



# ANNUAL REPORT 2013

For the Year Ended March 31, 2013

Changing tomorrow





Making medicine alone  
Does not make medicine medicine.  
It should be used correctly,  
it should be used on right patients.  
Once the proper information is imparted,  
it becomes real medicine.  
Bringing that information to the doctor,  
Breathing life into the medicine,  
That's the work of an MR.

\*MR: Medical Representative



To make the world's first discovery.  
To save people of the world from diseases.  
Researchers hold on to two dreams.  
One resonates with the scientist,  
The other with the human being.  
Researchers continue gazing through test tubes,  
Waiting for the day those dreams turn real.

## Changing tomorrow



Today again,  
the newspaper reports about the disease.  
People battling with diseases, alone,  
where nobody can see.  
Stories about a family helping and dealing  
with an ill loved one.  
For those awaiting a new drug.  
And for those simply hoping.  
Researchers steel their resolve.  
We will create a drug that is yet to exist.



A new drug turns an incurable disease  
into a curable one.  
But this world is  
still full of illnesses with no cure.  
New diseases are being identified.  
A fierce race between diseases and cures.  
A race we cannot afford to lose.



I thought I simply had poor bladder control.  
But that stopped me from traveling.  
And all I really wanted was  
to create memories with my family.  
... There is a drug created for that person.  
A new drug.  
It has brought happy smiles to many faces.  
Shining moments for this medicine.



One day faster.  
Once the medicine is out there,  
Many people across the globe will benefit.  
To save that one day,  
Astellas development never sleeps.  
Today, again, the global development team  
Unites as one  
To battle against time  
And deliver a new drug.



Even the most effective drug  
Can't cure an illness  
With just one dose.  
When that drug is perfected  
And manufactured to meet  
The unmet needs of patients around the world,  
That one drug becomes the world's healer.



The anxieties of a patient awaiting organ transplant.  
Will the transplant succeed?  
Will my body reject the new organ?  
One small drug came along, erased those fears.  
Immunosuppressant.  
This is a story about a drug that gave hope  
to everyone awaiting an organ transplant.

# Editorial Policy

## Editorial Policy

---

With the aim of deepening stakeholders' understanding of our business activities and CSR-based management, which is the base for those activities, we have integrated our Annual Report with our CSR report, and now publish this report as an integrated Annual Report.

The information contained in this Annual Report 2013 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 basis of this report is to provide an overview of the activities of Astellas Pharma Inc. and its consolidated subsidiaries worldwide in fiscal 2012, which covers the period from April 1, 2012 to March 31, 2013. The figures indicated in the fiscal 2012 status report for the field of "Environment," however, present the results for fiscal year 2012 (April 1, 2012 to March 31, 2013) in Japan and the calendar year 2012 (January 1, 2012 to December 31, 2012) 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. This report also includes the latest information available at the time of publishing.

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

## Guidelines

---

### - ISO26000

Our challenges were sorted out and chosen for each field of Astellas' CSR-based management with reference to the core subjects of ISO26000.

### - GRI (Global Reporting Initiative)

The Annual Report 2013 was prepared in compliance with the Sustainability Reporting Guideline (Version 3.1) published by the Global Reporting Initiatives (GRI).

Astellas believes that its Annual Report 2013 satisfies the GRI Application Level B for reporting standards.

A GRI Contents index is posted on the Company's website:

(<http://www.astellas.com/en/csr/>)

### - The Environmental Reporting Guidelines

The Annual Report 2013 was also prepared with reference to the Environmental Reporting Guidelines (Fiscal Year 2012 Version) issued by Japan's Ministry of the Environment.

## SRI Index

---

Astellas is included in the following global "social responsible investment (SRI) indexes."



### 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 Overview	012 Fiscal 2012 Topics	In Brief
		007 CSR-based Management	014 Interview with the CEO	
		010 Financial and Non-Financial Highlights	022 United Nations Global Compact Initiatives	
023	<b>Economy (Business Activities)</b>	024 Special Feature: New Growth Drivers	036 Review of Global Operations	Economy
		028 Research & Development (including Pipeline)	044 CSR Initiatives in Business Processes	
		033 Review of Operations by Therapeutic Area	049 Initiatives to Improve Access to Health	
051	<b>Employees</b>	052 Basic Policy	054 Creating a Motivating Workplace	Employees
		053 Human Resource Strategy and People Development	056 Respect for Human Rights	
			056 Five Messages for the Astellas Way	
057	<b>Society</b>	058 Basic Policy	061 Enrich Healthcare Systems	Society
		059 Enrich the Lives of Patients	063 Link with Society	
065	<b>Environment</b>	066 Basic Policy	070 Initiatives for Sustainable Biodiversity	Environment
		067 Environmental Action Plan	071 Initiatives for Resource Recycling	
		068 Measures to Combat Global Warming	072 Environmental Accounting	
073	<b>Compliance</b>	074 Basic Policy		Compliance
		075 Compliance		
	<b>Corporate Governance</b>	078 Corporate Governance		Corporate Governance
		082 Dialogue (between Representative Director and Chairman, and Outside Director)		
		086 Directors and Corporate Auditors		
		088 Global Management Committee Members		
		090 CSR Communication	136 Principal Subsidiaries and Affiliates	Financial Section
		091 Financial Section	138 Corporate Data/Investor Information	

# Astellas Overview

## 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 in terms of prescription drugs.



\* According to a survey by Cegedim Strategic Data K.K.

## Our Strengths

1

### Focus on New Drug Business

Global competitiveness in transplantation and urology

2

### Astellas' Own Distribution Channel in About 50 Countries

Covering emerging countries including BRICs

3

### Robust Sales and Marketing Platform in Japan

2nd largest market share

4

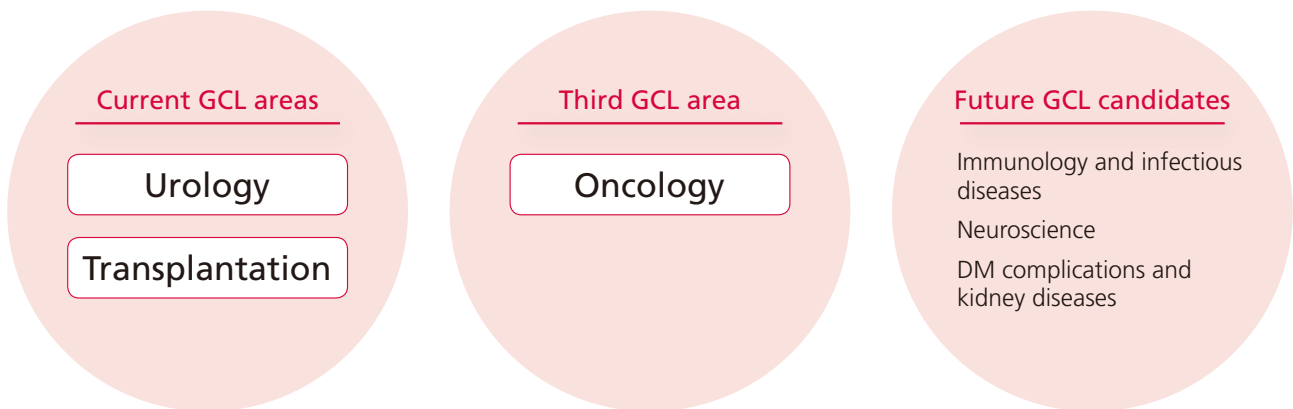
### Superior R&D Capabilities

Rich development pipeline

## Business Model

Astellas pursues a business model named Global Category Leader (GCL), based on which we establish a competitive edge as a leader in multiple categories (therapeutic areas) with a high level of unmet medical needs by delivering products globally.

### Global Category Leader (GCL)



## 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	Regional Strategy	R&D Innovation Strategy <small>(Strengthen drug discovery research capabilities)</small>	Efficiency Strategy <small>(Improve cost efficiency)</small>
<ul style="list-style-type: none"> <li>Maintain and strengthen GCL position in urology and transplantation</li> <li>Strengthen oncology franchise to realize third GCL</li> </ul>	<ul style="list-style-type: none"> <li>Expand well-balanced four-region business base (Japan, Americas, Europe, and Asia)</li> <li>Invest further in emerging countries with high potential</li> </ul>	<ul style="list-style-type: none"> <li>Actively approach Precision Medicine drug discovery</li> <li>Prioritize strategic therapeutic areas</li> <li>Utilize cutting-edge technologies in drug discovery research</li> <li>Leverage global development framework to bolster pipeline</li> </ul>	<ul style="list-style-type: none"> <li>Efficiently allocate resources through execution of therapeutic area strategy</li> <li>Manage well-focused expenditures</li> <li>Review business processes to achieve cost efficiency</li> </ul>

# 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

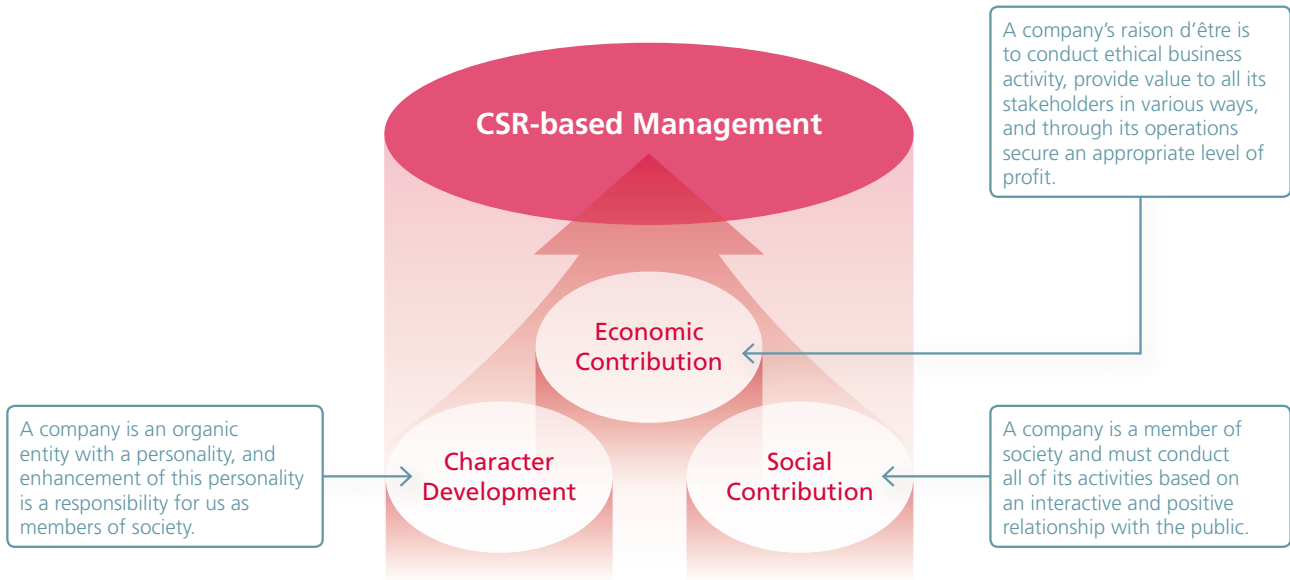
Our eyes will always be directed to the outside world, and we will continue to create better value faster.



# CSR-based Management

## What Does CSR-based Management Mean at Astellas?

Astellas defines its CSR-based management as “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.”



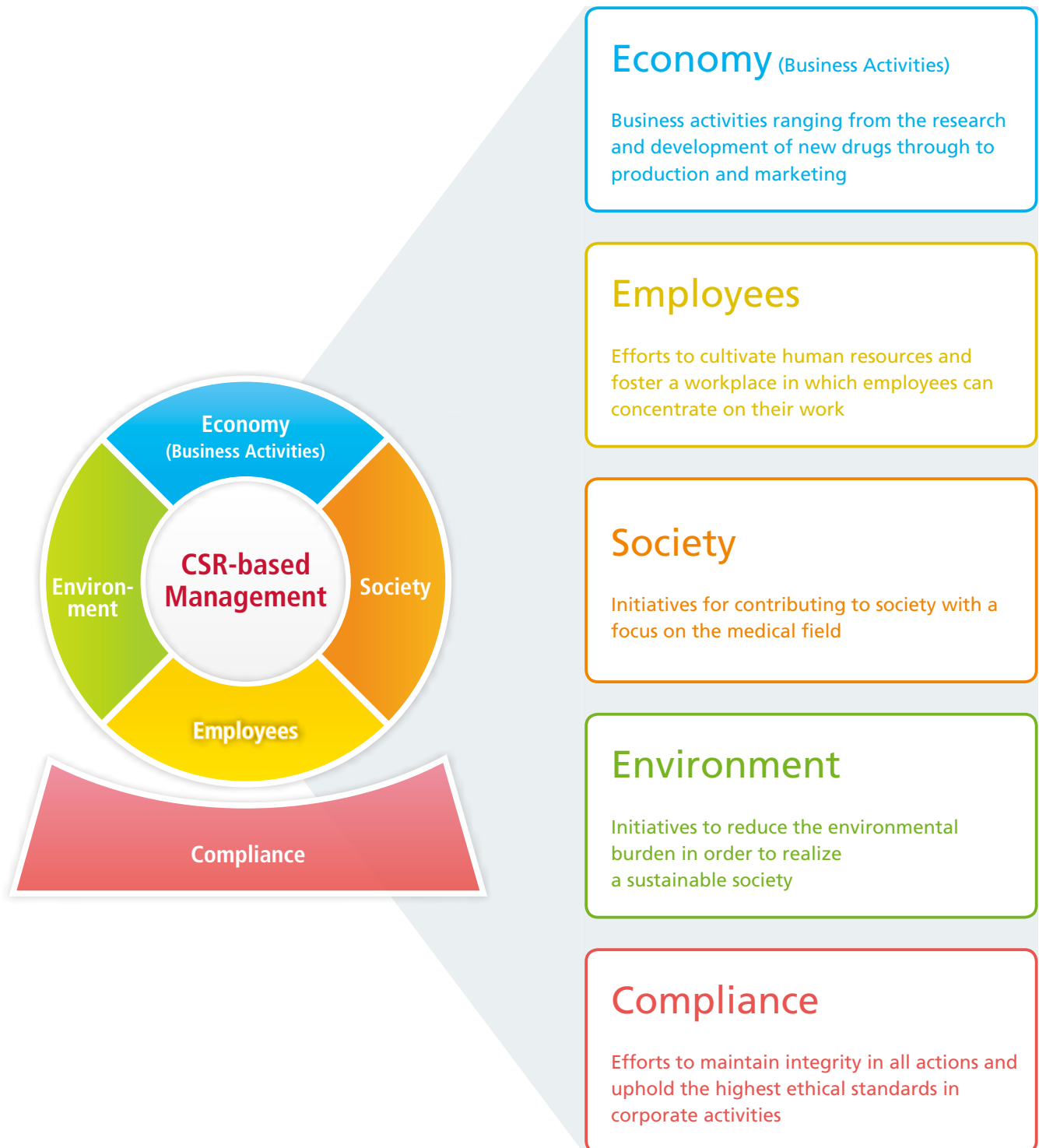
## Positioning of Our CSR-based Management

Astellas positions its CSR-based management objectives at the heart of its business philosophy, monitors all of its corporate activities from a CSR perspective, and takes appropriate action as needed.



# The Five Fields of CSR-based Management

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.



# Priority Issues of CSR-based Management (Materiality) and the Method to Specify Them

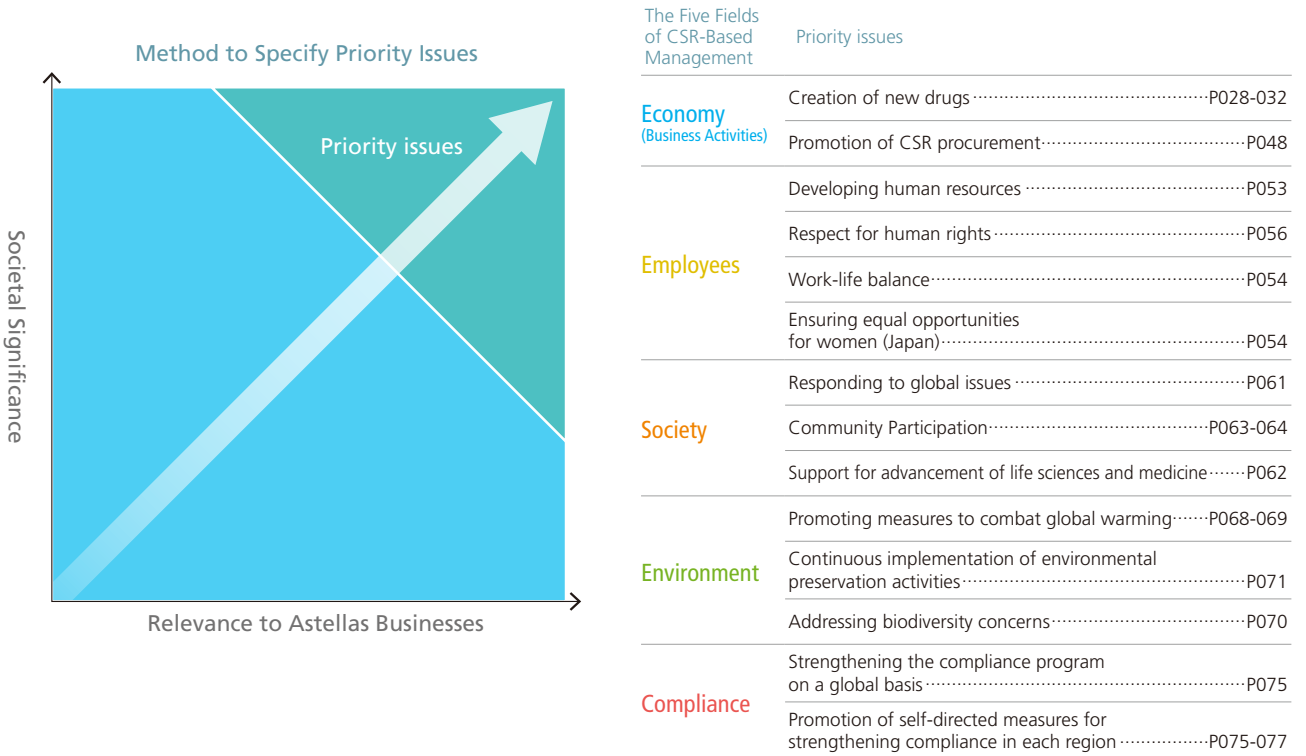
## Materiality of CSR-based Management at Astellas

Astellas believes CSR-based management should set a high value on addressing social issues through the provision of top quality products and services. We have listened to people's ideas and comments, and identified priority issues that we feel ought to be addressed through our corporate activities going forward. One of the main factors that we take into account when identifying priority issues is social sustainability.

**Step 1**  
**Identifying social Issues**  
 Social issues will be identified through communications with stakeholders, Social Responsibility Investment (SRI) questionnaires, etc. in line with the ten principles of Global Compact and the seven core subjects of ISO26000.

**Step 2**  
**Prioritizing issues by evaluating their societal significance and relevance to our business**  
 We will prioritize Astellas activities after evaluating issues' societal significance and relevance to our business.

**Step 3**  
**Review and verification**  
 Priority issues will be periodically reviewed and verified. They will be modified depending on the progress of initiatives implementation and any change to society.



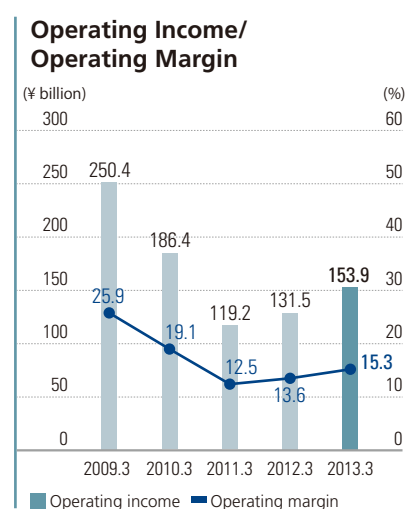
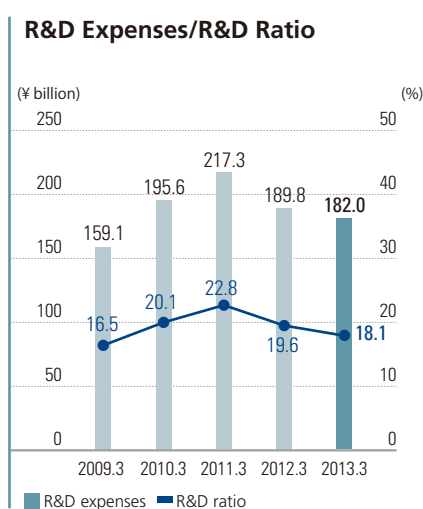
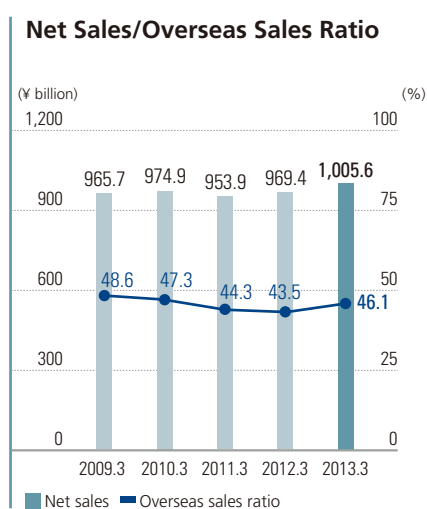
# Financial and Non-Financial Highlights

Years ended March 31

					(¥ billion)	(US\$ million)	(% Change)
	2009.3	2010.3	2011.3	2012.3	2013.3	2013.3	2013/2012
<b>For the year</b>							
Net sales	¥ 965.7	¥ 974.9	¥ 953.9	¥ 969.4	¥ 1,005.6	\$ 10,698	3.7
Cost of sales	264.4	289.2	296.0	318.6	324.1	3,448	1.7
SG&A expenses (incl. R&D expenses)	450.9	499.2	538.8	519.2	527.6	5,613	1.6
R&D expenses	159.1	195.6	217.3	189.8	182.0	1,936	(4.2)
R&D ratio (%)	16.5	20.1	22.8	19.6	18.1	—	—
Operating income	250.4	186.4	119.2	131.5	153.9	1,637	17.0
Operating margin (%)	25.9	19.1	12.5	13.6	15.3	—	—
Net income	171.0	122.3	67.7	78.2	82.9	881	5.9
<b>At year-end</b>							
Total assets	1,348.4	1,364.2	1,335.1	1,400.6	1,445.6	15,378	3.2
Total net assets	1,030.2	1,053.9	1,021.1	1,018.1	1,062.0	11,298	4.3
Working capital	680.1	711.4	413.5	466.9	513.7	—	10.0

					(¥)	(US\$)	(% Change)
<b>Per share data</b>							
Net income	¥ 356.11	¥ 261.84	¥ 146.49	¥ 169.38	¥ 180.40	\$ 1.92	6.5
Total net assets	2,189.26	2,278.77	2,207.70	2,200.64	2,349.61	25.00	6.8
Cash dividends	120.00	125.00	125.00	125.00	130.00	1.38	4.0

<b>Major indicators</b>							
ROE (%)	16.0	11.7	6.5	7.7	8.0	—	—
DOE (%)	5.4	5.6	5.6	5.7	5.7	—	—
Shareholders' equity ratio (%)	76.3	77.1	76.4	72.6	73.3	—	—
EBITDA*1 (¥ billion/US\$ million)	305.6	235.3	168.9	192.6	182.5	1,941	(5.2)
Free cash flows (¥ billion/US\$ million)	168.8	118.6	(142.0)	146.7	95.5	1,016	—
Average exchange rate (¥/US\$)	101	93	86	79	83	—	—
(¥/€)	143	131	113	109	107	—	—

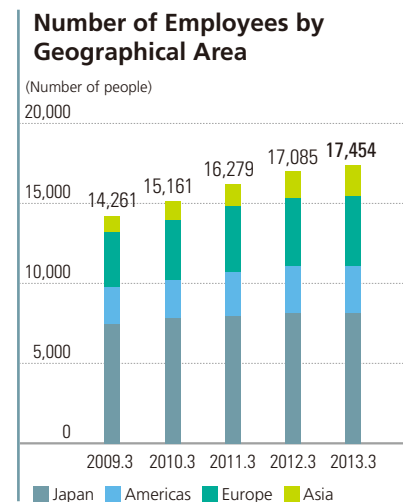
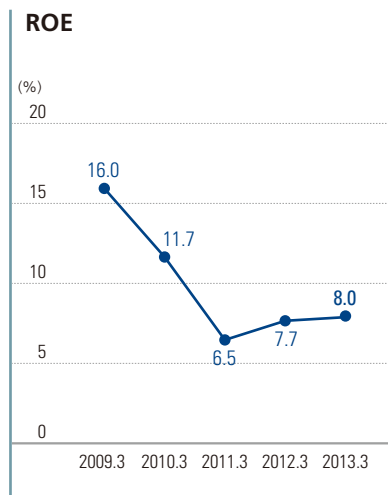
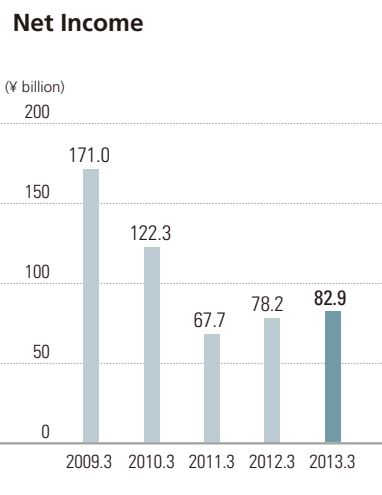


Other indicators	2009.3					2010.3		2011.3		2012.3		2013.3		2013.3		2013/2012	
						(¥ billion)	(US\$ million)	(% Change)									
Number of shares outstanding	503,964,635	475,964,635	467,964,635	467,964,635	467,964,635	—	—	—	—	—	—	—	—	—	—	—	
Overseas sales* <sup>2</sup>	¥ 469.0	¥ 460.7	¥ 422.5	¥ 421.6	¥ 464.0	\$ 4,937	10.1	—	—	—	—	—	—	—	—	—	
Overseas sales ratio (%)	48.6	47.3	44.3	43.5	46.1	—	—	—	—	—	—	—	—	—	—	—	
Sales by geographical area* <sup>3</sup>																	
Japan	510.5	529.2	543.8	558.4	557.5	5,931	(0.2)	—	—	—	—	—	—	—	—	—	
Americas	188.9	179.8	186.5	183.5	208.7	2,220	13.7	—	—	—	—	—	—	—	—	—	
Europe (incl. the Middle and Near East, Africa)	239.1	235.9	189.9	191.7	196.5	2,089	2.5	—	—	—	—	—	—	—	—	—	
Asia & Oceania	27.2	30.0	33.7	35.7	42.9	456	20.1	—	—	—	—	—	—	—	—	—	

Number of employees by geographical area	2009.3					2010.3		2011.3		2012.3		2013.3		2013/2012	
						(Number of people)	(Change)								
Total	14,261	15,161	16,279	17,085	17,454	369	(23)	—	—	—	—	—	—	—	
Japan	7,522	7,860	8,023	8,176	8,153	61	(23)	—	—	—	—	—	—	—	
Americas	2,318	2,375	2,742	2,919	2,980	61	61	—	—	—	—	—	—	—	
Europe (incl. the Middle and Near East, Africa)	3,390	3,775	4,102	4,286	4,356	70	70	—	—	—	—	—	—	—	
Asia & Oceania	1,031	1,151	1,412	1,704	1,965	261	261	—	—	—	—	—	—	—	

Key environmental impact indicators	FY2008					FY2009		FY2010		FY2011		FY2012		FY2012	
														(% Change)	
Amounts of energy consumption (thousand GJ)	4,431	4,359	4,463	4,257	4,274	0.4	—	—	—	—	—	—	—	—	
Water usage (thousand m <sup>3</sup> )	14,917	14,441	14,110	12,365	12,114	(2.0)	—	—	—	—	—	—	—	—	
Greenhouse gas emissions (kilotons)	211	205	203	189	212	12.2	—	—	—	—	—	—	—	—	
VOC emissions (tons)	149	132	102	94	66	(29.8)	—	—	—	—	—	—	—	—	
NOx emissions (tons)	43	44	41	31	33	6.5	—	—	—	—	—	—	—	—	
SOx emissions (tons)	5	5	5	1	0	—	—	—	—	—	—	—	—	—	

Note: US dollars have been converted at the rate of ¥94 to US\$1, the approximate exchange rate on March 31, 2013. 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 2012 Topics

June

### Launch in Europe of DIFICLIR for *Clostridium Difficile* Infection Treatment

DIFICLIR provides a new option for the treatment of *Clostridium difficile* infections, which cause inflammation of the colon and severe diarrhea.

June

### Launch in Japan of Kiklin for Hyperphosphatemia Treatment

Indication: Treatment of hyperphosphatemia in patients on dialysis with chronic kidney disease

September

### Launch in the United States of XTANDI for Prostate Cancer Treatment

XTANDI (generic name: enzalutamide) was launched in the U.S. for treating patients with metastatic castration-resistant prostate cancer who have previously received docetaxel. As for Europe, XTANDI was released in the United Kingdom in July 2013. In May 2013, we submitted an application for marketing approval for the indication of prostate cancer in Japan.

July

### Launch in Japan of Regnite for Restless Legs Syndrome Treatment

Indication: Treatment of moderate-to-severe primary restless legs syndrome (RLS)

2012

4

5

6

7

8

9

April

### Reorganization of Global Management Structure

In April 2012, Astellas established two new corporate executive positions—Chief Strategy Officer and Chief Financial Officer—to enable the president to delegate authority and expedite management decision-making processes. Both officers report directly to the president. We also reinforced our global management structure in various ways. These included establishing the Global Human Resources Committee, reinforcing our product compliance structure, and creating new organizations aimed at maximizing product value in each therapeutic area.

July

### Initiatives to Contribute to Access to Health

Astellas took part in an international public-private partnership for the development of a pediatric formulation of praziquantel to combat schistosomiasis.

June and after

### Initiatives to Contribute to Access to Health

Astellas signed agreements with an international non-profit organization and five Japanese research institutions to undertake collaborative research on the exploration of anti-parasitic drugs for neglected tropical diseases (NTDs).

**October**

**Launch in the United States of Myrbetriq for Overactive Bladder Treatment**

Myrbetriq (generic name: mirabegron) was launched for treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. The addition of a new option to current standard therapy is expected to contribute to OAB treatment.

**February**

**Launch in Europe of BETMIGA for OAB Treatment**

Following the United States, Astellas obtained European authorization for mirabegron in December 2012, and launched the drug under the brand name BETMIGA in the United Kingdom in February 2013.

**October**

**Launch in Japan of Quattrovac Subcutaneous Injection Syringe**

The combined vaccine prevents pertussis, diphtheria, tetanus, and poliomyelitis

**March**

**Launch in Japan of Cimzia for the Treatment of Adults with Rheumatoid Arthritis**

Astellas released this new drug in Japan for the indication of adult patients with rheumatoid arthritis who have had an inadequate response to conventional treatment (including inhibition of progression of bone structural damage).

**October**

**Launch in Japan of Gonax for Prostate Cancer Treatment**

Indication: Prostate cancer

**2013**

10

11

12

1

2

3

**September**

**Successive Inclusion in the Dow Jones Sustainability Asia Pacific Index**

Astellas was included for the second consecutive year in the Dow Jones Sustainability Asia Pacific Index (DJSI Asia Pacific), the Asia Pacific version of the Dow Jones Sustainability Index (DJSI), one of the world's premier indexes for social responsible investment (SRI).

**March**

**Awarded "2013 Supreme Mentor Award" in Japan**

In Japan, Astellas has a unique program through which directors and corporate executives mentor women in management positions as part of promoting right-person-in-the-right-place employment regardless of nationality, gender, or age. Astellas received the "Excellence Award" at "Mentor Award 2013"\* based on positive evaluation of this program.

\* "Mentor Award 2013" was sponsored by Working Women's Empowerment Forum and Japan Productivity Center.

**March**

**Initiatives to Contribute to Access to Health**

Astellas signed joint research agreements with two Japanese research institutions to discover new drugs for the treatment of NTDs caused by dengue virus.

## Interview with the CEO

Yoshihiko Hatanaka, President and CEO, explains Astellas' business strategies and CSR-based management approach in the following interview.



**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 aims to achieve continuous growth and fulfill its corporate social responsibilities.**

Yoshihiko Hatanaka  
Representative Director,  
President and CEO

A handwritten signature in white ink, appearing to read 'Y. Hatanaka', is positioned in the lower right corner of the teal banner.



## Q How would you summarize the business environment and Astellas' performance in fiscal 2012?

**Although our market environment is becoming more challenging, our growth products and newly-launched products contributed to steady business growth, resulting in year-on-year increases in both net sales and operating income for the second consecutive period.**

### Business Environment

The global pharmaceutical market continues to grow against a backdrop of growing populations in emerging countries and aging populations primarily in advanced nations. In the medium-term, the market is forecast to grow 3-6%\* on average annually. However, in both advanced and emerging countries, governments are stepping up measures to lower healthcare expenditures, including drug price reductions and promoting the use of generic products. In Japan as well, a further push to use generic drugs in April 2012 has triggered greater adoption of these products.

Furthermore, developing new drugs has become harder and harder. In Germany, for example, the Act on the Reform of the Market for Medical Products (AMNOG), implemented in 2011, has brought about an increasing number of cases where new drugs are found to not offer any added value compared with existing treatments, having an impact on the establishment of drug reimbursement prices. This implies that even if approval for a new product is obtained, that approval does not necessarily guarantee success in the market. In today's world, the true test is how much new value a product is able to add, so it is not enough to simply develop a new drug. This shift is also having a significant impact on Astellas' drug development activities. Nevertheless, there has been support for healthcare innovation such as in Japan, where the government has positioned the development of innovative drugs as a national growth strategy.

The business environment surrounding the pharmaceutical industry is undergoing major change at a faster rate

than many expected. At the same time, global competition is becoming increasingly intense. Under such circumstances, pharmaceutical companies are required more than ever to respond flexibly to changes in the business environment in order for them to achieve continuous growth.

\* 2012 IMS Health. All rights reserved

Source: Documents available on IMS Health Web site

### Fiscal 2012 Performance

As for business results, Astellas generally performed well in fiscal 2012 under these challenging conditions. We achieved growth in both net sales and operating income for the second consecutive year, with consolidated net sales surpassing the ¥1 trillion mark for the first time since the foundation of Astellas.

Bases on our R&D capabilities, we remain steadfast in our pursuit of a business model that we call "Global Category Leader" (GCL), under which we are establishing a competitive edge in multiple therapeutic areas with unmet medical needs.

In fiscal 2012, we obtained approval for multiple drugs and successively launched new products in all four geographical regions: Japan, the Americas, Europe, and Asia. Included among these were the particularly successful releases of mirabegron—a drug for overactive bladder (OAB) treatment—in the United States and Europe, and the prostate cancer treatment enzalutamide launched in the United States. These products are expected to be drivers of growth for Astellas.

**Q** The 2014 Mid-Term Management Plan\* sets out the following strategies: a therapeutic area strategy, a regional strategy, and an R&D innovation strategy. How much progress has been made on these strategies?

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

**We made steady progress in the therapeutic areas of oncology and urology, including the launch of our new growth drivers.**

### **Therapeutic Area Strategy**

We have made steady advances in the therapeutic areas of urology and oncology.

In the field of urology, sales of the mainstay product Vesicare, which is used for OAB treatment, are increasing on a global scale. Vesicare has already cemented its position as the No. 1 drug in OAB treatment markets in Japan, the United States, and Europe. In addition, following its launch in Japan, we released mirabegron (generic name)—another OAB drug with a different mechanism of action from Vesicare that offers a new treatment option for patients—in the United States and Europe. We are confident that mirabegron will penetrate the market, and these two products will play an important role to reinforce our urology franchise in the medium and long terms.

Astellas is focusing on establishing oncology as the third Global Category Leader (GCL) area. We launched XTANDI for the treatment of prostate cancer in the United States in September 2012, and then released the product in Europe in July 2013. The filing of an application for regulatory approval in Japan in May 2013 marked a further milestone in the global rollout of this new drug. The strong performance of XTANDI in the U.S. market indicates the success of our investment to date in this therapeutic area. Astellas recognizes that it stands at the threshold of establishing oncology as another GCL area.

In the area of transplantation, we are continuing efforts to maximize the value of the immunosuppressant Prograf. In the Americas and Europe, the impact of generic drugs has led to a decrease in sales. However, sales growth in

Japan and Asia has helped maintain sales on a global level in line with initial estimates.

### **Regional Strategy**

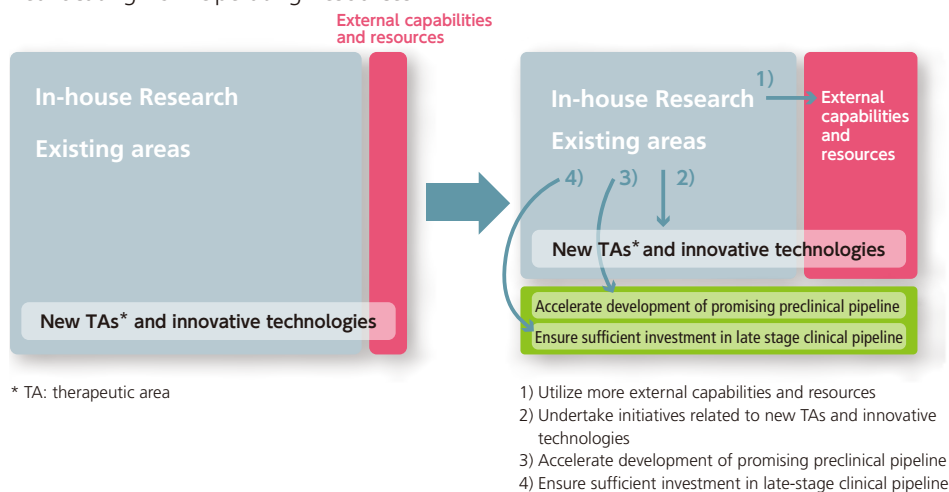
With its own sales network that covers approximately 50 countries, Astellas has a well-balanced global business spanning the four regions of Japan, the Americas, Europe, and Asia. In addition to global products, such as Prograf and Vesicare, we also market local products distinctive to each region. These local products underpin our growth and constitute one of our key strengths.

Astellas is also paying attention to emerging markets with growth potential. We are enjoying particularly strong growth in China and Russia. Although the markets of emerging countries continue increasing in size, these nations are implementing measures to curb medical expenditures, such as drug price reductions, at an even faster rate than advanced nations. Also, the characteristics of markets vary greatly from country to country. While taking these into sufficient account, our regional strategy centers on the delivery of new drugs with high added value as we are doing in Japan, the United States, and Europe. Pursuing this approach enables us to steadily develop businesses that can generate stable earnings in the future.

### **R&D Innovation Strategy**

Under the current Mid-Term Management Plan, we are undertaking a variety of initiatives to enhance our ability to generate innovative drugs. In addition to actively promoting a “Precision Medicine” approach, we are also utiliz-

## Reshaping Research Framework Reallocating R&D Operating Resources



ing external capabilities and resources under a “Multi-Track R&D” approach.

In May 2013, Astellas decided to reshape its research framework by introducing new initiatives to further enhance its ability to generate innovative drugs. By optimizing the allocation of resources, these reforms aim to utilize more external capabilities and resources, undertake initiatives related to new therapeutic areas and innovative technologies, including regenerative medicine and vaccines, accelerate the development of our promising preclinical pipeline, and ensure sufficient investment in the late-stage clinical pipeline. In other words, through a flexible research framework with greater freedom in resource allocation, we will introduce a variety of innovative approaches from the outside and rise to the challenge for diseases which we have not dealt with. We will build a framework that is receptive to new opportunities, while valuing the strategy of selectivity and concentration we have pursued to date without allowing this strategy to become too firmly entrenched.

One element of building this framework is the establishment of Astellas Innovation Management (AIM). AIM's role will be to enhance the process of screening external opportunities to strengthen innovation during the preclinical development stage. In order to bolster research management, the research units for each therapeutic area will be assigned broader authority and responsibility for exploring potential candidates for development to enhance the autonomy and agility of each unit. The current “Multi-Track R&D” process will be actively implemented at an earlier stage of the research process. To facilitate the strategic

reallocation of resources, we have also decided to reshape our research framework, which will include the closing and downsizing of research functions.

The aims of these initiatives are to enhance our own research capabilities in existing focus therapeutic areas, and to open up more opportunities for new drug discovery by flexibly incorporating outside innovation in new therapeutic areas and technologies. Astellas will expand its R&D pipeline by responding flexibly to ongoing advances in science and technology while properly managing the risks and costs associated with new drug R&D activities.

### New Initiatives for Optimizing Resource Allocation

In May 2013, we entered into a strategic alliance in Japan with Amgen Inc. There are two elements to the alliance. The first is a long-term collaboration between both companies to co-develop and co-commercialize in Japan five of Amgen's pipeline medicines, most of which are biologics. The second is the establishment of a Tokyo-based joint venture company called Amgen Astellas BioPharma KK, through which the companies will work together. By blending the strengths of both companies, the alliance seeks to create a win-win situation in our quest to deliver innovative pharmaceuticals to patients in Japan. For Astellas, the partnership will help expand its product portfolio in Japan.

The alliance is one of our initiatives to enhance our own capabilities by actively utilizing external resources through the optimization of resource allocation.

## Q What is your outlook for fiscal 2013?

**We pursue operational excellence and resilience in order to anticipate changes in the business environment and continue growth.**

We believe the pharmaceutical industry will continue to face an increasingly challenging business environment in fiscal 2013. Under such conditions, we aim to achieve continued growth by enhancing the quality of our operational excellence, which is the source of our competitive edge, while anticipating and responding flexibly and swiftly to changes in the business environment.

In fiscal 2013, we project increases in both net sales and operating income for the third consecutive year on forecast consolidated net sales of ¥1,170 billion, up 16.3% from fis-

cal 2012, and forecast operating income of ¥170 billion, up 10.5% year on year.

Fiscal 2010 marked Astellas' transition into a new growth phase. To further accelerate this progress, we will promote the optimization of resource allocation, including the reshaping of our research framework. At the same time, we will convert opportunities for growth—provided by the introduction of new products, such as mirabegron and enzalutamide—into a steady stream of positive results.

## Q What is the Company's policy with regard to shareholder returns?

**Astellas is pursuing sustained growth in dividends while prioritizing business investments aimed at realizing future growth.**

Our basic policy remains unchanged. We are working to achieve stable and sustained growth in dividends taking into account the dividend-on-equity (DOE) ratio and other factors, based on medium to long-term earnings growth on a consolidated basis, while prioritizing business investments to assure future growth. We will also flexibly implement share buybacks to improve capital efficiency and boost the level of return to shareholders.

Guided by this basic policy, in fiscal 2012 we paid annual dividends of ¥130 per share, up ¥5 from the previous year. As a result, the DOE ratio was 5.7%. In addition to acquiring 10.8 million of its own shares valued at ¥49.3 billion, we cancelled 11.0 million shares of treasury stock we had held in May 2013.

In fiscal 2013, we plan to increase the annual dividend paid by ¥5, to ¥135 per share.

## Q What is Astellas' understanding of CSR-based management?

**Our main business itself is the core of CSR, which is firmly rooted in our corporate culture.**

Astellas attaches great importance to its *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.” By constantly evaluating business activities from a CSR perspective, we strive for the continuous enhancement of corporate value.

The first reason for Astellas' commitment to CSR-based management can be found in the Company's contribution to the health of people throughout the world. We do this by developing innovative products in therapeutic areas where high unmet medical needs exist and delivering the best possible drugs to patients. In other words, our main business itself is the core of CSR.

The second reason is that, through serving patients in our core businesses, we maintain our desire to put Astellas' expertise, know-how, and resources to good use in any way possible in order to solve social problems—and this desire is firmly rooted in our corporate culture. As a company that targets sustainable growth while reinvesting earnings into the development of the next set of new drugs, our most important principle is to resolve such problems within the scope of our business activities. One part of this is our drug

discovery initiative aimed at neglected tropical diseases as a way to address global health problems.

Thirdly, we aim to maintain a healthy relationship with society as a corporate citizen and carry out certain social contribution activities to enhance the sustainability of society. These initiatives are also important for our own sustainability and for enhancing corporate value.

Astellas has established 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.

Since November 2011, we have been supporting the United Nations Global Compact. In signing the Global Compact, we incorporated the ten principles covering the four fields of human rights, labor, the environment, and anti-corruption into our daily business activities. This endorsement of the Global Compact has enhanced the quality of our CSR-based management.



To contribute to society as a corporate citizen, Astellas employees undertake volunteer activities related to health and the environment during Changing Tomorrow Day.

**Q** Could you tell us about Astellas' initiatives relating to support for healthcare in developing countries?

**We are actively engaged in resolving global health issues.**

At present, there are two major global health issues. One is the existence of many therapeutic areas with unmet medical needs. The other is the existence of many people who are unable to access the healthcare they need due to such reasons as poverty and healthcare system flaws. Astellas refers to these two problems as the "Access to Health" issues.

Astellas aims to address the first issue through its core business activities, which are to develop innovative new drugs and deliver better medicines to patients and thus contribute toward improving the health of people around the world.

As for the second issue, we provide support for healthcare in developing countries. To give concrete examples, in 2012, we started drug discovery research into neglected tropical diseases and also began developing a new pediatric formulation of a drug to treat schistosomiasis. Improving

access to health is a series of initiatives aimed at enhancing corporate value. As with our core businesses, through which we deploy our assets and strengths to solve social problems, we anticipate that in the long term these initiatives will bring a synergistic effect on our business. For instance, the process of addressing these issues involves building and strengthening relationships with various stakeholders, such as governments and local partners in the countries concerned. These relationships will serve as a springboard when Astellas enters new markets in the future. Furthermore, we anticipate that working in partnership with a wide range of research organizations will lead to an open innovation-oriented new drug discovery model.

Going forward, Astellas will continue practicing its unique form of CSR-based management by actively communicating with stakeholders involved in global healthcare.

**Q** What is Astellas' approach to manage business risks?

**We are further reinforcing risk management to ensure the stable delivery of pharmaceuticals to patients.**

Astellas is working on a variety of frameworks that enhance its risk management capabilities, including the adoption of a Global Code of Conduct, the establishment of a Risk Management Committee, a Global Compliance Committee, and internal control systems in every part of the Astellas Group.

We aim to create a structure that allows for the stable delivery of drugs to patients even in the advent of an unforeseen incident or disaster. To this end, we are focus-

ing on reinforcing the Company's business continuity plan (BCP), which can be activated when a pandemic or natural disaster occurs. But having in place this kind of infrastructure alone is not sufficient. We must also constantly raise employee awareness so they can take appropriate actions when the unexpected happens. To this end, we are also conducting educational activities and other human-level initiatives.

## Q How is Astellas improving corporate governance?

**We are building a system of corporate governance that ensures transparency and objectivity.**

We have built a system of corporate governance that ensures transparency and objectivity. The introduction of the Corporate Executives System clearly separates the business execution and management oversight functions. Also, highly independent outside Directors account for more than half of the members on our Board of Directors. This ensures that decisions are reached based on a wide variety of opinions and perspectives. In addition, outside Directors also account for more than half of the members of the Nomination Committee and Compensation Committee.

For business execution, we promote a “matrix management” structure. It consists of a functional axis, which is separated into the four areas of research, development, technology, and quality assurance (QA), regulatory affairs (RA) and pharmacovigilance (PV), and a geographical region axis that manages sales and marketing departments.

The aim here is to ensure expeditious and appropriate decision-making in response to changes in the business environment.

Measures to reinforce Astellas’ management included the establishment in April 2012 of a global new structure of Medical Affairs for increasing product value from a medical and scientific perspective in our main therapeutic areas. Moreover, in April 2013, we established the position of Chief Medical Officer. As well as reinforcing the benefit-risk assessment of drugs, the addition of this role clearly delineates responsibilities and decision-making concerning QA, RA, and PV functions, which are becoming increasingly important worldwide. Going forward, we will continually reinforce our system of business execution to ensure our management makes sophisticated decisions and runs efficient operations in the globally competitive pharmaceutical industry.

## Astellas’s challenge is to transform innovation into value that will benefit patients

### To our stakeholders

We believe that Astellas’ rationale as a company is to transform scientific progress—namely innovation—into value that will benefit patients, and to deliver such value to those patients. We will continuously develop new innovative drugs while responding with resilience to the rapidly changing business environment. We hope that by contributing to the health of people in this way, we will continue meeting the expectations of patients, their families, and all other stakeholders with integrity.



# United Nations Global Compact Initiatives

## Endorsing the United Nations Global Compact

In November 2011, Astellas expressed its support for the United Nations Global Compact, which consists of ten basic principles related to human rights, labor, the environment, and anti-corruption. The Global Compact requires its signatory to make voluntary efforts in realizing the ten principles.

Since the signing of the Global Compact, we have been further reinforcing our CSR-based management approach in order 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	<p><b>Principle 1</b> Businesses should support and respect the protection of internationally proclaimed human rights; and</p> <p><b>Principle 2</b> Make sure that they are not complicit in human rights abuses.</p>	<ul style="list-style-type: none"> <li>• Respect for human rights <b>Employee</b> P056</li> <li>• Emphasis on diversity <b>Employee</b> P054</li> <li>• Protection of human rights and personal information of patients undergoing clinical trials <b>Economy</b> P045</li> <li>• Ethical considerations in the use of specimens derived from humans <b>Economy</b> P044</li> <li>• Promotion of CSR procurement (Respect for human rights and fair employment practices at our business partners) <b>Economy</b> P048</li> <li>• External and internal helplines for employees <b>Compliance</b> P076</li> </ul>
	<p><b>Principle 3</b> Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;</p> <p><b>Principle 4</b> The elimination of all forms of forced and compulsory labor;</p> <p><b>Principle 5</b> The effective abolition of child labor; and</p> <p><b>Principle 6</b> The elimination of discrimination in respect of employment and occupation.</p>	<ul style="list-style-type: none"> <li>• Provision of opportunities for communication between labor and management <b>Employee</b> P054</li> <li>• Prohibition of forced and compulsory labor <b>Employee</b> P056</li> <li>• Promotion of CSR procurement (Management of occupational health and safety practices and prohibition of child labor at our business partners) <b>Economy</b> P048</li> </ul>
Environment	<p><b>Principle 7</b> Businesses should support a precautionary approach to environmental challenges;</p> <p><b>Principle 8</b> Undertake initiatives to promote greater environmental responsibility; and</p> <p><b>Principle 9</b> Encourage the development and diffusion of environmentally friendly technologies.</p>	<ul style="list-style-type: none"> <li>• Reduction of greenhouse gas emissions <b>Environment</b> P068</li> <li>• Initiatives for sustainable biodiversity <b>Environment</b> P070</li> <li>• Effective use of water resources <b>Environment</b> P071</li> <li>• Waste management <b>Environment</b> P071</li> </ul>
	<p><b>Principle 10</b> Businesses should work against corruption in all its forms, including extortion and bribery.</p>	<ul style="list-style-type: none"> <li>• Reinforcement of global compliance system <b>Compliance</b> P075</li> <li>• Emphasis on preventing bribery <b>Compliance</b> P077</li> <li>• Promotion of CSR procurement (Compliance with laws and promotion of CSR at our business partners) <b>Economy</b> P048</li> </ul>

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.



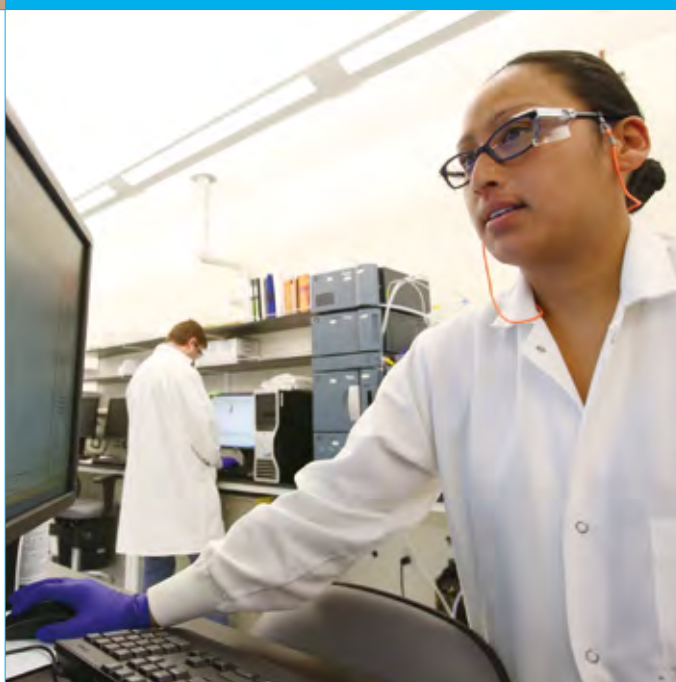
Astellas will continuously grow  
by creating new drugs and  
delivering them to patients.



# Economy

(Business Activities)

- 024 Special Feature: New Growth Drivers
- 028 Research & Development  
(including Pipeline)
- 033 Review of Operations by Therapeutic Area
- 036 Review of Global Operations
- 044 CSR Initiatives in Business Processes
- 049 Initiatives to Improve Access to Health



# New Growth Drivers

Astellas has overcome the “patent cliff” of certain mainstay products, and is forging a new growth trajectory. By adding promising new drugs to our product portfolio, we are strategically positioned to achieve continued growth.

## New Drugs Driving Future Growth

Astellas pursues a Global Category Leader (GCL) business model aimed at establishing a competitive edge in multiple therapeutic areas with a high level of unmet medical needs, and which delivers high-value-added pharmaceuticals worldwide.

In fiscal 2012, Astellas launched many products in markets around the world thanks to its successful investment in research and development. The launch of XTANDI for the treatment of prostate cancer in the United States marked an important milestone in establishing oncology as the third GCL area behind urology and transplantation. The market release of the overactive bladder (OAB) treatment mirabegron (generic name) in the United States and Europe is the

driving force to further strengthen our franchise in urology, a current GCL area. Including these drugs, we obtained approval, launched many products worldwide, and filed applications for many new drugs in fiscal 2012. One example is ipragliflozin for the treatment of type 2 diabetes, for which we applied for market authorization in Japan.

We are making steady progress in the new growth trajectory after fiscal 2010, having overcome the “patent cliff” of mainstay products Harnal and Prograf. We will continue working to deliver a steady stream of innovative new drugs to patients worldwide and thus achieve continuous growth.

In this Special Feature, we introduce products that show particular promise as drivers of future growth.

## Mainstay Products and New Growth Drivers

**Astellas' Mainstay Products Driving Growth**

- PROGRAF<sup>®</sup> tacrolimus capsules and injection
- VESicare<sup>®</sup> (bifrenodin succinate) tablets
- ADVAGRAF<sup>®</sup> tacrolimus prolonged release
- MYCAMINE<sup>®</sup> micafungin
- Harnal OCAS<sup>®</sup> (ipratropium bromide)
- eligard<sup>®</sup> (mirabegron)
- Symbicort<sup>®</sup> (budesonide/formoterol)
- CELECOX<sup>®</sup> (celecoxib)
- Micardis<sup>®</sup> (nifedipine)

**New Growth Drivers**

- Betanis (ipragliflozin): Japan: Launched Sep. 2011
- Myzbetriq (empagliflozin): US: Launched Oct. 2012
- Betmiga (mirabegron): Europe: Launched Feb. 2013
- Gonax (enzalutamide): Japan: Launched Oct. 2012
- DIFCLIR (difeliquin): Europe: Launched May 2012
- Quattrovac (vaccines): Japan: Launched Oct. 2012
- Kiklin (ketoconazole): Japan: Launched Jul. 2012
- Regnite (regorafenib): Japan: Launched Jun. 2012
- Xtandi (enzalutamide): US: Launched Sep. 2012; Europe: Launched Jul. 2013
- CIMZIA (corticosteroids): Japan: Launched Mar. 2013

## New Global Products

### ▶ **XTANDI** (generic name: enzalutamide, prostate cancer treatment)

#### Establishing Oncology as Our Third GCL Therapeutic Area

Astellas is focusing on establishing oncology as its third GCL therapeutic area. The key to building a leading position lies in the new prostate cancer treatment XTANDI.

It is estimated that prostate cancer is the second most common type of cancer among men\*. With various treatment options, such as surgery, radiation, hormone treatment, and chemotherapy, patients are treated depending on the progression of the disease and their state of health.

The development of XTANDI started for the indication of the most advanced prostate cancer. In a Phase 3 AFFIRM clinical trial involving patients with prostate cancer who had previously received chemotherapy, patients treated with the drug had a significant increase in median overall survival compared with the placebo group.

With this favorable result, Astellas and Medivation, Inc. filed for approval in the United States and Europe. It was approved just three months after making the application in the United States, and then launched in September 2012 for the indication of metastatic castration-resistant prostate cancer in patients who have previously received docetaxel. In Europe, we obtained approval for this population in June 2013 and launched XTANDI in the United Kingdom in July 2013. In Japan, we filed for approval for the indication of

prostate cancer in May 2013. We are working to expand the drug's indications to include earlier-stage prostate cancer. Currently, we are conducting a Phase 3 PREVAIL clinical trial for patients with prostate cancer who have not received chemotherapy. Development is also underway for the additional indication of breast cancer.

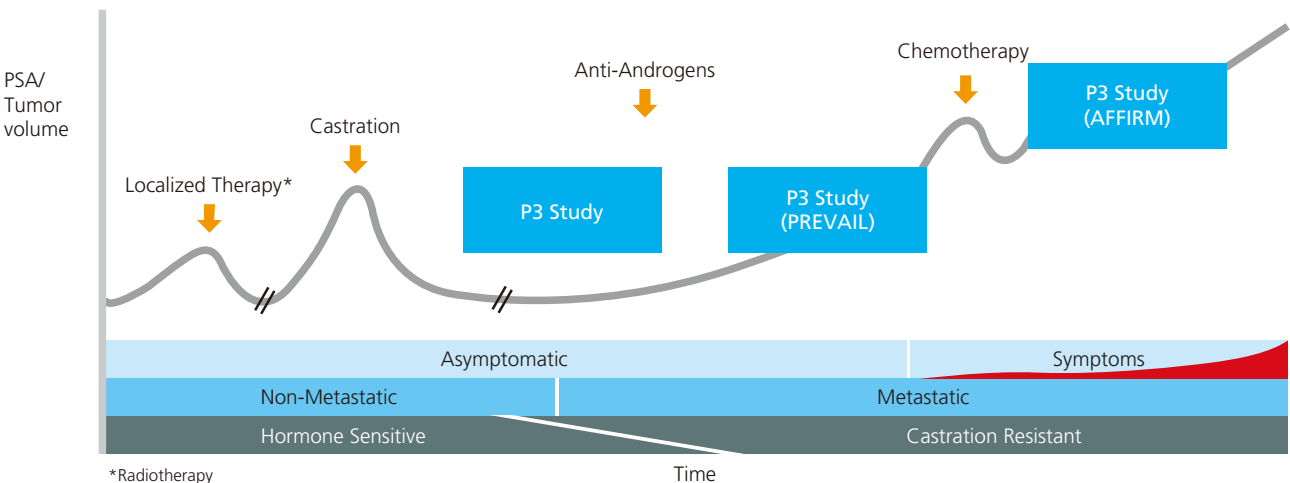
In fiscal 2012, sales of XTANDI were \$146 million in the United States approximately seven months after the launch. The sales organization for XTANDI in the United States includes 150 medical representatives, 90 from Astellas and 60 from Medivation. In Europe, where Astellas already has experience in selling the prostate cancer treatment Eligard, we are establishing a sales and marketing organization for XTANDI for oncologists.

In the U.S. market, Astellas and Medivation co-promote XTANDI and share costs and profits equally. In all countries excluding the United States, Astellas will develop and sell XTANDI, while paying Medivation royalties based on sales.

Because XTANDI is an anti-cancer agent in the therapeutic area of urology, where we command a strong position, we expect to achieve beneficial synergies with our existing business. XTANDI has increased treatment options for prostate cancer, and we will leverage this to boost the value of the new drug.

\* Estimate by GLOBOCAN 2008

#### Stages of Prostate Cancer and Current Therapies



## ▶ **Mirabegron** (generic name, overactive bladder treatment) [brand name: Betanis/Japan, Myrbetriq/the United States, and BETMIGA/Europe]

### A New Option for OAB Treatment

Astellas discovered and developed the overactive bladder treatment (OAB) mirabegron, which has a distinct mechanism of action. We intend to maximize sales of mirabegron together with those of Vesicare, which has already cemented its position as the No. 1 brand drug in the OAB treatment market.

OAB is a urological condition whose symptoms include urinary frequency, urinary urgency, and urge urinary incontinence. It is estimated that around 400 million people worldwide suffer from this condition\*. At present, antimuscarinics, including Vesicare, are the current OAB treatment standard. However, there are patients for whom antimuscarinics are not adequately effective, as well as those who have difficulty continuing treatment due to side effects.

Mirabegron is the world's first beta-3 adrenergic ago-

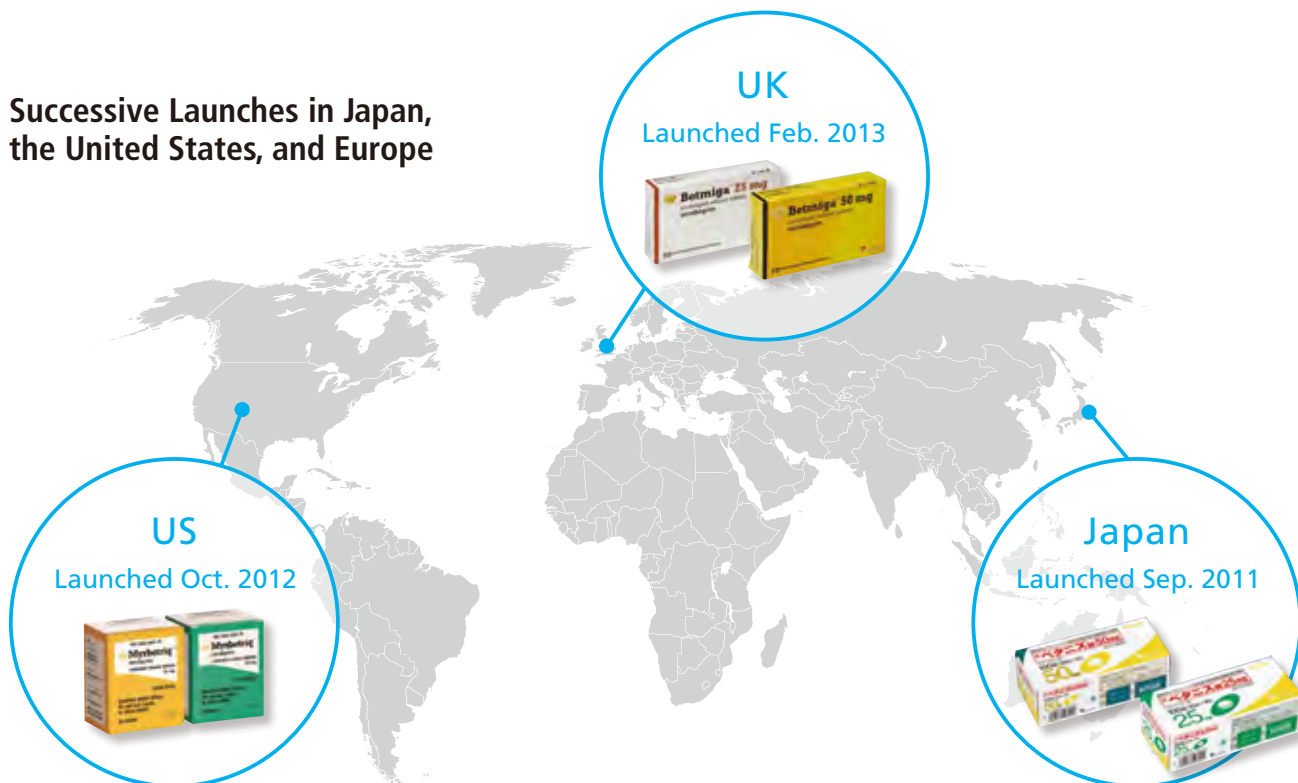
nist used for the treatment of OAB. The drug increases bladder capacity by activating beta-3 adrenergic receptors selectively on the bladder's smooth muscles. As a result, the availability of an additional option to patients is expected to make a valuable contribution to the treatment of OAB.

Astellas first released mirabegron in Japan in September 2011 under the brand name of Betanis. We then released it in the United States in October 2012 under the brand name of Myrbetriq. We received approval in Europe in December 2012, and launched sales in the United Kingdom in February 2013 under the brand name of BETMIGA. In fiscal 2012, sales of mirabegron increased steadily, amounting to ¥6.9 billion on a global basis.

With Vesicare and mirabegron in its lineup, Astellas is aiming to further consolidate its No. 1 position in the OAB field.

\* Irwin D.E., et al., BJU Int 2011; 108(7):1132-8

### Successive Launches in Japan, the United States, and Europe



## New Local Products

In fiscal 2012, Astellas launched a succession of new products in local areas. In addition to the *Clostridium difficile* treatment DIFICLIR in Europe, in Japan we released Regnite for the treatment of restless leg syndrome, Kiklin for the treatment of hyperphosphatemia, Gonax for the treatment of prostate cancer, Quattrovac, a combined vaccine for the prevention of pertussis, diphtheria, tetanus, and poliomyelitis, and Cimzia for the treatment of rheumatoid arthritis. Also in Japan, we submitted applications for approval of promising new drugs, including ipragliflozin, a treatment for type 2 diabetes.

Here, we will focus on Cimzia and ipragliflozin, two new drugs intended for Japan, which is an important market. With these two drugs positioned as future growth drivers, we will harness our sales structure in Japan, which performs at the highest level in terms of both quality and quantity.

### ▶ **Cimzia** (generic name: certolizumab pegol, rheumatoid arthritis treatment)

#### Further Contributing to Rheumatoid Arthritis Treatment

Rheumatoid arthritis is an autoimmune disease that causes joint inflammation and chronic pain, and in severe cases can cause deformation of the joints. It is estimated that 650,000 people in Japan suffer from rheumatoid arthritis\*.

Cimzia, which is in-licensed from UCB Pharma, S.A., is the world's first PEGylated anti-TNF (tumor necrosis factor)-alpha antibody and directly suppresses TNF-alpha, a factor involved in the onset and exacerbation of inflammatory diseases such as rheumatoid arthritis. It is an effective and safe treatment that has been designed for self-administration by the patient once trained by a healthcare professional. Cimzia is expected

to play an important role in improving the symptoms of rheumatoid arthritis and the quality of life of patients.

Cimzia was launched in Japan in March 2013 for the indication of patients with rheumatoid arthritis who have had an inadequate response to conventional treatment (including inhibition of progression of bone structural damage). At present, we are working on the development for patients who have not received the conventional treatment.

With the addition of Cimzia to our lineup in the rheumatoid arthritis field consisting of the immunosuppressant Prograf and the anti-inflammatory agent Celecox, we intend to boost our contribution to the treatment of rheumatoid arthritis.

\* Miyasaka N, Rheumatoid Arthritis, Internal Medicine 9th Edition, edited by T. Sugimoto and Y. Yazaki, Asakura Shoten, Tokyo, 2007; 1053-1057

### ▶ **Ipragliflozin** (generic name, type 2 diabetes treatment)

#### Strengthening Our Presence in the Diabetes Area in Japan

In March 2013, Astellas submitted a market authorization application for ipragliflozin, a drug for the treatment of type 2 diabetes. Ipragliflozin was discovered as a result of research collaboration with Kotobuki Pharmaceutical Co., Ltd.

Ipragliflozin has a novel mechanism of action that inhibits sodium-glucose co-transporter (SGLT) 2. The drug lowers blood glucose levels by selectively inhibiting SGLT2, which is a membrane protein that plays a key role in the reuptake of glucose in renal proximal tubules of the kidneys.

According to a national survey, 8.9 million people in Japan are deemed to be at high risk for diabetes\*. Astellas expects to further contribute to the treatment of type 2 diabetes by introducing ipragliflozin into the Japanese market.

In the Phase 3 pivotal study in monotherapy for type

2 diabetes in Japan, ipragliflozin demonstrated significant decreases of HbA1c, an index of glycemic control, in change from baseline compared to placebo. The study found that ipragliflozin was safe and well tolerated. Astellas also conducted Phase 3 clinical trials on the drug's use in combination with the long-term administration of six other hypoglycemic agents. The six Phase 3 studies confirmed the efficacy and safety of ipragliflozin in combination with other drugs. We are hopeful that ipragliflozin will become a new diabetes drug that can be used either on its own or in combination with various existing therapies.

Astellas already has expertise and marketing experience in the diabetes therapeutic area through sales of the oral hypoglycemic agent Starsis. By drawing on this platform for the provision of ipragliflozin, we intend to reinforce our presence in the field of diabetes.

\* "Outline of the National Health and Nutrition Survey Japan, 2007," Ministry of Health, Labour and Welfare

## Research & Development (including Pipeline)

Astellas sets five therapeutic areas as its research focus areas and pursues research and development in order to fulfill unmet medical needs. We are also engaged in active research into new technologies in the fields of regenerative medicine and vaccines. We strive to create innovative drugs guided by the principles of “Best Science,” “Best Talent,” and “Best Place.”

### Research



**Shinichi Tsukamoto, Ph.D.**

Senior Vice President and  
President, Drug Discovery  
Research

Astellas’ five focus therapeutic areas in research are urology, immunology (including transplantation) & infectious diseases, oncology, neuroscience, and diabetes mellitus complications & kidney diseases. Astellas is actively promoting our Precision Medicine approach to drug discovery research centering on oncology by leveraging translational science, which bridges the stages from basic research through to clinical phase. This approach entails the development of drugs that accurately target specific molecules that cause a particular disease combined with the development of diagnostic agents for identifying patients who will receive the most benefit from those drugs.

Since establishing the Disease Frontier Research Laboratory in April 2012, we have been exploring new opportunities for drug discovery research that will meet unmet medical needs in areas other than the above therapeutic areas. In the field of regenerative medicine, we were previously focusing on the exploration of drugs which can act on cells (regenerative drugs) and the application of induced pluripotent stem (iPS) cells to drug discovery. However, we have expanded the scope of research with the aim of embarking on full-scale research into cell therapies, which utilize cells themselves as remedies.

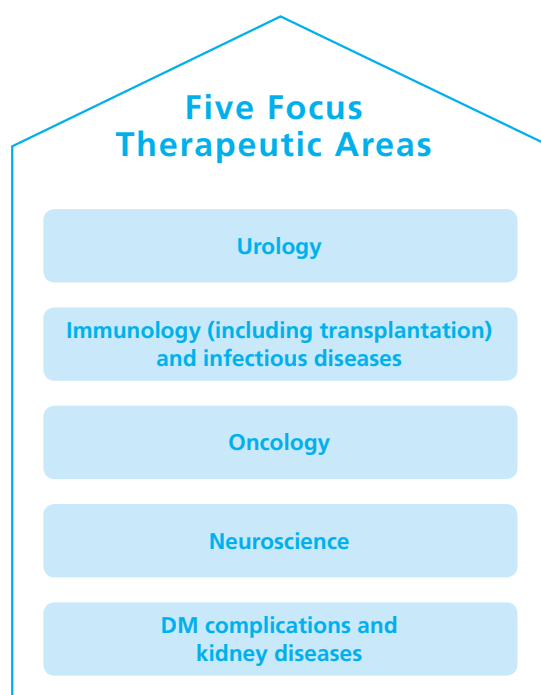
In May 2013, we decided to reshape our research framework for the purpose of reinforcing our drug discovery capabilities.

As part of this reshape, we will enhance research management to work on cutting-edge science at all times. Research

units covering each therapeutic area will be granted increased autonomy and agility through the delegation of wide-ranging authority and responsibilities concerning the exploration for potential development candidates.

As well as allocating management resources to high-priority research projects, Astellas is also improving access to external resources to promote expeditious and efficient R&D on unique and challenging projects.

The drug discovery environment is changing largely along with advances in science and technology. Under such conditions, the utilization of external technology and research know-how is more important than ever. Underpinned by cutting-edge science (Best Science), Astellas will continue discovering innovative drugs by recruiting appropriate human resources and researchers from both within and outside the group (Best Talent) to engage in flexible research activities in optimal environments (Best Place).



## Progress Status of Drug Development



**Sef Kurstjens, M.D., Ph.D.**

Chief Medical Officer  
President, Astellas Pharma  
Global Development, Inc.

In order to deliver innovative new pharmaceutical products to patients as quickly as possible, Astellas is working to accelerate product development by reinforcing its global development structure and optimizing the allocation of resources to high-priority projects.

The R&D pipeline that underpins Astellas' future business features many unique compounds centered on our focus therapeutic areas. Amid steady progress in our development pipeline, we achieved application and approval milestones in many projects in fiscal 2012.

Two representative examples are the prostate cancer treatment enzalutamide and the overactive bladder (OAB)

treatment mirabegron, both of which are positioned as new growth drivers in their respective therapeutic areas of oncology and urology. Since April 2012, there have been significant milestones of application, approval and launch in the United States and Europe, as well as application in Japan. We also received approval for mirabegron and launched it in the United States and Europe. In addition, approval has been granted in Japan for four products, including the prostate cancer treatment Gonax, the rheumatoid arthritis treatment Cimzia, and the functional dyspepsia treatment Acofide. We also moved forward with the development of many other medicines, including our application for ipragliflozin, a drug for the treatment of type-2 diabetes.

In April 2013, I was appointed President of Astellas Pharma Global Development, Inc. Going forward, we aim to make an even greater contribution to the development of significant new medicines for patients by extracting the maximum value from the products within our pipeline by leveraging our integrated global capabilities to best effect.

### Products approved in/after April 2012

(as of August 1, 2013)

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
YM178 mirabegron	Myrbetriq (Jun. 2012)	Beta-3 receptor agonist	Overactive bladder associated with symptoms of urgency, urinary frequen- cy, and urge urinary incontinence	US	Oral	In-house	
	Europe						
ASP3550 degarelix	Gonax (Jun. 2012)	GnRH antagonist	Prostate cancer (One-month formulation)	Japan	Injection	Ferring	
MDV3100 enzalutamide	XTANDI (Aug. 2012)	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer in patients who have previously received docetaxel	US	Oral	Medivation	
	Europe						
certolizumab pegol	Cimzia (Dec. 2012)	PEGylated anti-tumor necrosis factor-alpha antibody	Treatment of rheumatoid arthritis not responding to conventional therapy (including inhibition of progression of bone structural damage)	Japan	Injection	UCB	
amoxicillin	Sawacillin (Feb. 2013)	Penicillin antibiotic	<i>Helicobacter pylori</i> eradication in pa- tients with <i>Helicobacter pylori</i> gastritis by triple therapy with proton pump inhibitors and either clarithromycin or metronidazole	Japan	Oral	In-house	New indication
YM443 acotiamide	Acofide (Mar. 2013)	Acetylcholine esterase inhibitor	Postprandial fullness, upper abdominal bloating, and early satiation associated with functional dyspepsia	Japan	Oral	Zeria	
erlotinib	Tarceva (May 2013)	HER1/EGFR tyrosine kinase inhibitor	First-line treatment of people with met- astatic non-small cell lung cancer whose tumors have certain epidermal growth factor receptor activating mutations as detected by an FDA-approved test	US	Oral	In-house (co-development with Roche/ Genentech)	New indication

## Products approved in/after April 2012

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Origin	Remarks
EC905 solifenacin/ tamsulosin	VESOMNI (May 2013)	Fixed dose combination of solifenacin and tamsulosin	Moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy	Europe	Oral	In-house	
FK506 tacrolimus	Prograf (Jun. 2013)	Immunosuppressant	Interstitial pneumonia associated with polymyositis/dermatomyositis	Japan	Oral	In-house	New indication
	ASTAGRAF XL (Jul. 2013)		Prophylaxis of organ rejection in adult kidney transplant recipients (Extended release capsules)	US	Oral		New formulation
FK463 micafungin	MYCAMINE (Jun. 2013)	Candin-type antifungal agent	Treatment of pediatric patients four months and older with Candidemia, acute disseminated candidiasis, <i>Candida</i> peritonitis and abscesses, esophageal candidiasis, prophylaxis of <i>Candida</i> infections in patients undergoing hematopoietic stem cell transplants	US	Injection	In-house	New indication

## Products currently under clinical development

(as of August 1, 2013)

Code No. Generic Name	Classification	Target Disease	Phase I	Phase II	Phase III	Filed	Area	Dosage Form	Origin	Remarks
<b>Urology</b>										
YM905 solifenacin	Muscarine M <sub>3</sub> receptor antagonist	Neurogenic detrusor overactivity and idiopathic overactive bladder in pediatric patients					US/ Europe	Oral	In-house	New indication
EB178 solifenacin/ mirabegron	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder					US/ Europe/ Asia	Oral	In-house	
ASP3652	Inhibition of afferent nerve activity	Bladder pain syndrome/Interstitial cystitis					Europe Japan	Oral	In-house	
ASP4901 (AKP-002)	PDE9 inhibitor	Lower urinary tract symptoms associated with benign prostatic hyperplasia					Japan	Oral	ASKA	
ASP0306		Lower urinary tract symptoms associated with benign prostatic hyperplasia						Oral	In-house	
ASP6432		Lower urinary tract symptoms associated with benign prostatic hyperplasia					Japan	Oral	In-house	
<b>Immunology (including Transplantation) and Infectious Diseases</b>										
certolizumab pegol	PEGylated anti-tumor necrosis factor-alpha antibody	Methotrexate-naive rheumatoid arthritis					Japan	Injection	UCB	New indication* <sup>1</sup>
isavuconazole	Azole antifungal	Invasive aspergillosis					US/ Europe	Injection Oral	Basilea	
		Candidemia/Invasive candidiasis					US/ Europe			
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients					US/ Europe		Vical	
		Cytomegalovirus infection or reactivation in solid organ transplant recipients					Japan US/ Europe			
ASP7374	Influenza vaccine	Prophylaxis of seasonal influenza					Japan	Injection	UMN Pharma	* <sup>1</sup>
ASP7373	Influenza vaccine	Prophylaxis of H5N1 influenza					Japan	Injection	UMN Pharma	* <sup>1</sup>



## Products currently under clinical development

(as of August 1, 2013)

Code No. Generic Name	Classification	Target Disease	Phase I	Phase II	Phase III	Filed	Area	Dosage Form	Origin	Remarks
ASP015K	JAK inhibitor	Rheumatoid arthritis					Japan	Oral	In-house	
							US/ Europe*2			
ASKP1240	Anti-CD40 antagonist	Prevention of organ transplant rejection					US	Injection	Kyowa Hakko Kirin	
							Japan			
ASP2408		Rheumatoid arthritis						Injection	In-house	
ASP2409		Prevention of organ transplant rejection						Injection	In-house	
fidaxomicin		<i>Clostridium difficile</i> associated diarrhea					Japan	Oral	Optimer	

\*1 Local Development (Japan)

\*2 A license agreement was executed with Janssen Biotech, Inc. for the development and commercialization worldwide except for Japan. Phase-IIb studies will be completed by Astellas.

## Oncology

MDV3100 enzalutamide	Androgen receptor inhibitor	Prostate cancer				(13/05)	Japan	Oral	Medivation		
		Prostate cancer (Chemotherapy-naive etc.)					US			New indication	
								Europe			
								Japan			
								Asia			
		Breast cancer					US/ Europe			New indication	
erlotinib	HER1/EGFR tyrosine kinase inhibitor	Non-small cell lung cancer (Adjuvant, combination with MetMab), Pediatric ependymoma					US	Oral	In-house (co-development with Roche/Genentech)	New indication	
ASP3550 degarelix	GnRH antagonist	Prostate cancer (Three-month formulation)					Japan	Injection	Ferring	New formulation*1	
ASP4130 tivozanib	Inhibitor of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3	Colorectal cancer, Breast cancer					US/ Europe	Oral	AVEO		
ASP7487(OSI-906) linsitinib	IGF-1R/IR tyrosine kinase inhibitor	Ovarian cancer, Non-small cell lung cancer					US	Oral	In-house		
AGS-16M8F/ AGS-16C3F		Cancer (ADC technology)						Injection	In-house (In-licensing of ADC technology from Seattle Genetics)		
ASP1707	GnRH antagonist	Prostate cancer					Europe	Oral	In-house		
ASP3026		Cancer						Oral	In-house		
ASG-22ME		Cancer (ADC technology)						Injection	In-house (co-development with Seattle Genetics)		
ASP9853		Cancer						Oral	In-house		
ASG-15ME		Cancer (ADC technology)						Injection	In-house (co-development with Seattle Genetics)		
ASP2215		Cancer						Oral	In-house		
AMG 102 rilotumumab		Gastric cancer					Japan	Injection	Amgen (co-development with Amgen Astellas)	*	

\* Local Development (Japan)

Products currently under clinical development

(as of August 1, 2013)

Code No. Generic Name	Classification	Target Disease	Phase I	Phase II	Phase III	Filed	Area	Dosage Form	Origin	Remarks
<b>midazolam</b>	Benzodiazepine sedative	Conscious sedation in dentistry and dental surgery				(13/02)	Japan	Injection	Roche	New indication* <sup>1</sup>
<b>FK949E quetiapine</b>	Serotonin/dopamine antagonist	Depressive episode in bipolar disorders					Japan	Oral	AstraZeneca	New indication/ New formulation* <sup>1</sup>
		Major depressive disorder					Japan			
<b>NGX-4010 capsaicin</b>	TRPV1 agonist	Peripheral diabetic neuropathy					Europe	Patch	NeurogesX	New indication* <sup>2</sup>
<b>ASP8477</b>		Neuropathic pain						Oral	In-house	
<b>ASP9226</b>		Neuropathic pain						Oral	In-house	
<b>ASP3662</b>		Alzheimer's disease						Oral	In-house	

\*1 Local Development (Japan)

\*2 Local Development (Europe)

DM Complications and Kidney Diseases, Others

<b>ASP1941 ipragliflozin</b>	SGLT2 inhibitor	Type 2 diabetes				(13/03)	Japan	Oral	In-house (co-development with Kotobuki)	*
<b>YM060 ramosetron</b>	5-HT3 receptor antagonist	Diarrhea-predominant irritable bowel syndrome in male (Orally-disintegrating tablet)				(12/08)	Japan	Oral	In-house	New formulation* <sup>1</sup>
		Irritable bowel syndrome Female patients					Japan			New indication*
<b>YM533 beraprost sodium</b>	Prostacyclin receptor stimulator	Chronic renal failure (primary, nephrosclerosis)					Japan/ Asia	Oral	Toray	New indication/ New formulation*
<b>ASP1585 (AMG223) bixalomer</b>	Amine-functional polymer	Hyperphosphatemia in patients not on dialysis with chronic kidney disease					Japan	Oral	Ilypsa/ Amgen	New indication*
<b>ASP1517 (FG-4592)</b>	HIF stabilizer	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis					Europe	Oral	FibroGen	
							Japan			
<b>YM311 (FG-2216)</b>	HIF stabilizer	Renal anemia					Europe	Oral	FibroGen	
							Japan			
<b>nateglinide</b>	Fast acting insulin secretion enhancer	Type 2 diabetes Combination with DPP-4 inhibitors					Japan	Oral	Ajinomoto	New indication*
<b>AMG 785 romosozumab</b>	Anti-Sclerostin monoclonal antibody	Osteoporosis					Japan	Injection	Amgen (co-development with Amgen Astellas)	*
<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	*
<b>AMG 145</b>	Anti-PCSK-9 monoclonal antibody	Hyperlipidemia					Japan	Injection	Amgen (co-development with Amgen Astellas)	*
<b>ASP7991</b>		Secondary hyperparathyroidism						Oral	In-house	
<b>ASP8232</b>		Diabetic nephropathy						Oral	In-house	
<b>ASP3325</b>		Hyperphosphatemia						Oral	In-house	
<b>CK-2127107</b>		Skeletal muscle disease (non-neuromuscular indications)						Oral	Cytokinetics	

\* Local Development (Japan)

# Review of Operations by Therapeutic Area

## Urology

With Vesicare and mirabegron in its lineup, Astellas is going to be an overwhelming leader in the OAB field.

Urology is a therapeutic area in which Astellas has established its status as a Global Category Leader (GCL). Through sales of Harnal and Vesicare, we command a strong presence in the market for drugs used to treat the conditions of benign prostatic hyperplasia (BPH) and overactive bladder (OAB). Based on this solid status, we are working on various initiatives to further solidify our business foundation by launching new products into the market.

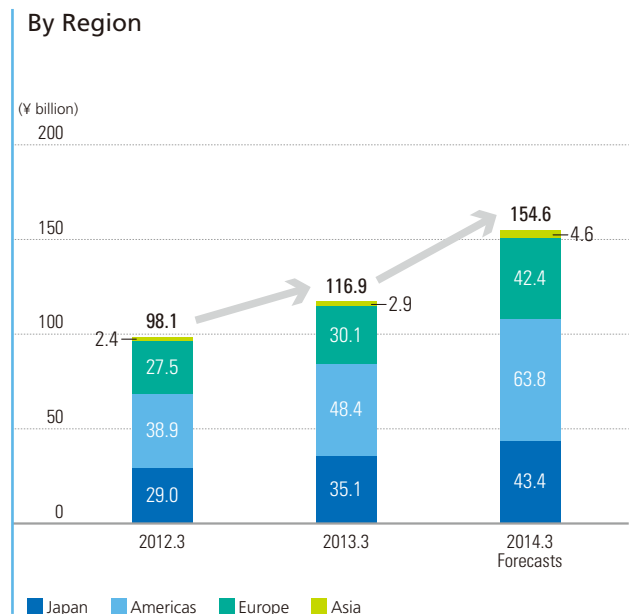
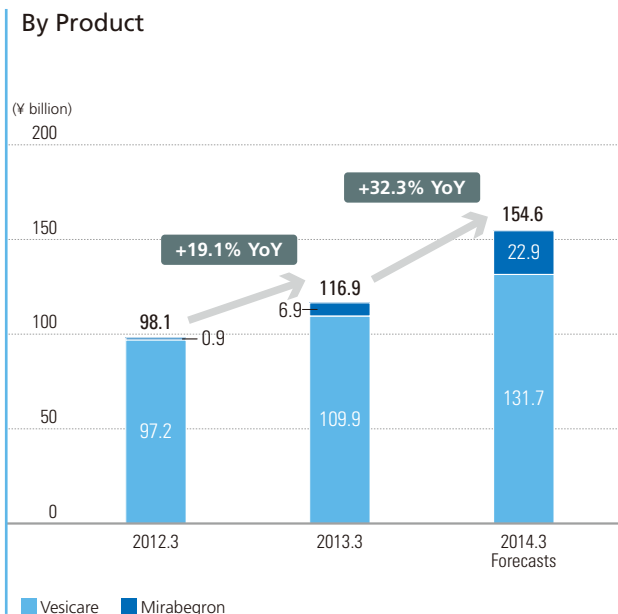
In fiscal 2012, sales of Vesicare showed steady growth in all geographic regions. In addition to Vesicare, sales in the OAB treatment market were boosted by successive launches of mirabegron (generic name). Following the first release under the brand name Betanis in Japan in September 2011, we launched the drug in the United States in October 2012 under the brand name Myrbetriq, and in Europe in February 2013 under the brand name BETMIGA. With anticholinergics including Vesicare as the current OAB treatment standard, the release of mirabegron, which is a beta-3 adrenergic receptor agonist and different from anticholinergics, is expected to bring a new treatment option for OAB patients.

In fiscal 2012, combined sales of Vesicare and mirabegron amounted to ¥116.9 billion, up 19.1% year on year. On a geographical basis, we recorded double-digit sales growth in all four regions of Japan, Europe, the Americas, and Asia. Going forward, we will strive to maximize total sales of Vesicare and mirabegron with the intention of becoming the undisputed leader in the OAB treatment market.

Sales of Harnal declined in Japan and Europe due to the impact of price reductions and the erosion of generic versions. By contrast, sales of Harnal continued increasing in Asia.

In the field of urology, we received marketing authorization in Europe for VESOMNI, a Vesicare/Harnal combination drug, in May 2013. In addition, Astellas has several other compounds under clinical development as potential candidates for treating urological conditions, which include EB178 (concomitant use of solifenacin and mirabegron) and ASP3652 (for the treatment of bladder pain syndrome/interstitial cystitis).

### Total Sales of Vesicare and Mirabegron



# Immunology (including Transplantation) and Infectious Diseases

Astellas aims to make further contributions to transplant community while maximizing the value of its Prograf business.

In the field of immunology, including transplantation, Astellas is working to maximize the value of its Prograf business on a global scale.

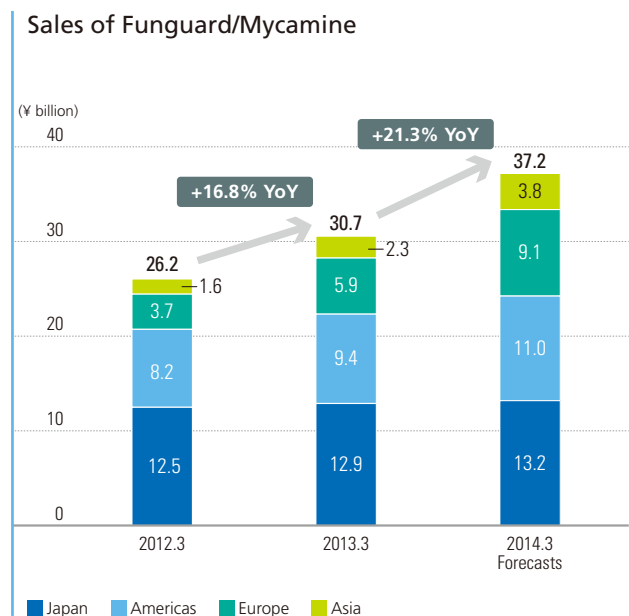
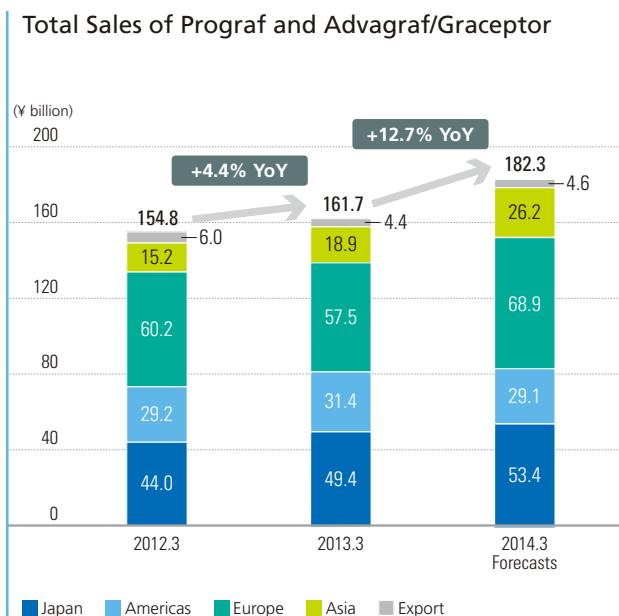
In fiscal 2012, sales of Prograf (including the once-daily formulation Graceptor/Advagraf) increased 4.4% year on year, to ¥161.7 billion. Although generic products had a negative impact on sales in the Americas and Europe, higher sales in Japan and Asia contributed to firm sales on a global level. Sales in the Americas increased 2.4% year on year on a U.S. dollar basis, owing to a slowdown in growth of the market share held by generic drugs, as well as temporary factors during the period. Sales continued rising steadily in Japan and Asia thanks to the once-a-day formulation of Graceptor/Advagraf, as well as steady sales for the treatment of rheumatoid arthritis and other autoimmune disease indications. Meanwhile, although sales of Advagraf continued growing in Europe, sales through our own distribution channel recorded a 2.9% decline on a euro basis due to price reductions in multiple countries and the impact

of generic products.

In March 2013, Cimzia (generic name: certolizumab pegol), for the treatment of rheumatoid arthritis, was released in Japan, which was in-licensed from UCB.

In the field of infectious diseases, sales of Funguard/MYCAMINE rose 16.8% year on year, owing to steady sales in Japan and the Americas, as well as demand growth in Europe and Asia. In May 2012, DIFICLIR was launched in Europe, a drug for the treatment of *Clostridium difficile* infections, which was in-licensed from Optimer Pharmaceuticals, Inc.

Astellas has a number of candidate compounds in the clinical development stage, which include ASP015K (for the treatment of rheumatoid arthritis) and ASKP1240 (for the prevention of organ transplant rejection) in the field of immunology (including transplantation). Candidates in the field of infectious diseases include the azole antifungal isavuconazole, the DNA vaccine for cytomegalovirus ASP0113, and the influenza vaccines ASP7373 and ASP7374.



# Oncology

Astellas intends to establish a Global Category Leader position in the field of oncology, with enzalutamide as a driving force.

Astellas is focusing on establishing a Global Category Leader (GCL) position in the field of oncology after urology and transplantation.

In fiscal 2012, we added two more drugs to our oncology lineup. The new products, XTANDI and Gonax, are both used for the treatment of prostate cancer, and join Tarceva (for the treatment of non-small cell lung cancer and pancreatic cancer) and Eligard (for the treatment of prostate cancer) in the oncology market. We will seize the opportunity presented by this expanded lineup to reinforce our business platform in the oncology field. Combined sales of these four products in this area reached ¥64.4 billion in fiscal 2012, up 35.2% from the previous year, and we expect further sales growth in the future.

XTANDI was launched in the United States in September 2012 for the indication of metastatic castration-resistant prostate cancer in patients who have previously received docetaxel. XTANDI made a successful start with sales of

US\$146 million in fiscal 2012. As for Europe, XTANDI was launched in the United Kingdom in July 2013. In Japan too, we filed an application for approval in May 2013. We are currently holding clinical trials for patients with earlier-stage prostate cancer and breast cancer with the aim of expanding XTANDI's indications.

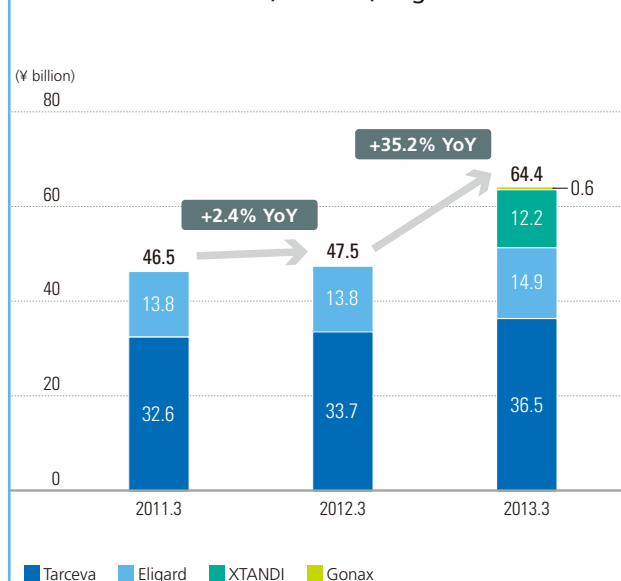
In fiscal 2012, Tarceva-related revenues grew steadily, increasing 3.1% year on year on a U.S. dollar basis, to US\$439 million. In the United States, Astellas is co-promoting Tarceva with Genentech, Inc., with earnings split equally. In regions outside the United States, Astellas has a license agreement with F. Hoffmann-La Roche Ltd and receives royalties based on sales.

Sales of Eligard, which is marketed in Europe, steadily rose 9.7% year on year, to €139 million.

In Japan, Gonax was released in October 2012.

As for new drug candidates, clinical trials are also ongoing for more than ten projects in the oncology field at present.

Total Sales of XTANDI, Tarceva, Eligard and Gonax



Oncology Pipeline

(as of August 1, 2013)

	Project	P1	P2	P3	Filed	
Small molecule	Enzalutamide (XTANDI)	Prostate cancer: Japan				
		Prostate cancer: Pre-chemo, EU/US/ Japan/Asia				
		Breast cancer (BC): EU/US				
	Erlotinib (Tarceva)	Non-small cell lung cancer, Pediatric ependymoma: US				
	Degarelix (Gonax)	Prostate cancer: Japan (3M formulation)				
	Tivozanib ASP4130	Colorectal cancer, BC: EU/US				
	Linsitinib ASP7487 (OSI-906)	Ovarian cancer, Non-small cell lung cancer: US				
	ASP1707	Prostate cancer				
	ASP3026	Cancer				
	ASP9853	Cancer				
ASP2215	Cancer					
Antibody	AGS-16M8F/AGS-16C3F	Renal cancer				
	ASG-22ME	Solid tumors				
	ASG-15ME	Bladder cancer				
	Rilotumumab	Gastric cancer				
	AMG 102	Gastric cancer				

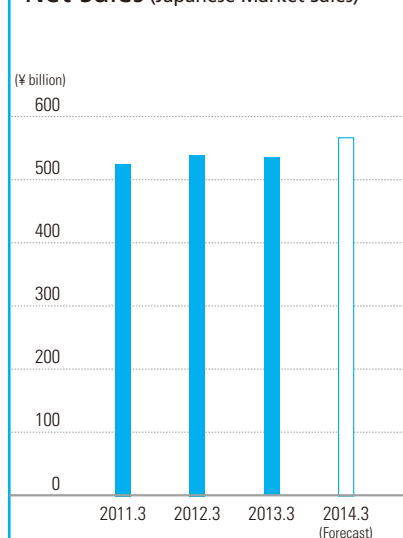
## Review of Global Operations

# Japan

We are further enhancing our business platform through the successive launch of new products.

### ► Fiscal 2012 Overview

#### Net Sales (Japanese Market Sales)



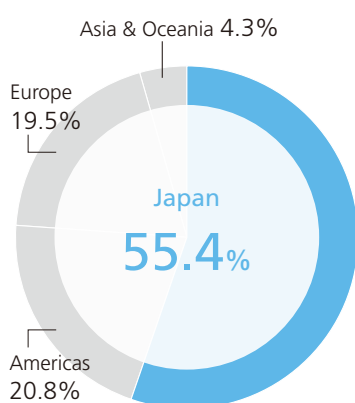
Note: Invoiced prices base

Net sales in Japan in fiscal 2012 amounted to ¥557.5 billion, down 0.2% from the previous year. This included ¥535.8 billion in the domestic prescription drug market, which is a slight decrease by 0.8% despite an NHI drug price revision in April 2012 and the impact of generic products.

By product, sales of Vesicare rose 6.2% from the previous year. Sales of Betanis, launched in September 2011, reached ¥5.3 billion, contributing with Vesicare to the further expansion of our share of the overactive bladder (OAB) treatment market. Sales of Prograf continued growing, recording a 12.2% increase. Sales of the Micardis product line, including the combination drugs Micombi and Micamlo, were favorable, up 5.0% from the previous term. We also reported steady sales increases for Symbicort, Celecox, and Bonoteo. Meanwhile, the impact of generic drugs resulted in lower sales of Lipitor, Harnal, and Gaster. During the year, we launched Kiklin, Regnite, Gonax, Quattrovac, and Cimzia in Japan.

#### Sales by Geographical Area

2013.3



Note: Yen base  
Calculated according to the location of sellers

#### Sales of Major Products

		¥ billion		
		2012.3	2013.3	2014.3 (Forecasts)
Prescription drugs sales in Japanese market		539.9	↓ 535.8	↑ 567.3
Hypercholesterolemia treatment	Lipitor	96.3	↓ 70.6	↓ 65.1
	Caduet	4.9	↑ 9.6	
Hypertension treatment (Long-acting angiotensin II receptor blocker)	Micardis	85.3	↑ 89.6	↑ 100.6
	Micombi	10.4	↑ 11.5	
	Micamlo	10.6	↑ 15.6	
Immunosuppressant	Prograf	44.0	↑ 49.4	↑ 53.4
Treatment for peptic ulcers and gastritis	Gaster	37.5	↓ 30.2	↓ 27.3
Insomnia treatment	Myslee	35.2	↓ 32.2	↓ 29.8
Anti-inflammatory agent (Selective COX-2 inhibitor)	Celecox	33.0	↑ 37.4	↑ 48.5
OAB treatment	Vesicare	28.0	↑ 29.8	↑ 32.4
Schizophrenia treatment	Seroquel	27.8	↑ 28.5	↓ 22.9
Treatment for the functional symptoms associated with benign prostatic hyperplasia	Harnal	27.4	↓ 22.9	↓ 21.4
Vaccines		26.5	↑ 28.8	↑ 34.1
Treatment for adult bronchial asthma	Symbicort	20.0	↑ 27.7	↑ 35.6
Candin-type antifungal agent	Funguard	12.5	↑ 12.9	↑ 13.2
Oral quinolone antibiotic	Geninax	11.9	↑ 12.3	↑ 13.8
Treatment for osteoporosis	Bonoteo	5.0	↑ 10.6	↑ 17.5
OAB treatment	Betanis	0.9	↑ 5.3	↑ 10.9

Note: Invoiced prices base



**Yukihiko Sato**

Senior Vice President  
and President,  
Sales & Marketing-Japan



**► Fiscal 2013 Outlook**

For fiscal 2013, we project a 4.5% year-on-year increase in domestic sales, to ¥582.6 billion. This estimate includes a 5.9% sales rise in Japan's prescription drug market, to ¥567.3 billion. We expect sales growth for such drugs as Vesicare, Prograf, Micardis (including Micombi and Micamlo), Symbicort, Celecox, and Bonoteo, as well as for new drugs, including Betanis, Gonax, and Cimzia. However, we project decreases in sales of Lipitor, Gaster, Myslee, and Seroquel.

**Launch of New Products (2012.4-2013.6)**

2012	2013
<b>Jun.</b> Kiklin launch (Hyperphosphatemia)	<b>Jan.</b> ARGAMATE Granule launch (Hyperkalemia)
<b>Jul.</b> Regnite launch (Restless legs syndrome)	<b>Mar.</b> Cimzia launch (RA not responding to conventional therapy)
<b>Oct.</b> Gonax launch (Prostate cancer)	<b>May</b> Micamlo BP launch (Hypertension)
<b>Oct.</b> Launch of Quattrovac Subcutaneous Injection Syringe, Combined vaccine	<b>Jun.</b> Acofide launch (Functional dyspepsia)

**We will become the market leader in Japan by leveraging our top-level sales and marketing platform.**

Astellas is building a top-level sales and marketing platform in terms of both quality and quantity in Japan. We have approximately 2,400 Medical Representatives (MRs) covering medical institutions throughout Japan, and we are reinforcing efforts aimed at becoming the domestic market leader as set out in our Mid-Term Management Plan.

Net sales in Japan in fiscal 2012 decreased slightly on the back of the NHI drug price revisions and the impact of generic products. However, the launch of new drugs, such as Gonax and Cimzia, released during the period further expanded Astellas' broad product portfolio. Sales of our global offerings Vesicare, Betanis and Prograf, as well as our mainstay products in Japan such as Micardis, Celecox, Bonoteo and Symbicort, are continuing to grow.

Astellas is facing major changes in its business environment, including measures implemented by the government targeting the optimization of medical expenditures and revisions to the voluntary standards of the industry covering the activities of MRs. The quality of our sales and marketing organization, including the MR activities, are being put to the test now in Japan.

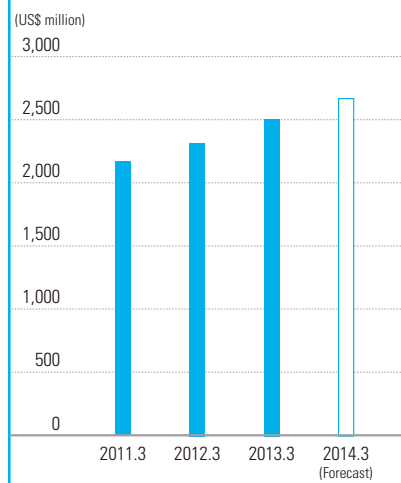
By seizing the opportunities presented by such changes, we remain committed to meeting unmet medical needs through the ongoing delivery of new drugs with high value to patients.

# Americas

We will further reinforce our No. 1 position in the OAB treatment market and solidify our business platform in oncology.

## ► Fiscal 2012 Overview

### Net Sales



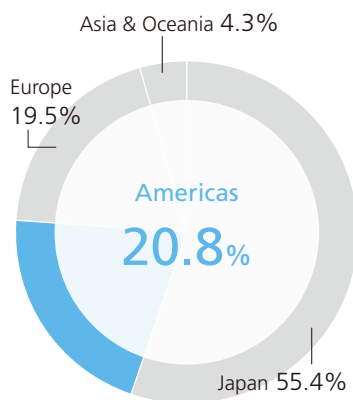
Note: U.S. dollar base

Net sales in the Americas amounted to US\$2,512 million, up 8.2% from the previous year on a U.S. dollar basis. When converted to yen, net sales grew 13.7% to ¥208.7 billion.

By product, we recorded steady sales of two new drugs launched during the year. Specifically, we posted US\$146 million in sales of XTANDI, a drug for treating prostate cancer, launched in September 2012, and US\$19 million in sales of the overactive bladder (OAB) treatment Myrbetriq, launched a month later in October 2012. Sales of VESicare were strong, increasing 14.3% on a U.S. dollar basis. Our share of the total prescription market for OAB treatments, including VESicare and Myrbetriq, expanded following the release of Myrbetriq, reaching around 25% as of March 2013. Sales of Prograf rose 2.4% on a U.S. dollar basis due to temporary factors in fiscal 2012. We also reported increased sales of Lexiscan, MYCAMINE, and Tarceva which contributed to higher revenue in the Americas.

### Sales by Geographical Area

2013.3



Note: Yen base  
Calculated according to the location of sellers

### Sales of Major Products

		(US\$ million)		
		2012.3	2013.3	2014.3 (Forecasts)
Sales in the Americas		2,320	↑ 2,512	↑ 2,672
Immunosuppressant	Prograf	370	↑ 378	↓ 291
Pharmacologic stress agent	Scan (Adenoscan and Lexiscan)	619	↑ 639	↓ 508
	Lexiscan	536	↑ 572	
Antifungal agent	AmBisome	69	↑ 76	↓ 68
Treatment for atopic dermatitis	Protopic	94	↑ 95	↑ 106
OAB treatment	VESicare	492	↑ 563	↓ 535
OAB treatment	Myrbetriq (launched in October 2012)	—	↑ 19	↑ 102
Candin-type antifungal agent	MYCAMINE	104	↑ 114	↓ 110
	Tarceva	426	↑ 439	
Lung and pancreatic cancer treatment	US	250	↑ 284	
	Outside of the US	175	↓ 155	
Prostate cancer treatment	XTANDI	—	↑ 146	↑ 400



## Masao Yoshida

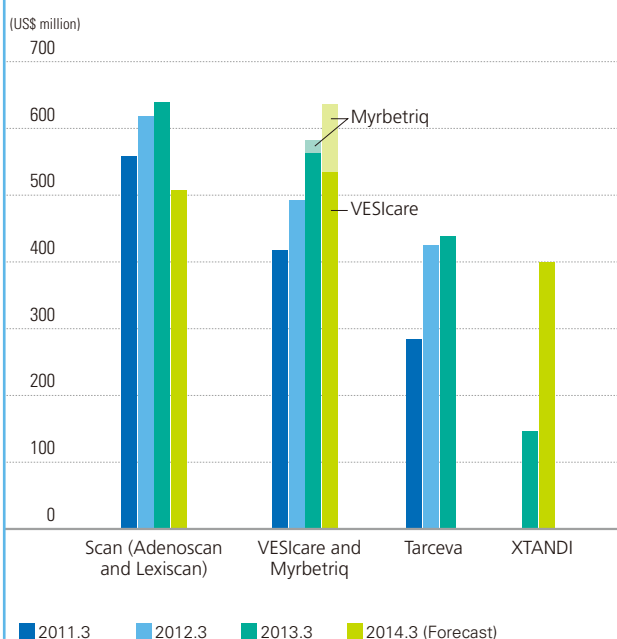
President and CEO,  
Astellas US LLC



### ► Fiscal 2013 Outlook

We forecast regional net sales of US\$2,672 million, a year-on-year increase of 6.4% on a U.S. dollar basis. This forecast is equivalent to ¥267.2 billion, up 28.0% in Japanese yen terms. We expect sales of XTANDI to make a substantial contribution to revenue. Although we forecast a decline in sales of VESicare, we anticipate growth in sales of Myrbetriq, with combined sales of the two OAB treatments projected to grow 10% on a U.S. dollar basis. Meanwhile, sales of Prograf and the pharmacologic stress agents Adenoscan and Lexiscan are expected to decline due to the impact of generics.

### Sales/Revenues of Mainstay Products



### We will strengthen our position in urology and oncology.

In the Americas, multiple products in our core therapeutic areas have maintained top market share. This has been supported by Astellas' effective, high-quality commercial operations that keep pace with the constantly changing business environment. In addition, the strong sales networks in Canada and Latin America are helping drive growth across the broader Americas region.

As a result of fully harnessing these strengths, the successful release of Myrbetriq and XTANDI in fiscal 2012 was quickly followed by the steady penetration of both new offerings into the market. By maximizing sales of both Myrbetriq and VESicare, we are further reinforcing our No. 1 position in the OAB treatment market. We will also capitalize on the launch of XTANDI to further solidify our business platform in oncology.

In the United States, the business environment remains challenging due to sluggish macroeconomic recovery and more stringent screening and regulatory requirements when filing new drug applications. It is imperative that we keep a close eye on the healthcare policies and market access trends amid a fierce competitive landscape.

Under these conditions, we will strengthen our position in each market in the Americas by growing our urology and oncology businesses.

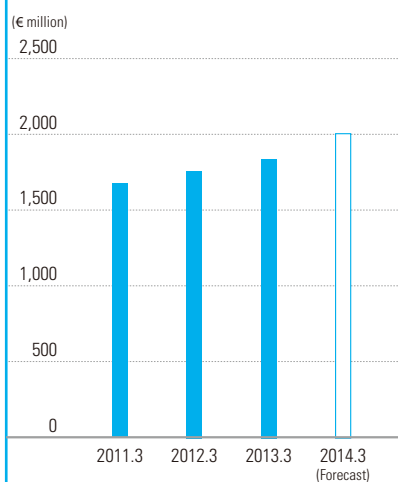
# Europe\*

We will focus on continuous growth by maintaining and expanding the therapeutic areas of urology, transplantation, and infectious diseases, and expanding our reach in the region.

\*includes Europe (including NIS countries), the Middle and Near East, and Africa

## ► Fiscal 2012 Overview

### Net Sales



Note: Euro base

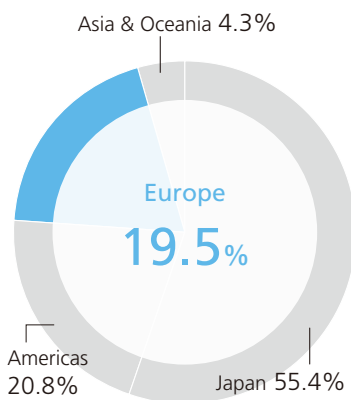
In the year under review, net sales in Europe grew 4.2%, to 1,834 million on a euro basis. When converted to yen, net sales rose 2.5%, to ¥196.5 billion.

By products, sales of Vesicare continued growing, up 11.1% on a euro basis, and sales of MYCAMINE and Eligard also rose steadily. Sales of Prograf through our own distribution channel, including the once-daily formulation Advagraf, declined 2.9% in euro terms due to several factors, such as price reductions in each country and the impact of generic products, even though sales of Advagraf continued to grow. Sales of Omnic through our own distribution channel, which goes by the brand name Harnal in Japan, decreased due to price reductions and the impact of generic drugs.

In fiscal 2012, we launched BETMIGA, a treatment for overactive bladder (OAB), and DIFICLIR for the treatment of *Clostridium difficile* infections.

### Sales by Geographical Area

2013.3



Note: Yen base  
Calculated according to the location of sellers

### Sales of Major Products

		(€ million)		
		2012.3	2013.3	2014.3 (Forecasts)
Sales in Europe		1,759	↑ 1,834	↑ 2,004
Treatment for the functional symptoms associated with benign prostatic hyperplasia	Harnal (Omnic, Omnic OCAS)	209	↓ 180	↓ 166
	Sales by Astellas	165	↓ 143	↓ 136
	Bulk and Royalties	43	↓ 36	↓ 30
Immunosuppressant	Prograf and Advagraf (Incl. exports to third parties)	606	↓ 577	↓ 565
	Sales by Astellas	552	↓ 536	↓ 530
	Exports to third parties	54	↓ 40	↓ 35
OAB treatment	Vesicare	252	↑ 280	↑ 314
OAB treatment	BETMIGA (launched in February 2013)	—	0	↑ 12
Treatment for atopic dermatitis	Protopic	46	↓ 43	↑ 47
Candin-type antifungal agent	MYCAMINE	34	↑ 55	↑ 70
Advanced prostate cancer treatment	Eligard	127	↑ 139	↑ 155
Peripheral neuropathic pain treatment	Qutenza	5	↑ 8	



**Ken Jones**

Astellas Pharma Europe Ltd.  
President and CEO



► **Fiscal 2013 Outlook**

In fiscal 2013, we project a 9.3% increase in regional net sales, to €2,004 million. This equates to ¥260.6 billion in yen terms, representing a 32.7% increase. Our forecast is based on ongoing growth in Vesicare sales, as well as increases in sales of MYCAMINE and Eligard. We also expect sales of the recently launched XTANDI and BETMIGA to contribute to increased revenues. Although sales of Prograf and Omnic are forecast to decline, we expect the foreign exchange impact to result in higher sales for these two products on yen basis.

**Our presence is also growing in Russia and NIS countries.**

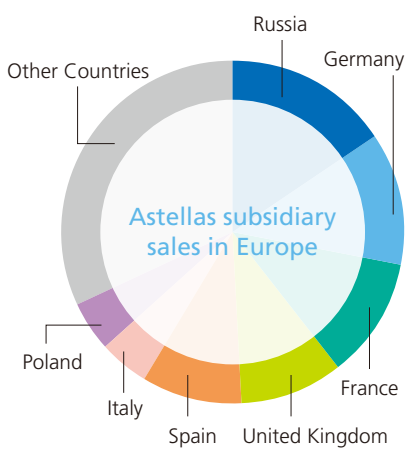
Astellas has a broad business platform in Europe that continues growing.

In fiscal 2012, the rate of Astellas' sales increase in Europe outstripped overall market growth rate. Highlights include strong growth in Russia and other NIS countries as the sales subsidiary for these countries recorded the highest level of sales in Europe for the period, growing their presence in the region.

During the year, we released two new products: DIFICLIR and BETMIGA. These were followed in July 2013 by the launch of XTANDI in the United Kingdom. While we have established a sales organization for the oncology area managing all of Europe, our sales subsidiaries are also setting up their own sales and marketing networks. The gradual release of DIFICLIR and BETMIGA in additional countries will help drive growth in the region.

The effects of policies to curb medical expenditures accompanying ongoing austerity measures in Europe, including a reduction in drug prices, are emerging. Furthermore, we face more difficulties to obtain the approval of new drugs and insurance reimbursements. Even in this environment, Astellas will strive to achieve sustainable growth through the delivery of new products that meet unmet medical needs.

**Sales by European Subsidiary\***



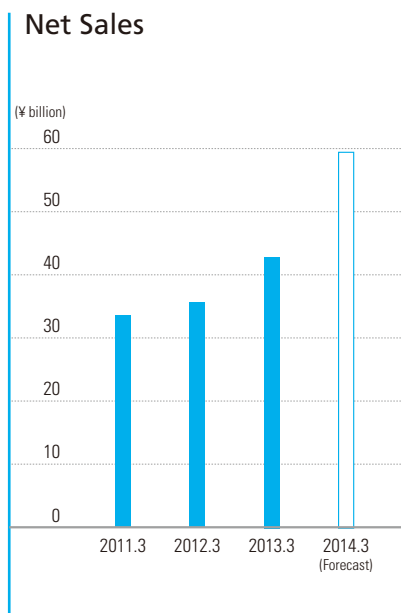
\* Sales share of each subsidiary in aggregate sales in Europe through its own distribution channels

# Asia & Oceania

We will achieve sustainable growth with China as the driving force.

## ► Fiscal 2012 Overview

### Net Sales

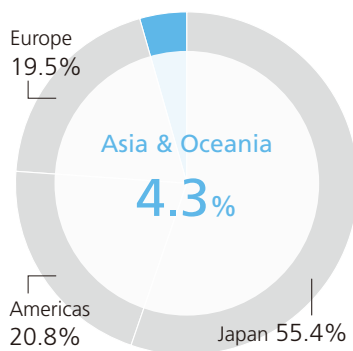


Net sales in Asia increased 20.1% year on year, to ¥42.9 billion. Excluding the foreign exchange impact, sales maintained double-digit growth, up 13.7% from the previous year. Particularly, we reported strong growth in China, accounting for nearly 50% of sales in the Asian region, with sales rising approximately 22% on a local currency basis.

By product, sales of all mainstay products, including Prograf, Harnal, Vesicare, and MYCAMINE, increased during the year. In emerging countries such as Asia, we are working to expand our business through our own high-value products, like we are doing in developed nations. In the year under review, we released a succession of products around the region. These included FEBURIC, the treatment of gout, in Taiwan in May 2012 and in Hong Kong in August 2012, as well as Advagraf in Singapore and Malaysia in August 2012 and January 2013, respectively.

### Sales by Geographical Area

2013.3



Note: Yen base  
Calculated according to the location of sellers

### Sales of Major Products

		Sales (¥ billion)		
		2012.3	2013.3	2014.3 (Forecasts)
Sales in Asia & Oceania		35.7	42.9	59.5
Immunosuppressant	Prograf	15.2	18.9	26.2
Treatment for the functional symptoms associated with benign prostatic hyperplasia	Harnal	9.8	10.8	14.4
OAB treatment	Vesicare	2.4	2.9	4.6
Candin-type antifungal agent	MYCAMINE	1.6	2.3	3.8
Treatment for atopic dermatitis	Protopic	1.2	1.7	2.6

## Shinichiro Katayanagi

Senior Vice President and  
President, Asia International

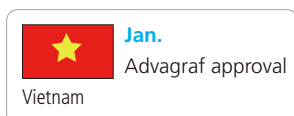
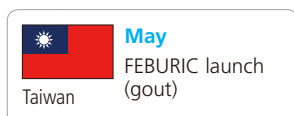


## ► Fiscal 2013 Outlook

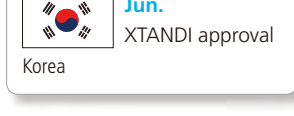
In fiscal 2013, we project regional net sales of ¥59.5 billion, up 38.7%. Excluding the foreign exchange rate impact, we forecast continued double-digit growth of around 14%. This includes a strong year-on-year sales increase in China of around 25% in local currency terms. By product, we forecast steady sales growth for all mainstay products, including Prograf, as well as Harnal, Vesicare, and MYCAMINE.

## Continuous Product Introductions (Approvals and Launches) (2012.4-2013.6)

2012



2013



## We will expand our business by focusing on high-value-added proprietary products.

Astellas has an extensive business platform in the Asia & Oceania region, with ten sales subsidiaries including the one established in Singapore in July 2013. Our key strategy is to focus on high-value-added proprietary drugs and maximize product value, including Prograf and Harnal.

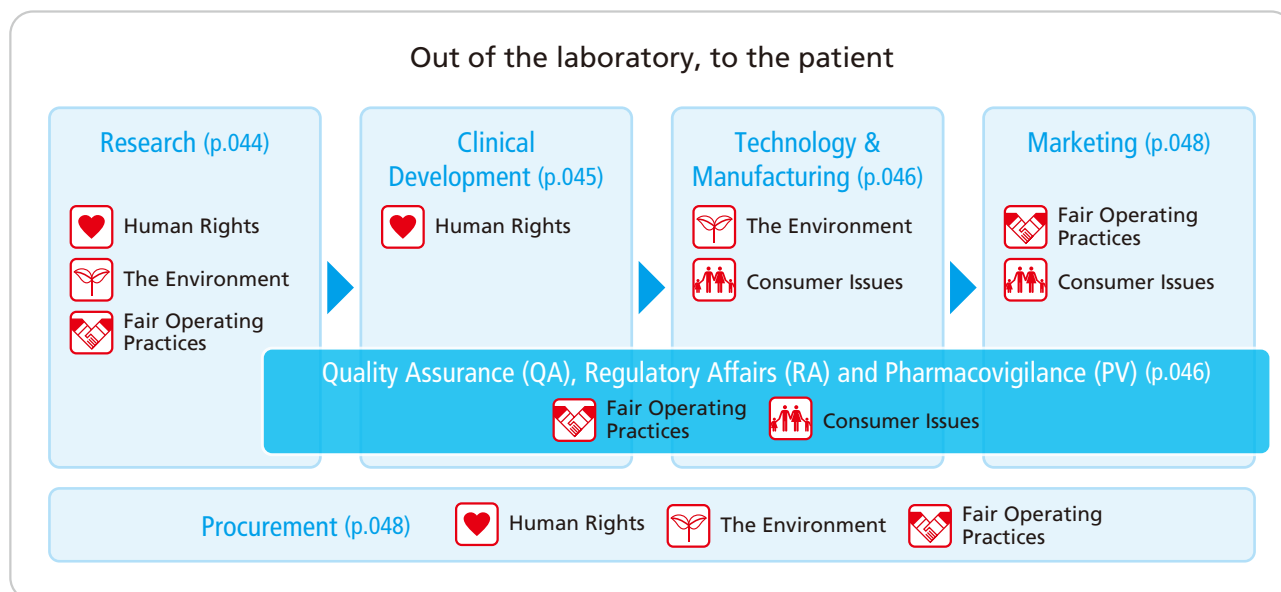
In fiscal 2012, sales of all mainstay products recorded continued growth. In particular, we have enjoyed steady sales increases for Prograf, which is driving our growth in the region as a strategic product. Looking ahead, we expect to release new drugs successively in each country in fiscal 2013, including anti-cancer agents, and we will further expand our business in the region.

To expand the business, we will promote our marketing strategy while paying attention to various systems for intellectual properties and healthcare in each country, and understanding characteristics of the particular market accurately.

Astellas will continue investment in China, a market that consistently achieves high growth. At present, our expansion in that country is sustained by a sales force of about 700 MRs. Going forward, we plan to focus on human resource development while increasing the number of MRs.

# CSR Initiatives in Business Processes

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



Of the CSR initiatives in each business process, the chart shows whether the contents of this section relates to certain core subjects of ISO26000, which is an international standard for social responsibility.

## 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, ethical considerations in the use of specimens derived from humans, and ethical considerations relating to animal testing. In addition, we properly consider the risk of biohazards affecting humans and ecosystems.

\* 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 (COP10) adopted a set of international protocols 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 agreements. Going forward, Astellas will continue using genetic resources appropriately for the development of pharmaceuticals pursuant to international agreements.

## 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.

Especially in Japan, we established the Ethics Review Board on Human Tissue Research, consisting of members of the public and experts in the fields of the natural sciences, the social sciences, and the humanities. The Committee deliberates on the scientific propriety and the ethical acceptability of research on human genome and the use

of tissue samples derived from humans. In fiscal 2012, the Committee met 11 times and deliberated on 35 issues.

### Ethical Considerations in Animal Testing

Astellas has established the Institutional Animal Care and Use Committee, in which outsiders participate as committee members in overseeing the Company's animal testing and breeding plans in Japan. In addition to internal guidelines that consider animal welfare, the committee applies the three Rs<sup>\*1</sup>, plus a fourth principle, which is "Responsibility" (responsibility in animal testing). The committee also rigorously screens animal breeding environments, facilities, and activities. Moreover, the committee confirms 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) <sup>\*2</sup>, a third-party assessment organization. In addition, our U.S. subsidiaries Agensys and OSI Pharmaceuticals have acquired the same accreditation.

<sup>\*1</sup> 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 principles which the international community is following to encourage the humane care and use of laboratory animals.

<sup>\*2</sup> 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.

#### Clinical Development



Astellas conducts clinical trials in which it assesses the efficacy and safety in humans of drug candidate substances. Under the Declaration of Helsinki, while protecting the human rights and personal information of participants, we must ensure safety and reliability in conducting clinical trials. Astellas has established the Ethics Committee inside the Company that monitors and checks ethical propriety and scientific validity from the clinical trial formulation stage. We observe ICH<sup>\*1</sup> Guidelines<sup>\*2</sup>, which include Good Clinical Practice<sup>\*3</sup>, in the conduct of

clinical trials. Moreover, our clinical trials are conducted only at medical institutions complying with these guidelines. We obtain informed consent from patients who participate in clinical trials. In line with these guidelines, we undertake drug development activities with the aim of providing patients with the drugs they need as quickly as possible.

### Responding to Biohazards

Testing using genetically modified organisms, pathogens, or materials containing pathogens are performed according to the laws of individual countries. In Japan, we have established biosafety management rules and meticulous handling procedures. We also set up the Biosafety Committee to share and resolve various issues and conduct appropriate training, in order to ensure safe, proper management and utilization of these organisms and the like. In the United States, we file for and obtain approval to perform such testing from FDA<sup>\*1</sup>, USDA<sup>\*2</sup>, and various state governments.

<sup>\*1</sup> FDA: U.S. Food and Drug Administration

<sup>\*2</sup> USDA: United States Department of Agriculture

### Handling of Intellectual Property

As a research and development-oriented pharmaceutical company, Astellas regards its intellectual property (patents in particular) relating to new compounds or other findings as valuable business assets. Starting from when they join the Company, employees receive ongoing training to raise their awareness on obtaining patents and swiftly making patent applications and acquiring rights. At the same time, we emphasize respecting the rights of others. When commencing research, therefore, we make sure our research does not infringe on third-party patents, and if necessary, we obtain approval to use them so as not to infringe on the patent estate of others.

clinical trials. Moreover, our clinical trials are conducted only at medical institutions complying with these guidelines. We obtain informed consent from patients who participate in clinical trials. In line with these guidelines, we undertake drug development activities with the aim of providing patients with the drugs they need as quickly as possible.

<sup>\*1</sup> 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.

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

<sup>\*3</sup> Good Clinical Practice: An international quality standard for clinical trials of pharmaceuticals.

## Technology & Manufacturing



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

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 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 minimize environmental impact and safety risks at the time of commercial production. At multiple stages in the production research process, we establish various research objectives, such as reducing the volume of dangerous and harmful solvents and finding safe alternatives to such solvents, apply the results to production, and verify outcomes.

Astellas is implementing the aforementioned assess-

ments at its production facilities in Japan and is transferring the technologies to its overseas plants. In this way, we are spreading improvements realized via these assessments throughout the group.

For more information on our environmental initiatives, which also include reducing emissions of greenhouse gases and recycling resources, please refer to the Environment section on page 065.

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

## Recycling of Packaging Materials and Safe Disposal of Drugs

After using prescription drugs, their containers and packaging are discarded at hospitals, pharmacies, or regular households. The packaging of pharmaceutical products must maintain the stability of products and display information specified under the Pharmaceutical Affairs Act. However, Astellas goes even further, by also adding information that encourages recycling at the time of disposal. In Japan, companies are required to shoulder the cost of recycling containers and packaging discarded by regular households, pursuant to the Containers and Packaging Recycling Law.

Procedures and methods for collecting and disposing of unused drugs differ according to nation, and for this reason we follow the rules of individual countries.

## QA, RA and PV



Astellas' Quality Assurance (QA), Regulatory Affairs (RA) and Pharmacovigilance (PV) ensure that accurate information is provided together with its high-quality products with verified efficacy and safety.

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 actively works on measures to deliver safe and high-quality products to patients around the world. As part of this effort, we established the Chief Medical Officer (CMO) position on April 1, 2013. In addition, we have global heads to coordinate the Company's organizations for Pharmacovigilance, Medical Affairs, Regulatory Affairs, Clinical and Research Quality Assurance, and Quality Assurance in each region, which constitute the foundation of our global quality assurance systems, pursuing further operational excellence.

## Supplying High-Quality Pharmaceuticals

Astellas has introduced ICH Q10\* management across the



Company, which covers a product's entire lifecycle from development through to the end of medication. The system ensures a higher level of quality management. We also use ICH Q10 techniques to manage contracted manufacturers of Astellas-brand products, complementing our own ICH Q10 management at the development stage. In these ways, we are building an advanced quality assurance system.

\* 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.

### Safety Information

Astellas collects and sorts information on adverse events 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. In addition, we conduct an e-learning program on PV every year for all employees.

### 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 a recall of the product in question.

In fiscal 2012, Astellas recalled two products. As of June 2013, we have not received any reports of health impairment related to these recalls.

### Anti-Counterfeiting Measures

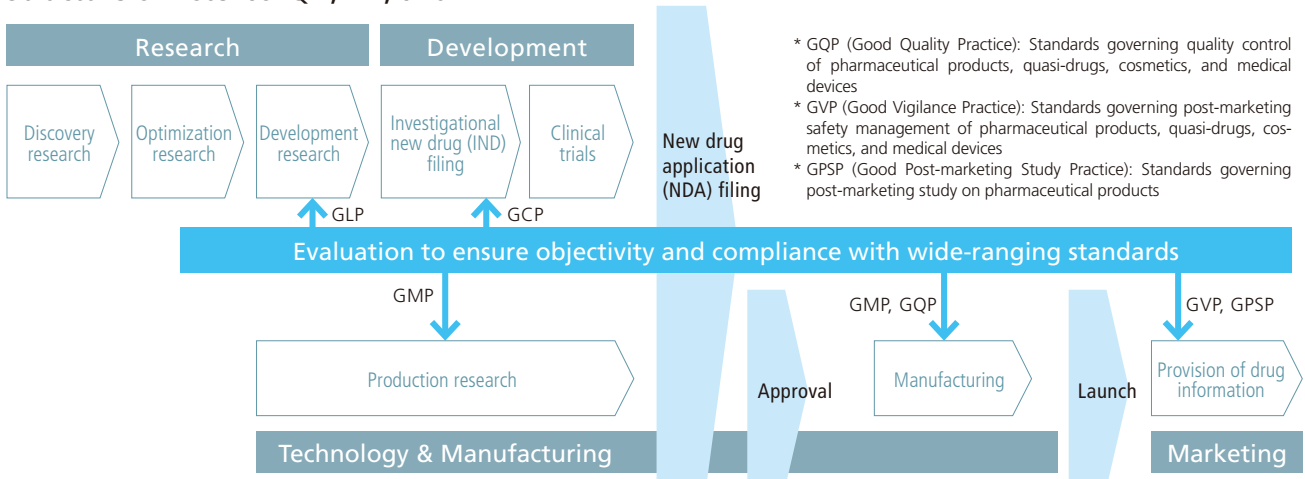
A counterfeit medicine is a formulation that is not produced by the manufacturer displayed on the packaging and does not contain the specified ingredients it claims to contain. Counterfeit medicines have become a serious worldwide health problem because they not only prevent a patient from receiving medical treatment due to the absence of specified active 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. The Committee implements measures to counter the spread of counterfeit medicines under our medium to long-term action plan. It also appoints members to investigate and take measures against counterfeit medicines. Astellas endeavors to ensure patient safety by systematically introducing anti-counterfeit technologies based on guidelines and other initiatives, and by implementing 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 support and cooperate with law enforcement agencies, such as INTERPOL\*, to crack down on counterfeit medicines.

\* INTERPOL: International Criminal Police Organization

### Structure of Astellas' QA, RA, and PV



## Marketing



Astellas' Medical Representatives (MRs) gather and provide information to ensure that drugs are used properly in clinical settings. Because they handle information related to human life and health, MRs must

observe high ethical standards. At the same time, MRs must make compliance their top priority, going beyond the Astellas Global Code of Conduct to observe local behavioral standards, pharmaceutical laws, and various related ordinances.

In addition to providing information on the correct and appropriate use of our products and possible adverse effects, our MRs supply wide-ranging information on pharmaceuticals in general as well as the latest knowledge and findings on medical conditions to people on the medical front line in various countries. In these ways, they strive to contribute to the treatment of patients. Our 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 serves as the contact point for product related inquiries and fields inquiries from healthcare professionals, patients, and MRs. For inquiries that require urgent attention, we have a system that allows 24-hours-a-day responses, even late at night and on business holidays. We also 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. We receive more than 100,000 inquiries a year. Based on inquiries, feedback, and complaints, we regularly have discussions with departments overseeing product quality, and make changes to product descriptions and packaging designs to improve legibility and make products more easily identifiable.

Outside of Japan, we also have systems to respond to inquiries from local healthcare professionals, patients, and MRs.

## Procurement



Astellas believes it is important for us to fulfill our social responsibility across our entire supply chain, including suppliers.

To this end, we have formulated our "CSR Procurement Guiding Principles," which set out for suppliers our requirements

in terms of CSR-based measures. We also conduct regular questionnaire-based surveys of all suppliers of materials directly used in our products. In fiscal 2012, we received new responses from 13 companies and confirmed from these responses that there were no problematic issues.

In addition, we are currently preparing a set of audit procedures to help ascertain the status of initiatives being undertaken.

### CSR Procurement Guiding Principles

#### I Compliance with laws and promotion of CSR

Compliance with relevant laws and rules  
Fair business operations based on ethical standards  
Maintenance of information security  
Encouragement and promotion of CSR activities

#### II Respect for human rights and fair employment practices

Respect for human rights and prohibition of child labor  
Employment consistent with labor-related laws

#### III Management of occupational health and safety practices

Maintenance of a safe workplace environment, and the management of occupational health and safety practices

#### IV Responsible environmental and sustainability-related practices

Reduction of the global environmental impact, and contribution to sustainability

#### V Social contribution initiatives

Participation in and support for social contribution activities

# Initiatives to Improve Access to Health

## Policy on Access to Health

**Astellas draws on its strengths and partnerships to help solve global healthcare issues through the promotion of an open innovation model of drug discovery.**

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, we will continue fulfilling our mission to improve people's access to health as specified in our "Access to Health Mission Statement" by harnessing our strengths and assets, and by taking advantage of partnerships with other organizations. We do this in two ways: through our core business activities in which we develop innovative new drugs in therapeutic areas with a high level of unmet medical needs; and by providing a variety of support activities in countries where standards of healthcare require improvement.

One example of support for improving healthcare in developing countries is the commencement in 2012 of drug discovery research into neglected tropical diseases (NTDs). Another example is the development of a new pediatric formulation of a drug to treat schistosomiasis.

NTDs are infectious diseases caused by parasites, bacteria, or viruses, which are endemic mainly

among poor populations in tropical regions. It is said that today more than one billion people worldwide suffer only from any of 17 NTDs on which the World Health Organization (WHO) focuses. However, these diseases have been out of the scope of pharmaceutical companies' drug discovery research on such grounds as marketability.

Astellas is a member of the Global Health Innovative Technology Fund (GHIT Fund), launched in November 2012. The GHIT Fund is a public-private partnership, established by the Japanese government, a consortium of pharmaceutical companies, and the Bill & Melinda Gates Foundation. The objective of the GHIT Fund is to promote research and development on new medicines and vaccines to fight infectious diseases in developing countries, as well as the marketing of such products. The Fund aims to reinforce contribution to global health through the development of new drugs using the advanced scientific and technological capabilities of pharmaceutical companies, and academic and research institutions.

### Column

#### **Masafumi Nogimori, Representative Director and Chairman of Astellas, promotes active dialog on global health issues as Vice President of the International Federation of Pharmaceutical Manufacturers & Associations**

Masafumi Nogimori, Representative Director and Chairman of Astellas, has served, since November 2010, as Vice President of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), which is composed of research and development-oriented pharmaceutical companies and industry pharmaceutical associations. As Vice President of IFPMA, he meets with international organizations, governments, and non-governmental organizations in this field around the world to exchange opinions on issues including global healthcare where the pharmaceutical industry can make contributions. His experience working at the IFPMA has also benefited Astellas' efforts to promote access to health.



Examples of Initiatives

## 1 Joint Drug Discovery Research on Neglected Tropical Diseases

During the period between June 2012 and November 2012, Astellas signed agreements with five Japanese research institutions and an international non-profit organization to undertake joint drug discovery research on neglected tropical diseases focusing on three parasite infections of leishmaniasis, Chagas disease, and sleeping sickness. This research project involves collaboration between IT and medical researchers under an open innovation model on the development of new drugs using a number of cutting-edge approaches.

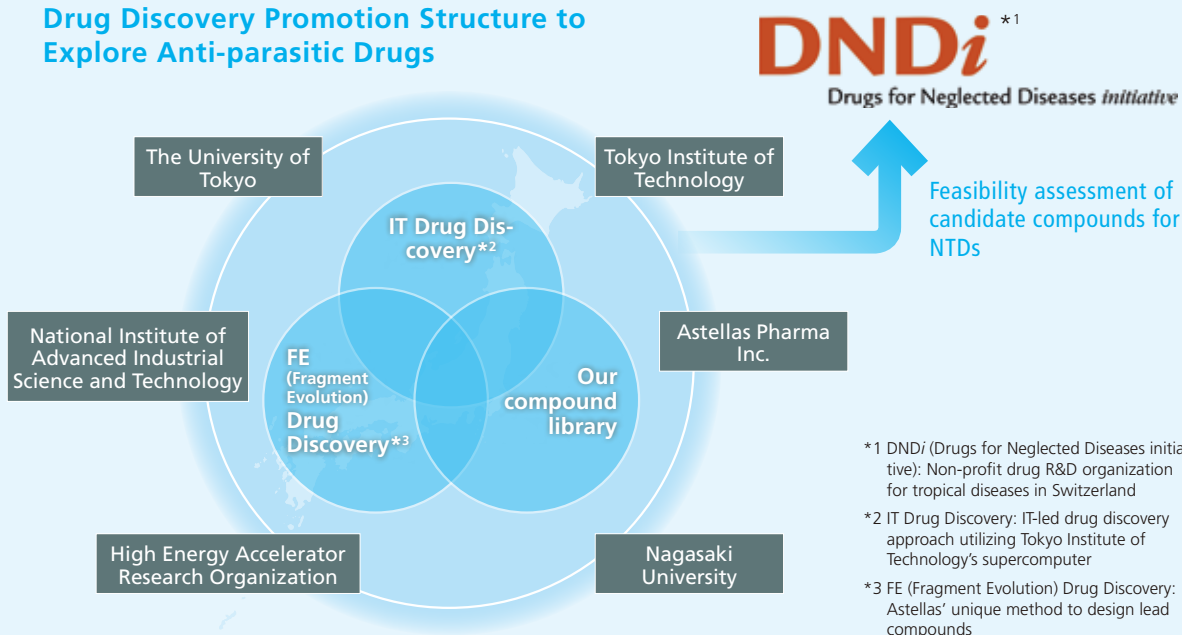
The research has resulted in the development and publication of an integrated drug discovery

database called iNTRODB\*. The database, which exhaustively consolidates bioscientific data related to parasitic protozoa, is used to extract information on target molecules and candidate compounds in an efficient manner. With researchers from around the world able to access the database, it is anticipated that this project will contribute to acceleration in research on neglected tropical diseases.

In a separate initiative, in March 2013, Astellas commenced collaborative drug discovery research into the dengue virus infections with Tokyo Institute of Technology and Nagasaki University.

\* iNTRODB: Integrated Neglected TROPical disease Data Base

### Drug Discovery Promotion Structure to Explore Anti-parasitic Drugs



## 2 Development of Pediatric Formulation for Schistosomiasis

More than 243 million people, mainly in developing countries, are infected with schistosomiasis every year. If not treated properly, the disease can cause anemia and stunting, and can even be life-threatening.

Many preschool children are also infected with the disease, but at present the only treatment available is an oral tablet formulation of praziquantel that can be taken by adults or children from the age of six. However, because children under six have trouble taking this formulation due to the size of the tab-

let and its bitter taste, the most vulnerable group is unable to receive therapy.

In July 2012, Astellas joined an international public-private partnership established to develop a new pediatric formulation of praziquantel. Astellas utilizes its world-class pharmaceutical technologies to develop a pediatric formulation that can be produced efficiently while also addressing existing obstacles, including the size and bitter taste of the formulation and its stability in hot and humid environments.

Developing human resources capable of responding to dramatic social changes is key to Astellas' growth.



# Employees

- 052 Basic Policy
- 053 Human Resource Strategy and People Development
- 054 Creating a Motivating Workplace
- 056 Respect for Human Rights
- 056 Five Messages for the Astellas Way



## Basic Policy

Astellas employees play the most valuable role in shaping the Company and continuously creating new levels of corporate value, and they are one of our important stakeholders. At the same time, employees are subject to direct influence of corporate management, and the Company fully recognizes the various social responsibilities that it must fulfill on their behalf. Astellas understands the need to provide a clear direction for their career development, a workplace that corresponds to the direction, and a personnel system that enables them to fully demonstrate their capabilities. As for the utilization of human resources from around the world, we believe that respecting the human rights, personalities, and individualities of all employees and providing them with motivating workplaces are linked to accelerating the globalization and maintaining and strengthening our competitiveness.

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

- 1 Develop human resources
- 2 Respect human rights
- 3 Provide motivating workplaces

### Fiscal 2012 Initiatives

Launched the Senior Leadership Series (SLS), training sessions to enhance the business skills of group leaders and managers

Formulated the Astellas Global Code of Conduct, which stipulates the respect for employees' human rights

Introduced a new time management system with the aim of appropriately managing the working hours of employees and curbing long working hours (Japan)

Introduced a system giving employees temporary retirement upon notification that a family member is terminally ill (April 2013) (Japan)

### Review of Fiscal 2012 Initiatives

During the year, Astellas expanded its global human resource program to cover not only senior managers but also the next subordinate level of group leaders and managers. In Japan, we also introduced a new time management system to appropriately manage the working hours of employees and prevent long working hours. In fiscal 2013, we plan to further expand the global human resource program to cover younger leaders while improving working hours under the new time management system.

## 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.



# Human Resource Strategy and People Development

To develop employees who can achieve our Business Philosophy and VISION 2015 while responding to rapid social changes, we have established personnel strategies, including “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 is 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 a variety of responsibilities to employees as stakeholders.

Astellas, which comprises people from around the world with diverse value perceptions, has established its human resource strategy, including the factors of “Astellas’ Desired Talent” and “Astellas’ Desired Organization.” Based upon these, we have built a “Human Resources Management System,” which sets out policies and processes for employee recruitment, placement, evaluation, compensation, and career development. In fiscal 2012, we launched personnel transfer programs—between Japan and countries in other regions, between the Americas and European countries, and between Asian countries—on a full-scale basis.

Astellas offers career development opportunities to employees who show a willingness to take responsibility and possess the required skills. Moreover, we provide a high level of development support for talented and capable employees who show strong commitment to improvement in performance. Here, we place foremost priority on

meritocracy irrespective of race, nationality, gender, or age.

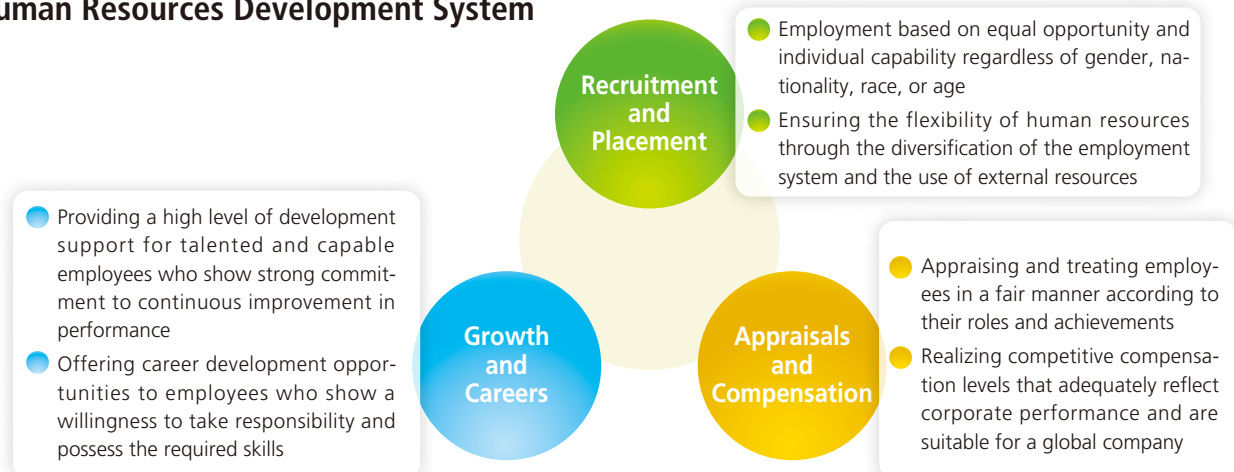
Furthermore, it is important that all employees who are working in various different countries move in the same direction to create Astellas’ corporate value. Consequently, in 2010 we formulated the “Five Messages for the Astellas Way,” which defines values and actions to be embraced by our employees around the world, and we are nurturing a corporate culture to realize our Business Philosophy.

## ► Global Human Resource Development Systems (Global Leadership Programs)

The progressive globalization of business has made global talent development an increasingly important priority for Astellas. To this end, it is important to strengthen both “leadership” (the driving force for value creation) and “management” (the basis to foster a corporate culture embracing the spirit of challenge).

As part of this initiative, Astellas launched the Executive Leadership Series (ELS) for senior managers selected from across functions and regions to discuss Astellas’ challenges and its future plans. In March 2013, we launched the Senior Leadership Series (SLS), designed to enhance the functional strategy formulation, communication, and project delivery skills of group leaders and managers who are one rank lower than the vice presidents.

## Human Resources Development System



## Creating a Motivating Workplace

Seeking sustainable growth while pursuing ongoing reforms, Astellas is promoting the concept of diversity management to deploy its diversified pool of human resources. We recognize the diversified value perceptions of individuals and empathize with the specific attributes of various nations and regions, and we are targeting a number of initiatives aimed at providing motivating and safe workplaces in which employees can be devoted to their jobs.

### ► Respect for Diversity

At present, females account for more than 40% of our entire workforce. However, compared with other world regions, the proportion of female employees in Japan is low, particularly the ratio of women who hold management roles. For this reason, we are taking steps to increase these ratios. These include establishing various frameworks and work environments that encourage women to continue working, as well as a career support program run by executive officers aimed at helping women in supervisory positions. We also promote 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 2012)

	Japan	Americas	Europe	Asia	Total
Male	72.7%	49.7%	44.3%	47.1%	58.8%
Female	27.3%	50.3%	55.7%	52.9%	41.2%
Ratio of female managers	5.7%	45.0%	49.1%	43.5%	28.0%

### ► Labor and Management Communication

As a supporter of the principles of the United Nations Global Compact, Astellas guarantees the basic labor rights of its employees. We also provide opportunities across the group for labor and management to exchange opinions on various themes, and we do not impose any restrictions on labor union membership or formation in our 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, 2013, there were 5,100 union members in Japan.

### ► Work-Life Balance

Seeking to provide employees with motivating workplaces, Astellas gives consideration to a work-life balance, and has introduced systems that enable employees to work in ways that suit their lifestyles according to regional situations. 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. In Asia, we are also establishing systems that provide paid leave and substitute days off, and are encouraging employees to use their vacation days based on the systems. We have a campaign to cut back on overtime work. In fiscal 2012, we introduced a new time management system in Japan with the aim of appropriately managing the working hours of employees and curbing long working hours.

In addition, we have introduced a system in Japan since April 2013 giving employees unpaid leave of absence, for a maximum of 12 months, upon notification that a family member is terminally ill.

### ► Improving Employee Health/Mental Healthcare

Astellas recognizes that well-being is the most important factor in earning employee devotion to work. The concept of "mental healthcare" is growing in importance, regardless of geographical region. For this reason, we are stepping up our responses to mental healthcare issues at our various operations worldwide, for example, through in-house psychiatrists and external Employee Assistance Programs.





## ► Occupational Safety and Health

Ensuring the safety of employees in their business activities is a crucial element of corporate management. Accordingly, prevention of work-related accidents and minimization of accidents caused by workplace mishaps and hazards play an important role in Astellas' ability to provide motivating workplaces and fulfill its responsibilities to employees as stakeholders.

Under its Environmental and Safety Policy, Astellas is independently building environmental and safety management systems at each of its workplaces and promoting associated initiatives.

The number of work-related injuries increased in Japan and overseas during the period between January and December 2012 compared to the same period of the previous year, totaling 35 incidents. While paying meticulous attention to occupational safety and health, we will continue working to assure safe workplaces.

### Incidence of Work-Related Injuries in Japan

	2010.1-12	2011.1-12	2012.1-12
Number of work-related injuries	33	19	35
Frequency rate of work-related injuries* <sup>1</sup>	0.31	0.00	0.30
Severity rate of work-related injuries* <sup>2</sup>	0.001	0.000	0.007

### Incidence of Work-Related Injuries at Overseas Plants (January-December 2012)

	Norman Plant	Meppel Plant	Dublin Plant	Kerry Plant	Shenyang Plant
Number of injuries requiring leave of absence	0	2	0	1	0
Frequency rate of work-related injuries* <sup>1</sup>	0.00	4.544	0.00	1.621	0.00
Severity rate of work-related injuries* <sup>2</sup>	0.000	0.018	0.000	0.003	0.000

\*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.

## ► Best Place to Work

Astellas' efforts to provide employees with a motivating workplace have garnered praise both inside and outside the Company. In 2012, the Great Place to Work Institute selected our European headquarters in the United Kingdom and the sales subsidiary in Spain as Best Workplaces. The Astellas regional headquarters for the Americas received CEO Cancer Gold Standard accreditation from the CEO Roundtable on Cancer for its efforts in cancer risk reduction for its employees. The South Korean government commended the sales subsidiary in South Korea for being a family-friendly company with a system and culture that respect work-life balance (refer to the photo above).

In addition, in Japan, Astellas' human resource development program for directors and corporate executives to mentor women in management positions received the "Excellence Award" at "Mentor Award 2013."\*

Astellas aims to be an employer of choice and will continue to provide a motivating workplace.

\* Mentor Award 2013 was sponsored by Working Women's Empowerment Forum and Japan Productivity Center, and awards were presented to companies implementing unique measures to promote mentoring activities.

### Number of Employees per Region and Turnover Rate

		2011.3	2012.3	2013.3
Japan	Number of employees	8,023	8,176	8,153
	Turnover rate	1.7%	1.5%	1.7%
Americas	Number of employees	2,742	2,919	2,980
	Turnover rate	—	12.6%	12.9%
Europe	Number of employees	4,102	4,286	4,356
	Turnover rate	—	8.1%	13.7%
Asia	Number of employees	1,412	1,704	1,965
	Turnover rate	—	13.3%	16.3%
Total	Number of employees	16,279	17,085	17,454
	Turnover rate	—	6.2%	8.3%

## Respect for Human Rights

Astellas is dedicated to respecting fundamental human rights and rejecting discriminatory practices. Moreover, we have declared our commitment to rejecting discriminatory statements with respect to such factors as race, religion, gender, nationality, disability, and age. We also reject acts of violence, sexual harassment, and other activities that do not respect people's characters. In addition, we are a signatory to the United Nations Global Compact, which supports the prohibition of child labor and forced and compulsory labor.

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, also sets

out standards on various initiatives, including respect for the human rights of employees, elimination of forced and compulsory labor, equal opportunities for employment and training, employee health and safety, and the prevention of harassment in the workplace. In order to completely spread the mindset to respect human rights, we have established a system to swiftly deal with human rights issues by setting up external and internal helpline for constant monitoring, as well as conducting training sessions for employees.

## Five Messages for the Astellas Way

To achieve the Astellas mission of realizing continuous growth in corporate value, it is essential that all of our employees working in various countries share our values and actions globally, and work as a unified group to create and quickly deliver innovative new products to patients.

To this end, we have authored the Astellas Way, which is composed of five messages outlining the desired course of actions for employees. We implement various measures to deepen the commitment to the Astellas Way, including the annual Astellas Way Global Recognition Program (GRP) that shares with all employees outstanding examples of the Astellas Way being put into practice through our daily work.

At the GRP for the year ended in March 2013, several initiatives were chosen as examples of excellence, which were related to the development, production, marketing, and product training of "XTANDI," a prostate cancer treatment released in the United States. One good practice example shared globally this year was introduced by the Technology division. It established an investigational drug and product

supply system that swiftly responds to unexpected schedule changes for the launch of new products.

### The Five Messages to achieve Astellas' VISION



#### 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— whoever they are.



#### Integrity

Act with integrity. Always consider the implications of your actions and take responsibility for them.

Through dialogue with communities and response to social requirements, we work to gain support from society and achieve corporate sustainability.



# Society



- 058 Basic Policy
- 059 Enrich the Lives of Patients
- 061 Enrich Healthcare Systems
- 063 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.

## Basic Policy

Corporations, being members of society, must foster a sustainable overall society while maintaining good reciprocal relationships with communities. At the same time, sustainable development of society has to be pursued by society as a whole and expectation for corporations is growing in the society. Based on this stance, we place importance on maintaining ties with local communities in which we conduct business, and we focus our social contribution activities on three areas based on our business, as outlined in the chart below. Moreover, Astellas strives to address issues facing society by leveraging our characteristics.

Astellas supports proactive initiatives by its employees via various programs, such as a "Matching Gifts Program"\* and a "Volunteer Leave" system.

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

### Core 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 2012 Initiatives

Conducted joint drug discovery research into neglected tropical diseases and new pediatric drug development, with the aim of improving the availability of healthcare (Access to Health) in developing countries

Pursued support activities related to United Nations Millennium Development Goals (MDGs) in healthcare field

Supporting patients associations' activities

Provided support for advancement of medicine in Japan, North America, and Europe by Astellas foundations

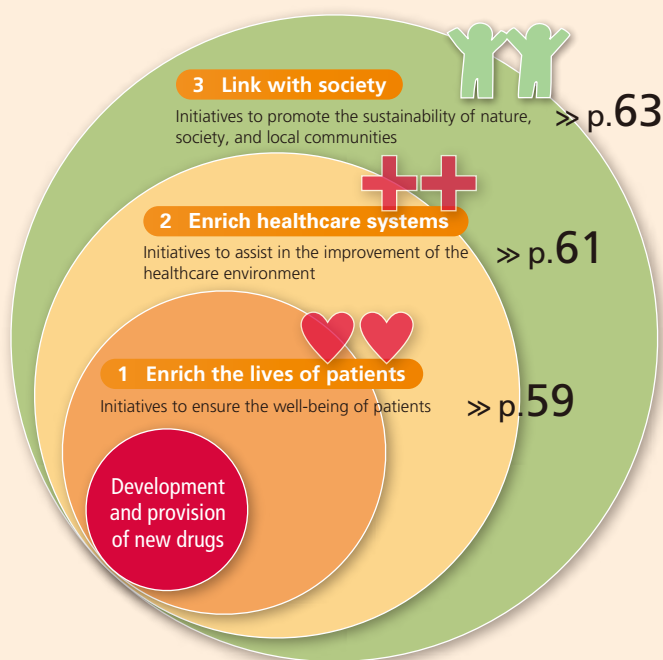
Implemented group-wide "Changing Tomorrow Day" activities

### Review of Fiscal 2012 Initiatives

Astellas started a program for early drug discovery for patients suffering from neglected tropical diseases by leveraging our in-house research know-how and partnership. The Astellas Asia-Oceania Foundation embarked on support activities, through the collaboration with NGO Save the Children, for a project aimed at improving the health of mothers and children in slum areas in India as part of "Improve Maternal Health," which is one of the main goals of Millennium Development Goals. We also continued various initiatives, including activities for patients associations, support for advancement of medicine by Astellas foundations in Japan, North America, and Europe, and group-wide "Changing Tomorrow Day" activities.

## Three Areas of Community Participation

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."



## Enrich the Lives of Patients

Seeking to help patients lead better lives, Astellas supports activities to address the needs of patients and families fighting diseases. These social contribution activities also help to deepen the understanding of patients' issues among our employees.

### ▶ Starlight Partners Activities (Support for Patients Associations in Japan)

Through Starlight Partners Activities (support for patients association) undertaken in Japan, Astellas provides assistance to patient associations in their efforts to support patients and their families. Based on specialist advice from our advisory board, which is essentially a group of professional outside counselors, we engage in the below three activities to support patient associations. When such associations hold events, we also provide materials and logistical assistance, and cooperate in organizing and managing the event.



Support for a patient association through a peer support training session

#### Funding for Patients Association Activities

Astellas provides patients associations with the funding needed for their activities. Our support is aimed at promoting the self-reliance of the associations and human resources development of leaders and association members. Applications are accepted once a year.

\* Fiscal 2012: 61 organizations received funding totaling ¥8.5 million.

#### Peer Support Training Program

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. Astellas hopes to create an environment for building a system through which patient associations are able to exchange ideas and support each other.

\* Fiscal 2012: Held in Iwate, Tokyo, and Osaka with 34 organizations and 48 people in attendance

#### Instructor Dispatch

Astellas dispatches instructors yearly to two patient associations or patient family groups that independently host training and study sessions.

\* Fiscal 2012: Dispatched instructors to two organizations in Tokyo and Osaka

### Column

#### Participation in Astellas Peer Support Training Sessions "Simply listening is a way to give peer support."

I realized that there's no need to think too deeply about providing peer support—just look people in the eye, hear their words sincerely, and learn the art of "listening." I thought that, for a person like me who is not good at speaking in front of people, the most important thing is to be a good listener when communicating with friends who share similar concerns or problems. Through the Astellas training sessions, I was able to deepen my interaction with many other people and become friends with them. I gained a sense of community, knowing that I am not alone, even though our diseases may be different. The sessions were wonderful, and I'm truly grateful.



**Mr. Toshio Seki**

Akita Prefecture Chapter Accountant  
National Collagen Disease Tomo no Kai  
(National Association for Collagen Disease Patients)

## ▶ Global Support Activities

Similar to Starlight Partners Activities in Japan, Astellas provides indirect support overseas aimed at helping patient associations achieve self-reliance and sustainable development.

We also want to alleviate the psychological burden of patients receiving treatment in unfamiliar locations as well as their families. For example, we run a program in which volunteers conduct cleaning and furniture maintenance work and make home-cooked meals for patients and their families staying at a Ronald McDonald House in the U.S.

In Europe, we have since 2002 been supporting an event (TACKERS: Transplant Adventure Camps for Kids), which provides opportunities for children who have had transplants to meet peers who have shared the same experience, and our employees also join the event as volunteers.



Volunteer activities at a Ronald McDonald House



TACKERS

## ▶ Web-Based Information Service Activity for Patients: Yuuki-Tsunagare.com

As part of its information service activity for patients in Japan, Astellas Pharma Inc. has opened a user-generated Web site called Yuuki-Tsunagare.com (<https://www.yuuki-tsunagare.com/>). This website carries more than 200 episodes posted by people battling illness and their family members. We hope a lot of courage will be passed among patients who are still fighting illness through the episodes on this Web site.



Through “Yuuki-Tsunagare.com,” we provide information about patient support initiatives

# Enrich Healthcare Systems

As a pharmaceutical company, Astellas strives to solve healthcare issues where we can best leverage our strengths referencing issues listed in the United Nations Millennium Development Goals (MDGs). The MDGs aim at resolving concerns shared by the international community pertaining to people's lives and the environment. Moreover, we have started collaborating with partners for new drug discovery for Neglected Tropical Diseases (NTDs) and developing a new pediatric formulation of a drug to treat tropical diseases as a part of our Access to Health initiative, which addresses the issue of accessibility to healthcare in developing countries. At the same time, we seek to foster advances in life sciences and medical treatment. To this end, we work through Astellas foundations in Japan, North America, and Europe to help support activities aimed at nurturing research technicians who will spearhead the future of life science, drug discovery, and medical research.

## 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, Astellas focuses its support on initiatives in public health-related fields in which we can deploy our expertise 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.

### 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.

## Global Support for MDGs

### Indonesia



Through health and medical NPO Peoples' HOPE Japan, Astellas donated birth centers and health clinics in impoverished Indonesian villages and supports a project aimed at reducing infant and maternal mortality rates.



### India



Working together with NGO Save the Children, Astellas tackles a project aimed at improving the health of mothers and children in India, including by visiting slum areas by bus to provide free medical treatment.



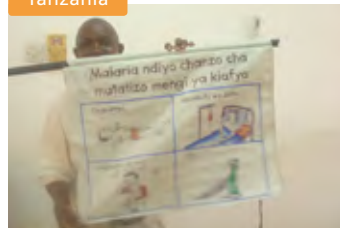
### Ghana



Obstetric fistula is a severe medical condition that cause patients to become incontinent due to long and uncontrolled deliveries or other traumas. In Ghana, where many women suffer from obstetric fistulas, Astellas works with the Ananse Foundation\* and the Dutch Urology Association to alleviate the situation. Under this project, physicians are dispatched to Ghana, and local doctors are provided with specialist medical training.

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

### Tanzania



Seeking to reduce the mortality rate among children aged five and under, Astellas supports the NGO Save the Children's malaria prevention project in Tanzania. This project involves distribution of insecticide-treated mosquito nets.



### ► Support for Advancement of Medicine by Astellas Foundations in Japan, North America, and Europe

Seeking to foster progress in life sciences and medicine, we pursue various initiatives through Astellas Foundations in Japan, North America, and Europe. These include providing scholarships to promote research into natural science, offering grants to researchers involved in life sciences, drug discovery, and medical research, and bestowing awards to recognize outstanding research outcomes.

For example, the Astellas Europe Foundation presents “Astellas Awards” to researchers deemed to have made significant contributions to basic and medical research. Since 2011, meanwhile, the Astellas USA Foundation has been working in partnership with public charities to give scholarships to exemplary science students. In addition, in Japan the Astellas Foundation for Research on Metabolic Disorders fosters basic research into diseases and new drug discovery, as well as the development of treatment methods and research into their practical realization by offering financial assistance for outstanding original and groundbreaking research initiatives and providing financial aid for studying abroad.

\* In fiscal 2012, the Astellas Foundation for Research on Metabolic Disorders provided assistance to 100 researchers.



Professor Munetaka Kunishima, who was awarded Chairperson Award 2012 by Astellas Foundation for Research on Metabolic Disorders, and his laboratory members at Bioorganic Chemistry, School of Pharmacy, Kanazawa University College of Medical, Pharmaceutical and Health Sciences

### ► Providing Health-Related Information For General Consumers

#### Good Life Forum (Japan)

Since 1997, we have held Astellas Good Life Forum, a seminar on health for the general public, on an annual basis. In March 2013, we held the forum with medical specialists and celebrities under the theme of “Brightening tomorrow’s senior life” in Toyama city.

### ► Donation of Ambulances and Wheelchair-Friendly Vehicles (Japan)

To provide support for emergency medical treatment in Japan, Astellas has donated ambulances to local governments since 1970, bringing the cumulative total of 225. In recent years, demand for “high-grade” ambulances, which enable advanced in-vehicle emergency treatment, is growing. In fiscal 2012, we donated three such high-grade ambulances to local governments, raising the cumulative total to 46. Through our Flying Star Fund, an initiative of Astellas employees, we also donate wheelchair-friendly vehicles to welfare institutions on an annual basis. In fiscal 2012, we donated six such vehicles, bringing the cumulative total to 171 over the 17-year period since the establishment of the program.





# Link with Society

Corporations are members of society and thus have a responsibility to serve as good corporate citizens in the countries, regions, and communities in which they do business. Accordingly, Astellas pursues social contribution activities matched to local needs. These activities include support for the healthy lives of people, 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 themes of health and the environment. We have been globally conducting Changing Tomorrow Day activities as a Group-wide initiative, in which we support employees' volunteer activities within local communities. In fiscal 2012, the third consecutive year of this initiative, employees engaged in a more diversified range of activities, with participation by more than 7,000 people.

## Employee participation in Changing Tomorrow Day

Region	Participants	Volunteering hours	Countries
Japan	4,306	4,392 hours	150 events
Americas	1,915	7,079 hours	3 countries 14 events
Europe	516	3,422 hours	18 countries 20 events
Asia & Oceania	578	567 hours	8 countries 12 events
<b>Total</b>	<b>7,315</b>	<b>15,460 hours</b>	<b>30 countries 196 events</b>

## Outline of Regional Activities

### Japan: Support at aged-care facilities



Employees at our Kurume sales office interacted with people at an aged-care facilities by cleaning the facilities and assisting recreational activities including playing origami (the art of paper folding) and singing children's songs.

### Americas: Repair of hospitals housing sick children (United States)



We provided maintenance work on facilities, including flower beds, so that people living there can be comfortable.

### Europe: Activities at aged-care facilities (Italy)



We visited aged-care facilities and assisted with the care of the elderly.

### Asia/Oceania: Event to speak about work experience to children (China)



We provided elementary school students with a class to increase understanding of medicines.

### ► Supporting Web-Based Scientific Education: Science Worx (U.S.A.)

Astellas provides support for high-school and junior high-school education in the field of life science and medicine, and science, respectively. One part of that in the United States is "Science Worx," a program supporting science teachers (<http://www.scienceworx.org/Home.aspx>). It includes a mentoring program, called "Science Pro Mentors," in which Astellas scientists give lectures to science teachers and answer various questions from them.

### ► Disaster Relief Activities

Astellas has a business continuity plan (BCP) in place to address unforeseen events, such as natural disasters. We are reinforcing our system to ensure that medicines are delivered to patients in a reliable manner, with no interruption to supplies. The world has recently seen various types of disasters. Astellas responds to needs in afflicted areas, not only in Japan but also in other nations.

#### Support for Typhoon Victims in the Philippines

The Astellas Asia-Oceania Foundation made a donation of US\$20,000 to NGO GMA Kapuso Foundation in order to provide relief for those affected by Typhoon Bopha, which struck southern Mindanao in the Philippines in December 2012.

#### Supporting reconstruction from the Great East Japan Earthquake: Participation in activities to alleviate chloride damage of disaster-stricken farms

The Great East Japan Earthquake in March 2011 caused a tsunami, inundating many farms with salt water, and evidence of salt-related destruction remains to this day. Astellas undertook volunteer activities aimed at helping salt-damaged areas recover as much as possible. These included pulling weeds, planting seeds, and improving the condition of the soil.



Participation in activities to alleviate salt damage on farmland (Japan)

#### Column

#### Report from an Astellas employee who joined the Great East Japan Earthquake disaster relief activities organized by Astellas labor union

I took volunteer leave to participate in disaster relief activities in Otsuchi town, Iwate prefecture. What surprised me at the site was the fact that almost no progress had been made in reconstruction. I deeply felt that we had had only limited information provided by the media, and paid little attention to the disaster-stricken areas. I supported the setup of "Herb Garden," which was a place of relief for people living in temporary housing, and helped the development of a planned construction site for Kirikiri nursery school, which had been washed away in the tsunami. I do not think I did something special for Otsuchi town, but I was able to feel the seriousness of the disaster through the volunteer work and listen to the feelings of the affected people, and through these precious experiences, I have started to think about what they really would like us to do.



Aya Shionoiri  
from Osaka 1st Sales Office

Aiming at realizing a sustainable society,  
which is crucial to maintaining  
its corporate activities, Astellas works  
to lower the environmental burden of  
its business.



# Environment



- 066 Basic Policy
- 067 Environmental Action Plan
- 068 Measures to Combat Global Warming
- 070 Initiatives for Sustainable Biodiversity
- 071 Initiatives for Resource Recycling
- 072 Environmental Accounting

\* The figures indicated in the fiscal 2012 status report for the field of Environment present the results for fiscal year 2012 (April 1, 2012 to March 31, 2013) in Japan and the calendar year 2012 (January 1 to December 31, 2012) for overseas operations as a combined total.

## Basic Policy

Astellas understands that maintaining a healthy global environment is essential for building a sustainable society and is also an important element in maintaining sound business activities.

In addition to complying with legal regulations covering various environmental issues, companies must fulfill their corporate social responsibilities in order to sustainably grow. If they cannot meet their responsibilities, their corporate value could be damaged due to a loss of social trust.

Going forward, Astellas aspires to be a responsible corporation based on a long-term global perspective that keeps future generations in mind. At the same time, we will continue efforts to address regional social issues and pursue corporate activities in harmony with the global environment.

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

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

### Fiscal 2012 Initiatives

- Reduction of greenhouse gas emissions
- Promotion of resource saving measures (such as reducing water usage and cutting waste)
- Ongoing improvement in the Biodiversity Index

### Review of Fiscal 2012 Initiatives

With respect to greenhouse gas (GHG) emissions, which is an indicator of global warming prevention measures, Astellas' direct carbon dioxide (CO<sub>2</sub>) emissions\*<sup>1</sup>, which can be reduced through self-reliant efforts, remained unchanged in fiscal 2012 from the previous year in spite of an increase in business activity. This was despite an increase in indirect CO<sub>2</sub> emissions\*<sup>2</sup> caused by deterioration in the CO<sub>2</sub> emission coefficient of Japan's electricity providers. In Europe, moreover, we began utilizing renewable energy sources, such as wind and biomass, which reduced our reliance on fossil fuels. As for environmental protection, we achieved our numerical target for fiscal 2015 for reductions in water usage three years ahead of schedule. We also again achieved our targets for zero emission of waste in fiscal 2012, as we have done since fiscal 2008. In addition, the Company's biodiversity index was improved compared with the previous year.

\*1 Direct GHG emissions: The amount of greenhouse gases that a company emits directly from its business facilities through the combustion of fossil fuels, natural gas, and the like (Scope 1).

\*2 Indirect GHG emissions: The amount of greenhouse gases that a company emits indirectly, such as through purchases of electricity and steam (Scope 2).



### Environmentally-friendly new building, Mirai House

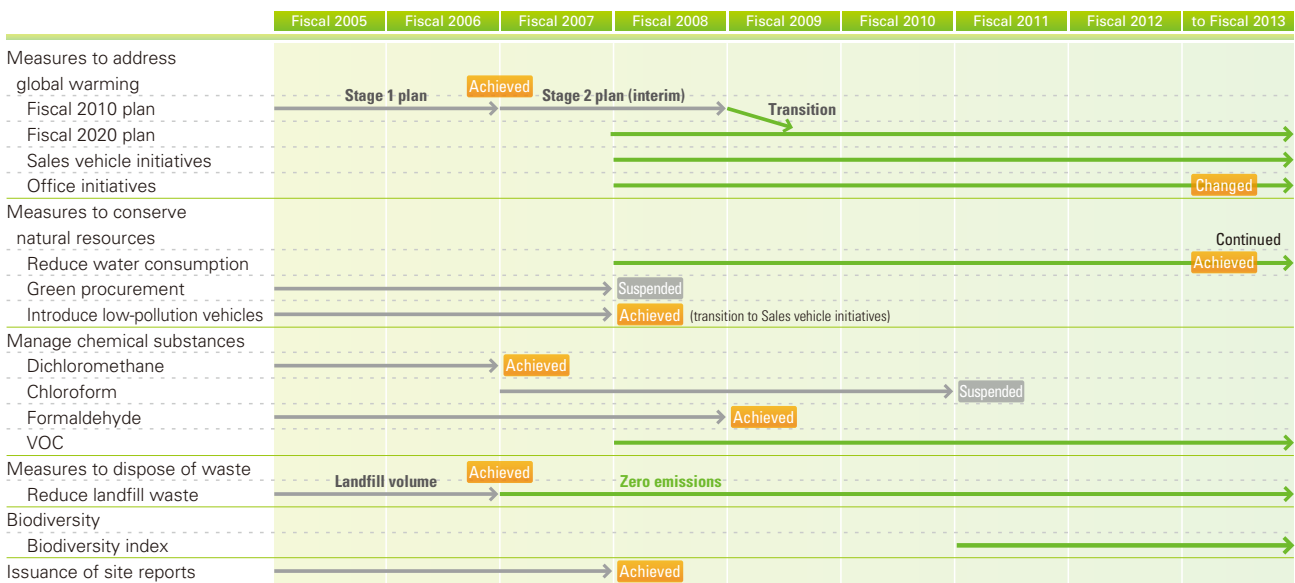
Mirai House, our new company building in Leiden, the Netherlands, was completed in December 2012 and was awarded a "Very Good" rating by BREEAM, which assesses building's environmental performance and initiatives for sustainability.

# Environmental Action Plan

Having determined its basic policy on the environment and identified aspirational guidelines, Astellas formulated its Environmental Action Plan, which outlines short to medium-term activity targets, and has continued pursuing initiatives aimed at achieving its numerical targets. Going forward, we will reconsider various factors by reviewing progress status and social circumstances, and add new initiatives and/or set more challenging targets.

The current Environmental Action Plan is based on fiscal 2005, the year of the Company's inauguration, and sets targets for fiscal 2015 and fiscal 2020 depending on the relevant items. Since its foundation, Astellas has made the following changes to the Plan.

## Environmental Action Plans since Fiscal 2005 and Implementation Progress



The Environmental Action Plan for fiscal 2013 is outlined below. We will keep some targets which were already achieved in fiscal 2012 at the current levels for the remaining period.

## Fiscal 2013 Environmental Action Plan

Initiatives	Environmental Action Plan
<b>Measures for Global Warming Prevention</b>	<ul style="list-style-type: none"> <li>- Reduce greenhouse gas emissions by 35% or more compared with fiscal 2005 levels by the end of fiscal 2020 (Global).                             <ul style="list-style-type: none"> <li>• Reduce greenhouse gas emissions in Japan by 30% or more compared with fiscal 2005 levels by the end of fiscal 2020.</li> <li>• Reduce greenhouse gas emissions at overseas production facilities by 45% or more compared with fiscal 2005 levels by the end of fiscal 2020.</li> </ul> </li> <li>- 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).</li> <li>- Reduce electricity consumption at our offices to 80% or less compared with fiscal 2005 levels (Japan).</li> </ul>
<b>Measures for the Conservation of Resources</b>	<ul style="list-style-type: none"> <li>- Reduce water consumption to the levels of 80% or less compared with the fiscal 2005 levels by the end of fiscal 2015 (Global).</li> </ul>
<b>Management of Chemical Substances</b>	<ul style="list-style-type: none"> <li>- Reduce the amount of volatile organic compounds (VOCs) discharged by 25% or more compared with fiscal 2006 levels by the end of fiscal 2015 (Japan).</li> </ul>
<b>Waste Management</b>	<ul style="list-style-type: none"> <li>- Reduce the final volume of waste for disposal to less than 2% of total discharged volume (Japan).</li> </ul>
<b>Biodiversity</b>	<ul style="list-style-type: none"> <li>- Raise the biodiversity index to double the fiscal 2005 level by fiscal 2020 (Global).</li> </ul>

# Measures to Combat Global Warming

Astellas believes that taking proactive measures to combat global warming is part of its corporate social responsibility. We also recognize reliance on fossil fuels, which is one of the causes of global warming, as a factor limiting the continuation of future corporate activities from the perspectives of cost and procurement. Accordingly, we have positioned measures to address this problem as one of our key management priorities.

## ▶ Reducing Greenhouse Gas Emissions

**Environmental Action Plan** (Fiscal 2005 as base year; plan effective through fiscal 2020 year-end)

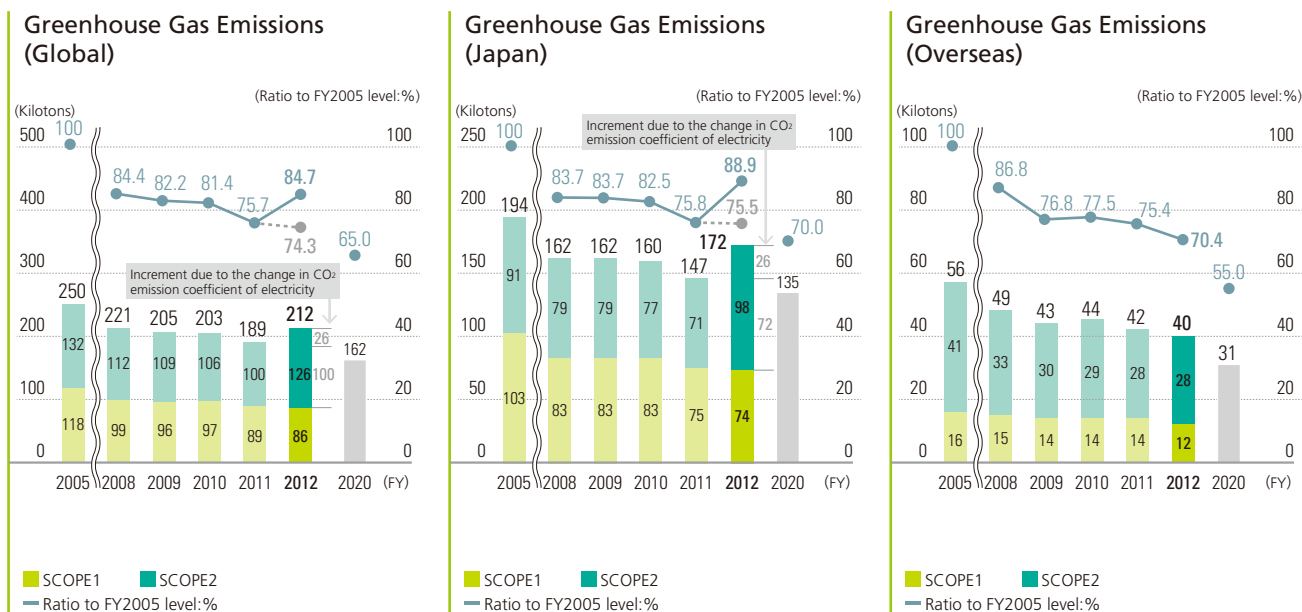
- Global: Reduce by **35%** or more
- Japan: Reduce by **30%** or more
- Overseas production facilities: Reduce by **45%** or more

In fiscal 2012, the Astellas group's global greenhouse gas emissions, while 15.3% (38 kilotons in CO<sub>2</sub> equivalent) lower than the base year level, were 22 kilotons higher than the previous year, or a 9.0-point deterioration. This was due to an increase in CO<sub>2</sub> emissions in Japan, although the group's overseas greenhouse gas emissions declined.

The group's greenhouse gas emissions in Japan, while 11.1% (22 kilotons) below the base year level, were 25 kilotons higher than in fiscal 2011, or a 13.0-point deterioration. Direct emissions (Scope 1) from business facilities were mostly unchanged from the previous year, but indirect emissions (Scope 2) increased due to significant deterioration in the CO<sub>2</sub> emission coefficient of electric power companies.

If assumed that there was no year-on-year change in the CO<sub>2</sub> emission coefficient of electric power companies, the group's greenhouse gas emissions were 24.5% (47 kilotons) below the base year, representing a 1-kiloton year-on-year decline, or a 0.3-point improvement. One factor boosting emissions was the resumption of normal operations at the Takahagi Facilities, which were damaged by the Great East Japan Earthquake. However, our analyses show that this was offset by the benefits of converting to alternative fuels, renewal of facilities as measures to combat global warming, and entrenchment of electricity saving efforts.

The group's overseas greenhouse gas emissions were 29.6% (17 kilotons) lower than the base year, for a 3-kiloton year-on-year decline, or a 5.0-point improvement. The commissioning of a wood-chip boiler at the Kerry Plant in Ireland led to a 2.2-kiloton decrease in direct emissions. While use of wind power generation cut indirect emissions by 800 tons, an increase in purchased electricity by other factories left the overall level of indirect emissions largely unchanged year on year.



## ► 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. Here, we adopt a two-pronged approach emphasizing both improvement of facilities at our various business operations—including introduction of highly efficient equipment—and day-to-day energy-conserving measures.

### Fuel Conversion

The amount of CO<sub>2</sub> generated in order to obtain the same level of heating value reached by a steam boiler and other equipment varies depending on whether fuel oil, city gas, or LPG is used as the energy source. Therefore, switching energy sources from fuel oil or kerosene to city gas, which generates less CO<sub>2</sub>, helps prevent global warming.

In Japan, Astellas actively converted the energy sources of its steam boilers so that, instead of fuel oil and kerosene, they run on city gas. By the end of fiscal 2011, we had completed the energy source conversion of all steam boilers at our R&D and production facilities.

### 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 its facilities in Japan, such as the Takahagi Facilities and the Tsukuba Biotechnology Research Center, upon the completion of a heat pump conversion program at these facilities. Going forward, we will continue introducing heat pump technologies while ensuring a stable supply of electric power.

### Introduction of an Energy Monitoring System

Tracing exactly how much energy we use does not directly lead to lower energy consumption. However, the ability to visually monitor energy usage can contribute to the formulation of new strategies, including elimination of wasteful practices. For this reason, Astellas is introducing energy monitoring systems at its various facilities in Japan.

### Using Renewable Energy

The direct use of renewable energy sources, such as solar energy 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.

In March 2012, the Kerry Plant in Ireland began operating a wind turbine power generation station with a maximum output of 800 kW and a wood chip biomass boiler. In the year under review, the wind power station generated 1,416 MWh of electricity, all of which was used at Astellas business facilities, and the wood chip biomass boiler also used 32,246 GJ of heat. These two initiatives account for a CO<sub>2</sub> emission reduction of 3,031 tons.

In Japan, we have installed photovoltaic generation systems at the Tsukuba R&D Center and the Kashima R&D Center. In fiscal 2012, those systems together generated 88 MWh of electricity, all of which was used at Astellas business facilities. The equivalent reduction in CO<sub>2</sub> emissions was 42 tons compared with purchasing electricity generated at a thermal power plant.

The Norman Plant in the United States purchases electricity generated by wind turbine farms. In fiscal 2012, electricity generated by wind turbine accounted for 20,410 MWh of the plant's overall electricity purchased, which totaled 20,852 MWh.

## Column

### Global Warming Prevention Measures Using Renewable Energy

Within the premises of its Kerry Plant in Ireland, Astellas has installed a wind turbine power generation station—measuring 99m in total height, including a 73m-long support pillar and a 53m rotor diameter—as well as a wood chip biomass boiler that uses forest thinning timber as its main fuel source. Both facilities started operation in March 2012.

The use of wind power generation enables the plant to reduce the volume of purchased electricity. In fiscal 2012, it was able to cut such purchases by the equivalent of around 800 tons of CO<sub>2</sub> emissions. Thanks to the operation of the wood chip biomass boiler, moreover, the plant's boilers no longer use diesel oil. In fiscal 2012, this equated to a reduction of around 2,200 tons of CO<sub>2</sub> emissions that would otherwise have been generated through diesel oil combustion.



# 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.

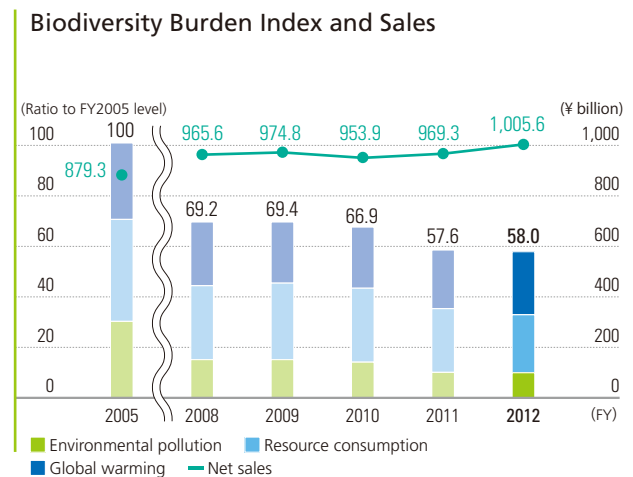
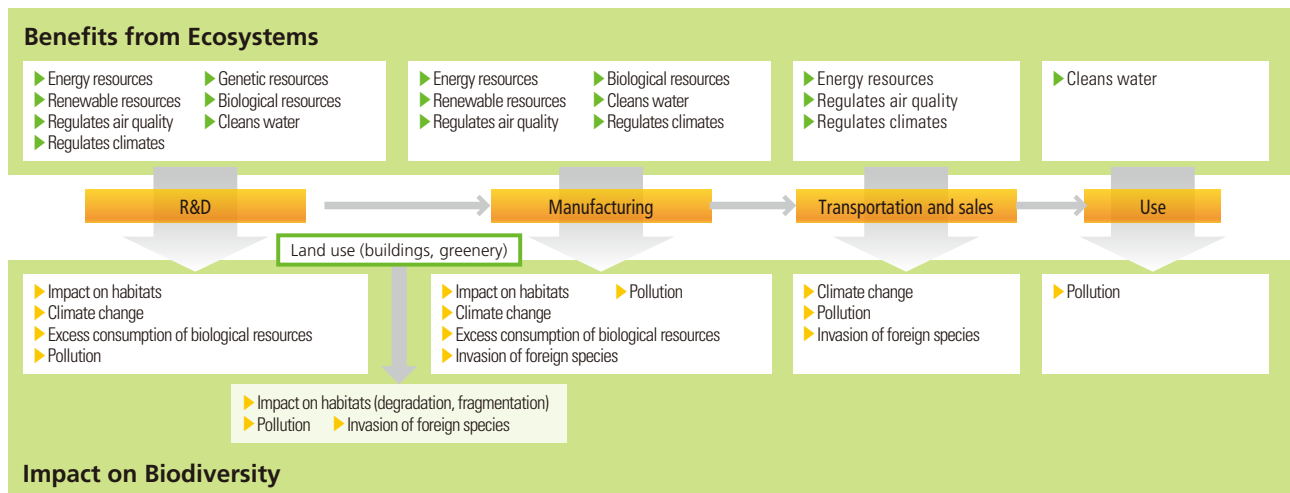
## ► Basic Policy

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.

## ► Biodiversity Index

Astellas has created a biodiversity 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 status of related initiatives. Going forward, we will continue making improvements in each category while working toward achieving the target set for fiscal 2020, which is two times the fiscal 2005 level.

(method: [http://www.astellas.com/en/csr/environment/biodiversity\\_big\\_02.html](http://www.astellas.com/en/csr/environment/biodiversity_big_02.html))





# 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 2020 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 2012, the Astellas group used 12,114 thousand m<sup>3</sup> of water on a global basis, a 28.7% reduction from the base year.

Of all the water used by the Group, 97.3% was used in Japan, and 85.1% of that used in Japan was industrial-use water.

As we have achieved the numerical target since the fiscal 2011, we are planning to keep the target at the current level without setting the target year for fiscal 2013 and onwards.

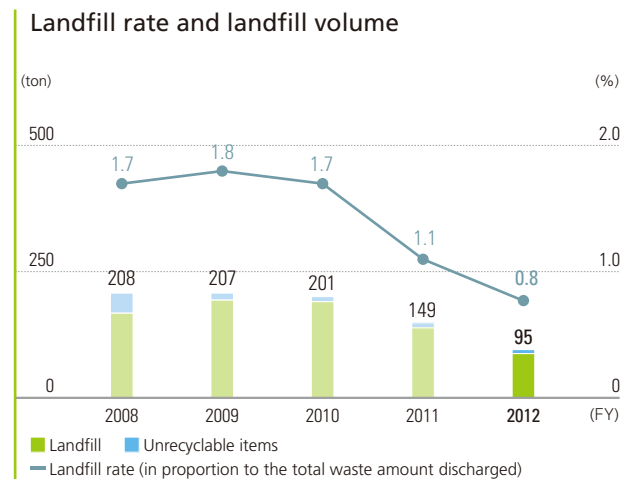
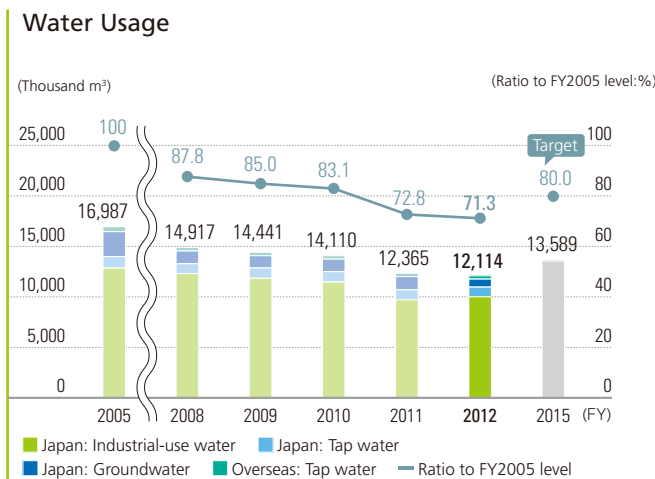
## ▶ Waste Management

**Environmental Action Plan**  
 Volume of waste materials subject to final disposal (Japan): 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. 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. For this reason, we first examine appropriate methods of waste disposal, and we conduct regular onsite visits to confirm that waste management contractors are using appropriate waste disposal methods.

In fiscal 2012, the volume of waste materials subject to final disposal was 0.8% of total waste discharged, meaning that Astellas has achieved its zero emission targets consistently since fiscal 2008.

\* Astellas' zero emission targets are to reduce the final volume of waste for disposal to less than 2% of total discharged volume. These targets do not include items that are extremely difficult to recycle, such as waste pharmaceutical products from distribution centers.



## Environmental Accounting

With respect to environmental conservation costs, in fiscal 2012 Astellas made investments of ¥753 million and incurred expenses of ¥1,943 million including depreciation and amortization. To prevent pollution, we conducted various activities, including maintenance on wastewater treatment facilities, and examined and maintained underground pipes. To help protect the global environment, we enhanced the operational management efficiency of existing equipment, and so on.

The economic benefits generated through environmental protection activities amounted to ¥101 million, which includes lower costs owing to energy savings, the sale of waste metals and solvents, and lower costs of treating waste materials.

Environmental remediation costs in the fiscal 2012 environment-related expenses totaled ¥224 million due to such factors as allowance for polychlorinated biphenyl (PCB) waste treatment.

### Environment-Related Investment and Expenses

(¥ million)

	FY2008		FY2009		FY2010		FY2011		FY2012	
	Investment	Expenses	Investment	Expenses	Investment	Expenses	Investment	Expenses	Investment	Expenses
Pollution prevention	211	614	161	461	177	687	225	489	239	479
Global environmental conservation	100	203	80	231	403	287	730	413	465	413
Resource recycling	2	411	1	340	6	344	0	432	21	441
Upstream/downstream costs	0	33	0	73	0	67	0	65	0	66
Administration costs	0	417	0	331	18	364	0	331	0	304
R&D costs	2	28	8	28	13	37	7	36	29	13
Social activity costs	0	7	0	6	0	3	0	2	0	2
Environmental remediation costs	0	21	0	141	0	76	0	255	0	224
<b>Total</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>	<b>753</b>	<b>1,943</b>

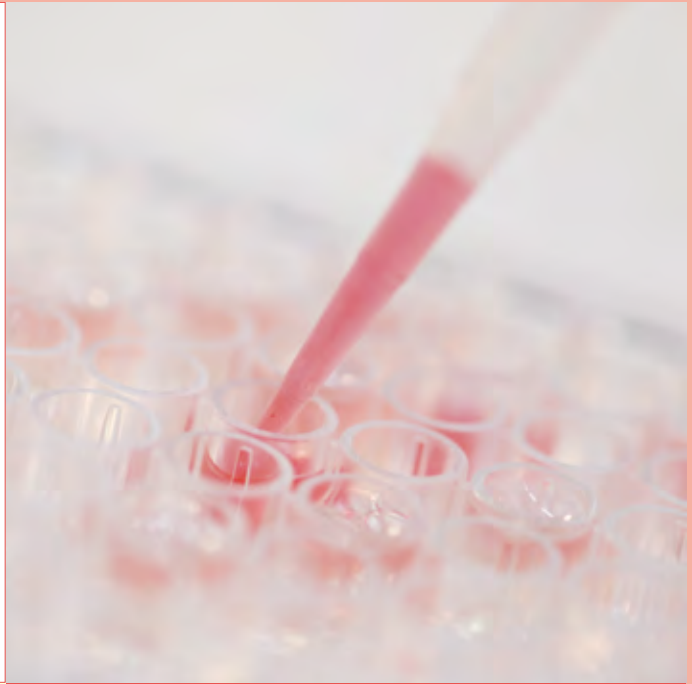
### Environmental Performance Trends in Japan (Annual Basis)

			FY2008	FY2009	FY2010	FY2011	FY2012		
INPUT	Energy	Electricity	(MWh)	211,001	212,472	218,364	203,533	205,346	
		City gas	(thousand m <sup>3</sup> )	21,401	21,982	23,813	24,134	24,167	
		LPG	(tons)	2,255	2,301	2,118	2,056	2,000	
		LNG	(tons)	—	—	—	1,618	2,540	
		Fuel oil	(kL)	4,677	4,480	4,110	840	44	
		Kerosene	(kL)	1,303	1,147	661	428	52	
		Diesel oil	(kL)	9	16	17	19	31	
		Gasoline	(kL)	3,353	3,171	3,077	3,106	2,930	
		Purchased heat energy	(GJ)	2,225	2,225	2,225	2,183	1,677	
	Resources	Water	(thousand m <sup>3</sup> )	14,579	14,105	13,760	12,031	11,786	
Raw materials*		(tons)	10,481	12,630	2,000	1,324	4,717		
OUTPUT	Global warming	CO <sub>2</sub> emissions	(thousand tons)	162	162	161	147	172	
		Air pollution	SO <sub>x</sub>	(tons)	5	5	5	1	0
			NO <sub>x</sub>	(tons)	43	44	41	31	33
	VOCs		(tons)	149	132	102	94	66	
	Water pollution	BOD load	(tons)	26	20	17	14	14	
		Drainage water	(thousand m <sup>3</sup> )	13,829	13,006	12,766	10,658	10,363	
	Waste	Volume generated	(tons)	19,469	20,882	19,508	13,422	11,455	
		Volume discharged	(tons)	10,038	10,876	10,778	13,069	11,415	
		Landfill volume	(tons)	208	207	201	149	95	

\* Raw materials have been separately tabulated on a weight-basis and on a volume-basis since fiscal 2010.

We aim to earn the trust of society  
and thus forge a pathway to  
sustainable progress.

To this end, all the members of  
Astellas complies with laws and  
regulations, and perform our business  
with high ethical standards.



# Compliance



- 074 Basic Policy
- 075 Compliance

## Basic Policy

Legal compliance is fundamental to business activities. Further, we believe that we must uphold high ethical standards in our business activities and continually ask ourselves whether our activities are acceptable to society in light of common social norms and customs. Astellas defines compliance broadly to mean conducting our business activities with high ethical standards in addition to legal compliance. This concept of compliance is the cornerstone of our CSR-based management.

We believe that always holding ourselves to high ethical standards and fulfilling our social responsibilities toward creating a sustainable society will help us earn and maintain the trust of stakeholders and enable us to achieve sustainable growth as a company.

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

- 1 Continually strengthen the compliance program on a global basis through close cooperation
- 2 Promote self-directed measures for strengthening compliance in each region

### Fiscal 2012 Initiatives

Local codes of conduct, which supplement the Astellas Global Code of Conduct, were either updated or prepared for each country or region

Global Compliance Committee meetings were convened

Training courses on various aspects of compliance were conducted in each region (training strengthened especially in Asia)

Compliance sessions led by the Chief Compliance Officer were held at our offices in Japan and overseas to enhance recognition of compliance

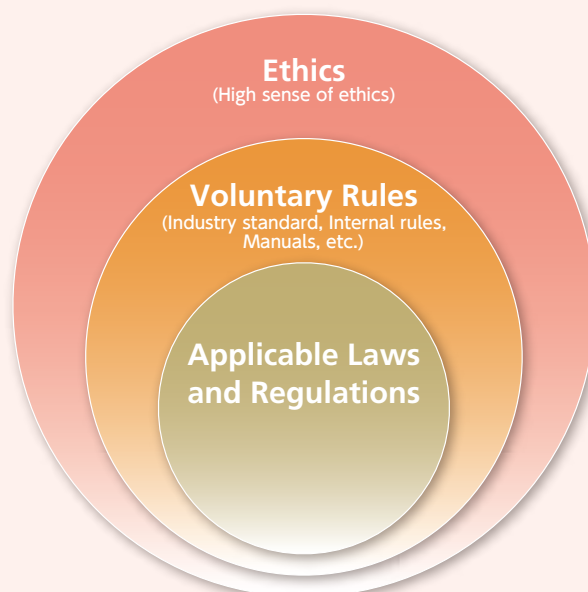
Surveys and analysis of potential compliance risks were conducted, and action plans to counter these potential risks were drawn up in Japan and other regions

### Review of Fiscal 2012 Initiatives

In fiscal 2012, the Astellas Global Code of Conduct took effect for all employees worldwide, supplemented by local codes of conduct for each region. Moreover, each region provided various training sessions that further advanced understanding of compliance across the whole group. In Japan and other regions, we conducted compliance risk surveys and analyses and devised action plans. Implementation of the action plans and its outcome assessment are scheduled for fiscal 2013.

## Astellas' Compliance

Our compliance requires to observe all applicable laws and regulations and uphold high ethical standards



## Promoting Compliance

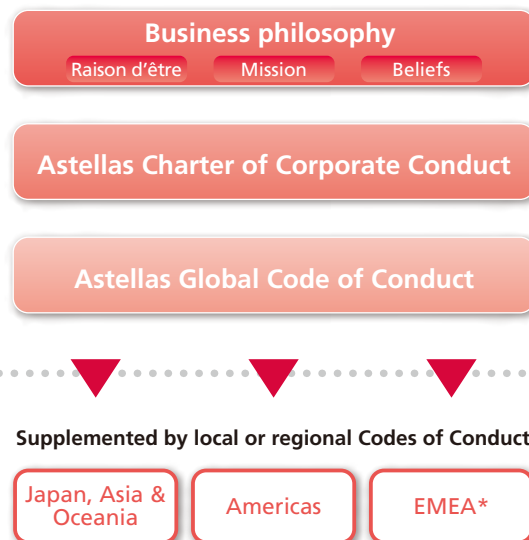
In addition to requiring all employees to observe applicable laws and regulations, we believe specific criteria for making value judgments are necessary to uphold high ethical standards in our business activities. Moreover, such criteria must be continuously reviewed and implemented as appropriate to accommodate changes in society and systems.

Under this basic approach, we revised the Astellas Charter of Corporate Conduct, which specifies the Company's business philosophy (raison d'être, mission, beliefs) in terms of corporate behavior in April 2012. At the same time, we formalized the "Astellas Global Code of Conduct" as a code that applies uniformly to Astellas employees throughout the world. Furthermore, we restructured our system of global compliance. Thus, we reinforced compliance in terms of both rulemaking and structural reform.

As first-tier rules that apply throughout the group, we rank the Astellas Global Code of Conduct next in importance to our business philosophy and the Astellas Charter of Corporate Conduct. However, it is not possible for the Astellas Global Code of Conduct to encompass all facets of the business activities of a global company like Astellas. Therefore, we have in place codes of conduct and policies for each region or country that take into account local requirements, enabling our compliance programs to function in an effective manner.

As part of our reorganization of our global compliance system, we established the new position of Chief Compliance Officer ("CCO"). The CCO is responsible for compliance across the entire Astellas group. We also appointed Regional Compliance Officers ("RCO") in each geographical region: (a) Japan/Asia/Oceania, (b) the Americas, and (c) Europe/Middle East/Africa. The RCOs are responsible for compliance in their respective regions. In fiscal 2012, the Global Compliance Committee, which is chaired by

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



\* EMEA: Europe, the Middle East and Africa

the CCO, met on two occasions. The Committee deliberated and made decisions concerning the updating or preparation of codes of conduct for each region, as well as what actions it will take in response to potential breach of compliance. Furthermore, at a regional level, local compliance committees met to deliberate and make decisions on, among others, devising local criteria and policies and measures for promoting compliance.

### ► Compliance Training

In addition to enhancing compliance from a global perspective through rulemaking and structural reform, we are strengthening compliance training in each region to help maintain a compliance-oriented mindset in our employees. We have increased compliance initiatives with a focus on strengthening training, particularly in Asia, a region that has experienced a notable expansion of business activities in recent years.

In fiscal 2012, Japanese employees deepened their knowledge of the Astellas Japan Code of Conduct by par-

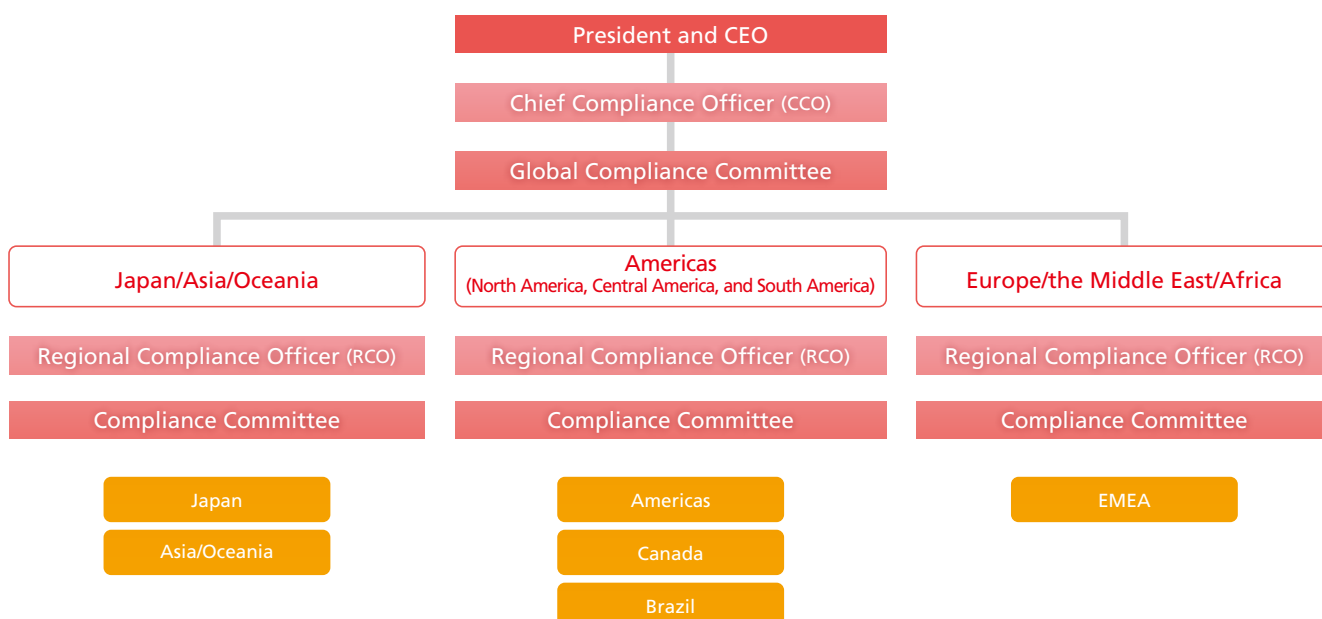
ticipating in e-learning programs. In addition, we provided training on new subjects such as potential risks and countermeasures associated with social media usage. We have continued to provide training designed to bolster anti-harassment measures. We also provided position-specific training for new directors, new managers, new graduate employees and new employees hired in mid-career.

Overseas employees also participated in training aimed to improve their understanding of applicable codes of conduct, as well as training in various areas of compliance that takes local requirements into account, such as anti-bribery, fraud awareness, off-label promotion, and conflicts of interest.

### ► Compliance Helpline

We have compliance helplines/hotlines in each region. By making use of these helplines/hotlines, employees can report and receive advice on how to react in the event they discover actual or suspected misconduct or are directed or ordered to carry out such misconduct. In Japan and other

## Astellas Global Compliance System



Asian countries, an external helpline/hotline has also been put into place, along with an internal helpline/hotline. In Japan a sexual harassment helpline is also available.

These helplines/hotlines are available in employees' native languages. Astellas has a policy of non retaliation against those who raise a concern or report a suspected compliance breach in good faith, even if the concern or report is not substantiated. In addition, Astellas fosters an environment that will make it easier for employees to use the compliance helplines/hotlines, since employees may have concerns about retribution and penalization.

In fiscal 2012, our helplines/hotlines received consultation requests in each region. Matters raised include power harassment, sexual harassment, conflicts of interest, and unfair business practices. In response, we conducted thorough investigations and took appropriate actions in accordance with local requirements and processes. We also took steps to prevent the reoccurrence of similar problems, as appropriate.

### ► Anti-Corruption Initiatives

Globally, countries have pledged to get more serious about potential corruption and bribery. In some countries, new stricter laws have been implemented. Authorities in both the United States and United Kingdom have increased enforcement efforts on bribery of foreign government officials. Anti-corruption is one of the ten prin-

ciples of the United Nations Global Compact, to which Astellas is a signatory.

Against this backdrop, Astellas has strengthened initiatives to prevent bribery and other forms of corruption. In fiscal 2011, we informed through our internal website all employees of our global CEO's commitment to prevent corruption. In addition, we established the Astellas Global Code of Conduct in fiscal 2012 and followed this with the formulation of local codes of conduct based on the Global Code of Conduct, all of which display our commitment to prevent corruption. We have anti-bribery and corruption policies and have conducted anti-bribery and corruption training so that employees can fully recognize the importance of preventing any instances of bribery and corruption. Furthermore, the CCO held training sessions at our offices in Japan, Asia, Europe and the Americas to enhance recognition of compliance with the aim of preventing bribery and corruption.

Astellas strives to detect improper and corrupt behavior as early as possible through a number of measures. These include fraud audits conducted worldwide, as well as helpline/hotline reports from employees and improved purchasing processes. In the event any improper or corrupt behavior is identified, the responsible RCO informs the CCO without delay and timely and appropriate actions are taken, including reprimanding the parties involved and examining ways to prevent recurrence.



The Global Compliance Committee met on two occasions in fiscal 2012

# 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, we strive to earn the support and trust of all stakeholders, including customers, shareholders, employees, and society.

## ► Corporate Governance Systems and Measures

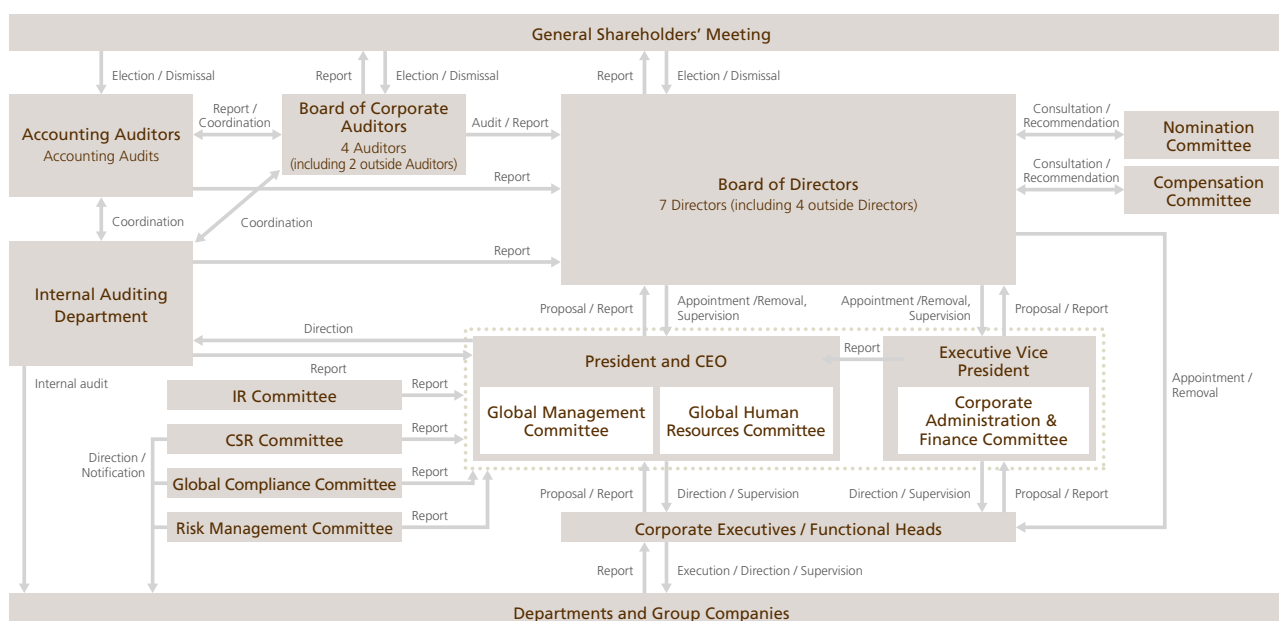
### Board of Directors

The Company has put into place a Corporate Executive 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.

With respect to the Board of Directors, it now comprises seven members, including four outside 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 elected at the annual General Shareholders’ Meeting. In the interest of clarifying management responsibilities and strengthening corporate governance, each Director is elected for a one-year term.

At Astellas, the Nomination Committee and the Compensation Committee serve as advisory bodies to the Board of Directors. Outside Directors account for the majority of

## Corporate Governance at Astellas





members on these committees. These committees ensure the transparency and objectivity of the deliberation process for the nomination and the compensation system of Directors and Corporate Executives.

### Board of Corporate Auditors

Astellas uses a Corporate Auditor System. The Board of Corporate Auditors consists of four Corporate Auditors, including two outside ones, and each Corporate Auditor conducts audits of performance of duties by Directors. Audits are carried out effectively by both full-time internal Corporate Auditors, who are very familiar with issues in the Company, and outside Corporate Auditors, who 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 outside Director has a specific area of expertise, such as business management, law, or medicine. They make use of their wide-ranging experience and expertise to participate in decision-making at Board of Directors meetings and oversee business execution from an independent standpoint.

Both of the two outside Corporate Auditors are also independent Auditors. They draw on their specific expertise in such areas as finance, accounting, and business management, and their 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 enterprise 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 system to meet the duties and responsibilities of the Directors and

## 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 2012
Outside Director	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.	16/16 times
	Yutaka Kase	Yutaka Kase has abundant experience in corporate management. The Company is confident that he will draw on his experience in management of the Company from an independent position.	Inaugurated in June 2013
	Hironobu Yasuda	Hironobu Yasuda has abundant specialized knowledge and experience. The Company is confident that he will draw on his knowledge and experience in management of the Company from an independent position as an attorney-at-law.	Inaugurated in June 2013
Outside Corporate Auditor	Yukiko Kuroda	Yukiko Kuroda currently plays a key role as an outside Corporate Auditor from an independent position. The Company is confident that she will draw on her abundant experience in corporate management in audit of the Company in the future as well.	16/16 Board of Directors meetings 14/14 Board of Corporate Auditors meetings
	Shigeru Nishiyama	Shigeru Nishiyama currently plays a key role as an outside Corporate Auditor from an independent position. The Company is confident that he will draw on his abundant specialized knowledge and experience as a business scholar and a certified public accountant in audit of the Company in the future as well.	13/13 Board of Directors meetings 10/11 Board of Corporate Auditors meetings

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.

	Type of Compensation*			
	Total Compensation*	Base Salary	Stock Options	Bonus
Directors (excluding outside Directors): 3	523	292	114	116
Corporate Auditors (excluding outside Corporate Auditors): 2	87	87	-	-
Outside Directors and outside Corporate Auditors: 7	72	72	-	-

(¥ million)

\* The total amount of compensation shown here is the amount paid as compensation for the performance of duties during fiscal 2012, and includes the amount paid to one outside Corporate Auditor who retired during fiscal 2012.

## ► 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 that consists of a functional axis—covering the functions of research, development, technology, and quality assurance (QA), regulatory affairs (RA), and pharmacovigilance (PV)—as well as a geographical region axis covering the sales & marketing function.

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

Astellas also has committees responsible for other

## Top Management Structure (as of April 1, 2013)

Current Position	Department in-charge
President and CEO Yoshihiko Hatanaka	Internal Auditing, Drug Discovery Research, Global Development, QA, RA and PV, Technology, Sales & Marketing, Asia International, Astellas Pharma Europe Ltd., Astellas US LLC, Agensys, Inc.
Executive Vice President Yoshiro Miyokawa	External Relations, General Affairs, Human Resources, Legal & Compliance, Executive Office
Chief Financial Officer Yasumasa Masuda	Corporate Finance & Control, Accounting & Tax, Corporate Communications, Procurement, Information Systems
Chief Strategy Officer Kenji Yasukawa	Corporate Planning, Product and Portfolio Strategy, Licensing & Alliances, Intellectual Property, Global Vaccine Business Development
Chief Medical Officer Sef Kurstjens	Global Pharmacovigilance, Global Medical Affairs

## 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 executive 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, revision, and other matters concerning the Company's corporate disclosure policy.

aspects of business execution. They are the CSR Committee, the Global Compliance Committee, the Risk Management Committee, and the IR Committee.

### ► Accounting Audit

Ernst & Young ShinNihon LLC serves as the Company's Accounting Auditor. The Accounting Auditor and the Company's Corporate Auditors maintain close cooperation by meeting several times a year. At these meetings, they discuss their annual audit plans and the results of audits, and they 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 2012	141
Total amount of cash and other material benefits payable to Accounting Auditor by the Company and its subsidiaries	182

### ► Measures to Improve the Internal Control System

The Company has put into practice 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 available at the Company's Web site, and in the reports concerning corporate governance submitted to the stock exchanges, etc.

### ► Efforts to Invigorate the General Shareholders' Meeting and Facilitate Smooth Exercise of Voting Rights

Seeking to invigorate its General Shareholders' Meeting, the Company sends out convocation notices three weeks in advance of its annual General Shareholders' Meeting. We also hold such meetings on days when there is no concentration of other companies' shareholders' meetings. To enhance the environment for the exercise of voting rights, meanwhile, we utilize an electronic voting platform operated by a joint venture in which the Tokyo Stock Exchange and other entities own equity stakes.

Astellas also prepares an English translation of its convocation notices and makes both the Japanese original and its English translation available on its corporate website.

### ► 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 in fiscal 2012 included holding regular briefings on financial results and on R&D for securities analysts, institutional investors, and news media, as well as participation in conferences held by securities companies both in Japan and overseas. In Japan, we also held briefings for individual shareholders and other individual investors.

# Masafumi Nogimori × Kanoko Oishi

We asked two members of the Board of Directors—Representative Director and Chairman Masafumi Nogimori and outside Director Kanoko Oishi—about three topics that form the basis for Astellas' sustainable growth.

**Masafumi Nogimori**

Representative Director  
and Chairman

**Kanoko Oishi**

Outside Director



## Corporate Governance

**Q.** Since its inception, Astellas has consistently sought to reinforce corporate governance. How does Astellas' system of corporate governance actually work?

**Nogimori:** Our system of corporate governance has a few notable features including the clear separation between business execution and management supervision, and the composition of the Board of Directors, of which independent outside Directors comprise more than half. When Astellas was established in 2005, we believed it was absolutely necessary to have an objective system of corporate governance that was evident from the outside, as well as one that actually functioned in order for the Company to prosper as a global company. That is why we established

this corporate governance system. Although attention is often focused on the number of outside Directors, having many outside Directors does not in itself guarantee good governance. For outside Directors to function well, a company must appoint outside Directors who are independent and can contribute to corporate management, and it must listen and respond respectfully to their opinions. Monitoring governance to ensure it is functioning properly is an important role I perform as Chairman of the Board.

**Oishi:** As far as the actual functioning goes, I believe that my role as an outside Director is to have my objective opinions as a third party reflected in the Company's management. In my experience, the atmosphere at Board meetings encourages members to talk candidly and frankly, and everyone listens respectfully when someone is expressing

an opinion, whether they are in agreement with, require clarification about, or are opposed to the matter up for discussion. At Astellas' Board meetings, there is thorough discussion of each important agenda item that requires consideration and a decision by Board members.

**Nogimori:** Yes, that is right. The agenda of Board meetings is set by the Company's regulations, and matters such as large-scale investment or particulars related to long-term corporate management require Board approval. In addition, general matters such as corporate culture are discussed at meetings, where the views of outside Directors are taken into account.

**Oishi:** From my position outside the Company, and also as someone who runs their own business and has experience as a consultant, I strive to translate and voice my understanding of macro-level movements and employees' thinking. Other outside Directors as well are not afraid to express their opinions.

**Nogimori:** I believe we have created an environment in which outside Directors can express their views freely. In fact, I would welcome even more open discussion. Our outside Directors certainly speak up if they have a particular issue with something. On many occasions, I have been reminded of a particular point thanks to an outside Director's comment. Let me give an example. In other industries, when discussing medium- to long-term management plans it is normal to start with forecasts for the external business environment and devise an action plan needed to achieve the plan's goals, including product development plans and the like. But in the case of Astellas, we tend to discuss medium- to long-term plans based on and within the scope of the existing drug development pipeline. In the course of talking with outside Directors, I have learned that this kind of approach differs from standard business practices, and that there is room for improvement in the way we formulate our plans.

I believe that we must not shy away from pursuing reforms and must not become mired in a rigid style of management constrained by the conventions that exist within the narrow confines of the pharmaceutical industry.

**Oishi:** When considering what matters will be crucial to

advancing reform, diversity comes to mind as an urgent initiative. Most companies in Japan today are still run mainly by men from a largely male perspective. In my view, introducing new values not only achieves diversity, but also leads to enhanced corporate value.

**Nogimori:** Since our business activities will become increasingly global, we face the task of improving corporate governance, which includes the policy of personnel recruitment and allocation, in order to establish a system befitting a global corporation.

## Diversity

**Q. How is Astellas promoting diversity?**

**Nogimori:** As Ms. Oishi mentioned, historically, Japanese companies have generally been dominated by men. Even at Astellas, the first step toward diversity has been to encourage female employees to take a more active role. The next stage is fostering global human resources comprising employees of different ethnicities and nationalities, who have different cultural backgrounds and values. On this point, we are in the process of establishing a framework that will ensure diversity. In addition to values and a code of conduct that are shared globally, this entails creating systems of compliance that can address the rules and customs of local communities, and employment and personnel systems compatible with local cultures. In addition, we believe that Astellas' mission is also to help people with disabilities display their skills at Astellas and lead independent lives.

It is not possible to achieve diversity in the workplace overnight through the setting of numerical targets. However, we are pursuing a multi-pronged approach for fostering a corporate culture that embraces diversity.

**Oishi:** Looking at Astellas' stance on the promotion of diversity from a female perspective, it has very extensive, well-designed systems that support working mothers and the like, and I feel strongly that Astellas is committed to seeing diversity succeed not only in form, but also in substance. It has a good program in Japan under which executive officers mentor female employees in managerial

positions. It is often said that in Japan, where traditionally there have been few women in top management positions, it is difficult for female employees who do not have role models to continue working. But I think role models do not necessarily have to be women. If I were a mentor, I would want to tell female managers that you do not have to be perfect at everything in order to keep working for the long term. It benefits women in managerial positions to hear first-hand from male mentors who are executive officers how they managed to overcome difficulties and achieve their goals. It also provides a good opportunity for executive officers to deepen their understanding of the feelings of female managers.

**Nogimori:** As well as improving systems on the structural side, we are also promoting a mindset that is more

“Astellas is an ever-changing company.”



understanding of the various life events occurring in employees' lives. Today, our employees are also more aware of the diversity of nationalities in the workplace. I believe that deliberate initiatives are essential, although changing attitudes takes some time. In my view, promoting diversity generates high-quality outcomes by taking into account different opinions and allowing for balance achieved through diversification of areas where employees excel.

**Oishi:** To give a specific example, from a female perspective there are many women engaged in the provision of healthcare. A doctor once said to me that this might be because women are more inclined than men to care for and support others. If the purpose of a pharmaceutical company is to offer ongoing support to healthcare professionals who want to care for patients, then I think that women's strengths have an important role to play.

### Long-Term Vision and Astellas' Corporate Culture

**Q.** Looking at Astellas' corporate culture overall, what are its unique characteristics? Also, what are your views on Astellas' long-term direction?

**Nogimori:** In an ideal world, a company's culture should take root naturally over a period of many years. However, Astellas was formed through the merger of two companies with different cultures, on top of which we chose a path aimed at rapid global development. As a result, we have had to establish values that can be shared by employees worldwide. We came up with the Five Messages for the Astellas Way through a process of holding exhaustive discussions with all members of the Global Management Committee.

The Five Messages consist of easy-to-understand values and a code of conduct for all, and place patients at the heart of all decisions and actions. Putting them into practice is no easy task. Conversely, if all employees can strive to observe these values and actions, then I am certain we will become a wonderful company without equal.

**Oishi:** My impression is that Astellas is a company for which the keywords "sincere" and "fair" fit perfectly. Also, hearing Mr. Nogimori talk about the history of the

formulation of the Astellas Way and the initiatives taken to ensure its widespread adoption, I regard Astellas as a company that first identifies the kind of company it wants to be and then makes every effort to follow a step by step path toward its goal. I fully expect that advancing fairly and steadily while earnestly incorporating outside opinions, coupled with top management's ongoing demonstration of such a stance, will enhance employee trust and enable the desired corporate culture to take hold.

**Nogimori:** I am always saying to people that Astellas is an ever-changing company. By this, I am not referring to implementing sweeping reforms under pressure from changes in the business environment. I want Astellas to be a company that continuously rises to the challenge of change on a daily basis, even if the effort seems mundane, and responds assertively to changing times. On this aspect, I feel that today's management has come pretty close to achieving the ideal.

**Oishi:** Developing new drugs that do not yet exist and delivering them to patients who are waiting for such drugs is a wonderful endeavor. The progressive aging of populations, primarily in the developed world, is increasing health awareness and placing more and more demand on health-care systems. Astellas' execution of its business model in response to such needs is also significant in a social context. We can foster a high-motivation corporate culture by enabling employees to take pride in their jobs and aspire to do more while doing their work day after day with passion and enthusiasm. Of course, this kind of company ought to attract outstanding human resources. Because Astellas possesses strong drug development capabilities even when viewed from a global perspective, I would like to see Astellas focus on these strengths while working to achieve its big dreams and aspirations.

**Nogimori:** I think that concentrating on new drugs underpinned by research and development while adapting deftly to changes in the external environment is the right direction to take at this point in time. I say this because there are many unmet medical needs and delivering innovative new drugs to patients is Astellas' *raison d'être*. Businesses that make generic drugs and non-prescription drugs owe

their existence to businesses making new drugs. In other words, the pharmaceutical industry would neither advance nor prosper without new drug development.

The pharmaceutical industry is governed by numerous regulations, and changes to such regulations have a huge impact on the business environment. While this susceptibility to change poses risks, addressing such changes also presents opportunities. Accordingly, we must review our organizational structure and various frameworks constantly so that when there is change we can respond flexibly and swiftly to turn that change into an opportunity. Indeed, a major challenge for Astellas going forward will be the "resilience" with which it responds to changes in the business environment.

“Astellas identifies the kind of company it wants to be and then makes every effort to follow a step by step path.”



## Directors and Corporate Auditors (as of June 19, 2013)



**Hironobu Yasuda**  
Outside Director

April 1978: Public Prosecutor, Tokyo District Public Prosecutors Office  
April 2004: Public Prosecutor, Tokyo High Public Prosecutors Office  
January 2005: Chief Appeals Judge (Director of Tokyo Regional Tax Tribunal)  
January 2009: Chief Prosecutor, Yamaguchi District Public Prosecutors Office  
June 2010: Public Prosecutor, Supreme Public Prosecutors Office  
October 2010: Registered as an attorney-at-law (Dai-ichi Tokyo Bar Association)  
January 2012: Partner, Seiryō Law Office (present post)  
June 2013: Director of the Company (present post)

**Yutaka Kase**  
Outside Director

May 1970: Joined Nissho Iwai Corporation  
June 2001: Executive Officer, Nissho Iwai Corporation  
April 2003: Managing Executive Officer and Director, Nissho Iwai Corporation  
April 2004: Senior Managing Executive Officer and Representative Director, Sojitz Corporation  
August 2004: Executive Vice President and Representative Director, Sojitz Corporation  
April 2007: President and Representative Director, Sojitz Corporation  
April 2012: Chairman and Representative Director, Sojitz Corporation (present post)  
June 2013: Director of the Company (present post)

**Naoki Aikawa, M.D., Ph.D.**  
Outside Director

April 1969: Assistant in Surgery, School of Medicine, Keio University  
January 1973: Research Fellow in Surgery, Harvard Medical School  
July 1978: Chief Surgeon, Saiseikai Kanagawaken Hospital  
May 1988: Associate Professor, Emergency & Critical Care Medicine, School of Medicine, Keio University  
June 1992: Professor, School of Medicine, (Emergency and Critical Care), Keio University  
October 1999: Director, Keio University Medical Media Center  
October 2003: General Director, Keio University Hospital  
April 2009: Professor Emeritus, Keio University (present post)  
April 2009: Special advisor (Part-time), Social Welfare Organization Tokyo Saiseikai Central Hospital (present post)  
June 2011: Director of the Company (present post)

**Yoshirou Miyokawa**  
Representative Director and Executive Vice President

April 1975: Joined the Company  
January 2003: Vice President of Business Process Reengineering of the Company  
April 2005: Vice President of Post Merger Integration Operation of the Company  
June 2005: Corporate Executive and Vice President of Post Merger Integration Operation of the Company  
September 2005: Corporate Executive and Vice President of Business Innovation of the Company  
April 2006: Corporate Executive and Vice President of Human Resource, Corporate Administration Division of the Company  
April 2007: Corporate Executive and Vice President of Human Resource of the Company  
April 2008: Corporate Executive of the Company, Corporate Administration (CAO)  
June 2008: Senior Corporate Executive of the Company, Corporate Administration (CAO)  
June 2011: Executive Vice President and Senior Corporate Executive of the Company  
June 2013: Executive Vice President and Representative Director of the Company (present post)

**Kanoko Oishi**  
Outside Director

April 1983: Joined Nippon Life Insurance Company  
November 1988: Joined McKinsey & Company, Inc.  
January 1993: Partner, McKinsey & Company, Inc.  
June 2000: Established MEDIVA, Inc.; Representative Director, MEDIVA, Inc. (present post)  
July 2000: Established Seinan MEDIVA Co., Ltd. (currently Seeds 1); Representative Director, Seinan MEDIVA Co., Ltd. (present post)  
August 2004: Established Medical corporation PLATANUS; COO, PLATANUS (present post)  
June 2010: Director of the Company (present post)

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

April 1980: Joined Fujisawa Pharmaceutical Co., Ltd.  
April 2003: Director of Corporate Planning, Fujisawa Pharmaceutical Co., Ltd.  
April 2005: Vice President of Corporate Planning, Corporate Strategy Division of the Company  
June 2005: Corporate Executive and Vice President of Corporate Planning, Corporate Strategy of the Company  
April 2006: Corporate Executive of the Company and President & CEO, Astellas US LLC and President & CEO, Astellas Pharma US, Inc.  
June 2008: Senior Corporate Executive of the Company and President & CEO, Astellas US LLC and President & CEO, Astellas Pharma US, Inc.  
April 2009: Senior Corporate Executive of the Company Corporate Strategy and Corporate Finance (CFO & CSTO)  
June 2011: President & CEO and Representative Director of the Company (present post)





#### Masafumi Nogimori

Representative Director  
and Chairman

April 1970: Joined Fujisawa Pharmaceutical Co., Ltd.  
June 1997: Member of the Board, Fujisawa Pharmaceutical Co., Ltd.  
July 1998: President, Fujisawa GmbH  
June 2000: Resigned as Member of the Board, Fujisawa Pharmaceutical Co., Ltd. Corporate Vice President, Fujisawa Pharmaceutical Co., Ltd.  
April 2001: Corporate Vice President, Associate Executive Director of Ethical Pharmaceuticals and Director of Pharmaceutical Planning, Fujisawa Pharmaceutical Co., Ltd.  
June 2001: Corporate Senior Vice President and Director of Global Corporate Strategies Planning, Fujisawa Pharmaceutical Co., Ltd.  
June 2003: Member of the Board, Fujisawa Pharmaceutical Co., Ltd.  
June 2004: Corporate Executive Vice President and Member of the Board, Fujisawa Pharmaceutical Co., Ltd.  
April 2005: Executive Vice President and Representative Director of the Company  
June 2006: President & CEO and Representative Director of the Company  
June 2011: Chairman and Representative Director of the Company (present post)

#### Yukiko Kuroda

Outside Corporate Auditor

April 1986: Joined Sony Corporation  
January 1990: Representative Director, People Focus Consulting  
July 1991: Senior Consultant, Gemini Consulting  
August 1996: Member of the Board, CICOM BRAINZ Inc.  
June 2010: Corporate Auditor of the Company (present post)  
April 2012: Founder/Managing Director, People Focus Consulting (present post)

#### Go Otani

Corporate Auditor

April 1980: Joined the Company  
April 2009: Vice President of Internal Auditing Department of the Company  
April 2013: Assistant to President  
June 2013: Corporate Auditor of the Company (present post)

#### Shigeru Nishiyama

Outside Corporate Auditor

April 1984: Joined Sanwa Tokyo Marunouchi Audit Corporation (currently Deloitte Touche Tohmatsu LLC)  
September 1995: Established Nishiyama Associates  
April 2002: Associate Professor, Graduate School of Asia-Pacific Studies, Waseda University  
April 2006: Professor, Graduate School of Asia-Pacific Studies, Waseda University  
April 2008: Professor, Graduate School of Commerce, Waseda University (present post)  
June 2012: Corporate Auditor of the Company (present post)

#### Seigo Kashii

Corporate Auditor

April 1978: Joined Fujisawa Pharmaceutical Co., Ltd.  
April 2006: Director of Legal Department of the Company  
June 2007: Corporate Executive and Director of Legal Department of the Company  
April 2009: Corporate Executive of the Company and President & CEO, Astellas US LLC and President & CEO, Astellas Pharma US, Inc.  
April 2011: Assistant to President and Corporate Executive of the Company  
June 2011: Corporate Auditor of the Company (present post)

# Global Management Committee Members (as of June 19, 2013)

**Shinichiro Katayanagi**

Senior Vice President and  
President, Asia International

**Yoshihiko Hatanaka**

Representative Director,  
President and CEO



**Mitsunori Matsuda**

Senior Vice President and  
President, Technology

**Kenji Yasukawa, Ph.D.**

Senior Vice President and  
Chief Strategy Officer

Representative Director,  
President and CEO

Yoshihiko Hatanaka

Representative Director,  
Executive Vice President  
CAO & CCO

Yoshirou Miyokawa

Senior Corporate Executives

Masao Yoshida

Shinichi Tsukamoto,  
Ph.D.

Masaru Imahori

Masaharu Asano  
Ph.D.

Yasumasa Masuda

Kenji Yasukawa,  
Ph.D.

Corporate Executives

Hidetoshi Shuto

Hirofumi Seki

Shinichiro Katayanagi

Toshihiko Iwata

Yoshihiro Minami

Mitsunori Matsuda

Shoji Yokota

Takahisa Iizuka

Yukihiko Sato

Haruhisa Hiroasaki

Kenji Sumi

Chihiro Yokota

Wataru Uchida

Makoto Takeuchi

Masatoshi Kuroda

Atsushi Kamide

Kiyotaka Hayashi

Kazunori Okimura

**Yoshirou Miyokawa**

Representative Director,  
Executive Vice President  
CAO\*1 & CCO\*2



**Shinichi Tsukamoto, Ph.D.**

Senior Vice President and  
President, Drug Discovery Research



**Yukihiko Sato**

Senior Vice President and  
President, Sales & Marketing-Japan

**Sef Kurtstjens, M.D., Ph.D.**

Chief Medical Officer  
President, Astellas Pharma  
Global Development, Inc.

**Ken Jones**

President and CEO,  
Astellas Pharma Europe Ltd.



**Masao Yoshida**

President and CEO,  
Astellas US LLC

**Yasumasa Masuda**

Senior Vice President and  
Chief Financial Officer

**Masaharu Asano, Ph.D.**

Senior Vice President and  
President, QA, RA and Pharmacovigilance

\*1 CAO: Chief Administrative Officer  
\*2 CCO: Chief Compliance Officer

# CSR Communication

Astellas places a high value on communication with stakeholders in advancing its CSR-based management. Accordingly, we report a variety of our activities through our corporate website and various publications, where you can see how Astellas works.



The latest CSR-related topics are introduced.

The President explains the Top Commitment.

Astellas' CSR-based management, particularly as it pertains to ISO 26000, is explained.

Astellas' initiatives to improve access to health are shown.

The GRI Content Index is shown.

 <http://www.astellas.com/en/csr> 

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



**Integrated Annual Report/CSR Reports**  
Integrated Annual Reports since 2012 and all CSR reports up to 2011 can be accessed

<http://www.astellas.com/en/csr/management/report.html>



**Environmental Report 2013**  
Details of our environmental activities are disclosed. (To be issued in Sep. 2013)

<http://www.astellas.com/en/csr/pdf/EnvironentalReport2013.pdf>



**Corporate Governance Report (Japanese version only)**  
A detailed update on the status of our corporate governance is provided.

<http://www.astellas.com/jp/corporate/pdf/gvnnce.pdf>

# Financial Section

092	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
135	Independent Auditor's Report

# Management's Discussion and Analysis

In this section, the Americas and Europe are used as follows: the Americas refers to North, Central, and South America; Europe includes Europe along with the Middle and Near East, and Africa

## ► Overview of Year Ended March 31, 2013 (Fiscal 2012)

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. 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 2012 showed increases in net sales, operating income, and net income.

In the year under review, consolidated net sales increased by 3.7%, to ¥1,005.6 billion. New products contributed to increased sales, including XTANDI, a treatment for prostate cancer, and Betanis/Myrbetriq, a treatment for overactive bladder (OAB). While sales of Vesicare, a treatment for OAB, and Funguard/MYCAMINE, a Candin-type anti-fungal agent, continued to increase, sales of Prograf, the immunosuppressant, showed expansion. However, sales of Harnal, a treatment for functional symptoms of benign prostatic hyperplasia, declined mainly due to the impact of generics.

Operating income increased 17.0%, to ¥153.9 billion, thanks to an increase in gross profit that offsets rises in selling, general and administrative expenses. Net income increased 5.9%, to ¥82.9 billion, despite a recording of ¥34.8 billion in loss on impairment of fixed assets and other factors.

### Foreign Exchange Impact for Fiscal 2012

The exchange rates for the yen in fiscal 2012 are shown in the table below. Movements in the rates led to a ¥9.0 billion increase in the value of net sales and a ¥7.5 billion decrease in operating income. Due to the depreciation in the yen in the run-up to March 31, 2013, the effect of an elimination of unrealized gains related to foreign currency-

denominated inventories held by overseas subsidiaries in intra-group transactions put downward pressure on gross profit in the consolidated financial statements after these items were converted into yen. This is in contrast with the previous fiscal year, when the exchange rates were moving in the direction of a stronger yen on March 31, 2012, and the effect of an elimination of unrealized gains raised gross profit. Consequently, the impact of the exchange rates on financial results is to increase net sales but to decrease operating income.

### Foreign Exchange Rates (Average)

	2012.3	2013.3
US\$1	¥ 79	¥ 83
€1	109	107

### Fluctuation in Foreign Exchange Rates from April to March

	2012.3	2013.3
US\$	up ¥1	down ¥12
€	up ¥8	down ¥11

### Net Sales

In fiscal 2012, consolidated net sales amounted to ¥1,005.6 billion, a year-on-year increase of ¥36.2 billion, or 3.7%.

### Net Sales by Product Sales of Global Products

#### Prograf, Advagraf/Graceptor (Immunosuppressant)

Sales in Japan increased by 12.2%, to ¥49.4 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 45% of sales of Prograf in Japan. In the transplantation area, sales of the once-daily formulation Graceptor increased steadily.

Sales in the Americas on a U.S. dollar basis increased by 2.4%, to US\$378 million, thanks to some temporary factors in the fiscal 2012 on top of the slowdown in the rate of market-share expansion of generic versions. When converted to yen, sales increased by 7.6%, to ¥31.4 billion.

The share of generic products in the tacrolimus market, which includes Prograf and its generics, was approximately 67% on a total prescription basis during fiscal 2012. Meanwhile, we obtained approval for the once-daily formulation ASTAGRAF XL in the United States for the indication of prophylaxis of organ rejection in patients receiving a kidney transplant with mycophenolate mofetil (MMF) and corticosteroids, with or without basiliximab induction in July 2013.

In Europe, despite a continuous increase in sales of the once-daily formulation Advagraf, sales of Prograf (including Advagraf) through Astellas' own distribution channels declined by 2.9%, to €536 million on a euro basis, due primarily to price reductions in each country and the

impact of generic versions. Sales decreased by 4.5%, to ¥57.5 billion when converted to yen. Advagraf is sold in 39 countries in Europe, and sales of the drug accounted for around 30% of total Prograf sales in the region. The share of the generic versions in Europe was approximately 6% (on a volume basis) during fiscal 2012.

In Asia and Oceania, sales grew by 23.7%, to ¥18.9 billion. Sales showed steady growth mainly in China and South Korea. Advagraf was launched in Singapore in August 2012 and in Malaysia in January 2013.

#### Vesicare (Overactive bladder (OAB) treatment)

Sales in Japan expanded steadily, amounting to ¥29.8 billion, year-on-year increase of 6.2%. In fiscal 2012, Vesicare's

#### Sales by Product (Global Products)

	(¥ billion)			(%)
	2012.3	2013.3	YoY	CER*1
<b>Prograf</b>	¥ 154.9	¥ 161.8	4.4	—
Japan	44.0	49.4	12.2	—
Americas	29.2	31.4	7.6	2.4
Europe	60.2	57.5	(4.5)	(2.9)
Asia & Oceania	15.2	18.9	23.7	—
Exports	6.0	4.4	(26.7)	(25.7)
<b>Harnal/Omnice</b>	60.8	54.0	(11.3)	—
Japan	27.4	22.9	(16.2)	—
Europe	18.0	15.4	(14.6)	(13.2)
Asia & Oceania	9.8	10.8	10.7	—
Bulk/Royalties	4.7	3.9	(18.0)	(16.6)
<b>Vesicare</b>	97.2	110.0	13.1	—
Japan	28.0	29.8	6.2	—
Americas	38.9	46.8	20.1	14.3
Europe	27.5	30.1	9.2	11.1
Asia & Oceania	2.4	2.9	20.7	—
<b>Betanis/Myrbetriq/BETMIGA</b>	0.9	6.9	641.1	—
Japan	0.9	5.3	466.7	—
Americas	—	1.6	—	—
Europe	—	0.0	—	—
<b>Funguard/MYCAMINE</b>	26.2	30.7	16.8	—
Japan	12.5	12.9	2.6	—
Americas	8.2	9.4	14.9	9.4
Europe	3.7	5.9	58.3	61.0
Asia & Oceania	1.6	2.3	38.9	—
<b>Protopic</b>	16.9	17.8	5.3	—
Japan	3.1	3.4	11.5	—
Americas	7.4	7.9	6.1	1.0
Europe	5.1	4.6	(9.3)	(7.7)
Asia & Oceania	1.2	1.7	42.7	—
<b>XTANDI*2</b>	—	12.2	—	—
Americas	—	12.2	—	—
<b>Eligard</b>				
Europe	13.8	14.9	7.8	9.7

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

\*2 Including "Temporary authorization for use" in France.

share in the OAB treatment market was approximately 47% (on a value basis). The combined share of Vesicare and Betanis has reached approximately 55% (on a value basis) and is still expanding. Owing to the considerable number of potential subjects in the OAB treatment market, we are working to increase market penetration of Vesicare and Betanis by raising public awareness of this condition.

In the Americas, sales of VESicare rose 14.3%, to US\$563 million on a U.S. dollar basis. When converted to yen, sales grew by 20.1%, to ¥46.8 billion. Despite the ongoing gradual decline in the size of the OAB treatment market, sales of VESicare achieved strong double-digit growth, as was the case in the previous fiscal year. VESicare's share in the OAB treatment market reached approximately 23% (on a total prescription basis) in fiscal 2012, further expanding its market share as the leading branded drug.

In Europe, sales of Vesicare were strong, increasing 11.1%, to €280 million on a euro basis, while sales grew by 9.2%, to ¥30.1 billion when converted to yen. Vesicare's share in the OAB treatment market reached approximately 45% (on a value basis) in fiscal 2012.

In Asia and Oceania, sales of Vesicare increased 20.7%, to ¥2.9 billion. The favorable sales expansion was driven by growth in South Korea.

#### Betanis/Myrbetriq/BETMIGA (generic name: mirabegron, OAB treatment)

In Japan, sales of Betanis increased to ¥5.3 billion in fiscal 2012, compared with ¥0.9 billion in fiscal 2011, after it became eligible for long-term prescriptions in October 2012. Betanis' share of the OAB treatment market reached approximately 8% (on a value basis) in fiscal 2012.

In the United States, mirabegron was approved in June 2012 and launched in October 2012 under the brand name Myrbetriq, registering US\$19 million sales in fiscal 2012 on a U.S. dollar basis. When converted to yen, sales were ¥1.6 billion.

Mirabegron was approved in Europe in December 2012 and launched in the United Kingdom in February 2013 under the brand name BETMIGA.

Mirabegron is a once-daily oral selective beta-3 adrenergic agonist used in OAB treatment which was dis-

covered and developed by Astellas. The drug relaxes the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle by activation of beta-3 adrenergic receptors which increases bladder capacity. While anticholinergics, such as Vesicare, are used as the standard treatment for OAB at present, mirabegron uses a distinct mechanism of action versus anticholinergics and is expected to become another treatment option.

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

Although its sales in Japan declined 16.2%, to ¥22.9 billion, due primarily to the impact of generic drugs, Harnal still maintained its top position in the alpha-1 blocker market. The market share for generic drugs among all tamsulosin products, including Harnal and its generics, was approximately 29% (on a volume basis) in fiscal 2012.

In Europe, the drug is marketed under the brand name Omnic. In fiscal 2012, sales of Omnic through our own distribution channels declined 13.2%, to €143 million on a euro basis, due primarily to price reductions and the impact of generics. When converted to yen, sales declined 14.6%, to ¥15.4 billion.

In Asia and Oceania, sales increased 10.7% year on year, to ¥10.8 billion. Sales grew steadily in China.

Bulk sales and royalty income from Harnal, which are recorded under European sales, declined 16.6% to €36 million on a euro basis. When converted to yen, sales were down 18.0%, to ¥3.9 billion.

#### Funguard/MYCAMINE (Candin-type antifungal agent)

Sales in Japan increased 2.6%, to ¥12.9 billion. Funguard's share in the market of injectable antifungal agents remained high at around 55% during fiscal 2012 (on a value basis).

In the Americas, sales remained steady with growth of 9.4%, to US\$114 million on a U.S. dollar basis. When converted to yen, sales increased 14.9%, to ¥9.4 billion. In terms of patient days per month, MYCAMINE gained an over 80% share in the U.S. market for injectable candin-type antifungal agents. In the United States, we obtained approval for an additional pediatric indication in June 2013.

In Europe, sales steadily grew by 61.0% to €55 mil-



lion, which was a 58.3% increase, to ¥5.9 billion on a yen basis. Distribution of MYCAMINE has expanded to cover 31 European countries.

In Asia and Oceania, sales grew 38.9%, to ¥2.3 billion, including healthy growth in China. Meanwhile, this product was approved in Australia in May 2013.

#### Protopic (Treatment for atopic dermatitis)

Sales in Japan increased 11.5%, to ¥3.4 billion. Protopic's distribution rights in Japan are scheduled to be transferred in April 2014 to Maruho Co., Ltd., which has already been promoting Protopic since April 2011 under an agreement with Astellas.

In the Americas, sales grew by 1.0%, to US\$95 million on a U.S. dollar basis. When converted to yen, sales increased by 6.1%, to ¥7.9 billion.

In Europe, sales declined 7.7%, to €43 million on a euro basis. When converted to yen, sales decreased 9.3%, to ¥4.6 billion.

In Asia and Oceania, sales increased 42.7%, to ¥1.7 billion.

#### Eligard (Prostate cancer treatment)

Currently being sold in Europe, Eligard's sales increased 9.7%, to €139 million on a euro basis. When converted to yen, sales increased 7.8%, to ¥14.9 billion. This favorable sales expansion was resulting from the contribution of the six-month formulation and other factors.

In the Asia and Oceania region, this product was launched in Hong Kong in June 2013.

#### XTANDI (Generic name: enzalutamide, prostate cancer treatment)

XTANDI was approved in August 2012 through a priority review in the United States, for the indication of metastatic castration-resistant prostate cancer in patients who have previously received docetaxel. It was launched in September 2012 under the brand name XTANDI and proved to be a success, registering US\$146 million in fiscal 2012. When converted to yen, sales were ¥12.2 billion.

In Europe, Enzalutamide was launched in the U.K. in July 2013 (brand name: XTANDI), while an application for approval was filed in Japan in May 2013.

Enzalutamide is a once-daily oral androgen receptor signaling inhibitor, which is being developed jointly with Medivation, Inc. ("Medivation"). Enzalutamide inhibits androgen receptor signaling, which plays a key role in facilitating the growth of prostate cancer, in three distinct ways, namely by: 1) inhibiting testosterone from binding to androgen receptors; 2) inhibiting nuclear translocation of androgen receptors; and 3) inhibiting DNA binding and activation by androgen receptors.

In the United States, Astellas and Medivation co-promote XTANDI and share costs and profits equally. In all countries excluding the United States, Astellas will develop and sell XTANDI, while paying Medivation double-digit royalties based on sales.

### 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 26.7%, to ¥70.6 billion, due primarily to NHI drug price reductions and the impact of generic drugs. In fiscal 2012, the market for statins in Japan shrank 13.4% year on year to approximately ¥268.0 billion on a NHI drug price basis. Lipitor's share of the market fell 7.8 percentage points, to 25.9% (on a value basis) compared to the previous fiscal year. Meanwhile, the market share for generic drugs among all atorvastatin products, including Lipitor and its generics, was around 21% (on a volume basis) in fiscal 2012.

We will continue maximizing the value of the Lipitor product line under co-promotional efforts with Pfizer Japan Inc.

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, including Micombi and Micamlo, increased by 5.0%, to ¥89.6 billion, which showed year-on-year growth of over 10% on a volume basis despite the impact of the NHI drug price reductions. Sales grew favorably for both Micombi, a combination drug with a diuretic, and Micamlo, a combination drug with a calcium antagonist. In fiscal 2012, the market for angiotensin II receptor blockers (ARB) in Japan shrank 3.3%, to around ¥591.0 billion. Steady expansion in sales of the Micardis line of drugs contributed to its current ARB market share of 16.8% (on a value basis). Furthermore in May 2013, "Micamlo Combination Tablets BP," a combination drug of telmisartan 80 mg and amlodipine 5 mg was

launched. In Japan, Astellas is co-promoting the Micardis product line with Nippon Boehringer Ingelheim Co., Ltd.

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

Sales of Celecox increased 13.3%, to ¥37.4 billion, despite the impact of 14.9% NHI drug price reduction. This product has shown remarkable sales growth, following the acquisition of approvals for additional indications of lumbago and acute pain, on top of the indications of rheumatoid arthritis and osteoarthritis. We further strengthened the reputation of Celecox as an anti-inflammatory that causes minimal gastrointestinal tract disturbance, capitalizing on the revision of prescribing information as of April 2011 to reflect the results of post-marketing clinical trials, along with the "Clinical Guidelines for the Management of Low Back Pain," issued in October 2012 by the Japanese Orthopaedic Association.

### Sales by Product (Local Products)

	¥ billion			CER*
	2012.3	2013.3	YoY	
<b>Japan</b>				(%)
Lipitor	¥ 96.3	¥ 70.6	(26.7)	—
Caduet	4.9	9.6	94.8	—
Micardis	85.3	89.6	5.0	—
Micombi	10.4	11.5	11.0	—
Micamlo	10.6	15.6	47.5	—
Gaster	37.5	30.2	(19.5)	—
Myslee	35.2	32.2	(8.6)	—
Seroquel	27.8	28.5	2.5	—
Vaccines	26.5	28.8	8.3	—
Cefzon	8.2	7.1	(13.0)	—
Frاندول	9.4	8.6	(8.3)	—
Celecox	33.0	37.4	13.3	—
Geninax	11.9	12.3	2.6	—
Bonoteo	5.0	10.6	110.1	—
Symbicort	20.0	27.7	38.2	—
ARGAMATE	0.1	6.1	—	—
Kiklin	—	0.5	—	—
Gonax	—	0.6	—	—
<b>Americas</b>				
Scan (Adenoscan and Lexiscan)	49.0	53.1	8.3	3.1
Lexiscan	42.4	47.5	12.2	6.7
AmBisome	5.5	6.3	14.4	8.9
Tarceva	33.7	36.5	8.3	3.1
<b>Europe</b>				
Qutenza	0.5	0.8	51.8	54.4

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

In fiscal 2012, the market for anti-inflammatory agents in Japan was worth approximately ¥84.0 billion, down 4.7% from the previous fiscal year. The market share of Celecox grew 6.9 percentage points, to 48.0% (on a value basis). Astellas will continue co-promoting this drug with Pfizer Japan Inc. while targeting an even higher share of the oral anti-inflammatory market.

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

Sales of Gaster declined 19.5%, to ¥30.2 billion. In fiscal 2012, the overall market for H2 receptor antagonists and proton pump inhibitors shrank 7.4%, to approximately ¥292.0 billion. Gaster recorded a share of 11.7% (on a value basis), a decline of 2.0 percentage points compared with the previous fiscal year. The share of generics in the famotidine market, including Gaster and its generics, in fiscal 2012 increased to around 36% (on a volume basis).

#### Myslee (Insomnia treatment)

Sales of Myslee decreased 8.6%, to ¥32.2 billion due primarily to the impact of its generics launched in June 2012 in Japan. In fiscal 2012, the market for drugs to treat insomnia in Japan shrank 2.1% year on year, to approximately ¥84.0 billion. Myslee maintained its position as a first-choice therapy for insomnia treatment, despite the decline of its market share by 2.9 percentage points, to 42.1% (on a value basis). The share of generics in the zolpidem market, including Myslee and its generics, in fiscal 2012 was around 10% (on a volume basis). In Japan, Astellas co-promotes Myslee with Sanofi K.K.

#### Seroquel (Schizophrenia treatment)

Sales of Seroquel continued to grow in Japan, with an increase of 2.5%, to ¥28.5 billion. Its generics launched in Japan in December 2012 had minimal impact on Seroquel's sales during fiscal 2012. The Japanese market for anti-schizophrenic agents showed growth of 6.2%, to approximately ¥164.0 billion in fiscal 2012. Seroquel's share in this market declined 0.9 percentage point to 19.0% (on a value basis). The share of generics in the quetiapine market, which includes Seroquel and its generics, in fiscal 2012 was around 4% (on a volume basis).

#### Symbicort (Treatment for adult bronchial asthma and chronic obstructive pulmonary disease)

Sales of Symbicort, which is a combination drug of an inhaled corticosteroid and a rapid and long-acting beta-2 agonist, registered favorable growth of 38.2%, to ¥27.7 billion. Additional approval for this drug was obtained in June 2012 for new dosage and administration on an as-needed basis for reliever therapy in addition to maintenance therapy for adult bronchial asthma. Approval for Symbicort was also acquired in August 2012 for the additional indication of chronic obstructive pulmonary disease. Symbicort's sales expanded significantly thanks to these additional indications along with growth in the combination-drug market. The market in Japan for adult inhaled steroid treatment including combination drugs grew 12.2% year on year, to approximately ¥93.0 billion in fiscal 2012. Symbicort also grew its share of this market, by 5.5 percentage points, to 32.1% (on a value basis). 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.

#### Geninax (Oral quinolone antibiotic)

Sales of Geninax increased 2.6%, to ¥12.3 billion, thanks to favorable growth of approximately 10% on a volume basis, offsetting the impact of NHI drug price reductions. In fiscal 2012, the Japanese market for oral quinolone antibiotics grew 0.5% year on year, to approximately ¥64.0 billion. Geninax boosted its share by 0.2 percentage points, to 21.1% (on a value basis), 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 110.1% year on year, to ¥10.6 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 ¥9.2

billion. In fiscal 2012, the Japanese market for the treatment of osteoporosis shrank 6.1%, to around ¥81.0 billion. Bonoteo's share in this market increased 7.9 percentage points, to 14.3% (on a value basis). Astellas will continue emphasizing the patient's convenience as well as the bone fracture prevention effect of Bonoteo 50 mg tablets while aiming to further boost its share in this market.

### Other new products

Besides the aforementioned mainstay products, quite a few new products were launched in fiscal 2012, including the hyperkalemia treatment ARGAMATE (on sale from April 2012), the hyperphosphatemia treatment Kiklin (launched in June 2012), the restless legs syndrome treatment Regnite (launched in July 2012), the prostate cancer treatment Gonax (launched in October 2012), Quattrovac, a combined vaccine for the prevention of pertussis, diphtheria, tetanus and poliomyelitis (launched in October 2012), and Cimzia, a treatment for adult patients with rheumatoid arthritis (launched in March 2013).

#### ● Americas

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

Total sales of Adenoscan and Lexiscan in the United States rose by 3.1%, to US\$639 million on a U.S. dollar basis. Lexiscan showed favorable growth, rising 6.7%, to US\$572 million. Total sales increased 8.3%, to ¥53.1 billion when converted to yen.

##### Tarceva (Lung and pancreatic cancer treatment)

Tarceva-related revenues increased 3.1%, to US\$439 million on a U.S. dollar basis. When converted to yen, sales increased 8.3%, to ¥36.5 billion.

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 F. Hoffmann-La Roche Ltd in other countries, and receive royalties based on sales. These revenues are recorded as sales in the Americas.

Furthermore, in the United States, approval was obtained in May 2013 for the additional indication of the first-line treatment for people with metastatic non-small cell lung

cancer whose tumors have certain epidermal growth factor receptor (EGFR) activating mutations as detected by an FDA-approved test.

### Sales by Geographical Area

	2012.3	2013.3 (¥ billion)
Consolidated	¥ 969.4	¥ 1,005.6
Japan	558.4	557.5
Americas	183.5	208.7
Europe	191.7	196.5
Asia & Oceania	35.7	42.9

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

#### ● Japan

Sales in Japan decreased 0.2% year on year, to ¥557.5 billion. Sales in the Japanese market declined by 0.8% from the previous fiscal year to ¥535.8 billion, but the decline was limited despite the impacts of NHI drug price revisions carried out in April 2012 and generic drugs.

Products such as Prograf and Vesicare, as well as Micardis (including combination drugs Micombi and Micamlo), Celecox, Symbicort and Bonoteo showed growth in sales. In addition, new products including Betanis and ARGAMATE contributed to sales. Meanwhile, sales declined for products such as Lipitor, Gaster and Harnal, mainly due to the impact of generic drugs.

#### ● Americas (Sales in North America and Central and South America)

Sales in the Americas increased 13.7% year on year, to ¥208.7 billion. On a U.S. dollar basis, sales grew 8.2%, to US\$2,512 million.

Sales of XTANDI and Myrbetriq, launched in the United States in September and October 2012 respectively, contributed to an increase in sales. In addition, sales of Prograf, VESicare, MYCAMINE and Lexiscan grew, and revenue from Tarceva also increased.

#### ● Europe (Sales in Europe, the Middle and Near East, and Africa)

Sales in Europe rose 2.5% year on year, to ¥196.5 billion.

On a euro basis, sales also rose 4.2%, to €1,834 million.

Sales of Vesicare and MYCAMINE grew, and those of Eligard also expanded. Meanwhile, sales of Prograf (including Advagraf) and Omnic through our own distribution channels decreased as a result of the impacts of price reductions and generic drugs in each country.

### ● Asia and Oceania

In Asia and Oceania, sales rose 20.1% year on year, to ¥42.9 billion. On a basis excluding the impact of foreign exchange, sales increased 13.7% from the previous year. Sales expansion of all mainstay products, including Prograf, Harnal, Vesicare, MYCAMINE and Protopic, led to the increase in revenues.

### Overseas Sales

	2013.3	
	2012.3	2013.3
Consolidated	¥ 421.6	¥ 464.0
Americas	182.7	215.6
Europe	187.4	188.8
Asia & Oceania	51.6	59.7
Overseas sales ratio (%)	43.5	46.1

Overseas sales are attributed by location of customers.

The overseas sales ratio increased 2.6 percentage points, to 46.1% in fiscal 2012.

### Cost of Sales

	2013.3	
	2012.3	2013.3
Net sales	¥ 969.4	¥ 1,005.6
Cost of sales	318.6	324.1
Cost of sales ratio (%)	32.9	32.2

Cost of sales increased by ¥5.5 billion, or 1.7%, to ¥324.1 billion.

The cost of sales ratio fell 0.7 percentage points in fiscal 2012, to 32.2%, mainly due to changes in the product mix.

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

SG&A expenses increased by ¥8.4 billion, or 1.6%, to ¥527.6 billion. The ratio of SG&A expenses to net sales

declined 1.1 percentage points, to 52.5%.

Research and development (R&D) expenses fell by ¥7.9 billion, or 4.2%, to ¥182.0 billion, mainly owing to a change in the method for depreciating property, plant and equipment and a decrease in R&D expenses of Prosidion Ltd., our subsidiary in the United Kingdom. The ratio of R&D expenses to net sales fell 1.5 percentage points, to 18.1%.

SG&A expenses, excluding R&D expenses increased by ¥16.3 billion, or 4.9%, to ¥345.7 billion, owing to increased expenditures related to oncology business in the United States and to a strengthening of sales and marketing capabilities in emerging countries, coupled with the impact of foreign exchange rates and other factors. Looking at a breakdown by item of expenses, advertising and sales promotional expenses were ¥86.5 billion, almost the same level as the previous fiscal year. Personnel expenses rose by ¥9.3 billion, or 7.1%, to ¥139.7 billion, and other expenses grew by ¥6.9 billion, or 6.1%, to ¥119.5 billion.

	2013.3	
	2012.3	2013.3
Total SG&A expenses	¥ 519.2	¥ 527.6
SG&A ratio (%)	53.6	52.5
R&D expenses	189.8	182.0
R&D ratio (%)	19.6	18.1
SG&A excluding R&D	329.4	345.7
SG&A ratio excluding R&D (%)	34.0	34.4
Advertising and sales promotional expenses	86.4	86.5
Personnel expenses	130.4	139.7
Other	112.6	119.5

### Operating Income

	2013.3	
	2012.3	2013.3
Net sales	¥ 969.4	¥ 1,005.6
Operating income	131.5	153.9
Operating margin (%)	13.6	15.3

As a result of the above-mentioned factors, operating income increased by ¥22.3 billion, or 17.0%, to ¥153.9 billion. The ratio of gross profit to sales increased 0.7 percent-

age points year on year, while the ratio of R&D expenses to net sales was down 1.5 percentage points. Consequently, the operating margin rose 1.7 percentage points, to 15.3%.

### Other Income (Expenses)

Interest and dividend income decreased by ¥0.6 billion from the previous fiscal year, to ¥1.8 billion. An exchange gain of ¥1.5 billion was recorded in fiscal 2012 (compared with ¥1.0 billion in fiscal 2011). A gain on sale of investment securities of ¥5.4 billion was recorded. However, we recorded a ¥34.8 billion loss on impairment of tangible and intangible fixed assets, and other losses.

### 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 declined ¥2.4 billion, or 1.9%, to ¥124.7 billion.

Income taxes decreased by ¥7.0 billion, or 14.4%, to ¥41.8 billion. The income tax burden rate fell 4.9 percentage points, to 33.5% compared to the previous fiscal year, when the rate rose temporarily due to a revision of the policy on dividends from subsidiaries outside of Japan, the impact of the revised corporation TAX Act, and other factors.

As a result, net income increased by ¥4.6 billion, or 5.9%, to ¥82.9 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 works on promoting R&D activities as a priority measure.

#### ● Drug Discovery Research Measures

Our drug discovery research, in which we are concentrating management resources, focuses on the following prioritized therapeutic areas: urology, immunology (including transplantation) & infectious diseases, oncology, neurosci-

ence, and diabetes mellitus (DM) complications & kidney diseases.

In drug discovery research, we aim to discover innovative new drugs, while promoting Precision Medicine approach, which is based on molecular targeting and precision diagnostics, and proactively making use of leading-edge technologies and know-how through alliances with outside organizations. Furthermore, in preparation for future changes in market structures, we embrace the challenge of R&D in new technologies such as regenerative medicine and vaccines.

In April 2013, Astellas entered into a collaboration with Ambrx Inc. for the discovery and development of novel antibody drug conjugates (ADCs) to acquire worldwide rights to develop and commercialize Ambrx ADCs for oncology.

#### ● Clinical Development Initiatives

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

(Major Progress of Clinical Development in Japan)

Gonax (generic name: degarelix acetate) was approved for the indication of prostate cancer in June 2012 and was launched in October 2012.

Astellas submitted an application in August 2012 for approval of the orally disintegrating tablet Irribow (generic name: ramosetron hydrochloride), a treatment for diarrhea-predominant irritable bowel syndrome, as an additional formulation.

In October 2012, we entered into a joint development agreement with Ajinomoto Pharmaceuticals Co., Ltd. for trials of Starsis (generic name: nateglinide), a fast-acting postprandial hypoglycemic agent, in combination with DPP-4 inhibitors.

Approval for Cimzia (generic name: certolizumab pegol), a treatment for adult patients with rheumatoid arthritis under joint development with UCB Japan was obtained in December 2012 for the indication of treating rheumatoid arthritis that does not respond to conventional therapy

(including inhibition of progression of bone structural damage). It was launched in March 2013.

In February 2013, an application for approval was submitted for hypnosedative, Dormicum (generic name: midazolam) for an additional indication of conscious sedation in dentistry and dental surgery.

We obtained approval in February 2013 for synthetic penicillin Sawacillin (generic name: amoxicillin hydrate) for the additional indication of *Helicobacter pylori* eradication in patients with *Helicobacter pylori* gastritis by triple therapy with proton pump inhibitors and either clarithromycin or metronidazole.

We submitted an application in March 2013 for approval of ipragliflozin (generic name/code name: ASP1941), for the indication of type 2 diabetes. Development in the United States and Europe was discontinued after comprehensive consideration of the intensified competition for this product and the prioritization in our pipeline, etc.

In March 2013, approval was obtained for Acofide, a treatment for functional dyspepsia (generic name: acotiamide hydrochloride hydrate) jointly developed with Zeria Pharmaceutical Co., Ltd., for the indication of postprandial fullness, upper abdominal bloating, and early satiation due to functional dyspepsia. Acofide was launched in June 2013.

In May 2013, we submitted an application for approval for enzalutamide (generic name/code name: MDV3100), an oral androgen receptor inhibitor under joint development with Medivation, Inc. for the indication of prostate cancer.

In June 2013, we obtained approval for Prograf for the indication of interstitial pneumonia associated with polymyositis/dermatomyositis.

(Major Progress in Clinical Development Outside of Japan) For enzalutamide (generic name/code name: MDV3100), applications for approval were submitted for the indication of metastatic castration-resistant prostate cancer in patients who have previously received docetaxel, in the United States in May 2012 and in Europe in June 2012. In the United States, approval was obtained for the treatment through a priority review in August 2012, and it was

launched under the brand name XTANDI in September 2012. In Europe, approval was also obtained in June 2013 for the indication of metastatic castration-resistant prostate cancer in patients who have previously received docetaxel, and XTANDI was launched in the United Kingdom in July 2013.

We obtained approval in the United States in June 2012 for mirabegron (generic name/code name: YM178), a treatment for OAB, for the indication for treating OAB with symptoms of urge urinary incontinence, urgency and urinary frequency. It was launched in the United States in October 2012 under the brand name Myrbetriq. We also obtained approval for this drug in Europe in December 2012, and it was launched under the brand name BETMIGA in February 2013.

We submitted an application for approval in the United States in September 2012 for micafungin (generic name/code name: FK463), a candidin-type injectable antifungal agent, for the additional indication of the treatment of pediatric patients four months and older with candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses, esophageal candidiasis, and prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplants (HSCT), and the approval was obtained in the United States in June 2013.

With respect to the HER1/EGFR tyrosine kinase inhibitor Tarceva (generic name: erlotinib), an application for approval was submitted in the United States in November 2012 for the additional indication of first-line treatment of people with metastatic non-small cell lung cancer whose tumors have certain epidermal growth factor receptor activating mutations as detected by an FDA-approved test. Approval was subsequently obtained in May 2013.

Approval was obtained for VESOMNI, the solifenacin/tamsulosin combination drug (brand name in Europe/code name: EC905), in the Netherlands in May 2013 for the indication of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy.

We obtained approval in the United States in July 2013

for tacrolimus extended release capsules (generic name/code name: FK506), an immunosuppressant for the indication of prophylaxis of organ rejection in patients receiving a kidney transplant with mycophenolate mofetil (MMF) and corticosteroids, with or without basiliximab induction (brand name in the United States: ASTAGRAF XL).

With respect to the exclusive option granted by our British subsidiary, Prosidion Ltd., to AstraZeneca to acquire assets related to PSN821 and PSN842, a potential new class of medicines for type 2 diabetes, we received notice in November 2012 from AstraZeneca of its decision not to exercise the option. In response, we decided to discontinue the development based on the strategic priority among focused therapeutic areas and pipeline at Astellas.

In March 2013, Astellas exercised its right to terminate the worldwide license agreement with Ambit Biosciences Corporation of the United States concluded in 2009 for the joint development and commercialization of FLT3 kinase inhibitors including quizartinib (generic name/code name: AC220). The agreement, which we have decided to terminate for strategic reasons, will come to an end on September 3, 2013.

In September 2012, an application was submitted for approval for tivozanib (generic name/code name: ASP4130), an inhibitor of all three vascular endothelial growth factor (VEGF) receptors 1, 2 and 3, which was under joint development with AVEO Pharmaceuticals, Inc., for the indication of the treatment of patients with advanced renal cell carcinoma in the United States. However, in June 2013, AVEO received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) informing the company that FDA cannot approve the application in its present form.

(Initiatives to Optimize the Allocation of Resources in R&D) Astellas is proactively promoting utilization of the "Multi-Track" process. This approach includes having multiple strategies at every stage of the R&D process and promoting the uptake of innovative research, as well as constructing a high-quality and robust pipeline for us while at the same time managing risks and costs through the effective use of outside resources. As part of this approach, Astellas entered into a partnership in April 2012 with Drais Pharma-

ceuticals, Inc. ("Drais") to transfer ownership of ASP3291, which we have been developing as a treatment for ulcerative colitis, to a company operated by Drais. In June 2012, the two companies entered into a similar partnership regarding ASP7147, which we have been developing as a treatment for diarrhea-predominant irritable bowel syndrome. Moreover, in April 2013, Astellas entered into an exclusive license agreement with a company operated by Drais regarding ASP7035, which we discovered and have been developing for the treatment of nocturia.

In October 2012, we entered into a license agreement with Janssen Biotech, Inc. of the United States for the exclusive development and commercialization of our compound ASP015K, an oral Janus Kinase (JAK) inhibitor, worldwide except for Japan. We will continue to develop and commercialize ASP015K in Japan.

In March 2013, we entered into an agreement with Cubist Pharmaceuticals, Inc. ("Cubist") of the United States, under which Cubist obtains the rights from Astellas for ceftolozane (generic name), an injectable cephalosporin antibiotic for certain regions in the Asia-Pacific and Middle East. With the acquisition of these rights, Cubist now owns worldwide rights to develop, manufacture, and commercialize a combination of ceftolozane and tazobactam (CXA 201).

In June 2013, Astellas concluded a collaboration agreement with Cytokinetics, Inc., focusing on the research, development and commercialization of skeletal muscle activators. The primary objective of the collaboration is to advance novel therapies for diseases and medical conditions associated with muscle weakness. The two parties will jointly conduct research in the area of skeletal muscle activation.

In June 2013, Seattle Genetics, Inc. exercised an option to co-develop ASG-15ME with Astellas' subsidiary Agensys, Inc, under the companies' existing collaboration agreement relating to antibody-drug conjugate (ADC) technology.

On December 31, 2012, we closed a U.S. subsidiary, Urogenix, Inc. ("Urogenix"), a research facility focusing on the drug discovery in the field of urologic diseases. As we continue to place importance on the research of urologic diseases, the research functions of Urogenix were transferred to our Tsukuba Research Center in Japan.



### ● Technical Development Initiatives

With the aim of ensuring a stable supply of active pharmaceutical ingredients with high pharmacological activities, for which demand is expected to increase in line with expansion of the development pipeline focused on oncology, construction of Building No. 8 at Takahagi Technology Center of Astellas Pharma Tech Co., Ltd. began in August 2012.

### ● Other Measures to Bolster the Business Platform

In April 2012, Astellas entered into an agreement with KAKETSUKEN (The Chemo-Sero-Therapeutic Research Institute) for a sales and promotional framework for a combined vaccine for the prevention of pertussis, diphtheria, tetanus, and poliomyelitis that the Institute manufactures. Under the agreement, Astellas will conduct sales and promotional activities for the vaccine throughout Japan, although promotional activities in the Kyushu region will be carried out jointly by both companies. The vaccine was launched under the brand name Quattrovac in October 2012.

### ● Other Important Matters concerning Present State of the Astellas Group

(Reshape of Research Framework)

In May 2013, Astellas announced plans to reshape its research framework by introducing new initiatives to further enhance its ability to generate innovative drugs. By optimizing the allocation of resources for its research and development function, Astellas aims to achieve the following objectives: i) utilize more external capabilities and resources; ii) undertake initiatives related to new therapeutic areas and innovative technologies including regenerative medicine and vaccines; iii) accelerate the development of its promising preclinical pipeline; and iv) ensure sufficient investment in its late-stage clinical pipeline.

To enhance the process of screening external opportunities to strengthen innovation during the preclinical development stage, we plan to establish Astellas Innovation Management (AIM) in October 2013. In addition, we are working to promote measures to enhance research management and introduce multiple-path pro-

ject management. With the aim of facilitating the strategic reallocation of management resources and realizing operational excellence, Astellas will reorganize its research functions and structures in a sequential manner. Specifically, Astellas plans to close OSI Pharmaceuticals, LLC (United States) and Perseid Therapeutics LLC (United States); scale back Astellas Research Institute of America LLC (United States); cease in-house fermentation research; and integrate and transfer the multiple functions of the Kashima facility in Osaka to appropriate sites, including the Tsukuba Research Center.

(Strategic Alliance with Amgen)

In May 2013, Astellas entered into a strategic alliance in Japan with Amgen, Inc. ("Amgen").

This alliance comprises two elements. The first element is a long-term collaboration between both companies that will focus on the co-development and co-commercialization in Japan of five Amgen pipeline medicines. The five medicines include the hyperlipidemia treatment (AMG145), the osteoporosis treatment (AMG785), and three treatments for cancer (AMG102, 337, and 103). The second element is the establishment of a joint venture company (Amgen Astellas BioPharma KK) through which the companies work together. Amgen Astellas BioPharma KK and Astellas will work on the co-development and co-commercialization in Japan of the above mentioned five pipeline medicines.

## ► Consolidated Forecasts for Year Ending March 31, 2014 (Fiscal 2013) (Announced May 2013)

Consolidated forecasts for fiscal 2013 are as follows:

### Fiscal 2013 Forecasts

	(¥ billion)	
	2013.3	2014.3 (forecasts)
Net sales	¥ 1,005.6	¥ 1,170.0
Operating income	153.9	170.0
Net income	82.9	110.0

	(¥)	
	2013.3	2014.3 (forecasts)
Average foreign exchange rates		
US\$1	83	100
€1	107	130

Note: The Company plans to voluntarily adopt International Financial Reporting Standards (IFRS) effective the year ending March 31, 2014. However, consolidated forecasts for the year ending March 31, 2014 are prepared based on Japanese accounting standards.

We project increases in both revenues and earnings. We assume yen weakening against the U.S. dollar and the euro compared with fiscal 2012, and we expect foreign exchange factors to have a ¥101.1 billion positive impact on net sales and a ¥17.6 billion positive impact on operating income.

#### ● Net Sales

In fiscal 2013, we forecast a 16.3% year-on-year increase in net sales, to ¥1,170.0 billion.

Sales of new products, such as XTANDI and Betanis/Myrbetriq/BETMIGA, are expected to expand. We also expect sales of Vesicare and Funguard/MYCAMINE to continue to grow. In addition, we forecast an increase in revenues from Prograf and Harnal due to the impact of the lower yen.

Sales in Japan are expected to increase by 4.5% year on year, to ¥582.6 billion. This includes an increase in sales of 5.9% year on year, to ¥567.3 billion in the Japanese market. Sales are forecast to expand for Vesicare, Prograf, Micardis (including Micombi and Micamlo), Celecox, Symbicort and Bonoteo. In addition, new products such as Betanis and

Cimzia are expected to contribute to the increase in revenues. Meanwhile, sales of Lipitor, Gaster, Myslee and Seroquel are expected to decrease mainly due to the impact of generic drugs.

In the Americas, we forecast a 28.0% year-on-year increase in sales, to ¥267.2 billion. Sales on a U.S. dollar basis are expected to increase 6.4% year on year, to US\$2,672 million. Sales of new products, such as Myrbetriq and XTANDI, are expected to expand. We also expect sales of VESicare and MYCAMINE and revenue from Tarceva to continue growing. Meanwhile, sales of Prograf and the total sales of the pharmacologic stress agents including Adenoscan and Lexiscan are forecast to decline due to the impact of generic drugs.

In Europe, we forecast a 32.7% year-on-year increase in sales, to ¥260.6 billion. Sales on a euro basis are expected to increase 9.3% year on year, to €2,004 million. Sales of such products as Vesicare, MYCAMINE and Eligard are expected to continue to expand. Although sales of Prograf and Harnal through our own distribution channels are forecast to decrease on a local currency basis, sales on a yen basis are expected to increase due to the impact of foreign exchange rates.

Sales in Asia and Oceania are expected to grow 38.7% year on year, to ¥59.5 billion. Excluding the impact of foreign exchange rates, we forecast an approximately 14% increase. Continued growth in sales of such products as Prograf, Vesicare and MYCAMINE is expected.

#### ● Operating Income and Net Income

Gross profit is expected to increase due to growing net sales, as well as a decrease in the cost of sales ratio resulting from the impact of foreign exchange rates and other factors.

SG&A expenses are expected to increase due to increases in selling expenses related to new products and various development project expenses, as well as the impact of foreign exchange rates. Within such expenses, we project a 16.5% increase in R&D expenses, to ¥212.0 billion, with a ratio of R&D expenses to net sales of 18.1%.

As a result, we forecast a 10.5% year-on-year increase in operating income, to ¥170.0 billion.

We forecast an 8.2% year-on-year increase in ordi-

nary income, to ¥170.0 billion. Net income is expected to increase 32.8% year on year, to ¥110.0 billion. Along with the reshaping of our research framework, we project about ¥11.0 billion in special losses including the restructuring costs in connection with reshaping the research framework.

## ► Number of Employees

As of March 31, 2013, Astellas worldwide employed 17,454 people, a year-on-year increase of 369. The total number of Medical Representatives (MRs) was approximately 6,350, a year-on-year increase of about 160.

In Japan, we had 8,153 employees, down 23 from the previous year-end. In the Americas, regional headcount was 2,980 employees, up 61 from the previous year-end. In Europe, we had 4,356 employees, up 70 year on year. In Asia and Oceania, we had 1,965 employees, up 261 from the previous year-end, mainly reflecting increases in MRs in China.

### Number of Employees by Geographical Area

	(persons)	
	2012.3	2013.3
Total	17,085	17,454
Japan	8,176	8,153
Americas	2,919	2,980
Europe	4,286	4,356
Asia & Oceania	1,704	1,965

### Number of MRs

	(persons)	
	2012.3	2013.3
Total (Global)	6,190	6,350

## ► Financial Condition

### Assets

Total assets as of March 31, 2013 amounted to ¥1,445.6 billion, up ¥44.9 billion from a year earlier.

Current assets increased ¥46.1 billion, to ¥827.2 billion at the fiscal year-end. Cash and cash equivalents, and notes and accounts receivable increased.

Property, plant and equipment at cost was ¥218.5 billion, up ¥ 19.3 billion from the previous fiscal year-end.

Investments and other assets decreased ¥20.5 billion, to ¥399.9 billion. Patents declined ¥23.4 billion year on year, to ¥138.1 billion, mainly due to the impairment loss including intangible assets related to in-process R&D. Goodwill was ¥96.0 billion, up ¥1.8 billion from the previous year-end.

### Liabilities

Total liabilities as of March 31, 2013 amounted to ¥383.5 billion, up ¥1.0 billion from a year earlier.

Current liabilities decreased ¥0.6 billion, to ¥313.5 billion.

Total long-term liabilities rose ¥1.7 billion, to ¥70.0 billion.

### Net Assets

Net assets as of March 31, 2013 amounted to ¥1,062.0 billion, up ¥43.9 billion from a year earlier, and shareholders' equity ratio was 73.3%.

Major items in this section include net income of ¥82.9 billion, payments of ¥60.1 billion in cash dividends from retained earnings, and treasury stock purchases of ¥49.4 billion. Translation adjustments showed a positive movement, raising net assets by ¥66.2 billion.

### 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 outside of 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 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 main-

tain 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, 2013 amounted to ¥264.9 billion, an increase of ¥12.5 billion compared with the previous fiscal year-end.

### Cash Flows from Operating Activities

Net cash provided by operating activities amounted to ¥144.2 billion, a decrease of ¥28.5 billion in year-on-year terms. During the year, income before income taxes and minority interests fell ¥2.4 billion to ¥124.7 billion, and income taxes paid decreased ¥6.8 billion to ¥43.4 billion.

In fiscal 2012, depreciation of property, plant and equipment and amortization of intangible assets amounted to ¥47.4 billion (compared with ¥53.7 billion in the previous fiscal year), while amortization of goodwill amounted to ¥10.3 billion (compared with ¥11.7 billion in the previous fiscal year).

### Cash Flows from Investing Activities

Net cash used in investing activities totaled ¥48.6 billion, up ¥22.7 billion from the previous fiscal year. Among the sources of cash outflows were purchases of property, plant and equipment of ¥31.3 billion.

### Cash Flows from Financing Activities

Net cash used in financing activities totaled ¥109.7 billion, up ¥51.8 billion from the previous fiscal year. Cash dividends increased ¥2.3 billion year on year, to ¥60.1 billion. Purchases of treasury stock amounted to ¥49.4 billion.

## ► Capital Expenditures

Astellas makes capital expenditures on an ongoing basis with the aim of reinforcing its capabilities and efficiency in R&D and production, its capabilities in sales and marketing, and its operational efficiency. Capital expenditures in fiscal 2012 totaled ¥32.1 billion, down 28.8% year on year (based on the value of property, plant and equipment).

In fiscal 2013, capital expenditures are forecast to decrease 15.8% to ¥27.0 billion.

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

### Per Share Data

	2012.3	2013.3
Net income		(¥)
Basic	¥ 169.38	¥ 180.40
Diluted	169.17	180.15
Cash dividends	125.00	130.00
Net assets	2,200.64	2,349.61

### 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

	2012.3	2013.3
Total number of shares issued	467,965	467,965
Shares in treasury	6,045	16,789

### Treasury Stock

	2012.3	2013.3
Number of shares bought back*	—	10,800 thousand
Acquisition cost*	—	¥ 49.4 billion

\* Excludes purchases of shares constituting less than a trading unit

### ROE and DOE

Return on equity (ROE) was 8.0%, up 0.3 percentage points from fiscal 2011. The DOE ratio was 5.7%, the same level as fiscal 2011.

	2012.3	2013.3
ROE	7.7	8.0
DOE	5.7	5.7

## ► 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. Some governments 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, 2013 and 2012

	(Millions of yen)		(Millions of U.S. dollars) (Note 4)
	2013	2012	2013
<b>Assets</b>			
<b>Current assets:</b>			
Cash and cash equivalents (Note 17)	¥ 264,912	¥ 252,380	\$ 2,818
Short-term investments (Note 17)	47,765	46,719	508
Notes and accounts receivable (Note 17)	302,047	286,798	3,213
Allowance for doubtful receivables	(1,926)	(2,887)	(20)
	300,121	283,911	3,193
Inventories (Note 5)	128,180	111,823	1,364
Deferred tax assets (Note 9)	61,746	71,550	657
Other	24,466	14,696	260
<b>Total current assets</b>	<b>827,190</b>	<b>781,079</b>	<b>8,800</b>
<b>Property, plant and equipment, at cost:</b>			
Land	30,181	31,037	321
Buildings and structures	261,519	236,408	2,782
Machinery and equipment	232,626	222,873	2,475
Other	3,013	3,093	32
Construction in progress	25,796	34,887	274
Accumulated depreciation	(334,656)	(329,138)	(3,560)
<b>Property, plant and equipment, net</b>	<b>218,479</b>	<b>199,160</b>	<b>2,324</b>
<b>Investments and other assets:</b>			
Investment securities (Note 17)	61,404	60,302	653
Investments in and advances to affiliates	1,204	830	13
Patents	138,070	161,499	1,469
Goodwill	95,978	94,193	1,021
Other intangible assets	60,794	58,587	647
Deferred tax assets (Note 9)	27,126	33,875	289
Other	15,316	11,105	162
<b>Total investments and other assets</b>	<b>399,892</b>	<b>420,391</b>	<b>4,254</b>
<b>Total assets</b>	<b>¥ 1,445,561</b>	<b>¥ 1,400,630</b>	<b>\$ 15,378</b>

See accompanying notes to consolidated financial statements.

	(Millions of yen)		(Millions of U.S. dollars)
	2013	2012	2013 (Note 4)
<b>Liabilities and net assets</b>			
<b>Current liabilities:</b>			
Notes and accounts payable (Note 17):			
Trade	¥ 178,439	¥ 179,028	\$ 1,898
Construction	12,113	11,768	129
Accrued expenses	98,848	84,960	1,052
Other (Note 6)	24,136	38,414	256
Total current liabilities	313,536	314,170	3,335
<b>Long-term liabilities:</b>			
Accrued retirement benefits for employees (Note 11)	18,273	16,979	194
Deferred tax liabilities (Note 9)	34,715	30,932	369
Other (Note 6)	17,011	20,426	182
Total long-term liabilities	69,999	68,337	745
<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 2013 and 467,964,635 shares in 2012	103,001	103,001	1,096
Capital surplus	176,822	176,822	1,881
Retained earnings	917,511	894,737	9,761
Treasury stock, at cost:			
16,788,579 shares in 2013 and 6,044,560 shares in 2012	(72,285)	(23,132)	(769)
Total shareholders' equity	1,125,049	1,151,428	11,969
Accumulated other comprehensive income			
Unrealized holding gain on securities	15,966	12,257	170
Translation adjustments	(80,926)	(147,167)	(861)
Total accumulated other comprehensive income	(64,960)	(134,910)	(691)
Stock subscription rights	1,937	1,605	20
Total net assets	1,062,026	1,018,123	11,298
<b>Contingent liabilities (Note 14)</b>			
<b>Total liabilities and net assets</b>	<b>¥ 1,445,561</b>	<b>¥ 1,400,630</b>	<b>\$ 15,378</b>

# Consolidated Statements of Income

Astellas Pharma Inc. and Subsidiaries  
Years ended March 31, 2013, 2012 and 2011

	(Millions of yen)			(Millions of U.S. dollars)
	2013	2012	2011	2013 (Note 4)
<b>Net sales</b>	<b>¥ 1,005,612</b>	<b>¥ 969,387</b>	<b>¥ 953,948</b>	<b>\$ 10,698</b>
<b>Cost of sales</b>	<b>324,127</b>	<b>318,633</b>	<b>295,973</b>	<b>3,448</b>
Gross profit	681,485	650,754	657,975	7,250
<b>Selling, general and administrative expenses (Note 12)</b>	<b>527,618</b>	<b>519,235</b>	<b>538,794</b>	<b>5,613</b>
Operating income	153,867	131,519	119,181	1,637
<b>Other income (expenses):</b>				
Interest and dividend income	1,806	2,365	2,338	19
Exchange gain (loss)	1,464	1,005	(6,556)	16
Equity in earnings (losses) of affiliates	33	194	(89)	0
Gain on sale of investment securities	5,428	2,716	1,280	58
Loss on impairment of fixed assets (Note 20)	(34,790)	(9,234)	(2,782)	(370)
Loss on sales and disposal of fixed assets	(733)	(5,924)	(1,277)	(8)
Business integration expenses	—	(645)	(4,723)	—
Loss on disaster	—	(3,193)	(3,029)	—
Loss on adjustment for changes of accounting standard for asset retirement obligations	—	—	(560)	—
Other, net	(2,402)	8,271	(300)	(26)
	(29,194)	(4,445)	(15,698)	(311)
Income before income taxes and minority interests	124,673	127,074	103,483	1,326
<b>Income taxes (Note 9):</b>				
Current	25,360	51,158	43,554	270
Deferred	16,462	(2,314)	(7,722)	175
	41,822	48,844	35,832	445
Income before minority interests	82,851	78,230	67,651	881
<b>Net income (Note 15)</b>	<b>¥ 82,851</b>	<b>¥ 78,230</b>	<b>¥ 67,651</b>	<b>\$ 881</b>

See accompanying notes to consolidated financial statements.



# Consolidated Statements of Comprehensive Income

Astellas Pharma Inc. and Subsidiaries  
Years ended March 31, 2013, 2012 and 2011

	(Millions of yen)			(Millions of U.S. dollars)
	2013	2012	2011	(Note 4) 2013
<b>Income before minority interests</b>	<b>¥ 82,851</b>	<b>¥ 78,230</b>	<b>¥ 67,651</b>	<b>\$ 881</b>
<b>Other comprehensive income (Note 10):</b>				
Unrealized holding gain on securities	3,709	2,778	(4,674)	39
Translation adjustments	66,241	(26,580)	(38,045)	705
<b>Total other comprehensive income</b>	<b>69,950</b>	<b>(23,802)</b>	<b>(42,719)</b>	<b>744</b>
<b>Comprehensive income</b>	<b>¥ 152,801</b>	<b>¥ 54,428</b>	<b>¥ 24,932</b>	<b>\$ 1,625</b>
<b>Total comprehensive income attributable to:</b>				
Shareholders of the Company	¥ 152,801	¥ 54,428	¥ 24,932	\$ 1,625
Minority interests	¥ —	¥ —	¥ —	\$ —

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Changes in Net Assets

Astellas Pharma Inc. and Subsidiaries  
Years ended March 31, 2013, 2012 and 2011

	2013	2012	2011
<b>Number of shares issued</b>			
Beginning of year	467,964,635	467,964,635	475,964,635
Cancellation of treasury stock	—	—	(8,000,000)
<b>End of year</b>	<b>467,964,635</b>	<b>467,964,635</b>	<b>467,964,635</b>

	(Millions of yen)								
	Shareholders' equity				Total shareholders' equity	Accumulated other comprehensive income	Stock subscription rights	Minority interests	Total net assets
	Common stock	Capital surplus	Retained earnings	Treasury stock					
<b>Balance as of April 1, 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
Cash dividends paid			(60,051)		(60,051)				(60,051)
Net income			82,851		82,851				82,851
Purchase of treasury stock				(49,392)	(49,392)				(49,392)
Disposal of treasury stock			(26)	239	213				213
Cancellation of treasury stock					—				—
Net change in items other than shareholders' equity						69,950	332		70,282
Total movements during the year	—	—	22,774	(49,153)	(26,379)	69,950	332	—	43,903
<b>Balance as of March 31, 2013</b>	¥ 103,001	¥ 176,822	¥ 917,511	¥ (72,285)	¥ 1,125,049	¥ (64,960)	¥ 1,937	¥ —	¥ 1,062,026

	(Millions of U.S. dollars) (Note 4)								
	Shareholders' equity				Total shareholders' equity	Accumulated other comprehensive income	Stock subscription rights	Minority interests	Total net assets
	Common stock	Capital surplus	Retained earnings	Treasury stock					
<b>Balance as of March 31, 2012</b>	\$ 1,096	\$ 1,881	\$ 9,518	\$ (246)	\$ 12,249	\$ (1,436)	\$ 17	\$ —	\$ 10,830
Cash dividends paid			(638)		(638)				(638)
Net income			881		881				881
Purchase of treasury stock				(526)	(526)				(526)
Disposal of treasury stock			(0)	3	3				3
Cancellation of treasury stock					—				—
Net change in items other than shareholders' equity						745	3		748
Total movements during the year	—	—	243	(523)	(280)	745	3	—	468
<b>Balance as of March 31, 2013</b>	\$ 1,096	\$ 1,881	\$ 9,761	\$ (769)	\$ 11,969	\$ (691)	\$ 20	\$ —	\$ 11,298

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Cash Flows

Astellas Pharma Inc. and Subsidiaries  
Years ended March 31, 2013, 2012 and 2011

	(Millions of yen)			(Millions of U.S. dollars) (Note 4)
	2013	2012	2011	2013
<b>Operating activities</b>				
Income before income taxes and minority interests	¥ 124,673	¥ 127,074	¥ 103,483	\$ 1,326
Depreciation and amortization	57,856	65,501	65,674	615
Loss on impairment of fixed assets	34,790	9,234	2,782	370
Gain on sale of investment securities	(5,428)	(2,716)	(1,280)	(58)
Notes and accounts receivable	2,177	(12,382)	(43,893)	23
Inventories	(6,222)	(18)	(10,678)	(66)
Notes and accounts payable	(19,169)	27,416	(4,340)	(204)
Accrued expenses	7,732	6,541	7,280	82
Accrued retirement benefits for employees	60	712	1,346	1
Other	(10,686)	(805)	22,600	(113)
Subtotal	185,783	220,557	142,974	1,976
Interest and dividends received	1,811	2,374	2,288	19
Interest paid	—	—	(220)	—
Income taxes paid	(43,441)	(50,255)	(44,403)	(461)
Net cash provided by operating activities	144,153	172,676	100,639	1,534
<b>Investing activities</b>				
Purchases of property, plant and equipment	(31,333)	(47,679)	(33,630)	(333)
Proceeds from sale of property, plant and equipment	706	11,979	628	8
Acquisition of subsidiaries' shares	—	(3,737)	(284,148)	—
Decrease (increase) in short-term investments	11,500	(17,680)	89,598	122
Decrease in investment securities	9,617	3,495	5,385	102
(Increase) decrease in other assets	(36,213)	28,941	(17,083)	(385)
Other	(2,892)	(1,273)	(3,397)	(31)
Net cash used in investing activities	(48,615)	(25,954)	(242,647)	(517)
<b>Financing activities</b>				
Redemption of bonds	—	—	(34,968)	—
Purchases of treasury stock	(49,392)	(12)	(30)	(525)
Cash dividends	(60,051)	(57,729)	(57,728)	(639)
Other	(284)	(197)	(542)	(3)
Net cash used in financing activities	(109,727)	(57,938)	(93,268)	(1,167)
<b>Effects of exchange rate changes on cash and cash equivalents</b>				
	26,721	(11,870)	(21,178)	283
Increase (decrease) in cash and cash equivalents	12,532	76,914	(256,454)	133
Cash and cash equivalents at beginning of year	252,380	175,466	431,920	2,685
Cash and cash equivalents at end of year	¥ 264,912	¥ 252,380	¥ 175,466	\$ 2,818

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, 2013, the numbers of consolidated subsidiaries and affiliates accounted for by the equity method were 78 and 1 (82 and 2 in 2012), 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 consolidated 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 consolidated subsidiaries are stated principally at the lower of cost or market, cost being determined by the average method. However, inventories of the foreign consolidated 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 Astellas is calculated by the straight-line method at rates based on the estimated useful lives of the respective assets. 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 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 derivative 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, 2013.

### 3. Accounting Changes

(a) Effective April 1, 2012, the Company and its domestic consolidated subsidiaries changed their depreciation method for property, plant and equipment from hitherto adopted declining-balance method to straight-line

method, which has been adopted by its foreign consolidated subsidiaries.

In order to mitigate the impact on business results from the expiry of the mainstay products' patents as well as

to adapt to changes in business environment, Astellas has, under the mid-term management plan as already announced, defined the field of oncology along with the fields of urology and transplants, as crucial therapeutic area in which competitive advantage must be established on a global scale, while shifting research and development focus from the conventional approach in development, aiming to provide the same drug (Mass Medicine) on a broader scale for treating the cases with identical diagnosis, to active promotion of drug discovery approach to treatments, Precision Medicine approach, which shows high efficacy for strictly-defined specific patient segments.

Based on the progress in the reinforcement of business infrastructure to develop oncology field into Astellas' preferred franchise, including progress in the aforementioned initiatives, completion in the previous fiscal year of the post-merger integration process for OSI Pharmaceuticals, Inc., an anticancer drug specialist, as well as the progress in the development of anticancer drug introduced from other companies, Astellas reexamined the method for depreciation as part of the review of individual measures starting from FY2012 under the mid-term management plan for five years. As a result, Astellas decided, in comprehensive view of the following reasons, that unification of accounting treatment within the Group in respect of depreciation method, involving allocation of expenses over the service lives under the straight-line method, should contribute to further optimizing the profit/loss calculation of profits and losses for each period, as well as to enhancing the precision of performance management across the Group.

- i. Under the future capital expenditure plan, Astellas is scheduled to make capital expenditures to develop a high-mix low-volume manufacturing framework including the manufacture of antibody drugs, which

is expected to contribute to more constant operation of manufacturing facilities. Meanwhile, as the current key products are reaching their maturity stages, operation of existing manufacturing facilities is also likely to level off and stabilize.

- ii. In research and development, whereas Astellas adopted a product development framework focused on enhancing proprietary research and development capabilities, alliance with other companies shall be more actively promoted in the future, on top of the ongoing proprietary drug discovery effort, whereby enhanced synergy in research and development is expected to reduce the risk of uncertainty inherently involved therein.
- iii. Adopting the regional strategy based on a well-balanced global development in Japan, the Americas, Europe and Asia, Astellas is in need of a global control involving unified approach across the Group including cost accounting, for further efficient allocation of resources based on cross-regional framework for research and development as well as production.

As a result of the change of depreciation method, gross profit increased ¥2,160 million (\$23 million) and increased operating income and income before income taxes and minority interests increased ¥8,138 million (\$87 million) for the year ended March 31, 2013, compared to the corresponding amounts which would have been recognized under the previous method.

- (b) 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.

## 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 ¥94 = US \$1.00, the approximate rate of exchange on March 31, 2013. 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, 2013 and 2012 were as follows:

	(Millions of yen)		(Millions of U.S. dollars)
	2013	2012	2013
Merchandise and finished goods	¥ 92,663	¥ 82,233	\$ 986
Work in process	13,281	13,473	141
Raw materials and supplies	22,236	16,117	237
Total	¥ 128,180	¥ 111,823	\$ 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, 2013 and 2012. Current portion of lease obligations of ¥410 million (\$4 million) at March 31, 2013 and ¥420 million at March 31, 2012 were included in other current liabilities, and lease obligations excluding current portion of ¥737 million (\$8

million) at March 31, 2013 and ¥800 million at March 31, 2012 were included in other long-term liabilities.

The aggregate annual maturities of lease obligations for 5 years subsequent to March 31, 2013 are summarized as follows:

Year ending March 31,	(Millions of yen)	(Millions of U.S. dollars)
2014	¥ 410	\$ 4
2015	310	3
2016	229	2
2017	145	2
2018 and thereafter	53	1
Total	¥ 1,147	\$ 12

## 7. Net Assets

Changes in net assets for the year ended March 31, 2013 were as follows:

### a. Treasury stock

Types of share	(Thousands of shares)			Number of shares as of March 31, 2013
	Number of shares as of March 31, 2012	Increase	Decrease	
Treasury stock:				
Common stock (Notes 1 and 2)	6,045	10,805	61	16,789

Notes: 1. Breakdown of the increase of treasury stock is as follows:

	(Thousands of shares)
Increase due to purchase of stocks	10,800
Increase due to purchase of stocks of less than standard unit	5

2. Breakdown of the decrease of treasury stock is as follows:

	(Thousands of shares)
Decrease due to exercise of stock subscription rights	61
Decrease due to sale of stocks of less than standard unit	0

## b. Dividends

### 1) Dividends paid during the year ended March 31, 2013

Resolution	Type of shares	Total amounts paid	Dividends per share	Cut-off date	Total amounts paid (Millions of U.S. dollars)	Dividends per share (U.S. dollars)
		(Millions of yen)	(Yen)		(U.S. dollars)	(U.S. dollars)
Annual shareholders' meeting on June 20, 2012	Common stock	30,025	65	March 31, 2012	319	0.69
Board of Directors on November 1, 2012	Common stock	30,026	65	September 30, 2012	319	0.69

### 2) Dividends whose cut-off date was in the year ended March 31, 2013 and effective date is in the year ending March 31, 2014

Resolution	Type of shares	Total amounts paid	Dividends per share	Cut-off date	Total amounts paid (Millions of U.S. dollars)	Dividends per share (U.S. dollars)
		(Millions of yen)	(Yen)		(U.S. dollars)	(U.S. dollars)
Annual shareholders' meeting on June 19, 2013	Common stock	29,326	65	March 31, 2013	312	0.69

## c. Stock subscription rights

In July 2012, the Company issued 1,270 units of stock subscription rights, for which ¥290 million (\$3 million) was recorded as a component of net assets as of March 31, 2013. The stock subscription rights included rights unvested as of March 31, 2013.

## 8. Stock Option Plan

The Company has implemented a stock option plan under which stock subscription rights were granted to Directors, corporate executives 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 executives 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 executives 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 executives 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

		Stock subscription rights granted as a stock option plan
		Granted on July 5, 2012
Individuals covered by the plan	Directors of the Company	3
	Corporate executives of the Company	25
	Employees of the Company	—
	Total	28
Type and number of shares to be issued upon the exercise of the stock subscription rights	Common stock	127,000
Vesting period		From July 1, 2012 to June 19, 2013
Exercise period		From July 6, 2012 to June 20, 2032

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, 2012	—	—	—
Granted	—	—	—
Forfeited	—	—	—
Vested	—	—	—
<b>Outstanding as of March 31, 2013</b>	<b>—</b>	<b>—</b>	<b>—</b>
Vested stock subscription rights (shares)			
Outstanding as of March 31, 2012	13,800	69,100	46,300
Vested	—	—	—
Exercised	9,300	37,600	5,000
Forfeited	—	—	—
<b>Outstanding as of March 31, 2013</b>	<b>4,500</b>	<b>31,500</b>	<b>41,300</b>
Exercise price (Yen)	3,209	3,690	1
Weighted average exercise price (Yen)	4,125	4,510	4,151
Weighted average fair value per stock at the granted date (Yen)	—	—	—
Exercise price (U.S. dollars)	34.14	39.26	0.01
Weighted average exercise price (U.S. dollars)	43.88	47.98	44.16
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, 2012	—	—	—
Granted	—	—	—
Forfeited	—	—	—
Vested	—	—	—
<b>Outstanding as of March 31, 2013</b>	<b>—</b>	<b>—</b>	<b>—</b>
Vested stock subscription rights (shares)			
Outstanding as of March 31, 2012	48,000	60,600	59,600
Vested	—	—	—
Exercised	5,400	3,300	—
Forfeited	—	—	—
<b>Outstanding as of March 31, 2013</b>	<b>42,600</b>	<b>57,300</b>	<b>59,600</b>
Exercise price (Yen)	1	1	1
Weighted average exercise price (Yen)	4,585	3,624	—
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)	48.78	38.55	—
Weighted average fair value per stock at the granted date (U.S. dollars)	53.29	49.35	42.34

	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, 2012	—	—	31,275
Granted	—	—	—
Forfeited	—	—	—
Vested	—	—	31,275
<b>Outstanding as of March 31, 2013</b>	<b>—</b>	<b>—</b>	<b>—</b>
Vested stock subscription rights (shares)			
Outstanding as of March 31, 2012	99,500	123,900	93,825
Vested	—	—	31,275
Exercised	—	—	—
Forfeited	—	—	—
<b>Outstanding as of March 31, 2013</b>	<b>99,500</b>	<b>123,900</b>	<b>125,100</b>
Exercise price (Yen)	1	1	1
Weighted average exercise price (Yen)	—	—	—
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)	—	—	—
Weighted average fair value per stock at the granted date (U.S. dollars)	31.30	25.96	28.48

	Stock subscription rights granted as a stock option plan
	Granted on July 5, 2012
Unvested stock subscription rights (shares)	
Outstanding as of March 31, 2012	—
Granted	127,000
Forfeited	—
Vested	95,250
<b>Outstanding as of March 31, 2013</b>	<b>31,750</b>
Vested stock subscription rights (shares)	
Outstanding as of March 31, 2012	—
Vested	95,250
Exercised	—
Forfeited	—
<b>Outstanding as of March 31, 2013</b>	<b>95,250</b>
Exercise price (Yen)	1
Weighted average exercise price (Yen)	—
Weighted average fair value per stock at the granted date (Yen)	3,048
Exercise price (U.S. dollars)	0.01
Weighted average exercise price (U.S. dollars)	—
Weighted average fair value per stock at the granted date (U.S. dollars)	32.43

Stock option expense was included in selling, general and administrative expenses for the year ended March 31, 2013 and amounted to ¥374 million (\$4 million). The fair value of options granted on July 5, 2012 was estimated using the binomial model with the following weighted average assumptions.

	Stock subscription rights granted on July 5, 2012 as a stock option plan
Expected volatility	29.33%
Expected holding period	4 years
Expected dividend per share	125 yen
Risk-free rate	1.65%

## 9. Income Taxes

Income taxes applicable to the Company and its domestic consolidated subsidiaries comprise corporation tax, inhabitants' taxes and enterprise tax which, in the aggregate, resulted in statutory tax rate of 37.7%, 41.0% and 41.0% for 2013, 2012 and 2011, respectively. Income taxes of the foreign consolidated subsidiaries are based generally

on the tax rates applicable in their countries of incorporation.

The effective tax rates reflected in the consolidated statements of income for the years ended March 31, 2013, 2012 and 2011 differ from the statutory tax rate for the following reasons:

	2013	2012	2011
Statutory tax rate	37.7%	41.0%	41.0%
Effect of:			
Different tax rates applied to income of foreign consolidated subsidiaries	(8.9)	(7.9)	(9.1)
Expenses not deductible for income tax purposes	3.6	4.9	5.8
Amortization of goodwill	3.1	3.8	4.4
Tax credit for research and development expenses	(2.3)	(7.4)	(9.6)
Undistributed earnings of foreign consolidated subsidiaries	0.6	5.6	0.0
Impact from reorganization in foreign consolidated subsidiaries	—	(8.8)	—
Impact from changes in tax rates	—	6.9	—
Other, net	(0.3)	0.3	2.1
Effective tax rate	33.5%	38.4%	34.6%

The significant components of the deferred tax assets and liabilities as of March 31, 2013 and 2012 were as follows:

	(Millions of yen)		(Millions of U.S. dollars)
	2013	2012	2013
Deferred tax assets:			
Loss on devaluation of investment securities	¥ 1,310	¥ 2,159	\$ 14
Accrued retirement benefits	6,458	6,578	69
Depreciation and amortization	40,726	45,091	433
Loss on impairment of fixed assets	2,268	1,915	24
Accrued expenses	28,596	22,205	304
Inventories	20,753	20,640	221
Accrued enterprise and other taxes	94	1,330	1
Tax loss carryforwards	7,508	7,708	80
Other	37,619	56,327	400
Gross deferred tax assets	145,332	163,953	1,546
Valuation allowance	(20,371)	(12,538)	(217)
Total deferred tax assets	124,961	151,415	1,329
Deferred tax liabilities:			
Unrealized holding gain on securities	7,802	5,797	83
Depreciation and amortization	2,073	839	22
Intangible assets related to business combination	42,776	53,507	455
Other	18,337	16,779	195
Total deferred tax liabilities	70,988	76,922	755
Net deferred tax assets	¥ 53,973	¥ 74,493	\$ 574

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 decrease in deferred tax assets (after deducting deferred tax liabilities), as well as a ¥8,725 million increase in income taxes-deferred and a ¥936 million increase in unrealized holding gain on securities for the year ended March 31, 2012.

## 10. Other Comprehensive Income

The following table shows reclassification adjustments for each component of other comprehensive income for the years ended March 31, 2013 and 2012:

	(Millions of yen)		(Millions of U.S. dollars)	
	2013		2013	
Unrealized holding gain on securities				
Amount arising during the year	¥ 10,705		\$ 114	
Reclassification adjustment	(4,980)	¥ 5,725	(53)	\$ 61
Translation adjustments				
Amount arising during the year	¥ 66,241	66,241	\$ 705	705
Total other comprehensive income before tax effect		71,966		766
Tax effect		(2,016)		(22)
Total other comprehensive income		¥ 69,950		\$ 744

	(Millions of yen)	
	2012	
Unrealized holding gain on securities		
Amount arising during the year	¥ 3,240	
Reclassification adjustment	170	¥ 3,410
Translation adjustments		
Amount arising during the year	¥ (26,580)	(26,580)
Total other comprehensive income before tax effect		(23,170)
Tax effect		(632)
Total other comprehensive income		¥ (23,802)

The following table shows the amount of income tax effect to each component of other comprehensive income for the years ended March 31, 2013 and 2012:

	(Millions of yen)			(Millions of U.S. dollars)		
	2013			2013		
	Pre-tax amount	Tax effect	Net-of-tax amount	Pre-tax amount	Tax effect	Net-of-tax amount
Unrealized holding gain on securities	¥ 5,725	¥ (2,016)	¥ 3,709	\$ 61	\$ (22)	\$ 39
Translation adjustments	66,241	—	66,241	705	—	705
Total other comprehensive income	¥ 71,966	¥ (2,016)	¥ 69,950	\$ 766	\$ (22)	\$ 744

	(Millions of yen)		
	2012		
	Pre-tax amount	Tax effect	Net-of-tax amount
Unrealized holding gain on securities	¥ 3,410	¥ (632)	¥ 2,778
Translation adjustments	(26,580)	—	(26,580)
Total other comprehensive income	¥ (23,170)	¥ (632)	¥ (23,802)

## 11. Retirement Benefit Plans

The Company and its domestic consolidated 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 actu-

arial calculation required by the accounting standard for retirement benefits.

Certain foreign consolidated 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, 2013 and 2012 for the defined benefit plans:

	(Millions of yen)		(Millions of U.S. dollars)
	2013	2012	2013
Retirement benefit obligation	¥ (176,952)	¥ (144,363)	\$ (1,882)
Plan assets at fair value	135,936	119,294	1,446
Unfunded retirement benefit obligation	(41,016)	(25,069)	(436)
Unrecognized actuarial gain/loss	29,592	15,557	314
Unrecognized past service cost	(5,559)	(6,408)	(59)
Net retirement benefit obligation	(16,983)	(15,920)	(181)
Prepaid pension cost	1,290	1,059	13
Accrued retirement benefits	¥ (18,273)	¥ (16,979)	\$ (194)

The components of retirement benefit expenses for the years ended March 31, 2013, 2012 and 2011 are outlined as follows:

	(Millions of yen)			(Millions of U.S. dollars)
	2013	2012	2011	2013
Service cost	¥ 4,587	¥ 4,545	¥ 4,539	\$ 49
Interest cost	3,785	3,829	3,739	40
Expected return on plan assets	(3,439)	(3,556)	(4,060)	(37)
Amortization of actuarial gain/loss	2,618	3,775	3,074	28
Amortization of past service cost	(863)	(868)	(872)	(9)
Other	8,681	6,739	5,897	93
Total	¥15,369	¥14,464	¥12,317	\$164

The assumptions used in accounting for the above plans were as follows:

	2013	2012
Discount rates	0.9% - 4.8%	2.0% - 5.7%
Expected rates of return on plan assets	2.5% - 5.0%	2.5% - 5.0%
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, 2013, 2012 and 2011, totaled ¥181,955 million (\$1,936 million), ¥189,840 million and ¥217,326 million, respectively.

## 13. Leases

Future minimum lease payments subsequent to March 31, 2013 on non-cancelable operating lease transactions are summarized as follows:

Year ending March 31,	(Millions of yen)	(Millions of U.S. dollars)
2014	¥ 7,302	\$ 78
2015 and thereafter	23,982	255
<b>Total</b>	<b>¥ 31,284</b>	<b>\$ 333</b>

## 14. Contingent Liabilities

Contingent liabilities of Astellas as of March 31, 2013 and 2012 were as follows:

	(Millions of yen)		(Millions of U.S. dollars)
	2013	2012	2013
Contingent liabilities as guarantors of indebtedness of the Company's employees and business partners	¥ 2,133	¥ 2,509	\$ 23

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)
	2013	2012	2011	2013
Net income:				
Basic	¥ 180.40	¥ 169.38	¥ 146.49	\$ 1.92
Diluted	180.15	169.17	146.33	1.92
Cash dividends	130.00	125.00	125.00	1.38
Net assets	2,349.61	2,200.64	2,207.70	25.00

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, 2013 and 2012.



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 global cash 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, 2013 and 2012.

	(Millions of yen)			(Millions of U.S. dollars)		
	2013	2013		2013	2013	
	Carrying value	Fair value	Difference	Carrying value	Fair value	Difference
Cash and cash equivalents	¥ 264,912	¥ 264,912	¥ —	\$ 2,818	\$ 2,818	\$ —
Notes and accounts receivable	302,047	302,047	—	3,213	3,213	—
Short-term investments and Investment securities:						
Other securities	95,597	95,597	—	1,017	1,017	—
Notes and accounts payable	(190,552)	(190,552)	—	(2,027)	(2,027)	—
Derivative transactions	¥ 178	¥ 178	¥ —	\$ 2	\$ 2	\$ —

	(Millions of yen)		
	2012		
	Carrying value	Fair value	Difference
Cash and cash equivalents	¥ 252,380	¥ 252,380	¥ —
Notes and accounts receivable	286,798	286,798	—
Short-term investments and Investment securities:			
Other securities	93,725	93,725	—
Notes and accounts payable	(190,796)	(190,796)	—
Derivative transactions	¥ —	¥ —	¥ —

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.

*Derivative transactions:* The fair value of derivative transactions is based on prices provided by the financial institutions making markets in these transactions.

## Securities

Information regarding marketable securities classified as other securities as of March 31, 2013 and 2012 is summarized as follows:

### Other securities

	(Millions of yen)			(Millions of U.S. dollars)		
	2013			2013		
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:						
Stock	¥ 19,466	¥ 45,453	¥ 25,987	\$ 207	\$ 484	\$ 277
Debt securities	—	—	—	—	—	—
Other	2,000	2,081	81	21	22	1
Subtotal	21,466	47,534	26,068	228	506	278
Securities whose acquisition cost exceeds their carrying value:						
Stock	295	262	(33)	3	3	(0)
Debt securities	65,396	65,396	(0)	696	696	(0)
Other	13,513	13,503	(10)	144	144	(0)
Subtotal	79,204	79,161	(43)	843	843	(0)
Total	¥ 100,670	¥ 126,695	¥ 26,025	\$ 1,071	\$ 1,349	\$ 278

	(Millions of yen)		
	2012		
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Stock	¥ 23,159	¥ 44,602	¥21,443
Debt securities	27,497	27,497	0
Other	2,000	2,077	77
Subtotal	52,656	74,176	21,520
Securities whose acquisition cost exceeds their carrying value:			
Stock	323	292	(31)
Debt securities	53,795	53,795	(0)
Other	6,863	6,854	(9)
Subtotal	60,981	60,941	(40)
Total	¥ 113,637	¥135,117	¥21,480

Carrying values of other securities, which were reclassified to "Cash and cash equivalents" in the consolidated balance sheets at March 31, 2013 and 2012 as the investment with a maturity of three months or less when purchased, amounted to ¥31,098 million (\$331 million) and

¥41,392 million, respectively.

Proceeds from sales of securities classified as other securities and the related aggregate gains and losses for the years ended March 31, 2013, 2012 and 2011 are summarized as follows:

	(Millions of yen)			(Millions of U.S. dollars)		
	2013			2013		
	Proceeds	Aggregate gain	Aggregate loss	Proceeds	Aggregate gain	Aggregate loss
Stock	¥ 8,948	¥ 4,977	¥ 55	\$ 95	\$ 53	\$ 1
Debt securities	9,999	—	—	106	—	—
Other	220,592	453	254	2,347	5	2
Total	¥ 239,539	¥ 5,430	¥ 309	\$ 2,548	\$ 58	\$ 3

	(Millions of yen)					
	2012			2011		
	Proceeds	Aggregate gain	Aggregate loss	Proceeds	Aggregate gain	Aggregate loss
Stock	¥ 913	¥ 369	¥ 109	¥ 2,793	¥ 1,280	¥ 325
Debt securities	1,345	9	5	82,395	105	108
Other	281,067	2,344	—	275,110	0	—
Total	¥ 283,325	¥ 2,722	¥ 114	¥ 360,298	¥ 1,385	¥ 433

The redemption schedule for securities with maturities as of March 31, 2013 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	¥ 15,400	¥ —	¥ —	¥ —
Corporate bonds	—	—	—	—
Other debt securities	50,000	—	—	—
Other	13,467	—	—	—
Total	¥ 78,867	¥ —	¥ —	¥ —

	(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	\$ 164	\$ —	\$ —	\$ —
Corporate bonds	—	—	—	—
Other debt securities	532	—	—	—
Other	143	—	—	—
Total	\$ 839	\$ —	\$ —	\$ —

## Securities without determinable fair value

	(Millions of yen)		(Millions of U.S. dollars)
	2013	2012	2013
	Carrying value	Carrying value	Carrying value
Non marketable stocks	¥ 13,809	¥ 13,512	\$ 147
Total	¥ 13,809	¥ 13,512	\$ 147

### Impairment loss on securities

Impairment loss on securities in the years ended March 31, 2013 and 2012 amounted to ¥1,067 million (\$11 million) and ¥792 million, respectively.

## Derivative Transactions

The notional amounts and the estimated fair value of derivatives outstanding as of March 31, 2013 are summarized as follows:

2013	(Millions of yen)			(Millions of U.S. dollars)		
	Notional amount	Fair value	Unrealized gain	Notional amount	Fair value	Unrealized gain
Forward foreign exchange contracts						
Buy Euro/Sell U.S. Dollars	¥ 92,014	¥ 178	¥ 178	\$ 979	\$ 2	\$ 2
Total	¥ 92,014	¥ 178	¥ 178	\$ 979	\$ 2	\$ 2

There were no outstanding derivative transactions as of March 31, 2012.

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 "VISION2015" 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
Total acquisition cost	\$ 3,544

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

As Astellas operates business in single business segment of "Pharmaceutical", the disclosure of business segment information has been omitted.

### Segment-related information

#### Sales by products to third parties

	(Millions of yen)			(Millions of U.S. dollars)
	2013	2012	2011	2013
Prograf	¥ 161,763	¥ 154,877	¥ 162,651	\$ 1,721
Vesicare	109,973	97,201	86,703	1,170
Other	733,876	717,309	704,594	7,807
<b>Total</b>	<b>¥ 1,005,612</b>	<b>¥ 969,387</b>	<b>¥ 953,948</b>	<b>\$ 10,698</b>

## Information by region

### Net sales

	(Millions of yen)			(Millions of U.S. dollars)
	2013	2012	2011	2013
Japan	¥ 541,573	¥ 547,796	¥ 531,416	\$ 5,761
Americas	215,577	182,660	189,471	2,293
U.S. (included in Americas)	197,787	165,006	171,778	2,104
Europe	188,783	187,370	181,984	2,008
Asia and other	59,679	51,561	51,077	636
Total	¥ 1,005,612	¥ 969,387	¥ 953,948	\$ 10,698

### Property, plant and equipment

	(Millions of yen)		(Millions of U.S. dollars)
	2013	2012	2013
Japan	¥ 144,154	¥ 140,720	\$ 1,534
Americas	40,807	31,669	434
U.S. (included in Americas)	40,480	31,329	431
Europe	31,269	24,886	332
Asia and other	2,249	1,885	24
Total	¥ 218,479	¥ 199,160	\$ 2,324

## Information by major customer

### Net sales

	(Millions of yen)			(Millions of U.S. dollars)
	2013	2012	2011	2013
Suzuken Co., Ltd.	¥ 123,175	¥ 119,635	¥ 114,039	\$ 1,310
MEDICEO CORPORATION	115,956	117,084	114,339	1,234
Alfresa Corporation	106,534	110,758	106,422	1,133

## 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, 2013, 2012 and 2011 amounted to ¥34,790 million (\$370 million), ¥9,234 million and ¥2,782 million, respectively. Loss on impairment of fixed assets for the year ended March 31, 2013 mainly consists of losses on patents in the aggregate amount of ¥30,414 million (\$324

million), losses on other intangible assets in the aggregate amount of ¥2,427 million (\$26 million), and losses on land in the aggregate amount of ¥1,096 million (\$12 million). 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 and losses on patents in the aggregate amount of ¥6,724 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 other intangible assets in the aggregate amount of ¥1,105 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 sheet as at March 31, 2013, 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, 2013, and their consolidated financial performance and cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

## *Emphasis of Matter*

We draw attention to Accounting Changes to the consolidated financial statements, which describes that, effective from April 1, 2012, Astellas Pharma Inc. and its domestic consolidated subsidiaries changed their depreciation method for property, plant and equipment from hitherto adopted declining-balance method to straight-line method.

Our opinion is not qualified in respect of this matter.

## *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.



June 19, 2013  
Tokyo, Japan

## Principal Subsidiaries and Affiliates (as of August 2013)

Astellas is a group of companies engaged solely in the pharmaceutical business. The group consists of 82 companies, which include Astellas Pharma Inc., 78 consolidated subsidiaries, and three affiliates 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

#### 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.

Sylviusweg 62, PO Box 344, 2300 AH Leiden,  
The Netherlands  
TEL: +31-71-5455745

#### European headquarters

Astellas Pharma Europe Ltd.

2000 Hillswood Drive, Chertsey, Surrey, 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)  
 Astellas Pharma Singapore Pte. Ltd. (Singapore)

## 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	
	Astellas Pharma Tech Co., Ltd.	Branches/Sales Offices	14 branches, 159 sales offices
Nishine Plant		Hachimantai, Iwate	Manufacturing
Takahagi Technology Center		Takahagi, Ibaraki	
Yaizu Technology Center		Yaizu, Shizuoka	
Fuji Plant		Fuji, Shizuoka	
Toyama Technology Center		Toyama, Toyama	
Takaoka Plant	Takaoka, 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)

# Corporate Data/Investor Information

## Company Name

Astellas Pharma Inc.

## Head Office

2-5-1, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan

TEL: +81-3-3244-3000

<http://www.astellas.com/en/>

## Capital (as of March 31, 2013)

¥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 (as of March 31, 2013)

Authorized: 2,000,000,000

Issued: 467,964,635 (including 16,788,579 treasury stock)

Number of shareholders: 49,335

## Stock Exchange Listing

Tokyo

(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 2013 to:**

Astellas Pharma Inc.

Corporate Communications

TEL: +81-3-3244-3202

FAX: +81-3-5201-7473

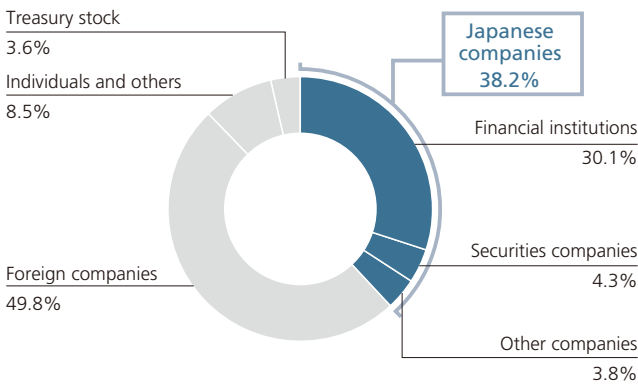
Issued in August 2013 (Our next annual report is scheduled to be issued in August 2014)

### Major Shareholders (as of March 31, 2013)

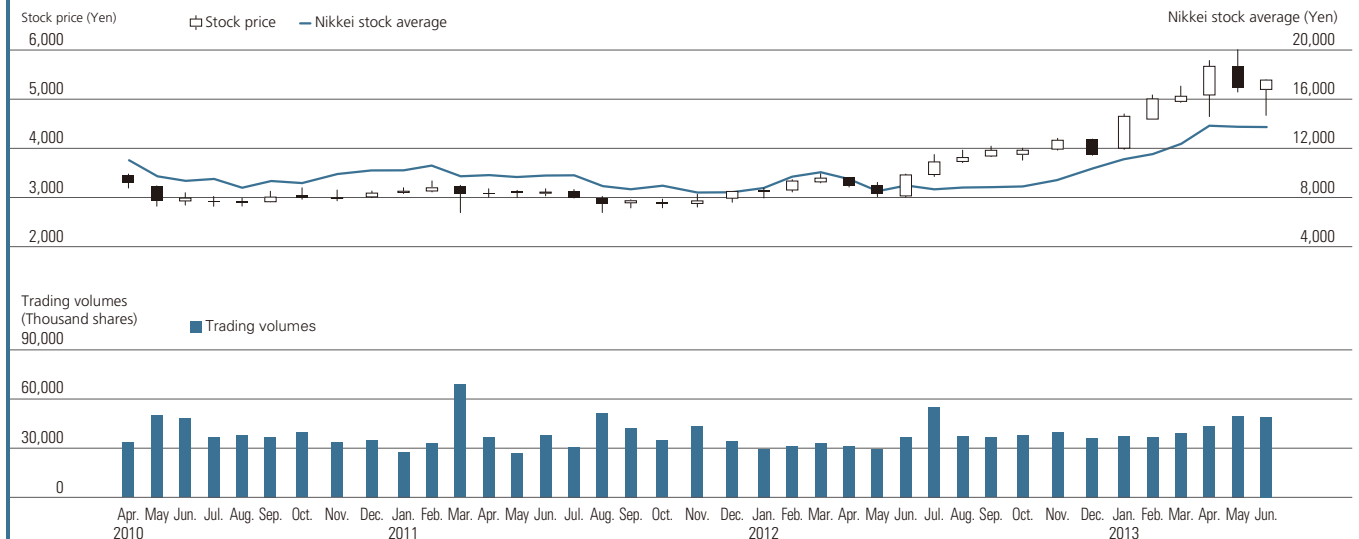
Name	Shares owned Thousand shares (Thousand)	Percentage of total common shares outstanding
The Master Trust Bank of Japan, Ltd. (trust account)	25,036	5.35
Japan Trustee Services Bank, Ltd. (trust account)	24,929	5.32
State Street Bank and Trust Company	24,275	5.18
Nippon Life Insurance Company	14,509	3.10
JP Morgan Chase Bank 385147	14,365	3.06
SSBT OD05 OMNIBUS ACCOUNT - TREATY CLIENTS	10,776	2.30
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	9,881	2.11
State Street Bank and Trust Company 505225	8,648	1.84
The Chase Manhattan Bank, NA London, SL Omnibus account	6,927	1.48
Mellon Bank N.A. as agent for its client Mellon Omnibus U.S. Pension	6,173	1.31

Notes: 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.  
The company holds 16,788 thousand shares of treasury stock, but it is not included in the above list of major shareholders.

### Breakdown of Shareholders (as of March 31, 2013)



### Stock Prices and Trading Volumes on the Tokyo Stock Exchange (highest/lowest in the month; yen)





**Astellas Pharma Inc.**  
2-5-1, Nihonbashi-Honcho,  
Chuo-ku, Tokyo 103-8411, Japan  
<http://www.astellas.com/en/>



This report is printed with environmentally friendly vegetable-based inks on FSC™-certified paper made of wood sourced from responsibly managed forests, using a waterless printing process.

Printed in Japan