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Contact:
Corporate Advocacy & Relations,
Astellas Pharma Inc.
TEL +81-3-3244-3201

Financial Results of Astellas for the First Nine Months of FY2022

Japan, February 6, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, “the Company”) today announced the financial results for the first nine months (April 1, 2022 – December 31, 2022) of the fiscal year 2022 ending March 31, 2023 (FY2022).

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

(Millions of yen)

	First nine months of FY2021	First nine months of FY2022	Change (%)
Revenue	992,293	1,164,365	+172,072 (+17.3%)
Core operating profit	220,047	233,668	+13,622 (+6.2%)
Core profit	169,677	188,922	+19,246 (+11.3%)

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 FY2022

(1) Business performance

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

Consolidated financial results (core basis) in the first nine 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 nine months of FY2021	First nine months of FY2022	Change (%)
Revenue	992,293	1,164,365	+172,072 (+17.3%)
Cost of sales	194,094	226,073	+31,979 (+16.5%)
Selling, general and administrative expenses	406,420	470,977	+64,557 (+15.9%)
R&D expenses	177,648	206,052	+28,404 (+16.0%)
Amortisation of intangible assets	20,247	29,174	+8,927 (+44.1%)
Gain on divestiture of intangible assets	24,130	208	-23,923 (-99.1%)
Share of profit (loss) of investments accounted for using equity method	2,032	1,371	-660 (-32.5%)
Core operating profit	220,047	233,668	+13,622 (+6.2%)
Core profit	169,677	188,922	+19,246 (+11.3%)
Basic core earnings per share (yen)	91.57	103.61	+12.03 (+13.1%)

(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/FY2022 Financial Results."

Revenue

- Sales of main products XTANDI for the treatment of prostate cancer, PADCEV for the treatment of urothelial cancer and XOSPATA for the treatment of acute myeloid leukemia showed steady growth. Sales of EVENITY for the treatment of osteoporosis in Japan also grew, contributing to revenue growth.

As a result of the above, revenue in the first nine months of FY2022 increased by 17.3% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥1,164.4 billion.

Core operating profit / Core profit

- Gross profit increased by 17.6% year-on-year to ¥938.3 billion. The cost-to-revenue ratio decreased by 0.1 percentage points year-on-year to 19.4%.
- Selling, general and administrative expenses increased by 15.9% year-on-year to ¥471.0 billion. Although expenses decreased as a result of global optimization of commercial-related personnel (decrease of approximately ¥8.0 billion year-on-year) and reduction of mature products-related costs (decrease of approximately ¥6.0 billion year-on-year), the total amount increased due to an increase in investment for new product launch readiness (increase of approximately ¥8.0 billion year-on-year) and foreign exchange rate impact (increase of ¥64.1 billion year-on-year). Selling, general and administrative expenses, excluding co-promotion fees of XTANDI in the United States, increased by 11.8% year-on-year to ¥332.7 billion. Excluding the foreign exchange rate impact, the total amount decreased on a year-on-year basis.
- Research and development (R&D) expenses increased by 16.0% year-on-year to ¥206.1 billion. In addition to the foreign exchange rate impact (increase of ¥23.0 billion year-on-year), the total amount increased due to the recording of expenses (¥13.8 billion) associated with the use of priority review voucher for fezolinetant in the first three months of FY2022. The R&D cost-to-revenue ratio was down 0.2 percentage points year-on-year to 17.7%.
- Amortisation of intangible assets increased by 44.1% year-on-year to ¥29.2 billion.

As a result of the above, core operating profit increased by 6.2% year-on-year to ¥233.7 billion, and core profit increased by 11.3% year-on-year to ¥188.9 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in the first nine months of FY2022 are shown in the table below. The resulting impacts were a ¥135.2 billion increase in revenue and a ¥34.8 billion increase in core operating profit compared with if the exchange rates of the first nine months of FY2021 were applied.

Average rate	First nine months of FY2021	First nine months of FY2022	Change
US\$/¥	111	137	¥25 (Weakening of yen)
€/¥	131	141	¥10 (Weakening of yen)

Change from beginning to end of period	As of December 31, 2021	As of December 31, 2022
US\$/¥	¥4 (Weakening of yen)	¥9 (Weakening of yen)
€/¥	¥1 (Weakening of yen)	¥6 (Weakening of yen)

<Consolidated financial results (full basis)>

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

Revenue, operating profit, profit before tax 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 nine months of FY2022, “Other income” was ¥2.5 billion (¥4.2 billion in the corresponding period of the previous fiscal year) and “Other expenses” was ¥54.9 billion (¥54.9 billion in the corresponding period of the previous fiscal year).

Consolidated financial results (full basis)

(Millions of yen)

	First nine months of FY2021	First nine months of FY2022	Change (%)
Revenue	992,293	1,164,365	+172,072 (+17.3%)
Operating profit	169,371	181,279	+11,908 (+7.0%)
Profit before tax	167,402	180,238	+12,836 (+7.7%)
Profit	132,495	144,839	+12,345 (+9.3%)
Basic earnings per share (yen)	71.51	79.43	+7.92 (+11.1%)
Comprehensive income	164,538	218,550	+54,012 (+32.8%)

<Sales of Main Products>

(Billions of yen)

	First nine months of FY2021	First nine months of FY2022	Change
XTANDI	411.6	511.9	+24.4%
PADCEV	14.6	33.1	+126.9%
XOSPATA	25.7	36.3	+41.1%
EVRENZO	2.1	2.4	+15.0%
Betanis / Myrbetriq / BETMIGA	126.9	141.0	+11.1%
Prograf*	141.1	151.6	+7.5%

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

<XTANDI>

- Sales increased in all regions.
- In particular, market share for “metastatic hormone-sensitive prostate cancer (M1 HSPC)” expanded primarily in Germany, Italy and Canada, contributing to sales growth.

<PADCEV>

- Sales increased in all regions.
- In Europe, where approval was obtained in April 2022, the total number of countries where it was launched increased steadily to 20, contributing to sales growth.

<XOSPATA>

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

<EVRENZO>

- While sales grew in Europe in line with an increase in the number of countries where it was newly launched, 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.

(Billions of yen)

	First nine months of FY2021	First nine months of FY2022	Change
Japan	203.2	204.5	+0.6%
United States	407.9	501.1	+22.8%
Established Markets* ¹	233.0	271.1	+16.4%
Greater China* ²	50.3	65.2	+29.4%
International Markets* ³	89.2	105.2	+18.0%

(Note) From the third quarter of FY2022, the commercial segment of Australia was changed from Established Markets to International Markets. Figures of the first nine months of FY2021 and the first nine months of the FY2022 reflect this change.

*1 Established Markets: Europe, Canada.

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

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

(2) Financial position

1) Assets, equity and liabilities

An overview of the consolidated statement of financial position as of December 31, 2022 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets as of December 31, 2022 saw an increase of ¥181.6 billion compared to the end of the previous fiscal year to ¥2,513.9 billion.

<Non-current assets> As of December 31, 2022: ¥1,441.4 billion (an increase of ¥32.3 billion)

- Property, plant and equipment increased by ¥0.1 billion compared to the end of the previous fiscal year to ¥269.1 billion.
- Goodwill increased by ¥21.0 billion compared to the end of the previous fiscal year to ¥324.1 billion, and intangible assets decreased by ¥6.9 billion compared to the end of the previous fiscal year to ¥616.5 billion.

<Current assets> As of December 31, 2022: ¥1,072.6 billion (an increase of ¥149.2 billion)

- Cash and cash equivalents increased by ¥65.8 billion compared to the end of the previous fiscal year to ¥381.8 billion.

Equity

Total equity as of December 31, 2022 saw an increase of ¥110.1 billion compared to the end of the previous fiscal year to ¥1,570.4 billion, making the ratio of equity attributable to owners of the parent to total assets 62.5%.

- While profit stood at ¥144.8 billion, the Company paid ¥100.4 billion of dividends of surplus.

Liabilities

Total liabilities increased by ¥71.4 billion compared to the end of the previous fiscal year to ¥943.5 billion.

<Non-current liabilities> As of December 31, 2022: ¥237.6 billion (an increase of ¥52.9 billion)

- Other financial liabilities increased by ¥52.9 billion compared to the end of the previous fiscal year to ¥148.7 billion mainly due to the issuance of straight bonds of ¥50.0 billion.

<Current liabilities> As of December 31, 2022: ¥705.9 billion (an increase of ¥18.5 billion)

- As of December 31, 2022, other financial liabilities amounted to ¥180.4 billion (a

decrease of ¥4.6 billion). Of this amount, current portion of long-term borrowings and commercial papers 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 nine months of FY2022 increased by ¥3.3 billion year-on-year to ¥212.2 billion.

- Income tax paid increased by ¥24.3 billion year-on-year to ¥58.2 billion.

Cash flows from investing activities

Net cash flows used in investing activities in the first nine months of FY2022 was ¥61.8 billion, an increase in outflow of ¥14.2 billion year-on-year.

Cash flows from financing activities

Net cash flows used in financing activities in the first nine months of FY2022 was ¥91.1 billion, a decrease in outflow of ¥50.1 billion year-on-year.

- Proceeds from issuance of bonds and long-term borrowings increased by ¥50.0 billion year-on-year due to the issuance of straight bonds.
- Dividends paid increased by ¥15.1 billion year-on-year to ¥100.4 billion.

As a result, cash and cash equivalents totaled ¥381.8 billion as of December 31, 2022, an increase of ¥65.8 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 on a core basis unchanged from the forecasts announced in October 2022 ("previous forecasts").

On the other hand, as for business forecasts on a full basis, the Company has downwardly revised its forecasts for profit items, due to the recording of foreign exchange losses (¥6.7 billion) in the first nine months of FY2022 (the Company recorded foreign exchange gains of ¥13.9 billion in the first six months of FY2022), and mainly in anticipation of the recognition of an increase in fair value of contingent consideration for zolbetuximab as "Other expenses" in the fourth quarter of FY2022.

Consolidated full-year business forecasts (core basis)

(Millions of yen)

	FY2022 Previous forecasts	FY2022 Latest forecasts	Change	FY2021 Results
Revenue	1,529,000	1,529,000	—	1,296,163
Selling, general and administrative expenses	642,000	642,000	—	548,840
R&D expenses	278,000	278,000	—	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 Previous forecasts	FY2022 Latest forecasts	Change	FY2021 Results
Revenue	1,529,000	1,529,000	—	1,296,163
Operating profit	269,000	195,000	-74,000	155,686
Profit before tax	267,000	193,000	-74,000	156,886
Profit for the year	208,000	150,000	-58,000	124,086
Basic earnings per share (yen)	113.84	82.10	-31.74	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)

	Nine months ended 31 December 2021	Nine months ended 31 December 2022
Revenue	992,293	1,164,365
Cost of sales	(194,094)	(226,073)
Gross profit	798,199	938,293
Selling, general and administrative expenses	(406,420)	(470,977)
Research and development expenses	(177,648)	(206,052)
Amortisation of intangible assets	(20,247)	(29,174)
Gain on divestiture of intangible assets	24,130	208
Share of profit (loss) of investments accounted for using equity method	2,032	1,371
Other income	4,209	2,517
Other expenses	(54,885)	(54,906)
Operating profit	169,371	181,279
Finance income	2,306	5,666
Finance expenses	(4,274)	(6,707)
Profit before tax	167,402	180,238
Income tax expense	(34,908)	(35,399)
Profit	132,495	144,839
Profit attributable to:		
Owners of the parent	132,495	144,839
Earnings per share:		
Basic (Yen)	71.51	79.43
Diluted (Yen)	71.47	79.40

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended 31 December 2021	Nine months ended 31 December 2022
Profit	132,495	144,839
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(2,986)	4,411
Remeasurements of defined benefit plans	1,271	917
Subtotal	<u>(1,715)</u>	<u>5,328</u>
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	33,759	68,384
Subtotal	<u>33,759</u>	<u>68,384</u>
Other comprehensive income	<u>32,044</u>	<u>73,711</u>
Total comprehensive income	<u>164,538</u>	<u>218,550</u>
Total comprehensive income attributable to:		
Owners of the parent	164,538	218,550

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2022	As of 31 December 2022
Assets		
Non-current assets		
Property, plant and equipment	269,044	269,106
Goodwill	303,030	324,068
Intangible assets	623,431	616,538
Trade and other receivables	29,796	24,804
Investments accounted for using equity method	10,035	12,601
Deferred tax assets	72,331	93,225
Other financial assets	91,844	90,102
Other non-current assets	9,531	10,910
Total non-current assets	<u>1,409,041</u>	<u>1,441,355</u>
Current assets		
Inventories	153,072	163,221
Trade and other receivables	382,462	451,275
Income tax receivable	21,539	11,670
Other financial assets	21,297	31,480
Other current assets	28,997	31,864
Cash and cash equivalents	315,986	381,816
Subtotal	<u>923,354</u>	<u>1,071,325</u>
Assets held for sale	—	1,268
Total current assets	<u>923,354</u>	<u>1,072,593</u>
Total assets	<u><u>2,332,395</u></u>	<u><u>2,513,948</u></u>

(Millions of yen)

	As of 31 March 2022	As of 31 December 2022
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	179,467	180,591
Treasury shares	(13,934)	(23,020)
Retained earnings	944,261	996,246
Other components of equity	247,512	313,607
Total equity attributable to owners of the parent	1,460,308	1,570,424
Total equity	1,460,308	1,570,424
Liabilities		
Non-current liabilities		
Trade and other payables	676	4,378
Deferred tax liabilities	5,823	6,033
Retirement benefit liabilities	37,226	37,092
Provisions	5,831	4,041
Other financial liabilities	95,886	148,738
Other non-current liabilities	39,234	37,337
Total non-current liabilities	184,676	237,619
Current liabilities		
Trade and other payables	130,739	134,235
Income tax payable	32,388	18,449
Provisions	16,570	12,613
Other financial liabilities	184,964	180,413
Other current liabilities	322,751	360,196
Total current liabilities	687,411	705,905
Total liabilities	872,087	943,524
Total equity and liabilities	2,332,395	2,513,948

(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	—	—	—	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
As of 1 April 2022	103,001	179,467	(13,934)	944,261	630	233,621
Comprehensive income						
Profit	—	—	—	144,839	—	—
Other comprehensive income	—	—	—	—	—	68,384
Total comprehensive income	—	—	—	144,839	—	68,384
Transactions with owners						
Acquisition of treasury shares	—	—	(10,555)	—	—	—
Disposals of treasury shares	—	(1,351)	1,468	(86)	(29)	—
Dividends	—	—	—	(100,355)	—	—
Share-based payments	—	2,475	—	—	—	—
Transfers	—	—	—	7,587	—	—
Total transactions with owners	—	1,123	(9,087)	(92,854)	(29)	—
As of 31 December 2022	103,001	180,591	(23,020)	996,246	601	302,005

(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	—	—	—	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
As of 1 April 2022	13,261	—	247,512	1,460,308	1,460,308
Comprehensive income					
Profit	—	—	—	144,839	144,839
Other comprehensive income	4,411	917	73,711	73,711	73,711
Total comprehensive income	4,411	917	73,711	218,550	218,550
Transactions with owners					
Acquisition of treasury shares	—	—	—	(10,555)	(10,555)
Disposals of treasury shares	—	—	(29)	2	2
Dividends	—	—	—	(100,355)	(100,355)
Share-based payments	—	—	—	2,475	2,475
Transfers	(6,670)	(917)	(7,587)	—	—
Total transactions with owners	(6,670)	(917)	(7,616)	(108,434)	(108,434)
As of 31 December 2022	11,002	—	313,607	1,570,424	1,570,424

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Nine months ended 31 December 2021	Nine months ended 31 December 2022
Cash flows from operating activities		
Profit before tax	167,402	180,238
Depreciation and amortisation	58,602	82,721
Impairment losses (reversal of impairment losses)	26,718	24,237
Finance income and expenses	1,968	1,040
(Increase) decrease in inventories	17,262	2,648
(Increase) decrease in trade and other receivables	(17,707)	(38,716)
Increase (decrease) in trade and other payables	1,130	(15,565)
Other	(12,683)	33,731
Subtotal	242,693	270,335
Income tax paid	(33,834)	(58,160)
Net cash flows from operating activities	208,859	212,174
Cash flows from investing activities		
Purchases of property, plant and equipment	(20,239)	(25,193)
Purchase of intangible assets	(38,937)	(35,229)
Proceeds from sales of intangible assets	24,155	208
Proceeds from sales of equity instruments	687	12,168
Payments for acquisition of subsidiaries	(659)	—
Interest and dividends received	549	2,084
Other	(13,142)	(15,819)
Net cash flows provided by (used in) investing activities	(47,586)	(61,781)
Cash flows from financing activities		
Increase (decrease) in short-term borrowings and commercial papers	(40,000)	(15,000)
Proceeds from issuance of bonds and long-term borrowings	—	50,000
Acquisition of treasury shares	(716)	(10,555)
Dividends paid to owners of the parent	(85,236)	(100,355)
Repayments of lease liabilities	(13,472)	(12,933)
Other	(1,840)	(2,276)
Net cash flows provided by (used in) financing activities	(141,264)	(91,120)
Effect of exchange rate changes on cash and cash equivalents	4,076	6,557
Net increase (decrease) in cash and cash equivalents	24,085	65,830
Cash and cash equivalents at the beginning of the year	326,128	315,986
Cash and cash equivalents at the end of the period	350,213	381,816

(6) Notes to condensed interim consolidated financial statements

Notes on going concern assumption

Not applicable.