

May 10, 2012

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Financial Results of Astellas for Fiscal Year 2011

Japan, May 10, 2012 – Astellas Pharma Inc. (hereinafter referred to as “the Company”) today announced the financial results for the fiscal year 2011 (FY2011) ended March 31, 2012.

Consolidated financial results for FY2011 (April 1, 2011 – March 31, 2012)

(Millions of yen – fractions dropped)

| | FY2010 | FY2011 | Change (%) |
|----------------------|---------|----------------|----------------------|
| Net sales | 953,947 | 969,387 | +15,439 (+1.6%) |
| Operating income | 119,180 | 131,519 | +12,338 (+10.4%) |
| Ordinary income | 115,058 | 135,107 | +20,048 (+17.4%) |
| Net income | 67,650 | 78,230 | +10,579 (+15.6%) |
| Comprehensive income | 24,932 | 54,429 | +29,497 (+118.3%) |

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. Consequently, any statements herein do not constitute assurances regarding actual results by the Company. 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.

1. Business performance

(1) Analysis of business performance

1) Overview of FY2011

Consolidated business performance in FY2011 showed increases in net sales, operating income, ordinary income and net income, as follows.

Compared to the previous fiscal year (“year-on-year”), the exchange rate for the yen in FY 2011 appreciated ¥7 and ¥4 against the US dollar and the euro, respectively. As a result, there was a ¥24.1 billion decrease in net sales and a ¥5.1 billion decrease in operating income.

Consolidated financial results

(Millions of yen – fractions dropped)

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| Comprehensive income | 24,932 | 54,429 | +29,497 (+118.3%) |

Research and development (R&D) expenses

| | FY2010 | FY2011 |
|--------------|------------------|-------------------------|
| R&D expenses | ¥217,325 million | ¥189,840 million |

Exchange rate

| | FY2010 | FY2011 |
|--------|--------|-------------|
| ¥/US\$ | ¥86 | ¥79 |
| ¥/€ | ¥113 | ¥109 |

Net sales

Consolidated net sales increased by 1.6% year-on-year to ¥969.3 billion.

- In terms of global products, sales of Vesicare, a treatment for overactive bladder (OAB), continued to increase. Sales of Prograf, the immunosuppressant, declined due to the impact of generics in the US, in spite of sales growth in Japan and Asia.
- Sales of ethical pharmaceuticals in the Japanese market expanded steadily owing to contributions from mainstay products and new products.

Sales by region

*Sales by region calculated according to locations of sellers.

<Japan>

Net sales in Japan increased by 2.7% year-on-year to ¥558.4 billion. Sales of ethical pharmaceuticals in the Japanese market showed a steady growth of 2.7% year-on-year to ¥539.9 billion.

- Products such as Prograf, Vesicare, Myslee, an insomnia treatment, Celecox, a non-steroidal anti-inflammatory and anti-pain drug and vaccines, showed growth in sales.
- Sales also grew for Micardis, an angiotensin II receptor blocker, owing to the addition of Micombi, its combination drug with a diuretic, and Micamlo, its combination drug with a calcium antagonist.
- In addition, sales of new products grew, including Symbicort, for the treatment of bronchial asthma, and Bonoteo, an oral osteoporosis treatment.
- On the other hand, sales declined for Gaster, a peptic ulcer and gastritis treatment, Harnal, a treatment for functional symptoms of benign prostatic hyperplasia and Lipitor, a treatment for hypercholesterolemia.

<Outside of Japan>

Net sales in the Americas decreased by 1.6% year-on-year to ¥183.5 billion. The sales on a local currency basis increased by 6.7% year-on-year to US\$2,320 million.

- In addition to VESicare, Lexiscan, a pharmacologic stress agent, continuously grew. Also, income from anticancer drug Tarceva contributed to increased revenue.
- Sales of Prograf fell due to the impact of generics.

Net sales in Europe increased by 1.0% year-on-year to ¥191.7 billion. The sales on a local currency basis increased by 4.8% year-on-year to €1,759 million.

- Sales of Vesicare grew and Mycamine, an injectable antifungal agent, showed steady expansion.
- Sales of Prograf sold through the Company's own distribution channel decreased as a result of the impact of forex factors, however, sales on a local currency basis expanded, partly owing to the contribution from Advagraf, a once-a-day formulation. Generic versions of Prograf are already being sold in several countries in Europe. Sales of Harnal through the Company's own distribution channel declined.

Net sales in Asia increased by 6.0% year-on-year to ¥35.7 billion.

- Products such as Prograf, Harnal and Vesicare showed growth in sales, resulting in an increase in revenue.

Operating income

Consolidated operating income increased by 10.4% year-on-year to ¥131.5 billion.

- Although net sales increased, gross profit decreased by 1.1% year-on-year to ¥650.7 billion as the cost-to-sales ratio rose 1.9 percentage points year-on-year to 32.9% due to changes in product mix.
- Selling, general and administrative expenses decreased by 3.6% year-on-year to ¥519.2 billion.
- Research and development (R&D) expenses included therein were ¥189.8 billion, down 12.6% year-on-year, owing mainly to a decline in upfront and milestone payments associated with in-licensing compared to the previous fiscal year. The R&D cost-to-sales ratio was down 3.2 percentage points year-on-year to 19.6%.
- Selling, general and administrative expenses, excluding R&D expenses, increased by 2.5% year-on-year to ¥329.3 billion, owing to increased expenditure to strengthen sales and marketing capabilities in each region.

Ordinary income

Consolidated ordinary income increased by 17.4% year-on-year to ¥135.1 billion.

- Non-operating income increased by ¥0.9 billion year-on-year to ¥4.1 billion. Non-operating expenses decreased by ¥6.7 billion compared to the previous fiscal year, in which exchange loss was recorded, to ¥0.5 billion.

Net income

Consolidated net income increased by 15.6% year-on-year to ¥78.2 billion.

- Special gains totaled ¥14.0 billion, mainly due to the booking of ¥10.0 billion in gain on sales of fixed assets associated with the sales of the property where the Tokyo Research Center was located.
- Special losses totaled ¥22.1 billion. Loss on impairment of fixed assets amounting to ¥9.2 billion was booked, mainly due to the sale of assets, which were owned by the Company's subsidiary Prosidion Limited. In addition to this, a loss on sales and disposal of fixed assets of ¥5.9 billion and a loss of ¥3.1 billion resulting from the Great East Japan Earthquake were recorded.
- During FY2011, the Company changed its policy regarding dividends from subsidiaries outside of Japan. This and other temporary factors such as the impact of the revised Corporation Tax Act etc. caused the effective tax rate to rise compared to the previous fiscal year.

2) Other

R&D and in-licensing activities

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

[Drug discovery research]

Drug discovery research, to which we target management resources, focuses on the prioritized therapeutic areas of Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience, and Diabetes Mellitus (DM) Complications and Kidney Diseases.

Among efforts to fortify our drug discovery technology platform, we are also actively working towards the establishment of antibody and protein-related pharmaceutical technologies, in addition to the synthesis of small-molecular compounds technologies and fermentation technologies which are some of our strengths.

- We are also developing an open approach to innovation in order to strengthen our future drug discovery capabilities. In May 2011, the Company set up a public open innovation site called “a³(a-cube)” to support collaborative research on drug discovery leading to innovative and useful new pharmaceutical products by building our partnerships with universities and public research facilities in Japan, and with industry researchers.
- In the neuroscience field, the Company and RIKEN, Japan (Independent Administrative Institution) signed a five year joint research agreement in November 2011 for the purpose of “deciphering the pathogenic mechanism and identifying novel drug targets for Alzheimer’s disease”.

[Clinical development]

In tandem with moves to further reinforce its global development framework, the Company plans to accelerate the pace of product development by channeling resources into high-priority projects. The following are main development advances made during FY2011.

(Clinical development in Japan)

- The Company obtained approval in October 2010 for an additional formulation of the OAB treatment Vesicare to be manufactured and distributed as Vesicare OD (orally-disintegrating tablet). Vesicare OD was launched in Japan in April 2011.
- The Company obtained approval in July 2011 for mirabegron (generic name / code name: YM178), a treatment for OAB, to be manufactured and distributed as Betanis with the indication of urinary frequency, urgency, and urge incontinence associated with OAB. Betanis was launched in September 2011.
- The Company obtained approval in July 2011 for Bonoteo tablets 50mg, a once-per-four-week osteoporosis treatment, co-developed in Japan with Ono Pharmaceutical Co., Ltd., to be manufactured and distributed. Bonoteo tablets 50mg was launched in September 2011.

- The Company obtained approval for additional indication in July 2011 for Prograf and Graceptor, a once-a-day formulation, to be marketed for the prophylaxis of organ rejection in patients receiving allogeneic small bowel transplants.
- The Company obtained approval for additional indication in December 2011, for non-steroidal anti-inflammatory and anti-pain drug Celecox to be marketed for anti-inflammatory and anti-pain effects in post-operation, post-trauma and post-tooth extraction.
- In January 2012, restless legs syndrome treatment Regnite Tablets (generic name: gabapentin enacarbil) received marketing approval for the treatment of moderate-to-severe primary restless legs syndrome.
- In February 2012, the Company obtained approval for an additional indication application for changes in the maximum pediatric dosages of its synthetic penicillin Sawacillin, when used for the treatment for pediatric infectious diseases. The Company submitted an application based on evidence in the public domain in August 2011 in response to an assessment regarding the applicability by the “Review Committee on Unapproved Drugs and Indications with High Medical Needs” conducted in June 2011 by the Ministry of Health, Labor and Welfare.
- The Company obtained approval in March 2012, for the hyperphosphatemia treatment Kiklin Capsules (generic name: bixalomer).

(Clinical development overseas)

- In August 2011, a new drug application for mirabegron to be marketed for the indication of urinary frequency, urgency, and urge incontinence associated with OAB, was submitted to the European Medicines Agency and the U.S. Food and Drug Administration (FDA) respectively. In the US, in April 2012, the Reproductive Health Drugs Advisory Committee of the FDA voted that the overall risk/benefit assessment supports approval of mirabegron for the treatment of OAB.
- In November 2011, MDV3100 (code name), an oral androgen receptor signaling inhibitor, being jointly developed with US company Medivation, Inc., generated positive results from an interim analysis of the global Phase 3 clinical study (AFFIRM) in men with advanced prostate cancer previously treated with chemotherapy and successfully met the study’s pre-specified interim efficacy stopping criteria that allowed the trial to be stopped early. In response to this, applications for drug approvals in the US and Europe are now progressing.
- In January 2012, tivozanib (generic name), an oral inhibitor of all three vascular endothelial growth factor (VEGF) receptors under joint development with AVEO Pharmaceuticals Inc. of the US, generated positive results in a global Phase 3 clinical study (TIVO-1) in advanced renal cell carcinoma. Applications for drug approval in the US and Europe are now progressing.
- In December 2011, the Company’s European subsidiary obtained approval from the European Medicines Agency for DIFICLIR (generic name: fidaxomicin) tablets for the treatment of adults with Clostridium difficile infections.
- In March 2012, a market authorization application (mutual recognition for other EU

countries) was submitted in the Netherlands for solifenacin / tamsulosin combination tablets (code name: EC905) to treat lower urinary tract symptoms associated with benign prostatic hyperplasia, with storage symptoms.

- The Company decided in September 2011 to discontinue the global development of darexaban maleate (generic name / code name: YM150), an oral direct Factor Xa inhibitor, which the Company had been developing globally for the indications of the prevention of venous thromboembolism in patients at risk, such as those undertaking orthopedic surgical procedures in the lower limbs; stroke prevention in atrial fibrillation; and ischemic events prevention in acute coronary syndrome.

In parallel with in-house drug discovery, the Company is also actively working to boost its development pipelines through in-licensing from other companies.

- In June 2011, US company Seattle Genetics, Inc. exercised an option to co-develop the ASG-22M6E (code name) with Agensys, the Company's subsidiary, based on a license agreement that Agensys and Seattle Genetics had entered into relating to the antibody-drug conjugate (ADC) technology, an area of the antibody pharmaceutical technology field.
- In July 2011, the Company entered into an exclusive license agreement with US company Vical Incorporated to globally develop and commercialize ASP0113 / VCL-CB01 (code name), a therapeutic vaccine designed to control cytomegalovirus reactivation in transplant recipients that is being created and developed by Vical. Vical retains an option to co-promote ASP0113 / VCL-CB01 in the US.
- In September 2011, the Company and Evec, Inc. entered into a license agreement for one of Evec's fully-human antibodies against infectious diseases. Based on the agreement, the Company obtained worldwide exclusive development, manufacturing and commercialization rights for the program.
- In January 2012, the Company and Belgian company UCB entered into an agreement to jointly develop and commercialize UCB's PEGylated anti-Tumor Necrosis Factor (TNF)-alpha antibody certolizumab pegol (generic name) for rheumatoid arthritis in Japan. Under the agreement, UCB will manufacture the product, while the Company will manage distribution and sales. Both UCB and the Company will co-develop and co-promote certolizumab pegol.
- In March 2012, the Company and Optimer Pharmaceuticals, Inc. of the US concluded an exclusive collaboration and license agreement to develop and commercialize fidaxomicin tablets (generic name) in Japan. In February 2011, the Company's European subsidiary received exclusive rights from Optimer Pharmaceuticals for the development and commercialization of fidaxomicin in Europe, the Middle East, Africa, and the Commonwealth of Independent States (CIS).

[Other initiatives]

- In May 2011, the Company completed its acquisition of all of the ownership interest of US company Maxygen, Inc. in Perseid Therapeutics LLC, which was a joint venture between the Company and Maxygen. As a result of this transaction, the Company secured valuable

- world-leading technology related to variant protein pharmaceutical development.
- In July 2011, the Company and Pfizer Japan Inc. agreed to change the co-promotion agreement in Japan for Caduet Combination Tablets, a combination drug of hypertension treatment and hypercholesterolemia treatment, for which Pfizer holds the manufacturing and distribution rights in Japan. Pursuant to the new agreement, since October 1, 2011, the Company holds the distribution rights of this drug and books its sales. Both companies will continue to conduct the co-promotion activities.
 - Also, in March 2012, the Company and Pfizer Japan Inc. agreed to partially revise the development and marketing agreement for Lipitor. Under the revised agreement, the period of the agreement has been extended from July 2016 to March 2021.
 - In August 2011, the Company entered into an exclusive distribution agreement with Teijin Pharma Limited in Southeast Asia (Thailand, the Philippines, Indonesia, Singapore, Malaysia and Vietnam) and India for febuxostat (generic name / code name: TMX-67), a novel drug for the treatment of gout and hyperuricemia. The exclusive distribution rights for this drug in Taiwan, China and Hong Kong are already held by the Company's subsidiaries of those respective countries.
 - In February 2012, the Company and Sanwa Kagaku Kenkyusho Co., Ltd. (SKK) established a strategic alliance in Japan in the field of kidney disease. Under the agreement, the Company will distribute and both companies will co-promote the hyperkalemia treatment ARGAMATE, which SKK is currently manufacturing and distributing. Also, the Company will distribute and both companies will co-promote the Company's Kiklin Capsules.
 - In June 2011, Astellas' subsidiary Prosidion Limited entered into an agreement to sell its patent estate and associated royalty stream relating to the use of DPP-IV inhibitors for the treatment of type 2 diabetes to Royalty Pharma, and the transaction was completed in July 2011.
 - Also, in December 2011, Prosidion Limited and AstraZeneca entered into an option agreement for PSN821 and PSN842 (code name), a potential new class of medicines for type 2 diabetes, being developed by Prosidion. Under the agreement, Prosidion granted AstraZeneca an exclusive option to acquire assets related to PSN821 and PSN842.
 - In July 2011, Astellas US LLC, US subsidiary of the Company, and US company Merck & Co., Inc. entered into an agreement under which Astellas US LLC transfers to a subsidiary of Merck the rights to co-develop and exclusively distribute in North America the intravenous formulation of vernakalant (generic name / code name: RSD1235), for which application for US approval has been submitted with the indication of atrial fibrillation.
 - In January 2012, the Company exercised its right to terminate the global license, development and commercialization agreement it had with US company Theravance, Inc. related to antibiotic VIBATIV. As a result, the global license granted to the Company ceased upon termination of the agreement and the Company also stopped promotional sales efforts.

<Overseas>

In the Americas, although we anticipate a decrease in sales of Prograf and an overall decrease in sales of the pharmacologic stress agents Adenoscan and Lexiscan, we project sales expansion for VESicare, Mycamine and Tarceva.

In Europe, we anticipate a decrease in sales of Prograf and Harnal through the Company's own distribution channel, however, we project sales growth for Vesicare, Mycamine, and other products.

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

Operating income, ordinary income and net income

Although we project an increase in net sales, we expect a decrease in gross profit owing to a rise of the cost-to-sales ratio as a result of changes in the product mix and other factors.

Selling, general and administrative expenses are expected to decrease. Among them, we project research and development (R&D) expenses of ¥179.0 billion (down 5.7% year-on-year) and the R&D cost-to-sales ratio of 18.4%. Research and development (R&D) expenses excluding upfront and milestone payments associated with in-licensing are expected to remain the same level as the fiscal year under review. Also, we project a decrease in selling, general and administrative expenses excluding R&D expenses.

As a result, we project an operating income of ¥146.0 billion (up 11.0% year-on-year).

From FY 2012, the straight-line method has been adopted as the Astellas Group's unified method of depreciating property, plant and equipment. As a result, we forecast this change will lead to an increase in operating income of ¥9.0 billion compared with the previous method.

Ordinary income is forecasted at ¥147.0 billion (up 8.8% year-on-year) with ¥98.0 billion in net income (up 25.3% year-on-year).

(2) Analysis of financial conditions

1) Assets, liabilities and net assets

An overview of the consolidated balance sheets as of March 31, 2012 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets as of March 31, 2012 saw an increase of ¥65.5 billion compared to the end of the previous fiscal year to ¥1,400.6 billion.

<Current assets> ¥781.0 billion (an increase of ¥127.9 billion)

- Cash on hand and in banks as well as marketable securities increased.

<Fixed assets> ¥619.5 billion (a decrease of ¥62.3 billion)

- Property, plant and equipment increased by ¥8.9 billion compared to the end of the previous fiscal year to ¥199.1 billion.
- Intangible fixed assets decreased by ¥52.8 billion compared to the end of the previous fiscal year to ¥314.2 billion.

Patents declined by ¥75.2 billion owing to the transfer of the patent estate and associated royalty stream relating to the use of DPP-IV inhibitors, which was owned by the Company's subsidiary Prosidion Limited.

- Investments and other assets amounted to ¥106.1 billion, a decrease of ¥18.4 billion compared to the end of the previous fiscal year.

Liabilities

Liabilities increased by ¥68.5 billion compared to the end of the previous fiscal year to ¥382.5 billion.

<Current liabilities> ¥314.1 billion (an increase of ¥74.5 billion)

- Other accounts payable increased by ¥31.7 billion and trade notes and accounts payable increased by ¥19.8 billion.

<Long-term liabilities> ¥68.3 billion (a decrease of ¥6.0 billion)

Net assets

Net assets decreased by ¥2.9 billion compared to the end of the previous fiscal year to ¥1,018.1 billion making the equity ratio 72.6%.

- While net income stood at ¥78.2 billion, ¥57.7 billion of dividends of surplus were paid. In addition, the change in translation adjustments of ¥26.5 billion had the effect of reducing net assets by the same amount.

2) Cash flow

Cash flows from operating activities

Net cash provided by operating activities increased year-on-year by ¥72.0 billion to ¥172.6 billion.

- Income before income taxes and minority interests increased year-on-year by ¥23.5 billion to ¥127.0 billion and income taxes paid was ¥50.2 billion, an increase in outflow of ¥5.8 billion year-on-year.

Cash flows from investing activities

Net cash used in investing activities was ¥25.9 billion, a decrease in outflow of ¥216.6 billion year-on-year.

- In the previous fiscal year, cash of ¥284.1 billion was used for the acquisition of shares of subsidiaries associated with the OSI acquisition and other activities.
- In the fiscal year under review, proceeds from sales of intangible fixed assets such as the transfer of intangibles related to DPP-IV inhibitors provided cash of ¥45.3 billion, and proceeds from sales of property, plant and equipment provided cash of ¥11.9 billion. Purchases of property, plant and equipment used cash of ¥47.6 billion and purchases of intangible fixed assets used cash of ¥16.4 billion.

Cash flows from financing activities

Net cash used in financing activities was ¥57.9 billion, a decrease in outflow of ¥35.3 billion year-on-year.

- In the previous fiscal year, cash of ¥34.9 billion was used for the redemption of corporate bonds issued by OSI.
- In the fiscal year under review, cash dividends paid totaled ¥57.7 billion, roughly the same as the amount paid in the previous fiscal year.

As a result of the above, cash and cash equivalents totaled ¥252.3 billion as of March 31, 2012, an increase of ¥76.9 billion compared to the end of the previous fiscal year.

Cash flow indicators

| | FY2007 | FY2008 | FY2009 | FY2010 | FY2011 |
|--|---------|--------|--------|--------|--------|
| Equity ratio (%) | 77.1 | 76.3 | 77.1 | 76.4 | 72.6 |
| Equity ratio on a fair market value basis (%) | 133.6 | 105.3 | 114.6 | 106.5 | 112.1 |
| Cash flows to interest-bearing liabilities ratio (%) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Interest coverage ratio (times) | 5,786.2 | – | – | 659.9 | – |

- 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 strive to increase dividend payments continuously taking into consideration the dividend on equity ratio (DOE) and other factors based on medium- to long-term profit growth on a consolidated basis. Further, the Company will flexibly purchase treasury stock whenever necessary to improve capital efficiency and further increase the level of return to shareholders.

The annual dividend for FY2011 is planned to be ¥125 per share (including a year-end dividend of ¥65 per share) to shareholders, yielding a DOE of 5.7 %.

The Company anticipates that the annual dividend in FY2012 will be ¥130 per share (composed of interim dividend of ¥65 per share and a year-end dividend of ¥65 per share).

The Company is not planning any amendment to the articles of incorporation in regard to delegation of the dividend to the Board of Directors, and nor in regard to a quarterly dividend etc., at this moment.

(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 investment 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, thus 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, 2011 | As of March 31, 2012 |
|-------------------------------------|-------------------------|-------------------------|
| Assets | | |
| Current assets | | |
| Cash on hand and in banks | ¥142,895 | ¥210,986 |
| Trade notes and accounts receivable | 262,512 | 264,687 |
| Marketable securities | 33,908 | 88,112 |
| Merchandise and finished goods | 82,655 | 82,233 |
| Work in process | 13,610 | 13,472 |
| Raw materials and supplies | 20,615 | 16,116 |
| Deferred tax assets | 67,803 | 71,549 |
| Other | 30,548 | 36,807 |
| Allowance for doubtful receivables | (1,395) | (2,887) |
| Total current assets | 653,154 | 781,078 |
| Fixed assets | | |
| Property, plant and equipment | | |
| Buildings and structures | 97,106 | 95,682 |
| Machinery, equipment and vehicles | 24,660 | 25,269 |
| Tools, furniture and fixtures | 11,425 | 10,736 |
| Land | 31,374 | 31,037 |
| Construction in progress | 24,128 | 34,886 |
| Other | 1,464 | 1,547 |
| Total property, plant and equipment | 190,160 | 199,159 |
| Intangible fixed assets | | |
| Goodwill | 101,255 | 94,192 |
| Patents | 236,736 | 161,499 |
| Other | 29,186 | 58,586 |
| Total intangible fixed assets | 367,178 | 314,278 |
| Investments and other assets | | |
| Investment securities | 60,204 | 60,525 |
| Deferred tax assets | 52,294 | 33,875 |
| Other | 12,144 | 11,750 |
| Allowance for doubtful receivables | (44) | (39) |
| Total investments and other assets | 124,598 | 106,112 |
| Total fixed assets | 681,936 | 619,550 |
| Total assets | ¥1,335,091 | ¥1,400,629 |

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

| | As of March 31, 2011 | As of March 31, 2012 |
|--|-------------------------|-------------------------|
| Liabilities | | |
| Current liabilities | | |
| Trade notes and accounts payable | ¥88,601 | ¥108,408 |
| Other accounts payable | 50,631 | 82,387 |
| Accrued expenses | 73,089 | 80,932 |
| Accrued income taxes | 19,813 | 24,757 |
| Accrued consumption tax | 1,401 | 1,396 |
| Accrued bonus for directors | 31 | 76 |
| Allowance for sales rebates | 3,469 | 3,951 |
| Other | 2,609 | 12,259 |
| Total current liabilities | 239,648 | 314,170 |
| Long-term liabilities | | |
| Deferred tax liabilities | 42,248 | 30,932 |
| Accrued retirement benefits for employees | 17,235 | 16,979 |
| Other | 14,862 | 20,424 |
| Total long-term liabilities | 74,346 | 68,336 |
| Total liabilities | 313,994 | 382,506 |
| Net assets | | |
| Shareholders' equity | | |
| Common stock | 103,000 | 103,000 |
| Capital surplus | 176,821 | 176,821 |
| Retained earnings | 874,351 | 894,737 |
| Treasury stock | (23,492) | (23,131) |
| Total shareholders' equity | 1,130,682 | 1,151,427 |
| Accumulated other comprehensive income | | |
| Unrealized holding gains on securities | 9,479 | 12,257 |
| Foreign currency translation adjustments | (120,587) | (147,166) |
| Total accumulated other comprehensive income | (111,107) | (134,909) |
| Stock subscription rights | 1,522 | 1,604 |
| Total net assets | 1,021,096 | 1,018,123 |
| Total liabilities and net assets | ¥1,335,091 | ¥1,400,629 |

(2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income

(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, 2011 | For the year ended March 31, 2012 |
|--|--------------------------------------|--------------------------------------|
| Net sales | ¥953,947 | ¥969,387 |
| Cost of sales | 295,972 | 318,632 |
| Gross profit | 657,974 | 650,754 |
| Selling, general and administrative expenses | 538,794 | 519,235 |
| Operating income | 119,180 | 131,519 |
| Non-operating income | | |
| Interest income | 1,120 | 1,223 |
| Dividend income | 1,217 | 1,141 |
| Equity in earnings of affiliates | — | 194 |
| Exchange gain | — | 1,004 |
| Other | 848 | 548 |
| Total non-operating income | 3,186 | 4,111 |
| Non-operating expenses | | |
| Interest expense | 111 | 123 |
| Equity in losses of affiliates | 89 | — |
| Exchange loss | 6,556 | — |
| Other | 551 | 399 |
| Total non-operating expenses | 7,308 | 522 |
| Ordinary income | 115,058 | 135,107 |
| Special gains | | |
| Gain on sales of fixed assets | 298 | 10,424 |
| Gain on sales of investment securities | 1,280 | 2,715 |
| Other | 97 | 943 |
| Total special gains | 1,676 | 14,083 |
| Special losses | | |
| Loss on sales and disposal of fixed assets | 1,276 | 5,923 |
| Loss on impairment of fixed assets | 2,782 | 9,234 |
| Loss on disaster | 3,029 | 3,192 |
| Business integration expenses | 4,723 | 644 |
| Loss on adjustment for changes of accounting standard for asset retirement obligations | 559 | — |
| Other | 881 | 3,120 |
| Total special losses | 13,253 | 22,116 |
| Income before income taxes and minority interests | 103,482 | 127,074 |
| Income taxes-current | 43,554 | 51,157 |
| Income taxes-deferred | (7,722) | (2,313) |
| Total income taxes | 35,831 | 48,843 |
| Income before minority interests | 67,650 | 78,230 |
| Net income | ¥67,650 | ¥78,230 |

(Consolidated Statements of Comprehensive Income)

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

| | For the year ended March 31, 2011 | For the year ended March 31, 2012 |
|--|--------------------------------------|--------------------------------------|
| Income before minority interests | ¥67,650 | ¥78,230 |
| Other comprehensive income | | |
| Unrealized holding gains on securities | (4,674) | 2,777 |
| Foreign currency translation adjustments | (38,044) | (26,579) |
| Total other comprehensive income | (42,718) | (23,801) |
| Comprehensive income | ¥24,932 | ¥54,429 |
| - attributable to owners of the parent | ¥24,932 | ¥54,429 |
| - attributable to minority interests | — | — |

(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, 2011 | For the year ended March 31, 2012 |
|---------------------------------|--------------------------------------|--------------------------------------|
| Shareholders' equity | | |
| Common stock | | |
| Balance at beginning of year | ¥103,000 | ¥103,000 |
| Movements during the year | | |
| Total movements during the year | — | — |
| Balance at end of year | <u>103,000</u> | <u>103,000</u> |
| Capital surplus | | |
| Balance at beginning of year | 176,821 | 176,821 |
| Movements during the year | | |
| Total movements during the year | — | — |
| Balance at end of year | <u>176,821</u> | <u>176,821</u> |
| Retained earnings | | |
| Balance at beginning of year | 895,101 | 874,351 |
| Movements during the year | | |
| Cash dividends paid | (57,727) | (57,729) |
| Net income | 67,650 | 78,230 |
| Disposal of treasury stock | (45) | (116) |
| Cancellation of treasury stock | (30,627) | — |
| Total movements during the year | <u>(20,749)</u> | <u>20,385</u> |
| Balance at end of year | <u>874,351</u> | <u>894,737</u> |
| Treasury stock | | |
| Balance at beginning of year | (54,160) | (23,492) |
| Movements during the year | | |
| Purchase of treasury stock | (29) | (11) |
| Disposal of treasury stock | 70 | 372 |
| Cancellation of treasury stock | 30,627 | — |
| Total movements during the year | <u>30,668</u> | <u>360</u> |
| Balance at end of year | <u>(23,492)</u> | <u>(23,131)</u> |
| Total shareholders' equity | | |
| Balance at beginning of year | 1,120,763 | 1,130,682 |
| Movements during the year | | |
| Cash dividends paid | (57,727) | (57,729) |
| Net income | 67,650 | 78,230 |
| Purchase of treasury stock | (29) | (11) |
| Disposal of treasury stock | 24 | 255 |
| Cancellation of treasury stock | — | — |
| Total movements during the year | <u>9,918</u> | <u>20,745</u> |
| Balance at end of year | <u>¥1,130,682</u> | <u>¥1,151,427</u> |

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

| | For the year ended March 31, 2011 | For the year ended March 31, 2012 |
|---|--------------------------------------|--------------------------------------|
| Accumulated other comprehensive income | | |
| Unrealized holding gains on securities | | |
| Balance at beginning of year | ¥14,153 | ¥9,479 |
| Movements during the year | | |
| Net change in items other than shareholders' equity | (4,674) | 2,777 |
| Total movements during the year | (4,674) | 2,777 |
| Balance at end of year | 9,479 | 12,257 |
| Foreign currency translation adjustments | | |
| Balance at beginning of year | (82,542) | (120,587) |
| Movements during the year | | |
| Net change in items other than shareholders' equity | (38,044) | (26,579) |
| Total movements during the year | (38,044) | (26,579) |
| Balance at end of year | (120,587) | (147,166) |
| Total accumulated other comprehensive income | | |
| Balance at beginning of year | (68,388) | (111,107) |
| Movements during the year | | |
| Net change in items other than shareholders' equity | (42,718) | (23,801) |
| Total movements during the year | (42,718) | (23,801) |
| Balance at end of year | (111,107) | (134,909) |
| Stock subscription rights | | |
| Balance at beginning of year | 1,205 | 1,522 |
| Movements during the year | | |
| Net change in items other than shareholders' equity | 316 | 82 |
| Total movements during the year | 316 | 82 |
| Balance at end of year | 1,522 | 1,604 |
| Minority interests | | |
| Balance at beginning of year | 352 | — |
| Movements during the year | | |
| Net change in items other than shareholders' equity | (352) | — |
| Total movements during the year | (352) | — |
| Balance at end of year | — | — |
| Total net assets | | |
| Balance at beginning of year | 1,053,933 | 1,021,096 |
| Movements during the year | | |
| Cash dividends paid | (57,727) | (57,729) |
| Net income | 67,650 | 78,230 |
| Purchase of treasury stock | (29) | (11) |
| Disposal of treasury stock | 24 | 255 |
| Cancellation of treasury stock | — | — |
| Net change in items other than shareholders' equity | (42,754) | (23,719) |
| Total movements during the year | (32,836) | (2,973) |
| Balance at end of year | ¥1,021,096 | ¥1,018,123 |

(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, 2011 | For the year ended March 31, 2012 |
|--|--------------------------------------|--------------------------------------|
| Cash flows from operating activities | | |
| Income before income taxes and minority interests | ¥103,482 | ¥127,074 |
| Depreciation and amortization | 54,541 | 53,781 |
| Loss on impairment of fixed assets | 2,782 | 9,234 |
| Amortization of goodwill | 11,132 | 11,719 |
| Increase in accrued retirement benefits for employees | 1,346 | 711 |
| Interest and dividend income | (2,338) | (2,364) |
| Net loss (gain) on sales and disposal of fixed assets | 978 | (4,500) |
| Increase in trade notes and accounts receivable | (31,711) | (6,091) |
| Increase in inventories | (10,678) | (17) |
| Increase in trade notes and accounts payable | 7,388 | 21,711 |
| (Decrease) increase in other accounts payable | (11,728) | 5,704 |
| Other | 17,779 | 3,592 |
| Subtotal | 142,974 | 220,556 |
| Interest and dividends received | 2,287 | 2,373 |
| Interest paid | (220) | — |
| Income taxes paid | (44,402) | (50,254) |
| Net cash provided by operating activities | 100,639 | 172,675 |
| Cash flows from investing activities | | |
| Purchases of marketable securities | (2,931) | (6,997) |
| Proceeds from sales of marketable securities | 83,845 | 7,524 |
| Purchases of property, plant and equipment | (33,630) | (47,678) |
| Proceeds from sales of property, plant and equipment | 628 | 11,978 |
| Purchases of intangible fixed assets | (17,083) | (16,449) |
| Proceeds from sales of intangible fixed assets | — | 45,389 |
| Purchases of investment securities | (1,373) | (749) |
| Proceeds from sales of investment securities | 6,759 | 4,243 |
| Purchases of investments in subsidiaries resulting in change in scope of consolidation | (284,148) | (3,736) |
| Net decrease (increase) in short-term investments | 8,683 | (18,206) |
| Other | (3,397) | (1,272) |
| Net cash used in investing activities | (242,648) | (25,953) |
| Cash flows from financing activities | | |
| Redemption of bonds | (34,968) | — |
| Purchases of treasury stock | (29) | (11) |
| Cash dividends paid | (57,727) | (57,729) |
| Other | (542) | (197) |
| Net cash used in financing activities | (93,267) | (57,938) |
| Effects of exchange rate changes on cash and cash equivalents | (21,178) | (11,869) |
| (Decrease) increase in cash and cash equivalents | (256,454) | 76,914 |
| Cash and cash equivalents at beginning of year | 431,920 | 175,465 |
| Cash and cash equivalents at end of year | ¥175,465 | ¥252,379 |