Otsuka Holdings Co., Ltd.

Financial Results Presentation Q1 FY2012

(Three Months Ending June 30, 2012)

Q&A

August 9, 2012

Otsuka
Otsuka-people creating new products for better health worldwide

Q1: What is the future schedule for U.S. approval of Abilify IM depot?

A1: A meeting with the FDA is scheduled in August to discuss the course of action, including alternative plans. As we have not yet met with the FDA, the future schedule is not clear. As soon as we know it, we will disclose it.

Q2: The agreement provides for a milestone payment from Lundbeck on the approval of Abilify IM depot, and is there a chance that the payment might not be received this fiscal year if approval is delayed?

A2: It may be delayed if the approval is not granted during the current fiscal year.

Q3: What were the negative factors for progress on R&D expenses in 1Q, and will there be any changes to the full-year forecasts?

A3: The negative factors for progress in 1Q were the persistently strong yen and the outcome of certain project reviews (we decided to out-license Cimzia and Saxagliptin). For the full fiscal year, there are no changes to projections, as IM depot Phase III trials for schizophrenia in Japan and Europe and OPC-34712 Phase III trials for schizophrenia and major depression are underway, and global trials for TAS-102 and IM depot Phase III trials for bipolar disorder are scheduled to commence in the current fiscal year.

Q4: 1Q business results in the nutraceutical business were poor. Could you explain the recovery plan?

A4: This fiscal year's 1Q results seem poor by comparison because the extremely hot weather from the end of June through July in Japan last year created extraordinary demand in the previous fiscal year. The current sales for April – June are in line with sales in a regular year. This fiscal year, it has been hot since the end of July, so we are undertaking business in order to attain the full year projections.

Q5: What are the latest trends for Abilify sales, including the impact of generics?

A5: In terms of prescriptions for January to June, the U.S. market for atypical antipsychotics rose 1.8%, whereas Abilify was up 1.9%, outperforming the market, albeit slightly. The impact of generics has been visible gradually among new patients since this March. With regard to the sales, we have explained the problems with inventory and PBMs in the previous fiscal year. The main reason was trade inventory and overstocking at pharmacies. This was resolved in May, and things returned to normal in June and July. According to IMS statistics, the U.S. market for atypical antipsychotics declined 16.7% from January to June, whereas Abilify increased 8.9%.

Q6: How much did you receive in milestone payments from Lundback in 1Q? Can you give the amount and a breakdown?

A6: The total of the lump sum and milestone payments was about ¥5 billion with a ratio of around 4:1. The milestone payment was for uploading of data regarding OPC-34712.

Q7: In the alliance with Kyowa Hakko Kirin in the oncology domain, is there any possibility of an alliance outside of the Asian region?

A7: For the present, it is focused on the Asian region only (as we announced before).

Q8: What is the concrete schedule for the oncology alliance with Kyowa Hakko Kirin?

A8: The schedule is under negotiation, and we will disclose it as soon as it becomes definite.

Q9: The ¥2.1 billion increase in other SG&A expenses in the pharmaceutical business was due to personnel expenses for IM depot sales. Will this amount be incurred in the future?

A9: We are working on this steadily. The amount is not so big, but it will also be incurred in 2Q (July – September) and beyond.

Q10: What have conditions for Pocari Sweat sales been like in July?

A10: I am not able to give you any concrete details, but sales have been down slightly compared with the previous fiscal year. We believe that sales will rise if the current hot weather continues in August and beyond.

Q11: What was the US$200 million paid to Otsuka in Lundbeck's announcement of business results?

A11: It is the lump sum on the agreement, which Otsuka records in proportional allocation for the contract period.

Q12: Is it correct that the amount to be received from Lundbeck during the current fiscal year will be US$100 million respectively for the current fiscal year's portion of the lump sum in the agreement, the milestone payment in the development of OPC-34712 and the milestone payment for the approval of IM depot?

A12: Those estimates are largely correct.

Q13: What is the FDA's position on the IM depot review?

A13: As we are going to meet with the FDA this month, we are not able to discuss the details at present. We can say, however, that we know there are no problems concerning Abilify IM depot.

Q14: What level of interest does Otsuka have in Lundbeck's compound for Alzheimer's disease?

A14: I have no comment on whether we are evaluating the compounds or not.

Q15: Does Otsuka have the first refusal right to Lundbeck's compound for Alzheimer's disease?

A15: The details of Lundbeck's agreement with the licensor of the compound need to be confirmed, and I think we should make a decision after that.

Q16: What is the reason for the decline in profit in the consumer segment?

A16: The main reason for the decline in profit is the fall in sales of mineral water which has a high gross margin.

Q17: Will Otsuka cancel shares purchased in buybacks?

A17: We have not yet made any decisions, including on whether to cancel shares or not.

Q18: Will there be any changes to the annual projections for Abilify sales?

A18: Sales are in line with our projections.

Q19: We hear that the evaluation will be made at six months in the Delamanid global trial, so when will the results come out?

A19: In Europe, we filed an MAA at the end of last year, but are conducting the Phase III trial at the same time. The Phase III trial is scheduled to be completed in September 2015.

Q20: Is the Phase III trial currently underway for filing in the U.S.? If so, could it be terminated prematurely depending on the circumstances?

A20: We will carry out the Phase III trial to the end.

Q21: What is the filing schedule for Abilify IM depot in Europe? According to Lundbeck, it will be earlier than previously expected.

A21: The trials finished this March, so we plan to file during the current fiscal year. We will be discussing the schedule with Lundbeck.

Q22: What is the schedule of milestone payments for Abilify IM depot in Europe?

A22: The milestone payment is US$75 million on approval for schizophrenia. There is no milestone payment on submission.

Q23: What is the reason for the growth of Abilify sales in Japan?

A23: It has grown due to the additional indication of bipolar disorder which was approved in January 2012. Only Zyprexa and Abilify have this indication in Japan.

Q24: What type of tumor is TS-1 mainly used for?

A24: It is mainly used for gastric cancer.

Q25: When TAS-102 is approved in the U.S., who will market the product??

A25: The plan is for Taiho Pharmaceuticals to market the drug, and for that, steady preparations are now underway.

Q26: Is the right to ACU-4429 only for the U.S. and when will the Phase III trials start?

A26: The rights are for Japan and the U.S. The trials will take longer time because suppression of the disease progression must be evaluated, but Phase III should finish before 2020.

Q27: To sum up 1Q, what is your evaluation of the projections? Were projections on target, or were there any miscalculations?

A27: Although the pharmaceutical business made steady progress, the nutraceutical and consumer businesses were behind projections. These segments are strongly affected by weather, so one cannot make a judgment based on 1Q alone. We would like to have a look at the half or full year figures.

Q28: It seems that the beverage market overall was not positive in July. Was this true for Pocari Sweat as well?

A28: For the Otsuka Group, overall beverage sales, on a volume base, were at 78% of the previous year for the month of July and at 82% of the previous fiscal year total through July.