



MEMORANDUM

Abbott 2Q15 - Global sales up 5%, Int'l up 10% operationally; FreeStyle Libre "a real winner" in EU; Pro version submitted to FDA - July 22, 2015

Executive Highlights

- Global Diabetes Care sales totaled \$278 million in 2Q15, down 5% as reported and up 5% operationally year-over-year (YOY) from a very easy base. This performance was driven by the international business, where sales rose 10% operationally YOY on a modest comparison (up 2% operationally in [2Q14](#)). The US business hit a low for the past decade, with sales of \$93 million declining 4% YOY.
- Abbott has submitted FreeStyle Libre Pro system (retrospective, blinded) for regulatory approval in the US; launch is expected in approximately one year. There is no US timing on the consumer version that is currently available in Europe.
- There is company-wide enthusiasm about FreeStyle Libre, which management called "a real winner of a product." There is still capacity constraint on the Libre manufacturing front, though management expects this to start easing in "mid-to-late fall."

Early this morning, Abbott CEO Mr. Miles White led the company's [2Q15 financial update](#). Below, we bring you our top financial and pipeline highlights from the call, followed by Q&A.

Financial Highlights

1. Global Diabetes Care sales totaled \$278 million in 2Q15, down 5% as reported and up 5% operationally year-over-year (YOY). Performance was at the upper-end of guidance from [1Q15](#) -low-to-mid single-digit operational improvement. Still, this was the second consecutive quarter of sales below \$280 million, a trend not seen since 2005. Sales rose 4% sequentially on an easy comparison to \$267 million in 1Q15.

2. US Diabetes Care sales declined 4% YOY, totaling just \$93 million in 2Q15. This marks the lowest quarterly sales recorded for Abbott's US business in the past decade and comes on a strikingly easy comparison to sales in [2Q14](#), when sales had fallen 27%. This was disappointing to see sales under \$100 million again (it's happened a couple of quarters in recent memory) and this reinforces massive pressure in this business. We salute Abbott for being so bold as to re-imagine the category in the midst of such weakness in the business - it says a lot about the entrepreneurial nature of the leaders and the support that came from the top executives, including CEO Miles White.

3. International Diabetes Care revenue totaled \$185 million, declining 6% as reported though growing 10% operationally. The growth was somewhat impressive given that the comparison was moderately challenging (for the BGM industry!) - there was 2% operational growth in [2Q14](#).

4. Pooled global revenue from Abbott and J&J totaled \$779 million in 2Q15, down 9% relative to pooled revenue in [2Q14](#) (\$852 million). Notably, the pooled quarterly sales mark the second lowest recorded for the two businesses since 1Q11.

Pipeline Highlights

5. Abbott has submitted its FreeStyle Libre Pro system (retrospective, blinded) for regulatory approval in the US; launch is expected in approximately one year (we wonder however if it could be even sooner - we'd assume the aim would be for launch at ADA 2016). There is no US timing on the consumer version (real-time) that is currently available in Europe. It is unclear what this submission means for the consumer

version in the US, though we assume the submissions cannot overlap. Our speculation on Abbott's strategy is below ... this update was a major positive in our view given that we think particularly needy patients would benefit from this.

6. Abbott CEO Mr. Miles White shared significant optimism on FreeStyle Libre - "We think we've got a real winner of a product." Notably, FreeStyle Libre was highlighted under "innovation" in a [one-page infographic summary](#) of Abbott's quarter - impressive high-level recognition! As expected, specifics on revenue/trajectory and patient adds were absent. The Libre was also shown in a cool picture in Abbott's [2014 annual report](#) (we note - if you haven't looked at the company's website in awhile, take a look - it's very hip).

7. There is still capacity constraint on the Libre manufacturing front, though management expects this to start easing in "mid-to-late fall." We believe enthusiasm for the product continues to grow internationally as well as domestically, where some patients have managed to get their hands on one.

8. Despite being pushed on reimbursement in Q&A, Abbott declined to comment on the progress of its two ongoing reimbursement studies, [REPLACE](#) and [IMPACT](#). Completion is slated for December 2015 and September 2015, respectively. Even still, demand is clearly high without reimbursement right now, and we imagine it will take time for countries to adopt the results of these studies (if positive).

9. Libre has continued its popularity on social media in the EU. Now that patients have gotten over the initial excitement ("No fingersticks!!") and honeymoon phase, some more critical reviews of Libre are emerging: (i) accuracy not meeting standards; (ii) dissatisfaction with customer service; and (iii) sensors falling off/reporting error messages. It's hard to know how much of this is driven by response bias; given the positive demand for this product, we assume these negative experiences are a minority. There is also from what we hear (and personally experience in our testing) growing enthusiasm for the software and AGP.

10. There were no additional pipeline updates on FreeStyle Libre or other Abbott meters.

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Table 1: Pipeline Summary

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FreeStyle Libre System Accuracy Study

Questions and Answers

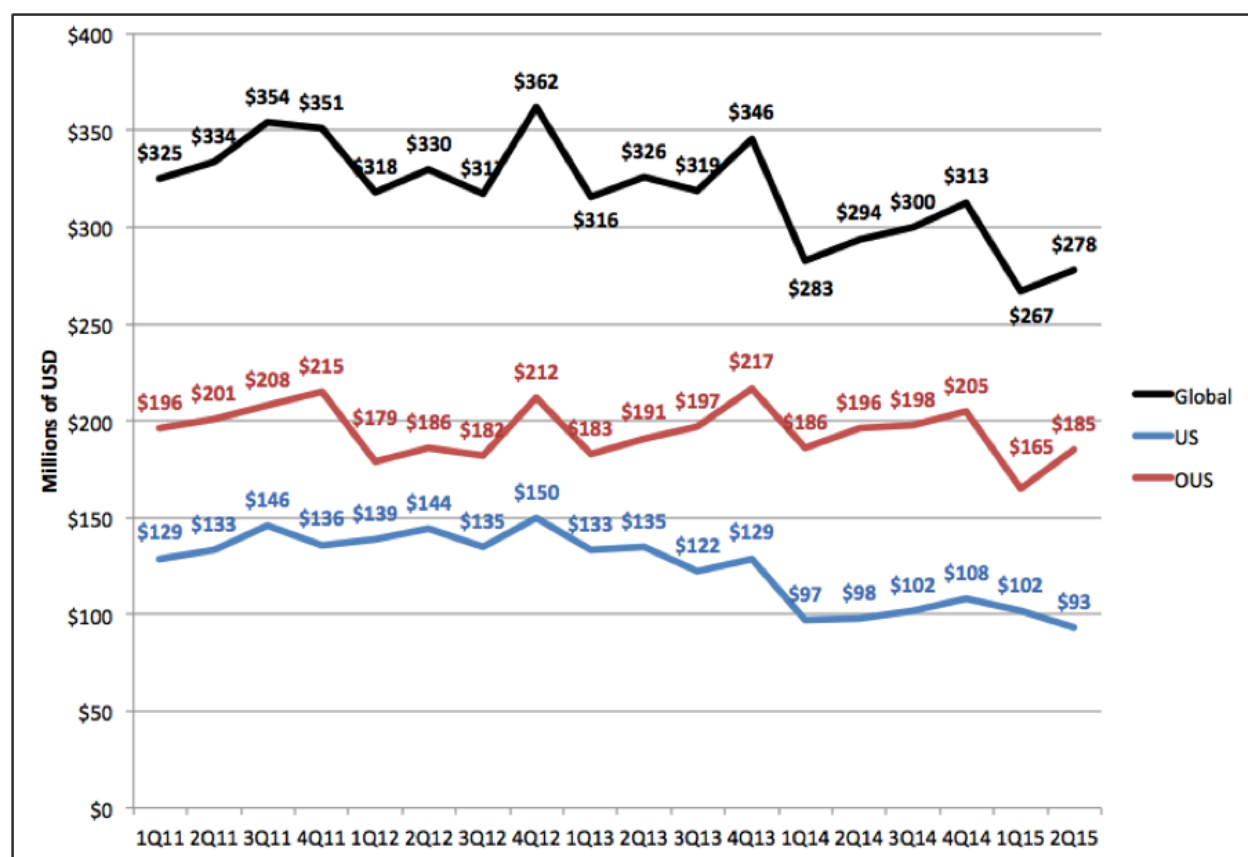
Financial Highlights

1. Global Diabetes Care sales totaled \$278 million in 2Q15, down 5% as reported and up 5% operationally year-over-year (YOY). It tough to read into this "growth" considering the easy comparison to [2Q14](#) when sales fell 10% as reported and operationally. For context, this was the seventh consecutive quarter of reported declines (since [4Q14](#)). Performance was at the upper-end of management's guidance from [1Q15](#) - low-to-mid single-digit operational improvement - though it was disappointing to see global sales fall below \$300 million again (see Figure 1 below). This was the second consecutive quarter of sales below \$280

million (a trend not seen since 2005), and sales have been under the \$300 million mark in four of the past six quarters (\$283 million in 1Q14; \$294 million in 2Q14; \$267 million in 1Q15).

- However, there were some pieces of the traditional blood glucose business that were not wholly negative:** (i) the 5% reported YOY decline in sales was the most benign since 4Q13 (when sales fell 4%); and (ii) the 5% operational growth marked two consecutive quarters of operational improvement - a pattern we have not seen since 4Q10-1Q11. In addition, sequential sales grew 4% in 2Q15, though this came against an incredibly easy comparison (sales of \$267 million in 1Q15 were the lowest since 2Q05 when sales reached just \$264 million).
- CEO Mr. Miles White remarked that the global Diabetes Care business performed "ahead of expectations" - this was a pretty surprising statement from our view and we did feel the placement was notable** - this commentary came in opening remarks about Abbott's overall business. It was a bit reassuring to hear his optimism given implications for the business. While the company hit the upper-end of the guidance for low-to-mid single-digit operational growth, this was not that notable given that guidance has not been ambitious. But, the statement about the business was certainly deliberate. Management maintained guidance for the remainder of the year, forecasting low single-digit operational growth. Revenue will continue to be assessed relative to easy comparisons from 2014 (3Q14: down 6%; 4Q14: down 10%), so this guidance seems like it will not be problematic to achieve.

FIGURE 1: GLOBAL, US, OUS QUARTERLY SALES (1Q11 - 2Q15)



2. US Diabetes Care sales declined 4% YOY, totaling just \$93 million in 2Q15; the quarterly performance marks the lowest ever recorded for Abbott's US business in our financial model (which stretches back over a decade). This came on a strikingly easy comparison as sales fell 27% in 2Q14; sales have now declined in nine of the past ten quarters (1Q15 was the exception when sales grew 5%). Ultimately, the US continues to be an incredibly challenging region for Abbott, as sales 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. Sequential sales also fell 9% against a low base (sales of \$102 million [1Q15](#) tied for the third-lowest ever for the business).

- **Based on the performance, it seems that the April launch of the Precision Neo low-cost-focused BGM ("Skip the co-pay") did not drive significant growth during the quarter.** Prepared remarks did highlight [the launch of the new BGM](#), which offers low-cost test strips over-the-counter at \$14-17 for 25 strips (~\$0.62 per strip). Perhaps sales will tick up in 3Q15 as the meter becomes more broadly available alongside greater marketing. And, even if sales were decent, it's hard to know how decent they'd have to be to help show positive results - this is incredibly low pricing. We're glad to see this, of course, for the most needy of all patients, those with few or any resources.

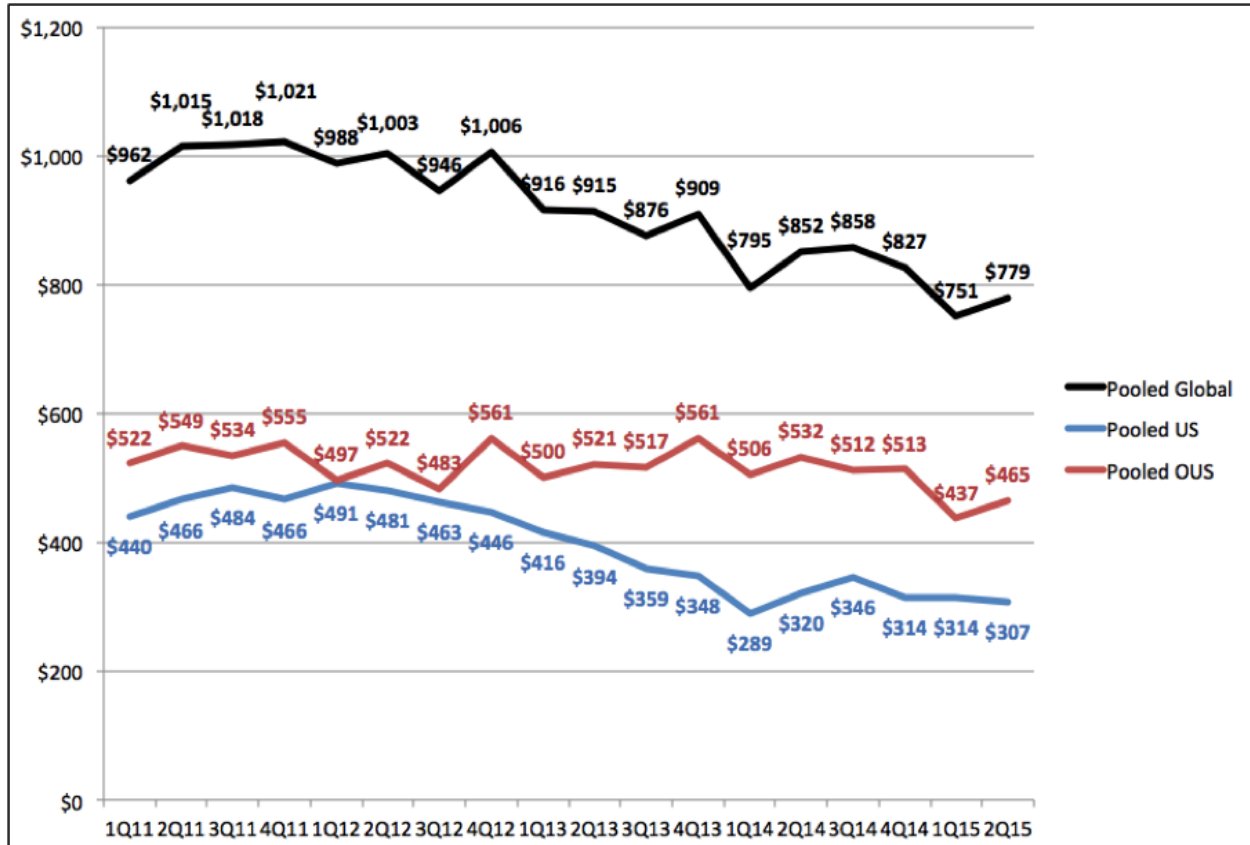
3. International Diabetes Care revenue totaled \$185 million, declining 6% as reported but growing an impressive 10% operationally, driven by sales of FreeStyle Libre. The comparison was also moderately challenging (in this BGM environment!), with revenue in [2Q14](#) growing 3% as reported and 2% operationally. The reported financials reflect the significant strengthening of the US dollar (negative 16% currency impact) as opposed to underlying weakness in the business' fundamentals. Sequentially, sales grew 12%, though this came against a very low base (sales in [1Q15](#) marked the lowest-recorded in the business since 1Q09 - \$165 million).

- **Abbott attributed the global operational strength (relatively speaking of course) in diabetes to "strong international performance."** Indeed, it's not too hard to be positive on the international business considering how it has been certainly much stronger than the US - most notably, of course, there is massive upside here for FreeStyle Libre.
- **The International business accounted for ~67% of global Diabetes sales in 2Q15, identical to 2Q14 though up from ~62% in 1Q15.** A decade ago, the split was 50% international and 50% US.

4. Pooled global revenue from Abbott and [J&J](#) totaled \$779 million in 2Q15, down 9% relative to pooled revenue in [2Q14](#) (\$852 million) - that's a lot lower. The weakness is not particularly surprising considering that [J&J's global business](#) declined 12% in reported sales in 2Q15, while Abbott's declined 5%. This quarter's pooled revenue marks the second lowest recorded for the two businesses over this period (only [1Q15](#), when pooled sales totaled \$751 million was lower). Sequential sales grew 4% against the lowest pooled base in at least the last five years.

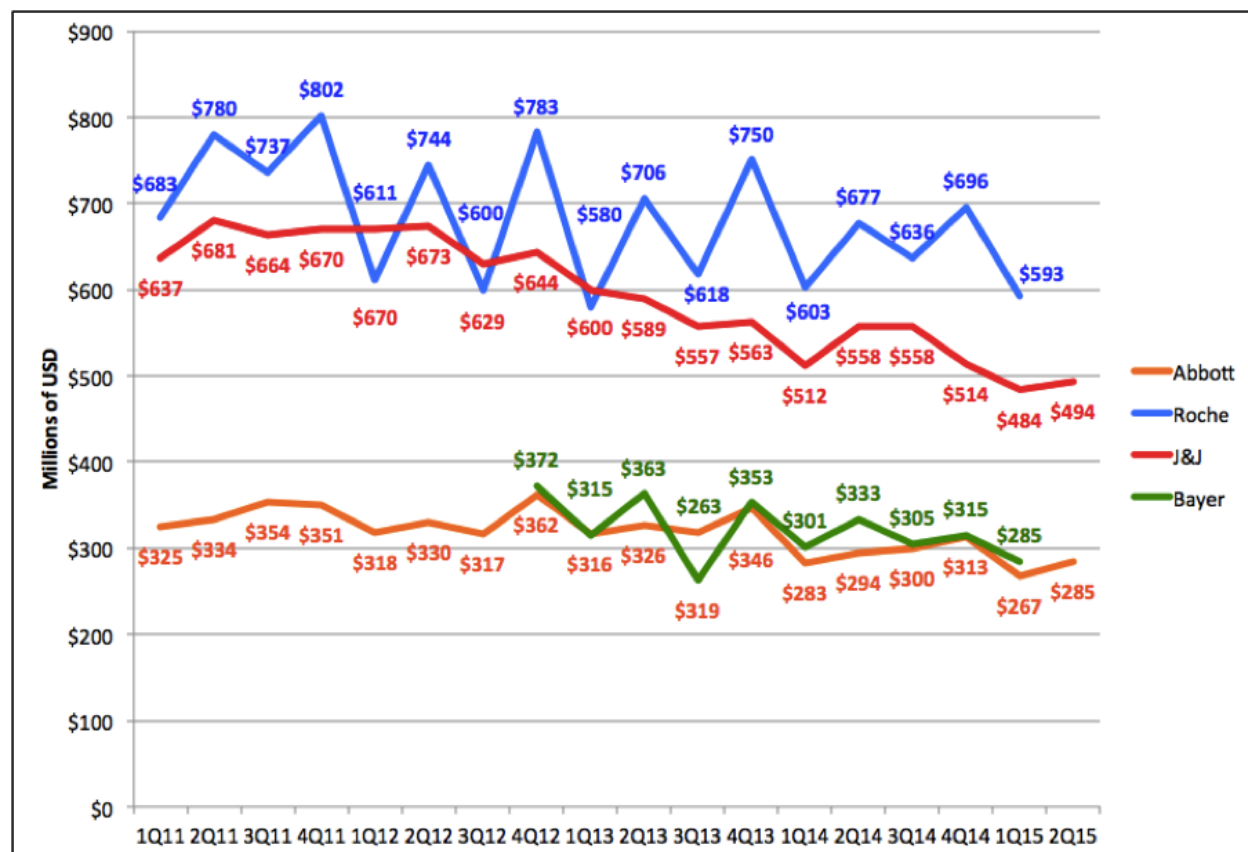
- **As shown in Figure 2 below, pooled sales for Abbott and J&J have experienced a steady decline since 1Q11.** This has been driven by US weakness (sales falling ~\$133 million) while the international business has been steadier (sales falling ~\$57 million).

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



- We look forward to adding Roche and Bayer's updated financials to the pooled analysis (See Figure 3) when each reports on July 23 (tomorrow) and July 29, respectively. As a reminder, Bayer's Diabetes business is expected transfer to [Panasonic Healthcare](#) starting in 1Q16.

FIGURE 3: BIG FOUR GLOBAL COMPARISON (1Q11 - 2Q15)



Pipeline Highlights

5. Notably, in the biggest news on the call today, Abbott announced that it has submitted its FreeStyle Libre Pro system (retrospective, blinded) for regulatory approval in the US; the company is targeting a launch in approximately one year. It is interesting to see Abbott moving ahead with the Pro version in the US, which launched in India earlier this year and began recruiting type 2 participants for a US pilot study in March (ClinicalTrials.gov Identifier: NCT02336945). Management did not comment on the US timeline for a consumer version of Libre on the call. As a reminder, the Pro is approved for 14-day wear and is designed to record glucose levels every 15 minutes over a two-week period (~1,340 data points). Patients do not get a reader, but would put the sensor on and come back to the provider in two weeks to have it downloaded. The Pro stands in contrast to the consumer version of Libre, which takes readings more frequently (~once/minute) and comes with a real-time touchscreen reader for scanning the data and obtaining the current value. We love the idea of this coming to the US as we think it will draw in more type 2 patients, particularly those not doing well and in greatest need of therapeutic changes (not all will wear CGM). We await news on pricing for this two week wear.

- Upon seeing this news, we immediately wondered what the Pro submission means for US timing of a consumer version of FreeStyle Libre (currently out in Europe) - see below for our speculation. We are not entirely sure whether Abbott can have two PMA applications open at the same time, one for FreeStyle Libre Pro and one for FreeStyle Libre. That could imply FreeStyle Libre Pro would need FDA approval before FreeStyle Libre can be submitted, placing a potential subsequent submission at least 6-12 months out.
- Here is our speculation as to Abbott's rationale for submitting the Libre Pro before the consumer version in the US:

- **Faster review for real-time version?** We assume that the regulatory approval pathway is less stringent for the blinded device given that: (i) patients do not make potentially dangerous dosing decisions based on the device's accuracy; and (ii) doctors reviewing data can use their judgment to interpret data that may be erroneous. Perhaps the review of FreeStyle Libre would go faster once Pro is approved.
- **An underpenetrated Professional market?** The market for professional CGM is definitely in need of better products. Dr. David Klonoff (Mills-Peninsula Health Services, San Mateo, CA) estimated [earlier this year](#) that "Medtronic sales are 95% for real-time [CGM] and 5% for professional [CGM]." We assume Dexcom has a roughly similar split. If those numbers are true, Abbott could build a significant professional business off of Pro, particularly given the excellent insights offered from its download software.
- **Higher margins on Professional business?** Abbott doesn't have to supply touchscreen readers for Libre Pro, which could result in higher margins relative to the real-time business.
- **Building early patient/provider enthusiasm?** Could Libre Pro serve as a stepping stone to Libre, assuming Abbott builds early enthusiasm for the form factor in a more controlled setting that patients trust (providers' offices)? CGM has been handicapped by provider baggage and the hassles of prescribing; perhaps if Libre Pro is a home run in helping HCPs assess patients, a consumer version will see faster adoption and more of a push from HCPs.
- **Buying time to get an insulin-dosing claim?** If an insulin-dosing claim is still in the plans, Abbott may have to conduct a dedicated US study to receive it. Dexcom has been wrestling with this for some time now (though FDA clarity on an insulin dosing claim trial [is expected](#) during Dexcom's 2Q15 call on August 5). As a reminder, commentary [during Q&A in Abbott's 4Q14](#) call hinted at ongoing struggles with the FDA regulatory path - "I'm frustrated with the pace of regulatory approval in the US." We wonder whether the submission of Libre Pro provides Abbott buffer room to get a less dangerous version to market while waiting on further regulatory clarity for an insulin-dosing claim for the consumer version. On the other hand, since Libre could be targeted at a type 2 audience, is insulin-dosing vital? Hard to know what's happening here!
- **Integrating the Libre reader into a smartphone/watch?** We wonder if the FreeStyle Libre reader could be incorporated into a phone/watch that has NFC built-in. This could be important to compete with the smartphone integrated Dexcom Gen 5 system (US launch expected by end of year) and Medtronic Guardian Mobile ([pivotal study](#) to complete this month). At the same time, it's unclear whether the FDA will allow smartphones to be used as the primary display device with no backup at all, meaning Libre users might still need to buy a reader, and Abbott could develop a phone app for secondary display (similar to Dexcom's Share or Medtronic's MiniMed Connect). [Note - Even though Gen 5 will send CGM data straight to a phone app, the FDA may require patients to purchase a backup dedicated receiver.]
- **CGM version of Libre?** Could a "real" continuous version of Libre (with alarms) be developed? This would likely increase the cost and potentially change the on-body form factor, though management has alluded to expanding the Flash Glucose Monitoring category to other areas. (We doubt this is the case.)
- **US CGM Market Competition?** The real-time glucose monitoring market is more crowded in the US than internationally. Perhaps Abbott can sufficiently differentiate itself with Libre Pro and sees less value in launching the real-time version in the US until manufacturing capacity expands. On the other hand, the real-time CGM market is underpenetrated (~10% of type 1s), so it's tough to argue that the US market is that packed.

- **Distribution model?** Will the FDA let Abbott sell the real-time version of Libre over the counter without a prescription, similar to how it's sold in web shops in Europe? We assume this has contributed very positively to uptake in Europe, and a required prescription adds hassle for patients and providers.
- **Highest need?** It's definitely true that many patients with very high need could benefit from a "one time" boost associated with their doctors and nurses understanding far better what is wrong with their therapeutic regimen - this is particularly true in our view given the strong AGP reports that will come with this product that we believe are especially easy to understand.
- **Study results for Abbott's US pivotal trial (ClinicalTrials.gov Identifier: [NCT02283411](#)) of the consumer version of FreeStyle Libre have not yet been posted.** As of [4Q14](#), the trial was ongoing at six sites in the US and had enrolled both type 1 and type 2 patients. It had an estimated completion date of March 2015. The purpose of the study (n= 164) was to evaluate the point and rate accuracy of the system against YSI and to characterize the safety through Adverse Device Effects and Serious Adverse Device Effects experience by participants.

6. Abbott CEO Mr. Miles White shared significant optimism on FreeStyle Libre - "We think we've got a real winner of a product." He acknowledged that the response with consumers has been "terrific," which is in line with everything we have heard [at previous updates](#). Unfortunately, specifics on revenue/trajectory and patient adds continue to be absent - "I don't think I could forecast for you how big it's going to be. I don't know. What I do know is anything I'd tell you would be wrong." The cautious optimism is understandable, though from his overall language, it is clear that Abbott continues to have high expectations - "I think it'll be a significant product." (We know it will - it already is in many respects.)

- **Notably, FreeStyle Libre was highlighted under "innovation" in a [one-page infographic summary](#) of Abbott's overall quarter** - impressive high-level recognition for the diabetes franchise and this particularly product!

7. There are still capacity constraints on the Libre manufacturing front, though management expects this to start easing in "mid-to-late fall." The company continues to expand scale and according to Mr. White, has intentionally slowed down marketing efforts to stem high demand. It is fairly remarkable to hear how quickly patients have flocked to Libre and notable to hear commentary that the company has actively backed down on advertising in order to quell some of the enthusiasm - we NEVER hear that in diabetes devices! Management noted that the company is getting close to the point where they can pursue more aggressive marketing once again. Given Abbott's resources, it does continue to surprise us that capacity is still constrained; we wonder what is driving that. Once supply is unconstrained, we will be very curious to see how adoption of Libre accelerates.

8. Despite being pushed on reimbursement in Q&A, Abbott declined to comment on the progress of ongoing studies. The company is still in the process of conducting two six-month outcomes studies to support reimbursement. [REPLACE](#) (n=210 type 2s on MDI, A1c>7.5%) and [IMPACT](#) (n=225 type 1s on MDI or pumps, A1c <7.5%) are both ongoing and not currently recruiting participants. Completion is slated for December 2015 and September 2015, respectively. The goal of the [type 2 study](#) is to show a change in A1c at six months, while the [type 1 study](#) seeks to improve time spent in hypoglycemia at six months. Both trials will compare FreeStyle Libre to standard SMBG.

9. We continue to see on EU social media sites that Libre is popular - however, now that patients have gotten over the honeymoon phase, we are starting to see more critical reviews of Libre. We can place critiques of the product we see into three main buckets: (i) accuracy not meeting standards in the eyes of the wearer; (ii) dissatisfaction with customer service; and (iii) sensors falling off/ reporting error messages. Of course, these criticisms are not particularly surprising considering how high expectations have been set - those most likely to take to social media are those who have either had spectacular or disappointing experiences, and the latter are probably more likely as scale expands and the newness factor wears off. Certainly, demand is only going one direction on this product, and [the diaTribe](#)

[experience](#) with Libre did not see any of these challenges. See our appendix for a look at what patients have recently been saying.

- **The biggest testament to Libre comes on convenience - we continue to hear anecdotal reports that patients feel confident dosing insulin without fingersticks.** As a reminder, Libre is indicated for adjunctive use in the hypoglycemia range, though in the real world, it is clear that Libre's "no fingersticks" marketing approach has really resonated with patients.

10. There were no additional pipeline updates on FreeStyle Libre or other Abbott meters.

Prepared remarks did highlight the [recent US launch of Abbott's newest BGM](#), the FreeStyle Precision Neo, in April 2015. Overall, it is promising to see Abbott continue to invest in new products stateside despite the challenging environment and striking to see it clearly trying to help the group of patients who needs the most help - those that have few financial resources..

TABLE 1: PIPELINE SUMMARY

Device	Device Type	Status/Timeline
FreeStyle Libre	Flash Glucose Monitoring	EU launch in September 2014; No US launch timeline
FreeStyle Libre Pro	Flash Glucose Monitoring	India launch in April 2015; FDA submission in July 2015
FreeStyle Precision Neo	BGM	US launch in April 2015

Questions and Answers

Q: Can you give us an update on FreeStyle Libre? How big do you think that product can be for you in 2015 and 2016? When do you think you won't be supply constrained? When are we going to see the key European and US reimbursement studies that you have ongoing?

Mr. Miles White: We think we've got a real winner of a product here. However, we are capacity constrained, and that's our own problem. We obviously didn't build enough capacity for what we anticipated. We expect that to start easing in the mid-to-late fall. We'll have considerably more capacity on line at that point, and we continue to invest in capacity because we believe in the impact of this product and because the response from diabetics and consumers is, frankly, terrific. We intentionally slowed down our marketing because there's no point in creating greater difficulty in terms of demand until we can fix that capacity issue. We're getting close to that point now where we can go back to a more aggressive marketing of the product. But in the meantime, we're just waiting for that capacity to come on line.

Mr. Brian Yoor: Recall that we just got this approved in India. This is a great opportunity for us to go after the doctors and the patients in a different way. We did file and submit the Pro in the US, and the typical timeline is approximately a year. Again, this is probably a modest professional segment, but it's still an important one. Overall, between this strategy as well as what we have internationally with Libre, our approach to the market here in the US is going to be really balanced and help us return to growth for the Diabetes Care business. I mean, to be performing in the mid-single digits is where we expected to be. So I think everything's on track.

Mr. White: I don't think I could forecast for you how big it's going to be. I don't know. What I do know is anything I'd tell you would be wrong. So I think it'll be a significant product. I think after, say, six to 12 months of unfettered availability, we'll know pretty well. However, I'd like to hit that capacity or the capacity release point where we've got plenty of manufacturing and we're unconstrained. Then we'll get a better sense of its potential.

Appendix - European Social Media on FreeStyle Libre

- [#FreeStyle Libre on Twitter: Criticism](#)

- @dr_shackleton: Sensor stopped working after 6 days! 2nd time this has happened! Can #freestylelibre cope with summer?
- @laurenfriel: Going to give #freestylelibre another go. Hope it more accurate this time #t1diabetes #Type1west
- @NatalieKermath: My [brother has] used 5 sensors in 3 weeks as they won't stay on, the sensor bends in his arm so [we] can't get a reading or [they] peel off
- @RheeseyB: Still no response about my faulty #freestylelibre sensors. It's been almost a month. Plus I sent another email via the site :/
- @ninjabetic1: Just tried to scan to start the sensor but the 60 mins start up time has re-set again. It said it may have been loose? #freestylelibre
- **#FreeStyle Libre on Twitter: Praise**
 - @MartinGirvan: No more stabbing my fingers for blood glucose readings #freestylelibre #type1diabetes
 - @Mrs_Nichola_D: I didn't think such a straight line was possible!!! #doc #freestylelibre
 - @caterina_oneto: I wonder if/when #freestylelibre will be available in America. One of my patients has it: no finger pricking needed.
 - @AdrianLong3: So...still resisting temptation? Go on, you know you want to...#freestylelibre
 - @alistair1975: 60% of the last seven days my blood sugar was in the target range. First time I've achieved that. #freestylelibre

What Social Media Was Saying in April 2015

- **Every day ups and downs**: "What has it been like so far? In a word, amazing ... One of the other things I have already noticed is that the Libre makes glucose monitoring so effortless that I am inclined to check more frequently rather than less."
- **Type I Diabetes, Coeliac Disease, Tennis**: A more technical analysis of FreeStyle Libre, highlighted by thoughts on pros and cons + a comparison to Dexcom's G4 Platinum.
- **How Fast?**: "Personally I think the biggest game changer is for those on MDI (multiple daily injections). On MDI if you wanted to try out a CGM you would be looking at upwards of £1000 start up costs ... on Libre its £134 for a start up pack that includes 2 sensors and a reader. Sensors after that are £48."
- **DiabetesTechReview**: "In my opinion CGM is the future for insulin dependent diabetics, strips just leave too many blind spots. The Abbott Freestyle Libre is not a perfect system, but its relative affordability, and ease of use make it a good step in the right direction."
- **#FreeStyle Libre on Twitter**
 - @Hansuppih: "#FreeStyleLibre: 1 week in. Have become addicted to scanning and am blown away by the lovely #eyeopening data. #DOC"
 - @rustyjellybaby: "Can #freestylelibre be considered an addiction? I'm without sensor and missing it."
 - @alistair1975: "Time in Target ... just broke 25% for the 1st time. Was 13% three weeks ago. #freestylelibre"

What Social Media Was Saying in September 2014

- **Fun, Young, and Type 1**: "I must have tested 40 times on the first day, just because I could...Having that kind of detailed data in front of me is not only allowing me to take control, but it's persuading me to do so."

- **Diabetogenic:** "For me, the benefit of not having to prick my finger to check my BGL is a huge, huge bonus and I know that there are many people who find this the thing they hate most about diabetes management."
- **Ninjabetic:** "I can't feel a thing when I'm wearing it, sleeping on the side that it's on or when I'm moving my arm (not that I madly flap my arms around anyway!)...If you can afford it then perhaps it might be worth trying it out for yourself as the initial start-up cost is much lower than CGM technology."
- **The Tangerine Diabetic** - Compares the FreeStyle Libre and Enlite CGM across availability, accuracy, convenience, software, setup, size, and more.
- **#FreeStyleLibre on Twitter:**
 - @misswhiplash: "Excited and very impatient about the impending arrival of my #freestylelibre ... I WISH IT WAS HERE ALREADY."
 - @justinkb: "Wow. Just wow. Tech geeks will almost want to be diabetic! <https://www.freestylelibre.co.uk/default.aspx> #freestylelibre"
 - @rustyjellybaby: "First wake up and I'm in love. Not only can I see I've been low but been low since 2am #FreeStyleLibre"
 - @docsamphillips: "#FreeStyleLibre @doctorinsulin @karen_a_adamson. i have been wearing this 7th day. Close to capillary readings"

Appendix - ATTD 2015 Coverage of FreeStyle Libre

FREESTYLE LIBRE SYSTEM ACCURACY STUDY

Timothy Bailey, MD (UCSD, San Diego, CA)

Dr. Tim Bailey shared never-before-seen data from Abbott's 72-patient, 14-day pivotal CE Mark trial of its factory calibrated FreeStyle Libre system, which demonstrated a solid overall MARD of 11.8% vs. YSI (the study had 1,238 paired sensor-YSI points). We first saw top line results from this study at [EASD 2014](#), where Libre demonstrated an overall MARD of 11.4% vs. FreeStyle Precision BGM (13,195 paired points). One criticism of the data shared at EASD was the use of BGM as the reference device, as most CGM studies have in-clinic days with YSI - it was good to see that the 14-day, factory calibration holds up against that standard as well. New subgroup analyses also showed that the sensor remains accurate near the hypoglycemic range, where MAD was 9.5 mg/dl vs. YSI for glucose values in the 51-80 mg/dl range - this is the first time Abbott has shared this data (see below). As a reminder, the product label recommends a confirmatory fingerstick when hypoglycemic, though commentary during Q&A suggested that patients are routinely skipping these steps, testament to its real-world accuracy. Similarly, the sensor maintained its accuracy even when glucose values were rapidly changing as Dr. Bailey shared a comparison of data excluding vs. including all points < 80 mg/dl or changing at > 2 mg/dl. Reported MARD were not statistically different for the two subgroups: 10.4% (exclusive) vs. 11.4% (inclusive).

- **As a reminder, the pivotal study was conducted in four centers across the US in type 1 and type 2 patients on insulin therapy.** Patients wore two sensors on the back of their arm for 14 days and were asked to: (i) perform eight capillary blood glucose tests daily; (ii) scan the sensor following each test; and (iii) attend three in-clinic eight-hour YSI sessions. Notably, Dr. Bailey shared that 24% of patients had a baseline A1c > 8.5% and that 22% of patients had a baseline A1c < 7.0% - a nice mix of well-controlled and out-of-control patients.
 - **We saw topline results from this study at [EASD 2014](#)** where Abbott's factory calibrated FreeStyle Libre system demonstrated an overall MARD of 11.4% vs. FreeStyle Precision capillary fingersticks (87% of points were in Zone A of the Consensus Error Grid, 13% in Zone B). MARD was lowest on day one (15.7%), improved to 11.9% on day two, and hovered between 10.3% and 11.8% on days 3-14. The study had 13,195 paired FreeStyle Libre-BGM data points (range: 23-498 mg/dl).

- FreeStyle Libre demonstrated excellent accuracy in the hypoglycemic range vs. both YSI and fingersticks.** MAD was just 9.5 mg/dl vs. YSI (n=53) and just 10.0 mg/dl vs. fingersticks (n=901). A bigger testament to Libre's hypoglycemic accuracy came from Dr. Bailey's colleague, **Dr. Iain Cranston who noted, "Half my patients have not done a fingerstick in two months. They come to rely on Libre."** The data below is cut at 50 mg/dl and 80 mg/dl, so it is tough to know what the accuracy is for <70 mg/dl vs. > 70 mg/dl (i.e., did most of the 50-80 mg/dl points fall in the 70-80 mg/dl bucket?). Even still, based on our experience wearing the device, it is very accurate in hypoglycemia, so the point is more semantics than anything.

Table 1: FreeStyle Libre vs. YSI in Hypoglycemia

Glucose Level (mg/dl)	MAD (mg/dl)	N
< 50	26.0	2
51-80	9.5	53

Table 2: FreeStyle Libre vs. BG Capillary for Low Blood Glucose

Glucose Level (mg/dl)	MAD (mg/dl)	N
< 50	12.6	145
51-80	10.0	901

- Libre demonstrated impressive results even when glucose values were rapidly changing.** Dr. Bailey shared subgroup analysis for results excluding vs. including all points < 80 mg/dl or changing at > 2 mg/dl/min. Impressively, the reported MARD were not statistically different: 10.4% (exclusive) vs. 11.4% (inclusive). We thought this was a clever and smart way to summarize the data.

Table 3: Sensor Results During Times of Rapidly Changing/Low Blood Glucose

Glucose level	Measurement vs. capillary BG	All Data		Excluding results < 80 mg/dl or changing at >2 mg/dl/min	
		Results	N	Result	N
< 100 mg/dl	MAD	11.3 mg/dl	2,153	10.3 mg/dl	905
> 100 mg/dl	MARD	10.7%	11,042	10.2%	9,341
All	MARD	11.4%	13,195	10.4%	10,246

- Mr. Bailey shared positive data from user experience studies of FreeStyle Libre in the pivotal study.** There was no background on how these questions were asked - we assume Yes/No. Still, the data pointed to why patient uptake has been so strong in these early days, especially in those that have avoided current CGM due to comfort/wearability:
 - 100% agreed that the sensor was easy to apply.
 - 88% agreed that applying the sensor was less painful than a routine fingerstick (more to the point, we'd add that it's only required every 14 days).
 - 86% agreed that the sensor did not get in the way of daily activities.
 - 96% agreed that Libre is comfortable to wear.

- 96% agreed that scanning the sensor is less painful than pricking my finger (We're not quite sure how these 4% of patients were scanning or what magical lancing device they were using - Adam and Kelly have both used it and say the scanning is completely painless.).
- **Very few adverse events were reported among patients in the study.** Only 26 subjects reported any sort of discomfort around the sensor insertion site and all reports were consistent with what would be expected following insertion of a sensor into the skin:
 - Moderate to severe erythema - 4% of the time
 - Other moderate symptoms - 1% of the time
 - Mild symptoms - less than 9% of the time (Moderate vs. mild symptoms were not defined.)
- **Although Libre is only approved for upper arm wear, commentary during Q&A suggested that most patients are taking liberties with sensor placement** - the re-location does not appear to be affecting accuracy. Said Dr. Iain Cranston (Portsmouth Hospitals NHS Trust, Portsmouth, England) during Q&A: "Most people using Libre have purchased the devices themselves, so will put it where they damn well like. The upper quadrant of the buttocks is a popular place, and it stays on for two weeks. On the abdomen is another popular place, but more likely to fall off. It's incredibly anecdotal reporting thus far though." The upper arm can be a tough sell for patients (less body fat for some; more visible), so we are not surprised to see patients taking initiative, as they have with traditional CGM as well. The company has said it is exploring approval for some of these other sites for wear, though that would simply allow for different marketing and training more than greater uptake.

QUESTIONS AND ANSWERS

Q: You mentioned Libre's great precision - why would you want to cross check with fingersticks?

Dr. Bailey: It turns out that the precision of this can replace fingersticks. There are still some caveats with rapid changes or with hypo but **a replacement is here and that's pretty exciting for patients.**

Dr. Cranston: **Half of my patients have not done a fingerstick in two months. Patients have come to rely on Libre.**

Q: Do you have to wear the sensor on your arm? Could you wear it anywhere else? What would be the differences?

Dr. Bailey: **At my site, you had to wear it on your arm. In reality, you can't even imagine all the places patients actually put the devices,** but I don't know the data.

Dr. Cranston: **Most people using Libre have purchased the devices themselves, so will put where they damn well like. The upper quadrant of the buttocks is a popular place, and it stays on for two weeks.** On the abdomen is another popular place, but more likely to fall off. It's incredibly anecdotal reporting thus far though.

Q: Is there any data on interfering substances?

Dr. Cranston: I have not seen study data relating to it, though I believe it is there. It is not something I recommend people need to avoid. I think the clinical sheet that comes with it tested against 20 substances, and although they can measure differences in the value from that, they are not clinically different.

Q: Could you tell us more about the first hour of insertion after the new sensor?

Dr. Bailey: The first hour is the calibration. In our study, 100% of the sensors came online. The only sensors that did not perform had to do with problems with insertion. Once they were inserted, they all reported accurate data.

Dr. Riveline: In my experience, patients noted that accuracy was not as good in the first day.

Dr. Cranston: I tend to advise people to not act according to what they see on the sensor in the first 12 to 14 hours. In an anecdotal way, it does appear that the sensor will tend to read a little bit lower on day one. It's totally anecdotal and someone from the company will probably shoot me for saying that but that's what I've heard.

Dr. Bailey: This is the first presentation of the YSI data; there will be more data pretty soon.

Q: Any allergic reactions to adhesives? Are there any case reports on that? Maybe on social media?

Dr. Cranston: Yes, on social media there are absolutely reports of that. There were photos of that - like people can be allergic to any adhesive. What I've found absolutely stunning and what I've seen is that they leave them on! It shows how much they like Libre. Normally when you have something that itches, you take it off. Some patients have had quite a nasty reaction because they want to leave the sensor on.

Q: What about the sensor in a hairy area? Or the abdomen? Do people need to be careful about knocking it off?

Dr. Cranston: It's only a five-millimeter sensor. So if it's really hairy area, then you might have problems with getting the sensor inserted. On the back of the arm, I have never shaved an arm to put it on. As for knocking a sensor off, of course you can. People tend to put it on the front part of the arm and it gets knocked off. But on the back, it is better.

Q: Can you talk about Libre vs. BGM?

Dr. Cranston: This should pass as a glucose meter. It meets all the criteria.

Q: Would you recommend patients to do more or less fingerstick measurements in the first 24 hours after putting the sensor on?

Dr. Riveline: I would recommend the same number of SMBGs as usual due to the lower accuracy.

Dr. Cranston: I would say it depends on why they have it. But what I tell patients is not to react to what's happening actually. I tell them to try not to react too much in the first week. Once you have an idea of what your profiles look like, then in the second week, you can react.

Q: What happens to the needle used to insert the sensor?

Dr. Clifford Bailey (Moderator): It's in and out before you can see it.

Q: Do insurance companies pay in the US, UK, and France?

Dr. Bailey: It's not clear in the US. Reimbursement is critical for patients to have access. It would be wonderful if this were covered. It's not covered in the US or France.

Dr. Cranston: In the UK, it has not been looked at by NICE. I'm not aware of any immediate plans to do that. There is the question of whether an individual can get it funded, but that's a conversation between the patient and insurance companies and I'm not sure that anyone's managed it.

Dr. Riveline: I think we have to fight to obtain reimbursement but it hasn't happened yet.

Dr. Clifford Bailey: If you look at the costs incurred by fingersticks compared with this, then this is very competitively priced. I think that that's going to be a very big factor in actually deciding the mass use of this new device.

Dr. Cranston: Yes, about ten tests a day is the same price.

Q: How do you think about Libre plus a pump?

Dr. Riveline: I think it's a good thing for a lot of patients but there is no combination with a pump. It depends on the patient. There are patients who don't want to have alarms. For some patients with a pump, that's a good thing.

Dr. Cranston: It's important to say what it's not. The Libre plus a pump cannot be an artificial pancreas since data is not continuously collected but instead is episodically collected. That said, many Libre users don't have pumps. They are treating with insulin injections as they normally would. Is it accurate? In my eyes, yes it is. Do they do it? Yes, they do. Some patients have used a wizard with this and nobody's factored in an arrow-based wizard, but they visually adjust.

Q: In a situation of rapidly changing glucose, there is a lag time. How does this work out for Libre?

Dr. Bailey: **The overall lag time is 4.5 minutes. We don't have data on rapid change.** This is when you want to confirm with fingersticks. Particularly when it's trending down, check with fingersticks.

Dr. Cranston: When they see a vertical arrow, it is easy to flash again in five minutes. I say, don't work on a single value. The first flash tells you that you need another again. It's not that hard to get a second look.

Q: How is it possible to have this MARD without calibration?

Dr. Bailey: Everyone is working on this technology. This is the first released product. Every product out there has its advantages. That's the one thing about this product.

Dr. Cranston: Let's make it clear that it's not that this isn't calibrated. It is. It's just not calibrated against fingersticks. It's calibrated in the lot.

Dr. Bailey: It also has to do with drift. Other sensors would drift and you would have to recalibrate. This one doesn't drift. Standard meters aren't that accurate too. So factory calibration is great because it gets rid of using inaccurate meters in calibration.

Q: Can I walk across the street to the nearest pharmacy and buy one?

Dr. Riveline: **In France, it was possible to have the device directly bought from the company. But it's no longer available because a lot of type 1 patients asked for the device.** So we have to wait for more devices to be built. The cost is 120 euros for the device and 60 euros for each sensor.

Q: Could you comment on the clinical relevance of using Libre?

Dr. Cranston: **I don't think that there is anybody who has come to me with a profile or that I have put a sensor on where we haven't gotten clinical value from the profile. There is always something we can clinically get out of the profile.**

Q: Is there enough data yet to make diabetes diagnoses in previously undiagnosed patients?

Dr. Cranston: I think it's a really good question. We're trying to collect some data about that. Traditionally, diagnosis is based on complications. So we'd have to do it indirectly. I have to say, when you see a normal glucose profile on one of these devices, there's nothing else that looks like a normal glucose profile. Low variability and a completely flat profile is what normal looks like. We're looking at Libre in post-transplant profiles to see how it changes.

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