Closer Look

MEMORANDUM

J&J 1Q12 - Diabetes Care revenue up 5% overall and 13% in the US; Animas completes feasibility study of artificial pancreas precursor - April 17, 2012

Executive Highlights

- J&J Diabetes Care revenue reached $670 million, up 5.2% as reported (6.6% operationally) year-over- year, and flat sequentially. Sales were up 13% year-over-year in the US, and down 2.5% abroad.

This morning, Johnson and Johnson DFO Dominic Caruso led the company's 1Q12 financial results update - the company's final quarterly call before Alex Gorsky succeeds CEO Bill Weldon on April 26. Diabetes Care (LifeScan/Animas) revenue totaled $670 million, up 5.2% as reported and 6.6% operationally from $637 million in 1Q11, and flat sequentially. Supplemental materials listed LifeScan as a major growth driver for Medical Devices and Diagnostics as a whole. US Diabetes Care sales shot up 13.2% to reach $352 million, making 1Q12 J&J's highest quarter of domestic revenue since 4Q07 ($362 million). Management attributed the US revenue growth in part to launches of new products, most notably the pattern-recognizing LifeScan Verio IQ, which is now in the process of global launch (as well as a US voluntary recall due to a software bug). This makes sense as we assume there was revenue related to stocking. Revenue outside the US fell to $318 million, down 2.5% as reported and up 0.2% operationally. Management said that sales in emerging markets were "strong" but that growth was hurt by pricing pressures in some developed markets, presumably Europe. As a reminder, European reimbursement woes were an even bigger 1Q12 hindrance for Roche, which posted revenue declines of 12% as reported and 7% operationally. We look to hear the results from the rest of the "Big Four" on April 18 (Abbott) and April 26 (Bayer), as well as from relative BGM newcomer Sanofi (April 27).

No major updates were announced in J&J's device pipeline. A next-generation hospital point-of-care glucose test has received CE mark since the start of 2012, and submission of the system in Japan remains on track for later this year. Regulatory submission targets were confirmed for the third- generation Verio meter (2012), the next-generation OneTouch Ping pump/BGM (2012 in the US), the Animas Vibe (2012 in the US - it would be great to see this happen), a new Diabetes Care platform (presumably a BGM technology; 2013 or later), and version 1.5 of the POC product (EU and Japan in 2013 or later). Also, though not mentioned during the call, Animas has concluded a feasibility study (n=30, 24 hours) of its Dexcom-enabled hypo-/hyperglycemia minimizer, the company's first step toward closed-loop glucose control (clinicaltrials.gov ID: NCT01401751).

Canagliflozin, J&J's SGLT-2 inhibitor, remains on track for US and EU filing in 2Q12. This makes it the closest-to-market drug in the class outside BMS/AZ's dapagliflozin - the timing is uncertain on that one due to the FDA's complete response letter earlier this year (see the January 20, 2012 Closer Look at bit.ly/yxJzBF). Management also looked forward to the presentation of "some" canagliflozin data at ADA in June (no specifics provided; we will be especially on the lookout for any potential carcinogenicity signals and/or any early implications for CV outcomes studies. Management did not announce any other updates to J&J's cardiometabolic drug pipeline.

FINANCIALS

- **Worldwide revenue for J&J Diabetes Care (LifeScan/Animas) totaled $670 million, up 5.2% as reported and 6.6% operationally from $637 million in 1Q11.** This makes 1Q12 J&J's highest-revenue first quarter to date - good news that builds on a trend from 2011, when the company set quarter-specific revenue records in each of the first three quarters. As usual

management gave no details on the revenue split between LifeScan and Animas, though supplemental materials listed only the former as a major growth driver. We continue to estimate J&J's worldwide pump revenue at approximately $50 million (predominantly in the US), with blood glucose monitoring making up the remainder (a rough estimate of $600-plus million in 1Q12).

	1Q12 Revenue in millions	Reported/Operational Growth from 1Q11
J&J Diabetes Care	$670	5.2% / 6.6%
US	$352	13.2%
International	$318	-2.5% / 0.2%

- **J&J's US Diabetes Care revenue reached $352 million, its highest mark since the fourth quarter of 2007.** Management attributed the 13.2% year-over-year growth mainly to new product launches (see bullet on the OneTouch Verio IQ below) and "favorable mix" (also referenced in the 4Q11 call; we assume this refers to product mix). By comparison Roche's North American revenue fell to roughly $129 million, barely one-third of J&J's mark.

	1Q12 Revenue in Millions	Reported/Operational Growth from 1Q11
J&J, *US*	$352	13.2%
Roche, *North America*	~$129 (119 CHF)	-11% / -5%

Currency conversion based on average exchange rate from January 1 - March 31 on oanda.com: 1.0835 USD per CHF.

- **Ex-US revenue of $318 million was down slightly year-over-year as reported (flat operationally) despite strong growth in emerging markets.** Management alluded to pricing pressures in some developed countries; we assume this refers mainly to European markets. Roche, the BGM revenue leader in Europe, posted large negative growth in non-North- American regions as a whole, despite also growing well in developing countries. For a more detailed analysis of the European BGM landscape, see our Roche 1Q12 report at http://www.closeconcerns.com/knowledgebase/r/2b4f8005.

	1Q12 Revenue in Millions	Reported/Operational Growth from 1Q11
J&J, *International*	$318	-2.5% / 0.2%
Roche, *ex-North America*	~$482 (445 CHF)	-13% / -8*%

*Quarterly ex-North American operational growth roughly estimated from Roche's regional results. Currency conversion based on average exchange rate from January 1 - March 31 on oanda.com: 1.0835 USD per CHF.

- **Overall sequential growth was flat in 1Q12 - the first time in the past five years that 4Q-1Q sequential growth has been non-negative.** Historically the transition from year-end to year-start is difficult across the industry. Indeed, since posting 1.3% sequential growth in 1Q07, J&J Diabetes Care's 4Q-1Q shift has ranged from -1% to -9%. The break from this trend is likely due in part to J&J's somewhat slow 4Q11 (when sales were up 4.0% year-over-year in a relatively easy comparison, and only 0.9% sequentially), but overall, this is certainly an encouraging result.

	1Q12 Revenue in millions	Reported Growth from 4Q11
J&J Diabetes Care	$670	0.0%
US	$352	6.7%
International	$318	-6.5%

DIAGNOSTICS AND DEVICES PIPELINE

- **It was excellent to hear that the OneTouch Verio IQ, LifeScan's meter with pattern recognition and real-time feedback, is in the process of global launch.** The Verio IQ has so far launched in Canada (September 2011) and the US (January 2012), and it has been approved for sale in the EU since 4Q11. As a reminder, in J&J's 4Q11 call management guided for a near-term launch of the Verio platform, but we hadn't been sure whether the rollout would also include the 'generation 1.0' Verio or the 'generation 2.0' Verio Pro. Now it sounds like LifeScan is focusing mainly on the 'generation 2.5' Verio IQ. This is clearly good news from a patient perspective. Compared to the Verio Pro (which has been available in various European countries since 1Q11), the Verio IQ has a sleeker form factor and a user-friendlier interface for pattern- based recommendations. (For our "Test Drive" review of the Verio IQ, see *diaTribe* #41 at http://www.diatribe.us/issues/41/test-drive.php). Of course, to generalize broadly, the EU's reimbursement landscape is generally unfavorable and unpredictable; we could envision that European access to the Verio IQ would be limited to patients that are willing to pay a premium out of pocket (historically a small population in Europe), and/or that the margins on the meter itself would be less favorable than for other LifeScan products. We anticipate that in emerging markets, LifeScan will continue to focus on pared-down, low-cost products such as the OneTouch SelectSimple - a button-less meter that requires no startup - which debuted in India in September 2011. However, we could also see the company someday introducing a complementary strategy in the same markets: using the Verio IQ or similar products to target high-volume testers, just as in the US and EU. We understand that a substantial number (albeit a small percentage) of emerging-markets patients have the means to self-pay for differentiated medical products, though we are not sure when (and in which countries) the numbers would make sense for LifeScan to introduce its most advanced products in the developing world.
    - **In February, LifeScan initiated a voluntary recall of the Verio IQ due to a software bug with the meter's settings;** as of this writing, the recall is ongoing and the meter is once again labeled as "coming soon" on OneTouch.com. In certain cases, the Verio IQ delivers an error that causes the meter to turn itself off when a user attempts to access the "Results Log" to view past test results. When this error occurs, the meter enters "set up" mode when it is powered back on. The date and time settings must then be resetbefore testing can occur again. This does not affect the accuracy of test results, meter functions, or test results stored on the meter. The company is currently removing and replacing all OneTouch Verio IQ Meters in the US and has developed the software update to correct this issue. We understand that product shipments have resumed and that the meter will soon be widely available.
- **As of Dexcom's 4Q11 results call in late February, the Animas Vibe was in position for FDA filing in late 2012 at the earliest.** During that call, Dexcom planned to submit a pre-market approval application (PMA) of its fourth-generation standalone sensor by early 2Q12. The PMA supplement for the Animas Vibe could then be filed 100 days later, which means that FDA approval of the Animas Vibe is unlikely until mid-2013 or later. We anticipate more insights on regulatory timing in Dexcom's 1Q12 call (date TBA; we anticipate early May).

- **Animas has concluded a feasibility study of its hypo-/hyperglycemia-minimizing system, which uses an Animas pump and Dexcom CGM** (clinicaltrials.gov identifier: NCT01401751). As a reminder, the 24-hour, single-arm study had a target enrollment of 30 adults with type 1 diabetes and was led by Dr. Howard Zisser (Sansum Diabetes Research Institute in Santa Barbara, CA). We hope to see early-stage data on performance of the system's algorithm at ADA. We are also curious about the next phase of the company's closed-loop work: in January, Animas entered the third and final year of its $8-million JDRF grant to develop an automated precursor to the artificial pancreas using Dexcom sensors.
- **J&J continues to expect 2012 submissions for the third-generation OneTouch Verio meter (regions unspecified) and the next-generation OneTouch Ping pump/meter (US only).** We believe that these products could be called the OneTouch Verio Sync and the OneTouch Ping Verio, based on trademarks that J&J filed in 2010 and 2011, although we have no confirmation at this stage.
- **The first version of a "Next Generation Platform" remains on track for regulatory filing in 2013 or later.** We think that this new product may be the new blood glucose meter product that is being studied by Universal Biosensors (the Australia-based company that developed the Verio platform) in a 12-month, $4.5-million feasibility assessment announced in October 2011. For more thoughts on the LifeScan/Universal partnership and the new platform in development, see our J&J 4Q11 report at http://www.closeconcerns.com/knowledgebase/r/f825408a.
- **J&J's next-generation hospital point-of-care (POC) testing system has been approved in the EU, in line with the target given in the 4Q11 update.** Submission of the same system in Japan remains on track for later this year, and submission of version 1.5 in both the EU and Japan is slated to occur in 2013 or later.
- **Cellnovo's cloud-connected pump, which uses OneTouch Vita test strips1, entered a large usability study (n=100, 10 centers) in the UK in February.** (See the February 9, 2012 Closer Look email for details.) As of the study's announcement, Cellnovo was targeting UK market launch in the April/May 2012 timeframe - coming up soon!

1 OneTouch Vita strips are have been available in the UK since 2009 for use with the OneTouch Vita meter, which enables flagging results of results as fasting, pre-meal, or post-meal. Vita strips are not as accurate as Verio strips, according to the respective UK labels for the Vita (98% of results within 0.83 mmol/l [15 mg/dl] or 20% of reference) and Verio Pro (99% within the tighter range of 0.67 mmol/l [12 mg/dl] or 15% of reference). We have previously reported that the Cellnovo system uses OneTouch Verio strips. We apologize for this error.

- **An unspecified metabolic surgery product remains on track for regulatory submission in 2012;** we know few details on this but assume that this device will be designed to capture the benefits of gastric bypass surgery with a less-invasive procedure.

PHARMACEUTICALS PIPELINE

- **Following the company's extensive pipeline review in May 2011, few new updates were provided regarding J&J's cardiometabolic pipeline.** Management confirmed that they are on schedule to submit J&J/Mitsubishi Tanabe's SGLT-2 inhibitor, canagliflozin, to the FDA and EMA in 2Q12. A fixed-dose combination product with metformin is also in phase 3 studies. We were excited to hear management confirm that they would present canagliflozin data at ADA; as a reminder, J&J did not reveal any data on the product at EASD 2011 or IDF 2011. Management also did not provide an update on J&J's MTP inhibitor (JNJ-16269110, phase 2) for the treatment of type 2 diabetes, the company's insulin sensitizer/weight loss agent in phase 2 studies (name not disclosed), or any preclinical candidates developed through their partnership with Metabolex or internal metabolism discovery program. For more details on canagliflozin development and these early-stage programs, see the May 26, 2011 Closer Look at bit.ly/wYfhS0.

- **The supplementary new drug application for Nucynta ER (tapentadol extended release) in diabetic peripheral neuropathy remains under FDA review following J&J's submission in October 2011.** The FDA's typical review time for sNDAs is 10 months, so we expect that the agency will issue a decision in mid-2012. As a reminder, Nucynta ER is a centrally acting oral analgesic that acts as both a (mu) opioid receptor agonist and a norepinephrine uptake inhibitor. For details on the drug's clinical program and the diabetic peripheral neuropathy field broadly, see the November 13, 2012 Closer Look at bit.ly/wAXbMQ.

Questions and Answers

Q: Can you provide an update on canagliflozin?

A: We expect to file in the second quarter for type 2 diabetes, so we're very pleased there. We also plan to show some data at ADA. It's all on target.

--by Joseph Shivers and Kelly Close