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Olympus Corporation

1Q FY2026 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 of the first quarter of the fiscal year ending March 31, 2026 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 the sales of EVIS X1 were exceptionally strong and there was a positive impact from the elimination of the order backlog caused by the Noto earthquake in the previous year's 1Q. But even so, I don't think these factors can explain the 18% YoY decline in sales of the North America GIS business in this 1Q. I think one reason for this is likely to be delayed purchases ahead of the launch of the EDOF scope, which was approved in the U.S. in May, However, a similar sales decline was not observed in Europe or Japan when the EDOF scope was launched. Additionally, it is difficult to imagine U.S. endoscopists using the magnification function during diagnosis. So, can you explain in detail what is happening in the North America GIS business this year, including whether the sales decline of 18% was due simply to last year's high comparison or whether there were other factors at play? Also, please tell us how much of the sales and profit contribution from the EDOF scope are included in the full-year GIS forecast.

A: As you pointed out, the results were affected by a tough comp from the great performance in the previous year's 1Q and slow purchase patterns in advance of new products. We see a strong sales pipeline in both GIS and SIS.

Due to the phased launch of the EDOF scope in various regions worldwide, U.S. physicians have come to recognize its benefits. Olympus has provided physicians with opportunities to experience the product through demonstrations, which has led to delayed purchases. Delays in actual orders and installations in this 1Q were beyond expectations. However, we believe that this delay is temporary, and we can come back to the sales target in the U.S. market within the remaining quarters of this fiscal year.

Q: Can you tell us about the objectives and overall strategies of Swan EndoSurgical? Also, is this Mr. White's initiative or something that was already in place before he arrived?

A: Regarding the future vision for Swan EndoSurgical, we weren't too specific for several reasons. First, this is a complex robotic system with many components, and it is being designed from a platform standpoint. While robotic-assisted bronchoscopes entered the market several years ago, endoluminal robotics in the GI field have not yet been launched. In this field, we see significant potential in the platform strategy and view robotics as one of the key long-term growth drivers. Therefore, we consider it an important area where we need to be. I cannot speak as to whether the Swan EndoSurgical's initiative existed during the tenure of the previous CEO, Mr. Kaufman. However, given my (Bob White's) own experience in the field of medical robotics, I prioritized this area as a key growth driver after carefully evaluating and ranking priorities post-appointment. Additionally, in GIS, we were already focusing on this area and viewed it as a strategic move to quickly capture growth opportunities in the market, which led us to get this in place quickly. The development approach adopts a 'Build to Buy' strategy, which has proven effective in the companies I worked with in the past. While I have a lot of confidence in our R&D engine, a flexible approach is essential in today's world, where both speed and technological innovation are required. Moving forward, we will continue this approach, aiming for further technological innovation and market expansion.

We are conceptualizing a platform that can address a wide range of applications related to GI endoscopy. Initially, we plan to start with the GI field, which we see as the most promising. Leveraging our deep knowledge and technical expertise in the GI endoscopy field, and collaborating with U.S.-based robotics ecosystems, we are advancing developments with stable financial and technological foundations, while maintaining startup-like speed and agility. Additionally, in the future, we are considering addressing more advanced and minimally invasive procedures, such as NOTES (Natural Orifice Transluminal Endoscopic Surgery).

Q: Can you update us on the progress of the revised full-year forecasts? In 1Q, sales and profit were very weak. Now three months have passed since the initial FY26 guidance were presented at the beginning of the fiscal year. What has changed significantly during this period? Particularly, even with the low progress rate in 1Q, the revised forecasts seem to only incorporate the impact of the FDA import alerts. I just wonder if there is a downside risk, heading into the second half.

A: You are right that we created the initial FY26 full-year guidance only 3–4 months ago, but a few important things have changed in that time. In particular, the increase of tariffs in the U.S. to 15% has an immediate impact on cost of goods sold, making offsetting this impact difficult in the short term. In response, we have taken some very specific actions and will continue efforts to mitigate that in the medium term. Regarding your question of whether there is a downside risk, we have really looked at the forecasts hard in terms of specific leading indicators such as sales pipeline, product supply, backlog levels, and market trends (especially in China and Japan). We are confident that we can deliver. The management team is committed to this plan. Additionally, we are very much focused on getting much better cost management. It is a plan we believe in.

It's a plan that we've assigned accountability very specifically for us to deliver.

We had factored in the initial guidance that the U.S. business was extremely strong in 1Q of the previous year, and a tough comparison was expected. However, what was unexpected was the magnitude of delayed purchases ahead of the launch of the EDOF scope. The response of doctors during product demonstrations was very positive, which led to the "wait until launch" attitudes being more widespread than expected. That said, as we have a great sales pipeline, once the product is launched, we believe that it can contribute to sales growth. Next, regarding the Chinese market, we recognize that we somewhat underestimated the toughness of the competitive environment. We are currently strengthening our sales structure, and the possibility of starting local production by the end of Calendar Year 2025 is increasing. Once local production begins, we can expect a recovery as demand certainly exists there.

Q: The U.S. business appears to have growth potential, including the pipeline. However, it still sounds unclear whether you can turn around the Chinese business in the short term. Given that, I would like to hear about the cost management plan and KPI frameworks in place to ensure profitability even if sales fall short.

A: Regarding the Chinese market, we understand the risks, which have already been factored into the forecasts. We believe that China will be a phenomenal growth market in the long term, with the largest scale in the world in terms of the number of hospitals, doctors, and patients, making its potential as a medical device market extremely high. Certainly, short-term impacts are being felt due to the Chinese government policies, but to address this, we are preparing for local production, with the expectation that the first locally made products can be introduced within this calendar year. And equally important to that, this is about 'sales execution'. We are focusing on sales pipeline, the right people, and incentive plans, to strengthen local operational capabilities. All our general managers have recently visited China, and I (Bob White) myself plan to visit in a couple of months. Regarding profitability, if risk exists in the top line, we are fully focused on controlling the bottom line.

On GIS: To restore the Chinese business, we are going to accelerate local product registration and manufacturing, and product supply. By expediting the registration of existing products and starting local production, we can introduce new products to the Chinese market more quickly. And we are reorganizing our sales structure. From April 2025, we transitioned from the traditional geographically based sales structure to a business unit based one. We have already seen a much more transparent way of managing pipelines and have enabled more effective sales activities. Through these initiatives, we aim for recovery in the Chinese market.

On SIS: As medium- to long-term initiatives, we have outlined three pillars. The first is selection and concentration in the SIS field. For example, we have strengths in ultrasound bronchoscopes and are currently considering new product lines. Not only products but also human resources are strategically prioritized in recourse allocation. The second is to strengthen collaboration and partnerships with local companies. In particular, in the Urology field, we believe that by making integrated proposals with local partners that combine Olympus solutions, we will be able to respond to the market more effectively. The third is to strengthen our sales structure. Previously,

sales activities in the Chinese market were divided into four regions, but this has now been reorganized by business unit to improve efficiency. We aim to control SG&A expenses firmly while monitoring sales trends going forward.

Q: Regarding the FDA import alerts, I believe that you have been communicating with the FDA. What issues do you recognize and what changes do you intend to make? Can you update us about your discussions with the FDA after receiving the import alerts? You also explained that the Elevate-related expenses will remain unchanged in this fiscal year and are expected to decrease in the next fiscal year. However, you mentioned that you plan to spend on improving and strengthening quality management. In response to the FDA import alerts, are expenses that were originally planned to decrease in the next fiscal year now going to increase? It raises concerns about the extent of the decrease compared to your communication three months ago. So can you explain your outlook for the Elevate-related expenses for next fiscal year?

A: Certainly it was disappointing to get import alerts, but we understand that the alerts are tied to the warning letters and no additional measures are required for the alerts. Rather, we see this as an opportunity to accelerate and focus on our actions. We met with the FDA in mid-July, and the FDA expects us to have successful outcomes for the upcoming re-inspections.

Over the past 2-3 years, we have done a lot of work in consolidating our quality systems and establishing complaint handling processes. Additionally, in consultation with the FDA, we have brought a third party to audit us to verify the implementation and the effectiveness of that implementation and have shared those results with the FDA. The FDA has not yet re-inspected our facilities, but we expect inspectors to visit our facilities soon to verify the effectiveness of our actions. We have made significant investments to raise the overall competency across our organizations. We have brought in many new talents into the quality organization. We have done the same thing in the regulatory affairs team, which helps with communication with regulatory authorities, including the FDA. And we have done the same thing in operations and R&D to improve how we do investigations and how we improve our products. All these efforts are part of our responses to the warning letters and import alerts.

We expect the Elevate-related expenses for this fiscal year to be approximately 10 billion yen in SG&A and approximately 10 billion yen in other expenses, with approximately one-quarter of that amount already spent in 1Q. Because we have already been preparing for re-inspections, assuming they would happen within this fiscal year, we do not expect the import alerts to result in significant additional costs at this time. While it is difficult to make an accurate prediction about the next fiscal year and beyond, we expect project Elevate to be completed as planned this fiscal year, and we anticipate that expenses will decrease after that. However, this will depend on the results of the re-inspections, and some uncertainty remains depending on the results, but at this stage we expect things to proceed as planned.

Q: In relation to the context of corporate transformation, I saw four management initiatives listed on page 11 of the presentation material. I understand that the previous management teams have also implemented similar initiatives, so what is different this time? Where do you think there is room

for further efforts?

A: I cannot comment on the efforts of my predecessors, but what I can tell you is that my team and I have spent a lot of time on sharpening and placing a premium on execution, optimizing cost structure, and resource allocation. We are really focusing our time on investing in things that have an impact. We do that on a weekly basis with clear accountability, and we track progress. We think a big part of moving Olympus to a high-performance team is being much clearer on accountability and responsibility. We want to be evaluated not by our words but by our actions. These are not just words. These are the commitments that the senior leadership team and I have made to each other.

Q: You mentioned that you met with the FDA. Do you think similar issues could arise in the field of GI? Did the meeting result in your conclusion that the measures you have taken so far are sufficient? It seems there are still risks, such as additional actions, costs, and a potential expansion of the products covered. What are your thoughts on this?

A: The import alerts are tied to the warning letters, and our actions are specifically with completing those requirements, getting to root cause, understanding and executing with urgency. So it's not a different set of actions nor do we believe that there is an additional significant risk in the rest of the portfolio. The FDA wants us to deliver safe and effective products, and our company is acting in line with that goal. While they have not been back yet, this was a good reminder for us to execute with urgency around the work from the warning letters. Our focus is on completing that work sincerely. Regarding the risk of import alerts in the GI field, I don't want to speak for the FDA, but their focus is to make sure we deliver on our commitments that they gave us in the warning letters, and they reminded us of in the import alerts.

We had a productive meeting with the FDA, reviewed with them the improvements that we've implemented over the last two and a half years, and showed the remaining part of the plan.

We did get confirmation from them that we are focused on the right things. But ultimately, they need to come in and verify that. We have of course been in constant communication with the FDA regarding our progress, sending regular updates in a formal way in response to the warning letters. So they have been closely watching our progress. In future inspections, it will be necessary to demonstrate that we have improved the quality system and the execution within the system.

Q: In the Japanese market, performance was not particularly good in 1Q of the previous year, then further declined in this 1Q. Can you explain in detail of the background behind the decline in both GIS and SIS?

A: On GIS: Our analysis of the Japanese market is that we are operating in a market that is suffering from a limited budget, and we are seeing that our market share in the high-end hospital segment is protected and sound. But in the medium to small hospital and clinic segment, we are starting to lose market share against low price competition. As countermeasures, we are strengthening collaboration with IT and AI-based technologies, adding new features to the EVIS X1 processor (CV-1500 series), and building product bundles. Additionally, we are working with the Japanese

sales team to strengthen sales execution, and we anticipate recovery starting in the second half of this fiscal year.

On SIS: In 1Q, a major product in the Urology field faced a global backorder. Also, as the main reason for the sales decline, we saw delays in budget execution for surgical endoscopes. However, the pipeline is improving, so we expect a recovery in the future. Since we hold a high share in the Japanese market in areas other than surgical devices, we will strengthen customer touchpoints and introduce differentiated products to expand business in key diseases. For example, we plan to introduce SOLTIVE SuperPulsed Laser System, which has been highly regarded in the U.S. and Europe, to the Japanese market this fiscal year, broadening the range of our solutions and strengthening customer engagement.

Q: It looks like Olympus holds a 45% minority stake in Swan EndoSurgical. How is this reflected in your financial statements?

A: Regarding Swan EndoSurgical, we hold a 45% stake, while the remaining 55% is held by a partner company. This is reflected under the equity method in our financial statements.

Q: You estimate the impact of the FDA's import alerts to be approximately 15 billion yen for this FY26. Do you expect the impact to continue in the next fiscal year onwards?

A: It is unclear when the FDA's import alerts will be lifted. So assuming the alerts are valid for the rest of this fiscal year, we estimated an impact of approximately 15 billion yen for this fiscal year.

(End)