



Astellas Pharma Inc.

Financial Results for the Q2 of FY2022

October 31, 2022

Event Summary

[Company Name]	Astellas Pharma Inc.	
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[Event Name]	Financial Results for the Q2 of FY2022	
[Fiscal Period]	FY2022 Q2	
[Date]	October 31, 2022	
[Time]	17:00 - 18:34 (Total: 94 minutes, Presentation: 40 minutes, Q&A: 54 minutes)	
[Number of Speakers]	5	
	Kenji Yasukawa	Representative Director, President and CEO
	Yoshitsugu Shitaka	Chief Scientific Officer (CScO)
	Minoru Kikuoka	Chief Financial Officer (CFO)
	Tadaaki Taniguchi	Chief Medical Officer (CMO)
	Hiromitsu "Hiro" Ikeda	Head of Corporate Advocacy & Relations
[Participant Names]	Hidemaru Yamaguchi	Citigroup Global Markets
	Motoya Kohtani	Nomura Securities
	Fumiyoshi Sakai	Credit Suisse Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Kazuaki Hashiguchi	Daiwa Securities
	Akinori Ueda	Goldman Sachs
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Presentation

Yasukawa: Hello, everyone. Yasukawa speaking. Thank you very much for joining our FY2022 Q2 financial results announcement meeting on your very busy schedule today.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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

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Page two is a cautionary statement regarding forward-looking information. I'm going to skip reading this page.

AGENDA

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I Q2/FY2022 Consolidated Financial Results
FY2022 Revised Forecasts

II Initiatives for Sustainable Growth



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Page three is the agenda for today. I will cover these topics in line with the agenda.

Q2/FY2022 FINANCIAL RESULTS: OVERVIEW

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Revenue increased 17% YoY and was on track when excluding FX impact

- XTANDI: Sales in the US were below initial full-year forecast. Strong performance in Europe and Japan covered the underachieving performance in the US
- Strategic products: Sales of PADCEV exceeded initial full-year forecast; strong performance mainly in Japan
- Cost of sales ratio was above initial full-year forecast due to changes in product mix
Considering recent rapid exchange rate fluctuations, the exchange rate used for eliminating unrealized profit was changed from Q2 to exclude the impact on profit, based on the principle of materiality (see slides 20 and 21 for details)
- SG&A expenses were controlled in line with initial full-year forecast
- R&D expenses were on track

Operating profit

- Core OP increased 16% YoY, increased even excluding FX impact and was on track
- Full basis increased 33% YoY



Strategic products: PADCEV, XOSPATA, EVRENZO

Page four is an overview of FY2022 to Q2 financial results, I'd like to start explaining from this page.

Revenue and profit increased in Q2. Revenue increased by 17% YoY and was on track when the Forex impact was excluded.

As for XTANDI, sales in the United States were below the initial full year forecast, but strong performance in Europe and Japan covered the underachieving performance in the United States.

PADCEV showed a strong performance, mainly in Japan, and sales exceeded our initial full year forecast.

COGS ratio was higher than our initial full year forecast due to changes in the product mix.

But as we announced last week, considering recent rapid exchange rate fluctuations, the exchange rate used for eliminating unrealized profit was changed from Q2 to exclude the impact on profit. Please see slides 20 and 21 for details.

SG&A and R&D expenses were controlled in line with the initial full year forecast, excluding Forex impact. As a result, core operating profit increased by 16% YoY, even excluding Forex impact and was in line with our initial forecast. Full basis operating profit increased by 33% YoY.

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Q2/FY2022 FINANCIAL RESULTS

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(billion yen)	Q2/FY21	Q2/FY22	Change	Change (%)	FY22 Initial FCST	Progress	FX impact
Revenue	651.7	762.2	+110.5	+17.0%	1,443.0	52.8%	+84.3 bil. yen
Cost of sales	124.7	151.7	+26.9	+21.6%			+12.5 bil. yen (Incl. the impact of elimination of unrealized profit remaining in Q2/FY21: +0.6 bil.yen)
% of revenue	19.1%	19.9%	+0.8 ppt				
SG&A expenses	270.5	308.0	+37.4	+13.8%	598.0	51.5%	+40.2 bil. yen
US XTANDI co-pro fee	71.1	89.7	+18.6	+26.1%			
SG&A excl. the above	199.4	218.3	+18.9	+9.5%	416.0	52.5%	+24.0 bil. yen
R&D expenses	119.1	139.2	+20.1	+16.9%	254.0	54.8%	+15.1 bil. yen
Amortisation of intangible assets	12.4	20.0	+7.6	+61.3%			
Gain on divestiture of intangible assets	-	0.2	+0.2	-			
Core operating profit	125.3	145.4	+20.1	+16.0%	290.0	50.1%	+16.0 bil. yen
<Full basis>							Ref.
Other income	2.8	16.2	+13.4	+470.7%			(Other income)
Other expenses	38.0	41.7	+3.8	+9.9%			Net foreign exchange gains: 13.9 bil. yen
Operating profit	90.2	119.9	+29.7	+33.0%	269.0	44.6%	(Other expenses) Booked in Q1 Impairment losses on intangible assets (AT702, AT751, AT753): 22.8 bil. yen
Profit before tax	89.1	120.5	+31.4	+35.2%	267.0	45.1%	fezolinetant increased fair value of contingent consideration: 13.7 bil. yen
Profit	71.6	96.4	+24.8	+34.7%	208.0	46.4%	

Next, on page five, I will explain the FY2022 to Q2 financial results.

Revenue increased to JPY762.2 billion, up 17% YoY. Core operating profit was JPY145.4 billion, up by 16% YoY. You can see the Forex impact column on the right-hand side of the table. Revenues, increase, and profit increased by 4% and 3%, even excluding Forex impact.

As I explained on the previous page, Q2 cost of sales does not include Forex impact from the elimination of unrealized profit. On the other hand, we are not restating our historical consolidated financial statements. So, the Forex impact of the elimination of unrealized profit for JPY0.6 billion remains in Q2 of FY2021.

The bottom half of this page shows our full basis results. Operating profit was JPY119.9 billion, up 33% YoY. Profit increased to JPY96.4 billion, up 34.7% YoY.

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Q2/FY2022 FINANCIAL RESULTS & OUTLOOK: XTANDI

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Expect continued global growth despite the challenging market conditions in the US

(billion yen)	Q2/FY2022 Act	YoY	FY2022 Initial FCST	Progress	FY2022 Revised FCST	
 Xtandi (enzalutamide)	332.0	+64.4 (+24%) (Excl. FX impact +22.8 (+9%))	642.5	52% (Excl. FX impact 48%)	670.0 (FX impact +55.8)	<ul style="list-style-type: none"> ✓ Global sales are in line with expectations up to Q2, as strong performance in Europe and JP covered the underachieving performance of the US ✓ In the US, sales are still expected to be challenging from Q3 onward considering the current market conditions. FCST has been revised downward excluding FX impact, yet near double-digit growth is expected in a global basis
US (Unit: \$)	\$1,304M	+19 (+1%)	\$2,949M	44%	\$2,618M	<ul style="list-style-type: none"> ✓ Shifting to mature phase in current indications <ul style="list-style-type: none"> • Levels of PAP and generic competitor continue to be higher than expected • New patient starts are below expectations, not returned to pre COVID-19 levels ✓ Factors above are not expected to improve, FCST has been revised downward ✓ Future growth driver is the anticipated additional indication of M0 CSPC, expect contribution after approval
Established Markets (Unit: €)	€715M	+74 (+12%)	€1,349M	53%	€1,429M	<ul style="list-style-type: none"> ✓ M1 CSPC showed strong growth, contributing to demand increase (YoY +21%) ✓ Positive price impact from the agreement of higher price than assumed in Q1 (Germany), also contributed to the upward revision of FCST
Japan	27.5	+3.9 (+17%)	52.6	52%	55.4	<ul style="list-style-type: none"> ✓ Maintained high market share. NHT market expansion higher than expected ✓ Factoring in the NHT market expansion, FCST has been revised upward
Greater China	6.0	+2.4 (+66%)	13.3	45%	12.3	<ul style="list-style-type: none"> ✓ Although demand expanded (YoY +34%), competitive pressure increased ✓ Expecting competitive pressure to continue, FCST has been revised downward
International Markets	24.4	+9.0 (+59%)	40.6	60%	44.3	<ul style="list-style-type: none"> ✓ Continue to be growth market. Performance looks strong due to early shipment ✓ Outlook for full-year to be in line with initial FCST excluding FX impact

Exchange rates for initial FCST: 120 USD/¥en, 135 EUR/¥en, Exchange rates for revised FCST: 137 USD/¥en, 139 EUR/¥en (FCST rates Q3 onwards: 140 USD/¥en, 140 EUR/¥en)
 FCST: Full-year forecast, PAP: Patient Assistance Program, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, NHT: Novel Hormonal Therapy
 Established Markets: Europe, Canada, Australia, Greater China: China, Hong Kong, Taiwan, International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Export sales, etc.

On page six, let me explain Q2 results and the future outlook for XTANDI.

Due to a substantial Forex impact in Q2, we're showing the results in local currencies as well. First, global sales reached JPY332 billion in Q2, up by 24% YoY, and up by 9% when Forex impact is excluded.

Up to Q2, the progress was in line with the full year forecast. We'll explain the outlook for the future later, but we continue to expect challenging market conditions in the United States, and we have made a substantial downward revision of a full year forecast in the United States.

We're making an upward revision of our full year forecast in Europe and Japan, with strong performance, which is not sufficient to cover the downward revision in the United States. So, the full year forecast of global sales, excluding Forex impact, is revised downward. On the other hand, in spite of the downward revision, we are expecting continued near double-digit growth, even with sales already exceeding JPY600 billion.

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

In the United States, Q2 sales reached USD1,304 million, growing by 1% YoY, 1% based on the local currency.

Continuing from the previous quarter, there has been a negative impact from the so-called PAP, Patient Assistance Program, and competitive Zytiga generics. We were expecting a recovery in our initial forecast, but their levels remain higher than our expectations.

New patient starts have not returned to pre-COVID-19 levels and below expectations. We are assuming that the duration of treatment with XTANDI is 18 months on the average, due to a drop in patient starts one to two years ago when COVID-19 has the biggest impact. We believe that demand, as a basis of our current sales, is also being affected.

These factors, including PAP, have a lot of uncertainties. So, we're not expecting an improvement for now. We factored in the challenging market conditions for Q3 and beyond. As a result, we decided to revise our full year forecast downward to USD2,618 million. Comparing H1 and H2, it may seem that we are not expecting

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growth in our plan, but this is due to the impact of the so-called donut hole or coverage gap on our price in Q4.

On a demand basis, we're expecting an increase by a higher single-digit percentage figure in H2 compared to H1. So, we are planning to grow based on the actual demand. As you know, more than 10 years have already passed since the launch in the United States. Sales have gone to a scale of USD2.5 billion on a full year basis and shifting to a mature phase in the current indications, in our view.

On the other hand, the future growth opportunity and EMBARK study is ongoing, with which we are aiming to obtain an additional indication of M0 CSPC, we're expecting top line results by the end of the current fiscal year. We're expecting for its contribution to sales after approval, as a growth driver for FY2023 and beyond.

Next, Established Markets. Established markets are above initial forecast and contributing to the expansion of global sales the most. Prescription for early-stage M1 CSPC showed strong growth, mainly in Germany. While Italy and Canada also contributed as well, with the start of reimbursement for M1 CSPC, so demand rose substantially by 21% YoY.

As for the price, we were able to reach agreements on the price higher than our initial assumptions in the reimbursement negotiations in Germany. We reflected these positive factors and made an upward revision of our full year forecast.

In Japan, as a result of active educational and promotion activities by us and our competitors, we are maintaining a high market share in the growing market of novel hormonal therapies, with the market expansion higher than expected. Reflecting the situation up to Q2, we revised our full year forecast upward.

In Greater China, demand expanded substantially, but due to the impact of intensifying competition, progress is lower than our initial forecast. We are expecting competitive pressure to continue in Q3 and beyond and made a downward revision of our forecast. However, we are continuing to see Greater China as a growth market.

In the International Markets, performance looks strong, but that's due to early shipments. Excluding that factor, performance is in line with our initial forecast. So, excluding Forex impact, full year outlook is in line with our initial forecast. We have expectations on International Markets, as the growth market like Greater China.

In the United States, XTANDI is approaching the mature phase, but outside of the United States, we have expectations for Greater China and International Markets in particular, as growth market. We continue to expect sales expansion globally as a whole.

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Q2/FY2022 FINANCIAL RESULTS & OUTLOOK: STRATEGIC PRODUCTS

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Sales growth exceeding expectations for PADCEV, especially in Japan, upward revision of FCST

(billion yen)	Q2/FY2022 Act	YoY	FY2022 Initial FCST	Progress	FY2022 Revised FCST	
 PADCEV enfortumab vedotin injection for IV infusion 20 mg & 50 mg vials	20.8	+11.7 (+128%) [Excl. FX impact +8.9 (+98%)]	36.5	57% [Excl. FX impact 53%]	45.4 [FX impact +4.1]	<ul style="list-style-type: none"> ✓ Global sales exceeding expectations ✓ Countries with approval expanded to 41 countries (as of Sep 2022) ✓ FCST has been revised upward, mainly factoring in the strong performance in JP
US (Unit: \$)	\$105M	+22 (+27%)	\$230M	46%	\$230M	<ul style="list-style-type: none"> ✓ In line with initial FCST, FCST remains unchanged ✓ Expect significant growth after the anticipated approval of 1L mUC indication
Established Markets (Unit: €)	€19M	+19 (-)	€34M	56%	€40M	<ul style="list-style-type: none"> ✓ Since the approval in Apr 2022, launched countries have increased ✓ Expect reimbursement to start in the near future ✓ Market penetration exceeding expectations, upward revision of FCST
Japan	4.0	+4.0 (-)	4.3	93%	8.3	<ul style="list-style-type: none"> ✓ Continued from Q1, market penetration far exceeding expectations ✓ Significant upward revision of FCST
 XOSPATA gilteritinib tablets	23.5	+7.0 (+43%) [+3.9 (+24%)]	46.2	51% [47%]	45.8 [+3.9]	<ul style="list-style-type: none"> ✓ Global sales below expectations. Maintained high market share in US, the largest market, while market growth was lower than expected ✓ Factoring in the slowdown of the US market and increased competitive pressure in JP, FCST has been revised downward
 Evrenzo roxadustat	1.5	+0.1 (+9%)	9.9	15%	5.0	<ul style="list-style-type: none"> ✓ Sales in JP and Europe are below expectations. Continued to be impacted by competitive pressure in JP and low penetration of differentiation from standard of care in Europe ✓ Expect launch and reimbursement in France, Italy and Spain in 2H/FY22. However FCST has been revised downward factoring in the challenging situation up to Q2

Exchange rates for initial FCST: 120 USD/yen, 135 EUR/yen, Exchange rates for revised FCST: 137 USD/yen, 139 EUR/yen (FCST rates Q3 onwards: 140 USD/yen, 140 EUR/yen)
FCST: Full-year forecast, 1L: First Line, mUC: Metastatic urothelial cancer, Established Markets: Europe, Canada, Australia

Next, on page seven, let me explain our strategic products.

First on PADCEV. Global sales grew to JPY20.8 billion, exceeding our initial expectations. Countries with approval expanded to 41 countries. Regional expansion is making steady progress. Factoring in the strong performance, mainly in Japan, we revised the full year forecast upward.

In the United States, PADCEV is growing in line with our initial forecast. We already achieved a high market share with the current indications. We're expecting significant sales growth after the anticipated approval of first-line metastatic urothelial cancer indication.

In the Established Markets, the number of launched countries has increased to 16. Since the approval in April this year, market penetration is exceeding our initial expectations. Reflecting the situation after Q2, we made an upward revision of our full year forecast. We are expecting a further increase in the number of launched countries. Reimbursement is expected to start in Austria, Switzerland, Belgium, and Nordic countries in the latter half of FY2022.

In Japan, market penetration is continuing to exceed expectations at the speed faster than our initial forecast. New patient starts are substantially above our expectations, and the duration of treatment in the clinical settings is actually confirmed to be longer than the clinical trials in many cases, which we think is contributing to sales expansion. Reflecting the market penetration much above our initial assumptions, we made a significant upward revision of our full year forecast.

In the International Markets, PADCEV was launched in Singapore in July this year. We are hoping for contribution to sales, as we expect an increase in the number of launch countries in the future. The key to global growth in the future is the expansion in the current indications, as well as the additional indication in the first-line settings. We're expecting full-scale sales contribution starting from the United States.

As for XOSPATA, due to the impact of a weak performance, mainly in the United States and Japan, global sales were below expectations. In the United States, the largest market, we maintained a high market share and demand has been increasing. But the market growth was lower than expected.

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As a factor for the slowdown of the US market, FLT3 screening rate is already high, but has not reached our goals we set at the beginning of the fiscal year. So, new patient starts are below our expectations, according to our analysis.

In Japan, increased competitive pressure is serving as a factor for the weak performance. Reflecting these situations in the United States and Japan, we made a downward revision of our full year forecast.

As for Evrenzo, sales in Japan and Europe are below expectations. Factors behind have not changed much from the previous quarter. Evrenzo has continued to be affected by competitive pressure in Japan and low penetration of differentiation from the existing standard of care in Europe.

We are expecting launch and reimbursement in France, Italy, and Spain. In the latter half of this fiscal year, but factoring in the challenging situation after Q2, we made a substantial downward revision of our full year forecast.

Q2/FY2022 FINANCIAL RESULTS: COST ITEMS

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*Cost of sales ratio increased YoY and was above full-year forecast
SG&A expenses were on track and decreased YoY when excluding FX impact
R&D expenses were on track when excluding FX impact*

Core basis: Main items for YoY and progress against FCST

Cost of sales % of revenue YoY: +0.8 ppt	<ul style="list-style-type: none"> ✓ Increase due to changes in product mix (mainly XTANDI (ex-US) and EVENITY) (+0.9 ppt) ✓ Cost of sales ratio was above forecast, mainly due to above factor
SG&A expenses excl. US XTANDI co-pro fee YoY: +9.5% (-2.6%) Progress against FCST: 53% (50%)	<ul style="list-style-type: none"> ✓ Global optimization of commercial-related personnel aligned with transformation of product portfolio (YoY approx. -6.0 bil. yen) ✓ Reduction of mature products-related costs (Approx. -4.0 bil. yen) ✓ Investment for new product launch readiness (Approx. +4.0 bil. yen) ✓ As a result of thoroughly reviewing costs that do not contribute to improving competitiveness and value, and actively making necessary investments, SG&A expenses were in line with initial forecast
R&D expenses YoY: +16.9% (+4.2%) Progress against FCST: 55% (52%)	<ul style="list-style-type: none"> ✓ Booked one-time expenses for using PRV in Q1 for the application of fezolinetant ✓ In line with forecast, including the above expenses

() YoY change and forecast progress excluding FX impact

PRV: Priority Review Voucher



On page eight, I will explain cost items.

COGS ratio increased by 0.8 percentage points YoY and was above initial forecast due to changes in product mix, such as sales increase for XTANDI ex-US, and EVENITY in Japan.

SG&A cost, excluding XTANDI US co-promotion fees, increased by 9.5% YoY. When Forex impact is excluded, SG&A expenses decreased by 2.6% or JPY5.1 billion YoY, and the control in line with our initial forecast.

Personnel costs fell by about JPY6 billion, with global optimization of commercial-related personnel aligned with transformation of product portfolio. We're also trying to reduce sales promotion costs related to mature products, such as mirabegron, which decreased costs by about JPY4 billion YoY.

On the other hand, we are making active investments for a new product launch readiness for PADCEV and Fezolinetant. Sales promotion expenses rose by about JPY4 billion YoY. We will continue to allocate our resources to strategic products with higher priority.

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R&D expenses increased by 16.9% YoY but by 4.2% when Forex impact was excluded. We booked onetime expenses of JPY13.5 billion for using a priority review voucher in Q1 for the application of Fezolinetant. Excluding this cost, R&D expenses decreased YoY.

The progress against the initial forecast, excluding Forex impact, was high at 52%, but the use of a priority review voucher was already factored in at the beginning of the current fiscal year. This is in line with our initial forecast.

FY2022 REVISED FORECAST

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- **Revenue: Upward revision**

- XTANDI: Downward revision in US; Challenging market conditions to continue Q3 onwards.
Upward revision in Europe and Japan
- Reflect positive FX impact

- **Core OP: No Change**

(billion yen)	FY2022 Initial FCST	FY2022 Revised FCST	Change
Revenue	1,443.0	1,529.0	+86.0
SG&A expenses	598.0	642.0	+44.0
US XTANDI co-pro fee	182.0	186.0	+4.0
SG&A excl. the above	416.0	456.0	+40.0
R&D expenses	254.0	278.0	+24.0
Core operating profit (% of revenue)	290.0 (20.1%)	290.0 (19.0%)	-
<Full basis>			
Operating profit	269.0	269.0	-

Exchange rates for revised forecast:
137 USD/yen, 139 EUR/yen
(Forecast rates Q3/FY2022 onwards:
140 USD/yen, 140 EUR/yen)

FX impact: +115.5
XTANDI: US -39.7, ex-US +12.8,
PADCEV: +4.6, XOSPATA: -4.4, Evrenzo: -5.0
FX impact, decrease in US XTANDI co-pro fee

FX impact, increase in inventories related to
commercial production of zolbetuximab:
Approx. +6.0

FX impact: +21.5
(Increase in cost of sales ratio and R&D
expenses are factors for decrease in core
operating profit margin)



Next, on page nine, I'd like to explain our revised FY2022 full year forecast.

First, we reviewed our Forex rate assumptions and decided to use JPY140 against the US dollar and JPY140 against the euro for Q3 and beyond.

In our revised forecast, revenue is expected to increase to JPY1.529 trillion, up by JPY86 billion from the initial forecast announced in April. Forex impact is raising our revenue by JPY115.5 billion. So, in reality, this is a downward revision by about JPY30 billion.

As I explained on page six, we expect XTANDI's challenging market conditions in the United States to continue in Q3 and beyond. Sales forecast, excluding Forex impact, was revised downward. On the other hand, we made an upward revision for Europe and Japan, with performance higher than our assumptions.

SG&A costs, as a whole, are expected to reach JPY642 billion, up by JPY44 billion, mainly due to Forex impact.

US XTANDI co-promotion fees will decrease, along with the downward revision of sales forecast in the United States. But we slightly increased on a Japanese-yen basis due to Forex impact. R&D expenses will increase to JPY278 billion, up by JPY24 billion. According to our forecast, we factored in a Forex impact, an increase in inventories related to commercial production of zolbetuximab for about JPY6 billion. These factors could reduce the core operating profit, but partly due to positive Forex impact, we decided to keep JPY290 billion in our revised forecast.

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The core operating profit margin is expected to fall by 1.1 percentage point from our initial forecast. This is mainly due to an increase in cost of sales ratio, as well as a one-off factor, an increase in R&D expenses from an increase in inventories related to commercial production of zolbetuximab. Our full basis forecast remains unchanged, as there is no particular event beyond our expectations

AGENDA

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I Q2/FY2022 Consolidated Financial Results
FY2022 Revised Forecasts

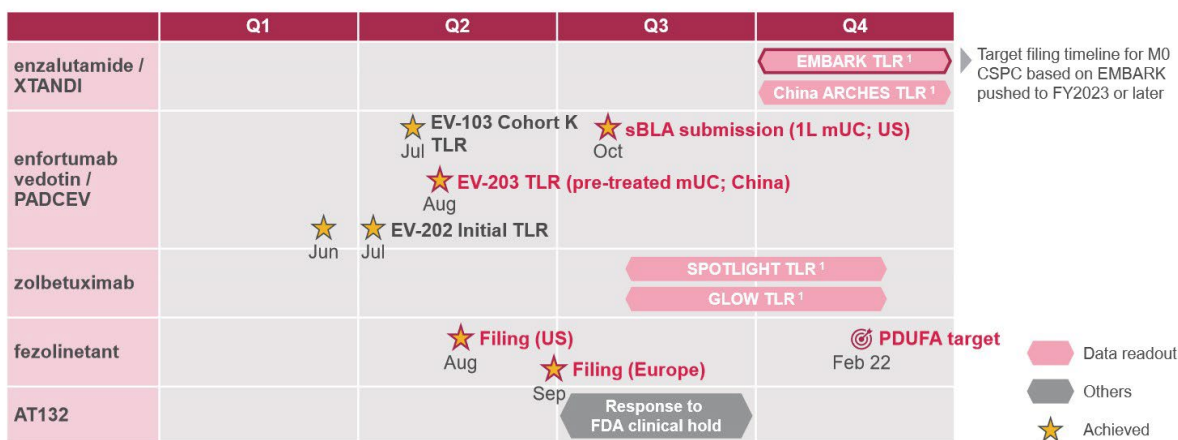
II Initiatives for Sustainable Growth



Page 10. Here's a description of our initiatives for sustainable growth.

XTANDI & STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2022

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1. The timeline of TLR is subject to shift due to its event-driven nature.
TLR: Topline results, M0 CSPC: Non-metastatic castration-sensitive prostate cancer, sBLA: Supplemental Biologics License Application, 1L: First line, mUC: Metastatic urothelial cancer, PDUFA: Prescription Drug User Fee Act, FDA: Food and Drug Administration, GEJ: Gastroesophageal junction



On page 11, we discuss the progress of key events expected in FY2022 for XTANDI and our Strategic products.

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Because the onset of events are happening later than originally anticipated, the expected timing of obtaining top line results from the EMBARK study has been moved to Q4. Accordingly, we expect filing in the following fiscal year or later.

Regarding PADCEV, based on the positive equity results of the EV-103 study, including Cohort K, we discussed with the FDA and submitted sBLA in October for an additional indication of first line locally advanced or metastatic urothelial cancer that are cis ineligible. In addition, we obtained positive results from our bridging study in China in treated metastatic urothelial cancer.

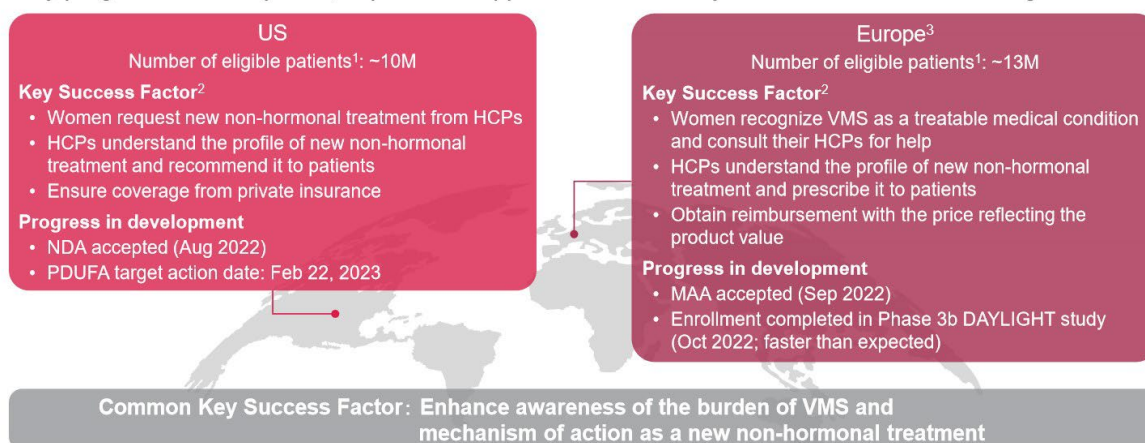
The application for fezolinetant was accepted for review in the US in August, and the FDA has set the PDUFA target date, February 22 next year. The filing in Europe for fezolinetant was also accepted in September.

Other updates include the fast track designation granted from the FDA for XTANDI for the treatment of MO CSPC and zolbetuximab for the treatment of gastric and GEJ adenocarcinoma. We look forward to further accelerating the development of these components and the timing of the duration until the launch will be shortened.

FEZOLINETANT: KEY SUCCESS FACTORS AND LATEST STATUS IN US AND EUROPE

12

Steady progress of development, important to approach different Key Success Factors in each region



1. Moderate to severe VMS associated with menopause, for 2030 (Source: Global impact of vasomotor symptoms 2020 VMS epidemiology). 2. Key success factors after approval. 3. Germany, France, Italy, Spain, UK. HCP: Healthcare professional, VMS: Vasomotor symptoms, NDA: New Drug Application, PDUFA: Prescription Drug User Fee Act, MAA: Marketing Authorization Application

On page 12, I described the key success, factors, and development progress for fezolinetant in the US and in Europe, where we have submitted filings. It is estimated that there are approximately 10 million patients with moderate to severe VMS who are eligible for fezolinetant in both the US and Europe. In the case of Europe, it's about 13 million.

In both markets, we believe it is important to raise awareness of VMS and to promote fezolinetant hormonal properties, but there are differences in the market environment. Based on the market research conducted by ourselves, we recognize that in the US, it is relatively easy for patients to communicate their intention for prescribed drugs to their physicians; and therefore, educating VMS patients to seek treatment with non-hormonal agents is an important initiative.

In Europe, on the other hand, the first important approach is to make sure that the patients recognize VMS as a treatable disease and actively go to their doctors for consultation.

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In terms of pricing and reimbursement, in the US, where the pharmaceutical companies can have the right to set the price, it is important to create an environment in which patients have optimal access to new non-hormone products through private insurance. Whereas, in Europe, where governments are involved in setting prices, the key to success is to obtain a reimbursement at prices that reflect the product value in each country.

The progress in development relating to reimbursement in Europe, the patient enrollment in the Phase IIIb DAYLIGHT study was completed faster than planned. For the SKYLIGHT study, which was conducted for submission in the US and Europe, and the late-stage Phase II STARLIGHT study being conducted in Japan, both also completed enrollment earlier than planned, indicating that both healthcare professionals and patients participating in these clinical trials, are highly interested in nonhormonal treatment of VMS.

PROGRESS IN FOCUS AREA APPROACH (1/4): CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

(Red: Updates since the last financial results announcement)

Primary Focus	Biology/Modality/Technology ¹	Project	Current status	No. of projects aiming PoC by end FY25 ²
Genetic Regulation	Gene replacement (AAV)	AT132	ASPIRO study put on clinical hold by FDA in Sep 2021	4
	Gene regulation (AAV)	AT845	FORTIS study put on clinical hold by FDA in Jun 2022	
Immuno-Oncology	Checkpoint	ASP1570	Phase 1 study ongoing	12
	Artificial adjuvant vector cell (aAVC)	ASP7517	Phase 2 study in R/R AML and MDS ongoing Phase 1 study in advanced solid tumors ongoing	
	Oncolytic virus (intratumoral)	ASP0739	Phase 1 study ongoing	
	Oncolytic virus (systemic)	ASP9801	Phase 1 study ongoing	
	Bispecific immune cell engager	ASP2138 ASP2074	Phase 1 study ongoing Phase 1 study to start in Q4 FY2022	
	Cancer cell therapy (UDC)			
	Cell replacement	ASP7317	Screening and enrollment in Phase 1b study restarted in Aug 2022	
Blindness & Regeneration	Cell replacement (UDC)			3
	Gene regulation (AAV)			
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	Phase 2/3 study in PMM ongoing Additional screening activity discontinued in Phase 1b study in DMD	4
	Mitochondrial stress	ASP8731	Phase 1 study ongoing. Orphan drug designation granted by FDA in Sep 2022	
	Mitochondrial transfer			
Targeted Protein Degradation	Protein degradation	ASP3082	Phase 1 study ongoing	1
Primary Focus Candidate	Immune modulating/regulatory cells			-
	Tissue-specific immune regulation			-
Total				24

Modality

- Small molecule
- Antibody
- Gene
- Cell
- Other

13

1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Oct 2022)
PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell, FDA: Food and Drug Administration, R/R: Relapsed and refractory, AML: Acute myeloid leukemia, MDS: Myelodysplastic syndrome, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy

On page 13, I would like to explain about the progress made in the Focus Area Approach.

The progress during the quarter is shown in red. In immuno-oncology primary focus, ASP2074 is scheduled to enter Phase I trials in January and March for the bispecific immune cell engager. The details of the target molecule are not disclosed at this time, but it will be disclosed at an appropriate time in the future. This is the second project to enter clinical trials in the focus area approaches in the bispecific antibody. And we intend to continue to create subsequent projects based on the concept of the Focus Area Approach.

In the cell therapy program, the screening of ASP7317 clinical study was restarted in August.

In ASP0367, our metal mitochondrial primary focus, additional screening activity was discontinued in the Phase Ib study in DMD. The reason for this decision was not that safety issues were observed, but that it was more difficult than expected to enroll patients in the study and to obtain sufficient data for analysis, even if the study continued as it is. We will consider the future development strategy in DMD after analyzing the available data. We are going to let you know about the things that will happen afterwards.

ASP8731 received the orphan drug designation from the FDA for the treatment of sickle cell disease in September. In addition, we have selected targeted protein degradation, which had been a primary focus

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candidate, as our fifth primary focus. The details will be explained in the following slides on page 14 or afterwards.

Targets that are difficult approach with ordinary compounds are cold, as undruggable targets. In this primary focus, we approach undruggable targets by utilizing the ubiquitin-proteasome system and intrinsic proteolytic mechanism as an approach.

As you see on the right picture, the new modality consisting of three more traits, one that binds to the target protein, and one that induces degradation on the linker that binds them together, was created to establish a series of technology platform.

We believe now we can continuously generate promising assets from the technology platform, and we will proactively invest the resources to the primary focus to continuously create programs in oncology and extend it into non-oncology fields as our Primary Focus.

PROGRESS IN FOCUS AREA APPROACH (2/4):
NEW PRIMARY FOCUS “TARGETED PROTEIN DEGRADATION” (1) 14

Primary Focus “Targeted Protein Degradation”

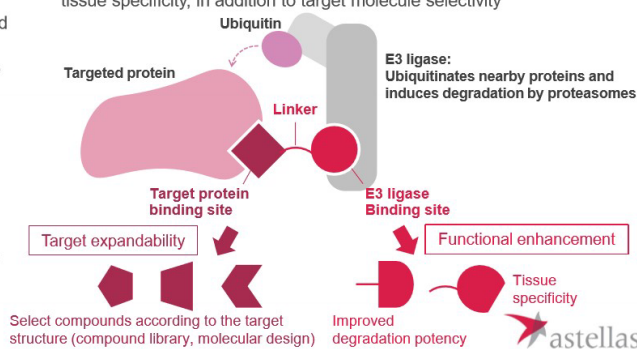
- Utilizes the ubiquitin-proteasome system, an intrinsic proteolytic mechanism, as an approach to access undruggable targets
- New modality consisting of three moieties, one that binds to the target protein and one that induces degradation, and a linker that bridges them (see right figure)
- Established a technology platform for creating protein degrader
- Created a lead program ASP3082 (KRAS G12D degrader) and advanced to clinical trial stage. Multiple follow-on programs under creation
- Proactively invest resources to the Primary Focus to continuously create programs in oncology and extend it into non-oncology fields

Advantages of technology

- Positioned as the most promising modality/technology at Astellas to approach intracellular undruggable targets
 - **Applicable to a wide range of targets:** Promotes degradation as a catalyst rather than inhibitory effect based on strong binding => Effective even with lower binding affinity than conventional molecules (fewer restrictions on binding sites)
 - **Retain advantages of small molecules:** Possibility of systemic administration (incl. oral), established manufacturing process and regulation, etc.

Applicability and expandability

- Applicable to various targets without conversion of target protein binding sites. Proteins without enzymatic activity (transcription factors, scaffold proteins, etc.) can be targeted
- Optimization including E3 ligase binding site and linker enables creation of compounds with enhanced functions such as degradation efficacy and tissue specificity, in addition to target molecule selectivity



KRAS: Kirsten rat sarcoma viral oncogene homologue

Next, I talk about the advantages of this technology. The first characteristic is that it can be applied for wider targets. It has a strong binding to the target for the direct inhibition. That is not what this mechanism has. It is serving as the catalyst to promote the degradation of the target. Therefore, it does not require high binding affinity, like conventional modalities, and is expected to be effective against target proteins that now have a structure suitable for compound binding, such as shallow pockets.

Second, because of its physical properties as a low molecular weight, it can be administered systemically, including orally and conventional established methods, and knowledge can be applied to its manufacturing process and regulatory compliance matters.

Next, I will explain the applicability and expandability of this technology. On the right picture, the left part of the figure binds to the target protein. By replacing this part, the technology can be applied to a wide variety of targets.

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The right side binds to E3 ligase and is involved in inducing degradation. By modifying this site or the structure of the linker, we can aim to enhance the efficacy and tissue specificity of degradation. We believe that this new modality could be an innovative therapeutic tool, and we aim to create a program continuously to address previously undruggable target proteins by converting targets or further improving function.

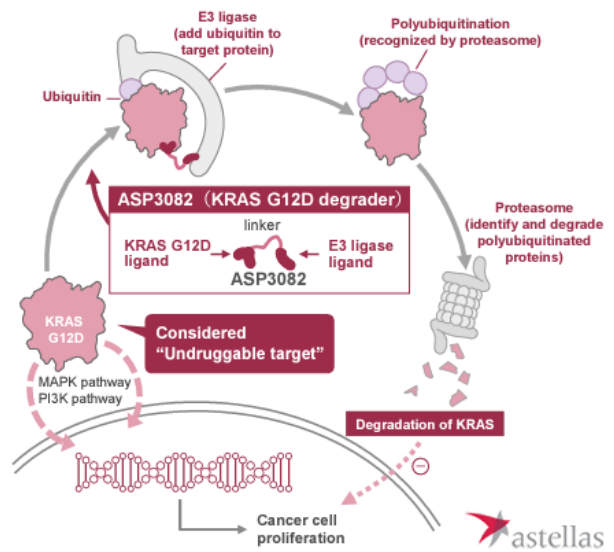
PROGRESS IN FOCUS AREA APPROACH (3/4):
NEW PRIMARY FOCUS “TARGETED PROTEIN DEGRADATION” (2)

Lead program ASP3082

- KRAS has been considered an undruggable target with less druggable pockets, making it difficult to develop inhibitors
- Multiple types of KRAS mutations are known
 - G12D mutation occurs most frequently: More than 51,000 new cancer cases annually in the US¹
 - Inhibitors for G12C mutant have been developed which covalently bind to highly reactive cysteine residue
 - Difficult to create compounds that bind tightly to G12D mutant



- ASP3082 is a protein degrader targeting KRAS G12D mutant



¹ Cancer Discov 12:924 (2022)
KRAS: Kirsten rat sarcoma viral oncogene homologue, MAPK: Mitogen-activated protein kinase, PI3K: Phosphatidylinositol-3 kinase

Page 15. Here, I will explain the details of ASP3082, the lead program for the targeted protein degradation as a supplement to the previous financial results presentation.

As shown in the figure, on the right, ASP3082 has the mechanism to bring the target protein, KRAS G12D mutants and E3 ligase into close proximity, and the E3 ligase ubiquitinate the KRAS G12D mutant.

The ubiquitinate of the KRAS G12D mutant makes it more easily recognized by proteasomes, which are enzymes that selectively degrade proteins and Proteasome degrader KRAS G12D mutants. Tests by degrading KRAS, a major factoring cancerous proliferation, it is expected to have an inhibitory effect on cancer cells.

The KRAS mutation, the target of ASP3082, is widely known to be involved in cancer development, but because of the lack of suitable pockets and sites for compound binding, it is regarded as an undruggable target, making it difficult to develop inhibitors.

Among the many mutations, the G12D mutations frequently and occurs approximately in more than 51,000 new cancer cases per year in the United States.

A small molecule inhibitor for the G12C mutant, another type of mutation is already on the market. G12C mutation has highly reactive sites called sustaining residues. And with the tight binding to the side, it is believed to inhibit KRAS function.

On the other hand, in the case of G12D mutant, which does not have such a site, it is believed to be difficult to create compounds that bind tightly here. ASP3082 is expected to be an innovative therapeutic approach to inhibit the function of KRAS G12D mutants as a pertained degrader.

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In order to further deepen your understanding of this primary focus, we are planning to hold an R&D meeting on December 9, where our representative will provide a comprehensive explanation. We look forward to your participation.

PROGRESS IN FOCUS AREA APPROACH (4/4): STRATEGIC INVESTMENT WITH TAYSHA GENE THERAPIES

16

Strategic investment with Taysha to expand gene therapy pipeline

Overview of agreement

- Investment of \$50 million in total
 - 15% of the outstanding common stock of Taysha
 - One Board observer seat on Taysha's Board of Directors
 - Exclusive option to obtain exclusive license for two of Taysha's programs (TSHA-102 and TSHA-120)
 - Certain rights related to any potential change of control of Taysha

Strategic significance

- Taysha's strengths
 - Possesses multiple gene therapy programs in CNS
 - Employs AAV9, a clinically proven vector
 - Employs intrathecal dosing which avoids high systemic exposure
- Expand pipeline in CNS genetic diseases
- Possible to utilize the new manufacturing facility in Sanford, North Carolina

TAYSHA
GENE THERAPIES

CNS: Central nervous system, AAV: Adeno-associated virus, MeCP2: methyl CpG binding protein 2, FDA: Food and Drug Administration

TSHA-102

- Target disease: Rett syndrome
 - Severe genetic neurodevelopmental disorder, mostly in females
 - Estimated incidence: 1 in 10,000 female births
- Mechanism of action: *MECP2* gene replacement
- Development phase: Phase 1/2
 - Preliminary clinical data from adult study expected in 1H 2023
- Timing of option exercise: After receipt of preliminary clinical data from pediatric study (to be initiated following the report of preliminary clinical data from adult study)

TSHA-120

- Target disease: Giant axonal neuropathy (GAN)
 - Progressive, ultra-rare neurodegenerative disease
- Mechanism of action: *gigaxonin* gene replacement
- Development phase: End-of-Phase 2
 - Positive motor function improvement and safety data obtained
- Timing of option exercise: After receipt of FDA Type B meeting minutes (Jan 2023)

 **astellas**

Page 16. I would like to explain strategic investment with Taysha announced the other day. Under the terms of the agreement, Astellas will invest a total of USD50 million to acquire 15% of the outstanding common stock of Taysha. One Board observer seat on Taysha's Board of Directors, an exclusive option to obtain exclusive license for two of Taysha's programs, as well as certain rights related to any potential change of control of Taysha. Taysha possesses multiple gene therapy programs in CNS.

It uses AAV9, a clinically proven vector; and in traffic, our administration is adopted as the route of administration to improve the balance between efficacy and systemic exposure. This investment gives us the potential to expand our pipeline in its genetic diseases in addition to our existing muscle-related diseases.

In addition, Astellas's new manufacturing facility in Sanford, North Carolina is capable of manufacturing AAV9. This service manufacturing technology is a major factor that led us to this mutually complementary partnership with Taysha's promising pipeline.

On the right side of the slide, I will discuss the two programs that are the subject of these exclusive licenses.

TSHA-102 targets Rett syndrome, which is a severe genetic neurodevelopmental disorder happening mostly in females, and it replaces the mutated *MECP2* gene. Currently, it is on the stage of Phase I/II clinical trials, with preliminary clinical data from adult study expected in H1 of 2023. The timing for exercising the option will be after receipt of the preliminary clinical data from the pediatric study, which will be initiated following the report of preliminary adult data.

TSHA-120 targets GAN, or giant axonal neuropathy, which is an ultra-rare progressive neurodegenerative disease, and it is designed to replace the mutated *gigaxonin* gene.

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 **SCRIPTS**
Asia's Meetings, Globally

Currently, Phase III trials have been completed and a positive data have been obtained in terms of motor function improvement and safety. A type meeting with the FDA based on the study will be held in December of this year. And the minutes of the meeting are scheduled to be received in January 2023 based on which we will consider exercising our option wise. While we continue to actively consider partnering by leveraging our capabilities to accelerate the development of gene therapy and expand the pipeline.

PROGRESS TOWARD ACHIEVING CSP2021

17

Revenue, Pipeline Value

- 1** XTANDI and Strategic products: \geq ¥1.2T in FY2025
 - ✓ XTANDI: Sales in the US were below expectations, offset by strong performance in Europe and Japan
 - ✓ PADCEV: Global sales growth exceeding expectations. sBLA submitted for 1L mUC in the US
 - ✓ fezolinetant: Regulatory submission accepted in US and Europe

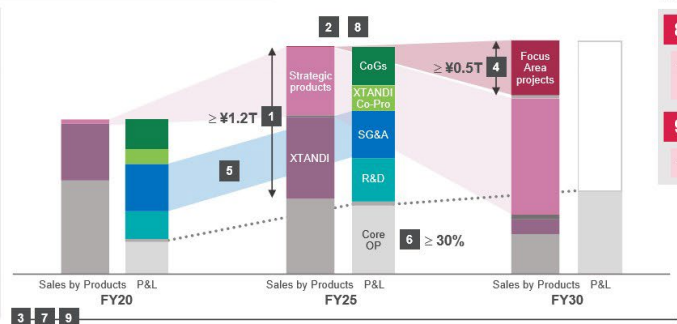
- 2** Post-PoC projects from Primary Focuses
- 3** Multiple technology platforms
- 4** Focus Area projects: \geq ¥0.5T in FY2030
 - ✓ ASP2074: Phase 1 entry
 - ✓ ASP7317: Phase 1b study restart
 - ✓ Launch Primary Focus "Targeted Protein Degradation"
 - ✓ Gene Therapy: Strategic investment with Taysha

Core OP

- 5** Flat SG&A in absolute terms
 - ✓ SG&A expenses controlled in line with full-year forecast, decreased YoY when excluding FX impact
- 6** Sufficient R&D investments
 - Core OP margin of \geq 30% in FY2025
- 7** Steady increase in dividends

Future growth

- 8** Rx+: Breakeven by FY2025
 - ✓ ASP5354: Initiation of Phase 2 study for additional indication
- 9** Sustainability
 - ✓ Integrated Report 2022 released



Strategic products: PADCEV, XOSPATA, zolbetuximab, EVRENZO, fezolinetant, AT132
 CSP: Corporate Strategic Plan, sBLA: Supplemental Biologics License Application, 1L: First line, mUC: Metastatic urothelial cancer



Page 17. This summarizes the progresses made in H1 of the current fiscal year toward achieving CSP2021.

In XTANDI, left above, sales in the US were below full year forecast or initial forecast, but were offset by strong sales in Europe and Japan and progress was in line with the initial forecast. PADCEV showed better-than-expected growth globally, and sBLA was submitted for the first-line metastatic urothelial cancer, an important growth driver for us.

For fezolinetant, we achieved an important milestone with acceptance of regulatory submissions in the US and Europe. The Focus Area Approach, left bottom, in addition to the development of individual projects, activities to further expand the pipeline, such as the launch of new primary focus, and the strategic investment progressed.

In terms of core OP, right upper, we continue to thoroughly review costs, while securing proactive investments for new product launches, and SG&A expenses, excluding the impact of exchange rate fluctuations, decreased YoY

In our Rx+ program, which was not discussed today, we have initiated a Phase II study of ASP5354 for lymph node mapping, prior to cancer resection surgery, with the aim of expanding the indication. In terms of sustainability, we have released Integrated Report 2022. The report presents an easy-to-understand manner our medium to long-term goals, or the way we would like to be, as well as the initiatives and progress for the goals. If you have not yet read the report, please take a look at it, and feel free to contact our IR group with your comments and feedbacks so that we can make improvements in the coming fiscal year and beyond.

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R&D Meeting

➤ Dec 9th 2022, 10:00-11:30 (JST)

Sustainability Meeting

➤ Feb 17th 2023, 14:00-15:30 (JST)



Page 18. This is the last slide for today.

Here's a schedule of upcoming events. The R&D Meeting will be held on December 9, as previously mentioned. Sustainability Meeting will be held on February 17. I hope you will join us.

That is all I have to say here today.

Thank you so much for your attention.

Ikeda: That's all about our presentation.

Next, we'd like to entertain your questions.

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Question & Answer

Ikeda [M]: You can ask questions only through Zoom webinar. You cannot ask questions through live streaming. If you have a question, at the bottom of the Zoom screen, there is a raise hand button, so please press it. If you're joining from the smartphone, if you tap the details, raise hand will be shown, so please press that bottom. The MC will name you, so please unmute yourself on your Zoom screen, and please mention your name and affiliation, and then ask questions, please.

Thank you for waiting. First, Citi Group Securities, Mr. Yamaguchi, please. Mr. Yamaguchi from Citi group Securities, you may on mute. Please unmute yourself.

Yamaguchi [M]: Yes. I have two brief questions. First, the foreign exchange rate changes. Q1 results, last year's figures have not been changed. In Q2, you are making a revision. No changes in Q1, but you are eliminating the impact of the Forex impact on Q1 and Q2, and you are eliminating all these impacts in Q2, all at once, correct?

Kikuoka [A]: If you look at page 21 in the presentation material, as I showed here, with an auditing firm, we discussed, this does not constitute a change in the accounting policy. So, as you said, we didn't restate our historical statements. Not really all at once, but in Q2, in the account settlement for the April to September period, we decided to introduce the system. So, the Q1 numbers have not been changed.

What is the meaning of this table? In FY2021, or we can go back if we want. But the impact was not so big in some years. So, if we were to follow this method from Q1 of last fiscal year, what would be the core operating profit? The red portions are explaining that question.

What is the difference compared to the numbers announced already? That's shown on this page. As you see here, in Q2, in the current fiscal year, from the six months account settlement, if you deduct Q1 from the April or September period, that is the figure. Up to Q1, the yen continued to depreciate, so JPY4.5 billion for Q4, as we said before, JPY12.8 billion, as we announced. The JPY12.8 billion figure is included in Q1. Because you are deducting that figure, Q2 is plus/minus zero.

JPY77.3 billion, minus JPY12.8 billion. That figure is the appropriate number. Sorry, rather than JPY77.3 billion, the higher figure, by deducting the figure for Q1, if you look at Q2 figure, just appropriately, JPY77.3 billion is the correct figure for Q2.

Do you have a clear understanding?

Yamaguchi [Q]: Yes. Next question, fezolinetant. Today, you introduced as key success factors. The situation is well understood. So, as a community, while the level of the success in the United States, that is going to be one important key factor to consider the success of this product. But next fiscal year, well, the approval is going to be a melk maar. And after that, you are ready to go. Next fiscal term should be asked in the next fiscal term, but sales-wise, this will contribute.

Well, you will make an investment, but the sales will be increased. I think that's your forecast for the preparation. Is this understanding right?

And also, considering the Western countries, I just wonder if the penetration rate will be higher in the United States compared to Europe.

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Yasukawa [A]: Thank you for the question. Around the end of the fiscal year, the detailed number is planned to be explained. And still, it's under review. Therefore, the pricing forecast, that is something we rather refrain ourselves from explaining.

And the target in the United States next year is about the mid triple digits, hundreds of millions. Therefore, I would like to refrain on talking about the further details.

Yamaguchi [Q]: The triple-digit millions of yen of the middle is around JPY50 billion. That's between 100 to 1,000, right?

Yasukawa [A]: Yes. That's right.

Yamaguchi [M]: Thank you very much.

Ikeda [M]: Next, Mr. Kohtani from Nomura Securities, please.

Kohtani [M]: Kohtani from Nomura Securities. First, a very simple question. Continuously XTANDI patient assistance program and the Zytiga Generics product leader is your competitor. In Q3, it's growing in the United States. So, it seems that competitive products are taking market share away from you. Is that correct?

And the diagnosis rate of the prostate cancer is declining. Is that rising now?

If nothing has changed, according to forecast XTANDI in the United States may not grow so much. There's another study which will be coming to an end. But other than that, it may not grow as is.

Yasukawa [A]: We are behind Zytiga in terms of the market share because of the rapid inflation and economic slowdown or recession. Not all patients are economically rich. So cheaper Zytiga generics may be the drugs they want. And some patients, or more patients are using PAP according to assumptions.

So, this tendency will continue. Given the current economic conditions, this tendency is expected to continue in our view. On the other hand, competition against the new products, we are not behind, according to analysis.

Patients who are newly diagnosed, we are looking at various statistics. It's slightly increasing as a trend, but it's not returned to pre-COVID-19 levels yet. That's our understanding based on the statistics. COVID-19 is coming to an end, and now, there is almost no impact of the pandemic. But in the past 2.5 years, patients who were under diagnosed. Risk factors overlap between COVID-19 and prostate cancer. We cannot calculate the numbers. Some patients, unfortunately, might have passed away by now. Those who are still alive in the COVID-19, it does not mean that they would not develop prostate cancer. And because of the underdiagnosis, they would progress, and they would come back to the market.

Regarding this return of the patients, how sales force will approach these occasions to gain the business. That's going to be the key. As I said during the presentation, already in the United States, close to 10 years have passed since the launch in the United States, considering the situation in the US society, untapped market does not remain much. For the past 2.5 years, there has been underdiagnosed patients, and that may be an untapped market for us.

Kohtani [Q]: Next, on fezolinetant, as you say, to a certain extent, penetration will be quite fast because globally, 10% of the patients are not indicated for hormonal therapy. So, there can be a depreciation among those patients, but this is just 10%, it's just around JPY200 billion. And about 50% of the patients, they have to be careful about hormonal therapy BMI, therapy, or all higher or hypertension, or dyslipidemia, or diabetic diabetes.

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What do you think about the ramp-up in these patients? Are you expecting an increase in one step or two steps? You go into the initial patient population and then gradually, it's going to expand. Is that the image you have? This is my last question

Yasukawa: Today, Matsui is absent. I don't know further details about marketing strategies. So, when Matsui is attending, we'd like to explain further details.

Kohtani [M]: Understood. Okay. Thank you very much.

Ikeda [M]: Thank you very much. Next, Credit Suisse, Mr. Sakai, please.

Sakai [Q]: Credit Suisse Securities Sakai speaking. First question, the commercial inventory production of zolbetuximab has increased. Therefore, you increased R&D costs for this as well. What is the current status for zolbetuximab with the revised forecast? I would like to know your outlook. That's the first question.

Second question is about fezolinetant. Will an adversary committee be held or not? That's what I want to know. The notification will be probably three months or three months before the PFUDA date. But what kind of communication are you having with FDA, or no communication?

Yasukawa [A]: The first point, let me answer the first question. And Taniguchi is going to talk after.

The first question about the zolbetuximab. As you know, the two Phase III studies are ongoing. If you refer to slide 11, the result is going to be available soon. For example, fezolinetant's 12-month administration or four weeks administration, that is not the case for zolbetuximab's clinical study. This is an event-driven study, the accumulation of the event is the key. We cannot predict the details when the top line result will come out. That's why we have these bars from the late Q3 of this fiscal year to the middle of the next year, Q4. So, some point around this time, we believe that we can communicate with you the result. That's the response to the first question.

The second question is going to be answered by Taniguchi-san.

Taniguchi [A]: Thank you. There is a question about the submission status of the fezolinetant in the US. With the US FDA, day-to-day basis, we have very close communication. The data is very clear. We have great confidence in the data we submitted.

So currently, US FDA Advisory Committee is not expected to be held. So far, things are ongoing in a smooth manner. So far, the discussion after submission is going well without any problems. Thank you very much.

Sakai [Q]: Thank you. One more additional question about Taysha. With your investment with Taysha while Audentes's AT132 is still pending. Under these circumstances, AAV8 for that and Taysha's AAV9, there are some differences exist for different AAV. But in this area, your initiatives, and your activities in this field, if one is going to be successful, are you expecting that you will have consecutive successes one after another? How should we interpret this? Adeno virus used for gene therapy; this is very difficult. And you are making additional investments into Taysha. There can be some associated risks you have considered by now. So, from where you have decided to make strategic investments in Taysha, including your experiences with Audentes, could you explain, please?

Ikeda [M]: Okay. Shitaka would like to respond first.

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Shitaka [A]: It's the same AAV, but systemic administration into the blood and local administration are different things. Ophthalmology or Taysha are using a local administration, or also intrathecal administration. It's not a systemic administration. So, there would be a lower risk for liver side effects.

In that sense, those in the clinical stage, there are two programs for us, and we are using systemic administration. And what's different from that is a local administration. So continuously, it's the same AAVs, but there is a slightly different risk philosophy in here. From that perspective, we decided to advance Taysha's programs.

Kikuoka [A]: This is Kikuoka, I would like to add to that. As you know, biotech shares, of course, we took that into account because of the situation of biotech shares, and we decided to secure the rights to these two programs. We would like to minimize the risks in doing this in our investment. So, please take that into consideration as well.

In principle, in being opportunistic, we'd like to leverage these opportunities in a flexible manner, and that's why we are doing this. For investing in a listed company to secure the development rights, uniquely, we had this transaction. understood.

Sakai [Q]: In the R&D meeting on December 9, you're going to focus on gene therapies, correct?

Kikuoka [A]: In the R&D meeting on December 9, we're going to discuss the targeted protein degradation.

Sakai [M]: Thank you very much.

Ikeda [M]: Thank you. Morgan Stanley MUFG Securities, Mr. Muraoka, please.

Muraoka [M]: Good afternoon. This is Muraoka from Morgan Stanley.

Ikeda [M]: Thank you, please go ahead.

Muraoka [Q]: Sorry I haven't really read through the materials yet. So, my question might not be really pinpointed, but the generics of Lexiscan. Lexiscan's number, in dollars, there is no change in budget. But generic, it's already on the market or not?

And also, what is the precondition of the budgeting this time? And the budgeting up until last time, I think it was somewhat included in the forecast. But what about the designing this time? Would you please explain about that?

Yasukawa [A]: First of all, let me explain about the history of litigation from this May. And after that, Kikuoka is going to explain about the condition of the budgeting.

First of all, in May, the patent infringement litigation with the first instance, our appeal was not approved. So, we lost the case. Then in June, we appealed the case to the Court of Appeals for the Federal Circuit or CFAFC. And on top of that, to the District Court, which made the first instance, we appealed for a preliminary injunction, but that was rejected.

On the other hand, for the District Court in 2022, up until October 5, the preliminary junction order for the generic launch was now granted. And the September 27 CFC issued the temporary stay to Hospira that refrained themselves for launching the generics risk temporarily. Then October 28, only recently, CAFC entered an order extending a temporary stay through December 6, 2022. That's what's happened recently.

Of course, the situation is still ongoing. But by December 6, there will be no launch of the generics.

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Muraoka [Q]: And December 7 and afterwards, what would happen?

Company Representative [A]: Well, Hospira might launch the generics at risk. That's the current situation.

Kikuoka [A]: Regarding the budget, let me explain about it. This is Kikuoka speaking. As you mentioned, when we made budget for this fiscal year, we didn't change the forecast of the sales and the risk and opportunity within the overall sales of the revenue, we took this factor into consideration. But just like Yasukawa explained, our assumption in the beginning, of course, the result of this litigation is something that we need to wait. Compared to what we expected in the very beginning, there are lower risk for us. So compared to the past, the impact to this fiscal year is smaller.

Muraoka [Q]: I see. So, you reduced the portion that was partially included in the others. Is that right?

Kikuoka [A]: Yes, that's about it.

Muraoka [Q]: Understood. Thank you very much. One more question, if I could ask a question again regarding fezolinetant. Next fiscal year, you expect sales between JPY10 billion to JPY100 billion. Profit contribution by fezolinetant, we don't think there's going to be a contribution to profit in the initial year. But can it contribute to profit in the second year or the third year, and beyond? What should be the image we should have?

Kikuoka [A]: I would like to respond. As Yasukawa explained, it's difficult to communicate the details of the marketing strategy now. But as for the numerical image, we are discussing right now with the sales team.

From that perspective, the contribution to profit is in sight for the next fiscal year.

Muraoka [Q]: So, is it going to be work positively from the profit from the initial year? Is that within your scope or insight?

Kikuoka [A]: Yes.

Muraoka [Q]: You said that expenses in the next fiscal year, costs for legacy products such as mirabegron are being reduced. But at the same time, in the first year, fezolinetant is going to contribute to profit positively, while reducing costs for mirabegron and other products?

Kikuoka [A]: For legacy products, we will try to reduce the cost for those products. We also have PL for each brand. We're looking at, compared to the expenses used for education activities, based on the expected launch, sales promotion costs will increase. Even with that, profit contribution by an individual product could be a possibility. So, we are discussing based on that.

Muraoka [Q]: Understood. Sorry to ask again but partnering is insight? That's why you are thinking that there's going to be a contribution from the initial year?

Kikuoka [A]: No. No, that's not our assumption.

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

Ikeda [M]: Thank you. Next, Daiwa Securities, Mr. Hashiguchi, please.

Hashiguchi [Q]: This is Hashiguchi speaking. Thank you very much. Fezolinetant, you have the forecast and based upon that, next fiscal year's SG&A in total, what's your outlook? In these five years of CSP, SG&A is set as a flat and maintained in your plan.

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In the previous fiscal year, there's a bit of increase. But this time, excluding the foreign currency impact, you are trying to bring it back to the two fiscal years before level. But you explained to us the forecast of the cells. Considering that for mid- to long term, you can spend a lot, and still that is reasonable from a strategic perspective. So, what do you think about the possibility of that inflating a little bit tentatively?

Kikuoka [A]: As for SG&A, the strategy is similar with this fiscal year and also for the products that we mentioned. As we mentioned already, we are going to make a proactive investment. However, even that is taken into consideration. The factors of the currency, that is something we have to consider based upon the initial assumption. We do not think that there will be a bigger impact out of that.

But November and afterwards, we are going to work harder for the budgeting for next fiscal year. We need to communicate with the sales team as well, so that we can have a discussion for another opportunity of the revenue. If we can grow in certain areas, then we'll make a certain investment. Here, I cannot tell you any detailed number. But anyhow, there is no change about the policy of continuing the SG&A flattened as now.

Hashiguchi [Q]: I see. It's okay. But for SG&A for five years, well, so far, there was no change about the flattening it, right?

Kikuoka [A]: That is the current policy. And as has been explained repeatedly, we've done the proactive investment. We have to get the result out of that. So, now what we can do is the selection and consideration. We continue to make the necessary investments to be efficient.

Hashiguchi [M]: Thank you. That's all.

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

Ueda [Q]: Ueda from Goldman Sachs Securities. Initially, I'd like to ask you about the PADCEV. In the United States, if you look at the quarterly figures, Q2 figures look weak. But as Dr. Yasukawa mentioned, because of the coverage already for the second line, already, if there is any information about the inventory. Could you explain the first-line data disclosure, and any assessment in the clinical setting, or any change in how they use the drug?

Yasukawa [A]: In the United States, it's USD105 million. Before we showed you a long-term diagram. The first-line treatment and noninvasive will be boosted for the future. Then we would have the second rocket to be launched.

Recently, at academic societies, we are disclosing the data. What has been the reaction? Taniguchi-san, any information you may have?

Taniguchi [A]: Thank you. As you know, at ESMO, EV-103 study Cohort K was presented. There was a very good response. Their cisplatin-ineligible or intolerant. You see patient ORR was 64.5%, which is a very high response. So, there are high expectations about this data. With this, we had used this data to file a submission, first in the United States. We did file the submissions. In our discussions with doctors, there are higher expectations about this drug among the physicians.

Ueda [Q]: Understood. Thank you very much. Second question, it's about fezolinetant's line expansion of the indication. Bayer is working for the expansion of the indication for hot flash for the breast cancer patients.

So, Astellas as well, you're thinking about the expansion of the indication beyond the VMS, the hot flash, this NK-1, 3 receptor inhibitor. That's one thing and face a limited NK-3 receptor inhibition. So, when you think about these two types of the inhibition, what will be the difference?

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Yasukawa [A]: The first question, Taniguchi-san, could you answer the first question?

Taniguchi [A]: Thank you. The breast cancer indication is probably a question. Of course, as well as we also have a knowledge about the development situation of other companies.

Yasukawa [A]: Regarding the second question, what would the difference when one thing different is tapped on, what kind of difference would have happened so far? We don't have any doubt and information. So, I would rather not answer.

Ueda [M]: Understood. Thank you very much. That's all.

Ikeda [A]: The first question by Mr. Ueda, we don't have Matsui here, so I would like to add. Q1 and Q2 difference for PADCEV. Q1, temporary clinical order sales for JPY10 million was included in Q1. If you deduct this from the Q1 to Q2, you can see good growth. So that's something I wanted to add on behalf of the IR team. Thank you very much.

Ikeda [M]: JPMorgan, Mr. Wakao, please.

Wakao [Q]: Wakao from JP Morgan. Thank you very much. First, XTANDI, explain the details. Sorry to ask again. In the United States, those who are not diagnosed may contribute positively. On the other hand, if you look at the number of prescriptions, Zytiga generics are growing, XTANDI growth is slowing, or becoming flat. Considering the situation, the diagnosis may increase, but XTANDI may not necessarily benefit from that, as I felt. So, could you elaborate on this? In the United States, you already explained the situation. But what about Europe, similar things must be included in your assumptions for Europe, like the US? Zytiga generics already launched in the European regions as well. So, what is the impact?

That's my first question

Yasukawa [A]: Patients with under diagnosis, we cannot investigate the details of the economic conditions of the underdiagnosed patients. Patients who are not economically in good conditions may be diagnosed. When their disease is already progressing, it might be discovered at the time, they may go to cheaper generics. There is such a possibility. So, patients who would return may not necessarily receive the prescription for XTANDI. But still, we'd like to continue appropriate educational activities.

Then, for patients who would best fit for the XTANDI prescription, we would like to deliver the prescription drug to them. That is appropriate activities. Underdiagnosis is continuing in the United States, and economic conditions right now, would you intensify the competition against generics right now.

Similar signs, not only in Europe, but in other regions globally. In the quarterly meeting, I asked this question to salespeople at such a meeting. There are no clear signs according to their reply. For the time being, we don't have clear signs, but continuously, we'd like to pay attention and watch it carefully.

Wakao [Q]: Thank you very much. Second, the last question about fezolinetant. The other day, in the meeting, I got a very good understanding and understand the status of the potential patients. But ICER draft version is currently available. And if I refer to that, regarding the safety, with the long-term usage, there might be the risk regarding safety. Especially for those over 60 years old, the risk might go up. So, the risk just you explained is not covered by the ICER draft version. So, I feel a bit of the gap existing here. How do you view?

Well, it's ICER. So, that's about for the reduction of the cost. Therefore, the way of the description might be quite conservative. But what's your opinion about this as a draft version?

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Ikeda [A]: I am Ikeda speaking. Regarding ICER, well, that is independent or reported by themselves. So, we don't have any clear stance position for their view. I'm sorry I couldn't answer you some clear answers.

Wakao [Q]: I see. So, you do your own analysis and study, right?

Ikeda [A]: So, for the safety, we have a Skylight 4. Result is available with the comparison to placebo, and the safety requested by the authority is secured to such a great extent. So that is our position.

Wakao [M]: Thank you very much. That's all.

Ikeda [M]: Next, Jefferies Securities, Mr. Baker, please. You may be on mute. Please unmute yourself.

Barker [Q]: Stephen Barker from Jeffrey Securities. Thank you very much. Fezolinetant, sales in the initial year is my question. As you said, JPY10 billion, somewhere between JPY10 billion, to 100 billion could be achieved. But could you be more specific regarding this number?

Yasukawa [A]: Thank you for your question. What I mentioned earlier is the middle of the three-digit Oku yen, it's not like you can do away with JPY10 billion or JPY99 billion, but somewhere in the middle in that range.

Barker [M]: Okay. Thank you very much. That's all for me.

Ikeda [M]: Thank you. From the media, we have received a question, Nikko Biotech, Ms. Kubota, please.

Kubota [Q]: Two questions about gene therapy that you touched upon at the very end. In your explanation AAV can be also produced in your new production site in the US. So, this production capability of GMP production of AAV is something looked for by the Taysha, and you have it. That's why you came to this investment, or your production capacity may be also made use of through this investment as well?

Shitaka [A]: Thank you for the question. Taysha, well, our GMP production site in Sanford, that is where also Taysha having great interest. That's one of the reasons why we were selected. So, the investigational product and also the production size, those are what Taysha does not have. Probably, they are outsourcing for such process. However, for the commercial production, if the approach will be continued, or their partnership with us, so that we ourselves can produce the products. I think that's what currently they are thinking.

Kubota [Q]: Thank you. One more question about this investment partnership. To control the overexpression of the trans gene, they have the technology program. Is there any possibility of using this for your systemic administration programs of Astellas?

Shitaka [A]: You're talking about the TSHA-102 is using the miRARE platform to control the overexpression of the genes. And MECP2 gene is half. You'd like to regain one. There are duplications of the gene in other diseases, it should not be true. So, there should be a feedback mechanism to make it always one. Such a mechanism is entailed. Similarly, if there is a need for a similar thing in the genetic diseases, a similar technology might be required.

Kubota [M]: Thank you very much. That's all for me. Thank you.

Ikeda [M]: Thank you very much. Next will be the last question. Tokyo Tokai Research Center, Mr. Akahane, please.

Akahane [Q]: Can you hear me? Thank you very much. The first question, that's about the business in China. Greater China sales that is on a progress smoothly 36% increase, and there's an increase in the plan as well.

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But 80% is Prograf that is contributing to this increase. But as you know, in China, there's an issue of COVID-19, and also their own program for purchasing. And there's the case that only the richer people can get the benefit of the treatment. But overall, how do you view the Chinese business?

Yasukawa [A]: Thank you. Yasukawa is going to explain first of all, and Kikuoka will make a supplement comment if necessary. It's been more than 30 years since we started business in China. For a longer time, Prograf and tamsulosin dependent business is what I've been doing there.

But of course, only these two products will not make us to further expansion, rather shrink, especially tamsulosin, there is no future expansion. Prograf might be survived for a certain period of time. So that's one thing.

The percent in mid-2010 and afterwards, the foreign companies for China, meaning us. And towards them, they opened the door. That's a big change of their policy. And also, their economy is enriched currently and also iPhone and such communication measures, although there is still certain restrictions, but they can get the information about the treatment taking place in overseas.

So, in Western countries and Japan, the treatment available, that market is not available in the Chinese market. If that is lined by the national public, that's going to be the risk for the Communist regime. So, in China, it's not approved, but as long as it is a superior product, they are going to grant approval immediately.

Next, we will be looking at China. Therefore, we enhanced the development group in China. XOSPATA, XTANDI, we've been doing even before this. So, it took time. But XOSPATA and afterwards, in the Western advanced countries, we are trying to shorten the interval, so that we can launch the kind of products in the Chinese market soon.

So XOSPATA, PADCEV, as well. We have the bridging study for China that made a success. Zolbetuximab, that is for gastric cancer, Southeast Asian countries, the gastric cancer prevalence is really high. So, we are aiming at the development even from the beginning in China. So Prograf, tamsulosin, such condition drugs are going to be replaced, especially with the area of oncology.

Akahane [M]: Thank you. I understood very well.

Kikuoka [A]: May I add? Regarding Prograf, you asked the question. So let me add. As you said, Greater China is growing, a little less than JPY6 billion. We have Prograf in China. At the end of FY2021, due to COVID-19, Shenyang factory, we were shut down. The market inventory, it was depleting. And because of the resumption, the shipment increased. There were some special factors behind. Please take that into consideration as well.

Akahane [Q]: Understood and the last question. Sorry to ask again, but fezolinetant, on page 12, in the US and Europe, the expression is slightly different in prescription to patients. Hot flash, there is an ethnic difference, and also whether to see this as a disease or not, there may be some cultural differences in the markets.

My point is that, in expanding this, there may be a lot of costs required for education activities. In China, it was not so successful, but how should I see this for the future in China?

Yasukawa [A]: Today, we don't have Matsui. In Europe, how much the patients are aware of this? We cannot give you a concrete explanation today. So, we'd like to do this next time to explain by Matsui or from Corporate Communications.

In China, as you know, China, Korea, and Taiwan, we had a study there, and endpoints set for the study were not met. In China, 30 milligram, we had a study up to 30 milligrams in China. The 45 milligram is submitted in

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Europe and the United States only. So, using all the data from our Western countries, we cannot file our submissions using that data only.

According to that adjudgment, the team is now considering the next program. Once we have further discussions, and are ready to announce the next plan, we'd like to explain the details to you.

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

Ikeda [M]: Thank you very much. Time is up. So, with this, we'd like to close today's explanatory meeting here.

Thank you very much for your attendance today.

[END]

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1. *Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.*
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