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Financial Results of Astellas for the First Nine Months of FY2021

Japan, February 2, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, “the Company”) today announced the financial results for the first nine months (April 1, 2021 – December 31, 2021) of the fiscal year 2021 (FY2021) ending March 31, 2022.

Consolidated financial results for the first nine months of FY2021 (core basis)

(Millions of yen)

	First nine months of FY2020	First nine months of FY2021	Change (%)
Revenue	940,907	992,293	+51,386 (+5.5%)
Core operating profit	203,746	220,047	+16,300 (+8.0%)
Core profit	166,641	169,677	+3,035 (+1.8%)

Cautionary Notes

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. 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.

1. Qualitative information on consolidated financial results for the first nine months of FY2021

(1) Business performance

<Consolidated financial results (core basis ^(Note))>

Consolidated financial results (core basis) in the first nine months of FY2021 are shown in the table below.

Revenue, core operating profit and core profit increased across the board.

Consolidated financial results (core basis)

(Millions of yen)

	First nine months of FY2020	First nine months of FY2021	Change (%)
Revenue	940,907	992,293	+51,386 (+5.5%)
Cost of sales	187,736	194,094	+6,358 (+3.4%)
Selling, general and administrative expenses	363,044	406,420	+43,376 (+11.9%)
R&D expenses	168,821	177,648	+8,827 (+5.2%)
Amortisation of intangible assets	17,294	20,247	+2,952 (+17.1%)
Gain on divestiture of intangible assets*	-	24,130	+24,130 (-)
Share of profit (loss) of investments accounted for using equity method	-266	2,032	+2,298 (-)
Core operating profit	203,746	220,047	+16,300 (+8.0%)
Core profit	166,641	169,677	+3,035 (+1.8%)
Basic core earnings per share (yen)	89.71	91.57	+1.86 (+2.1%)

* Established a new account, which includes gain on sale of rights of in-market products or pipeline assets

(Note) The Company discloses financial results on a core basis as an indicator of its recurring profitability. Certain items reported in financial results on a full basis that are deemed to be non-recurring items by the Company are excluded as non-core items from these financial results on a core basis. These adjusted items include impairment losses, gain/loss on sales of property, plant and equipment, restructuring costs, loss on disaster, a large amount of losses on compensation or settlement of litigations and other legal disputes, and other items that are deemed to be excluded based on the Company's judgment. A reconciliation table between results on a full basis and results on a core basis is provided in the "Supplementary Documents for Q3/FY2021 Financial Results."

Revenue

- Main products XTANDI for the treatment of prostate cancer, XOSPATA for the treatment of acute myeloid leukemia and PADCEV for the treatment of urothelial cancer showed steady growth as expected. In addition, the sales growth of EVRENZO for the treatment of renal anemia, Betanis / Myrbetriq / BETMIGA for the treatment of overactive bladder (“OAB”) and EVENITY for the treatment of osteoporosis contributed to revenue growth as well.
- Moreover, another factor for the increase in sales in the first nine months of FY2021 was the sales of pharmacologic stress agent Lexiscan returning to pre-pandemic level which decreased mainly in the first three months of the previous fiscal year by the impact of the spread of COVID-19.
- The sales growth of the products above offset the sales decrease mainly due to the termination of sales agreements for Celecox for the treatment of inflammation and pain and Lipitor for the treatment of hypercholesterolemia, and the divestiture of Eligard for the treatment of prostate cancer.

As a result of the above, revenue in the first nine months of FY2021 increased by 5.5% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥992.3 billion.

Core operating profit / Core profit

- Gross profit increased by 6.0% year-on-year to ¥798.2 billion. The cost-to-revenue ratio fell by 0.4 percentage points year-on-year to 19.6%, mainly due to changes in product mix.
- Selling, general and administrative expenses increased by 11.9% year-on-year to ¥406.4 billion. The total amount increased mainly due to the increase of co-promotion fees associated with the growth of sales of XTANDI in the United States (increase of ¥18.5 billion year-on-year), impact of the foreign exchange rates (increase of ¥16.5 billion year-on-year), investment in Digital Transformation (increase of approximately ¥6.0 billion year-on-year), and the increase in sales promotion expenses for new product launch readiness (increase of approximately ¥2.5 billion year-on-year), despite a decrease in expenses due to the global optimization of personnel aligned with transformation of product portfolio (decrease of approximately ¥5.0 billion year-on-year). Selling, general and administrative expenses, excluding co-promotion fees of XTANDI in the United States, increased by 9.1% year-on-year to ¥297.7 billion.
- Research and development (R&D) expenses increased by 5.2% year-on-year to ¥177.6 billion. While there was a decrease in development expenses for fezolinetant, a selective neurokinin-3 receptor antagonist, for which patient enrollment in Phase III trials in the United States and Europe has been completed, the total amount increased mainly due to increases in development expenses for zolbetuximab, an anti-Claudin 18.2 monoclonal antibody and R&D investment for Rx+ business (related to iota).

- Amortisation of intangible assets increased by 17.1% year-on-year to ¥20.2 billion.
- Gain on divestiture of intangible assets was ¥24.1 billion. Including such as transfer of five products to Cheplapharm which were sold in Europe and other regions (¥12.3 billion), transfer of a pipeline asset (¥9.2 billion) and transfer of Bendamustine (¥2.0 billion).

As a result of the above, core operating profit increased by 8.0% year-on-year to ¥220.0 billion, and core profit increased by 1.8% year-on-year to ¥169.7 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in the first nine months of FY2021 are shown in the table below. The resulting impacts were a ¥42.8 billion increase in revenue and a ¥15.4 billion increase in core operating profit compared with if the exchange rates of the first nine months of FY2020 were applied.

Average rate	First nine months of FY2020	First nine months of FY2021	Change
US\$/¥	106	111	¥5 (Weakening of yen)
€/¥	122	131	¥8 (Weakening of yen)

Change from beginning to end of period	As of December 31, 2020	As of December 31, 2021
US\$/¥	¥5 (Strengthening of yen)	¥4 (Weakening of yen)
€/¥	¥7 (Weakening of yen)	¥1 (Weakening of yen)

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in the first nine months of FY2021 are shown in the table below.

Revenue and operating profit increased, and profit remained largely unchanged year-on-year.

The full basis financial results include “Other income,” “Other expenses,” which are excluded from the core basis financial results. In the first nine months of FY2021, “Other income” was ¥4.2 billion (¥7.0 billion in the corresponding period of the previous fiscal year) and “Other expenses” was ¥54.9 billion (¥51.3 billion in the corresponding period of the previous fiscal year).

As “Other expenses,” the Company recorded severance expenses in relation to the early retirement incentive program in Japan of ¥15.8 billion in the first nine months of FY2021.

Consolidated financial results (full basis)

(Millions of yen)

	First nine months of FY2020	First nine months of FY2021	Change (%)
Revenue	940,907	992,293	+51,386 (+5.5%)
Operating profit	159,470	169,371	+9,901 (+6.2%)
Profit before tax	164,227	167,402	+3,175 (+1.9%)
Profit	132,917	132,495	-422 (-0.3%)
Basic earnings per share (yen)	71.56	71.51	-0.05 (-0.1%)
Comprehensive income	155,897	164,538	+8,642 (+5.5%)

<Sales of Main Products>

(Billions of yen)

	First nine months of FY2020	First nine months of FY2021	Change
XTANDI	342.7	411.6	+20.1%
XOSPATA	17.6	25.7	+45.8%
PADCEV	9.4	14.6	+55.7%
EVRENZO	0.7	2.1	+198.6%
Betanis / Myrbetriq / BETMIGA	122.3	126.9	+3.8%
Prograf*	138.3	141.1	+2.0%

* Prograf: Includes Advagraf, Graceptor, and ASTAGRAF XL.

<XTANDI>

- Sales grew in all regions. Sales grew substantially in the United States compared to the corresponding period of the previous fiscal year, and in Europe, an increase in the number of countries where reimbursement for additional indication “metastatic hormone-sensitive prostate cancer (M1 HSPC)” (approved in April 2021) began contributing to sales growth. In addition, sales continued to show strong growth in Japan and China.

<XOSPATA>

- Sales expanded in all regions, especially in the United States and Europe. In addition, sales in China also contributed, where the product was launched in April 2021. In the International Markets, XOSPATA was approved in Russia, Saudi Arabia and Turkey in the first nine months of FY2021.

<PADCEV>

- In the United States, revenue from co-promotion grew as expected, as the additional indication “locally advanced or metastatic urothelial cancer patients who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy” (approved in July 2021) contributed to the growth, along with the contribution from the existing indication. In addition, it was launched in Japan in November 2021, and the uptake was higher than expected.

<EVRENZO>

- Although sales expanded in Japan, sales were lower than expected due to the strong

competition in the market. In addition, in Europe, where EVRENZO was launched in September 2021, initial uptake was below expectation, as sales promotion activities at the time of launch were restricted by the impact of the spread of COVID-19.

<Betanis / Myrbetriq / BETMIGA>

- Sales expanded globally, mainly in Europe and Japan offsetting a decline in sales in the United States.

<Prograf>

- Global sales were in line with expectation, although there were regional differences, such as sales growth in Europe and China, while sales decreased in other regions.

<Revenue by region>

Revenue by region is shown in the table below. Revenue in United States, Established Markets and Greater China increased, while in Japan and International Markets decreased.

(Billions of yen)

	First nine months of FY2020	First nine months of FY2021	Change
Japan	221.8	203.2	-8.4%
United States	355.8	407.9	+14.7%
Established Markets	218.0	239.2	+9.8%
Greater China	43.8	50.3	+14.8%
International Markets	87.6	83.0	-5.3%

Established Markets: Europe, Canada, Australia.

Greater China: China, Hong Kong, Taiwan.

International Markets: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

(2) Financial position

1) Assets, equity and liabilities

An overview of the consolidated statement of financial position as of December 31, 2021 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets saw an increase of ¥82.6 billion compared to the end of the previous fiscal year to ¥2,356.2 billion.

<Non-current assets> As of December 31, 2021: ¥1,416.9 billion (an increase of ¥15.9 billion)

- Property, plant and equipment increased by ¥3.2 billion compared to the end of the previous fiscal year to ¥267.8 billion.
- Goodwill increased by ¥9.6 billion compared to the end of the previous fiscal year to ¥293.6 billion, and intangible assets increased by ¥0.8 billion compared to the end of the previous fiscal year to ¥652.3 billion.

<Current assets> As of December 31, 2021: ¥939.3 billion (an increase of ¥66.7 billion)

- Cash and cash equivalents increased by ¥24.1 billion compared to the end of the previous fiscal year to ¥350.2 billion.

Equity

Total equity as of December 31, 2021 saw an increase of ¥80.2 billion compared to the end of the previous fiscal year to ¥1,466.3 billion, making the ratio of equity attributable to owners of the parent to total assets 62.2%.

- While profit stood at ¥132.5 billion, the Company paid ¥85.2 billion of dividends of surplus.

Liabilities

Total liabilities increased by ¥2.4 billion compared to the end of the previous fiscal year to ¥890.0 billion.

<Non-current liabilities> As of December 31, 2021: ¥292.0 billion (a decrease of ¥3.2 billion)

<Current liabilities> As of December 31, 2021: ¥598.0 billion (an increase of ¥5.6 billion)

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in the first nine months of FY2021 decreased by ¥16.3 billion year-on-year to ¥208.9 billion.

- Income tax paid increased by ¥23.3 billion year-on-year to ¥33.8 billion.

Cash flows from investing activities

Net cash flows used in investing activities in the first nine months of FY2021 was ¥47.6 billion, a decrease in outflow of ¥20.1 billion year-on-year.

- Proceeds from sales of intangible assets amounted to ¥24.2 billion.

Cash flows from financing activities

Net cash flows used in financing activities in the first nine months of FY2021 was ¥141.3 billion, a decrease in outflow of ¥30.1 billion year-on-year.

- The balance of bonds and short-term borrowings decreased by ¥40.0 billion.
Dividends paid increased by ¥9.1 billion year-on-year to ¥85.2 billion.

As a result, cash and cash equivalents totaled ¥350.2 billion as of December 31, 2021, an increase of ¥24.1 billion compared to the end of the previous fiscal year.

(3) Consolidated business forecasts for FY2021 and other forward-looking statements

The Company's business forecasts are presented on a core basis and full basis.

The consolidated full-year business forecasts for FY2021 are shown below.

The Company has left its business forecasts unchanged from the consolidated full-year business forecasts announced in October 2021.

Consolidated full-year business forecasts (core basis)

(Millions of yen)

	Results (FY2020)	Forecasts (FY2021)	Change (%)
Revenue	1,249,528	1,323,000	+73,472 (+5.9%)
Selling, general and administrative expenses	504,316	541,000	+36,684 (+7.3%)
R&D expenses	224,489	242,000	+17,511 (+7.8%)
Core operating profit	251,375	270,000	+18,625 (+7.4%)
Core profit for the year	209,906	213,000	+3,094 (+1.5%)
Basic core earnings per share (yen)	113.03	114.95	+1.92 (+1.7%)

Consolidated full-year business forecasts (full basis)

(Millions of yen)

	Results (FY2020)	Forecasts (FY2021)	Change (%)
Revenue	1,249,528	1,323,000	+73,472 (+5.9%)
Operating profit	136,051	218,000	+81,949 (+60.2%)
Profit before tax	145,324	216,000	+70,676 (+48.6%)
Profit for the year	120,589	174,000	+53,411 (+44.3%)
Basic earnings per share (yen)	64.93	93.90	+28.97 (+44.6%)

Expected exchange rate for

FY2021 (Forecast)	¥110/US\$	¥130/€
FY2020 (Result)	¥106/US\$	¥124/€

2. Condensed Interim Consolidated Financial Statements and Notes
(1) Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Nine months ended 31 December 2020	Nine months ended 31 December 2021
Revenue	940,907	992,293
Cost of sales	(187,736)	(194,094)
Gross profit	<u>753,171</u>	<u>798,199</u>
Selling, general and administrative expenses	(363,044)	(406,420)
Research and development expenses	(168,821)	(177,648)
Amortisation of intangible assets	(17,294)	(20,247)
Gain on divestiture of intangible assets	—	24,130
Share of profit (loss) of investments accounted for using equity method	(266)	2,032
Other income	7,045	4,209
Other expenses	(51,322)	(54,885)
Operating profit	<u>159,470</u>	<u>169,371</u>
Finance income	6,504	2,306
Finance expenses	(1,746)	(4,274)
Profit before tax	<u>164,227</u>	<u>167,402</u>
Income tax expense	(31,310)	(34,908)
Profit	<u><u>132,917</u></u>	<u><u>132,495</u></u>
Profit attributable to:		
Owners of the parent	132,917	132,495
Earnings per share:		
Basic (Yen)	71.56	71.51
Diluted (Yen)	71.52	71.47

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended 31 December 2020	Nine months ended 31 December 2021
Profit	132,917	132,495
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	24,423	(2,986)
Remeasurements of defined benefit plans	(656)	1,271
Subtotal	<u>23,767</u>	<u>(1,715)</u>
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(787)	33,759
Subtotal	<u>(787)</u>	<u>33,759</u>
Other comprehensive income	<u>22,980</u>	<u>32,044</u>
Total comprehensive income	<u>155,897</u>	<u>164,538</u>
Total comprehensive income attributable to:		
Owners of the parent	155,897	164,538

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2021	As of 31 December 2021
Assets		
Non-current assets		
Property, plant and equipment	264,623	267,817
Goodwill	284,011	293,649
Intangible assets	651,427	652,251
Trade and other receivables	33,924	30,365
Investments accounted for using equity method	7,117	10,870
Deferred tax assets	54,176	58,457
Other financial assets	95,850	93,436
Other non-current assets	9,913	10,070
Total non-current assets	1,401,040	1,416,914
Current assets		
Inventories	164,080	151,576
Trade and other receivables	343,178	373,923
Income tax receivable	13,984	16,799
Other financial assets	5,560	17,880
Other current assets	19,658	28,940
Cash and cash equivalents	326,128	350,213
Total current assets	872,588	939,331
Total assets	2,273,628	2,356,245

(Millions of yen)

	As of 31 March 2021	As of 31 December 2021
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	177,830	179,042
Treasury shares	(15,377)	(15,520)
Retained earnings	953,289	999,640
Other components of equity	167,373	200,129
Total equity attributable to owners of the parent	1,386,115	1,466,291
Total equity	1,386,115	1,466,291
Liabilities		
Non-current liabilities		
Trade and other payables	400	664
Deferred tax liabilities	18,161	10,618
Retirement benefit liabilities	38,982	37,942
Provisions	5,796	4,322
Other financial liabilities	199,021	201,534
Other non-current liabilities	32,782	36,897
Total non-current liabilities	295,141	291,978
Current liabilities		
Trade and other payables	124,777	136,892
Income tax payable	8,395	21,983
Provisions	22,187	13,973
Other financial liabilities	148,163	108,710
Other current liabilities	288,851	316,418
Total current liabilities	592,372	597,976
Total liabilities	887,513	889,954
Total equity and liabilities	2,273,628	2,356,245

(4) Condensed Interim Consolidated Statement of Changes in Equity

(Millions of yen)

	Equity attributable to owners of the parent					
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Subscription rights to shares	Exchange differences on translation of foreign operations
As of 1 April 2020	103,001	177,506	(7,178)	905,851	899	93,277
Comprehensive income						
Profit	—	—	—	132,917	—	—
Other comprehensive income	—	—	—	—	—	(787)
Total comprehensive income	—	—	—	132,917	—	(787)
Transactions with owners						
Acquisition of treasury shares	—	—	(882)	—	—	—
Disposals of treasury shares	—	(444)	876	(308)	(124)	—
Dividends	—	—	—	(76,157)	—	—
Share-based payments	—	583	—	—	—	—
Transfers	—	—	—	709	—	—
Total transactions with owners	—	139	(5)	(75,756)	(124)	—
As of 31 December 2020	103,001	177,644	(7,184)	963,012	775	92,489

As of 1 April 2021	103,001	177,830	(15,377)	953,289	745	147,024
Comprehensive income						
Profit	—	—	—	132,495	—	—
Other comprehensive income	—	—	—	—	—	33,759
Total comprehensive income	—	—	—	132,495	—	33,759
Transactions with owners						
Acquisition of treasury shares	—	—	(716)	—	—	—
Disposals of treasury shares	—	(377)	573	(130)	(66)	—
Dividends	—	—	—	(85,236)	—	—
Share-based payments	—	1,589	—	—	—	—
Transfers	—	—	—	(777)	—	—
Total transactions with owners	—	1,212	(143)	(86,144)	(66)	—
As of 31 December 2021	103,001	179,042	(15,520)	999,640	679	180,783

(Millions of yen)

	Equity attributable to owners of the parent				Total equity
	Other components of equity			Total	
	Financial assets measured at fair value through other comprehensive income	Remeasurements of defined benefit plans	Total		
As of 1 April 2020	15,813	—	109,989	1,289,168	1,289,168
Comprehensive income					
Profit	—	—	—	132,917	132,917
Other comprehensive income	24,423	(656)	22,980	22,980	22,980
Total comprehensive income	24,423	(656)	22,980	155,897	155,897
Transactions with owners					
Acquisition of treasury shares	—	—	—	(882)	(882)
Disposals of treasury shares	—	—	(124)	1	1
Dividends	—	—	—	(76,157)	(76,157)
Share-based payments	—	—	—	583	583
Transfers	(1,365)	656	(709)	—	—
Total transactions with owners	(1,365)	656	(833)	(76,456)	(76,456)
As of 31 December 2020	38,871	—	132,136	1,368,609	1,368,609

As of 1 April 2021	19,604	—	167,373	1,386,115	1,386,115
Comprehensive income					
Profit	—	—	—	132,495	132,495
Other comprehensive income	(2,986)	1,271	32,044	32,044	32,044
Total comprehensive income	(2,986)	1,271	32,044	164,538	164,538
Transactions with owners					
Acquisition of treasury shares	—	—	—	(716)	(716)
Disposals of treasury shares	—	—	(66)	0	0
Dividends	—	—	—	(85,236)	(85,236)
Share-based payments	—	—	—	1,589	1,589
Transfers	2,048	(1,271)	777	—	—
Total transactions with owners	2,048	(1,271)	712	(84,363)	(84,363)
As of 31 December 2021	18,666	—	200,129	1,466,291	1,466,291

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Nine months ended 31 December 2020	Nine months ended 31 December 2021
Cash flows from operating activities		
Profit before tax	164,227	167,402
Depreciation and amortisation	54,090	58,602
Impairment losses (reversal of impairment losses)	35,280	26,718
Finance income and expenses	(4,758)	1,968
(Increase) decrease in inventories	(1,534)	17,262
(Increase) decrease in trade and other receivables	5,385	(17,707)
Increase (decrease) in trade and other payables	(59,192)	1,130
Other	42,136	(12,683)
Subtotal	235,634	242,693
Income tax paid	(10,491)	(33,834)
Net cash flows from operating activities	225,143	208,859
Cash flows from investing activities		
Purchases of property, plant and equipment	(22,915)	(20,239)
Proceeds from sales of property, plant and equipment	6,567	405
Purchase of intangible assets	(35,947)	(38,937)
Proceeds from sales of intangible assets	—	24,155
Payments for acquisition of subsidiaries	(14,903)	(659)
Interest and dividends received	553	549
Other	(1,090)	(12,860)
Net cash flows provided by (used in) investing activities	(67,735)	(47,586)
Cash flows from financing activities		
Increase (decrease) in bonds and short-term borrowings	(161,000)	(40,000)
Proceeds from long-term borrowings	80,000	—
Acquisition of treasury shares	(882)	(716)
Dividends paid to owners of the parent	(76,157)	(85,236)
Repayments of lease liabilities	(11,589)	(13,472)
Other	(1,709)	(1,840)
Net cash flows provided by (used in) financing activities	(171,337)	(141,264)
Effect of exchange rate changes on cash and cash equivalents	2,052	4,076
Net increase (decrease) in cash and cash equivalents	(11,877)	24,085
Cash and cash equivalents at the beginning of the year	318,391	326,128
Cash and cash equivalents at the end of the period	306,514	350,213

(6) Notes to condensed interim consolidated financial statements
Notes on going concern assumption

Not applicable.