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# Otsuka Holdings Co., Ltd.

# Financial Results Presentation Q2 FY2015
## (Three Months Ending June 30, 2015)

# Q&A

**August 7, 2015**

Q1: In the full year results forecasts for fiscal 2015, while sales and operating income are upwardly revised by ¥10 billion, R&D expenses are revised down by ¥25 billion. Would it be correct to interpret the discrepancy as an increase in the cost of goods due to inventory revaluation for *NUEDEXTA* and additional investment in Avanir Pharmaceuticals ?

A1: As you point out, in the second half of fiscal 2015, the temporary increase in the cost of goods due to inventory revaluation of *NUEDEXTA* and additional investment in order to strengthen marketing activities at Avanir Pharmaceuticals are projected to be a little under some ¥10 billion, respectively. Other than that, the forecast also takes into account beefed up investment in growth for the Three Global Products. The milestone revenue for *REXULTI* that was scheduled to be recorded in the second half was brought forward to be received during the first half, and we have started recording it pro rata, but the amount received for the full year is in line with projections.

Q2: Why have full year sales forecasts for *Lonsurf* for fiscal 2015 been revised down to one third of the initial projection, and why did the results in the first half fail to meet projections?

A2: The reason is that we conservatively excluded fiscal 2015 *Lonsurf* sales forecasts for the United States from projections. The PDUFA action date in the United States has been set for December 19, 2015, but an earlier timeframe for the approval was anticipated at the stage of the initial projections. Sales in Japan are mostly progressing in line with projections.

Q3: With regard to the Japanese market for atypical antipsychotic long-acting injections, have physicians become cautious about prescribing them due to the issue of a Blue Letter (safety information) for a rival product? Is there any impact of this since the May 2015 launch of the *extended-release injectable Abilify*?

A3: Otsuka has emphasized safety in marketing activities from the outset, and we have also obtained the trust of physicians. The safety of *ABILIFY* is already widely recognized, and we will carefully check for side effects and safety profile of the *extended-release injectable Abilify* in the six-month post-marketing surveillance.

Q4: What is the status of *ABILIFY* sales in the United States for April to June 2015? Sales projections for the second half of fiscal 2015 look conservative.

A4: *ABILIFY*'s current share of all aripiprazole prescriptions is approximately 30%. Most of these are prescribed under Medicaid, which has a high gross-to-net discount rate. We have projected second-half sales conservatively taking into account changes in market trends such as the possibility that the Medicaid proportion of prescriptions could rise further in future increasing gross-to-net and the potential for market entry of additional generic drugs.

Q5: What is the current likelihood of achieving the fiscal 2016 target of ¥100.0 billion in operating income indicated in the Second Medium-Term Management Plan?

A5: New products, including our Three Global Products of *Abilify Maintena*, *REXULTI*, and Tolvaptan, as well as *Lonsurf*, new drugs in Japan and *NUEDEXTA*, are all growing steadily. On the other hand, we are considering further accelerating investments for the future growth of these new drugs. We will have to consider the balance between profit and investment carefully, partly due to the effect of exchange rates. However, Otsuka has not changed the fiscal 2016 operating income target at the present time.

Q6: Could you explain the breakdown of upfront and milestone payments in the first half of fiscal 2015 and in the upwardly revised full-year projections? In addition, could you also explain whether the second half of fiscal 2015 will include a period of deficit in real operating income and how much in upfront and milestone payments will be left in fiscal 2016?

A6: In terms of the breakdown for the ¥32.2 billion in upfront and milestone payments in the first half of fiscal 2015, the *REXULTI* milestone revenue from Lundbeck totaled slightly less than ¥30.0 billion, including the portion that was recorded ahead of schedule, the *ABILIFY* upfront revenue from Bristol-Myers Squibb was slightly less than ¥2.5 billion, and the upfront revenue for the license agreement on *Lonsurf* with Servier was received. They were recognized as income for each respective period on a pro rata basis. Otsuka plans to record ¥65.0 billion for fiscal 2015 full-year, including a remaining development milestone revenue of approximately ¥5.0 billion for *REXULTI*, the ongoing pro rata recording of the *Lonsurf* upfront revenue and an approval milestone revenue for *REXULTI* in the second half. As you point out, we anticipate a deficit in real operating income for the second half of fiscal 2015, mainly because some of the development milestone revenue for *REXULTI*, which had been projected for the second half, has already been recorded ahead of schedule in the first half and due to the additional growth investment. In fiscal 2016, the *Lonsurf* upfront payment will continue to be recorded pro rata, and we also expect to receive an approval milestone payment in the event that it is approved in Europe.

Q7: Could you tell us about the current situation regarding the ADPKD indication for *SAMSCA* in Japan, including its proportion of sales and the number of registered patients for post-marketing surveillance covering all patients? From the report on adverse reactions that was released on website, a certain number of cases of serious liver dysfunction appear to have occurred; has this impacted on physicians' evaluation?

A7: We are not disclosing *SAMSCA*'s Japanese sales for the ADPKD indication. The number of registered patients for post-marketing surveillance covering all patients is available for healthcare professionals on the Otsuka Pharmaceutical website. Given that Samsca's background involves risks of hypernatremia and liver dysfunction, we have been ensuring the drug's proper use for physicians. With regard to the ADPKD indication for which the prescribed dose is high, we have strictly limited its use to allow only pre-certified physicians who have completed e-learning for prescribing. Because liver function is being monitored with particular care and the medication is ceased when liver injury occurs, it has not led to any serious cases at the present time.

Q8: We've heard that projections for the second half of fiscal 2015 are somewhat conservative. However, if profit overshoots projections, is there a possibility of active investments in new in-licensing or research and development?

A8: We are starting to see some good results from the strategy for medium- and long-term growth we have developed so far, including in-house research and development in which we carried out active investments, as well as the products of Avanir Pharmaceuticals and the drug discovery technology of Astex Pharmaceuticals, which we acquired. Naturally, we are fully aware of our immediate responsibility for profit, but I believe that we cannot miss any opportunities to further accelerate growth into the future in an era like today when groundbreaking innovation as a company and an industry is demanded.

Q9: With regard to the marketing strategy for *REXULTI*, will you actively switch from *ABILIFY* for which a certain number of prescriptions still remains, or will acquire market share from a completely different area?

A9: We'd like a bit more time with regard to the strategy for *REXULTI*. We will report further as things develop.

Q10: Have you agreed with the FDA on the use of the Phase II study data for AVP-923 to conduct the AVP-786 Phase III study on agitation in patients with dementia of the Alzheimer's type? Also is there any overlap in definitive diagnosis between agitation in Alzheimer's disease and pseudobulbar affect (PBA) with a background of Alzheimer's disease?

A10: We have agreed with the FDA on the commencement of the Phase III study for AVP-786 based on the Phase II study data for AVP-923. We plan to initiate the study during the third quarter of fiscal 2015. With regard to the overlap of agitation with the PBA diagnosis, although awareness of PBA is still low, the symptoms of agitation and PBA are different.

Q11: On July 3, 2015, the sensor technology of Proteus Digital Health was approved by the FDA for measurement of medication adherence. Will this have any impact on the alliance with Otsuka in the future?

A11: We have an alliance with Proteus Digital Health in the CNS area, and we are conducting development related to *ABILIFY* tablets.