

Otsuka Holdings Co., Ltd.

Financial Results Presentation FY2015 (Year Ending December 31, 2015)

Q&A

February 12, 2016

Q1: We thought the growth of new drugs and the NC business would be able to absorb the negative effects on the operating income that emerged after the formulation of the Second Medium-Term Management Plan, such as foreign exchange fluctuations and amortization burdens associated with the acquisition of Avanir Pharmaceuticals, Inc. Are stricter operating conditions, such as those involving four medicines sold in Japan designated for repricing following market expansion, the cause of the downward revision of the operating income forecast for fiscal 2016 from the 100 billion yen stated in the Second Medium-Term Management Plan to 70 billion yen?

A1: We revised our consolidated operating income forecast downward from 100 billion yen stated in the Medium-Term Management Plan to 70 billion yen on this occasion in response to the effects of foreign exchange fluctuations and the acquisition of Avanir Pharmaceuticals, Inc. There are external factors we cannot control, such as repricing for market expansion and price reduction of long-listed drugs. However, we will develop new drugs and expand our NC business under such conditions. We are steadily implementing measures for diversifying revenue structure, a direction we spelled out in our Second Medium-Term Management Plan.

Q2: Prescription number for *Abilify* remains higher than your projection in the US. Is your sales plan for fiscal 2016 conservative?

A2: *Abilify* still occupies slightly more than 20% of prescriptions in the US as of January 2016. We predict *Abilify*'s sales will be not as much as the current prescription level for the impact of generic drugs grows and the gross-to-net discount rate expands because the percentage of prescriptions under Medicaid will increase further. We adopted the latest forecast taking into account the difficulty involved in predicting future conditions.

Q3: Have you just made an exchange rate adjustment to an estimate of the fiscal 2016 sales plan for *Abilify* in the US in the Second Medium-Term Management Plan?

A3: We raised our fiscal 2016 sales projection for *Abilify* in the US from the one in our Second Medium-Term Management Plan. We made an exchange rate adjustment after raising the forecast.

Q4: Excluding the effects of foreign exchange fluctuations and amortization burdens associated with the acquisition of Avanir Pharmaceuticals, Inc., Otsuka Holdings revised its forecast for operating income from existing businesses in fiscal 2016 upward from 100 billion yen to 110 billion yen. Does this upward revision take factors other than major assumptions into account, such as a sales growth forecasted for *Abilify* in the US?

A4: We took cost reduction and various other factors into account in our fiscal 2016 plan. Our forecasts for fiscal 2018 are reference figures that take only major preconditions after the formulation of the Second Medium-Term Management Plan into account. Foreign exchange fluctuations and investment involved in acquiring Avanir Pharmaceuticals, Inc. represent the major changes in the preconditions. They had an extremely large effect on our initial estimates. Other unexpected changes will arise as we move businesses forward. But their effects will fall within a certain scope.

Q5: I heard factors, such as the degree of achievement for the Second Medium-Term Management Plan, would determine the coefficient for performance-linked stock options introduced on this occasion. Which management index do you attach importance to in determining the coefficient?

A5: Net sales and operating income are two management indexes we consider to be our main targets. But we must materialize our investment to sustainable growth as medium- and long-term results, instead of managing businesses just to produce figures. The Second Medium-Term Management Plan will end in 2018, but Otsuka Holdings will continue on after that. We must hand over our assets to the next generation. Our sales structure will be more complex, and the Group will become more difficult to manage. The combination of all these factors will be our index. We need more than just temporary results. Stock options are our incentive plan to adequately reflect this background of factors, based on our understanding of what each factor is.

Q6: Pfizer Inc. suspended the development of a compound with the same mechanism of action as Lu AE58054. What progress has been made at your company? Are you planning to file for approval for the drug by the end of fiscal 2017?

A6: We are aware that it is not easy to develop a therapeutic agent for Alzheimer's disease. We are currently undertaking three P3 trials for Lu AE58054 on a scale of 700 or more patients. The results of those tests are scheduled to come out in 2017.

Q7: Is donepezil used in combination in all three P3 trials for Lu AE58054?

A7: Donepezil is used in combination with Lu AE58054 in two of the three P3 trials. General acetylcholinesterase inhibitors including donepezil are used in combination in the third P3 trial.

Q8: What is the breakdown of 16 billion yen projected as milestone and upfront revenue in fiscal 2016?

A8: Time-weighted revenue from *Lonsurf*'s upfront revenue and milestone for its approval in Europe associated with the license agreement with Servier account for more than half of the projected 16 billion yen. In addition, this amount includes time-weighted revenue from Bilastine's upfront revenue and milestone for its approval in Japan associated with the co-marketing agreement with Meiji Seika Pharma. The amount does not include upfront revenue of 22 million US dollars from the agreement with Medimetrix in the US, which was announced on February 9, 2016, for licensing OPA-15406, a drug developed for the treatment of atopic dermatitis.

Q9: I understand that Otsuka Holdings revised the target operating income set in its Second Medium-Term Management Plan downward, prioritizing prior investment for sustainable growth in the period from 2018. Indications for *Nuedexta* and AVP-786, which are growth drivers, appear to be spreading horizontally. Does this mean these drugs may still have potentials for various indications? What points we should direct our attention to?

A9: We are currently undertaking various investigative developments for drug candidates of Avanir Pharmaceuticals, Inc. In the field of psychiatric diseases, we have accumulated knowledge and experience focused on those involving dopamine and serotonin pathways. But the potential of dextromethorphan and quinidine combination remains unknown. For that reason, we are making investments, anticipating various potential.

Q10: I understand you will market *Onzetra Xsail* (AVP-825) on your own. Will you make additional investments in your sales force?

A10: We are planning on doing that. Interesting possibilities emerged as we thoroughly investigated the needs of migraine patients. *Onzetra Xsail* (AVP-825) is an innovative drug-device combination product.

Q11: Give us the details of an impairment loss in fiscal 2015.

A11: We posted a loss on the impairment of the intangible fixed assets, etc. of a subsidiary that undertakes the parenteral nutrition business in India. The loss resulted mainly from intensified price competition and reduction in prices of high-cost soft bags owing to drug price controls under the changed economic conditions in India. We also posted an impairment loss at a subsidiary in the film business of Otsuka Chemical Co., Ltd. due to the downsizing of smartphone market.

Q12: Onset of action of oral sumatriptan, which is now used widely, is relatively quick. Does *Onzetra Xsail* (AVP-825) express its effects faster than oral sumatriptan?

A12: Compared to tablets, *Onzetra Xsail* (AVP-825) requires a shorter period to express its effects.

Q13: Your product was designated under the Prior Designation System (Sakigake Shinsei) established by the Ministry of Health, Labour and Welfare. Please provide us with an outline of its designation.

A13: A liquid adhesion-preventive agent made from trehalose under development by Otsuka Pharmaceutical Factory Co., Ltd. has been designated under this System. This agent reduces postoperative adhesion formation throughout the abdominal cavity.

Q14: Is the adhesion-preventive agent used after gastrointestinal surgical operations?

A14: That's right. The agent is used for operations of the entire abdomen.