

# Otsuka Holdings Co., Ltd.

## Financial Results Presentation Q3 FY2015 (Three Months Ending September 30, 2015)

**Q&A**

**November 13, 2015**

Q1: Were there any significant changes between the provisional accounting treatment up until the results for the second quarter of fiscal 2015 and the accounting treatment after it was finalized accompanying the acquisition of shares in Avanir Pharmaceuticals? What is the impact on business results for the current fiscal year?

A1: There were no significant changes from the assumptions at the time of the announcement of the results for the second quarter of fiscal 2015. Up until the results for the second quarter of fiscal 2015, the total share acquisition cost other than cash and other assets and liabilities was provisionally recorded to goodwill, but the accounting treatment has now been finalized, with allocations to intangible assets, inventories, goodwill and so on, respectively. We forecast that this will produce a negative impact of at least ¥30.0 billion on full-year operating income for fiscal 2015, including the buildup of investment for growth in addition to the amortization expenses, product inventory revaluation, and acquisition costs.

Q2: What is the impact of inventory revaluation for *Nuedexta*?

A2: ¥6.8 billion for the third quarter of fiscal 2015 and about ¥8.3 billion for the full year.

Q3: What are the factors in the improvement of profits in nutraceuticals business? Will it be sustained?

A3: In addition to favorable sales of *Pocari Sweat* in Japan and China, cost control has been successful. The expansion in supplement sales in the United States has also contributed to profits. While there are seasonal factors with regard to beverages, we believe that profits will continue to improve in the future if the business in the United States and China remains favorable.

Q4: What is the situation for *REXULTI* following the United States launch? Are you disclosing sales?

A4: We are not disclosing sales, but the number of prescriptions is expanding steadily.

Q5: With regard to accounting treatment accompanying the acquisition of shares in Avanir Pharmaceuticals, is it correct to understand that the majority of in-process R&D is for AVP-786?

A5: AVP-786 is the main constituent, but it also includes AVP-825. We do not disclose the amount for each product.

Q6: Is it correct to interpret the fiscal 2018 global sales of *ABILIFY* shown in the graph on page 8 of the results briefing materials as around ¥90.0 billion?

A6: You can take it to be about that. The figure for fiscal 2018 global sales of *ABILIFY* shown in the graph is the value calculated when we formulated the Second Medium-Term Management Plan.

Q7: In the United States, the value of *ABILIFY* sales has not declined that much in comparison with the decline in the number of prescriptions. Are there any special factors related to rebates and so on?

A7: There aren't any special factors.

Q8: In the revised full-year forecasts for fiscal 2015, the fourth quarter results outlook for *ABILIFY* in the United States is \$110 million. What are the assumptions for this forecast? Prescriptions for October only fell around 10% compared to the third quarter. Also, what volume of prescriptions do you expect to maintain in fiscal 2016?

A8: Our forecasts are conservative, taking into consideration: the fact that the gross-to-net discount rate is expected to expand because the percentage of prescriptions under Medicaid will increase further; and changing market trends due to the entry of new generic products. I'd like to explain the forecasts for fiscal 2016 when we announce the full-year projections.

Q9: Could you explain current therapies, unmet needs and the promise of AVP-786, currently under development, in relation to residual schizophrenia? Also, is AVP-786 a monotherapy or an adjunct to existing antipsychotic drugs?

A9: The mainstay treatment for schizophrenia is medication for positive symptoms such as hallucinations and delusions. However, when these treatments are continued long-term, depressive negative symptoms such as lethargy and decrease in activity appear. This is residual schizophrenia. There are currently no medications that demonstrate adequate clinical efficacy against it. We are promoting development of AVP-786 with the expectation that it will be used in addition to existing anti-psychotic drugs to combat these symptoms.

Q10: Could you explain the current business strategy regarding digital medicine, the reason you are providing it with *ABILIFY* and not *REXULTI*, and whether it is under consideration for *REXULTI* in the future?

A10: When we started developing digital medicine, *REXULTI* was still at the clinical trial stage. We will explain the business strategy after its approval. It is uncertain whether digital medicine will be considered for *REXULTI*.

Q11: What is the current outlook for the ¥100.0 billion in operating income for fiscal 2016 announced in the Second Medium-Term Management Plan?

A11: We are not optimistic about achieving ¥100.0 billion in operating income in fiscal 2016, due to negative impacts from such factors as exchange rates, the acquisition of Avanir Pharmaceuticals, and the government policy to promote generic drugs in Japan. These present factors all represent differences from the assumptions made when formulating the Second Medium-Term Management Plan. We are currently aiming to achieve our projections by offsetting these negatives with growth in areas such as global products. I'd like to explain the concrete forecast amounts when we disclose full-year projections for fiscal 2016.

Q12: Have you disclosed the sales performance for *Nuedexta*?

A12: We haven't disclosed it. We plan to start disclosing it next fiscal year.

Q13: Peak sales for *Nuedexta* were disclosed as ¥50.0 billion, but where are the PBA patients? What is the evaluation and reaction from the market?

A13: Sales remain firm, growing more than 30% year on year. There are over two million potential PBA patients in the United States. It is mainly diagnosed in long-term care facilities, nursing facilities, and general internal medicine. The number of patients prescribed *Nuedexta* is still just a single-digit percentage of the potential number of patients.

Q14: What is the distribution of the underlying diseases of patients prescribed *Neudexta*?

A14: We do not disclose the percentages. We are currently preparing an application in order to add study results for traumatic brain injury to promotional materials, since this accounts for the largest number of potential patients. We expect to gain even more cases.

Q15: You project a loss for the fourth quarter of fiscal 2015, but is this conservative considering the current sales situation for *ABILIFY* in the United States?

A15: The projection could go up depending on the situation of *ABILIFY* in the United States.

Q16: In the projections for the fourth quarter of fiscal 2015, R&D expenses have gone up and SG&A expenses other than R&D expenses have gone down. Is it correct to understand that full-year SG&A expenses for fiscal 2016 will follow the same trend as in the fourth quarter of fiscal 2015?

A16: In the fourth quarter, there will be special factors related to accounting treatments, including the exchange rate, and it is difficult to forecast the situation for the next full fiscal year based on that result alone.

Q17: Is it correct that SG&A expenses must be reduced more than the current fiscal year to achieve the projections for fiscal 2016 stated in the Second Medium-Term Management Plan?

A17: We are currently implementing a cost reduction program. We intend to continue pursuing this program in fiscal 2016 and will keep working to reduce SG&A expenses going forward.

Q18: What is the timeframe for the release of Phase III trial data for Lu AE58054 in Alzheimer's dementia? In the Lundbeck conference call, there was a comment that it is expected in the first quarter of fiscal 2017.

A18: Lu AE58054 is a Lundbeck product, and Phase III trial is also being led by Lundbeck. Our understanding of the timing for the release of the data is the same as Lundbeck's understanding.

Q19: In the *REXULTI* label for the United States, a black-box warning on use for behavioral disorders in Alzheimer's dementia has been granted, so is it going to be possible to gain an indication for agitation? Is there any possibility of approval through demonstration of safety alone in the clinical trial results?

A19: The same black-box warning has been attached to all anti-psychotic drugs because an increase in the risk of death from cerebrovascular disorders has been reported in dementia patients from the clinical trial results for a wide range of anti-psychotic drugs. With regard to *REXULTI*, we have been conducting clinical trials in this therapeutic area and believe that differentiation from other anti-psychotic drugs will be possible if we gain the indication. However, as it is a comparative trial with placebo, we consider that it will not be approved without demonstrating efficacy as well as safety.