
Dexcom 3Q17 - Record sales of \$185M up 24%, strong 85% OUS growth; G6 filed, potential no-calibration by end of 2018; confident with Libre's pending US entrance- November 2, 2017

Executive Highlights

- **Worldwide sales hit a record-high \$185 million, up 24% YOY** on a tough comparison, and smashing the previous record (\$171 million in 4Q16). US sales (\$151 million) rose a softer 16% YOY and 8% sequentially, marking the lowest US growth ever recorded in our Dexcom model. Record OUS sales of \$33 million rose an impressive 83% YOY, 12% sequentially, and drove a record 42% of 3Q17 growth.
- **Guidance was "narrowed" to the "lower end"** of the range: \$710-\$740 million (+25%-30% YOY). Mid-teens sequential growth is expected in Q4 (~\$215 million), which would put 2017 sales just crossing the bottom threshold of the range.
- **G6 filed, no calibration by end of 2018?** The G6 sensor with one calibration/day was submitted to the FDA in 3Q17. There is now a regulatory path to launch a "no calibration" G6 "sometime before the end of 2018." Dexcom is still in discussions with the FDA, there are "a bunch of pathways," and the team has "been given clear direction." Dexcom may get 1 cal/day approved, and then file a supplement for no calibration. An alternative is to skip right to the no calibration version, depending on the timing in 2018.
- **4,000+ Medicare beneficiaries have been shipped G5 bundles.** Dexcom aims to ship the remaining "close to 20,000" patients before the end of 2017. On the reimbursement front, "these early submissions have gone well" - major progress! Absence of Share for Medicare is still a major complaint but it's a big deal that all these folks are taken care of.
- **How will FreeStyle Libre in the US impact Dexcom?** Is it a category builder? Does it pave the way for pharmacy and factory calibration? Is it a pricing threat? Does it target a different patient population? Management shared a lot of confidence today and we share it.
- **Verily gen one sensor will complete development in 1H18.** A commercial launch now depends on the G6 no calibration regulatory strategy. R&D efforts are "accelerating" on the smaller, second-gen, bandage-like sensor.

Dexcom [announced](#) record 3Q17 financial results Wednesday in a call led by CEO Kevin Sayer, new CFO Quentin Blackford, and EVP Steve Pacelli. The main focus was on G6 (just filed with FDA, but now with a no-calibration launch potentially in 2018!) and the competitive impact of Abbott's upcoming [4Q17 US launch of FreeStyle Libre](#).

Mr. Sayer boldly noted that "product innovation in 2018 promises to be the most remarkable year in Dexcom's history." Now that is saying something. He also went out of his way in concluding remarks to put 3Q17 in perspective: "I just want to make sure it is not lost on everybody. We had an amazing quarter - the biggest quarter in Dexcom's history. Look at the cash we generated from operations. Look at the management of our expenses. Look at the gross profit and gross margin lines hitting the targets that we've established. The company had a wonderful quarter ... There has never been a better time to be in our industry than we are now. Our confidence in our new pipeline ... has never been higher." We want to point out that for patients with access, life has also never been better, largely due to CGM.

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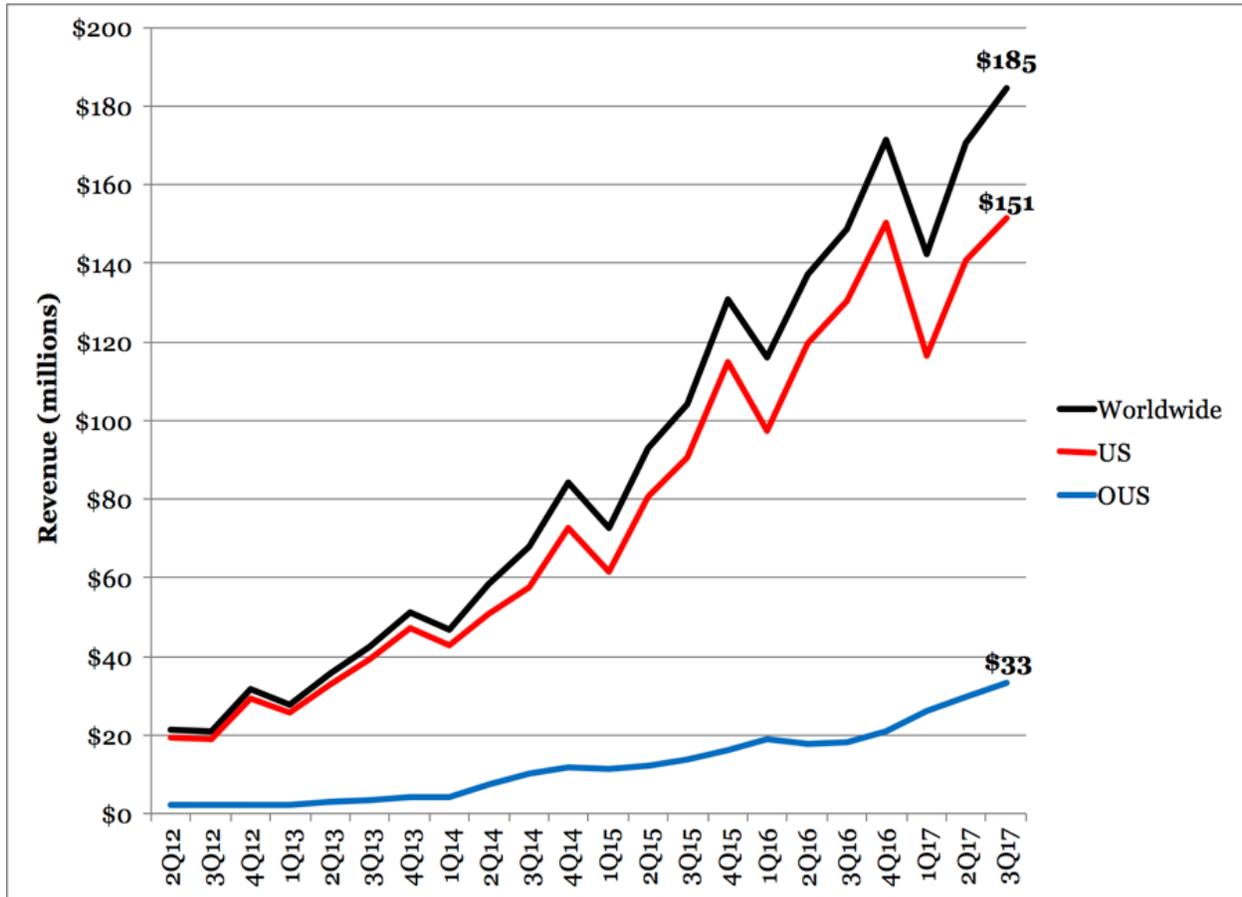
1. Record Worldwide Sales of \$185M up 24% YOY, 8% Sequentially; 2/3 of New US Patient Adds from MDI

Dexcom's worldwide revenue hit a record high \$185 million in 3Q17, growing 24% YOY on a challenging comparison to 3Q16 (41% growth). The record performance smashed the previous record of \$171 million in 4Q16, a very impressive achievement given the competitive environment. Sales grew 8% sequentially, in line with typical seasonality. Dexcom's business seems to have reached a new "normal," given the rising base of sales - YOY growth in 2017 has steadily been in the 23%-24% range in every quarter, a downtick from 43%-60% YOY growth in the first three quarters of 2016. (That said, 4Q17 will have the easiest

YOY comparison this year - growth was 31% in 4Q16.) Management highlighted strong OUS momentum (see below), some upside as Medicare sales in the US start to ramp up in 4Q17, the base continuing to expand into MDI, and serious optimism for the 2018 pipeline.

- Dexcom has now had three straight quarters with approximately 2/3 of new US patient adds on MDI** - a great sign it is expanding the market and reaching a broader population than pumpers. Of course, this also reflects some softness in the US pump market.

Dexcom Quarterly Sales, millions (2Q12-3Q17) - Worldwide (Black), US (Red), International (Blue)



- Sensor revenue of \$131 million grew 24% YOY, comprising 71% of the business.** Transmitter revenue of \$38 million grew 29% YOY, comprising 21% of the business. Receiver revenue of \$14 million grew 15% YOY, representing only 8% of the business. As we said in [2Q17](#) - the first time this breakdown was shared - sensor revenue is the most important metric to follow, since it is Dexcom's core business, where its margins are highest, and where it adds the most proprietary value. In this second segmented performance readout, we were again struck by how small the receiver revenue is - clearly, many are using the G5 app now, a trend we only expect to increase.
- Average sensor pricing (ASP) came in just under \$70/sensor in 3Q17, due to strength of the international business.** Outside the US, a larger percentage of Dexcom's revenue is running through distributors, bringing a lower ASP.

2. US Sales of \$151M Grow 16% YOY, But Mark the Slowest Growth Dexcom Has Ever Seen; "We Need a New Product in the US"

US sales of \$151 million rose 16% YOY and 8% sequentially. This was a US sales record (just beating out ~\$150 million in 4Q16), and although it marked the lowest US growth ever recorded in our Dexcom model, and three straight quarters with sub-20% YOY gains in US, this is expected as the base increases. The US business provided 58% of the quarter's growth, also an all-time low for Dexcom (the previous low was in 2Q17's 63%). We point out that 3Q17 did have a very challenging YOY comparison in the US (+44% YOY in 3Q16!), and initial Medicare hassles did disrupt the field sales force in the US. Indeed, Mr. Sayer commented that the "noise" from Medicare was "very real" - reps would go into offices and get a list of Medicare patients waiting to get on Dexcom CGM, but the impact on revenue won't translate immediately.

- **"We need a new product in the US. G5 is wonderful with the connectivity, and we've added Android, but our reps need something new to sell."** We cannot ever recall Mr. Sayer sharing a pipeline comment like this - a sign of how fast innovation is moving, how much competition there is, and how Dexcom has indeed not had a major launch since G5 came out [in 3Q15](#). The G6 launch in 2018 - either with one calibration per day or no calibration, along with the better applicator and smaller transmitter (see the pipeline section) - will be very key for Dexcom's US business.
- **The "US commercial pipeline is very robust" and "very large,"** and Dexcom's digital marketing continues to generate "a large number of leads." This was not quantified further, though it will be interesting to see if FreeStyle Libre puts more pressure on US sales in Q4 and early 2018. We continue to believe more discussion of CGM will be positive for all players (minus possibly Medtronic who continues to have manufacturing and capacity issues - although it's positive for them longer term).
- **Philosophically we can't begin to express how incredible it is that Medicare now covers Dexcom** - and we await the "noise" reduction when Share is included (this is a weird government thing related to DME definitions, not anything related to Dexcom).

3. International Sales Accelerate: Record \$33M in Revenue Grows 83% YOY; Germany "Very Strong," 43% of Covered Lives

International sales of \$33 million hit a record high for the fourth straight quarter, rising an impressive 83% YOY, 12% sequentially, and driving a record 42% of Dexcom's growth this quarter. Again, continued strong uptake in Germany was the driver - Dexcom now has access to 43% of covered lives in Germany, and will be over 50% by the end of the year. **Mr. Sayer noted that revenue roughly doubled in all of Dexcom's direct geographies, and in markets where it is competing head-to-head with FreeStyle Libre, sales were up over 80% YOY** (this is what we mean by CGM visibility helping all players). In Australia, Dexcom believes it has >70% market share in terms of what the government is paying for. In the UK, Dexcom's sales more than doubled YOY, even though Abbott recently secured [FreeStyle Libre reimbursement on NHS](#). Sales in Canada also "more than doubled" YOY. Read more on the Dexcom-Abbott dynamics below.

- **Interestingly, in countries where the receiver is optional, Dexcom believes it is driving a "nice uptick in demand"** - patients are going direct to the phone right from the start. For those with some out-of-pocket component, the startup costs would therefore be lower. This also makes the "extra CGM gear" seem smaller, since someone would just be shipped a sensor and transmitter.

4. 2017 Sales Guidance "Narrowed" To "Lower End" of \$710M-\$740M range (+25%-30% YOY); Continued Goal of >70K patient Adds in 2017

Management "narrowed" 2017 sales guidance to the "lower end" of the previous guidance range: \$710-\$740 million (+25%-30% YOY). "Mid-teens" sequential growth is expected from Q3 to Q4,

implying Q4 sales of ~\$215 million, and 2017 sales *just* crossing the very bottom threshold of the guidance. Why the conservatism? (i) The timing of the Medicare ramp and the lower upfront revenue contribution from this patient base (i.e., a more meaningful sales impact won't come until 2018) ; (ii) competition (i.e., FreeStyle Libre US launch in Q4); and (iii) uncertainty surrounding "partners" (presumably meaning what will happen with Animas' customers). We continue to believe that all Animas pump wearers should at minimum be receiving information about all pumps and sensors, especially because the latest Medtronic sensor is not possible to get nor is the latest Medtronic pump - this is a [Credo](#) thing.

- **Dexcom still expects a worldwide patient base of 270,000+ by year-end (+35% YOY, outpacing revenue), meaning 70,000 net new patients added in 2017.** The new patient number is growing faster than revenue for a few reasons: (i) onboarding Medicare patients contribute less sales upfront, since they have a monthly revenue model; (ii) growing international sales through distributors (outside of Germany) mean lower pricing for Dexcom; and (iii) a broader base of new customers, some of whom have different utilization patterns (e.g., using CGM for two months, then taking a month off).

5. Medicare: >4,000 Customers Shipped, Early Submissions "Have Gone Well"; Pipeline Close to 20,000 Remains, Hope to Complete by End of 2017

In a big win, Dexcom has now shipped the G5 CGM to more than 4,000 Medicare beneficiaries. Management aims to ship the remaining "close to 20,000" patients before the end of the year.

This is a tremendous update from 2Q17, when only the first few "test case" shipments had gone through - hearing that thousands have gone out signals real progress in our view. Indeed, management said on the reimbursement front, "these early submissions have gone well." We did not detect the uncertainty or frustration of prior calls, though Mr. Sayer apologized to Medicare patients who have "simply been waiting too long" - just another example of his great leadership. Obviously, there were a lot of administrative hoops to jump through, and it's taken quite a while following the victory earlier this year but this is night and day from the prices of strips being slashed and quantities very limited for people 65 and over. As shared in 2Q17, therapeutic CGM billing codes are now in effect, meaning Dexcom does not need to use "miscellaneous" codes to get coverage. The pipeline is roughly the same size as in 2Q17, when it stood at "20,000+" - now that 4,000+ have been shipped, "close to 20,000" are remaining. We think with greater awareness, this number will increase - the government has a big push to expand awareness of the dangers of hypoglycemia and we believe this will increase awareness and demand of CGM.

- **G5 Medicare approvals and reorders "have been strong," and management believes there is "significant demand" in the field.** Real marketing has not even begun - it will start to ramp in 4Q17 and 2018. In 2018, management believes "Medicare will become a key contributor."
- **Dexcom is paid \$236-\$277 per durable receiver + a monthly price of \$248.38 for sensors. This translates to a Medicare startup pulling in ~\$750-\$900 per quarter,** and multiplied by ~20,000 patients in the pipeline would come out to \$15 million-\$18 million in Q4. As in prior quarters, Mr. Sayer and Mr. Pacelli reiterated the monthly subscription model, which results in lower upfront revenue to Dexcom - a first shipment brings ~\$500 from Medicare (~\$250 for one month of sensors + ~\$250 for the receiver) vs. ~\$1,500 from commercial payers. The investment will pay off into Q4 and 2018 as the Medicare base grows. On the plus side, Medicare won't have the seasonality of private insurance deductibles.
- **Management did not comment on efforts to get remote monitoring/Share back into the G5 Medicare product.** As a reminder, to ensure CMS reimbursement compliance, Dexcom had to turn off app communication for Medicare G5 transmitters (i.e., no remote monitoring). Per the Medicare coverage criteria, even if patients use the G5 receiver, they are not allowed to use their smartphone to share or view CGM data - doing so makes the system ineligible for reimbursement. This remains a source of enormous frustration for many users; it was surprising it did not come up in today's call. At [Keystone](#), Mr. Sayer said the team was working aggressively to remedy the situation: "*We have literally plans A, B, C, and D in development if they won't let us use the phone,*

because we believe remote monitoring is so important. In a year, we won't be talking about this issue." This is good to hear.

- **We'll be interested to see if/how quickly Abbott obtains Medicare reimbursement for FreeStyle Libre. For now, Dexcom has quite a head start.** As noted in the [Libre approval announcement](#) and in [3Q17](#), Abbott told us it will be "beginning discussions right away" with CMS. 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; if it is, it 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 is only just beginning shipping systems).

6. Gross Margin of 69%; Cash-based Net Income Improves to \$27 million; New CFO Focused on Cost Reduction, Improving Margins

- **Gross margin came in at 69%**, flat sequentially and up from 68% in 2Q17.
- **Cash-based net income was \$27 million**, up from \$23 million in 2Q17 and nearly doubling the \$15 million in 3Q16. Including ~\$30 million in non-cash charges, Dexcom's GAAP net loss was \$2.0 million in 3Q17.
- **Dexcom ended 3Q17 with a remarkable \$526 million in cash/marketable securities**, up from \$497 million in 2Q17.
- **New CFO Quentin Blackford - two months into the job - participated enthusiastically in his first call.** He shared excitement for "numerous opportunities to identify and drive efficiencies in [Dexcom's] cost structure." Mr. Blackford believes there are multiple levers to improve operating expenses and sales/marketing spending, without impacting the customer experience. No specifics were offered, though his remarks made it clear - he's focused on improving the business' profitability. As noted in [2Q17](#), Mr. Blackford previously served as CFO at NuVasive, a medical device company focused on spine surgery. There, "he played a key role through a phase of significant growth and improvements in profitability since 2009."

Comments on FreeStyle Libre and Animas Shutdown

7. How Will FreeStyle Libre in the US Impact Dexcom - A Category Builder, Paving the Way for Pharmacy and Factory Calibration, a Pricing Threat, A Different Patient Population?

A good portion of prepared remarks and most of Q&A addressed the impending US launch of Abbott's FreeStyle Libre, following the sensor's [FDA approval in September](#) (no calibration, 12-hour warmup, 10-day wear, non-adjunctive claim). Mr. Sayer and Mr. Pacelli made a number of points today, and we felt four in particular are worth emphasizing. First, the US remains a large, highly underpenetrated market for CGM - Abbott may well be an advantage for Dexcom as it drives category awareness in type 1 and type 2. Second, there is now a US regulatory pathway for CGM to completely replace fingersticks, something Dexcom can now be a fast follower on with G6 (see below). Third, Abbott may pave the way for sensors into the pharmacy channel, which has to date been an "uphill battle" for Dexcom. Last, Dexcom's real-world sensor utilization with restarts - ~10-14 day wear - puts its pricing more on par with Abbott's ~\$5 per day. More direct quotes and thoughts below.

- **"Ultimately, if [Abbott] creates more awareness for CGM, and once people find out what they're not getting with Libre, it might be our best advertising campaign ever."** -

Mr. Sayer in response to an analyst question about Abbott's larger marketing budget (this is very unsurprising in our view)

- **FDA pathway for factory calibration:** "Overall, there's a very positive conclusion here for Dexcom. We believe the pathway is clearly paved for sensors to replace fingersticks, and we're going to take this opportunity to move faster."
- **Dexcom's real-world utilization translates to daily pricing that is closer to FreeStyle Libre.** While Dexcom is labeled for 7 days and \$70 per sensor - i.e., \$10 per day - when patients use G4/G5 for 10-14 days, the daily price drops closer to ~\$5-\$6. This is more in line with the ~\$4-\$5 per day Abbott charges for FreeStyle Libre in Europe. In the US, we're not sure what the reimbursed price for Libre will be; we assume the cash-pay price for Libre will be in line with Europe, which would be ~\$120 per month (~\$40 per 10-day sensor).
- **Will payers view G5 and Libre's features differently?** "Many international payers have recognized that flash-based systems are not equivalent to real-time CGM and have created different reimbursement categories for each. Early signs in the US suggest that payers feel the same way. We also know that many of our new international patients have transitioned from Libre to Dexcom because of these important differences." From our view, it's important to emphasize patient heterogeneity - many patients from a safety perspective want alarms and/or want the data on Clarity, AGP, etc. There's more than enough room in our view for multiple companies to succeed.
 - **"With respect to pricing ... we've been able to maintain a higher price level than [Abbott]** because of the additional features of our product, because of the actionable alerts, the alarms, the continuous data, the connectivity, the ability to share data, all the things that really make our system unique and have a great benefit to our intensively managed patients. And we will continue to emphasize those features as we go forward."
 - **We'll have to wait and see if payers appreciate the differences and price/tier accordingly.** We're somewhat skeptical payers *will* appreciate the difference although data can solve this.
 - **"For us, the most important thing in considering pricing is what does that do to access. Having a race to the bottom doesn't do much for us.** To the extent we can really expand access ... we have always been open for different pricing structures with payers ... We're prepared for wherever market goes." We point out that more data showing the benefits of CGM should help substantially (e.g., the [Belgian data on productivity from EASD](#)).
 - **"We always believed the FDA would approve this system [Libre]. And while we understand why it has been labeled as CGM, it is *not* real-time CGM.** The benefits of real-time CGM are clear: reliable accuracy, actionable alerts and alarms, and connectivity. [These] will all drive clinical outcomes in the intensive world and will deliver value in all applicable markets."
- **Will Abbott open the pharmacy benefit channel, which has been an "uphill battle" for Dexcom? Could Dexcom be a fast follower on pharmacy?** "With respect to the distribution channel, we pushed hard on the pharmacy benefit channel for quite some time, and of all our initiatives, this has very much been an uphill battle. We'll win one. We lose one. Medicare is in the DME channel, so that's where we're focusing a lot of our distribution efforts right now ... **quite honestly, it would be nice if somebody else would go somewhere first instead of us.** We've been first everywhere here. So if, in fact, there's a big push to pharmacy and we can get acceptable reimbursement rates there, we'd be happy to follow...several payers have told us, as we pushed for pharmacy benefit, that CGM is a DME product, regardless of how we want to put it in pharmacies. So it has been an uphill fight for us. **If they get pharmacy coverage with payers, certainly we will take the opportunity to follow if that simplifies distribution and we can generate the type of gross profits**

that are acceptable to us." As a sidenote, Kelly got her latest sensors and transmitter from the 24-hour Walgreen's down the street from her in San Francisco's Castro district ...

- **Management reminded listeners that stronger OUS growth is coming in markets where G5 must compete head-to-head with Libre:** "We have been competing against Libre outside the US for three years, and our growth there has accelerated for the fifth consecutive quarter." Later, management added that growth has been strong in Australia (sales doubled YOY), UK (sales doubled YOY), and Canada (more than doubled YOY) - all places where FreeStyle Libre is available. In the Nordics, Mr. Sayer said Dexcom is "getting a lot" of "former Libre users." A caveat is that Dexcom's base of sales in all these countries is still fairly low, at least compared to the US - this makes it easier to show strong YOY growth.
 - **Mr. Sayer did concede that "the products are appealing to different people,"** which makes sense to us - it's possible Libre is more of a mass market device, and G5 is more for early adopter/intensive users. We expect this to evolve over time as both companies innovate - Abbott moving to continuous communication, Dexcom moving to Verily.
- **Dexcom also has cost reduction initiatives to enable more competitive pricing.** Obviously as the G6 sensor moves to 10-14 days, sensor pricing will presumably come down - same cost of manufacturing for more days of use = less dollars per day. Meanwhile, Dexcom is building its automated manufacturing plant in Arizona, and the work with Verily is specifically focused on aggressive cost reductions for the second-gen sensor.
- **Overall, we're elated to see both systems competing and think a rising tide will lift all boats here - far too few people are on sensors globally,** and more options benefits people with diabetes! [See our coverage of Abbott 3Q17](#) for the latest on FreeStyle Libre, which now has 400,000+ users globally - roughly twice the size of Dexcom's installed base. The loss of Bigfoot as a partner was again not acknowledged on today's call.

8. Animas Exit is "Manageable" - Minimal New Patient Adds Recently, Peds Upside for Dexcom (?), Tandem, Insulet Programs

Just a few sentences today addressed Animas decision to exit the insulin pump market ([last month](#)). Dexcom believes it is "manageable" for the business. Animas' contribution to Dexcom's new patient additions "has been minimal for some time," which comes as no surprise - the business will not be negatively impacted in a big way, unless of course many Dexcom/Animas users switch completely to Medtronic. On a positive note, Animas has historically been strong in pediatrics, which could be an advantage for Dexcom - the 670G is currently only approved for 14+ years (though the [peds trial in 2-13 year olds has a near-term completion date in April 2018](#)). Management added that "people chose an Animas pump for a reason," which should also be an asset to Dexcom - e.g., they don't want to be a Medtronic user, they specifically chose a *different* pump, they prefer the Dexcom sensor, etc. Medtronic has its own ongoing sensor shortage that is impacting new shipments until early 2018, another possible advantage for Dexcom. Partners Insulet and Tandem both have generous welcome programs for Animas users, including a \$200 gift card from Dexcom. Overall, we agree this exit is not that bad for Dexcom and "manageable" felt appropriately conservative. We continue to be surprised by J&J's offer, overall, to patients, [given J&J's original commitment to people with diabetes](#) - night and day from when the company purchased Animas.

Pipeline Highlights

9. G6 Filed with FDA, Pathway for No Calibration Version to Launch Before the End of 2018; Multiple Options Under Discussion with FDA

Dexcom submitted the G6 sensor (one calibration/day) to the FDA at the end of 3Q17, as expected. In big news, there is a regulatory path to launch a "no calibration" G6 "sometime before the end of 2018." This has come up following conversations with the Agency, presumably in light of

the FDA approval of Abbott's factory calibrated FreeStyle Libre. Dexcom is still in discussions with the FDA, and management said there are "a bunch of pathways" and the team has "been given clear direction and clear guidance" from the FDA. One option is getting the one calibration per day G6 approved, and then filing a supplement to get a no calibration G6 approved. An alternative is to skip right to the no calibration version, depending on the timing in 2018. Mr. Sayer suggested that if this would allow a no calibration G6 launch before September 1, 2018, "or something like that," it might be the path forward. This will come down to timing and FDA discussions, since (as noted above) Dexcom does need something new and compelling in the US. These remarks were also clearly intended to assuage investors: "We just want to let everybody know that we will have a no calibration system out relatively soon. We will meet that need with real time CGM."

- **The G6 calibration scheme is an algorithm (software) change - not a hardware tweak - so getting it done quickly and on top of the current filing seems doable (to us).** We imagine a remote software update could even be taken post launch, similar to how Dexcom improved G4 with the Software 505 algorithm - this would allow a quick follow-on upgrade if the one calibration/day version is launched first. Dexcom showed strong no-calibration G6 pre-pivotal data [at last year's DTM](#), and we'll hope to hear more this week at DTM.
- **G6 will finally launch the long-awaited one-touch applicator, a point Mr. Sayer emphasized: the current "applicator looks the same way it did in 2006. It works lovely, but it's kind of scary.** And if you read the blogs and the patients' comments, 'man, I got my new Dexcom, but I don't know if I want to push that plunger.' That problem's gone when we launch G6. It's pushing a button, and the ease of use of this product and the lower profile, the consistency of the sensor - this is going to give our guys a fabulous story to tell in the field, and they need one. We owe them one and we're going to give it to them." We are elated to hear this and believe this change will be a major turning point in the user experience for many.
- **G6 also brings a 30% thinner wearable than G5 and no acetaminophen interference.** Mr. Sayer again emphasized the large G6 pivotal trial: n=300+ and 30,000+ matched CGM-YSI pairs - the largest CGM study that the FDA has ever seen. At Keystone, Mr. Sayer stated that the leap from G5 to G6 will be almost as big as Seven+ to G4 - strong words! We believe them.
- **What did the FDA approval of Abbott's FreeStyle Libre with factory calibration and non-adjunctive labeling teach Dexcom? "I can tell you we're going to be more aggressive.** If I could take one learning away from the whole experience and labeling there, I think we're going to push ourselves to do better and to move faster. We need to. And we went through a year and a half timeframe working on that non-injunctive claim because it was the first they had ever done and the first they had ever seen, and it's great - we got it. But it literally slowed us down for about a year and a half to work through all that data and all that processing and the panel meeting and all of that stuff. I think, moving forward, we can go much more aggressively ... After the shock and surprise, we sat back and said you know what? We really can replace fingersticks. Fingersticks can go away now. We can make devices that can replace them across the board and we'll work with the Agency to make those devices."

10. Verily Gen One Timing to Complete Development in 1H18; Launch Timing Depends on G6 No Calibration Regulatory Strategy

The first-gen sensor with Verily is expected to complete development in 1H18. A commercial launch now depends on the G6 no calibration regulatory strategy. As a reminder, this product has long been positioned as a "2018" launch, though we wouldn't be surprised if it gets pushed back a bit - unless G6 is approved quite quickly next year. The first-gen will move to a fully disposable transmitter, and Dexcom will have to make a decision about 14-day vs. 10-day life within the next six months. We assume this first-gen product will maintain an insulin dosing claim, and therefore, presumably cross over to Dexcom's current installed base of intensively managed users. Previous remarks have positioned it as a type 2/non-intensive product, though given the major improvements, current Dexcom users are obviously going to want it.

- **Meanwhile, the Dexcom/Verily R&D teams are "accelerating" efforts on the smaller, second-gen, bandage-like sensor - this has "aggressive" cost targets and quite a compelling form factor.** Previously, it was slated for a 2020-2021 launch, which feels reasonable - assuming Verily gen one launches in 2019 (our speculation), 1-2 years later to follow with a much smaller and lower cost version that is already in development seems quite possible.

The Future of CGM Technology



- Factory Calibrated
- 14 Day Use Life
- Real-Time CGM
- Single-use Transmitter
- Significant Cost Reduction¹

1) Cost reduction targeted for second generation sensor

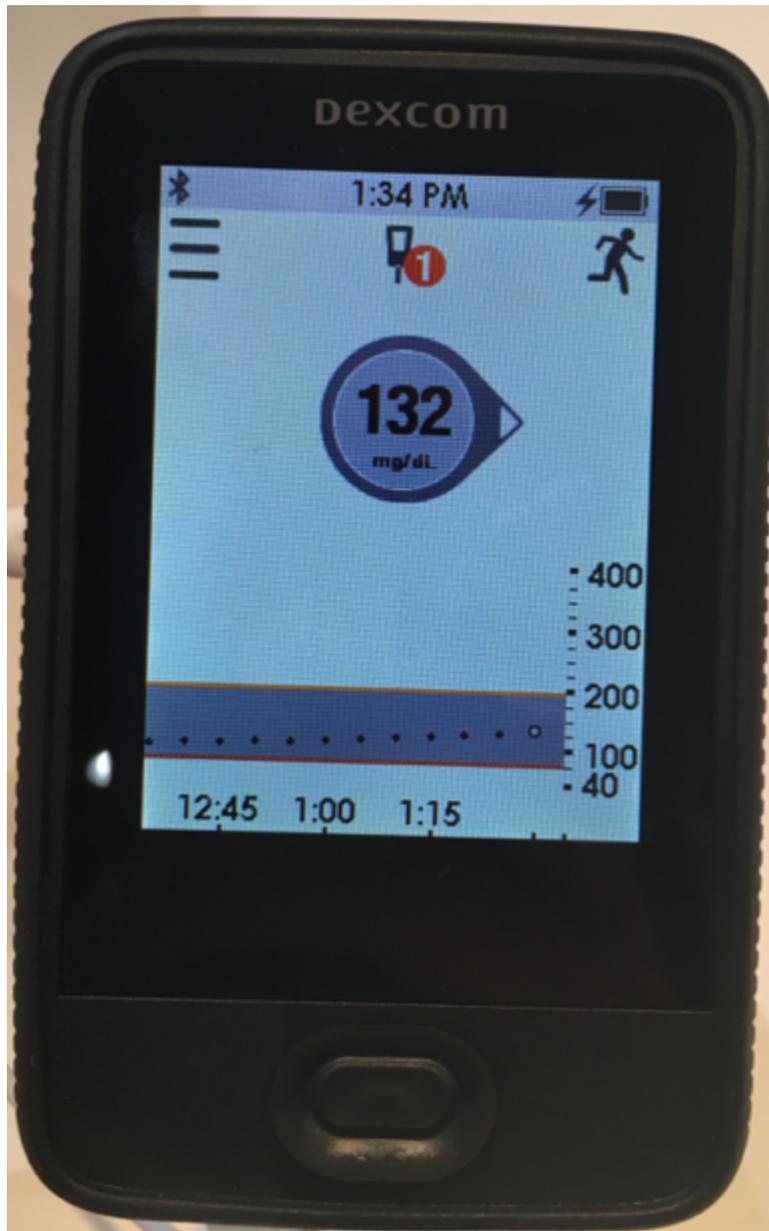
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DEXCOM

- **Dexcom's pilot programs in the non-intensive diabetes population continue to make good progress. Efforts will expand in 2018,** though no further details were shared. Presumably this means clinical studies, either in-house or externally. We'd be fascinated to learn more about what these entail - what software and additional guidance is layered on top? What education is added? We're not sure if these data will be shared publicly, but certainly this will inform the design of the Verily products.

11. G5 Touchscreen Receiver Launches

In Q&A, Mr. Sayer mentioned briefly that the G5 touchscreen receiver has launched (in line with expectations). We had previously thought this receiver was less expensive to make, but today's comments didn't confirm that - Mr. Sayer only said "the actual cost profile" is not "any higher," though the warranty return rate on it will be much less significant. This more durable receiver is larger and definitely loses the cool factor of the current slim receiver, but it does help with the three-year durability requirement from Medicare, fixes previous reliability issues, and brings a user interface in line with the G5 app. The receiver was on display at ADA (picture below) and the bulkier form factor took us by surprise - we had expected something sleeker. We'd have to assume it will encourage even more patients to move to the phone, which benefits Dexcom's business. The device received FDA approval [in March](#).



12. Mentioned in Passing: Insulet, Tandem, Apple/Android smartwatches, Fitbit, Open API, Smart Pens; No Major Updates

The following Dexcom R&D partners were succinctly mentioned at various points during the call, though there were no updates on product details or timing. We include quotes and links to recent coverage below.

- **"Insulet has shown tremendous dedication to our partnership** and our teams are working hard to bring our connected systems to market. Once launched, we see a number of differentiating features in our combined systems including an attractive form factor and opportunities for smartphone connectivity. In the meantime, we have embarked on a few commercial activities together and will continue to work with Insulet to deliver attractive options for our shared patients."
 - **With this quote above, Insulet got the most air time and enthusiasm out of all the partners mentioned.** We do think the Omnipod Horizon product form factor looks outstanding and will be a very nice complement to G6.

- **Insulet has guided for a 2019 launch of Horizon**, though we'll hopefully hear an update in tomorrow's call.
- **"Tandem recently launched its G5 sensor augmented pump, representing the first insulin pump system that carries a non-adjunctive sensor claim.** And because Tandem's pump offering is field upgradeable, patients won't be locked into a legacy technology and will be able to use enhancements as soon as they are available."
 - **Tandem most recently guided for a summer 2018 launch of predictive low glucose suspend with Dexcom G5, with a free remote software upgrade for current t:slim X2 users.** A 1H19 launch is now expected for the treat-to-range system with TypeZero and G6 -a six-month delay from the previous timing. We wonder if the G6 filing (see above) played any role - obviously the sensor's calibration scheme is quite a major thing to lock down for an AID pivotal trial.
- **CGM display on Apple Watch and Android Wear was mentioned in one sentence. For the second straight quarter, there was no update on the exciting potential for direct transmitter-to-Apple Watch communication** (i.e., no phone nearby). As we understand it, this is now technically feasible with the already-launched WatchOS4 ("Native Core Bluetooth"), but Dexcom has never commented on it outside of [Apple's June Keynote presentation](#).
- **Dexcom and Fitbit announced a [partnership in September](#), starting with display of CGM data on Fitbit's new smartwatch (Ionic) in 2018.** This received just one sentence on today's call, which was a surprise - it's possible this partnership has not moved forward very much, given Fitbit's own revenue challenges and only recent release of the software developer kit for Ionic.
- **Dexcom's open API platform launched [in September](#) and "received a great response."** [See our detailed coverage here](#). This allows third-party software developers to register at [developer.dexcom.com](#) and build novel retrospective CGM data apps. Partners One Drop, Tidepool, Nutrino (food), App Practice (physician monitoring), Rimidi (population management), Achievement (rewards), Ensa (supplement recommendations), and Evidation are already integrating the API into their apps. Dexcom users authorize which apps can access their CGM data, enabling patient choice. Like Dexcom Clarity, this platform remains a Class I device. In our trials on Apple iOS, HealthKit is a far more seamless CGM data integration than using the API. (We found Nutrino to be very buggy.) Of course, not everyone understands Apple Health or wants to use it, and presumably the API enables more customization than HealthKit.
- **"With respect to smart pen development/integration, we've got a number of irons in the fire. [We're] not really in a position to give an update on this call, but we hope to provide some additional color before the end of this year or early part of next year."** [Glooko/Novo Nordisk](#) seem like a possible candidate, as does [Common Sensing/Sanofi/One Drop](#). Companion Medical is also located in the San Diego area and would be a logical partner - its reusable pen was expected to launch this year. We very much look forward to a commercial market developing here, and Dexcom could help enable the insulin dose titration piece.

Pipeline Summary

Sensor and Software Pipeline

| Pipeline Product | Timeline |
|---|---------------------------|
| Touchscreen receiver | Launched |
| G6 sensor <i>Current submission is for 10-day wear and one calibration per day after startup, though ongoing</i> | Submitted to FDA in 3Q17. |

| | |
|--|--|
| <i>FDA discussions could enable no calibration version. Insulin-dosing label claim, acetaminophen blocking, predictive alerts, one-button insertion system, 30% smaller transmitter.</i> | Launch expected in 2018, with one calibration per day and/or factory calibration - both currently under discussion with FDA |
| Direct Apple Watch-to-transmitter communication ("Native Core Bluetooth") | Dexcom's timeline unclear. Mentioned in Apple's June event , update this fall in WatchOS4 makes it possible. |
| Fitbit Ionic smartwatch integration | Launch expected in 2018 following partnership announcement in September |
| Verily [Google Life Sciences] partnership <i>Simple, low-cost, disposable, 14 day, Bluetooth-enabled, factory calibrated sensor. First-gen smaller than FreeStyle Libre, second-gen bandage-like.</i> | First gen depends on G6 no-calibration regulatory pathway (see above). Second gen, bandage-like sensor previously expected to launch in 2020-2021. No timing update in 3Q17 call. |

Automated Insulin Delivery Partner Pipeline

See our [updated competitive landscape here](#).

| | |
|---|---|
| <p>Tandem</p> <ul style="list-style-type: none"> ▪ t:slim X2 with Dexcom G5 integration ▪ Predictive low glucose suspend ▪ Treat-to-Range hybrid closed loop (TypeZero algorithm) with G6 | <ul style="list-style-type: none"> ▪ Launched in US in 3Q17 ▪ Pivotal underway, launch expected in summer 2018 ▪ Pivotal trial (IDCL) in 1H18, launch expected in 1H19. |
| <p>Diabeloop</p> <p>Diabeloop algorithm running on a wireless handheld, Cellnovo patch pump, Dexcom CGM</p> | <ul style="list-style-type: none"> ▪ Ongoing CE Mark pivotal trial expected to reach completion in February/March 2018, per ClinicalTrials.gov. First trial phase completed. Commercial agreement being discussed with Cellnovo. EU launch now expected in early 2018. |
| <p>Insulet</p> <ul style="list-style-type: none"> ▪ Next-gen OmniPod Dash PDM with possible G5 app integration on phone ▪ OmniPod Horizon Automated Glucose Control System | <ul style="list-style-type: none"> ▪ FDA submission in 4Q17. ▪ Launch in "2019," with a pivotal study in 2018. |
| <p>Beta Bionics</p> <p>Bionic Pancreas dual-chamber iLet with integrated Dexcom CGM, insulin-only or insulin+glucagon modes.</p> | <ul style="list-style-type: none"> ▪ Insulin-only: pivotal trial to start in the beginning of 2019, with possible launch in 1H20. |

- Bihormonal: pivotal trial expected to start in the beginning of 2019. FDA submission and launch timing depend on a stable glucagon, among other things.

-- by Adam Brown and Kelly Close