Q&A summary for the 162nd Annual General Meeting of Shareholders

Pre-meeting Question from shareholders 1

Question	Regarding DMD drugs, are you developing new therapeutic agents such as iPS cells following nucleic acid and cell therapy drugs? Also, if other companies develop iPS cells, can they coexist rather than competing?
Answer	We are not currently researching iPS cell-based DMD therapies but are considering research on next-generation nucleic acid drugs that improve on DDS technology, gene therapy, genome editing, and other new technologies, including open innovation with academia, venture companies, and others. Even if other companies develop iPS cell products, we believe that there is potential for coexistence, as the diversity of diseases and patient needs will lead to the expansion of treatment options.

Pre-meeting Question from shareholders 2

Question	Regarding the work-related invention compensation lawsuit regarding the Uptravi substance patent, aren't there any other inventors besides the former employee who was the plaintiff? Are you prepared for the risk of another lawsuit being filed by them?
Answer	At this point, we have not identified any specific signs that similar lawsuits will be filed by other inventors. We have established an employee invention reward system in accordance with laws and regulations and have informed our employees of its contents. We've also explained to inventors the basis for calculating compensation and the payment process and believe that the amount of compensation is competitive with other companies in the Japanese pharma industry. We will continue to respect the contributions of inventors and respond appropriately.

Question 1

Question	What lessons have you learned from the failure of NS-304 (selexipag) in the clinical study for LSS (lumbar spinal stenosis)? How are these lessons being applied to the development of ASO (arteriosclerosis obliterans)? NS-304 has vasodilatory and antiplatelet effects, which may lead to indication expansion and additional dosage forms for cerebral infarction, hair growth, and ED treatment. Are you investigating these possibilities using AI or other technologies?
Answer	Both ASO and LSS are evaluated based on motor function, making clinical study difficult. The main cause of failure in LSS clinical study was the enrollment of patients whose condition had not progressed sufficiently. Based on this lesson, preliminary motor function tests were conducted in advance for the ASO study. With the careful selection of appropriate patients, the study is progressing smoothly.

Question 2

Question	Nucleic acid drugs have extremely high manufacturing costs, but are you using AI and other tools to improve production process efficiency and reduce costs? Also, are you trying supplemental New Drug Applications for partial changes?
Answer	As regulated pharmaceuticals, it is not easy to change the manufacturing process of nucleic acid therapeutics. However, we are working to improve our proprietary manufacturing processes, as well as partnering with contracted manufacturers. We aim to apply for supplemental New Drug Applications for partial change on areas where improvement has been confirmed, and gradually reduce costs. Moreover, we are also working to improve efficiency throughout the supply chain and are taking practical steps to reduce manufacturing costs, such as increasing batch sizes. We will continue to make improvements, including the use of AI.

Question 3

Question	I would like to ask about your compliance system for research and development. How do you train employees with specialized knowledge and pass on their expertise within the company? Continuous response is necessary in the rapidly changing field of pharmaceutical research and development. How do you organize your internal system?
Answer	We have established an independent committee, which is separate from the research department, to address compliance issues in research and development. This committee convenes as needed and conducts reviews and makes decisions with the involvement of external experts. Additionally, we are strengthening our internal systems under the guidance of a Chief Medical Officer (CMO) with expertise in research ethics and are actively working to accumulate and share best practices. In recent years, we have accumulated expertise under the guidance of our CMO, but we recognize that developing employees with specialized knowledge is an important challenge. We plan to continue passing on and updating specialized knowledge by utilizing research experience and external recruitment.

Question 4

Question	You raised the base salaries of your employees in the spring labor negotiations. You achieved record high sales and profits in FY2024. Considering the dividend per share, will you continue to prioritize stability? Does the level of 62 yen per share mean that you will continue to pay modest dividends in the future? I would like to hear your thoughts on shareholder returns.
Answer	The 6th Five-Year Medium Term Management Plan adopted a performance-based dividend policy (dividend payout ratio of 35%), but the 7th Five-Year Medium Term Management Plan will focus on growth investments to overcome the patent cliff for Uptravi. We intend to maintain stable dividends even if profits decline during this process. Under this policy of maintaining stable dividends, despite a projected decline in profits for FY2025, we plan to pay the same annual dividend of 124 yen per share (62 yen per share for interim and annual dividends) as in the previous fiscal year.

Question 5

Question	How does management view the current stock price ? If you are unable to overcome the patent cliff, there is a possibility that the stock price will fall further. Please provide a clear explanation of your thinking.
Answer	Although stock prices are influenced by various external factors, we, the management team, take the current stock price, which has been weak since last year, very seriously. Thanks to the results of our growth investments, including the filing of a BLA for CAP-1002 in the US by our partner Capricor Therapeutics in September 2024, our share price rose in the second half of 2024, but has since fallen temporarily due to the impact of the new US administration's drug pricing policy. However, please note that the FDA review of the BLA for CAP-1002 is progressing smoothly. We are steadily building a growth foundation to overcome the patent cliff. We will continue to advance our plans with a sense of urgency to achieve profit growth and a high stock price.

Question 6

Question	I tried to get a prescription for Urocalun at the hospital, but they said they didn't have any. There was no information about the shortage on your website, so I would like you to publish the stock status properly.
Answer	Since February 2024, shipments of Urocalun have been limited due to unstable procurement of Quercus salicina, the raw material used in its manufacture. This is due to the effects of unfavorable weather and climate change. The raw material situation is currently improving, and we expect to be able to lift the shipping restrictions soon. We apologize for any inconvenience this may cause, and we hope you will be able to wait a little longer as we are taking steps to ensure a stable supply.