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Financial Results of Astellas for the First Nine Months of FY2009

Japan, February 2, 2010 – Astellas Pharma Inc. (hereinafter referred to as “the Company”) today announced the financial results for the first nine months of the fiscal year 2009 (FY2009) ending March 31, 2010.

Consolidated financial results for the first nine months of FY2009 (April 1, 2009 – December 31, 2009)

(Millions of yen – fractions dropped)

	First nine months of FY2008	First nine months of FY2009	Changes (%)
Net sales	758,984	772,778	+13,794 (+1.8%)
Operating income	221,155	182,620	-38,534 (-17.4%)
Ordinary income	243,348	184,004	-59,343 (-24.4%)
Net income	152,389	116,061	-36,327 (-23.8%)

Exchange rate for the first nine months of FY2009: ¥94/US\$, ¥133/€

Exchange rate for the first nine months of FY2008: ¥103/US\$, ¥151/€

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

Consolidated business performance in the first nine months ended December 31, 2009 showed an increase in net sales while operating income, ordinary income and net income decreased, as follows. The exchange rate for the yen in the first nine months rose by ¥9 and ¥18 against the U.S. dollar and the euro, respectively, compared to the corresponding period of the previous fiscal year (“year-on-year”) bringing down net sales by ¥40.5 billion and operating income by ¥22.8 billion.

Consolidated financial results

(Millions of yen – fractions dropped)

	First nine months of FY2008	First nine months of FY2009	Changes (%)
Net sales	758,984	772,778	+13,794 (+1.8%)
Operating income	221,155	182,620	-38,534 (-17.4%)
Ordinary income	243,348	184,004	-59,343 (-24.4%)
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Net sales

Consolidated net sales increased by 1.8% year-on-year to ¥772.7 billion.

- In terms of global products, along with Vesicare, a treatment for overactive bladder, which showed steadily expanded sales, Mycamine, an injectable antifungal agent, had increased sales. The sales of the immunosuppressant Prograf declined due to the intensified competition following the launch of generic tacrolimus in August 2009 in the U.S. as well as the effect of the strong yen. Favorable sales of Harnal, a treatment for functional symptoms of benign prostatic hyperplasia, in the U.S. by our licensee, led to an increase in bulk sales and royalty income.
- Sales in the Japanese market expanded steadily by 4.3% year-on-year to ¥408.4 billion. In addition to Prograf and Vesicare, the long-acting angiotensin II receptor blocker Micardis, and its combination drug with a diuretic Micombi (launched in June 2009), had increased sales along with others including Lipitor, the treatment for hypercholesterolemia and selective COX-2 inhibitor Celecox. Also, vaccines including those for seasonal and Novel Influenza made a great contribution to the sales expansion.
- Additionally, Lexiscan, a pharmacologic stress agent showed strong growth in the U.S. and Eligard for the treatment of advanced prostate cancer contributed to sales expansion in Europe.

- Overseas sales fell 0.7% year-on-year to ¥360.5 billion due to the effect of the strong yen, accounting for 46.7% of net sales, down 1.2 points year-on-year.

Operating income

Consolidated operating income decreased by 17.4% year-on-year to ¥182.6 billion.

- Although net sales increased, the cost-to-sales ratio for the first nine months rose 2.9 points year-on-year to 30.3% following changes in product mix, resulting in a gross profit of ¥538.6 billion, down 2.3% year-on-year.
- Selling, general and administrative expenses increased by 7.9% year-on-year to ¥356.0 billion. Main factor for this increase was an increase in research and development (R&D) expenses.
- R&D expenses were up 21.1% year-on-year to ¥140.1 billion. The R&D cost-to-sales ratio was up 2.9 points year-on-year to 18.1%. In addition to increases in expenses incurred due to the advancement of development projects and the depreciation of the new research facilities at the Tsukuba Research Center, upfront payments related to in-licensing increased year-on-year. The Company concluded several in-licensing agreements during this nine months, including MDV3100 for the treatment of prostate cancer with Medivation Inc. (U.S.) in October, linaclotide for the treatment of irritable bowel syndrome with constipation with Ironwood Pharmaceuticals, Inc. (U.S.) in November and FLT3 kinase inhibitors with Ambit Biosciences Corporation (U.S.) in December.

Ordinary income

Consolidated ordinary income decreased by 24.4% year-on-year to ¥184.0 billion.

- In addition to a decline in interest income due to lower interest rates, an exchange loss of ¥2.1 billion was recorded for the first nine months, compared to ¥11.8 billion in exchange gain recorded for the corresponding period of the previous fiscal year, resulting in a ¥18.5 billion decrease in non-operating income and a ¥2.2 billion increase in non-operating expenses. As a result, non-operating income/expenses (net) worsened.

Net income

Consolidated net income decreased by 23.8% year-on-year to ¥116.0 billion.

- Special gains of ¥0.2 billion and special losses of ¥3.5 billion were posted in the first nine months compared to special gains of ¥0.7 billion and special losses of ¥6.9 billion in the corresponding period of the previous fiscal year resulting in an improvement in special gains/losses (net).

<Segment information>

Japan

Net sales in the Japan segment increased by 4.3% year-on-year to ¥424.1 billion, with a 22.0% year-on-year decrease in operating income to ¥117.5 billion.

- Sales in the Japanese market expanded steadily. Mainstay products such as Micardis (including Micombi), Prograf, Lipitor, Vesicare, an insomnia treatment Myslee and the treatment for schizophrenia Seroquel showed growth in sales. Vaccines as well as new products such as Celecox, an oral quinolone antibacterial agent Geninax and a treatment for osteoporosis Bonoteo, contributed to sales expansion. On the other hand, sales declined for the peptic ulcers and gastritis treatment Gaster.
- Although net sales increased, operating income declined due to factors including higher cost of sales and an increase in R&D expenses.

Overseas

Net sales in the North America segment decreased by 2.1% year-on-year to ¥141.6 billion, with a 39.0% year-on-year decrease in operating income to ¥17.6 billion.

- The sales on a local currency basis rose 7.6% year-on-year, although revenue went down due to factors such as the strong yen.
- VESicare, Lexiscan and Mycamine progressed favorably. On the contrary, revenue from Prograf fell due to the intensified competition following the launch of generic tacrolimus in August 2009 in the U.S.
- Gross profit dropped due to factors including a decrease in net sales, changes in product mix and an increase in transfer price for Prograf in intra-group transactions. Factors including an increase in R&D expenses led to lower operating income.

Net sales in the Europe segment decreased by 1.4% year-on-year to ¥183.9 billion, with a 5.2% year-on-year increase in operating income to ¥40.8 billion.

- The sales on a local currency basis rose 11.7% year-on-year, although revenue went down due to the effect of the strong yen,
- Bulk sales and royalty income of Harnal increased. Sales of Harnal (brand name in Europe: Omnic/Omnic OCAS) through our own distribution channel declined due to the effect of the strong yen, however, they leveled off on a local currency basis. Sales of Prograf also decreased as a result of the strong yen, however, sales continued to expand on a local currency basis. Regarding Prograf, no launches of generic have been confirmed during the first nine months even though the substance patent expired in June 2009 in major European countries. Furthermore, Vesicare and Eligard showed steadily expanded sales, along with contributions from Mycamine.
- Despite a decrease in net sales, operating income increased with the help of factors such as a decrease in transfer price for Prograf in intra-group transactions and an increase in refunds of marketing expenses by a licensee related to Harnal.

(Note) The Astellas Group promotes optimal business structure that effectively utilizes funds retained mainly in Europe. As a result, items such as gross profit and expenses relating to sales promotions for some of the businesses in North America are recorded in the Europe segment in “Geographical segment information.”

Net sales in the Asia segment increased by 10.2% year-on-year to ¥23.0 billion, with a year-on-year decrease of 6.3% in operating income to ¥2.8 billion.

- Net sales increased despite the effects of the strong yen. Prograf demonstrated steady growth along with contributions from Vesicare and Mycamine. Harnal also showed steady growth. Revenue increased but operating income decreased.

2. Qualitative information on consolidated financial conditions

<Balance sheets>

Total assets as of December 31, 2009 saw an increase of ¥14.4 billion compared to the end of the previous fiscal year to ¥1,362.9 billion, of which trade notes and accounts receivable increased by ¥39.7 billion and marketable securities decreased by ¥33.2 billion.

Liabilities decreased by ¥16.2 billion compared to the end of the previous fiscal year to ¥302.0 billion. Accrued income taxes fell by ¥19.1 billion.

Net assets increased by ¥30.6 billion compared to the end of the previous fiscal year to ¥1,060.8 billion making the equity ratio 77.7%. While net income stood at ¥116.0 billion, ¥56.4 billion in dividends of surplus were paid and ¥26.9 billion was spent for purchases of treasury stock. On June 23, 2009, 28 million shares of treasury stock valued at ¥128.0 billion were cancelled.

<Statements of cash flows>

Net cash provided by operating activities decreased year-on-year by ¥54.7 billion to ¥109.7 billion. Income before income taxes and minority interests was decreased by ¥56.5 billion.

Net cash used in investing activities was ¥38.3 billion, an increase in outflow of ¥8.0 billion year-on-year. While expenditures for purchases of marketable securities went up, proceeds from sales of marketable securities also increased. More cash was also used for purchases of intangible fixed assets.

Net cash used in financing activities was ¥85.2 billion, a decrease in outflow of ¥98.7 billion year-on-year. Purchases of treasury stock amounted to ¥26.9 billion, a year-on-year decrease of ¥96.5 billion, and cash dividends paid decreased by ¥2.2 billion year-on-year to ¥56.4 billion.

As a result of the above, cash and cash equivalents totaled ¥395.2 billion as of December 31, 2009, a decrease of ¥14.5 billion compared to the end of the previous fiscal year.

3. Qualitative information on consolidated business forecasts for FY2009

Consolidated full-year business forecasts for FY2009 are shown in the table below. No changes have been made to the forecasts announced in November 2009.

Consolidated full-year business forecasts

(Millions of yen – fractions dropped)

	FY2008 Full-year results	FY2009 Full-year forecasts	Changes (%)
Net sales	965,698	976,000	+10,301 (+1.1%)
Operating income	250,394	200,000	-50,394 (-20.1%)
Ordinary income	271,451	200,500	-70,951 (-26.1%)
Net income	170,986	125,000	-45,986 (-26.9%)

Expected exchange rate for FY2009: ¥93/US\$, ¥132/€

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

Taking into account the changing environment, such as internal factors including the revision of launch timing of new products and external factors including the progression of government policies to restrain medical expenditures, global recession and exchange rate fluctuation, the Company plans to formulate a new five-year mid-term management plan to begin in fiscal year 2010 ending March 31, 2011. The announcement for the plan is scheduled on May 25, 2010.

Consolidated Financial Statements

(1) Consolidated Balance Sheets

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

	As of December 31, 2009	As of March 31, 2009
Assets		
Current assets		
Cash on hand and in banks	¥279,168	¥267,460
Trade notes and accounts receivable	262,775	222,982
Marketable securities	213,176	246,463
Merchandise and finished goods	81,941	80,755
Work in process	13,996	12,505
Raw materials and supplies	15,878	12,169
Other	121,205	122,324
Allowance for doubtful receivables	(1,244)	(1,020)
Total current assets	986,898	963,640
Fixed assets		
Property, plant and equipment	184,020	181,447
Intangible fixed assets		
Goodwill	21,166	26,377
Other	41,808	31,984
Total intangible fixed assets	62,974	58,361
Investments and other assets		
Investment securities	76,750	89,562
Other	52,322	55,489
Allowance for doubtful receivables	(56)	(57)
Total investments and other assets	129,016	144,995
Total fixed assets	376,011	384,805
Total assets	¥1,362,910	¥1,348,446

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

	As of December 31, 2009	As of March 31, 2009
Liabilities		
Current liabilities		
Trade notes and accounts payable	¥100,400	¥89,769
Accrued income taxes	20,563	39,681
Provision	4,442	2,918
Other	146,068	151,183
Total current liabilities	<u>271,475</u>	<u>283,553</u>
Long-term liabilities		
Accrued retirement benefits for employees	15,039	15,029
Other provision	21	15
Other	15,481	19,626
Total long-term liabilities	<u>30,543</u>	<u>34,671</u>
Total liabilities	<u>302,018</u>	<u>318,224</u>
Net assets		
Shareholders' equity		
Common stock	103,000	103,000
Capital surplus	176,821	176,821
Retained earnings	888,906	957,346
Treasury stock	(54,165)	(155,295)
Total shareholders' equity	<u>1,114,563</u>	<u>1,081,873</u>
Valuation, translation adjustments and others		
Unrealized holding gains on securities	13,782	10,018
Translation adjustments	(68,911)	(62,904)
Total valuation, translation adjustments and others	<u>(55,129)</u>	<u>(52,886)</u>
Stock subscription rights	1,136	894
Minority interests	321	338
Total net assets	<u>1,060,891</u>	<u>1,030,221</u>
Total liabilities and net assets	<u>¥1,362,910</u>	<u>¥1,348,446</u>

(2) Consolidated Statements of Income

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

	For the nine months ended December 31, 2008	For the nine months ended December 31, 2009
Net sales	¥758,984	¥772,778
Cost of sales	207,708	234,093
Gross profit	551,275	538,685
Selling, general and administrative expenses (Note)	330,120	356,065
Operating income	221,155	182,620
Non-operating income		
Interest income	8,535	2,461
Dividend income	1,432	1,085
Equity in earnings of affiliates	—	166
Exchange gain	11,837	—
Other	1,062	638
Total non-operating income	22,867	4,351
Non-operating expenses		
Equity in losses of affiliates	77	—
Exchange loss	—	2,183
Other	596	783
Total non-operating expenses	674	2,967
Ordinary income	243,348	184,004
Special gains		
Gain on sales of fixed assets	321	45
Gain on sales of investment securities	413	—
Other	59	164
Total special gains	794	209
Special losses		
Loss on sales and disposal of fixed assets	1,636	1,755
Loss on impairment of fixed assets	—	1,056
Special retirement benefits	2,644	—
Loss on devaluation of investment securities	1,877	—
Other	755	732
Total special losses	6,913	3,544
Income before income taxes and minority interests	237,229	180,669
Income taxes	83,228	63,149
Minority interests	1,610	1,457
Net income	¥152,389	¥116,061

Note;

	For the nine months ended December 31, 2008	For the nine months ended December 31, 2009
Total amounts of research and development expenses	¥115,698 million	¥140,101 million

(3) Consolidated Statements of Cash Flows

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

	For the nine months ended December 31, 2008	For the nine months ended December 31, 2009
Cash flows from operating activities		
Income before income taxes and minority interests	¥237,229	¥180,669
Depreciation and amortization	26,020	28,307
Loss on impairment of fixed assets	—	1,056
Amortization of goodwill	5,780	5,960
Interest and dividend income	(9,968)	(3,546)
Net loss on sales and disposal of fixed assets	1,314	1,710
Increase in trade notes and accounts receivable	(38,669)	(40,397)
Increase in inventories	(14,551)	(7,188)
Increase in trade notes and accounts payable	30,952	11,206
Other	(5,073)	3,321
Subtotal	233,033	181,099
Interest and dividends received	10,173	3,718
Income taxes paid	(78,733)	(75,063)
Net cash provided by operating activities	164,472	109,754
Cash flows from investing activities		
Purchases of marketable securities	(46,408)	(137,324)
Proceeds from sales of marketable securities	62,091	143,508
Purchases of property, plant and equipment	(23,273)	(28,365)
Proceeds from sales of property, plant and equipment	3,786	936
Purchases of intangible fixed assets	(8,918)	(20,793)
Purchases of investment securities	(17,878)	(9,370)
Proceeds from sales of investment securities	786	6,694
Other	(396)	6,411
Net cash used in investing activities	(30,210)	(38,301)
Cash flows from financing activities		
Purchases of treasury stock	(123,586)	(26,986)
Cash dividends paid	(58,624)	(56,401)
Cash dividends paid to minority shareholders	(1,595)	(1,454)
Other	(283)	(451)
Net cash used in financing activities	(184,090)	(85,294)
Effects of exchange rate changes on cash and cash equivalents	(43,168)	(741)
Decrease in cash and cash equivalents	(92,997)	(14,582)
Cash and cash equivalents at beginning of period	460,485	409,826
Cash and cash equivalents at end of period	¥367,488	¥395,243

(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 nine months ended December 31, 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	¥406,825	¥144,654	¥186,630	¥20,874	¥758,984	—	¥758,984
(2) Intergroup sales and transfers	99,225	51,287	47,860	10	198,383	¥(198,383)	—
Total	506,050	195,942	234,490	20,884	957,367	(198,383)	758,984
Operating income (loss)	¥150,581	¥28,968	¥38,805	¥3,028	¥221,383	¥(228)	¥221,155

For the nine months ended December 31, 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	¥424,128	¥141,649	¥183,997	¥23,003	¥772,778	—	¥772,778
(2) Intergroup sales and transfers	89,742	49,755	51,210	22	190,732	¥(190,732)	—
Total	513,870	191,405	235,208	23,026	963,511	(190,732)	772,778
Operating income (loss)	¥117,505	¥17,669	¥40,807	¥2,836	¥178,819	¥3,800	¥182,620

【Overseas Sales】

For the nine months ended December 31, 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	¥176,261	¥143,689	¥28,516	¥14,763	¥363,232
2. Consolidated net sales					¥758,984
3. Overseas sales as a percentage of consolidated net sales	23.2%	18.9%	3.8%	2.0%	47.9%

For the nine months ended December 31, 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	¥178,614	¥139,653	¥31,138	¥11,125	¥360,532
2. Consolidated net sales					¥772,778
3. Overseas sales as a percentage of consolidated net sales	23.1%	18.1%	4.0%	1.5%	46.7%