

Thursday, May 9, 2013 from 2:30pm to 3:40pm

Michihiro Tsuchiya, President & Representative Director, CEO

<u>Kenichi Yanagisawa.</u> Board Director and Senior Managing Executive Officer, Division Manager of Sales & Marketing Division

<u>Kenkichi Kosakai</u>, Board Director and Managing Executive Officer, Corporate Management <u>Masayuki Mitsuka</u>, Board Director and Managing Executive Officer, Division Manager of Development Division

[Business Results for FY2012]

<u> PL</u>

- Q. Why did sales in domestic ethical drug sales in FY2012 underperform your estim forecasts?
- A. The main factor was an impact of the generics. The market share of generics for our long-term listed drugs, including Radicut, expanded further than we expected. Moreover, although sales of new products launched in these two years are steadily growing, their growths have been lower than we estimated.
- Q. In FY2012, although "licensing fee, etc." exceeded the estimate (+¥7.2 billion) and SG&A costs were lower than expected (-¥4.2 billion), operating income fell short of the target by ¥1.0 billion. What is the reason aside from the shortfall in the domestic ethical drug sales (-¥12.4 billion)?
- A. Because we had factored some reduction in purchasing prices at the start of FY2012; it is not likely to be seen until FY2013 or sometime thereafter. It is one of the reason.

Remicade

- Q. Pfizer's oral rheumatoid arthritis drug, Xeljanz, has been approved in Japan and expected to be launched soon. What do you see its impact on Remicade and Simponi sales?
- A. We understand the Japan College of Rheumatology submitted the request to Pfizer and Pfizer gave the response to it. It suggests that all-patients post-marketing surveillance which is the same high level as for biologics should be required. We anticipate the products will be used very carefully. In light of this, at this stage, we do not believe it will have a major impact on Remicade and Simponi sales.
- Q. Johnson & Johnson's 1Q FY2013 Form 10-Q indicated that the company reviewed

- the supply price for Remicade in February 2013, and an arbitration panel has given its ruling. What is the status of this?
- A. It is true that the arbitration panel did rule on the issue, Remicade's supply price. At present, based on the panel's decision, Johnson & Johnson is discussing how it will respond. At the moment there is nothing further we can say on this matter.

[FY2013 earnings estimates]

PL

- Q. In FY2013 sales estimates for the domestic ethical drugs, can you explain why you estimate a sales decline in 1st half but an increase in 2nd half?
- A. We have factored in an increase in prescriptions for Tenelia from September when a long-term prescription is approved. In addition, new products sales will grow more in 2nd half than 1st half.
- Q. How many MRs do you have?
- A. In Japan, we have around 1,800 MRs, including 500 general MRs and area-specialist MRs. Also, there are roughly 300 MRs in total at our group companies Yoshitomi Yakuhin and Tanabe Seiyaku Hanbai.
- Q. The ethical drug market condition is getting tough. Are you planning to implement radical measures, such as a review of your MRs' system or a reduction in headcount?
- A. Given the extensive number of products we handle, we have implemented a system in which our MRs' resources focus on priority products. At present, we have 1,500 general MRs, which we believe to be a reasonable number. Meanwhile, the MRs who have deep levels of knowledge in specialized fields are required. In addition to the general MRs, we have positioned area-specialist MRs. Also, in the area of long-term listed drugs, we are taking measures to sustain the prescription levels by utilizing multiple channels to provide information to medical professionals and build relations.
- Q. What progress are you making in the review of the number of products in your products lineups?
- A. Since the company's merger, we have recognized that the reduction of the number of products is an essential and have been tackling this issue. However, we will require time to reorganize them, mainly as we will have to go through a number of procedures and will require coordination with related parties. In some cases, we ultimately may not obtain the consent of our business partners.

Foreign exchange impact

- Q. What is the foreign exchange impact to the Company?
- A. The impact is minimal. Because the increase in royalty income from overseas is offset by an increase in costs, mainly for purchasing merchandise. At this stage, we estimate a ¥1 decline in the yen's value vs. the US dollar triggers a decline of ¥100 million in operating income.

Personnel costs

- Q. Can you explain why you anticipate a 7.3% decline in total personnel costs despite plans to increase group headcount by 275 people in FY2013?
- A. The planned increase in the total number of group employees reflects a rise in headcount at our overseas subsidiary in Asia and the conversion of temporary staff into full-time employees in Japan. Meanwhile, the planned reduction in personnel costs reflects a decrease in 1st half spending owing to the October 2012 transfer of the plasma fractionation operations to Japan Blood Products Organization, a reduction in retirement costs, and a return by our overseas subsidiaries to a 12-month fiscal year in FY2013 (FY2012 was an irregular 15-month fiscal year due to a change in fiscal periods). This cost reduction sharply overshadows the rise in headcount.

Radicut

- Q. In FY2013, Radicut sales are forecast to sharply decline by 26% year-on-year. What is your outlook?
- A. In March 2013, the market share for generics of Radicut was over 35% on a volume basis. In FY2013, we forecast the generics will expand their share due to the government's measures to promote generics use. Ultimately, we predict the generics' share will expand to around 40%.

Gilenya (licensed out to Novartis)

- Q. A competitor (Tecfidera, an oral medication to treat multiple sclerosis) was released in the US. What impact do you think this will have on Gilenya?
- A. The US multiple sclerosis drug market, which is led by Copaxone, is a very large market. Gilenya's efficacy and advantage as an oral medication are being promoted and it is gaining market share. We anticipate the drug will continue to win market share despite the introduction of a competitive product.

INVOKANATM (licensed out to Janssen Pharmaceuticals)

- Q. What is the current status of sales for INVOKANA™ (TA-7284) in the US?
- A. According to Janssen Pharmaceuticals, US sales of INVOKANATM are off to a smooth start since hospitals began prescribing the drug in the first week of April 2013. Moreover, according to reports, the number of prescriptions is growing at a rapid pace, in contrast with the earlier launch of the DPP-4 inhibitors. INVOKANATM is building up a high level of expectation in the US medical community as an oral glucose lowering drug that is effective in reducing body weight and which has a low risk of hypoglycemia.

[Medium-term management plan]

- Q. FY2013 earnings forecasts look to be off target based on the goals you have set for FY2015, which is the final fiscal year of your current medium-term management plan. Are you planning to revise the goals in the plan? Also, SG&A cost control is an essential element in achieving your goals but is there still leeway for cost reduction?
- A. At this stage, we remain committed to accomplishing the FY2015 goals in our medium-term management plan. Excluding special factors such as the transfer of our fine chemical business, the dissolution of our alliance with Choseido Pharmaceutical, and the review of accounting procedures, we expect sales, after adjustment for these special items, to grow nearly ¥20.0 billion in FY2013 year-on-year. This is basically in line with the growth we forecast in the plan. However, there is a gap between recent sales trends for long-term listed drugs and the goals in the plan. We plan to offset this gap by developing new product sales, sustaining earnings from long-term listed drugs, and by making adjustments to achieve a reasonable cost structure. To accomplish the cost structure, we plan to reduce our SG&A costs, which includes a far-reaching review of our administrative outlays.

[Development pipeline]

TA-7284 (Type 2 diabetes)

- Q. When will a market authorization application for TA-7284, SGLT2 inhibitor, be filed in Japan?
- A. Currently, we are preparing for filing. It should be submitted soon.
- Q. Is hypoglycemia a potential side effect of TA-7284?
- A. Based on mechanism of action and clinical data, we believe SGLT2 inhibitors are a class of drug with a low risk of hypoglycemia.

MT-1303 (multiple sclerosis)

- Q. Will MT-1303 potentially have fewer side effects than Gilenya (bradycardia or slow heart rate at the first administration)?
- A. We are developing MT-1303 with the expectation that it will have fewer side effects than Gilenya. At this stage, we have not obtained the data that is of concern.
- Q. Can you tell us if the drug is being developed for other indications than multiple sclerosis?
- A. We are preparing clinical trials to obtain Proof of Concept (POC) for several other autoimmune diseases.