CLOSER LOOK

MEMORANDUM

Abbott FreeStyle Libre Pro receives FDA approval, launch in coming weeks; real-time consumer version submitted to FDA in 3Q16 - September 28, 2016

Executive Highlights

- Abbott announced this morning that the FDA has approved FreeStyle Libre Pro (blinded, retrospective, factory calibrated) following a 14+ month review. The professional CGM system will launch to HCPs in the coming weeks with very favorable pricing: sensors will cost $60 each (fully disposable), while each reader device will be just $65 (and a practice only needs one). Pro will be reimbursed under existing professional CGM CPT codes.
- With low cost, factory calibration, 14-day wear, and ultra-low hassle startup, download, and maintenance, Libre Pro brings a dramatic upgrade in professional CGM for time-pressed HCPs. We think uptake could be very significant, given how easy this is to use and how much better the data is vs. infrequent fingersticks.
- In a major surprise, Abbott also revealed that it submitted the consumer version of FreeStyle Libre (real-time) to the FDA in 3Q16. Today's approval bodes well for that review and makes the ambitious 1Q17 launch plan (per July's call) more realistic.

It has been "imminent" since July, and now it's official: The FDA has approved the Professional version of Abbott's FreeStyle Libre, a long-time coming following the submission in 2Q15. The approval brings HCPs a dramatically better professional CGM in a less expensive package. And in major news, Abbott shared that the consumer, real-time version of FreeStyle Libre is under FDA review (submitted in 3Q16!). We're excited about what this means for the future of diabetes technology in the US, which is still inaccessible for too many people with diabetes or too hard to use and prescribe. We see this announcement as very positive for the entire field and believe it will expand CGM use dramatically. See our top highlights from the announcement below, followed by our questions on what it means for the field.

Highlight Summary

1. Abbott announced that the FDA has finally approved FreeStyle Libre Pro, the retrospective (blinded), 14-day wear, factory calibrated sensor and HCP-owned reader device. The professional CGM will be made available to US healthcare professionals in the coming weeks (www.FreeStyleLibrePro.us). Pro is going to be a dramatic improvement for HCPs currently using professional CGM devices; those miffed by inconsistent and unreliable fingerstick data; and especially HCPs using A1c alone to guide care.

2. FreeStyle Libre Pro has outstanding pricing: each 14-day sensor will cost just $60 (fully disposable), while each HCP-owned reader device will cost only $65. Notably, a reader is compatible with multiple sensors, meaning a practice could own just one reader and have hundreds of patients running sensor sessions simultaneously. Wow! FreeStyle Libre Pro will be reimbursed under existing professional CGM codes. Patients will just have a co-pay to see their provider.

3. In major news, Abbott revealed that it filed the real-time version of FreeStyle Libre (consumer) with the FDA in 3Q16! Per the 2Q16 financial update (which occurred before submission), it could be approved as early as 1Q17. We wonder if the Agency's longer-than-expected review for the Pro version was forward-looking - the FDA knew that it would have to review the consumer version, which has a lot of similarities. Will today's approval speed up review of the real-time consumer version? We always remind ourselves how incredibly under-resourced the FDA is given all it is working on - kudos to them for making this happen, which has tremendously positive implications for public health in our view.

4. FreeStyle Libre Pro has been approved in India since early April 2015. Sales have never been disclosed, but providers from India in Abbott's recent symposia have been major fans (including the legendary Dr. Viswanathan Mohan, who used Pro in over 1,000 patients in nine months).

5. 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 (going beyond A1c to hypoglycemia, time-in-range, variability).

6. Libre Pro has potential to be used in new business models and novel diabetes care models. Could Libre Pro sensors be placed in the pharmacy? Could sensors be placed in HCP offices but mailed back to Abbott for analysis? Could Abbott launch a coaching platform?

7. FreeStyle Libre Pro has a number of benefits compared to the current professional CGM competition (Dexcom and Medtronic): less expensive, less HCP and patient time to train, easier startup and maintenance, longer wear, and far more scalable for HCPs. How will the professional CGM competitive landscape change in the coming years? To date, it has been very exciting to see Dexcom and Medtronic forge a path - this approval will expand the market dramatically if all goes right. (In a smart, perfect world, we would see public/private funding for the most underserved patients to wear this and funding for their HCPs to analyze the results and help individualize diabetes management.)

Table of Contents

Highlights

1. This morning, Abbott announced that the FDA has finally approved FreeStyle Libre Pro, the retrospective (blinded), 14-day wear, factory calibrated sensor and HCP-owned reader device. The professional CGM will be made available to US healthcare professionals in the coming weeks (www.FreeStyleLibrePro.us). As with traditional professional CGM (e.g., Medtronic's iPro2), a healthcare provider owns FreeStyle Libre Pro and places the sensor on a patient in the office. The patient wears the sensor at home (in this case for 14 days) and doesn't need to take any fingersticks or carry around a reader device (factory calibration is a big advantage relative to Medtronic and Dexcom for patients who will not use traditional SMBG). FreeStyle Libre Pro stores 14 days of data right on the fully disposable patch (one glucose data point every 15 minutes), after which the healthcare provider can download the data in a return office visit (as little as five seconds to download). Libre Pro collects data in a blinded fashion (no real-time readings are available), enabling unbiased capture of patients' glycemic patterns.

- **The approval process was a lengthy one, drawn out for well over a year (Abbott submitted back in 2Q15) for reasons unknown to us.** This is purely speculative, but we wonder if the Agency's longer-than-expected review for the blinded version was forward-looking - the FDA knew that it would have to review the consumer version, which has a lot of similarities to the Pro version. Will the approval of Pro now speed up review of the real-time consumer version?
- **The FreeStyle Libre Pro sensor and applicator have the same form factor as the real-time consumer version** - impressive considering the very slim sensor patch stores all 14 days of glucose data without requiring an intermediate download or receiver. The real-time version, as a reminder, can only store up to eight hours of data at a time before the patch must be scanned. The key difference is the sampling frequency - Pro takes a reading every 15 minutes, while the real-time version samples every minute. We think this is brilliant from a manufacturing perspective.
- **The Pro reader device looks different than the consumer version, sporting a white paint coat and only two menu options: "Start New Sensor" and "Get Sensor Data."** Abbott absolutely nailed ease-of-use with FreeStyle Libre (consumer version) and we expect the same - or even better - in the Pro version.

- **The FreeStyle Libre Pro reader will download to the Ambulatory Glucose Profile,** the widely-praised one-pager that Abbott initially launched with FreeStyle Libre. The print-out does a great job of identifying trends and we think the simplicity bodes well for uptake of this system in a broad HCP population.
- **FreeStyle Libre Pro is going to be a dramatic improvement for HCPs currently using professional CGM devices or miffed by inconsistent and unreliable fingerstick data:** providers can own one Pro reader and use it to start multiple disposable sensors (unlike Medtronic and Dexcom systems, which can only be used on one patient at a time); there are no fingersticks for patients or providers to deal with (also a huge advantage over competitors - we imagine the competitors will catch up on this front soon); and HCPs don't have to disinfect reusable transmitters or receivers (like with Medtronic and Dexcom). All of those things waste time and we think Pro will significantly improve the HCP experience of prescribing and using professional CGM.

2. Abbott has outstanding pricing for FreeStyle Libre Pro: each 14-day sensor will cost just $60 (fully disposable), while each HCP-owned reader device will cost only $65. A reader is compatible with multiple sensors, meaning a practice could own just one reader and have hundreds of patients running sensor sessions simultaneously. Wow! This design makes the system "significantly less expensive" and far more usable for HCPs than current professional CGMs from Medtronic and Dexcom - both have expensive reusable transmitter and receiver/recorder devices and can only be used on one patient at a time. While the sensor costs among competitors is comparable, FreeStyle Libre Pro's sensor has a wear time of 14 days vs. competitors' wear time of 6-7 days, meaning more data and a better sense of trends from Pro for a similar cost. Of course, for best use, it will be helpful for patients to watch what they are doing during this period - although for many patients, just the "first pass" of understanding when they have high and low blood glucose will be so valuable. We can imagine follow up uses when they track what they are eating, etc - this is more of a "hassle" for sure but the value has multiple levels depending on the degree to which patients and HCPs are engaged.

- **Patients will just have a co-pay to see their provider, as FreeStyle Libre Pro will be reimbursed under existing professional CGM codes.** We assume providers will be

reimbursed for setup (CPT code 95250) and data interpretation (CPT code 95251) although we can imagine this will vary by plan and of course so many patients in the US are burdened today by far less attractive coverage (higher deductibles and co-pays) than was available years back. Though so many more have coverage, which is a positive, vast work to help patients with diabetes management is needed.

    - **As a reminder, professional CGM is broadly reimbursed among private payers AND Medicare.** We expect a product this easy to use could drive much more use of professional CGM in primary care, particularly in older patients that may have lots of undetected dangerous hypoglycemia.

3. In big news, Abbott also revealed that it filed the real-time version of FreeStyle Libre (consumer) with the FDA in 3Q16! This was very upfront in the press release and we applaud the company for answering this openly. According to Abbott CEO Mr. Miles White in the company's July financial update (which occurred before submission), the consumer version could be approved as early as 1Q17. At the time, given the uncertainty, we felt that this timing was extremely ambitious, but the approval of the professional version is very good news and makes 1Q17 seem possible.

- **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" - increasingly we're noticing FreeStyle Libre is explicitly "excluded" from decisions (Germany reimbursement; new Endocrine Society Guidelines). Though it doesn't have alarms, Libre does capture glucose data "continuously," meaning it should conceivably be covered under existing US reimbursement for CGM (we're not positive on that).
- **This FDA filing is also a good sign that manufacturing capacity constraints are not a concern any longer**. We expect a lot of pent-up US demand for the consumer version of Libre particularly when the consumer version is approved, and it's a positive sign that Abbott has filed with the FDA - the company clearly has the confidence it can meet global demand for the factory calibrated sensor.
- **We're not sure if Abbott will seek an insulin-dosing claim with the real-time version of FreeStyle Libre** - Dexcom remains in FDA discussions on this front (nearly two years at this point) and it will be interesting to see whether Abbott pursues such a claim too. Abbott has the REPLACE and IMPACT outcome studies (six months each) and 125,000+ users on FreeStyle Libre in Europe, showing an insulin-dosing claim is safe with this device. On the other hand, the company ran into challenges with Navigator's labeling and we would not be surprised to see a standard CGM label (i.e., approved for tracking and trending). While some see the labeling as a formality - people with diabetes are going to use Abbott's factory-calibrated sensor to dose insulin anyways - it is important to some HCPs, who won't otherwise encourage it for various reasons (including fears about legal, etc). If we had to guess, Abbott will likely not go for the dosing claim, enabling it to get to market faster, but this is pure speculation.
- **Uptake of FreeStyle Libre (consumer) has been very strong internationally and demonstrates a few key lessons from our view:**
    - **Cost, cost, cost is a huge driver of uptake for any therapy or device** - this sounds obvious but is too often underestimated. Libre has filled demand for CGM in the EU market where reimbursement is only starting to trickle in. We think the low price of Libre will also resonate in the US, where deductibles are only going up and CGM is still not covered as well as many headlines imply.
    - **Outstanding benefit vs. burden balance.** In diabetes technology, it's just as important to take things away as to add them. FreeStyle Libre takes away fingersticks and adds the benefit of painless, real-time glucose data and trends. It's a slam-dunk

combination for reducing burden and improving the benefits relative to fingersticks. And relative to CGM, FreeStyle Libre has less intimidating insertion, smaller on the body, a fully disposable design, and no fingerstick calibrations.

    - **Online ordering, no prescription needed** - In Europe, users buy Libre online over-the-counter with a credit card - like ordering from Amazon! We assume the device will need a prescription in the US, but we do not have information on this.

- **As a reminder, the consumer version of FreeStyle Libre is currently available in the EU, Australia, Israel, Brazil, and Argentina.** Uptake has been strong - as of 2Q16, there were over 125,000 users in the EU alone. For perspective, that's ~85% of Dexcom's global installed base (140,000-150,000 patients), and was achieved in less than two years on the market. Libre is reimbursed in Belgium, though it was excluded from Germany's decision to reimburse CGM for patients on intensive insulin therapy. Dr. Lutz Heinemann (Profil Institut, Neuss, Germany) pointed out in a Diabetes Technology & Therapeutics editorial that some German patients are still willing to pay the costs - which are 50%-70% lower than that of CGM on a per-day basis) - out of pocket for the device.

4. FreeStyle Libre Pro has been approved in India since early April 2015. Sales have never been disclosed, but providers in Abbott's recent symposia have been major fans. We heard glowing praise at ADA in June (Dr. KM Prasanna Kumar) and at IDF in December (the legendary Dr. Viswanathan Mohan). Dr. Mohan floored us with an estimate that he had already used the blinded 14-day sensor in ~1,000 patients in just nine months (at the time). He spoke in glowing terms about the pattern recognition in Abbott's Ambulatory Glucose Profile, the value in optimizing patients' therapy by helping providers feel more successful, and - most importantly - making the invisibility of diabetes more tangible to patients. It sounded like the device had been used far more often in type 2s, though Dr. Mohan suggested that the device holds value for anyone on insulin. Dr. Kumar also spoke positively on the value of Pro, reminding attendees that 89% of the Indian population has no insurance coverage. As a result, the average person with diabetes in India spends only ~$120 on diabetes medication and monitoring annually - enough, Dr. Kumar continued, to buy one SMBG per week, one venous blood test per three months, and one A1c test per six months. In this climate, he typically uses the Pro in his patients once every three months to calibrate and assess the prescribed treatment.

5. 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. The factory calibration, 14-day wear, glucose data point every 15 minutes (including overnight), excellent form factor, blinded wear, no need to carry a receiver, and ability to start multiple sensors with one reader make Pro highly appealing for patients in any kind of trial (particularly drug trials)- post-insertion, there is no daily maintenance, but investigators get two weeks of in-depth glycemic information in the form of AGP. Patients could presumably even mail the used sensor in after two weeks. Libre Pro could help better characterize glycemic responses beyond A1c, particularly showing unbiased changes in hypoglycemia (especially overnight) - this will be key for differentiating new therapies that improve time-in-range but may not change A1c.

- **In the clinic, Pro could be very useful in** (i) giving a real sense of patients' glucose trends where none currently exists (e.g., two fingersticks per day); (ii) guiding medication titration (high and low patterns, variability, dangerous glucose levels at certain times of day); (iii) assessing the impact of a therapy change on a patient's glycemic profile; (iv) evaluating how well a therapy is working; and (v) as a shared-decision making and educational tool to make the invisibility of diabetes more tangible.

6. We also see high potential for Libre Pro to be used in new business models and novel diabetes care models. Will Abbott go this route? For instance, could Libre Pro sensors be placed in the pharmacy? Could sensors be placed in HCP offices but mailed back to Abbott for analysis? Could Abbott add a premium data analysis or coaching service on top of Libre Pro? The product is so easy to use that lower-level

providers could insert and even analyze the data - we love the scalable potential and how it could really change diabetes care with better data.

7. FreeStyle Libre Pro is substantially better than the current competition (Dexcom and Medtronic) in professional CGM: less expensive, less HCP and patient hassle, easier startup and maintenance, longer wear, and far more scalable for HCPs. But how will the professional CGM competitive landscape change in the coming years?

- **Medtronic is making major investments in professional CGM, given its mission to "Make Glucose a Vital Sign" in its type 2 diabetes business.** How will its pipeline stack up to FreeStyle Libre Pro? Medtronic's June Analyst Day shared ambitious plans to launch three new Professional CGM products over the next five years: (i) iPro 3 by April 2018 (single-use, blinded, clamshell transmitter, MARD: ~11%); (ii) iPro 4 by April 2019 (adding real-time data to iPro 3); and (iii) iPro 5 by April 2019-April 2020 (dramatic hardware upgrade, appearing as a slim, round bandage, seven-day wear, <10% MARD). The Medtronic and Qualcomm partnership will drive these products, but the vision already seems behind what Abbott has with FreeStyle Libre Pro's form factor right now. On the bright side, Medtronic can rely on the exclusive distribution agreement with Henry Schein, which reaches an impressive 55% of US physician offices. This partnership has been driving professional CGM sales in the type 2 business for the past few quarters now: 250%+, 230%+, and 75%+ year-over-year growth. Medtronic also has the one-page Pattern Snapshot report, which prominently shows a patient's top three glucose patterns and lists up to six possible causes for each one (e.g., Pattern: low glucose, pre-dinner (5-8 pm); Possible Causes: Dinner delayed? Exercised before dinner? Oral medication(s) too high or incorrectly timed? Basal insulin injections too high?).
- **Dexcom has not historically focused on professional CGM. Will that change? The company's big bet on the future is with its type 2-focused product with Verily (low-cost, disposable, bandage-like CGM sensor), which will offer real-time guidance based on what we've heard.** Though we had a long list of initial questions about how the sensor would work (Bluetooth to a phone? Factory calibrated? Real-time CGM?), subsequent comments have implied it will give users glucose data in real-time and offer other behavioral advice on a smartphone app. As of Dexcom's 2Q16 call, the companies were "on track" to launch a first-gen product in 2018, with the first feasibility to start this fall. The ultimate vision, a smaller bandage-like sensor, "could be available as early as 2020." Management characterized the Verily sensor as a "homerun" for type 2 diabetes, assuming the product design works out and the cost gets low enough.

Close Concerns Questions

Q: What does this approval mean for the FDA review of the real-time, consumer version of FreeStyle Libre? Will it be approved by 1Q17? Will it have an insulin-dosing claim? Will intermittent Libre Pro use drive uptake of the consumer version?

Q: What percentage of US diabetes care providers use professional CGM right now? Will Abbott's FreeStyle Libre Pro address the gating factors to broader adoption? Is limited use of professional CGM an awareness problem, a hassle problem, a time/reimbursement problem, a scientific evidence problem, or something else? Will laggard providers see the value in professional CGM?

Q: Could professional CGM sales become as large one day as personal CGM? How long will that take?

Q: Which physicians will Abbott target in their marketing: PCPs or endocrinologists?

Q: How will different physicians deploy this technology in different patient populations? How will patients differ in Libre Pro wear frequency (e.g., 1 vs. 4 times per year)?

Q: How many providers are prescribing Libre Pro in India? How many patients have used it?

Q: Will analytics (software) drive use of different professional CGMs? Will providers prefer Medtronic's one-page Pattern Snapshot report or Abbott's Ambulatory Glucose Profile?

Q: Which factor will drive uptake of Libre Pro (and professional CGM in general) to a greater degree: cost, ease of use, analytics, etc.?

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