# Otsuka Holdings Co., Ltd.

# Financial Results Presentation Q1 FY2016

## (Three Months Ending March 31, 2016)

# Q&A

**May 13, 2016**

Q1: Operating income for 1Q FY2016 has already exceeded the forecasted operating income for 1H FY2016. In addition, because you plan to record an approximately ¥10 billion milestone for the approval of *LONSURF* in Europe in April 2016, will the forecasted operating income for 1H FY2016 be revised in the future?

A1: We expect to record an approximately ¥10 billion milestone for the approval of *LONSURF* in Europe and other items in 2Q FY2016. However, because R&D expenses were brought forward and other factors have arisen, we expect to review the forecast for 1H FY2016 after examining the situation in detail. We will examine the review of the forecast for FY2016 after looking into forecast for 1H FY2016, the performance of the Nutraceutical business from 2Q FY2016 onward, and other factors.

Q2: In regards to factors attributable to the outperformance of operating income compared with the plan for 1H FY2016, did bringing forward the recording of R&D expenses have a significant impact on the results?

A2: The outperformance of operating income is partly attributable to the progress of R&D expenses. The progress of cost streamlining and improvements in the COG of supplement business in the United States and *Pocari Sweat* also contributed to the results.

Q3: Is it correct to assume that the COG of the Nutraceutical business has improved because of the structural improvement of the earning structure, and not because of seasonal factors?

A3: The improvement in the COG in the supplement business in the United States in 1Q FY2016 is expected to level out at some point during the fiscal year. However, we do expect the improvement in the COG of *Pocari Sweat* to continue throughout the fiscal year.

Q4: The sales of *LONSURF* significantly exceeded the plan. Is it correct to assume that this is because sales were stronger than originally expected?

A4: Yes. Sales were stronger than the plan.

Q5: Is it correct to assume that sales of *REXULTI* were as expected?

A5: Sales were nearly as expected in our plan.

Q6: The US sales of Abilify of $110 million for 1Q FY2016 are considered to be generally in line with your plan. In light of the fact that, based on past results, the sales in the period of January through March tend to be low in the United States, do you think that the sales for FY2016 will exceed the plan?

A6: The decline in the prescription number was gradual in FY2015, and, looking at the situation in 1Q FY2016, the prescription number declined while the gross-to-net discount rate expanded as explained in the previous meeting. As a result, at this time we believe that the full-year plan is appropriate.

Q7: As the potential candidate compound of the global alliance with Lundbeck, do you plan to choose Lu AF35700, which has entered the P3 in patients with treatment resistant schizophrenia?

A7: At this time, Lu AF35700 is not included in the three products for which we have the rights to choose. Based on the agreement with Lundbeck, we obtain acquisition rights after they complete P2. However, it is not entirely necessary for us to determine whether to introduce it after P2.

Q8: What are the points that differentiate TAS3681 from the drugs with the same mechanism of action that are available on the market?

A8: Characteristic of TAS3681 is that it has an androgen receptor downregulating activity.

Q9: Do you have the financial capacity and desire to acquire more products in the central nervous system space?

A9: With earnings hitting the bottom, we understand that FY2016 will be a tough period. At this time, we believe that the most important thing is to carry out measures in a proactive manner to maximize the value of the companies and products that we have recently acquired. For this reason, although we may consider examining an acquisition opportunity if it is very attractive and offered at a reasonable price, we currently have no plans to make any acquisitions.

Q10: What factors led to the significant underuse of costs, such as R&D and SG&A expenses, compared with the plan? Was it simply a result of bringing forward the recording of expenses, or was it because cost improvement measures have been implemented effectively?

A10: Factors that led to the underuse of R&D expenses compared with the plan include the effects of bringing forward the recording of expenses, the review of priority, the efficient use of indirect costs, and the exchange rates. In regards to other expenses, we may spend advertising expenses and other expenses in the future, but in general we have been making steady progress in streamlining and optimizing costs.

Q11: Please tell us about the level of penetration of *LONSURF* in colorectal cancer market. Do you believe that there is still more room for further growth?

A11: We believe that *LONSURF* is contributing to the third-line and further treatments. *LONSURF*'s main side effect is hematopenia (low blood counts) and thus the drug is prescribed partly because of few side effects with subjective symptoms. We understand that the penetration speed is high, but we have not reached out to all the potential prescriptions.

Q12: Looking at the prescription trend of *NUEDEXTA*, growth appears to be slowing down. Is there any need to pay attention to short-term prescriptions trend?

A12: The trends of short-term prescription change due to a number of factors. That is why we believe long-term view help us better understand the overall trend. We think that prescriptions are growing steadily at this time.

Q13: Because a milestone payment for the approval of *LONSURF* in Europe is originally expected to be recorded in 1H FY2016, you will examine the revision of the full-year plan by taking into account other factors, such as the timing at which costs are incurred? Is this assumption correct?

A13: We will examine the revision of the full-year plan by taking into account the summer sales performance of Nutraceutical business that is now performing well, as well as the timing at which costs are incurred.

Q14: Is it correct to assume that the majority of sales of *REXULTI* are for adjunctive therapy in major depressive disorders?

A14: Although prescriptions for schizophrenia have been growing, you are correct to assume that the majority of sales are from prescriptions for adjunctive therapy in major depressive disorders.

Q15: You have received a Complete Response Letter (CRL) from the FDA for digital medicines that are considered to have a very promising future. What kind of development do you plan in the future?

A15: We need to have some more time because we are currently holding discussions with the FDA in response to the CRL. If we become successful, we think that we will be able to explore and expand a variety of possibilities in the future.

Q16: Since there are preceding products indicated for breast cancer available in the market, you have an option of starting TAS3681 clinical trials in breast cancer instead of prostate cancer. What are the reasons for conducting trials in prostate cancer?

A16: We recognize that development in breast cancer is also an important approach, but we consider that indication as the next target. First, we would like to focus on demonstrating efficacy of TAS3681 in prostate cancer.