Astellas Pharma Inc.

Financial Results for the Q2 of FY2023

November 1, 2023

Event Summary

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[Number of Speakers] 6

Naoki Okamura	Representative Director, President and CEO
Yoshitsugu Shitaka	Chief Scientific Officer (CSO)
Tadaaki Taniguchi	Chief Medical Officer (CMO)
Claus Zieler	Chief Commercial Officer (CCO)
Atsushi Kitamura	Chief Financial Officer (CFO)
Hiromitsu Ikeda	Chief Communications & Investor Relations Officer (CCIRO)

[Participant Names]

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Kazuaki Hashiguchi	Daiwa Securities
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Seiji Wakao	JPMorgan Securities
Akinori Ueda	Goldman Sachs Japan
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Presentation

Ikeda: Thank you very much for joining Astellas Pharma Inc.'s FY2023 Second Quarter Financial Results Announcement Meetings out of your very busy schedule. I'm delighted to serve as emcee today. I'm Ikeda, Chief Communications IR Officer.

You can join this meeting through Zoom webinar or live streaming. Live streaming is available in Japanese language only. After our presentation, we will move on to a Q&A session. You can ask questions just on Zoom Webinar. You cannot ask questions through live streaming.

Including Q&A session, simultaneous interpretation is available in Japanese and English. We cannot guarantee the accuracy of the translation. If you're joining on Zoom webinar, from the menu on Zoom screen, you can select the language of your preference. If you select the original language, you can listen to the original sound without going through the translation.

And today, we are going to make a presentation based on the meeting materials posted on our website. This material or presentation by representatives for the Company and their answers and statements in the Q&A session includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties.

Actual financial results may differ materially depending on a number of factors. They contain information on pharmaceuticals, including compounds under development, but this information is not intended to make presentations or advertisements regarding the efficacy or effectiveness of these preparations.

The participants are as follows: Representative Director, President and CEO, Naoki Okamura; Chief Scientific Officer, Yoshitsugu Shitaka; Chief Medical Officer, Tadaaki Taniguchi; Chief Commercial Officer, Clause Zieler; and Atsushi Kitamura, who has assumed the post of CFO executive today. We have five participants from the Company.

Before going into financial results, Kitamura will give you a few words of greetings. Kitamura-san, please.

Kitamura: Thank you for the introduction. I'm Atsushi Kitamura. I've been appointed CFO of Astellas Pharma Inc. effective today. Thank you very much for your support in advance.

Here is my brief background. I started my career at Procter & Gamble, P&G, and then at the Skylark Holdings, where I experienced the relisting on the stock market and direct interaction with investors as CFO. Most recently, I've been involved in corporate management as CFO of Pioneer.

By leveraging my global experience and expertise in our finance area, I will find the ultimate resource allocation for us, so as to achieve sustainable growth and maximize corporate value. I would like to further accelerate Astellas' ongoing efforts to optimize its cost structure and for the financial discipline and cost of ownership, and I will commit to achieve CDP2021 as a member of top management.

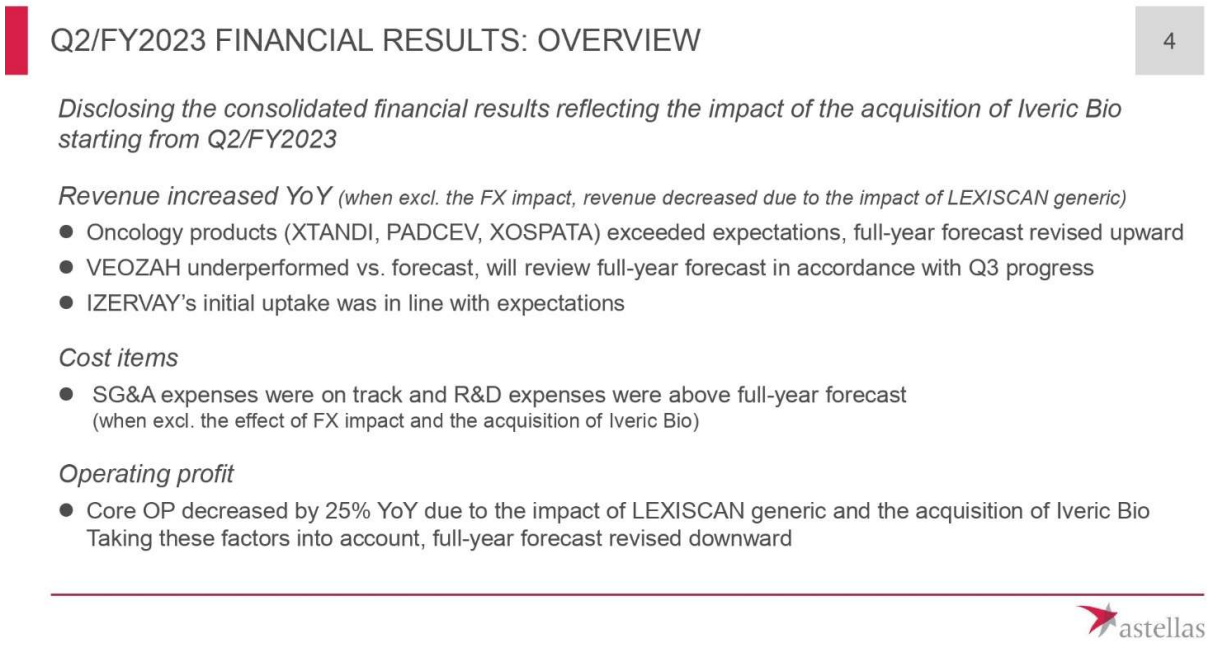
Also, I see it as one of my important roles to deepen dialogue with the investors and bring it back to the management of this company. I sincerely am looking forward to having open and constructive dialogue with all of you. Thank you very much.

Ikeda: Thank you. Now we would like to start the presentation. Okamura-san, please start.

Okamura: Hello, everyone. I'm Naoki Okamura from Astellas Pharma Inc. Thank you very much for joining our FY2023 Q2 Financial Results Announcement Meeting out of your very busy schedule today.

This is a cautionary statement regarding forward-looking information. As this was explained by Ikeda earlier, I'm going to skip this page.

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



On page four, I will give you an overview of FY2023 Q2 financial results.

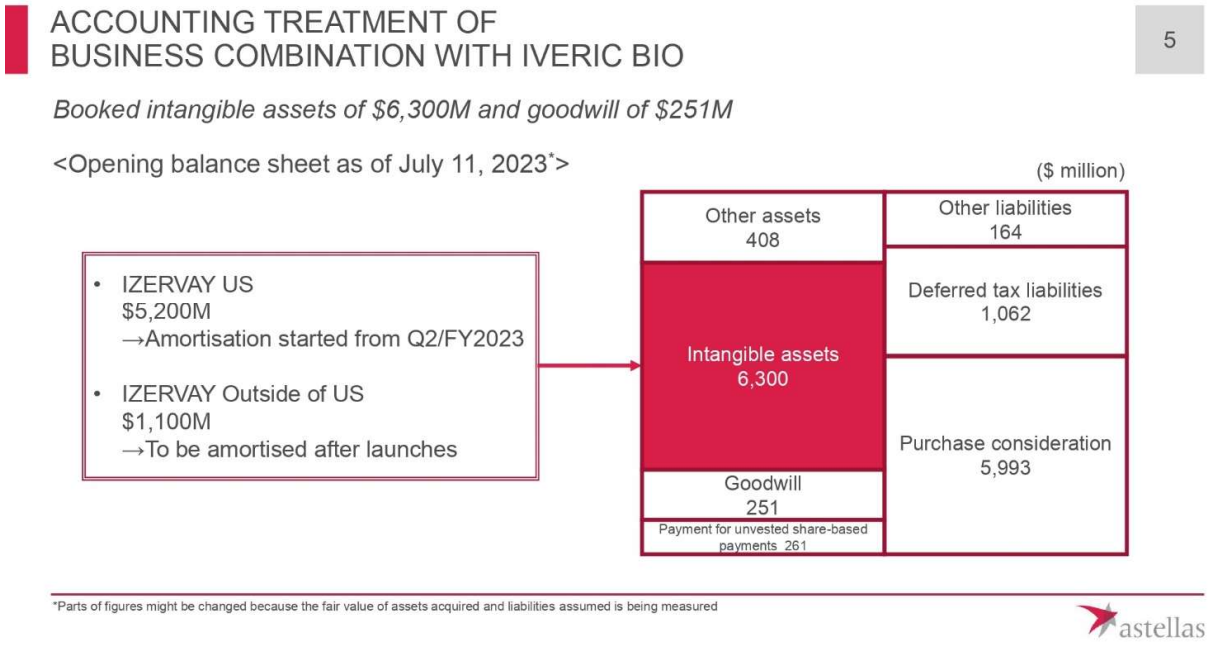
We are disclosing the consolidated financial results, reflecting the impact of the acquisition of Iveric Bio starting from Q2 of FY2023. Revenue increased YoY, but decreased YoY due to the impact of LEXISCAN generic when excluding the Forex impact. Oncology products, XTANDI, PADCEV, and XOSPATA combined exceeded expectations. We revised our full-year forecast upward accordingly.

On the other hand, VEOZAH underperformed versus our forecast. We will review our full-year forecast in accordance with Q3 progress.

The initial uptake of IZERVAY launched in September was in line with our expectations. I will explain these products on page seven through nine in detail.

Next on cost items. When excluding the effect of Forex impact and the acquisition of Iveric Bio, SG&A expenses were on track and R&D expenses were above full-year forecast.

As a result, core operating profit decreased by 25% YoY, mainly due to the impact of LEXISCAN generic and the acquisition of Iveric Bio. Taking these factors into account, we revised our full-year operating profit forecast downward. I will explain our revised forecast on page 11 in more detail.



On page five, before explaining the quarterly financial results, I will explain accounting treatment of business combination with Iveric Bio.

Based on the fair-value assessment as of the date of business combination, we booked intangible assets of USD6,300 million and goodwill of USD251 million. Out of the intangible assets, we booked USD5,200 million for IZERVAY in the United States and amortization started in Q2 of FY2023. For IZERVAY outside of the United States, we booked USD1,100 million, which will be amortized after launches.

What I have just explained is subject to change due to the provisional accounting treatment at this moment. If there is a change, we will update at future earnings.

Q2/FY2023 FINANCIAL RESULTS

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(billion yen)	Q2/FY22	Q2/FY23	Change	Change (%)	FY23 Initial FCST*	Progress	FX impact (YoY)
Revenue	**762.2**	**767.1**	**+5.0**	**+0.6%**	**1,520.0**	**50.5%**	+37.8 bil. yen
Cost of sales	151.7	143.4	-8.3	-5.5%			+6.5 bil. yen
% of revenue	19.9%	18.7%	-1.2 ppt				
SG&A expenses	308.0	347.5	+39.5	+12.8%	661.0	52.6%	+16.1 bil. yen
US XTANDI co-pro fee	89.7	93.0	+3.4	+3.8%	176.0	52.8%	
SG&A excl. the above	218.3	254.4	+36.1	+16.5%	485.0	52.5%	+11.6 bil. yen
R&D expenses	139.2	141.9	+2.8	+2.0%	251.0	56.5%	+4.5 bil. yen
Amortisation of intangible assets	20.0	33.7	+13.8	+68.9%			
Gain on divestiture of intangible assets	0.2	9.4	+9.2	-			
Core operating profit	**145.4**	**109.8**	**-35.6**	**-24.5%**	**290.0**	**37.9%**	+11.0 bil. yen
<Full basis>							
Other income	16.2	7.1	-9.2	-56.4%			
Other expenses	41.7	65.9	+24.1	+57.8%			
Operating profit	**119.9**	**51.0**	**-68.9**	**-57.4%**	**259.0**	**19.7%**	
Profit before tax	120.5	52.2	-68.3	-56.7%	260.0	20.1%	
Profit	**96.4**	**31.7**	**-64.8**	**-67.2%**	**204.0**	**15.5%**	

Other expenses
- Payment for Iveric Bio's unvested share-based payments: 36.7 bil. yen
- Fair value increase contingent consideration due to FX impact (zolbetuximab): 8.8 bil. yen

* Exchange rates for initial FCST: 130 USD/yen, 140 EUR/yen, Core basis: disclosed on Apr 27, Full basis: revised on Aug 1

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On page six, I will explain FY2023 Q2 financial results.

Revenue increased to JPY767.1 billion, up 0.6% YoY. The progress was 50.5% of our full-year forecast.

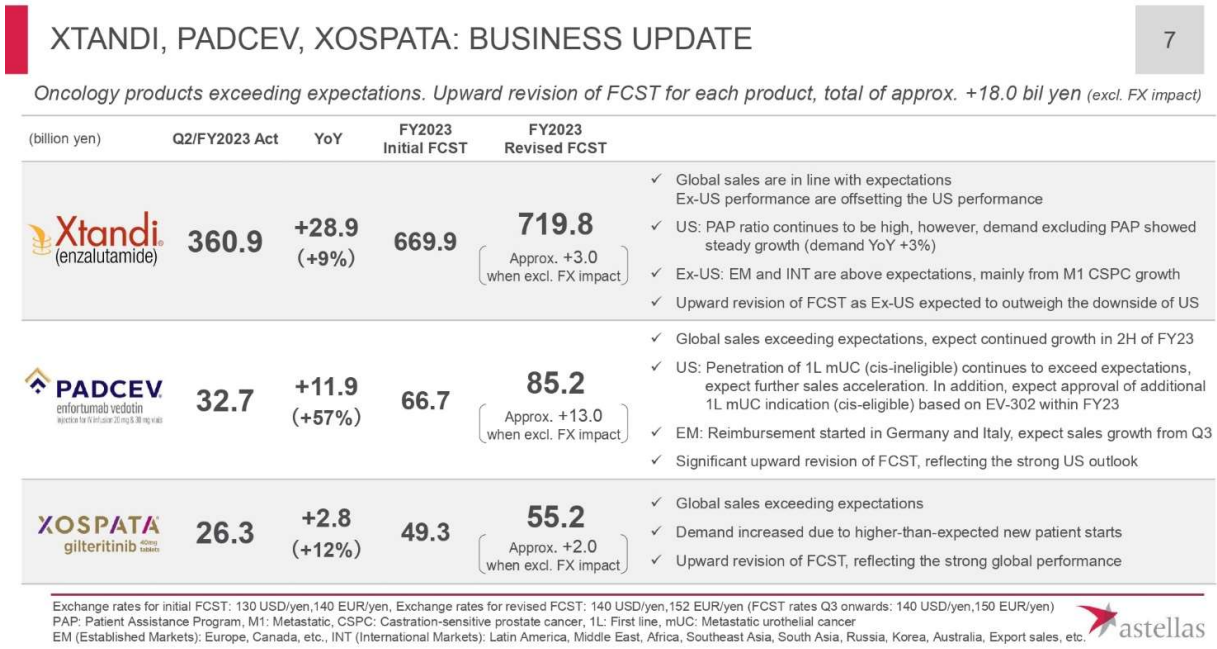
Core operating profit was JPY109.8 billion, down by 24.5% YoY. The progress was 37.9% of our full-year forecast.

In addition to the impact of LEXISCAN generic, we booked SG&A costs, R&D expenditure, and amortization cost for intangible assets related to the acquisition of Iveric Bio, which we did not anticipate initially, so the progress of core operating profit was much lower than expected.

You can see the Forex impact on the right-hand side of the table. There was a positive impact on revenue by JPY37.8 billion and core operating profit by JPY11 billion.

The bottom half of this page shows full basis results. In the right bottom of the table, we included other expenses booked in Q2. In Q2, we booked JPY36.7 billion as payment for Iveric Bio's unvested share-based payment with the acquisition of Iveric Bio. Also, we booked JPY8.8 billion as fair-value increase of contingent consideration for zolbetuximab due to Forex rate fluctuations. The contingent consideration for zolbetuximab is looked as liabilities in euro. From the end of FY2022, the euro substantially fluctuated towards the lower yen, which resulted in fair-value increase of contingent consideration.

As a result, operating profit was JPY51 billion, down by 57.4% YoY. Profit decreased to JPY31.7 billion, down 67.2% YoY.



On page seven, I will explain the progress of XTANDI, PADCEV, and XOSPATA, and the future outlook.

First, about XTANDI. Global sales increased to JPY360.9 billion, up by 9% YoY. Following Q1, ex US performance offset the US performance. Global Progress as a whole was in line with our initial assumptions, even excluding Forex impact.

In the United States, the ratio of PAP, Patient Assistance Program, to enable patients to access drugs for fee, continues to be higher than expected, but volume, excluding PAP, grew by 3% YoY, so actual demand increased.

Other than the United States, established markets and international markets in particular, exceeded expectations. Prescription for M1 CSPC continued to grow, which contributed to the expansion of sales.

Regarding the future outlook, expecting the high PAP ratio to continue in the United States, we made a downward revision of our US dollar-based full-year forecast. On the other hand, we made an upward revision of our full-year forecast for good performing established markets and international markets, which are expected to outweigh the downside of the United States. As a result, we are making an upward revision of our global full-year forecast as a whole, even excluding Forex impact.

Next, for PADCEV, global sales increased to JPY32.7 billion, up by 57% YoY. The progress in the United States, in particular, is exceeding our initial forecast, which contributed greatly to the expansion of global sales.

The penetration of the additional first-line cisplatin-ineligible metastatic urothelial cancer indication approved in April continued to exceed expectations. Further sales acceleration is expected for the future.

Also, EV-302 study results presented at ESMO recently were extremely favorable, exceeding our expectations. Based on these results, we are preparing to file a submission earlier than initial plan and are expecting approval of additional first-line cisplatin-eligible indication in the United States by the end of the current fiscal year.

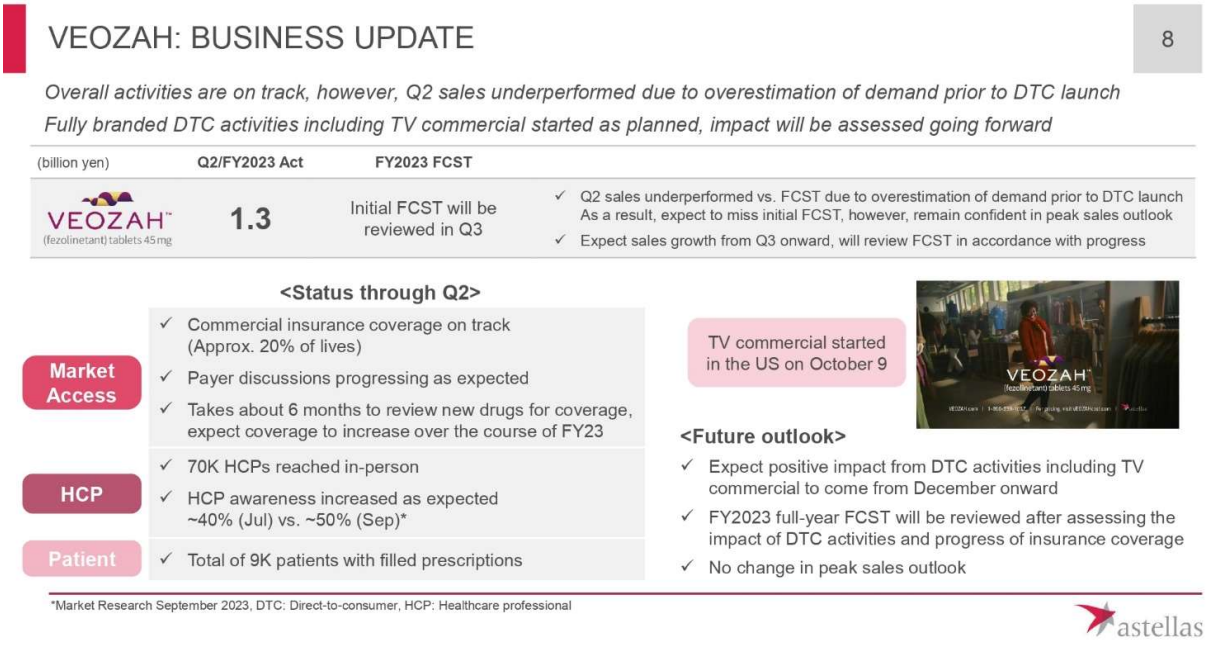
In established markets, reimbursement started in big markets, Germany and Italy, and we are expecting further sales growth from Q3.

Regarding the future outlook, we made a significant upward revision of full-year global sales forecast, reflecting the strong performance and the sales contribution expected from the approval of the additional first-line cisplatin-eligible indication by the end of this fiscal year.

Regarding XOSPATA, global sales increased to JPY26.3 billion, up 12% YoY. In all regions, new patient starts were higher than expected and demand increased.

Reflecting the strong global performance, we made an upward revision of our full-year forecast.

Overall, the three oncology products are performing well. We made an upward revision of our forecast by about JPY18 billion in total for the three products combined. Even excluding Forex impact, starting with PADCEV, we have high expectations on them as growth drivers for the future as well.



On page eight, I will explain the progress of VEOZAH and the future outlook.

Including market access, activities for HCPs and patients are on track. On the other hand, Q2 sales underperformed versus initial forecast due to overestimation of demand prior to the launch of DTC, such as TV commercial.

From the beginning, we are expecting full-scale sales growth from Q3 onward, but we're expecting more demand up to Q2 as well. There are two main factors for the lower volume. First, usage by out-of-pocket payment, not covered by insurance was lower than expected. Secondly, there was some impact of prior authorization required for prescription despite insurance coverage in some cases. The procedural burden to complete this prior authorization process has been perceived as more bothersome than we expected. To tackle this issue, we are working to increase awareness of the program to support the prior authorization process.

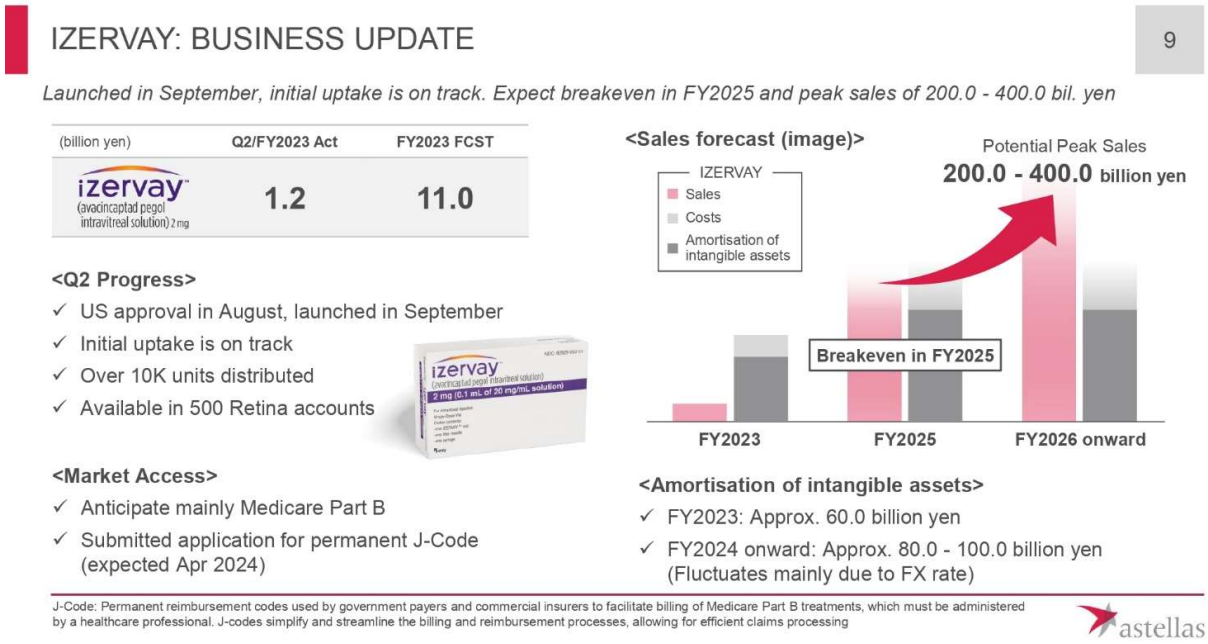
It's difficult to recover the downside through Q2, and we're expecting a downside also in our full-year forecast. But as of now, we are not changing our full-year forecast on a local currency basis because the progress in Q3 with DTC launch is going to be extremely important. Based on the impact of DTC activities and the progress of insurance coverage, we will review our full-year forecast at the time of Q3 earnings.

Next, let me explain the progress through Q2. Regarding the status of the market access as a whole, commercial insurance coverage is on track, around 20% of lives right now. Payer discussions are progressing as expected. We're expecting coverage to increase over the course of FY2023.

In our activities for HCPs, we have reached 70,000 HCPs in person. We believe that the product profile of VEOZAH has penetrated as expected. Actually, based on the results of the market research with a few hundred HCPs, we have been able to confirm steady increase in the awareness of VEOZAH since launch.

With regards to activities for patients, we started TV commercial from the 9 of October in the United States as planned. Industry benchmark suggests that it takes about two months in general for the impact of TV commercial to appear on a full scale, so we are hoping that this will lead to sales expansion from December.

For the future outlook, the initial uptake was lower than our assumptions, but the factors behind would not affect the mid to long-term business of VEOZAH per se, in our opinion. Also, from our recent market research, we confirmed HCP's high assessment of user. We remain confident about our peak sales forecast. We will continue to maximize the value of VEOZAH going forward.



On page nine, I will explain the progress of IZERVAY and the future outlook.

It was launched in September in the United States. Sales in about one month since launch was JPY1.2 billion. The initial uptake was on track. Our full-year forecast for this fiscal year is JPY11 billion.

Through our activities for just one month, it already became available in about 500 Retina accounts as of September. We feel the high expectations for IZERVAY [TD].

As for insurance coverage, we are anticipating mainly Medicare Part B. We already submitted application for permanent J-Code to facilitate [billing] of Medicare Part B treatments for health care professional. We're expecting J-Code in April next year.

Next, I will explain our future outlook. Before sales forecast, I will explain the amortization for intangible assets for IZERVAY. We are expecting about JPY60 billion this fiscal year and JPY80 billion to JPY100 billion from FY2024 onward.

Regarding IZERVAY sales forecast, between sales and amortization of intangible assets, SG&A expenses, and costs related to IZERVAY, we're expecting breakeven in FY2025, with contribution to profit expected from FY2026. We're expecting peak sales of JPY200 billion to JPY400 billion. As the product is just launched recently with a lot of uncertainties such as the impact of competitive products, we are disclosing with a range by taking into account a certain degree of opportunity and risk. The potential impact of competitive product is still under examination right now.

Based on the future uptake and the market environment, we will review the range of peak sales. We have high expectations for the expansion of IZERVAY sales in the future as an important product to help compensate for the decline in sales from XTANDI LOE.

Q2/FY2023 FINANCIAL RESULTS: COST ITEMS

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Cost of sales ratio was as expected

SG&A expenses were on track and R&D expenses were above full-year forecast (when excl. FX impact and the acquisition of Iveric Bio)

Core basis: YoY comparison, ratio to revenue, and progress against FCST, for major cost items

Cost Items	YoY change	Ratio to Revenue	Progress against FCST	
Cost of sales	-5.5%	18.7% (-1.2 ppt YoY)	-	✓ Cost of sales ratio was as expected
SG&A expenses excl. US XTANDI co-pro fee	+16.5% (+11.2% excl. FX impact)	33.2% (+4.5 ppt YoY)	52.5%	✓ Increase in VEOZAH-related costs (approx. +13.0 bil. yen YoY) ✓ Reduction of mature products-related costs (approx. -4.0 bil. yen YoY) ✓ Impact of acquisition of Iveric Bio: approx. +10.0 bil. yen
R&D expenses	+2.0% (-1.2% excl. FX impact)	18.5% (+0.2 ppt YoY)	56.5%	✓ zolbetuximab development costs above full-year forecast ✓ Impact of acquisitions of Iveric Bio: approx. +4.0 bil. yen

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Next, on page 10, I will explain cost items.

Cost of sales ratio was as expected. SG&A costs, excluding US XTANDI co-promotion fees, increased by 16.5% YoY. When Forex impact was excluded, SG&A expenses increased by 11.2% YoY. The progress was 52.5% versus our full-year forecast.

We position FY2023 as a year to make active investments for future growth. Sales promotion expenses related to VEOZAH increased by about JPY13 billion YoY. On the other hand, sales promotion costs related to mature products such as Mirabegron decreased by about JPY4 billion YoY.

The impact of the acquisition of Iveric Bio on SG&A cost was about JPY10 billion. This includes onetime expenses associated with the acquisition, in addition to the actual business costs. Excluding the impact of Forex and the acquisition of Iveric Bio, SG&A costs are in line with our initial expectations.

R&D expenditure increased by 2% YoY and decreased by 1.2% when Forex impact was excluded. The progress was 56.5% versus the full-year forecast and was higher than expected.

Due to the steady progress of Phase II study for zolbetuximab in pancreatic adenocarcinoma and earlier subject enrollment than we assumed, development costs were higher than expected, which was the main factor behind the increase. With the acquisition of Iveric Bio, we booked R&D expenditure of about JPY4 billion.

FY2023 REVISED FORECAST

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- *Revenue: Upward revision*
  - ✓ *Reflect positive FX impact. Upward revision in XTANDI, PADCEV, XOSPATA, Downward revision in LEXISCAN*
- *Core OP: Downward revision*
  - ✓ *Downward revision due to the impact of LEXISCAN and Iveric Bio acquisition*

Exchange rates for revised forecast:
140 USD/yen, 152 EUR/yen
(Forecast rates Q3/2023 onwards:
140 USD/yen, 150 EUR/yen)

(billion yen)	FY2023 Initial FCST*	Main items of revision (excl. the impact of Iveric Bio acquisition)	FY2023 Revised FCST (excl. the impact of the acquisition)	The impact of the acquisition	FY2023 Revised FCST
Revenue	**1,520.0**	FX impact: approx. +90.0 XTANDI, PADCEV, XOSPATA: total approx. +18.0 LEXISCAN: approx. -26.0	**1,597.0**	IZERVAY: +11.0	**1,608.0**
SG&A expenses	661.0		699.0	Approx. +38.0	737.0
US XTANDI co-pro fee	176.0	Mainly FX impact	187.0	(incl. one-time costs associated with acquisitions)	187.0
SG&A excl. the above	485.0		512.0		550.0
R&D expenses	251.0	FX impact zolbetuximab development cost	271.0	Approx. +19.0	290.0
				IZERVAY amortisation: approx.+60.0	
Core operating profit	**290.0**	FX impact: approx. +19.0	**302.0**		**199.0**
<Full basis>					
Operating profit	**259.0**	Fair value increase contingent consideration due to changing exchange rates (zolbetuximab): approx. +7.0	**263.0**	Payment for unvested share-based payments: approx. +37.0	**123.0**

* Exchange rates for initial FCST: 130 USD/yen, 140 EUR/yen, Core basis: disclosed on Apr 27, Full basis: revised on Aug 1

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Page 11. I will explain the revised focus for FY2023.

I will divide the revised focus into two parts: one, based on the progress of the business to date, excluding the impact of the Iveric Bio acquisition; and the other on the impact of the Iveric Bio acquisition itself.

The first is the revised focus excluding the impact of the Iveric Bio acquisition, which is shown in the center of the table. We have revised our Forex assumptions in a certain exchange rate of JPY140 per USD1 and JPY150 per EUR1 from Q3 onward. While factoring in a decrease in the sales of LEXISCAN due to the impact of generics with taking into account the positive impact of foreign exchange rates of approximately JPY90 billion and a total increase of approximately JPY18 billion for the three oncology products as a whole, the revenue is forecasted as JPY1,597 billion.

The forecast for SG&A expenses is at JPY699 billion, mainly due to the impact of Forex rate.

R&D expenses are expected to be JPY271 billion, taking into account the impact of foreign exchange and an increase in development expenses due to the positive progress of studies of zolbetuximab as explained earlier.

As a result, core operating profit, excluding the impact of the Iveric Bio acquisition is expected to be JPY302 billion.

About JPY7 billion of the fair-value increase of consideration for zolbetuximab is included into other expenses. But the full-year operating profit is forecasted as JPY263 billion, thanks to the positive impact of Forex rate.

Next, I will explain the revised focus, including the impact of the acquisition of Iveric Bio, shown on the right side of the table. Revenues are expected to be at JPY1,608 billion, including JPY11 billion of IZERVAY's sales forecast.

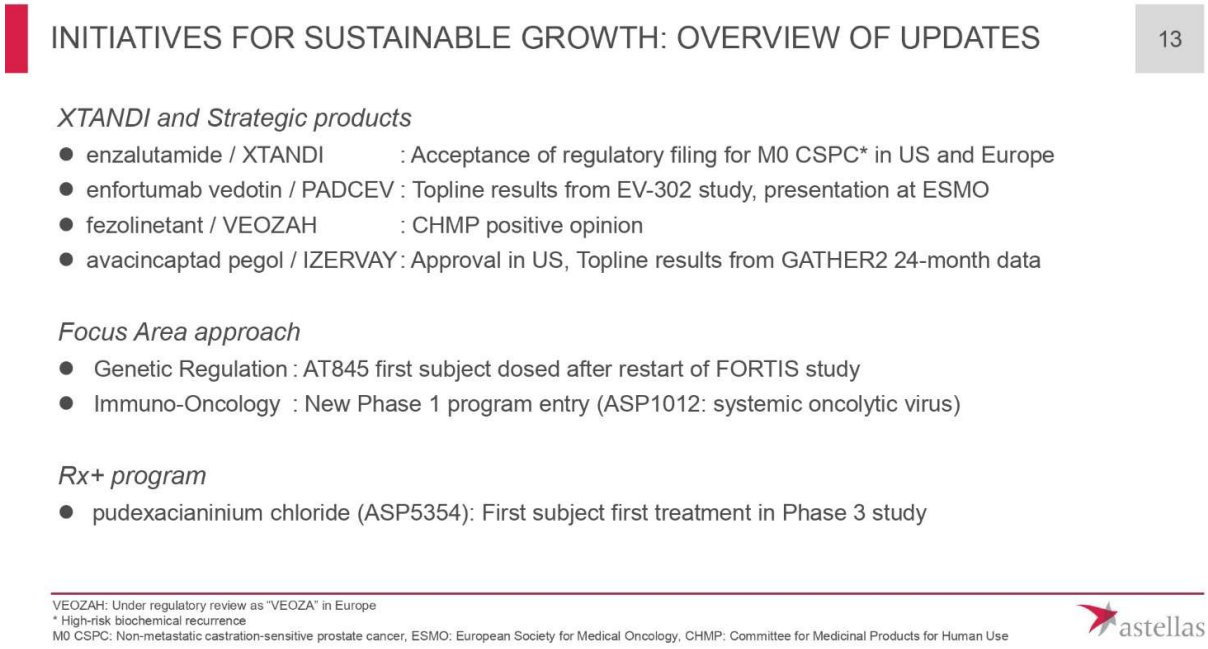
SG&A expenses are expected to be JPY737 billion, including about JPY38 billion. This also includes the increase of SG&A expenses in the actual business as well as one-time costs associated with acquisitions.

R&D expenses are expected to be JPY290 billion, including about JPY19 billion.

In addition, amortization of intangible assets of about JPY60 billion has been factored in.

As a result, core operating profit is projected to be JPY199 billion. On a full basis, operating income is expected to be JPY123 billion, including about JPY37 billion in payment for unvested share-based payment associated with the acquisition of Iveric Bio.

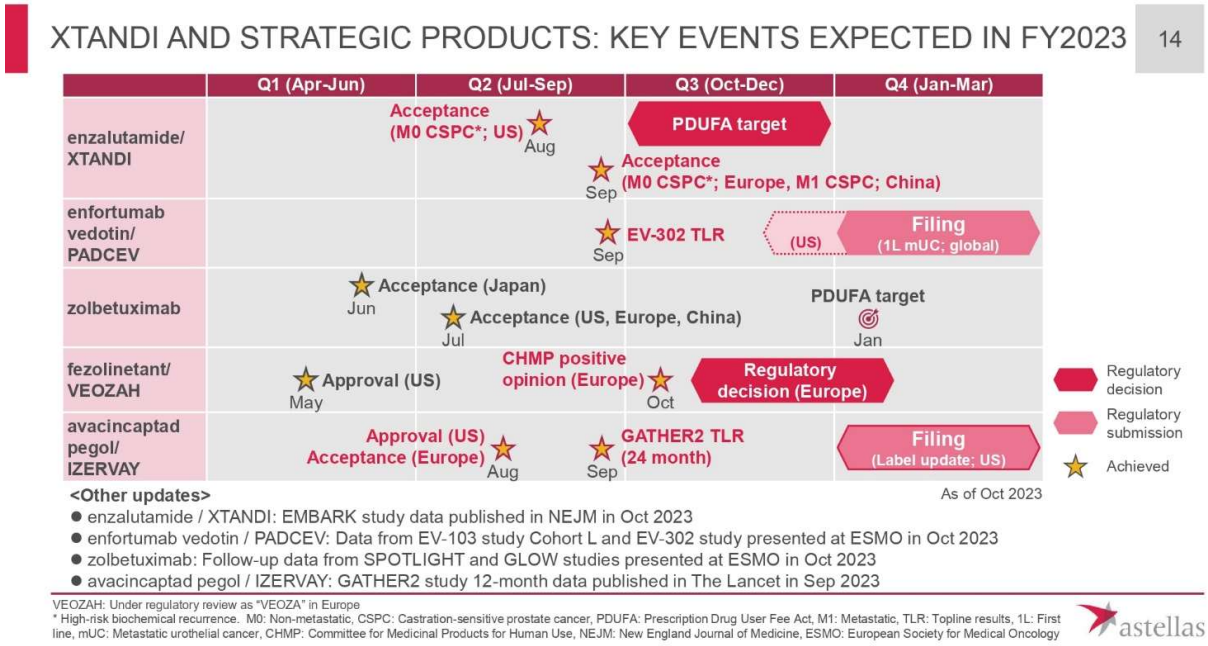
From here, I would like to explain the initiatives for sustainable growth.



Page 13 shows the overview of key updates on initiatives for sustainable growth since the last financial announcement.

There has been significant development progress in XTANDI and Strategic products and Focus Area Approach projects. Details are provided in the following slides.

In the Rx+ program, a Phase III trial evaluating ASP5354, our fluorescent contrast agent for urothelial visualization during surgery, has started and achieved the first subject first treatment.



On page 14, here, I will discuss the key events we expect to see in FY2023 for XTANDI and Strategic products. The progress made in the past three months is shown in red.

About XTANDI, the submission was accepted for the additional indication of M0 CSPC, nonmetastatic castration-sensitive prostate cancer with a high risk of chemical recurrence in the US in August and in Europe in September. The US application was granted priority review status by the FDA, where the PDUFA target was set as Q3.

The application for an additional indication of M1 CSPC, metastatic castration-sensitive prostate cancer based on the China ARCHES study has been accepted in China in September.

As for PADCEV, the EV-302 study showed positive top-line results in September. Based on these results, we are now moving ahead of our initial plan to file a global application and aiming at the submission in the US by December.

For VEOZAH, Astellas received CHMP positive opinion in October.

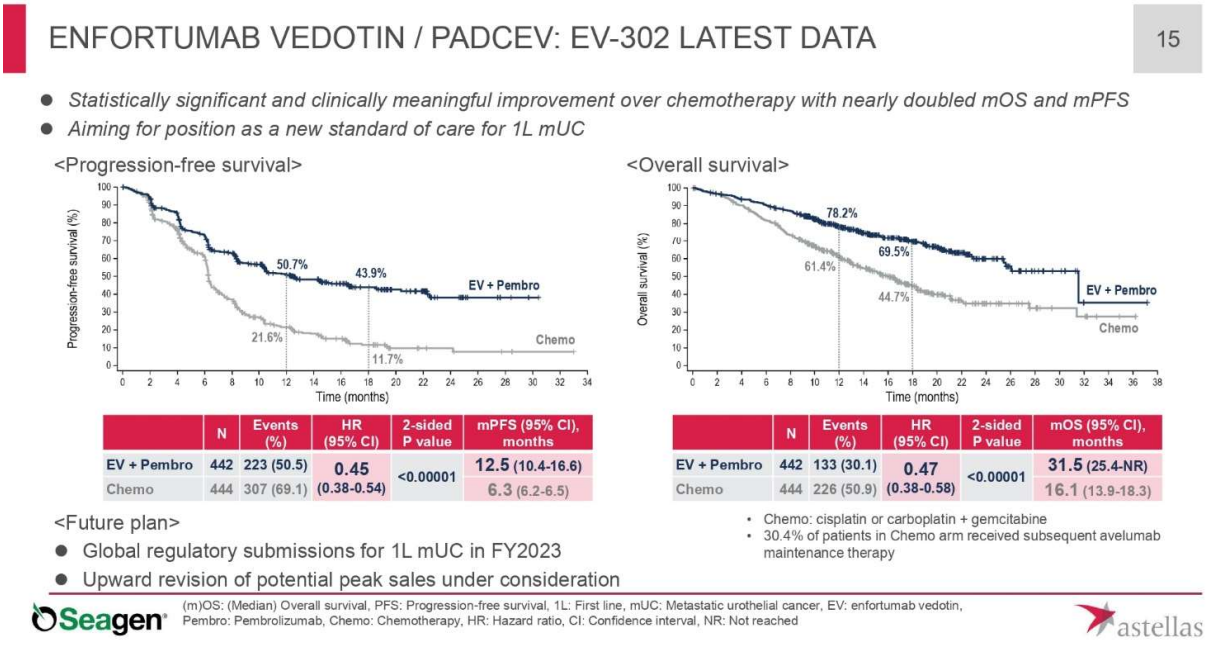
IZERVAY received approval from the US FDA and it was accepted for filing in Europe in August. In September, we received positive 24-months top-line results from the GATHER2 study. Based on these results, we plan to submit an application for a label of revision in Q4. The current label specifies there's a maximum dosing period of 12 months and a dosing frequency of once a month, but we plan to discuss with the regulatory authorities to improve the convenience for patients and physicians. We plan to hold a presentation meeting on the 24 months GATHER2 study on November 6, immediately following the presentation at the American Academy of Ophthalmology, or AAO, to provide more details.

Other updates are listed outside of this chart. Regarding XTANDI, the EMBARK study data was published in *The New England Journal of Medicine*.

For PADCEV, results from the EV-103 study Cohort L and the EV-302 study in muscle-invasive bladder cancer were presented at ESMO. EV-302 study data will be explained with the next slide.

For zolbetuximab, follow-up data from SPOTLIGHT and GLOW studies were presented at ESMO. Other activities underway to bring the product to market will be described in the later slide.

IZERVAY month data of the GATHER2 trial was published in *The Lancet*.



On page 15, I discuss the EV-302 trial data for PADCEV, which was presented at the ESMO in October.

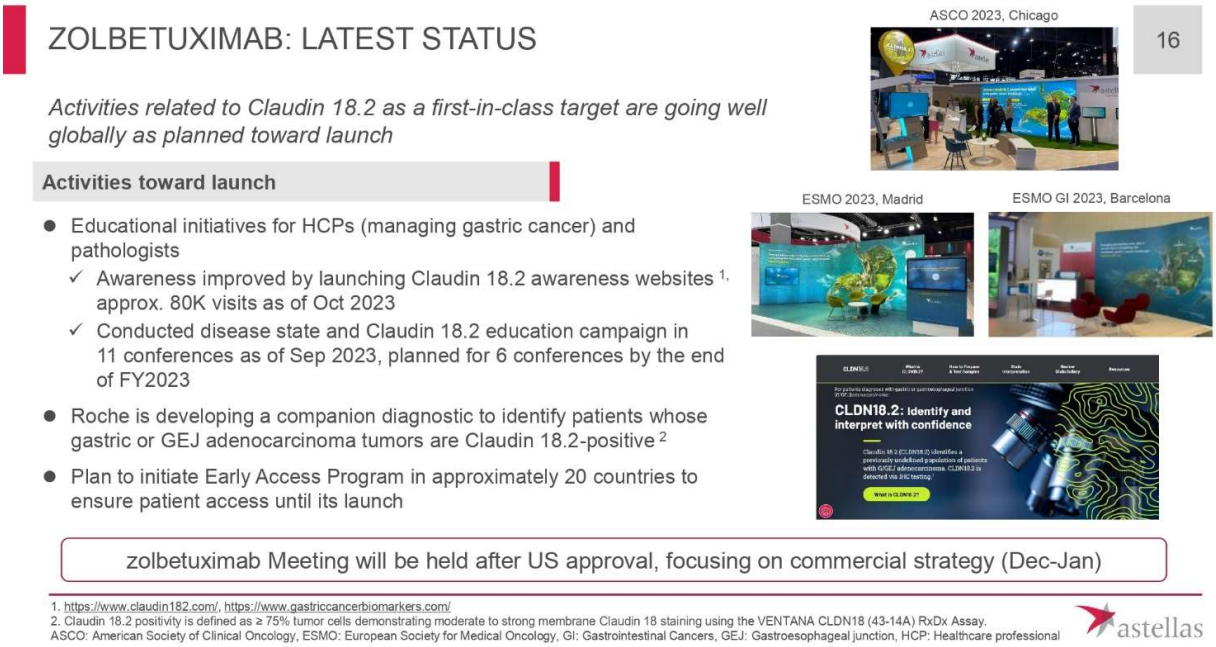
The EV-302 study compared the efficacy and the safety of PADCEV in combination with KEYTRUDA to chemotherapy with platinum and gemcitabine in patients with treatment-naïve locally advanced or metastatic urothelial cancer.

As shown in the chart, the combination of PADCEV and KEYTRUDA reduced the risk of cancer progression or death by 55% versus chemotherapy with a hazard ratio of 0.45 for PFS and the risk of death by 53% with a hazard ratio of 0.47 for overall survival. The median survival in both PFS and OS was approximately twice as long as that in chemotherapy.

In the subgroup analysis, consistent improvement in OS was observed in various patient populations regardless of cisplatin eligibility and PD-L1 expression level. When PADCEV was presented at the ESMO the other day, there was a standing ovation in the audience. That's what I heard. This means the presentation was highly acclaimed by the experts and attracted a lot of attention.

Aiming at the position as a new standard first-line treatment for metastatic urothelial cancer, we are planning to submit regulatory applications globally, starting with the US.

In addition, due to the extremely positive results that exceeded our expectations, we have started to consider the possibility of raising our peak sales forecast. At this time, we don't comment on the specific range of the increase, but we will provide further guidance after we have conducted a thorough review.

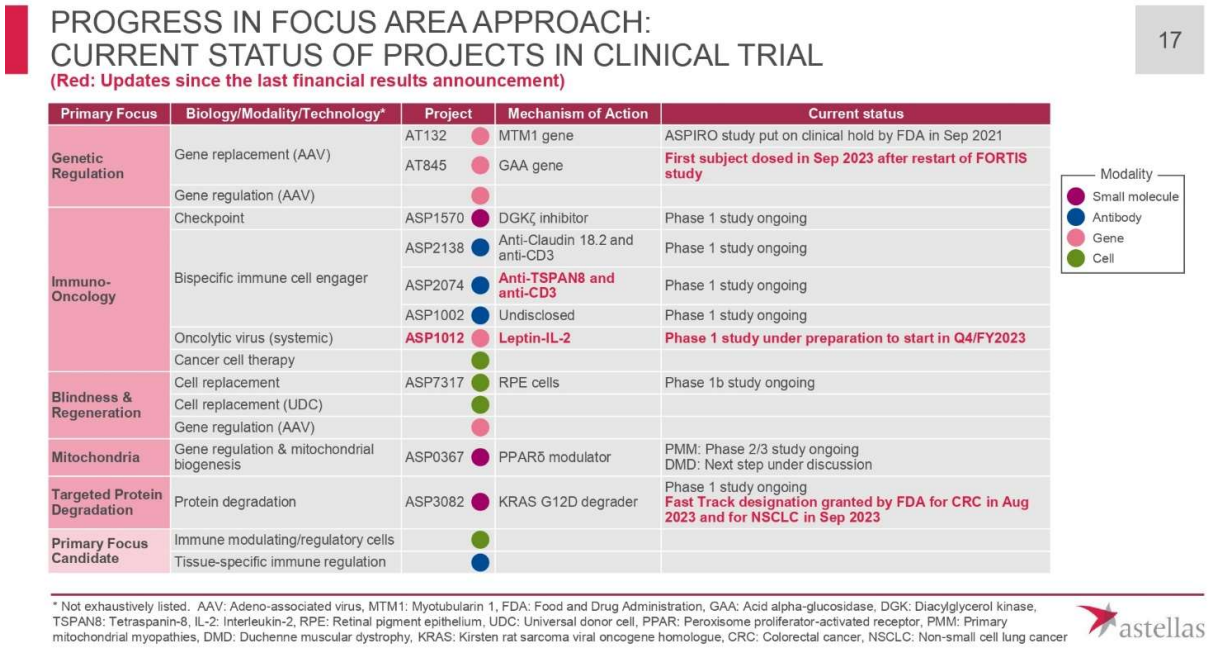


Next is the zolbetuximab update.

We have submitted applications for zolbetuximab in Japan, the US, Europe, and China and are working with the regulatory authorities in [a tuition] on the review process. If approved, zolbetuximab will become a first-in-class drug targeting Claudin 18.2. In parallel with it, we are proactively conducting activities to raise awareness of importance of Claudin 18.2 as a biomarker, and its recognition by setting up a booth at major academic conferences around the world and by launching our website to educate physicians and pathologists who treat gastric cancer.

Roche is developing the companion diagnostic needed for patient screening. In addition, Early Access Programs are planned in about 20 countries to ensure patient access to zolbetuximab until its launch.

We plan shareholder meeting to explain in detail our commercial strategy and sales outlook after the approval in the US. The timing will depend on the timing of the approval, but we are currently anticipating it will be a December to January time frame.



On page 17, I will explain progress in Focus Area Approach. Projects in clinical trials, clinical stages that have been updated in the past three months are shown in red.

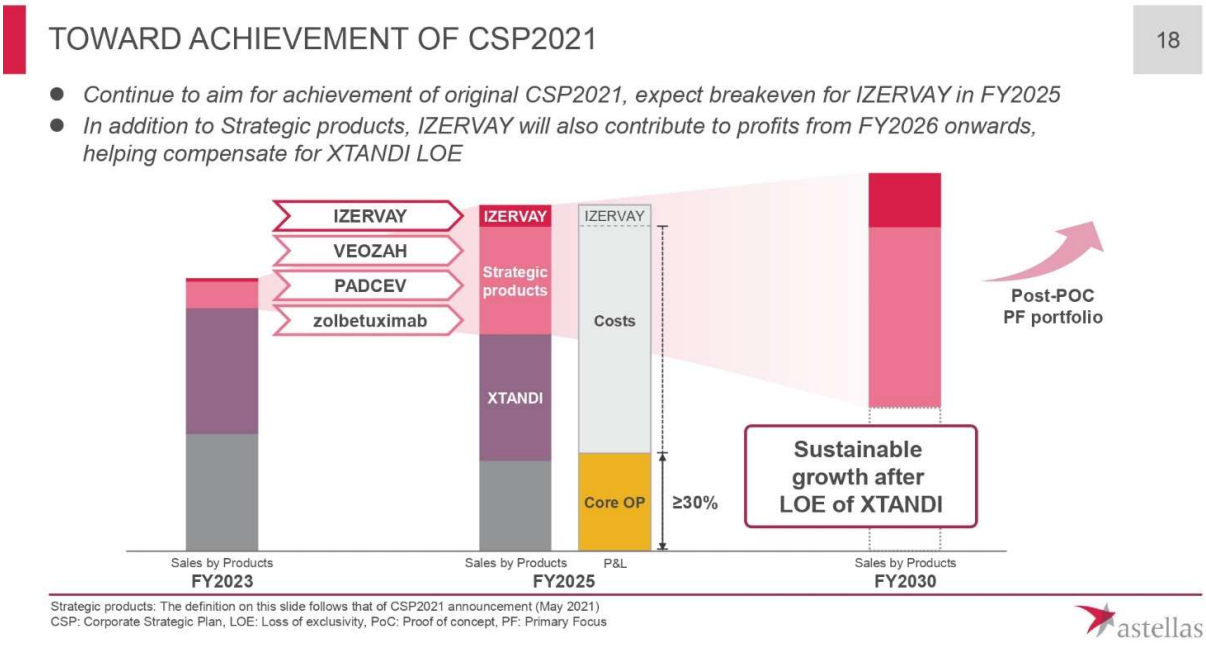
In the primary focus of genetic regulation, we have been working on resuming the administration of AT845 since the clinical hold of the FORTIS trial was lifted. The first subject was dosed in September as planned. We'll continue to enroll and evaluate subjects to determine the POC.

In the area of immuno-oncology, we disclosed that the target molecules of ASP2074, a bispecific immune cell engager, Tetraspanin-8 and CD3. Tetraspanin-8 is a known tumor-associated antigen that is overexpressed in various types of cancers. The mechanism of action is that ASP2074 specifically binds to cancer cells expressing Tetraspanin-8 and CD3-positive cells, bringing them closer together and activating the T-cells to cause cancer cell damage.

ASP1012, a systemic oncolytic virus, has entered the clinical stage and is expected to enter Phase I trials in Q4. ASP1012 is a program acquired through an exclusive license agreement with KaliVir in 2020, and this is oncolytic vaccine virus carrying the gene for future protein of Leptine and Interleukin-2.

After intravenous administration, the virus is designed to reach tumor tissues throughout the body to simultaneously cause local damage to cancer cells and enhance the cancer immune response. We expect that the drug will easily access cancers that are difficult to treat with local administration to Teratoma tissue and will be applicable to many cancer therapies.

ASP3082, a targeted protein degrader, has been granted Fast Track designation by the FDA for the treatment of locally advanced or metastatic colorectal cancer and non-small cell lung cancer with KRAS G12D mutation respectively. Together with pancreatic adenocarcinoma, for which the designation was also granted in February of this year, we were able to obtain Fast Track designation for three cancer types known to have a high frequency of KRAS G12D mutations. We look forward to accelerating the development of this innovative treatment for these cancers with high unmet needs.

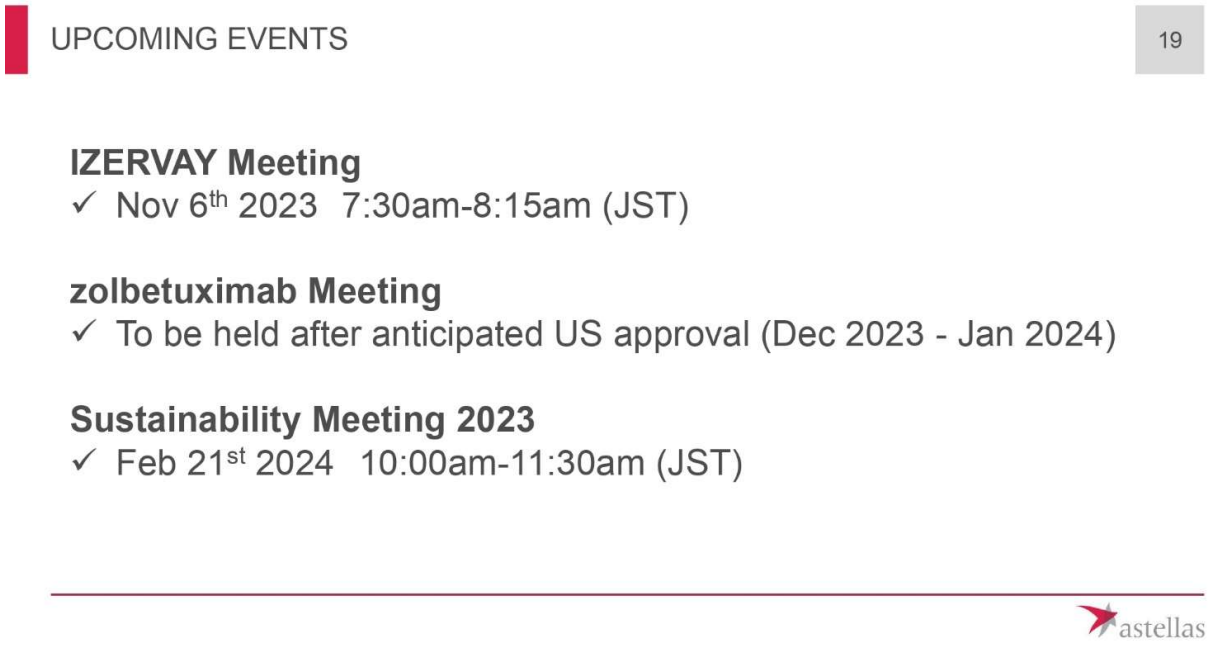


On page 18, I would like to explain the current outlook toward achievement of CSP2021.

For the full-scale sales of VEOZAH, further acceleration of growth of PADCEV based on the EV302 study and the global launch of zolbetuximab, we will achieve significant growth in revenue and profits toward FY2025. This initial plan hasn't been changed, and we will continue to aim to achieve our goals, including a core OP of 30%.

In addition to this, we expect IZERVAY sales to grow and reach breakeven with associated expenses, including amortization of intangibles in FY2025. As a result, when the impact of IZERVAY included, we expect that it will be difficult to achieve a core OP of 30% in FY2025.

On the other hand, we expect IZERVAY to continue to grow in FY2026 and beyond, contributing to profit growth along with other Strategic products. This will bring us on solid ground to achieve what we are aiming for in our CSP2021, namely sustainable growth after the loss of the XTANDI exclusivity period.



Page 19, this is the last slide. You see the schedule of upcoming events.

The IZERVAY meeting for 24-months data will be held on November 6.

The zolbetuximab meeting will be held after anticipated US approval between December this year to January next year.

The Annual Sustainability Meeting is scheduled to be held on February 21 this year.

I hope you will join us. That is all I have to say. Thank you very much for your attention.

Ikeda: This will [conclude] our presentation.

Question & Answer

Ikeda [M]: We now would like to entertain questions from the audience. You can ask questions only through Zoom webinar. You cannot ask questions as we live streaming.

Today, our Chief Commercial Officer, Claus, is joining us well. As we said at the beginning, if you select original from the Zoom screen menu, you can listen to the original sound without going through simultaneous translation. You can change the sound settings at this time, if you want.

We now would like to enter any questions, please.

Operator [M]: Thank you for waiting. Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi [Q]: Thank you very much. I'm Yamaguchi from Citigroup Securities. There were so many topics included in the presentation. Thank you for the presentation. Regarding the VEOZAH business update, I have a question first. This was a topic during the Q1 earnings. Even if there is a prescription, there is a hurdle to clear until the actual prescription. That was explained today. After the insurance reimbursement, it takes some time, and you're going to resolve this issue as was mentioned. You have a variety of programs going on to resolve these issues. In the short term, these issues will be resolved. Insurance coverage will increase. And even after insurance coverage, there may be some issues because of the process. I'm sure there is some impact. Including time frame, how much you can resolve these issues?

Okamura [A]: Thank you for your question. First of all, I'd like to briefly explain and then Claus may add some comments, if any, afterwards. First of all, as you said, what is going to happen to insurance reimbursement, that's one factor. And also, for DTC, those who respond to DTC, patients usually would have an annual health checkup to visit physicians. But because they looked at DTC, they have certain symptoms and they want physicians to check their symptoms. Whether they would go to the physicians or not, so there are these two factors.

Insurance reimbursement, once we began discussions with payers, insurance reimbursement is not decided immediately. We need negotiations for a few months before decision. As you know, US payers varies, small ones and big ones. The number of people they cover is also very different. Some payers adopt something new quite quickly and others need a lot of discussions before approval.

For the time being, we mentioned 20% of lives being covered of the population in the United States, and we received a reimbursement from such payers. As for the remaining ones, you have larger accounts. One insurance has many people being covered. We are to discuss with those payers. Of course, we're expecting tough negotiation system. We shouldn't be too easy to determine the price because it will continue over the life cycle as a whole. The value of VEOZAH must be fully recognized to determine the insurance reimbursement. Probably by the end of FY2023, the ratio of the US population, it's going to be more than 50% of the coverage of lives according to our forecast right now.

On the other hand, after launch until now, prescription is not growing so much. There is another reason behind. At the Super Bowl, we had an advertisement. Awareness increased in society as a whole. We thought that happened. And including the results of the market research, with or without prescription, quite a large number of patients visit their HCPs. That's what we thought, but not so much as we expected. And to write the prescription, it didn't happen or they brought a prescription to fill at the pharmacies, but they know that it's not going to be filled for their insurance, they decided not to receive it for the time being. That's the situation up until now since launch. We started DTC from October. So more than before, the target patient population for VEOZAH exists.

VMS, as you know, has subjective symptoms. If patients have subjective symptoms, they have an annually held checkup, but rather, because of the symptoms, and “I heard about this product, doctors, please check my symptom”. By increasing such visits to HCPs, it's easier to write a prescription and they may have no other choice but to write a prescription.

Because of the perceptions, payers would be pressured to know that there are so many patients. And the discussions about insurance reimbursement will accelerate. If we have those factors as we expected, we can draw a picture as we expected. And prior to that, whether it's going to be realized in accordance with expectations, in Q3, we'd like to identify the situation. And based on that, JPY49 billion we communicated at the beginning of the year, how much we can achieve, the figure will be reviewed so that we can announce to you.

Claus, any additional comments from you?

Zieler [A]*: I think Okamura-san described the situation very accurately. Maybe I can only add that the payer negotiations and the direct-to-consumer demand, of course, are linked because the payers are also trying to estimate what demand they should be expecting. The direct-to-consumer campaign that we have started on the 9 of October, as it increases demand, we expect that, that will then also enable us to progress with the payer negotiations. The two go hand-in-hand.

Yamaguchi [Q]: Thank you very much. Another simple question. The start-up of IZERVAY is really good, and I understand in that way, but probably the competitor show the news of the inflammation in eyes. And I just wonder if it is the product specific or the class problems. For IZERVAY, I just wonder if the kind of side effects that happened or not happen or how the HCPs are talking about this? What's the current situation?

Okamura [A]: Thank you for the question. As a fact regarding the IZERVAY, the vasculitis is reported, although it's just one case. In that sense, it's difficult for us to say that this drug is completely clean. But how we evaluate that, rather than myself, Taniguchi is better to explain about this.

Taniguchi-san, would you please answer for this?

Taniguchi [A]: Let me answer for this. For intraocular vasculitis, this now observed in our competitors' or other companies' product, and that is collecting addition. In GATHER1, GATHER2, two studies are conducted and the result is disclosed and there, such event didn't take place.

At the same time, although this is reported from other company, post-marketing, just one case of the vasculitis was reported. But this patient used this drug outside of the indication. And method of the administration is that with using other company's drug in one site, IZERVAY was administered in other site, so the situation was quite complicated. There is such one patient report. And for this patient, we're currently still checking the current situation.

Yamaguchi [Q]: In other words, that is only one case that this vasculitis is observed?

Taniguchi [A]: Yes, that is only one case that we recognize.

Yamaguchi [M]: Thank you very much. I understand that.

Operator [M]: Next question, Mr. Hashiguchi from Daiwa Securities, please.

Hashiguchi [Q]: Hashiguchi from Daiwa Securities. Thank you very much for your time. First of all, I also have a question about VEOZAH and IZERVAY. Regarding VEOZAH insurance reimbursement, you have negotiations to get the reimbursement and also the timing to get the coverage. Okamura-san explained. Listening to his

explanation, compared to before, you will plan to spend a longer time to negotiate. That's what I thought. Is my understanding correct?

Okamura [M]: Claus is going to explain.

Zieler [A]*: The payer negotiations right now are fully on track. The 20% of lives covered that we achieved by the end of September is exactly what we were expecting. I think so far, we can say we are fully on track with the payer negotiations.

Of course, going forward, we are negotiating with the bigger payers, and we're negotiating larger volumes. Again, it goes hand-in-hand with the direct-to-consumer campaigns, adding demand to the payers. It's a little bit difficult to predict. But I would say we are on track. And I would not say that we will be far off our initial expectations at the end of the fiscal year.

Hashiguchi [Q]: Thank you very much. Now about IZERVAY. The start-up is in line with the expectations as you explained. But the expectation itself, the expectation of when, at what point of time, and what exactly the expectation is, well, because of this situation, I just would like to hear.

And after you decide the acquisition, the competitor's safety-related issue took place. After you made the decision and the situation afterwards might have been changed. Regarding the impact of the competitor's product, the mechanism is closer. That's why some doctors might be cautious about adopting IZERVAY or there's the situation where the treatment option is limited, that's why IZERVAY is utilized. There are such a complicated situation, so I just wonder what factor works in what way? And how do you see about the new patient share?

Okamura [A]: Thank you for the question. First of all, I explained about the contents of the accounting treatment of business combination. And that is a valuation based upon the time that we decide this acquisition. Therefore, in line with the expectation or better than the expectation, that means that the valuation result that we've done on our own is always referred to. JPY200 billion to JPY400 billion of peak sales that we expect, there are several reasons of this wider range. That's because we need to take into consideration about the competitor situation, meaning that this is not a factor that is handled only on our own, meaning that we need to look at the data disclosed from the competitor. And also, the causality identification is also needed to be considered as a factor.

There are various parameters. And if it is getting a positive, we can reach to nearly JPY400 billion. But if it is not really so, then it becomes smaller, to the level like JPY200 billion. It's been only three months after the closure of the contract of this acquisition, and it's just one month after the launch of the product. What would happen cannot be precisely predicted at this moment. However, we decide the purchasing price, the acquisition price based upon the due diligence. The valuation we made at that time is also the foundation to think about what will happen to the future. And peak sales guidance, therefore, is going to be let you know in appropriate way at appropriate timing so that you can have a better understanding.

Hashiguchi [Q]: I understood it quite well. The current market, what about the current share of this product amongst new patients.

Zieler [A]*: Thank you for your question. As Okamura-san said, it's very, very early with one-month data. We are in a data set that is too thin to really estimate accurately. We do have some anecdotal evidence from doctors when our salespeople contact them. And that anecdotal evidence seems to suggest that we get a mixture of reactions. We get some doctors saying, "I'm aware of the adverse events of the competitor product, so I'll be more careful." But we have other doctors saying, "I'm aware of the competitor's adverse events, so I will prefer either way." Anecdotally, we get a big mix of hesitancy and switch behavior, which is impossible

to quantify at this point. I would argue that we will need probably another 4 to 6 months data before we have stable market share trends.

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

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

Muraoka [Q]: Muraoka from Morgan Stanley. Thank you very much. First of all, amortization cost, JPY60 billion or JPY80 billion or JPY100 billion, what is the duration of the amortization period? Around 10 years? Or I think it can be a little bit shorter until when you would amortize. And the countermeasures against LOE, with this drug, generic could be launched quite soon given the modality. Did you take that into account in calculating the amortization period?

Okamura [A]: Thank you for your question. Regarding the amortization period, we are not disclosing the information. However, this year, our amortization amount this year, for eight months, starting from August for this fiscal year. When I explain the amortization cost of JPY80 billion to JPY100 billion, well, there are two reasons. One is this would include the amount outside of the United States. And because of the long period, based on yen, we cannot make a specific amount in Japanese yen. That's why there is a range.

In FY2023, the amortization cost for FY2023 is for eight months. And we have intangible assets outside of the United States. What is the assumption for the amortization period, you can back calculate the period. With your calculation, you can set the duration. That's our stance.

As for life cycle management, based on the intellectual properties of the product, we determine the amortization period. But the life cycle management, we may change formulations or we may go for different indications. And we may be able to get the usage pattern, for example. Depending on what is going to happen in the future, if there's anything we should disclose to you, at the proper timing, we'd like to explain to you in an easy-to-understand fashion.

For the time being, there are a few puzzle pieces. There is still some space. But from the remaining puzzle pieces, you're going to fill the space. That's the stance we are taking for the time being. Thank you for your understanding.

Muraoka [Q]: Thank you very much. This nucleic acid-based drug, considering about 10 years later, are you thinking that it is not easy to make a generic for nucleic acid product?

Okamura [A]: I don't know if I'm the right person to answer this. But probably 10 years later, technologically, I assume that it will not be extremely difficult to make it. When the antibody becomes available, at that time, it was said antibody is difficult to be made and also there are multiple layers of the intellectual property. Therefore, generic is difficult to be developed. But currently, biosimilar is not that difficult to be made. Same situation might happen no matter what the modality is. That way we better assume. That's our stance.

Muraoka [Q]: Thank you very much. For IZERVAY, initial anecdotal feeding is what you talked about. And you talked about the safety, but the 12-month restriction of the usage and currently, just a once-monthly product available. Regarding this point, although it's just one month after the launch, what is the doctors' response about this? Is there any negative comment about this?

Okamura [A]: What you're asking is rather than the doctors conducting clinical trials, but the doctors who are actually using this product in the market, you want to hear the reaction of them?

Muraoka [M]: Yes, that's right.

Okamura [A]: Now, Claus, would you please answer to that?

Zieler [A]*: Yes. Thank you for your question. We don't have robust market research data to answer that question. But as an indicator, we do get reorders from clinics who have ordered multiple times now. That gives us a lot of confidence that the doctors who are using the product are satisfied with the effect.

Muraoka [Q]: Thank you very much. Last question, this is going to be a brief question. Somewhere in the supplemental documents, you discontinued Phase III of Mirabegron in pediatric patients. Because of the issues in the clinical study, I think this was to extend our LOE for Mirabegron for six months, but we shouldn't expect this further for the future. Correct?

Taniguchi [A]: Mirabegron pediatric indication, clinical studies for that indication, we decided to terminate because of the enrollment. Enrollment was not so favorable with the European authorities. We had consultations and decided to do this. We made that decision.

And into the future, how this will affect the LOE and the six-month extension, probably, discussions with authorities will continue. We don't have any information we can disclose. We cannot respond right now.

Muraoka [Q]: It's limited to Europe?

Ikeda[A]: Yes.

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

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

Wakao [Q]: Thank you. First question is about VEOZAH from me as well. This might be the repetition, but I'd like to make a confirmation. for the coverage, it seems it might take longer than you've expected. In the material in Q1, in the aesthetical and afterwards, you are expecting the coverage of the private insurance and at the end of FY2023, the coverage will be established to a greater extent. But based upon the current assumption, that coverage is going to be reduced? I believe you mentioned about the 50% of the coverage. By the end of this fiscal year, what will be your target of the coverage?

And also, the impact of this time, well, it's not a level enough to change the peak forecast. But FY2025, JPY300 billion, for example, a midterm target. Against that, do you think that the situation will have an impact? Or this is just a couple of months delay? Because I cannot fully understand the magnitude of impact of this situation.

Zieler [A]*: Thank you so much for your question. I believe your first question was about the payer coverage and what we are expecting at the end of the fiscal year. Our projections that I believe we have communicated since the beginning was that we would achieve a majority of lives covered by the end of the fiscal year. And as I alluded to, to an earlier question, at this point, we are fully on track with the lives covered, and we don't see any indication that we should be off target from that more than 50% expectation of lives covered by the end of fiscal 2023. That would be what I can share today on the expectations.

Wakao [Q]: And what about the impact against the sales so far? This is just about a couple of months delay? Or FY2025, JPY300 billion forecast is also difficult to be achieved?

Okamura [A]: Let me explain about this a bit. And if there is additional information, Claus will make a comment. In the response in your first question, I mentioned there are two stages, meaning that the DTC impact after the launch, there will be a certain period of time. And the DTC effect is that it appeared and the patients go to the doctors and explain about the symptoms and prescription is written. There is a phase 1 and phase 2.

And what is currently ongoing now and what you see is this phase 1. For this phase 1, we were too aggressive for the forecast; we thought it could have been better than our current situation. For this itself, our forecast was not accurate enough. And within this couple of months, there were supposed to be some patients who have started to use this drug which continues to use it within this fiscal year. In other words, the refill would take place, but that is already done, so you cannot recover that.

But on the other hand, phase 2 would come, meaning that the DTC efficacy becomes effective, tangible, and the patient actually goes to the hospital further for the prescription. And for the setup, we need to have very clean eyes, so that we can—therefore, it is in line with our expectation or not. And if that situation is completely in line with our expectation, we believe we can achieve the targeted peak sales. I would like you to wait 'til the end of Q3.

Wakao [Q]: Meaning that we have to wait another few months, so phase 2 forecast, that might be varied. Is this understanding right?

Okamura [A]: Yes, that's right. That's right.

Wakao [Q]: Understand. Thank you. Now I understand clearly.

Next, about IZERVAY, the slide on the impact on the business results this year, you explained the impact on SG&A and R&D expenditure. Next fiscal year, IZERVAY, Iveric Bio's SG&A cost and R&D expenditure, how much should we expect on a full-year basis? There can be a decrease for R&D costs, but there can be a possibility of an increase in SGA cost. What's your view on this?

Okamura [A]: It's rather difficult to understand, perhaps, but SGA costs include, as you can see here, onetime expenses associated with the acquisition. In FY2024 and beyond, business as usual, what is going to be the amount, it's very difficult to tell, perhaps based on these figures. On the other hand, IZERVAY is a new product. It's not as much as VEOZAH, but for the launch of a new product, we need spending. Right now, it's just for the United States, but in FY2024, outside of the United States, we are going to launch it as well. What I want to say here is that from FY2023, some of the costs will disappear, but some of the costs included in FY2023, but the amount may increase for the future. It's not included in FY2023, and it's going to be added to FY2024, for example. We have to take these factors into consideration to think this could be an approximate level.

For R&D expenditure, in the life cycle management, for that purpose, new formulations might be developed or every other month dosing may require the automation of more clinical data, we can assume such scenarios. Iveric Bio's trend, based on the trends by now, there can be a slight decrease. But on the other hand, we will continue to make these efforts as well. Reducing, coming down to 0 or suddenly doubling are not expected.

Wakao [Q]: Understood. Lastly, IZERVAY vasculitis, could you elaborate on that? The one case is out of 10,000 vials, so 0.01%. This rate is similar to the competitor's product? And you explained us about the case of the vasculitis. The administration is quite complicated. If the administration is in line with the guided administration way, this kind of vasculitis will not take place. What do you think about it?

Okamura [A]: That's a clinical perspective, so Taniguchi-san is going to explain about it. But the 10,000 vials in one case, so 1 out of 10,000, I don't think that is the right way, so please abolish that way of the thinking. And what Taniguchi explained a little while ago is that, first of all, why this is complicated? Well, first of all, this patient is off-label use. And one eye is where the competitor's product is used and the other is IZERVAY. Once something like this happens, it's very difficult to identify what's the cause. That's why I'm saying this is quite a complicated situation. So 1 case per 10,000 is a completely different way of thinking. Please do understand it in that way.

Taniguchi, do you have any additional comment on this?

Taniguchi [A]: Well, onset rate, well for post-marketing, that is very difficult to define the nature. We are going to make an effort, but for the future as well, it might be difficult to give you the precise number. What is clear is the calculation of data in the clinical trial. I believe that, that is the precise event rate of AE that can be communicated and I believe that other companies do the same way.

Wakao [Q]: I asked this because compared to Apellis, what is going to be the incidence? On the other hand, your company's product may have a lower incidence? The difference may affect the upcoming penetration in the market. That's why I wanted to confirm.

Okamura [A]: Yes, you're right. That's why our current guidance has a big range. You may not think this is the right guidance, but for us, with our efforts, we would like to clarify various factors. And the third party, we may have to depend on information from third parties in some aspects, so there are certain uncertainties. That's why we have a wide range in our guidance right now.

If there is any event, we become aware to narrow the range and if there is any supporting information, based on that, we will change our guidance, and we'll communicate to you at an appropriate timing.

Wakao [M]: Understood. That's all from me.

Ikeda [M]: Thank you. Next, Goldman Sachs Securities, Ueda-san, please.

Ueda [Q]: Thank you. Ueda speaking from Goldman Sachs. My first question is also about VEOZAH. What's the current evaluation by the user doctors? For this drug, efficacy, safety, the onset of efficacy, convenience – looking at it in a comprehensive manner, I think this is the drug very easy to use. But what is the actual voice from the using doctors or prescribing doctors?

Okamura [M]: Claus is going to answer for that.

Zieler [A]*: Yes. Thank you for your question, Ueda-san. We conducted recently market research to confirm doctors' impression of VEOZAH. And quite honestly, we were very positively surprised how positive the reaction is of those doctors who are writing, who are actively writing VEOZAH, prescribing VEOZAH, the confirmation of the unmet medical need, the confirmation of the scientific progress that VEOZAH offers, the confirmation that it helps patients. The reaction is resoundingly positive from doctors who have used VEOZAH. That, of course, gives us a lot of confidence that VEOZAH is really going to fill the need that women have in this indication.

Ueda [Q]: About VEOZAH, what kind of VEOZAH profile is being highly evaluated in your view?

Zieler [A]*: It's above all the efficacy and, of course, also the fact that it's a non-hormonal treatment. Those would be the two aspects that stand out in our market research: the mechanism of action and the effectiveness of the treatment.

Ueda [Q]: Thank you very much. Secondly, regarding IZERVAY, I have a question. Towards FY2025, sales are going to grow substantially according to the image you have shared with us. For the future, what's your view of the speed of market development? It's going to grow in parallel? Or if there's going to be certain acceleration at some point in time? The label update with the 24-month data, are you assuming certain trigger events?

Okamura [A]: Thank you for your question. Of course, it's not going to be linear in our view because 24-months data, from the current data, reflecting that data to change and to update the label, that is going to be a major trigger in our view.

One more thing is as follows. In the actual clinical settings, instead of the clinical studies with a controlled environment, in the real-world usage, doctors will have their impression if this is the product, this could be used in these patients. If that is going to happen or not is going to be a major driving force. In that sense, it's just one month. And the doctors who are using seem to be using a lot.

But the true capability of IZERVAY must be fully understood in the clinical settings so that it can be used in patients. That would facilitate the growth in an accelerated fashion.

Ueda [M]: Thank you understood. That's all for me.

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

Sakai [Q]: UBS, Sakai is my name. For VEOZAH and IZERVAY, there are a lot of detailed questions already asked, and I believe that the questions are exhausted. But this question might be a bigger-picture perspective one. Like OAB, BPH, such a disease, what you said as the new target and new areas, you made a success in the past. VMS and dry AMD, roughly speaking, these are also very new treatment area. Okamura-san is repeatedly saying you are still in the early staged phase, and I think that is right.

The developing a new field, of course, you have already accumulated your experience so far getting into such a new field. What do you see the current situation? This current hurdle you are facing is what you've expected from the beginning? Or you have to change your way to look at it, your attitude toward this drastically? Do you have any qualitative information? Do you have any particular answer for this question?

And if that is the case, then the way of issuing the guidance is going to be quite important, JPY200 billion to JPY400 billion, I want to be closer as much as possible, there'll be the request for that as well. I believe it doesn't have to be per quarter, but at certain timing, I would like you to work on that as well. That's a request.

The second question is quite similar to the first question, so let me ask continuously. Would the IZERVAY get the dose once in two months and how that data is handled or treated? I don't understand that quite well. It's the design of study itself is not really to proves or shows the superiority. In the meeting in November, you are going to explain about that further, but as of this moment, is it possible for you to make some specific comments?

Okamura [A]: Thank you very much. Before answering your question, I would like to confirm your intention of the first question, Sakai-san. We've tried. Astellas tried something new conventionally. And based upon that, we have VEOZAH and IZERVAY currently. And the peak sales, even for PADCEV peak sales, those are information provided based upon our past experience.

Sakai [Q]: Yes, that is right. You've tried new challenges, challenged new disease or new treatment area. In the urology, ophthalmology, now you get into new field again. And there, have you used your experience, know-how established so far to come up with the prediction? For example, DTC in a Super Bowl but the reaction is not as expected. You see that in that way, for us it was surprising. But those unexpected thing sometimes happens. I believe you are saying that it's because you are still in a very early phase. I just wonder what's your perspective toward the future? That's my intention of the question.

Okamura [M]: Claus would like to answer something, so Claus will make a comment first.

Zieler [A]*: Yes. I just wanted to respond to your use of DTC in the Super Bowl campaign. That is not DTC. That is disease awareness. Disease awareness is without the name of the drug. DTC is with the name of the drug. The coverage that we got before we got approval had a very different character from the DTC campaign that we launched on the 9 of October. The DTC campaign on the 9 of October says VEOZAH and please consult your doctor, whereas before, we were informing the public on what is VMS, and we did not say there's a new

drug in our Super Bowl commercial. That came later through the media in May when we got the approval from the FDA. Then the media spontaneously, without us doing anything said, "Oh, there's a new treatment." And that fact led us to believe that because they were saying, "Oh, there's a new treatment", we thought women would start consulting with the doctor. But now we see that it really takes a targeted DTC campaign, a TV commercial, the way we have started on 9 of October, which says the brand name, which explains the context, and asks women who are interested to consult their physician. That's a much more targeted approach than before.

You have to divide these two phases from the disease state awareness phase before and the targeted DTC branded campaigning that we're doing now.

Sakai [M]*: Okay. Well understood. Thank you.

Okamura [A]: And coming back to me, of course, what we have done by now, capabilities we can use under the current circumstances, and we have the knowledge and skills. We are using all of what we can use right now.

On the other hand, what we are seeing right now, regarding the growth of new products, Tamsulosin for BPH, and OAB like Vesicare and Mirabegron, compared to them, some look different. If we depend too much on what we did before, we shouldn't make a mistake. We are trying to be careful. We are using whatever we can. But at the same time, we try not to depend too much on what we have done before. Because it's too early. I don't want to say that too much. But in reality, it's just one month after the launch or three months after launch. And we are getting asked what is going to happen in 10 years' time, right? We cannot say. I think it's irresponsible to say what is going to happen definitively. You have to accept this kind of a range, otherwise, it will become difficult for us to talk to you, in my view.

On our end, we try to be transparent as much as possible. And we should not say what comes to our mind instantly. We need to be consistent. If we see something a year ago, normal update for the subsequent year, we try to be careful in this regard. Having something in our hands without disclosing or based on our intention, which is not right to manipulate the information, please don't think so. We are very serious minded. We are thinking that we are responding to questions with sincerity. We are disclosing whatever can be disclosed to you. Thank you for understanding.

Sakai [Q]: I don't think you are hiding anything. Of course, as Okamura-san said, I totally agree with a good understanding of your company situation. Thank you very much.

What about the GATHER 2 question, by the way?

Okamura [M]: Taniguchi is going to respond.

Taniguchi [A]: Regarding the GATHER2 data, as has been mentioned from before, this week, at the end of this week, it’s going to be a presentation at AAO. I'd like you to look at the data at the time. And then at an explanatory meeting, we're going to explain further details to you. As of now, what we can say about is that 24-months data, regarding the design, first, monthly dosing for 12 months, and then reallocated to monthly dosing or once every 2 months dosing. Then, followed the subject up to 24 months.

And we have the results regarding the efficacy: the primary endpoint, we achieved the suppression of GA secondary to AMD. And with 24-month data, there is consistency in safety with what we have seen with 12-months dosing.

Regarding the other details, I'd like to refrain from further comments.

Sakai [Q]: So you have confirmed those two points?

Taniguchi [A]: As a data, of course, we've corrected such data.

Sakai [M]: Understand. Thank you very much.

Taniguchi [M]: Thank you.

Ikeda [M]: Next, Mizuho Securities, Tsuzuki-san, please.

Tsuzuki [Q]: Tsuzuki from Mizuho Securities. IZERVAY and PADCEV, I have one question each. Just like asked by Sakai-san, IZERVAY, that is once in two months dosing. That is the regimen in the clinical trial as well. In AAO, the data out of that will be published, but, of course, the background of the patient will be different, but say SYFOVRE comparison will be also possible in that data?

Ikeda [A]: Let me answer. The once in two-months data, that is going to be shown together with once-monthly data. But in comparison with SYFOVRE, that is not done within the study. That kind of a head-to-head, the comparison data is not going to be shown.

Tsuzuki [M]: I see.

Ikeda [A]: So that is going to be in direct comparison done by ourselves.

Tsuzuki [Q]: Thank you. And another is about PADCEV. PD-L1 CPS over 10 or less than 10, the result is—efficacy is really good and the peak sales is going to be revised and seems the data itself is really good. And it's difficult to what extent you are going to revise, it's difficult to be answered, but the first line MUC, overall market says that you are expecting, how big would that be? Is it possible for you to mention that size? Is that information available somewhere?

Ikeda[A]: I believe that a slide is on the screen currently.

Tsuzuki [Q]: Is it about the target patient or overall market? Or looking at this, it's say JPY300 billion to JPY400 billion in the first-line mUC, that's a little less than 1/2 of that in your assumption. To what extent it will be? Because originally, this first-line mUC, there are various drugs that are already available. And what's the assumption of the market size? And if you've that kind of data, would you please share that with us?

Ikeda [M]: No, no. It's not this one. Oh here. Here we see our market size, JPY300 billion to JPY400 billion is the total. Out of that, about 1/2 is the first-line mUC.

Tsuzuki [Q]: But the market says including other competitors', other companies' product. This is your own market. Right? Including other products, what would be the overall market size, including other checkpoint inhibitor?

Ikeda[A]: We don't have any market size information disclosed. But the target patient number 76,000, that is overall market size we assume. And also as additional information sales-wise, out of this, about 2/3 will be from the United States. And out of that, 1/2 is cis-ineligible and 1/2 is cis-eligible. Number of the patients and data-based calculation, that might be a bit different, but that is the guidance that we have provided already.

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

Operator [M]: Thank you very much. This is going to be the last question. Sanford C. Bernstein, Sogi-san, please?

Sogi [Q]: Thank you very much. Regarding IZERVAY, I have a question. It's just after the launch and the information from the field and the market research you have conducted so far can be the basis for your answer to my question. How is this drug used in reality? We interviewed a US ophthalmologist and heard that GA occurs in both eyes. If it's just one eye and there's almost no vision in that eye, and regarding the other eye, the symptoms begin for that patient, this drug is going to be used. This is the approach mentioned by the physicians. What's your view on this, regarding this approach? Depending on the doctors, is there going to be any difference? Or if one eye is almost blind, are you going to focus on such patients or no problem at all in one eye, but GA begins in the other eye, is that the timing to start the treatment? I'd like to know more.

Zieler [A]*: As far I am informed, our label covers both unilateral and bilateral use. We are not focusing on any particular patient type.

Sogi [Q]: In the actual clinical settings, no information yet from the physicians in the clinical settings yet?

Zieler [A]*: No, that would be much too early. I'm sorry. That would be much too early to have that specific information. Of course, when we gather that information, we'll be happy to share that with you.

Sogi [Q]: Thank you. And for PADCEV, you are going to do the submission by the end of December. The approval is planned around the end of March. I think that's what's stated within the presentation material, but I think that is very fast. Is this understanding right?

Taniguchi [A]: The PADCEV EV-302 study, as has been explained, we say that it's quite valuable, high value. And also unmet medical needs in this field is extremely high. For us, this is most prioritized product. As early as possible, we would like to receive the approval in the United States and also would like to expand the launch activity in other countries so that we can get approval as well.

FDA discussion is ongoing. And at this timing, we are doing our best so that we can get the approval at the timing that is expected and described here.

Sogi [M]: Thank you very much.

Ikeda [M]: Thank you very much. Some of you are still waiting to ask questions but time is up, so we'd like to close this meeting today. Thank you very much for joining this meeting.

[END]

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