Astellas Pharma Inc.

Financial Results for the Q3 YTD/FY2024

February 4, 2025

Event Summary

[Company Name]	Astellas Pharma Inc.
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[Time]	16:00 – 17:30 (Total: 90 minutes, Presentation: 28 minutes, Q&A: 62 minutes)
[Venue]	Webcast
[Number of Speakers]	5

Atsushi Kitamura	Chief Financial Officer (CFO)
Yoshitsugu Shitaka	Chief Scientific Officer (CScO)
Tadaaki Taniguchi	Chief Medical Officer (CMO)
Claus Zieler	Chief Commercial Officer (CCO)
Hiromitsu Ikeda	Chief Communications and IR Officer (CCIRO)

[Questioner]

Hidemaru Yamaguchi	Citigroup Global Markets
Seiji Wakao	JPMorgan Securities
Shinichiro Muraoka	Morgan Stanley MUFG Securities
Akinori Ueda	Goldman Sachs
Hiroyuki Matsubara	Nomura Securities
Shinichiro Hyogo	Mitsubishi UFJ Trust and Banking Corporation
Miki Sogi	Sanford C. Berstein
Fumiyoshi Sakai	UBS Securities
Kazuaki Hashiguchi	Daiwa Securities

Presentation

Ikeda: Thank you very much for your attendance to this Q3 YTD FY2024 financial results announcement meeting. I'm going to serve as the moderator. I'm Chief Communications and IR Officer, Ikeda. We'll make a presentation first, and after that, we'll have a Q&A session. The presentation is given based upon the presentation material posted on our website, including a Q&A. The simultaneous translation for both Japanese and English are provided. For the simultaneous translation, the accuracy cannot be guaranteed by us, the Company.

This is some disclaimer. This material or presentation by representatives for the Company and answers and statements by representatives for the Company in the Q&A session includes forward-looking statements based on assumptions and beliefs in light of the 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.

Now let me introduce you the participants here: Atsushi Kitamura, CFO, Chief Financial Officer; Yoshitsugu Shitaka, Chief Scientific Officer; Tadaaki Taniguchi, Chief Medical Officer; Claus Zieler, Chief Commercial Officer. We have these four representatives here.

Now Kitamura-san, please start the presentation.

Kitamura: Hello, everyone. I'm Atsushi Kitamura from Astellas Pharma Inc. Thank you very much for joining our FY2024 Q3 YTD financial results announcement meeting out of your very busy schedule today.

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 Q3 YTD/FY2024 Consolidated Financial Results
FY2024 Revised Forecast

II Initiatives for Sustainable Growth

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

Q3 YTD/FY2024 Financial Results: Key Message

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Revenue

- **Increased significantly YoY (+22%)**
- Strategic Brands: Expanded to over 240.0 bil. yen **(+140.0 bil. yen YoY)**

*SG&A expenses**

- SG&A ratio **improved by 4.0ppt** YoY, driven by robust progress of SMT (Sustainable Margin Transformation)

Core operating profit

- **Increased significantly YoY (+44%)**, driven by growth of XTANDI, Strategic Brands and SMT cost optimization

Revised full-year forecast

- Upward revision of revenue **(+100.0 bil. yen)**, core OP **(+70.0 bil. yen)** based on robust core business progress

Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA
SMT (Sustainable Margin Transformation): See slide 28 for overview
*Excl. US XTANDI co-pro fee

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On page four, I will give you highlights of FY2024 Q3 YTD financial results.

Revenue increased substantially YoY by 22%. Sales of Strategic Brands as a whole expanded to over JPY240 billion in total, with growth of about JPY140 billion YoY.

As for SG&A expenses, excluding US XTANDI co-promotion fees, SG&A ratio improved by 4 percentage points YoY, driven by robust growth progress of sustainable margin transformation or SMT initiatives to pursue company-wide cost optimization.

Core operating profit increased significantly YoY by 44%, driven by the growth of XTANDI and Strategic Brands as well as the contribution of SMT cost optimization.

As was announced in the press release on the 24 of January, we made an upward revision of our full-year forecast for revenue by JPY100 billion and core operating profit by JPY70 billion based on robust core business progress. I will explain the details of our revised forecast on page nine.

Q3 YTD/FY2024 Financial Results

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(billion yen)	Q3 YTD FY2023	Q3 YTD FY2024	Change	Change (%)	FY2024 Latest FCST	FX impact (YoY)
Revenue	**1,189.1**	**1,453.0**	**+264.0**	**+22.2%**	**1,900.0**	+66.3
Cost of sales	219.3	272.3	+53.1	+24.2%	345.0	+7.6
SG&A expenses	547.0	631.7	+84.8	+15.5%	845.0	+31.7
US XTANDI co-pro fee	146.2	200.1	+53.9	+36.8%	255.0	+12.1
SG&A excl. the above	400.7	431.6	+30.9	+7.7%	590.0	+19.6
(SG&A ratio')	33.7%	29.7%	-4.0ppt		31.1%	
R&D expenses	216.3	251.4	+35.1	+16.2%	340.0	+9.9
(R&D ratio)	18.2%	17.3%	-0.9ppt		17.9%	
Core operating profit**	**206.5**	**297.5**	**+91.0**	**+44.1%**	**370.0**	+17.1
(Core OP margin)	17.4%	20.5%	+3.1ppt		19.5%	
<Full basis>						
Amortisation of intangible assets	66.2	104.2	+38.0	+57.5%		
Other income	8.5	4.4	-4.1	-47.9%		
Other expenses	84.0	220.6	+136.6	+162.7%		
Operating profit	**74.1**	**-22.5**	**-96.6**	**-**	**11.0**	
Profit before tax	73.6	-29.3	-102.9	-	1.0	
Profit	**50.3**	**-24.1**	**-74.5**	**-**	**14.0**	

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

Other expenses (booked in Q3)

- Impairment losses on intangible assets: 180.5
  Major impairment losses include:
  IZERVAY (Ex-US): 115.1,
  AT466: 51.8, iota: 8.0

Latest FCST for revenue and profit at each stage were announced on Jan 24, 2025. FX rates for Latest FCST: 153 yen/USD, 164 yen/EUR. Actual FX rates for Q3 YTD/FY2024: 152 yen/USD, 165 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 Q3 YTD financial results.

Revenue reached JPY1.453 billion, up by 22% YoY. Core operating profit rose to JPY297.5 billion, up by 44% YoY.

The bottom half of this page shows our full basis results. In the right bottom of the table, we included other expenses booked in Q3. We booked JPY180.5 billion as impairment losses on intangible assets for IZERVAY ex US, AT466, iota, et cetera.

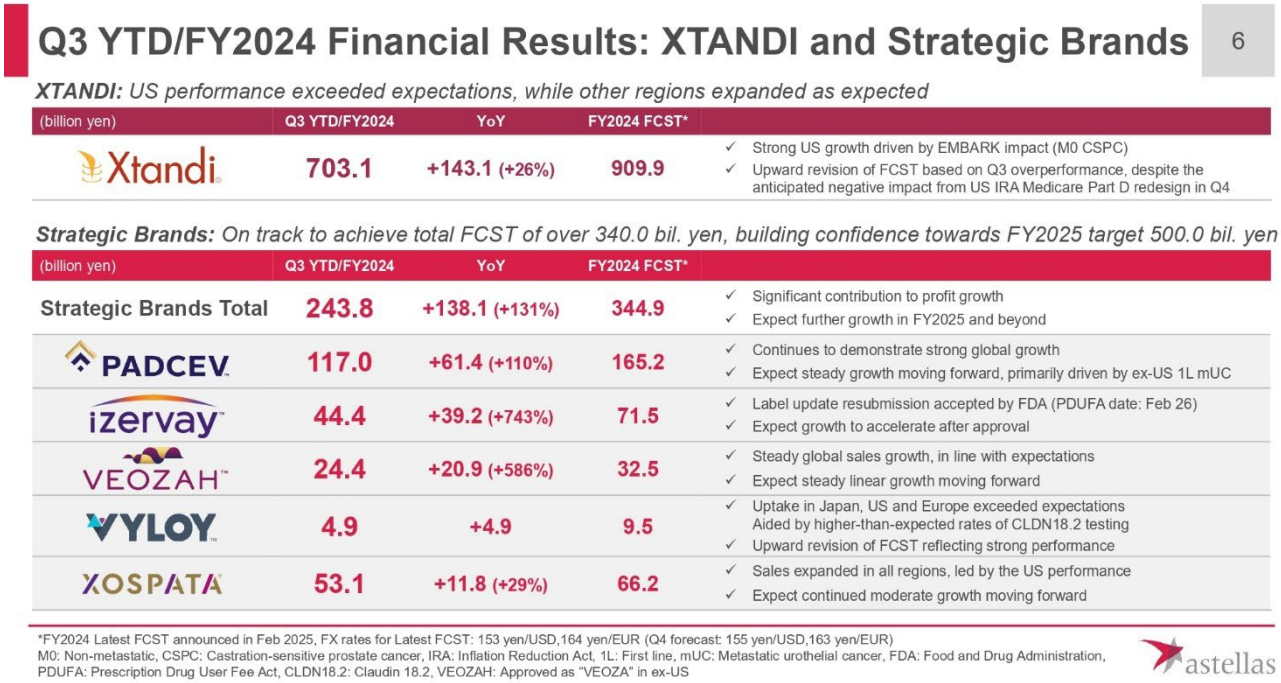
As for impairment losses for IZERVAY ex US, we reevaluated based on our decision to withdraw regulatory application in Europe. Based on our discussions with CHMP by now and the competitive situation, we conducted a reassessment from various perspectives, such as target countries for filing or submission, the probability of approval and timelines. We have conducted a review of the asset value based on a conservative scenario. As a result, we booked an impairment loss of JPY115.1 billion.

I will explain the details of the latest status of regulatory activities outside of the United States on page 12.

AT466 is a gene therapy program for myotonic dystrophy. In R&D, we optimize technology to be utilized. There is a possibility that we can create highly effective therapeutic candidates, but the development timeline

and the competitive environment have changed from our initial assumptions. Based on these circumstances, we have conducted a review of the asset value. As a result, we booked an impairment loss of JPY51.8 billion.

Regarding iota, we examined the project related to its implantable medical devices. As a result, we booked an impairment loss of JPY8 billion on intangible assets of the projects that we decided to terminate. As a result, operating profit was minus JPY22.5 billion.



Q3 YTD/FY2024 Financial Results: XTANDI and Strategic Brands

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XTANDI: *US performance exceeded expectations, while other regions expanded as expected*

(billion yen)	Q3 YTD/FY2024	YoY	FY2024 FCST*	
Xtandi	703.1	+143.1 (+26%)	909.9	✓ Strong US growth driven by EMBARK impact (M0 CSPC) ✓ Upward revision of FCST based on Q3 overperformance, despite the anticipated negative impact from US IRA Medicare Part D redesign in Q4

Strategic Brands: *On track to achieve total FCST of over 340.0 bil. yen, building confidence towards FY2025 target 500.0 bil. yen*

(billion yen)	Q3 YTD/FY2024	YoY	FY2024 FCST*	
Strategic Brands Total	243.8	+138.1 (+131%)	344.9	✓ Significant contribution to profit growth ✓ Expect further growth in FY2025 and beyond
PADCEV	117.0	+61.4 (+110%)	165.2	✓ Continues to demonstrate strong global growth ✓ Expect steady growth moving forward, primarily driven by ex-US 1L mUC
izervay	44.4	+39.2 (+743%)	71.5	✓ Label update resubmission accepted by FDA (PDUFA date: Feb 26) ✓ Expect growth to accelerate after approval
VEOZAH	24.4	+20.9 (+586%)	32.5	✓ Steady global sales growth, in line with expectations ✓ Expect steady linear growth moving forward
VYLOY	4.9	+4.9	9.5	✓ Uptake in Japan, US and Europe exceeded expectations Aided by higher-than-expected rates of CLDN18.2 testing ✓ Upward revision of FCST reflecting strong performance
XOSPATA	53.1	+11.8 (+29%)	66.2	✓ Sales expanded in all regions, led by the US performance ✓ Expect continued moderate growth moving forward

*FY2024 Latest FCST announced in Feb 2025, FX rates for Latest FCST: 153 yen/USD,164 yen/EUR (Q4 forecast: 155 yen/USD,163 yen/EUR)
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, IRA: Inflation Reduction Act, 1L: First line, mUC: Metastatic urothelial cancer, FDA: Food and Drug Administration, PDUFA: Prescription Drug User Fee Act, CLDN18.2: Claudin 18.2, VEOZAH: Approved as "VEOZA" in ex-US

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On page six, I will explain FY2024 Q3 YTD results for XTANDI and Strategic Brands.

First, about XTANDI. Global sales increased to JPY703.1 billion, up by JPY143.1 billion or 26% YoY. In the United States, M0 CSPC performance and its ripple effects on other indications exceeded expectations, while sales in other regions expanded as expected.

Reflecting the overperformance in the United States, we revised our full-year forecast once again following the revision in Q2. In line with our guidance from before, we are factoring in the anticipated negative impact from US IRA Medicare Part D redesign in the Q4 forecast without major changes in our assumptions.

The impact from Medicare Part D redesign is expected to continue also in FY2025. We will internally assess the specific level of impact based on the Q4 situation. Next time when we announce FY2024 full-year results, we will provide our guidance of FY2025 outlook, so please wait until then.

Sales of Strategic Brands supporting our future growth, namely PADCEV, IZERVAY, VEOZAH, VYLOY, and XOSPATA expanded to over JPY240 billion in total, with a growth of nearly JPY140 billion YoY.

Furthermore, the profit margin of these Strategic Brands is also high, substantially contributing to sales and also to the overall profit growth. We believe that we are fully on track to achieve our full-year forecast of over JPY340 billion, building confidence towards FY2025 target of JPY500 billion.

Let me explain individual Strategic Brands as well. I will explain the details of PADCEV, IZERVAY and VYLOY on the next page.

Global sales of PADCEV increased to JPY117 billion, up by JPY61.4 billion or 110% YoY, growing more than twofold.

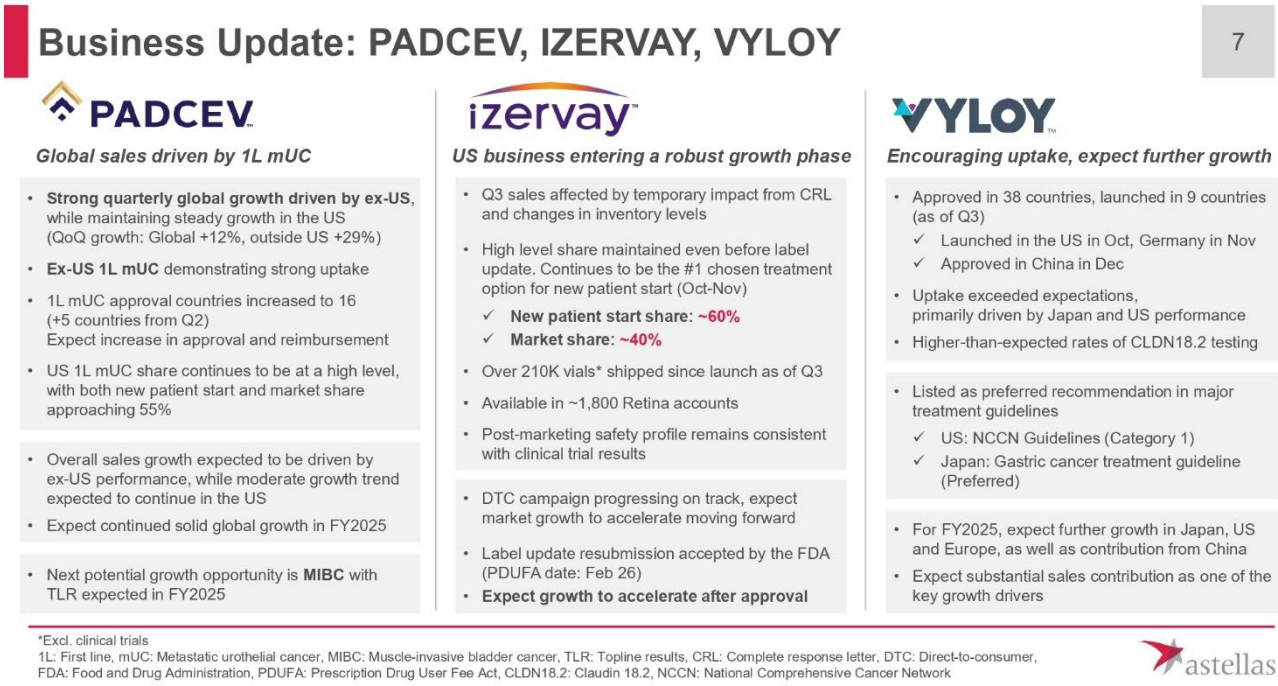
IZERVAY was launched in the United States less than 1.5 years ago, but its sales expanded to JPY44.4 billion.

Global sales of VEOZAH reached JPY24.4 billion, making a steady growth.

We are continuing to identify initiatives with a focus on ROI and working on them with priority. We're expecting a linear sales growth going forward as well.

As for VYLOY, since its launch in Japan in June last year, the number of launched countries has steadily increased and its global sales reached JPY4.9 billion.

Regarding XOSPATA, global sales increased to JPY53.1 billion, up by JPY11.8 billion or 29% YoY. Sales expanded in all launched regions. We're expecting continued moderate growth going forward as well.



On page seven, I will explain business update for PADCEV, IZERVAY, and VYLOY.

First, about PADCEV. Ex US regions, such as Japan and Europe, grew strongly in line with our full-year forecast that we revised upward when we announced our Q2 YTD results, driving strong quarterly global growth. First-line mUC indication is demonstrating an extremely strong uptake. We are hoping this will serve as a growth driver to increase our future sales.

Regional expansion of the first-line mUC indication is making steady progress. The number of countries with approval increased to 16 in total, up by 5 from Q2. We're expecting further increase in countries with approval and reimbursement initiation.

In the United States, first-line mUC share continues to be at a high level, with both new patient start and market share approaching 55%. On the other hand, market share expansion is slightly lower than our initial assumptions, so we revisited our full-year forecast. Based on the recent progress status, we reviewed market

share and growth rate assumptions and made a slightly downward adjustment. Having said so, volume is increasing steadily, and there is no change in our outlook for continued moderate growth trend going forward.

As we mentioned when we announced our Q2 YTD results, going forward, we're expecting overall sales growth to be driven by ex US performance and anticipating continued solid global growth as a whole. We have high expectations on PADCEV as an important growth driver also in FY2025.

Furthermore, the next potential growth opportunity is the additional indication of MIBC, muscle invasive bladder cancer. There is no change in our outlook to obtain top-line results within FY2025. After approval, we are hoping that it will boost sales growth for PADCEV.

Next, about IZEVAY. The Q3 sales were affected by temporary impact from unexpected CRL, complete response letter, for label update submission and changes in inventory levels. These became factors to temporarily slow down our sales growth. We have heard that for patients who have reached 12 months of treatment, many retina specialists are pausing treatment with IZERVAY, which affected our sales. However, for patients whose treatment was paused, we rarely heard of switching to a competitive drug. Once the label update is approved, we assume that retina specialists will quickly resume treatment of patients whose treatment was paused, so we believe the impact is going to be temporary.

Sales slowed down due to temporary factors, but in Q3, which was even before label update, high-level share was still maintained. IZERVAY continued to be the number one treatment option chosen for new patient start. New patient start share is estimated at 60% from October to November last year, with 40% market share. Over 210,000 vials have been shipped since launch and the number of vials is increasing steadily every quarter. Increase in the number of new retina accounts is also accelerating. The number of retina accounts where IZERVAY is available has increased from 1,300 as of the end of September to about 1,800. Nearly 1.5 years have passed already since launch, but post-marketing safety profile remains consistent with clinical trial results, which is highly valuated by physicians.

In addition, the DTC campaign is also progressing steadily. We have obtained analysis results showing high engagement by patients with GA, geographic atrophy. I'm not going into details today as this is still early data. Once we have more mature results, we will share that with you. We have high expectations that the DTC campaign will motivate new patients to seek treatment earlier and further expand the GA market going forward.

We received unexpected CRL, complete response letter, but then we proceeded with resubmission process rapidly. Our label updates resubmission was accepted by the FDA in January and PDUFA date was set for the 26 of February.

As I mentioned earlier, treatment was paused for many patients who reached 12 months of treatment. Many, including patients and retinal specialists, are long awaiting label update. We are hoping that after approval, retinal specialists will resume treating patients whose treatment was paused.

Combined with the market expansion, thanks to the DTC campaign, we're expecting more accelerated growth trajectory after label update approval, so we have not changed our full-year forecast in local currency basis. We will be entering a robust growth phase from now and are expecting strong sales growth in FY2025.

Last but not the least, about VYLOY. Starting with the launch in Japan in June last year, regional expansion is making extremely good progress. The number of approved countries has increased to 38, and VLOY is launched in 9 countries. Main progress includes launch in the United States in October and in Germany in November last year and approval in China in December.

Uptake exceeded expectations in all launched regions, primarily driven by Japan and US. performance. Higher-than-expected rate of Claudin 18.2 testing was the main factor behind.

Despite the recent launch, VYLOY is already listed as preferred recommendation in many treatment guidelines. For example, many doctors in the United States refer to NCCN guidelines when they determine prescriptions. There, VYLOY is listed as Category 1, which is the highest level of recommendation.

Also in Japan's gastric cancer treatment guideline, VYLOY is recommended as preferred treatment. Overall, VYLOY is performing well, so we reflected the higher-than-expected progress in each region, driven by Japan and the United States and nearly doubled our full-year forecast. In FY2025, we're expecting further growth in Japan, the United States, and Europe, as well as sales contribution from China with a big market. We are expecting substantial sales growth of VYLOY as one of the key growth drivers.

Q3 YTD/FY2024 Financial Results: SG&A and R&D Expenses

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- *Robust progress of SMT initiatives toward the FY2024 target of 40.0 bil. yen in cost optimization*
- ***SG&A ratio improved to 29.7% (-4.0ppt YoY)***

Core basis: YoY comparison and ratio to revenue

(billion yen)

Cost Items	YoY change	Ratio to Revenue	
SG&A expenses **excl. US XTANDI co-pro fee**	+7.7% (+2.8% excl. FX impact)	SG&A ratio: 29.7%	✓ Global organizational restructuring (approx. -12.0 YoY) ✓ Reduction of mature products-related expenses (approx. -8.0 YoY) ✓ Enhance company-wide efficiency with AI and digital (approx. -4.0 YoY) Allocate generated resources to Strategic Brands investment
R&D expenses	+16.2% (+11.6% excl. FX impact)	R&D ratio: 17.3%	✓ PF, Strategic Brands LCM and enhanced R&D functions (approx. +16.0 YoY) ✓ One-time co-development cost payments in Q1 ✓ Steady progress in outsourcing reduction through strengthening in-house capabilities

SMT (Sustainable Margin Transformation): See slide 28 for overview
PF: Primary Focus, LCM: Lifecycle management

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On page eight, I will explain SG&A and R&D expenses.

SG&A expenses increased 7.7% YoY when US XTANDI co-pro fee is excluded and 2.8% when the foreign exchange impact is excluded. The SG&A ratio was 29.7%, a 4-percentage point improvement YoY. As for the result of progress in cost optimization through SMT, SG&A expenses decreased about JPY12 billion YoY through the progress of global organization restructuring.

Sales promotion expenses related to mature products decreased about JPY8 billion YoY.

In addition, company-wide efficiency is achieved through the use of digital and AI and it leads to JPY4 billion reduction YoY. The generated resources are reinvested to maximize the potential of Strategic Brands.

R&D expenses increased 16.2% YoY, or 11.7% excluding the impact of Forex rates. The major reasons of this increase are the investments for primary focus, life cycle management of Strategic Brands, and enhanced R&D functions and about JPY16 billion is increased YoY. Onetime co-development cost payments booked in Q1 also contributed to the increase.

One of the initiatives at SMT is to reduce outsourcing costs by strengthening in-house capabilities, and it is making steady progress. Each initiative in company-wide SMT is making robust progress toward the FY2024 target of JPY40 billion in cost optimization, and we will continue to control costs with discipline.

FY2024 Revised Forecast

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- ***Core basis***: *Upward revision based on robust progress of revenue and SMT*
- ***Full basis***: *Downward revision of profit mainly due to impairment losses on IZERVAY (Ex-US) and AT466*
- *No change in dividend forecast of 74 yen*

Exchange rates for Latest forecast: 153 yen/USD, 164 yen/EUR
(Forecast rates Q4: 155 yen/USD, 163 yen/EUR)

(billion yen)	FY2023 Actual	FY2024 Previous FCST	FY2024 Latest FCST	FY2024 Change	Main items of revision
Revenue	**1,603.7**	**1,800.0**	**1,900.0**	**+100.0**	• XTANDI: approx. +30.0 • FX impact: approx. +45.0
SG&A expenses	740.1	823.0	845.0	+22.0	
US XTANDI co-pro fee	194.9	229.0	255.0	+26.0	• Incorporate robust progress of SMT
SG&A excl. the above	545.2	594.0	590.0	-4.0	
(SG&A ratio*)	34.0%	33.0%	31.1%	-1.9ppt	
R&D expenses	294.2	341.0	340.0	-1.0	• No significant change
(R&D ratio)	18.3%	18.9%	17.9%	-1.0ppt	
Core operating profit**	**276.9**	**300.0**	**370.0**	**+70.0**	• FX impact: approx. +10.0
(Core OP margin)	17.3%	16.7%	19.5%	+2.8ppt	
＜Full basis＞					
Operating profit	**25.5**	**80.0**	**11.0**	**-69.0**	• Impairment loss: approx. -180.0 (Ex-US IZERVAY: -120.0, AT466: -50.0, iota: -10.0) • Release of impairment loss risk and other expenses incorporated in initial FCST

FY2024 Previous FCST announced in Oct 2024. FX rates for Previous FCST: 149 yen/USD, 160 yen/EUR
SMT (Sustainable Margin Transformation): See slide 28 for overview
*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 nine, I will explain the revised forecast for FY2024.

In addition to XTANDI and Strategic Brands, we have also reviewed other products and cost items to ensure that we have the most probable forecast at this time.

First, we have revised our full-year forecast for foreign exchange rates to JPY153 to the US dollar and JPY164 to the euro. For Q4, we assume exchange rates of JPY155 to the US dollar and JPY163 to the euro.

The revenue is estimated to be JPY1,900 billion, an upward revision of JPY100 billion from the previous forecast. This mainly reflects an increase of about JPY30 billion in XTANDI and JPY45 billion of the impact of foreign exchange.

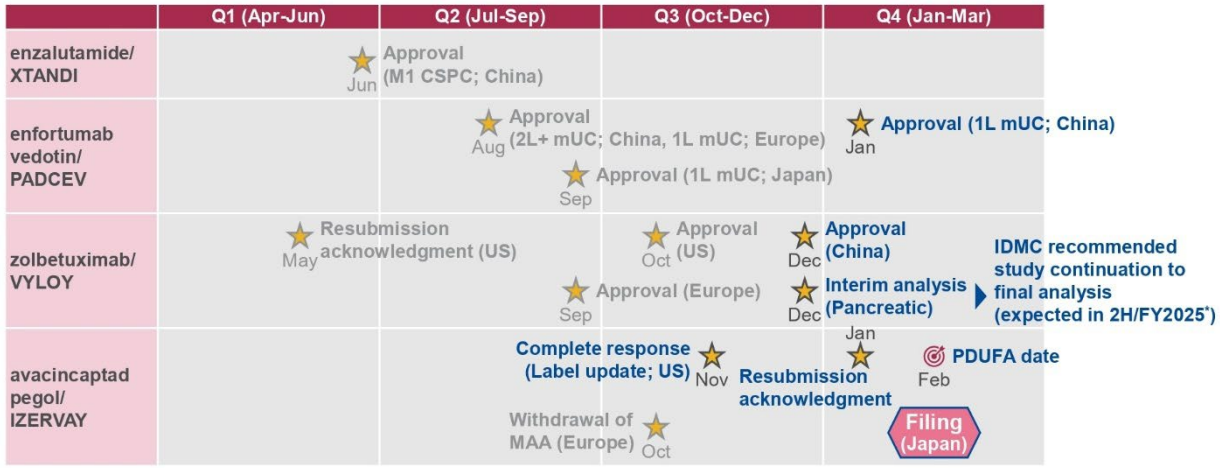
SG&A expenses, excluding the US XTANDI co-promotion fee are expected to be JPY590 billion, incorporating the robust progress of SMT. As a result, the SG&A ratio is expected to decrease 1.9 percentage points from the previous forecast.

R&D expenses are expected to be JPY340 billion, which is not significant change from the previous forecast as R&D expenses are being used as planned.

As a result, we revised the core operating profit upward to JPY370 billion. Our full base of OP incorporates the impairment loss of about JPY180 billion recorded in Q3 as other expenses. On the other hand, we have released impairment loss risk and other expenses of JPY60 billion, which had been incorporated in the initial forecast and we now expect a final figure of JPY11 billion.

XTANDI and Strategic Brands: FY2024 Key Expected Events

(Blue: Updates since the last financial results announcement)



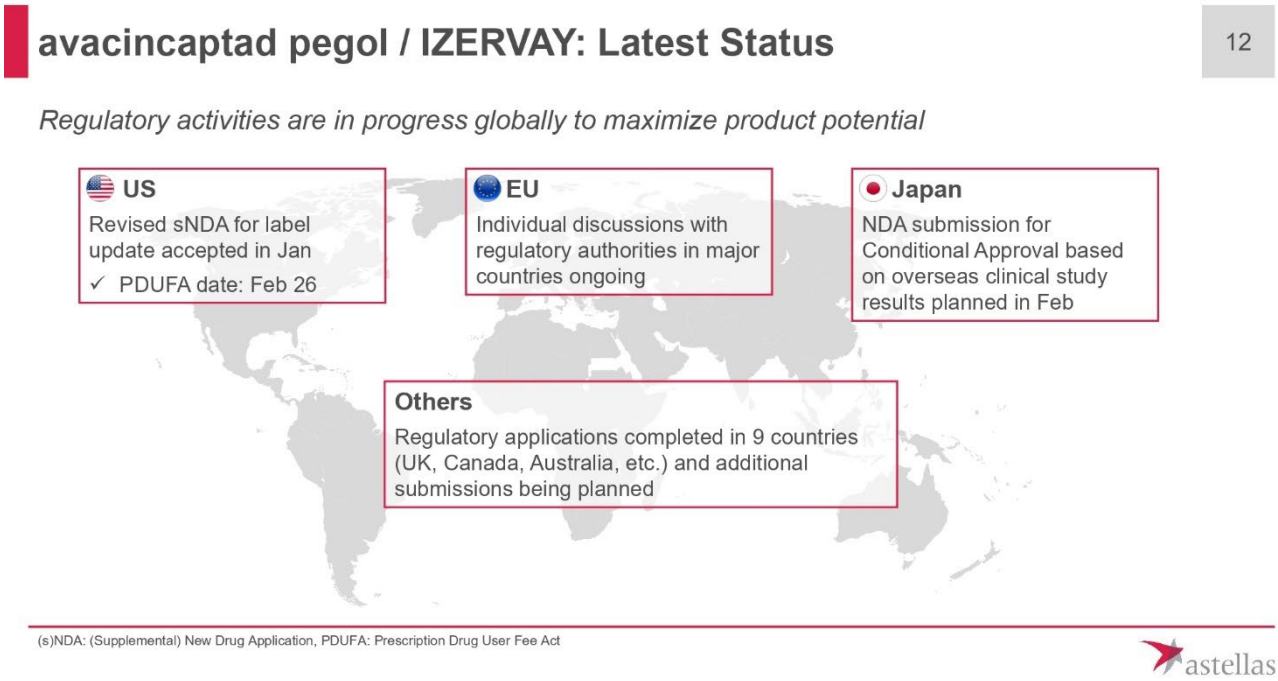
As of Feb 2025. *The timeline is subject to shift due to its event-driven nature.
M1: Metastatic, CSPC: Castration-sensitive prostate cancer, 2L+: Second or later line, mUC: Metastatic urothelial cancer, 1L: First line, IDMC: Independent Data Monitoring Committee, MAA: Marketing Authorization Application, PDUFA: Prescription Drug User Fee Act

Now I'm going to explain the initiatives for sustainable growth. On page 11, we provide an overview of the progress of key events expected in FY2024 for XTANDI and Strategic Brands.

Progress since the last financial announcement is indicated in blue. PADCEV was approved in China in January for the additional indication of first-line treatment of mUC based on the EV-302 study.

VYLOY was approved in China in December for the treatment of patients with locally advanced or metastatic gastric and GEJ adenocarcinoma last December. In the Phase II trial for pancreatic adenocarcinoma, a protocol interim analysis was conducted by an independent data monitoring committee. As a result, it was recommended to continue the study until the final analysis and to conduct a more comprehensive evaluation by increasing the number of events to be analyzed. The final analysis results are currently expected to be available in late FY2025.

IZERVAY will be explained on the next slide.



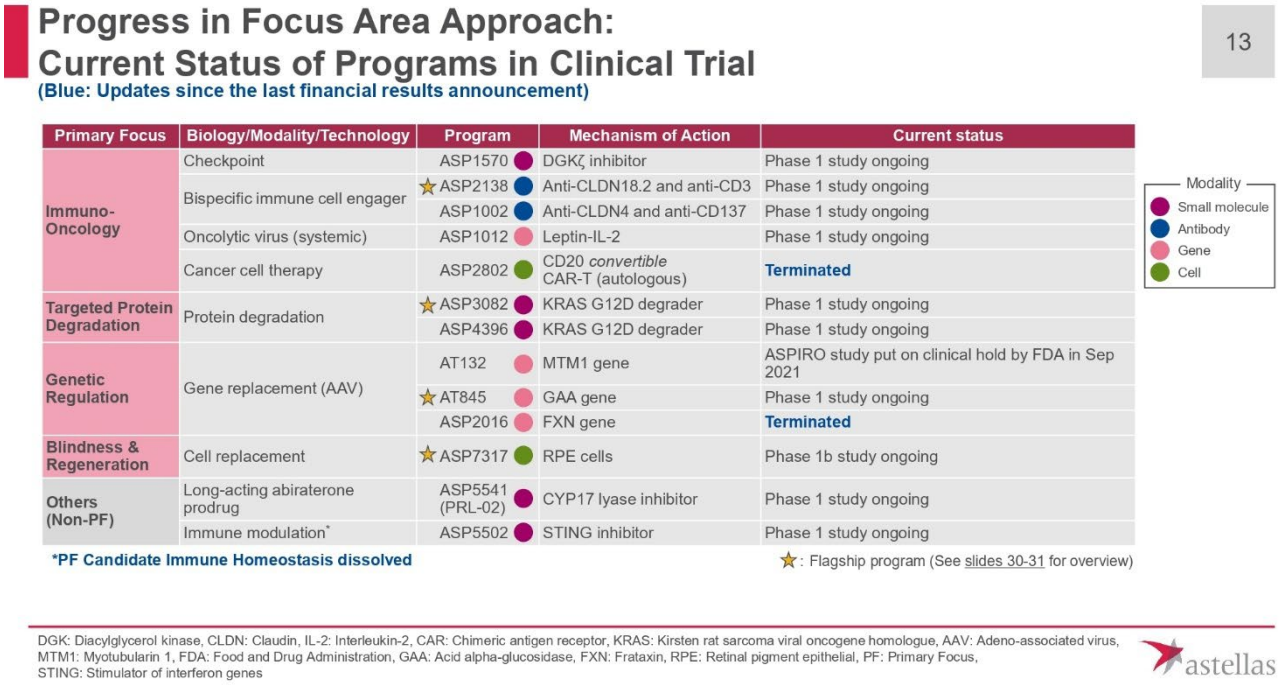
Slide 12 provides the latest status of the IZEVAY global regulatory activities.

In the United States, as explained earlier on page seven, the revised sNDA for label update was accepted and a PDUFA date is set as February 26.

In the EU, we have just started discussions with the regulatory authorities in major countries. We will consider the way of submission in the EU after the discussions with regulatory authorities are completed. At this point, we will refrain from providing individual updates on the status of discussions, but we will provide a further explanation once we decide the strategy.

In Japan, we plan to make an NDA submission for conditional approval in February based on the results of the GATHER study and other overseas clinical trials.

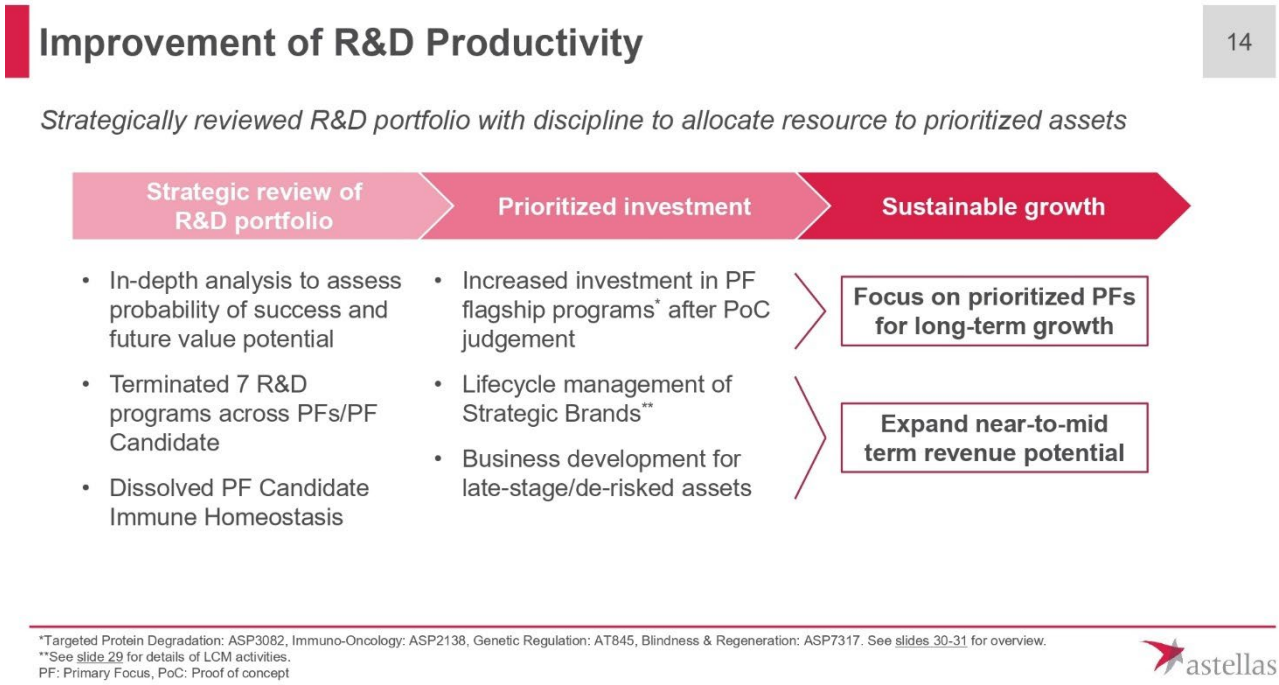
We are also working on the regulatory applications in other regions to bring IZERVAY to the world. To date, we have completed regulatory applications in nine countries, including the UK, Canada, and Australia, and additional submissions are planned. We will update this appropriately when there is progress.



On page 13, I will explain the progress of the Focus Area Approach. The updates of programs in the clinical trial phase since the last financial results announcement are indicated blue.

We have decided to terminate ASP2802 in immuno-oncology and ASP2016 in genetic regulation. As noted at the bottom of this slide, we have also decided to dissolve the primary focus candidate, immune homeostasis. The background to this is explained on the next slide.

The four flagship programs for each primary focus marked with a star are progressing according to plan, toward a PoC judgment by the end of FY2025. We will provide an update when there is a significant progress.



On page 14, I will explain our approach to the improvement of R&D productivity.

In order to achieve sustainable growth for Astellas, it is necessary to strategically review the priorities of R&D and improve productivity. In Q3, we have conducted in-depth analysis to assess probability of success and future value potential individually across the entire R&D portfolio.

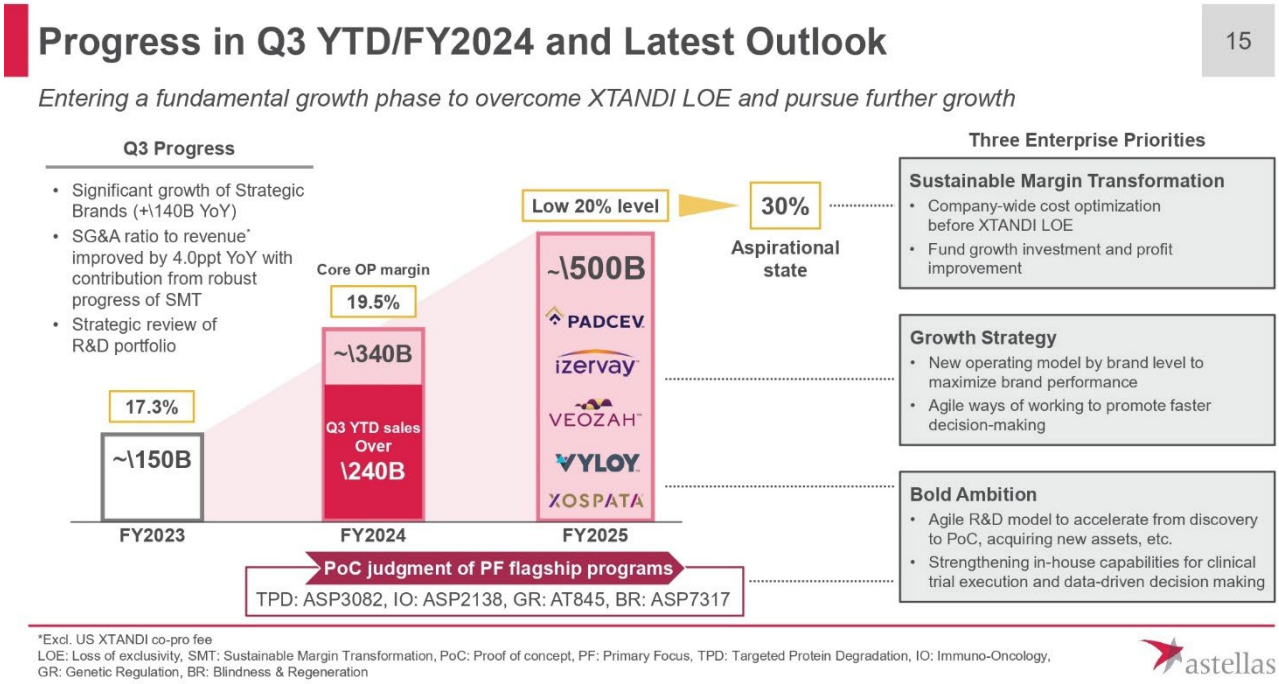
As a result, we have decided to strategically terminate a total of seven programs, including ASP2802 and ASP2016, which I mentioned on the previous slide, as well as those in the preclinical stage. We have also decided to dissolve the primary focus candidate, immune homeostasis.

From now on, we will further increase the allocation of resources to the high-priority assets shown in the center of the slide. First, we will increase investment in the late-stage development of the primary focus flagship programs after the PoC judgment.

In addition, we will focus more on the development for education expansion as part of our life cycle management in order to accelerate the growth of our Strategic Brands.

In business development, we will look for opportunities to acquire de-risked assets in the later stages. Up until now, we have been forming many partnerships in the early stages of technology and assets that lead to the strengthening of our existing primary focus. But as we move into the convergence phase, we'll be evaluating our late-stage deals more strictly.

Through these priority investments, we aim to expand our earnings potential in the short to midterm while also aiming for the assets created from our primary focus to contribute to the long-term growth.



Slide 15, this slide summarizes the progress and the latest outlook for Q3 FY2024.

In Q3, our Strategic Brands continued to show strong growth and the SG&A ratio has been improving since the start of FY2024. As shown in the figure, total sales of Strategic Brands expanded to over JPY240 billion as of Q3. And we will believe that achieving the target of JPY340 billion for FY2024 is well within reach. We are steadily progressing towards our target of JPY500 billion in FY2025.

We also expect the core OP margin to improve to 19.5% in FY2024, and we are becoming more confident that it will grow to low 20% level by FY2025.

We believe that the reason for the strong progress is that the three enterprise priorities listed on the right side of the slide have continued to be successful, and we have entered a full-fledged growth phase. We'll continue to promote these initiatives and aim for further growth beyond XTANDI loss of exclusivity.

Sustainability Meeting 2024

- Feb 21st 2025, 10:00-11:30 (JST)

Page 16 shows the schedule of upcoming events. The Annual Sustainability Meeting is scheduled to be held on February 21 this year. I hope you will be able to attend.

This concludes my presentation. Thank you very much for your attention.

Question & Answer

Ikeda [M]: That's all as regards the presentation. We now would like to entertain questions from the audience. Anyone with a question? Thank you for waiting.

First, Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi [Q]: Yamaguchi from Citigroup. Thank you very much. It's an individual question. I have two questions about IZERVAY. PDUFA date is newly set. And according to the presentation, patients are waiting for the treatment and it's going to be addressed sufficiently. The details have not been disclosed, but is it going to be every other month or one-year or two-year administration? What is prioritized? The details of the PDUFA and also the relationship with marketing assumptions, I'd like to hear your comments.

Kitamura [A]: Thank you very much, Yamaguchi-san. Regarding the specifics, we'd like to refrain from commenting right now. As you pointed out, as soon as possible, we would like to realize the label update as soon as possible, so it's up to 26 February right now, but our resubmission is accepted and if the label update is going to be approved, we'd like to take action.

Yamaguchi [Q]: Understood. A similar question to you. When patients who received a one-year treatment is paused, they are waiting without switching to another drug as you presented. You have heard such cases, so you're hoping to pass the PDUFA date and there's going to be a lot of resumption of treatment for those patients. Right?

Kitamura [A]: Yes, you're right. Regarding IZERVAY, it's very important. If Claus has any additional comments, please.

Zieler [A]*: Your summary is absolutely correct. What we are hearing in the market is that doctors are not switching patients. They're essentially delaying patients. And exactly as you said, we are expecting that once the label update comes, that all these patients will be then called back into the clinics for their next injection. That would suggest that once the label update is granted, that we would expect a bolus of patients for injections that have been waiting so far.

Yamaguchi [Q]: Thank you very much. And zolbetuximab, sorry to switch the topic. But regarding zolbetuximab, the pancreatic adenocarcinoma, I'd like to hear about the analysis.

Kitamura [A]: The Independent Data Monitoring Committee recommended the continuation of the study. According to the interim results, efficacy and safety issues did not occur. There can be discontinuation due to effectiveness or futility. VYLOY, zolbetuximab, you're talking about the pancreatic adenocarcinoma. Originally, top-line results analyzed for interim analysis, but the clinical trial itself is planned until the final stage, and we are going to do it as planned.

Any additional comments from a medical perspective? Taniguchi-san, please?

Taniguchi [A]: Thank you for the question. Yes, you are right. We have the interim analysis we were planning. And Independent Data Monitoring Committee check the details of the results. In terms of safety and efficacy, they look at both until the final analysis. They recommended that we proceed until the final analysis.

Final analysis, as was mentioned during the presentation, is expected in H2 2025, next fiscal year. But depending on the onset of events, it may shift a bit. But for the time being, it's going to be H2 FY2025 for the time being.

Yamaguchi [Q]: One additional question. That's about IZERVAY. I believe you mentioned about the inventory. Does that impact negatively or positively?

Kitamura [A]: Negative or—well, basically, as a part of post-merger integration, distribution integration is also taking place and the inventory level is, therefore, reduced tentatively. Tentatively, it has a negative impact. However, we are quite sure that it's going to be built up. In Q4 and afterwards, we would like to show the growth afterwards.

Yamaguchi [Q]: Is it okay to consider this a Q3 event?

Kitamura [A]: Yes.

Yamaguchi [Q]: That's all from me. Thank you.

Ikeda [M]: Thank you very much. Next question is JPMorgan Securities, Mr. Wakao, please.

Wakao [Q]: Thank you. JPMorgan, Wakao. First question is about IZERVAY. Yamaguchi-san asked almost all the questions that I wanted to know, but I still have a couple of questions here. Why no switch to SYFOVRE? Why the patients are pausing the treatment? How do you analyze that situation? I'm asking this question because Apellis, well, based upon this situation, they are fully prepared to accept the IZERVAY patients when they want to switch, but there are no such patients so far? In that case, the safety of IZERVAY might be far better. That's what I assume, so I want to clarify about that.

And also the resubmission details are not disclosed, but this EOM dosing administration, even if that is not achieved, considering the current market share, the growth of this product in the market, even the indication is just once per month, still, the market is quite viable for the IZERVAY.

Kitamura [M]: Thank you, Wakao-san. Claus, could you make a comment about this?

Zieler [A]*: Thank you, Wakao-san. Let me take your questions one at a time. The first question you asked was about why are doctors not switching. And if we do go into claims data, so real processing of claims from the insurances, we see that about 60% of the new patients receive IZERVAY. That gives us the feeling that there is a very strong belief in the marketplace that is starting to consolidate in favor of IZERVAY. That is probably due to the safety profile that we have established since launch with now 210,000 vials shipped and safety signals, which are very much in line with the labeled indication and the studies that we saw. That is a very impressive record for doctors, and they take that into account when they make a product choice.

We hear that very consistently from doctors that they have a 60/40 favorability towards IZERVAY, and it's usually due because of the safety profile that doctors attribute to IZERVAY. I think that also explains why doctors are saying, "Before I take the risk of switching, let me wait, 26 February is not that far, and then I can start my patients up again."

A lot of what I'm telling you here is anecdotal. We've not conducted formal market research, but that is the picture we are getting from how the market is behaving.

Let me go to your second question. I think your second question was about is it the 12-month extension in the label? Or is it the every-other-month part of the label that we are focusing on? We're very clearly focusing on the 12-month extension. That's what doctors are waiting for. That's what insurance is waiting for. Doctors are saying, "I have started a patient, I want to continue the patient, but please give me the label, so I'm within the label to do so." That's the main question that they are asking. The question on every other month is something I would like to describe it this way. In every indication, you have a label, but you also have clinical practice. And I don't want to be perceived of speaking outside of label, but what we observe in real life in the

marketplace, both for our competitor product as well as for IZERVAY, is that doctors tend to take more a six-week interval for the injections, so they're not strictly following labels. That is clinical practice that we are observing.

We don't know the reasons for that. We don't know why doctors are doing that, but that's what we are observing. That is also why we have prioritized the 12-month extension in our label update versus the every-other-month data, which, of course, is useful for doctors, but doesn't happen to coincide with clinical practice anyway.

Wakao [Q]: Clear. Understood. Thank you very much indeed. I have a second question. Your outlook for next fiscal year, I'd like to know more. On page 15, achieving JPY500 billion and core OP margin of a 20% level, to achieve this, you are building confidence. Then you are making an upward revision, OP, JPY370 billion. An increase in revenue and profit may be in your sight to a certain degree. Am I too optimistic? Or any other negative factors, if any? Anything we should monitor more carefully?

Regarding XTANDI, Q4 assumption figures based on that, the products you have to grow, compared to their growth, Medicare Part D impact on a full-year basis is going to be smaller. On a net basis, next fiscal year, you can generate a certain amount of revenues and OP margin can be improved. Then I'm not sure about the revenue increase, but you can achieve a profit increase. What do you think? I'd like to hear your current philosophy or view.

Kitamura [A]: Thank you for your question. Next fiscal year's outlook, for the details, when we announce our full-year results, including our Q4 results, we will give you our outlook.

Regarding our current plan, we are now entering a growth phase, so this is for both revenue and profits. As you mentioned, we have Strategic Brands, how far they would grow, including VYLOY, we have global launches we have been able to realize, so in that sense, continuing the growth is very important for us. Just revenue increase and improvement of the profit, of course, we will achieve profit increase. We'd like to work on this.

As for XTANDI, Medicare Part D impact is expected in Q4. On the other hand, right now, a strong growth has been seen. The base situation is going up for XTANDI, so we are taking this positively.

Any downside, we are going to look into details from now, but the current growth phase is not anything temporary. For us, this is something we can continue. It's sustainable for us. That's our stance right now. That's something I'd like to communicate to you.

For details, in three months' time, we'd like to explain to you. Thank you for your question.

Wakao [M]: Thank you very much. That's all from me.

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

Muraoka [Q]: Muraoka from Morgan Stanley speaking. Thank you very much. Regarding Wakao-san's question about your stance on the business results, OP margin would be expanded. That's your goal, close to 25%. I thought you would increase your profit by 20% or so. That's my personal view.

I have a question about dividend. JPY74 YoY, JPY4 increase is maintained. On page 24, there is a chart on dividend. Up to JPY80, it can increase next fiscal year, just to that level. I think there's going to be a dividend increase. But the pace of dividend increase, it was increased from JPY70 to JPY74. Should I consider the extension of this growth? Or are you saying you're growing, so there is room for further growth or increase in dividend level?

Kitamura [A]: Thank you very much, Muraoka-san. Thank you for a difficult question for us to respond. We wonder how to respond. We reviewed the pace of dividend increase/ For our growth story, we are confident that we can fulfill our goals. That's why we decided to increase our dividend to JPY74 by increasing JPY4.

No. Continuity for a certain period of time was considered, and this is our conclusion we came up with in the end. We had profits. Because we couldn't increase, a dividend decrease is not considered. We'd like to ensure a stable dividend for a certain period of time to return to shareholders. As such means, we are paying out dividends, so it's not going to change our stance overnight.

More specifically, next fiscal year, we are going to brush up our plan for the next fiscal year. We need to think about the financial needs for various perspectives. And in line with that, we would like to discuss and we share the information when it is available.

I hope this answers your question.

Muraoka [Q]: Understand. Three months after, we will wait. I will wait for the coming three months. Next question is about IZERVAY. In Europe, you are discussing with the authorities. But what I feel, based upon your presentation explanation, is that the current priority is lifting of this 12-month restriction. Every two-month indication in Europe or something more, I feel that you need to conduct additional study. I just wonder if you should do to that extent. Up until 2030 or up until 2034, you have the patent of this material and also usage. But how do you calculate overall this situation?

Kitamura [A]: Thank you for the question. First of all, the label update, I cannot tell you the very details here. But what we view or what we think, based upon the opinions of the specialists, the priority is just like that. I cannot tell you the details about that.

For GA unmet medical needs, this is for sure. We would like to expand the market. And at the same time, we would like to provide this product to the global level. That is extremely important. That's why we are doing the activities currently. And we have the US data and that can be made use of for the expansion. And when it comes to EU, in the major countries, we are having the discussions with the authorities. And with doing that, we can increase our probability. That is currently what we are working on.

More specifically, what we can share with you is quite difficult, but Taniguchi might have additional comment here.

Taniguchi [A]: I believe there are two questions in your question. First of all, especially about the US market, this 12-month restriction and every two months, administration. Claus already mentioned about this or explained about this. First of all, there are patients who are waiting for the additional treatment. This lifting of the dose restrictions of 12 months, that is definitely the priority. And to that, we are going to make use of GATHER2 data that is available. Actually, we're using that, we are already discussing with the authority.

When it comes to European countries, as has been explained, currently, at each country, we have been working on the discussions. And after that discussion, our next strategy is going to be considered. Once it becomes clear, then we believe we can share that with you.

Muraoka [Q]: Understood. Thank you for your explanation. A little while ago, I mentioned about the 2030/2034 patent situations, but this is a different angle question about IZERVAY. As long as I know, generic development hasn't been in the clinical development phase yet. But if the patent is 2030, then some companies are expected to start the development of the generics, but it is not ready, so the generic launch opportunity or the possibility in 2030 is extremely low. Rather, you think probably if there will be the generic launch, it will be around 2034 or so?

Kitamura [A]: Well, that's again difficult area that we make a comment. But basically, it's not only IZERVAY. Our approach is that, of course, we do whatever we can do for the preparation of the worst case. For the risks, we try to do what we can do beforehand. That's part of day-to-day activities. We shouldn't be too optimistic and we still need to do the preparation, especially about what we can do. I'm not going to tell you any specific information here about that.

Muraoka [M]: Understood. Thank you very much. That's all from me.

Ikeda [M]: Thank you very much. Next question, Goldman Sachs Securities, Mr. Ueda, please.

Ueda [Q]: I'm Ueda from Goldman Sachs Securities. First, PADCEV plan was reviewed. Forecast was revised downward. In the Q2 results announcement, there was a revision of the plan. The revision seems to be larger. What changed in the assumptions? According to Mr. Kitamura, there seems to be no particular problem. But this is one of the future drivers, so I'd like to know the background.

Kitamura [A]: Mr. Ueda, thank you very much. Regarding PADCEV, first-line uptake was fast in the United States. in the Q1 compared to our initial plan, there was a speedy increase. That's part of the fact. And first-line share was like 52% or 55%. It was at a high level. There were expectations for higher figures initially. But now it's between 52% to 55%, which is maintained and sustained. Based on this, our forecast was reviewed. We maintain this going forward.

And outside of the United States, we have the first-line indication. We'd like to increase this quickly similar to the US. That is going to be the driver for PADCEV. Claus, anything to add?

Zieler [A]*: Yes. Hindsight is 2020, as they say. Right? When you look back, you always know a little bit more than when you look forward. The pattern that we see is very similar to what we saw in the second line. Remember, PADCEV has had an extremely steep uptake from the very beginning. That was true in second-line launch. It was also true in first-line launch. And then it came very quickly to—after about six months, it comes to a plateau. That plateau is not flat, but it's just slower growth. We reached that plateau in the United States with first line in June. And we predicted a mid-single-digit growth from then on. And that is still true.

When we now look back and we compare with the second-line pattern, we also see that there's a little bit of a lull for about three months. We can't explain it, but it's as if the market takes a deep breath and then starts growing again. And that's what we think is happening now with the first line in Q3. We are very confident on the growth. Even though it's mid-single digits, we're confident on the growth of PADCEV going forward in the United States. Of course, ex-US is now in the steep uptake and will grow the brand very steeply from now on. But it's just that lull in Q3 was too much for us to say we can catch up in Q4. And then we said, well, let's be transparent and just revise the numbers down for FY2024, even though we think that the growth trajectory into FY2025 is intact.

Ueda [Q]: Thank you very much. I have my second question. AT466 impairment loss-related question. Right now, in the field of gene therapies, I'd like to hear your company's view. In this field, you have Audentes-related products such as AT132 and AT466 and AVB-101 is in-license, so you're still focusing on this area. But how do you evaluate the progress in this field? And Audentes-related products have any issues? What have you reviewed? And what is going to be the direction you'd like to head into, into the future?

Kitamura [A]: Thank you very much for your question. Our stance on gene therapy was your question. In principle, there is no change. Gene therapy is one of the important Primary Focus areas for us. There is no change in that. And AT845 is a lead program, and we are going to judge PoC by the end of FY2025. That's a major milestone for us.

AT466, initially, when we acquired Audentes, the assumptions have changed in some cases. There were some substances where we should do different things, so based on this, we changed the plans. As a result, timeline was a bit delayed, and we reviewed the plans. For gene therapy, it's still one of the important Primary Focus areas, and we have to identify AT466. Taniguchi-san, anything to add?

Taniguchi [A]: Thank you. Just like Kitamura explained, for gene therapy, that's the center of the Primary Focus. Strategic-wise, this AT466 impairment, those is not having the impact. AviadoBio or Taysha and such other companies' collaboration, our partnerships are ongoing. And for AT845, PoC judgment timing is almost there. In reality, when it comes to gene therapy, especially AAV platform is what we have great confidence. How we can make use of this AAV platform for the generation of the new programs for the future, including the partnership with other companies, we consider that strategic good direction and what we take is quite important. There is no change about this. We are going to pursue what we've decided as the strategies that we take. That's all.

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

Ikeda [M]: Thank you. Next question, Nomura Securities, Mr. Matsubara, please.

Matsubara [Q]: Matsubara speaking. Thank you. First question is about VEOZAH, this insurance coverage rate. elinzanetant will be available from Bayer. In that situation, what kind of promotional activities would you do? What will be the growth strategy?

Kitamura [A]: First of all, about VEOZAH, as has been mentioned a little while ago, the growth is quite steady, and it's all according to the plan. And what about the competitive situation? We haven't seen the level yet, so until then, we cannot say anything. But things are just what we expected in the very beginning. With this product, competitors' product, we can make market together or it's going to be head-to-head competition. But for us, before the launch, we consider it is important to establish the market for this area.

For the VEOZAH, do you have any additional comments, Claus?

Zieler [A]*: Not really much to add, Kitamura-san. I mean the product is growing on track. The label from the Bayer competitor is not known yet, so we can't really speculate. We are fully prepared in terms of sales force deployment, direct-to-consumer deployment.

Across the market, we're fully prepared for Bayer entry into the market. We have a very selective molecule that targets one receptor. We'll have to wait and see what the FDA grants for the Bayer competitor.

Matsubara [Q]: Next question is about mirabegron. The US sales in Q3 is greatly increasing these days. What's the background of this?

Kitamura [A]: In the beginning of this fiscal year, generic entry was confirmed and towards that, based on the forecast, we came up with the conservative forecast and expect it to be a negative impact. And for that, we are adjusting the cost or expenses.

On the other hand, we want to, of course, defend our assets as we've been conducting the current activities. Currently, we see two generic companies' entry and the price erosion is not that extreme. That's the current situation, and that is adjusted in December to a certain extent. That's why the number in December is a bit high.

But as for what's happening currently, well, is that worst cases expected, we did our activities and our defense is a good level and the erosion is not taking place now.

Matsubara [Q]: What about the future then?

Kitamura [A]: Well, of course, we would like to always prepare for the countermeasures to deal with this situation. It's going to be about the next fiscal year and afterwards, so please wait for a moment.

Matsubara [Q]: Then, in that case, to consider about the next fiscal year and afterwards, because you have the countermeasures, so there would not be a great reduction of the revenue. Is that okay to understand in that way?

Kitamura [A]: Well, that's something we can talk three months later. But as has been mentioned, for the risks, we are not going to deal with that in an optimistic manner. We look at the downside, we come up with a plan. And we will defense what we can defense. That process is always the same. As a result, what will happen to the figure on the next fiscal year, that's coming later on. But our position and the stance will not be changed. Please do understand in that way.

Matsubara [M]: Understood. Thank you.

Ikeda [M]: Thank you very much. Next, Mitsubishi UFJ Trust Bank, Mr. Hyogo, please.

Hyogo [Q]: Hyogo from Mitsubishi UFJ Trust Bank. Thank you for naming me. Thank you for the presentation as well. According to the press release, there was announcement about the change of the management structure. From the initial stage of R&D, to launch across the board, you'd promote this efficiently and rapidly. According to this, what would be the bottlenecks? What's the reason for the change? Because of the silo or because of bottlenecks, you'd like to make these changes. That's why you are expressing such an intention. What's in the background? There have been impairment losses one after another. And is that related to this? I'd like to know.

And also, legal and compliance is going to be newly launched, established. By separating the functions, what could be achieved? I'd like you to explain. The details may be explained in May, but together with the results announcement, there was a press release. I'd like you to explain.

Kitamura [A]: Mr. Hyogo, thank you very much. We issued a press release, the management structure as of 1 April. The objective, as you said, is as follows: for Astellas Pharma, patient VALUE would be created. That's our primary, most important goal. We generate and create value for the patients and deliver it to the patients. What is the most important thing necessary for that? From R&D up to the launch, we'd like to enhance the speed to do this across the board. Any bottlenecks, we have not been able to launch, setting that aside, we have to increase the speed. That's for sure. Across the board, we are going to handle this. That's one thing.

At the same time, deliver VALUE is important. Commercial and Medical would be able to promote co-work further into the future. Commercial and Medical officer is going to be close to supervise both functions. This fiscal year, we think we explained this before, but the field are focusing on the brand teams. They should be able to work in an organic fashion without the borders of the functions. At a fast speed, they should do business. This was worked on in the United States and very good results were achieved. That's one of the reasons why the growth is fast in the United States. Brand-delegated system would be built to remove the layers in the middle. We'd like to have a rollout globally. That's part of the Growth Strategy led by Claus. Together, we are going to combine these.

So any major bottleneck? No. But rather, we'd like to accelerate growth further. That's the nature of the initiative we are working on.

Legal and compliance would be integrated? Regarding that, for details, how far I can talk about it today, there was an announcement today. Tatjana, in charge of legal and compliance, she's a lawyer. And Ethics and Compliance head is her current role. She's going to wear two hats. That's the main objective behind.

It's not about impairment loss. Her expertise is taken into account and her role is going to be expanded. Impairment loss is related to this? No, not at all. But in order for us to further accelerate our sustainable growth, this is a measure necessary for that purpose.

Thank you very much for your question.

Hyogo [Q]: Thank you very much. I was able to understand clearly. If you are going to evolve how you're going to change, including that, I'd like you to explain in the future. That would be highly appreciated. Thank you very much.

And also, at a certain time point into the future, impairment loss management, how you are evolving in this respect? There can be impairment losses for sure, but I'd like you to explain.

Kitamura [A]: Regarding impairment loss, I'd like to add. Regarding in-process R&D, AT466 impairment losses were booked. The programs and projects, when they make progress, the priorities may be lowered or something may not work, and we have to select and discontinue some. In-process R&D was impaired a lot so the balance which remains is not so large compared to what existed up until now.

On the other hand, we did have a large size of impairment losses, so we would like to increase the accuracy, and we will work on this. Thank you very much.

Hyogo [Q]: I raised some difficult points, so sorry about that, but thank you very much for your response.

Ikeda [M]: Thank you. Let's move on. Sanford C. Bernstein, Ms. Sogi, please.

Sogi [Q]: Thank you very much. First of all, question to Kitamura-san. Q3, this time the guidance is revised so you have remaining just one quarter. This revision, I understand its precision is quite high. Accuracy is quite high. The revenue is plus JPY100 billion and FX impact is JPY45 billion and XTANDI US maybe JPY30 billion is coming, and there is a gap of JPY25 billion. There is a talk about US mirabegron, that might be another factor to be taken into. Then this JPY25 billion gap, to what extent it is now well calculated?

Kitamura [A]: Well, the revision is in the situation exactly what you mentioned; we have remaining just one quarter. We try to make it as accurate as possible. What about the difference? We are going to sell further in Q4. But of course, what's been delivered up until Q3 is incorporated. In that perspective, we believe that a great portion is already delivered.

On top of that, the Q3 number, just like you pointed out with a metric that you pointed out the defense for the product is quite well. There is an increase here.

Sogi [Q]*: Thank you very much. Next is a question to Claus. It's about PADCEV. I understand that in the United States, the PADCEV sales have been almost flat. It was completely almost flat or slightly declined from Q1 to Q2. We understood that it was because there was a onetime growth to net adjustment while actually volume grew the high single digit, I believe. And then this time, there was an increase from JPY174 million to JPY179 million to this quarter for the US and so I assume that there's no gross to net adjustment this time. And so that's just a confirmation of—so the current—the US dollar-based sales is reflecting the actual volume growth. That's the first question.

And also kind of granular level, I'm a little bit surprised that we don't see the QoQ, growth for PADCEV because unlike a chronic disease, yes, it is true that PADCEV's penetration in new patients has been very quick. But at the same time, for cancer, there are always new patients coming in every month and there are the continuing patients as well. Of course, there are patients who are drop off, but in first line, there are patients who—the patients should stay longer on the treatment.

So if I can know. Just we have not really done really the granular math, but we believe that—we expect that then there will be a more stronger growth QoQ. I just wanted to see whether we are missing something here.

Zieler [A]*: No, no, no, you're not missing something. First of all, if you look at Q3 growth, we reported 12% growth globally. If you divide that into US and ex US, ex US grew 29% QoQ, US grew 3% QoQ. It's not a decline. It's just a more moderate growth rate than we had assumed. That's what I meant before when one of your colleagues asked the question. We had assumed after reaching that inflection point, which is very, very marked for PADCEV. Honestly, it's more marked for PADCEV than I've seen in other drugs, but that extremely steep uptake. And then within one month, it goes into single-digit growth mode. Right? That's the pattern we're seeing in every single country we launched in.

Now we had assumed for the US from June onwards a mid-single-digit growth, but 3% was just a little bit lower than we had assumed. And that's what I meant that maybe like in second line, we saw the same pattern that there's a little bit of a lull for about three months and then growth picks up just a little bit. 3% is not a bad growth. We had assumed a little bit higher. That's the basis of the numbers that you see.

But let me also comment your maybe exploratory part of your question on how high can it go. We are approaching 55% patient share—new patient share, 55%. If you look at analogs, that is quite high. That's usually when cancer drugs start plateauing out. There are some exceptions which go higher. We've seen a little bit higher in some countries. But remember that first line is a combination treatment with PADCEV and pembro. That means you have two molecules with two side effects. And doctors take that, of course, into account when they see more fragile patients.

So we're approaching 55%. How much higher can we go? Maybe a little bit. But I don't think you should expect 60%, 70%, 80% patient shares. I think it's probably not in the realistic realm in this kind of disease setting.

Sogi [Q]*: Thank you. One more question. In terms of the duration of treatment, in the trial, I think and believe PFS was around 10 months for this combination. What is the treatment duration? I know that it's been a little bit over 12 months since the actual approval, so you may not get the actual sense. But do you see—what are you hearing about the treatment duration in first-line setting with this combination?

Zieler [A]*: Yes. DOT is still evolving, Sogi-san. I don't think it's stabilized at a number yet. We're still below the trial rate, so we think it will grow more. I would be hard-pressed to make a prediction at this point. But it's still evolving. It's still extending as we get more patients on the drug.

Sogi [Q]*: Thank you very much.

Ikeda [M]: Thank you very much. Next question, UBS Securities, Mr. Sakai, please.

Sakai [Q]: Sakai from UBS speaking. Kitamura-san, you touched on impairment, so I'd like to ask you questions. Rather than impairment losses, your core and reported, the gap is widening between the two. You're always exposed to the risk of impairment. Accounting-wise, it's not a healthy, sound status. And impairment might be accepted according to the wording. I shouldn't say this to Kitamura-san. You are like booking losses for the past investments. You have to ensure good management could not be done, but this gap should shrink, otherwise, the undervaluation of your stock price could be seen. As CFO, what's your opinion? That's my first question.

Kitamura [A]: Sakai-san, thank you very much. We are not underestimating impairment, but we have to address impairment in a timely manner, so we have to evaluate very well the assets on the balance sheet in a timely manner, in a conservative fashion. We have to do this according to the rules. That's the basic stance.

Full and core gap, there are two major elements here. First, the amortization of intangible assets. Iveric Bio was acquired. After that, it's increasing, so amortization of intangible assets up to the Q3, it's like JPY100 billion in the current fiscal year up to the Q3. This is not really a surprise, but every year, this is going to be amortized every year this much. Rather than a surprise, this is what we're expecting.

Regarding impairment, that is going to be something additional. This time, we have a big impairment loss. We are reviewing why. It's not just a matter in the past, but rather, when we acquire something from outside, well, how we should use our learnings there, we are discussing that.

On the other hand, like in the past, we do have impairment losses on the balance sheet. With regards to in-process R&D, the book prices are declining, so a big impairment is going to be repeated. We don't have a lot of base figures. What to do with the forecast is a difficult question. If you know impairment losses, we have to account for it. But we shouldn't confuse the market when we provide our guidance. Did I respond to your question?

Sakai [Q]: We just want you to do the earnest management. That's the only thing I can say. If the gap is not shrunken, there is definitely the amortization of this intangible asset remains. We cannot avoid that. But how it is reflected into the stock price, I haven't really digested that part yet. But if the dividend is not as favorable level for us, that will be the problem if that continues. Please have that in your mind.

And next question is about IZERVAY. The retinal specialists, among the retinal specialists, efficacy-wise SYFOVRE is better. IZERVAY is better in terms of the safety. It seems that, that recognition is now quite prevailed in the United States. 12 months and after that the level is changed or not, there will be the lift of the restriction. But 12 months thing, well, Claus mentioned when this level issue is settled, then the patient would come back. I think that's the comment basically made by Claus. But after the drug holiday of 12 months, some patients might drop. Based upon your experience, how many patients drop out from the treatment of IZERVAY during this drug post period?

Zieler [A]*: I don't have the number on hand, I'm sorry. Of course, we do already, after 1.5 years in the market, see some patients dropping out. But I would have to get back to you in terms of quantification of that percentage of patients.

I do want to respond to one thing you said. You said in efficacy, SYFOVRE, of course, you said is better. I would challenge you on that statement.

Sakai [Q]*: I'm sorry, that's not my observation. It's the hearing from the expert calls.

Zieler [A]*: Yes. I think these experts are comparing studies, which are not head-to-head studies with different placebo arms. I really think you cannot make that statement on the efficacy unless you have a head-to-head trial of the two drugs. What you can say, however, is that our safety profile is in line with our clinical study, and I don't think Apellis can say that about its competitor drug.

Sakai [Q]*: How about this 12-months duration?

Zieler [A]*: Yes, we have a 12-month label at this point. That's what we are focusing on to extending and then we'll be at par.

Sakai [Q]*: Then patient can stay out of the medication for 12 months and coming back to the treatment?

Zieler [A]*: Of course, yes, that's exactly what we are assuming.

Sakai [Q]*: So 12 months could be a time horizon, time frame that we're talking about, the patient coming back to the treatment after all.

Zieler [A]*: We were licensed in August of 2023. We launched on 1 September of 2023. That means the first patients that were put on drug, which at the time were very, very few in September of 2023, they started elapsing outside of the 12-month label in September of 2024. If the FDA gives us the 24-month label on 26 February, so September, October, November, December, January, February, these patients would be maximum five months out of treatment.

Sakai [Q]*: Right. Yes. Okay. All right. Thank you.

Ikeda [M]: Thank you very much. Next question, Daiwa Securities, Mr. Hashiguchi, please.

Hashiguchi [Q]: Hashiguchi speaking. Thank you very much. My question is about page 14 of your slide. That is about your strategy for R&D. What will be the trigger? And what's the background to come up with this idea? Would you please explain about that?

On the left, there are seven programs. I understood that two are clinical and five are pre-clinical. You take high risk to pursue high returns by now according to my understanding. Then, at a broad base, pursuing a variety of possibilities is going to be important as well, in my opinion. You have to have something new, but there is just a mention of terminated programs. What do you think of the expansion of the base?

In the middle, at the bottom, business development for late-stage de-risked assets. Late stage, for each of the programs, the probability of success is going to be higher for each of the programs. But value-wise, it's going to be big for each of the programs. And it's necessary to make each of these programs a success. If it's early stage, one by one, the value-wise is going to be smaller, so you can work on many programs or projects. And if there's anything with a big success, you can get a high return. Where to focus on depends on what kind of a pharma company you're going to aim for. I think that's core. I'd like to hear more about your approach you're going to take.

Kitamura [A]: Hashiguchi-san, thank you very much. Improvement of R&D productivity, in principle, our stance is not going to change, but it's about phases. We have primary focuses we worked on by now. And last year, mitochondria was reviewed in terms of the priority to remove focus area approach, primary focus area instead of working broadly, which primary focus area is going to win. We try to select the winners.

We have four lead programs. Lead programs, they are such in a stage as a primary focus program, so we try to converge. Those who can win would have more lead on more broadly. Our decision would not be eternal. There can be dynamic changes. And we are now at such a timing.

Primary focus, in order to strengthen primary focus, we try to get early-stage assets in many cases, but in addition, where we can win and also where we can reinforce the portfolio in late stage. The late-stage and de-risked assets, those would also be explored. We're going to consider that. That's our idea.

The value is going to increase. Is that going to be okay? We will strengthen our balance sheet. At the same time, in order to increase the probability of success, we will consider necessary countermeasures. This is about portfolio. Taniguchi, our CMO, is going to make additional comments.

Taniguchi [A]: Thank you very much. I'd like to make some additional comments from my side. I'd like to look at portfolio. As you can see on the right on this page, we are aiming for sustainable growth, which is very

important issue for us. In particular, as you know, 2027 and beyond, we will have XTANDI LOE, so we have to look into the future to make up for our pipeline, which is an urgent task we have to address.

Late-stage development programs, there is a gap in our pipeline in that regard, so de-risked late-stage assets and business development for those at the core is important for our strategy.

In parallel, needless to say, there are four early-stage important programs or products, ASP2138, ASP7317, AT845, and ASP3082. Early-stage programs should be accelerated.

And as there was a question earlier, having a broader base is important for strategy we have taken. At the same time, what we have to do right now is to in-license late-stage and de-risked assets, but we should also focus on our current late-stage assets and promote the development for launch and how we can accelerate is also a very important challenge for us.

Because of this, in PF areas, we are reviewing the PF area and individual products in pre-clinical stage to clinical stage inclusive, where to focus on, where we will increase our investments. That's a very important strategic issue for us. Needless to say, at any company, such work is ongoing.

Focusing on discontinuing or terminating development programs is a critical decision. It's not an easy decision for us. But going forward, for sustainable stage, we have to review our portfolio continuously. And important products, the products we believe are important must be focused on in terms of investments, we have to allocate resources with priority. Prioritized products, which do not fit our strategy, the project termination should also be considered, including that possibility, we have to do this on an ongoing basis. We have to do this continuously. And then we can achieve sustainable growth and we can create value in an accelerated fashion. That's our belief in ensuring resource allocation, and we can improve R&D productivity.

Hashiguchi [Q]: Understood well. Thank you very much. That's all from me.

Ikeda [M]: Thank you. There are still those waiting for further questions, but time is up. With this, we would like to close this meeting. Thank you very much for your joining with us.

[END]

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