

Otsuka Holdings Co., Ltd.

Financial Results Presentation Q2 FY2011 (Fiscal Year Ending March 31, 2012)

Q&A

November 11, 2011
Tokyo, Japan

Q1: Will Otsuka have to make a payment for the compounds that will be coming from Lundbeck in the future?

A1: Yes, that is correct.

Q2: The financial terms of this agreement have milestone payments being made to Otsuka in the short term, but eventually both companies will equally share profits. Will this result in an increase in overall profits? Considering Lundbeck's sales force, are you not concerned that total sales will shrink, resulting in a decrease in profits?

A2: We have given thorough consideration to this matter and chose to partner with Lundbeck rather than go it alone in order to maximize product values.

Q3: Will this agreement decrease Otsuka's burden of R&D expenses for OPC-34712, which is now in Phase III trials?

A3: Yes, that is correct. It means that we will be able to attempt to raise the drug's potential to the maximum.

Q4: Has a clear difference in efficacy against negative symptoms been shown with OPC-34712, compared to ABILIFY?

A4: No, the difference is not statistically significant.

Q5: Will comparative data with ABILIFY be required for filing of OPC-34712? Or will the placebo-controlled study data suffice?

A5: We believe we can use the data of placebo-controlled study.

Q6: When will the aripiprazole intramuscular depot application be submitted?

A6: We will inform you of our filing once the FDA accepts the application, so, at the moment, we are in a filing process.

Q7: Why did you conclude this agreement with Lundbeck, not Bristol-Myers Squibb?

A7: Bristol-Myers Squibb's strategic focuses are now on oncology and immunology. When considering our long-term growth, we decided to partner with Lundbeck at this time, with whom we can share corporate strategies more effectively.

Q8: Will sales of ABILIFY continue to grow even in an environment marked by healthcare reform in the U.S., especially the expansion of Medicaid, and the lapse of patents of the competing products, Zyprexa and Seroquel?

A8: We think there should be no major impact of Zyprexa, since its drug characteristics are different, but there could be an impact of Seroquel. However, unlike drugs in other fields, in the central nervous system field, it is difficult to switch to other drugs. Abilify has been impacted by Medicaid since last year, but in terms of prescriptions, sales of ABILIFY grew at an annual rate of 5%, outweighing the market growth of 1.4%. We think the major effect of Medicaid seems to have completed for now.

Q9: Is the fact that the dose response of OPC-34712 has not been seen in the Phase II trial due to the small number of subjects? Will this become a problem if the same results are obtained in Phase III trials?

A9: We will verify that in our Phase III trials that are currently underway. In the Phase III trials, separations from placebo arm need to be shown.

Q10: What is the current situation of ABILIFY after generic version of Zyprexa was launched? Are there any states in the U.S. where insurance no longer available?

A10: The IMS cumulative data for 3rd quarters show sales growth of ABILIFY of 14.6% on a dollar terms whereas the market grew by 13.5%. In terms of prescriptions, ABILIFY was up 5% while overall market grew by 2.7%. Right now we are not aware of any states where insurance is no longer available.

Q11: Estimating and calculating the cost of goods manufactured in the nutraceuticals business, it seems that SG&A have not been cut so much. Has your plan remained unchanged from the previous approach of making a focused investment in growth areas and controlling expenditures rather than cutting costs?

A11: SG&A such as advertising expenses and sales promotion costs have decreased. We are considering the use of expenses while cutting costs. Of course we will increase sales, but at the same time we are checking promotion costs for each selected item.

Q12: So, you will secure the profitability of the nutraceuticals business?

A12: Not only the profitability. We think it also important to look at long-term growth potential, such as the extent to which core users will increase. Without such an understanding, it is not possible to think about how the expense should be used.

Q13: Could you tell us the side effects of OPC-34712 observed in the Phase II trials (for schizophrenia)?

A13: Compared with ABILIFY, more cases of weight gain were observed and incidence of akathisia was slightly higher in the highest dose group. Other than that, OPC-34712 is comparable to ABILIFY. At the moment details of the side effect profile are not known from this P-II trial because of the small number of patients.

Q14: Will you pursue bipolar disorder in the future as an indication of OPC-34712?

A14: Regarding future LCM, we will make decisions in consultation with Lundbeck.

Q15: Considering Lundbeck's sales force in the U.S., Otsuka will have to take the lead in sales efforts. Are you going to increase the number of MRs in the future?

A15: Naturally, we will have more MRs than the current number in the US. From our experience with ABILIFY, we know that the optimum number of MRs in the U.S. in the central nervous system field is a little less than 1,000. We have a two-step sales strategy in which Lundbeck will learn from us as we take the lead on marketing aripiprazole intramuscular depot. and then both companies will join forces on marketing OPC-34712 in the future.

Q16: When will this agreement expire?

A16: Basically at the end of the year when the exclusivity expires.

Q17: Cash will pile up again as a result of this agreement. How are you going to use the cash?

A17: It will be used to ensure medium/long-term growth.

Q18: Has the upfront payment of USD 200 million already been incorporated in the fiscal year forecasts?

A18: Yes, it has. The upfront payment will be booked proportionately over the current fiscal year and the next fiscal year.

Q19: Are the three compounds from Lundbeck in this agreement already decided on, or will they be selected later?

A19: They are not decided yet. Otsuka has the right to select Lundbeck's compounds in the central nervous system field when Phase IIb trials are completed.

Q20: Is there any possibility of dividend policy change in the next five years?

A20: At present, it is anticipated that the dividend policy will stay the same.