
Dexcom 1Q17 - Sales of \$142 million rise 22% YOY, buoyed by 37% OUS growth; 10,000+ Medicare patients awaiting G5 shipment, as final coverage decision still needed; G6 filing in 3Q17 - May 2, 2017

Executive Highlights

- Dexcom's Worldwide sales totaled \$142 million in 1Q17, up 22% YOY on a very tough comparison to 1Q16's 60% growth. The challenging YOY comparison represented Dexcom's lowest YOY growth ever. Sales declined 17% sequentially from a record-high 4Q16.
- The US business saw sales of \$116 million grow 20% YOY, while international sales hit a record-high \$26 million and rose 37% YOY. Management maintained 2017 guidance for sales of \$710-\$740 million (+25%-30% YOY).
- In a disappointing update, patients on Medicare cannot get claims processed/reimbursed for Dexcom's G5 until "final" "local coverage decisions" come through. Management hopes this will wrap up before the end of 2Q17, though it seems hard to call. Dexcom has more than 10,000 Medicare patients in line who have not yet been shipped sensors. Dialogue with CMS is ongoing and Dexcom is pulling "every lever" at its disposal to get through this logistical hoop.
- There were no major pipeline updates. A US launch of Android G5 is still expected by "mid-year" (under FDA review). The new touchscreen receiver was approved [in March](#) and new patients will start transitioning "later this year." The one-touch inserter/lower profile transmitter (G5x) remain under FDA review ([3Q16](#) submission). The majority of the G6 pivotal trial has concluded, and Dexcom still expects a PMA filing of the next-gen sensor by the end of 3Q17. A launch is still expected in 2018. The Verily partnership expects a first-gen launch "by the end of 2018," with a second-gen launch in "2020-2021."

Dexcom [reported](#) 1Q17 financial results today in a call led by CEO Kevin Sayer, with a big focus on the early Medicare coverage hiccups. We enclose the top business and pipeline updates below, followed by a pipeline summary.

Financial Highlights

1. Dexcom's 1Q17 worldwide revenue totaled \$142 million, a 22% year-over-year (YOY) gain on a very challenging comparison to 1Q16 (60% growth when G5 mobile was ramping). Sales declined a larger-than-usual 17% sequentially from a record-high 4Q16. The challenging YOY comparison resulted in Dexcom's lowest YOY growth ever, and now marks four straight quarters with growth under 48% YOY - from what we can tell, this reflects the very large sales base more than underlying weakness in the business.
2. US sales totaled \$116 million, rising 20% YOY and down 23% sequentially. International sales hit a record high \$26 million, rising 37% YOY and 24% sequentially on strong uptake in Germany. The US business still contributed 73% of the quarter's growth, though this was the lowest level in two years (since 1Q15).
3. Management maintained previous 2017 revenue guidance for sales of \$710-\$740 million (+25%-30% YOY) and a worldwide patient base of 270,000 by year-end (+35% YOY, outpacing revenue). Though Medicare coverage came earlier than expected, there are still hurdles to clear.
4. Notably, more than two-thirds of new 1Q17 patients came from MDI, a notable uptick from ~60% in the prior two quarters and up from ~40% historically. This is more in line with the general type 1 population, a good sign the market is expanding and "CGM first" is resonating.

5. Dexcom's cash-based net loss was \$7 million, down from a cash-based net income of \$9 million in 1Q16 and a cash-based net income of \$27 million in 4Q16. Average sensor pricing also fell to just below \$70, down from the historic \$70-\$75.

Medicare Coverage Highlights

6. In a disappointing update, patients on Medicare cannot get claims processed/reimbursed for Dexcom's G5 until "final" "local coverage decisions" come through. Management hopes this will wrap up before the end of 2Q17, though it seems hard to call. Dexcom has more than 10,000 Medicare patients in line who have not yet been shipped sensors. Dialogue with CMS is ongoing and Dexcom is pulling "every lever" at its disposal to get through this logistical hoop.

7. Management quelled two other concerns that have come up with Medicare coverage: (i) reimbursement for G5 is only possible if patients use the receiver and NOT the app (the receiver is the critical "durable" component of the system); and (ii) distributor Liberty Medical has decided to no longer process G5 orders. The short summary is that neither is a gating factor for launch or a concern for Dexcom.

8. Dexcom estimates that Medicare covers ~300,000 type 1s in the US (~20% of the market) and ~500,000 type 2 intensive insulin users (~33% of the market). The business model will change a bit under Medicare, as upfront revenue will be ~50% lower than for commercial patients. The real business impact will come from having a large base of Medicare users (e.g., "30,000-40,000") with the monthly recurring "rental" for receiver + sensors/transmitters paid by CMS. Medicare coverage + German reimbursement added an incremental ~1.3 million covered lives for Dexcom, roughly doubling the number entering 2016.

9. Dexcom also continues to explore new business models as it thinks about type 2 diabetes. Notably, Mr. Sayer characterized this piece AS difficult and intensive as developing the technology.

Pipeline Highlights

10. A US launch of Android G5 is still expected by "mid-year," on par with the 4Q16 update. It sounds like this won't be ready for ADA, however.

11. Following FDA approval of the new touchscreen receiver [in March](#), Dexcom plans to start transitioning new patients "later this year." There were no pricing or additional product details shared, though we know this new receiver is more reliable.

12. The one-touch inserter and lower profile transmitter (G5x) remain under FDA review after a [3Q16](#) submission. No approval or launch timeline was shared, though as the year goes on, Dexcom will evaluate this launch in tandem with the launch of G6. This is a big logistical launch.

13. The majority of the G6 pivotal trial has concluded, and Dexcom still expects a PMA filing of the next-gen sensor by the end of 3Q17. A launch is still expected in 2018, assuming things go well at the FDA. Management's enthusiasm remains sky high for this sensor, which will initially be 10-day wear and one calibration per day.

14. The Verily partnership expects a first-gen launch "by the end of 2018," with a second-gen launch in "2020-2021." JPM and 4Q16 used the first-gen timing of "late 2018," so we're not sure whether to read that as a delay; the 2020-2021 timing is identical to that shared on the 4Q16 call. Both Verily products are expected to be 14-day wear, factory calibrated, real-time CGM, fully disposable, lower cost, and talk to a phone via Bluetooth (no receiver expected). The Verily partnership actually received the most pipeline airtime in prepared remarks, with comments focused on the business model and broader treatment of non-intensively managed type 2s

15. There were no pump partner updates, though Dexcom remains committed to this field and to partnering with smart pens and interconnected diabetes management platforms. And EVP Mr. Steve Pacelli put to bed any open questions: "No, we're not looking to buy a pump company."

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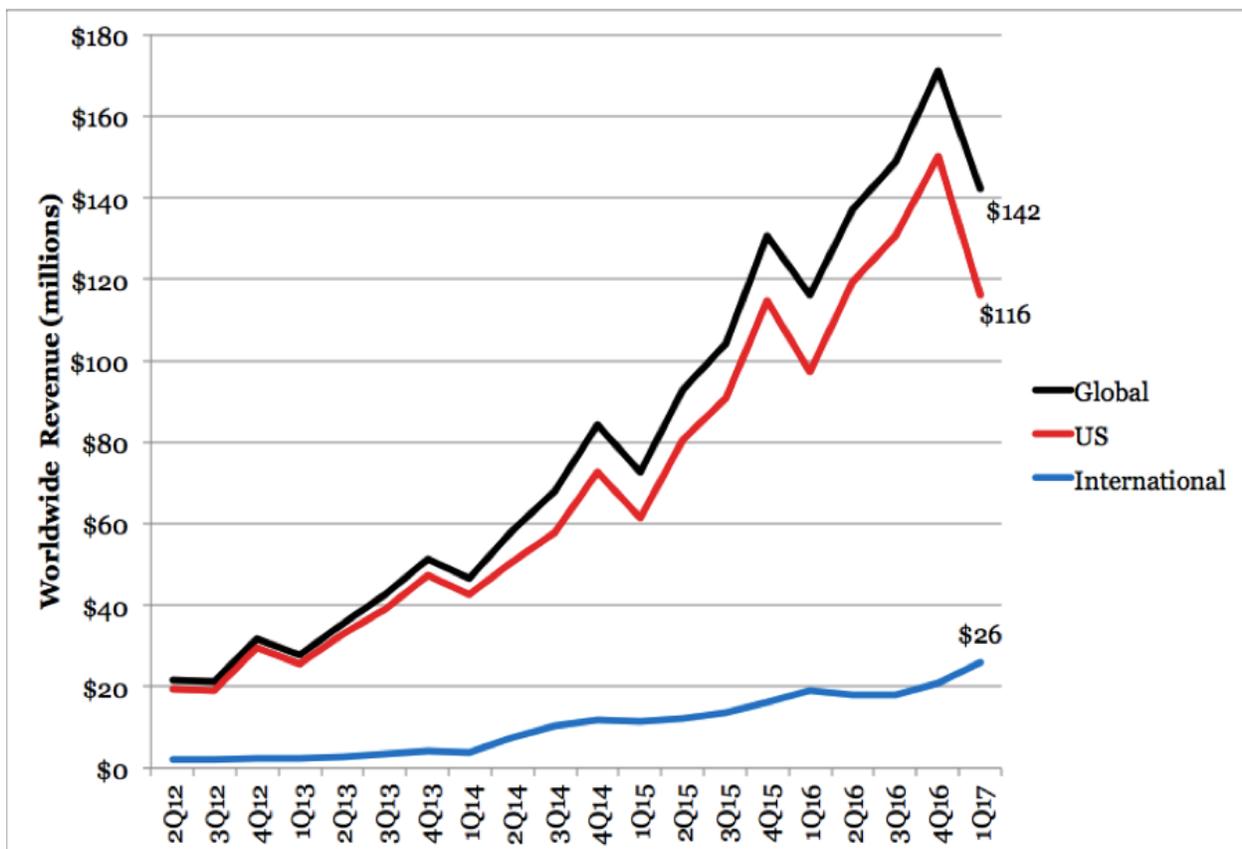
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Financial Highlights

1. Dexcom's 1Q17 worldwide revenue totaled \$142 million, a 22% year-over-year (YOY) gain on a very challenging comparison to 1Q16 (60% growth when G5 mobile was ramping). Sales declined a larger-than-usual 17% sequentially from a record-high 4Q16. The challenging YOY comparison resulted in Dexcom's lowest YOY growth ever, and now marks four straight quarters with growth under 48% YOY - from what we can tell, this reflects the very large sales base more than underlying weakness in the business (see patient base comments below). The international business had a very strong quarter and definitely compensated for lower YOY growth in the US. Overall, sales were in line with management's expectations, and since guidance was not updated on the call, there wasn't much commentary on revenue. As he always does, CEO Kevin Sayer put Dexcom's remarkable growth in perspective: in his first quarterly call six years ago to the day, Dexcom reported \$13 million in Q1 revenue. Fast forward to 2017, and that's now one week of revenue!

Dexcom Quarterly Sales, millions (2Q12-1Q17)



2. US sales totaled \$116 million, rising 20% YOY and down 23% sequentially. International sales hit a record high \$26 million, rising 37% YOY and 24% sequentially on strong uptake in Germany. The US business still contributed 73% of the quarter's growth, though this was the lowest level in

two years (since 1Q15). A big advantage of the international business is it doesn't have the Q4-Q1 seasonality that so affects the US market. Management noted that on a year-over-year basis, the US faced a particularly tough comparison: sales grew 58% YOY in 1Q16 when G5 mobile was still rolling out (and obviously, the US base of sales is much bigger). The US also saw softer sales from CGM-integrated pumps, no surprise given tougher quarters for Tandem and Animas.

- **Germany has been "very successful" for Dexcom (following [last summer's positive decision](#)) and contributed 20% of International revenue in 1Q17. Dexcom only has contracts with less than 20% of the payers in Germany, so there is clear upside.** Management said contracts should be executed shortly with two of the largest German payers, which would expand coverage "up to 50%" (the wording was confusing, but we interpreted this as roughly doubling current coverage in Germany). Patients can get coverage on a one-off basis if their payer isn't contracted with Dexcom, but it requires lots of documentation. This momentum follows revenue from Germany tripling in December (per [JPM](#) remarks).
- **Dexcom continues to work with France and UK authorities on reimbursement, with an update expected in the next 6-12 months.** The necessary paperwork has been filed, though these processes seem very difficult to predict.

3. Management maintained previous 2017 revenue guidance for sales of \$710-\$740 million (+25%-30% YOY) and a worldwide patient base of 270,000 by year-end (+35% YOY, outpacing revenue). This is very prudent, given the uncertainty around Medicare timing (see below) and competitive products coming from Medtronic (MiniMed 670G starting in June, Guardian Connect by October) and possibly from Abbott (FreeStyle Libre consumer launch most recently expected in 2H17). Given Dexcom's robust new patient pipeline (see below), some analysts wondered whether there is upside to the revenue guidance; management was clear that it is "not comfortable" changing guidance right now, given all the moving parts.

4. Notably, more than two-thirds of new 1Q17 patients came from MDI, a notable uptick from ~60% in the prior two quarters and up from ~40% historically. Management emphasized that this is in line with the general type 1 population, a good sign that Dexcom's "CGM first" message is resonating - particularly on the heels of the DIaMonD study. CEO Kevin Sayer was clear that new patient adds from pump partners have slowed down, which is not a surprise - both Tandem and J&J reported challenging 4Q16 and 1Q17 results. We expect this trend to continue until both launch G5-enabled pumps and/or a Dexcom-integrated automated insulin delivery product comes to market.

- **Said CEO Kevin Sayer on the MiniMed 670G:** "We've heard the 670G has been put on ~500 people (in the Customer Training Phase). They probably picked those 500 people specifically, and we've heard some relatively good feedback. There are some mixed reviews on the complexity of the system. I don't think the book can be written on the 670G until this has been commercialized to a broad group of patients. On the pump front, based on Tandem's call, we have heard some doctors are waiting to see. In all reality, pumps have a four-year warranty cycle....There are a lot of MDI patients that can really use CGM, and we'll continue to focus on our other pump partners' patients as well."

5. Dexcom's cash-based net loss was \$7 million, down from a cash-based net income of \$9 million in 1Q16 and a cash-based net income of \$27 million in 4Q16. Average sensor pricing also fell to just below \$70, down from the historic \$70-\$75. We have long suspected Dexcom's pricing would be under pressure with FreeStyle Libre, and perhaps this is partially responsible. Said EVP Steve Pacelli: "In one of our reimbursed markets, we elected to lower our price slightly to drive sales and volume, and there's been a wonderful response - particularly against the competition that is priced lower." In a plus, Dexcom's pricing in Germany is similar to the pricing it has in the US.

- **Gross margin came in lower than expected at 66%, down from 68% in 4Q16, but up from 65% in 1Q16. Management shared a few reasons why:** (i) a higher percentage of sales

from the lower-margin international business; (ii) lower overall revenue with seasonality, relative to Q4; and (iii) more hardware sales going to the lower-margin G5 transmitters.

- **Dexcom increased its cash balance to \$181 million, reflecting a \$75 million draw from a credit facility to build out its new manufacturing plant in Arizona.** Cash balance stood at \$124 million at the end of 4Q16. Management did not comment on financial runway or additional financing going forward.

Medicare Coverage Highlights

6. In a disappointing update, patients on Medicare cannot get claims processed/reimbursed for Dexcom's G5 until "final" "local coverage decisions" come through. Management hopes this will wrap up before the end of 2Q17, though it seems hard to call. Dexcom has more than 10,000 Medicare patients in line who have not yet been shipped sensors. Dialogue with CMS is ongoing and Dexcom is pulling "every lever" at its disposal to get through this logistical hoop.

For context, CMS issued an administrative [ruling in March](#), which announced Medicare coverage for therapeutic CGM (Dexcom's G5) for intensive insulin users with type 1 and type 2 diabetes - this came far earlier than expected and quickly followed the Medicare Part B benefit category determination [in January](#). However, the administrative ruling has left uncertainty in the process: without a "formal coverage decision" (management's term), the logistics of getting Medicare reimbursement are still unclear. For instance, Medicare patients need to be taking four fingersticks per day to qualify for therapeutic CGM, but there is currently no criteria on how to document that. These pending local coverage decisions will provide more specifics, allowing Dexcom to bill Medicare, get claims approved, and quickly ship sensors. While patients can technically submit claims one-by-one under the current announcement, the few claims that Dexcom has pushed through have been "pretty much denied" across the board. Overall, we expected this process to move fairly slowly, though we were under the impression [in March](#) that Dexcom had cleared all the administrative hurdles and Medicare patients could go through the reimbursement process. Clearly this is not the case quite yet, but Mr. Sayer put things into perspective quite nicely: "What is lost on many in this process is that we're about a year ahead with where we thought we'd be." Well said.

- **On the plus side, management said that patient interest "has been outstanding" - the 10,000 prospective new Medicare patients are in the sales pipeline *before* any real marketing effort.** Dexcom will not openly advertise Medicare coverage until the aforementioned formal coverage decisions come through: "The last thing we want to do is add another 10,000 patients to the 10,000 we aren't shipping to now."

7. Management quelled two other concerns that have come up with Medicare coverage: (i) reimbursement for G5 is only possible if patients use the receiver and NOT the app (the receiver is the critical "durable" component of the system); and (ii) distributor Liberty Medical has decided to no longer process G5 orders. The short summary is that neither is a gating factor for launch or a concern for Dexcom. The Liberty piece was news to us, while the G5 receiver vs. phone issue has been an area of confusion since the CMS ruling in March. Though the ruling says G5 will only be reimbursed if the receiver is used, we don't see how Medicare could prevent or police patients from using the G5 phone app.

- **On the phone vs. receiver: "In order to get DME approval, we had to have a durable component of the system that would last a specific period of time that we would cover.** And working with Medicare, again, they worked very hard, and they determined that the durable component is the receiver. So, we'll start with the rules that we have...while we may sit here today with that position on the receiver being the durable part and being the centerpiece and the most important component of the system, we have a number of options here. We can certainly work with CMS over time to see if we can move it to another category. We can also go back to what we did in the past with Share and have the receiver talk to the phone. We don't have that product in our portfolio right now, but since we were the first to make it, we know how to do that. We have a number of options here. We just need to let this play out. We need to get this technology on patients.

We need them to explain how it has changed their lives and how beneficial it is. And we need to be pleased with where we are and not get too crazy. I don't think that's going to be a factor."

- **On Liberty: "As far as Liberty concluding this...it is by far and away the least important gating factor in doing this...**And as we've looked at this and, quite frankly, spoke with other distribution channels, not knowing exactly what the coverage decision looks like and not knowing what you're going to have to have in your file to get paid when you have a Medicare license at risk and your business is very much Medicare-oriented is something of a risk that Liberty just wasn't ready to take at this point in time - even though they could get paid on individual claims and go through the process and do a lot of work. So, they stepped back and they're waiting. They want to wait for this local coverage decision as much as we do. Once this becomes clear, we'll determine how to best proceed. And I think it's important for everybody to understand, this has been a one-time thing, this has been a process over several years."
 - **As a reminder, Dexcom has to ship Medicare patients the G5 receiver, sensors, transmitters, and, notably, BGM and related supplies (60 test strips/month) for calibration and "checks."** Dexcom has not shared which meter is being used or who is providing it.

8. Dexcom estimates that Medicare covers ~300,000 type 1s in the US (~20% of the market) and ~500,000 type 2 intensive insulin users (~33% of the market). For context, Dexcom's current US installed base is ~150,000 users on a total market (excluding Medicare) of roughly 1.2 million type 1s; adding runway for ~800,000 new potential users will be "highly additive to the business." Compared to the start of 2016, Medicare coverage + German reimbursement has added an incremental ~1.3 million covered lives for Dexcom.

- **The business model will change a bit under Medicare, as upfront revenue will be ~50% lower than for commercial patients. The real business impact will come from having a large base of Medicare users (e.g., "30,000-40,000") with the monthly recurring "rental" for receiver + sensors/transmitters paid by CMS.** Dexcom currently gets ~\$1,500-\$2,000 in a quarter to start a commercial patient on CGM - \$800-\$900 for the starter kit, and then 12 sensors at \$70-\$75 each. On Medicare, Dexcom will receive ~\$250-\$300 per month for a new patient starting on CGM (monthly receiver rental + disposables), meaning a new Medicare patient will bring in \$750-\$900 in a given quarter. On a yearly basis, this means Dexcom gets ~\$3,000 for Medicare patients - quite favorable pricing, considering the decimation in BGM.

9. Dexcom also continues to explore new business models as it thinks about type 2 diabetes. Notably, Mr. Sayer characterized this piece AS difficult and intensive as developing the technology: "It's become very clear to us that [type 2 diabetes] will be a different type of business model for us. We can't have the one-on-one ordering that we have now and walk patients through their DME benefits. It's going to have to be different and we are exploring new business models that can do that. As Steve talked about earlier, outcome-based programs that we can sell to employers, payers, communities and things of that nature - that's going to have to be leveraged and it's going to have to be done differently than what we do today. We think we can leverage that and be successful. **And so, we are taking as much time with the business model in this area as we are taking with the technology. And the development of the business model is every bit as high tech and challenging and different as developing the technology is. It's really been a wonderful effort so far and you'll hear more, probably more towards late this year and early next year as to what that's going to look like for us.**

Pipeline Highlights

10. A US launch of Android G5 is still expected by "mid-year," on par with the 4Q16 update. In a question on what to expect from Dexcom at ADA, management said, "We'd love to launch Android if we could, but we're not there yet." With that in mind, we might expect a launch after ADA. This has taken surprisingly long at FDA (following the [3Q16](#) submission), which underscores how big of a deal it is to put a class III app on Android - testing all the phone models is likely challenging.

11. Following FDA approval of the new touchscreen receiver [in March](#), Dexcom plans to start transitioning new patients "later this year." Management characterized it as "more reliable," and has previously shared that it offers a user interface in line with the G5 mobile app. We have not seen a recent picture of the receiver, but assume it will be a nice refresh. Presumably current patients will transition over as they order new receivers, but this was not commented on today.

12. The one-touch inserter and lower profile transmitter (G5x) remain under FDA review after a [3Q16](#) submission. No approval or launch timeline was shared, though as the year goes on, Dexcom will evaluate this launch in tandem with the launch of G6. Given the magnitude of the new inserter (tons of manufacturing changes), perhaps Dexcom will wait until G6 or shortly after G6 is out? As a reminder, Dexcom received FDA **questions in February (not commented on today), and the [JPM](#) presentation** positioned this as a "2017" launch - we might assume this will come in the later part of the year at the earliest.

13. The majority of the G6 pivotal trial has concluded, and Dexcom still expects a PMA filing of the next-gen sensor by the end of 3Q17. A launch is still expected in 2018, assuming things go well at the FDA. G6 will initially be one calibration per day and 10-day wear, but ultimately move to no calibration and 14-day wear with the Verily gen one product (see below). The 10-day wear version is not expected to have a hard shut-off, meaning patients will be able to restart the sensor like the current G4/G5. Echoing his [4Q16](#) comments, Mr. Sayer shared continued excitement for this product: "We have very high expectations for G6 based on its impressive [early data](#). Assuming this performance continues, we expect patients will quickly appreciate what G6 means for standard in CGM performance, even with a reduction in the number of daily calibrations. In addition, G6 represents the basis of our future no-calibration technology."

14. The Verily partnership expects a first-gen launch "by the end of 2018," with a second-gen launch in "2020-2021." JPM and 4Q16 used the first-gen timing of "late 2018," so we're not sure whether to read that as a delay; the 2020-2021 timing is identical to that shared on the 4Q16 call. Both Verily products are expected to be 14-day wear, factory calibrated, real-time CGM, fully disposable, lower cost, and talk to a phone via Bluetooth (no receiver expected).

- **The Verily partnership actually received the most pipeline airtime in prepared remarks, with comments focused on the business model and broader treatment of non-intensively managed type 2s:** "Turning to our Verily partnership, our collaboration continues to march towards a continuous real-time, low cost, no-calibration, disposable sensor system, allowing us to target the non-intensive type 2 market. In addition to the progress we're making in product development, we are beginning to explore a variety of commercial channels to support our non-intensive strategy. **As we've said in the past, the business models we consider in the non-intensive market will likely differ from what we've pursued in our intensive business to-date.** These include a shift to value-based programs and working in collaboration with payers, providers and employers to develop diabetes management solutions that leverage CGM and our data platform to facilitate both therapeutic and behavioral change. Considering the importance and costs associated with the broader Type 2 patient population and healthcare management today, these efforts are driving significant interest in solutions for this important category. **The noise in the type 2 diabetes market is only getting louder, with new drugs and new programs, all with different outcomes - it seems like we have a new answer every week. It is our belief that none of these offer the diabetes community as much value as CGM. More specifically, there is a tremendous void in the information provided to these patients to manage their condition. The system's answer today is to take a pill, eat less and exercise more. Patients have heard this for years and yet those ineffective treatments cost the system a fortune. The opportunity lies with an approach that can not only provide better outcomes, but the alleviate expenses. For the first time, accurate, reliable and intuitive CGM data will provide payers, providers, and patients with real-time feedback about timing and efficacy of medications and how eating, sleeping and exercise can impact their diabetes. One of our early learnings is that CGM accuracy matters in the non-intensive market every bit as much as it matters in our intensive market. Many of these patients are truly interacting with their diabetes for the first time and they must have confidence in the data and information they receive. Our early pilot studies in the non-intensive Type 2 space have demonstrated this with reductions in average**

glucose as well as improvements in A1c, time and range, and glycemic variability over relatively short periods of time. Once patients begin using CGM, they quickly understand the repercussions of their decisions around both medication and behavior. These benefits will ultimately drive significant cost reductions in the care of these patients."

15. There were no pump partner updates, though Dexcom remains committed to this field and to partnering with smart pens and interconnected diabetes management platforms. More details are expected as these products get closer to launch. We were glad to hear management say, "We see several highly competitive Dexcom insulin delivery systems, both on the near- and long-term horizons that will provide attractive options for the diabetes community." Neither Mr. Sayer nor Mr. Pacelli mentioned any companies, but remarks noted that Dexcom's two "commercial pump partners" (Animas, Tandem) have experienced "softness" in new patient adds and have "encountered difficulties."

- Will Dexcom buy a pump company (i.e., Tandem or Animas)? "No, we're not looking to buy a pump company.** I think we will continue to evaluate our partnership relationships. You could see us become a little more involved with one or more of the partners if some of them seem to fall off. But at this point in time, we're going to continue with our partnership strategy, again, both on the pump side and on interconnected pens and other software platforms. So, no, we're not interested in buying a pump." - Mr. Pacelli
- While Dexcom is focusing on MDI - and clearly the most excited about it - management emphasized that pumps and automated insulin delivery remain important. The company's partnership strategy will remain key going forward.** "I think there is an extremely important segment of the market that will look to utilize these semi-automated or hybrid closed loop systems, and we remain active with folks who you know, with Insulet and some others, and there are some others that you don't know. I think those are critically important to some subset of the market. **We also think a smart pen paired with a CGM is extraordinarily compelling** - particularly when you think about the computing power that we have on the phone, and being able to really mimic using similar algorithms that to those in the pump to provide detailed dosing assistance to the patient. But then if you really look out at the market, thinking about type 2s, there's a much, much broader opportunity, even in the non-insulin taking patient population. And I think we're starting to see some really compelling preliminary data that will marry up with the appropriate products as we continue forward with our Verily relationship. So, I don't think our partnership strategy has changed. In fact, I think our partners are becoming, frankly, more important, perhaps more diverse. We're not just going to focus on closed loop or hybrid closed-loop systems. I think there is a broad spectrum of partnership product opportunities for us, but they're all going to be critically important over time."

Pipeline Summary

SENSOR AND SOFTWARE PIPELINE

Pipeline Product	Timeline
Touchscreen receiver	FDA approved in March. Will start transitioning new patients later in 2017.
Android G5 app	US launch expected in mid-2017. Submitted to FDA in 3Q16. Launched in international markets in January.
Next-gen one-button insertion system and 50% smaller transmitter (G5x)	<i>FDA questions received in early 2017, following 3Q16 submission.</i> Launch was previously expected in 2017, per JPM . Timing may be impacted by G6 launch.

G5 enhanced app improvements, including ability to receive insulin dose data from other devices	Under FDA review as of 4Q16 call. Not commented on today.
G6 sensor <i>New sensor and algorithm, initially with 10-day wear and one calibration per day after startup. Insulin-dosing label claim, acetaminophen blocking, predictive alerts</i>	Launch expected in 2018. PMA submission by the end of 3Q17.
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 to launch by end of 2018. Second-gen, bandage-like sensor in 2020-2021.

AUTOMATED INSULIN DELIVERY PARTNER PIPELINE

Tandem <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) 	<ul style="list-style-type: none"> ▪ Launch expected in Summer 2017 (under FDA review) ▪ Early 2018 launch (IDE for pivotal filed). ▪ Pivotal trial (IDCL) getting underway, launch by the end of 2018.
Bigfoot Biomedical smartloop automated insulin delivery service with Dexcom CGM, Asante pump, and smartphone app	Completed first feasibility study in adults and pediatrics. Pivotal expected later in 2017, FDA submission in 2018, potential launch in early 2019. Raised \$35.5 million in October 2016 , with subsequent funding from JDRF and T1D Exchange .
Diabeloop Diabeloop algorithm running on a wireless handheld, Cellnovo patch pump, Dexcom CGM	CE Mark pivotal trial expected to reach primary completion in October 2017. EU filing and launch expected in 2018.
Beta Bionics Bionic Pancreas dual-chamber iLet with integrated Dexcom CGM, insulin-only or insulin+glucagon modes.	Insulin-only: Pivotal trial start by end of 2017/early 2018. Bihormonal: Pivotal trial expected in mid-2018; PMA submission timing to be discussed with the FDA.
Animas Hypoglycemia-Hyperglycemia Minimizer with Dexcom CGM	No recent updates. As of November , pivotal study was being planned, with a launch expected in late 2018/early 2019.
Insulet Next-gen OmniPod Dash PDM with G5 app integration on phone OmniPod Horizon Automated Glucose Control System	"Debut" at ADA 2017, launch by end of 2017 ("limited market release" going into 1Q18). Launch expected in late 2019. Two feasibility studies now complete, totaling over 50 adults and children (down to age six years).

-- by Adam Brown and Kelly Close