Otsuka Holdings Co., Ltd.

Financial Results Presentation Q2 FY2018
(Six Months Ending June 30, 2018)

Q&A

August 8, 2018
**Q1:** The full-year revenue plan for Samsca/JINARC/JYNARQUE has been revised up. Please tell me about the post-launch progress for JYNARQUE in the US.

**A1:** We have cautiously started sales of JYNARQUE in cooperation with registered physicians and pharmacies under the REMS program. JYNARQUE's revenue has not yet reached the level for disclosure, but we will be disclosing it if it increases to a certain extent. Progress is steady, since many patients have been waiting for the drug.

**Q2:** Revenue for LONSURF and NUEDEXTA in the US has been slack. What are the reasons and what measures are you taking to address them?

**A2:** In the last year, Avanir adopted a new management structure, and it has also been implementing new marketing tactics for NUEDEXTA, including direct-to-consumer (DTC) marketing. We are expecting revenue to recover. Current indication for LONSURF is only end-line treatment of metastatic colorectal cancer, and the number of patients is limited. We hope to further raise the product value by expanding its indications in the future.

**Q3:** The heatwave has persisted. What are Otsuka's actions to address it, and what impact is it having on business performance?

**A3:** As revenue for beverages usually peaks in July – September, we are expecting good results this year. We know from analysis of past results that sales of POCARI SWEAT are extremely sensitive to temperature and rainfall. However, there are few data for when the temperature exceeds 35 °C, so we cannot estimate the impact on revenue. There are also limits on the production capabilities, but we are doing the best that we can. Meanwhile, we have been implementing a voluntary recall for ORONAMIN C drink since July 2018, and recorded recall expenses in June. We expect that there will be a certain opportunity loss associated with the incident, even in July – September. Even accounting for these factors, we hope to achieve revenue and profit growth.
Q6: I would like to ask about the balance between short-term and long-term investment. I get the impression that Otsuka has been leading only with long-term investment recently. The original plan in the Second Medium-Term Management Plan presented a scenario in which FY 2018 revenue and operating profit would return to FY 2013 levels, thereby providing for well-balanced investment. However, that balance seems to have broken down at the moment.

A6: In the First Medium-Term Management Plan, we set a goal to maximize the value of Abilify, and in the Second Medium-Term Management Plan, we set a goal to diversify revenue. At the current stage, we believe that obtaining the indication for agitation associated with dementia of the Alzheimer’s type for REXULITI and AVP-786 and the growth of Samsca/JINARC/JYNARQUE as a treatment for ADPKD will form the revenue base in the medium term. Meanwhile, it is also vital that we respond to changes in the medication trend and to address unmet needs in existing fields and treatment methods, so it is necessary for a certain percentage of investment to be made with a long-term perspective. This is not to say that the majority of investment is aimed at 2030 and beyond; we keep an optimal balance.

Q4: With regards to the impairment loss for centanafadine, what kind of development plan did you initially have and what kinds of changes have now been made to the plan?

A4: The development of a pediatric formulation has been delayed, and the commencement of clinical trials in children has been delayed.

Q5: Regarding centanafadine, the Phase III trial information for adults has already been disclosed. Will you apply for the adult indication first?

A5: We plan to apply for the adult and pediatric indications together.

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Q7: The Phase III trial results of SGI-110 for treatment-naive acute myeloid leukemia (AML) were negative, and there is stiff competition in the relapsed or refractory AML field where the trial is currently underway. Other companies have adopted a development strategy to add treatment-naive AML after obtaining an indication for relapsed or refractory AML. Is there any sense in developing SGI-110 for relapsed or refractory AML from now on? Also, what do you think about the impairment risk associated with the drug?

A7: First, we need to analyze the detailed data from the treatment-naive AML trial that recently ended and study where it differed from our initial hypothesis. The Phase III trial for relapsed or refractory AML is underway, and we will consider our strategy comprehensively.

Q8: Were most of the assets recorded for centanafadine impaired?

A8: We recorded approximately ¥19.0 billion in assets for centanafadine, and ¥8.4 billion of those assets were impaired.

Q9: Has Abilify Maintena’s growth been exceeding that of the US LAI market?

A9: The additional indication of bipolar disorder has been driving the growth in Abilify Maintena. Revenue in the US was up approximately 17% year on year in the first half of FY2018. Its share of the LAI market for bipolar disorder has increased to around 30%. We believe that the convenience of the once in 4 weeks formulation is highly rated.

Q10: RXULTI was approved in Europe. How has this been factored into revenue plans? Will it be part of Lundbeck’s territory?

A10: We will engage in joint sales with Lundbeck in Europe as well. One hundred percent of the revenue for the main European countries will be recorded to Otsuka, and we will pay 50% to Lundbeck as co-promotion fees.
Q11: Please explain your approach for the next Medium-Term Management Plan with regard to the level of research & development expenses, profit targets and others.

A11: Under the reforms in the Second Medium-Term Management Plan, we diversified revenue and engaged in investments for further growth. During the next Medium-Term Management Plan, the effects of those investments will appear sequentially. One of our strategies will be to maximize the product value of our existing growth drivers while fostering and securing revenue from next-generation products. Meanwhile, we must continue investments aimed at addressing changes in treatment methods and the environment from a medium-to-long term perspective. At present, we are discussing the scenarios for investments in technology, regional expansion, and existing core therapeutic areas with each operating company. With regard to research & development investment, we recognize that there will be a ceiling to a certain extent because of the need to balance and allocate operating profit before research & development expenses, which is the underlying source of funds.

Q12: Is double-digit growth in profit possible in the next Medium-Term Management Plan?

A12: I think it is possible if the effects of our current investment materialize. We have great expectations for growth of Abilify Maintena and REXULITI.

Q13: You revised the full-year revenue plan for NUEDEXTA down. Is there a possibility of impairment if the results are lower than the revised figures?

A13: At present, no impairment loss has been recorded, but the possibility of impairment is not zero, depending on the results in the second half.
Q14: Why did you revise the plan for full-year revenue for LONSURF down in other regions?

A14: It is mainly because we have downwardly revised shipment plans in the second half in conjunction with inventory adjustment at Servier. We are steadily increasing the number of countries where LONSURF is sold, and also increasing the volume of actual sales.

Q15: I see revenue for JYNARQUE in the US going up after listing at formularies has progressed to a certain extent. Please tell me about the current progress and a potential expansion of future revenue.

A15: Listing at formularies is important for expansion in revenue of the product. However, the establishment of a comprehensive system including usage status and safety measures is the most important. The top priority is the registration of physicians under the REMS program. Only after registered physicians inform patients about the risk to liver function, can they provide a prescription. At present we are promoting these tasks and negotiating with payers simultaneously, and implementing the tasks steadily one by one. We are not disclosing any concrete figures, but listing at formularies is gradually proceeding, and the registration of physicians is progressing in line with plan. Direct comparisons between Japan and the US cannot be made due to the different environments, but approximately 3,000 out of an estimated 30,000 patients in Japan have started using the drug in three years since launch. The number of Samsca-treated ADPKD patients has been increasing in almost linearly up to now.

Q16: With regard to the ReCor Medical acquisition, what is the differentiation point from forerunner Medtronic products and others? The SOLO study is a single blind trial, but will it be known that the sham surgery patients are in the sham group? I am aware that this is a field in which designing the trial protocol is extremely difficult.

A16: As you point out, developing appropriate trial design is extremely difficult. For this trial, we also took sufficient measures to set the trial conditions to prevent the subjects from finding out the sham operation group. At present, a comparison with forerunners on effectiveness is not possible, but only Recor Medical's renal denervation system uses ultra-sound waves, and this allows deeper ablation than other forerunner products using radio waves. Another major feature is that it also has a balloon cooling function to protect the blood vessel walls.