

Q&A at the 19th Annual Shareholders Meeting

The contents of the question and answer has been partially revised to better understand.

Pre-submitted Questions

Pre-submitted Questions Q1:

Questions about future plan such as “Measures to cope with falling stock price” and “Future business policy.”

A

Although stock prices can fluctuate due to numerous factors, we believe that enhancing communication is crucial for investors to understand our measures for future growth.

In FY2023, we made multiple downward revisions to our forecasts on both a core basis and a full basis. These revisions were driven by factors such as the introduction of generic products for LEXISCAN, increased expenses from the acquisition of IVERIC bio Inc., slower progress with VEOZAH than initially anticipated, and impairment losses. As a management team, we take the disappointment of not meeting the stock market's expectations seriously.

Therefore, we have done a lot of different scenario analysis for our FY2024 forecast and developed a more balanced plan that is both ambitious and achievable, taking into account risks and opportunities. Additionally, in our initial forecast on a full basis, we have factored in other expenses, including impairment loss in our initial forecast to mitigate the impact of unexpected downward revisions during the period. There are no specific indications of impairment at this time, and our estimate is based on past expenses and the balance of intangible assets.

Furthermore, we believe that demonstrating Astellas' future growth to the stock market is of utmost importance. The main focus of our Corporate Strategic Plan 2021 is to establish a structure that will enable us to overcome the XTANDI loss of exclusivity. We consider it extremely important to solidly establish this system within the remaining period of the strategic plan. By making steady progress with the initiatives and milestones outlined on the right side in slide 19 of the presentation materials, which are crucial for the future growth of our strategic products, such as PADCEV, IZERVAY, VEOZAH, and VYLOY, we anticipate significant profit expansion aligned with the sales growth of these main drivers. Furthermore, if we are able to obtain proof of concept (PoC) by the end of FY2025, meaning successful clinical trial data supporting late-stage development, we expect to build a pipeline that will enable sustainable growth.

[Presentation material \(Japanese only\)](#)

Pre-submitted Questions Q2:

Questions about the status of clinical development, such as "What pharmaceutical products are in development?" and "When will IZERVAY be available in Japan?"

A

Here we would like to provide an explanation of our future development outlook. Firstly, let us highlight the key events anticipated for our strategic products in FY2024.

Regarding PADCEV, a treatment for urothelial carcinoma, we expect regulatory decisions in Japan and Europe regarding the application for an additional indication for first-line treatment of urothelial carcinoma based on the EV-302 trial in Q3 of FY2024. The resubmission to the FDA for VYLOY, a treatment for gastric cancer, was accepted in May 2024, and the PDUFA date for the completion of the review has been set as November 9, 2024. Regulatory decisions in other regions are expected in H2 of FY2024 in Europe and in Q4 of FY2024 in China. As for IZERVAY, a treatment for age-related macular degeneration, the PDUFA for completion of the review of the level revision in the US is November 19, 2024. The decision by regulatory authorities in Europe is still pending, and we currently expect a decision in H2 of FY2024. Regarding the development of the product in Japan that you inquired about, we are currently in preliminary discussions with the authorities. We will provide updates as appropriate based on the results of these discussions.

In terms of the progress of our Focus Area Approach, we anticipate obtaining clinical trial data by the end of FY2025 for four programs to determine whether to proceed to the later stages of development. These programs include AT845, a gene therapy for Pompe disease; ASP2138, a bispecific antibody for gastric cancer; ASP7317, a cell therapy for geographic atrophy secondary to age-related macular degeneration; and ASP3082, a KRAS G12D degrader for solid tumors.

Please note that the timing of data release has not been decided at this time, but we plan to make announcements at the right time.

Please refer to the slide 12 of the presentation for key developments in the Focus Area Approach for 2023.

FDA: U.S. Food and Drug Administration

PDUFA : Prescription Drug User Fee Act

[Presentation material \(Japanese only\)](#)

Pre-submitted Questions Q3:

Please explain the dividend policy, including "shareholder return policy" and "the background behind the decision to increase dividends despite a significant decrease in profits in FY2023 compared to the previous fiscal year", and "how you view the current extremely high dividend payout ratio."

A

Our shareholder return policy remains unchanged, with the top priority being placed on business investment to realize growth. Based on mid- to long-term profit growth, we strive to increase dividends stably and continuously.

As for FY2024 dividend, in addition to the slowdown of profit growth, we are paying attention to the need to repay the borrowings incurred from IVERIC bio Inc. acquisition and recover our financial health as soon as possible. We are forecasting a JPY4 dividend increase.

Based on the newly introduced definition of "core operating profit," we expect the profitability of our core businesses to continue to grow, and we will strive to achieve both sustainable growth and a stable financial base.

As for dividend yield and dividend payout ratio, we are not disclosing specific targets or guidance. However, during the course of CSP2021, we aim for higher dividend levels, assuming growth in FY2024 onwards.

For details on the new core definition, please see below:

[Global News | Astellas](#)

Pre-submitted Questions Q4:

"There have been a series of scandals at KOBAYASHI Pharmaceutical and the automobile industry, but is the Company okay? How do you view the problem?"

A

While we will refrain from commenting on other companies, we see this is not someone's problem, but rather as a part of our own company and the pharmaceutical industry.

Pharmaceuticals are manufactured using manufacturing methods that have been reviewed and approved by regulatory authorities, and we guarantee that the processes and quality are properly controlled for each production lot. We also thoroughly maintain a consistent high level of quality control right up to delivery, so you can rest assured.

Ensuring the quality and safety of pharmaceuticals is the foundation of a pharmaceutical company, and we are always conscious of delivering reliable and safe pharmaceuticals to patients under a strict management system.

In the Company, we have established a strict control system by appointing an independent quality assurance manager who reports directly to the President, separate from the manufacturing manager. In addition, we constantly communicate the need for compliance with laws and regulations within the Company, and when a problem occurs, we not only issue instructions to quickly resolve it, but also strive to create a system and atmosphere where information about the problem reaches the President on a daily basis, while it is still small. As a company, we are building a system where we can give instructions to take measures to improve things before small discomforts develop into problems.

We will continue all efforts to ensure the delivery of innovative and reliable pharmaceutical products to patients.

Pre-submitted Questions Q5:

Why are there Directors and candidates who do not hold company shares?

A

For executive Directors (Chairman of the Board, President and CEO, Executive Vice President), we provide stock compensation with the aim of strengthening the alignment of interests with shareholders and further enhancing awareness of long-term corporate value and shareholder value improvement. In addition, we have established shareholding guidelines and encourage the Directors to hold company shares.

As for outside Directors and other non-executive Directors, there are varying perspectives on whether they should hold company shares. Some view shareholding positively as a means to align the interests of Directors and shareholders, while others are concerned about compromising their independence.

Moreover, shareholding is related to personal assets. Therefore, for outside Directors and other non-executive Directors, we leave the decision to hold company shares to their individual judgment.

For each Director candidate, we propose individuals who can contribute to the management and supervision of the Company based on their experience, insights, etc. We are confident that they can fulfill their duties as Directors regardless of whether they hold company shares.

Pre-submitted Questions Q6:

It is questionable whether Ms. Sakurai, the candidate for the First Proposal, and Ms. Aramaki, the candidate for the Second Proposal, can fully dedicate themselves to their duties as Directors of the Company, as they hold concurrent positions as external directors in three or more companies. It is wrong to appoint them solely based on their gender.

A

Regarding concurrent positions and the number of concurrent positions, we confirm with the candidates themselves that there are no obstacles to fulfilling their duties as outside Directors of the Company. In cases where the number of concurrent positions becomes high, we request a more careful judgment from the outside Directors. We have determined that the number of concurrent positions and concurrent positions of the Directors elected at this Annual Shareholders Meeting, including Ms. Sakurai and Ms. Aramaki, do not pose any problems in fulfilling their responsibilities as outside Directors of the Company.

Furthermore, in order for the Board of Directors to function appropriately in accordance with our management strategy, we select candidates for Directors after identifying the specific skills, knowledge, experience, and abilities that the Board of Directors as a whole should possess. The reasons for selection of Director and outside Director candidates are stated in the convocation notice, and selections are not based on gender.

Pre-submitted Questions Q7:

Corporate Strategic Plan 2021 sets a target of a core operating profit margin of 30% or higher (compared to approximately 18% until 2022). Will the optimization of business efficiency through the utilization of digital technology, as stated in the countermeasures, actually lead to such a significant increase in the core operating profit margin? Could you please provide a more detailed and specific explanation?

A

As specific projects and initiatives are still under consideration, we will disclose information at the appropriate timing in the future.

One example of optimizing business efficiency through the utilization of digital technology is the use of generative AI in our business. Nick Eshkenazi, Chief Digital & Transformation Officer, is leading the effort to actively explore both internal and external generative AI tools and establish guidelines to ensure the appropriate use and protection of internal data, including personal and confidential information, in order to create an environment where employees can effectively utilize generative AI in their daily work. In addition, in our research and development activities, we have developed and adopted numerous systems internally that leverage large-scale language models, and we will continue to promote such initiatives in the future.

Pre-submitted Questions Q8:

The current management structure is facing significant challenges in terms of market research, market expansion strategies, and other aspects, as evidenced by the impairment of AT808 and the significantly lower-than-expected sales of VEOZAH, a treatment for vasomotor symptoms, VMS. We would like to hear your views on management responsibility and the reduction of executive compensation, as well as whether you are prepared to reevaluate the development and market strategies from the ground up, including a review of the executive structure.

A

Regarding the sales deviation between the initial plan and the actual sales of VEOZAH, we believe that the main factor is the market changes rather than a lack of market research capabilities. The market research conducted at the time of planning was based on pre-launch data, but the market has since changed. The plan for the FY2024 has been formulated and implemented based on the latest data. Instead of fundamentally revising the market strategy, we aim to achieve the sales target for FY2024 by accelerating the three current activities that are most crucial for improving the product value of VEOZAH: accelerating insurance reimbursement, increasing physician awareness of the product, and improving patient disease awareness.

We acknowledge the fact that we were unable to meet the expectations of the stock market in the FY2023 and take it seriously as the management team. The main theme of the current Corporate Strategic Plan 2021 is to establish a structure that can overcome XTANDI loss of exclusivity, and we consider it extremely important to solidify that system during the remaining period. We anticipate that our key strategic products will contribute significantly to sales from the FY2024 onwards. We, including the Directors appointed at this Annual Shareholder Meeting, will work together as one company and continue to devote our full efforts towards sustainable growth.

Pre-submitted Questions Q9:

It is encouraging that the acquisition of IZERVAY has provided a prospect for avoiding XTANDI loss of exclusivity. However, I am very concerned about the inferior quality and quantity of the early and mid-stage pipeline that will drive Astellas' future development. The concept of the Focus Area Approach does not seem to align with the scale of Astellas' research and development, and a bold reassessment is necessary. Shouldn't there be a narrowing down of the types of modalities and a focus on product and development introductions?

A

Thank you for your valuable feedback.

In our investment in research and development, we allocate resources to Primary Focus based on the concept of the Focus Area Approach and are committed to the development of innovative therapies.

Since the initiation of the Focus Area Approach, we have designated a total of six Primary Focus. However, based on the progress and results of trials, we make choices and currently have four Primary Focus: Genetic Regulation, Immuno-Oncology, Blindness & Regeneration, and Targeted Protein Degradation. We expect to obtain data by FY2025 to determine whether the lead program of each Primary Focus can enter late-stage clinical trials. We will continue to make future investments by prioritizing based on comprehensive assessments of trial results and the progress of follow-up products.

We also consider the internal portfolio and external environment and conduct ongoing evaluations for the introduction of products and development candidates.

Pre-submitted Questions Q10:

What measures are being taken to expand the sales of EVRENZO, a treatment for renal anemia?

A

For FY2024, EVRENZO's global sales forecast is JPY 4.7 billion. EVRENZO operates in a challenging environment due to the presence of competing products. However, we are working towards achieving our sales targets by providing appropriate information and implementing necessary measures.

Questions from the venue

Questions from the venue Q1:

With regards to business performance forecasts, it is common for Japanese companies to initially set conservative projections and subsequently make upward revisions. I would appreciate hearing the President's thoughts on this matter. Additionally, I would like to inquire about the Company's internal culture, specifically whether there is a practice of reporting sales targets at higher levels to demonstrate enthusiasm or motivation within the organization.

A

We believe that our mission is to strive for greater heights and deliver our medicines to as many patients as possible. We aim to foster a corporate culture where we set ambitious goals that go beyond what is easily achievable and dedicate ourselves to their achievement. However, we are also aware that there are voices, even within our organization, expressing concerns that some individuals may mistakenly set unrealistic goals, thinking that it demonstrates their motivation. We understand that our focus should not solely be on sales figures, but rather on fulfilling our mission of delivering our medicines to the patients who need them. Taking into account the lessons learned from multiple downward revisions in FY2023, we have set target for FY2024 that not only reflect ambition but also outline the steps and strategies to achieve them. We have aimed to strike a balance between achievability and ambition in setting the target.

Questions from the venue Q2:

Drug discovery has high hurdles and difficult aspects, as evidenced by impairment losses in FY2023. Please tell us whether the Company utilize artificial intelligence, AI, in drug discovery and whether there are plans to further enhance the utilization of AI in the future.

A

We are actively utilizing AI in our drug discovery activities. As a specific example, we have been utilizing AI in optimization research of small molecule compounds for several years, and we have achieved highly promising results. This includes significant reductions in the time required for optimization, up to 70%. We also employ AI in research of new modalities such as antibody drugs and gene therapies, and are working on optimizing gene sequences. In the previous fiscal year, we acquired access rights to NVIDIA's leading GPU, further accelerating our AI-driven drug discovery activities. We have grand expectations for the impact of AI utilization in our drug discovery efforts this fiscal year as well.

GPU: Graphics Processing Unit, a specialized processor primarily used for visual information processing, including graphics rendering, image processing, and 3D rendering. In recent years, GPUs have also been utilized for advanced computing tasks such as AI.

Questions from the venue Q3:

If it is true that achieving the Performance Goals of the Corporate Strategic Plan 2021, CSP2021, is challenging, I believe that maintaining the same goals without revision will not lead to an increase in market evaluation. By reassessing the Performance Goals of CSP2021 and engaging with the market once again, there is a potential for Astellas' evaluation to rise and market capitalization to increase. I would like to know your thoughts on revising CSP2021.

A

Rather than making changes to CSP2021 itself at this point, we would like to communicate achievable targets to the capital markets while taking into account the current outlook.

Regarding the revenue target for FY2025, the original goal was to aim for a total of JPY 1.2 trillion in sales revenue from XTANDI and other key strategic products. Based on the current outlook, we are aiming for sales revenue of approximately JPY five hundred billion from key strategic products in the FY2025, so we have a certain level of confidence in achieving this target.

As for the value of our pipeline, we anticipate obtaining data on whether each key projects of the four Primary Focus can enter late-stage clinical trials by FY2025. If these are successful, we can expect subsequent projects to emerge from these Primary Focuses, further enhancing the value of our pipeline.

Lastly, regarding the core operating profit margin, taking into account the change in the definition of core-based performance, we will continue to set a long-term target of a 30% core operating profit margin, like the North Star, and recognize that strengthening our profitability until XTANDI loss of exclusivity is a challenge for the Company.

Questions from the venue Q4:

Sales are increasing, but the reason for the decrease in operating profit and operating profit margin is explained to be due to the acquisition of IVERIC bio Inc. Was this expected? Additionally, as a request, I would like to see the use of katakana for drug names to be standardized, as having drug names in English characters may potentially deter individuals who wish to invest in stocks.

A

The acquisition of IVERIC bio Inc. was agreed upon in May 2023 and was therefore not included in the original FY2023 plan. Therefore, after the acquisition, we conducted a thorough examination of the costs and future outlook related to the acquisition and made adjustments at the end of the second quarter. Since M&A transactions are uncertain until they are completed, it was difficult to incorporate them into the annual plan at the pre-completion stage.

Regarding product names, products in the development stage are typically indicated by alphanumeric project codes, which are later replaced by commercial names as they approach market launch. In documents such as convening notices, we use katakana to represent products approved in Japan, while products not yet available in Japan are represented by English names. We will continue to explore better ways to represent product names in order to facilitate understanding for everyone.

Questions from the venue Q5:
Regarding Astellas employee who is currently detained in China.

A

This incident has caused us all a great deal of concern. We will continue to coordinate with relevant parties to ensure the health and safety of our employee and respond appropriately.

Questions from the venue Q6:

I would like to ask President Okamura if there are any episodes when you felt that your management judgment was wrong, or any achievements that you would like to brag about to shareholders.

A

It is natural for assessments to differ in various situations, but the quality of management is determined by how well we can respond to those differences. Unfortunately, the financial results for FY2023 were disappointing, but as a new management team, we aim to conduct more detailed scenario analysis for risks and opportunities and have various response measures in place before steering the Company.

Additionally, while I do not intend to boast, Astellas' greatest strength lies in our unwavering commitment to innovation. It is regrettable that we have not yet achieved data that suggests progression from Primary Focus to proof of concept, indicating late-stage development. However, this is a result of our pursuit of cutting-edge science that no one else in the world has ventured into. I believe that solid products will emerge from this innovation in the near future. While shareholders may need to be patient for a while longer, we hope to continue to receive your support.

Questions from the venue Q7:

Return on equity, ROE, is also a factor in market evaluation, but ROE has been low for the past four or five years. What are your thoughts on ROE? Also, what exchange rate is assumed in setting your target value?

A

We recognize that awareness of capital costs and stock prices is essential for sustainable growth and improvement of corporate value. In particular, to enhance corporate value, it is important to ensure a return on capital that exceeds the cost of capital. We regularly calculate and verify the Weighted Average Cost of Capital, WACC, as one of the indicators for decision-making on business investments.

On the other hand, we understand that in the pharmaceutical business, the evaluation of stock prices is influenced not only by the current performance but also by the future value of the development pipeline. Instead of relying solely on capital profitability indicators such as ROE or Return on Invested Capital, ROIC, calculated as annual performance figures, we believe it is more appropriate to use the evaluation based on the future pipeline value as one of the indicators. We have formulated and are promoting Corporate Strategic Plan 2021 based on this perspective.

Additionally, for FY2024, we assume an exchange rate of JPY145 against the US dollar and JPY155 against the euro.

Questions from the venue Q8:

Considering market potential, it seems correct that the Company is focusing on the research and development of anticancer drugs. Are there any promising development candidates, such as new mechanisms? Also, there are no development candidates for diseases like Alzheimer's disease, but as the aging population increases, market expansion is expected. What are your thoughts on this?

A

Among Astellas' anticancer drugs, we have diverse types, including XTANDI and XOSPATA, which are traditional small molecules, VYLOY, which is a drug that uses the antibody itself, and PADCEV, which is an Antibody-Drug Conjugate, ADC, which combines the antibody with a compound that has other functions and kills cancer cells after being taken up by them, demonstrating therapeutic effects. In two of our four Primary Focus areas, which are Immune-Oncology and Targeted Protein Degradation, we are not simply using traditional small molecules or antibodies as they are, but rather modifying them to enhance efficacy or improve safety.

For example, the first compound for Immune-Oncology is a bispecific antibody, an antibody in which one arm targets the same antigen of cancer cells as VYLOY, and the other arm captures the T cells that control the immune system, thereby bringing cancer cells and the T cells closer together. There is a possibility of obtaining proof of concept or clinical trial data supporting progression to late-stage development by FY2025.

In addition, Targeted Protein Degradation is based on the concept of linking two small molecules with a linker to degrade cancer-related proteins that were difficult to target with conventional small molecules. We also expect to be able to make a PoC decision or to determine the possibility of progressing to later-stage development for this core project by FY2025.

While we believe in pursuing innovation, it is not possible to cover all areas evenly. For certain diseases like Alzheimer's disease, we have strategically decided not to focus on them and instead allocate our resources to areas such as cell therapy or gene therapy.

Online Questions

Online Questions Q1:

The current performance is in a difficult state. When do you expect the performance and stock price to recover? We are looking forward to it. Please provide specific measures to improve the stock price.

A

Stock prices are influenced by numerous factors and can fluctuate. However, we believe that it is important to enhance communication to ensure understanding from the stock market regarding our future growth initiatives. We take the questions and opinions received from numerous shareholders regarding our stock price seriously as the management team, and we are committed to working towards restoring trust from the stock market.

Regarding our thoughts on the stock price, please refer to the answer to Q1 on Pre-submitted Questions.

Online Questions Q2:

Recently, employee wage increases have become a hot topic in Japan market. How does the Company's wage increase level compare to other companies? Also, how does it compare to overseas?

A

Our company sets competitive compensation levels by monitoring the trends in compensation levels in the labor market for each country and region, aiming to attract talented individuals. In Japan, in addition to regular salary increases, we plan to implement additional salary increases in FY2024, with an average increase of approximately 4% scheduled for July. In overseas labor markets, some countries and regions have implemented salary increases higher than 4%, surpassing those in Japan. As business environments vary significantly from company to company, we prioritize maintaining appropriate compensation levels by considering overall labor market trends and competitiveness, rather than comparing directly with other companies.

Online Questions Q3:

The Company said to aim for a market capitalization of seven trillion yen, but the progress is quite challenging. Can you provide Astellas' perspective on this? What happened to the talk of doubling the market capitalization? I believed in those words and invested, feeling deceived. While I currently plan to hold onto my investment, when do you anticipate the realization of doubling the market capitalization?

A

The Company does not have the market capitalization itself as a specific target, but in Corporate Strategic Plan 2021, CSP2021, we stated our aim to become a company valued at a market capitalization of over seven trillion yen by FY2025 by achieving three Performance Goals. We are not oblivious to the importance of stock price in our management. We recognize that stock prices are influenced by factors such as current profits, future growth prospects, and the trust of various stakeholders.

We are working towards the recovery of the stock price by achieving our targets for revenue, core operating profit margin, and enhancing the value of our pipeline through research and development driven by new innovations.

While we cannot predict stock price fluctuations, we aim to restore trust from the capital market through the solid implementation of CSP2021, which we hope will contribute to the recovery of our market capitalization.

Online Questions Q4:

Which clinical development projects have high feasibility and expected sales? When do you expect them to contribute to the Company's performance?

A

We are driving two strategies: accelerating the development of additional indications for strategic products and creating new products through Focus Area Approach.

For strategic products, VYLOY and PADCEV, we are exploring additional indications and evaluating their efficacy in other cancer types. For VYLOY, we have an ongoing trial for pancreatic adenocarcinoma, and we anticipate obtaining topline results in the fourth quarter of this fiscal year. For PADCEV, we are progressing with development in cancer types other than urothelial carcinoma and have presented clinical trial results for head and neck cancer, breast cancer, lung cancer, and esophageal cancer at conferences. Additionally, we are also developing a bispecific antibody called ASP2138 that targets the same target protein and immune cells as VYLOY, aiming to enhance efficacy when combined with immunotherapy.

While we have not disclosed specific sales figures or launch dates for these programs, we are fully committed to advancing their development to provide effective treatments to patients as early as possible, including the lead programs of each Primary Focus.

Online Questions Q5:

I have a question about the audit system. Regarding the recent system troubles that have become an issue for another company, a major confectionery company, I would like to confirm if the Company's audit firm has the ability to check the system or if there are knowledgeable individuals properly auditing the system. Furthermore, I would like to inquire with the Audit & Supervisory Committee, which is the Board of Directors, if they consider the audit by the Financial Auditor to be appropriate.

A (Answered by Director Yoshimitsu on the day of the Annual Shareholders Meeting)

Regarding the Company's accounting system, we have transitioned to a unified system throughout the Company since 2020. From the initial implementation, the adequacy of the system has been confirmed by the specialized staff of our Financial Auditor, Ernst & Young ShinNihon LLC. Additionally, as part of internal controls, the operation of the system is audited by the Financial Auditor, and the Audit & Supervisory Committee regularly receives audit reports. Based on the regular reports received, the Audit & Supervisory Committee acknowledges the adequacy of the audit by the Financial Auditor regarding the system.

Online Questions Q6:

In Japan, there is a serious shortage of pharmaceutical products, mainly generics. As a leading company in the industry, what are your thoughts on how to address the shortage of pharmaceuticals, including drug price revisions, through collaboration between the government and the private sector? Additionally, what impact do you think the overall shortage of pharmaceuticals in the industry will have on the Company's performance?

A

As a pharmaceutical company focused on research and development pursuing innovation in new drug development, we do not have the intention to actively promote generics.

However, based on that, we recognize the situation of drug lag and drug loss, where products already available in Europe and the United States are not reaching Japan or are not even being developed, as a significant issue.

We have been actively advocating for broad systemic reforms, including activities targeting industry organizations and Keidanren (Japan Business Federation), to address this issue.

Ensuring the delivery of high-quality and safe products is the pharmaceutical industries' and the Company's greatest mission. For our major products, we have established a supply system that can reliably deliver the necessary pharmaceuticals to patients through measures such as diversifying raw materials and production bases, as well as building backup systems.

Online Questions Q7:

Could you please provide more details about your future shareholder returns?

A

For FY2024, we are expecting a dividend increase of JPY 4 compared to the previous year, with a projected dividend of JPY74.

Taking into account the current situation where profit growth is slower than anticipated, we have reviewed the previous dividend increase range. However, we remain confident in future profit growth and are forecasting a dividend increase of 4 yen.

During the period of Corporate Strategic Plan 2021, we will determine the pace of dividend increases while considering further growth prospects.

As for share buybacks, there are no changes in our current policy. While putting priority on business investment to realize growth, the Company strives to increase dividend payments stably and continuously based on its medium- to long-term profit growth on a consolidated basis. Furthermore, the Company flexibly acquires its own shares whenever necessary to increase capital efficiency and shareholder return.

Online Questions Q8:

I would like to inquire about your future hiring policy. With the decrease in operating profit, do you have any plans to reduce new graduate or experienced hires in research and development positions?

A

We do not make hiring policy decisions based on short-term fluctuations in performance. Based on our long-term strategy, we actually plan to actively conduct recruitment activities and internships in the future. We aim to achieve hiring that takes into consideration not only the progress of our business but also our future portfolio and the necessary capabilities.

Online Questions Q9:

Regarding Astellas employee who is currently detained in China.

A

This incident has caused us all a great deal of concern. We will continue to coordinate with relevant parties to ensure the health and safety of our employee and respond appropriately.

Online Questions Q10:

A significant decrease in profit during the financial statement stage undermines the trust of shareholders and the market. It is a major issue that the following factors leading to the decrease in profit, which could have been identified by at least the third quarter, were not disclosed. The substantial increase in "intangible asset amortization expenses" due to the acquisition of IVERIC bio Inc. could have been anticipated at the time of the acquisition and should have been separately reserved, similar to provisions. Additionally, I believe that preparations should have been made in advance for VEOZAH private insurance.

A

For FY2023, we made multiple downward revisions to the forecast, both on a core basis and a full basis, due to factors such as the entry of generic products for LEXISCAN, increased expenses from the acquisition of IVERIC bio Inc., progress below expectations for VEOZAH, and recognition of impairment losses. We acknowledge the fact that we were unable to meet the expectations of the stock market, and we take this responsibility seriously as the management team.

For FY2024 forecast, we conducted various scenario analyses and formulated a more balanced plan that is ambitious yet takes into consideration achievability, while considering risks and opportunities. In the full basis forecast, we incorporated other expenses such as impairment loss risks into the initial forecast to mitigate the impact of unexpected downward revisions that may occur during the period. At present, there are no specific signs of impairment, and we estimate based on past expense records and the balance of intangible assets.

According to market research, the majority of healthcare professionals, such as doctors and pharmacists, state that the insurance coverage for VEOZAH is currently the biggest barrier to prescription. By continuing to invest in healthcare professionals, patients, and market entry, we anticipate that awareness, education, and adoption of VEOZAH will be promoted, leading to a linear increase in demand throughout the year. As a future measure, we aim to achieve private insurance coverage in the United States of 80% or more by the end of FY2024.

Online Questions Q11

Could you please provide a clearer explanation of the cause analysis, future response measures, and the reliability of future prospects regarding the underperformance of VEOZAH sales?

A

We consider the following two factors as the main causes.

1. The promotional activities for VEOZAH in the United States are taking longer than expected to impact sales.
We believe that direct advertising using the product name would be effective in promoting VEOZAH sales in the United States, but it takes a considerable amount of time for the advertising activities to actually influence the increase in demand. It has been revealed that the effectiveness of the advertising activities is taking longer than initially anticipated, and the patient process and time required for patients to discuss with their physicians about VEOZAH, receive prescriptions, and have them dispensed are longer than initially expected.
2. Trends among U.S. healthcare payers also temporarily impact the increase in demand. According to market research, the majority of healthcare professionals, such as doctors and pharmacists, state that the insurance coverage for VEOZAH is currently the biggest barrier to prescription. By continuing to invest in healthcare professionals, patients, and market entry, we anticipate that awareness, education, and adoption of VEOZAH will be promoted, leading to a linear increase in demand throughout the year.

Future measures include;

- Aiming to achieve private insurance coverage in the United States of 80% or more by the end of FY2024.
- Striving continuously for improved consumer and physician motivation through direct advertising activities using the product name.
- Focusing on implementing activities to sustain the growth of the VMS, Vascular Motor Symptoms market.
- In FY2024, Prioritizing implementing information provision through a combination of various methods to adapt to the diversification of information media.

Online Questions Q12:

Regarding the current situation of the stock price falling by more than 30% in the past year, the responsibility of the Directors is significant. I would like to know how each Director thinks about this matter, especially Executive Vice President's opinion.

A

As the management team, we take the fact that we were unable to meet the expectations of the stock market very seriously. Please refer to the answer to the pre-submitted question, Q1, for our thoughts on the stock price.

Online Questions Q13:

Please let us know if there are any factors that could lead to an increase in the Company's stock price in the future.

A

Please refer to the answer to the pre-submitted question, Q1, for our thoughts on the stock price.

Online Questions Q14:

It is important to leverage external knowledge from universities and other companies, but what do you think about collaborating with external entities in research?

A

Pharmaceutical companies are now in an era where they must create value not only through their own research but also through collaboration with others. Since around 2013, the Company has actively collaborated with external entities, mainly in Europe and the United States. In Japan, the environment for external collaboration among industry stakeholders is not as developed as in Europe and the United States, and we believe that it is necessary for industry, government, and academia to work together to mature in this area.

In Astellas, we are engaged in open innovation through various methods, such as strategic partnerships with universities, establishment of joint research laboratories, and the development of research facilities that can be used by external parties. Rather than simply incorporating external innovation as in the past, we aim to support the growth of our partners and develop a collaborative environment to create value together and contribute to the creation of new pharmaceuticals.

As recent examples of Astellas' initiatives, we have been expanding research facilities that can be used by external parties, such as SakuLab™ and TME iLab, both domestically and internationally. One of these facilities, SakuLab™ -Tsukuba, is located within the premises of Astellas Tsukuba Research Center. It provides users with opportunities to network with various experts from Astellas in drug discovery and receive support, creating a stimulating environment for our researchers as well. Most recently, we have also started activities for external research facilities in the Boston area, specifically in Cambridge.

Open innovation: the process of incorporating knowledge and technology from organizations and institutions other than one's own in product development, technological advancements, research and development, and organizational reforms, moving away from self-reliance.

For detailed information, please see below.

[Open Innovation in Drug Discovery Research | Astellas Pharma Inc.](#)