CLOSER LOOK

MEMORANDUM

Novartis 1Q16 - Galvus (vildagliptin) revenues down 3% as reported YOY to $283 million; Lucentis (ranibizumab) revenues fell 16% YOY as reported; Growth plan of Alcon division (Verily collaborator) underway - April 21, 2016

Executive Highlights

- Galvus (vildagliptin) revenues for 1Q16 totaled $283 million, representing a year-over-year (YOY) decline of 3% as reported (up 4% operationally) and a sequential decline of 4% - though it looks like the drug will still be a blockbuster in 2016 if revenues stay steady. Lucentis (intravitreal ranibizumab) revenues fell 16% YOY as reported (down 11% operationally) and 9% sequentially to $452 million.
- Management shared that the company's Alcon (the division partnered with Verily) growth plan is underway and that the division has transferred its ophthalmology pharma business to Novartis' pharmaceuticals division.

This morning, Novartis held its 1Q16 financial update in a call led by CEO Mr. Joseph Jimenez. Below are our top highlights from the call, followed by Q&A.

1. Galvus (vildagliptin) revenues for 1Q16 totaled $283 million, representing a 3% YOY decline as reported (up 4% operationally) and a sequential decline of 4%.

2. Lucentis (intravitreal ranibizumab) revenues fell 16% YOY as reported (down 11% operationally) and 9% sequentially to $452 million.

3. Management shared that the company's Alcon (the division partnered with Google) growth plan is underway and that the division has transferred its ophthalmology pharma business to Novartis' pharmaceuticals division.

TOP THREE HIGHLIGHTS

1. Galvus (vildagliptin) revenues for 1Q16 totaled $283 million, representing a 3% YOY decline as reported (up 4% operationally) and a sequential decline of 4%. As in previous quarters, the product received very little attention during the call and was not mentioned a single time in the press release. As a reminder, Galvus is only marketed ex-US and its revenue has suffered since its German withdrawal in 2Q14. We imagine that the continued downward trend of Galvus sales is partly driven by some combination of SGLT-2 competition and pricing pressure as well as reduced strategic focus by Novartis. During Q&A, management suggested that price reductions throughout Europe and emerging markets are also negatively impacting products such as Galvus, while investors noted that the company's resource allocations toward new product launches may be hurting Galvus revenues. Indeed, we similarly noticed the company's de-prioritization of diabetes at our recent visit to Novartis' booth at ENDO, which notably had virtually no marketing on Galvus. Novartis is the first DPP-4 inhibitor manufacturer to report and we will be back later with a class-wide look at revenues after Lilly (April 26), AZ (April 29), Merck (May 5), and Takeda (May 10) report their updates.

2. Lucentis (intravitreal ranibizumab) revenues fell 16% YOY as reported (down 11% operationally) and 9% sequentially to $452 million. Similar to Galvus, Lucentis received no attention during the call but according to the supplementary financial data, the product's sales were "impacted by competitive pressures," which we suspect refer to greater branded competition as well as the increased use of Roche's Avastin (bevacizumab). According to the supplementary material, the council of state recently suspended Novartis' appeal against the decision in Italy that upheld fines due to "alleged collusion to artificially differentiate Avastin and Lucentis." Indeed, we believe Lucentis will find it very difficult to grow with its higher price tag compared to Avastin as well as the FDA's recent approval of Bayer/Regeneron's Eylea (intravitreal aflibercept) for diabetic retinopathy with DME (diabetic macular edema). 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. See our 2Q15 report for more on conflicts regarding the off-label use and reimbursement of Avastin.

3. Management shared that the company's Alcon (the division partnered with Google) growth plan is underway and that the division has transferred its ophthalmology pharma business to Novartis' pharmaceuticals division. As a reminder, Alcon experienced slow growth throughout 2015, which prompted the announcement and further hints of a growth acceleration plan for the division in 3Q15 and at JP Morgan, respectively. In prepared remarks, management highlighted that the division's growth plan is on track, with "clear focus on fixing the basics: accelerate innovation and sales; reinforce strong customer relationships; and improve basic operations." Management also announced that the company has transferred Ophtha Pharma from Alcon to Novartis' pharmaceutical division and that Alcon Pharma development has been transferred to a "new global function" as of April 1. As background, we see this component of the growth plan as most relevant to readers watching diabetes, as the plan aims to separate the division's devices from its pharma business to better focus efforts, which could potentially have positive implications for diabetes in terms of the Verily-partnered contact lens project. However, management has not specifically referred to the contact lens project, although management briefly pointed to technologies for presbyopia as an opportunity for Alcon's growth during Q&A, which confirms our impression that the contact lens seems to be a longer-term project within the Google collaboration. As a reminder, the most recent mentions of Google's partnership with Novartis has focused mostly on an "accommodating lens" project, which appears to be a lens application for presbyopia and myopia.

HONORABLE MENTION

- **In addition, we learned outside of the call that Novartis has recently partnered with the Red Cross to "tackle chronic diseases in refugee populations" through the Novartis Access program**. Specifically, Novartis will provide medicines for high blood pressure and diabetes to Syrian refugees in Lebanon. The drugs will be supplied through Novartis Access, which was launched last October and offers chronic disease medicines for $1 per treatment per month. Through this new partnership, the Red Cross will be able to receive these drugs at the lower price, helping the organization distribute the medicines to a larger population. We applaud Novartis for joining these partnerships across sectors and for helping put non-communicable diseases higher up on the global health agenda - see a blog from the Red Cross for more on the potential impact of this new collaboration.

QUESTIONS AND ANSWERS

Q: Just looking beyond the headline brands, it looks like some of your second line assets saw weakness particularly ex-US in Q1. So, Galvus, Diovan, and others were all below expectations. Is there a risk that you're sacrificing in-market sales by focusing the cardiometabolic effort on Entresto ex-US?

A: So, you're right in that we need to balance providing a reasonable margin in a year of generic pressure to find the money to invest in Entresto and Cosentyx. We did resource reallocation around the world and it would be easy to jump to the conclusion that maybe that had some impact on sales for other products. But the reality is when you dive into it, it's driven much more by price reductions that we're seeing across the business in Europe and the emerging world. There are a number of countries where we're seeing the impact of low commodity prices and lower ordering for the emerging market growth. It's quite a bit slower than it used to be. And in Japan, there is quite a lot of pressure particularly overall because wholesalers were drawing down inventory prior to their price cuts and continued erosion of Diovan and Exforge in the Japanese market.

Q: On Alcon, you referred to new business expansion areas. I was just wondering if you could expand on that. What particularities are you looking at that we perhaps aren't thinking about?

A: So, if you think about new business, I think about it in two ways. One is, actually, new business. And the other one is thinking about old business in new ways. So, let's deal with the new business to start with.

So, we did this deal with Transcend. And so, essentially, it is an opportunity in, what's called minimally invasive glaucoma surgery, where you insert a stent in the eye during a cataract procedure to alleviate the symptoms of glaucoma. And so, at the end of the day, what you have there is a great situation for us where we're already number one in cataract, and we simply have an add-on to the sales force that allows us to get into the glaucoma market, and about 15% to 20% of cataract patients actually have glaucoma. So, that is what I would call a new business using our existing resources.

Then, when I think of talking about old business in new way, there's the example of presbyopia. So, presbyopia has been around a long time. There are some solutions for it, but it really hasn't been pushed. The penetration into the presbyopic market - that is, people who need reading glasses - has been very poor. In my mind, there are many opportunities here to look at our technology to penetrate that market in a more aggressive way than we have in the past and I refer to that as new business as well and also point out new business in the LASIK market. So lots of opportunities out there in my mind.

Q: With that organizational structure effective from the first of April, where is your focus first and foremost now that you have a different organizational structure?

A: In terms of the organizational changes, after products moving to Pharma, of course, Pharma continues to be a significant part of the company. I think the realignment now made it easier for the Alcon colleagues to focus on the devices business and therefore, focus continues to be mainly on Pharma but of course, also on the turnaround of Alcon. As well as of course, to make sure that the resource allocation into the biosimilars at Sandoz also are appropriate, given the very good opportunity.

-- by Melissa An, Emily Regier, and Kelly Close