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Otsuka Holdings Co., Ltd.

Financial Results FY2013

(Year Ending March 31, 2014)

Q&A

May 14, 2014

Q1: What is the development status of Samsca for autosomal dominant polycystic kidney disease (ADPKD) in the U.S. and the reason sales growth is projected for fiscal 2014? Do the sales forecasts include ADPKD sales in Japan and Europe?

A1: We are in final discussions with the FDA regarding the trial protocol on the assumption of implementing an additional Phase III trial for the U.S. The projections for fiscal 2014 include sales for ADPKD in Japan. We submitted the application for ADPKD in Europe in December 2013, so it is not included in the projections.

Q2: Could you explain the fiscal 2013 results and the fiscal 2014 projections for Abilify Maintena in the U.S. and Europe, as well as the impact of the U.S. guidance on recommending depot?

A2: We've launched Abilify Maintena in three European countries as of March 2014, with plans for a gradual roll out in other countries. We are not yet at the stage of being able to release sales figures, but prescriptions have been steady. Fiscal 2013 sales in the U.S. were less than ¥10.0 billion, and projections for fiscal 2014 exceed that mark. We believe that the guidance in the U.S. will be a boost, but results will depend to a large extent on patient awareness.

Q3: Development of aripiprazole lauroxil by Alkermes plc has advanced, and how do you view the impact from this?

A3: Alkermes plc is the company that originally has manufactured and supplied Risperdal Consta and Invega Sustenna. Alkermes' selection of aripiprazole as main composition for their proprietary product shows their recognition of the compound's potential. Our outlook for their product launch timing differs from their plans. We believe that the increase in the number of products in the depot injection market will have the benefit of increasing patient awareness. We need to accelerate our U.S. sales of Abilify Maintena a little more. However, Johnson & Johnson has struggled to create a market to date, so we understand that it will not be easy. We understand that awareness and acceptance of depot injections a re higher in Europe than in the U.S.

Q4: Can Brexpiprazole, Abilify Maintena and smart tablets entirely resolve problems associated with the treatment adherence of patients in the central nervous system field?

A4: One must understand the patient's background. Existing treatments are effective for patients who can understand the significance of the treatment. Depot injection is an option for patients with a lower comprehension of the importance of adherence, and smart tablets are another solution. Treatment adherence is a fundamental but extremely important issue, and we will continue taking initiative in this area going forward.

Q5: What is the progress of the Astex merger? Has it produced any positive feedback for Otsuka Pharmaceutical and Taiho Pharmaceutical?

A5: Not one of the just under 70 researchers has resigned at present. We understand that this is the result of clearly communicating Otsuka's expectations and approach at the acquisition stage. Communications with researchers in Japan are now commencing. We hope that this will produce results in a number of forms in the future.

Q6: What will be the scale of R&D expenses and SG&A expenses in fiscal 2015? Will you continue to invest at the current level in the future?

A6: At present, R&D expenses are expanding, which is partly attributable to the research and development being brought forward ahead of the Abilify patent expiry and to expenditure on up-front payment under the co-promotion agreement for TAK-438 with Takeda Pharmaceutical. However, we will prioritize investments even more carefully in fiscal 2015 and beyond. For the central nervous system, we will continue to actively address Alzheimer's Disease and issues around treatment adherence. In oncology, we are considering the potential for additional indications for TAS-102. Of the product pipeline we obtained through the Astex acquisition, SGI-110 is currently completing Phase II. We have begun to consider our order of priorities and resource allocations, and we plan to discuss the details when we release our Second Medium-Term Management Plan.

Q7: We hear that you plan to file for colorectal cancer indication for TAS-102 in the U.S. during 2014, but could you tell us about your plans for filing in Europe and for additional indications?

A7: We consider the U.S. to be our top priority for the colorectal cancer filing. We do plan to submit an application in Europe, as well. We are considering additional indications. We know that an investigator-initiated clinical trial focusing on gastric cancer is being conducted.

Q8: What were the milestone payments from Lundbeck in fiscal 2013, and what are the forecasts for fiscal 2014?

A8: The milestone payments were between ¥14.0 billion and ¥15.0 billion in fiscal 2013. We forecast around a similar amount in the nine months for fiscal 2014.

Q9: What was the level of anticipatory demand ahead of the 2014 drug price revisions like?

A9: We estimate it to be about ¥3.0 billion, mainly for products with a premium to promote the development of new drugs.