Q&A Highlights: FY2025 Q1 Financial Results

Date: August 8, 2025

[Question]

- AkirunoCube figures list one-time, running, and depreciation costs, but omit the usual lab efficiency benefits figure. Did Q1 deliver lab efficiency benefits?

[Answer]

- Efficiency improvements are progressing well, but since AkirunoCube efficiency benefits are incorporated in the operating profit plan, we no longer disclose this figure separately.
- Q1 benefits were limited, as savings from the mainframe shutdown will begin in July, with most benefits expected from Q2 onward.

[Question]

- What is the reason that KPI data showing negative net changes in domestic Lumipulse units and in-hospital testing contracts?
- Is this due to a strategic prioritization of profitability and margins?

[Answer]

- Some in-hospital losses are strategic exits, causing a net decrease of six. Clinic contracts are being reduced with price increases prioritizing profitability.
- Domestic Lumipulse units declined due to removals, but sales policy remains unchanged, and we are continuing to work on expanding installations. Reagent sales are growing steadily. The unit decline is not viewed as a significant concern.

[Question]

- Esoteric testing sales up 7%. Was this driven by volume or price increases?
- What is background behind the growth: industry-wide dynamics or company-specific factors?

[Answer]

- Growth is mainly driven by higher volumes, with some price increases.
- While it is too early to confirm if this trend will continue, it has shown steady growth reflected in sales.

[Question]

・ Does growth reflect increased hospital inpatient volumes?

[Answer]

・ This is partly the case, combined with seasonal and timing effects in Q1; we will keep monitoring as the year progresses.

[Question]

・ Regarding pTau 217 reagent, is there any update on regulatory application status or US reimbursement?

[Answer]

・ in terms of approval preparation, there is no significant change in Japan, Europe, China, or other regions since the last update.

[Question]

・ Regarding LTS, Q1 showed an ¥800 million loss despite ¥900 million costs, implying an underlying positive ¥100 million. Has pricing impact started?
・ Will Q2 see significant underlying profit following system shutdown benefits?

[Answer]

・ Pricing impact started in Q1, with approximately 70% of contract renewals completed. As contract renewals are complex and vary by hospital; benefits are expected to materialize gradually, mainly from H2.
・ One-time costs of ¥900 million ended, but ongoing IT issues are keeping running costs high. We aim to offset the costs and achieve breakeven in Q2.

[Question]

・ Will pricing effects be seen this fiscal year, and how are they reflected in the plan?

[Answer]

・ The plan reflects expected progress in contract renewals, which we aim to complete within this fiscal year. However, as timing varies by hospital, actual results may differ from assumptions.

[Question]

・ CDMO business growth has slowed in local currency since FY2024 Q2, possibly due to Chinese market policy impacts on major IVD customers.

・ How do you assess the current trend?

[Answer]

・ The Chinese market has impacted major IVD manufacturers, contributing to softness in the CDMO business.
・ Recovery is expected from Q3, and the annual plan remains on track.

[Question]

・ Do customers have committed volumes that reduce the risk of slippage?
・ Or could supply volumes be renegotiated if the recovery slows?

[Answer]

・ Shipments follow customer forecasts influenced by end demand; if end demand worsens, we would be affected.

[Question]

・ IVD M&A-related costs of ¥470 million seem higher than expected. Was this included in the plan?

[Answer]

・ M&A costs were planned but initially budgeted lower, actual costs rose partly due to success fees.
・ We expect to offset these costs and maintain the full-year profit forecast.

[Question]

・ IVD operating profit excluding M&A costs was in line with plan, should I interpret that IVD performs ahead of the plan?

[Answer]

・ We hadn’t originally expected to close the deal so quickly.
・ Therefore, when we say Q1 performance is on track excluding M&A costs, it means exactly that—the timing of M&A costs shifted earlier, so Q1 excluding those costs is performing as expected.

[Question]

・ Will NEURO sales run ahead of plan?

[Answer]

・ While the plan did not initially assume large figures, if the Q1 trend continues, we expect full-year sales could exceed the initial plan by about ¥2 billion.

[Question]

- Labcorp uses your pTau217 reagent, reporting 95% sensitivity and specificity. Are you the only company achieving this level of performance?
- How should we understand the competitive landscape, including your OEM customers?

[Answer]

- We are unable to comment on the status of other companies.

[Question]

- The AAIC guideline states that tests with over 90% sensitivity and specificity can be used for definitive diagnosis. Does your US-approved product meet these criteria?
- What business impact do you expect from the guideline announcement at the conference?

[Answer]

- Guideline and FDA approval are not directly linked. Achieving over 90% sensitivity does not guarantee approval.
- However, FDA approval combined with the guidelines suggests increased demand for plasma reagents.

[Question]

- Is it still uncertain whether your product will be used for definitive diagnosis?

[Answer]

- That's correct.
- At this stage, we recognize that diagnosis should be made by combining the test results with other factors, not on the test results alone.