Otsuka Holdings Co., Ltd.

Financial Results Presentation FY2018
(Year ending December 31, 2018)

Q&A

February 13, 2019
Q1: How does JYNARQUE's progress to date and plans for fiscal 2019 compare with its performance in Japan?

A1: In fiscal 2018, the drug was prescribed to 1,500 patients during the 7 months after its launch, excluding the patients transitioning from clinical trials. Total number of patients with ADPKD in the U.S. is estimated to be 140,000, but not all patients will be the target for JYNARQUE. We are looking carefully at our sales plans. JYNARQUE/JINARC's revenues in fiscal 2018 in the U.S. and Canada are 6.8 billion yen and 1.5 billion yen respectively, and the forecasts in fiscal 2019 are 28.5 billion yen and 2 billion yen respectively.

Q2: I have recognized that the US label covers wider target patient population for JYNARQUE than that of SAMSCA in Japan. Is the JYNARQUE's forecast revenue in fiscal 2019 conservative because you think its target population is more limited than in Japan?

A2: In the U.S., the registration of physicians, patients, and pharmacies are required in the REMS for prescriptions of JYNARQUE and the system is more strictly restricted than in Japan. The launch of JYNARQUE in the U.S. took some time after SAMSCA's additional indication approval of ADPKD in Japan and the launch of JINARC in Europe, so we had kept many patients waiting for this drug's approval in the U.S. Therefore, the speed of the prescription growth was quite fast for now. As I mentioned previously, JYNARQUE has been prescribed to approximately 1,500 new patients in the 7 months since its launch, and this was at a pace of 200 cases per month, which is similar to the prescribing pace after the designation of intractable diseases in Japan.

Q3: What marketing practices were at issue in the settlement with the U.S. Department of Justice over the promotion of NUDEXTA? At what point in the past did this affect sales?

A3: Avanir and the United States government are negotiating civil, criminal and administrative agreements. As a result of where Avanir is in the process, we cannot discuss the government’s investigation of Avanir or its conduct. Avanir will provide more information regarding this matter once the agreements are reached.
| Q4: | Could there be additional costs in the settlement with the U.S. Department of Justice over **NUEDEXTA**? Although you are making good progress in the actual business, the apparent profit has been deteriorated due to various special factors within a recent year and a half, and there is a constant concern in the market.  
A4: | Avanir and the United States government are negotiating civil, criminal and administrative agreements. Avanir will provide more information regarding this matter once the agreements are reached. A number of investment projects is increasing including M&A and in-licensing. We have recognized that has impacted the apparent earnings due to impairment, etc., and has given a certain degree of concern to the market. |
| Q5: **NUEDEXTA**’s revenue has struggled since CNN's negative reportings. Is there a possibility of an impairment loss if the 2019 plan is not met?  
A5: | We carefully review our business plans each quarter, but as it stands, there is no need for impairment. We will report if the situation changes. |
| Q6: The P3 trials for **REXILTI**’s bipolar disorder seem to be completed. When will the top line results be disclosed?  
A6: | The trials are completed and in the process of unblinding the keys. Top line data will be disclosed as soon as it is available |
| Q7: CEO’s presentation materials contain information on late-stage products whose P3 trials end in 2019 and 2020. Are there any other products that will make a significant contribution to the performance by the end of the 3rd Mid-Term Management Plan in 2023?  
A7: | In addition to the later-stage development products disclosed in the slide, development of medical device for renal denervation is also progressing. To create Innovation requires money, time and patience. |
Q8: The first P3 study for AD agitation of AVP-786 is scheduled to be completed in April 2019. Will the top line result be disclosed around May and June? Is this study the same design as the P2 study conducted with AVP-923?
A8: The top line data will be disclosed within 2-3 months from the study completion. The study design is not disclosed.

Q9: In the summary of the 2nd Medium-Term Management Plan, there was an explanation that operating profit before R&D expenses had progressed almost as planned. However, the actual results appear to be quite different from the 395 billion yen figure when applying IFRS to the initial plan. Also, you explain in the press release that the purpose of introducing a restricted stock compensation plan is to share the value with shareholders. In that case, I would like you to consider the conditions for releasing the transfer restriction not only in terms of performance but also stock price.
A9: We would like to discuss the conditions for releasing the transfer restriction internally.

Q10: Regarding the settlement in principle with the U.S. Department of Justice over NUEDEXTA, 3 billion yen expense was already booked in fiscal 2017. Does that mean the negotiation related to this matter had already started in fiscal 2017? Will this matter affect NUEDEXTA's future business plans and impairment risk?
A10: The agreement in principle is subject to the negotiation of civil, criminal and administrative agreements before the agreement is final. In fiscal 2017, 3 billion yen was booked in ‘other expenses.’ Based on the agreement in principle, approximately 10 billion yen was added to the expenses as the current estimate of the anticipated damages, fines, disgorgement, restitution, legal fees and interest charges. Impairment risk depends on sales performance.
| Q11: In the medical devices business segment, aggressive acquisitions have been made including ReCor Medical, Biomedical Solutions and Veryan Medical. In general, there are two types of business strategies for medical device field: 1) acquiring companies one after another to expand business, and 2) improving the acquired assets to gain market share over the years. I understand that your current stage is the former, but how do you view product improvement? |
| A11: Our medical devices business includes marketing of *Adacolumn*, a leukocyte apheresis column, development of brain coils, and investment in a Chinese company that operates stents business. I believe that various studies are necessary for starting a new business, and it is extremely important to develop a strategic business model. We do not intend to conduct a commoditized business and focus on developing novel and unique technologies. As is the case with the pharmaceutical business, it is important to derive business from other businesses and create synergies. At present, we believe that our medical devices business is on its way to the next stage. |

| Q12: Why is *SAMSCA*’s revenue in the U.S. projected to decline in fiscal 2019 from the previous year? |
| A12: *SAMSCA*’s revenue is viewed conservatively in fiscal 2019 due to a plan to focus resources on promoting *JYNARQUE*. |

| Q13: Isn't *REXULTI*’s revenue weak in the fourth quarter of 2018? |
| A13: On a half-year basis, its performance is going well. There are no special factors. |
Q14: The actual R&D expenses, excluding impairment, are expected to increase by approximately 32 billion yen in fiscal 2019 compared to the previous year. Will this trend continue in the first half of the Third Medium-Term Management Plan?

A14: In fiscal 2019, R&D investment in the field of CNS will increase. Programs such as AD agitation and PTSD, and, in Japan, major depression for REXULTI are progressing, as well as for centanafadine. In the field of oncology, the number of early stage clinical trials is expected to increase, led by Taiho and Astex. Expectations for the future increase when the development programs are expanded, but the current cost burden will also increase. We will prioritize investments while balancing them with profits. Growth drivers such as global new products are currently growing steadily, which allows us to make active investments in R&D. The development of JYNARQUE took considerable time. In the first U.S. application, we received a complete response letter from the FDA, but after that, we proved its efficacy with excellent data in the additional P3 study. Nowadays only highly innovative drugs can be approved. New challenges come with costs. It is, of course, necessary to try to minimize them.

Q15: Acquiring external assets through M&A or in-licensing inevitably entails an impairment risk. But I think you need to look at things a bit differently and take a different approach. I would like you to minimize the risk as much as possible.

A15: We fully understand your point. In the case of in-licensing assets, it is necessary to check the details of production and quality as well as marketing activities if the products are already on the market. On the other hand, as for home-grown assets, since we are developing unique products, we may not be able to obtain results as we hoped in the first pivotal study. But, even in such a case, it is important to learn from failures and make persistent efforts to utilize the lessons to gain success. As you pointed out, efforts to minimize risks are necessary.