Otsuka Holdings Co., Ltd.

Financial Results Presentation Q3 FY2017

(Nine Months Ending September 30, 2017)

Q&A

November 14, 2017

Q1: Regarding the sales projections by product, do the current revisions include a ¥3.0 billion increase to the ABILIFY in the U.S. and a ¥3.0 billion decrease in Japan as well as a ¥3.0 billion decrease to Nuedexta and so on?

A1: Yes. We have also slightly modified projections for LONSURF and MUCOSTA.

Q2: I'd like to confirm the probability of achieving the fiscal 2017 operating profit projections. Also, please explain the reasons for the increase of ¥5.0 billion in the projection for share of profit from equity method affiliates and the increase of ¥5.0 billion in the projection for SG&A expenses.

A2: The share of profit from equity method affiliates is increasing by ¥5.0 billion, mainly at Alma S.A., which is involved in the mineral water business in France, and SG&A expenses are increasing by ¥5.0 billion due to investment in such growth drivers as ABILIFY MAINTENA and REXULTI. The impact on operating profit is flat. Therefore, there is no change from the fiscal 2017 operating profit projection of ¥120.0 billion.

Q3: Are there any plans to change the fiscal 2018 operating profit figure of ¥155.0 billion that is presented as a reference in the Medium-Term Management Plan?

A3: The IFRS-based operating profit forecast initially projected under the Medium-Term Management Plan was ¥215.0 billion, but at the moment we estimate ¥155.0 billion as the forecast operating profit for fiscal 2018. This is due to a decline of approximately ¥30.0 billion in sales of long-listed drugs, approximately ¥10.0 billion in the impact from the unsuccessful development of LuAE58054, and approximately ¥20.0 billion from the impact of the acquisition of Avanir and licensing agreement of vadadustat with Akebia as well as acceleration of R&D investment. We will formally announce the fiscal 2018 projections when we release the full-year financial results in February 2018.

Q4: Abilify MyCite, a digital medicine, has been approved, but the FDA press release stated that its ability to improve patient compliance has not been shown. Will this impede sales?

A4: We believe that the statement will not impede sales. Abilify MyCite is the world's first digital medicine, so we think it will be important to promote it carefully.

Q5:	Even though Otsuka obtained fast track designation for brexpiprazole, which is under development for agitation associated with Alzheimer's dementia, why was it not approved promptly based on the two clinical trials that were conducted? Has the FDA indicated any concerns with the data?
A5:	The FDA has not indicated any concerns with the data in particular. During consultations with the FDA, the conclusion was reached that an additional clinical trial is needed.
Q6:	In terms of the handling of the impairment loss recorded in the second quarter financial results, am I right in thinking that there is no changes to the fiscal 2017 operating profit projection of ¥120.0 billion, even taking the impairment loss into account?
A6:	That's correct.
Q7:	Safety monitoring that includes liver function testing seems to be important in ADPKD. Can Otsuka provide such monitoring properly not only in Japan but also in the U.S.?
A7:	We have made preparations that enable us to provide proper monitoring in the U.S., as well as in Japan and Europe.
Q8:	How long is the study period for the additional trial for brexpiprazole, which is under development for agitation associated with Alzheimer's dementia, and when is it scheduled to commence?
A8:	We will consult with the FDA on the trial plan and develop the protocol from now on, so I cannot discuss the details at present. The trial is scheduled to commence during the first half of fiscal 2018.
Q9:	If the additional trial is needed for the approval of brexpiprazole, the AVP-786 results will come first. What are your thoughts on the distinction between the two agents?
A9:	They have different mechanisms of action, so there is expected to be potential to be able to contribute to an even wider range of patient groups.

Q10: In terms of the conditions for functional drinks in the Nutraceutical Business, could you explain the market trends and share for POCARI SWEAT in Japan?

A10: Sales volume for POCARI SWEAT in Japan fell 0.9% year on year. The sports drink market overall declined in Japan, but the share of the market held by POCARI SWEAT is growing.

Q11: Please tell us what you think about the inability to show consistency on the results of the two Phase III trials for brexpiprazole, which is under development for agitation associated with Alzheimer's dementia, and about the points for which it is thought that approval will be obtained if an additional trial is conducted.

A11: The inconsistency was that the results of the primary endpoint and the secondary endpoint did not match, but this does not mean that the data on efficacy and safety was not consistent. We think that we have gained the understanding of the FDA on efficacy and safety. We hope to increase the probability of success by using the findings obtained from the two trials and reflecting them in the additional trial. We will not disclose the details in view of the competitive situation and other factors.

Q12: LCL-161, which has the same mechanism of action as ASTX660, is being developed in various indications. What are the points of differentiation of ASTX660 from LCL-161?

A12: ASTX660 is a dual inhibitor which inhibits two types of IAP, so it is expected to have a greater effect.

Q13: We heard that sales of ABILIFY MAINTENA in the U.S. for bipolar disorder are going well. Could you please give us some data on prescription breakdown, if any such information is available?

A13: It has not been very long since this indication was added, so there isn't any information yet on the breakdown of prescriptions for each indication. ABILIFY MAINTENA is the only once monthly injection with indications for schizophrenia and bipolar disorder, so it has been highly anticipated by physicians.

Q14: Long-acting injectable drugs had a low penetration rate for bipolar disorder compared with schizophrenia. Has it increased?

A14: It has not been very long since the indication was added, so we don't have any data yet.

Q15: Are there any statistics on reduction in re-hospitalization due to the use of long-acting injectables in bipolar disorder?

A15: In the Phase III trial, we compared period to recurrence, recurrence rate, and period to re-hospitalization and were able to show a significant differences compared to the placebo on all three endpoints. The results obtained show that period to recurrence, which was the primary endpoint, was delayed by about 50%.

Q16: When are the Phase III trials of AVP-786 for agitation in Alzheimer's dementia scheduled to be complete? What is the filing timeline?

A16: The first Phase III trial is scheduled to be complete in July 2018, and the second Phase III trial is scheduled to be complete in December 2019. The filing for approval will be based on the results of these trials.

Q17: Have the Phase III trials for vadadustat finished?

A17: At the moment, we are running four Phase III trials for renal anemia. We are conducting Phase III trials in non-dialysis patients (using/not using erythropoietin) and dialysis patients (using/not using erythropoietin). The completion of the Phase III trials is scheduled for December 2018 for non-dialysis patients and for September 2019 for dialysis patients.

Q18: In terms of the application schedule, will Otsuka apply for approval for non-dialysis patients first?

A18: We will basically file for approval at the same time. We will make decisions in consultation with Akebia.

Q19: I think that the primary endpoints in the Phase III trials for brexpiprazole and AVP-786 were the CMAI score and the NPI score, respectively. Is there a possibility that the primary endpoint for the additional trial of brexpiprazole will be the NPI score?

A19: We are using CMAI as the primary endpoint in the Phase III trials for both brexpiprazole and AVP-786 we are currently running.

Q20: I get the impression that there is a significant milestone revenue in the third quarter at ¥8.4 billion. Are there any amounts other than the milestone payments from Lundbeck?

A20: Other than the one from Lundbeck, the milestone payment for the European approval of LEE011 received from Novartis is included, among other payments.

Q21: How much has been recorded to assets as in-process R&D for SGI-110, which is undergoing Phase III trials for untreated acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS)?

A21: We have recorded approximately ¥25.0 billion for SGI-110 overall as in-process R&D.