

May 12, 2011

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

## **Financial Results of Astellas for Fiscal Year 2010**

Japan, May 12, 2011 – Astellas Pharma Inc. (hereinafter referred to as “the Company”) today announced the financial results for the fiscal year 2010 (FY2010) ended March 31, 2011.

### Consolidated financial results for FY2010 (April 1, 2010 – March 31, 2011)

(Millions of yen – fractions dropped)

	FY2009	<b>FY2010</b>	Change (%)
Net sales	974,877	<b>953,947</b>	-20,929 (-2.1%)
Operating income	186,407	<b>119,180</b>	-67,226 (-36.1%)
Ordinary income	190,986	<b>115,058</b>	-75,927 (-39.8%)
Net income	122,257	<b>67,650</b>	-54,606 (-44.7%)

**Comprehensive income for FY 2010      ¥24,932 million      (-77.1%)**

FY 2009      ¥108,693 million

#### 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, 2011 (FY2010) and consolidated business forecasts for the fiscal year ending March 31, 2012 (FY2011) of the Company are as follows.

#### Business performance of FY2010

##### 1) Overview of FY2010

Consolidated business performance in FY2010 showed decreases in net sales, operating income, ordinary income and net income, as shown in the table below.

The exchange rate for FY2010 rose by ¥7 and ¥18 against the U.S. dollar and the euro, respectively, compared to the previous fiscal year (“year-on-year”) bringing down net sales by ¥47.3 billion and operating income by ¥8.6 billion.

#### Consolidated financial results

(Millions of yen – fractions dropped)

	FY2009	FY2010	Change (%)
Net sales	974,877	<b>953,947</b>	-20,929 (-2.1%)
Operating income	186,407	<b>119,180</b>	-67,226 (-36.1%)
Ordinary income	190,986	<b>115,058</b>	-75,927 (-39.8%)
Net income	122,257	<b>67,650</b>	-54,606 (-44.7%)

#### Research and development (R&D) expenses

	FY2009	FY2010
R&D expenses	¥195,570 million	<b>¥217,325 million</b>

#### Exchange rate

	FY2009	FY2010
¥/US\$	¥93	<b>¥86</b>
¥/€	¥131	<b>¥113</b>

### **Impact of the Eastern Japan Earthquake**

The Company is currently doing its utmost to minimize the impact of the Eastern Japan Earthquake, which occurred on March 11, 2011, on its operations.

The conditions and the losses of the Company and its group companies due to the earthquake for FY2010 are as follows.

- The Tsukuba Research Center (Miyukigaoka) and the Tsukuba Biotechnology Research Center (Tokodai), which were damaged by the earthquake, resumed normal operations in late March, and sales offices and branches in the Tohoku region have also resumed marketing activities. The Nishine Plant also resumed full manufacturing activities in early April.
- All employees at the Takahagi Chemistry & Technology Development Center and the Takahagi Technology Center returned to work from mid April. Research activities at the Takahagi Chemistry & Technology Development Center have already resumed, and the facilities are expected to restart full operations in June, 2011. Furthermore, restoration of manufacturing facilities is progressing at the Takahagi Technology Center and production is expected to begin from October.
- Although at the Takahagi Technology Center, where the active pharmaceutical ingredients of products such as Harnal, a treatment for functional symptoms of benign prostatic hyperplasia and Bonoteo, a treatment for osteoporosis, are manufactured, with regard to the major products, the Company has sufficient inventories in place, including those of products, and does not expect any problem with stable product distribution.
- Based on all the information available as of March 31, 2011, the Company has booked special losses totaling ¥3.0 billion for earthquake-related damage in FY2010, including the expenses for the repair of buildings, machinery, research equipment and others, and fixed costs related to the suspension of operation in the Takahagi Chemistry & Technology Development Center, the Takahagi Technology Center, the Nishine Plant, the Tsukuba Research Center, the Tsukuba Biotechnology Research Center and other sites.

### **Acquisition of OSI Pharmaceuticals, Inc.**

In June 2010, the Company acquired all the shares of US Pharmaceuticals company OSI Pharmaceuticals, Inc. (hereinafter referred to as “OSI”) through a tender offer, making OSI its consolidated subsidiary. The Company has positioned oncology as one of its focus therapeutic areas and is actively working to establish its business base in this field. The acquisition will provide the Company with a top-tier oncology platform in the U.S. immediately and further expanded product portfolio and R&D pipelines in the oncology field.

## **Net sales**

Consolidated net sales decreased by 2.1% year-on-year to ¥953.9 billion.

- In terms of global products, Vesicare, a treatment for overactive bladder, and Funguard/Mycamine, an injectable antifungal agent, showed steady increase in sales. The sales of Prograf, the immunosuppressant, declined due to the intensified competition following the launch of generics in the U.S. Regarding Harnal, bulk sales and royalty income from the licensee decreased significantly following the launch of generics in the US market. In the Japanese market, despite the impact from the NHI drug price revision, sales expanded steadily owing to contributions from new products and other factors.
- The Company booked sales of ¥31.8 billion generated by OSI.

## **Sales by region**

\*Sales by region calculated according to locations of sellers.

### **<Japan>**

Net sales in Japan increased by 2.8% year-on-year to ¥543.8 billion. Despite the impact from the NHI drug price revision implemented in April 2010, sales in the Japanese market showed a steady growth of 3.1% to ¥525.6 billion.

- Products such as Prograf, Vesicare, Celecox, a non-steroidal anti-inflammatory and anti-pain drug, Myslee, an insomnia treatment and Seroquel, the treatment for schizophrenia showed growth in sales.
- New products such as Symbicort for the treatment of bronchial asthma, which was launched in January 2010, contributed to sales expansion. Meanwhile, sales also grew for Micardis, an angiotensin II receptor blocker (ARB), owing to the addition of Micombi, its combination drug with a diuretic, and Micamlo, its combination drug with a calcium antagonist, which was launched in October 2010.
- On the other hand, sales declined for Gaster, a peptic ulcer and gastritis treatment, Harnal and Lipitor, a treatment for hypercholesterolemia.

### **<Overseas>**

Net sales in the Americas increased by 3.7% year-on-year to ¥186.5 billion while the sales on a local currency basis increased by 12.4% year-on-year to US\$2,176 million.

- In addition to VESicare and Mycamine, Lexiscan, a pharmacologic stress agent continuously grew. On the contrary, revenue from Prograf fell due to the intensified competition following the launch of generics.
- Also, the Company booked sales of ¥31.8 billion generated by OSI in the Americas.

Net sales in Europe decreased by 19.5% year-on-year to ¥189.8 billion. The sales on a local currency basis fell 6.7% year-on-year to €1,678 million.

- Vesicare and Mycamine showed steady expansion in sales.
- Sales of Prograf decreased as a result of the impact of forex factors, however, sales on a local currency basis showed steady expansion, partly owing to the contribution from

Advagraf, a once daily formulation. Regarding Prograf, the launch of generics has been confirmed in several countries in Europe.

- Bulk sales and royalty income from the Harnal licensee in the U.S. declined significantly following the launch of generics in the U.S. in March 2010.

Net sales in Asia increased by 12.5% year-on-year to ¥33.7 billion.

- Products such as Prograf, Harnal, Vesicare and Mycamine demonstrated steady growth resulting in an increase in revenue.

### **Operating income**

Consolidated operating income decreased by 36.1% year-on-year to ¥119.1 billion.

- Gross profit was ¥657.9 billion, down 4.0% year-on-year, as net sales decreased and the cost-to-sales ratio was 31.0%, an increase of 1.3 of a percentage point year-on-year, due to a change in the product mix and other factors.
- Selling, general and administrative expenses increased by 7.9% year-on-year to ¥538.7 billion. Research and development (R&D) expenses included therein were ¥217.3 billion, up 11.1% year-on-year, and the R&D cost-to-sales ratio was up 2.7 percentage points year-on-year to 22.8%. In addition to an increase in expenses incurred due to the advancement of development projects, upfront and milestone payments increased for in-licensing, including a payment for the extension of a VelocImmune antibody technology agreement with U.S. pharmaceutical company Regeneron Pharmaceuticals, Inc. (concluded July 2010) and a payment for the conclusion of an agreement with AVEO Pharmaceuticals, Inc. of the US related to the co-development and commercialization of cancer treatment tivozanib (February 2011). Also, the Company recorded R&D costs of ¥12.7 billion incurred by OSI.
- Selling, general and administrative expenses, excluding R&D expenses, increased by 5.9% year-on-year to ¥321.4 billion. In addition to an increase in sales promotion expenses related to the launch of new products and expansion in business area, this reflected a year-on-year decline in refunds of marketing expenses from the licensee owing to the expiration of a co-promotion contract for Harnal in the U.S. In addition, the Company recorded amortization expenses of ¥20.1 billion for patents and goodwill recognized in association with the OSI acquisition.

### **Ordinary income**

Consolidated ordinary income decreased by 39.8% year-on-year to ¥115.0 billion.

- Non-operating income decreased by ¥1.9 billion year-on-year to ¥3.1 billion owing to a decline in interest income due to a drop in operating funds, while non-operating expenses increased by ¥6.7 billion year-on-year to ¥7.3 billion due to an increase in exchange loss.

### **Net income**

Consolidated net income decreased by 44.7% year-on-year to ¥67.6 billion.

- Special gains totaled ¥1.6 billion, reflecting the booking of gains on sales of investment securities and other items. Special losses totaled ¥13.2 billion, including, ¥4.7 billion in business integration expenses related to the acquisition of OSI as well as ¥3.0 billion related to the Eastern Japan Earthquake.

## 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 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.

[Initiatives in drug discovery research]

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 Diabetes Mellitus (DM) 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.

- In July 2010, the Company reached agreement with US pharmaceutical company Regeneron to extend its non-exclusive license agreement that allows Astellas to utilize Regeneron's VelocImmune technology in its internal research programs to discover fully human monoclonal antibody product candidates until 2023. The agreement was initially concluded in March 2007.

[Initiatives and progress with major projects in clinical development]

The Company plans to accelerate the pace of product development by channeling resources into high-priority projects. The following are main development advances by region made during FY 2010.

- In Japan, in June 2010, the Company submitted a market authorization application for mirabegron (generic name / code name: YM178), which is under development as a treatment for overactive bladder (OAB) to the Ministry of Health, Labour and Welfare of Japan (hereinafter referred to as "the MHLW"). The Company is seeking approval for the indication of urgency, urinary frequency, and urge urinary incontinence associated with OAB.
- In July 2010, Nippon Boehringer Ingelheim Co., Ltd. obtained approval of Micamlo Combination Tablets AP, a combination drug of telmisartan (Micardis), an angiotensin II receptor blocker (ARB), and amlodipine besylate, a calcium channel blocker (CCB), and the drug was released in October 2010. The Company sells Micamlo Combination Tablets AP and co-promotes its sales with Nippon Boehringer Ingelheim Co., Ltd.
- In September 2010, the Company submitted a market authorization application for Bonoteo,

a monthly oral tablet treatment for osteoporosis, co-developed in Japan with Ono Pharmaceutical Co., Ltd to the MHLW.

- In September 2010, Zeria Pharmaceutical Co., Ltd. submitted an application for marketing approval for therapeutic agent YM443 (Zeria's development code: Z-338), a treatment for functional dyspepsia that the Company has co-developed in Japan with Zeria to the MHLW.
- In October 2010, the Company submitted a market authorization application for prostate cancer treatment Degarelix (drug effective for one month), for which it secured exclusive rights to develop and market in Japan from Ferring Pharmaceuticals, to the MHLW.
- In October 2010, the Company obtained approval for the manufacture and distribution of Vesicare OD as an additional formulation (orally-disintegrating tablet) of the overactive bladder treatment Vesicare with the indication of urinary frequency, urgency, and urge incontinence associated with overactive bladder. Vesicare OD was launched in Japan in April 2011.
- In March 2011, the Company submitted an application in Japan for marketing approval for bixalomer (ASP1585) for the treatment of hyperphosphatemia in patients on dialysis with chronic kidney disease, and a supplemental new drug application for Celecox for the indication of anti-inflammatory and analgesic effects in post-operation, post-trauma, and post-tooth extraction.
- In February 2011, the Company decided to withdraw its market authorization application for oral Factor Xa direct inhibitor darexaban maleate (YM150), which was submitted in September 2010, after the Pharmaceuticals and Medical Devices Agency (PMDA) provided their view that Astellas should conduct additional clinical studies to supplement the current application package in order to achieve approval. The original application was for the indication of the prevention of venous thromboembolism ("VTE") in patients at risk, such as those undertaking orthopedic surgical procedures in the lower limbs.

[Status of product in-licensing and alliance activities]

In parallel with in-house drug development, the Company is actively working to boost its development pipeline of new drug candidates through in-licensing from and sales alliance with other companies. The following are the main product in-licensing made during FY 2010.

- In September 2010, the Company entered into a co-development and exclusive commercialization license agreement in Japan with UMN Pharma Inc. for UMN-0501 and UMN-0502, which are cell culture based influenza vaccine programs being developed by UMN Pharma.
- In October 2010, the Company concluded an exclusive worldwide license agreement to develop, manufacture and commercialize AKP-002 being developed by ASKA Pharmaceutical Co., Ltd. AKP-002 is under development for the treatment of functional symptoms of benign prostate hyperplasia.
- In October 2010, the Company entered into a definitive option agreement with Alavita Pharmaceuticals, Inc. of the U.S., pursuant to which the Company is granted an exclusive option to acquire all of Alavita's assets and rights relating to Diannexin, a drug to prevent

impairment of organ function after kidney transplantation.

- In February 2011, the Company concluded a license agreement with Optimer Pharmaceuticals Inc. of the US for the development and commercialization of fidaxomicin, an investigational antibiotic for Clostridium difficile infection (CDI), in Europe, the Middle East, Africa, and the Commonwealth of Independent States (CIS).
- In February 2011, the Company and AVEO Pharmaceuticals, Inc. of the U.S. entered into a worldwide agreement outside Japan, Asia and the Middle East to develop and commercialize cancer treatment tivozanib.

Other initiatives during FY2010 included the following:

- In December 2010, the Company and Cytos Therapeutics, Inc. of the US entered into a strategic equity agreement to evaluate the potential of adipose derived stem and regenerative cells for the treatment of serious illnesses as part of efforts to reinforce basic technologies in regenerative drug creation.
- In March 2011, the Company exercised a buy-out option to acquire all of the ownership interest (83.3%) of Maxygen, Inc. in Perseid Therapeutics LLC, the joint venture between Maxygen and Astellas, for \$76 million. The Company aims to make Perseid a wholly owned subsidiary in the first quarter of FY2011. As a result of the deal, the Company will secure the sole ownership of protein pharmaceutical programs including MAXY-4 program, which it is currently co-developing with Perseid.

[Technological development]

In October 2010, the Company transferred the antibody research group at the Fermentation and Biotechnology Laboratories in Kiyosu, Aichi Prefecture to Tokodai in Tsukuba to promote closer cooperation with the drug discovery research functions of the Tsukuba Research Center (Miyukigaoka). A facility to manufacture drug substances for development of antibody was completed in March 2011, which will further accelerate the Company's antibody biotechnology research efforts.

#### **Other initiatives to reinforce business platform**

The Company is actively working to reinforce its business platform through the initiatives, etc. described below.

- The Company's subsidiaries in China and Hong Kong concluded exclusive agreements in April 2010 with Teijin Pharma Limited covering the sale in China and Hong Kong of TMX-67, a Teijin Pharma's treatment for hyperuricemia in patients with gout. This followed an exclusive sales agreement for TMX-67 for the Taiwanese market.
- Concerning the treatment for advanced prostate cancer Eligard that we are selling in Europe, we concluded a contract with TOLMER Inc. of the US in December 2010 expanding the sales region to newly include countries in Asia, the Middle East, North Africa and the Commonwealth of Independent States (CIS).

- In January 2011, the Company issued a notice that it had exercised its right under its agreement with co-promotion partner, the US subsidiary of GlaxoSmithKline plc, to assume full commercial responsibility in the US for VESicare. The US subsidiary of GlaxoSmithKline plc sales representatives will no longer co-promote VESicare after December, 2011. The Company's US subsidiary will undertake all promotional activities for the drug from January 2012.
- In March 2011, the Company entered into an exclusive license agreement with Cardeus Pharmaceuticals, Inc. of the US to develop, manufacture and commercialize three Astellas compounds in all territories excluding Japan. Under the agreement, two clinical stage compounds, an I<sub>f</sub> channel inhibitor, YM758, and a selective COX1 inhibitor, ASP6537, as well as one pre-clinical stage compound are licensed to Cardeus.
- Also, the Company is expanding its business globally, particularly in Europe, the U.S. and Asia, and at present, it has constructed its own sales distribution channels in more than 40 countries across the globe. The Company has already established sales subsidiaries in China, Russia, Brazil and India, all of which are experiencing high rates of economic growth, and it steadily expanded its operating reach further in FY2010 with the establishment of a sales subsidiary in Australia and a sales subsidiary in Slovenia in December 2010 to oversee all sales activities in Southeast Europe.
- The Company established Astellas Pharma Tech Co., Ltd. on April 1, 2011 through the merger of its three manufacturing subsidiaries, Astellas Tokai Co., Ltd., Astellas Toyama Co., Ltd., and Astellas Pharma Chemicals Co., Ltd, for the purpose of enhancing functions for reliable and timely supplies of active pharmaceutical ingredient for clinical trial material and investigational drugs, early establishment of manufacturing know-how for new products, and stable supplies of products for the Astellas Group.

## Consolidated business forecasts for FY2011

### Consolidated first six months business forecasts

(Millions of yen – fractions dropped)

	FY2010 First six months results	FY2011 First six months forecasts	Change (%)
Net sales	461,729	<b>488,000</b>	+26,270 (+5.7%)
Operating income	67,920	<b>77,000</b>	+9,079 (+13.4%)
Ordinary income	65,499	<b>78,000</b>	+12,500 (+19.1%)
Net income	43,887	<b>43,000</b>	-887 (-2.0%)

### Consolidated full-year business forecasts

(Millions of yen – fractions dropped)

	FY2010 Full-year results	FY2011 Full-year forecasts	Change (%)
Net sales	953,947	<b>974,000</b>	+20,052 (+2.1%)
Operating income	119,180	<b>135,000</b>	+15,819 (+13.3%)
Ordinary income	115,058	<b>136,500</b>	+21,441 (+18.6%)
Net income	67,650	<b>81,000</b>	+13,349 (+19.7%)

(Notes)	<b>Expected exchange rate for FY2011</b>	<b>¥80/US\$</b>	<b>¥110/€</b>
	Exchange rate for FY2010	¥86/US\$	¥113/€
	Exchange rate for the first six months of FY2010	¥89/US\$	¥114/€

The annual forecasts for the fiscal year ending March 31, 2012 (FY2011) are shown above; Net sales is anticipated to increase whereas operating income, ordinary income and net income are anticipated to increase 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 ¥19.6 billion decrease in net sales and ¥2.9 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 addition to our projections for an expansion in sales in Japan from mainstay products and new products, we also project the sales from OSI Pharmaceuticals to contribute to increasing net sales. As a result, the net sales forecast is ¥974.0 billion (up 2.1% year-on-year).

## **Sales by geographical segments**

### **<Japan>**

We expect growth in mainstay products such as Vesicare, Prograf (including a once-daily modified release formulation, Graceptor), Micardis (including Micombi and Micamlo) and Myslee as well as contributions from new products, including Symbicort, Celecox, Bonoteo, and Geninax, an oral type quinolone antibacterial agent, which will increase sales of ethical pharmaceuticals in Japanese market.

### **<Overseas>**

In the Americas, while Prograf is expected to decline due to intensified competition following the launch of generics, we project a steady expansion in sales from VESIcare and Mycamine and we also project the sales from OSI Pharmaceuticals to contribute to an increase in net sales.

In Europe, while we project a steady expansion in sales from Vesicare, Mycamine and Eligard, we also project royalty income from bendamustine to contribute to increasing net sales. On the other hand sales by our own distribution channel for Prograf and Harnal (Omnice/Omnice OCAS) are expected to decline.

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

## **Operating income, ordinary income and net income**

We project an increase in gross profit due to an increase in net sales. We also project a rise in the cost to sales ratio due to changes in product mix.

Selling, general and administrative expenses are expected to increase. Among them, we project research and development (R&D) expenses of ¥199.0 billion (down 8.4% year-on-year) and the R&D cost-to-sales ratio of 20.4% representing a decrease compared to the fiscal year under review, during which upfront payments in relation to in-licensing were recorded to R&D expense. We project an increase in selling, general and administrative expenses excluding R&D expenses due not only to the costs accompanying product sales promotion and expansion of the sales area, but also amortization expenses for patents and goodwill recognized in association with the OSI acquisition and others.

As a result, we project an operating income of ¥135.0 billion (up 13.3% year-on-year).

Ordinary income is forecasted at ¥136.5 billion (up 18.6% year-on-year) with ¥81.0 billion in net income (up 19.7% year-on-year).

The Company estimates that ¥1.5 billion of fixed cost arising from the suspension of operations of

disaster affected research centers and plants and others are to be booked as special losses.

## **(2) Analysis of financial conditions**

### **1) Assets, liabilities and net assets**

An overview of the consolidated balance sheets as of March 31, 2011 and the main changes from the end of the previous fiscal year are shown below.

#### **Assets**

Total assets as of March 31, 2011 saw a decrease of ¥29.0 billion compared to the end of the previous fiscal year to ¥1,335.0 billion.

**<Current assets>** ¥653.1 billion (a decrease of ¥335.3 billion)

- Partly reflecting the acquisition of OSI shares, cash on hand and in banks decreased by ¥169.3 billion and marketable securities decreased by ¥191.1 billion.

**<Fixed assets>** ¥681.9 billion (an increase of ¥306.3 billion)

- Property, plant and equipment increased by ¥5.6 billion compared to the end of the previous fiscal year to ¥190.1 billion.
- Intangible fixed assets increased by ¥304.4 billion compared to the end of the previous fiscal year to ¥367.1 billion.

The OSI acquisition resulted in an increase in intangible fixed assets owing to the booking of patents and goodwill.

- Investments and other assets amounted to ¥124.5 billion, a decrease of ¥3.7 billion compared to the end of the previous fiscal year, due to a decrease of ¥10.5 billion in investment securities.

#### **Liabilities**

Liabilities increased by ¥3.7 billion compared to the end of the previous fiscal year to ¥313.9 billion.

**<Current liabilities>** ¥239.6 billion (a decrease of ¥37.5 billion)

- Liabilities such as other accounts payable declined by ¥43.3 billion.

**<Long-term liabilities>** ¥74.3 billion (an increase of ¥41.2 billion)

- Partly as a result of the amounts booked through the application of business combination accounting for the OSI acquisition, deferred tax liabilities increased by ¥42.2 billion.

#### **Net assets**

Net assets decreased by ¥32.8 billion compared to the end of the previous fiscal year to ¥1,021.0 billion making the equity ratio 76.4%.

- While net income stood at ¥67.6 billion, ¥57.7 billion of dividends of surplus were paid. In addition, the change in translation adjustments of ¥38.0 billion had the effect of reducing net

assets by the same amount.

In May 2010, 8 million shares of treasury stock valued at ¥30.6 billion were cancelled.

## 2) Cash flow

### Cash flows from operating activities

Net cash provided by operating activities decreased year-on-year by ¥49.4 billion to ¥100.6 billion.

- Income before income taxes and minority interests decreased year-on-year by ¥83.3 billion to ¥103.4 billion and income taxes paid was ¥44.4 billion, a decrease of ¥34.9 billion year-on-year.

### Cash flows from investing activities

Net cash used in investing activities was ¥242.6 billion, an increase in outflow of ¥211.0 billion year-on-year.

- Cash of ¥284.1 billion was used for the acquisition of shares of subsidiaries. Meanwhile, the net balance of purchases and sales of marketable securities and investment securities provided cash of ¥86.3 billion, an increase in cash inflow of ¥53.8 billion year-on-year.
- ¥17.0 billion was used for purchases of intangible fixed assets, a decrease of ¥7.6 billion year-on-year.

### Cash flows from financing activities

Net cash used in financing activities was ¥93.2 billion, an increase in outflow of ¥7.3 billion year-on-year.

- Cash dividends paid increased by ¥1.3 billion year-on-year to ¥57.7 billion. In addition, the Company used ¥34.9 billion for the redemption of corporate bonds issued by OSI.
- However, cash used for the purchases of treasury stock declined by ¥26.9 billion year-on-year.

As a result of the above, cash and cash equivalents totaled ¥175.4 billion as of March 31, 2011, a decrease of ¥256.4 billion compared to the end of the previous fiscal year.

### **Cash flow indicators**

	FY2006	FY2007	FY2008	FY2009	FY2010
Equity ratio (%)	74.7	77.1	76.3	77.1	76.4
Equity ratio on a fair market value basis (%)	177.7	133.6	105.3	114.6	106.5
Cash flows to interest-bearing liabilities ratio (%)	0.8	0.0	0.0	0.0	0.0
Interest coverage ratio (times)	694.6	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.

Annual dividend for FY2010 is planned to be ¥125 per share (including year-end dividend of ¥65 per share) to shareholders, yielding DOE of 5.6 %.

The Company anticipates that the annual dividend in the FY2011 to be ¥125 per share (composed of interim dividend of ¥60 per share and year-end dividend of ¥65 per share).

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, 2010	As of March 31, 2011
<b>Assets</b>		
Current assets		
Cash on hand and in banks	¥312,196	¥142,895
Trade notes and accounts receivable	228,088	262,512
Marketable securities	225,078	33,908
Merchandise and finished goods	82,749	82,655
Work in process	12,152	13,610
Raw materials and supplies	16,151	20,615
Deferred tax assets	63,316	67,803
Other	50,461	30,548
Allowance for doubtful receivables	(1,650)	(1,395)
Total current assets	988,544	653,154
Fixed assets		
Property, plant and equipment		
Buildings and structures	96,123	97,106
Machinery, equipment and vehicles	22,317	24,660
Tools, furniture and fixtures	15,818	11,425
Land	30,190	31,374
Construction in progress	18,679	24,128
Other	1,359	1,464
Total property, plant and equipment	184,489	190,160
Intangible fixed assets		
Goodwill	22,159	101,255
Patents	—	236,736
Other	40,601	29,186
Total intangible fixed assets	62,760	367,178
Investments and other assets		
Investment securities	70,797	60,204
Deferred tax assets	46,899	52,294
Other	10,740	12,144
Allowance for doubtful receivables	(56)	(44)
Total investments and other assets	128,382	124,598
Total fixed assets	375,632	681,936
Total assets	¥1,364,176	¥1,335,091

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

	As of March 31, 2010	As of March 31, 2011
<b>Liabilities</b>		
Current liabilities		
Trade notes and accounts payable	¥84,024	¥88,601
Other accounts payable	93,964	50,631
Accrued expenses	62,317	73,089
Accrued income taxes	21,216	19,813
Accrued consumption tax	2,588	1,401
Deferred tax liabilities	12	—
Accrued bonus for directors	34	31
Allowance for sales rebates	3,697	3,469
Other	9,301	2,609
Total current liabilities	277,157	239,648
Long-term liabilities		
Deferred tax liabilities	—	42,248
Accrued retirement benefits for employees	17,638	17,235
Accrued retirement benefits for directors	24	—
Other	15,422	14,862
Total long-term liabilities	33,085	74,346
Total liabilities	310,243	313,994
<b>Net assets</b>		
Shareholders' equity		
Common stock	103,000	103,000
Capital surplus	176,821	176,821
Retained earnings	895,101	874,351
Treasury stock	(54,160)	(23,492)
Total shareholders' equity	1,120,763	1,130,682
Accumulated other comprehensive income		
Unrealized holding gains on securities	14,153	9,479
Foreign currency translation adjustments	(82,542)	(120,587)
Total accumulated other comprehensive income	(68,388)	(111,107)
Stock subscription rights	1,205	1,522
Minority interests	352	—
Total net assets	1,053,933	1,021,096
Total liabilities and net assets	¥1,364,176	¥1,335,091

## (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, 2010	For the year ended March 31, 2011
Net sales	¥974,877	¥953,947
Cost of sales	289,240	295,972
Gross profit	685,637	657,974
Selling, general and administrative expenses	499,229	538,794
Operating income	186,407	119,180
Non-operating income		
Interest income	2,781	1,120
Dividend income	1,157	1,217
Equity in earnings of affiliates	83	—
Exchange gain	225	—
Other	920	848
Total non-operating income	5,168	3,186
Non-operating expenses		
Equity in losses of affiliates	—	89
Exchange loss	—	6,556
Other	589	662
Total non-operating expenses	589	7,308
Ordinary income	190,986	115,058
Special gains		
Gain on sales of fixed assets	48	298
Gain on sales of investment securities	2,700	1,280
Other	277	97
Total special gains	3,026	1,676
Special losses		
Loss on sales and disposal of fixed assets	2,282	1,276
Loss on impairment of fixed assets	4,082	2,782
Loss on disaster	—	3,029
Business integration expenses	—	4,723
Loss on adjustment for changes of accounting standard for asset retirement obligations	—	559
Other	846	881
Total special losses	7,211	13,253
Income before income taxes and minority interests	186,802	103,482
Income taxes-current	64,716	43,554
Income taxes-deferred	(2,110)	(7,722)
Total income taxes	62,606	35,831
Income before minority interests	—	67,650
Minority interests	1,938	—
Net income	¥122,257	¥67,650

## (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, 2010	For the year ended March 31, 2011
Income before minority interests	—	¥67,650
Other comprehensive income *Note1		
Unrealized holding losses on securities	—	(4,674)
Foreign currency translation adjustments	—	(38,044)
Total other comprehensive income	—	(42,718)
Comprehensive income *Note2	—	24,932
- attributable to owners of the parent	—	24,932
- attributable to minority interests	—	—

Notes;

\*1 Other comprehensive income for the year ended March 31, 2010

Unrealized holding gains on securities	¥4,134 million
Foreign currency translation adjustments	¥(19,637) million
Total other comprehensive income	¥(15,502) million

\*2 Comprehensive income for the year ended March 31, 2010

- attributable to owners of the parent	¥106,754 million
- attributable to minority interests	¥1,938 million
Total comprehensive income	¥108,693 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, 2010	For the year ended March 31, 2011
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	957,346	895,101
Movements during the year		
Cash dividends paid	(56,401)	(57,727)
Net income	122,257	67,650
Disposal of treasury stock	(16)	(45)
Cancellation of treasury stock	(128,083)	(30,627)
Total movements during the year	(62,244)	(20,749)
Balance at end of year	895,101	874,351
Treasury stock		
Balance at end of previous year	(155,295)	(54,160)
Movements during the year		
Purchase of treasury stock	(26,996)	(29)
Disposal of treasury stock	48	70
Cancellation of treasury stock	128,083	30,627
Total movements during the year	101,134	30,668
Balance at end of year	(54,160)	(23,492)
Total shareholders' equity		
Balance at end of previous year	1,081,873	1,120,763
Movements during the year		
Cash dividends paid	(56,401)	(57,727)
Net income	122,257	67,650
Purchase of treasury stock	(26,996)	(29)
Disposal of treasury stock	31	24
Cancellation of treasury stock	—	—
Total movements during the year	—	9,918
Balance at end of year	¥1,120,763	¥1,130,682

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

	For the year ended March 31, 2010	For the year ended March 31, 2011
Accumulated other comprehensive income		
Unrealized holding gains on securities		
Balance at end of previous year	¥10,018	¥14,153
Movements during the year		
Net change in items other than shareholders' equity	4,134	(4,674)
Total movements during the year	4,134	(4,674)
Balance at end of year	14,153	9,479
Foreign currency translation adjustments		
Balance at end of previous year	(62,904)	(82,542)
Movements during the year		
Net change in items other than shareholders' equity	(19,637)	(38,044)
Total movements during the year	(19,637)	(38,044)
Balance at end of year	(82,542)	(120,587)
Total accumulated other comprehensive income		
Balance at end of previous year	(52,886)	(68,388)
Movements during the year		
Net change in items other than shareholders' equity	(15,502)	(42,718)
Total movements during the year	(15,502)	(42,718)
Balance at end of year	(68,388)	(111,107)
Stock subscription rights		
Balance at end of previous year	894	1,205
Movements during the year		
Net change in items other than shareholders' equity	310	316
Total movements during the year	310	316
Balance at end of year	1,205	1,522
Minority interests		
Balance at end of previous year	338	352
Movements during the year		
Net change in items other than shareholders' equity	13	(352)
Total movements during the year	13	(352)
Balance at end of year	352	—
Total net assets		
Balance at end of previous year	1,030,221	1,053,933
Movements during the year		
Cash dividends paid	(56,401)	(57,727)
Net income	122,257	67,650
Purchase of treasury stock	(26,996)	(29)
Disposal of treasury stock	31	24
Cancellation of treasury stock	—	—
Net change in items other than shareholders' equity	(15,178)	(42,754)
Total movements during the year	23,712	(32,836)
Balance at end of year	¥1,053,933	¥1,021,096

#### (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, 2010	For the year ended March 31, 2011
Cash flows from operating activities		
Income before income taxes and minority interests	¥186,802	¥103,482
Depreciation and amortization	38,683	54,541
Loss on impairment of fixed assets	4,082	2,782
Amortization of goodwill	9,782	11,132
Increase in allowance for doubtful receivables	700	—
Increase in accrued retirement benefits for employees	1,547	1,346
Interest and dividend income	(3,938)	(2,338)
Exchange gain	(198)	—
Equity in earnings of affiliates	(83)	—
Net loss on sales and disposal of fixed assets	2,233	978
Increase in trade notes and accounts receivable	(8,400)	(31,711)
Increase in inventories	(8,740)	(10,678)
(Decrease) increase in trade notes and accounts payable	(3,591)	7,388
Increase (decrease) in other accounts payable	1,540	(11,728)
Other	4,937	17,779
Subtotal	225,355	142,974
Interest and dividends received	4,097	2,287
Interest paid	—	(220)
Income taxes paid	(79,323)	(44,402)
Net cash provided by operating activities	150,130	100,639
Cash flows from investing activities		
Purchases of marketable securities	(153,625)	(2,931)
Proceeds from sales of marketable securities	184,112	83,845
Purchases of property, plant and equipment	(39,524)	(33,630)
Proceeds from sales of property, plant and equipment	1,014	628
Purchases of intangible fixed assets	(24,775)	(17,083)
Purchases of investment securities	(9,477)	(1,373)
Proceeds from sales of investment securities	—	6,759
Purchases of investments in subsidiaries resulting in change in scope of consolidation	—	(284,148)
Loans receivable made	(40)	—
Collection of loans receivable	67	—
Net (increase) decrease in short-term investments	(1,902)	8,683
Other	1,155	(3,397)
Net cash used in investing activities	(31,580)	(242,648)
Cash flows from financing activities		
Redemption of bonds	—	(34,968)
Purchases of treasury stock	(26,996)	(29)
Cash dividends paid	(56,401)	(57,727)
Cash dividends paid to minority shareholders	(1,907)	—
Other	(596)	(542)
Net cash used in financing activities	(85,902)	(93,267)
Effects of exchange rate changes on cash and cash equivalents	(10,554)	(21,178)
Increase (decrease) in cash and cash equivalents	22,093	(256,454)
Cash and cash equivalents at beginning of year	409,826	431,920
Cash and cash equivalents at end of year	¥431,920	¥175,465

## (5) Business Combination

For the year ended March 31, 2011

[Acquisition of stock of OSI Pharmaceuticals, Inc. ]

### (1) Outline of the business combination

#### a. Name and the primary business of the acquired company

Name of the acquired company: OSI Pharmaceuticals, Inc. (“OSI”)

Primary business of the acquired company: Research and development, and marketing of pharmaceuticals in oncology and diabetes/obesity fields

#### b. Primary reasons for the business combination

The Company has set goals of becoming a “Global Category Leader” (“GCL”) in its “VISION 2015”. In order to realize GCL in the oncology field, the Company has defined that therapeutic field as one of its prioritized research areas and has been taking initiatives to quickly establish the oncology platform. This acquisition will quickly provide a top-tier oncology business in the United States and further expand its product portfolio and pipeline. Furthermore, by adding not only OSI’s oncology infrastructure, but also its discovery platform and talent base to the Company’s existing business, the Company can strengthen its growth strategies through maximizing the value of business resources possessed by both companies. In addition to these contributions to mid- and long-term growth, this acquisition is expected to contribute the Company’s performance even in shorter-term through the revenue from Tarceva, an anti-cancer blockbuster product generated by OSI.

#### c. Date of the business combination

June 8, 2010

#### d. Legal form of the business combination and the name of the acquired company after the business combination

Legal form of the business combination: Cash acquisition of OSI’s stock

Name of the company after the business combination: OSI Pharmaceuticals, Inc.

#### e. Ratio of voting rights acquired

100%

#### f. Reason to determine the acquiring company

The transaction was the all-cash acquisition by the Company’s subsidiary, Astellas US Holding, Inc.

- (2) Period of the operating results of the acquired company included in the consolidated statement of income for the cumulative period

From July 1, 2010 to March 31, 2011

- (3) Acquisition cost and its breakdown

Cost for the acquisition by tender offer \$3,525 million (¥293,123 million)

Direct costs for the acquisition \$18 million ( ¥1,557 million)

Total acquisition cost \$3,543 million (¥294,681 million)

- (4) Goodwill

- a. Amount of goodwill

\$1,107 million (¥92,106 million)

- b. Reason to recognize goodwill

Goodwill was recognized as the acquisition cost exceeded the net amount allocated to assets acquired and liabilities assumed.

- c. Amortization method and period

Goodwill will be amortized by the straight-line method over twenty years.

- (5) Breakdown of assets acquired and liabilities assumed as of the date of the business combination

Current assets \$539 million ( ¥44,827 million)

Non-current assets \$4,578 million (¥380,722 million)

Assets total \$5,117 million (¥425,549 million)

Current liabilities \$522 million ( ¥43,486 million)

Non-current liabilities \$1,050 million ( ¥87,382 million)

Liabilities total \$1,573 million (¥130,868 million)

As a result of purchase price allocation, the acquisition cost has been allocated to intangible assets except goodwill by \$2,815 million (¥234,067 million). The intangibles are composed of (1) already launched or approved products amounting \$2,024 million (¥168,295 million) and (2) in-process research and development amounting \$791 million (¥65,771 million). Amortization period of each of those assets has been individually determined based on a useful life of each asset.

- (6) Estimated impacts of the business combination on the Company's business results assuming the business combination occurred at the beginning of the fiscal year

If the business combination had been completed at the beginning of the fiscal year, the effect on net sales would have increased by approximately ¥9.3 billion, while operating income and income before income taxes and minority interests would have decreased by approximately ¥13.3 billion and ¥13.5 billion, respectively. These figures include the operating results of OSI during April 1 to

June 30, 2010 and estimated amortization of goodwill and intangibles for the relevant period.  
(note) These estimated figures have not been audited by our independent auditor.