Otsuka
Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd.

Financial Results Presentation Q3 FY2013

(Nine Months Ending December 31, 2013)

Q&A

February 13, 2014

Q1: What is the development status of tolvaptan for autosomal dominant polycystic kidney disease (ADPKD) in the U.S.?

A1: We are in discussion with the FDA, and there has been no conclusion as yet.

Q2: What is the sales promotion situation for Abilify Maintena in the U.S.?

A2: According to IMS data, cumulative March through December sales for Abilify Maintena were US$44 million, although the capture rate of sales is about 70 – 80% as it only covers retail sales. After the March 2013 launch, sales were steady until July, and we stepped up sales promotion in October 2013 as we had fallen behind our competitors on promotional campaigns. It will take a bit of time for the results of the stronger sales promotion to appear. Sales were in line with initial projections, but did not achieve our upwardly revised in-house projections.

Q3: Is there fierce competition in the U.S. depot injection market?

A3: Since Risperdal Consta's launch in 2003, together with Invega Sustenna, J&J has practically dominated the depot injection market. J&J is currently running a sales promotion campaign using free samples to actively encourage the switch from Risperdal Consta to Invega Sustenna. We are entering the depot injection market, which J&J has built up over the years.

Otsuka
Otsuka-people creating new products for better health worldwide

Q4: Cumulative results for 3Q fiscal 2013 exceeded projections, and this trend will continue for the full year. However, is it correct that the company will not revise the full-year forecast up, partly due to costs, the fluctuating exchange rate and other factors?

A4: Results may be somewhat better than expected. However, we have not revised our projections because the cost of co-promotion for Abilify will be increased in 4Q fiscal 2013 due to the impact of different settlement dates in accounting for overseas subsidiaries, and research and development expenses could be higher than expected.

Q5: Is there a strong possibility that negotiations on licensing and other areas could affect costs in 4Q fiscal 2013?

A5: I cannot disclose any details concerning licensing and other areas, but we are considering a number of perspectives.

Q6: Will fiscal 2014 forecast sales for Abilify be around US$4,800 million due to factors that include price increases? Also, what was the inventory status for Abilify at the end of 2013?

A6: We plan to release next year's sales forecasts with the results for the current fiscal year in May 2014. We believe there was no excess year-end inventory.

Q7: With regard to brexpiprazole, what is your timeframe for presentations of the phase 3 trials results for major depressive disorder (MDD) and for schizophrenia respectively, and what is your timeframe for the NDA submission in the U.S.?

A7: The NDA in U.S. is scheduled for 2014. We plan to present the data at scientific conferences at they become available.

Q8: In accounting for the Astex acquisition, which assets account for significant percentages in the breakdown of the ¥56.2 billion in intangible fixed assets?

A8: Dacogen, in-process R&D and the pipeline in collaboration with other companies combined came to ¥56.2 billion. We are not disclosing further details.

Q9: Is it possible that you will conduct long-term administration trials for SPRYCEL?

A9: With regard to SPRYCEL, BMS has been primarily involved in its development, and we have been promoting in collaboration. We have not received any information on new trials at the present stage.

Q10: Will there be any global expansion for Pletal?

A10: Pletal is sold across Europe, the U.S. and Asia, but its patent has expired. We have no plans for any further global expansion in future.

Q11: What is the review status for TAS-102, and what is the timeline for its launch?

A11: We submitted an application in February 2013, and we are waiting for response from the authority. With regard to the launch timeline, we plan to release it during 2014 if it is approved.

Q12: You are conducting three Phase 3 trials for Lu AE58054. Are these all?

A12: We plan to implement a total of four Phase 3 trials, including the trials that have been announced already.

Q13: How much do the milestone payments from Lundbeck total? How much have you forecast for the nine months of the shortened fiscal 2014?

A13: The cumulative through 3Q fiscal 2013 was just under ¥12 billion. Approximately ¥15 billion for fiscal 2013 is in line with projections. It is fair to think that the amount in fiscal 2014 will be about the same as in fiscal 2013.

Q14: On page 6 of the Financial Results Presentation material, Other Expenses in the pharmaceutical segment increased ¥36.6 billion, or ¥12.0 billion a quarter. Will it increase at the same pace in 4Q fiscal 2013? Also, what is the forecast for next year?

A14: Other expenses will increase at the same pace in 4Q as in 3Q fiscal 2013. We expect there will not be any large increases next year as our expansion of personnel is almost complete.

Q15: According to a previous release from Astex, Phase 3 trials for SGI-110 will start in 2014. Have there been any changes to the plans?

A15: Interim data for Phase 2 trials on SGI-110 has been presented. We plan to start the Phase 3 trials if the Phase 2 trials are complete.

Q16: According to ClinicalTrials.gov, the Phase 2 trials of AT7519 for multiple myeloma finished in 2013. What is the current status of the trials?

A16: We are waiting for the results to come out.

Q17: What are your thoughts on research and development expenses for the nine months of the shortened fiscal 2014?

A17: We plan to announce projections for next year in May, so we will not disclose them at the present time.

Q18: Is it correct that the European application for brexpiprazole will be in 2015 because it is necessary to look at the recurrence data?

A18: We are implementing active comparator trial for the European application, so it will be later than the U.S. application.

Q19: What is your launch plan of Abilify Maintena in European countries? What is the status of the European Abilify Maintena situation?

A19: After the U.K. launch at the end of January 2014, we plan to launch sequentially following approval for sale in each country.

Q20: Will Abilify Maintena be sold mainly by Lundbeck in Europe?

A20: We will co-promote it in the five main countries as well as Nordic countries, and for other European countries, Lundbeck will be in charge.

Q21: Is it correct that Acucela has development rights for OPA-6566?

A21: OPA-6566 is a compound discovered and developed by Otsuka, and Acucela is co-developing it with us.