
Abbott 3Q16 - Global sales grow 13% on Libre momentum, over 200,000 users in EU!; Libre Pro approved in US, now available to HCPs; consumer version submitted to FDA - October 19, 2016

Executive Highlights

- Abbott's Global Diabetes Care sales totaled \$306 million in 3Q16, rising 12% as reported and 13% operationally year-over-year (YOY). The international business drove the performance with revenue of \$210 million up 19% as reported and 21% operationally on the strength of FreeStyle Libre. US sales, on the other hand, declined 2% YOY, but grew 32% sequentially from a rough [2Q16](#).
- Mr. White shared that there are now "more than 200,000 patients" using FreeStyle Libre in Europe - up ~60% from the estimate of 125,000+ shared one quarter ago in [2Q16](#), and impressive adoption in just two years on the market. EU Libre sales back out to just over ~\$70 million if all patients are using two sensors per month (~120 euros per month) - we estimate sales are probably closer to \$55-\$70 million in light of samples, not all using two per month, discounts, etc.
- The FDA approved FreeStyle Libre Pro (blinded, retrospective) [in late September](#), and the 14-day sensor and HCP-owned reader just began rolling out to US healthcare providers. The real-time consumer version of FreeStyle Libre was filed with the FDA in 3Q16, but no launch update was provided on this call. [2Q16](#) guidance ambitiously called for approval of the consumer version in 1Q17.

Early this morning, Abbott CEO Mr. Miles White led the company's [3Q16 financial update](#). Below, we bring you our top financial and pipeline highlights from the call followed by Q&A. The topline summary is that FreeStyle Libre is doing extremely well in Europe (200,000+ users), is coming to the US soon in both Pro ([launching now](#)) and real-time versions (under FDA review), and has serious commitment and enthusiasm from the highest levels of the company.

Financial Highlights

1. Abbott's Global Diabetes Care business had an excellent quarter, with revenue of \$306 million growing 12% as reported and 13% operationally year-over-year (YOY). The performance came against an easy comparison to [3Q15](#)'s 8% sales decline, but far outperformed guidance from [2Q16](#) for "mid-single digit" growth. Double-digit growth is expected in 4Q16. With the advent of Libre, Abbott Diabetes Care's business has gone from weak to outstanding.

2. US Diabetes Care sales declined 2% YOY, totaling \$96 million in 3Q16. This came on an easy comparison (-4% in [3Q15](#)) and now marks 14 of the past 15 quarters with US sales declines. Revenue did, however, rise an encouraging 32% sequentially from a very weak [2Q16](#) (\$73 million). We expect to see the US return to growth in the coming year as FreeStyle Libre Pro comes to the US (launching) and the FDA eventually approves the consumer version.

3. International Diabetes Care revenue of \$210 million grew a strong 19% as reported and a remarkable 21% operationally YOY. FreeStyle Libre drove the quarter's success, or as Mr. White said, it is "going gangbusters in Europe." This represented Abbott's highest YOY growth in the past eight years and marks six consecutive quarters of operational growth outside the US. This product has impressive momentum at this point and we do not see it abating near term.

Pooled Financial Highlights

4. Pooled global revenue for J&J and Abbott reached ~\$733 million, falling 2% YOY on an easy comparison to [3Q15](#) (~\$745 million, down 13% YOY). It was a tale of two companies: J&J's business declined 9% as reported vs. Abbott's 12% reported YOY growth.

Pipeline Highlights

5. There are >200,000 FreeStyle Libre users in Europe now, a remarkable increase (~60%) from the >125,000 EU patients using the system as of the [2Q16](#) call. Wow! This impressive adoption has been achieved in only two years on the EU market and with a patient-driven cash-pay business model. EU Libre sales ballpark to just over ~\$70 million if all patients are using two 14-day sensors per month (~120 euros every four weeks).

6. In late September, [FDA finally approved FreeStyle Libre Pro](#), the retrospective (blinded), 14-day wear, factory calibrated sensor and HCP-owned reader device. The professional CGM is now available to US healthcare professionals and can be ordered directly at www.FreeStyleLibrePro.us, which Abbott has recently updated with great details on the product and reimbursement. The fully disposable sensors cost only \$60 each, and each practice needs only one \$65 reader to start multiple sensors. Libre Pro will be [reimbursed](#) under existing professional CGM codes that more than cover the cost for HCPs. We see this as a major ease-of-use, wearability, scalability, and cost improvement over current professional CGMs.

7. We also learned in [September](#) that Abbott submitted the real-time consumer version of FreeStyle Libre to the FDA in 3Q16. No approval timing was shared today, but the [2Q16](#) call expected approval by 1Q17. Can Abbott hit this ambitious timing? The Pro approval is certainly a positive for this review, but it did take over a year to get through the FDA (to our surprise), and the consumer version has at least two additional moving parts: it shows real-time data and will presumably need an insulin-dosing label claim. It is a different FDA these days, of course.

8. The big-time publication of Abbott's six-month [IMPACT](#) study in major UK medical journal [The Lancet](#) was not mentioned on today's call. The paper brings strong visibility for FreeStyle Libre and the glucose sensing field overall, and is hopefully a positive for broader reimbursement and HCP acceptance.

9. A number of FreeStyle Libre studies have been added or updated on ClinicalTrials.gov, including a 1,000-patient observational quality of life [study in Belgium](#) (investigator-initiated), a 100-patient quality of life [study in type 2s](#) (investigator-initiated), a completed Abbott-sponsored [trial](#) in 83 pregnant women, and a 76-patient Abbott-sponsored pediatric [glycemic control \(time-in-range\) study](#).

10. There were no specific pipeline updates on FreeStyle Libre, though CEO Miles White commented in Q&A that the product is "core" to Abbott's business and "there's a lot of opportunity for Libre ... depending on how we develop it and how we take it." The company has made recent moves on the data front ([mySugr](#) and [Social Diabetes](#) announced [at EASD](#)), and the LibreLink Android app has been downloaded on [Google Play](#) 10,000-50,000 times.

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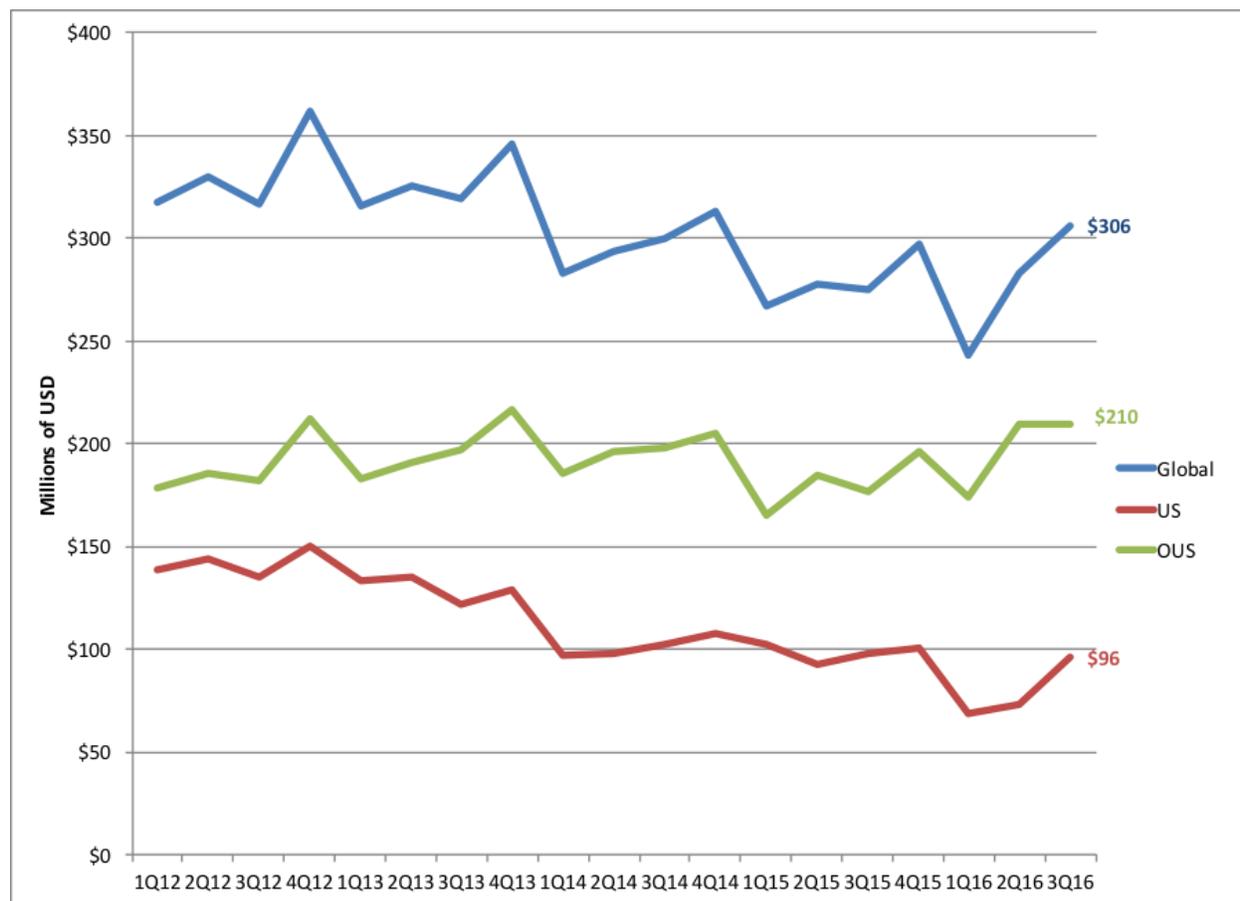
Financial Highlights

1. Abbott's Global Diabetes Care business had an excellent quarter, with revenue of \$306 million growing 12% as reported and 13% operationally year-over-year (YOY). The performance came against an easy comparison to an 8% sales decline YOY in [3Q15](#), but far outperformed guidance calling for mid-single digit growth this quarter. Indeed, 3Q16 marked the first quarter in which revenues topped

\$300 million since 4Q14 (\$313 million). Worldwide sales grew 8% sequentially from [2Q16](#). A challenging US environment continues to dilute the strong momentum from international Libre sales.

- Management expects to carry this quarter's momentum into 4Q16, guiding for sustained double-digit growth.** After an extended rough patch capped off by an all-time low \$243 million in revenue in [1Q16](#) - just two quarters ago - the US business seems to be stabilizing and international may even be accelerating (we certainly would expect it to be, with Libre!). In Q&A, Mr. White forecasted "pretty heavy double-digit growth out of Libre for the foreseeable future."

Figure 1: Global, US, and International Quarterly Sales (1Q12-3Q16)



- CEO Miles White emphasized the company's incredible commitment to diabetes and to FreeStyle Libre in Q&A. Divesting the business is NOT in the company's plans:** "Diabetes is definitely strategic for Abbott. There have been a number of occasions over the past I think five years when I've had inbound phone calls of people interested in acquiring the Diabetes Care business, and we have absolutely said no because - we had a program here that started with Navigator years ago that became Libre that fundamentally changes diabetic monitoring, glucose monitoring, etc., that we believe is game-changing, market changing, healthcare changing, etc. And we believe that the notion and the opportunity was such that we just plain had a different game plan than everybody else and that it was worth us making that core and pursuing it, and we have. And we're seeing the benefit of that now with the rollout of Libre in Europe and soon a rollout in the United States. And there's a lot of opportunity for Libre beyond that, depending on how we develop it and how we take it. So it is strategically core to us. If you think that's kind of on my radar screen for some strategic move, take it off your screen. That is core to Abbott and will remain core to Abbott, and the opportunity there we think is nothing but great looking forward."

2. US Diabetes Care sales declined a modest 2% YOY, totaling \$96 million in 3Q16. This came on an easy comparison to [3Q15](#) (when sales fell 4% YOY) and now marks 14 of the past 15 quarters with US sales declines ([1Q15](#) was the lone exception, and it was against a very easy comparison). Five of the past six quarters have seen US sales under \$100 million, though the quarter did see an encouraging 32% from a very weak [2Q16](#) (\$73 million) - the largest quarter-to-quarter to sequential growth in our model (dating back to 2008). We wonder if this relates to stocking, formulary coverage, the low-cost Neo BGM, or something else.

- **In Q&A, Mr. White acknowledged that the BGM market is "clearly under both volume and price pressure" and he hopes that it will be overtaken by Libre at some point. How quickly will US growth pick up now that Libre Pro is available and Libre is coming soon (under FDA review)?** We assume the revenue ramp from Pro sales may be fairly modest to start- it's a more HCP-driven product and clinical practice is extremely slow to change. But from what we see on social media, there is tremendous pent-up patient demand for the consumer version of FreeStyle Libre here in US. Assuming the real-time version is approved in early 2017 as expected, Abbott should see significant growth next year, particularly given the easy YOY comparisons.
 - **As an aside, CGM reimbursement in the US is often discussed as "taken care of," but we continue to hear other views from patients and HCPs:** CGM is still very expensive (even with insurance), remains difficult or impossible to get covered or prescribe (prior authorizations, documentation), and is unaffordable out of pocket for many people with diabetes and especially for those with high deductible plans (e.g., Dexcom sensors at \$70-\$75 each translate to well over \$3,000 per year if worn 24/7).
- **Abbott has played the long game beautifully with Libre (it was years in the making following Navigator, as Mr. White noted in Q&A). The franchise can now drive Abbott Diabetes growth in the face of significant headwinds in traditional BGM:** (i) [CMS's competitive bidding program](#), which recently forced mail order blood glucose strips down an additional ~20% and continues to hurt all BGM companies; (ii) greater use of CGM in high frequency testers; (iii) less use of fingersticks with non-hypoglycemia-causing type 2 therapies (GLP-1s/SGLT-2s should continue to expand with better applications and positive CVOT data); and (iv) more high deductible health plans, causing users to buy less strips; and other factors.

3. International Diabetes Care revenue totaled \$210 million, growing 19% as reported and 21% operationally YOY. As expected, FreeStyle Libre drove the quarter's success. Or as Mr. White put it, Libre is "going gang busters in Europe." *Notably, the growth came on a tougher comparison to [3Q15](#) (when sales grew 4% operationally), and the international performance was the highest YOY growth in the past eight years. This also marks the sixth consecutive quarter of operational improvement, a clear alignment with the initial EU launch of Libre [eight quarters ago](#). Sales were flat sequentially from 2Q16 following strong 21% sequential growth from Q1 to Q2. Given tens of thousands more Libre users in Europe alone this quarter, we assume the flat sequential performance reflected a drop in the legacy BGM portfolio.*

- **EU Libre sales ballpark to just over ~\$70 million if all 200,000+ patients are using two sensors per month (~60 euros per 14-day sensor).** This is up from the estimated ~\$45 million generated from the 125,000+ using Libre in [2Q16](#). Revenue would obviously be lower if many use Libre intermittently, or the 200,000+ users includes those who tried it and stopped using it. In a more conservative case of one 14-day sensor per month, revenue would be just under ~\$40 million. If the larger number is true, this is a striking one-third of international sales already, not including the readers or sales in other countries outside of Europe! Abbott did not report specific sales for FreeStyle Libre - this is our guess - but the user number does give a good broad stroke on the larger-than-expected size of the business.
- **Outside of Europe, FreeStyle Libre recently expanded into [Argentina](#), [Australia \(June 2016\)](#), and [Israel and Brazil \(July 2016\)](#).** The Pro version is also available in India and has received strong reviews from clinicians there. We're not sure of the relative size of these markets vs. Europe, but assume they are much smaller at this stage. Still, it's terrific to see the broad global

footprint for this product already - Abbott can really bring this to the masses in a way that hasn't been done with CGM yet.

Pooled Financial Highlights

4. Pooled global revenue for J&J and Abbott reached ~\$733 million, falling 2% YOY relative to pooled revenue in 3Q15. This came against an easy comparison as combined revenue declined 13% YOY a year ago. It was a tale of two companies: J&J saw a 9% reported YOY drop vs. Abbott's 12% reported YOY growth.

- **US weakness drove the pooled declines in 3Q16, with combined sales of ~\$287 million down 5% YOY** against an easy comparison to pooled sales in 3Q15 (when sales fell 12%). J&J's quarter was behind most of the decline: sales dropped 7% YOY relative to Abbott's 2% decline. Pooled sales rose 15% sequentially from the very low base of \$250 million in 2Q16.
- **Pooled international sales of ~\$446 million grew 1% YOY in 3Q16 against an easy comparison to pooled revenue in 3Q15 (down 14% YOY).** This was only the second positive pooled YOY growth since 2Q14. Abbott drove the gains with 19% reported growth vs. J&J's 11% YOY decline. Given the current trends, it's hard to bet the future of these businesses on traditional BGM, a storm Abbott is well positioned to weather with FreeStyle Libre. It will be interesting to see how and if J&J's Diabetes Care business adapts with upcoming launches (OneTouch Via, WellDoc/Verio, Animas G5, automated insulin delivery) - these have taken longer than expected, but the OneTouch Via, in our view, could be a very big product globally.
- **As a reminder, direct BGM comparisons between Abbott and J&J are impossible because each company's Diabetes Care business includes a fraction of non-BGM revenue that is not reported.** J&J has Animas insulin delivery and Abbott has continuous glucose monitoring (Navigator II, Libre) outside of the US. If Mr. White's hopes of Libre "overtaking" the BGM business come to fruition (we assume they will eventually), then it will no longer even be appropriate to consider Abbott as one of the "Big Three" BGM companies! [[Please let us know](#) how you would like to see this market modeled going forward -would you like estimated total CGM market sales to include FreeStyle Libre?]

Pipeline Highlights

5. There are "over 200,000" patients using FreeStyle Libre in Europe now, a remarkable increase (~60%) from the 125,000+ EU patients using the system as of the 2Q16 call. Wow! This impressive adoption has been achieved in only two years on the EU market and with a patient-driven cash-pay business model - and Europeans are not used to paying out of pocket for diabetes supplies. For a rough comparison, this is a bit larger than Dexcom's *global* installed base, which totaled roughly ~170,000-180,000 patients as of 2Q16 (piecing together management's installed base comments in 2Q16 with the installed base number shared in 4Q16).

- **CEO Mr. Miles White shared strong enthusiasm in Q&A for the economics behind Libre:** "A lot of payers and a lot of governments will tell you today, 'don't bring me new technology; bring me something more cost-effective that impacts my ability to spread my budget further and treat patients better.' Well, Libre has got that in the equation in a big way."
 - **Of course, CGM has historically been poorly reimbursed in the EU, a factor that has certainly helped drive Libre uptake in the EU.** However, with a positive reimbursement decision [in Belgium for Libre](#), [The Lancet publication of IMPACT](#), and a host of other studies in the works (see below), reimbursement might be opening up.
- **Will Libre's EU adoption continue to ramp at this impressive trajectory?** There are a few interesting competitive forces swirling in Europe: a [positive CGM reimbursement decision in Germany](#) (FreeStyle Libre is not included, unfortunately); Medtronic's upcoming standalone Guardian Connect mobile CGM (its first CGM offering for MDIs, [launching in November-January](#)); and Dexcom opening its EU headquarters. The market is more than large enough for three

companies (and beyond) to excel, though we wonder how the competitive dynamics will play out - what will most drive market expansion?

6. In late September, [FDA finally approved FreeStyle Libre Pro, the retrospective \(blinded\), 14-day wear, factory calibrated sensor and HCP-owned reader device.](#) The professional CGM is now available to US healthcare professionals and can be ordered at www.FreeStyleLibrePro.us. The website has been highly updated since the initial announcement, and we appreciated the [impressively comprehensive reimbursement section](#). The fully disposable sensors cost only \$60 each, and each reader device, which is compatible with multiple sensors such that a practice only needs one, costs just \$65. Providers can order directly [online](#), and current CPT codes for professional CGM more than cover the cost for HCPs (see pictures below). We see Libre Pro as a critical companion diagnostic for titrating medications in type 2 diabetes; adjusting insulin in those not willing/able to wear a sensor 24/7/365; and as an ideal tool for use in clinical trials. See our [September report](#) for a deeper dive into the product and view [Abbott's updated website here](#).

- **Libre Pro offers major ease-of-use, cost, wearability, and scalability improvements over current professional CGMs, and we expect (and hope) the category could become a big market over time.** Clinical practice is always S-L-O-W to change, and demand for this product will presumably be more HCP-driven than patient-driven - hence, the ramp may be slow at first as the product assimilates into routine US clinical practice. But given how easy the device is to use and how much better the data is vs. infrequent fingersticks, it feels like a no-brainer for intermittent use in any patient not on real-time CGM (i.e., most people with diabetes).

We're not sure why the FDA review took so long (Abbott submitted back in [2Q15](#)), but we wonder if the Agency's lengthy review was forward-looking in anticipation of the review of the real-time consumer version, which has many similarities to Pro (e.g., on-body form factor, factory calibration, sensor chemistry). Aside from the data display in retrospective (Pro) vs. real-time (consumer) formats, the key difference between the products is the sampling frequency: Pro takes a reading every 15 minutes and store all 14 days of data without needing an interim scan vs. the real-time version samples every minute but can only store eight hours of data before the patch needs to be scanned.



Coverage

Coding

Payment

Reimbursement support

Professional CGM is a reimbursable procedure with broad coverage for people with diabetes*



88% of commercial lives are members of a plan with written pro-CGM coverage¹



100% of fee-for-service Medicare patients have pro-CGM coverage^{2†}

Reimbursement

CY 2016 National Payments for CPT® Codes 95250 and 95251

Definition	Medicare physician fee schedule ^{1,2}	Private payer ³
	Medicare allowable	Median billed
95250 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording (Do not repeat more than once per month.)	\$159.69	\$303
95251 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report	\$44.04	\$87

7. We also learned in [September](#) that Abbott submitted the real-time consumer version of **FreeStyle Libre to the FDA in 3Q16**. As of [2Q16](#), approval was expected by 1Q17, but there was no timing update today. Can Abbott hit this ambitious timing? The Pro approval is certainly a positive for this review, but to our surprise, it did take over a year to get through the FDA. The consumer version of FreeStyle Libre has at least two additional moving parts: it shows real-time data (higher risk than retrospective) and will presumably need an insulin-dosing claim (something Dexcom has been talking to the FDA about for two years). Abbott had a rocky relationship with the FDA in the Navigator era, though it is a different agency now,

and the company has many things going for it (see below). We hope things can move quickly, since many people with diabetes in the US cannot access CGM but would benefit from this product.

- **The consumer version of FreeStyle Libre will presumably need an insulin-dosing claim to keep Abbott's major marketing message ("No fingersticks!").** [And of course, to keep pace with Dexcom's G5, which is likely coming soon following the [positive July vote](#).] Despite a rocky regulatory history, Abbott has some critical advantages: (i) a factory calibrated system has no noise from fingerstick calibrations, which is the biggest source of danger with CGM; (ii) two large outcomes studies in IMAPCT and REPLACE show non-adjunctive use is safe in large RCTs; and (iii) 200,000+ users (!) on FreeStyle Libre are using it non-adjunctively in the EU (not to mention customers in Australia, Israel, Brazil, and Argentina). On the other hand, Libre does not have alarms and has slightly lower point accuracy than G5, though these realistically pale in comparison to the aforementioned factors.
- **Notably, FreeStyle Libre (consumer) is called a "continuous glucose monitoring system" in Abbott's press release, departing from the international use of "Flash Glucose Monitoring."** We wonder if this was an FDA categorization or Abbott's re-positioning to align the product with the positive reimbursement and/or clinical practice guideline trends for "CGM," particularly in the US where reimbursement already exists. Increasingly we're noticing FreeStyle Libre is explicitly "excluded" from decisions ([Germany reimbursement](#); new [Endocrine Society Guidelines](#)), and though it doesn't have alarms, Libre does capture glucose data "continuously." We assume - but are not positive - that it will be covered under existing US reimbursement for CGM. Some reimbursement is quite good, but given that most employers are pushing more costs onto consumers, consumers will definitely have to shoulder more, due to higher co-pays and higher deductibles.
- **Presumably (we can't imagine otherwise!), FreeStyle Libre (consumer) will require a prescription in the US,** meaning it won't be as easy to get as it is in Europe (online order with just a credit card).

8. The publication of Abbott's six-month [IMPACT](#) study in major UK medical journal *The Lancet* was not mentioned on the call. This publication represents a solid victory for the company and the field and hopefully a positive for broader EU reimbursement. Getting the dramatic 38% hypoglycemia reduction (~74 minutes fewer per day) published in such a prestigious journal helps build the evidence base and cost-effectiveness proposition around this device, corroborates the REPLACE outcomes study in type 2 ([presented at ATTD](#)), and helps reduce the noise factor around "no alarms." Helping doctors drive therapeutic change will be important for healthcare professionals.

- **The publication was accompanied by [a balanced \(but mostly positive\) accompanying Comment from Cambridge's Dr. Roman Hovorka and colleagues](#).** Dr. Hovorka et al. noted that the Libre's lack of alarms "has surprisingly little effect on user acceptability," that the device could alleviate many of the barriers to wider adoption of CGM, such as the need for calibrations, alarm fatigue, frequent sensor changes, and cost, and that the convenience of FGM trumps that of SMBG. The comment cautioned that "studies in a more generalizable clinical population, in which aspects of behavior modification induced by use of this technology can be ascertained, are needed to provide further guidance to healthcare providers and funders, as well as comparisons with emerging automated insulin-delivery systems."
- **See our coverage of the [IMPACT poster](#) from ADA 2016 for a refresher on the study's findings.**

9. A number of FreeStyle Libre studies have been added or updated on ClinicalTrials.gov, including a 1,000-patient observational quality of life [study in Belgium](#) (investigator-initiated), a 100-patient quality of life [study in type 2s](#) (investigator-initiated), a completed Abbott-sponsored [trial](#) in 83 pregnant women, and a 76-patient Abbott-sponsored [pediatric glycemic control \(time-in-range\) study](#). See the table below for an overview, which only includes studies in ClinicalTrials.gov when searching "FreeStyle Libre."

Trial	Trial Population	Primary Outcome(s)	Status
Flash Glucose Monitoring Study for Diabetes (FUTURE)	1000 patients (ages 18+) using FGM after entering in the new diabetes reimbursement program in Belgium	Quality of life	Recruiting participants
Effect on QOL in Type 2 Diabetes Patients (Clinicaltrials.gov Identifier: NCT02809365)	100 type 2 diabetes patients (ages 30-80) treated with MDI (≥ 2 injections/day); A1c between 7.5% and 10%	Treatment satisfaction as measured by DTSQ (Diabetes Treatment Satisfaction Questionnaire)	Not yet open for recruitment
Accuracy study investigating FreeStyle Libre in pregnant women with type 1, type 2, or gestational diabetes (ClinicalTrials.gov Identifier: NCT02665455).	83 pregnant women (age 18+) with type 1, type 2, or gestational diabetes	Point accuracy judged using the Clarke Error Grid	Complete; no results posted yet
SELFY is comparing the efficacy of FreeStyle Libre vs. SMBG in self-management of diabetes	76 type 1 patients ages 4-17	Time in range	Ongoing; primary completion slated for December 2016.
An evaluation of the FreeStyle FGM system (Clinicaltrials.gov Identifier: NCT02824549)	50 children (ages 4-18) with type 1 diabetes	Usability of the system	Not yet open for recruitment
An accuracy study of FreeStyle Libre in type 1 patients in the UK (Clinicaltrials.gov Identifier: NCT02734745)	24 adults with type 1 diabetes	Accuracy - MARD vs. YSI during CRC visit and vs. glucometer during home setting	Recruiting participants

10. There were no specific pipeline updates on FreeStyle Libre, though CEO Miles White commented in Q&A that "there's a lot of opportunity for Libre ... depending on how we develop it and how we take it." The company has made recent moves on the data front with mySugr and Social Diabetes (announced [at EASD](#); see below), and the LibreLink Android app is now broadly available on the Google Play store (10,000-50,000 downloads, 3.4/5 stars). We wonder if a continuous version of FreeStyle Libre will eventually be developed that adds Bluetooth and/or alarms. This would expand from the principles that went into the original FreeStyle Libre (no alarms!), though we assume it is very possible. A tough call, and obviously, more SKUs add manufacturing complexity and could reduce margins.

- **Mr. White did not mention the recent [integration agreement](#) between Abbott and mySugr**, which will allow Libre users to automatically and passively upload data to their mySugr accounts via the LibreLink Android app. We're glad to see Abbott now enabling a broader data ecosystem around Libre, much like Medtronic and Dexcom are also doing. This news is also a win for the widely loved mySugr app, which has nearly 800,000 users globally (!) and a partnership with

Roche's Accu-Chek Connect BGM. LibreLink is currently only available in Sweden, the Netherlands, Germany, Italy, and the UK, but with FDA approval of Libre on the horizon, the data integration agreement could presumably be relevant to American customers soon.

- **We also recently learned about a new partnership between Abbott and [Social Diabetes](#)**, a popular [Android app](#) in the EU that enables users to log their food and insulin and get dosing recommendations from the app. We have not ever heard of this app, but it has a notable 50,000+ downloads [on Android](#) and very positive reviews.

Questions and Answers

Q: How are things going in medical devices?

Mr. White: Our FreeStyle Libre launch in Europe has gone well. We have over 200,000 patients now. That's a lot. And that's a really good success rate so far. We had very ambitious plans for this product. And to be honest, we're behind our plans by a month or two, but it's a fairly vertical ramp. It's a pretty high ramp. And that ramp is occurring at the trajectory we projected, but about a month or two behind what we projected, and it'll probably stay that way. So we're going to have a terrific performance as you can already see in the numbers for this year and even that was behind what we had hoped. But it's not because it's not on that trajectory. It just started slower than we had planned, but now it's pretty on track and we're anxious to launch the consumer version in the United States and enjoy the same sort of success here. And I think it owes to the capability of the product, the unique medical proposition of the product and frankly, the economic proposition of the product. A lot of payers and a lot of governments will tell you today, 'don't bring me new technology; bring me something more cost-effective that impacts my ability to spread my budget further and treat patients better.' Well, Libre has got that in the equation in a big way. So we're looking forward to the launch of that.

Q: Is Diabetes still strategic for Abbott now that the focus is more on Cardiovascular Devices?

Mr. White: [Laughs] Yeah. Diabetes is definitely strategic for Abbott. There have been a number of occasions over the past I think five years when I've had inbound phone calls of people interested in acquiring the Diabetes Care business, and we have absolutely said no because - we had a program here that started with Navigator years ago that became Libre that fundamentally changes diabetic monitoring, glucose monitoring, etc., that we believe is gamechanging, market changing, healthcare changing, etc.

And we believe that the notion and the opportunity was such that we just plain had a different game plan than everybody else and that it was worth us making that core and pursuing it, and we have. And we're seeing the benefit of that now with the rollout of Libre in Europe and soon a rollout in the United States. And there's a lot of opportunity for Libre beyond that, depending on how we develop it and how we take it. So it is strategically core to us. If you think that's kind of on my radar screen for some strategic move, take it off your screen. That is core to Abbott and will remain core to Abbott, and the opportunity there we think is nothing but great looking forward.

Q: Diabetes was a standout in the quarter. Is double digit growth how you expect the franchise to play out in the next few years?

Mr. White: Well you have two franchises going here. You've got the old established legacy franchise of blood glucose monitoring, and then you've got what we call flash glucose monitoring or Libre, and that older blood glucose market is clearly under both volume and price pressure. And Libre is growing rapidly in Europe, and we expect to grow rapidly in the United States. So at some point, we would hope that Libre would grow so significantly that it would overtake the other. So I don't expect that kind of growth out of the base, but I think we're going to keep experiencing pretty heavy double-digit growth out of Libre for the foreseeable future. So, yeah, I think it drives a lot of growth. But we're at crosses and, you know, the overall business is somehow double-digit, I'm not sure I can project.

- by Brian Levine, Adam Brown, and Kelly Close