



## MEMORANDUM

### J&J 3Q13 - Worldwide Diabetes Care revenue down 11%; US Diabetes Care revenue down 28%; Invokana continues capturing strong NBRx share - October 30, 2013

#### Executive Highlights

- Worldwide Diabetes Care sales totaled \$557 million, down 11% on a reported and operational basis.
- Invokana has captured 17% of the US new to brand prescription share in endocrinology in people with type 2 diabetes, excluding insulin and metformin.

On October 15, Johnson and Johnson CEO Alex Gorsky led the company's 3Q13 financial update. Worldwide Diabetes Care revenue totaled \$557 million, down 11% year-over-year (YOY) on both a reported and operational basis. While the global 3Q13 decline is not quite as steep as it was in 2Q13, this is still the sixth consecutive quarter of revenue decline. Sequentially, worldwide Diabetes Care dropped 5% as reported. US Diabetes Care revenue totaled \$237 million in 3Q13 - the lowest quarterly revenue since we began reporting J&J financials eight years ago. Sales declined 28% YOY (J&J's steepest YOY US decline in eight years), and 8% sequentially from 2Q13. Management only briefly mentioned Diabetes Care during the call, remarking that the marked decline in the US was "primarily related to competitive bidding." As a reminder, 3Q13 was the first full quarter in which competitive bidding had been implemented in full force; that said, J&J's US Diabetes Care business has been under pressure for some time. Unfortunately, considering that Medicare sales account for approximately 20% of J&J's Diabetes Care device sales (as reported in the 2Q13 call), we are not optimistic that these sales will return to growth in the near future. Internationally, Diabetes Care totaled \$320 million, up 6% as reported and 7% operationally, YOY. Sequentially, international sales declined 3%. During the call, management noted that success of the launch of the Animas Vibe insulin pump contributed to the international growth; as a reminder, the Animas Vibe was approved in Canada on September 9. We don't have a good idea of progress in the US but we assume the overall business decline is not a positive on this front. J&J is the first of the Big Four blood glucose monitoring (BGM) companies to report. Both Abbott and Roche fared better than J&J, with Abbott worldwide Diabetes Care relatively flat as reported and up 1% operationally. Similarly, Roche worldwide Diabetes Care was flat as reported and up 3% operationally. For more information, please see our Abbott Quick Take at <http://www.closeconcerns.com/knowledgebase/r/cd650b72> and our Roche Quick Take at <http://www.closeconcerns.com/knowledgebase/r/5eb965f7>. We await Bayer's results on October 31; in 2Q13, our estimates show Diabetes Care grew ~8-10% YOY in 2Q13 (Bayer provides limited information on its Diabetes Care business), likely due to the April Contour Next launch in the US.

While management did not disclose sales for Invokana (3Q13 is its second full quarter on the market), we learned that Invokana has now captured 17% of the US new to brand prescription share (NBRx) in endocrinology in people with type 2 diabetes (excluding insulin and metformin). As a reminder, in September, the EMA's CHMP issued a positive opinion on Invokana approval in Europe. The Invokana/metformin IR fixed-dose combination (FDC) remains under regulatory review in both the US and EU, and the Invokana/metformin XR FDC remains in phase 3 in the US; notably, J&J has previously indicated interest in positioning this FDC as a first-line option. Whether or not this is possible remains a question; payers usually ask patients to take metformin solely first, and for dosing purposes, taking a FDC as a starting point may be challenging (we aren't certain the degree to which Janumet is popular as a first-line drug and are doing some work on this). While J&J has not explicitly stated the intention to enter the market

with a branded SGLT-2 inhibitor FDC (it could partner with a DPP-4 inhibitor manufacturer), we would be surprised if J&J were not planning on this, with timing and partner being the main questions. Management did not provide updates on Invokana's cardiovascular outcomes trial (CVOT), CANVAS, which has a primary completion date of March 2017. As we understand it, J&J plans to initiate a new CVOT for Invokana to investigate cardiovascular superiority (details below). It seems a shame that trials have a hard time proving both safety and superiority; this is a lot of resources and patients to tie up.

## FINANCIAL UPDATES - DIAGNOSTICS

- Worldwide Diabetes Care (LifeScan/Animas) revenue totaled \$557 million in 3Q13, down 11% year-over-year (YOY) both as reported and operationally.** This was a relatively easy comparison against a 5% YOY decline as reported and 1% YOY operational growth in 3Q12. For the fourth quarter in a row, the US fared worse than international, with US revenue falling 28% YOY. This is the steepest decline in J&J's US revenue since we began reporting in 2006. International sales grew 6.3% YOY and 6.5% YOY on a reported and operational basis, respectively, in 3Q13. While we are excited to once again see growth in the international market (the last time J&J reported positive YOY growth was in 4Q12), we note that this was a relatively easy comparison, as international revenue fell 7.7% YOY in 3Q12.

**Table 1:** Worldwide Diabetes Care Revenue in 3Q13.

	3Q13 Revenue in millions	Reported (Operational) Growth from 3Q12
<b>J&amp;J Diabetes Care</b>	\$557	-11.4% (-11.3%)
<i>US</i>	\$237	-27.7%
<i>International</i>	\$320	6.3% (6.5%)

- The Worldwide Diabetes Care revenue of \$557 million represents J&J's lowest quarterly Diabetes Care revenue since 1Q09.** The 11% YOY decline (both as reported and operationally) is roughly in line with recent quarterly performances - worldwide Diabetes Care fell 10% in 1Q13 and 13% in 2Q13. With the exception of the 13% decline in 2Q13, the 3Q13 drop was the sharpest decline since 1Q09 when revenues fell 12% YOY as reported and 6% operationally, which itself was a challenging comparison as revenue grew 7% YOY as reported in 1Q08.

**Table 2:** Worldwide Diabetes Care Revenue (2Q12-3Q13).

Worldwide Sales						
	2Q12	3Q12	4Q12	1Q13	2Q13	3Q13
<b>Worldwide Revenue</b> (millions)	\$673	\$629	\$644	\$600	\$589	\$557
<b>Reported Growth</b> (year-over-year)	-1.2%	-5.3%	-3.9%	-10.4%	-12.5%	-11.4%
<b>Operational Growth</b> (year-over-year)	2.9%	-1.1%	-2.6%	-9.8%	-11.8%	-11.3%

- US Diabetes Care revenue totaled \$557 million in 3Q13, J&J's lowest quarterly total in the US since we began reporting J&J financials eight years ago.** Revenue declined a steep 28% YOY, an even greater decline than in 2Q13, when revenue declined 23%. The comparison for

3Q13 was easier than in 2Q13 (US revenue fell 3% in 3Q12 as reported and grew 1% in 2Q12), again reminding us the extent to which the BGM industry has been hit by pricing pressures.

- **During the call, management attributed the steep decline primarily to competitive bidding.** With competitive bidding having gone into effect July 1, 3Q13 was the first quarter that recorded the full impact of this measure. We expect that revenue growth will continue to be challenging for J&J in the US in the near term. In 2Q13, J&J remarked that it is adapting its business model to meet the challenges brought on by competitive bidding; we believe details will be scarce for some time. As a reminder, J&J remarked in 2Q13 that Medicare sales accounted for just over 20% of US sales. The low prices of mail-order strips (\$0.21 per strip) from CMS' competitive bidding affects the revenue of BGM companies, which cannot afford to sell their strips at such a low price. Although 3Q13 was the first full quarter that competitive bidding had been implemented, the Big Four began attributing revenue decline to competitive bidding in 1Q13. For more background on CMS' competitive bidding, please see our February 2013 report at <http://www.closeconcerns.com/knowledgebase/r/993d586e>.
- **Competitive bidding with insulin pumps may become an issue in the US at some stage,** although at present, we do not believe there are low-cost suppliers. This could change with Asante or other new entrants.

**Table 3:** US Diabetes Care Revenue (2Q12-3Q13).

US Sales						
	2Q12	3Q12	4Q12	1Q13	2Q13	3Q13
<b>US Revenue</b> (millions)	\$337	\$328	\$295	\$283	\$259	\$237
<b>Reported/Operational Growth</b> (year-over-year)	1.2%	-3.0%	-10.6%	-19.6%	-23.1%	-27.7%

- **International Diabetes Care sales totaled \$320 million, up 6% YOY as reported and 7% operationally.** The comparison against an 8% reported decline in 3Q12 (and 0.8% operational growth) was relatively easy. Management used similar language as in previous recent quarters, noting that strong growth in emerging markets were partially offset by lower sales in developed markets. Additionally, from a product perspective on the international front, management remarked that successes of the Animas Vibe launch contributed to international sales growth in 3Q13.

**Table 4:** International Diabetes Care Sales (2Q13-3Q13).

International Sales						
	2Q12	3Q12	4Q12	1Q13	2Q13	3Q13
<b>International Revenue</b> (millions)	\$336	\$301	\$349	\$317	\$330	\$320
<b>Reported Growth</b> (year-over-year)	-3.4%	-7.7%	2.6%	-0.3%	-1.8%	6.3%
<b>Operational Growth</b> (year-over-year)	4.6%	0.8%	5.2%	0.9%	-0.5%	6.5%

- **Worldwide Diabetes Care revenue fell 5% sequentially.** By geographic region, US sales declined 8.5% sequentially (the same in 2Q13), and internationally, Diabetes Care revenue declined 3% sequentially. Historically, international sequential performance alternates growth and decline, so a 3% decline in 3Q13 was not surprising.

**Table 5:** Diabetes Care Sequential Performance (2Q13-3Q13).

Sequential Performance						
	2Q12	3Q12	4Q12	1Q13	2Q13	3Q13
<b>Worldwide Sequential Growth</b>	0.4%	-6.5%	2.4%	-6.8%	-1.8%	-5.4%
<b>US Sequential Growth</b>	-4.3%	-2.7%	-9.9%	-4.2%	-8.5%	-8.5*%
<b>International Sequential Growth</b>	5.7%	-10.4%	15.8%	-9.0%	4.1%	-3.0%

\*This value is rounded from 8.49%, which is why the text reports US sequential growth as 8%.

- **As it often is, J&J was the first of the Big Four BGM companies to report 3Q13 results.** Similarly to 2Q13, Abbott (who reported October 16) and Roche (who reported October 17) performed better than J&J in terms of growth. Overall, Abbott's Diabetes Care division increased 0.4% as reported and 1% operationally while Roche remained relatively flat (decline of 0.2% YOY as reported). Internationally, Abbott grew ~1% YOY as reported; Roche remained relatively flat YOY as reported. In the US, Abbott declined 10% YOY (although this was an easy comparison, with revenue declining 8% YOY in 3Q12). Similarly, Roche declined 10% YOY in North America with a relatively easy comparison (revenue declined 11% YOY in 3Q12). We await Bayer's report on October 31. Our full reports for Abbott, Roche, and Bayer will have further comparisons of the financials of the Big Four BMG companies.
- **Pooled revenue for J&J, Abbott, and Roche totaled \$1.5 billion in 3Q13, down 3.3% as reported from combined revenue in 3Q12.** As a reminder, direct comparison between J&J, Abbott, and Roche is difficult because each company's Diabetes Care business includes a fraction of non-BGM revenue (J&J and Roche have global insulin delivery and Abbott has continuous glucose monitoring).

## FINANCIAL UPDATES - PHARMACEUTICALS

- **While management did not break out sales for Invokana (3Q13 is its second full quarter on the market), we learned on the call that through mid-October, J&J's SGLT-2 Invokana has now captured 17% of the US new to brand prescription share (NBRx) in endocrinology in people with type 2 diabetes (excluding insulin and metformin).** NBRx share measures share of new patient starts and switches. For comparison, in 2Q13 (Invokana's first full quarter on the market), Invokana had captured ~15% of NBRx share amongst US endocrinologists in week 13 of the drug's launch, surpassing that of the major US DPP-4 inhibitors (Januvia, Tradjenta, and Onglyza) - at that time J&J did not specify whether or not the analysis included insulins or generics.
- **Invokana remains under regulatory review in Europe - as announced on September 20, 2013, management noted that Invokana has received a positive opinion from the EMA's CHMP.** This would suggest that the EMA should make a final decision in the coming months. J&J submitted Invokana in June 2012, meaning that Invokana will have experienced a longer-than-standard 12-month review cycle.

- **The Invokana/metformin IR fixed dose combination (FDC) remains under regulatory review in the US and Europe, while the Invokana/metformin XR FDC remains in phase 3 in the US.** The XR formulation is currently being investigated in one phase 3 trial that began in June 2013 and has an estimated primary completion date of May 2014 and full study completion date of December 2014 (Clinical Trials Identifier: NCT01809327). The trial is currently enrolling with a target enrollment of 1,180 treatment-naïve patients with type 2 diabetes and inadequate glycemic control. Please see our J&J 2Q13 report for more details at <http://www.closeconcerns.com/knowledgebase/r/164d9ab5>.
  - **J&J has not stated intentions of developing an Invokana/DPP-4 inhibitor FDC.** Although J&J does not have a proprietary DPP-4 inhibitor, it could partner with a DPP-4 inhibitor company that does not have an SGLT-2 inhibitor. As a potential option, Takeda has a DPP-4 inhibitor (Nesina [alogliptin]) and no SGLT-2 inhibitor. Other companies with SGLT-2 inhibitors in development have expressed great interest in SGLT-2/DPP-4 combination therapies. Merck and Pfizer partnered earlier this year to develop Pfizer's SGLT-2 inhibitor ertugliflozin and eventually Januvia/ertugliflozin FDCs. Lilly, at its October Investor Meeting, indicated that it plans to file an empagliflozin/linagliptin (Lilly/BI's DPP-4 inhibitor Tradjenta) and empagliflozin/metformin FDC in 2014. BMS/AZ is testing its Forxiga/Onglyza (dapagliflozin/saxagliptin) in phase 3 as well as a triple combination therapy Forxiga/Onglyza/metformin.
- **Management did not comment on Invokana's ongoing CANVAS cardiovascular outcomes trial.** Because J&J was unblinded to interim CANVAS data at the FDA Advisory Committee meeting for Invokana, J&J can no longer use CANVAS to investigate whether Invokana is cardioprotective. CANVAS can now only be used to show non-inferiority, and as we understand it, J&J plans to initiate a new cardiovascular outcomes trial to investigate superiority. CANVAS remains ongoing with an estimated primary completion date of March 2017 and estimated trial completion date of June 2018.
- **Other SGLT-2 inhibitors on the market or in development include:** BMS/AZ's Forxiga (dapagliflozin; on the market in Europe and submitted in the US with PDUFA date of January 14, 2014), Lilly/BI's empagliflozin (submitted in the US and EU), Astellas/Kotobuki's ipragliflozin (submitted in Japan), Taisho's luseogliflozin (submitted in Japan), Pfizer/Merck's ertugliflozin (phase 3 expected 2H13), BHV Pharma/Kissei's remogliflozin (phase 2), Theracos' EGT0001442 (phase 2), Lexicon's SGLT-1/SGLT-2 dual inhibitor LX4211 (phase 3 initiation was expected in 1H13 and is now expected in 2H13), and Novartis' SGLT-1/SGLT-2 dual inhibitor LIK066 (phase 2). Roche/Chugai's phase 3 tofogliflozin has been discontinued.
  - **Our J&J 2Q13 report included detailed discussion on where we feel potential areas for differentiation exist for SGLT-2 inhibitors.** Please see our 2Q13 report at <http://www.closeconcerns.com/knowledgebase/r/164d9ab5> for our thoughts on patient and prescriber hassle factor and use in the population with renal impairment, potency, selectivity for SGLT-2 over SGLT-1, and indications beyond type 2 diabetes.
- **For those following this market extremely closely, Dr. Sanjay Kaul (Cedars Sinai Medical Center, Los Angeles, CA) delivered a very comprehensive and truly outstanding address at EASD 2013 on his evaluation of SGLT-2 inhibitors to date** (please see page 3 of our report at <http://www.closeconcerns.com/knowledgebase/r/a436c2c2>). A major theme of his presentation was uncertainty - uncertainty with regards to SGLT-2 inhibitors' long-term safety concerns, durability, and the future of cardiovascular safety requirements for diabetes drugs as a whole.

## PIPELINE UPDATES - DIAGNOSTICS

- **Management announced the approval of the Animas Vibe in Canada on September 9,** although to our knowledge no launch date has been established and shared. We have still not heard

news on the US approval of the Vibe. As a reminder, J&J submitted the application for premarket approval (PMA) in 1Q13, making a potential approval possible before the end of 2013. For greater detail on the submission and implications of a US Animas Vibe launch, please see page five of our J&J 1Q13 report at <http://www.closeconcerns.com/knowledgebase/r/59b616b4>.

- **The new OneTouch Verio meter was a focus of LifeScan's marketing at EASD.** The new meter features blood glucose levels in large font, a color-code indicating low, in-range, and high blood glucose results, and automatic messages such as "your average over the last 7 days is 6.2 mmol/l." Representatives at the booth remarked that this meter may be especially beneficial for those who need more guidance and feedback on how they are managing their blood glucose levels.
- **J&J provided no updates on the next feasibility study of the hypoglycemia-hyperglycemia minimizer (HHM) system.** As a reminder, J&J received an Investigational Device Exemption (IDE) for this system in June 2013, allowing the system to be used in clinical trials. We assume the system will incorporate Dexcom's G4 Platinum CGM instead of the Seven Plus.
  - **As a reminder, J&J presented results from the 24-hour overnight study at this year's ADA.** For more information, please see our 1Q13 report at <http://www.closeconcerns.com/knowledgebase/r/59b616b4>.
- **Management also did not discuss the possibility of combining Calibra Medical's bolus-only insulin with Invokana.** In 2Q13 J&J noted the possibility of using Calibra to market Invokana with Diabetes Care products. We understand that J&J will commence additional clinical studies of the device as J&J prepares to launch. For more information, please see our J&J 2Q13 report at <http://close.cx/JJ2Q13>.
- **J&J did not provide any additional pipeline updates and did not include a Medical Devices & Diagnostics pipeline update in its supplementary materials for 3Q13.** The information below is our summary of J&J's future device products, derived from press releases, conferences, and the 3Q13 call.

**Table 6: J&J Device Pipeline.**

Pipeline Product	Updated Timeline	Change from 2Q13	Notes
<b>OneTouch Verio Sync Blood Glucose Meter</b>	Launch date not specified	Demoed in the exhibition hall at ADA 2013	Allows wireless communication between a Verio meter and an iPhone app. For more information, please see our report at <a href="http://close.cx/OneTouchVerioSync">http://close.cx/OneTouchVerioSync</a> .
<b>OneTouch Verio Blood Glucose System (Version 3)</b>	Planned US and EU submissions in 2013+	No information given on the product in 3Q13	We are not clear on what advancements this might have, though based on the nomenclature we believe the strips will be the same as those used for current Verio products.
<b>Animas Vibe Insulin Pump with integrated</b>	Pending FDA approval (PMA submitted)	Canadian approval in September; no information	We expect approval could come sometime in late 2013 or early 2014.

<b>Dexcom G4 Platinum CGM</b>		given on the product in 3Q13	
<b>OneTouch Ping Verio Insulin Pump with Meter Remote</b>	Planned US submission in 2013+	No information given on the product in 3Q13	We suspect this will resemble the current OneTouch Ping insulin pump and meter remote but replace the handheld with a Verio meter. As we understand it, this product will not have Dexcom G4 integration - we wonder if the company will decide to pursue this if launch of the Vibe is very successful.
<b>OneTouch Verio Pro+ Point of Care Glucose Meter</b>	Recently recalled for software issue	No information given on the product in 3Q13	This in-hospital meter is approved in Japan and the EU; intentions US submission has not been expressed in the pipeline. A "version 1.5" is targeted for submission in 2013+ in both the EU and Japan; again, the US is not included and we wonder why this is the case.
<b>Next Generation Glucose Testing Platform</b>	Planned US and EU submission in 2013+	No information given on the product in 3Q13	We assume this is a new line of strips beyond the current Verio platform.
<b>Next Generation OneTouch UltraVue Verio Platform</b>	Planned Japan submission in 2013+	No information given on the product in 3Q13	This could be the same as the above entry, though we cannot be sure since they were listed separately on a past slide.
<b>Hypoglycemia-Hyperglycemia Mitigation System</b>	-	J&J recently presented a study at ADA 2013	The system pairs an insulin pump, a continuous glucose monitor, and a model predictive control algorithm. Historically, the CGM has been the Dexcom Seven Plus; we assume Animas will or already has switched over to the G4 Platinum.
<b>Metabolics (surgical care product)</b>	Planned submission in 2013+; region not detailed	No information given on the product in 3Q13	The product is unspecified, but we assume that this device will be designed to capture the benefits of gastric bypass surgery with a less-invasive procedure.

- **Notably, J&J is collaborating on two different studies that evaluate the clinical efficacy of telehealth systems for diabetes management.**
  - **Recruiting began in August 2013 for Digital Assisted MONitoring for Diabetes (DIAMONDS), which will assess a telemedicine- and web-based system platform for SMBG data transmission and analysis** (ClinicalTrials.gov Identifier: NCT01804803). The phase 3 trial will compare a regular blood glucose meter to a smartphone-connected blood glucose meter (we assume the OneTouch Verio Sync) that

enables real-time collection and transmission of measured glucose values to a remote server. The server processes results and delivers feedback to patients and medical staff. DIAMONDS will assess the primary outcome of change in A1c from baseline at three and six months. We hope to learn that it will also measure time in range as a secondary endpoint. The trial was posted on February 25, 2013 and is slated for primary completion in May 2014. The trial is currently recruiting participants (n=250). The University of Bari is the study's sponsor and Lilly is listed as a second collaborator. Please see page eight of our J&J 1Q13 report at <http://www.closeconcerns.com/knowledgebase/r/59b616b4> for further details.

- **A second randomized clinical trial will compare a behavioral intervention that combines patient education, SMBG, and remote patient monitoring to standard of care** (ClinicalTrials.gov Identifier: NCT01715649). Patients will connect their meters to a "Telehealth Unit" (details not provided), which will allow nurse care coordinators and the study team to remotely monitor data. The study team will send the patient weekly reminders and suggestions via the Telehealth Unit, and a study nurse will provide monthly telephonic feedback. The primary outcome is change from baseline A1c after six months; secondary outcomes include three-month measures of patient empowerment, behavior change, and knowledge. Here too, we hope to learn that it will also measure time in range as a secondary endpoint. The study is currently enrolling by invitation (n=150) and is slated for primary completion in December 2013. The trial has not been updated on ClinicalTrials.gov since October 2012. See page eight of our J&J 1Q13 report at <http://close.cx/JJ1Q13> for more details.

## PIPELINE UPDATES - PHARMACEUTICALS

- **Management did not provide updates to diabetes candidates aside from Invokana.** To our knowledge, J&J has an MTP inhibitor last known to be in phase 2 (JNJ-16269110; no active trials on ClinicalTrials.gov), an insulin sensitizer (which we suspect is JNJ-41443532 and was in phase 2 as of May 2011; also no ongoing studies listed on ClinicalTrials.gov), as well as various preclinical candidates developed through J&J's partnership with Metabolex, created through its own discovery program, or licensed from Evotec AG and Harvard, including Dr. Douglas Melton's potentially ground-breaking betatrophin for type 1 diabetes. As a reminder, J&J also entered into a partnership with NGM Biopharmaceuticals earlier this year to develop treatments for type 2 diabetes that mimic the glucoregulatory effects of metabolic surgery, and J&J has the option to acquire Vascular Pharma's VPI-2690B pending completion of phase 2 (no trials have begun yet). VPI-2690B is a monoclonal antibody against the  $\alpha V\beta 3$  receptor that inhibits IGF-1 mediated smooth muscle cell proliferation stimulated by hyperglycemia, which could mitigate the effects of prolonged hyperglycemia in the kidney.
  - **In mid-June, NGM entered into a partnership with AZ's biologic arm, MedImmune,** to discover, develop, and commercialize type 2 diabetes and obesity treatments from NGM's enteroendocrine cell program (which aims to identify secreted peptide hormones potentially related to the metabolic effects of bariatric surgery). NGM's partnerships with AZ and J&J appear highly similar, and we are as yet unclear how the J&J partnership will be affected.
- **For greater detail on J&J's Pharmaceutical Business Review in May, please see <http://close.cx/JJPharma1>.** In May, management noted that Invokana's long patent life will allow J&J to explore various opportunities, such as seeking additional indications in type 2 diabetes and exploring type 1 diabetes and obesity as potential areas for Invokana indications. Outside of Invokana, J&J highlighted its partnership with Evotec, Harvard, and Dr. Douglas Melton on betatrophin, as well its interest in exploring the potential of stem cell therapy - another area of Dr. Melton's laboratory.



## QUESTIONS AND ANSWERS

**Q: If you look at the geographic results, Europe is growing a lot faster than the US. I assume Pharma is a big part of it, but do you think you're also gaining share in Europe in MD&D? And then broadly for Europe, what do you think about the environment for Europe in 3Q13 vs. 2Q13?**

A: We do see strong growth in Europe. It is primarily driven by the Pharmaceutical business as, obviously, we've launched some exciting new products in the Pharma business. In MD&D, we continue to see government austerity pressures, and quite frankly, a reduction of overall volumes in those businesses. However, we seem to be making pretty good progress in the Ethicon Surgical Care business and even those in diabetes and the DePuy legacy business in Europe, as well.

*--by Hannah Martin, Jessica Dong and Kelly Close*