Closer Look

MEMORANDUM

BMS 4Q13 Quick Take - Final full quarter of sales for diabetes products; low to moderate growth for all diabetes products - January 27, 2014

Executive Highlights

- Worldwide Onglyza franchise sales grew 13% YOY in 4Q13 (the franchise's lowest quarterly growth to date though from a higher base); FY 2013 Onglyza franchise sales rose 24% to $877 million - so nearly hitting a billion dollars but not quite!
- Forxiga 4Q13 sales totaled $8 million, up from $7 million in 3Q13. FY 2013 Forxiga sales totaled $23 million. The drug's US approval in January should help boost future sales.
- Exenatide franchise sales grew 3% sequentially to $198 million.

BMS reported 4Q13 and 2013 financial results in a call led by CEO Lamberto Andreotti on Friday, January 24. Comments on diabetes were sparse, save for a reminder that BMS' divestiture of its diabetes business to AstraZeneca is expected to complete in 1Q14. Diabetes revenue totaled $430 million in 4Q13 and $1.6 billion in 2013, up 15% (on a very challenging comparison) and 64%, respectively. Notably, DPP-4 inhibitor sales experienced weaker growth globally for the year, up just 24% compared to 50% growth in 2012. By contrast, growth picked up for Bydureon, whose sales more than doubled to nearly $300 million (the sales are hard to calculate exactly due to the sale to BMS/AZ by Amylin/Lilly) - Byetta sales were weaker, as expected. Meanwhile SGLT-2 inhibitor Forxiga continued slow in the EU, depressed by ongoing access issues - total global sales hit $8 million for 4Q13 and $23 million for the year. In Q&A, management admitted that diabetes was a low gross margin business and forecast that its gross margin would improve after selling its diabetes business.

1. This is the last time that BMS will report a full quarter of revenue for diabetes products, as it expects that the divestiture of its diabetes business to AstraZeneca will close in 1Q14.

2. Growth for the Onglyza franchise continued to slow: 4Q13 worldwide Onglyza franchise sales grew 13% year-over-year (YOY) to $224 million, its lowest quarterly YOY growth to date. For the full year of 2013, worldwide Onglyza franchise sales rose 24% to $877 million, also its lowest full-year growth to date.

- **As in previous quarters, international growth has outpaced US growth for the Onglyza franchise, especially with Kombiglyze.** In 4Q13, the Onglyza franchise grew only 4% in the US (to $146 million), while for the full-year 2013, the franchise grew 15% to $591 million domestically. Internationally, the franchise grew 34% to $78 million in 4Q13, driven by 367% Kombiglyze growth (revenue totaling $14 million). For the full-year 2013, the Onglyza franchise grew 48% outside the US to $286 million, driven by a ten-fold rise in Kombiglyze sales (revenue totaling $44 million).

3. Forxiga revenue remains slow to rise. Sales in 4Q13 totaled $8 million, up from $7 million in 3Q13, $5 million in 2Q13, and $3 million in 1Q13 (which was its first full quarter on the market). The European market has not been kind to SGLT-2 inhibitors due to tough reimbursement measures - for example, BMS/AZ withdrew Forxiga from Germany in December after failing to reach a price agreement with the German Federal Joint Committee (G-BA). We expect that with the drug's recent approval in the US (under the trade name Farxiga), sales should pick up significantly (we learned during J&J's 4Q13 call that Invokana achieved sales between $45-75 million in its third full quarter on the US market). The European approval of Xigduo (Forxiga/metformin fixed-dose combination) as the first SGLT-2/metformin FDC may also help to boost future sales in Europe.

4. Worldwide GLP-1 exenatide franchise sales grew 3% sequentially to $198 million in 4Q13, with Bydureon growth (finally coming on stronger!) offset by a Byetta decline. Sequentially, worldwide Bydureon sales grew 7% to $93 million (up 11% in the US and down 14% OUS), and worldwide Byetta sales fell 1% to $105 million (down 8% in the US and up 17% OUS). In 2013, BMS' worldwide revenue for Bydureon reached $298 million, and worldwide 2013 revenue for Byetta reached $400 million.

- **Reliable YOY comparisons can only be made for US sales of Bydureon and Byetta because OUS exenatide rights only finished transitioning from Lilly to BMS on April 1, 2013.** In 4Q13, US Bydureon sales grew a fairly strong 47% YOY to $81 million, while US Byetta sales fell 24% YOY to $70 million.
- **We expect the introduction of the Bydureon dual-chambered pen to improve Bydureon performance but don't know how significantly yet!** We learned at Day #2 of this year's JP Morgan Healthcare Conference that the long-awaited dual-chambered pen is under regulatory review in the US and EU - the device should dramatically improve the convenience factor for patients, as the currently available formulation requires reconstitution - we look forward to test driving it with our type 2 friends. A US decision is expected in 2Q14 and a European decision in 4Q14.

5. No pipeline updates were provided during the call, unsurprisingly, and the company's online pipeline has not been updated since June 2013. As a reminder, in December, an FDA Advisory Committee voted 11-1 in favor of approval for BMS' leptin analog metreleptin, indicated for generalized lipodystrophy. At the time of BMS' 2Q13 financial update in July 2013, the company's cardiometabolic pipeline also included:

- a PEG-FGF21;
- an 11-beta-HSD inhibitor;
- a GPR119 agonist
- a GPR40 agonist, and
- a phase 1 PCSK9 adnectin (a PCSK9 inhibitor) in "exploratory development" (discovery through phase 2).

As of June 2013, the pipeline lists only the PEG-FGF21 (phase 1) and PCSK9 adnectin (phase 1) in addition to the phase 1 and phase 2 CCR2/5 agonist candidates. We are unsure if the candidates that were cleared from BMS' pipeline have been terminated or if AZ will be taking over development.

Questions and Answers

Q: What will your gross margins look like in the post-diabetes world?

A: Gross margin is always dependent on product mix, and as you will recall, the diabetes business was a relatively low gross margin business because we paid a share of margin through the cost of goods line to AZ. So we expect our 2014 gross margin rate to benefit going forward, and how much will depend on the time of closing. I would imagine it would be in the neighborhood of slightly above 75%.

-- by Jessica Dong, Manu Venkat, and Kelly Close