Astellas Pharma Inc.

Financial Results for the Q2 of FY2025

October 30, 2025

Event Summary

[Company Name]	Astellas Pharma Inc.
[Company ID]	4503-QCODE
[Event Language]	JPN
[Event Type]	Earnings Announcement
[Event Name]	Financial Results for the Q2 of FY2025
[Fiscal Period]	FY2026 Q2
[Date]	October 30, 2025
[Number of Pages]	28
[Time]	16:15 – 17:45 (Total: 90 minutes, Presentation: 31 minutes, Q&A: 59 minutes)
[Venue]	Webcast
[Venue Size]	
[Participants]	

[Number of Speakers]	5	
	Naoki Okamura	Representative Director, President and Chief Executive Officer (CEO)
	Tadaaki Taniguchi	Chief Research and Development Officer (CRDO)
	Claus Zieler	Chief Commercial & Medical Affairs Officer (CCMAO)
	Atsushi Kitamura	Senior Managing Executive Officer, Chief Financial Officer
	Nobuko Kato	Chief Communications & IR Officer
[Analyst Names]	Hidemaru Yamaguchi	Citigroup Global Markets
	Seiji Wakao	JPMorgan Securities
	Akinori Ueda	Goldman Sachs
	Hiroyuki Matsubara	Nomura Securities
	Fumiyoshi Sakai	UBS Securities

Shinichiro Muraoka	Morgan Stanley MUFG Securities
Tony Ren	Macquarie Capital Securities
Miki Sogi	Sanford C. Bernstein

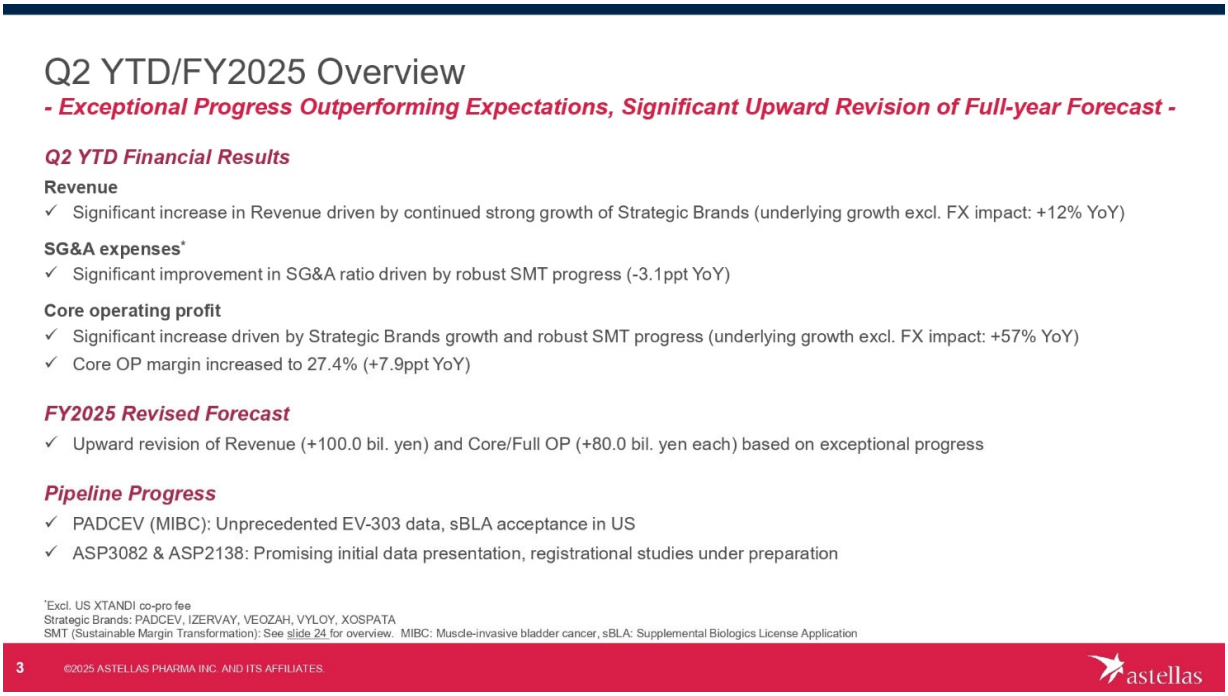
Presentation

Kato: Everyone, thank you very much for joining this Q2 YTD FY2025 Earnings Call by Astellas. I would like to serve as a moderator for today. I'm Chief Communications and IR Officer, Kato. Thank you for this opportunity. Today, first of all, we would like to give you the presentation. And after that, we'll have a Q&A session. On our website, presentation material is available. And in line with that, we are going to make a presentation. Including Q&A, we will provide you the simultaneous interpretation service between Japanese and English. For simultaneous interpretation service, we are not going to guarantee the accuracy of it.

When it comes to the language for this meeting, you can select from the Zoom webinar screen. And if you select the original, then you can listen to the original voices without hearing the interpretation voices. This is some notes. This material or presentation by representatives for the company and answers and statements by representatives for the company in the Q&A session includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management are subject to significant risks and uncertainties. Actual financial results may therefore, differ materially depending on a number of factors. So please do understand this. They contain information on pharmaceuticals, including compounds under development, but this information is not intended to make any representations or [inaudible] regarding the efficacy or effectiveness of these preparations, promote approved uses in any fashion or provide medical advice of any kind.

Now I'd like to introduce your participants here. President and Chief Executive Officer, Naoki Okamura; Chief Research and Development Officer, Tadaaki Taniguchi; Chief Commercial and Medical Affairs Officer, Claus Zieler. Chief Financial Officer, Atsushi Kitamura. We have the four representatives here. Now first of all, Okamura is going to start the presentation.

Okamura: Hello, everyone. I'm Naoki Okamura from Astellas Pharma Inc. Thank you very much for joining our FY2025 Q2 year-to-date financial results announcement meeting out of your very busy schedule today. This is a cautionary statement regarding forward-looking information. As this was explained by Kato earlier, I'm not going to read this page.



On page three, I will explain the highlights of FY2025 Q2 year-to-date financial results.

Overall, we have made exceptional progress outperforming expectations. We have made a significant upward revision of our full-year forecast. Driven by continued strong growth of our strategic brands, revenue increased significantly YoY with underlying growth of 12% YoY, excluding ForEx impact. As for SG&A expenses, thanks to the robust progress of SMT, sustainable margin transformation, our company-wide cost optimization initiative, SG&A ratio improved by 3.1 percentage points YoY.

Due to the growth of the strategic brands and robust cost management through SMT, core operating profit rose significantly YoY with underlying growth of 57%. Core operating profit margin increased by 7.9 percentage points YoY to reach 27.4%. Based on this exceptional progress exceeding our expectations, we revised our full-year forecast upward by JPY100 billion for revenue and by JPY80 billion for both core and full operating profit, respectively. Regarding pipeline progress for PADCEV, we have unprecedented EV-303 study data in MIBC, muscle invasive bladder cancer. And our sBLA for additional indication was accepted in the United States. As for focus area approach, we obtained promising initial data with ASP3082 and ASP2138 and registrational studies are now under preparation.

Agenda

I **Q2 YTD/FY2025 Consolidated Financial Results**
FY2025 Revised Forecast

II **Pipeline Progress**

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

Q2 YTD/FY2025 Financial Results

Revenue and Core/Full OP all increased by approx. 100.0 bil. yen YoY

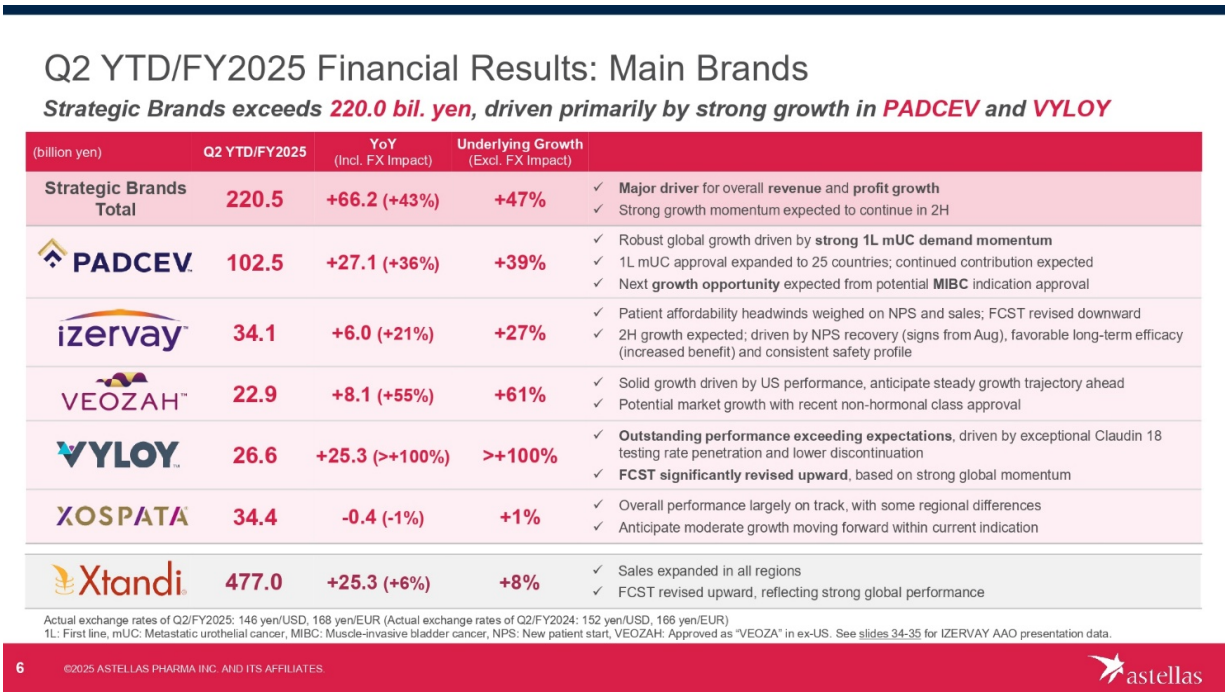
(billion yen)	Q2 YTD FY2024	Q2 YTD FY2025	Change	Change (%)	FY2025 Initial FCST*	FX impact (YoY)	Underlying Growth (Excl. FX Impact)
Revenue	**935.6**	**1,030.1**	**+94.5**	**+10.1%**	**1,930.0**	-22.2	**+12%**
Cost of sales	173.8	200.4	+26.5	+15.3%	373.0	-1.4	
SG&A expenses	406.4	403.8	-2.6	-0.6%	805.0	-12.5	
US XTANDI co-pro fee	126.0	127.2	+1.1	+0.9%	229.0	-5.6	
SG&A excl. the above	280.4	276.7	-3.7	-1.3%	576.0	-6.9	
(SG&A ratio**)	30.0%	26.9%	-3.1ppt		29.8%		
R&D expenses	172.3	143.3	-29.0	-16.9%	342.0	-3.8	
(R&D ratio)	18.4%	13.9%	-4.5ppt		17.7%		
Core operating profit	**183.1**	**282.6**	**+99.6**	**+54.4%**	**410.0**	-4.5	**+57%**
(Core OP margin)	19.6%	27.4%	+7.9ppt		21.2%		
<Full basis>							
Amortisation of intangible assets	69.2	65.5	-3.7	-5.4%			
Other income	4.5	5.2	+0.7	+16.0%			
Other expenses	26.9	25.4	-1.6	-5.8%			
Operating profit	**93.7**	**199.4**	**+105.7**	**+112.8%**	**160.0**		
Profit before tax	89.0	194.6	+105.6	+118.6%	150.0		
Profit	**73.5**	**147.6**	**+74.1**	**+100.8%**	**130.0**		

*Disclosed in Apr 2025, **Excl. US XTANDI co-pro fee
Exchange rate assumption of FY2025 initial FCST: 140 yen/USD, 160 yen/EUR
Actual exchange rates of Q2/FY2025: 146 yen/USD, 168 yen/EUR (Actual exchange rates of Q2/FY2024: 152 yen/USD, 166 yen/EUR)

Page five shows FY2025 Q2 year-to-date financial results. Revenue, core and core operating profit all increased by about JPY100 billion YoY.

Let me explain main items. Revenue reached JPY1,030.1 billion, up by 10.1% YoY. Core operating profit rose to JPY282.6 billion, up by 54.4% YoY. The ForEx impact is shown on the right-hand side of the table. ForEx had a negative impact on both revenue and core operating profit. Underlying growth, excluding this impact, was 12% for revenue and 57% for core operating profit, demonstrating a stronger growth. The bottom half of this

page shows our full basis results. Operating profit was JPY199.4 billion, up by 112.8% YoY. Profit increased to JPY147.6 billion, up by 100.8% YoY.



Page six shows FY2025 Q2 year-to-date results of our main brands.

Strategic brands grew substantially, driven primarily by strong growth in PADCEV and VYLOY. First, Q2 year-to-date sales of five strategic brands driving Astellas growth, namely PADCEV, IZERVAY, VEOZAH, VYLOY and XOSPATA exceeded JPY220 billion in total, substantially up by JPY66.2 billion or 43% YoY. Underlying growth, excluding ForEx impact, was 47%, showing a strong growth. Due to high profitability of these brands, they not just contributed to revenues, but also made a great contribution to profit growth on a consolidated basis as a whole. We are expecting the strong growth momentum to continue in H2 of FY2025.

Next, I will explain individual strategic brands and XTANDI. PADCEV, global sales increased to JPY102.5 billion, up by JPY27.1 billion or 36% YoY. Robust global growth has been continuously driven by strong first-line mUC demand momentum. Regional expansion in the first-line indication is also making steady progress. First-line mUC approval expanded to 25 countries. We're expecting further expansion of countries with approval as well as an increase in the number of countries where reimbursement will start.

Mainly based on the robust progress in the United States and Europe and FY2025 H2 outlook, we revised our forecast upward by JPY10 billion to expect JPY210 billion on a full-year basis. Next growth opportunity is expected from potential MIBC indication approval. EV-303 study in cis-ineligible MIBC presented at ESMO the other day, demonstrated extremely promising results, exceeding our expectations. Based on these results, we already filed a submission in the United States. We're expecting contribution to sales post approval.

Furthermore, based on this exceptional data exceeding our expectations, we are analyzing the possibility of any upside to our sales forecast, including peak sales. Also taking into account the status of EV-304 study for cis-eligible MIBC, we will share our latest outlook as soon as we complete our analysis.

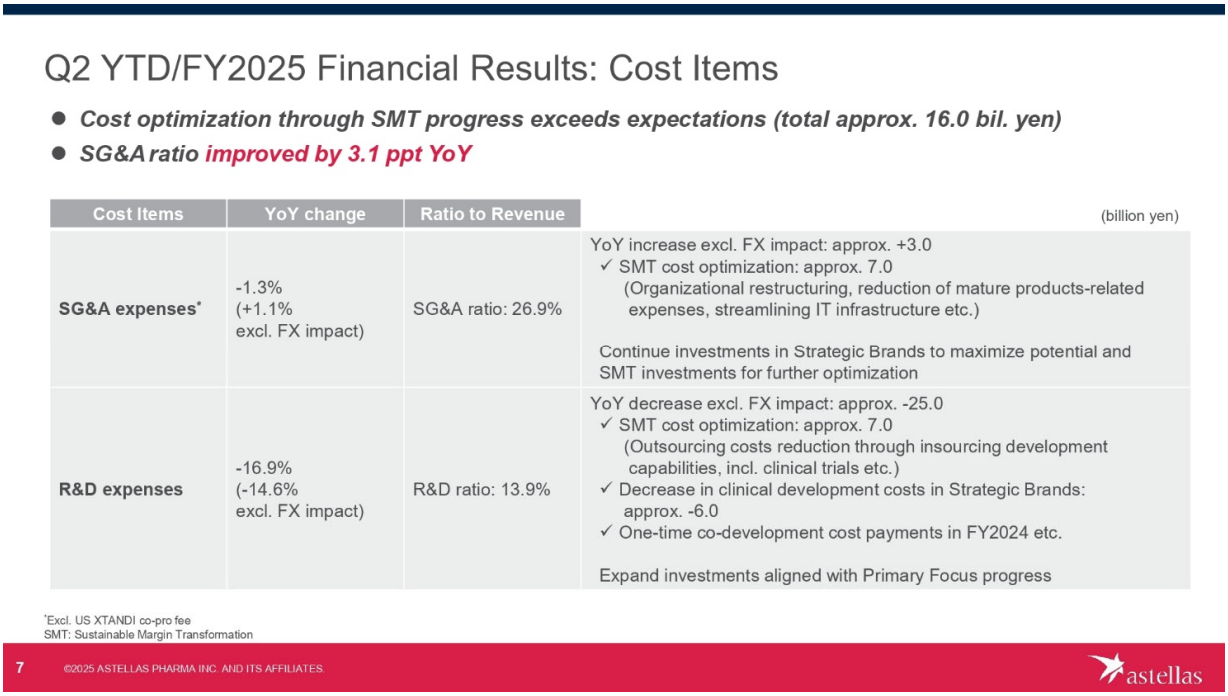
As for IZERVAY, sales rose to JPY34.1 billion, up by JPY6 billion or 21% YoY. On a quarterly basis, double-digit growth is continuously maintained, but patient affordability headwinds weighed on new patient starts and

sales. So progress was lower than initially expected. Based on the Q2 year-to-date progress and FY2025 H2 outlook, we revised our forecast downward by JPY25 billion and are expecting JPY80 billion on a full-year basis. We have revised our full-year forecast downward, but we are expecting continuous growth. Also from now on, one factor behind this new patient starts recovery. Although it's moderate, we are seeing signs of recovery in new patient starts from August. The share is also improving from the lower 50% level in June to the upper 50% level in August.

Another factor is the use of GATHER2 open-label extension study data presented at AAO, American Academy of Ophthalmology this month. Over 3.5 years post IZERVAY dosing, increased benefit was demonstrated according to long-term efficacy data. In addition, favorable long-term data was obtained also in terms of safety and tolerability as well. By broadly disseminating this kind of data in the market, we will aim to further increase the awareness of the importance of treating GA and the benefit of IZERVAY. You can find GATHER2 extension study data on page 34 and 35 in the appendix for your reference. Please refer to those pages at your leisure. We believe in the mid- to long-term potential of IZERVAY, and we're expecting that we can reach the peak sales forecast range. We have high expectations on IZERVAY as an important growth driver for Astellas also into the future. Global sales of VEOZAH increased to JPY22.9 billion, up by JPY8.1 billion or 55% YoY, demonstrating a solid growth continuously. We are anticipating the steady growth trajectory ahead in H2 of FY2025.

With regards to VYLOY, global sales reached JPY26.6 billion. Its outstanding performance is exceeding expectations. Due to active awareness campaign, we were able to realize exceptional Claudin 18 testing rate penetration and lower treatment discontinuation through appropriate information provision activities on adverse event management. Regional footprint is expanding steadily with approval in 47 countries and launches in 26 countries by now. Based on this strong global momentum as a whole, we have made a substantial upward revision of our full-year forecast from JPY40 billion to JPY60 billion, which is 1.5x compared to the initial forecast.

Regarding XOSPATA, global sales reached JPY34.4 billion. There are some regional differences, but overall performance is largely on track. We are anticipating a moderate growth trend within the current indication of relapsed or refractory AML. As a future growth driver, top line results for the additional indication in newly diagnosed AML are anticipated in H1 of F2026. If approved, we can offer a treatment option to a new patient population. So we are hoping for contribution to sales. Last but not the least, XTANDI. Global sales increased to JPY477 billion, up by JPY25.3 billion or 6% YoY. Sales expanded in all regions, reflecting strong global performance as a whole, we revised our full-year forecast upward.



Page seven is about cost items.

SMT initiative made more progress than our expectations. We realized cost optimization of about JPY16 billion in total for SG&A expenses, R&D expenditure and cost of sales combined. Excluding US XTANDI co-promotion fees, SG&A ratio improved by 3.1 percentage points YoY. Let me explain a specific breakdown of SG&A costs and R&D expenditure. SG&A expenses fell by 1.3% YoY, trending at a similar level compared to the previous year. SG&A ratio was 26.9%. As SMT progress, we realized cost optimization of about JPY7 billion through continuous global organizational restructuring, reduction of mature products-related expenses and streamlining 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. R&D expenditure decreased by 16.9% 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 JPY7 billion.

Furthermore, due to the completion of large clinical studies for strategic brands, clinical development costs decreased by about JPY6 billion. In addition, one-time co-development cost payment booked in FY2024 was another factor for cost decrease YoY. In H2 of FY2025 onwards, we are expecting expansion of investments aligned with primary focus progress. In April this year, we implemented R&D organization restructuring, enabling activities from research to development all throughout. By pursuing operational efficiency, we are creating a cycle of making investments needed for the future continuously.

FY2025 Revised Forecast

- ***Significant Upward revision of Revenue and Core/Full OP based on exceptional progress***
- ***Expect Core OP margin 24.1% (+2.9ppt vs. initial forecast)***

Exchange rates of FY2025 revised forecast: 145 yen/USD, 170 yen/EUR
(Forecast rates Q3/FY2025 onwards: 144 yen/USD, 172 yen/EUR)

(billion yen)	FY2024 Actual	FY2025 Initial FCST	FY2025 Revised FCST	Change	Main items of revision
Revenue	**1,912.3**	**1,930.0**	**2,030.0**	**+100.0**	• VYLOY: +20.0, PADCEV: +10.0, XTANDI: +70.0
SG&A expenses	843.0	805.0	831.0	+26.0	
US XTANDI co-pro fee	252.6	229.0	245.0	+16.0	
SG&A excl. the above	590.5	576.0	586.0	+10.0	• Expect decrease excl. FX impact
(SG&A ratio*)	30.9%	29.8%	28.9%	-1.0ppt	• Reflects robust SMT progress
R&D expenses	327.7	342.0	322.0	-20.0	• Reflects operational efficiency in R&D reorganization
(R&D ratio)	17.1%	17.7%	15.9%	-1.9ppt	
Core operating profit	**392.4**	**410.0**	**490.0**	**+80.0**	• Reflects robust core business progress
(Core OP margin)	20.5%	21.2%	24.1%	+2.9ppt	
<Full basis>					
Operating profit	**41.0**	**160.0**	**240.0**	**+80.0**	

FY2025 Initial FCST announced in Apr 2025. Exchange rates of initial FCST: 140 yen/USD, 160 yen/EUR
*Excl. US XTANDI co-pro fee, SMT: Sustainable Margin Transformation

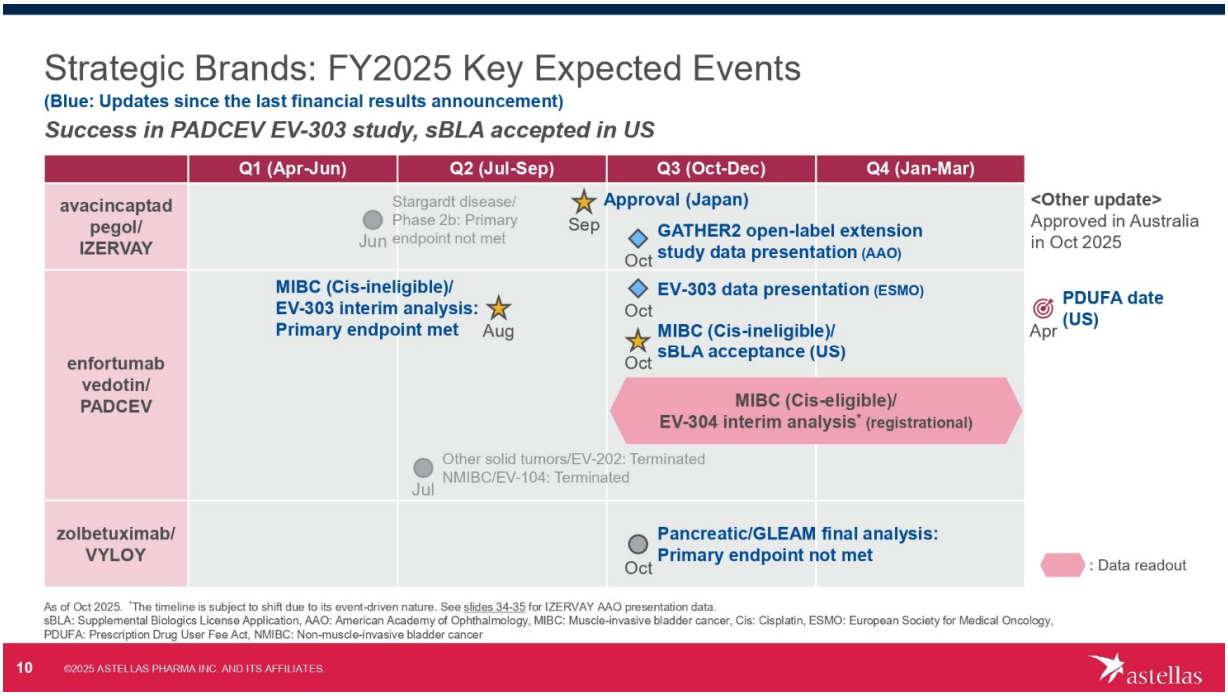
Page eight is about the revision of FY2025 full-year forecast.

Based on the robust progress exceeding our initial forecast up to Q2, we have made a significant upward revision of revenue, core and full operating profit. We are expecting core operating profit margin of 24.1%, improving by 2.9 percentage points compared to the initial forecast. We revised our full-year forecast ForEx assumptions to JPY145 against the US dollar and JPY170 against the euro. From Q3 onwards, we are assuming ForEx rates of JPY144 against the dollar and JPY172 against the euro. We have made an upward revision of revenue forecast by JPY100 billion, including JPY20 billion for VYLOY, JPY10 billion for PADCEV and JPY70 billion for XTANDI.

We are expecting revenue of JPY2.03 billion, exceeding the JPY2 trillion mark for the first time since the establishment of Astellas. We are expecting SG&A expenses, excluding US XTANDI co-promotion fees to decline from the initial forecast if we exclude ForEx impact, reflecting robust progress of SMT, we are expecting JPY586 billion.

As for R&D expenditure, reflecting operational efficiency in R&D reorganization, we are expecting JPY322 billion. Reflecting the strong progress in our core business, core operating profit is revised upward by JPY80 billion from the initial forecast now expected to be JPY490 billion. Core base operating profit is also revised upward by JPY80 billion from the initial forecast now projected to be JPY240 billion. We continue to incorporate a certain amount into the forecast for other expenses to prepare for risks such as impairment losses.

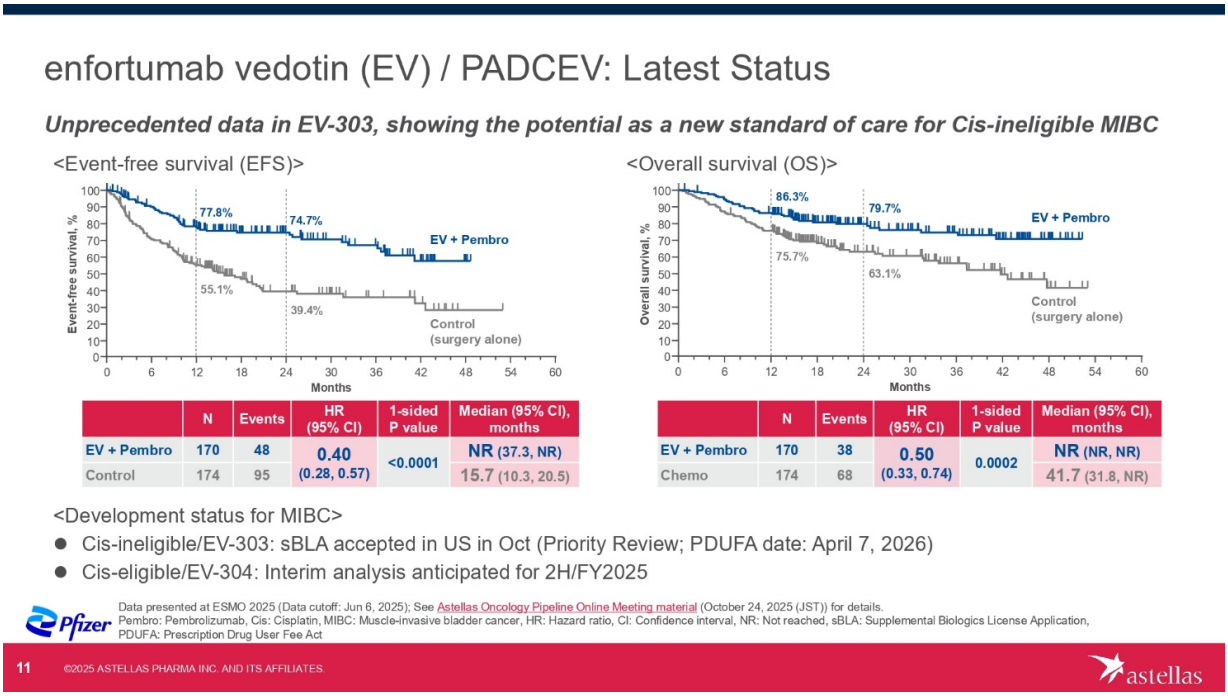
Next, I will explain the progress of our pipeline.



Page 10 shows the progress of key events expected in FY2025 for our strategic brands.

Particularly significant development, as shown in the center of the slide, is the successful completion of the PADCEV EV-303 trial and acceptance of its supplemental BLA in the US. Details are provided on the next page. IZERVAY was approved in Japan in September for the indication of suppression of GA growth in atrophic AMD. Aiming to rapidly deliver this treatment for severe GA with a high unmet need to Japanese patients, the development team engaged in constructive discussions with the authorities. This led to a submission based on overseas clinical trial results using the conditional approval system, resulting in approval just seven months later. Furthermore, as noted in outside of the table, approval was obtained in Australia in October as well. We'll continue to pursue further submissions in other countries and regions with the aim of delivering IZERVAY to patients worldwide.

In addition, we presented efficacy and safety data from the GATHER2 open-label extension study covering up to 3.5 years after administration of IZERVAY at the AAO in October. The final analysis results of the Phase II [inaudible] trial of VYLOY in pancreatic duct adenocarcinoma or PDAC became available and the primary endpoint was not met. We are currently analyzing the detailed data. As part of the life cycle management of VYLOY, the Phase III LUCERNA trial evaluating its combination with pembrolizumab and chemotherapy in gastric cancer is ongoing.

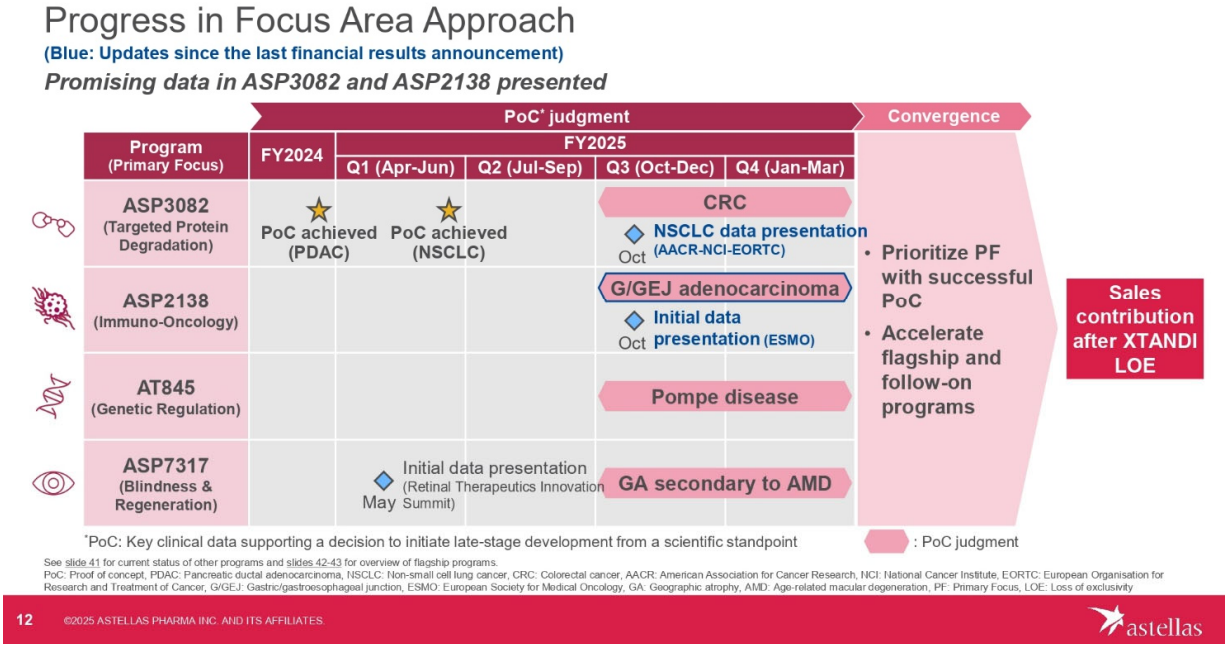


Page 11 shows the latest status of PADCEV MIBC development. For details, please refer to the materials from last week's online briefing on our oncology pipeline.

The EV-303 trial yielded unprecedented data, suggesting that PADCEV has the potential to become a new standard of care for cisplatin ineligible MIBC. EV-303 trial compared the efficacy and safety of PADCEV plus pembrolizumab as adjuvant therapy before and after radical cystectomy, the current standard of care in patients with MIBC who were ineligible for or declined cisplatin-based chemotherapy versus surgery alone. The figure shows the efficacy results from the first interim analysis. The left panel displays the primary endpoint, event-free survival or EFS and the right panel shows the key secondary endpoint of overall survival or OS.

Compared to surgery alone, the combination therapy group or arm showed a hazard ratio of 0.40 for EFS, representing a 60% reduction in the risk of tumor recurrence disease progression or death and a hazard ratio of 0.504 OS, indicating a 50% reduction in the risk of death. Subgroup analysis confirmed consistent improvements in EFS and OS regardless of age, sex or PD-L1 expression status. The safety profile of the combination therapy arm was consistent with the previously reported trials with no new safety concerns identified.

Following the top line results in August, we rapidly advanced the process for additional indications. Within just over two months, the US sBLA was accepted and granted prior review designation with a target PDUFA date set for April 7, 2026. We're also progressing discussions with the regulatory authorities in other regions towards submissions. Furthermore, the Phase III EV-304 trial for cisplatin-treated MIBC is ongoing with the interim analysis data anticipated in the latter half of FY2025.

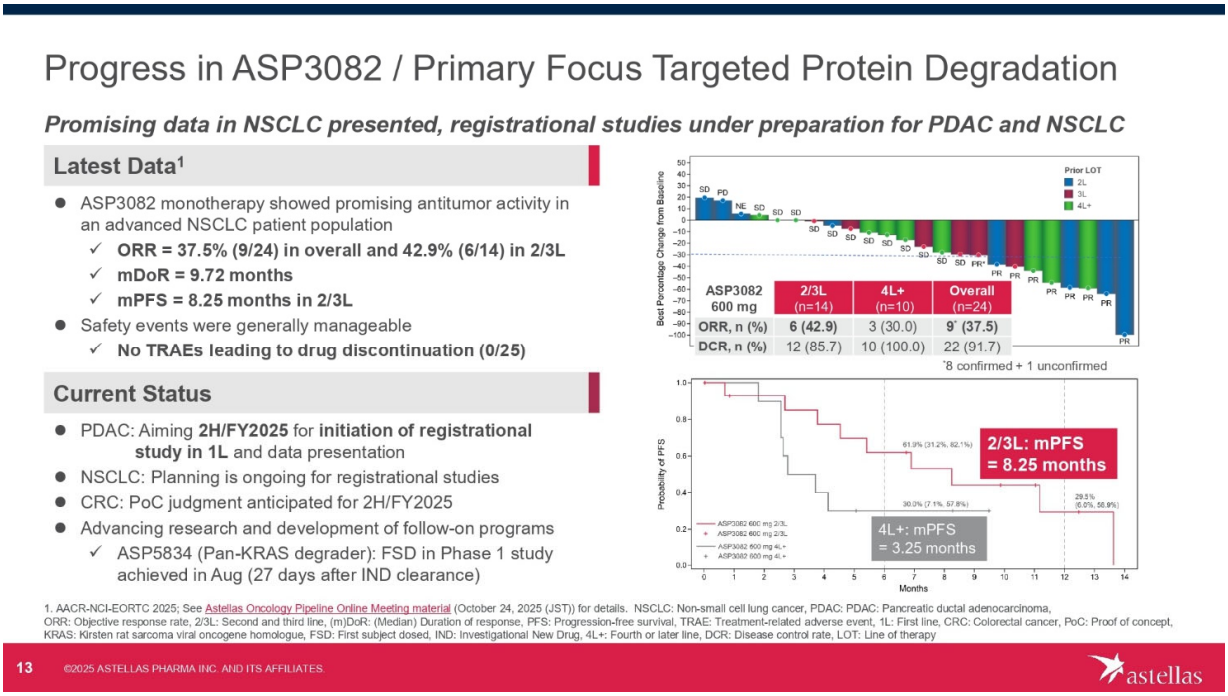


Page 12 for focus area approach. I will explain the progress on flagship programs.

ASP3082 targeted protein degradation and ASP2138 immuno-oncology presented promising clinical trial data in October.

While details were already explained during the last week's online briefing, the following slides briefly recap the current status. Clinical trials for AT845 in genetic regulation and ASP7317 in blindness and regeneration are progressing as planned with the POC assessment still scheduled for H2 of FY2025.

The current status of other programs is summarized on slide 41 in the Appendix.



1. AACR-NCI-EORTC 2025; See Astellas Oncology Pipeline Online Meeting material (October 24, 2025 (JST)) for details. NSCLC: Non-small cell lung cancer, PDAC: PDAC: Pancreatic ductal adenocarcinoma, ORR: Objective response rate, 2/3L: Second and third line, (m)DoR: (Median) Duration of response, PFS: Progression-free survival, TRAE: Treatment-related adverse event, 1L: First line, CRC: Colorectal cancer, PoC: Proof of concept, KRAS: Kirsten rat sarcoma viral oncogene homologue, FSD: First subject dosed, IND: Investigational New Drug, 4L+: Fourth or later line, DCR: Disease control rate, LOT: Line of therapy

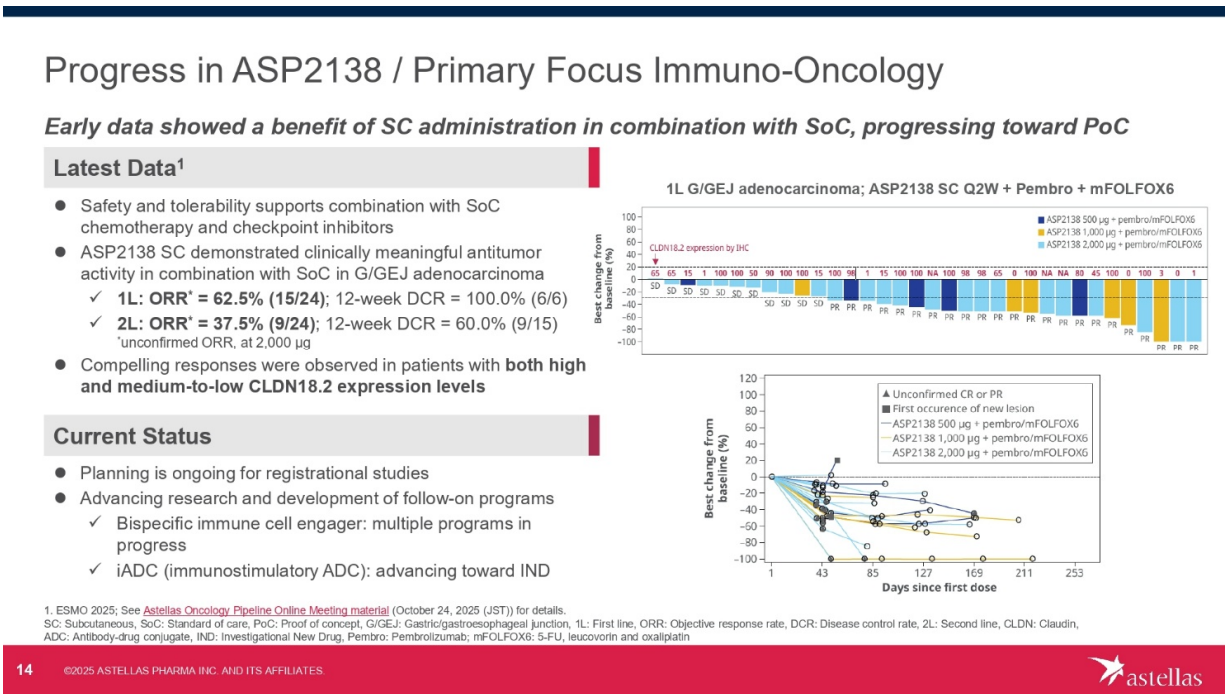
Page 13 explains the progress of ASP3082 and the primary focus targeted protein degradation.

Specifically, ASP3082 has presented promising data in NSCLC or non-small cell lung cancer, and we have initiated preparations for registration studies targeting PDAC and NSCLC. ASP3082 has achieved POC in both PDAC and NSCLC. This time, we presented clinical data for its monotherapy in second line and later treatment settings for NSCLC at an October Congress. Last week's online briefing preceded the congress presentation. So we provided an explanation aligned with the abstract.

Today, however, we will use the data presented at the Congress as shown in the figure on the right. NSCLC has a high unmet medical need. The objective response rate with the existing standard of care in the second line and beyond is reported to be in the single digits, reaching a maximum of around 18%. ASP3082 monotherapy demonstrated significantly superior antitumor activity compared to standard of care, achieving an ORR of 37.5% across all second line and beyond and 42.9% specifically in second and third line.

Furthermore, median duration of response was 9.72 months and median progression-free survival PFS in second and third line was 8.25 months, confirming sustained efficacy. The safety profile showed no major concerns with no treatment-related adverse events leading to discontinuation observed at the data cutoff date. Development of ASP3082 across various tumor types is progressing for PDAC. Preparations are underway to initiate a pivotal trial for first-line treatment in the latter half of FY2025 with data presentation also targeted for the latter half of FY2025.

For NSCLC, planning is ongoing to initiate registrational studies as early as possible. For CRC, colorectal cancer, the POC judgment remains targeted for H2 of FY2025. Furthermore, research and development for follow-on programs is advancing. ASP5834, a pan-KRAS degradation targeting diverse KRAS variants achieved its first subject dosing in August. Under the new R&D structure launched in April, the team achieved its first subject dosing in a record 27 days after the FDA IND clearance, thanks to close cross-functional collaboration. We will provide progress updates as the data becomes available from clinical trials.

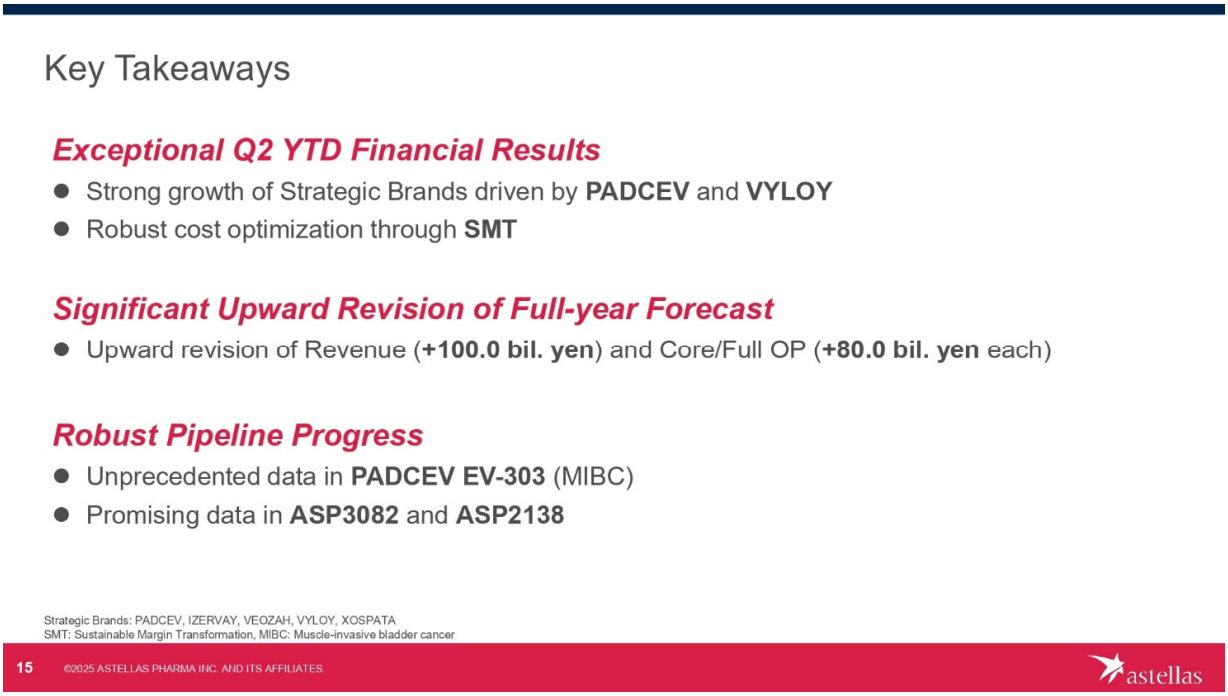


Page 14 details progress on ASP-2138 in primary focus immuno-oncology.

Specifically, ASP2138 is demonstrating the benefit of subcutaneous administration in combination with the standard of care, steadily progressing toward POC achievement. Phase I trials are currently underway for gastric and gastroesophageal junction adenocarcinoma, or GEJ as well as PDAC. These trials evaluate SB2138 as a monotherapy in combination with standard of care IV and subcutaneous across multiple treatment lines. Data presented at ESMO in October showed no major safety or tolerability concerns and supported combination with current standard of care. Furthermore, the ORR, when combined with the standard of care by a convenient biweekly subcutaneous administration demonstrated high antitumor activity in gastric cancer at a 2,000-microgram dose, 62.5% in first line and 37.5% in second line.

In the figure above right, the values indicated in red represent the Claudin 18.2 expression levels for each subject. By low targets patients with high expression of 75 and above. This data confirms efficacy not only in high expression patients, but also in those with moderate to low expression levels, suggesting the potential to expand the patient population eligible for this treatment. A POC judgment is planned for the latter half of FY2025 pending further data accumulation. Given the compelling data obtained thus far, we have initiated discussions on the development plan to enable the prompt execution of the registration trial following POC achievement. For Claudin 18.2 targeted therapy, we aim to provide treatment options to a broader patient population.

To strengthen our leading position, we are advancing the development of the antibody drug conjugate, ASP546C in addition to ASP2138. Research and development of follow-on programs are also progressing. Multiple programs utilizing a similar mechanism of action, including the clinical stage ASP1002 are advancing, including bispecific. Additionally, research is advancing toward clinical trials for iADC, immunostimulatory antibody drug conjugate, utilizing new antibody modification technologies. We will provide updates, including detailed explanations as progress is made in each program.



Page 15 shows today's key takeaways. The Q2 delivered exceptional financial results. PADCEV and VYLOY led the way with strategic brands demonstrating strong growth. SMT progressed well, achieving robust cost optimization. Based on this strong progress in our core business, we have revised our full-year revenue forecast upward by JPY100 billion and both core and full operating profit by JPY80 billion. Our pipeline also showed robust progress. PADCEV showed unprecedented data in the EB-303 trial, significantly advancing its development for MIBC. In the focus area approach, promising data was obtained for ASP3082 and ASP2138 and preparations are underway to conduct registration trials.

Throughout FY2025, we will aim for further profit growth and enhanced pipeline value. At the end, I would like to announce upcoming events. On Tuesday, December 9, we plan to hold a discussion session with outside directors. At this session, we will explain the evolution of Astellas governance structure. Additionally, directors newly appointed in June will share their perspectives on joining the Astellas Board of Directors as well as their experiences and impressions from their first 150 days in office. We encourage your participation.

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

Kato [M]: That's all for the presentation. We are going to entertain questions from the audience. If you have questions, please press the raise hand button at the bottom of your Zoom screen. If you're joining from your smartphone, if you tap details, raise hand function will be shown. So please press it. I will name you one by one. If your name is called, please unmute yourself on your screen, mention your name and your affiliation and then ask questions.

So we now would like to open the floor for questions. The first, Mr. Yamaguchi from Citigroup Securities. Mr. Yamaguchi, please.

Yamaguchi [Q]: Can you hear me? I'm Yamaguchi from Citigroup.

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

Yamaguchi [Q]: Thank you. First, about PADCEV. The data was better than you expected. Global sales are going to be JPY400 billion to JPY500 billion. MIBC is ineligible or data was better than expected. In this area, what is going to be the potential impact? How better compared to your initial expectations?

Okamura [A]: Thank you for your question. I will respond briefly. And then regarding sales forecast, Claus may add. And the data per se, where necessary, can be explained by Taniguchi. First of all, as I showed on the slide, EV-303 study results, even we are not experts see the separation in the Kaplan-Meier curve and the hazard ratio is 0.4 or 0.5. We don't see these numbers so often. We presented this at ESMO in the first-line settings, we said the same. We made a presentation at Congress, and there was a standing ovation naturally in the audience. So we think we had unprecedented data.

Yamaguchi [Q]: This great data exceeded our expectations, then is this going to lead to the sales forecast directly, not necessarily MIBC and the after metastasis in the urothelial cancer, mUC, it's not clearly separated completely. In the current indication, some part is covered in the United States. If the additional indication is approved, how much we can expand the target patient population?

Okamura [A]: It's difficult for us to say clearly how much we can expand. Cis-ineligible patient population was studied in EV-303 study. Patients on cisplatin EV-304 study is ongoing. And we'd like to look at the distribution of these patients in detail to share our sales forecast with you. First, Taniguchi-san, anything from you?

Taniguchi [A]: Thank you very much. For me, regarding this data, I'd like to add a bit. As Okamura explained, at ESMO, there was a very good response from the audience. First, the primary endpoint, EFS hazard ratio was 0.40. This is unprecedented in terms of the risk reduction. Secondary endpoint, overall survival, consistently 0.50. Regarding secondary endpoint, whether we could meet this in the interim analysis, but we made this much reduction. There was a statistically significant difference clearly. And number three, PCR ratio was 57% or even exceeding that level and 8.6% for the control group. Pathological CR was seen at such a high probability such drug is unprecedented. And this was highly evaluated as well. So these are the three effects. And as for safety, PADCEV pembrolizumab combination, it was consistent in terms of safety. In that regard, this data is very innovative and unprecedented. Cis-ineligible was the indication unfit population at high risk or with a variety of complications, the drug could be utilized in such patient population. So there are high expectations because of this.

Zieler [A]*: Yes. So the question that you asked is how this translates into a sales forecast. And there are a few considerations. Clearly, such an unprecedented data will help us convince physicians that this should be the new standard of care in the labeled indication of locally advanced and then after approval also in the MIBC

indication. There is, however, a difference between the two. If you look at the clinical trial in MIBC, there are two parts to it. There is the so-called neoadjuvant use. So you give it before you do the cystectomy, the removal of the bladder. And then you have the adjuvant use, which is after the surgery has been done. In clinical practice, these two parts are likely to be different from the clinical trial setting. And we need to observe carefully exactly how the market adopts the usage of PADCEV and pembrolizumab in these two different phases of the MIBC. So that's things we still have to learn. And I think once we have more data points, we can make a more accurate sales forecast.

Yamaguchi [Q]: Thank you very much. Next question, a brief question. Again, this time, performance was really good. However, from the midterm perspective, mirabegron and XTANDI are going to face the cliff of the patent and next year. And afterwards, a new midterm plan is going to be presented. So toward that, your foundational business is quite improved. So towards the next fiscal midterm plan, this performance level and also SMT included, how do you view about it? Would you give us a comment?

Okamura [A]: Thank you very much. We are still in the middle of the discussion about this. So I think it is inappropriate to come into the details about this here. However, the XTANDI and mirabegron where the patent is expired and we are going to extend their lives in order to cover the loss of those sales, we will do something, including business development. That's not something like that. Rather than that, we have the strategic brands in our hands. Those are getting stronger. So we would like to maximize its strength. So that's going to be the focus of the next midterm plan. That's what we expect, meaning that from the outsider's perspective, the breakdowns of the products are not really matters, rather the sales of the products will be reduced. That is one thing.

However, we are already having the three important Strategic Brands in the growth phase. So we would like to maximize the value of that. That focus is going to be incorporated into the next midterm plan. And also focus area approach, flagship pipelines achieving the clinical POC or coming to the phase of the POC judgment. So for the next five years, those flagship are going to get into the late phase of the development. And on top of that, the original focus area benefit that is when initial compound is successful, then with the same triangle, we come up with the follow-on programs. We introduced some of the follow-on programs today. So that will happen. So we have the five Strategic Brands. And on top of that, further ahead of the growth can be expected in these approaches. And if that is recognized in that way also, it's going to be the one key aspect of the midterm plan. And the current product sales increase is the job needed to be done by Claus. And the next preparation is Taniguchi's job and Kitamura, who is here, needs to think about changing the company with appropriate financial discipline in terms of the operation of this company based upon such background information.

Yamaguchi [M]: Thank you very much.

Kato [M]: Thank you very much. Now I would like to move on to the next question. That is JPMorgan, Mr. Wakao, please.

Wakao [M]: JPMorgan, Wakao is my name. Can you hear me?

Kato [M]: Yes, I can hear you now please.

Wakao [Q]: Thank you very much. Regarding strategic brands, how do you assess those products as of now? You made an upward revision, but XTANDI, mirabegron before in the previous upward revision, if you look at the total sales, the JPY470 billion, although the breakdown is different. And you're progressing according to your initial forecast, EV-303 is successful, and there are other factors as well. So what is your current assessment and also the future outlook of strategic brands? IZERVAY, how it's going to go up? That might be part of the question as well.

Okamura [A]: Thank you for your question. I'd like to give you a rough overview where necessary, Claus can add. As I mentioned before, how Astellas is going to be from now on, XTANDI, mirabegron, such mature products, how we can increase their value from now on is one question. But we made an upward revision. If you look at the face value, these two may be covering the majority of the upward revision at a glance. But IZERVAY, unfortunately, on a dollar basis, $750 million was revised downward to $550 million, but that reduction is covered by PADCEV and VYLOY because of their good performance, we are more than offsetting that decline.

So in total, there is no change in the Strategic Brands, you may say so from outside, but there are special circumstances for IZERVAY, and it may be difficult to perform as expected. But are we going to reduce the Strategic Brands? No, we would like to cover and more than offset this decline. And Astellas in the mid- to long term need to grow. To that end, this is going to be very important. So in the world of pharmaceuticals, regulations may change, there can be something unexpected. We often see such events in this sector. So instead of saying that this is what we can do only, if there is something negative, we'd like to offset the negative, and we can recover in the top line figures. And also, we'd like to do our best to control the cost, and we would like to achieve core operating profits and the bottom line. That's our discipline and how our management of the company should be. Anything additional from Claus about individual products?

Zieler [A]*: I think, Naoki, you've summarized it very well. I think the five strategic brands as a group have the potential to replace XTANDI and maybe even grow beyond that. I personally think the total potential is beyond that of XTANDI as a single brand. Now the different brands will vary and also in their phases, we see VEOZAH as a primary care, pretty much, primary care product with a much slower trajectory than an oncology drug, which has a very, very fast uptake, and we've seen that both with PADCEV and with VYLOY now. So I think each therapeutic area has its own dynamic. But as a group, the potential of these products is, as I said, in my estimation, at least the size of XTANDI.

Wakao [Q]: Thank you very much. Secondly, SMT initiative status is something I'd like to know more. In Q2, cost reduction was achieved, and I'm very surprised. And regarding your plan, OP margin is to improve. So I think this was great. And SMT is making very good progress. As of now, core OP, 30% or higher. What do you think in terms of this progress? You may have other hurdles to clear? Or are you approaching the achievement? You may need to invest in R&D for some of the products. So what is the current progress?

Okamura [A]: Thank you very much. In the end, operating profit was revised upward. If you look at the guidance, 24.1% for operating profit margin, are we satisfied? No, we are not completely satisfied yet. But still, in FY2027, we are targeting to achieve 30%. Towards that goal, we are beginning to solidify our basis. That's how I feel. But it's not easy to improve just 5% overnight. So there are many things we have to do. As you pointed out, development costs would go back to the original number. So we shouldn't sacrifice the development cost. We have to do something else elsewhere. Anything to add from Kitamura-san?

Kitamura [A]: Thank you very much. Regarding SMT, in the past, I've already made an explanation saying that this is not the single year short period of time of activity. This is the regular activities. I've mentioned that it's going to be JPY120 billion to JPY150 billion. And at the time of the announcement, it is clear that for the 70%, yes, we will do that, and we will execute the plan and the remaining 30% idea is going to be generated. That was the approach. And currently, against the JPY150 billion internally, we accumulated our ideas and they are going to be executed. That's the next phase. That's the current status.

Thanks to SMT, JPY40 billion of the impact was realized. And this fiscal year throughout the year, we are expecting to be JPY20 billion, it will be JPY60 billion for two years. In H1, it is JPY16 billion. So against the target of JPY20 billion, I think we are doing quite well. But as has been mentioned by Okamura, this is not an easy road. So we have to steadily execute the plan. So we have to have that in our mind. But as long as we do what we need to do, we definitely can see the result. Therefore, we have a commitment. We have confidence about it.

Wakao [M]: Understood clearly. Thank you very much.

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

Ueda [Q]: Goldman Sachs, Ueda is my name. My first question is the follow-up question about the currently discussed point. So R&D for this fiscal year, you changed the presumption for the FX, meaning that there's a wide range of review or revisit during the quarter. So what did you do to come up with these big changes? And also in the current new plan compared to the initial plan, the accuracy was increased? So would you please make your explanation for these two points?

Okamura [A]: Thank you very much. First of all, in my presentation, as I've already mentioned, in terms of YoY, the major clinical trials of the Strategic Brands are completed. So from a YoY perspective in the last year, Q1, one-off cost increase was canceled. And because of that, seemingly, there was a decrease. But overall flow, depending on that, because of that, the cost is reduced. But towards H2 of 2025, the focus area program achieved the POC. It will come to the later phase of the development, and this will come back. This portion will come back. That's why we have this guidance.

And on top of that, of course, we are doing the continuous work. But this time, within the SMT and strategy discussions, portfolio prioritization started to be more and more rigorous. So with that, selected projects with the keen eyes will receive more and more investment. So our R&D investment usage is shown in that way. And also clinical trials, we overall relied on the external CRO, but those are currently conducted more and more internally.

So, outsourcing cost is reduced and that is replaced as the internal expenses. So, seemingly, you see that substruction calculation leads to this reduction level as a number. However, with a long-term perspective with having this approach, we can realize more effective clinical trials, which leads to the shorter period of time of the study and clinical study design is going to be further precise. And with our execution of the studies, we can make the fine-tuning during the study. I think that's the way should be for conducting clinical trials, and I believe we can realize that.

And under Taniguchi, the R&D was separated, but now it's merged as one organization. So research division and the development divisions, those exchange between these two business units became smooth. Outsourcing change to in-sourcing and with just a simple deduction come up with this number. Well, you see only this because it's just started. But for a longer time, thinking about the next business plan, I think it's going to be more financially reflected into our actual business way of doing. Taniguchi-san, please.

Taniguchi [A]: Thank you very much. Most of the things already explained by Okamura. If I may add one thing, through in-sourcing of clinical trials, we can reduce outsourcing costs we paid before. And then we should develop our own system. AI and automation are fully leveraged for further cost reduction. And also the speed of enrollment, where are the patients and which institutions we should go to, we want to roll this out globally. By doing this, further business and clinical trial efficiency can be enhanced as well as the acceleration of the speed. And then we can reduce further cost reduction as well. So we're expecting an increase in the late-stage development and costs would also rise. As much as possible, we'd like to enhance the cost efficiency so that we can cover.

Ueda [Q]: Thank you very much. As a follow-up question, originally, compared to the initial forecast, in terms of the gap compared to the initial forecast, overall, all the items are progressing smoothly. Should I understand that way?

Taniguchi [A]: Basically, that understanding is fine.

Ueda [Q]: Okay. Understood. Thank you very much. Secondly, regarding the US business environment, how do you see it right now? Up until now, regarding the tariff, the situation is still unclear. And it was difficult for you to comment, as you said before.

But right now, you have a large exposure to the United States, including the risk of being imposed a tariff, how are you addressing the situation? Or how are you planning to address the situation from now on? And also including MFN, the drug prices, how do you see the risk factors? I'd like to hear from you.

Okamura [A]: Thank you very much. First, as for the tariff, at one point in time, we didn't know what could happen. From there, the situation is settling a lot. We are feeling relieved. As we said before, from your perspective, Astellas revenue times US ratio times COGS times tariff, it's going to be a huge amount, you may say so. But in reality, what we sell in the United States, a majority of those products are manufactured in the United States, as we said before. If that's the case, the denominator is small where tariff is going to be imposed. So it's not going to be a huge amount. That's our response. But the tariff might be imposed. There can be such announcement into the future. So by understanding our supply chain, if there's going to be any great impact and the profit may decrease, where are we going to recover elsewhere? We should start such discussions.

And also, the MFN pricing, as you might have heard in the press report, 17 companies received letters. And this does not include Astellas. In particular, Pfizer reached agreement with the authorities or the government according to the media report. We didn't receive such a letter. So we don't know what are the contents of the letter. But in the industry through a variety of routes, what is being communicated in the letter is captured by us. And regarding the agreement with the government on Pfizer, we don't know the details. But we can assume and imagine what's going on and what's being done. Before we receive a letter, nothing will be done by us or overreaction and doing a lot of things too much in advance, rather monitoring the situation to take necessary action where necessary. Of course, experts in the company are gathered to form a team, and they are monitoring the situation all the time. If it's time to take action and move forward, the team will come to the executives, management team so that we can discuss and take the best action.

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

Kato [M]: Thank you very much. Next question, Nomura Securities, Mr. Matsubara, please.

Matsubara [Q]: First question, that is about SMT. In the previous discussions, SMT is exerting its strength. And if that is so, then this fiscal year, we are going to see further cost reduction.

Okamura [A]: Thank you very much. Originally, JPY20 billion is our plan and to the Q2, we came to the JPY16 billion. And can you achieve JPY32 billion? The calculation is not in that way. What is decided is steadily being conducted. That's one thing.

However, we've been always looking for what else, something else we can do. So if we make a certain evaluation for a certain idea, even a certain advanced investment is necessary, then still we try to secure SMT. So in the first two quarters, what's been planned is already realized, and you came up with the cost reduction. But at the same time, you can think about the investment to the next idea. So we have to take the balance of reduction and investment.

So that is going to be final end of FY2025. Of course, the planned JPY20 billion, that is something we would like to secure. But at the same time, something it might go beyond. Is that going to be reflected in the profit? It's not necessarily so. So please do understand in that way. Kitamura-san, please?

Kitamura [A]: What Okamura mentioned is exactly right. Again, this is a repetition. SMT is not a single year, but rather multiple year programs. So there are some things should be done with a short period of time and

mid- to long term. Those ongoing in a parallel manner. If some things can be realized in an accelerated manner, then we can get the benefit in earlier phase.

Matsubara [Q]: Understood very well. Thank you very much. Next question is about VEOZAH. On page six, it is true that the competitor is available. So that is the market competition considered. But the competitor has less blood testing and specific limitation for the driving. And what do you think about it?

Okamura [A]: Yes, of course, there's an advantage for the predecessor, our label is not perfect, of course, but we've been doing our activities. So definitely, there are advantage as the firstcomer of pioneer for this. And within just one sentence, what I wanted to say is that another company or the competitor rather is very strong in this treatment area, and we are not really so. So compared to us doing the business in this field alone, together with them, the two companies toward the same target of patients with the same efficacy products, we can do the patient educational awareness increase activities. With that, I think we can increase the awareness more. However, they are very strong in this field. So until then, we are the largest player in the market, but now we have two and they have experience. So the share is going to obviously smaller. But to what extent of the market share we can have? That is, of course, something that we can tell from the data. But clinical data is well controlled. So the competitor launched their products and what kind of data will be available in the real market. I think that really decides the competitive situation of these two companies. Claus?

Zieler [A]*: Yes, I think two points. One, Naoki already made very, very well, which is this is a market we have to develop and two companies developing a market is always much better than a company doing it alone. So I think in that sense, the entry of a competitor actually helps grow the class. The other point I would make is that the label that elinzanetant has received in the US takes into account the fact that this particular molecule acts on two receptors, the NK1 and the NK3. So they have a warning on inducing sleep. So we will not know how the market will react to that. That is not something that's in our label. You pointed out that they have less liver monitoring. That is true. But that's what we also had when we began this journey. So what real-world evidence will then produce over time because remember, these liver incidences are very, very rare. You don't see them in clinical trials. You only see them in real-world practice. So again, only time will tell how that really plays out in the marketplace.

Matsubara [M]: Yes. Very clear. Thank you very much.

Kato [M]: Thank you very much. We would like to receive questions from USB Securities. Mr. Sakai, please.

Sakai [Q]: Sakai from UBS speaking. Initially, sorry for a negative question, but VYLOY didn't work in PDAC. You're now examining the details of your data. Claudin 18.2 and any learnings in association with Claudin 18.2 as the reason for the failure of the study? ASP2138, this is also Claudin 18.2 targeting PDAC. You are planning a clinical development, including these compounds. Could you give us an update on this? That's my first question.

Okamura [A]: Thank you very much. Well, it's technical, so I shouldn't say too much. But I'd like to hand over to Taniguchi from the beginning.

Taniguchi [A]: Thank you very much. First of all, VYLOY GLEAM study for PDAC, it was a Phase II study, but a randomized trial in Phase II. If the results are good, it could be registrational so that we can file a submission. That's how we were discussing with the regulatory authorities. In this study, VYLOY and first line pancreatic cancer, chemotherapy combination and chemotherapy were compared. This was close to POC study. We are analyzing the results of the study. Through the analysis, in what kind of patients there was a good response, and in what kind of patients, no response, we can know more details. So in the GLEAM study, we haven't made public the results yet. Once we are able to analyze the details with a deeper understanding, then we'd like to share.

Sakai [Q]: And regarding the results of the study, ASP2138 targeting Claudin 18.2, this is a bispecific antibody. This is CD3 or T cell engager is also added to this bispecific antibody. ASP2138 in PDAC, any potential impact on PDAC with this compound? CD3 T cell engager portion, how it's going to affect PDAC?

Taniguchi [A]: In clinical studies, Phase 1b right now, we are studying that part. We haven't published the data yet. But in the near future, once we collect the data, we will announce the results, including our future outlook. This bispecific antibody and VYLOY, the differences between the two can also be examined. So once we have the data, I will explain such a perspective as well.

Sakai [Q]: So you haven't changed your way of thinking in the development concept. As a concept, the GLEAM study, ASP2138, any direct impact?

Taniguchi [A]: I could say no impact.

Sakai [Q]: Understood. Thank you very much. Another question is about your response of the midterm plan. Okamura-san, you mentioned that they are very reinforced the strong or something like that. But if that is case, the number you come up with might be drastic. That is a bit of the concern that I feel. You are working on making the numbers. So you would not probably disclose anything specific, but the comment you made a little while ago is probably your honest thinking. And based upon that, we have to also come up with the forecast or our numbers. So do you think is it okay that we approach in this way?

Okamura [A]: Thank you very much. We get learnings every day. For example, CSP2021 review is currently ongoing. And based upon that, we are going to come up with the next plan. Frankly speaking, “over promise underperform” that such criticism is what we've already accepted. And so that we can avoid the repetition of that, we can place more discipline and well-balanced plan corporate plan that is going to be announced. In that sense, Kitamura is looking at the numbers with a perspective. And class well, based upon that number is calculated and coming up with. So you can feel safe about that as well.

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

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

Muraoka [Q]: Thank you. I'm Muraoka from Morgan Stanley. I think almost all the questions are covered already. But just one question. It was like this last year. So it will be okay this year. Just may be a bit mean question. That is about IZERVAY. Impairment loss risk is the question. Last year, in Q2, you said it was okay in Europe. But in Q3, impairment loss was incurred. And this time, the US sales is a relatively bigger reduction. And looking at this number, thinking about the future value, impairment loss triggered risk is likely to be higher compared to three months ago. I wouldn't say, of course, we cannot say it's all right, no problem at this point. However, how can we evaluate these potential risks?

Okamura [A]: Thank you very much. The valuation base is the sales prediction and forecast. Claus is going to make additional comment if necessary. But the way of my description is that when valuation is conducted, the uncertainty is increased. That's the current status. So if you ask me, impairment loss is higher or not, at this moment, I wouldn't think that impairment loss risk is higher. But for the valuation compared to what we've originally considered, kind of situation is lower. That is true. So if this is going to be recovered or ultimately, this will decide the trajectory of IZERVAY. That's something we have to always have a sharp eyes. And just like Claus mentioned, peak sales, we do not think that we have to revisit it right away.

Zieler [A]*: Yes, that's correct. So undoubtedly, there's in the US market, a dynamic on the affordability part where a part of the patients can't afford the co-pay that they need to contribute for their injections. That is different from saying from when we look at the peak potential and the size of the market that we can still develop in this disease. So one is a timing effect. The other is the question of what's the potential of this agent

in the geographic atrophy market. I'm very confident that the long-term potential for IZERVAY is intact. The question, how do we solve the current dynamic in the US is a tactical problem that we are working through, and we hope to find solutions in time to come.

Kato [M]: Kitamura also has a comment.

Kitamura [M]: May I add? Sorry.

Muraoka [M]: Yes, please.

Kitamura [A]: Last year, regarding IZERVAY impairment loss, the trigger was whether we can get the approval or not. It was about that probability. Now as you know, IZERVAY intangible assets in US and outside of US as we are registering US intangible because of the launch in United States already, we're going to sell it out, including the competitors, our drug is also a new treatment. How to develop the market is the main task for us. It's our job. Of course is going to do a good job according to him. So we think we can do it. Of course, there is a big asset number on the balance sheet. So I have to evaluate and assess it. I will do so. The company's stance has not changed. And we had impairment loss, which was incurred last year, but the root cause is different. So please understand.

Muraoka [Q]: Thank you very much. One more question, if I may. Earlier, you talked about CSP midterm business plan. I know you would say don't ask so many questions on this. Regarding the dividend, I understand the message that there can be a decrease. But the dividend level during the course of the next CSP on an absolute basis, do you think you can maintain the amount? Can we feel assured?

Okamura [A]: Sorry. What do you mean by decline? Which -- what are you talking about? The top line may decrease on a temporary basis. If you're talking about it, yes, you are right. But that may not necessarily lead to a decline in the bottom line. Regarding the specific numbers in May next year, CSP 2026 will be announced according plan. So please wait until then. And I think this is Kitamura's scope of responsibilities, but I also have my own views. So allow me to speak.

Regarding the dividend, just increasing the dividend would not happen. And also, even if the company's overall performance is good or bad, it's not something we should change dramatically. I'm talking about the dividend. For the past few years by now, intentionally, the dividend level may be too low and to increase it to a competitive level. So we increased the dividend at quite a fast pace. But from now on, for the company's growth in the longer term, we'd like to gradually increase the dividend in line. That's Astellas' basic stance. In the next five years with the next CSP, there's going to be some dip in revenues. So we have no intention to decrease the dividend because of that. So in that sense, you can feel assured. Kitamura-san, please.

Kitamura [A]: As Okamura said, I may be repeating myself, but a stable return to shareholders is an important factor as part of the capital allocation according to understanding, we're doing this already. So it's not going to change in my view. But on the other hand, when it comes to dividend, how much profit do we have? Cash flow is better or balance sheet is better. So we are working on this meticulously. Whatever is going to happen, we should have funds for investments for stable growth, and we have to have a stable return to shareholders. This is including my personal view. I think this is an important factor. It's not going to change substantially according to my assumptions.

Muraoka [M]: Understood. Thank you very much. That’s all for me.

Kato [M]: Thank you very much. Next, Macquarie Capital Securities, Tony Ren-san, please.

Ren [M]*: Tony Ren from Macquarie. Can you guys hear me?

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

Ren [Q]*: Perfect. Yeah. Thank you very much for the opportunity. Yeah. The first question is a simple one on gross profit margin. Your cost of sales in H1 appears to be increasing faster than the revenue, which probably suggests that the gross margin is declining a little bit. I just wanted to understand why that might be the case.

Okamura [A]*: Thank you. So I think the simple answer to your question is the change in the product mix. But if you would like to know a little bit more in detail, I will pass the button to [inaudible].

Kitamura [A]: Yes, it's all about product mix.

Ren [Q]*: Okay. Perfect. Yes. understood. Yes. The second question and my last question is about your ASP2138. It appears to me that you guys are really pursuing this clinical asset as part of combination therapies, but not as monotherapy. At ESMO 2025, which I attended, I think the monotherapy response rate was fairly modest. And the KOLs who I spoke to also think that the duration of response was good, but probably not something that knocked it out of the park. So, what's your thinking about using ASP2138 either as combination or as a monotherapy? Thank you.

Zieler [A]*: Thank you very much for the question. I will ask Taniguchi-san to answer those questions.

Taniguchi [A]*: Thank you for the question. So as you described, if you take a look at monotherapy of 2138, the ORR is relatively modest, but it's around 15% range. But I think this is quite consistent what we've seen in other CPI such as PD-1 or PD-1 inhibitors. And it's also seeing a very similar tendency that we see once tumor actually responded, the duration of response is longer. This is exactly what we've seen in other immuno-oncology products. So when I think that this is also quite encouraging data from monotherapy. By saying that if you're thinking about PD-1, most of the case is actually coming to the ARIA line in combination with other agents like chemotherapy or ADC. So what we believe is that thinking about the development of 2138, we believe that it makes sense for us to go into the earlier line in combination with the current standard of care. So that's what we believe this is the space that we can actually working on. But I think that this is also based on the data coming up from Phase I, current ongoing Phase I. So please wait the data is coming up. But I think we believe that this data we actually shown in ESMO is quite encouraging.

Ren [M]*: Okay. Understood. Very clear. Combination in earlier line with other current standard of care. Thank you very much.

Kato [M]: Thank you very much. Because of the time, I would like to ask the next question is the last question. [inaudible], Mr. Sogi, please.

Sogi [Q]: Thank you very much. MIBC, commercial potential, how do you view about that? I would like you to explain more details. To simply put, the patient number times market share times duration of therapy times price. It seems it's not that simple. Listening to you, first-line early line treatment overlapping in actual clinical practice, adjuvant, neoadjuvant usage differentiation seems also complicated. So could you be a little bit more specific about this? And also on top of that, this adjuvant neoadjuvant for MIBC, regarding first line and second line, the number of the patients, including the China major markets number were disclosed. But for MIBC, China is excluded according to the description here. Is this significant? Would you please explain about these two points?

Okamura [A]: Your first question, your understanding is correct. We do research. We should be able to respond with responsibility. And then we'd like to respond to your question. So please give us some more time to them. And I don't know the background of the second question. Claus, do you know the background for the second question?

Zieler [A]*: I would have to come back. Yes, on China. Yes, I would have to come back.

Okamura [A]: Sorry, among the participants today, we do not have a full understanding of the background. So we'd come back to you through our IR team at a later date.

Sogi [Q]: Okay. Next about IZERVAY. I have a question. IZERVAY, of course, you're going to expand the market from now on. You're still on the way. On the other hand, this year, from H1, Good Day is a charity foundation. For patients on Medicaid patient support funding is no longer available, and there was such an impact on your business. So what's the current status right now?

Zieler [A]*: So you're absolutely right. The drying up of the foundation funding in the United States is causing some patients to drop off from therapy because they simply can't afford the co-pay that the foundations picked up in the past. Now we see that both in the geographic atrophy market. We also see that in the wet AMD market. And what we see the retina clinics doing in the US is trying to adjust to that new situation. I mean, remember, it's not all the patients who can't afford the co-pay. There's still 70% or something like that. It's an estimate, but it's at least 60% of the patients who can afford the co-pay.

So I think it's a question for the clinics now to understand when they accept patients, how do they deal with a patient that can afford versus what support mechanisms are available for patients who can't afford. That's the turbulence in the market that we're seeing right now. We believe also on the basis of past analogs that the market will learn how to triage that and how to provide the right solution for different patient types. How long that will take and what the curve after that will be, that is the part that I'm still exactly struggling with. And that's why we've been more cautious to take down the projections for this year.

Sogi [Q]*: Great. Thank you. So if we did have funding this year, so would that fill the gap that you currently lowered in your guidance?

Zieler [A]*: Well, it would for the coming quarters, but we have lost time. So I don't think the original forecast is realistic simply because of the timing element that we have within a fiscal year.

Sogi [M]*: Thank you very much.

Kato [M]: Now time has come. So with this, we'd like to close today's explanatory meeting. Thank you very much for joining us today.

[END]

Document Notes

1. *Portions of the document where the audio is unclear are marked with [inaudible].*
2. *Portions of the document where the audio is obscured by technical difficulty are marked with [TD].*
3. *Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.*
4. *This document has been transcribed based on interpreted audio provided by the Company.*

Disclaimer

SCRIPTS Asia reserves the right to edit or modify, at its sole discretion and at any time, the contents of this document and any related materials, and in such case SCRIPTS Asia shall have no obligation to provide notification of such edits or modifications to any party. This event transcript is based on sources SCRIPTS Asia believes to be reliable, but the accuracy of this transcript is not guaranteed by us and this transcript does not purport to be a complete or error-free statement or summary of the available data. Accordingly, SCRIPTS Asia does not warrant, endorse or guarantee the completeness, accuracy, integrity, or timeliness of the information contained in this event transcript. This event transcript is published solely for information purposes, and is not to be construed as financial or other advice or as an offer to sell or the solicitation of an offer to buy any security in any jurisdiction where such an offer or solicitation would be illegal.

In the public meetings and conference calls upon which SCRIPTS Asia's event transcripts are based, companies may make projections or other forward-looking statements regarding a variety of matters. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the applicable company's most recent public securities filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are accurate and reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the anticipated outcome described in any forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE PUBLIC MEETING OR CONFERENCE CALL. ALTHOUGH SCRIPTS ASIA ENDEAVORS TO PROVIDE ACCURATE TRANSCRIPTIONS, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE TRANSCRIPTIONS. IN NO WAY DOES SCRIPTS ASIA OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BY ANY PARTY BASED UPON ANY EVENT TRANSCRIPT OR OTHER CONTENT PROVIDED BY SCRIPTS ASIA. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S PUBLIC SECURITIES FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS. THIS EVENT TRANSCRIPT IS PROVIDED ON AN "AS IS" BASIS. SCRIPTS ASIA DISCLAIMS ANY AND ALL EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE, FREEDOM FROM BUGS, SOFTWARE ERRORS OR DEFECTS, AND ACCURACY, COMPLETENESS, AND NON-INFRINGEMENT.

None of SCRIPTS Asia's content (including event transcript content) or any part thereof may be modified, reproduced or distributed in any form by any means, or stored in a database or retrieval system, without the prior written permission of SCRIPTS Asia. SCRIPTS Asia's content may not be used for any unlawful or unauthorized purposes.

The content of this document may be edited or revised by SCRIPTS Asia at any time without notice.