



**Astellas Pharma Inc.**

Financial Results for Q3 of FY2021

February 2, 2022

## Event Summary

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<b>[Company Name]</b>	Astellas Pharma Inc.	
<b>[Company ID]</b>	4503-QCODE	
<b>[Event Language]</b>	JPN	
<b>[Event Type]</b>	Earnings Announcement	
<b>[Event Name]</b>	Astellas Pharma Inc. Financial Results for Q3 of FY2021	
<b>[Fiscal Period]</b>	FY2021 Q3	
<b>[Date]</b>	February 2, 2022	
<b>[Time]</b>	16:00 – 17:23 (Total: 83 minutes, Presentation: 39 minutes, Q&A: 44 minutes)	
<b>[Number of Speakers]</b>	4	
	Naoki Okamura	Chief Strategy Officer and Chief Financial Officer, Chief Business Officer
	Yukio Matsui	Chief Commercial Officer
	Minetake Kitagawa	Senior Vice President, Development Project Management Head
	Ikuno Fujii	Head of Corporate Advocacy & Relations
<b>[Analyst Names]*</b>	Hidemaru Yamaguchi	Citigroup Global Markets Japan Inc.
	Kazuaki Hashiguchi	Daiwa Securities Co. Ltd.
	Fumiyoshi Sakai	Credit Suisse Securities (Japan) Limited
	Akinori Ueda	Goldman Sachs Japan Co., Ltd.
	Seiji Wakao	JPMorgan Securities Japan Co., Ltd.
	Shinichiro Muraoka	Morgan Stanley MUFG Securities Co., Ltd.

\*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

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### Document Notes.

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.*
2. *This document has been transcribed based on interpreted audio provided by the Company.*

## Presentation

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**Okamura:** Good afternoon, everyone. Naoki Okamura from Astellas Pharma Inc. speaking. Thank you very much for joining our FY2021 Third-Quarter Financial Results Announcement meeting. It will be a 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.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.



Page two is a cautionary statement regarding forward-looking information.

As this was explained by Fujii earlier, I'm not going to read this slide.

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# AGENDA

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I Q3/FY2021 Consolidated Financial Results

II Initiatives for Sustainable Growth



Page three is the agenda for today.

First, I will explain our FY2021 third-quarter financial results.

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## Q3/FY2021 FINANCIAL RESULTS: OVERVIEW

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*Revenue increased 6% YoY and is in line with full-year forecast*

*Core OP increased 8% YoY and is above full-year forecast*

- Sales of XTANDI and Strategic products increased more than 20% YoY, in line with ambitious full-year forecast offsetting sales decrease due to termination of sales and distribution / transfer of products
- SG&A expenses are slightly above full-year forecast  
R&D expenses are on track
- Gain on divestiture of intangible assets\*: 24.1 billion yen  
Established a new account, which includes gain on sale of rights of in-market products or pipeline assets
- Core basis profit is above full-year forecast

*Full basis: OP increased YoY and is above full-year forecast*

- Severance expenses due to early retirement incentive program in Japan  
(Booked in Q3: 15.8 bil. yen)

Applicant for early retirement program: 650 employees



Strategic products: XOSPATA, PADCEV, EVRENZO

\*Breakdown of Gain on divestiture of intangible assets: Transfer of products to Cheplapharm (12.3 billion yen), Transfer of pipeline asset (9.2 billion yen), Transfer of Bendamustine (2.0 billion yen), etc.

This is an overview of the third-quarter results. Revenue and profit increased in the third quarter. Revenue increased by 6% YoY in line with our full-year forecast revised in October. Core operating profit increased by 8% YoY and is above our full-year forecast slightly.

Sales of XTANDI and Strategic products increased more than 20% YoY as expected.

SG&A expenses are slightly above our full-year forecast. R&D expenses are on track.

Starting from the third quarter, we have a new account on our P&L. I will explain the details later, but this is the so-called gain on divestiture of intangible assets, where we booked JPY24.1 billion. Its main breakdown is described at the bottom of this page.

There are three items here. In general, this account includes gain on sales of rights of in-market products or pipeline assets. For us, in the case of legacy products, we may sell the future rights to those products to somebody else. We received up-front payment for the future revenue, so this was recognized as revenue before, but as a result of our discussion with our auditors, this should be taken as transactions for gain on divestiture of intangible assets. It should be booked not as revenue.

Whether it's on a balance sheet or not through R&D or sales and marketing, we create intangible assets, and if we are selling this to a third party, this is part of the core business. Before core operating profit, we have one additional line to set this new account.

As I said, because of this flow, what was booked as revenue is excluded from revenue to be included in the line beneath, but at the same time, if we continue to hold intangible assets and the rights are given through

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licensing agreements, or we may give marketing rights in a certain country, then this is booked as revenue as before. This is a business using intangible assets, so we will continue to recognize these transactions as revenue.

## GAIN ON DIVESTITURE OF INTANGIBLE ASSETS

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- P/L has a new account from Q3/FY2021: Gain on divestiture of intangible assets
  - This account includes gain on sale of rights of in-market products or pipeline assets from Q3 onward
  - Included this account as a core basis performance
  - Upfront payment and royalty income from license agreements to be booked as Revenue

<Type of transaction and Accounting>

P/L item	Revenue	Gain on divestiture of intangible assets
Form of transaction	✓ License-out of rights of in-market products or pipeline assets (The rights are owned by Astellas)	✓ Transfer of rights of in-market products or pipeline assets
Accounting	✓ Upfront payment, milestone and royalty income booked as Revenue	Followings booked as Gain on divestiture of intangible assets ✓ Difference between upfront payment and book value of intangible assets ✓ Milestone and royalty income

Reference information: Gain on transfer of products to Cheplapharm (¥12.3 billion), gain on transfer of pipeline asset (¥9.2 billion), and gain on transfer of Bendamustine (¥2.0 billion), etc. were booked as Gain on divestiture of intangible assets in Q3/FY2021.



Details are described on page 22 in the appendix, so please refer to that slide at your leisure.

As a result, core basis profit is above our full-year forecast. Full-basis operating profit increased YoY, rising above our full-year forecast.

Regarding the last one line here, in the third quarter, we booked JPY15.8 billion severance expenses due to early retirement incentive program in Japan. 650 employees applied for early retirement program.

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## Q3/FY2021 FINANCIAL RESULTS

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(billion yen)	Q3/FY20	Q3/FY21	Change	Change (%)	FY21 FCST*	Progress	FX impact
<b>Revenue</b>	<b>940.9</b>	<b>992.3</b>	<b>+51.4</b>	<b>+5.5%</b>	<b>1,323.0</b>	<b>75.0%</b>	+42.8 bil. yen
Cost of sales	187.7	194.1	+6.4	+3.4%			
% of revenue	20.0%	19.6%	-0.4 ppt				
<b>SG&amp;A expenses</b>	<b>363.0</b>	<b>406.4</b>	<b>+43.4</b>	<b>+11.9%</b>	<b>541.0</b>	<b>75.1%</b>	
US XTANDI co-pro fee	90.2	108.7	+18.5	+20.5%			
SG&A excl. the above	272.8	297.7	+24.9	+9.1%			
<b>R&amp;D expenses</b>	<b>168.8</b>	<b>177.6</b>	<b>+8.8</b>	<b>+5.2%</b>	<b>242.0</b>	<b>73.4%</b>	
Amortisation of intangible assets	17.3	20.2	+3.0	+17.1%			
Gain on divestiture of intangible assets	-	24.1	+24.1	-			
<b>Core operating profit</b>	<b>203.7</b>	<b>220.0</b>	<b>+16.3</b>	<b>+8.0%</b>	<b>270.0</b>	<b>81.5%</b>	+15.4 bil. yen
<Full basis>							
Other income	7.0	4.2	-2.8	-			
Other expense	51.3	54.9	+3.6	-			
<b>Operating profit</b>	<b>159.5</b>	<b>169.4</b>	<b>+9.9</b>	<b>+6.2%</b>	<b>218.0</b>	<b>77.7%</b>	
Profit before tax	164.2	167.4	+3.2	+1.9%	216.0	77.5%	
<b>Profit</b>	<b>132.9</b>	<b>132.5</b>	<b>-0.4</b>	<b>-0.3%</b>	<b>174.0</b>	<b>76.1%</b>	

\* Announced in Oct 2021

Next, on page five, let me explain our third-quarter results.

Revenue increased to JPY992.3 billion, up by 5.5% YoY. The progress against the full-year forecast was 75%, shown on the right. Core operating profit was JPY220 billion, up by 8% YoY. The progress against the full-year forecast was 81.5% as is shown on the right.

The bottom half of this page shows our full-basis results. In the third quarter, we booked JPY54.9 billion as other expense. Operating profit increased to JPY169.4 billion, up 6.2% YoY. Profit was JPY132.5 billion, down by 0.3% YoY, almost flat for us.

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## Q3/FY2021 FINANCIAL RESULTS: REVENUE

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*Revenue increase driven by growth of XTANDI and Strategic products, which offsets sales decrease due to termination of sales and distribution / transfer of products*


	Q3/FY20	Q3/FY21	Change	Change (%)
<b>Revenue</b>	<b>940.9 bil. yen</b>	<b>992.3 bil. yen</b>	<b>+51.4 bil. yen</b>	<b>+5.5%</b>

Increase in XTANDI and Strategic products

**XTANDI, XOSPATA, PADCEV, EVRENZO** **+83.6 bil. yen** 

➤ Returned sales of Lexiscan, negatively impacted by COVID-19 in Q1/FY20 **+12.8 bil. yen**

Termination of sales and distribution / transfer of products

**Celecox, Lipitor, Eligard** **-34.7 bil. yen** 



Strategic products: XOSPATA, PADCEV, EVRENZO

Page 6 is an additional explanation about the YoY revenue comparison.

This is a slide we always show. XTANDI and Strategic products, which is expected to contribute to our future growth, continued to grow from the previous fiscal year. With four products combined, revenue increased by JPY83.6 billion YoY.

It's not one of the Strategic products, but Lexiscan sales, negatively impacted by COVID-19 in the first quarter of FY2020, returned increasing by JPY12.8 billion YoY.

On the other hand, sales decreased for mature products due to termination of sales and distribution as well as transfer of products.

As you can see here, for Celecox, Lipitor, and Eligard, revenue decreased by JPY34.7 billion YoY in total for these three products. As a result, revenue increased driven by growth of XTANDI and Strategic products, as well as by positive FX impact. Growth of XTANDI and Strategic products were almost in line with our initial assumption.

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## Q3/FY2021 FINANCIAL RESULTS: SALES OF MAIN PRODUCTS

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### Q3/FY2021 Act and FY2021 FCST (billion yen)

<b>XTANDI</b> 411.6	YoY: +68.9 (+20%) Progress against FCST: 74% FY2021 FCST: 554.1	<ul style="list-style-type: none"> <li>✓ Global sales increased 20% YoY, in line with forecast</li> <li>✓ In addition to US, sales expansion in EU following approval of M1 HSPC indication</li> <li>✓ Strong growth continues in Japan and China</li> </ul>
<b>XOSPATA</b> 25.7	YoY: +8.1 (+46%) Progress against FCST: 73% FY2021 FCST: 35.4	<ul style="list-style-type: none"> <li>✓ Global sales increased, almost in line with forecast, driven by growth mainly in US and EU</li> <li>✓ Sales contribution from China newly launched in Apr. 2021</li> </ul>
<b>PADCEV</b> 14.6	YoY: +5.2 (+56%) Progress against FCST: 70% FY2021 FCST: 20.7	<ul style="list-style-type: none"> <li>✓ Revenue in US grew steadily, in line with forecast</li> <li>✓ Launched in Japan in Nov. 2021 and initial uptake has been very strong thus far</li> </ul>
<b>EVRENZO</b> 2.1	YoY: +1.4 (+199%) Progress against FCST: 29% FY2021 FCST: 7.2	<ul style="list-style-type: none"> <li>✓ Sales in Japan are behind full-year forecast</li> <li>✓ Launched in Established Markets from Sep. 2021 and initial uptake has been slower than forecast</li> </ul>
<b>mirabegron</b> 126.9	YoY: +4.6 (+4%) Progress against FCST: 72% FY2021 FCST: 176.3	<ul style="list-style-type: none"> <li>✓ Global sales are behind full-year forecast</li> <li>✓ In US, sales are behind forecast due to lower than expected US OAB market growth and increased pricing pressure</li> </ul>



M1: Metastatic, HSPC: Hormone-sensitive prostate cancer, PADCEV (US): Co-promotion revenue from Seagen, mirabegron (Product name: Betanis/Myrbetriq/BETMIGA), OAB: Overactive bladder

On page 7, I will explain the third-quarter results of our main products.

As for XTANDI, global sales increased as expected to JPY411.6 billion, up by JPY68.9 billion or 20% YoY. It's a product with over JPY400 billion sales but continues to make a strong growth.

Sales rose mainly in the United States and Europe. In Europe, sales expanded for M1 HSPC additionally approved in April last year. For this indication, because of the broader patient population, pricing pressure continued to rise in main countries in Europe, but reimbursement has started. Strong sales growth continues also in Japan and China.

XOSPATA sales increased to JPY25.7 billion, up JPY8.1 billion or 46% YoY, almost in line with our forecast. In addition to US and EU, sales in China, where it was launched in April last year, are also contributing. New prescriptions have been increasing steadily.

We have been making steady progress since the launch in China as expected. Recently, in the international markets, we also obtained approval in Russia, Saudi Arabia, and Turkey, where we expect sales contribution in the future.

As for PADCEV, co-promotion revenue in the United States was JPY14 billion. By adding the revenue in Japan, where it was launched in November 2021, PADCEV's revenue increased to JPY14.6 billion, up by JPY5.2 billion or 56% YoY.

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In addition to the existing indication, the second-line additional indication approved in July last year is also contributing to revenue increase. We have made a good start in Japan, better than expected. New prescriptions and initial uptake are rising steadily.

The progress against the full-year forecast may look a little low at 70%, but continuous growth in the United States and further revenue contribution in Japan are expected. We believe our full-year forecast is achievable.

EVRENZO sales were JPY2.1 billion. Sales in Japan are increasing steadily YoY, along with the entire HIF-PHI market expansion., but as you know, behind our full-year forecast, due to the impact of intensifying competition, it's slightly behind our full-year forecast.

In the established market, EVRENZO was launched in September last year. It's now available in Germany, UK, the Netherlands, Austria, Nordic countries, etc. After the launch, sales are behind our full-year forecast due to substantially slower-than-expected market penetration. It's soon after the launch, and we think this is substantially behind our full-year forecast. It's still soon after the launch, and we're examining the background right now. There have been restrictions on sales promotion activities at the launch time due to COVID-19.

In addition, this is for a disease area with relatively stable established standard of care, namely ESA, with many doctors being careful about prescribing new drugs according to a current analysis.

Mirabegron sales rose to JPY126.9 billion, up JPY4.6 billion or 4% YoY. The progress against our full-year forecast was 72% and global sales are behind our forecast, particularly in US, which accounts for about half of the global sales.

Sales are behind the full-year forecast due to lower-than-expected US OAB market growth and pricing pressure is increasing year after year.

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## Q3/FY2021 FINANCIAL RESULTS: COST ITEMS

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*SG&A expenses increased YoY and slightly above full-year FCST*  
*R&D expenses increased YoY and in line with full-year FCST*

### Core basis: Main items for YoY and progress against FCST

#### Cost of sales % of revenue



YoY: -0.4ppt

- ✓ Decrease mainly due to changes in product mix
- ✓ FX impact on elimination of unrealized gain: +0.2 ppt

#### SG&A expenses

YoY: +11.9%

Progress  
against FCST: 75.1%



- ✓ SG&A excl. XTANDI US co-pro fee: +24.9 bil. yen (YoY +9.1%)
- ✓ FX impact (+16.5 bil. yen)
- ✓ Investment in Digital Transformation (Approx. +6.0 bil. yen)
- ✓ Increase in sales promotion expenses for new product launch readiness (Approx. +2.5 bil. yen)
- ✓ Global optimization of personnel aligned with transformation of product portfolio (Approx. -5.0 bil. yen)

#### R&D expenses

YoY: +5.2%

Progress  
against FCST: 73.4%



- ✓ Increase in development cost of zolbetuximab and expanded investment in iota
- ✓ Decrease in development cost of fezolinetant
- ✓ On track with full-year forecast



Page 8 shows YoY comparison and progress against the full-year forecast for cost items.

COGS ratio, shown in the middle of this page, decreased by 0.4 percentage point YoY due to changes in product mix. Due to the impact of the yen's depreciation against the US dollar at the end of the third quarter, FX impact on elimination of unrealized gain increased the COGS ratio by 0.2 percentage points.

SG&A expenses increased by 11.9% YoY. SG&A costs, excluding US XTANDI co-promotion fee, increased by JPY24.9 billion or 9.1% YoY. Costs increased by JPY16.5 billion due to FX impact. In addition, in our actual business, there was an increase in investments in Digital Transformation, as well as sales promotion expenses for new product launch readiness and post-launch growth for Strategic products. These led to a cost increase of about JPY8.5 billion in total.

As for cost-decreasing factors, we are implementing multiple organizational reform projects globally aligned with the transformation of our product portfolio, and we are continuously trying to optimize our personnel. Due to these initiatives, cost decreased by about JPY5 billion by the end of the third quarter. As a result, the progress against the full-year forecast was 75.1%, a little higher than usual years and slightly above our internal plan up to the third quarter.

R&D expenses increased by 5.2% YoY. Compared to the previous fiscal year, development costs increased for zolbetuximab, and we expanded investments related to iota which we acquired in the middle of the previous fiscal year.

On the other hand, development cost for fezolinetant decreased with the completion of Phase III study patient enrollment. Overall, we are in line with our full-year forecast.

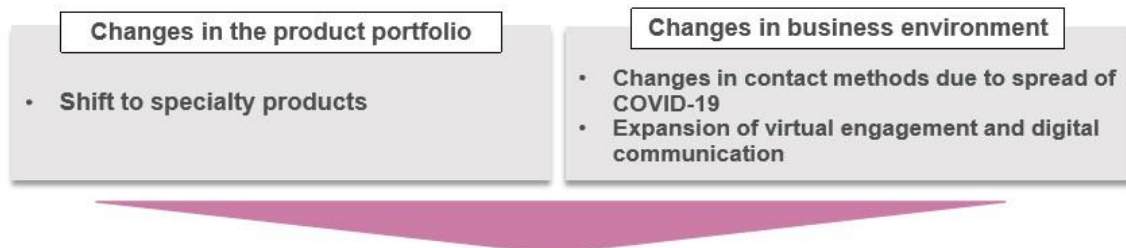
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*Aiming to maximize VALUE by pursuing optimal commercial organization to achieve CSP2021 goals*



- Establish commercial organization's response to the new business environment
  - Enhance Omni-Channel activities and shift to "product dedicated model" in Japan
  - Reducing resources for mature products and focusing on Strategic products
  - Decrease of approx. 1,000 personnel (Japan, Europe, U.S., China, South Korea, etc.)
  - Annual costs reduction when completed to be approx. 18.0 billion yen (Cost reduction in FY2021 to be approx. 9.0 billion yen)



Personnel: Subject to Works Council, consultative, and legal requirements

On page 9, I'd like to explain SG&A cost-decreasing factors.

I mentioned on the previous page the commercial organization reforms, including its financial impact. Right now, the internal and external environment surrounding our business has been changing rapidly and substantially. In addition to changes in our product portfolio, namely shift to specialty products, there have been changes in contact methods due to the spread of COVID-19 and expansion of virtual engagement and digital communication.

To deal with these changes in the business environment, we are promoting our commercial organizational reforms globally. We are enhancing omni-channel activities and will shift to a product dedicated model in Japan from an area-based model.

Also, we have been reducing resources for mature products and focusing on Strategic products.

After addressing these environmental changes, we revisited the optimal number of personnel all the time mainly in Japan, Europe, US, China, South Korea, et cetera. Thus far in the current fiscal year, these initiatives resulted in a decrease of about 1,000 personnel. Economically, we're expecting an annual cost reduction of about JPY18 billion.

At the same time, we're also trying to strengthen the capabilities of our commercial organization and enhance the business efficiency. We're expecting cost-reduction benefits also from these operational initiatives in the future.

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## FY2021 FULL-YEAR OUTLOOK

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- YoY Revenue increase is on track driven by XTANDI and Strategic products
- SG&A expenses are slightly above full-year FCST but aiming to control for the full year
  - Thorough budget control on a quarter basis
  - Starting to realize impact of global personnel optimization aligned with transformation of product portfolio
- R&D expenses are on track
- Booked “Gain on divestiture of intangible assets” in Q3/FY2021, not included into full-year forecast
  - Transfer of pipeline asset (9.2 billion yen)
  - Transfer of Bendamustine (2.0 billion yen)
- As a result, Core OP to exceed full-year forecast
- Full basis profit to slightly exceed full-year forecast, as with Core basis
- No changes have been made to FY2021 forecast for Revenue and OP



Strategic products: XOSPATA, PADCEV, EVRENZO

On page 10, let me explain our FY2021 full-year outlook.

XTANDI and Strategic products are driving revenue continuously. YoY revenue increase is on track vis-à-vis our full-year forecast. We are expecting continuous growth for the future as well.

SG&A expenses are slightly above our full-year forecast, but we will continue to ensure thorough budget control and take away unused budget from each department for control by the Finance division on a quarterly basis.

As was mentioned earlier, in the fourth quarter, we will see further cost reductions from global personnel optimization. We are aiming for a landing of SG&A expenses in line with the full-year forecast.

R&D expenditure is on track and in line with our full-year forecast.

As for the newly created account, gain on divestiture of intangible assets I explained at the beginning, there were three items shown. Gain on transfer of product to Cheplapharm for JPY12.3 billion was already factored in to a full-year forecast, but at that time, we didn't have this account, so it was included in the revenue for JPY12.3 billion, hitting the bottom line. This time, it's not recognized as revenue, so minus approx. JPY10 billion for the revenue, for the bottom line, it's going to be neutral.

On the other hand, there are two other items. They were not included in our full-year forecast, so this has been an addition to increase the bottom line.

As a result, core operating profit is expected to exceed our full-year forecast. The full basis profit is also expected to slightly exceed our full-year forecast due to these factors.

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As a result, no changes have been made to our full-year forecast announced in October, including core basis and full basis figures.

## AGENDA

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I Q3/FY2021 Consolidated Financial Results

II Initiatives for Sustainable Growth



Slide 11, I will now explain our initiatives for sustainable growth.

Excuse me for a moment. Thank you.

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# XTANDI & STRATEGIC PRODUCTS: HIGHLIGHT (1/2)

(Red: Updates since the last financial results announcement)

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## Key Events Expected in FY2021

Milestone	Project / Product	Indication / Clinical study	Achieved
Regulatory decision	enzalutamide / XTANDI	M1 hormone-sensitive prostate cancer (EU)	Apr 2021
	enfortumab vedotin / PADCEV	mUC, platinum and PD-1/L1 inhibitor pretreated (US <sup>a,b</sup> )	Jul 2021
		mUC, cis-ineligible and who have previously received one or more therapy (US <sup>a</sup> )	Jul 2021
		mUC, platinum and PD-1/L1 inhibitor pretreated (EU)	CHMP positive opinion received in Dec 2021 *The EC decision-making process has been paused for additional CHMP questions related to severe skin reactions in a French compassionate access program
	Radically unresectable UC that has progressed after anti-cancer chemotherapy (JP <sup>c</sup> )	Sep 2021	
	roxadustat / EVRENZO	Symptomatic anemia associated with CKD (EU)	Aug 2021
Regulatory submission	gilteritinib / XOSPATA	R/R AML (China <sup>d</sup> )	
Data readout	fezolinetant	52-week safety results from Phase 3 SKYLIGHT 1, 2 & 4 studies	Jul 2021 (SKYLIGHT 2) Oct 2021 (SKYLIGHT 1)

a: Priority Review granted, Real-Time Oncology Review pilot program and Project Orbis applied

b: sBLA to convert Accelerated Approval to regular approval

c: Priority Review granted

d: sNDA to convert conditional approval to full approval



Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132

M1: Metastatic, (m)UC: (metastatic) Urothelial cancer, CHMP: Committee for Medicinal Products for Human Use, EC: European Commission, CKD: Chronic kidney disease, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, sBLA: Supplemental Biologics License Application, sNDA: Supplemental New Drug Application

Slide 12 progress highlights of XTANDI and Strategic products.

I would like to explain the progress of the key events planned for this fiscal year, which was announced at the beginning of the fiscal year. Items achieved by the time of the last fiscal announcement are shown in the black on the very right side, and updates for this quarter since then are shown in the red.

As for the progress in this quarter, the European CHMP adapted the positive opinion for marketing authorization for enfortumab vedotin and PADCEV in December last year. Based on this positive opinion, the European Commission, or EC, will make the final decision on whether to approve or not.

After receiving the positive opinion, the EC approval process was underway, but due to additional inquiries from the CHMP related to severe skin reaction observed in patients using the French compassionate use system, a system that allows access to unapproved drugs, which is quite unique to France, the CHMP gave us the additional inquiries. In order for the response preparation, the EC decision-making process is currently paused. We will inform you of the impact on the review period as soon as we know the progress.

If you look at the blank space on the slide, that's about the remaining major key events for this fiscal year. That includes the filing for gilteritinib in China for the treatment of relapsed and refractory AML, and the acquisition of data from the SKYLIGHT 4 study for fezolinetant. Both of these are expected to be completed by the end of the fiscal year.

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## Other Updates since the last financial results announcement

Project / Product	Indication	Updated status
enzalutamide / XTANDI	M1 CSPC	Filed label update to include the OS data in US and EU in Dec 2021
gilteritinib / XOSPATA	AML, post-HSCT maintenance	Filing timeline shifted to FY2023 due to slower-than-expected RFS events in Phase 3 MORPHO study
	AML, newly diagnosed and HIC-ineligible	Phase 1 study in combo with venetoclax and azacitidine under preparation to start in Q1 FY2022
enfortumab vedotin / PADCEV	Muscle-invasive bladder cancer	Cohort H data in EV-103 study to be presented at ASCO GU in Feb 2022
	Non-muscle-invasive bladder cancer	FSFT in Phase 1 study in Jan 2022
fezolinetant	VMS associated with menopause	LSLV in Phase 3 SKYLIGHT 4 study in Jan 2022 FSFT in Phase 3b DAYLIGHT study in Nov 2021 FSFT in Japan Phase 2b STARLIGHT study in Nov 2021 Completed 12-week treatment <sup>a</sup> in Asia Phase 3 MOONLIGHT 1 study in Jan 2022

a: Double-blind, placebo-controlled period followed by 12-week active treatment extension period:



Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132  
M1 CSPC: Metastatic castration-sensitive prostate cancer, OS: Overall survival, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, RFS: Relapse-free survival, HIC: High-intensity chemotherapy, ASCO GU: American Society of Clinical Oncology Genitourinary Cancers Symposium, FSFT: First subject first treatment, VMS: Vasomotor symptoms, LSLV: Last subject last visit

Slide 13. I would like to discuss other important updates that have occurred since the last announcement and as mentioned at the beginning of the period.

We've had applications in the US and Europe for enzalutamide, or XTANDI, to add the previously reported OS data in M1 CSPC to the packaging starting December 2021, too. The details of gilteritinib, because it's quite detailed, I'm going to show it in slide 14.

Development of enfortumab vedotin, or PADCEV, in earlier stages and the currently approved in metastatic urothelial carcinoma is also progressing. In muscle-invasive bladder cancer, MIBC, data from the EV-103 Cohort H study in this patient population will be presented at ASCO GU in February. This will be the first published data for MIBC. The clinical trial in non-muscle-invasive bladder cancer, or NMIBC, is on schedule and the first subject first treatment was achieved in Phase I in January.

For fezolinetant, the SKYLIGHT 4 trial achieved the last subject last visit in January, and the safety analysis is expected to be completed by March. We will provide top-line results in a press release or so as soon as they are available.

As for other ongoing clinical trials, preparations for the Phase IIIb DAYLIGHT study and the Japanese Phase II STARLIGHT study late stage are progressing as planned, and the first subject first treatment was achieved in November last year.

In addition, the Phase III MOONLIGHT 1 study in Asia completed its 12-week double-blind and dosing period in January to evaluate efficacy and is currently undergoing analysis.

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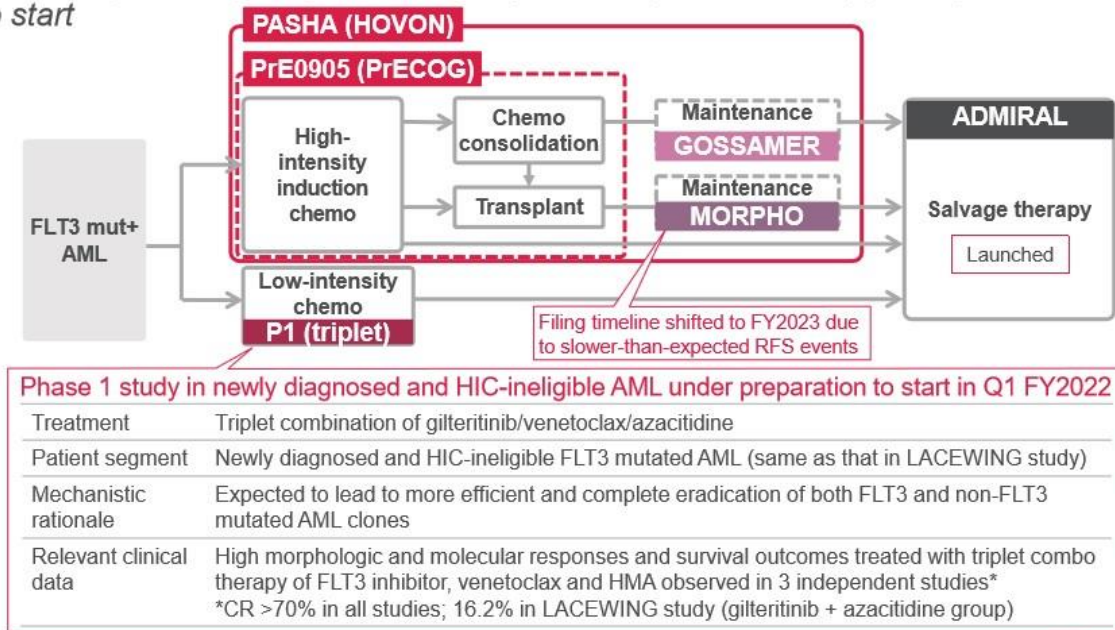




# GILTERITINIB: DEVELOPMENT STATUS

14

New study in newly diagnosed and high intensity chemotherapy-ineligible AML to start



AML: Acute myeloid leukemia, FLT3 mut+: FLT3 mutation positive, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands, RFS: Relapse-free survival, HIC: High-intensity chemotherapy, HMA: Hypomethylating agent, CR: Complete remission  
\*63rd ASH Annual Meeting & Exposition Abstract 696 (2021), Blood Cancer J 11:25 (2021), Blood Cancer J. 11:104 (2021)

Slide 14, that's about the development status about gilteritinib.

In acute myeloid leukemia, with high unmet needs, in addition to the already approved indication for relapsed refractory AML, clinical trials are underway to expand the indication for the earlier stage.

Regarding the MORPHO study, which is being conducted for maintenance therapy after hematopoietic stem cell transplantation, that is right bottom, red square, we announced at the time of the announcement of the CSP2021 that the planned filing would be in fiscal 2022. But due to the delay in the accumulation of events, it has been changed to fiscal 2023.

In addition, we have started preparations for a Phase I study of a three-drug combination of gilteritinib with venetoclax and azacitidine for AML patients who are newly diagnosed and are high-intensity chemotherapy ineligible. The patient population is the same as that of the previous LACEWING study. We believe that one of the factors that prevented the expected efficacy in the LACEWING study was the limited efficacy of azacitidine alone in FLT3 non-mutated clones.

Now that the standard treatment regimen has been updated and the combination of venetoclax and azacitidine is widely used, the effect on non-mutated clones has increased.

On the other hand, the combination of venetoclax and azacitidine seems to have limited efficacy in FLT3 mutated clones, so we expect the addition of gilteritinib to have a strong effect on both FLT3 mutated and non-mutated clones.

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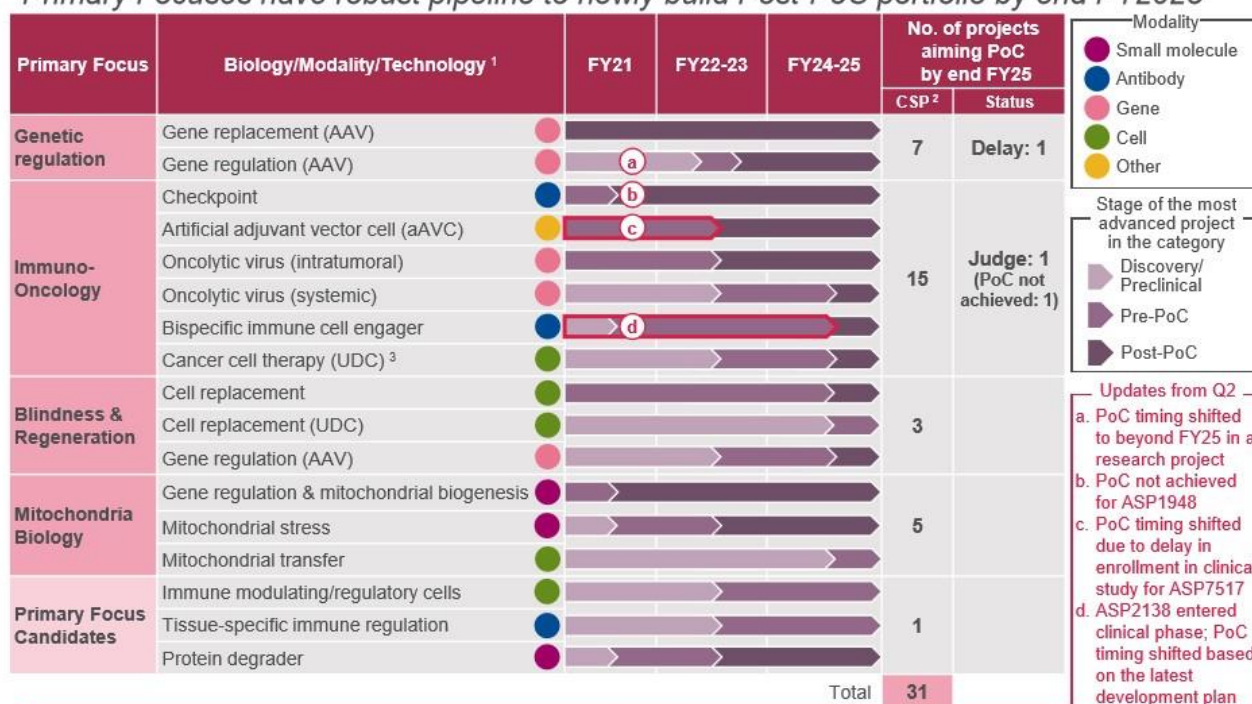


The high clinical efficacy of the combination of FLT3 inhibitors and DNA methylation inhibitors, such as venetoclax and azacitidine, has been reported in three, small, but different, studies, suggesting that it may be a superior treatment to the two-drug combination.

## PROGRESS IN FOCUS AREA APPROACH (1/3): CLINICAL PROOF AND EXPANSION OF KEY PLATFORMS

15

Primary Focuses have robust pipeline to newly build Post-PoC portfolio by end FY2025



1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (at CSP2021 announcement).  
 3. The first convertibleCAR program (with autologous cells) IND is planned for late FY2021.  
 PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell

Slide 15, advances in the focus area approach.

I will explain that with using the table used in the announcement of the CSP2021. Information is increasing, so every time that we show you, the slide is getting busier and busier, but we thought it is better to use the same slide as shown in the very beginning to make it clear. If this is too confusing, let us know.

In the regulation of genetic regulation and primary focus, one of the projects in the research stage has been virtually delayed and the proper identification of PoC timing has been set for FY2026 or later, so, outside of this scope of the chart.

Now the Immuno-Oncology, there are three updates for this. Regarding the checkpoint, the clinical trial of the lead project, ASP1948, unfortunately failed to achieve PoC.

Second, with respect to artificial adjuvant vector cells, or aAVC, due to the delay in the enrollment of the lead project, ASP7517, in the clinical trial, the expected timing of PoC has been shifted from FY2021 to FY2022-2023. That's the column in the middle.

In the area of bispecific immune cell engager, that lead project, ASP2138, has moved to the clinical stage. Details are shown in the following slide. As a result of reviewing the details of the clinical trial plan based on

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the latest situation and data, we have shifted the expected timing of PoC from FY2022-2023 to FY2024-2025, meaning from middle to the very right in this chart.

As explained in the announcement of the CSP2021, one of the major goals for the next five years is to generate late-stage development products from the focus area approach projects. Some of them, such as ASP1948, will be discontinued as a result of PoC assessment, while others, such as ASP2138, will be newly entered into clinical stage.

We are not quite sure how long we are continuously using this chart, but we will continue to definitely assess the PoC of each project and disclose the progress in a timely manner.

## PROGRESS IN FOCUS AREA APPROACH (2/3): CURRENT STATUS IN PRIMARY FOCUS

16

(Red: Updates since the last financial results announcement)

Primary Focus	Biology/Modality/Technology <sup>1</sup>	Project	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	Completed dosing in the second dose cohort in Phase 1 study Interim data in Phase 1 study to be presented at WORLDSymposium in Feb 2022
Immuno-Oncology	Gene regulation (AAV)		
	Checkpoint	ASP1948	Terminated
		ASP1951	Phase 1 study ongoing
	Artificial adjuvant vector cell (aAVC)	ASP7517	Phase 2 study in R/R AML and MDS ongoing FSFT in Phase 1 study in advanced solid tumors in Dec 2021
		ASP0739	FSFT in Phase 1 study in Jan 2022
	Oncolytic virus (intratumoral)	ASP9801	Phase 1 study ongoing
	Oncolytic virus (systemic)		
Blindness & Regeneration	Bispecific immune cell engager	ASP2138	Phase 1 study to start in Q1 FY2022
	Cancer cell therapy (UDC)		
	(other)	ASP1570	FSFT in Phase 1 study in Nov 2021
Mitochondria Biology	Cell replacement	ASP7317	Screening and enrollment in Phase 1b study put on hold, due to a manufacturing delay
	Cell replacement (UDC)		
	Gene regulation (AAV)		
Primary Focus Candidates	Gene regulation & mitochondrial biogenesis	ASP1128	Enrollment discontinued in Phase 2a study, based on the interim analysis for fertility
		ASP0367	Phase 2/3 study in PMM ongoing Phase 1b study in DMD ongoing
	Mitochondrial stress		
	Mitochondrial transfer		
	Immune modulating/regulatory cells		
	Tissue-specific immune regulation		
	Protein degrader		

1. Not exhaustively listed.

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, FSFT: First subject first treatment, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy

Slide 16. This shows the current status of projects in the clinical trial stage for each primary focus.

Just like other slides, well, we've achieved some in the fiscal year, but if that was before the previous financial announcement, that was described in black, and then let us indicate the progress made since the previous financial announcement.

In Genetic Regulation, we completed the dosing of Cohort 2 in the Phase I study of AT845 for Pompe disease and the interim data from this trial will be presented at the WORLDSymposium this month.

In Immuno-Oncology, we have made progress in several projects. In addition to those mentioned in the previous slide, we have achieved dosing of the first patients in Phase I trials for two aAVC projects, ASP7517 and other cancer antigen type ASP0739 in solid tumors, and ASP1570 small molecule.

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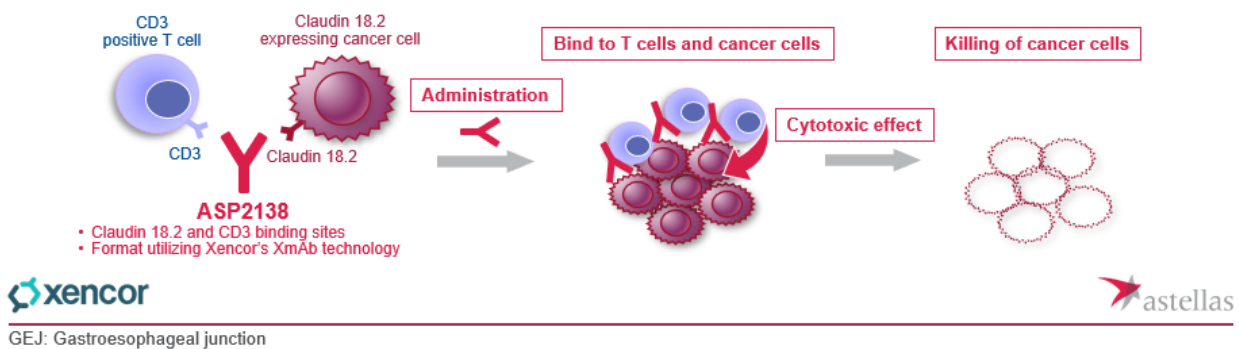
## PROGRESS IN FOCUS AREA APPROACH (3/3): ASP2138

17

*The lead program of bispecific immune cell engager to enter clinical phase*

### Characteristics of ASP2138

- Bispecific antibody targeting Claudin 18.2 and CD3
  - ✓ Forms a synapse between Claudin 18.2 expressing cancer cells and CD3 positive T cells and kills cancer cells by cytotoxic effect
  - ✓ Created through research collaboration with Xencor
  - ✓ Positioned as a successor of zolbetuximab with expected higher efficacy
- Under preparation to initiate Phase 1 study in Q1 FY2022
  - ✓ Target disease: gastric and GEJ adenocarcinoma, pancreatic adenocarcinoma



Slide 17. I will explain additional explanation about ASP2138.

ASP2138 is the first program with the mechanism of bispecific immune cell engager and it is a bispecific antibody targeting Claudin 18.2 and CD3. Claudin 18.2 is the same target as the zolbetuximab. What the difference here is that because this is a bispecific one arm is binding to Claudin 18.2, and the other is CD3, this antibody binds these two to make them close in distance and causes cytotoxic effects on cancer cells.

This antibody was developed in collaboration with Xencor, utilizing their platform technology. As a successful project to zolbetuximab, we expect to achieve high efficacy.

We are currently preparing to initiate a global Phase I study in patients with gastro adenocarcinoma as gastroesophageal junction adenocarcinoma, and pancreatic adenocarcinoma, the same indications as zolbetuximab. The immuno-oncology, I repeatedly mentioned there might be a bit of the delay, but for ASP2138 the preparation for the clinical trials is underway in Japan leading the situation.

Currently, in the US, due to the impact of COVID-19, it is generally difficult to enroll patients and conduct clinical trials. Under these circumstances, for ASP2138, Astellas was able to strategically prepare for the early start of the clinical trials by utilizing its capabilities and network in Japan, which Astellas has cultivated.

We would like to make the most of this advantage in other projects as well in order to accelerate clinical trials. Focus area approach, well, Dr. Yasukawa often says that the success leads to another access. We'll continue to work on the creation of follow-on programs for bispecific antibodies following the lead project.

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## PROGRESS IN Rx+ PROGRAM



18

### Key events expected in FY2021 (announced in Apr 2021)

Sphere *	Program	Event	Achieved
Chronic disease progression prevention	Fit-eNce	Initiation of pilot marketing for at-home service (Fit-eNce Home)	Sep 2021
	Game application for exercise support	Initiation of pilot marketing	
	BlueStar	Initiation of clinical study (Japan)	
	My Holter II	Commercialization of service	Jul 2021
Patient outcome maximization	ASP5354 (pudexacianinium chloride)	Topline results for Phase 2 study	Nov 2021

### Topline results for Phase 2 study of ASP5354

- Safety and efficacy support proceeding to Phase 3 study
- Study results will be announced at SAGES in March 2022



\* Business areas to focus on for realization of Rx+ Story  
SAGES: Society of American Gastrointestinal and Endoscopic Surgeons

Slide 18. That is the progress of the Rx+ Program.

The progress results achieved up to the last financial announcement are shown in the black, and updates for this quarter since then are shown in red.

In November last year, we gained the top-line result from the Phase II study of ASP5354, and safety and efficacy of this compound was confirmed and it supports progress to Phase III trials. This result is planned to be presented at the SAGES in March 2022.

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# PROGRESS TOWARD ACHIEVING CSP2021

19

## Revenue, Pipeline Value

- 1** XTANDI and Strategic products:  $\geq$  ¥1.2T in FY2025
  - ✓ Sales growth in line with ambitious forecast
  - ✓ XTANDI: Filing label update to include OS data in US & EU
  - ✓ XOSPATA: Initiating Phase 1 study of triplet combo therapy for newly diagnosed and HIC-ineligible AML
  - ✓ PADCEV: CHMP positive opinion, presentation of MIBC data, FSFT in Phase 1 study for NMIBC
  - ✓ fezolinetant: LSLV in SKYLIGHT 4 study, progress of clinical studies as planned
  - ✓ Lexiscan (US): Settled patent infringement litigation against some defendants. Litigation ongoing against other defendants. Currently predict generic entry of Lexiscan within CSP2021 period

- 2** Post-PoC projects from Primary Focuses
- 3** Multiple technology platforms
- 4** Focus Area projects:  $\geq$  ¥0.5T in FY2030
  - ✓ AT845: Dosing completion in Cohort 2 in Phase 2 study
  - ✓ ASP7517 (solid tumors), ASP0739, ASP1570: FSFT in Phase 1 study
  - ✓ ASP2138: Entry into clinical phase

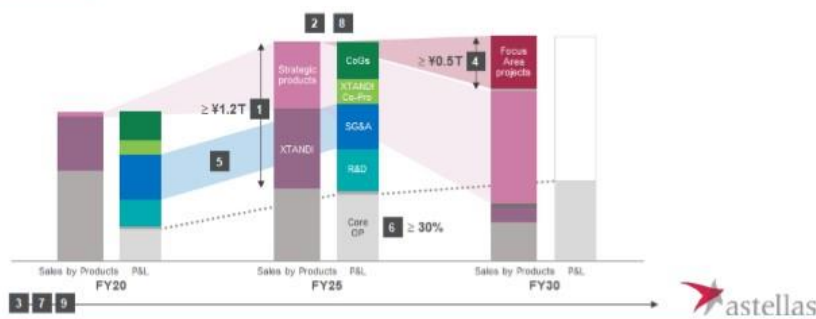
## Core OP

- 5** Flat SG&A in absolute terms
- 6** Sufficient R&D investments  
Core OP margin of  $\geq$  30% in FY2025
- 7** Steady increase in dividends

- ✓ Investment for new product launch
- ✓ Thorough budget control on a quarter basis
- ✓ Starting to realize impact of global personnel optimization aligned with transformation of product portfolio

## Future Growth

- 8** Rx+:  
Breakeven by FY2025
  - 9** Sustainability
- ✓ ASP5354: Topline results obtained



Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132  
 CSP: Corporate Strategic Plan, OS: Overall survival, HIC: High-intensity chemotherapy, AML: Acute myeloid leukemia, CHMP: Committee for Medicinal Products for Human Use, MIBC: Muscle-invasive bladder cancer, NMIBC: Non-muscle-invasive bladder cancer, FSFT: First subject first treatment, LSLV: Last subject last visit

Slide 19. In line with the CSP2021, the progress is summarized here.

First, at the left-top, revenue and the pipeline value. Sales of XTANDI and other Strategic products are on track to meet the ambitious targets set for the first year of CSP2021. In addition, the development of Strategic products to maximize product value is progressing as planned.

As stated at the bottom of the slide, at the very last bullet point, we have settled our dispute in the US with some of the patent infringement litigation defendants. At the time of disclosure in May 2021, CSP2021, we did not forecast the generic entry of Lexiscan in the US in the CSP2021 period, since we have patents covering our Lexiscan product that will expire in February 2027. However, based on the recent situation, we now expect a generic entry of Lexiscan within the CSP2021 period, meaning up to FY2025.

Although we cannot disclose the detailed timing, we currently predict generic entry of Lexiscan later in the CSP2021 period. Also, the litigation against other defendants is still ongoing. We do not comment on ongoing litigation.

We will thoroughly review our midterm forecast for revenue and profit in the future based on the litigation process. If something needed to be reported, we would report it in a timely manner.

Now, the Focus Area approach shown in the lower-left corner. Clinical trials have progressed in the genetic regulation and immuno-oncology projects. ASP2138, a new project, born from research, has advanced to the clinical stage.

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On the upper right, Core OP. We are continuously viewing the allocation of management resources with the aim of improving the Core OP margin. Although SG&A expenses are slightly higher than expected, we will pursue higher quality and more efficient operations and continue to thoroughly manage the budget on a quarterly basis, aiming to achieve the expected results for the full year.

As an overall summary, in the first year of the CSP2021, in which we ambitiously set targets, we are making progress as we expected. We will continue to implement the strategies set forth in the CSP so that we can achieve increased sales and profits as planned for the full year, for FY2021.

Although not shown in the slide, we have decided to conduct a share buyback as announced in the press release today. We plan to acquire 29 million shares with an upper limit of JPY50 billion from February 3 to March 24. We will continue our efforts to improve capital efficiency and shareholder returns.

## SCHEDULE

20

### Sustainability Meeting

➤ Feb 28<sup>th</sup> 2022, 15:00-16:30 (JST)

### R&D Meeting

➤ Mar 9<sup>th</sup> 2022, 9:30-11:00 (JST)

- Initiatives for gene therapy -



This is the last slide. This slide summarizes the schedule of future IR events. On February 28, we will hold a Sustainability Meeting. That is strategy target number four in CSP. That is about the sustainability. We will explain our approach to it and specific ESG initiatives.

In addition, we will hold an R&D Meeting on March 9. Probably you are looking forward to it. There, although I did not mention AT132, our genetic regulation program in today's presentation, but we plan to explain the latest status of AT132 at that moment as well as the entire genetic regulation systematically joining the R&D Meeting in March. That's all from me. Thank you for your attention.

That's all for the presentation.

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## Question & Answer

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**Fujii [M]:** Next, we want to take your questions.

**Operator [M]:** Mr. Yamaguchi from Citigroup, please.

**Yamaguchi [Q]:** Yamaguchi from Citigroup. Thank you.

SG&A expenses. The actual numbers, according to the comments, it's going to be slightly above Q1, Q2 and Q3, for your forecast, you have a gain on sales. Your initiative to reduce SG&A costs, I understand there are many factors behind. Do you have a plan to reduce the SG&A costs? In the second half, they're slightly above your forecast in the third quarter, but is it within a controllable range or not? I couldn't fully understand. That's my first question.

**Okamura [A]:** Thank you for your question. Sorry for the unclear explanation. We have core operating profit. That's not the only target for us. As we said in the CSP2021, SGA expenses are going to be flat in absolute terms according to our target, so SGA cost plan, we would like to have a landing according to our initial plan. That's our goal and target.

We have a prior investment near the beginning of the fiscal year. We will have effect later. Regarding the commercial organization reforms I mentioned today, we have the benefits in the middle of the fiscal year, and we will have the full benefits in the fourth quarter. We think we can make it in the end.

If you take a closer look at the financial results of Astellas, in the fourth quarter, we tended to have more costs in the fourth quarter. To prevent this from happening again, the annual budget is approved. If we cannot use all the amount in the first, second, and the third quarter, if there is a remaining budget, I don't think that's the case, but we were able to use the money flexibly. But now on a quarterly basis, starting from this fiscal year, we have a budget.

If you don't use the budget, unless there are exceptions to use the money in the next quarter, you cannot use that money forever. We have to see whether this initiative is going to work or not. Please judge later.

**Yamaguchi [Q]:** And as for share buyback, that's based upon your conventional policy, but at this time, you decided to do the share buyback. Because you have excessive funds, so you decided to do this?

**Okamura [A]:** Your understanding is right. Our basic policy is always the same. In order for the growth, we invest for the business. That's always a priority, and dividend is continuously provided and the increased level is higher than the past. The Audentes-related borrowing is returned according to the plan, and we have sufficient cash and the case going to return to the shareholders. That's completely based upon our basic policy.

**Yamaguchi [M]:** Understood. Thank you very much.

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

**Hashiguchi [Q]:** Hashiguchi from Daiwa Securities. My first question is on page 7. Mirabegron, pricing pressure increasing in the United States. I'd like to know the background. There are competitive products with the same mechanism. Is this a specific phenomenon for mirabegron? Or this has gone on across a category of similar products. And you have this effect adjust in the third quarter and the price will change. And we should be concerned about the continuing declining trend for the future as well?

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**Matsui [A]:** First of all, about mirabegron, regarding pricing pressure on it, as you know, last year, in March or April, a drug with a similar or the same mechanism of action was launched by another company in the United States. To deal with this, a contract with each payer is being reviewed to ensure access of mirabegron. That drug should be available as a first-line therapy. This is what we have done.

Compared to last year, there seems to be a decline here. As for the volume, it's growing, but pricing wise, to ensure access, discount was expanded. That's one reason.

As for your second question, continuously, do we see a declining trend continuously for the future? A continuous decline substantially in the future is not expected for now, but we have competition and we have to see what's going on in the market, so we will monitor the trends of the market and the competitors to deal with the situation flexibly. That's all for me.

**Hashiguchi [Q]:** Thank you. Second question, page 15, the focus area approach progress slide. c and d compared to before; the way of the color of the arrows is different. And now a and b, the coloring is the same; no change about it. But thinking about the current situation, what's the color coding here? A means at the very left, that goes toward the very right, but for b, 1951 status, if that status is reflected, what will be the color for the arrow?

**Okamura[A]:** a is the gene regulation. There's a bit of a delay, but the deregulation mechanism itself, meaning the missed genes are going to be replaced, it's not something like that.

But for example, exon-skipping, that is available already in the market as a technology. In that way, genes are to be regulated. Such biology is used in some of the projects and Audentes have the following projects as well. Concerning them, as for later compound, there's a bit of a delay, but they're coming. That's why the color of the arrow is the same.

And b, 1948 will be discontinued, but the color is the same, which means the remaining program, 1951 G1TR agonistic antibody, within FY2021, the PoC timing would come for that as well.

Sorry, the explanation might not be so clear, but the color has not changed, meaning that there is no difference, so a and b, both are colored in this way with a reflection of the current status. That understanding is right.

**Hashiguchi [Q]:** Last question. zolbetuximab, Phase III result, when it will be available? Completion date of the clinical trial, SPOTLIGHT trial this month, and GROW trial September, so that timing will be still delayed.

**Kitagawa [A]:** Of course, we have to think about event rate, and based upon that final readout would take place. Depending on that timing, the schedule might be ahead or later.

The ClinicalTrials.gov completion date is something you can refer to currently. The data other than that are not disclosed at this moment.

**Hashiguchi [Q]:** Primary endpoint/report would lead to a press release for one of the two studies?

**Kitagawa [A]:** Once we have the results through appropriate ways including conferences, we will be in the direction to disclose the information.

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

**Operator [M]:** Mr. Sakai from Credit Suisse Securities, please.

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**Sakai [Q]:** Sakai from Credit Suisse. As for personnel optimization, not by country, but 1,000 in total for multiple countries or regions. How many in Japan? I think this is the sales reps. Optimization efforts have been completed for the time being?

According to Mr. Okamura, there can be a continuous review, but how much have you completed? If you can comment on that, that would be highly appreciated. That's my first question.

**Okamura [A]:** Thank you for your question. Out of 1,000 personnel reduction, Japan accounts for about half; 650 applied I mentioned. About 500 of them belong to sales and marketing. If I say too much, Matsui may be offended, but this will not lead to a completion. We have to review all the time. That's essential.

Partly because of the COVID-19 pandemic there is an acceleration of our review, but we do not intend to end here. I think Matsui can agree to this.

**Sakai [Q]:** Understood. So 2138, Claudin 18. 2, zolbetuximab. I was following the project for that position in ASP2138. This is a bispecific and another target is the CD3. So focus currently is the GI. GI cancer is the target, but for the future, solid tumors and other organs are also in the scope of your development? Do you have any idea about that?

**Okamura [A]:** I don't have every information with me, so I cannot tell you the details, but generally speaking the way of thinking here is that because this is a bispecific antibody, and for the solid tumor, we would like to try the T cell engaging. If you move the parameters all at once, then you don't know what is the cause and what is the result.

For us, first, we target first the Claudin 18.2 because zolbetuximab worked for that, so we selected that one. This is likely to be effective for GI cancer. That's why this is selected. If this bispecific antibody engages T cells and the result is better than zolbetuximab; that's something we would like to verify. That's the very starting point of this research and development.

If this bispecific works well, then from that we can do whatever is likely to be possible. We can think about other tumor types. We can think about another tumor or antigen to be replaced or to be added. We would like to do this as a staged manner.

In order for the proof of principle, what's seen clear is fixed, and after that, with the bispecific and CD3 is added with that, T cell is really engaged. In order to try that, we are currently working on the current process.

**Sakai [Q]:** I see. So Claudin 18.2, because you have zolbetuximab already; and if this makes success, then you can come and realize the followings. After that, you'll think about CD3 and its potential. Right?

**Okamura[A]:** Claudin 18.2, this is a cancer antigen that is already known. For gastric and gastroesophageal junction adenocarcinoma and the pancreatic adenocarcinoma, for those Claudin 18.2 will be probably okay, so CD3 is added. If that works well, then CD3 is fixed and then the branch of the cancer antigen will be changed and Claudin 18.2 plus CD3 combinations with this, other cancer types might be viable. In that way, we would like to expand and develop our programs.

**Sakai [Q]:** Thank you. One last question. Prograf, which was not talked about much, you may wonder why I ask this question. Xenotransplant was a topic in the United States. Prograf is shrinking in the US, so there may be no impact of a xenograft, but JPY180 billion size, and Prograf has not been protected by IP.

Regarding the current status, RA in Japan a little. For the rest, it's used for transplantation. This franchise may be important to achieve your CSP targets. Could you explain the current status based on this?

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**Matsui [A]:** Thank you for your question. I wonder how to respond to this big question. As you said, LOE was reached and more than 10 years have passed, but patients and physicians have a deep brand stick, so this product is used.

As for xenotransplant, there was some individual news coverage. Since 20, 30 years ago, xenotransplant has been tried a few times as I remember. One case of the xenotransplant using a pig heart was done. I am aware of that. Reengagement is not considered by Astellas for now, but this is used a lot, and there are patients who depend on our product. We'd like to ensure a stable supply for them to use the product. Minimally required information provision will continue and supporting the academic societies, that is going to continue so that this drug is going to be used for a long time. We'd like to make such efforts.

Because of one case report of xenotransplant, we are not considering a reengagement here. That's all from me. Thank you very much.

**Sakai [Q]:** Because of the xenotransplant topic, I look at it. You have sales mainly in Europe?

**Matsui [A]:** Right. Europe is a big market. In Europe, from the regulatory authorities, in principle, as we said, narrow therapeutic window drug for Prograf, so to speak. Even if it's the same tacrolimus, there's a slight difference. Affecting the upper blood concentration and also the PK and the transplantation results, that's a concern. Many doctors and patients are raising such potential risks to the regulatory authorities, and there are many European countries issuing guidance.

Because of that, even after patent expiry, this drug is still being used, but because of the situation it's already reached LOE, so pricing pressure is continuing every year. There is a decline every year. In spite of the usage a lot, we cannot maintain the price and the price is declining little by little as we are aware.

**Sakai [M]:** Understood. Thank you very much.

**Operator [M]:** Goldman Sachs, Mr. Ueda, please.

**Ueda [Q]:** Ueda from Goldman Sachs Securities. Thank you very much.

First question, it's about the XTANDI US status. Quarterly basis, this quarter, that is not much of a growth. Inventory, the pricing and action situation, what's the current growth level?

Also in order to achieve the target, if there is a further decrease in the fourth quarter, it's going to be difficult to achieve the target. But what do you think about your progress toward the target?

**Matsui [A]:** Thank you for the question. XTANDI, well, first of all, Q3, that is not much of the growth when we see it, and there is an impact of inventory, just like you pointed out. But also gross to net, meaning about the discount is the issue.

In the third quarter, what has been already existing was recognized and posted this time, this quarter. That has a great impact into the result of this third quarter. The monetary sales wise, it's almost flat or seemingly, it's a bit minus, a negative level. That's the actual situation, but overall, volume in actual volume is a bit of an increase, not a great increase, but there is a bit of an increase.

Thinking about the fourth quarter, just like you pointed out, the coverage gap for the donut hole is going to be paid, and that amount is going to be larger. We know that's happening, but at the same time we have several activities ongoing. One of them is about the gross to net from different angles. We are going to conduct several projects in order to reduce gross to net. The global team, the US team, together with them, we consider a lot and we execute the plan.

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We expect the impact of this would happen in the fourth quarter, although currently, there's a bit of a delay, but in the fourth quarter we would like to catch up to the goal. This is a stretched goal, so we may not be able to achieve that, but so far, we believe that we can marginally achieve it anyhow. That's all.

**Ueda [Q]:** Thank you very much. Second, OAB in the United States, there was a mention of the pricing pressure earlier. Due to the impact of COVID-19, any factors for the recovery next fiscal year and beyond? Could you explain?

**Matsui [A]:** First of all, if you look at the entire OAB market, as you said, because of COVID-19, patient visits and prescriptions were lower slightly than expected, but our share in the OAB market is rising. You may have accessed the IQVIA data and Myrbetriq US share is 24%. We have reached up to that level, marking a record high.

The OAB market in the next fiscal year and beyond, how it's going to grow? As one factor, COVID-19 impact, now the Omicron variant is prevalent, how it's going to be stabilized and how patients can make visit? We're expecting a positive recovery. That's our expectations.

Also, as for the competition, there are two companies. One more company is trying to increase awareness of the OAB market and beta-3 drugs. Through such awareness activities, the market itself is going to grow according to how we see. We may not expect a big growth, but as for the market, for patients and the volume, it's going to grow. Pricing pressure, as was explained, does exist, so a slight increase or remaining flat in the US according to our outlook. That's all from me.

**Ueda [Q]:** Thank you. Last question. That's about page 12. The compassionate-use situation in France, that's about the skin reaction. In other indications, is there any impact, we don't need to worry about that? How should we view about this situation?

**Kitagawa [A]:** First of all, at Astellas, of course, the safety of the patient is always a priority. For this situation, well, there's approach from the French authority, and to that with the collaboration with the authority, necessary information is duly provided. This is skin reaction. By the way, well actually, Nectin-4, that is expressed in the skin as well and mode of action wise, regardless of indication, there is a possibility of such a skin reaction. US and Japan packaging inserts, such warnings or box warnings state about the appropriate warnings, because in these two countries this drug is approved. And also, prepared to use guideline and side-effect management leaflets are available.

Also, we are promoting for the appropriate prescription. If this skin reaction happens, this adjustment is suggested. In that way, we are trying to secure the safety of the patients.

Regarding this event this time, as they mentioned, there is a warning available through the package insert, but we are going to continue to reinforce that.

Well, there is no change about the already existing risk and benefit. That's our approach.

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

**Fujii [M]:** Thank you very much. Next person, please.

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

**Wakao [Q]:** Thank you very much. Wakao from JPMorgan. First, SG&A expenses. Next fiscal year, the level of SG&A costs. Compared to the third quarter, is it going to be more easily controlled?

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For the third quarter, if there is an upside of the SG&A cost, next time, are you going to maintain at that level with an upside? Or are SG&A costs to be flat in absolute terms according to your targets? Are you going to maintain that level? Or are you going to aim for a lower level?

You have investments into Digital Transformation and after restrictions on COVID-19-affected activities, it may be more easily controlled next term. Could you explain from that perspective?

**Okamura [A]:** First of all, if we change our targets and goals every time, it doesn't serve as a target. I am not thinking about setting the 2022 targets after looking at the 2021 results. The basis SG&A absolute levels, hopefully, would be maintained as flat as possible, which we used in setting the CSP2021. Of course, it's going to be easier for the control. That's my wish, but in FY2022, if you look at the development catalysts, we had to prepare for commercialization in many projects in the next fiscal year.

We announced CSP and in the initial year, if you have an unused budget, your remaining budget would be taken away. In that sense, it's going to be easier a bit, but this may be an element of a headache for Matsui, but we cannot say it's going to be fine so easily in FY2022, in my view.

Having said so, just cost reduction in the entire Company as a direction, if that's the case, we may tend to be passive. We may not be able to do what we need to do, so rather, where we have to use our money, we should spend money. That's what I say. If you want to use your money somewhere, there is a capacity of each one of you, so it cannot be everything. If you want to use your money somewhere, you have to prioritize and focus. Otherwise, you can't do it.

Where you have to use, you can spend your money, but you have to save somewhere else. Based on this theory, this is what I tell the organization. You can spend, but if you ignore savings, some people may try to do so, then that can be a factor for an upside. How much we can ensure discipline is going to be a key, so what would happen in the fourth quarter is going to be a milestone. Otherwise, if it doesn't work, what additional measures do we need to take in FY2022? We are considering about it right now. Sorry for my long answer to your question.

**Wakao [Q]:** I understood it quite well. The next question is AT845. February WORLDSymposium, the interim data are going to be announced. What kind of data would that be?

According to ClinicalTrials.gov, endpoint is safety, alpha-glucosidase expression level and also activity level. But the data you are planning to announce this time, those are about the safety for these endpoints, expression, activity observed? I don't know if that's a PoC, but the initial level of the efficacy, suggestible data are going to be announced?

Also regarding AT845, capsid vector encapsulation rate, such a formulation designing, that's not necessary to be particularly considered for this AT845?

**Kitagawa [A]:** This AT845 WORLDSymposium, what kind of announcement we would make? The primary announcement will be safety, of course, but for the efficacy we believe that we can announce some sort of data.

**Okamura [A]:** And the latter half of the question, I'm not a scientist, but I would like to make an effort to answer that question.

In AAV, the truly necessary transgene is applied. Well, when we make something and there is a bag and put something inside and you make a product, you tend to think in that way. but for AAV there is a social gene and with the cells, they make the parts randomly. They combine together and the gene constructs are encapsulated. That's the construct of AAV. That process itself cannot be changed.

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Of course, we can do something on the primer. Scientists, they have different ideas. but with the increase of the accuracy of the manual work, full ratio increases, that would not apply for this case. There are some things made in a random manner and we select fully completed, and that is purified. That kind of engineering will be the direction that we would go for.

Overall, currently, when it comes to genetic treatment or gene treatment, full/empty ratio is considered and a ratio of the full construct should be increased. That's what the authority says, and that's an initiative currently for the industry as a whole.

For example, AT132, because there are no alternative options, rather than using up a lot of time there, effective treatment should be available. That's a request.

However, when it comes to Pompe disease, I don't know if it is really the—or rather putting aside if there's a good therapy or not. That is the option that we continue to do it or the product is continued to be used. In that case, the accuracy of the preciseness of the product is quite important. Full/empty ratio, when it's considered, the proportion of the full should be higher. but when it comes to the threshold for that, there was no standard set goal in industry, in academia as well.

But overall, the requirement toward that is going to be quite high. That's why we need to prepare for that. That's what we think.

**Wakao [M]:** I understood it quite well. Thank you. I'm looking forward to the future R&D meeting.

That's all from me. Thank you very much.

**Operator [M]:** Mr. Muraoka from Morgan Stanley Securities.

**Muraoka [Q]:** Muraoka from Morgan Stanley. Thank you for your time.

First, Lexiscan, generics. I understand fully that there isn't much you can explain, but you mentioned later in the CSP2021 period, so I imagine it's going to be 2024, 2025. How are generics going to be launched? On day one, many products to replace the product 80% or 90%? Or by limiting the volume, it's going to replace in a milder fashion? What's your image? Based on the current information, how should we look at this?

**Okamura[A]:** Sorry. There are so many things we cannot answer, so I cannot respond.

In principle, we settled our dispute with some defendants. Generics will be launched at a certain timing. Based on this assumption, it's not through paragraph 4, but some got the approval for generics. Then how they're going to behave is also a question. It's difficult to make the right assumptions in my view.

But generally speaking, unless it is very unique and special products, or very unique and special channels, or very special customers, or very special and unique patients, once it is lifted, it would be replaced with generics in the US generic business.

One day earlier, compared to competitors, that difference is going to be a main source of profit for such generic business. According to my understanding, that's how I see it. Those companies would look at the situation around to consider their behavior, in my view. I'm not a generics manufacturer, so I'm not in a position to comment on their strategy. That's all.

**Muraoka [Q]:** Thank you. That refreshes your information for me. And this gain on divestiture of intangible asset? Well, in the current business plan, in the next fiscal year, to a certain extent, this type of gain would

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happen in some noncore business or noncore products. Okamura-san, do you have some such ideas or that isn't likely?

**Okamura [A]:** Thank you for the question. Rather than if it's in a mind or not, but basically, for commercial units, where they put their resource, and sales and profit is worth inputting that resource. That's the beginning of the thinking or it becomes a legacy product; sales are reduced. The price reduced, but the volume is maintained, and for that cost of manufacturing increase: it will be the programmatic, or marketing authorization will be maintained, and safety information has continued to be collected, the cost to maintain the rights of the sales. Considering all the factors, we decide what to be done. If we say "please get this product," then there has to be the counter, but otherwise, this contract is not going to be established. There are such factors involved. Needless to say, such factors I mentioned, we set up the criteria for such factors and discuss about the different products.

Of course, I see some picture, but from when, with whom we start the discussion, in what way of the transactions will be started? Such kind of a specific picture is not drawn yet. There is no clear view available that is available to be explained to you. That's all.

**Muraoka [M]:** Thank you very much. I understand.

**Fujii [M]:** That's all the questions we have received. With this, we'd like to close today's meeting.

Thank you very much for joining today.

[END]

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