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Financial Results of Astellas for the First Three Months of FY2024

Japan, August 1, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, “the Company”) today announced the financial results for the first three months (April 1, 2024 – June 30, 2024) of the fiscal year 2024 ending March 31, 2025 (FY2024).

Consolidated financial results for the first three months of FY2024 (core basis)

(Millions of yen)

	First three months of FY2023	First three months of FY2024	Change (%)
Revenue	374,990	473,124	+98,134 (+26.2%)
Core operating profit	73,268	88,290	+15,021 (+20.5%)
Core profit	57,914	67,150	+9,237 (+15.9%)

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. Overview of business performance and others

(1) Overview of business performance for the first three months of FY2024

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

Consolidated financial results (core basis) in the first three months of FY2024 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 three months of FY2023	First three months of FY2024	Change (%)
Revenue	374,990	473,124	+98,134 (+26.2%)
Cost of sales	68,947	91,136	+22,189 (+32.2%)
Selling, general and administrative expenses	168,182	206,877	+38,695 (+23.0%)
R&D expenses	64,592	86,821	+22,228 (+34.4%)
Core operating profit	73,268	88,290	+15,021 (+20.5%)
Core profit	57,914	67,150	+9,237 (+15.9%)
Basic core earnings per share (yen)	32.28	37.50	+5.22 (+16.2%)

(Note) The Company changes the definition of core basis from Q1/FY2024, and newly excludes amortisation of intangible assets, gain on divestiture of intangible assets, and share of profit (loss) of investments accounted for using the equity method from the financial results on a full basis as certain significant adjusted items defined by the company. Financial results on the new core basis, as an indicator of the Company's profitability, exclude certain significant adjusted items defined by the Company that are reported in financial results on a full basis. These adjusted items include amortisation of intangible assets, gain on divestiture of intangible assets, share of profit and loss of investments accounted for using equity method, 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 certain other items defined by the Company. Figures of the first three months of FY2023 reflect this change. A reconciliation table between results on a full basis and results on a core basis is provided in the "Supplementary Documents for Q1/FY2024 Financial Results."

Revenue

- Sales of 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. Furthermore, sales of VEOZAH for the treatment of vasomotor symptoms due to menopause and sales of IZERVAY for the treatment for geographic atrophy secondary to age-related macular degeneration, both of which were launched in the previous fiscal year, contributed to increased revenue.
- The sales growth of the above offset the sales decrease due to the generic entry of MYRBETRIQ for the treatment of overactive bladder, in the US.

As a result of the above, revenue in the first three months of FY2024 increased by 26.2% compared to that in the previous fiscal year (“year-on-year”) to ¥473.1 billion.

Core operating profit / Core profit

- Gross profit increased by 24.8% year-on-year to ¥382.0 billion. The cost-to-revenue ratio increased by 0.9 percentage points year-on-year to 19.3%, mainly due to one-off factors including provision for MYRBETRIQ inventory disposal and royalty payment adjustment.
- Selling, general and administrative expenses increased by 23.0% year-on-year to ¥206.9 billion. Although expenses decreased as a result of reduction of mature products-related costs (decrease of approximately ¥4.0 billion year-on-year) and global organizational restructuring in the previous fiscal year (decrease of approximately ¥2.0 billion year-on-year), the total amount increased due to foreign exchange rate impact (increase of ¥20.8 billion year-on-year) and increase in expenses for Strategic Brands (mainly VEOZAH and IZERVAY) (increase of approximately ¥12.0 billion year-on-year). Selling, general and administrative expenses, excluding co-promotion fees of XTANDI in the United States, increased by 17.5% year-on-year to ¥145.3 billion.
- Research and development (R&D) expenses increased by 34.4% year-on-year to ¥86.8 billion. The total amount increased mainly due to foreign exchange rate impact (increase of ¥6.9 billion year-on-year) and increase in R&D investment for Primary Focus, such as targeted protein degradation and immuno-oncology, and enhanced R&D functions (increase of approximately ¥7.0 billion year-on-year). Additionally, one-time co-development cost payments were also a factor in the increase.

As a result of the above, core operating profit increased by 20.5% year-on-year to ¥88.3 billion, and core profit increased by 15.9% year-on-year to ¥67.2 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in the first three months of FY2024 are shown in the table below. The resulting impacts were a ¥45.4 billion increase in revenue and a ¥11.6 billion increase in core operating profit compared with if the exchange rates of the first three months of FY2023 were applied.

Average rate	First three months of FY2023	First three months of FY2024	Change
US\$/¥	137	156	¥19 (Weakening of yen)
€/¥	150	168	¥18 (Weakening of yen)

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in the first three months of FY2024 are shown in the table below.

Operating profit and profit both increased.

The full basis financial results include “other income” and “other expenses,” which are excluded from the core basis financial results. In addition, the full basis financial results also include “amortisation of intangible assets”, “gain on divestiture of intangible assets”, and “share of profit (loss) of investments accounted for using the equity method,” which have been newly excluded from the core basis financial results starting from the first three months of FY2024.

In the first three months of FY2024, “amortisation of intangible assets” was ¥35.0 billion (¥9.1 billion in the same period of the previous fiscal year), “other income” was ¥4.9 billion (¥3.9 billion in the same period of the previous fiscal year), and “other expenses” was ¥10.4 billion (¥23.1 billion in the same period of the previous fiscal year).

The increase of “amortisation of intangible assets” was mainly due to the amortisation of intangible assets for IZERVAY, which was launched in the second quarter of the previous fiscal year.

As “other expenses,” the Company booked expenses related to the increase in fair value of contingent consideration for zolbetuximab, an anti-Claudin 18.2 monoclonal antibody (¥5.5 billion) mainly due to the fluctuations of the foreign exchange rate.

Consolidated financial results (full basis)

	First three months of FY2023	First three months of FY2024	(Millions of yen) Change (%)
Revenue	374,990	473,124	+98,134 (+26.2%)
Operating profit	45,794	50,657	+4,864 (+10.6%)
Profit before tax	46,850	50,495	+3,646 (+7.8%)
Profit	33,129	37,603	+4,474 (+13.5%)
Basic earnings per share (yen)	18.46	21.00	+2.54 (+13.7%)
Comprehensive income	134,507	149,456	+14,949 (+11.1%)

<Sales of Main Products>

(Billions of yen)

	First three months of FY2023	First three months of FY2024	Change
XTANDI	174.1	224.2	+28.8%
PADCEV	15.2	38.4	+152.3%
IZERVAY	-	12.7	-
VEOZAH*1	0.6	6.6	+972.0%
VYLOY	-	0.3	-
XOSPATA	13.0	17.3	+32.8%
BETANIS / MYRBETRIQ / BETMIGA	49.2	46.1	-6.4%
PROGRAF*2	49.1	53.9	+9.8%

<XTANDI>

- Global sales expanded significantly, driven especially by the United States.
- In the United States, sales growth was driven by the penetration of nonmetastatic castration-sensitive prostate cancer (M0 CSPC) with biochemical recurrence at high risk for metastasis (approved in Nov 2023) and the halo effect to other indications, as well as the overall market growth.

<PADCEV>

- Global sales expanded significantly, driven especially by the United States and Established Markets*3.
- The sales growth was driven by the penetration of combination therapy with pembrolizumab as first-line therapy for patients with locally advanced or metastatic urothelial cancer in the United States (approved in Dec 2023) and the demand growth for current indications in Established Markets.

<IZERVAY>

- In the United States, where the product has been launched, sales growth exceeded expectations.

<VEOZAH>

- Launched countries expanded to 14, with steady growth of global as expected, mainly in the United States.

<VYLOY>

- Launched in Japan in June 2024 for “CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer.”

<XOSPATA>

- Global sales expanded in all regions.

<BETANIS / MYRBETRIQ / BETMIGA>

- Global sales decreased mainly due to the generic entry in the United States.

<PROGRAF>

- Although there were regional differences, global sales increased, aided by the positive foreign exchange rate impact.

*1 VEOZAH: Approved as “VEOZA” in ex-US.

*2 PROGRAF: Includes ADVAGRAF, GRACEPTOR, and ASTAGRAF XL.

*3 Established Markets: Europe, Canada, etc.

<Revenue by region>

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

(Billions of yen)

	First three months of FY2023	First three months of FY2024	Change
Japan	68.3	66.7	-2.4%
United States	150.0	212.1	+41.4%
Established Markets ^{*1}	96.8	121.0	+25.0%
China ^{*2}	18.2	18.7	+2.4%
International Markets ^{*3}	39.1	52.0	+33.2%

(Note) Region title of Greater China changed China from the first three months of FY2024.

In addition, commercial segment of Taiwan is changed from China to International Markets.

Figures on the above table reflect this change.

*1 Established Markets: Europe, Canada, etc.

*2 China: China, Hong Kong

*3 International Markets: Latin America, Middle East, Africa, South East Asia, South Asia, Russia, Korea, Taiwan, 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, 2024 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets as of June 30, 2024 saw an increase of ¥165.9 billion compared to the end of the previous fiscal year to ¥3,735.5 billion.

<Non-current assets> As of June 30, 2024: ¥2,494.8 billion (an increase of ¥120.0 billion)

- Property, plant and equipment increased by ¥15.9 billion compared to the end of the previous fiscal year to ¥309.7 billion.
- Goodwill increased by ¥25.0 billion compared to the end of the previous fiscal year to ¥443.7 billion, and intangible assets increased by ¥49.3 billion compared to the end of the previous fiscal year to ¥1,503.2 billion.

<Current assets> As of June 30, 2024: ¥1,240.7 billion (an increase of ¥45.9 billion)

- Cash and cash equivalents decreased by ¥32.8 billion compared to the end of the previous fiscal year to ¥302.9 billion.

Equity

Total equity as of June 30, 2024 saw an increase of ¥80.5 billion compared to the end of the previous fiscal year to ¥1,676.4 billion, making the ratio of equity attributable to owners of the parent to total assets 44.9%.

- While profit stood at ¥37.6 billion, the Company paid ¥62.8 billion of dividends of surplus.

Liabilities

Total liabilities increased by ¥85.5 billion compared to the end of the previous fiscal year to ¥2,059.1 billion.

<Non-current liabilities> As of June 30, 2024: ¥685.3 billion (a decrease of ¥2.6 billion)

- Bonds and borrowings decreased by ¥4.7 billion compared to the end of the previous fiscal year to ¥443.1 billion, of which bonds remained unchanged from the end of the previous fiscal year at ¥250.0 billion and long-term borrowings decreased by ¥4.7 billion compared to the end of the previous fiscal year to ¥193.1 billion.

<Current liabilities> As of June 30, 2024: ¥1,373.8 billion (an increase of ¥88.1 billion)

- Bonds and borrowings increased by ¥77.3 billion compared to the end of the previous fiscal year to ¥549.6 billion, of which short-term borrowings increased by ¥35.0 billion compared to the end of the previous fiscal year to ¥170.4 billion, and commercial papers increased by ¥40.7 billion compared to the end of the previous fiscal year to ¥325.7 billion.

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in the first three months of FY2024 increased by ¥0.4 billion year-on-year to ¥12.6 billion.

- Income tax paid increased by ¥30.0 billion year-on-year to ¥36.8 billion.

Cash flows from investing activities

Net cash flows used in investing activities in the first three months of FY2024 was ¥39.3 billion, an increase in outflow of ¥27.0 billion year-on-year.

Cash flows from financing activities

Net cash flows used in financing activities in the first three months of FY2024 was ¥11.9 billion (inflow of ¥165.0 billion in the same period of the previous fiscal year).

- Dividends paid increased by ¥8.9 billion year-on-year to ¥62.8 billion.

As a result, cash and cash equivalents totaled ¥302.9 billion as of June 30, 2024, a decrease of ¥32.8 billion compared to the end of the previous fiscal year.

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

(Millions of yen)

	Three months ended 30 June 2023	Three months ended 30 June 2024
Revenue	374,990	473,124
Cost of sales	(68,947)	(91,136)
Gross profit	306,043	381,988
Selling, general and administrative expenses	(168,182)	(206,877)
Research and development expenses	(64,592)	(86,821)
Amortisation of intangible assets	(9,068)	(34,992)
Gain on divestiture of intangible assets	54	909
Share of profit (loss) of investments accounted for using equity method	686	1,929
Other income	3,915	4,900
Other expenses	(23,061)	(10,379)
Operating profit	45,794	50,657
Finance income	3,776	4,333
Finance expenses	(2,720)	(4,495)
Profit before tax	46,850	50,495
Income tax expense	(13,721)	(12,892)
Profit	33,129	37,603
Profit attributable to:		
Owners of the parent	33,129	37,603
Earnings per share:		
Basic (Yen)	18.46	21.00
Diluted (Yen)	18.42	20.94

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three months ended 30 June 2023	Three months ended 30 June 2024
Profit	33,129	37,603
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(6,614)	(779)
Remeasurements of defined benefit plans	(161)	1,821
Subtotal	(6,775)	1,042
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	94,387	110,811
Cash flow hedges	10,848	—
Hedging cost	2,919	—
Subtotal	108,153	110,811
Other comprehensive income	101,379	111,853
Total comprehensive income	134,507	149,456
Total comprehensive income attributable to:		
Owners of the parent	134,507	149,456

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2024	As of 30 June 2024
Assets		
Non-current assets		
Property, plant and equipment	293,742	309,686
Goodwill	418,694	443,674
Intangible assets	1,453,824	1,503,157
Trade and other receivables	20,043	22,041
Investments accounted for using equity method	15,684	19,476
Deferred tax assets	45,594	54,179
Other financial assets	108,694	113,422
Other non-current assets	18,597	29,214
Total non-current assets	2,374,873	2,494,850
Current assets		
Inventories	248,738	256,045
Trade and other receivables	534,985	587,667
Income tax receivable	13,051	12,336
Other financial assets	28,784	35,717
Other current assets	32,241	45,972
Cash and cash equivalents	335,687	302,928
Subtotal	1,193,485	1,240,664
Assets held for sale	1,245	—
Total current assets	1,194,730	1,240,664
Total assets	3,569,603	3,735,514

(Millions of yen)

	As of 31 March 2024	As of 30 June 2024
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	184,070	182,593
Treasury shares	(33,783)	(38,530)
Retained earnings	809,400	783,777
Other components of equity	533,300	645,601
Total equity attributable to owners of the parent	1,595,988	1,676,442
Total equity	1,595,988	1,676,442
Liabilities		
Non-current liabilities		
Bonds and borrowings	447,738	443,061
Trade and other payables	2,199	8,466
Income tax payable	—	222
Deferred tax liabilities	51,346	45,068
Retirement benefit liabilities	24,674	25,377
Provisions	7,369	9,986
Other financial liabilities	105,602	105,756
Other non-current liabilities	48,962	47,327
Total non-current liabilities	687,889	685,262
Current liabilities		
Bonds and borrowings	472,278	549,596
Trade and other payables	185,193	173,146
Income tax payable	38,515	29,687
Provisions	15,700	14,140
Other financial liabilities	97,565	104,239
Other current liabilities	476,474	503,002
Total current liabilities	1,285,725	1,373,811
Total liabilities	1,973,615	2,059,073
Total equity and liabilities	3,569,603	3,735,514

(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 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	—	—	—	—
Transfer to retained earnings	—	—	—	(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

As of 1 April 2024	103,001	184,070	(33,783)	809,400	376	518,302
Comprehensive income						
Profit	—	—	—	37,603	—	—
Other comprehensive income	—	—	—	—	—	110,811
Total comprehensive income	—	—	—	37,603	—	110,811
Transactions with owners						
Acquisition of treasury shares	—	—	(6,957)	—	—	—
Disposals of treasury shares	—	(2,184)	2,211	—	(21)	—
Dividends	—	—	—	(62,759)	—	—
Share-based payments	—	708	—	—	—	—
Transfer to retained earnings	—	—	—	(468)	—	—
Total transactions with owners	—	(1,477)	(4,747)	(63,226)	(21)	—
As of 30 June 2024	103,001	182,593	(38,530)	783,777	355	629,113

(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 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
Transfer to retained earnings	—	—	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

As of 1 April 2024	—	—	14,623	—	533,300	1,595,988	1,595,988
Comprehensive income							
Profit	—	—	—	—	—	37,603	37,603
Other comprehensive income	—	—	(779)	1,821	111,853	111,853	111,853
Total comprehensive income	—	—	(779)	1,821	111,853	149,456	149,456
Transactions with owners							
Acquisition of treasury shares	—	—	—	—	—	(6,957)	(6,957)
Disposals of treasury shares	—	—	—	—	(21)	6	6
Dividends	—	—	—	—	—	(62,759)	(62,759)
Share-based payments	—	—	—	—	—	708	708
Transfer to retained earnings	—	—	2,289	(1,821)	468	—	—
Total transactions with owners	—	—	2,289	(1,821)	447	(69,002)	(69,002)
As of 30 June 2024	—	—	16,133	—	645,601	1,676,442	1,676,442

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Three months ended 30 June 2023	Three months ended 30 June 2024
Cash flows from operating activities		
Profit before tax	46,850	50,495
Depreciation and amortisation	23,244	50,268
Impairment losses (reversal of impairment losses)	10,535	520
Finance income and expenses	(1,056)	162
(Increase) decrease in inventories	(16,756)	790
(Increase) decrease in trade and other receivables	8,374	(26,786)
Increase (decrease) in trade and other payables	(33,167)	(23,076)
Other	(18,989)	(2,957)
Subtotal	19,036	49,416
Income tax paid	(6,838)	(36,816)
Net cash flows from operating activities	12,198	12,600
Cash flows from investing activities		
Purchases of property, plant and equipment	(10,062)	(13,997)
Purchases of intangible assets	(6,301)	(10,541)
Proceeds from sales of intangible assets	1,322	909
Interest and dividends received	1,416	1,638
Other	1,326	(17,357)
Net cash flows provided by (used in) investing activities	(12,300)	(39,349)
Cash flows from financing activities		
Increase (decrease) in short-term borrowings and commercial papers	234,000	71,804
Redemption of bonds and repayments of long-term borrowings	—	(6,667)
Acquisition of treasury shares	(10,731)	(6,957)
Dividends paid to owners of the parent	(53,903)	(62,759)
Repayments of lease liabilities	(3,284)	(2,880)
Other	(1,041)	(4,461)
Net cash flows provided by (used in) financing activities	165,041	(11,919)
Effect of exchange rate changes on cash and cash equivalents	19,708	5,908
Net increase (decrease) in cash and cash equivalents	184,647	(32,759)
Cash and cash equivalents at the beginning of the year	376,840	335,687
Cash and cash equivalents at the end of the period	561,487	302,928

(6) Notes to condensed interim consolidated financial statements

Notes on segment information

Segment information is omitted because the Group has a single reporting segment, "Pharmaceutical."

Notes on going concern assumption

Not applicable.