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Financial Results of Astellas for Fiscal Year 2009

Japan, May 12, 2010 – Astellas Pharma Inc. (hereinafter referred to as “the Company”) today announced the financial results for the fiscal year 2009 (FY2009) ended March 31, 2010.

Consolidated financial results for FY2009 (April 1, 2009 – March 31, 2010)

(Millions of yen – fractions dropped)

	FY2008	FY2009	Changes (%)
Net sales	965,698	974,877	+9,179 (+1.0%)
Operating income	250,394	186,407	-63,987 (-25.6%)
Ordinary income	271,451	190,986	-80,464 (-29.6%)
Net income	170,986	122,257	-48,729 (-28.5%)

Exchange rate for FY2009: ¥93/US\$, ¥131/€

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

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. Business performance

(1) Analysis of business performance

Consolidated business performance for the fiscal year ended March 31, 2010 (FY2009) and consolidated business forecasts for the fiscal year ending March 31, 2011 (FY2010) of the Company are as follows.

Business performance of FY2009

1) Overview of FY2009

Consolidated business performance in FY2009 showed an increase in net sales while operating income, ordinary income and net income decreased, as shown in the table below.

The exchange rate for FY2009 rose by ¥8 and ¥12 against the U.S. dollar and the euro, respectively, compared to the previous fiscal year (“year-on-year”) bringing down net sales by ¥39.3 billion and operating income by ¥17.2 billion.

Consolidated financial results

(Millions of yen – fractions dropped)

	FY2008	FY2009	Changes (%)
Net sales	965,698	974,877	+9,179 (+1.0%)
Operating income	250,394	186,407	-63,987 (-25.6%)
Ordinary income	271,451	190,986	-80,464 (-29.6%)
Net income	170,986	122,257	-48,729 (-28.5%)

Exchange rate for FY2009: ¥93/US\$, ¥131/€

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

Net sales

Consolidated net sales increased by 1.0% year-on-year to ¥974.8 billion.

- In terms of global products Vesicare, a treatment for overactive bladder, which showed steadily expanded sales, Funguard/Mycamine, an injectable antifungal agent, had increased sales. The sales of the immunosuppressant Prograf declined due to the intensified competition following the launch of the generic in August 2009 in the U.S. as well as the effect of the strong yen. Sales of Harnal, a treatment for functional symptoms of benign prostatic hyperplasia, also declined mainly due to the effect of the strong yen. Regarding Harnal (brand name in the U.S.: Flomax), the generic was launched in the U.S. in March 2010.

- Sales in the Japanese market expanded steadily by 3.7% year-on-year to ¥509.8 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 1.8% year-on-year to ¥460.7 billion due to the effect of the strong yen, accounting for 47.3% of net sales, down 1.3 points year-on-year.

Operating income

Consolidated operating income decreased by 25.6% year-on-year to ¥186.4 billion.

- Although net sales increased, the cost-to-sales ratio for FY2009 rose 2.3 points year-on-year to 29.7% following changes in product mix, resulting in a gross profit of ¥685.6 billion, down 2.2% year-on-year.
- Selling, general and administrative expenses increased by 10.7% year-on-year to ¥499.2 billion. Of which, research and development (R&D) expenses were up 23.0% year-on-year to ¥195.5 billion and the R&D cost-to-sales ratio was up 3.6 points year-on-year to 20.1%. 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 including MDV3100 for the treatment of prostate cancer from Medivation Inc. (U.S.) increased year-on-year. Selling, general and administrative expenses excluding R&D expenses increased due to factors such as increase in expenses associated with launches of new products.

Ordinary income

Consolidated ordinary income decreased by 29.6% year-on-year to ¥190.9 billion.

- In addition to a decline in interest income due to lower interest rates, exchange gain recorded decreased year-on-year, resulting in a ¥17.0 billion decrease in non-operating income. Non-operating expenses decreased by ¥0.5 billion. As a result, non-operating income/expenses (net) worsened.

Net income

Consolidated net income decreased by 28.5% year-on-year to ¥122.2 billion.

- Special gains of ¥3.0 billion and special losses of ¥7.2 billion were posted in FY2009 compared to special gains of ¥1.9 billion and special losses of ¥10.6 billion in FY2008 resulting in an improvement in special gains/losses (net).

2) Segment information

Japan

Net sales in the Japan segment increased by 3.7% year-on-year to ¥529.2 billion, with a 34.8% year-on-year decrease in operating income to ¥114.5 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, a treatment for osteoporosis Bonoteo and Symbicort for the treatment of bronchial asthma, contributed to sales expansion. On the other hand, sales declined for the peptic ulcers and gastritis treatment Gaster and Harnal.
- Although net sales increased, operating income declined due to an increase in R&D expenses in addition to higher cost of sales mainly due to the revision of transfer price in intra-group transactions.

Overseas

Net sales in the North America segment decreased by 4.8% year-on-year to ¥179.8 billion, with a 54.9% year-on-year decrease in operating income to ¥14.8 billion.

- The sales on a local currency basis rose 3.1% 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 the generic 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 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 ¥235.8 billion, with a 10.3% year-on-year increase in operating income to ¥43.9 billion.

- The sales on a local currency basis rose 7.9% year-on-year, although revenue went down due to the effect of the strong yen.
- Sales of Harnal (brand name in Europe: Omnic/Omnicon OCAS) through our own distribution channel as well as its bulk sales and royalty income from a licensee declined due to the effect of the strong yen, however, they both increased on a local currency basis. Sales of Prograf decreased as a result of the strong yen, however, sales continued to expand on a local currency basis. The substance patent for Prograf expired in June 2009 in major European countries and marketing approval of generics in several countries has been confirmed during the fiscal year under review. Furthermore, Vesicare and Eligard showed steadily expanded sales, along with contributions from Mycamine.
- Despite a decrease in net sales, operating income increased due to a decrease in price for Harnal and Prograf in intra-group transactions.

(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 10.0% year-on-year to ¥29.9 billion, with a year-on-year decrease of 31.7% in operating income to ¥2.3 billion.

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

3) Other

R&D

The Company is aiming for mid- to long-term sustainable growth through the continuous and early creation of new pharmaceuticals that are innovative and reliable in therapeutic areas where no effective drugs exist and the unmet medical needs exist. To achieve this, R&D activities are being rigorously advanced as top priority.

Drug discovery research, to which we target management resources, focuses on the prioritized therapeutic areas of urology, immunology & infectious diseases, oncology, neuroscience as well as DM (Diabetes Mellitus) complications & metabolic diseases. Among efforts to fortify our drug discovery technology platform, we are actively working towards the establishment of antibody pharmaceutical technologies, in addition to the synthesis of small-molecular compounds technologies and fermentation technologies which are some of our strengths. Furthermore, in order to increase the speed and quality of drug discovery research, the concentration of drug discovery research functions in Tsukuba in April 2009 was followed by the reorganization of fermentation research functions and the establishment of Bioimaging Research Labs in October 2009.

In the area of clinical development, development is accelerated by centralizing resources on highly prioritized projects. To further strengthen our global development organization, we introduced in April 2009 a framework that would serve to reinforce our global operational platform, enhance project management capabilities and build up development strategy proposition and promotion capabilities for each therapeutic area.

Regarding technological development, for the stable, global supply of active pharmaceutical ingredient for clinical trial material for the candidate compounds obtained from fermented natural substances, construction on the Fermentation Technology Research Building began in September 2009 in the Toyama Plant of Astellas Toyama Co., Ltd. Its completion is scheduled for October 2010.

The following are main development advances made during FY2009.

In Japan, Prograf was approved for additional indications for ulcerative colitis in July 2009 and for all types of myasthenia gravis in October 2009. Celecox was approved for additional indications for lumbago, scapulohumeral peri-arthritis, cervico-omo-brachial syndrome, and

tendinitis/tendosynovitis in June 2009. Additionally, applications for approval were submitted for ASP8825 (XP13512) with the indication of restless legs syndrome in November 2009 and for orally disintegrating tablet YM905 developed as an additional formulation of Vesicare in December 2009. In the U.S., Prograf was approved in May 2009 for use in conjunction with mycophenolate mofetil (MMF) for the prevention of organ rejection in kidney transplant recipients. Concerning Flomax (brand name in Japan: Harnal), our partner, Boeinger Ingelheim Pharmaceuticals, Inc., received notice in September 2009 from the Food and Drug Administration (FDA) stating that the pediatric data provided by them on “pediatric patients with neurogenic bladder” satisfactorily met the terms of its Written Request. Based on this determination, marketing exclusivity was extended to April 2010 even though the substance patent for Flomax in the U.S. expired in October 2009. U.S. litigations regarding the infringement of the patent for Flomax were settled with Ranbaxy Inc. and Impax Laboratories, Inc respectively. As result of this settlement, the generic was launched in March 2010. Moreover, in September 2009, antibiotic telavancin (brand name in the U.S.: VIBATIV) was approved for the treatment of adult patients with complicated skin and skin structure infections caused by susceptible Gram-positive bacteria. Also, concerning telavancin, Theravance, Inc., the licensor, received a complete response letter from the FDA for an application for approval submitted for nosocomial pneumonia in November 2009.

In Europe, the immunosuppressant Modigraf (granules, generic name: tacrolimus) was approved in May 2009 for the indication of suppression of graft rejection in organ transplants. Also, an application for approval was submitted for telavancin in October 2009 for the treatment of noncomial pneumonia, including ventilator-associated pneumonia, and complicated skin and soft tissue infections in adults.

With regard to ASK8007 anti-human osteopontin antibody, which has been co-developed with Chemo-Sero-Therapeutic Research Institute, its development for rheumatoid arthritis was terminated in October 2009. As for functional dyspepsia agent YM443 (Z-338), which was introduced from Zeria Pharmaceutical Co., Ltd., its development was terminated in the U.S. and the agreement concluded between Zeria Pharmaceutical and the Company concerning exclusive rights for development and commercialization for the U.S. and Canada was terminated in January 2010. Also, in February 2010 the Company withdrew the application for approval that was submitted in Japan for the additional indication of type 2 diabetic incipient nephropathy for “Micardis”.

Alongside the in-house drug discovery research activities, the Company also actively seeks to expand and improve the R&D pipeline through in-licensing activities from other companies. Maxygen, Inc. (U.S.) and the Company have executed an agreement in September 2009 to establish a joint venture focused on the research and development of multiple protein pharmaceutical programs, including Maxygen’s MAXY-4 program for all autoimmune diseases and transplant rejection and other early stage drug discovery research programs. Medivation, Inc. (U.S.) and the Company entered into worldwide agreement in October 2009, to develop and commercialize MDV3100 for the treatment of prostate cancer. In November 2009, the Company entered into an agreement with Ironwood Pharmaceuticals, Inc. (U.S.) concerning linaclotide (generic name) an agent for the treatment of irritable bowel syndrome with constipation and chronic constipation for its exclusive development and commercialization rights in Japan, Indonesia, South Korea, the

Philippines, Taiwan and Thailand. Also, a worldwide agreement with Ambit Biosciences Corporation (U.S.) in December 2009 concerning the co-development and commercialization of FLT3 kinase inhibitors, including AC220, for cancer and other indications was executed. The Company concluded an exclusive licensing agreement with Basilea Pharmaceutica International Ltd.(Switzerland) in February 2010 concerning development and marketing in all countries except Japan for isavuconazole (generic name), an azole antifungal agent. In November 2009, the Company's U.S. affiliate Agensys, Inc. partially amended a license agreement with Seattle Genetics, Inc. (U.S.) concerning antibody-drug conjugate (ADC) technology, which is technology related to Seattle Genetics' antibody pharmaceuticals, to expand the scope of the license.

The Company is actively pursuing alliance activities in the commercial rights during FY2009. The Company's Taiwan affiliate signed an exclusive distributorship agreement with Teijin Pharma Limited in May 2009, regarding the marketing of TMX-67 (generic name: febuxostat) for treating hyperuricemia in patients with gout in Taiwan. Also, NeurogesX, Inc. (U.S.) and the Company's European affiliate entered into an exclusive Distribution, Marketing and License agreement for the commercialization of Qutenza for the treatment of peripheral neuropathic pain in the Europe, the Middle East and Africa in June 2009. In August 2009, Zogenix, Inc. (U.S.) and the Company's U.S. affiliate concluded a co-promotion agreement for Sumavel DosePro, a needle-free delivery system for the acute treatment of migraine, with or without aura, and the acute treatment of cluster headaches. And the Company concluded an agreement with AstraZeneca AB, an affiliate of AstraZeneca K.K. for a co-promotion alliance for Symbicort for the treatment of adult bronchial asthma in Japan. Also, Pfizer Japan Inc. and the Company concluded a co-promotion agreement for the combination drug of hypertension treatment and hypercholesterolemia treatment Caduet Combination Tablets in Japan respectively.

Reinforcement and expansion of global business platform

The Company is expanding its business globally, particularly in Europe, the U.S. and Asia, and it is constructing its own sales distribution channel in more than 40 countries across the globe. The Company is also steadily expanding its business areas. In addition to establishing an Indian affiliate, Astellas Pharma India Pvt. Ltd., in November 2008 and starting marketing of Prograf from March 2010, the Company established a Brazilian affiliate, Astellas Farma Brasil Importacao e Distribucao de Medicamentos Ltda., in July 2009. The Company now has affiliates in all of the BRICs (Brazil, Russia, India and China), whose economies are undergoing remarkable growth.

Concerning tender offer to purchase shares of OSI Pharmaceuticals, Inc.

Ruby Acquisition, Inc., wholly owned subsidiary of Astellas US Holding, Inc. (headquarters: Deerfield, Illinois), the U.S. holding subsidiary of the Company, launched a tender offer to purchase common stock of U.S. pharmaceuticals company OSI Pharmaceuticals, Inc. for \$52 per share in cash on March 2, 2010 (U.S. time). This comes to a total amount for all outstanding shares of approximately \$3.5 billion.

The Company, aiming to become a Global Category Leader as stated in its “VISION 2015,” has made the area of oncology one of its priority therapeutic areas, and it is working energetically to quickly establish a business platform. For this reason, in addition to further strengthening its own research and development capabilities, the Company aims to enhance its pipeline through alliance activities. This tender offer is one of the Company’s efforts to achieve this, and the Company views this endeavor as an important investment.

The announcement of a new five-year mid-term plan

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 business forecasts for FY2010

Consolidated first six months business forecasts

(Millions of yen – fractions dropped)

	FY2009 First six months results	FY2010 First six months forecasts	Changes (%)
Net sales	494,644	457,000	-37,644 (-7.6%)
Operating income	129,319	80,000	-49,319 (-38.1%)
Ordinary income	128,327	81,500	-46,827 (-36.5%)
Net income	83,488	57,000	-26,488 (-31.7%)

Consolidated full-year business forecasts

(Millions of yen – fractions dropped)

	FY2009 Full-year results	FY2010 Full-year forecasts	Changes (%)
Net sales	974,877	940,000	-34,877 (-3.6%)
Operating income	186,407	152,000	-34,407 (-18.5%)
Ordinary income	190,986	155,000	-35,986 (-18.8%)
Net income	122,257	107,000	-15,257 (-12.5%)

(Notes) Expected exchange rate for FY2010: ¥90/US\$, ¥130/€

Exchange rate for FY2009: ¥93/US\$, ¥131/€

Exchange rate for the first six months of FY2009: ¥95/US\$, ¥133/€

The annual forecasts for the fiscal year ending March 31, 2011 (FY2010) are shown above; net sales is anticipated to decrease whereas operating income, ordinary income and net income is anticipated to decrease compared to the fiscal year under review. The yen is anticipated to appreciate against both the dollar and the euro among others compared with the fiscal year, and these fluctuations in exchange rate are anticipated to cause ¥7.7 billion decrease in net sales and ¥4.5 billion decrease in operating income.

Net sales

Although continued expansion is projected for global products Vesicare and Funguard/Mycamine, Prograf and Harnal are expected to decline due to intensified competition following the launch of generics resulting from substance patents expirations. In Japan, despite the impact from National Health Insurance(NHI) drug price reductions implemented in April of this year, contributions from mainstay products as well as new products are expected. As a result, the net sales forecast is ¥940.0 billion (down 3.6% year-on-year).

Sales by geographical segments

<Japan>

Despite the impact from NHI drug price reductions implemented in Japan in April of this year, we expect growth in mainstay products such as Vesicare, Prograf (including a once-daily modified release formulation, Gracaptor), Micardis (including Micombi) and Myslee as well as contributions from new products including Geninax, Celecox and Symbicort that will increase sales of ethical pharmaceuticals in Japanese market.

<Overseas>

In the Americas, while Prograf is projected to decline due to intensified competition following the launch of generics, we expect sales of Vesicare, Mycamine and Lexiscan to expand steadily. Please note that the enactment of the Affordable Health Care for America Act in March 2010 is to have a negative impact on revenue by approx. ¥6.0 billion.

In Europe, solid sales expansion is expected for Vesicare, Mycamine and Eligard, however, Prograf sales are to decline due to expected generic entries in major countries. Also, while we project sales of Harnal to decrease through our own distribution channel (Omnic/Omnic OCAS), bulk sales and royalty income from our licensee are to decrease significantly following the launch of a generic in the U.S.

In Asia, sales of Prograf, Vesicare, Mycamine and others are forecasted to expand.

Operating income, ordinary income and net income

In addition to a decrease in net sales, we project gross profit to decrease due to a higher cost-to-sales ratio resulting from changes in product mix.

Selling, general and administrative expenses are expected to decrease. Among them, we project R&D expenses of ¥182.0 billion (down 6.9% year-on-year) and an R&D cost-to-sales ratio of 19.4% representing a decrease compared to the fiscal year under review, during which upfront payments were recorded to in-licensing. Selling, general and administrative expenses excluding R&D expenses are to go up due to factors such as a projected increase in sales promotion expenses from new product sales and the lack of refunds of marketing expenses by a licensee related to Harnal in the U.S.

As a result, we project an operating income of ¥152.0 billion (down 18.5% year-on-year).

Ordinary income is forecasted at ¥155.0 billion (down 18.8% year-on-year) with ¥107.0 billion in net income (down 12.5% year-on-year).

(2) Analysis of financial conditions

1) Assets, liabilities and net assets

Main changes in the consolidated balance sheets compared to the end of the previous fiscal year are as follows.

Assets

Total assets as of March 31, 2010 saw an increase of ¥15.7 billion compared to the end of the previous fiscal year to ¥1,364.1 billion.

<**Current assets**> ¥988.5 billion (an increase of ¥24.9 billion)

- Cash on hand and in banks increased by ¥44.7 billion compared to the end of the previous fiscal year while marketable securities decreased by ¥21.3 billion.

<**Fixed assets**> ¥375.6 billion (a decrease of ¥9.1 billion)

- Property, plant and equipment increased by ¥3.0 billion compared to the end of the previous fiscal year to ¥184.4 billion.
- Intangible fixed assets increased by ¥4.3 billion compared to the end of the previous fiscal year to ¥62.7 billion.
- Investments and other assets amounted to ¥128.3 billion, a decrease of ¥16.6 billion compared to the end of the previous fiscal year, due to a decrease of ¥18.7 billion in investment securities.

Liabilities

Liabilities decreased by ¥7.9 billion compared to the end of the previous fiscal year to ¥310.2 billion.

<**Current liabilities**> ¥277.1 billion (a decrease of ¥6.3 billion)

- Accrued income taxes decreased by ¥18.4 billion compared to the end of the previous fiscal year while accrued expenses increased by ¥10.1 billion.

<**Long-term liabilities**> ¥33.0 billion (a decrease of ¥1.5 billion)

Net assets

Net assets increased by ¥23.7 billion compared to the end of the previous fiscal year to ¥1,053.9 billion making the equity ratio 77.1%.

- While net income stood at ¥122.2 billion, ¥26.9 billion was spent for purchases of treasury stock from the stock market in addition to ¥56.4 billion for the payment of dividends of surplus.

In June 2009, 28 million shares of treasury stock valued at ¥128.0 billion were cancelled.

2) Cash flow

Cash flows from operating activities

Net cash provided by operating activities decreased year-on-year by ¥47.6 billion to ¥150.1 billion.

- Income before income taxes and minority interests decreased year-on-year by ¥75.8 billion to ¥186.8 billion and income taxes paid was ¥79.3 billion, a decrease of ¥7.2 billion year-on-year.

Cash flows from investing activities

Net cash used in investing activities was ¥31.5 billion, an increase in outflow of ¥2.5 billion year-on-year.

- While expenditures for purchases of marketable securities went up, proceeds from sales of marketable securities also increased.
- ¥24.7 billion was used for purchases of intangible fixed assets, an increase of ¥13.8 billion year-on-year.

Cash flows from financing activities

Net cash used in financing activities was ¥85.9 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 ¥96.6 billion.
- 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 ¥431.9 billion as of March 31, 2010, an increase of ¥22.0 billion compared to the end of the previous fiscal year.

Cash flow indicators

	FY2005	FY2006	FY2007	FY2008	FY2009
Equity ratio (%)	76.8	74.7	77.1	76.3	77.1
Equity ratio on a fair market value basis (%)	157.5	177.7	133.6	105.3	114.6
Cash flows to interest-bearing liabilities ratio (%)	0.5	0.8	0.0	0.0	0.0
Interest coverage ratio (times)	148.2	694.6	5,786.2	–	–

- Equity ratio: total equity / total assets
- Equity ratio on a fair market value basis: market capitalization / total assets
- Cash flows to interest-bearing liabilities ratio:
interest-bearing liabilities / cash flows from operating activities (before eliminating interests and income taxes)
- Interest coverage ratio:
cash flows from operating activities (before eliminating interests and income taxes) / interest payment

(Notes)

1. Each indicator is calculated using financial data on a consolidated basis.
2. Market capitalization is calculated based on the total number of issued shares at the end of the reporting period (after eliminating treasury stock).
3. Of all liabilities included in the consolidated balance sheets, those on which the Company pays interest are computed as interest-bearing liabilities.
4. Cash flows from operating activities reported in the consolidated statements of cash flows are used as cash flows from operating activities (before eliminating interests and income taxes).
5. The interest expense reported in the consolidated statements of cash flows is used as interest payment.

(3) Profit distribution policy

The Company is working aggressively towards increasing corporate value on a continual basis and, as a consequence, improves its return to shareholders. While putting priority on business investment to assure future growth, the Company will also strive to increase dividend steadily and continuously based on medium- to long-term profit growth on a consolidated basis taking into consideration the indicators such as dividend on equity ratio (DOE). Further, we will flexibly purchase treasury stock whenever necessary to improve capital efficiency and the level of return to shareholders.

Annual dividend for FY2009 is planned to be ¥125 per share (including year-end dividend of ¥65 per share) to shareholders, yielding DOE of 5.6 %. As a part of profit distribution and as measures of its capital policy, the Company implemented share buyback from the stock market of 8.2 million shares, which amounted to ¥26.9 billion, during the fiscal year under review.

Further, the Company decided to cancel 8.0 million shares of its treasury stock.

The Company anticipates that the annual dividend in the FY2010 to be ¥125 (composed of interim dividend of ¥60 and year-end dividend of ¥65).

The Company is not planning to amend the article of incorporation in regard to delegation of dividend, quarterly dividend and others to the meeting of the Board of Directors as of today.

(4) Risk Factors

The main risks that could significantly impact the business results and financial position of the Astellas Group are outlined below.

Inherent Uncertainties in Pharmaceutical R&D

In general, the probability of discovering a promising compound through drug discovery research is not high. Further, it takes a large amount of investments and a great deal of time to successfully launch a new product after discovery of a new compound. However, it may be necessary to discontinue clinical development if the effectiveness of a drug is not proven as initially expected, or if safety issues arise. In addition, pharmaceuticals are subject to legal restrictions in each country,

so that authorization from local regulatory authorities is a prerequisite for a product launch in each country. It is difficult to accurately foresee if and when approvals for new products can be obtained.

The Astellas Group's research and development activities are subject to these inherent risks.

Sales-related Risk

The pharmaceutical industry operates in a highly competitive environment characterized by rapid technological innovation. The Astellas Group faces fierce competition from drug makers and generics manufacturers based in Japan and overseas. The launch of competitive products by rivals could impact the Astellas Group's business results significantly.

Intellectual Property (IP) Risk

The Astellas Group's ethical pharmaceuticals business benefits from the protection of many patents. Although the Astellas Group manages intellectual property rights properly and is vigilant against third-party violation of such rights, the adverse impact on the Astellas Group's business results of actual IP violations may still be substantial. The Astellas Group's business results are also subject to the outcome of litigation undertaken by the Astellas Group to protect patents where infringement has occurred.

While the Astellas Group strives to ensure that its actions do not infringe the IP rights of other parties, there is a risk of litigation in the event of any inadvertent violations. Such litigation could also impact the Astellas Group's business results significantly.

Risks Relating to Product Side Effects and Safety

Any problems arising due to serious side effects or other safety issues that are caused by the Astellas Group's products could impact the Astellas Group's business results significantly.

Pharmaceutical Regulatory Risk

The ethical pharmaceutical business is governed by a wide variety of regulations in each country. In Japan, for example, the authorities periodically revise the NHI drug prices. Governments in developed countries in particular continue to adopt measures aimed at containing medical expenditures. Any trend toward stricter regulations governing the development, production and distribution of pharmaceuticals is a factor that could impact business results.

Environment-related Risks

The Astellas Group is careful to observe laws and regulations relating to environmental or health and safety issues, and has instituted internal standards that aim to exceed most statutory requirements. Despite such precautions, the costs involved in the unlikely event of a business-related incident causing a serious breach of compliance in this area could impact the Astellas Group's business results significantly.

Foreign Exchange Rate Fluctuations

The Astellas Group's business results and financial position are subject to the impact of exchange rate fluctuations due to the Astellas Group's extensive international operations.

In addition to the risks outlined above, the Astellas Group is exposed to a wide range of business-related risks, including but not limited to (1) general commercial litigation, (2) delays or suspension of manufacturing activities due to natural disasters or other factors, and (3) partial dependence on licensing or sales agreements relating to pharmaceuticals developed by other companies.

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 March 31, 2009	As of March 31, 2010
Assets		
Current assets		
Cash on hand and in banks	¥267,460	¥312,196
Trade notes and accounts receivable	222,982	228,088
Marketable securities	246,463	225,078
Merchandise and finished goods	80,755	82,749
Work in process	12,505	12,152
Raw materials and supplies	12,169	16,151
Deferred tax assets	67,564	63,316
Other	54,760	50,461
Allowance for doubtful receivables	(1,020)	(1,650)
Total current assets	<u>963,640</u>	<u>988,544</u>
Fixed assets		
Property, plant and equipment		
Buildings and structures	96,143	96,123
Machinery, equipment and vehicles	23,606	22,317
Tools, furniture and fixtures	16,801	15,818
Land	29,115	30,190
Construction in progress	13,964	18,679
Other	1,817	1,359
Total property, plant and equipment	<u>181,447</u>	<u>184,489</u>
Intangible fixed assets		
Goodwill	26,377	22,159
Other	31,984	40,601
Total intangible fixed assets	<u>58,361</u>	<u>62,760</u>
Investments and other assets		
Investment securities	89,562	70,797
Deferred tax assets	46,222	46,899
Other	9,266	10,740
Allowance for doubtful receivables	(57)	(56)
Total investments and other assets	<u>144,995</u>	<u>128,382</u>
Total fixed assets	<u>384,805</u>	<u>375,632</u>
Total assets	<u>¥1,348,446</u>	<u>¥1,364,176</u>

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

	As of March 31, 2009	As of March 31, 2010
Liabilities		
Current liabilities		
Trade notes and accounts payable	¥89,769	¥84,024
Other accounts payable	91,792	93,964
Accrued expenses	52,139	62,317
Accrued income taxes	39,681	21,216
Accrued consumption tax	413	2,588
Deferred tax liabilities	833	12
Accrued bonus for directors	134	34
Allowance for sales rebates	2,784	3,697
Other	6,004	9,301
Total current liabilities	<u>283,553</u>	<u>277,157</u>
Long-term liabilities		
Accrued retirement benefits for employees	15,029	17,638
Accrued retirement benefits for directors	15	24
Other	19,626	15,422
Total long-term liabilities	<u>34,671</u>	<u>33,085</u>
Total liabilities	<u>318,224</u>	<u>310,243</u>
Net assets		
Shareholders' equity		
Common stock	103,000	103,000
Capital surplus	176,821	176,821
Retained earnings	957,346	895,101
Treasury stock	(155,295)	(54,160)
Total shareholders' equity	<u>1,081,873</u>	<u>1,120,763</u>
Valuation, translation adjustments and others		
Unrealized holding gains on securities	10,018	14,153
Translation adjustments	(62,904)	(82,542)
Total valuation, translation adjustments and others	<u>(52,886)</u>	<u>(68,388)</u>
Stock subscription rights	894	1,205
Minority interests	338	352
Total net assets	<u>1,030,221</u>	<u>1,053,933</u>
Total liabilities and net assets	<u>¥1,348,446</u>	<u>¥1,364,176</u>

(2) Consolidated Statements of Income

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

	For the year ended March 31, 2009	For the year ended March 31, 2010
Net sales	¥965,698	¥974,877
Cost of sales	264,430	289,240
Gross profit	701,267	685,637
Selling, general and administrative expenses (Note)	450,872	499,229
Operating income	250,394	186,407
Non-operating income		
Interest income	9,921	2,781
Dividend income	1,457	1,157
Equity in earnings of affiliates	—	83
Exchange gain	9,250	225
Other	1,613	920
Total non-operating income	22,243	5,168
Non-operating expenses		
Equity in losses of affiliates	47	—
Other	1,139	589
Total non-operating expenses	1,186	589
Ordinary income	271,451	190,986
Special gains		
Gain on sales of fixed assets	1,333	48
Gain on sales of investment securities	499	2,700
Other	68	277
Total special gains	1,902	3,026
Special losses		
Loss on sales and disposal of fixed assets	3,078	2,282
Loss on impairment of fixed assets	1,340	4,082
Special retirement benefits	2,526	—
Loss on devaluation of investment securities	1,975	—
Compensation for cancellation of contracts	1,364	—
Other	376	846
Total special losses	10,662	7,211
Income before income taxes and minority interests	262,691	186,802
Income taxes-current	86,851	64,716
Income taxes-deferred	2,770	(2,110)
Total income taxes	89,621	62,606
Minority interests	2,083	1,938
Net income	¥170,986	¥122,257

Note;

	For the year ended March 31, 2009	For the year ended March 31, 2010
Total amounts of research and development expenses	¥159,058 million	¥195,570 million

(3) Consolidated Statements of Changes in Net Assets

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

	For the year ended March 31, 2009	For the year ended March 31, 2010
Shareholders' equity		
Common stock		
Balance at end of previous year	¥103,000	¥103,000
Movements during the year		
Total movements during the year	—	—
Balance at end of year	103,000	103,000
Capital surplus		
Balance at end of previous year	176,821	176,821
Movements during the year		
Total movements during the year	—	—
Balance at end of year	176,821	176,821
Retained earnings		
Balance at end of previous year	917,205	957,346
Movements during the year		
Cash dividends paid	(58,624)	(56,401)
Net income	170,986	122,257
Disposal of treasury stock	(79)	(16)
Cancellation of treasury stock	(72,140)	(128,083)
Total movements during the year	40,140	(62,244)
Balance at end of year	957,346	895,101
Treasury stock		
Balance at end of previous year	(104,122)	(155,295)
Movements during the year		
Purchase of treasury stock	(123,600)	(26,996)
Disposal of treasury stock	287	48
Cancellation of treasury stock	72,140	128,083
Total movements during the year	(51,172)	101,134
Balance at end of year	(155,295)	(54,160)
Total shareholders' equity		
Balance at end of previous year	1,092,905	1,081,873
Movements during the year		
Cash dividends paid	(58,624)	(56,401)
Net income	170,986	122,257
Purchase of treasury stock	(123,600)	(26,996)
Disposal of treasury stock	207	31
Cancellation of treasury stock	—	—
Total movements during the year	(11,032)	38,890
Balance at end of year	¥1,081,873	¥1,120,763

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

	For the year ended March 31, 2009	For the year ended March 31, 2010
Valuation, translation adjustments and others		
Unrealized holding gains on securities		
Balance at end of previous year	¥27,852	¥10,018
Movements during the year		
Net change in items other than shareholders' equity	(17,833)	4,134
Total movements during the year	(17,833)	4,134
Balance at end of year	10,018	14,153
Translation adjustments		
Balance at end of previous year	(10,860)	(62,904)
Movements during the year		
Net change in items other than shareholders' equity	(52,044)	(19,637)
Total movements during the year	(52,044)	(19,637)
Balance at end of year	(62,904)	(82,542)
Total valuation, translation adjustments and others		
Balance at end of previous year	16,991	(52,886)
Movements during the year		
Net change in items other than shareholders' equity	(69,877)	(15,502)
Total movements during the year	(69,877)	(15,502)
Balance at end of year	(52,886)	(68,388)
Stock subscription rights		
Balance at end of previous year	636	894
Movements during the year		
Net change in items other than shareholders' equity	258	310
Total movements during the year	258	310
Balance at end of year	894	1,205
Minority interests		
Balance at end of previous year	328	338
Movements during the year		
Net change in items other than shareholders' equity	10	13
Total movements during the year	10	13
Balance at end of year	338	352
Total net assets		
Balance at end of previous year	1,110,862	1,030,221
Movements during the year		
Cash dividends paid	(58,624)	(56,401)
Net income	170,986	122,257
Purchase of treasury stock	(123,600)	(26,996)
Disposal of treasury stock	207	31
Cancellation of treasury stock	—	—
Net change in items other than shareholders' equity	(69,609)	(15,178)
Total movements during the year	(80,641)	23,712
Balance at end of year	¥1,030,221	¥1,053,933

(4) Consolidated Statements of Cash Flows

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

	For the year ended March 31, 2009	For the year ended March 31, 2010
Cash flows from operating activities		
Income before income taxes and minority interests	¥262,691	¥186,802
Depreciation and amortization	35,439	38,683
Loss on impairment of fixed assets	1,340	4,082
Amortization of goodwill	7,450	9,782
Increase in allowance for doubtful receivables	334	700
(Decrease) increase in accrued retirement benefits for employees	(93)	1,547
Interest and dividend income	(11,379)	(3,938)
Exchange gain	(310)	(198)
Equity in losses (earnings) of affiliates	47	(83)
Net loss on sales and disposal of fixed assets	1,745	2,233
Increase in trade notes and accounts receivable	(13,228)	(8,400)
Increase in inventories	(26,569)	(8,740)
Increase (decrease) in trade notes and accounts payable	28,828	(3,591)
(Decrease) increase in other accounts payable	(2,817)	1,540
Other	(11,353)	4,937
Subtotal	<u>272,124</u>	<u>225,355</u>
Interest and dividends received	12,196	4,097
Income taxes paid	(86,529)	(79,323)
Net cash provided by operating activities	<u>197,791</u>	<u>150,130</u>
Cash flows from investing activities		
Purchases of marketable securities	(76,091)	(153,625)
Proceeds from sales of marketable securities	104,606	184,112
Purchases of property, plant and equipment	(36,653)	(39,524)
Proceeds from sales of property, plant and equipment	5,810	1,014
Purchases of intangible fixed assets	(10,902)	(24,775)
Purchases of investment securities	(20,964)	(9,477)
Proceeds from sales of investment securities	2,951	11,417
Loans receivable made	(70)	(40)
Collection of loans receivable	98	67
Net increase in short-term investments	(4,061)	(1,902)
Other	6,288	1,155
Net cash used in investing activities	<u>(28,987)</u>	<u>(31,580)</u>
Cash flows from financing activities		
Purchases of treasury stock	(123,600)	(26,996)
Cash dividends paid	(58,624)	(56,401)
Cash dividends paid to minority shareholders	(2,066)	(1,907)
Other	(384)	(596)
Net cash used in financing activities	<u>(184,676)</u>	<u>(85,902)</u>
Effects of exchange rate changes on cash and cash equivalents	(34,786)	(10,554)
(Decrease) increase in cash and cash equivalents	<u>(50,658)</u>	<u>22,093</u>
Cash and cash equivalents at beginning of year	460,485	409,826
Cash and cash equivalents at end of year	<u>¥409,826</u>	<u>¥431,920</u>

(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, operating income and total assets 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 year ended March 31, 2009

(Millions of yen)

	Japan	North America	Europe	Asia	Total	Eliminations	Consolidated
1. Sales and operating income							
Sales							
(1) Sales to third parties	¥510,499	¥188,853	¥239,113	¥27,231	¥965,698	—	¥965,698
(2) Intergroup sales and transfers	130,153	68,003	54,648	17	252,823	¥(252,823)	—
Total	640,653	256,856	293,762	27,249	1,218,521	(252,823)	965,698
Operating expenses	465,066	224,012	253,937	23,881	966,898	(251,594)	715,303
Operating income	¥175,586	¥32,844	¥39,825	¥3,367	¥251,623	¥(1,228)	¥250,394
2. Total assets	¥909,020	¥201,034	¥271,138	¥16,869	¥1,398,063	¥(49,617)	¥1,348,446

- (Notes)
1. Countries and areas are segmented based on their geographical proximity
 2. Major countries and areas which belong to segments other than Japan are as follows:
 - (1) North America -- The United States and Canada
 - (2) Europe ----- The United Kingdom, The Republic of Ireland, The Netherlands, Germany, France, Italy and Spain
 - (3) Asia ----- Korea, The Peoples' Republic of China and Taiwan

For the year ended March 31, 2010

(Millions of yen)

	Japan	North America	Europe	Asia	Total	Eliminations	Consolidated
1. Sales and operating income							
Sales							
(1) Sales to third parties	¥529,242	¥179,807	¥235,860	¥29,966	¥974,877	—	¥974,877
(2) Intergroup sales and transfers	106,851	67,495	66,193	28	240,568	¥(240,568)	—
Total	636,093	247,303	302,054	29,995	1,215,446	(240,568)	974,877
Operating expenses	521,562	232,484	258,120	27,694	1,039,861	(251,391)	788,470
Operating income	¥114,531	¥14,818	¥43,933	¥2,301	¥175,584	¥10,822	¥186,407
2. Total assets	¥877,071	¥202,982	¥303,871	¥18,873	¥1,402,799	¥(38,622)	¥1,364,176

- (Notes)
1. Countries and areas are segmented based on their geographical proximity
 2. Major countries and areas which belong to segments other than Japan are as follows:
 - (1) North America -- The United States and Canada
 - (2) Europe ----- The United Kingdom, The Republic of Ireland, The Netherlands, Germany, France, Italy and Spain
 - (3) Asia ----- Korea, The Peoples' Republic of China and Taiwan

【Overseas sales】

For the year ended March 31, 2009

	North America	Europe	Asia	Other	Total
1. Overseas sales (<i>Millions of yen</i>)	¥235,022	¥180,393	¥35,875	¥17,687	¥468,979
2. Consolidated net sales (<i>Millions of yen</i>)					¥965,698
3. Overseas sales as a percentage of consolidated net sales	24.3%	18.7%	3.7%	1.9%	48.6%

- (Notes)
1. Countries and areas are segmented based on their geographical proximity
 2. Major countries and areas in each segment are as follows:
 - (1) North America -- The United States and Canada
 - (2) Europe ----- The United Kingdom, Germany, France, Italy and Spain
 - (3) Asia ----- Korea, The Peoples' Republic of China and Taiwan
 3. Overseas sales consist of export sales of the Company and its domestic consolidated subsidiaries and sales (other than exports to Japan) of its foreign consolidated subsidiaries.

For the year ended March 31, 2010

	North America	Europe	Asia	Other	Total
1. Overseas sales (<i>Millions of yen</i>)	¥224,865	¥181,249	¥40,470	¥14,127	¥460,712
2. Consolidated net sales (<i>Millions of yen</i>)					¥974,877
3. Overseas sales as a percentage of consolidated net sales	23.1%	18.6%	4.2%	1.4%	47.3%

- (Notes)
1. Countries and areas are segmented based on their geographical proximity
 2. Major countries and areas in each segment are as follows:
 - (1) North America -- The United States and Canada
 - (2) Europe ----- The United Kingdom, Germany, France, Italy and Spain
 - (3) Asia ----- Korea, The Peoples' Republic of China and Taiwan
 3. Overseas sales consist of export sales of the Company and its domestic consolidated subsidiaries and sales (other than exports to Japan) of its foreign consolidated subsidiaries.

(Tax-Effect Accounting)

As of March 31, 2009	As of March 31, 2010
1. Significant components of deferred tax assets and liabilities	1. Significant components of deferred tax assets and liabilities
(Millions of yen)	(Millions of yen)
Deferred tax assets	Deferred tax assets
Loss on devaluation of investments in securities	Loss on devaluation of investments in securities
¥3,604	¥2,742
Accrued retirement benefits	Accrued retirement benefits
6,400	6,945
Depreciation	Depreciation
34,395	39,804
Loss on impairment of fixed assets	Loss on impairment of fixed assets
4,663	4,906
Accrued expenses	Accrued expenses
23,129	22,844
Inventories	Inventories
24,797	20,401
Accrued enterprise tax	Accrued enterprise tax
2,915	1,778
Other	Other
<u>44,235</u>	<u>36,899</u>
Total gross deferred tax assets	Total gross deferred tax assets
144,141	136,323
Valuation allowance	Valuation allowance
<u>(14,940)</u>	<u>(8,581)</u>
Total deferred tax assets	Total deferred tax assets
129,201	127,741
Deferred tax liabilities	Deferred tax liabilities
Unrealized holding gain on securities	Unrealized holding gain on securities
(6,229)	(9,071)
Depreciation	Depreciation
(1,135)	(564)
Other	Other
<u>(8,882)</u>	<u>(7,902)</u>
Total deferred tax liabilities	Total deferred tax liabilities
<u>(16,247)</u>	<u>(17,538)</u>
Net deferred tax assets	Net deferred tax assets
<u><u>112,953</u></u>	<u><u>110,203</u></u>
2. The reconciliation between the effective tax rate reflected in the consolidated financial statements and the statutory tax rate is summarized as follows:	2. The reconciliation between the effective tax rate reflected in the consolidated financial statements and the statutory tax rate is summarized as follows:
(%)	(%)
Domestic statutory tax rate	Domestic statutory tax rate
41.0	41.0
(Reconciliation)	(Reconciliation)
Tax credit for research and development expenses	Tax credit for research and development expenses
(4.5)	(7.0)
Permanently non-deductible expenses such as entertainment expenses	Permanently non-deductible expenses such as entertainment expenses
2.2	3.3
Amortization of goodwill	Amortization of goodwill
1.2	2.1
Different tax rates applied to foreign subsidiaries	Different tax rates applied to foreign subsidiaries
(4.2)	(6.3)
Other	Other
<u>(1.5)</u>	<u>0.3</u>
Effective tax rate after adoption of tax-effect accounting	Effective tax rate after adoption of tax-effect accounting
<u><u>34.1</u></u>	<u><u>33.5</u></u>

(Subsequent Events)

For the year ended March 31, 2009

Not applicable

For the year ended March 31, 2010

Not applicable