MEMORANDUM

Novartis 4Q15 - Galvus 2015 revenues down 7% as reported YOY to $1.1 billion; Alcon division (Google collaborator) to separate surgical/vision care and ophthalmology pharma in new plan; Novartis Access includes Galvus in portfolio - January 27, 2016

Executive Highlights

- Galvus (vildagliptin) revenues for 2015 totaled $1.1 billion, representing a year-over-year (YOY) decline of 7% as reported (up 8% operationally); sales totaled $294 million in 4Q15, remaining roughly flat YOY with a slight decline of 0.3%. Lucentis (ranibizumab) revenues remained disappointing at $2.1 billion in 2015, an annual decline of 16% as reported.
- Management announced details of Alcon's (the division partnered with Google) growth acceleration plan. The division will focus on surgical and vision care while transferring its ophthalmology pharma business to Novartis' pharmaceuticals division. In addition, we learned that Novartis Access will include Galvus in its portfolio of medicines.

This morning, Novartis held its 4Q15 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 the year totaled $1.1 billion, representing a 7% YOY decline as reported; sales for 4Q15 totaled $294 million, remaining roughly flat YOY with a slight decline of 0.3%.

2. Management announced that in Alcon's growth acceleration plan, the division will focus on surgical and vision care while transferring its ophthalmology pharma business to the pharmaceuticals division. This may potentially have positive implications for diabetes if it leads to a greater focus on the Google-partnered contact lens project.

3. We learned from Novartis' annual report that the company's Novartis Access program will include Galvus in its portfolio, whose medicines will be offered to low- and middle-income countries for $1 per treatment per month.

TOP THREE HIGHLIGHTS

1. Galvus (vildagliptin) revenues for the year totaled $1.1 billion, representing a 7% YOY decline as reported (up 8% operationally); sales for 4Q15 totaled $294 million, remaining roughly flat YOY with a slight decline of 0.3%. Sequentially, Galvus revenues grew slightly at 5% from 3Q15's $281 million. As in previous quarters, the product received very little attention during the call. As a reminder, Galvus is only marketed ex-US and its revenue has suffered since its German withdrawal in 2Q14. This year marks Galvus' first reported annual decline (it grew 2% and 32% YOY in 2014 and 2013, respectively) - we imagine this is due to some combination of SGLT-2 competition and pricing pressure. In addition, the annual report mentions that Sanofi is suing Novartis over a terminated DPP-4 inhibitor partnership in Japan; the French insulin manufacturer seeks damages of $356 million (plus legal fees) - this started in 2013 and has resulted in a counter-suit. It is unsurprising that Novartis has not included it in any of their recent updates. 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 (January 28), Merck (February 3), and Takeda (February 3) report their updates.

- **Management characterized Lucentis' (intravitreal ranibizumab) revenues as "disappointing," as its 2015 sales totaled $2.1 billion, marking a 16% decline YOY as reported (down 2% operationally).** As for 4Q15, the product's revenues totaled $499 million, declining 15% YOY as reported but slightly growing sequentially at 3%. Lucentis has been struggling in recent quarters and management brought up reasons similar to ones we've heard in the past: the company pointed out that Lucentis continues to face pressures from branded competition as well as the increased use of Roche's Avastin (bevacizumab) - see our 2Q15 report for more on conflicts regarding the off-label use and reimbursement of Avastin.

2. Management announced that in Alcon's growth acceleration plan, the division will focus on surgical and vision care while transferring its ophthalmology pharma business to the pharmaceuticals division. The company stressed three core elements of Alcon's growth plan: (i) focus the business; (ii) strengthen the foundation; and (iii) invest for growth. Notably to us, Novartis aims to "give the critical devices business 100% focus from division management" and accelerate innovation by implementing the "best-in-class surgical innovation model." Management also highlighted plans to accelerate "near-term BD&L and M&A to augment the pipeline." 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. We are curious to see if this new plan may potentially have positive implications for diabetes. There were no mentions of the Google-partnered projects (the contact lens seems to be a longer-term project, since we last heard), but we wonder if the division's heavier focus on devices may shift greater attention to the contact lens project. On the other hand, the Q&A around Alcon seemed to demonstrate that the division will be dedicating most of its near-term attention to "small deals," which likely does not refer to anything close to the Google contact lens project - see the Q&A below for more of the discussion around Alcon's new plan.

3. We learned from the company's annual report that the Novartis Access program, which offers medications to low- and middle-income countries for $1 per treatment per month ,will include Galvus in its portfolio. As a reminder, the company launched the program last October, addressing diabetes, cardiovascular diseases, respiratory illness, and breast cancer. Our guesses from previous coverage were incorrect - we had assumed that Novartis was not including the branded Galvus in the program (pg 63) due to the portfolio's basis on the World Health Organization's Essential Medicines List. Indeed, it would be very easy and still helpful of Novartis to include only generic medicine for diabetes, and we are glad to see valuable branded products like Galvus included as well. That's clearly not all they need but it could be a great start for newly diagnosed patients that benefit from the Novartis Access work on the diagnostic front. We don't know much about the scale yet, but "confronting the global spread of chronic disease" is the ambitious goal of the new initiative and we were very pleased to see diabetes as one of four areas of focus. See the video on the site that opens with the news that diabetes in Vietnam has tripled in the last decade - indeed, this work seems very ambitious and we're excited to point this out as a very interesting public/private partnership model to follow. We applaud Novartis for taking the initiative to acknowledge and act upon what its annual report calls a "double disease burden," (pg 62) as countries need new ways to detect chronic disease and provide long-term treatment, in contrast to the challenges of infectious diseases.

- **As we reported earlier, Novartis plans to expand the program to 30 countries in the coming years and the initial countries are Vietnam, Kenya, and Ethiopia** - these geographies all have a strong Novartis presence, an existing infrastructure and/or substantial partnerships with NGOs according to the company. They'll seek to build the program to increase awareness of key NCDs and strengthening systems capabilities, including diagnosis and treatment - a key strategy to sustaining the progress the program can make. We'll be watching this closely - the potential return on investment is very high.

HONORABLE MENTION

- **We were also impressed to see the annual report feature a photo essay on obesity.** Overall, there's a vivid series of photo essays (of which obesity is one) beginning with the cover of the report, which is one of the most visually stunning we've seen in 20 years of looking at annual reports (closely!). Specifically, the report highlighted an obesity program from Michigan's Dr. Amy Rothberg (pg 75) - although Novartis is not working on obesity that we know of, the visibility is welcome, as was learning that Dr. Rothberg is one of the first in the nation to receive certification in obesity medicine from the American Board of Obesity Medicine. Though skeptics may say that Novartis is implying it is working on obesity without really doing so, we welcome the attention given to Dr. Rothberg and her program.

QUESTIONS AND ANSWERS

Q: Regarding Alcon and the business plan that you outlined in terms of investing in the current product, what happens if the business doesn't turn around by midyear? You've given us a very clear target that it should turn around so we'd love to hear just your thoughts on maybe your plan B there.

A: In terms of the Alcon turnaround, obviously, we're executing now. We don't expect to see the turn until mid-year. We then expect to see improvement, and as I said, exit the year with low- to mid-single digit growth. And your question was, what happens if that doesn't happen? And we are right now totally focused on executing that because the plan that I've seen is credible. If we execute it, we should turn it and then if we don't - if we're not able to turn it, then we obviously have to step back and ask why. But we've got a year to look, and we're going to execute. And then in the fall and as we build the plan for 2017, we're going to evaluate where we are.

Q: This may sound a little bit unfair but over the last few years, we've kind of moved from crisis to crisis in terms of the consumer business falling below expectations. Now, Alcon is falling below expectations. Can you help us better understand where and when investors should have conviction that the business is really going to be on the right path, on a sustainable basis.

A: So, I think as we move through 2016 and exit 2016, I believe we will put Alcon on a more, let's say, stable base where we've got predictability, where we've got maybe not scintillating double-digit growth, but growth that we can rely on and count on, sustainable growth. But in the pharma business - it also has that kind of predictability and sustainability. I think by definition, the generics business is going to continue to be volatile. We saw that in the fourth quarter.

Q: On Alcon, perhaps give us some feel for the size or scale of M&A that you consider to build a pipeline at Alcon.

A: These are all relatively small deals. Because now that we focus the division on surgical and medical devices, they are mainly small companies with interesting new technologies that we could click in. But you're looking at relatively small up-fronts significantly below $1 billion. But those are the kinds of things that we think we'll be able to bring in and click right in and move into a period where we could launch in 2017 and start to impact 2017, 2018, and 2019.

Q: My question relates to M&A and particularly for Alcon. I understand that it will be essentially made of bolt-on acquisitions for new technologies, but is there a tradeoff between the pharma M&A and the M&A for Alcon?

A: We look very, very hard at how we're going to spend our capital spend across the different businesses, and we have the same hurdles for each of the businesses around what it's going to take to get capital allocated from the group. Now again, what we're talking about at Alcon are relatively small transactions where you might have $100 million or $200 million or maybe $300 million upfront with milestones after that. And we've all seen the impact of being able to show steady and consistent sales growth and earnings growth. So, there is something to be said in terms of how investors would reward small bolt-on acquisitions in Alcon and in that surgical business. And that's why that's still on the list.

Q: On ophthalmology pharmaceuticals, how could you reenergize this business knowing that it is quite difficult to innovate and you're suffering from generics, and recently it is not growing? Could you envisage any inorganic growth?

A: We actually see a number of opportunities to develop products faster than were possible before given the depth of the pharma development organization. I mean, in particular, there are three opportunities. One is to do additional lifecycle management in some of the existing brands. Ophthalmologists sometimes want versions of the product that are single-use, preservative-free, etc. Second, in the area of retina, we now have an opportunity to put together, in a more seamless way, a program that developed both Fovista, RTH, and Lucentis in a way that will be more powerful and more impactful. So, essentially, we hope to bring innovation forward.

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