Q&A

Q&A Session at the Financial Results Briefing for the FYE Ended March 2025

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Q&A

Q1	For the U.S. business in the fiscal year ending March 2026, growth of approximately 10% is projected on a U.S. dollar basis. I believe the Trivicta Hip Stem is expected to enter full-scale sales. What are the sales projections for hip replacements and knee replacements, respectively?
A	In the U.S. market, we expect double-digit growth in sales on a U.S. dollar basis for the FYE ending March 2026. The primary growth driver is the expansion of Trivicta Hip Stem sales. Specifically, in the hip joint segment, growth for the FYE ending March 2025 was limited to +2% YoY. However, this fiscal year, we plan to achieve double-digit growth by fully launching Trivicta Hip Stem sales. In the knee joint segment, growth remained robust at approximately +10% for the FYE ending March 2025. We anticipate continued growth of around 10% for the FYE ending March 2026. Consequently, overall U.S. sales for joints are projected to achieve double-digit growth on a U.S. dollar basis.
Q2	As the proportion of U.S. ASCs increases, I believe ASP will decline. Is it correct to understand this as a strategy to acquire more cases than sales revenue?
A	In the U.S. market, the proportion of ASCs , medical facilities that perform low-cost surgeries, is increasing at a rate of approximately 5% annually, and accordingly, the number of cases performed at ASCs is also expanding. In this market environment, the unit price per case is trending downward. Under these circumstances, we are expanding our sales scale by acquiring more cases while also working to reduce costs through the SAICO project. Please note that the cost reduction effects of the SAICO project will be reflected in the cost of goods sold when the inventory of products manufactured at reduced costs is actually sold, resulting in a certain time lag.

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Q3	If there are any topics regarding the ODEV products discussed at the UHKAS Meeting, please share them.
A	The recent UHKAS Meeting primarily focused on discussions regarding the Trivicta Hip Stem. Additionally, discussions were held regarding a new type of cup used in total hip replacement surgery and new knee joint products. We plan to further expand our product lineup in the U.S. market while capturing these market needs, aiming to increase the number of acquired cases.
Q4	Could you please tell us about the quantitative cost reduction targets for the SAICO project? Can we expect the reduction effect to continue expanding in the future? Or should we anticipate that it will level off at some point?
A	Last year, the SAICO project aimed to achieve $1.8 million in cost reductions. We achieved $1.9 million in cost reductions, exceeding our target and delivering results that surpassed our expectations. We expect cost reduction effects to continue expanding going forward. However, several factors also hinder the achievement of these results. One is the risk of reimbursement price revisions in Japan. If a significant reduction in redemption prices is implemented, the cost-saving effect may be offset. Another factor is the impact of healthcare reform in the U.S. market. Specifically, the number of cases performed at ASCs, which offer low-cost surgeries, is increasing at an annual rate of approximately 5%. ASPs are trending downward at these facilities due to extremely tough price negotiations. This decline in per-case pricing is negatively impacting our profitability. We will continue to closely monitor these risks while striving to secure more cases and strengthen our sustainable cost structure through the SAICO project, thereby maintaining and improving profitability.

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Q5	What factors will influence the additional tariffs imposed by the Trump administration in the U.S.?
A	Our U.S. subsidiary, ODEV, operates a manufacturing facility in Utah. However, some raw material procurement and manufacturing processes rely on imports from regions with lower production costs, such as Europe, making them susceptible to the impact of additional tariffs. At this time, we estimate that the impact of applying a 10% additional tariff would be approximately US$1 million. However, depending on future movements in additional tariff rates, the impact amount could potentially increase further. In light of this situation, we are currently conducting cost simulations and impact analyses for shifting some manufacturing processes to the U.S. Should additional tariffs be determined to significantly impact our Rolling Plan 2028 business plan in the future, we will provide a renewed explanation of the impact and countermeasures.
Q6	President Trump's executive order is reported to significantly lower drug prices, but will the same happen for medical devices and procedures?
A	This measure applies to pharmaceuticals, and the therapeutic materials handled by our company are not subject to it. Therefore, we currently believe there will be no direct impact on our company. However, since it cannot be ruled out that therapeutic materials may be included in the scope of coverage in the future, we believe the most effective countermeasure is to continue monitoring the situation while persistently pursuing efforts to reduce manufacturing costs.

Regarding forward-looking statements

- Statements regarding the future, such as business performance forecasts, contained in this material are based on information currently available to the Company and certain assumptions that the Company deems to be reasonable, and the Company is committed to realizing them. Not.
- Actual results may differ significantly due to various factors.