Otsuka Holdings Co., Ltd.

Financial Results Presentation Q1 FY2019
(Three Months Ending March 31, 2019)

Q&A

May 14, 2019
Q1: Am I correct in understanding that costs such as R&D expenses have been brought forward and the rate of progress with income has been slow, but the performance of actual businesses, including sales for JYNARQUE, has been steady? Will these R&D expenses continue to increase going forward?

A1: Revenues have been steady, including for JYNARQUE. R&D expenses increased significantly year on year, but are in line with forecasts for this fiscal year.

Q2: The phase 2/3 clinical study for the negative symptoms of schizophrenia of AVP-786 has begun. I was under the impression that the diseases that AVP-786 has targeted so far have often been overactive symptoms. Is it also effective in negative symptoms?

A2: AVP-786 acts on NMDA receptor, Sigma-1 receptor and multiple other receptors. A wide range of clinical data on the effects of these receptors on negative symptoms has been reported. We started phase 2/3 study because the POC study conducted before this trial also showed good results.

Q3: The first phase 3 trial results, evaluating AVP-786 for agitation associated with Alzheimer's dementia, showed that, of the two doses, only one showed a significant difference in the primary endpoint. However, were there enough data to file for approval in the future? Was there a dose dependency?

A3: From the beginning, we had planned to decide on whether we would apply for approval based on the two phase 3 test results. We cannot yet disclose details on the data at this point, including information on dose dependency.

Q4: The evaluation results for cardiovascular events with roxadustat, the competitor for vadadustat, have been released. In the US application, major adverse cardiovascular events (MACE) is used, and in the European filing MACE+ is used. What are the endpoints and strategies for vadadustat?

A4: Four pivotal phase 3 studies are currently underway, two for dialysis patients and two for non-dialysis patients. Both are non-inferiority tests relative to darbepoetin with MACE and an increase in hemoglobin as the endpoints.
Q5: Please tell us about the factors behind the strong performance for JYNARQUE in the US. When the results for fiscal 2018 were released three months ago, you explained that the drug had been prescribed to about 200 patients per month. What is the most recent figure?

A5: Our first priority has been registering physicians in the Risk Evaluation and Mitigation Strategy (REMS), and this is moving ahead smoothly now. Patient registration has exceeded our plans. As of the end of 2018, the drug had been prescribed to about 2,000 people, including patients who had continued over from the clinical trial. In 2018, it was prescribed to about 200 new patients every month. We had expected the same rate in January-March 2019, but it was actually about 250 per month, exceeding our expectation. We believe that this favorable progress is due to the successful start of REMS operation and steady progress in negotiating with payers and insurance reimbursement.

Q6: Earnings of N&S and Pharmavite are poor. You mentioned in the presentation that the transient factors are currently being resolved, but this explanation pertains to Pharmavite, whereas in the case of N&S, the entry of competitors is driving the low earnings. Given this, can we expect these conditions to continue?

A6: As you mentioned, the decline in revenue for Pharmavite is due to a one-off factor of severe weather conditions in the US, and sales recovered in April. About half of the decline in revenue for N&S is due to the impact of exchange rates, which is an external factor. We are completely overhauling our management team and moving ahead with new initiatives. As of the first quarter, there were no results as of yet, but we are striving to generate results within this fiscal year.
Q7: The tax rate was high in the first quarter. Will this continue in the first half and the full fiscal year?
A7: We adopted the new accounting standard “IFRIC 23 Uncertainty over Income Tax Treatments” from the beginning of this fiscal year. With this standard, in cases in which there is a possibility that the tax treatment used by a company may not be approved, tax liabilities are recognized using estimates based on conditions on the last day of the fiscal year. Since we posted tax liabilities in the first quarter as transient costs based on this standard, the tax liability rate increased. We expect the impact to decline for the full year.

Q8: The first phase 3 study evaluating AVP-786 for the treatment of agitation associated with Alzheimer’s dementia used a sequential parallel comparison design (SPCD), and the second and third phase 3 studies used a regular comparative trial design. SPCD reduces the placebo effect and is expected to increase the success rate, so why wasn’t SPCD used in the second and third studies? Also, is there a chance that the results of the second phase 3 study will be released this year?
A8: After consulting with the FDA on the trial plans, we decided to adopt a regular comparative test design for the second study and beyond. We are doing all that we can to ensure that the results of the second phase 3 trial are released within the year.

Q9: What is the status for pediatric trials off centanafadine? Will trials begin this year? Will the application for approval be submitted once both the adult and pediatric clinical trials are complete?
A9: We are working to optimize the once-a-day dose. As soon as the formulation conditions are finalized, we plan to begin clinical trials. After both the adult and pediatric clinical trials are complete, we plan to file for approval.
Q10: Prescriptions for NUEDEXTA are flat. The price was raised in May 2019, but how did performance in the first quarter compare to the initial forecast? Is there a risk of an impairment loss?
A10: Performance was generally in line with plans. Prescriptions are recovering, and there is no possibility of an impairment loss unless sales fall far below the plan.

Q11: Have the patients waiting for JYNARQUE in the US begun to receive prescriptions? What is the status of efforts to find new patients?
A11: We were able to begin providing prescriptions to almost all waiting patients in fiscal 2018. Education programs on the disease made good progress, which, we believe, has led to an increase in the pace of prescriptions in January-March 2019.

Q12: In the Third Medium-Term Management, is business profit set as a key performance indicator? Or is something other than existing indicators being considered?
A12: We have set business profit as the key performance indicator. Please confirm other indicators when the Third Medium-Term Management is released.

Q13: Do you plan to file for approval of AVP-786 for the negative symptoms of schizophrenia based solely on the first set of results from the phase 2/3 study that has begun? Also, is only one dose for AVP-786 used in this trial? In that case, which dose (high dosage, low dosage) for agitation associated with Alzheimer’s dementia is used in the trial? Have you adopted any devising in the program for negative symptoms of schizophrenia through the findings from the agitation programs?
A13: We think that filing for approval for negative symptoms of schizophrenia requires not only the results of the current phase 2/3 study but also the results of another phase 3 trial. However, this depends on our negotiations with the authorities. We do not disclose any information on doses and trial design other than what has already been announced.
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<th>Q14: In the US, did you raise prices for <strong>REXULTI</strong> and <strong>Abilify Maintena</strong>?</th>
<th>A14: They were both raised 5% in April 2019.</th>
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<td>Q15: At present, there are many debates on drug price hikes. Were there any problems with price hike this time?</td>
<td>A15: We made the decision considering the market environment, and there were no particular problems.</td>
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<td>Q16: Janssen Pharmaceutical’s <strong>BALVERSA</strong> was approved in the US, but did Otsuka receive milestone payment? In addition, is this included in the earnings for the first quarter of fiscal 2019? Is it included in the plans for fiscal 2019?</td>
<td>A16: We received the milestone payment on approval in April 2019. This has been factored into the full-year plan. We expect to receive royalties going forward based on revenue.</td>
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<td>Q17: The operating profit rate for the nutraceutical business has been steady at levels over 10% thus far, but earnings seem to have suddenly deteriorated this fiscal year. The full-year forecast for profit has not been disclosed, but is the target expected to be achieved? Also, what is the intention behind the reorganization of products by segment?</td>
<td>A17: We are actively investing in sales promotion and advertisement for summer which is an important season, and everything is going according to the plan. There were some one-off impacts and exchange rates also had an impact, and as a result, revenue declined at some subsidiaries outside Japan, but progress has been steady for many businesses including those in Japan. We have reformed N&amp;S’s business as described previously. We will make an announcement if we decide that changes are needed in light of results in the first half of the fiscal year. We reorganized product segments to adapt to actual conditions.</td>
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<td>Q18:</td>
<td>Janssen Pharmaceutical’s SPRAVATO was launched. Has this had any impact on REXULTI’s current performance?</td>
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<td>A18:</td>
<td>We have priced in the impact of this competition to our full-year plan. SPRAVATO is not expected to have a major impact since the target patients differ from REXULTI.</td>
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