

# Otsuka Holdings Co., Ltd.

## Financial Results Presentation Q3 FY2011 (Fiscal Year Ending March 31, 2012)

### Q&A

February 10, 2012  
Tokyo, Japan

Q1: After making a simple calculation based on the company's forecast, around 50 billion yen designated for research and development expenses should still remain. Is this going to be used up?

A1: We are going to use these budgets according to plans, for bringing forward the projects ahead of schedule and accelerating existing projects..

Q2: A U.S. firm, Alkermese, Inc., is developing an aripiprazole depot formulation and has published the data. When will Otsuka publish detailed data on its IM depot formulation?

A2: We will publish the data in May 2012 as planned. We are not in a position to comment on developments of other companies, but since Alkermese's depot product is a pro-drug, we understand, that full development program will be required although we are unaware of the FDA's decision.

Q3: Does it look like the nutraceutical business will be in the black in the fourth quarter?

A3: The nutraceutical business may record a slight loss in the fourth quarter, but we expect to achieve its operating income ratio target of 8% for this fiscal year .

Q4: The termination of the Cimzia agreement was announced the other day, but what is the future plan for saxagliptin (brand name: Onglyza)? Will it be marketed by Otsuka?

A4: Otsuka is on track to file for approval by the end of this fiscal year, by March 31, 2012. If we are later than that, the delay will not be much. We are planning to market this product using our own sales force.

Q5: When will the results of clinical study for OTS102 be made available?

A5: As announced by OncoTherapy Science, the results will be released in March.

Q6: In the oncology field, Otsuka has few products outside of Japan. There was a mention of a bolt-on deal at the time of IPO, but is anything being planned?

A6: We hope to forge an agreement for good products if any, but in this field, it is hard to find good products. We hope to make such a deal as soon as we can.

Q7: Research and development expenses are being used to accelerate existing projects, but which specific projects are being targeted, and to what extent can they be made shorter?

A7: Projects that we are accelerating include the development of IM depot in Europe and Japan, along with global development of OPC-34712 for multiple indications. We are unable to comment on the extent of speed-up.

Q8: In the nutraceutical business, sales promotion expenses as well as advertising costs have been cut. How much of this decrease is due to the appreciation of the yen?

A8: Almost none.

Q9: What is the breakdown of research and development expenses in dollars, euro, and yen?

A9: About half of research and development expenses are spent outside of Japan, and most of it is in dollars.

Q10: Sales of Abraxane appear to be weak. Is this because of Sanofi's launch of Taxotere 1 in July 2011? Even though Abraxane is a first-line treatment for breast cancer, sales have not grown.

A10: That is because Abraxane is currently used to treat late-stage breast cancer only, namely recurrent breast cancer or metastatic breast cancer. If additional indications such as lung cancer and stomach cancer are approved, sales will expand. We feel the pressure from generic drugs, and it is indeed true that the sales growth is slow.

Q11: In the United States, growth in prescriptions of ABILIFY in January seemed to have slowed down a little. What levels of growth do you expect in the future?

A11: We will discuss the fiscal 2012 plan for ABILIFY at the presentation on fiscal 2011 financial results. The reason for the slow growth in January had to do with distribution inventories. But despite this weakness, contracts with payers have been increasing since October of last year, and we believe further growth will continue.

Q12: What is the current status of the patent litigation against companies seeking approval to market ABILIFY in the United States?

A12: The case went to the court of appeals on February 6, and based on everything so far, we feel confident. We expect to obtain the outcome by around this summer.

Q13: Will the annual dividend be raised from the planned 45 yen?

A13: So far we have made no change to our plans, but we will consider raising the dividend after looking at the settlement of accounts for the full fiscal year.

Q14: Approximately when will Otsuka file for approval of saxagliptin in Japan? And what is your view on this DPP4 inhibitor market with other competing products?

A14: We are aiming to file by the end of this fiscal year, or a little later than that. In the market, sales of Merck's Januvia are growing, making it hard for Takeda, so we know that we must step up our efforts in such a market. We are unable to answer questions regarding product differentiation.

Q15: How has the patent expiration of Zyprexa affected ABILIFY?

A15: It has affected ABILIFY to some extent on a prescription basis for the treatment of schizophrenia, but overall, there has been no major impact. In the future, as well, we do not believe that the patent expiration of Zyprexa will affect our business much. The patent for Seroquel, however, will expire in March of this year, and we expect to see some impact of that because the prescription trend of Seroquel is similar to that of ABILIFY. Going forward, with the release of generic drugs, we expect that prescription restrictions for new patients and price reductions will have a negative effect.

Q16: Could you provide more details about increasing contracts with payers? We would also like to have more information regarding the impact of payment terms after March in comparison with generic drugs.

A16: The number of contracts has gone up, with the prescriptions in the 2nd tier increasing slightly. There is a possibility that payers will also give instructions on priority use of generic drugs, but this will depend on future negotiations. We want to examine this very carefully.

Q17: How does the European filing for delamanid differ from the Phase III trials being carried out in Japan, the U.S., and Europe? And could you also tell us about Otsuka's marketing strategies?

A17: We were recommended to file for approval in Europe by the authorities because of the positive results of the phase IIb trial. In this phase IIb trial, doses of 200 mg and 400 mg and placebo were administered twice a day. The phase III trial being conducted now is a global trial, in which placebo and 200-milligram doses are administered twice per day initially and once per day later.