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Financial Results of Astellas for the First Six Months of FY2022

Japan, October 31, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, “the Company”) today announced the financial results for the first six months (April 1, 2022 – September 30, 2022) of the fiscal year 2022 ending March 31, 2023 (FY2022).

Consolidated financial results for the first six months of FY2022 (core basis)

(Millions of yen)

	First six months of FY2021	First six months of FY2022	Change (%)
Revenue	651,666	762,185	+110,519 (+17.0%)
Core operating profit	125,293	145,384	+20,091 (+16.0%)
Core profit	98,756	119,973	+21,217 (+21.5%)

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 six months of FY2022

(1) Business performance

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

Consolidated financial results (core basis) in the first six months of FY2022 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 six months of FY2021	First six months of FY2022	Change (%)
Revenue	651,666	762,185	+110,519 (+17.0%)
Cost of sales	124,736	151,651	+26,916 (+21.6%)
Selling, general and administrative expenses	270,506	307,956	+37,449 (+13.8%)
R&D expenses	119,060	139,177	+20,118 (+16.9%)
Amortisation of intangible assets	12,379	19,967	+7,588 (+61.3%)
Share of profit (loss) of investments accounted for using equity method	308	1,779	+1,471 (+477.8%)
Core operating profit	125,293	145,384	+20,091 (+16.0%)
Core profit	98,756	119,973	+21,217 (+21.5%)
Basic core earnings per share (yen)	53.30	65.78	+12.48 (+23.4%)

(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 Q2/FY2022 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, contributing to revenue growth.
- The growth of sales of EVENITY for the treatment of osteoporosis in Japan also contributed to revenue growth.

In addition to the above, the rapid depreciation of the yen had a favorable foreign exchange impact on our business, revenue in the first six months of FY2022 increased by 17.0% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥762.2 billion.

Core operating profit / Core profit

- Gross profit increased by 15.9% year-on-year to ¥610.5 billion. The cost-to-revenue ratio increased by 0.8 percentage points year-on-year to 19.9%, mainly due to changes in product mix.
- Selling, general and administrative expenses increased by 13.8% year-on-year to ¥308.0 billion. Although expenses decreased as a result of global optimization of commercial-related personnel aligned with transformation of product portfolio (decrease of approximately ¥6.0 billion year-on-year) and reduction of mature products-related costs (decrease of approximately ¥4.0 billion year-on-year), the total amount increased due to an increase in investment for new product launch readiness (increase of approximately ¥4.0 billion year-on-year) and foreign exchange rate impact (increase of ¥40.2 billion year-on-year). Excluding the foreign exchange rate impact, the total amount decreased on a year-on-year basis. Selling, general and administrative expenses, excluding co-promotion fees of XTANDI in the United States, increased by 9.5% year-on-year to ¥218.3 billion.
- Research and development (R&D) expenses increased by 16.9% year-on-year to ¥139.2 billion. In addition to the foreign exchange rate impact (increase of ¥15.1 billion year-on-year), the total amount increased due to the recording of expenses (¥13.5 billion) associated with the priority review voucher used for fezolinetant in the first three months of FY2022.
- Amortisation of intangible assets increased by 61.3% year-on-year to ¥20.0 billion.

As a result of the above, core operating profit increased by 16.0% year-on-year to ¥145.4 billion, and core profit increased by 21.5% year-on-year to ¥120.0 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in the first six months of FY2022 are shown in the table below. The resulting impacts were a ¥84.3 billion increase in revenue and a ¥16.0 billion increase in core operating profit compared with if the exchange rates of the corresponding period of the previous fiscal year were applied.

Average rate	First six months of FY2021	First six months of FY2022	Change
US\$/¥	110	134	¥24 (Weakening of yen)
€/¥	131	139	¥8 (Weakening of yen)

Change from beginning to end of period	As of September 30, 2021	As of September 30, 2022
US\$/¥	¥1 (Weakening of yen)	¥23 (Weakening of yen)
€/¥	¥1 (Strengthening of yen)	¥7 (Weakening of yen)

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in the first six months of FY2022 are shown in the table below.

Revenue, operating profit and profit increased across the board.

The full basis financial results include “Other income” and “Other expenses,” which are excluded from the core basis financial results. In the first six months of FY2022, “Other income” was ¥16.2 billion (¥2.8 billion in the corresponding period of the previous fiscal year) and “Other expenses” was ¥41.7 billion (¥38.0 billion in the corresponding period of the previous fiscal year).

As “Other income,” the Company recorded foreign exchange gains of ¥13.9 billion (¥2.3 billion in the corresponding period of the previous fiscal year).

Consolidated financial results (full basis)

(Millions of yen)

	First six months of FY2021	First six months of FY2022	Change (%)
Revenue	651,666	762,185	+110,519 (+17.0%)
Operating profit	90,169	119,891	+29,722 (+33.0%)
Profit before tax	89,085	120,480	+31,395 (+35.2%)
Profit	71,609	96,434	+24,825 (+34.7%)
Basic earnings per share (yen)	38.65	52.87	+14.23 (+36.8%)
Comprehensive income	70,077	243,707	+173,630 (+247.8%)

<Sales of Main Products>

(Billions of yen)

	First six months of FY2021	First six months of FY2022	Change
XTANDI	267.6	332.0	+24.1%
PADCEV	9.1	20.8	+127.8%
XOSPATA	16.5	23.5	+42.5%
EVRENZO	1.4	1.5	+8.7%
Betanis / Myrbetriq / BETMIGA	84.4	93.4	+10.7%
Prograf*	92.3	100.4	+8.7%

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

<XTANDI>

- Sales increased in all regions. Particularly in Europe, where additional indication was approved for “metastatic hormone-sensitive prostate cancer (M1 HSPC)” in April 2021, the expansion of prescriptions, primarily in Germany, contributed to sales growth.

<PADCEV>

- In Japan, where the product was launched in November 2021, sales increased as the number of new patients far exceeded expectations. In Europe, where approval was obtained in April 2022, the number of countries where it was launched increased to 16, contributing to sales growth.

<XOSPATA>

- Sales increased in all regions compared to the corresponding period of the previous fiscal year.

<EVRENZO>

- While sales increased in Europe, sales decreased in Japan due to the continued strong competition in markets.

<Betanis / Myrbetriq / BETMIGA>

- Sales increased in all regions except in Japan.

<Prograf>

- Global sales increased, as sales increased in all regions except in Japan.

<Revenue by region>

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

(Billions of yen)

	First six months of FY2021	First six months of FY2022	Change
Japan	130.5	133.3	+2.1%
United States	270.1	328.3	+21.5%
Established Markets ^{*1}	157.4	180.1	+14.5%
Greater China ^{*2}	33.1	45.0	+36.2%
International Markets ^{*3}	55.3	63.3	+14.5%

*1 Established Markets: Europe, Canada, Australia.

*2 Greater China: China, Hong Kong, Taiwan.

*3 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 September 30, 2022 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets saw an increase of ¥251.3 billion compared to the end of the previous fiscal year to ¥2,583.7 billion.

<Non-current assets> As of September 30, 2022: ¥1,524.5 billion (an increase of ¥115.5 billion)

- Property, plant and equipment increased by ¥11.5 billion compared to the end of the previous fiscal year to ¥280.6 billion.
- Goodwill increased by ¥50.1 billion compared to the end of the previous fiscal year to ¥353.1 billion, and intangible assets increased by ¥30.2 billion compared to the end of the previous fiscal year to ¥653.6 billion.

<Current assets> As of September 30, 2022: ¥1,059.1 billion (an increase of ¥135.8 billion)

- Cash and cash equivalents increased by ¥45.1 billion compared to the end of the previous fiscal year to ¥361.1 billion.

Equity

Total equity as of September 30, 2022 saw an increase of ¥189.2 billion compared to the end of the previous fiscal year to ¥1,649.5 billion, making the ratio of equity attributable to owners of the parent to total assets 63.8%.

- While profit stood at ¥96.4 billion, the Company paid ¥45.7 billion of dividends of surplus.

Liabilities

Total liabilities increased by ¥62.1 billion compared to the end of the previous fiscal year to ¥934.1 billion.

<Non-current liabilities> As of September 30, 2022: ¥172.7 billion (a decrease of ¥11.9 billion)

- Other financial liabilities decreased by ¥13.5 billion compared to the end of the previous fiscal year to ¥82.4 billion.

<Current liabilities> As of September 30, 2022: ¥761.4 billion (an increase of ¥74.0 billion)

- As of September 30, 2022, other financial liabilities amounted to ¥205.6 billion (an

increase of ¥20.6 billion). Of this amount, current portion of long-term borrowings and bonds amounted to ¥125.0 billion (a decrease of ¥15.0 billion).

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in the first six months of FY2022 increased by ¥0.5 billion year-on-year to ¥139.9 billion.

- Income tax paid increased by ¥11.1 billion year-on-year to ¥35.2 billion.

Cash flows from investing activities

Net cash flows used in investing activities in the first six months of FY2022 was ¥34.7 billion, a decrease in outflow of ¥21.1 billion year-on-year.

- Proceeds from sales of equity instruments amounted to ¥12.1 billion.

Cash flows from financing activities

Net cash flows used in financing activities in the first six months of FY2022 was ¥81.4 billion, a decrease in outflow of ¥8.5 billion year-on-year.

- The balance of bonds and short-term borrowings decreased by ¥15.0 billion.
- Dividends paid increased by ¥6.8 billion year-on-year to ¥45.7 billion.

As a result, cash and cash equivalents totaled ¥361.1 billion as of September 30, 2022, an increase of ¥45.1 billion compared to the end of the previous fiscal year.

(3) Consolidated business forecasts for FY2022 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 FY2022 are shown below.

Based on the financial results for the first six months of FY2022 and the trend of foreign exchange rates, the Company has upwardly revised its forecasts for revenue, selling, general and administrative expenses, and R&D expenses from those announced in April 2022 ("initial forecasts"). The Company has left its business forecasts for profit items on a core basis and full basis unchanged from the initial forecasts.

Consolidated full-year business forecasts (core basis)

(Millions of yen)

	FY2022 Initial forecasts	FY2022 Revised forecasts	Change	FY2021 Results
Revenue	1,443,000	1,529,000	+86,000	1,296,163
Selling, general and administrative expenses	598,000	642,000	+44,000	548,840
R&D expenses	254,000	278,000	+24,000	246,010
Core operating profit	290,000	290,000	—	244,744
Core profit for the year	223,000	223,000	—	190,584
Basic core earnings per share (yen)	122.05	122.05	—	103.03

Consolidated full-year business forecasts (full basis)

(Millions of yen)

	FY2022 Initial forecasts	FY2022 Revised forecasts	Change	FY2021 Results
Revenue	1,443,000	1,529,000	+86,000	1,296,163
Operating profit	269,000	269,000	—	155,686
Profit before tax	267,000	267,000	—	156,886
Profit for the year	208,000	208,000	—	124,086
Basic earnings per share (yen)	113.84	113.84	—	67.08

Expected exchange rate for**FY2022 (Forecast)****¥137/US\$****¥139/€**

FY2021 (Result)

¥112/US\$

¥131/€

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

(Millions of yen)

	Six months ended 30 September 2021	Six months ended 30 September 2022
Revenue	651,666	762,185
Cost of sales	(124,736)	(151,651)
Gross profit	526,931	610,534
Selling, general and administrative expenses	(270,506)	(307,956)
Research and development expenses	(119,060)	(139,177)
Amortisation of intangible assets	(12,379)	(19,967)
Gain on divestiture of intangible assets	—	172
Share of profit (loss) of investments accounted for using equity method	308	1,779
Other income	2,847	16,250
Other expenses	(37,972)	(41,743)
Operating profit	90,169	119,891
Finance income	1,888	4,493
Finance expenses	(2,972)	(3,904)
Profit before tax	89,085	120,480
Income tax expense	(17,476)	(24,046)
Profit	71,609	96,434
Profit attributable to:		
Owners of the parent	71,609	96,434
Earnings per share:		
Basic (Yen)	38.65	52.87
Diluted (Yen)	38.63	52.85

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Six months ended 30 September 2021	Six months ended 30 September 2022
Profit	71,609	96,434
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(6,369)	3,184
Remeasurements of defined benefit plans	1,573	1,375
Subtotal	<u>(4,796)</u>	<u>4,559</u>
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	3,264	142,714
Subtotal	<u>3,264</u>	<u>142,714</u>
Other comprehensive income	<u>(1,532)</u>	<u>147,273</u>
Total comprehensive income	<u>70,077</u>	<u>243,707</u>
Total comprehensive income attributable to:		
Owners of the parent	70,077	243,707

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2022	As of 30 September 2022
Assets		
Non-current assets		
Property, plant and equipment	269,044	280,552
Goodwill	303,030	353,095
Intangible assets	623,431	653,629
Trade and other receivables	29,796	26,688
Investments accounted for using equity method	10,035	14,316
Deferred tax assets	72,331	96,461
Other financial assets	91,844	87,952
Other non-current assets	9,531	11,823
Total non-current assets	1,409,041	1,524,516
Current assets		
Inventories	153,072	168,636
Trade and other receivables	382,462	452,485
Income tax receivable	21,539	11,022
Other financial assets	21,297	31,947
Other current assets	28,997	33,981
Cash and cash equivalents	315,986	361,073
Total current assets	923,354	1,059,145
Total assets	2,332,395	2,583,661

(Millions of yen)

	As of 31 March 2022	As of 30 September 2022
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	179,467	180,147
Treasury shares	(13,934)	(23,325)
Retained earnings	944,261	1,003,572
Other components of equity	247,512	386,123
Total equity attributable to owners of the parent	1,460,308	1,649,518
Total equity	1,460,308	1,649,518
Liabilities		
Non-current liabilities		
Trade and other payables	676	5,023
Deferred tax liabilities	5,823	6,104
Retirement benefit liabilities	37,226	36,918
Provisions	5,831	3,653
Other financial liabilities	95,886	82,391
Other non-current liabilities	39,234	38,641
Total non-current liabilities	184,676	172,730
Current liabilities		
Trade and other payables	130,739	146,533
Income tax payable	32,388	26,246
Provisions	16,570	14,012
Other financial liabilities	184,964	205,611
Other current liabilities	322,751	369,011
Total current liabilities	687,411	761,412
Total liabilities	872,087	934,143
Total equity and liabilities	2,332,395	2,583,661

(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 2021	103,001	177,830	(15,377)	953,289	745	147,024
Comprehensive income						
Profit	—	—	—	71,609	—	—
Other comprehensive income	—	—	—	—	—	3,264
Total comprehensive income	—	—	—	71,609	—	3,264
Transactions with owners						
Acquisition of treasury shares	—	—	(715)	—	—	—
Disposals of treasury shares	—	(357)	487	(87)	(44)	—
Dividends	—	—	—	(38,914)	—	—
Share-based payments	—	1,058	—	—	—	—
Transfers	—	—	—	(666)	—	—
Total transactions with owners	—	702	(227)	(39,667)	(44)	—
As of 30 September 2021	103,001	178,531	(15,605)	985,231	701	150,288

As of 1 April 2022	103,001	179,467	(13,934)	944,261	630	233,621
Comprehensive income						
Profit	—	—	—	96,434	—	—
Other comprehensive income	—	—	—	—	—	142,714
Total comprehensive income	—	—	—	96,434	—	142,714
Transactions with owners						
Acquisition of treasury shares	—	—	(10,553)	—	—	—
Disposals of treasury shares	—	(1,054)	1,162	(98)	(10)	—
Dividends	—	—	—	(45,677)	—	—
Share-based payments	—	1,733	—	—	—	—
Transfers	—	—	—	8,652	—	—
Total transactions with owners	—	679	(9,391)	(37,124)	(10)	—
As of 30 September 2022	103,001	180,147	(23,325)	1,003,572	620	376,335

(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 2021	19,604	—	167,373	1,386,115	1,386,115
Comprehensive income					
Profit	—	—	—	71,609	71,609
Other comprehensive income	(6,369)	1,573	(1,532)	(1,532)	(1,532)
Total comprehensive income	(6,369)	1,573	(1,532)	70,077	70,077
Transactions with owners					
Acquisition of treasury shares	—	—	—	(715)	(715)
Disposals of treasury shares	—	—	(44)	0	0
Dividends	—	—	—	(38,914)	(38,914)
Share-based payments	—	—	—	1,058	1,058
Transfers	2,239	(1,573)	666	—	—
Total transactions with owners	2,239	(1,573)	623	(38,570)	(38,570)
As of 30 September 2021	15,474	—	166,464	1,417,622	1,417,622

As of 1 April 2022	13,261	—	247,512	1,460,308	1,460,308
Comprehensive income					
Profit	—	—	—	96,434	96,434
Other comprehensive income	3,184	1,375	147,273	147,273	147,273
Total comprehensive income	3,184	1,375	147,273	243,707	243,707
Transactions with owners					
Acquisition of treasury shares	—	—	—	(10,553)	(10,553)
Disposals of treasury shares	—	—	(10)	0	0
Dividends	—	—	—	(45,677)	(45,677)
Share-based payments	—	—	—	1,733	1,733
Transfers	(7,277)	(1,375)	(8,652)	—	—
Total transactions with owners	(7,277)	(1,375)	(8,662)	(54,497)	(54,497)
As of 30 September 2022	9,168	—	386,123	1,649,518	1,649,518

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Six months ended 30 September 2021	Six months ended 30 September 2022
Cash flows from operating activities		
Profit before tax	89,085	120,480
Depreciation and amortisation	37,081	59,724
Impairment losses (reversal of impairment losses)	26,054	22,768
Finance income and expenses	1,083	(589)
(Increase) decrease in inventories	15,423	113
(Increase) decrease in trade and other receivables	(13,254)	(13,978)
Increase (decrease) in trade and other payables	(8,791)	(19,359)
Other	16,768	5,893
Subtotal	163,451	175,052
Income tax paid	(24,066)	(35,195)
Net cash flows from operating activities	139,385	139,857
Cash flows from investing activities		
Purchases of property, plant and equipment	(17,493)	(13,795)
Purchase of intangible assets	(30,382)	(25,894)
Proceeds from sales of intangible assets	—	172
Proceeds from sales of equity instruments	443	12,104
Payments for acquisition of subsidiaries	(649)	—
Interest and dividends received	292	1,022
Other	(7,955)	(8,268)
Net cash flows provided by (used in) investing activities	(55,744)	(34,660)
Cash flows from financing activities		
Increase (decrease) in bonds and short-term borrowings	(40,000)	(15,000)
Acquisition of treasury shares	(715)	(10,553)
Dividends paid to owners of the parent	(38,914)	(45,677)
Repayments of lease liabilities	(9,083)	(8,853)
Other	(1,224)	(1,348)
Net cash flows provided by (used in) financing activities	(89,936)	(81,431)
Effect of exchange rate changes on cash and cash equivalents	(1,539)	21,321
Net increase (decrease) in cash and cash equivalents	(7,834)	45,087
Cash and cash equivalents at the beginning of the year	326,128	315,986
Cash and cash equivalents at the end of the period	318,295	361,073

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

Not applicable.