

Otsuka Holdings Co., Ltd.

Financial Results Presentation Q2 FY2012 (Six Months Ending September 30, 2012)

Q&A

November 13, 2012

Q1: Could you explain the failure to achieve operating income projections for the first half of the fiscal year in detail?

A1: Otsuka has not disclosed detailed figures regarding operating income forecasts for each business segment. The pharmaceutical business did not receive the U.S. approval milestone payment of Abilify IM Depot, but it outperformed forecasts as the yen was weaker than the projection and due to the strong sales of new products in Japan. The nutraceutical business fell short of forecasts because sales of functional beverages, such as Pocari Sweat, hit the wall. The consumer product and other businesses were largely in line with forecasts.

Q2: Is it correct to believe that full-year operating income will follow the same trends as in the first half of the year?

A2: In the pharmaceutical business, we expect that the milestone payment of US\$100 million from Lundbeck on approval of Abilify IM Depot will be carried over to the second half of the fiscal year, and there will be growth in Abilify due to the change of exchange rates projection. We foresee that the second half of the fiscal year will be on a par with last year in the nutraceutical business.

Q3: Could you discuss the details surrounding the resubmission to the FDA regarding the sterile water for Abilify IM Depot. I would also like to confirm whether there will be a problem with the next PDUFA date.

A3: Otsuka received a complete response letter from the FDA on July 26, and we discussed improvements and so on with the FDA in mid-August. As a result, we made a resubmission on August 30, and the PDUFA date is scheduled for February 28. We would like to discuss the details when we obtain approval.

Q4: In its financial results announcement last week, Lundbeck commented that it is increasing the number of patients involved in the OPC-34712 trial and will release the top-line data for the Phase III trial in the second half of next year. Could you describe the future schedule?

A4: We are bringing forward the development schedule to time it with the patent expiry of Abilify. We will complete the trials currently underway within the next year, and we hope to release the top-line data after that.

Q5: Does Otsuka have license rights for the Alzheimer's drug for which Lundbeck announced the results of Phase II trial in May?

A5: Eli Lilly originated the compound. Otsuka does not know whether Eli Lilly has its first refusal right for licensing.

Q6: Is the 8.7% ROE for the current fiscal year a target to work towards or a firm target? Also, if profit does rise, will you be considering returns to shareholders?

A6: We believe we can achieve the ROE target. We are always mindful of shareholder returns. At the same time, growth is crucial in enabling us to compete globally, and investment in growth is also important. We are advancing the development of OPC-34712 with a sense of urgency as one of the measures to address the Abilify patent expiry.

Q7: At the end of October there were reports that BMS is reducing the number of its medical representatives. What impact will this have on Abilify next fiscal year and beyond, including profit and loss?

A7: There has been no official press release from BMS, and there is no change to the current agreement. At the time we concluded the extended agreement in 2009, adjustments to the future marketing structure were included. This should be considered as a step in the establishment of our own marketing structure. In addition, there will be no negative impact on profit and loss including sales, promotion expenses and so on next fiscal year and beyond.

Q8: Approximately how much did payments from Lundbeck in the first half of the year come to?

A8: In the first half of the year, up-front payment and OPC-34712 development milestone payment came to approximately ¥8 billion.

Q9: At the announcement of financial results in May, Otsuka gave implementation of investment in growth as its strategy for fiscal 2012. Could you describe the progress of the strategy and the approach for the second half of the fiscal year?

A9: The strategies for fiscal 2012 include accelerating development of new drugs, building sales infrastructure in each area, and improving business profitability in each region. For example, we moved forward the filing for the major depressive disorder indication in Japan, and we also commenced bipolar disorder trials for Abilify IM Depot in the US. In the nutraceutical business, we began operations in Vietnam. While financial investment is easy to see, Otsuka also considers its alliance activities as investments in growth.

Q10: Other expenses in the pharmaceutical business rose ¥7.8 billion, standing at ¥2.1 billion in the first quarter and ¥5.7 billion in the second quarter, which is a significant increase. Will this continue in the future?

A10: We expect the figures to be at the same level in the second half of the year.

Q11: Operating income in the nutraceutical business was just over ¥1.0 billion in the second half of last year, which is a slim profit. Do you think that the 9% operating profit ratio target for the full year will be difficult to achieve?

A11: We think that it will be difficult to achieve 9%. Although profitability has risen overseas, it has become difficult to generate profits in Japan as deflation is coupled with intense price competition. Otsuka believes it is crucial to develop our products and boost the strength of our brand. Therefore, we do not adjust expenses to ensure operating income. We employ the necessary expenses for medium- and long-term growth with the hope of increasing the sales. We think that the nutraceutical business should secure 7% operating income ratio in the current fiscal year.

Q12: Recently I've heard that the European market for the Depot formulation is even bigger than the US market. Could you talk about Otsuka's view on this?

A12: Market trends, including usage, differ in the US and Europe. We believe it is correct that the demand for the Depot formulation in the market is relatively larger in Europe. The population is roughly the same in the US and Europe. However, the uptake of the Depot formulation of typical antipsychotics has been faster in Europe, so the market is familiar with the Depot formulation. In the US, Risperdal® Consta® has been tapping into the market since its launch in 2003. The market is currently growing at an annual rate of about 20%. The price is about three times higher in the US than in Europe, so there are more patients in Europe, but I think that sales are the same or slightly higher in the US. According to IMS data (2011), the two drugs Consta® and Sustenna® alone have built a market worth US\$860 million in the US, whereas the five leading European markets total €440 million. In Japan, the single drug Risperdal® Consta® has grown into a market worth ¥10billion.

Q13: Will the approximately 500 medical representatives to be laid off by BMS mostly transfer to Otsuka? What will be the scale of promotion ultimately?

A13: We do not disclose medical representative numbers for strategic reasons. We will be maintaining our total marketing capacity itself at the existing level.

Q14: Full-year forecasts for the pharmaceutical business have been revised upwards from the initial forecasts. Could you explain what accounts for the increase, apart from the upswing in Abilify due to the change of exchange rates projection?

A14: Apart from the upswing in Abilify, the reasons include the growth of new products in Japan.

Q15: What is the reason for the postponement of the R&D meeting, which had been scheduled for the end of November?

A15: We postponed it in order to ensure sufficient information can be presented.