August 7, 2024

Olympus Corporation

1Q FY2025 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 first quarter of the fiscal year ending March 31, 2025 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: Regarding the great performance in the US, can you share with us the status of order backlog? Also, do you think this strong momentum will continue, enough to overcome the impact of the slowing economy?

A: The launch of EVIS X1 was announced in the first quarter of the previous fiscal year. Due to the air pocket that we experienced after that, the growth rate for this first quarter appears high. In addition, of the 4.8% YoY growth rate (on a local currency basis) for ESD in 1Q, 1.1-1.2% points were attributable to the elimination of backorders caused by the Noto Earthquake. Orders in the US are being favorable, not only for the EVIS X1 main system, but also for 1100 series scopes. All areas - GI, Urology, and Respiratory - are doing well. In particular, there is favorable momentum in the Urology field, which was affected by product supply restrictions in the previous fiscal year. Overall, growth is expected to be in the high single digits. The impact of the economic downturn is expected to be seen in orders, but although it is difficult to predict, we currently have solid backlog. We believe that this fiscal year's targets are achievable.

Q: Is the full-year outlook for the U.S. better than what was announced in May? If some of the EVIS X1 scopes, which have not yet received approval, are launched in the future, can you expect the effect will continue for the next several years?

A: The EVIS X1 main system and the 1100 series scopes have been launched. We expect the 1500 series (EDOF) scopes to be launched at the end of this fiscal year or the beginning of next fiscal year, depending on the approval process. This will have a positive effect for the next 3-4 years

from FY2026, and we will be able to achieve high-single-digit growth.

Q: You mentioned that the situation in China was tough. Is this just for 1Q or is your outlook for the second half also tough? Given the yen appreciation risk now emerging, is it correct to understand that you are trying to control expenses to achieve the full-year guidance if the situation in China becomes more difficult going forward?

A: In China, there was no anti-corruption campaign in 1Q of the previous year, but we had a negative impact this year, so the decline was as expected. We hoped that the campaign would end in June, which would lead to a sharp recovery from July onward, but this effect has not been seen yet. Although we are still hopeful for a recovery in the second half, the situation remains difficult to predict. At the beginning of this fiscal year, we had a more bullish outlook for the second half and predicted high-single-digit growth for the year, but we are now taking a more cautious view as we believe that there may be issues specific to the Chinese market, not just in MedTech. Having said that, we have not changed our full-year forecast and would like to respond to headwinds in China as much as possible.

Exchange rates have fluctuated significantly in the last few days. It is difficult to foresee how they will develop in the future, so we have not changed our FX assumptions in our outlook. Regarding the FX level, if it remains at today's level, it is roughly within our expected range. It is difficult to give specific explanations at this point, but we would like to take countermeasures in the event that the yen continues to appreciate.

On the other hand, there are opportunities for growth. First, North America achieved very strong growth in 1Q, especially in the United States. This strong performance was aided by the progress made in clearing back orders caused by the Noto Earthquake and the fact that sales in 1Q in the previous year were soft due to the air pocket after the announcement of the EVIS X1 launch. In South Korea, despite the recent impact of the doctors' strike, we expect growth opportunities in the medium term with EVIS X1 being launched in the previous year. In Europe, we look forward to the UK NHS budget, etc. for the remainder of this fiscal year. We are also strengthening budget monitoring and will flexibly control costs according to the situation, aiming to achieve our adjusted operating margin target of 19.6% for this fiscal year.

Q: Didn't 1Q sales include the effect of clearing backorders caused by the Noto Earthquake?

A: Some of the backlogs were partially cleared in 1Q. The rest is expected to be cleared by August. So the effects will be seen in 1Q and 2Q.

Q: You commented that momentum was improving in TSD in 1Q, especially in Urology. Is this due to backorders being cleared faster than expected, or is it due to better market conditions?

A: Although TSD was affected by supply chain and quality related product supply constraints throughout the previous fiscal year, the situation is improving, and for some products the market is growing on the backdrop of increasing procedures. Despite the headwinds of product supply constraints in the previous fiscal year, thanks to the sales team's efforts, we grew in 1Q, especially the U.S. and Europe, particularly in the areas of resection and lithotripsy, including SOLTIVE.

Q: ESD's adjusted operating margin was 22.1% in 1Q, which deviates from the full-year forecast of 27.1%. Do you expect the margin to improve from 2Q onwards, or in the second half?

A: Our past trends show that profit margins tend to improve as sales increase from 2Q onwards.
In 1Q, particularly in GI, margins were affected by sluggish sales in China, where margins are relatively high. However, if business performance in China recovers in the second half, that is expected to contribute to overall margin improvement.

Q: How do you foresee sales in China for 2Q compared to 1Q?

A: It is difficult to predict. We believe that we will see an improvement in 2Q compared to 1Q, but do not expect any major improvement.

Q: Regarding the Project Elevate cost, the actual figure for other expenses in 1Q was 6 billion yen. This represents one-third of the full-year forecast of 19.4 billion yen. Was the 1Q result in line with the initial plan, or did you have a cost overrun vs. plan? Did you originally expect that more expenses would be incurred in the first half of the year?

A: The Elevate-related expenses in 1Q were 6 billion yen in other expenses and 2.2 billion yen in SG&A. This was in line with the initial plan at the beginning of the fiscal year.

Q: The expenses for the “Career support for external opportunity” program amounted to 2.6 billion yen in 1Q. Was this also in line with the initial plan? How much do you expect to incur for the full year?

A: There is a possibility that a few hundred million yen might be incurred in the remaining nine months of this fiscal year, but there are no plans to incur a large lump-sum of expenses like 1Q.

Q: Can you share with us the progress of addressing the issues pointed out in the FDA Warning Letters and the timing of their inspections?

A: We are making steady progress in corrective activities. In addition, through Project Elevate, we are taking various steps not only for corrective activities but also to become a global MedTech leader. We have reported progress on hundreds of commitments for the issues pointed out, and 95% of those commitments have been completed. Regarding Medical Device Report (MDR), we have set a target of 99% or higher for the achievement rate of reporting on time, and although the new MDR system is not yet fully operational, we have been able to achieve this level. Furthermore, we are pursuing culture that puts patient safety first, such as adding "Patient Focus" to our Core Values and holding workshops in which executive officers also participate. Progress is very good. The new system is scheduled to be fully operational at the end of this year, and although there is a big challenge of connecting it to the subsystem, progress is being made very well. Also, all sites have been audited by a third-party organization and have received positive evaluations.
It is not yet fixed when the next inspection will take place. We have informed them that we expect to complete preparations for inspections at the three sites that received the Warning Letters by mid-2025. We imagine that the three sites will be inspected over 1-1.5 years. Although lifting the Warning Letters is important, we have been able to obtain product approvals at this time. We will

continue to work toward lifting the Warning Letters during FY2026.

Q: Is there any change in your view that Elevate-related expenses will decrease significantly from next fiscal year onwards?

A: We cannot yet comment on next fiscal year, but at this point there is no significant change to our previous outlook. Expenses related to corrective activities are expected to decrease significantly in the next fiscal year, and no expenses are expected to be incurred in other expenses in the future. Note that the Elevate expenses also include investments for the future, such as investments related to the strengthening of our capabilities for obtaining approvals and the digitization of manufacturing, etc. Therefore, we plan to integrate them into the budgets of each function and manage as part of SG&A expenses, rather than as expenses for Project Elevate in the future.

Q: I would like to confirm again the timing of re-inspection by the FDA and lifting Warning Letters in terms of the calendar year.

A: This is merely our assumption and has not been confirmed by the FDA, but we would like to give you an idea of what it will be like. We believe that we will be ready for the inspections by the middle of the calendar year 2025. They will need to see the three locations that received the Warning Letters, and the inspections will likely take place over a 12-month period starting in the summer or fall (around August or September) of 2025.

Q: Are you satisfied with your current product portfolio? While Olympus has made it clear that it focuses on the three areas of GI, Urology, and Respiratory, I personally believe that THUNDERBEAT, which is not included in these three areas, has potential. I believe that a company with a portfolio of general surgery, including laparoscopic as well as open surgery, would be more competitive by marketing this product, and it would be desirable to form a strategic alliance with such a company.

A: We have recently made a decision regarding our portfolio, and we hope to provide no more surprises related to M&A deals during FY2025. We consider M&A as one of the sources of value for growth, and will continue to look for opportunities, especially in our three focus areas of GI, including GI endotherapy devices and services, Urology, and Respiratory. We think that M&A will account for 1-2% points of revenue CAGR in the future. To do so, we need to continuously strengthen our M&A structure and capabilities, and in those areas, we would like to achieve growth that exceeds market growth.

On the other hand, we would like to optimize our business portfolio and improve profitability in the field of surgical imaging and devices, and ENT. We recognize that THUNDERBEAT is a good product and is highly competitive. Although its market share in the United States is low, it has a certain market presence in Japan and Europe, and we believe that we are qualified to be a player in this field. With various options available, we need to continuously review our portfolio and consider optimizing it. At this time, we have no specific plans and there are no matters to disclose.

Q: Olympus has a varied track record of M&A and collaborations. While there are cases such as Veran Medical Technologies, there are also cases where future business contributions are expected, such as Sony Olympus Medical Solutions Inc., Medi-Tate, and Arc Medical. How have you improved your

due diligence and M&A structure recently?

A: While for various reasons Veran Medical Technologies and other cases did not meet initial expectations, other cases have contributed to our value creation, strengthening of our services, and provision of comprehensive solutions. To learn from past experiences for future M&A, we are conducting "learning sessions" and inviting external experts to look for areas where we can improve. We have also launched a "transformation program" for Business Development. Furthermore, we are improving our M&A support system by establishing the committee led by CFO Izumi, with the aim of pursuing patient safety and enhancing the probability of success in M&A and alliances, and by acquiring experienced personnel who can support the entire Business Development process. In addition, from October this year, Business Development will report directly to the CEO to achieve faster decision-making. We aim to handle M&A not just in some functions, but also throughout the entire organization.

(End)