

July 30, 2021

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Financial Results of Astellas for the First Three Months of FY2021

Japan, July 30, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, “the Company”) today announced the financial results for the first three months (April 1, 2021 – June 30, 2021) of the fiscal year 2021 (FY2021) ending March 31, 2022.

Consolidated financial results for the first three months of FY2021 (core basis)

(Millions of yen)

	First three months of FY2020	First three months of FY2021	Change (%)
Revenue	306,969	326,143	+19,175 (+6.2%)
Core operating profit	63,370	62,820	-551 (-0.9%)
Core profit	51,990	49,241	-2,749 (-5.3%)

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 three months of FY2021

(1) Business performance

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

Consolidated financial results (core basis) in the first three months of FY2021 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 FY2020	First three months of FY2021	Change (%)
Revenue	306,969	326,143	+19,175 (+6.2%)
Cost of sales	59,654	62,231	+2,578 (+4.3%)
Selling, general and administrative expenses	120,776	137,109	+16,333 (+13.5%)
R&D expenses	57,288	58,313	+1,025 (+1.8%)
Amortisation of intangible assets	5,855	5,963	+107 (+1.8%)
Share of profit (loss) of investments accounted for using equity method	-26	292	+318 (-)
Core operating profit	63,370	62,820	-551 (-0.9%)
Core profit	51,990	49,241	-2,749 (-5.3%)
Basic core earnings per share (yen)	27.99	26.58	-1.41 (-5.0%)

(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/FY2021 Financial Results."

Revenue

- Sales of XTANDI for the treatment of prostate cancer and Strategic products XOSPATA for the treatment of acute myeloid leukemia, PADCEV for the treatment of urothelial cancer and Evrenzo for the treatment of renal anemia increased as expected.
- Moreover, factors for the increase in sales in the first three months of FY2021 included the growth of sales of Betanis / Myrbetriq / BETMIGA for the treatment of overactive bladder (“OAB”), and the sales of pharmacologic stress agent Lexiscan returning to pre-pandemic level which decreased mainly in the corresponding period of the previous fiscal year because of the impact of the spread of COVID-19.
- The sales growth of the products above offset the sales decrease mainly due to the termination of sales promotion activities for Celecox for the treatment of inflammation and pain, the transfer of manufacturing rights of Lipitor for the treatment of hypercholesterolemia, and the divestiture of Eligard for the treatment of prostate cancer.

As a result of the above, revenue in the first three months of FY2021 increased by 6.2% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥326.1 billion.

Core operating profit/ Core profit

- Gross profit increased by 6.7% year-on-year to ¥263.9 billion. The cost-to-revenue ratio fell by 0.4 percentage points year-on-year to 19.1%, mainly due to changes in product mix.
- Selling, general and administrative expenses increased by 13.5% year-on-year to ¥137.1 billion. The total amount increased due to the up-front investment to support CSP2021 initiatives (increase of Approx. ¥3.0 billion year-on-year), the increase of co-promotion fees associated with the growth of sales of XTANDI in the United States (increase of ¥3.0 billion year-on-year), the impact of the exchange rate (increase of ¥4.4 billion year-on-year), and moreover there was a one-off increase factor from the decrease of expenses for sales promotion activities and travel expenses due to the impact of the spread of COVID-19 in the corresponding period of the previous fiscal year (increase of Approx. ¥6.0 billion year-on-year). Excluding co-promotion fees associated with the growth of sales of XTANDI in the United States, selling, general and administrative expenses increased by 15.0% year-on-year to ¥102.6 billion.
- Research and development (R&D) expenses increased by 1.8% year-on-year to ¥58.3 billion. While there was a decrease in development expenses for fezolinetant, a selective neurokinin-3 receptor antagonist, for which patient enrollment in Phase III trials in the United States and Europe has been completed, the total amount increased mainly due to increases in development expenses for zolbetuximab, an anti-Claudin 18.2 monoclonal antibody and R&D investment for

Primary Focus, such as genetic regulation, cell therapy and immuno-oncology.

- Amortisation of intangible assets increased by 1.8% year-on-year to ¥6.0 billion.

As a result of the above, core operating profit decreased by 0.9% year-on-year to ¥62.8 billion, and core profit decreased by 5.3% year-on-year to ¥49.2 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in the first three months of FY2021 are shown in the table below. The resulting impacts were a ¥13.6 billion increase in revenue and a ¥6.1 billion increase in core operating profit compared with if the exchange rates of the first three months of FY2020 were applied.

Average rate	First three months of FY2020	First three months of FY2021	Change
US\$/¥	108	109	¥2 (Weakening of yen)
€/¥	118	132	¥13 (Weakening of yen)

Change from beginning to end of period	As of June 30, 2020	As of June 30, 2021
US\$/¥	¥1 (Strengthening of yen)	¥0 (Strengthening of yen)
€/¥	¥2 (Weakening of yen)	¥2 (Weakening of yen)

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in the first three months of FY2021 are shown in the table below. While revenue increased, operating profit and profit decreased.

The full basis financial results include “Other income,” “Other expenses,” which are excluded from the core basis financial results. In the first three months of FY2021, “Other income” was ¥0.4 billion (¥2.2 billion in the corresponding period of the previous fiscal year) and “Other expenses” was ¥27.1 billion (¥4.8 billion in the corresponding period of the previous fiscal year).

As “Other expenses,” the Company recorded impairment losses in relation to the termination of development projects (DNA vaccine ASP0892: ¥21.5 billion, anti-CD40 monoclonal antibody bleselumab: ¥4.1 billion), and as a result, in the financial results on a full basis, the decrease in profit was larger compared to the financial results on a core basis.

Consolidated financial results (full basis)

(Millions of yen)

	First three months of FY2020	First three months of FY2021	Change (%)
Revenue	306,969	326,143	+19,175 (+6.2%)
Operating profit	60,815	36,090	-24,724 (-40.7%)
Profit before tax	60,238	35,830	-24,408 (-40.5%)
Profit	50,413	30,687	-19,726 (-39.1%)
Basic earnings per share (yen)	27.14	16.56	-10.58 (-39.0%)
Comprehensive income	55,426	36,206	-19,219 (-34.7%)

<Sales of Main Products>

(Billions of yen)

	First three months of FY2020	First three months of FY2021	Change
XTANDI	112.0	132.9	+18.7%
XOSPATA	5.6	8.3	+47.7%
PADCEV	3.0	4.2	+41.9%
Evrenzo	0.2	0.6	+282.9%
Betanis / Myrbetriq / BETMIGA	40.4	44.0	+8.8%
Prograf*	45.3	45.2	-0.3%

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

- Sales of XTANDI grew in all regions. In Europe, additional indication was approved for metastatic castration-sensitive prostate cancer (M1 CSPC) in April 2021, and it was recommended by the National Institute for Health and Care Excellence (NICE) in the U.K. for use as a treatment for M1 CSPC in June 2021. In addition, in China, where reimbursement started in March 2021, the adoption of the product by hospitals has been accelerated, and the demand grew higher than expected.
- Sales of XOSPATA expanded globally, especially in the United States and Europe, where sales grew significantly compared to the corresponding period of the previous fiscal year. In China, where the product was launched in April 2021, sales have been higher than expected. In Europe, in addition to the U.K., Germany and Italy, reimbursement has also started in Nordics the Netherlands, and Belgium.
- Co-promotion revenue of PADCEV grew steadily in the United States. In July 2021, an additional indication was approved in the United States, for locally advanced or metastatic urothelial cancer who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.
- Sales of Evrenzo expanded in Japan due to increased adoption in major institutions.
- Global sales of Betanis / Myrbetriq / BETMIGA increased due to factors such as an increase in demand in China, where reimbursement started in March 2021.
- For Prograf, global sales were in line with the full-year forecasts, although there were differences in increases and decreases by region, such as growth in Europe and China, while sales decreased in the United States and Japan.

<Revenue by region>

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

(Billions of yen)

	First three months of FY2020	First three months of FY2021	Change
Japan	77.8	67.5	-13.2%
United States	117.2	133.6	+14.1%
Established Markets	64.0	78.0	+21.8%
Greater China	14.2	16.4	+15.5%
International Markets	30.2	27.8	-8.1%

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, 2021 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets saw a decrease of ¥24.2 billion compared to the end of the previous fiscal year to ¥2,249.5 billion.

<Non-current assets> As of June 30, 2021: ¥1,380.7 billion (a decrease of ¥20.3 billion)

- Property, plant and equipment increased by ¥5.1 billion compared to the end of the previous fiscal year to ¥269.7 billion.
- Goodwill increased by ¥0.1 billion compared to the end of the previous fiscal year to ¥284.1 billion, and intangible assets decreased by ¥21.1 billion compared to the end of the previous fiscal year to ¥630.3 billion. Intangible assets decreased mainly due to the recognition of impairment losses in relation to the termination of the development of the DNA vaccine ASP0892 and the anti-CD40 monoclonal antibody bleselumab.

<Current assets> As of June 30, 2021: ¥868.7 billion (a decrease of ¥3.9 billion)

- Cash and cash equivalents decreased by ¥24.2 billion compared to the end of the previous fiscal year to ¥301.9 billion.

Equity

Total equity as of June 30, 2021 saw a decrease of ¥3.2 billion compared to the end of the previous fiscal year to ¥1,382.9 billion, making the ratio of equity attributable to owners of the parent to total assets 61.5%.

- While profit stood at ¥30.7 billion, the Company paid ¥38.9 billion of dividends of surplus.

Liabilities

Total liabilities decreased by ¥20.9 billion compared to the end of the previous fiscal year to ¥866.6 billion.

<Non-current liabilities> As of June 30, 2021: ¥285.0 billion (a decrease of ¥10.1 billion)

<Current liabilities> As of June 30, 2021: ¥581.6 billion (a decrease of ¥10.8 billion)

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in the first three months of FY2021 increased by ¥18.5 billion year-on-year to ¥40.1 billion.

- Income tax paid increased by ¥6.9 billion year-on-year to ¥10.3 billion.

Cash flows from investing activities

Net cash flows used in investing activities in the first three months of FY2021 was ¥21.1 billion, a decrease in outflow of ¥7.2 billion year-on-year.

Cash flows from financing activities

Net cash flows used in financing activities in the first three months of FY2021 was ¥44.7 billion, a decrease in outflow of ¥28.2 billion year-on-year.

- Dividends paid increased by ¥1.8 billion year-on-year to ¥38.9 billion.

As a result, cash and cash equivalents totaled ¥301.9 billion as of June 30, 2021, a decrease of ¥24.2 billion compared to the end of the previous fiscal year.

(3) Consolidated business forecasts for FY2021 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 FY2021 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 2021.

On the other hand, regarding business forecasts on a full basis, the Company has downwardly revised the operating profit, profit before tax and profit for the year, considering the impairment losses in relation to the termination of development projects (DNA vaccine ASP0892: ¥21.5 billion, anti-CD40 monoclonal antibody bleselumab: ¥4.1 billion) and severance expenses due to early retirement incentive program which is to be recorded in the third quarter of FY2021 (Approx. ¥10.0 billion).

Consolidated full-year business forecasts (core basis)

(Millions of yen)

	Initial forecasts (FY2021)	Latest forecasts (FY2021)	Change	Results (FY2020)
Revenue	1,323,000	1,323,000	–	1,249,528
Selling, general and administrative expenses	541,000	541,000	–	504,316
R&D expenses	242,000	242,000	–	224,489
Core operating profit	270,000	270,000	–	251,375
Core profit for the year	213,000	213,000	–	209,906
Basic core earnings per share (yen)	114.95	114.95	–	113.03

Consolidated full-year business forecasts (full basis)

(Millions of yen)

	Initial forecasts (FY2021)	Latest forecasts (FY2021)	Change	Results (FY2020)
Revenue	1,323,000	1,323,000	–	1,249,528
Operating profit	265,000	227,000	-38,000	136,051
Profit before tax	263,000	225,000	-38,000	145,324
Profit for the year	209,000	183,000	-26,000	120,589
Basic earnings per share (yen)	112.79	98.76	-14.03	64.93

Expected exchange rate for

FY2021 (Forecast)	¥110/US\$	¥130/€
FY2020 (Result)	¥106/US\$	¥124/€

2. Condensed Interim Consolidated Financial Statements and Notes

(1) Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Three months ended 30 June 2020	Three months ended 30 June 2021
Revenue	306,969	326,143
Cost of sales	(59,654)	(62,231)
Gross profit	247,315	263,912
Selling, general and administrative expenses	(120,776)	(137,109)
Research and development expenses	(57,288)	(58,313)
Amortisation of intangible assets	(5,855)	(5,963)
Share of profit (loss) of investments accounted for using equity method	(26)	292
Other income	2,245	403
Other expenses	(4,800)	(27,133)
Operating profit	60,815	36,090
Finance income	379	1,457
Finance expenses	(956)	(1,717)
Profit before tax	60,238	35,830
Income tax expense	(9,825)	(5,144)
Profit	50,413	30,687
Profit attributable to:		
Owners of the parent	50,413	30,687
Earnings per share:		
Basic (Yen)	27.14	16.56
Diluted (Yen)	27.12	16.55

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three months ended 30 June 2020	Three months ended 30 June 2021
Profit	50,413	30,687
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	4,572	(2,935)
Remeasurements of defined benefit plans	273	803
Subtotal	4,845	(2,132)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	168	7,652
Subtotal	168	7,652
Other comprehensive income	5,013	5,520
Total comprehensive income	<hr/> 55,426	<hr/> 36,206
Total comprehensive income attributable to:		
Owners of the parent	55,426	36,206

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2021	As of 30 June 2021
Assets		
Non-current assets		
Property, plant and equipment	264,623	269,698
Goodwill	284,011	284,114
Intangible assets	651,427	630,322
Trade and other receivables	33,924	32,829
Investments accounted for using equity method	7,117	8,046
Deferred tax assets	54,176	54,556
Other financial assets	95,850	91,524
Other non-current assets	9,913	9,652
Total non-current assets	<hr/> 1,401,040	<hr/> 1,380,741
Current assets		
Inventories	164,080	157,254
Trade and other receivables	343,178	364,233
Income tax receivable	13,984	17,295
Other financial assets	5,560	4,075
Other current assets	19,658	23,938
Cash and cash equivalents	326,128	301,920
Total current assets	<hr/> 872,588	<hr/> 868,715
Total assets	<hr/> <hr/> 2,273,628	<hr/> <hr/> 2,249,456

	(Millions of yen)	
	As of 31 March 2021	As of 30 June 2021
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	177,830	177,657
Treasury shares	(15,377)	(15,663)
Retained earnings	953,289	945,961
Other components of equity	167,373	171,914
Total equity attributable to owners of the parent	<u>1,386,115</u>	<u>1,382,869</u>
Total equity	1,386,115	1,382,869
Liabilities		
Non-current liabilities		
Trade and other payables	400	308
Deferred tax liabilities	18,161	8,175
Retirement benefit liabilities	38,982	38,435
Provisions	5,796	7,621
Other financial liabilities	199,021	201,362
Other non-current liabilities	32,782	29,106
Total non-current liabilities	<u>295,141</u>	<u>285,007</u>
Current liabilities		
Trade and other payables	124,777	108,453
Income tax payable	8,395	14,634
Provisions	22,187	19,704
Other financial liabilities	148,163	147,493
Other current liabilities	288,851	291,296
Total current liabilities	<u>592,372</u>	<u>581,580</u>
Total liabilities	<u>887,513</u>	<u>866,587</u>
Total equity and liabilities	<u>2,273,628</u>	<u>2,249,456</u>

(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 2020	103,001	177,506	(7,178)	905,851	899	93,277
Comprehensive income						
Profit	—	—	—	50,413	—	—
Other comprehensive income	—	—	—	—	—	168
Total comprehensive income	—	—	—	50,413	—	168
Transactions with owners						
Acquisition of treasury shares	—	—	(880)	—	—	—
Disposals of treasury shares	—	(444)	635	(168)	(23)	—
Dividends	—	—	—	(37,150)	—	—
Share-based payments	—	121	—	—	—	—
Transfers	—	—	—	(55)	—	—
Total transactions with owners	—	(322)	(245)	(37,374)	(23)	—
As of 30 June 2020	103,001	177,183	(7,423)	918,890	876	93,445

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

(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			
As of 1 April 2020	15,813	—	109,989	1,289,168	
Comprehensive income					
Profit	—	—	—	50,413	
Other comprehensive income	4,572	273	5,013	5,013	
Total comprehensive income	4,572	273	5,013	55,426	
Transactions with owners					
Acquisition of treasury shares	—	—	—	(880)	
Disposals of treasury shares	—	—	(23)	0	
Dividends	—	—	—	(37,150)	
Share-based payments	—	—	—	121	
Transfers	328	(273)	55	—	
Total transactions with owners	328	(273)	32	(37,909)	
As of 30 June 2020	20,713	—	115,034	1,306,684	

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

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Three months ended 30 June 2020	Three months ended 30 June 2021
Cash flows from operating activities		
Profit before tax	60,238	35,830
Depreciation and amortisation	17,999	18,144
Impairment losses (reversal of impairment losses)	3,295	26,052
Finance income and expenses	577	260
(Increase) decrease in inventories	(3,197)	8,256
(Increase) decrease in trade and other receivables	(13,226)	(19,991)
Increase (decrease) in trade and other payables	(30,222)	(13,163)
Other	(10,558)	(5,055)
Subtotal	24,906	50,333
Income tax paid	(3,306)	(10,251)
Net cash flows from operating activities	21,600	40,083
Cash flows from investing activities		
Purchases of property, plant and equipment	(7,586)	(9,352)
Proceeds from sales of property, plant and equipment	8	186
Purchase of intangible assets	(25,676)	(10,560)
Payments for acquisition of subsidiaries	(1,667)	(648)
Interest and dividends received	347	135
Other	6,244	(846)
Net cash flows provided by (used in) investing activities	(28,330)	(21,085)
Cash flows from financing activities		
Increase (decrease) in bonds and short-term borrowings	(110,000)	—
Proceeds from long-term borrowings	80,000	—
Acquisition of treasury shares	(880)	(713)
Dividends paid to owners of the parent	(37,150)	(38,914)
Repayments of lease liabilities	(4,302)	(4,469)
Other	(644)	(634)
Net cash flows provided by (used in) financing activities	(72,977)	(44,730)
Effect of exchange rate changes on cash and cash equivalents	1,250	1,524
Net increase (decrease) in cash and cash equivalents	(78,457)	(24,208)
Cash and cash equivalents at the beginning of the year	318,391	326,128
Cash and cash equivalents at the end of the period	239,934	301,920

(6) Notes to condensed interim consolidated financial statements

Notes on going concern assumption

Not applicable.