CLOSER LOOK

MEMORANDUM

Dexcom 1Q16 - July 21 FDA panel on CGM insulin-dosing claim; Sales rise very strong 60%; corrective actions in progress for receiver recall; upcoming submissions for new receiver, inserter - April 27, 2016

Executive Highlights

- Dexcom reported 1Q16 revenue of $116 million, a very strong 60% year-over-year (YOY) gain on a very challenging comparison to 1Q15. Sales declined 11% sequentially from a record-high 4Q15, slightly better than expected. This marked Dexcom's second highest revenue ever and 14 (!) straight quarters of 49%+ YOY growth.
- Following a February 23 customer notification, the FDA determined that the speaker malfunction in some G4/G5 receivers warranted a Class I recall. Three corrective actions are in the works. Dexcom has also experienced some recent customer service challenges stemming from the larger patient base, the G5 launch, and the receiver recall.
- In a surprise, the FDA will hold a July 21 advisory panel to discuss a non-adjunctive, insulin-dosing label claim for Dexcom CGM. Dexcom is still on track to launch an Android version of G5 mobile later this year. The touchscreen receiver will be filed with the FDA before the end of 2Q16. A submission of the next-gen, one-button sensor insertion device is being prepared. A G6 pivotal is slated for late 2Q16-early 3Q16.

Dexcom reported 1Q16 financial results this afternoon in a call led by CEO Kevin Sayer. It was another quarter of outstanding revenue growth (60%), offset by some internal challenges and disappointing news of a July 21 FDA advisory panel on an insulin-dosing claim. We include below the top business and R&D highlights, followed by a pipeline summary and Q&A.

Financial and Business Updates

1. Dexcom reported 1Q16 worldwide revenue of $116 million, a striking 60% year-over-year (YOY) gain on a very tough comparison to 1Q15. Sales declined 11% sequentially from a record-high 4Q15, slightly better than the guidance for a 15% decline. This marked Dexcom's second highest revenue ever and 14 (!) straight quarters of 49%+ YOY growth.

2. Cash-based net income was $9 million, on par with 1Q15 ($9 million), though down significantly from 4Q15's record-high ($29 million). Lower Q1 seasonal sales volumes, increased warranty expense (receiver recall; see below), and lower yields on the new G5 mobile transmitter contributed to the decline in margins and profitability.

3. Following a February 23 customer notification, the FDA determined that the speaker malfunction in some G4/G5 receivers (failure to provide audible alarms) warranted a dedicated press release and Class I recall. Three corrective actions are in the works: (i) a manufacturing change has been filed with the FDA; (ii) a software upgrade for the current receiver; and (iii) the more durable touchscreen receiver will be filed before the end of 2Q16.

4. Recent customer service challenges have stemmed from the much larger patient base, the complicated G5 mobile launch (Bluetooth, app, shorter transmitter life), and the receiver recall. G5 technical support calls are approximately 40% longer than for G4! Said Mr. Sayer, "We are providing medical device and consumer product support all at the same time." It's a good reminder that diabetes technology has a major service component, even easy to use products.

5. In Q&A, management said the move to pharmacy distribution is "progressing," but "going a little slower than anticipated." We're not sure if the previous goal still stands: 70% of the business through pharmacy in the next three years.

R&D Pipeline Highlights

6. In a surprise, the FDA will hold a July 21 advisory panel meeting in Gaithersburg, MD to discuss a non-adjunctive, insulin-dosing label claim for Dexcom CGM. The news follows almost 18 months of FDA discussions, and for the first time, management shared that a PMA supplement was actually filed last fall seeking the label update. The FDA only notified Dexcom recently, reflecting a step back from 4Q15 confidence that a claim would come through in 2H16. The news is a potential headwind for the competition (particularly Abbott's FreeStyle Libre) and reflects a higher regulatory bar for CGM.

7. Dexcom is still on track to launch an Android version of G5 mobile later this year. Submissions are also planned for enhanced versions of the G5 mobile app, including "possible" incorporation of insulin data. Management mentioned an intelligent insulin pen for the first time, in addition to its pump partners.

8. The new touchscreen receiver will be filed with the FDA before the end of 2Q16, meaning a launch could still happen by end of year. This receiver will be more durable and offer a user interface in line with the G5 mobile app.

9. Dexcom recently completed a 97-patient accuracy study of the next-gen, one-button automatic sensor insertion device. The FDA submission is being prepared, with more color on timing expected in the 2Q16 call. Previously this inserter was expected to launch by the end of 2016, meaning Dexcom could still hit the timing if things go well at the FDA.

10. An IDE application for the G6 sensor should be approved in the coming weeks. A pivotal trial is slated for late 2Q16 or early 3Q16, depending on the IDE approval. The timing has slipped a bit from 4Q15, where the pivotal was positioned as a Q2 activity. The FDA is putting the G6 through a "very rigorous process" - it is not getting easier to get a CGM approved.

11. Management called out "positive results" for Animas' and Tandem's G4-integrated pumps. Work is ongoing with automated insulin delivery partners to incorporate G6 into research and clinical studies.

12. The Verily partnership update used similar language to the 4Q15 call: work is "going extremely well" and Verily has completed the first-gen transmitter and is testing performance with G5 and G6 sensors. Initial results have been "very promising," and launch of the combined next-gen CGM product appears to be very much "on schedule" (i.e., ~2018, though the year was not specifically mentioned today). It is a major plus for Dexcom that star researcher and clinician Dr. Howard Zisser is now Verily's Diabetes Clinical Lead.

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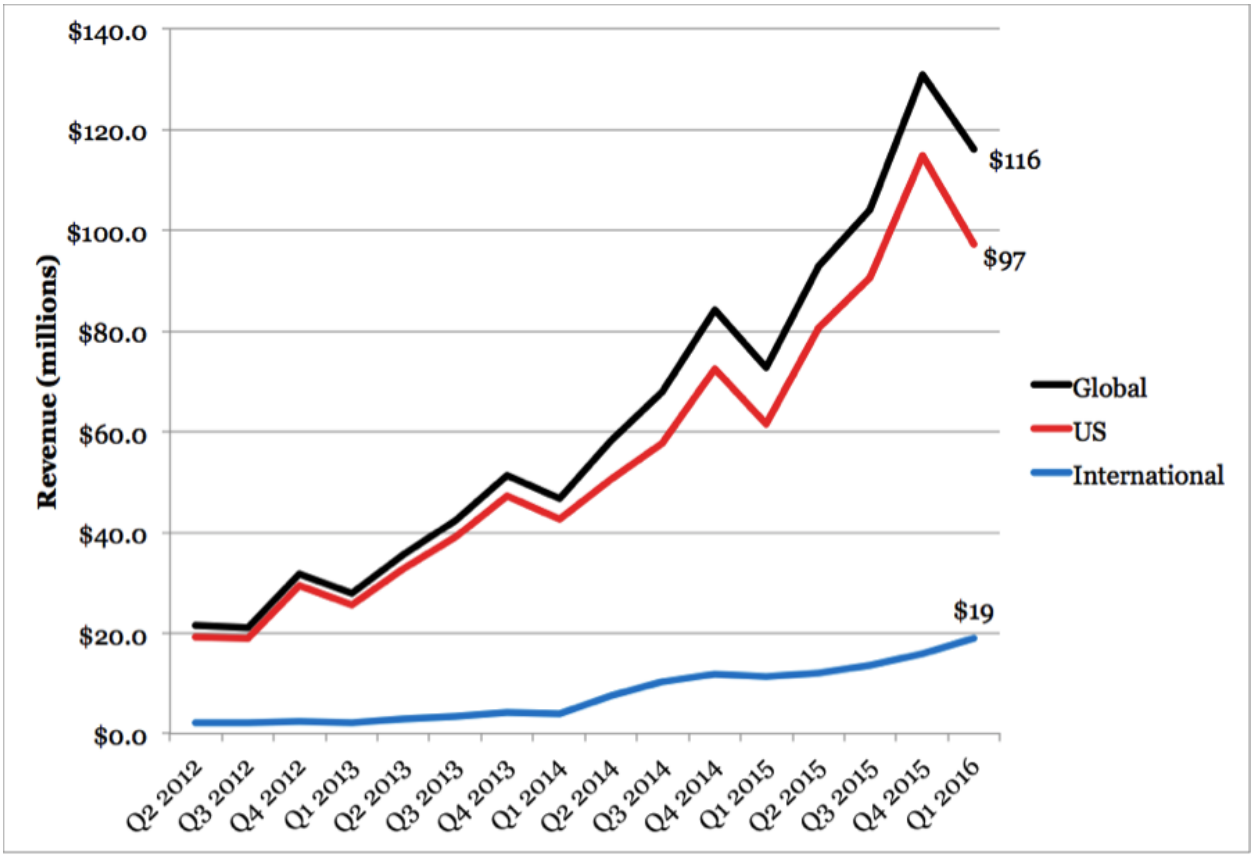
Financial and Business Updates

1. Dexcom reported 1Q16 worldwide revenue of $116 million, a striking 60% year-over-year (YOY) gain on a very tough comparison to 1Q15. Sales declined 11% sequentially from a record-high 4Q15, slightly better than the guidance for a 15% decline. The sequential decline was consistent with previous 4Q-1Q declines, and was especially unsurprising given the blowout 4Q15 sales of $131 million. Even still, this marked Dexcom's second highest revenue ever and 14 straight quarters of 49%+ YOY growth

since the launch of G4 in late 2012. We say it every quarter, but it's remarkable how this company continues to drive topline revenue. The broader launch of G5 mobile drove the quarter's growth - management remains "very pleased" with feedback on the product and response continues to be "exceptional." Dexcom's prospective patient pipeline is also "robust." There was minimal commentary on the quarter's revenue, as remarks focused on the receiver recall, customer support, and the dosing claim (see below). The US business provided 82% of the quarter's growth on sales of $97 million (58% YOY growth).

Figure 1: Dexcom Quarterly Worldwide, US, International Product Revenue (2Q12-1Q16)



- **The international business saw record-high 1Q16 sales of ~$19 million, growing 68% YOY, 19% sequentially, and driving 18% of the quarter's overall growth.** The international business reached a record-high ~16% of company-wide revenue, up slightly from the previous 1Q15 high of 15.5%. Dexcom is "very close" to opening its European headquarters in Scotland. Consistent with 4Q15, management believes reimbursement is close in Germany, France, and the UK - one or more of those this year would open a "huge opportunity up." Dexcom currently has reimbursement in Sweden, Switzerland, and the Netherlands.
- Management maintained the **guidance issued at JPM: 2016 revenue in the range of $540 million-$565 million (35%-40% growth YOY).** This quarter's 60% YOY growth far outpaced that expectation - management said it will re-evaluate the guidance as appropriate in Q2.

2. Cash-based net income was $9 million, on par with 1Q15 ($9 million), though down significantly from 4Q15's record-high ($29 million). Lower seasonal sales volumes, increased warranty expense (receiver recall; see below), and lower yields on the new G5 mobile transmitter contributed to the slight decline in margins and profitability. Overall net loss was $19 million, which included a striking $29 million in non-cash expenses (primarily share-based compensation) - the stock price is currently at ~$68, identical to where it was in April 2015.

- **Operating expenses rose 59% (consistent with sales) to $94 million. Dexcom expects choppy spending in 2016 as it invests up to $40 million in four key areas:** the Verily partnership, expanded manufacturing, international expansion, and investment in an advanced data platform. This quarter saw "less than $10 million" invested in the Verily partnership and international expansion; no further guidance was given on these initiatives going forward, though all seem key to the company's mid- and long-term viability.
- **Gross margin was 65%, consistent with 1Q15 (64%) and down from 4Q15's impressive 70% margin.** Gross margin in 1Q16 would have been 68% subtracting out the additional warranty expenses (two margin points) and scrap costs (one margin point). Full year gross margins are expected to return to the 67-70% range, though the receiver recall is an unknown that could impact expenses up to $5 million in the worst-case scenario (see below).
- The mix between durable and consumable shifted slightly to 28% durable and 72% consumable. Historically this has been 70%/30%, though the shift makes sense as the patient base grows larger (i.e., more sales from consumables). Average selling prices have not changed: $70-$75 per sensor, $800-850 per starter kit.

3. Following a February 23 customer notification, the FDA determined that the speaker malfunction in some G4/G5 receivers (failure to provide audible alarms) warranted a dedicated press release and Class I recall (April 11). Three corrective actions are in the works: (i) a manufacturing change has been filed with the FDA to replace the speaker component; (ii) a potential software upgrade for the current receiver can systematically test the audio functionality, automating the process for patients (now, the testing is manual in the "Try It" menu); and (iii) the more durable touchscreen receiver will be filed before the end of the second quarter. It's great to see the company taking so many routes forward, since this issue is definitely a patient safety concern.

- **The FDA is aware of these corrective actions, though the financial impact on Dexcom could range from very little (a software upgrade to current receivers) to a worst-case scenario of $5 million** (if Dexcom is required to implement the new speaker component and has to scrap all of its in-house receiver inventory). It sounds like the FDA has not weighed in on what is acceptable, though financial analysts did not seem terribly concerned about the worst-case scenario.
- **Management declined to answer what percentage of receivers are affected by this recall, which technically applies to all G4/G5 receivers.** The increase in warranty expense negatively impacted 1Q16 margins by a fairly significant two percentage points (see above); management did not quantify the absolute dollar amount of spending. The April 11 press release reminded patients NOT to send in perfectly functioning receivers, suggesting some may be misinterpreting whether a receiver is actually broken (and consequently, raising expenses further).
- **Management also shared a recap of how events unfolded, implying the FDA changed its mind about this issue's importance.** Initially, Dexcom noted an increase in the number of receiver speaker failures in its MDR reporting. With the FDA, Dexcom determined the appropriate course of action was a customer notification and Class II recall. In compliance with the FDA, Dexcom issued the notification on February 23; the letter was posted online and sent to all Dexcom patients, either directly from Dexcom or through distributors. The notification reminded patients of the importance of alarms and detailed how to test the receiver's audio functionality. The local FDA office inspected Dexcom in March, finding the company in compliance. The FDA reviewed the matter further and felt it was more appropriately deemed a class I recall. After this determination, Dexcom issued a press release on April 11 and the FDA posted the class I recall notice on its website.

4. Management apologetically described customer service challenges stemming from the larger patient base, the complicated launch of G5 mobile (Bluetooth, app, shorter transmitter life), and the receiver recall. The company has added and trained more customer service team members (right sized in a couple weeks), is in the final stages of an IT efficiency project, and a new phone system will be turned on over the next 30 days. "We apologize for slipping," noted CEO Kevin Sayer, and the company remains committed to its #1 customer satisfaction and loyalty ranking (not sourced, but we assume he meant

in dQ&A's patient panel; contact Richard Wood). Mr. Sayer was adamant that Dexcom has learned many lessons and apologized repeatedly for falling short on this front. It was great to see such humility, even after another terrific quarter of sales.

- **Several trends have stretched the customer service infrastructure and led to long call times:**
  - **During the past 15 months, Dexcom has more than doubled its US patient base, which now is over 100,000 patients** (per 4Q15). Dexcom is serving a much broader group of patients now, and as one analyst pointed out, these are probably well beyond the tech-savvy early adopters.
  - **G5 technical support calls are approximately 40% longer than for G4** - in addition to the CGM system, there is troubleshooting for Bluetooth pairing, Bluetooth range, app downloads, Dexcom Share, etc. "We are providing medical device and consumer product support all at the same time," said Mr. Sayer.
  - **Purchasing two G5 transmitters vs. one G4transmitter for six months has led to "inordinate of customer service time.** This is despite the fact that pricing is the same. We're not sure if this is more of payer issue or a technical support issue.
  - **The recent receiver recall** (see above).
- **This serves as a good reminder that customer service is a major barrier to commercializing any new diabetes technology, particularly CGMs that talk to apps**. Startup companies often argue that smartphone connectivity and superior ease-of-use will reduce customer service needs - Dexcom's experience with G5 is the exact opposite, and we believe this product is pretty well designed (it passed our no-instruction-manual-needed test).

5. In Q&A, management said the move to pharmacy distribution is "progressing," but "going a little slower than anticipated right out of the gate." This was not mentioned in prepared remarks, given no major updates on this channel and all the other noise this quarter. As of 3Q15, Dexcom's goal was to move 70% of its business to pharmacy benefits as the primary reimbursement source over a three-year period. We're not sure if that is still the goal.

R&D Pipeline Highlights

6. In a major surprise, the FDA will hold a July 21 advisory panel meeting in Gaithersburg, MD to discuss a non-adjunctive, insulin-dosing label claim for Dexcom CGM. The news follows almost 18 months of FDA discussions, and for the first time, management shared that a PMA supplement was actually filed last fall seeking the label update (G4/G5 using Software 505, MARD: 9%) - this was not previously disclosed. The FDA only notified Dexcom recently (earlier this quarter), and this news was a step back from 4Q15's confidence that this claim would be approved in 2H16. The submission includes thousands of computer simulations of CGM treatment scenarios (e.g., what if the CGM said X but the meter said Y?), multiple human factors studies, revised labeling language, and a new G5 app for a non-adjunctive label claim. Whatever the advisory committee's decision, CEO Kevin Sayer said a "very significant post-market study" to support the label will probably be required - this is unfortunate to hear, given how many patients are already dosing off their CGMs in the real-world. Mr. Sayer was admirably confident and balanced in his commentary, noting the FDA's concerns about patient safety: "This is such a paradigm shift. They want to make sure we have the public panel and everybody can digest the data." He emphasized that this panel meeting "could set the tone for all future CGM products," and certainly, it reinforces Dexcom's trailblazing leadership at FDA.

- **We are extremely disappointed that the FDA is requesting this advisory committee, which does not seem like a prudent use of resources.** While a dosing claim is indeed a big change, we'd point out that:
  - **Current BGMs don't have an insulin-dosing claim** - Insulin-related hypoglycemia and errors cause over 97,000 ED visits each year in the US. How many of these stem from

fingerstick meters, and how many could be avoided if all insulin-using patients were on CGM?

- **Many patients are routinely dosing off their CGMs in the real-world** - The label is a formality for this group, and more broadly, we don't believe patients routinely read long and often highly clinical product labels.
- **CGM is safer than fingersticks on multiple fronts: alarms, trend arrows, and minimizing how often dirty hands affect readings** - Adam has had countless false-high fingerstick values of 200+ mg/dl, only because he hadn't washed his hands (many patients don't). The only thing that reminds him to wash his hands and re-test is that his CGM reads much lower (80 mg/dl) - a massive discrepancy. Adam has found that in 90%+ of the cases where the meter and CGM differ markedly, it's the meter that is reading falsely high, and the CGM actually prevents a dangerous overdose of insulin. In that framework, CGM is safer than a fingerstick meter!)
- **Dexcom's MARD at 9.0% is probably more accurate than the low-quality meters many patients receive** - particularly those on Medicare who have been switched to lower-quality products after competitive bidding.
- **A dosing claim is a gating factor for Medicare coverage, and these are the patients most in need of CGM** - Any potential harms from a dosing claim are arguably outweighed by the benefits of bringing CGM to a hypoglycemia-prone population with long-standing diabetes.
- **A dosing claim could massively expand the number of patients willing to go on CGM and the number of providers willing to prescribe it** - The benefits of expanding CGM access to more patients with this claim arguably outweigh the risk of negative outcomes that could stem from non-adjunctive labeling.

- **The news is a potential short-term negative for Medtronic and Abbott, who both have to think about a dosing claim with the MiniMed 670G/Enlite 3 and FreeStyle Libre, respectively. How is FDA viewing those products?** We assume Dexcom is further ahead with the FDA than either company on this issue. A dosing claim is particularly critical for Abbott, who has a rough history with the FDA on this topic and ideally wants the same label FreeStyle Libre has in Europe. Can FreeStyle Libre be modified to take calibrations? How does the FreeStyle Libre value proposition change if Abbott has to drop the "No fingersticks" marketing? Will the FDA approve a factory calibrated sensor that doesn't have an insulin dosing claim? If Abbott gets FreeStyle Libre approved with an adjunctive claim, will it matter from a real-world patient use or uptake perspective? Will Medtronic's MiniMed 670G/Enlite 3 need a dosing claim?
- **Assuming Dexcom ultimately gets the FDA label, we wonder how the FDA will evaluate future products:** will it get more comfortable that a dosing claim for CGM is safe, or will it hold all future products to the standard of G4/G5's accuracy? At JPM, Dexcom positioned the insulin-dosing claim as a competitive barrier to entry for the first time: "We will undoubtedly be the first company to have this label. And we want to set the bar high. You've got to have a sensor that performs as well as ours does."
- **As a reminder, Dexcom received a CE Mark for non-adjunctive CGM labeling in August 2015 (first announced at EASD 2015).** We wonder if real-world data from Europe could somehow support Dexcom's case at the July 21 panel meeting.

7. Dexcom is still on track to launch an Android version of G5 mobile later this year. Submissions are also planned for enhanced versions of the G5 mobile app. "A mute override on alarms and alerts" was mentioned for the first time, which would be a welcome enhancement - this presumably means the iPhone will still sound an audible CGM alarm, even if the vibrate-silent mode switch is activated. [As an aside, we'd note that the current G5 app does not enable alarms to be cleared from the phone

lock screen; a user must actually open the app to clear an alarm, otherwise it will keep repeating every five minutes. Hopefully app updates will also correct this.]

- **"Possible" incorporation of insulin data is also a planned G5 app enhancement, consistent with the 4Q15 call.** Management mentioned an intelligent insulin pen for the first time, in addition to its pump partners (Animas, Tandem, Insulet, Bigfoot, Beta Bionics, TypeZero/ IDCL). We're not sure who owns the intelligent pen, though Companion Medical is one possible partner (CEO Sean Saint used to work at Dexcom; the last update was a year ago when Companion received $3 million in Series B financing led by Lilly. The pen is not FDA cleared as far as we know...). Of Dexcom's pump partners, Insulet has talked most openly about sending data to Dexcom's app - the most recent 4Q15 update suggested an FDA submission of the Bluetooth-enabled next-gen PDM "later this year."
- **No other app enhancements were mentioned in the call, though there is probably a lot in the consideration set, particularly with the paired Clarity data analysis app (which only shows a static PDF).** We would love to see a time-in-range metric and automatic pattern recognition notifications within either the G5 app or the paired Clarity app. The upside to the Clarity app is its lower risk, meaning it can iterate more quickly. We also hope the three-hour delay for posting to Apple Health Kit diminishes over time.

8. The new touchscreen receiver will be filed with the FDA before the end of 2Q16, meaning a launch could happen by end of year (on par with previous guidance). This receiver will be more durable (i.e., less susceptible to wear) and offer a user interface in line with the G5 mobile app. We do wonder what percentage of Dexcom users use the G5 smartphone app vs. dedicated receiver - both have advantages and disadvantages, though we're definite fans of the updated G5 app. The app can be updated at a faster cadence than the receiver, meaning patients could increasingly migrate to the phone as successive versions improve.

9. Dexcom recently completed a 97-patient accuracy study of the next-gen, one-button automatic sensor insertion device. The FDA submission is being prepared, with more color on timing expected in the 2Q16 call. Previously this inserter was expected to launch by the end of 2016, meaning Dexcom could still hit the timing if things go well at the FDA. The study was just marked on ClinicalTrials.gov as "completed" - it compared the G5's accuracy with the automatic inserter vs. the current manual syringe-like inserter. We have to imagine the performance is the same or better with an automated inserter, which should be more predictable than manual insertion. Management summarized the feedback thus far in four words: "patients love this system."

- **Manufacturing scale is "t**he biggest variable" with the new inserter and accompanying smaller G5 transmitter. We imagine Dexcom will take its time on this one, given the recent receiver recall and the major manufacturing change this will entail. On the plus side, the three-month G5 transmitter life means it will be easier to transition patients over to the new product. The current insertion system has been used since Dexcom's first product, and changing it requires swapping out "every mold" - the biggest operational change Dexcom has ever undertaken.
- **The new insertion device is also important in an increasingly competitive glucose sensor field.** Dexcom's current manual insertion device lags behind Abbott's FreeStyle Libre and Medtronic's Enlite, which both use inserters (Abbott's is particularly good). Dexcom's new insertion device will only require patients to peel a piece of tape; place the device on the skin; and push a button. The hidden needle (as far as we understand) and the ability for a one-handed insertion are both major wins. We have long thought the current system works fine for some patients and not as well for others and we welcome this imminent upgrade.

10. An IDE application for the G6 sensor should be approved in the coming weeks. A pivotal trial is slated for late 2Q16 or early 3Q16, depending on the IDE approval. The timing has slipped a bit from 4Q15, where the pivotal was positioned as a Q2 activity. Management said the FDA is putting the G6 IDE through a "very rigorous process" and the "standards are not getting easier; they are getting harder." The G6 pivotal trial will be "robust," given the high regulatory bar for a non-adjunctive sensor. While there are

multiple years of data on G4/G5 with Software 505, G6 does not have nearly as much supportive data - it sounds like FDA is thus requiring a more ambitious study.

- **The product profile expectations for G6 remain the same:** 10-day wear, one calibration per day after startup, acetaminophen blocking, and other features to enhance the CGM experience (e.g., predictive alerts, per ATTD). Management expects overall performance to be consistent with G4/G5 with Software 505 (MARD: 9.0%), even with the reduced calibrations and extended wear.
- **"We know that we can run G6 sensors with no calibration. What we don't know is the FDA path for this configuration, especially for intensively managed, insulin-using patients."** Management suggested a lower-cost, diagnostic CGM could be factory calibrated, while a more accurate system labeled for insulin dosing (e.g., G6) will probably still require some calibration from a regulatory perspective. This commentary was almost identical to 4Q15, and given FDA's continued caution around a dosing claim (see above), this seems like a prudent stance moving forward. We do wonder what this means for the real-time consumer version of FreeStyle Libre. Will it have an adjunctive label with factory calibration? Would that label even matter if patients dose insulin off FreeStyle Libre readings anyways? Is FDA drawing an arbitrary line in the sand on factory calibrated CGM approved for insulin dosing, given the additional BGM dangers of hand-washing and erroneous calibrations?
- **Medtronic's Diabetes Advocate Forum two weeks ago shared that its fifth-generation sensor is also about to start an FDA pivotal trial.** Consistent with the ATTD poster shown in Milan in February, the plan is 10-day wear and one fingerstick calibration per day, matching Dexcom's G6. Medtronic expects a sub-10% MARD, though Enlite's labeled accuracy was not generally seen in real=world use.

11. Management called out "positive results" for Animas' and Tandem's G4-integrated pumps. Work is ongoing with artificial pancreas partners to incorporate G6 into research and clinical studies. No partners were called out by name, though the full list includes: Tandem, Animas, Insulet, Bigfoot Biomedical, Beta Bionics, and potentially TypeZero/IDCL. See our automated insulin delivery landscape here, which we'll be updating this week once Tandem and Insulet report tomorrow.

12. The Verily partnership update used similar language to the 4Q15 call: work is "going extremely well" and Verily has completed the first-gen transmitter and is testing performance with G5 and G6 sensors. Initial results have been "very promising," and launch of the combined next-gen CGM product appears to be very much "on schedule" (i.e., ~2018, though the year was not specifically mentioned today). We assume much is happening behind the scenes here, especially given the major spending in 2016 on this project. When the initial partnership was announced last August, the first launch was expected in two to three years (~2017-2018), with a follow-on product to be commercialized within five years (~2019-2020).

- **It is a major plus for Dexcom that star researcher and clinician Dr. Howard Zisser is now Verily's Diabetes Clinical Lead.** Dr. Zisser has long worked with Dexcom on the artificial pancreas front, and more recently, helping to reinvigorate the CGM integration partnership at Insulet. Dr. Zisser is a perfect choice to help advise and prioritize Verily's diabetes partnerships with Dexcom, Novartis, and Sanofi and to help build Verily's strength in the field. Dr. Zisser has already started working at Verily (no downtime for this guy!), where he brings deep knowledge of glucose sensing, automated insulin delivery, diabetes data, clinical trials, and patient and HCP needs and constraints to the position.
- **In 4Q15, management confirmed that the first-gen Verily sensor will presumably not hit** all **the lofty goals: low-cost, disposable, bandage-like (size of a penny), 10-14-day sensor integrated into an advanced data analytics platform**. This makes sense - we had been a bit surprised by any implication that the first-gen sensor would have all that. The first-gen sensor will use some of the initial prototypes, including miniaturized electronics, batteries, and advanced algorithms. The second-gen sensor is when the product will really start to look like a tiny bandage on the skin, making it truly minimally invasive and taking cost out of the system.

- **Dexcom and Verily plan to go beyond just showing a glucose number and trend with these sensors. The goal is to link glucose values to behavior changes in a far more interactive and intuitive interface - critical for penetrating into non-intensively managed type 2s.** Said CEO Kevin Sayer in 4Q15, "The one thing that we've learned about this market is it's not going to do us any good just to display a number and say, here you go. We're going to have to really give patients the ability to learn from the system that we provide and provide interactive suggestions like, "You exercised today. Look, how much better you did." And that's the type of system interface that we're going to develop to address that market, again, which is different than what we have now. Just flashing a number on a screen isn't going to be enough, particularly for those that aren't using insulin. I would maintain that intensive insulin using type 2 patients can have the exact same experience as our type 1 patients have today."

Sensor and Software Pipeline

Pipeline Product	Timeline
Android G5 app	Launch later in 2016
Touchscreen receiver	FDA submission in 2Q16
Insulin dosing claim	FDA advisory panel meeting on July 21
Enhanced G5 app with additional features Mute override on alarms, potential incorporation of insulin-on-board data from pumps or smart pens	Submission and potential launch in 2016
Next-gen insertion system, smaller transmitter	Accuracy study complete, FDA submission being prepared. Timing update on 2Q16 call
G6 sensor New sensor and algorithm with 10-day wear, one calibration per day, insulin dosing claim, acetaminophen blocking, predictive alerts	Pivotal study in late 2Q16 or early 3Q16
Verily [Google Life Sciences] partnership Simple, low-cost, disposable, 10-14 day sensor system the size of penny integrated into an advanced data analytics platform.	"On schedule" - First product to launch in ~2018, with follow-on product in ~2019-2020.

Pump Partner Pipeline

Animas Vibe Tandem t:slim G4	Launched worldwide Launched in US
Insulet next-gen OmniPod with G5 transmitter/ smartphone app integration	2016 FDA 510(k) submission of next-gen PDM with Bluetooth and a paired Insulet app that integrates Dexcom G5 CGM data
Tandem next-gen t:slim with G5 and G6 transmitter/smartphone app integration	Pivotal trial in 2016 for predictive suspend
Bigfoot Biomedical automated insulin delivery system with Dexcom CGM, Asante pump, and smartphone app	Pivotal study in 1H17. Potential connected insulin management system to launch in late 2016.

Beta Bionics (Bionic Pancreas dual-chamber iLet with integrated Dexcom CGM)	Bridging study in 4Q16, pivotal study in 2Q17, FDA submission of insulin-only system by end of 2017.
International Diabetes Closed Loop consortium (TypeZero algorithm; multiple pump brands, including Cellnovo; Dexcom CGM)	IDCL study to start in 2H16

Questions and Answers

Q: The FDA advisory panel creates another hurdle, but the positive side is that the bar for anybody else getting a fingerstick replacement claim just went up that much higher. I'd love to get your additional thoughts on that?

A: This is going to be such a paradigm shift in diabetes care to have that replacement claim. We're okay going to panel, and we will just prepare and do the absolute best that we can. It's important that we learn exactly what we have to do, because we do have to get this claim to get Medicare coverage. As I've gone out in the field and met with physicians, the number one question I get when I walk into an office is: When are you going to get Medicare coverage? So, we need this labeling. We look forward to the opportunity and will take what comes, but we will be ready, rest assured. We will not lack for preparation here.

Q: With the challenges with the G5 launch and the learning curve on some of it, how has that impacted the timing for G6?

A: This really hasn't impacted our G6 timing. We've continued to work on our G6 IDE. I can tell you the FDA is putting our IDE through a very rigorous process and standards are not getting easier. They're getting harder. I think some of this is in anticipation of the non-adjunctive claim that, as they look at G6, they think, is this going to be a non-adjunctive sensor? While we have multiple years of data on that G5 system with the 505 software, we don't have multiple years of data on the new sensor. So that trial is going to be very, very robust.

Q: What data will we see at ADA from the DIaMonD trial?

A: We haven't seen the data yet. This is an independent study, so we do not know how it is going to read. I believe we'll see the data a month or six weeks before the presentation. Certainly, our hope for the study was to show improved outcomes through the use of CGM in this patient population. We anticipate that we will see that, but we don't know what those outcomes are. This is a very independent group of diabetes thought leaders who are going to tell us what happened and what they saw.

Q: You didn't spend any time on this call talking about your efforts to develop the pharmacy channel. Can you just talk about where you are with that? Will there be a point when you will start to talk about percentage of your business that is going to the pharmacy?

A: We're not going to disclose that today, but you're right. Because there was so much information on this call, we didn't provide a specific update on pharmacy. We continue to say it's progressing, and going a little slower than we anticipated out of the gate. We'll certainly update you as we see more progress, but there's not a whole lot to talk about there today.

Q: At the FDA panel, will it just be the Dexcom submission being discussed?

A: To our knowledge, that is correct.

Q: Let's say it goes well and the FDA approves the insulin dosing claim towards the end of the year, how will your messaging change and how material do you think that that claim will be as you talk to clinicians and patients vs. the other products that are available or that might come out in 2017?

A: That's really a fascinating question, and it's a subject we debate all the time. Obviously, I can tell you one segment where this claim would play very well: there are still physicians out there who don't recommend CGM regularly because they say you still have to stick your finger anyway. With this claim, we will be able to go to that group and say, look, recommend this for your patients because they don't have to take fingersticks before they make treatment decisions. This will be a very, very good outcome for us, and we'll be able to get into more physicians.

With respect to the rest of the community, I think it certainly sets us above everybody else, which is where we already are. So, it would give us an advantage in terms of continuing that marketing and continuing to push. I think it will be helpful. There is certainly no downside here at all.

Q: Can you talk about the sequential decline in patient-adds in the first quarter? It seems like it was smaller than in previous quarters. How would you characterize the tone of the business going through the quarter? Was it a typical first quarter progression or did it surprise you?

A: I think it was a typical first quarter progression, similar seasonality to prior years. I would say, one thing we might be starting to see - though it's a little early to tell - is maybe a reduction in the seasonality over time as we move more of the business to the pharmacy channel. However, other than that, it was a very typical first quarter for us.

Q: How would you guess the sensor mix exiting the year? You came down a couple of points this quarter. Should we look for that to keep moving or how do you look at that?

A: I would look for the mix to probably normalize and be in the 70/30% range. In prior years, we have had some fluctuation of consumables being in the 69-72% mix.

Q: Just a question on some of the receiver issues ... Did you see any change in patient attrition during this time or in terms of sensor days per patients?

A: Our internal checks would indicate that we haven't seen any attrition and one of our larger distributors said last week that they've seen retention at an all-time high. I'll tell you, I've taken a couple of frustrated patient calls because of wait times - I do that from time to time - and in no case has somebody called me and said, "I want to get rid of your product." They just say, "I just want you to answer the phone and get on the line quicker and help me." So, we haven't seen that. However, if we don't fix the things we're working on, we would see that, and that's why we're still committed to making the improvements and getting through these issues.

Q: I have a question on the adjunctive claim. Can you give us some color into what exactly the FDA is looking for here? I mean, you're already at a MARD of 9% and that should be good enough. What more does FDA need to see? I'm happy to hear you guys are doing the panel but I'd like to understand why we cannot get it approved without a panel.

A: This is such a paradigm shift. I think they want to have a public panel so that everybody can digest the information. As we've gone through this process, it's not only the MARD that matters. It's the overall patient safety. We gone through hundreds of thousands of simulations with the FDA where the CGM reads X and the fingerstick reads Y, and the fingerstick is right and the CGM is wrong. We've talked about what could happen, and what they want to see is how we protect patients. In all cases, the best way to protect patients is with the CGM, because if they make a decision and even if the CGM - for whatever reason - is off, the only way you know you've made a bad decision is with an alert or alarm. So with the alerts and alarms in our system, we believe that it is much safer than the decisions patients make today with only fingersticks. However, we've had to simulate and build those cases and ensure that we have a very strong data. Ultimately, we're trying to make a big change. I think what the FDA is saying is that, "we need to make sure we get this in public and make sure we proceed down the proper path."

The accuracy issue is fine. The thing that we have to prove is with regard to outliers. The 505 software was the best ever filed for this. We really want to eliminate outlier sensors more than anything else, and our system does that. We need to show that it does that. So, all these things are being considered by the FDA. And listen, we're going to comply.

Q: I wanted to ask you about the G5 upgrade cycle. Can you give us a sense of what percent of your user base has converted to G5 mobile or is on the G5 mobile now?

A: We've decided not to break that out. What we've said before is still holding true in that we've always offered a low-cost cash upgrade to the next-gen platform and, frankly, very few patients take us up on it. So, what we're seeing is a transition from G4 to G5 as patients' warranties expire and as they are eligible for a new system. They're just processing it through insurance. So, we're not aggressively pursuing an upgrade at this point, and you should just assume over the next 12 to 18 months that the vast majority of patients will transition ... Remember that from a sensor perspective, the G4 and G5 sensor configuration is identical. So, you're really just talking about some hardware upgrades.

Q: Is there anything new with the alternative taps to Medicare? We've been hearing a little bit about individual successes on the judicial front. Is there an option to maybe escalate that to a broader scale? Similarly, anything on the legislator front?

A: We're doing the best we can with those individual cases on the judicial front. The legislative front is a little slow right now. We continue to work on that channel but we feel we've got to get the labeling to get there. So, that's where we are right now.

Q: You've seen robust new patient growth over the last several years. Can you talk a little bit about what these patients look like? It feels like you've moved past early adopters and you're now feeling some of the pain - from a customer service standpoint - of a higher maintenance patient. Can you also talk about the strength of the pipeline from an attrition standpoint in terms of the type of new patients that are coming on? How could that potentially affect the utilization of the product?

A: I think you're absolutely correct that we are moving past the early adopters and those who would wear a product and put up with anything we had to offer because it was so much better than what they had had before. We have to take more care to service these new patients. From an attrition standpoint, I don't think we're going to lose them because, all in all, their experiences have been remarkable. Again, I'll go back to parents. We run into parents who say, "We were just able to go out on our first date and watch our child while we were at dinner." This Share feature has been huge.

The other thing that has been huge in our pediatric population is the ability to look at this on your phone. There are many, many 11-year-olds around the US who need to thank Dexcom for getting them a cell phone two years earlier than their parents were going to let them have one, because kids are willing to look at their phone and to look at the CGM data there. So, I think the patient base is going to be every bit as sticky as what we've had before and the quality of the pipeline is very, very good. CGM is becoming the standard of care for type 1 diabetes. It is absolutely essential to maintain safety and to achieve the outcomes that patients need to achieve.

Q: Assuming you get a positive response from the panel and you get FDA approval before the year's end, what are your expectations for the timing of Medicare coverage? Is it a month? Is it a couple quarters afterwards?

A: It's somewhat to be determined. I'll tell you that it's a multi-pronged strategy in the sense that we haven't made the decision to immediately go for a national coverage decision. The more likely event is that we will target the individual MACs first and try to obtain coverage on a regional basis. That can happen much more rapidly. The national coverage decision process can take a year or more. So, my expectation is that we would probably do this in parallel. But, you would see us going after the MACs first. I don't want to try to guide you on specific timing as we just don't know yet.

Q: I wanted to touch on the impact of the recall on momentum exiting the first quarter. Is there any risk of disruption? Will we see disruption in the second quarter, like a delayed impact of the recall?

A: We have not experienced that to date, but we manage and watch it closely. However, that has not been our experience so far.

Q: Would you be able to break out how much of the three-point margin delta was scrap vs. warranty? Is there anything that we know about that we should be putting in our models if this is going to be non-recurring in terms of those additional scrap or warranty expenses? Are those still unknown risks at this point?

A: The incremental cost we experienced this quarter was about two points due to extra warranty cost and about one margin point due to scrap.

As far as anything unknown in future quarters, we don't know. We tried to outline what we believe would be the worst-case scenario - zero to up to $5 million, if we had to rework the entirety of our inventory.

And let me clarify something. We haven't had any impact on the company as a result of the recall. The impact we've had has been as a result of the G5 launch and that's not being ready for everything. We needed to be a little more ready and prepared from an infrastructure perspective. The recall and the patient notification did not impact our business or sales, but it did impact our ability to serve our customers in the way we wanted to.

Q: I was wondering about the rate of the events that you're seeing with the alerts. Do you have a figure you'd like to share?

A: Nothing we're going to disclose, no.

Q: I mean one of the things that has surprised me when I've looked at the blogs is that this is hardly mentioned. When it is mentioned, folks just recommend putting the receiver next to the bed, since it will vibrate and wake you up. It doesn't sound so alarming, but I might be wrong?

A: We dealt with it and notified patients to retest the speaker. Obviously, the FDA had a different opinion. I think what this tells you again is how important alerts and alarms are in the system, and we continue to emphasize that as we look at future product offerings, we need to make sure that we meet people's alert and alarm expectations. It really relates to the importance of the alerts and the alarms.

Q: In terms of impact on the sales force, does the sales force deal with this at all or are they completely separate?

A: I'm sure they deal with it in phone calls they get from customers and discussing it with the physicians. However, they don't have to deal with the actual execution of this at all.

Q: You mentioned the incorporation of insulin data into the next-generation app that will come out. Is that in collaboration with any specific pump manufacturer or is it not necessarily pump related? Could it be from an injection pen?

A: You're thinking about it the right way. It could be from an intelligent insulin pen that has near field or Bluetooth connectivity to a phone. Or it could come from one of our existing or even future pump partners. Our belief is that aggregating a patient's data in a single place on the phone is going to be the key to diabetes management going forward. So, we're making that available to patients and really evaluating any partner who is willing to come and participate here as a meaningful partner.

Q: Regarding the FDA panel, could you paint in broad strokes how you think the timeline could play out from there and when we might then see the dosing claim?

A: I really can't. I'm not going to anticipate what the panel is going to do.

Q: If it is a favorable decision, do you think that approval and launch could come quickly? Are you prepared for that or is there anything from a high level that you can provide?

A: We certainly will have designed the app along with the user guide and things of that nature. However, as far as launching immediately, we are going to have to go print things and get a new app file and do a lot of stuff. It's not going to happen immediately, but we can prepare very rapidly for it after panel approval. However, I can't give you a timeframe as to how quick after it's going to be with the launch.

Look, we try to be ready for launch every time we get an approval. We try to be as ready as we possibly can. We will behave in that manner. You saw with G5 that we got approved and launched very shortly thereafter … the same thing in Europe. With our Share receiver that we launched in 2015, we got approval one week and we were shipping it two weeks or three weeks later. Our culture around here is to be prepared, as prepared for approval as we possibly can. This is a little bit different because we are going to the panel and that approval may be different than the typical approval we get from the agency. So we will prepare every bit as much as we can, but we need to make sure we do it prudently. We don't want to do things twice; we want to do them once.

Q: And then, on the DIaMonD study, how would you think about the near to intermediate term impact? Are you just looking for CGM to show better control A1c control? Do you want better data that you can take out to the field to show patients or docs?

A: We mentioned we haven't seen the data yet, but this is going to be the preliminary portion of the DIaMonD study, so don't expect the full-blown study results. This is really to put to bed for once and for all that with CGM versus traditional finger sticks, there is no question that CGM provides the bigger benefit. One of the things we hear in the field is that there is not sufficient data to support the efficacy of CGM and this should put that to bed for physicians, for payers, etc. Then, some of the other data that you're talking would come in a later date.

Q: This has been another strong international quarter, growing faster year-over-year than the overall company. Do you believe this is sustainable moving throughout the rest of the year? Do you think that international may revert back a little bit closer to the corporate average?

A: It really depends on reimbursement. If we were to get reimbursement in Germany, France, or the UK this year, that would open up a huge opportunity for patients that are operating today in a cash pay world. So, if two or three happen this year or even in the first half of next year, I believe that will help continue to accelerate European growth.

Q: On the G5 transmitter, you've talked about capacity constraints in the past. Are you fully passed out at this point?

A: We are with the G5 transmitter, yes. But again, getting through that had some scrap and some yield issues, as we launched that product and built it out.

Q: And lastly on Medicaid, you've talked about some impressive progress in public forums over the past several months. Can you give us an update on where that stands today and how you guys think about the total patient opportunity there?

A: I don't have great numbers for you on total patient opportunity, but we're pushing close to 25 states now, with Medicaid coverage. We obviously know that in the ObamaCare regime, the number of eligible patients for Medicaid in the various states has gone out pretty significantly. So, it is an important opportunity for us. Much like the private payers, we have to go state-by-state to negotiate knock-off coverage. So, we're as focused on that as we are on the private payers and on Medicare.

-- by Adam Brown, Varun Iyengar, Ava Runge, and Kelly Close