



MEMORANDUM

Abbott 2Q13 - Worldwide Diabetes Care revenue down ~1% on a reported and operational basis; next-generation sensor on track for 2H14 EU launch - July 18, 2013

Executive Highlights

- Worldwide Diabetes Care revenue totaled \$326 million in 2Q13, down ~1% on both a reported and operational basis.
- Management confirmed that Abbott's next-generation sensor (which is the 3rd-gen) is on track for a 2H14 EU launch, but did not discuss the sensor's pivotal trial (previously slated to begin by year end).

Yesterday, Abbott CEO Miles White led the company's 2Q13 financial update. Worldwide Diabetes Care declined ~1% on both a reported (down 1.3%) and operational basis (down 0.7%) from 2Q12, when sales declined 1% and grew 3%, respectively (reported and operational). US sales of \$135 million in 2Q13 fell 7% on a challenging comparison (2Q12 growth was 9%, an extremely positive result in recent years). For this region, management noted share gains in the hospital and retail segments that were offset by market pricing and reimbursement pressures - while this may relate to an initial sales impact from CMS' competitive bidding program, pricing has been under pressure for some time - CMS of course will exacerbate this. Initially, this will hurt the companies in the big 4 with the most exposure to CMS, which does not include Abbott, though pricing pressure has already and will continue to intensify further. Indeed, looking forward to the remainder of 2013, management certainly expects the implementation of competitive bidding to affect US sales overall; as a reminder, the new payment amounts went into effect on July 1. For 3Q13, management forecasted flat operational growth. International Diabetes Care revenue of \$191 million rose 3% on a reported basis and 4% on an operational basis from 2Q12 (when sales were down 8% and flat, respectively). Similar to 1Q13, management emphasized the strong growth of emerging markets and continued uptake of the FreeStyle InsuLinx meter. Abbott also announced that it was selected to be the exclusive supplier for Saudi Arabia's National Diabetes Awareness Program.

Abbott was the second of the Big Four blood glucose monitoring (BGM) companies (Abbott, J&J, Roche, and Bayer) to report 2Q13 financial results, behind J&J who reported earlier this week. US sales for J&J declined more severely than US sales for Abbott (23% vs. 7% year-over-year [YOY]). Combined Diabetes Care revenue for J&J and Abbott was ~\$915 million, down ~9% as reported from the companies' pooled revenue in 2Q12. In contrast to 2Q12, in 2Q13 the companies' international businesses performed noticeably better than their US businesses (by YOY growth metrics). We look forward to gaining a more complete picture of the Big Four's 2Q13 performance after Roche and Bayer report on July 25 and 31st.

Turning to the pipeline, management confirmed that Abbott was on track to launch its next-generation sensor in the EU in 2H14. While the company made no mention of its pivotal trial timeline, we presume the trial is also on track with previous forecasts, which have it slated to commence by the end of the year. We look forward to learning how Abbott will improve its sensor technology with this third-gen iteration; as a reminder, the FreeStyle Navigator II continuous glucose monitor (fall 2012 EU launch) made several ease-of-use improvements over the first-generation FreeStyle Navigator but did not advance the sensor technology. As expected, management gave no indication of plans to pursue approval for its FreeStyle Navigator II or next-generation sensor in the US. With work on the artificial pancreas front moving so rapidly, we would expect Abbott to be getting back into the game.

FINANCIALS

- Global Diabetes Care revenue totaled \$326 million in 2Q13, down ~1% on both a reported (-1.3%) and operational basis (-0.7%).** The comparison was not particularly challenging as 2Q12 sales were down 1% and up 3%, respectively. The 2Q13 performance was relatively in line with expectations from the company's 1Q13 financial update, during which management guided for flat operational growth in 2Q13. Second quarter Diabetes Care revenue seemed to be relatively consistent with past results: sales totaled \$330 million in 2Q12, \$334 million in 2Q11, and \$325 million in 2Q10. Overall, this shows the challenging state that BMG has been in in recent years - virtually no growth for the company in global revenue over the past three years.

	2Q13 Revenue in Millions	Reported (Operational) Growth from 2Q13
Abbott Diabetes Care	\$326	-1.3% (-0.7%)
<i>US</i>	\$135	-6.8%
<i>International</i>	\$191	3.0% (4.1%)

Worldwide Sales						
	1Q12	2Q12	3Q12	4Q12	1Q13	2Q13
Worldwide Revenue (millions)	\$318	\$330	\$317	\$362	\$316	\$326
Reported Growth (year-over-year)	-2.4%	-1.2%	-10.3%	3.1%	-0.5%	-1.3%
Operational Growth (year-over-year)	-1.4%	3.3%	-6.2%	4.2%	0.2%	-0.7%

- US Diabetes Care revenue totaled \$135 million in 2Q13, falling 7% from 2Q12 on challenging comparison** (US sales grew 9% in 2Q12). Management described share gains in the hospital and retail segments that were offset by market pricing and reimbursement pressure, which may be in part to an initial impact from CMS' competitive bidding program though probably reflects general price pressure overall as well as growing access issues. Indeed, management remarked that the implementation of CMS' competitive bidding program will affect US sales in 2013 - basically, an understatement. As a reminder, payment amounts from the program went into effect on July 1 (the first day of 3Q13) and we'll be looking to the 3Q13 financial update to gain a sense of how much sales impact was weathered in advance of the program's effective date.
 - Abbott recently aired two television spots on Medicare's payment adjustments.** The ads mention that suppliers could try to switch patients to a brand "you've never heard of" and "that might not be as accurate." J&J also recently issued a patient advisory pertaining to Medicare's move that had a similar message. The companies' announcements seem to suggest that suppliers are circumventing CMS' Anti-Switching provision, which is particularly worrisome for patients. And indeed, from what we've heard from patients, this appears to be the case. (As a reminder, the Anti-Switching provision, finalized in November 2010, "prohibits contract suppliers from influencing or incentivizing beneficiaries to switch their current glucose monitor and testing supplies brand to another brand.")

- **For additional discussion of Abbott's television ads, see our July 3 Closer Look at <http://www.closeconcerns.com/knowledgebase/r/204f4c8f>.**
- **For additional discussion of J&J's patient advisory, see our July 16 Closer Look at <http://www.closeconcerns.com/knowledgebase/r/5cd5a964>.**
- **Abbott was not present in the exhibit hall at ADA 2013, nor was Bayer.** The absence of these two Big Four blood glucose monitoring (BGM) companies (a group that also includes J&J and Roche) seems to speak to the growing challenges in the BGM market, which we are largely tied to competitive bidding.

US Sales						
	1Q12	2Q12	3Q12	4Q12	1Q13	2Q13
US Revenue (millions)	\$139	\$144	\$135	\$150	\$133	\$135
Reported/Operational Growth (year-over-year)	7.3%	8.6%	-7.1%	9.8%	-3.7%	-6.8%

- **International Diabetes Care revenue totaled \$191 million in 2Q13, growing 3% as reported and 4% operationally from 2Q12.** The comparison was fairly easy, as international sales declined 8% on a reported basis and remained flat operationally in 2Q12. Management remarked that international growth was driven by double-digit growth in emerging markets and continued uptake of the FreeStyle InsuLinx meter.
 - **Abbott announced that it has become the exclusive supplier for the National Diabetes Awareness Program in Saudi Arabia.** We are interested to better understand what this agreement entails, though certainly, the contract is an important win for Abbott and could potentially provide the company with opportunity to increase penetration in nearby markets as well. The National Diabetes Awareness Program was launched in June under the umbrella of Saudi Arabia's Ministry of Health. According to the ministry's website, the ministry currently has 20 diabetes centers throughout Saudi Arabia and we are curious what portion of the 30% of people living with diabetes in Saudi Arabia these centers service.

International Sales						
	1Q12	2Q12	3Q12	4Q12	1Q13	2Q13
International Revenue (millions)	\$179	\$186	\$182	\$212	\$183	\$191
Reported Growth (year-over-year)	-8.7%	-7.7%	-12.5%	-1.2%	1.9%	3.0%
Operational Growth (year-over-year)	-7.0%	-0.3%	-5.5%	0.6%	3.2%	4.1%

- **Sequentially, worldwide revenue grew 3% from 1Q13.** By geographic region, US revenue grew 2% sequentially and international revenue grew 4% sequentially. Abbott was coming off of a challenging 1Q13, when worldwide Diabetes Care sales fell 13% sequentially. We note of course that first quarters are typically challenging for medical device companies due to the seasonality of

patients' insurance plans. Historically, sequential growth from the first to the second quarter is common for Abbott; however, **we note that this is the lowest sequential growth from 1Q to 2Q since 2008 (when sales declined sequentially by 1.5%).**

Sequential Performance						
	1Q12	2Q12	3Q12	4Q12	1Q13	2Q13
Worldwide Sequential Growth	-9.4%	3.8%	-3.9%	14.2%	-12.7%	3.2%
US Sequential Growth	-6.8%	2.2%	3.6%	11.1%	-11.3%	1.5%
International Sequential Growth	3.4%	-16.7%	3.9%	16.5%	-13.7%	4.4%

- **Looking forward to 3Q13, management guided for Diabetes Care sales to be relatively flat on an operational basis.** Abbott expects continued growth from emerging markets, tempered by less US revenue due to the implementation of CMS' competitive bidding program for diabetes care supplies (and presumably ongoing pricing pressure outside the Medicare market). Management has not updated its full-year guidance since the 4Q12 call, when they forecasted flat sales on both a reported and operational basis; this seems an ambitious goal given CMS and CMS implications.
- **Combined 2Q13 revenue for Abbott and J&J totaled \$915 million, down ~9% on a reported basis from the companies' pooled revenue in 2Q12 (~\$1 billion).** In contrast to 2Q12 when both companies trended towards stronger US performance compared to international performance, changing reimbursement pressures and macroeconomic conditions seem to have set the stage for a more challenging US market. In 2Q12 Abbott had high single digit US sales growth (9%) in 2Q12 and international sales decline (down 8% as reported and nearly flat operationally [-0.3%]). J&J had slight US sales growth (1%) and mixed international performance (sales decline of 3% as reported and sales growth of 5% operationally). In 2Q13, however, Abbott and J&J both experienced steep US sales declines (down 7% and 23%, respectively) with comparatively stronger international performance (sales growth for Abbott and low single digit declines for J&J).
 - **Compared to J&J, Abbott experienced a smaller sales decline in the US, a region that we expect to drive weak overall Diabetes Care performance in 2Q13.** Both Abbott and J&J management spoke to challenges related to competitive bidding. When J&J reported earlier this week, management said that its Medicare business accounted for over 20% of US sales. In Abbott's 1Q13 update, management remarked that the company did not have a high Medicare share and had "one of the lowest shares in mail order." As such, management believed that the sales impact from the competitive bidding program would be comparatively less for Abbott than other industry players. While for the 2Q13 comparison between J&J and Abbott, this sentiment seems to ring true, we believe J&J's Medicare percent of business is also on the lower side.
 - **We note that direct comparison between Abbott and J&J is challenging since each company's Diabetes Care business includes a fraction of non-BGM revenue** (Abbott has continuous glucose monitoring outside of the US and J&J has insulin delivery; the latter is significantly larger but neither company reports these segments). We look forward to adding Roche and Bayer to this comparison on July 25 and July 31, respectively. For greater detail on J&J's 2Q13 performance, see our report at <http://www.closeconcerns.com/knowledgebase/r/164d9ab5>.

2Q13 Diabetes Care Revenue Comparison

Company	Worldwide		US		International	
	2Q13 Revenue in Millions	Reported (Operational) Growth from 2Q12	2Q13 Revenue in Millions	Reported (Operational) Growth from 2Q12	2Q13 Revenue in Millions	Reported (Operational) Growth from 2Q12
Abbott	\$326	-1.3% (-0.7%)	\$135	-6.8%	\$191	3.0% (4.1%)
J&J	\$589	-12.5% (-11.8%)	\$259	-23.1%	\$330	-1.8% (-0.5%)

DEVICE PIPELINE

- **Abbott management confirmed that the company remains on track to launch its next-generation sensor in the EU in 2H14.** We look forward to learning greater detail on the improvements this device will provide over the FreeStyle Navigator II continuous glucose monitor, which launched in the EU in fall 2012. As we noted in our ATTD 2013 coverage, improvements in the FreeStyle Navigator II focused on ease of use and form factor (see below), and we hope the next-generation sensor will bring improved accuracy to the system.

 - **Unsurprisingly, Abbott management did not make any mention of US regulatory submission plans for the company's FreeStyle Navigator II or next-generation sensor** (they rarely talk about this business).
 - **Management did not comment on the timing of its pivotal trial for the next-generation sensor;** however, since the company's launch timeline is consistent with previous guidelines we presume that Abbott's pivotal trial timeline is also on track, which would translate to a trial start date before the end of 2013.
 - **For background, the FreeStyle Navigator II has an updated receiver and a 33% smaller transmitter; otherwise, the sensor technology and measurement methods are the same as the previous version.** To this end, in the company's ATTD 2013 presentation, the FreeStyle Navigator II showed similar accuracy scores to the FreeStyle Navigator (12.3% mean absolute relative difference [MARD] and 10-13% MARD, respectively). For greater discussion on the company's ATTD presentation, please see our [ATTD report](#).
- **Abbott completed a phase 4 efficacy study of its FreeStyle Navigator in patients on multiple daily injections,** according to a July ClinicalTrials.gov update (Identifier: NCT01713348; Sensor and Software Use for Improved Glucose Control in MDI Managed Diabetes [SIGN]). After a 14-day run-in with blinded continuous glucose monitoring (CGM) wear, patients were randomized to either real-time CGM or standard SMBG (with blinded CGM wear) for a 14-day period. The primary outcome measurement was time in range; secondary outcomes included mean glucose, glycemic variability, frequency of finger-stick testing, and hyper- and hypoglycemic events to name a few. The study enrolled 105 patients. We look forward to being apprised of the results and hope the study can be used to lobby payers for improved CGM reimbursement.
- **In a recent investigator-initiated head-to-head-to-head accuracy comparison of commercialized CGM systems, the FreeStyle Navigator demonstrated a MARD of 12.3%.** Dr. Steven Russell (Massachusetts General Hospital, Boston, MA) presented results at ADA 2013; the study compared the Abbott FreeStyle Navigator, Dexcom G4 Platinum, and Medtronic Enlite CGMs in 24 patients simultaneously wearing all three sensors in 48-hour closed loop experiments. Dexcom's G4 Platinum was the most accurate sensor (MARD: 10.8%, 85% of readings in Zone A of the Clarke Error Grid), followed closely by Abbott's FreeStyle Navigator (12.3%, 84% in Zone A); both appeared to be significantly more accurate than Medtronic's Enlite with the Veo

algorithm (17.9%, 68% in Zone A). For more detail, see page 62 of our ADA full report at <http://www.closeconcerns.com/knowledgebase/r/94f937d8>.

- **Abbott management did not provide any additional updates on its diabetes pipeline.** In 4Q12, management had stated that "in 2013, we're planning on several new product and software launches." As we had understood it, this was to include emerging market launches of products previously approved in other countries, as well as "next generation products" in developed markets, including a product based off the FreeStyle Precision platform. Management also did not discuss these products during its 1Q13 update.

-- by Hannah Martin, Kira Maker, and Kelly Close