Otsuka Holdings Co., Ltd.

Financial Results Presentation Q2 FY2014

(Three Months Ending September 30, 2014)

Q&A

November 13, 2014

Otsuka
Otsuka-people creating new products for better health worldwide

Q1:	Is it correct to understand that the amount of branded prescription drug fee not factored into the forecasts established at the beginning of fiscal 2014 is another ¥8.2 billion?
A1:	That's correct.
Q2:	I get the impression that the progress rate for research and development expenses is poor. What is the progress forecast for the remaining three months?
A2:	There is a possibility that the full year forecasts for FY 2014 will not be met, because we have carried out a review of research and development themes based on our order of priority.
Q3:	What is the status of the review of Tolvaptan for Autosomal Dominant Polycystic Kidney Disease (ADKPD) in Europe?
A3:	We believe the review is proceeding on schedule. Tolvaptan was filed in December 2013 for ADPKD, so the review by European Commission is expected to take about 18 months under the usual schedule.
Q4:	What are the sales for Abilify Maintena in the US? When do you plan to begin disclosing sales?
A4:	According to IMS data, sales are approximately ¥8.0 billion for April – September period in 2014. We are considering sales disclosure from FY 2015.
Q5:	Is the establishment of the sales structure for Abilify Maintena progressing smoothly overseas?
A5:	It's smooth. The pace of sales is expected to go up by summer of 2015.

Q6: Could you tell us about any plans for future inventory adjustments ahead of the expiry of ABILIFY patent in the US in 2015?

A6: We are at the stage of proceeding with progressive estimates regarding inventory adjustments, but I cannot provide a concrete answer.

Q7: Regarding the status of review for Brexpiprazole in the US, is it possible that an FDA Advisory Committee will be held?

A7: At present, we have not been contacted by the FDA on that.

Q8: According to FACT BOOK, the reasons for discontinuing development of S-1 in the US are the changes in the investigational and clinical practice landscape that the study focused on. Is it impacted by ramucirumab, which was approved recently?

A8: Changes in the external environment, including the ramucirumab approval and other issues, were one of the factors.

Q9: What are the sales for Lonsurf in Japan?

A9: It was launched in May 2014 and the cumulative sales to September 2014 were just under ¥2.0 billion.

Q10: Have you already launched the dual chamber syringe formulation of Abilify Maintena in the US?

A10: We plan to launch it in January 2015.

Q11: What is your planned timing for considering shareholder returns?

A11: We will consider a flexible shareholder returns policy including share buybacks depending on income, but we have not decided on any details.

Q12: Is it correct to understand that ABILIFY's contribution to the increase in gross profit is big?

A12: New drugs are contributing as well, but you can consider the ABILIFY contribution to be around 80%. We do not disclose concrete costs.

Q13: ABILIFY sales in the US are significant at present, but will the depreciation of the yen have a positive or negative impact on income in FY 2015 when the patent expires?

A13: With the decline in sales of ABILIFY in the US, the impact of the exchange rate on operating income in FY2015 is expected to be negligible.

Q14: The ABILIFY patent has already expired in Europe. What is the situation with generic drugs?

A14: At the moment, ABILIFY generics in Europe have no impact as they have already been approved but not been launched yet.

Q15: The Phase II results for SGI-110 on myelodysplastic syndrome (MDS) are scheduled to be presented at the 2014 American Society of Hematology, but what is the point of differentiation from Dacogen? Is the only difference in the dosage forms of intravenous versus subcutaneous injection?

A15: Based on the clinical data, we believe that the safety is comparable, but the efficacy is slightly superior.

Q16: Although sales of ABILIFY exceeded the forecast, overall sales did not meet the forecasts. What do you think are the reasons for this? Japanese pharmaceutical and nutraceutical businesses failed to meet the forecasts, but which one of them gave major impact?

A16: For pharmaceuticals business in Japan, it's true that the impact of NHI price revisions, namely price reductions of long-listed products and temporary demands for new products with premiums before consumption tax hike were greater than expected, but we believe that failure to meet FY2014 forecasts was mainly due to nutraceutical business.

Q17: Why have you not revised the full year forecasts?

A17: Although sales fell short of forecasts for the first half of FY 2014 by about ¥6.0 billion, we expect to be able to achieve them for full year.

Q18: With respect to nutraceutical business, I understand that things have been tough for the entire domestic beverage industry, but I have the impression that Otsuka has suffered more than the industry average. What measures will you take in the future?

A18: In addition to unseasonal weather during the summer, we struggled after the increase in consumption tax as a result of our sales policy of avoiding price-focused approach. We are currently dealing with structural reforms in order to get out of this situation. We also plan to expand our sales overseas where profitability is high.

Q19: I get the impression that growth in domestic sales of new drugs is weak. What factors are involved in the failure of E Keppra and ABILIFY to meet the forecasts?

A19: With regard to the new drugs with premiums (to promote the development of new drugs and eliminate off-label use), there was a big impact from temporary demands prior to the increase in consumption tax. In August and September 2014, sales recovered and remained steady. As for E Keppra, we expect that sales will increase further after we obtain the additional indication of monotherapy in partial seizure epilepsy for which we filed in March 2014. .

Q20: What points of differentiation does TAS-121 have from competing products, including that of AstraZeneca?

A20: In order to show the difference, we need to confirm the compound profile with clinical trial results.

Q21: What points of differentiation does TAS-119 have from competitors' products?

A21: Takeda's compound, which is in the most advanced stage, is being developed as monotherapy, but we are considering development as adjunct therapy to taxanes. Our non-clinical data show that selectivity of TAS-119 for Aurora A kinase is higher than those of the competitors.

Q22: What is the geographic breakdown of Tolvaptan sales? What indication is the sales growth driver in Japan?

A22: The sales breakdown is just under ¥8.0 billion in Japan, just over ¥4.0 billion in the US, and just under ¥2.0 billion in other areas. In Japan, sales increase come from the existing indications of cardiac edema and hepatic edema. Early post marketing surveillance has been completed for ADPKD, but we do not expect a sharp increase in sales due to strict total management with ongoing complete count survey.

Q23: When will you complete the filing for TAS-102 in the US? Has it been designated for priority review?

A23: We think that filing will be completed by the end of 2014. Designation for priority review is yet to be determined.