
Abbott 3Q17 - Following FDA approval, FreeStyle Libre could hit \$50M-\$100M in 2018 US revenue; Global sales grow 19%, with Libre driving 34% international growth - October 18, 2017

Executive Highlights

- Exactly [three weeks ago today](#), FDA approved the real-time consumer FreeStyle Libre for adults in the US as a replacement for fingersticks (10-day wear, 12-hour warmup) - it will launch in retail pharmacies by the end of the year. CEO Mr. Miles White generally endorsed analyst Mike Weinstein's estimate of "\$50 million? \$100 million?" in US Libre revenue in 2018. By our estimates, that would represent a strong launch, with ~80,000-150,000 US patients getting on Libre within 12 months (assumptions below).
- Global Diabetes Care sales grew a strong 19% YOY operationally to a record \$373 million in 3Q17 on a tough comparison to 13% growth in [3Q16](#). International diabetes sales rose a striking 34% YOY operationally to record-high revenue of \$289 million - the second straight record quarter and a continued sign of Libre's momentum. Libre sales were not broken out, but based on the same assumption as in our [1H17 roundup](#), they ballpark at ~\$130 million. US sales fell to \$84 million, down 13% YOY on an easy comparison to [3Q16](#) (when sales declined 2%).
- Abbott expects another quarter of double-digit growth in 4Q17. Growth will look particularly good for the next four quarters, of course, since the YOY US comparisons will be very easy as Libre finally launches.
- As noted with the FDA approval, FreeStyle Libre is currently used by 400,000+ patients in >40 countries globally, up from 300,000+ as of the prior update in early September. Mr. White referenced adding "50,000 per quarter" internationally, which has been true in recent updates given the regulatory and reimbursement gains. Recent national reimbursement victories include France (May), Japan (August), and the UK (September).

Early this morning, energized CEO Mr. Miles White led Abbott's [3Q17 financial update](#). It was the best quarter yet for the emerging FreeStyle Libre franchise: Over 400,000 users internationally, FDA approval in the US (and sky-high launch expectations), and national reimbursement achieved in the UK and Japan. The momentum drove 34% operational growth for Abbott outside of the US. Plus, we were very interested to learn that Mr. White wears FreeStyle Libre himself. Below, we bring you our top pipeline and financial highlights from the call followed by a [very interesting Q&A](#) with Mr. White.

We are excited that FreeStyle Libre is really growing the CGM market - as noted in [our 1H17 roundup](#), we believe the CGM category grew an estimated ~50% YOY in 1H17 (nearly \$400 million in sales), with FreeStyle Libre contributing nearly 60% of the estimated growth.

FreeStyle Libre's US Approval and Launch Expectations

1. In Q&A, CEO Mr. Miles White said he'll "take" analyst Mike Weinstein's estimate of \$50 million or \$100 million in 2018 US FreeStyle Libre revenue, calling it "a nice range." He added that he expects a "good, strong out-of-the-blocks performance." By our calculations, the revenue estimate translates to ~80,000-150,000 Libre real-time users, a strong but doable ramp (see our calculations below on this). With [FDA approval \(with replacement claim\)](#) three weeks ago, Libre is expected to launch in US pharmacies as a prescription-only product by the end of the year (10-day wear, 12-hour warmup). **Mr. White shared for the first time (perhaps because it wasn't previously approved in the US) that he wears FreeStyle Libre, calling it a "phenomenal device" and a "super product."**

Financial and User Base Highlights

2. Abbott's Global Diabetes Care business had yet another strong quarter on Libre momentum, with record revenue of \$373 million growing 19% operationally and 22% as reported year-over-year (YOY) against a difficult comparison to 12% operational growth in [3Q16](#). Since Libre took off in Europe, this is the sixth straight quarter of positive YOY growth for the overall business, a stretch preceded by 10 quarterly declines. We see this as very positive for CGM overall - it is fantastic that Abbott, Dexcom, and Medtronic now strong and accurate sensors, and we have high expectations for this category in the next five years (see [our roundup](#)).

3. International Diabetes Care revenue rose a striking 34% operationally and 38% as reported to \$289 million in 3Q17 - a record-high for the second quarter in a row. This growth comes against a very tough comparison of 21% growth in revenue [a year ago](#). Libre sales were not broken out; based on the assumptions in our [1H17 roundup](#), they ballpark at ~\$130 million in 3Q17.

4. US Diabetes Care sales fell 13% YOY in 3Q17, totaling \$84 million against an easy comparison (down 2% in [3Q16](#)). We've received no indication of Libre Pro uptake stateside, though the declining BGM business in the US could be masking Libre Pro sales growth. Given the above sales estimate for FreeStyle Libre consumer in the US, we might expect 2018 US YOY growth between 9% and 30%.

5. As noted in the [FreeStyle Libre FDA approval announcement](#), management confirmed that there are currently over 400,000 FreeStyle Libre customers in >40 countries internationally. If the user base continues to grow by ~50,000 per quarter (particularly once Libre real-time is in the US), the base would eclipse 650,000 users globally by the end of 2018.

Other Pipeline Highlights

6. The [Bigfoot partnership](#) to automate insulin delivery with a next-gen Libre was not mentioned. Bigfoot CEO Mr. Jeffrey Brewer told us this week that a launch of the pump-based automated system is possible in "2020," pending FDA approval. Bigfoot still expects a pivotal trial in 2018, though this is the first launch timing shared since the [July partnership announcement](#). A pivotal trial for the MDI auto-titration system (FreeStyle Libre + smart pen cap [Timesulin]) is also expected to begin in 2018, the first timing we've heard there.

7. There are at least 19 studies on "FreeStyle Libre" or "Flash Glucose Monitoring" on ClinicalTrials.gov - [see here](#), including a 1,100-patient observational quality of life [study in Belgium](#) (investigator-initiated), a 100-patient quality of life [study in type 2s](#) (investigator-initiated), a four-site [US accuracy study](#), and a study in the Netherlands that uses [FreeStyle Libre Pro to assess workplace wellness](#). See the table below.

Pooled Abbott and J&J Financial Highlights

8. J&J and Abbott pooled global revenue reached ~\$778 million, up 6% YOY relative to [3Q16](#) on a modest comparison (-2% one year ago). Obviously, it was a tale of two companies, and pooling them makes less sense as time goes by. However, we do feel it is important to do so in order to assess the combined BGM/CGM markets. Libre has further separated these two business trajectories: LifeScan/Animas fell 7% YOY to \$421 million in [3Q17](#), while Abbott's sales rose 19%. J&J recently [closed Animas and exited the pump market](#) as it continues to evaluate strategic options for its LifeScan business.

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FreeStyle Libre's US Approval and Launch Expectations

1. FOLLOWING FDA APPROVAL AND 4Q17 LAUNCH IN PHARMACIES, POTENTIAL FOR \$50M-\$100M IN US FREESTYLE LIBRE REVENUE IN 2018

In Q&A, CEO Mr. Miles White said he'll "take" analyst Mike Weinstein's estimate of \$50 million or \$100 million in 2018 US FreeStyle Libre revenue, characterizing it as "a nice range." He added that he expects a "good, strong out-of-the-blocks performance." Per the approval announcement, US launch in pharmacies is expected by end of year. By our calculations, that would represent a strong launch, with ~80,000-150,000 US patients getting on Libre within 12 months and using three sensors per month. This assumes an average per-patient US Libre revenue of ~\$650 in 2018.

- **This user base estimate assumes:**
 - \$120/month US sensor pricing (cash), with a 30% discount to payers. Assuming every person gets it reimbursed, Abbott's sensor revenue would be \$252/quarter per Libre user. Revenue would be higher if a sizeable number of patients pay cash, or there is no payer discount.
 - An equal cadence of new users throughout 2018 - 25% wear FreeStyle Libre for four quarters (~\$1000 in 2018 sensor revenue), 25% wear it for three quarters (~\$750 in sensor revenue), etc. If more patients get on FreeStyle Libre in the first half of the year, revenue would be higher.
 - 100% utilization - every user gets three sensors per month.
 - One \$60 reader sold to each patient.
- **See the table in highlight #5 below for comparison to the international market, where the user base reached 125,000 seven quarters following launch in fall 2014;** the revenue estimates use the assumptions listed explicitly in [our 1H17 roundup](#). With those in mind, international FreeStyle Libre sales ballpark to ~\$130 million this quarter. (Of course, it's possible sales are lower or higher, depending on the user base, pricing, utilization, and other factors we don't know.) Even on the low end, \$50 million in new US sales in 2018 would be a serious boon to the freight stateside business, representing ~9% YOY growth from 2017 (assuming Abbott secures \$80 million in overall 4Q17 US revenue and BGM sales are flat between 2017 and 2018). On the high end, using the same assumptions, YOY growth in the US could reach ~30%, a nice uptick from a 3% decline in 2015 and an 18% decline in a tumultuous 2016.

- **With FDA approval (with replacement claim) late last month - ~one year after 3Q16 submission - Libre is expected to launch in US pharmacies as a prescription-only product by the end of the year.** Mr. White described the US market as "more educated, ready, prepared, anticipating, demanding." "I expect demand to be pretty strong," he said, "the US market knows a lot about Libre because of all of the experience" outside of the US. We would agree that there is a likely a lot of pent up demand in the US, especially since Libre: doesn't require fingerstick calibrations; offers low cash pricing and pharmacy distribution; adds a fully disposable sensor+transmitter design; and a sleeker on-body form factor vs. Medtronic and Dexcom. Of course, Libre also has two RCTs to share with healthcare providers in [IMPACT](#) and [REPLACE](#), and a real-world cohort of 55,000+ Libre users demonstrating A1c, time-in-range, and hypoglycemia data (see [ATTD](#) + [ADA](#); we expect to see more at the upcoming [DTM meeting](#) in Bethesda).
- **On the US payer front, Mr. White said that he believes discussions will all go very well - the stated intention is to get "as much and broad access as possible and as rapidly as possible."** We'd be surprised to see lots of Dexcom users move to Abbott unless they need a lower price or unless they receive pressures from payers. We do expect far more people to consider CGM, particularly type 2s and type 1s who have opted not to move to CGM to date - we see this helping Dexcom ultimately. Notably, anyone on the "Loop" system or other automated insulin dosing systems cannot use Abbott currently and AID is also rising in popularity, albeit things are early. This makes it doubly important for all the Bigfoot/Abbott milestones to hit (see below).
- **Mr. White shared for the first time (perhaps because it wasn't previously approved in the US) that he wears FreeStyle Libre, calling it a "phenomenal device" and a "super product."** I can see why consumers like it as much as they do." This was amazing to hear; the CEO of a major medical device manufacturer who *uses* his company's core diabetes product and can embrace the perspective of someone living with diabetes. No wonder he is so excited to see it approved. We wish that every diabetes executive, healthcare provider, regulator, caregiver, and payer would wear a CGM simply to understand the user experience, type of information, quantity of information, and most of all, the benefits of CGM.
- **The Q&A discussion was good to hear - we have never heard Mr. White spend this much time talking about Abbott's diabetes business** and it is SO far from the recent string of years in which "pricing pressure" and "Medicare" were the brief SMBG talking points with little or no discussion of patient needs.
 - **"Over the course of the year, there was a lot of skepticism** on the part of analysts and/or investors about all the things that we had to get accomplished that were backend-loaded, a lot of third-quarter fourth-quarter things."
 - **Mr. White reiterated this point a couple minutes later:** "You'll all have to admit you had a lot of skepticism about some of this, and maybe rightly so after 2016. But look, we've hit every target we had for this year. And with all those approvals, one ought to think that should bode positively for 2018." He followed up both comments with a reference to excitement over Libre.
 - **When asked about 2018 guidance, Mr. White responded, "I'm trying to think about how to sound conservative to you," followed by a hearty laugh.** It's rare in this era to convey levity on an earnings call when discussing a diabetes technology business. We're glad that Mr. White is back to referring to revenue, driven partly by Diabetes Care, in a positive light - it certainly beats the "impatient" Mr. White of [1Q17](#).
- **As a reminder, the US version of FreeStyle Libre is different from the one overseas (at least for now), though it remains factory-calibrated and carries an insulin-dosing (fingerstick replacement) claim, which we see as very key attributes.** In the US, FreeStyle Libre will have 10-day wear (vs. 14 days OUS) and a much longer 12-hour warmup after insertion (vs. one-hour warmup OUS). On the plus side, the factory-calibrated MARD has improved to 9.7% and we believe this is very important for patients who experience hypoglycemia. Though Libre's

absence of alarms is a drawback for many, this new device platform should expand the US CGM, which is still wildly underpenetrated. Patients could technically buy two readers to overlap wear times and avoid the 12-hour period without data, although then analyzing data would be more of a pain since data would be on two readers. (We're not sure if the FreeStyle Libre computer software can combine glucose data from two reader devices into a single trace.) Another challenge for Abbott initially is age: the Libre approval is only for ages 18+ at the moment though we do expect some off-label use. We imagine there are paths forward for longer wear, shorter warmup, and surely pediatric use. Pricing will be in line with cash-pay monthly prices in Europe - we're speculating that this means sensors will go for ~\$120/month and readers (one-time expense) will be around ~\$60. If true, this technically reflects a ~50% price cut over Dexcom, though we believe the right comparison is closer to 25% since so many people on Dexcom "extend" the sensor. [Read all about the specifications and competitive implications of the approval here.](#)

- **Given the non-adjunctive labeling and FreeStyle Libre's *de facto* classification as a "therapeutic CGM," we wonder if and when we might see Medicare coverage - Abbott told us that it will be "beginning discussions right away."** Next, we assume Medicare will have to determine that Libre falls in the DME Part B category (durable equipment like Dexcom's G5, because of the reader), followed by a coverage decision. As we understand it, FreeStyle Libre *does* meet the requirement of therapeutic CGM - "CGM used as a replacement for fingerstick blood glucose testing for diabetes treatment decisions i.e., non-adjunctive use," per [Medicare's site](#). We're not sure if the lack of alarms will be a stumbling block for Medicare; presumably it won't be, or will be addressed in Libre's next-generation. Medicare coverage would certainly open up a huge market chunk for Abbott; we think it would be positive for Dexcom too, as more awareness of CGM will drive penetration in Medicare (where Dexcom has only just beginning shipping systems).
- **We ultimately expect that FDA's FreeStyle Libre approval will be positive for the CGM field/category expansion in the US.** [Dexcom's stock price](#) dropped ~25% when the approval came through, a complete overreaction in our view to the replacement claim that many somehow didn't foresee; we didn't think FDA would approve the device *without* a replacement claim. Regardless, CGM penetration in type 1s in the US stands at roughly ~15% by our estimates, given the 24% penetration in the highly engaged T1D Exchange. The type 1 market could easily triple and still have massive growth opportunity left. Having three very strong sensors on the US market (Dexcom G5, FreeStyle Libre, and Medtronic's Guardian Sensor 3), each with different price points and feature sets, will benefit the field given the heterogeneity of the patient population and given that to date, very few type 2s globally have been on CGM (we think most of the EU Libre customers are type 1). As always, competition drives innovation: we look forward to Dexcom's easier-to-use, factory calibrated, smaller, disposable CGM with Verily, leveraging the G6 sensor (one calibration per day, 10-day wear, 30% smaller wearable, automatic inserter; FDA submission was expected in September), and the launch of Medtronic's Sugar.IQ pattern recognition app in tandem with the Guardian Sensor 3 in the near future. All the companies with CGM are doing very well and should all benefit from this approval.

Financial and User Base Highlights

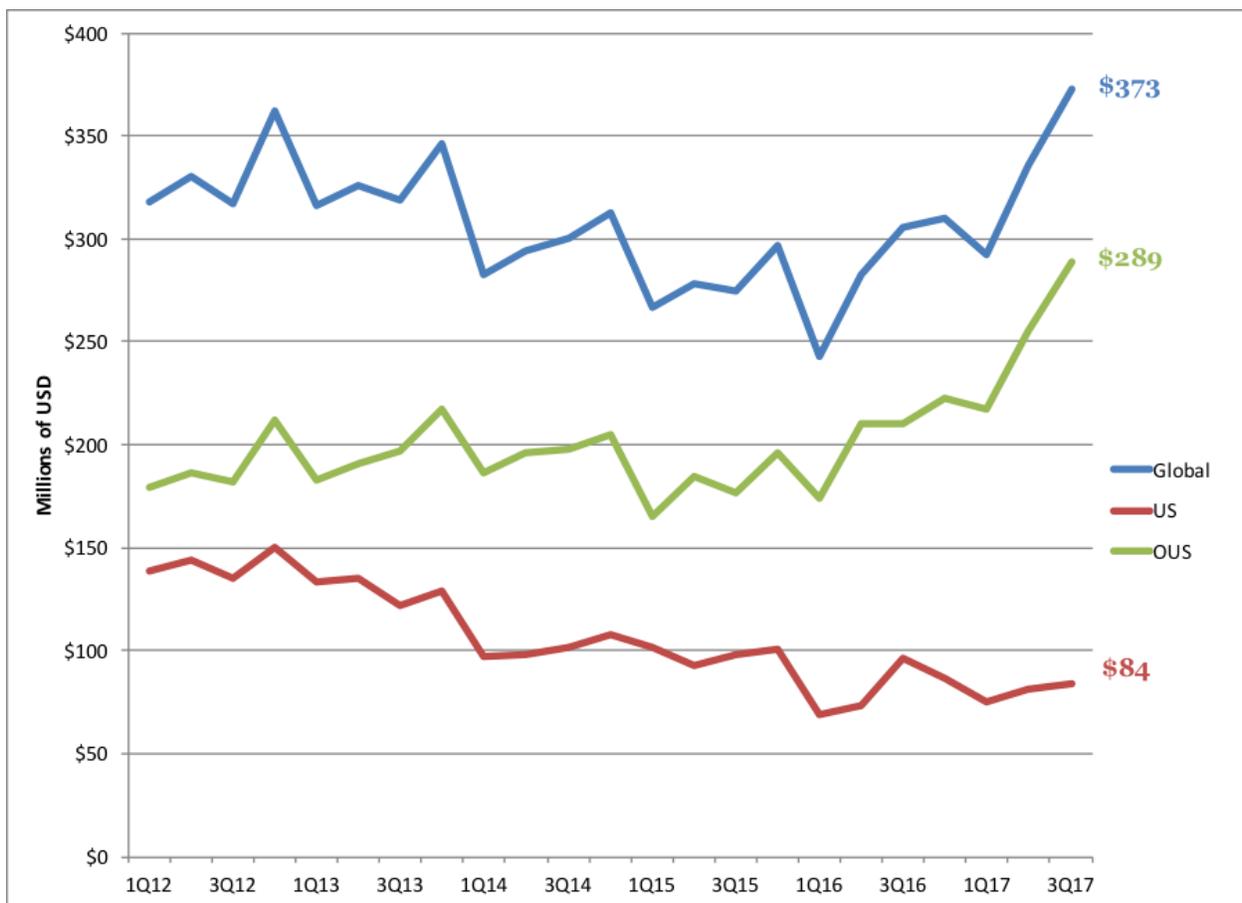
2. GLOBAL DIABETES REVENUE UP 19% YOY; CONTINUED DOUBLE DIGIT GROWTH PROJECTED FOR 4Q17

Abbott's Global Diabetes Care business had yet another strong quarter on Libre momentum, with record revenue of \$373 million growing 19% operationally and 22% as reported year-over-year (YOY) against a difficult comparison to 12% operational growth in 3Q16. Since Libre took off in Europe, this is the sixth straight quarter of positive YOY growth, a stretch preceded by 10 quarterly declines. It is also the highest quarterly revenue recorded in our model and the third straight quarter of 20%+ growth! Management forecasted continued double-digit sales growth over the next three months, on par with 3Q16 expectations for "pretty heavy double-digit growth out of Libre for the foreseeable future." Now that FreeStyle Libre has been approved in the US and will launch in retail pharmacies soon, those double digits

should climb even higher. The graph below, especially beginning in 1Q16 is astounding, showing the degree to which the investment in Libre is paying dividends - Abbott was certainly not caught flat-footed in the face of BGM pressures - what a marvelous story of a company doubling down on great technology (Navigator) and repackaging it to disrupt its own declining business. Even in terms of sequential growth, Abbott's Worldwide Diabetes business has grown in the double digits in each of the past two quarters (+15% in 2Q17, +11% this quarter) - impressive considering the high base and momentum. We wonder how long it will take for the red line in the graph to shoot up as well...

- **Unfortunately, Abbott doesn't specify sales beyond "Diabetes Care,"** so we're not positive of the relative contributions of BGM, FreeStyle Libre (in >40 countries), and FreeStyle Libre Pro (in the US, India, Japan, South Africa, and others). Based on our assumption of 90% utilization of FreeStyle Libre in the 400,000+ users, we estimate that Libre (real-time consumer version) accounts for ~\$130 million in sales, or 35% of overall revenue. We have no basis to estimate Libre Pro sales, unfortunately.

FIGURE 1: GLOBAL, US, AND INTERNATIONAL QUARTERLY SALES (1Q12-3Q17)



3. LIBRE DRIVES UNPRECEDENTED 34% YOY INTERNATIONAL GROWTH TO RECORD \$289M

International Diabetes Care revenue rose 34% operationally and 38% as reported to \$289 million in 3Q17 - the highest our model has ever seen for the second quarter in a row. Note the green line's trajectory above. This growth comes against strong 21% growth in revenue a year ago. As expected, continued consumer uptake of FreeStyle Libre drove the quarter's success. Relative declines in the value of the US dollar also worked in Abbott's favor for the quarter (a favorable 2.6% effect of foreign exchange). The performance reflects strong 13% sequential growth from 2Q17 - a \$34 million margin.

Revenue did come in past the \$200 million mark in 2Q16 and has stayed there, which will make for more difficult YOY comparisons outside the US in the upcoming quarters - though we haven't seen the law of large numbers begin to kick in yet (where growth slows as the base increases), and recent reimbursement victories in [France](#), [Japan](#), and the [UK](#) plus approvals in [Canada and Mexico](#) suggest there is plenty of international runway.

4. US DIABETES CARE FALLS 13% AGAINST EASY COMPARISON

US Diabetes Care sales fell 13% YOY in 3Q17, totaling \$84 million against an easy comparison (down 2% in 3Q16). Revenue did grow 4% sequentially from \$81 million in [1Q17](#). We're not sure how much of this quarter's revenue can be attributed to Libre Pro sales, but we suspect it's small given the large legacy BGM business and the slow pace to change clinical practice in primary care and type 2 diabetes management. Of course, now that FDA approval has come through for FreeStyle Libre consumer version, management expects a "good, strong out-of-the-blocks performance." See [highlight #1](#) above for details.

5. 400,000+ USERS IN >40 COUNTRIES WORLDWIDE; REIMBURSEMENT MOMENTUM CONTINUES

As noted in the FreeStyle Libre FDA approval press release [last month](#), management confirmed that there are currently over 400,000 FreeStyle Libre customers in >40 countries internationally. Mr. White noted that the company has been accruing ~50,000 additional users every quarter: 300,000+ FreeStyle Libre users [last quarter](#) (which we roughly estimate to be ~350,000), up from "about 300,000" as of [three months ago](#), 250,000+ EU patients in [4Q16](#), and nearly three times the 125,000 indicated [five quarters ago](#). We'd guess that the bulk of new additions came from France, where national reimbursement was achieved [in May](#).

	2Q16	3Q16	4Q16	1Q17	2Q17	3Q17
FreeStyle Libre Global User Base	125,000+	200,000+	250,000+	"about 300,000"	~350,000* (est)	400,000+
Est quarterly sales, assuming ~90% utilization, \$120 per month sensor pricing (rounded to nearest \$5 million increment)	~\$40 million	~\$65 million	~\$80 million	~\$90 million	~\$115 million	~\$130 million

*Abbott's [2Q17](#) call did not give an update on the size of the FreeStyle Libre user base. However, the 1Q17 update shared that there were "about 300,000" global Libre users. Subsequently, September's FDA approval shared there were 400,000+ global Libre users. We felt the midpoint of the two was a reasonable assumption for 2Q17's base.

- **For comparison, Dexcom [hopes to expand](#) its user base to "270,000+" by the end of the year on sales of \$710-\$740 million.** At the midpoint, this implies revenue of ~\$2,700 per user. Assuming Abbott shows similar sequential growth for Libre in Q4 (a conservative estimate,

given US launch), estimated 2017 Libre sales would come in at ~\$480 million. If Libre's global user base hits 450,000 by year-end, revenue would come in at ~\$1,100 per user, or roughly half of Dexcom. This feels in the ballpark, based on what we know about Abbott and Dexcom's pricing.

- **We aren't surprised that Abbott's user base has climbed with such rapidity, since reimbursement momentum has been steady and Dexcom has a much smaller international business.** FreeStyle Libre is currently fully or partially covered in 17 countries, with the most recent reimbursement victories coming from [UK's NHS](#) and [Japan's national payer](#) (two of the biggest diabetes markets). [See here a list of markets with reimbursement](#). As of last quarter, half of all Libre sales were to patients who have at least partial reimbursement - we assume this has only gone up!
- **If the user base continues to grow by ~50,000 per quarter (particularly once Libre real-time is in the US), the base could eclipse 650,000 users globally by the end of 2018.** Mr. White mentioned casually "50,000 new users a quarter" as an aside. This feels reasonable given the US launch; France, the UK, and Japan have all recently achieved national reimbursement; and Libre was approved in Mexico and Canada in [late June](#). Although it is hard for Libre, no matter how well it does, to affect Abbott's stock price in a major way (today, Abbott revenue overall for the entire company was \$6.8 billion), it is undoubtedly a very nice growth driver for the company - indeed, FreeStyle Libre had two dedicated bullets at the top of Abbott's [corporate press release today](#). This easy-to-teach-and-use CGM is proving transformative for the field and we look forward to future generations and rising competition.
- **Assuming that each of the 400,000+ customers is using two sensors per month (at \$60/sensor) 90% of the time, then Libre revenue of roughly \$130 million is ~45% of total international sales for the third consecutive quarter.** Of course, that may not be the right actual price everywhere and 90% utilization is an estimate, so this is pure speculation. [See our 1H17 roundup](#) for a more complete list of assumptions and what we don't know - actual FreeStyle Libre sales could be higher or lower than this, depending on how a user is defined, how often sensors are being used, how pricing varies by country and with reimbursement, and other factors.
- **Mr. White's enthusiasm in the Q&A section is definitely worth considering.** He gives his high-level perspective on the rate of adoption in EU (in the absence of reimbursement in year one), and said that it's "extremely gratifying" that the value proposition is so strong" for type 1s and type 2s, as well as payers. Adoption in the US could be much more rapid in the US than in the EU, he pointed out, because the EU required tackling one country, one reimbursement system at a time, vs. in the US where Medicare coverage is within reach and we imagine commercial payers will be highly interested. On the other hand, the US is far more competitive with Dexcom at this time, so the ramp may be slower. Ultimately, Abbott management has a "fair amount of optimism," but is "trying not to get too far ahead of [them]selves."

Other Pipeline Highlights

6. BIGFOOT NOT MENTIONED TODAY; POSSIBLE 2020 LAUNCH WITH ABBOTT'S NEXT-GEN LIBRE AND PUMP; PUMP + MDI PIVOTAL TRIALS EXPECTED IN 2018

The [Bigfoot partnership](#) to automate insulin delivery with a next-gen Libre was not mentioned. However, Bigfoot CEO Mr. Jeffrey Brewer told us in an email this week that the company's automated insulin delivery (AID) system - which will leverage Abbott's next-gen FreeStyle Libre with real-time communication - could launch in 2020, pending FDA approval. The pivotal trial is still expected to begin in 2018, reflecting no change in timing [since the July partnership announcement](#). We previously hadn't heard proposed *launch* timing for the pump system, though "2020" seems reasonable to us, assuming the next-gen Libre is developed quickly and incorporated into Bigfoot's system. ([In July](#), we speculated a "2019-2020" launch was possible.) Mr. Brewer also told us that a pivotal trial for Bigfoot's auto-titration system for MDI (with next-gen FreeStyle Libre and the dose capture device acquired from Timesulin) will begin in 2018 - the first such timing we've heard on this front. (He didn't

specify launch timing.) Assuming it secures approval, Bigfoot would likely enter a crowded hybrid closed loop market in the US behind Medtronic and possibly behind Tandem, Insulet, and Beta Bionics. Of course, timelines are always in flux so the cadence is impossible to call at this stage. Bigfoot will still likely have the first system driven by a factory-calibrated sensor, and its plan for a subscription/bundled pricing model will be novel and highly differentiated (unless other players rapidly shift to it). Libre's exclusive inclusion in the AID and auto-titration bundles gives Abbott a very exciting additional revenue stream a few years down the line. See our [coverage of the Abbott-Bigfoot partnership announcement here](#).

- **Last quarter, Mr. White had highly positive things to say about the Bigfoot agreement.** He acknowledged that he probably sounded like a brochure as he delivered an amazingly positive 450-word answer with ample enthusiasm for Bigfoot's "fairly clever" monthly subscription service model, "compelling" value proposition, and potential to augment pump penetration in type 1s and make insulin far easier and safer. We wonder if Abbott will aim to forge similar deals with other companies in the near future (Abbott can partner with others, but Bigfoot is exclusively tied to using FreeStyle Libre), or possibly other sorts of deals in additional sensor-augmented pumps, patch delivery devices, smart pens, insulin dose titration, and behavior change programs.

7. FREESTYLE LIBRE TRIALS COMING DOWN THE PIKE

There are at least 19 studies on "FreeStyle Libre" or "Flash Glucose Monitoring" on [ClinicalTrials.gov](#) - [see here](#) - including a 1,100-patient observational quality of life [study in Belgium](#) (investigator-initiated), a 100-patient quality of life [study in type 2s](#) (investigator-initiated), a four-site [US accuracy study](#), and a study in the Netherlands that uses [FreeStyle Libre Pro to assess workplace wellness](#). See the table below for a topline overview of key trials we noticed. For comparison, the same search criteria for Dexcom [reveals 30 studies](#). We'll be looking in the future to see how this trend changes.

Trial	Trial Population	Primary Outcome(s)	Status
Flash Glucose Monitoring Study for Diabetes (FUTURE)	1,100 patients (ages 18+) using FGM after entering in the new diabetes reimbursement program in Belgium	Quality of life	Recruiting participants; Completion slated for August 2019
FreeStyle Libre Flash Accuracy Study (NCT03257501)	150 insulin-using type 1s and type 2s 18+ years old	MARD vs. YSI; Adverse device effects	Currently recruiting participants; completion slated for December 2017
Effect on QOL in Type 2 Diabetes Patients (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 of FreeStyle Libre (NCT02734745)	48 type 1s (18 years and up)	MARD vs. YSI during visit and vs. SMBG at home	Currently recruiting participants; completion slated for December 2017
Blood Glucose, Cognition and Wellbeing @ Work (NCT03295578)	45 Jumbo supermarket (Netherlands) employees ages 18-67	Daily glucose levels, food intake, cognition tests, + wellbeing (with FreeStyle Libre Pro)	Ongoing study; Completion slated for December 2017

Pooled Abbott and J&J Financial Highlights

8. POOLED J&J AND ABBOTT REVENUE UP 6% YOY - US DOWN 12%, ABBOTT LIFTS INTL SALES TO 18% YOY GROWTH

J&J and Abbott pooled global revenue reached ~\$778 million, up 6% YOY relative to [3Q16](#) on an easy comparison (-2% one year ago). Obviously, it was a tale of two companies, and pooling them without considering SMBG only may make less sense as time goes by. For now, we are pooling the companies here to offer a high-level sense on glucose monitoring including both SMBG and CGM (and some Animas revenue for J&J). Pooled 3Q17 sales of ~\$252 million fell 12% in the US, whereas pooled international sales of ~\$526 million grew 18% YOY on the strength of Abbott's FreeStyle Libre. Libre has further separated these two business trajectories: LifeScan/Animas fell 7% YOY to \$421 million in [3Q17](#), while Abbott's sales rose 19%. Further, J&J recently [closed Animas and exited the pump market](#) as it continues to evaluate strategic options for its LifeScan business, and Libre is in the midst of striking reimbursement and adoption momentum. Neither company separates out BGM sales from other portfolio components, so an exact comparison between these two companies is not possible.

Selected Questions and Answers

Mr. Mike Weinstein (JP Morgan, New York, NY): One, obviously everyone's excited, not only based on all your success outside the US with Libre but now that you have this opportunity in the US. **What would you view as a successful launch for Libre in 2018? Is there something you could characterize from a revenue number? Is it \$50 million? Is it \$100 million if you want to take a stab at that?** And then second, what is your expectation for commercial payers? Can you tell us about the conversations you've had and the willingness and the timing of commercial payers getting on board? Thanks.

Mr. White: Well, I'd say a couple of things. Your estimate is - let's just say your estimate I'll take - and you gave me a nice range there, so thank you. And I think that you can assume that we'll be looking at this from a lot of perspectives because we've got a lot of data, having had a run rate in Europe. We launched in Europe and it basically went country by country. We started as full patient pay and we had really terrific uptake in consumer interest, and that was the first introduction of Libre to the market. The fact that there was no reimbursement early on was an unknown to us, and it was a new concept and a new way for diabetics to test. And we experienced tremendous demand. Our first year, we were capacity limited and yet we had a fair bit of demand. And second year, obviously, has gone exceptionally well.

And so, as I indicated, we've got over 400,000 customers. It was remarkably well embraced for reimbursement by government bodies in Europe and regions in Germany, etc. That's extremely gratifying, that the value proposition that we see with Libre is strong, and it's intended to be. And consequently, we believe that part of the appeal is not just what Libre can do and the information that it provides to a diabetic,

who's a very informed patient and a very self-managing patient; it provides them tremendous information, tremendous guidance in the management of diabetes.

And I know that firsthand. I wear one and I got to tell you, it's just a phenomenal device. It's a super product. I can see why consumers like it as much as they do, and that's true for both type 1s and type 2s. And we're seeing that universally across the board. They use it in different ways or at least the information means something to them in different ways, whether they're managing insulin or whether they're managing diet and exercise and other things.

I'd say, first of all, I expect demand to be pretty strong. Secondly, the US market knows about Libre. It knows a lot about Libre because of all the experience that we've had in the last year in Europe. I do expect a more educated, ready, prepared, anticipating, demanding market in the US. As it relates to payers, which I would call the second dimension of this, I think our value proposition is quite strong. The product is priced at a very economic and affordable level. The intention there is as much and broad access as possible and as rapidly as possible. And I think that value proposition is stunning compared to competitive offerings, and I think that's going to make it strong. We are in discussions with payers about that value proposition, and I believe that will all go very well.

I know that's not as much detail as you'd like to have but it's as much as I'm willing to share at this point because right now, I would tell you, we expect a good, strong out-of-the-blocks performance like you described. And beyond that, I mean, right now we're adding about 50,000 patients a quarter, and that's across a continent that we had to go at one country at a time, one reimbursement system at a time. Of course, the US is quite large and Japan and the UK as additions to this are also quite large. So, I mean, we have a fair amount of optimism and are trying not to get too far ahead of ourselves.

Q: First thing I wanted to ask about was, certainly, it was encouraging that you got MRI conditional labeling for your ICD in the quarter. So, was hoping we could get an update on how things are going in Sylmar and then when we might expect the approval for CRT-D (cardiac resynchronization therapy) and maybe the ICM (insertable cardiac monitor) as well.

Mr. White: First of all, let me back up and give a bigger context to this. Over the course of the year, there was a lot of skepticism on the part of analysts and/or investors about all the things that we had to get accomplished that were backend-loaded, a lot of third-quarter fourth-quarter things. Depending on how you look at it, it looks pretty daunting and we all know everything doesn't go right ... We stuck to our guns on what our estimates were and our projections were about when we would get product approvals and claim approvals, licensure approvals and so forth. And the third quarter alone here has been pretty gratifying in that we basically got every approval we forecasted ...

And I think that has been pretty gratifying that what we said is what happened and that includes Libre, that includes the high-voltage MRI claim, that includes HeartMate, it includes the closure of Alere, it includes Libre, it includes a lot of things. I don't generally like being backend-loaded because it feels like a lot of risk that everything has to go right but everything did...

Q: Miles, just after a solid quarter, again coming out in 2017 to the upper end of the range, I know it's early on to put all these pieces together in 2018. But as I reflect on it, in 2018 with multiple large new-product opportunities launching: St. Jude, Alere, working. Shouldn't we expect at least similar top line growth and potentially better if not accelerating top line growth against - especially when you think about some of the headwinds you've faced and worked through in 2017. Is that the right way to think about it?

Mr. White: I'm trying to think about how to sound conservative to you. Look, we got our acquisitions closed. We're going to have a number of product approvals that happened in the third quarter and fourth quarter that, obviously, should hit their stride. I mean, ideally you look at 2018 and you'd like to have your product approvals exactly where we got them going into the next year. We've had a really good 2017. We beat all expectations, not just in the numbers, but in the approvals. And you'll all have to admit you had a lot of skepticism about some of this, and maybe rightly so after 2016. But look, we've hit every target we had for this year. And with all those approvals, one ought to think that should bode positively for 2018...

We're extremely excited about Libre. We're excited about all the medical device products, everything that St. Jude represented to Abbott about its pipeline has come to fruition and is coming to fruition. And so we are very, very bullish about all of that...

Q: Into the fourth quarter because I think you could set the tone for investors as we think about next year's growth rate. You're certainly guiding for sequential accelerations sort of mid to high. Can you run through sequentially what are those key components that get that acceleration? Because as I said, I think it sets the tone for 2018. Thanks so much.

Mr. Brian Yoor (CFO): [...] If we look in diagnostics to sustain what you're doing, we do expect improvement of that business over time as we continue to roll out our Alinity platforms across the globe. Diabetes Care, you know that story. It's growing very strong and we're excited to bring that here to the US. And most notably, and I mention the semi-guidance on the medical device side, that's where the step-up is where I talked about a mid to high single digit. And Scott kind of brought color to that by saying you should expect further sequential improvement on the CRM side of the business because we've always said the magic formula is just bring that back to flat and the double-digit growth of all these high-growth areas will shine through and deliver 5% or 6% on our medical device business. Those are really the key catalysts here, so we're looking forward to a good fourth quarter here.

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