Astellas Pharma Inc.

Financial Results for FY2024

April 25, 2025

Event Summary

[Company Name]	Astellas Pharma Inc.	
[Company ID]	4503-QCODE	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	Financial Results for FY2024	
[Fiscal Period]	FY2024 Annual	
[Date]	April 25, 2025	
[Time]	17:00 – 18:30 (Total: 90 minutes, Presentation: 37 minutes, Q&A: 53 minutes)	
[Venue]	Webcast	
[Number of Speakers]	5	
	Naoki Okamura	President and Chief Executive Officer (CEO)
	Tadaaki Taniguchi	Chief Research & Development Office (CRDO)
	Claus Zieler	Chief Commercial & Medical Affairs Officer (CCMAO)
	Atsushi Kitamura	Chief Financial Officer (CFO)
	Hiromitsu Ikeda	Chief Communications & IR Officer (CCIRO)
[Questioner]	Hidemaru Yamaguchi	Citigroup Global Markets
	Seiji Wakao	JPMorgan Securities
	Akinori Ueda	Goldman Sachs
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Hiroyuki Matsubara	Nomura Securities
	Miki Sogi	Sanford C. Bernstein
	Kazuaki Hashiguchi	Daiwa Securities
	Fumiyoshi Sakai	UBS Securities

Presentation

Ikeda: Thank you very much for joining our FY2024 financial results announcement meeting by Astellas Pharma Inc. out of your very busy schedule today. I'm delighted to serve as the moderator. I'm Ikeda, Chief Communications and IR Officer. Thank you for your time.

Today, after presentation, we will move on to a Q&A session. Presentation will be made based on the material posted on our website under the IR Meeting section. We have simultaneous translation between Japanese and English, including Q&A. We cannot guarantee the accuracy of the translation. Thank you for your understanding. You can choose the language from the menu on the Zoom webinar screen. If you select the original language, you can listen to the original sound without going through the translation.

Disclaimer for today. This material or presentation by representatives for the company and their answers and statement in the Q&A session includes forward-looking statements based on assumptions and beliefs in light of information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors. They contain information on pharmaceuticals, including compounds under development, but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations, promote unapproved use in any fashion or provide medical advice of any kind.

Let me introduce the participants: Naoki Okamura, President and Chief Executive Officer; Chief Research and Development Officer, Tadaaki Taniguchi; Chief Commercial and Medical Affairs Officer, Claus Zieler; and Chief Financial Officer, Atsushi Kitamura. We have four executives.

We would like to have the presentation. Okamura-san, please.

Okamura: Ikeda-san, thank you very much. Hello, everyone. I'm Naoki Okamura from Astellas Pharma Inc. Thank you very much for joining our FY2024 financial results announcement meeting out of your very busy schedule today.

Cautionary Statement Regarding Forward-Looking Information

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In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice. Information about investigational compounds in development does not imply established safety or efficacy of the compounds; there is no guarantee investigational compounds will receive regulatory approval or become commercially available for the uses being investigated.

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This is a cautionary statement regarding forward-looking information. As this was explained by Ikeda earlier, I'm not going to read this page.

Agenda

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I FY2024 Consolidated Financial Results

II FY2024 Pipeline Update

III FY2025 Outlook

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Page three is the agenda for today. Starting from the next page, I will explain these topics in this order.

FY2024 Financial Results: Overview

*Revenue and Core operating profit reached **record high** since establishment of Astellas*

Revenue

- **Increased significantly YoY (+19%)**
- Strategic Brands: Expanded to approx. 340.0 bil. yen (approx. **+180.0 bil. yen** YoY)

*SG&A expenses**

- Achieved SMT target (optimization of 40.0 bil. yen), SG&A ratio **improved by 3.1ppt** YoY

Core operating profit

- **Increased significantly YoY (+42%)** driven by growth of Strategic Brands and SMT cost optimization
- Core OP margin increased to 20.5% (**+3.3ppt** YoY)

*Excl. US XTANDI co-pro fee
Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA
SMT (Sustainable Margin Transformation): See slide 32 for overview

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On page four, I will give you highlights of FY2024 financial results.

In FY2024, revenue and core operating profit reached a record high since the establishment of Astellas. Revenue increased significantly YoY by 19%. Sales of strategic brands as a whole expanded to over JPY340 billion in total with growth of about JPY180 billion YoY.

As for SG&A expenses, excluding US XTANDI co-promotion fees, driven by sustainable margin transformation or SMT, our initiatives to pursue company-wide cost optimization, we achieved our cost optimization target of about JPY40 billion. SG&A ratio improved by 3.1 percentage points YoY.

Core operating profit increased significantly YoY by 42%, driven by the growth of strategic brands as well as the continuation of SMT cost optimization. Core operating profit margin went up by 3.3 percentage points YoY to reach 20.5%.

FY2024 Financial Results

(billion yen)	FY2023	FY2024	Change	Change (%)	FY2024 FCST	FX impact (YoY)
Revenue	**1,603.7**	**1,912.3**	**+308.7**	**+19.2%**	**1,900.0**	+68.1
Cost of sales	292.5	349.2	+56.7	+19.4%	345.0	+6.9
SG&A expenses	740.1	843.0	+102.9	+13.9%	845.0	+34.9
US XTANDI co-pro fee	194.9	252.6	+57.7	+29.6%	255.0	+13.1
SG&A excl. the above	545.2	590.5	+45.2	+8.3%	590.0	+21.8
(SG&A ratio')	34.0%	30.9%	-3.1ppt		31.1%	
R&D expenses	294.2	327.7	+33.5	+11.4%	340.0	+11.1
(R&D ratio)	18.3%	17.1%	-1.2ppt		17.9%	
Core operating profit**	**276.9**	**392.4**	**+115.5**	**+41.7%**	**370.0**	+15.1
(Core OP margin)	17.3%	20.5%	+3.3ppt		19.5%	
＜Full basis＞						
Amortisation of intangible assets	98.8	136.8	+37.9	+38.4%		
Other income	8.7	20.3	+11.7	+134.1%		
Other expenses	167.8	235.8	+68.0	+40.5%		
Operating profit	**25.5**	**41.0**	**+15.5**	**+60.8%**	**11.0**	
Profit before tax	25.0	31.2	+6.3	+25.1%	1.0	
Profit	**17.0**	**50.7**	**+33.7**	**+197.7%**	**14.0**	

Note) Amortisation of IZERVAY's intangible assets started from Q2/FY2023

Other expenses (Main items)

- Impairment losses on intangible assets: 187.6
  Major impairment losses include:
  IZERVAY (Ex-US): 115.1,
  AT466: 51.8, iota: 8.0

FX rate assumption for FY2024: 153 yen/USD, 164 yen/EUR, Actual FX rates for FY2024: 152 yen/USD, 164 yen/EUR
*Excl. US XTANDI co-pro fee, **The definition of core-basis was changed from Q1/FY2024. In addition to the old definition's adjustments, 'Amortisation of intangible assets', 'Gain on divestiture of intangible assets' and 'Share of profit (loss) of investments accounted for using equity method' were newly excluded as new adjustment items.

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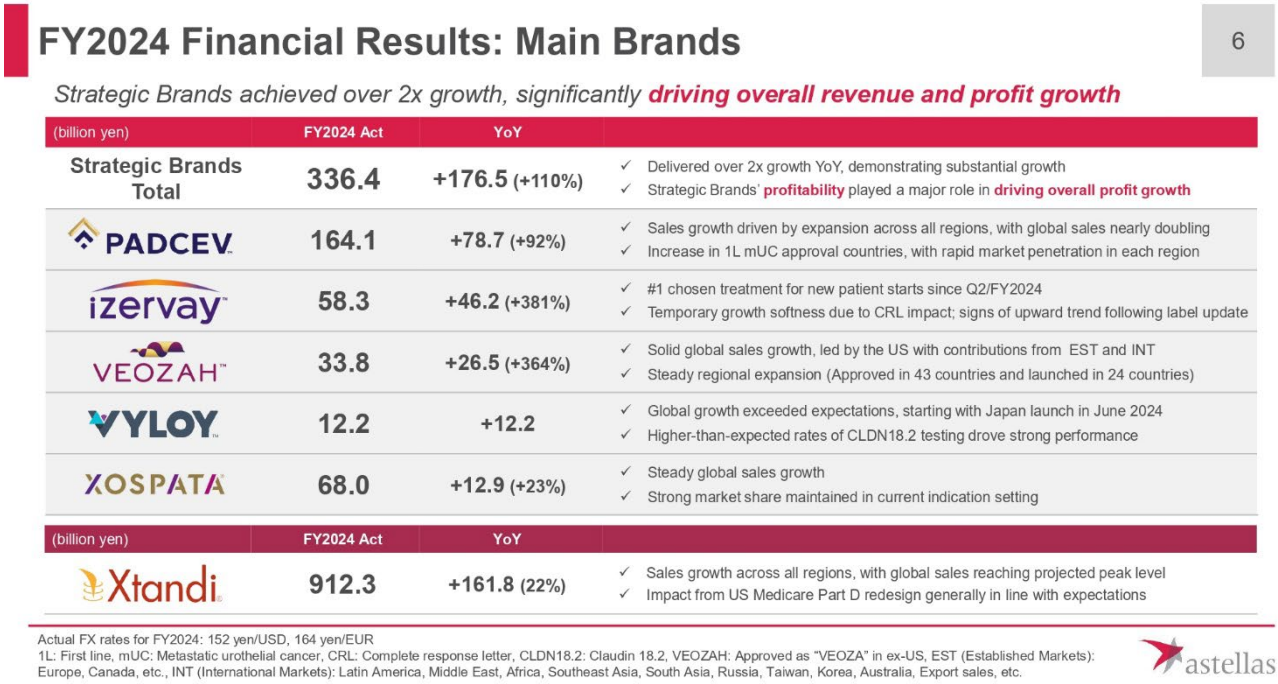
On page five, I will explain FY2024 financial results.

Revenue reached JPY1,912.3 billion, up by 19.2% YoY. Core operating profit rose to JPY392.4 billion, up by 41.7% YoY. Both revenue and core operating profit exceeded our full-year forecast.

The ForEx impact is shown on the right-hand side of the table. There was a positive impact on revenue by JPY68.1 billion and on core operating profit by JPY15.1 billion.

The bottom half of this page shows our full basis results. In the right bottom of the table, we included other expenses booked in FY2024. This was explained when we announced the Q3 year-to-date results, so I will skip the details today. In the end, operating profit was JPY41 billion, up by 60.8% YoY. Profit increased to JPY50.7 billion, up by 197.7% YoY.



On page six, I will explain FY2024 financial results of our main products.

Sales of strategic brands and future growth drivers, namely PADCEV, IZERVAY, VEOZAH, VYLOY, and XOSPATA more than doubled to approach JPY340 billion in total with a growth of about JPY180 billion or 110% YoY. Due to high profitability of these brands, they not just contributed to revenue, but also played a major role in driving the overall profit growth on a consolidated basis as well. Let me also explain individual strategic brands. I will explain the details of PADCEV, IZERVAY, and VYLOY later in FY2025 outlook section, including our sales forecast and the progress status.

Global sales of PADCEV increased to JPY164.1 billion, up by JPY78.7 billion or 92% YoY, realizing nearly twofold growth. Sales expanded in all regions where it's launched. The number of first-line metastatic urothelial cancer approval countries has been increasing steadily with rapid market penetration after approval.

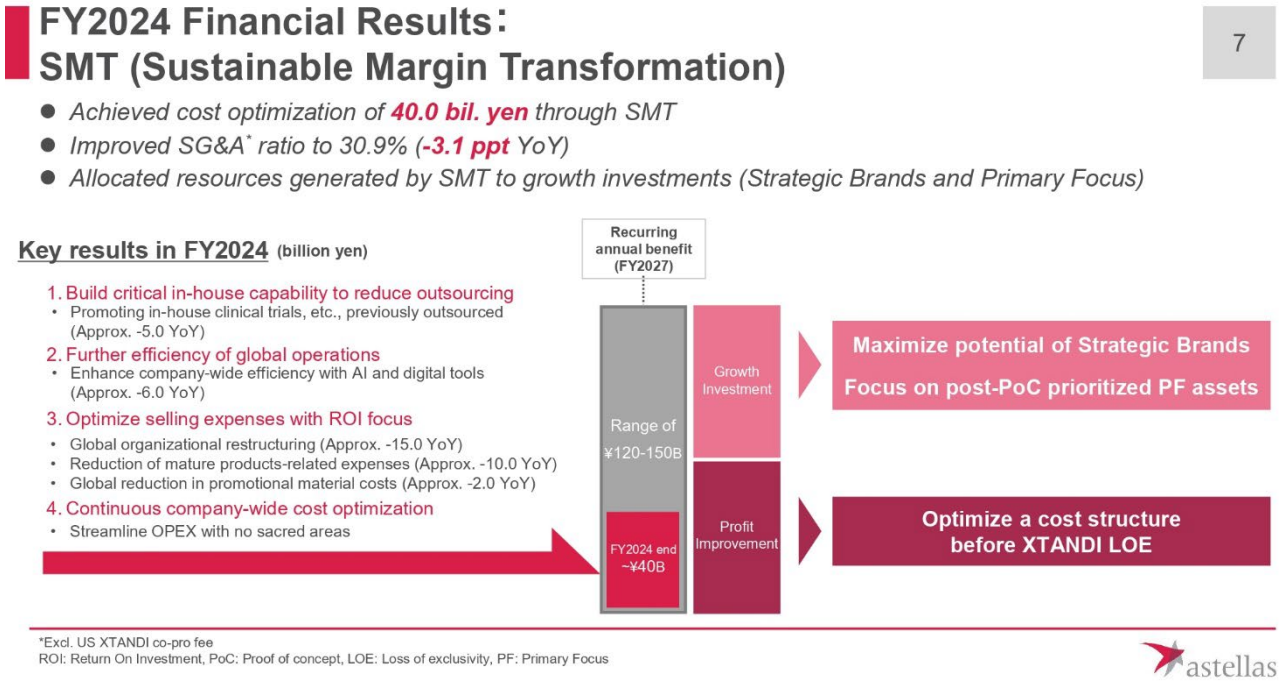
IZERVAY was launched in the United States just about 1.5 years ago, but its sales expanded to JPY58.3 billion. IZERVAY was launched about six months later than the competitive product, but it has established its positioning as the first-line treatment for new patient starts since FY2024 Q2. After November last year, its growth temporarily slowed down due to the impact of CRL, complete response letter, for label update submission, but in February, the label update was approved and we have been able to confirm signs of the prescription expansion trend recovery since.

Global sales of VEOZAH expanded to JPY33.8 billion. In addition to its growth in the United States, the number of countries where it's launched in the established and international markets has steadily expanded, contributing to sales growth. Globally, VEOZAH has already been approved in 43 countries and launched in 24 countries.

As for VYLOY, starting with the launch in Japan in June last year, the number of approval countries has increased steadily. Global sales reached JPY12.2 billion. Higher-than-expected rates of Claudin 18.2 testing drove strong performance, with uptake exceeding expectations.

Regarding XOSPATA, global sales increased to JPY68 billion, up by JPY12.9 billion or 23% YoY. Sales expanded steadily in all regions where it's marketed. XOSPATA is maintaining a high market share in the current indication of relapsed or refractory AML.

As for XTANDI, global sales increased to JPY912.3 billion, up by JPY161.8 billion or 22% YoY. In all markets led by the United States, sales expanded. We believe global sales are reaching projected peak level. Impact from US Medicare Part D redesign was mostly within our assumptions. Sales landed in line with our full-year forecast.



On page seven, let me explain FY2024 SMT achievements.

Through SMT initiatives, we achieved cost optimization target of JPY40 billion in FY2024. As a result, SG&A ratio, excluding US XTANDI co-promotion fees, improved to 30.9%, down by 3.1 percentage points YoY. On the left side of this page, you can find our specific initiatives towards cost optimization and the achievements shown in four categories.

First, in order to build critical in-house capability to reduce outsourcing, we promoted in-house clinical trials, et cetera, which were previously outsourced. This led to the optimization of about JPY5 billion YoY.

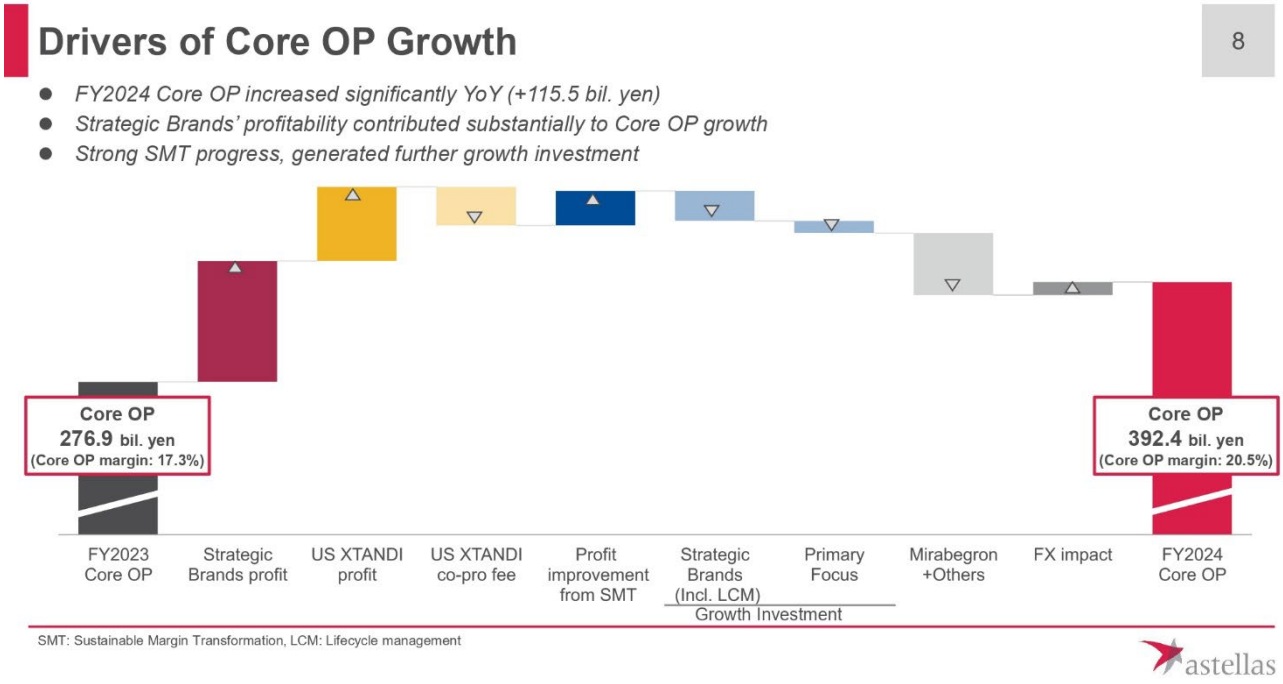
Number two, as for further efficiency of global operations, we made progress mainly in the use of digital and AI tools, with which we enhanced company-wide efficiency and optimized costs by about JPY6 billion YoY.

Third, in order to optimize selling expenses with ROI focus, we achieved cost optimization of about JPY27 billion in total. This includes JPY15 billion cost optimization by making progress in the global organizational restructuring, about JPY10 billion by reducing mature products-related expenses, and about JPY2 billion by sharing sales promotion materials globally.

In addition, we will promote continuous company-wide cost optimization as well.

We were able to allocate these resources generated by SMT to growth investments for strategic brands and primary focus. SMT is a source of future investments, and we will continue to work on this in FY2025 and

beyond. We're expecting JPY120 billion to JPY150 billion recurring annual benefit in FY2027. We will continue to promote each of these initiatives and ensure cost management with disciplines.



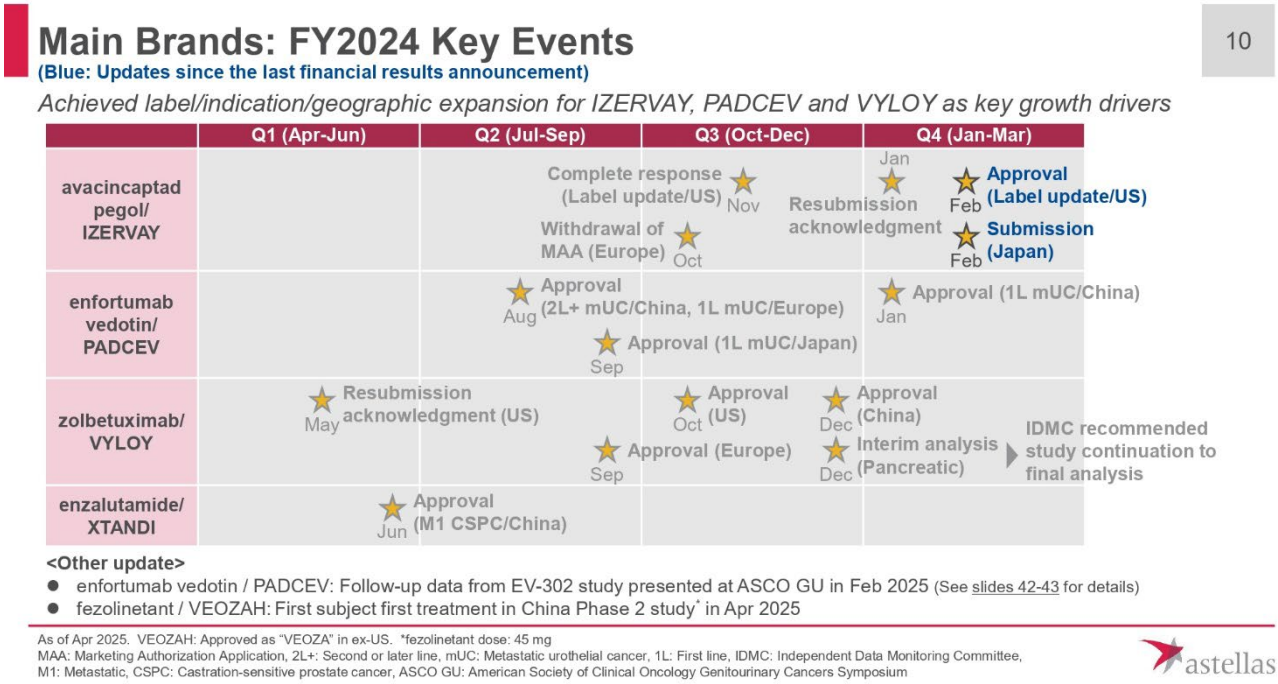
On page eight, I will explain core operating profit growth drivers in FY2024.

FY2024 core operating profit increased significantly, up by JPY115.5 billion YoY. This graph shows YoY comparison of main factors affecting core operating profit shown on the horizontal axis.

Starting from the left, expansion of highly profitable strategic brands made a contribution to profit growth the most. Next, expansion of US XTANDI sales shown in a yellow bar also contributed. Also, half of the US sales is booked as co-promotion fee, so all the sales growth has not necessarily been directly linked to profit contribution. Next, a bar in blue shows cost reduction and growth investments. Part of the resources generated by SMT cost optimization were allocated to growth investments for strategic brands and primary focus. As others, there was some impact from US mirabegron generics.

Core operating profit in the end reached JPY392.4 billion. Core operating profit margin went up by 3.3 percentage points to 20.5%.

From here, I will give you FY2024 pipeline update.



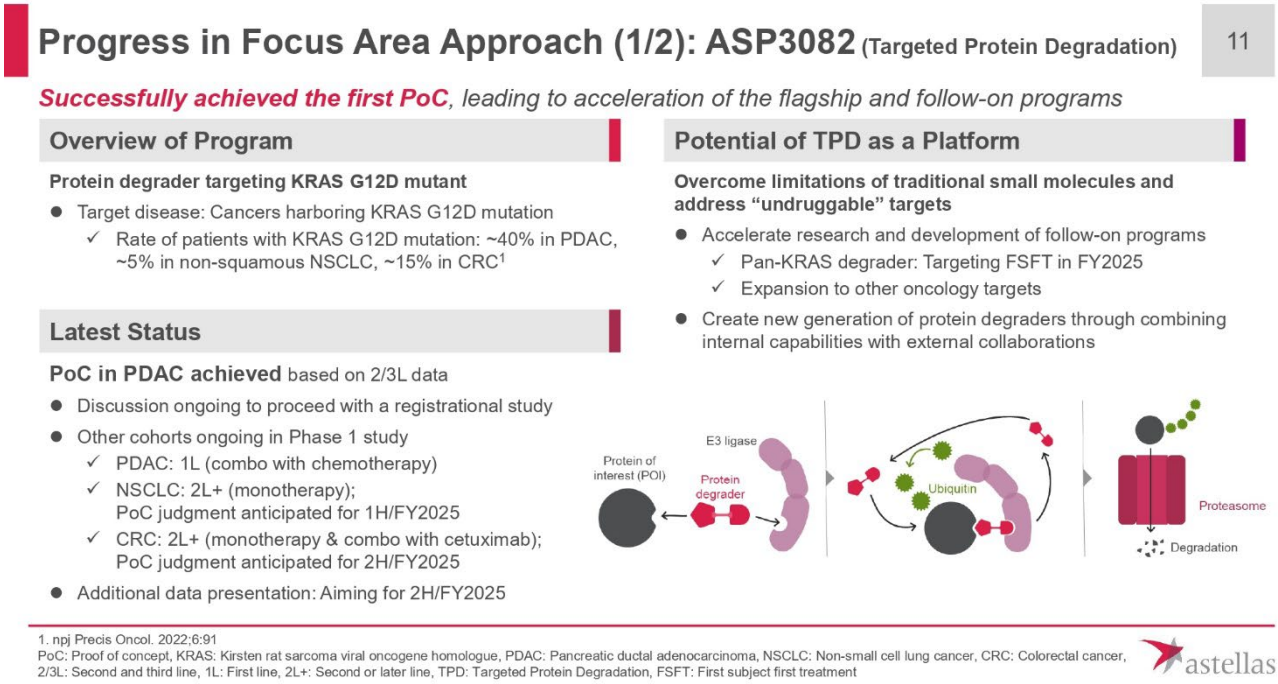
On page 10, I will explain main brands' key events achieved in FY2024.

Updates since the last financial results announcement are shown in blue. For IZERVAY, we obtained label update approval in the United States in February. Restriction on the duration of dosing was lifted, enabling dosing of IZERVAY beyond 12 months. Also, in Japan, based on the results of overseas clinical studies, including AGADA data, we filed a submission by using the conditional approval system in February.

As other updates, for PADCEV, we presented EV-302 study follow-up data in first-line metastatic urothelial cancer at ASCO GU in February. The updated data is included on page 42 and 43 in the appendix.

With regards to VEOZAH, for application of approval in China, we started Phase II study to evaluate efficacy and safety with 45 milligram, which is the same as the approved dose in the United States and Europe. We achieved first subject first treatment in February.

In FY2024, we achieved label indication and geographic expansion for IZERVAY, PADCEV, and VYLOY, our important growth drivers, and we're able to make substantial progress towards product value maximization.



On page 11 and 12, I will explain the update for ASP3082 and AT845, which have made particular progress in the last three months among focus area approach programs. The current status of each of the other programs is summarized on page 34 in the appendix.

First, I will explain the progress of ASP3082, the flagship program of primary focus targeted protein degradation. ASP3082 is a protein degrader targeting KRAS G12D mutant. KRAS G12D mutation is seen at a high rate in tumors such as PDAC, pancreatic ductal adenocarcinoma, NSCLC, non-small cell lung cancer, and CRC, colorectal cancer. As a recent major progress, we achieved PoC in PDAC based on second and third-line data from Phase I data. This is the first PoC achieved from primary focus, and we are very pleased to have been able to achieve an extremely important milestone. Based on these results, discussion is ongoing on how to proceed from now towards early implementation of a registrational study in PDAC. We will let you know our specific plan once we make a decision.

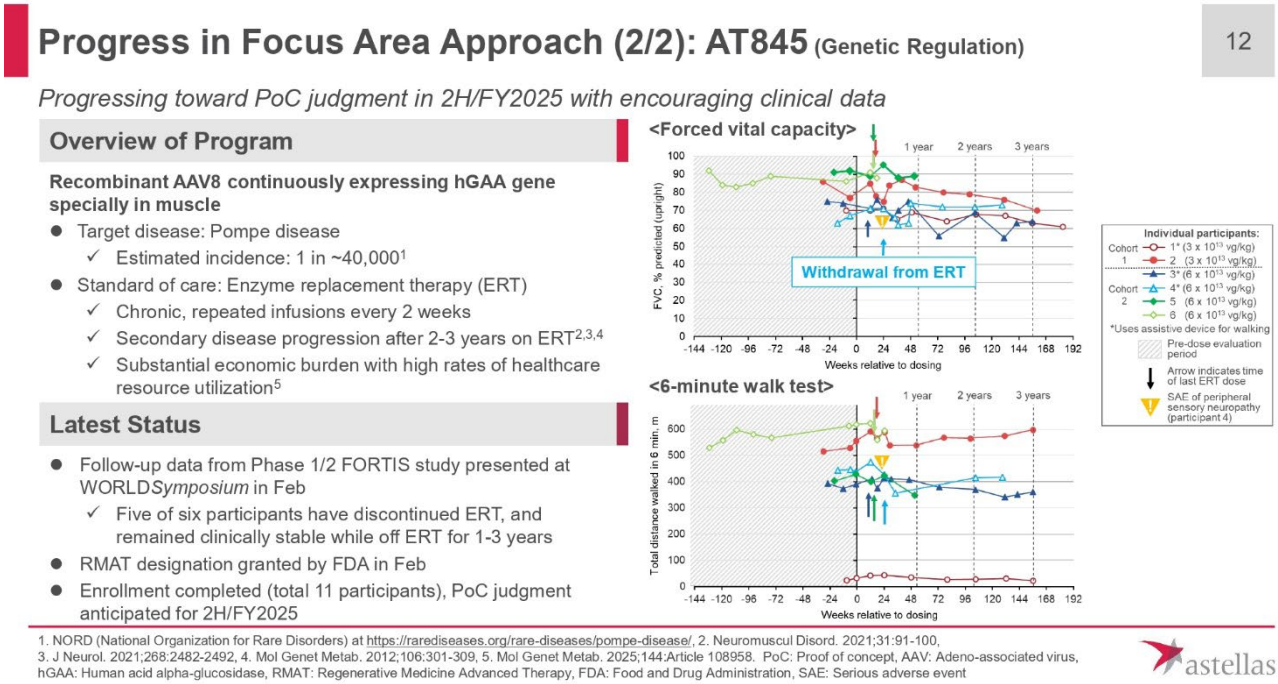
In Phase I study, assessment in other cohorts is also ongoing in parallel. In PDAC, we are assessing combination with chemotherapy in the first-line settings as well. In NSCLC, assessment is ongoing in the second-line settings and beyond. PoC judgment is anticipated for H1 of FY2025.

Also, in CRC, assessment is ongoing in the second-line settings and beyond. PoC judgment is anticipated for H2 of FY2025. As for additional data presentation, we are aiming for H2 of FY2025. Once we decide on the timing, we will let you know.

With the achievement of PoC this time, we are increasingly confident not only about the probability of success of ASP3082 individually, but also about the potential of TPD, targeted protein degradation, as a platform. We are hoping that TPD will be an effective means to overcome limitations of traditional small molecules and address undruggable targets.

Going forward, in addition to ASP3082, we will further accelerate research and development of follow-on programs as well. Pan-KRAS degrader targeting various KRAS mutants is in the IND preparation stage. We are aiming to start a clinical study within FY2025. Also, we are conducting research targeting non-KRAS

undruggable cancer-related proteins as well. We will actively combine internal capabilities with external collaborations and also work on the creation of new generation of protein degraders.



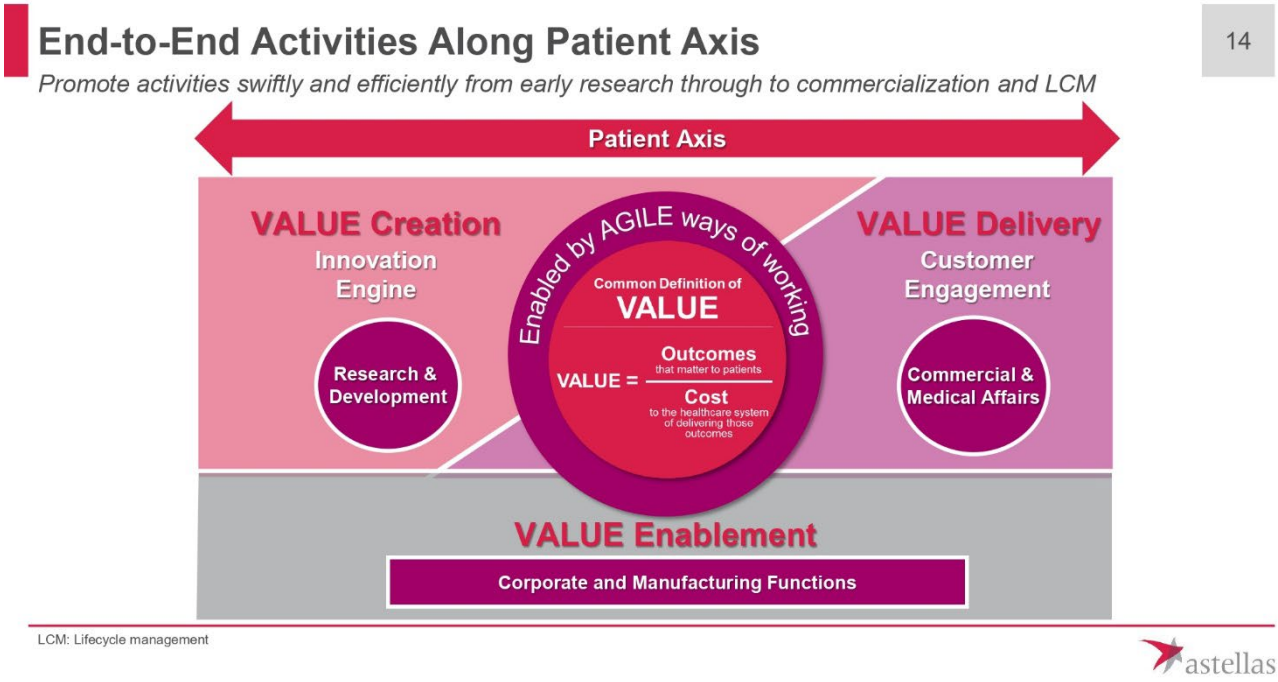
On page 12, I will explain AT845, a flagship program for primary focus genetic regulation.

AT845 is a recombinant AAV8 designed to specifically and continuously express hGAA, human acid alpha-glucosidase genes, in muscle. It's under development for Pompe disease. Pompe disease is a rare disease caused by GAA gene mutation, with progressive muscle weakness and respiratory failure as main symptoms. Currently, as a standard of care, ERT, enzyme replacement therapy, is being used to administer deficient GAA enzyme formulations. ERT has various challenges, such as the need for chronic repeated infusions once every two weeks, secondary disease progression after two to three years on ERT, and substantial economic burden associated with hospital visits and drug infusions. To address these challenges, gene therapy with AT845 is expected to offer long-term improvement of disease conditions with a single dosing.

At present, Phase I/II FORTIS study is ongoing. We presented follow-up data on six participants at a congress in February. Participants are patients with late-onset Pompe disease receiving treatment with ERT. They can choose to discontinue ERT after AT845 administration. Five out of the six participants in the study assessment chose to discontinue ERT. As is shown in the right diagram, we confirmed that even after ERT discontinuation, physical functional endpoints, such as forced vital capacity and six-minute walk test, have been maintained over one to three years approximately.

In addition, RMAT, regenerative medicine advanced therapy, designation was granted by FDA in February. FDA grants RMAT designation if a regenerative medicine product demonstrates, with preliminary clinical evidence, the possibility to be able to meet unmet medical needs in serious diseases. If designated, opportunities for priority review and accelerated approval will be offered. FORTIS study completed the enrollment of all participants. Towards PoC judgment in H2 of 2025, we are making progress in line with our plan.

From here, I will explain FY2025 outlook.



Page 14. Before explaining the outlook of FY2025, I would like to explain the new organization launched on April 1.

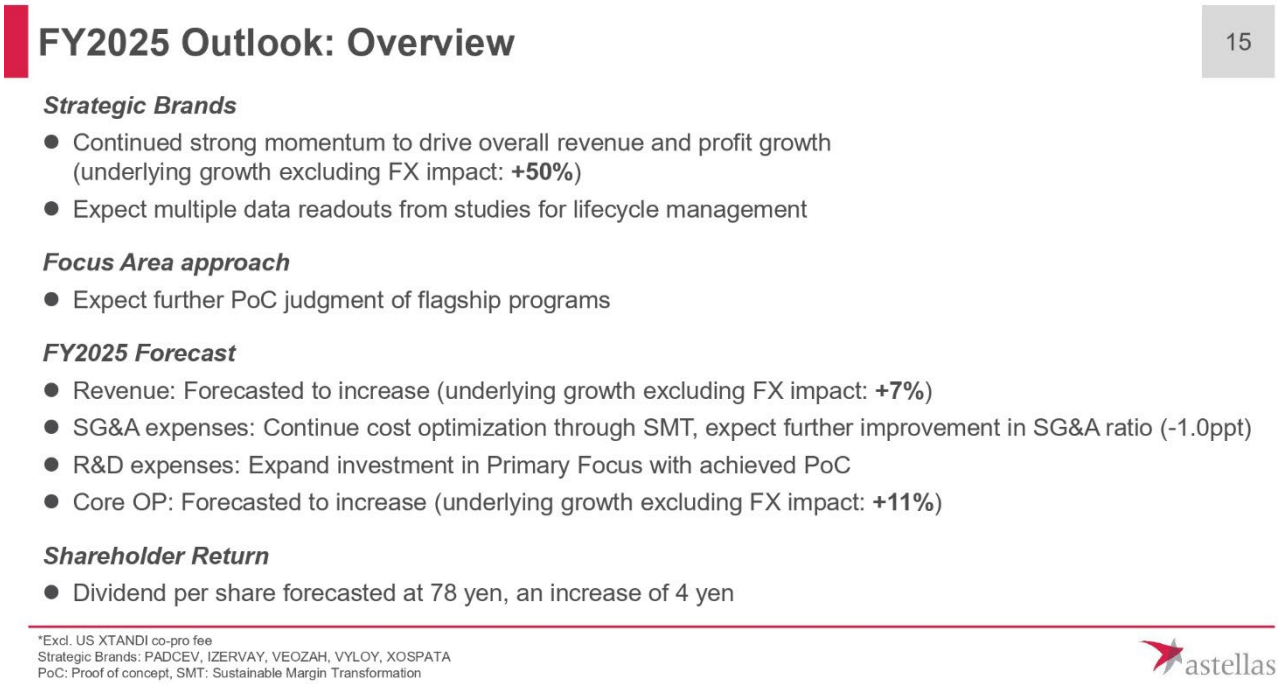
The new structure is not based on original function but rather on a patient access that will allow us to move forward with end-to-end activities from the early research stages through to marketing and life cycle management. These roles are served by value creation, value delivery, and value enablement.

Value creation integrates the divisions of research development and primary focus lease and plays a role as an innovation engine to create value for patients. Taniguchi, who is here today, will serve as the function of overseeing this as the Chief Research and Development Officer.

Value delivery integrates the commercial and medical affairs divisions while maintaining the independence of each function and aims to deliver value to patients through industry-leading customer engagement. The Chief Commercial and Medical Affairs Officer, Claus, who is here today, will oversee this.

As value enablement, the specialized functions such as corporate and manufacturing will work closely with value creation and value delivery to support activities along the patient access.

In FY2025, under this structure, we will further strengthen our agile and cross-functional operations and quickly and efficiently promote projects, brands, and other assets.



On page 15, I will explain the outlook for FY2025.

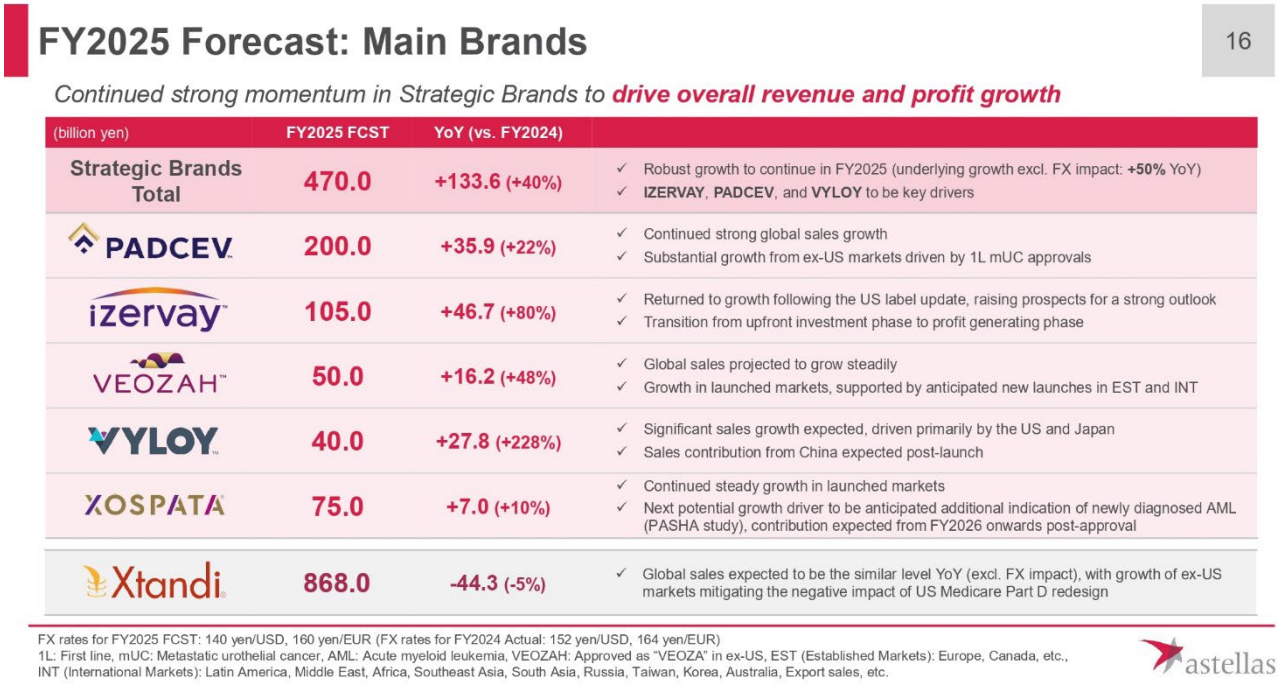
We expect continued strong momentum in our strategic brands from FY2024, driving overall revenue and profit growth. In addition, we expect multiple data readouts from studies for life cycle management.

In the focus area approach, we expect further PoC judgment following ASP3082. We forecasted a revenue increase in FY2025 due to the expansion of our strategic brands.

Underlying growth, excluding negative ForEx impact, is expected to be 7%. SG&A expenses are expected to improve by 1 percentage point as we continue cost optimization through SMT.

For R&D expenses, the investment will be expanded and primary focus with achieved PoC. Core OP is forecasted to increase. Underlying growth, excluding ForEx impact, will be double-digit growth of 11%.

As for shareholder return, we are forecasting a dividend per share of JPY78, an increase of JPY4. In anticipation of future profit growth, we forecast a dividend increase of JPY4 just like previous year.



On page 16, I'll explain our forecast for main brands for FY2025.

We expect continued robust growth in our strategic brands in FY2025 and a forecast of sales of JPY470 billion, an increase of JPY133.6 billion or 40% YoY. In underlying growth, excluding ForEx impact, sales will increase by 50% to the level close to JPY500 billion YoY. In particular, we expect IZEVAY, PADCEV, and VYLOY to drive growth, and the details of these three products are explained in the subsequent slides.

Our forecast for PADCEV for FY2025 is JPY200 billion, an increase of JPY35.9 billion or 22% YoY, and we expect strong and continuous growth.

IZERVAY is forecasted at JPY105 billion, a significant increase of JPY46.7 billion or 80% YoY. Following the US label update, there are signs of an upward trend, and we expect strong growth in the future.

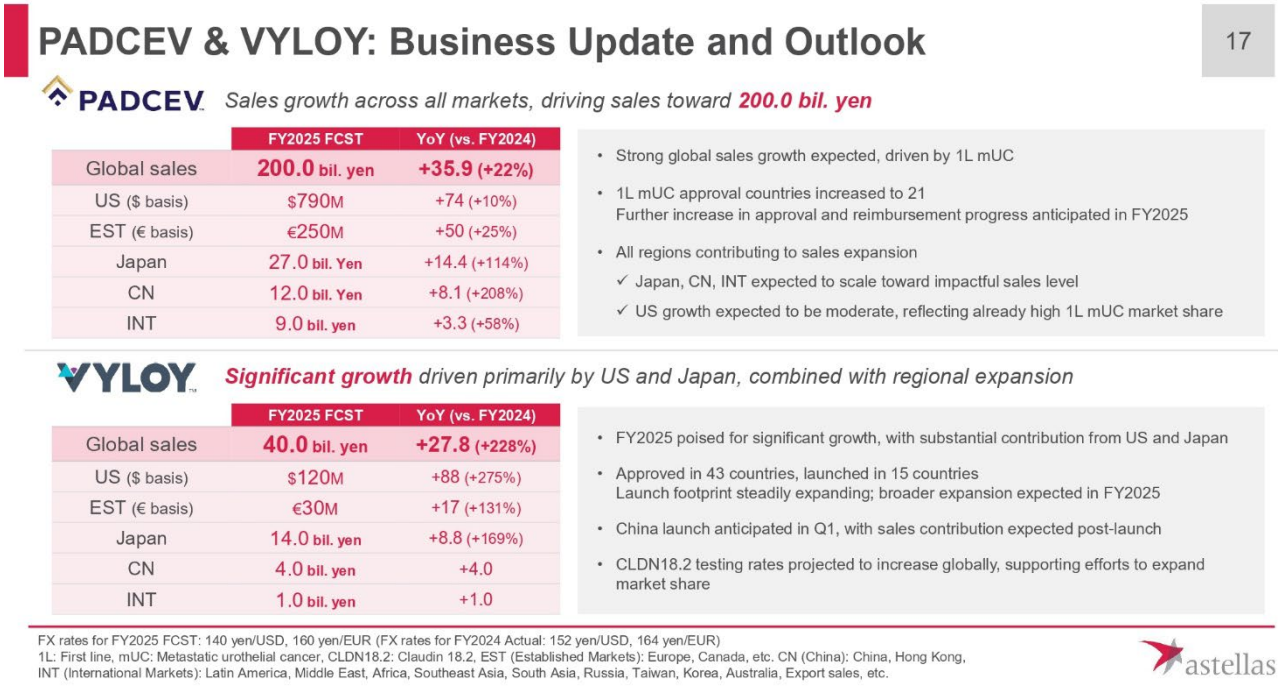
VEOZAH is expected to make a steady global growth with a forecast of JPY50 billion, an increase of JPY16.2 billion or 48% YoY. In the US and other launched markets, we anticipate the number of launched countries will increase in established international markets, which are expected to make a sales contribution.

VYLOY is forecasting significant sales growth of JPY40 billion YoY, an increase of JPY27.8 billion. We expect expansion in the US and Japan as well as post-launch sales contribution in China.

XOSPATA is expected to grow to JPY75 billion, an increase of JPY7 billion or 10% YoY, and we anticipate stable and continued growth in existing indications. Future growth drivers include additional indications for newly diagnosed AML, acute myeloid leukemia, for which we expect to receive top line results in H1 of FY2026 and expect sales contribution after approval.

Finally, for XTANDI, our FY2025 forecast is JPY868 billion, 5% decrease YoY. In the US, although the negative impact of the Medicare Part D redesign is expected, our outlook is to partially be offset by the volume increase due to improved access through a reduced patient out-of-pocket payment, resulting in only a slight decrease on a dollar basis. On the other hand, we expect continued growth in markets outside the US, and this growth

will offset the negative impact in the US. Thus, on an underlying basis, excluding the ForEx impact, global sales will be at a similar level as in FY2024.



Page 17, business update and outlook for PADCEV and VYLOY.

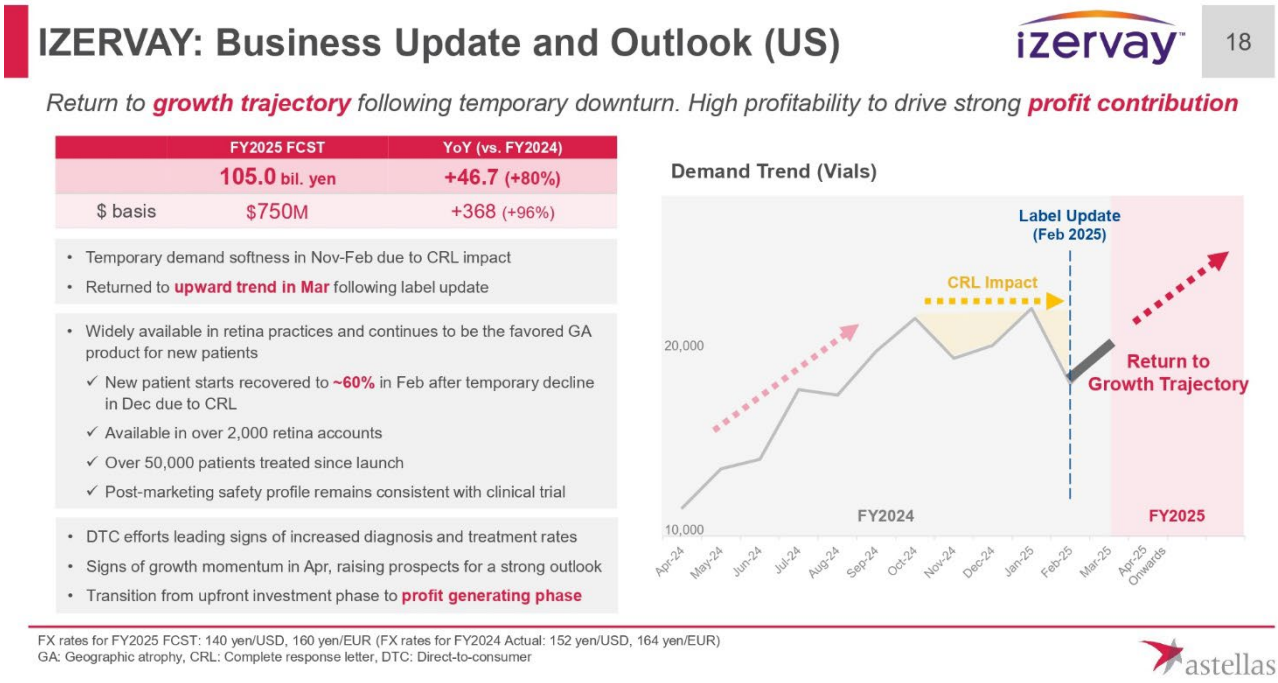
First, PADCEV is expected to reach JPY200 billion. The first-line mUC continues to be the largest growth driver, with the first-line approved countries expanding to 21 as of April, and we anticipate further approval and reimbursement progress in FY2025.

All regions will contribute to sales expansion, especially Japan, China, and the international market are expected to scale toward impactful sales level. For the US, the growth is expected to be moderate in FY2025 compared to other regions, reflecting already high first-line market share close to 55%.

Growth opportunities in FY2026 and beyond include an additional indication for MIBC, muscle invasive bladder cancer. We expect the readout from the interim analysis by the end of this year, and if the results are favorable, we will proceed to NDA submission. Once approved, we expect that it will help PADCEV grow further.

Next, VYLOY. We expect significant sales growth, with further growth in the US and Japan and contributions from the expansion of launched countries. Since its launch in Japan last June, the number of approved countries has expanded to 43, and in 15 of which, the product was already launched. The regional expansion has been extremely successful so far, and a further increase of launched countries will be expected in FY2025.

In China, which has a large gastric cancer market, a launch is anticipated in Q1, and we are expecting post-launch sales contribution. We are working to increase the testing rate of Claudin 18.2 globally to expand market share. VYLOY is expected to be a key growth driver for sales expansion with an expectation of its full-scale contribution to sales.



Page 18, IZERVAY business update and outlook.

In dollar basis representing underlying growth, the FY2025 forecast is USD750 million, an increase of 96% YoY, nearly doubling. In FY2024, there was a temporary demand slowdown from November of last year to February of this year due to the impact of the CRL or complete response letter. But since much after the revision, the trend has returned upward. IZERVAY is already widely adopted by retinal treatment setting, and it has established itself as a first line in newly diagnosed GA, geographic atrophy. After temporary decline in new patient share to the low 50% range last December due to the CRL, it recovered to about 60% in February.

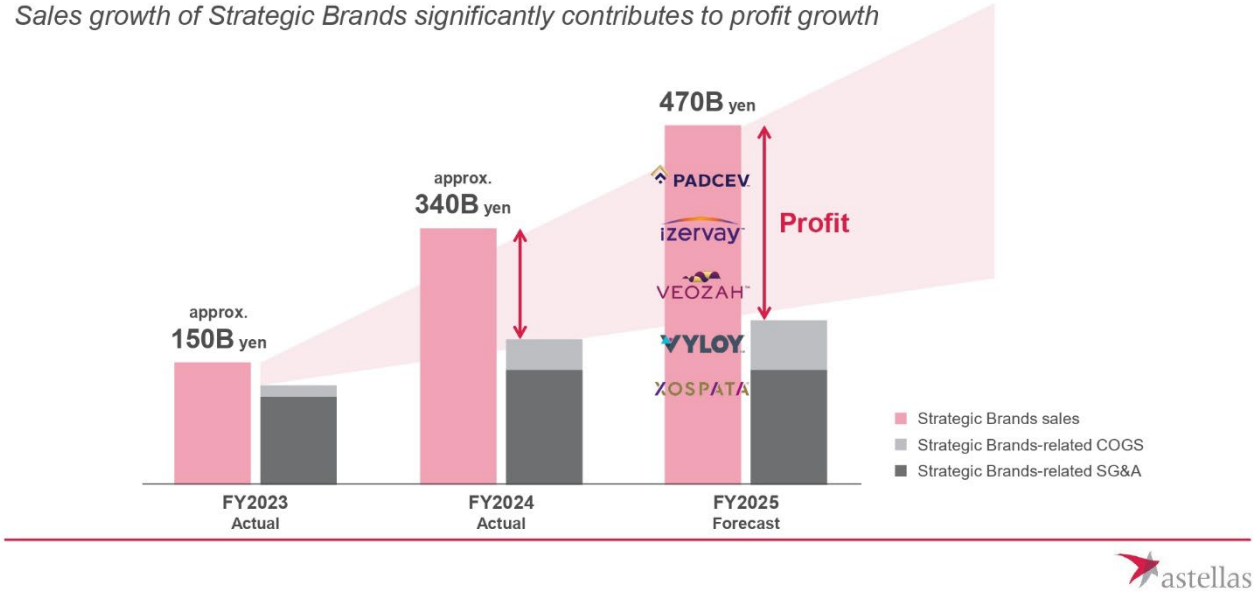
Currently, more than 2,000 retina accounts have adopted the drug and more than 50,000 patients have been treated with IZERVAY since its launch. The post-marketing safety profile remains consistent with the clinical trials results and has been well received by physicians.

In addition, we are beginning to see signs of improved diagnosis and treatment rates as a result of our DTC efforts, and we expect further market expansion in FY2025. Although FY2025 has just begun, we believe we are off to a good start for strong future growth as we saw signs of growth momentum in March as well as April.

While last fiscal year was an upfront investment phase for future growth, we expect to move into full-fledged profit-generating phase in FY2025 through further sales growth as well as optimization of IZERVAY to achieve high profitability and appropriate expenses level. We are currently planning an IR event focusing on the progress of the US business and its future prospects and are considering holding it in H1. We will provide further details when they are finalized.

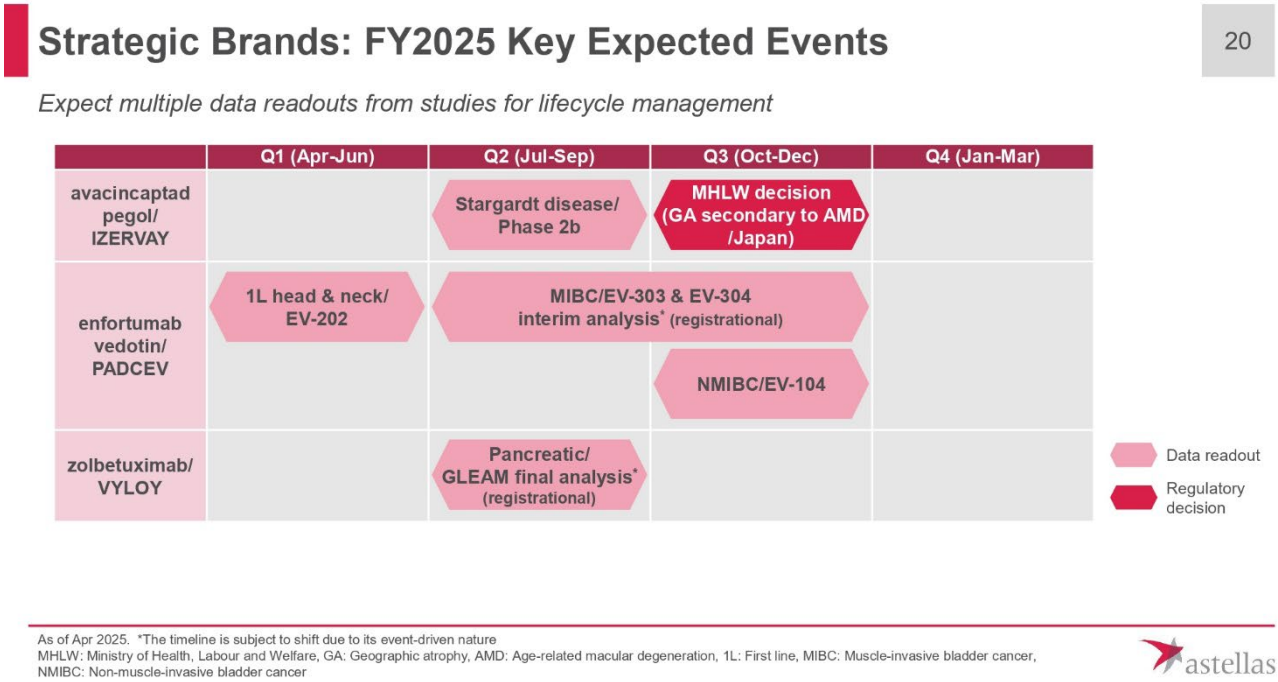
Image of Profit Contribution from Strategic Brands

Sales growth of Strategic Brands significantly contributes to profit growth



On page 19, we used an image to explain the profit contribution of strategic products, our strategic brands. The pink and gray both represent the total sales and related expenses of the strategic brands, respectively, while the lighter and the darker bars represent COGS and SG&A, respectively. Sales are expected to grow significantly with the continued growth of PADCEV and XOSPATA as well as the full-scale growth of VEOZAH and IZERVAY launched in FY2023 and VYLOY in FY2024.

As for expenses, while COGS is expected to increase in line with sales growth, SG&A is planned to be maintained at a certain level with the cost optimization through SMT. Profit contribution from strategic brands were limited in FY2023, but full-scale profit contributions began in FY2024. Rapid growth is expected in the future, and from FY2025 onward, we expect the sales expansion of strategic products to directly contribute to profit growth.

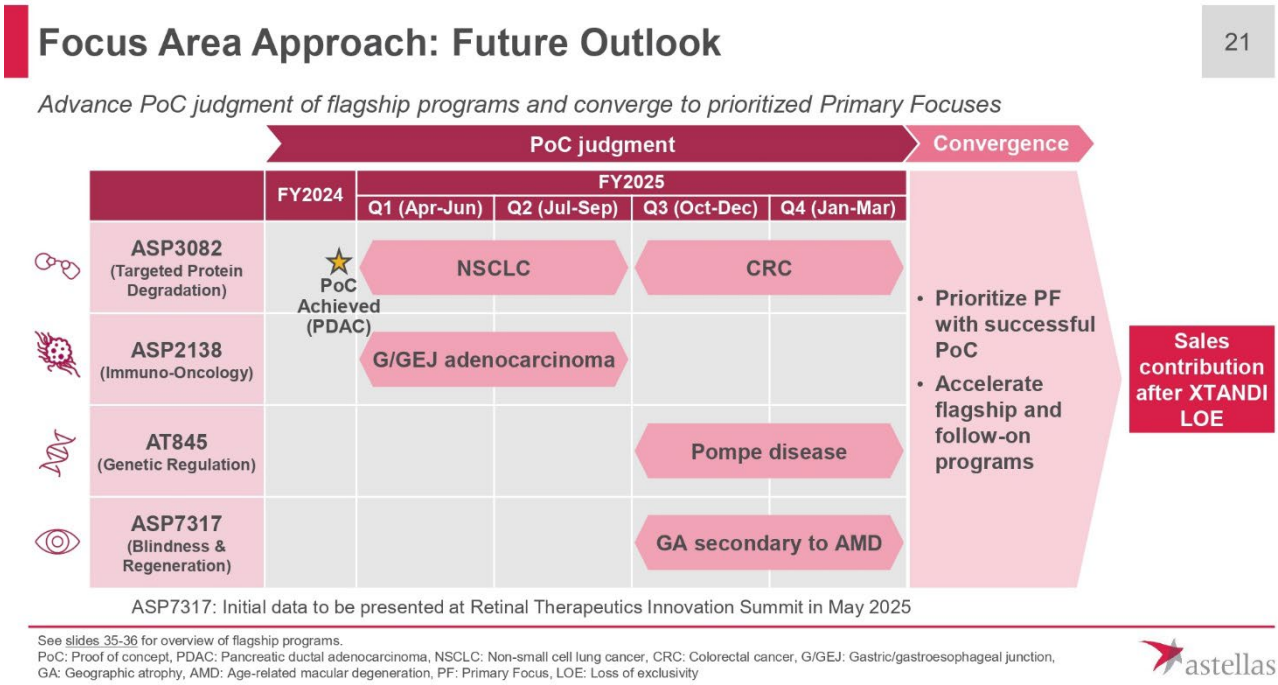


Page 20. Key events expected in FY2025 for strategic brands are described.

For IZERVAY, we expect the Phase II study readout for Stargardt disease in Q2. MHLW decision on the J-NDA is expected in Q3.

As of PADCEV, Phase II EV-202 study targeting various solid tumors other than urothelial carcinoma, the readout of the first-line head and neck cancer cohort is expected to be available in Q2. We also expect to have interim analysis data from both the Phase III EV-303 and EV-304 studies in muscle invasive bladder cancer in Q2 and Q3. If the data are favorable, we plan to proceed with the submission for an additional indication based on this result. In addition, data from the Phase I EV-104 study in NMIBC, non-muscle invasive bladder cancer, is expected in Q3.

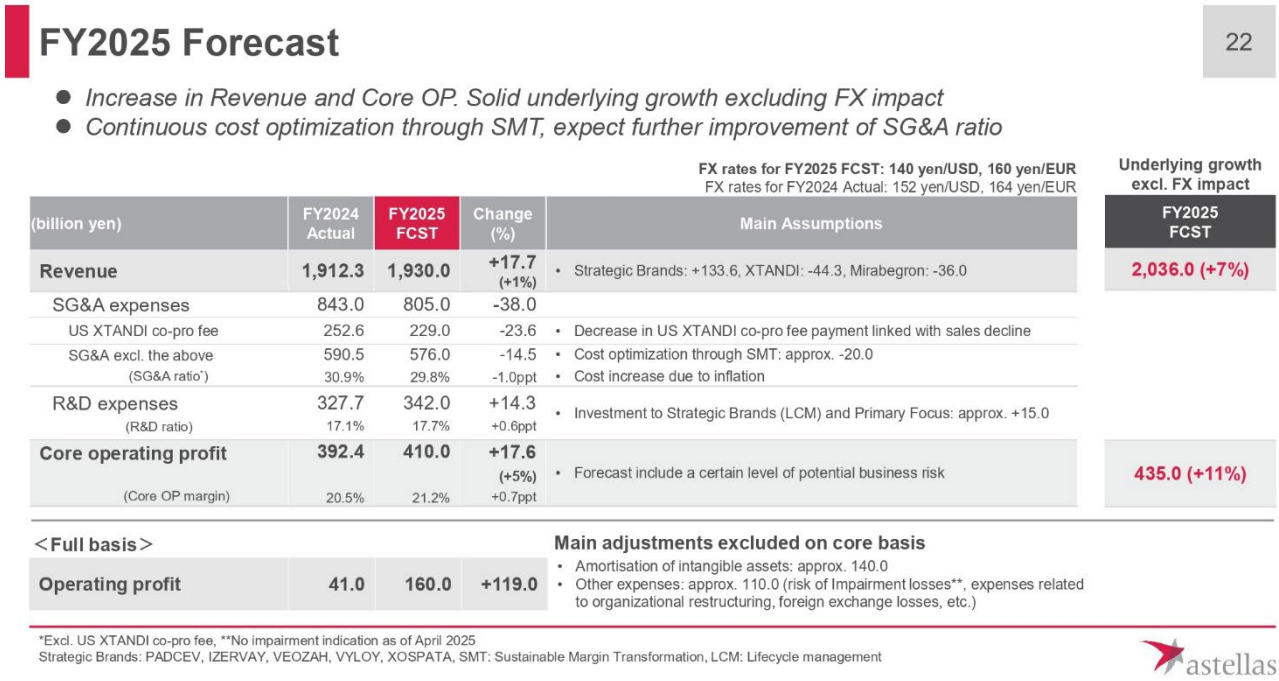
For VYLOY, data from the final analysis of the Phase II GLEAM study in pancreatic ductal carcinoma is expected in Q2. In FY2025, we expect to see data from a number of clinical trials for expanded indications, which we hope will be successful and lead to accelerated growth of our key strategic brands.



Page 21 is the future outlook for our focus area approach.

As we have reported, we plan to make PoC judgment in each of our primary focus flagship programs by the end of FY2025. ASP3082 achieved PoC decision in pancreatic duct adenocarcinoma at the end of FY2024, and then in 2025, we expect to make PoC judgment in non-small cell lung cancer in H1, NSCLC in H2. Other programs remain unchanged from the plans. ASP2138 is expected to achieve PoC judgment in H1 and AT845 and ASP7317 in H2. ASP7317 will make a presentation, including early data from the ongoing Phase IB trial, at the Retina Therapeutics Innovation Summit in May. We will then move into the conversion phase depending on the results of the PoC judgment.

We will prioritize allocation of management resources to the primary focus that have successfully achieved PoC, and we will accelerate R&D for the flagship and follow-on programs to increase pipeline value. We expect the multiple programs generated from our focus area approach to progress and contribute to post-XTANDI LOE sales and generate sustainable growth.



Page 22 is our full-year focus for FY2025. Revenue is projected to be JPY1,930 billion, an increase of JPY17.7 billion YoY. On top of the sales decline of XTANDI and mirabegron, ForEx negative impact is expected, but thanks to the strong growth of the strategic brands, we expect revenue increase.

Excluding the ForEx impact, underlying sales are expected to be JPY2,036 billion, a 7% increase, and continue to expand steadily.

In the litigation of the formulation patent of mirabegron in the US, we have recently received a ruling in favor of the validity of our patent. The lawsuit is still ongoing, but in light of the ruling, we have assumed that no other generic products will enter the market for a certain period of time.

SG&A is expected to be JPY805 billion, a decrease of JPY38 billion YoY. Of this amount, co-promotion expenses for XTANDI in the US are expected to shrink in line with the decline of sales. Therefore, the impact on profit will be partially mitigated. SG&A, excluding co-promotion fee, is expected to be JPY576 billion, a decrease of JPY14.5 billion YoY. Cost optimization of about JPY20 billion is expected through SMT.

R&D expenses are expected to be JPY342 billion, an increase of JPY14.3 billion YoY. Investments will be focused on life cycle management of strategic brands and primary focus achieved PoC.

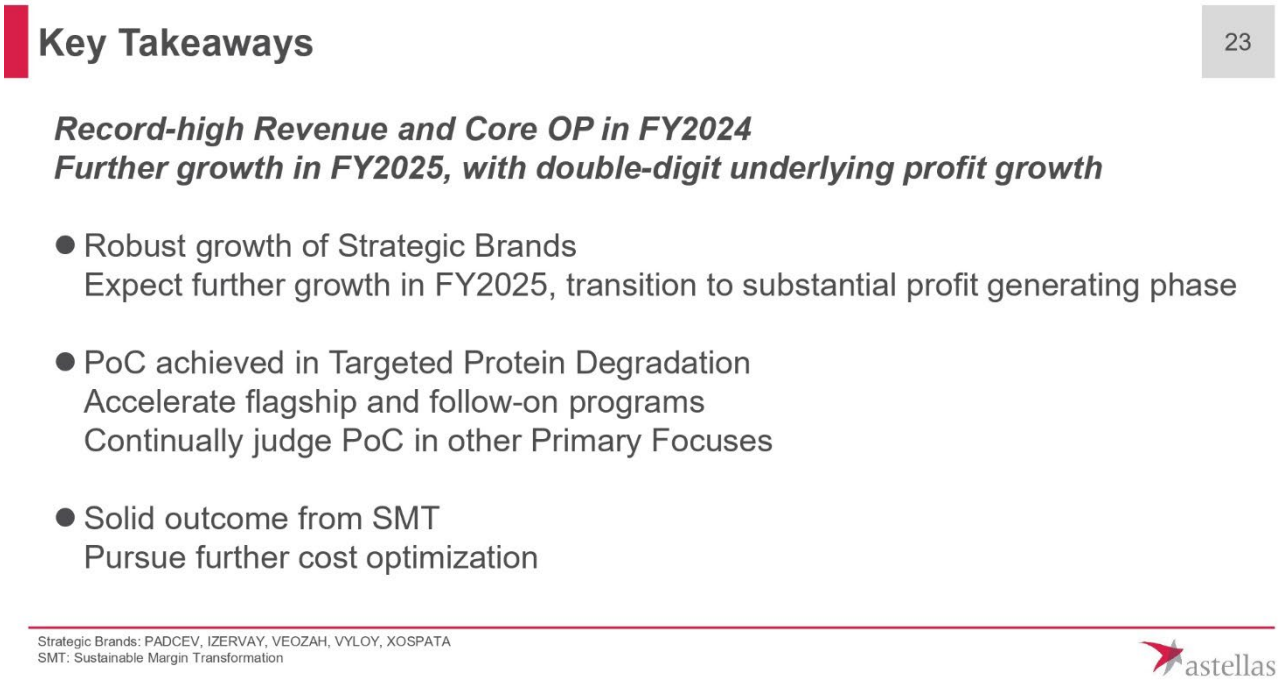
As a result, we expect core OP to be JPY410 billion, an increase of JPY17.6 billion YoY, and core operating margin to be 21.2%, up 0.7 percentage points over the previous year.

On an underlying basis, excluding the ForEx impact, the growth will be JPY435 billion, double-digit growth of 11%.

In consideration of potential business risks, we have factored in the impact of US tariffs and others to a certain extent in core OP.

The lower on this slide shows the full basis forecast. OP is projected to be JPY160 billion, an increase of JPY119 billion YoY. The main adjustment item excluded from the core basis is amortization of intangible assets, which is anticipated to be about JPY140 billion. In addition, we have factored in other expenses of about JPY110

billion. This includes impairment loss risk of JPY60 billion, which is the same level as in the previous year, initial focus, as well as expenses related to reorganization and ForEx losses.



Page 23, today's summary.

In FY2024, we achieved a record high revenue and core OP. We expect further growth in FY2025 with a double-digit profit growth in an underlying basis. Our strategic brands expanded strongly in FY2024. In FY2025, we expect them to grow further and enter a full-scale profit contribution phase. In the primary focus, we achieved our first PoC with ASP3082 targeted protein degradation. In FY2025, we will accelerate the development of ASP3082 and subsequent progress. In addition, we will continuously charge PoC in other primary focus. In SMT, based on the positive results achieved in FY2024, we will pursue further cost optimization.

Continuing the momentum of FY2024 in FY2025, we will aim to further increase the value of the pipeline, which will be the foundation for further profitable and sustainable growth.

That's all from me. Thank you very much for your attention.

Question & Answer

Ikeda [M]: Okamura-san, thank you very much. That's all as for our presentation. We'd now like to entertain questions from the audience. If you have a question, please press the raise hand button at the bottom of your Zoom screen. If you're joining from a smartphone, please tap details and then the raise hand button will be shown so please press it. The moderator will name you one by one. Once your name is called, please unmute yourself on the screen and mention your name and affiliation, and then ask your question.

Anyone with a question? Thank you very much. Thank you for waiting. First, Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi [M]: Can you hear me?

Ikeda [M]: Yes, we can hear you.

Yamaguchi [Q]: Thank you very much. Yamaguchi from Citigroup Securities. First, I have a question about your forecast. You factored in a certain level of risks with regards to tariffs. What kind of risks were included? How much? You incorporated the risks of tariffs. You are the first company to do so. You have Ireland and other specific situations. How did you think and how much was included in your forecast? And what you're planning to do? Could you briefly explain?

Okamura [A]: Thank you for your question. We incorporated these factors, but it's still very rough calculation results only. This is very uncertain and with lots of uncertainties. Forecasting the actual impact is currently very difficult. We are not doing business just on our own. We have business partners with whom we collaborate. We have to understand the potential impact. We have to discuss the necessary measures, and we'd like to implement those measures where necessary. How much for what is not going to be mentioned. We don't have a granularity of information we can share today based on our analysis.

Yamaguchi [Q]: Next, about IZERVAY, your forecast for IZERVAY prescriptions, because of CRL, kind of stopped, and then there is a growth trend after that. You are assuming 80% growth. Some think that's achievable, others think it's not going to be achievable. The competitor may have a higher penetration rate by now. Based on your feelings, this is your company's forecast. Looking at the trends, patients who were kind of away are coming back, or are they waiting? You have, again, a growth trend. Could you please explain the current status in more detail?

Okamura[A]: Thank you for your question. In 2024, in H1, as you say, the market penetration started. There is a slope of growth. Unfortunately, temporarily because of CRL, it kind of stopped or there was a slowdown to decline. But in February, we got the approval. One month later, if you look at the data in March, there was a declining trend, and then there is a growth trend again according to adjustment. After April, it's going to continue the growth, like the slope in H1 last year according to our outlook.

If you look at the size of the market, this is mentioned a lot. Some time ago, there was no treatment option for this disease, so patients are underdiagnosed. If there is no treatment, even if there is a diagnosis, nothing can be done. Diagnosis did not make a lot of progress before. Retina specialists, patients are already seeing retina specialists, then the usage will be promoted rapidly. But if patients are seen by eye doctors in the community or patients who haven't seen even such doctors yet, how they would be referred to specialists is going to be a challenge. We are continuing the disease awareness campaign. Just accessing the retina specialists would not be enough. Patients may not be able to come to the specialists, so our customer engagement have to be considered for the better.

Sorry, I spoke too much. Claus may have something to add. Claus, please.

Zieler [A]*: Yes. Let me explain a little bit what we think happened during the CRL period. As you mentioned, our growth trajectory before the complete response letter was extremely strong. We know we had 60% new patient capture at the time that the CRL was issued. The new patient capture was one factor that we started stagnating because that dropped. It never dropped below 50% but it dropped, from the 60% down probably to 52% of new patient capture. Now that we have the label as of February, it very quickly resumed. We know we are now already at 59%, which is why we can say that we are the number one prescribed agent in the United States since Q2 of last year.

One factor clearly was the acquisition of new patients, which simply slowed down after the CRL was issued because doctors were just uncertain of the label that we were going to get. The second factor, and you alluded to that, was that patients who were on drug, doctors did not know exactly what to do. Remember, we launched 1.5 years ago, and we had a label initially for 12 months. That means doctors came to us with a question: what do I do with patients once they reach 12 months? Will the payer reimburse after 12 months if it's off label?

Now, in real life, we don't know of any case where payers refused payment, but it created uncertainty for doctors. They started sort of postponing the injection. At first, it was just a delay. And then, we saw some switches happening, but we also saw simply people waiting, just waiting until the label came. You know also that we resubmitted very quickly, and that, to some doctors, gave confidence back. They were willing to wait with the injection until the label came through. And then, some other doctors simply continued to inject, and as I said, the payers continue to pay. You see different behaviors in subsegments of the market.

But if you add all of that up, a drop from 60% to 52% in new patient capture, a little bit of delay, a tiny amount of switching, if you add all of that up, that is what you see on this curve as a stagnating zigzag line. Now comes the good news. As of March, and I just checked the April numbers month-to-date, we are seeing a very strong rebound. Patients are coming back, doctors are resuming the injection, and we are very much on the same tangent, if you want, as we were before the CRL. The whole curve, we believe, has simply shifted out over time. We have, if you want, lost four months of growth rate where we had a flat curve, but we are now back on track. We believe that IZERVAY will continue to be the market leader that it was before the CRL.

Yamaguchi [M]: Thank you very much. That's all.

Ikeda [M]: Thank you. Next, JPMorgan Securities, Mr. Wakao, please.

Wakao [Q]: Wakao speaking, JPMorgan. Thank you very much. First is about the tariffs. It's not about the quantitative question. But you are trying to make the supply chain for the products and especially at the positioning of Ireland. You export from Ireland to United States and the percentage of those products in the US sales and those produced in Ireland. Those are traded with the price near to the cost of the production. Just a little bit of the markup is added for the export or loyalty is also added on top of that, that's what I want to know.

Also, each company, especially looking at the Western companies, the increase of inventory is currently what other Western companies are doing. Do you do the same thing? Also, you do not have a manufacturing site in the United States. Is there any possibility that you are going to establish a manufacturing site in the United States?

Okamura[A]: Thank you for your question. First of all, unfortunately, supply chain for product in detail is not disclosed. We'd like to refrain from answering that question today.

I think I can say this. The Ireland factory we have right now is planned for small molecules. What's coming out of the Irish plant is the compounds based on the small molecule technology, in principle. What's the relationship with the cost of goods sold and how this is traded in transactions? This is a corporate secret so we cannot disclose.

Where is the IP, including IP, royalty, do we need to discuss including IP? What do you think? Where do we have the IP, the countries with IP and other countries and affiliates? What is the economic condition between them? That's a very confidential information for us so I cannot respond to that question.

You said that we don't have a manufacturing site in the United States, but for gene therapy and cell therapies, we have GMP manufacturing facility in the United States in reality. Because of the current circumstances, building a factory in the United States, it takes time, many years, to build a factory, and it takes further many years to transfer the technology so it's not going to be a very effective method. If it's to a certain degree, CDMO in the United States could be utilized. According to some, that could be one possible option. But still, it's not an industry to transfer the technology very easily.

Once it's clear that what is going to happen to be in time, touching on the supply chain is not going to be a realistic solution. What about the inventory buildup right now? It depends on the situation. It depends on the features of the product. We take necessary measures.

Wakao [Q]: Understood. Thank you very much. My second question, about the ASP3082, you're able to achieve a PoC, which is great. But what kind of data do you have? I don't know. To support your long-term growth, I think that's an important aspect. What kind of data have you achieved? What about the data in PDAC, pancreatic ductal adenocarcinoma? You have competitive products. Have you been able to capture data which is competitive?

Okamura[A]: Let me briefly explain, then Taniguchi is going to take over. Of course, in order to judge PoC, we have the criteria even before the start of the studies. In that criteria, for example, TPD-specific MOA in humans have been reproduced. We have such parameters and various tumor types, and the treatment results, we have several parameters. Not only the ones which are being used, but including the competitive products under development, we set the criteria that we need this much, for example. Then we check against the actual results to judge PoC. It's not because of the data. We don't decide what to do after looking at the data, as you understand.

Next, Taniguchi-san, please.

Taniguchi [A]: Next, from me, ASP3082 in pancreatic adenocarcinoma PoC, let me explain. As you know, in pancreatic cancer, second-line and the third-line treatments, only chemotherapy has been approved. Efficacy is set to be less than 10% for the second-line therapy. Tumor shrinkage could not be seen with the third-line treatment right now. Unmet medical needs are very high in this segment. Therefore, we have been able to collect a very good data here, so we can move on to the next phase. That's our decision.

As you know, last year, in autumn at ESMO, 3082 initial data was presented. You can check that for your reference. Regarding the data presentation, it will depend on the future situations, but later this year, in H2 perhaps, at a congress, we want the abstract to be accepted. Once there is a decision, we'd like to share that with you.

Wakao [Q]: Thank you very much. Some are under the development, so my question is what I think about that. You look at that and you would consider further. That's my understanding. The last one, mirabegron, the litigation of the patent. My understanding is that, in September, that decision will be made. Is this understanding right? If you win this litigation, then the patent will be until March of 2030. Is this understanding right?

Okamura[A]: Well, first of all, the status of the litigation, let me sort it out. First of all, our formulation patent is decided to be effective, and based upon that, two generic manufacturers joined the market. But we complained about this decision-making to the appeal court, and this was returned to the first court and litigation. Then they came up with the decision that our patent is valid.

Currently, there are two generic manufacturers, and their products are infringing our formulation patent or the compound patent or not, that is a different decision and litigation. Likely in early CY2026, this is going to be decided by the court there. There is no consideration and a decision is made about the infringement of the patent so far. At least we are saying that our formulation patent is viable without waiting for a decision about that with risk other generic manufacturers might not getting into the market. I don't think that percentage is not that high. The two generic companies currently, ultimately, if they receive the decision that that is the violation of the patent, then they have to pay from the business that they've gained during before that decision-making. That possibility is not really high.

All in all, based upon those factors, we came up with this forecast.

Ikeda [M]: Now, Mr. Ueda from Goldman Sachs Securities.

Ueda [Q]: Ueda from Goldman Sachs Securities. First question is about the status of XTANDI. January to March volume and also the price trend, and for the plan, especially in the United States, what is the current precondition assumption? For the price perspective, Medicare redesign, that leads to the increase of the burden from the manufacturer that leads to the negative impact. Is that within just the 20% range of the burden from the manufacturer or is that expanding outside of the Medicare? Or is there any increase of the volume? Would you please share with us your track record and also the way of thinking?

Okamura[A]: So that I do not speak something not necessary, I would like to ask Claus to make an explanation about this.

Zieler [A]*: Yes. Thank you for the question. I just want to emphasize we've had an impressive year with XTANDI, both in the United States and outside of the United States, with double-digit growth in essentially every region. Now, in the United States, which is your question, yes, we have had the growth to net impact from the IRA Medicare redesign as of January 1, 2025. That decreases essentially our net price. But with the volume increase of 27% last year, that volume increase over 12 months versus a gross to net impact of only one quarter, that is really what you see as a net effect for XTANDI in the United States. Now, the volume growth will continue, maybe not at the same rate because the EMBARK data that we published now almost 1.5 years ago, that's when we got the approval. That, of course, will not drive growth forever. But we do foresee a significant growth in the mid-teen level on a volume basis in the United States also in FY2025.

Did that answer your question?

Ueda [Q]: Thank you very much. I have a follow-up question. What was your assumption in the plan?

Zieler [M]*: For FY2025 or for FY2024? Let me just confirm what your question is.

Ueda [M]: FY2025 plan and assumptions.

Zieler [A]*: The assumption on a volume basis for FY2025 in the United States is a growth in the mid-teen, middle between 10% and 20%, mid-teen range of growth on a volume basis. Of course, we are now carrying the gross to net impact that started January 1 over a 12-month period. That impact, we will not be able to dodge. That's why you see, on a net basis in revenue, you will see a flat picture in the United States. On top of that, you have an FX effect because, as you know, the dollar is weakening versus the yen. That will have a slight decrease in yen basis from the United States in FY2025. Those are the three factors: mid-teen volume

growth in the United States, gross to net impact that started January 1 carrying all the way through the fiscal year, and then the FX rate from the dollar to the yen.

Ueda [Q]: Thank you very much. Secondly, capital allocation, your current way of thinking is my second question. As of now, the peak sales forecast of your strategic brands has been kept at the same level compared to a year ago. The need for business investments and for your budget, you haven't changed your way of thinking. A JPY4 dividend increase can continue into the future. There is a decreased transparency in the business environment. Any impact on your capital allocation policy?

Okamura [A]: Thank you for your question. From me, I'd like to talk about the capital allocation policy. There is no basic change in our capital allocation policy. That's my comment. But from before, our top priority is the growth of the business and then return to shareholders. The cash flow and profit for the future must be considered. In a sustainable fashion, we'd like to increase the dividend payment. If there is excess cash, of course, as a means to return to shareholders, we would have a share buyback. These are the three stages in our policy. That has not changed by now.

On the other hand, for strategic brands, we look at the growth of the strategic brands. Should we have another business development project? Of course, we are always watching. In that sense, Iveric Bio was acquired in a sense for our strategic brands at the time, the potential of those. In order for us to grow continuously and sustainably into the future, we needed firepower. In addition to that, we decided that we need to acquire Iveric Bio. There can be a similar decision into the future. But in reality, if you look at the actual balance sheet, there is a lot of debt at the time of the acquisition of Iveric Bio. We don't have a lot of capabilities to borrow so much. It's difficult to think that there's going to be a very big deal in the near future, as you can tell.

Kitamura-san, anything to add?

Kitamura [A]: Thank you very much. As Okamura mentioned, we think the most important thing is to have a sustainable growth. We would make growth investments. That's the top priority. After the acquisition of Iveric Bio, we have debt. As a challenge, how to create a balance sheet to realize this, that's a very important point. Last year, or two years ago, at the end of FY2023, after the acquisition of Iveric Bio, interest-bearing debt and EBITDA gross leverage ratio was 3.4x, but at the end of last year, it was down to 2.2x. We'd like to strengthen our balance sheet to decrease the leverage, which we should aim for where necessary. If there is a potential big deal, we should be ready. First, we'd like to strengthen our balance sheet, which we focus on right now. That's all from me.

Ueda [M]: Understood. Thank you very much. That’s all from me. Thank you.

Ikeda [M]: Thank you. Next, Morgan Stanley MUFG Securities, Mr. Muraoka, please.

Muraoka [Q]: Thank you. Muraoka from Morgan Stanley. Capital allocation was raised by Ueda-san, and this is a follow-up. Three months ago, at the time of Q3 announcement, the late phase new drug acquiring is under your consideration. I believe you talked about that. Relating to that and also this capital allocation matter, I would like you to make an explanation incorporating those two factors together. Is it better for us to have a size of what you are trying to do?

Okamura [A]: Thank you very much. It seems to me that there is a misunderstanding here. Let me work on that, first of all. At Q3, it was not me that I made a presentation. But at the time of the Q3 announcement, what we are thinking is now going to be explained with my words. So far, the new Primary Focus is made or existing Primary Focus is added with the technology and assets so that Primary Focus can be stronger. That kind of business development deals are relatively larger in terms of the numbers. But in the past, we have VEOZAH and VYLOY. Those are relatively derisked assets. But afterwards, if you look at our business

development activities, relatively advanced technology assets and technologies are trying to be captured and the size is not that big. Those are coming with as a couple of deals.

Now we have four Primary Focuses and flagship comes to the timing of the clinical PoC judgment. It's not something we are continuously expanding. But for Primary Focus, we try to converge that based upon the PoC judgment. Suppose there is some deal of the business development, early stage, innovative, something advanced, rather than that, the project that is derisked to a certain extent, but of course, it's difficult to achieve the contribution next year or two years later. Probably the early of 2030s, something is likely to contribute to our profit.

That's the things that we are trying to identify. That's what we wanted to say at the time of Q3. On the other hand, derisked in the late phase development project and contributing to our growth. Then in that case, that is likely to be quite expensive, and that kind of asset is quite limited in number. If we want to do such a deal, it's going to be quite a competitive situation. Considering that, just like Kitamura explained a little while ago, we would like to prepare, first of all. When such kind of deal becomes available so that we can compete with our competitors, we would like to have a sufficient capability. We like to focus on preparing for that. For example, next month, there's a very good deal, a promising deal for us, but we cannot acquire that with getting the borrowings. In the case, we cannot go for that because of our current capability. We have to prepare ourselves so that we can acquire the deal that we really want to do. That's something currently Kitamura is working on for the preparation.

Policy-wise, not early, but the late phase. But considering our current financial capability, those on late phase and competitive and very expensive, can we try to acquire that tomorrow? In reality, we cannot do that. That is the current status.

Muraoka [M]: I understand. Thank you very much. PADCEV growth is stagnant, and you are going to sell that outside to make your cash. I thought you are thinking about something greater like that, but it's not so. The deal, what we are saying is not such a bold deal.

Okamura [A]: PADCEV, that is what we develop, and with our hands, we would like to continue to provide our products to the patient. That's our mission that we think.

Muraoka [M]: Thank you. That’s all from me.

Ikeda [M]: Thank you very much, Mr. Muraoka. Next, Nomura Securities, Matsubara-san, please.

Matsubara [M]: Matsubara from Nomura Securities. Can you hear me?

Ikeda [M]: Yes.

Matsubara [Q]: Thank you very much. First, I have a question about IZERVAY. GA area increase suppression is important by dosing, but in terms of the visual acuity, over time, it would worsen. Some patients may decide to postpone dosing. In order to expand the market for the patients in the latter case, how are you going to appeal to such patients? What's your strategy?

Okamura [A]: Thank you for your question. The details will be explained by Taniguchi, but what I can explain from my side is as follows. Patients with GA would lose the visual acuity in the center in the visual acuity exam. They would have a disease condition, which is not very good for the visual acuity test. without the progression of the onset, they should receive the treatment. That's the ideal state of IZERVAY treatment, in my view. To do so, as we mentioned in the Q&A, disease awareness is important. Even if they are in early stage, they should be seen by doctors, and the doctors should think there are signs of GA, so they should be seen by specialists. Such a route should be established. I think that's going to be important.

More scientifically, clinically, Taniguchi is going to explain such aspects.

Taniguchi [A]: Thank you very much. How much patients' visual acuity is worsening? How much they should continue the treatment when their visual acuity is worsening? As Okamura explained, IZERVAY efficacy, if you look at the GATHER2 data, you can tell its efficacy. In principle, GA progression can be prevented or suppressed. In the longer term, progression can be stopped or suppressed, which is important. In the longer term, the impact of the visual acuity hopefully can be seen. But unfortunately, at the center of the field of vision is very difficult to measure right now. That cannot be done. For patients, still, their central visual acuity would worsen over time, which is a very big problem in their daily life. For the portion with GA, if that area's growth should be suppressed with treatment clinically, that's very meaningful to prevent the progression of the GA area.

As far as I see the data, if they can continue treatment, the longer, the better. The speed of the progression of GA can be suppressed. In the end, it's going to be the discussion and the decision to be made between the patient and their physicians. The longer the progression can be suppressed, the bigger clinical benefit.

Matsubara [Q]: Understood. Thank you. Additionally, I have another question. Regarding the 60% from February as the new patient start share, the trend is expanding, according to the response to the earlier question. Now, in March or by now, the new patient start share is increasing further?

Zieler [A]*: As I said, our lowest point was 52%. Our latest data point is already back up at 59%, and we'll gather more data and confirm in the next quarter. But honestly, there's no reason to believe that we should not stay at that 60% level as we did before the CRL. I think the real question is not so much our market share because we're a market leader and will stay market leader in this market. The real question is, how do we now expand this market? And how do we invest in DTC and in the right educational activities to make patients aware and make doctors aware of the opportunity this agent delivers to slow the progression of geographic atrophy? Expanding the market is our main focus at this point.

Matsubara [Q]: Thank you very much. Second, sorry if I missed the information, that is VYLOY PDAC. FY2025 Q2 analysis, after the result become available, around what time point do you think you are going to do the NDA?

Taniguchi [A]: Well, VYLOY PDAC, in accordance with the protocol, the study is ongoing. In Q2, the final analysis readout is planned to be available. Needless to say, for this as well, it's an event-driven study so there might be a bit of delay or difference from the expected timeline. Looking at the result, we make the decision for the NDA timing. If the result is positive in the case, as early as possible, we would like to do the NDA submission as early as possible. Like the case of ASP3082 for the pancreatic cancer, the current treatment is limited. Claudin 18.2 antibody and also combination with the chemotherapy, there is the study for the pancreatic cancer, and as soon as the result is available, we would like to go for further.

Matsubara [Q]: The best case is that in Q2, the result is favorable. There's a possibility that you are going to do NDA within this fiscal year.

Taniguchi [A]: Yes, of course, we are aiming at that.

Matsubara [M]: Thank you. That's all from me.

Ikeda [M]: Thank you, Mr. Matsubara. Next, Sanford C. Bernstein, Ms. Sogi, please.

Sogi [Q]: Thank you very much. First of all, question is about the guidance for the next year. Other expenses, you incorporate certain numbers, and there, there is no ones for the impairment likely to be included. There is expectation that the onetime expenses for the reorganization might be included. Is this understanding

right? And if that is right, for HR cost, the positive impact will continue in FY2026 and afterwards. Is this way of the understanding appropriate? That's the question.

Okamura [A]: Thank you for the question. Are you talking about the JPY110 billion breakdown?

Sogi [Q]: Yes. And also the HR cost impact FY2026 and afterwards.

Okamura [A]: First of all, FY2024, we took the same approach, and within this FY2025, we never expect a failure, but we see that it's likely to fail and that impairment is included, it's not that way. But we look at the past trend, and also current intangible asset absolute value is used a factor for the consideration. We have this level of buffer, and then furthermore, the impairment would not take place. That's the JPY60 billion of the ballpark figure that was included in FY2024 as well. JPY110 billion minus JPY60 billion, so JPY50 billion is others, and that breakdown is going to be explained by Kitamura.

Kitamura [A]: The breakdown of the remaining JPY50 billion, that is not disclosed. But just like you pointed out, there is population changes, operation changes that leads to the organizational changes, and our asset increases its fair value and also the FX changes, they are the same type of decision happened in the past. A certain level of the estimate is included.

Also, the bigger changes of the operation and the benefit of that, well, this is reflected into SMT as well. What we have done last year is something that is sort of like a low-hanging fruit. But what we are trying to do now requires a certain period of time because that includes a certain level of the big transformation. Benefit is likely to be next year and afterwards, just like you pointed out.

Sogi [Q]: Thank you. Another question is gene therapy AT845. Within the muscular cells, the genes there are going to be treated with this treatment. But generally speaking, when it comes to gene therapy, like the myocyte, that is abundant in number, and the efficacy on that is very difficult from gene therapy. But with this AT845 for Pompe disease, we are trying to develop this product. Is there any different approach for this AT845 compared to the conventional gene therapy? For the muscle gene therapy, what kind of challenges are you thinking? And how do you feel about the development for this field?

Taniguchi [A]: Thank you very much, Ms. Sogi. For Pompe disease, AT845, any difference compared to other gene therapies, there isn't a big difference compared to others. But as you know, Pompe disease is a progressive disease. The physical function will decline, including the vital capacity and respiratory function. It's a very serious disease.

As we showed you data earlier, including forced vital capacity, six-minute walking test, based on these endpoints, patients with Pompe disease, most of them are receiving ERT, enzyme replacement therapy. Even if they discontinue ERT, the efficacy of this compound can continue, according to the follow-up data, for up to three years. This is going to be a big benefit for the patients. ERT requires infusions once every two weeks. Pompe disease patients have difficulty in their physical conditions, but they have to go to the hospitals once every two weeks, which is very difficult for them to do so. With gene therapy, just with a single dose, a single treatment, efficacy can be sustained, and as long as that's going to be demonstrated, there's going to be a big benefit for the patients.

We have previous data as well. PD marker and the increase in the GAA was also seen. The sample size is small, so we cannot say anything definitive yet. But if you look at the data as a whole, FDA granted us with RMAT designation. With US FDA and the health authorities in the respective countries, we will consult with them to promote the development at the fastest possible pace.

Sogi [Q]: Understood. I have another question to you. Listening to your explanation, gene therapies, just a single treatment is going to be enough to replace the mutated or deficient genes. After that treatment, ERT treatment would continue after gene therapy? Any such possibility to continue ERT after gene therapy?

Taniguchi [A]: Regarding that question, we cannot rule out that possibility. But if you look at patients and their family members and patients' advocacy groups and also physicians, according to them, the biggest burden is the ERT. As for ERT, if you continue the treatment, sometime it's difficult to enjoy the efficacy anymore. There can be a secondary disease progression. So there's going to be a burden for the patients, not just physical burden, but economic burden would also be seen. Ideally speaking, a single treatment with gene therapy can be administered, and then there can be freed from the burden of ERT. That is going to be the most ideal and would bring a big benefit for the patients and their family members.

Sogi [M]: Understood. Thank you very much.

Ikeda [M]: Ms. Sogi, thank you very much. Next, Daiwa Securities, Mr. Hashiguchi, please.

Hashiguchi [Q]: Hashiguchi speaking. First question is about Strategic Brands and contribution to profit on page 19. I'd like to ask your question for the future in FY2026 and beyond. This fiscal year, SG&A costs in yen will decrease a bit. Excluding ForEx impact, it's going to remain flat, according to my understanding. It may depend on the situation of sales and revenues, as is mentioned on page 20. How much you can expand the indications is going to be important. When we think of the opportunities to expand indications for the future, just increasing SG&A cost would not happen, in my view, for the future. SG&A costs would remain flat at most. Rather, you would like to reduce the cost to regain the profits, to harvest the profits, correct?

Okamura [A]: Thank you for your question. Overall, yes, that's the overall image. Indication expansion, we are not going to a very faraway place. We don't need to create the sales force in a completely different field. If you look at the situation as a whole, we don't spend too many costs, but it would contribute to sales and revenues and it would contribute to profit as well. We can simplify in that way.

Hashiguchi [Q]: If you look at the individual aspect, if you invest more, there can be higher return for some products and indications. There can be such indications or rather regarding the indications you have or indications you may be able to get in the near future.

Okamura [A]: Thank you for your question. What's under development or the current indications we have, if we invest more, we can deliver them to more patients. If any, we are already doing so if there is such a product and indication. Having said so, we don't have resources without any limitations. If we allocate resources, where to allocate such resources, that's decided by Claus. Return on investment should be the highest. High unmet medical needs, we try to allocate resources there to deliver value to the patients. That's my belief.

Hashiguchi [Q]: Thank you very much. Another question is about tariff. Supply chain details cannot be disclosed. I understand that. But in this performance forecast, how the tariff matter is incorporated or factored and the monthly value of the tariff impact factored in, what's the level? What's the size? Currently, the reciprocal tariff that is hold at this moment alone is factored in or the raw materials and other materials where the tariff supplied is taken into consideration, or pharmaceutical products or intermediates currently are considered tariff. Do you have a certain level of the assumptions that is already also included with this forecast?

Kitamura [A]: First of all, from overall perspective, it's not only tariff, but there are risks here and there. For example, foreign exchange and also the pharmaceutical products-related tariff or the direct material-related tariffs. There are certain risks. Monetary value-wise, at this moment, we cannot disclose specifically, but a certain risk scenario is prepared so that we can decide the number.

There are two things we can tell you here. First of all, overall framework is decided, and if that is needed to be reflected into the forecast in the case, of course, it will be done so and that will be communicated to you. I think the second matter here is more important. For example, there are, in that sense, areas that we cannot control on our own. We do, in a very appropriate manner, in the areas that we can control. What can we do? Well, how we can incorporate the benefit of the cost reduction? 2025 forecast, SMT benefit and effect, favorable effect of that is incorporated. What we are considering currently is to make it earlier, to realize it earlier, to a greater extent. Claus is now calculating the number of the sales and try to achieve that. We all trying to do the preparation for that kind of scenario. That is where we put our most effort currently.

Hashiguchi [Q]: Thank you. SMT JPY20 billion, that's what you said. For this as well, if things go better, this can be also bigger?

Kitamura [A]: Well, SMT itself, this is not the single-year activities. We have the midterm target for the actions. Of course, if we can realize earlier, we'll do it earlier. That's all depending on our ways of executions.

Hashiguchi [M]: Thank you very much. That's all.

Ikeda [M]: Thank you very much. It's time, but just one last question. UB Securities, Mr. Sakai, please.

Sakai [Q]: Thank you very much. UBS, Sakai speaking. March 28, Pfizer, for the investors in the US, IRA Part D design presentation was done by Pfizer to investors, and there, XTANDI was talked about, saying that this impact is very large. Probably all IR people have already seen those materials. This year, 16%, I don't know if that is a discount of the price, but the reduction impact is 16%. That's what they disclosed. Against that, your current US sales base is larger for this fiscal year. I think Claus mentioned 16% is volume, 20% minus for the price or the monetary value. Why is there a gap? What made this gap? That's the first question from me.

Zieler [A]*: Let me clarify the three factors that I see for XTANDI in the US. If your volume grows in the mid-teens and you have a gross to net impact, in about the same order of magnitude, you will stay largely flat, and that's what we expect for XTANDI in the US in dollar basis. We expect the gross to net impact, which is negative, and the volume increase, which is positive, to more or less cancel each other out. Then you have the FX impact, as I explained before, from the dollar to the yen.

Sakai [Q]*: Yeah, but there shouldn't be no ForEx impact. I'm talking about local currency in the US.

Zieler [A]*: Yes. And then you have a flat curve.

Sakai [Q]*: I'm sorry?

Zieler [A]*: You have a flat evolution in the US in dollar basis because you're growing double digit in volume and you're taking a double-digit hit in gross to net. The two cancel out, more or less, not 100%, but more or less. XTANDI in US dollars is flat from 2024 to 2025.

Sakai [Q]*: That's what you have factored in in your forecast this year in the US.

Zieler [A]*: Correct.

Sakai [Q]: Okay. That's fine. Thank you. One more question, sorry to run over. It's not related to the financial results. R&D structure has substantially changed this time. Research, development, primary focus is now under one organization. The management also changed hands accordingly. What's your objective? Any big change in the direction going forward? I'd like to hear from Okamura-san, in your own words.

Okamura [A]: Thank you very much. In CSP2018, before CSP2021, we defined the VALUE. Astellas would create the VALUE and deliver the VALUE we create. We said that we would work on this. It doesn't mean that we haven't done this before. The three axis pharmaceutical companies should have for management, initially, we talked about regions to manage, then functional capabilities would be enhanced. We reinforced the functional axis. What happened as a result? Between the functions, there was a silo. There should have been overlaps to work in a cross-functional team to make a decision together, but we couldn't overcome the barriers between the two different functions in the past.

This time, those who create VALUE, the so-called innovation engine, according to the slide, are those who are in charge of VALUE creation, and the VALUE being created would be delivered to customers and particularly patients. That's the customer engagement responsibility for other people, according to this rough classification, brands, technologies, and farmers' role. When you want to introduce yourself as a farmer, I am a brand manager in Japan in charge of brand. Region, product and function will be mentioned. Region was the first axis, and then we switched to function axis. And then from here on, brand, technology, and project would be the first management axis as events so that we can be agile. When we say event axis, it's difficult to communicate the meaning. We are a pharma company, luckily, so this is what we call the patient axis. Those who don't speak Japanese, we can talk about patient axis in the same meaning. That's why we are calling this patient axis.

Going back to your question, as you know, before research, we had a Chief Scientific Officer to look at research. After the clinical studies, the Chief Medical Officer was to oversee that area. Primary Focus lead is the Chief Strategy Officer to be reporting to because of the strategy. Those who create and deliver VALUE, we separate the two. Those in research, those in development, and those who develop strategy for primary focus, it's better for them to belong to the same organization, then we don't have unnecessary conflicts. Chief Research and Development Officer, these are the functions under that officer. Needless to say, the Chief Strategy Officer would not go there. CXO looking at research, CXO looking at the situation after development, either of the two would be the Chief Research and Development Officer. Now we decided to give this responsibility to Taniguchi.

Productivity-related benchmarks have been introduced. Is it directly linked to the reorganization? Setting that aside, in clinical studies, when we execute clinical studies, there are a variety of parameters. IND would be accepted, and then first subject dosing, time to first subject dosing, for example, and how many patients would be enrolled over how much period. We have a variety of parameters as the benchmark for the industry, so we refer to that to measure our performance. If we cannot measure, we cannot improve. Using these KPIs to change to higher quality operations, we have been making efforts this way all throughout. Thank you very much.

Sakai [M]: Thank you very much. Thank you.

Ikeda [M]: Thank you very much. I'm sure that you still have questions. There are people who are waiting for asking questions, but it's time. With this, we would like to close today's meeting. Everyone, thank you very much for joining with us. Thank you.

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