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Contact:
Corporate Communications,
Astellas Pharma Inc.
TEL +81-3-3244-3201

Financial Results of Astellas for the First Quarter of FY2009

Japan, August 3, 2009 – Astellas Pharma Inc. (hereinafter referred to as “the Company”) today announced the financial results for the first quarter of the fiscal year 2009 (FY2009) ending March 31, 2010.

Consolidated financial results for the first quarter of FY2009 (April 1, 2009 – June 30, 2009)

(all amounts are in millions of yen – fractions dropped)

	1Q/FY2008	1Q/FY2009	Changes (%)
Net sales	254,550	252,136	-0.9%
Operating income	68,297	69,166	+1.3%
Ordinary income	73,168	69,633	-4.8%
Net income	45,181	44,010	-2.6%

Cautionary statement regarding forward-looking information

This press release includes forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors, including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launches, the pricing and product initiatives of competitors, the inability of the company to market existing and new product effectively, interruptions in production, infringement of the company's intellectual property rights and the adverse outcome of material litigation.

[Qualitative information and financial statements]

1. Qualitative information on consolidated business performance

In the first quarter of the fiscal year ending March 31, 2010 (April 1 to June 30, 2009), net sales decreased, operating income increased, and ordinary and net income decreased compared to the same period of the previous fiscal year as shown in the table below.

Exchange rate fluctuations had negative impacts of ¥16.8 billion on net sales and ¥3.0 billion on operating income due to the appreciation of the yen against the US dollar and euro, up ¥7 per dollar and up ¥31 per euro, compared to the corresponding period of the previous fiscal year.

Consolidated financial results

(Millions of yen – fractions dropped)

	1Q/FY2008	1Q/ FY2009	Changes (%)
Net sales	254,550	252,136	-2,413 (-0.9%)
Operating income	68,297	69,166	+869 (+1.3%)
Ordinary income	73,168	69,633	-3,535 (-4.8%)
Net income	45,181	44,010	-1,171 (-2.6%)

Exchange rate for 1Q/FY2009: ¥97/US\$, ¥133/€

Exchange rate for 1Q/FY2008: ¥105/US\$, ¥163/€

Net sales

Consolidated net sales decreased by 0.9% to ¥252.1 billion.

- Among global products, **Vesicare**, a treatment for overactive bladder, showed continuous strong growth in sales. Sales of the immunosuppressant **Prograf** decreased due to the strong yen, but local currency-based sales increased. Its substance patent expired in the US in April 2008 and in major European countries in June 2009, but no generics have been launched in any of these countries. Sales decreased for **Harnal**, a treatment for functional symptoms of benign prostatic hyperplasia (BPH), due to the strong yen. However, bulk sales and royalty income increased due to good sales in the US market by the US licensee.
- Sales in the Japanese market increased steadily to ¥128.3 billion, up 2.8%. In addition to global products, the long-acting angiotensin II receptor blocker **Micardis**, as well as its combination drug with a diuretic, **Micombi**, launched in June 2009, expanded sales.

Sales of the treatment for hypercholesterolemia **Lipitor** also increased. New products launched in and after 2007, such as the selective COX-2 inhibitor **Celecox** and the oral quinolone antibacterial agent **Geninax**, contributed to increases in sales.

- Overseas, in addition to global products, **Lexiscan**, a pharmacologic stress agent launched in the US in June 2008, performed well. In Europe, **Eligard** for the treatment of advanced prostate cancer contributed to increases in sales.
- Overseas sales totaled ¥122.8 billion, down 4.3% compared to the corresponding period of the previous fiscal year, accounting for 48.7% of consolidated net sales, down 1.7 points.
- In June 2009, a transport trailer loading our products was stolen in the US. The Company decided to voluntarily withdraw all quantities of specific product lots stolen in transit from the market and to discard together with those held in stock to ensure patient safety. This resulted in lost sales of ¥4.5 billion.

Operating income

Consolidated operating income increased by 1.3% to ¥69.1 billion.

- Gross profit decreased by 2.0% to ¥176.5 billion due to decreases in sales and a 0.8-point increase in the cost-to-sales ratio to 30.0% in this quarter as a result of changes in the product mix and the above-mentioned loss from the theft of the transport trailer in the US.
- Selling, general and administrative expenses, including research and development (R&D) expenses, decreased by 4.0% to ¥107.3 billion, resulting in increases in operating income. R&D expenses decreased by 4.7% to ¥38.4 billion, or 15.3% of consolidated sales, down 0.6 points compared to the corresponding period of the previous fiscal year. R&D expenses other than in-licensing fees increased due to the advancement of development projects and the depreciation of the new research facilities constructed last year at the Tsukuba Research Center. The upfront payment to the third party decreased to ¥1.6 billion in this quarter in comparison to the upfront payment at ¥8.0 billion in the corresponding period of the previous fiscal year. In April 2008, the Company paid ¥8.0 billion to CoMentis, Inc. for a licensed Alzheimer's disease treatment. Other selling and general administrative expenses decreased compared to the corresponding period of the previous fiscal year due to the impact of exchange rate.

Ordinary income

Consolidated ordinary income decreased by 4.8% to ¥69.6 billion.

- Non-operating income decreased by ¥3.2 billion, while non-operating expenses increased by ¥1.1 billion, resulting in a reduction of non-operating income/expenses (net), due to decreases in interest income received and a currency exchange loss in this quarter of the

current fiscal year, compared to a currency exchange gain in the corresponding period of the previous fiscal year.

Net income

Consolidated net income decreased by 2.6% to ¥44.0 billion.

- Extraordinary losses of ¥0.3 billion were posted in this quarter of the current fiscal year compared to extraordinary gains of ¥0.1 billion and extraordinary losses of ¥0.8 billion in the corresponding period of the previous fiscal year.

<Segment information>

Japan

Sales in Japan segment increased by 2.2% to ¥133.4 billion with a 3.5% increase in operating income to ¥51.0 billion.

- Sales in the Japanese market showed steady growth. **Micardis** (including **Micombi**), **Prograf**, **Lipitor**, **Vesicare**, the hypnotic **Myslee**, and the treatment for schizophrenia **Seroquel** posted growth in sales. **Celecox** and **Geninax**, launched in 2007, as well as a treatment for osteoporosis **Bonoteo** launched in April 2009, also contributed to increases in sales. However, sales of the peptic ulcers and gastritis treatment **Gaster** decreased.
- Operating income in Japan increased mainly due to increases in sales and decreases in R&D expenses.

Overseas

Sales in North America segment decreased by 2.4% to ¥47.3 billion with a 49.3% decrease in operating income to ¥5.9 billion.

- Sales decreased due to factors such as the strong yen, but local currency-based sales increased by 4.9% compared to the corresponding period of the previous fiscal year. Sales of **VESicare** continued to increase. Sales of **Lexiscan** also steadily increased. Sales of **Prograf** was decreased due to the impact of exchange rate, but its local currency-based sales showed steady growth. No generic has been launched yet despite the fact that its substance patent expired in the US in April 2008.
- Operating income in North America decreased due to decreases in net sales, as well as decreases in gross profits following a transfer pricing (intra-group transaction price) revision for **Prograf** and changes in the product mix.

Sales in Europe segment decreased by 7.6% to ¥63.2 billion, whereas operating income increased by 5.8% to ¥13.8 billion.

- Sales decreased due to the strong yen, but local currency-based sales increased by 13.9% compared to the corresponding period of the previous fiscal year. Bulk sales and royalty income for **Harnal** showed a large increase. Local currency-based sales of **Harnal** (brand name in Europe: **Omnice/Omnice OCAS**) increased although yen-based sales decreased due to the strong yen. **Prograf**, **Vesicare**, and **Eligard** also showed continuous growth in sales on a local currency basis. No generics of **Prograf** have been launched although its substance patent in major European countries expired in June 2009.
- While net sales decreased, operating income in Europe increased due to factors such as the revision of transfer pricing (intra-group transaction price) for **Prograf** and decreases in expenses booked by European segment partly because of increased refund of expenses for Harnal by licensees.

(note) Astellas has been promoting establishment of an optimal business structure with an effective use of the funds retained mainly in Europe in connection with inter-regional transactions between Europe and North America. As a result, gross profit and a portion of expenses for some businesses in North America are accounted for in the Europe segment in the geographical segment information.

Sales in Asia segment increased by 15.8% to ¥8.1 billion with a 34.5% increase in operating income to ¥1.4 billion.

- Sales increased despite the impact of the strong yen. **Prograf** showed a steady growth in sales. **Vesicare** also contributed to increases in sales. Sales of **Harnal** steadily increased.
- Operating income increased as sales increased.

2. Qualitative information on consolidated financial conditions

<Balance sheet>

Total assets as of June 30, 2009 increased by ¥4.2 billion compared to the end of the previous fiscal year, to ¥1,352.7 billion. While marketable securities decreased ¥18.3 billion, cash and cash equivalents increased by ¥15.6 billion. Trade notes and accounts receivable increased by ¥7.7 billion.

Liabilities decreased by ¥22.2 billion to ¥295.9 billion. Income tax payable decreased by ¥15.0 billion.

Total net assets increased by ¥26.5 billion to ¥1,056.7 billion, resulting in a shareholders' equity ratio of 78.0%. While net income of ¥44.0 billion was accounted, the Company paid ¥28.2 billion of dividend. On June 23, 2009, 28 million shares with the value of ¥128.0 billion were cancelled.

<Cash flow statement>

Cash inflows from operating activities increased by ¥3.5 billion compared to the corresponding period of the previous fiscal year to ¥39.3 billion. Income before income taxes decreased by ¥3.1 billion to ¥69.3 billion. Income taxes decreased by ¥3.2 billion to ¥36.7 billion.

Cash outflows from investing activities were ¥17.3 billion, an increase in cash outflow of ¥12.3 billion. Cash outflows increased following acquisition of marketable securities. Cash inflows from sale of marketable securities and investment securities increased.

Cash outflows from financing activities were ¥28.8 billion, a decrease in cash outflows of ¥41.7 billion. Cash dividends paid decreased by ¥1.6 billion to ¥28.2 billion. Outflows from the share buyback totaled ¥40.0 billion in the corresponding period of the previous fiscal year.

As a result, cash and cash equivalents as of June 30, 2009 totaled ¥409.3 billion, down ¥0.4 billion compared to the end of the previous fiscal year.

3. Qualitative information on consolidated business forecasts for FY2009

The six-month and full-year business forecasts for the fiscal year ending March 31, 2010 (FY2009) are as follows. There have been no changes from the initial forecasts announced in May 2009.

Consolidated six-month business forecasts

(Millions of yen – fractions dropped)

	Six-Month of FY2008	Six-Month of FY2009 forecasts	Changes (%)
Net sales	493,257	486,000	-7,257 (-1.5%)
Operating income	131,351	117,000	-14,351 (-10.9%)
Ordinary income	147,631	119,000	-28,631 (-19.4%)
Net income	90,937	73,000	-17,937 (-19.7%)

Consolidated full-year business forecasts

(Millions of yen – fractions dropped)

	FY2008 Full-year	FY2009 Full-year forecasts	Changes (%)
Net sales	965,698	968,000	+2,302 (+0.2%)
Operating income	250,394	215,000	-35,394 (-14.1%)
Ordinary income	271,451	219,000	-52,451 (-19.3%)
Net income	170,986	135,000	-35,986 (-21.0%)

(Notes) Expected exchange rate for FY2009: ¥100/US\$, ¥130/€

Exchange rate for FY2008: ¥101/US\$, ¥143/€

Exchange rate for the six-month of FY2008: ¥106/US\$, ¥163/€

Consolidated Financial Statements

(1) Consolidated Balance Sheets

(All amounts are in millions of yen and amounts less than one million have been omitted.)

Accounts	As of June 30, 2009	As of March 31, 2009
	Amounts	Amounts
Assets		
I. Current assets		
1. Cash on hand and in banks	¥283,136	¥267,460
2. Trade notes and accounts receivable	230,773	222,982
3. Marketable securities	228,102	246,463
4. Merchandise and finished goods	78,191	80,755
5. Work in process	12,621	12,505
6. Raw materials and supplies	15,090	12,169
7. Other	119,076	122,324
Allowance for doubtful receivables	(1,131)	(1,020)
Total current assets	965,861	963,640
II. Fixed assets		
1. Property, plant and equipment	183,336	181,447
2. Intangible fixed assets		
(1) Goodwill	24,062	26,377
(2) Other	37,646	31,984
Total intangible fixed assets	61,708	58,361
3. Investments and other assets		
(1) Investment securities	88,956	89,562
(2) Other	52,908	55,489
Allowance for doubtful receivables	(57)	(57)
Total investments and other assets	141,807	144,995
Total fixed assets	386,853	384,805
Total assets	¥1,352,714	¥1,348,446

(All amounts are in millions of yen and amounts less than one million have been omitted.)

Accounts	As of	As of
	June 30, 2009	March 31, 2009
	Amounts	Amounts
Liabilities		
I. Current liabilities		
1. Trade notes and accounts payable	¥91,061	¥89,769
2. Accrued income taxes	24,662	39,681
3. Provision	3,421	2,918
4. Other	146,503	151,183
Total current liabilities	265,649	283,553
II. Long-term liabilities		
1. Accrued retirement benefits for employees	14,474	15,029
2. Other provision	19	15
3. Other	15,821	19,626
Total long-term liabilities	30,315	34,671
Total liabilities	295,964	318,224
Net assets		
I. Shareholders' equity		
1. Common stock	103,000	103,000
2. Capital surplus	176,821	176,821
3. Retained earnings	845,059	957,346
4. Treasury stock	(27,205)	(155,295)
Total shareholders' equity	1,097,675	1,081,873
II. Valuation, translation adjustments and others		
1. Unrealized holding gains on securities	13,284	10,018
2. Translation adjustments	(55,527)	(62,904)
Total valuation, translation adjustments and others	(42,242)	(52,886)
III. Stock subscription rights	967	894
IV. Minority interests	349	338
Total net assets	1,056,750	1,030,221
Total liabilities and net assets	¥1,352,714	¥1,348,446

(2) Consolidated Statements of Income

(All amounts are in millions of yen and amounts less than one million have been omitted.)

Accounts	For the three months ended June 30, 2008	For the three months ended June 30, 2009
	Amounts	Amounts
I. Net sales	¥254,550	¥252,136
II. Cost of sales	74,369	75,599
Gross profit	180,180	176,537
III. Selling, general and administrative expenses (Note)	111,882	107,370
Operating income	68,297	69,166
IV. Non-operating income	<u>5,176</u>	<u>1,945</u>
Interest income	2,887	1,033
Dividend income	722	510
Exchange gain	1,319	—
Other	246	402
V. Non-operating expenses	<u>305</u>	<u>1,479</u>
Equity in losses of affiliates	65	122
Exchange loss	—	1,264
Other	239	92
Ordinary income	73,168	69,633
VI. Special gains	<u>140</u>	<u>43</u>
Gain on sales of fixed assets	91	17
Other	49	25
VII. Special losses	<u>855</u>	<u>369</u>
Loss on sales and disposal of fixed assets	835	348
Other	20	21
Income before income taxes and minority interests	72,453	69,308
Income taxes	26,704	24,785
Minority interests	567	512
Net income	¥45,181	¥44,010

Note;

Total amounts of research and development expenses

For the three months ended June 30, 2008	For the three months ended June 30, 2009
¥40,371 million	¥38,467 million

(3) Consolidated Statements of Cash Flows

(All amounts are in millions of yen and amounts less than one million have been omitted.)

Accounts	For the three months ended June 30, 2008	For the three months ended June 30, 2009
	Amounts	Amounts
I. Cash flows from operating activities		
Income before income taxes and minority interests	¥72,453	¥69,308
Depreciation and amortization	7,793	8,773
Amortization of goodwill	1,871	1,742
Interest and dividend income	(3,609)	(1,543)
Net loss on sales and disposal of fixed assets	744	330
Increase in trade notes and accounts receivables	(10,153)	(5,771)
Decrease in inventories	4,983	1,231
Increase in trade notes and accounts payables	6,857	344
Other	(9,169)	(9)
Subtotal	71,770	74,404
Interest and dividends received	3,964	1,719
Income taxes paid	(39,936)	(36,733)
Net cash provided by operating activities	35,799	39,389
II. Cash flows from investing activities		
Purchases of marketable securities	(11,616)	(50,477)
Proceeds from sales of marketable securities	30,515	44,562
Purchases of property, plant and equipment	(11,108)	(9,269)
Proceeds from sales of property, plant and equipment	1,844	810
Purchases of intangible fixed assets	(4,745)	(5,521)
Purchases of investment securities	(7,688)	(5,652)
Proceeds from sales of investment securities	46	5,274
Other	(2,249)	2,895
Net cash used in investing activities	(5,001)	(17,377)
III. Cash flows from financing activities		
Purchases of treasury stock	(40,018)	(9)
Cash dividends paid	(29,885)	(28,200)
Cash dividends paid to minority shareholders	(547)	(493)
Other	(131)	(149)
Net cash used in financing activities	(70,581)	(28,853)
IV. Effects of exchange rate changes on cash and cash equivalents	13,091	6,400
V. Decrease in cash and cash equivalents	(26,692)	(440)
VI. Cash and cash equivalents at beginning of period	460,485	409,826
VII. Cash and cash equivalents at end of period	¥433,792	¥409,386

(4) Segment Information

【Business segment information】

The Company's businesses are segmented into "Pharmaceutical and related products" and "Other" based on their proximity in terms of distribution methods, the nature and types of the products sold, and the manufacturing methods. As net sales and operating income of "Pharmaceutical and related products" segment constituted more than 90% of the consolidated totals, the disclosure of business segment information has been omitted.

【Geographical segment information】

For the three months ended June 30, 2008

(All amounts are in millions of yen and amounts less than one million have been omitted.)

	Japan	North America	Europe	Asia	Total	Eliminations	Consolidated
Sales							
(1) Sales to third parties	¥130,608	¥48,460	¥68,472	¥7,009	¥254,550	—	¥254,550
(2) Intergroup sales and transfers	33,213	17,293	16,573	2	67,083	¥(67,083)	—
Total	163,822	65,753	85,045	7,011	321,633	(67,083)	254,550
Operating income (loss)	¥49,295	¥11,685	¥13,061	¥1,086	¥75,129	¥(6,831)	¥68,297

For the three months ended June 30, 2009

(All amounts are in millions of yen and amounts less than one million have been omitted.)

	Japan	North America	Europe	Asia	Total	Eliminations	Consolidated
Sales							
(1) Sales to third parties	¥133,450	¥47,300	¥63,271	¥8,114	¥252,136	—	¥252,136
(2) Intergroup sales and transfers	34,161	18,169	18,587	10	70,928	¥(70,928)	—
Total	167,612	65,469	81,859	8,124	323,065	(70,928)	252,136
Operating income (loss)	¥51,034	¥5,919	¥13,816	¥1,461	¥72,231	¥(3,065)	¥69,166

【Overseas Sales】

For the three months ended June 30, 2008

(All amounts are in millions of yen and amounts less than one million have been omitted.)

	North America	Europe	Asia	Other	Total
1. Overseas sales	¥60,935	¥52,175	¥10,311	¥4,836	¥128,259
2. Consolidated net sales					¥254,550
3. Overseas sales as a percentage of consolidated net sales	23.9%	20.5%	4.1%	1.9%	50.4%

For the three months ended June 30, 2009

(All amounts are in millions of yen and amounts less than one million have been omitted.)

	North America	Europe	Asia	Other	Total
1. Overseas sales	¥62,549	¥45,489	¥11,198	¥3,562	¥122,800
2. Consolidated net sales					¥252,136
3. Overseas sales as a percentage of consolidated net sales	24.8%	18.0%	4.5%	1.4%	48.7%