Astellas Pharma Inc.

Financial Results for the Q2 YTD/FY2024

October 30, 2024

Event Summary

[Company Name]	Astellas Pharma Inc.
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[Event Name]	Financial Results for the Q2 YTD/FY2024
[Fiscal Period]	Q2 YTD/FY2024
[Date]	October 30, 2024
[Time]	15:30 – 17:00 (Total: 90 minutes, Presentation: 34 minutes, Q&A: 56 minutes)
[Venue]	Webcast
[Number of Speakers]	6

Naoki Okamura	Representative Director, President and CEO
Yoshitsugu Shitaka	Chief Scientific Officer (CScO)
Tadaaki Taniguchi	Chief Medical Officer (CMO)
Atsushi Kitamura	Chief Financial Officer (CFO)
Claus Zieler	Chief Commercial Officer (CCO)
Hiromitsu "Hiro" Ikeda	Chief Communications and IR Officer (CCIRO)

[Questioner]

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

Presentation

Ikeda: Thank you very much for coming to Astellas Pharma Inc.'s Q2 YTD/FY2024 Financial Results. I'm Ikeda, CC, IRO, Chief Communications and IR Officer, serving as the moderator for today.

Today, we'll make a presentation first; it's followed by Q&A. The presentation is based upon the presentation material posted on our website. For question-and-answer as well, we are going to provide simultaneous translation in English and Japanese. The accuracy of translation is not guaranteed by Astellas. Please do understand that.

Cautionary statement. This material or presentation by representatives of the Company and answers and statements by them in the Q&A session includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and is 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.

Now, let me introduce you to the participants here today: the Representative Director, President, and CEO, Naoki Okamura; Chief Scientific Officer, Yoshitsugu Shitaka; Chief Medical Officer, Tadaaki Taniguchi; Chief Financial Officer, Atsushi Kitamura; and Chief Commercial Officer, Claus Zeller. We have five representatives here from Astellas.

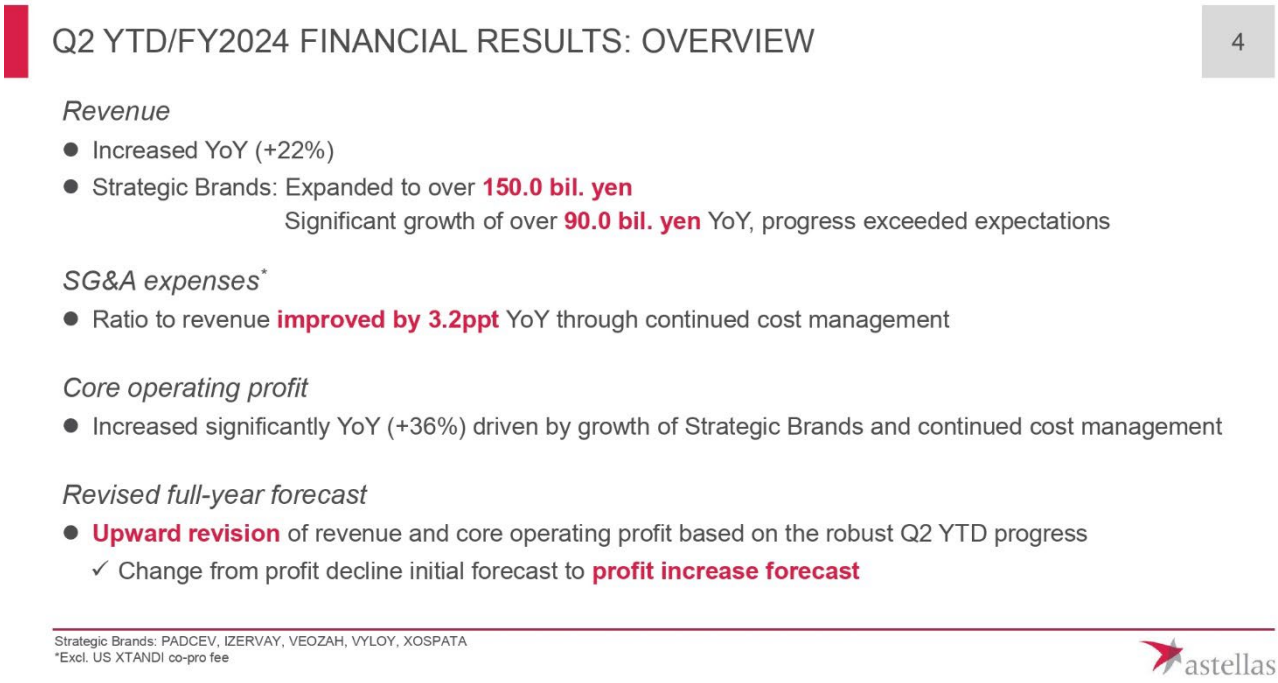
Now, I'll start the presentation. Okamura-san?

Okamura: Hello, everyone. I'm Naoki Okamura from Astellas. Thank you very much for joining our FY2024 Q2 year-to-date 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.

Page three is the agenda for today.

Starting from the next page, I will explain these topics in this order.



On page four, I will give you an overview of FY2024 Q2 year-to-date financial results.

Revenue increased by 22% YoY. Sales of Strategic Brands as a whole expanded to over JPY150 billion in total, exceeding expectations with a significant growth of over JPY90 billion YoY.

As for SG&A expenses, excluding US XTANDI co-promotion fees, ratio to revenue improved by 3.2 percentage points YoY through continued cost management with a focus on ROI.

Core operating profit significantly increased YoY, mainly driven by growth of XTANDI and Strategic Brands and continued cost management.

Full-year forecast of revenue and core operating profit was revised upward based on the robust Q2 year-to-date progress. As a result, we shifted from profit decline initial forecast to profit increase forecast.

I will explain the details of our revised forecast on page 10.

Q2 YTD/FY2024 FINANCIAL RESULTS

(billion yen)	Q2 YTD FY2023	Q2 YTD FY2024	Change	Change (%)	FY2024 Initial FCST	FX impact (YoY)
Revenue	**767.1**	**935.6**	**+168.5**	**+22.0%**	**1,650.0**	+54.8
Cost of sales	143.4	173.8	+30.5	+21.3%	326.0	+6.7
SG&A expenses	347.5	406.4	+58.9	+17.0%	757.0	+25.9
US XTANDI co-pro fee	93.0	126.0	+33.0	+35.5%	189.0	+9.5
SG&A excl. the above	254.4	280.4	+26.0	+10.2%	568.0	+16.4
(SG&A ratio')	33.2%	30.0%	-3.2ppt		34.4%	
R&D expenses	141.9	172.3	+30.4	+21.4%	317.0	+8.5
(R&D ratio)	18.5%	18.4%	-0.1ppt		19.2%	
Core operating profit**	**134.4**	**183.1**	**+48.7**	**+36.2%**	**250.0**	+13.7
(Core OP margin)	17.5%	19.6%	+2.0ppt		15.2%	
<Full basis>						
Amortisation of intangible assets	33.7	69.2	+35.5	+105.2%		
Other income	7.1	4.5	-2.6	-36.9%		
Other expenses	61.7	26.9	-34.8	-56.4%		
Operating profit	**55.2**	**93.7**	**+38.6**	**+69.9%**	**48.0**	
Profit before tax	56.3	89.0	+32.7	+58.1%	43.0	
Profit	**35.8**	**73.5**	**+37.7**	**+105.3%**	**30.0**	

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

Other expenses (booked in Q2)

- Net foreign exchange losses: 12.2

FY2024 Initial FCST announced in Apr 2024. FX rates for initial FCST: 145 yen/USD, 155 yen/EUR. Actual FX rates for Q2 YTD/FY2024: 152 yen/USD, 166 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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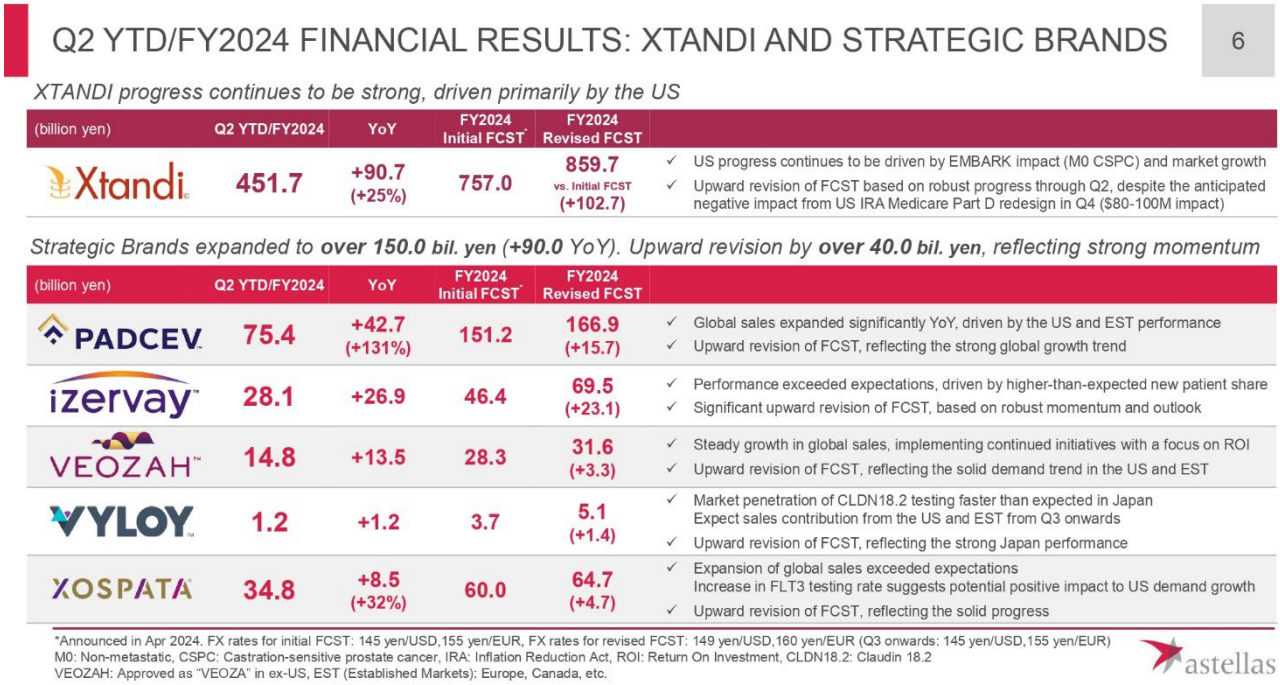
On page five, I will explain FY2024 Q2 year-to-date financial results.

Revenue reached JPY935.6 billion, up by 22% YoY. Core operating profit rose to JPY183.1 billion, up by 36.2% 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 Q2. We booked net foreign exchange losses of JPY12.2 billion associated with forex rate fluctuations. As a result, operating profit increased to JPY93.7 billion, up by 69.9% YoY. Profit increased to JPY73.5 billion, up by 105.3% YoY.



On page six, I will explain FY2024 Q2 year-to-date results of XTANDI and Strategic Brands, as well as our revised full-year forecast.

First, about XTANDI. Global sales increased to JPY451.7 billion, up by JPY90.7 billion or 25% YoY. XTANDI progress continues to be strong globally, driven primarily by the United States from Q1. In the United States, in addition to the growth of the overall market, the penetration of M0 CSPC indication and its ripple effects on other indications have contributed to higher-than-expected sales growth. In ex-US regions, demand was as expected or exceeded expectations.

We have updated our forecast based on the progress by now. In line with our initial guidance, we are anticipating a three-month negative impact from US IRA Medicare Part D redesign in Q4 in the United States. Initially, we were anticipating the impact of USD50 million to USD70 million. But along with the revision of our forecast, we have updated the impact to USD80 million to USD100 million. Robust progress through Q2 globally, as a whole, is expected to more than offset the negative impact from US IRA Medicare Part D redesign. We have made an upward revision of our global full-year forecast to JPY859.7 billion.

Sales of Strategic Brands are supporting the future growth, namely PADCEV, IZERVAY, VEOZAH, VYLOY, and XOSPATA expanded to over JPY150 billion in total with a robust growth of additional JPY90 billion or more YoY.

We have made an upward revision of our full-year forecast by more than JPY40 billion in total, reflecting strong momentum overall. As a result, we are expecting growth to about JPY340 billion in FY2024.

PADCEV global sales increased to JPY75.4 billion, up by JPY42.7 billion, expanding substantially with a growth of 131%.

IZERVAY sales expanded to JPY28.1 billion, substantially exceeding initial expectations. Reflecting the respective robust progress, we revised the full-year forecast upward. I will explain the details on later slides.

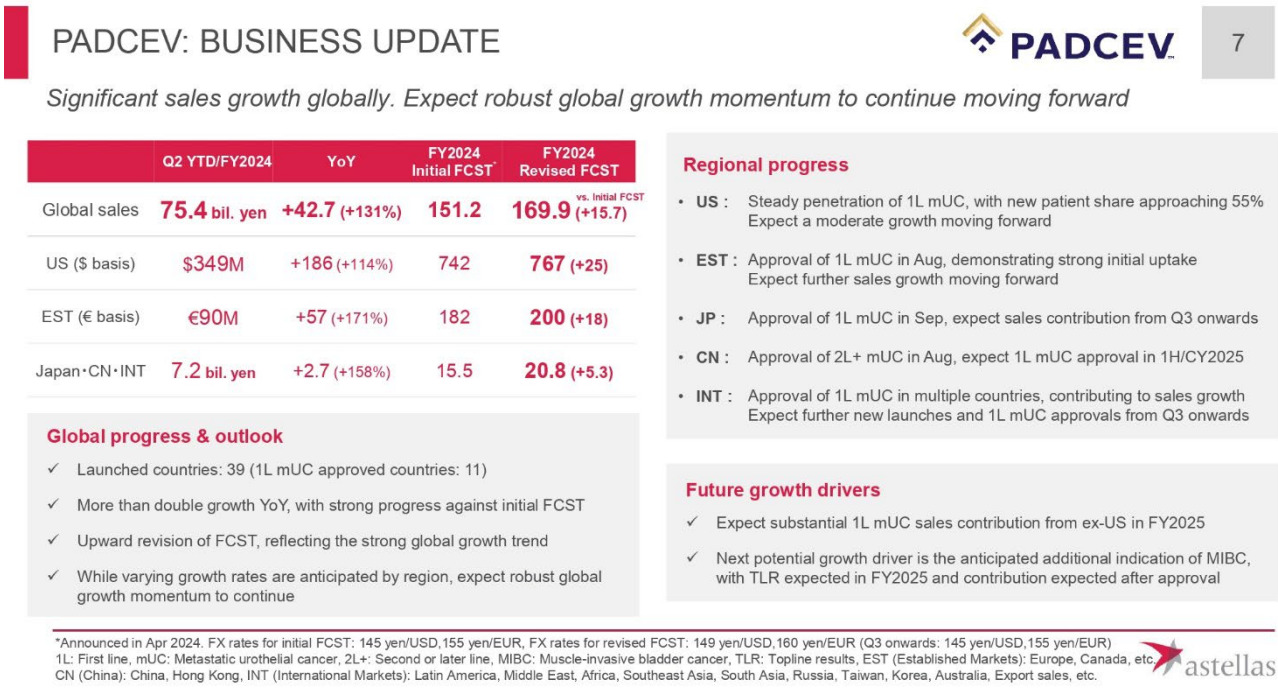
Global sales of VEOZAH reached JPY14.8 billion, making a steady growth. Since Q1, we have continued to implement initiatives with a focus on ROI. The number of launched countries has increased to 17. Regional expansion has also contributed to sales growth. Reflecting the solid demand trend globally as a whole, we have made an upward revision of our full-year forecast.

As for VYLOY in Japan or VYLOY globally, sales for about four months since its launch in Japan in June reached JPY1.2 billion. This progress exceeded our initial expectations. Faster-than-expected market penetration of CLDN 18.2 testing has contributed greatly.

Steady progress is being made towards regional expansion as well. VYLOY was approved in Europe in September and in the United States in October. It was launched in the United States last week. It will be launched from Q3 onwards in the respective countries in Europe. In China, we are expecting approval in Q4. Reflecting the strong performance in Japan, we made an upward revision of our full-year forecast. We are expecting further sales growth along with regional expansion from now on.

XOSPATA performed well globally as a whole. Global sales increased to JPY34.8 billion, up by 32% YoY. Increase in FLT3 testing, especially in the United States, has contributed to demand increase, driving the overall sales.

Reflecting the solid progress through Q2, we made an upward revision of our full-year forecast. We're expecting continuous stable growth going forward as well.



On page seven, I will explain the business update for PADCEV.

Global sales of PADCEV grew more than twofold YoY, progressing well vis-à-vis our initial assumptions. The number of launch countries has increased to 39, out of which 11 countries have the approval of first-line metastatic urothelial cancer indication.

Based on the robust growth trend globally as a whole, we have revised our full-year forecast upward. We are assuming different growth rates in different regions, but we are expecting continuous strong growth globally as a whole.

Let me also explain the progress by region.

First, in the United States, first-line indication based on EV-302 study has penetrated rapidly in the market since approval in December last year with new patient share approaching 55%.

Due to the already high penetration rate, we are expecting a more moderate growth going forward. We are not expecting growth to stop, but rather, we are anticipating a mild but stable growth.

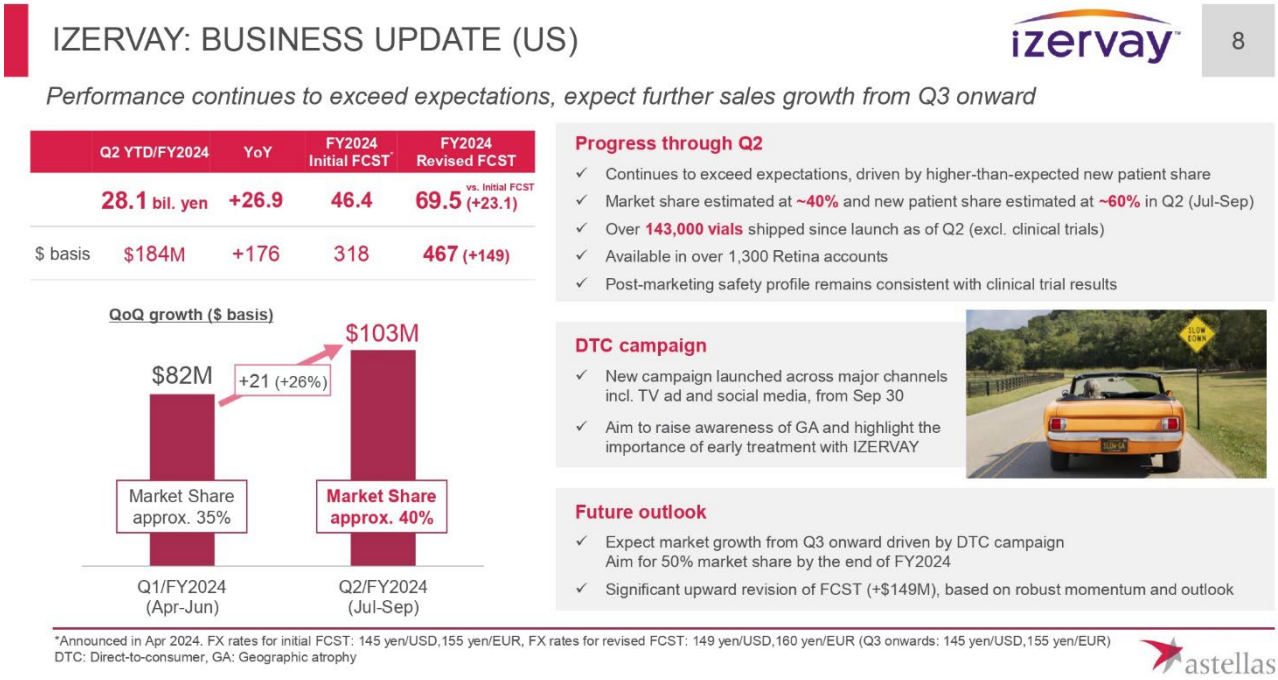
In Europe, prescription is rising in the second-line settings and beyond, where we are obtaining reimbursement. The additional first-line indication approved in August has also contributed to sales growth. For the penetration of the first-line indication, it is necessary to go through procedures to obtain reimbursement once again, so we are expecting full-fledged sales growth from FY2025 onwards.

In Japan, the additional first-line indication was approved in September. We are expecting PADCEV to serve as a growth driver from Q3 onwards.

In China, the indication in the second-line settings and beyond was approved in August. We're expecting future contribution to sales. Furthermore, the additional first-line indication is expected in H1 of calendar year 2025. We can expect further acceleration of sales after approval.

In the international markets, the additional first-line indication was approved in multiple countries such as Korea and UAE, contributing to sales growth. We're expecting further new launches and first-line mUC approvals from Q3 onwards.

Lastly, on this page, let me also touch on future growth drivers. We're expecting substantial first-line mUC sales contribution from ex-US regions on a full scale in FY2025. Furthermore, the next potential growth driver is the anticipated additional indication of MIBC, muscle invasive bladder cancer, with top-line results expected in FY2025 and sales contribution expected after approval.



On page eight, I will explain business update for IZERVAY in the United States.

IZERVAY has continued to perform well since Q1. Sales in US dollars reached USD184 million, growing steadily by 26% QoQ. Market share has risen from about 35% in Q1 to about 40% in Q2. Also, new patient share is estimated at about 60% in Q2, with a steady increase in the number of new patients.

Given the fact that the competitor's product was launched about six months earlier, we think we are making great achievements. Over 143,000 vials have been shipped since launch. Adoption at new accounts is also making steady progress. As of the end of September, IZERVAY was available in over 1,300 Retina accounts.

Post-marketing safety profile remains consistent with clinical trial results without new safety signals observed. We believe physicians' high assessment of IZERVAY's safety profile is also contributing to its robust progress.

In addition, from September 30, a new DTC campaign was launched across major channels, including TV and social media. We are aiming to raise disease awareness of GA, geographic atrophy, and highlight the importance of early treatment with IZERVAY. Only one month has passed since the start of the campaign, but we are already receiving positive feedback from retina specialists and patients.

As a future outlook, we are anticipating the overall market expansion due to the DTC campaign from Q3 onwards. Based on the progress exceeding expectations through Q2, we have raised our target market share at the end of FY2024 from the initial 40% to 50%. Based on the good performance so far and the latest outlook, we have revised our full-year forecast substantially upward. Very good performance has continued since launch in September last year in the United States. We're expecting further growth.

Q2 YTD/FY2024 FINANCIAL RESULTS: SG&A AND R&D EXPENSES

SG&A ratio to revenue improved by 3.2ppt YoY through continued cost management

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**	+10.2% (+3.8% excl. FX impact)	SG&A ratio: 30.0% **(-3.2ppt YoY)**	YoY increase excl. FX impact: approx. +10.0 ✓ Strategic Brands-related expenses mainly IZERVAY (approx. +19.0 YoY) ✓ Reduction of mature products-related expenses (approx. -6.0 YoY) ✓ Global organizational restructuring in FY2023 (approx. -5.0 YoY)
R&D expenses	+21.4% (+15.4% excl. FX impact)	R&D ratio: 18.4% (-0.1ppt YoY)	YoY increase excl. FX impact: approx. +22.0 ✓ Primary Focus and enhanced R&D functions (approx. +13.0 YoY) ✓ One-time co-development cost payments in Q1

ROI: Return On Investment

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

Excluding US XTANDI co-promotion fees, SG&A expenses increased by 10.2% YoY. When forex impact was excluded, SG&A expenses increased by 3.8% YoY. As a main factor behind, sales promotion costs increased for Strategic Brands, and IZERVAY in particular, by about JPY19 billion YoY. During the same period last year, IZERVAY was in a stage before full-scale investments, so this is a factor to increase our costs.

On the other hand, sales promotion costs related to mature products decreased by about JPY6 billion YoY. Also, due to the global organizational restructuring implemented in FY2023, including the reorganization of Japan commercial, costs fell by about JPY5 billion YoY. As a result, SG&A ratio to revenue improved by 3.2 percentage points YoY through continued cost management with a focus on ROI and the expansion of Strategic Brands.

R&D expenditure rose by 21.4% YoY and by 15.4% when forex impact was excluded. As main factors behind, we have made investments in order to make progress in clinical trials for primary focus, immuno-oncology, and targeted protein degradation, and enhanced in-house capabilities necessary for clinical development, resulting in an increase by about JPY13 billion YoY.

One-time co-development cost payment booked in Q1 is another factor to increase our R&D expenditure.

FY2024 REVISED FORECAST

- *Upward revision of revenue and core operating profit based on the robust Q2 YTD progress*
- *Change from profit decline initial forecast to profit increase forecast*

Exchange rates for revised forecast: 149 yen/USD, 160 yen/EUR
(Forecast rates Q3 onwards: 145 yen/USD, 155 yen/EUR)

(billion yen)	FY2023 Actual	FY2024 Initial FCST	FY2024 Revised FCST	FY2024 Change	Main items of revision
Revenue	**1,603.7**	**1,650.0**	**1,800.0**	**+150.0**	• FX impact: approx. +30.0 • XTANDI and Strategic Brands: approx. +120.0
SG&A expenses	740.1	757.0	823.0	+66.0	
US XTANDI co-pro fee	194.9	189.0	229.0	+40.0	• FX impact: approx. +15.0 • Increase in US pharma fee, etc.
SG&A excl. the above	545.2	568.0	594.0	+26.0	
(SG&A ratio*)	34.0%	34.4%	33.0%	-1.4ppt	
R&D expenses	294.2	317.0	341.0	+24.0	• FX impact: approx. +5.0 • Faster patient enrollment of VYLOY (pancreatic) & VEOZAH (Japan)
(R&D ratio)	18.3%	19.2%	18.9%	-0.3ppt	
Core operating profit**	**276.9**	**250.0**	**300.0**	**+50.0**	• FX impact: approx. +7.0
(Core OP margin)	17.3%	15.2%	16.7%	+1.5ppt	
＜Full basis＞					
Operating profit	**25.5**	**48.0**	**80.0**	**+32.0**	

FY2024 Initial FCST announced in Apr 2024. FX rates for initial FCST: 145 yen/USD, 155 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.

On page 10, I will explain FY2024's revised full-year forecast.

First, we revised our full-year forecast forex assumptions to JPY149 against the US dollar and JPY160 against the euro. From Q3 onwards, we are assuming forex rates of JPY145 against the dollar and JPY155 against the euro. We have made an upward revision of revenue forecast by JPY150 billion to expect JPY1.8 trillion. We have factored in an increase of about JPY30 billion due to forex impact and an increase of about JPY120 billion for XTANDI and Strategic Brands.

We are expecting JPY823 billion SG&A expenses as a whole. We have factored in about JPY15 billion due to forex impact, about JPY40 billion as US XTANDI co-promotion fees with an upward revision for XTANDI in the United States, and increase in pharma fee to be paid to the government in accordance with sales amount in the United States, which rose due to good performance.

We are forecasting R&D expenditure to reach JPY341 billion by factoring in an increase in development costs due to faster patient enrollment in the ongoing clinical studies for VYLOY and VEOZAH in addition to forex impact.

As a result, through sales growth for Strategic Brands exceeding expectations and stringent cost management, we are expecting core operating profit to reach JPY300 billion, changing from profit decline initial forecast to profit increased forecast.

We are forecasting JPY80 billion for full-basis operating profits by factoring in other expenses booked up to Q2. We are also incorporating a certain amount in our forecast for other expenses in case of potential risks such as impairment loss.

From here, I will explain our initiatives for sustainable growth.

INITIATIVES FOR SUSTAINABLE GROWTH: OVERVIEW OF QUARTERLY UPDATES

Strategic Brands

- enfortumab vedotin / PADCEV : Approval for 1L mUC (Europe, Japan) and 2L+ mUC (China)
- zolbetuximab / VYLOY : Approval (Europe, US)
- avacincaptad pegol / IZERVAY : Withdrawal of Marketing Authorization Application (Europe)
- fezolinetant / VEOZAH : Phase 3 study for additional indication initiated

Focus Area approach

- Data presentation : ASP3082 (Targeted Protein Degradation), ASP1570 (Immuno-Oncology)
- First subject first treatment : ASP5502 (Immune Homeostasis)
- Partnering : AviadoBio (Genetic Regulation)

Rx+ program

- DIGITIVA (digital health solution for heart failure management) : FDA listed, pilot launch under preparation
- Implantable device for underactive bladder (iota Biosciences) : IDE approval for early feasibility study by FDA

VEOZAH: Approved as "VEOZA" in ex-US.
See slide 33 for overview of collaboration with AviadoBio.
1L: First line, mUC: Metastatic urothelial cancer, 2L+: Second or later line, FDA: Food and Drug Administration, IDE: Investigational Device Exemption

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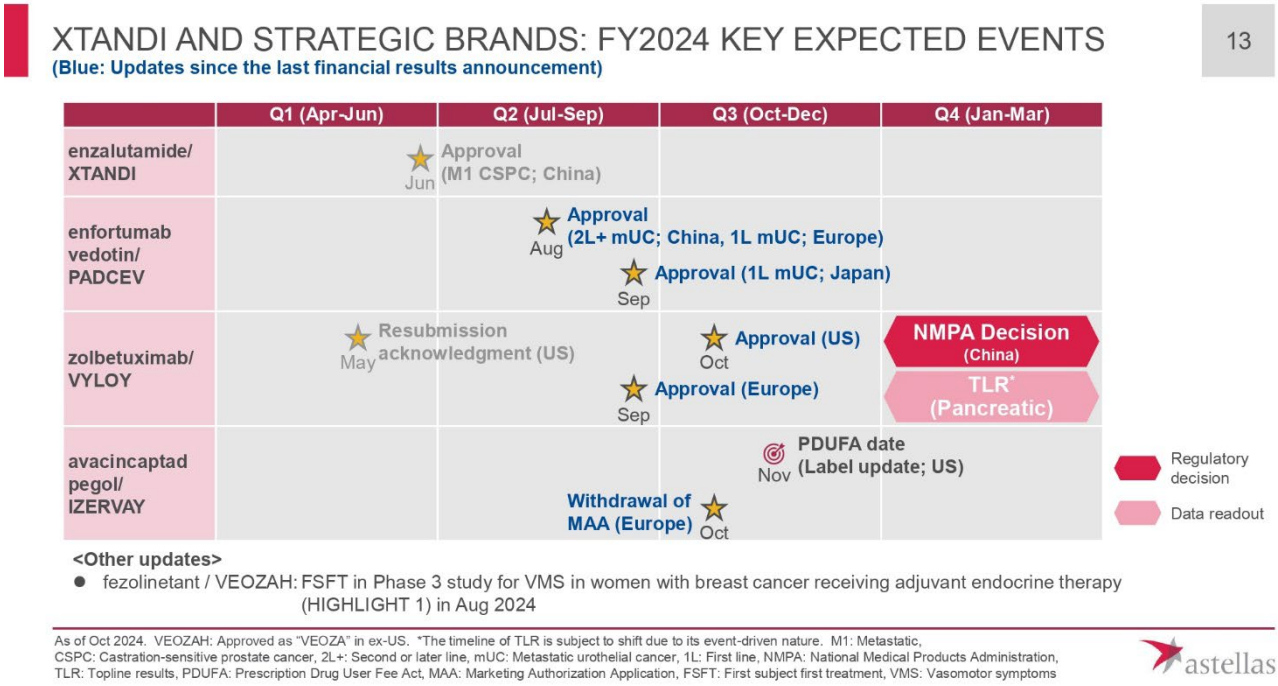
Page 12 summarizes key updates on R&D since the last financial announcement.

The details of the Strategic Brands and individual programs of the Focus Area Approach will be explained in the following slides.

Slide 33 in the appendix provides an overview of the partnership of AviadoBio, which is one of the primary focuses in genetic regulation. Please refer to it if you are interested.

Rx+ made progress in two programs. DIGITIVA, our digital health solution for health failure management, has been certified by the FDA as software as medical device. Preparations are currently underway for pilot sales in the United States.

Regarding an implantable device from iota Biosciences, early feasibility study of a program targeting underactive bladder was approved by the FDA for an IDE, investigational device exemption, which is the equivalent of an IND for pharmaceutical products.



On page 13, I will explain the progress of key events expected in FY2024 for XTANDI and Strategic Brands.

I have indicated in blue the progress that has been made since the previous financial results announcement. PADCEV was approved in China in August for the second-line treatment of mUC based on the EV-203 study. In addition, an additional indication for first-line treatment based on the EV-302 study was approved in Europe in August and in Japan in September.

VYLOY was approved in Europe in September and in the US in October for the treatment of gastric adenocarcinoma and GEJA, or gastroesophageal junction adenocarcinoma.

As announced during the press release of the day before yesterday, we have withdrawn the marketing authorization application submitted to the EMA based on the results of discussions with the CHMP in EMA. We remain confident in the clinical profile of IZERVAY as we continue to believe that the clinical meaningful effect of IZERVAY in the slowing progression of geographic atrophy lesions demonstrated in the clinical trials outweighs the risk.

While geographic atrophy is a serious condition that can lead to irreversible visual impairment and blindness, there are currently no approved treatments outside the United States. We will continue to evaluate available options to bring IZERVAY to patients around the world, including in Europe.

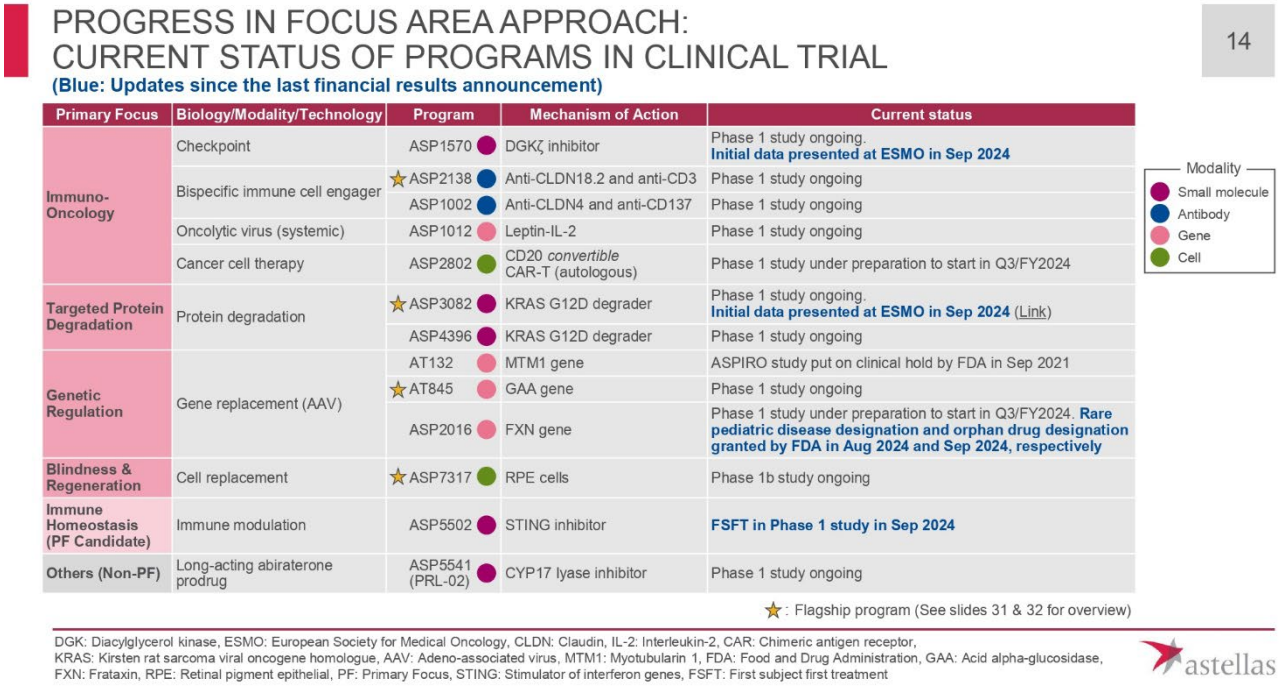
In Europe, in addition to the process of centralized marketing authorization based on a single submission through the EMA, there are also multiple application processes that involve individual procedures for each member country. We will consult with the authorities in each European country to confirm what application processes are possible and consider what we can do.

As we haven't started the consultation with the authorities yet, we are unable to provide any specific information regarding the future direction or timeline at this point. We'll provide an update once the situation becomes clearer. Please wait for further information.

I would also like to touch on the risk of impairment losses on IZERVAY, which is of great interest to the investors. We have booked USD1.1 billion in intangible assets outside the US for IZERVAY. We will reevaluate the asset value and perform appropriate accounting procedures.

In revaluing the asset, we need to consider factors such as the availability of the submission processes in our target countries in Europe as well as the fact that sales are exceeding expectations in the US and the competitive environment is different from the assumptions made at the time of acquisition.

In addition, the target region for this asset is outside the US and the possibility of submissions in countries and regions outside Europe that we are currently considering will also be reflected in the evaluation of the asset value. Today, I cannot give you any specific answer about whether or not there will be impairment losses or, if there is, scale of the loss. But since we have already factored in other expenses such as the risk of impairment losses into our full-year forecast, we believe that even if an impairment loss were to occur this fiscal year, we would be able to absorb a certain amount of it.



PROGRESS IN FOCUS AREA APPROACH:
CURRENT STATUS OF PROGRAMS IN CLINICAL TRIAL

14

(Blue: Updates since the last financial results announcement)

Primary Focus	Biology/Modality/Technology	Program	Mechanism of Action	Current status
Immuno-Oncology	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1 study ongoing. **Initial data presented at ESMO in Sep 2024**
	Bispecific immune cell engager	★ASP2138	Anti-CLDN18.2 and anti-CD3	Phase 1 study ongoing
		ASP1002	Anti-CLDN4 and anti-CD137	Phase 1 study ongoing
	Oncolytic virus (systemic)	ASP1012	Leptin-IL-2	Phase 1 study ongoing
	Cancer cell therapy	ASP2802	CD20 *convertible* CAR-T (autologous)	Phase 1 study under preparation to start in Q3/FY2024
Targeted Protein Degradation	Protein degradation	★ASP3082	KRAS G12D degrader	Phase 1 study ongoing. **Initial data presented at ESMO in Sep 2024** (Link)
		ASP4396	KRAS G12D degrader	Phase 1 study ongoing
Genetic Regulation	Gene replacement (AAV)	AT132	MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
		★AT845	GAA gene	Phase 1 study ongoing
		ASP2016	FXN gene	Phase 1 study under preparation to start in Q3/FY2024. **Rare pediatric disease designation and orphan drug designation granted by FDA in Aug 2024 and Sep 2024, respectively**
Blindness & Regeneration	Cell replacement	★ASP7317	RPE cells	Phase 1b study ongoing
Immune Homeostasis (PF Candidate)	Immune modulation	ASP5502	STING inhibitor	**FSFT in Phase 1 study in Sep 2024**
Others (Non-PF)	Long-acting abiraterone prodrug	ASP5541 (PRL-02)	CYP17 lyase inhibitor	Phase 1 study ongoing

Modality: Small molecule, Antibody, Gene, Cell

★: Flagship program (See slides 31 & 32 for overview)

DGK: Diacylglycerol kinase, ESMO: European Society for Medical Oncology, CLDN: Claudin, IL-2: Interleukin-2, CAR: Chimeric antigen receptor, KRAS: Kirsten rat sarcoma viral oncogene homologue, AAV: Adeno-associated virus, MTM1: Myotubularin 1, FDA: Food and Drug Administration, GAA: Acid alpha-glucosidase, FXN: Frataxin, RPE: Retinal pigment epithelial, PF: Primary Focus, STING: Stimulator of interferon genes, FSFT: First subject first treatment

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Slide 14. I will now explain the progress of the Focus Area Approach.

The programs that are in the clinical trial stage and have been updated since the previous fiscal announcements are results indicated in blue. Primary focus immuno-oncology, ASP1570, initial data including Phase I data was presented as a poster at ESMO in September.

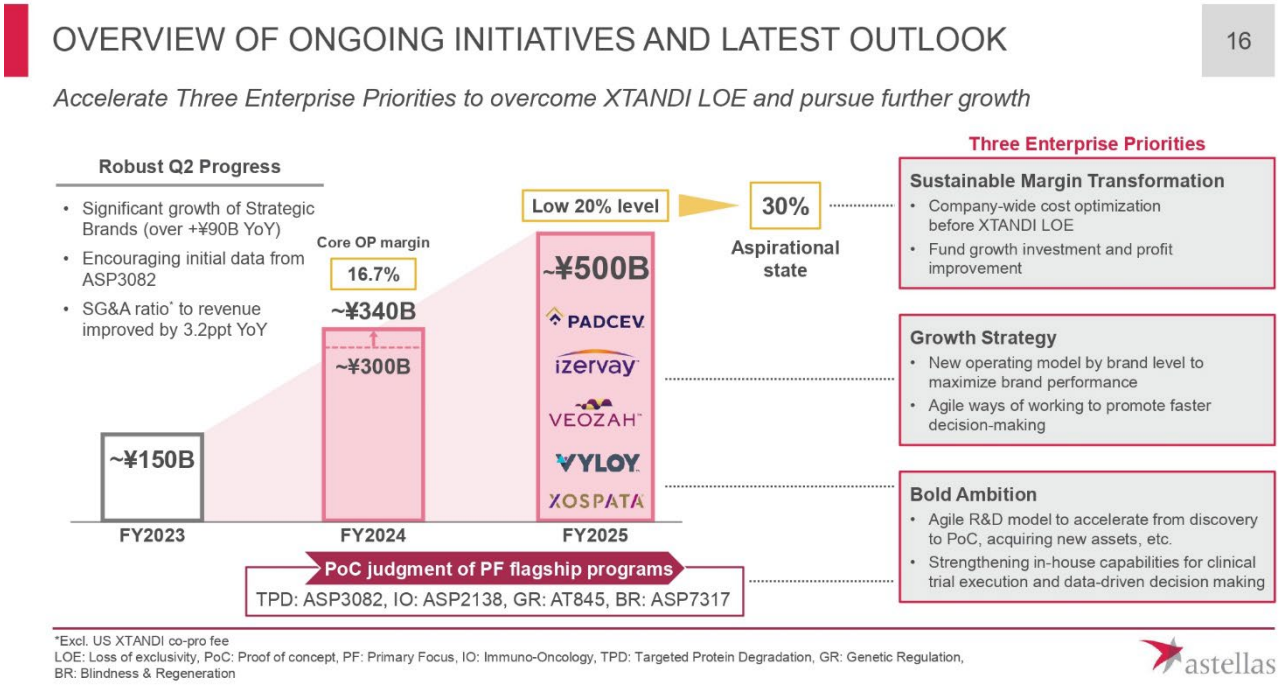
ASP3082 in targeted protein degradation was presented orally at ESMO as well on initial data from the Phase I trial. We introduced the details of the data at the briefing session held on September 27, so please see the materials from the link if you are interested.

ASP2016 in genetic regulation received rare pediatric disease designation and orphan drug designation from FDA in August 2024 and September 2024, respectively.

ASP5502 in immune hemostasis and primary focus candidate achieved the first subject first treatment in Phase I trials in September.

Please refer to appendix slides 31 and 32 for an overview of each primary focus flagship program marked with a star mark.

As I have explained so far, the overall business has been steadily progressing through Q2. I will now explain the midterm initiatives that are supporting this favorable progress as well as the latest outlook based on these initiatives and situations.



On page 16, I will first explain the overview of midterm initiatives.

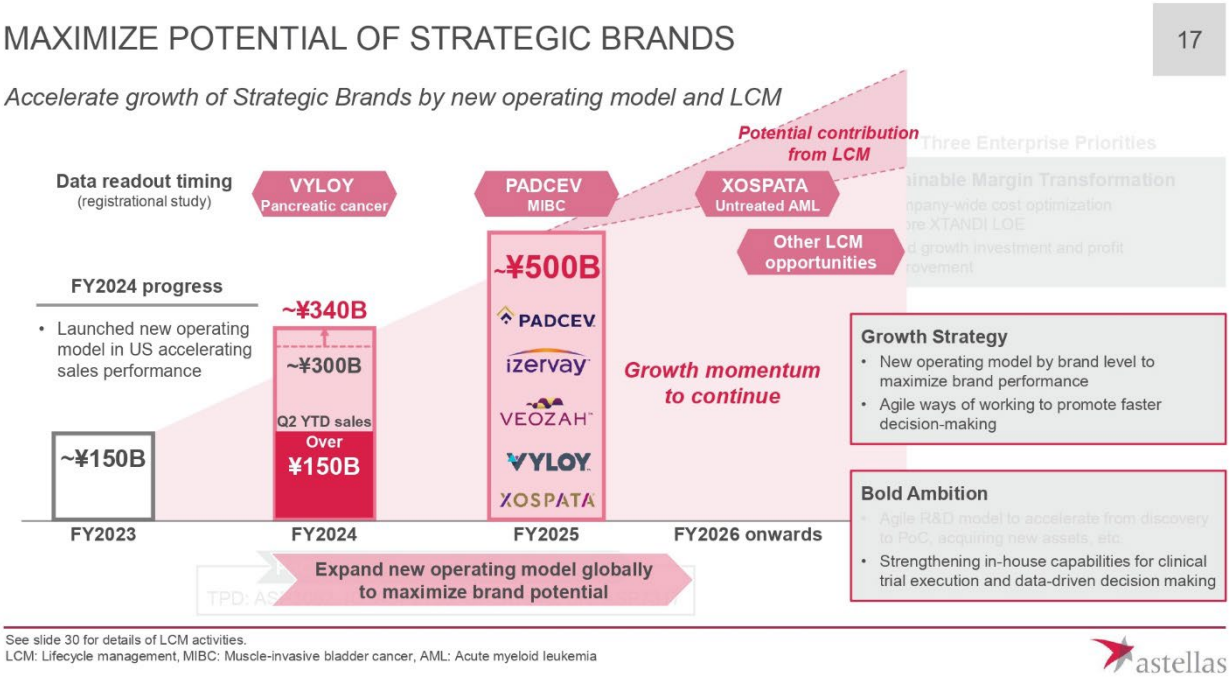
In Q2, we were able to show good progress, including significant growth of Strategic Brands, the acquisition of encouraging initial data from ASP3082, and an improvement in the SG&A ratio to revenue, which led to an upward revision of the full-year forecast for revenue and core OP. In order to ensure a successful implementation of the CSP2021, we have established three enterprise priorities that are closely linked to our performance targets, and we have begun to work on this in a full-fledged manner from this fiscal year. An overview of each is shown on the right side of the slide.

First, growth of Strategic Brands is essential for expanding future revenue and the growth strategy is an initiative to maximize their potential.

Next, the bold ambition is an initiative to accelerate R&D for life cycle management of Strategic Brands and the Focus Area Approach in order to improve pipeline.

Sustainable margin transformation is an initiative to pursue cost optimization in order to achieve our target of a core operating margin of 30%.

We have set KPIs for each initiative and are steadily implementing them as a priority issue while rigorously monitoring progress. Based on the results through Q2, we are seeing positive results from these initiatives. In the following slides, I will explain the initiatives and the latest outlook for each of the three enterprise priorities.



On page 17, first, I will explain the initiatives to maximize the potential of Strategic Brands, which are extremely important to expanding future revenue.

The total sales of our Strategic Brands through Q2 have grown to over JPY150 billion, achieving growth that exceeds our initial forecast. At the beginning of the fiscal year, we expected sales to grow to JPY300 billion for the full year. But based on the strong progress and the latest forecast, we believe we can aim for JPY340 billion.

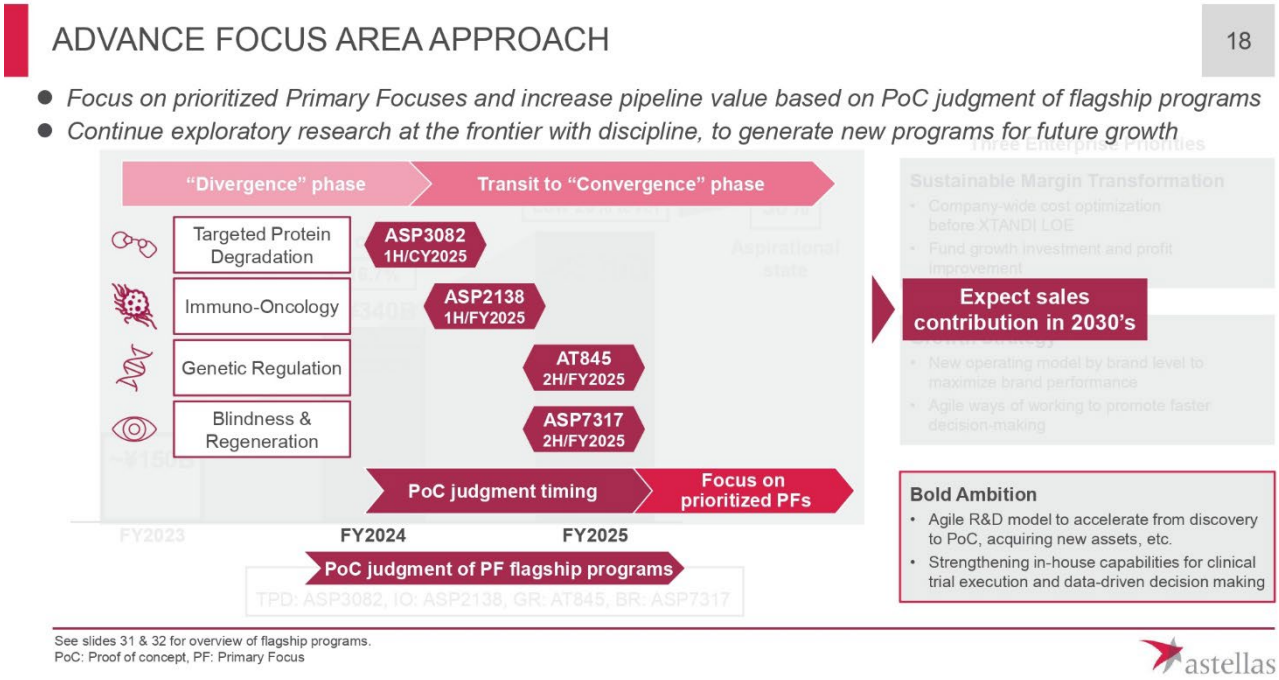
In order to further accelerate growth, we are introducing a new operating model by brand level. We have already started introducing this in the US from July, and it is already showing results in accelerating sales growth in the US market.

By shifting from a hierarchical organization to a cross-functional organization by products and the commercial organization's senior management work with each product team, we are now able to promote faster decision-making. We will continue to expand this model in regions outside the United States.

In order to accelerate the growth of Strategic Brands, we are also focusing on life cycle management, LCM initiatives. We are accelerating the progress of clinical trials for expanding indications, and we expect this to contribute to an additional sales growth on top of the existing indications.

We expect to receive top-line results for VYLOY in pancreatic adenocarcinoma this fiscal year, PADCEV in MIBC in FY2025, and XOSPATA in treatment-naïve AML in FY2026. In addition, LCM initiatives that are expected to achieve milestones in FY2026 and beyond are shown on slide 30 of the appendix.

Our Strategic Brands are making steady progress towards achieving about JPY500 billion in sales in FY2025, and we expect further growth from 2026 onwards. We will maximize the potential through our new operating model and are looking forward to the potential sales contribution of LCM.



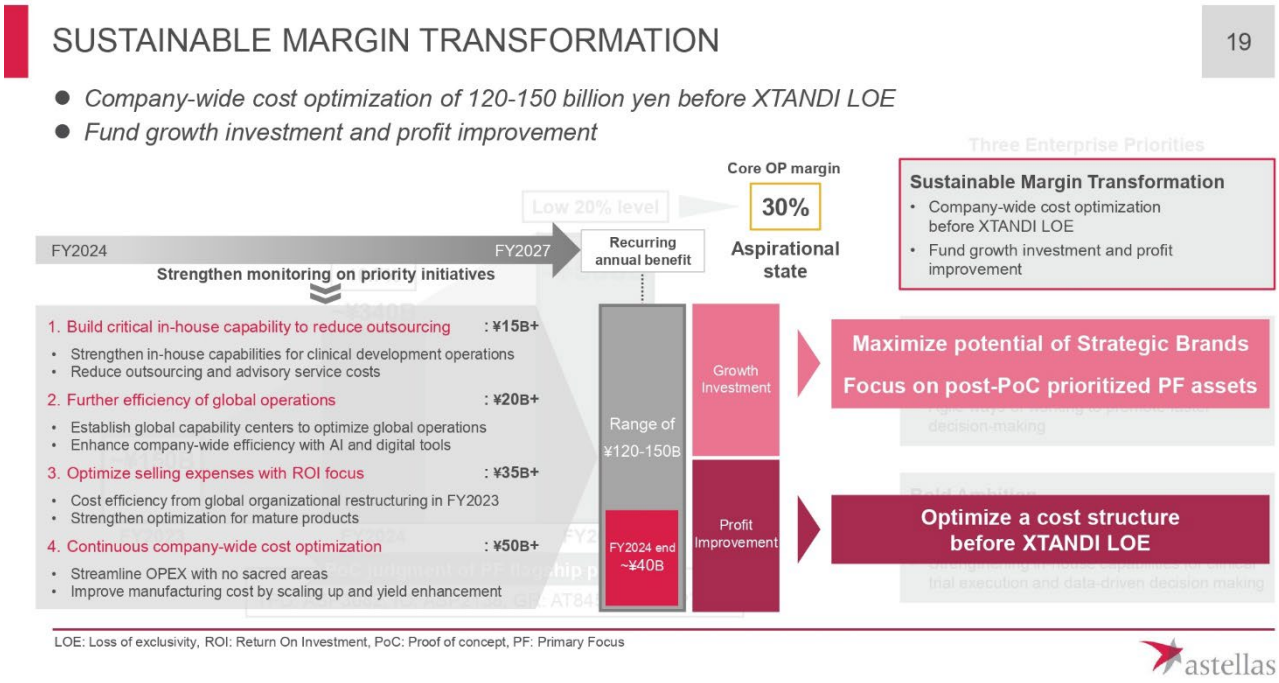
On page 18, I will explain our outlook for the Focus Area Approach.

At the announcement of our FY2023 financial results in April, we announced that we plan to advance four flagship programs in each of our primary focus areas, namely: ASP3082 for targeted protein degradation; ASP2138 for immuno-oncology; AT845 for genetic regulation; and ASP7317 for blindness and regeneration, to the PoC judgment stage by the end of FY2025.

In order to accelerate PoC judgment, we are working to build an agile organization structure and strengthen our in-house capabilities in early development. The chart in the middle of the slide shows the expected timing of the PoC judgment for each program. We expect to have the PoC judgment timing in H1 of the calendar year 2025 for ASP3082; in H1 FY2025 for ASP2138; and in H2 FY2025 for AT845 and ASP7317.

To date, the Focus Area Approach has been in a phase of divergence as we have explored the potential of each platform. In the future, depending on the results of the PoC judgment, the current primary focus will move to a phase of convergence, and we will strive to improve the value of the pipeline by investing management resources, preferentially in primary focus that have achieved clinical PoC.

The R&D portfolio will be constantly reviewed and prioritized based on the technical difficulty and the value of the programs and will be turned over repeatedly. We expect that the programs created through the Focus Area Approach will progress and contribute sales in the 2030s, bringing about sustainable growth.



On page 19, I will explain sustainable margin transformation.

As I have explained so far, our Strategic Brands have entered a growth phase that will contribute significantly to sales expansion. We can also see expansion from FY2025 and onwards, and we are becoming more confident that they will grow to a scale that will make up for the decline in sales due to the loss of exclusivity for XTANDI.

In R&D, we have entered the stage of PoC judgment for the four flagship programs in our primary focus. Depending on future developments, we will invest management resources in priority areas to drive growth in the 2030s.

To support the growth and investment and ensure sustainable growth after the loss of exclusivity for XTANDI, it will be important to work on optimizing our cost structure. Since Kitamura took up his new position as CFO, we have been working to control costs in a disciplined manner. But at the point, we will review our efforts and optimize the cost to achieve over the next four years, which is between JPY120 billion and JPY150 billion. I'm going to explain that with this slide.

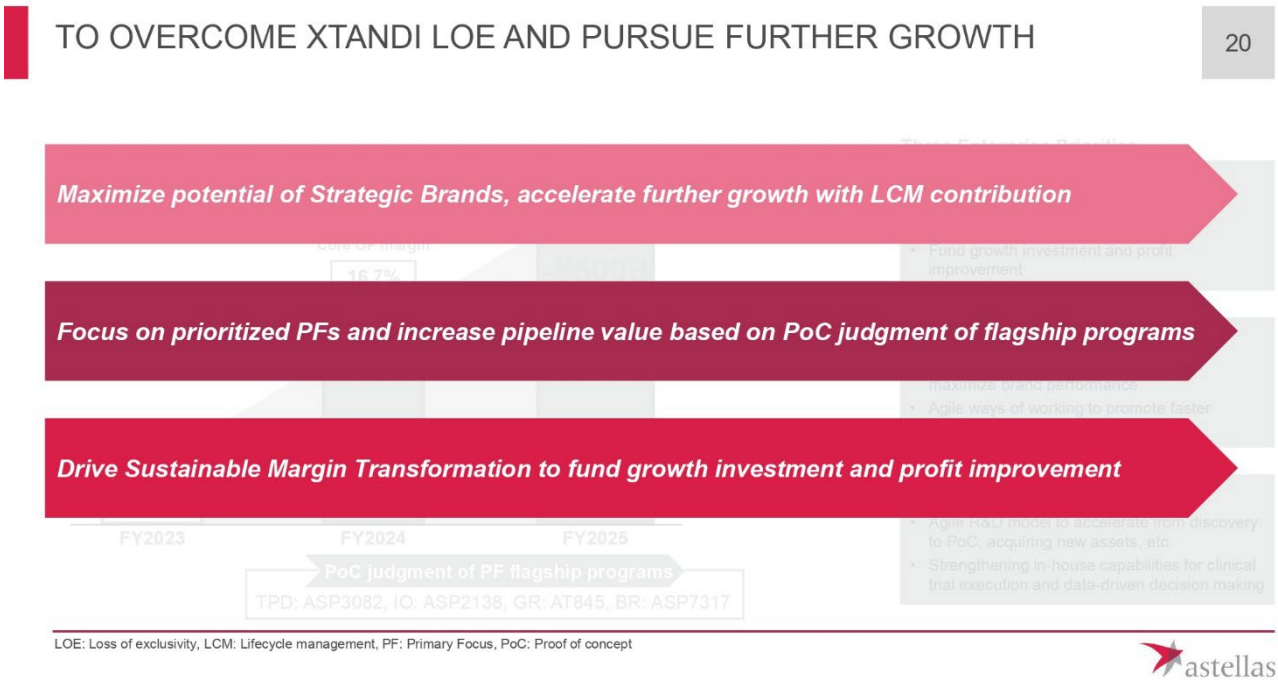
On the left side of the slide, we have divided the specific measures for cost optimization into four categories. The progress of these measures is being monitored strictly under the strengthened management system to enhance the effectiveness of these initiatives.

In addition, many of the measures have already completed the planning phase and have moved to the implementation phase. For example, in clinical development operations, we enhance our in-house capabilities for early development while minimizing outsourcing.

In addition, in order to further consolidate and streamline global operations, we are considering establishing a global capability center with the aim of building a flexible resource provision system for the entire value chain and all functions that support it as needed.

We are also working to improve manufacturing costs through manufacturing scale-up and yield improvement through our review of the manufacturing process. We will continue to implement these measures from FY2024 to FY2027. As a result, we aim to achieve cost optimization of JPY120 billion to JPY150 billion on a company-wide level by the end of FY2027 as an expected annual effect. Of this, an annual equivalent of JPY40 billion is expected to reach by the end of this fiscal year.

The resources generated from here will be used for growth investment, such as further sales promotion of Strategic Brands, life cycle management initiatives, and late-stage development of prioritized primary focused products after PoC. We will continue our effort to secure midterm profits by increasing profitability.



Page 20. This slide summarizes the initiatives we'll focus on in the midterm as explained so far.

We'll commit to these initiatives, which include: maximizing the potential of Strategic Brands; focusing on prioritized primary focus products and increasing the pipeline value; as well as pursuing cost optimization to improve profitability; and aiming for further growth after XTANDI loss of exclusivity.

This concludes my presentation. Thank you for your attention.

Ikeda: Thank you very much. That's all as our explanation.

Question & Answer

Ikeda [M]: We now would like to entertain questions from the audience. Questions, please.

First, Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi [Q]: Yamaguchi speaking from Citigroup Securities. Thank you very much. My first question, as you explained, IZERVAY, this may be a question, but I think you can respond. Rather than questions, you cannot respond. There would be a PDUFA date for label update. IZERVAY and update for sales in the United States, any impact? There would be DTC and share-up. What about the impact of the label update? Is that included or not? If that's the case, can I understand that the impact is going to be positive? That's my first question.

Ikeda [M]: Kitamura would like to respond.

Kitamura [A]: Thank you for your question. Kitamura speaking. Regarding the label update impact, that was included in the initial plan. That continues to be part of the plan. That's my response to your question.

Yamaguchi [Q]: Understood. Also, this is my second question. In Europe, you may not be able to talk about the progress, but in Europe, there can be an individualized procedure to file in the respective countries in Europe. I'm not asking about specific countries, but in which country that procedure can be applied. In ex-US regions, Europe is one of them. For example, in Japan, Asia, China, do you plan to have a development program in those countries and regions?

Okamura [A]: First, I'd like to respond briefly. If there is anything missing, Taniguchi would like to add. Originally, in Europe, through CHMP or the region across Europe, before that procedure, each country had a filing and that filing still remains.

It takes time and effort to do this in each country and clinical studies may also change. Usually, through CHMP to get the approval for all Europe through EMA, after Brexit, UK is no longer part of Europe. Switzerland, which is not a member of EC, has its own filing system so that is possible in each country.

Instead of submitting our documents to the respective countries, but based on the data package, we consult with the regulatory authorities. If they say they can review it, we'd like to file, that is going to be the process, which will be in operation. A few countries, first, with the regulatory authorities, we will use our current dataset to consult with them to see whether we can file a submission or not. That is going to be the first step.

Outside of EMA, US and Switzerland, we are filing in those countries. Also in Japan, we are consulting with PMDA. We started the consultation process. In other Asian countries and South American countries, as much as possible, we'd like to deliver IZERVAY to patients, we will continue to make efforts.

Taniguchi-san, anything missing?

Taniguchi [A]: Thank you very much. I don't need to add, but as Okamura explained, in Europe, there's going to be a review by the individual countries, which we are considering. Regarding other countries, UK, the filing is being submitted. Canada, Japan, China, and other countries, we are considering the possibility in those countries as well. Once we have the discussions with regulatory authorities in their respective country, we'd like to update you.

Yamaguchi [Q]: Lastly, just briefly, regarding VEOZAH, you had an upward revision. Liver function test frequency is higher. In the Q1 earnings call, we discussed the potential impact. Any feedback from the sales field? Any feedback by now?

Okamura [A]: Thank you very much. For the time being, there is no signal to tell that it's going to be negative. What is going to be the potential impact? We are doing market research, but this is just only market research. The prescription trends in the field would be the best performance indicator. If there's anything to add, Claus?

Claus Zieler [A]*: You summarized it very well, Naoki. Prescriptions are continuing their upward trend. And anything else, we'll have to wait for the market research to read out. Thank you.

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

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

Wakao [Q]: JPMorgan, Wakao is my name. Thank you very much. My question is about IZERVAY. This is a question that shouldn't be asked because you cannot answer. But still, with regards to the way of answering by Okamura-san, I would like to have a deeper understanding, so please tell me.

In the case of impairment loss, currently, JPY60 billion is expected, so a certain level can be absorbed. I think that's the way of your expression or explanation. US sales status and with regards to EU, the filing will take place at each country and you're thinking about the development in the Japanese market. Current JPY60 billion, I assume that still impairment loss could be within the scope of this JPY60 billion expected. Is it too optimistic? There might be just a nuance-wise explanation which will be still helpful for me.

Okamura [A]: Thank you very much. When we acquired Iveric Bio, a purchase price allocation precondition was there; that is, the market should be outside of the United States. However, Europe, roughly speaking, or Japan, those are the countries that we incorporate for the evaluation in earlier phase. That is considered as the foundation of the forecast.

As you know now, Europe is separated, not centralized for the submission. Also, Japan, which we didn't have any plan, we started to see the venue or the journey ways to go for the approval. At the time of the assumption of PPA, some countries are not included, but now they are potential, as Taniguchi mentioned. We've started the preparation already.

Therefore, this USD1.1 billion relationship, rather than just perspective, further, we would like to think about various factors and situations to consider objectively the value of this outside of the United States. Based upon that, we would like to calculate the impairment loss.

This JPY60 billion as a whole, this is not the impairment loss, but USD1.1 billion intangible asset outside the United States and because of that, we withdraw our submission in Europe. It may be considered that this USD1.1 billion is all for impairment loss. In order to avoid that misunderstanding, I made that expression.

Wakao [Q]: Understood. I will stop there. Second, about the future next fiscal year and afterwards, I have a question about XTANDI. PADCEV, IZERVAY, VEOZAH, you made an explanation and they are quite steadily progressing. My concern is about XTANDI. This time, you made upward revision, so it is progressing in a steady manner.

IRA impact in the next fiscal year and afterwards, this Q4, USD80 million to 100 million. Considering the next fiscal year, this IRA impact would take place throughout the fiscal year. I understand about that. IRA out-of-pocket is set at USD2,000. Also, M0 CSPC, that is on the progress of the market expansion and that is likely to impact into the next fiscal year as well.

All in all, XTANDI in the next fiscal year, do you think it will grow further? I think you are going to scrutinize it further. As of this moment, especially in the United States, how do you view about the XTANDI in the United States next fiscal year?

Okamura [A]: Thank you very much. I don't want to say something irresponsible, so I don't want to go into details or the deep dive. Just like Wakao-san mentioned, basically, the number of patients is on the increase in M0 CSPC. Of course, the patients who received the treatment in earlier phase and also the duration of the administration will be longer and M0 CSPC, that leads to the ripple effect for other indications as well, and the patient will pay less.

Therefore, in terms of the affordability, those patients who receive their drugs without making any payment would now be shifted toward those who need to pay. The balance of the patients will be different. There are so many factors mixed up and it's very difficult to tell. 2025 and afterwards, when we made the announcement of the FY2024 as a whole full year, we'll give you the guidance for FY2025. At that time, you might say that this is just one quarter, but this calendar year 2024, the Q1 situation will be clearer. Based upon that, I would like to explain that at that time.

Claus-san, do you have any additional comment on this?

Zieler [A]*: Thank you, Naoki. I think we need to remember that the volume growth of this market, of this class is still double digit. That's true not only in the United States, but essentially, across the world in many, many countries. We have a very strong volume momentum behind XTANDI and the class that XTANDI represents.

The question of the IRA impact and other pricing impacts that we will have to face is, as Naoki has said, the question will be which of these factors is dominant, the pricing factor or the fact that patients stay longer on drug or the volume growth of this market? That's what we'll have to calculate and then give guidance on when we look at FY2025.

Wakao [Q]: Very clear. One last question. Regarding the costs, you're going to ensure good cost management and cash flow compared to assumptions, it's going to be better. Regarding capital allocation, I have another question to you. This is going to be a future discussion point, but the profit level is going to be high, then dividend increase and shareholder returns, there would be high expectations on that.

At the same time, you have JPY900 billion of loans or borrowings. You make a priority to the repayment of loans. Shareholder returns, how much is the room to use the money to make shareholder returns? There is a table showing the possibility of shareholder returns and increasing the dividend. What's the situation?

Okamura [A]: Capital allocation approach from a long time ago remains the same with consistency. We'd like to use the money for the business growth investments.

In terms of shareholder returns, the dividend in the longer term would be increased in a stable fashion. In the longer term, if there's still excess cash, we would buy our own shares flexibly in a different way. We'd like to return the money back to the shareholders in a different way.

Based on the original plan, we developed other plans. If there's going to be an excess of cash above that level, based on the current situation, is it better to repay borrowings or is it better to invest in our businesses? We had the initial guidance of JPY74 as a dividend payment. Or is it better to increase the dividend? There would be a variety of options.

We will have excess cash to begin with. What is the amount if we buy our own shares? It's not going to be a size and scale, which is meaningful enough. We have to consider and think about which option to take.

As you said, if we have long-term borrowings for too long to do business, because of the nature of our business, I think it's a bit risky. At a certain pace, we have to repay the interest-bearing debt. If we have excess cash, are we going to repay at an accelerated pace or are we going to use that for other purposes? That is going to be considered by Kitamura.

Kitamura-san, anything to add?

Kitamura [A]: Thank you for the question. In principle, I agree with what Okamura said. You may say what if, but we have to achieve good business results. Based on the capital allocation, we have to make investments for growth. Now, we have to consider the balance vis-à-vis the borrowings and loans, and Iveric Bio liabilities in five years to seven years, that is going to be repaid, so first, we have to increase our profitability for sure. That is the most important thing. Continuously, we'd like to work on this. That's all from me.

Wakao [Q]: Thank you very much. Having said so, core operating profit is increasing. I think it's improving than before, right?

Kitamura [A]: In principle, as far as we see the performance up to Q2, it's not just because of what we did in the past two quarters, but including what we have done so far. Compared to the initial forecast, we are progressing very well. I think we can say so.

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

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

Muraoka [Q]: Morgan Stanley, Muraoka is my name. Thank you. XTANDI, January to March IRA negative impact, its calculation range is expanded. Is that because of the increase of the sales? Or if there are some other factors involved, would you please explain that? That's the first question from me. Thank you.

Okamura [A]: In my understanding, just the denominator becomes bigger, so this model application leads to the bigger number. Claus-san, is this answer right?

Zieler [A]*: That's correct. This is just the mathematical calculation of the IRA Medicare Part D impact as it's been laid out in the legislation by the US government.

Muraoka [Q]: Thank you very much. Next is about XTANDI once again. I haven't studied this yet much, but Pluvicto by Novartis is doing quite well, so pre-taxane CRPC also incorporates that product as well. Looking at FY2025 and 2026, considering the competition of the XTANDI, is it going to be the bigger competitor for you or it is not necessary to consider about that regimen as the competitor?

Okamura [M]: I don't know who will be the right person to answer this. Claus, could you answer this?

Zieler [A]*: Yes, I can try. Essentially, the competitive landscape with new launches into this market, they're coming into very, very late-stage populations. As you know, with EMBARK, we have been able to position XTANDI in the very, very earliest stage, and we're the only compound that has that dataset. Our position, XTANDI's position in this class is absolutely unique and doctors are recognizing that. We're seeing a good response to the EMBARK data.

The question really is, what is the competitive landscape in the early stages of the disease? There, our competitors are well known to you. It's Johnson & Johnson with ERLEADA and it's Bayer with NUBEQA.

Muraoka [Q]: Thank you very much. The last question is about the capital allocation. Probably my question is a bit with a different angle. Acquiring a new drug from outside, for the primary focus next year, four PoC

judgments will be available. If all of these four make a success, then you don't need to acquire something big from outside. Is it okay to consider either way or it's not like that? Whenever if you come up with something new as a candidate, then, even from the beginning of the next fiscal year, you are going to acquire such a candidate? Would you please sort out the situation for you?

Okamura [A]: Thank you for the question. Considering only about the BD, then Primary Focus flagship situation, of course, good is good, bad is bad, so we make a judgment depending on the situation of that. What is great about the Primary Focus is when a flagship makes success, there are following projects waiting after that success.

For example, Immuno-Oncology or the Targeted Protein Degradation, we have the next programs just before the clinical phase. What I want to say here is that if such great things happen, of course, I will be really happy. Making success with these four flagships would lead to the late development phase. At the same time, the following programs would follow, so it's going to lead to the really big cash needs.

Even in that situation, would we need to do BD or not? The individual BD of this is good or bad, that is a different decision-making phase, or I rather don't want to say about this. If flagship clinical PoC is not really good, that means from this 2030 and afterwards, in other words, XTANDI business is attenuated, then that is covered by the Strategic Brands and the following growth will be covered by these primary focus products.

If you don't see any success for that, then at that time, probably, we need to do BD so that we can buy more time. That is likely. That's what I think. Whatever case, my answer is that BD, that is not something you can plan beforehand. This is quite a difficult area. We would say that this is an ideal opportunity for us, but that is not always waiting for us.

I don't know if this is the right way to say, but this is like the sushi on the conveyor. You want to eat something, but you have to wait until that dish would come, even if you want to have it. How our flagship would show the PoC, that really matters. It's quite complicated and is a complex situation, so we have to make a decision case by case.

Muraoka [M]: Thank you very much.

Ikeda [M]: Next, Goldman Sachs Securities, Mr. Ueda, please.

Ueda [Q]: Ueda from Goldman Sachs Securities, speaking. This is my first question regarding IZERVAY. In the United States, share is increasing steadily. During the presentation, you talked about the assessment of safety. In the selection compared to SYFOVRE, there may be a criterion. Any other points in the clinical settings? IZERVAY is performing very well. What are the factors behind this? Anything to add?

Okamura [M]: From the clinical perspective, Taniguchi may want to say something, so first, Taniguchi is going to respond. Then, with regards to commercial aspects, Claus is asked to add. Taniguchi-san, please?

Taniguchi [A]: Regarding IZERVAY, as was mentioned, safety aspect from the physicians, we are hearing their feedback. Compared to the other company's products, safety seems to be more favorable and higher. That is the impression of many doctors. GA associated with AMD may result in blindness in this disease. This is a very serious disease. Through receiving treatment, we would like to avoid adverse events as much as possible such as visual impairment. That is the wish of the doctors that is leading to the market share of IZERVAY.

As for the efficacy, as far as I have heard, compared to the competitor, there is not much difference, according to the feedback we have received in many cases. The efficacy and safety, balance is being considered, and that is why we are getting this market share at the current level. Claus, anything to add?

Zieler [A]*: Yes. I would like to give a perspective. Thank you, Tadaaki. As Tadaaki said, this is a serious disease. We're estimating 1.5 million patients in the US alone that have not had any option for this disease until the launch in FY2023 of two products. What you're seeing are two things.

Number one, patients who have not had an option for a long, long time are coming to the doctors to be treated, so that's the one wave that is pushing the development of this market. The other thing is then that doctors are favoring our product. As Naoki said in his presentation, we are estimating 60%, six-zero percent, of new patients to be placed on IZERVAY at this point. That gives us a very good feeling that, A, the product is doing what it's supposed to do; and B, that the safety profile is being recognized in the marketplace.

Now, let me just remind you, it's been only one year since we launched IZERVAY. This is a fantastic result, both in terms of market growth as well as the market share, the new patient share that we've been able to achieve.

Ueda [Q]: Thank you very much. I have a second question. Regarding the introduction of AVB-101, regarding the indication, it's a franchise you didn't have in the existing business before. Regarding the gene therapy, in the existing pipeline, there was delay in development. In your in-licensing, what is the point you kept on your mind in in-licensing this compound?

Okamura [A]: Thank you for your question. First, I'd like to briefly explain and then Taniguchi and Claus or Shitaka can respond. First, the target disease developed in very famous people who confess that they have this disease, it's a topic people are talking about and basically, it's progressive. There is no treatment for this.

This is a transformative treatment required in this field. When we have gene therapies for the future, we are hoping to expand. This can be a technology platform we can use to expand into various diseases into the future. The target disease for the time being is monogenic. There is a single gene deletion we're missing, which is the cause of the disease. Roughly speaking, neuromuscular disease or CNS diseases, I think I can classify as such.

We acquired the option for this project. The latter, CNS disease, is monogenic; that is going to be the category it's going to belong to. Generally speaking, gene therapies in very serious diseases without treatment options mostly, if you look at the prevalence, there's a certain number of patients already. Every year, how many of them will develop the disease, the number is going to be very small in most cases.

When the gene therapy product becomes available, the treatment is spread amongst the patients who've been long waiting for the treatment. When the drugs are utilized amongst them, their performance after that is greatly reduced, so the trend is going to be quite spiky.

The disease that we gained the option right this time, because there is no option of the treatment, the prevalence is higher. There are many patients. Considering the demographics, the development or the incidence rate would follow. It's not exactly the spiky, but the sustainable business is possible to be expected. That's the trigger of this deal this time. Whichever case is, at this moment of time, we acquire the Company or we acquired the asset, it's not something like that.

We would refer to the data from ongoing clinical trials and with that, we can make the decision if we go [forward] or not. Once the data becomes available, if the data is really good, then every other company would like to jump on that, so the price goes up and it will be more competitive.

For us, when we execute the option with what conditions that asset is possible to be acquired, that is pre-decided. Even if the price goes up, the already defined condition is applied for our acquisition. This is the structure of the deal. We will reduce the risk and once a good readout becomes available, then we don't need to pay an excessive amount. This is not the deal that I myself did. As a person who got involved in the BD, I think this is a really good approach. That's all.

Taniguchi [A]: Let me make some additional comment. From BD's perspective, a deal perspective, Okamura gave you a very detailed explanation. Here, I would like to make the medical perspective comment. Why did we make this contract of the license with them? This disease, this is the frontotemporal dementia, so this is what is called early onset dementia. This is a really devastating form. With the age of 40s to 60s, the disease is developed, and within 3 years to 13 years, the patient dies, so this is a really devastating disease.

Also, at the same time, unmet medical needs are really high. On top of that, for this disease, GRN, that is identified as the causal gene, so the target gene is quite clear. When the disease has such a clear target gene, gene therapy has a high potential for the method of the treatment. For this population, there is no existing treatment, and there, we can bring new therapy. In that sense, this program is extremely wonderful. That is one thing from me.

Point two from me is that AAV8-based genetic therapy is on the development phase. We have experience in gene therapy for mainly rare diseases. There, we established an experience together with AviadoBio. As it is possible, we would like to support the development in an appropriate manner, and we might be able to go forward after acquiring this option right.

This frontotemporal dementia is the target for this product. The population of the patient is likely to be bigger than what we targeted in the past. Gene therapy, only for the rare disease, is economically difficult as a business, so is the coming strategies of Astellas for gene therapy. We also would like to target the bigger population of the disease. This AviadoBio collaboration is really fitting the aspect that we are looking at.

Just like Okamura mentioned a little while ago, for this option contract, the ultimate final decision is after result. This contract itself, we can make our judgment after we see the data. It is relatively safe. We can have a good understanding of the data and also, we can view the regulatory perspective, including FDA, to make a final judgment if we execute the option right or not. In that perspective, we believe this is a really good contract.

Ueda [M]: Understood. Thank you very much for explaining the details. That's all from me.

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

Matsubara [Q]: Matsubara from Nomura Securities. Thank you for explaining. I have a question about IZERVAY. Regarding label update and DTC activities or campaign, prescription is going to go up. Looking at the GATHER2, disease after two years, there was not much difference in the visual acuity. Is that going to affect the prescription into the future? What's your view?

Okamura [M]: Thank you very much. First, clinically speaking, how to interpret GATHER2 data will be explained by Taniguchi. Then, how this is going to be perceived in the market, that is going to be additionally explained by Claus later. Taniguchi-san, please?

Taniguchi [A]: GATHER2 results and the BCVA, you're talking about the best corrected visual acuity, secondary endpoint, that is the secondary endpoint being assessed. BCVA is being used in the assessment and limitation, there are assessment challenges. GA lesions, in which area in the retina, the GA lesion could occur, depending on that, how patients are able to see would be very different. There is a difference.

You may know ophthalmology very well. From the central fovea, it's going to be closer to the central fovea or is that going to be far away from the central fovea in terms of the lesion? Depending on that, how patients are able to see, it would be very different. Missing part in the visual field, depending on the patient, that location is different.

By measuring BCVA, what is the clinical meaningfulness or significance to how appropriate it is to measure the efficacy, that's a challenge. Regardless of the location in the retina, the progression of the lesion can be slowed. We think that's very important. Irreversible retinal cell death could progress, then BCVA will decrease, and there can be a variety of retinal visual impairment. We hope that those patients will be treated earlier.

Zeiler [M]*: Yes. Thank you. Tadaaki explained the link very nicely between the functional endpoints and the lesions that we see growing in this disease. I think your second question was on the DTC, if I understood correctly. Is that correct?

Matsubara [M]*: Yes.

Zieler [A]*: Let me explain how we see this market developing. As I said in an earlier answer, this is a disease where there's been no option at all for many, many years. What you first see are patients who have been waiting for an option to come back to the doctor for a treatment but not everyone in the patient population knows that there is a new option available. We have to make that known. That is where the direct-to-consumer is playing. We're really trying to essentially already anticipate that the current penetration rate will have to be enhanced by informing more patients of new treatment options available.

There's one other way that we're thinking about increasing the market as such and that is if you think of the way patients go for their checkup in ophthalmology in the United States, you have the retina specialists. The retina specialists are the ones who are doing the injection for a disease like geographic atrophy. There's also many, many, many ophthalmologists who don't have that specialization. In addition to DTC, we're also thinking about how we can potentially reach these generalist ophthalmologists and help them diagnose and understand the disease and then refer to a retina specialist for treatment.

These are both mechanisms that we are exploring to make sure that the treatment that IZERVAY and the hope that IZERVAY provides really reaches every patient, every appropriate patient in the marketplace. For that, we have to communicate. We have to communicate directly to the consumer, and that's the DTC campaign, and/or we have to communicate to the generalist ophthalmology to diagnose and then refer the appropriate patients.

I hope that helps explain how the dynamic of the market, we see it changing over time. We are now only at the very, very beginning where the patients who are interested and who know and who are always asking for new options are now coming back to the retina specialist for consultation and for treatment but that dynamic will change over time.

Matsubara [Q]: Thank you very much. The second question is about the cost. IZERVAY DTC, I understand it quite well. VEOZAH DTC is also what you are going to do. What is the cost or expenses perspective? Would you please make a comment?

Okamura [A]: Thank you. Generally speaking, the several channel mix is considered. If we consider that is effective, we will continue or we will expand it further. If we cannot get the positive impact that we expected, then we'll stop. The measures will be turned over depending on the situation. More specifically, what are we concerned about? If you have any additional comments about that, would you make it, Claus-san?

Zieler [A]*: Yes. Naoki's absolutely right and we are looking very, very carefully at channel mix, and we're looking very, very carefully at ROI of the DTC campaigns. There are data points we can use to measure the impact of the DTC campaign. It usually comes with a little bit of a timing delay. In IZERVAY, we'll probably need some time before we can make that assessment. In VEOZAH, it's now already very clear that our DTC campaigns are correctly sized and are yielding the results that we anticipated.

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

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

Hyogo [Q]: Mitsubishi UFJ Trust Bank, Hyogo is my name. Thank you very much for giving me this opportunity. Thank you for your presentation. One question from me. Page 19, sustainable margin transformation is my question. Thank you for making this kind of presentation material this time. My question is what is considered as a challenge to share this slide with us and what exactly do you want to do? That's the core of my question.

This core operating motion, that's what you have been quite particular about. For the operational excellence, you're always aiming for the profit margin increases. Looking at these items, many of them are quite orthodox, if I use this time, which means that there is nothing new much, there is nothing added on. You shared this slide with us, that's because you have a strong commitment on these numbers or you also would like to communicate this internally as well as saying that you haven't done everything well, so you would like to improve that part. What's the significance of this slide? What are you thinking? That's my question.

Okamura [M]: Thank you very much. Kitamura is going to directly respond to you.

Kitamura [A]: Thank you very much. First of all, about the challenges. When this fiscal year started or, in other words, at the time of the last fiscal year financial announcement for the review of CSP2021, the three targets are reviewed in terms of the progress. There, cost management or margin improvement or the cost management, those were not well done. In the first three years, we haven't done it in a sufficient manner. That's what we feel.

Also, on the other hand, for the improvement of productivity, yes, we've been doing each matter, but that is controlled in the Company as a whole manner. For the cost management, especially, these kind of initiatives have been started about one year, and we also worked for the establishment of the mechanism for that. Just like Okamura mentioned, looking at our growth strategies, we see the growth room for the Strategic Brands, including SCM as well. If PoC is judged and established and coming towards the later phase of the development, there is a higher demand of R&D cost. We have to review our calculation, if that is the right calculation or not. That is revisited and that result is reflected into this slide.

On top of that, there's still room for growth, so we can spend all the assets or the budgeting to it. It's not like that. We also have to have a view about the profitability. We do the investment for the growth field. At the time, we need to see the profitability. That's our commitment for the management of control.

It is said that if the margin increases, then what kind of capital allocation we could think about. Of course, at the same time, we need to think about the return of the borrowings. If it has the capability of gaining revenue and a profit, then capacity of the borrowings will be increased as well.

Thinking about the long-term sustainable growth for us, this is quite a necessary approach. We will do this. We can do this. That's why we shared this with you this time.

Hyogo [Q]: Thank you very much. Then, before, you were doing this already individually, but including the top-down management, you have not been able to do this because of the growth investment. It was kind of mixed up. With a certain mechanism, you can now manage very well. Is my understanding correct?

Kitamura [A]: Yes, you're right.

Hyogo [Q]: Understood. Including the companies you acquired, you're going to ensure that management, that type of management?

Kitamura [A]: Yes, of course.

Hyogo [Q]: Understood. Then, I don't know in fiscal years, but you will give us an update on what kind of benefits you're achieving are likely to show into the future. Among employees, is this ensured among your employees? What's your impression? An initiative like this, even because of the top-down approach, the bottom part may not catch up. It may take time for this to penetrate at many companies. Over time, changes may not be being expressed as benefits because of an orthodox item, it may take time. That's my view. What about the penetration of this among your employees? This is my last question.

Okamura [A]: It is penetrating among our employees. We talked about the growth strategy, board ambition, and sustainable margin transformation. I talked about three. These are the three enterprise priorities we are working on. Top-down approach is one thing, but in a bottom-up approach, how much we can do, we are accumulating the initiatives and there are a variety of ideas. In that sense, this is an enterprise-wide initiative. It's not just being talked about by the top management, but I'm sure this is penetrating in our organization.

Hyogo [M]: Thank you very much. That's all from me. I am counting on you with high expectations.

Ikeda [M]: Next, today, from 5:00 PM, there's going to be another earnings call by another company. In four minutes or five minutes, we'd like to close.

From Sanford C. Bernstein, Ms. Sogi, we can entertain just one question from you.

Sogi [Q]: Thank you very much. Sustainable margin transformation is a topic I'd like to ask you. Regarding the development, enhancing our in-house capabilities, specifically, what kind of initiatives are you working on? Could you share?

Okamura [A]: Thank you for your question. I will explain the overall situation. For details, Taniguchi can add. Up until now, in the conduct of the clinical studies, we almost depended on CROs completely. Using CROs, there are benefits as well. For example, a three-arm Phase III study with 1,000 patients in each arm, we cannot do this alone, so we have to approach a variety of study sites to join us in our study. We have to spend a long time. We have to monitor the patient enrollment process. A third party with a broad network can do this. That was meaningful enough.

From some time ago, and if you look at the future portfolio to come, that kind of a clinical study will not exist at all into the future. If there's a middleman in between, the investigators joining the studies, we may not be able to communicate directly, but rather, we can go there directly to talk with the investigators. That's more valuable. That's very evident.

We used to pay money outside to CRO for outsourcing, but rather, we can do the operation of clinical studies. Once again, that's been restored. We did this in the 20th century, but we changed it to a CRO approach. Because of the progress of our pipeline and conducting the clinical studies is a core capability as a pharmaceutical company, depending on third party in this regard is not so good. We are trying to do this internally.

If there's anything to add, Taniguchi-san, please?

Taniguchi [A]: Okamura already explained, but if you just depend on outsourcing, it's costly. In terms of capabilities, what's happening at study sites and what are the issues and how we can address the situation quickly, we have to think about it. It may not be the best option in all cases.

There were such big issues to CROs, we will continue the collaboration with them wherever necessary. Internally, global clinical studies can be done. We'd like to have such a structure. At the same time, cost management there can be done by us, by establishing such a structure. We can reduce outsourcing costs, but also in the study, we can enhance efficiency within the study.

More recently, digitization or the use of AI can be done to enhance efficiency and quality. Various companies are working on this challenge. Such capabilities can be developed internally. In addition to cost reduction, quality can be higher at a faster sense of speed in the conduct of clinical studies at a relatively lower cost. We'd like to make efforts to that end.

Sogi [M]: Thank you very much.

Ikeda [M]: Thank you so much. I'm sure that you are waiting for the [attendance] of the questions, but because of the time, with this, we would like to close today's announcement.

Thank you very much for your participation.

[END]

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