Q&A at the 18th Annual Shareholders Meeting

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

Pre-submitted Questions

Pre-submitted Questions Q1:
I believe that Targeted Protein Degradation will greatly accelerate drug discovery research for a wide variety of target proteins once the ubiquitin ligase binding site and linker technology is established. I was wondering what impression your research department has of Targeted Protein Degradation.

A

The targeted protein degradation inducer consists of a binding site to the target protein, a binding site for E3 ligase, and a linker connecting the two. By converting the parts that bind to the target protein according to the target molecule, it is possible to efficiently conduct drug discovery research on a wide variety of targets.
Steps will obviously be needed to optimize the molecule as a whole, but we hope that drug discovery research will be accelerated.
Targeted protein degradation inducers exhibit different forms of medicinal effects than conventional small-molecule drugs, in other words, lysis. Therefore, we expect to be able to target proteins that have been difficult to target with conventional small-molecule drugs for drug discovery.
It has been said that only about 20% of disease-related proteins are suitable targets for conventional small-molecule compounds. We are very hopeful that targeted protein degradation inducers will be able to target the remaining 80%. Therefore, the research division intends to increase its investment in the future.

Pre-submitted Questions Q2:
The market for conventional small-molecule drugs is also increasing slightly, although the development of new modalities is currently very active. What is the future position of small-molecule drug development in your company? You asked about research strategy, do you consider small-molecule drugs to be the most important modality to focus on?

A

In recent years, many modalities or means of treatment have been developed, each with its own characteristics. We believe that in drug discovery, it is important to select the most appropriate modality to achieve the desired efficacy.
Synthetic pharmaceuticals, including small-molecule drugs, are currently one of the Company's priority modalities, along with antibodies, cell therapy, and gene therapy. Targeted protein degradation is a technology that we are excited about and that we have designated as our Primary Focus. If synthetic drugs, including targeted protein degradation, are to be defined as small-molecule drugs in the broad sense of the term, then this will be a modality in which we will focus our investments in the future.

Pre-submitted Questions Q3:
Is the investment in research and development sufficient?

A

As for actual results, in fiscal 2022, JPY 276.1 billion was spent on R&D in FY2022. That amounts to 18.2% of our revenue for the period.
According to the data book of the Japan Pharmaceutical Manufacturers Association, the ratio of R&D expenses to sales revenue in FY2021 is 3% on average for all industries and 10% for the pharmaceutical manufacturing industry. Our figure is obviously much higher. The average figure in FY2021 for major pharmaceutical companies is approximately 18%. We are investing in R&D at a similar or higher level.
Under the Corporate Strategic Plan 2021, we are prioritizing investments in Primary Focus and other areas. We plan to continue to invest in research and development to achieve sustainable growth.

Pre-submitted Questions Q4:
I don't see any proposals regarding executive compensation. Please give an explanation of the method for calculating compensation for Directors.

A

Remunerations for Directors who are not Audit & Supervisory Committee Members (excluding outside Directors) are composed of a fixed amount basic remuneration as well as bonuses and stock compensation that are performance-linked remunerations. Remunerations for outside Directors and Directors who are Audit & Supervisory Committee Members are composed of a fixed amount basic remuneration only.

At the past Annual Shareholders Meetings of the Company, the ceiling amount of each of basic remuneration, bonuses and stock compensation for Directors was resolved.
Remunerations for each Director who is not an Audit & Supervisory Committee Member are determined by resolutions of the Board of Directors within such ceiling amount. Also, remunerations for each Director who is an Audit & Supervisory Committee Member are determined by the deliberations of the Audit & Supervisory Committee Members within such ceiling amount.

Through the deliberations at the Compensation Committee prior to the resolution of the Board of Directors, the Company ensures greater transparency and objectivity of the deliberation process for remunerations for Directors who are not Audit & Supervisory Committee Members.

There were no revisions to the ceiling amounts of remunerations for Directors or revisions to the remuneration system that would require a resolution at this Annual Shareholders Meeting, so there were no proposals regarding remuneration for Directors.

Please refer to pages 70 to 73 of the Notice of Convocation for the amounts by type of remuneration paid or recorded as expenses for the business year under review for each Director category, as well as targets, actual results, etc. of bonuses and stock compensation that are performance-linked remuneration. The policies and procedures for determining remunerations for Directors are described on pages 74 to 86 of the Notice of Convocation.

Please also see the remuneration levels and the specific remuneration structure for Representative Director, Chairman of the Board; Representative Director, President and CEO; and Representative Director, Executive Vice President for the business year under review and the next business year, that are also described in the Notice of Convocation.

Notice of Convocation of The 18th Annual Shareholders Meeting

Pre-submitted Questions Q5:
From the perspective of business efficiency, the manufacture of Repatha and the single-use electrocardiograph "EG Holter" should be discontinued. Sales transfer is also nonsense.

A

In addition to the products you pointed out, we are considering all possibilities to maximize product value and VALUE for patients.

Regarding the Repatha and EG Holter you pointed out, we do not manufacture them and are not in a position to decide to discontinue them. Although our company is responsible for sales, there are currently no plans to discontinue sales or transfer sales.

Repatha, a human anti-PCSK9 monoclonal antibody preparation, is manufactured and marketed by Amgen K.K., and is distributed and promoted in Japan as the distributor.
Repatha is indicated as a treatment option for patients with hypercholesterolemia who are at high risk for cardiovascular events and who are inadequately treated with statins. In 2019, it became possible for patients with familial hypercholesterolemia and hypercholesterolemia who have difficulty taking statins to use Repatha as a monotherapy, and to prevent coronary artery disease such as angina pectoris and myocardial infarction. It is used for LDL cholesterol management, which is important for prevention.

The single-use electrocardiograph "EG Holter" is a Holter electrocardiograph designed and developed by Nitto Denko Corporation. M.Heart Co., Ltd. acquires manufacturing and sales, and our company, as a sales company, conducts pilot sales for medical professionals in Japan. doing.
In addition, the data obtained by EG Holter is analyzed by the Holter analyzer program "My Holter II" jointly developed by our company and M.Heart Co., Ltd.
This kind of business model is the first of its kind for us, and we will verify the business model through pilot sales of EG Holter and consider the points of view that you have pointed out.

Pre-submitted Questions Q6:
In addition to increasing dividends, will you not implement measures to further raise the stock price through the acquisition of treasury stock?

A

In addition to striving to sustainably improve corporate value, we are actively working to return profits to shareholders. While prioritizing business investment to realize growth, we will work to achieve stable and sustainable increases in dividends based on medium- to long-term profit growth on a consolidated basis, and will also flexibly acquire treasury stock as necessary. We will strive to improve capital efficiency and return levels.

Regarding the repurchase of treasury stock, most recently, from February to March 2023, we acquired 50 billion yen worth of treasury stock.

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Questions from the venue

Questions from the venue Q1:
Question regarding Astellas employee being held captive in China.

A

This incident has caused us all a great deal of concern. Our top priority is the safety of the employee, and we are working to gather information and understand the current situation through the Ministry of Foreign Affairs.
But so far, we do not have more information beyond what has been reported in the media.

Questions from the venue Q2:
Reasons for the appointment of candidates Dr. Yasukawa and Mr. Okamura

A

The reasons for appointing candidates Dr. Yasukawa and Mr. Okamura are described on page 14 and 15 of the Notice of Convocation.

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Questions from the venue Q3:
The target for market capitalization in FY2025 is more than JPY 7 trillion, but the current market capitalization is JPY 3.99 trillion. Please explain how you intend to get to the target.

A

Market capitalization is calculated by multiplying the current share price by the number of shares outstanding. On the other hand, when considering the meaning of market capitalization, we believe that it can be interpreted as the product of current profits, future growth, and the trust placed in us by our shareholders.

Corporate Strategic Plan 2021 discloses the following three targets as performance goals.

1. Revenue: Sales of XTANDI and key strategic products will exceed 1.2 trillion yen in FY2025
2. Pipeline value: Sales from Focus Area projects will exceed 500 billion yen in FY2030
3. Core operating margin: 30% or more in FY2025

The product of sales revenue and core operating profit margin is the current profit, and the value of the pipeline is the future growth. I believe that you will appreciate it.

The assumptions for these figures do not specifically include, for example, mergers with other companies. This shows our hope that we will receive such an evaluation.

Questions from the venue Q4:
Will your company work to increase sales in Japan or optimize the workforce in Japan?

A

The Japanese prescription drug market is the second largest in the world at over JPY 10 trillion, and is a market that we will continue to focus on. In addition, Astellas Pharma is a Japanese company listed on the Tokyo Stock Exchange, so we would like to contribute to the Japanese market as much as possible.

On the other hand, there are factors that do not work favorably for the Japanese market compared to overseas markets, such as new drug reviews, approval procedures, and drug price calculation methods in Japan. I'm going to think about it.

Starting with zolbetuximab, for which we applied for approval in Japan in June 2023, we plan to introduce a series of key strategic products into the Japanese market, and we expect significant growth in the future.

Questions from the venue Q5:
As the new president, how will you approach management in the future? I would like to hear your current thoughts, such as your image of growth.

A

Since I was appointed Vice President of Corporate Planning in 2016, I am proud to have played a central role in the formulation and implementation of Astellas Pharma's strategy for seven years. In that sense, I feel very honored to have been able to put the finishing touches on this as president and CEO.
Fundamentally, we would like to push forward to properly execute the Corporate Strategic Plan 2021 and achieve our goals, but the pharmaceutical business is a business that entails a certain amount of risk, so changes in the situation, etc. I would like to properly invest management resources while thinking about it.

As clearly stated in our Vision and Corporate Strategic Plan 2021, we have declared that Astellas will be a Cutting-Edge, VALUE-driven life science innovator. To this end, continuous innovation is our lifeline.
While taking smart risks as a company as a whole, we should learn from our failures, and each and every employee should demonstrate leadership. Furthermore, we should not focus too much on the details of each function, and aim for even greater heights as One Astellas. We believe that it is an urgent task to develop such a corporate culture, and we would like to devote our efforts.

Astellas is making efforts to create such drugs that somehow change the root cause of the pathology rather than drugs that only improve symptoms, such as cell therapy and gene therapy.
Of course, there are risks involved, but we would like to proceed with these, keeping in our hearts the Sense of Urgency that "patients are waiting for us."
Thank you for your continued support.

Questions from the venue Q6:
How do you assess, for example, the ratio of sales between regions, or the exchange rate risk going forward, in order to achieve the performance targets of Corporate Strategic Plan 2021?

A

There are figures that serve as the basis for the target figures for sales revenue and operating margin disclosed in the Management Plan 2021. However, exchange rates and the situation in each country are constantly changing, so we are moving forward while reviewing each time and assessing whether we can really achieve the goals of the management plan.

For example, business development in the Chinese market depends on conditions such as the establishment of a medical delivery system that can accept advanced medical care, the acceptance of development or examination methods similar to those in other developed countries, and the handling of intellectual property. If the above conditions are met, we are preparing to do business in China, the country with the largest population in the world.
Partly due to the impact of the weaker JPY, the United States will account for over 40% of sales in fiscal 2022. In the U.S. as well, there is increasing pressure to shrink the overall pharmaceutical market through various measures, and when such measures become apparent, we are constantly verifying whether our strategy is truly viable.

Questions from the venue Q7:
How are our R&D, commercialization, and manufacturing capabilities, and other functions being deployed globally? Do you manufacture antibodies in Japan?

A

Astellas Pharma is a global organization with most of its functions.
In terms of research, the research institute in Tsukuba has the largest number of people, but various research projects are conducted in various places around the world, and Shitaka, who is in charge of research, organizes them as a global research organization.
For example, we have a base for cell therapy in Massachusetts, the United States, Universal Cells, which has technology to transform cells so that they are not attacked by the immune system, in Washington State, and Xyphos, a base for cancer cell therapy, in San Francisco. One research center for mitochondria is located in Massachusetts, USA, and there is a research institute in the UK under its control.

Regarding the development function, most of our staff are in the United States, but we have the ability to develop globally, including Japan and China.
In terms of production capacity, we have three factories in Japan, two in Ireland, and one in the Netherlands. Our supply chain does not mean that we manufacture all products on our own, but with external cooperation, we form a global and complex supply chain.
Regarding commercialization organizations, we have arranged various organizations according to the characteristics of each product portfolio and market.
The head office functions are not limited to Japan, but also span national borders, and are composed of extremely complex organizational systems.
Antibodies are also manufactured in Japan.

Questions from the venue Q8:
According to a newspaper report, it plans to acquire a company called IVERIC bio for 800 billion yen. Are there any specific products that could become large-scale products to complement XTANDI's patent expiry?

A

We would like to overcome the expiry of XTANDI's exclusivity period by having several key strategic products such as VEOZAH, PADCEV, and zolbetuximab, which we have just filed for approval in Japan.
Regarding the acquisition of IVERIC bio, the flagship compound Avacincaptad Pegol (ACP) is already under review in the United States, and a regulatory decision is expected in August of this year. We have strong expectations that this ACP, along with VEOZAH and PADCEV, will become a product that will support the future of our company.
However, as the acquisition of IVERIC bio has not been completed, we will refrain from disclosing sales forecasts for individual products at this time.

Online Questions

Online Questions Q1:
The Notice of Convocation states that you are conducting a global engagement survey and visualizing employee engagement. How do you see Astellas' current situation compared to other companies?

A

What we call a Global Engagement Survey is what other companies call job satisfaction surveys or employee satisfaction surveys. It is a survey to measure whether it is facing in the same direction as the direction in which it is.
We grasp the status and trends of our company's engagement in a timely manner globally and for each department and region, and consider and implement specific measures to address the issues identified. By repeating this cycle, we can improve employee engagement, job satisfaction, and satisfaction. This is the purpose of the Global Engagement Survey.
Regarding the comparison with other companies, we will refrain from mentioning it because the items of the survey and the situation of the company are different.
We conducted a survey last year and this year, and the response rate of employees is extremely high. 75% of the survey items showed an improvement in scores, and we believe that one of our company's strengths is that we scored particularly high in terms of company integrity, and we will foster an appropriate corporate culture. I believe that this is proof that we are able to do so.
Going forward, we will continue to conduct engagement surveys to regularly confirm whether the various measures implemented by the company are being properly communicated to employees and other stakeholders, and whether they are functioning properly. I would like to create a highly engaged organizational culture as a result of turning the cycle of thinking.

Online Questions Q2:
Since the company will be borrowing to acquire IVERIC bio, does this mean that it will not be repurchasing Astellas shares in the near term?

A

As you pointed out, we will be borrowing for the acquisition of IVERIC bio.
This loan will be repaid in a planned manner.
However, there will be no change in our shareholder return policy as a result of this acquisition or borrowing.

With investment in growth as our top priority, we will continuously and stably increase dividends while taking into account long-term profit trends. On top of that, if we have cash on hand, we will flexibly return it to our shareholders through share buybacks. This is the basic policy and will not change.
Even if we actually plan to repay according to the plan, if we have cash flow that exceeds the repayment plan assumptions, should we use that cash to make early repayments of borrowings? We would like to make a decision on whether to use it as a return on a case-by-case basis, taking into account trends in interest rates and exchange rates.

Online Questions Q3:
I would appreciate if the new President Mr. Okamura and the new Executive Vice President Mr. Sugita would share their thoughts about what kind of company you want Astellas to be in the future from a longer-term perspective.

A

Aspirations of President Okamura
Please refer to the answer to the question No.5 at the venue, " As the new president, how will you approach management in the future?"

Aspirations of Executive Vice President Sugita
As you asked, I believe that a long-term perspective is essential.

(1) Innovation, risk-taking, (2) talent and leadership, and (3) One Astellas or One Team.
Astellas has taken measures to strongly promote these three points, and when we look back five or ten years from now, Astellas will be a very innovative company. And it is a company that tackles things as one team. And all leaders and all managers are seriously working on leadership and talent. I would like to take the form of such a company, and I hope that this will lead to the success and growth of a large company.

(1) Innovation and risk-taking
Innovation is what we aim for. President Okamura mentioned this in a different way that we aim to be a company that is capable of risk-taking.
How much innovation can occur within a company? There is innovation in all departments, not research and development. Tomorrow is better than today, the day after tomorrow is better than tomorrow, and next year is better than this year. It keeps getting better, getting bigger and better. I would like to make this a company that all employees aspire to.

(2) Talent and leadership
Employees challenge various things in the company and feel that they want to grow further, which leads to the growth of the company. I want to be a company with such a virtuous cycle.

(3) One Astellas or One Team
I don't think we live in an era where we can achieve great results just because we have one genius or one great leader. How much you can involve the people around you, and how well you can cooperate with those around you to complete a big job. I would like to make a team of people who can do that.

Online Questions Q4:
For projects in the clinical development stage, please tell us when you plan to launch or apply for approval.

A

In April of this year, we obtained approval in the United States for PADCEV for cisplatin-ineligible urothelial cancer. In addition, a Phase 3 study of EV-302 is currently underway, and based on these results, we plan to submit an additional global application in the fourth quarter of FY2023.
VEOZAH has already received approval in the United States in May, and an application for approval has been filed in Europe. We expect to obtain approval after the fourth quarter of this year.
Regarding zolbetuximab, we applied for approval in Japan in June 2023 for the indications of gastric cancer and gastroesophageal junction cancer. We are also preparing to apply for approval in the United States, Europe, China, and other global markets.
For XTANDI, results from the EMBARK Phase 3 clinical trial in non-metastatic castrating prostate cancer were presented in American Urological Association data. Based on these results, we are proceeding with applications for approval of additional indications in the United States and Europe.

Online Questions Q5:
Please explain in more detail how sustainability indicators are reflected in executive compensation.

A

From the 19th term, FY2023, we will revise the system to add or subtract within the range of plus or minus 10% from the evaluation coefficient calculated by the conventional performance evaluation index according to the degree of achievement of the sustainability performance target. However, the overall evaluation coefficient and bonus payment rate are linked to performance within the range of 0% to 200%, but we will not exceed this range.
The evaluation items are "Initiatives for Access to Health", "Initiatives for Talent and Organization", "Initiatives for Stable Products Supply", and "Initiatives for Environment Sustainability", which is often mentioned when talking about sustainability in general.
The reasons for the selection of the evaluation items were mainly those of our sustainability initiatives for important social issues that we believe are not adequately reflected in our evaluations using existing performance indicators. We plan to reflect a wide range of major initiatives that involve as many stakeholders as possible, especially patients, shareholders, investors, employees, suppliers, and society as a whole, in our evaluations.

Online Questions Q6:
When do you anticipate the launch of fezolinetant in Europe? Do you expect it to take time to consider approval, like the launch in the US? Please let me know as much as possible.

A

Fezolinetant is currently under review by European regulatory authorities, and we are in contact with them on a daily basis.
We are currently proceeding with the expectation that European regulatory authorities will make a decision on approval or rejection between November of this year and January of 2024. We are currently doing everything in our power to obtain approval in Europe as soon as possible.

Online Questions Q7:
Thank you for the increase of dividend. I have high hopes for the future.
Aiming for a market capitalization of 7 trillion yen in 2025 is very positive. Please tell us specifically what you think about dividends to shareholders.

A

I will answer about our capital allocation (capital policy).
While striving to sustainably improve corporate value, the Company is actively working to return profits to shareholders, and will continue to do so. While prioritizing business investment to achieve growth, we will strive to steadily and sustainably increase dividends based on medium- to long-term profit growth on a consolidated basis.
In addition, if we have cash on hand, we will flexibly acquire treasury stock as necessary to continuously improve capital efficiency and return levels.