# Astellas Pharma Inc.

Financial Results for the Q3 of FY2022

February 6, 2023

# Event Summary

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| **[Company Name]** | Astellas Pharma Inc. |
| **[Company ID]** | 4503-QCODE |
| **[Event Language]** | JPN |
| **[Event Type]** | Earnings Announcement |
| **[Event Name]** | Financial Results for the Q3 of FY2022 |
| **[Fiscal Period]** | FY2023 Q3 |
| **[Date]** | February 6, 2023 |
| **[Time]** | 15:30 – 16:58<br>(Total: 88 minutes, Presentation: 40 minutes, Q&A: 48 minutes) |
| **[Number of Speakers]** | 7 |

| | |
|---|---|
| Kenji Yasukawa | Representative Director, President and CEO |
| Naoki Okamura | Representative Director, Executive Vice President, Chief Strategy Officer (CStO) |
| Minoru Kikuoka | Chief Financial Officer (CFO) |
| Yukio Matsui | Chief Commercial Officer (CCO) |
| Yoshitsugu Shitaka | Chief Scientific Officer (CScO) |
| Tadaaki Taniguchi | Chief Medical Officer (CMO) |
| Hiromitsu “Hiro” Ikeda | Head of Corporate Advocacy & Relations |

**[Participant Names]**

| | |
|---|---|
| Fumiyoshi Sakai | Credit Suisse Securities |
| Hidemaru Yamaguchi | Citigroup Global Markets |
| Kazuaki Hashiguchi | Daiwa Securities |
| Motoya Kohtani | Nomura Securities |
| Shinichiro Muraoka | Morgan Stanley MUFG Securities |
| Naomi Kumagai | Mitsubishi UFJ Morgan Stanley Securities |
| Akinori Ueda | Goldman Sachs |
| Seiji Wakao | JPMorgan Securities |

## Presentation

**Ikeda:** Everyone, thank you very much for your participation of this announcement of the financial results in the FY2022 Q3.

I'm Ikeda from Corporate Advocacy and Relations, serving as the moderator for today.

Before starting the financial results announcement, we would like to explain the Astellas Pharma Inc.'s announcement of a change of our President and CEO, announced at 11:30 AM, and Yasukawa is going to make the opening remarks, first of all. That is followed by the explanation by the appointed President as of April 1, Okamura.

**Yasukawa:** Hello, I am Yasukawa. I would like to thank you for joining the Board of Directors' meeting here. Today, we decided to appoint Mr. Naoki Okamura, our CEO effective April 1.

I would like to start by saying thank you for your kind attention. I'd like to begin by explaining the background behind this change in CEO.

Astellas has been working on its Corporate Strategic Plan 2018 and the Corporate Strategic Plan 2021 since FY2018, when myself was appointed as President and CEO, to realize its vision on the forefront of health care change to turn innovative sense into value for patients.

During this time, Astellas overcame the pertinent cliff associated with the expiration of products' exclusivity that has supported its growth in the past and revenue has turned upward trend after bottoming out in FY2020.

In addition, Astellas moved away from its past business model of creating products with a focus on specific disease areas and promoted a shift to the focus area approach of determining R&D areas from a modified perspective. It's also making progress in developing a new drug candidates that will drive future revenues.

FY2023 is the right time to go on the aggressive to further accelerate growth, and Naoki Okamura will take over as a new President and CEO. Astellas decided it is best for it to consider and implement strategies for achieving CSP 2021, which ends in FY2025, and long-term growth beyond that under the new leadership. The environment surrounding the Company is changing rapidly, such as increasing geopolitical risks and the changes in the finances and the markets of each country due to the COVID-19 crisis, but a new top management has the ability to be flexible in response to such changes.

Since joining the Company in 1986, Mr. Okamura has served as the Head of Business Development and Corporate Planning. In 2018, he became Chief Strategy Officer, and from FY2019, he participated in management as Representative Director and Vice President, overseeing a wide range of business units and driving the business forward. In addition, he provides a leadership in setting direction for organizational goals in promoting the reorganization of R&D.

In a highly uncertain business environment, he's not bound by stereotypes or preconceived notions, but he's also able to make decisions with a bird's eye view of the entire Astellas organization free from stereotypes. He places great importance on direct dialogue with employees, always speaking to them in his own words ,and sincerely listening to their voices. He's both logical and passionate, strict and warm, serious and humorous, and has earned the trust of many people within the Company.

I will assume the position of Representative Director and the Chairman of the Board. I will fulfil the roles not for management execution but for management decision-making and supervision of business execution, to

ensure that Astellas moves in the right direction to meet the expectations and demands of its stakeholders. I will also focus on advocacy activities to let the public know what value the pharmaceutical industry brings and how it contributes to society. We look forward to your continued support.

Thank you very much.

**Ikeda:** Yasukawa-san, thank you very much. Next, Okamura-san, please.

**Okamura:** As of April 1, I'm going to serve as the Representative Director, President, and CEO. I am Okamura.

In 2016, I was appointed as the Head of Corporate Planning. For seven years since, I am proud that I was at the center of Strategic Development and its implementation at Astellas. Being able to assume my responsibility in this way is a great honor for me. We are now at a turning point in a year for CSP 2021. But, in a bigger framework, there is no change in the priorities raised as strategic organizational health and performance goals.

I'm going to continue the management policy and the direction of the business in principle. If you look at each individual goal, the business environment and the progress of the project are changing every day. I maintain principles and reorganize priorities flexibly so that we can allocate limited management resources appropriately.

I'd like to solidify the sustainable growth after LOE of XTANDI, and my mission is to hand over to the next leader by doing so.

As is shown in Vision and CSP 2021, Astellas is aiming to be cutting-edge, value-driven, life science innovator, so creating innovations continuously is our lifeline. We should learn from mistakes and failures, take wise risks, so that each one of the employees can demonstrate leadership. There's a need to further foster corporate culture, aiming for a higher level as well in Astellas, and we would raise ambitious goals to do our best to achieve the goals, but we'd like to be an outcome generation companies.

Astellas is working on the regeneration of medicines to improve the root cause of the diseases substantially, like cell therapy and gene therapy. Going into the unknown areas entails business risks, but we give priority to the safety of the patients with a sense of urgency that patients are waiting. We'd like to steer the Company with a sense of speed, so we appreciate your continued support and guidance for the future. Thank you very much.

**Ikeda:** From here, we would like to start FY2022 Q3 financial results announcement.

For this announcement, Zoom webinar and live streaming are available, but the questions are accepted only through webinar, not from live streaming. Today, including Q&A, Japanese and English simultaneous translations are available. For those participating from Zoom webinar, from the screen of Zoom, please select your favored language. When it comes to simultaneous interpretation, we, as a Company, do not guarantee the accuracy of that.

The participants for today, on top of Yasukawa and Okamura, we have Minoru Kikuoka, CFO; Yukio Matsui, CCO; Yoshitsugu Shitaka, CScO; and Tadaaki Taniguchi, CMO. We have four.

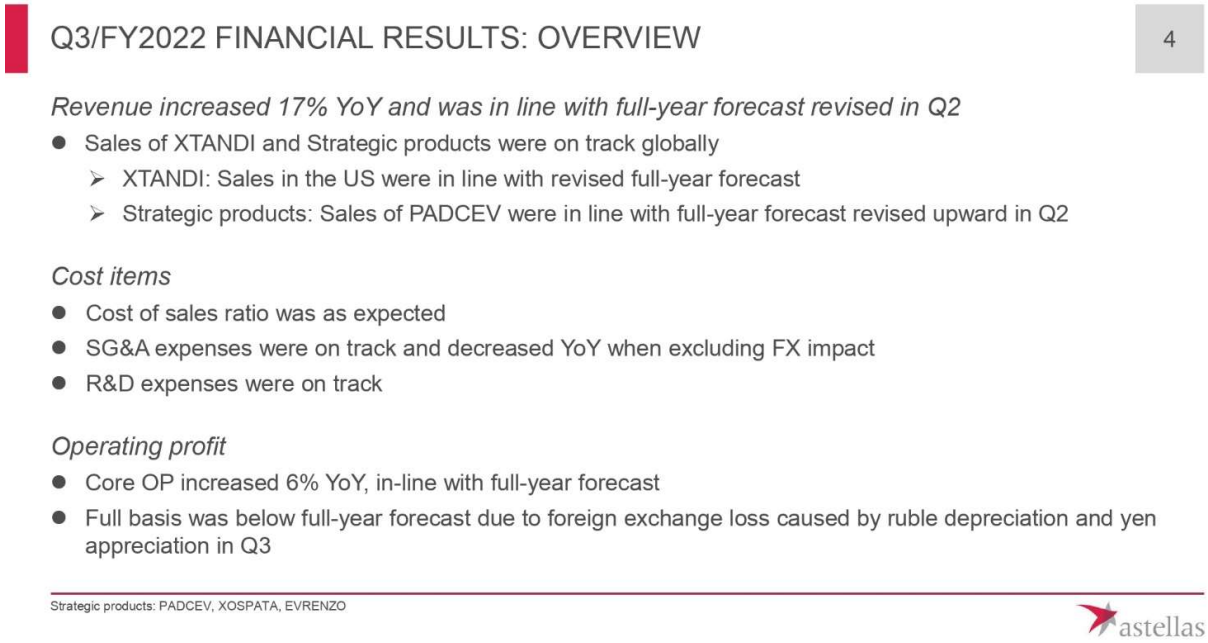
In addition, the presentation material is available on the website, so please refer to it. The material or presentation by representatives for the Company, and answers and statements by them in the Q&A session include forward-looking statements based on the assumption of their beliefs in light of the information currently available to management, subject to significant risks and uncertainties. Actual financial results may differ materially, depending on a number of factors. They contain information on pharmaceuticals, including

compounds under development, but this information is not intended to make any representation, advertisement, or medical advice.

Now, please start Kikuoka-san.

**Kikuoka:** Hello, everyone. I'm Minoru Kikuoka, our CFO at Astellas Pharma Inc. Thank you very much for joining our FY2022 Q3 financial results announcement meeting out of your very busy schedule today.


This is the agenda for today. I will cover these topics in this order from the next page.



Page four is an overview of FY2022 Q3 financial results.

Revenue and profit increased in Q3. Revenue increased 17% YoY and was in line with our full year forecast revised upward in Q2. Sales of XTANDI and strategic products were on track globally. Sales of XTANDI in the United States were in line with our full year forecast, which was revised downward in Q2. Sales in Japan and Europe also progressed in line with our full year forecast. Sales of PADCEV were in line with our full year forecast, which was revised upward in Q2.

I will explain the details of each product on page six and page seven.

Next, on cost items.

Cost of sales ratio was as expected. SG&A expenses were on track and decreased YoY when Forex impact was excluded. R&D expenses were on track. As a result, core operating profit increased by 6% YoY, in line with our full year forecast. Full basis operating profit was below our full year forecast due to the booking, as other expenses of foreign exchange loss were caused mainly by the roble depreciation against the euro and the yen's rapid depreciation against the US dollar from the JPY150 level to the JPY120 level in just two months in Q3.

## Q3/FY2022 FINANCIAL RESULTS

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| (billion yen) | Q3/FY21 | Q3/FY22 | Change | Change (%) | FY22 FCST* | Progress | FX impact |
|---|---|---|---|---|---|---|---|
| **Revenue** | **992.3** | **1,164.4** | **+172.1** | **+17.3%** | **1,529.0** | **76.2%** | +135.2 bil. yen |
| Cost of sales | 194.1 | 226.1 | +32.0 | +16.5% | | | +13.3 bil. yen (Incl. the impact of elimination of unrealized profit remaining in Q3/FY21: +3.3 bil.yen) |
| % of revenue | 19.6% | 19.4% | -0.1 ppt | | | | |
| SG&A expenses | 406.4 | 471.0 | +64.6 | +15.9% | 642.0 | 73.4% | +64.1 bil. yen |
| US XTANDI co-pro fee | 108.7 | 138.2 | +29.5 | +27.2% | 186.0 | 74.3% | |
| SG&A excl. the above | 297.7 | 332.7 | +35.0 | +11.8% | 456.0 | 73.0% | +38.4 bil. yen |
| R&D expenses | 177.6 | 206.1 | +28.4 | +16.0% | 278.0 | 74.1% | +23.0 bil. yen |
| Amortisation of intangible assets | 20.2 | 29.2 | +8.9 | +44.1% | | | |
| Gain on divestiture of intangible assets | 24.1 | 0.2 | -23.9 | -99.1% | | | |
| **Core operating profit** | **220.0** | **233.7** | **+13.6** | **+6.2%** | **290.0** | **80.6%** | +34.8 bil. yen |
| <Full basis> | | | | | | | **Ref. Other expenses** |
| Other income | 4.2 | 2.5 | -1.7 | -40.2% | | | Impairment losses on intangible assets (AT702, AT751, AT753):23.2 bil. yen |
| Other expenses | 54.9 | 54.9 | +0.0 | +0.0% | | | fezolinetant increased fair value of contingent consideration:13.4 bil. yen |
| **Operating profit** | **169.4** | **181.3** | **+11.9** | **+7.0%** | **269.0** | **67.4%** | Net foreign exchange losses:6.7 bil. yen (Net foreign exchange gains as of Q2 : 13.9 bil. yen) |
| Profit before tax | 167.4 | 180.2 | +12.8 | +7.7% | 267.0 | 67.5% | |
| **Profit** | **132.5** | **144.8** | **+12.3** | **+9.3%** | **208.0** | **69.6%** | Xyphos increased fair value of contingent consideration:4.0 bil. yen |

*Announced in Oct 2022

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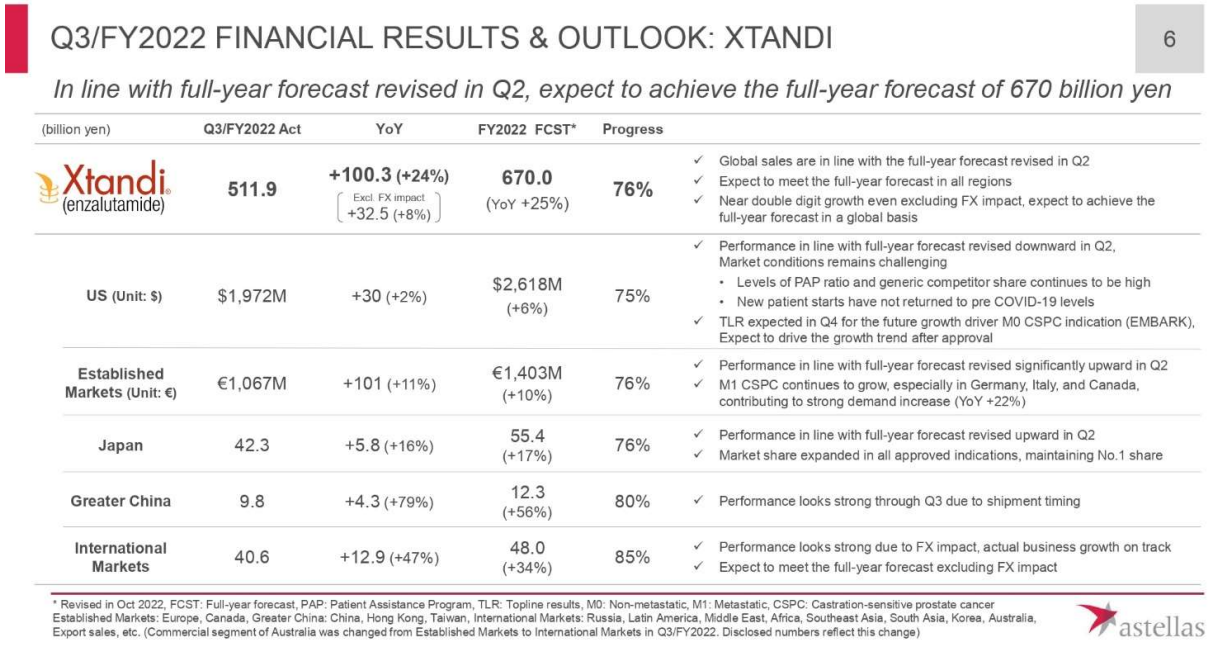
On page five, I will explain FY2022 Q3 financial results.

Revenue increased to JPY1,164.4 billion, up 17.3% YoY. The progress against the full year forecast was 76.2%. Core operating profit was JPY233.7 billion, up by 6.2% YoY. The progress was 80.6% of our full year forecast. You can see the Forex impact on the right-hand side of the table. Revenue increased even when Forex impact was excluded. On the other hand, core operating profit decreased when excluding the Forex impact. This is partly due to the booking of JPY24.1 billion gain on divestiture of intangible assets in Q3 of FY2021.

The bottom half of this page shows a full basis results. In the right bottom of the table, we included other expenses booked so far. In Q1, we booked impairment losses on intangible assets in the gene therapy programs and increased fair value of contingent consideration related to fezolinetant. Also, due to the booking

of net foreign exchange losses of JPY6.7 billion in Q3, net foreign exchange gains and losses worsened by JPY20.6 billion compared to Q2.

As for a positive event, Xyphos' fair value of contingent consideration increased by JPY4 billion as we reviewed the development plan for the Xyphos-derived initial stage program. As a result, operating profit was JPY181.3 billion, up by 7% YoY, progressing at 67.4% of our full year forecast. Profit increased to JPY144.8 billion, up 9.3% YoY. The progress was 69.6% of our full year forecast.



Q3/FY2022 FINANCIAL RESULTS & OUTLOOK: XTANDI

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*In line with full-year forecast revised in Q2, expect to achieve the full-year forecast of 670 billion yen*

| (billion yen) | Q3/FY2022 Act | YoY | FY2022 FCST* | Progress | |
|---|---|---|---|---|---|
| Xtandi (enzalutamide) | 511.9 | +100.3 (+24%) Excl. FX impact +32.5 (+8%) | 670.0 (YoY +25%) | 76% | ✓ Global sales are in line with the full-year forecast revised in Q2<br>✓ Expect to meet the full-year forecast in all regions<br>✓ Near double digit growth even excluding FX impact, expect to achieve the full-year forecast in a global basis |
| US (Unit: $) | $1,972M | +30 (+2%) | $2,618M (+6%) | 75% | ✓ Performance in line with full-year forecast revised downward in Q2, Market conditions remains challenging<br>• Levels of PAP ratio and generic competitor share continues to be high<br>• New patient starts have not returned to pre COVID-19 levels<br>✓ TLR expected in Q4 for the future growth driver M0 CSPC indication (EMBARK), Expect to drive the growth trend after approval |
| Established Markets (Unit: €) | €1,067M | +101 (+11%) | €1,403M (+10%) | 76% | ✓ Performance in line with full-year forecast revised significantly upward in Q2<br>✓ M1 CSPC continues to grow, especially in Germany, Italy, and Canada, contributing to strong demand increase (YoY +22%) |
| Japan | 42.3 | +5.8 (+16%) | 55.4 (+17%) | 76% | ✓ Performance in line with full-year forecast revised upward in Q2<br>✓ Market share expanded in all approved indications, maintaining No.1 share |
| Greater China | 9.8 | +4.3 (+79%) | 12.3 (+56%) | 80% | ✓ Performance looks strong through Q3 due to shipment timing |
| International Markets | 40.6 | +12.9 (+47%) | 48.0 (+34%) | 85% | ✓ Performance looks strong due to FX impact, actual business growth on track<br>✓ Expect to meet the full-year forecast excluding FX impact |

* Revised in Oct 2022, FCST: Full-year forecast, PAP: Patient Assistance Program, TLR: Topline results, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer
Established Markets: Europe, Canada, Greater China: China, Hong Kong, Taiwan, International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc. (Commercial segment of Australia was changed from Established Markets to International Markets in Q3/FY2022. Disclosed numbers reflect this change)

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On page six, let me explain the Q3 results and the future outlook of XTANDI.

First, global sales reached JPY511.9 billion in Q3, up by 24% YoY and up by 8%, when Forex impact was excluded. Global sales are in line with the full year forecast revised in Q2. Regarding the future outlook, XTANDI is expected to meet our full year forecast in all regions. Globally, as a whole, we're expecting near double-digit growth. Even excluding Forex impact, XTANDI is expected to achieve fixed sales of JPY670 billion in our full year forecast.

Next, let me explain the current situation and the future outlook for each region.

In the United States, Q3 sales reached USD1,972 million, growing by 2% YoY. This 2% is the growth rate on a local currency basis. Performance is in line with our full year forecast, revised downward in Q2. Market conditions remain challenging as we included this factor in our forecast.

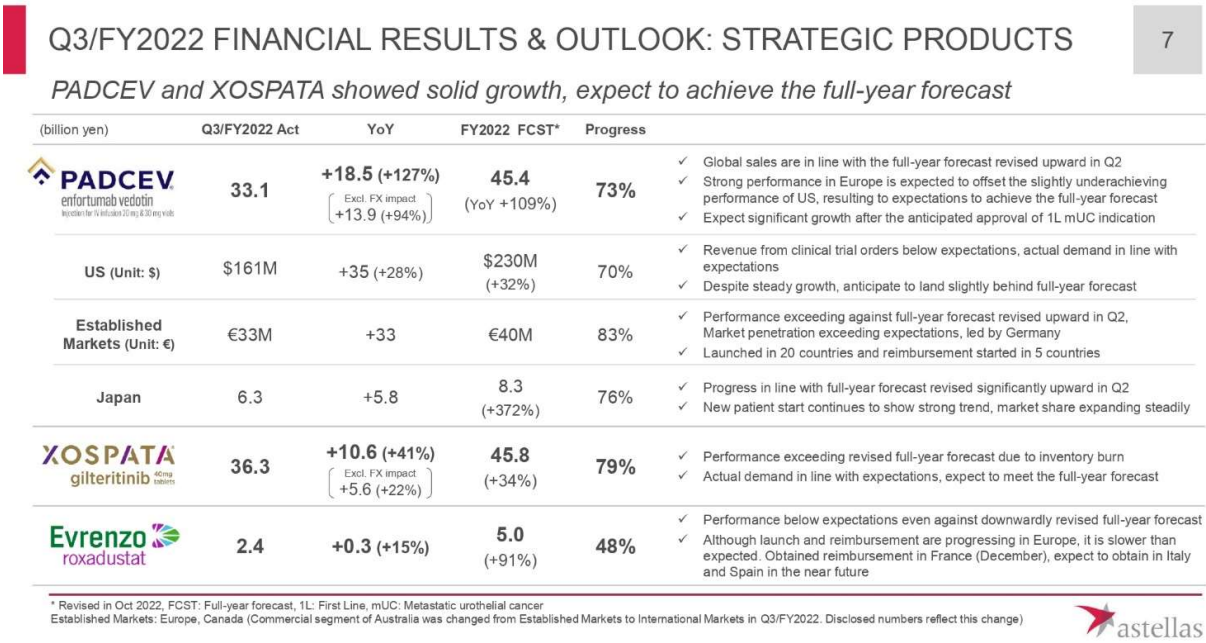
Levels of patient assistance program, PAP ratio and share of Zytiga generic competitors continue to be high. New patient starts have not returned to pre COVID-19 levels. On the other hand, we don't see any worsening of the situation compared to assumptions reviewed in Q2. We are expecting the achievement of full year forecast of over USD2,600 million. Top line results are expected in Q4 for the future growth driver, M0 CSPC indication from the EMBARK study, with which we are aiming to obtain the additional indication. This is expected to drive the growth trend after approval.

Next, in established markets.

Performance is in line with our full year forecast revised significantly upward in Q2, contributing the most to global sales increase. In terms of the volume, M1 CSPC continues to grow, especially in Germany, Italy, and Canada, contributing to strong demand increase by 22% YoY. As of now, we don't see any clear impact of Zytiga generic competitors. We are expecting the achievement of our full year forecast.

By the way, commercial segment of Australia was changed from established markets to international markets in Q3. Disclosed numbers already reflect this change and actual results of the same period in the previous fiscal year and forecast figures are slightly changed. Also in Japan, performance is in line with the full year forecast revised upward in Q2. Market share expanded in all approved indications, maintaining number one share. In Greater China, performance looks strong, but this is due to shipment timing. When this factor is excluded, performance is almost in line with our full year forecast.

In international markets, performance looks strong due to big Forex impact, particularly from the ruble, but in line with our full year forecast, excluding this factor, there are some regional differences. Globally as a whole, we continue to expect growth in the next fiscal year as well.



## Q3/FY2022 FINANCIAL RESULTS & OUTLOOK: STRATEGIC PRODUCTS

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*PADCEV and XOSPATA showed solid growth, expect to achieve the full-year forecast*

| (billion yen) | Q3/FY2022 Act | YoY | FY2022 FCST* | Progress | |
|---|---|---|---|---|---|
| PADCEV enfortumab vedotin | 33.1 | +18.5 (+127%) Excl. FX impact +13.9 (+94%) | 45.4 (YoY +109%) | 73% | ✓ Global sales are in line with the full-year forecast revised upward in Q2<br>✓ Strong performance in Europe is expected to offset the slightly underachieving performance of US, resulting to expectations to achieve the full-year forecast<br>✓ Expect significant growth after the anticipated approval of 1L mUC indication |
| US (Unit: $) | $161M | +35 (+28%) | $230M (+32%) | 70% | ✓ Revenue from clinical trial orders below expectations, actual demand in line with expectations<br>✓ Despite steady growth, anticipate to land slightly behind full-year forecast |
| Established Markets (Unit: €) | €33M | +33 | €40M | 83% | ✓ Performance exceeding against full-year forecast revised upward in Q2, Market penetration exceeding expectations, led by Germany<br>✓ Launched in 20 countries and reimbursement started in 5 countries |
| Japan | 6.3 | +5.8 | 8.3 (+372%) | 76% | ✓ Progress in line with full-year forecast revised significantly upward in Q2<br>✓ New patient start continues to show strong trend, market share expanding steadily |
| XOSPATA gilteritinib | 36.3 | +10.6 (+41%) Excl. FX impact +5.6 (+22%) | 45.8 (+34%) | 79% | ✓ Performance exceeding revised full-year forecast due to inventory burn<br>✓ Actual demand in line with expectations, expect to meet the full-year forecast |
| Evrenzo roxadustat | 2.4 | +0.3 (+15%) | 5.0 (+91%) | 48% | ✓ Performance below expectations even against downwardly revised full-year forecast<br>✓ Although launch and reimbursement are progressing in Europe, it is slower than expected. Obtained reimbursement in France (December), expect to obtain in Italy and Spain in the near future |

* Revised in Oct 2022, FCST: Full-year forecast, 1L: First Line, mUC: Metastatic urothelial cancer
Established Markets: Europe, Canada (Commercial segment of Australia was changed from Established Markets to International Markets in Q3/FY2022. Disclosed numbers reflect this change)

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On page seven, let me explain our strategic products.

First about PADCEV.

Global sales were JPY33.1 billion, in line with our full year forecast revised upward in Q2. Strong performance in Europe is expected to offset a slightly underachieving performance of the United States, resulting in expectations to achieve before year forecast. In the United States, the actual business is progressing in line with our assumptions, and PADCEV is growing steadily.

On the other hand, revenue from clinical trial orders was below our expectations. Taking this impact into consideration, we anticipate landing slightly behind our full year forecast. We have already acquired a high market share in the current indication. We're expecting significant sales growth after the approval of the additional indication in the first-line treatment. We hope this will be a growth driver in the next fiscal year and beyond.

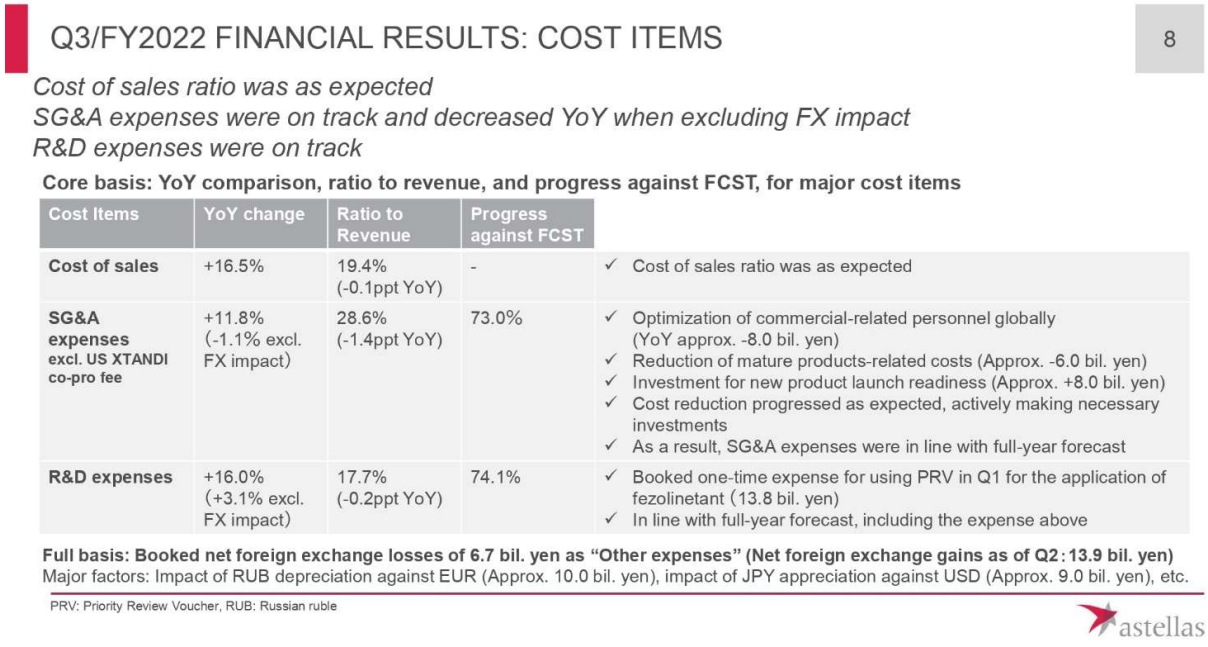
In established markets led by Germany, market penetration is exceeding our expectations. Performance is also exceeding our full year forecast revised upward in Q2. Furthermore, PADCEV was launched in four more countries compared to Q2 in a total of 20 countries. Reimbursement started in 5 countries. We are expecting an upside from our full year forecast and further growth into the future.

In Japan, progress is in line with our full year forecast to revise significantly upward in Q2. New patient starts continues to show strong trend and market share is expanding steadily. We're expecting landing in line with the full year forecast.

In international markets, PADCEV was launched in Singapore in July and in UAE in December last year. We are expecting PADCEV to be launched in more countries in the future, hoping it will contribute to sales. Once again, the key to further growth globally in the future will be the expansion of the current indications and the additional first-line indication. Starting with the approval anticipated in the United States in the next fiscal year, we are hoping for significant sales growth.

With regards to XOSPATA, sales are increasing in all regions where it's launched. The actual business is growing steadily. Performance looks strong, but this is mainly due to high inventory level in the United States. Assuming the leveling of the inventory level in Q4, XOSPATA is expected to meet our full year forecast.

As for Evrenzo, performance is below expectations even against the downwardly revised full year forecast. Although launch and reimbursement are progressing in Europe, it is lower than expected. Reimbursement was obtained in France in December. We are expecting reimbursement also in Italy and Spain. In the near future, we are hoping for sales contribution.




On page eight, I will explain cost items.

Cost of sales increased by 16.5% YoY, along with revenue increase. COGS ratio was down by 0.1 percentage point YoY to reach 19.4%, in line with our expectations. SG&A costs, excluding XTANDI US co-promotion fees, increased by 11.8% YoY. When Forex impact was excluded, SG&A expenses decreased by 1.1% or JPY3.4 billion YoY. The ratio to revenue decreased by 1.4 percentage points YoY to 28.6%.

The progress against our full year forecast was 73% under full control, in line with our full year forecast. Personnel costs fell by about JPY8 billion YoY with global optimization of commercial-related personnel. We are trying to reduce sales promotion costs related to mature products such as mirabegron, which decreased the cost by about JPY6 billion YoY.

On the other hand, we are making active investments for new product launch readiness for PADCEV and fezolinetant. Sales promotion expenses rose by about JPY8 billion YoY. We will continue to allocate our resources to strategic products with higher priorities. R&D expenditure increased by 16% YoY, but by 3.1% when Forex impact was excluded.

The main reason for this is the booking of onetime expense of JPY13.8 billion for using the priority review voucher, PRV, in Q1 for the application of fezolinetant. Excluding this cost, R&D expenditure decreased YoY. Ratio to revenue was 17.7%, down by 0.2 percentage YoY. The progress against the full year forecast was 74.1% in line with our full year forecast, including the use of PRV for fezolinetant.

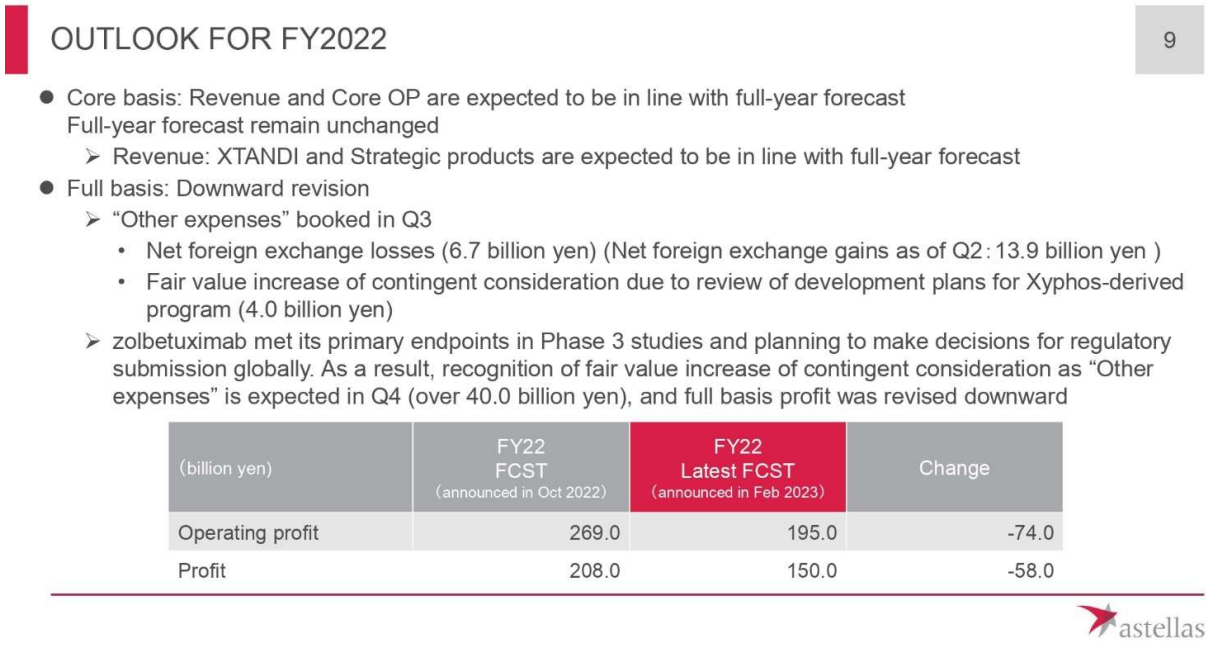
On a full basis, we booked net foreign exchange losses of JPY6.7 billion of other expenses. Net foreign exchange gains were JPY13.9 billion as of Q2, but we booked net foreign exchange losses of expenses, mainly due to the impact of the depreciation of the ruble against the euro for about JPY10 billion and the impact of the yen's depreciation against the US dollar for about JPY9 billion. The net foreign exchange gains and losses worsened by JPY20.6 billion from the Q2.

Unlike the Forex impact to occur from a special factor elimination of unrealized profit, excluding the impact from Q2, we can say this is the most difficult Forex impact to occur due to adjustment based on the year-end rate for claims and debt denominated in foreign currency, which are currently nonoperating items, according to the Japanese accounting standards.

This time, a relatively big impact occurred not only for the yen against the US dollar, but also for the ruble, because of an impact not only from the sales amount in ruble, but also from the relatively long payment period for receivables denominated in ruble and the special circumstances these days.

When the Forex doesn't move much, there is almost no impact on gains and losses. But when it fluctuates a lot, there was a big depreciation of the ruble in December, then there can be a huge impact to occur like this time. For the future, we would like to consider countermeasures more than before to appropriately manage the impact of Forex fluctuations.

However, regarding the ruble, which caused a huge impact in Q3, I don't go into the details, but there are seasonal factors and special factors as well. Also, in Q4, claims denominated in rubles are expected to remain high in value. We will work to shrink the exposure for the future as much as possible, as Forex hedge costs are high for these currencies.




I would like to explain the outlook for FY2022 full year on page nine.

First, on a core basis, we expect revenue in Core OP to be in line with our full year forecast. Therefore, full year focus remain unchanged, and our Core OP focus also remain unchanged at JPY290 billion. On the other hand, we have revised downward our full year profit forecast. As explained earlier, we booked a net foreign exchange loss of JPY6.7 billion and a fair value increase of contingent consideration due to a review of development plans for a Xyphos-derived program, which totaled JPY4 billion in other expenses in Q3.

In addition, we has announced in a press release that zolbetuximab met its primary endpoint in Phase III studies. If we make decisions for regulatory submission globally in Q4, we expect to recognize the fair value increase of contingent consideration that is over JPY40 billion as other expenses in our Q4. The same is true for the Xyphos-derived development program, but the increase in the fair value of the contingent consideration reflects positive development progress for the business.

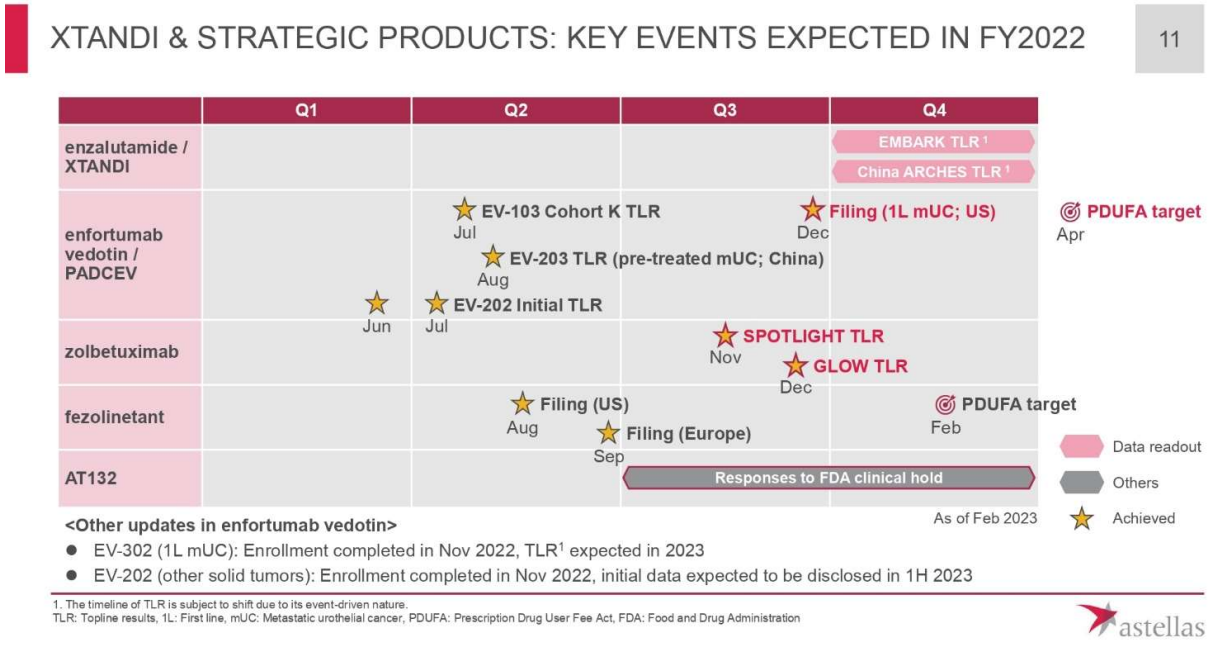
The full basis appropriate has been revised downward, primarily to reflect these events. Operating profit on a full year basis is expected to be JPY195 billion, a decrease of JPY74 billion from the previous forecast of JPY269 billion. Profit is expected to be JPY150 billion, down JPY58 billion from the previous focus of JPY208 billion.

In addition to the forementioned events, which are incorporated in this forecast although not shown on the slide, I would like to explain a few other events that may occur in Q4 and beyond.

First, I would like to discuss the possibility of the booking and impairment loss on intangible assets of Evrenzo. The amount of the impairment loss has now been incorporated in the forecast for FY2022 full year because it is still undetermined and difficult to estimate the specific amount at this time. The Company is currently in the process of obtaining reimbursement for Evrenzo in Europe and plans to reverse its future focus in Q4, taking into consideration the sales in each country. Depending on the outcome of this review, Evrenzo may record an impairment loss on intangible assets.

In addition, other events are currently under scrutiny to optimize the appropriate cost structure, looking ahead to FY2024 and FY2025 in order to achieve this CSP. At this time, we are still in the steady stage and have not incorporated the cost to be incurred through this optimization in our forecast for FY2022, but we may book onetime costs in the future.

Again, we haven't incorporated these factors into our full year focus because they are uncertain at this moment. However, we have shared this information in advance as they may impact the full basis profit level if they are booked. These are expectations of the FY2022 Q3 results and the outlook for the future.



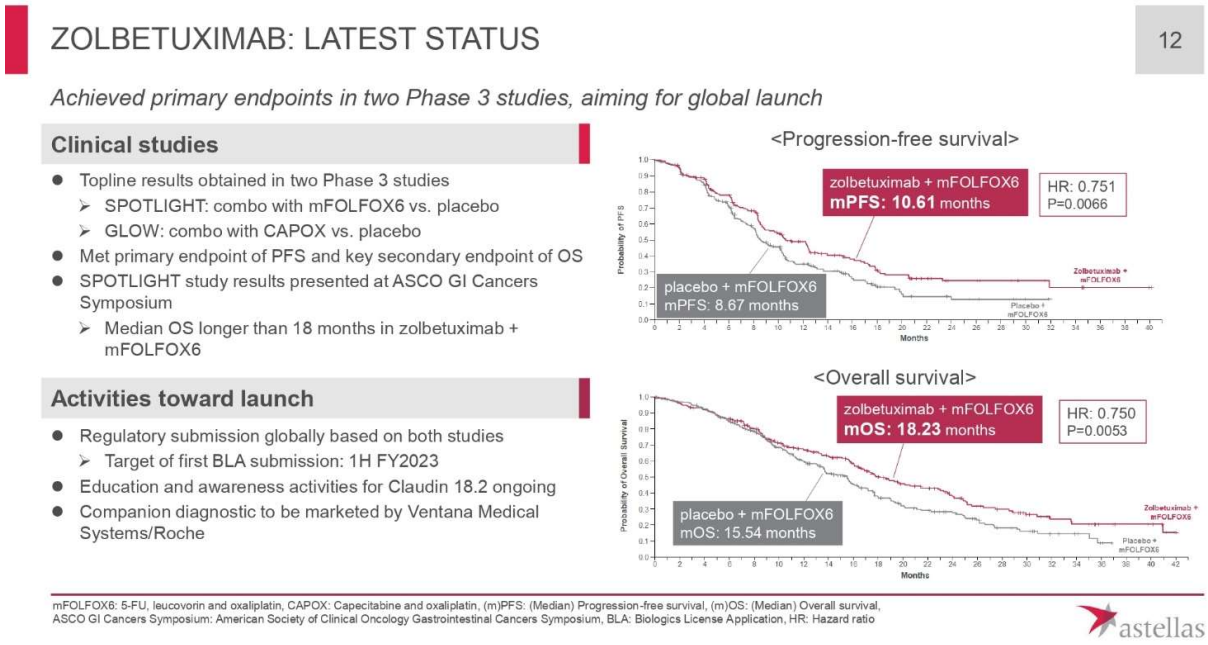

Now, I'd like to explain the initiatives for sustainable growth.

Page 11 is about extending and strategic products. Key events expected in FY2022 will be explained.

In December, the filing to the FDA was completed for PADCEV for additional indication of first line locally advanced or metastatic urothelial cancer who are not eligible for cisplatin. The submission received the priority review designation and a target date of April 21, 2023, for completion of review.

As shown on the bottom of the slide, other updates include the ongoing Phase III EV-302 study for the global submission for the first-line urothelial cancer completed enrollment in November, and top line results are expected in FY2023. In addition, the EV-202 study evaluating the efficacy and safety of zolbetuximab in other solid tumors completed enrollment of all patients in November, and initial data is expected to be disclosed in H1 of 2023.

Next, for zolbetuximab, we received top line results from two Phase III trials in November and December. Details will be explained in the next slide. For AT132, we submitted our initial response to the FDA regarding the clinical hold in Q3 of this year, and we are still in ongoing discussions with the agency. Details to be explained later again.

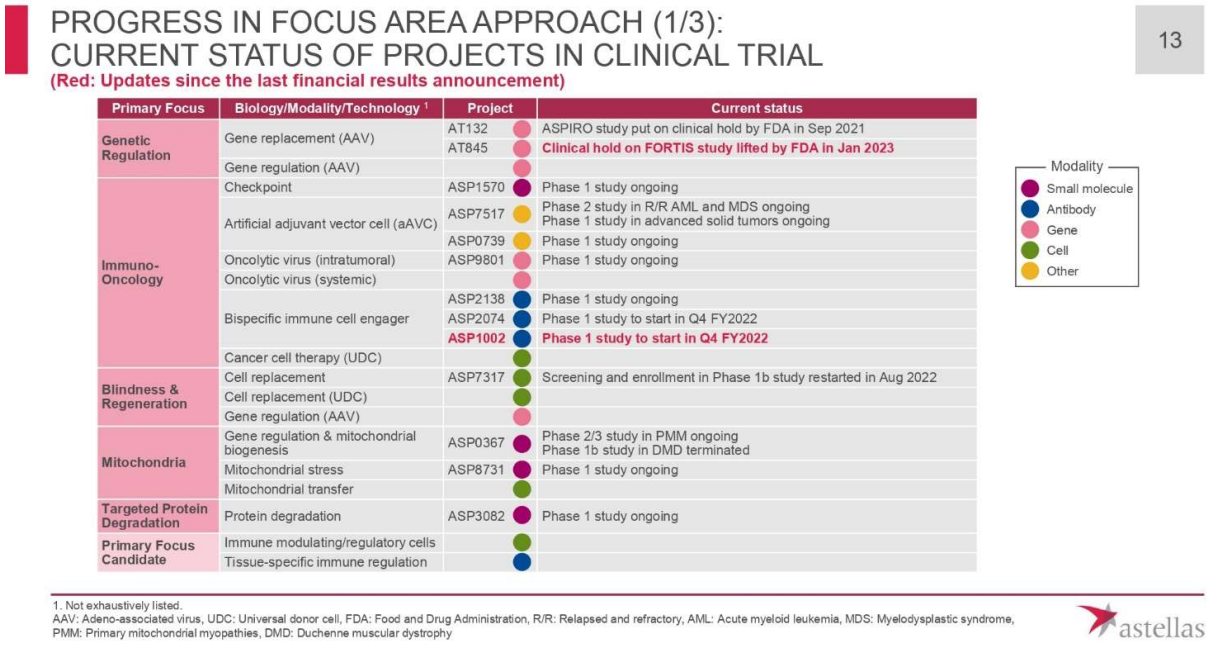



Page 12 is about the latest status of zolbetuximab.

We have top line results from two Phase III studies, SPOTLIGHT and GLOW studies. The SPOTLIGHT study evaluated the efficacy and safety of zolbetuximab in combination with mFOLFOX6, a chemotherapy regimen is primarily in the United States and Europe. GLOW evaluated efficacy and safety of zolbetuximab in combination with CAPOX, a chemotherapy regimen used primarily in Asia.

In both studies, zolbetuximab demonstrated statistically significant improvements versus placebo in both the primary endpoint of PFS and the primary secondary endpoint of OS. As we introduce the details of the SPOTLIGHT study at the recent IR meeting, we presented the results at the ASCO GI meeting in January. As shown in the lower right figure, the combination therapy of zolbetuximab and mFOLFOX6 resulted in long OS over 18 months. This data was highly evaluated and accepted by the ASCO GI.

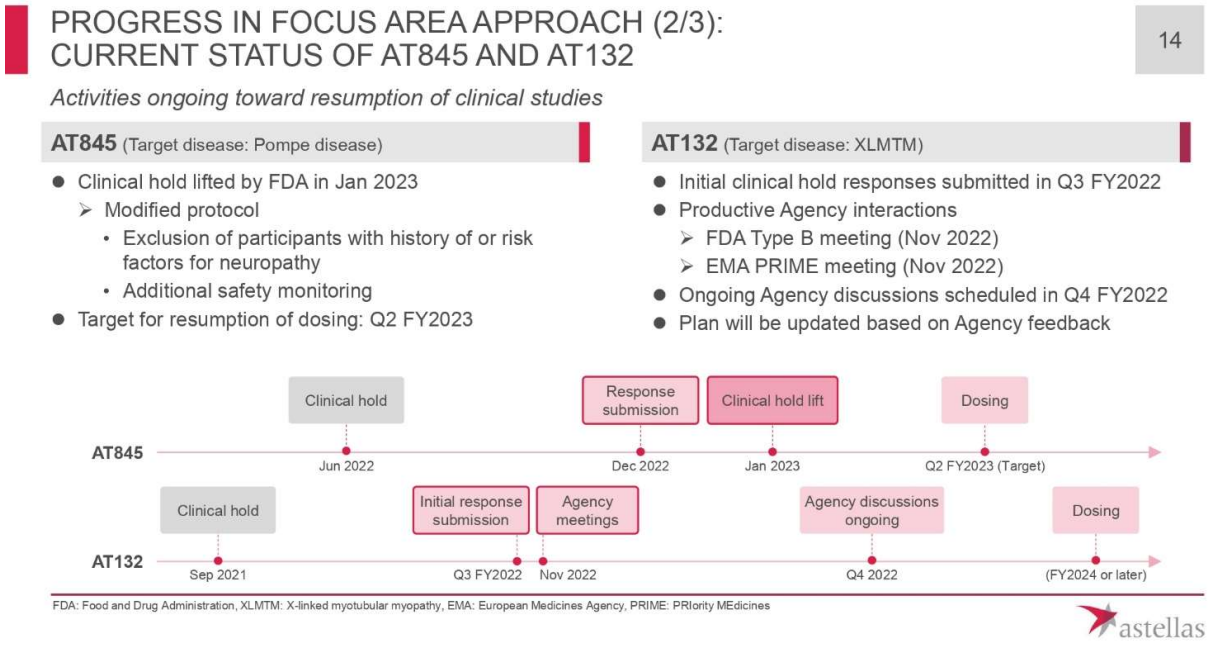
Based on the results of both studies, we are working for a regulatory submission globally and targeting of the first BLA submission in H1 of FY2023. In addition, activities are underway to raise awareness of the importance of Claudin 18.2, the drug's target as a biomarker in preparation for its launch. The companion diagnostics needed for patient screening will be marketed by our partner, Ventana, in conjunction with the timing of marketing of zolbetuximab.




From here, page 13, I would like to talk about focus approach.

As for current status of projects and clinical trials, those that made progress in the past quarter are shown in red. In the genetic regulation, the FDA's clinical hold on AT845 was lifted in January. The details are explained on the next slide. In the area of bispecific immune cell engager in immuno-oncology, ASP1002 has entered the clinical stage and is scheduled to start Phase I trials in Q4.

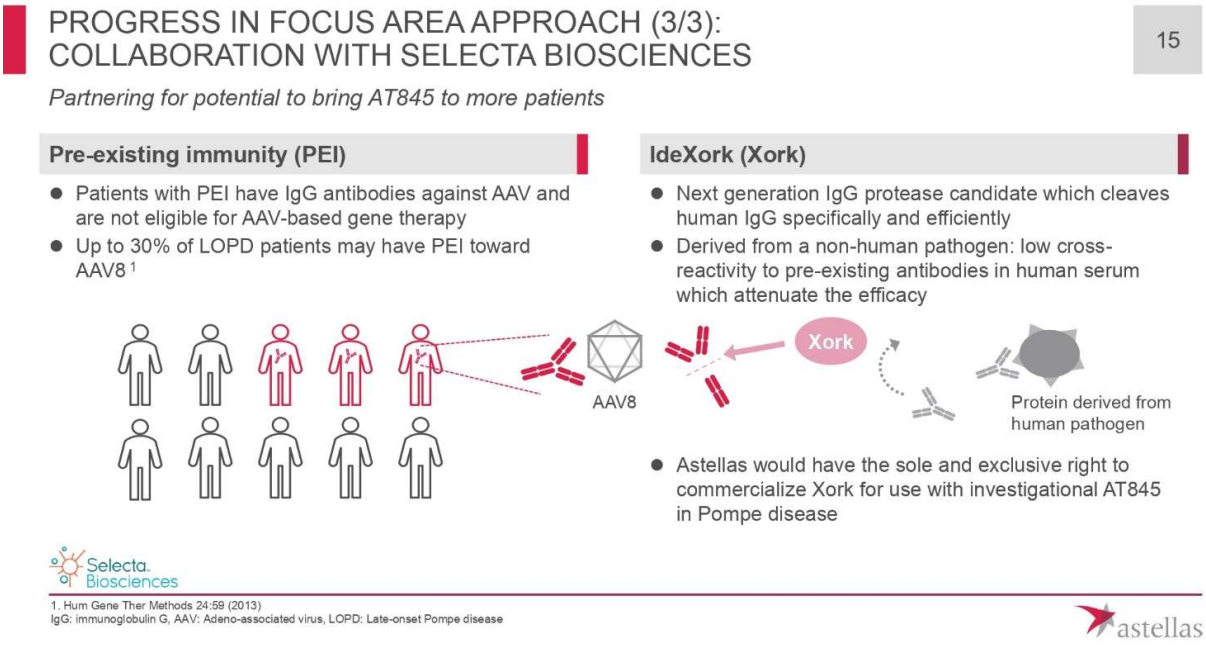
The details of the detected molecule are not disclosed at this time, but we still introduce them at an appropriate time in the future. This is the third project using bispecific antibodies to inter-clinical trials following ASP2138, which is a positioned as a successor to zolbetuximab and ASP2074 in the previous fiscal results announcement. Based on the focus area approach concept, projects have been continuously generated.




On page 14, we describe the progress of the genetic regulation program, AT845 and AT132 towards the resumption of their respective clinical studies.

In AT845, we received a clinical hold from the FDA in June 2022, as has been mentioned already, but we submitted a response in December based on which, the clinical hold was lifted in January. The protocol will be modified to reduce the risk of similar adverse events before resuming clinical trials. One is to exclude participants with the history of all risk factors for neuropathy, and the other is to reinforce the safety monitoring further. We are currently working on the necessary procedures for resumption of dosing with a target resumption date of Q2 of FY2023.

Regarding AT132, its initial response to the clinical hold given by FDA in September 2021 was submitted in Q3 of the current fiscal year. We have had constructive discussions with the United States and the European authorities, and we plan to continue to do discussions with them in Q4. We will update our overall plan based on feedback from the authorities. At this point, we expect to resume dosing in FY2024 or later.

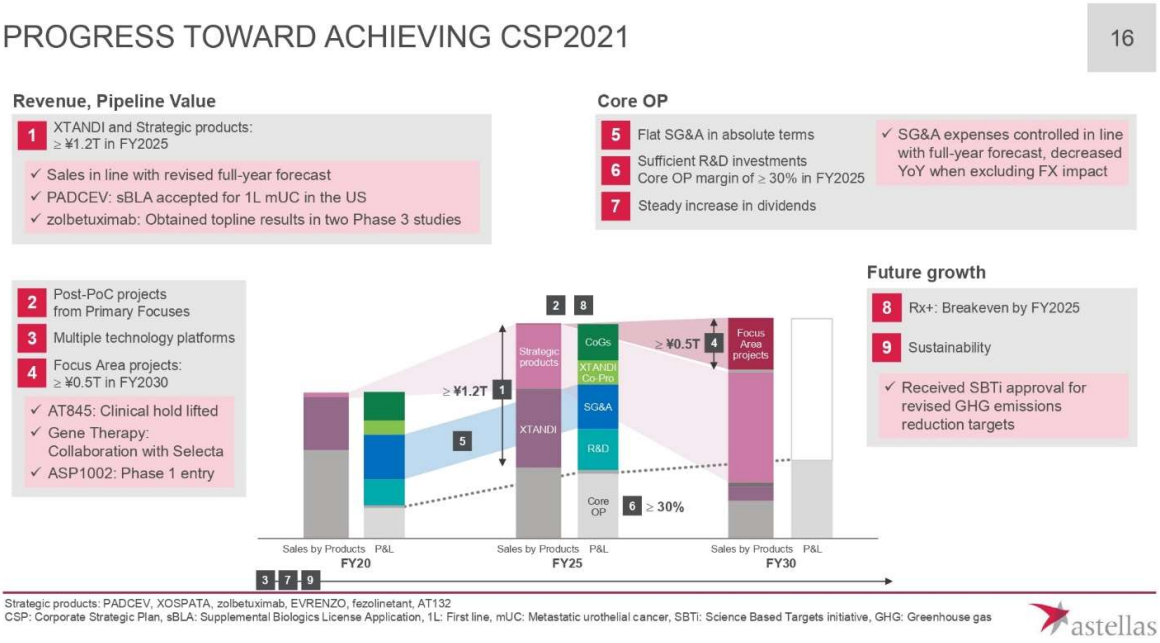



On page 15, I will explain our collaboration with Selecta Biosciences in relation to the progress of AT845.

First, on the left side of the slide, I will explain preexisting immunity or PEI. A certain percentage of people have naturally acquired IgG antibodies that react to adeno-associated virus or AAV. It is difficult to expect such individuals to benefit from gene therapy using AAV cap sites. They are excluded from the eligibility criteria in clinical trials and cannot receive treatment. It is estimated that up to 30% of adults have acquired antibodies to AAV8 using AT845.

As shown on the right side of the slide, aiming at dealing with this issue, Selecta has created Xork, an IgG protein assay that specifically and efficiently cleaves to human IgG. There are other IgG protein assays under development by other companies, but most of them are derived from human pathogen. So many patients are considered to have antibodies against AAV. Xork, on the other hand, is not derived from human pathogens and is expected to have local cross-reactivity to pre-existing antibodies in human serum, which attenuated the efficacy.

Astellas would have the sole and exclusive right to commercialize Xork for use with investigational AT845 in Pompe disease. Through this collaboration, Astellas expects to expand the patient population for AT845.



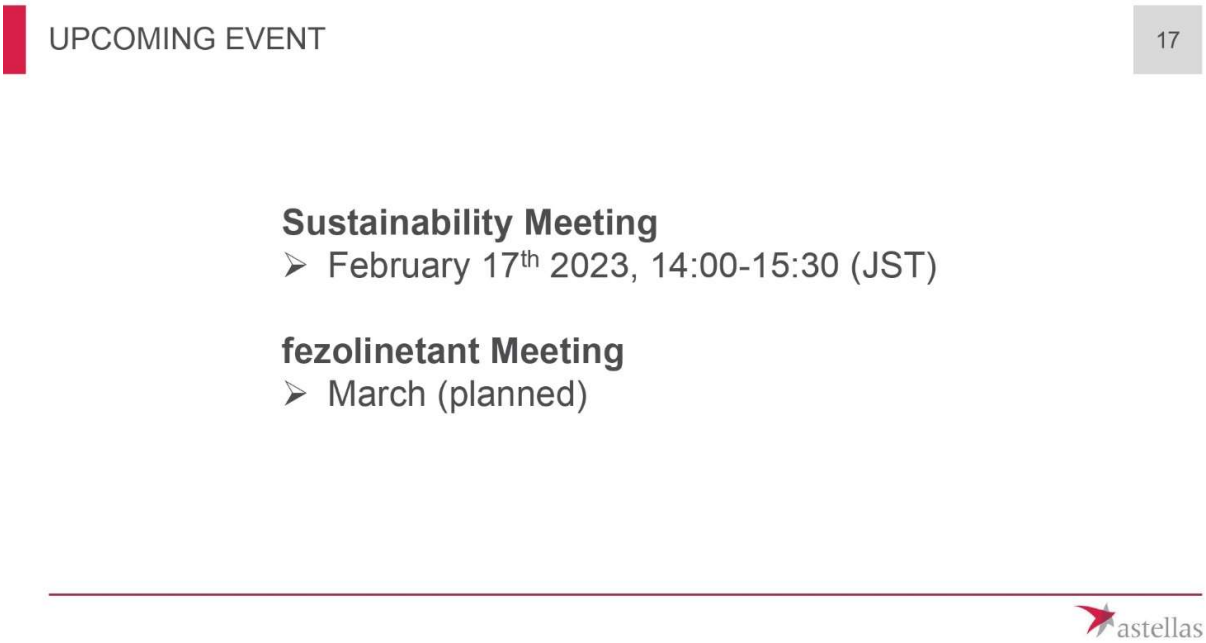

On page 16, I'll summarize the progress made in Q3 toward the achievement of CSP 2021.

In the upper left-hand corner, revenue from XTANDI and strategic products are showing progress in line with the revised full year forecast. The US sBLA for parts for the first-line treatment of metastatic urothelial cancer, an important growth driver for us has been accepted, and it was designated as priority review. For zolbetuximab, we obtained top line results in two Phase III studies, both of which met their primary endpoint.

In the focus area approach on the left bottom, progress was made on AT845, including the lifting of the clinical hold and the new collaboration. In addition, one new immuno-oncology project entered in the clinical phase. In terms of core OP, while securing proactive investments for new product launches, continued efforts to thoroughly review costs has been made. As a result of SG&A, expenses, excluding an impact of foreign exchange, were down YoY.

In the lower right-hand corner, although I will not explain it today, with respect to sustainability, we have revised our greenhouse gas emission reduction targets and have received approval from the SBT initiative. The details will be explained at Sustainability Meeting to be held this month.

In addition, again, although not shown on the slide, as announced in the press release today, we have decided to acquire our own shares. The share will be up to 29 million shares to JPY50 billion, and we'll conduct it from February 7 through March 24. We will continue our efforts to improve the capital efficiency and shareholder return.




Page 17, this is the last slide. This is a schedule for upcoming events.

We are planning to hold the Sustainability Meeting on February 17. We want to do in-depth initiatives that are unique to Astellas and that are of great interest to the investment community. We are also considering holding a meeting on fezolinetant after it is approved. It is expected to be around in March, but we will inform you of the details as soon as they are determined.

To summarize, in Q3, the basis of the core business is in line with the forecast, but when it comes to business of a full basis, due to the unexpected matters, including the foreign exchange loss against the ruble, it went down. This is considered to be tentative situation. For the full year, our core business has been forecasted. For the full base business, again, due to the impact of the foreign currency, and also the progress of the zolbetuximab, which are all positive for us, there's likely to be a downward shift.

With the value review of Evrenzo and also further optimization of our cost structure, we believe that these are going to work for our corporate strength. That's all.

Thank you very much. That's all for the presentation.

## Question & Answer

**Moderator [M]:** We now would like to entertain questions from the audience.

First, Credit Suisse Securities, Mr. Sakai, please.

**Sakai [Q]:** I have two simple questions.

First, today, there was no update about the Lexiscan. What is the current status right now? You overcame patent cliff, as was mentioned, but for the Lexiscan, it's not against my expectations, but it is a product with quite a big size, so I'd like to know the current status.

Another question is about XTANDI in the United States. My concern is that levels of new patient start have not yet returned to the pre-COVID-19 pandemic level. Is this because of the competition against generics having an impact? You mentioned there's going to be further growth in the next fiscal year and beyond because of an additional indication in the future. I'd like you to explain the situation of XTANDI in the United States once again.

Those are my two questions.

**Company Representative [A]:** Regarding your first question, I'd like to respond. The second question will be explained by Matsui, CCO.

For Lexiscan, right now in the lawsuit, we applied for the extension of the petition up to March 31. We received the extension. Regarding the impact on the current fiscal year, it's going to be quite limited. But, in the next fiscal year and beyond, we have to closely monitor the situation. In that respect, in the current fiscal year, there's a smaller likelihood of a decrease in sales. As for the XTANDI, Matsui is going to explain.

**Matsui [A]:** As for XTANDI in the United States, the diagnosis of cancer for new patients, it's not just about our company but companies doing active business in the oncology area, you might have heard from them, there is no complete recovery yet. The number of new patients is facing the delayed diagnosis.

As for the generics, there is some impact. As we mentioned before, in terms of the volume, it's growing. In FY2023 and beyond, we think that there's going to be a gradual recovery. We are expecting the EMBARK study for the additional indication too.

What's negatively working in the entire market is that the lower new patient starts and PAP, comparing FY2021 and FY2022. There is still some impact of PAP even more than the previous fiscal year. However, we included this in our budget this year, the revised forecast, so it is in line with the revised forecast. New patient starts, together with the economic, we expect to see a further recovery, then we can see an increase in the new patient starts. That's all for me.

**Sakai [Q]:** Let me make one confirmation, Kikuoka-san. For Lexiscan, other than what's been presented, there is no new topic? In the next fiscal year, generic injunction, you expect the generics to enter the market? Do you have this in your mind as the risk?

**Kikuoka [A]:** Well, the situation with Hospira, we lost the case in the first instance. In that respect, including at-risk launch, certain risks have to be incorporated in the next fiscal year. However, litigation is still ongoing, I would like to refrain from making a comment about the specific numbers.

**Ikeda [M]:** Today, Yasukawa and Okamura are still here. Of course, this is the Earnings Call, but if there are any questions, they are here to answer as well.

Citigroup Securities, Mr. Yamaguchi, please.

**Yamaguchi [Q]:** Next fiscal year, CEO will be changed, I don't think this is directly related to it, but the growth trend for fezolinetant next fiscal year and afterwards. This growth is extremely important for your midterm plan.

In the previous meeting, I think you mentioned that from the next fiscal year, this product is likely to be big. Of course, it is not approved yet, and I've heard that you are going to give us some explanation in March. How do you view the next fiscal year and afterwards? Are you looking towards making this product big so that it could be the business driver for you? Would you please make a comment about this?

**Ikeda [M]:** Well, this is a good question made, so Matsui is going to give you the comment.

**Matsui [A]:** Thank you very much for pointing out, as you mentioned, the final approval hasn't been given to us, so we need to wait for that. However, so far, we are doing many pre-launch activities especially disease awareness activities. In the United States, the doctors and consumers are highly reactive to the information we provide, more than we expected. In that way, we are earnestly working for the effort to make this product bigger.

**Yamaguchi [Q]:** One more question. This may be related to the change of the President and CEO, as Dr. Yasukawa mentioned, particularly from the global niche to FA, that's a big change of your strategy looking from outside.

Looking at the pipeline, you explained, I'm sure you are heading into this direction overall, but you have to go into this direction for the future? You are making a transformation, and a few years have passed since the shift. How this is perceived internally, and including the results you're achieving externally, I think your direction is not wrong, but what is your comment on this?

**Yasukawa [A]:** If you look at our initiatives, in 2013, it has been around nine years since we are working on this. This strategy was incorporated in CSP in 2018. And by around 2018, we had the confidence to create the backbone of the Company by this strategy. From that time, of course there are in and out, but we continued to develop five or six primary focuses. Initially, they were kind of independent. However in the past one or two years, cell differentiation and culture technics can be used in immuno-oncology, and gene editing technologies can be used in other areas as well, so we think there was a lot of development in this respect.

On the other hand, because of the impact of COVID-19, it's not just for Astellas, but also broadly, for the entire pharmaceutical industry, pre-POC clinical studies were postponed because of priorities at each study site. We couldn't see progress as we expected.

Cells or genes, and especially assay for analytical technologies in recent years, also progressed. Very detailed issues we couldn’t recognize before are now visible. Because we can see those issues now, we have to ensure the safety of the patients solving the issues and impurities or abnormalities, which are now visible. We have improved various technical problems such as strange cells and empty capsids, and also have reached an agreement with the FDA and other authorities in various countries on standardized testing methods for small molecule compounds. That is the past year or so.

We made progress, but as I mentioned before, we couldn't achieve POC. That's a regret in my tenure.

**Moderator [M]:** Next, Daiwa Securities, Mr. Hashiguchi, please.

**Hashiguchi [Q]:** There are a couple of questions.

The first question, at the end of the term, the possibility of additional cost after the revision of the cost structure, Mr. Kikuoka, you've mentioned that if there is some distortion to the mid-year plan, you will consider filling that gap. In the presentation, I think you also mentioned that you are looking toward FY24 and FY25. In your earlier presentation, I think you also mentioned that you are looking toward FY24 and FY25. Is the issue you are considering this time an initiative to fill in the gaps in the existing FY25 profit target, which is becoming increasingly difficult to achieve? Or is it correct to say that it is an initiative to further increase the profit target for FY25?

**Kikuoka [A]:** What I mentioned is that, well, number-wise, it's still at the stage that we are not able to disclose any specific numbers. The perspective has been there for a long time, including before I joined Astellas. For example, the ERP globalization so that you actively invested so that the efficiency can be further improved. You prepare the setting for that. For the go-live of the product, there is an increase of the cost sometimes. However, it seems that, that is started to be offset. We've made an investment beforehand. Thanks to that, we started to offset that.

There are some areas that are ramping, so we want to make it further efficient. We are working for the various activities. Especially after I became CFO, we look at the whole debt perspective in a thorough review approach. Well, the situation is not particularly difficult compared to the past. In order to secure the formal result from what we've been making as an effort, we would like to grow further.

For that purpose, so that we can allocate our investment to the strategic area further, we want to increase the efficiency further. In that perspective, in reality, there are not many expenses that can be allocated in FY2022. It will be probably after FY2024 because in FY2022 and FY2023, we would like to verify the situation so that we can prepare for FY2024, where we expect larger expenses.

**Hashiguchi [Q]:** Secondly, about zolbetuximab.

In early expenditure, you booked costs for the increase of the commercial production. This time, you are supporting your filing, you have an outlook for filing, so it's going to be deducted from R&D expenditure.

When you acquire fezolinetant, with regards to the acquisition of Ogeda, there was a conditional consideration. If you can obtain the approval by mid-February, another possibility of reviewing the fair value again?

**Kikuoka [A]:** Yes, you're right. Regarding zolbetuximab, I talked about the contingent consideration only, but by doing this, what we are booking in the R&D expenditure would be seen as product. They would be shifted to the inventory. We are going to book them as assets. We are assuming that possibility. My answer to the first question is, yes, As for fezolinetant, there's already a change to the fair value. We're not expecting a further change to the fair value.

**Hashiguchi [Q]:** So, for the impact of zolbetuximab on R&D expenses, even including it, will not have enough of an impact to cause a deviation from the full-year forecast?

**Kikuoka [A]:** Even including that factor, it's not going to be an impact to impact or have a gap on a full year forecast. Because of the shift in conversion, JPY6 billion, as a short-term profit, we are expecting.

**Hashiguchi [Q]:** Lastly, Xyphos collaboration. Again, the contingent consideration, and there's a positive revisit for the development plan. Could you be specific about that? What actually happened? If it is possible, would you please share that information with us as well?

Sorry, it's not a collaboration. It's about the acquisition. Sorry about that.

**Moderator [M]:** IR is going to give you the answer.

**Ikeda [A]:** Program is in the pre-clinical stage, so detailed programs haven't been really disclosed. We visited the study development plan and the value went up, and that is a Xyphos-derived product. That was disclosed.

**Moderator [M]:** Next, Mr. Kohtani from Nomura Securities.

**Kohtani [Q]:** First, about EVRENZO.

In the end, I'm sorry to go into the past, but Repatha, Linzess, your outlook with extending products, you tend to make a mistake or you tend to be wrong. As for EVRENZO, what was your expectations? What was not achieved? Could you elaborate on that once again to clarify? That's not going to apply to fezolinetant at all. If you don't say that, regarding the accuracy of your forecast, we still have some doubts or questions. I would like you to clarify.

That's my first question.

**Kikuoka [A]:** On this point, Matsui, our CCO is going to respond.

**Matsui [A]:** Thank you for your very tough comments. We take it seriously. Regarding EVRENZO, what was different in our forecast?

This is an oral agent for CKD-induced anemia which can be treated with an oral agent. According to our market research, we found strong earnings. In reality, intent to use, we're asking doctors whether they have intention to use or they do have strong interest.

If you look at the response from the physicians on this point, because of the strong comments, we assumed it would expand more rapidly.

We thought that we can maintain a high market share as a company to enter into this market ahead of the competitors. Unfortunately, in our experience in Japan, in the field of nephrology and treatment of anemia, the health care policies are very complicated in a variety of frameworks. From the government, it's strictly controlled by the government. Switching from the existing treatments, it's not going to be changed so quickly. Based on the speed we assumed, we think that's the reason for our wrong forecast.

What's the difference compared to fezolinetant? In the case of EVRENZO, it was a doctor's selection. As for fezolinetant, particularly in the United States, as you know, consumers themselves to be highly engaged in the selection of this drug. In the United States, we mentioned a bit, fezolinetant and vasomotor symptoms for fezolinetant, regarding this disease, they are very strong unmet medical needs. Patients themselves are strongly interested in this drug, particularly for the 1H of the year, we felt it strongly.

You may know this, but for example, if you search on the Internet, recently, CBS News spent five mins to show how women are struggling to advance into society and how much burden they are suffering. There was a talk program for about five minutes on CBS. This may be a coincidence, but Michelle Obama, the wife of the former President, Barack Obama, also commented on this disease on the Internet.

Oprah, she is very popular emcee in the United States, and she's also mentioned this disease recently. Regarding this disease and the drug in the field, patients and women's interest are very high. CKD treatment is a more specialized on HCP As a decision-maker have a higher proportion, but in the case of fezolinetant patients, particularly in the United States, have a big say in the decision-making process. They have a very high

awareness and interest level right now as we observed. In this sense, we are very confident about fezolinetant that we can grow this to a big product. That's our belief.

**Kohtani [Q]:** What you just mentioned is also included within the handout material?

**Ikeda [A]:** No.

**Kohtani [Q]:** Maybe you better put that in the material. Oprah Winfrey, Michelle Obama, those have a very strong voice to all the American females. Well, they are not directly talking about fezolinetant, but they are talking about this disease and our winners activities related to talk is made by them, right?

**Matsui [A]:** Yes, that's right.

**Kohtani [Q]:** I think that is a very worthy information to be put on to the material. Now, about the JPY40 billion of zolbetuximab, the relation of the fair value, it seems that it's larger than expected. Is this number a big surprise for you or is the pancreatic cancer also included? Is that why the number goes in this way?

**Kikuoka [A]:** Well, basically, as for the monetary amount, it hasn't been really discussed with the partner, that's why the number is seemingly bigger than we've expected. In the countries where we are aiming at the submission and further considering the relationship, we come up with a disproportionate estimate of the possibility of submission as well to come to this number. This is in line with our assumption as well.

In Q4, if this really happens or not, well, in the beginning of the fiscal year, our assumption is, yes, it will be the next fiscal year. In that perspective, guidance-wise, this might look very sudden information from your perspective. However, from the beginning, we are saying that if we come to that kind of situation, then fair value change will be triggered. That is already in our mind. Looking at these couple of months, we believe that the accuracy and the possibility of the submission goes up. It is likely to be within this fiscal year.

**Kohtani [Q]:** In Europe, this year, this is going to be a year of the clawback. This year, in France, a clawback, sales of pharmaceuticals would be regained with excess, and VPAS is rising in the UK as well. In Europe, the risk of reduced revenue, what's your view on this?

This is my last question.

**Kikuoka [M]:** This is related to sales and marketing, so Matsui is going to explain.

**Matsui [A]:** You know the details. VPAS in UK, 5% in 2021, CE ratio, 15% in 2022 15%, 26.5% in 2023, which is a big burden. In France, as you pointed out, unfortunately, Macron introduced such a system. 5% tax increase in Germany as well. XTANDI and mainstay products' growth is affected by this greatly. We are including this in our outlook in France and other countries' innovation and social security access, they are trying to keep a good balance between the two. In that sense, VPAS clawback, depending on the economic conditions, can change a lot. Not only for us, but also for the industry association, we are going to appeal to each country.

For us, as you pointed out, regarding the three countries you mentioned, we are factoring this thing as a risk in our forecast.

**Kohtani [Q]:** They have not established yet. They are still under discussions. Somewhere during this year, are they going to be established?

**Matsui [A]:** No. Regarding those three countries, starting from January, it's already being applied.

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

**Muraoka [Q]:** Yasukawa-san, thank you very much for your hard work, and Okamura-san, thank you for the continuous relationship with the community as well.

Now, the first question is about this midterm plan.

You mentioned the word flexibility. There are so many in depth, and there are so many items that you need to look at. However, out of those, I think there are some particular numbers that you definitely like to stick to, 8% revenue or OP 30% or something like that. Are there anything specific that you would like to particularly stick to achieve, Okamura-san?

**Okamura [A]:** If I answer all the numbers, that will be the answer. If you would say, which out of those all, of course, the sales of the revenue has to increase. Otherwise, we cannot gain their profit for reinvestment.

Definitely, we would like to increase the revenue. A core OP percentage, 30%. That itself is not the goal. This is the just assumption for the future and saying 30%. This is definitely hard to achieve. This is a must percentage that we need to achieve. As we mentioned, rather than thinking about FY2025, my mission is to prepare for the XTANDI patent expiry still, we can continuously grow ourselves. That is what we have to prepare now.

Of course, revenue and profit are both important. For Focus Area Approach, that is something I would like to stick to. This JPY500 billion for FY2030. Well, we have to think about that carefully. But the further view that I have is the pipeline value has properly accumulated above a certain level in FY2025. Otherwise, we can say that we achieved 2021 CSP.

**Muraoka [Q]:** Another question to Mr. Okamura to confirm.

Last year, I think it was the time of the Q2 results, Dr. Yasukawa talked about fezolinetant in the initial year. They meet dozens of billions of yen to be achieved. Unfortunately, in the market, there are some doubt. I'd like to ask Mr. Okamura to explain this in your own words regarding the numbers mentioned by Dr. Yasukawa.

**Okamura [A]:** That's also my belief. How much, we explained in our own words repeatedly, the products are going to sell well or there are prescriptions, we have to show evidence on data to you. We're already in such a stage. Yasukawa and I are kind of united, so we are going to believe this. I believe in this, and we are going to show it to you.

**Moderator [M]:** Mitsubishi UFJ Morgan Stanley Securities, Ms. Kumagai, please

**Kumagai [Q]:** There are two questions.

First, fezolinetant. The disease awareness activities that are ongoing that you mentioned, what are the specific activities? What kind of media are you using? Would you please explain about that? Relating to that, Q4 pre-launch cost or expenses that is included within the planned expenses that currently you have as a number?

**Kikuoka [A]:** Regarding the expenses, let me answer the second question by myself, and the first question will be answered by Matsui. What you mentioned is probably the cost booking for the launch. That is already incorporated within our financial plan. For the marketing activities, Matsui is going to answer.

**Matsui [A]:** As has been mentioned, the patient, HCPs, for both. Hot flash and such symptom challenges, those are covered by our disease awareness activities. We use TikTok, we use SNS, emails, we utilize different media. Of course, those 45 to 65 year older female, that is the target for this drug, and we are considering the most appropriate media for such a generation. Depending on the situation, we might do the fine-tuning to make it effective.

**Kumagai [Q]:** Secondly, about AT845, you are adding the protocol change. When Xork is going to be available, as is shown on page 15, there is going to be an increase in the patient population. How should we see the increase or decrease in the patient population? There are some subjects to be enrolled with some limitation. But if Xork is going to be available, you can expand the patient population regarding AT845.

**Kikuoka [M]:** On this matter, Taniguchi, joining remotely overseas, is going to explain.

**Taniguchi [A]:** I would like to explain AT845. As we explained earlier, there was clinical hold, which is now lifted by FDA. Continuously, we will discuss with the FDA what kind of protocol amendment is going to be necessary. We are now discussing with the FDA. Patients with prior neuropathy or patients at high risk of neuropathy would be excluded from the clinical study.

But, in Phase I right now, we will accumulate data. In the late stage development, what kind of patients would be a target, what kind of patients should be excluded from the protocol; we are discussing right now. We have the exclusion criteria in the protocol, and those patients excluded cannot use this drug for the future? We don't know yet. That's one thing.

As for Xork, in patients with AAV antibody, that's around 30%. We can make efforts to increase the population. This is not directly linked to the protocol amendment we made. By using Xork, because of the AAV antibody, patients were not eligible for the administration, could be eligible. This is separate from the protocol amendment. We'd like to make this drug available to broader patient population into the future, we've really made efforts.

**Moderator [M]:** Next, Goldman Sachs Securities, Mr. Akinori Ueda

**Ueda [Q]:** Zolbetuximab, fair value increase of contingent consideration is something I would like to double check with you. In your presentation, with the probability of submission, approval launch increased. So, this probability of success went up, but there is nothing to change about the potential whatsoever?

**Kikuoka [A]:** Yes, your understanding is right.

**Ueda [Q]:** Secondly, about PADCEV sales trend. Right now, sales are growing steadily right now. This is the expansion in the current indication after the announcement of EV-103, cohort K, it's not used in the first line yet. Is it going to expand after you get the approval for the first line indication?

**Kikuoka [M]:** As explained a bit initially, there may be some additional comments. Matsui would like to add.

**Matsui [A]:** Actually, I don't have much to add, but you're right. According to our observations, off-label use is not so much in principle, in just usage in the current indication. That's the majority of sales right now, according to my understanding.

**Ueda [Q]:** Third question, the collaboration with Selecta, with Xork, the efficacy is less likely to be attenuated. For the gene therapy, do you consider the usage of this technology for the multiple administration of gene therapy?

**Kikuoka [M]:** Yoshitsugu Shitaka is going to explain about it.

**Shitaka [A]:** AAV multiple administration might be possible, thanks to this kind of technology. But for the collaboration with Selecta, this time, it is only for Pompe. IgG protease, the immunogenicity, with this regard is also needed to be observed. Depending on data the possibility of the multiple usage, it will be different.

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

**Wakao [Q]:** My first question is about your forecast for the next fiscal year.

I'd like to get a sense of your company. In February, fezolinetant may be approved. Then, on a full year basis, next fiscal year, fezolinetant is going to contribute to your results. On the other hand, excluding fezolinetant in your existing business, based on the situation up until now, the existing businesses will grow? Then, fezolinetant will be on top of that? But according to my own impression, my model, rather than that, the existing business may face challenges and fezolinetant growth can offset the stagnant situation of the existing businesses in my view. Right now, what is your future outlook of the existing businesses in the next fiscal year?

As a negative factor, the yen's depreciation and the stagnant growth of XTANDI and mirabegron and there can be generics of Lexiscan. There are some impact of generics for some products. So, in the existing businesses, the next fiscal year may be a challenging year. What do you think?

**Kikuoka [A]:** Then, I'd like to explain. Right now, we are developing our budget internally for the next fiscal year.

In terms of our philosophy here, in XTANDI, we reviewed in the second half. We have to be aware of the mature phase. But still, a high sales contribution is what we are expecting. XOSPATA and PADCEV, we're forecasting steady growth and expansion. In principle, the patent cliff for the future, how to deal with this is going to be an issue. For next fiscal year, fezolinetant will be launched. That's what we're expecting.

Regarding the existing products towards the next fiscal year, difficulties. Lexiscan, we will have a severe outlook for Lexiscan, but as strategic products, we are expecting growth in many of them right now. By adding fezolinetant, towards 2026 and 2027, we'd like to be ready.

**Wakao [Q]:** Second question, PADCEV, a first line will be approved in April that will contribute throughout the year that is likely to be that positive factor. On the other hand, there was not much of the explanation about the mirabegron today. GEMTESA, the competitor became available, so the situation is getting tougher. I believe you mentioned that.

And the US dollar basis situation, if we look at the quarterly basis, yes, it might be a difficult situation for you. Gemtesa is not listed on the Medicare Part D, but from January, so mirabegron is obviously used for Medicare Part D. Competition is highly likely to be more fierce.

Now, my question is that it is likely that situation is a bit fragile for you. That's one thing. Next fiscal year and afterwards, the mirabegron sales might be negatively impacted because of this competition situation.

**Kikuoka [M]:** Matsui is going to answer this.

**Matsui [A]:** Your question is only about the United States?

**Wakao [Q]:** US market is my question.

**Matsui [A]:** Regarding the US market, first of all, our observation is that GEMTESA market share is within what we expected. So far, we haven't seen any bigger impact, and we don't see that is a bigger factor causing a difficulty for us. Why this is a difficult situation for us? Well, market growth, that is about 2%. Our share is gradually increasing, 24 point certain percentage is the current market share maintained.

In that situation, why is it difficult? That's about a price pressure. That is a negative impact, and that is likely to be continued, so the competition is getting fierce and that might be what would happen in the United

States. So far, in the United States, the competition of the market share with GEMTESA is not really negatively impacting overall.

**Wakao [Q]:** Yes, there is an impact of the price, but the Medicare Part D, if your competitor comes into that list, then competition is likely to be tougher. It is not happening now. For the future, is it better to expect that would happen?

**Matsui [A]:** Well, so that we can do with that situation with the insurance companies, including the contracts, yes, we are working to prepare for that. We wouldn't say that the situation is further worse than what we expected, but we are doing the preparation anyway.

**Wakao [Q]:** Lastly, briefly about fezolinetant. In Q2, you gave us a rough amount of sales. No change since that? In Q2, you had a suggestion. We will have the numbers within that range. Should I understand this way? Also, in the explanatory meeting previously, it was not approved, and the price has not been determined yet. So, your strategy in detail numbers were not discussed much. But this time, at this timing, the price should be determined, and the approval may be determined. I think that we can discuss numbers more. Can we have high expectations for the numbers as well?

**Kikuoka [A]:** Yasukawa responded to an earlier question. In principle, we'd like to achieve that level. We will work on that. In that sense, there's going to be no change. This is before the launch. As I said at the end, as early as March, we'd like to have an explanatory meeting after the launch where we want to explain the details if possible.

**Moderator [M]:** Everyone, thank you very much for your participation. With this, we would like to close today's meeting.

Thank you.

[END]

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