

Otsuka Holdings Co., Ltd.

Financial Results Presentation Q2 FY2016 (Three Months Ending June 30, 2016)

Q&A

August 9, 2016

Q1: There seem to be some expenses carried forward from the first half, and performance forecasts for the second half of fiscal 2016 were revised down. Are there any other special factors?

A1: We forecast operating income of ¥45.0 billion for the second half of fiscal 2016 in the projections at the beginning of the period. However, we are reducing this by ¥10.0 billion to approximately ¥35.0 billion. Excluding the impact of exchange rates, we expect that an improvement in gross profit will have a positive impact on operating income by ¥4.0 – 5.0 billion. However, expenses carried forward from the first half of the fiscal year amount to about ¥15.0 billion, which is expected to impact negatively on operating income of the second half. Carried-forward R&D expenses account for some ¥10.0 billion. We are continuing to promote streamlining of expenses and plan to allocate cost reductions from this to investment in growth.

Q2: The discussion of the first quarter results reported that the improvement in the cost ratio in the nutraceutical business also involved temporary factors. It seems that the profit margin improved as of the end of the second quarter as well, so would it be correct to consider this to a recurring trend to some extent?

A2: We aim to see nutraceutical business become one of the two mainstay businesses with pharmaceutical business while promoting both ongoing improvement and investment in growth. The review of the value chain from R&D through to sales is a medium-to-long term strategy, and we are promoting streamlining of productivity as an initiative that is part of this, in conjunction with the expansion of existing brands and launch of new products.

Q3: What are the positive factors for sales of *REXULTI* and *LONSURF*?

A3: With regard to the positive factors for *REXULTI* sales, it is successfully inheriting and taking advantage of assets and infrastructure developed for *ABILIFY*. In addition to this, the success of direct-to-customer (DTC) promotion (advertising to patients) is also a factor. However, it is a fact that issues remained even in treatment with *ABILIFY*, and the product profile of *REXULTI*, which was developed to overcome these issues from the research stage, is consequently highly rated in medical practice. For *LONSURF*, we believe that, in the absence of third- and fourth-line treatments that give a sufficiently high degree of satisfaction for the indication of colorectal cancer, the provision of a new option for the unmet needs of patients and medical practitioners is a positive factor.

Q4: With regards to the ¥430.0 billion + α which was announced as the sales projection for new drugs in fiscal 2018, will you be able to revise this figure up, excluding the impact of exchange rates, given that sales are currently positive?

A4: We will look at market conditions and the progress of development, and consider it going forward.

Q5: Will an increase in the dividend be considered around next fiscal year?

A5: We regard maintaining stable dividends to be important, regardless of ups and downs in performance. We consider any increases in the dividend, taking account of the balance with investment for growth and the market environment.

Q6: According to IMS data, prescriptions for *NUEDEXTA* and new prescriptions for *REXULTI* seem to have peaked out already. What do you think?

A6: In the U.S., marketing teams from Avanir Pharmaceuticals and Otsuka America Pharmaceutical Inc. (OAPI), the U.S. subsidiary of Otsuka Pharmaceutical, are conducting sales promotion activities for *NUEDEXTA*. Avanir has been progressing largely in line with projections, but OAPI also has to focus on promoting *REXULTI*. Pseudobulbar Affect (PBA), for which *NUEDEXTA* is indicated, is a disease with no previous treatment, and, therefore, awareness of the condition will take some time.

Q7: The U.S. market for long-acting injectable (LAI) atypical antipsychotics grew by an annual average of 20% between 2007 and 2015. The market share for *Abilify Maintena* is currently approximately 15%. In the tough competitive environment, will there be a breakthrough for *Abilify Maintena* in the future or will it continue to grow at around the rate of the market?

A7: Our target market share of 30% in fiscal 2018 announced in the 2nd Mid-Term Plan has not changed. Medication adherence is a fundamental issue in the treatment of schizophrenia. We will continue our efforts to expand the market share of *Abilify Maintena*, taking advantage of its high safety profile and ease of use.

Q8: In Japan, deaths associated with a competing product have raised concerns. Could you explain the impact on Japan's market for atypical antipsychotic LAI overall as well as the impact on specialists' evaluation of *Abilify Maintena* (Japanese brand name: *ABILIFY for extended-release injectable suspension, for intramuscular use*) and its sales?

A8: It is true that specialists have become cautious about prescribing LAIs. The progress of *ABILIFY for extended-release injectable suspension, for intramuscular use* has slowed, but no serious problems have emerged, so we believe that prescriptions will increase gradually .

Q9: What is the significance for Taiho Pharmaceutical of the co-promotion agreement with MSD for pembrolizumab?

A9: The agreement covers melanoma and non-small cell lung cancer (NSCLC). We believe that being involved in cancer immunotherapy, the most up-to-date treatment, is a major advantage.

Q10: Do the sharing of development expenses and the sales system pose any significant risk with regard to co-promotion agreement with MSD for pembrolizumab?

A10: The agreement only covers co-promotion in Japan, and there will be no development expenses.

Q11: Japanese pharmaceutical companies are conducting reviews of their product portfolios, including the sale of their long-listed drug businesses. What are the issues for Otsuka?

A11: Our in-house drug discovery assets not only have value shown in the financial numbers but also significant value related to accumulated R&D expertise. Business streamlining based on selection and concentration is easy to understand from the external viewpoint, but we believe it is necessary to consider it carefully, while also taking the importance of business continuity and depth into account.

Q12: Could you tell us about *LONSURF* sales by area? Are the lower fiscal 2016 second half sales projections than the first half results due to the impact of exchange rates? It seems that clinical trials in combination with *Avastin* are ongoing for colorectal cancer in Japan and the U.S. Do you have any plans for indication expansion to front-line treatment?

A12: Approximately 80% of *LONSURF* sales for the first half of fiscal 2016 were in the U.S. The negative impact of exchange rates on sales will be greater in the second half. In the process of investigating a variety of approaches to lifecycle management, we are also considering indication expansion to front-line treatment of colorectal cancer.

Q13: What contribution does *TAKECAB* make to profits?

A13: We cannot disclose the terms of the agreement, but both companies will further expand sales going forward.

Q14: LEE011 out-licensed to Novartis by Astex Pharmaceuticals has received breakthrough designation in the U.S. Do you think its contribution to profits at Otsuka will be significant if the sales expand in the future?

A14: We will receive royalty income, but do not disclose its rate.

- Q15: With regard to residual schizophrenia and disinhibition syndrome in neurodegenerative disorders for which you are aiming to expand the indications of AVP-786, could you explain existing medications, the compound's positioning and the number of patients?
- A15: Residual schizophrenia is the negative symptoms such as social withdrawal and apathy that remain during continued treatment of schizophrenia. There is currently no effective treatment. Disinhibition syndrome in neurodegenerative disorders is a condition in which patients cannot suppress their impulses and feelings, such as shoplifting and cutting before others waiting in lines. There is currently no effective medication as well. Patient population seems to be large, as it develops in conjunction with frontotemporal dementia and Alzheimer's dementia.