

Novo Nordisk 2Q17 - Diabetes/obesity portfolio grows 6% to \$3.5B driven by Tresiba, Victoza; GLP-1 class grows 29% to \$1.6B; Basal insulin market down 3%, rapid-acting market flat - August 10, 2017

Executive Highlights

- Novo Nordisk's diabetes/obesity portfolio grew 6% YOY to \$3.5 billion, driven primarily by Tresiba - the next-generation basal insulin posted \$338 million in sales (more than doubling YOY, up 47% sequentially), comprising <10% of total revenue, but well over 50% of growth. Novo Nordisk's "new-generation insulins" (comprised of Tresiba + Xultophy + Ryzodeg + Fiasp) accounted for a whopping 65% of growth in the diabetes/obesity portfolio in 2Q17.
- GLP-1 agonist Victoza (Novo Nordisk's biggest product) sales rose 17% YOY to \$887 million, and the product accounted for 35% of overall portfolio growth in 2Q17. Victoza maintained its frontrunner status within the GLP-1 agonist class, capturing 56% of the \$1.6 billion market by value. Lilly's once-weekly Trulicity is playing catch-up, and captured 30% of the market by value as well as 34% TRx compared to Victoza's 46% TRx (share of total prescriptions in the US). Table 1 below shows how incredibly well Victoza as well as the GLP-1 class are doing and Novo Nordisk is very well positioned with semaglutide up next, although there is also more competition coming (Intarcia).
- Pooled basal insulin sales were down 3% YOY to \$2.5 billion in 2Q17, while pooled rapid-acting insulin sales rose a modest 1% to \$1.6 billion. Sanofi's Lantus and Novo Nordisk's NovoRapid remain the respective market leaders by value (both capturing ~50% of whole class sales), though the Lantus business is suffering from CVS Health and UnitedHealthcare formulary exclusions (in favor of Lilly/BI's biosimilar Basaglar).
- Xultophy (insulin degludec/liraglutide fixed-ratio) sales grew 76% sequentially to \$28 million, which represents 82% of pooled class revenue. Sanofi's Soliqua (insulin glargine/lixisenatide) captured the remaining 18% of sales (\$6 million in 2Q17, up 25% sequentially). We expected this highly-anticipated therapy class to show more dramatic growth in its second full quarter on the market and we think it is tragic (some say shameful) to have such good therapy approved but not only not accessible but not being propelled by HCPs, many of whom "don't really understand" how to start patients on combo medication.
- Management expressed tremendous enthusiasm for GLP-1 semaglutide's potential applications in obesity, following ~16% weight loss with one year of once-daily treatment in phase 2. A phase 3 study of semaglutide in people with obesity is slated to start in 1H18, and notably, will use once-weekly dosing. We expect this to be a blockbuster. Once-weekly semaglutide is currently under regulatory review in the US, Europe, and Japan for a type 2 diabetes indication. An FDA decision is expected in 4Q17; it is not yet known whether the agency will convene an Advisory Committee meeting beforehand.

Novo Nordisk provided its [2Q17 financial update](#) in a call this morning led by CEO Mr. Lars Jørgensen. This powerhouse company is doing extraordinarily well in terms of performance and upside even though this market has never been tougher or more competitive or had the noise the PBMs continue to create. Our full report contains 18 detailed highlights - starting with five pooled market analyses on basal insulin, next-gen basal insulin (Novo Nordisk's Tresiba and Sanofi's Toujeo), rapid-acting insulin, GLP-1 agonists, and fixed-ratio basal insulin/GLP-1 combos (Novo Nordisk's Xultophy and Sanofi's Soliqua). As you scroll down, you'll find graphs depicting sales trends for each major diabetes/obesity product in Novo Nordisk's

portfolio, and you'll come across comprehensive tables on financials, candidates in the pipeline, the phase 3 PIONEER program (oral semaglutide), and more. Take a look as well at Novo Nordisk's 2Q17 [presentation](#), [roadshow slide deck](#), and [press release](#). We think the pictures show a thousand words for the graphs - although we don't write for investors, we think there has never been a better time to invest in Novo Nordisk.

Big picture, we want to mention that we admire the way Novo Nordisk does financial reporting, and we appreciate that Xultophy and Tresiba sales have been broken out individually in 1H17. We're eager for Fiasp (faster-acting insulin aspart) sales to be broken out as well, though we understand the company may be waiting for US approval. Novo Nordisk's new-generation insulin portfolio, which now includes Fiasp, is performing particularly well - sales totaled \$383 billion in 2Q17, up 47% sequentially from \$242 million in 1Q17. We see potential for this group of four products (Tresiba, Xultophy, Ryzodeg, and Fiasp) to surpass \$2.5 billion in 2017 if growth continues as it has been, which would be a marked increase from just \$661 million in the full year 2016. Moreover, we imagine these new-gen insulins will buffer any headwinds for Novo Nordisk's other products going forward, as they accounted for a 65% share of growth in the company's overall diabetes/obesity portfolio in 2Q17 by our calculations (but only accounted for 11% of total sales).

Table 1: 2Q17 Financial Results for Novo Nordisk's Major Diabetes and Obesity Products

| Product | 2Q17 Revenue (billions) | Year-Over-Year Reported (Operational) Growth | Sequential Growth |
|--|-------------------------|--|-------------------|
| Modern Insulins | DKK 11.3 (\$1.7) | -4% (-5%) | -7% |
| - NovoLog | DKK 5.1 (\$0.8) | 4% (3%) | -4% |
| - NovoMix | DKK 2.6 (\$0.4) | -2% (-1%) | -6% |
| - Levemir | DKK 3.6 (\$0.6) | -16% (-17%) | -10% |
| Human Insulin | DKK 2.5 (\$0.4) | -6% (-5%) | -3% |
| New-Generation Insulins (Tresiba, Xultophy, Ryzodeg, Fiasp) | DKK 2.5 (\$0.4) | 154% (149%) | 47% |
| - Tresiba | DKK 2.1 (\$0.3) | 143% (139%) | 47% |
| -Xultophy | DKK 0.2 (\$0.03) | -- | 76% |
| -Ryzodeg | DKK 0.1 (\$0.02) | -- | 6% |
| Victoza | DKK 5.8 (\$0.9) | 17% (15%) | <1% |
| Saxenda | DKK 0.7 (\$0.1) | 82% (77%) | 27% |
| Total Diabetes/Obesity Portfolio | DKK 23.1 (\$3.5) | 6% (7%) | -1% |

Pooled Market Highlights

1. The GLP-1 agonist class grew 29% YOY and 11% sequentially to \$1.6 billion in 2Q17, from a high base of \$1.2 billion in 2Q16 and \$1.4 billion in 1Q17 (when the market grew 35% YOY and 6% sequentially). Novo Nordisk's Victoza continues to lead with 56% market share by value (the product posted \$887 million in

2Q17, up 17% YOY as reported), though management cited underlying class growth as a driving factor for its GLP-1 agonist business. Moreover, management acknowledged increasing competition from Lilly's Trulicity (which comes with once-weekly dosing and a very patient-friendly IDEO-designed pen). With sales more than [doubling YOY](#), Trulicity captured 30% of pooled GLP-1 sales in 2Q17, up from 26% in [1Q17](#), when Victoza accounted for 57% of sales. Novo Nordisk's [presentation slides](#) show that Victoza is also losing prescription volume to Trulicity: As of May 2017, Victoza's share of total GLP-1 agonist prescriptions (TRx) in the US was 46%, down from 48% in [1Q17](#), 50% in [4Q16](#), and 51% in [3Q16](#). Trulicity's US TRx share is trending in the opposite direction, at 22% in 3Q16, 25% in 4Q16, 30% in 1Q17, and 34% in 2Q17. An FDA Advisory Committee recently [voted 17-2](#) in favor of a new CV indication on the Victoza label, and the EMA [approved](#) this label change for the product's European label - this expanded indication could very well boost Victoza volume and sales. All this said, we see plenty of room for both products to sustain commercial success, given that many more patients could benefit from GLP-1 agonists than those currently on them. AZ's Bydureon accounted for 9% of pooled GLP-1 agonist sales in 2Q17, while Byetta accounted for 3%. GSK's Tanzeum captured 2% of this market by value (notably, GSK management [announced plans](#) to cease manufacturing of Tanzeum and to withdraw support), while Sanofi's Lyxumia captured <1%.

2. Pooled revenue for the basal insulin market fell 3% YOY to \$2.5 billion in 2Q17. This represents an 8% sequential increase against the easy comparison of a steep 12% sequential decline in [1Q17](#). We attribute this continued decline in 2017 largely to falling revenue from Sanofi's flagship product Lantus, following its exclusion from the [CVS Health](#) (effective January 2017) and [UnitedHealthcare](#) (effective April 2017) formularies. Sanofi has [maintained 50%](#) of its Lantus volume among patients on CVS Health thus far, in part due to patient savings programs, though realized price and revenue for Lantus dropped substantially as a result. According to Sanofi's recent [2Q17 update](#), the declining trend in Lantus prescription volume is expected to accelerate in future quarters as co-pay cards expire and as the full force of the recently-implemented UnitedHealthcare exclusion sets in. Despite falling sales, Lantus continues to lead the class and captured 52% of the \$2.5 billion market by value in 2Q17, followed by Novo Nordisk's Levemir (22%) and next-generation newcomers Novo Nordisk's Tresiba (13%) and Sanofi's Toujeo (9%). Lilly/BI's Basaglar, the first biosimilar to enter the basal insulin market, captured the remaining 3% of pooled sales. By volume, Lantus captured 50% of market share in terms of total prescriptions (TRx) in 2Q17, while Levemir held 23%, Toujeo held 9%, Tresiba held 8%, and Basaglar held 4% (this is according to slide 8 in Novo Nordisk's earnings [presentation](#)). Novo Nordisk management noted that it expects Tresiba to capture 10% TRx by year-end, and highlighted its impressive value share (by sales) in select international markets, including Japan (41%), Italy (30%), Switzerland (28%), and Denmark (28%).

3. Sales of next-generation basal insulins - Sanofi's Toujeo and Novo Nordisk's Tresiba - nearly doubled YOY to \$569 million (from a base of \$296 million in 2Q16). The class grew 36% sequentially against an easy comparison of 12% sequential decline in [1Q17](#). Tresiba captured 59% of this market by value, with Toujeo claiming the remaining 41%. This compares to a more even split of 51% (Tresiba) vs. 49% (Toujeo) in [1Q17](#), the first quarter in which Tresiba revenue surpassed Toujeo revenue. That said, both products experienced strong quarters in 2Q17, with Tresiba sales more than doubling YOY to \$338 million and Toujeo sales rising 49% YOY to \$231 million (we were particularly impressed by Toujeo's performance in international markets). According to Novo Nordisk's 2Q17 presentation ([slide 8](#)), Tresiba held 8% of total basal insulin prescriptions (TRx) in 2Q17 vs. Toujeo's 9%.

4. The rapid-acting insulin market showed modest 1% YOY growth to \$1.6 billion in 2Q17. Sequentially, revenue fell 1% against the easy comparison of 8% sequential decline in [1Q17](#). Novo Nordisk's NovoRapid continues to lead with 50% of the market by value, ahead of Lilly's Humalog at 43%. Sanofi's Apidra comprises the remaining 7%. We see challenges ahead for the rapid-acting insulin class, as competitive pressure from GLP-1 agonists and SGLT-2 inhibitors (alternative methods to address postprandial excursions) intensifies. In contrast to the sluggish rapid-acting insulin market, the GLP-1 agonist and [SGLT-2 inhibitor](#) classes are experiencing skyrocketing growth, rising 29% and 20% YOY respectively in 2Q17. We anticipate this challenge to the rapid-acting insulin class will only steepen with continued uptake of basal insulin/GLP-1 agonist fixed-ratio combinations.

5. Pooled sales of basal insulin/GLP-1 agonist fixed-ratio combinations totaled \$34 million in 2Q17, up 79% sequentially from \$19 million in [1Q17](#) (the first quarter in which Novo Nordisk and Sanofi broke out sales for Xultophy and Soliqua, respectively). By value, Xultophy held 82% market share with \$28 million in revenue. Soliqua held the remaining 18% with \$6 million in revenue. This larger share for Xultophy reflects its longer time on the market - the product has been available in international markets for over two years, since January 2015, while [US launch](#) occurred in May 2017. Thus, US sales likely did not contribute substantially to Xultophy's 2Q17 showing. In contrast, Soliqua's revenue is largely driven by US sales since the product's [launch](#) in January 2017. Payer negotiations for both combination products are ongoing, and we'll be watching this closely to see how the dynamics for this class shape up in the US, which we expect to drive the lion's share of sales in the future (if the GLP-1 agonist market is any indication). We see enormous potential for this new class, which we think could reach \$1-\$3 billion in the next several years and which might exceed \$5 billion in a decade. (This is based on the conservative assumption that 10%-20% of the 8-10 million people in the US with diabetes and suboptimal glycemic control will convert to this new class). Without factoring in rebates, Sanofi has priced Soliqua in the US at parity to other GLP-1 agonists on the market (~\$20-25/day) to prioritize market growth, whereas Novo Nordisk has priced Xultophy at a premium (~\$31/day). Soliqua has the advantage of lower list price, while Xultophy has the advantage of a next-generation insulin component and a GLP-1 agonist component with demonstrated cardioprotective benefits - presumably resulting in a stronger clinical profile, though no head-to-head trials of Xultophy vs. Soliqua have been conducted. We spoke to Ms. Davida Kruger this morning, who reiterated our view that this emerging class of fixed-ratio combination therapies could be so beneficial for so many patients, and we desperately want to see Xultophy and Soliqua in the hands of more people with diabetes. We'd also like to see more outcomes data and CGM data for these therapies, which we think would only corroborate the profound benefits shown in phase 3 clinical trials.

Financial Highlights

6. Novo Nordisk's overall diabetes/obesity portfolio grew 6% YOY as reported (7% in constant currencies) to DKK 23.1 billion (\$3.5 billion) in 2Q17, against a modest comparison of 2% YOY growth as reported (7% in constant currencies) in [2Q16](#). Sequentially, total sales from all major diabetes/obesity products fell 1% from DKK 23.3 billion (\$3.3 billion) in [1Q17](#). Tresiba was the primary growth driver, even though it only accounts for <10% of total portfolio revenue (management shared an expectation for Tresiba to reach 10% volume share within the basal insulin market by end of 2017). Victoza was another growth driver, and we note that the GLP-1 agonist is Novo Nordisk's most profitable diabetes product. Despite the strong quarter overall, management alluded to pricing pressure around diabetes drugs in the US, and cautioned that looking at price in isolation does not provide good context without also considering prescription volume, patient discounts, and segment mix (or a higher proportion of prescriptions going to patients on Medicaid). This has been a recurring theme on earnings calls from pharma companies in 1H17 (including [AZ in 2Q17](#), [Sanofi in 2Q17](#), [J&J in 1Q17](#) and [2Q17](#), [Lilly in 2Q17](#), and [Merck in 1Q17](#) and [2Q17](#)).

7. Market leading GLP-1 agonist Victoza posted DKK 5.8 billion (\$887 million) in 2Q17, marking 17% YOY growth as reported (18% in constant currencies) and driving 35% of growth in Novo Nordisk's overall diabetes/obesity portfolio by our calculations. This strong financial performance occurred against a backdrop of >25% volume growth for the GLP-1 agonist class as a whole in the US. While YOY growth has been steady since product launch, management acknowledged a downward trend in Victoza's market share by volume in the US (with prescriptions yielded to Lilly's GLP-1 agonist Trulicity). Still, management pointed to upcoming milestones that could spur further growth for Novo Nordisk's GLP-1 agonist business: (i) In June, an FDA Advisory Committee [voted 17-2](#) in favor of a new CV indication for Victoza (this indication for CV risk reduction has already been approved for the [EU label](#)), and (ii) an [FDA decision](#) on once-weekly semaglutide is expected in 4Q17.

8. Next-gen basal insulin Tresiba was an indisputable bright spot for Novo Nordisk in 2Q17, with sales more than doubling YOY to DKK 2.2 billion (\$338 million). Sequentially, revenue rose an impressive 47%, a reassuring sign following a disappointing 4% sequential loss in [1Q17](#) (the very first sequential drop in Tresiba sales). Notably, management shared that the FDA will now be evaluating SWITCH 1 and 2 in conjunction with DEVOTE to determine if a hypoglycemia benefit should be reflected on Tresiba's label. The

company [submitted](#) SWITCH 1 and 2 data to FDA in September 2016, but [full results from the DEVOTE CVOT](#) presented at ADA 2017 showed an even more compelling 40% risk reduction for severe hypoglycemia and a 53% risk reduction for severe hypoglycemia overnight with Tresiba vs. standard of care Lantus. A regulatory decision on inclusion of the SWITCH results was originally expected in September 2017, which has now been pushed back to end of 1Q18 so FDA can evaluate in the context of DEVOTE as well. We see this is as very good news - DEVOTE was a larger trial producing more robust hypoglycemia findings, and data from the CVOT can only help Tresiba's chances of getting a new hypoglycemia indication. Novo Nordisk's new-generation insulin portfolio, consisting of Tresiba, Xultophy, Ryzodeg, and - for the very first time! - next-gen prandial insulin Fiasp, more than doubled YOY to DKK 2.5 billion (\$383 million) in 2Q17. Of course, part of this growth would be explained by the new addition of Fiasp to this portfolio. Novo Nordisk has yet to break out sales of Fiasp individually, but the product is approved in Europe and Canada and is pending FDA approval (decision expected in 3Q17). We imagine this new-gen insulin portfolio will buffer any headwinds for Novo Nordisk's other diabetes products going forward, and we see potential for this group of four therapies to post \$2.5 billion in 2017 (up from \$661 million in the full year 2016).

9. Xultophy (insulin degludec/liraglutide fixed-ratio injection) posted DKK 181 million (\$28 million) in sales, which represents 76% sequential growth from DKK 103 million (\$15 million) in [1Q17](#) (the first quarter in which Novo Nordisk broke out sales for the product). This level of sequential growth for Xultophy seems muted so early in the product's launch cycle (it only became available in US pharmacies this past May, and the US is the largest market for diabetes globally). That said, this is consistent with management's previous statements that Tresiba and Victoza will remain top commercial priorities for now, in order to generate familiarity with both monotherapies before promoting their combination.

10. Novo Nordisk's modern insulins - basal insulin Levemir, prandial insulin NovoLog, and NovoMix - experienced another challenging quarter in 2Q17, with portfolio revenue falling 4% YOY as reported (5% operationally). The lion's share of this negative growth was attributed to Levemir, which fell 16% YOY as reported (17% operationally) to DKK 3.6 billion (\$553 million). Sales of NovoMix fell a more modest 2% YOY as reported (1% operationally) to DKK 2.6 billion (\$400 million), whereas NovoLog revenue rose 4% YOY as reported (3% operationally) to DKK 5.1 billion (\$782 million).

11. Human insulin sales fell 6% YOY as reported (5% operationally) to DKK 2.5 billion (\$387 million) in 2Q17. Sequentially, sales fell 3% from \$372 million in [1Q17](#).

12. Saxenda revenue rose 82% YOY as reported (77% in constant currencies) to DKK 686 million (\$105 million), growing 27% sequentially following a flat quarter in [1Q17](#). Management highlighted Saxenda, now launched in 19 countries, as an important growth driver for the company's pharmaceutical business as a whole - quite a rare feat for an obesity drug, considering sluggish sales for other products in the class and the stigma, under-prescription, and poor reimbursement that surrounds obesity pharmacotherapy. Ultimately, we're glad to see Saxenda doing well globally despite its high price.

Pipeline Highlights

13. Management reviewed [very promising phase 2 data](#) on semaglutide for obesity (released in June), and announced that Novo Nordisk will initiate phase 3 studies in 1H18 with once-weekly dosing of the GLP-1 agonist, rather than once-daily injections as administered in phase 2. During Q&A, Chief Science Officer Dr. Mads Thomsen alluded to "a new level of efficacy" with semaglutide, which produced ~16% weight loss (from a baseline 244 lbs) among phase 2 study participants who completed one full year of treatment vs. ~8% weight loss for patients randomized to Saxenda (liraglutide 3.0 mg). Mean weight loss was ~14% in the semaglutide group when including participants who discontinued treatment before the end of the 52-week trial. Dr. Thomsen explained the decision to use a higher-dose, once-weekly injection scheme in phase 3 based on semaglutide's strong safety/tolerability profile in the phase 2 obesity study - the agent showed no major side-effects other than what's expected for a GLP-1 agonist (namely nausea and other GI symptoms). We're already enthusiastic about the weight loss efficacy of semaglutide, and we'll be even more excited if this holds true for a once-weekly formulation, offering lower injection burden and more convenience to people with obesity.

14. Phase 3 SUSTAIN 7 results are expected in 3Q17, and management mentioned that the head-to-head data comparing semaglutide vs. Lilly's Trulicity (dulaglutide) could give Novo Nordisk's once-weekly GLP-1 candidate an edge over in-class competition (Trulicity is also indicated for once-weekly dosing). The company has filed semaglutide with the [FDA, EMA](#), and regulatory authorities in [Japan](#). An FDA decision is expected in 4Q17, and we'll be curious to see if the agency convenes an Advisory Committee meeting beforehand.

15. Novo Nordisk's PIONEER program for oral semaglutide (comprised of 10 phase 3 studies) remains on track. Clearly, this highly-potent molecule has inspired a lot of confidence within the company, given that a majority of pipeline-related remarks during the call discussed semaglutide, whether injectable or oral.

16. While not mentioned in prepared remarks, Novo Nordisk's [presentation slides](#) (specifically, slide 13) confirmed that an FDA decision on Fiasp (next-gen faster-acting insulin aspart) is anticipated in 3Q17, following a Class II resubmission in [March 2017](#). Notably, Fiasp is already approved in Europe and Canada, and revenue from these ex-US markets was included in Novo Nordisk's reported sales for "new-generation insulins" in 2Q17. We look very forward to getting Fiasp sales broken out, as we continue to hear resounding positive feedback on this therapy - some may say it's an "incremental" benefit over existing mealtime options, but we'll take incremental improvement when the products we have available are not good enough in terms of speed or hypoglycemia risk.

17. Novo Nordisk's [roadshow presentation](#) (slide 76) explained the logic behind liver-preferential mealtime insulin (better mimics insulin as released by pancreatic beta cells, potential for less hypoglycemia/weight gain), and shared that phase 1 data on NN1406 is expected in 4Q17. This phase 1 study is ongoing according to [ClinicalTrials.gov](#), despite expected completion still listed as July 2017.

18. A Novo Nordisk representative recently informed us that the connected NovoPen 5 Plus has been made available in a limited volume in 10 participating Swedish clinics.

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Pooled Market Highlights

1. GLP-1 AGONISTS: REVENUE RISES 29% YOY TO \$1.6 BILLION; VICTOZA MAINTAINS LEADER STATUS, TRULICITY CLIMBS SKYWARD

The GLP-1 agonist class grew 29% YOY and 11% sequentially to \$1.6 billion in 2Q17, from a high base of \$1.2 billion in 2Q16 and \$1.4 billion in 1Q17 (when the market grew 35% YOY and 6% sequentially). We're excited about the continued impressive growth of this class, particularly as it means more patients are gaining access to these agents and their multitude of benefits - including glucose-lowering, weight loss, blood pressure-lowering, and possible cardioprotection. And, we feel there is tremendous upside. The market has grown to comprise ~11% of total diabetes prescriptions globally, compared to 9% 12 months ago (May 2017 data vs. May 2016 data, displayed in table 2 below). That said, recent [estimates](#) indicate that only 5% of type 2 diabetes patients in the US were prescribed a GLP-1 agonist as of 2013, so we see great potential for continued class growth with new innovations in GLP-1 therapy, and as payers come to recognize the long-term cost-savings associated with treatments from this class. Novo Nordisk's Victoza continues to lead with 56% market share by value (the product posted \$887 million in 2Q17, up 17% YOY as reported), though management cited underlying class growth as a driving factor for its GLP-1 agonist business. Moreover, during Q&A, management alluded to competition from long-acting GLP-1 agonists and especially from Lilly's once-weekly Trulicity (which also comes in a very patient-friendly IDEO-designed pen). With sales more than [doubling YOY](#), Trulicity captured 30% of pooled GLP-1 sales in 2Q17, up from 26% in 1Q17, when Victoza accounted for 57% of sales. [Novo Nordisk's presentation slides show that Victoza is also losing prescription volume to Trulicity: As of May 2017, Victoza's share of total GLP-1 agonist prescriptions \(TRx\) in the US was 46%, down from 48% in 1Q17, 50% in 4Q16, and 51% in 3Q16. Trulicity's US TRx share is trending in the opposite direction, at 22% in 3Q16, 25% in 4Q16, 30% in 1Q17, and 34% in 2Q17.](#) All this said, we see plenty of room for both products to sustain commercial success, given that many more patients could benefit from GLP-1 agonists than those currently on them. AZ's Bydureon accounted for 9% of pooled GLP-1 agonist sales in 2Q17, while Byetta accounted for 3%. GSK's Tanzeum captured 2% of this market by value (notably, GSK management [announced plans](#) to cease manufacturing of Tanzeum and to withdraw support), while Sanofi's Lyxumia captured <1%.

- **In Q&A, Novo Nordisk management mentioned "differentiated products" within "the GLP-1 agonist segment," the suggestion being that liraglutide's status as the only GLP-1 agent with known cardioprotective value will be an important stimulus for growth in the near-term future.** An FDA Advisory Committee recently [voted 17-2](#) in favor of a new CV indication on the Victoza label, and the EMA [approved](#) this label change for the product's European label - this expanded indication could very well boost Victoza volume and sales. Management described early market research in Germany, where company reps have been able to promote Victoza's CV benefit ahead of a formal label update: The findings give reason to believe that

an established CV indication will indeed increase Victoza uptake and sustain the product's GLP-1 agonist market share. Lessons from Lilly/Bi's roll out of the expanded Jardiance indication (SGLT-2 inhibitor empagliflozin) for the reduction of CV death suggest that it may take some time before we see an appreciable uptick in sales, but boy are we excited to have two diabetes drugs available with CV indications on the label. This is changing the way patients/providers can think about diabetes care. Patients have become accustomed to taking medicine for glucose-lowering, but a therapy that can really prevent CV outcomes is so enormously valuable in our treatment arsenal. Of note, the [REWIND CVOT for Lilly's Trulicity](#) is ongoing, with expected completion in July 2018. The ELIXA study of Sanofi's Adlyxin (lixisenatide) found neutral CV effects, and we also saw neutral CV effects in [topline data from the EXSCCEL trial](#) for AZ's Bydureon (exenatide twice-weekly), with full results scheduled for a slot at EASD 2017.

- Potential new market entries include Novo Nordisk's semaglutide (a potent, once-weekly GLP-1 agonist formulation with demonstrated CV benefit in [SUSTAIN 6](#)) and Intarcia's [ITCA 650](#) (an implantable mini pump offering continuous, subcutaneous release of exenatide for three-six months, ensuring adherence).** If approved, these therapies will bring meaningful new innovation to the class and could boost sales for all GLP-1 agonist products and the class as a whole. Novo Nordisk management expects both an FDA decision and a CHMP opinion on semaglutide in 4Q17, and also noted during 2Q17 prepared remarks that semaglutide offers an expansion opportunity with both injectable and oral administration (the oral version is in phase 3 - much more on this below). This could be incredibly good news for Novo Nordisk's diabetes business, given that liraglutide's first patent expiration is in August 2017, and Teva Pharmaceuticals filed the first [abbreviated NDA](#) for generic liraglutide in February of this year.

Figure 1: Total GLP-1 Agonist Sales (1Q06-2Q17)

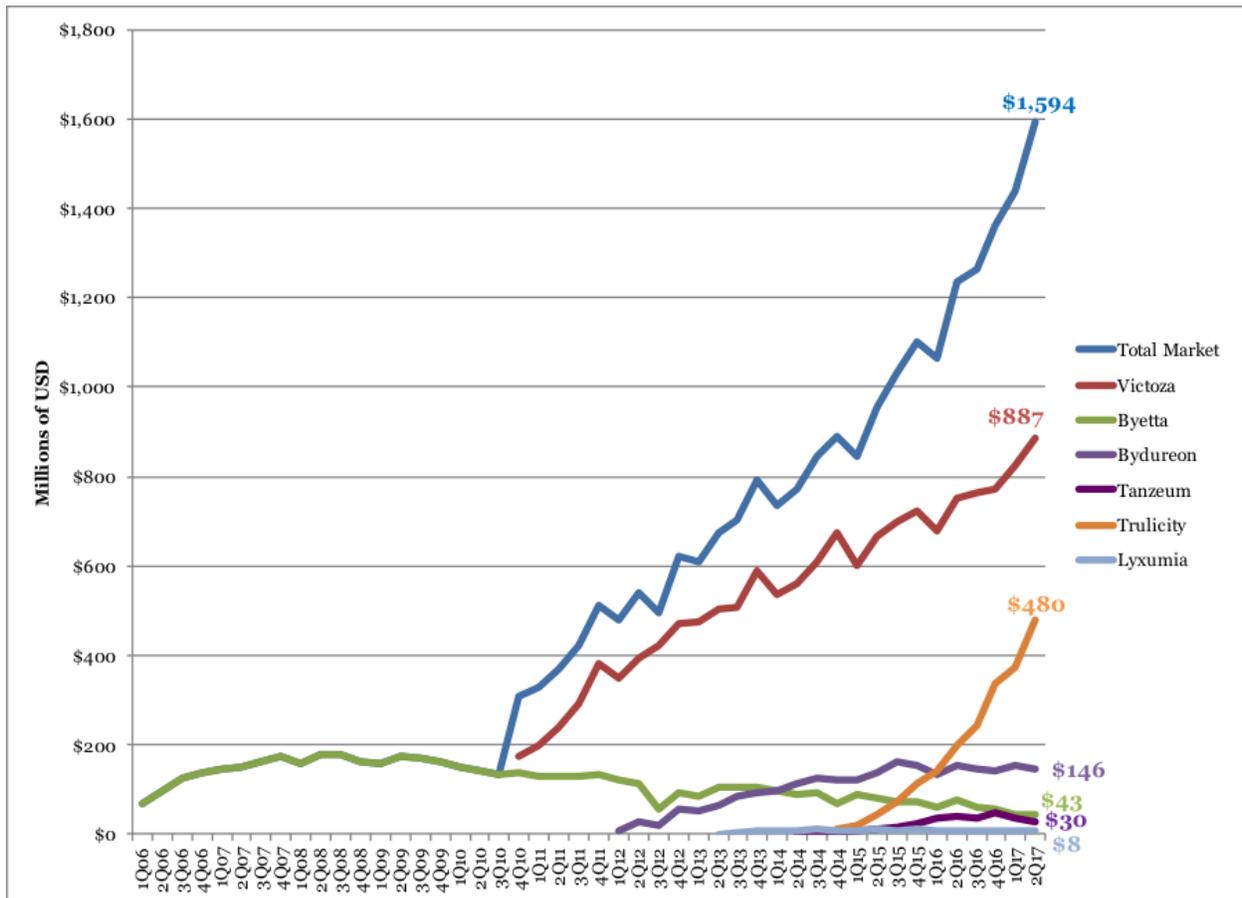


Table 2: GLP-1 Agonist Market Share

| | GLP-1 Agonist Share of Total Diabetes Market (by value) | | Victoza Share of GLP-1 Agonist Market (by value) | |
|----------------------|---|-------------|--|------------|
| | May 2017 | May 2016 | May 2017 | May 2016 |
| US | 12.7% | 10.2% | 52% | 59% |
| Europe | 10% | 9.2% | 61% | 70% |
| AAMEO | 2.5% | 2.1% | 51% | 58% |
| China | 0.9% | 0.8% | 61% | 53% |
| Japan + Korea | 4% | 2.8% | 50% | 67% |
| Latin America | 4.9% | 3.9% | 83% | 92% |
| Global Totals | 10.7% | 8.8% | 54% | 62% |

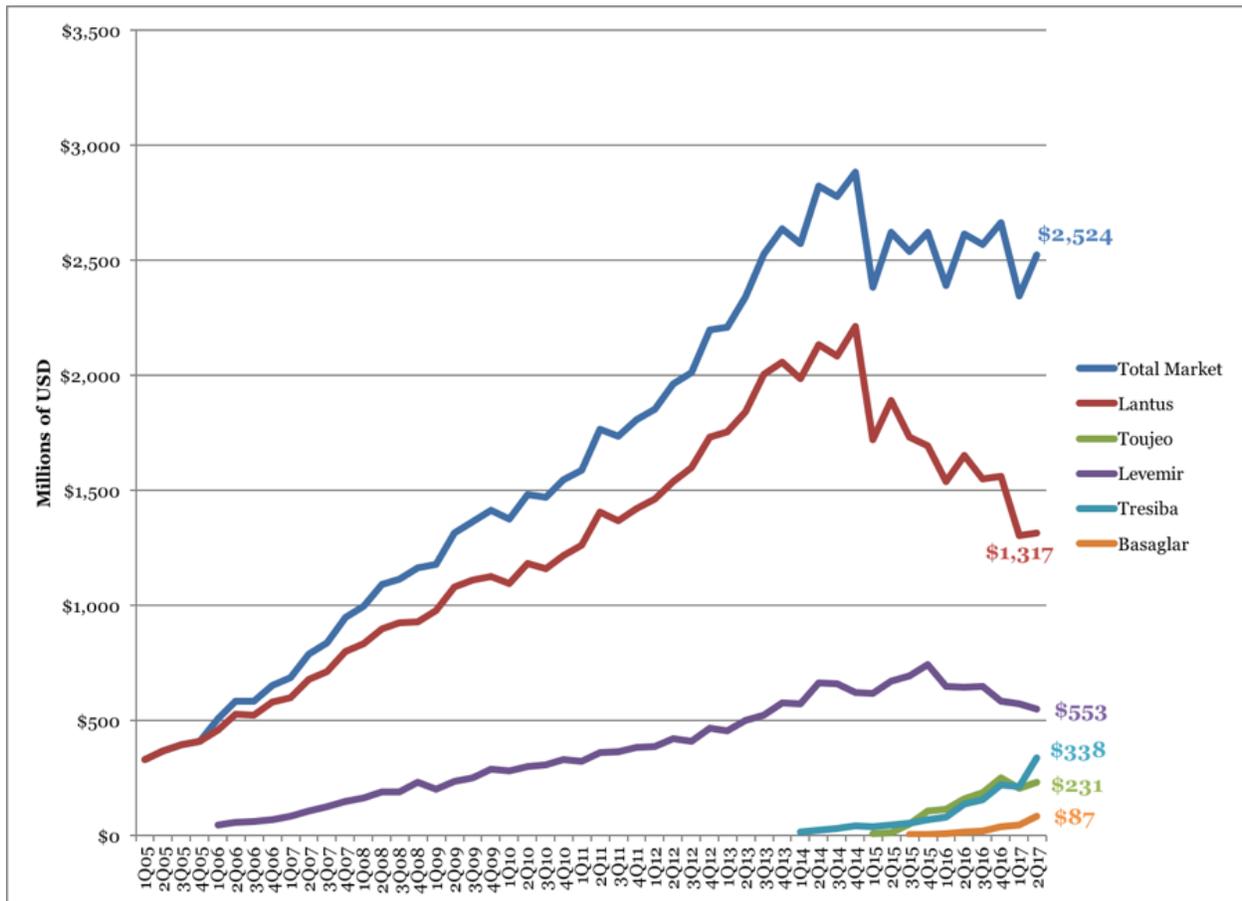
2. BASAL INSULIN: REVENUE FALLS 3% YOY DRIVEN BY LANTUS DECLINE

Pooled revenue for the basal insulin market fell 3% YOY to \$2.5 billion in 2Q17. This represents an 8% sequential increase against the easy comparison of a steep 12% sequential decline in 1Q17. We attribute this continued decline in 2017 largely to falling revenue from Sanofi's flagship product Lantus, following its exclusion from the [CVS Health](#) (effective January 2017) and [UnitedHealthcare](#) (effective April 2017) formularies. Sanofi has [maintained 50%](#) of its Lantus volume among patients on CVS Health thus far, in part due to patient savings programs, though realized price and revenue for Lantus dropped substantially as a result. According to Sanofi's recent [2Q17 update](#), the declining trend in Lantus prescription volume is expected to accelerate in future quarters as co-pay cards expire and as the full force of the recently-implemented UnitedHealthcare exclusion sets in. Despite falling sales, Lantus continues to lead the class and captured 52% of the \$2.5 billion market by value in 2Q17, followed by Novo Nordisk's Levemir (22%) and next-generation newcomers Novo Nordisk's Tresiba (13%) and Sanofi's Toujeo (9%). Lilly/BI's Basaglar, the first biosimilar to enter the basal insulin market, captured the remaining 3% of pooled sales. By volume, Lantus captured 50% of market share in terms of total prescriptions (TRx) in 2Q17, while Levemir held 23%, Toujeo held 9%, Tresiba held 8%, and Basaglar held 4% (this is according to slide 8 in Novo Nordisk's earnings [presentation](#)). **Novo Nordisk management noted that it expects Tresiba to capture 10% TRx by year-end**, and highlighted its impressive value share (by sales) in select international markets, including Japan (41%), Italy (30%), Switzerland (28%), and Denmark (28%).

- Against the backdrop of declining basal insulin sales overall, biosimilar Basaglar (newly-launched in the US, as of December 2016) and next-generation Tresiba and Toujeo represent bright spots of growth.** We attribute Basaglar's success largely to its strong reimbursement status: The biosimilar boasts exclusive positioning over its originator, Sanofi's Lantus, on the [CVS Health](#) and [UnitedHealthcare](#) formularies, plus equal footing to Lantus on the [Express Scripts](#) formulary. This favorable formulary status will continue into [2018](#). Lilly management emphasized in the company's recent [2Q17 update](#) that Basaglar has captured an impressive 20% share of new-to-brand prescriptions (NBRx) for basal insulin in the US, placing the product on par with well-established Levemir - very well for its third quarter on the market! Merck's biosimilar insulin glargine candidate recently received [tentative FDA approval](#) under brand name Lusduna Nexvue, and pending resolution of Sanofi's patent infringement lawsuit, we imagine this second biosimilar will eventually make waves in the basal insulin market as well (especially since [past experience](#) tells us that at least two generics are needed to see appreciable price changes on the market). On the other hand, we view the gains from Tresiba and Toujeo as a reflection of the improved clinical profile of these next-generation agents, to the tune of a flatter action profile,

flexible dosing, and less hypoglycemia. More on these products below in our pooled analysis of the next-generation basal insulin market.

Figure 2: Basal Insulin Market (1Q05-2Q17)



3. NEXT-GENERATION BASAL INSULIN MARKET: OVERALL MARKET NEARLY DOUBLES YOY TO \$569 MILLION, NOVO NORDISK'S TRESIBA PULLS AHEAD OF SANOFI'S TOUJEO

While revenue in the overall basal market fell 3% YOY to \$2.5 billion in 2Q17, sales of next-generation basal insulins - Sanofi's Toujeo and Novo Nordisk's Tresiba - nearly doubled YOY to \$569 million (from a base of \$296 million in 2Q16). The class grew 36% sequentially against an easy comparison of 12% sequential decline in 1Q17. This performance is encouraging following the steep 12% sequential decline seen in 1Q17, when Tresiba fell 4% and Toujeo fell 19%; we suspect this was due to pricing pressure and the launch of cheaper biosimilar Basaglar in the US, and it's reassuring to see these new agents return to growth. Tresiba captured 59% of the next-gen basal insulin market by value, with Toujeo claiming the remaining 41%. This compares to a more even split of 51% (Tresiba) vs. 49% (Toujeo) in 1Q17, the first quarter in which Tresiba revenue surpassed Toujeo revenue. That said, both products experienced strong quarters in 2Q17, with Tresiba sales more than doubling YOY to \$338 million and Toujeo sales rising 49% YOY to \$231 million (we were particularly impressed by Toujeo's performance in international markets). According to Novo Nordisk's 2Q17 presentation ([slide 8](#)), Tresiba held 8% of total basal insulin prescriptions (TRx) in 2Q17 vs. Toujeo's 9%.

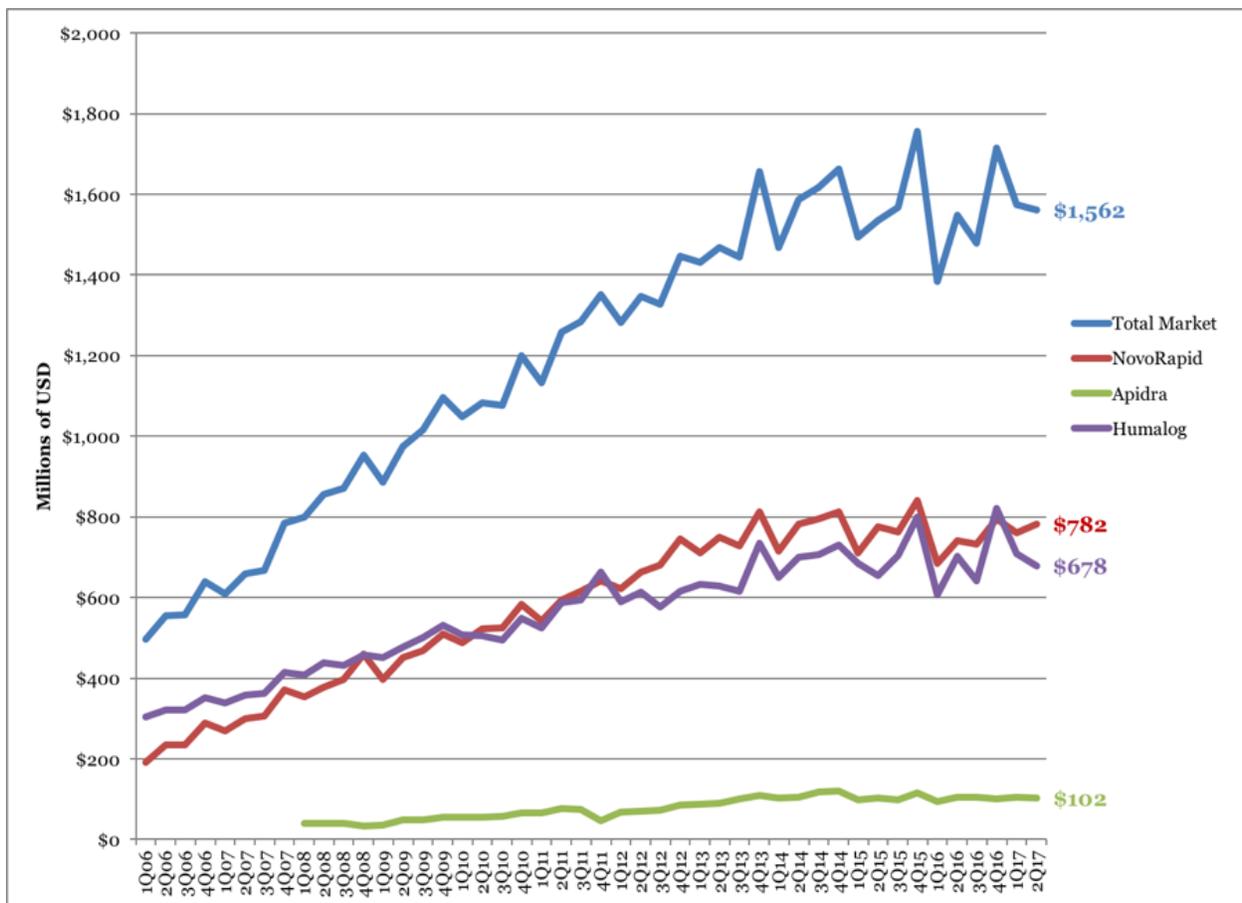
4. RAPID-ACTING INSULIN: SALES UP A MODEST 1% YOY TO \$1.6 BILLION; COMPETITIVE PRESSURE CONTINUES FROM GLP-1 AGONISTS AND SGLT-2 INHIBITORS

The rapid-acting insulin market showed modest 1% YOY growth to \$1.6 billion in 2Q17.

Sequentially, revenue fell 1% against the easy comparison of 8% sequential decline in [1Q17](#). This 2Q17 performance marks a return to the pattern of low to negative growth, which we have seen over the past several quarters (-7% in 1Q16, +1% in 2Q16, -6% in 3Q16, and -2% in 4Q16), with the exception of an especially strong [1Q17](#) with 14% YOY class growth. Novo Nordisk's NovoRapid (insulin aspart) continues to lead with 50% of the market by value, ahead of Lilly's Humalog (insulin lispro) at 43%. Sanofi's Apidra (insulin glulisine) comprises the remaining 7%. We see challenges ahead for the rapid-acting insulin class, as competitive pressure from GLP-1 agonists and SGLT-2 inhibitors (alternative methods to address postprandial excursions) intensifies. In contrast to the sluggish rapid-acting insulin market, the GLP-1 agonist and [SGLT-2 inhibitor](#) classes are experiencing skyrocketing growth, rising 29% and 20% YOY respectively in 2Q17. We anticipate this challenge to the rapid-acting insulin class will only steepen with continued uptake of basal insulin/GLP-1 agonist fixed-ratio combinations.

- **We are curious to see how Fiasp will impact the rapid-acting insulin market - the product is already available in Europe and Canada, and Novo Nordisk included these sales in reported revenue for "new-generation insulins" in 2Q17, but has yet to break out Fiasp revenue separately.** Novo Nordisk [resubmitted](#) its New Drug Application (NDA) for Fiasp following a [Complete Response Letter](#) in October 2016, and a decision is now expected in 3Q17. Based on the >doubling YOY and 47% sequential growth for the new-gen insulin portfolio in 2Q17, we imagine Fiasp is performing well where it has launched - could this faster-acting therapy revitalize the mealtime insulin drug class? We'd like to think so, but we're also aware that Fiasp will not be immune to pricing pressure in the US or to competition from GLP-1 agonists and SGLT-2 inhibitors (major challenges for the rapid-acting insulin class today). Fiasp is the only next-gen insulin currently available, and likely will remain so for the mid-term future, given Lilly's [termination](#) of its partnership with Adocia for phase 3-ready ultra-rapid BioChaperone Lispro, which will delay the phase 3 program for BioChaperone Lispro until Adocia secures a new partner. MannKind's inhaled insulin Afrezza is [pending FDA approval](#) of an ultra-rapid-acting label claim (decision expected by September 30), which could bolster that franchise and make Afrezza a bigger contender in the rapid-acting insulin class, though we still see a very long road ahead for MannKind to build commercial traction for this product. Afrezza sales have been sluggish to-date, totaling only \$1.5 million in [2Q17](#) and \$1.2 million in [1Q17](#).

Figure 3: Rapid-Acting Insulin Market (1Q06-2Q17)



5. BASAL INSULIN/GLP-1 AGONIST FIXED-RATIO COMBINATIONS: XULTOPHY + SOLIQUA SALES SUM TO \$34 MILLION, UP 79% SEQUENTIALLY IN SECOND QUARTER OF REPORTED REVENUE

Pooled sales of basal insulin/GLP-1 agonist fixed-ratio combinations totaled \$34 million in 2Q17, up 79% sequentially from \$19 million in 1Q17 (the first quarter in which Novo Nordisk and Sanofi broke out sales for Xultophy and Soliqua, respectively). By value, Xultophy (insulin degludec/liraglutide) held 82% market share with \$28 million in revenue. Soliqua (insulin glargine/lixisenatide) held the remaining 18% with \$6 million in revenue. This larger share for Xultophy reflects its longer time on the market - the product has been available in international markets for over two years, since January 2015, while [US launch](#) occurred in May 2017. Thus, US sales likely did not contribute substantially to Xultophy's 2Q17 showing. In contrast, Soliqua's revenue is largely driven by US sales since the product's [launch](#) in January 2017. Payer negotiations for both combination products are ongoing, and we'll be watching this closely to see how the dynamics for this class shape up in the US, which we expect to drive the lion's share of sales in the future (if the GLP-1 agonist market is any indication). Overall, we see enormous potential for this class from both a clinical and financial perspective, and we desperately want to see Xultophy and Soliqua in the hands of more people with diabetes, a view Ms. Davida Kruger espoused in a conversation with us this morning. We're also reminded of a [quote](#) from the renowned Dr. John Buse, who called Xultophy "the most effective anti-hyperglycemic agent on the planet," based on superior glucose-lowering and weight loss vs. component monotherapies, plus a milder side-effect profile (mitigated nausea and some neutralizing of hypoglycemia risk). It's disappointing that commercial enthusiasm for these fixed-ratio combos is lagging behind the clinical enthusiasm we've gathered from diabetes thought leaders (we certainly expected to see a stronger showing from Soliqua than \$6 million in 2Q17). That said, if Novo Nordisk and Sanofi are able to overcome the reluctance from HCPs (particularly in the US) to prescribe fixed-ratio combination drugs and are able to secure strong reimbursement status for their respective products, we think the class could reach

\$1-\$3 billion in the next several years and might even exceed \$5 billion in a decade. (This is based on the conservative assumption that 10%-20% of the 8-10 million people in the US with diabetes and suboptimal glycemic control will convert to this new class). Without factoring in rebates, Sanofi has [priced Soliqua](#) in the US at parity to other GLP-1 agonists on the market (~\$20-25/day) to prioritize market growth, whereas Novo Nordisk has [priced Xultophy](#) at a premium (~\$31/day).

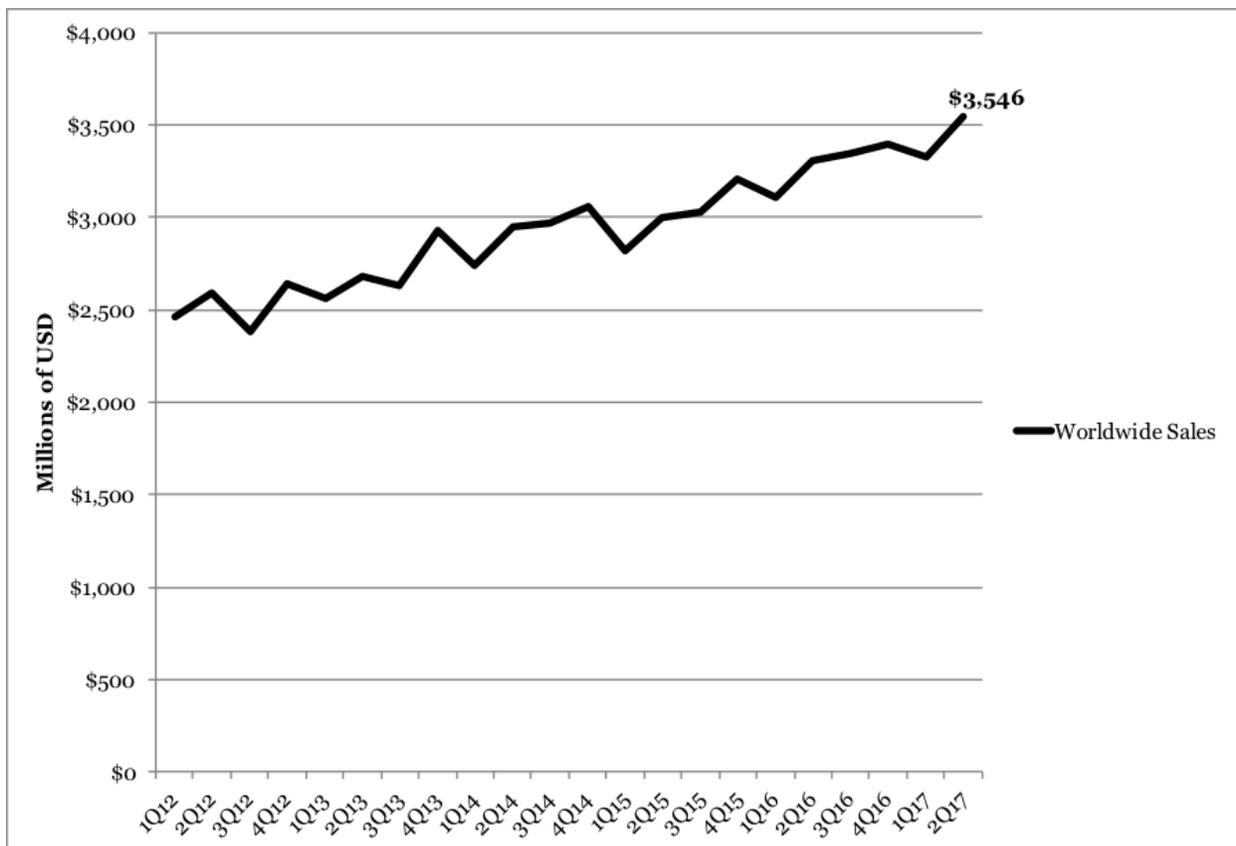
- **As we see it, Soliqua has the advantage of lower list price, while Xultophy has the advantage of a next-generation insulin component and a GLP-1 agonist component with demonstrated cardioprotective benefits - presumably resulting in a stronger clinical profile, though no head-to-head trials of Xultophy vs. Soliqua have been conducted.** On the insulin front, Xultophy's Tresiba (insulin degludec) component has demonstrated a significant hypoglycemia benefit vs. Soliqua's Lantus (insulin glargine) component in both the [SWITCH 1 and 2 trials](#) and the recent [DEVOTE CVOT](#). On the GLP-1 agonist front, Xultophy's Victoza (liraglutide) component boasts significant CV benefits from the [LEADER trial](#), whereas the [ELIXA trial](#) for Soliqua's Lyxumia (lixisenatide) component found neutral CV effects. Furthermore, Xultophy has been shown to promote weight loss, whereas Soliqua appears to be weight neutral based on phase 3 clinical trial results. All this said, we see plenty of room for both Soliqua and Xultophy to be successful on the market. The best case scenario would be whole class growth, since both of these advanced therapies are superior to drugs that have come before them. Beyond a head-to-head comparison of Xultophy vs. Soliqua, we hope the future holds more outcomes data and CGM data for these therapies, which we think would only corroborate the profound benefits shown in phase 3.

Financial Highlights

6. STRONG QUARTER FOR DIABETES/OBESITY OVERALL, WITH 6% YOY GROWTH

Novo Nordisk's overall diabetes/obesity portfolio grew 6% YOY as reported (7% in constant currencies) to DKK 23.1 billion (\$3.5 billion) in 2Q17, against a modest comparison of 2% YOY growth as reported (7% in constant currencies) in 2Q16. Sequentially, total sales from all major diabetes/obesity products fell 1% from DKK 23.3 billion (\$3.3 billion) in 1Q17. Tresiba was the primary growth driver, even though it only accounts for <10% of total portfolio revenue (management shared an expectation for Tresiba to reach 10% volume share within the basal insulin market by end of 2017). **Novo Nordisk's "new-generation insulins," comprised of Tresiba, Xultophy, Ryzodeg, and Fiasp (sold ex-US in Europe/Canada) accounted for a whopping 65% of portfolio growth in 2Q17 compared to 11% of total revenue, by our calculations.** GLP-1 agonist Victoza was another growth driver, and we note that the GLP-1 agonist is Novo Nordisk's most profitable diabetes product. By our calculations, Victoza accounted for a 35% share of growth and for 25% of total revenue for Novo Nordisk Diabetes and Obesity. Management further mentioned that NovoRapid and Saxenda have helped offset declining Levemir sales. Despite the strong quarter overall, management alluded to pricing pressure around diabetes drugs in the US, and cautioned that looking at price in isolation does not provide good context without also considering prescription volume, patient discounts, and segment mix (or a higher proportion of prescriptions going to patients on Medicaid). This has been a recurring theme on earnings calls from pharma companies in 1H17 (including [AZ in 2Q17](#), [Sanofi in 2Q17](#), J&J in [1Q17](#) and [2Q17](#), [Lilly in 2Q17](#), and Merck in [1Q17](#) and [2Q17](#)). Novo Nordisk management shared that formulary negotiations with PBMs in the US and with managed care organizations are ongoing - the major takeaway was that market access for the company's major diabetes/obesity products is expected to remain roughly the same in 2018 as in 2017.

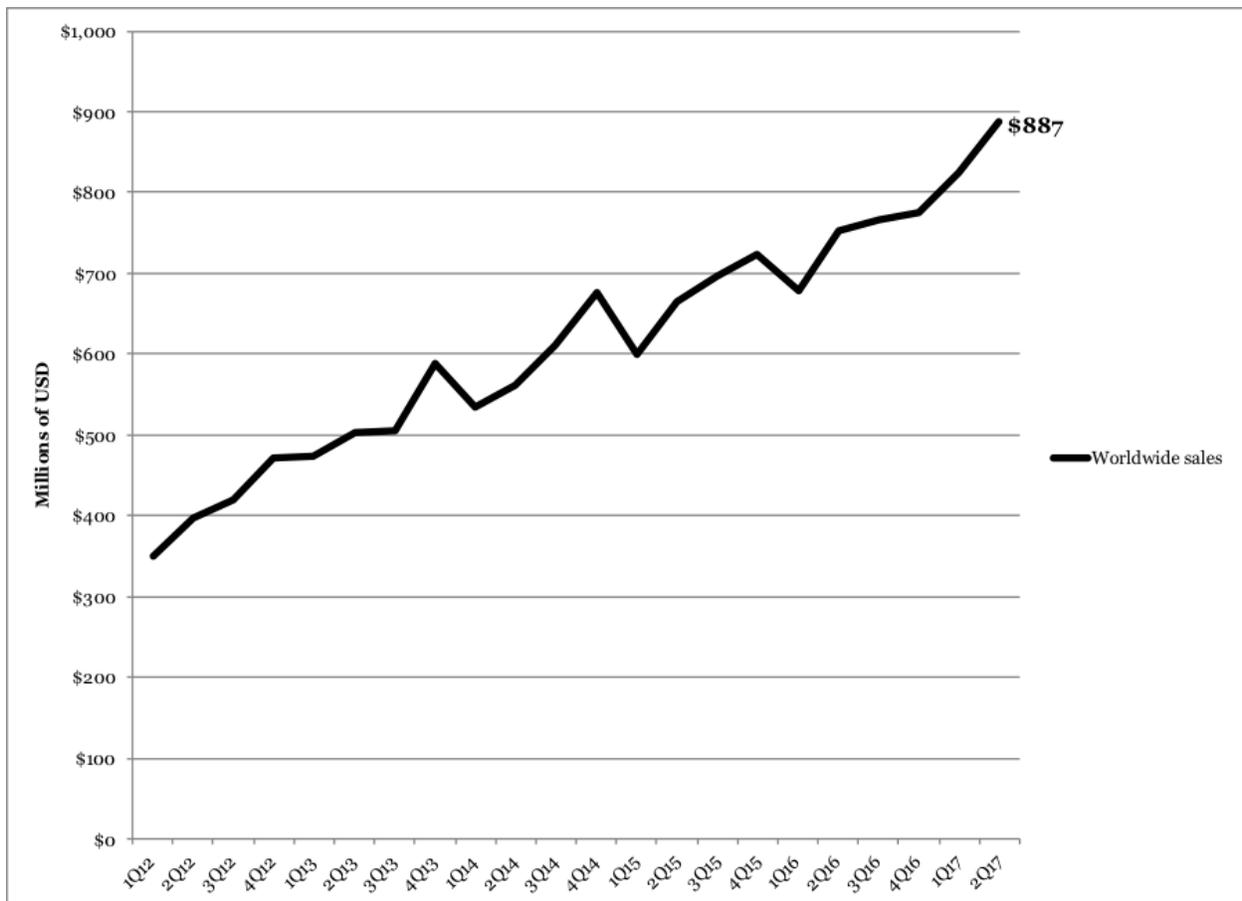
Figure 4: Total Diabetes/Obesity Sales (1Q12-2Q17)



7. VICTOZA: SALES CLIMB 17% YOY TO \$887 MILLION, DESPITE COMPETITION FROM TRULICITY

Market leading GLP-1 agonist Victoza posted DKK 5.8 billion (\$887 million) in 2Q17, marking 17% YOY growth as reported (18% in constant currencies) and driving 35% of growth in Novo Nordisk's overall diabetes/obesity portfolio by our calculations. Growth for the Victoza business was driven by the US, China, and Latin America/AAMEO (Africa, Asia, Middle East, and Oceania), where sales increased 21%, 40%, and 32% YOY as reported, respectively. In contrast, sales declined 3% YOY as reported in Europe, and a fell a more marked 45% YOY in Japan/Korea. This overall strong financial performance occurred against a backdrop of >25% volume growth for the GLP-1 agonist class as a whole in the US, and "despite intensified competition" from Lilly's Trulicity. While YOY growth has been steady since product launch, management acknowledged a downward trend in Victoza's market share by volume in the US (with prescriptions yielded to Trulicity). As of May 2017, Victoza held 46% TRx (share of total prescriptions) for GLP-1 agonists in the US, on a downward trend, while Trulicity held 34% on an upward trend. Still, management pointed to upcoming milestones that could spur further growth for Novo Nordisk's GLP-1 agonist business: (i) In June, an FDA Advisory Committee [voted 17-2](#) in favor of a new CV indication for Victoza (this indication for CV risk reduction has already been approved for the [EU label](#)), and a regulatory decision for the US label is anticipated in 3Q17. (ii) An [FDA decision](#) on once-weekly semaglutide is expected in 4Q17. (iii) During Q&A, management also remarked that Victoza has just secured reimbursement in China, and company reps will now promote the GLP-1 agonist more aggressively in that market (which is sizeable for diabetes).

Figure 5: Victoza Sales (1Q12-2Q17)



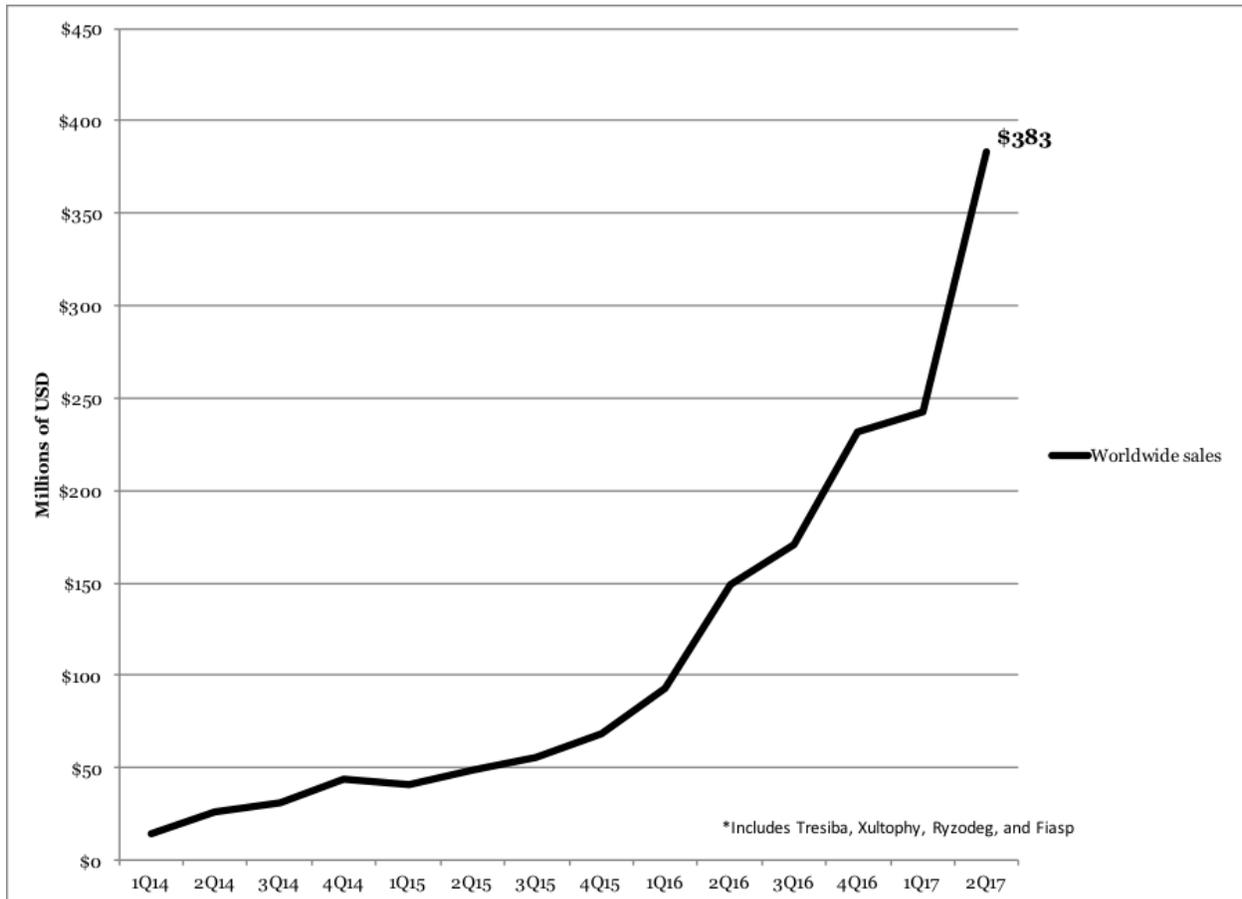
8. TRESIBA: REVENUE >DOUBLES YOY TO \$338 MILLION; ROBUST DEVOTE DATA SUBMITTED TO FDA FOR HYPOGLYCEMIA BENEFIT

Next-gen basal insulin Tresiba was an indisputable bright spot for Novo Nordisk in 2Q17, with sales more than doubling YOY to DKK 2.2 billion (\$338 million). Sequentially, revenue rose an impressive 47%, a reassuring sign following a disappointing 4% sequential loss in 1Q17 (the very first sequential drop in Tresiba sales). Tresiba's new-to-brand prescription share (NBRx) is ~12%, and its share of total basal insulin prescriptions (TRx) is 8% in the US. Management expects Tresiba to reach 10% US TRx by the end of 2017 - for reference, [Sanofi's next-gen Toujeo](#) currently holds 9% US TRx among all basal insulin products. Management explained that Tresiba uptake has been concentrated in commercial channels so far, with lower sales to patients on Medicare Part D (this follows the typical trend for a new prescription drug, while Levemir, as a more "mature" product, is seeing stronger uptake in Part D). Novo Nordisk's new-generation insulin portfolio, consisting of Tresiba, Xultophy, Ryzodeg, and - for the very first time! - next-gen prandial insulin Fiasp, more than doubled YOY to DKK 2.5 billion (\$383 million) in 2Q17. These agents drove a striking 65% of growth in Novo Nordisk's overall diabetes/obesity business by our calculations. Of course, part of this growth would be explained by the new addition of Fiasp to this portfolio. Novo Nordisk has yet to break out sales of Fiasp individually, but the product is approved in Europe and Canada and is pending FDA approval (decision expected in 3Q17). Tresiba sales alone grew 66% sequentially in the US, followed by 21% sequentially in Latin America/AAMEO.

- **Notably, management shared that the FDA will now be evaluating SWITCH 1 and 2 in conjunction with DEVOTE to determine if a hypoglycemia benefit should be reflected on Tresiba's label.** The company [submitted](#) SWITCH 1 and 2 data to FDA in September 2016, but [full results from the DEVOTE CVOT](#) presented at ADA 2017 showed an even more compelling 40% risk reduction for severe hypoglycemia and a 53% risk reduction for severe hypoglycemia overnight

with Tresiba vs. standard of care Lantus. A regulatory decision on inclusion of the SWITCH results was originally expected in September 2017, which has now been pushed back to end of 1Q18 so FDA can evaluate these data in the context of DEVOTE as well (a similar submission has been made to the EMA). We see this is as very good news - DEVOTE was a larger trial producing more robust hypoglycemia findings, and data from the CVOT can only help Tresiba's chances of getting a new hypoglycemia indication.

Figure 6: New-Generation Insulin Sales (1Q14-2Q17)



9. XULTOPHY: SALES GROW 76% SEQUENTIALLY TO \$28 MILLION IN SECOND-EVER QUARTER OF REPORTED REVENUE

Xultophy (insulin degludec/liraglutide fixed-ratio injection) posted DKK 181 million (\$28 million) in sales, which represents 76% sequential growth from DKK 103 million (\$15 million) in 1Q17 (the first quarter in which Novo Nordisk broke out sales for the product). This level of sequential growth for Xultophy seems muted so early in the product's launch cycle (it only became available in US pharmacies this past May, and the US is the largest market for diabetes globally). That said, this is consistent with management's [previous statements](#) that Tresiba and Victoza will remain top commercial priorities for now, in order to generate familiarity with both monotherapies before promoting their combination. Management remarked today that Xultophy is now launched in 15 countries, and that launch is "progressing as planned." Novo Nordisk's marketing strategy for Xultophy stands in direct contrast to [Sanofi's promotional/educational efforts](#) surrounding Soliqua (insulin glargine/lixisenatide fixed-ratio injection). We suspect this is due to the fact that the Tresiba and Victoza franchises are individually major drivers of growth for Novo Nordisk, which is less true for Soliqua's individual components, Lantus (insulin glargine) and Adlyxin (lixisenatide). In this sense, Soliqua may be more critical for Sanofi's diabetes business in the short term than is Xultophy for Novo Nordisk's diabetes business, considering the context of other portfolio assets

and overall portfolio growth. Novo Nordisk reps have also [explained the company's strategy](#) as an effort to cultivate familiarity - insulin degludec itself is relatively new-to-market, and patients/providers have to be comfortable with an agent before they prescribe it in combination. That said, we take the fact that the company is now breaking out sales for Xultophy as a sign of Novo Nordisk's long-term confidence in the combination. We're happy to note this positive outlook, given how [highly-anticipated](#) Xultophy was in the US - and rightfully so, since the fixed-ratio combination offers superior A1c-lowering and weight loss alongside a milder side-effect profile vs. basal insulin or GLP-1 agonist monotherapy. For more on this emerging drug class, refer to our pooled market analysis of basal insulin/GLP-1 agonist fixed-ratio combinations above.

- **We were pleased to see that Novo Nordisk launched Xultophy with a \$1/day savings card for eligible patients with commercial insurance, thereby expanding access to this costly combination therapy.** This savings program effectively reduces co-pay for a monthly supply of Xultophy to \$30 - quite a contrast to the drug's steep [list price](#) of ~\$31/day (a premium vs. ~\$20-25/day for existing GLP-1 agonists), not reflecting rebates. That said, this savings card will not be able to help those in the high deductible phase of their health plans or uninsured cash-pay patients, per the [eligibility criteria](#). As payer negotiations progress, we hope the future holds meaningfully expanded access for this innovative therapy (and for its in-class competitor Soliqua as well).

10. MODERN INSULINS: PORTFOLIO DOWN 4% YOY TO \$1.7 BILLION, DRIVEN BY FALLING LEVEMIR SALES

Novo Nordisk's modern insulins - basal insulin Levemir, prandial insulin NovoLog, and NovoMix - experienced another challenging quarter in 2Q17, with portfolio revenue falling 4% YOY as reported (5% operationally) to DKK 11 billion (\$1.7 billion). The lion's share of this negative growth was attributed to Levemir, which fell 16% YOY as reported (17% operationally) to DKK 3.6 billion (\$553 million). Sales of NovoMix fell a more modest 2% YOY as reported (1% operationally) to DKK 2.6 billion (\$400 million), whereas NovoLog revenue rose 4% YOY as reported (3% operationally) to DKK 5.1 billion (\$782 million). During prepared remarks, management partially explained the declining trend in Levemir sales in terms of continued uptake of Tresiba, its next-generation counterpart in Novo Nordisk's basal insulin portfolio. That said, continued pricing pressure in the basal insulin sector - particularly in the US - remains a major factor if not the defining factor.

- **To this end, the negative portfolio growth in 2Q17 was driven primarily by sluggish performance in the US market, where modern insulin sales fell 12% YOY to DKK 5.5 billion (\$843 million).** In contrast, ex-US sales rose 5% YOY to DKK 5.8 billion (\$891 million). This is a trend we have come to expect, given the challenging pricing environment that diabetes drugs face in the US, particularly surrounding insulin. Indeed, the other two big players in insulin manufacturing - [Sanofi](#) and [Lilly](#) - explicitly called out US pricing pressure during their 2Q17 financial updates, citing high discounts, high rebates, and increased segment mix (a greater proportion of prescriptions going to patients on Medicaid) as reasons for sluggish sales. However, we note that despite these overarching challenges, Novo Nordisk remains a true giant in the insulin domain. According to the company's [press release](#), Novo Nordisk captured 46% of the total insulin market and 44% of the modern/new-generation insulin market as of May 2017, as shown in the table below.

Table 3. Novo Nordisk Insulin Market Share

| | Share of Total Insulin Market | | Share of Modern and New-Generation Insulin Market | |
|----|-------------------------------|----------|---|----------|
| | May 2017 | May 2016 | May 2017 | May 2016 |
| US | 37% | 37% | 38% | 38% |

| | | | | |
|---------------------|------------|------------|------------|------------|
| Europe | 45% | 46% | 44% | 46% |
| AAMEO | 57% | 57% | 51% | 52% |
| China | 59% | 60% | 61% | 61% |
| Japan + Korea | 49% | 49% | 49% | 48% |
| Latin America | 42% | 40% | 40% | 41% |
| Global Total | 46% | 47% | 44% | 45% |

11. HUMAN INSULIN: SALES DECLINE 6% YOY TO \$387 MILLION

Human insulin sales fell 6% YOY as reported (5% operationally) to DKK 2.5 billion (\$387 million) in 2Q17. Sequentially, sales fell 3% from \$372 million in [1Q17](#). The negative growth was driven by steep revenue declines in all ex-US geographic regions, including Japan and Korea (-57%), Europe (-13%), China (-12%), and to a lesser extent Latin America and Region AAMEO (Africa, Asia, Middle East, and Oceania; -5%). By contrast, US sales grew 25% YOY operationally to DKK 461 million (\$71 million). We suspect this is driven by US patients seeking less expensive insulin options in this era of skyrocketing insulin prices.

12. SAXENDA: SALES GROW 82% YOY AND 27% SEQUENTIALLY TO \$105 MILLION

Saxenda revenue rose 82% YOY as reported (77% in constant currencies) to DKK 686 million (\$105 million), growing 27% sequentially following a flat quarter in 1Q17. The lion's share of Saxenda sales came from the US market, where the drug posted DKK 536 million (\$82 million). The remaining revenue came from Europe (DKK 23 million [\$4 million]) and AAMEO/Latin America (DKK 87 million [\$13 million]). Management highlighted Saxenda, now launched in 19 countries, as an important growth driver for the company's pharmaceutical business as a whole - quite a rare feat for an obesity drug, considering sluggish sales for other products in the class and the stigma, under-prescription, and poor reimbursement that surrounds obesity pharmacotherapy. Saxenda's growth potential is further reinforced by a recent positive CHMP opinion [endorsing](#) the inclusion of LEADER data on the Saxenda product label. Management has previously noted that only 2% of 600 million people with obesity are being treated with any therapy, and a label that reflects liraglutide's proven CV benefit should help grow Saxenda's TRx by allowing Novo Nordisk reps to promote the agent's cardioprotection to HCPs. Also in 2Q17, the FDA [approved](#) the inclusion of positive three-year [SCALE data](#) on Saxenda's label. These results showed a 79% risk reduction for new-onset type 2 diabetes in patients who persisted on high-dose liraglutide treatment for three years and should only bolster Saxenda's status as the market-leading obesity medication. To be sure, there are enormous challenges in the obesity market, including poor reimbursement that makes these agents inaccessible, stigmatization of the medical treatment of obesity, and provider reluctance to treat obesity with pharmacotherapy. We'll be back later this month with a pooled analysis of major obesity medications. In the meantime, see our [1Q17 pooled analysis](#) (Saxenda was the main driver of 74% YOY growth). Ultimately, we're glad to see Saxenda doing well globally despite its high price, and we're pleased to see Novo Nordisk's continued commitment to obesity therapies as well as diabetes.

Pipeline Highlights

13. DR. MADTS THOMSEN: SEMAGLUTIDE SHOWS A "NEW LEVEL OF EFFICACY" IN WEIGHT LOSS

Management reviewed [very promising phase 2 data](#) on semaglutide for obesity (released in June), and announced that Novo Nordisk will initiate phase 3 studies in 1H18 with **once-weekly dosing of the GLP-1 agonist, rather than once-daily injections as administered in phase 2.** During Q&A, Chief Science Officer Dr. Mads Thomsen alluded to "a new level of efficacy" with semaglutide, which produced ~16% weight loss (average drop of 39 lbs from a baseline 244 lbs) among phase 2 study

participants who completed one full year of treatment vs. ~8% weight loss for patients randomized to Saxenda (liraglutide 3.0 mg) and only 2% weight loss for patients on placebo (all treatment was adjunct to diet/exercise). Mean weight loss was ~14% in the semaglutide group when including participants who discontinued treatment before the end of the 52-week trial. Still, this is remarkable and clinically-meaningful weight loss efficacy, and definitely supports advancement of the agent into phase 3 toward an obesity indication. The recently-completed [phase 2 trial](#) (n=957) evaluated various doses of once-daily semaglutide, ranging from 0.05 mg to 4 mg. Dr. Thomsen explained the decision to use a higher-dose, once-weekly injection scheme in phase 3 based on semaglutide's strong safety/tolerability profile in phase 2 - the agent showed no major side-effects other than what's expected for a GLP-1 agonist (namely nausea and other GI symptoms). We're already enthusiastic about the weight loss efficacy of semaglutide, and we'll be even more excited if this holds true for a once-weekly formulation, offering lower injection burden and more convenience to people with obesity. Moreover, management's high confidence in the potential for once-weekly semaglutide to treat obesity is yet another sign of Novo Nordisk's fierce commitment to developing the next generation of advanced weight loss therapies. This is an enormous unmet need: 600 million people worldwide have obesity, and a mere 2% are receiving any form of medical management. See our pipeline summary (table 5) below for a glimpse at the company's earlier-stage obesity candidates, including a PYY analog, a long-acting amylin analog, a glucagon analog, a GLP-1/glucagon dual agonist, an FGF21 analog, and a GLP-1/GIP/glucagon tri-agonist (all in phase 1).

- **Management underscored that there was no signal for retinopathy associated with semaglutide in this [phase 2 obesity trial](#)** (completed April 2017). This is a reassuring safety finding, and it lends additional support to what Dr. Tina Vilsbøll shared in [her presentation at ADA 2017](#) - that the 76% increase in risk for retinopathy seen in [SUSTAIN 6](#) was most likely due to steep A1c reductions after initiation of semaglutide therapy, rather than a safety concern inherent to the molecule. Dr. Vilsbøll suggested that proper patient selection and careful monitoring will be successful strategies to mitigate this risk in the real world, if/when semaglutide is approved. The candidate is currently under review with the [FDA](#), [EMA](#), and regulatory authorities in [Japan](#) for a type 2 diabetes indication. An FDA decision is expected in 4Q17, and we're curious to see if the agency will convene an Advisory Committee beforehand... if so, we imagine retinopathy risk would be a major topic of conversation, though we're hopeful that this very potent, efficacious GLP-1 agonist will be swiftly approved and made available to real-world patients. Notably, Dr. Vilsbøll also pointed to semaglutide's profound weight loss benefit in her SUSTAIN 6 talk at [ADA 2017](#), arguing that the body weight reduction could not be explained by GI side-effects alone. The more recent phase 2 trial enrolled people with obesity but not diabetes.

14. SEMAGLUTIDE VS. DULAGLUTIDE (LILLY'S TRULICITY) DATA EXPECTED IN 3Q17 (SUSTAIN 7)

Phase 3 SUSTAIN 7 results are expected in 3Q17, and management mentioned that the head-to-head data comparing semaglutide vs. Lilly's Trulicity (dulaglutide) could give Novo Nordisk's once-weekly GLP-1 candidate an edge over in-class competition. Trulicity is also indicated for once-weekly dosing, and comes in a patient-friendly IDEO-designed pen that has received resounding positive feedback from real-world users. As we note in our pooled market and financial highlights above, the bar for GLP-1 agonists is rising as competition intensifies. Ultimately, we view this as great news from the patient perspective, because it will drive innovation toward more effective, safer, more patient-friendly products that also address outcomes beyond A1c - to this end, semaglutide has already demonstrated a CV benefit in the [SUSTAIN 6 trial](#), though Novo Nordisk plans to conduct a larger CVOT post-approval. Cardioprotection may become a more defining commercial factor for GLP-1 agonists following [topline results from the EXSCEL CVOT](#) for AZ's Bydureon (exenatide once-weekly), which reported neutral CV effects. Thought leaders are beginning to [speculate](#) that cardioprotection is not a class effect for GLP-1 agonists, which could mean a boost in uptake for drugs that have demonstrated CV benefit (liraglutide, semaglutide), but also further challenges for GLP-1 agents that have not (exenatide, Sanofi's lixisenatide - branded as Adlyxin in the US). The [REWIND trial](#) investigating CV effects of Lilly's Trulicity is expected to complete in July 2018. Victoza and Trulicity currently dominate the GLP-1 agonist market, but Novo Nordisk management seems

optimistic that semaglutide will join Victoza to markedly grow the company's GLP-1 agonist business. We see distinct potential for semaglutide to grow the GLP-1 agonist class as a whole, which we're eager to see, given the glycemic efficacy of these agents along with weight loss and possible cardioprotection.

- **The company has filed semaglutide with the [FDA](#), [EMA](#), and regulatory authorities in [Japan](#). An FDA decision is expected in 4Q17, and we'll be curious to see if the agency convenes an Advisory Committee meeting beforehand.**

15. ORAL SEMAGLUTIDE FORGES AHEAD IN PIONEER CLINICAL PROGRAM

Novo Nordisk's PIONEER program for oral semaglutide (comprised of 10 phase 3 studies) remains on track. Clearly, this highly-potent molecule has inspired a lot of confidence within the company, given that a majority of pipeline-related remarks during the call discussed semaglutide, whether injectable or oral. See the table below for a summary of PIONEER trials, and note in table 5 that once-daily injectable semaglutide is also being investigated in NASH.

Table 4: PIONEER Phase 3 Program for Oral Semaglutide

| Trial | Estimated Enrollment | Comparator/Design | Estimated Completion |
|----------------------------|-----------------------------|--|----------------------------------|
| PIONEER 1 | 704 | Placebo | December 2017 |
| PIONEER 2 | 816 | Lilly/BI's Jardiance (empagliflozin) | March 2018 (enrollment complete) |
| PIONEER 3 | 1,860 | Merck's Januvia (sitagliptin) | March 2018 (enrollment complete) |
| PIONEER 4 | 690 | Novo Nordisk's Victoza (liraglutide) | March 2018 |
| PIONEER 5 | 324 | Moderate renal impairment | May 2018 |
| PIONEER 6 | 3,176 | CVOT | October 2018 |
| PIONEER 7 | 500 | Flexible dose escalation | March 2019 (enrollment complete) |
| PIONEER 8 | 720 | Insulin add-on | August 2018 |
| PIONEER 9 | 230 | Placebo and liraglutide in Japan | September 2018 |
| PIONEER 10 | 336 | Lilly's Trulicity (dulaglutide) as an add-on to oral agents in Japan | August 2018 |

16. COMPANY AWAITS FDA DECISION ON CLASS II RESUBMISSION OF FIASP, EXPECTED 3Q17

Novo Nordisk's [presentation slides](#) (specifically, slide 13) confirmed that an FDA decision on Fiasp (next-gen faster-acting insulin aspart) is anticipated in 3Q17, following a Class II resubmission in [March 2017](#). Notably, Fiasp is already approved in Europe and Canada, and revenue from these ex-US markets was included (for the first time) in Novo Nordisk's reported sales for "new-generation insulins" in 2Q17. We look very forward to getting Fiasp sales broken out, as we continue to hear

resounding positive feedback on this therapy. Some may say it's an "incremental" benefit over existing mealtime options, but we'll take incremental improvement when the products we have available are simply not good enough in terms of speed or hypoglycemia risk. We were excited to learn at [Diabetes UK 2017](#) that Fiasp is [priced on par](#) with NovoRapid (insulin aspart) in that market, and our fingers are crossed for a similar pricing strategy in the US. In fact, we think parity pricing may be smart given the controversy over soaring insulin costs in the US - it would certainly help Novo Nordisk in formulary negotiations and in marketing the product to patients/providers. We'd like to see this faster-acting bolus insulin in the hands of as many people as possible to bring down hypoglycemia rates and to improve what is currently suboptimal postprandial glucose control at the population level. During [Novo Nordisk's 1Q17 update](#), management suggested that Fiasp will be less of a commercial priority in the near-term future, with more resources allocated to Tresiba, Victoza, and Saxenda. There was no commentary on this topic at all during the company's 2Q17 call. As we understand it, Novo Nordisk is approaching Fiasp as more of a defensive measure to sustain its overall insulin portfolio as older products yield market share to newer, better therapies (as an example, in the basal insulin class, Levemir is losing market share to Tresiba and Toujeo). This fits with the inclusion of Fiasp in the "new-generation insulins" category. On the other hand, Fiasp sales seem to have made a meaningful contribution to the >doubling YOY and 47% sequential growth of this new-gen insulin portfolio, although we can only speculate until revenue from faster-acting insulin aspart is broken out separately. We'll be curious to see how US launch activities progress, and we'll be pleased to see any efforts from Novo Nordisk to ensure widespread access to the more advanced prandial therapy.

17. PHASE 1 READ OUT ON LIVER-PREFERENTIAL MEALTIME INSULIN ANTICIPATED FOR 4Q17

Novo Nordisk's [roadshow presentation](#) (slide 76) shared that **phase 1 data on liver-preferential mealtime insulin NN1406 is expected in 4Q17**. This phase 1 study is ongoing according to [ClinicalTrials.gov](#), despite expected completion still listed as July 2017. The company's roadshow slide deck explained some of the logic behind liver-preferential insulin: Elevated hepatic glucose drives postprandial hyperglycemia in type 2 diabetes, and >50% of endogenous insulin is typically cleared by the liver. A prandial insulin analog targeted to the liver is thus more physiologic in that it better mimics insulin as released by pancreatic beta cells. In line with this, NN1406 holds exciting potential to show less frequent hypoglycemia and lower weight gain compared to existing mealtime insulin options. In a similar vein, [Diasome Pharmaceuticals](#) is investigating liver-targeted insulin lispro (Lilly's Humalog), which uses Hepatocyte Directed Vesicle (HDV) technology to enhance its prandial action. The company [recently received](#) grants from Medicxi, the JDRF T1D Fund, and others to support three phase 2 studies of liver-targeted insulin lispro in type 1 diabetes. Notably, Lilly discontinued its internal liver-targeted insulin lispro candidate in [December 2015](#) due to liver toxicity and other safety concerns, so we'll be keen to see how NN1406 circumvents these issues; we see it as "best in class" in all therapies so we believe it will ultimately be hard for anyone to "exceed" it, including Diasome's HPV-powered agent - we also think there's more than room for one. Safety data on both of these novel mealtime insulins will be key as they progress through clinical development. We look forward to the phase 1 results on Novo Nordisk's candidate, and we're glad to see the company's continued innovation in the insulin arena with early-stage pipeline products - both this liver-preferential insulin analog and NN1436, a once-weekly basal insulin in phase 1 - especially following the decision to [discontinue oral insulin](#) from phase 2 in [3Q16](#).

18. NOVOPEN 5 PILOTED IN SWEDEN

A Novo Nordisk representative recently informed us that the connected NovoPen 5 Plus has been made available in a limited volume in 10 participating Swedish clinics. The pen has built-in near field communication (NFC) function, enabling providers to upload insulin usage data to Glooko/Diasend using the NFC pad on [Glooko's new transmitter](#). They can then visualize blood glucose values vs. insulin dosage, filling a major gap in MDI therapy, to help them better guide treatment. Novo Nordisk anticipates that findings from this pilot will inform future digital health offerings. We assume that the plan is for Glooko to build a paired smartphone app, eventually with dose titration guidance, for this product down the line. At [AADE 2017](#) this past weekend, Dr. Bruce Bode shared that Novo Nordisk (along with other insulin giants

Sanofi and Lilly) is committed to getting dose information from its insulin devices into the cloud ASAP, "hopefully by the end of 2018." In our view, pharma companies and especially insulin manufacturers will have to invest in support tools to help real-world patients succeed on their therapies, and Novo Nordisk's increasing emphasis on digital health is great to see (the company formalized its partnership with Glooko in [January 2017](#)).

Table 5: Novo Nordisk Diabetes/Obesity Pipeline Summary

| Candidate | Indication | Class/Mechanism of Action | Phase | Timeline/Notes |
|---|----------------------------|---|--|---|
| Faster-acting insulin aspart (approved as Fiasp in EU and Canada) | Type 1 and type 2 diabetes | Next-generation rapid-acting insulin analog | Approved in EU and Canada; Pending FDA decision following Complete Response Letter (CRL) | Received FDA CRL in October 2016 ; Resubmitted in March 2017 with FDA decision expected 3Q17 |
| Once-weekly injectable semaglutide | Type 2 diabetes | Once-weekly GLP-1 agonist | Filed | US and EU submission in December 2016 with decision expected 4Q17; Japan submission in February 2017 |
| Oral semaglutide | Type 2 diabetes | Once-daily oral GLP-1 agonist | Phase 3 | 10-trial phase 3 PIONEER program initiated; Phase 2 data presented at EASD 2016 |
| Once-daily injectable semaglutide | Obesity, NASH | Once-daily GLP-1 agonist | Phase 2 | Phase 2 trial in obesity reports positive data in 2Q17; Plans to initiate phase 3 in 1H18 (with once-weekly dosing!); phase 2 NASH trial ongoing (expected to complete January 2020); Phase 2 results in type 2 |

| | | | | |
|------------------|-----------------------------------|---|---------|---|
| | | | | diabetes reported 4Q16 |
| NN9828 | Type 1 diabetes (newly-diagnosed) | Anti-IL 21/GLP-1 agonist (liraglutide) combination for beta cell preservation | Phase 2 | Phase 2 trial announced May 2015 and initiated 4Q15 (expected to complete April 2019); FDA orphan drug designation in January 2017 |
| LAI287 (NN1436) | Type 1 and type 2 diabetes | Once-weekly injectable basal insulin | Phase 1 | Phase 1 trial completed 3Q15 ; New phase 1 trial initiated in November 2016, expected to complete December 2017 |
| PI406 (NN1406) | Type 1 and type 2 diabetes | Liver-preferential prandial insulin analog | Phase 1 | Phase 1 trial initiated 4Q15 ; Completed June 2016; New phase 1 trial initiated October 2016 with results expected 4Q17 |
| PYY1562 (NN9748) | Type 1 and type 2 diabetes | PYY | Phase 1 | Added to pipeline in 4Q15 |
| PYY1562 (NN9747) | Obesity | PYY; Under development both as a standalone therapy and in combination with semaglutide | Phase 1 | Advanced into phase 1 3Q15 ; Phase 1 trial completed February 2017 |
| AM833 (NN9838) | Obesity | Long-acting amylin analog | Phase 1 | Announced in 4Q14 ; Completed phase 1 trial in March 2016; New phase 1 trial initiated in November 2016 |

| | | | | |
|---------------------------|---------|--------------------------------|---------|---|
| | | | | and expected to complete December 2017 |
| G530S (NN9030) | Obesity | Glucagon analog | Phase 1 | Announced in 3Q14 ; Completed phase 1 trial July 2016; Phase 1 trial of standalone agent completed July 2017; Phase 1 trial of co-administration with liraglutide expected to complete September 2017 |
| GG-co-agonist (NN9277) | Obesity | GLP-1/glucagon dual agonist | Phase 1 | Phase 1 trial expected to complete October 2017 |
| FGF21 Obesity (NN9499) | Obesity | FGF21 analog | Phase 1 | Phase 1 trial expected to complete October 2017 |
| Tri-agonist 1706 (NN9423) | Obesity | GLP-1/GIP/glucagon tri-agonist | Phase 1 | Added to pipeline in 1Q17; Phase 1 trial expected to complete September 2017 |

Questions and Answers

ON TRESIBA

Q: Can you explain some of the dynamics you are seeing in Medicare Part D? You note that you saw modest sales for Tresiba in this area - why is this, and how did Levemir sales compare?

Mr. Lars Jørgensen (CEO, Novo Nordisk): Bear in mind that when we launch new products, they typically start out by penetrating the commercial segment, and then later expand into the lower priced segments, like Medicare Part D. That's really the explanation for why we see the dominant part of the Tresiba business in the commercial space, and it will move more into Part D come 2018. We have a more than normalized split between commercial and Part D for Levemir because it's a more mature product.

Q: You've talked about how you can still hit the 10% market share for Tresiba in the US. Could you give us some color on the measures that you'll be undertaking to achieve that, especially as you won't yet be able to promote the SWITCH hypoglycemia data to PCPs, as you perhaps predicted at the beginning of the year?

Mr. Jørgensen: We ended 2016 with a market share of around 5% for Tresiba in the US. We have added another 3.5% so far this year, partly fueled by the contract changes, and we believe it's realistic to anticipate another 1.5% to reach 10% by year-end. You are right that this would be easier if we had the SWITCH data on Tresiba's label, but we believe we can still educate providers about this via our medical liaisons based on peer-reviewed articles. And, of course, patients and physicians are already feeling the benefit of being on Tresiba, so it's not only about label claims. Our experience in the market that will also continue fueling the growth of Tresiba. We still believe 10% by year-end is achievable.

Q: Should we be expecting a similar rate of growth in market share for Tresiba in 2018-2019 as in 2017, or should we expect it to slow down?

Mr. Jørgensen: There are some different moving parts. On one hand, market share may slow after the initial spike in uptake following launch. On the other side, we all expect to have the benefit of the SWITCH and DEVOTE data on Tresiba's label soon. Adding that all up, our expectations for next year would be basically a straight line from 2017.

Q: Why is the FDA choosing to club the SWITCH 1 and 2 trials together with DEVOTE? What does that imply? Are you still expecting to get a label for lower hypoglycemia for Tresiba, or should that not be our assumption going forward?

Dr. Mads Thomsen (CSO, Novo Nordisk): Bear in mind that the DEVOTE study is in a very different league than that of the SWITCH studies in terms of the data's robustness and strength and the ability to analyze it left, right, and center. As you can see in the papers that came out last month, the SWITCH studies are really good studies as well, but the FDA has taken the prerogative to look at the big overall hypoglycemia benefits with Tresiba versus insulin glargine with everything that we know from both SWITCH and DEVOTE together. This decision comes at a point in time where the FDA is hosting a number of workshops looking into how we can go beyond hemoglobin A1c as a labeling endpoint in the field of diabetes. One of the most obvious targets for a non-A1c related label outcome is severe hypoglycemia due to the danger that that it imposes upon patient, family, and society. That's how we see it. My optimism as regards to the Tresiba label update is therefore completely unchanged, but the timing is not - the target is now shifted to late 1Q18.

ON VICTOZA

Q: We saw good growth for Victoza in the US, but in Europe and Japan growth was declining. Can you discuss what you're seeing in these regions and for the GLP-1 agonist class as a whole?

Mr. Jørgensen: We have very strong growth for Victoza in the US, but across the world - particularly in Europe and Japan - we see tough competition from other long-acting GLP-1 agonists taking share and growth away from us. On a positive note, we have just obtained reimbursement in China for Victoza. We are quite encouraged by this and we'll now go out and push Victoza heavily in the Chinese market.

Q: What is going on in terms of the cardiovascular benefit claims - does this actually hold much sway in terms of formulary positioning? What are your expectations for how the CV benefit of Victoza (and eventually semaglutide) will impact the market?

Mr. Jørgensen: We actually have a bit of internal data from Germany where we have been able to promote the CV benefit for Victoza even before obtaining the label update. There we saw a slowdown in our loss of GLP-1 agonist market share to competitors, suggesting that we will see a similar impact in other markets now that the (European) label has been updated.

Q: We saw GSK talk of withdrawing Tanzeum from the market. This product was the lowest priced GLP-1 agonist. Do you have any comments in terms of pricing in the GLP-1 agonist space and where you think that will go from here?

Mr. Jørgensen: What we see in the GLP-1 agonist segment is that it's still a market with quite differentiated products. So, unless a product is up at the efficacy level of Victoza it's really difficult to compete, in my view. I think it's a positive sign that even if you reduce the pricing and give steep rebates, you're not going to penetrate the market without good efficacy. So I think that bodes well for next year, when we hopefully will be

launching semaglutide, which is the GLP-1 agonist with the strongest clinical profile by far. This should promote continued growth of the GLP-1 market, and also a rebound of market share for Novo Nordisk.

ON NOVO NORDISK'S PIPELINE

Q: What are your thoughts on GLP-1 analogues as a potential treatment option for other diseases, given the recent Lancet paper examining exenatide as a potential treatment for Parkinson's disease?

Dr. Mads Thomsen (CSO, Novo Nordisk): There were indeed some interesting observations in *Lancet* a few days ago. Novo Nordisk is currently conducting in vivo animal studies on semaglutide, and it appears that this drug induces a rescue of the dopaminergic neurons that are critical to Parkinson's patients. If that is the case in humans, it's truly exciting and something we will potentially elaborate on a lot more. We're also investigating whether the effect is due to general anti-inflammatory effects, action on glucose transporters in the brain, or even effects on insulin siphoning. Some mechanisms are more interesting than others and we will see what we find. We'll have the data from some of these animal studies toward the end of this year, and then they will form the basis for the next movement, if any, in this area. In regards to Alzheimer's disease, a phase 2 study of liraglutide is ongoing at Imperial College, sponsored by us and the Alzheimer's Society.

Q: You mentioned that semaglutide would be dosed once-weekly for the phase 3 obesity program. Could you confirm what dosage you're planning, and what degree of weight loss you saw at those dosages in phase 2?

Dr. Thomsen: We plan to conduct phase 3, as you correctly stated, using once-weekly application (as we've done also in type 2 diabetes) in more than 8,000 individuals. The basis for calculating the dose is the usual benefit/risk assessment. Since there were no unexpected risks or adverse events or side-effects associated with semaglutide other than those related to GLP-1 agonist therapy in general, it's obvious that we will go toward the higher end of the dose range. At both of the highest doses in the phase 2 program, 0.3 mg and 0.4 mg, we saw weight loss to the tune of 15-17 kg or more after one year of treatment, so that's what we're expecting in phase 3. This is a new level of efficacy compared to Saxenda in the SCALE studies, which is why we are already now planning for the phase 3 program.

Q: Should we still be thinking about a potential Advisory Committee meeting for semaglutide?

Dr. Thomsen: The FDA Amendments Act of 2007 actually states specifically that one should expect Advisory Committee meetings for a new molecule - and semaglutide is indeed a very new molecule. We are working and preparing under the assumption that this could easily happen within the realm of the PDUFA action period.

ON FINANCIAL GUIDANCE, PRICING, AND FORMULARY NEGOTIATIONS

Q: Can you provide any more detail on how access is shaping up for the basal insulin franchise and for Victoza?

Mr. Jørgensen: The discussions and contract negotiations are still ongoing. You have all seen that Express Scripts and CVS Health have announced their formularies, and these are the two biggest PBMs for Novo Nordisk. We've had quite a number of disruptions this year with products being excluded, and based on what we can see and what has been announced already, we believe we'll have a more stable environment going into 2018. I will refrain from speculating more about what has led to this, but I think it's a positive thing for Novo Nordisk to have a stable environment in which to sell a leading portfolio of products.

Q: Could you please try to talk us through the second part of this year? What will it take for you to reach the low end of the guidance? It seems like we should see quite some deterioration in 3Q17 and 4Q17. I'm especially interested in your assumptions around Victoza, as it seems like this could disturb things quite a lot if there's continued pressure from Trulicity.

A: It would be nice if we were providing detailed guidance per quarter, but life is not that good for an analyst yet. We would have to see a negative impact from the pipeline situation we have in the US in order to bring us

to the low end of the sales guidance. We would also have to see a slowdown in the penetration of Victoza in the GLP-1 agonist market, where we are currently significantly supported by a very high growth level.

-- by Ann Carracher, Abigail Dove, Payal Marathe, and Kelly Close