Otsuka Holdings Co., Ltd.

Financial Results Presentation FY2017

(Year ending December 31, 2017)

Q&A

February 14, 2018

Q1: Regarding the fiscal 2017 results, you commented at the end of the third quarter that it would be possible to cover the impairment loss and achieve the operating profit projection of ¥120 billion. What changed in the fourth quarter? What kind of expenses arose specifically?

A1: In addition to the additional growth investment for new products, which I explained, the main factors were consulting expenses and study expenses, which were more than expected at the time of the third quarter, and an additional ¥2.3 billion in impairment loss. Also, R&D investment for vadadustat, centanafadine, fremanezumab, and others increased beyond initial expectations.

Q2: Are sales for autosomal dominant polycystic kidney disease (ADPKD) in the U.S. included in the fiscal 2018 sales projections for *Samsca/JINARC*?

A2: Yes, we have factored U.S. sales for ADPKD into the projections.

Q3: Could you explain why you extended the Phase III trial of SGI-110 for treatment-naïve acute myeloid leukemia?

A3: We were supposed to carry out the final analysis at the point when the planned number of events was reached, but as that was delayed, we are in the process of follow up.

Q4: The fiscal 2017 results for *NUEDEXTA* are not good. Has an impairment test been performed and passed?

A4: We have performed an impairment test for *NUEDEXTA*, and it passed without any problems. Also, we have been rebuilding the marketing organization at Avanir since mid-2017, and plan to continue the active implementation of marketing strategies such as DTC.

Q5: Is there any possibility that you will increase the forecast dividend in the Second Medium-Term Management Plan above ¥100?

A5: We plan a dividend of ¥100. We will provide stable returns for shareholders continuously.

Q6: Regarding the alliance with Lundbeck, the agreement is that in-licensing rights for the remaining three compounds are for ten years starting in 2011. Is there any possibility of extending this period in the event that the rights are not exercised within the term of the agreement?

A6: Any extension to the term of the agreement is yet to be determined.

Q7: Regarding the status of the Phase III trial of AVP-786 for agitation associated with Alzheimer's dementia, could you explain why readout of the first Phase III trial results, which was scheduled for during fiscal 2018, has been delayed?

A7: There were some delays in recruitment for the first Phase III trial, and the trial period was extended. We plan to file a manufacturing and marketing application based on the results of two pivotal Phase III trials. As the second trial is proceeding according to its initial schedule, it does not change the expected timing for the filing.

Q8: The trial progress status of the Phase I trial for the long-acting injection for brexpiprazole that was published on Clinicaltrial.gov was "terminated." Could you tell us the current status?

A8: Two formulations, namely an intramuscular formulation and a subcutaneous formulation, are currently under development.

Q9: With regard to SG&A expenses, you said that you made additional investments in the fourth quarter of fiscal 2017, but plan to reduce this year-on-year in fiscal 2018. Could you tell us about your approach to SG&A expenses in the future?

A9: SG&A expenses for fiscal 2017 included ¥27.3 billion in impairment loss. SG&A expenses excluding impairment loss will increase by approximately ¥14.0 billion in the fiscal 2018 projections. Co-promotion fees for products on which we are collaborating with Lundbeck such as *Abilify Maintena* and *REXULTI* will increase in tandem with rising sales, but we will work to optimize other expenses.

Q10: The fiscal 2018 sales projections for *NUEDEXTA* seem aggressive. What kind of measures are you planning specifically aimed at achieving the projections?

A10: We will aim to achieve the projections through the active implementation of media strategies, such as DTC, in marketing.

Q11: Why are you conducting the Phase II trial for the *Samsca* prodrug (OPC-61815) in Japan rather than globally? Isn't there also a need in Europe and the U.S.?

A11: There was a high need for the injection in clinical settings in Japan where *Samsca* is indicated for cardiac edema, so we are conducting the Phase II trial for OPC-61815. We are currently reviewing the need in Europe and the U.S., but potential may be lower than in Japan.

Q12: The fiscal 2018 U.S. sales projections for *Samsca/JINARC* seem low to me, if ADPKD is included. What is the reason for that?

A12: I cannot comment on that at the current time because sales will be affected by the drug price and penetration rate. The market potential is high, but ADPKD is a hereditary disease, and we plan a careful roll-out.

Q13: Are you planning to conduct *Samsca/JINARC* marketing activities for ADPKD in the U.S. with the current *Samsca* team?

A13: Yes.

Q14: When will the launch of the two-month formulation of *Abilify Maintena* be? *Abilify Maintena* sales are expanding due to the approval of the bipolar disorder indication. If the two-month formulation is approved, will it contribute to further sales growth?

A14: At present, the two-month formulation is undergoing the Phase I trial, and I cannot comment on the specific timing of the launch. However, we are making development efforts to ensure an early launch. As *Abilify Maintena* is the only four-week formulation for bipolar disorder, it has been receiving positive reputations in clinical settings. We are promoting development of the two-month formulation in the belief that it will also contribute to sales growth of *Abilify Maintena*.

Q15: Could you give us a breakdown of the ¥12.0 billion in milestone and upfront revenue in the fiscal 2018 projections?

A15: Based on the change in an accounting standard (IFRS 15; Revenue from contracts with customers) beginning in fiscal 2018, milestone income will be recorded proportionately over the contract period, including the portion that was recorded to sales in the past. In addition to proportionately recording milestone and upfront revenues for *Abilify Maintena* and *REXULTI* received from Lundbeck in the past, the breakdown of ¥12.0 billion in the fiscal 2018 projections includes the proportionate recording of the milestone for European approval of *REXULTI* for schizophrenia scheduled to be received during fiscal 2018, as well as income relating to Taiho Pharmaceutical's *LONSURF* and *Bilanoa* and others. New cash revenue in for fiscal 2018 will be the milestone payment of $50 million (to be recorded proportionately) for European approval of *REXULTI* for schizophrenia in addition to several hundred million yen from others.

Q16: Why did operating profit for the Consumer Products Business increase in the fiscal 2017 results?

A16: The Consumer Products Business experienced profit growth from ALMA S.A. and CG Roxane LLC in the form of equity in earnings of affiliates, which saw profit rising from ¥11.5 billion in fiscal 2016 to ¥13.3 billion in fiscal 2017. The difference also looks bigger year-on-year because the business recorded ¥4.6 billion in impairment loss in fiscal 2016.

Q17: As for the development of AVP-786 for traumatic brain injury (TBI), does it also include TBI from sport-related accidents in addition to accident-related injury?

A17: As TBI results from a variety of accidents, sport-related TBI patients will also be included in the trial.

Q18: In AVP-786 development for intermittent explosive disorder (IED), I get the impression that patient recruitment in clinical trials will be difficult as patients do not have insight into their condition.

A18: As you point out, there are some cases in which IED patients have no insight into their condition, so recruitment might be difficult. We would like to conduct the current Phase II trial carefully.