Q&A Highlights: Medium-term Plan Briefing

Date: May 19, 2025

Q-1: Shareholder Return Policy

Question:

- Based on the dividend amount and share buyback scale for FY2025, the total payout ratio comes to over 200%, and share buybacks will continue in the next few years. However, a 200% payout ratio in this fiscal year implies that unless net profit grows 4x–5x from current levels, it would not align with typical company's payout ratios. Does the company anticipate such significant increase in net profit?
- On the other hand, the medium-term plan indicates substantial decrease in investments. Could you please explain in detail the reason behind continuing the buybacks? Was this decision based more on free cash flow rather than net profit?

Answer:

- One of the reasons behind the decision of share buybacks is our current cash balance of over ¥40 billion. We also expect steady cash growth after FY2025, including operating cash flow growth and asset sales. As mentioned earlier, ROE is projected to increase in FY2027 due to a significant drop in depreciation expenses. Although payout ratios will remain high in FY2025 and FY2026, we anticipate net profit to normalize from FY2027 onward.
- Additionally, due to our exit from PingAn JV, and Baylor Genetics' recent fundraising, equity method loss becomes lighter as our ownership percentage has been declining. As a results, we expect ordinary profit to improve going forward.
- In summary, considering both the cash available for shareholder returns and the expected steady rise in ROE from FY2027, we have decided to enhance shareholder returns and we believe this plan is fully executable.

Q-2: Investment Strategy for "2035 Vision"

Question:

・ You mentioned that this medium-term management plan was 'formulated through backcasting from 2035 vision.' When looking beyond FY2029, I assume significant investment will be required again to drive future growth. Given that and considering the cash outflows associated with shareholder returns, wouldn’t it be better to retain cash for investments over the next five year? Could you explain your thinking behind this?

Answer:

・ As mentioned earlier, we expect a significant increase in operating cash flow starting in FY2027, which should also drive an increase in EBITDA. In line with this outlook, we anticipate that our investment focus will gradually shift from capital expenditures toward M&A, particularly in areas like the IVD business.
・ In terms of M&A funding, we project further expansion in debt capacity from FY2027 onward. With this in view, we expect to have greater financial flexibility for investments beyond FY2027 and FY2030.
・ At that stage, we believe we will be in a strong position to actively pursue investments, including M&A. Given the debt capacity we expect to have, we believe we can maintain a balance between such investments and shareholder returns. The scale of shareholder returns announced this time reflects these projections.

Q-3: CEO Succession Background

Question:

・ In FY2016, Mr. Shigeharu Takeuchi was appointed as CEO from outside the company, but this time, the process is different. Could you share the reasoning behind choosing candidates from the existing internal leadership team?

Answer:

・ As an outside director, I would like to explain both the reason for choosing internal candidates this time and the process behind it. Since Mr. Takeuchi joined the company as CEO from outside, we have seen a positive shift in our corporate culture, and the base to pursue integration across the group has established. The Nominating Committee held in-depth discussions on whether the next CEO should be chosen from within the organization or from outside.
・ Given the current circumstances, we concluded that appointing internal executives, someone with a deep understanding of our business, is the right choice to lead the company into its next phase. We also believe this decision is aligned with the best interests of shareholder value, which guided our conclusion.

Q-4: CDMO Growth Outlook

Question:

- Congratulations on receiving FDA approval for your Alzheimer's blood test reagent. Looking at Slide 26 and the growth forecast for NEURO, we see a strong upward trend for "Lumipulse AD reagents," while "CDMO AD items" show weaker growth than I expected. As other companies are also working towards FDA approvals, some of which may be your partners, could you share more about your collaborations with these players and how you view the competitive landscape?

Answer:

- First, regarding the differences between Lumipulse reagent sales and CDMO sales, when we sell Lumipulse reagents directly, the entire sales amount is recorded as our sales. In contrast, under the CDMO model, we manufacture raw materials or reagents and supply them to our partner companies, who then manage sales to end users. As a result, only a portion of the total market sales is reflected in our CDMO business, which accounts for the proportions shown in the graph. That said, raw materials are a high-margin business.
- The actual growth of this market will depend on multiple factors. For instance, pharmaceutical companies are actively pursuing global rollout of therapeutic drugs, and broader societal adoption will drive the demand. However, the exact pace and scale remain uncertain. The current graph reflects our latest projections, but if our CDMO partners scale up more rapidly across global markets, the gray portion (CDMO) in the graph could grow accordingly. We will continue to update these forecasts as the situation develops.

Question:

- You have multiple CDMO partnerships—does this outlook assume they are not yet factored in, or is it based on the expectation that they will not see significant development in the short term?

Answer :

- Each company is responsible for developing its own reagents and obtaining regulatory approvals—not only in the U.S., but also in various other countries—which naturally leads to time lags. Since each partner operates on a different timeline, it is difficult to make precise forecasts. The graph reflects a general expectation of gradual market growth, but we will continue to update our forecast as more concrete data on market expansion becomes available.

Question:

- Could you comment on competitors? For instance, C2N Diagnostics plans to seek FDA approval for its blood test service. How do you view such developments?

Answer :

- While we cannot comment definitively on competitors, Lumipulse's key strength lies in its existing installed base of instruments—such as the G1200, which can process 120 tests per hour—in the U.S. and Europe, where they are already used for routine diagnostics. These systems offer full random-access capability, allowing for continuous, efficient sample processing, which makes them highly practical in clinical settings.
- Our reagents have also earned high regard, which represents a key competitive advantage. By further strengthening this, we aim to expand the blue segment shown in the graph. At the same time, we are focused on collaborating proactively with our diverse partners to grow the market. Rather than viewing this as a competition, we see it as a collaborative effort to drive market expansion together.

Q-5: Alzheimer's Strategy

Question:

- Now that U.S. approval has been secured, and you are collaborating with partners like Eisai and Biogen, could you update us on the status of applications and development in other regions such as Japan and Europe? Additionally, could you share any recent developments regarding these partnerships both domestically and internationally?

Answer:

- Regarding our NEURO business, we have previously announced partnerships with diagnostic manufacturers and pharmaceutical companies. These agreements are designed for global collaboration rather than being limited to specific regions.
- Currently, therapeutic drugs are at the approval application stage in various countries, including the U.S. Meanwhile, we are working to rapidly expand blood-based testing capabilities through collaborations involving both our own company and our partners. We believe this approach is the best way to grow the overall market, and progress with our partners is moving well.
- As for approval applications outside the U.S., for our "pTau217" reagent, we first secured approval in the U.S. and plan to submit applications in Japan as early as this summer. We are also preparing to submissions for Europe within this year. For

major markets— particularly where coordination with therapeutic drugs is important—we will move quickly when conditions are favorable. Regarding CDMO partners in key markets like China and India, our partners will lead the approval process. We currently understand that approvals in India may come around summer, with applications expected in China early next year.

Q-6: Management Restructuring

Question:

- I would like to ask for some further details regarding the recent management restructuring. From an external viewpoint, the timing feels sudden. While I assume the operational timeline of the new lab may have played some roles, could you explain, as much as possible, why this timing was chosen now rather than before the medium-term plan announcement?
- Additionally, the 'future process' section mentions "reflect the results of compiling management innovation measures in the new medium-term management plan and deepen them." Does this imply that the current medium-term plan might be revised within a year or at some point in the future?
- Regarding the integrated management of the IVD and LTS businesses—although there are some apparent synergies, the market seems uncertain about the rationale for combining these two. While they share certain similarities, their investment needs and customer bases differ significantly. As an outside director, could you share how the Board has assessed the advantages of keeping both businesses under one umbrella?

Answer:

- First, regarding the timing of announcing the succession plan: we have been developing this succession plan since last year, narrowing down to four candidates and conducting one-on-one coaching with external experts for assessment.
- We chose to make the announcement at this stage because the succession plan is well underway, and we wanted to enhance transparency around the CEO selection process by sharing both the direction we are taking and how the process will proceed.
- On integrated management, the unification of the LTS and IVD businesses has been a long-standing strategic theme. The biggest challenge lies in realizing true synergies between the two.

・ As part of the CEO selection process, we have placed strong emphasis on finding a candidate who demonstrates leadership not only within their own domain but across the entire group.

Question:

・ Based on these discussions and the result of the succession, is there a possibility that the medium-term plan could be revised?

Answer :

・ Under the new medium-term management plan, we aim to further deepen integrated management. Rather than revising the plan itself, our focus will be on more deeply and effectively executing what is already outlined.

Q-7: LTS Profitability Target

Question:

・ Regarding the 10% operating profit margin target for the LTS business in FY2029, I understand that the new laboratory facility has about 20–30% more capacity compared to the former Hachioji lab—please correct me if that is inaccurate. Given the strategic shift, achieving higher utilization may present some challenges.
・ Also, the 10% OPM target is close to the historical peak, which was achieved during a period of minimal investment. Since then, market conditions have changed significantly, particularly with the government's push toward home healthcare and a decline in inpatient volumes at some hospitals. Could you explain the reasoning behind setting this target under the current circumstances?

Answer:

・ As previously explained, the testing volume is showing an upward trend, reflecting a gradual recovery as the impact of the COVID-19 pandemic subsides. Additionally, changes in treatment strategies are shifting the lifecycle of certain testing items. The increase in higher unit-price tests is contributing to business growth, and we expect this trend will continue for the near future.
・ Regarding the 10% target, as you pointed out, this reflects our baseline prior to the current phase of active investment. We expect a meaningful change in our cost structure once AkirunoCube reaches stable operations. Previously, at the Hachioji laboratories, we operated five separate buildings, in addition to having pathology and cytology functions in Hamura, which incurred substantial costs for test reception and related operations.

- We anticipate double-digit cost improvements driven by consolidation at the new lab, as well as increased use of in-house reagents developed by Fujirebio. These reagents deliver cost efficiencies more than 10% compared to competitors' immunological reagents. These material cost reductions and consolidation benefits form the basis for our 10% operating profit margin target.
- Finally, regarding the external environment, as you noted, we are seeing a trend toward hospital reorganization and a shift to home-based care. Hospital consolidation is progressing in regional areas. In response, we are adjusting our strategy by focusing on esoteric testing at the AkirunoCube and anticipating increased demand in advanced testing fields as hospitals redefine their functions. To address these shifts, we are actively pursuing the adoption of modern technologies, preparing to ensure profitability as we help create new markets, and advancing our unique product strategies.

Q-8: CEO Selection Criteria

Question:

- Regarding the succession plan, it was mentioned that you would choose based on the perspective of "who can best demonstrate leadership." Could you please explain more specific criteria for the CEO selection process?

Answer:

- This is Ito, speaking as an outside director. As Mr. Aoyama, Chairman of Nominating Committee, mentioned earlier, since January of last year, we have been continuously receiving executive coaching support from specialized external institutions. This coaching has covered specific areas, such as how to unify the organization, as well as communication and collaboration methods.
- Looking ahead to the next six months, we will place particular emphasis on three key factors: attributes, capabilities, and leadership. At the same time, we will continue advancing our management innovation initiatives. Based on the new medium-term management plan, we will engage in concrete discussions about what is needed to guide the company’s development over the next five to ten years.
- We anticipate a range of topics coming into focus, including organizational design and talent development. The four candidates will take a practical approach to leading these discussions. As outside directors, we will closely monitor their efforts and evaluate their progress through the lens of these three key qualities.

Q-9: Alzheimer’s Blood Test Competition

Question:

- Looking ahead at the prospects for Alzheimer’s blood testing - while market conditions remain uncertain, how significant do you believe your first-mover advantage in securing approval will be over the long term? Conversely, if another biomarker were to emerge as the global standard, is there a risk that the market dynamics could shift quickly? We would appreciate hearing your current perspective on the future competitive landscape.

Answer:

- Our first-to-market approval enables us to immediately begin selling IVD reagents in the U.S. For both the "pTau217" and "β-amyloid 1-42" reagents, we expect demand to grow particularly among existing customers who already have Lumipulse instruments installed and operational. We also anticipate expanding adoption among new users over time.
- In parallel, we are pursuing regulatory approvals in other countries and intend to expand sales in regions where Lumipulse systems are already in place. That said, since the number of instruments we can directly install is limited, we plan to accelerate market expansion through a CDMO model in collaboration with partner companies. This forms the core of our strategy. In the near term, reagent sales will be driven primarily by our existing Lumipulse user base.
- As mentioned earlier, our broader role in the industry is to continue introducing new testing items—including both AD-related and non-AD RUO items. We hope these will be actively utilized by researchers as they explore the clinical potential of new biomarkers. Our strategy lies in not only the expansion of approved items sales, but also the accelerated development of next generation testing solutions.

Q-10: U.S. CDMO Partners

Question:

- Beyond the "Lumipulse"-based reagent, could you disclose your current CDMO partners for AD reagents in the U.S. market?

Answer:

- While we do not disclose the names of specific CDMO partners, nor the regions or reagents they are focused on, we can say that the U.S. remains a top-priority market for us—as clearly demonstrated by our first-mover advantage in securing approval for our AD reagents. This view is broadly shared across the industry.

Question:

- Does this mean you already have a U.S. partner company that will immediately begin commercial promotion of these reagents?

Answer:

- We were the first to obtain approval, and while the timeline for other companies entering the market remains uncertain, we expect that once they complete their regulatory applications and receive approval, they will also move forward with market expansion.

Q-11: the Rationality of the New Medium-Term Management Plan and Succession Plan

Question:

- Regarding the disclosure of the new medium-term management plan and the succession plan - while the CEO succession process is currently underway, why was this timing chosen to present the new medium-term management plan?
- Furthermore, could you explain why the newly announced medium-term plan will serve as the basis for future succession plan discussions? From a shareholder's perspective, considering the company's current performance challenges, it might expect a new leader to develop and take full ownership of their own strategy and medium-term plan.
- In this case, however, the plan is being announced during—not after—the leadership transition, and it has been stated that this plan will guide future succession discussions. This implies that the incoming leader will be working from a framework developed under their predecessor's leadership. Could you please clarify the reasoning behind this approach?

Answer:

- Given that the new medium-term management plan includes several highly time-sensitive initiatives, we determined that announcing and implementing it promptly, immediately following the conclusion of the previous plan. We believe that it would be the most effective way to enhance corporate value. Accordingly, our current priority is to clearly announce this new plan and focus on executing the key value creation measures it outlines. FY2025 is particularly critical, as we aim to drive forward the integration of core themes and deliver concrete results across all business.
- This new medium-term plan is designed to deliver measurable outcomes within the current fiscal year. Importantly, it was not only developed by CEO Takeuchi, but

rather led by the current executive team. The candidates currently under consideration for CEO succession were directly involved in shaping the plan.

- As part of this process, we have launched a management reform project to further refine the plan in parallel with the CEO selection. Moreover, regardless of who assumes the CEO role, the fact that each candidate has been directly involved in developing the current medium-term plan ensures they will be well-positioned to continue refining and executing it.

Q-12: Timeline for CEO Selection Process

Question:

- Regarding the succession plan, you mentioned that "the process to select the next top management has been ongoing since last year." Since all the candidates are long-serving internal executives who are well-known to the Board of Directors including the Nominating Committee.
- Could you explain why additional time is needed to evaluate these familiar internal candidates, leading to the leadership transition being scheduled as late as next January? What factors justify this extended timeline?

Answer:

- As I mentioned earlier, this medium-term plan marks our "harvesting phase," during which we aim to quickly realize returns from past major investments and shift toward sustained sales and profit growth.
- At such a critical stage, ensuring a smooth leadership transition is essential from an organizational perspective. Accordingly, we have designed the succession timeline to minimize operational risks as much as possible.
- Additionally, this schedule was set after thorough discussions by the Board of Directors. As a company with a Nominating Committee, we have placed great importance on transparency throughout this process. We appreciate your understanding that this timing reflects careful and deliberate consideration.

Q-13: Strategy for NEURO Deployment

Question:

- Regarding the NEURO business, is it correct to understand that you do not pursue standalone development without collaborating with external partners?
- Also, the medium-term plan targets a higher ROIC for the IVD business, do you consider the current investment levels sufficient to meet these targets?

Answer:

- Regarding the NEURO business, our fundamental strategy is to sequentially develop new testing items. Initially, these are launched as “Lumipulse” products, focusing on adoption and deployment in locations where our instruments are already installed.
- Simultaneously, we operate a business model that includes supplying raw materials to other interested companies as CDMO partners, as well as managing the entire process from reagent selection through manufacturing and supply.
- Our basic approach is to first implement new developments on Lumipulse and afterwards make them available to partner companies. We intend to continue with this model going forward.

Q-14: LTS Growth Strategy

Question:

- While LTS topline growth aims only about 3%, your OPM target is significantly higher. Does this imply that you will be actively reviewing or rationalizing less profitable testing services?

Answer:

- Exactly as you have noted, regarding our LTS business, our major initiatives are not sales expansion but operating profit growth. Accordingly, we will implement strategic shifts from the previous medium-term management plan. Moving forward, our profit growth efforts will be centered around the AkirunoCube, advancing in line with the new medium-term management plan. In conclusion, we are moving toward a growth stage that is accompanied by profits.
- Additionally, we will continue discontinuing certain services and conducting operational reviews as part of ongoing optimization efforts that began under the previous medium-term management plan.
- Under the new medium-term management plan, certain areas are still being reviewed for further optimization. Especially strategy for General Practitioners, we plan to adopt the general testing management model used by our subsidiary, Nihon Rinsho, Inc., which specializes in general testing. Applying this model aims to enhance overall profitability across the LTS business.