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Financial Results of Astellas for the First Three Months of FY2022

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

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

(Millions of yen)

	First three months of FY2021	First three months of FY2022	Change (%)
Revenue	326,143	381,791	+55,647 (+17.1%)
Core operating profit	62,820	55,292	-7,527 (-12.0%)
Core profit	49,241	45,843	-3,399 (-6.9%)

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 three months of FY2022

(1) Business performance

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

Consolidated financial results (core basis) in the first three months of FY2022 are shown in the table below.

While revenue increased, core operating profit and core profit decreased.

Consolidated financial results (core basis)

(Millions of yen)

	First three months of FY2021	First three months of FY2022	Change (%)
Revenue	326,143	381,791	+55,647 (+17.1%)
Cost of sales	62,231	88,870	+26,639 (+42.8%)
Selling, general and administrative expenses	137,109	153,396	+16,287 (+11.9%)
R&D expenses	58,313	74,007	+15,695 (+26.9%)
Amortisation of intangible assets	5,963	10,745	+4,782 (+80.2%)
Share of profit (loss) of investments accounted for using equity method	292	350	+58 (+19.8%)
Core operating profit	62,820	55,292	-7,527 (-12.0%)
Core profit	49,241	45,843	-3,399 (-6.9%)
Basic core earnings per share (yen)	26.58	25.12	-1.46 (-5.5%)

(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 Q1/FY2022 Financial Results."

Revenue

- Sales of XTANDI for the treatment of prostate cancer and XOSPATA for the treatment of acute myeloid leukemia continued to grow.
- PADCEV for the treatment of urothelial cancer contributed to revenue growth due to significant expanding of sales in the United States and Japan as well as an increase in the number of countries in which the product was launched in Europe.
- Additionally, the expansion of sales of Betanis / Myrbetriq / BETMIGA for the treatment of overactive bladder (“OAB”) and the immunosuppressant agent Prograf as well as the growth of sales of EVENITY for the treatment of osteoporosis in Japan contributed to revenue growth.

As a result of the above, revenue in the first three months of FY2022 increased by 17.1% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥381.8 billion.

Core operating profit / Core profit

- Gross profit increased by 11.0% year-on-year to ¥292.9 billion. The cost-to-revenue ratio increased by 4.2 percentage points year-on-year to 23.3%, mainly due to the foreign exchange rate impact from the elimination of unrealized profit in intra-group transactions (increase of ¥12.3 billion year-on-year).
- Selling, general and administrative expenses increased by 11.9% year-on-year to ¥153.4 billion. Although expenses decreased as a result of global optimization of personnel aligned with transformation of product portfolio (decrease of approximately ¥3.0 billion year-on-year) and reduction of mature products-related costs (decrease of approximately ¥2.0 billion year-on-year), the total amount increased due to foreign exchange rate impact (increase of ¥16.7 billion year-on-year) and an increase in investment for new product launch readiness (increase of approximately ¥2.0 billion year-on-year). Selling, general and administrative expenses, excluding co-promotion fees of XTANDI in the United States, increased by 7.4% year-on-year to ¥110.3 billion.
- Research and development (R&D) expenses increased by 26.9% year-on-year to ¥74.0 billion. The total amount increased due to foreign exchange rate impact (increase of ¥7.5 billion year-on-year) in addition to one-time expenses recorded during this period, which was included in the full-year forecast.
- Amortisation of intangible assets increased by 80.2% year-on-year to ¥10.7 billion.

As a result of the above, core operating profit decreased by 12.0% year-on-year to ¥55.3 billion, and core profit decreased by 6.9% year-on-year to ¥45.8 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in the first three months of FY2022 are shown in the table below. The resulting impacts were a ¥35.5 billion increase in revenue and a ¥7.4 billion decrease in core operating profit compared with if the exchange rates of the first three months of FY2021 were applied.

Average rate	First three months of FY2021	First three months of FY2022	Change
US\$/¥	109	130	¥20 (Weakening of yen)
€/¥	132	138	¥6 (Weakening of yen)

Change from beginning to end of period	As of June 30, 2021	As of June 30, 2022
US\$/¥	¥0 (Strengthening of yen)	¥14 (Weakening of yen)
€/¥	¥2 (Weakening of yen)	¥8 (Weakening of yen)

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in the first three months of FY2022 are shown in the table below. While revenue increased, operating profit and profit decreased.

The full basis financial results include “Other income” and “Other expenses,” which are excluded from the core basis financial results. In the first three months of FY2022, “Other income” was ¥16.3 billion (¥0.4 billion in the corresponding period of the previous fiscal year) and “Other expenses” was ¥38.4 billion (¥27.1 billion in the corresponding period of the previous fiscal year).

As “Other income,” the Company recorded foreign exchange gains of ¥14.1 billion (¥0.3 billion in the corresponding period of the previous fiscal year). Impairment loss of intangible assets due to the termination of the research and development of the gene therapy programs AT702, AT751 and AT753 (¥22.0 billion) as well as the increase in fair value of contingent consideration resulting from the application for approval of fezolinetant in the United States (¥13.6 billion) were recorded as “Other expenses.”

Consolidated financial results (full basis)

(Millions of yen)

	First three months of FY2021	First three months of FY2022	Change (%)
Revenue	326,143	381,791	+55,647 (+17.1%)
Operating profit	36,090	33,147	-2,943 (-8.2%)
Profit before tax	35,830	31,679	-4,152 (-11.6%)
Profit	30,687	24,812	-5,875 (-19.1%)
Basic earnings per share (yen)	16.56	13.59	-2.97 (-17.9%)
Comprehensive income	36,206	134,396	+98,190 (+271.2%)

<Sales of Main Products>

(Billions of yen)

	First three months of FY2021	First three months of FY2022	Change
XTANDI	132.9	162.4	+22.2%
PADCEV	4.2	10.6	+151.6%
XOSPATA	8.3	10.5	+26.3%
EVRENZO	0.6	0.7	+19.3%
Betanis / Myrbetriq / BETMIGA	44.0	47.9	+9.0%
Prograf*	45.2	51.8	+14.6%

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

<XTANDI>

- Sales increased in all regions. Particularly, sales grew substantially in the United States compared to the corresponding period of the previous fiscal year. Furthermore, in Europe, an increase in the number of new countries where reimbursement began contributed to sales growth in addition to the expansion of prescriptions for “metastatic hormone-sensitive prostate cancer (M1 HSPC)” (additional indications from April 2021).

<PADCEV>

- In the United States, revenue from co-promotion grew. In Japan, where the product was launched in November 2021, market share expanded more than expected and sales increased significantly. In Europe, where approval was obtained in April 2022, the number of countries where it was launched increased, and uptake has been strong thus far.

<XOSPATA>

- Sales increased in all regions except in China.

<EVRENZO>

- Continuing from the previous fiscal year, sales were lower than expected due to the strong competition in Japanese markets as well as being unable to sufficiently differentiate EVRENZO from existing standard treatments in Europe.

<Betanis / Myrbetriq / BETMIGA>

- Sales increased in all regions except in Japan.

<Prograf>

- Sales increased in line with the full-year forecasts in all regions except in Japan.

<Revenue by region>

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

(Billions of yen)

	First three months of FY2021	First three months of FY2022	Change
Japan	67.5	66.8	-1.0%
United States	133.6	160.9	+20.4%
Established Markets	78.0	88.7	+13.7%
Greater China	16.4	23.2	+41.0%
International Markets	27.8	31.8	+14.5%

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

Assets

Total assets as of June 30, 2022 saw an increase of ¥149.4 billion compared to the end of the previous fiscal year to ¥2,481.8 billion.

<Non-current assets> As of June 30, 2022: ¥1,492.6 billion (an increase of ¥83.5 billion)

- Property, plant and equipment increased by ¥11.1 billion compared to the end of the previous fiscal year to ¥280.2 billion.
- Goodwill increased by ¥31.2 billion compared to the end of the previous fiscal year to ¥334.3 billion, and intangible assets increased by ¥16.4 billion compared to the end of the previous fiscal year to ¥639.8 billion.

<Current assets> As of June 30, 2022: ¥989.3 billion (an increase of ¥65.9 billion)

- Cash and cash equivalents decreased by ¥3.0 billion compared to the end of the previous fiscal year to ¥313.0 billion.

Equity

Total equity as of June 30, 2022 saw an increase of ¥78.7 billion compared to the end of the previous fiscal year to ¥1,539.1 billion, making the ratio of equity attributable to owners of the parent to total assets 62.0%.

- While profit stood at ¥24.8 billion, the Company paid ¥45.7 billion of dividends of surplus.

Liabilities

Total liabilities increased by ¥70.7 billion compared to the end of the previous fiscal year to ¥942.8 billion.

<Non-current liabilities> As of June 30, 2022: ¥202.3 billion (an increase of ¥17.6 billion)

- Other financial liabilities increased by ¥15.7 billion compared to the end of the previous fiscal year to ¥111.6 billion.

<Current liabilities> As of June 30, 2022: ¥740.5 billion (an increase of ¥53.1 billion)

- As of June 30, 2022, other financial liabilities amounted to ¥206.5 billion (an increase of ¥21.5 billion). Of this amount, bonds and current portion of long-term borrowings amounted to ¥155.0 billion (an increase of ¥15.0 billion).

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in the first three months of FY2022 increased by ¥8.7 billion year-on-year to ¥48.8 billion.

- Income tax paid increased by ¥22.4 billion year-on-year to ¥32.7 billion.

Cash flows from investing activities

Net cash flows used in investing activities in the first three months of FY2022 was ¥19.1 billion, a decrease in outflow of ¥1.9 billion year-on-year.

Cash flows from financing activities

Net cash flows used in financing activities in the first three months of FY2022 was ¥46.6 billion, an increase in outflow of ¥1.9 billion year-on-year.

- Dividends paid increased by ¥6.8 billion year-on-year to ¥45.7 billion.

As a result, cash and cash equivalents totaled ¥313.0 billion as of June 30, 2022, a decrease of ¥3.0 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.

The Company has left its business forecasts unchanged from the consolidated full-year business forecasts announced in April 2022.

Consolidated full-year business forecasts (core basis)

(Millions of yen)

	FY2021 Results	FY2022 Forecasts	Change (%)
Revenue	1,296,163	1,443,000	+146,837 (+11.3%)
Selling, general and administrative expenses	548,840	598,000	+49,160 (+9.0%)
R&D expenses	246,010	254,000	+7,990 (+3.2%)
Core operating profit	244,744	290,000	+45,256 (+18.5%)
Core profit for the year	190,584	223,000	+32,416 (+17.0%)
Basic core earnings per share (yen)	103.03	122.05	+19.02 (+18.5%)

(Note) The forecast of the basic core earnings per share is calculated based on the number of shares issued at the end of FY2021 (excluding treasury shares).

Consolidated full-year business forecasts (full basis)

(Millions of yen)

	FY2021 Results	FY2022 Forecasts	Change (%)
Revenue	1,296,163	1,443,000	+146,837 (+11.3%)
Operating profit	155,686	269,000	+113,314 (+72.8%)
Profit before tax	156,886	267,000	+110,114 (+70.2%)
Profit for the year	124,086	208,000	+83,914 (+67.6%)
Basic earnings per share (yen)	67.08	113.84	+46.76 (+69.7%)

(Note) The forecast of the basic earnings per share is calculated based on the number of shares issued at the end of FY2021 (excluding treasury shares).

Expected exchange rate for

FY2022 (Forecast)	¥120/US\$	¥135/€
FY2021 (Result)	¥112/US\$	¥131/€

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

(Millions of yen)

	Three months ended 30 June 2021	Three months ended 30 June 2022
Revenue	326,143	381,791
Cost of sales	(62,231)	(88,870)
Gross profit	263,912	292,920
Selling, general and administrative expenses	(137,109)	(153,396)
Research and development expenses	(58,313)	(74,007)
Amortisation of intangible assets	(5,963)	(10,745)
Gain on divestiture of intangible assets	—	170
Share of profit (loss) of investments accounted for using equity method	292	350
Other income	403	16,291
Other expenses	(27,133)	(38,436)
Operating profit	36,090	33,147
Finance income	1,457	927
Finance expenses	(1,717)	(2,396)
Profit before tax	35,830	31,679
Income tax expense	(5,144)	(6,867)
Profit	30,687	24,812
Profit attributable to:		
Owners of the parent	30,687	24,812
Earnings per share:		
Basic (Yen)	16.56	13.59
Diluted (Yen)	16.55	13.59

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three months ended 30 June 2021	Three months ended 30 June 2022
Profit	30,687	24,812
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(2,935)	981
Remeasurements of defined benefit plans	803	1,610
Subtotal	<u>(2,132)</u>	<u>2,591</u>
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	7,652	106,993
Subtotal	<u>7,652</u>	<u>106,993</u>
Other comprehensive income	<u>5,520</u>	<u>109,585</u>
Total comprehensive income	<u>36,206</u>	<u>134,396</u>
Total comprehensive income attributable to:		
Owners of the parent	36,206	134,396

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2022	As of 30 June 2022
Assets		
Non-current assets		
Property, plant and equipment	269,044	280,179
Goodwill	303,030	334,260
Intangible assets	623,431	639,834
Trade and other receivables	29,796	27,386
Investments accounted for using equity method	10,035	11,735
Deferred tax assets	72,331	92,100
Other financial assets	91,844	94,284
Other non-current assets	9,531	12,783
Total non-current assets	1,409,041	1,492,562
Current assets		
Inventories	153,072	164,828
Trade and other receivables	382,462	438,413
Income tax receivable	21,539	18,140
Other financial assets	21,297	23,746
Other current assets	28,997	31,141
Cash and cash equivalents	315,986	313,013
Total current assets	923,354	989,281
Total assets	2,332,395	2,481,843

(Millions of yen)

	As of 31 March 2022	As of 30 June 2022
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	179,467	179,045
Treasury shares	(13,934)	(23,377)
Retained earnings	944,261	924,981
Other components of equity	247,512	355,402
Total equity attributable to owners of the parent	1,460,308	1,539,052
Total equity	1,460,308	1,539,052
Liabilities		
Non-current liabilities		
Trade and other payables	676	4,870
Deferred tax liabilities	5,823	6,201
Retirement benefit liabilities	37,226	36,334
Provisions	5,831	7,695
Other financial liabilities	95,886	111,621
Other non-current liabilities	39,234	35,531
Total non-current liabilities	184,676	202,252
Current liabilities		
Trade and other payables	130,739	152,220
Income tax payable	32,388	18,859
Provisions	16,570	17,555
Other financial liabilities	184,964	206,484
Other current liabilities	322,751	345,420
Total current liabilities	687,411	740,538
Total liabilities	872,087	942,791
Total equity and liabilities	2,332,395	2,481,843

(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	—	—	—	30,687	—	—
Other comprehensive income	—	—	—	—	—	7,652
Total comprehensive income	—	—	—	30,687	—	7,652
Transactions with owners						
Acquisition of treasury shares	—	—	(713)	—	—	—
Disposals of treasury shares	—	(347)	428	(52)	(29)	—
Dividends	—	—	—	(38,914)	—	—
Share-based payments	—	174	—	—	—	—
Transfers	—	—	—	951	—	—
Total transactions with owners	—	(173)	(285)	(38,015)	(29)	—
As of 30 June 2021	103,001	177,657	(15,663)	945,961	717	154,676

As of 1 April 2022	103,001	179,467	(13,934)	944,261	630	233,621
Comprehensive income						
Profit	—	—	—	24,812	—	—
Other comprehensive income	—	—	—	—	—	106,993
Total comprehensive income	—	—	—	24,812	—	106,993
Transactions with owners						
Acquisition of treasury shares	—	—	(10,553)	—	—	—
Disposals of treasury shares	—	(1,000)	1,109	(104)	(5)	—
Dividends	—	—	—	(45,677)	—	—
Share-based payments	—	578	—	—	—	—
Transfers	—	—	—	1,689	—	—
Total transactions with owners	—	(422)	(9,444)	(44,092)	(5)	—
As of 30 June 2022	103,001	179,045	(23,377)	924,981	625	340,614

(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	—	—	—	30,687	30,687
Other comprehensive income	(2,935)	803	5,520	5,520	5,520
Total comprehensive income	(2,935)	803	5,520	36,206	36,206
Transactions with owners					
Acquisition of treasury shares	—	—	—	(713)	(713)
Disposals of treasury shares	—	—	(29)	0	0
Dividends	—	—	—	(38,914)	(38,914)
Share-based payments	—	—	—	174	174
Transfers	(148)	(803)	(951)	—	—
Total transactions with owners	(148)	(803)	(979)	(39,452)	(39,452)
As of 30 June 2021	16,521	—	171,914	1,382,869	1,382,869
As of 1 April 2022	13,261	—	247,512	1,460,308	1,460,308
Comprehensive income					
Profit	—	—	—	24,812	24,812
Other comprehensive income	981	1,610	109,585	109,585	109,585
Total comprehensive income	981	1,610	109,585	134,396	134,396
Transactions with owners					
Acquisition of treasury shares	—	—	—	(10,553)	(10,553)
Disposals of treasury shares	—	—	(5)	0	0
Dividends	—	—	—	(45,677)	(45,677)
Share-based payments	—	—	—	578	578
Transfers	(79)	(1,610)	(1,689)	—	—
Total transactions with owners	(79)	(1,610)	(1,694)	(55,652)	(55,652)
As of 30 June 2022	14,163	—	355,402	1,539,052	1,539,052

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Three months ended 30 June 2021	Three months ended 30 June 2022
Cash flows from operating activities		
Profit before tax	35,830	31,679
Depreciation and amortisation	18,144	36,872
Impairment losses (reversal of impairment losses)	26,052	22,035
Finance income and expenses	260	1,468
(Increase) decrease in inventories	8,256	4,113
(Increase) decrease in trade and other receivables	(19,991)	(16,747)
Increase (decrease) in trade and other payables	(13,163)	(17,568)
Other	(5,055)	19,667
Subtotal	50,333	81,519
Income tax paid	(10,251)	(32,688)
Net cash flows from operating activities	40,083	48,832
Cash flows from investing activities		
Purchases of property, plant and equipment	(9,352)	(8,235)
Purchase of intangible assets	(10,560)	(10,024)
Proceeds from sales of intangible assets	—	170
Payments for acquisition of subsidiaries	(648)	—
Interest and dividends received	135	287
Other	(660)	(1,341)
Net cash flows provided by (used in) investing activities	(21,085)	(19,144)
Cash flows from financing activities		
Increase (decrease) in bonds and short-term borrowings	—	15,000
Acquisition of treasury shares	(713)	(10,553)
Dividends paid to owners of the parent	(38,914)	(45,677)
Repayments of lease liabilities	(4,469)	(4,690)
Other	(634)	(682)
Net cash flows provided by (used in) financing activities	(44,730)	(46,602)
Effect of exchange rate changes on cash and cash equivalents	1,524	13,941
Net increase (decrease) in cash and cash equivalents	(24,208)	(2,973)
Cash and cash equivalents at the beginning of the year	326,128	315,986
Cash and cash equivalents at the end of the period	301,920	313,013

(6) Notes to condensed interim consolidated financial statements

Notes on going concern assumption

Not applicable.