

Otsuka Holdings Co., Ltd.

Financial Results Presentation Q3 FY2016 (Three Months Ending September 30, 2016)

Q&A

November 11, 2016

Q1: In the revised full-year plan for fiscal 2016, gross profit was revised upward by ¥5 billion. Is this due to an increase in sales of products with higher profit margins?

A1: Yes.

Q2: The full-year sales plan for *Samsca/JINARC* was revised upward. Are there any factors behind this besides foreign exchange?

A2: The full-year plan was revised upward because sales of this product are performing well globally.

Q3: The full-year sales plan for *LONSURF* was revised upward. Are you expecting sales to increase in the U.S.?

A3: We are expecting sales to increase in the U.S., and we have kept our expectations somewhat conservative.

Q4: What is causing the recent decline in sales performance of *Abilify Maintena*?

A4: The competitive climate has intensified.

Q5: How will the recall of *Calorie Mate Jelly* affect business performance?

A5: We deeply apologize that our voluntary recall has caused a lot of trouble to customers and other parties concerned. Its impact on business performance will be minor.

Q6: The therapeutic effect of SGI-110 seems to be relatively mild. Will this be approved for acute myelocytic leukemia (AML), an indication currently under development?

A6: We are currently conducting a Phase 3 trial in elderly patients with treatment native AML. Whether it is approved or not depends on the trial results. In the future, we plan to conduct Phase 3 trials for recurrent AML and recurrent myelodysplastic syndrome (MDS).

Q7: I believe that you have received a payment from Teva in relation to the patent lawsuit settlement in the U.S. regarding *ABILIFY*. Deducting the disclosed sales for your leading products from your net sales in North America for the pharmaceuticals business, I guess the amount was about ¥10 billion? Is this amount correct?

A7: We are not disclosing the specific amount.

Q8: Growth of *LONSURF* prescriptions in the U.S. is slowing down. Should we expect sales to stay at the current level? What is the coverage of target doctors?

A8: We are not disclosing the coverage of target doctors. We have not yet covered all target doctors, so you can expect future sales to be based on the current level.

Q9: When will you sign a contract regarding an indication of gastric cancer for *Keytruda*, for which you have a sales tie-up for Japan with MSD?

A9: The indications covered by the current contract are melanoma and non-small cell lung cancer. A contract for gastric cancer has not yet been determined.

Q10: The estimated study completion dates of the Phase 3 trials on *REXULTI* for agitation associated with dementia of the Alzheimer's type have been moved up by three to four months. Does that mean you are making good progress? When do you plan to file an application for approval?

A10: We moved up the estimated study completion dates of the trials because patient registration is going well. We are not disclosing the date of application, but the results of the clinical trials should come out in fiscal 2017.

Q11: Sales of *Abilify Maintena* slumped in the third quarter of 2016, but the plan has them returning to an upward trend in the fourth quarter. Why is that? Was there any special factor in the third quarter?

A11: There was no special factor in the third quarter. Growth just slowed temporarily due to the intensifying competitive climate. Going forward, we will further strengthen our marketing efforts, which should lead to sales growth.

Q12: Was the payment from Teva related to the patent lawsuit settlement in the U.S. regarding *ABILIFY* included in the initial plan?

A12: It was not included in the initial plan.

Q13: With respect to estimated operating profit for fiscal 2018 in the Second Medium-Term Management Plan, ¥170 billion $\pm\alpha$, was presented as the reference value, taking into account subsequent events since the ¥200 billion of the initial plan. In light of the present situation, won't it surpass the originally planned ¥200 billion?

A13: New product lines, etc., are growing smoothly, but an upturn in operating profit for the current term is also affected by R&D costs being behind budget and carried forward as well as special factors such as settlement money. Additionally, there will be a need for further growth investments. That is why, at present, there is no change in the forecast (reference value) for operating profit for fiscal 2018 of ¥170 billion $\pm\alpha$.

Q14: What are your sales forecasts for the additional indication of autism for *ABILIFY*, which was newly approved in Japan in September, as well as *Iclusig*, *Mikeluna*, and *Bilanoa*? Which drug do you think will contribute to the sales most?

A14: At this time we cannot comment on definite numbers, but we are not yet anticipating big sales in the current term. We will be implementing measures for each product so that they contribute to the results of the next Medium-Term Management Plan.

Q15: Current sales of *NUEDEXTA* have leveled off. Do you anticipate growth to progress around this rate going forward?

A15: We are aware that the sales growth has leveled off. We will continue to strengthen our sales efforts.

Q16: With the accounting standards being changed to International Financial Reporting Standards (IFRS), ¥12.5 billion in share of profit of entities accounted for using the equity method will be added to operating profit. What is the breakdown by segment? Will consumer segments move significantly into the black?

A16: We are not disclosing the breakdown by segment for the increase in operating profit attributable to the adoption of IFRS, but the increase in the consumer segments is large.

Q17: It seems that prescriptions for *Aristada*, which is a competitor of *Abilify Maintena*, are expanding. What kind of medical institutions are adopting it?

A17: We are not disclosing a detailed analysis. Intensification of the competitive climate has resulted in some price competition.

Q18: Can you give us details on the suspension of development of AVP-786 for major depression?

A18: We cannot comment on the detailed data, as it has not yet been announced. We will shift resources to development of other indications such as residual symptoms of schizophrenia and disinhibition.

Q19: OPA-15406 is a PDE4 inhibitor, which belongs to the same class with Anacor's drug which Pfizer acquired. What is the outside assessment?

A19: We cannot comment on the detailed data, as it has not yet been announced. We will shift resources to development of other indications such as residual symptoms of schizophrenia and disinhibition.