



Changing tomorrow

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ANNUAL REPORT 2012

For the Year Ended March 31, 2012

# Changing tomorrow

Astellas' raison d'être is to "contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products." Guided by this business philosophy, Astellas is actively developing its business operations as a research and development-oriented global pharmaceutical company.

To realize this philosophy, we are committed to the ongoing research and development of innovative and highly useful new drugs in therapeutic areas where there is a high degree of unmet medical needs, meaning that there are still insufficient therapies for treatment. In delivering our new drugs to the world, our desire is to be a source of strength for each and every patient battling illness.



Our communications slogan, "Changing tomorrow," was born from this desire. This slogan encapsulates the commitment and resolve of Astellas employees worldwide to constantly rise to the challenge of creating drugs that are truly needed. It also reflects our desire to give courage and hope to patients afflicted by illness.

Astellas will continue working to change tomorrow for patients and their families with new ethical pharmaceutical products.

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## This annual report

From this year's annual report for fiscal 2011, we have integrated the contents of our Annual Report and the CSR report into a single publication.

## What CSR-Based Management Means at Astellas



Astellas constantly monitors its corporate activities from a CSR perspective

Astellas has positioned its CSR-based management objectives at the heart of its business philosophy. It is "a means through which we strive toward sustained enhancement of enterprise value while remaining acutely aware of our social responsibilities and taking a broad view that considers economics, society, and humanity so that we can exist not merely as a market entity, but also as a valuable member of society."

# The Five Fields of CSR-Based Management



### Economy (Business Activities)

Business activities ranging from the research and development of new drugs through to production and marketing



### Employees

Efforts to cultivate human resources and foster a workplace in which employees can concentrate on their work



### Society

Initiatives for contributing to society with a focus on the medical field



### Environment

Initiatives to reduce the environmental burden in order to realize a sustainable society



### Compliance

Efforts to maintain integrity in all actions and uphold the highest ethical standards in corporate activities

Astellas has established five fields of CSR-based management—the economy, employees, society, the environment, and compliance. We consider compliance to be the foundation for the other four fields. In all five fields, we act with integrity as we continuously fulfill our social responsibilities.

## Business Philosophy

### Raison d'être

#### Contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products

- To go beyond all others in exploring and tapping the potential of the life sciences.
- To continue tackling new challenges and creating innovative pharmaceutical products.
- To deliver quality products along with accurate information and retain solid credibility among customers.
- To support healthy living for people around the world.
- To continue shining on the global pharmaceutical field.

### Mission

#### Sustainable enhancement of enterprise value

- Astellas will seek to enhance its enterprise value in a sustainable manner.
- Astellas will seek to be the company of choice among all its stakeholders, including its customers, shareholders, employees, and the global community. Astellas will strive to gain the trust of all stakeholders and thereby enhance its enterprise value.

### Beliefs

Our "beliefs" provide the code of conduct we prize at all times. Astellas will always be a group of people who act upon these beliefs.

**High Sense of Ethics** We will always manage our business with the highest sense of ethics.

**Customer Focus** We will always seek to understand customer needs and our focus will always be on achieving customer satisfaction.

**Creativity** We will not be complacent and will always seek to innovate to create new value.

**Competitive Focus** Our eyes will always be directed to the outside world, and we will continue to create better value faster.

## Editorial Policy

This report has integrated Astellas' Annual Report with its CSR report. Until now, these two reports had been published separately. We decided to merge these two publications as a means of deepening stakeholders' understanding of our business activities and CSR-based management, which is the base for those activities.

The information contained in this Annual Report 2012 is organized according to the five fields of CSR-based management, namely, the economy, employees, society, the environment, and compliance. Please note that content related to employees concerning aspects such as the work environment and human rights, which would normally be found under "Society," have been included in the "Employees" field. Similarly, content related to the value chain is included under "CSR Initiatives in Business Processes" in the "Economy" field.

The basic purpose of this report is to provide an overview of the activities of Astellas Pharma Inc. and its consolidated subsidiaries worldwide in fiscal 2011, which covers the period from April 1, 2011 to March 31, 2012. The figures indicated in the fiscal 2011 status report for the field of "Environment," however, present the results for fiscal year 2011 (April 1, 2011 to March 31, 2012) in Japan and the calendar year 2011 (January 1, 2011 to December 31, 2011) for overseas operations as a combined total. In each instance where the period or scope of particular content varies from these parameters, we have provided clarification.

We have used charts, photographs, and other visual aids to make the report easy to understand so that it may aid communication between the Company and its many stakeholders.

### Note about forward-looking statements and forecasts

Statements made in this annual report with respect to current plans, estimates, strategies and beliefs and other statements of Astellas that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. Consequently, undue reliance should not be placed on these statements. Astellas cautions the reader that a number of important factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions, and in the Pharmaceutical Affairs Law and other laws and regulations relating to markets of Astellas, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of intellectual property rights of third parties.

Note: Market size, market share and product ranking are sourced from IMS Health Information Services.

# Contents

- 004 Astellas Today and Tomorrow
- 008 Financial and Non-Financial Highlights
- 010 Fiscal 2011 Topics
- 012 Interview with the President
- 020 United Nations Global Compact Initiatives

## Economy (Business Activities)

021

- 022 Special Feature: Oncology
- 026 Review of Operations by Therapeutic Area
- 028 R&D Pipeline
- 032 Review of Global Operations
- 040 CSR Initiatives in Business Processes

## Employees

045

- 046 Basic Policy
- 047 Human Resource Strategies and Policies
- 049 Developing Human Resources  
—Training Programs—
- 052 Creating the Ideal Workplace
- 054 Five Messages for the Astellas Way

## Society

055

- 056 Basic Policy
- 057 Enrich the Lives of Patients
- 059 Enrich Healthcare Systems
- 061 Link with Society

## Environment

063

- 064 Basic Policy
- 065 Environmental Management
- 068 Reducing Greenhouse Gas Emissions
- 070 Global Warming Prevention Framework  
and Initiatives
- 072 Initiatives for Sustainable Biodiversity
- 074 Initiatives for Resource Recycling
- 075 Initiatives for Preventing Pollution
- 076 Environmental Accounting

## Compliance

077

- 078 Basic Policy
- 079 Compliance
- 082 Corporate Governance
- 086 Interview with an Outside Director
- 088 Global Management Committee Members
- 090 Directors, Corporate Auditors and  
Executive Officers

- 092 CSR Communication
- 093 Financial Section
- 134 Principal Subsidiaries and Affiliates
- 136 Corporate Data/Investor Information

## A S T E L L A S T O D A Y

### Our Profile

Leveraging our research and development capabilities, we are creating innovative new drugs by concentrating management resources in prescription drugs.

Net sales amount to approximately ¥1 trillion. We deliver a large number of highly useful new drugs to patients around the world. Today, Astellas is the second-largest pharmaceutical company in Japan and ranks among the top 20 in the world.

#### Vesicare—Treatment for overactive bladder (OAB)



Vesicare is an anticholinergic that relieves OAB symptoms, such as urinary urgency, urinary frequency, and urge urinary incontinence. At present, Vesicare is sold in approximately 70 countries and regions.

#### Prograf—Immunosuppressant



Prograf is an immunosuppressant that is used to prevent rejection in organ transplants. Sold in approximately 100 countries, it is establishing an enduring position in the transplantation field.

#### Harnal—Treatment for functional symptoms associated with benign prostatic hyperplasia (BPH)



Harnal is an alpha-1 blocker that relieves symptoms associated with BPH, including weak urinary stream nocturia, and the sensation of incomplete emptying of the bladder. Sold in approximately 100 countries and regions, Harnal has become the global standard treatment in this therapeutic area.

#### Fungard/Mycamine—Candin-type antifungal agent



This drug is a candin-type antifungal agent that features a new mechanism that inhibits cell wall biosynthesis. It is sold in approximately 40 countries and regions.

#### Protopic—Treatment for atopic dermatitis



Protopic is the world's first in the immunomodulator class ointment for the treatment of atopic dermatitis, and is available in some 70 countries and regions.



# Our Strengths

Astellas has five characteristic strengths. These strengths serve as a powerful force driving our growth.



\* **First-in-class**: Novel new drugs with high efficacy and a basic chemical structure that differs from existing drugs, and unique drugs that seek to significantly change conventional therapeutic systems

**Best-in-class**: Drugs that are clearly superior to other existing drugs

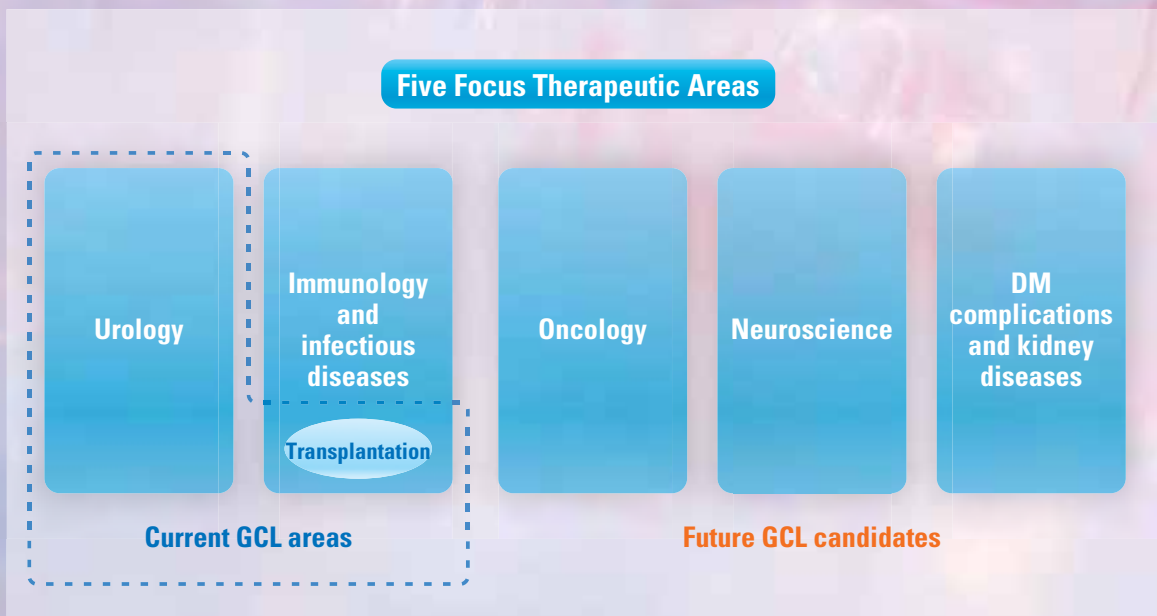
Source: The Pharmaceutical Society of Japan (Pharmaceutical Glossary)

# ASTELLAS TOMORROW

## VISION 2015

As a Global Category Leader (GCL) that delivers high-value-added pharmaceuticals worldwide, Astellas pursues a business model that establishes a competitive edge in therapeutic areas with a high level of unmet medical needs.

Astellas strives to create innovative new drugs in five focus therapeutic areas.





# 2014 Mid-Term Management Plan\*

To propel Astellas to a new stage, the Mid-Term Management Plan sets out three types of growth strategies—a therapeutic area strategy, a regional strategy, and an R&D innovation strategy—and also an efficiency strategy.

The plan calls for the swift establishment of a business platform to make oncology the third GCL therapeutic area behind urology and transplantation.

\*2014 Mid-Term Management Plan: Covers the five-year period from fiscal 2010 to fiscal 2014

## Therapeutic Area Strategy

- Maintain and strengthen GCL position in urology and transplantation
- Strengthen oncology franchise to realize third GCL

## Regional Strategy

- Expand well-balanced four-region business base
- Invest further in emerging countries with high potential

## R&D Innovation Strategy (Strengthen drug discovery research capabilities)

- Actively approach Precision Medicine drug discovery
- Prioritize strategic therapeutic areas
- Utilize cutting-edge technologies in drug discovery research
- Leverage global development framework to bolster pipeline

## Efficiency Strategy (Improve cost efficiency)

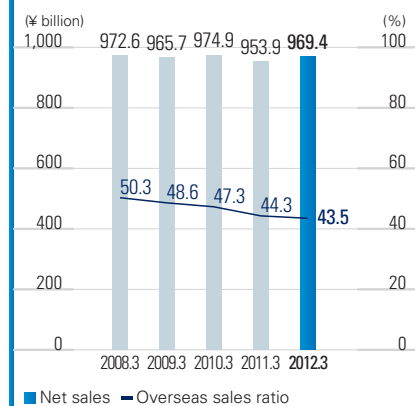
- Efficiently allocate resources through execution of therapeutic area strategy
- Manage well-focused expenditures
- Review business processes to achieve cost efficiency

# Financial and Non-Financial Highlights

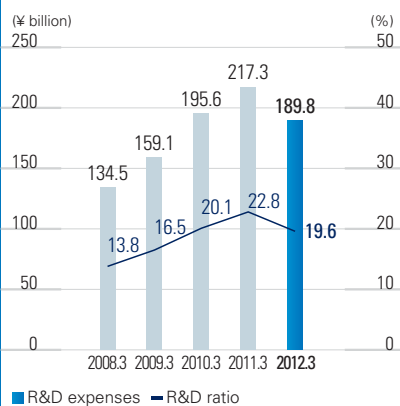
Years ended March 31

					(¥ billion)	(US\$ million)	(% Change)
	2008.3	2009.3	2010.3	2011.3	2012.3	2012.3	12/11
<b>For the year</b>							
Net sales	¥ 972.6	¥ 965.7	¥ 974.9	¥ 953.9	¥ 969.4	\$ 11,822	1.6
Cost of sales	279.3	264.4	289.2	296.0	318.6	3,886	7.7
SG&A expenses (incl. R&D expenses)	417.3	450.9	499.2	538.8	519.2	6,332	(3.6)
R&D expenses	134.5	159.1	195.6	217.3	189.8	2,315	(12.6)
R&D ratio (%)	13.8	16.5	20.1	22.8	19.6	—	—
Operating income	275.9	250.4	186.4	119.2	131.5	1,604	10.4
Operating margin (%)	28.4	25.9	19.1	12.5	13.6	—	—
Net income	177.4	171.0	122.3	67.7	78.2	954	15.6
<b>At year-end</b>							
Total assets	1,439.2	1,348.4	1,364.2	1,335.1	1,400.6	17,081	4.9
Total net assets	1,110.9	1,030.2	1,053.9	1,021.1	1,018.1	12,416	(0.3)
Working capital	692.7	680.1	711.4	413.5	466.9	5,694	12.9
<b>Per share data</b>							
Net income	¥ 349.89	¥ 356.11	¥ 261.84	¥ 146.49	¥ 169.38	\$ 2.07	15.6
Total net assets	2,228.34	2,189.26	2,278.77	2,207.70	2,200.64	26.84	(0.3)
Cash dividends	110.00	120.00	125.00	125.00	125.00	1.52	0.0
<b>Major indicators</b>							
ROE (%)	16.1	16.0	11.7	6.5	7.7	—	—
DOE (%)	5.0	5.4	5.6	5.6	5.7	—	—
Shareholders' equity ratio (%)	77.1	76.3	77.1	76.4	72.6	—	—
EBITDA*1 (¥ billion/US\$ million)	305.8	305.6	235.3	168.9	192.6	2,348	14.0
Free cash flows (¥ billion/US\$ million)	178.5	168.8	118.6	(142.0)	146.7	1,789	—
Average exchange rate (¥/US\$)	114	101	93	86	79	—	(8.1)
(¥/€)	162	143	131	113	109	—	(3.5)

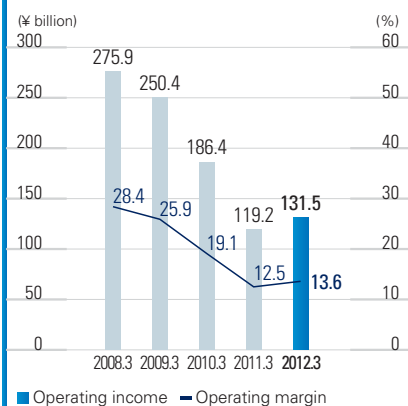
## Net Sales/Overseas Sales Ratio



## R&D Expenses/R&D Ratio



## Operating Income/Operating Margin



	(¥ billion)					(US\$ million)	(% Change)
	2008.3	2009.3	2010.3	2011.3	2012.3	2012.3	12/11
<b>Other indicators</b>							
Number of shares outstanding	518,964,635	503,964,635	475,964,635	467,964,635	467,964,635	—	—
Overseas sales* <sup>2</sup>	¥ 489.6	¥ 469.0	¥ 460.7	¥ 422.5	¥ 421.6	\$ 5,141	(0.2)
Overseas sales ratio (%)	50.3	48.6	47.3	44.3	43.5	—	—
<b>Sales by geographical area*<sup>3</sup></b>							
Japan	505.6	510.5	529.2	543.8	558.4	6,810	2.7
Americas	194.5	188.9	179.8	186.5	183.5	2,238	(1.6)
Europe	244.6	239.1	235.9	189.9	191.7	2,338	1.0
Asia	27.8	27.2	30.0	33.7	35.7	435	6.0
<b>Number of employees by geographical area</b>							
							(Number of people, Change)
Total	13,666	14,261	15,161	16,279	17,085		806
Japan	7,453	7,522	7,860	8,023	8,176		153
Americas	2,084	2,318	2,375	2,742	2,919		177
Europe	3,177	3,390	3,775	4,102	4,286		184
Asia	952	1,031	1,151	1,412	1,704		292

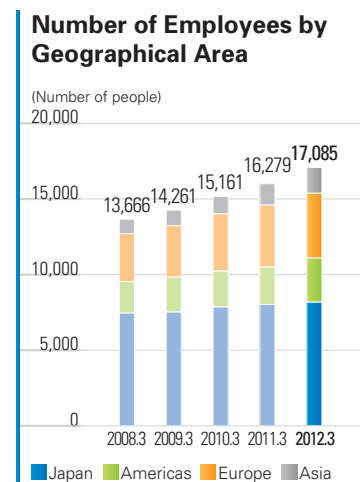
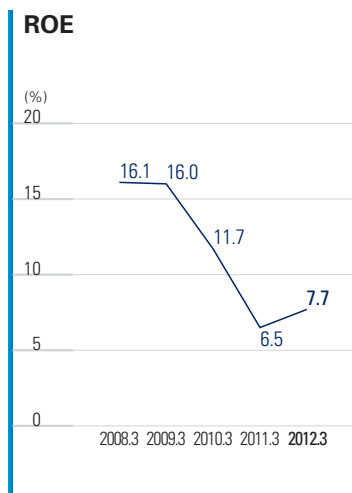
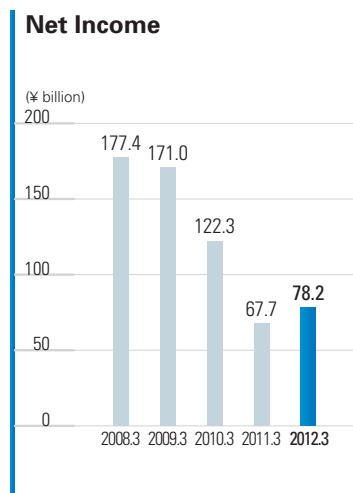
	2008.3	2009.3	2010.3	2011.3	2012.3	(% Change)
<b>Key environmental impact indicators</b>						
Amounts of energy consumption (thousand GJ)	4,350	4,431	4,359	4,463	4,257	(4.6)
Water usage (thousand m <sup>3</sup> )	15,446	14,917	14,441	14,110	12,365	(12.4)
Greenhouse gas emissions (kilotons)	225	211	205	203	189	(6.9)
VOC emissions (tons)	142	149	132	102	94	(7.8)
NOx emissions (tons)	48	43	44	41	31	(24.4)
SOx emissions (tons)	6	5	5	5	1	(80)

Note: US dollars have been converted at the rate of ¥82 to US\$1, the approximate exchange rate on March 31, 2012. US dollar amounts are included solely for convenience.

\*1 EBITDA = Income before income taxes and minority interests + interest expense + depreciation and amortization

\*2 Sales attributed by the location of customers

\*3 Attributed by the location of sellers



# Fiscal 2011 Topics

## April **Launch in Japan of Vesicare OD Tablets for Overactive Bladder Treatment**

An additional formulation of Vesicare, Vesicare OD Tablet is an orally disintegrating tablet that can be ingested without water. This new dosage form can further improve compliance for patients with overactive bladder (OAB).

## September **Launch in Japan of Bonoteo Tablets 50 mg for Osteoporosis Treatment**

Astellas launched Bonoteo Tablets 50 mg to be taken once every four weeks. The decrease in dose frequency offers enhanced convenience for patients.

## September **Launch in Japan of Betanis Tablets for Treatment of OAB**

The Betanis Tablet (generic name: mirabegron) is the world's first beta-3 adrenoceptor agonist used for the treatment of OAB. The addition of a new option to current standard therapy is expected to contribute to OAB treatment.

## August **Applications Filed for Mirabegron in United States and Europe**

Astellas filed applications in the United States and Europe for regulatory approval of the OAB treatment mirabegron. In June 2012, we obtained approval for mirabegron from the FDA in the United States (brand name: Myrbetriq).

## July **Astellas' Subsidiary Prosidion Sells Patent Estate for Type 2 Diabetes Drugs**

Subsidiary Prosidion Ltd. sold its patent estate and associated royalty stream relating to the use of dipeptidyl peptidase IV (DPP-IV) inhibitors for the treatment of type 2 diabetes to Royalty Pharma, a U.S. investment fund.

## May **Perseid Therapeutics Becomes Wholly-Owned Subsidiary**

Astellas completed its purchase of all of Maxygen, Inc.'s equity interest in Perseid Therapeutics LLC ("Perseid"), making the joint venture between Astellas and Maxygen a wholly-owned subsidiary. As a result of the acquisition, Astellas now has world-leading technology useful for developing protein therapeutics. Perseid is engaged in the research and development of protein therapeutics used for treating certain autoimmune diseases and preventing organ rejection after organ transplants.

## June **Yoshihiko Hatanaka Takes the Helm as Representative Director, President and CEO**

2011

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**November Positive Trial Results for Enzalutamide (code name: MDV3100) Currently Under Development**

Positive results were obtained from the Phase 3 AFFIRM trial of enzalutamide in men with metastatic castration-resistant prostate cancer previously treated with chemotherapy. Applications were filed in the United States and Europe, in May and June 2012 respectively, for patients with metastatic castration-resistant prostate cancer that had previously been treated with docetaxel-based chemotherapy.

**January Positive Trial Results for Tivozanib Currently Under Development**

Tivozanib demonstrated positive results in Phase 3 of the TIVO-1 clinical trial in patients with advanced renal cell carcinoma.

2012

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**March Wins Grand Prize in Japan's J-Win Diversity Awards**

Astellas became the first pharmaceutical company to receive the grand prize in the J-Win Diversity Awards. The awards recognize businesses that take a proactive and innovative approach to diversity and inclusion.

**November Signatory to United Nations Global Compact**

▶ Please see pages 17, 20 for details.

**March Wind Turbine Power Generation Station and Wood Chip Biomass Boiler Commissioned at Astellas' Kerry Plant in Ireland**

▶ Please see page 71 for details.

**September Debut on Dow Jones Sustainability Asia Pacific Index**

Astellas was included in the Dow Jones Sustainability Asia Pacific Index (DJSI Asia Pacific), which is the Asia Pacific version of the Dow Jones Sustainability Index, one of the world's premier indexes for socially responsible investment (SRI). The index assesses the sustainability of companies based on economic, environmental, and social criteria.



## Interview with the President



Our commitment is to deliver new drugs with high value to patients, aiming to achieve continuous growth and fulfill corporate social responsibilities.

Yoshihiko Hatanaka, president and CEO, explains the business strategies and CSR-based management in an interview.

Yoshihiko Hatanaka  
Representative Director,  
President and CEO

A handwritten signature in black ink, appearing to read 'Y. Hatanaka', written in a cursive style.







the United States and Europe in May and June 2012, respectively. These accomplishments demonstrate how recent investment in this area is steadily beginning to bear fruit.

### Regional Strategy

Astellas is developing a well-balanced global business spanning the four regions of Japan, the Americas, Europe, and Asia. Today, we have our own sales network that markets our products in more than 40 countries. In addition to global products such as Prograf, Harnal, and Vesicare, we also market local products distinctive to each region. Such local products underpin our growth, and add to one of Astellas' strengths.

We are also actively building a presence in emerging markets. We are focusing particular attention on China and Russia, where we are enjoying high growth thanks to the increase in the number of Medical Representatives (MRs) and other measures to reinforce our sales and marketing capabilities.

Pharmaceutical markets in emerging countries are expanding mainly as a result of generic drugs. However, we do not intend to increase sales using generic drugs. In emerging markets too, we are developing businesses that can and will be able to generate stable earnings in the future under the GCL model, centering on proprietary products with high added value.

### R&D Innovation Strategy

Our goal is to continuously create innovative drugs with high added value in therapeutic areas where high unmet medical needs exist. To this end, we are working to further improve our ability to generate new products through the strategies of "selectivity and concentration," "Precision Medicine," and "Multi-Track R&D."

Astellas' five focus therapeutic areas are urology, immunology (including transplantation) & infectious diseases, oncology, neuroscience, and diabetes mellitus complications & kidney diseases. Furthermore, we are selecting specific targets at the level of diseases in these areas. We optimize the allocation of resources by strictly prioritizing individual technologies and development projects.

We are reinforcing our "Precision Medicine" approach to drug discovery. This approach refers to the development of drugs that accurately target specific molecules that cause a particular disease combined with the development of diagnostics for identifying patients who will receive the most benefit from those drugs. Here at Astellas, we adopt this approach mainly in the field of oncology, and have already implemented it in roughly half of our oncology development projects. The development of companion diagnostic drugs is also ongoing

primarily through alliances with other companies.

The "Multi-Track R&D" strategy is based on the concept of actively utilizing not only our own resources, but also outside resources at each stage in the research and development process. The aim here is to deliver as many innovative drugs as possible to patients through optimization of costs and the control of risks associated with new drug R&D activities.

This strategy calls for forming alliances with outside institutions, such as Kyoto University and RIKEN, in the drug discovery phase. With the help of such alliances, we seek to discover innovative drugs by utilizing promising technologies and know-how that we do not possess.

In the development phase, there are compounds that we cannot promote at that particular time given their lower priority compared with other compounds, despite having the potential to be effective drugs. In such cases, our aim is to continue development while accessing outside capital and expertise through the formation of various alliances. Part of this initiative is our partnership with Drais Pharmaceuticals, Inc. concerning ASP3291 and ASP7147, which are currently in the early stages of clinical development.





Our challenge is to transform scientific progress into value for patients.



**Astellas is stepping up promotion of CSR-based management by becoming a signatory to the United Nations Global Compact.**

**QUESTION**

What is Astellas' understanding of CSR-based management?

We believe that it is imperative to practice CSR-based management in order to realize our *raison d'être*, which is "to contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products." Astellas has established the five fields of CSR-based management in order to promote its implementation at both the management level and at the level of daily operations. The five fields are the economy (business activities), employees, society, the environment, and compliance—with compliance as a fifth field that underpins activities in the first four fields. We are working toward achieving the key targets set for each field.

Our definition of CSR-based management includes not existing merely as a market entity, but also being accepted

as a valuable member of society. This means continuously creating innovative new drugs to meet unmet medical needs, or in other words, to meet demand in therapeutic areas where existing drugs are inadequate and current therapeutic options are unsatisfactory. Delivering maximum value to patients in the form of new drugs through the core businesses is our *raison d'être* and the embodiment of our CSR-based management.

Furthermore, Astellas recognizes that it has a social responsibility to fulfill. It is to contribute toward improving the health of people around the world through the stable and continuous supply of pharmaceutical products needed by patients under different healthcare systems in each country.

In addition, to execute CSR-based management, a company must recognize issues through communication

between itself and its many stakeholders, and work to continuously improve enterprise value by finding solutions to such issues. Astellas will continue incorporating the opinions of stakeholders in its business activities through a variety of methods, and use such feedback to enhance its enterprise value.

In October 2011, we declared our support for, and became a signatory to, the United Nations Global Compact, thus demonstrating our commitment to CSR-based management. As a signatory, we will further boost CSR-based management by embracing the ten principles advocated by the United Nations on human rights, labor, the environment, and anti-corruption in our daily business activities.







# United Nations Global Compact Initiatives

## Endorsing the United Nations Global Compact

Astellas expressed its support for the United Nations Global Compact, which consists of ten principles related to human rights, labor, the environment, and anti-corruption, by becoming a signatory in November 2011.

In signing the Global Compact, we aim to highlight our CSR-based management approach, which is designed to realize our raison d'être of "contributing toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products."



### The Ten Principles of the Global Compact and Astellas' Initiatives

#### United Nations Global Compact's Ten Principles

#### Our Initiatives



**Human Rights**

- Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights; and
- Principle 2: Make sure that they are not complicit in human rights abuses.

- Fair and equitable use of genetic resources **Economy** p.40
- Protection of human rights and personal information of patients undergoing clinical trials **Economy** p.41
- Promotion of CSR procurement (Respect for human rights and fair employment practices at our business partners) **Economy** p.43
- Introduction of "Color Universal Design" for new products **Economy** p.44
- Respect for human rights **Employees** p.52
- Emphasis on diversity **Employees** p.53
- Support for the medical treatment of patients with obstetric fistulas **Society** p.60
- External and internal helplines for employees **Compliance** p.81



**Labor**

- Principle 3: Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;
- Principle 4: The elimination of all forms of forced and compulsory labor;
- Principle 5: The effective abolition of child labor; and
- Principle 6: The elimination of discrimination in respect of employment and occupation.

- Promotion of CSR procurement (Management of occupational health and safety practices at our business partners) **Economy** p.43
- Occupational health and safety initiatives **Employees** p.53
- Provision of opportunities for communication between labor and management **Employees** p.53

**Environment**



- Principle 7: Businesses should support a precautionary approach to environmental challenges;
- Principle 8: Undertake initiatives to promote greater environmental responsibility; and
- Principle 9: Encourage the development and diffusion of environmentally friendly technologies.

- Reduction of greenhouse gas emissions **Environment** p.68-71
- Initiatives for sustainable biodiversity **Environment** p.72-73
- Effective use of water resources **Environment** p.74
- Waste management **Environment** p.74
- Prevention of pollution **Environment** p.75

**Anti-Corruption**



- Principle 10: Businesses should work against corruption in all its forms, including extortion and bribery.

- Promotion of CSR procurement (Compliance with laws and promotion of CSR at our business partners) **Economy** p.43
- Reinforcement of global compliance system **Compliance** p.79-80
- Renewed emphasis on preventing bribery **Compliance** p.81

The United Nations Global Compact asks companies, as responsible members of society, to pursue voluntary activities aimed at building global frameworks for realizing sustainable growth. Signatory companies to the Global Compact are asked to undertake ongoing autonomous efforts to fulfill the aforementioned ten principles.

## Economy

(Business Activities)

**In today's world, there remain many diseases that lack adequate therapies. Astellas contributes to the health of people around the world through the discovery and development of innovative drugs with high efficacy, focusing on several highly specialized fields with a high degree of unmet medical needs.**

- 022 Special Feature: Oncology
- 026 Review of Operations by Therapeutic Area
- 028 R&D Pipeline
- 032 Review of Global Operations
- 040 CSR Initiatives in Business Processes

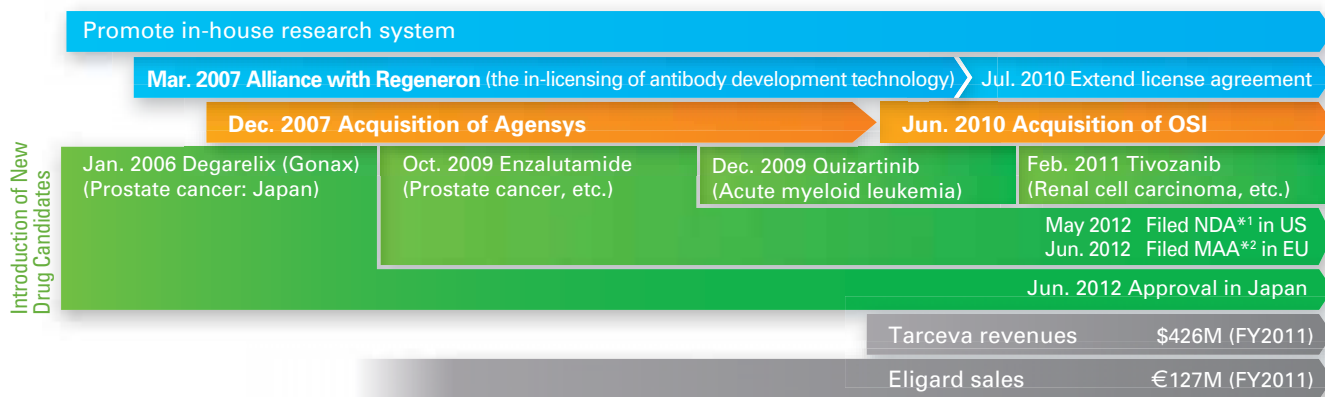
## Establishing Oncology as Our Third Global Category Leader Area

Astellas is focusing on establishing oncology as its third “Global Category Leader” (GCL) area after urology and transplantation. Since the designation of oncology as a core therapeutic area in 2006, we have worked to reinforce our business platform in the oncology field. Measures taken include the in-licensing of antibody development technology, as well as the acquisition of Agensys and OSI Pharmaceuticals. We have enriched our development pipeline with first-in-class and best-in-class compounds, and have made steady progress in developing late-stage compounds as well.

### Reinforcement of Oncology Business Base

2006 Select “oncology” as a focus therapeutic area

2012



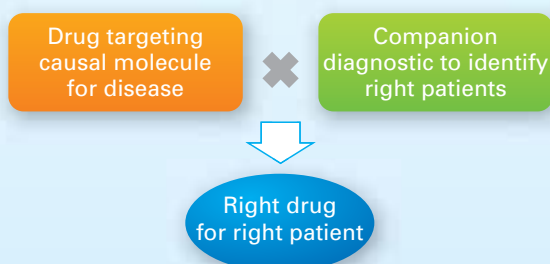
\*1 NDA : New drug application

\*2 MAA: Marketing authorization application

We strive to continually improve productivity in our research and development activities. For example, using our cross-functional “Oncology STAR” (Strategy Team for Therapeutic Area Reinforcement) team, we have strengthened collaboration among the functions of research, development, and marketing. In addition, we are actively

promoting a Precision Medicine approach in the oncology field. We are also pursuing “Multi-Track R&D” (open innovation) initiatives, such as conducting joint research with universities and research institutions and utilizing the technologies of other companies.

### Precision Medicine



This approach entails the development of drugs together with companion diagnostics. Targeting specific patient segments enables us not only to develop medicines with high efficacy and fewer side effects, but also to conduct clinical trials on a smaller scale. Moreover, there are pharmacoeconomical advantages to prescribing drugs only to patients who will derive the most benefit.



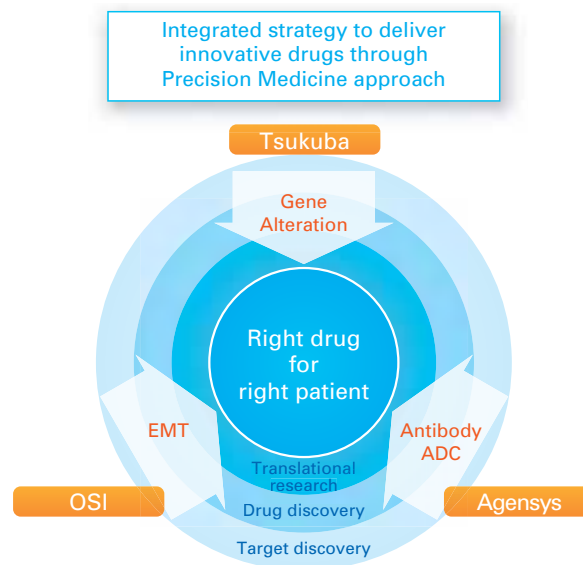
## Drug Discovery Approach at Our Three Research Sites

Astellas has three research sites for oncology, namely the Tsukuba Research Center, OSI Pharmaceuticals, and Agensys. We adopt an integrated Precision Medicine approach to our drug discovery, while leveraging the unique research platforms and methods of each site.

The Tsukuba Research Center focuses on genetic alteration related to tumor growth and survival. The Center engages in cutting-edge research using technologies it has fostered over many years, such as “omics\*1” technologies.

OSI Pharmaceuticals excels in research into Epithelial-Mesenchymal Transition (EMT) related to refractory tumors and treatment resistance. OSI’s research targets the molecules related to EMT.

Agensys specializes in oncology antibody discovery, early clinical development, and early manufacturing. Its drug discovery activities target antibody drugs and antibody-drug conjugates (ADCs\*2).



\*1 “Omics” technologies: “Omics” is a general term that refers to a field of biology ending in “—omics” where all biological constituents considered are collectively analyzed, e.g. genomics for genes, transcriptomics for RNA, and proteomics for proteins. “Omics” technologies are used for the analysis of the types and quantities of these constituents which are important for elucidating the cause of diseases.

\*2 ADC: An antibody attached to a toxin designed to destroy the cancer cell by binding to a certain antigen on the cancer cell followed by internalization into the cell and release of the toxin.

## Advances in Development of Anti-Cancer Agents

### Dedicated to Delivering the Greatest Benefit to Patients



**Steven Ryder, M.D., F.A.C.P.**  
President,  
Astellas Pharma  
Global Development, Inc.

Despite remarkable medical advances in the field of oncology, new therapies are required to meet the high level of unmet medical needs that continues to exist in this therapeutic area. Astellas aims to improve the lives of cancer patients through the advancement of innovative new drugs that provide benefits to a well-defined patient population.

In fiscal 2011, Astellas achieved significant advances in compounds in the later stages of development, such as the favorable results demonstrated in Phase 3 clinical trials of enzalutamide (code name: MDV3100) and tivozanib. Development milestones reached since then include the filing of new drug applications for enzalutamide with regulatory authorities in the United States and Europe, and the granti-

ng of approval for Gonax in Japan. These milestones are evidence of the steady progress being made in our development activities.

In the near term, Astellas will focus on obtaining approval for enzalutamide and filing an application for tivozanib. At the same time, we will work on the expansion of multiple indications for both compounds. We will also leverage our expertise in urology to establish a leadership position in uro-oncology.

In the medium and long term, Astellas will develop life-cycle management strategies for each drug and investigate combinations with in-house products to maximize the value of its portfolio. We will also promote Precision Medicine to find the right patient and deliver the greatest benefit.

Oncology Pipeline Expansion (as of August 2012)

Project	Target cancer	Characteristics	Phase-I	Phase-II	Phase-III	Filed	
Small molecule	<b>Enzalutamide MDV3100</b>	Prostate cancer (PC), Breast cancer (BC)	Androgen receptor inhibitor	PC: Post-chemo PC: Pre-chemo EU/US/JP/Asia BC: US			Filed in US/EU
	<b>Tivozanib ASP4130</b>	Renal cell carcinoma (RCC), Colorectal cancer (CRC), Breast cancer (BC)	Potent, selective, long half-life inhibitor of VEGF receptors 1,2 and 3	RCC: EU/US CRC, BC: EU/US			
	<b>Quizartinib AC220</b>	Acute myeloid leukemia	Potent and selective 2nd generation FLT3 kinase inhibitor	EU/US			
	<b>Degarelix (Gonax)</b>	Prostate cancer	1st GnRH antagonist in Japan	1M formulation: JP 3M: JP			Approved
	<b>Sepantronium YM155</b>	Breast cancer, Non-Hodgkin's lymphoma	First-in-class survivin suppressant	EU/US/JP			
	<b>ASP1707</b>	Prostate cancer	Oral GnRH antagonist				
	<b>ASP3026</b>	Cancer	ALK tyrosine kinase inhibitor				
	<b>ASP9521</b>	Prostate cancer					
	<b>ASP9603</b>	Prostate cancer					
	<b>Erlotinib* (Tarceva)</b>	Non-small cell lung cancer (first line for patients with EGFR mutation, adjuvant, combination with MetMab), Colorectal cancer, Pediatric ependymoma	HER1/EGFR tyrosine kinase inhibitor	US			
	<b>Linsitinib* ASP7487(OSI-906)</b>	Ovarian cancer, Non-small cell lung cancer	IGF-1R/IR tyrosine kinase inhibitor	US			
	<b>OSI-027*</b>	Renal cell cancer	mTOR kinase inhibitor	US			
	Antibody	<b>AGS-1C4D4</b>	Pancreatic cancer	Antibody (target: PSCA)	EU/US		
<b>AGS-16M8F/AGS-16C3F</b>		Renal cancer	Antibody utilizing ADC (target: ENPP3)				
<b>ASG-5ME</b>		Prostate cancer, Pancreatic cancer	Antibody utilizing ADC (target: SLC44A4)				
<b>ASG-22ME</b>		Solid tumors	Antibody utilizing ADC (target: Nectin-4)				

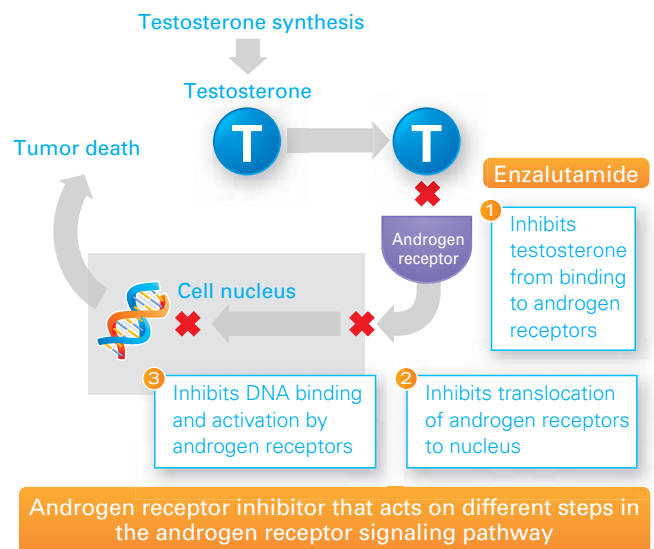
\*OSI compounds

**Enzalutamide (Therapeutic target: prostate cancer and breast cancer)**

Enzalutamide is an androgen receptor inhibitor. Enzalutamide inhibits androgen receptor signaling, which plays a key role in facilitating the growth of prostate cancer, in three distinct ways.

In November 2011, favorable interim analysis results were obtained from Phase 3 AFFIRM clinical trials of the drug on patients with metastatic castration-resistant prostate cancer (mCRPC) previously treated with chemotherapy. Based on these findings, in May and June 2012 applications for regulatory approval were filed in the United States and Europe, respectively, for the indication of mCRPC in men previously treated with docetaxel-based chemotherapy. Clinical trials for patients with earlier-stage prostate cancer and breast cancer are ongoing, and there are plans to expand indications for the new drug in future.

**Enzalutamide: Mechanism of Action**



Source: Tran et al. *Science* 2009; 324: 787-90



### Tivozanib (Therapeutic target: renal cell carcinoma, colorectal cancer, and breast cancer)

Tivozanib is a potent and selective inhibitor of all three vascular endothelial growth factor (VEGF) receptors 1, 2, and 3. In January 2012, it was reported that the drug had generated favorable results in a TIVO-1 Phase 3 clinical trial of patients with advanced renal cell carcinoma. According to the findings, tivozanib demonstrated a statistically significant improvement in the primary endpoint of progression-free survival compared with a comparator (sorafenib), and was also well tolerated. Currently, an application is being prepared for approval for the indication of renal cell carcinoma. Clinical trials are also ongoing for the additional indications of colorectal cancer and breast cancer.

### Quizartinib (Therapeutic target: acute myeloid leukemia)

Quizartinib is a potent and highly selective second-generation FLT3 kinase inhibitor. Quizartinib is currently under evaluation in Phase 2 trials for patients with acute myeloid leukemia.

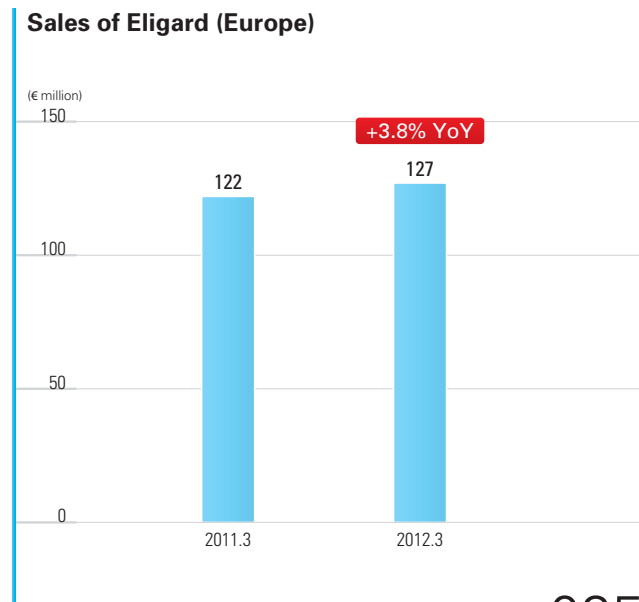
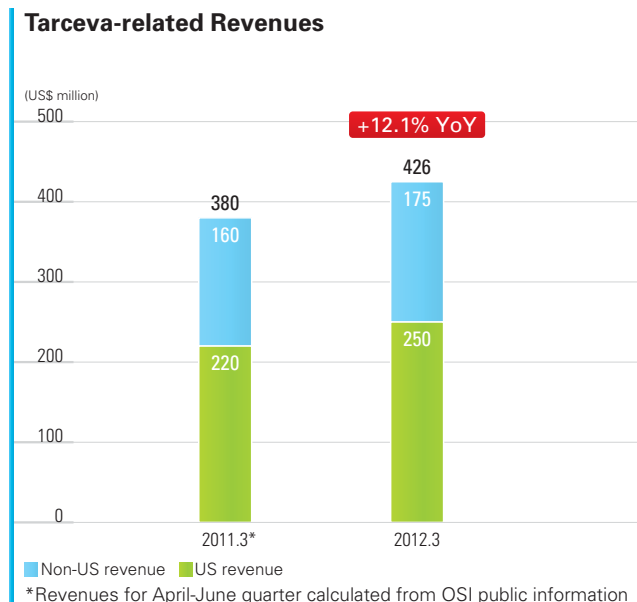
Acute myeloid leukemia is considered to be one of the most challenging hematological malignancies to treat. Very few treatment advances have been made in the past several decades. Astellas is keen to explore the full potential of quizartinib as a new option for patients.

## Expanding Oncology

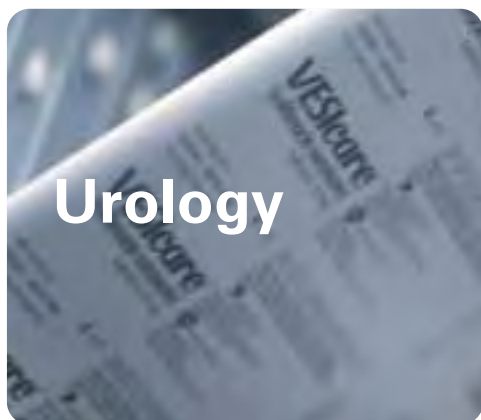
Astellas currently markets two oncology drugs: Tarceva and Eligard. Tarceva is used for the treatment of non-small cell lung cancer and pancreatic cancer, and is co-promoted with Genentech, Inc. in the United States, with earnings split equally. In regions outside the United States, Astellas has a license agreement with Roche and receives royalties based on sales. Eligard, which is used for the treatment of advanced prostate cancer, is marketed in Europe. Sales of both products continue to grow. In fiscal 2011, Astellas recorded revenues of ¥47.5 billion

from these products.

In Japan, Astellas obtained manufacturing and marketing approval for Gonax for the indication of prostate cancer in June 2012, and is currently preparing for the market launch of this new drug. With recent advances in the development of enzalutamide and tivozanib, Astellas is building a marketing network in each of its three key regions (Japan, the Americas, and Europe), which will serve as a springboard for the launch and early start-up of new oncology products in the near future.



## Review of Operations by Therapeutic Area



With Vesicare and mirabegron in its lineup, Astellas is aiming to be the overwhelming No.1 in the OAB field.

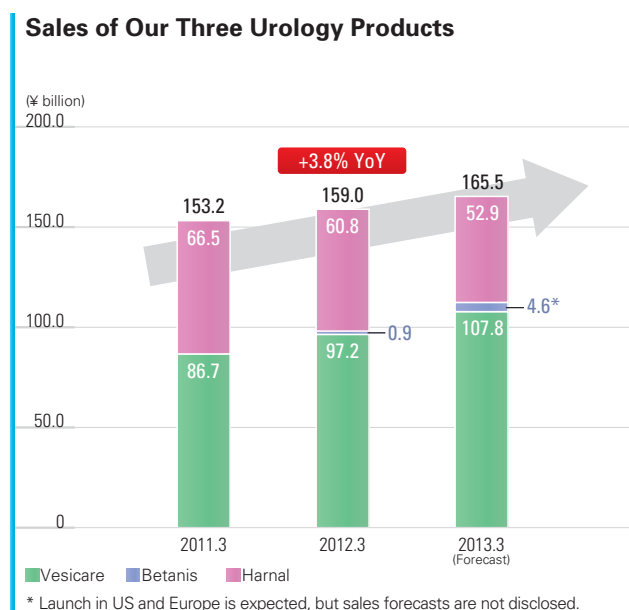
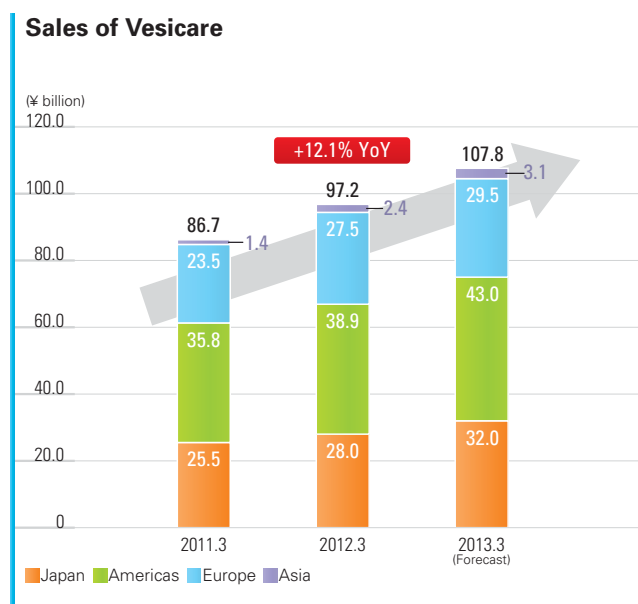
In the field of urology, Astellas commands a strong presence in the market for drugs used to treat the conditions of benign prostatic hyperplasia (BPH) and overactive bladder (OAB).

In fiscal 2011, Vesicare, used in OAB treatment, showed especially strong growth in sales in Japan, the Americas, Europe, and Asia, resulting in a 12.1% year-on-year increase in global sales. Following the end of a co-promotional arrangement for marketing VESicare in the United States with GlaxoSmithKline in December 2011, Astellas took over full responsibility for all promotional activities from January 2012. In September 2011, Astellas released its new drug for OAB treatment, mirabegron, in Japan under the brand name Betanis. In August 2011, Astellas submitted applications for approval for mirabegron in the United States and Europe. In June 2012, we received approval for mirabegron in the United States (brand name: Myrbetriq).

With anticholinergics including Vesicare as the current OAB treatment standard, the release of the novel OAB treatment mirabegron, the world's first beta-3 adrenergic receptor agonist, is expected to bring a new treatment option for OAB patients.

Sales of Harnal, used to treat BPH, declined in Japan and Europe due to the impact of generic versions. By contrast, sales in Asia grew steadily.

Astellas has several compounds under clinical development as potential candidates for treating urological conditions. In Europe, marketing authorization for EC905 (fixed dose combination of solifenacin and tamsulosin) has been submitted. In addition, a number of projects are ongoing, such as EB178 (concomitant use of solifenacin and mirabegron) and ASP3652 (for the treatment of chronic prostatitis/chronic pelvic pain syndrome, etc.).



# Immunology (including Transplantation) and Infectious Diseases

As a Global Category Leader in the transplantation field, Astellas aims to make further contributions to transplantation medicine.

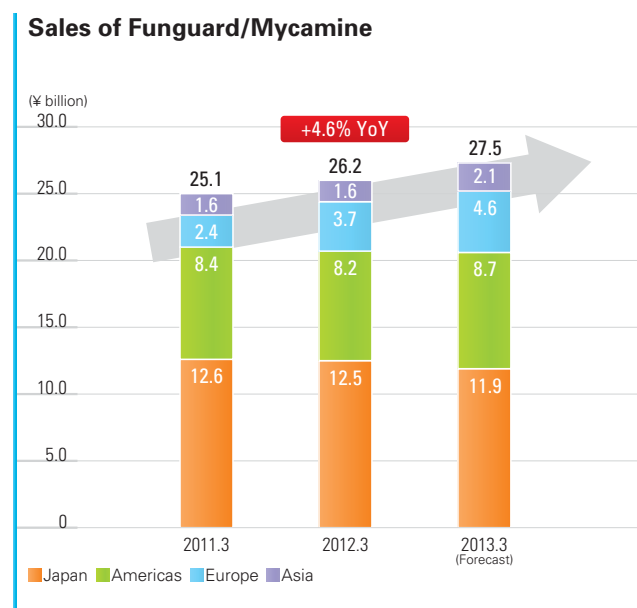
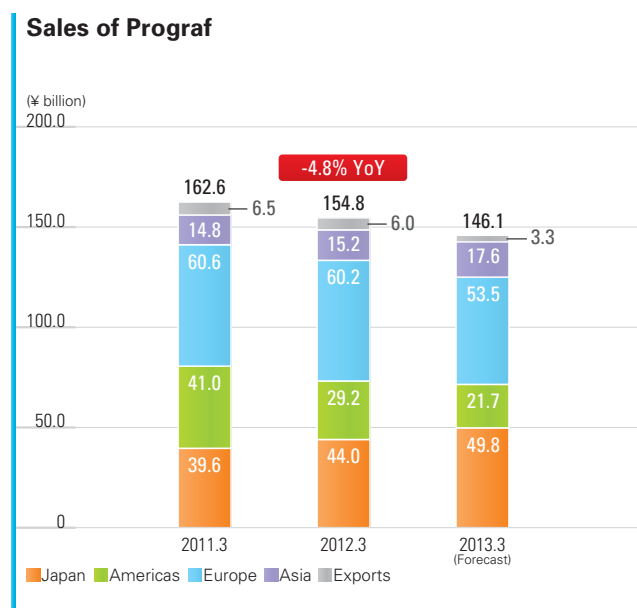
In the transplantation field, sales of Prograf declined 4.8% year on year. In the United States, generic products had a negative impact on sales. Meanwhile, sales were steady in Europe thanks to the contribution of the once-a-day formulation Advagraf. Sales continued to grow in Japan and Asia. In fiscal 2012, we forecast sales declines in the Americas and Europe. Nevertheless, we will work to maximize the value of our Prograf business on a global basis by promoting sales growth in Japan and Asia.

In the field of infectious diseases, sales of Funguard/Mycamine increased 4.6% year on year, thanks to sales growth in Europe.

Astellas has a number of candidate compounds for use in the field of immunology including transplantation. In January 2012, certolizumab pegol for the treatment of

rheumatoid arthritis, which was in-licensed from UCB, is in the marketing authorization application stage in Japan. Other drug candidates currently in the clinical development stage include ASP015K (for the treatment of rheumatoid arthritis, etc.), ASKP1240 (for the prevention of organ transplant rejection), and Diannexin (for the prevention of delayed graft function in kidney transplantation).

In the field of infectious diseases, approval granted in December 2011 to market Dificlir (for the treatment of Clostridium difficile infections) in Europe resulted in the drug's launch in that market in May 2012. Other drugs for treating infectious diseases in the clinical development stage include the azole antifungal isavuconazole, the DNA vaccine for cytomegalovirus ASP0113, and the influenza vaccines ASP7373 and ASP7374.



## R&D Pipeline (as of August 1, 2012)

Astellas engages in research and development in order to deliver innovative new drugs to patients as quickly as possible. At present, we are developing many unique compounds in the focus therapeutic areas such as urology, immunology (including transplantation) and infectious diseases, and oncology.

In fiscal 2011, Astellas made steady progress on many projects, including the OAB treatment mirabegron, as well as the prostate cancer treatment enzalutamide (code name: MDV3100). In Japan, we received approval for seven products. Three of these products—Betanis (generic name: mirabegron), Regnite, and Kiklin—were

newly granted approval. In the case of four drugs, approval was granted for new indications and new formulations, such as Bonoteo Tablets 50 mg. In Europe, the EMA granted approval for Dificlir. In June 2012, Gonax was granted marketing approval in Japan, and Myrbetriq (generic name: mirabegron) was approved in the United States.

In addition, tivozanib generated positive results in a Phase 3 clinical study in patients with advanced renal cell carcinoma. For ipragliflozin, recruitment and treatment were completed and favorable results were obtained in multiple trials in patients with type 2 diabetes.

### Products approved in/after April 2011

Code No./Generic Name	Brand Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
<b>YM178</b> <b>mirabegron</b>	Betanis (Jul. 2011)	Beta-3 receptor agonist	Urgency, urinary frequency, and urinary incontinence associated with overactive bladder	Japan	Oral	In-house	Launched Sep. 2011
	Myrbetriq (Jun. 2012)		Overactive bladder associated with symptoms of urgency, urinary frequency, and urge urinary incontinence	US			
<b>YM529</b> <b>minodronic acid</b>	Bonoteo [50 mg] (Jul. 2011)	Bisphosphonate	Osteoporosis (Once per four weeks)	Japan	Oral	In-house (co-development with Ono)	New formulation Launched Sep. 2011
<b>FK506</b> <b>tacrolimus</b>	Prograf Graceptor (Jul. 2011)	Immunosuppressant	Prophylaxis of organ rejection in patients receiving allogenic small bowel transplants	Japan	Oral Injection	In-house	New indication
<b>fidaxomicin</b>	Dificlir (Dec. 2011)	Macrocyclic antibiotic	Treatment of clostridium difficile infection	Europe	Oral	Optimer	Launched May 2012
<b>YM177</b> <b>celecoxib</b>	Celecox (Dec. 2011)	Cyclooxygenase-II inhibitor	Anti-inflammatory and analgesic effects in post-operation, post-trauma, and post-tooth extraction	Japan	Oral	Pfizer	New indication
<b>ASP8825 (XP13512)</b> <b>gabapentin enacarbil</b>	Regnite (Jan. 2012)	Prodrug of gabapentin	Moderate-to-severe primary restless legs syndrome	Japan	Oral	XenoPort	Launched Jul. 2012
<b>amoxicillin</b>	Sawacillin (Feb. 2012)	Penicillin antibiotic	Changes in the maximum pediatric dosages for infections excluding helicobacter pylori infection	Japan	Oral	In-house	Additional dosage and administration
<b>ASP1585 (AMG223)</b> <b>bixalomer</b>	Kiklin (Mar. 2012)	Amine-functional polymer	Hyperphosphatemia in patients on dialysis with chronic kidney disease	Japan	Oral	Ilypsa/Amgen	Launched Jun. 2012
<b>ASP3550</b> <b>degarelix</b>	Gonax (Jun. 2012)	GnRH antagonist	Prostate cancer (One-month formulation)	Japan	Injection	Ferring	

### Products currently under clinical development

Code No./Generic Name	Classification	Target Disease	Phase-I	Phase-II	Phase-III	Filed	Area	Dosage Form	Origin	Remarks
<b>Urology</b>										
<b>YM178 mirabegron</b>	Beta-3 receptor agonist	Overactive bladder associated with symptoms of urgency, urinary frequency, and urge urinary incontinence				(Aug. 2011)	Europe	Oral	In-house	
<b>EC905 solifenacin/tamsulosin</b>	Fixed dose combination of solifenacin and tamsulosin	Lower urinary tract symptoms associated with benign prostatic hyperplasia, with storage symptoms				(Mar. 2012)	Europe	Oral	In-house	*2
<b>YM905 solifenacin</b>	Muscarinic M <sub>3</sub> receptor antagonist	Neurogenic detrusor overactivity and idiopathic overactive bladder in pediatric patients					US/ Europe	Oral	In-house	New indication
<b>EB178 solifenacin/mirabegron</b>	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder					Europe	Oral	In-house	
<b>ASP3652</b>	Inhibition of afferent nerve activity	Chronic prostatitis/ Chronic pelvic pain syndrome					Europe	Oral	In-house	
							Japan			
		Bladder pain syndrome/ Interstitial cystitis					Europe			
<b>ASP7035</b>		Nocturia						Oral	In-house	
<b>ASP0306</b>		Lower urinary tract symptoms associated with benign prostatic hyperplasia						Oral	In-house	
<b>ASP4901 (AKP-002)</b>		Lower urinary tract symptoms associated with benign prostatic hyperplasia						Oral	ASKA	
<b>ASP6432</b>		Lower urinary tract symptoms associated with benign prostatic hyperplasia						Oral	In-house	
<b>Immunology (including Transplantation) and Infectious Diseases</b>										
<b>certolizumab pegol</b>	PEGylated anti-tumor necrosis factor-alpha antibody	Rheumatoid arthritis in patients who respond insufficiently to current therapies				(Jan. 2012)	Japan	Injection	UCB	*1
		Methotrexate-naïve rheumatoid arthritis					Japan			New indication, *1
<b>isavuconazole</b>	Azole antifungal	Invasive aspergillosis					US/ Europe	Injection Oral	Basilea	
		Candidemia/ Invasive candidiasis					US/ Europe			
<b>ASP0113 (VCL-CB01)</b>	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic stem cell transplant recipients					US/ Europe	Injection	Vical	
		Cytomegalovirus infection or reactivation in solid organ transplant recipients					US/ Europe			
<b>ASP015K</b>	JAK inhibitor	Rheumatoid arthritis					US/ Europe	Oral	In-house	
							Japan			
		Prevention of organ transplant rejection					US			
<b>ASKP1240</b>	Anti-CD40 antagonist	Prevention of organ transplant rejection					US	Injection	Kyowa Hakko Kirin	
							Japan			
<b>ASP8597 diannexin</b>	Inhibition of monocyte and platelet binding to phosphatidylserine	Prevention of delayed graft function in kidney transplantation					US	Injection	Alavita	
<b>ASP7373</b>	Influenza vaccine	Prophylaxis of H5N1 influenza					Japan	Injection	UMN Pharma	*1
<b>ASP7374</b>	Influenza vaccine	Prophylaxis of seasonal influenza					Japan	Injection	UMN Pharma	*1
<b>ASP4058</b>		Multiple sclerosis						Oral	In-house	
<b>ASP2408</b>		Rheumatoid arthritis						Injection	In-house (Perseid)	
<b>ASP2409</b>		Prevention of organ transplant rejection						Injection	In-house (Perseid)	

\*1 Local Development (Japan) \*2 Local Development (Europe)

Code No./Generic Name	Classification	Target Disease	Phase-I	Phase-II	Phase-III	Filed	Area	Dosage Form	Origin	Remarks			
<b>Oncology</b>													
<b>MDV3100 enzalutamide*</b>	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer in patients who have received docetaxel-based chemotherapy					US	Oral	Medivation				
								Europe					
								Japan					
								US			New indication		
								Europe					
								Japan					
								Asia					
					Prostate cancer (chemotherapy-naive, etc.)					US			
					Breast cancer					US			New indication
			<b>erlotinib (tarceva)</b>	HER1/EGFR tyrosine kinase inhibitor	Non-small cell lung cancer (first line for patients with EGFR mutation, adjuvant, combination with MetMab), Colorectal carcinoma, Pediatric ependymoma						US	Oral	In-house (OSI)
<b>ASP4130 tivozanib</b>	Inhibitor of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3	Renal cell carcinoma					US/ Europe	Oral	AVEO				
		Colorectal cancer, Breast cancer					US/ Europe						
<b>ASP7487 (OSI-906) linsitinib</b>	IGF-1R/IR tyrosine kinase inhibitor	Ovarian cancer, Non-small cell lung cancer					US	Oral	In-house (OSI)				
<b>YM155 sepantronium bromide</b>	Survivin suppressant	Breast cancer, Non-Hodgkin's lymphoma					US	Injection	In-house				
							Europe						
							Japan						
<b>AC220 quizartinib</b>	FLT3 kinase inhibitor	Acute myeloid leukemia					US	Oral	Ambit				
							Europe						
<b>AGS-1C4D4</b>	Antibody (Prostate stem cell antigen)	Pancreatic cancer					US/ Europe	Injection	In-house (Agensys)				
<b>OSI-027</b>	mTOR kinase inhibitor	Renal cell cancer					US	Oral	In-house (OSI)				
<b>ASP3550 degarelix</b>	GnRH antagonist	Prostate cancer (Three-month formulation)					Japan	Injection	Ferring	New formulation, *1			
<b>AGS-16M8F/ AGS-16C3F</b>		Cancer (ADC technology)						Injection	In-house (Agensys)				
<b>ASG-5ME</b>		Cancer (ADC technology)						Injection	In-house (Agensys) (co-development with Seattle Genetics)				
<b>ASP1707</b>	GnRH antagonist	Prostate cancer					Europe	Oral	In-house				
<b>ASP3026</b>		Cancer						Oral	In-house				
<b>ASP9521</b>		Prostate cancer						Oral	In-house				
<b>ASG-22ME</b>		Cancer (ADC technology)						Injection	In-house (Agensys) (co-development with Seattle Genetics)				
<b>ASP9603</b>		Prostate cancer						Oral	In-house				

\*p-INN (proposed international nonproprietary name)



Code No./Generic Name	Classification	Target Disease	Phase-I	Phase-II	Phase-III	Filed	Area	Dosage Form	Origin	Remarks
<b>Neuroscience</b>										
<b>FK949E quetiapine</b>	Serotonin/dopamine antagonist	Depressive episode in bipolar disorders					Japan	Oral	AstraZeneca	New indication New formulation, *1
		Major depressive disorder					Japan			
<b>NGX-4010 capsaicin</b>	TRPV1 agonist	Peripheral diabetic neuropathy					Europe	Patch	NeurogesX	New indication, *2
<b>ASP0777</b>		Alzheimer's disease [Dementia]						Oral	In-house	
<b>ASP8477</b>		Neuropathic pain						Oral	In-house	
<b>ASP9226</b>		Neuropathic pain						Oral	In-house	
<b>ASP6973</b>		Osteoarthritis, Chronic low back pain						Oral	In-house	
<b>DM Complications and Kidney Diseases, Others</b>										
<b>YM443 acotiamide</b>	Acetylcholine esterase inhibitor	Functional dyspepsia					Japan	Oral	Zeria	*1
<b>ASP1941 ipragliflozin</b>	SGLT2 inhibitor	Type 2 diabetes								In-house (co-development with Kotobuki)
								US		
								Europe		
<b>YM533 beraprost sodium</b>	Prostacyclin receptor stimulator	Chronic renal failure (primary, nephrosclerosis)					Japan/Asia	Oral	Toray	New indication New formulation, *1
<b>YM060 ramosetron</b>	5-HT3 receptor antagonist	Irritable bowel syndrome Female patients					Japan	Oral	In-house	New indication, *1
		Irritable bowel syndrome (Orally-disintegrating tablet)	Bioequivalent study				Japan			New formulation, *1
<b>ASP1585 (AMG223) bixalomer</b>	Amine-functional polymer	Hyperphosphatemia in patients not on dialysis with chronic kidney disease					Japan	Oral	Ilypsa/ Amgen	New indication, *1
<b>ASP1517 (FG-4592)</b>	HIF stabilizer	Renal anemia					Europe	Oral	FibroGen	
							Japan			
<b>YM311 (FG-2216)</b>	HIF stabilizer	Renal anemia					Europe	Oral	FibroGen	
							Japan			
<b>PSN821</b>	GPR119 agonist	Type 2 diabetes, Obesity					Europe	Oral	In-house (OSI)	
<b>ASP1707</b>	GnRH antagonist	Endometriosis					Europe/ Japan	Oral	In-house	
<b>ASP0456 linaclotide</b>	Guanylate cyclase type-C receptor agonist	Irritable bowel syndrome					Japan	Oral	Ironwood	*1
<b>ASP7991</b>		Secondary hyperparathyroidism						Oral	In-house	

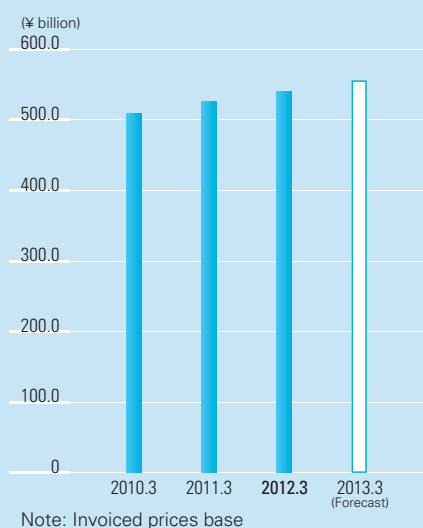
\*1 Local Development (Japan) \*2 Local Development (Europe)

# Review of Global Operations

## Japan

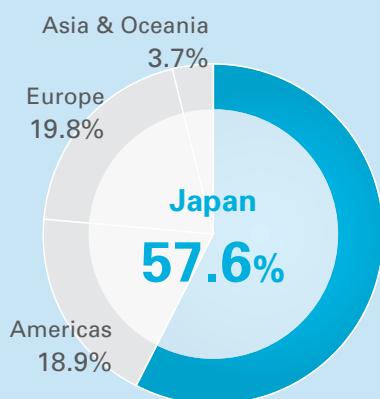
We are targeting the No.1 market share in Japan through the launch of new products and the leveraging of existing growth products.

### Net Sales (Japanese Market Sales)



### Sales by Geographical Area

2012.3



### Fiscal 2011 Overview

Net sales in Japan in fiscal 2011 amounted to ¥558.4 billion, up 2.7% from the previous year. This included ¥539.9 billion in sales in the domestic prescription drug market, a year-on-year increase of 2.7%. The year saw steady growth in sales of mainstay products and new products.

By product, sales of Vesicare rose 10% from the previous year, further expanding its share as the leading product in the overactive bladder (OAB) treatment market. Sales of Prograf increased 11% from the previous year owing to higher sales not

only for the transplantation area but also for rheumatoid arthritis and other autoimmune diseases. Sales of the Micardis product line, including the combination drugs Micombi and Micamlo, were favorable, up 13% from the previous term. Steady increases were also recorded in sales of new products, including Symbicort, Celecox, Geninax, and Bonoteo. Sales of Betanis, a drug for OAB treatment launched in September 2011, amounted to ¥0.9 billion. Sales of Lipitor were down, partly due to the impact of the launch of generics in November 2011.

### Sales of Major Products

		Sales (¥ billion)		
		2011.3	2012.3	2013.3 (Forecasts)
<b>Prescription drugs sales in Japanese market</b>		525.6	↑ 539.9	↑ 556.1
Hypercholesterolemia treatment	Lipitor	97.2	↓ 96.3	↓ 89.8
	Caduet	—	4.9	—
Hypertension treatment (Long-acting angiotensin II receptor blocker)	Micardis	75.8	↑ 85.3	↑ 88.9
	Micombi	6.1	↑ 10.4	—
	Micamlo	2.3	↑ 10.6	—
Immunosuppressant	Prograf	39.6	↑ 44.0	↑ 49.8
Treatment for peptic ulcers and gastritis	Gaster	41.7	↓ 37.5	↓ 32.1
Insomnia treatment	Myslee	32.7	↑ 35.2	↓ 33.5
Anti-inflammatory agent (Selective COX-2 inhibitor)	Celecox	25.1	↑ 33.0	↓ 36.6
OAB treatment	Vesicare	25.5	↑ 28.0	↑ 32.0
Schizophrenia treatment	Seroquel	26.4	↑ 27.8	↑ 29.5
Treatment for the functional symptoms associated with benign prostatic hyperplasia	Harnal	29.6	↓ 27.4	↓ 24.0
Vaccines		18.5	↑ 26.5	↓ 22.7
Treatment for adult bronchial asthma	Symbicort	11.9	↑ 20.0	↑ 29.6
Candin-type antifungal agent	Funguard	12.6	↓ 12.5	↓ 11.9
Oral quinolone antibiotic	Geninax	10.2	↑ 11.9	↑ 12.1
Treatment for osteoporosis	Bonoteo	2.4	↑ 5.0	↑ 11.0
OAB treatment	Betanis (launched in September 2011)	—	0.9	↑ 4.6

Note: Invoiced prices base

## Yukihiko Sato

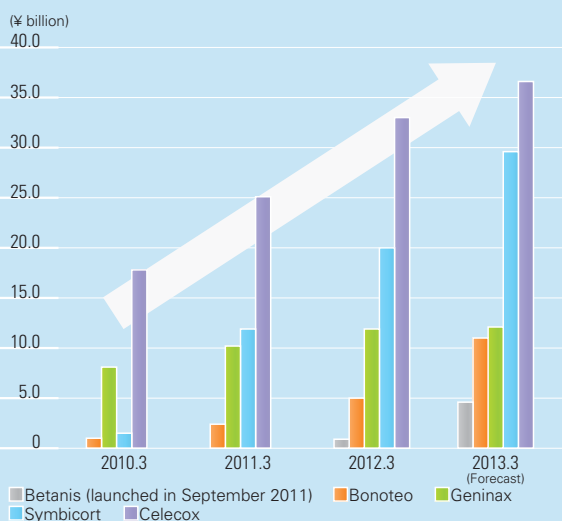
Senior Vice President and  
President, Sales & Marketing-Japan



### Fiscal 2012 Outlook

For fiscal 2012, we project a 2.5% year-on-year increase in Japan, to ¥572.5 billion. This estimate includes a rise in sales of 3.0% over the previous year in Japan's prescription drug market, to ¥556.1 billion. Despite factoring in a decline in sales stemming from the NHI drug price revision in April 2012, we expect to post higher revenues owing to sales growth for such drugs as Vesicare, Prograf, Micardis, Symbicort, Celecox, Bonoteo, and Betanis.

### Sales of Growth-driving New Products



## We are building top-level domestic sales and marketing operations in terms of both quality and quantity.

Japan's pharmaceutical industry is currently undergoing significant transformation due to various changes, including the ongoing trial of a new drug price system and further strengthening of measures to encourage the use of generics. Under these conditions, Astellas will grow further through continuous delivery of high-value-added new drugs to patients.

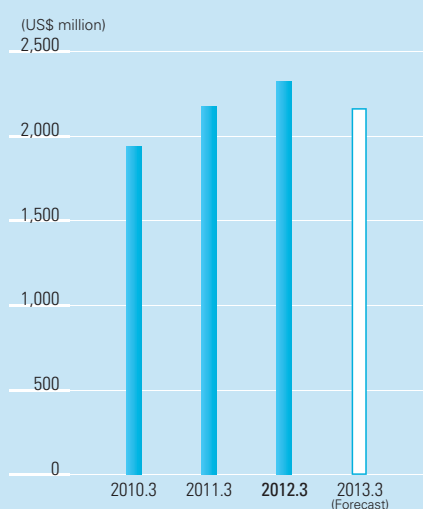
The driving force for our growth is approximately 2,400 Medical Representatives (MRs) covering medical institutions throughout Japan, which enables the creation of a top-level sales and marketing platform in terms of both quality and quantity. Our sales and marketing prowess in Japan is reflected in the achieved success of a number of co-promotional activities conducted through good relationships with our close partners, covering such products as Lipitor, Celecox, Micardis, and Symbicort.

In fiscal 2012, we are releasing a number of new products, including the restless legs syndrome drug Regnite, as well as Kiklin for the treatment of hyperphosphatemia, Gonax for the treatment of prostate cancer, and a combined vaccine Quattrovac subcutaneous injection syringe. By leveraging these new offerings and existing growth products, our aim is to become the market leader in Japan, as set out in our Mid-Term Management Plan.

# Americas

We will increase sales in urology and oncology, as well as maintain therapeutic category leadership in transplantation, myocardial perfusion imaging and the antifungal agents market.

## Net Sales



Note: U.S. dollar base

## Fiscal 2011 Overview

Net sales in the Americas amounted to US\$2,320 million, up 6.7% over the previous year on a U.S. dollar basis in fiscal 2011. However, due to the foreign exchange impact resulting from the high yen, net sales declined 1.6%, to ¥183.5 billion when converted to yen.

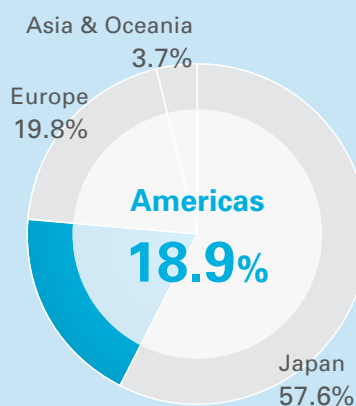
By product, sales of VESicare were strong on a U.S. dollar basis, increasing 18% as a result of favorable customer access with many health insurance prescription plans. VESicare, with a

total prescription market share of approximately 22% as of March 2012, is the leader among all branded drugs in the overactive bladder (OAB) market. The increased revenue was also driven by the sales of Lexiscan, Mycamine, and Tarceva-related revenue.

Sales of Prograf fell 23% in U.S. dollars due to the continued impact of generic drugs. The share of generics in the tacrolimus market averaged approximately 59% in fiscal 2011 on a total prescription volume basis.

## Sales by Geographical Area

2012.3



Note: Yen base  
Calculated according to the location of sellers

## Sales of Major Products

		(US\$ million)		
		2011.3	2012.3	2013.3 (Forecasts)
Sales in the Americas		2,176	↑ 2,320	↓ 2,165
Immunosuppressant	Prograf	478	↓ 370	↓ 272
Pharmacologic stress agent	Scan (Adenoscan and Lexiscan)	559	↑ 619	↓ 516
	Lexiscan	455	↑ 536	—
Antifungal agent	AmBisome	73	↓ 69	↑ 70
Treatment for atopic dermatitis	Protopic	83	↑ 94	↓ 90
OAB treatment	VESicare	418	↑ 492	↑ 537
Candin-type antifungal agent	Mycamine	98	↑ 104	↑ 108
Anticancer	Tarceva	285	↑ 426	—
	US	165	↑ 250	—
	Outside of the US	120	↑ 175	—

## Masao Yoshida

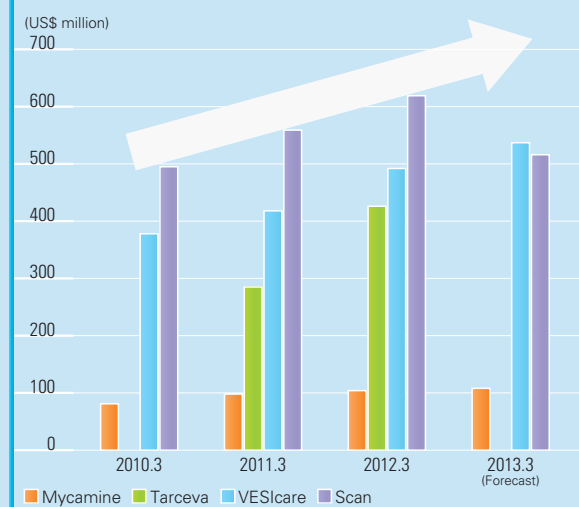
President and CEO,  
Astellas US LLC/  
President and CEO,  
Astellas Pharma US, Inc.



### Fiscal 2012 Outlook

We forecast regional net sales of US\$2,165 million in fiscal 2012, a year-on-year decrease of 6.7%. The outlook for VESicare sales is for ongoing growth, with a 9% year-on-year sales increase, as well as higher sales of Mycamine and increased revenues related to Tarceva. We expect that Prograf sales and combined sales of Adenoscan and Lexiscan will decline due to the impact of generic drugs.

### Sales/Revenues of Mainstay Products



Note: Forecast for Tarceva-related revenues has not been disclosed.

## We will further solidify our future growth by continuing our No.1 position in the OAB market and expanding our oncology franchise.

Our aim in the Americas is to lay the foundation for future growth and continue product sales growth in our key strategic areas. This entails bolstering our business platform through product portfolio optimization and increased organizational efficiency. We will focus on accelerating growth in urology, as well as expanding our oncology business, while retaining our dominant positions in the therapeutic areas of transplantation, myocardial perfusion imaging and antifungal agents.

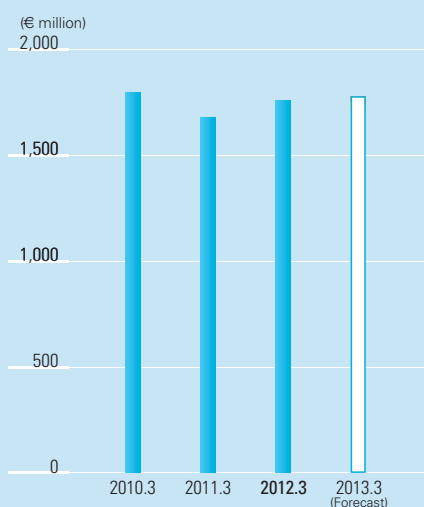
In the field of urology, we will add to the OAB franchise the exciting new product Myrbetriq, which was developed during the time VESicare has been on the market. By maximizing the value of both drugs, we will further reinforce our No.1 position in the OAB market and offer patients novel choices to treat their symptoms. In oncology, we expect to release enzalutamide (code name: MDV3100) and tivozanib, which will join Tarceva as new products in the future. We plan to build a strong network to promote the swift uptake of these new products. To this end, we will utilize highly specialized sales forces and maintain strong alliances with each partner.

In addition to the United States, we are strengthening our sales networks in Canada and Latin America, which we believe will help drive growth in the Americas region.



We will maintain growth by investing in oncology, urology, transplantation, infectious diseases and other focus therapeutic areas.

### Net Sales



Note: Euro base

### Fiscal 2011 Overview

In the year under review, net sales in Europe grew 4.8% year on year to €1,759 million on a euro basis. When converted to yen, net sales still rose 1.0% to ¥191.7 billion, despite the impact of the yen's appreciation.

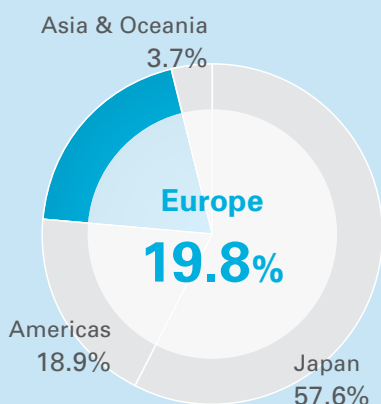
Sales of Vesicare continued to increase, climbing 21% on a euro

basis, and sales of Mycamine also grew steadily. Sales of Prograf through our own distribution channel, which include the once-daily formulation Advagraf, increased 3.1% in euro terms.

Sales of Omnic, which goes by the brand name Harnal in Japan, decreased due to the impact of generic drugs, etc.

### Sales by Geographical Area

2012.3



Note: Yen base  
Calculated according to the location of sellers

### Sales of Major Products

		(€ million)		
		2011.3	2012.3	2013.3 (Forecasts)
<b>Sales in Europe</b>		1,678	↑ 1,759	↑ 1,779
Treatment for the functional symptoms associated with benign prostatic hyperplasia	Harnal (Omnic, Omnic OCAS)	237	↓ 209	↓ 175
	Sales by Astellas	190	↓ 165	↓ 140
	Bulk and Royalties	46	↓ 43	↓ 35
Immunosuppressant	Prograf and Advagraf (Incl. exports to third parties)	592	↑ 606	↓ 540
	Sales by Astellas	535	↑ 552	↓ 510
	Exports to third parties	56	↓ 54	↓ 30
Overactive bladder treatment	Vesicare	208	↑ 252	↑ 281
Treatment for atopic dermatitis	Protopic	46	→ 46	↑ 52
Candin-type antifungal agent	Mycamine	21	↑ 34	↑ 44
Advanced prostate cancer treatment	Eligard	122	↑ 127	↑ 130
Peripheral neuropathic pain treatment	Qutenza	1	↑ 5	—



**Ken Jones**

President and CEO,  
Astellas Pharma Europe Ltd.

**Fiscal 2012 Outlook**

In fiscal 2012, the projection is for a 1.1% increase in regional net sales, to €1,779 million. This is based on a rise in Vesicare sales, as well as increases in sales of Mycamine and Eligard, together with bendamustine-related revenue and higher sales of other local products. Meanwhile, we project a decrease in sales of Prograf and Omnic due to the impact of generic drugs and reductions in drug prices in certain countries.

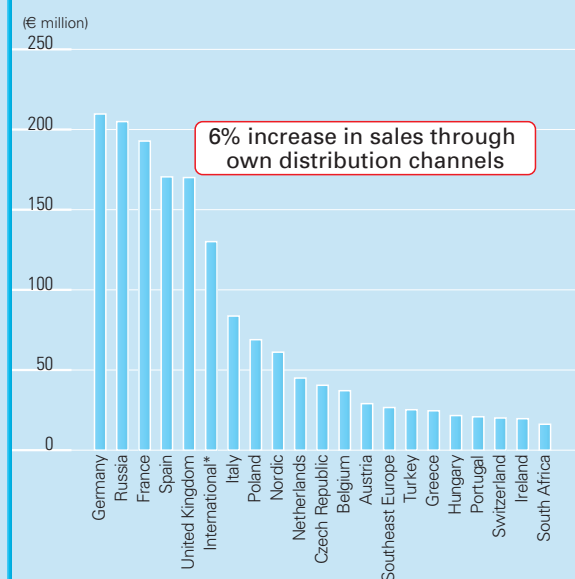
**We have established a solid business platform that covers a broad area, including emerging markets.**

Today, Astellas has a strong business platform in Europe, with 21 sales subsidiaries covering around 40 countries. We are expanding our reach in the region to encompass the rapidly growing markets of Russia and other CIS countries, as well as emerging markets in South East Europe. Although the business outlook remains uncertain due to factors such as the European financial crisis, Astellas will continue growing through an optimal balance of investments in its focus therapeutic areas.

We have established a solid franchise in the urology field, thanks to sales of Vesicare, Harnal, and Eligard. Going forward, we will pursue further growth through the release of new products, such as mirabegron and EC905. In the field of transplantation, we aim to continue maximizing our Prograf business franchise. In the area of infectious diseases, we expanded our product portfolio with the launch of Difclir in May 2012, and we intend to roll out this new offering in other European countries. Furthermore, in the area of oncology, we are focusing on building an efficient sales network in preparation for the future release of enzalutamide and tivozanib.

Astellas has consistently gained recognition as an Employer of Choice. In the UK and Spain, for example, the Company has been recognized as one of the best places to work by the Great Place to Work Institute. We hope our commitment to being an Employer of Choice will provide momentum for our future growth.

**Sales by Country (2012.3)**



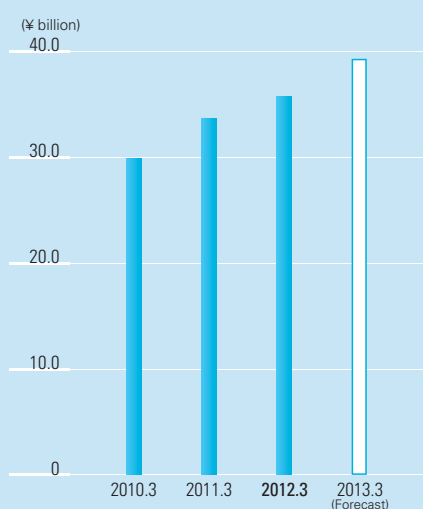
\*International covers the rest of our territories in Eastern Europe, the Middle East and Africa through local agents.



## Asia & Oceania

We will target significant business expansion, with China as the region's growth driver.

### Net Sales



### Fiscal 2011 Overview

Net sales in Asia rose 6.0% year on year, to ¥35.7 billion. In local currency terms excluding the foreign exchange impact, sales continued posting double-digit growth, up 10.1% from the previous year.

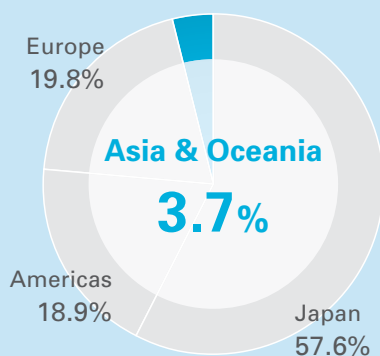
Sales in China, accounting for roughly 40% of sales in the Asian region, grew 12%, showing a favorable performance on a local currency basis compared with the previous year. By product, sales of all mainstay products, including Prograf, Harnal and Vesicare,

increased during the year.

We are working continuously to release our own high-value products and also to steadily expand business in Asia and Oceania. In fiscal 2011, we launched Advagraf in India and Thailand, and received regulatory approval in Singapore in April 2012. We also commenced sales of Vesicare in Australia through our own distribution channels. In Hong Kong, Taiwan, and the Philippines, we launched new products or obtained regulatory approval.

### Sales by Geographical Area

2012.3



Note: Yen base  
Calculated according to the location of sellers

### Sales of Major Products

		¥ billion		
		2011.3	2012.3	2013.3 (Forecasts)
Sales in Asia & Oceania		33.7	↑ 35.7	↑ 39.3
Immunosuppressant	Prograf	14.8	↑ 15.2	↑ 17.6
Treatment for the functional symptoms associated with benign prostatic hyperplasia				
	Harnal	9.2	↑ 9.8	→ 9.8
Overactive bladder treatment				
	Vesicare	1.4	↑ 2.4	↑ 3.1
Candin-type antifungal agent				
	Mycamine	1.6	→ 1.6	↑ 2.1
Treatment for atopic dermatitis				
	Protopic	0.9	↑ 1.2	↑ 1.5




### Shinichiro Katayanagi


Senior Vice President and  
President, Asia International

## Fiscal 2012 Outlook


Despite forecasts of reductions of drug prices in China and South Korea, in fiscal 2012, we project regional net sales of ¥39.3 billion, up 10.0% from the previous year. This projection includes a year-on-year increase in sales of around 19% in China. By product, we forecast sales growth for such products as Prograf, Vesicare, Mycamine, and Protopic, while we expect sales of Harnal to remain unchanged.

## Continuous Product Introductions (Approvals and Launches) (2011.4 - 2012. 6)


 **China**  
Start of ATG\* distribution


 **Taiwan**  
Harnalidge OCAS  
(Harnal OCAS) launch  
Febic (febuxostat) launch

 **India**  
Advagraf launch  
Vesicare approval  
Prograf for lupus  
nephritis approval  
Mycamine for aspergillus  
indication approval

 **Hong Kong**  
Approval of Febic  
(febuxostat)

 **Thailand**  
Advagraf launch

 **Philippines**  
Prograf for lupus  
nephritis approval

 **Singapore**  
Advagraf approval

 **Australia**  
Start of Vesicare distribution  
through own channel

\* ATG (Anti-human T-lymphocyte immunoglobulin, rabbit)

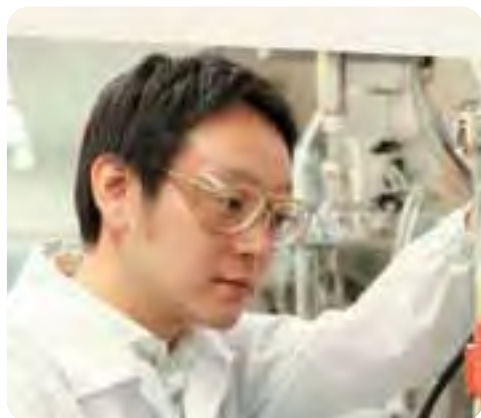
## We have built a stable profitable business platform primarily with proprietary products in the therapeutic areas of transplantation and urology.

Astellas has extensive coverage of the Asia & Oceania region, with nine sales subsidiaries (in China, Hong Kong, South Korea, Taiwan, the Philippines, Thailand, Indonesia, India, and Australia). With a focus on proprietary products in the therapeutic areas of transplantation and urology, we have built a business platform that is capable of generating stable profits. Astellas will deliver new drugs to patients with its focus on being a Global Category Leader.

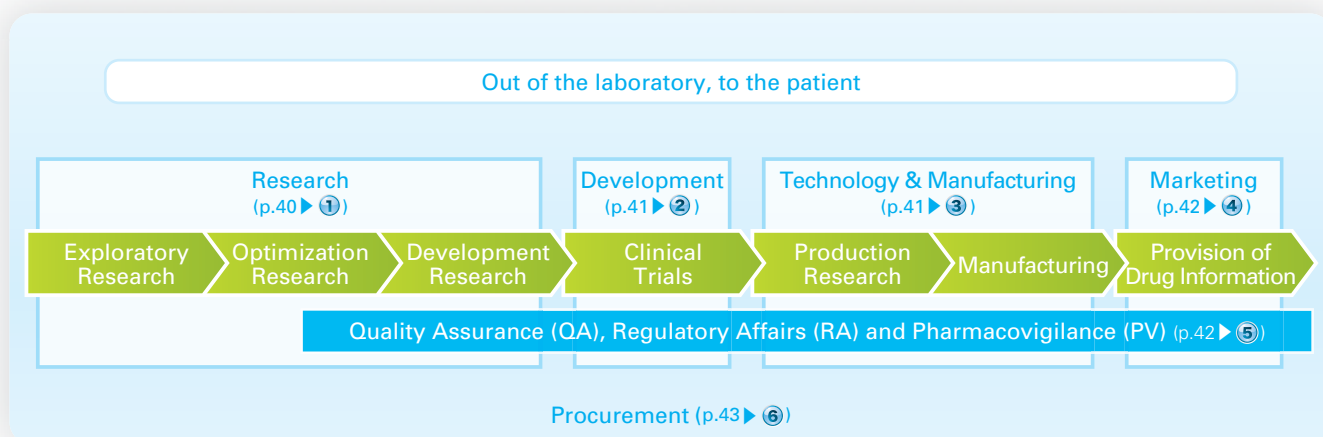
Even in the medium term, the drug market in Asia & Oceania is expected to grow more than 13% a year on average. In this promising market, Astellas is targeting high growth that outstrips the market growth rate. We will achieve this by successively launching new products and implementing a marketing strategy that accurately meets the particular market needs in each country.

Astellas has positioned China as the region's growth driver. In the medium term, it is estimated that the pharmaceutical market in China will become the second largest in the world. We will further expand our business in China through aggressive investments, such as substantially increasing the number of MRs and focusing on human resource development.

## CSR Initiatives in Business Processes



Astellas pursues CSR initiatives in all business processes, from R&D to the distribution of final products.



### ① Research

At Astellas, research encompasses three phases: “Exploratory Research,” which searches for compounds or substances to work on target molecules that are the cause of a medical disorder; “Optimization Research,” which selects the optimal compound based on an assessment from various angles, including efficacy, absorption, metabolism, and toxicity; and “Development Research,” which performs animal testing and other tests to evaluate whether or not the compound is safe for human use.

In the research process, we formulate drug candidate substances by using a variety of genetic resources and specimens derived from humans. At the same time, in addition to complying with Good Laboratory Practice (GLP\*), we also emphasize the proper use of genetic resources, the use of specimens derived from humans, and ethical considerations relating to animal testing.

\* GLP: Safety standards for pharmaceutical products in non-clinical studies

#### The Fair and Equitable Use of Genetic Resources

The Tenth Conference of the Parties to the Biodiversity Convention has established a set of international proto-

cols governing the use of genetic resources, including microorganisms as well as flora and fauna and the allocation of profits derived from their application.

In the past, Astellas has undertaken joint research on the exploration of new microorganisms and their use in drug discovery in accordance with international protocols. Going forward, Astellas will continue using genetic resources appropriately for the development of pharmaceuticals.

#### Ethical Considerations in the Use of Specimens Derived from Humans

Astellas obtains and uses specimens derived from humans in accordance with the laws, regulations, and guidelines of individual countries. In Japan in particular, a committee comprising members of the public and experts in the fields of the natural sciences, the social sciences and the humanities, as prescribed in the guidelines, deliberates on the propriety and the ethical acceptability of research on human genome and tissue samples.

## Ethical Considerations in Animal Testing

Astellas has established the Institutional Animal Care and Use Committee, which includes outside members, to oversee the activities of the Company's animal testing facilities in Japan. In addition to our own guidelines that consider animal welfare, we apply the three Rs\*<sup>1</sup>, which are international principles governing animal testing, plus a fourth principle, which is "Responsibility," (responsibility in animal testing). The Company also rigorously screens animal breeding environments, facilities, and activities. Moreover, we confirm that animal testing is being properly conducted through a self-check and self-assessment system. As a result of such initiatives, all of

Astellas' animal testing facilities in Japan have acquired accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) International\*<sup>2</sup>, a third-party assessment organization. In addition, our U.S. subsidiaries Agensys and Urogenix acquired the same accreditation in fiscal 2011.

\*1 The three Rs: "Replacement" (replace the use of animals with other non-animal testing methods), "Reduction" (minimize the number of animals used), and "Refinement" (minimize pain and distress) are the three principals which the international community is following to encourage the humane care and use of laboratory animals.

\*2 AAALAC International: An organization that promotes the humane treatment of animals through voluntary accreditation and assessment programs. Studies are undertaken both from scientific and ethical standpoints to verify the quality of animal control and use programs.

## ② Development

In the development process, we conduct clinical trials in which we assess the efficacy and safety in humans of drug candidate substances discovered in the research process. While protecting the human rights and personal information of patients, we must ensure safety and reliability in conducting clinical trials. Astellas has established a system that monitors and checks ethical propriety and scientific validity from the clinical trial plan formulation stage. We observe the Declaration of Helsinki and the ICH\*<sup>1</sup> Guidelines\*<sup>2</sup>, which include Good Clinical

Practice\*<sup>3</sup>, in the conduct of clinical trials. Our clinical trials are conducted only at medical institutions complying with these guidelines. In line with these guidelines, we are undertaking drug development activities with the aim of providing patients with the drugs they need as quickly as possible.

\*1 ICH: International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, brings together the regulatory authorities and pharmaceutical industries of Japan, the United States, and Europe.

\*2 ICH Guidelines: A set of guidelines governing the collection of data on a drug's quality, efficacy, and safety required for drug approval.

\*3 Good Clinical Practice: An international quality standard for clinical trials of pharmaceuticals

## ③ Technology & Manufacturing

In this process, we search for the most suitable formulation design of tablets, injections, or eyedrops, etc. based on the properties of individual drugs. We also investigate mass production and quality assurance methods that will preserve the quality of drugs.

In manufacturing, we place top priority on the continuous supply of high-quality pharmaceuticals. To ensure this, we have established our own standards that exceed Good Manufacturing Practices (GMP)\*. Under these standards, we apply rigorous integrated quality assurance that encompasses manufacturing facilities, equipment, and processes, as well as all stages from the procurement of raw materials through to storage and product shipments.

Our manufacturing system maintains a balance between cost management and high quality by way of efficiency gains achieved through automated and unmanned manufacturing processes and a cutting-edge production management system.

We use environment, hygiene, and safety assessment systems to ascertain and minimize environmental impact and safety risks in the production process.

For more information on environmental initiatives, please refer to pages 63 to 76 in the Environment section.

\* GMP: Control and management standards for manufacturing and quality assurance of pharmaceutical products.

## 4 Marketing

The marketing process involves providing and gathering information so that drugs are used properly in clinical settings. The aim here is to contribute to patient treatment while meeting the detailed requirements of each clinical setting.

In addition to providing information to ensure the effective use of our products and information on adverse effects, our Medical Representatives (MRs) supply wide-ranging information on pharmaceuticals in general as well as the latest knowledge and findings on medical conditions to the medical front line. MRs also provide feedback on the requirements of clinical settings to research and development departments, leading to the development of new drugs with even higher added value.

In Japan, Astellas has a Drug Information Center, which fields inquiries 24 hours a day from patients, medical institutions, and MRs. We have a system that ensures the continuation of the Center’s functions in emergency situations, such as in the event of a major earthquake or the outbreak of an influenza pandemic.

The Drug Information Center receives more than 80,000 external inquiries a year. We use the inquiries and feedback we receive to improve product value. For example, we make products easier to use by displaying the product name and dosage on capsules and tablets. We also make changes to designs to improve legibility and make products more easily identifiable.

## 5 Quality Assurance (QA), Regulatory Affairs (RA) and Pharmacovigilance (PV)

Astellas’ QA, RA and PV ensure that accurate information is provided together with its high-quality products with verified efficacy and safety. The improvement and expansion of these systems are an ongoing initiative.

Under these systems, we conduct objective assessments that comply with laws, regulations, and guidelines at all stages, including the research, development, and

manufacturing processes. We keep the correct records required for each specific procedure and assess these records and procedural compliance. To promote the appropriate use of pharmaceuticals, we assess information relating to their efficacy and safety, which we pass on to medical professionals.



### Astellas QA (Quality Assurance) Policy

**This policy is applied across the entire Astellas group in accordance with Astellas’ raison d’être, which is “to contribute to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.”**

- To meet customer requirements and acquire customer’s confidence
- To comply with current regulatory requirements and the Astellas QA Manual
- To assure the high quality products throughout their life cycle using scientific and risk-based approach
- To distribute products with Astellas quality activities developed under the concept “Quality is built up during development stage and built in throughout the manufacturing process” and “Quality is an integral part of every employee’s duties”



## Supplying High-Quality Pharmaceuticals

Astellas has introduced ICH Q10\* management, which covers a product's entire lifecycle from development through to product discontinuation. The system ensures a higher level of quality management.

\* ICH Q10: A pharmaceutical quality management system that clarifies top management's obligations and contribution to quality management with the aim of making continuous improvements to quality control and systems to ensure the supply of products with appropriate levels of quality.

## Information on Adverse Effects

Astellas collects and sorts information on the adverse effects of pharmaceuticals through a number of methods. These include notifications from medical institutions and companies, as well as studies by regulatory authorities. Where necessary, we take appropriate action, such as

revising product package inserts.

## Product Recalls

Astellas has a recall system that is activated when the safety, efficacy, or quality of a product is brought into question. The system ensures that the relevant information is promptly passed on to medical institutions and other affected parties, and the recall of the product in question.

In fiscal 2011, Astellas recalled three products. To date, we have not received any reports of health impairment related to these recalls.

## 6 Procurement

Appropriate procurement activities are indispensable for carrying out principled business activities. At Astellas, we implement CSR-related procurement throughout our entire network, including suppliers. We have formulated our own regulations to ensure equitable and fair procurement activities, which fall under our "Basic Policy for Procurement Activities Involving Suppliers." In addition to seeking compliance with this basic policy, we have formulated "CSR Procurement Guiding Principles" that set out for suppliers our requirements in terms of CSR-based measures. According to these principles, Astellas requires that suppliers pay particular attention to, and

monitor, respect for human rights and the prohibition of child labor.

In addition, the Company has produced the Astellas CSR Procurement Guidebook\* to facilitate the implementation of CSR-based procurement. In addition, we monitor suppliers' CSR-related initiatives through questionnaires covering their business activities, which we conduct in all regions. Astellas is reinforcing its global links to promote deeper understanding and dissemination of CSR-based procurement to which it aspires.

\* For further details on the Astellas CSR Procurement Guidebook, please visit the following site:  
<http://www.astellas.com/en/csr/enterprise/client.html>

### CSR Procurement Guiding Principles

- |   |  |
|---|--|
| <p><b>I Compliance with laws and promotion of CSR</b><br/>         Compliance with relevant laws and rules<br/>         Fair business operations based on ethical standards<br/>         Maintenance of information security<br/>         Encouragement and promotion of CSR activities</p> | <p><b>III Management of occupational health and safety practices</b><br/>         Maintenance of a safe workplace environment, and the management of occupational health and safety practices</p>  |
| <p><b>II Respect for human rights and fair employment practices</b><br/>         Respect for human rights and prohibition of child labor<br/>         Employment consistent with labor-related laws</p>   | <p><b>IV Responsible environmental and sustainability-related practices</b><br/>         Reduction of the global environmental impact, and contribution to sustainability</p> <p><b>V Social contribution initiatives</b><br/>         Participation in and support for social contribution activities</p> |



## Universal Design\*1 Initiatives

In clinical settings, to prevent the selection of the wrong type of drug and incorrect administration, before a drug is prescribed to a patient various checks are made relating to the drug's name, dosage, method of administration, and other important details. Astellas is actively promoting a new barcode system to prevent patients, physicians, nurses, and pharmacists from selecting the wrong type or dose of a drug. Other initiatives include displaying a product's name directly on tablets.

As part of these initiatives, we took an exceptionally innovative approach when designing the package for Bonoteo Tablets 50mg used in the treatment of osteoporosis. The design has been highly praised and has earned Astellas several awards\*2.

We followed the principles of "Color Universal Design"

in the color and design of the overactive bladder (OAB) treatment Betanis (mirabegron) tablets launched in September 2011, in Japan. The opinions of medical professionals and patients were incorporated to improve distinguishability and legibility, especially for people with color vision impairment.

The Company intends to apply the same efforts to future products to be launched in Japan.

\*1 Universal Design: Design that is accessible to as many people as possible regardless of age, ability, or situation.

\*2 Received the Pharmaceuticals and Medical Packaging Award in the "2012 Japan Packaging Competition," sponsored by the Japan Federation of Printing Industries.

Received the Japan Packaging Institute's Kinoshita Award in the Innovation category.



A package of Bonoteo Tablets 50 mg, a treatment for osteoporosis

- ① Clear indication of administration time
- ② Clear display of tablets through the packaging
- ③ Box that protects the PTP aluminum foil sheets
- ④ Print that is easy to read ("Universal Design")



Overactive bladder (OAB) treatment, Betanis (mirabegron) tablets

- ⑤ Yellow PTP sheets for 50mg tablets, for easy identification by users, whether they have defective or normal color vision
- ⑥ Printing alignment (easy identification even when the sheets become separated)
- ⑦ Color variations for 50mg tablets and 25mg tablets (for easy identification)

## Anti-Counterfeiting Measures

A counterfeit medicine is a formulation that is not produced by the manufacturer it claims to have been made by and does not contain the specified ingredients it claims to contain. Counterfeit medicines have become a serious worldwide health problem because they not only prevent a patient from receiving medical treatment due to the absence of specified effective ingredients, but they are also reported to impair people's health because of the harmful substances they contain.

To ensure the quality of its products during the distribution stage, Astellas has established the Anti-Counterfeit Committee and appoints members to investigate and take measures

against counterfeit medicines. We endeavor to ensure patient safety by including the implementation of various countermeasures to prevent counterfeit medicines in line with our global medium to long-term action plan. In addition, we adopt timely and appropriate measures based on our findings in the surveillance of counterfeit medicines.

Astellas carries out educational activities to prevent the spread of counterfeit medicines, working together with members of the pharmaceutical industry and international entities, such as the World Health Organization. We also cooperate with law enforcement agencies to crackdown on counterfeit medicines.



## Employees

For Astellas, employees are the most important component of the value chain that creates enterprise value. Employees are also important stakeholders. Astellas fosters proactive employees dedicated to realizing the Company's business philosophy. At the same time, Astellas respects the dignity and autonomy of each individual and maintains a workplace in which employees can concentrate on their work with a sense of security.

- 046 Basic Policy
- 047 Human Resource Strategies and Policies
- 049 Developing Human Resources—Training Programs—
- 052 Creating the Ideal Workplace
- 054 Five Messages for the Astellas Way



## Astellas formulates basic strategies and develops the necessary systems to help employees maximize their potential.

To help employees maximize their capabilities and contribute to the ongoing evolution of Astellas, we believe in providing opportunities for personal development coupled with a human resource system that allows individual employees sufficient scope to demonstrate their individual talents. At the same time, we are working to achieve a human resources management system that asks what it can do or should do for employees, while adhering to policy.

### Core Important Medium to Long-Term Priority Issues

- 1 Foster human resources
- 2 Respect human rights
- 3 Achieve a work-life balance
- 4 Promote opportunities for women to excel (Japan)

### Fiscal 2011 Initiatives

- ▶ Commenced a leadership development program for senior managers (global)
- ▶ Launched a program that helps employees create career plans and supports those plans (the United States)
- ▶ Commenced a next-generation executive training program used by a business school (Europe)
- ▶ Introduced an initiative that clarifies the roles and levels of specific jobs and creates clear links with career plan designs (Europe)
- ▶ Established a scheme for the exchange of personnel (Asia and Oceania)
- ▶ Introduced WIND mentoring\* (Japan)
- ▶ Received the Grand Prize in the J-Win Diversity Awards (Japan)

\* A mentoring program for female employees under which all executives in Japan encourage self-development and self-reliant growth through discussions of career planning, work problems, and other relevant issues.

## Astellas' Desired Talent

Astellas has identified its ideal conceptual image of desired talent of its human resources. This image clarifies the direction for employee career building and is outlined in the diagram at right.



To achieve its Business Philosophy and VISION 2015, Astellas has established “Astellas’ Desired Talent” and “Astellas’ Desired Organization.” At the same time, we are building a framework for effective deployment of our human resources.

## Global Human Resource Strategy

Astellas recognizes that the value of a business enterprise rests in the value created by its employees. Accordingly, corporate activities are sustainable only if they are supported by employees. Because employees are the most directly affected by changes to a company’s business strategies, etc., Astellas recognizes that it has responsibilities to employees as stakeholders.

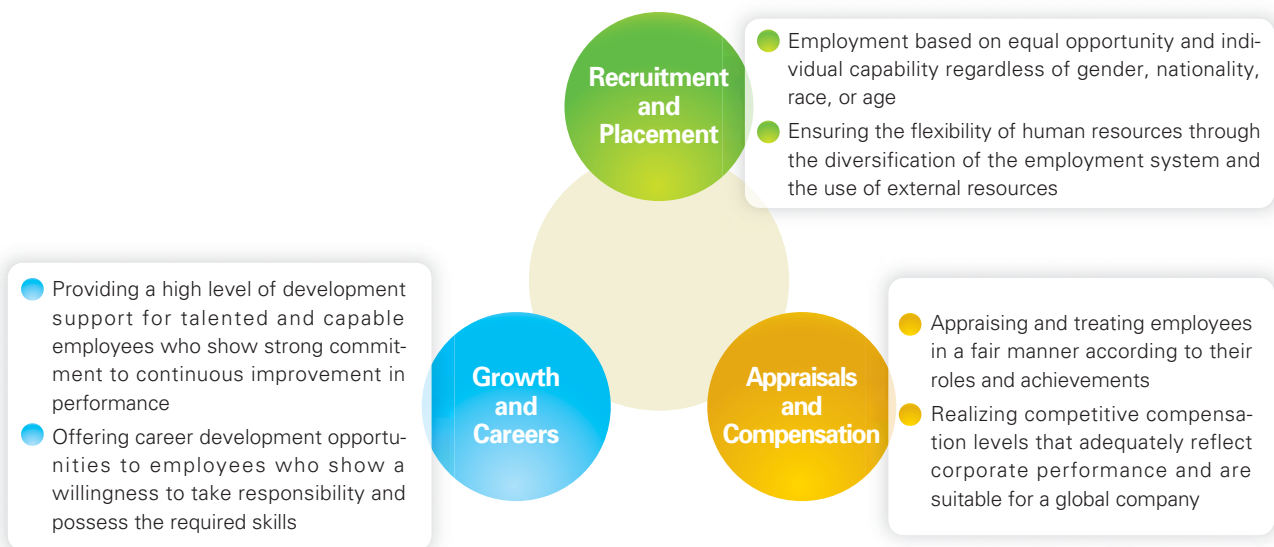
In “Astellas’ Desired Talent,” Astellas spells out the employee attributes it looks for as an employer, and specifies the actions its employees need to take. In “Astellas’ Desired Organization,” the company describes its agile and highly productive structure, which enables such employees to flourish in their jobs. In addition, Astellas has established a “Human Resources Management

System,” which sets out policies and processes for employee recruitment, placement, evaluation, compensation, and career development.

Furthermore, it is important that all employees who are working in various different countries share the same vision in their daily business activities. Astellas intends to foster a universal yet empathetic corporate culture. Consequently, in 2010 members of top management defined the values and actions Astellas requires of employees in their day-to-day work activities as the “Five Messages for the Astellas Way.”

Using these policies and practices as a foundation, each company has its own human resource system and work environment that are optimized to meet local requirements and needs.

## Human Resources Management System



### (1) Human Resources Policy in Japan

In Japan, Astellas examines and implements systems and policies on recruitment, placement, evaluation, compensation, and career development based on the human resource vision to realize VISION 2015.

In order to maximize the achievements of employees and be a successful organization, Astellas recognizes the importance of ensuring that employees devote themselves to their jobs, and maintain and improve their mental and physical health. Accordingly, Astellas provides an appropriate work environment, as well as the necessary support. As a management strategy, Astellas seeks to effectively utilize employees by implementing initiatives that promote diversity through the recruitment and placement of a broad spectrum of employees.

Astellas has introduced systems that help employees achieve a work-life balance. In addition, we actively promote measures aimed at transforming traditional attitudes towards work.

### (2) Human Resources Policy in the Americas

Being an Employer of Choice is a top priority for Astellas in the Americas. Research shows that companies regarded as an Employer of Choice experience better performance. Therefore, Astellas evaluates high performers and give them proper compensation that matches their performance level. At the same time, we provide career development opportunities to all employees and foster the next generation of leaders with an eye to the company's future. To create an ideal workplace, meanwhile, we strive to be more transparent in all our communications with employees and foster a healthy work-life balance.

### (3) Human Resources Policy in Europe

In Europe, as well, Astellas aims to be an Employer of Choice. Adhering to the principle of providing appropriate compensation to the right employees at the right time, we have a leader development program that encourages managers with high potential and provides them with a

personal career development plan. Meanwhile, we are making efforts to foster an environment in which a healthy work-life balance can be realized.

During the past approximately 30 years of its business presence in Europe, Astellas has implemented throughout the region a variety of measures that take account of diversity in the workplace. As a result, the ratio of female and male employees working for Astellas in Europe is roughly the same, and includes employees of over 50 different nationalities representing a diversity of religions, races, and a wide range of ages that spread from 18 to 65 years old. The diverse workforce that we have achieved in Europe includes employees with disabilities.

### (4) Human Resources Policy in Asia & Oceania

In the constantly expanding Asian market, Astellas aims to develop talented employees who will drive future business growth in this region. Our human resources strategy consists of four main elements: (1) reinforcement of leadership and management skills; (2) expansion of the pool of future managers and the fostering of pan-Asian employees; (3) employee placement in alignment with business strategies; and (4) enhancement of compensation to competitive levels, and expansion and enhancement of various human resource programs. Astellas headquarters in Japan provides support for these programs, while each subsidiary also has its own independent initiatives.

#### Number of Employees per Region and Turnover Rate

		2010.3	2011.3	2012.3
Japan	Number of employees	7,860	8,023	8,176
	Turnover rate	2.2%	1.7%	1.5%
Americas	Number of employees	2,375	2,742	2,919
	Turnover rate	—	—	12.6%*
Europe	Number of employees	3,775	4,102	4,286
	Turnover rate	—	—	8.1%
Asia	Number of employees	1,151	1,412	1,704
	Turnover rate	—	—	13.3%
Total	Number of employees	15,161	16,279	17,085
	Turnover rate	—	—	6.2%

\*Includes OSI Pharmaceuticals and Perseid post merger and acquisition restructuring activities. Excluding OSI and Perseid, the turnover rate was 9.5%.

# Developing Human Resources—Training Programs—

Astellas believes that it must provide opportunities that allow employees to develop their talents and acquire the skills it needs as a company. We recognize that training is a means of achieving these aims. The group's training and development programs are implemented either on a cross-departmental and cross-regional basis, or on a national, regional, or occupational basis to address specific issues.

## Approach to Training Programs

For employees who possess the commitment and the aptitude to be high achievers, Astellas supports the development of their capabilities to a high level. We offer appropriate career development opportunities that reflect the commitment and the aptitude of employees who show a willingness to take responsibility.

### (1) Global Leadership Programs (ELS, SLS)

The progressive globalization of business has made the globalization of the Astellas workforce an increasingly important priority. Therefore, we established and have begun implementing a global leadership development program to help prepare the next-generation of senior managers, managers and group leaders who will take on global leadership roles in the future.

In fiscal 2011, Astellas launched the Executive Leadership Series (ELS) for senior managers. This program helps to strengthen collaboration across functions and regions, enables participants to forge strong personal networks with other leaders, and reinforces their management capabilities so that strong leadership can be exercised anywhere in the world. The ultimate aim of the program is to develop executives capable of finding solutions to the various issues from a global perspective.

In fiscal 2012, Astellas is launching the Senior Leadership Series (SLS) for managers and group leaders who are one rank lower than the executives.

### (2) Astellas Pharma Global Development (APGD) Initiative

To strengthen its development framework, Astellas is integrating its global development operations. Today, employees need to coordinate between regions in the course of their daily work activities. Therefore, in a departure from previous activities undertaken in Japan, the United States, and Europe, Astellas employees are currently expected to adopt a global perspective and a global mindset.

The aim of the Astellas Pharma Global Development (APGD) Initiative is to promote stronger and more effective team management. Since fiscal 2010, we have held training seminars under the theme "Working Globally in Astellas," to foster a deeper understanding of different cultures.

The main focus of this initiative is to foster a global mindset by discussing issues related to the cultural backgrounds and perspectives found in the United States, Japan, and the Netherlands—locations where APGD employees are based. Topics of discussion include "What must I be mindful of when working with people who come from a different cultural background?" "What is the cultural background of the community/society to which I belong, and how is it different from other cultures?" and "What is the key to success in today's global business world from the perspective of recognizing and overcoming cultural differences?"

In 2010 and 2011, approximately 400 employees working on the APGD Initiative took part in these seminars. Unlike previous seminars that were held in each region, these seminars marked a new approach in that they were held around the same time and used the same training materials.



### (3) Japan



**Yoshiaki Nakashima**  
Vice President, Human Resources

In Japan, we hold specialized training programs designed for specific business areas. Complementing these programs is the Astellas Learning Institute, a member of the Astellas group that provides a broad range of training programs.

We also have the Astellas Business School, which helps employees develop the skills and competencies needed to fulfill the employee profile set out in our corporate vision. The school offers a two-tiered program. The Astellas Growth Program is a general education and training program for employees in their first five years of employment. The Astellas Professional Program is for specialists and managers. In fiscal 2011, some 3,100 employees, including those from domestic group companies, took part in these programs either through onsite participation or distance learning.

In addition, we have introduced the Job Challenge Program for employees who take the initiative to seek out new opportunities, and we are also creating a career development support system under which all employees meet with their immediate manager once a year to discuss their jobs and receive career guidance.

### (4) The Americas



**Collette Taylor**  
Senior Vice President,  
Human Resources & Corporate  
Administration,  
Astellas US LLC

Making Astellas an Employer of Choice is the key aim of all Human Resources activities in the Americas. We believe it is vital to attract the best people, reward high performance, and create an environment in which employees can fully develop and contribute their talents. Our emphasis on development spans our entire region, across all companies and all functions, and our development programs go beyond the typical employee training curriculum.

One program we are particularly excited to have recently launched is Taking Charge of Your Career. Taking Charge of Your Career is grounded in the most up-to-date thinking and research on how employees approach their own career development. It is our belief that building a high-performance culture begins with empowering employees to take responsibility for their career growth, enabling them to make choices that suit their career aspirations or changes in their personal lives.

This program includes employee self-assessments, the development of individualized career plans (including on-the-job learning, attendance at networking events, mentoring programs, etc.), training for managers so that they can provide support and guidance to their teams, and formal talent reviews and succession planning.

By investing resources in such cutting-edge, unique programs, the Americas region will ensure that it is a place where high-performing employees will do their best work for Astellas and for patients.

## (5) Europe



**Arjen Vermazen**

Senior Vice President,  
Human Resources, EMEA,  
Astellas Pharma Europe Ltd.

In Europe, Astellas has teamed up with INSEAD, one of the world's leading business schools, to create two key Leadership Development programs (Future Leaders and Leadership Journey) as training programs to support the cultivation of leadership talent. Both programs support the development of executive and senior leaders with the aim of increasing their leadership capabilities.

The Future Leaders educational program takes high-potential managers and raises their management capabilities, and then readies them for leadership positions. It consists of two separate four-day sessions that focus on practical work. Even after employees have completed the program, coaching takes place to ensure that what is learned is continuously applied in each workplace. To date, 90 high-potential managers from 18 different EMEA\* group companies have taken part in the program.

All of Astellas Europe's senior leaders, 280 in total, have attended the Leadership Journey program at INSEAD. The eight-day experiential program emphasizes the importance of continuous learning and great leadership, and plays a very key role in shaping the corporate culture of Astellas.

\*EMEA: Europe, the Middle East and Africa

## (6) Asia & Oceania



**Shinichiro Katayanagi**

Senior Vice President and President,  
Asia International

Training and development programs in this region focus on leadership development for employees with high potential as future leaders at Astellas. We offer a variety of training programs that target three specific groups: subsidiary presidents, senior managers, and young employees with leadership potential.

In the program for subsidiary presidents, we use outside experts to evaluate participants and to provide executive coaching in order to further reinforce their management skills.

The program for senior managers centers on the implementation of training in organizational culture. The aim is to foster a sense of unity among senior managers in Asia & Oceania by deepening their understanding of our corporate culture, fostering loyalty, and strengthening interaction among sales companies.

We hold a Stellar College seminar for young employees destined for leadership roles in which they acquire in-depth knowledge on VISION 2015 and the Astellas Way. The training for participants selected from sales companies throughout the region is based on a business simulation format. After they have returned to their home countries, participants become coaches and hone their leadership skills by conducting the same simulations in their own companies.

We also offer hands-on training under the Action Learning program for high-performing employees working in subsidiaries in Asia. We send successful applicants to Japan, where they gain overseas work experience, either through a temporary overseas work assignment or a long-term business trip.

# Creating the Ideal Workplace

To create the ideal workplace, Astellas adopts a broad range of measures that match the needs and characteristics of each country and region. We work to foster a workplace where all employees can concentrate on their work with a sense of security while promoting workplace diversity that attracts a broad spectrum of employees to Astellas.

## Work-Life Balance

Fostering a healthy work-life balance is very important at Astellas. In each region we maintain a workplace environment that more than meets local standards.

Many of our group companies around the world have systems that allow their employees to choose work schedules that match their lifestyles. Options include flexible working hours, part-time work, and working from home.

Flexible working hours have been adopted in many Astellas workplaces, including those in Japan, the Americas, the United Kingdom, and Taiwan. The adoption of part-time working hours is common among our European affiliates. Working from home has already been introduced in Japan, the Americas, Belgium, and France.

In Asia, we are also establishing systems that provide paid leave and substitute days off, and are encouraging employees to use their vacation days. We also have a campaign to do away with overtime work. Astellas will continue examining the introduction of various work systems while monitoring employment practices in the region.

## Improving Employee Health

Astellas recognizes that the well-being of its employees is important in the workplace.

Many group companies employ various measures aimed at the maintenance of good health. In Japan, employees undergo annual health checks. Employees who need more detailed testing or re-testing are urged to do so. In Japan, the Americas, and Europe, Astellas strives to improve employees' health through health promotion programs. For example, Astellas encourages staff members to walk more and give up smoking.

Mental health problems, which are becoming a serious concern worldwide, can arise due to a variety of factors, including stress from work or daily life. Astellas has been building a system that offers employees counseling with a company psychiatrist as well as providing help through external Employee Assistance Programs.

Astellas in the Americas adopts a progressive approach toward employee mental health. It independently offers mental health counseling services, as well as programs and seminars that teach employees how to eliminate stress so they can lead happy and healthy lives. In Japan, we established a system offering employees the opportunity to see a company psychiatrist or consult an external health specialist. We also perform mental health checks in which we use objective data to ascertain stress levels among employees. If the results indicate there is a need for improvement in a particular workplace, we consult with the relevant managers to develop countermeasures.

## Respect for Human Rights

The Astellas Charter of Corporate Conduct clearly states that members of the Astellas group shall respect human rights, the personality and individuality of all its employees, observe all applicable international rules and local regulations, and also respect all cultures and customs. The recognition of the importance of respecting human rights is shared in group companies worldwide. In accordance with this principle of respect for human rights, the Astellas Global Code of Conduct established in April 2012 sets out standards on respect for the human rights of employees, equal opportunities for employment and training, employee health and safety, and the prevention of harassment in the workplace.

## Respect for Diversity

On the whole, the ratio of male and female employees working for Astellas worldwide is roughly the same. However, compared with the Americas, Europe, and Asia, the proportion of female employees in Japan is low, particularly the ratio of women who hold management roles. Recognizing that changing attitudes regarding women in the workplace and promoting opportunities for women to excel are important issues in Japan, Astellas has instituted various systems to improve the work environment in ways that provide support for women so they can continue working.

As part of fostering respect for diversity in the workplace, Astellas promotes the employment of people with disabilities. Employees with disabilities at the Green Supply Support Office established at the group company Astellas Business Service account for more than 2% of all staff in Japan.

### Male/Female Employee Ratio per Region, and Ratio of Female Managers (Fiscal 2011)

	Japan	Americas	Europe	Asia
Male	72.9%	49.2%	44.9%	47.7%
Female	27.1%	50.8%	55.1%	52.3%
Ratio of female managers*	4.8%	41.7%	42.5%	45.5%

\*Applies to key management positions in Japan, as well as Directors in the Americas, Europe, and Asia

## Occupational Safety and Health

Supporting our employees as Company stakeholders is an important social responsibility, and in addition to providing an ideal workplace, ensuring the safety of employees while they are engaged in corporate activities is an essential management priority at Astellas. Understanding the importance of preventing work-related accidents and minimizing accidents caused by workplace mishaps and hazards, Astellas promotes a range of initiatives to ensure a safe working environment for all employees.

From January to December 2011, there were 19 incidents in Japan in which employees required medical treatment, although none required a leave of absence. Overall, initiatives aimed at preventing serious accidents have become firmly established in the workplace, and Astellas believes it is maintaining its intended safety standards.

Overseas, there were six incidents in total involving injuries that required time off work. Most of these injuries involved sprains or other injuries sustained as a result of incorrect body position. There was one incident at the Kerry Plant in Ireland in which the tip of an employee's finger became trapped during machine maintenance operations. Although an operating procedure manual had been prepared and preliminary training had been conducted, operating procedures were not being followed closely enough. To ensure the proper observance of operating procedures in the future, we are working to further enhance our training and awareness-raising activities.

### Incidence of Work-Related Injuries in Japan

	2009.1-12	2010.1-12	2011.1-12
Number of work-related injuries	27	33	19
Frequency rate of work-related injuries*1	0.37	0.31	0.00
Severity rate of work-related injuries*2	0.002	0.001	0.000

### Incidence of Work-Related Injuries at Overseas Plants (January—December 2011)

	Norman Plant	Meppel Plant	Dublin Plant	Kerry Plant	Shenyang Plant
Number of injuries requiring leave of absence	0	4	0	1	1
Frequency rate of work-related injuries*1	0.00	7.76	0.00	1.976	0.314
Severity rate of work-related injuries*2	0.000	0.037	0.000	0.106	0.009

\*1 Frequency rate of work-related injuries: This rate shows the number of employee deaths or injuries resulting from work-related accidents causing leave of absence per million hours of work. The larger the number, the more frequently work-related injuries occur.

\*2 Severity rate of work-related injuries: This rate shows the number of days absent from work due to work-related injuries per thousand hours worked. The higher the number, the more serious the injury.

## Labor and Management Communication

Astellas believes that it is important to promote direct communication between labor and management. Accordingly, there are numerous opportunities available across the Company for labor and management to exchange opinions on various themes.

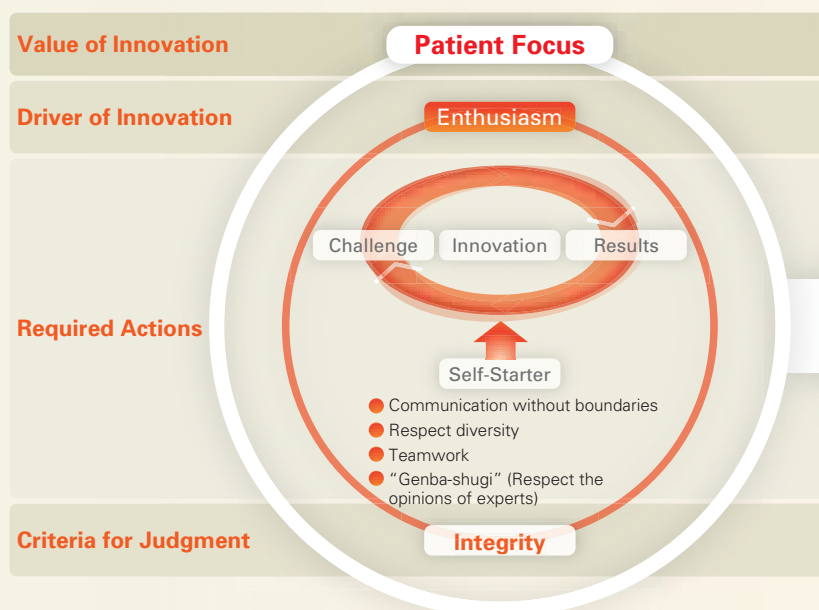
Astellas does not impose any restrictions on labor union membership or formation in its global operations. In Japan, the Astellas Labor Union comprises employees of Astellas Pharma Inc. and some consolidated group subsidiaries. The union is a member of the Japanese Federation of Energy and Chemistry Workers Unions. As of March 31, 2012, there were 5,108 union members in Japan.

# Five Messages for the Astellas Way

## The Five Messages define the shared values and actions that must be put into practice by the Astellas group's 17,000 employees worldwide

Your first thoughts must always be for the health of the patient...  
Five Messages to Change Ourselves and the Company

### The elements of behavior to achieve innovation



### Five Messages to Change Ourselves and the Company

- Patient Focus**  
Ask yourself if your decisions or actions contribute to improving patient health.
- Enthusiasm**  
Your passion to overcome barriers can inspire others, and together you will achieve greater success.
- Results**  
Commit to results each time you face a challenge, and consider a fresh approach to achieving them.
- Communication**  
Open up discussion, share your concerns or good ideas, and be receptive to ideas from others.
- Integrity**  
Act with integrity. Always consider the implications of your actions and take responsibility for them.

In April 2010, Astellas defined the Five Messages for the Astellas Way, as actions now required of Astellas employees. They set out the actions required today that will enable Astellas to create innovative new drugs as a unified group and deliver them to patients immediately without fail. The Five Messages consist of values and actions to be shared globally.

### Practical Examples

## Assistance given to transplant patients requiring blood monitoring at a time when flooding in Bangkok forced the laboratory to close

Damage from the heavy flooding in Thailand affected even Bangkok's city center, and it was so extensive that the clinical laboratory in Thammasat University Hospital's Organ Transplant Center was forced to suspend operations. As the damage caused by the floods escalated, Krid Sakronkhan, an Astellas Medical Representative in Thailand, visited the Organ Transplant Center and extended aid to a renal physician there who was searching for a hospital where he could have blood monitoring done. Even after they had found a hospital that could do the monitoring, Mr. Sakronkhan continued working to

facilitate smooth collaboration between the two hospitals.

By taking a series of steps as a volunteer, Mr. Sakronkhan "contributed to the improvement of patient health," and in so doing acted in a way that appropriately reflects the Astellas Way. In fiscal 2011, Mr. Sakronkhan was presented with a Special Recognition Award, along with nine other worthy recipients, under the Astellas Way Global Recognition Program, which aims to achieve the widespread adoption of the Astellas Way and seeks to share such practical examples with all Astellas employees.



**Krid Sakronkhan**

Sales Section  
Astellas Pharma (Thailand) Co., Ltd.



## Society

Corporations, being members of society, must foster a sustainable overall society while maintaining good reciprocal relationships with communities. We at Astellas address the needs of local and global communities by deploying our knowledge as a pharmaceutical company to help realize a sustainable society, and earn the trust of society through these efforts.

- 056 Basic Policy
- 057 Enrich the Lives of Patients
- 059 Enrich Healthcare Systems
- 061 Link with Society

\* Astellas' initiatives with respect to workplace environments and human rights, which are key elements of society, are outlined in two sections of this report: "Employees," which relates to our employees, and "CSR Initiatives in Business Processes" which relates to the value chain. In the field of "Society," we introduce social contribution initiatives aimed at supporting people's healthy lives.



## We support healthcare activities for the benefit of patients and society.

Advancing society in a sustainable way requires corporate activities that take into account three crucial aspects, specifically the economy, the environment, and society.

In addition to contributing to the health of people around the world through its business activities, Astellas helps build environments to support people's healthy lifestyles via its social contribution activities. We place importance on maintaining ties with the local communities in which we conduct business, and we pursue our social contribution activities based on the three areas outlined below.

In order to encourage proactive initiatives by its employees, Astellas has established various programs in each region, such as a "Matching Gifts Program"\* and a "Volunteer Leave" system. In addition, we promote information disclosure and subject our activities to regular reassessments.

\* Charitable donation system in which financial contributions by employees are matched with equal amounts by Astellas.

### Core Important Medium to Long-Term Priority Issues

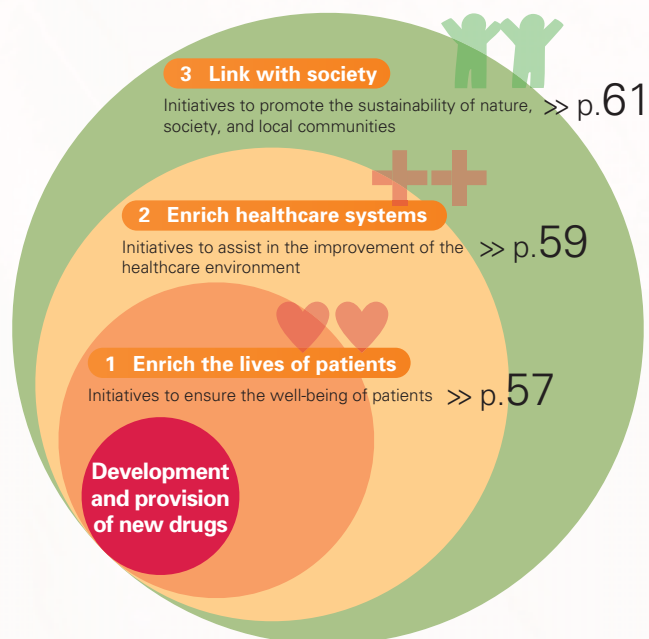
- 1 Respond to global issues
- 2 Participate in local communities
- 3 Support the strengthening of the healthcare environment

### Fiscal 2011 Initiatives

- ▶ Modified our Social Contribution Basic Policy (October 2011)
- ▶ Implemented group-wide "Changing Tomorrow Day" activities
- ▶ Participated in United Nations Millennium Development Goals (MDGs) (reduce child mortality, improve maternal health, and prevent malaria)
- ▶ Supported the advancement of medical science

## Three Areas of Social Contribution Activities

This chart shows the concept and the realm of our Social Contribution Activities being categorized into three areas, which extend from our business, centered primarily on the "development and provision of new drugs."



Astellas thinks of the patient, and supports activities to help alleviate the concerns of patients fighting against diseases and their families. These social contribution activities also help to deepen the understanding of patients' issues among our employees.

## Starlight Partners Activities (Support for Patients Association in Japan)

Through Starlight Partners Activities (support for patients association) which are undertaken in Japan, Astellas provides assistance to patients associations in their efforts to support patients and their families. We engage in four activities to promote the sustainable development of patients associations. In the process, we receive specialist advice from our advisory board, which is essentially a group of professional outside counselors.



Peer support training session

<b>Funding for Patients Association Activities</b>	Astellas provides patients associations with the funding needed for their activities. Our support targets the promotion of self-reliance and human resource development for leaders and association members. Applications are accepted once a year. Fiscal 2011: 48 organizations received funding
<b>Peer Support Training Program</b>	Astellas holds peer support training sessions to encourage people who have experienced similar concerns and problems to become peer supporters, and also to nurture the skills of current peer supporters. Additionally, Astellas hopes to create an environment for building a system through which the organizations are able to exchange ideas and support each other. Held three times a year nationwide Fiscal 2011: Held in Sapporo, Fukuoka and Nagoya with 40 organizations and 49 people in attendance
<b>Instructor Dispatch</b>	Astellas dispatches instructors yearly to two patient associations or patient family groups that independently host training and study sessions. Fiscal 2011: Dispatched instructors to two organizations in Osaka and Kanagawa
<b>Event Materials</b>	Astellas cooperates with groups (including patients associations) in organizing and managing events. This includes the provision of event materials, such as pens and notebooks. Fiscal 2011: Provided to 39 organizations

### Participation in Peer Support Training Sessions

I am grateful to have had the chance to talk with people suffering from various diseases and disabilities at the peer support training sessions, which was for me something of a fresh experience. This was an opportunity for me to evaluate whether I have been really listening to people who need advice. I appreciate Astellas giving me this opportunity, and when I do counseling in the future, I will try harder to really listen to people—from

the heart—and actually share their pain and sorrows. If I can empathize with them and understand their feelings, I will also feel better. This process, done daily, will help me personally to improve.

In the future, I would be extremely grateful if support could be given to the implementation of educational activities that would help raise awareness toward rare disorders and intractable diseases across the broader community.



**Masuo Kawachi**  
Branch Manager of the Fukuoka Chapter of Japan Ostomy Association, Inc.

## For the Benefit of Patients Fighting Illness and Their Families

### Donation of boxes of toys and support for clown visits to children's pediatric wards (Japan)

Employees of Astellas have taken the initiative to establish the Flying Star Fund. The fund uses the Matching Gifts Program, in which employee contributions are matched by donations of equal amounts by the Company. Currently, our Flying Star Fund supports a variety of initiatives with the help of around 5,300 participating employees.

The Flying Star Fund provides assistance to the NPO Japan Good Toy Committee, for their visits to children's hospitals around Japan and the donation of the boxes of toys they use on their visits. These activities are done under the guidance of medical practitioners, and it is hoped that they will bring smiles to the faces of children playing with the toys.

We also support two other NPOs—the Japan CliniClown Association and the Japan Hospital Clown Team—which dispatch clowns to children's hospitals. These activities provide some fun to children who have

been hospitalized and help create a less stressful environment for playing.

### Relaxation through home-style cooking (USA)

Many patients suffering from serious illnesses, as well as their families, can often experience long periods of loneliness while in unfamiliar locations when receiving treatment. Seeking to alleviate the psychological burden of people in these situations, Astellas conducts a program in which volunteers make home-cooked meals for patients and their families staying at a Ronald McDonald House. Sick children and their families can use Ronald McDonald Houses as accommodation facilities under a program supported by donations and volunteer efforts.

Since January 2011, Astellas employees in the United States have volunteered on a monthly basis to prepare meals at a Ronald McDonald House near Chicago. Home-cooked meals prepared include spaghetti, grilled vegetables, and chocolate cake. We hope that recipients will be reminded of home from time to time as a result of these efforts.

Our Meppel Plant in the Netherlands and U.S. subsidiary Urogenix also participate in similar volunteer activities at these accommodation facilities.



Children in the pediatric ward play with a clown



Toys donated to the pediatric ward



Preparing meals at a Ronald McDonald House



As a pharmaceutical company driven by research and development, Astellas pursues healthcare-related initiatives among items listed in the United Nations Millennium Development Goals (MDGs) aimed at resolving global issues shared by the international community. We also target activities that enrich the healthcare system, including the provision of support for researchers, who hold the key to the future of medicine.

## United Nations MDGs

The United Nations MDGs consist of eight targets aimed at addressing various global challenges, such as the eradication of extreme poverty and hunger, by 2015. Among these, healthcare is positioned as an extremely important issue—one in which Astellas can make a contribution by deploying its experience as a pharmaceutical company. Accordingly, we have concentrated our commitment on the fourth, fifth, and sixth MDGs, namely “Reduce child mortality,” “Improve maternal health,” and “Combat HIV/AIDS, malaria and other diseases,” respectively.



### Reducing infant and maternal mortality rates (Indonesia)

Since fiscal 2009, Astellas has been supporting a project to reinforce the regional maternal healthcare system in Indonesia by donating birth centers to impoverished villages via PH-Japan, a health and medical NPO. Thanks to the project, those villages now have midwives in residence who can provide 24-hour birthing, medical, and health services, enabling significant reductions in infant and maternal mortality rates. In fiscal 2011, Astellas donated a birth center to the village of Tengkurak, which has a population of 3,086 and is located in the autonomous region of Tirtayasa, Serang.



Birth center donated in fiscal 2011

### United Nations Millennium Development Goals (MDGs)\*

- 1 Eradicate extreme poverty and hunger
- 2 Achieve universal primary education
- 3 Promote gender equality and empower women
- 4 Reduce child mortality**
- 5 Improve maternal health**
- 6 Combat HIV/AIDS, malaria and other diseases**
- 7 Ensure environmental sustainability
- 8 Develop a global partnership for development

\* MDGs are a series of eight time-bound targets with a deadline of 2015 drafted under the United Nations Millennium Declaration, which was adopted in September 2000 and builds on a decade of major United Nations conferences and summits that were held in the 1990s.

Medical examination room at birth center



Asniah, a resident midwife (center)





### Support for Treatment of Obstetric Fistulas (Ghana)

Obstetric fistulas (open connections) are severe medical conditions, which cause patients to become incontinent due to long and uncontrolled deliveries or other traumas. In Ghana, many women suffer from obstetric fistulas. This medical condition also poses a serious social problem in depriving women of their dignity, as these patients are frequently abandoned by their partners or exiled from communities. However, such patients typically remain untreated since medical care for obstetric fistulas requires advanced medical skills.

To alleviate the situation, our subsidiary in the Netherlands is undertaking initiatives to improve access to urological health-care in Ghana through partnerships with the Ananse Foundation\* and the Dutch Urology Association. Under the project, physicians are dispatched from the Netherlands to a urology specialist hospital in Ghana, where they provide local doctors with medical knowledge and skills in the field of urology through training sessions on medical techniques.

\* Ananse Foundation: Established in 1998, this organization aims to improve the access to and quality of urological care in Africa



### Support for the Malaria Prevention Project (Tanzania)

Malaria is the leading cause of death among children (aged five and under) in the Lindi region of Tanzania. Seeking to reduce the infant mortality rate, the Astellas European Foundation supports the NGO Save the Children's malaria prevention project in Tanzania. In fiscal 2011, our support led to the distribution of 15,000 insecticide-treated mosquito nets.



Medical support for the prevention of malaria among infants (Tanzania)  
© Piers Benatar/Save the Children



Local training session on medical techniques (Ghana)



Scholarship presentation ceremony (Astellas USA Foundation)

### Contributing to Advancement of Medicine

Astellas endeavors to foster advances in medicine through various initiatives. These include offering scholarships to students who represent the future of scientific research and providing awards and research grants to researchers who contribute to medical advances.

As part of these efforts, in 2011 the Astellas USA Foundation created a scholarship program through partnerships with public charities to provide financial assistance to exemplary science students. Meanwhile, the Astellas European Foundation awards grants to researchers contributing to basic scientific and medical research. In addition, in Japan the Astellas Foundation for Research on Metabolic Disorders fosters new drug discovery, as well as the development of treatment methods and research into their practical realization, by assisting with research expenses and providing financial aid for studying abroad.

### Donation of Ambulances (Japan)

With Japan's rapidly aging society, the number of ambulances dispatched continues to grow. To provide support for emergency medical treatment, each year Astellas donates "high-grade" ambulances that can be fitted with medical equipment enabling advanced in-vehicle emergency treatment to local governments. In fiscal 2011, Astellas donated three ambulances, bringing the cumulative total to 222, including 43 high-grade vehicles, since starting the program in 1970.

Corporations are members of society and thus have a responsibility to serve as good corporate citizens within their local communities. Accordingly, Astellas pursues social contribution activities matched to local needs. These activities include support for the healthy lives of children, the elderly, and the needy, as well as reforestation activities, neighborhood cleanup campaigns, and assistance in times of emergencies and disasters.

## Changing Tomorrow Day

The Changing Tomorrow Day initiative consists of volunteer activities undertaken by Astellas employees to contribute to their local communities based on the theme of health and the environment. Astellas recognizes that the links with its local communities are essential elements of its social contribution activity. In our aim to encourage employees' volunteer activities within local communities, we have been working on Changing Tomorrow Day activities as a group-wide initiative. In fiscal 2011, Changing Tomorrow Day activities took place for the second consecutive year. Astellas employees managed a variety of social contribution activities in a more proactive manner. Over 6,000 Astellas employees worldwide took part in the volunteer activities.

Exercise class aimed at preventing the need for nursing care



Community center painting project aimed at contribution to local community revitalization (Chicago)



For three months from June to August 2011, around 4,500 Astellas employees participated in Changing Tomorrow Day events around Japan. These activities took place at over 150 locations nationwide.

### Japan

More than 700 Astellas employees across the United States, Canada, and Brazil participated in a variety of service activities in their local communities.

### Americas

### Europe

Employees volunteering at a children's hospital (Spain)



Between July and November 2011, 434 Astellas employees participated in 29 volunteer activities at 18 offices throughout Europe.

### Asia

Event enjoyed by orphans with disabilities (Philippines)



During the year, around 700 Astellas employees participated in social contribution activities at eight business locations: China, South Korea, Taiwan, Hong Kong, the Philippines, Thailand, Indonesia, and India.



## Emergency Relief Activities

In times of natural disaster, such as earthquakes and flooding, Astellas works to achieve an uninterrupted supply of drugs and deliver them reliably to patients, and also helps the disaster-stricken areas.

### Support for Victims of the Great East Japan Earthquake

We made financial contributions and offered other types of support to victims of the Great East Japan Earthquake, which struck on March 11, 2011.

In addition, employees at our office in Sendai participated in volunteer activities in areas that suffered major damage by the tsunami. Activities included cleaning and restoring items of sentimental value to disaster victims, such as photographs and certificates that had been covered in mud.

### Support for Earthquake Victims in Turkey

Employees at our subsidiary in Turkey collected and donated 26 boxes of clothing to victims of the major earthquake that struck the nation in October 2011.



Washing items of sentimental value for disaster victims (Japan)



Donating clothes to earthquake victims (Turkey)



Donating daily necessities to flood victims (Thailand)



Installing flushing toilets for typhoon victims living in tents (Philippines)

### Support for Flood Victims in Thailand

Seeking to provide support for those affected by flooding in Thailand and assist with recovery work in the stricken area, in October 2011 the Astellas Asia-Oceania Foundation worked with the Thai Red Cross Society to provide daily necessities and other items to flood victims. Employees of our subsidiary in Thailand also participated in volunteer activities organized by the Thai Red Cross Society, including distribution of relief supplies.

### Support for Typhoon Victims in the Philippines

In December 2011, the Astellas Asia-Oceania Foundation made a financial donation to the Philippine Urological Association (PUA) to provide relief for those affected by Typhoon Sendong in the Philippines. The money was used to send daily necessities to 900 families living in tents, and also helped pay for the installation of simple shower cubicles and flushing toilets.

## Donating flowers to Great East Japan Earthquake victims living in temporary accommodation

Seeking to help heal the hearts of Great East Japan Earthquake victims, we are providing flowers to people living in temporary accommodation in Tagajo City, in conjunction with the Sendai-Miyagi NPO Center. The donated flowers were grown by our Green Supply

Support Office\*, which promotes reforestation through cultivating flowers and materials recycling.

\* As part of our effort to promote employment for the disabled, we established the Green Supply Support Office in April 2011. The Office currently employs 15 people with intellectual disabilities.



# Environment

Companies that operate businesses on the world stage are required to play an active role in addressing important global issues. Environmental issues are one such example. Through efforts to lower the environmental burden of its business activities, Astellas manages environmental risks and contributes to the realization of a sustainable society.

- 064 Basic Policy
- 065 Environmental Management
- 068 Reducing Greenhouse Gas Emissions
- 070 Global Warming Prevention Framework and Initiatives
- 072 Initiatives for Sustainable Biodiversity
- 074 Initiatives for Resource Recycling
- 075 Initiatives for Preventing Pollution
- 076 Environmental Accounting

\* The figures indicated in the fiscal 2011 status report for the field of Environment present the results for fiscal year 2011 (April 1, 2011 to March 31, 2012) in Japan and the calendar year 2011 (January 1 to December 31, 2011) for overseas operations as a combined total.



# To maintain a healthy environment, Astellas is committed to addressing environmental issues with integrity on both a local and global scale.

Recognizing that maintaining a healthy global environment is essential for sustainable development, Astellas strives to attain harmony between its business activities and the environment.

Specifically, Astellas does this by setting medium to long-term targets centering on the issues of climate change and biodiversity. In the prevention of environmental pollution as well, Astellas keeps a close watch on legislative changes and strives to ensure full compliance with laws and regulations.

Going forward, Astellas will continue initiatives aimed at resolving issues facing local communities and achieving a symbiotic co-existence and cooperation with society, while aspiring to be a responsible corporate entity from a long-term global perspective.

### Core Important Medium to Long-Term Priority Issues

- 1 Promoting measures to combat global warming
- 2 Continuously improving environmental preservation activities
- 3 Addressing biodiversity concerns

### Fiscal 2011 Initiatives

- ▶ Overall reduction of the environmental burden in the wake of the March 2011 disaster in Japan
- ▶ Formulation of the fiscal 2012 investment plan for preventing global warming
- ▶ Completion of the conversion from fuel oil to gas
- ▶ Reduction of the environmental burden owing to a change in the product lineup at the Takaoka Plant
- ▶ Introduction of wind turbine power generation and a biomass boiler at the Kerry Plant
- ▶ Ongoing improvement in the Biodiversity Index

# Environmental Management

The Astellas group's basic stance toward the environment and employee health and safety is encapsulated in its Environmental and Safety Policy. We work systematically and continuously toward achieving the fiscal 2015 targets set out in our Environmental and Safety Guidelines. Astellas has also established medium to long-term targets for priority issues to be tackled in the Environmental Action Plan.

## Environmental Management Framework

Environmental initiatives are a key component of CSR-based management. Accordingly, the CSR Committee deliberates Astellas' basic policy on the environment and the Environmental Action Plan. The plan is set up for each work site to use as a basis for formulating its own policies and action plans in keeping with its specific business activities, and these policies and actions are followed with the objective of achieving the targets. The efficacy of action plans is improved through the application of the PDCA (Plan-Do-Check-Act) cycle, which involves audits conducted group-wide to check on the implementation and progress of action plans.

## Environmental Management System

In response to internationally accepted standards regarding environmental and management systems, Astellas obtained ISO14001 certification for all domestic and overseas manufacturing plants except the Norman Plant in the United States. Regarding our research centers, we have established a management system that addresses both

environmental and safety issues, and are making efforts to continue improvements in environmental and safety activities. Also, in offices and the sales & marketing departments, we will continue to enhance our organizational structure, with the aim of raising the level of activities.

## Environmental and Safety Audits

To identify issues at group facilities and to ascertain the status of environmental and safety activities, Company-wide audits of environmental and safety activities are conducted by the headquarter departments using the Environmental and Safety Guidelines. Where an issue has been identified, improvements made to rectify the situation are verified by means of a follow-up audit as well as an audit conducted in the next fiscal year. The headquarter departments responsible for environmental and safety issues and individual facilities hold discussions in which they share information on various issues, developing a common understanding of social requirements and a heightened awareness of issues at the workplace level. One of the objectives of these audits is to ensure that all members of the Astellas group work constantly toward the same goals.



## Environmental Action Plan

Astellas' Environmental Action Plan was drawn up to specify short to medium-term targets for key environmental items.

### Environmental Action Plans since Fiscal 2005 and Their Implementation Status

	Fiscal 2005	Fiscal 2006	Fiscal 2007	Fiscal 2008	Fiscal 2009	Fiscal 2010	Fiscal 2011	to Fiscal 2012
Measures to address global warming		Stage 1 plan	Achieved	Stage 2 plan (interim)	Transition			
Fiscal 2010 plan								
Fiscal 2020 plan								
Sales vehicle initiatives								
Office initiatives								
Measures to conserve natural resources								
Reduce water consumption								
Green procurement				Suspended				
Introduce low-pollution vehicles				Achieved	(transition to Sales vehicle initiatives)			
Manage chemical substances								
Dichloromethane			Achieved				Suspended	
Chloroform								
Formaldehyde						Achieved		
VOC								
Measures to dispose of waste								
Reduce landfill waste		Landfill volume	Achieved	Zero emissions				
Biodiversity								
Biodiversity index								
Issuance of site reports				Achieved				

The Environmental Action Plan for fiscal 2012 is outlined below. The plan contains some targets that have already been achieved in fiscal 2011. However, because it includes targets that were achieved because of temporary factors, such as the effects of the Great East Japan Earthquake, all items in the fiscal 2012 plan, excluding items concerning waste management, are unchanged from fiscal 2011.

#### 1 Measures for Global Warming Prevention

- Reduce greenhouse gas emissions by 35% or more compared with fiscal 2005 levels by the end of fiscal 2020 (Global).
  - Reduce greenhouse gas emissions in Japan by 30% or more compared with fiscal 2005 levels by the end of fiscal 2020.
  - Reduce greenhouse gas emissions at overseas production facilities by 45% or more compared with fiscal 2005 levels by the end of fiscal 2020.
- Reduce CO<sub>2</sub> emissions generated through sales activities by 30% or more compared with fiscal 2005 levels by the end of fiscal 2015 (Japan).
- Reduce CO<sub>2</sub> emissions caused by office electricity consumption by 20% or more compared with fiscal 2005 levels by the end of fiscal 2015 (Japan).

#### 2 Measures for the Conservation of Resources (Global)

- Reduce water consumption by 20% or more compared with fiscal 2005 levels by the end of fiscal 2015.

#### 3 Management of Chemical Substances (Japan)

- Reduce the amount of volatile organic compounds (VOCs) discharged by 25% or more compared with fiscal 2006 levels by the end of fiscal 2015.

#### 4 Waste Management (Japan)

- Reduce the final volume of waste for disposal to less than 2% of total discharged.

#### 5 Biodiversity (Global)

- Raise the biodiversity index to double the fiscal 2005 level by fiscal 2020.

## Interaction between Astellas and the Environment

### Japan

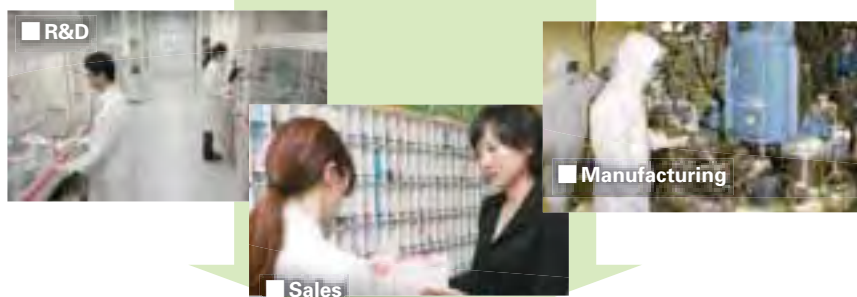
#### INPUT

Energy	Electricity	203,533 MWh
	City gas	24,134 thousand m <sup>3</sup>
	LPG	2,056 tons
	LNG	1,618 tons
	Fuel oil	840 kL
	Kerosene	428 kL
	Diesel oil	19 kL
	Gasoline	3,106 kL
	Purchased heat energy	2,183 GJ
	Resources	Water
Raw materials		1,324 tons
Solvents		4,229 kL
Copier paper		234 tons

### Overseas

#### INPUT

Energy	Electricity	50,383 MWh
	City gas	5,303 thousand m <sup>3</sup>
	LPG	3 tons
	Diesel oil	831 kL
	Purchased heat energy (steam)	17,392 GJ
Resources	Water	334 thousand m <sup>3</sup>



#### OUTPUT

Greenhouse gases	CO <sub>2</sub>	147 thousand tons
	SO <sub>x</sub>	1 ton
Pollutants	NO <sub>x</sub>	31 tons
	VOC	94 tons
	BOD	14 tons
	Chemical substances*	16 tons
	Water discharge	Drainage into rivers
Drainage into sewerage system		460 thousand m <sup>3</sup>
Waste materials	Volume of waste generated	13,422 tons
	Volume of waste discharged	13,069 tons
	Landfill volume	149 tons

#### OUTPUT

Greenhouse gases	CO <sub>2</sub>	42 thousand tons	
	SO <sub>x</sub>	3 tons	
Pollutants	NO <sub>x</sub>	13 tons	
	VOC	25 tons	
	BOD	14 tons	
	Water discharge	Drainage into rivers	334 thousand m <sup>3</sup>
	Waste materials	Volume of waste generated	1,286 tons
Recycled volume		675 tons	

SO<sub>x</sub> : sulfur oxides  
 NO<sub>x</sub> : nitrogen oxides  
 VOCs : volatile organic compounds  
 BOD : the biochemical oxygen demand

\* Substances specified under the PRTR Act (the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to Management)

### Greenhouse Gas Emissions (Scope 3\*)

	Unit: tons	
Commuting	4,629	
Overseas business trip	8,384	
Product shipments	Plant→Warehouse	334
	Distribution warehouse	643
	Warehouse→Wholesaler	1,732
Waste shipments	162	
<b>Total</b>	<b>15,883</b>	

\* Scope 3: Indirect greenhouse gas emissions by companies resulting from supply chain activities (manufacturing, shipping, business trips, commuting, etc.)



# Reducing Greenhouse Gas Emissions

Global warming is regarded as one of the environmental problems that could threaten the very survival of the human race. Mitigating and adapting to the threat posed by global warming requires active involvement on all levels. Astellas is making efforts to reduce greenhouse gas emissions as part of various measures to address global warming.

## Reducing Greenhouse Gas Emissions

### Environmental Action Plan

(Fiscal 2005 as base year; plan effective through fiscal 2020 year-end)

- Global: Reduce by **35% or more**
- Japan: Reduce by **30% or more**
- Overseas production facilities: Reduce by **45% or more**

In fiscal 2011, the Astellas group's greenhouse gas emissions amounted to 189 kilotons on a global basis, down 6.9% year on year. In Japan, emissions totaled 147 kilotons, down 8.1% from the previous year, while overseas emissions totaled 42 kilotons, down 2.7%. In Japan, the cutback of operations at the Takahagi Facilities and lower electricity consumption as a result of the Great East Japan Earthquake resulted in approximately a 5 kiloton reduction in greenhouse gas emissions. The suspension of an incinerator and the termination of the synthetic process at the Takaoka Plant in Toyama Prefecture contributed to approximately a 5 kiloton reduction. The conversion to alternative fuels at the Tsukuba Biotechnology Research Center in Ibaraki Prefecture, the Nishine Plant in Iwate Prefecture, and the Takahagi Facilities in Ibaraki Prefecture reduced emissions by approximately 2 kilotons.

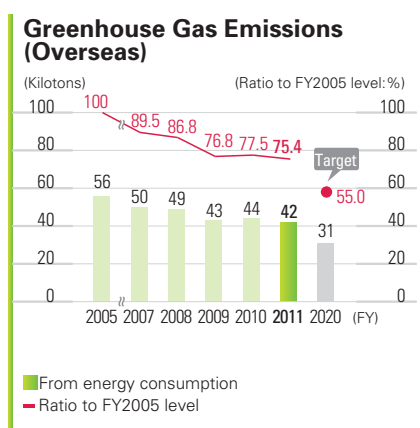
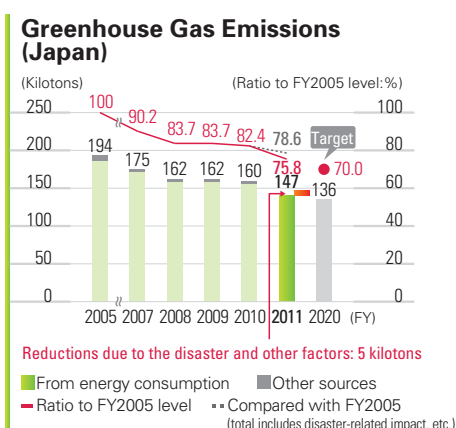
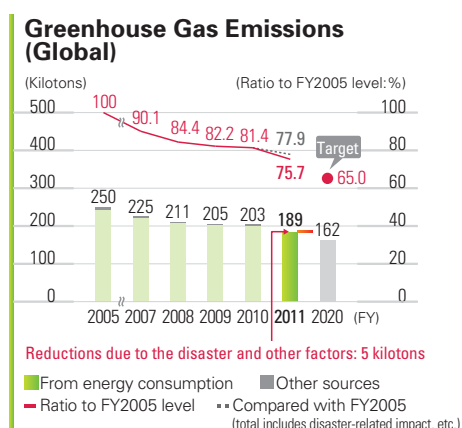
Energy sources account for a large portion of the group's greenhouse gas emissions. In Japan, in response to a government ordinance restricting electricity con-

sumption over the summer period, Astellas succeeded in meeting a group-wide target of lowering electricity consumption by 15% or more compared with peak consumption recorded the previous year. We did this by operating emergency power generators, consolidating the space used for experiments, controlling air conditioner temperatures, shutting down some air conditioners, and turning off or reducing lighting. Each facility in the Tokyo Electric Power Company service area implemented a rotational schedule for extended summer holidays.

Greenhouse gas emissions due to causes other than energy consumption are CO<sub>2</sub> emissions from waste oil burnt in liquid waste incinerators. There was a large reduction in greenhouse gas emissions due to causes other than energy consumption owing to the suspension of waste oil incinerator operation at the Takahagi Facilities and the Takaoka Plant during fiscal 2011.

In fiscal 2012, the reduction caused by the conversion to alternative energy sources and the shutdown of incinerators is expected to continue. However, the anticipated increase in energy consumption accompanying the restoration of the Takahagi Facilities will result in an increase in greenhouse gas emissions.

The graphs below show the reductions made as a result of the disaster and electricity-saving activities, and comparisons with other years when these amounts have been added.



## Reduction of CO<sub>2</sub> Emissions from Sales Activities and Offices

**Environmental Action Plan** (Fiscal 2005 as base year; plan effective through fiscal 2015 year-end)

CO<sub>2</sub> emissions generated through sales activities (Japan): Reduce by **30% or more**

CO<sub>2</sub> emissions caused by office electricity consumption (Japan): Reduce by **20% or more**

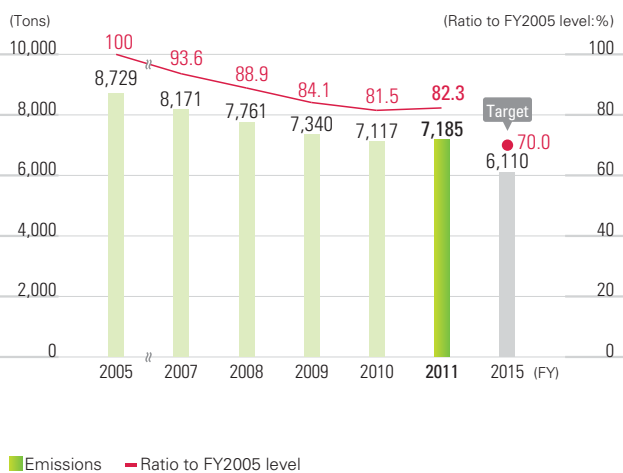
In response to the problem of increasing greenhouse gas emissions by the commercial, residential and transportation sectors in Japan, Astellas has set specific targets. In addition to the Action Plan, which specifies reduction targets covering all of the group's activities, Astellas has set separate numerical targets for CO<sub>2</sub> emission reductions by its domestic sales vehicles and its offices.

Astellas is steadily converting its fleet of sales vehicles

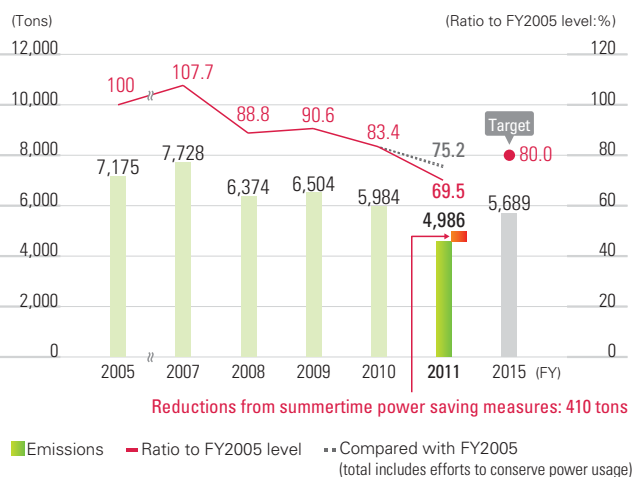
to hybrid vehicles. In fiscal 2011, CO<sub>2</sub> emissions from gasoline used in our sales vehicles were 17.7% lower compared with fiscal 2005. We had considered introducing electric vehicles, but have decided to defer their full-scale introduction due to practical reasons related to their use for sales activities. These include restrictions on traveling distance when air conditioners are used, and problems related to recharging vehicles when visiting clients and rescheduling.

Meanwhile, in fiscal 2011, total electricity consumption by the group's offices amounted to 14,245 MWh. When converted to CO<sub>2</sub> emissions, this becomes 4,986 tons, a 30.5% reduction compared with fiscal 2005. The group's response to government-imposed restrictions on electricity consumption over the summer period and efforts throughout the year to conserve power usage contributed to this substantial reduction in emissions.

### CO<sub>2</sub> Emissions from Sales Vehicles



### CO<sub>2</sub> Emissions due to Electricity Consumption at Offices



### New Environmentally Friendly Company Buildings

To accommodate the expansion of its work force and consolidate functions that had previously been dispersed, Astellas is building new office facilities incorporating environmentally friendly construction methods.

In the case of a new building to house the headquarters for the Americas region, which was completed in June 2012, we obtained Gold certification under the Leadership in Energy and Environmental Design (LEED) rating system. The ratings cover six items (Sustainable Sites, Water Efficiency, Energy and the Atmosphere, Materials and Resources, Indoor Environmental Quality, and Innovation in Design), and our new systems, which include a geothermal heating system, were also included in this assessment, and received a positive evaluation.



Regional headquarters for the Americas

# Global Warming Prevention Framework and Initiatives

Astellas recognizes that global warming could become an even greater obstacle to the continuation of corporate activities in the future. Accordingly, Astellas has positioned measures to address this problem as a key management priority. By establishing medium-term targets for global warming prevention in its Environmental Action Plan, Astellas actively promotes reduced energy consumption by existing facilities and strategic investments aimed at reducing greenhouse gas emissions.

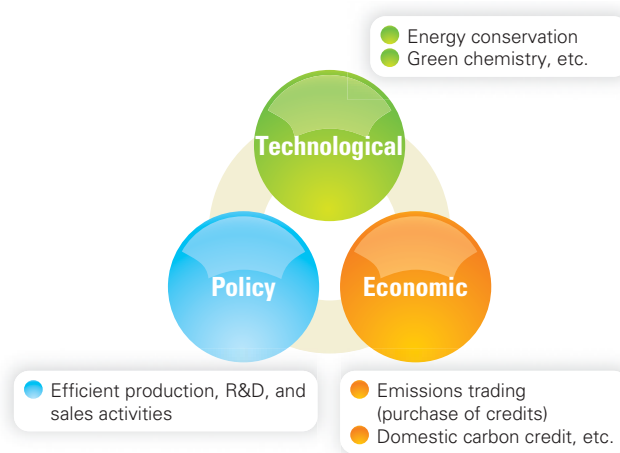
## Global Warming Prevention Framework

Astellas believes that it will not be possible to achieve the level of greenhouse gas emission reductions demanded of private enterprises by simply continuing with existing energy conservation measures implemented independently by each facility. Consequently, in fiscal 2009 Astellas established the Global Warming Prevention Committee as a special task force under the CSR Committee, which is chaired by a member of top management. As a result, in addition to the independent measures adopted by each facility, Astellas is pursuing measures to achieve medium to long-term numerical targets set in accordance with a group-wide strategy formulated by the Global Warming Prevention Committee.

## Investment Plan for Preventing Global Warming

Measures for preventing global warming are a key management priority under the 2014 Mid-Term Management Plan. Accordingly, it was decided that the Global Warming Prevention Committee would be responsible for formulating medium to long-term action plans and investment plans for the entire Astellas group, and advancing strate-

## Measures for Reducing Greenhouse Gas Emissions Considered by Astellas



gic measures. In fiscal 2011, Astellas invested a total of approximately ¥0.7 billion in initiatives instigated by the Global Warming Prevention Committee over and above the amount spent on energy-saving activities by group facilities. The group expects to reduce the amount of greenhouse gases it generates by 10,312 tons. The decision to invest approximately ¥0.4 billion in fiscal 2012 is expected to achieve greenhouse gas emission reductions totaling 1,502 tons.

	Fiscal 2011		Fiscal 2012	
	Investment Amount (¥ million)	Reduction (projection) (tons of CO <sub>2</sub> )	Amount of fixed investment (¥ million)	Reduction (projection) (tons of CO <sub>2</sub> )
Energy sources conversion	200	2,005	—	—
Introduction of advanced technologies, including heat pumps and LEDs	199	616	40	115
Introduction of wind turbine and photovoltaic generation	160	2,580	—	—
Introduction of energy monitoring systems	74	—	—	—
Investment in improved operational efficiency	23	5,111	358	1,387
<b>Total</b>	<b>656</b>	<b>10,312</b>	<b>398</b>	<b>1,502</b>

## Our Efforts to Reduce Greenhouse Gas Emissions

Astellas' manufacturing plants, research centers, and offices are implementing a variety of initiatives with the aim of reducing greenhouse gas emissions. Efforts to improve facilities, which include the introduction of high-efficiency equipment and the conversion to alternative fuels, are expected to make a significant contribution to reducing the level of CO<sub>2</sub> emissions generated by energy sources. Measures as part of everyday activities and energy-saving activities by all employees are also important. To this end, each facility adopts a two-pronged approach, comprising measures for improving equipment and undertaking routine energy-saving activities.

### Fuel Conversion

The amount of CO<sub>2</sub> generated in order to obtain the same level of heating value reached by boilers and other equipment varies depending on whether fuel oil, city gas, or LPG is used as the energy source. Therefore, switching to a fuel that generates less CO<sub>2</sub> helps prevent global warming. Because fuel oil and kerosene generally produce more CO<sub>2</sub> than city gas, Astellas is actively converting its boilers so that they run on city gas instead of fuel oil and kerosene. To date, facilities where the use of city gas is possible have already finished their conversion to this fuel source.

In fiscal 2011, the Takahagi Facilities and the Nishine Plant, which had installed LNG tanks in the previous fiscal year due to the unavailability of city gas, began using LNG to operate their boilers. As a result, the conversion to alternative fuels for boilers has been completed, except for the fuel oil and kerosene used in winter at Astellas' Tokyo headquarters.

### Installation of Heat Pump Devices

Astellas has actively introduced heat pump technology that makes effective use of heat in the air when upgrading existing air conditioning equipment or installing new

equipment. In fiscal 2011, Astellas began using heat pumps at the Takahagi Facilities and the Tsukuba Biotechnology Research Center upon the completion of a heat pump conversion program at these facilities.

Going forward, while ensuring a stable supply of electricity in the wake of the Great East Japan Earthquake, we will continue introducing heat pump technology.

### Introduction of an Energy Monitoring System

We have instituted a program to gradually introduce energy monitoring systems at our facilities, including the Takahagi Facilities, Yaizu Facilities, and Fuji Plant and other locations.

Knowing exactly how much energy we use does not directly lead to lower energy consumption. However, the ability to confirm the status of energy usage can help reduce energy consumption indirectly, such as through the elimination of wasteful practices and the formulation of new strategies.

### Using Renewable Energy

The direct use of renewable energy sources, such as sun and wind, is the most effective method of addressing the issue of global warming. Accordingly, Astellas hopes to actively introduce renewable energy technology where feasible.

Astellas decided to introduce renewable energy sources by taking advantage of the location of its Kerry Plant in Ireland. In March 2011, the plant began operating a wind turbine power generation station with a maximum output of 800 kW and a wood chip biomass boiler system that is fueled primarily by wood chips sourced from managed forest. In Japan, the Kashima R&D Center in Osaka Prefecture installed a photovoltaic generation system with a maximum output of 30 kW in its new staff building.

The Norman Plant in the United States purchases electricity generated by wind turbine. In fiscal 2011, electricity generated by wind turbine accounted for 20,930 MWh of the plant's overall electricity purchased, which totaled 21,602 MWh.

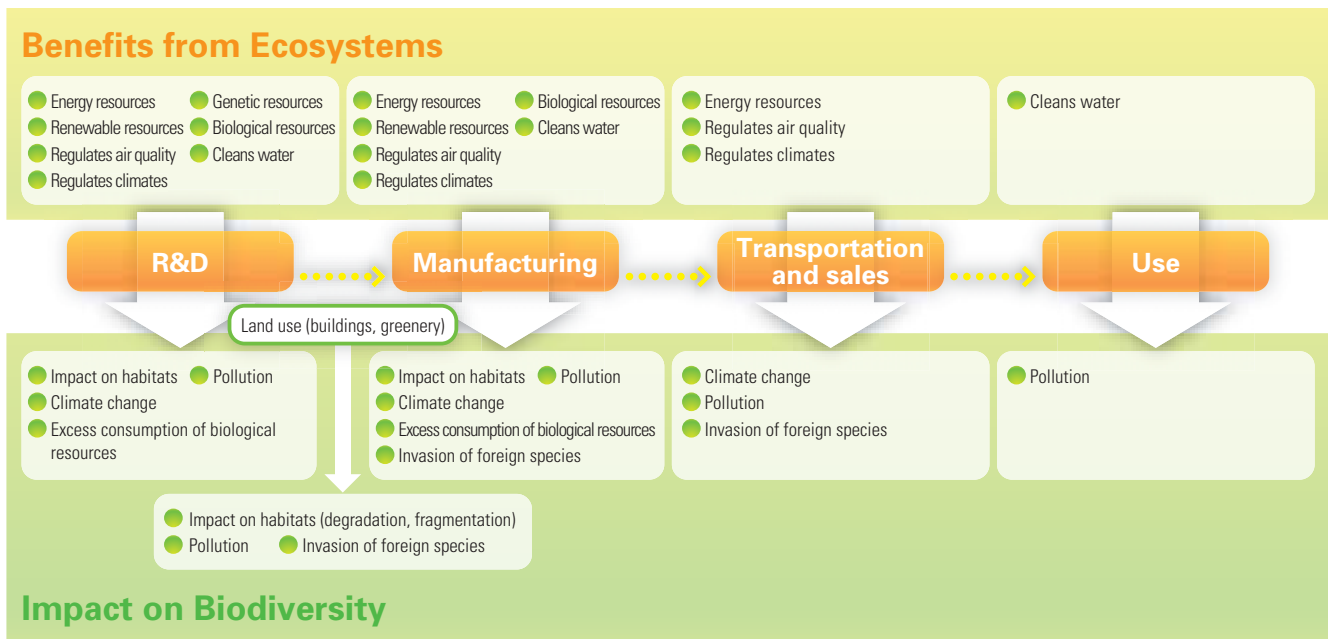
# Initiatives for Sustainable Biodiversity

In addition to global warming, the loss of biodiversity is one of the most serious environmental problems that mankind must address in order to ensure its survival. Recently, the governments of many countries have adopted policies aimed at conserving biodiversity, and businesses too are being called upon to adopt their own initiatives. Astellas also recognizes the importance of sustainable biodiversity, and is actively addressing this global problem.

## Basic Policy

Astellas is thankful for the benefits brought about by biological diversity, and understands its business activities in all fields have an impact on the ecosystem. We will make a positive contribution to the preservation of biodiversity by working to lessen that impact. At the same time, we actively contribute to the creation of a society that coexists with the natural world, enabling the preservation of biodiversity and the sustainable use of the benefits of healthy ecosystems.

In our business activities, Astellas strives to minimize its impact on the environment by developing technologies that are environmentally friendly and minimize the amount of natural resources it consumes. Regarding the use of genetic resources, which are integral to drug discovery, we consider and pursue appropriate initiatives that are compatible with international standards and the regulations of producing nations.

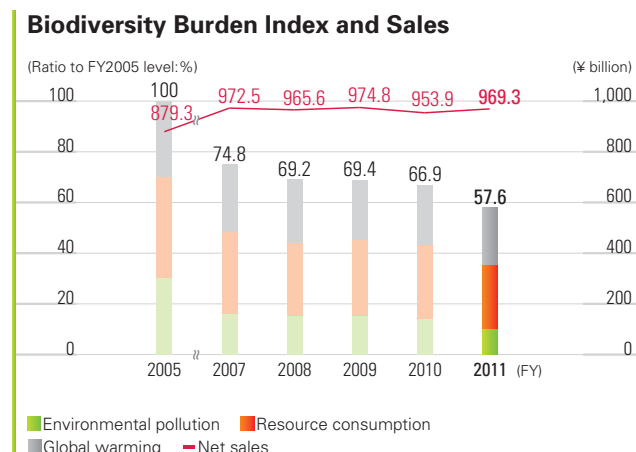
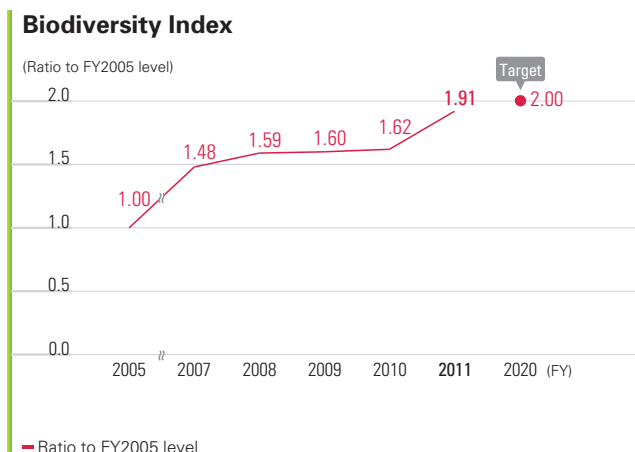


## Biodiversity Index

Astellas has created an index by assessing the three main factors responsible for the deterioration of biodiversity, which are environmental pollution, resource consumption, and global warming. We use the index to

quantify improvements that reduce our impact on biodiversity and the progress made on related initiatives.

Going forward, we will continue making improvements in each category while working toward achieving the targets established for fiscal 2020.



(Calculation method)

The environmental burden for each sub-category of environmental pollution, resource consumption, and global warming in the assessment fiscal year is divided by the corresponding burden in the base year and then multiplied by the weight to derive the "biodiversity burden index." The "biodiversity index" is calculated by dividing Astellas' consolidated sales in the assessment fiscal year by the total of all the biodiversity burden index figures. Improvement can be determined by comparing this index to the base year. The more improvements are made in each category, the higher the value of the biodiversity index.

Categories	Sub-categories	Weight (%)
Environmental pollution	NOx, SOx emissions	10
	Chemical substance emissions	10
	BOD load	10
	(Subtotal)	(30)
Resource consumption	Water usage	20
	Biological raw material usage	10
	Landfill waste volume	10
	(Subtotal)	(40)
Global warming	Greenhouse gas emissions	30
(Subtotal)	(30)	
Total		100

$$\text{Biodiversity index} = \frac{\text{Consolidated sales in the assessment fiscal year}}{\sum \left[ \frac{\text{Burden in the assessment fiscal year}}{\text{Burden in the base year}} \times \text{Weight} \right]}$$

## Forest Regeneration on Mount Tsukuba

Tacrolimus, the main ingredient in the immunosuppressant Prograf produced by Astellas, was discovered in a microorganism found in the soil on the foothills of Mount Tsukuba. Grateful for this blessing from Mount Tsukuba's healthy ecosystem, in October 2010 Astellas began a forest regeneration program.

We first decided that the most suitable trees to plant are those that are native to the area. Consequently, we collected acorns from trees growing on the grounds of the Tsukuba R&D Center, which is located near Mount Tsukuba. Once the acorns have germinated, we nurture the seedlings until they reach an appropriate size for planting out on the mountain.





# Initiatives for Resource Recycling

Astellas recognizes that since the use of sustainable resources is essential for continuing its business activities, it must play an active role toward the creation of a recycling-oriented society. Astellas does this through various initiatives, including the effective use of water resources, and the recycling of waste materials (reuse, recycling, and use of all thermal energy).

## Effective Use of Water Resources

**Environmental Action Plan** (Fiscal 2005 as base year; plan effective through fiscal 2015 year-end)

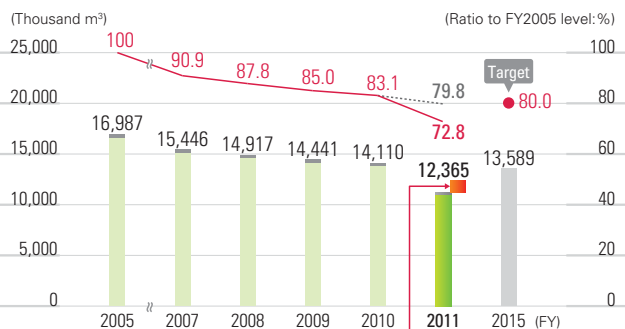
Amount of water used (global): Reduce by **20% or more**

Since the effective use of water resources serves as a useful indicator for gauging society's impact on biodiversity, Astellas has set numerical targets for reducing water usage.

In fiscal 2011, the Astellas group used 12,365 thousand m<sup>3</sup> of water on a global basis, down 12.4%, or 1,745 thousand m<sup>3</sup> from the previous year, and down 27.2% from fiscal 2005, the base year of the Environmental Action Plan. One contributing factor to this decrease was a reduction in water usage by the Takahagi Facilities stemming from the impact of the Great East Japan Earthquake.

In fiscal 2012, we expect water usage to increase due to the resumption of operations at the Takahagi Facilities. We will, therefore, continue reducing water usage while retaining the same numerical targets.

### Water Usage



Impact of reduced operations due to the March 2011 disaster: 1,137 thousand m<sup>3</sup>

■ Japan ■ Overseas — Ratio to FY2005 level  
 \*\* Compared with FY2005 as base year (includes the reduction caused by disaster)

## Waste Management

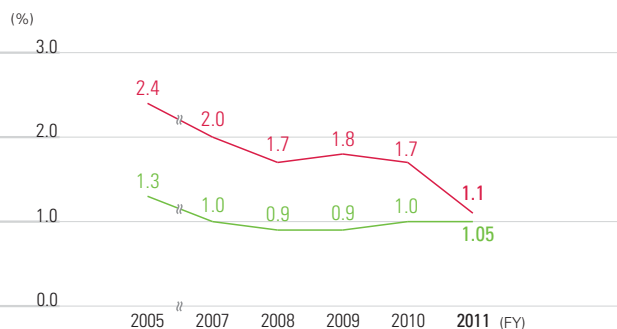
**Environmental Action Plan**

Volume of waste materials subject to final disposal (Japan):  
 less than **1%** of total generated,  
 or less than **2%** of total discharged

Astellas believes that efforts to reduce waste landfill volume to as close to zero as possible will encourage the recycling and reuse of waste materials. To realize this goal, we set targets for the zero emission of waste at our domestic business facilities, which have been achieved since 2008.

In waste management, it is also important to prevent the illegal disposal of waste and environmental pollution caused by hazardous waste generated by research centers and plants. At Astellas, we first examine appropriate methods of waste disposal, and each time we choose a waste management contractor we check that the contractor uses appropriate waste disposal methods.

### Landfill Rate (Zero Emissions)



■ Landfill rate (in proportion to the total waste amount discharged)  
 ■ Landfill rate (in proportion to the total waste amount generated)

# Initiatives for Preventing Pollution

The prevention of environmental pollution in local communities is just as important as global environmental issues. This is reflected in the increasing severity of relevant laws and regulations in recent years.

Astellas sets its own levels for the major environmental management indicators used to measure air quality and water quality that are more rigid than legal standards and levels and agreed values. In addition to reducing the discharge of contaminants, we also set voluntary targets for lowering the discharge of chemical substances into the atmosphere.

## Air Pollution

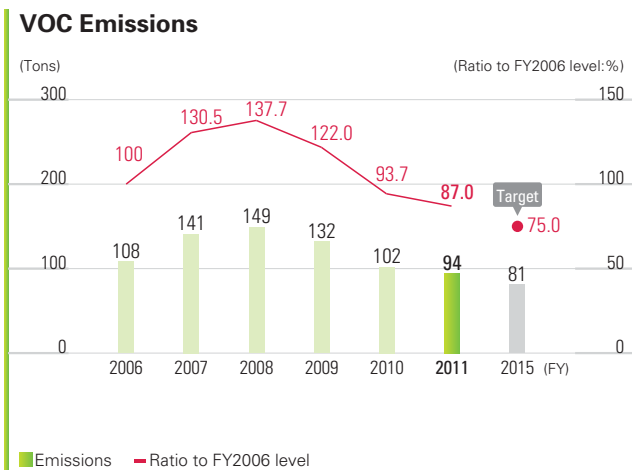
### Environmental Action Plan

(Fiscal 2006 as base year; plan effective through fiscal 2015 year-end)

Volume of VOC emissions (Japan): Reduce by **25% or more**

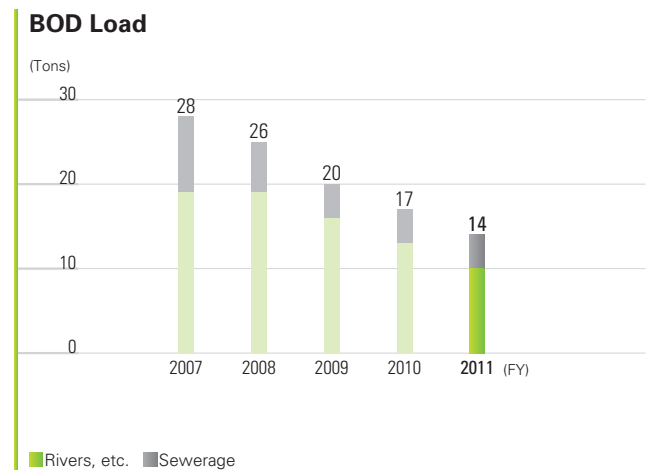
Astellas sets voluntary numerical targets for reducing the amount of volatile organic compounds (VOCs) it discharges accompanying the use of solvents in production and research activities, and is implementing measures to achieve these reduction targets.

In fiscal 2011, we discharged 94.3 tons of VOCs into the atmosphere, a year-on-year decrease of 7.9 tons. Since a main factor in this decrease was a reduction in solvents used as synthetic raw materials at the Takaoka Plant, we need to make further efforts to reduce usage in order to achieve our target. To this end, we will adopt the necessary measures, including the installation of equipment that curbs the discharge of VOCs in processes that use large quantities of VOCs.



## Water Pollution

Astellas measures the extent of its impact on aquatic environments by adopting the biochemical oxygen demand (BOD) load as an index, and makes the data available to the public. In fiscal 2011, a reduction in the amount of effluent discharged owing to reduced water usage resulted in a BOD load of 14.1 tons, down 3.3 tons, or 19.0%, from the previous year. In fiscal 2012, the Company's BOD load is expected to increase along with higher water usage. We will continue working to reduce the burden we place on water, including the appropriate operation of wastewater treatment facilities. Meanwhile, because the discharge into water of chemical substances used in the manufacturing process can have a negative environmental impact, we are examining ways to reduce their discharge into the environment wherever possible, from the R&D stage prior to the start of actual production.



# Environmental Accounting

With respect to environmental conservation costs, in fiscal 2011 Astellas made investments of ¥963 million and incurred expenses of ¥2,023 million. To prevent pollution, we conducted maintenance on wastewater treatment facilities, and to help protect the global environment we switched to alternative fuels and introduced energy monitoring and related systems. The economic benefits generated through environmental protection activities amounted to ¥139 million, which includes lower costs owing to energy savings and the sale of waste metals and solvents.

## Environment-related Investment and Expenses

	(¥ million)									
	FY2007		FY2008		FY2009		FY2010		FY2011	
	Investment	Expenses	Investment	Expenses	Investment	Expenses	Investment	Expenses	Investment	Expenses
Pollution prevention	190	662	211	614	161	461	177	687	225	489
Global environmental conservation	29	397	100	203	80	231	403	287	730	413
Resource recycling	0	416	2	411	1	340	6	344	0	432
Upstream/downstream costs	0	37	0	33	0	73	0	67	0	65
Administration costs	1	270	0	417	0	331	18	364	0	331
R&D costs	4	81	2	28	8	28	13	37	7	36
Social activity costs	0	8	0	7	0	6	0	3	0	2
Environmental remediation costs	0	21	0	21	0	141	0	76	0	255
<b>Total</b>	<b>224</b>	<b>1,892</b>	<b>315</b>	<b>1,734</b>	<b>250</b>	<b>1,611</b>	<b>616</b>	<b>1,865</b>	<b>963</b>	<b>2,023</b>

## Environmental Performance Trends in Japan (Annual basis)

				FY2007	FY2008	FY2009	FY2010	FY2011
INPUT	Energy	Electricity	(MWh)	201,662	211,001	212,472	218,364	203,533
		City gas	(thousand m <sup>3</sup> )	20,721	21,401	21,982	23,813	24,134
		LPG	(tons)	2,258	2,255	2,301	2,118	2,056
		LNG	(tons)	—	—	—	—	1,618
		Fuel oil	(kL)	4,981	4,677	4,480	4,110	840
		Kerosene	(kL)	1,437	1,303	1,147	661	428
		Diesel oil	(kL)	10	9	16	17	19
		Gasoline	(kL)	3,528	3,353	3,171	3,077	3,106
		Purchased heat energy	(GJ)	2,225	2,225	2,225	2,225	2,183
	Resources	Water	(thousand m <sup>3</sup> )	15,080	14,579	14,105	13,760	12,031
Raw materials*		(tons)	11,261	10,481	12,630	2,000	1,324	
		(kL)	—	—	—	9,128	4,229	
OUTPUT	Global warming	CO <sub>2</sub> emissions	(thousand tons)	175	162	162	161	147
	Air pollution	SO <sub>x</sub>	(tons)	6	5	5	5	1
		NO <sub>x</sub>	(tons)	48	43	44	41	31
		VOCs	(tons)	141	149	132	102	94
	Water pollution	BOD load	(tons)	28	26	20	17	14
		Drainage water	(thousand m <sup>3</sup> )	14,353	13,829	13,006	12,766	10,658
	Waste	Volume generated	(tons)	19,494	19,469	20,882	19,508	13,422
		Volume discharged	(tons)	10,097	10,038	10,876	10,778	13,069
Landfill volume		(tons)	237	208	207	201	149	

\* Raw materials and solvents have been tabulated separately from fiscal 2010

## Compliance

For a company to be sustainable, it is vital to earn the solid credibility as a part of society. At Astellas, compliance means more than that a company and its employees observe all applicable laws and regulations. We believe in the importance of conducting ourselves with integrity while upholding high ethical standards.

- 078 Basic Policy
- 079 Compliance
- 082 Corporate Governance
- 086 Interview with an Outside Director
- 088 Global Management Committee Members
- 090 Directors, Corporate Auditors and Executive Officers



## Astellas observes all applicable laws and regulations and upholds the highest ethical standards in all its business activities.

Legal compliance is fundamental to business activities. Further, we believe that we must uphold high ethical standards in business activities, while questioning whether these activities are acceptable to society and whether they conform to common social norms and customs. Astellas has positioned compliance together with high ethical standards as the fundamental concept of its CSR management.

Under the "Beliefs" of its business philosophy, Astellas pledges to manage its business with the highest sense of ethics.

### Core Important Medium to Long-Term Priority Issues

- 1 Share a unified approach to compliance on a global basis
- 2 Promote self-directed compliance in each region

### Fiscal 2011 Initiatives

- ▶ Reinforcement of the global compliance system
- ▶ Revision of the Astellas Charter of Corporate Conduct and formulation of the Astellas Global Code of Conduct
- ▶ Provision of bribery prevention training for all employees in the Americas and Europe, and for managers in Japan and Asia
- ▶ Provision of training on power harassment for all employees in Japan

## Relation between Business Philosophy, Charter of Corporate Conduct, and Code of Conduct

### Business philosophy

Raison d'être

Mission

Beliefs

Astellas Charter of Corporate Conduct

Astellas Global Code of Conduct

Supplemented by local or regional Codes of Conduct

Japan

Americas

Europe

Asia & Oceania



Astellas is building a compliance system by fostering a corporate culture that encourages each and every employee to perform his/her duties with integrity while upholding the highest ethical standards.

## Promoting Compliance

In addition to observing all applicable laws and regulations, Astellas believes that it is essential that employees uphold the highest ethical standards in their business activities for the promotion of compliance.

Employees need criteria by which to make value judgments when taking specific actions. The Astellas Charter of Corporate Conduct specifies the Company's business philosophy (Raison d'être, Mission, Beliefs) in terms of corporate behavior. In April 2012, we revised the Charter to better fulfill our social responsibilities to accommodate a changing society. The global expansion of business activities has necessitated a review of our code of conduct. As a result, we have formulated the "Astellas Global Code of Conduct" as a code that applies uniformly to Astellas employees throughout the world.

In order to promote compliance within business activities, there needs to be more than basic rules in the form of a code of conduct. This is because it is important to devise a strategy for pursuing specific action plans and to have a system that can address issues when they arise. With this in mind, in April 2012 we restructured our system of global compliance with the objective of reinforcing compliance on a global level and promoting collaboration among regions.

In these ways, we have developed a framework that promotes compliance via a two-pronged approach: a code of conduct and a compliance system.

## Astellas Global Code of Conduct

The Astellas Global Code of Conduct was the outcome of two imperatives. Astellas believes that in order to promote compliance, it must spell out its position and thoughts on compliance, which forms the foundation of all corporate activities. We also believe that the Company must be an organization in which each and every employee steadfastly observes and practices compliance in the form of a code of conduct.

This code of conduct comprises standards that enable employees to meet the expectations of stakeholders by adhering to the highest ethical standards. We have incorporated the existing "Astellas Business Ethics Policy" and "Global CSR Policy" without any modification of their contents in the Astellas Global Code of Conduct. In so doing, we have produced a unified code of conduct for Astellas employees.

The Astellas Global Code of Conduct does not encompass all the obligations, business-related laws, regulations, rules, guidelines, and industry practices that we must follow, nor does it cover all facets of business activities. Rather, it is to be complemented at the regional and country levels by the behavioral standards, regulations, and policies of each particular region or country. Each group company will formulate its own code of conduct as necessary for each region or country, and promote a compliance program based on that code. These codes themselves will be constantly reviewed as the systems evolve.

## Global Compliance System

In April 2012, Astellas restructured its global system of compliance with the aim of reinforcing compliance on a global level.

As part of this restructuring, we established the new position of Chief Compliance Officer (CCO), and the position of Regional Compliance Officer (RCO) in the three regions. The CCO is responsible for compliance across the entire Astellas group, while the three RCOs are responsible for compliance in their specific regions. The three regions are Japan (including Asia and Oceania), the Americas, and Europe. The CCO will chair the Global Compliance Committee, and the three RCOs will each chair a Compliance Committee for their respective regions.

The Global Compliance Committee will deliberate compliance policies and plans for the Astellas group and deal with matters requiring a global response. The regional compliance committees will deliberate items pertaining to their respective regions.

Under the supervision of the CCO, the Legal &

Compliance Department will formulate, promote and spread the specific global compliance plans by working with the relevant departments in each group company. This new system is structured so that the CCO and RCOs are able to work together on matters requiring a global-level response.

The RCO who oversees each region is responsible for establishing and maintaining an optimal and efficient compliance system. At the same time, the Compliance Committee that is responsible for the same region deliberates matters, such as measures for promoting compliance in group companies.

In Japan, each department has a compliance promotion supervisor and a compliance promotion representative. Consequently, each department clearly defines its own compliance promotion responsibilities. To help compliance take root in their respective departments, the compliance promotion supervisors work in collaboration with the Legal & Compliance Department. Under the guidance of the Compliance Committee, Astellas holds ongoing training on a variety of topics to equip Astellas employees with their own compliance-related knowledge and skills.

### Astellas Global Compliance System



## Compliance Helpline

If an employee is uncertain about whether someone's conduct is ethical and/or complies with legal or regulatory requirements, that employee should consult the Legal & Compliance Department. Also, if an employee learns of any conduct that is in breach of laws, the Astellas Global Code of Conduct, and company policy or rules, or else suspects such a breach, that employee should inform his or her boss, the Human Resources Department, or the Legal & Compliance Department, as appropriate.

We have established a global Compliance Helpline that employees can contact at any time so that they do not have to tackle problems on their own, such as in the event of discovering conduct that could be in breach of compliance, or when directed or ordered to carry out such conduct. We have set up external helplines for each

of the three regions—Japan/Asia and Oceania, the Americas, and Europe—so that employees can seek advice in their native language. In Japan, there is an internal helpline, as well as a sexual harassment helpline.

Employees may use these helplines at any time in order to seek advice on, or report, a compliance-related matter. Even if a report made in good faith by an employee later turns out to be unsubstantiated, employees will not be treated unfairly for voicing their concerns as an act of good faith, and nor will any employee who reports a breach be treated unfairly.

In these ways, Astellas is working to reinforce compliance under a system that prevents violations of ethics, laws and regulations, and is building a framework that makes it possible to detect a breach before it escalates into a more serious incident.

## Local Training to Prevent Improper Acts and Corruption

Recently, legislation against improper and corrupt behavior, including bribery, has become increasingly stringent. For example, in July 2011 the United Kingdom enacted new bribery legislation. Furthermore, U.S. authorities' oversight of solicitous behavior toward foreign government officials has become extremely strict under the U.S. Foreign Corrupt Practices Act. In response to this tightening of regulations, Astellas is placing considerable weight on training that aims to prevent any instances of corruption and bribery.

In fiscal 2011, we conducted bribery prevention training for those in charge of compliance at the Company's branches and sales offices in Japan, and also for the presidents and compliance officers of each of our sales affiliates in Asia. In addition, we pro-



Training for presidents and compliance officers of sales affiliates (Asia)

vided training to all employees in Europe (including the Middle East and Africa) on the UK Bribery Act. In the Americas, we amended the content of training programs to include not only the Foreign Corrupt Practices Act but also the UK Bribery Act, and all employees participated in e-learning-based training.

In addition to this training, Astellas has undertaken continuous educational

and training activities under the direction of the Compliance Committee. In fiscal 2011, we held seminars for all employees on power harassment, with management-level and non-management employees taking part in separate programs in Japan.

# Corporate Governance

Astellas strives to improve its corporate governance system based on the basic policy of maximizing its enterprise value, improving business transparency, and fulfilling accountability requirements to society.

## Basic Policy on Corporate Governance

The Astellas business philosophy comprises three elements—Raison d'être, Mission, and Beliefs. The company's Raison d'être is to "contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products." Our Mission is to achieve sustainable enhancement of our enterprise value. And our four beliefs—a high sense of ethics, customer focus, creativity and competitive focus—underpin our Code of Conduct.

The Company has established the "Charter of Corporate Conduct," which states this business philosophy in concrete terms of specific business conduct, and the "Astellas Global Code of Conduct," as basic compliance rules that

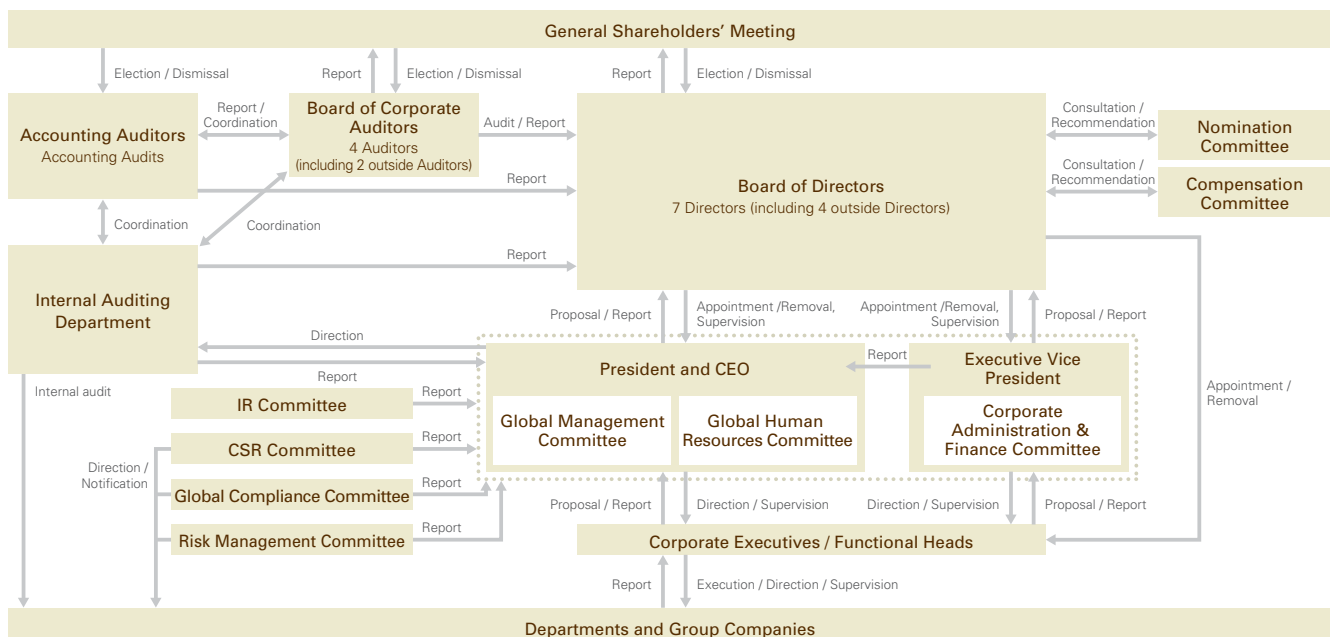
are common throughout the group. By adhering steadfastly to these principles and standards, our goal is to earn the support and trust of all stakeholders, including customers, shareholders, employees, and society.

## Corporate Governance Systems and Measures

### Board of Directors

The Company has introduced the Corporate Executives System. This system clearly separates the roles of the Directors, who are in charge of management decision-making and supervising business execution, from the roles of the Corporate Executives, who are in charge of business execution.

## Corporate Governance at Astellas



With respect to the Board of Directors, it now comprises seven members, including four outside Directors who are independent Directors, in order to promote decision making and supervise business execution from a broader viewpoint, and it meets once every month as a general rule. Directors are appointed for a one-year term.

At Astellas, the Nomination Committee and the Compensation Committee serve as advisory bodies to the Board of Directors. These committees ensure the transparency and objectivity of the deliberation process for the nomination and the compensation system of these individuals. Outside Directors account for the majority of members on these committees.

### Board of Corporate Auditors

Astellas adopts a Corporate Auditor System. Audits are carried out effectively by the Board of Corporate Auditors, which comprises four Corporate Auditors, two of whom are full-time internal Corporate Auditors, and two of whom are outside Corporate Auditors. The former are very familiar with issues in the Company, whereas the

latter have a high degree of independence and a wealth of actual experience and familiarity in various specialist fields. Furthermore, a full-time staff member is assigned to assist the Corporate Auditors in carrying out their duties. The function of the Corporate Auditors is enhanced through cooperation with the Accounting Auditors and the Internal Auditing Department.

As a general rule, the Board of Corporate Auditors meets once a month.

### Outside Directors and Outside Corporate Auditors

All four outside Directors are independent Directors with no conflict of interest with general shareholders. Each Director has a specific area of expertise, such as business management, law, or medicine. They make use of their wide-ranging experience and technical expertise to engage in decision-making and oversee business execution from an independent standpoint at Board of Directors meetings.

Both of the two outside Corporate Auditors are also independent Auditors. They draw on their specific expertise in areas such as finance, accounting, and busi-

### Expected Role of Outside Directors and Outside Corporate Auditors

Position	Name	Expected Role	Attendance at meetings of the Board of Directors and Board of Corporate Auditors during fiscal 2011
Outside Director	Shiro Yasutake	Shiro Yasutake currently plays a key role as an outside Director for management of the company from an independent position. The company is confident that he will draw on his abundant experience in corporate management in management of the company in the future as well.	16/16 times
	Yasuyuki Takai	Yasuyuki Takai currently plays a key role as an outside Director for management of the company from an independent position. The company is confident that he will draw on his abundant specialized knowledge and experience as an attorney-at-law in management of the company in the future as well.	14/16 times
	Kanoko Oishi	Kanoko Oishi currently plays a key role as an outside Director for management of the company from an independent position. The company is confident that she will draw on her abundant experience in corporate management in management of the company in the future as well.	16/16 times
	Naoki Aikawa MD, Ph.D.	Naoki Aikawa currently plays a key role as an outside Director for management of the company from an independent position. The company is confident that he will draw on his abundant specialized knowledge and experience as a doctor of medicine in management of the company in the future as well.	13/13 times
Outside Corporate Auditor	Yukiko Kuroda	Yukiko Kuroda currently plays a key role as an outside Corporate Auditor from an independent position. Based on her abundant experience in business as a CEO, the company is confident that she will fulfill her duties in the future as well.	15/16 Board of Directors meetings, 14/14 Board of Corporate Auditors meetings
	Shigeru Nishiyama	Shigeru Nishiyama has outstanding knowledge as a business scholar and a certified public accountant. Based on his knowledge and insight, the company is confident that he will perform his duties from an independent position as an outside Corporate Auditor.	Inaugurated in June 2012



ness management, and extensive experience to audit the Directors' performance of their duties from an independent standpoint.

### Compensation of Directors and Corporate Auditors

With a basic policy of contributing to continued growth of business results and improved corporate value of the Company, the compensation paid to Directors and Corporate Auditors of the Company is designed to enable the Company to attract and retain competent persons, and maintain sufficient compensation standards and a system to meet the duties and responsibilities of the Directors and Corporate Auditors. In establishing compensation standards, the Company has improved objectivity by using, among other things, research data issued by an outside research company.

Compensation paid to Directors consists of three components, namely, basic fixed compensation, bonuses and stock options. Outside Directors receive only basic fixed compensation.

Corporate Auditors (including outside Corporate Auditors) receive only basic fixed compensation.

	Total Compensation*	Type of Compensation*		
		Base Salary	Stock Options	Bonus
Directors*				
(excluding outside Directors): 4	444	289	102	51
Corporate Auditors*				
(excluding outside Corporate Auditors): 3	87	87	—	—
Outside Directors and Corporate Auditors: 7	72	72	—	—

\* The total amount of compensation shown here is the amount paid as compensation for the execution of duties during fiscal 2011, and includes the amount paid to two Directors (including one outside Director) and one Corporate Auditor who retired during fiscal 2011.

### Reinforcement of the Global Management System

The Company has established the Global Management Committee, the Corporate Administration & Finance

Committee, and the Global Human Resources Committee to ensure the smooth execution of business at a global level. These committees discuss important issues related to global management, finance, accounting and administration, and human resources, respectively.

In order to respond quickly to changes in the business environment and to make quicker and more appropriate decisions, Astellas is promoting a "matrix management" structure, which consists of a functional axis and a geographical region axis.

Top management and the officers responsible for each of the functions and regions attend Global Management Committee meetings.

Astellas has committees responsible for other aspects of business execution. They are the CSR Committee, the Global Compliance Committee, the Risk Management Committee, and the IR Committee.

### Business Execution Committees

Committee Name	Role
Global Management Committee	Discusses important matters pertaining to product strategy as well as management-related matters such as research, development, technology, and sales and marketing.
Corporate Administration & Finance Committee	Discusses important matters related to finance, accounting and administration such as budget execution and asset retirement and disposal, basic policy for governance of the group in Japan, and matters for proposal to the General Shareholders' Meeting.
Global Human Resources Committee	Discusses evaluation of performance and duties, as well as the appointment, dismissal, promotion and demotion of Corporate Executives, selection of department general managers, and successor development plans. In addition, it discusses certification of highly specialized positions, and the selection of Astellas group company presidents.
CSR Committee	Discusses matters pertaining to CSR initiatives for Astellas as a whole.
Global Compliance Committee	Discusses policies and plans concerning compliance covering the whole of Astellas, as well as important matters concerning compliance.
Risk Management Committee	Discusses important policies, measures and other matters for promoting risk management.
IR Committee	Discusses investor relations (IR) activity policies and plans, as well as the formulation, update and other matters concerning the company's corporate disclosure policy.

## Accounting Audit

Ernst & Young ShinNihon LLC serves as the Company's Accounting Auditor. Its Accounting Auditors and the Company's Corporate Auditors maintain close cooperation by meeting several times a year. At these meetings they discuss their annual audit plans, the results of audits, and share important audit information. Furthermore, to ensure the reliability of financial reporting, the Company has established and is operating an internal control system for financial reporting that complies with standards generally accepted in Japan, and assesses the effectiveness of the system as appropriate.

	(¥ million)
Accounting Auditor's compensation in fiscal 2011	142
Total amount of cash and other material benefits payable to Accounting Auditor by the Company and its subsidiaries	185

## Measures to improve the Internal Control System

The Company has put into practice, as a basic rule, a group-wide system to promote honest corporate activities firmly rooted in a disciplined and sound corporate culture. The Company has established an internal control system in every part of the group and will further establish, develop, and enhance systems, such as the system to improve work efficiency, the risk management system, the system for compliance with laws and other matters, and the internal audit system, as well as promote systems and an environment for ensuring that audits by Corporate Auditors are carried out effectively. Through these efforts, the company is working to ensure that the entire Astellas group's business is duly executed.

Details on this system of internal controls are also available at the company's website, and in the reports concerning corporate governance submitted to the stock exchanges, etc. (Japanese version only).

## Disclosure of Information

Astellas recognizes that the timely and appropriate disclosure of corporate information underpins the creation of a healthy capital market. The Company has established the Disclosure Policy based on its policy to make timely and fair disclosure of accurate corporate information concerning financial results and other matters to participants of capital markets and the news media in accordance with laws, regulations, and listing regulations.

The company has established the IR Committee, with the aim of implementing proper IR activities for investors. The IR Committee discusses matters such as the disclosure of material information pursuant to the Disclosure Policy.

The Company's main IR activities include holding briefings on financial results and on R&D for securities analysts, institutional investors and news organizations. In fiscal 2011, we held briefings for individual investors in Japan on 22 occasions.

## Interview with an Outside Director



Shiro Yasutake, Outside Director

We asked outside Director Shiro Yasutake for his frank opinion about Astellas' corporate governance and CSR-based management.

### Question

In your view, what is the role that outside Directors should play?

**The role of outside Directors is to fulfill a supervisory function, to provide oversight of the execution of business by top management, and to foster the continuous enhancement of enterprise value.**

Outside Directors oversee and keep in check the activities of management from an independent perspective. At the same time, it is important that they contribute to the continuous enhancement of enterprise value. They do this by drawing on their specialist knowledge and experience when dealing with resolutions on important matters relating to basic policy and the performance of duties by the Company's management team.

At Astellas, four of the seven Directors are outside Directors, and two of the four Corporate Auditors are outside Auditors. The Company notifies the stock exchange of all outside Directors and Auditors as independent in accordance with the exchange's regulations. We are chosen as outside Directors because of our neutral and objective standpoint and because we do not have any relationships of interest with the Company or its top management. In this sense, we recognize that our role is also to supervise man-

agement as agents for the Company's various stakeholders.

From my personal experience as president of Nissho Iwai Corporation (currently Sojitz Corporation), I feel that in many Japanese companies the president has an enormous amount of authority. Therefore, to enable corporate governance to function adequately, it is important that outside Directors—as persons who can express their viewpoints from a completely neutral and objective perspective—establish a presence by fulfilling their supervisory and oversight functions with respect to management.

In a global business, there is much that is not known. I believe that with their broader perspective, outside Directors must decide whether the decisions that are made in such a global business are appropriate in the context of a company's business philosophy, as well as from the standpoint of enhancing enterprise value in the medium and long terms, rather than for short-term interests.

**Question**

How do you rate Astellas' corporate governance?

**Astellas' system is among the best of any publicly listed company in Japan.**

Before I accepted the job as an outside Director, I looked into the Company's governance systems. I found that there is a clear separation between the business execution and supervisory functions. With more than half of the Directors coming from outside the Company, they bring a highly independent perspective to Board meetings. Frankly, I was impressed with this great system that has been put in place.

The significance of this kind of governance system lies in the strong supervisory function of Board meetings. For instance, in the case of a corporate scandal, the Board could decide, with a majority of four to three, to remove the president from office. When you look around at other companies, you will find that none of Japan's biggest and most powerful corporations has designed this type

of system. Furthermore, outside Directors have held a majority on Astellas' Nomination Committee and Compensation Committee for the past five years. Recently, corporate scandals have led to calls for tightening up governance systems in Japan. I think that Astellas' early establishment of the type of system you see today was insightful and something that required plenty of courage.

On the operational side, too, Board of Directors' meetings are occasions where participants can engage in lively discussion, and we outside Directors also engage in vigorous debate. Since I have been a member of the Board, there have been times when proposals by corporate executives have been voted down or have been passed subject to conditions. In my estimation, the Astellas Board of Directors functions effectively.

**Question**

What is your impression of Astellas' "CSR-based management?"

**Creating value through core business activities is the key to effective implementation of CSR-based management.**

Astellas' raison d'être is to "contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products." Based on this philosophy, Astellas has clearly signaled that its business direction is to deliver new drugs to patients suffering from diseases in therapeutic areas where there are large unmet medical needs. Fulfilling our social mission of helping people lead healthy lives is also consistent with improving enterprise value. It is extremely important that a company not only pursues economic viability, but also practices "CSR-based management" so that it can exist as a valuable member of society. We would like to contribute to those efforts from our standpoint as outside Directors.

In targeting new heights, I expect

Astellas to fulfill its social responsibilities as a company on an even greater scale, conscious of the obligations that come with privilege, embodied in the concept of noblesse oblige.





**Global Management Committee Members** (as of June 20, 2012)



**Masao Yoshida**

President and CEO,  
Astellas US LLC/  
President and CEO,  
Astellas Pharma US, Inc.

**Yukihiko Sato**

Senior Vice President and  
President, Sales & Marketing-Japan

**Ken Jones**

President and CEO,  
Astellas Pharma Europe Ltd.

**Shinichiro Katayanagi**

Senior Vice President and  
President, Asia International

**Yasumasa Masuda**

Senior Vice President and  
Chief Financial Officer

**Yoshihiko Hatanaka**

Representative Director,  
President and CEO





**Mitsunori Matsuda**

Senior Vice President and  
President, Technology

**Shinichi Tsukamoto**

Senior Vice President and  
President, Drug Discovery Research

**Steven Ryder**

President,  
Astellas Pharma  
Global Development, Inc.

**Masaharu Asano**

Senior Vice President and  
President, QA, RA and Pharmacovigilance

**Yoshiro Miyokawa**

Executive Vice President,  
Chief Administrative Officer and  
Chief Compliance Officer

**Kenji Yasukawa**

Senior Vice President and  
Chief Strategy Officer



**Yasuyuki Takai**  
Outside Director

**Shiro Yasutake**  
Outside Director

**Naoki Aikawa MD.  
Ph.D.**  
Outside Director

**Kanoko Oishi**  
Outside Director

**Yoshihiko Hatanaka**  
Representative Director,  
President and CEO

Executive Vice President  
and Senior Corporate  
Executive

**Yoshiro Miyokawa**

Senior Corporate Executives

**Masao Yoshida**  
**Shinichi Tsukamoto**  
Ph.D.  
**Masaru Imahori**

**Masaharu Asano**  
Ph.D.  
**Yasumasa Masuda**  
**Kenji Yasukawa**  
Ph.D.



**Masafumi Nogimori**Representative Director  
and Chairman**Yukiko Kuroda**Outside Corporate  
Auditor**Yasuo Ishii**Representative Director and  
Vice Deputy Chairman**Shigeru Nishiyama**Outside Corporate  
Auditor**Seigo Kashii**

Corporate Auditor

**Shigeo Aoyagi**

Corporate Auditor

## Corporate Executives

**Hidetoshi Shuto****Masaki Doi Ph.D.****Hirofumi Seki****Shinichiro Katayanagi****Yoshiaki Nakashima****Toshihiko Iwata****Yoshihiro Minami****Mitsunori Matsuda****Shoji Yokota****Takahisa Iizuka****Yukihiko Sato****Haruhisa Hirotsuki****Kenji Sumi****Chihiro Yokota****Wataru Uchida****Ph.D.****Makoto Takeuchi****Masatoshi Kuroda****Atsushi Kamide**

# CSR Communication

Astellas believes that communication with stakeholders plays an important role in advancing its CSR-based management. Accordingly, we actively disclose our CSR-related activities through our corporate website and various publications.

The screenshot shows the 'Social Responsibility' page on the Astellas website. The page features a navigation menu on the left and several content blocks. Callout boxes provide the following information:

- Top Commitment:** The President explains the Top Commitment.
- Topics:** Astellas' CSR-based management, particularly as it pertains to ISO 26000, is explained.
- Five Fields of CSR-based Management:** Initiatives in the Five Fields of CSR-based Management are shown.
- Left Navigation:** The latest CSR-related topics are introduced.
- Bottom Left:** The GRI Content Index is shown.

At the bottom of the screenshot, a browser address bar shows the URL: <http://www.astellas.com/en/csr/>

The publications shown below can be viewed in PDF format at our corporate website.



### CSR Reports

All CSR reports up to CSR Report 2011 can be accessed.



### Environmental Report 2012

Details of our environmental activities are disclosed. (To be issued in Sep. 2012)



### Corporate Governance Report (Japanese version only)

A detailed update on the status of our corporate governance is provided.

## Financial Section

094	Management's Discussion and Analysis
108	Consolidated Balance Sheets
110	Consolidated Statements of Income
111	Consolidated Statements of Comprehensive Income
112	Consolidated Statements of Changes in Net Assets
113	Consolidated Statements of Cash Flows
114	Notes to Consolidated Financial Statements
133	Independent Auditor's Report



# Management's Discussion and Analysis

## ■ Overview of Year Ended March 31, 2012 (Fiscal 2011)

In the year under review, the pharmaceutical industry continued to face an increasingly challenging operating environment. This was due to a number of factors, including stricter regulatory processes for approval of new drugs, and increased government moves to curb medical expenditures, not only in developed nations but also in emerging countries. Against this backdrop, Astellas actively pursued growth in all aspects of its business, from research and development through to manufacturing and sales. We continued our strategy of developing high-value-added innovative drugs in fields with unmet medical needs for worldwide supply.

### Operating Performance Overview

Consolidated operating results for fiscal 2011 showed increases in net sales, operating income, and net income.

In the year under review, consolidated net sales increased by 1.6% to ¥969.4 billion. In global products, sales of Vesicare, the overactive bladder (OAB) treatment, continued to grow. Sales of

### Net Sales

In fiscal 2011, consolidated net sales amounted to ¥969.4 billion, a year-on-year increase of ¥15.4 billion, or 1.6%.

A review of sales by product is provided below.

### Sales by Product (Global Products)

	¥ billion		%	
	2011.3	2012.3	YoY	CER*
<b>Prograf</b>	¥ 162.6	¥ 154.8	(4.8)	—
Japan	39.6	44.0	11.1	—
Americas	41.0	29.2	(28.6)	(22.6)
Europe	60.6	60.2	(0.7)	3.1
Asia	14.8	15.2	3.0	—
Exports	6.5	6.0	(7.4)	—
<b>Harnal/Omnice</b>	66.5	60.8	(8.5)	—
Japan	29.6	27.4	(7.6)	—
Europe	21.5	18.0	(16.2)	(13.1)
Asia	9.2	9.8	6.1	—
Bulk and Royalties	5.2	4.7	(9.3)	(5.9)
<b>Vesicare</b>	86.7	97.2	12.1	—
Japan	25.5	28.0	9.9	—
Americas	35.8	38.9	8.6	17.8
Europe	23.5	27.5	16.9	21.4
Asia	1.4	2.4	73.1	—
<b>Betanis (Launched in September 2011)</b>	—	0.9	—	—
Japan	—	0.9	—	—
<b>Funguard/Mycamine</b>	25.1	26.2	4.6	—
Japan	12.6	12.5	(0.7)	—
Americas	8.4	8.2	(1.9)	6.4
Europe	2.4	3.7	56.0	61.9
Asia	1.6	1.6	3.4	—
<b>Protopic</b>	16.2	16.9	4.3	—
Japan	2.9	3.1	6.0	—
Americas	7.1	7.4	4.5	13.3
Europe	5.2	5.1	(1.9)	1.8
Asia	0.9	1.2	23.1	—

\* Year-on-year comparison, local currency base

Prograf, the immunosuppressant drug, declined due to the impact of generic drugs in the United States, in spite of sales growth in Japan and Asia. In Japan, mainstay products and new products both contributed to a steady increase in sales.

Despite a decrease in gross profit, operating income increased 10.4%, to ¥131.5 billion. This was attributable to a decrease in R&D expenses owing to a decline in upfront and milestone payments associated with in-licensing compared with the previous fiscal year, among other factors. Net income rose 15.6%, to fiscal ¥78.2 billion.

### Foreign Exchange Impact for Fiscal 2011

In fiscal 2011, the yen appreciated by ¥7 on average against the U.S. dollar and ¥4 on average against the euro compared with the previous fiscal year. The impact was a ¥24.1 billion decline in the value of net sales and a ¥5.1 billion decrease in operating income.

### Foreign Exchange Rates (Average)

	¥	
	2011.3	2012.3
US\$1	¥ 86	¥ 79
€1	113	109

## Sales by Product (Local Products)

	¥ billion		%	
	2011.3	2012.3	YoY	CER*1
<b>Japan</b>				
Lipitor	¥ 97.2	¥ 96.3	(1.0)	—
Caduet	—	4.9	—	—
Micardis	75.8	85.3	12.5	—
Micombi	6.1	10.4	70.9	—
Micamlo	2.3	10.6	360.6	—
Gaster	41.7	37.5	(9.9)	—
Myslee	32.7	35.2	7.8	—
Seroquel	26.4	27.8	5.1	—
Vaccines	18.5	26.5	43.3	—
Cefzon	9.4	8.2	(12.5)	—
Frاندول	10.1	9.4	(6.6)	—
Luvox*2	8.2	6.1	(24.7)	—
Celecox	25.1	33.0	31.2	—
Geninax	10.2	11.9	17.5	—
Bonoteo	2.4	5.0	108.1	—
Symbicort	11.9	20.0	67.3	—
<b>Americas</b>				
Scan (Adenoscan and Lexiscan)	47.9	49.0	2.2	10.8
Lexiscan	39.0	42.4	8.6	17.7
AmBisome	6.2	5.5	(11.8)	(4.4)
Tarceva	24.5	33.7	37.7	49.2
<b>Europe</b>				
Eligard	13.8	13.8	(0.0)	3.8
Qutenza	0.1	0.5	200.4	211.9

\*1 Year-on-year comparison, local currency base

\*2 Distribution and promotion for Luvox ended on March 31, 2012.

## Net Sales by Product

## Sales of Global Products

## Prograf (Immunosuppressant)

Sales in Japan increased by ¥4.3 billion, or 11.1%, to ¥44.0 billion. In addition to steady growth in the transplantation area, Prograf recorded steady sales increases for treating autoimmune diseases, including rheumatoid arthritis (RA), lupus nephritis, myasthenia gravis, and ulcerative colitis. The RA indication now accounts for approximately 40% of sales of Prograf in Japan. In the transplantation area, sales of the once-daily formulation Graceptor increased steadily. In July 2011, Astellas obtained approval for Prograf and Graceptor for the additional indication of the prophylaxis of organ rejection in patients receiving allogeneic small bowel transplants.

Sales in the Americas fell by ¥11.7 billion, or 28.6%, to ¥29.2 billion due to the impact of generic versions launched in the United States. In local currency terms, sales of Prograf fell by US\$108 million, or 22.6%, to US\$370 million. The share of generic products in the

tacrolimus market, which includes Prograf and generics, averaged approximately 59% on a total prescription basis during fiscal 2011.

In Europe, sales of Prograf through Astellas' own distribution channels declined by ¥0.3 billion, or 0.7%, to ¥60.2 billion. In local currency terms, however, sales continued to show an upward trend, increasing by €16 million, or 3.1%, to €552 million. The once-daily formulation Advagraf is now sold in 30 European countries, and steadily increasing sales of the drug accounted for around 26% of total Prograf sales in the region. Generic versions of the drug are available in a number of European countries, but the generic versions remained around a 3% share on average (on a volume basis) in Europe during fiscal 2011.

In Asia, sales grew by ¥0.4 billion, or 3.0%, to ¥15.2 billion. Sales showed steady growth in China and South Korea. In 2011, approval was obtained for the additional indication of lupus nephritis for Prograf in the Philippines in July, and in India in August. Advagraf was released in India and Thailand in April and July 2011, respectively.

**Vesicare (Overactive bladder (OAB) treatment)**

Sales in Japan expanded steadily, amounting to ¥28.0 billion, year-on-year increase of ¥2.5 billion, or 9.9%. In fiscal 2011, Vesicare's share of the OAB treatment market was approximately 49%, further reinforcing its position as the leading drug in this category. In April 2011, Astellas released an orally disintegrating (OD) tablet formulation. Vesicare OD tablets are formulations which dissolve quickly upon contact with saliva in the mouth, meaning they can be taken without water. Owing to the considerable number of potential subjects in the OAB treatment market, there is plenty of opportunity for further expansion. We are working to increase Vesicare's market penetration by raising public awareness of this condition.

In the Americas, VESicare sales rose ¥3.0 billion, or 8.6%, to ¥38.9 billion. On a local currency basis, sales grew by US\$74 million, or 17.8%, to US\$492 million. Despite a year-on-year decrease in the size of the OAB treatment market due to stagnation of the United States economy, sales continued to show strong growth. In March 2012, VESicare's market share was approximately 22% (on a total prescription basis), the highest of any branded drug in the market. The Company's co-promotion of VESicare in the United States market with GlaxoSmithKline ended in December 2011. As a result, Astellas took over these promotional activities in January 2012.

In Europe, sales of Vesicare increased by ¥3.9 billion, or 16.9%, to ¥27.5 billion. On a local currency basis, sales continued to show a high level of growth, rising €44 million, or 21.4%, to €252 million. Vesicare is sold in 48 countries throughout Europe, and has a market share of approximately 43% (on a value basis, as of March 2012).

In Asia, sales of Vesicare climbed ¥1.0 billion, or 73.1%, to ¥2.4 billion, with sales growth in South Korea driving this appreciable market expansion. Our subsidiary commenced distribution of Vesicare through its own distribution channel in Australia in April 2011.

**Betanis (generic name: mirabegron, OAB treatment)**

In Japan, Astellas received approval for mirabegron in July 2011, and released it under the brand name of Betanis in September 2011. Sales of Betanis amounted to ¥0.9 billion in fiscal 2011.

Mirabegron is a once-daily oral selective beta-3 adrenoceptor agonist used in OAB treatment which was discovered and developed by Astellas. The drug enhances the urine collection function by activating beta-3 adrenoceptor selectively on the bladder's smooth muscles and improves symptoms associated with OAB such as urgency, urinary frequency and urge urinary incontinence. At present, anticholinergics, such as Vesicare, are used as the standard treatment for OAB. In addition to Vesicare, the offering of an additional option to patients is expected to make a valuable contribution to the treatment of OAB.

Astellas submitted a new drug application and a market authorization application for mirabegron to the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), respectively, in August 2011. The approval was obtained in the United States in June 2012 (brand name: Myrbetriq).

**Harnal (Treatment for functional symptoms associated with benign prostatic hyperplasia (BPH))**

Sales of Harnal in Japan declined ¥2.2 billion, or 7.6%, to ¥27.4 billion. Despite declining sales affected by the impact of generic drugs, Harnal maintained its top market position with a share of around 42% in the alpha-1 blocker market in fiscal 2011. The market share for generic drugs among all tamsulosin products, which includes Harnal and its generics, was approximately 23% on a volume basis, excluding direct sales.

In Europe, the drug is marketed under the brand name Omnic. In fiscal 2011, sales of Omnic through our own distribution channel declined ¥3.5 billion, or 16.2%, to ¥18.0 billion. This decline reflected the yen's appreciation and the impact of generics. On a local currency basis, sales decreased by €24 million, or 13.1%, to €165 million. Sales of Omnic OCAS accounted for roughly 60% of total Omnic sales.

In Asia, sales increased ¥0.5 billion year on year, or 6.1%, to ¥9.8 billion. Sales grew steadily in China and South Korea. In March 2012, an OCAS formulation was released in Taiwan.

Bulk sales and royalty income of Harnal, which are recorded under European sales, declined ¥0.4 billion, or 9.3%, to ¥4.7 billion. On a local currency basis, sales were down €2 million, or 5.9%, to €43 million.

#### Fungard/Mycamine (Candin-type antifungal agent)

Sales in Japan decreased 0.7% to ¥12.5 billion. This result represented stable sales, with Astellas securing a market share of around 56% for injectable antifungal agents during fiscal 2011.

In the Americas, sales edged down ¥0.1 billion, or 1.9%, to ¥8.2 billion, due to the impact of the yen's appreciation. However, on a local currency basis, sales grew steadily by US\$6 million, or 6.4%, to US\$104 million. In terms of patient days per month, the market share held by Mycamine for injectable candin-type antifungal agents steadily increased to around 76% in March 2012.

In Europe, sales grew by ¥1.3 billion, or 56.0%, to ¥3.7 billion. On a local currency basis, sales increased by €13 million, or 61.9%, to €34 million. This sales growth was largely attributable to the drug's strong reputation in the region, as well as an increase in the number of countries where Mycamine is sold, which rose to 26 in fiscal 2011.

In Asia, sales grew 3.4% to ¥1.6 billion. In December 2011, the additional indication of aspergillosis was approved in India.

#### Protopic (Treatment for atopic dermatitis)

Sales in Japan rose by ¥0.1 billion year on year, or 6.0%, to ¥3.1 billion. Under an agreement reached with Maruho Co., Ltd. in July 2010, that company began promotional activities for Protopic in April 2011. Under the terms of the agreement, Astellas will transfer distribution rights in Japan to Maruho Co., Ltd. in April 2014.

In the Americas, sales grew by ¥0.3 billion, or 4.5%, to ¥7.4 billion. On a local currency basis, sales increased steadily, growing by US\$11 million, or 13.3%, to US\$94 million.

In Europe, sales declined 1.9%, to ¥5.1 billion, but on a local currency basis sales increased 1.8% to €46 million.

#### Mainstay Products by Geographical Area

One of the features of Astellas is the large number of distinctive products offered in each region, in addition to the global products mentioned above. Growth in sales of these local products also contributes to consolidated net sales.

#### • Japan

##### Lipitor (Hypercholesterolemia treatment)

##### Caduet (Combination drug containing Lipitor and a long-acting calcium antagonist)

In Japan, sales of the Lipitor product line, which includes Caduet, declined by ¥0.9 billion, or 1.0%, to ¥96.3 billion. The expiration of the substance patent in June 2011 saw the release of generic drugs in the domestic market in the following November. In fiscal 2011, the market for statins in Japan grew 3.1% year on year, to approximately ¥310.0 billion on a NHI drug price basis. Lipitor's share of the market fell 2.4 percentage points, to 33.7%, compared to the previous fiscal year. We will continue maximizing the value of the Lipitor family under co-promotional efforts with Pfizer Japan Inc.

In July 2011, Astellas and Pfizer Japan Inc. amended the co-promotion agreement for Caduet in Japan. As a result, from October 2011, Astellas gained distribution rights and began recording sales of Caduet. In March 2012, we also partially amended a licensing agreement for Lipitor that we have with Pfizer. Under the amended agreement, the agreement's expiration has been extended to March 2021.

##### Micardis (Hypertension treatment)

##### Micombi (Combination drug with a diuretic)

##### Micamlo (Combination drug with a long-acting calcium antagonist)

Sales of drugs in the Micardis product line, which included Micombi and Micamlo, increased by ¥9.5 billion, or 12.5%, to ¥85.3 billion. Sales grew for both Micombi, a combination drug with a diuretic that was launched in June 2009, and Micamlo, a combination drug with a calcium antagonist, which was launched in October 2010. In fiscal 2011, the market for angiotensin II receptor blockers (ARB) in Japan grew 6.1%, to around ¥611.0 billion. Steady expansion in sales of the Micardis line of drugs contributed to its current ARB market share of 15.8%. In Japan, Astellas is co-promoting Micardis with Nippon Boehringer Ingelheim Co., Ltd.

**Gaster (Treatment for peptic ulcers and gastritis)**

Sales of Gaster declined ¥4.1 billion, or 9.9%, to ¥37.5 billion. In fiscal 2011, the overall Japanese market for H2 receptor antagonists and proton pump inhibitors grew 4.3% year on year, to approximately ¥316.0 billion. Gaster recorded a share of 13.7%, a decline of 1.9 percentage points compared with the previous fiscal year. The share of generics in the famotidine market, including Gaster and its generics, increased to around 30% on a volume basis, excluding direct sales.

**Myslee (Insomnia treatment)**

Sales of Myslee showed steady growth, rising by ¥2.5 billion, or 7.8%, to ¥35.2 billion from the previous fiscal year. In fiscal 2011, the market for drugs to treat insomnia in Japan expanded 4.7% year on year, to approximately ¥86.0 billion. Myslee solidified its position as a first-choice therapy for insomnia treatment by increasing its market share by 1.9 percentage points, to 45.0%. In Japan, Astellas co-promotes Myslee with Sanofi-Aventis K.K.

**Seroquel (Schizophrenia treatment)**

Sales of Seroquel continued to expand in Japan, rising ¥1.3 billion, or 5.1%, to ¥27.8 billion. The market for anti-schizophrenic agents in Japan grew 8.2%, to approximately ¥154.0 billion in fiscal 2011. Seroquel ranked second in this market with a share of 19.9%. The market for anti-schizophrenic agents in Japan is expanding year after year. Astellas will continue emphasizing the safety and outstanding symptomatic improvement effect of Seroquel while endeavoring to achieve further market penetration.

**Celecox (Anti-inflammatory agents  
(Selective COX-2 inhibitor))**

Celecox recorded strong sales, climbing ¥7.8 billion, or 31.2%, to ¥33.0 billion. Sales of Celecox grew with the addition of new indications. On top of the initial indications of rheumatoid arthritis and osteoarthritis, in June 2009 Celecox received approval for the indication including lumbar, and in December 2011 for the indication of acute pain. The revision of prescribing information as of April 2011 to reflect the results of post-marketing clinical trials has further strengthened the drug's reputation as an anti-inflammatory that causes minimal gastrointestinal tract disturbance.

In fiscal 2011, the market for anti-inflammatory agents in Japan was worth approximately ¥89.0 billion, up 5.7% from the previous fiscal year. The market share of Celecox in this market grew 8.5 percentage points, to 41.1%. Astellas will continue co-promoting this drug with Pfizer Japan Inc. while targeting an even higher share of the oral anti-inflammatory market.

**Geninax (Oral quinolone antibiotic)**

Sales of Geninax grew steadily, increasing ¥1.7 billion, or 17.5%, to ¥11.9 billion. The Japanese market for oral quinolone antibiotics grew 4.5% year on year, to approximately ¥64.0 billion in fiscal 2011. Geninax boosted its share by 2.3 percentage points, to 20.9%, making it the second largest seller in the market. Astellas continues working hard to achieve further market penetration through co-promotion with Taisho Toyama Pharmaceutical Co., Ltd.

**Bonoteo (Treatment for osteoporosis)**

Sales of Bonoteo rose ¥2.6 billion year on year, to ¥5.0 billion. The release in September 2011 of a 50 mg tablet to be taken once every four weeks contributed to this increase in sales. Sales of Bonoteo Tablets 50 mg amounted to ¥2.7 billion. In fiscal 2011, the Japanese market for the treatment of osteoporosis grew 0.6%, to around ¥87.0 billion. Bonoteo's share in this market edged up 3.3 percentage points, to 6.3%. Astellas is taking advantage of the release of the 50 mg tablets to further expand the drug's market share.

**Symbicort (Treatment for adult bronchial asthma)**

Sales of Symbicort, which is a combination drug of an inhaled corticosteroid and a rapid and long acting beta-2 agonist, climbed ¥8.0 billion year on year, or 67.3%, to ¥20.0 billion. Symbicort became eligible for long-term prescriptions in January 2011, which contributed to this substantial sales growth. In fiscal 2011, the adult inhaled steroid treatment market including combination drugs in Japan grew 15.0% year on year, to approximately ¥83.0 billion. Symbicort also grew its share of this market, by 9.1 percentage points, to 26.6%. The dissemination of guidelines on controlling and preventing asthma and activities to raise public awareness of this condition has contributed to annual growth of the market for combination drug. Astellas will continue co-promoting Symbicort with AstraZeneca K.K. in Japan to achieve further market penetration.



• Americas and Europe

**Adenoscan/Lexiscan (Pharmacologic stress agent)**

Total sales of Adenoscan and Lexiscan in the United States rose by ¥1.0 billion, or 2.2%, to ¥49.0 billion. On a local currency basis, sales increased US\$60 million, or 10.8%, to US\$619 million. Sales of Lexiscan, which was launched in June 2008, increased steadily, rising US\$80 million, or 17.7%, to US\$536 million.

**Tarceva (Anticancer)**

Following the acquisition of OSI in June 2010, Astellas began recording Tarceva-related revenues in the Americas from July 2010 onward. In the United States, we have been co-promoting Tarceva with Genentech, Inc., with earnings split equally between both companies. We also have a license agreement with Roche in other countries, and receive royalties based on sales.

In fiscal 2011, Astellas' Tarceva-related revenues amounted to ¥33.7 billion, or US\$426 million on a local currency basis.

**Eligard (Advanced prostate cancer treatment)**

Sales of Eligard in Europe amounted to ¥13.8 billion, remaining on par with the previous fiscal year's sales due to the impact of the yen's appreciation. However, boosted by the contribution of the six-month formulation and other factors, sales rose €4 million, or 3.8%, to €127 million on a local currency basis.

**Sales by Geographical Area**

	¥ billion)	
	2011.3	2012.3
Consolidated	¥ 953.9	¥ 969.4
Japan	543.8	558.4
Americas	186.5	183.5
Europe	189.9	191.7
Asia	33.7	35.7

Note: Sales by geographical area are calculated according to the location of sellers.

• Japan

Sales in Japan increased 2.7% year on year, to ¥558.4 billion. This included steady growth in the Japanese market excluding exports, which also grew 2.7%, to ¥539.9 billion.

Prograf, Vesicare, Myslee, Celecox, and vaccines all reported growth in sales. Sales of Micardis, including combination drugs Micombi and Micamlo, also increased, as did sales of new offerings, such as Symbicort and Bonoteo. Meanwhile, sales of Gaster, Harnal, and Lipitor declined.

• Americas

Sales in the Americas declined 1.6% year on year, to ¥183.5 billion. However, on a local currency basis, sales grew 6.7%, to US\$2,321 million. Sales of VESIcare continued to rise, and sales of Lexiscan were also up. The increase in revenue from Tarceva also contributed to higher sales. By contrast, sales of Prograf declined due to the impact of generic drugs.

• Europe

Sales in Europe rose 1.0% year on year, to ¥191.7 billion. On a local currency basis, sales also rose 4.8%, to €1,759 million. Sales of Vesicare increased, while sales of Mycamine also steadily expanded. Sales of Prograf through our own distribution channels declined due to the impact of foreign exchange rates, although sales of Advagraf and other factors contributed to continuous higher sales on a local currency basis in fiscal 2011. Generic versions of Prograf have entered into the market in several European countries. Sales of Harnal through our own distribution channels decreased.

### • Asia

In Asia, sales rose 6.0% year on year, to ¥35.7 billion. Sales of Prograf, Harnal, and Vesicare grew steadily.

### Overseas Sales

	¥ billion	
	2011.3	2012.3
Consolidated	¥ 422.5	¥ 421.6
Americas	189.5	182.7
Europe	182.0	187.4
Asia and Other	51.1	51.6
Overseas sales ratio (%)	44.3	43.5

Overseas sales are attributed by location of customers. The overseas sales ratio declined 0.8 percentage point in fiscal 2011, to 43.5%, due to the appreciation of the yen against the U.S. dollar and the euro.

### Cost of Sales

	¥ billion	
	2011.3	2012.3
Net sales	¥ 953.9	¥ 969.4
Cost of sales	296.0	318.6
Cost of sales ratio (%)	31.0	32.9

Cost of sales increased by ¥22.7 billion, or 7.7%, to ¥318.6 billion.

The cost of sales ratio rose 1.9 percentage points in fiscal 2011, to 32.9% due to changes in the product mix, including the impact of the partial amendment of the licensing agreement for Lipitor.

### Selling, General and Administrative (SG&A) Expenses

	¥ billion	
	2011.3	2012.3
Total SG&A expenses	¥ 538.8	¥ 519.2
SG&A ratio (%)	56.5	53.6
R&D expenses	217.3	189.8
R&D ratio (%)	22.8	19.6
SG&A excluding R&D	321.5	329.4
SG&A ratio excluding R&D (%)	33.7	34.0
Advertising and sales promotional expenses	89.0	86.4
Personnel expenses	120.8	130.4
Other	111.7	112.6

SG&A expenses decreased ¥19.6 billion, or 3.6%, to ¥519.2 billion. The ratio of SG&A expenses to net sales declined 2.9 percentage points, to 53.6%.

R&D expenses fell ¥27.5 billion, or 12.6%, to ¥189.8 billion. The ratio of R&D expenses to net sales fell 3.2 percentage points, to 19.6%. The main contributing factor was the decrease in upfront and milestone payments associated with in-licensing compared with the previous fiscal year.

SG&A expenses, excluding R&D expenses increased by ¥7.9 billion, or 2.5%, to ¥329.4 billion. Advertising and sales promotional expenses decreased by ¥2.6 billion, or 2.9%, to ¥86.4 billion. Personnel expenses rose by ¥9.6 billion, or 8.0%, to ¥130.4 billion accompanying expenses allocated for the strengthening of the sales force in each region. Other expenses increased by ¥0.9 billion, or 0.8%, to ¥112.6 billion. In the year under review, amortization expenses for patents and goodwill recognized in association with the acquisition of OSI amounted to ¥19.0 billion.

### Operating Income

	¥ billion	
	2011.3	2012.3
Net sales	¥ 953.9	¥ 969.4
Operating income	119.2	131.5
Operating margin (%)	12.5	13.6

As a result of the above-mentioned factors, operating income increased by ¥12.3 billion, or 10.4%, to ¥131.5 billion. The ratio of gross profit to sales decreased 1.9 percentage points year on year, while the ratio of R&D expenses to net sales was down 3.2 percentage points. Consequently, the operating margin rose 1.1 percentage points.

### Other Income (Expenses)

Interest and dividend income, at ¥2.4 billion, remained at almost the same level as the previous fiscal year. Whereas in fiscal 2010 an exchange loss of ¥6.6 billion was recorded, in fiscal 2011 an exchange gain of ¥1.0 billion was recorded. A gain on the sale of investment securities of ¥2.7 billion was recorded. However, we recorded a ¥9.2 billion loss on impairment of tangible and intangible fixed assets, a ¥5.9 billion loss on sales and disposal of fixed assets, and a ¥3.2 billion loss resulting from the Great East Japan Earthquake.

## Foreign Exchange Trends (Year-end rate)

	(¥)	
	2011.3	2012.3
US\$1	¥ 83	¥ 82
€1	118	110

## Income Before Income Taxes and Minority Interests, Income Taxes, and Net Income

As a result of the above-mentioned factors, income before income taxes and minority interests rose ¥23.6 billion, or 22.8%, to ¥127.1 billion.

Income taxes increased by ¥13.0 billion, or 36.3%, to ¥48.8 billion. In the year under review, the income tax burden rate rose 3.8 percentage points, to 38.4%, due to temporary factors, including the revision of the policy on dividends from subsidiaries outside of Japan and the impact of the revised Corporation Tax Act, etc. in Japan.

As a result, net income increased by ¥10.6 billion, or 15.6%, to ¥78.2 billion.

## Status of R&D and In-Licensing Activities and Other Measures to Bolster the Business Platform

Astellas aims to achieve sustained growth over the medium and long terms through the early and ongoing discovery of a stream of innovative and useful new drugs in therapeutic areas where a high degree of unmet medical needs exist. To this end, Astellas actively promotes R&D activities as a priority measure.

### • Drug Discovery Research Measures

Drug discovery research, in which we are concentrating management resources, focuses on the following prioritized therapeutic areas: urology, immunology (including transplantation) & infectious diseases, oncology, neuroscience, and diabetes mellitus (DM) complications & kidney diseases.

Astellas is also actively seeking to reinforce its technological platform for drug discovery by establishing a presence in antibody and protein-related pharmaceutical technologies. This approach promises to supplement our traditional strengths in small molecule synthesis and fermentation technology.

With research activities concentrated in our research centers in Ibaraki Prefecture's Tsukuba City as well as in Osaka Prefecture's Osaka City, we are establishing a global research network.

Additionally, we are adopting an open innovation approach utilizing an outside network of knowledge and expertise to further improve our future drug discovery capabilities. In May 2011, Astellas set up a public open innovation site called "a<sup>3</sup>" on its website to support collaborative research on drug discovery leading to innovative and useful new pharmaceutical products by building partnerships with universities, public research facilities, and corporate researchers in Japan.

In the neuroscience field, Astellas signed a five-year joint research agreement with RIKEN, Japan (an independent science and technology research institute in Japan) in November 2011 for the purpose of "deciphering the pathogenic mechanism and identifying novel drug targets for Alzheimer's disease."

### • Clinical Development Initiatives

In clinical development, Astellas is working to accelerate the pace of product development by channeling resources into high-priority projects under its global development structure.

(Major Progress of Clinical Development in Japan)

Vesicare OD (orally-disintegrating tablet), an additional formulation of Vesicare, was launched in Japan in April 2011, following approval in October 2010. In July 2011, Betanis (generic name: mirabegron) and Bonoteo tablets 50 mg for administration once every four weeks were approved and launched in September 2011. Also in July 2011, we obtained approval for Prograf and Graceptor for the additional indication of prophylaxis of organ rejection in patients receiving allogenic small bowel transplants. In December 2011, Celecox was approved for the additional indication of anti-inflammatory and analgesic effects in post-operation, post-trauma, and post-tooth extraction. In January 2012, Regnite (generic name: gabapentin enacarbil) was approved for the treatment of restless legs syndrome, and the drug was launched in July 2012. In February 2012, we received approval to alter the maximum pediatric dosages of the synthetic penicillin Sawacillin, which is used to treat pediatric infectious diseases. Astellas had submitted an application based on evidence in the public domain in August 2011 in response to an assessment of its applicability in June 2011 by the Review Committee on Unapproved Drugs and Indications with High Medical Needs conducted by Japan's Ministry

of Health, Labor and Welfare. In March 2012, Astellas obtained approval for the hyperphosphatemia treatment Kiklin (generic name: bixalomer). The drug was launched in June 2012.

(Major Progress in Clinical Development Outside of Japan)  
Astellas submitted a new drug application and a market authorization application for mirabegron to the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), respectively, in August 2011. In the United States, the approval was obtained in June 2012, and preparations are underway for its launch under the brand name Myrbetriq. In November 2011, enzalutamide (code name: MDV3100), a drug we had developed jointly with Medivation, Inc., generated positive results from an interim analysis of the global Phase 3 AFFIRM trial in men with metastatic castration-resistant prostate cancer previously treated with chemotherapy. An application for approval was filed in the United States in May 2012, and in Europe in June 2012. In January 2012, tivozanib (generic name), under joint development with Aveo Pharmaceuticals Inc., generated positive results in a global Phase 3 clinical study of patients with advanced renal cell carcinoma. Applications for approval are currently being prepared in the United States and Europe. In December 2011, the EMA granted approval for Dificlir (generic name: fidaxomicin) for the treatment of adults with clostridium difficile infections. In May 2012, it was launched in Europe. In March 2012, Astellas submitted a marketing authorization application in Europe for solifenacin/tamsulosin combination drug (code name: EC905). In September 2011, Astellas decided to discontinue global development of darexaban (generic name, code name: YM150), an oral direct Factor Xa inhibitor.

(Expanding Our Development Pipeline through In-Licensing)  
Along with conducting in-house drug discovery, Astellas actively seeks to expand and improve the development pipeline through the in-licensing of compounds from other companies.

In June 2011, Seattle Genetics, Inc. exercised an option to co-develop ASG-22ME (code name) with Astellas' subsidiary Agensys. Under the companies' existing licensing agreement relating to antibody-drug conjugate (ADC) technology, an area of the antibody

pharmaceutical technology field.

In July 2011, Astellas entered into an exclusive licensing agreement with Vical Incorporated to globally develop and commercialize ASP0113/VCL-CB01 (code name). This therapeutic vaccine, which Vical discovered and has been developing, is designed to control cytomegalovirus reactivation in transplant recipients. Vical retains the option to jointly promote the drug in the United States.

In September 2011, Astellas and the Japanese company Evec, Inc., signed a license agreement for one of Evec's fully human antibodies against infectious diseases. Under the agreement, Astellas holds worldwide exclusive rights for the development, manufacture, and commercialization of the program.

In January 2012, Astellas and UCB entered into an agreement to jointly develop and commercialize UCB's certolizumab pegol (generic name) in Japan, which is a PEGylated anti-Tumor Necrosis Factor (TNF)-alpha antibody for treating rheumatoid arthritis. Under the agreement, UCB will manufacture and supply the product, while Astellas will manage distribution and sales. Both companies will co-develop and co-promote the antibody. In March 2012, Astellas and Optimer Pharmaceuticals, Inc., concluded an exclusive collaboration and license agreement for the development and commercialization of fidaxomicin (generic name) in Japan. In February 2011, Astellas received exclusive rights from Optimer for the development and commercialization of fidaxomicin in Europe, the Middle East, Africa, and the Commonwealth of Independent States (CIS).

#### • Technological Development Initiatives

In April 2011, three of the Company's production subsidiaries—Astellas Tokai Co., Ltd., Astellas Toyama Co., Ltd., and Astellas Pharma Chemicals Co., Ltd., responsible for formulation, biotechnology, and chemical synthesis, respectively—were integrated into a new company called Astellas Pharma Tech Co., Ltd. The objectives behind this move were to build a more expeditious and effective decision-making and operational structure, and to improve the various functions, such as the supply of active pharmaceutical ingredients for clinical trial material and investigational drugs in a reliable and timely manner, accelerating the establishment of new drug manufacturing know-how, and the stable supply of products.

#### • Other Measures to Bolster the Business Platform

In the year under review, Astellas pursued other initiatives designed to reinforce its business platform.

In May 2011, Astellas completed its purchase of all of Maxygen, Inc.'s equity interests in Perseid Therapeutics LLC, a joint venture between Astellas and Maxygen, Inc. As a result of this acquisition, we have secured valuable world-leading technology related to variant protein pharmaceutical creation and development.

In July 2011, Astellas and Pfizer Japan Inc. agreed to change the co-promotion agreement in Japan for Caduet. In accordance with the new agreement, since October 2011, Astellas holds the distribution rights of this drug and records the drug's sales. Astellas and Pfizer Japan Inc. will continue to conduct co-promotion activities. In March 2012, we signed an agreement with Pfizer concerning a partial amendment to the licensing agreement we have with that company for Lipitor. According to the amendment, the expiration of the agreement has been extended from July 2016, to March 2021.

In August 2011, Astellas entered into an exclusive distribution agreement with Teijin Pharma Limited covering Southeast Asia (Thailand, the Philippines, Indonesia, Singapore, Malaysia, and Vietnam) and India for febuxostat (generic name, code name: TMX-67), a new drug for treating gout and hyperuricemia. Our subsidiaries in Taiwan, China, and Hong Kong already hold exclusive distribution rights for the drug in those territories.

In February 2012, Astellas and Sanwa Kagaku Kenkyusho Co., Ltd. (SKK) established a strategic alliance in Japan in the field of kidney disease. Under the agreement, Astellas distributes and both companies co-promote the hyperkalemia treatment Argamate, which SKK currently manufactures and distributes. Also, Astellas distributes and both companies co-promote our Kiklin.

In June 2011, our subsidiary Prosidion Ltd. entered into an agreement to sell to Royalty Pharma its patent estate and associated royalty stream relating to the use of DPP-IV inhibitors for the treatment of type 2 diabetes. The transaction was completed in July 2011.

In December 2011, Prosidion and AstraZeneca entered into an option agreement for PSN821 and PSN842 (code names), a drug for treating type 2 diabetes that has a

new mechanism and is being developed by Prosidion. Under the agreement, Prosidion has granted AstraZeneca the exclusive option to acquire assets related to PSN821 and PSN842.

In July 2011, our U.S. subsidiary and Merck signed an agreement under which Astellas US transfers to a subsidiary of Merck the rights to co-develop and exclusively distribute in North America an intravenous formulation of vernakalant (generic name, code name: RSD1235). An application has been submitted for approval in the United States for the use of the formulation for the indication of atrial fibrillation.

In January 2012, Astellas exercised its right to terminate the global license, development and commercialization agreement it had with Theravance, Inc. related to the antibiotic Vibativ. As a result, the global license granted to Astellas ceased upon termination of the agreement, and Astellas also stopped promotional sales activities.

### ■ Consolidated Forecasts for Year Ending March 31, 2013 (Fiscal 2012) (Announced May 2012)

Consolidated forecasts for fiscal 2012 are as follows:

#### Fiscal 2012 Forecasts

	¥ billion	
	2012.3	2013.3 (forecasts)
Net sales	¥ 969.4	¥ 972.0
Operating income	131.5	146.0
Net income	78.2	98.0
¥		
Average foreign exchange rates		
(US\$1)	¥ 79	¥ 80
(€1)	109	105

We project increases in both revenues and earnings. However, taking into account assumptions of the continued appreciation of the yen against the euro compared with fiscal 2011, we forecast that foreign exchange factors will have a ¥4.4 billion negative impact on net sales and a ¥2.3 billion negative impact on operating income.



#### • Net Sales

In fiscal 2012, net sales are forecast to increase by 0.3% year on year, to ¥972.0 billion. We expect sales of global products Vesicare, Fungard/Mycamine to continue showing a growth trend. However, we forecast a decline in revenues from Prograf and Harnal. In Japan, we project higher sales for mainstay products and new products.

Sales in Japan are expected to increase 2.5% year on year, to ¥572.5 billion. Although NHI drug price revisions carried out in April 2012 will have a negative impact, we expect this to be offset by steady growth in sales of mainstay products, such as Vesicare, Prograf, Micardis product line (including Micombi and Micamlo), and Celecox, as well as healthy sales of new products, such as Symbicort, Bonoteo, Betanis, and Argamate. We project sales growth in the Japanese market.

In the Americas, we forecast a 5.6% year-on-year decline in sales, to ¥173.2 billion. We expect sales of VESicare, Mycamine, and Tarceva to increase, although we project a decline in sales of Prograf and the total sales of the pharmacologic stress agents including Adenoscan and Lexiscan.

In Europe, we forecast a 2.6% year-on-year decline in sales, to ¥186.8 billion. While sales of Vesicare and Mycamine are projected to grow, we expect a decline in sales of Prograf and Harnal through our own distribution channels.

Sales in Asia are expected to grow 10.0% year on year to ¥39.3 billion. We look forward to continued growth in sales of such products as Prograf, Vesicare, and Mycamine.

#### • Operating Income and Net Income

In fiscal 2012, we forecast an 11.0% year-on-year increase in operating income, to ¥146.0 billion.

Despite the expected rise in net sales, we project an increase in the cost of sales ratio due to a change in the product mix and other factors, which will lead to a decline in gross profit.

We forecast a decrease in SG&A expenses. Within such expenses, we project a 5.7% decline in R&D expenses, to ¥179.0 billion, with a ratio of R&D expenses to net sales of 18.4%. Excluding the effect of the upfront and milestone payments associated with in-licensing, we expect R&D expenses to remain mostly unchanged from fiscal 2011. SG&A expenses (excluding R&D expenses) are projected to decline.

Since the beginning of fiscal 2012, Astellas has unified the method for calculating depreciation of property, plant and equipment to use the straight-line method. For the year, we expect this change to boost operating income by approximately ¥9.0 billion compared with the previous method.

We forecast a 25.3% increase in net income, to ¥98.0 billion.

### ■ Number of Employees

As of March 31, 2012, Astellas worldwide employed 17,085 people, a year-on-year increase of 806, among them, the total number of Medical Representatives (MRs) was approximately 6,190, a year-on-year increase of about 390.

In Japan, we had 8,176 employees, up 153 from the previous year-end. In the Americas, regional headcount was 2,919 employees, up 177, reflecting an increase in MRs associated with the end of a co-promotion agreement for VESicare with GlaxoSmithKline. In Europe, we had 4,286 employees, up 184 year-on-year, due mainly to an increase in staff associated with the expansion of our business in the region. In Asia, we had 1,704 employees, up 292 from the previous year-end, mainly reflecting increases in MRs in China.

#### Number of Employees by Geographical Area

	(persons)	
	2011.3	2012.3
Total	16,279	17,085
Japan	8,023	8,176
Americas	2,742	2,919
Europe	4,102	4,286
Asia	1,412	1,704

#### Number of MRs by Geographical Area

	(persons)	
	2011.3	2012.3
Total	5,800	6,190
Japan	2,400	2,400
Americas	1,000	1,140
Europe	1,630	1,740
Asia	770	910

## ■ Financial Condition

### Assets

Total assets as of March 31, 2012 amounted to ¥1,400.6 billion, up ¥65.5 billion from a year earlier.

Current assets increased ¥127.9 billion, to ¥781.1 billion at the fiscal year-end. Cash and cash equivalents increased by ¥76.9 billion, and short-term investments rose by ¥45.4 billion.

Property, plant and equipment at cost was ¥199.2 billion, up ¥9.0 billion from the previous fiscal year-end.

Investments and other assets decreased ¥71.4 billion, to ¥420.4 billion. Patents declined ¥75.2 billion year on year, to ¥161.5 billion, mainly due to the transfer of patent estate and associated royalty stream related to DPP-IV inhibitors held by subsidiary Prosidion Ltd. Goodwill was ¥94.2 billion, down ¥7.1 billion from the previous year-end.

### Liabilities

Total liabilities as of March 31, 2012 amounted to ¥382.5 billion, up ¥68.5 billion from a year earlier.

Current liabilities increased ¥74.5 billion, to ¥314.2 billion. Notes and accounts payable rose ¥54.7 billion.

Total long-term liabilities declined ¥6.0 billion, to ¥68.3 billion. Deferred tax liabilities fell ¥11.3 billion, to ¥30.9 billion.

### Net Assets

Net assets as of March 31, 2012 amounted to ¥1,018.1 billion, down ¥3.0 billion from a year earlier.

Total shareholders' equity rose ¥20.7 billion, to ¥1,151.4 billion from the previous year-end. Major items included net income of ¥78.2 billion and payments of ¥57.7 billion in cash dividends from retained earnings.

Total accumulated other comprehensive income was negative ¥134.9 billion, ¥23.8 billion more than the previous fiscal year-end. Translation adjustments amounted to negative ¥147.2 billion, ¥26.6 billion more than the previous fiscal year-end, due to the impact of the yen's appreciation.

### Liquidity and Financing

Seeking to strengthen its pharmaceutical business, Astellas is constantly working to expand its share of the Japanese market while also building a global sales and marketing network to boost its presence in global markets excluding Japan. Moreover, Astellas will continue reinforcing its R&D capabilities to maintain a strong drug discovery capability.

In addition, Astellas will actively introduce new products and otherwise pursue strategic business investment opportunities, to further reinforce its product lineup.

A sufficient level of cash and cash equivalents is maintained to enable Astellas to target such strategic investment opportunities, while also supplying working capital and fund capital expenditures. As of March 31, 2012, the balance sheet carried no interest-bearing debt other than lease obligations.

As outlined in the section on business risks, Astellas' operations face a varied set of risks that are peculiar to the ethical pharmaceutical business. Astellas believes that it is advisable to finance business development with internal funds. In preparation for the event of demand for funding beyond this, the group's financial policy is to maintain a healthy balance sheet at all times so it can finance smoothly at low interest rates.

## ■ Cash Flows

The balance of cash and cash equivalents as of March 31, 2012 amounted to ¥252.4 billion, an increase of ¥76.9 billion compared with the previous fiscal year-end.

### Cash Flows from Operating Activities

Net cash provided by operating activities amounted to ¥172.7 billion, an increase of ¥72.0 billion in year-on-year terms. During the year, income before income taxes and minority interests rose ¥23.6 billion to ¥127.1 billion, and income taxes paid increased ¥5.9 billion to ¥50.3 billion.

### Cash Flows from Investing Activities

Net cash used in investing activities totaled ¥26.0 billion, down ¥216.7 billion from the previous fiscal year. There was a ¥284.1 billion outflow in the previous fiscal year, mainly due to acquisition of subsidiaries' shares related to the purchase of OSI. In the year under review, major inflows included ¥12.0 billion associated with proceeds from the sale of property, plant and equipment. Contrasting factors included purchases of property, plant and equipment of ¥47.7 billion.

### Cash Flows from Financing Activities

Net cash used in financing activities totaled ¥57.9 billion, down ¥35.3 billion from the previous fiscal year. There was a ¥35.0 billion cash outflow in the previous fiscal

year due to redemption of bonds issued by OSI. In the year under review, cash dividends amounted to ¥57.7 billion, practically unchanged from the previous fiscal year.

## ■ Capital Expenditures

Astellas makes capital expenditures on an ongoing basis with the aim of reinforcing its R&D, production, sales, and marketing capabilities and boosting operational efficiency. Capital expenditures in fiscal 2011 totaled ¥45.0 billion, up 28.2% year on year (based on the value of property, plant and equipment).

In fiscal 2012, capital expenditures are forecast to decrease 9.0%, to ¥41.0 billion.

## ■ Net Income, Cash Dividends, and Net Assets per Share

### Per Share Data

	(¥)	
	2011.3	2012.3
Net income		
Basic	¥ 146.49	¥ 169.38
Diluted	146.33	169.17
Cash dividends	125.00	125.00
Net assets	2,207.70	2,200.64

### Policy on Shareholder Returns

Astellas is working to boost shareholder returns through sustained growth in enterprise value. While prioritizing the re-investment of funds in the business to foster growth, Astellas strives to achieve stable and sustained growth in dividends, based on medium to long-term consolidated earnings growth and taking the dividend-on-equity (DOE) ratio into consideration. Furthermore, Astellas will flexibly purchase treasury stock as necessary to improve capital efficiency and the level of return to shareholders.

### Common Stock

	(thousands of shares)	
	2011.3	2012.3
Total number of shares issued	467,965	467,965
Shares in treasury	6,138	6,045

### Treasury Stock

	2011.3	2012.3
Number of shares bought back*	—	—
Acquisition cost*	—	—
Number of shares cancelled	8,000 thousand	—
Amount cancelled	¥30.6 billion	—

\* Excludes purchases of shares constituting less than a trading unit

### ROE and DOE

	(%)	
	2011.3	2012.3
ROE	6.5	7.7
DOE	5.6	5.7

Return on equity (ROE) was 7.7%, up 1.2 percentage points from fiscal 2010. The DOE ratio was 5.7%, up 0.1 percentage point from fiscal 2010.

## ■ Business Risks

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 R&D 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 or 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, manufacture or 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 Balance Sheets

Astellas Pharma Inc. and Subsidiaries  
March 31, 2012 and 2011

Assets	(Millions of yen)		(Millions of U.S. dollars)
	2012	2011	2012 (Note 4)
<b>Current assets:</b>			
Cash and cash equivalents (Note 17)	¥ 252,380	¥ 175,466	\$ 3,078
Short-term investments (Note 17)	46,719	1,338	570
Notes and accounts receivable (Note 17)	286,798	279,112	3,497
Allowance for doubtful receivables	(2,887)	(1,396)	(35)
	283,911	277,716	3,462
Inventories (Note 5)	111,823	116,882	1,364
Deferred tax assets (Note 9)	71,550	67,804	873
Other	14,696	13,948	178
<b>Total current assets</b>	<b>781,079</b>	<b>653,154</b>	<b>9,525</b>
<b>Property, plant and equipment, at cost:</b>			
Land	31,037	31,374	379
Buildings and structures	236,408	232,006	2,883
Machinery and equipment	222,873	221,745	2,718
Other	3,093	2,944	38
Construction in progress	34,887	24,128	425
Accumulated depreciation	(329,138)	(322,037)	(4,014)
<b>Property, plant and equipment, net</b>	<b>199,160</b>	<b>190,160</b>	<b>2,429</b>
<b>Investments and other assets:</b>			
Investment securities (Note 17)	60,302	59,370	735
Investments in and advances to affiliates	830	2,190	10
Patents	161,499	236,737	1,970
Goodwill	94,193	101,255	1,149
Other intangible assets	58,587	29,186	714
Deferred tax assets (Note 9)	33,875	52,294	413
Other	11,105	10,745	136
<b>Total investments and other assets</b>	<b>420,391</b>	<b>491,777</b>	<b>5,127</b>
<b>Total assets</b>	<b>¥ 1,400,630</b>	<b>¥ 1,335,091</b>	<b>\$ 17,081</b>

\* See accompanying notes to consolidated financial statements.



Liabilities and net assets	(Millions of yen)		(Millions of U.S. dollars)
	2012	2011	2012 (Note 4)
<b>Current liabilities:</b>			
Notes and accounts payable (Note 17):			
Trade	¥ 179,028	¥ 124,293	\$ 2,183
Construction	11,768	14,940	144
Accrued expenses	84,960	76,590	1,036
Accrued income taxes (Note 9)	24,758	19,814	302
Other (Note 6)	13,656	4,011	166
<b>Total current liabilities</b>	<b>314,170</b>	<b>239,648</b>	<b>3,831</b>
<b>Long-term liabilities:</b>			
Accrued retirement benefits for employees (Note 11)	16,979	17,235	207
Deferred tax liabilities (Note 9)	30,932	42,248	377
Other (Note 6)	20,426	14,863	250
<b>Total long-term liabilities</b>	<b>68,337</b>	<b>74,346</b>	<b>834</b>
<b>Net assets (Notes 7 and 15):</b>			
Shareholders' equity:			
Common stock, without par value:			
Authorized: 2,000,000,000 shares;			
Issued: 467,964,635 shares in 2012 and 467,964,635 shares in 2011	103,001	103,001	1,256
Capital surplus	176,822	176,822	2,156
Retained earnings	894,737	874,351	10,912
Treasury stock, at cost:			
6,044,560 shares in 2012 and 6,138,000 shares in 2011	(23,132)	(23,492)	(282)
<b>Total shareholders' equity</b>	<b>1,151,428</b>	<b>1,130,682</b>	<b>14,042</b>
Accumulated other comprehensive income			
Unrealized holding gain on securities	12,257	9,480	149
Translation adjustments	(147,167)	(120,588)	(1,794)
<b>Total accumulated other comprehensive income</b>	<b>(134,910)</b>	<b>(111,108)</b>	<b>(1,645)</b>
Stock subscription rights	1,605	1,523	19
<b>Total net assets</b>	<b>1,018,123</b>	<b>1,021,097</b>	<b>12,416</b>
<b>Contingent liabilities (Note 14)</b>			
<b>Total liabilities and net assets</b>	<b>¥ 1,400,630</b>	<b>¥ 1,335,091</b>	<b>\$ 17,081</b>

# Consolidated Statements of Income

Astellas Pharma Inc. and Subsidiaries  
Years ended March 31, 2012, 2011 and 2010

	(Millions of yen)			(Millions of U.S. dollars)
	2012	2011	2010	2012 (Note 4)
<b>Net sales</b>	¥ 969,387	¥ 953,948	¥ 974,878	\$ 11,822
<b>Cost of sales</b>	318,633	295,973	289,241	3,886
Gross profit	650,754	657,975	685,637	7,936
<b>Selling, general and administrative expenses (Note 12)</b>	519,235	538,794	499,230	6,332
Operating income	131,519	119,181	186,407	1,604
<b>Other income (expenses):</b>				
Interest and dividend income	2,365	2,338	3,939	29
Exchange gain (loss)	1,005	(6,556)	225	12
Equity in earnings (losses) of affiliates	194	(89)	84	2
Gain on sale of investment securities	2,716	1,280	2,700	33
Loss on impairment of fixed assets (Note 20)	(9,234)	(2,782)	(4,082)	(113)
Loss on sales and disposal of fixed assets	(5,924)	(1,277)	(2,282)	(72)
Business integration expenses	(645)	(4,723)	—	(8)
Loss on disaster	(3,193)	(3,029)	—	(39)
Loss on adjustment for changes of accounting standard for asset retirement obligations	—	(560)	—	—
Other, net	8,271	(300)	(189)	102
	(4,445)	(15,698)	395	(54)
Income before income taxes and minority interests	127,074	103,483	186,802	1,550
<b>Income taxes (Note 9):</b>				
Current	51,158	43,554	64,717	624
Deferred	(2,314)	(7,722)	(2,111)	(28)
	48,844	35,832	62,606	596
Income before minority interests	78,230	67,651	124,196	954
<b>Minority interests</b>	—	—	(1,939)	—
<b>Net income (Note 15)</b>	¥ 78,230	¥ 67,651	¥ 122,257	\$ 954

\* See accompanying notes to consolidated financial statements.

# Consolidated Statements of Comprehensive Income

Astellas Pharma Inc. and Subsidiaries  
Years ended March 31, 2012, 2011 and 2010

	(Millions of yen)			(Millions of U.S. dollars)
	2012	2011	2010	(Note 4) 2012
<b>Income before minority interests</b>	<b>¥ 78,230</b>	<b>¥ 67,651</b>	<b>¥ 124,196</b>	<b>\$ 954</b>
<b>Other comprehensive income (Note 10):</b>				
Unrealized holding gain on securities	2,778	(4,674)	4,135	34
Translation adjustments	(26,580)	(38,045)	(19,638)	(324)
<b>Total other comprehensive income</b>	<b>(23,802)</b>	<b>(42,719)</b>	<b>(15,503)</b>	<b>(290)</b>
<b>Comprehensive income</b>	<b>¥ 54,428</b>	<b>¥ 24,932</b>	<b>¥ 108,693</b>	<b>\$ 664</b>
<b>Total comprehensive income attributable to:</b>				
Shareholders of the Company	¥ 54,428	¥ 24,932	¥ 106,754	\$ 664
Minority interests	¥ —	¥ —	¥ 1,939	\$ —

\* See accompanying notes to consolidated financial statements.

# Consolidated Statements of Changes in Net Assets

Astellas Pharma Inc. and Subsidiaries  
Years ended March 31, 2012, 2011 and 2010

Number of shares issued	2012	2011	2010
Beginning of year	467,964,635	475,964,635	503,964,635
Cancellation of treasury stock	—	(8,000,000)	(28,000,000)
End of year	467,964,635	467,964,635	475,964,635

	(Millions of yen)								
	Shareholders' equity					Accumulated other comprehensive income	Stock subscription rights	Minority interests	Total net assets
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity				
<b>Balance as of April 1, 2009</b>	¥103,001	¥176,822	¥957,346	¥(155,295)	¥1,081,874	¥ (52,886)	¥ 895	¥338	¥1,030,221
Cash dividends paid			(56,402)		(56,402)				(56,402)
Net income			122,257		122,257				122,257
Purchase of treasury stock				(26,997)	(26,997)				(26,997)
Disposal of treasury stock			(17)	49	32				32
Cancellation of treasury stock			(128,083)	128,083					
Net change in items other than shareholders' equity						(15,503)	311	14	(15,178)
Total movements during the year			(62,245)	101,135	38,890	(15,503)	311	14	23,712
<b>Balance as of March 31, 2010</b>	103,001	176,822	895,101	(54,160)	1,120,764	(68,389)	1,206	352	1,053,933
Cash dividends paid			(57,728)		(57,728)				(57,728)
Net income			67,651		67,651				67,651
Purchase of treasury stock				(30)	(30)				(30)
Disposal of treasury stock			(46)	71	25				25
Cancellation of treasury stock			(30,627)	30,627					
Net change in items other than shareholders' equity						(42,719)	317	(352)	(42,754)
Total movements during the year			(20,750)	30,668	9,918	(42,719)	317	(352)	(32,836)
<b>Balance as of March 31, 2011</b>	103,001	176,822	874,351	(23,492)	1,130,682	(111,108)	1,523	—	1,021,097
Cash dividends paid			(57,728)		(57,728)				(57,728)
Net income			78,230		78,230				78,230
Purchase of treasury stock				(12)	(12)				(12)
Disposal of treasury stock			(116)	372	256				256
Cancellation of treasury stock									
Net change in items other than shareholders' equity						(23,802)	82		(23,720)
Total movements during the year			20,386	360	20,746	(23,802)	82		(2,974)
<b>Balance as of March 31, 2012</b>	¥103,001	¥176,822	¥894,737	¥ (23,132)	¥1,151,428	¥(134,910)	¥1,605	¥ —	¥1,018,123

	(Millions of U.S. dollars) (Note 4)								
	Shareholders' equity					Accumulated other comprehensive income	Stock subscription rights	Minority interests	Total net assets
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity				
<b>Balance as of March 31, 2011</b>	\$ 1,256	\$ 2,156	\$ 10,663	\$ (286)	\$ 13,789	\$ (1,355)	\$ 19	\$ —	\$ 12,453
Cash dividends paid			(704)		(704)				(704)
Net income			954		954				954
Purchase of treasury stock				(0)	(0)				(0)
Disposal of treasury stock			(1)	4	3				3
Cancellation of treasury stock									
Net change in items other than shareholders' equity						(290)	0		(290)
Total movements during the year			249	4	253	(290)	0		(37)
<b>Balance as of March 31, 2012</b>	\$ 1,256	\$ 2,156	\$ 10,912	\$ (282)	\$ 14,042	\$ (1,645)	\$ 19	\$ —	\$ 12,416

\* See accompanying notes to consolidated financial statements.

# Consolidated Statements of Cash Flows

Astellas Pharma Inc. and Subsidiaries  
Years ended March 31, 2012, 2011 and 2010

	(Millions of yen)			(Millions of U.S. dollars)
	2012	2011	2010	2012 (Note 4)
<b>Operating activities</b>				
Income before income taxes and minority interests	¥ 127,074	¥ 103,483	¥ 186,802	\$ 1,550
Depreciation and amortization	65,501	65,674	48,466	799
Loss on impairment of fixed assets	9,234	2,782	4,082	113
Gain on sale of investment securities	(2,716)	(1,280)	(2,700)	(33)
Notes and accounts receivable	(12,382)	(43,893)	1,310	(151)
Inventories	(18)	(10,678)	(8,741)	(0)
Notes and accounts payable	27,416	(4,340)	(2,051)	334
Accrued expenses	6,541	7,280	12,032	80
Accrued retirement benefits for employees	712	1,346	1,547	9
Other	(805)	22,600	(15,391)	(11)
Subtotal	220,557	142,974	225,356	2,690
Interest and dividends received	2,374	2,288	4,098	29
Interest paid	—	(220)	—	—
Income taxes paid	(50,255)	(44,403)	(79,323)	(613)
Net cash provided by operating activities	172,676	100,639	150,131	2,106
<b>Investing activities</b>				
Purchases of property, plant and equipment	(47,679)	(33,630)	(39,525)	(581)
Proceeds from sale of property, plant and equipment	11,979	628	1,014	146
Acquisition of subsidiaries' shares	(3,737)	(284,148)	—	(46)
(Increase) decrease in short-term investments	(17,680)	89,598	28,584	(216)
Decrease in investment securities	3,495	5,385	1,940	43
Decrease (increase) in other assets	28,941	(17,083)	(24,776)	353
Other	(1,273)	(3,397)	1,182	(16)
Net cash used in investing activities	(25,954)	(242,647)	(31,581)	(317)
<b>Financing activities</b>				
Redemption of bonds	—	(34,968)	—	—
Purchases of treasury stock	(12)	(30)	(26,997)	(0)
Cash dividends	(57,729)	(57,728)	(56,402)	(704)
Other	(197)	(542)	(2,503)	(3)
Net cash used in financing activities	(57,938)	(93,268)	(85,902)	(707)
<b>Effects of exchange rate changes</b>				
on cash and cash equivalents	(11,870)	(21,178)	(10,555)	(144)
Increase (decrease) in cash and cash equivalents	76,914	(256,454)	22,093	938
Cash and cash equivalents at beginning of year	175,466	431,920	409,827	2,140
Cash and cash equivalents at end of year	¥ 252,380	¥ 175,466	¥ 431,920	\$ 3,078

\* See accompanying notes to consolidated financial statements.



# Notes to Consolidated Financial Statements

Astellas Pharma Inc. and Subsidiaries

## 1. Basis of Presentation

Astellas Pharma Inc. (the "Company") and its domestic subsidiaries maintain their accounting records and prepare their financial statements in accordance with accounting principles generally accepted in Japan, and its foreign subsidiaries maintain their books of account in conformity with International Financial Reporting Standards (IFRS) or accounting principles generally accepted in the United States.

The accompanying consolidated financial statements

have been prepared in accordance with accounting principles generally accepted in Japan, which are different in certain respects as to the application and disclosure requirements of IFRS, and are compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Law.

Certain amounts in the prior years' consolidated financial statements have been reclassified to conform to the current year presentation.

## 2. Summary of Significant Accounting Policies

### (a) Basis of consolidation and accounting for investments in subsidiaries and affiliates

The accompanying consolidated financial statements include the accounts of the Company and all subsidiaries ("Astellas"). Companies over which the Company exercises significant influence in terms of their operating and financial policies are included in the consolidated financial statements on an equity basis. As of March 31, 2012, the numbers of consolidated subsidiaries, and subsidiaries and affiliates accounted for by the equity method were 82 and 2 (82 and 3 in 2011), respectively. All significant intercompany balances and transactions are eliminated in consolidation.

All subsidiaries close their books of account at March 31 for financial reporting purposes.

The excess of cost over underlying fair value of net assets at the date of acquisition is amortized over periods not exceeding 20 years on a straight-line basis except that when the excess amount is immaterial, it is fully charged to income in the year of acquisition. Such amortization is included in selling, general and administrative expenses.

### (b) Foreign currency translation

Receivables and payables denominated in foreign currencies are translated into Japanese yen at the year-end rates, and foreign exchange gains or losses are charged to current income/expense.

Revenue and expense accounts of the foreign subsidiaries are translated into yen using the average exchange rates during the year and, except for the components of net assets excluding minority interests, the balance sheet accounts are translated into yen at the

exchange rates in effect at the balance sheet date. The components of net assets excluding minority interests are translated into yen at their historical exchange rates. Differences arising from the translation are presented as translation adjustments and minority interests in the accompanying consolidated financial statements.

### (c) Cash equivalents

All highly liquid investments with a maturity of three months or less when purchased are considered as cash equivalents.

### (d) Inventories

Inventories of the Company and its domestic subsidiaries are stated principally at the lower of cost or market, cost being determined by the average method. However, inventories of the foreign subsidiaries are stated principally at the lower of cost or market, cost being determined by the first-in, first-out method.

### (e) Depreciation and amortization (excluding lease assets)

Depreciation of property, plant and equipment of the Company and its domestic subsidiaries is calculated principally by the declining-balance method at rates based on the estimated useful lives of the respective assets. However, depreciation of property, plant and equipment of the foreign subsidiaries is calculated principally by the straight-line method. The useful lives of property, plant and equipment are summarized as follows:

Buildings and structures	2 to 60 years
Machinery and equipment	2 to 20 years

Intangible assets are amortized by the straight-line method over their estimated useful lives.

#### (f) Allowance for doubtful receivables

For normal receivables, an allowance for doubtful receivables is provided using the historical experienced default ratio. For specific receivables such as bankruptcy/rehabilitation claims, an allowance for doubtful receivables is provided for the estimated amounts considered to be uncollectible after reviewing individual collectability.

#### (g) Leases

Non-cancelable leases are generally classified and accounted for as either finance or operating leases. Depreciation of finance leases for which ownership of the leased assets is not transferred to the lessee is calculated principally by the straight-line method over their lease period with residual value being zero.

#### (h) Short-term investments and investment securities

Securities other than equity securities issued by the Company's subsidiaries and affiliates are classified into held-to-maturity or other securities. Held-to-maturity securities are carried at amortized cost. Marketable securities classified as other securities are carried at fair value with changes in unrealized gain or loss, net of the applicable income taxes, included directly in net assets. Non-marketable securities classified as other securities are stated at cost. Cost of securities sold is determined by the moving average method.

#### (i) Research and development expenses

Research and development expenses are charged to income as incurred.

#### (j) Income taxes

Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax bases of the assets and liabilities, and are measured using the effective tax rates and laws which will be in effect when the differences are expected to reverse.

#### (k) Retirement benefits

Accrued retirement benefits for employees and prepaid pension cost are recorded mainly at an amount calculated based on the retirement benefit obligation and the fair value of the pension plan assets at the balance sheet date, as adjusted for unrecognized actuarial gain or loss and unrecognized past service cost.

Actuarial gain and loss are being amortized from the following year in which the gain or loss is recognized primarily by the straight-line method over the average remaining years of service of the employees. Past service cost is being amortized as incurred by the straight-line method over the average remaining years of service of the employees.

#### (l) Derivative financial instruments

Astellas utilizes various derivatives transactions in order to manage certain risks arising mainly from adverse fluctuations in foreign currency exchange rates and interest rates. Derivative financial instruments are carried at fair value with any changes in unrealized gain or loss charged or credited to operations, except for those which meet the criteria for deferral hedge accounting under which unrealized gain or loss is deferred as a component of net assets.

#### (m) Reclassification

Certain reclassifications have been made to the prior years' consolidated financial statements to conform to the presentation for the year ended March 31, 2012.

### 3. Accounting Changes

- (a) Effective April 1, 2011, Accounting Standard for Accounting Changes and Error Corrections and Guidance on Accounting Standard for Accounting Changes and Error Corrections have been adopted.
- (b) Effective April 1, 2010, Accounting Standard for Asset Retirement Obligations and Guidance on Accounting Standard for Asset Retirement Obligations have been

adopted. This change negatively impacted operating income by ¥73 million and income before income taxes and minority interests by ¥633 million for the year ended March 31, 2011 compared to the corresponding amounts which would have been recognized under the previous method.

(c) Effective April 1, 2010, the Company and its domestic subsidiaries adopted the following new standards: Accounting Standard for Business Combinations, Accounting Standard for Consolidated Financial Statements, Partial Amendments to Accounting Standard for Research and Development Costs,

Revised Accounting Standard for Business Divestitures, Revised Accounting Standard for Equity Method of Accounting for Investments, and Revised Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures.

#### 4. U.S. Dollar Amounts

U.S. dollar amounts presented are solely for convenience, as a matter of arithmetic computation only, translated from yen at ¥82 = US \$1.00, the approximate rate of exchange on March 31, 2012. The translation should not

be construed as a representation that the yen has been, could have been, or could in the future be, converted into U.S. dollars at the above or any other rates.

#### 5. Inventories

Inventories as of March 31, 2012 and 2011 were as follows:

	(Millions of yen)		(Millions of U.S. dollars)
	2012	2011	2012
Merchandise and finished goods	¥ 82,233	¥ 82,656	\$ 1,003
Work in process	13,473	13,611	164
Raw materials and supplies	16,117	20,615	197
Total	¥ 111,823	¥ 116,882	\$ 1,364

#### 6. Short-Term Borrowings and Long-Term Debt

There were no short-term borrowings or long-term debt except for lease obligations at March 31, 2012 and 2011. Current portion of lease obligations of ¥420 million (\$5 million) at March 31, 2012 and ¥399 million at March 31, 2011 were included in other current liabilities, and lease obligations excluding current portion of ¥800 million

(\$10 million) at March 31, 2012 and ¥755 million at March 31, 2011 were included in other long-term liabilities.

The aggregate annual maturities of lease obligations for 5 years subsequent to March 31, 2012 are summarized as follows:

Year ending March 31,	(Millions of yen)	(Millions of U.S. dollars)
2013	¥ 420	\$ 5
2014	335	4
2015	234	3
2016	153	2
2017 and thereafter	78	1
Total	¥ 1,220	\$ 15

## 7. Net Assets

Changes in net assets for the year ended March 31, 2012 were as follows:

### a. Treasury stock

Types of share	(Thousands of shares)			Number of shares as of March 31, 2012
	Number of shares as of March 31, 2011	Increase	Decrease	
Treasury stock:				
Common stock (Notes 1 and 2)	6,138	4	97	6,045

(Thousands of shares)

Notes: 1. Breakdown of the increase of treasury stock is as follows:

Increase due to purchase of stocks of less than standard unit 4

2. Breakdown of the decrease of treasury stock is as follows:

Decrease due to exercise of stock subscription rights 96

Decrease due to sale of stocks of less than standard unit 1

### b. Dividends

#### 1) Dividends paid during the year ended March 31, 2012

Resolution	Type of shares	Total amounts paid (Millions of yen)	Dividends per share (Yen)	Cut-off date	Total amounts paid (Millions of U.S. dollars)	Dividends per share (U.S. dollars)
Annual shareholders' meeting on June 20, 2011	Common stock	30,019	65	March 31, 2011	366	0.79
Board of Directors on November 1, 2011	Common stock	27,710	60	September 30, 2011	338	0.73

#### 2) Dividends whose cut-off date was in the year ended March 31, 2012 and effective date is in the year ending March 31, 2013

Resolution	Type of shares	Total amounts paid (Millions of yen)	Dividends per share (Yen)	Cut-off date	Total amounts paid (Millions of U.S. dollars)	Dividends per share (U.S. dollars)
Annual shareholders' meeting on June 20, 2012	Common stock	30,025	65	March 31, 2012	366	0.79

### c. Stock subscription rights

In July 2011, the Company issued 1,251 units of stock subscription rights, for which ¥251 million (\$3 million) was recorded as a component of net assets as of March 31, 2012. The stock subscription rights included rights unvested as of March 31, 2012.

## 8. Stock Option Plan

The Company has implemented a stock option plan under which stock subscription rights were granted to Directors, corporate officers and employees of the Company.

The following table summarizes the Company's stock option plan:

		Stock subscription rights granted as a stock option plan		
		Granted on July 1, 2003	Granted on July 1, 2004	Granted on August 31, 2005
Individuals covered by the plan	Directors of the Company	18	4	6
	Corporate officers of the Company	—	16	26
	Employees of the Company	37	36	—
	Total	55	56	32
Type and number of shares to be issued upon the exercise of the stock subscription rights	Common stock	141,000	147,000	104,800
Vesting period		—	—	From July 1, 2005 to June 23, 2006
Exercise period		From July 1, 2005 to June 27, 2013	From July 1, 2006 to June 24, 2014	From September 1, 2005 to June 24, 2025

		Stock subscription rights granted as a stock option plan		
		Granted on February 13, 2007	Granted on August 10, 2007	Granted on September 16, 2008
Individuals covered by the plan	Directors of the Company	4	4	3
	Corporate officers of the Company	27	26	23
	Employees of the Company	—	—	—
	Total	31	30	26
Type and number of shares to be issued upon the exercise of the stock subscription rights	Common stock	75,700	74,000	72,700
Vesting period		From July 1, 2006 to June 26, 2007	From July 1, 2007 to June 25, 2008	From July 1, 2008 to June 23, 2009
Exercise period		From February 14, 2007 to June 27, 2026	From August 11, 2007 to June 26, 2027	From September 17, 2008 to June 24, 2028

		Stock subscription rights granted as a stock option plan		
		Granted on July 8, 2009	Granted on July 8, 2010	Granted on July 5, 2011
Individuals covered by the plan	Directors of the Company	3	3	3
	Corporate officers of the Company	25	26	25
	Employees of the Company	—	—	—
	Total	28	29	28
Type and number of shares to be issued upon the exercise of the stock subscription rights	Common stock	114,900	138,700	125,100
Vesting period		From July 1, 2009 to June 22, 2010	From July 1, 2010 to June 22, 2011	From July 1, 2011 to June 19, 2012
Exercise period		From July 9, 2009 to June 23, 2029	From July 9, 2010 to June 23, 2030	From July 6, 2011 to June 20, 2031



Conditions for the exercise of stock subscription rights are as follows:

- 1) For stock options granted in 2003 and 2004, there are no vesting conditions.
- 2) For stock options granted in 2005 and thereafter, individuals granted stock options are required to meet certain criteria.

The following table summarizes the movements of stock subscription rights:

	Stock subscription rights granted as a stock option plan		
	Granted on July 1, 2003	Granted on July 1, 2004	Granted on August 31, 2005
Unvested stock subscription rights (shares)			
Outstanding as of March 31, 2011	—	—	—
Granted	—	—	—
Forfeited	—	—	—
Vested	—	—	—
<b>Outstanding as of March 31, 2012</b>	<b>—</b>	<b>—</b>	<b>—</b>
Vested stock subscription rights (shares)			
Outstanding as of March 31, 2011	13,800	69,100	76,100
Vested	—	—	—
Exercised	—	—	29,800
Forfeited	—	—	—
<b>Outstanding as of March 31, 2012</b>	<b>13,800</b>	<b>69,100</b>	<b>46,300</b>
Exercise price (Yen)	3,209	3,690	1
Weighted average exercise price (Yen)	—	—	3,090
Weighted average fair value per stock at the granted date (Yen)	—	—	—
Exercise price (U.S. dollars)	39.13	45.00	0.01
Weighted average exercise price (U.S. dollars)	—	—	37.68
Weighted average fair value per stock at the granted date (U.S. dollars)	—	—	—

	Stock subscription rights granted as a stock option plan		
	Granted on February 13, 2007	Granted on August 10, 2007	Granted on September 16, 2008
Unvested stock subscription rights (shares)			
Outstanding as of March 31, 2011	—	—	—
Granted	—	—	—
Forfeited	—	—	—
Vested	—	—	—
<b>Outstanding as of March 31, 2012</b>	—	—	—
Vested stock subscription rights (shares)			
Outstanding as of March 31, 2011	64,600	70,200	72,700
Vested	—	—	—
Exercised	16,600	9,600	13,100
Forfeited	—	—	—
<b>Outstanding as of March 31, 2012</b>	<b>48,000</b>	<b>60,600</b>	<b>59,600</b>
Exercise price (Yen)	1	1	1
Weighted average exercise price (Yen)	3,098	3,055	3,063
Weighted average fair value per stock at the granted date (Yen)	5,009	4,639	3,980
Exercise price (U.S. dollars)	0.01	0.01	0.01
Weighted average exercise price (U.S. dollars)	37.78	37.26	37.35
Weighted average fair value per stock at the granted date (U.S. dollars)	61.09	56.57	48.54

	Stock subscription rights granted as a stock option plan		
	Granted on July 8, 2009	Granted on July 8, 2010	Granted on July 5, 2011
Unvested stock subscription rights (shares)			
Outstanding as of March 31, 2011	—	34,675	—
Granted	—	—	125,100
Forfeited	—	—	—
Vested	—	34,675	93,825
<b>Outstanding as of March 31, 2012</b>	—	—	<b>31,275</b>
Vested stock subscription rights (shares)			
Outstanding as of March 31, 2011	112,100	104,025	—
Vested	—	34,675	93,825
Exercised	12,600	14,800	—
Forfeited	—	—	—
<b>Outstanding as of March 31, 2012</b>	<b>99,500</b>	<b>123,900</b>	<b>93,825</b>
Exercise price (Yen)	1	1	1
Weighted average exercise price (Yen)	3,049	3,049	—
Weighted average fair value per stock at the granted date (Yen)	2,942	2,440	2,677
Exercise price (U.S. dollars)	0.01	0.01	0.01
Weighted average exercise price (U.S. dollars)	37.18	37.18	—
Weighted average fair value per stock at the granted date (U.S. dollars)	35.88	29.76	32.65

Stock option expense was included in selling, general and administrative expenses for the year ended March 31, 2012 and amounted to ¥336 million (\$4 million). The fair value of options granted on July 5, 2011 was estimated using the binominal model with the following weighted average assumptions.

	Stock subscription rights granted on July 5, 2011 as a stock option plan
Expected volatility	29.61%
Expected holding period	4 years
Expected dividend per share	125 yen
Risk-free rate	1.93%

## 9. Income Taxes

Income taxes applicable to the Company and its domestic subsidiaries comprise corporation tax, inhabitants' taxes and enterprise tax which, in the aggregate, resulted in statutory tax rate of approximately 41% for 2012, 2011 and 2010. Income taxes of the foreign subsidiaries are based generally on the tax rates applicable in their coun-

tries of incorporation.

The effective tax rates reflected in the consolidated statements of income for the years ended March 31, 2012, 2011 and 2010 differ from the statutory tax rate for the following reasons:

	2012	2011	2010
Statutory tax rate	41.0%	41.0%	41.0%
Effect of:			
Impact from reorganization in foreign subsidiaries	(8.8)	—	—
Different tax rates applied to income of foreign subsidiaries	(7.9)	(9.1)	(6.3)
Tax credit for research and development expenses	(7.4)	(9.6)	(7.0)
Impact from changes in tax rates	6.9	—	—
Undistributed earnings of foreign subsidiaries	5.6	0.0	0.0
Expenses not deductible for income tax purposes	4.9	5.8	3.3
Amortization of goodwill	3.8	4.4	2.1
Other, net	0.3	2.1	0.4
Effective tax rate	38.4%	34.6%	33.5%

The significant components of the deferred tax assets and liabilities as of March 31, 2012 and 2011 were as follows:

	(Millions of yen)		(Millions of U.S. dollars)
	2012	2011	2012
Deferred tax assets:			
Loss on devaluation of investment securities	¥ 2,159	¥ 2,294	\$ 26
Accrued retirement benefits	6,578	7,887	80
Depreciation and amortization	45,091	53,647	550
Loss on impairment of fixed assets	1,915	3,934	23
Accrued expenses	22,205	23,376	271
Inventories	20,640	21,598	252
Accrued enterprise and other taxes	1,330	1,519	16
Tax loss carryforwards	7,708	26,796	94
Other	56,327	35,958	687
Gross deferred tax assets	163,953	177,009	1,999
Valuation allowance	(12,538)	(10,211)	(152)
Total deferred tax assets	151,415	166,798	1,847
Deferred tax liabilities:			
Unrealized holding gain on securities	5,797	5,111	71
Depreciation and amortization	839	728	10
Intangible assets related to business combination	53,507	75,205	653
Other	16,779	7,904	204
Total deferred tax liabilities	76,922	88,948	938
Net deferred tax assets	¥ 74,493	¥ 77,850	\$ 909

Pursuant to the promulgation on December 2, 2011 of the "Act for Partial Revision of the Income Tax Act, etc. for the Purpose of Creating Taxation System Responding to Changes in Economic and Social Structures" (Act No. 114 of 2011) and the "Act on Special Measures for Securing Financial Resources Necessary to Implement Measures for Reconstruction Following the Great East Japan Earthquake" (Act No. 117 of 2011), effective from the fiscal years beginning on and after April 1, 2012, the corporate tax rate will be reduced and a special reconstruction corporate tax will be imposed.

In accordance with this reform, the effective statutory tax rates, which are used to measure deferred tax assets and deferred tax liabilities, have been changed for temporary differences that are expected to be realized or settled on or after April 1, 2012.

The changes in effective statutory tax rates led to a ¥7,789 million (\$95 million) decrease in deferred tax assets (after deducting deferred tax liabilities), as well as a ¥8,725 million (\$106 million) increase in income taxes-deferred and a ¥936 million (\$11 million) increase in unrealized holding gain on securities.

## 10. Other Comprehensive Income

The following table shows reclassification adjustments for each component of other comprehensive income for the year ended March 31, 2012:

	(Millions of yen)		(Millions of U.S. dollars)	
	2012		2012	
Unrealized holding gain on securities				
Amount arising during the year	¥	3,240	\$	40
Reclassification adjustment		170		2
		¥ 3,410		\$ 42
Translation adjustments				
Amount arising during the year	¥	(26,580)	\$	(324)
Total other comprehensive income before tax effect		(23,170)		(282)
Tax effect		(632)		(8)
Total other comprehensive income		¥ (23,802)		\$ (290)

The following table shows the amount of income tax effect to each component of other comprehensive income for the year ended March 31, 2012:

	(Millions of yen)			(Millions of U.S. dollars)		
	2012			2012		
	Pre-tax amount	Tax effect	Net-of-tax amount	Pre-tax amount	Tax effect	Net-of-tax amount
Unrealized holding gain on securities	¥ 3,410	¥ (632)	¥ 2,778	\$ 42	\$ (8)	\$ 34
Translation adjustments	(26,580)	—	(26,580)	(324)	—	(324)
Total other comprehensive income	¥ (23,170)	¥ (632)	¥ (23,802)	\$ (282)	\$ (8)	\$ (290)

## 11. Retirement Benefit Plans

The Company and its domestic subsidiaries have defined benefit plans, corporate pension fund plans and lump-sum payment plans, and defined contribution plans.

In addition, certain employees may be entitled to additional special retirement benefits upon early termination of employment based on the conditions under which termination occurs. Such benefits are not subject to the actuarial calculation required by the accounting standard

for retirement benefits.

Certain foreign subsidiaries have defined benefit plans and defined contribution plans.

The following table sets forth the funded and accrued status of the plans, and the amounts recognized in the consolidated balance sheets as of March 31, 2012 and 2011 for the defined benefit plans:

	(Millions of yen)		(Millions of U.S. dollars)
	2012	2011	2012
Retirement benefit obligation	¥ (144,363)	¥ (146,105)	\$ (1,761)
Plan assets at fair value	119,294	117,570	1,455
Unfunded retirement benefit obligation	(25,069)	(28,535)	(306)
Unrecognized actuarial gain/loss	15,557	20,367	190
Unrecognized past service cost	(6,408)	(7,607)	(78)
Net retirement benefit obligation	(15,920)	(15,775)	(194)
Prepaid pension cost	1,059	1,460	13
Accrued retirement benefits	¥ (16,979)	¥ (17,235)	\$ (207)



The components of retirement benefit expenses for the years ended March 31, 2012, 2011 and 2010 are outlined as follows:

	(Millions of yen)			(Millions of U.S. dollars)
	2012	2011	2010	2012
Service cost	¥ 4,545	¥ 4,539	¥ 4,399	\$ 55
Interest cost	3,829	3,739	3,984	47
Expected return on plan assets	(3,556)	(4,060)	(3,778)	(43)
Amortization of actuarial gain/loss	3,775	3,074	4,101	46
Amortization of past service cost	(868)	(872)	(869)	(11)
Other	6,739	5,897	5,792	82
<b>Total</b>	<b>¥ 14,464</b>	<b>¥ 12,317</b>	<b>¥ 13,629</b>	<b>\$ 176</b>

The assumptions used in accounting for the above plans were as follows:

	2012	2011
Discount rates	2.0% - 5.7%	2.0% - 5.4%
Expected rates of return on plan assets	2.5% - 5.0%	3.0% - 4.4%
Amortization period of actuarial gain/loss	8 - 19 years	8 - 19 years
Amortization period of past service cost	8 - 19 years	8 - 19 years

## 12. Research and Development Expenses

Research and development expenses, all of which were included in selling, general and administrative expenses for the years ended March 31, 2012, 2011 and 2010, totaled ¥189,840 million (\$2,315 million), ¥217,326 million and ¥195,570 million, respectively.

## 13. Leases

Future minimum lease payments subsequent to March 31, 2012 on non-cancelable operating lease transactions are summarized as follows:

Year ending March 31,	(Millions of yen)	(Millions of U.S. dollars)
2013	¥ 5,790	\$ 71
2014 and thereafter	14,575	178
<b>Total</b>	<b>¥ 20,365</b>	<b>\$ 249</b>

## 14. Contingent Liabilities

Contingent liabilities of Astellas as of March 31, 2012 and 2011 were as follows:

	(Millions of yen)		(Millions of U.S. dollars)
	2012	2011	2012
Contingent liabilities as guarantors of indebtedness of the Company's employees, affiliates and business partners	¥ 2,509	¥ 2,165	\$ 31

Astellas may be involved in various lawsuits during the ordinary course of business. The management believes the lawsuits in which Astellas is currently involved would not have material adverse impacts on the financial conditions and/or operating results.

## 15. Amounts per Share

	(Yen)			(U.S. dollars)
	2012	2011	2010	2012
Net income:				
Basic	¥ 169.38	¥ 146.49	¥ 261.84	\$ 2.07
Diluted	169.17	146.33	261.62	2.06
Cash dividends	125.00	125.00	125.00	1.52
Net assets	2,200.64	2,207.70	2,278.77	26.84

Basic net income per share is computed based on net income available for distribution to shareholders of common stock and the weighted-average number of shares of common stock outstanding during the year.

Diluted net income per share is computed based on net income available for distribution to the shareholders and the weighted-average number of shares of common stock outstanding during each year after giving effect to the dilutive potential of shares of common stock to be issued upon the exercise of stock subscription rights.

There were no outstanding issues of convertible bonds during the years ended March 31, 2012 and 2011.

Cash dividends per share represent the annual cash dividends declared as applicable to the respective years including the interim cash dividends paid.

Net assets per share are computed based on the amount of net assets at the year end excluding stock subscription rights and minority interests, and the number of common stock outstanding at the year end.

## 16. Supplementary Cash Flow Information

Astellas acquired 100% of shares of OSI Pharmaceuticals, Inc. ("OSI") during the year ended March 31, 2011. The following is reconciling the assets acquired and liabilities assumed as of the acquisition as well as the acquisition cost to net cash used in the acquisition:

	(Millions of yen)
Current assets	¥ 44,827
Long-term assets	288,616
Goodwill	92,106
Current liabilities	(43,486)
Long-term liabilities	(87,382)
Acquisition cost of stock of OSI	294,681
Cash and cash equivalents of OSI	(19,193)
Effect of exchange rate fluctuation	8,514
Net cash used in the acquisition of OSI	¥ 284,002

## 17. Financial Instruments

### Basic policy to manage financial instruments and related risks

Astellas has set its financial investment policy, which aims to preserve financial assets for strategic investment opportunities, by putting priority on safety, and mitigating opportunity loss while keeping sufficient liquidity. In the case that financing is necessary, the most appropriate measure will be chosen among the various options

including bank loans, bond issuance or stock offering, taking into account business circumstances and financial market conditions. Derivative transactions are utilized solely for the purpose of hedging exposure to adverse fluctuation primarily in foreign currency exchange rates or interest rates, but Astellas does not enter into such transactions for speculative or trading purposes.

With regard to bank deposits, Astellas enters into

transactions only with financial institutions with high credit ratings. Although accounts receivable are exposed to credit risk in relation to customers, the risk is managed by monitoring business conditions, creditworthiness and outstanding balances by individual customer. In addition, monthly collections of accounts receivable are monitored. With regard to listed stocks that Astellas has invested in, Astellas manages the price volatility risk by monthly monitoring of market prices of those stocks. Derivative transactions are executed based on internal

rules and the balance of derivative transactions is monitored monthly. To minimize credit risk in the event of nonperformance by the counterparties, Astellas enters into derivative transactions only with financial institutions with high credit ratings.

#### Fair value of financial instruments

The following table summarizes carrying values and fair values of financial instruments at March 31, 2012 and 2011.

	(Millions of yen)			(Millions of U.S. dollars)		
	2012	2012		2012	2012	
	Carrying value	Fair value	Difference	Carrying value	Fair value	Difference
Cash and cash equivalents	¥ 252,380	¥ 252,380	¥ —	\$ 3,078	\$ 3,078	\$ —
Notes and accounts receivable	286,798	286,798	—	3,497	3,497	—
Short-term investments and Investment securities:						
Other securities	93,725	93,725	—	1,143	1,143	—
Notes and accounts payable	(190,796)	(190,796)	—	(2,327)	(2,327)	—
Derivative transactions	¥ —	¥ —	¥ —	\$ —	\$ —	\$ —

	(Millions of yen)		
	2011	2011	
	Carrying value	Fair value	Difference
Cash and cash equivalents	¥ 175,466	¥ 175,466	¥ —
Notes and accounts receivable	279,112	279,112	—
Short-term investments and Investment securities:			
Other securities	46,636	46,636	—
Notes and accounts payable	(139,233)	(139,233)	—
Derivative transactions	¥ 16	¥ 16	¥ —

Numbers with parenthesis represent liabilities in the above table.

The above table does not include financial instruments for which it is extremely difficult to determine fair value because no quoted market price nor future cash flow is available.

The following methods and assumptions were used in estimating fair value disclosures for financial instruments:

*Cash and cash equivalents, notes and accounts receivable, notes and accounts payable:* The carrying amount approximates fair value because of the short maturity of the instruments.

*Short-term investments and investment securities:* The fair value of stocks is based on quoted market prices. The fair value of debt securities is based on either quoted market prices or prices provided by the financial institutions making markets in these securities.

## Securities

Information regarding marketable securities classified as other securities as of March 31, 2012 and 2011 is summarized as follows:

### Other securities

	(Millions of yen)			(Millions of U.S. dollars)		
	2012	2012	2012	2012	2012	2012
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:						
Stock	¥ 23,159	¥ 44,602	¥ 21,443	\$ 282	\$ 544	\$ 262
Debt securities	27,497	27,497	0	335	335	0
Other	2,000	2,077	77	24	25	1
Subtotal	52,656	74,176	21,520	641	904	263
Securities whose acquisition cost exceeds their carrying value:						
Stock	323	292	(31)	4	4	(0)
Debt securities	53,795	53,795	(0)	656	656	(0)
Other	6,863	6,854	(9)	84	84	(0)
Subtotal	60,981	60,941	(40)	744	744	(0)
Total	¥ 113,637	¥ 135,117	¥ 21,480	\$ 1,385	\$ 1,648	\$ 263

	(Millions of yen)		
	2011	2011	2011
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Stock	¥ 24,009	¥ 42,041	¥ 18,032
Debt securities	684	695	11
Other	2,000	2,094	94
Subtotal	26,693	44,830	18,137
Securities whose acquisition cost exceeds their carrying value:			
Stock	242	228	(14)
Debt securities	9,664	9,663	(1)
Other	24,497	24,487	(10)
Subtotal	34,403	34,378	(25)
Total	¥ 61,096	¥ 79,208	¥ 18,112

Carrying values of other securities with a maturity of three months or less when purchased, which were reclassified to "Cash and cash equivalents" in the consolidated balance sheets at March 31, 2012 and 2011, amounted to ¥41,392 million (\$505 million) and ¥32,572

million, respectively.

Proceeds from sales of securities classified as other securities and the related aggregate gains and losses for the years ended March 31, 2012, 2011 and 2010 are summarized as follows:

	(Millions of yen)			(Millions of U.S. dollars)		
	2012			2012		
	Proceeds	Aggregate gain	Aggregate loss	Proceeds	Aggregate gain	Aggregate loss
Stock	¥ 913	¥ 369	¥ 109	\$ 11	\$ 5	\$ 1
Debt securities	1,345	9	5	16	0	0
Other	281,067	2,344	—	3,428	28	—
Total	¥ 283,325	¥ 2,722	¥ 114	\$ 3,455	\$ 33	\$ 1

	(Millions of yen)					
	2011			2010		
	Proceeds	Aggregate gain	Aggregate loss	Proceeds	Aggregate gain	Aggregate loss
Stock	¥ 2,793	¥ 1,280	¥ 325	¥ 3,705	¥ 2,700	¥ 39
Debt securities	82,395	105	108	4,613	—	3
Other	275,110	0	—	53,558	—	—
Total	¥ 360,298	¥ 1,385	¥ 433	¥ 61,876	¥ 2,700	¥ 42

The redemption schedule for securities with maturities as of March 31, 2012 is summarized as follows:

	(Millions of yen)			
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Government/local bonds	¥ 49,300	¥ —	¥ —	¥ —
Corporate bonds	—	—	—	—
Other debt securities	32,000	—	—	—
Other	6,821	—	—	—
Total	¥ 88,121	¥ —	¥ —	¥ —

	(Millions of U.S. dollars)			
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Government/local bonds	\$ 601	\$ —	\$ —	\$ —
Corporate bonds	—	—	—	—
Other debt securities	390	—	—	—
Other	84	—	—	—
Total	\$ 1,075	\$ —	\$ —	\$ —

#### Securities without determinable fair value

	(Millions of yen)		(Millions of U.S. dollars)
	2012	2011	2012
	Carrying value	Carrying value	Carrying value
Non marketable stocks	¥ 13,512	¥ 14,889	\$ 165
Total	¥ 13,512	¥ 14,889	\$ 165



### Impairment loss on securities

Impairment loss on securities in the year ended March 31, 2012 and 2010 amounted to ¥792 million (\$10 million) and ¥675 million, respectively.

### Derivative Transactions

There were no outstanding derivative transactions as of March 31, 2012.

The notional amounts and the estimated fair value of derivatives outstanding as of March 31, 2011 are summarized as follows:

	(Millions of yen)		
	2011		
	Notional amount	Fair value	Unrealized gain
Forward foreign exchange contracts			
Buy:			
U.S. dollars	¥ 810	¥ 16	¥ 16
<b>Total</b>	<b>¥ 810</b>	<b>¥ 16</b>	<b>¥ 16</b>

The notional amounts of the derivatives do not necessarily represent the amounts exchanged by the parties and, therefore, are not a direct measure of risk exposure in connection with derivatives.

## 18. Acquisitions

### OSI Pharmaceuticals, Inc.

On June 8, 2010, Astellas acquired 100% shares of OSI, a US-based biotechnology company focusing on oncology and diabetes/obesity fields. Astellas has set goals of becoming a "Global Category Leader" ("GCL") in its "VISION 2015" and has defined the oncology field as one

of its prioritized research areas. This acquisition provides a top-tier oncology business in the U.S., including an anti-cancer blockbuster product, Tarceva, and accelerates Astellas' initiatives to quickly establish its oncology platform to realize a GCL position in the therapeutic field.

The acquisition cost and its breakdown are as follows:

	(Millions of U.S. dollars)
Cost for the acquisition by tender offer	\$ 3,525
Direct costs for the acquisition	19
<b>Total acquisition cost</b>	<b>\$ 3,544</b>

The total purchase price of \$3,544 million was paid in cash.

The breakdown of assets acquired and liabilities assumed as of the date of the business combination is as follows:

	(Millions of U.S. dollars)
Current assets	\$ 539
Non-current assets	4,579
<b>Total assets</b>	<b>\$ 5,118</b>
Current liabilities	\$ 523
Non-current liabilities	1,051
<b>Total liabilities</b>	<b>\$ 1,574</b>

As a result of purchase price allocation, the acquisition cost has been allocated to intangible assets except goodwill by \$2,815 million, which are composed of (1) already launched or approved products amounting to \$2,024 million and (2) in-process research and development amounting to \$791 million. Amortization periods for each of those intangible assets have been individually determined based on the useful life of each asset.

The excess of cost over underlying net assets at fair value at the date of the acquisition was recognized as goodwill in the amount of \$1,108 million. The goodwill is amortized by the straight-line method over twenty years.

The consolidated statements of income for the year

ended March 31, 2011 includes the results of operations of OSI from July 1, 2010. If the business combination had been completed at the beginning of the fiscal year, the effect on the 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 from April 1 to June 30, 2010 and estimated amortization of goodwill and intangibles for the relevant period and have not been audited by our independent Auditor.

(note) U.S. dollar amount in this note 18 are actual figures incurred in this transaction.

## 19. Segment Information

### For the years ended March 31, 2012 and 2011

Astellas operates business in single business segment of "Pharmaceutical."

#### Segment-related information

##### Sales by products to third parties

	(Millions of yen)		(Millions of U.S. dollars)
	Year ended March 31, 2012	Year ended March 31, 2011	Year ended March 31, 2012
Prograf	¥ 154,877	¥ 162,651	\$ 1,889
Vesicare	97,201	86,703	1,185
Other	717,309	704,594	8,748
Total	¥ 969,387	¥ 953,948	\$ 11,822

#### Information by region

##### Net sales

(Millions of yen)					
Year ended March 31, 2012					
Japan	Americas	U.S. (included in Americas)	Europe	Asia and other	Total
¥ 547,796	¥ 182,660	¥ 165,006	¥ 187,370	¥ 51,561	¥ 969,387
(Millions of U.S. dollars)					
\$ 6,680	\$ 2,228	\$ 2,012	\$ 2,285	\$ 629	\$ 11,822

(Millions of yen)					
Year ended March 31, 2011					
Japan	Americas	U.S. (included in Americas)	Europe	Asia and other	Total
¥ 531,416	¥ 189,471	¥ 171,778	¥ 181,984	¥ 51,077	¥ 953,948

## Property, plant and equipment

(Millions of yen)

Year ended March 31, 2012					
Japan	Americas	U.S. (included in Americas)	Europe	Asia and other	Total
¥ 140,720	¥ 31,669	¥ 31,329	¥ 24,886	¥ 1,885	¥ 199,160

(Millions of U.S. dollars)

\$ 1,717	\$ 386	\$ 382	\$ 303	\$ 23	\$ 2,429
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(Millions of yen)

Year ended March 31, 2011

Japan	Americas	U.S. (included in Americas)	Europe	Asia and other	Total
¥ 144,337	¥ 20,869	¥ 20,697	¥ 23,158	¥ 1,796	¥ 190,160

## Information by major customer

(Millions of yen)

(Millions of U.S. dollars)

	Year ended March 31, 2012	Year ended March 31, 2011	Year ended March 31, 2012
	¥ 119,635	¥ 114,039	\$ 1,459
Suzuken Co., Ltd	117,084	114,339	1,428
MEDICEO CORPORATION	110,758	106,422	1,351
Alfresa Corporation			

## For the year ended March 31, 2010

## Business segments

Astellas' businesses are segmented into "Pharmaceutical" and "Other" based on their similarity in terms of distribution methods, the nature and type of products sold, and manufacturing methods. As net sales, operating income and total assets in the "Pharmaceutical" segment constituted more than 90% of the consolidated totals, the disclosure of business segment information has been omitted.

## Geographical areas

Geographical areas, which include the results of the operation attributed by the location of the Company and its subsidiaries, for the year ended March 31, 2010 are summarized as follows:

(Millions of yen)

Year ended March 31, 2010

	Japan	North America	Europe	Asia	Total	Eliminations	Consolidated
Sales to third parties	¥ 529,243	¥ 179,807	¥ 235,861	¥ 29,967	¥ 974,878	¥ —	¥ 974,878
Intergroup sales and transfers	106,851	67,496	66,193	28	240,568	(240,568)	—
Total sales	636,094	247,303	302,054	29,995	1,215,446	(240,568)	974,878
Operating expenses	521,563	232,484	258,121	27,694	1,039,862	(251,391)	788,471
Operating income	¥ 114,531	¥ 14,819	¥ 43,933	¥ 2,301	¥ 175,584	¥ 10,823	¥ 186,407
Total assets	¥ 877,072	¥ 202,982	¥ 303,872	¥ 18,873	¥ 1,402,799	¥ (38,622)	¥ 1,364,177

**Overseas sales**

Overseas sales, which include sales attributed by the location of customers, for the year ended March 31, 2010 are summarized as follows:

	(Millions of yen)				Total
	Year ended March 31, 2010				
	North America	Europe	Asia	Other	
Overseas sales	¥ 224,865	¥ 181,249	¥ 40,470	¥ 14,128	¥ 460,712
Consolidated net sales					974,878
Overseas sales as a percentage of consolidated net sales	23.1%	18.6%	4.2%	1.4%	47.3%

**20. Impairment Loss**

Astellas bases the grouping for assessing impairment losses on the business segments. However, Astellas determines whether an asset is impaired on an individual asset basis when the asset is deemed idle or if it is scheduled to be disposed of. Loss on impairment of fixed assets, which was recognized by reducing the book value of such assets to their respective realized value, for the years ended March 31, 2012, 2011 and 2010 amounted to ¥9,234 million (\$113 million), ¥2,782 million and ¥4,082 million, respectively. Loss on impairment of fixed assets for the year ended March 31, 2012 mainly consists of

losses on buildings and structures in the aggregate amount of ¥2,240 million (\$27 million) and losses on patents in the aggregate amount of ¥6,724 million (\$82 million). Loss on impairment of fixed assets for the year ended March 31, 2011 mainly consists of losses on equipment in the aggregate amount of ¥843 million and losses on intangible assets in the aggregate amount of ¥1,105 million. Loss on impairment of fixed assets for the year ended March 31, 2010 mainly consists of losses on buildings and structures in the aggregate amount of ¥3,602 million.

# Independent Auditor's Report

The Board of Directors  
Astellas Pharma Inc.

We have audited the accompanying consolidated financial statements of Astellas Pharma Inc. and its consolidated subsidiaries, which comprise the consolidated balance sheets as at March 31, 2012, and the consolidated statements of income, comprehensive income, changes in net assets, and cash flows for the year then ended and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

## *Management's Responsibility for the Consolidated Financial Statements*

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for designing and operating such internal control as management determines is necessary to enable the preparation and fair presentation of the consolidated financial statements that are free from material misstatement, whether due to fraud or error.

## *Auditor's Responsibility*

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. The purpose of an audit of the consolidated financial statements is not to express an opinion on the effectiveness of the entity's internal control, but in making these risk assessments the auditor considers internal controls relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

## *Opinion*

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Astellas Pharma Inc. and its consolidated subsidiaries as at March 31, 2012, and their consolidated financial performance and cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

## *Convenience Translation*

We have reviewed the translation of these consolidated financial statements into U.S. dollars, presented for the convenience of readers, and, in our opinion, the accompanying consolidated financial statements have been properly translated on the basis described in Note 4.

*Ernst & Young ShinNihon LLC*

June 20, 2012  
Tokyo, Japan



# Principal Subsidiaries and Affiliates (as of August 2012)

Astellas is a group of companies engaged solely in the pharmaceutical business. The group consists of 83 companies, which include Astellas Pharma Inc., 81 consolidated subsidiaries, and one affiliate accounted for by the equity method. Major group companies are listed as follows.

## Americas

### Holding company in North America

Astellas US Holding, Inc.

1 Astellas Way Northbrook, IL 60062, U.S.A.  
TEL: +1-800-695-4321

### Headquarters in North America

Astellas US LLC

1 Astellas Way Northbrook, IL 60062, U.S.A.  
TEL: +1-800-695-4321

### R&D bases

Astellas Pharma Global Development, Inc.

Agensys, Inc.

Astellas Research Institute of America LLC

Urogenix, Inc.

OSI Pharmaceuticals LLC

Perseid Therapeutics LLC

### Manufacturing bases

Astellas Pharma Technologies, Inc.

Astellas US Technologies, Inc.

### Sales bases

Astellas Pharma US, Inc.

Astellas Pharma Canada, Inc. (Canada)

Astellas Farma Brasil Importação e Distribuição de Medicamentos Ltda. (Brazil)

### Other

Astellas Venture Management LLC

Astellas Scientific and Medical Affairs, Inc.

Note: All subsidiaries for which no country has been indicated are located in the United States

## Europe

### Holding company in Europe

Astellas B.V.

Elisabethhof 19, P.O. Box 108, 2353 EW, Leiderdorp,  
The Netherlands  
TEL: +31-715-455-500

### European headquarters

Astellas Pharma Europe Ltd.

1st Floor Lovett House, Lovett Road, Staines, Middlesex,  
TW18 3AZ, U.K.  
TEL: +44-1784-419-400

(After September 24, 2012)

2000 Hillswood Drive, Chertsey, KT16 0RS, U.K.

TEL: +44-203-379-8000

### R&D and manufacturing bases

Astellas Pharma Europe B.V.

(R&D and Manufacturing, Netherlands)

Astellas Ireland Co., Limited

(Development and Manufacturing, Ireland)

### Sales bases

Astellas Pharma Ges. mbH (Austria)

Astellas Pharma B.V. (Branch) (Belgium)

Astellas Pharma s.r.o (Czech Republic)

Astellas Pharma A/S (Denmark)

Astellas Pharma S.A.S (France)

Astellas Pharma GmbH (Germany)

Astellas Pharmaceuticals AEBE (Greece)

Astellas Pharma Kft. (Hungary)

Astellas Pharma Co., Limited (Ireland)

Astellas Pharma S.p.A. (Italy)

Astellas Pharma B.V. (Netherlands)

Astellas Pharma International B.V.

(Export, Netherlands)

Astellas Pharma Sp.zo.o. (Poland)

Astellas Farma Limitada (Portugal)

ZAO Astellas Pharma (Russia)

Astellas Pharma d.o.o. (Slovenia)

Astellas Pharma (Pty) Limited (South Africa)

Astellas Pharma S.A. (Spain)

Astellas Pharma A.G. (Switzerland)

Astellas Pharma ilaç Ticaret ve Sanayi A.Ş. (Turkey)

Astellas Pharma Ltd. (United Kingdom)

## Asia & Oceania

### Sales bases, other

**Astellas Pharma China, Inc.**

(Sales and Manufacturing, China)

**Astellas Pharma Hong Kong Co., Ltd.** (Hong Kong)

**Astellas Pharma Taiwan, Inc.** (Taiwan)

**Astellas Pharma Korea, Inc.** (Korea)

**Astellas Pharma Philippines, Inc.** (Philippines)

**Astellas Pharma (Thailand) Co., Ltd.** (Thailand)

**P.T. Astellas Pharma Indonesia** (Indonesia)

**Astellas Pharma India Private Limited** (India)

**Astellas Pharma Australia Pty Ltd** (Australia)

## Japan

### Manufacturing base

**Astellas Pharma Tech Co., Ltd.**

### R&D bases

**Astellas Research Technologies Co., Ltd.**

**Astellas Analytical Science Laboratories, Inc.**

### Other

**Astellas Business Service Co., Ltd.**

**Astellas Learning Institute Co., Ltd.**

**Astellas Marketing and Sales Support Co., Ltd.**

**Lotus Estate Co., Ltd.**

### Scope of environmental information report

Company name	Facility	Location	Function
Astellas Pharma Inc.	Nihonbashi Office	Chuo-ku, Tokyo	Headquarters
	Hasune Office	Itabashi-ku, Tokyo	Development
	Takahagi Chemistry & Technology Development Center	Takahagi, Ibaraki	Research
	Tsukuba Research Center	Tsukuba, Ibaraki	
	Tsukuba Biotechnology Research Center	Tsukuba, Ibaraki	
	Yaizu Pharmaceutical Research Center	Yaizu, Shizuoka	
	Kiyosu Research Office	Kiyosu, Aichi	
	Kashima R&D Center	Yodogawa-ku, Osaka	Sales & marketing
	Branches/Sales Offices	18 branches, 159 sales offices	
Astellas Pharma Tech Co., Ltd.	Nishine Plant	Hachimantai, Iwate	Manufacturing
	Takahagi Technology Center	Takahagi, Ibaraki	
	Yaizu Technology Center	Yaizu, Shizuoka	
	Fuji Plant	Fuji, Shizuoka	
	Toyama Technology Center	Toyama, Toyama	
Astellas Pharma Technologies Inc.	Norman Plant	U.S.A.	
Astellas Ireland Co., Limited	Dublin Plant	Ireland	
	Kerry Plant		
Astellas Pharma Europe B.V.	Meppel Plant	Netherlands	
Astellas Pharma China, Inc.	Shenyang Plant	China	

Note: Operating sites throughout this report are in principle identified according to the name of each facility. In instances where there are multiple facilities on the same site, the following names may be applied.

Takahagi Facilities (Takahagi Chemistry & Technology Development Center and Takahagi Technology Center)

Yaizu Facilities (Yaizu Pharmaceutical Research Center and Yaizu Technology Center)

## Company Name

Astellas Pharma Inc.

## Head Office

2-3-11, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan

TEL: +81-3-3244-3000

<http://www.astellas.com/en/>

## Capital

¥103 billion

## Representative

Yoshihiko Hatanaka

Representative Director, President and CEO

## Founded

1923

## Professional Institution Affiliation

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

\*Masafumi Nogimori (Representative Director and Chairman) was appointed

Vice President of the IFPMA in November 2010.

## Common Stock

Authorized: 2,000,000,000

Issued: 467,964,635 (including 6,044,560 treasury stock)

Number of shareholders: 56,167

## Stock Exchange Listing

Tokyo, Osaka

(Ticker Code: 4503)

## Independent Auditors

Ernst & Young ShinNihon LLC

Hibiya Kokusai Building, 2-2-3 Uchisaiwai-cho, Chiyoda-ku, Tokyo 100-0011, Japan

## Transfer Agent for Common Stock in Japan

Sumitomo Mitsui Trust Bank, Limited

1-4-1, Marunouchi, Chiyoda-ku, Tokyo 100-8233, Japan

### \*Please direct inquiries concerning Annual Report 2012 to:

Astellas Pharma Inc.

Corporate Communications

TEL: +81-3-3244-3202

FAX: +81-3-5201-7473

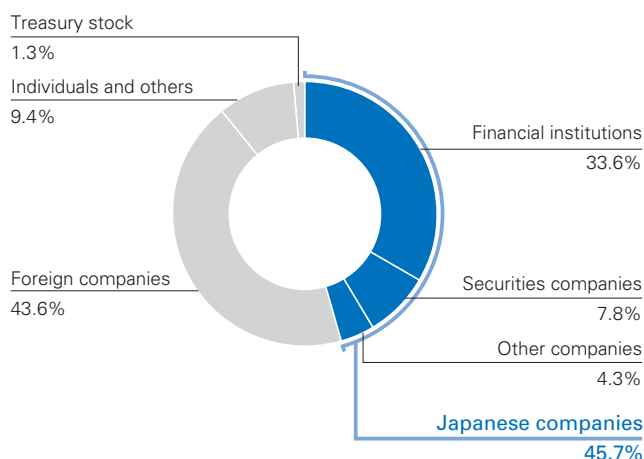
Issued in September 2012 (Our next annual report is scheduled to be issued in August 2013)

## Major Shareholders

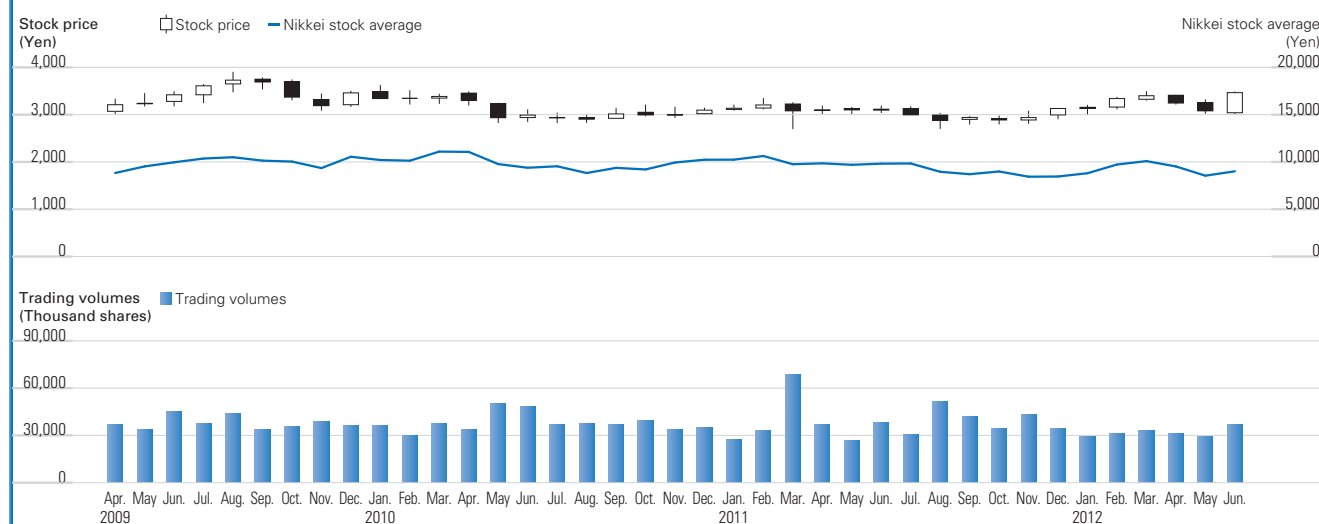
Name	Shares owned (Thousand shares)	Percentage of total common shares outstanding (%)
Japan Trustee Services Bank, Ltd. (trust account)	27,519	5.88
State Street Bank and Trust Company	26,037	5.56
The Master Trust Bank of Japan, Ltd. (trust account)	25,966	5.54
Nippon Life Insurance Company	16,121	3.44
JP Morgan Chase Bank 385147	14,365	3.06
SSBT OD05 OMNIBUS ACCOUNT - TREATY CLIENTS	10,895	2.32
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	9,881	2.11
State Street Bank and Trust Company 505225	8,507	1.81
Japan Trustee Services Bank, Ltd. (trust account 9)	8,101	1.73
Barclays Capital Japan Limited	7,460	1.59

Note: Shares owned are rounded down to the nearest thousand shares, while the percentage of total common shares outstanding is rounded down to two decimal places.

## Breakdown of Shareholders



## Stock Prices and Trading Volumes on the Tokyo Stock Exchange (highest/lowest in the month; yen)





**Astellas Pharma Inc.**  
2-3-11, Nihonbashi-Honcho,  
Chuo-ku, Tokyo 103-8411, Japan  
<http://www.astellas.com/en/>



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