in May](#) and has expanded into Germany, Denmark, Switzerland, Australia, and possibly Italy and others, was not mentioned** on the call or in supplementary materials. Mr. Diggelmann has [previously expressed](#) that the Guide will "protect and safeguard this franchise" - based on apparent 3Q BGM growth (BGM fell 3% in the [first six months](#) of 2017, but is only down 1% for the first nine months), it may be that Guide and Instant bG are already having a positive impact.
- **See our [mini test drive](#) of the next-gen Guide system** - we especially liked the strips' very wide blood application area. We're also huge fans of the [SimplePay program](#), making a highly accurate meter/strips very affordable at a cash-pay price. As we covered in May, Patients can get the meter for free and sign up for the SimplePay savings card at [Accu-Chek's website](#). With the card, a vial of 50 strips is \$19.99, and each incremental 50 strips thereafter will add just \$10. This means 100 strips for \$29.99, 150 strips for \$39.99, etc. That's between \$0.22-\$0.40 per strip without insurance, depending on the quantity purchased - nice!

8. ROCHE/SENSEONICS/TYPESZERO LONG-TERM ARTIFICIAL PANCREAS PIVOTAL TRIAL FOR CE MARK TO WRAP UP IN 2018

On the Senseonics 2Q17 call, we learned that the [Senseonics/Roche/TypeZero long-term closed loop system](#) iDCL pivotal trial should begin enrolling in early 2018 and wrap up later in 2018 to support a CE mark. We hope to receive another update when NIH's Dr. Guillermo Arreaza-Rubin speaks about the NIH AP Consortium (iDCL is one of the four NIH-funded closed loop "pivotal" trials) at [DTM next month](#). We can only assume the system is at least partly what Mr. Diggelman had in mind when he referred to opportunities going forward in "sensors, continuous monitoring, and pumps." With the pivotal wrapping up in 2018, we could see an EU market launch in 2019-2020 (our speculation) - plans to bring the system to the US have not been shared.

- **As a reminder, the "long-term" automated insulin delivery system will include Senseonics' "Eversense XL" (180-day implantable CGM), Roche's Accu-Chek Insight pump, and TypeZero's inControl AP algorithm.** The integrated system will be tested soon at three EU universities - Amsterdam, Padova, and Montpellier. We wonder if Roche will be the company to commercialize the system, and if so, when that might happen - by our estimates, it could be anywhere from third to fifth to market in the EU, likely behind MiniMed 670G and possibly behind Cellnovo, Diabeloop, and/or Insulet. We also wonder what effect this would have on the business, how hard it will be to have three partners on a system, and if the 180-day Senseonics sensor will be a compelling value-add.

Drug Highlights

9. "STABILIZED" LUCENTIS SALES UP 7% YOY DRIVEN BY NEW INDICATIONS + PRE-FILLED SYRINGE

US sales of Lucentis (intravitreal ranibizumab) rose 7% YOY to 399 million CHF (~\$415 million) - the highest total since 2Q15 - and against a tough comparison to 14% growth in [3Q16](#).

For the first nine months of the year, Lucentis is up 4% YOY. Sequentially, sales grew 19% in 3Q17 against an easy comparison, as revenue declined 15% sequentially in 2Q17. Management noted that Lucentis has stabilized and anticipates positive full-year growth - it is in good position to do so. According to Roche Pharmaceuticals CEO Daniel O'Day, growth was driven by [new indications](#) for mCNV (myopic choroidal neovascularization, a complication of near-sightedness) and diabetic retinopathy without DME (launches ongoing), as well as the launch of the 0.5 mg pre-filled syringe earlier this year. An FDA submission for a 0.3 mg pre-filled Lucentis syringe is expected before the year closes. With these milestones under Lucentis' belt, we'd love to see market share numbers vs. Bayer/Regeneron's Eylea (intravitreal aflibercept) and Genentech's Avastin (bevacizumab).

- **Management declined to comment in detail on a question about Novartis' phase 3 neovascular age-related macular degeneration candidate, RTH258 (brolocizumab).** In the wake of positive phase 2 and 3 results, Novartis has scaled up manufacturing ahead of a potential 2H18 regulatory submission. During the 2Q17 financial update, Novartis' head of Global Drug Development Dr. Vas Narasimhan shared that the company would move forward with studies for other indications, including DME. This is challenging from a partnership perspective, as Novartis licenses Lucentis for ex-US sale. When asked if they were "comfortable with this dynamic," Roche management responded that the data isn't that different between the two drugs and that "for Novartis, we really don't want to comment specifically."

10. PHASE II RESULTS FOR LUCENTIS PORT DELIVERY STUDY AND ANTI-VEGF/ANG2 BISPECIFIC ANTIBODY EXPECTED BOTH IN 2018

Management shared that enrollment for the phase 2 Lucentis port delivery study - [LADDER](#) (n=220) - is completed ahead of schedule, and results are expected in 2018 (September, per [CT.gov](#)). The desired outcome from this study is to expand Lucentis' indication to a port delivery device - we expect additional options for delivery can help with patient and provider acceptance. The slides also noted that phase 2 results for the anti-VEGF/Ang2 bispecific antibody with dual mechanism of action (RG7716) are expected in 2018. We're not sure which trial the deck was referring to, as there are three investigating RG7716 (two in wet age-related macular degeneration). However, the ongoing [BOULEVARD trial](#) (n=230) is comparing RG7716 to an active comparator of intravitreal ranibizumab in treating center-involving diabetic macular edema (a condition in which the central macula is damaged in patients with diabetes). This study was expected to reach primary completion in September according to [ClinicalTrials.gov](#), with an estimated completion date of May 2018.

11. PHASE 1 PROGRAM FOR FGF21 ANALOG REMAINS ON TRACK IN OBESITY, TYPE 2 DIABETES

There were no updates on Roche's FGF21 candidate, though the company's presentation slides highlighted two phase 1 clinical trials: One [study in obesity](#) (n=79 adults with overweight/obesity and no type 2 diabetes, but suspected insulin resistance) was completed in March 2017, while another is ongoing in [type 2 diabetes](#) (n=120) and is expected to complete in June 2018. It's unclear whether Roche will pursue a diabetes indication, an obesity indication, or both for this candidate RG7992. Given that [Lilly](#) and [Pfizer](#) both discontinued FGF21 analogs in development for type 2 diabetes due to lackluster glucose-lowering results, we're inclined to have more confidence in the weight loss prospects of this therapeutic target for now. [Novo Nordisk](#) also has an FGF21 analog in phase 1 for obesity.

Selected Questions and Answers

Q: Could you just outline the contractual relationship that you have with Novartis given their impending or their anticipated RTH258 launch sometime in 2018 given the potential conflict? [Editors Note: *Regulatory Submission* may occur sometime in 2H18.]... When we saw Novartis recently, they were talking about launching RTH258 in a way that sounds like they still are completely unconstrained by any kind of contractual agreement by building separate sales forces. And, obviously, there is inherent conflict there in Europe given the licensing from

you. So, I'm just wondering, are you comfortable with this dynamic or does it request some kind of resolution?

A: We are aware that they have released the phase 3 data. We saw the 57% and the 52%, which maintained two 12-week intervals [see [Novartis' press release here](#) for clarity]. Actually, for your background information, it is the same for Lucentis and we didn't see a huge difference. But we are focusing, at the moment, on the VEGF/Ang2 bispecific as well as on the port Lucentis delivery. And on the specific situation, actually, for Novartis, we really don't want to comment specifically.

Q: We have seen that Diabetes Care is costing about 2% of growth for a number of quarters and maybe a number of years. I wondered whether there was - you could make a general comment on whether it's business strategic or synergies for the rest of year in Diagnostic business.

Mr. Diggelman: So, what you can see there is a certain volatility in Diabetes Care. Pretty big swings that has largely got to do with the US and the reimbursement cuts made there, and then year-over-year comparisons, and then also the private pay sector. So, obviously, last year, we had another 20% reimbursement cut in the US in diabetes and we're seeing some of these effects now spilling over into the private sector in the US.

So, that holds true for the traditional blood glucose monitoring. There are opportunities going forward in sensors, continues monitoring, in pumps, and also very much so in the entire holistic management with diabetes patients and that's something that we want to focus on...

-- by Brian Levine, Adam Brown, Payal Marathe, and Kelly Close