February 10, 2023

Olympus Corporation

3Q FY2023 Earnings Conference Q&A (Summary)

(Disclaimer)
For your reference, please find an English translation of the question and answer session at the conference for financial results for the third quarter of the fiscal year ending March 31, 2023 below.
This transcript has been edited/modified from the original Q&A conversations for the sake of clarity.
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[Q&A (Summary)]

Q: How do you evaluate the progress up to the third quarter? What is your outlook for the fourth quarter?

A: Compared to previous forecasts, sales are largely in line, but we saw a weakness in TSD. This is the background for the slight revision to revenue forecasts. Cost of sales was slightly higher than expected. In addition, SG&A expenses were slightly higher than estimated three months ago. This is due to increased sales activities, hiring to strengthen operational infrastructure, and costs to resolve specific issues for us, such as QARA. For the remaining three months, adjusted operating profit remained unchanged even after the performance review. In other words, we will catch up in areas where there is a slight delay, especially in SG&A expenses, in the remaining three months by taking further strengthening measures.

Despite various uncertainties, including the impact of COVID in China and Japan, and supply chain issues, GI endoscope in ESD still grew by 10% in the third quarter. Particularly even in China, ESD could grow, despite lockdowns. In the meantime, TSD was in a bit more complicated situation. The inability to fulfill orders due to supply chain issues and lockdowns impacted our performance. We would have delivered growth of more than 4.5% in TSD if there were no impact of COVID in China and supply chain constraint. EVIS X1 is maintaining its momentum in the launched regions. We believe we would follow the same path once we start to sell the product in the U.S. Regarding TSD, Urology is also progressing on track, except for China and supply chain issues.

Q: Question regarding the FDA Warning Letters (WLs): There were two WLs, one regarding lacking validation process at Aizu Olympus, and the other regarding late submission of MDR (Medical Device Report). We would like to know the status of the response to each. Considering that there were delayed submission of MDRs and you paid fines in the past, I don't think you have made much progress. Tell us how long the MDR submission was delayed and how you plan to address this issue in the future.

A: Before answering your question, I would like to introduce myself: I joined Olympus as CQO in March 2021 and have been working on the globalization of QARA and improving Quality and Compliance. We are currently in the process of hiring a number of new senior executives in the QARA area and establishing a global organization. The new leadership team includes many members with decades of industry experience. We will be changing from regional management to a centralized global organization in order to strengthen our monitoring function. The most important thing is to properly respond to new compliance challenges, and we have done our best to respond to the FDA inspections and WLs with a globalization initiative. We consider these investments to be very important and will continue to make more investments in this area in the coming years. We will also strengthen our global assurance function and establish Quality and Compliance to ensure the safety of patients around the world.

You asked how many days the MDR submission was delayed, and I recall that it took about 45 to 60 days to submit the report. Another important point is that when the FDA inspected Aizu, they went back three years in time. We had been looking for a new way of working for about a year during the COVID period, and we were not able to submit our work on time.

Q: I would like to know more details about the documentation at Aizu. Also, regarding regulations, I think it will become difficult to sell medical devices in India due to changes in regulations. Some competitors are saying that their costs will increase. In Italy, a change in policy is also having an impact, and as a result some competitors are estimating large reserves. What are your views on these issues?

A: The delay in MDR submission was not entirely due to COVID, but also due to operational issues. Since the control system was based on each region, the systems were not connected to each other, making it difficult to submit the MDR within 30 days. The solution would be to globalize the system, but this has not been completed at this time, and is expected to be done by the middle to end of the next fiscal year. Regarding the matters pointed out to Aizu, the issue is related to the documentation management and design validation, not product safety. We are currently in the process of analyzing which processes need to be validated, and in this analysis, we have confirmed again that there is no problem with product safety. We will closely work with the FDA on this analysis.

Regulations are continuously changing, and so is the environment in India. Our business in India has been stable. Although the market size is not large, our market share is growing, and sales are strong. We don't think there will be a significant impact on business. Regarding Italy, there has been a change in the claw-back policy but the situation in both countries is good. At this point,

we have set aside approximately several million EUR.

Q: Regarding the delay in the EVIS X1 launch in the U.S., what exactly do you mean by regulatory requirements? Also, what is the background behind the schedule change to the middle of FY2024?

A: At this point, we are working to prepare for the submission of the necessary documents and to obtain FDA approval, and once FDA approval is obtained, we will promote the product in the U.S. However, it will take several months to prepare for this, including the validation of processes that was mentioned earlier. Therefore, we expect to launch the product in the U.S. market around the middle of the next fiscal year.

The reason for revising the launch timing is that necessary actions must be taken to obtain FDA approval, and product design validation must be done at a factory with the FDA's required standards, which will take time to prepare even after approval is obtained.

In order to obtain FDA approval, it is necessary to communicate with the FDA and ensure that the requirements are met. For example, changing the label, validating the processes for all product changes before production, etc. Also, in order to obtain FDA approval, it is necessary to reach an agreement with the FDA on what kind of validation is necessary. For EVIS X1, we proposed how to validate the modules, and since we were able to reach an agreement, we are now proceeding with the necessary validation based on the details of that agreement. The reason for the revision of the launch date is that it took time for us to consider the best way to reach an agreement with the FDA.

Q: How do you think the delay of the EVIS X1 launch in the U.S. will affect business performance? In the U.S., many capital products are sold under lease contracts, so is it correct to assume that the contribution to revenue during the next fiscal year would be limited?

A: Business in the U.S. is centered on leasing. We don’t think there will be an immediate impact on business performance after the launch of the new product, but rather that it will grow gradually. In other words, the delay does not mean that business will be affected largely in FY2024.

Q: Is there a possibility that the Chinese government's low-interest loan program, which was not expected at the beginning of the fiscal year, will become a factor for the full-year upturn in China?

A: The low-interest-rate program was announced in August 2022. In the third quarter, we benefited from the program to a certain extent. Although we expect it to be a positive factor in the fourth quarter as well, we do not expect the program to have enough impact to change our full year forecasts for China. We haven’t changed our views on ESD. Demand has been increasing in this second half, as expected. We expect this momentum to continue in the fourth quarter.

China has been a bit complicated this year. In the first two months, sales were almost non-existent due to the lockdown. After that, business recovered. The low-interest-rate program pushed up orders a little, but, in the third quarter, the number of COVID cases surged again, making it a complicated year with both positive and negative factors. Under these circumstances, we believe we were able to control the business well throughout. In ESD, despite the lack of sales in the first

two months, we are seeing strong momentum in GI endoscope, and ESD is expected to grow 4-5% for the full year, so I think the situation is very good. TSD is in a more complicated situation due to cancelled surgeries. We should recognize that the situation in China is always in flux. Although the low-interest-rate program will end at the end of the fiscal year, orders are coming in well, and we think fourth quarter will be in line with our plan.

Q: Has there been any change regarding the Buy China policy? Also, do you envision local manufacturing in China?

A: Regarding your second question, China remains an important market for us, and we believe that we should provide stable services and products to the Chinese people. Based on this, we are considering various measures to address the Buy China policy.

We are considering necessary actions to maintain our competitiveness in China. Especially in the field of GI endoscope, we are technologically differentiated. In China, we have no competitors, and our market share has not been taken by other companies due to the Buy China policy. We haven't changed our strategy in that country, regardless of the Buy China policy, and it is important to continue to provide the best products, services, and technological capabilities in China. We will continue to consider necessary measures and actions to maintain its strong performance in China, including local manufacturing.

Q: ESD sales in China grew 57% in the third quarter (see P. 5 of "Financial Data"). This is an extremely high growth rate. How much of that growth rate should we consider to be based upon actual value?

A: For China, the third quarter sales in the last fiscal year were lower because the second quarter captured some of the sales in the third quarter. We do not have figures on hand as to what would be an appropriate baseline considering this factor. In this fiscal year, we do not expect the same level of growth in the fourth quarter as in the third quarter.

Q: Olympus' business in China is recovering, but other medical devices manufacturers are struggling, due in part to COVID and the Buy China policy. I am just curious as to why you are on a recovery trend. Is it due to any special factor such as product competitiveness, or is it just due to a reaction to last year's performance?

A: Our trend in this fiscal year is that ESD is performing well, while TSD is not recovering as well as ESD, mainly because ESD's product and service platform has been established in China over a long period of time. This is what makes ESD different from other companies.

In general, TSD's business, like other companies, depends on the number of procedures. In Japan and China, the number of procedures declined, resulting in a declined sales trend. The important point is the status of competition in TSD. We believe that we are on a recovery trend. In the field of stone treatment, the market share of capital products is growing, and if the number of procedures recovers, business will expand because single-use consumables will be sold. We have had many headwinds this year, limiting growth, but on the other hand, there are areas where

market share is expanding. The Urology business is in a strong position, and GI endotherapy is expanding its footprint and growing faster than the market in the U.S. We expect TSD to grow in the future.

Q: During two years after COVID-19 pandemic, your business has been recovering relatively well, especially in the U.S. What are your thoughts on the impact of the economic situation in 2023 (such as rising interest rates in the U.S.) on your business?

A: The healthcare industry has been viewed as resilient to the economic cycle. Having said that, we think it is necessary to pay attention to the state of the economy. For example, hospital budgets. a rise in lease interest rates due to rising interest rates might have an impact. Also, higher costs due to inflation. Given the recent inflationary trend, we believe that we need to exercise caution in planning and execution.

(End)