Closer Look

MEMORANDUM

Medtronic F3Q13 - Diabetes up 3%, with US down 1%; MiniMed 530G approval in late spring/summer; MiniMed 640G EU launch this summer - February 19, 2013

Executive Highlights

- Worldwide diabetes revenues of $377 million represented 3% reported and operational growth. US sales were down 1%, while international sales grew 9% as reported and 11% operationally.
- FDA approval of the MiniMed 530G is expected "later this spring or summer," back from previous estimates of approval by April 2013. Launch of the MiniMed 640G is expected in the EU this summer.

In a call led by CEO Omar Ishrak, Medtronic reported F3Q13 results this morning. Worldwide diabetes revenues totaled $377 million, representing 3% reported growth and 3% operational growth from $367 million in F3Q13. This marked the third straight quarter of growth <3%, compared to much stronger FY12 quarterly growth numbers ranging from 8-17%. Sequentially, worldwide F3Q13 revenues declined 0.3%. In the US, sales of $223 million represented a 1% decline, "as US consumers continued to wait for FDA approval of the MiniMed 530G insulin pump and Enlite sensor". This is the first time diabetes growth has been negative in the US since 2007. Management noted that the company "faced some near- term pressure in the US," though growth is expected to return once the MiniMed 530G is approved. Outside the United States, sales in F3Q13 grew 9% as reported and 11% operationally to a record-tying

$154 million, "although insulin pump growth slowed somewhat in Western Europe." Remarks attributed the slower performance to consumers awaiting the launch of the MiniMed 640G this summer. We assume this is a qualitative judgment, given that this seems challenging to measure in practice, though the sales force no doubt picks up anecdotal trends. For the fourth straight quarter, Medtronic saw double-digit growth in CGM - in Q&A, management emphasized that CGM is not seeing any slowdown, and it's really the pump side of the equation (especially in the US) that has been more challenging.

Medtronic "hopes" FDA approval of the MiniMed 530G will occur "later this spring or summer" - this could represent a delay from previous timelines, which consistently called for approval by late FY13 (which ends in April 2013). Of course, it could also be just uncertainty a bit given an unpredictable regulatory environment. In response to an analyst question about another round of FDA questions, CEO Omar Ishrak was vague, only noting that "we're working with the FDA closely and we're pretty optimistic that we'll get [approval] in the next few months." Indeed, Medtronic actually deferred $9 million in US revenue this quarter, as the company plans to convert some of the recently sold pumps to the MiniMed 530G once it is approved - we would guess this wouldn't have been done unless management truly believed approval was imminent. Still, the late FY13 timeline has felt ambitious. We do recall sensing FDA was turning around and trying to speed approvals for patients in areas like diabetes. The delay is a certainly a negative for patients in the US - patients in the UK have had the VEO since 2009. The product pipeline is moving faster in Europe, where launch of the MiniMed 640G predictive low glucose management (PLGM) pump is expected this summer (on par with the early FY14 timeline outlined in the F3Q12 call). Management did not give updates on the EU launch of the Sentrino in-hospital CGM (CE Marked on December 3, 2012, with a controlled rollout in Europe starting immediately in the UK and Germany). On the clinical trial front, Medtronic recently posted a new study that will test an integrated CGM sensor and infusion set (ClinicalTrials.gov Identifier: NCT01775059). Additionally, the company is a collaborator on a notable new closed-loop study testing liraglutide in type 1 with the Medtronic ePID system/Enlite CGM. So much interesting is happening!

FINANCIALS

- **F3Q13 worldwide Diabetes revenue of $377 million grew 3%, driven by double-digit growth in CGM.** This marks three straight quarters of <3% reported growth, a trend we have not ever seen in the last eight years of tracking Medtronic's diabetes revenue. F3Q13 operational performance also marked a noticeable downtick from the 6-8% growth in the prior four quarters.

	F3Q12	F4Q12	F1Q13	F2Q13	F3Q13
Worldwide Sales (millions)	$367	$392	$364	$378	$377
Year-on-Year Reported Growth	7.6%	6.5%	2.5%	3.0%	2.7%
Year-on-Year Operational Growth	8%	8%	6%	6%	3%

- **Sequentially, worldwide revenues declined 0.3% from F2Q13 sales of $378 million.** This was mainly due to US performance, which was down 3% sequentially, compared to positive 3% sequential growth internationally.

	F3Q12	F4Q12	F1Q13	F2Q13	F3Q13
Worldwide Sales (millions)	$367	$392	$364	$378	$377
Sequential Growth	0%	6.8%	-7.1%	3.8%	-0.3%

- **Growth in the US declined 1%, while the international revenues rose 9% as reported and 11% operationally; this continued a two-year trend of relatively stronger international growth** (albeit from a lower base). Management attributed the lackluster US performance to US consumers awaiting FDA approval of the MiniMed 530G insulin pump and Enlite sensor. We think this is true, though in practice, we believe it's hard to actually track how much sales are impacted by consumers waiting on FDA approval. Certainly, however, anecdotally, we would not be surprised to learn that patients do not want to accept an "older" model, especially when they know the current model in Europe has been approved for many years (since 2009). On an interesting note, Medtronic deferred $9 million in US revenue during the quarter, as the company plans to convert some of the recently sold pumps to the MiniMed 530G once it is approved. We have not seen this happen before and assume it conveys confidence that the 530G will be approved shortly. Although growth outside the US was a strong 9% (11% operationally), management noted that "insulin pump growth slowed somewhat in Western Europe." Like the US, this was attributed to consumers awaiting the launch of a new product (in this case, the MiniMed 640G).
    - **Based on historical performance, launch of the MiniMed 530G is expected to reaccelerate growth in the US**. As a reminder, the international launch of the Veo and Enlite were accompanied by a doubling in Medtronic's growth rate in insulin pumps (10% to 20%) and CGM (~20% to 49%).

Year-on-Year Sales (Reported) by Geography					
	F3Q12	**F4Q12**	**F1Q13**	**F2Q13**	**F3Q13**
US Sales Growth	3.2%	4.4%	0.5%	0.4%	-1.3%
International Sales Growth	15.6%	10%	5.7%	7.2%	9.2%

International Contribution to Overall Growth	73.1%	58.3%	88.9%	90.9%	100%

PRODUCT PIPELINE

- **FDA approval of the MiniMed 530G low glucose suspend pump/Enlite sensor (the US version of the Veo) is now expected "later this spring or summer."** In the F2Q13 call, management called for approval in "late FY13," which ends in April 2013. We cannot be sure if this is a delay, or perhaps management just hedging slightly given the uncertain regulatory process. As a reminder, the PMA for the MiniMed 530G was submitted to the FDA in June 2012. The submission includes data from the in-clinic ASPIRE study and the six-day study of the Enlite sensor. The in-home ASPIRE study (n=260; ClinicalTrials.gov Identifier: NCT01497938) is no longer recruiting participants, and is still slated to conclude in June 2013. We wonder if FDA will ask to see the data from this ongoing study before approving the device. Originally, we had thought that the FDA was requiring the data from this trial before approval.
- **Medtronic plans to launch the MiniMed 640G predictive low glucose management (PLGM) pump this summer in western Europe, consistent with previous estimates.** Based on the slides shown at the June Analyst Day, we believe the MiniMed 640G will have a color screen and updated form factor. See slide #26 at http://www.closeconcerns.com/knowledgebase/r/5295029f.
    - **Simulation data suggests the new PLGM algorithm can reduce the number of hypoglycemia events (<70 mg/dl) by 18% and the average duration of hypoglycemia by 50%,** a significant improvement over the Veo's corresponding reductions of 1% and 28% - very exciting news in our view if that can really be replicated in human trials. This data is derived from the FDA-approved UVA/Padova computer simulator (n=300) and was presented by Dr. Barry Keenan (Medtronic Diabetes, Northridge, CA) at EASD 2012 (see pages 3-4 of our EASD Diabetes Technology report at http://www.closeconcerns.com/knowledgebase/r/9f88794c). In our view, predictive low glucose management would be very beneficial for patients and represents a very achievable step near-term.
- **Management did not give an update on the Sentrino in-hospital CGM, which received a CE Mark on December 3, 2012.** At the time, a controlled rollout of Sentrino was slated to occur in Europe, starting immediately in the UK and Germany. Medtronic is also working with the FDA to support US commercialization, though there is no timeline yet. The device incorporates redundant sensing (two subcutaneous sensors), a cable, and a bedside monitor.
    - **Patients can wear the Sentrino for up to 72 hours before the sensors need to be replaced.** The device is accurate within 10-15% of reference glucose and is approved for adjunctive use. It is calibrated using the hospital's standard of care blood glucose measurement. Warm-up time is 30 minutes (pretty fast!) and a blood glucose calibration is required upon insertion, at one hour, two hours, eight hours, and then every eight hours thereafter. One hundred patients were studied prior to CE Mark submission, and 50 of them were critically ill patients.
- **Management did not give any updates on the mid-term or long-term diabetes product pipeline.** The near-term pipeline is on track to meet the initial June 2012 Analyst Day forecasts (and in the case of the Sentrino, already has). For more detail, see our complete 2012 Analyst Day report at http://www.closeconcerns.com/knowledgebase/r/cbcebe6a.

Near-Term **May 2012-April 2014**	**Mid-Term** **May 2014-April 2016**	**Long-Term May 2016+**

▪ Medtronic Mini ▪ Med 530G (US)Medtronic MiniMed 640G (EU) ▪ Sentrino Hospital CGM (EU)	▪ Medtronic MiniMed 640G (US) ▪ Next-Gen Enlite ▪ Patch Pump	▪ Optical Sensor ▪ Overnight Closed Loop ▪ Fingerstick Replacement

- **Medtronic has a number of studies currently listed on ClinicalTrials.gov.** The list below only includes relevant diabetes studies that list Medtronic as a collaborator or sponsor. For brevity, we have shortened the list to include the most exciting studies.
    - **"Collection of Performance Data From the Integrated Sensor and Infusion Set. TRIAL 4" (ClinicalTrials.gov Identifier: NCT01775059).** Medtronic Diabetes R&D (Denmark) will test an integrated sensor and infusion set for approximately 15 days, with each subject wearing five sets for three days each. The 50-patient study is expected to start in March 2013 and complete in July 2013. It will take place at three Danish hospitals under PI Dr. Ulrik Pedersen-Bjergaard. We assume this will test a version of Medtronic's Combo-set, which reported encouraging data at ADA 2012 in poster #901. That study showed that insulin pharmacodynamics and CGM accuracy with the Combo- set were comparable to standard, independently located CGM and insulin infusion sites. For more information, see page 73 of our report at http://www.closeconcerns.com/knowledgebase/r/c6afb200.
    - **"Liraglutide Versus Insulin Mono-therapy in the Closed Loop Setting" (ClinicalTrials.gov Identifier: NCT01755416).** Medtronic is a collaborator on this exciting study taking place at the Albert Einstein College of Medicine. Closed-loop control using the Medtronic ePID algorithm and Enlite sensor will be compared with insulin alone or insulin plus injections of liraglutide. The study is currently recruiting 17 participants and has an estimated primary completion date of December 2013. We're veryglad to see closed-loop research expanding into use of GLP-1, since early data has suggested benefits in type 1s. As a reminder, Novo Nordisk expects to start phase 3a for Victoza in type 1 diabetes in 2H13.
    - **"User Evaluation of the MiniMed 620G Insulin Pump" (ClinicalTrials.gov Identifier: NCT01726621).** The objective of this six-center international study is to evaluate user acceptance of the MiniMed 620G insulin pump and Guardian Link Transmitter. We have never heard of the MiniMed 620G, though we assume it differs from the MiniMed 640G predictive low glucose management pump mentioned above - perhaps it has the same updated form factor and design but no predictive algorithms or suspension capabilities. The study was expected to start in January 2013, though it is listed as not yet recruiting participants. It will include 60 patients, and will ask participants to fill out a satisfaction questionnaire after wearing the pump for four to six weeks. The study will take place at King's College London (PI Dr. Pratik Choudhary) and University College Hospital (PI Dr. Peter Hindmarsh).
    - **"Safety and Effectiveness Study of a Closed Loop System Maintaining Patients' Glucose Levels During an Overnight Period" (ClinicalTrials.gov Identifier: NCT01712594).** This study will test an Android-phone-based mobile closed-loop system in 18 participants over two inpatient nights. It is listed as not yet recruiting participants, though was slated to start in January 2013; it has an estimated completion date of December 2014. Patients will remain under closed-loop control overnight (approximately 11 pm-6 am). Interestingly, during one of the closed-loop nights, the system will be challenged by a calibration error of 30%. It's great to see this type of real world challenge

being incorporated into the trial design, especially since FDA has long been skittish about CGM accuracy. The study will take place at King's College London under PI Dr. Pratik Choudhary.

- **"Examining The Role of CGM in T2DM" (ClinicalTrials.gov Identifier: NCT01614262).** Although this study is still listed as not yet recruiting (it was last updated in June 2012), we look very, very forward to seeing results. It is led by principal investigators Drs. John Buse (UNC Chapel Hill, NC) and Bruce Bode (Atlanta Diabetes Associates, Atlanta, GA). The study is notable because the enrolled type 2s are on oral therapies only. The 90-patient trial has an estimated primary completion date of December 2013. For a more thorough review of the trial and recent studies of CGM in type 2 diabetes, see our Medtronic F1Q13 report at http://www.closeconcerns.com/knowledgebase/r/89e500e6.
- **"Outpatient Pump Shutoff Pilot Feasibility and Efficacy Study" (ClinicalTrials.gov Identifier: NCT01591681).** This NIDDK-sponsored, nocturnal outpatient study will evaluate a predictive low glucose suspend system (using an Enlite CGM, Medtronic pump, and laptop driven control algorithm; note this is not the MiniMed 640G) - we are glad to see an impressive list of PIs that includes Drs. Bruce Buckingham, Roy Beck, and Peter Chase. This study is currently recruiting participants and has an estimated completion date of July 2013. For more information on Dr. Bruce Buckingham's previous research of the system, see pages 17-19 of our DTM 2012 Day #2 Highlights report at http://www.closeconcerns.com/knowledgebase/r/53c19846.
- **"Outpatient Study to Evaluate Safety and Effectiveness of the Low Glucose Suspend Feature (ASPIRE)" (ClinicalTrials.gov Identifier: NCT01497938).** The study has a primary completion date of June 2013 and an expected enrollment of 260patients. It is no longer recruiting participants. As a reminder, this is the home study of the MiniMed 530G that FDA had previously asked the company to do prior to submitting the device for approval. That the company was allowed to file prior to completing this study was the biggest news of the June Analyst Day and a real step forward from FDA in our view that should also help other pump companies. Still, we would not be terribly surprised to see the FDA ask for data from this study before making an approval decision.
- **"OpT2mise Glucose Control in Type 2 Diabetes Mellitus (DM) With Insulin Pump Therapy" (ClinicalTrials.gov Identifier: NCT01182493).** The study has a primary completion date of December 2012 and an expected enrollment of 400 patients at 30 centers. It is still listed as recruiting participants as was last updated in March 2012. We cannot wait to see data from this trial and we hope it can be used to change reimbursement policies. As a reminder, many insurers (e.g., Medicare, Aetna) restrict pumps to insulin deficient type 2s - this is not at all forward thinking in our view as we know that insulin use is associated with poor adherence for many patients.

Questions and Answers

Q: On the diabetes business, it sounded like you got a round of questions on the 530G approval. Any sense of the likelihood that pushes out beyond just a three-month turnaround?

A: Well, I can't really say. We're working with the FDA closely and we're pretty optimistic that we'll get it in the next few months. But the regulatory process has unknowns that we cannot control. At this stage, we're working closely with them and expect to achieve a positive outcome.

Q: In diabetes, the US was down 1%, and I know in the pump business, you're being held up by the new approval. How is the disposable business tracking? In your view, is the diabetes market for pumps slowing overall?

A: We're such a big piece of the market, I think we obviously have an impact on that. There are some pressures that the other competitors have also faced, but I think the new pump [i.e., the MiniMed 530G] is a strong enough catalyst that it'll trigger growth in the market - we're a big enough player in that space.

The disposables overall are growing fine. On the CGM margin disposables, we're not seeing any real slowdown there - it's primarily on the pump side of the equation, and we do believe it's related to the fact that people are waiting for the new pump approval, and so that's clearly had an impact.

I think the overall pump market in the US had been somewhat slower, even if you went back over the last year. What we've seen outside the United States, is that when you get this new pump approved, the 530G with its low glucose suspend feature, we've seen that actually reaccelerates the market. We saw that outside the United States in Europe, where we saw double-digit growth for really two years since the pump has been launched. So we are expecting that will accelerate pump growth in the US. And as Omar said, we're such a large part of the market that it clearly will drive market growth.

Q: You gave us a more detail on the acquisition strategy than we've had in prior quarters. How are you thinking about the size of the transaction - we have become comfortable with Medtronic in the last couple of years doing deals that were less than a billion dollars. It sounds like your preference is still emerging markets over developed markets.

A: The goals and the hurdles don't change based on whether it's a geographic broadening acquisition or a new technology acquisition. We really look at three things. First, we look at strategic fit. We've already described our businesses in three groups, the Cardiovascular Group, the Restorative Therapy Group (ortho and spine and diabetes). And we are aiming to fill gaps within these groups. That's one area of strategic focus. As we fill those gaps, we're also looking at acquisitions that can help us deliver economic value - that could mean broadening our focus in the continuum of care, but always related to our therapies. By that I mean looking at businesses that help us identify patients better or more efficiently, as well as patient and management offerings. The other area is globalization. It's primarily at this stage approaching the value segment, although we're quite interested in market growth as well if we see fit. Distribution companies who have got high share, who have credibility in certain marketplaces are also areas that we look at. That's the first thing, the strategic focus.

The second part is it's got to have certain hurdle rates in the mid-teens, and that applied to everybody, no matter who we buy.

And the third is that we've got to cover dilution within the company. And by covering dilution, I mean our goal of delivering mid-single digit growth, with 200-400 basis points of leverage and EPS. We want to protect that despite an acquisition. The acquisition should help us get there rather than get in the way of achieving that. These are the things that we try to look at for an acquisition. The size, if it meets all these criteria, is a secondary factor.

-- by Adam Brown and Kelly Close