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Olympus Corporation

4Q 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 fourth quarter of the fiscal year ended 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: What are your views on revenue growth for ESD and TSD by region for FY2024, respectively? You expect ESD and TSD to grow 5% and over 5% in CAGR over the three-year period from FY2024 to FY2026, respectively. What do you think are the risks and opportunities?

A: The performance in Q4/FY2023 was solid, but we recognize that the macroeconomic outlook remains uncertain. While the semiconductor supply situation is improving, other supply chain issues continue, and we need to undertake QARA transformation as a top priority. Those figures are targets set in consideration of the balance of both risks and opportunities. We believe that setting an overly ambitious sales target will lead to an increase in costs, so our principle is to set the sales target at a reasonable level.

(ESD) Especially in medical institutions in the U.S. and Europe, staffing shortages and cost pressures such as rising wages are headwinds for overall capital business in GI. On the other hand, it is a tailwind that the EVIS X1 is expected to be launched in the middle of FY2024 in the U.S., Canada, Latin America, South Korea, and some countries in APAC. Europe and Japan, where EVIS X1 has already been launched, are expected to grow in the mid to high single digits. But note that in U.K., we cannot rely upon the NHS budget effects in this fiscal year, and in Russia, business is contracting, and the outlook is uncertain. In China, EVIS X1 has not been launched and there is competition from local companies especially in Surgical Endoscopy area. We are considering local production in China, but there will be no impact in this fiscal year. APAC has performed well, mainly in emerging countries.

(TSD) High growth is expected in the U.S. and Europe. In China, while growth is expected in the GI-endotherapy area, we are concerned about the impact of Value Based Procurement (VBP) and preferential treatment for local products in the urology and surgery areas. There are also supply chain concerns.

Q: Regarding TSD, the Urology segment has growth drivers such as electrodes and SOLTIVE in the U.S. and Europe, and iTind has great potential. In China, the hurdles are low due to the lockdowns. Considering these factors, TSD's FY2024-26 sales CAGR target of over 5% seems conservative. Would you explain why this level is reasonable?

A: There are positive factors for the business as a whole, with growth in key therapeutic areas. On the other hand, we had supply constraints in FY2023. Although the situation is improving in some areas, we expect continued constraints in some products in FY2024 and have factored these risks into our forecast. For example, SOLTIVE in Urology has had supply constraints in the past two years, but sales are growing steadily, and it is expected to be launched in Japan this fiscal year. In addition, we expect growth in the bile duct-related products in GI-endotherapy. On the other hand, we also considered that supply delays of some products are still expected, and that the number of procedures has not fully recovered in some parts of Asia such as China and Japan. As for iTind, the area of benign prostatic hyperplasia (BPH) treatment itself is performing well, and we expect it to become one of the drivers for TSD and are working on initiatives related to market development and insurance reimbursement. In FY2023, China was the only region with negative growth in TSD. We are focusing on getting back on a growth trajectory.

Q: How do you perceive the opportunities of obtaining CPT codes in the area of ESD (endoscopic submucosal dissection)?

A: ESD procedures have an opportunity to change the standard of care, and the entire industry, including us, is committed to it. In addition to insurance reimbursement, we are working on market development through training as well as insurance reimbursement.

Q: Is there any possible upside that you can think of in relation to the 20% adjusted operating margin target in the new company strategy?

A: Over the past three years, we have made significant improvements in operating margin and SG&A ratio. We believe that we can potentially achieve an adjusted operating profit margin in excess of 20%. In order to foster improved productivity in the future, it is necessary for us to further streamline the operating model, processes, and organization as a global medtech. At the same time, in addition to establishing a manufacturing base in China and launching single-use endoscopes, we will invest in strengthening QARA and innovation. Over the next three years, we will continue our efforts to ensure the success of transformation and our long-term sustainability.

Q: In the FY2024 forecast, the operating loss from Elimination and Corporate is expected to worsen by 23.1 billion yen compared to FY2023. Could you provide the breakdown of this? Also, could

you update us on the status of responses related to the Warning Letters ("WLs") issued by the FDA?

A: The main reason is the absence of the approx. 16.4-billion-yen gain on the sale of land recorded in FY2023. There is also an increase in IT-related expenses. Note that QARA expenses including FDA compliance in FY2024 are expected to be recorded on the business side, and SG&A expenses for it are expected to be approx. 7 billion yen, and other expenses are expected to be approx. 15 billion yen. We have started coordinating with the FDA for QARA remediation plans in FY2023 and have started making the necessary investments related to late submission of MDRs, corrective and preventive actions, and process and design validations. It is necessary not only to deal with WLs, but also to deal with the root cause. We are promoting a comprehensive QARA transformation, through which we review the operating model, IT, culture, capabilities, and management. Although we need resources, we see this as an opportunity to bring them up to global medtech standards. This is an issue that should be addressed as a whole company.

Q: What level of QARA expenses, including IT systems and FDA compliance, do you expect in the period of FY2024-26?

A: We plan to spend approx. 60 billion yen over the next three years to globalize processes throughout the company, including IT systems as part of the operating model. Specific expenses expected to be incurred in relation to IT are not determined yet.

Q: How much do you expect QARA expenses, including FDA compliance, to increase in FY2024 compared to FY2023? Also, do you expect further increases through FY2025 and FY2026?

A: In FY2023, we recorded approx. 1.9 billion yen in other expenses, and in our forecasts for FY2024, we have factored in approx. 7 billion yen in SG&A expenses and approx. 15 billion yen in other expenses, so in total, related expenses in FY2024 will increase by approx. 20 billion yen compared to FY2023. We plan to spend 60 billion yen in total over the three-year period from FY2024 to FY2026, with slightly less in FY2026 than in FY2025.

Q: With the remarks on glueing process validation in the WL in mind, I recognize that the FDA's way to interpret the manufacturing process of endoscopes is becoming more stringent. What are your thoughts?

A: Currently, spot inspections are conducted for the glueing process, but the FDA has pointed out that spot inspections are insufficient. We are reviewing the entire process and the capabilities of the teams involved in the process. We provide monthly updates to the FDA and maintain close communication. Regulatory intelligence is at work within our company. A former FDA investigator has joined our Quality and Regulatory Compliance team, and we are making changes to our structure to ensure we have a good understanding of FDA regulations and can keep them updated.

Q: Slide 45 of the financial results presentation states that share buybacks and improvement of

capital efficiency will exceed 100 billion yen from FY2024 to FY2026. Today, you announced that you repurchase up to 100 billion yen of treasury stocks. Will you implement any additional share buybacks or other forms of return through FY2026?

A: We will continue to implement shareholder returns in line with the capital allocation policy that we have previously laid out. Cash will be needed for business investments, including M&A, but we cannot set a monetary target for M&A for the next two to three years at this time. Considering rising interest rates, we would like to secure a larger amount of cash. If we have surplus cash, we will consider returning them to shareholders, but we cannot make a commitment at this time.

(End)