



Astellas Pharma Inc.

Financial Results for the Q3 of FY2025

February 4, 2026

Event Summary

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[Participants]			
[Number of Speakers]	4		
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Presentation

Kato: Thank you very much for joining us. This is the FY2025 Q3 earnings call. My name is Kato. I'm serving as the moderator for today. I am Chief Communications and IR Officer.

Today, following our presentation, we will proceed to the Q&A session. The presentation will follow the presentation materials available on our website. The session, including Q&A, will be conducted with simultaneous interpretation in Japanese and English. Please note that we cannot guarantee the accuracy of the simultaneous interpretation. You may select your language from the menu on the Zoom webinar screen. If you choose the original language, you can view the presentation in the original audio without simultaneous interpretation.

These are some notes for today's presentation. This material presentation and answers and statements by representatives for the Company in the Q&A session includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors. They contain information on pharmaceuticals, including compounds under development, but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations, promote unapproved uses in any fashion, nor provide medical advice of any kind.

The participants for here today are Atsushi Kitamura, CFO, Chief Financial Officer; Tadaki Taniguchi, CRDO, Chief Research and Development Officer; Claus Zieler, Chief Commercial and Medical Affairs, CCMAO. We have three of them with us here today.

We start the presentation now. Kitamura-san, the floor is yours.

Kitamura: Hello, everyone. I am Atsushi Kitamura from Astellas Pharma Inc. Thank you very much for joining our Q3 year-to-date financial results announcement meeting out of a very busy schedule today.

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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Q3 YTD/FY2025 Overview

- Strong Momentum Continues; Another Upward Revision of Full-year Forecast -

Q3 YTD Financial Results

Revenue	Continued strong growth of Strategic Brands (Over +100.0 bil. yen YoY), driving double-digit revenue growth (+10% YoY)
SG&A expenses*	Robust SMT progress, driving continued improvement in SG&A ratio (-2.7ppt YoY)
Core OP	Significant increase driven by Strategic Brands growth and robust SMT progress (+49% YoY) Core OP margin increased to 27.6% (+7.1ppt YoY)

Revision of FY2025 Full-year Forecast

- ✓ Upward revision of Revenue (+70.0 bil. yen), Core OP (+30.0 bil. yen) and Full OP (+100.0 bil. yen)

Pipeline Progress

- ✓ PADCEV (MIBC): US approval based on EV-303 study / Positive topline results from EV-304 study
- ✓ VYLOY (gastric cancer): Promising combination data presented / Phase 3 LUCERNA study ongoing
- ✓ ASP3082: Promising 1L PDAC data presented / Phase 3 study planned to start by March
- ✓ ASP2138: PoC achieved (gastric cancer) / Phase 3 study under preparation

*Excl. US XTANDI co-promote fee
Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA. SMT (Sustainable Margin Transformation): See [slide 24](#) for overview
MIBC: Muscle-invasive bladder cancer, 1L: First line, PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept

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On page three, I will explain the highlights of Q3 year-to-date financial results.

Strong momentum from H1 continues. Based on this, we have made another upward revision of our full-year forecast. Continued strong growth of strategic brands by over JPY100 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 2.7 percentage points YoY.

Due to the growth of strategic brands and robust cost management through SMT, core operating profit rose significantly, up by 49% YoY. Core operating profit margin increased by 7.1 percentage points YoY to reach 27.6%.

Based on this strong momentum, like the Q2 year-to-date results announcement, we made another upward revision of our full year forecast by JPY70 billion for revenue, by JPY30 billion for core operating profit and by JPY100 billion for full operating profit, respectively.

Regarding our pipeline, there were four major important progresses. For PADCEV, as part of life cycle management of strategic brands, development for MIBC muscle invasive bladder cancer made a substantial progress. The additional indication based on EV-303 study was approved in the United States. Also, in EV-304 study, positive top line results were obtained.

Regarding VYLOY, promising combination data in gastric cancer was obtained. Phase III study for combination therapy is ongoing.

As for focus area approach, for ASP3082, promising first-line PDAC data was obtained. We plan to start Phase III study by March.

Furthermore, regarding ASP2138, PoC was achieved in gastric cancer. Phase III study is now under preparation.

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Agenda

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Q3 YTD/FY2025 Consolidated Financial Results FY2025 Revised Forecast

II

Pipeline Progress

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Page four is the agenda for today. From the next page, I will explain these topics.

Q3 YTD/FY2025 Financial Results

Revenue and Core OP each **increased by approx. 150.0 bil. yen YoY**, Full OP increased significantly

(billion yen)	Q3 YTD FY2024	Q3 YTD FY2025	Change	Change (%)	Fx impact (YoY)	FY2025 FCST [*]
Revenue	1,453.0	1,601.3	+148.3	+10.2%	-2.2	2,030.0
Cost of sales	272.3	314.8	+42.4	+15.6%	+3.4	387.0
SG&A expenses	631.7	625.6	-6.1	-1.0%	-7.1	831.0
US XTANDI co-promote fee	200.1	193.1	-7.0	-3.5%	-4.8	245.0
SG&A excl. the above	431.6	432.6	+0.9	+0.2%	-2.2	586.0
(SG&A ratio ^{**})	29.7%	27.0%	-2.7pt			28.9%
R&D expenses	251.4	218.9	-32.5	-12.9%	-2.7	322.0
(R&D ratio)	17.3%	13.7%	-3.6pt			15.9%
Core operating profit	297.5	442.1	+144.5	+48.6%	+4.2	490.0
(Core OP margin)	20.5%	27.6%	+7.1ppt			24.1%
<Full basis>						
Amortisation of intangible assets	104.2	100.2	-4.0	-3.8%		
Other income	4.4	25.4	+21.0	+475.4%		
Other expenses	220.6	35.8	-184.8	-83.8%		
Operating profit	-22.5	333.9	+356.4	-		240.0
Profit before tax	-29.3	328.6	+357.9	-		230.0
Profit	-24.1	248.0	+272.1	-		180.0

*Disclosed in Oct 2025, **Excl. US XTANDI co-promote fee
Exchange rate assumption of FY2025 FCST: 145 yen/USD, 170 yen/EUR
Actual exchange rates of Q3 YTD/FY2025: 149 yen/USD, 172 yen/EUR (Actual exchange rates of Q3 YTD/FY2024: 152 yen/USD, 165 yen/EUR)

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Page five shows the Q3 year-to-date financial results.

Revenue and core operating profit, respectively, increased by about JPY150 billion YoY. Core operating profit increased significantly as well.

Let me explain main items. Revenue reached JPY1,601.3 billion, up by 10.2% YoY. Core operating profit rose to JPY442.1 billion, up by 48.6% YoY.

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The bottom half of this page shows our full basis results. Operating profit was JPY333.9 billion, and profit was JPY248.0 billion, both grew significantly YoY.

Q3 YTD/FY2025 Financial Results: Main Brands

All Brands increased across the board, with Strategic Brands total growing over 100.0 bil. yen YoY

(billion yen)	Q3 YTD/FY2025	YoY	
Strategic Brands Total	353.2	+109.3 (+45%)	✓ High profitability of Strategic Brands contributing to elevation of core OP margin
PADCEV	162.6	+45.6 (+39%)	✓ Progress exceeding expectations, driven mainly by the strong US and EST performance ✓ US approval of MIBC cis-ineligible in Nov 2025; uptake on track and now included in NCCN guideline ✓ Positive TLR achieved in EV-304 study (MIBC cis-eligible); MIBC expected to contribute to FY2026 growth
izervay	55.8	+11.4 (+26%)	✓ Continues to grow double digit QoQ, driven by increase in new patient starts ✓ Overall progress in line with expectations
VYLOY	46.1	+41.1 (>+100%)	✓ Progress exceeding expectations, supported by high Claudin 18 testing rates and low discontinuation rates ✓ Effective AE management—particularly in initial cycle—supporting reduced discontinuation
VEOZAH	35.2	+10.8 (+44%)	✓ Commercial lives covered (payer coverage) expanded to ~80% with recent new coverage in Jan ✓ Recent non-hormonal class launch impact in line with expectations
XOSPATA	53.5	+0.4 (+1%)	✓ Overall progress in line with expectations ✓ TLR expected in 1H/CY2026 for PASHA study, with newly diagnosed AML as potential new indication
Xtandi	732.2	+29.1 (+4%)	✓ Progress exceeding expectations, driven by continued global demand growth

EST (Established Markets): Europe, Canada, etc., VEOZAH: Approved as "VEOZA" in ex-US.
MIBC: Muscle-invasive bladder cancer, Cis: Cisplatin, NCCN: National Comprehensive Cancer Network, TLR: Topline results, AE: Adverse event, AML: Acute myeloid leukemia

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Page six shows the Q3 year-to-date results of our main brands.

Sales of all brands increased across the board with strategic brand sales combined growing by over JPY100 billion in total YoY.

First, Q3 year-to-date sales of five strategic brands, namely PADCEV, IZERVAY, VYLOY, VEOZAH, and XOSPATA exceeded JPY350 billion in total, substantially up by JPY109.3 billion or 45% YoY. PADCEV and VYLOY, in particular, drove the strong growth. We are expecting total sales of strategic brands as a whole to reach close to JPY500 billion on a full-year basis. Also, these brands have high profitability, and their growth made a great contribution to core operating profit increase. We are expecting further growth to continue in FY2026 as well.

Next, I will explain individual strategic brands and XTANDI. PADCEV sales increased to JPY162.6 billion, up by JPY45.6 billion or 39% YoY. While robust global growth has been continuing, overall progress is exceeding our expectations, mainly driven by the strong trends in the United States and Europe. As a major progress in Q3, in November last year, based on EV-303 study, the additional indication of cis-ineligible MIBC was approved in the United States. Uptake after approval is on track. In December, PADCEV was included in the NCCN guideline many physicians are referring to. In addition, in the EV-304 study in cis-eligible MIBC, positive top line results were achieved. We are now preparing for filing a submission. MIBC is expected to drive further growth of PADCEV in FY2026.

As for IZERVAY, sales rose to JPY55.8 billion, up by JPY11.4 billion or 26% YoY. New patient starts, which are important metrics, are steadily increasing. IZERVAY continues to grow double digit QoQ, both in terms of sales and volume. Overall progress is in line with our expectations vis-a-vis our full year forecast we updated in Q2. We continue to have high expectations on IZERVAY as one of the important growth drivers.

With regard to VYLOY, sales reached JPY46.1 billion, performing well at a pace higher than our full-year forecast we revised upward in Q2. Continuously from H1, high Claudin 18 testing rates and lower-than-

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expected discontinuation rates are contributing to the overall good progress. We are meticulously conducting information provision activities about AE management. By focusing on the prevention of nausea and vomiting, particularly in the initial cycle, we believe we can reduce discontinuation and enhance treatment continuation rate. Regional footprint is expanding steadily with approval in 48 countries and launches in 30 countries by now. VYLOY, since launch, has been performing extremely well by now. We're expecting further growth also in FY2026 and beyond.

Sales of VEOZAH increased to JPY35.2 billion, up by JPY10.8 billion or 44% YoY, demonstrating a solid growth continuously. With recent new coverage starting in January this year, commercial lives covered expanded to about 80%. With improved access, we're expecting stable growth also into the future. A new non-hormonal drug was launched in the United States, but the launch impact as of now is in line with our assumptions. With the launch of another treatment in the same class, we are hoping that the market will expand further going forward.

Regarding XOSPATA, sales reached JPY53.5 billion. Overall, it's making steady progress. Top line results are expected in H1 of 2026 for Phase III PASHA study with newly diagnosed AML as a potential new indication, where we have high expectations as a future growth driver for XOSPATA. If approved, we can offer this treatment option to a new patient population, so we're expecting contribution to sales.

Last but not the least, XTANDI. Sales increased to JPY732.2 billion, up by JPY29.1 billion or 4% YoY. Progress is exceeding expectations, driven by continued global demand growth. We're expecting XTANDI to reach its peak level in the current fiscal year.

Q3 YTD/FY2025 Financial Results: Cost Items

- **Cost optimization (SMT): Progressing ahead of plan (Q3 YTD: approx. 20.0 bil. yen)**
Fully on track to achieve FY2027 cost optimization target of 150.0 bil. yen
- **SG&A ratio improved by 2.7 ppt YoY**

Cost Items	YoY change	Ratio to Revenue	(billion yen)
SG&A expenses*	+0.2% (+0.7% excl. FX impact)	SG&A ratio: 27.0%	<p>YoY increase excl. FX impact: approx. +3.0</p> <p>✓ SMT cost optimization: approx. 9.0 (Organizational restructuring, reduction of mature products-related expenses, streamlining IT infrastructure, etc.)</p> <p>Continue investments in Strategic Brands to maximize potential and SMT investments for further optimization</p>
R&D expenses	-12.9% (-11.9% excl. FX impact)	R&D ratio: 13.7%	<p>YoY decrease excl. FX impact: approx. -30.0</p> <p>✓ SMT cost optimization: approx. 8.0 (Outsourcing costs reduction through insourcing development capabilities, incl. clinical trials etc.)</p> <p>✓ Decrease in clinical development costs in Strategic Brands: approx. -9.0</p> <p>✓ One-time co-development cost payments in FY2024, etc.</p> <p>Investments to increase from Q4 and FY2026 onward, aligned with progression to late-stage development</p>

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

Page seven is about cost items.

SMT initiative is progressing ahead of our plan. We realized cost optimization of about JPY20 billion in total for SG&A expenses, R&D expenditure, and cost of sales combined. We are fully on track to achieve FY2027 cost optimization target of JPY150 billion. Excluding US XTANDI co-promotion fees, SG&A cost ratio improved by 2.7 percentage points YoY.

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Let me explain a specific breakdown of SG&A costs and R&D expenditure.

SG&A expenses trended at a similar level compared to the previous year. SG&A cost ratio was 27%. As an SMT progress, we realized cost optimization of about JPY9 billion through continuous global organizational restructuring, reduction of mature products-related expenses and streamlined IT infrastructure, et cetera. In addition to investments to maximize the potential of strategic brands driving our future growth, we will continue to make investments needed for SMT execution in order to realize further cost optimization from next fiscal year onward.

R&D expenditure decreased by JPY12.9% YoY. As a main factor behind, in addition to ForEx impact, we made progress in outsourcing cost reduction through in-sourcing development capabilities, including clinical trials, et cetera, under SMT, which led to cost optimization of about JPY8 billion. Furthermore, due to the completion of large clinical studies for strategic brands, clinical development costs decreased by about JPY9 billion. Onetime co-development cost payments booked in FY2024, et cetera, was another factor for the YoY cost reduction.

Up to Q3, we were in a transitional period with the completion of large clinical studies for strategic brands moving on to prepare for new late-stage development studies. From now on, we are planning to initiate multiple Phase III studies. From Q4 and FY2026 onwards, we are expecting investments to increase aligned with the progression to late-stage development.

FY2025 Revised Forecast

- **Another upward revision of Revenue and Core/Full OP, reflecting continued strong momentum**
- **Expect Core OP margin to achieve 24.8% (+4.2ppt vs. FY2024)**

Exchange rates of FY2025 latest forecast: 150 yen/USD, 174 yen/EUR
(Forecast rates of Q4/FY2025: 154 yen/USD, 180 yen/EUR)

(billion yen)	FY2024 Actual	FY2025			Main items of revision
		Previous FCST	Latest FCST	Change	
Revenue	1,912.3	2,030.0	2,100.0	+70.0	• XTANDI, mirabegron and FX impact
SG&A expenses	843.0	831.0	859.0	+28.0	
US XTANDI co-promote fee	252.6	245.0	259.0	+14.0	
SG&A excl. the above (SG&A ratio*)	590.5 30.9%	586.0 28.9%	600.0 28.6%	+14.0 -0.3ppt	• Similar level excl. FX impact
R&D expenses	327.7 17.1%	322.0 15.9%	315.0 15.0%	-7.0 -0.9ppt	• Reflects prioritization of early-stage research programs
Core operating profit (Core OP margin)	392.4 20.5%	490.0 24.1%	520.0 24.8%	+30.0 +0.6ppt	
<Full basis>					
Operating profit	41.0	240.0	340.0	+100.0	• Other income: 30.0 (fair value remeasurements on contingent consideration, etc.) • Partial release of other expenses previously incorporated: 40.0 (risk of impairment losses, etc.)

FY2025 previous FCST announced in Oct 2025. Exchange rates of previous FCST: 145 yen/USD, 170 yen/EUR
*Excl. US XTANDI co-promote fee

No impairment indication as of Feb 2026

Page eight is about the revised full-year forecast of FY2025. Based on strong momentum through Q3, we have again revised upward our full-year forecast for revenue, core, and full OP.

The core OP margin is expected to increase by 4.2 percentage points YoY to achieve 24.8%.

Regarding foreign exchange assumptions, we have revised the full-year forecast exchange rates to JPY150 per US dollar and JPY174 per euro. For Q4, we assume an exchange rate of JPY154 per US dollar and JPY180 per euro.

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Revenues are projected to reach JPY2.1 trillion, an upward revision of JPY70 billion from the previous forecast in the Q2 announcement, incorporating the upward revision of the full-year forecast for XTANDI and mirabegron as well as the impact of the change in exchange rate assumptions.

SG&A expenses, excluding US co-promotion fee for XTANDI, are projected at JPY600 million. Excluding the ForEx impact, this is a similar level as the previous forecast.

R&D expenses are projected at JPY315 billion, reflecting the prioritization of programs in the research phase.

As a result, core operating profit has been revised upward by JPY30 billion from the previous forecast. We expect our core operating profit to reach JPY520 billion, exceeding the JPY500 billion mark for the first time since Astellas's inception.

Next, full basis operating income. We have incorporated JPY30 billion into the latest forecast under other income, including changes in the fair value of contingent consideration related to VYLOY following the discontinuation of PDAP program booked in Q3. Additionally, we partially released JPY40 billion of other expenses, including an impairment loss risk previously booked at the start of the period, reflecting this in the latest forecast. As a result, full-year operating profit is projected at JPY340 billion.

Strategic Brands: FY2025 Key Expected Events

(Blue: Updates since the last financial results announcement)

Significant progress in development of PADCEV MIBC: US *approval just 1 month* after sBLA acceptance

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
avacincaptad pegol/ IZERVAY		● Jun Stargardt disease/ Phase 2b: Primary endpoint not met	★ Sep Approval (Japan) ◆ Oct GATHER2 open-label extension study data (AAO)		<Other update> Approved in Australia in Oct 2025
enfortumab vedotin/ PADCEV		MIBC (Cis-ineligible)/ EV-303 interim analysis: ★ Primary endpoint met ● Aug Other solid tumors/ EV-202: Terminated NMIBC/EV-104: Terminated	★ Oct Acceptance (US) Approval in 1 month ★ Nov MIBC (Cis-ineligible)/ Approval (US), Filing (Europe)	● Oct EV-303 data (ESMO) ★ Jan MIBC (Cis-ineligible)/ Filing (Japan)	● Apr MIBC (Cis-ineligible)/ PDUFA date (US)
zolbetuximab/ VYLOY			● Oct MIBC (Cis-eligible)/ EV-304 interim analysis: ★ Primary endpoint met	● Dec Pancreatic/GLEAM final analysis: Primary endpoint not met ● Jan ILUSTRO data (ASCO GI, late-breaking)	● Feb EV-304 data (ASCO GU, late-breaking)

<Other Update in Strategic Brands>

- fezolinetant/VEOZAH: Positive topline results obtained from Phase 3 STARLIGHT 2 (Japan pivotal) study in Jan

★ : Key milestone

◆ : Data presentation

As of Feb 2026. VEOZAH: Approved as "VEOZAH" in ex-US. MIBC: Muscle-invasive bladder cancer. AAO: American Academy of Ophthalmology. Cis: Cisplatin, NMIBC: Non-muscle-invasive bladder cancer, ESMO: European Society for Medical Oncology, ASCO: American Society of Clinical Oncology, GU: Genitourinary, GI: Gastrointestinal

We will now discuss pipeline progress. Page 10, progress on key events expected in FY2025 for our strategic brands. Particularly significant advancement, as shown in the center of the slide, was approval in the US last November for the expanded indication of PADCEV based on EV-303 trial for cis-ineligible MIBC patients.

Another worthy of attention is the remarkable speed of this approval achieved just one month after the submission was accepted in October, more than four months ahead of the PDUFA date. Following the US, we submitted for this expanded indication in Europe in November and in Japan in January. Furthermore, the EV-304 trial for cis-eligible MIBC also met its primary endpoint.

Detailed data from this trial will be presented at the February ASCO GU meeting.

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VYLOY data from the Phase II ILUSTRO trial was presented at ASCO GI in January. Details are provided on the following pages.

As for other updates, as noted in the table photo, we obtained favorable top line results from the Phase III STARLIGHT 2 study, the pivotal Japanese trial for VEOZAH. We plan to submit for regulatory approval in Japan after obtaining results from the STARLIGHT 3 trial, evaluating long-term safety.

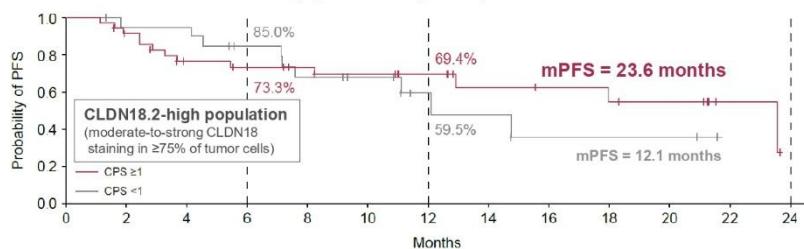
zolbetuximab/VYLOY: Latest Status

Promising data supporting combination with checkpoint inhibitor + chemotherapy presented

Latest Data¹

- Phase 2 ILUSTRO study Cohort 4B (zolbetuximab + nivolumab + mFOLFOX6; moderate-to-strong CLDN18 staining in $\geq 50\%$ of tumor cells)
 - ✓ mPFS = 14.8 months overall
 - 18.0 months in CLDN18.2-high
 - 23.6 months in CLDN18.2-high and CPS ≥ 1

(Ref) mPFS in zolbetuximab + Chemo: 9.2 months²
nivolumab + Chemo: 7.7 months (all) / 7.5 months (CPS ≥ 1)³



1. ASCO GI 2026, 2. N Engl J Med. 2024;391:1159-62, 3. Lancet. 2021;398:27-40
mFOLFOX6: 5-FU, leucovorin and oxaliplatin, CLDN: Claudin, mPFS: Median progression-free survival, CPS: Combined positive score, Chemo: Chemotherapy, CAPOX: Capecitabine and oxaliplatin

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Page 11 shows the latest status of VYLOY. We presented promising data at ASCO GI supporting its combination with immune checkpoint inhibitors plus chemotherapy. Cohort 4B of the Phase II ILUSTRO trial evaluated the efficacy and safety of VYLOY in combination with nivolumab and chemotherapy for first-line treatment of gastric cancer.

The median PFS progression-free survival, the efficacy endpoint was 14.8 months across the entire cohort, 18 months in patients with Claudin 18.2 high expression. As indicated by the red line in the graph, 23.6 months in patients with both Claudin 18.2 high and CPS 1 or higher. This significantly exceeded previously reported data for combination therapy with chemotherapy alone.

Currently, the Phase III LUCERNA trial is underway as a confirmatory study for the combination therapy. The LUCERNA trial evaluates the efficacy and safety of the combination therapy of VYLOY pembrolizumab and chemotherapy in gastric cancer patients with Claudin 18.2 high expression CPS 1 or higher who demonstrated the longest PFS in the ILUSTRO trial. Patient enrollment is progressing smoothly with interim analysis data expected to become available in FY2027 or later. We anticipate that this combination therapy will further contribute to the treatment of gastric cancer, an area of high unmet medical need, and maximize the product value of VYLOY.

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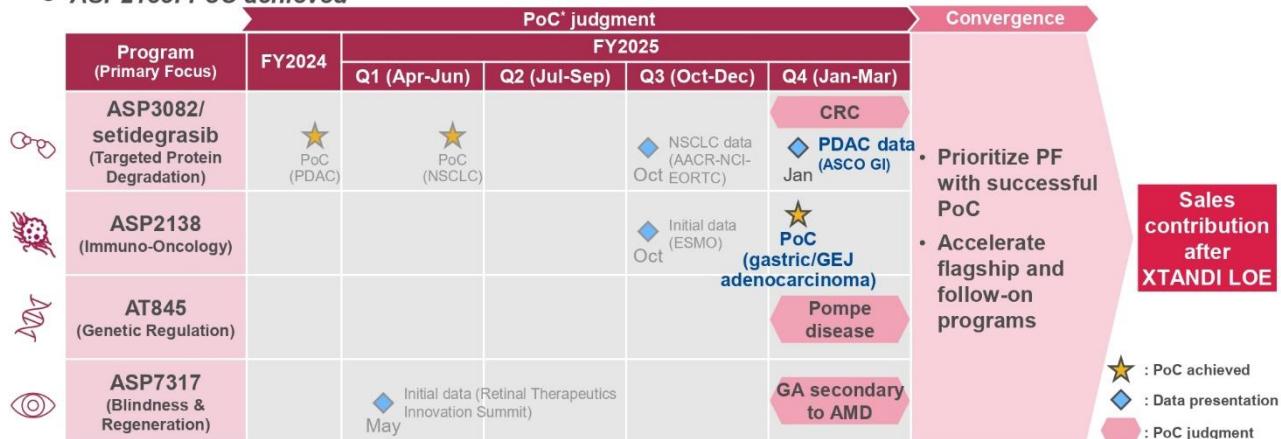
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Progress in Focus Area Approach

(Blue: Updates since the last financial results announcement)

- **ASP3082/setidegrasib: Promising data in PDAC with high unmet medical need presented**
- **ASP2138: PoC achieved**



*PoC: Key clinical data supporting a decision to initiate late-stage development from a scientific standpoint

See slide 38 for current status of other programs and slides 39-40 for overview of flagship programs. PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer, AACR: American Association for Cancer Research, NCI: National Cancer Institute, EORTC: European Organisation for Research and Treatment of Cancer, ASCO: American Society of Clinical Oncology, GI: Gastrointestinal, ESMO: European Society for Medical Oncology, GEJ: Gastroesophageal junction, GA: Geographic atrophy, AMD: Age-related macular degeneration, PF: Primary Focus, LOE: Loss of exclusivity

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Page 12, regarding the focus area approach, we describe the progress of the flagship programs for each primary focus. For ASP3082 under targeted protein degradation, clinical trial data for PDAC was presented at ASCO GI in January. Details are provided on the following page.

ASP2138 and immuno-oncology achieved critical milestones by demonstrating proof of concept in gastric adenocarcinoma and GEJ adenocarcinoma. This is based on the promising first-line data presented at ESMO last October. Preparations are underway to initiate Phase III trials promptly.

Clinical trials for AT845 in gene regulation and ASP7317 in blindness and regeneration are progressing as planned with the PoC judgment still targeted by March.

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Progress in ASP3082/setidegrasib & Primary Focus Targeted Protein Degradation

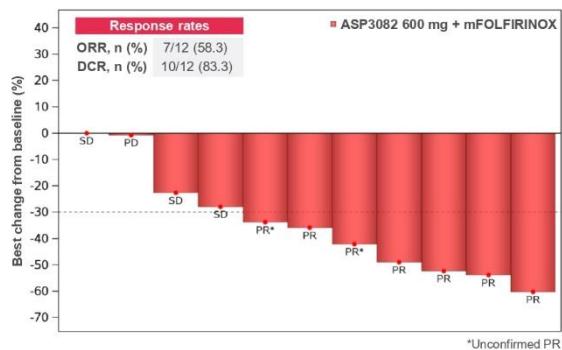
Promising data in 1L PDAC presented, anticipated to initiate Phase 3 study by March

Latest Data1

- ASP3082 + mFOLFIRINOX combination showed promising antitumor activity in 1L PDAC
 - ORR = 58.3% (7/12), DCR = 83.3% (10/12)
- No new safety signals observed
- Findings support further development in PDAC

Current Status

- ASP3082/setidegrasib
 - PDAC: Plan to initiate Phase 3 study in 1L setting by Mar
 - NSCLC: Planning is ongoing for registrational studies
 - CRC: PoC judgment anticipated for Q4
- Follow-on programs
 - ASP5834 (Pan-KRAS):**
Fast Track designation granted by FDA for NSCLC in Jan
 - ASP4396 (KRAS G12D): Terminated to focus on ASP3082



1. ASCO GI 2026
1L: First line, PDAC: Pancreatic ductal adenocarcinoma, mFOLFIRINOX: Leucovorin, fluorouracil, irinotecan and oxaliplatin, ORR: Objective response rate, DCR: Disease control rate, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer, PoC: Proof of concept, KRAS: Kirsten rat sarcoma viral oncogene homologue, FDA: Food and Drug Administration, SD: Stable disease, PD: Progressive disease, PR: Partial response

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Page 13. Progress on ASP3082 and primary focus targeted protein degradation regarding ASP3082 for first-line PDAC, pancreatic carcinoma treatment, promising data was presented at ASCO GI, and we anticipate to initiate the Phase III by March.

PDAC is a disease with a high unmet medical need as the current standard chemotherapy-based treatment struggle to achieve sufficient efficacy. In evaluating ASP3082 in combination with chemotherapy as first-line treatment for PDAC, we observed a high antitumor activity and ORR of 58.3% and DCR, disease control rate, of 83.3%. ORR stands for objective response rate. The safety profile showed no major concerns, yielding promising findings supporting further development in PDAC.

Based on these results, preparations are underway for Phase III trial targeting first-line treatment of PDAC scheduled to start by March.

For NSCLC, development plans are being reviewed to initiate registrational studies earlier.

For colorectal cancer, PoC judgment is anticipated by March. Regarding follow-on program progress, ASP5834, a Pan-KRAS degradation, received fast track designation from the FDA for NSCLC. We anticipate this will accelerate its development.

ASP4396, which was being developed as a drug targeting the same KRAS G12D mutation as ASP3082, has been terminated based on data obtained to date. Going forward, we will focus development efforts on ASP3082, which has demonstrated promising data for this target.

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Key Takeaways



Strong Momentum Continues in Q3

- **Strategic Brands:** Continued strong growth
- **SG&A ratio** continues to improve driven by robust cost optimization progress

Another Upward Revision of Full-year Forecast

- Revenue **+70.0 bil. yen**
- Core OP **+30.0 bil. yen**
- Full OP **+100.0 bil. yen**

Significant Advancement of Pipeline

- **PADCEV and VYLOY:** Progress in LCM
- **ASP3082 and ASP2138:** Progress toward initiation of Phase 3 studies

Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA
LCM: Lifecycle management

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Page 14, today's summary. Strong momentum continued in Q3. Strategic brands maintained strong growth. Cost optimization through SMT progressed well with SG&A ratio continuing to improve.

Following the Q2 earnings announcement, we have made another upward revision of our full-year forecast of revenue by JPY70 billion, core OP by JPY30 billion, and full OP by JPY100 billion.

Our pipeline also made significant advancement. As for strategic brands, life cycle management progressed, notably for PADCEV and VYLOY. In the focus area approach, ASP3082 and ASP2138 progress towards initiation of Phase III trials. We'll continue pursuing further profit growth and enhancing pipeline value.

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Upcoming Events



Sustainability Meeting
February 26, 10:00-11:15 (JST)



R&D Day
Late March



FY2025 Earnings
Late April



Next Corporate Strategic Plan
Late May

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At the end, this is an update on upcoming events.

Our annual sustainability meeting is scheduled for the 26th of this month. We'll present Astellas' sustainability philosophy, specific initiatives, and the outcomes achieved through these efforts. We really encourage you to participate.

Next, we plan to hold an R&D Day in late March. This session will provide an in-depth explanation of our current R&D status and further direction.

In late April, we will hold the FY2025 earnings call.

Then in late May, we plan to hold a briefing on our next corporate strategic plan. We hope to demonstrate how Astellas will achieve sustainable growth beyond the expiration of XTANDI's exclusivity. Details for all these events will be announced as soon as they are finalized. We look forward to your continued interest. That's all from me. Thank you very much for your attention.

Kato: That was a presentation by Kitamura.

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Question & Answer

Kato [M]: Next, we are going to entertain questions from the audience. If you have a question, press the raise hand button at the bottom of your Zoom screen. If you're joining from a smartphone, please tap details and you will find raise hand, so please press that button. I will name you one by one. If your name is called, please unmute yourself on your own screen. Please mention your name and affiliation and ask your question.

We now would like to entertain questions. First, Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi [Q]: Yamaguchi from Citigroup Securities. My first question is about the upward revision. In Q2, you made an upward revision. Once again, in Q3, this is a very positive message to the market. Mirabegron, XTANDI, ForEx, SMT, and R&D are the factors. The main factor you see is the upside of the important products. On a full-year basis, do you think you can have some room for another upward revision? We still have Q4.

Kitamura [A]: I'd like to confirm a bit. We made another upward revision, and you'd like to ask about the factors behind ForEx, XTANDI, and mirabegron.

We made another upward revision. Up to Q3, there was a very strong momentum. We are seeing a lot of progress in cost optimization. In Q3, everything is to be updated to create another forecast? No. Rather, we create an annual plan, and we check the progress in the PDCA cycle. At the end of Q3, we made a review. If there's anything major in Q3, others can be updated. Now this time, up to Q3, we have seen a strong momentum.

We didn't include everything into the upward revision on a full-year basis. We selected some. That was a major factor. Overall, priority strategic brands are growing very strongly, in accordance with our plan. We see some great performance. In a month or two months, to come, we didn't touch on that very much. Mirabegron and XTANDI, clearly speaking, overachievement is continuing, so we decided to reflect it as well as the ForEx rate. Regarding the visible cost elements, we did some update. Full-basis numbers also revised upward, full-basis cost in Q2, the visibility did not change much, so we didn't change. At the end of Q3, we reviewed, and full-basis costs had higher visibility as well, so we decided to reflect that as well.

With this, in Q4, did we redo from the bottom up? Not really. We do what we need to do. Based on our plan for FY2026 and beyond, we are developing our plan, so thank you for your understanding.

Yamaguchi [Q]: Okay. Thank you very much. Just briefly, another question about IZERVAY, in Q2, you made a revision. You said you are on track. Going forward, in order to increase the momentum for IZERVAY, do you have any initiatives? Please share, if any.

Kitamura [A]: Thank you for your question. As has been pointed out, IZERVAY is an extremely important brand for us, so we're doing different activities. Rather than me, Claus is going to explain what we are doing currently. Claus, please?

Zieler [A]: Yes, Yamaguchi-san, thank you for your question. Let me just briefly sketch what we see in the US market for geographic atrophy.

As you're aware, in the beginning of the fiscal year, we had significant turbulence in the market due to affordability issues with the foundations withdrawing, and that meant certain patients couldn't afford their co-pay. Since that time, we have seen demand coming back steadily. We now have two quarters in a row where we see the underlying demand, so the new patient starts growing by about 10% QoQ. That gives us confidence that we will be able to achieve the forecast that we made at the end of Q2.

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Does that answer your question?

Yamaguchi [Q]: Yes, thank you. Is there any new initiative you have at the moment or not?

Zieler [A]: Not since our disclosure in forecast too. At the end of Q2, you may remember that we had reorganized our market access team to provide better support for the retina clinics. That is ongoing, and we see very good success from that. We are continuing to focus our promotion on the retina specialists because we think that that's the education that first needs to be embedded, and we're seeing good progress there. There's nothing new, if you want. Of course, our DTC campaign is continuing to educate patients, so there's nothing new, but just a continuation of the activities we started after Q2.

Kitamura [A]: Thank you very much, Yamaguchi-san.

Let me make some additional comments. Claus was very modest. He just explained what should be done is done. During the DTC, what is actually working? What kind of message is communicated? Of course, we have to make a new market as well, so the PDCA is turning around. In terms of the contents of what we are doing, we have to establish the market. For that, we are working as a team effort. Also, this product is launched in Japan as well, so not only US, but also we are thinking about global expansion. As a company, as a big world, we are currently working on that.

Kato [M]: Next, JPMorgan, Wakao-san, please.

Wakao [M]: JPMorgan Wakao, can you hear me?

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

Wakao [Q]: Page eight of your presentation, I have a question on the slide. SG&A and R&D expenses, based upon the current currency level, it's quite suppressed. Seemingly, it's on the increase, but I have an impression that those are quite well controlled. Now my question is, next fiscal year, SG&A, excluding XTANDI co-promotion fee, then how do you feel about R&D expenses? For SG&A, with this ForEx status, it is suppressed in this way. SMT is ongoing in a very smooth manner. In that case, absolute value basis, next fiscal year, the direction will be on the decrease. At the same time, R&D, you are going to set some more pivotal studies, so it's likely to increase. That's the view that I have. Would you please make a comment?

Kitamura [A]: Wakao-san, thank you very much. Regarding the numbers for next fiscal year, we will explain the details when we announce the FY2025 full-year results. Basically, we should continue the good momentum, and we are trying to develop a plan for revenue and profit increase. SMT is optimizing the cost by JPY20 billion this year. We still have balance to go, so we have to handle this. That's important. We do have a plan. We have to increase the accuracy of our execution so that we can front-load our planning.

Wakao [Q]: What about SG&A cost in the end?

Kitamura [A]: For me to say this is going to be the situation, it's not appropriate. Needless to say, we have to clarify where to increase and where to reduce. Based on the SMT philosophy, there is a huge room for reduction. We are assuming that we are going to work on it.

As for R&D expenditure, clearly, late-stage development is something we are going to move on to. There's going to be an increase there.

Overall, to what extent we can offset. In the budgeting process, we are discussing right now. Increasing the revenue, because if we increase the revenue or increase the R&D, it may not lead directly to R&D cost increase. How can we take measures to optimize our costs first? This fiscal year, last fiscal year, that's how we have

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been addressing it, so that approach is not going to change in principle. Regarding the specific numbers, please wait for some more moment.

Wakao [Q]: I have a follow-up question. SMT target is JPY150 billion. Its effectiveness will be higher in FY2026 rather than compared to FY2025. That's my understanding. You will have sales promotion, but it doesn't mean that you have a new drug to be launched. SMT effectiveness can be seen more easily in terms of the balance. Am I wrong?

Kitamura [A]: SMT effectiveness up to FY2027, we are going to reduce the cost by JPY150 billion. JPY40 billion out of that was done last year. This year's plan was JPY20 billion. On a cumulative basis, it's going to be added up. On a cumulative basis, this year's target, JPY40 billion last year and JPY20 billion this year, so that's JPY60 billion in total. We had to do this by the end of March according to plan. Right now, as of December last year, we reached a JPY60 billion cost reduction. We have JPY90 billion to go to reach JPY150 billion target. How to do this is the SMT's approach philosophy. What we are discussing right now is as follows: how we can realize the remaining part in the next fiscal year at an accelerated pace. Late-stage development studies will be initiated, as you said. As a company, it's not a net increase, but rather, we can manage the cost to a certain degree.

Wakao [M]: Understood.

Kitamura [A]: Anyway, it's working well.

Wakao [Q]: My second question, ASP3082, I have a question. ASP3082, ASCO GI had a presentation about good data. Revolution Medicines are the competitors. The data were similar, according to the presentations. How you can differentiate is something I'd like to know. One element is going to be the speed. Anything else as well? ASP4396 was discontinued. ASP4396 had higher expectations at certain timing. Terminating this program, what's the intention behind? ASP3082 data are better? That's why you terminated ASP4396.

Kitamura [A]: ASP3082, our philosophy including the competitive edge against the competitors. On that point, first, Taniguchi is going to explain.

Taniguchi [A]: Let me explain first, ASP3082, particularly from the differentiation perspective compared to Revolution Medicines products, Revolution Medicines drugs, oral KRAS inhibitors, ASP3082 and their products are completely different. Our product is targeted protein degrader. Protein with KRAS mutation is going to be degraded by the product. The target is the same, but MOA is different.

Then, how it is represented within the clinical data, of course, we have to look to the data. Needless to say, when it comes to the protein inhibitor, the resistance against inhibitors was quite frequently reported, so we have to have our eyes on it. At the same time, our protein degrader against ASP3082, some resistance is under the research in our end as well. Likely to be the biggest difference is the continuation level of the efficacy. We are going to accumulate more data to look at the sustainability of the effect as well.

In our knowledge, the first-line study of pancreatic cancer hasn't been started by the competitor. We would like to accelerate our speed so that we can start the combination treatment with the chemotherapy for the PDAC. For PDAC or pancreatic cancer, the prognosis is quite poor. We would like to start clinical trials as early as possible so that we can deliver better therapies to the patients.

ASP4396 termination of the development, ASP4396, KRAS G12D is a target. It is exactly the same target as that of ASP3082. The one difference is that E3 ligase is a cereblon type. E3 ligase of ASP3082 is VHL, it is quite different. According to our original plan, compared to the efficacy of ASP3082 and ASP4396, if there are some differences, we are going to consider. We haven't opened the data yet, but ASP4396, the data are not better

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than ASP3082. Because ASP3082 is more advanced compared to it, we decided to prioritize ASP3082 in terminating ASP4396.

Kato [M]: Next, Goldman Sachs Securities, Ueda-san, please.

Ueda [Q]: Ueda from Goldman Sachs Securities. Thank you very much for this opportunity. First question, that's about the progress of SMT. I have an additional question about that. Currently, your core OP margin in FY2027, 30% is the target. Currently, I think your progress level is more than you've expected or this effect of SMT is way more effective than expected. Is that how you view? Please explain about this.

Kitamura [A]: Thank you, Ueda-san.

SMT, by FY2027, JPY150 billion net benefit is what we would like to realize. Then, within two years, JPY40 billion and JPY20 billion, in total, JPY60 billion. The speed is not extremely fast. Rather, with the wider scope, we see that it's in line with the plan, a little faster than planned. Last year, it was JPY40 billion, but we worked toward only the lower-hanging fruits because it came up with the result quickly.

On the other hand, transformation type of the measures, that takes a bit more time. Last year, we've been working on the planning before coming up with the result. From this year, that transformation realizing measures started to be working or operating. This is a transformation, so it takes a relatively longer time. For those, you have to change something, so you have to spend a certain level of the money. That's why including that time is JPY20 billion.

Without such an initial investment, it could be more beneficial. Currently, we are focusing on transformation part now, so it's not extremely faster than expected. Basically, it is on track of the plan, but if you look into more details, there was something that could be accelerated more in terms of the speed. That is exactly currently what we are working.

Ueda [Q]: Thank you very much. Understood.

My second question, the trend of the main brands in the United States. In the quarter between October and December, XTANDI, at the end of the year, did not have a high level of sales unlike usual years. PADCEV, in the United States, QoQ, it was almost flat according to my image. Any sense of deceleration? What's the current trend of the businesses here?

Kitamura [A]: Thank you for your question. I'd like to briefly respond. Then, I'd like to hand it over to Claus later so that you can have more information.

What you have said is different from our perspective. As for PADCEV in the United States also, there is very good progress being made. In Q3, that is continuing as well on a continuous basis. XTANDI, in terms of the volume, there is a strong demand growth, which is continuing, so there is no slowdown in our viewpoint. Claus, anything to add from you, please?

Zieler [A]*: Yes. No, you're absolutely right. PADCEV is continuing to surprise us positively. You noted the very fast approval by the FDA of the MIBC, the EV-303 MIBC indication. We're already seeing uptake in that indication. It's been included in the NCCN guidelines. All of that is going very, very well.

Please do note, however, that our experience with PADCEV has consistently been that we see a very fast uptake in the first six months and then a very sharp plateau as we penetrate the relevant patient population. I think that's exactly what's happening right now. The uptake right now is faster than we expected, which is why we are saying it's above expectations, but there will be a plateau after about six months as we penetrate the new patient population completely.

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Ueda [Q]: Thank you very much. What about XTANDI?

Zieler [A]*: XTANDI is continuing at an amazing pace for a drug that's on the market for, what is it, almost 14 years now. The underlying demand growth in paid demand in the US, but also outside of the US, is continuing at a double-digit pace. In the US, more than 20% demand growth in paid demand, so that's continuing. However, we do see a consistent slowing of the increase in paid demand from the high 20% and 30% to now the lower 20%. You're right, there's some slowing, but it's still at an amazingly robust pace, which is why we're increasing the guidance of XTANDI at this point in time.

Ueda [M]: Thank you very much, I was able to understand clearly. That's all from me. Thank you very much.

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

Matsubara [Q]: Thank you very much. My first question is about VEOZAH. There is now a competitor, but it's within your assumptions in terms of the progress.

If I look at Q3, the growth rate is slowing a bit. New patient starts and the existing patients, VEOZAH, and the competitor's product, what about the shares, and how is it going to grow? I'd like to hear about your assumptions, Astellas' assumption.

Kitamura [A]: Matsubara-san, thank you very much. Regarding VEOZAH, I'd like to briefly comment. If there's anything to add, I'd like to ask Claus to comment.

As for VEOZAH, basically, it's on track. As is described here, there is now a competitor, which has been launched, but the real impact to be judged will require more time. As of now, it's not very different from our assumptions as of now. This is a new non-hormonal drug, so it's important to create a market here. We have been working on this by now. One of the important elements here is access. How to enhance and increase access, we have been working on this. In January this year, a new commercial coverage started, and it's now 80% by commercial lives coverage. We'd like to continuously increase further. Claus, anything to add from you?

Zieler [A]*: Yes. I think there are three factors to note on VEOZAH. VEOZAH is just chugging along. It's very consistent in its underlying demand growth. It's fully on track and in line with expectations, especially in the United States.

Now, as Kitamura-san noted, it's very early days to judge the market share distribution between the competitor and VEOZAH. We do have now 80% of lives covered in the US from a market access standpoint. That gives us a very good basis, which the competitor first has to establish. I think it will be some time before we can fully judge how the market decides between the two products. Right now, it's fully aligned with our expectations, as Kitamura-san said.

I think the more important factor, however, is how will two companies trying to develop this market, how will we be able to displace the SSRIs and the other off-label nonhormonal drugs in this market? Remember, VEOZAH right now only has about 14%, 15% of the non-hormonal market, so there's a lot of room to grow. I think two companies working on that will be more effective than one company alone. That is what I really would like to watch as the new year unfolds.

The third factor, maybe just to complete is the question of different monitoring requirements and different side effects like the somnolence that our competitor has. We don't know yet how that will play out, but we can say for VEOZAH that the wobble in the market that we had when we had the label update on the liver monitoring in the US, that has washed out, and we're back on that growth track.

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Ex-US, where the label update came later, we're seeing the same pattern replay, right? A certain uncertainty in the market, then a stabilization, then a reuptake of the growth. We're seeing exactly the same pattern ex-US as we had in the US, just with a delay in timing. That's why I say it's in line with our expectations because we're seeing the same pattern replay in the ex-US markets. I hope that answers your question.

Matsubara [Q]: Thank you very much for your response. Next is AT845. In Q4, you are going to judge the PoC, and adenovirus is administered. I just want to confirm if any liver adverse event has not taken place and the stability is maintained for 3 years or so, I think that is being mentioned. Considering the impairment risks, I would like you to explain about this liver toxicity matter.

Taniguchi [A]: Let me explain about that. AAV8 vector is utilized as the gene therapy. That is AT845 and this is targeting Pompe disease. Currently, the patient enrollment is completed, and we're just waiting for the data readout becomes available.

For liver toxicity, of course, I wouldn't say there is no liver toxicity at all. Just like other AAV8, the increase of the liver enzyme is observed in some cases. So far, it is not really a big issue.

Therefore, as has been planned, by the end of March, data are going to be collected, and we will make the final analysis, looking at the balance of efficacy and safety. Then, we are going to make a judgment on PoC.

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

Kato [M]: Next, Sanford C. Bernstein, Sogi-san, please.

Sogi [Q]: Thank you. First question is about PADCEV.

Year-to-date number and updated guidance. If we look at Q3, you showed strong growth. For Q4, the growth level is a bit lower according to your guidance. That's my understanding. Full-year guidance, do you think there is a potential for further upside or Q3, Q4 for the phasing, are there any background?

Kitamura [A]: As for the full-year forecast, Sogi-san, as I said at the beginning, revisiting everything to update? No. We saw the strong momentum and updated some elements. If you look at the numbers by brand, for Strategic Brands, we have the same numbers as before. We are not expecting a slowdown in Q4. Rather than updating that, we wanted to reflect what's working well right now to discuss what we are going to see for the next fiscal year. That's how we are steering our operations on a full-year basis.

If we update everything, the numbers might be different, but we do whatever we need to do in the current fiscal year and how to address the further growth next fiscal year. That's how we are discussing. Thank you for understanding.

Sogi [Q]: Okay. Next, about R&D costs. From Q4, R&D costs and expenditure will increase because you will shift to more investments. Full-year and year-to-date numbers can be compared. Then, in Q4, a little less than JPY100 billion will be spent, according to my understanding.

In 2026, Phase III trials in oncology would be initiated. At that pace, are you going to proceed? Is my understanding correct? Also, you have SMT initiative. It would take time for transformation, and initial investment period will transition to harvest the fruits. How is it going to be offset into the future?

Kitamura [A]: Let me start with SMT. Your basic understanding is correct. Upfront investments are being made. We are going to recover those investments, so you're right. However, we have things to do in the remaining two years, so we will recover investments, and we will make another investment to recover the investment. This is a series of activities. It's not just for a short term in a single year, but this is a more continuous activity.

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For each product, you're right, but overall, it's going to be slightly different. In the end, by FY2027, we are going to optimize the cost by JPY150 billion.

Regarding R&D expenditure in Q4, you may think the number looks large. We understand your concern. What about this space, including the outlook for next fiscal year and so forth? We'd like to explain when we announce our forecast next fiscal year. It's not JPY100 billion times 4.

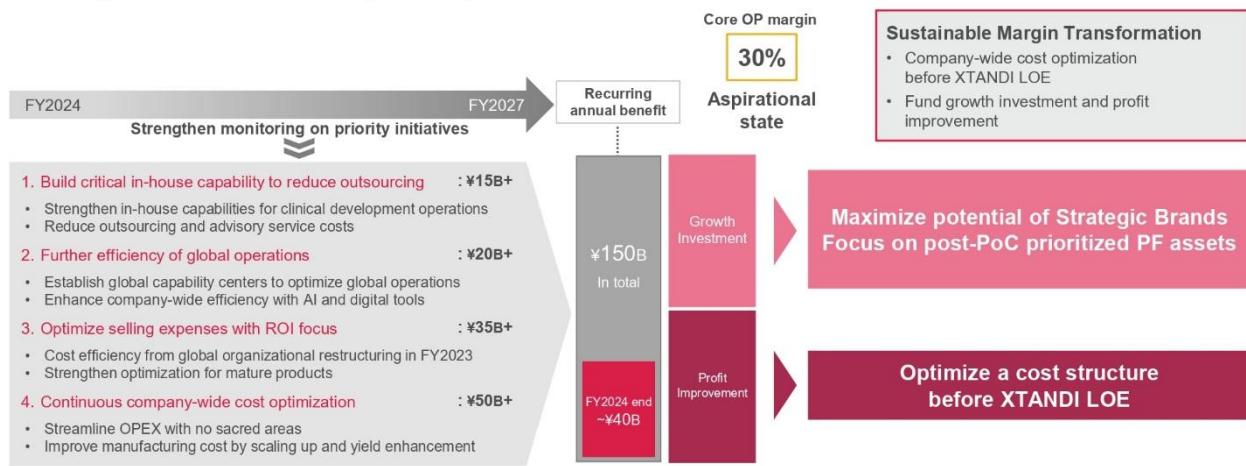
Sogi [M]: Understood. Thank you very much.

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

Seki [Q]: Seki from UBS Securities. Thank you very much for your presentation.

Sustainable Margin Transformation

- **Company-wide cost optimization of 150.0 billion yen before XTANDI LOE**
- **Fund growth investment and profit improvement**



LOE: Loss of exclusivity, ROI: Return On Investment, PoC: Proof of concept, PF: Primary Focus

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On page 24, I have also a question about SMT. Taking away the lower limit of JPY120 billion, it's now JPY150 billion. I assume this is due to confidence level getting higher. That said, will the 30% core operating margin going to be sustained even after XTANDI LOE?

Kitamura [A]: Our confidence level is enhanced. The answer is yes. In the summer of 2023, we started the discussion on SMT internally. In 2024, we disclosed this activity to you. At that time, multiple-year plan was developed. Back then, what we can do, and there are other elements we are not sure about. 70% was the plan. The remaining 30% gap must be filled. We worked on the execution together. To build our ideas, we have accumulated that much. Our confidence level is higher. The answer is yes.

If we do this after XTANDI LOE, is it going to be sufficient? No, maybe. Up until FY2027, before XTANDI LOE starts, we are going to do this. After LOE, we have to address that situation. The state of the Company after LOE must be discussed, so this is not going to be the end of the story. By FY2027, this is what we are going to do as preparation.

Seki [Q]: Once it starts or after it starts, what's the aspirational state of the Company?

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Kitamura [A]: We would develop a new plan, which we are discussing. In May this year, we will explain further details.

Seki [Q]: Thank you very much. We are looking forward to May.

Next question is about XTANDI. This is an extremely big product. Therefore, are there some possibilities in Japan, US, Europe, the generic market launch is going to be delayed? Could that kind of a scenario be conceivable? How do you view about it?

In this pharma world, after the exclusivity expired, there are sometimes generics are not going to be launched in a timely manner. Do you view that is also possible for XTANDI as well?

Kitamura [A]: I will make a brief comment. If there is additional, Claus, please.

First of all, because of LOE, everything is done. It's not really so. How we can continuously provide the value of this drug? That is an extremely important point. Having said that, this is again a very big product, and there are the matters of generics to be launched.

Our corporate plan is not the assumption that we can protect completely. Of course, we have a certain assumption, but it's not something that we are looking at, the situation that is on the decrease of sales. We are thinking about the countermeasures and to what extent we can protect XTANDI. That is also something we are discussing under the new strategic plan. Claus, do you have any additional comments?

Zieler [A]*: Yes, a few considerations maybe. I think the first consideration is that the patent that we have, the compound patent for XTANDI expires at different times in different geographies. In 2026, we'll already see patent expiry in some geographies like Brazil, Turkey, Korea, and China. Then 2027, the patent expires in the US, 2028 in Europe, but we do have some geographies like Japan, which you mentioned, which go all the way to 2029. There are some other geographies as well, which have a very, very long patent life.

The first comment I would like to make is that this is not one timing, but it's more a curve as different geographies where the patent expires come into play. We do expect generics to enter as soon as they can because it is a big asset, and it is a big market. We've seen that also with abiraterone, when abiraterone went generic.

However, the other thing I would like to mention is that we have two formulations in the market, a capsule formulation and a tablet formulation. For the tablet, we have a formulation patent, which extends the life and the protection of the tablet into the early 30s. Now, how the market is going to play between capsule generics and protected tablets is going to be a tricky analysis, and we're working on that right now. We do see some potential to maybe protect XTANDI partially with the formulation patent on the tablets that we have in place.

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

Kato [M]: Thank you. Next, SMBC Nikko Securities, Wada-san, please.

Wada [M]: SMBC Nikko Securities, my name is Wada. Full-base operating profit increase is my question. Impairment loss risk, and that is released partially, I think that's what it is about. Would you please explain the background of that? This time, focus area approach for programs are coming up with the favorable result of that data, and that impairment loss risks are likely to be now lowered down. When it comes to Strategic Brands, IZERVAY, VEOZAH, they are on track. Impairment loss risks, I think there are no supporting backgrounds for that. That's how we look at it.

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The question is, could please explain the background of this? That's one thing. Focus area approach with four programs. If you achieve PoC in March for everything, next fiscal year, you can move on to late-stage development. Is there any such possibility?

Kitamura [A]: Thank you very much, Wada-san, for your question. Full-basis review, the core was increased in Q2 and also in Q3 as well for the upward revision. Because of the increase in the core, the full was also increased. After three months following Q2, we reviewed everything, and we are conservative in developing the initial numbers. We could review.

We are checking the progress of various programs and projects, but it has not achieved a PoC. We cannot guarantee that it's going to work for sure. The assets in question, what about the probability of each? That's how we check. It's not just about the impairment loss, but there was a change or remeasurement of the fair value on contingent consideration. In some, we review non-core costs and additional JPY100 billion forecast for revenue as our assumption this time after upward revision.

If we achieve PoC for all four programs, are we going to go to Phase III in the next fiscal year? That's our wish. Yes

Wada [Q]: One more question, ASP3083. There was a mention of the discontinuation of ASP4396 E3 ligase, which is cereblon. Did you see the depreciation in ASP4396? I'm wonder whether the E3 ligase is effective.

Taniguchi [A]: We haven't disclosed the data yet, so I'd like to refrain from touching on the details. As we said, ASP3082 and ASP4396, the difference is the E3 ligase. What would be the results? I know you're very interested. Once the data is compiled, including ASP4396, we are hoping to disclose as soon as possible.

Wada [M]: Okay, understood. Thank you very much. That's all from me.

Kato [M]: Due to the limited time, the next question is going to be the last question. Morgan Stanley MUFG Securities, Mr. Muraoka, please.

Muraoka [Q]: Thank you very much. Muraoka from Morgan Stanley speaking. MFN tariff, I have a question for you.

Western major companies were able to settle by the end of the year, but for Japanese companies, no one has mentioned this yet at all. For your company, on a stand-alone basis, have you negotiated already, and do you have an outlook? By country, it's negotiated by group, by country. You may say that you cannot tell us at all. In the near future, can we expect that this is going to be settled or resolved? You have a high proportion of business in the United States and Medicare, so I am very concerned.

Kitamura [A]: Muraoka-san, thank you very much.

As you said, there are things we can tell you, and there are things we cannot tell you. Thank you for your understanding. Mega pharmas are discussing with the US government, so we are monitoring. As of now, an official letter has not been received by us, so that's the status right now. Internally, as we said from before, there are a variety of potential scenarios, so we are discussing such scenarios.

Still, there's nothing we can comment as anything specific. As for the tariff, as we said in the previous meeting, we have US business whose size is quite large. We have a large proportion of manufacturing in the United States, that's like 70%. We don't know about other companies, but for us, given the current status of our supply chain, is tariff going to be a big obstacle for us? We don't think so, according to analysis, but this is a very important topic. Internally, we are discussing and doing simulations right now to respond to your question.

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Muraoka [Q]: One more question. This is the second big revision, upward revision. The question is about dividend. In the beginning of the fiscal year, you came up with the level of dividend, and that is maintained. What's the background of not changing it?

Kitamura [A]: Thank you for your question. Basically, our principle for capital allocation hasn't been changed. We continue to invest for growth. At the same time for the shareholders, we are going to return to a stable manner. If there is an excessive fund, we are going to purchase our shares so that they can be returned to the shareholders. Iveric Bio has been acquired, and net is increased, and that is considered to be returned according to the capital allocation.

For the dividend, it's not something that we are thinking with just one-year performance. We are considering for the couple of years when we think about the cash flow. It was good this year. That's why it will be increased. Next year, it is not really good, so it reduced. It's not something like that. That is our basic principle for our capital allocation, and we stick to that. That is how we are.

Muraoka [Q]: Understood. Thank you very much. One last question from me. That is a follow-up question by Wada-san a little while ago. It's about IZERVAY. It is related to impairment loss. I would like to confirm, especially about IZERVAY. This time, the range of the impairment is reduced, and IZERVAY business is ongoing quite well. IZERVAY US impairment loss proportion is not something that you have as a concern for the operation?

Kitamura [A]: For IZERVAY, there's no change. We have to continue to grow it as well, and we are working on the initiative one by one. Of course, we don't think that the sales would be flat as it is. Of course, we have to grow it further. That is an assumption with our activities, but we haven't seen any big impairment loss risk. Ex-US, well, it's been mentioned that the approval here in Japan is also granted, and also the launch of sales is started. This is an asset that is not amortized, but it is now in that process. For IZERVAY, the situation is going quite well.

Muraoka [M]: Thank you very much.

Kato [M]: Thank you very much for giving us so many questions, but time is up. With this, we would like to close this earnings call. Thank you very much for your participation.

[END]

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