



**Astellas Pharma Inc.**

Earnings Call for FY2025

April 27, 2026

## Event Summary

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<b>[Company Name]</b>	Astellas Pharma Inc.	
<b>[Company ID]</b>	4503-QCODE	
<b>[Event Language]</b>	JPN	
<b>[Event Type]</b>	Earnings Announcement	
<b>[Event Name]</b>	Earnings Call for FY2025	
<b>[Fiscal Period]</b>	FY2025	
<b>[Date]</b>	April 27, 2026	
<b>[Number of Pages]</b>	36	
<b>[Time]</b>	16:00 - 17:33 (Total: 93 minutes, Presentation: 36 minutes, Q&A: 57 minutes)	
<b>[Venue]</b>	Webcast	
<b>[Venue Size]</b>		
<b>[Participants]</b>		
<b>[Number of Speakers]</b>	5	
	Naoki Okamura	President and Chief Executive Officer (CEO)
	Atsushi Kitamura	Chief Financial Officer (CFO)
	Tadaaki Taniguchi	Chief Research and Development Officer (CRDO)
	Claus Zieler	Chief Commercial & Medical Affairs Officer (CCMAO)
	Nobuko Kato	Chief Communications & IR Officer
<b>[Questioners]</b>	Hidemaru Yamaguchi	Citigroup Global Markets
	Seiji Wakao	JPMorgan Securities
	Atsushi Seki	UBS Securities
	Akinori Ueda	Goldman Sachs
	Hiroyuki Matsubara	Nomura Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Tony Ren	Macquarie Capital Securities
	Miki Sogi	Sanford C. Bernstein
	Tatsuya Ozaki	Nikkei Inc.

## Presentation

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**Kato:** Thank you very much for your attendance in this FY2025 earnings call by Astellas Pharma Inc. I am Kato, Chief Communications and IR Officer. I would like to serve as the moderator for today.

Following our presentation today, we will move on to the Q&A session. The presentation will be based on the presentation materials available on our website.

Simultaneous interpretation in Japanese and English will be provided throughout the event, including the Q&A session. Please note that we cannot guarantee the accuracy of it. You can select your preferred language from the menu at the top of the Zoom webinar screen. If you select the original language, you will be able to listen to the audio in the original language without simultaneous interpretation.

This is some note from us. This material or presentation and answers and statements 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 advertisements nor provide medical advice of any kind.

Now, let me introduce you the participants from Astellas here today. Naoki Okamura, President and CEO; Chief Research and Development Officer, Tadaaki Taniguchi; Chief Commercial and Medical Affairs Officer, Claus Zieler; CFO, Atsushi Kitamura. These four are attending in this meeting.

Now, I would like to start the presentation of Okamura-san. The floor is yours.

**Okamura:** Hello, everyone. I'm Naoki Okamura from Astellas Pharma. Thank you very much for joining our FY2025 financial results announcement meeting out of a very busy schedule today.

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## Cautionary Statement Regarding Forward-Looking Information

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

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

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## Agenda



**FY2025 Results**



**FY2026 Outlook**



**Review of Corporate Strategic Plan 2021**

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Page three is the agenda for today. First, I start with FY2025 financial results.

## FY2025 Overview

**- Record-high Revenue (over 2.1 trillion yen) and Core OP (over 550.0 billion yen) -**

### Financial Results

<b>Revenue</b>	Significant growth of Strategic Brands (over +140.0 bil. yen YoY), driving double-digit revenue growth (+12% YoY)
<b>SG&amp;A expenses*</b>	Robust SMT progress, driving improvement in SG&A ratio (-2.3ppt YoY)
<b>Core OP</b>	Significant increase driven by Strategic Brands growth and robust SMT progress (+42% YoY) Core OP margin increased to 26.0% (+5.5ppt YoY)

### Pipeline Progress

- ✓ PADCEV: Significant progress in MIBC development
- ✓ 3 PoCs achieved (setidegrasib NSCLC, ASP2138, ASP7317)
- ✓ Phase 3 study initiated (setidegrasib 1L PDAC)\*\*
- ✓ Promising external assets in-licensed (ASP546C, VIR-5500)

\*Excl. US XTANDI co-promote fee. \*\*Apr 2026

Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA. SMT (Sustainable Margin Transformation): See [slide 36](#) for overview

1L: First line, MIBC: Muscle-invasive bladder cancer, NSCLC: Non-small cell lung cancer, PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept

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On page four, I will give you an overview of FY2025 results. Revenue reached over JPY2.1 trillion and core operating profit exceeded JPY550 billion, both achieved record high results. Significant growth of strategic brands by over JPY140 billion YoY has driven double-digit revenue growth. As for SG&A expenses, thanks to the robust progress of what we call SMT, sustainable margin transformation, our company-wide cost optimization initiative, SG&A ratio improved by 2.3 percentage points YoY.

Driven by strategic brands growth and robust cost management through SMT, core operating profit rose significantly, up by 42% YoY. Core operating profit margin increased by 5.5 percentage points YoY to reach 26%.

Our pipeline also progressed substantially. PADCEV made a significant progress in MIBC, muscle-invasive bladder cancer development. Following PoC achievement by setidegrasib in PDAC, pancreatic ductal adenocarcinoma in FY2024, a total of three PoCs were achieved in FY2025, namely, setidegrasib for NSCLC, ASP2138, and ASP7317. For setidegrasib, a Phase III study was initiated for PDAC in first-line settings. Promising external assets, ASP546C and VIR-5500 were licensed in, and our pipeline expansion made progress.

## FY2025 Financial Results

**Breaking records across Revenue, Core OP and Full OP - All-time highs**

(billion yen)	FY2024	FY2025	Change	Change (%)	Fx impact (YoY)	FY2025 FCST
<b>Revenue</b>	<b>1,912.3</b>	<b>2,139.2</b>	<b>+226.9</b>	<b>+11.9%</b>	+30.1	<b>2,100.0</b>
Cost of sales	349.2	408.4	+59.2	+17.0%	+10.3	406.0
SG&A expenses	843.0	860.3	+17.3	+2.0%	+3.6	859.0
US XTANDI co-promote fee	252.6	248.2	-4.3	-1.7%	-2.8	259.0
SG&A excl. the above	590.5	612.1	+21.6	+3.7%	+6.3	600.0
(SG&A ratio <sup>1</sup> )	30.9%	28.6%	-2.3ppt			28.6%
R&D expenses	327.7	314.8	-12.8	-3.9%	-0.5	315.0
(R&D ratio)	17.1%	14.7%	-2.4ppt			15.0%
<b>Core operating profit</b>	<b>392.4</b>	<b>555.7</b>	<b>+163.2</b>	<b>+41.6%</b>	+16.8	<b>520.0</b>
(Core OP margin)	20.5%	26.0%	+5.5ppt			24.8%
<b>&lt; Full basis &gt;</b>						
Amortisation of intangible assets	136.8	136.0	-0.8	-0.6%		
Other income	20.3	32.8	+12.5	+61.2%		
Other expenses	235.8	72.4	-163.3	-69.3%		
<b>Operating profit</b>	<b>41.0</b>	<b>382.6</b>	<b>+341.6</b>	<b>+832.4%</b>		<b>340.0</b>
Profit before tax	31.2	376.6	+345.4	-		330.0
<b>Profit</b>	<b>50.7</b>	<b>291.6</b>	<b>+240.8</b>	<b>+474.6%</b>		<b>250.0</b>

<sup>1</sup>Excl. US XTANDI co-promote fee  
Actual exchange rates of FY2025: 151 yen/USD, 175 yen/EUR (Actual exchange rates of FY2024: 152 yen/USD, 164 yen/EUR)  
Exchange rate assumption of FY2025 FCST: 150 yen/USD, 174 yen/EUR

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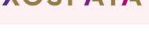

On page five, I will explain the FY2025 financial results. Across revenue, core operating profit, and full operating profit, we broke records to hit all-time highs since the founding of Astellas. Let me explain the main items.

Revenue exceeded the JPY2 trillion mark for the first time to reach JPY2,139.2 billion, up by 11.9% YoY, achieving a double-digit growth for two consecutive years. Core operating profit substantially exceeded the JPY500 billion mark to reach JPY555.7 billion, significantly increasing by 41.6% YoY.

The bottom half of this page shows our full basis results. Operating profit was JPY382.6 billion, and profit was JPY291.6 billion, both up significantly YoY.

## FY2025 Financial Results: Main Brands

*All Brands increased across the board, with Strategic Brands total growing over 140.0 bil. yen YoY*

(billion yen)	FY2025 Act	YoY Growth	
<b>Strategic Brands Total</b>	<b>480.3</b>	<b>+143.9 (+43%)</b>	<b>Significant growth driving overall revenue and profit growth</b>  <b>PADCEV</b> <ul style="list-style-type: none"> <li>Sales growth driven by strong 1L mUC penetration</li> <li>Early momentum for cis-ineligible MIBC in the US</li> </ul> <b>IZERVAY</b> <ul style="list-style-type: none"> <li>Sales growth driven by increased momentum in new patient starts</li> <li>Steady increase in treatment rate, estimate ~20% on complement inhibitor</li> </ul> <b>VYLOY</b> <ul style="list-style-type: none"> <li>Sales growth driven by rapid expansion across all regions</li> <li>High Claudin 18 testing rates drove strong performance</li> </ul>
 <b>PADCEV</b>	<b>221.2</b>	<b>+57.1 (+35%)</b>	
 <b>IZERVAY</b>	<b>77.6</b>	<b>+19.3 (+33%)</b>	
 <b>VYLOY</b>	<b>63.1</b>	<b>+50.9 (&gt;+100%)</b>	
 <b>VEOZAH</b>	<b>46.6</b>	<b>+12.8 (+38%)</b>	
 <b>XOSPATA</b>	<b>71.8</b>	<b>+3.9 (+6%)</b>	
 <b>Xtandi</b>	<b>960.8</b>	<b>+48.5 (+5%)</b>	Steady global sales growth, reaching projected peak levels

VEOZAH: Approved as "VEOZA" in ex-US.  
 1L: First line, mUC: Metastatic urothelial cancer, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer

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On page six, I will explain the FY2025 financial results of our main brands.

Sales of all brands increased across the board, with strategic brand sales combined strongly growing by over JPY140 billion in total YoY. First, sales of five strategic brands, namely, PADCEV, IZERVAY, VYLOY, VEOZAH, and XOSPATA reached JPY480 billion in total, substantially up by JPY143.9 billion or 43% YoY.

PADCEV and VYLOY, in particular, drove the strong growth, increasing by more than JPY50 billion, respectively.

Strategic brands have high profitability, and their growth made a great contribution to the FY2025 consolidated revenue and profit increase as a whole.

Next, I will explain individual strategic brands and XTANDI.

PADCEV sales increased to JPY221.2 billion, up by JPY57.1 billion or 35% YoY. Global sales growth was driven by strong first-line mUC penetration continuously. Sales expanded in all regions. In addition, early momentum for cis-ineligible MIBC approved in November last year in the United States also contributed greatly to sales expansion.

As for IZERVAY, sales rose to JPY77.6 billion, up by JPY19.3 billion or 33% YoY. New patient starts, which are important metrics, steadily increased. In the recent Q4 between January and March, demand grew more than 10% QoQ. Treatment rate for complement inhibitors as a whole, including the competitors' product, rose to about 20%. Market penetration made steady progress.

With regard to VYLOY, sales reached JPY63.1 billion, substantially up by JPY50.9 billion YoY, significantly exceeding our initial expectations. Market penetration progressed extremely well across all regions. High Claudin 18 testing rates contributed greatly to strong performance.

VEOZAH and XOSPATA sales rose steadily, respectively.

XTANDI sales increased to JPY960.8 billion, up by JPY48.5 billion or 5% YoY, reaching projected peak sales levels 13 years after launch.

## FY2025 Financial Results: Cost Items

- **Cost optimization (SMT): Achieved ~25.0 bil. yen (SG&A expenses, R&D expenses, cost of sales)**
- **SG&A ratio improved by 2.3ppt YoY**

Cost Items	YoY change	Ratio to Revenue	(billion yen)
<b>SG&amp;A expenses*</b>	+3.7% (+2.6% excl. FX impact)	SG&A ratio: 28.6%	YoY increase excl. FX impact: approx. +15.0 ✓ Strategic Brands-related expenses for further growth: approx. +10.0 ✓ SMT cost optimization: approx. 11.0 (Organizational restructuring, reduction of mature products-related expenses, streamlining IT infrastructure, etc.)
<b>R&amp;D expenses</b>	-3.9% (-3.8% excl. FX impact)	R&D ratio: 14.7%	YoY decrease excl. FX impact: approx. -12.0 ✓ Increase in pipeline clinical development costs (setidegrasib and ASP546C): approx. +5.0 ✓ SMT cost optimization: approx. 10.0 (Outsourcing costs reduction through insourcing development capabilities, incl. clinical trials etc.) ✓ Decrease in Strategic Brands clinical development costs: approx. -5.0

\*Excl. US XTANDI co-promote fee  
SMT: Sustainable Margin Transformation

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Page seven is about cost items. With the SMT initiative, we realized cost optimization of about JPY25 billion in FY2025 for SG&A expenses, R&D expenditure, and cost of sales combined. Partly due to the SMT effect, excluding US XTANDI co-promotion fees, SG&A cost ratio improved by 2.3 percentage points YoY.

Let me explain the specific breakdown of SG&A costs and R&D expenditure. SG&A expenses, excluding FX impact, rose by 2.6% YoY. While we increased our revenue by more than 10%, we were able to manage SG&A expenses at a level almost similar to the previous year.





Investment toward further growth of strategic brands increased by about JPY10 billion YoY. On the other hand, as a SMT progress, we realized cost optimization of about JPY11 billion through steady progress in continuous global organizational restructuring, reduction of mature products-related expenses, and streamlining IT infrastructures, etc. As a result, by fully executing investments for strategic brands, we were able to offset the increase through SMT cost optimization, according to assessment.

R&D expenditure, excluding FX impact, decreased by 3.8% YoY. While clinical development costs for pipeline drugs such as setidegrasib and ASP546C increased by about JPY5 billion, we made progress in outsourcing cost reduction through in-sourcing development capabilities, including clinical trials, etc., under SMT, which led to cost optimization of about JPY10 billion, so we were able to fully offset the cost increase factors. In addition, with the completion of large clinical studies, development costs for strategic brands decreased by about JPY5 billion.

# Lifecycle Management of Strategic Brands: FY2025 Achievements

(Blue: Updates since the last financial results announcement)

**Strong development progress toward maximization of Strategic Brands value, notably for PADCEV**

Brand	Indication	Key achievements
	Muscle-invasive bladder cancer (MIBC)	<b>Cis-ineligible:</b> Phase 3 EV-303 study primary endpoint met (Aug) US: sBLA approved (Nov), Europe: Type II variation accepted (Nov), Japan: sBLA submitted (Jan)
		<b>Cis-eligible:</b> Phase 3 EV-304 study primary endpoint met (Dec) <b>Europe: Type II variation accepted (Mar), US: sBLA accepted under priority review (Apr)</b>
		<b>Bladder-sparing:</b> <b>Phase 2 EV-209 study initiated (Apr)</b>
	GA secondary to AMD	Japan: Approved (Sep)
	Gastric and GEJ cancer	Phase 3 LUCERNA study initiated (Jun)
	VMS associated with menopause	Japan: Phase 3 STARLIGHT 2 study primary endpoint met (Jan) <b>China: Phase 2 study primary endpoint met (Apr)</b>

Not exhaustively listed. VEOZAH: Approved as "VEOZA" in ex-US. \*Apr 2026  
 AMD: Age-related macular degeneration, Cis: Cisplatin, GA: Geographic atrophy, GEJ: Gastroesophageal junction, sBLA: Supplemental Biologics License Application, VMS: Vasomotor symptoms

Page eight shows the life cycle management of strategic brands. Let me explain the main achievements in FY2025.

Updates since the last financial results announcement are shown in blue, including the achievements in April 2026. Strong development progress was made toward the maximization of our strategic brands value, notably for PADCEV.

I will explain the latest status of PADCEV on the next page.

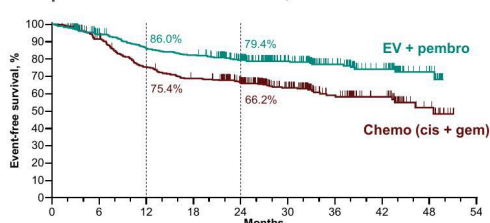
Regarding VEOZAH, in the Phase II study in China, primary endpoint was met in April this year. Based on the study results, we are planning to file a submission in China.

## enfortumab vedotin (EV) / PADCEV: Latest Status

Starting development for **bladder-sparing MIBC** to potentially maximize PADCEV's impact

### Cisplatin-eligible MIBC

- EV-304 study data<sup>1</sup>:  
(Perioperative EV + pembro vs. neoadjuvant chemo)
  - ✓ **Event-free survival (EFS): HR=0.53, P<0.0001\***
  - ✓ **Overall survival (OS): HR=0.65, P=0.0029\***
  - ✓ **pCR rate: 55.8% vs. 32.5%, P<0.0001\***



- Regulatory applications accepted in Europe (Mar) and US (Apr<sup>\*\*</sup>)
  - ✓ US PDUFA date: Aug 17, 2026 (priority review)

1. ASCO GU (American Society of Clinical Oncology Genitourinary Cancers Symposium) 2026. 2. NCT07475906. \*1-sided P value. \*\*Apr 2026  
chemo: Chemotherapy, cis: Cisplatin, FSD: First subject dosed, gem: Gemcitabine, HR: Hazard ratio, MIBC: Muscle-invasive bladder cancer, pCR: Pathological complete response, PDUFA: Prescription Drug User Fee Act, pembro: Pembrolizumab

### Potential upside in MIBC

- Bladder-sparing MIBC
  - ✓ ~30% of MIBC patients are ineligible for or refuse radical cystectomy (RC)
  - ✓ High unmet medical need for a treatment option that delays or avoids RC, and preserves the bladder
  - ✓ **Single-arm Phase 2 study (EV-209)**<sup>2</sup>: FSD in Apr 2026
    - MIBC patients who are eligible for but do not undergo RC
    - EV + pembro combo (EV: 9 x 21-day cycles)
    - Primary endpoints: clinical complete response (cCR) rate, bladder-intact EFS (BI-EFS) rate at 2 years
  - ✓ **Registrational Phase 3 study (EV-309)**
    - Under preparation to start in 1H/FY2026
- China
  - ✓ Regulatory application under preparation based on EV-303 and EV-304 studies

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On page nine, I will explain the latest status of PADCEV development in MIBC. In addition to development in the perioperative settings we have worked on so far, we also started development for bladder-sparing MIBC to potentially maximize PADCEV's impact. As for cisplatin-eligible MIBC shown on the left, we presented the latest data from the EV-304 study at the ASCO GU in February.

As is shown in the figure, perioperative PADCEV and pembrolizumab significantly improved EFS event-free survival, a primary endpoint compared to neoadjuvant chemotherapy.

Also, OS, overall survival, pCR, pathological complete response, improved significantly as well. Based on the study results, we took procedures for an additional indication globally.

Regulatory applications were accepted in Europe in March. In the United States in April this year, we were granted priority review designation with a PDUFA date set for the August 17, 2026.

Next, let me explain the right-hand side, development for bladder-sparing MIBC as an opportunity for further growth. It is known that about 30% of MIBC patients are ineligible for or refuse radical cystectomy or RC. These patients will not be eligible for EV-303 or EV-304 studies.

There are high unmet medical needs for treatment option that delays or avoids RC and preserves the bladder.

Based on the extremely favorable data obtained consistently from clinical studies in MIBC by now, we initiated development of PADCEV for bladder-sparing MIBC. EV-209 is a single-arm Phase II study initiated in April. The study enrolls MIBC patients who are eligible for, but select not to undergo RC, to evaluate the efficacy and safety of PADCEV and pembrolizumab combination. PADCEV is administered in nine cycles, the same duration of treatment with MIBC studies so far.

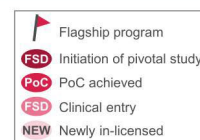
Primary endpoints are clinical complete response, cCR and bladder intact event-free survival, BI-EFS at two years.

In addition, EV-309 as a registrational Phase III study is under preparation in parallel. We are planning to start this study in H1.

Also in China, regulatory application is under preparation based on EV-303 and EV-304 studies. Bladder-sparing treatment in China is not factored in to our current peak sales forecast for PADCEV. If successful, there can be further upside potential.

## Progress in Focus Area Approach: FY2025 Achievements

**Significant pipeline progress: 3 PoCs achieved, 1 Phase 3 study initiated  
3 clinical entries, 2 promising assets in-licensed**



Primary Focus	Biology/Modality/Technology	Program	MoA	Preclinical	Pre-PoC	PoC achieved	Pivotal study
Immuno-Oncology	T-cell engager	ASP2138	Anti-CLDN18.2/anti-CD3			PoC	G/GEJ
		VIR-5500	Anti-PSMA/anti-CD3		NEW		
	iADC	ASP2998	TROP2-targeted iADC		FSD		
Targeted Protein Degradation	Protein degradation	setidegrasib (ASP3082)	KRAS G12D degrader			PoC	FSD PDAC
		ASP5834	Pan-KRAS degrader		FSD	PoC	NSCLC
Genetic Regulation	Gene replacement (AAV)	AT845	GAA gene			PoC judgement ongoing	
		ASP2957	MTM1 gene		FSD		
Blindness & Regeneration	Cell replacement	ASP7317	RPE cells			PoC	
Others (non-PF)	ADC	ASP546C	ADC targeting CLDN18.2			NEW	

\*Apr 2026. AAV: Adeno-associated virus, iADC: (immunostimulatory) Antibody-drug conjugate, CLDN: Claudin, GAA: Acid alpha-glucosidase, G/GEJ: Gastric/gastroesophageal junction, KRAS: Kirsten rat sarcoma viral oncogene homologue, MoA: Mechanism of action, MTM1: Myotubularin 1, NSCLC: Non-small cell lung cancer, PDAC: Pancreatic ductal adenocarcinoma, PF: Primary focus, PoC: Proof of concept, PSMA: Prostate-specific membrane antigen, RPE: Retinal pigment epithelial, TROP2: Trophoblast cell-surface antigen 2

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On page 10, regarding focus area approach, I will explain the main achievements in FY2025. Achievements made in April 2026 are also included here. Over the past year, our pipeline made significant progress and expansion with three PoCs was achieved, one Phase III study initiated, three clinical entries, and two promising external assets in-licensed. ASP2138 in immuno-oncology achieved PoC in gastric and GEJ, gastroesophageal junction adenocarcinoma. Preparation is now underway for rapid initiation of Phase III study.

Furthermore, as a follow-on program, we licensed in VIR-5500 from Vir Biotechnology.

ASP2998 made a clinical entry to expand our portfolio.

Setidegrasib in TPD, targeted protein degradation, achieved multiple important advances.

In PDAC, where PoC was achieved at the end of FY2024, Phase III study was initiated in the first-line settings. Furthermore, PoC was achieved also in NSCLC. Phase III study is now under preparation.

In addition, ASP5834, a pan-KRAS degrader, also made clinical entry. Pipeline expansion is making steady progress.

As for AT845 in genetic regulation, additional analysis is ongoing for PoC judgment.

ASP2957 also made clinical entry.

New programs, including ASP2998 in immuno-oncology will be explained in detail on the next page.

ASP7317 in blindness and regeneration achieved PoC in patients with severe vision impairment due to GA, geographic atrophy. The next study plan is now under discussion with the regulatory authorities.

Also, we licensed in ASP546C from Evopoint to further solidify our leadership position in the Claudin 18.2 space.

## Progress in Focus Area Approach: New Clinical Programs

*Next-generation innovative programs advancing into clinical development*

### ASP2998

**TROP2-targeted immunostimulatory ADC (iADC) with dual payloads**

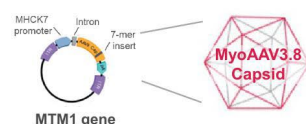
- Target disease: Solid tumor
- TROP2-directed monoclonal antibody conjugated with cytotoxic topoisomerase I inhibitor and immunomodulator STING agonist
- Superior efficacy vs. TROP2-directed toxin ADC demonstrated in mouse model<sup>1</sup>
- FSD in Phase 1b/2 study in Feb 2026 (NCT07287995)



### ASP2957

**Next-generation gene therapy for XLMTM with novel AAV capsid**

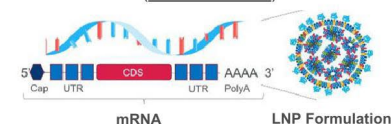
- Target disease: XLMTM
- Delivers a human MTM1 gene using a muscle-targeted MyoAAV3.8 capsid
- High muscle specificity and reduced liver targeting demonstrated in nonclinical studies<sup>2</sup>
- FSD in Phase 1/2 VALOR study in Apr 2026: ~100-fold lower dose level vs. AT132 (NCT07052929)



### ASP2246

**Direct reprogramming using mRNA-LNP for ischemic stroke recovery**

- Target disease: Motor dysfunction associated with ischemic stroke
- mRNA encoding human NeuroD1 encapsulated in novel LNP for neuronal regeneration
- Conversion of astrocytes into neurons and improved motor dysfunction in monkey model demonstrated<sup>3</sup>
- FSD in Phase 1/2 study anticipated for Q1/FY2026 (NCT07318714)



1. American Association for Cancer Research (AACR) 2026, 2. Muscular Dystrophy Association 2026, 3. International Stroke Conference 2026. See slide 37 for nonclinical data.  
ADC: Antibody-drug conjugate, AAV: Adeno-associated virus, FSD: First subject dosed, LNP: Lipid nanoparticle, mRNA: Messenger RNA, MTM1: Myotubularin 1, STING: Stimulator of interferon genes, TROP2: Trophoblast cell-surface antigen 2, XLMTM: X-linked myotubular myopathy

On page 11, I will explain new clinical programs. Next-generation innovative programs have advanced into clinical development.

ASP2998 is a program which leverages a platform called immunostimulatory ADC or iADC generated from joint research with Sutro. TROP2-directed monoclonal antibody is conjugated with two payloads, cytotoxic topoisomerase 1 inhibitor and immunomodulator STING agonist.

In nonclinical studies in the mouse model, superior efficacy was demonstrated versus the existing TROP2-directed ADCs. From now on, efficacy and safety will be confirmed in human in clinical studies.

ASP2957 has been created as a gene therapy for XLMTM, X-linked myotubular myopathy like AT132. It uses a novel muscle-targeted AAV capsid; high muscle specificity and reduced liver targeting was demonstrated in nonclinical studies. This enables clinical study initiation at a dose level about 100-fold lower compared to AT132. With the progress of ASP2957, we decided on a strategic hold for AT132. Moving forward, we will focus on the development of ASP2957 as a gene therapy for XLMTM.

ASP2246 is a program aimed at recovery from motor dysfunction associated with ischemic stroke by using an approach called direct reprogramming. Messenger RNA encoding human NeuroD1 is encapsulated in novel LNP, lipid nanoparticles, to enhance efficiency of delivery into cells.

Messenger RNA encoding human NeuroD1 promotes conversion of brain astrocytes into neurons and induces neuronal regeneration. In a nonclinical study using a monkey model, improved motor dysfunction was demonstrated with intracerebral infusion of ASP2246.

Phase I/II study enrollment has been initiated by now. FSD first subject dose is anticipated for Q1. You can find nonclinical study data of these programs summarized on page 37 in the appendix. Please refer to it at your leisure.

From here, I will explain FY2026 outlook.

## FY2026 Outlook: Overview

### - Expected to reach record-high Revenue and OP -

#### FY2026 Forecast

- Revenue: Over **2.2 trillion yen** (+4% YoY) driven by significant growth in Strategic Brands (**+130.0 bil. yen, +27% YoY**)
- Cost items: Continue cost optimization through SMT (**~40.0 bil. yen**)
  - ✓ SG&A expenses\*: Further improvement in SG&A ratio (-2.3ppt YoY)
  - ✓ R&D expenses: Expand investments from FY2026 onward aligned with Phase 3 study initiations
- Core OP: Over **600.0 bil. yen** (+12% YoY) and margin **27.9%** (+2.0ppt YoY)

#### Pipeline

- PADCEV: Multiple filings and regulatory decisions, Phase 3 study for bladder-sparing MIBC
- Phase 3 studies for setidegrasib and ASP2138

#### Shareholder Return

- Dividend per share forecasted at 80 yen, an increase of 2 yen

\*Excl. US XTANDI co-promote fee  
Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA  
SMT: Sustainable Margin Transformation, MIBC: Muscle-invasive bladder cancer

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On page 13, I will explain an overview of the FY2026 outlook. In FY2026, our performance is forecast to reach record-high results. Revenue is expected to expand to over JPY2.2 trillion, driven by growth of strategic brands by over JPY130 billion YoY, according to our forecast. Due to this significant growth, we're expecting a revenue increase.

Regarding cost items, we will continue the initiative to achieve about JPY40 billion in cost optimization. SG&A ratio is expected to improve by 2.3 percentage points YoY. We plan to increase investment in R&D in line with the growing number of new Phase III trials. Core OP is expected to increase by 12% to over JPY600 billion, and the core OP margin is projected to rise to 27.9%.

In our pipeline regarding PADCEV for MIBC, we plan to conduct multiple filings and regulatory decisions as well as initiate new Phase III trials. We also plan to initiate Phase III trials for setidegrasib and ASP2138.

Regarding shareholder returns, we forecast dividend per share at JPY80, up JPY2.

## FY2026 Forecast

- **Record-high Revenue over 2.2 trillion yen and Core OP over 600.0 billion yen**
- **Core OP margin to reach 27.9% driven by Strategic Brands growth and SMT cost optimization**

FX rates for FY2026 FCST: 150 yen/USD, 180 yen/EUR  
FX rates for FY2025 Actual: 151 yen/USD, 175 yen/EUR

(billion yen)	FY2025 Actual	FY2026 FCST	Change	Main Assumptions
<b>Revenue</b>	<b>2,139.2</b>	<b>2,220.0</b>	<b>+80.8</b>	• Strategic Brands: approx. +130.0, XTANDI: approx. -50.0
SG&A expenses	860.3	800.0	-60.3	• SMT cost optimization: approx. 40.0 (mainly SG&A)
US XTANDI co-promote fee	248.2	216.0	-32.2	
SG&A excl. the above (SG&A ratio)	612.1 28.6%	584.0 26.3%	-28.1 -2.3ppt	Factor for increase in R&D expenses:
R&D expenses (R&D ratio)	314.8 14.7%	355.0 16.0%	+40.2 +1.3ppt	• Mainly clinical development costs increase incl. Phase 3 study initiations (PADCEV & VYLOY LCM, setidegrasib, ASP2138, ASP546C, VIR-5500, etc.)
<b>Core operating profit</b> (Core OP margin)	<b>555.7</b> 26.0%	<b>620.0</b> 27.9%	<b>+64.3</b> <b>+2.0ppt</b>	• Increase driven by Strategic Brands growth and SMT cost optimization
<b>&lt;Full basis&gt;</b>				
<b>Main adjustments excluded on core basis</b>				
<b>Operating profit</b>	<b>382.6</b>	<b>395.0</b>	<b>+12.4</b>	• Amortisation of intangible assets: approx. 140.0 • Other expenses: approx. 80.0 (risk of impairment losses**, expenses related to organizational restructuring, etc.)

\*Excl. US XTANDI co-promote fee  
Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA, SMT: Sustainable Margin Transformation, LCM: Lifecycle Management

\*\*No impairment indication as of April 2026

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On page 14, I will explain the full-year forecast for FY2026. For FY2026, we anticipate revenue of over JPY2.2 trillion and core OP of over JPY600 billion, surpassing the record high achieved in FY2025. First, for FX rates, we are assuming JPY150 to the US dollar and JPY180 per euro for FY2026. We forecast revenue of JPY2.22 trillion, an increase of JPY80.8 billion YoY.

Although we anticipate a decline in sales of XTANDI, we expect to secure overall revenue growth driven by the strong performance of strategic brands. We forecast SG&A expenses of JPY800 billion, down JPY60.3 billion YoY. Of this amount, XTANDI co-promotion expenses in the US are expected to decrease in line with the decline in its US sales.

Excluding co-promotion expenses, SG&A is projected to be JPY584 billion, down JPY28.1 billion YoY. The cost optimization through SMT is estimated to be about JPY40 billion. The majority of this relates to SG&A optimization and is expected to contribute to the reduction in SG&A. R&D expenses are projected to be JPY355 billion, up JPY2 billion YoY. This increase is primarily due to the high clinical development costs, including initiations of Phase III studies.

To further solidify our mid- to long-term growth, we will accelerate investment in promising pipeline candidates such as setidegrasib, ASP2138, ASP546C, and VIR-5500 in addition to the life cycle management of PADCEV and VYLOY.

As development progresses, we expect to continue investing at this level or higher. As a result, the focus is core OP of JPY620 billion, up JPY64.3 billion YoY, representing double-digit growth of 12%. We anticipate that growth in strategic brands and cost optimization through the SMT will contribute significantly to this profit increase. We expect the core OP margin to be 27.9%, up 2 percentage points YoY.

Next is the full basis operating profit. As a major adjustment item excluded from the core basis, we anticipate amortization of intangible assets of about JPY140 billion. Additionally, we have factored in about JPY80 billion in other expenses. This includes impairment loss risks of about JPY40 billion and the costs associated with organizational restructuring. As a result, we focus on operating profit of JPY395 billion, an increase of JPY12.4 billion YoY.

## FY2026 Forecast: Main Brands

Strategic Brands to **drive overall revenue and profit growth, led by PADCEV, IZERVAY and VYLOY**



FX rates for FY2026 FCST: 150 yen/USD, 180 yen/EUR (FX rates for FY2025 Actual: 151 yen/USD, 175 yen/EUR). VEOZAH: Approved as "VEOZA" in ex-US. 1L: First line, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, IRA: Inflation Reduction Act, EST (Established Markets): Europe, Canada, etc.,

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Page 15, the explanation of the outlook for our main brands for FY2026. The strategic brands will continue to drive growth in consolidated revenue and profit, with particular contributions expected from PADCEV, IZERVAY, and VYLOY. We anticipate double-digit growth for each of these brands, with total sales expected to exceed the JPY600 billion mark, reaching JPY610 billion, a YoY increase of about JPY130 billion or 27%.

PADCEV, we expect continued strong growth driven by further market penetration of first-line mUC. In particular, we anticipate growth in EU, where reimbursement is progressing. In the US, in addition to the full-year contribution from cisplatin-ineligible MIBC, we anticipate sales contributions from the cisplatin-ineligible MIBC indication, for which the filing was recently accepted starting during the current fiscal year.

IZERVAY is expected to see steady sales growth, building on the sales infrastructure expanded last fiscal year. We will further strengthen promotional activities and through strategic initiatives. We will aim to expand the inhibitor market and increase the number of new patients.

VYLOY, we anticipate continued solid growth across all regions, driven by a further increase in testing rates and expansion of the patient base and market share. We expect steady growth for both VEOZAH and XOSPATA.

XTANDI, the negative impact of price reduction associated with the IRA, which takes effect on January 2027 in the US, is expected to become apparent starting in Q4. In addition, combined with the impact of patent expiration in certain countries, global sales are expected to decrease by about JPY50 billion YoY.

Please note that starting in FY2026, we have discontinued the disclosure of sales forecast for individual products. We believe it is important to grow our five strategic brands as one whole, and we hope to engage in dialogue focused on third mid- to long-term growth trajectory rather than being preoccupied with the short-term fluctuations in individual products.

Regarding XTANDI and mirabegron, we anticipate that they will be significantly affected by external factors such as patent situations in the future. As an exception, we are disclosing the sales forecast for your better understanding of our assumptions and outlook going forward. Through timely and appropriate information

disclosure and communication, we will continue to strive to enhance our mid- to long-term corporate value by engaging a constructive dialogue with investors.

## Lifecycle Management of Strategic Brands: FY2026 Key Expected Events

Expecting multiple regulatory events across Strategic Brands

Brand	Indication	FY2026				FY2027+
		Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
 PADCEV	Cis-ineligible	Europe: Regulatory decision		Japan: Regulatory decision		
	Muscle-invasive bladder cancer (MIBC)	China: filing		US: Regulatory decision (PDUFA date: Aug.17)		
		Cis-eligible	Japan: filing		Europe: Regulatory decision	
	Bladder-sparing	Phase 3 EV-309 study initiation				
 izervay	GA secondary to AMD	China: filing				
 VYLOY	Gastric and GEJ cancer					Phase 3 LUCERNA study data readout
 VEOZAH	VMS associated with menopause	Phase 3 STARLIGHT 3 study data readout	Japan: filing	China: filing		
	VMS in breast cancer women					Phase 3 HIGHLIGHT 1 study data readout

VEOZAH: Approved as "VEOZA" in ex-US

AMD: Age-related macular degeneration, Cis: Cisplatin, GA: Geographic atrophy, GEJ: Gastroesophageal junction, PDUFA: Prescription Drug User Fee Act, VMS: Vasomotor symptoms

Page 16 about the life cycle management of the strategic brands. I will explain the major events expected in FY2026. We are expecting multiple regulatory events across strategic brands.

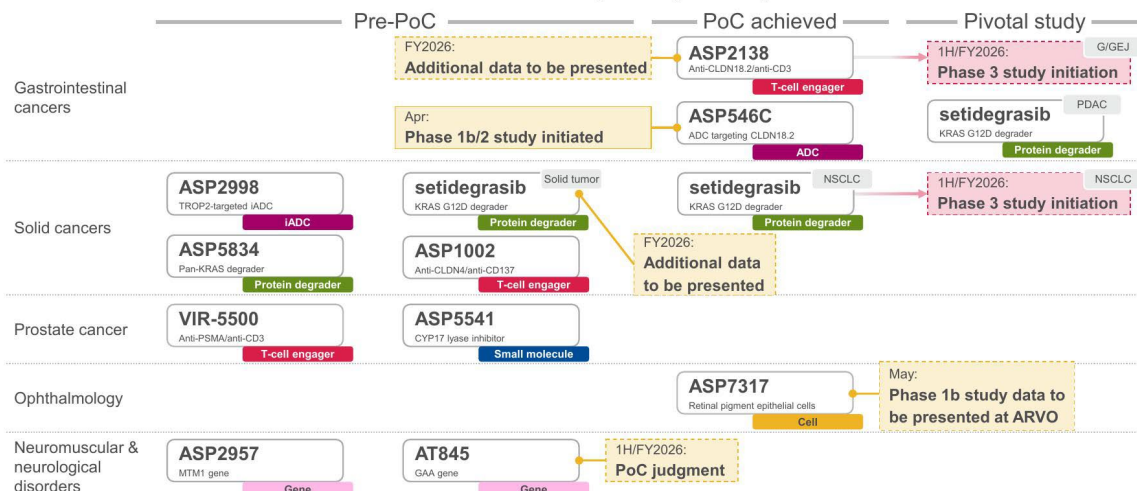
For PADCEV, we expect regulatory decisions on the EU and Japanese filing based on EV-303 study for cisplatin-ineligible MIBCs in H1 and H2, respectively. In addition, we expect the Japanese filing based on the EV-304 study for cisplatin-eligible MIBC in Q1, with regulatory decisions for the US and EU submissions anticipated in Q2 and H2, respectively. Furthermore, we plan to file in China based on both the EV-303 and EV-304 studies in Q1. We also plan to initiate the Phase III EV-309 study for bladder-sparing therapy in H1.

IZERVAY, we plan to file in China in Q1. There are currently no approved treatments in China for geographic atrophy and serious conditions. Following constructive discussions with the authorities, we plan to file based on data from overseas clinical trials.

VEOZAH, we expect study data readout from the STARLIGHT 3 trial, which evaluates long-term safety in Japanese women, to become available in Q1, and we plan to file in Japan in Q2 based on those results. We also plan to file in China in Q3.

## Progress in Pipeline: FY2026 Key Expected Events

**Phase 3 studies to be initiated for ASP2138 and setidegrasib (NSCLC)**



As of Apr 2026. Not exhaustively listed. (i)ADC: (immunostimulatory) Antibody-drug conjugate, ARVO: Association for Research in Vision and Ophthalmology, CLDN: Claudin, GAA: Acid alpha-glucosidase, G/GEJ: Gastric/gastroesophageal junction, KRAS: Kirsten rat sarcoma viral oncogene homologue, MTM1: Myotubularin 1, NSCLC: Non-small cell lung cancer, PoC: Proof of concept, PDAC: Pancreatic ductal adenocarcinoma, PSMA: Prostate-specific membrane antigen, TROP2: Trophoblast cell surface antigen-2

On page 17, this is an outline of the key pipeline events expected in FY2026. We plan to initiate Phase III trials for ASP2138 in first-line gastric cancer and for setidegrasib in second line or later non-small cell lung cancer in H1. We are also considering announcing additional data for each of these studies within the current fiscal year. Details will be provided once the announcements are officially confirmed.

Although this is an event that has already been achieved, we initiated a global Phase Ib/II study of ASP546C led by Astellas in April.

ASP7317, we will present additional data from Phase Ib trial at ARVO, Association for Research in Vision and Ophthalmology in May.

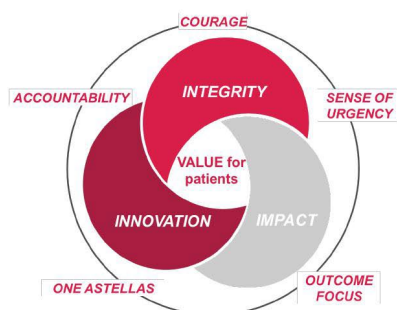
For AT845, we are currently conducting additional analysis of PoC judgment and expect to reach a decision in H1.

## Transformation of Organizational Culture and Operating Model

*Executed initiatives to continuously generate innovations and embedded them across company*

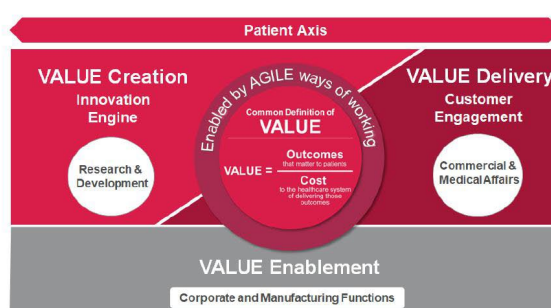
### Fostering organizational culture

- Set Organizational Health Goals
- Defined “Organizational Values & Behaviors” as a culture foundation



### End-to-end operating model

- Shift from region- or function-based to “patient axis”
- Enabled faster decision-making through empowerment and agile ways of working



Finally, I would like to review our corporate strategy plan for CSP2021. On page 19, I will explain the transformation of our organizational culture and operating model that we undertook during the CSP2021 period.

As a foundation to continuously generate innovations, we have implemented various initiatives related to human resources and organization structure and have embedded them across the Company. In fostering organizational culture, we established organizational health goals at the start of CSP2021 and in advancing efforts company-wide. As reported in the previous sustainability meetings, we have achieved many results directly linked to our business over the past five years.

Furthermore, in April 2025, we simplified and consolidated our culture foundation to define organizational values and behavior. By ensuring that every employee acts based on a clear shared understanding, we aim to strengthen collaboration and create and deliver greater value to patients more quickly. We have also significantly transformed our operating models.

Under the new structure launched in April 25, we shifted the top-level management focus from region or function to a “patient axis” and introduced an end-to-end business model.

With empowering cross-functional teams organized around programs and brands and strongly promoting agile ways of working, we have enabled a clear and rapid decision-making process, thereby improving productivity and efficiency.

## Review of Performance Goals in Corporate Strategic Plan 2021

*Established a foundation to overcome XTANDI LOE and deliver sustainable growth*

Performance Goal 1	Performance Goal 2	Performance Goal 3
<b>Revenue:</b> XTANDI and Strategic Brands sales ≥ ¥1.2T in FY2025	<b>Pipeline Value:</b> Focus Area projects expected sales ≥ ¥0.5T in FY2030	<b>Core OP Margin:</b> ≥ 30% in FY2025
<ul style="list-style-type: none"><li>• Acquisition of Iveric Bio</li><li>• VEOZAH, IZERVAY, VYLOY launch</li><li>• Acceleration of LCM</li><li>• <b>Total sales: over ¥1.4T</b></li></ul>	<ul style="list-style-type: none"><li>• Transformation of R&amp;D organization and capabilities</li><li>• Turnover of Primary Focuses and programs</li><li>• 12 clinical entries, addition of promising external assets</li><li>• <b>4 PoCs from 3 assets achieved</b></li></ul>	<ul style="list-style-type: none"><li>• Formulation and execution of Sustainable Margin Transformation</li><li>• <b>Achieved cost optimization of ¥65.0B</b></li><li>• <b>Core OP margin: 26.0% (+4.0ppt vs. FY2020)</b></li></ul>

VEOZAH: Approved as "VEOZA" in ex-US  
LCM: Lifecycle management, LOE: Loss of exclusivity, PoC: Proof of concept

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Page 20, a review of the performance goals in CSP2021. Overall, we believe we have succeeded in establishing a foundation to overcome XTANDI exclusivity and deliver sustainable growth beyond it, which was our original objective.

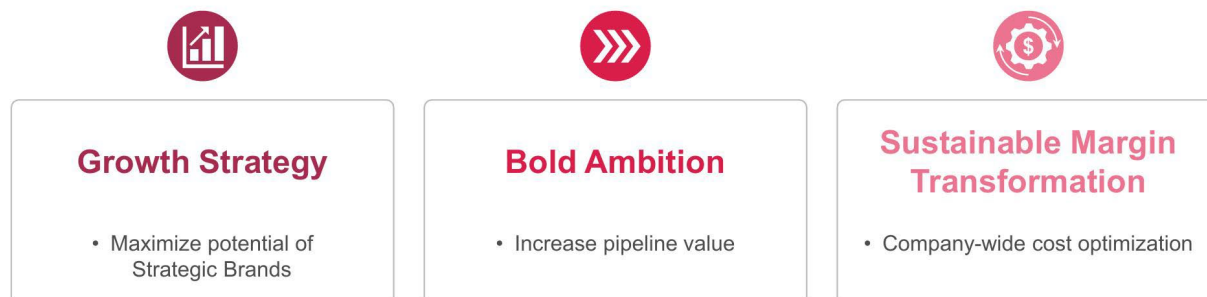
Regarding performance goal one, revenue, thanks to our newly launched products such as VEOZAH, IZERVAY, VYLOY, and the acceleration of life cycle management centered on PADCEV, the total sales of the strategic brands and XTANDI exceeded JPY1.4 trillion.

Performance goal two, pipeline value. We faced a situation where programs already underway at the start of CSP2021 did not progress as anticipated. However, as I explained at the R&D Day in March, we thoroughly focused on strength and discipline and improving productivity through the transformation of our R&D organization. By accelerating the development of priority programs, we achieved significant progress in expansion of the pipeline, including the achievement of a total of four PoCs.

About performance goal three, core operating margin, while we made investment associated with the launch of multiple new products, the SMT initiative progressed well, achieving cumulative cost optimization of JPY65 billion over two years. As a result, the core OP margin for FY2025 reached 26%, up 4 percentage points YoY compared to FY2020.

## Three Enterprise Priorities

Set “Three Enterprise Priorities” closely linked to Performance Goals and launched full-scale implementation in FY2024

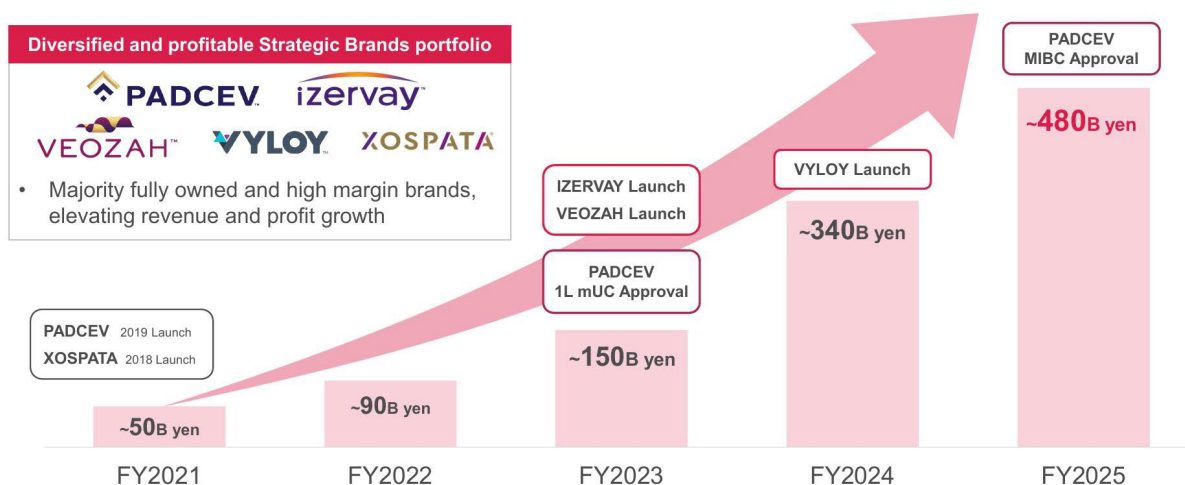


Page 21. To ensure the reliable execution of CSP2021, we set three enterprise priorities closely linked to our performance goals and launched full-scale implementation in FY2024.

Growth strategy aims to maximize the potential of strategic brands, bold ambition aims to increase pipeline value, and sustainable margin transformation aims for company-wide cost optimization. The following slides will explain the result of each.

## Growth Strategy: Maximize Potential of Strategic Brands

Strategic Brands delivered exceptional growth, Achieving ~10x growth over five years



Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA. VEOZAH: Approved as “VEOZA” in ex-US. 1L: First line, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer

Page 22, I will explain the result of maximizing the potential of strategic brands.

In addition to PADCEV and XOSPATA, which were already on the market at the start of CSP2021, we successfully launched VEOZAH, IZERVAY, and VYLOY during the period of CSP2021, establishing a diverse high-margin portfolio of strategic brands.

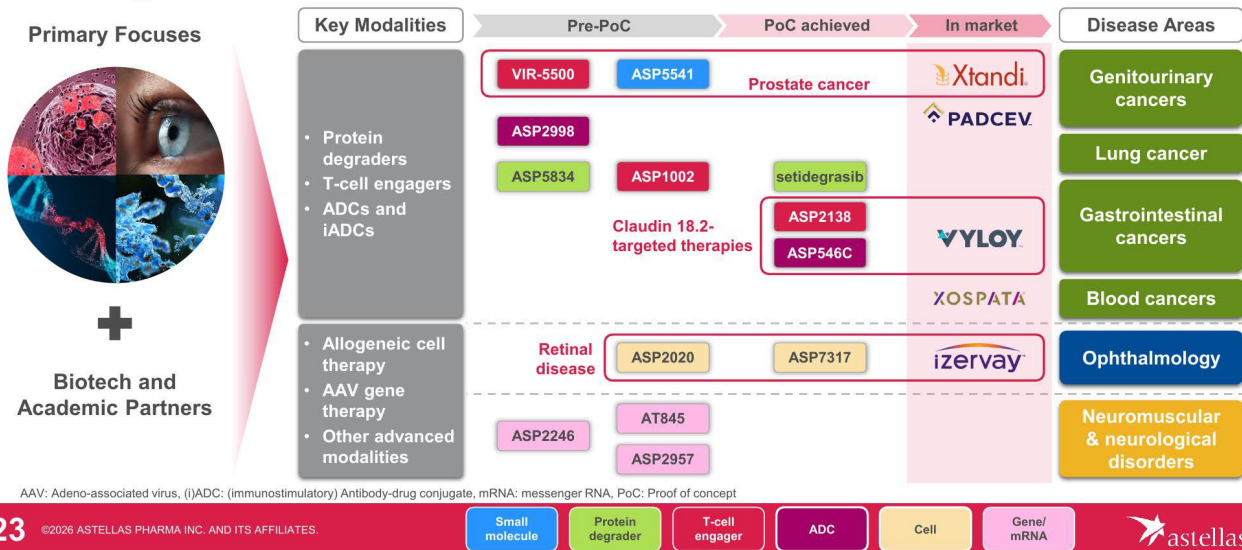
Furthermore, we obtained approvals for PADCEV as first-line treatment for mUC and for the additional indication of MIBC, which serve as a key growth drivers, thereby further strengthening our growth foundation. As a result, our strategic brands expanded robustly, achieving a remarkable tenfold growth over five years.

Since the majority of strategic brands are fully owned and high-margin brands, they have strongly elevated Astellas' overall revenue and profit growth during the CSP2021 period.

The solid track record built over the past five years has further increased the certainty of our future growth. We will carry this growth momentum forward into the next corporate strategic plan.

## Bold Ambition: Increase Pipeline Value

- **4 PoCs achieved** from 3 Primary Focus flagship programs
- **Forming franchises** by leveraging strengths, together with follow-on programs and external assets

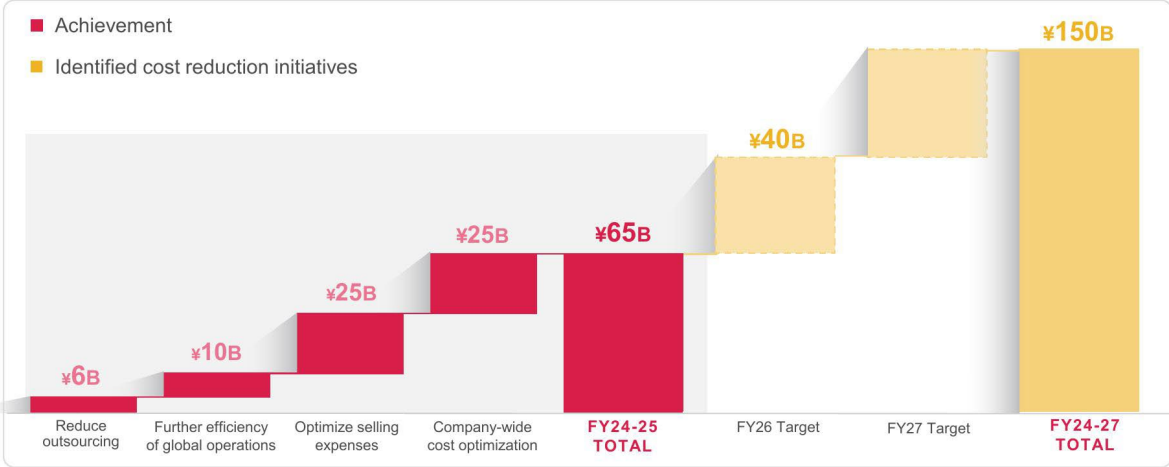


On page 23, I will explain the increase of pipeline value. We accelerated the development of flagship programs in each primary focus area and achieved four PoCs from three assets. Furthermore, we strategically and systematically generated follow-on programs and incorporated external innovation based on our focus area approach, thereby expanding our pipeline.

As a result, we have established a franchise in multiple therapeutic areas, such as prostate cancer, Claudin 18.2 targeted therapies, and retinal diseases, where we have cultivated strength through the development and sales of main products, thereby building a foundation for sustainable growth.

# Sustainable Margin Transformation: Company-wide Cost Optimization

- **Achieved cumulative total 65.0 bil. yen cost optimization over 2 years**
- **Fully on track to achieve total cost optimization target of 150.0 bil. yen**

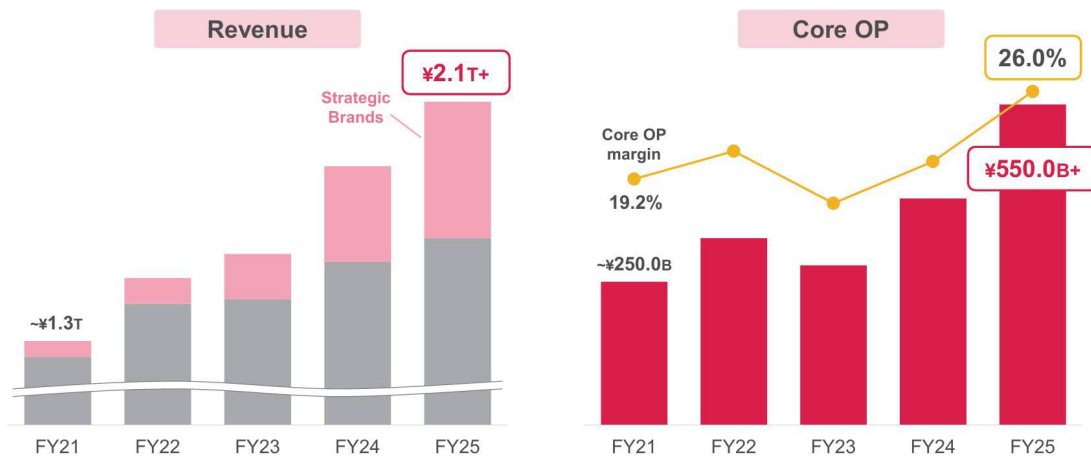


Page 24, I will explain the outcome of the SMT. Since launching the SMT in FY2024, we have achieved cumulative cost optimization of JPY65 billion over two years. Furthermore, cost optimization measures for FY2026 and FY2027 have already been identified, and we are now at the stage of ensuring their reliable execution. We are fully on track to achieve a total cost optimization target of JPY150 billion.

In addition, the SG&A ratio improved by a total of more than 5 percentage points over the two-year period from FY2024 to FY2025, and we are gaining clear traction toward improving profitability. Moving forward, we will continue to advance cost optimization through SMT to establish a highly profitable financial structure.

## Revenue and Core OP Growth over CSP2021 Period

Significant increase in **Revenue and Core OP** by **1.7x** and **2.2x**, respectively, over 5 years



Core OP is based on the new definition introduced in FY2024. Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA  
CSP: Corporate Strategic Plan

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Page 25, I will explain the revenue and core growth over the CSP2021 period. Revenue expanded 1.7-times over the five years, driven by the strong growth of strategic brands. Core OP expanded 2.2-times over five years, driven not only by the revenue growth, but also by significant contributions from cost optimization through SMT starting in FY2024. The core OP margin also improved significantly.

## Key Takeaways

**Established a foundation to overcome XTANDI LOE and deliver sustainable growth**



**Strategic Brands** delivered exceptional growth, raising prospects for further expansion



Established a **robust pipeline**, building confidence towards post-XTANDI LOE growth



Significant progress towards **resilient cost structure** driven by SMT cost optimization

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Page 26, today's key takeaways. Our strategic brands delivered exceptional growth, raising confidence for future expansion. Furthermore, we have established a robust pipeline and built a foundation toward post-XTANDI loss of exclusivity growth. Additionally, through SMT cost optimization, we have made significant progress toward a resilient cost structure.

Over the five-year period of CSP2021, we are now fully prepared to overcome XTANDI's loss of exclusivity and to continue to grow. In our next corporate strategic plan, we aim to demonstrate how we will achieve sustainable growth by building on the foundation we have established to date.

At the end, I would like to remind you of the briefing session for CSP2026. It will be held on May 26, and we hope you will be able to attend.

That concludes my presentation. Thank you for your attention.

## Question & Answer

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**Kato [M]:** That's all for our presentation. We now would like to entertain questions from the audience.

We'd like to take questions. First, Citigroup Securities, Mr. Yamaguchi, please.

**Yamaguchi [M]:** Yamaguchi from Citigroup. Can you hear me?

**Kato [M]:** Yes, we can hear you.

**Yamaguchi [Q]:** My first question is as follows. As you explained during the presentation, for strategic brands, in particular, you could share some forecast for some of the products, but not for strategic brands, so external parties cannot see the forecast. It may be seen as restating. How are you going to, what are you going to do about the individual trends of each product?

The disclosure of individual product information is not going to happen. What's the reason why? Could you explain once again?

**Okamura [A]:** The results will be explained for each product as we have been doing up until now, but in the process of the growth of new products, there are uncertainties for each product. There is an increase or decrease for individual products. Focusing on such a fluctuation is not very constructive, in our view. Based on that, what kind of action are we going to take? How is that going to be reflected on the actual results? That's something we want analysts and investors to see. This product is expected to have this much revenue or sales in this particular region.

Rather than having such discussions, what we are hoping to discuss is the situation of five strategic brands as a whole. In the mid- to long term, we are going to capture the development and growth of the products. It may not be the right expression, but you can demonstrate your capabilities. I'm looking forward to future interaction.

**Yamaguchi [Q]:** Once again, on May 26 at 4:00 PM, you're going to explain the next CSP. You are not going to talk about individual products very much. Between 4:00 PM and 5:30 PM, you are going to share the presentation materials on the same day or the previous day. It will change based on how we can prepare.

**Okamura [A]:** After market close, we are planning to disclose the documents after the close of the market, like at 3:00 PM like today.

**Yamaguchi [Q]:** Thank you very much.

**Kato [M]:** Next, JPMorgan Securities, Mr. Wakao, please.

**Wakao [Q]:** Wakao from JPMorgan speaking. I have a question about XTANDI and the five strategic brands, the results in Q4, and also the outlook for the current fiscal year.

As for XTANDI, you can just talk about the actual results. Q4 was a little bit weak in the United States. I'd like to know why. Five strategic brands, PADCEV was doing very well. What's going to happen this year, particularly in MIBC? How should we look at the situation? I'd like to hear your view. IZERVAY as well, the plan was not achieved, but in principle, it's going to grow continuously in the current fiscal year. I'd like to know more details.

**Okamura [A]:** Thank you. I'll make a summarized comment briefly. Because Claus is here, the rest is going to be explained by him. As has been mentioned, XTANDI in Q1, the business was a bit weak, and we did our own analysis. Of course, the countermeasures for that are planned to be executed.

As you know, for XTANDI in January 2027, in line with the IRA, the price is going to be revised. In the history of XTANDI, it's going to be a year of reduction, and that impact was already explained within my presentation.

Just like you mentioned, in FY2025, the track record is that PADCEV and VYLOY, monetary value-wise, their growth level was outstanding, and VYLOY, that was just launched in the market, the growth rate was over our expectation. What is going to happen in FY2026? We are not going to share about the individual product situation. I don't know if it is right to talk about it. However, for PADCEV, for the first line, other than the United States, it's going to grow further. The US market as a trigger for the MIBC market as well, we expect that sales is going to contribute to it. IZERVAY as well; 2025 is a little bit on a resting situation. However, in these couple of months, looking at the track record of that time, still, there is room for growth. That's why we didn't revise our sales forecast. It has to grow further. We are having such an expectation. Claus-san, do you have any additional comment?

**Zieler [A]:** Maybe just briefly on the brands you asked about – XTANDI, PADCEV, and IZERVAY. I think Q4 was indeed a little bit weaker, but we see the entire ARPI market being weaker. I think it's probably a mix of market effect and turbulent, competitive, and market dynamics for XTANDI in that particular quarter. We've grown very, very well over the year, and we've now reached peak sales for XTANDI. I think that's a very strong contribution to our growth rate.

Let me turn to PADCEV because PADCEV, I think we need to distinguish between US growth, where we have the EV-303, so the cis-ineligible MIBC indication was already approved. On approval, as always with PADCEV, we see the market responding very, very quickly, and uptake goes up. However, please let me also remind you that, that uptake usually plateaus after about six months, so we are expecting that also to happen. US growth is very strong right now, but we do expect the plateau to come at the end of Q1 or Q2, whereas Europe and the other ex-US countries do not have MIBC in any noticeable fashion in FY2026. Here, we expect strong growth to be driven by reimbursements coming through on the first-line metastatic indication, so you get a very different dynamic in the two parts of the world. Overall, I think PADCEV will continue its strong growth trajectory.

Now, let me talk about IZERVAY. You do remember about a year ago, when the foundation funding dried up, the entire market, the new patient starts for the entire market, both in geographic atrophy and also in wet AMD, went down significantly. It has affected, sort of, the base from which we have regrown. As Naoki said, we have regrown from that lower base since then, but we've done it in a very consistent and very successful fashion. It's about 11% QoQ that we've grown since that rebasing.

I also would like to draw a comparison to other products in the intravitreal space. If you look at, let's say, Eylea, VABYSMO, and SYFOVRE, they've actually all decreased in sales. Eylea by 27%, Vabysmo by 10%, SYFOVRE by 4%. We actually have grown more than 30%. I think in a very difficult market environment, IZERVAY has really produced a very, very impressive performance of consistently growing from that lower base. We do expect that to continue as the complement inhibitor class also grows.

**Wakao [Q]:** As a follow-up, MIBC has a good market penetration, but it could reach a plateau quickly. That's understandable. As for MIBC to get the approval, so a similar thing can happen. Is that factored into the forecast? If the uptake is so fast, overall, there can be a further increase by PV.

**Zieler [A]:** We do expect the EV-304 approval by the PDUFA date, as stated previously. That would indeed then produce another uplift for PADCEV.

**Wakao [Q]:** My second question. In the past five years, XTANDI cliff is to be exceeded, and you have a platform to increase your product. You have an improved pipeline as well. I have a question for you. Large-sized M&A, any possibility? How much leverage are you going to use? I think that's in the appendix, but in principle, according to the pipeline, which is shared with us, you would exceed XTANDI cliff to grow. Is that your assumption? Is my understanding correct?

Depending on the status of the products under development, you may need an M&A deal. As a base case scenario, you would use your own pipeline to grow. Can I understand that way?

**Okamura [A]:** Thank you for your question. Up until now, as we said a few times by now, this is an illustrative XTANDI figure. XTANDI will decline. Strategic products will increase. We would have programs from the focus area approach to be added in a chart like this.

In 2026, a peak is expected for sales. Then, during the course of CSP2026, our revenue may decline, and then we go back to growth trend once again. Your view and our view may not be so different. Then, if there's going to be a dip, a large M&A deal is going to be used to prevent the dip, to minimize the dip, or to make it flat. If that's your question, we are not going to do such an M&A. That's my response.

This is the so-called rescue BD, to rescue us from a dip or decline. We have no intention of doing such a thing because such a deal would have an increasing price because everybody wants such an asset or a transaction. After we get something, if there is small room for us to get the value, it's not going to be very good. Cash for Cash flow deal. This is just an exchange for cash. There aren't many elements to force us to do something like this. If we don't do a rescue deal, then are we going to pause BD? You may interpret it that way in an extreme fashion.

As we have been doing before, our franchises and the existing primary focuses to be reinforced by technologies and attractive assets, we are going to pursue such opportunities very actively. Everybody talks about M&A very easily. In the world of pharma, sharing the risks with the owners, there are many ways to do so. Back-end licensing agreement is one way or milestone payments, to be linked with regulatory outcome by doing so. A huge amount of payment is made at the beginning, but nothing happens. We can prevent such a situation. Of course, we are making such efforts. Still, having said so, how attractive our pipeline is right now because of this world situation, failures could occur. 2030 and beyond, the growth we want to achieve could not be envisioned. In that case, we should be able to use flexibility.

Under Kitamura, we try to repay the debt as soon as possible. Gross leverage ratio, EBITDA 1x up to 1.5x as we declared, we think we are already sufficiently within this range. If necessary, large-size BD can be done because we have such extra financial capabilities. EBITDA is growing bigger than before, so the money we earn would be returned to shareholders partially. Also, we'd like to make R&D investments for future growth, and various investments will be made by using such money for the details. On May 26, we will announce our CSP2026. We will try to talk about our plan as much as possible, and you can ask further questions during that meeting. That's all the information I can share today.

**Kato [M]:** Next, UBS Securities, Seki-san, please.

**Seki [Q]:** UBS Securities, Seki is my name. First question is about dividend. This time, JPY80 increased with JPY2. In the past two times, the increase was JPY4 every time, but this time, JPY2 increase. I believe that you had a lot of discussions about the situation. I believe that discussion was quite difficult. You had JPY4, and this time JPY2. I think that itself includes some message. Not about the CSP, but this JPY2 increase, what's your intention? What's the message?

**Okamura [A]:** Kitamura is going to explain.

**Kitamura [A]:** Thank you for your question. I'm Kitamura, CFO. First of all, this dividend, as Okamura explained, investment for growth and also return to shareholders, those are continued. That is our policy for capital allocation. There is no change whatsoever on that. For dividend, rather than single year performance, mid- to long-term performance, cash flow forecast against that or based upon that, a stable dividend is provided. That is our decision. JPY2 per year, and the performance was good, so dividend is increased. It's not something like that. We have a sustainable plan.

This time, JPY2. In the past, a JPY4 increase. Rather than talking about a single year, again, mid- to long-term perspective is necessary. Based upon that, we decided to increase by JPY2. For details, around the end of May, when we make a presentation at the next CSP, we would like to give a further explanation.

Currently, the margin is good, cash flow is good. Financial performance is strong. Just like Okamura mentioned, when we do something, we are fully prepared. We'd like to be flexible to think about capital allocation. That's all.

**Seki [Q]:** The second question is about pipeline. Last week, AACR took place in KRAS competitors' data, Revolution Medicines, good data was shared, not only data, but also RM-055, the nonclinical data was also good. Based upon such data, your franchise KRAS project, your ways to look at it is not different. The area is still the therapeutic area worth investing.

**Okamura [A]:** I am going to make an answer, first of all, and followed by Taniguchi. We consider that KRAS is quite an important target. Their success means that KRAS is definitely a target that we should focus more on. Their success is proving it. The difference of mechanism of action.

First of all, that data was at a very earlier phase. For us, the benefit due to the difference of mechanism of action is available in our product. At the very end, when the late phase of data becomes available, that is the time we can say which wins or loses. I think as has been mentioned, thanks to their success, that became our confidence of targeting the KRAS.

**Taniguchi [A]:** Taniguchi speaking. As has been explained by Okamura, Revolution Medicines data, KRAS inhibitor by Revolution, that data is disclosed, and this is really good data. We have a KRAS target project, so the KRAS itself is quite promising. That's what we've learned. Including PDAC, NSCLC, KRAS is suggested to be a really good target for the treatment.

Setidegrasib that we have, the first line of PDAC, Phase III has just started. Regarding this indication, we are a bit ahead compared to Revolution Medicines. Our KRAS G12D targeting, setidegrasib, not only efficacy but safety as well, the [inaudible] result is available, so it is easier to combine with chemotherapy. That is the current standard of medicine.

In the case of PDAC, in severe patients, it's difficult to administer the drug orally. IV infusion, setidegrasib can be used for such patients as well. That's our expectation. As for the data, we disclosed some of the data already. Based on our data as well, KRAS target is going to be important in the future for important PDAC and lung cancer targets.

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

**Ueda [Q]:** I'm Ueda from Goldman Sachs Securities. My first question, your initiatives in SMT, I'd like to know more details. JPY40 billion reduction is going to be incorporated into your plan for the current fiscal year. What kind of items are going to be the major ones?

In 2027, your measures, as were shown here, some are already identified. What are you planning to do? Specifically, is there anything you have already decided? What about the certainty of these measures to be implemented.

**Okamura [A]:** As we said, we are going to do something which is already identified, so we will just work on it. Still, in areas like this, if we do something like this, we may not be able to realize the effect as we planned or it may take more time as we were planning. The value could be diluted, so there can be such risks.

Now that everything is already identified, do we just need to work on that? No. We have to pursue further opportunities for SMT continuously. Kitamura-san can talk about the further details as far as we can share.

**Kitamura [A]:** In 2026, we are expecting additional JPY40 billion. By FY2025, we work on various measures. We'd like to harvest the benefits there. Specifically, as you know, we have global operations. In order to increase the productivity in FY2025, we made huge investments, creating new bases. To concentrate our operations there to come up with a scale and implemented automation, that took such a major action. We'd like to harvest the effectiveness there. It will generate a certain level of huge benefits. Creating necessary capabilities in-house, that's also one of the measures we are working on. Capabilities integration, including integration with vendors, are also ongoing. Sales promotion-related back office or material development, and there can be a lot of synergy, so we are going to harvest the results. Those are the main things we are considering for FY2026.

What about 2027? We will explain in the future. SMT is not a single year initiative, but it's a multiyear initiative. In the first year, we worked on lower-hanging fruits, easier to realize to prepare for the mid- to longer term in 2027, that is going to be the final year. Action, which requires a longer time, we are going to harvest the results from longer-term projects, such as supply chain, and larger scale projects with longer lead time would be realized in 2027. That's what we are expecting.

**Ueda [Q]:** Understood. My second question, in the United States, I'd like to ask you about the business environment in the States, pharmaceutical duties and MFN. Do you have anything you can share in terms of the negotiation with the US government? Also, MFN and the tariff, how do you see the potential risks in your plan? Is that going to be fully manageable in your plan?

**Okamura [A]:** I'd like to ask you this question. Thank you for your question. Needless to say, receiving a letter. Based on that, negotiation with the authorities by some companies, you know those company names, and what was the result? We heard such a rumor. The first round seems to come to an end. We haven't received a letter from the US government, but still, we try to open a channel to discuss with the government authorities.

Looking at the components of the agreement, we can learn what kind of factors are incorporated for each factor; what we cannot do. Those are, of course, we've already considered and discussed. Tariff or MFN, there are some rumors or stories are ongoing, but we don't know any specifics. We have prepared ourselves, but those are not really quantified so that it could be incorporated into the corporate strategic plan. Of course, we do a certain level of risk analysis.

We have upcoming products from the focus area approach. Once they come to the market, what kind of price environment will we face around that time? For that purpose, we have to have a very sensitive antenna from a marketing access perspective, what can we do and what kind of preparation we need to do, those are all under consideration. This might be repetition, but regulations and rules, those are not something we can set by ourselves. The rules and regulations are decided by somebody else, and we basically have to follow that. In order to follow that, we do whatever we can do in a maximum way. The rules are likely to be changed. If there are some countermeasures conceivable, then we would do so. That's probably the only way we can do for this type of issue.

Is this a big problem? Yes, it is likely to become a big problem. Nothing can be started, just being moved or make action, only with partial information because we have patients, the patients are around the world. We cannot make a decision. We think about only US patients and ignoring other countries' patients. We always would like to think about delivering value in a uniform manner throughout the world. I think that's probably what we can do. Did I answer your question?

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

**Kato [M]:** Next, Nomura Securities, Matsubara-san, please.

**Matsubara [Q]:** Matsubara from Nomura speaking.

I have two questions as well. The first one is a question related to Ueda-san. A follow-up question about SMT. You might say that please wait up until the CSP2026 announcement. There are some areas you can do about the cost reduction. In FY2027 and afterwards, is cost reduction through SMT possible to be expected?

**Kitamura [A]:** Thank you very much. Partly, this is a personal opinion. First of all, cost optimization and the journey toward that, that is going to be continued. If you were to ask me, have you completed that? Well, that's one way to look at it. At the same time, technology has been advancing day by day. From my personal perspective, cost optimization never ends. However, cost cutting is not the only way, not only pursuing the numbers just in front of us. What is important is to continue to deal with that from a mid- to long-term perspective. For that purpose, you need a certain mechanism. When you say cost, you tend to talk about only input, but maximizing output is also important. The bigger value is going to be delivered to the patients as early as possible. With doing that, we need to increase the productivity.

For your question, are we going to do this in FY2027 and afterwards? Of course, we will do that. What about approaches? Well, we have conventional approaches that are based upon Sustainable Margin Transformation or SMT with a four-year plan and execute those plans, and PDCA is turned around. It will continue the same thing. Well, this approach itself has to be evolved, rather than doing the same type of SMT for the next four years. Rather, we are going to accelerate that so that we can broadly work on this. Such details are going to be further explained, possible to be explained at the time of the CSP2026 presentation.

**Matsubara [Q]:** Thank you. Then, I'm looking forward to that.

My second question is about XOSPATA. In partial study, primary endpoint was not achieved. Peak sales assumption is JPY100 billion to JPY200 billion, no change. What's your view on the peak sales?

**Okamura [A]:** Thank you for your question. Unfortunately, primary endpoint was not met. Regarding this indication, in principle, we are not going to pursue this indication globally anymore. As for the change in the sales forecast and what is going to be happening into the future, Claus Zieler is going to add.

**Zieler [A]:** Yes. I mean XOSPATA is on a stable growth path. It's not a very fast growth path, but it's a stable growth path. So we do expect that continue. Even in the PASHA study, there are some elements which are actually quite interesting for doctors to study. Our reputation for XOSPATA or gilteritinib as an FLT3 inhibitor is very much intact even with a lot of first-line competition coming into this market. We expect this agent to continue on that slow single-digit growth path that we've had in the past.

**Matsubara [Q]:** Then for the future, in subgroup with gene mutations, administering this to those patients or in combination with chemotherapy, primary endpoint was not met, but this XOSPATA could be utilized in different types of patients. Is my understanding correct?

**Taniguchi [A]:** As for the XOSPATA PASHA study, primary endpoint was not met. Analysis is now underway. Of course, subgroup analyses are included as well from various angles, analysis is being performed. As soon as we get the results, we're hoping to share with you. In which segments we are going to go for or not go for, we are hoping to have such an opportunity so that we can explain.

**Kato [M]:** Next, Morgan Stanley, MUFG Securities, Mr. Muraoka, please.

**Muraoka [Q]:** Morgan Stanley, Muraoka speaking. Most of the topics are already covered, but XTANDI quarterly results or quarterly figures, hopefully, will be explained. Today, it doesn't make sense to talk about the details of each product. My question is, according to your forecast for FY2026, in the initial nine months, it may be flat or increase. In Q4, there can be a big decrease YoY. Is that your image perhaps? If you can share such an image, I'd like to hear it.

**Okamura [A]:** First of all, discussing the figures for XTANDI as a whole, it can be dangerous. We have to discuss US and ex-US separately.

As for the US, as you said, in Q4, IRA will kick in. So how much is a different question, but it's clear that it's going to be negative. In other countries outside of the United States, there was the pace of growth. Up until now, it's going to slow down, needless to say, because more than 10 years have passed since the launch. If it's going to grow at the same pace as before, no, that's not going to happen. We have EMBARK data and other data we can use. We still have room in the market where we can grow or we should grow. That's my basic principle. Claus, anything to add?

**Zieler [A]:** No. Only to add that, of course, ex-US, the patent, the exclusivity is much longer, 28 in Europe. But in Japan, in Australia, in Russia and some other markets, we have quite a long patent life. This is not just one patent exclusivity that we lose. It's really country by country over many, many years, about over four years in total. So that's the only thing I wanted to add.

**Muraoka [Q]:** One more question for you. Core OP margin, 30% has been discussed quite often by now. I may ask a question about CSP, so I hesitate a bit. But 30% core operating profit margin is something you are very particular about in pursuing. If that's the case, how are you going to work on this? It's difficult to imagine because of the cliff, how are you going to achieve, where are you going to achieve this? There can be a decline and then you go up again. What's your philosophy? How much do you want to be particular about this?

**Okamura [A]:** In a word, please look forward to May 26, but I would like to make some comment here just a little bit before that day. I think in the past, I mentioned about it, we are the size of a pharmaceutical company. With the innovation, we try to contribute to society. This is our style. As such a biopharma company, cost of goods 25%, SG&A 25%, and the cost is reduced a little bit, and SG&A might be increased a little bit and vice versa might happen. Anyhow, adding up these two, 50% is the level that we would like to manage. Before the deduction of R&D, the profit is 50%. Out of that, the 20% of sales is allocated to R&D because that leads to continuous delivery of innovation. That's my way of thinking.

Based upon that, we come up with a number of 30%. Sales is reduced, so you cannot do in that way. I understand you would say in that way, but further details are going to be described on May 26.

**Muraoka [Q]:** Understood. One brief question. Myrbetriq, the actual January to March, USD180 million. It increased to that extent. What's the background of that? I just got a little bit confused.

**Kitamura [A]:** First of all, Myrbetriq with the generic companies, we come to the settlement. In line with that, the royalty aspects are agreed, including the royalty as well in Q4. Afterwards, some adjustment is applied. That was the situation, and that will continue. Please look at the number of Myrbetriq as that was a precondition.

**Muraoka [A]:** Some others, a one-time factor is also added, which leads to the increase in Q4?

**Kitamura [A]:** Rather than one time, precisely speaking, the transaction not included until Q3 is now included, and the agreed patent period. During that period, this will continue. That's the way to look at it. So, 2026 Myrbetriq number is disclosed. As you know, the number is not that low. That's because of the inclusion of royalty adjustment.

**Kato [M]:** Next, Macquarie Capital Securities, Tony Ren, please.

**Ren [Q]:** Okay. Perfect.

I have two. The first one is about your intangible assets on slide 35. You commented that you had some impairments for your gene therapy. It appears to me that the value for some very successful products, such as VYLOY and IZERVAY, have also decreased a little bit. Could you comment. Is it because of impairment, or is it because of normal amortization? So that's my first question.

**Kitamura [A]:** Thank you for your question. I think the intangible asset is a combination of amortization, especially that is more like moved to the sales rate in the market, product related, and the intangible asset is now classified from the in-process R&D to the sales right and others. Sales right, yes, they will be amortized over years, so it's kind of very healthy transactions.

Now, the impairment loss is sometimes bigger in the in-process R&D because the in-process R&D amount is still as it is, and up until the product will qualify to the market. If we fail to qualify to the market, we need to write off the asset 100%.

Now, we did have the impairment loss recorded in AT132, that is the gene therapy product asset, but we have the new asset in the clinical trial. We shift our focus from AT132 to ASP2957, as already mentioned. Overall, this time, we make progress so that we shift the focus from one project to a new project and also the amortization can start and move as we planned because the product is in the market. I hope I answered your questions.

**Ren [Q]:** Yes, it's very clear. Thank you very much, Kitamura-san. My second question is about your clinical collaboration partner, Kelonia. Obviously, Eli Lilly acquired Kelonia. You have been cooperating with Kelonia over in vivo CAR-T cell therapy since early 2024. It's about two years now. Have you guys considered acquiring Kelonia? Was it because you did not want to compete against Eli Lilly, or was it because CAR-T or blood cancer is not part of your key priorities? How does your collaboration with Kelonia change after the Eli Lilly acquisition?

**Okamura [M]:** Thank you for the question. Probably that question should be answered in a very scientific aspect, so I would like Tadaaki to answer those.

**Taniguchi [A]:** Thank you. Our Kelonia collaboration actually has one project. As you mentioned, that in vivo CAR-T platform, we work together in the preclinical program. Our decision is that we're not pursuing that project moving forward further, so we terminated that project. That's where we are now. I don't think there is any impact that Lilly is going to acquire Kelonia. Of course, we still have connection with them, but we don't have any significant project working with them now.

**Ren [Q]:** Okay. Did you guys have the discussion over possibly acquiring Kelonia?

**Zieler [A]:** Obviously, we haven't. We have no intention to do that.

**Kato [M]:** Next, Sanford Bernstein, Ms. Sogi, please.

**Sogi [Q]:** First, about KRAS, I have a question for you. Revolution Medicines, KRAS daraxonrasib. Phase III results were announced for second-line plus for PDAC. As for the first line, they have a PDAC program, monotherapy and chemotherapy combination. Your setidegrasib KRAS G12D, the competitor is going to be earlier. Because of the pan-RAS for Revolution Medicines, this one may be more effective or similarly effective. KRAS G12D, this specific target is your product. This can be a disadvantage for your product. Pan-RAS versus KRAS G12D specific. In terms of efficacy, what kind of scenario are you hoping to see?

**Okamura [M]:** It's too early to say specifics to explain the differences, but Taniguchi is going to explain as much as he can.

**Taniguchi [A]:** Thank you very much for your question. It's pan-RAS, so it's not just limited to KRAS, but RAS(ON) inhibitor more broadly. Because of this, the target patient population is broader according to our understanding. Maybe because of that, we don't know clearly, but I saw the data. For example, skin-related adverse events and GI-related adverse events seem to be high in the incidence, according to our impression.

Regarding our setidegrasib, not just efficacy but safety, relatively speaking, is also favorable according to our understanding. We just started PDAC's first-line study. Chemotherapy combination is going to be the main regimen in the study we are planning to execute. When I discuss with the doctors, the appearance might be different from doctor to doctor, but in the targeted population, by the drug and drug with broader coverage, which one to use first. As far as we have heard from the doctors, the more targeted product is the one they would like to use. Such responses are more frequent. Once the Phase III data is going to be available, they would decide.

**Sogi [Q]:** One more question. ASP2998 TROP2 targeting iADC that is a new type of ADC. Regarding linkers, within the cancer cells, selectively, it is cleaved or outside, especially regarding STING agonist outside of the cancer cells when it's released, it comes into the cancer cells for the action? Is it already confirmed? These linkers are cleaved only within the cancer cells?

For that, I think there has to be a patient selection strategy considering the TROP2 ADC development so far. With this regard, what is your strategy?

**Taniguchi [A]:** Thank you very much. That is a very scientific question. ASP2998, as has been mentioned, STING agonist and also Topo-I are used as dual payload targeting TROP2. This is ADC. That is cleaved surrounding the target, the design is in that way, according to my understanding. One of the characteristics of this drug is TROP2 target, not only ADC, but because of the existence of STING, the tumor microenvironment, then activity is promoted to enhance the antitumor action. That is the concept of the design.

Looking at the preclinical data, compared to the conventional ADC targeting TROP2, efficacy is superior. That is where we have higher expectation. What is the focus of STING? If we learn about that, we can share that with you. So far, I don't remember the data. If I identify some information, I would like to share that.

**Kato [M]:** There are some more waiting for asking questions, but because of the time, the next is the last question. Nikkei Newspaper, Ozaki-san, please.

**Ozaki [M]:** Ozaki from Nikkei Newspaper. Can you hear me?

**Kato [M]:** Yes, please.

**Ozaki [Q]:** This might be a little bit of a different question. The current Middle East situation, I just wonder if that has an impact on your business. Not just the last fiscal year. For this fiscal year, does it have any impact?

**Company Representative [A]:** Thank you for your question. The Middle East countries where we have footprint and having operations, of course, employee safety is a priority. At the same time, because it's the area of the war, there are patients who are still requiring our products, so we definitely would like to make sure the delivery of the products to them.

The Hormuz Strait is now closed. Because of that, the various types of oil-related materials are a bit delayed in terms of the delivery. With that impact perspective, so far, we can say that there is no big impact on us, and we are not thinking that we will have a bigger impact, but our product is one of the components of all of the medicines or health care. As has been mentioned, if there are some more problems that will happen for the materials -- for example, the infusion bag issue or cylinder for the injections -- if there were some problems in terms of the supply of those, there might be questions or problems incurred. We always would like to continue to pay attention.

As has been mentioned, the topic of the US administration, we are not going to be reactive for each individual event. Of course, we do our preparation. We do not consider that the business is going to be all of a sudden better or worse. Just one thing. We would like to be prepared all the time.

**Kato [M]:** Thank you for the many questions. The time has come. With this, we'd like to close today's meeting here. Thank you very much for joining us once again.

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#### **Document Notes**

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