CLOSER LOOK

MEMORANDUM

Novartis 2Q16 - DPP-4 inhibitor Galvus sales up 12% YOY to $306 million; Lucentis sales decline 12% YOY to $475 million; No mention of glucose-sensing contact lens partnership with Verily - July 20, 2016

Executive Highlights

- DPP-4 inhibitor Galvus (vildagliptin) revenue grew 12% year-over-year (YOY) as reported and operationally and 8% sequentially to $306 million in 2Q16, surpassing $300 million for the first time in seven quarters. Lucentis (intravitreal ranibizumab) sales totaled $475 million for 2Q16, falling 12% YOY as reported (10% operationally) and growing 5% sequentially.
- While management highlighted expansion of Alcon (division partnered with Verily) as a key priority for Novartis, there was no mention of the glucose-sensing contact lens.

Yesterday, Novartis provided its 2Q16 financial update in a call led by CEO Mr. Joseph Jimenez. Below are our top highlights from the call, followed by Q&A. This is a follow up to our initial report yesterday.

1. Galvus (vildagliptin) revenues for 2Q16 totaled $306 million, representing a 12% year-over-year (YOY) growth as reported and operationally.

2. Lucentis (intravitreal ranibizumab) sales fell 12% YOY as reported (falling 10% operationally) to $475 million.

3. There was no mention of the glucose-sensing contact lens that Novartis is developing in partnership with Verily (formerly Google Life Sciences) although management did remark that expanding Alcon (the division collaborating with Verily) is a company priority.

Honorable Mention: Management highlighted the inclusion of Novartis' new heart failure drug Entresto (sacubitril/valsartan) as a class I therapy in US and European heart failure treatment guidelines.

TOP THREE HIGHLIGHTS

1. Galvus (vildagliptin) revenues for 2Q16 totaled $306 million, representing a 12% year-over-year (YOY) growth as reported and operationally. Sequentially, sales rose 8% from $283 million in 1Q16. Notably, 2Q16 represents the first quarter that Galvus has experienced double-digit YOY growth since 2Q14, and this is also the first time in the last seven quarters that the drug's revenue exceeded $300 million. That said, Galvus faced an easy comparison in 2Q16 since the franchise fell nearly 15% YOY in 2Q15 and nearly 4% sequentially in 1Q16 vs. 4Q15. As a reminder, Galvus is only marketed ex-US. While management did not mention Galvus during the call, the supplementary materials continued to share that the company will continue targeting Galvus to key segments such as elderly and renal-impaired patients, as we have seen in recent quarters. We recently heard ADA Chief Medical Officer Dr. Robert Ratner, at the Practical Ways to Achieve Targets in Diabetes Care meeting, advocate for the use of DPP-4 inhibitors in the elderly based on their benign safety profile and easy dose administration. On the other hand, we've also heard strong commentary suggesting that DPP-4 inhibitors should not be the preferred choice for most patients due to their lower A1c efficacy compared to GLP-1 agonists. Furthermore, we wonder if DPP-4 inhibitors will become less popular among patients with renal impairment if SGLT-2 inhibitors are shown to have renal-protective effects. However, SGLT-2 inhibitors do have comparatively lower A1c efficacy in patients with renal impairment, so we believe the use of a DPP-4 inhibitor and SGLT-2 inhibitor may well be a winning combination for these patients. Despite the recent exciting advances of classes such as SGLT-2 inhibitors and GLP-1 agonists, the DPP-4 inhibitors' tolerability profile remains a huge advantage and we imagine that this along with primary care providers' strong familiarity with the class will keep DPP-4 inhibitors as a main

player in diabetes care for years to come. Novartis is the first DPP-4 inhibitor manufacturer to report in 2Q16 and we will be back later with a class-wide look at revenues after Lilly (July 26), AZ (July 28), Merck (July 29), and Takeda (July 29) report their updates.

2. Lucentis (intravitreal ranibizumab) sales fell 12% YOY as reported (falling 10% operationally) to $475 million. Sequentially, sales grew 5%, against an easy comparison as sales fell 9% sequentially to the $452 million recorded in 1Q16. The ophthalmologic drug, prescribed for some patients with diabetic macular edema (DME), has seen almost consistent sequential decline since 1Q14 with the exception of 4Q15. Lucentis was not mentioned during the call, but supplemental materials cited competition for Lucentis as one of the main reasons for the overall decline in sales for the company's ophthalmology portfolio and for the decline in overall sales internationally. Indeed, in our eyes, Lucentis' higher price tag compared to Roche's Avastin (bevacizumab) may prove to be challenging (see our 2Q15 report for more on conflicts regarding the off-label use and reimbursement of Avastin) and the market added a new competitor with the approval of Bayer/Regeneron's Eylea (intravitreal aflibercept) for diabetic retinopathy with DME at the end of 1Q16. That said, as we've mentioned before, one potential bright spot for Lucentis highlighted in Roche's 1Q16 update was the publication of new results from the protocol T study showing no significant difference in visual outcomes between Lucentis and Eylea. One-year results from the study demonstrated greater gains with Eylea in patients with worse vision at baseline and may have contributed to Eylea's better performance over the past year.

3. We continued to hear no mention of the glucose-sensing contact lens that Novartis is developing in partnership with Verily (formerly Google Life Sciences), although management did remark that expanding Alcon (the division collaborating with Verily) is a priority. We haven't heard an update on the contact lens project in almost a year, since a WSJ article reported in August 2015 that the contact lens is slated to enter high-volume production and large-scale human trials in 2016. During the call's Q&A, management did mention plans to develop an intraocular lens (IOL) for presbyopia - this is in line with Novartis' referral to the project in 4Q14, where it seemed like the company is shifting more towards broader ophthalmologic indications. Thus, the mention continues to confirm our impression that a glucose-sensing contact lens is farther out within the timeline (if at all), though the expansion of Alcon keeps us somewhat hopeful. As a reminder, this Alcon expansion focuses on surgical and vision care while transferring its ophthalmology pharma business to the pharmaceuticals division, which could potentially bring greater attention to greater applications of the contact lens project - for more details on the expansion and acceleration plan, please see our 1Q16 and 4Q15 reports.

HONORABLE MENTION

- **Much of the update call focused on Novartis' new heart failure drug Entresto (sacubitril/valsartan).** Management especially highlighted its inclusion as a class I therapy in US and European heart failure treatment guidelines. The company also emphasized a recent JAMA Cardiology publication demonstrating that the drug could prevent or postpone 28,000 cardiovascular (CV) deaths/year in the US alone and that it is a cost-effective alternative to enalapril and suggested that, together, the findings and the class I designation support much broader use of Entresto. For context, Entresto's list price is ~$4,600 per patient per year, far lower than the ~$14,000+/year list prices for the PCSK9 inhibitor class. Novartis management announced that the company has decided to increase spending on Entresto's launch in the second half of 2016, a clear indication that Novartis sees Entresto as a significant area for investment in future growth.
    - **As type 2 diabetes and heart failure are common co-morbidities, we're eager to see if and how Entresto makes an impact on CV outcomes for people with diabetes, and how the diabetes market will impact Entresto sales going forward.** In particular, we're curious to see how Lilly/BI's SGLT-2 Jardiance (empagliflozin) will stack up against Entresto in people with diabetes. Specifically, will prescribers be more likely to prescribe Jardiance (with its demonstrated impressive heart failure benefits in the EMPA-REG OUTCOME trial) rather than Entresto for patients with diabetes and heart failure? We believe that a lot of this will ultimately depend on cost and

coverage, but as more diabetes drugs demonstrate cardioprotection, the overlap and cross-influence between these markets will likely grow moving forward.

Questions and Answers

Q: Following up on Alcon, could you give us an update on your intraocular lens (IOL) pipeline progress there? We saw Abbott got an FDA approval last week for a next-generation multifocal lens. Perhaps you could give us an update in light of the competitive progress?

A: I'll turn your attention to Europe where we've just launched the PanOptix trifocal as well as our UltraSert offerings. We've also launched the UltraSert here in the US. As I look down the road, we've got a new material IOL coming along, expected in the midterm. And then, as I look further out, we have another IOL, which is an accommodating IOL for presbyopia and the power vision as you've heard us refer to it. So, we seem to have, I think, a reasonably robust pipeline in there. We believe that the market for AT-IOLs, where we have the multi-focal and the toric, is relatively underpenetrated. So one of our investment hypotheses is to put more money behind that and grow the marketplace there.

-- by Payal Marathe, Helen Gao, Melissa An, and Kelly Close