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Financial Results of Astellas for the First Three Months of FY2023

Japan, August 1, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, “the Company”) today announced the financial results for the first three months (April 1, 2023 – June 30, 2023) of the fiscal year 2023 ending March 31, 2024 (FY2023).

Consolidated financial results for the first three months of FY2023 (core basis)

(Millions of yen)

	First three months of FY2022	First three months of FY2023	Change (%)
Revenue	381,791	374,990	-6,800 (-1.8%)
Core operating profit	55,292	64,940	+9,648 (+17.4%)
Core profit	45,843	51,815	+5,972 (+13.0%)

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 FY2023

(1) Business performance

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

Consolidated financial results (core basis) in the first three months of FY2023 are shown in the table below.

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

Consolidated financial results (core basis)

(Millions of yen)

	First three months of FY2022	First three months of FY2023	Change (%)
Revenue	381,791	374,990	-6,800 (-1.8%)
Cost of sales	88,870	68,947	-19,923 (-22.4%)
Selling, general and administrative expenses	153,396	168,182	+14,787 (+9.6%)
R&D expenses	74,007	64,592	-9,415 (-12.7%)
Amortisation of intangible assets	10,745	9,068	-1,677 (-15.6%)
Share of profit (loss) of investments accounted for using equity method	350	686	+336 (+96.2%)
Core operating profit	55,292	64,940	+9,648 (+17.4%)
Core profit	45,843	51,815	+5,972 (+13.0%)
Basic core earnings per share (yen)	25.12	28.88	+3.76 (+15.0%)

(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/FY2023 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.
- On the other hand, the main factor of the decrease in revenue was the significant decrease in sales of pharmacologic stress agent Lexiscan sold in the United States affected by generic brands.

As a result of the above, revenue in the first three months of FY2023 decreased by 1.8% compared to that in the same period of the previous fiscal year (“year-on-year”) to ¥375.0 billion.

Core operating profit / Core profit

- Gross profit increased by 4.5% year-on-year to ¥306.0 billion. The cost-to-revenue ratio fell by 4.9 percentage points year-on-year to 18.4%, mainly owing to the foreign exchange rate impact from the elimination of unrealized gains (¥12.8 billion) included in the cost of sales in the same period of the previous fiscal year.
- Selling, general and administrative expenses increased by 9.6% year-on-year to ¥168.2 billion. Although expenses decreased as a result of the reduction of mature products-related costs (decrease of approximately ¥1.0 billion year-on-year), the total amount increased mainly due to an increase in investment for VEOZAH for the treatment of vasomotor symptoms due to menopause (increase of approximately ¥5.0 billion year-on-year) and foreign exchange rate impact (increase of ¥8.0 billion year-on-year). Selling, general and administrative expenses, excluding co-promotion fees of XTANDI in the United States, increased by 12.1% year-on-year to ¥123.6 billion.
- Research and development (R&D) expenses decreased by 12.7% year-on-year to ¥64.6 billion. The total amount decreased year on year due to the recording of expenses (¥13.1 billion) associated with the use of priority review voucher for VEOZAH in the same period of the previous fiscal year.
- Amortisation of intangible assets decreased by 15.6% year-on-year to ¥9.1 billion.

As a result of the above, core operating profit increased by 17.4% year-on-year to ¥64.9 billion, and core profit increased by 13.0% year-on-year to ¥51.8 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in the first three months of FY2023 are shown in the table below. The resulting impacts were a ¥17.5 billion increase in revenue and a ¥5.4 billion increase in core operating profit compared with if the exchange rates of the first three months of FY2022 were applied.

Average rate	First three months of FY2022	First three months of FY2023	Change
US\$/¥	130	137	¥8 (Weakening of yen)
€/¥	138	150	¥11 (Weakening of yen)

Change from beginning to end of period	As of June 30, 2022	As of June 30, 2023
US\$/¥	¥14 (Weakening of yen)	¥12 (Weakening of yen)
€/¥	¥8 (Weakening of yen)	¥14 (Weakening of yen)

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in the first three months of FY2023 are shown in the table below.

Operating profit and profit increased, while revenue 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 FY2023, “Other income” was ¥3.9 billion (¥16.3 billion in the same period of the previous fiscal year), and “Other expenses” was ¥23.1 billion (¥38.4 billion in the same period of the previous fiscal year).

As “Other expenses,” the Company booked an increase in fair value of contingent consideration for zolbetuximab, an anti-Claudin 18.2 monoclonal antibody (¥7.6 billion), mainly due to the fluctuations of the foreign exchange rate, and impairment loss (¥7.3 billion) based on the intended decision to sell and transfer the manufacturing plant and business based in Meppel, the Netherlands.

Consolidated financial results (full basis)

(Millions of yen)

	First three months of FY2022	First three months of FY2023	Change (%)
Revenue	381,791	374,990	-6,800 (-1.8%)
Operating profit	33,147	45,794	+12,647 (+38.2%)
Profit before tax	31,679	46,850	+15,171 (+47.9%)
Profit	24,812	33,129	+8,317 (+33.5%)
Basic earnings per share (yen)	13.59	18.46	+4.87 (+35.8%)
Comprehensive income	134,396	134,507	+111 (+0.1%)

<Sales of Main Products>

(Billions of yen)

	First three months of FY2022	First three months of FY2023	Change
XTANDI	162.4	174.1	+7.2%
PADCEV	10.6	15.2	+44.2%
XOSPATA	10.5	13.0	+24.2%
VEOZAH	-	0.6	-
Betanis / Myrbetriq / BETMIGA	47.9	49.2	+2.7%
Prograf*1	51.8	49.1	-5.3%

<XTANDI>

- Sales increased in all regions, except for in International Markets*2.
- In Europe, prescriptions continued to expand for M1 CSPC (metastatic castration-sensitive prostate cancer), contributing to sales growth.

<PADCEV>

- Sales increased in all regions.
- In the United States, "PADCEV combined with pembrolizumab as first-line therapy for locally advanced or metastatic urothelial cancer," which was approved in April 2023, has penetrated the market faster than expected, contributing to sales growth.

<XOSPATA>

- Sales increased in all regions.

<VEOZAH>

- VEOZAH was launched in the United States in May 2023 as treatment for moderate-to-severe vasomotor symptoms associated with menopause.

<Betanis / Myrbetriq / BETMIGA>

- Global sales increased, although there were regional differences.

<Prograf>

- Although global sales were in line with the full-year forecasts, sales decreased year on year.

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

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

<Revenue by region>

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

(Billions of yen)

	First three months of FY2022	First three months of FY2023	Change
Japan	66.8	68.3	+2.2%
United States	160.9	150.0	-6.8%
Established Markets* ¹	86.6	96.8	+11.8%
Greater China* ²	23.2	22.5	-2.7%
International Markets* ³	33.9	34.7	+2.4%

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

*1 Established Markets: Europe, Canada, etc.

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

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

(2) Financial position

1) Assets, equity and liabilities

An overview of the consolidated statement of financial position as of June 30, 2023 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets as of June 30, 2023 saw an increase of ¥341.4 billion compared to the end of the previous fiscal year to ¥2,798.0 billion.

<Non-current assets> As of June 30, 2023: ¥1,480.5 billion (an increase of ¥73.9 billion)

- Property, plant and equipment increased by ¥4.3 billion compared to the end of the previous fiscal year to ¥290.8 billion.
- Goodwill increased by ¥27.3 billion compared to the end of the previous fiscal year to ¥355.7 billion, and intangible assets increased by ¥27.9 billion compared to the end of the previous fiscal year to ¥590.4 billion.

<Current assets> As of June 30, 2023: ¥1,317.5 billion (an increase of ¥267.5 billion)

- Cash and cash equivalents increased by ¥184.6 billion compared to the end of the previous fiscal year to ¥561.5 billion.

Equity

Total equity as of June 30, 2023 saw an increase of ¥70.5 billion compared to the end of the previous fiscal year to ¥1,578.4 billion, making the ratio of equity attributable to owners of the parent to total assets 56.4%.

- While profit stood at ¥33.1 billion, the Company paid ¥53.9 billion of dividends of surplus.

Liabilities

Total liabilities increased by ¥271.0 billion compared to the end of the previous fiscal year to ¥1,219.5 billion.

<Non-current liabilities> As of June 30, 2023: ¥228.0 billion (an increase of ¥5.5 billion)

- Other financial liabilities increased by ¥2.9 billion compared to the end of the previous fiscal year to ¥92.9 billion.

<Current liabilities> As of June 30, 2023: ¥991.5 billion (an increase of ¥265.5 billion)

- The Company have procured requisite funds for the acquisition of IVERIC bio, Inc., resulting in the balance of commercial papers amounting to ¥309.0 billion (an increase of ¥234.0 billion)
- Other current liabilities increased by ¥27.5 billion compared to the end of the previous fiscal year to ¥410.2 billion.

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in the first three months of FY2023 decreased by ¥36.6 billion year-on-year to ¥12.2 billion.

- Income tax paid decreased by ¥25.9 billion year-on-year to ¥6.8 billion.

Cash flows from investing activities

Net cash flows used in investing activities in the first three months of FY2023 was ¥12.3 billion, a decrease in outflow of ¥6.8 billion year-on-year.

Cash flows from financing activities

Net cash flows from financing activities in the first three months of FY2023 was ¥165.0 billion (outflow of ¥46.6 billion in the same period of the previous fiscal year).

- The increase of ¥234.0 billion in commercial papers as a result of having procured requisite funds for the acquisition of IVERIC bio, Inc.
- Dividends paid increased by ¥8.2 billion year on year to ¥53.9 billion.

As a result, cash and cash equivalents totaled ¥561.5 billion as of June 30, 2023, an increase of ¥184.6 billion compared to the end of the previous fiscal year.

(3) Consolidated business forecasts for FY2023 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 FY2023 are shown below.

Regarding business forecasts on a core basis, the Company has left its business forecasts unchanged from the consolidated full-year business forecasts announced in April 2023 ("initial 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 booking of impairment losses associated with the intended decision to transfer its manufacturing plant and business based in Meppel, the Netherlands in the first three months of FY2023 (approximately ¥7.0 billion) and one-time expenses related to organizational restructuring on a global scale, including the review of Japan commercial structure which is to be booked in FY2023 (approximately ¥20.0 billion).

Consolidated full-year business forecasts (core basis)

(Millions of yen)

	FY2023 Initial forecasts	FY2023 Latest forecasts	Change	FY2022 Results
Revenue	1,520,000	1,520,000	–	1,518,619
Selling, general and administrative expenses	661,000	661,000	–	630,272
R&D expenses	251,000	251,000	–	276,128
Core operating profit	290,000	290,000	–	286,902
Core profit for the year	228,000	228,000	–	224,619
Basic core earnings per share (yen)	126.89	126.89	–	123.42

Consolidated full-year business forecasts (full basis)

(Millions of yen)

	FY2023 Initial forecasts	FY2023 Latest forecasts	Change	FY2022 Results
Revenue	1,520,000	1,520,000	–	1,518,619
Operating profit	288,000	259,000	-29,000	133,029
Profit before tax	289,000	260,000	-29,000	132,361
Profit for the year	227,000	204,000	-23,000	98,714
Basic earnings per share (yen)	126.34	113.54	-12.80	54.24

Expected exchange rate for

FY2023 (Forecast)	¥130/US\$	¥140/€
FY2022 (Result)	¥135/US\$	¥141/€

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

(Millions of yen)

	Three months ended 30 June 2022	Three months ended 30 June 2023
Revenue	381,791	374,990
Cost of sales	(88,870)	(68,947)
Gross profit	292,920	306,043
Selling, general and administrative expenses	(153,396)	(168,182)
Research and development expenses	(74,007)	(64,592)
Amortisation of intangible assets	(10,745)	(9,068)
Gain on divestiture of intangible assets	170	54
Share of profit (loss) of investments accounted for using equity method	350	686
Other income	16,291	3,915
Other expenses	(38,436)	(23,061)
Operating profit	33,147	45,794
Finance income	927	3,776
Finance expenses	(2,396)	(2,720)
Profit before tax	31,679	46,850
Income tax expense	(6,867)	(13,721)
Profit	24,812	33,129
Profit attributable to:		
Owners of the parent	24,812	33,129
Earnings per share:		
Basic (Yen)	13.59	18.46
Diluted (Yen)	13.59	18.42

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three months ended 30 June 2022	Three months ended 30 June 2023
Profit	24,812	33,129
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	981	(6,614)
Remeasurements of defined benefit plans	1,610	(161)
Subtotal	<u>2,591</u>	<u>(6,775)</u>
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	106,993	94,387
Cash flow hedges	—	10,848
Hedging cost	—	2,919
Subtotal	<u>106,993</u>	<u>108,153</u>
Other comprehensive income	<u>109,585</u>	<u>101,379</u>
Total comprehensive income	<u>134,396</u>	<u>134,507</u>
Total comprehensive income attributable to:		
Owners of the parent	134,396	134,507

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2023	As of 30 June 2023
Assets		
Non-current assets		
Property, plant and equipment	286,459	290,784
Goodwill	328,411	355,683
Intangible assets	562,496	590,424
Trade and other receivables	24,173	22,955
Investments accounted for using equity method	12,689	14,715
Deferred tax assets	84,169	100,640
Other financial assets	97,886	95,780
Other non-current assets	10,280	9,522
Total non-current assets	1,406,564	1,480,504
Current assets		
Inventories	174,386	200,224
Trade and other receivables	427,965	462,503
Income tax receivable	17,813	14,711
Other financial assets	19,784	41,326
Other current assets	32,428	36,003
Cash and cash equivalents	376,840	561,487
Subtotal	1,049,216	1,316,254
Assets held for sale	738	1,200
Total current assets	1,049,954	1,317,454
Total assets	2,456,518	2,797,958

(Millions of yen)

	As of 31 March 2023	As of 30 June 2023
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	181,280	180,640
Treasury shares	(25,123)	(34,476)
Retained earnings	908,158	884,534
Other components of equity	340,640	444,719
Total equity attributable to owners of the parent	1,507,954	1,578,417
Total equity	1,507,954	1,578,417
Liabilities		
Non-current liabilities		
Bonds and borrowings	50,000	50,000
Trade and other payables	4,217	2,368
Deferred tax liabilities	6,048	6,539
Retirement benefit liabilities	24,818	27,130
Provisions	6,537	9,594
Other financial liabilities	89,924	92,850
Other non-current liabilities	40,987	39,567
Total non-current liabilities	222,530	228,047
Current liabilities		
Bonds and borrowings	75,000	309,000
Trade and other payables	140,236	138,439
Income tax payable	5,137	16,271
Provisions	17,855	17,621
Other financial liabilities	105,131	99,972
Other current liabilities	382,675	410,190
Total current liabilities	726,034	991,494
Total liabilities	948,564	1,219,541
Total equity and liabilities	2,456,518	2,797,958

(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 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

As of 1 April 2023	103,001	181,280	(25,123)	908,158	536	324,276
Comprehensive income						
Profit	—	—	—	33,129	—	—
Other comprehensive income	—	—	—	—	—	94,387
Total comprehensive income	—	—	—	33,129	—	94,387
Transactions with owners						
Acquisition of treasury shares	—	—	(10,731)	—	—	—
Disposals of treasury shares	—	(1,217)	1,378	(106)	(44)	—
Dividends	—	—	—	(53,903)	—	—
Share-based payments	—	577	—	—	—	—
Transfers	—	—	—	(2,744)	—	—
Total transactions with owners	—	(640)	(9,353)	(56,753)	(44)	—
As of 30 June 2023	103,001	180,640	(34,476)	884,534	493	418,663

(Millions of yen)

	Equity attributable to owners of the parent						Total equity
	Other components of equity					Total	
	Cash flow hedges	Hedging cost	Financial assets measured at fair value through other comprehensive income	Remeasurements of defined benefit plans	Total		
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

As of 1 April 2023	—	—	15,827	—	340,640	1,507,954	1,507,954
Comprehensive income							
Profit	—	—	—	—	—	33,129	33,129
Other comprehensive income	10,848	2,919	(6,614)	(161)	101,379	101,379	101,379
Total comprehensive income	10,848	2,919	(6,614)	(161)	101,379	134,507	134,507
Transactions with owners							
Acquisition of treasury shares	—	—	—	—	—	(10,731)	(10,731)
Disposals of treasury shares	—	—	—	—	(44)	12	12
Dividends	—	—	—	—	—	(53,903)	(53,903)
Share-based payments	—	—	—	—	—	577	577
Transfers	—	—	2,584	161	2,744	—	—
Total transactions with owners	—	—	2,584	161	2,701	(64,045)	(64,045)
As of 30 June 2023	10,848	2,919	11,797	—	444,719	1,578,417	1,578,417

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Three months ended 30 June 2022	Three months ended 30 June 2023
Cash flows from operating activities		
Profit before tax	31,679	46,850
Depreciation and amortisation	36,872	23,244
Impairment losses (reversal of impairment losses)	22,035	10,535
Finance income and expenses	1,468	(1,056)
(Increase) decrease in inventories	4,113	(16,756)
(Increase) decrease in trade and other receivables	(16,747)	8,374
Increase (decrease) in trade and other payables	(17,568)	(33,167)
Other	19,667	(18,989)
Subtotal	81,519	19,036
Income tax paid	(32,688)	(6,838)
Net cash flows from operating activities	48,832	12,198
Cash flows from investing activities		
Purchases of property, plant and equipment	(8,235)	(10,062)
Purchases of intangible assets	(10,024)	(6,301)
Proceeds from sales of intangible assets	170	1,322
Interest and dividends received	287	1,416
Other	(1,341)	1,326
Net cash flows provided by (used in) investing activities	(19,144)	(12,300)
Cash flows from financing activities		
Increase (decrease) in short-term borrowings and commercial papers	15,000	234,000
Acquisition of treasury shares	(10,553)	(10,731)
Dividends paid to owners of the parent	(45,677)	(53,903)
Repayments of lease liabilities	(4,690)	(3,284)
Other	(682)	(1,041)
Net cash flows provided by (used in) financing activities	(46,602)	165,041
Effect of exchange rate changes on cash and cash equivalents	13,941	19,708
Net increase (decrease) in cash and cash equivalents	(2,973)	184,647
Cash and cash equivalents at the beginning of the year	315,986	376,840
Cash and cash equivalents at the end of the period	313,013	561,487

(6) Notes to condensed interim consolidated financial statements

Notes on going concern assumption

Not applicable.