Otsuka
Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd.

Financial Results Presentation FY2016

(Year ending December 31, 2016)

Q&A

February 14, 2017

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Q1: With regard to the operating profit forecasts for FY2018, ¥170.0 billion was indicated as a reference figure at the time of the announcement of results for FY2015, reflecting the impact of certain events that followed the formulation of the medium-term plan, such as the effect of exchange rates and the Avanir Pharmaceuticals acquisition. You've now revised the forecast again to ¥155.0 billion. Are R&D expenses and long-listed drugs the additional factors?

A1: This time, we have calculated a reference figure that takes account of the impact of the external environment, which has changed significantly since we formulated the Second Medium-Term Management Plan, and factors that were uncertain at that time. Primarily, there is an increase in the amount of negative impact from long-listed drugs in Japan and a decrease in forecast contribution to profit due to the unsuccessful clinical trials of Lu AE58054. There has been steady progress in the vital drivers of sustained growth. We are making steady progress on building the foundation for diversifying the earnings structure, which is the main feature of the Second-Term Management Plan, and we have entered the regrowth stage when indexed on operating profit before investment of R&D expenses (R&D expenses + operating profit). There is no change in our orientation of prioritizing R&D expenses for sustained growth over the medium to long term.

Q2: We would like you to disclose results promptly when clinical trials complete as other global companies do.

A2: We hope to disclose results promptly, taking your observation into account.

Q3: What is your objective in acquiring the rights to develop and market vadadustat in the U.S.? There are few renal area-related products that Otsuka is developing in the U.S. at present, and the results of the additional Phase III trial for tolvaptan in Autosomal Dominant Polycystic Kidney Disease (ADPKD) is being awaited as well. There are also competing products already developed in the same category.

A3: One of our business models is to in-license assets and new technologies that we do not have and integrate them with our own drug discovery assets to develop further. We hope to develop the renal area into another pillar of our core therapeutic areas in addition to the central nervous system (CNS) and oncology areas.

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Q4:	What is “the global category leader” that Otsuka is aiming for in the oncology area?
A4:	The environment for the oncology area continues to change, and is profound. Unmet needs exist in a variety of forms and require a long battle. In terms of category, *LONSURF* is an antimetabolite (conventional anticancer drug), but we think that it is addressing needs that have not been resolved by existing drugs. Epigenetics drug discovery by Astex Pharmaceuticals is also opening up a lot of possibilities such as combination therapies with other drugs. We have also implemented various initiatives at various research stages.
Q5:	Did you account for asset sales and impairments in the FY2017 operating profit projection of ¥120.0 billion?
A5:	Special factors such as impairments are not included in the ¥120.0 billion.
Q6:	In order to achieve the operating income projection of ¥200.0 billion for FY2018 made at the time when the Second Medium-Term Management Plan was formulated, are you going to secure profit through sale of assets etc. or aim to achieve it through organic growth, or are you going to abandon the achievement of ¥200.0 billion?
A6:	It is important for management to grow the business continuously and in a stable manner. While the figures are obviously an important element, we also want to emphasize the significance of steadily building up the vital business base for growth.
Q7:	We’ve heard how you are aiming for further growth for tolvaptan in the future with the ADPKD indication. However, is there any assurance that the development of the brand as a therapy for ADPKD will be unaffected even when generics are launched after the hyponatremia patent expires?
A7:	If the ADPKD indication is approved in the U.S., the drug will obtain a seven-year exclusivity period under orphan designation. We have recognized the risk that generics for *SAMSCA* will be used. Product growth also is expected in Japan and Europe.
Q8:	The Phase III trials for Lu AE58054 failed. What is the future impairment risk?
A8:	Impairment for this drug has already been included in R&D expenses for FY2016.

Q9:	Could you indicate the future development timeline for the *REXULTI* long-acting injectable? Will you be able to start Phase III trial immediately after the end of Phase I trial?
A9:	The timeline will be determined in consultation with Lundbeck, while looking at the results.

Q10:	Profit in the fourth quarter of 2016 looks to have declined considerably. Is this due to impairments and an increase in growth investment?
A10:	In the fourth quarter of 2016, in addition to increases in research and development expenses and growth investment as expenses, Lu AE58054 impairment of about ¥15.0 billion was included in fourth quarter research and development expenses under IFRS. Under Japanese GAAP, a upfront payment of USD125 million relating to the vadadustat development and marketing alliance was included in research and development expenses.

Q11:	Has the trail protocol for the clinical trial targeting the agitation associated with dementia of the Alzheimer's type indication for *REXULTI* been agreed with the FDA and the EMA?
A11:	The evaluation criteria have been established in consultation with the FDA. The primary endpoint is the Cohen-Mansfield Agitation Inventory (CMAI), which evaluates agitation.

Q12:	While sales projections for FY2017 are up ¥65.0 billion year on year, substantial operating profit, excluding special factors such as impairments and milestone payments, will be largely flat in FY2016 and FY2017. Could you indicate a breakdown of the increase in expenses in FY2017?
A12:	FY2016 operating profit includes the impact of special factors such as the settlement payment from Teva Pharmaceutical Industries, milestone income, and impairments. Substantial operating profit, deducting those factors, will be roughly the same in FY2016 and FY2017. Impairments for in-process R&D such as Lu AE58054 have been accounted for in FY2016 R&D expenses. Compared with R&D expenses in FY2016 with the amounts deducted, R&D expenses in FY2017 are expected to increase slightly by ¥30.0 billion. Therefore, operating profit before investment of R&D expenses is expected to increase by ¥30.0 billion.

Q13:	Could you tell us under what kind of category the digital health solutions business will be disclosed in Otsuka's performance in the future? Will it be service revenue, or social contribution, or will it be accounted for as the sale of some kind of product?
A13:	We are aware that it is a sector with extremely high potential. We are currently considering what form specific development of its value will take in the future.

Q14:	Will the joint business with IBM be incorporated globally in the future?
A14:	We have established a joint venture with IBM in Japan to develop data analysis and information provision services to Japanese psychiatric hospitals. We have also partnered with IBM in a digital solutions business for payers operating in the U.S.