Closer Look

MEMORANDUM

J&J 3Q15 - Invokana sales of $340 million, double YOY and up 7% sequentially; LifeScan/Animas down 6%; Finesse trial recruiting (!); Vibe sees "double-digit" growth - October 14, 2015

Executive Highlights

- Invokana (canagliflozin) and Invokamet (canagliflozin/metformin) posted $340 million in sales in 3Q15, up 95% year over year (YOY) and 7% sequentially. The US accounted for 95% of revenue.
- Global LifeScan/Animas revenue totaled $470 million in 3Q15, declining 16% as reported and 6% operationally YOY. The US was down ~16% YOY and international sales declined 16% as reported, but rose 1% operationally YOY (major negative currency impact).
- J&J is recruiting for a 24-week clinical trial (n=312) of the Calibra Finesse bolus-only insulin delivery patch device. The trial is evaluating glycemic control and satisfaction, with primary completion slated for December 2016. Guidance in 2Q15 called for a Finesse launch in 2016.

J&J provided its 3Q15 update in a call led by CFO Mr. Dominic Caruso yesterday. Below we include our top ten highlights from the call, along with relevant Q&A, as a follow up to our Closer Look reporting yesterday morning.

Janssen Highlights

1. Invokana (canagliflozin) and Invokamet (canagliflozin/metformin) posted $340 million in sales in 3Q15, up 95% year over year (YOY) from $174 million in 3Q14 and 7% sequentially from $318 million in 2Q15.

2. During Q&A, management suggested that the positive EMPA-REG OUTCOME results are most likely indicative of an SGLT-2 inhibitor class effect and declined to comment on whether there has been any impact on Invokana's performance.

3. Management pushed back against the suggestion during Q&A that the SGLT-2 inhibitor/ketoacidosis controversy has had a negative impact on Invokana sales.

4. J&J highlighted obesity as a "fast-growing segment where we see a lot of opportunity." We wonder if this has implications for Invokana, which recently completed a phase 2 trial for obesity in combination with phentermine.

5. In response to a question about the recent public outcry over prescription drug prices, management suggested that there is currently no consensus on policy solutions that would lower prices without negatively impacting innovation and stressed that the pharmaceutical industry intends to be a "constructive partner" in the debates.

LifeScan/Animas Highlights

6. Revenue from LifeScan BGM and Animas pumps totaled $470 million, declining 16% as reported and 6% operationally year-over-year (YOY). Global declines have characterized 13 of the past 14 quarters. Financials were again negatively impacted by the strengthening US dollar.

7. US LifeScan and Animas sales reached just $205 million in 3Q15, falling ~16% YOY against a moderate comparison to 3Q14 (when sales grew ~3% YOY). Sales fell 4% sequentially against a low base of $214 million in 2Q15.

8. International Diabetes Care revenue totaled $265 million, declining 16% as reported and growing 1% operationally YOY in 3Q15 against a neutral comparison (sales fell 2% as reported, were flat operationally in 3Q14). In actual revenue, this marks 3Q15 international sales as the lowest since 1Q07, though much of this is currency driven.

9. J&J is recruiting for a 24-week clinical trial (n=312) of the Calibra Finesse bolus-only insulin delivery patch device. The trial is evaluating glycemic control and satisfaction, with primary completion slated for December 2016. Guidance in 2Q15 called for a Finesse launch in 2016. To stick to that guidance, we assume this trial would report post-launch.

10. Reiterating commentary from 2Q15, management noted that the Animas Vibe has seen strong "double digit" growth following its January launch. J&J did not provide an update on the pediatric indication (expected by the end of year), a future integration with the Dexcom G5, or automated insulin delivery. J&J will be playing catch-up to pump competitors unless it is working on AP under-the-radar.

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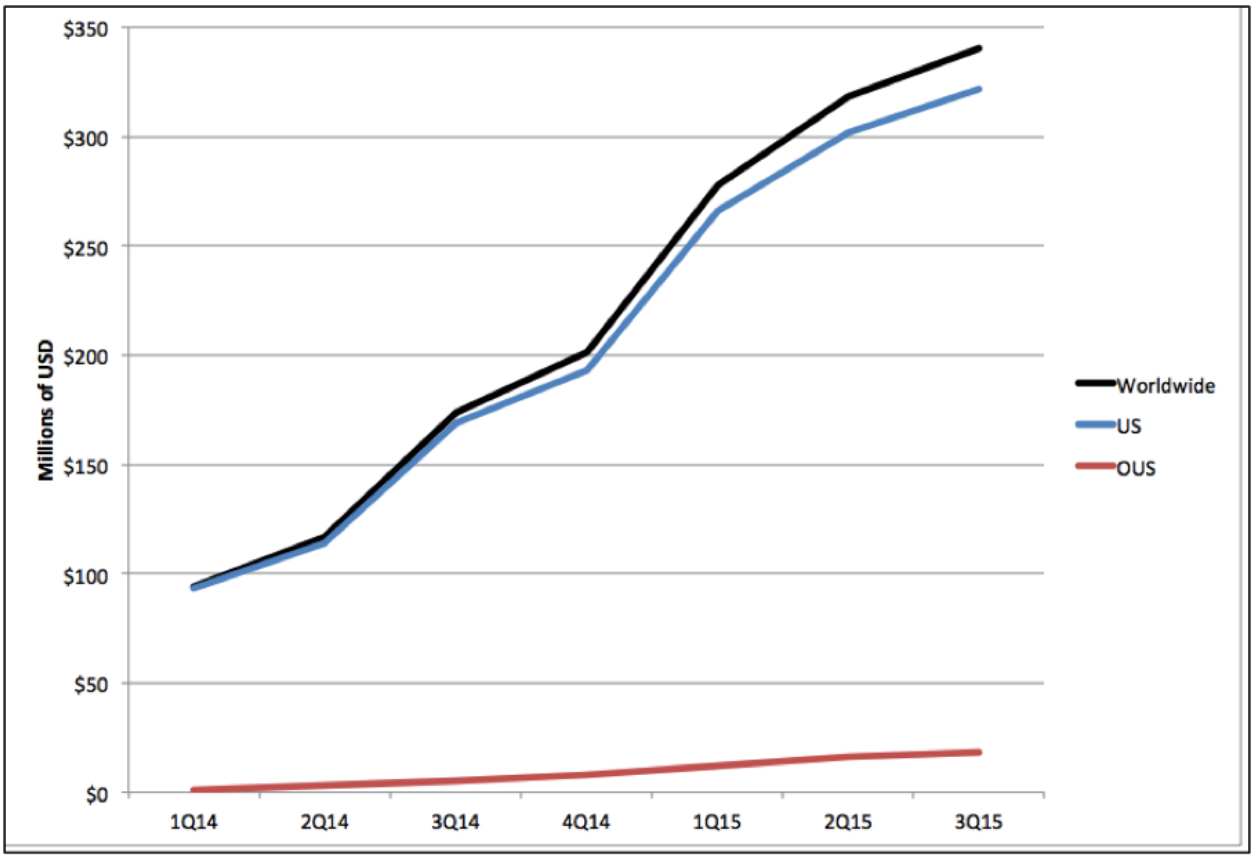
Janssen Highlights

1. Invokana (canagliflozin) and Invokamet (canagliflozin/metformin) posted $340 million in sales in 3Q15, up 95% year over year (YOY) from $174 million in 3Q14 and 7% sequentially from $318 million in 2Q15. While YOY growth remains impressive, the 7% sequential growth represents a bit of a slowdown from the double-digit growth rates in recent quarters. This is perhaps to be expected as the product becomes more established, though it also may reflect more new starts going to Lilly/BI's Jardiance (empagliflozin) as a result of the recent positive CVOT results or the SGLT-2 inhibitor/ketoacidosis controversy, both of which were mentioned as concerns during Q&A. We view the EMPA REG OUTCOME results as positive for the class longer term and believe they represent a strategic positive for J&J (although of course if canagliflozin did not prove to be cardio- or renal-protective, that would be a major challenge - it's too early to know but we wouldn't forecast that given thought leader commentary to date). Management continued to characterize Invokana as an important contributor to growth and referred to "strong momentum in market share increases." As in past quarters, US revenue accounted for 95% of total sales at $322 million - we believe international sales will continue to increase as more commentary emerges about cardioprotection being a class effect.

- **Invokana achieved 6.3% total prescription share (TRx) in the US type 2 diabetes market (excluding insulin and metformin), up from 5.9% in 2Q15.** TRx was 13.1% among US endocrinologists, down slightly from 13.2% in 2Q15, and 5.6% among US primary care physicians, up from 5.2% last quarter. It is encouraging to see uptake in primary care continue to rise, but the overall figures point to somewhat of a plateau compared to the market share gains in past quarters.
- **Reimbursement for Invokana remains strong.** Management shared that the drug has achieved over 80% access among commercial insurers (unchanged from 2Q15) and over 90% in

Medicare Part D (up from over 80% in 2Q15). Strong reimbursement likely represents a key factor behind Invokana's leadership in the US SGLT-2 inhibitor market since its launch, and it has been one of the company's main selling points in the exhibit hall at recent conferences. We recently learned that Express Scripts excluded Invokana/Invokamet from its 2016 formulary in favor of Jardiance and AZ's Farxiga (dapagliflozin), and we will be curious to see how much of an impact this decision has on next year's sales. We also wonder whether the positive EMPA-REG OUTCOME results will give Jardiance a boost over other agents in terms of formulary positioning or whether payers will want to wait until other SGLT-2 inhibitor CVOTs have reported results before changing policies.

Figure 1: Invokana Sales (1Q14-3Q15)



2. During Q&A, management suggested that the positive EMPA-REG OUTCOME results are most likely indicative of an SGLT-2 inhibitor class effect. The views we have heard from the scientific community have been somewhat more cautious: most speakers at EASD agreed that a class effect was the most likely explanation, but they also emphasized the need to avoid over-generalizing from the results of one trial. It appears that a class effect is the most likely explanation, as the SGLT-2 inhibitor class has appeared quite homogenous in clinical trials thus far. The main mechanistic difference between Jardiance and Invokana is selectivity for SGLT-1 vs. SGLT-2 (Jardiance is highly selective for SGLT-2 while Invokana has some activity at SGLT-1), but there is no reason at this point to expect that this would lead to a differential effect on CV outcomes. That said, EMPA-REG OUTCOME was as good a reminder as any that clinical trials can produce completely unexpected results, and we feel it is important to keep expectations in check until the CANVAS and CANVAS-R trials for Invokana report results in 2017.

- **J&J declined to comment on whether the EMPA-REG OUTCOME results have had any impact on Invokana's performance.** Even though an SGLT-2 inhibitor class effect seems to be the consensus explanation for the results, Lilly/BI's Jardiance should almost certainly derive some disproportionate benefit in the next few years in terms of sales and reimbursement. If this benefit

takes the form of patients already on SGLT-2 inhibitors switching to Jardiance, Invokana stands to suffer the most given its current dominance in the class. However, the impact would be smaller if any gains Jardiance makes come mainly from patients new to SGLT-2 inhibitors. We hope to gain more insight on this front during Lilly's 3Q15 update on October 22 - and again, longer term, we certainly believe cardio-protection and renal-protection are now more likely to be found for Invokana as a result of EMPA-REG OUTCOME and that the class, including (and especially) first-in-class Invokana will stand to benefit quite significantly. .

3. Management pushed back against the suggestion during Q&A that the SGLT-2 inhibitor/ ketoacidosis controversy has had a negative impact on Invokana. During Q&A, an analyst inquired about a flattening of volume for Invokana (based on IMS data) since the release of an FDA warning about ketoacidosis in May. In response, management stressed that the warning applied to the entire SGLT-2 inhibitor class, that rates of DKA have been very low in all clinical trials of Invokana, and that both overall market growth and YOY growth and TRx for Invokana have been strong and consistent over the past two quarters. While awareness of this issue has increased dramatically in recent months, we continue to assume that the impact on prescribing patterns in type 2 diabetes should be minimal, as DKA appears to be rare and influenced by clear risk factors like surgery or insulin deficiency in this population. EMPA-REG OUTCOME provided further reassurance about the risk in type 2 diabetes (albeit with a different agent), as rates of DKA in that trial were very low (≤0.1%) and balanced between groups.

- **The situation in type 1 diabetes remains more uncertain.** Phase 2 results for Invokana in type 1 diabetes presented at EASD demonstrated placebo-adjusted reductions in A1c (0.3%), body weight (~3-5%), and insulin doses (8 U/day for the 300 mg dose and 4 U/day for the 100 mg dose) but a significant increase in ketone-related adverse events (11 events and 6 events with the two respective doses vs. none with placebo). All events were associated with precipitating factors such as pump failure, missed insulin doses, or concurrent illness, and presenter Dr. Robert Henry (UCSD, San Diego, CA) suggested that the risk could likely be reduced in phase 3 with more frequent monitoring, lower doses, less of a reduction in basal insulin dose, and/or temporary cessation of treatment during illness or stress. We hope that J&J and other companies will continue efforts to understand how best to maximize the benefits and minimize the risks of this class in type 1 diabetes, perhaps by using lower doses or targeting specific subpopulations such as obese patients. In the meantime, the clinical recommendations that emerge from the upcoming AACE/ACE meeting on DKA with SGLT-2 inhibitors should help give providers more clarity on how best to manage the risk until more data is available. We also continue to believe that "managing" this DKA risk can be made more explicit - we doubt that most type 1 patients know what ketone levels are normal and most don't have ketone kits though we don't have explicit data on this.

4. J&J highlighted obesity as a "fast-growing segment where we see a lot of opportunity." Based on management's comments, the company's primary interest in obesity lies in minimally invasive surgical treatments. However, we wonder whether an expanded indication for Invokana or other efforts in the pharmacotherapy arena could also be in the cards. A phase 2 trial of Invokana in combination with phentermine for obesity is now complete according to ClinicalTrials.gov, suggesting that results should be available shortly - we await eagerly these results. Another trial investigating Invokana's effect on body weight and metabolism in overweight/obese patients with type 2 diabetes is currently recruiting participants, with completion expected in August 2017. Obesity pharmacotherapy is clearly a daunting arena at the moment due to factors including limited reimbursement, the high cost and modest efficacy of current drugs, and a lack of full buy-in around conceptualizing obesity as a disease - we had underestimated the significance of the aggregate impact of all three. However, J&J's impressive resources and reputation would make it more equipped than most to compete in this area, whether by pursuing an expanded indication for Invokana, acquiring one of the smaller obesity drug or device companies currently facing challenges, or investing in its own early-stage research.

5. Management fielded a question during Q&A about the recent public outcry over prescription drug prices. The company acknowledged the significant media attention around this issue in recent weeks but suggested that there is currently no consensus on policy solutions that would lower drug

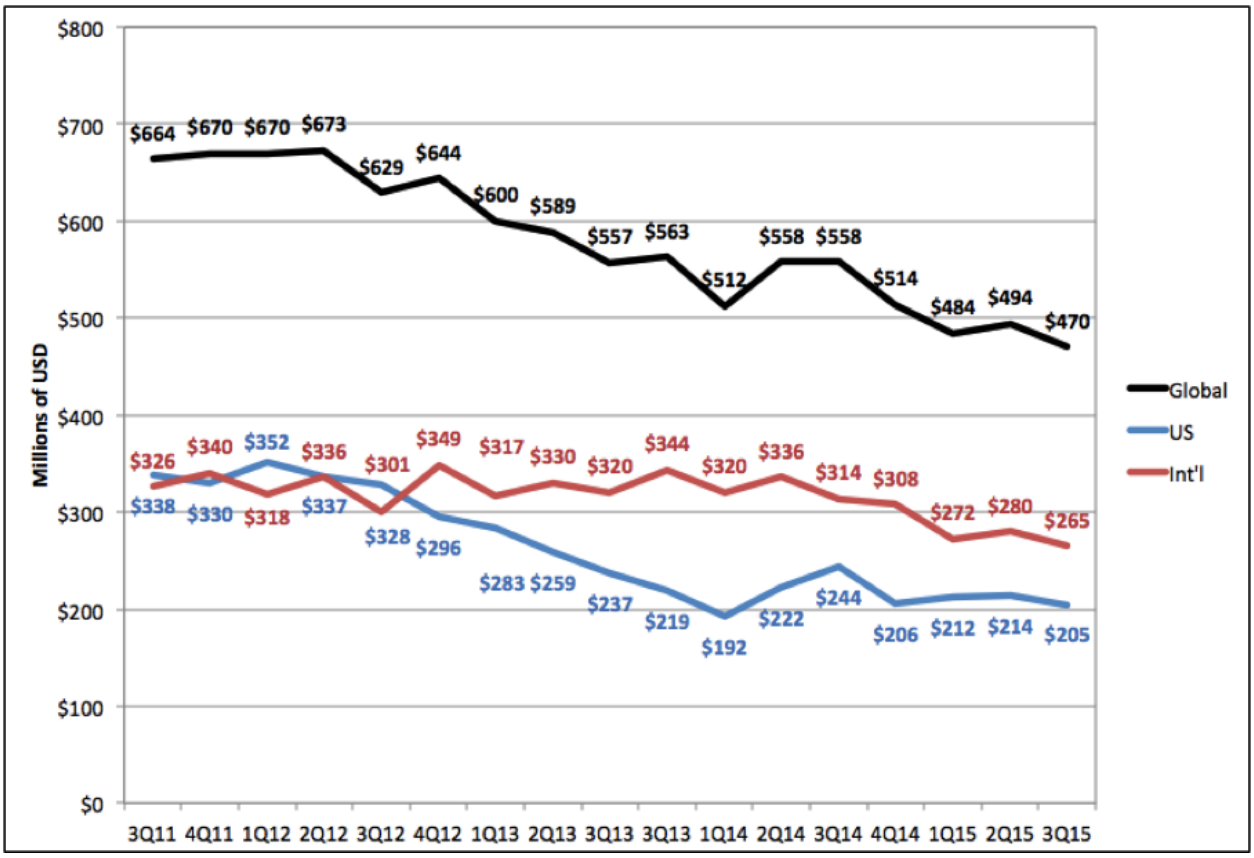
prices without negatively impacting innovation. J&J stressed that the pharmaceutical industry intends to be a "constructive partner" in the policy debates over drug pricing, noting that it agreed to increased Medicaid rebates and other fees as part of the Affordable Care Act. Management also noted that the US healthcare system, including the pharmaceutical industry, is moving toward a focus on value and outcomes rather than price alone and suggested that this will be reflected in future contracts with public and private payers. Public concern over drug prices has been gradually building in recent years (focused mainly on insulin prices in the diabetes field), and the topic has received a particularly large burst of media attention following the recent news that Turing Pharmaceuticals raised the price of its antiparasitic drug Daraprim by over $700. The topic has also entered the 2016 presidential race, with Democratic candidates Hillary Clinton and Bernie Sanders both proposing plans that involve capping out-of-pocket expenses for prescription drugs, requiring companies to invest a certain percentage of profits in R&D, and allowing Medicare to negotiate directly with companies over prices, among other measures. We see this discussion as a sign that investors are taking these sorts of proposals seriously, and we are curious to see if this level of attention continues for the rest of the 3Q15 earnings season.

LifeScan/Animas Highlights

6. Global revenue from LifeScan BGM and Animas pumps reached just $470 million, declining 16% as reported and 6% operationally year-over-year (YOY). This now marks 13 of the past 14 quarters with global sales declines (3Q14 was the lone exception and that was a particularly easy comparison). The decline was on an easy comparison, too, as sales were flat YOY in 3Q14. The quarterly performance in actual revenue marks the lowest ever in our J&J financial model (which stretches back to 2004) and the third-consecutive quarter in which J&J's global sales have dropped under $500 million - a pattern we had not seen since in a decade (2Q05-4Q05). Of course, much of this is currency driven (negative 10% impact), though the trend does not give much reason for optimism. As J&J did in 2Q15, accompanying slides attributed the weakness to US price declines that were partially offset by the "double-digit" growth of the Animas Vibe and volume growth in SMBG.

- **Sales fell 5% sequentially from a low base in 2Q15 ($494 million in sales),** marking the third period in the past year that quarter-to-quarter sequential results have been negative.
- **J&J's financials were not wholly surprising considering the impact of the strengthening US dollar.** We had been hopeful that the business might be stabilizing after operational (1Q) and sequential (2Q) growth earlier this year. Those performances came against low base, however, and it is a bit worrying that the business struggled even on a neutral comparison.

FIGURE 1: GLOBAL, US, INTERNATIONAL QUARTERLY SALES (3Q11 - 3Q15)



- **Management commented broadly on the potential to divest device businesses that are underperforming** - this was not at all diabetes specific, though is pertinent given the business's recent struggles. Said Worldwide Chairmen-Global Surgery Mr. Gary Pruden on medical devices: "We have a company-wide premise that we should be number one or number two in the categories where we're committed and have a clear technology path to getting to either a number one or number two position. If we don't, we're going to consider our options." Historically, J&J has stood by its commitment in diabetes technology, but is the company innovating fast enough to keep up with Abbott (FreeStyle Libre), Dexcom (G5, Google partnership), Medtronic (MiniMed 670G), Roche, Insulet, Tandem, Bigfoot, and others?
- **We are eager for the remaining Big Four blood glucose monitoring companies (Abbott [October 21], Roche [October 22], and Bayer [October 29]) to report later in the quarter,** particularly to see whether these comparable companies experienced similar global challenges. As a reminder, J&J and Bayer (down 12%) suffered the steepest reported declines in 2Q15 followed by Roche (down 9%) and Abbott (down 5%). J&J has the most US heavy portfolio relative to the Big Four - see Table 1 below - which certainly has not helped its case given the tough stateside market.

TABLE 1: 2Q15 BIG FOUR MARKET SPLIT

	Abbott	Bayer	J&J	Roche
2Q15 Global Sales	$285	$260	$494	$584

US/ International Split	33%/66%	NA	40%/60%	20%/80%

7. US Diabetes Care sales in 3Q15 reached just $205 million, falling ~16% YOY against a moderate comparison to 3Q14 (when sales grew ~3% YOY). Sales fell 4% sequentially against a low base in 2Q15 (sales of just $214 million). As expected, management did not comment extensively on the US business except to acknowledge pricing pressures (a given in recent updates). In the past 14 quarters (since 2Q12), J&J has recorded only three quarters of positive YOY reported growth in the US. The US business has been pretty much flat for the past four quarters, and is approaching *half* of the quarterly sales figure that it recorded in 1Q12 ($352 million).

8. International Diabetes Care revenue totaled $265 million, declining 16% as reported and growing 1% operationally YOY in 3Q15 against an easy comparison to 3Q14 (when sales fell 2% as reported YOY and were flat operationally). This marks 3Q15 as the fifth consecutive quarter of reported YOY decline, and in actual revenue, marks 3Q15 as the lowest international sales since 1Q07 ($261 million). Considering the operational growth, however, the performance reflects the significant strengthening of the US dollar (negative 17% currency impact) as opposed to underlying weakness in the business' fundamentals. In addition, the international segment has declined from Q2 to Q3 in the past five years, and a sequential decline of 5% is in line with that pattern.

9. Though not mentioned on the call, J&J is recruiting for a 24-week clinical trial (n=312) of the Calibra Finesse bolus-only insulin delivery patch device. The trial will randomize type 2 diabetes patients not achieving glycemic targets (A1c 7.5-10%) to either Finesse or the Novo Nordisk FlexPen to initiate bolus insulin therapy. The primary endpoint is A1c at 24 weeks, with secondary endpoints that include time-in-range (YES!) and treatment satisfaction. Primary completion is slated for December 2016.

- **Guidance in 2Q15 called for a Finesse launch in 2016, and we assume that has not changed.** To stick to that timing, we assume this trial would report post-launch and help with reimbursement. We see this trial as a sign of J&J's commitment to this device, notable given the LifeScan challenges and numerous competitors.
- **As a reminder, the Finesse is a three-day, very slim profile (2 inches long, 1 inch wide, and 0.25 thick), bolus-only delivery device.** It was acquired from Calibra Medical in July 2012.
- **We wonder what the Finesse will cost and how it will stack up against other competitive options on the market, particularly the Valeritas V-Go (basal/bolus) and CeQur's PaQ (basal/bolus).** The V-Go is already on the market through a small regional rollout; Valeritas filed to go public in February but postponed the IPO in March. CeQur has an EU launch of its PaQ device planned for 2016 with a potential US launch in 2017.
- **We'd note that Sanofi/MannKind's Afrezza is also an important Finesse competitor.** Some of the J&J/Calibra device's key selling points - more discreet, lower hassle bolus insulin - are also key advantages of Finesse. Like any new device, big drivers of Finesse uptake will include cost, any outcomes data (probably not much to start), ease of prescribing, and ease of training.

10. Reiterating commentary from 2Q15, management noted that the Animas Vibe saw strong "double-digit" growth following the January launch. J&J did not provide an update on the pediatric indication that is expected by the end of year. Management did not remark further on Vibe trajectory/sales. The first-to-market-Dexcom-integrated pump status certainly seems to be benefitting J&J. Management estimated in 2Q15 that Animas has now achieved the "number two share position" among pump companies, per "internal estimates" - we don't read too much into these, since no one reports pumps shipped except Tandem. Big questions on our radar include how the ongoing launch of Dexcom's G5 and Tandem's t:slim G4 will impact Vibe uptake. The Tandem pump is a highly competitive Dexcom-integrated offering (t:slim G4 has a much better screen and user interface), while with G5, patients have to choose between

getting data on their phone/receiver (with the G5 transmitter) and getting it on their pump (with the G4 transmitter). The Vibe also doesn't have Dexcom's latest Software 505 algorithm, nor is it compatible with Dexcom Share (a key advantage for parents).

- **Disappointingly, management was silent on the pipeline front. Is Animas still in the artificial pancreas race?** There was no commentary on the progress of the "next-generation CGM-integrated pump" with Dexcom (presumably the hybrid closed-loop project alluded to at AACE 2015) that is in the works. At 2Q15, management remarked that the product will combine a more user-friendly design with a more accurate pumping algorithm (presumably with Dexcom's G5 system). J&J's artificial pancreas project has moved at a glacial pace since signing its partnership with JDRF in 2010, though Dr. Aaron Kowalski has repeatedly mentioned Animas in his recent artificial pancreas remarks. It does seem like the company is working on it, though at what pace and how it will compare to Medtronic and others is a big question.

Pipeline Summary

Pipeline Product	Timeline
Finesse insulin delivery device (acquired from Calibra Medical)	Launched slated for "2016"; A1c and treatment satisfaction trial underway
Second-gen CGM-integrated pump	Project termed "a priority" at AACE 2015. Feasibility studies presented at ADA 2013 and ADA 2014.
Digital health adjacencies	In development; "actively pursuing programs and partnerships" per 2Q15 remarks
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

Automated Insulin Delivery Competitive Landscape

- **See below for an overview of the automated insulin delivery landscape, as far as we aware.** We acknowledge this list may be incomplete, as there may be other stealth startups or academic groups working to commercialize closed-loop technology.
    - **It's essential for Animas to move on automated insulin delivery, given the competition from other companies.** JDRF's Dr. Aaron Kowalski has publicly stated multiple hybrid closed loop systems are coming in the ~2017-2018 timeframe, led by Medtronic's MiniMed 670G (currently in a pivotal study).

Group/Company	Product	Latest Timing	Recent Coverage
Medtronic	- MiniMed 670G (hybrid closed loop) - Fully automated closed loop	- US launch expected by April 2017 - Following 670G	Medtronic F1Q16
Tandem	Predictive low glucose suspend or basal closed-loop system	FDA IDE filing by end of 2015 for a clinical	FDA approves Tandem t:slim G4

		study. Potential launch in late 2017.	
Insulet	Plans to be involved in the artificial pancreas and is developing strategies on the CGM and algorithm fronts.	Hopes to fast-track an AP device	Insulet 2Q15
Animas	Predictive Low Glucose Suspend or Hypoglycemia-Hyperglycemia Minimizer with Dexcom CGM	In Development. Called "a priority" at AACE 2015.	Enclosed
Roche	Working internally on a new CGM, with future potential application to an artificial pancreas device	CGM to launch in next 18 months	Roche Diagnostics Division Analyst Event 2Q15
Bigfoot Biomedical	Asante pump body (disposable), custom built, durable, Bluetooth-enabled controller that talks to Dexcom's Gen 5 CGM and includes a control algorithm	In a pivotal trial by end of 2016	Acquires Asante's Assets Partners with Dexcom
Cambridge	Overnight and 24-hour, hybrid closed-loop using Abbott Navigator CGM, algorithm on portable computer, and Abbott Florence pump	Plans to commercialize, but timing is unknown	Two three-month, at-home, unsupervised closed-loop studies published in NEJM
MGH/BU	Bionic Pancreas (24-hour, hybrid closed loop, insulin + glucagon, dual chambered pump with built-in algorithm, Dexcom CGM)	Pivotal Study slated for late 2016-early 2017	EASD 2015
TypeZero (licensed from UVA)	DiAs (24-hour or overnight-only, hybrid closed loop, insulin-only, algorithm that can be embedded in a pump or reside on smartphone. The current systems include a Dexcom sensor and Roche/Tandem insulin pumps.	Large-scale clinical trials are planned for 2015 and 2016.	Raises seed funding

Questions and Answers

Q: I feel compelled to ask a question about the rhetoric coming out of Washington on pharmaceutical pricing and price controls that has gotten a lot of media attention recently. Where do you see that ultimately going? What's J&J's perspective?

A: You're right, there's been a lot of rhetoric about pharmaceutical drug pricing, and despite significant media attention on drug pricing, there really isn't a consensus on policy solutions that would lower prices without negatively impacting innovation. That's the key point. I think every time we talk about drug pricing we unfortunately miss the balance of the other side of the coin, which is the innovation that comes from the pharmaceutical industry and the improvement in the health and wellbeing in the lives of many people around the world. The pharmaceutical has been and continues to be a constructive partner in many of these policy debates and we look for solutions to the issue along with policymakers. Just as a reminder, as part of the Affordable Care Act, the industry agreed to increased rebates in Medicaid and many other additional fees, and as the US healthcare system evolves, I think we'll have more of a focus on outcomes and value. We're working with both public and private payers to develop innovative outcome-based contracts. We think the real answer to this dilemma is to monitor and provide outcome-based metrics and not simply focus only on price.

Q: In the early 1990s when Hillary Clinton was trying to reform healthcare, a lot of pharmaceutical companies pledged not to raise drug prices by more than inflation. Is that something J&J would reconsider?

A: I think we're very responsible in our drug pricing and we tend to support the price for our drugs with strong economic data. So rather than pledge to a particular number, I think it's important that we continue to develop robust data that provides a solid foundation for the value that our products provide to healthcare systems. We'll continue to do that.

Q: Has the positive outcomes data for Lilly's SGLT-2 inhibitor had any initial impact on Invokana, or do you expect to see much of an impact given that you're the market leader in that class?

A: We do think that the positive benefits seen with the Lilly compound is most likely a class effect for SGLT-2 inhibitors. It's too early to comment on any effect that we've seen, and we're also studying our compound regarding cardiovascular impacts, but that data is a couple of years away. But we do think there's a positive effect to the overall class as a result of the cardiovascular data that Lilly shared.

Q: If you look across your businesses, where are the holes that you'd like to fill in as you look at the markets that are higher growth that you don't currently play in?

A: We're really focused on five key unmet needs...Second is in the area of obesity. That is still a fast-growing segment where we see a lot of opportunity, especially as you start to think about more minimally invasive surgical procedures that produce outcomes similar or close to the surgical interventions today.

Q: On Invokana, IMS volumes flattened off since the FDA notice on ketoacidosis in May. Can you talk about the product's recent performance in the US, what is driving this, and when you'd hope to see an improvement or address any of those concerns?

A: You're right, there was an FDA notice, and it wasn't solely related to Invokana. In our clinical trials for Invokana, the ketoacidosis rate was very, very low. I'd like to point out that Invokana did grow 91% in the quarter in the US. We think that's pretty good. The markets consistently are growing 7%. I just looked at the trends and it's very consistent for the second and third quarter. As far as TRx, we're at 6.3%, up from 6% in the second quarter. Primary care is up to 5.6% from 5.3% and endocrinology at 13.1% is about the same as it was in the second quarter, so I think it's doing very well.

Q: As a follow-up, what I'm really referring to is if you look at the IMS data over the last quarter or six months, there is a clear flattening off. Are you getting any feedback as to why that may be? I'm not talking about the year-on-year growth, which is obviously strong because the product had a very strong ramp, but just the recent performance.

A: I just gave you sequential TRx's, so I think that's the most recent we would have. I'm also looking at the market growth for that, and it's at 7%. And as we said, it's a very low incidence: 0.1% in our phase 3 trials.

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