

# Otsuka Holdings Co., Ltd.

## Financial Results Presentation Q1 FY2013 (Three Months Ending June 30, 2013)

**Q&A**

**August 8, 2013**

Q1: Please tell us about sales for Abilify Maintena.

A1: Sales were US\$5.9 million for January to June according to IMS data. IMS data has a capture rate of approximately 60%. Sales to date are going well compared with projections.

Q2: Please tell us about the rate of progress compared with full-year sales projections. Progress overall is as expected, but what is progress in operating income by segment like? Is it correct to see the Pharmaceutical business as exceeding expectations and the Nutraceutical business as falling short?

A2: In the Pharmaceutical business, global ABILIFY sales and total sales in Japan are both in line with projections, research and development investment is ahead of schedule, and operating income has exceeded projections. In the Nutraceutical business, operating income declined because of investment in advertising and promotion. As summer sales are going well, we expect that future operating income will also be in line with projections.

Q3: When will you release the results of the Brexpiprazole Phase 3 trials?

A3: At present, we are proceeding with the aim of releasing data at the end of the year. However, we cannot guarantee whether we will be able to release results for both of the two indications; adjunctive therapy for major depressive disorder and schizophrenia. The information might come out at different times.

Q4: Otsuka has already spent at least ¥50.0 billion on research and development in the first quarter, so will you be able to keep the spending within the projected ¥200.0 billion for the full year?

A4: Otsuka has been ahead on its research and development investment since last year. During the first quarter this year, expenses arose due to trials for additional indications for Brexpiprazole and Abilify Maintena and for an additional indication for Brexpiprazole. As a result, research and development expenses have increased considerably year on year, with the weakening yen also having an impact. If we exclude the impact from the weaker yen, research and development expenses are roughly in line with expectations albeit ahead of schedule. We could exceed projections over the year with respect to the exchange rate impact of the weaker yen.

Q5: The impact of exchange rates on operating income is placed at +¥1.0 billion, but shouldn't it be a bit more in view of the exchange rate sensitivity announced at the beginning of the fiscal year?

A5: The impact of exchange rates on income became smaller mainly because dollar-based costs increased. Exchange rate sensitivity for the full year is as projected.

Q6: In the supplementary materials, looking by market, there was a ¥4.0 billion operating loss in North America, which is a considerable decline from the ¥1.4 billion in operating income last year. Why is this?

A6: Otsuka America Pharmaceutical, Inc. is building up its sales structure to establish a system for marketing its products by itself, which increases costs and reduces income. Moreover, Pharmavite LLC's Nature Made® experienced a decline in sales and income from January to March, affected by competitors. However, it is now on a recovery trend.

Q7: Are you planning an additional clinical trial in the future for the additional indication of ADPKD for Tolvaptan? Has there been any feedback from patient groups?

A7: We have conducted an open-label extension trial and a follow-up trial. We hope to report on whether we will conduct an additional trial after receiving the response on September 1 (the PDUFA action date). I cannot confirm the feedback from patient groups at present, but I believe discussions are being carried out.

Q8: I have the impression that Japanese sales of mainstay products are generally weak, meaning Taiho Pharmaceutical products and long-listed drugs. Are sales, including sales of these, in line with expectations?

A8: Japanese sales in the Pharmaceutical business are progressing in line with expectations. Pletaal has also contained the impact of generics better than forecast. ABILIFY gained an additional indication for treatment-resistant depression in June, so we believe that sales will increase in the future.

Q9: Do you have any future plans that you can reveal as strategies to differentiate Abilify Maintena from its competitors and bridge the gap such as administration site other than gluteal muscle, prefilled syringe and multi-dosing.

A9: It is currently available in two formulations, in different dosages of 300mg and 400mg. Seventy percent of the prescriptions are for the 400mg dose. For the time being, we are not disclosing information on additional dosage forms and so on. Naturally, we are considering our future plans.

Q10: The dose for the Phase 2 trial for Lundbeck's Lu AE58054 was 90mg. Why are the doses (10 – 60mg) in the Phase 3 trial different?

A10: The dosage was set in view of the safety and efficacy results from Phase 2b.

Q11: How much are the milestone payments from Lundbeck which were recorded to sales for the first quarter?

A11: We recorded ¥1.4 billion in the first quarter. We expect to record a little under ¥20.0 billion for the year.

Q12: What is behind increased Abraxane sales?

A12: Sales have increased because it gained additional indications for gastric cancer and lung cancer in February. We believe this trend will also continue in the future.

Q13: I think that TS-1 sales have declined due to the influence of generic drugs, but are there any factors affecting current situation?

A13: The volume of prescriptions is trending flat. It is possible that unit prices are falling because of shortened prescribing period and the trend to switch to low-cost regimens.

Q14: Pocari Sweat sales volume has risen, but have revenues not increased very much?

A14: The increase on the value base is about the same as in volume. And this is without any change in prices.

Q15: What is the reason for the increase in the cost ratio in the Nutraceutical business?

A15: The cost ratio in the Nutraceutical business has fallen slightly compared with last year. It has not increased.

Q16: What is the status of insurance coverage for Abilify Maintena?

A16: The access ratio to drug formulary of Abilify Maintena at month 3 since launch is 70% of that of Invega Sustenna at month 12 since launch.

Q17: What countermeasures do you have to address the price reduction for Invega Sustenna?

A17: We are dealing with this carefully because of the regulations on promotion in the U.S.

Q18: Otsuka has projected increased operating income in all business segments, but there is an impression that the Nutraceutical and Consumer Products businesses have got off to a slow start. The projection for the full-year operating margin is 15%, so is it correct to assume that the profit margin in the Pharmaceutical business will decline if the income in the Nutraceutical and Consumer Products businesses rise in the future?

A18: At present, we expect that the full-year operating margin will also rise. We believe that the Nutraceutical business will achieve projections, which is partly attributable to the impact of exchange rates, but it is possible that we will not manage to achieve projections in the Consumer Products business without reconsidering our strategy. Overall, we expect we can achieve projections for operating income.

Q19: BS inventory is ¥77.5 billion. What is the reason for the 8% increase compared with last year?

A19: Inventory has risen because of the addition of 23 newly consolidated companies and the establishment of U.S.-based Pharmavite's new factory in Alabama for the East Coast market.

Q20: By market, North American sales were up approximately 25%, but there was a ¥4.0 billion operating loss. Is unrealized income on inventory the reason for the deterioration in profit margins overall?

A20: We do not see the increase in inventory as the principal reason for the decline in income.