



MEMORANDUM

J&J 4Q14 - Invokana sales reach \$201 million; LifeScan/Animas declines 9%; US launch of OneTouch Verio BGM - January 20, 2015

Executive Highlights

- J&J broke out sales for its SGLT-2 Invokana (canagliflozin) franchise for the first time: combined 4Q14 sales of Invokana and Invokamet (canagliflozin/metformin) reached \$193 million in the US and \$8 million internationally. Overall this was a very good result though international sales appear a bit low relatively speaking given that Invokana is approved in 56 countries (albeit many recently).
- [A new trial from Dr. Ralph DeFronzo](#) will investigate the combination of Invokana and Novo Nordisk's once-daily GLP-1 Victoza (liraglutide). Recent hallway chatter is raising interest in this combo, even though it is not as convenient as a "one-bill, one co-pay" fixed dose combo.
- Worldwide LifeScan/Animas sales in 4Q14 declined 9% as reported and 3% operationally year-over-year (YOY). Weakness was attributed to US price declines, where revenues declined 6% YOY despite a very easy comparison to [4Q13](#). We would have guessed volume had played a role given Medtronic's strength of late.
- LifeScan [announced](#) following the call (but not on it) the US launch of the OneTouch Verio BGM; the new meter includes color-coding based on in-range results and motivational progress notifications. Management said it is "putting together the [Animas Vibe] launch literally as we speak."

J&J provided its 4Q14 update early this morning in a call led by CEO Mr. Alex Gorsky. As in the past several quarterly updates, the company's diabetes discussion focused almost solely on the SGLT-2 inhibitor Invokana (canagliflozin), with little mention of the LifeScan/Animas portfolio (this is actually not new that J&J says pretty little about LifeScan/Animas; for 4Q14, however, saying literally nothing, not even a sentence, was new). Below, we bring you our top ten highlights from the call and supporting materials, followed by selected Q&A.

Invokana Highlights

1. Notably, J&J broke out sales of the SGLT-2 Invokana franchise for the first time; combined 4Q14 sales of Invokana and Invokamet (canagliflozin/metformin) reached \$193 million in the US and \$8 million internationally.
2. During Q&A, management expressed confidence in Invokana's strong position with payers despite increased pricing pressure in the overall field. Indeed, we've heard that there is a bit of a co-pay war going on with SGLT-2s, among BI/Lilly, AstraZeneca, and J&J. The highest co-pay is \$10 as we understand it and the lowest is \$0.
3. Though it was not mentioned during the call, we were intrigued to see a new trial investigating Invokana in combination with Novo Nordisk's once-daily GLP-1 Victoza (liraglutide) currently [listed as recruiting on ClinicalTrials.gov](#).
4. As a reminder, several trials are underway that could support expanded indications for Invokana in [type 1 diabetes](#), [obesity](#), and [diabetic nephropathy](#). We're extremely happy for patients and HCPs to see such robust investment in this arena.

LifeScan/Animas Highlights

5. Global LifeScan/Animas sales totaled \$514 million in 4Q14, declining 9% as reported and 3% operationally year-over-year (YOY); for 2014, sales totaled just \$2.1 billion, down 7% as reported and 5% operationally, the lowest full-year total since 2006.
6. US Diabetes Care revenues totaled \$206 million in 4Q14, dropping 6% YOY despite a quite easy comparison to [3Q14](#) when sales declined a sizable 26% YOY; for the full year, revenue declined 13% to reach \$864 million. We felt this decline was pretty big given that the "competitive bidding" impact annualized mid-year - another sign of ongoing and persistent pricing pressure.
7. International Diabetes Care revenue totaled \$308 million, down 11% as reported and 2% operationally YOY in 4Q14. Sales for the full year totaled \$1.3 billion, down 3% as reported and rising 1% operationally. We know that fairly recently, US and international revenue were on par with each other - international has not declined as fast as US, though we suspect average US profit margins are still higher than average profit margins outside the US - even though the US margins have declined precipitously in the past two years.
8. Separate from the call, LifeScan [announced](#) the US launch of the [OneTouch Verio meter today](#). The new meter includes color coding based on in-range results and motivational progress notifications, both of which we're excited about. The meter is available now at a retail price of \$19.99. Its form factor is clunkier than the sleek VerioIQ, and we look forward to a test drive to better understand its additional capabilities.
9. The [slide deck](#) highlighted the FDA approval of the Animas Vibe pump as an "Important Development." The December 1 [approval announcement](#) called for a US launch this month, and management said it is "putting together the launch literally as we speak." See [our diaTribe test drive](#) for our views on the device.
10. In Q&A, management said more information on the Calibra Finesse insulin delivery device is expected in the "back end of the year 2016." It was hard to know if this was a delayed launch timeline from the May 2016 guidance shared at last year's [Medical Devices & Diagnostics Day](#) - once upon a time, of course, the product was expected by 2010.

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Invokana Highlights

1. Excitingly, J&J broke out sales for the Invokana (canagliflozin) franchise for the first time; combined sales of Invokana and Invokamet (canagliflozin/metformin) were \$193 million in the US and \$8 million internationally in 4Q14. This would represent an impressive ~50% sequential increase from the \$123-\$132 million in US sales we estimated in [3Q14](#) and places full-year 2014 domestic sales at ~\$410-\$515 million (according to our estimates from previous quarters). We suggested in our [4Q13](#) report that Invokana would be able to achieve \$500 million in sales in 2014, and looking further forward the drug appears well positioned to reach blockbuster status in 2015. Invokana sales have shown a strong positive trajectory over the past year, and management continues to characterize the product as a strong driver of growth.

- **Invokana has achieved 4.1% of total prescription (TRx) share in the US type 2 diabetes market (excluding insulin and metformin), up from 3.3% in 3Q14.** TRx among US endocrinologists grew from 9.2% in 3Q14 to 10% in 4Q14, and led its category in new-to-brand share (NBRx) among endocrinologists, exceeding 19% at the end of the year.
- **While it was not mentioned during the call, we learned later from management that Invokana has been approved in 56 countries; Invokamet/Vokanamet has been**

approved in 3Q. Based on this quarter's results, ex-US sales currently account for only a small portion (~4%) of total Invokana revenue. We hope to learn more in the coming quarters about how the varying reimbursement decisions for Invokana in Europe (see our [3Q14 report](#)) have impacted its international performance. Germany, with its particularly tough stance on new diabetes drugs, is unlikely to grant Invokana much of a pricing premium over generics following a [comparative efficacy analysis](#) that found "no additional benefit" vs. sulfonylureas (largely due to technicalities) - this is absolutely unbelievable in our view given the hypoglycemia and weight advantages. Indeed, it is likely that the product will be withdrawn in Germany unless German authorities reverse the decision or if price negotiations fall strongly in J&J's favor. Generally, however, management did note during Q&A that the company has had "good success outside the United States" in terms of reimbursement - we hope to hear more details in the future but imagine that most authorities and payers would find the combination of solid A1c decreases, weight benefits, and blood pressure reductions compelling. Still - given the percentage of overall revenue and likely profit, it's hard to believe that the success is that meaningful relative to the US, where Invokana still seems to be benefiting from its first-in-class status.

2. During Q&A, management expressed confidence in Invokana's position with payers despite increased pricing pressure in the field as a whole. Management argued that Invokana's impressive clinical profile has led to strong formulary uptake and that while "we certainly see competitive pressures," the company still sees great potential for continued growth. This aligns with management's comments at last week's [JP Morgan Healthcare Conference](#), forecasting continued strong performance despite increasing payer pressure for diabetes drugs - reasons cited included Invokana's status as the market-leading SGLT-2 inhibitor as well as the potential for expanded indications (see highlight #4 below). The product's first-in-class status should continue to work to its advantage in terms of formulary positioning, though we wonder what the impact will be of the arrival of SGLT-2 inhibitor/DPP-4 inhibitor fixed-dose combinations (FDCs) from J&J's competitors in the near future and more generally whether certain competitors may be able to leverage the breadth of their diabetes portfolios to gain a slight advantage in negotiations. As a reminder, FDA approval for Lilly/BI's empagliflozin/linagliptin FDC is expected as early as next month, and AZ's saxagliptin/dapagliflozin FDC was recently [submitted](#) to regulatory authorities.

- **All three SGLT-2 inhibitors on the market in the US currently have associated savings programs that allow most patients with commercial insurance to pay very little; we will be curious to see how pricing dynamics change if and when these programs are discontinued (though we expect them to be in play for awhile).** We suspect that companies will be under increasing pressure from investors to phase out these programs if uptake continues to be strong - during AZ's November [Investor Day](#), one analyst inquired about ways to transition away from the cost-savings program for Farxiga (dapagliflozin) given the very successful launch of the drug. Management responded that the program was not intended to be indefinite but that more time was needed to see how the competitive SGLT-2 inhibitor market develops before making any predictions. Given that the SGLT-2 inhibitor class is still relatively new (Lilly/BI's Jardiance [empagliflozin] was just launched in [3Q14](#)), we do not expect any dramatic changes in the near future. The 4Q14 results for Invokana provide at least an early sign that the class is picking up enough steam for growth to continue well beyond the end of savings programs.

3. Though it was not mentioned during the call, we were intrigued to see a new trial investigating Invokana in combination with Novo Nordisk's Victoza (liraglutide) currently recruiting on ClinicalTrials.gov (Identifier: [NCT03234842](#)). Dr. Ralph DeFronzo (University of Texas Health Science Center, San Antonio, TX) is running the open-label trial (n=90) in collaboration with Janssen. The primary endpoint is change in hepatic glucose production after four months with the combination vs. either component alone; the rationale for this endpoint is the idea that SGLT-2 inhibitors increase hepatic glucose production as a counterregulatory response that blunts their efficacy (though this is not stated in Invokana's label). Secondary endpoints include change in A1c and fasting plasma glucose (we wish they were looking at time in zone!) and changes in blood pressure and total and visceral body fat. Primary completion is expected in February 2016. This will be closely watched, that is for sure.

- **There has been a great deal of excitement in the field recently around GLP-1 agonist/SGLT-2 inhibitor combinations.** The hope is that GLP-1 agonist/SGLT-2 inhibitor combination therapy could produce an additive or even (!) synergistic effect on glycemic control, along with favorable effects on body weight and blood pressure. Specifically, the hope is that GLP-1 agonists' ability to inhibit glucagon secretion could blunt the counterregulatory glucagon/hepatic glucose production response seen with SGLT-2 inhibitor monotherapy. AZ has [taken the lead](#) on this front with a phase 3 trial of exenatide/dapagliflozin combination therapy, and we expect that many more companies may jump in in the coming years. As management confirmed in [3Q14](#) that J&J does not have plans for an SGLT-2 inhibitor/DPP-4 inhibitor FDC, the company may be betting that such combinations will essentially represent an intermediate step and that GLP-1 agonist/SGLT-2 inhibitor combinations are likely to offer a greater leap forward in efficacy as well as an attractive "composite" - the combination of weight loss, glycemic dependency, A1c reduction, and once-daily status. J&J would of course need to pursue a partnership to develop such a combination - while Novo Nordisk is not directly involved in this trial to our knowledge, we imagine that the company would be a logical choice.

4. As a reminder, several trials are underway that could support expanded indications for Invokana in type 1 diabetes, obesity, and diabetic nephropathy:

- **Type 1 diabetes:** A [phase 2 trial](#) investigating the drug in type 1 diabetes is currently recruiting and expected to complete in May. This was one of the more exciting news items from J&J in [2Q14](#) and we believe it is part of a larger trend of exploration of type 2 diabetes drug classes (especially SGLT-2 inhibitors) in type 1 diabetes. This notion has the support of the JDRF and the Helmsley Charitable Trust - what more does one need?!
- **Obesity:** We learned in [3Q14](#) that Invokana is being investigated in combination with phentermine as a treatment for obesity; that [trial](#) is also currently recruiting and is expected to complete in June. We're very eager to see these results - we think this drug would be an excellent choice for patients at high risk of diabetes (but still pre-diabetic) and we're eager to learn more here from investigator-initiated trials.
- **Diabetic nephropathy:** The [CREDESCENCE renal outcomes study](#), initiated in February, is evaluating the potential protective effects of Invokana on the progression of diabetic nephropathy; the trial is currently recruiting and expected to complete in November 2019. This one is, of course, a very big deal - were one to find renal protection in this drug - all heck would break loose!

LifeScan/Animas Highlights

5. Worldwide Diabetes Care revenue from LifeScan BGM and Animas insulin pumps totaled \$514 million in 4Q14, falling 9% as reported and 3% operationally year-over-year (YOY); sales were down 8% sequentially. This marks 4Q14 as yet another quarter of decline globally that now includes ten of the past 11 quarters ([3Q14](#) was the lone exception). That too, the quarterly decline was on an easy comparison as sales fell 13% YOY in [4Q13](#). Accompanying slides attributed the weakness to US price declines that were partially offset by the "positive impact of adjustment to previously established reserves" (a comment echoed from [3Q14](#)) and volume growth - as we understand it, the former refers to excess US revenue reserves that the company set aside in [4Q13](#) (i.e., underreporting [4Q13](#) revenue) thereby enhancing the YOY comparison. J&J did not provide specific financials for the impact of these reserves, though in [3Q14](#), worldwide Diabetes Care revenues were ~3-4% less than reported after adjusting for the reserves. A similar calculation in 4Q14 would put the global Diabetes Care decline closer to ~10%. In either case, the financials are a bit disappointing considering the segment's poor results in [3Q14](#), though not wholly surprising considering how challenging the US environment has been in the past two years.

- **For the 2014 fiscal year, LifeScan/Animas sales totaled \$2.1 billion, down 7% as reported and 5% operationally** - this was against an easy comparison as sales fell 12% in [FY2013](#). This figure marks the lowest fiscal year total since 2006 when revenue first broke the \$2 billion plateau (\$2.2 billion in 2006). While the news is not positive, we did entertain thoughts earlier this year that the full year numbers might come in under \$2 billion - in this light, we would

note that the financials could have been more disappointing. That said, the performance does raise questions about what 2015 will look like. We are very, very concerned that US payers will miss the forest for the trees and that J&J will exit this business; with that in mind, we were very glad to hear continued expressly articulated support.

- **On that note, despite the challenges, J&J continues to express support for its LifeScan/Animas business** - "We've done a very good job [in keeping volume share]...and have been able to keep costs under control"). J&J has shown commitment to and strong interest in diabetes technology historically and that does not appear to have changed. Management acknowledged that the business is still in the process of reshaping itself in response to competitive bidding pressures in the US, and we do wonder whether the company is considering alternative device delivery models as it has shown a willingness to [reorganize its Diabetes Care business](#) in the past. We would be concerned for LifeScan given Abbott's recent launch of the Freestyle Libre, although we don't expect to see this in the US at least in the next 12-18 months.
- **Notably, Mr. Gorsky did not mention "Diabetes Care" (LifeScan/Animas) once in his prepared remarks.** This is the only instance we can recall in which the segment has been entirely disregarded, though it was highlighted in the Q&A. The business is certainly underperforming, and we can understand the desire to focus on other strides in diabetes, including Invokana. As we understand it, the area continues to be a bit of an orphan; we believe this area is managed by former Bayer Diabetes CEO Sandra Peterson, though the results don't hit her Consumer P&L - this is a very unusual set-up and don't think from a motivational perspective that it's advantageous for either Consumer or the medical device segment (previously run by Mr. Gorsky!).
- **We look forward to the remaining Big Four blood glucose monitoring companies (Roche [January 28], Abbott [January 29], and Bayer [February 26]) to report, particularly to see whether they have experienced similar challenges in the US and globally - we think it's pretty inevitable that they did.** For background, we were cautiously optimistic that declines were starting to taper a bit at [Roche](#), where North American Diabetes Care fell only 2% as reported YOY in [3Q14](#) (against a relatively easy comparison as revenue fell 10% in [3Q13](#)). [Abbott](#), too, expressed optimism that a more moderate rate of US revenue decline was indicative of declining pricing pressures despite the fact that Diabetes Care sales were down 16% YOY (on an easy comparison to a sales decline of 10% in [3Q13](#), though this was a significant improvement from the 27% decline the company had seen in the US for the previous two quarters.). Bayer, on the other hand, acknowledged that the company [anticipates continued declines](#) moving forward (US revenue was not provided though global declines were attributed to US weakness) - this candor was appreciated.

6. US Diabetes Care sales totaled just \$206 million in 4Q14, dropping 6% YOY despite a very easy comparison to 4Q13 when sales fell 26% YOY; for the full year, revenue fell 13% to reach \$864 million (on another very easy comparison as sales fell 24% in [FY2013](#)). Disturbingly, the quarterly financials mark the lowest ever 4Q revenue for J&J in our model (which tracks back to 2004). Sequential sales were down 15%, the largest quarter-to-quarter decline the segment has seen since [4Q08](#). The numbers are somewhat surprising considering that [3Q14](#) saw a promising sales trajectory with the US business' first quarter of YOY growth since 2Q12. The accompanying [slide deck](#) attributed the financial challenge to net price declines that were offset by volume growth (and reserve adjustments discussed above). We do continue to wonder how the OneTouch VerioSync is doing, which [launched in the US in January 2014](#).

- In Q&A, management emphasized that US weakness reflects the continued impact of pricing pressures from competitive bidding (carryover from the "70% price reduction") despite the fact that the program "anniversaried" over six months ago. According to Mr. Gorsky, the stateside market remains "very challenging," a characterization that has become customary at Big Four quarterly updates over the past 18 months. Management's commentary seemed quite optimistic overall, suggesting that the struggles are common to all companies involved in SMBG right now and that in relative terms J&J is no worse off. We will watch to see the impact of pipeline innovations, such as

the OneTouch Verio (launched [today](#); see below) - it is, of course, harder than ever to innovate and the Freestyle Libre is becoming the new comparison - pretty hard to beat this.

7. On the international front, Diabetes Care revenue totaled \$308 million, down 11% as reported and a modest 2% operationally YOY in 4Q14 against a relatively neutral comparison (down 1% in 4Q13). (We note there was a very large currency impact in 4Q14.) For the full year, sales totaled \$1.3 billion, down 3% as reported and up 1% operationally against another relatively neutral comparison (up 1% for [FY2013](#)). The financials do not stand out at first glance, though deeper analysis reveals two concerning trends: (i) the quarterly performance in hard and fast revenue marks 4Q14 international revenue as the lowest since [2Q12](#) (\$301 million); and (ii) the sequential decline of 2% from a low base in [3Q14](#) (\$314 million in sales) marks the third time in four quarters that quarter-to-quarter sequential results have been negative.

- **J&J has not recently brought a new product to the OUS market, which could help explain some of the flat performance.** J&J has previously mentioned two international pipeline products - the next-gen OneTouch UltraVue Verio in Japan and a next-gen Glucose Testing Platform for the EU (see pipeline summary below) - though the absence of recent updates makes us question whether they are still in development. Based on financials alone, this is a tough time to innovate in the field, though it will almost certainly continue to be a goal for J&J. As noted, we would look to competitor [Abbott's FreeStyle Libre](#) as a great example of a bold, outside-the-box attempt to disrupt the field - this has been in the works for years as we understand it

8. LifeScan announced today the US launch of the [OneTouch Verio BGM](#), which received its [FDA 510\(k\) clearance](#) in February 2014. Notably, the launch was not referenced in the call (prepared remarks or Q&A), though LifeScan has updated its [website](#) to include a [video](#) highlighting the features of the new meter, such as a color-coded range indicator and motivational patient messaging. We were most excited to see the latter, which automatically reviews past test results and provides two types of progress messages based on performance. An "achievement" message (displayed when the current result is in range following three consecutive above range results) and a "consistency" message appears when 70% of results in the past seven days are in range. We are big fans of such positive, motivating feedback and hope to see much more of it in BGM. The user interface also provides users immediate feedback on whether a glucose reading is in a patient's target range (green indicator), above range (red), or below range (blue).

- **Overall, the marketing message is clearly one of patient engagement and convenience ("better understand your results"),** and LifeScan has come through by delivering a product that does seem quite user-friendly (see it [here](#)). Indeed, after using the OneTouch Verio Meter for a week, 94% of people with diabetes said it made their test results simple to understand (n=102, per the press release footnote).
- **The meter is currently available nationwide at an estimated retail price of \$19.99.** More details are posted on [LifeScan's website](#).
- **It is great to see LifeScan pushing ahead with innovative efforts despite the financial difficulties in the US.** We are hopeful that revenue from this newest device will help put the business on even a slightly positive trajectory though it's tough to term that an official expectation. J&J's BGM arm has brought products to the US market with a slow but regular cadence over the past year (the OneTouch VerioSync was [launched in January 2014](#)), but as noted above, has not been as active on the international scene. We wonder whether this will change in 2015, but regardless, we see the R&D activity as a great indicator of the company's commitment to the BGM field.

9. Animas is currently [accepting order requests for the Vibe on its website](#) and is "putting together the launch literally as we speak." The December 1 [approval announcement](#) called for a US launch this month, meaning the company is running right down to the wire to hit that timing. The [4Q14 slide deck](#) highlighted [the November FDA approval](#) as an "Important Development" in J&J's Medical Device segment in 4Q14 - "We are excited about the Vibe approval ... We think that's going to represent a real nice breakthrough for patients." As a reminder, FDA approval took a lengthy ~20 months review from the [1Q13](#)

[PMA submission](#). The approval helps Animas stay competitive in an increasingly competitive pump marketplace, especially given upcoming Dexcom integrations with Tandem (currently under FDA), Asante (post-Gen 5 launch), and Insulet (post-Gen 5 launch). It's hard to know if the Vibe will have a major impact on Animas' US market share, though it can only help. See [our detailed Closer Look coverage](#) of the approval and [our diaTribe test drive](#) for specific views on the device.

10. In Q&A, management said more information on the Calibra Finesse insulin delivery device is expected in the "back end of the year 2016." It was hard to know if this was a delayed launch timeline from the May 2016 guidance shared at last year's [Medical Devices & Diagnostics Day](#) - it sounds like the product is still on track for the mid-year 2016 launch, though color on the market uptake obviously wouldn't be available until the second half of the year. It is great to see the product will be commercialized, though the timing has been somewhat slow- [the acquisition took place back in July 2012](#). We assume the Finesse has required quite a bit of clinical and manufacturing work to prepare for launch, which is understandable given the profound differences from the Animas business. Management thinks the device could be a "very nice opportunity, an unobtrusive way to have insulin delivery."

- **There continues to be no timing updates on the status of the company's automated insulin delivery efforts**, a partnership that was originally [signed with JDRF in 2010](#). A small feasibility study was presented at [ADA 2014](#), though this whole part of the pipeline hasn't really moved at all. We hope to see J&J jump in full force, since it will be a requirement to stay competitive with Medtronic (who has very openly stated its goal to close the loop, and is on the way with the MiniMed 640G and 670G), and presumably other pump companies like Asante, Roche, Tandem, Insulet.

Pipeline Product	Timeline
Animas Vibe Insulin Pump with integrated Dexcom G4 Platinum CGM	FDA approval December 2014; launched planned for January 2015
Finesse insulin delivery device (acquired from Calibra Medical)	Launch expected by May 2016, with more information in the "back end" of 2016
OneTouch Ping Verio Insulin Pump with Remote Meter	No recent updates
Next Generation OneTouch UltraVue Verio	No recent updates
Next Generation Glucose Testing Platform	No recent updates
Predictive Low Glucose Suspend	Inpatient feasibility study of algorithm presented at ADA 2014
Hypoglycemia-Hyperglycemia Mitigation (HHM) System	Feasibility study presented at ADA 2013; no recent updates
Metabolics (surgical care product)	No recent updates

Questions and Answers

Q: We've seen quite a lot of contracting pressure in some areas of Pharma. What is the situation like for Invokana, from a contracting perspective?

A: We take a very broad look in the very early stages of our compound development on what potential impact or scenarios we could face regarding pricing and reimbursement. As I mentioned earlier, **we think taking a very high-innovation approach in Pharma is the right approach, and it certainly has been the most successful one for us. And so part of it starts with selecting compounds that we feel have a strong probability of**

differentiation vs. current standards of care, and we think that's certainly the case with Invokana. If you take a look at the comparative labeling that we have vs. Januvia regarding A1c reduction, regarding weight loss and other parameters, that's enabled us to have a very differentiated and strong dossier to share with decision makers and payers around the world. So as a result, not only have we seen strong acceptance, we've seen good formulary uptake. I think it's somewhere around 70% or 80% in most cases. And we've had good success outside the United States as well.

And so we think it takes, again, a very good clinical development program, strong labeling, very strong reimbursement, and commercial expertise. And so that's the way we think about these compounds. We haven't seen additional pressures as of late. We certainly see competitive pressures. But we feel very good about our compounds that we're frankly still in the launch stage of, and their potential for future growth.

Q: Your Diabetes Care is underperforming. What do you need to do to turn it around? Can you remind us when price cuts anniversaried? Also, we heard great things about the launch of the Animas Vibe in Europe. Is that going to be a good proxy for what we should expect to see in the US? Finally, can you talk about your timeline for filing and launching Calibra in the US?

A: Diabetes is clearly one of those areas where - you know, with 350 million type 2 patients and so many not in control - there's a lot of unmet need. It's been a very challenging market, particularly in the areas of the market we've been in.

The price changes went into effect about a year ago in June, but you're still seeing the impact of them and you saw them earlier in the year and you're still seeing some of them.

Look, for a very significant portion of our market, we saw over a 70% price reduction. And as you know, whenever that happens in one of your businesses, you have got to reframe that entire business. I think all of the companies involved in SMBG have gone through that kind of transition over the last year and a half. If we look at the underlying fundamentals, things such as volume share, we've actually done a very good job. We've done a very good job in managed care contracting. So as a result, we've been able to keep our volumes up, our costs under control.

But nonetheless, that business has had to completely reshape itself. And they're still in the process of getting it stabilized. We are excited about the Vibe approval. We think that's going to represent a real nice breakthrough for patients. Over in Europe we've had strong results. We're looking and we're putting together the launch literally as we speak, so we're excited about that. We think Calibra could be a very nice opportunity, a very unobtrusive way to have insulin delivery. And it looks right now like by the back end of the year 2016, we should have more on that.

So again, overall, Diabetes is an area that we feel strongly about. And by the way, this is the same team that had a very significant role in the launch of Invokana as well. And we think the relationships that they've built with the endocrinologists have been quite important for us in the launch success of that brand. So it's an area that we're interested in but clearly one that's changed, and we still have more work to do to make sure we understand the best path forward.

Q: You spent a lot of time highlighting the successes that you've had in Pharmaceuticals. I'm wondering if you have any thoughts on how translatable that formula is over to your Medical Device business, which has continued to struggle to grow above market. Maybe you can talk about if there are any learnings there that could be translated over to Devices and what it will take either internally or externally for you to get that Device business growing above market.

A: First of all, we acknowledge our medical device group has faced challenges that many of the businesses have over the past several years, and we've got some very promising and very strong segments in our medical device group. [...] We think about the medical device market probably growing in the 3% to 5% range. It's been consistent with our longer-term projections. Of course, our goal is to outpace that growth because we want to gain share vis-à-vis innovation, the way we work with customers in our broader portfolio. [...]

And of course, we have some businesses that we're working hard on, areas such as diabetes, which as you know was challenged by the price setbacks, our vision care business is facing challenges in the marketplace. But they've done a lot of good changes recently, and we think they're well positioned for the future.

But as we look even longer term, we're clearly trying to take pages from the innovation playbook in Pharmaceuticals that you might say apply to the medical device segment. So whether it's in our clinical-development programs, the way we monitor safety, adverse event reporting, those are areas where we're spending a lot of time. We're doing more and more through our innovation centers that we're recently opening and utilizing [JJDC] on how do we better source early start-up innovation not only in Pharmaceuticals and devices, but even our consumer businesses going forward. And of course, we're looking at ways to partner with customers in new unique ways. So we remain confident in our medical device businesses. We've got some very strong businesses. We've realized there's others that we still have more work to do, but we think long-term they offer a significant opportunity for patients, for us, and for our shareholders.

Q: Just thinking through your comments in the slide deck this morning, is it safe to interpret your comments that within Pharmaceuticals, oncology probably sees an increase relative investment over the next couple of years relative to historical periods?

A: I would say we're really focused on all five of our therapeutic categories. Oncology is certainly an exciting one when you look at the science and what's happening there, and we think that there's a lot of opportunity to better address need for patients. We think there's a lot of very interesting science. However, when we look at immunology, when we look at infectious disease, and when we look at neuroscience as well as broader spaces in cardiovascular and diabetes, we think that all of those offer significant potential for us, too.

-- by Varun Iyengar, Emily Regier, and Kelly Close