CLOSER LOOK

MEMORANDUM

Medtronic 2Q17 (F1Q18) - Revenue of $449M down 1% YOY; FY18 guidance lowered to 1%-4% growth; Sensor shortage; Priority Access Program to ~35k enrollees to complete in fall - August 22, 2017

Executive Highlights

- A major topic of discussion throughout the whole call was the global sensor shortage (first disclosed in June), which has hurt the Diabetes business meaningfully, especially in the US. Management expects that a new manufacturing line will be up-and-running by April 2018; it is a replica of an existing line, but the entire manufacturing, installing, and FDA review process generally takes 16 months - Medtronic hopes it will take 13 months.
- Close to 35,000 patients enrolled in the Priority Access Program to upgrade from 630G to the 670G, up from 20,000+ as of the last call. Shipments to all of these customers are (perhaps ambitiously) expected to complete later this fall, and shipments to non-Priority Access members could begin in F3Q18 (as early as November, though we wonder how sensor constraints will impact a broader launch).
- Medtronic's Worldwide Diabetes sales of $449 million decline 1% year-over-year (YOY) as reported and operationally. This is the only quarter of negative growth in our model, which dates back to 2005, and follows two consecutive quarters of record-high revenue. Sensor shortages were in large part responsible for the weakness, which impacted the US heavily (down 8% YOY and 20% sequentially) to $243 million. International sales of $206 million grew 9% YOY as reported thanks to 640G and Guardian Connect adoption.
- Management now expects 1%-4% YOY Diabetes growth in FY18 (May 2017-April 2018), a highly significant drop-off from the ambitious 10%-12% growth they guided for last quarter.
- The Guardian Connect mobile CGM is still under FDA review and is now expected to launch later this year in tandem with the Sugar.IQ pattern-recognition app. The previous timeline, which it sounds like may not be met, called for a launch in October.

Medtronic reported 2Q17 (F1Q18) financial results this morning in a call led by CEO Omar Ishrak, including an accompanying slide deck (Diabetes is slide 12, pasted below). This was a really challenging call across the board, both on the pipeline and the financial fronts. From our nearly 15 years of covering Medtronic, there has never been as much focus on diabetes as on this conference call today. The headline from this quarter - acknowledged by Mr. Ishrak in his fifth prepared sentence and a massive topic of discussion in Q&A - was the global sensor shortage, leading to a reduction in growth projections from 10%-12% to 1%-4%. This contributed to a high-single digit decline in the US for F1Q18 for Medtronic, and the first reported global decline (-1%) in over a decade. We were very surprised that such a massive reduction in growth prospects could stem from this; although we did consider the growth prospects in F4Q17 as very ambitious, we would have felt 4%-6% growth was a reasonable possibility. Questions still remain on the sensor front, but to be sure, this is very positive news for Dexcom and Abbott (especially if the latter sees US approval soon for FreeStyle Libre) and for other pump manufactures, particularly Tandem. Read our highlights below, followed by relevant Q&A.

Sensor Shortage/MiniMed 670G Launch Highlights

1. Much of the call focused on the "temporary sensor supply constraint" we first heard about in mid-June. CFO Ms. Karen Parkhill suggested that sensor supply will be increased in the fourth quarter (i.e. February-April 2018) - this is a ways off and should therefore impact sales for a while. The shortage is a product of

higher-than-expected global demand for Medtronic's CGM products (Guardian Sensor 3 in US; Enhanced Enlite Sensor outside of the US). The delay is due to FDA approval of a new manufacturing line, and it seems like the changes are much bigger than Medtronic had realized.

2. Currently, "close to 35,000" people are enrolled in the MiniMed 630G Priority Access Program (enabling upgrade to 670G for a small fee), up from 20,000+ as of last quarter. According to Mr. Ishrak, fulfillment to all of the Priority Access customers is expected "later this fall," and Ms. Parkhill added that shipments to non-Priority Access customers could begin in F3Q18 (November 2017-January 2018; more specific than the previously-shared "later in FY18").

Financial and Business Highlights

3. Medtronic's Worldwide 2Q17 Diabetes revenue of $449 million fell 1% year-over-year (YOY) as reported and operationally - this is the lowest total in two years and the first year-over-year (YOY) decline in over a decade. Reported growth came on an easy comparison (up 2% in 2Q16), while operational growth was higher a year ago (up high single digits). Sales fell a significant 12% sequentially from a record-high in 1Q17. Although management attributed the declines to sensor shortages, we certainly had not expected this weak a quarter. In a very surprising update, management now expects 1%-4% YOY Diabetes growth in FY18 (May 2017-April 2018), a highly significant drop-off from the ambitious 10%-12% growth they guided for in F4Q17.

4. US Diabetes sales totaled $243 million in 2Q17, falling 8% YOY on a very easy comparison to -4% growth one year ago. 8% is easily the largest YOY decline in our model, which goes back to 2005 in its current form - and we were certainly watching Medtronic's acquisition of MiniMed closely (back in the day, they expected 30% growth from a much lower base). Sequentially, US revenue fell an astounding 20%. Some of this relates of course to how the revenue is booked, but this was presumably part of the projection.

5. International sales of $206 million grew 9% YOY as reported, including 8% operationally in developed markets ($167 million) and 15% operationally in emerging markets ($39 million). The 640G continues to do well outside the US (sensor volumes up ~2.5x and now account for over 40% of total MDT sensor shipments since F3Q15 640G launch - obviously massive growth from lower bases), while the new Guardian Connect standalone mobile CGM has seen "strong adoption."

6. The intensive insulin management division declined in the low-single digits operationally, due to mid-teens declines in the US related to the sensor shortage according to management. On the flip side, the division saw high-teens operational growth internationally due to the strength of 640G and sensors. CGM revenue for the quarter grew "nearly 50%" in international markets.

7. Sales in the Diabetes Service and Solutions division grew in the low-single digits operationally driven by patient engagement programs in the US and the Guardian Connect mobile CGM system internationally.

8. Sales in the non-intensive diabetes therapies division declined in the mid-single digits operationally. This was the second consecutive quarter with YOY declines for this segment, a first in the two years since growth has been disclosed. The decline was not characterized, and the slides noted positives, particularly in professional CGM, though we imagine the division felt an impact from more competition in the US professional CGM arena (from Abbott's FreeStyle Libre Pro). It's also possible that Medtronic is saturating the market now that this business has been growing, and the company would benefit from some new products. We think professional CGM can be much larger; like with the services arena, the margins are on average lower here since they aren't selling pumps and sets nearly as much.

Other Pipeline Highlights

9. Both Mr. Ishrak and Mr. Hakami indicated plans to launch Guardian Connect, which is still under FDA review, in the US in tandem with IBM Watson-partnered Sugar.IQ "later this year." The Sugar.IQ limited learning launch consisted of 250 patients. At best, Medtronic might hit the later end of the "May-October 2017" timing provided at JPM.

10. Slides showed that a "next-gen iPro" product (since confirmed to be iPro3) will launch in FY19 (May 2018-April 2019) outside the US. Previously, Medtronic has indicated that iPro3 would launch in FY18, meaning this product is significantly delayed (by ~one year).

11. The MiniMed Pro-set with partner BD was not mentioned on the call, slides, or in prepared remarks. BD's 2Q17 call noted that launch will resume in FY18 (October 2017-September 2018).

12. Mr. Ishrak proudly referenced Medtronic's outcomes-based deal with Aetna: If MDI users moving to pumps don't achieve a certain A1c benefit, Aetna gets a rebate.

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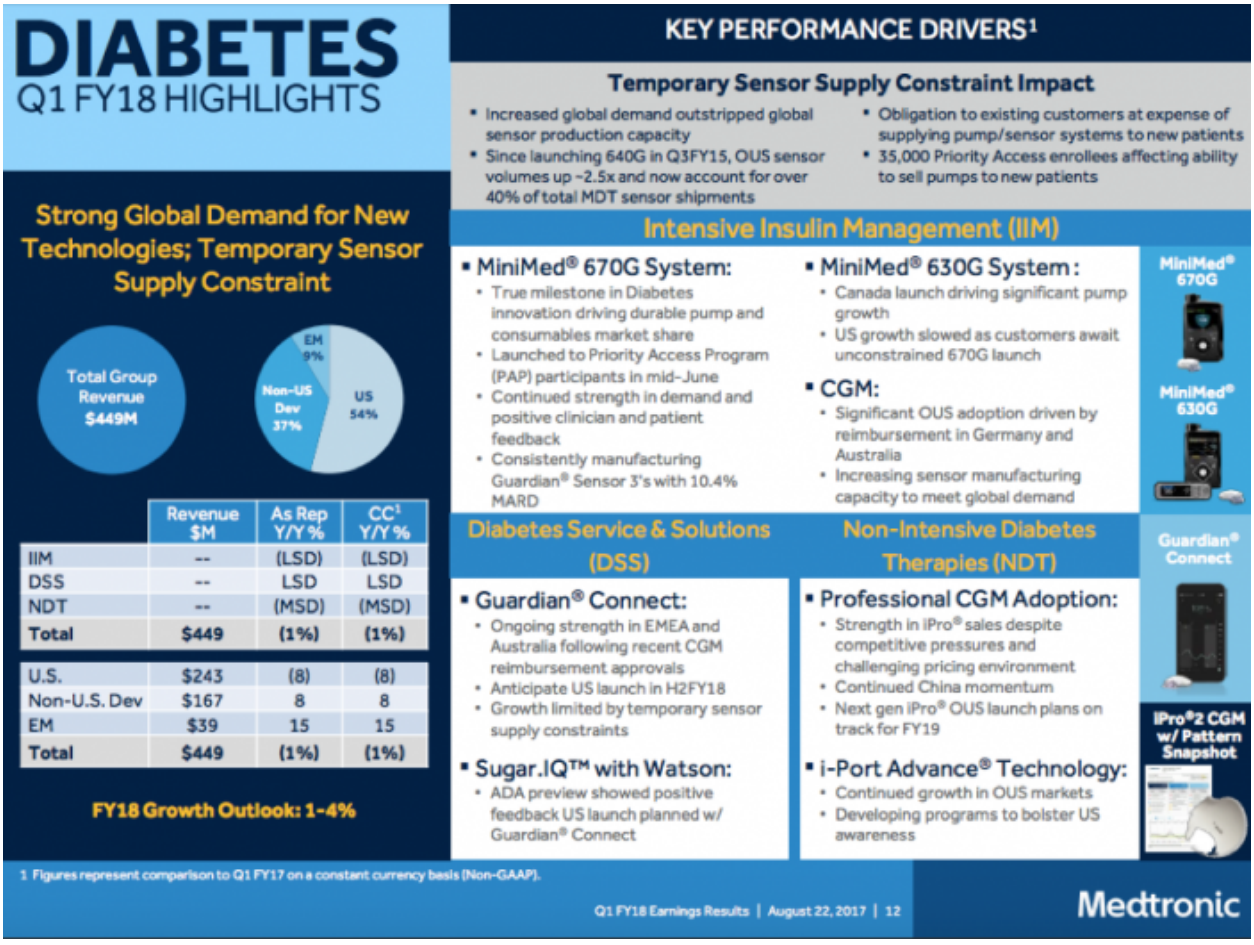


Sensor Shortage/MiniMed 670G Launch Highlights

1. The "temporary sensor supply constraint" first reported in mid-June - a result of higher-than-expected global demand for Medtronic's sensors- has stymied new shipments. CFO Ms. Karen Parkhill suggested that sensor supply will be increased in the fourth quarter (i.e. February-April 2018). There were a number of questions targeting the shortage in Q&A, during which Mr. Ishrak stated that "the major variable is just the FDA approval" for the manufacturing lines - the line is a replica of an existing one, so we imagine FDA review would be rather quick, but it is still expected to be at least four months before it is up and running. This could reflect the complexity of the components and equipment involved, the time for vendors to build, install, and test the equipment, and finally regulatory certification. The process typically takes 16 months, but Medtronic hopes it will take 13 months and be fully operational by April 2018. The increased demand stems from a number of sources: (i) Management shared that, in the 10 quarters since 640G launched outside the US (in F3Q15), sensor demand has doubled (including 50% installed base growth this quarter); (ii) 670G Priority Access Program enrollment has exceeded expectations (~35,000 participants; higher than the expected 20,000+); (iii) Increased CGM coverage by health systems and adoption outside of the US (including Germany and Australia). In the meantime, the company is prioritizing supplying the installed base, meaning that sales to new customers (and the associated revenue) will be affected in the near-term. A spokesperson told us last month: "As soon as we became aware of the increased demand, we immediately worked to increase our manufacturing capacity with new and expanded lines as well as additional shifts that are operating around the clock. Unfortunately, ramping up production particularly for sensors isn't something that can be executed quickly due to the complexity of the components involved and the regulatory certifications required of the manufacturing process." We had actually not even realized the new line needed approval, which suggests that manufacturing changes are bigger than we realized - and, it sounds, bigger than Medtronic realized. It's obviously never good to under-supply, but given that sensors are critical to the success of Medtronic's SAP/closed loop systems, as well as competition with Dexcom and Abbott in the standalone CGM field, this backlog could be particularly impactful.

- **In Q&A, Mr. Ishrak assured that manufacturing process/quality is not a concern:** "It is not an issue of yield at all. The yield is perfectly good and in line with our expectations…So that is really not the issue at all. We're extremely confident in our manufacturing, the process, the yields, and resulting in much more accurate sensor performance. This is purely an issue of acquiring capital equipment that needs to be approved by the FDA and put in place, and when that happens, we will release sensor capacity. This has got nothing to do with any yield differentials of any sort or a need for cycling sensors any quicker than is normally expected."
- **A supply gap for Medtronic is not only impactful financially in the short-term, but also may be reflected in competitive dynamics with the likes of Insulet and Tandem.** Insulet expects to launch a hybrid closed loop system in 2019, while Tandem expects to launch a PLGS system in 2018 and a hypoglycemia-hyperglycemia minimizer by the end of 2018. Though Medtronic is still well ahead of the rest of the pack, these supply constraints may effectively set them back - first-to-market status is less meaningful if access is limited. In the near-term, patients in line for 670G may be inclined to switch to Tandem with G5 (once approved; expected any day now), and then update via remote software update once the advanced algorithms are released. For others, the delay in access may be enough to tip the balance in favor of a different system with different features (e.g., Insulet's tubeless, smaller, disposable model). Notably, both Tandem and Insulet will use Dexcom CGM.
- **This does not come as a surprise, given the continued very deliberate rollout of the MiniMed 670G as part of the Priority Access Program** - Dr. Fran Kaufman said at Keystone last week that ~1,000 patients are on the device, implying only a couple hundred additional systems have been shipped beyond the ~750-person Customer Training Phase. Interestingly, the Priority Access Program FAQ page says MiniMed 670G pump and transmitters will be shipped first, followed by a separate Guardian Sensor 3 package between 30-90 days after the pump shipment.

2. Currently, "close to 35,000" people are enrolled in the MiniMed 630G to 670G Priority Access Program, up significantly from 20,000+ as of last quarter. [Prepared remarks suggested ~32,000, but the company has since confirmed it is closer to 35,000.] Management noted this is ~30% higher than expected. According to Mr. Ishrak, fulfillment to all of the Priority Access customers is expected "later this fall," and Ms. Parkhill added that shipments to non-Priority Access customers could begin in F3Q18 (November 2017-January 2018; more specific than the previously-shared "later in FY18"). Based on the sensor shortage and the fact that, as of a month ago, only ~250 patients had received shipments beyond the ~750 in the consumer training phase, we'd note that these goals are extremely ambitious given the pace of launch thus far. Regardless, enrollment in the Program is definitely higher than expectations - both ours from March (~5,000-15,000) and Medtronic's last quarter - a positive sign for pent up demand for the 670G. Medtronic will prioritize supplying these existing customers at the expense of taking on new patients, though there is an option to purchase the pump and wait for the sensors - Mr. Ishrak conceded that not many patients would be willing to go that route.

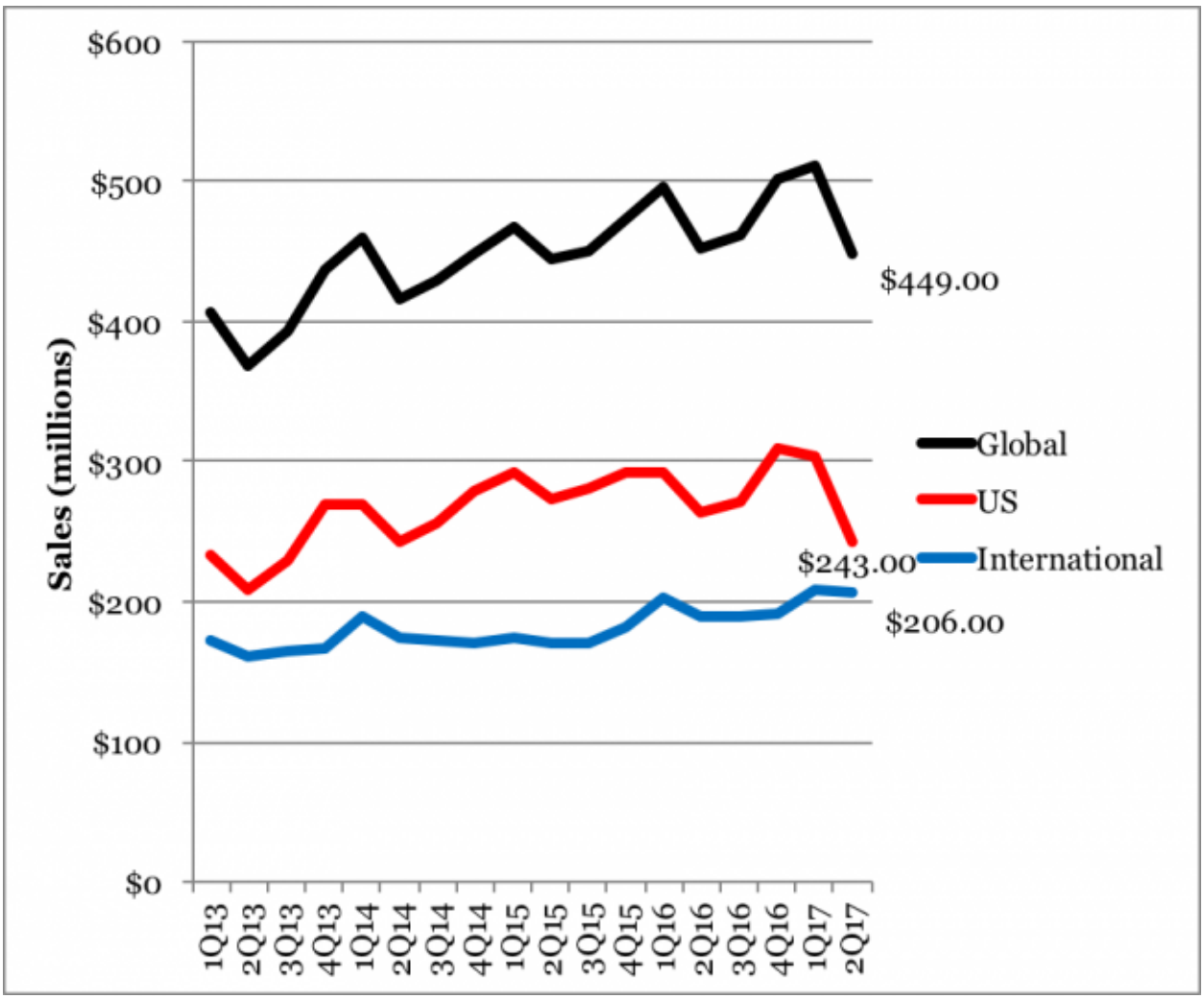
- **At Keystone, Diabetes CMO Dr. Fran Kaufman shared that the Medtronic team goes into CareLink every week to look for signals that 670G behaves differently in the real world from how it did in the pivotal study.** Based on the most up-to-date data (>24,000 patient days; n=730), time in auto mode, time in ranges, and mean sensor glucose values still strongly resemble that seen in the pivotal trial. If anything, as operators gain more experience, it may be that time in target is actually creeping up (72% in the pivotal and 76% now).
- **Dr. Kaufman also provided a number of updates on the 670G clinical trial program at Keystone in July:**
  - **As of Keystone, the 7-13 year-old study is almost complete and data will be ready "soon."** This is on track with timing for a mid-summer readout shared by Dr. Robert Vigersky at ENDO - he also suggested that data would be submitted to FDA by the end of the year. The trial enrolled 110 patients, 64 of which are in a continued access phase. Dr. Kaufman didn't share glycemic outcomes data, but she did say that in a total of 16,200 patient-days (36 patient-years), the safety profile is equivalent to that seen in previous studies.
  - **The 1,000-patient RCT - "the biggest and most complicated trial [Medtronic] has ever done" - had begun the process of randomization as of Keystone.** As a reminder, this multi-national trial (US, Canada, and the EU) will randomize patients to 670G, CSII, MDI, or SAP for six months, followed by six months during which every patient uses 670G. People of all ages and durations of diabetes will be included in the trial, though the study cohort will be enriched for the Medicare population - Medtronic hopes this will help its case for reimbursement. The only people excluded from participation are those on dialysis, those who have had a severe cardiac event in the past year, and those recently diagnosed who are still in the honeymoon phase. According to CT.gov, this trial isn't expected to read out until mid-to-late 2021. We hope interim readouts are possible, since the technology will have moved a long way four years from now!
  - **As of mid-July, there were 10 patients enrolled in the 2-6 year-old 670G trial.** The plan is to enroll 25 patients in the 5-6 year-old group and 25 in the 2-4 year old group. Great to see this moving quickly, since many parents would probably welcome a better night of sleep. The system is currently approved for ages 14+, and requires patients to have a minimum daily dose of eight units, though we assume this is because it has not been tested in these populations; that said, perhaps some modifications will need to be made for a safer device in these super tough populations.
  - **A Stanford study examining the clinical startup of 670G is listed on clinicaltrials.gov as "not yet recruiting."** Investigators aim to track 100 patients' time in auto mode and time in range over a one year period to assess the clinical approach to starting the system. This could lead to improved guidelines for initiation. We love this, since it's a major concern of several providers we've talked to.

Financial and Business Highlights

3. Medtronic's Worldwide 2Q17 Diabetes revenue of $449 million fell 1% year-over-year (YOY) as reported and operationally - this is the lowest total in two years and the first year-over-year (YOY) decline in over a decade. That the lowest total in two years comes when Medtronic is launching a major new product is not a good sign for the business. Reported growth came on an easy comparison (up 2% in 2Q16), while operational growth was higher a year ago (up high single digits). Sales fell 12% sequentially from a record-high in 1Q17. Although management implied that weakness in the quarter was largely expected due to the previously-disclosed issues over sensor production, we certainly had not expected this weak a quarter.

- **Notably, management now expects 1%-4% YOY Diabetes growth in FY18 (May 2017-April 2018), a highly significant drop-off from the ambitious 10%-12% growth they guided for in F4Q17.** We are surprised that the company was so far off just three months ago - presumably the sensor existed at that time and this is a very notable downtick in expectations. It's also possible that this quarter's adjustment could reflect some conservatism. Management expects revenue to decline sequentially again in F2Q18 before improving in the back half of the year due to less deferred revenue recognition in F2Q18 (more Priority Access pump shipments occurred this quarter), and new 670G sales are expected to be "muted" until sensor production accelerates. That said, the company anticipates entering FY19 with "strong double-digit growth" - we'd note that Medtronic has not seen sustained double-digit growth since 2014.
- **Impressively, global CGM revenue grew in the low-20% range for the second straight quarter, including growth of nearly 50% in international markets.** Last quarter, the company estimated share gain of 4-percentage points in durable pumps in the US on 20% growth in direct US pump shipments - we'd guess the gains came mostly from Animas and Roche pumpers. No specific numbers on the pump side were shared this quarter.

FIGURE 1: MEDTRONIC WORLDWIDE, US, AND INTERNATIONAL QUARTERLY SALES (1Q13-2Q17)



4. US Diabetes sales totaled $243 million in 2Q17, falling 8% YOY on a very easy comparison to -4% growth one year ago. 8% is easily the largest YOY decline in our model, which goes back to 2005 in its current form - and we were certainly watching Medtronic's acquisition of MiniMed closely (back in the day, they expected 30% growth from a much lower base). Sequentially, US revenue fell an astounding 20%. Some of this relates of course to how the revenue is booked, but this was presumably part of the projection. We expected some deceleration from previous quarters given high number of signups for the Priority Access Program and the continued wait for the full 670G rollout, but the sensor shortage caused significant damage. Mr. Ishrak forecasted further slowdown "in the next quarter or so," though on the plus side, Medtronic has a broader rollout of 670G (possibly beginning as soon as November 2017-January 2018) and a launch of the standalone Guardian Connect mobile CGM ("later this year" according to management on the call; November 2017-April 2018 according to a Medtronic rep) coming.

5. International sales of $206 million grew 9% YOY as reported, including 8% operationally in developed markets ($167 million) and 15% operationally in emerging markets ($39 million). The 640G continues to do well outside the US (sensor volumes up ~2.5x and now account for over 40% of total MDT sensor shipments since F3Q15 640G launch - obviously massive growth from lower bases), while the new Guardian Connect standalone mobile CGM has seen "strong adoption." Sales fell 1.5% sequentially from a record 1Q17.

6. The intensive insulin management division declined in the low-single digits operationally, due to mid-teens declines in the US related to the sensor shortage according to management. On the flip side, the division saw high-teens operational growth internationally due to the strength of 640G and sensors (CGM revenue for the quarter grew "nearly 50%" in international markets.) This is a departure from the past two quarters, which featured low double-digit growth in the US and high-single digit growth outside of the US. The slide noted 670G demand and positive clinician/patient feedback, Canadian 630G launch driving pump growth, and significant international CGM adoption (driven by Germany and Australia) and increasing sensor manufacturing capacity.

7. Sales in the Diabetes Service and Solutions division grew in the low-single digits operationally driven by patient engagement programs (no details provided) in the US and the Guardian Connect mobile CGM system internationally. Notably, a US launch of Guardian Connect is expected in November 2017-April 2018 (F2H18), though Diabetes President Mr. Hooman Hakami said the company is still working with FDA. The system has been under FDA review for well over a year and seems to be taking longer than Medtronic expected at JPM, when timing was May-October launch. Further international growth was presumably impeded by sensor supply constraints. The MiniMed Pro-set was not mentioned anywhere on the call or in prepared remarks, though BD indicated on its 2Q17 call that a re-launch could occur between October 2017-September 2018.

8. Sales in the non-intensive diabetes therapies division declined in the mid-single digits operationally. This was the second consecutive YOY decline for this segment, a first in the two years since growth has been disclosed. The decline was not characterized, and the slides noted positives: (i) the division grew in the mid-single digits in the US on PCP sales of the iPro2 Professional CGM with Pattern Snapshot despite competitive pressures (from the likes of Abbott's FreeStyle Libre Pro) and a challenging pricing environment; (ii) continued momentum in China for professional CGM adoption; (iii) the i-Port Advance injection port continues to grow outside the US; and (iv) Medtronic is developing programs to bolster US awareness. Presumably it was professional CGM outside the US that drove the quarter's decline, or perhaps weaker US growth than it has seen in the past. We think the professional CGM arena can be much larger; like with the services arena, the margins are on average lower here since they aren't selling pumps and sets nearly as much.

- **This is the smallest of Medtronic's three divisions and growth in this business has slowed in recent quarters. Has Abbott's FreeStyle Libre Pro cannibalized some of Medtronic's type 2 professional CGM business, or is the market becoming saturated in terms of the clinicians that Medtronic is reaching right now?** As a reminder, Libre Pro launched last fall in the US and has been available in places like India for some time. The 14-day, factory calibrated sensor is a substantially better product than iPro2 on pretty much every product dimension - cost, prescribing/setup hassle, patient burden, wear time, calibration and disinfection (none needed), etc.
- **In Q&A, an analyst asked if Medtronic will focus solely on the consumer side** - Mr. Hakami politely responded that this would not be part of the company's strategy.

Other Pipeline Highlights

9. Both Mr. Ishrak and Mr. Hakami indicated plans to launch Guardian Connect, which is still under FDA review, in the US in tandem with IBM Watson-partnered Sugar.IQ "later this year." A Medtronic rep told us a more conservative November 2017-April 2018 (F2H18) over email. This product has been quite delayed from JPM, when a US launch was expected in May-October - it was submitted in March 2016. Guardian Connect has now been with FDA for over a year, and the planned concurrent release with Sugar.IQ could explain the lengthy review (submission in March 2016 amounts to ~15 months with FDA). We wonder if a launch will be limited or delayed until the new manufacturing line is operational.

- **A Medtronic rep indicated that the Sugar.IQ limited learning launch consisted of 250 patients.** The slide deck called out the positive Sugar.IQ app (with IBM Watson) data (n=81) presented at ADA: Relative to baseline metrics (one month prior), this small group of Sugar.IQ users

has experienced a solid 37-minute/day improvement in time-in-range, an 11% reduction in sustained hypoglycemia, and an 8% drop in sustained hyperglycemia. We can't for a wider group of patients to try this app.

10. Slides showed that a "next-gen iPro" product will launch in FY19 (May 2018-April 2019) outside the US. This is presumably iPro3 (per the 2016 Analyst Day), which will be "Single-use," blinded, and have an expected MARD of ~11%. Last quarter, the slides showed that a next-gen iPro would launch in FY**18**, a year earlier. Medtronic has since confirmed that the sensor in question is indeed iPro3, which is now delayed by ~one year. We wonder if this also pushes back the timelines for iPro4 (previously by April 2019) and iPro5 (previously April 2019-April 2020).

11. The MiniMed Pro-set with partner BD was not mentioned on the call, slides, or in prepared remarks. BD's 2Q17 call noted that launch will resume in FY18 (October 2017-September 2018). An ongoing clinical trial to optimize user training materials provided in the product packaging is "going exactly as planned."

12. Mr. Ishrak proudly referenced Medtronic's outcomes-based deal with Aetna: If MDI users moving to pumps don't achieve a certain A1c benefit, Aetna gets a rebate. This deal represents an initial foray into outcomes-based reimbursement for pumps, since Medtronic will be paid whether it achieves outcomes or not. Short term, we don't imagine it will have a major impact on the commercial environment, but longer term, we expect the payer environment will increasingly be the battleground on which diabetes technology is fought.

- **We think much of Medtronic's work on value-based healthcare is very smart.** As such, competitors will welcome the fact that the exciting new pump is just not available to so many people (management even acknowledged few would pursue it actively without sensor availability); we wonder what United is going to do and we imagine they will have to be more open with new patients going on the pump who want to use Dexcom sensors and multiple other pumps (UHC selected Medtronic as its preferred provider of pumps last May). Dexcom is also focused on type 1 and type 2, and has discussed alternate business models on its calls. We believe these models will move slowly, and it's not clear how much of a growth driver they will be for Medtronic, nor how they will play competitively with Dexcom and Abbott.
- **During Q&A, Mr. Ishrak spoke at length about value-based care (not specifically in diabetes):** "I think there's general encouragement to move more towards value-based payments. And I think it's not only CMS, the commercial payers are also looking at it in that dimension. At the end of the day, value-based health care is around improving outcomes at a lower cost. And I think that trajectory is not going to change…I think with respect to the industry, look, value-based care is where the industry's got to move to. Consolidation gives you a capability to have a seat at the table. It gives you more assets to use to deliver value-based health care because you probably need a variety of capabilities to do so."

Questions and Answers

Q: Obviously, there's going to be a lot of focus on the Diabetes business in the step down to the outlook for the year. So, can you just spend a little bit more time on what's going on with the sensors and why now we're looking at a backlog all the way out to the fiscal fourth quarter versus previously fall? Thanks.

Mr. Ishrak: From Diabetes, look, what's happened is that our success rate with our products, which all now have sensors, has actually been very high, not only with the 670G here in the U.S. but also with the 640G which we launched in Europe roughly two years ago. And that, plus the Guardian Connect in Europe, has really gained traction. And what's happened is the demand for the sensor really grows by multiple factors compared to just pump revenue because for every pump, you need to supply sensors for the whole year and on an ongoing basis. And so when you do that demand equation, that number comes to be a very large number. And although we're accelerating plans to add a new line, it just takes a little longer than one would want. I think that's all I can say, that the attachment rates are much higher than previously envisaged, that even a

short while ago we were planning. The number of customers who want the Priority Access for 670G is also significantly higher than we were expecting. All of this leads to a multiplication of the number of sensors that are required. And when you do the math, it just comes to a very large number which we just couldn't fulfill immediately. But having said that, these are all things that are in our control and we are pretty confident that by the end of the year, we'll be able to take advantage of these new products which actually we've been driving to and are pretty revolutionary in their own right.

Weinstein: It appears part of the problem is that as you're moving to a lower MARD, it's harder to manufacture the sensors. We all are aware of that. But it sounds like the yields aren't as good and that the reliability in terms of the life of the sensors isn't as good so you have to include an extra sensor in the packets that you're shipping out. Can you comment on that?

Mr. Ishrak: It is not an issue of yield at all. The yield is perfectly good and in line with our expectations and the number of sensors that are required or the standard number of sensors that we expect for patients to cycle through. So that is really not the issue at all. We're extremely confident in our manufacturing, the process, the yields and resulting in much more accurate sensor performance. And this is purely an issue of acquiring capital equipment that needs to be approved by the FDA and put in place. And when that happens, we will release sensor capacity. This has got nothing to do with any yield differential of any sort or a need for cycle these sensors any quicker than is normally expected.

Mr. Hakami: The only thing I would just add to that, if you really take a look at what Omar mentioned with respect to the dynamics, this is purely a function of increased demand, not manufacturing output or manufacturing performance. And maybe two statistics to keep in mind, you heard in the commentary our installed base demand for sensors in Europe was 50%, 5-0%. We were expecting growth in Europe but 50% was more sensor utilization than what we were expecting. The second that you heard from the commentary is that there were 32,000 Priority Access patients that signed up, that was a 30% increase versus what we expected. So, this is purely a function of increased demand not, as Omar pointed out, of anything to do with yields or lower margin. Our margins are great. Our yields are totally in line with expectation. It's just our ability to meet demand and this is a temporary thing.

Ms. Parkhill: Keep in mind that our diabetes patients on the 640G do not need to use the sensor attached, but they are choosing to use it more and more often because of the accuracy with that sensor and that is one of the reasons that the demand was higher than we originally anticipated.

Q: On Diabetes, it sounds like the demand is just more overwhelmingly positive. Has this changed your mind from a strategic perspective as far as the background in terms of wanting to change your thoughts on going more from a consumer level? Because if you have 30% more demand for using the 640G with the sensors, why not think about going more just to a consumer basis and not going more the professional route?

Mr. Hakami: It is purely a demand equation. And as you rightly pointed out, we have our Enlite 1 sensor, our Enlite Enhanced sensor, our Guardian Sensor 3, all of those are experiencing strong demand, which as Omar and Karen mentioned, we are working to fill the capacity in order to meet that demand. It doesn't change our strategy overall, number one. So strategically, actually this increased demand means the strategy is working with respect to sensor-augmented systems. And then as far as personal versus professional CGM, I would say two things. One, as Karen and Omar alluded to in the commentary, we are still working with the FDA for the launch of our own personal CGM, which hopefully happen this year, the Guardian Connect sensor with Sugar.IQ. That's number one. And on top of that, we continue to go down the path within our non-intensive type 2 business to drive professional CGM more aggressively through primary care physicians. So we're pursuing all three of these angles, and that's been the strategy and we will continue to drive that strategy. It's not the yield, it's capacity to meet the demand.

Q: As you're moving toward getting this new line up and running and adding that capacity, can you help us understand what the gating factors are in terms of predicting that timing or what

the bottlenecks could be with setting up that new line and what could push that time line back or forward, if there's some conservatism in that guidance?

Mr. Ishrak: The major variable here is just the FDA approval that we need for the capital equipment that's needed for the line. The rest of it is pretty straightforward. We're replicating a line that - a process that we know how to do. And then, there's some level of things out of our control - is the FDA time cycle for approval. It's not anything that's different from what we've got approved in the past, and we expect this to go okay. But it is something that's out of our control, and I think that's the major factor in getting the line up.

Mr. Hakami: We know the equipment. We know the process. So, bringing the equipment in, doing all of the qualifications, that's something we feel very comfortable with. Then, there's obviously the variable of turning all of that over to the FDA and seeking their approval. So, as Omar pointed out, that's the single biggest variable in this that has uncertainty around it. The other elements, we feel very good about

Mr. Ishrak: And just to make it clear, we have gotten approval for this kind of stuff from the FDA in the past without any issues. So, there's nothing that's any different, but it is something that needs approval.

Pipeline Summary

PUMP, AUTOMATED INSULIN DELIVERY, AND INFUSION SETS

Pump/Infusion Set Pipeline Product	Latest Timeline
MiniMed 670G with Guardian Sensor 3 *Hybrid closed loop*	Priority Access Program launched in June, now with ~35,000 enrollees. Fulfillment expected later in the fall. Launch to non-Priority Access customers "in the third quarter" (November 2017-January 2018). International launch previously expected in May-October 2017 (not mentioned today) As of mid-July, pediatric pivotal clinical trial (7-13 years) is almost complete and data will be ready "soon." 1,000-patient RCT - "the biggest and most complicated trial [Medtronic] has ever done" - has begun the process of randomization. As of mid-July, there were 10 patients enrolled in the 2-6 year-old 670G trial.
MiniMed Pro-set Infusion Set with BD's FlowSmart technology	Limited launch began in September, but shipments halted in January due to higher-than-anticipated complaints associated with insertion. According to BD's F3Q17 call, launch to resume in FY18.
Future Bluetooth-enabled pumps incorporating Roche Accu-Chek Guide Link BGM	No official timing shared by Medtronic. A Roche webinar suggested that this could launch in mid-2018, but Medtronic has never confirmed this.
Advanced Hybrid Closed Loop (Formerly called the MiniMed 690G) *Incorporating DreaMed MD-Logic algorithm to add automatic correction boluses*	Feasibility study shared at ATTD 2017. NIH funded IDC/Schneider Children's Hospital study to start later in 2017 and compare to 670G. Not FDA submission or launch timing shared.

Other infusion set innovations: - An extended wear set - Two different CGM-insulin delivery combo sets - Two unknown innovations ("SC2," "Solo")	Over next three years (per the June 2016 Analyst Day)
Next-gen Advanced Hybrid Closed loop *Smaller touchscreen-looking pump with smartphone control, an algorithm that performs automatic bolus corrections, and "biometric," "multi-parameter" sensing*	May 2020+ (per the June 2016 Analyst Day)

CGM SENSOR PIPELINE (PERSONAL AND PROFESSIONAL)

CGM Pipeline Product	Latest Timeline
Guardian Connect standalone mobile CGM *Bluetooth-enabled transmitter, Enlite 2 (OUS) or Guardian Sensor 3 (US).*	Launched outside the US (EMEA, APAC). FDA PMA submission in March 2016, approval previously expected in April/May 2017. US launch now expected in F2H18 (November 2017-April 2018), in tandem with Sugar.IQ.
iPro 3 Professional CGM *"Single-use," blinded, MARD of ~11%.*	OUS launch in FY19 according to the slide deck today, a meaningful delay from previously-stated FY18.
Harmony 1 personal CGM sensor *10% MARD, 10-day wear, one calibration per day, 90-minute warm up, redundancy via two sensor flexes*	Pivotal trial previously expected in 1H17, launch by April 2019 (per the June 2016 Analyst Day).
iPro 4 Professional CGM *Adds real-time data to iPro 3*	Launch by April 2019 (per the June 2016 Analyst Day). We imagine this could be pushed back based on the iPro3 delay.
iPro 5 *Slim, round bandage-looking; seven-day wear, <10% MARD*	Launch by April 2019-April 2020 (per the June 2016 Analyst Day). We imagine this could be pushed back based on the iPro3 delay.
Harmony 2 Personal CGM sensor *<10% MARD, 30% reduced size, and "additional biometrics"*	Launch by April 2020 (per the June 2016 Analyst Day)
Combo seven-day CGM-insulin infusion set	Launch by April 2021 (per the June 2016 Analyst Day)

DATA ANALYTICS AND CONNECTIVITY PIPELINE

Data/Connectivity Pipeline Product	Latest Timeline

IBM Watson app, Sugar.IQ Gen 1 ("Personal Diabetes Assistant") *Analyzes retrospective data: "How have I been doing?"*	US launch "later this year" with Guardian Connect per today's call. Positive feedback from patient preview; first data from "limited learning launch" (n=81) presented at ADA. Per JPM, a US launch was expected in May-October.
Fitbit partnership for professional CGM	myLog mobile app launched **in December** to capture exercise, food, fingerstick data while wearing iPro2.
Turning Point Program with IBM Watson *Bluetooth-enabled BGM, a patient mobile app, a one-on-one health coach, clinical decision support for PCPs, and optional iPro2 to help patients with uncontrolled diabetes.*	Went live in F3Q17. Initial pilot data reported at ATTD demonstrated 2.0% A1c reduction from a 10.1% baseline in n=35 completers (view the poster here).
mySugr-CareLink integration for pump/CGM data management	Partnership announced in a mySugr industry update in November, but no launch timing shared.
Next-gen CareLink Pro reports, including analytics to optimize pump basal and bolus settings	No recent updates. Launch previously expected last summer (per ADA 2016).
IBM Watson app, Sugar.IQ Gen 2 *Adds glucose prediction: "How will I be doing?"*	Previously slated to launch in ~Summer 2017 (per the June 2016 Analyst Day), but seems unlikely.
Provider CGM Analytics: Outcomes Snapshot *Population health, quality metrics, benchmarking*	Launch by April 2018 (per the June 2016 Analyst Day)
IBM Watson app, Sugar.IQ Gen 3 *Adds therapy dialogue Q&A: "Watson, what should I be doing?"*	Launching in ~Summer 2018 (per the June 2016 Analyst Day)
Provider CGM Analytics: Patient Snapshot *Personalized care plans via proCGM and Biometrics*	Launch by April 2020 (per the June 2016 Analyst Day)

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