



**Astellas Pharma Inc.**

Financial Results for FY2021

April 27, 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>	Financial Results for FY2021	
<b>[Fiscal Period]</b>	FY2021 Annual	
<b>[Date]</b>	April 27, 2022	
<b>[Time]</b>	14:00 – 15:31 (Total: 91 minutes, Presentation: 50 minutes, Q&A: 41 minutes)	
<b>[Number of Speakers]</b>	5	
	Kenji Yasukawa	Representative Director, President and CEO
	Bernhardt Zeiher	Chief Medical Officer (CMO)
	Yukio Matsui	Chief Commercial Officer (CCO)
	Minoru Kikuoka	Chief Financial Officer (CFO)
	Hiromitsu Ikeda	Head of Corporate Advocacy & Relations
<b>[Analyst Names]*</b>	Hidemaru Yamaguchi	Citigroup Global Markets Japan Inc.
	Kazuaki Hashiguchi	Daiwa Securities Co. Ltd.
	Shinichiro Muraoka	Morgan Stanley MUFG Securities Co., Ltd.
	Fumiyoshi Sakai	Credit Suisse Securities (Japan) Limited
	Motoya Kohtani	Nomura Securities Co., Ltd.
	Akinori Ueda	Goldman Sachs Japan Co., Ltd.

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

### 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.*

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## Presentation

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**Yakusawa:** Hello, everyone. I'm Kenji Yakusawa from Astellas Pharma, Inc. Thank you very much for joining our FY2021 financial results announcement meeting out of 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.

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. Information about investigational compounds in development does not imply established safety or efficacy of the compounds; there is no guarantee investigational compounds will receive regulatory approval or become commercially available for the uses being investigated.



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Page two is a cautionary statement regarding forward-looking information. I'm not going to read this.

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I FY2021 Consolidated Financial Results

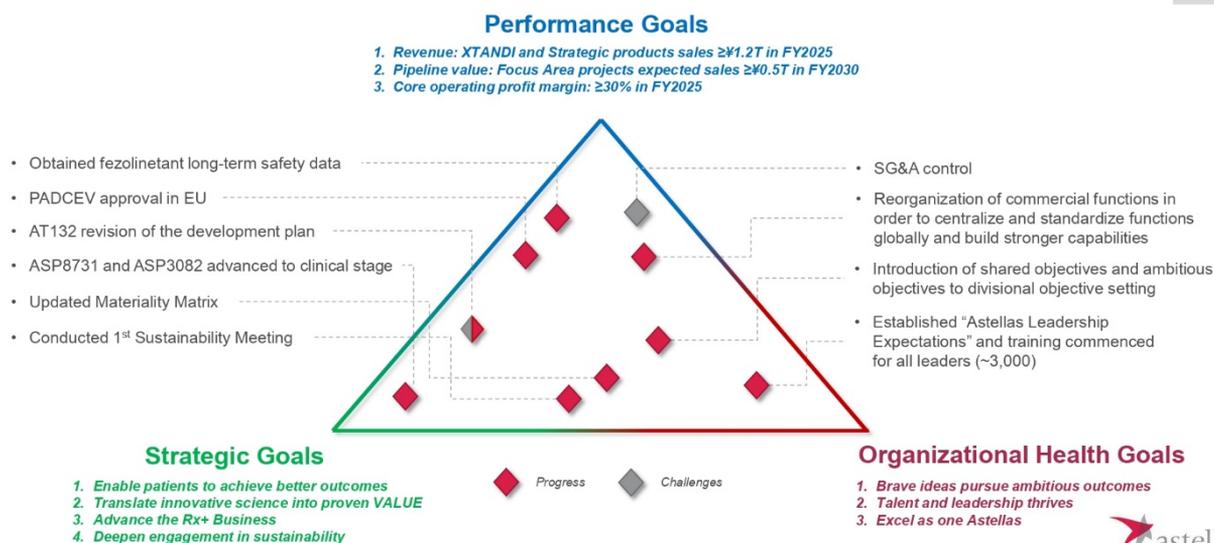
II Initiatives for Sustainable Growth

III FY2022 Forecasts and Key Expected Events



Page three is the agenda for today.

CSP2021 MAJOR PROGRESS IN Q4FY2021



From page four, I'd like to go into the main topics. First, I will explain the major progress in the fourth quarter based on our Strategic Goals, organizational health goals and performance goals set in the Corporate Strategic Plan, CSP2021. These three goals are not independent but complementary to each other. So they are intended to show the total picture on where our initiatives are positioned with respect to these goals and how they are progressing.

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The nonfinancial information is also contained here. The stock market is requesting for the disclosure of the nonfinancial information. It can be useful for the stock market to understand what we regard as meaningful progress. That's why I'm sharing this with you.

First, significant achievements in the fourth quarter, we completed fezolinetant long-term safety studies, obtained PADCEV approval in EU and advanced ASP8731 and ASP3082 to the clinical stage.

Regarding important progress in our sustainability initiatives, we updated the Materiality Matrix and conducted the first Sustainability Meeting. Furthermore, from the Organizational Health Goals perspective, in order to substantially transform our corporate culture, we established Astellas leadership expectations and conducted training to all leaders.

Commercial functions such as communication, market research, training and promotional material development, including digital, used to report to each region before, but we reorganized these commercial functions in order to centralize and further standardize the functions of the global organization.

As for AT132, our initiatives towards resuming development made progress, as scheduled. We reviewed adverse events and made preparation to meet with FDA. On the other hand, recognizing impairment loss had a financially negative impact. We understand SG&A cost control is a challenge we need to address.

Based on this CSP 2021 progress in the fourth quarter, I will explain our FY2021 financial results in more detail from the next page.

## FY2021 FINANCIAL RESULTS: OVERVIEW

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*Record revenue increase for the first time since FY2018  
Revenue increased 4% YoY and was slightly behind full-year forecast*

- Sales of XTANDI and Strategic products increased 19% YoY, offsetting sales decrease due to termination of sales and distribution / transfer of product, but were behind ambitious full-year forecast aligned to CSP2021
- SG&A expenses were above full-year forecast  
R&D expenses were on track, but below full-year forecast when excluding one-off factors

### *Operating profit*

- Core OP was behind full-year forecast due to promotion of standardization / rationalization investment for the future, temporary slowdown of XTANDI sales in Q4, and cost of sales increase due to rapid yen depreciation at end of FY2021
- Full basis was also behind full-year forecast
  - Booked impairment losses on intangible assets and goodwill in Q4/FY2021 not included in full-year forecast :  
Review of AT132 development plan (31.2 billion yen), termination of development for ASP2390 (11.3 billion yen), and termination of development for ASP1951 (5.2 billion yen)



Strategic products: XOSPATA, PADCEV, EVRENZO  
CSP2021: Corporate Strategic Plan 2021

Page five. In FY2021, revenue increased and profit decreased. We achieved revenue increase for the first time since FY2018. Revenue rose by 4% from the previous year and was slightly behind our full-year forecast. Sales of XTANDI and Strategic products increased by 19% YoY, offsetting sales decrease due to termination of sales and distribution, transfer of product, but we're behind our ambitious full-year forecast aligned to CSP 2021.

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S&A expenses rose above our full-year forecast. The expenses were on track but below our full-year forecast, excluding one-off factors.

Core operating profit was behind our full-year forecast due to proactive investment towards the future, temporary slowdown of XTANDI sales in the fourth quarter, and cost of sales increased by the yen's sharp depreciation at the end of FY2021. Full-basis operating profit was also behind our full-year forecast.

As you can see on the slide, we booked impairment losses in the fourth quarter which were not included in our full-year forecast.

## FY2021 FINANCIAL RESULTS

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(billion yen)	FY2020	FY2021	Change	Change (%)	FY2021 FCST*	Achievement	FX impact
<b>Revenue</b>	<b>1,249.5</b>	<b>1,296.2</b>	<b>+46.6</b>	<b>+3.7%</b>	<b>1,323.0</b>	<b>98.0%</b>	+59.6 bil. yen
Cost of sales	246.1	253.0	+6.9	+2.8%			
% of revenue	19.7%	19.5%	-0.2 ppt				
<b>SG&amp;A expenses</b>	<b>504.3</b>	<b>548.8</b>	<b>+44.5</b>	<b>+8.8%</b>	<b>541.0</b>	<b>101.4%</b>	+25.0 bil. yen
US XTANDI co-pro fee	120.2	139.3	+19.1	+15.9%			
SG&A excl. the above	384.2	409.5	+25.4	+6.6%			+17.2 bil. yen
<b>R&amp;D expenses</b>	<b>224.5</b>	<b>246.0</b>	<b>+21.5</b>	<b>+9.6%</b>	<b>242.0</b>	<b>101.7%</b>	+8.0 bil. yen
Amortisation of intangible assets	23.8	28.3	+4.5	+19.0%			
Gain on divestiture of intangible assets	-	24.2	+24.2	-			
<b>Core operating profit</b>	<b>251.4</b>	<b>244.7</b>	<b>-6.6</b>	<b>-2.6%</b>	<b>270.0</b>	<b>90.6%</b>	+18.5 bil. yen
<Full basis>							
Other income	7.6	15.3	+7.6	-			
Other expense	123.0	104.3	-18.6	-			
<b>Operating profit</b>	<b>136.1</b>	<b>155.7</b>	<b>+19.6</b>	<b>+14.4%</b>	<b>218.0</b>	<b>71.4%</b>	
Profit before tax	145.3	156.9	+11.6	+8.0%	216.0	72.6%	
<b>Profit</b>	<b>120.6</b>	<b>124.1</b>	<b>+3.5</b>	<b>+2.9%</b>	<b>174.0</b>	<b>71.3%</b>	



\* Announced in Oct 2021

Next, on page six, I will explain FY2021 financial results. Revenue increased to JPY1.2962 trillion, up 3.7% YoY. The achievement against our full-year forecast was 98%.

Core operating profit was JPY244.7 billion, down by 2.6% from the previous year. The achievement against the full-year forecast was 90.6%.

The bottom half of this page shows our full-basis results. In FY2021, we booked JPY104.3 billion as other expense. Operating profit was JPY155.7 billion, up 14.4% from the previous year. Profit increased to JPY124.1 billion, up 2.9% from the previous fiscal year.

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## FY2021 FINANCIAL RESULTS: SALES OF MAIN PRODUCTS

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FY2021 Actual (billion yen)

<b>XTANDI</b>	<b>534.3</b>	YoY: +75.9 (+17%) Achievement against FCST: 96% FY2021 FCST: 554.1	<ul style="list-style-type: none"> <li>✓ Double-digit growth continues globally</li> <li>✓ Sales against ambitious forecast were behind due to the following factors; US: Impact of COVID-19 (less sales promotion activities/ slowdown of new patient starts) and increased impact from competition EU: Reimbursement delay, increased pricing pressure and competition</li> </ul>
<b>XOSPATA</b>	<b>34.1</b>	YoY: +10.2 (+43%) Achievement against FCST: 96% FY2021 FCST: 35.4	<ul style="list-style-type: none"> <li>✓ Global sales increased driven by growth mainly in US, EU and China</li> <li>✓ Captured high market share in US and Japan within the current indication</li> <li>✓ Sales against full-year forecast were behind</li> </ul>
<b>PADCEV</b>	<b>21.7</b>	YoY: +8.9 (+70%) Achievement against FCST: 105% FY2021 FCST: 20.7	<ul style="list-style-type: none"> <li>✓ Global sales exceeded full-year forecast</li> <li>✓ Revenue in US grew steadily and in line with forecast</li> <li>✓ Launched in Japan in Nov. 2021 and initial uptake has been very strong and exceeded expected market penetration</li> </ul>
<b>EVRENZO</b>	<b>2.6</b>	YoY: +1.5 (+132%) Achievement against FCST: 36% FY2021 FCST: 7.2	<ul style="list-style-type: none"> <li>✓ Sales in Japan were behind forecast due to increased competitive pressure</li> <li>✓ Launched in EU from Sep. 2021 and sales were behind forecast due to the impact of COVID-19 (restriction of sales promotion activities) and the low penetration of differentiation from standard of care</li> </ul>
<b>mirabegron</b>	<b>172.3</b>	YoY: +8.7 (+5%) Achievement against FCST: 98% FY2021 FCST: 176.3	<ul style="list-style-type: none"> <li>✓ Global sales increased, but were behind full-year forecast</li> <li>✓ In the US, sales were behind forecast due to lower than expected US OAB market growth and increased pricing pressure</li> </ul>

PADCEV (US): Co-promotion revenue from Seagen.  
mirabegron (Product name: Betanis/Myrbetriq/BETMIGA), OAB: Overactive bladder



On page seven, let me explain the financial results for our main products.

As for XTANDI, global sales increased to JPY534.3 billion, up by JPY75.9 billion or 17% YoY. It is a product with over JPY500 billion sales but continues to make a strong double-digit growth. But sales were behind our full-year forecast with the 96% achievement rate.

By region, we were behind in the US and EU. In the United States, the impact of COVID-19 led to less sales promotion activities and slowdown of new patient starts. In addition, there was increased impact from competition in the fourth quarter. We were also affected by the temporary rise in the ratio of Patient Assistance Program, the so-called PAP, which is implemented to ensure access by patients who have difficulty paying for XTANDI drug costs. We think these are one-off factors during the fourth quarter and these impacts will decrease in FY2022. We are expecting continued sales growth in the United States.

In the EU, the main factors were a reimbursement delay in major countries, increased pricing pressure and intensifying competition.

XOSPATA Global sales increased to JPY34.1 billion, up JPY10.2 billion or 43% from the previous year. It captured a high market share in the US and Japan within the current indication and expanded sales in each region, but sales against our full-year forecast were behind with an achievement rate of 96%.

PADCEV global sales increased to JPY21.7 billion, up JPY8.9 billion or 70% compared to the previous year. The achievement against our full-year forecast was 105%. In the United States, in addition to the existing indication, the additional second-line indication we obtained in July last year has also contributed to sales growth.

In Japan, PADCEV was launched in November last year. Initial uptake has been very strong and exceeded expected market penetration. New prescriptions and adoptions have been increasing more than expected.

EVRENZO sales reached JPY2.6 billion, increasing by JPY1.5 billion YoY. The achievement rate was 36%, substantially behind our full-year forecast.

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Sales in Japan have been rising YoY due to the expansion of the HIF-PHI market as a whole, but we're behind our full-year forecast due to the impact of intensifying competition.

In the EU, EVRENZO was launched in September last year but sales were behind our full-year forecast due to much lower market penetration compared to our assumptions. As a background, the impact of COVID-19 led to restriction of sales promotion activities at the launch time. In addition, this is a drug for disease with relatively established standards of care and many doctors are careful about prescribing new treatments for the time being, according to our analysis.

Mirabegron global sales increased to JPY172.3 billion, up JPY8.7 billion, or 5% YoY, slightly behind our full-year forecast, with the achievement rate of 98%. Particularly in the United States, which accounts for about half of global sales, sales were behind our full-year forecast due to lower-than-expected US OAB market growth and increased pricing pressure.

## FY2021 FINANCIAL RESULTS: COST ITEMS

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*SG&A expenses increased YoY and were above full-year FCST*

*R&D expenses increased YoY and were below full-year FCST when excluding one-off factors*

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

#### Cost of sales % of revenue

YoY: -0.2ppt



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

#### SG&A expenses

YoY: +8.8%

Achievement  
against FCST: 101%



- ✓ SG&A excl. XTANDI US co-pro fee: +8.2 bil. yen (YoY +2.1%) (excl. FX impact)
- ✓ Investment in Digital Transformation (Approx. +8.0 bil. yen)
- ✓ Increase in sales promotion expenses for new product launch readiness (Approx. +5.0 bil. yen)
- ✓ Global optimization of personnel aligned with transformation of product portfolio (Approx. -9.0 bil. yen)

#### R&D expenses

YoY: +9.6%

Achievement  
against FCST: 102%



- ✓ FX impact (+8.0 bil. Yen)
- ✓ Increase in development cost of zolbetuximab and expanded investment in iota
- ✓ Inventories related to commercial production of development projects booked as R&D expenses (Approx.+8.0 bil. yen)
- ✓ Underspend against full-year forecast when excluding one-off factors



CSP: Corporate Strategic Plan

Next, on page eight, I will explain cost items compared to the previous fiscal year and full-year forecast. The COGS ratio decreased by 0.2 percentage points compared to the previous year due to changes in product mix. Towards the end of the fourth quarter, due to the yen's sharp depreciation against the US dollar and the euro, Forex impact on elimination of unrealized gain increased the COGS ratio by 0.2 percentage points.

SG&A expenses increased by 8.8% YoY. SG&A costs, excluding XTANDI US co-promotion fee, increased by JPY8.2 billion or 2.1% YoY, excluding Forex impact.

In our actual business, there was also an increase in our investment in digital transformation and sales promotion expenses for new product launch readiness and post-marketing growth of Strategic products, resulting in an increase by about JPY13 billion from the previous year. On the other hand, costs decreased by about JPY9 billion YoY due to global optimization of personnel aligned with transformational product portfolio. As a result, we spent above our full-year forecast.

R&D expenses increased by 9.6% YoY. In addition to an increase in development cost of zolbetuximab, investments related to iota we acquired in FY2020 also increased our R&D expenditure. Also, according to

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international accounting standards, inventories related to commercial production or pre-approval development projects, including drug substance and drug product manufactured for process performance qualification, are booked as R&D expenses.

In FY2021, an increase in zolbetuximab and fezolinetant inventories became another factor to increase our R&D expenditure, which had an impact of increasing the costs by about JPY8 billion YoY. Excluding these one-off factors, we underspent against the full-year forecast. Main factors were a clinical hold of AT132, DMD program termination and development delay in ASP7317.

## AGENDA

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I FY2021 Consolidated Financial Results

II Initiatives for Sustainable Growth

III FY2022 Forecasts and Key Expected Events



From here, on page nine, I will explain our initiatives for sustainable growth.

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## XTANDI & STRATEGIC PRODUCTS: HIGHLIGHT

(Red: Updates since the last financial results announcement)

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### Key Events Expected in FY2021 (announced in Apr 2021)

Milestone	Project / Product	Indication / Clinical study	Result	Timing
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)	✓	<b>Apr 2022</b>
		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> )	Not achieved	
Data readout	fezolinetant	52-week safety results from Phase 3 SKYLIGHT 1, 2 & 4 studies	✓	Jul 2021 (SKYLIGHT 2) Oct 2021 (SKYLIGHT 1) <b>Mar 2022 (SKYLIGHT 4)</b>

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

(✓ : Achieved)



Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132  
 M1: Metastatic, (m)UC: (metastatic) Urothelial cancer, CKD: Chronic kidney disease, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, sBLA: Supplemental Biologics License Application, sNDA: Supplemental New Drug Application

On page 10, regarding XTANDI and Strategic products, I'd like to explain the progress of major events we expected to achieve during FY2021 which we presented in April last year. The achievements by the previous results announcement by the third quarter are shown in black while quarterly updates since are shown in red. This is not an achievement in the fourth quarter of FY2021, but we obtained approval for enfortumab vedotin in EU in April last year.

As for fezolinetant, we obtained top-line results from Phase III long-term safety study, SKYLIGHT 4. As was planned at the beginning of the fiscal year, 52-week data is now available from all the three Phase III studies. I will explain the details later.

Regarding gilteritinib, XOSPATA, we were planning to submit sNDA for full approval in China but, unfortunately, we couldn't make it. In China, the product was already launched with conditional approval and we are expecting almost no impact of the submission delay on our business.

Throughout FY2021, we were able to achieve seven of the eight important events we set.

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Obtained encouraging data supporting the ongoing Phase 3 studies in MIBC

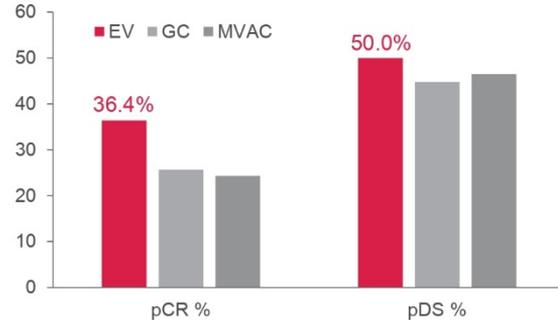
<Cohort H in EV-103 study>

<b>Patient segment</b>	Patients with MIBC who are ineligible for cisplatin-based chemotherapy
<b>Study design</b>	Neoadjuvant monotherapy 3 cycles, on days 1 & 8 of 21-day cycle
<b>Enrolled participants</b>	22
<b>Primary endpoint</b>	pCR rate by central pathology review
<b>Secondary endpoint</b>	pDS rate by central pathology review, safety, etc.

Neoadjuvant EV monotherapy

Radical cystectomy & pelvic lymph node dissection  
4 to 12 weeks after last dose of neoadjuvant EV  
microscopic examination

<Antitumor activity: comparison with cisplatin-based chemotherapy data\*>



EV: EV-103 Cohort H, cisplatin-ineligible MIBC patients  
GC, MVAC: cisplatin-eligible MIBC patients



MIBC: Muscle-invasive bladder cancer, pCR: Pathological complete response, pDS: Pathologic downstaging, GC: Gemcitabine and cisplatin/carboplatin, MVAC: Methotrexate, vinblastine, doxorubicin, and cisplatin  
\* Oncologist 21:708 (2016)

On page 11, I will explain the data on enfortumab vedotin in MIBC, muscle invasive bladder cancer, patients we presented at the conference the other day. In Cohort H of EV-103 study, neoadjuvant EV monotherapy was administered to cisplatin-ineligible MIBC patients. After radical cystectomy, tissue cells were collected for microscopic examination to evaluate antitumor activity. According to the results, pathological complete response, or pCR, which was the primary endpoint, was observed in 36.4% of the subjects. Pathologic downsizing, or PDS, in other words, tumor-size shrinkage, which was the secondary endpoint, was observed in 50% of the subjects.

On the right panel, you can see our results together with the literature data on neoadjuvant cisplatin-based chemotherapy in MIBC patients eligible for cisplatin which is used as the current standard of care. Due to the small sample sizes in cohort age and due to differences in protocol inclusion criteria in detail and different patient segments, we cannot make a direct head-to-head comparison. And we don't think it's appropriate to do so. But also in the CIS-ineligible patient segment, EV monotherapy demonstrated effects comparable to cisplatin-based chemotherapy. Based on these results, we are hoping that we can obtain good results from the ongoing Phase III studies in MIBC.

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## FEZOLINETANT: TOPLINE RESULTS OF MOONLIGHT 1 AND SKYLIGHT 4 STUDIES

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- Minimal impact of MOONLIGHT 1 study results on CSP2021 sales forecast is anticipated
- SKYLIGHT 4 study results further support proceeding with regulatory filings in US & EU

	MOONLIGHT 1	(ref.) SKYLIGHT 1/2	SKYLIGHT 4
<b>Study type</b>	<b>Non-IND study</b>	<b>IND study</b>	IND study
<b>Patient segment</b>	Women with moderate to severe VMS associated with menopause	Women with moderate to severe VMS associated with menopause	Women with VMS associated with menopause
<b>Study design</b>	<ul style="list-style-type: none"> <li>• First 12 weeks: DB, <b>30 mg</b> vs. placebo (1:1)</li> <li>• Last 12 weeks: active extension treatment, 30 mg</li> </ul>	<ul style="list-style-type: none"> <li>• First 12 weeks: DB, <b>30 mg and 45 mg</b> vs. placebo (1:1:1)</li> <li>• Last 40 weeks: active extension treatment, 30 mg or 45 mg</li> </ul>	<ul style="list-style-type: none"> <li>• 52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)</li> </ul>
<b>Study region</b>	<b>China, Korea and Taiwan</b>	<b>US, Canada and Europe</b>	US, Canada and Europe
<b>Enrolled participants</b>	<b>302</b>	<b>527 / 501</b>	1,831
<b>Primary endpoint</b>	<ul style="list-style-type: none"> <li>• Mean change in the frequency and severity of moderate to severe VMS from baseline to week 4 &amp; 12</li> </ul>	<ul style="list-style-type: none"> <li>• Mean change in the frequency and severity of moderate to severe VMS from baseline to week 4 &amp; 12</li> </ul>	<ul style="list-style-type: none"> <li>• Frequency and severity of adverse events</li> <li>• Percentage of participants with endometrial hyperplasia and/or endometrial cancer</li> </ul>
<b>Topline result</b>	<ul style="list-style-type: none"> <li>• Primary endpoints: <b>Not met</b></li> <li>✓ Numerical improvements from baseline observed but statistical significance not met</li> <li>• 12-week safety data: aligned with what was previously observed</li> </ul>	<ul style="list-style-type: none"> <li>• Primary endpoints: <b>Met</b></li> <li>• 12-week safety data: No new safety signal of concern</li> </ul>	<ul style="list-style-type: none"> <li>• Primary endpoint (endometrial health): Met</li> <li>• The most common TEAE: consistent with placebo</li> </ul>

**Red: difference between MOONLIGHT 1 and SKYLIGHT 1/2 studies (up to 12 weeks)**

<Upcoming conference presentation> May 2022: 12-week data of SKYLIGHT 1 study at ACOG  
Jun 2022: 52-week data of SKYLIGHT 2 study at ENDO



IND: Investigational New Drug, VMS: Vasomotor symptoms, DB: Double-blind, TEAE: treatment-emergent adverse events, ACOG: American College of Obstetricians and Gynecologists, ENDO: Endocrine Society

Next, on page 12, I'd like to talk about two fezolinetant studies whose top-line results have become available recently, namely MOONLIGHT 1 and SKYLIGHT 4 studies.

First, MOONLIGHT 1 is a pivotal study in women living in Asia. Twelve-week double-blind period data was evaluated but unfortunately, the primary endpoint change in the frequency and the severity of VMS was not met. Right now, we are investigating the reasons why from every angle.

As is shown in red in the table, study regions, races, doses, sample size, et cetera are different from SKYLIGHT studies but we have not yet reached any conclusion about the causes. So far, we have not identified any operational issue during the conduct of the study.

In the active drug fezolinetant arm in the study, numerical improvements from baseline similar to SKYLIGHT 1 and SKYLIGHT 2 studies were observed. On the other hand, in the placebo arm, response bigger than previous studies was observed, so we could not achieve statistically significant difference between the two arms. Twelve-week safety data was aligned with what was previously observed in other clinical studies.

MOONLIGHT and SKYLIGHT are implemented as separate studies aiming for regulatory filings in different regions. SKYLIGHT studies were conducted as US FDA IND studies and are positioned differently from the MOONLIGHT study. Our Asian development plan going forward is now under consideration but we're anticipating minimal impact of MOONLIGHT 1 study results on CSP 2021 peak sales forecast.

Next, let me explain the SKYLIGHT 4 study. According to the top-line results we obtained in March, the primary endpoint was met. Overall, we were able to confirm a long-term safety profile which supports proceeding with regulatory filings. Based on these results, we are making preparation for filings, such as analysis and document creation, together with already available SKYLIGHT 1 and 2 study results.

Here, I would like to share our plan for upcoming conference presentations. We are planning to present 12-week data of SKYLIGHT 1 study at ACOG in May and 52-week data of SKYLIGHT 2 study at ENDO in the United States in June.

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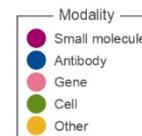


## PROGRESS IN FOCUS AREA APPROACH (1/2): CURRENT STATUS OF CLINICAL PROGRAMS

(Red: Updates since the last financial results announcement)

13

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
	Gene regulation (AAV)	AT845	Phase 1 study ongoing <b>Interim data presented at WORLD Symposium in Feb 2022</b>
Immuno-Oncology	Checkpoint	ASP1951	<b>Terminated</b>
		ASP1570	Phase 1 study ongoing
	Artificial adjuvant vector cell (aAVC)	ASP7517	Phase 2 study in R/R AML and MDS ongoing Phase 1 study in advanced solid tumors ongoing
		ASP0739	Phase 1 study ongoing
	Oncolytic virus (intratumoral)	ASP9801	Phase 1 study ongoing
	Oncolytic virus (systemic)		
	Bispecific immune cell engager	ASP2138	Phase 1 study to start in Q1 FY2022
Blindness & Regeneration	Cancer cell therapy (UDC)		
	Cell replacement	ASP7317	Screening and enrollment in Phase 1b study put on hold, due to a manufacturing delay
	Cell replacement (UDC)		
Mitochondria Biology	Gene regulation (AAV)		
	Gene regulation & mitochondrial biogenesis	ASP1128	<b>Terminated</b>
		ASP0367	Phase 2/3 study in PMM ongoing Phase 1b study in DMD ongoing
	Mitochondrial stress	ASP8731	<b>FSFT in Phase 1 study in Mar 2022</b>
	Mitochondrial transfer		
Primary Focus Candidates	Immune modulating/regulatory cells		
	Tissue-specific immune regulation		
	Targeted protein degradation	ASP3082	Phase 1 study to start in Q1 FY2022



<sup>1</sup>. 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

Next, on page 13, from here on, I will explain the progress of our Focus Area approach. This page shows, in red, the quarterly progress of Focus Area projects in the clinical stage.

During our R&D meeting in March, we talked about AT845 data presentation at the conference.

Regarding ASP1951, one of the immuno-oncology Primary Focus assets, we could not meet prespecified PoC, proof-of-concept, conditions in the clinical study, so we terminated the project.

As for ASP1128, in mitochondria biology, we suspended enrollment of new subjects based on the interim analysis, but we officially terminated the project based on the final analysis results.

ASP8731, our new project, entered the clinical stage and achieved first subject first treatment in March.

In targeted protein integrator, one of the Primary Focus candidates, the lead project, ASP3082, entered the clinical stage. Because of competition, we cannot disclose the details of this project at this moment.

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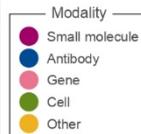
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## PROGRESS IN FOCUS AREA APPROACH (2/2): SUMMARY OF FY2021

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Primary Focus	Biology/Modality/Technology <sup>1</sup>	Achievement in FY2021			No. of projects aiming PoC by end FY25			
		Number of new drug candidates <sup>2</sup>	Phase 1 entry	PoC achieved	CSP2021 <sup>3</sup>	Terminated before PoC judgement	PoC not achieved	As of Apr 2022
Genetic regulation	Gene replacement (AAV)	1			7	3 (AT702, AT751, AT753)		4
	Gene regulation (AAV)							
Immuno-Oncology	Checkpoint	1	2 (ASP1570, ASP2138)		15	1 (preclinical project)	2 (ASP1948, ASP1951)	12
	Artificial adjuvant vector cell (aAVC)							
	Oncolytic virus (intratumoral)							
	Oncolytic virus (systemic)							
	Bispecific immune cell engager							
Cancer cell therapy (UDC)								
Blindness & Regeneration	Cell replacement	1			3			3
	Cell replacement (UDC)							
	Gene regulation (AAV)							
Mitochondria Biology	Gene regulation & mitochondrial biogenesis	1	1 (ASP8731)		5		1 (ASP1128)	4
	Mitochondrial stress							
	Mitochondrial transfer							
Primary Focus Candidates	Immune modulating/regulatory cells	5	1 (ASP3082)		1			1
	Tissue-specific immune regulation							
	Targeted protein degradation							
Others								
Total		9	4	0	31	4	3	24



<sup>1</sup> Not exhaustively listed. <sup>2</sup> Number of therapeutic entities that entered the preparation phase toward IND (Investigational New Drug)/clinical development. <sup>3</sup> Estimated based on standard development timelines, assuming 100% probability of success (at CSP2021 announcement).  
CSP: Corporate Strategic Plan, PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell



Next, page 14, this is a summary of FY2021 progress of Focus Area approach related projects. In the right table, we summarize the changes in the number of projects aiming for PoC by the end of FY2025 as we made public in CSP 2021 in May last year.

In genetic regulation, we had DMD research programs, which are AT702, AT751 and AT753. We terminated these projects as we could not obtain efficacy data we expected in preclinical studies. We also terminated one of the immuno-oncology Primary Focus projects in the research stage.

Regarding ASP1948, ASP1951 and ASP1128, we could not achieve PoC in clinical studies and terminated the development. So we judged PoC in seven projects in FY2021. As of now, we are aiming for PoC in the remaining 24 projects by the end of FY2025.

The table in the middle shows the number of projects which progressed in stages during FY2021 for each Primary Focus. Unfortunately, we did not have any projects which achieved PoC. When projects advance to late-stage research phase to become new drug candidates, we call them a CN candidate nomination as a milestone to judge the need for investment to prepare for the initiation of the clinical studies. Nine projects in total cleared this milestone and enter the late-stage research phase and four projects newly entered the clinical stage.

Primary Focus strategy will not be over in FY2025. We have continued to engage in research energetically. As a result, we have been continuing to create assets advancing to late-stage research phase.

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Key events expected in FY2021 (announced in Apr 2021)

Sphere *	Program	Event	Result	Timing
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	<b>Not achieved</b> (Product specifications under investigation)	
	BlueStar	Initiation of clinical study (Japan)	<b>Not achieved</b> (Clinical strategy under investigation)	
	My Holter II	Commercialization of service	✓	Jul 2021
Patient outcome maximization	pudexacianinium chloride (ASP5354)	Topline results for Phase 2 study	✓	Nov 2021

(✓: Achieved)

Other updates

- Partnering with Nitto and M. Heart for ECG testing service (Sep 2021)



\* Business areas to focus on for realization of Rx+ Story  
ECG: Electrocardiography

Now page 15, this is the summary of the main progress made in FY2021 with regard to the Rx+ program. The initial targets in the beginning of FY2021 was the initiation of pilot marketing of the game application for exercise support and the initiation of a clinical study in Japan for BlueStar digital therapeutics for diabetes but neither were achieved during FY2021.

For the exercise support game application, we are restructuring our policies and specifications against the original specification that we had initially set. For BlueStar, the product specifications and clinical development strategy were reviewed and the schedule was changed.

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## PROGRESS IN Rx+ PROGRAM (2/2): PUDEXACIANINIUM CHLORIDE (ASP5354)



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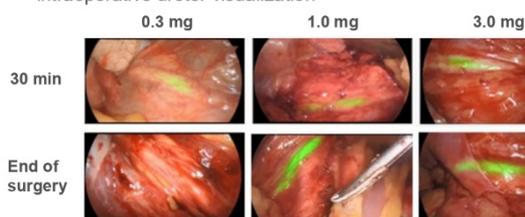
*Pudexacianinium showed favorable efficacy and safety in Phase 2 study, which support further development*

### Results of Phase 2 study

- Pudexacianinium enhanced intraoperative ureter visualization under near-infrared fluorescence conditions
- Pudexacianinium appeared safe and well-tolerated; To date, no safety issues have been reported, no clinically relevant changes in vital signs, ECG or hematology, biochemistry or urine analysis. No related SAE and only 1 TEAE assessed as related by the investigator (grade 1 = mild proteinuria).
- 1.0 mg/patient pudexacianinium is the effective dose for intraoperative ureter visualization

### Next steps

- Phase 3 study is planned to start in FY2022
- Regulatory submission for the U.S. is planned in FY2023
- Business partnership with a device manufacturer is under consideration for commercialization



Ureter Visualization at 30 Minutes Post Pudexacianinium Administration and at End of Surgery

Participants undergoing laparoscopic, minimally invasive colorectal surgery single intraoperative IV dose of 0.3 mg, 1.0 mg, or 3.0 mg  
The green signal indicates the fluorescence from pudexacianinium, which is the location of the ureter (SAGES conference in March 2022)



ECG: Electrocardiography, SAE: serious adverse event, TEAE: treatment-emergent adverse events, IV: intravenous, SAGES: Society of American Gastrointestinal and Endoscopic Surgeons

Now page 16. Here, I'll talk about another Rx+ program topic, Phase II results of ASP5354. ASP5354 is a compound that emits light when irradiated with near infrared light. When administered prior to surgery, it is expected to enable the surgeon to recognize the location of the ureter and reduce the risk of extendedly injuring the ureter during surgery. And also, the surgery time can be shortened.

In the Phase II study, the visualization of the ureter was confirmed at different doses of the compound. As a result, it was confirmed that the ureter could be visualized until the end of the surgery with doses of 1 milligram or higher. No major safety concerns were observed.

Based on these positive results, the project is currently preparing to conduct a Phase III study, which is scheduled to begin during FY2022. If all goes according to plan, we plan to do regulatory submission in the US during FY2023. In addition, since the visualization of the ureter using this compound also requires a device that radiates near-infrared light, we are considering a business partnership with a device manufacturer for future commercialization.

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# REVIEW OF THE FIRST YEAR OF CSP2021

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Performance Goals are achievable despite some challenges

Progress in CSP2021  
 ● As expected  
 ● Recognized as challenge

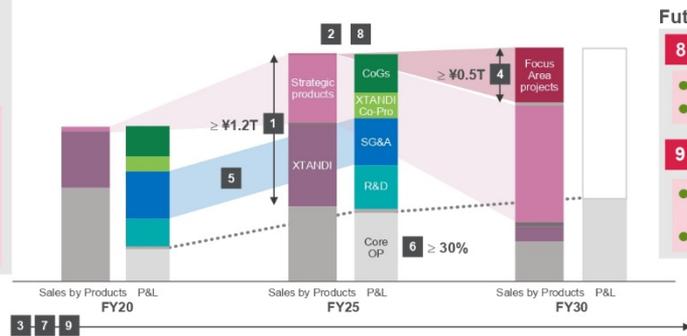
## Revenue, Pipeline Value

- 1** XTANDI and Strategic products\*:  $\geq$  ¥1.2T in FY2025
  - Sales growth by 19% YoY, on track toward the target
  - Achieved most of the expected key development milestones

- 2** Post-PoC projects from Primary Focuses
- 3** Multiple technology platforms
- 4** Focus Area projects:  $\geq$  ¥0.5T in FY2030
  - New drug candidates in 9 projects, Phase 1 entry in 4 projects
  - Judgement in 7 projects
  - No progress to Post-PoC stage from Primary Focus
  - Clinical hold of AT132

## 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
- Strategic upfront investment for future growth
  - Increase of SG&A more than expected (increased investment for future growth such as OHG activities, DX and new products could not be covered by reduction of traditional cost spending)



## Future growth

- 8** Rx+: Breakeven by FY2025
  - First commercialization of service
  - ASP5354: progress to Phase 3
- 9** Sustainability
  - Disclosure aligning with TCFD recommendations
  - Update of materiality matrix

Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132  
 CSP: Corporate Strategic Plan, PoC: Proof of concept, OHG: Organizational Health Goals, DX: Digital transformation, TCFD: Task Force on Climate-related Financial Disclosures



Now, page 17, this is the review of the first year of CSP 2021. In the top left corner, XTANDI and the Strategic products showed sales growth and achieved key development milestones, both in line with expectations. In the bottom left corner, in a Focus Area approach, we have continued to generate, promote or make decisions on projects. However, we have yet to obtain projects that will advance to a post-PoC stage.

Right top corner, in terms of core operating income, we were flat SG&A in absolute terms. With regard to SG&A expenses, our basic policy in this CSP2021 is to place the highest priority on our investments for long-term growth and future efficiency improvements. Specifically, these are company-wide projects to promote innovation and ensure the success of our talents and set forth in the organization of our health goals, DX-related investments such as global mission critical business systems and further efforts to maximize the value of new product lines.

On the other hand, it should be regretted that there was a slight delay in dealing with the various trouble-shooting issues that arise when introducing a new system and in narrowing down traditional cost spendings that should be reduced. Furthermore, regarding the rapid depreciation of the yen at the end of the fiscal year as well as the various geopolitical issues, the final costs temporarily exceed -- well, we decided not to cancel or postpone investments that will contribute to the future, even if the final cost temporarily exceeded our budget. However, we must accept these challenges with humility.

And in the current fiscal year, we have also decided to launch the Dansharism activities described later in order to strategically improve the efficient use of management resources and the intellectual and the labor productivity of our employees in order to recover these investments that will contribute to the future. Although we have identified some issues that needed to be recognized, we believe that, overall, we have made progress in accordance with the plan and addressing these issues going forward will be sufficient to achieve the performance targets of CSP2021.

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I FY2021 Consolidated Financial Results

II Initiatives for Sustainable Growth

III FY2022 Forecasts and  
Key Expected Events



From page 18, I will then discuss our focus for FY2022 and the major events we expect to see in the year.

## FY2022 FORECAST: OVERVIEW

- *Revenue and Profit to increase in FY2022  
Core OP margin for FY2022 to be 20.1%*
- *XTANDI and Strategic products continue to grow (+24%, YoY)  
Growth to more than offset the decrease of mature products*
- *Resource allocation to key strategic areas such as R&D investment for Primary Focus and investment for new product launch readiness (mainly for fezolinetant and zolbetuximab); reviewing costs not contributing to competitiveness and increase of value.  
Control SG&A strictly by cost reduction from global optimization of personnel, thorough reduction of mature products-related costs and optimization of procurement costs.  
Aiming to improve the labor productivity of Astellas by "Dansharism\*" movement*
- *Dividend per share: Forecasted 10 yen increase to 60 yen*



Strategic products: XOSPATA, PADCEV, EVRENZO  
\*Dansharism: Please refer to slide 28 in appendix

Page 19. We expect revenue and profits to increase in FY2022 and we believe that we will be able to secure a core OP margin of 20.1%. Also, we expect sales of XTANDI, our core products, as well as our Strategic products to continue to grow and expect a 24% increase in total sales of these products compared to the previous fiscal year.

R&D expenses will increase overall due to expanded investment in the Primary Focus area. SG&A budget will be allocated to strategic areas in this year. We will continue to thoroughly review costs not contributing to

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competitiveness and the corporate value increase. The effective global optimization of personnel in line with changes in the product portfolio will also continue to contribute to cost reductions. In addition, we will thoroughly reduce sales promotion expenses for activities with lower returns, and we will also optimize procurement costs to strictly control SG&A expenses.

We will apply the concept of Dansharism, which involves cutting out unnecessary things and moving away from excessive attachments to things to daily operations in order to increase the amount of time devoted to operations that need to be performed and improved the labor productivity of Astellas as a whole. This will transform the organization into one in which new innovations can easily occur. As a result, we believe this will contribute to cost reductions through the selection of operations. In this fiscal year, we will promote this concept of Dansharism.

For FY2022, we expect to pay a dividend of JPY60 per share, an increase of JPY10 per share. We have not changed our basic stance on capital allocation, i.e. to place the highest priority on business investment for a realization of growth and to maintain a policy of stable and sustainable dividend growth based on mid- to long-term profit growth.

## FY2022 FORECAST

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(billion yen)	FY2021 actual	FY2022 forecast	Change (%)
<b>Revenue</b>	<b>1,296.2</b>	<b>1,443.0</b>	<b>+11.3%</b>
SG&A expenses	548.8	598.0	+9.0%
US XTANDI co-pro fee	139.3	182.0	+30.6%
SG&A excl. the above	409.5	416.0	+1.6%
R&D expenses	246.0	254.0	+3.2%
<b>Core operating profit</b>	<b>244.7</b>	<b>290.0</b>	<b>+18.5%</b>
<b>&lt;Full basis&gt;</b>			
<b>Operating profit</b>	<b>155.7</b>	<b>269.0</b>	<b>+72.8%</b>
<b>Profit</b>	<b>124.1</b>	<b>208.0</b>	<b>+67.6%</b>

FY2022 FCST (FX rate)  
USD: 120 yen  
EUR: 135 yen

Impairment losses on intangible assets due to termination of development for AT702, AT751, AT753 to be booked in Q1/FY2022 (\$170M)

\*Already included this impact into full-year forecast (full basis)



Now, page 20, I will explain the forecast. Revenue is expected to be JPY1.443 billion, an increase of 11.3% over the previous year. SG&A expenses are expected to be JPY598 billion, an increase of 9% YoY. SG&A expenses, excluding co-promotion expenses for XTANDI in the US is JPY416 billion, an increase of 1.6% from the previous year. R&D expenses will be JPY254 billion, up 3.2% from the previous year. As a result, core operating profit is expected to be JPY290 billion, an increase of 18.5% over the previous year.

The lower part of the slide shows the forecast on a full basis. Operating profit is projected to be JPY269 billion, a 72.8% increase over the previous year compared to FY2021.

For AT702, AT751 and 753, the development of them will be terminated and an impairment loss of JPY170 million will be booked in the first quarter of FY2022 regarding this.

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## FY2022 FORECAST: XTANDI AND STRATEGIC PRODUCTS

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	FY2022 Forecast	FY2022 initiatives and growth factors
<b>XTANDI</b>	<b>642.5</b> billion yen +108.2, YoY (+20%)	<ul style="list-style-type: none"> <li>Expand sales in M1 CSPC in US, Japan and International Markets</li> <li>Continue strong growth in M1 CRPC in China</li> </ul>
<b>XOSPATA</b>	<b>46.2</b> billion yen +12.1 (+36%)	<ul style="list-style-type: none"> <li>Expect continued growth in US, Established Markets and sales contribution from International Markets due to the increase of launched countries</li> </ul>
<b>PADCEV</b>	<b>36.5</b> billion yen +14.8 (+68%)	<ul style="list-style-type: none"> <li>Expect continued growth in US within the current US indication</li> <li>Continued market share gain in Japan, launched in Dec 2021</li> <li>Launch in priority EU countries and the preparation for reimbursement</li> </ul>
<b>EVRENZO</b>	<b>9.9</b> billion yen +7.3 (+281%)	<ul style="list-style-type: none"> <li>Expect growth in Japan whilst reinforcing market position in the HIF-PHI class</li> <li>Secure reimbursement in European countries and drive market share growth</li> <li>Expect sales contribution from International Markets</li> </ul>



Strategic products: XOSPATA, PADCEV, EVRENZO

M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, HIF-PHI: Hypoxia-inducible factor prolyl hydroxylase inhibitor

Now, page 21, this slide shows the FY2022 forecast for XTANDI and Strategic products. First, XTANDI, the FY2022 forecast is JPY642.5 billion, an increase of JPY108.2 billion compared to the previous year. In the US, Japan and international markets, sales are expected to expand mainly in the M1 CSPC indication. And we plan to utilize OS data from the ARCHES study to further expand our market share.

In China, we expect continued growth in the indication of M1 CRPC, for which reimbursement started last year.

Especially in the US, which accounts for about half of global sales, we expect an increase of more than 20% in volume. Although the number of new patients decreased in FY2021 due to COVID-19, the most recent data shows an improving trend, and we expect the number of new patients to increase in FY2022.

In addition, we have been conducting recent awareness activities since last year to ensure that patients receive new hormonotherapy at the appropriate time, and we expect these activities to be effective.

Now XOSPATA, we forecast JPY46.2 billion for FY2022, an increase of JPY12.1 billion from the previous fiscal year. Continued growth is expected in the US and Japan where we have established market leadership positioning. In Europe, the number of countries where the product is reimbursed is expected to further increase. We can expect sales contribution from international markets due to the increase of launched countries.

PADCEV, the FY2022 forecast is JPY36.5 billion, an increase of JPY14.8 billion compared to the previous year. In the US, we expect continued growth through further market penetration in the current indications. In Japan, where the drug was recently launched, we expect further gain of market share. In Europe, where the drug was approved this month, we expect to launch the drug in major countries. Since the reimbursement process in each country takes a certain period of time, sales is expected to grow gradually.

EVRENZO, the forecast for FY2022 is JPY9.9 billion, an increase of JPY7.3 billion from the previous year. In Japan, we expect further growth by reinforcing our market position in the HIF-PHI market. In Europe, sales are expected to increase due to an increase in the number of countries where the product is launched and

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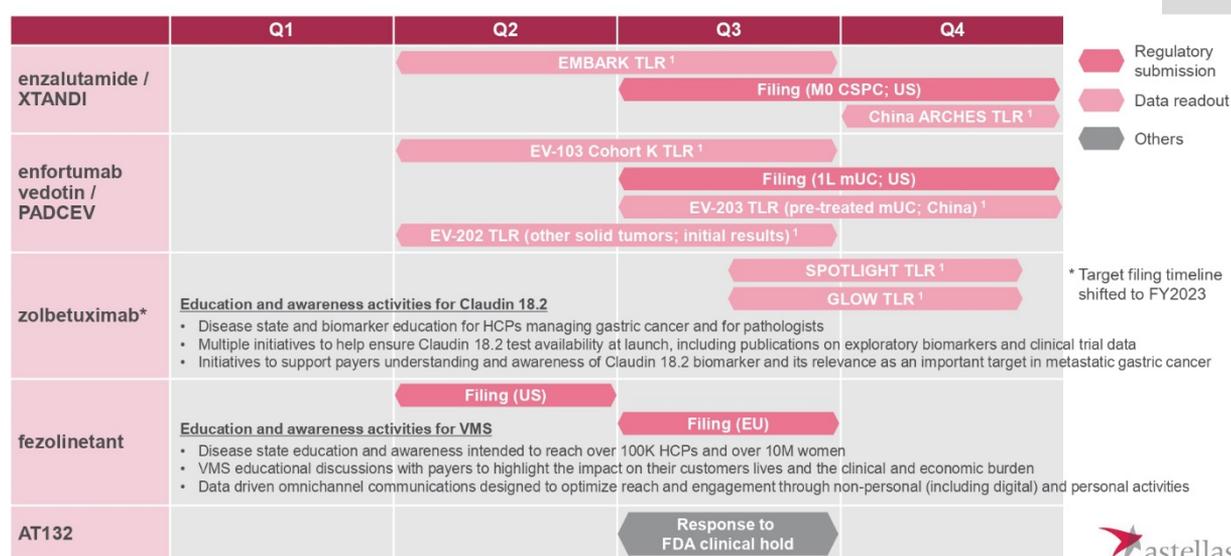


[have] reimbursement. While many physicians are cautious about new therapeutic agents, market research shows that specialists are highly aware of the new mechanism of HIF-PH inhibitor and many are interested in the convenience of oral administration effectiveness in patients who require a high dose of ESAs and the ability to reduce iron dosage due to high iron utilization efficiency.

With the promotion of information provisioning not only from MRs but from physicians with experience with this product, in other words doctor-to-doctor basis, we will promote the expansion of the HIF-PH inhibitor market. In FY2022, the international market will be expected to begin to contribute to sales.

## 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, 1L: First line, mUC: Metastatic urothelial cancer, VMS: Vasomotor symptoms, HCP: Healthcare Professionals, FDA: Food and Drug Administration

Now slide 22, key events for XTANDI and Strategic products expected in FY2022 are listed along with the specific timelines during the fiscal year. The top-line results of EMBARK study of XTANDI in M0 CSPC are expected in the second and the third quarters and the US regulatory submission based on these results is expected in the third and fourth quarters. The top-line results of China ARCHES study in M1 CSPC metastatic castration-sensitive prostate cancer are expected in the fourth quarter.

The top-line results of the EV-103 study Cohort K in first-line metastatic urothelial carcinoma are expected in the second to third quarter. For the enfortumab vedotin, US submission based on this result is expected in the third to fourth quarter.

In addition, top-line results from the bridging study, EV-203 in pretreated metastatic urothelial carcinoma, are expected in the third and the fourth quarters for submission in China. Furthermore, top-line results from the EV-202 study, which is being conducted in several solid tumors other than urothelial carcinoma, are expected to be available in the second and third quarters for the early results cohort.

The top now, this is about zolbetuximab. The top-line results of the two pivotal studies of it in gastro and adenocarcinoma and GEJ adenocarcinoma are expected in the third and fourth quarters of the fiscal year. The target timing for submission has been moved from FY2022, when the CSP 2021 was announced, to FY2023 due to a delay in the occurrence of events in these trials compared to our initial expectations.

For fezolinetant, we plan to file in the second quarter and in the third quarter in the US and EU, respectively.

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For AT132, we plan to submit a response to the FDA clinical hold in the third quarter as an action to the authorities for resumption of clinical trials.

In FY2022, we will also use digital tools to raise awareness among a wide range of stakeholders, including HCPs, patients and payers, about VMS, or vasomotor symptoms, for which fezolinetant is targeting, and about Claudin 18.2, the target biomarker for of zolbetuximab.

In particular for fezolinetant, we will conduct disease awareness activities for VMS with a goal of reaching more than 100,000 HCPs and more than 10 million women as well as academic discussions with the payer focused on the impact of VMS on women's lives and the clinical and economic burden of the disease. In addition, we will develop communications based on the deep understanding gained through dialogue with more than 4,800 women and 4,000 HCPs over the past several years.

## POTENTIAL PEAK SALES: XTANDI AND STRATEGIC PRODUCTS (UPDATE)

23

*Assumptions reviewed for each product, expect continued strong growth  
Downward revision of potential peak sales for AT132, reflecting the latest situation*

Product	Potential Peak Sales (Global, billions of yen)	Assumptions Update
XTANDI (enzalutamide)	600 - 700	✓ Reviewed assumptions for XTANDI, PADCEV and XOSPATA, taking into account the global competitive environment, recent sales and prescription trends (duration and treatment rate), and ongoing clinical studies
fezolinetant	300 - 500	
PADCEV (enfortumab vedotin) <sup>1</sup>	300 - 400	✓ Reviewed assumptions for fezolinetant, taking into account the latest market research, number of patients, and the results of Phase 3 studies obtained in FY2021
XOSPATA (gilteritinib)	100 - 200	✓ As a result of the review, potential peak sales remains unchanged
zolbetuximab	100 - 200	✓ Reviewed assumptions taking into account the competitive environment for zolbetuximab, and recent sales trend and market environment for EVRENZO. Potential peak sales revised downward within range
EVRENZO (roxadustat) <sup>2</sup>	50 - 100	
AT132 (resamirigene bilparvovec)	under 50 <sup>3</sup>	✓ Potential peak sales revised downward based on the assumptions of the delay of approval timing and change in target patient population

*Note) Only indications undergoing pivotal studies are included for projection (as of April 2022)*



1. Sales for Americas are calculated based on the sales booked by Seagen, 2. Astellas territories only; Japan, Europe, the Commonwealth of Independent States, the Middle East, South Africa, etc.  
3. Previous potential peak sales: 50 - 100 billion yen (announced in May 2021)

On page 23, I will explain the updated potential peak sales forecast for XTANDI and Strategic products. Although we have reviewed the assumptions for XTANDI, fezolinetant, PADCEV and XOSPATA taking into account the most recent competitive environment and market and research, the peak sales forecast remains unchanged from the time of CSP2021 in May of last year. As a result of reviewing the recent competitive environment for PD-1 antibodies and the recent sales trend and assumptions for the competitive HIF-PH inhibitors for zolbetuximab and EVRENZO, respectively, their potential big sales forecast has been reversed downward within range of the peak sales first announced in May last year.

Regarding AT132, whose asset value was reviewed, the potential peak sales was revised downward to less than JPY50 billion based on the assumption of the delay in the proof of timing and a change in the target patient population. Despite the downward revisions for several products in this update, we expect continued strong growth as a growth driver during the period of this CSP.

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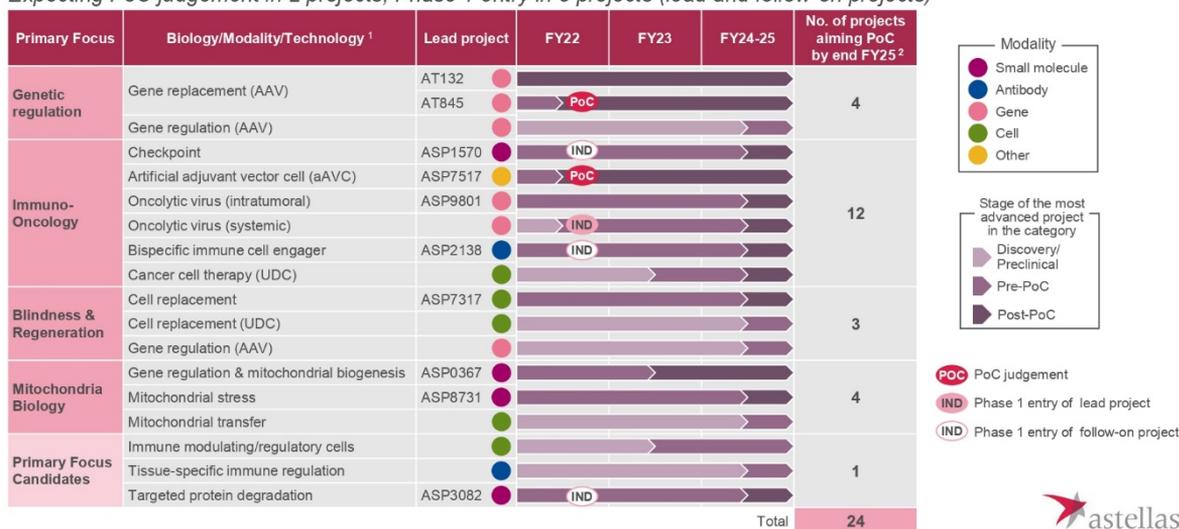
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## FOCUS AREA APPROACH: CLINICAL PROOF AND EXPANSION OF KEY PLATFORMS

Expecting PoC judgement in 2 projects, Phase 1 entry in 5 projects (lead and follow-on projects)



1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Apr 2022)  
PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell

Now slide 24. Here are the future plans for Primary Focus. This slide lists only the lead projects that are already in the clinical phase in each Focus Area approach.

In FY2022, we expect to make a judgment on PoC in the genetic regulation program, AT845, in artificial adjuvant vector cells, ASP7517. Among some approaches, follow-on projects have already passed the late phase of the research. Together with this follow-on and lead projects, five projects are expected to enter the clinical stage in FY2022.

We are also seeing the benefits of the reorganization and research function that took place in FY2021. And we are seeing examples of teams taking appropriate risks and changes and have significantly shortened the duration of clinical study. We hope to show you how we will use this most recent experience to create more projects on an ongoing basis in FY2022 than we have in the past.

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Category	Program	Event
Digital health Other services	EG Holter	Initiation of pilot marketing
Digital therapeutics	BlueStar	Initiation of clinical study (Japan)
Drug-device combination	pudexacianinium chloride (ASP5354)	FSFT in Phase 3 study

- Implantable medical devices (iota):  
Prepare for IDE submission in FY2022, toward initiation of clinical study in FY2023



IDE: Investigational Device Exemption, FSFT: First subject first treatment

On page 25, I describe the key events expected in FY2022 in our Rx+ program. In the ECG test service, in partnership with Nitto Denko and M. Heart, we plan to initiate the pilot marketing of the EG Holter, a single-use electrocardiogram.

For BlueStar, a digital therapeutics, we are planning to start clinical trials in Japan based on the reviewed product specifications and development plan. As has been mentioned, ASP5354 is scheduled to be administered to the first patient in Phase III trials.

Regarding iota's implantable medical devices, which are listed at the bottom, we will proceed with the preparations for the IDE submission for the first project with the aim of initiating clinical trial in the first half of FY2023. IDE submission is a clinical trial notification to the authorities equivalent to an IND for pharmaceutical products.

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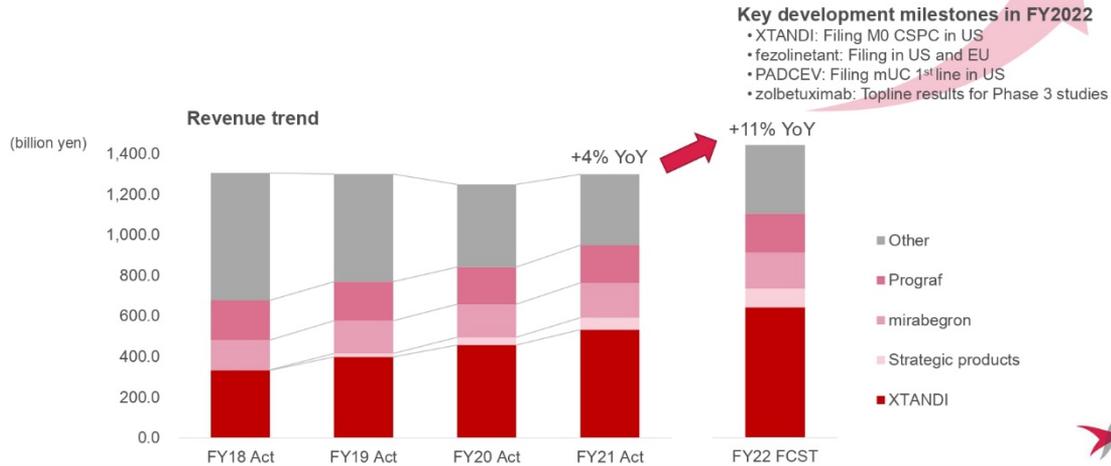
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## CONCLUSION: TOWARD MID- TO LONG-TERM GROWTH TREND

Product portfolio has changed and sales of XTANDI and Strategic products growing significantly  
Record revenue increase in FY2021 for the first time since FY2018  
Continued growth in FY2022 and aiming to achieve rich development milestones



Strategic products: XOSPATA, PADCEV, EVRENZO  
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, mUC: Metastatic urothelial cancer



Page 26, this is the last slide. As you can see from the slide, our product mix has changed dramatically over the past several years. In FY2022, the negative impact of the expiration of the exclusivity and the transfer of the cells will disappear and the sales of high-margin core products such as XTANDI and Strategic products will further expand. And we will aim to increase revenue and profits by improving our profit structure.

Furthermore, FY2022 will be a pivotal year for achieving our FY2025 targets and several important development milestones for Strategic products are scheduled to take place in the year. We believe that we will be establishing the foundation for achieving sustainable growth and will move toward a full-fledged mid-to long-term profit growth trend.

That's all from me for today. Thank you for your attention.

**Ikeda:** Thank you very much. That's all of the presentation. We'd now like to take questions from the audience.

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## Question & Answer

**Ikeda [M]:** We can take your questions through the teleconferencing system. You cannot ask a question through the live-streaming system. When your turn comes, the operator will name you, so please wait near the phone. As you wait, you can listen to the conference.

Thank you for waiting. The first question, please? The operator, please?

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

**Yamaguchi [Q]:** Thank you very much. Yamaguchi from Citigroup. I have two questions.

First, regarding the total picture, in the previous fiscal year, XTANDI co-promotion fees are excluded in your cost control in the previous fiscal year, and there's going to be a slight increase this fiscal year. So what are the factors behind why you couldn't control last year? And what are the factors for the increase this fiscal year?

**Yasukawa [M]:** Thank you for your question. So Kikuoka would you like to explain.

**Kikuoka [A]:** Your question is about XTANDI in particular. Excluding XTANDI, sorry. As Yasukawa explained, in principle, there are one-off factors, including Forex impact. That's one factor behind it. And also, as we mentioned before, towards the end of the fiscal year, XTANDI growth decreased, but still we decided not to constrain the proactive investments as a management decision.

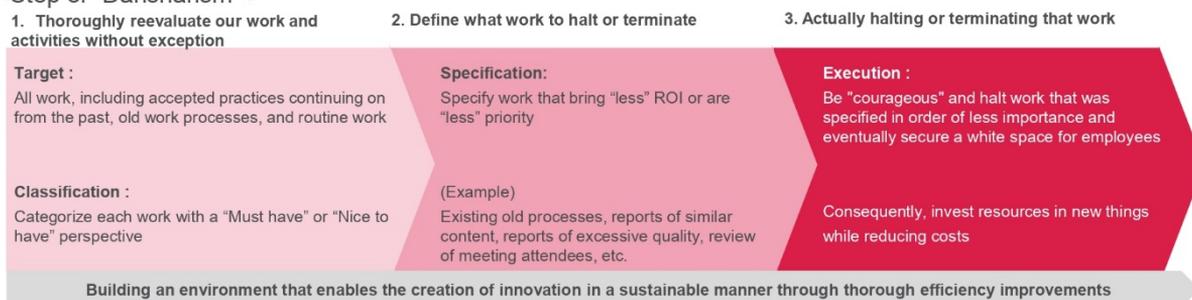
On the other hand, what would constitute the rationalization, streamlining investment for the future by doing such investments? As we said in the presentation, globalizing ERP requires troubleshooting. Honestly speaking, there were such needs as well. But, in principle, about what we decided to do, we have been implementing as scheduled so, in the current fiscal year and beyond, we will enjoy the benefits.

### “DANSHARISM” MOVEMENT

28

- Perfectly fitting for a Japanese company, expanding the concept of “Danshari,” which is the thorough elimination of waste, globally and into daily operations
- At the same time, ensuring that managers have financial discipline and cost ownership, and transforming into an organization that creates innovation by improving our labor productivity
- Having a mindset that enables us to invest resources into new initiatives while maintaining the absolute amount of SG&A expenses

<Step of “Dansharism” >



What is “Danshari”? -Japanese minimalism-  
 It is the Japanese concept of “decluttering” and is the process of cutting out what is unnecessary, detaching from things, and readjusting one’s life accordingly.



ROI: Return On Investment, White space: Resources needed to explore new ideas

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And personally, I'm now joining this team. So, if possible, as Yasukawa explained, if you go to the first page of the appendix, there is a slide on Dansharism. I joined from March. Yasukawa, Okamura and the top management and I had discussions amongst us. There's a so-called white space in English in building innovation. But pursuing efficiency, like a Japanese company, we added ism to the Japanese word Danshari. Including our CXO overseas, we had discussions. This was well received.

I'm not going to talk too much, but we have three steps to proceed. According to procedures for this process, cost reduction does not necessarily come first, but we have to change our mindset to eliminate any waste. And for the management, this must be thoroughly discussed with their subordinates.

I'm taking over this role from Okamura. I'm joining the team and the Company as a financial or dedicated person. If I don't improve, there is no meaning for me to join. There are some shortages, including the management. We have to ensure discipline. By doing this simultaneously in a more timely fashion, we can reduce our costs. I think we can do this.

Sorry for my long answer. The investments by now will enter a stage for investment recovery. Then we can control the costs in this way. Thank you.

**Yamaguchi [Q]:** Second, that's XTANDI the fourth quarter factor. Centering on the US, well, things tend to happen in January to March, but at the same time, there is COVID-19 and also the competitive situations explained by you. So the US volume this time, less than 20%, I don't know if that is aggressive or not. The previous time, you were too aggressive. That's why you couldn't achieve that. But what about this fiscal year? How do you look at the United States? How do you look at the European market? Just a brief explanation is fine with me. Would you please explain that?

**Yasukawa [M]:** Matsui would answer that question.

**Matsui [A]:** Matsui speaking. Thank you for your question.

First of all, US, we see it relatively positively. Well, in February and March, since this COVID-19 pandemic, newly prescribed patients and that number was not really increased. That is one of the reasons why we could not achieve the target.

And looking at the first report of February and March, there is an improvement. So, with that, we got relieved in the US. The COVID-19 situation has settled down to a certain extend and patients return to the clinics. And just like Yasukawa mentioned a little while ago, in order to accelerate this momentum from last year, Pfizer in the United States started a patient accelerator program. Patients with prostate cancer got the diagnosis as early as possible and understand the benefit of XTANDI. So this activation program has been promoted. This is another factor for the increase of our product in the market. And as has been mentioned, this settling down of the COVID-19 situation, our activities and Pfizer's activity can be further accelerated. Therefore, compared to the growth of FY2020 to FY2021, FY2022, our plan is exceeding in terms of the growth level. So we are challenging a very aggressive and ambitious target. That's how we view the US market.

Now, about Europe, if you look at the number of sales, you might feel this is a bit too conservative. But the reason why we couldn't achieve the FY2021 target, the major reason for that is that the delay of the reimbursement and also the impact of reimbursement in order to get the new indications, just like the case in Japan, there is a request of a reduction of the pricing. That became the negative factor. And volume-wise, in Europe, there is about a 16% increase planned. So again, we have a such ambitious plan. But the price impact that was incurred in FY2021 became the reason for this single growth in the sales.

But whichever the case is, our plan is always quite aggressive to set our target. That's the way I would like to go.

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

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

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

**Hashiguchi [Q]:** Hashiguchi speaking. Thank you very much.

I have two questions, first gene therapy capabilities. The three pipelines whose development are terminated altogether, the reason is that you couldn't reach the expected efficacy level. What do you think about the background in gene therapy? Your ideal state of research for genetic therapies is not appropriate shortage in capabilities. How should we think about the other pipelines? Any clues for this? Is it the factor just limited to DMD or is it something common to other pipelines? I'd like to hear about the factors behind it.

**Company Representative [A]:** First, I'd like to respond. AAV, we'd like to transfect the target genes in the adeno-associated vector. The size of the genes is not always the same. Even if it's the same DNA, depending on the sequence, physical or chemical properties can be different. So technology-wise, it may be easier or sometimes more difficult, depending on the technologies.

As for DMD, it's rather difficult to transact. Manufacturing was very costly and also yield was not so good. And what was completed was used in the clinical study.

Can we beat our competitors in the future? The data did not indicate that it's going to be possible. So, because of these factors, for DMD, instead of pursuing further, we decided to terminate here. That was our decision.

Is it just for DMD? If you ask that way, yes. We may face this kind of difficulty, technical difficulties, in the future again. The follow-on project, as a gene therapy, is there any competitor or not, any existing therapy or not? If there is, how much efficacy has been confirmed for the existing therapy? And technical difficulties must also be considered comprehensively together with those elements. There is no one who can talk about more specialized expertise today, so we will explain further when we have an expert.

**Hashiguchi [Q]:** The second question is about the forecast for the dividend. About one year ago, JPY50 with the increase of JPY8. The pace is greatly different from the previous situations, and we discuss if that is only a one-time thing or this trend would increase, or continue rather. And at that time, you mentioned that there shouldn't be any holder stoppage about this trend. I don't know if my expression is accurate or not, but that's what you mentioned. But this time, the JPY10 increase is not a reduction of the pace, rather accelerated. So this time, it was said as JPY60. What's the reason behind it? Because we want to know how we can predict the forecasted dividend now and toward the future.

**Yasukawa [M]:** Thank you. Kikuoka is going to answer that question. Thank you for your question. Kikuoka is going to answer this question.

**Kikuoka [A]:** So dividend for the future, especially the level of that, especially that all depends on the revenue for now and for the future. But as has been conventional speaking, we have the capital policy set that is used for the growth, first of all. And basically, for the dividend, however, continuously, we would like to increase, if it's possible, depending on the profitability. As a result, the cash that we can have in our hands, JPY250 billion to JPY300 billion, that is something we would like to maintain. And if we can increase that, we might do the share buyback in a quite a mobilized manner or flexible manner. So in line with the CSP, we also can fulfill the increase of the revenue.

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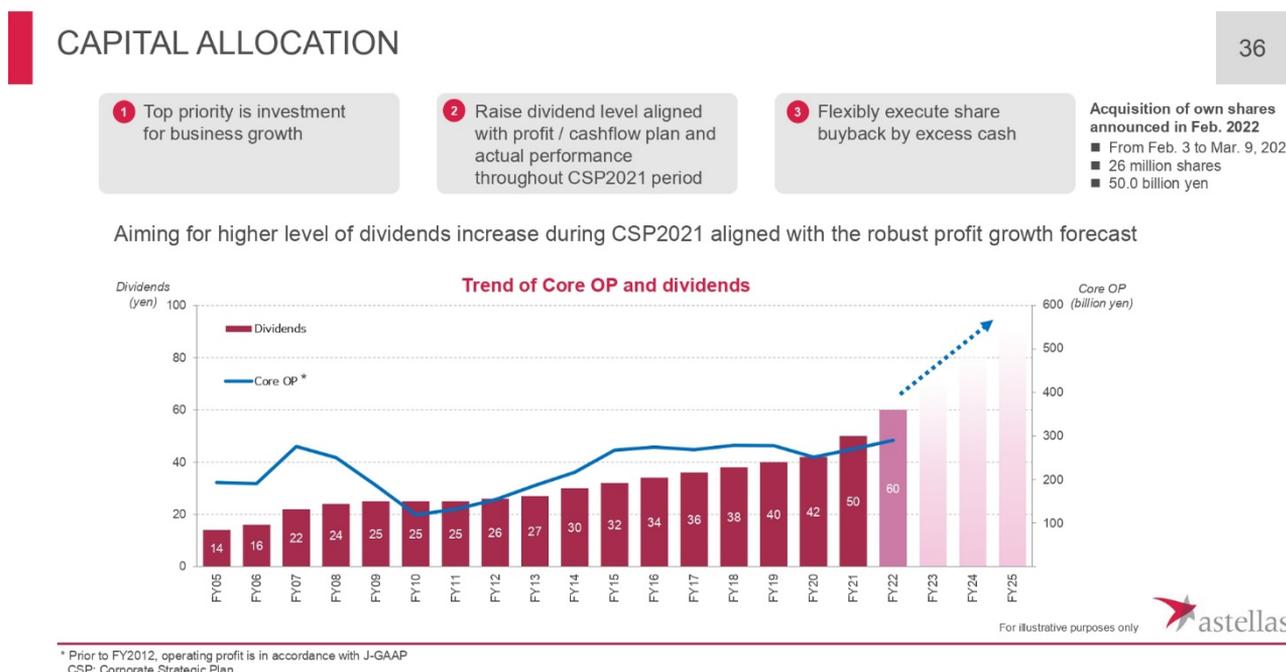
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we would decide the level of the dividend based upon the fluidity of the cash that we have. At this time, JPY290 billion, that's what I would like to aim at. And with that as a condition, we expect that we can provide this level of the dividend. So we decided to increase it by JPY10. That's all.

**Hashiguchi [Q]:** Thank you very much. Compared to the past, JPY250 billion to JPY300 billion, that is where you would like to achieve a share buyback and a dividend balance. The balance, the weight is going more towards the dividend. Is this understanding right?



**Yasukawa [A]:** Yasukawa speaking. If you look at page 36, on the top, you can see the description. The second is the continuous increase of the dividend level. Number three is to flexibly execute share buyback. So, in this order, we are executing what we are supposed to do.

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

**Ikeda [M]:** Thank you very much. The next person, please.

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

**Muraoka [Q]:** Thank you. Core operating profit of JPY290 billion, how to achieve this figure? XTANDI in the US and Europe, you have ambitious numbers for both regions to reach JPY290 billion. I'd like to ask about the buffer. If XTANDI cannot grow that much, where are you going to make ends meet? Cost-wise, considering Forex, it can be a difficult figure to achieve. If you cannot grow XTANDI, how are you going to achieve this? How should we think?

**Yasukawa [M]:** Yasukawa speaking. Thank you for your question. Kikuoka I would like to respond first.

**Kikuoka [A]:** Thank you for your question. So this is about if there can be some additional comments from Matsui later. We think we can achieve this figure with XTANDI, but it may not be perfect. In that case, how to curtail our costs is going to be an issue. I would be involved and we would run a PDCA cycle.

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We want to control SG&A costs. We overspent in the fourth quarter. Unfortunately, we learned a lesson here. Instead of every quarter, as soon as possible, we'd like to identify the growth of the product. In case we face the situation, as you mentioned, we'd like to strengthen controlling our costs. For example, we'd like to ensure such flexibility.

In CSP 2021, we showed our direction. We have no intention to change that direction. But we'd like to be very flexible. I think this is my responsibility as CFO. So, we have to identify what can be upfront and what cannot be upfront. That is the concept of Dansharism. It may be very abstract, but this is what we have to do. And in one month, one and a half months, after joining the Company, I think I feel confident that we can do this. That's all.

**Muraoka [Q]:** The separation of the cost that you mean, but concerning the Forex, you did maximum effort for the separation of the cost. But even from here, there is still room for the separation through Dansharism. Is it okay to interpret? Kikuoka-san, you see that possibility is still there?

**Kikuoka [A]:** Yes. As has been explained this time, listening to the opinions from the field, I myself am still in the learning phase. But as you can understand from expecting the situations, for example, ERP, that's what I call Apple, with introducing that, the conventional business process can be improved. But of course, we see some distortion and that is whether we have to put more investment, as that will be the expenses. Of course, that is done and there is the certain coordination internally. With that, we see the outcome from this effort. Yes, the troubleshooting would be costly to a certain extent. However, if we overcome that, we believe that we can suppress the expenses further through these troubleshooting activities. That's all.

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

**Matsui [A]:** I would be able to provide information with a message, but for main products, as an Astellas policy, we try to have a stretched target we'd like to aim for at the highest level so that we can infer it. In FY2021, this is what we worked on. In the US and Europe, unfortunately, we were behind, unfortunately. But within these goals, Japan and China exceeded the goals.

In the business environment, there may be an unexpected positive aspect as well. I may be optimistic, but there can be such events. As Kikuoka mentioned, more than before, on a quarterly basis, priorities should be reviewed. We should run a PDCA cycle more than before to see how we allocate our money and whether we need additional measures or not. As the management team, we would go deeper and more actively. Now Kikuoka has joined the management team and we are going to execute this. Whether there is any buffer, there is no clear buffer. But in this way, we'd like to achieve these challenging targets.

**Muraoka [Q]:** Thank you. Another question, the last question from me, is about XTANDI. The US number is not strong enough. I understand about the PAP situation, but what about competitors? Is there impact of Lynparza? I don't think so. It's too early. But when you say competitors, what do you mean? It's Novartis radio labeling product you're talking about?

**Matsui**

**[A]:** No. Our understanding of recognition is that, if we look at it in the fourth quarter, Zytiga generic, that is growing unexpectedly, and Erleada is growing gradually. What was most surprising for us is Zytiga generic. That is growing more than we had expected in the fourth quarter. Those are the competitors we're talking about.

**Muraoka [M]:** Understood. Thank you so much. It is true, generic prescription-wise, that is quite understandable. Thank you.

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**Ikeda [M]:** The next person, please.

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

**Sakai [Q]:** Sakai from Credit Suisse. Regarding your main products, you set stretch targets. According to our policy, if there is any exception, it can be PADCEV in the United States with Seagen. In November and December, they issued a guidance. About half of the US revenue you're booking. Considering this, the numbers would be consistent between the two companies. The Seagen numbers are rather conservative according to some. But depending on the changes in the Seagen guidance, your numbers can also be revised throughout the year or every quarter. Should I understand it this way? I'd like to confirm.

**Yasukawa [M]:** Thank you for your question. Matsui would you like to comment.

**Matsui [A]:** First of all, regarding the evaluation, Seagen has its own evaluation and assessment. We also have our own assessment. Analysts would look at the speed of penetration for this drug. Analysts expect this should be faster. We are grateful for that. But as we have been saying from before, the line extension or the expansion of the indications, particularly the first-line settings, until the first-line additional education, it would not increase so much according to our forecast.

The most important segment is the Cohort K. So in FY2022, first in the United States, that is going to grow in Europe. Why so late in spite of the approval obtained, you may wonder.

In Europe, as you know, even if approval is won, drug pricing listing is going to be done in the respective countries. In EU5, Germany and UK, you can market earlier because of the free pricing. In other countries, to obtain the drug price, it takes time. In the case of France, an early access program can enable us to book sales. But in many countries, it takes time. If you take this into consideration on a full scale, for this product to grow, we think it's going to be in FY2023 or beyond. In FY2022, it may look very conservative. But regarding this drug, in Europe, the drug price listing requires time. But taking that into consideration, these are very aggressive targets for us. That's all from me.

**Sakai [Q]:** Thank you, understood. Two brief questions about the pipeline fezolinetant Asia MOONLIGHT Study. As Yasukawa-san explained, placebo effect was higher. This means that this is the area that is most difficult to explain. So when the FDA asks about this, what would you do? Is it possible for you to prepare backup data? I don't know if that is possible, but that is one of my biggest concerns. So would you please explain?

The second question, that is zolbetuximab event-driven study and submission will be delayed from FY2022 to FY2023. But is this the very final timeline that you drew? Is this understanding right? Please explain about that.

**Yasukawa [M]:** Thank you for the question. For these two, these development-related questions. So Bernie would answer these questions. Bernie, please?

**Zeiber [A]\*:** Yes. Thank you for the questions. First, with regard to fezolinetant and the MOONLIGHT study, as Yasukawa-san explained, there was a higher-than-expected placebo response. We are investigating it. We're continuing to investigate it, and we will have explanations that we could share with the FDA if it comes up.

And a couple of things that were already mentioned that were different about this study, number one is the dose. It only included the 30-milligram dose. It didn't include the 45-milligram. And I think the other is really the location and the patient population. We know there's ethnic differences in the reporting of hot flashes and this likely contributed to some of the higher placebo effect. But we will be prepared to explain that to FDA.

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I think, most importantly, though, which is always a big concern for FDA in this population, is that there were no new safety signals identified in this study. So, I think that's very encouraging and I think will be important for FDA in their review.

Now, shifting to zolbetuximab, as you mentioned, the two Phase III studies are both event-driven. And as we described, the current best estimate is that they will read out in the third or fourth quarter of this fiscal year. We continue to monitor the events and these are our best estimates of when we will have sufficient events to close the studies and to look at the readouts.

So, obviously, things can change, but those are our best estimates now. And assuming it, again, is in that third or fourth quarter, that would then mean that our filing would be in FY2023.

**Yasukawa [A]:** Thank you, Bernie. Yasukawa speaking. If I may add a bit, as for zolbetuximab, until recently, patient recruitment was not over. Due to COVID-19, recruitment was affected.

As for the events, events did not occur at the speed we expected. Patient recruitment is now over, so one parameter has been gone. So now, just about occurrence of the event, we are tracking this. We don't think the speed is going to change dramatically from now. It's not absolute but compared to before, we are making an estimation with a higher accuracy than before.

Regarding fezolinetant, we had similar multiple experiences, VESicare, mirabegron in the Western studies positive, and Asian studies. In this way, we couldn't meet statistical significance according to the past experiences. In the United States, Japan and Western regions, we didn't experience any impact on the submission in other regions.

As you can see on the top of page 12, MOONLIGHT is a non-IND study. So Western submission safety data will be included, but efficacy data would not be asked for. That's all from me.

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

**Ikeda [M]:** Next question, please?

**Operator [M]:** Nomura Securities, Mr. Kohtani, please?

**Kohtani [Q]:** I have to ask only just one question. So my question now is about iota development. So this IDE is planned in FY2022, so the technical issues for the practical use are already solved. That I assume. That's a small device. You don't need to change batteries. And the indication is not really described, but the [sacral NAV] stimulation is possible. Even the technology improvement is done. What about the competitiveness? While this is a small device, no necessity of battery changes. And also, this is an implanted device and you do a first-in-human study; the next would be Phase III. If so, FY2025 would be the timing of the launch. What do you view about this?

**Yasukawa [A]:** Yasukawa speaking. Thank you for your question.

Technically speaking, I think this product is already in a very high level of completion and development. But this is a very first type of the product for us. So, for the commercialization, what do we have to be mindful of is needed to be concerned. IDE is equivalent to IND, so we are close to the start of the clinical trials.

And for considering our marketing, GMP equivalent areas are needed to be considered, especially with the perspective of what is necessary to be done more. For that, we need to negotiate with the authorities.

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The length of clinical trials, even internally, we haven't really approved the plan yet. So, here, I cannot tell you when would be the last timing or when will be the closing of the clinical trial. But I also consider that this is not the conventional type of development like a Phase I/II/III. So I hope that the launch will be around FY2025. This is the expectation from me as the President. Thank you.

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

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

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

**Ueda [Q]:** Ueda from Goldman Sachs Securities. I'd like to ask you questions about assumptions for your SG&A plan. XTANDI co-promotion fee increasing by 30.6%, US sales to grow by 27.8%, so the co-promotion fees are increasing at a higher pace. This can be explained by a Forex impact or any special factors behind it? And also upfront proactive investments were also explained. How much is this affecting your plan for FY2022?

**Yasukawa [M]:** The first question will be answered by Matsui. The second question will be answered by Kikuoka.

**Matsui [A]:** First, I'd like to confirm your question. XTANDI co-promotion fees are very high. So, you'd like to understand why anything behind. We have a bullish aggressive target for the sales. That's all, no other factor to increase the co-promotion fees.

The active investments and proactive investments, before Kikuoka, I'd like to comment. We, Astellas, for global commercial organization, in FY2022 and 2023, the biggest event is going to fezolinetant, preparing for the launch of fezolinetant. And dozens of billions of yen worth of proactive investments have been prepared. Fezolinetant can be explosive, according to expectations. We have to invest now. Otherwise, we cannot maximize its future growth. Even if we have to save other expenses, we have to make big investments here. So, because of sales and marketing, even compared to zolbetuximab in FY2022, we'd like to prepare for big investments into fezolinetant. We are making preparations for that.

**Matsui [A]:** If I may add, proactive investments, when we say it, I think fezolinetant is going to be our main product with such products. And we had been completing a series of investments in the previous year. For ERP deployment to other sites, we'd like to do this. But the biggest element of the proactive investment was explained by Matsui the next fiscal year to prepare for the full-scale launch.

Commercial functions are making proactive investments. We'd like to examine these investments in detail. If they would contribute to the enhancement of corporate value, we can increase them and reduce other investments. We can be flexible by running the PDCA cycle. I hope you understand our approach.

That's all from me.

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

**Ikeda [M]:** Thank you so much. I'm sure that you are still waiting for asking questions, but it is the time. And with this, we would like to close this earnings call. Everyone, thank you very much for your participation.

[END]

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