



## MEMORANDUM

### Abbott 1Q14 - US Diabetes Care falls a steep 28%; EU launch of Flash Glucose Monitoring expected in late summer - April 16, 2014

#### Executive Highlights

- Worldwide Diabetes Care sales fell 11% to \$283 million in 1Q14, the first time below the \$300 million mark since 2010.
- US revenue declined a sizable 28%, tempered by 2% reported growth in international sales.
- Notably, Abbott's Flash Glucose Monitoring system is slated to launch in the EU in late summer 2014, an update from the previous "2H14" timing.

Earlier today, Abbott CEO Miles White led the company's 1Q14 financial results call. We have for you our top five learnings from the call, including a Diabetes Care financial overview, an update on Abbott's Flash Glucose Monitoring device (late summer launch), thoughts on competitive bidding, and a comparison to [J&J](#) and [Roche](#)'s 1Q14 Diabetes Care sales, both of which were reported yesterday.

After the Diabetes Care financial results we heard yesterday from J&J and Roche (less so for the latter), it is clear it continues to be a very challenging time for blood glucose monitoring businesses, particularly in the US. Abbott's US business declined 28% year-over-year (YOY) in the US, in line with J&J's 32% decline. Like J&J, Abbott's international business was a bit more positive, growing 2% YOY as reported and 4% operationally. Still, the coming quarters will continue to be challenging, as management expects "low double digit" declines (operationally) in worldwide sales for 2H14 - we suspect mostly driven by a depressed US business. However, US weakness may be offset slightly by continued growth in select emerging markets, whose double-digit gains led international growth in 1Q14. For Abbott, as we understand it, the Middle East will be a major bright spot. To be sure, the upcoming EU launch of Abbott's Flash Glucose Monitoring system in the second half of 2014 ("late summer") should certainly help the company's business; the start will be in the EU and elsewhere internationally.. See below for our top five highlights from Abbott, which were the financial results, news on the Flash Glucose Monitoring system, further reimbursement characterizations, our update on BGM on an industry basis, and the recent FDA approval (two days ago!) of Abbott's Architect Clinical Chemistry Hemoglobin A1c test.

#### TOP FIVE HIGHLIGHTS

**1. Worldwide Diabetes Care revenue totaled \$283 million in 1Q14, declining 11% as reported and 10% operationally year-over-year (YOY).** The size of the drop this quarter was confirmed by a quick look at our financial model: Abbott's worldwide revenue hasn't dropped under \$300 million since early 2010. Sequentially, worldwide Diabetes Care sales declined 18% from the fourth quarter, worse than the 13% sequential decline observed between 4Q12 and 1Q13. In fact, this represented the steepest sequential decline we have seen for Abbott since we began reporting their quarterly results. We do note that the comparison was a bit more challenging given 1Q13 results, when revenue was effectively flat (that result given this environment is a positive one). In case anyone was expecting the tide to change a bit, management was clear that challenging days will continue; despite easier comparisons in the rest of the year, they still estimate low double-digit declines on an operational basis for Diabetes Care in the second half of the year. We assume the international business will continue to be decent, which suggests that fairly negative expectations in the US are appropriate (it is possible international weakness is expected, of course).

- **US Diabetes Care 1Q14 revenue dropped an unprecedented 28% YOY and 25% sequentially, with sales reaching just \$97 million.** This decline is the greatest we have seen for Abbott since we began reporting Abbott's results; quarterly revenue hasn't dropped below \$100 million since before 2004 when Abbott bought Freestyle manufacturer TheraSense. The 28% decline in sales was particularly disconcerting given the comparison to 1Q13, when sales in the US declined 4% - then again, these days, an "easy" comparison is at least a double digit drop. Management continued to attribute the US declines to CMS reimbursement reductions and competitive bidding dynamics.
- **International Diabetes Care fared better, with 1Q14 revenue totaling \$186 million, up 2% as reported and 4% operationally YOY** - this is the fourth consecutive quarter of international growth. The comparison to 1Q13 growth was moderately challenging (given the current BGM environment), as 1Q13 international revenue was up 2% YOY. Management commented that international sales make up ~65% of Abbott's Diabetes Care business, an uptick from the 60% reported in 4Q13. This is of course to be expected, given the declines Abbott is seeing in the US. The call also highlighted that growth in the international business is being driven by emerging markets - management confirmed in a follow-up conversation that Latin American and the Middle East are key players.

**2. The call discussed the Flash Glucose Monitoring system very optimistically in Q&A, and an EU launch is now expected in "late summer" (ahead of the previous "2H14" timeline).** In Q&A, management characterized the Flash Glucose Monitoring a "pretty significant" innovation and one that will "have a lot of impact on the business." The device is still pending a CE Mark, which as of the last update at [ATTD 2014](#), was expected in 2H14. From comments on the call, it sounds like things have moved faster than expected on the EU regulatory front, paving the way for the late summer launch. As expected, no timelines or details were shared on the US, though we are optimistic Abbott has not given up on the FDA but is working in the market (the EU) that will enable fastest time to commercialization. We would expect a launch at EASD, given the commentary on the call. For a complete overview of the system, see our coverage from [EASD 2013](#).

- **We last heard Abbott's Flash Glucose Monitoring system at [ATTD 2014](#), where the company's ambitiously titled workshop "Advancing Towards the Next Frontier in Glucose Monitoring: 14-day, No-Calibration Sensors and AGP" drew a two-deep standing-room-only crowd.** Abbott's Mr. Jared Watkin updated attendees on the slate of expected 2014 studies of the next-generation sensing system - an accuracy trial to support CE Mark approval and two European multi-center, multi-country, randomized controlled trials to demonstrate improved glycemic control (one in type 1 and the other in type 2). The latter are intended to show real clinical outcomes, and we imagine would help drive data to support reimbursement in Europe.
- **At [ATTD 2014](#), Mr. Watkin also provided brand new data from a six-lot factory calibration study** (the initial ENERGY study discussed at EASD only tested a single lot). The small study enrolled six patients with diabetes that each wore three sensors simultaneously over five days (Abbott has found that the full 14 days of wear are not necessary to get a sense of sensor stability/accuracy). Overall MARD (vs. FreeStyle Precision fingersticks) using a lot-specific pre-determined (prospective) factory calibration was a solid 11%, with 84% of points in Zone A of the Parkes consensus error grid (for context, the initial ENERGY study found a MARD of 8.5% vs. YSI and 9.6% vs. fingersticks).
- **Last, Mr. Watkin's ATTD presentation disclosed a few never-before-shared design details of the next-generation sensing system.** First, the system's sensor patch will be the size of a two-Euro coin - quite small and intended to be "simple," "low pain," and "low profile." This of course jives with the ambition to overcome some of the limitations of CGM and BGM. The system's sensor patch is also "water resistant" (e.g., showering), can be scanned through patients' clothing (key for discretion), and transmits data to the reader in less than one second after a scan. Mr. Watkin showed some example screens from the color touchscreen reader, which included time in range graphs - this has been missing on CGM receivers to date, so this is great to see.

**3. Unsurprisingly, Abbott attributed the 1Q14 revenue decline largely to the continued effect of CMS' reimbursement reductions and competitive bidding dynamics.** However, during Q&A, management commented that while Abbott minimized the damage by focusing on more profitable and less vulnerable segments of the market. These were not further characterized, but we assume this refers to insulin users and high frequency testers, a strategy Abbott has mentioned in the past and targeted with the FreeStyle Insulinx meter.

- **Abbott's stronger international growth was driven by double-digit gains in emerging markets.** No specifics on these emerging markets were noted in the call. However, based on a recent conversation we had at Abbott's Middle East, Africa, Turkey & Greece region office, we understand the company's presence in the Middle East is expanding. Specifically, **Abbott partnered with Saudi Arabia's Ministry of Health** to launch in June 2013 "Sahselo" (meaning "watch out" in a western Saudi dialect) a comprehensive public health initiative that provides blood glucose monitors and strips free of charge to Saudi nationals living with diabetes, increases patient access to diabetes educators, and conducts a national public health campaign featuring TV commercials on the importance of a healthy lifestyle for managing one's diabetes and preventing complications. Additionally, as part of the initiative, Saudi Arabia and Abbott are entering enrolled patients into a database so that patient follow-up and feedback can more easily be conducted. **The program has 400,000 patients in the system, of which 300,000 have received meters. The goal is to enroll 800,000.** Such a program seems like a big win given the tremendous needs in the middle east; as a reminder, according to the IDF, fully half of the 13 million people with diabetes diagnosed globally in 2013 were from the Middle East.
- **We imagine Abbott also views the Middle East as a huge opportunity region for Flash Glucose Monitoring,** as the device's ability to provide continuous data without a fingerstick would provide a low-hassle option for this region's diabetes population, which still experiences significant cultural stigma (much larger than in the US). Simplifying blood glucose testing and increasing its discretion would certainly provide an easier option for patients who are concerned about others' responses to the very visible, public act of doing a fingerstick. Additionally, we expect the Ambulatory Glucose Profile reports generated by the Flash Glucose Monitoring system to be a great aid to physicians in making treatment decisions and in discussing the need for lifestyle changes with patients.

**4. Combined revenue for Roche, J&J (both of which reported yesterday), and Abbott fared badly in the US but not as poorly overall, so that the total \$1.4 billion global revenue for the three companies experienced a 7% decline as reported from 1Q13 - offhand, we would have expected this to be worse, though the pooled US results (see below) were certainly weak.** Overall, Roche fared the best of the three both globally and in the US. Globally, Roche remained flat as reported and grew 5% operationally, while J&J fell 15% as reported and 14% operationally, and Abbott fell 11% as reported and 10% operationally. Roche's North American revenue grew 6% (13% operationally), compared to J&J's 32% decline and Abbott's 28% decline in the US. (As we noted in our Roche report, only ~20% of Roche's worldwide business comes from the US, so it is more shielded from competitive bidding than other companies.) Abbott had the edge internationally - its 2% reported growth was higher than J&J's modest 0.9% reported growth and Roche's 1.6% reported decline. Of these companies' combined 1Q14 worldwide revenue, Roche held the lion's share of 43%, J&J in close second with 37%, and finally Abbott with only 20%.

- **By contrast, pooled US/North America revenue for the three companies totaled \$407 million in 1Q14, falling a marked 21% YOY.** This was against an easy comparison, as pooled revenue fell 17% YOY in 1Q13. Internationally, the three fared much better, with combined revenue totaling \$1 billion, up 2% YOY from combined revenue in 1Q13.

**Table 1: 1Q14 Roche, J&J, and Abbott Diabetes Care Revenue Comparison**

Company	Worldwide	US/North America	International
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	<i>1Q14 Revenue in Millions</i>	<i>Reported (Operational) Growth from 1Q13</i>	<i>1Q14 Revenue in Millions</i>	<i>Reported (Operational) Growth from 1Q13</i>	<i>1Q14 Revenue in Millions</i>	<i>Reported (Operational) Growth from 1Q13</i>
<i>Roche</i>	\$603	-0.2% (5%)	\$112	6.4% (13%)	\$491	-1.6%
<i>J&amp;J</i>	\$512	-14.7 (-13.7%)	\$192	-32.2%	\$320	0.9% (2.9%)
<i>Abbott</i>	\$283	-10.5% (-9.5%)	\$97	-27.6%	\$186	2.0% (3.8%)

Currency conversion for Roche based on average exchange rate on oanda.com (e.g., 1.1200 USD per CHF for January 1 - March 31). Different results are possible with different currency conversion. Roche does not report revenues for an international category, and the international value we report includes the company's EMEA and RoW categories; as such, operational growth is not available. We also note that Roche's US value is slightly inflated, as it includes revenue from Canada ("North America" sales). Reported growth for Roche is calculated based on CHF.

**5. Abbott's Architect Clinical Chemistry Hemoglobin A1c test received 510(k) clearance from the FDA on April 14 and will be launched this month.** The Architect A1c test obtained a CE Mark in May and is already available in parts of Europe, Asia, Latin America, and Africa. The device will be used in clinical laboratories for the in vitro measurement of A1c, and management noted that this fully automated test would empower physicians to meet the anticipated increase in demand for A1c testing. We note that A1c testing is being used more frequently and the number of undiagnosed diabetes patients is dropping according to recent data; we're encouraged to see Abbott working to diagnose patients earlier. Certainly, there is a very long way to go in improving access in underserved areas - earlier diagnosis is certainly an important start.

- **Abbott did not mention it's FreeStyle InsuLinx, FreeStyle Precision Neo, and FreeStyle Precision Pro during prepared remarks or Q&A.** In a company presentation dated [August 2013](#), management referred to these devices as "near-term drivers."

<b>Device</b>	<b>Status and Timeline</b>
Flash Glucose Monitoring System	CE Mark expected in the second half of 2014; EU launch expected in late summer 2014
FreeStyle Precision Neo Blood Glucose Meter	Received CE Mark and launched in EU in September 2013; no updates on an FDA submission
FreeStyle Precision Pro Blood Glucose Meter	Received FDA clearance July 2013; no updates on US launch

## Questions and Answers

**Q: Looking at Diabetes Care, you've commented on next-generation sensing technology platform. However, with the headwinds that you're facing in the US market in terms of competitive bidding and pricing, what other key strategic initiatives can you put into play to support your diabetes business?**

**A:** This is one unit I'm actually very excited about, particularly the emerging innovation. I think that our team there did a wonderful job segmenting this market in a way that minimized the damage we took from competitive bidding. We took a hit just like everyone else, but I think to a lesser degree because we focused on segments that, frankly, were more profitable and less vulnerable than what the overall competitive bidding target was.

I think we played great defense in what is now a more challenged market. However, going forward, the innovation that's emerging, which we'll launch in Europe late this summer, is pretty significant, and I think it is a pretty unique product that I expect will be very well received by diabetes patients. It hasn't had a lot of visibility yet, but it will in the coming months. We keep referring to it as next-generation, but frankly, it's quite a creative product, and I think it's going to have a lot of impact on the business. I've got great hopes for this, and I think that the diabetic community in particular, both physicians and patients, are going to think it's a terrific product. I think that as that mode of testing progresses over time, this is going to be a pretty good business for us.

*-- by Jenny Tan, Hannah Martin, Adam Brown, and Kelly Close*