November 9, 2023

Olympus Corporation

2Q FY2024 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 second quarter of the fiscal year ending March 31, 2024 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: I understand that business performance has slowed down considerably, and that the situation looks difficult in this fiscal year. I would like to ask whether you think sales will recover next year. My understanding is that there are three main reasons for weak sales - the impact of the anti-corruption campaign in China, weakening CAPEX sentiment in Europe, and the prolonged shortages of parts and materials. Do you expect these factors to improve in the next fiscal year? In particular, I am curious about weakening CAPEX sentiment in Europe because it has not been mentioned much by competitors in the U.S. and Japan.

A: We think the macroeconomic and political landscape won't change much in both FY2024 and FY2025. For example, looking at the situation in Europe, sanctions against Russia have had a considerable sales impact. Also, in Germany, the reform of the healthcare system has caused hospitals to refrain from purchasing capital products. In the U.K., the NHS budget, which had benefited our business, is getting tighter. Looking at China, we have not been significantly affected by the anti-corruption campaign at this moment but will likely face headwinds from FY2024 3Q to FY2025 1Q. This is the macro situation. From an internal perspective, we are undertaking product ship-holds, recalls, and QARA remediation from FY2024. These activities will require more than a year, so we cannot expect optimistic numbers for FY2024. Although we expect FY2025 to exceed FY2024, we think achieving a CAGR of 5% is not realistic next year.

Having said that, there are great opportunities in our global operations. However, note that there are also significant risks in Europe and China. From an external perspective, we believe it is too

early to consider whether the situation will improve in both regions. In Europe, we think the difficult situation will continue, with inflationary pressures restraining hospital CAPEX. Considering that the NHS in the U.K. has invested heavily in endoscopes over the past few years, and that the reform of the healthcare system in Germany is beginning to take place, we think this difficult situation is likely to continue, and we need to keep a close eye on it. From an internal perspective, we will continue to respond very carefully to signals from the market through Project "ELEVATE", which integrated the FDA remediation and quality transformation projects. We will always consider the best solutions for patients, no matter how small a problem may be. As a result, the impact of product ship-holds is expected to continue in FY2025. Therefore, while the situation in FY2025 will improve, we believe that the recovery will be more pronounced in FY2026.

Q: Why is Europe so tough? Other companies have not specifically mentioned it. Is this a problem unique to the endoscopy business? Or is the hospital environment in general deteriorating?

A: What had a particular impact on us was a large-scale investment made by the NHS in the U.K. in endoscopes over the past three years. Russia was also quite strong before sanctions were imposed. These are unique to us. We believe that the healthcare system reform in Germany will have an impact not only on our company, but also on other companies. The situations in the U.K. and Russia were major factors for us.

Q: Regarding TSD, slide 36 of the presentation states that "Supply shortages due to supply chain issues - approx. 9-10 billion yen". If you could give us any figures for the first half, I would appreciate it. I would also like to revisit the situation in TSD. In particular, Urology continued to show weakness in Q2. Is this still continuing? Considering that it was weaker than competitors, I just wonder if there may be some issues in the competitive environment, in addition to the supply shortages. If the supply shortages continue, do you have a solution in your mind?

A: The backorders in TSD are attributable to two factors. One is parts shortages and the other is ship-holds. The total TSD backorder level for the first half was about 4 billion yen. This amount is too high, so we are trying to lower it. Within TSD, the situation differs by sub-segment. GI-ET is showing robust growth. For example, in the U.S., it grew double-digit in the first half. Meanwhile, in Urology, both Plasma (resection electrodes) and SOLTIVE experienced ship-holds. In addition, SOLTIVE is reviewing its go-to-market strategy due to the increasingly competitive environment. However, the outlook is that our market position remains stable in GI-ET, Urology, and Respiratory, and that our products have competitive edges.

All three focus areas of TSD remain stable. For GI-ET, the market share in the U.S. is growing. Urology is struggling, but there are two reasons for this. One is the increasingly competitive environment in the market for the Thulium Fiber Laser technology. We used to be the only provider of that technology, but we are seeing many competitors entering the market from this fiscal year. However, this was something we knew beforehand, and we are currently making investments to improve the situation. The other reason is the supply chain. We had to stop shipments, while some customers purchased from other companies because they could not wait. We believe this is a temporary impact. We are considering adding new products and solutions

and believe that we can get new products out ahead of the competition. We also believe that supply chain issues will improve over time. These measures will improve TSD's situation.

Q: TSD's growth outlook for this fiscal year is almost flat in sales on an operational basis. Is it correct to assume that the supply chain and quality issues will not improve much in the second half of the year? We would also like to know the actual figures for the negative impact of the supply chain in the first half.

A: The current backorder is about four times higher than the ideal level. It is difficult to predict the future of the supply chain situation accurately. However, our team has found a new direction for quality and is keeping a close eye on the market for any signals. We believe that the logistic problems can be solved by continuing and accelerating these process improvements. The problem is ongoing and difficult to predict in the months ahead. Although a rapid recovery in the short term is not realistic, we believe the situation will be resolved in FY2025.

Q: Is it correct to understand that the re-inspection by the FDA to lift the Warning Letters will come in 2025?

A: As this matter is decided by the FDA, when it is expected to happen is unknown. What we can say is that the remediation is progressing smoothly and we have engaged in constructive communication with the FDA.

Q: Slide 15 of the presentation states that “transforming Olympus into a best-in-class MedTech company". What elements do you need most now, compared to the best medtech companies in the industry? Although I think QARA is a necessary condition, I don’t think it is a sufficient condition. What is required for each business? I heard detailed initiatives, but I would also like to hear about the fundamental issues you face.

A: I believe that there is no universal definition for a best-in-class medtech company. Having said that, I think there are some areas where we haven’t reached the highest standards in the industry. First, patient safety is the top priority in all aspects. Second, financial performance. I think we need to improve not only growth, but also margin expansion and capital efficiency over the next two to three years. Finally, innovation from both organic and inorganic perspectives. We believe that not only M&A but also innovation will enable us to deliver new products to customers more quickly. These are what we think as the industry's highest standards for a medtech company.

Q: As you aim to become a best-in-class global medtech company, is there any possibility that it leads to discussions about reviewing business portfolio, including the surgical endoscope business? Also, regarding M&A, I think that the acquired companies over the past four years, including Veran Medical Technologies, were relatively small sales with limited growth contributions despite high expectations, except for Arc Medical. Is there any discussion regarding M&A pricing and what should be done? I would like to hear if there are any changes in the business portfolio review and M&A strategy.

A: We are constantly reviewing our business portfolio. Gastroenterology, urology, and respiratory

remain our areas of focus, and we are prioritizing resource allocation and investments. Although we have not yet decided to change our portfolio, we are constantly reviewing it and aiming for a portfolio that can create more value. Regarding M&A, our strategy remains unchanged. Basically, our policy is to conduct tuck-in deals to complement our portfolio in gastroenterology, urology, and respiratory, rather than large-size deals. Regarding Veran Medical Technologies, our Business Development department is a new department that was established about three or four years ago, and up until then we had not conducted M&A for a long time. Therefore, although we are still in the middle of the learning curve toward the highest standards in the industry, I believe that our capabilities of business development have grown dramatically over the past few years.

Q: I would like to ask about the outlook for QARA costs, including the FDA remediation. Previously, you explained that it would cost 60 billion yen over the three years including this fiscal year, and 22 billion yen for this fiscal year alone. The breakdown was 7 to 8 billion yen on SGA and 15 billion yen on other expenses for this fiscal year. In the first half, you spent 11.9 billion yen incurred in other expenses. Was this as planned or did you see a cost overrun?

A: The 60 billion yen amount was set when the plan for FY2024-FY2026 was formulated, which was an early stage of our corrective activities. Currently, we have a clearer path to what we want to accomplish over the next three years, and the current figure of 60 billion yen remains unchanged. Regarding cost management, it is difficult to clearly distinguish between the FDA remediation and QARA transformation project. This is because we view this as an opportunity to improve our capabilities and aim to reach a higher level by implementing quality transformation projects at the same time as the corrective activities for FDA findings in various fields. For example, the Warning Letters brought up process validation and MDR, and in response, we are aiming for a higher standard by investing in the digitalization of business processes related to MDR and the automation of manufacturing. Therefore, it was difficult to separate the investment amount between remediation and quality transformation, so they were combined into one comprehensive project.

Initially, we announced that the budget for FY2024 would be 22 billion yen, but based on actual results, we revised the forecast from 22 billion yen to 29 billion yen. This includes the impact of exchange rates of approximately 1.5 billion yen. Other expenses increased from approximately 15 billion yen to approximately 20 billion yen, and SGA increased from approximately 7 billion yen to approximately 9 billion yen. Basically, costs related to remediation are classified as other expenses, and costs related to quality transformation projects are classified as SGA. The cost for remediation has increased thanks to the activities for improving the process from complaint handling to MDR. This happened due to favorable progress made for that part.

Q: Will the target of 60 billion yen for three years potentially be revised later?

A: The amount of 60 billion yen was estimated based on fixed exchange rates, so an increase is possible depending on exchange rate fluctuations. Also, at the earnings briefing in May, it was expressed as “over” 60 billion yen, so we expected some range. Currently, we plan to work within the scope of that expression.

Q: The other expenses part has been revised from 15 billion yen to 20 billion yen. I don't think this

increase can be explained by the weaker yen alone. Could you give us more details of this revision?

A: The main differences are contractor fees, professional fees, and system development costs required for the series of processes from complaint handling to MDR.

Q: Regarding the annual forecast for Elimination and Corporate, it has been reduced by 5.5 billion yen from the previous plan. The new forecast is 46.5 billion yen. Do you think this level can be a base going forward? Or will it likely increase or decrease after the FDA remediation is done in three years?

A: This has been revised due to a change in internal allocations, and the base has been slightly adjusted. We assume Elimination and Corporate is going to be around this level. FDA related costs are not included in Elimination and Corporate.

(End)