Closer Look

MEMORANDUM

Medtronic 2012 Investor Conference - US version of Veo submitted to FDA; major product pipeline updates; 6-9% market growth expected in FY13 - June 1, 2012

Executive Highlights

- Medtronic recently submitted the US version of the Veo pump/Enlite sensor, the MiniMed 530G, to the FDA. This is at least one year ahead of schedule and approval is expected to take around one year.
- The MiniMed 640G, a hypoglycemia minimizer, is expected in early 2013 (EU) and 2014-2015 (US).
- The patch pump is in the final design phase and expected in the two-to-three-year timeframe.
- Medtronic announced a $17 million, three-year partnership with the JDRF-Helmsley Charitable Trust's Sensor initiative to develop a combination glucose oxidase/optical sensor.
- Management expects the worldwide pump and CGM market to grow 6-9% in FY13.

Medtronic held its 2012 investor conference today, featuring presentations from CEO Omar Ishrak, Cardiac and Vascular Group President Mike Coyle, Restorative Therapies Group President Chris O'Connell, and CFO Gary Ellis. Medtronic Diabetes, which "continues to roll," was a major part of Chris O'Connell's presentation. The day's highlights were in the product pipeline discussion - most notably, a PMA has recently been submitted to the FDA for the MiniMed 530G, the US version of the Veo insulin pump and Enlite sensor. This is an exciting development and a significant acceleration over the previous submission timeline of ~2H13 (following the completion of the ongoing outpatient ASPIRE study; clinicaltrials.gov identifier: NCT01497938). We understand that early interaction with the FDA has been favorable and Medtronic expects approval in about a year. Also on the near-term front is the MiniMed 640G, Medtronic's hypoglycemia minimizer, which it plans to launch "later this fiscal year" (early calendar 2013) in Europe. The Sentrino in-hospital CGM is also slated for a European launch in the next one to two years, though like the MiniMed 640G, no specific details were shared on its design.

In the next two to three years, Medtronic expects to launch its patch pump (!), the MiniMed 640G in the US, and a next-generation Enlite sensor. We were especially intrigued to see the update on the patch pump, an area that was characterized as more of a "niche" market at the last analyst day in 2010. At that time, management told investors to expect the product internationally in this past FY2012. It is unsurprising to us that Medtronic is moving this direction, given Insulet's success; the traditional pumps are likely more profitable, at least near term. In terms of the long-term pipeline, Medtronic is targeting its optical sensor, overnight closed loop delivery, and fingerstick replacement four or more years away. Also announced today was a major $17 million commitment from the Helmsley Charitable Trust-JDRF CGM Sensor Initiative, an impressive share of the program's up to $20 million in funding. The three-year partnership will support development of a combination, redundant glucose oxidase/optical sensor - very exciting from an artificial pancreas perspective. In all, Medtronic left little doubt that it has a rich product pipeline and a clear, purposeful drive toward the artificial pancreas.

On the financial side, management gave a conservative market growth estimate of 6-9% for pumps/CGM worldwide in the coming year; we expect them to beat this considering Medtronic Diabetes' 9.9% growth in FY12 and 8.9% growth in FY11. These estimates are down from 2010 analyst day forecasts of 10-12% market growth and 9-11% Medtronic diabetes growth. Notably, Medtronic gave some interesting market estimates:

1) there are 11 million patients around the world that have access to and could use a pump and/or CGM; 2) current global penetration is 18% in type 1s for pumps, 1% in type 2s on pumps, and <1% for CGM; and 3) Medtronic's pump/CGM market share is ~ 65%. Unlike 2010, management did not give a breakout of pump and CGM revenues and growth rates. Based on an unlabeled graphic, we estimate the revenue split at ~85% pumps and ~15% CGM in FY12.

FINANCIALS

- **Medtronic estimates the total *worldwide* pump and CGM market size in the recently completed FY12 was $2.2 billion, expected to grow 6-9% in the coming fiscal year (FY13).** We expect Medtronic will achieve growth in this range, as FY12 growth in diabetes was 9.9% and FY11 growth was 8.9% - US growth last quarter was just 4%, and the US slower growth is likely driving the lower estimates overall. The international business has driven pump growth in the past two years, with year-over-year growth in the 10-20% range compared to ~5-7% growth in the US (see table below).

Year-over-Year Growth		
	FY11	**FY12**
Worldwide	8.9%	9.9%
US	*6.5%*	*4.9%*
Intl	*13.3%*	*18.8%*

- **For comparison, the 2010 analyst day forecasted 10-12% market growth (9-11% Medtronic diabetes growth) in the following year (FY11), while this year's analyst day projected a lower 6-9% market growth for the coming year (FY13).** As noted in the table above, FY11 growth of 8.9% fell slightly short of 2010 analyst day expectations. We note that the 6-9% growth figure given today was the highest expected FY13 growth rate in Medtronic's restorative therapies group (Spine: flat growth; Neuro: 5-7%; Surgical Tech: 5-7%), although Diabetes had the smallest FY12 market size (Spine: $9.7 billion; Neuro: $2.4 billion; Surgical Tech: $5.2 billion; Diabetes: $2.2 billion)
- **Management noted it has a 65% worldwide share in pumps and CGM -** this is the same figure we heard at the last analyst day in 2010 (see our report at http://www.closeconcerns.com/knowledgebase/r/7fb135a5). "We now have higher market share today in our diabetes business than we did even 10 years ago, when we acquired MiniMed," said management. This was characterized as an "impressive achievement" given all the market entrants, though of course none has nearly the installed base and scale of Medtronic. We wonder how Medtronic's US share number differs from the worldwide figure - we would expect it is slightly lower considering the greater US presence of Insulet, Animas, and Dexcom.
- **Worldwide, Medtronic estimates that there are a total of 11 million patients who have access to and could use a pump, CGM, or integrated system.** Medtronic's definition of "access" isn't completely clear - we're not sure if this means the product is distributed/sold in a particular market or if the term also means that patients must be reimbursed for it. Nevertheless, this market is certainly significantly underpenetrated, especially in type 2s and CGM as noted in the table below.

	Accessible Prevalence	**Industry Penetration**

Type 1: Pumps	11 million	18%
Advanced Type 2: Pumps		1%
CGM		<1%

- **This is the first time we've heard these figures and found them quite interesting, especially the 1% of advanced type 2s on pumps around the world. This estimate sounds high, although we note that it wasn't obvious if this means 1% of type 2 patients on insulin or overall - we assume it means on insulin.** This is certainly and area of significant upside for Medtronic, and we look forward to results from Medtronic's ongoing OpT2mise trial - the study has improved upon earlier trials by testing the benefit of pumps in MDI failures (A1cs of 8- 12%), and results will hopefully be published in 2013 or 2014. We would be very interested to know pump and CGM accessible prevalence and penetration numbers for the US (not disclosed by Medtronic). At the recent Clinical Diabetes Technology Meeting (see page 21 of our report at http://www.closeconcerns.com/knowledgebase/r/703bfc41), Dr. Bruce Bode estimated that there are between 50,000 and 100,000 type 2 pumpers in the US. There are nearly 150 type 2 pumpers in Close Concerns' dQ&A database - for more information and analysis on this group, contact richard.wood@d-qa.com. This total of nearly 150 is up from fewer than 40 a couple of years ago.

- **Medtronic did not break out or give separate growth rates for pumps or CGM; we estimate the FY12 revenue split at 85% pumps and 15% CGM** (extrapolated from a graph on slide #26 in Chris O'Connell's presentation). Since FY08, this represents a 10% CAGR. By geography, we noted in Medtronic F4Q12 (see our report at http://www.closeconcerns.com/knowledgebase/r/703bfc41) that over the last three years, the fraction of Medtronic Diabetes' total revenues from its international business has been on a steady upward trend, growing from under 34% in FY09 to nearly 39% in FY12. The analyst day presentation also showed an unlabeled graph breaking down diabetes revenue by areas of the world; we estimate Western Europe occupies the majority share (~two-thirds of international revenue), with a tiny sliver for emerging markets and a slightly larger sliver for rest of world.

PRODUCT PIPELINE

- **Notably, Medtronic gave timelines on its diabetes product pipeline (see table below) over the next five years and beyond.** The MiniMed 530G insulin pump is the US version of the Veo with low glucose suspend and the Enlite sensor. We learned today that Medtronic recently submitted the PMA to the FDA and it expects approval in approximately one year - this was a major surprise and represents a major positive for Medtronic. The MiniMed 640G is a new insulin pump with predictive low glucose management (i.e., the Veo with predictive low glucose suspend) and is expected to launch late this fiscal year (May 2012-May 2013). No details were shared on the Sentrino in-Hospital CGM. For more details on each product, see bullets below the table.

Near-Term Current (FY13)-FY14	Mid-Term FY15-FY16	Long-Term FY17+
Medtronic MiniMed 530G (US)	Medtronic MiniMed 640G (US)	Optical Sensor
Medtronic MiniMed 640G (EU)	Next-Gen Enlite	Overnight Closed Loop
Sentrino Hospital CGM (EU)	Patch Pump	Fingerstick Replacement

- **Medtronic has recently filed the PMA for the MiniMed 530G with the FDA and expects it will take about one year to secure approval ("...typically what things are talking these days").** This is the US version of the Veo low glucose suspend (LGS) insulin pump and includes the Enlite CGM sensor. The submission includes data from the in-clinic ASPIRE study and

the six-day study of the Enlite sensor. We previously anticipated that Medtronic would need to complete the in-home ASPIRE study (clinicaltrials.gov identifier: NCT01497938) prior to a PMA submission (this is currently slated to conclude in June 2013). The fact that Medtronic has now submitted the device represents a much-accelerated timeline and is very exciting news considering the regulatory delays that have hampered this product for three- plus years in the US. We understand that Medtronic has been encouraged by interaction with the FDA.

    - **Notably, when the Veo was launched internationally, it doubled Medtronic's growth rate in insulin pumps and CGM.** Prior to the launch of the Veo insulin pump, average international revenue growth in pumps over the prior four quarters was 10%, compared to 20% post-launch (albeit presumably from a low base). At the same time, CGM growth more than doubled from ~20% to 49% with the launch of the Enlite sensor. Management credited the internationally available Veo and Enlite as current drivers of the diabetes business and the "next big catalyst" in the US business.
    - **As a reminder, the in-clinic study of the US version of the Veo, presented at ATTD 2012, demonstrated a 19% reduction in the duration and severity of hypoglycemia** (see page 11 of our report at http://www.closeconcerns.com/knowledgebase/r/5c03a58a). The complicated study protocol was designed to determine if LGS activation in adults could mitigate exercise-induced hypoglycemia without causing rebound hyperglycemia. The answer turned out to be a resounding yes: LGS activation was associated with statistically significantly shorter duration of hypoglycemia, significantly higher mean blood glucose nadir, and no evidence of subsequent hyperglycemia. The study was also published in *Diabetes Technology and Therapeutics* in March (Garg et al.). The pump used in the study suspended insulin delivery when the sensor crossed a pre-set threshold at 70 mg/dl. Given the differences between patients and daily life circumstances (e.g., at summer camp playing sports might warrant a higher suspend threshold), we hope the FDA gives the power to patients and/or HCPs to manually set the low glucose suspend threshold.

- **The Medtronic MiniMed 640G is the second step in the path to an artificial pancreas, what Medtronic is calling "predictive low glucose management" (i.e., a hypoglycemia minimizer).** Management plans to launch the pump "later this fiscal year" (early calendar 2013) in Europe and in two to three years in the US. No specific details were shared on the pump's hardware design or features, although we may have some clues from Dr. Thomas Danne's (Kinder- und Jugendkrankenhaus Auf der Bult, Hannover, Germany) recent talk at ATTD (see page six of our report at http://www.closeconcerns.com/knowledgebase/r/aa724a9a).
    - **At ATTD 2012, Dr. Thomas Danne previewed the Predictive Low Glucose Management in Realtime Sensing Insulin Pump Therapy (PILGRIM) study.** Results of this trial are expected at next year's ATTD in Paris. We are not sure if this study will use the MiniMed 640G pump or not, though we note that Dr. Danne was previously involved in a study of the Veo (see page 65 of our ADA 2011 report at https://closeconcerns.box.net/shared/dz9hr6m94muoehsteybc). At this past ATTD, Dr. Danne showed a picture of the hardware that will be used in the study: similar to the Medtronic closed-loop device that Dr. Michael Kremliovsky (Medtronic, Sylmar, CA) presented at last year's Diabetes Technology Meeting (see our DTM 2011 report at http://www.closeconcerns.com/knowledgebase/r/5f40a09f), the system included a Medtronic pump, a sensor with the MiniLink transmitter (Dr. Danne's picture at ATTD showed only one sensor/transmitter; the system Dr. Kremliovsky presented at DTM uses two), a proprietary translator that converts Medtronic's communication frequency to Bluetooth, and a Blackberry to run the predictive algorithms. The user interface for the suspension threshold looked quite simple - Dr. Danne showed a menu with just two options, prediction horizon and suspend threshold (e.g., for a prediction horizon of 30 minutes and suspend threshold of 60 mg/dl, the system will suspend insulin delivery

whenever it thinks the patient is within half an hour of dropping below 60 mg/dl). It's of course impossible to say whether this is what the final commercial version of the MiniMed 640G will look like - we are very curious on this front.

- **On May 24, Medtronic changed the status of the pivotal study of the six-day Enlite sensor (clinicaltrials.gov identifier NCT01464346) to "completed."** As noted above, this next-gen sensor will be part of the MiniMed 530G pump in the US. Management emphasized the "enormous difference" the product has made internationally, similar to comments made in the recent F4Q12 call (see our report at http://www.closeconcerns.com/knowledgebase/r/703bfc41). As a reminder, the Enlite is 69% smaller by volume and 38% shorter in length relative to the Sof-Sensor - from our European correspondents (see the diaTribe Test Drive), we understand this makes a major difference. This will be a positive for the CGM market as a whole.
    - **Competitively speaking, we expect Dexcom's Gen 4 to be on the market before Medtronic's Enlite: (**1) the Enlite PMA submission came a couple months after Dexcom's Gen 4 sensor submission (see Dexcom 1Q12 at http://www.closeconcerns.com/knowledgebase/r/109d0417) and (2) the Enlite sensor submission is part of the MiniMed 530G integrated pump submission, which we expect is subject to a tougher regulatory bar (i.e., more back and forth with the FDA and a longer approval window).
    - **Looking to next-gen sensors integrated into insulin pumps, we expect the Animas Vibe and Insulet OmniPod (both with Dexcom's Gen 4) will come to market around the same time as the MiniMed 530G with the Enlite.** Dexcom 1Q12 noted that the submission timeline for these products is on hold - given the FDA's speediness, the worry is a PMA supplement might unnecessarily delay the Gen 4 PMA review. Dexcom management will provide an update on the timeline for the integrated pumps in the next quarterly call. Assuming Dexcom secures FDA approval for the Gen 4 around the end of 2012, this would put the integrated pumps on track for approval sometime in 1H13 by our back-of-the-envelope math. This is right around the time the MiniMed 530G would be approved, assuming all goes well with FDA (a fairly big 'if' considering the last few years of negotiations). It will be interesting to see how this affects demand - presumably there will be major improvements on the G4 sensor, although we also believe from a safety perspective, a number of patients may opt for the LGS, even if they prefer the Dexcom G4 sensor in other respects. Currently, a non-insignificant percentage of Medtronic pumpers in our dQ&A patient panel (contact richard.wood@d-qa.com for details) use the Dexcom CGM, and presumably these could be the first patients to move back, though such movement is difficult to estimate.
- **Management is "excited" about the patch pump and "looking forward to making it a bigger play" - th**e product is currently in the final design and review phase. This decision represents a departure from comments made in the 2010 analyst day, which noted a delay in the product's timeline and characterized the patch pump market as "much more of a niche market and smaller than originally anticipated." The slide showing Medtronic's patch pump (slide #26 in Chris O'Connell's presentation) displayed a flat, iPhone-shaped controller with quad-directional navigation (up, down, left, right). The patch pump itself looks somewhat larger than Insulet's second-generation OmniPod, though it's tough to get a sense of scale and context from the slide. Introduction of this product should drive the pump market overall.
- **Medtronic is actively developing an in-hospital CGM, Sentrino, which is expected to launch in Europe in the next one to two years.** No details were shared on the device's accuracy or design. The in-hospital CGM field has winnowed in recent years, but it still includes Dexcom/Edwards (on schedule to receive the CE mark in 2H12; see Edwards 1Q12 at http://www.closeconcerns.com/knowledgebase/r/d526b964), Echo Therapeutics (an oral presentation [7-OR] on Day #1 of ADA 2012), Dipylon Medical, OptiScan, GluMetrics, and others. The FDA recently announced that it will hold a public meeting on June 25, 2012 to discuss the clinical study design and performance metrics for in-hospital glucose sensors. The Agency will be

gathering input from a broad array of stakeholders, including clinicians, academia, government, industry, clinical laboratories, and others. In the meeting's background description, FDA notes that in-hospital glucose sensors are "not widely available," in part due to the "challenges in designing and studying these complex devices." To that end, the public meeting will focus on (1) the clinical studies and data needed to adequately validate the performance of these devices in the intended use population and (2) discussion of metrics that may be used to evaluate results to demonstrate a safe and effective device. The workshop will be held from 8am-5pm at FDA's White Oak Campus and will also be webcast. Those wishing to attend must register at http://1.usa.gov/KJBa1r before the deadline on June 15, 2012. We certainly look forward to learning more about FDA's perspective and how future guidelines may soon shape the field.

- **Management briefly commented on mySentry, calling it "revolutionary" and noting, "We're not even reimbursed for this device, and we've already sold a large number of these to patients."** Medtronic is presenting an intriguing poster with mySentry data at ADA 2012 (914-P). For more on mySentry, see http://www.closeconcerns.com/knowledgebase/r/aca26119 for our report on the device's approval in early January 2012. As a reminder, mySentry allows parents and caregivers to see real-time insulin pump and glucose trend information from another room. The device fits into Medtronic's Lifetime Diabetes Care: Diagnostics (iPro2), Treatment (MiniMed 530G), Consumer CGM Monitoring (Enlite), Connected Care Monitoring (mySentry and CareLink).
- **In other big news today, Medtronic announced it has partnered with the Helmsley Charitable Trust and JDRF to develop a redundant glucose oxidase/optical CGM sensor for the artificial pancreas.** By combining both an optical sensor and a glucose oxidase sensor into a single device, Medtronic believes the CGM readings will become more accurate, reliable, and safe. Though it is quite intuitive, we cannot recall seeing data combining an optical and glucose oxidase sensor (we have seen presentations suggesting multiple sensors are better than one; see page 124 of our ADA 2011 Full Report at https://closeconcerns.box.net/shared/dz9hr6m94mu0ehsteybc).
    - **The partnership is one of the largest collaborations to date by JDRF and the commitments are up to $17 million in funding over the duration of the three-year program.** As a reminder, the Sensor Initiative is funded at a total $20 million, meaning Medtronic has certainly secured the lion's share of the funding. The initiative funds research for a maximum of three years and seeks to improve all aspects of sensors, including performance, reliability, accuracy, calibration, form factor, etc. Applications may be submitted by for-profit entities as well as nonprofit organizations, public and private universities, colleges, hospitals, laboratories, and units of state and local governments. This is Medtronic's first collaboration with the Helmsley Charitable Trust. The partnership's funding is tied to a series of performance-based milestones within an agreed upon research plan (no details specified). The full plan is expected to take up to three years to fully complete, depending on the speed of various plan components. Payments will be made by JDRF only upon satisfactory completion of each of the milestones
    - **As we understand it, Medtronic has built a prototype combo sensor.** No timeline has been disclosed, though we assume this would come to market in well over five years given the aforementioned optical sensor timeline. At ADA this year, we note that Medtronic is also presenting a poster on a combo CGM/insulin infusion set (901-P).
    - **We last heard about Medtronic's optical sensor in the ADA 2011 exhibit hall in a presentation by Dr. John Mastrototaro** (see page six of our report at bit.ly/vJL8Qc). As a reminder, Medtronic acquired the optical glucose sensing technology in 2009 from Denmark-based PreciSense A/S. Slides from the analyst day put the optical sensor in the "Long-Term - FY17+" category. As FY12 just ended, the optical sensor is at least five years away. We first heard about this deal at the analyst day that year and this is the first news of it since that of which we're aware.

    - **Medtronic will be holding a webcast in conjunction with JDRF and Helmsley on June 5 at 12:30 pm PST to discuss the partnership.** This is a call not to miss! Dr. Aaron Kowalski (Assistant VP of Treatment Therapies Research, JDRF), Mr. Greg Meehan (General Manager of CGM business, Medtronic Diabetes), and Mr. Mark Anderson (Senior Program Officer, Helmsley Charitable Trust) will speak. To register for the webcast, visit http://engage.vevent.com/rt/medtronic~060512.

- **In a discussion of globalization, management discussed its broad diagnostic CGM program in India - it hopes to touch 100,000 patients at 3,000 centers by FY16.** Medtronic is placing professional CGM in the country to identify patients who are candidates for pump therapy and continuous glucose monitoring. Pilot projects at ten centers were characterized as "very successful." We see this is a smart play from Medtronic, although we heard at IDF that India has distribution, access, and cost issues for just insulin (see pages 4 and 115 of our IDF Full Report at http://www.closeconcerns.com/knowledgebase/r/0f23ea08). We'll be interested to follow this ambitious plan in the coming years. Certainly, we believe many more patients could benefit from diagnostic CGM than are using it, especially in less developed countries.

--by Adam Brown and Kelly Close