



ANNUAL REPORT  
2016

For the Year Ended March 31, 2016

Changing tomorrow

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## 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.

Astellas promises to perform its obligations toward all stakeholders by acting ethically and seeking to actively disclose information.

#### Cautionary Note

In this annual report, statements made with respect to current plans, estimates, strategies and beliefs and other statements 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. A number of 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 laws and regulations relating to pharmaceutical markets, (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 Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this annual report is not intended to constitute an advertisement or medical advice.

# 1

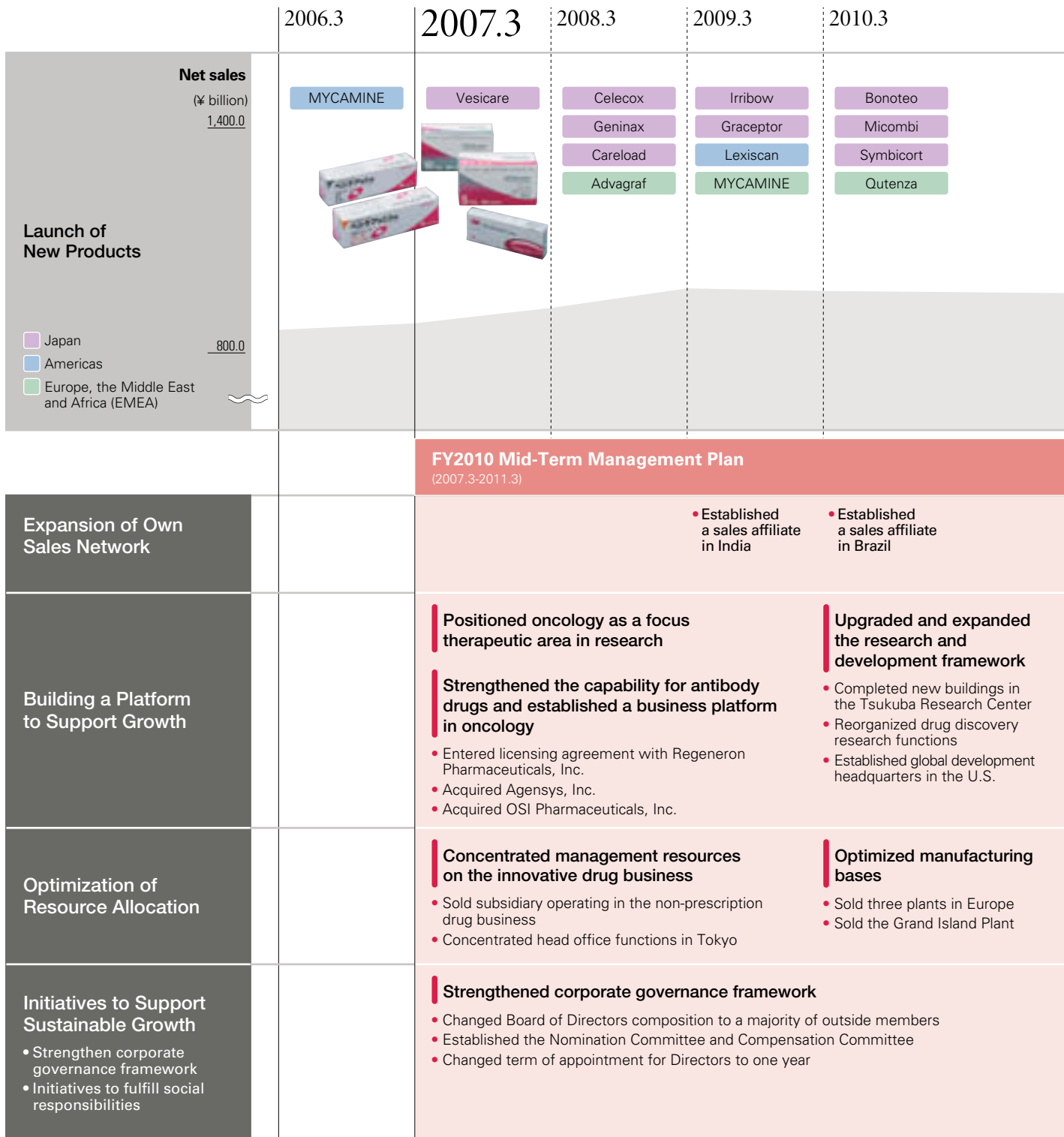
## About Astellas

# Contribute toward Health through Innovative Drugs

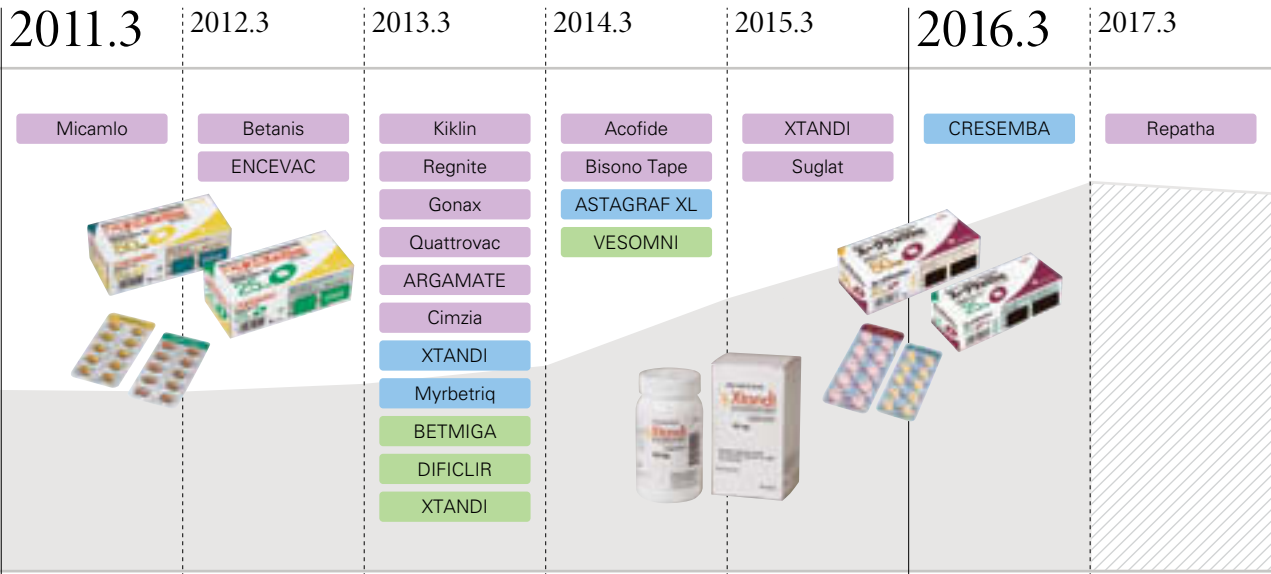
Astellas is concentrating on the innovative drug business, where it possesses key strengths. We are enhancing our ability to continuously develop innovative drugs, in conjunction with optimizing the allocation of resources, in an effort to deliver valuable medicines to patients worldwide.

# Retracing Astellas' Steps

Astellas has been achieving growth by contributing toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The Company is strengthening its business foundations through concentrating its resources on the innovative drug business.



■ : Summarized major activities for each medium-term management plan



**FY2010-FY2014 Mid-Term Management Plan**  
(2011.3-2015.3)

**Strategic Plan 2015-2017**  
(2016.3-2018.3)

<ul style="list-style-type: none"> <li>Established a sales affiliate in Australia</li> </ul>	<ul style="list-style-type: none"> <li>Established a sales affiliate in Slovenia (overseeing South East Europe)</li> </ul>	<ul style="list-style-type: none"> <li>Established a sales affiliate in Singapore</li> </ul>	<ul style="list-style-type: none"> <li>Established a sales affiliate in Dubai (overseeing MENA/SSA*)</li> </ul>	<ul style="list-style-type: none"> <li>Established a sales affiliate in Malaysia and an umbrella organization covering SESA*2</li> <li>Established a sales affiliate in Columbia</li> </ul>
<p><b>Reshaped research framework</b></p> <ul style="list-style-type: none"> <li>Captured external opportunities under the Network Research System</li> <li>Commenced full-scale regenerative medicine research</li> <li>Launched initiatives to boost R&amp;D productivity through FASTEN</li> </ul> <p><b>Formed strategic alliance with Amgen, Inc. in Japan</b></p>				<p><b>Conducted various initiatives for creating innovation</b></p> <ul style="list-style-type: none"> <li>Acquired Ocata Therapeutics, Inc. (currently Astellas Institute for Regenerative Medicine)</li> </ul>
<p><b>Withdrew from in-house fermentation research</b></p> <p><b>Closed and scaled back research facilities in the U.S.</b></p>	<p><b>Transferred the Fuji Plant to Nichi-Iko Pharmaceutical Co., Ltd.</b></p> <p><b>Outsourced Group-wide shared operations in Japan</b></p>	<p><b>Transferred Astellas' global dermatology business to LEO Pharma A/S</b></p>		
<p><b>Reinforced the global management system</b></p> <ul style="list-style-type: none"> <li>Strengthened compliance organization</li> <li>Strengthened organization for development and quality and reliability assurance</li> </ul>	<p><b>Declared support for the United Nations Global Compact</b></p> <p><b>Promoted various initiatives on neglected tropical diseases</b></p>	<p><b>Changed Audit &amp; Supervisory Board composition to a majority of outside members</b></p> <p><b>Enhanced compliance functions</b></p>		

\*1 Middle East, North Africa and Sub-Saharan Africa

\*2 The South East and South Asia regions

## Astellas Today (Fiscal 2015/as of March 31, 2016)

As a global pharmaceutical company with its own distribution channels in more than 50 countries around the world, Astellas is developing business in a well-balanced manner across its four main regions of Japan, the Americas, EMEA and Asia & Oceania.

**Market capitalization** (as of July 31, 2016)

¥3.7 trillion

**Number of employees**

17,217

**R&D expenses**

¥225.7 billion

Ratio to sales 16.4%

**Number of new molecular/  
biological entities in the pipeline**

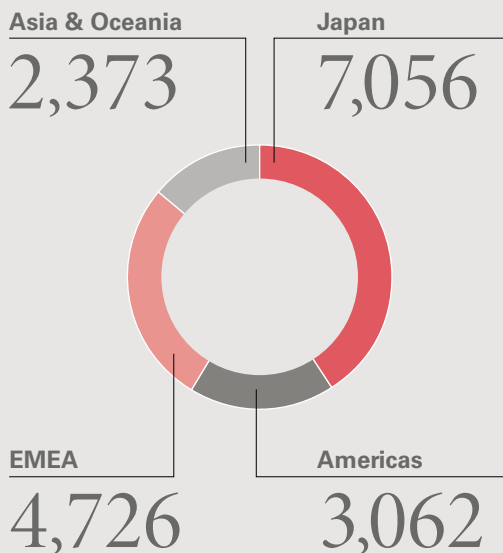
(as of July 2016)

36

**Number of ongoing collaborative  
research projects**

More than 100

**Number of employees  
by geographical area**



**Number of R&D personnel**

Approx. 3,020

Global sales

¥1,372.7 billion

Number of countries where Astellas has its own distribution channels

Approx. 50 countries

Number of Medical Representatives (MRs)

Approx. 6,000

Sales by geographical area

Asia & Oceania

¥91.1 billion  
6.6%

Japan

¥497.2 billion  
36.2%

EMEA

¥329.3 billion  
24.0%

Americas

¥455.1 billion  
33.2%

Sales composition of the three main therapeutic areas and main products



Transplantation

14.8%  
• Prograf

Oncology

23.3%  
• XTANDI



Urology

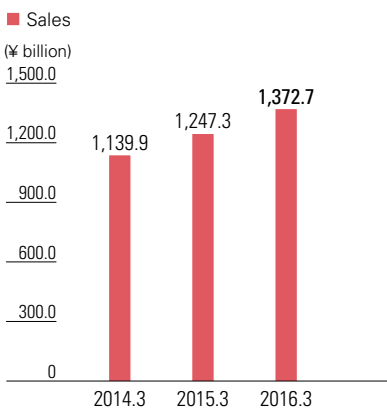
15.8%  
• Vesicare  
• Betanis/Myrbetriq/BETMIGA



# Financial and Non-Financial Highlights

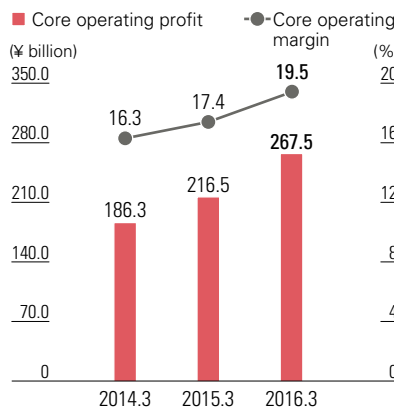
Astellas achieved double-digit growth in sales and profit year on year in fiscal 2015, fueled by global growth of products in the oncology field and the urology overactive bladder (OAB) franchise, the Company's growth drivers.

## Sales



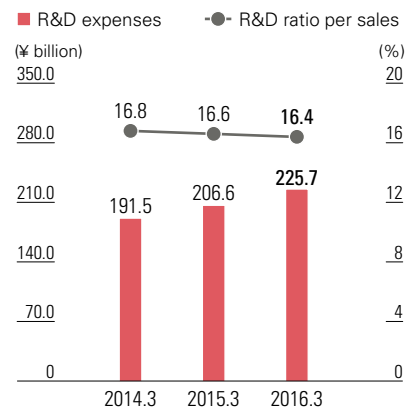
Consolidated sales in fiscal 2015 increased by 10.1% year on year to ¥1,372.7 billion, supported by growing sales of prostate cancer treatment XTANDI, OAB treatments (Vesicare and Betanis/Myrbetriq/BETMIGA) and other products.

## Core Operating Profit / Core Operating Margin



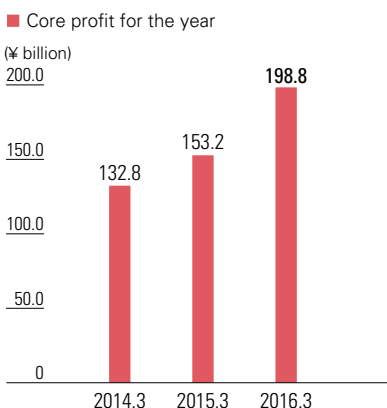
Core operating profit in fiscal 2015 increased by 23.5% year on year to ¥267.5 billion. The core operating margin was 19.5%. Following on from the previous fiscal year, Astellas achieved double-digit growth in core operating profit, along with a steady increase in the core operating margin in line with the strategic plan.

## R&D Expenses / R&D Ratio per Sales



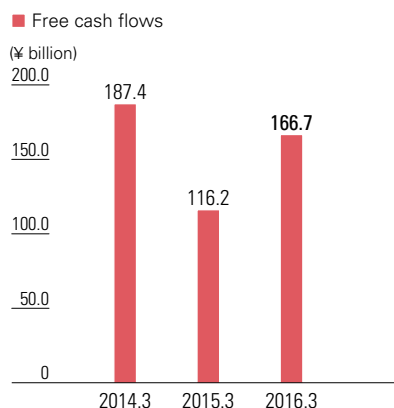
Research and development (R&D) expenses in fiscal 2015 rose by 9.2% year on year to ¥225.7 billion, which, in addition to increased expenses related to progress on development projects, was partly due to the foreign exchange rate impact. The ratio of R&D expenses to sales was 16.4%.

## Core Profit for the Year



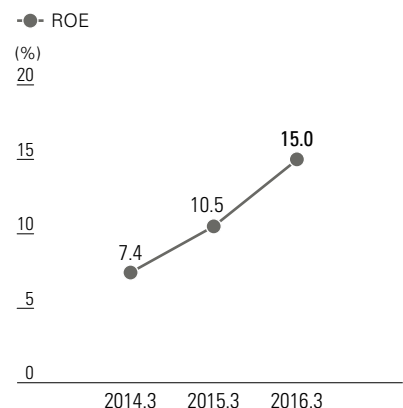
In fiscal 2015, core profit for the year increased by 29.7% year on year to ¥198.8 billion, tracking the increase in core operating profit.

## Free Cash Flows



Free cash flow in fiscal 2015 increased mainly due to an increase in profit before tax, and proceeds from the transfer of the global dermatology business, despite an increase in net cash flows used in investing activities.

## ROE\*

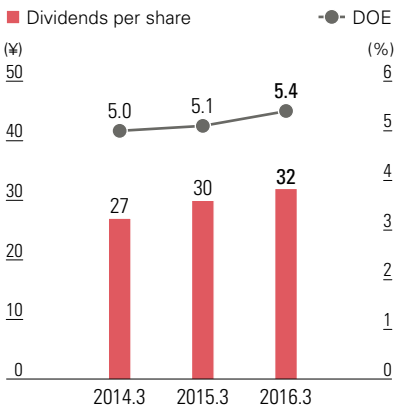


In fiscal 2015, ROE increased to 15.0%. Astellas aims to maintain and improve this level over the medium to long term by maximizing earnings capabilities and enhancing capital efficiency.

\* Return on equity



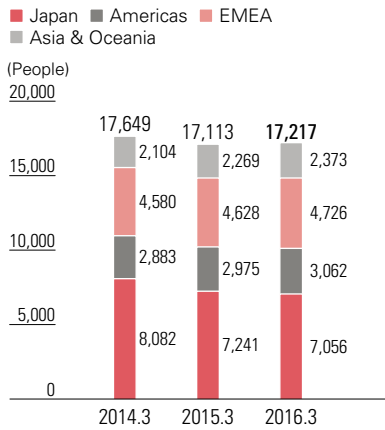
### Dividends per Share\*1 / DOE\*2



Astellas strives to increase dividend payments stably and continuously based on medium- to long-term profit growth. In fiscal 2015, the annual dividend was ¥32 per share, representing a DOE of 5.4%.

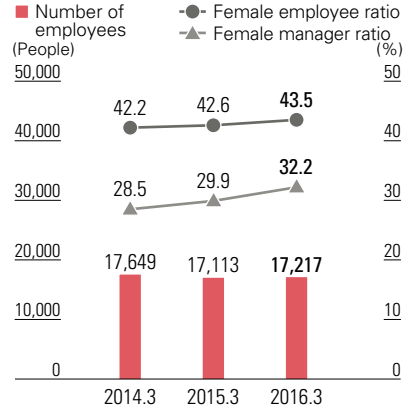
\*1 Calculated based on retrospective adjustment for a stock split of common stock at a ratio of 5 for 1 conducted on April 1, 2014.  
\*2 Dividend on equity attributable to owners of the parent

### Number of Employees by Region



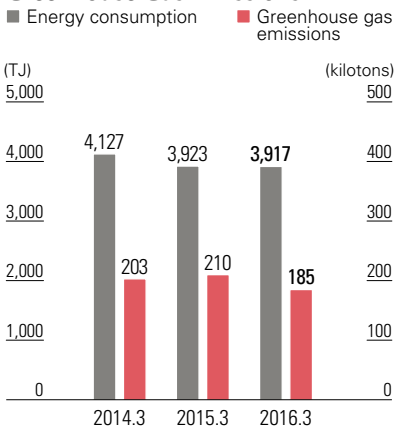
The number of employees increased by a combined total of around 100. It increased in the Americas, EMEA and Asia & Oceania, but decreased in Japan.

### Number of Employees / Female Employee Ratio / Female Manager Ratio



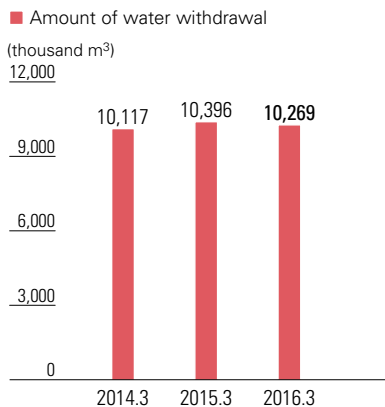
On a global basis, the female employee ratio was 43.5% and the female manager ratio was 32.2% in fiscal 2015. Improving female manager ratio in Japan is a particularly urgent issue for Astellas.

### Energy Consumption / Greenhouse Gas Emissions



In fiscal 2015, greenhouse gas emissions were 185 kilotons, reflecting efforts by Astellas to reduce greenhouse gas emissions accompanying its own activities. The amount of greenhouse gas emissions accompanying electricity use at overseas production sites was reviewed against international guidelines.

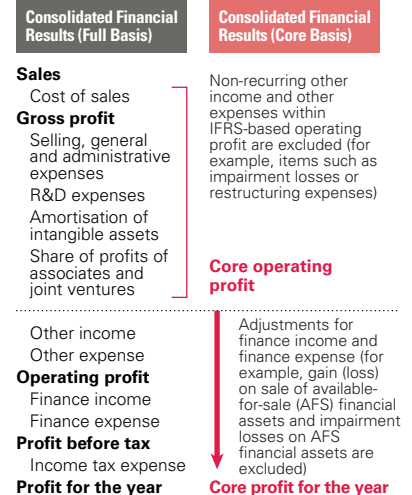
### Amount of Water Withdrawal



Aiming to establish a recycling-oriented society, Astellas has been striving to reduce water withdrawal. As a result, Astellas achieved its numerical target for water withdrawal in the final target year of fiscal 2015.

### Definition of Financial Results on a Core Basis

We disclose our financial results under IFRS on a core basis to help provide an accurate indication of the Group's recurring profitability. Certain items reported in financial results under IFRS on a full basis that are deemed to be non-recurring items by the Company are excluded as non-core items on a core basis.



## Editorial Policy

To enable deeper stakeholder understanding of Astellas' efforts to continue to create value for sustainable growth, the Company has published this annual report as an integrated report.

In this report, we have attempted to provide disclosure while taking note of the Guiding Principles and Content Elements of the international integrated reporting framework of the International Integrated Reporting Council (IIRC). We have also referred to G4 Sustainability Reporting Guidelines\* published by the Global Reporting Initiative and Environmental Reporting Guidelines (Fiscal Year 2012 Version) issued by Japan's Ministry of the Environment.

In creating the report, we have sought to make an effective tool for communicating with our many stakeholders. We have therefore used charts and photographs, and endeavored to use plain language that is easy to read.

Astellas has adopted the International Financial Reporting Standards (IFRS), effective from fiscal 2013. Information in this report is based on IFRS unless otherwise indicated.

\* For the GRI Content Index, please visit the following website:  
<https://www.astellas.com/en/csr/management/report.html>

### Scope of the Report

#### Period covered

Fiscal 2015 (April 1, 2015 - March 31, 2016)

- \* As much as possible, we have used the latest information available at the time of publication.
- \* The period and scope of coverage may vary depending on the subject. We have noted each such case individually.
- \* The figures indicated in the field of Environment represent the results for fiscal 2015 (April 1, 2015 to March 31, 2016) in Japan and the calendar year 2015 (January 1 to December 31, 2015) for overseas operations as a combined total.

#### Organizations covered

Astellas Pharma Inc. and its consolidated subsidiaries in Japan and overseas (referred to in the report as "Astellas")

- \* The Americas includes North America and Latin America, and EMEA includes Europe, the Middle East, and Africa.
- \* In the field of Environment, the report covers all business sites in Japan and production sites overseas, which are subject to the Environmental Action Plan, as well as overseas sites not covered by the plan such as principal office buildings, research facilities, sales office buildings, and sales fleets.

Note: In the information about pharmaceutical products in this report, market size, market share and product ranking are sourced from IMS Health Information Services.

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 Calculated based on IMS MIDAS 2016Q1 MAT  
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## Websites

### Corporate Website



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

### Investor Relations



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

### Social Responsibility



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

# 2

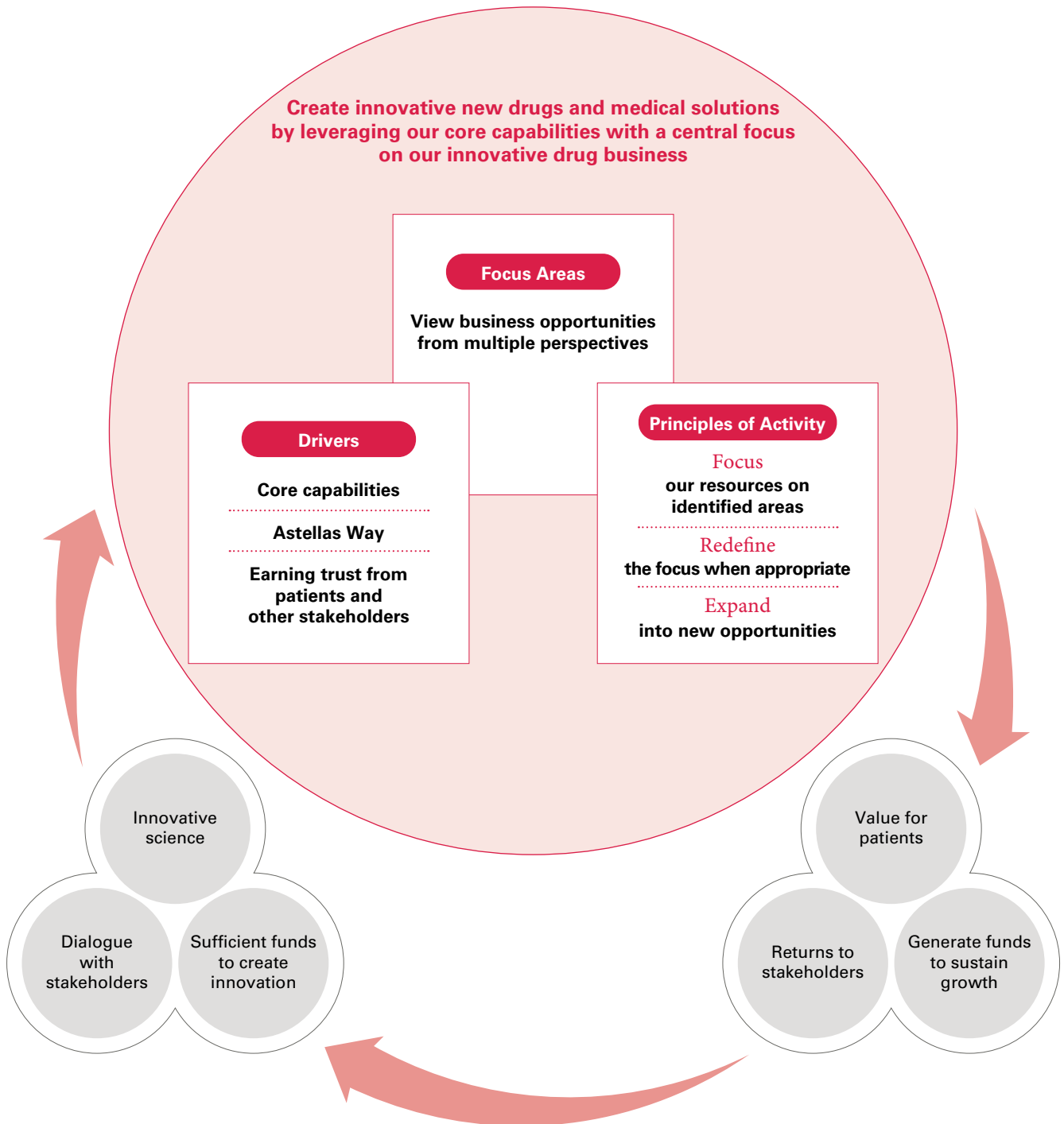
## Our Strategy

# Aiming to Realize Sustainable Growth over the Medium and Long Terms

Astellas aims to turn advances in science into value for patients on the forefront of healthcare change. Guided by this vision, Astellas is advancing three strategic priorities—“Maximizing the Product Value,” “Creating Innovation,” and “Pursuing Operational Excellence”—to realize sustainable growth over the medium and long terms.

# Astellas Value Creation Process

Astellas stands on the forefront of healthcare change, turning innovative science into value for patients. By repeating this cycle continuously, we are pursuing the sustainable growth of corporate value.



## Our Approach to the Value Creation Process

Astellas' raison d'être is to "contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products."

Based on this, we aim to stand on the forefront of healthcare change, turning innovative science into value for patients. The keys to our success will be our Focus Areas, Principles of Activity, and Drivers, which describe where we should create value and how we should act to realize that value. Guided by this approach, we will create innovation with a central focus on the innovative drug business.

This process originates with advances in science, and Astellas then allocates sufficient funds and implements measures to satisfy the requests and expectations of stakeholders. By creating value for patients, through this process, we will generate funds to sustain the next phase of growth and provide returns to stakeholders.

Astellas will continue to follow this cycle to achieve sustainable growth of corporate value.

## Focus Areas

Amid continuing evolution in the healthcare industry, Astellas needs to identify business opportunities more flexibly and efficiently than ever in order to achieve further growth. We will define our Focus Areas by adding multiple perspectives to our conventional viewpoint of therapeutic areas. We will factor in a consideration of new technologies and treatment approaches, product development feasibility and new possibilities for commercialization, market trends and changes in pharmaceutical laws and regulations. Our goal is to identify areas of unmet need and find new business opportunities.

## Principles of Activity

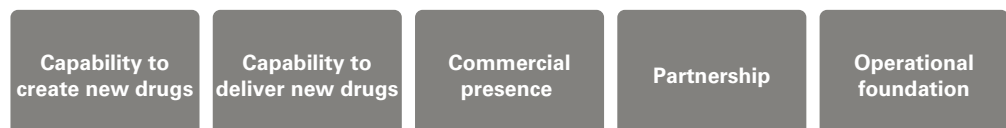
In a fast-changing business environment, it is crucial to have the flexibility to reexamine business fields as needed—even those that have been carefully selected as opportunities at some point in the past. Astellas aims to drive further evolution by having all employees remain mindful of the three-step process of Focus our resources on identified areas, Redefine the focus when appropriate, and Expand the focus for the next generation of activity, as they carry out their activities.

## Drivers

One of the drivers for Astellas to achieve sustainable growth is its core capabilities, which constitute the source of its competitive edge. It is vital to carefully identify our essential capabilities and enhance them until they are among the world's best. At the same time, when there are outstanding capabilities outside the Company, we will proactively form partnerships. By combining optimal capabilities, both internal and external, we enhance our productivity and creativity to maximize our value creation capabilities. Moreover, in the Astellas Way\*, we have defined a shared set of values and actions to be embraced by all our employees as part of efforts to foster a corporate culture to help realize our Business Philosophy. At the same time, we remain committed to understanding the requests and expectations of a multitude of stakeholders, including patients, and transforming that understanding into value.


\* For details on the Astellas Way, Five Messages for One Astellas—Patient Focus, Ownership, Results, Openness, and Integrity—please refer to p. 63.

### Astellas' Currently Identified Core Capabilities





## CEO Message

A portrait of Yoshihiko Hatanaka, the CEO of Astellas Pharma Inc. He is a middle-aged man with short, graying hair, wearing glasses, a dark suit, a light blue shirt, and a dark tie. He is standing with his hands clasped in front of him, leaning on a dark surface. The background is a blurred cityscape with blue and white tones.

On the Forefront of Healthcare  
Change to Turn Innovative  
Science into Value for Patients

**Yoshihiko Hatanaka**

Representative Director,  
President and CEO

## Performance and Short- and Medium-Term Outlook

### Remarkable First Year of the Strategic Plan with Strong Growth from Oncology and Urology OAB Franchises

In fiscal 2015, we achieved solid results and made significant progress on implementing the three strategic priorities contained in Strategic Plan 2015–2017, “**Maximizing the Product Value,**” “**Creating Innovation,**” and “**Pursuing Operational Excellence.**”

The initiatives of “**Maximizing the Product Value**” remained ontrack. We posted further growth in sales from the franchises of oncology and overactive bladder (OAB), which are key growth drivers for Astellas. On a core basis, we reported higher consolidated sales and earnings in year-on-year terms. Sales increased 10% to ¥1,372.7 billion, and operating profit rose 24% to ¥267.5 billion. Our investments to date are reaping returns.

We expect some degree of impact on our performance in 2018–2020 due to the expiries of patents for the OAB treatment Vesicare and the anticancer product Tarceva. However, we are confident that our core products in both franchises will bolster our growth throughout this period, including the prostate cancer treatment XTANDI and the OAB treatment Betanis/Myrbetriq/BETMIGA.

### Overcome the “Patent Cliff” by Advancing Late-Stage Development

For “**Creating Innovation,**” we are actively enhancing our capabilities to deliver innovative medicines. We achieved steady progress including marketing approvals for new products in fiscal 2015. We also have a number of projects with strong potential in late-stage clinical development, including gilteritinib and ASP8273 in the oncology field, and roxadustat for anemia associated with chronic kidney disease. We are looking forward to further progression of these development activities. The innovative drug business always has the risk of a so-called “patent cliff” in connection with the expiry of patents for core products. The best way to mitigate this risk is to steadily advance the late-stage projects in line with our development schedule.

### Targeting ROE of 15% or More by Maximizing Profits and Enhancing Capital Efficiency

Astellas positions return on equity (ROE) as an important management indicator. We are working to maintain and boost ROE by maximizing profits while enhancing capital efficiency. Our ROE reached 15.0% in fiscal 2015. We will continue to return profits to shareholders by increasing dividends in a stable and sustained manner, based on the medium- to long-term profit outlook. We will also flexibly implement share buybacks as needed based on an overall consideration of business environment, investment plans, and the level of cash-on-hand, among other factors, with a view to further enhancing capital efficiency and the level of return to shareholders.

#### Reference

Strategic Plan  
2015-2017

▶ P20

Financial Strategy

▶ P24

Business Review

▶ P30

## Initiatives to Drive Medium- to Long-Term Growth

### Anticipating Changes and Moving Toward Long-Term Growth

We have also made significant progress with various initiatives to realize long-term growth.

It is critical to pursue the challenges inherent in new therapeutic areas, technologies and modalities in terms of **“Creating Innovation.”** In February 2016, we successfully acquired Ocata Therapeutics, Inc., which was engaged in R&D in cell therapies for ophthalmic diseases. Ocata’s activities were a good strategic fit for Astellas from the perspective of a newly selected focus area and new technology we are exploring. We will continue to positively consider potential acquisitions, alliances and in-licensing opportunities. As part of focusing our investments on functional sources of competitive advantage, we transferred our global dermatology business to LEO Pharma A/S. This is a good example of the optimal allocation of business resources in **“Pursuing Operational Excellence.”** Through these kinds of activities, we aim to create an organization and system that can respond resiliently to changes in the business environment.

### Creating Innovation by Taking Ownership and Respecting Diversity

Our vision and strategies provide a common language uniting Astellas, which has a diverse workforce in terms of values and perspectives. My belief is that the driving force behind creating innovation will come from encouraging every individual employee to take ownership and move ahead step-by-step by translating the vision and strategic goals into daily work activities.

Over the past three years, we have established more than 20 joint research programs with external institutions and biotechnology companies. As part of this process, we have steadily entrenched the approach of actively incorporating the distinctive characteristics and R&D methodologies of our partners. The cycle of respecting and embracing diversity and converting our partners’ advantages into our own strengths is an essential element in building the platform for the sustained growth of Astellas.

Our business conditions are in constant flux. As shown in prominent recent advances in the Internet of Things (IoT) and the field of artificial intelligence, the advances of various scientific areas driven by their interaction and fusion are creating new business opportunities for Astellas. Meanwhile, as the public cost of healthcare continues to increase, the question of how to balance patient access to medicines and innovation requires our proactive initiative. Under such conditions, we cannot create any competitive advantage if we are reactive to change. Moving ahead faster than change and never being satisfied with the status quo are part of the DNA of Astellas. While making the most of our strengths in transplantation and urology, we will always seek and strive to take advantage of good opportunities in other fields, and we are steadily gaining the ability to act on those opportunities. We see our future success in terms of facing the ongoing challenge of utilizing cutting-edge science to create innovative drugs and therapies.

#### Reference

Feature: Our Initiatives to Create Innovation

▶ P33

Employees

▶ P63



## Aiming to Enhance Sustainability

### Social Responsiveness and Self-Driven Evolution as the Keys to Sustained Growth

Our commitment to attaining self-driven evolution by accepting change and diversity has also helped us to lay a stronger foundation for management.

At Astellas, we have adopted an advanced system towards corporate governance. Since June 2015, outside members have occupied a majority of the positions on the Audit & Supervisory Board, in addition to the Board of Directors. We saw the adoption of Japan's Corporate Governance Code as a good opportunity to take steps in earnest to improve the transparency, appropriateness and agility of management, such as further reinforcement of the effectiveness of the Board of Directors.

In April 2016, we also took steps to upgrade our compliance capabilities by newly creating a global compliance function to manage all of the regional functions as well as making the function independent within our organization. In June 2016, we replaced our former compliance standards, which existed in each region, to create the Astellas Group Code of Conduct as the globally integrated basis for compliance. These measures will ensure we are a global player in terms of compliance quality, and emphasize to employees the importance of responding sincerely to the needs of society.

One of the ways in which we are playing an active role in responding to social needs is through various Access to Health (ATH) initiatives. Astellas will use its capabilities and enhance its efforts to make a contribution in each of the following four areas: "creating innovation," "enhancing availability," "strengthening healthcare systems," and "improving health literacy." We are a consistent supporter of the United Nations Global Compact, and have incorporated its 10 principles covering the four fields of human rights, labor, the environment and anti-corruption into our daily business activities.

## To Our Stakeholders

### Turning Innovative Science into Value for Patients Based on Dialogue

Our mission is to turn advances in science into value for patients. Communication with our stakeholders is a vital part of realizing that mission at a high level. We are committed to ensuring that Astellas provides a consistent message and full disclosure regarding our current activities and future direction, including our challenges. Healthy and transparent dialogue with our stakeholders leads to continual business evolution and the creation of new value. We ask for your continued support in realizing the growth of Astellas.



Yoshihiko Hatanaka  
Representative Director,  
President and CEO

#### Reference

CSR-Based  
Management

▶ P18

Society

▶ P67

Ethics & Compliance

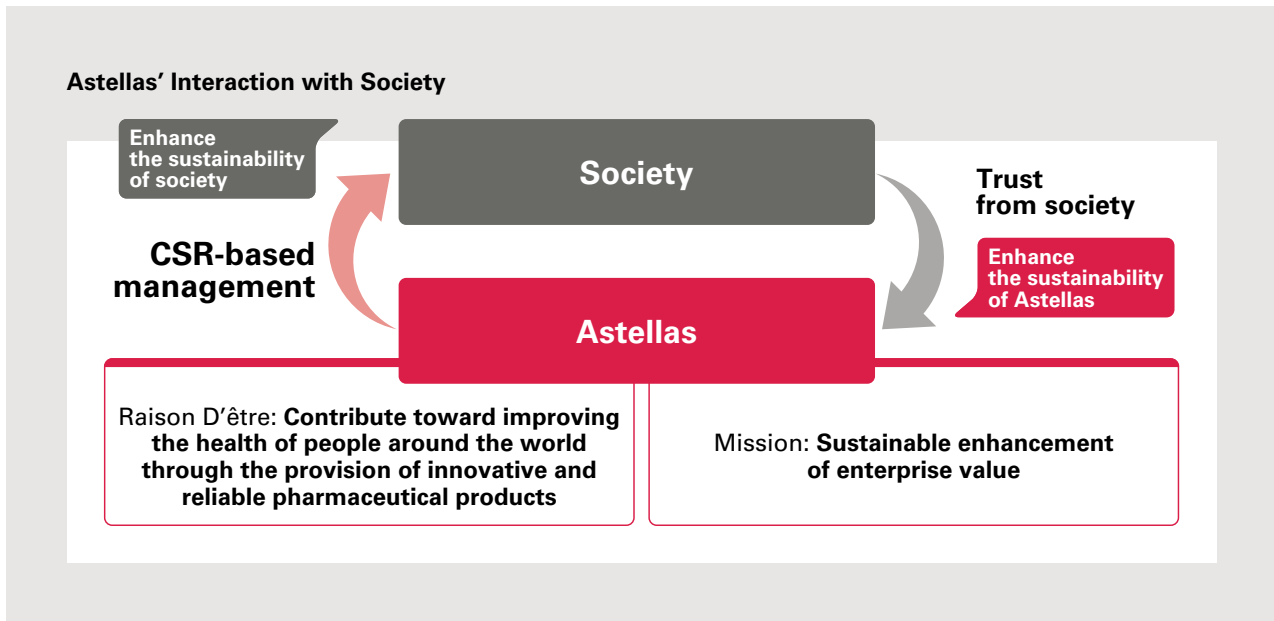
▶ P75

Corporate Governance

▶ P80

# CSR-Based Management

Create and protect value for both Astellas and society by fulfilling social responsibility



## Fulfilling Our Social Responsibility Means Realizing Our Business Philosophy

Astellas recognizes its Corporate Social Responsibility (CSR) is its responsibility for any impacts that its decisions and business activities have on society and the environment.

Astellas is helping to enhance the sustainability of society by fulfilling its social responsibilities as a pharmaceutical company by, for example, providing pharmaceutical products that satisfy unmet medical needs. We believe that we earn trust from society for both the Company and our products as a result of these activities, and that this trust enhances our sustainability. This positive cycle will lead to the realization of our mission, “sustainable enhancement of enterprise value” through fulfillment of our raison d’être “contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.” For Astellas, fulfilling our social responsibility means realizing our business philosophy.

## Value Creation and Protection for Both Astellas and Society

CSR for Astellas has two aspects: value creation and value protection.

### Value Creation

Through its business activities, Astellas is creating value for society by addressing social issues such as unmet medical needs, and by returning profits to stakeholders. By reinvesting the profit we gain through business activities, we strengthen our capabilities in research and development. In addition, by winning trust from government and business partners in each country, we create new business opportunities. This process creates value for Astellas.

### Value Protection

Astellas seeks to preserve biodiversity by reducing the environmental burden associated with its business activities, while maintaining social order by ensuring compliance, and preventing corruption. These activities will lead to the protection of value for society. In addition, Astellas protects its enterprise value by mitigating reputation risk and elevating Astellas’ corporate brand through these activities.

## Topics

### Astellas' Initiatives to Contribute to the United Nations' Sustainable Development Goals (SDGs)



Through business activities and measures to fulfill its corporate social responsibilities, Astellas aims to contribute to the United Nations' Sustainable Development Goals (SDGs), which were established through a collaborative effort by the international community.

#### Focus on Improving Access to Health in Four Areas

In regard to “Goal 3: Good Health and Well-Being” under the SDGs, Astellas has identified four areas where it is working to address Access to Health issues. The four areas are (1) Creating innovation, (2) Enhancing availability, (3) Strengthening healthcare systems, and (4) Improving health literacy.

One of our priorities for creating innovation is drug discovery research for the treatment of neglected tropical diseases (NTDs). In April 2016, Astellas signed a new collaborative research agreement with the National Institute of Advanced Industrial Science and Technology (AIST) to discover new drugs for the treatment of Chagas disease. This agreement is based on knowledge

obtained through collaborative research undertaken with AIST and other partners. Moreover, in June 2016, Astellas signed a new collaborative development agreement with the Institute of Medical Science, the University of Tokyo, on the rice-based oral vaccine “MucoRice-CTB” against cholera and enterotoxigenic *Escheria coli* (*E coli*) caused diarrheal diseases. Furthermore, Astellas is working closely with partners to develop a pediatric formulation of praziquantel tablets for the treatment of schistosomiasis.

Reference | Access to Health ► P67

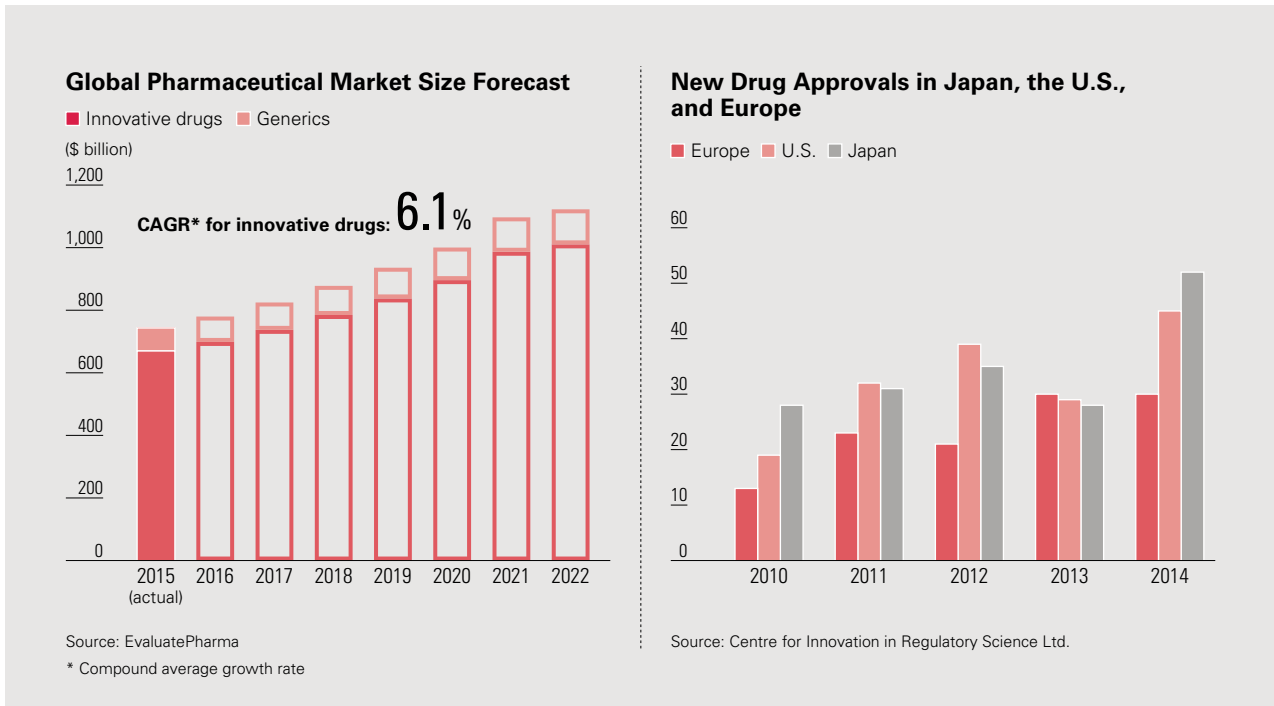
#### Advancing Various Initiatives to Reduce Environmental Impact

Astellas is advancing initiatives such as reducing greenhouse gas emissions, promoting resource recycling and improving the Biodiversity Index. Through these and other initiatives, Astellas will contribute to achieving SDGs such as “Goal 6: Clean Water and Sanitation,” “Goal 13: Climate Action,” and “Goal 15: Life on Land.”

Reference | Environment ► P71

# Business Environment

Market expansion driven by aging populations and economic development



## Trends in the Prescription Drug Market

There remain many diseases with high unmet medical needs for which patients are looking for new drugs to deliver value. In step with continuing scientific and technological advances, governments are putting frameworks in place for recognizing innovation and have created regulatory systems that can accelerate review of innovative drugs. Moreover, the global market for prescription drugs is expected to continue expanding against the backdrop of aging populations and economic development.

## Growth Challenges and Opportunities

While the market expands, there are also issues that must be overcome to achieve sustained growth. Measures to restrain the rapid growth in healthcare spending are accelerating in the form of reimbursement price cuts and the promotion of generic drugs. With insurance payers becoming increasingly more involved in the decision-making

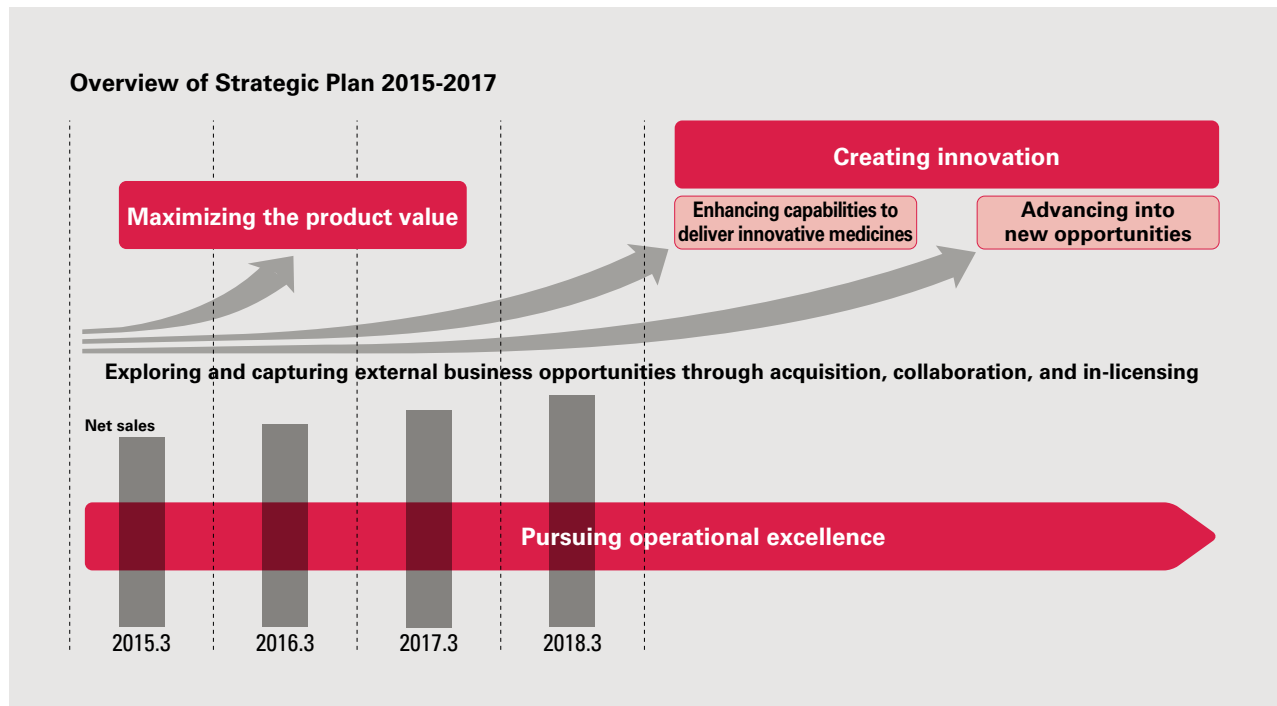
process, the requirements for a new drug to gain regulatory approval and secure price reimbursement at a reasonable level are also becoming more complex and more strict. Thus, it is more essential than ever to prove a new drug's added value over existing drugs and therapies during development.

In this environment, there are higher expectations for the development of innovative medicines and better general therapeutic solutions that can raise the quality of medical care from the patient's standpoint. In recent years, the development and application of new treatment modalities and drug discovery technologies, including cell and gene therapies, have been advancing, and these advances are expected to be applied to healthcare in a variety of fields.

This evolving healthcare environment also presents opportunities for Astellas to grow. Astellas will continue to deliver new value to patients by creating innovation through the execution of sound investments from a long-term perspective.

# Strategic Plan 2015-2017

Focusing on three strategic priorities for realizing sustainable growth over the medium and long terms



## Overview of the Strategic Plan

Under Strategic Plan 2015-2017, covering the three-year period from fiscal 2015 to fiscal 2017, we will work to overcome the impact of the substance patent expiries for our overactive bladder (OAB) treatment Vesicare and our anticancer product Tarceva in the period of 2018 to 2020, and focus on realizing further sustainable growth through three main strategic priorities.

### Maximizing the Product Value

First, we will steadily nurture and maximize the value of our growth drivers, including XTANDI and Betanis/Myrbetriq/BETMIGA, created through our investments so far.

### Creating Innovation

We will continue to make sufficient investments for creating innovation. Here, we will establish frameworks for continuously creating more innovative medicines and promote efficient research and development. Concurrently, we will also make sufficient investments in new

opportunities in the perspectives of new therapeutic areas, new technologies, and new modalities.

### Pursuing Operational Excellence

We will pursue operational excellence by creating a more efficient, higher-quality business operation infrastructure, in order to enhance our ability to address the changing environment.

Moreover, we will continue to actively explore and capture external business opportunities through acquisition, collaboration, and in-licensing.

## Financial Guidance

Astellas has recognized return on equity attributable to owners of the parent (ROE) as an important management indicator. Under Strategic Plan 2015-2017, we aim to achieve ROE of 15% or more by seeking to maximize our earnings capabilities while ensuring that we enhance capital efficiency. We also aim to maintain and improve

this level after the strategic plan period.

We aim to achieve growth in sales by maximizing the product value, while promoting measures to optimize cost of sales and SG&A expenses. In so doing, we seek to maximize operating profit prior to deduction of R&D expenses. Moreover, we plan to direct sufficient resources to investment in R&D, while also working to improve our operating margin.

CAGR in the mid-single-digit range is forecasted for sales during the strategic plan. R&D expenses will be maintained at the level of 17% or more of sales, and sufficient resources will be directed at new opportunities, in addition to existing therapeutic areas. For core operating profit, we are targeting a CAGR that exceeds sales CAGR. For core earnings per share (EPS), we are forecasting a CAGR that exceeds core operating profit CAGR.

In this way, we will work to enhance ROE by prioritizing the maximization of our earnings capabilities, while also pursuing balance sheet management and shareholder returns to enhance capital efficiency.

### Financial Guidance in Strategic Plan 2015-2017

<b>ROE</b>	<b>15% or more</b> Maintain and improve this level after the strategic plan period
Consolidated Sales	CAGR (%): Mid-single-digit
Core Operating Profit	CAGR that exceeds sales CAGR
R&D Expenses	Higher than 17% against sales
Core EPS	CAGR that exceeds core operating profit CAGR
DOE*	6% or more

\* Dividend on equity attributable to owners of the parent

### Maximizing the Product Value

#### Targeting Medium- to Long-Term Growth by Expanding New Product Group Sales

To ensure sustainable growth during and after the current strategic plan, Astellas will maximize the value of the products that have been realized through its investments to date.

In particular, Astellas will prioritize the investment of resources in its new product group centered on XTANDI and the OAB franchise. In this way, we forecast that the compositional ratio of key new products will expand during the strategic plan, whereas the relative composition ratio will decrease for key products for which patents will expire by 2020. Nurturing the new product group early is an important measure to overcome the impacts from patent expiry.

#### Nurturing the New Product Group in Various Therapeutic Areas

Astellas is working to expand sales of the new product group in its therapeutic areas including the oncology and OAB franchises.

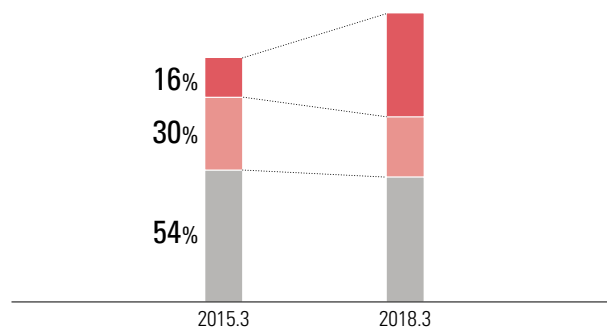
#### Oncology Franchise

Our efforts are focused on maximizing the value of XTANDI, our growth driver. We will work to expand the geographical sales area of XTANDI, while also working for label expansion to chemotherapy-naïve prostate cancer and early penetration in each country. Moreover, we will steadily advance clinical trials with the aim of expanding indications for earlier stages of prostate cancer, and other forms of

### Composition of Global Sales by Product

(For illustrative purposes only)

- Key new products\*
- Key products with patents expiring by 2020
- Others



\* Betanis/Myrbetriq/BETMIGA, XTANDI, Cimzia, Suglat, and CRESEMBA

cancer such as breast cancer and hepatocellular carcinoma. During the strategic plan, we expect sales of our oncology franchise to expand with a CAGR in the mid-twenties, driven by XTANDI.

**OAB Franchise**

To overcome the anticipated impact from the patent expiry of Vesicare and continue to increase the value of our franchise, we will work intensively to drive market penetration of Betanis/Myrbetriq/BETMIGA as a new option for OAB treatment. We expect to achieve CAGR for sales in the high single digits for the OAB franchise during the strategic plan. In the final year of the plan, sales of Betanis/Myrbetriq/BETMIGA are expected to have increased to account for approximately half of the overall sales of the OAB franchise.

**Other Areas**

The transplantation franchise has established a strong presence with the immunosuppressant Prograf. We expect growth in Prograf in emerging countries, despite decline in the Americas, EMEA, and Japan, where the substance patent has expired. The average annual decline in sales during the strategic plan is expected to be limited to the low single digits.

In resource allocation, we will prioritize new products in each region, aiming to achieve sales expansion at an early stage. In Japan, we will work to steadily achieve market penetration of new products including Suglat for type 2 diabetes, and Repatha for hypercholesterolemia, which was launched in April 2016.

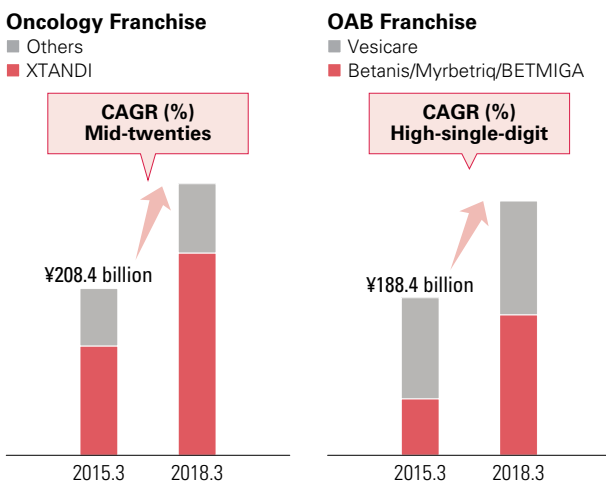
**Creating Innovation**

**Enhancing Capabilities to Deliver Innovative Medicines through Optimal Resource Allocation and Acquisition of Cutting-Edge Science**

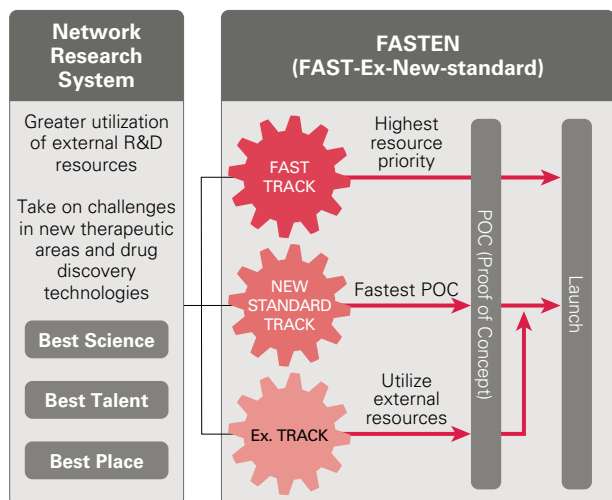
Astellas aims to continuously generate innovation through optimal resource allocation and the acquisition of cutting-edge science. Astellas is promoting open innovation by building a Network Research System. This system appoints optimal personnel and researchers from both inside and outside the Company to undertake dynamic research activities in the best possible environment, and based on the world’s most innovative science. By introducing a process named FASTEN to manage R&D projects along one of three different tracks, Astellas has achieved positive outcomes such as shortening of R&D duration and increased cost efficiency.

In addition to the fields we have focused on to date, namely urology, oncology, immunology, nephrology, and neuroscience, we have selected muscle diseases and ophthalmology as new focused disease areas for research where we will concentrate our resources. There is a high level of unmet medical needs in these therapeutic areas, and we aim to deliver new medicines while seeking alliance opportunities with external partners.

**Changes in the Compositional Ratio of Products in Sales** (For illustrative purposes only)



**Enhancing Capabilities to Deliver Innovative Medicines**





## Pursuing New Opportunities

Astellas will make sufficient investments in opportunities that pave the way for long-term growth, including new therapeutic areas and the use of new technologies and modalities, and medical solutions that leverage our strengths, centered on the innovative drug business.

### New Therapeutic Areas

Selecting muscle diseases and ophthalmology as focused disease areas for research, Astellas is undertaking groundbreaking research through partnerships with external entities. In the muscle disease area, we are targeting ways to control the progression of disease or achieve causal therapies. In the ophthalmology area, we are targeting disorders of the posterior eye segment for which no standard drug treatments are available.

### New Technologies and New Modalities

In addition to working to develop next-generation vaccines, we have commenced cell therapy research in earnest. As part of these efforts, in February 2016, Astellas acquired Ocata Therapeutics, Inc., which is primarily engaged in research and development focused on cell therapy in the ophthalmology field. In May 2016, this company's name was changed to the Astellas Institute for Regenerative Medicine. Astellas has positioned the new company as its hub for research and development in cell therapy and the ophthalmology field, underscoring its commitment to investing resources in this area.

## Pursuing Operational Excellence

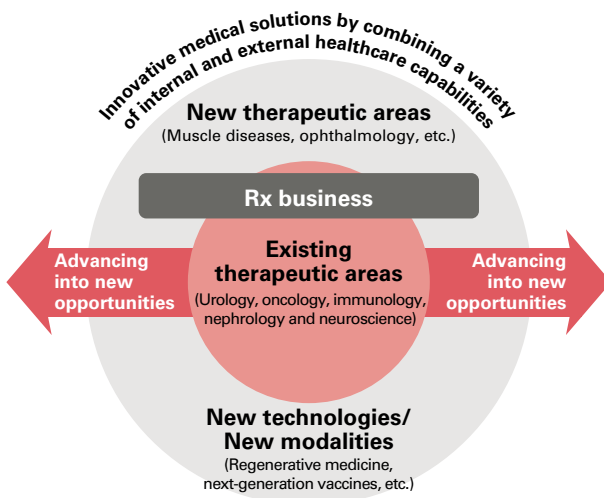
### Raising the Quality of Operations in Anticipation of Change

Astellas strives to improve the quality and efficiency of operations by keeping a close eye on changes in the business environment from a number of perspectives, and implementing measures in anticipation of these changes.

Astellas will optimize the allocation of management resources in conjunction with making effective use of external resources. We are constantly reviewing our organization and functions to optimize our business processes, cost structures and other aspects. From the perspective of compliance, we will actively address laws, regulations and social norms while working to further increase the reliability of our products.

Looking at recent initiatives, Astellas transferred its global dermatology business to LEO Pharma A/S, and transferred the business of the Kiyosu Plant in Japan to MicroBiopharm Japan Co., Ltd. Astellas will reinvest the funds generated by the transfer of these businesses into functions that will hone its competitive edge, thereby further enhancing its capabilities to create innovative medicines. Moreover, in order to strengthen compliance on a global basis, Astellas set up a global compliance function in April 2016, putting a structure in place to manage compliance functions in Japan, the Americas, EMEA and Asia & Oceania. Additionally, in July 2015, Astellas created a function designed to maximize big data utilization in the Company.

## Advancing into New Opportunities



## Our Approach to Operational Excellence





# Financial Strategy

Focusing on increasing enterprise value continuously, thereby improving shareholder returns

## Profit Distribution Policy

**Prioritize business investment to assure future growth**

**Increase enterprise value**

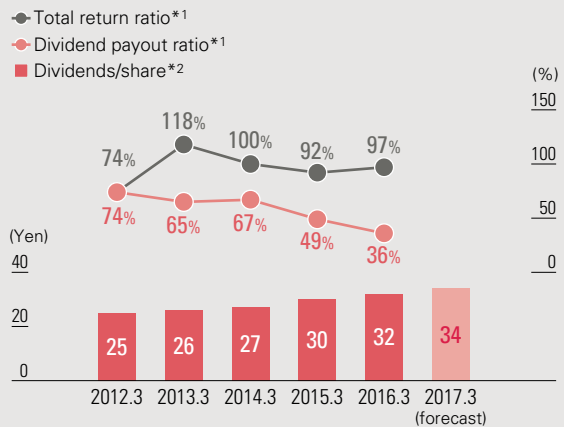
**Enhance capital efficiency**

**Continuously improve shareholder returns**

**Dividends to be increased stably and continuously based on medium- and long-term growth**

**Share buybacks to be implemented in a flexible manner**

## Initiatives for Shareholder Returns



\*1 Figures for fiscal 2011 are in accordance with J-GAAP and from fiscal 2012 are in accordance with International Financial Reporting Standards (IFRS).

\*2 The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014. Figures are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of fiscal 2011.

### Put Highest Priority on Allocating Funds to Business Investments for Future Growth

Astellas will put the highest priority on allocating funds to business investments for future growth in order to achieve a sustainable increase in enterprise value. In particular, we will allocate the funds necessary to create innovation. We will continue actively pursuing alliances or M&A opportunities relating to acquiring promising new drug candidates or cutting-edge technologies that are a good fit for our business strategy.

Looking at cash-on-hand, in line with the characteristics of the pharmaceutical business, we will maintain a certain level of cash-on-hand, in addition to the working capital needed to fund day-to-day operations, in order to respond flexibly to the need to make strategic investments for future growth. Moreover, we will endeavor to maintain a healthy balance sheet at all times so that we can finance smoothly at low costs, even if funding requirements exceed Astellas' internal funding capacity.

### Targeting Stable and Continuous Increases in the Level of Dividends

Astellas will target a stable and continuous increase in dividends based on the medium- to long-term growth prospects for consolidated earnings by taking into account DOE. During Strategic Plan 2015-2017, we are targeting DOE of 6% or more.

### Flexible Share Buybacks

We will implement share buybacks flexibly as needed based on an overall consideration of the business environment, investment plans, and the level of cash-on-hand, among other factors, with a view to further enhancing capital efficiency and the level of returns to shareholders.

Furthermore, our policy is to cancel acquired treasury stock, in principle, to ensure the overall balance does not exceed our target level of 1-2% of outstanding shares.

# Management Structure

## Executive Committee (as of August 2016)

The Executive Committee discusses important matters of management across Astellas. It is chaired by the Representative Director, President and CEO, and comprises top management as standing members. Extended members include the officers responsible for research, development and technological capabilities together with the officers responsible for each region, and these members participate in any necessary discussions at the request of the chairman.

### Standing Members



**Yasumasa Masuda**  
Chief Financial Officer

**Yoshiro Miyokawa**  
Representative Director and Executive Vice President, Chief Administrative Officer & Chief Compliance Officer

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

**Kenji Yasukawa, Ph.D.**  
Chief Strategy Officer

**Sef Kurstjens, M.D., Ph.D.**  
Chief Medical Officer

### Extended Members



**Nobuaki Tanaka**  
President, Japan Sales & Marketing



**Masatoshi Kuroda**  
President, Asia & Oceania Business



**James Robinson**  
President, Americas Operations



**Yukio Matsui**  
President, EMEA Operations



**Wataru Uchida, Ph.D.**  
President, Drug Discovery Research



**Mitsunori Matsuda**  
President, Technology



**Bernie Zeiher, M.D.**  
President, Development

### Global Heads

**Martin Golden**  
Head of Marketing Strategy

**Charlotte Kremer, M.D.**  
Head of Medical Affairs

**Songlin Xue, M.D., Ph.D.**  
Head of Pharmacovigilance

**Bill Fitzsimmons, Pharm.D.**  
Head of Regulatory Affairs and Clinical and Research Quality Assurance

**Kunihiko Kokubo**  
Head of Quality Assurance

## Directors and Audit & Supervisory Board Members (as of August 2016)



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

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

**3** **Yutaka Kase**  
Outside Director

**4** **Hironobu Yasuda**  
Outside Director

**5** **Etsuko Okajima**  
Outside Director

**6** **Yoshiharu Aizawa,  
M.D., Ph.D.**  
Outside Director

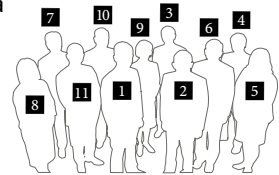
**7** **Tomokazu  
Fujisawa**  
Audit & Supervisory  
Board Member

**8** **Hiroko Sakai**  
Audit & Supervisory  
Board Member

**9** **Toshiko Oka**  
Outside Audit &  
Supervisory Board  
Member

**10** **Hitoshi Kanamori**  
Outside Audit &  
Supervisory Board  
Member

**11** **Noriyuki Uematsu**  
Outside Audit &  
Supervisory Board  
Member



## Interview with an Outside Director



I will contribute to improving the effectiveness of the Board of Directors in regards to the corporate governance of Astellas, which continues to evolve.

Yutaka Kase  
Outside Director

Joined Nissho Iwai Corporation (currently Sojitz Corporation) in 1970, and became Chairman and Representative Director in 2012 (present post). As of August 2016, he concurrently serves as an outside Director of Astellas, JAC Recruitment Co., Ltd., and SEKISUI CHEMICAL CO., LTD.

### Q1 In what ways do you think Astellas has good corporate governance?

**Astellas is ahead of competitors in continually working to evolve its governance, in my view.**

Astellas has been one of the pioneers of excellent corporate governance, since well before Japan's Corporate Governance Code was introduced. The Company has actively accelerated efforts to make corporate governance stronger in various ways since I was appointed an outside Director.

Outside Directors have been in the majority on the Board of Directors since 2006, and this happened on the Audit & Supervisory Board as well in 2015. It is not just about numbers—the outside Directors also have a varied range of background. As corporate managers, lawyers and medical doctors from a range of specialties, we provide management oversight from an independent standpoint and are involved in making important business decisions. The lawyer can give compliance insight, the medical doctor can speak from a scientific perspective, and the business

consultant woman can raise challenges regarding talent development to better inform the decisions made by the Board of Directors.

Another valuable aspect of governance is that we have access to information-sharing programs that help deepen our understanding of Astellas' operations and the pharmaceutical industry.

As shown by the way that it responded to Japan's Corporate Governance Code, Astellas is quick to seek outside opinions and advice and respond appropriately. The ability to anticipate important shifts and innovate is a major characteristic of Astellas, in my opinion.

For instance, Astellas has been quick to develop ways of evaluating Board effectiveness. While we evaluated that the Board as a whole is functioning very effectively, we have discussed how to make more progress in the future based on the results of the evaluations.

Furthermore, the Astellas guidelines on corporate governance also stipulate the need for planning for the CEO succession. The Nomination Committee that I chair can carry out the responsibility by making transparent discussions for the selection of the Company's next executive leader.

## Q2 What opportunities have you had to gain a better understanding of Astellas' operations?

**I am gaining a deeper understanding through various information-sharing programs, including visits to operating sites.**

Activities of Astellas are evolving year after year to draw on the abilities of the outside officers and make discussions by the Board of Directors more dynamic.

Astellas plans and organizes a program of events throughout the year to help the outside officers gain a greater, in-depth understanding of the Company's operations and the pharmaceutical industry. We are briefed on major developments prior to each meeting of the Board of Directors. Astellas also invites representatives of public-sector institutions or experts from the capital markets to make presentations to us on various industry-related issues. Twice a year we have off-site visits to Group R&D laboratories, factories or offices, where a Board meeting is held and we also receive presentations from executives and employees. These are valuable opportunities for us to get to know Astellas better.

In fiscal 2015, we also set up the Advisory Council, comprising the seven outside officers of Astellas. This body further supports communication between members and discussions with the Accounting Auditors and with the Audit & Supervisory Board Members so that we can improve our understanding of Astellas further.

My view is that, as outside officers, we need to study the new therapeutic areas and new technologies and modalities that Astellas is targeting. I expect there will be more opportunities in the future for M&As and alliances as the Company seeks good ways to manage time and risk. I think Astellas is already good at sharing information with outside officers, but I am hoping that we will be afforded more opportunities to learn about the new areas going forward.

## Q3 What kind of discussions take place at meetings of the Board of Directors?

**Our responsibility is to ask questions and to foster active debate on all Board resolutions.**

Regardless of whether they are outside or not, Directors are charged with clarifying their position towards resolutions

on solid grounds based on a good understanding of the related issues. To attend the Board, I work to understand resolutions as much as possible. My view is that outside Directors should take the responsibility to propose postponement of resolutions, request further discussions, or in some cases vote against them if they deem it necessary. I see that as the best route to ensuring transparent, sound management of Astellas. We have had some resolutions tabled at Board meetings where one or more outside Directors indicated they felt there had not been sufficient information for debate, and for these proposals we ensured that further discussions were held.

However, the fact that we, outside Directors, have had a majority on the Astellas Board of Directors for over 10 years means that any resolution tabled has to gain the understanding and support of the outside Directors. I believe this encourages sufficient preparation on the part of those tabling the proposal because they know that it will require a thorough explanation.

We examine each tabled Board resolution from the standpoints of impact on business performance; compliance, environmental and other risks; and the actual decision-making process itself. As part of ensuring the transparency and fairness of the decisions made by executive officers, I draw a mental line between myself and the executive who is making the proposal, and I ask questions if I am not convinced. Board meetings are very dynamic because all the other outside Directors will voice their opinions as well. I think questions from the outside officers tend to be the sorts that only outside stakeholders can raise. It is not just the outside officers who do this: the internal Audit & Supervisory Board Members also ask excellent questions based on an essential core understanding.

The multitude of questions and opinions at every Board meeting has resulted in close examination of M&A proposals in recent years, covering issues ranging from the valuation of the target business to the decision-making process and the potential for personnel leaving. We have adopted quite a strict stance on compliance issues, with demands for additional reporting. Mr. Hatanaka, the President and CEO, expects the outside Directors and the outside Audit & Supervisory Board Members to foster active debate of the proposals by asking questions from many and varied perspectives. The executives take our questions seriously and respond accordingly.

In serving as Chairman of the Board at Sojitz, I am always trying to foster active debate at Board meetings by eliciting the views of all the outside Directors and auditors, and by ensuring questions generate a considered response from the presenter or a Director. In this way, I work to ensure Board resolutions are properly debated. Based on this experience, I believe that Board meetings at Astellas achieve a high degree of openness and transparency.



### Q4 What are your views on compliance as an outside Director?

**Awareness and education are essential parts of promoting better compliance on an ongoing basis.**

Astellas supplies products that relate to lives. In terms of compliance, we must not only observe laws and regulations, but also promote an internal culture that goes beyond regulatory compliance. We adopt a fairly strict stance on compliance issues. We must build systems that stop compliance breaches from occurring because the reputation of the Company is on the line in these cases.

With social attitudes tending to become stricter on compliance matters worldwide, our relationships with the medical community are always changing. Our sales, development and research organizations need to be aware of these shifts in each organization, and we must keep training our people and raising awareness.

We need to reinforce governance and compliance at overseas Group subsidiaries. In particular, it is vital we inculcate the importance of compliance in our operations within emerging countries. This is a question of employing people with integrity and placing a premium on good management.

I think it is part of the role of outside officers to emphasize the importance of compliance on a continuous basis. At the moment, I feel there is a need for outside officers to have an opportunity to visit overseas Group subsidiaries because our level of knowledge is not high enough to gauge fully the status of these operations. Astellas has actually responded to this desire already, and in 2016 we plan to hold our first ever Board meeting outside Japan, in Republic of Korea.

Astellas is making steady progress in terms of its financial results at the moment. That is why it is important we continue to treat compliance and manage risks properly so that we do not inadvertently pull the rug out from under our feet.

### Q5 What issues do you think confront Astellas in today's globalized business environment?

**I see the issues as balancing speed with ethics, responding to international changes, and targeting the growth potential in developing countries.**

Navigating the so-called “patent cliff” caused by the expiry of substance patents is a key issue for the management team. I recognize three major issues, however, from my standpoint as an outside Director.

Besides the domains that have driven the growth of Astellas to date, the challenge is to develop a presence in new therapeutic areas, including ophthalmology, and also in new technologies and modalities such as next-generation vaccines and cell therapy. The rapid innovation in medicine and IT will lead to fierce competition with other companies. Under such conditions, I believe Astellas will need to do more than ever to speed up the pace of innovation. On the other hand, new modalities such as cell and gene therapies throw up a range of ethical issues that demand caution in the processes followed by Astellas in developing these areas. So I regard the first issue as one of balancing the need for speed with the demands of ethical business management as Astellas takes up the challenge of developing these new therapeutic areas and technologies.

The second issue is about responding to global changes. The recent vote by the U.K. to leave the EU illustrates how rapidly the situation is changing these days, and shows how these problems are multifaceted. Astellas needs to anticipate such shifts and respond accordingly.

I see the third issue as how to expand the business in growing overseas markets. The current innovative drug business of Astellas is heavily oriented towards advanced countries, where we still derive the bulk of our earnings. Yet the emerging countries of China, India, Southeast Asia and Africa make up a majority of the global population. By the end of the century, the global population is expected to grow from seven billion to over ten billion, of whom 80% will be living in Asia and Africa. With these two regions in the process of becoming huge, concentrated markets, succeeding there will undoubtedly help us to secure a stronger future for Astellas.

Establishing a presence in emerging markets will spawn a variety of issues such as the development of compliance structures. Along with the shifting international situation, I believe this will place a premium on human resource development, with a particular emphasis on flexibility and resilience. I see that as one of the key driving forces for the future growth of Astellas.

# 3

## Performance | Business Review

# Steady Advances in R&D and Global Business

In R&D, Astellas has delivered numerous accomplishments in terms of steadily advancing late-stage clinical development projects, along with forming partnerships to acquire innovation. Moreover, business has expanded steadily in all the regions of Japan, the Americas, EMEA and Asia & Oceania, driven by XTANDI and overactive bladder (OAB) products.



# Research

## Pursuing Cutting-Edge Science through a Network Research System

Astellas has a Network Research System with the slogan of “Best Science, Best Talent and Best Place.” Under this system, Astellas is pushing ahead with initiatives in new therapeutic areas and drug discovery platform technologies. To incorporate advances in science into drug discovery research in a timely manner, Astellas’ researchers have firmly embraced an awareness of the importance of conducting groundbreaking research in conjunction with proactively leveraging external innovation. Our researchers have continued to tackle the challenge of discovering innovative medicines by constantly remaining closely attuned to the latest trends and flexibly adapting to these changes.

In fiscal 2015, Astellas acquired Ocata Therapeutics, Inc. (Ocata), which possesses world-class R&D capabilities in cell therapy. Taking full advantage of Ocata’s most advanced technologies, Astellas will accelerate research aimed at building a pipeline focused on ophthalmology as early as possible. Furthermore, Astellas aims to establish a leading position in cell therapy by vigorously pursuing joint research with several academic institutions.

Moreover, Astellas formed several alliances in fields including immuno-oncology therapeutics and next-generation vaccines for allergic diseases.

One of Astellas’ current strengths is that it is able to conduct cutting-edge research while choosing the optimal option from various research approaches, including small molecular compounds, antibodies, proteins, genetics and cells, under its Network Research System.

## A Range of Initiatives to Create Innovation

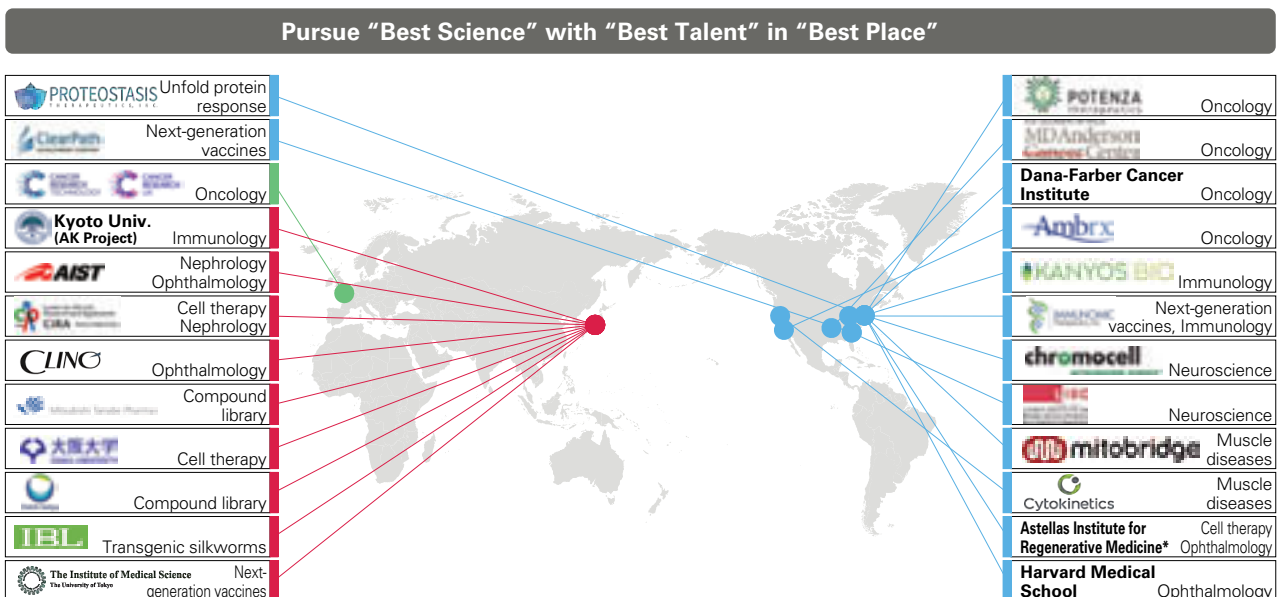
Looking ahead on the healthcare horizon, we will see an increasingly stronger need to raise the value of treatment for patients. This will accelerate the development of new treatment methods to progress further, driven primarily by advances in personalized medicine and new technologies such as gene and cell therapies, as well as the fusion of healthcare with IT.

Astellas is also speeding up various initiatives strongly focused on the rapid and multifaceted changes reshaping the environment. For example, these initiatives include establishment of a program that transcends existing organizational boundaries to support the development of new ideas. We have put an environment in place where our researchers are able to take on the challenges of various opportunities by thinking outside the box. These efforts have energized our unique, high-quality research activities.

In addition, Astellas is actively engaged in open innovation in basic research fields, notably the exchange of compound libraries with other pharmaceutical companies. In fields where the aim is to access basic technologies common to pharmaceutical companies, Astellas and its partners will pool together one another’s strengths. In fields where competitive advantages must be demonstrated, Astellas will closely collaborate with highly specialized partners. Through these approaches, Astellas will seek to discover innovative pharmaceuticals.

### Develop New Therapeutic Areas and Novel Technology Platform (as of July 2016)

Japan Europe U.S.



\* Formerly known as Ocata Therapeutics, Inc.



# Clinical Development

## Working to Enhance Productivity through a Robust Clinical Development Framework

Burden of disease for patients as well as their treatment options and the optimal treatments, differ greatly depending on the therapeutic area. In each therapeutic area, Astellas has its own empowered project teams which are under the leadership of scientific and medical experts. This organization enables us to make strategic and efficient decisions in line with the treatment landscape in each therapeutic area. Moreover, Astellas has built a globally integrated framework for clinical trial execution to enhance the quality and efficiency of development operations. One of Astellas' clinical development strengths is that it has put a system in place from both of these perspectives for delivering cutting-edge treatment methods.

The need to improve productivity in R&D is a major priority for the entire pharmaceutical industry. We prioritize projects in our portfolio by performing a robust and objective analysis of factors such as data obtained from clinical trials, the probability of success, and development costs. We channel adequate resources into prioritized projects from the early development stage, with the aim of achieving early filing and regulatory approval. When formulating clinical trial plans, Astellas considers the different healthcare insurance and drug pricing systems in each country or region, and fine tunes the design and evaluation endpoints to clearly demonstrate the added value of innovative drugs.

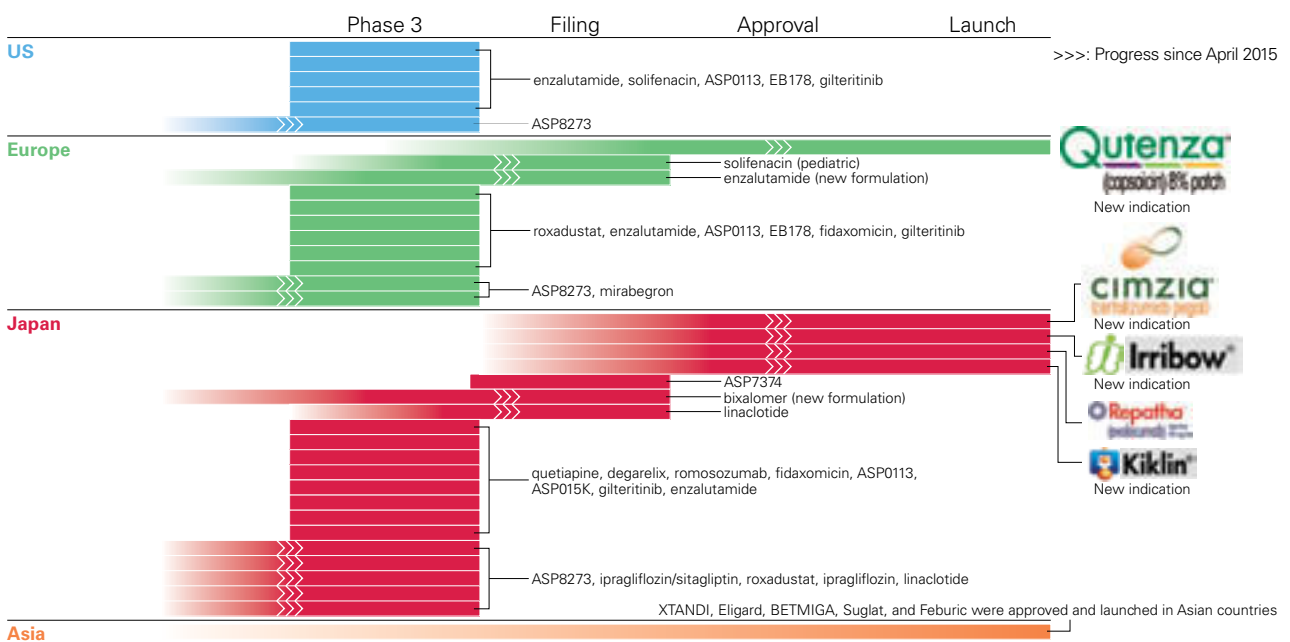
## Progress on Many Development Projects That Will Contribute to Growth

In clinical development, our mission is to extract the full value from pipeline programs and approved products, thereby turning advances in science into value for patients.

To fulfill this mission, it is crucial to continuously obtain regulatory approvals with commercially desirable labels. In fiscal 2015, Astellas obtained regulatory approvals for many projects, including an approval in Japan for Repatha, a treatment for hypercholesterolemia, and approvals for expanded indications for three drugs. In addition, Astellas has submitted a new drug application for linaclotide in Japan for the treatment of irritable bowel syndrome with constipation (IBS-C).

We are constantly aware of the need to generate highly reliable clinical trial data according to our development schedules. In fiscal 2015, Phase 3 clinical trial data became available for a combination therapy comprising solifenacin and mirabegron, two agents in our OAB franchise, and for romosozumab, which is being jointly developed with Amgen Astellas BioPharma K.K. for the treatment of osteoporosis. Furthermore, Astellas is making steady progress with various projects, including the start of several new Phase 3 clinical trials in the oncology field.

**FY2015 Progress of Late Phase Compounds** (April 2015 – July 2016)



# Feature Our Initiatives to Create Innovation

## Case 1 Accelerating R&D in Ophthalmology



We will establish a cell therapy franchise in ophthalmology by pursuing “Best Science, Best Talent, Best Place.”

**Yoshitsugu Shitaka, Ph.D**  
President, Astellas Institute for Regenerative Medicine (AIRM)

### Strong Start for AIRM Leveraging Both Companies’ Complementary Technologies, Experience, and Financial Bases

There remains many diseases of the eye with no therapeutic options. In particular, we are still waiting for groundbreaking drugs to treat conditions that lead to vision impairment. In addition to developing small molecule VAP-1 inhibitor ASP8232\* in-house, Astellas is researching new technologies to support cell and gene therapies in this area, including collaboration with Harvard Medical School, a global front-runner in gene therapies for ophthalmic diseases.

Many conditions that can lead to loss of sight involve the degeneration or loss of the cells responsible for visual function. There is a rational case for developing cell therapies to treat such conditions because (1) function can be restored with replacement of the affected tissue, (2) fairly few cells are needed for transplanting, (3) cells can be transplanted

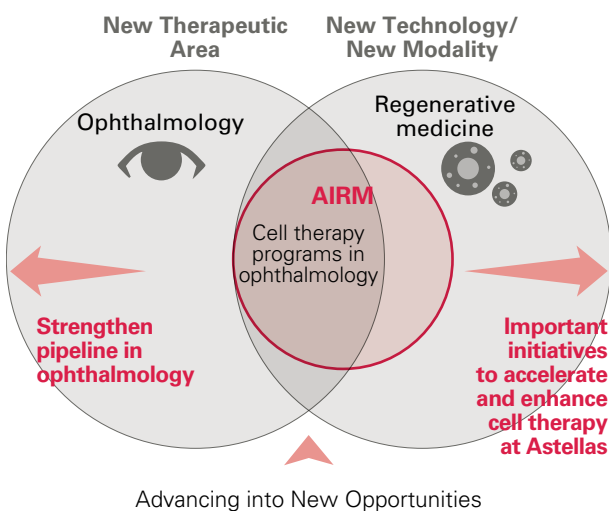
directly to diseased tissue, (4) rejection is rare, and (5) precise clinical trial endpoints can be defined.

We acquired Ocata Therapeutics, Inc. (Ocata), one of the leaders in cell therapy advancing ophthalmic R&D, in order to advance research and development largely with their capabilities. They have world-class technology and expertise in ways of sourcing differentiated cells from pluripotent stem cells. Ocata’s researchers lead the world in this field and they also have clinical development experience in cell therapy. The Company’s name was changed to the Astellas Institute for Regenerative Medicine after the acquisition. Following my appointment as President of AIRM and after only a few months in the job, I am convinced of the huge potential of these R&D activities.

Most of the former key Ocata staff have stayed at AIRM and are highly motivated to continue the R&D programs. One reason for this is the extremely good fit between Astellas and Ocata in terms of complementary functions. Astellas’ quality control, cross-divisional project management expertise, and understanding of diseases and conditions prove valuable in advancing current pipeline projects. The global network and experience of Astellas will also be essential in advancing the projects currently at the clinical trial stage to commercialization. In that sense, many have commented that Ocata and Astellas joined forces at an extremely opportune moment.

\* Currently in Phase II for diabetic macular edema.

### Positioning of AIRM in Strategic Plan 2015–2017

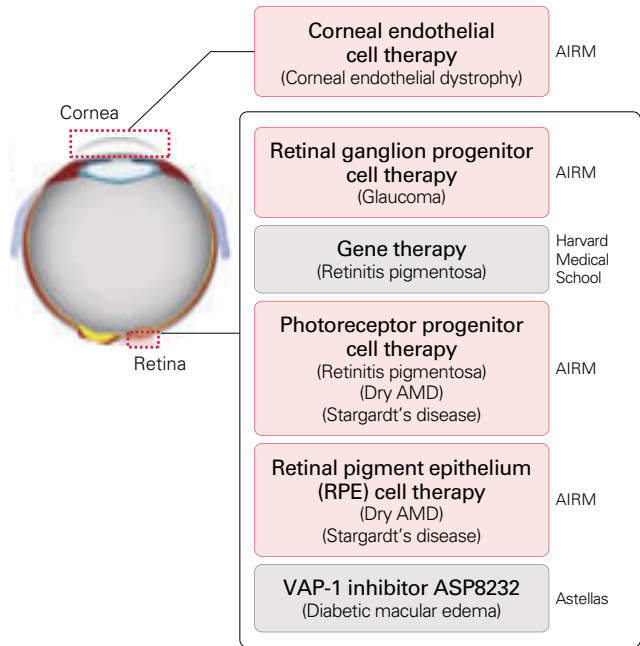


**Turning Challenge into Opportunity: First Aim to Create Cell Therapy Franchise in Ophthalmology**

Since we are the front-runner, the absence of useful precedents means we have to take projects forward based on internal debate over study protocols, manufacturing methods, and quality standards. We have a shared understanding that we must change our challenges into opportunities, targeting a world-first treatment by accelerating R&D projects as much as possible. The goal of AIRM is to advance multiple R&D projects as far as the clinical development stage within just a few years.

From a longer-term perspective, AIRM also aims to take on the challenge of regenerative medicine. In line with this, since becoming AIRM, we have resumed a number of projects with potential to broaden the project scope beyond our traditional focus on ophthalmology. AIRM is also actively hiring. Under the leadership of Dr. Lanza, AIRM’s talented personnel, technologies, and R&D projects in the field of regenerative medicine are attracting interest from many outstanding scientists who would like to join our team. Going forward, we expect to form a suitable team to work at the forefront of Astellas’ research in this area. Based on the “Best Science, Best Talent, Best Place” notion, Astellas will pursue cutting-edge medical science through the talents, technology and clinical development experience of AIRM, including regulatory expertise. We will leverage the research network comprising AIRM located in the

**Establishing a Presence in Ophthalmology**



Boston area where research in regenerative medicine thrives and the Group’s Regenerative Medicine Labs in Japan. The overall aim is to establish a cell therapy franchise in ophthalmology and to build a leading position in cell therapy.

*Adding the knowledge and understanding of Astellas’ talented researchers has made the company far stronger.*

Ocata’s vision was to be a leading ophthalmology company using its proprietary regenerative medicine platform to cure loss of vision. Astellas shares this same goal. Our pipeline includes several therapies with great clinical promise, notably the use of retinal pigment epithelium (RPE) cells for treating dry age-related macular degeneration (AMD). The creation of AIRM has made our organization stronger and enabled us to expand the scope of our research to include programs in other areas. Adding the knowledge and understanding of Astellas’ talented researchers, we will not only be able to advance our current projects in ophthalmology, but also help usher in a revolution by applying regenerative medicine across multiple fields.



**Robert Lanza, M.D.**  
 Head of Astellas Global Regenerative Medicine and Chief Scientific Officer AIRM

## Case 2 Steady Progress in Oncology



With several late-stage development projects progressing, we are taking up the challenge of making breakthroughs in cancer treatment.

**Bernie Zeiher, M.D.**  
President, Development

### Targeting Scientific Advances while Accelerating Development Using Varied Approaches

We have made progress in oncology on several fronts recently. In late-stage development, we have begun several new Phase 3 clinical trials with enzalutamide, gilteritinib and ASP8273. In early-stage development, the data obtained in metastatic bladder cancer with the two Agensys, Inc. antibody-drug-conjugates are also promising.

Oncology is a complex therapeutic area given the number of tumor types, differences in pathogenesis and changing treatment paradigm. What makes it even more complex is the pace of change recently due to the advancement of new breakthrough therapies.

Personalized or precision medicine approaches have made a significant impact on the development of treatments in oncology. Utilizing a more targeted approach, we anticipate an improved benefit-risk profile by administering the right drug to the right patient. This approach is taken with enzalutamide in triple-negative breast cancer, gilteritinib and ASP8273. Immunooncology is another area of interest, where we are engaged in partnership with Potenza Therapeutics, Inc.

It is vital to take advantage of accelerated development pathways. Gilteritinib is a good example where we have been granted SAKIGAKE designation in Japan.

Our challenge at Astellas is to improve cancer treatment globally by turning innovation into value for patients. We continue to follow the evolution of science so that we can remain on the forefront of the dramatic changes in the management of cancer patients.

### Clinical Development Program #1 Enzalutamide (Prostate/breast cancer, etc.)

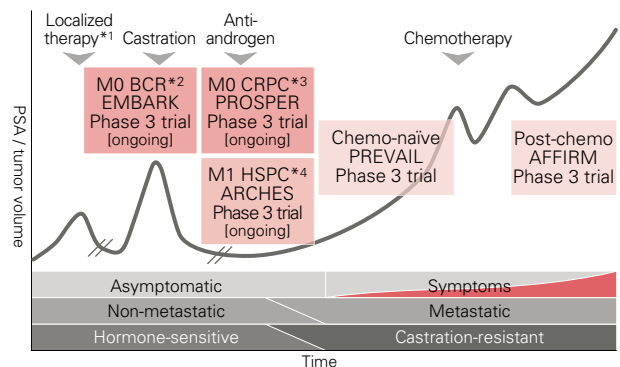
Prostate cancer is the second most prevalent type of cancer in men, with 1.1 million new cases diagnosed in 2012 globally. It has the fifth highest mortality rate among cancers in men\*.

Enzalutamide, which is indicated in treatment of metastatic castration-resistant prostate cancer, both post-chemo and chemo-naïve, has offered a new treatment option since its launch as XTANDI. It is currently in Phase 3 trials for three earlier stages of prostate cancer shown in the figure below. This comprehensive program, conducted with our partner Medivation, Inc., will help to characterize the optimal use of enzalutamide in this disease.

Enzalutamide is also being evaluated in breast cancer, including a Phase 3 program in triple-negative breast cancer and two Phase 2 studies in different breast cancer subtypes.

\* World Health Organization, GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012

### Maximizing the Value of Enzalutamide for Prostate Cancer Patients



\*1 Prostatectomy, radiotherapy  
\*2 Non-metastatic biochemically recurrent prostate cancer  
\*3 Non-metastatic castration-resistant prostate cancer  
\*4 Metastatic hormone-sensitive prostate cancer

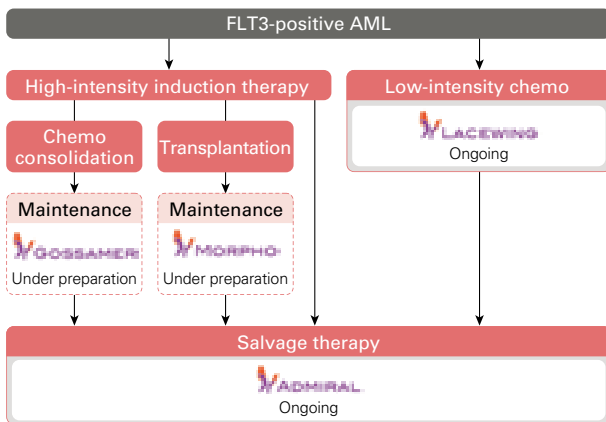
**Clinical Development Program #2  
 Gilteritinib (Acute myeloid leukemia)**

Acute myeloid leukemia (AML) is the most common form of adult leukemia and requires urgent medical treatment. The prognosis for patients with FLT3\*-positive AML is generally worse than other types of AML.

Besides inhibiting FLT3, gilteritinib also inhibits AXL, which is reported to be associated with resistance to some forms of chemotherapy. A comprehensive Phase 3 program for FLT3-positive AML is being conducted with gilteritinib. This includes studies in relapsed and refractory AML as well as in patients receiving low-intensity chemotherapy and after transplantation.

\* A receptor-type tyrosine kinase involved in cancer cell proliferation

**Gilteritinib in the AML Treatment Landscape**



**Clinical Development Program #3  
 ASP8273 (Non-small cell lung cancer)**

Astellas has Tarceva indicated for non-small cell lung cancer (NSCLC). It is known that first-generation drugs of this type can induce resistance over time, and ASP8273 has efficacy in these types of resistance mutations. With its high selectivity for mutated receptors over wild-type receptors, ASP8273 is expected to have an improved safety profile compared to the first-generation epidermal growth factor receptor tyrosine kinase inhibitors.

A Phase 3 trial for ASP8273 as a first-line NSCLC therapy is underway. Further studies in Japan and Asia for ASP8273 as a second-line therapy are being considered as well.

**Status of Development**



*Our development approach has been rapid with gilteritinib as we look to satisfy unmet medical needs.*

Gilteritinib was originally discovered with the intent of treating a different type of cancer, but molecular activity screens revealed its strong inhibition of FLT3, a target for AML, as well as the related resistance mutation. In Phase 1 we were able to demonstrate clinical response and identify a dose for advancement into later stages of development. This enabled us to move directly from Phase 1 to Phase 3 in 2 years. The data were promising enough to be selected for SAKIGAKE designation in Japan.

The investigators express strong expectations for the drug's potential. Our team members are excited that we can provide novel therapeutic options to AML patients. Because gilteritinib also inhibits AXL, it has the potential to treat tumor types other than AML. We are making every effort to deliver gilteritinib to patients worldwide who can benefit from it as soon as possible.

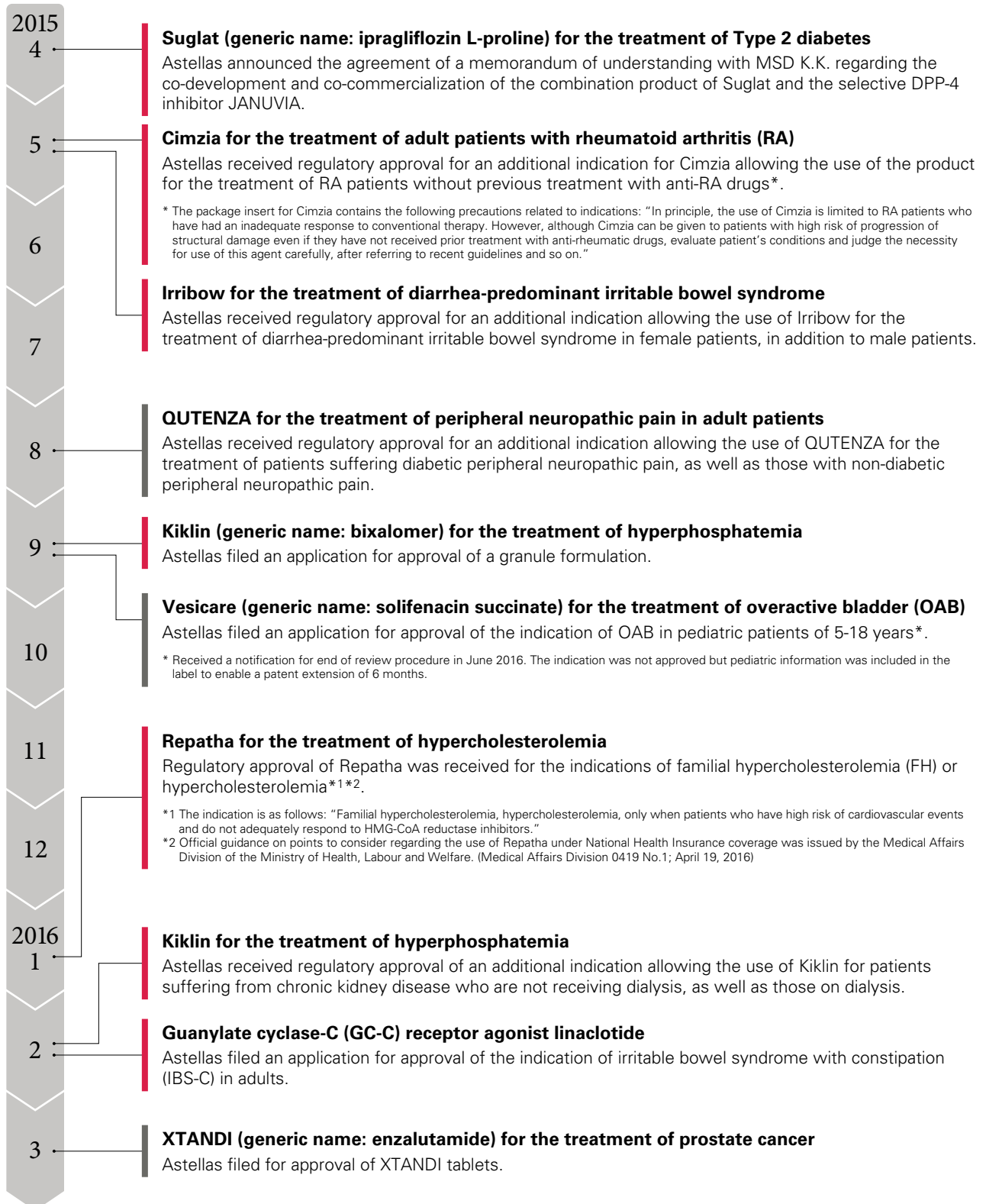


**Itsuro Nagase**  
 D.V.M., Ph.D.  
 Senior Director  
 Global Development  
 Project Leader

# R&D Topics During the Year

## Major Progress in Clinical Development (Approval, Filing, and Alliance)

■ Japan ■ Europe





## Capturing New Opportunities

### Oncology

Monoclonal antibody drug for acute myeloid leukemia

In April 2015, Astellas signed an agreement with The University of Texas MD Anderson Cancer Center on an option to firstly negotiate an exclusive, worldwide license concerning research and development of h8F4, a humanized monoclonal antibody, for patients with acute myeloid leukemia.

Building a portfolio of immuno-oncology therapeutics

In April 2015, Astellas entered into an agreement with Potenza Therapeutics, Inc. for exclusive research and development collaboration geared towards building a portfolio of immuno-oncology therapeutics. The agreement includes an exclusive option that allows for the future acquisition of Potenza by Astellas.

### Immunology

Creating therapeutic drugs for type 1 diabetes and celiac disease

In May 2015, Astellas signed an agreement with Kanyos Bio, Inc., a newly established company, to collaborate on research aimed at creating therapeutic drugs, based on technology for the induction of antigen-specific immune tolerance owned by Anokion SA. Astellas holds an exclusive option to acquire Kanyos Bio, Inc.

Next-generation vaccines

In October 2015, Astellas signed an exclusive worldwide license agreement with Immunomic Therapeutics, Inc. concerning the LAMP-vax products for the treatment or prevention of a wide range of allergic diseases in humans.

### Neuroscience

New therapeutics to treat neuropathic and other pain conditions

In September 2015, Astellas entered into a license and collaboration agreement with Chromocell Corporation for the worldwide development and commercialization of new therapeutics to treat neuropathic and other pain conditions.

### Ophthalmology

Gene therapy to treat retinitis pigmentosa

In January 2016, Astellas entered into a license agreement with CLINO Ltd. for the worldwide development and commercialization of a gene therapy, Adeno-associated Virus-modified Volvox channelrhodopsin-1 (AAV-mVChR1), to treat retinitis pigmentosa.

Cell therapy for ophthalmology

In February 2016, Astellas acquired Ocata Therapeutics, Inc., a biotechnology company focused on research and development of cell therapy for ophthalmology, and made it a consolidated subsidiary. In May 2016, the company's name was changed to the Astellas Institute for Regenerative Medicine.

### Other Areas

IT drug-discovery technologies

In July 2015, Astellas initiated collaborative research with the National Institute of Advanced Industrial Science and Technology (AIST), utilizing Astellas' own protein-ligand complex structural information and AIST's highly advanced IT drug-discovery technologies.

Sharing of compound libraries

In March 2016, Astellas and Mitsubishi Tanabe Pharma Corporation concluded an agreement for sharing their respective approximately 250,000 compounds selected from their respective compound libraries.

## Status of R&D Pipeline (as of July 2016)

Code No. / Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor*1	Remarks
<b>Oncology</b>						
MDV3100 enzalutamide	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer (Tablet)	Europe Filed (Mar. 2016)	Oral	Medivation	New formulation
		Non-metastatic castration-resistant prostate cancer	US/Europe/Asia Phase-III			New indication
		Prostate cancer in patients with non-metastatic biochemical recurrence	US/Europe/Asia Phase-III			New indication
		Metastatic hormone-sensitive prostate cancer	US/Europe/Japan/Asia Phase-III			New indication
		Triple-negative breast cancer	US/Europe/Japan/Asia Phase-III			New indication
		Breast cancer (ER/PgR positive, HER2 positive)	US/Europe Phase-II			New indication
		Hepatocellular carcinoma	US/Europe/Asia Phase-II			New indication
ASP2215 gilteritinib	FLT3/AXL inhibitor	Acute myeloid leukemia	US/Europe/Japan/Asia Phase-III	Oral	In-house	
		Non-small cell lung cancer	US/Japan/Asia Phase-I			
ASP3550 degarelix	GnRH antagonist	Prostate cancer (three-month formulation)	Japan Phase-III	Injection	Ferring	New formulation*2
ASP8273	Mutant-selective irreversible EGFR inhibitor	Non-small cell lung cancer	US/Europe/Japan/Asia Phase-III	Oral	In-house	
AGS-16C3F	ADC targeting ENPP3	Renal cell carcinoma	US/Europe Phase-II	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
AMG 103 blinatumomab	Anti-CD19 BiTE	Acute lymphoblastic leukemia	Japan Phase-II	Injection	Amgen (co-development with Amgen Astellas)	*2
ASG-22ME enfortumab vedotin		Solid tumors Urothelial cancer	Phase-I	Injection	In-house (co-development with Seattle Genetics)	
ASG-15ME		Urothelial cancer	Phase-I	Injection	In-house (co-development with Seattle Genetics)	
ASP5878		Cancer	Phase-I	Oral	In-house	
AGS67E		Lymphoid Malignancies	Phase-I	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
ASP4132		Cancer	Phase-I	Oral	In-house	
AGS62P1		Acute myeloid leukemia	Phase-I	Injection	In-house (ADC technology, EuCODE license from Ambrx)	

## Urology and Nephrology

YM905 solifenacin	Muscarinic M <sub>3</sub> receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	US/Europe Phase-III	Oral	In-house	New indication (pediatric)
ASP1585 (AMG 223) bixalomer	Amine-functional polymer	Hyperphosphatemia in patients on dialysis with chronic kidney disease (granule formulation)	Japan Filed (Sep. 2015)	Oral	Amgen	New formulation*2
EB178 solifenacin/mirabegron	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	US/Europe/Asia Phase-III	Oral	In-house	
ASP1517 (FG-4592) roxadustat	HIF stabilizer	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis	Europe/Japan Phase-III	Oral	FibroGen	
YM178 mirabegron	Beta 3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	Europe Phase-III	Oral	In-house	New indication (pediatric)
ASP8232	VAP-1 inhibitor	Diabetic nephropathy	Europe Phase-II	Oral	In-house	
YM311 (FG-2216)	HIF stabilizer	Renal anemia	Europe Phase-II Japan Phase-I	Oral	FibroGen	
ASP2205		Stress urinary incontinence	Phase-I	Oral	In-house	
ASP6282		Underactive bladder	Phase-I	Oral	In-house	
ASP7398		Nocturia	Phase-I	Oral	In-house	
ASP6294		Bladder pain syndrome / Interstitial cystitis	Phase-I	Injection	In-house	



Code No. / Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor*1	Remarks
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients	US/Europe/Japan Phase-III	Injection	Vical	
		Cytomegalovirus infection or reactivation in solid organ transplant recipients	US/Europe Phase-II			
ASP015K peficitinib	JAK inhibitor	Rheumatoid arthritis	Japan/Asia Phase-III US/Europe Phase-II	Oral	In-house	
FK949E quetiapine	Serotonin / dopamine antagonist	Depressive episode in bipolar disorders	Japan Phase-III	Oral	AstraZeneca	New indication*2 New formulation*2
ASKP1240 bleseelumab	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	US Phase-II	Injection	Kyowa Hakko Kirin	
ASP3662	11beta-HSD1 inhibitor	Painful diabetic peripheral neuropathy	US Phase-II	Oral	In-house	
		Alzheimer's disease	US Phase-I			
ASP1707	GnRH antagonist	Rheumatoid arthritis	Japan Phase-II	Oral	In-house	
ASP7962	TrkA inhibitor	Osteoarthritis	Europe Phase-II	Oral	In-house	
ASP5094		Rheumatoid arthritis	Phase-I	Injection	In-house	
ASP4345		Cognitive impairment associated with schizophrenia	Phase-I	Oral	In-house	
ASP4070 (JRC2-LAMP-vax)		Pollinosis caused by Japanese red cedar	Phase-I	Injection	Immunomic Therapeutics	
ASP0819		Fibromyalgia	Phase-I	Oral	In-house	
ASP8062		Fibromyalgia	Phase-I	Oral	In-house	
ASP7266		Severe asthma	Phase-I	Injection	In-house	
ASP0892		Peanut allergy	Phase-I	Injection	Immunomic Therapeutics	

### Others

ASP7374	Influenza vaccine	Prophylaxis of seasonal influenza	Japan Filed (May 2014)	Injection	UMN Pharma	*2
ASP0456 linaclotide	Guanylate cyclase-C receptor agonist	Irritable bowel syndrome with constipation	Japan Filed (Feb. 2016)	Oral	Ironwood	*2
		Chronic constipation	Japan Phase-III			New indication*2
fidaxomicin	Macrocyclic antibiotic	Infectious enteritis (bacterial target: <i>Clostridium difficile</i> )	Japan Phase-III	Oral	Merck	
		<i>Clostridium difficile</i> infection in pediatric patients	Europe Phase-III			
AMG 785 romosozumab	Anti-Sclerostin monoclonal antibody	Osteoporosis	Japan Phase-III	Injection	Amgen(co-devel opment with Amgen Astellas)	*2
ipragliflozin/ sitagliptin	Fixed dose combination of ipragliflozin and sitagliptin	Type 2 diabetes mellitus	Japan Phase-III	Oral	In-house (co-development with MSD and Kotobuki)	*2
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 1 diabetes mellitus	Japan Phase-III	Oral	In-house (co-development with Kotobuki)	New indication*2
ASP1707	GnRH antagonist	Endometriosis	Europe/Japan Phase-II	Oral	In-house	
ASP8232	VAP-1 inhibitor	Diabetic macular edema	US Phase-II	Oral	In-house	
CK-2127107	Fast skeletal tropoinin activator	Spinal muscular atrophy	US Phase-II	Oral	Cytokinetics	
		Chronic obstructive pulmonary disease	US Phase-II			
RPE cell program	Cell therapy (Retinal pigment epithelium cell)	Dry age-related macular degeneration Stargardt's macular degeneration	US Phase-II	Injection	In-house (Astellas Institute for Regenerative Medicine)	
ASP7373	Influenza vaccine	Prophylaxis of H5N1 influenza	Japan Phase-II	Injection	UMN Pharma	*2

\*1 Compounds with "In-house" include ones discovered by collaborative research. \*2 Local development (Japan)

# Review of Operations by Therapeutic Area

## Oncology

### Business Environment and Basic Strategy

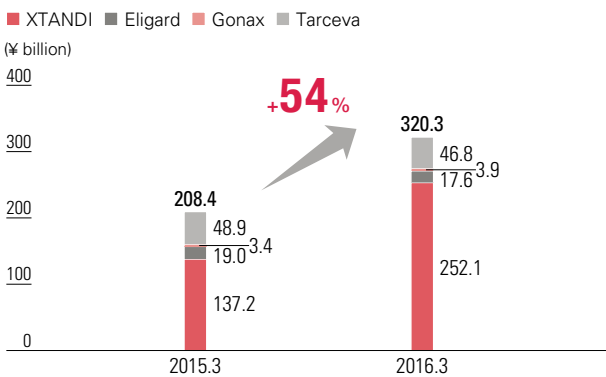
Given that cancer is one of the leading causes of death, oncology has urgent unmet patient needs. It is also an area that has seen the development of a steady string of new drugs in line with scientific advancement. Astellas is focused on the oncology field as one of its core business areas. We currently have four oncology products: the prostate cancer treatments XTANDI, Eligard and Gonax, and Tarceva for the treatment of non-small cell lung cancer and pancreatic cancer.

XTANDI stands out as a significant growth driver for us in oncology. Currently, we are working to expand sales of XTANDI to new regions, as we work to expand the indication in each country and further increase the market penetration of this drug to chemotherapy-naïve patients. XTANDI offers a product profile featuring excellent effectiveness proven in clinical trials, dosing conditions with few restrictions, and high tolerability. Furthermore, we have a solid presence in the urology field. Leveraging these strengths, we aim to become the market leader in this category.

### Fiscal 2015 Performance

Total sales of Astellas' four oncology products continued to rise sharply, increasing by 54% to ¥320.3 billion.

#### Sales by Product



Sales of XTANDI grew by 83.7% to ¥252.1 billion, owing to steady sales expansion in each region. Tarceva-related revenues were down 4.3% at ¥46.8 billion. Eligard is currently marketed in EMEA and Asia & Oceania. Sales declined 7.3% to ¥17.6 billion. Sales of Gonax, which is marketed in Japan, increased 14.3% to ¥3.9 billion.

### Outlook

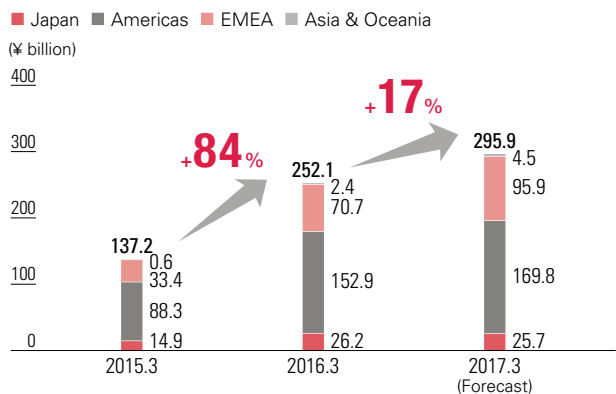
We are advancing various clinical trials targeting additional indications with the aim of maximizing the product value of XTANDI. We are conducting Phase 3 trials involving earlier stage prostate cancer patients. Efforts are also focused on conducting trials for other cancers, such as breast cancer and hepatocellular carcinoma.

Elsewhere, more than 10 projects are under way, including development of gilteritinib for acute myeloid leukemia, and ASP8273 for non-small cell lung cancer. These development projects will steadily reinforce our business platform in the oncology area.

In the research stage, we are pursuing drug discovery research targeting cancers and patients for which existing treatments do not provide any benefit, with a focus on immune evasion and metabolic disorders in oncology. By forming partnerships with the world's leading biotechnology companies and research institutions, we seek to establish a highly competitive drug pipeline.

Reference | Maximizing the Product Value ➤ P21  
 | Creating Innovation ➤ P22

#### Sales of XTANDI by Region



## Overview of Main Products

### XTANDI (Prostate cancer treatment)

This product is a once-daily oral androgen receptor inhibitor. XTANDI has been sold since 2012 in various regions for prostate cancer patients who had previously received chemotherapy. As of May 2016, XTANDI is sold in around 60 countries and regions. It was also approved in key countries for the treatment of chemotherapy-naïve prostate cancer patients.

Looking at regional sales of XTANDI in fiscal 2015, sales in Japan increased 76.1% to ¥26.2 billion. Sales in the Americas were up 58.4% to US\$1,272 million. In EMEA, sales rose sharply by 121.3% to €533 million. XTANDI is gaining traction among chemotherapy-naïve prostate cancer patients. In the Asia & Oceania region, sales in fiscal 2015 were ¥2.4 billion, with sales growing primarily in Australia. In Europe, clinical study data comparing XTANDI and bicalutamide were reflected in the package insert (SmPC) in April 2016. In the U.S., we also submitted a similar application for label update to the Food and Drug Administration.

In the U.S., Astellas and Medivation, Inc. co-promote XTANDI and share profits equally. In all countries excluding the U.S., Astellas develops and commercializes XTANDI, while paying Medivation royalties based on sales.



XTANDI

### Eligard (Prostate cancer treatment)

Eligard is a luteinizing hormone-releasing hormone (LHRH) agonist that is marketed under license from TOLMAR Inc.

In EMEA, sales declined by 3.7% to €131 million in fiscal 2015, mainly due to intensified competition. In Asia & Oceania, sales were ¥0.2 billion. We launched the product in Taiwan in fiscal 2015.

### Gonax (Prostate cancer treatment)

Gonax is a gonadotrophin-releasing hormone (GnRH)-receptor blocker with a subcutaneously injectable formulation in-licensed from Ferring Pharmaceuticals. It is sold by Astellas in Japan. In fiscal 2015, sales rose 14.3% to ¥3.9 billion. We will step up efforts to increase the market penetration of Gonax, along with that of XTANDI.

### Tarceva (Lung and pancreatic cancer treatment)

Tarceva is a small-molecule drug developed to target the epidermal growth factor receptor (EGFR) that plays a key role in cancer formation and growth. In fiscal 2015, Tarceva-related revenues decreased by 12.4% to US\$389 million, mainly due to intensifying competition with other drugs.

In the U.S., 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.

## Urology and Nephrology

### Business Environment and Basic Strategy

Astellas has established a strong presence in the urology area through the sale of Harnal, a treatment for functional symptoms of benign prostatic hyperplasia, as well as the overactive bladder (OAB) treatments Vesicare (generic name: solifenacin) and Betanis/Myrbetriq/BETMIGA (generic name: mirabegron).

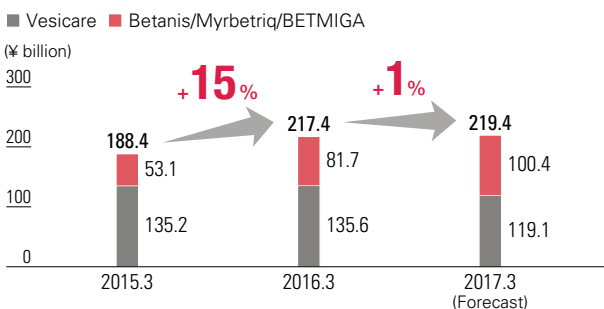
OAB treatments have now become one of Astellas' core growth drivers. We will continue to strengthen the position of Vesicare as the first choice among anticholinergics—the standard therapy for OAB. Betanis/Myrbetriq/BETMIGA has earned a strong reputation as a new treatment option with a different mechanism of action from Vesicare. In anticipation of the expiry of patent protection for Vesicare in various regions from 2018 onward, we will put more emphasis on Betanis/Myrbetriq/BETMIGA to achieve further market penetration. Considering the large number of potential subjects in the OAB treatment market, we will work to contribute to the treatment of many more patients by raising public awareness of this condition.

Moreover, the nephrology area offers prospects for synergies with Astellas' existing products and therapeutic areas, including urology. Accordingly, the development of several projects is now under way.

### Fiscal 2015 Performance

Sales increased steadily in our OAB franchise, underpinned by sales of Betanis/Myrbetriq/BETMIGA. In fiscal 2015, aggregate sales of our OAB franchise rose 15% to ¥217.4

#### Total Sales of the OAB Franchise (By Product)



billion. We saw double-digit sales growth in Japan, the Americas, and Asia & Oceania on a local currency basis. We have established a leading market position in this area. In fiscal 2015, our market share reached approximately 63% in Japan, approximately 62% in the U.S. and approximately 56% in Europe (on a value basis).

### Outlook

In urology, EB178, a combination therapy comprising solifenacin and mirabegron, is currently undergoing a Phase 3 trial. Towards building a next-generation franchise, we are advancing clinical development targeting new urologic disorders with a high level of unmet medical needs.

In the nephrology area, we are advancing Phase 3 trials of roxadustat in Europe and Japan for the target disease of anemia associated with chronic kidney disease in patients on dialysis and not on dialysis. In addition, we will work to develop therapies for disorders with a high level of unmet medical needs, such as diabetic nephropathy and chronic kidney disease.

Reference | Maximizing the Product Value > P21  
 | Creating Innovation > P22

### Overview of Main Products

#### Betanis/Myrbetriq/BETMIGA (OAB treatment)

This drug is a beta-3 adrenergic receptor agonist that helps to relieve symptoms associated with OAB such as urinary urgency, frequent urination, and urinary incontinence. It is sold in around 50 countries and regions worldwide under the brand name of Betanis in Japan, Myrbetriq in the Americas, and BETMIGA in EMEA and Asia & Oceania.

As an OAB treatment with a new mechanism of action, Betanis/Myrbetriq/BETMIGA has been achieving increased market penetration. In fiscal 2015, aggregate sales grew sharply by 53.8% to ¥81.7 billion. Sales have been expanding in every region. In Japan, sales of Betanis increased by 43.5% to ¥21.2 billion. Betanis' annual share of the OAB treatment market was approximately 28% (on a value basis). In the Americas, Myrbetriq sales continued to grow, up 49.8% to US\$380 million. Myrbetriq's annual share of the U.S. OAB treatment market reached

approximately 23% (on a value basis). In EMEA, sales of BETMIGA increased by 36.0% to €101 million. BETMIGA's annual share of the region's OAB treatment market was approximately 11% (on a value basis). In Asia & Oceania, sales of this product reached ¥1.4 billion (¥0.2 billion in the previous year).



Betanis/Myrbetriq/BETMIGA

#### Vesicare (OAB treatment)

Vesicare is an anticholinergic drug sold in approximately 80 countries and regions. It has continued to retain a high share in each region as the first choice of therapy in the OAB area.

In fiscal 2015, aggregate sales of Vesicare rose 0.3% to ¥135.6 billion. Looking at regional sales of Vesicare, sales in Japan rose 3.5% to ¥26.5 billion, sales in the Americas decreased 5.1% to US\$530 million, sales in EMEA declined 1.4% to €300 million, and sales in Asia & Oceania rose 0.1% to ¥5.3 billion.

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

This product is sold in approximately 100 countries and regions, and has established itself as a standard treatment of urinary disorders associated with BPH.

Sales in Japan declined 4.6% to ¥53.4 billion in fiscal 2015. Regionally, sales in Asia & Oceania increased 17.7% to ¥21.5 billion, owing to continued growth in various countries. Meanwhile, sales in Japan declined 15.6% to ¥12.7 billion, due to the impact of generic drugs. In EMEA, sales decreased 10.1% to €116 million.

## Immunology

### Business Environment and Basic Strategy

In the immunology area, Astellas is contributing to the field of transplantation through the immunosuppressant Prograf. The transplantation franchise is a vital earnings base globally and Astellas will continue to focus on the franchise.

### Fiscal 2015 Performance

Sales of Prograf rose 4.5% to ¥203.6 billion in fiscal 2015. Global Prograf sales are steady, underpinned by growth in Asia & Oceania, despite the impact of generics in Japan, the Americas, and EMEA.

### Outlook

Astellas has several new drug candidates in the late clinical development stage. These include ASP015K, which is under development for the treatment of rheumatoid arthritis and ASP0113, which is being developed for the prevention of cytomegalovirus infection or reactivation for hematopoietic cell transplants and solid organ transplants.

Looking ahead, we will work to develop drugs for causal therapy/cure of immune-related disorders, drugs that seek to completely cure immune-related disorders or substantially relieve their symptoms, and next-generation innovative, immunoregulatory drugs.

Reference | Maximizing the Product Value ➤ P21  
| Creating Innovation ➤ P22

**Overview of Main Products**

Prograf and Advagraf/Graceptor/ASTAGRAF XL/Prograf XL (Immunosuppressant)

This drug is an immunosuppressant used to suppress organ transplant rejection. Although the patent for this drug has already expired in major countries, it is sold in approximately 100 countries and regions and has made a significant global contribution to the field of transplantation.

Looking at regional sales in fiscal 2015, sales in Japan rose 3.4% to ¥49.8 billion, mainly due to growth in the once-daily formulation Graceptor. Sales in EMEA via in-house distribution channels rose 4.9% to €588 million, mainly supported by expanded sales of the once-daily formulation Advagraf. Supported by sales growth in China, Republic of Korea and certain other countries, sales in Asia & Oceania rose 20.2% to ¥38.4 billion. Meanwhile, sales in the Americas declined 4.1% to US\$288 million, mainly due to the impact of generics.

Cimzia (Rheumatoid arthritis treatment)

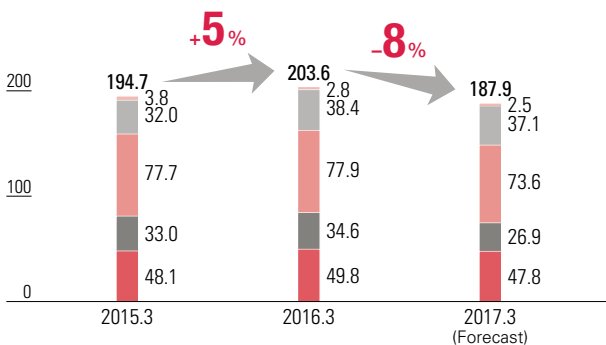
Cimzia is an anti-TNF (tumor necrosis factor)-alpha antibody that is co-promoted in Japan with UCB Japan Co., Ltd. Sales increased 30.2% to ¥6.6 billion in fiscal 2015. In May 2015, Cimzia's indications were expanded, permitting use in patients who have not received prior treatment with anti-rheumatic drugs when they present a high risk for progression of structural joint destruction.

**Sales of Prograf (By Region)  
(Including Advagraf/Graceptor/ASTAGRAF XL/Prograf XL)**

■ Japan ■ Americas ■ EMEA ■ Asia & Oceania ■ Export

(¥ billion)

300



**Other Areas**

**Overview of Main Products (Global Products)**

Funguard/MYCAMINE (Candin-type antifungal agent)

This drug is a candin-type antifungal agent used for the treatment of fungal infections. It is sold in approximately 60 countries and regions.

In fiscal 2015, global sales of the product rose 7.4% to ¥41.6 billion. In terms of regional sales, sales in Japan decreased 1.1% to ¥11.7 billion, and sales in the Americas declined 3.5% to US\$109 million. Meanwhile, sales continued to grow steadily in EMEA and Asia & Oceania. In EMEA, sales increased 14.7% to €85 million and in Asia & Oceania, sales increased 30.3% to ¥5.7 billion.

**Overview of Main Products (Japan)**

Micardis (Hypertension treatment)  
Micombi (Combination drug with a diuretic)  
Micamlo (Combination drug with a long-acting calcium antagonist)

Micardis is a once-daily oral angiotensin II receptor blocker (ARB). In Japan, Astellas is co-promoting the Micardis product line with Nippon Boehringer Ingelheim Co., Ltd. Sales of drugs in the Micardis product line, including Micombi and Micamlo, increased by 1.5% to ¥97.2 billion in fiscal 2015, mainly owing to continued steady expansion in sales of Micamlo in line with growth in the market for combination drugs. The total share of the Micardis line of drugs in the ARB market was around 21% (on a value basis).

In January 2016, Astellas extended the agreement with Nippon Boehringer Ingelheim Co., Ltd. pertaining to the sale and co-promotion of the Micardis line of drugs in Japan. As a result, the term of the agreement, which formerly ran to December 31, 2016, was extended by a year and 3 months to March 31, 2018.



#### Celecox (Anti-inflammatory agent)

Celecox is a selective cyclooxygenase-2 (COX-2) inhibitor that is co-promoted with Pfizer Japan Inc. In fiscal 2015, sales of Celecox increased 11.5% to ¥46.6 billion. Celecox's share of the market for oral anti-inflammatory analgesic agents was around 59% (on a value basis) based on the strong reputation of its product features. Going forward, we will target an even higher share of the market for oral anti-inflammatory analgesic agents.

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

Symbicort is a combination drug of an inhaled corticosteroid and a rapid and long-acting beta-2 agonist. Astellas is co-promoting Symbicort with AstraZeneca K.K. in Japan. In fiscal 2015, sales of Symbicort increased 13.3% to ¥37.4 billion. Symbicort's share of the market in Japan for adult inhaled steroid treatment including combination drugs was around 36% (on a value basis). The dissemination of guidelines and other positive factors have contributed to annual growth of this market, where Symbicort has a strong reputation.

#### Bonoteo (Treatment for osteoporosis)

Bonoteo is an oral bisphosphonate osteoporosis treatment. In fiscal 2015, sales of Bonoteo increased 8.6% to ¥14.1 billion. Bonoteo's share of the Japanese market for bisphosphonate agents was around 21% (on a value basis). Astellas will continue emphasizing the patient convenience offered by this drug, as well as its high clinical effect, with the aim of increasing Bonoteo's market share.

#### Suglat (Type 2 diabetes treatment)

Suglat is Japan's first sodium-glucose co-transporter 2 (SGLT2) inhibitor. In Japan, Astellas is co-promoting Suglat with Kotobuki Pharmaceutical Co., Ltd. and MSD K.K. In fiscal 2015, sales of Suglat grew 77.8% to ¥7.3 billion, following the availability of long-term prescriptions from May 2015. Suglat's share of the market for selective SGLT2 inhibitors in Japan was around 39% (on a value basis).

Astellas has been building up post-marketing data in regard to the efficacy and safety of Suglat. By supplying information based on this data, we aim to increase the market penetration of this drug.

#### Repatha (Hypercholesterolemia treatment)

In January 2016, Astellas obtained manufacturing and marketing approval of Repatha, the first proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor in Japan, indicated for the treatment of familial hypercholesterolemia or hypercholesterolemia\*. Repatha was launched in April 2016. It is being co-promoted by Astellas and Amgen Astellas BioPharma K.K. We are carrying out activities to supply information on Repatha, with an emphasis on encouraging proper drug use.

\* The indication is as follows: "Familial hypercholesterolemia, hypercholesterolemia, only when patients who have high risk of cardiovascular events and do not adequately respond to HMG-CoA reductase inhibitors."

\* Official guidance on points to consider regarding the use of Repatha under National Health Insurance coverage was issued by the Medical Affairs Division of the Ministry of Health, Labour and Welfare. (Medical Affairs Division 0419 No.1; April 19, 2016)



Repatha

### Overview of Main Products (U.S.)

#### Lexiscan (Pharmacologic stress agent)

Lexiscan is a pharmacologic stress agent in-licensed from Gilead Palo Alto, Inc. In fiscal 2015, combined sales of pharmacologic stress agents, comprising sales of Lexiscan and Adenoscan, for which generic products are already available, increased 5.1% to US\$634 million.

#### CRESEMBA (Azole antifungal)

CRESEMBA is an azole antifungal in-licensed from Basilea Pharmaceutica International Ltd. and launched in the U.S. in April 2015. In fiscal 2015, sales of CRESEMBA were US\$22 million. We will continue working to increase market penetration of this drug, which provides a new option for treating severe fungal infections.

# Review of Global Operations

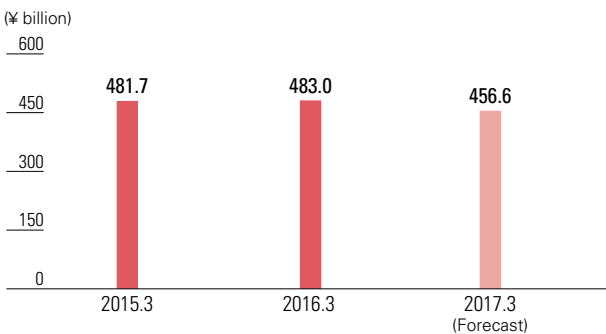


**Nobuaki Tanaka**  
President, Japan Sales & Marketing

## Business Environment and Strategy

In Japan, the government is implementing measures to optimize healthcare expenditures, and society requires more transparency and fairness than before. These changes are having a significant impact on our industry. With the background of a rapidly aging society, reforms in the healthcare delivery system are currently under way targeting the year 2025. Community medical care is expected to take on increasing importance in the reforms.

### Sales in Japan (Japanese Market Sales)



Considering these changes in the environment, Astellas revised its Medical Representative (MR) structure in October 2015. We have changed our previous system of assigning products to MRs based on therapeutic areas to a new system where each MR will be responsible for all of Astellas' products, in principle. This will enable MRs to provide more detailed information tailored to the respective treatment courses of healthcare professionals and the specific conditions of individual patients. Additionally, in the three therapeutic areas of oncology, immunology and transplantation, we created the new post of Therapeutic Area Specialist in order to more precisely convey the value of our specialty products to patients.

Under the new structure, as we continue carrying out our mission of bringing happiness to patients and their families, we will deliver drugs with high added value, such as the new products Repatha and XTANDI, and provide fair, high quality information.

## Fiscal 2015 Overview

Sales in Japan including revenues related to exports and licenses decreased 0.3% year on year to ¥497.2 billion. Of these, sales in the Japanese market increased by 0.3% to ¥483.0 billion.

By product, in addition to XTANDI and the OAB treatments including Vesicare and Betanis, products such as Prograf, Celecox, Symbicort, Suglat, and Micardis achieved sales growth. On the other hand, sales contracted for products such as Lipitor (for hypercholesterolemia) and Gaster (for peptic ulcers and gastritis) due to the impact of generics and other factors.

## Fiscal 2016 Outlook

Sales in Japan are forecasted to decrease by 3.3% year on year to ¥480.8 billion. Of these, sales in the Japanese market are expected to decrease by 5.5% to ¥456.6 billion, mainly based on the impact of NHI drug price revisions.

We are forecasting continuing sales growth in products such as Celecox, Symbicort, and Suglat, as well as the OAB treatments Vesicare and Betanis. Meanwhile, sales are forecast to contract for products such as XTANDI and Micardis (including its combination drugs, Micombi and Micamlo) based on NHI drug price revisions, although sales volumes are projected to continue growing.

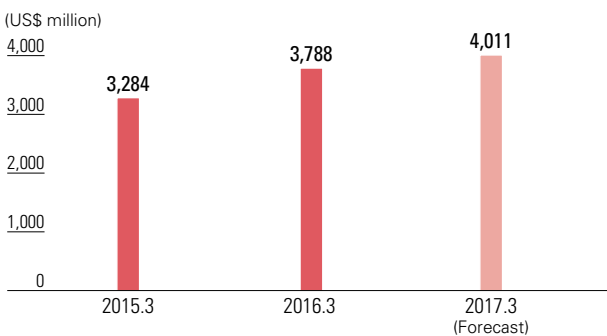


**James Robinson**  
 President, Americas Operations

### Business Environment and Strategy

In the past few years, the U.S. has implemented a series of reforms based on the Patient Protection and Affordable Care Act. And, in fiscal 2016, the impacts of these reforms on the business environment are expected to continue. In this climate, trends such as evolving benefit models focused on the value of care provided, the integration of insurance payers and medical institutions, and an increase in the medical cost outlays of patients are expected to have an

### Sales in the Americas



even larger impact on the industry.

In this environment, in fiscal 2015, we increased the sophistication of our organization to respond to entities such as large physician groups and integrated health networks (IHNs) that incorporate the management of community medical care functions and public welfare and nursing care functions. Looking ahead from a marketing perspective, we will further strengthen the leading market positions of XTANDI and Myrbetriq, along with maintaining the market position of our hospital franchise including newly launched CRESEMBA.

We know that people are crucial to anticipating and responding to the dynamic business environment. Accordingly, aiming to further enhance our competitiveness, we constantly strive to make Astellas a great place to work. To this end, we will continue working to recruit, train and retain outstanding talent; enhance diversity and inclusion further; and boost employee satisfaction.

### Fiscal 2015 Overview

Sales in the Americas amounted to US\$3,788 million, up 15.4% from the previous fiscal year on a U.S. dollar basis. When converted to yen, net sales rose by 26.1% to ¥455.1 billion.

By product, we posted US\$1,272 million in sales of XTANDI, up 58.4% year on year. In the U.S., XTANDI sales surpassed US\$1 billion for the first time, while in Canada, the reimbursement of XTANDI to chemotherapy-naïve patients was approved in all Canadian provinces. Sales of Myrbetriq continued to grow, increasing 49.8% year on year, to US\$380 million. Our share of the total prescription market for OAB treatments, including VESIcare and Myrbetriq, continued to expand. In other areas, our newest product, CRESEMBA, contributed to higher sales, in addition to the growth in sales of products such as Lexiscan.

### Fiscal 2016 Outlook

We forecast regional sales of US\$4,011 million, a year-on-year increase of 5.9% on a U.S. dollar basis. When converted to yen, the regional sales are expected to decline 3.1% to ¥441.2 billion, mainly based on the impact of foreign exchange rates.

We expect sales of XTANDI to grow. Meanwhile, total sales of OAB treatments, VESIcare and Myrbetriq, are projected to increase on a U.S. dollar basis, but these sales are expected to decrease when converted to yen, based on the impact of foreign exchange rates.



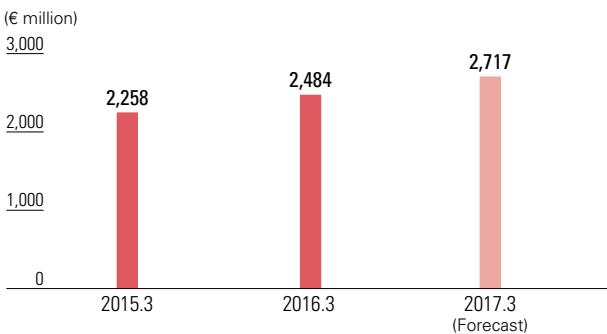
**Yukio Matsui**  
President, EMEA Operations

**Business Environment and Strategy**

In the EMEA region, many countries have adopted more stringent policies to curb medical expenditures, and there are increasing pricing, reimbursement and market access challenges.

Amid these conditions, Astellas will promptly respond to changes in the environment, while continuing to provide value to patients through innovative pharmaceuticals. Efforts are being made to execute growth strategies in

**Sales in EMEA**



major therapeutic areas, along with building optimal business models for each country. In oncology, we will work to expand sales of XTANDI, for which an indication for chemotherapy-naïve patients was approved in fiscal 2014. Moreover, we will strive to nurture OAB treatments including BETMIGA, as well as MYCAMINE, DIFICLIR, and Advagraf.

Astellas will take further steps to promote compliance activities in earnest. From fiscal 2016, the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on transparency requires new reporting obligations in many countries in the region. Compliance requirements have been increasing year after year. Therefore, Astellas will endeavor to fulfill those requirements, along with addressing compliance issues.

**Fiscal 2015 Overview**

Sales in EMEA in fiscal 2015 rose 10.0% to €2,484 million. When converted to yen, sales rose 5.1% to ¥329.3 billion.

Sales of XTANDI increased 121.3% to €533 million as a result of the approval of its expanded indication for chemotherapy-naïve patients in 10 countries in fiscal 2015. Sales of BETMIGA increased 36.0% to €101 million, with the continued expansion of the combined share of Vesicare and BETMIGA in the OAB market. Meanwhile, sales of Omnic, which goes by the brand name Harnal in Japan, through our own distribution channels decreased 10.1% on a euro basis, mainly due to the impact of generic drugs.

**Fiscal 2016 Outlook**

In fiscal 2016, we project a 9.4% increase in sales in EMEA on a euro basis to €2,717 million. This equates to ¥339.6 billion in yen terms, representing a 3.1% increase mainly based on the impact of foreign exchange rates.

Sales of XTANDI are projected to continue growing. Meanwhile, total sales of OAB treatments Vesicare and BETMIGA are expected to increase 1% on a euro basis, but decline when converted to yen based on the impact of foreign exchange rates.



## Asia & Oceania

**Masatoshi Kuroda**  
 President, Asia & Oceania Business

### Business Environment and Strategy

In the Asia & Oceania region, Astellas currently has 11 sales affiliates covering 13 countries and regions.

In terms of products, we are steadily expanding our business through high-value-added pharmaceutical products, just as in Japan, EMEA, and the U.S. We have high expectations of XTANDI and BETMIGA in particular for supporting our growth going forward.

In January 2016, we established a Malaysia-based sales

affiliate, Astellas Pharma Malaysia Sdn. Bhd., and commenced operations at the company in April 2016. Moreover, in April 2016 we established an umbrella organization to further increase both the quality and efficiency of operations in the South East and South Asia regions (SESA Umbrella Organization) in Singapore and commenced its operations. The SESA Umbrella Organization will oversee the operations of our business in Singapore, Thailand, the Philippines, Indonesia, India, Malaysia, Vietnam and Brunei.

We will further enhance our management and administration systems and continue to develop a structure for ensuring compliance. In addition, we will work to recruit and retain talented human resources and to bolster employee motivation by improving our corporate culture.

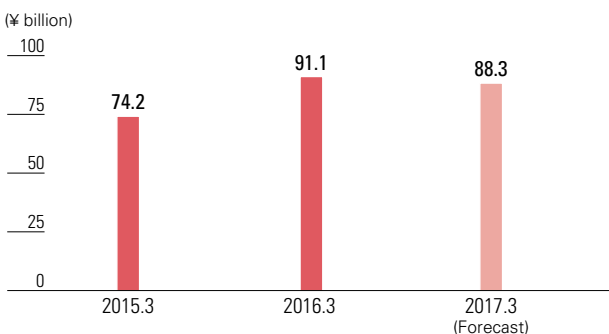
### Fiscal 2015 Overview

Sales in Asia & Oceania increased 22.8% year on year on a yen basis to ¥91.1 billion. Excluding the foreign exchange impact, sales maintained double-digit growth, up approx. 19% from the previous year.

By product, sales of products including Prograf and Harnal increased during the year. Sales growth in the OAB treatments including Vesicare and BETMIGA, as well as XTANDI, also contributed to the higher net sales.

During the year, we continued to launch many products into the markets. We commenced sales of XTANDI for patients who have received chemotherapy in the Philippines, Hong Kong/Macau, and Singapore. Additionally, we expanded the indication of XTANDI for chemotherapy-naïve patients in Republic of Korea and the Philippines. Moreover, BETMIGA was launched in Singapore, Thailand, and Malaysia, Eligard in Taiwan, Suglat in Republic of Korea, and Feburic in Thailand.

### Sales in Asia & Oceania



### Fiscal 2016 Outlook

In fiscal 2016, we project sales in Asia & Oceania of ¥88.3 billion, down 3.1% year on year. Excluding the impacts of foreign exchange rates and the dermatology business transfer, we are forecasting an increase of approx. 14% in sales.

By product, sales of XTANDI, the OAB treatments including Vesicare and BETMIGA, and MYCAMINE are expected to continue increasing. Also, sales of Prograf and Harnal are projected to expand on a local currency basis.



## Sales of Main Products by Region

### Japan

	¥ billion		
	2015.3	2016.3	2017.3 (Forecast)
<b>Sales in the Japanese market*1</b>	<b>481.7</b>	<b>483.0</b>	<b>456.6</b>
XTANDI	14.9	26.2	25.7
Vesicare	25.6	26.5	27.2
Betanis	14.8	21.2	27.4
Harnal	15.0	12.7	9.4
Prograf	48.1	49.8	47.8
Funguard	11.8	11.7	11.5
Micardis	95.7	97.2	90.8
Micombi	10.7	10.1	
Micamlo	23.8	26.0	
Celecox	41.8	46.6	50.4
Symbicort	33.0	37.4	41.1
Bonoteo	13.0	14.1	15.1
Geninax	10.4	10.8	10.2
Vaccines	38.8	41.1	25.9
ARGAMATE	5.9	6.2	6.1
Kiklin	1.5	1.6	2.0
Gonax	3.4	3.9	4.6
Cimzia	5.0	6.6	9.6
Suglat	4.1	7.3	12.5
Lipitor*2	36.7	30.9	22.4
Myslee	19.4	17.9	14.6
Gaster	18.0	14.7	10.5
Seroquel	12.6	10.5	7.2

### Americas

	US\$ million		
	2015.3	2016.3	2017.3 (Forecast)
<b>Sales in the Americas</b>	<b>3,284</b>	<b>3,788</b>	<b>4,011</b>
XTANDI	803	1,272	1,544
US	779	1,235	1,488
Outside of the US	24	37	56
Tarceva	444	389	
US	305	281	
Outside of the US	139	108	
VESIcare	559	530	488
Myrbetriq	254	380	472
Prograf and ASTAGRAF XL	301	288	245
Scan*3	603	634	637
MYCAMINE	112	109	107
AmBisome	82	91	89
CRESEMBA	-	22	45
Protopic*4	94	26	

### EMEA

	€ million		
	2015.3	2016.3	2017.3 (Forecast)
<b>Sales in EMEA</b>	<b>2,258</b>	<b>2,484</b>	<b>2,717</b>
XTANDI	241	533	767
Eligard	136	131	138
Vesicare	305	300	259
BETMIGA	74	101	146
Omnice	159	139	127
Sales by Astellas	130	116	109
Bulk and royalties	30	23	18
Prograf and Advagraf	588	609	609
Sales by Astellas	560	588	589
Advagraf	207	234	
Exports to third parties	28	21	20
MYCAMINE	74	85	90
Protopic*4	56	58	
QUTENZA	13	16	
DIFICLIR	14	20	

### Asia & Oceania

	¥ billion		
	2015.3	2016.3	2017.3 (Forecast)
<b>Sales in Asia &amp; Oceania</b>	<b>74.2</b>	<b>91.1</b>	<b>88.3</b>
Prograf	32.0	38.4	37.1
Harnal	18.3	21.5	20.5
Vesicare	5.3	5.3	5.4
BETMIGA	0.2	1.4	2.8
MYCAMINE	4.4	5.7	6.0
Protopic*4	3.4	4.6	
XTANDI	0.6	2.4	4.5
Eligard	0.1	0.2	0.3

\*1 Sales of products in Japan are shown on a gross sales basis.

\*2 Transferred distribution for Caduet to Pfizer Japan Inc. on April 1, 2015. Results for the previous fiscal year represent sales excluding Caduet.

\*3 Sales of Adenoscan and Lexiscan

\*4 Transferred the global dermatology business, including Protopic, to LEO Pharma A/S on April 1, 2016.

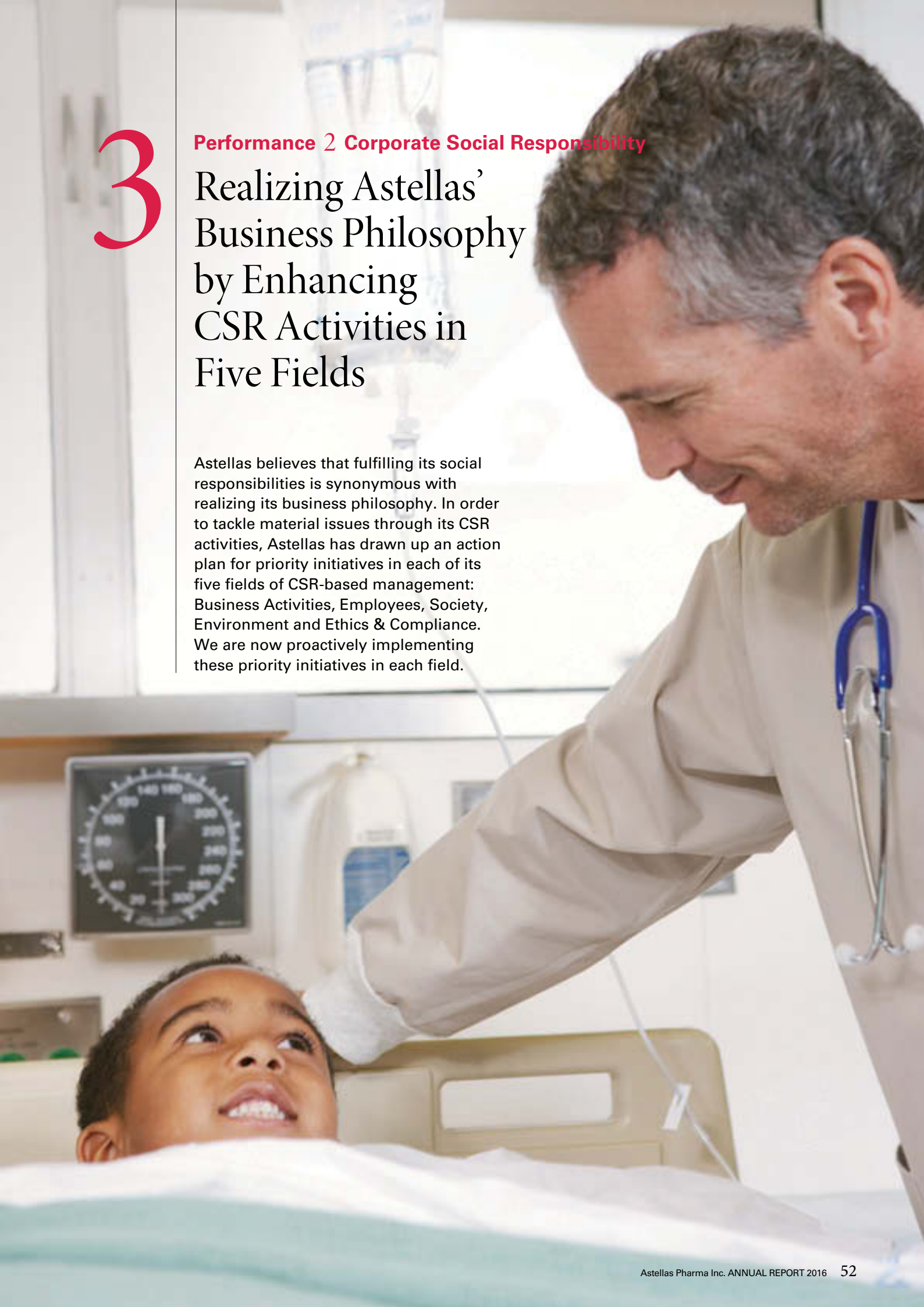


# 3

## Performance 2 Corporate Social Responsibility

### Realizing Astellas' Business Philosophy by Enhancing CSR Activities in Five Fields

Astellas believes that fulfilling its social responsibilities is synonymous with realizing its business philosophy. In order to tackle material issues through its CSR activities, Astellas has drawn up an action plan for priority initiatives in each of its five fields of CSR-based management: Business Activities, Employees, Society, Environment and Ethics & Compliance. We are now proactively implementing these priority initiatives in each field.



# Overview of CSR Activities

## Five Fields of CSR-Based Management

Astellas has established five fields of CSR-based management: Business Activities, Employees, Society, Environment, and Ethics & Compliance. Notably, we not only consider laws and regulations, but also conduct our corporate activities with the highest ethical standards. We consider this Ethics & Compliance field to be the cornerstone of all our activities.

\* Ethics & Compliance: The "Compliance" field, as shown previously, has been renamed as the "Ethics & Compliance" field with emphasis on encompassing the notion of conducting corporate activities based on the highest ethical standards.

## Identification and Prioritization of Material Issues in CSR Activities

Astellas identifies and prioritizes material issues in CSR activities, and uses these material issues to guide its CSR-based management.

Referring to various principles and guidelines, Astellas has identified material issues from among the issues to be addressed as prerequisites of its business activities, and social priorities including global issues related to medical care and health.

Making reference to expectations and requests from a broad range of stakeholders, we classified and prioritized the material issues into three categories by evaluating their social significance and relevance to our business (CSR Materiality Matrix). We are working to address material issues based on concrete action plans for initiatives we must intensively execute.

## Five Fields of CSR-Based Management



### Business Activities

Business activities from research and development (R&D) of new drugs through to production and marketing while fulfilling our social responsibility

### Employees

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

### Society

Initiatives aimed towards contributing to society with a focus on issues related to human health

### Environment

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

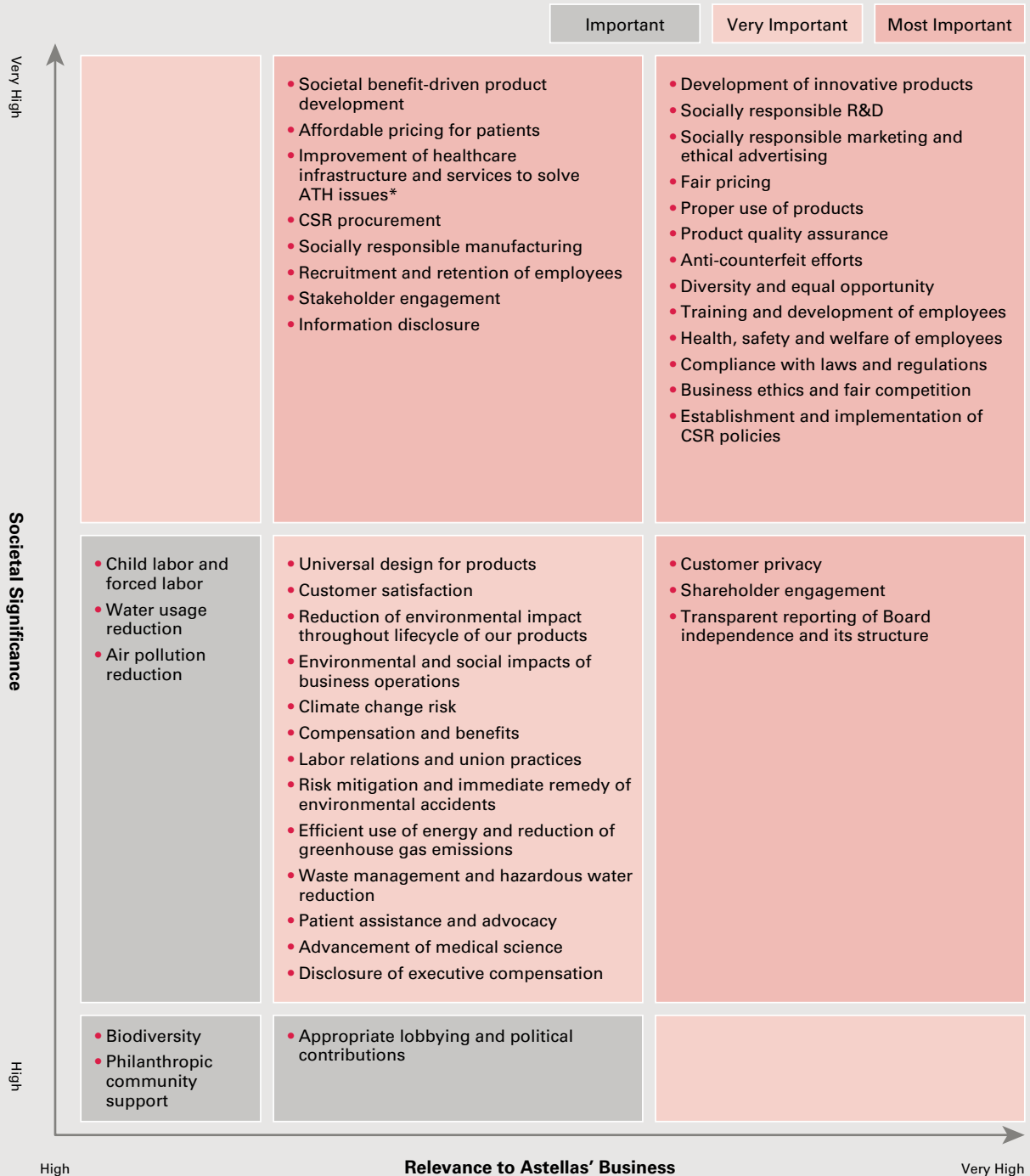
### Ethics & Compliance

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

### CSR Materiality Matrix

For more details, please refer to

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



\* ATH issues: There are many people with insufficient access to the healthcare they need due to the lack of available treatments, poverty, challenges in healthcare systems and limited healthcare information. Astellas recognizes this problem as the Access to Health issue and works to improve Access to Health by engaging in various initiatives.

## CSR Activities: Results and Plans

To solve material issues through its CSR activities, Astellas identifies priority activities in each field of CSR management every year based on their materiality and attainment level, along with monitoring the results of these activities.

In addition, we determine the activities to be undertaken in the following fiscal year based on progress with initiatives, changes in society and other factors.

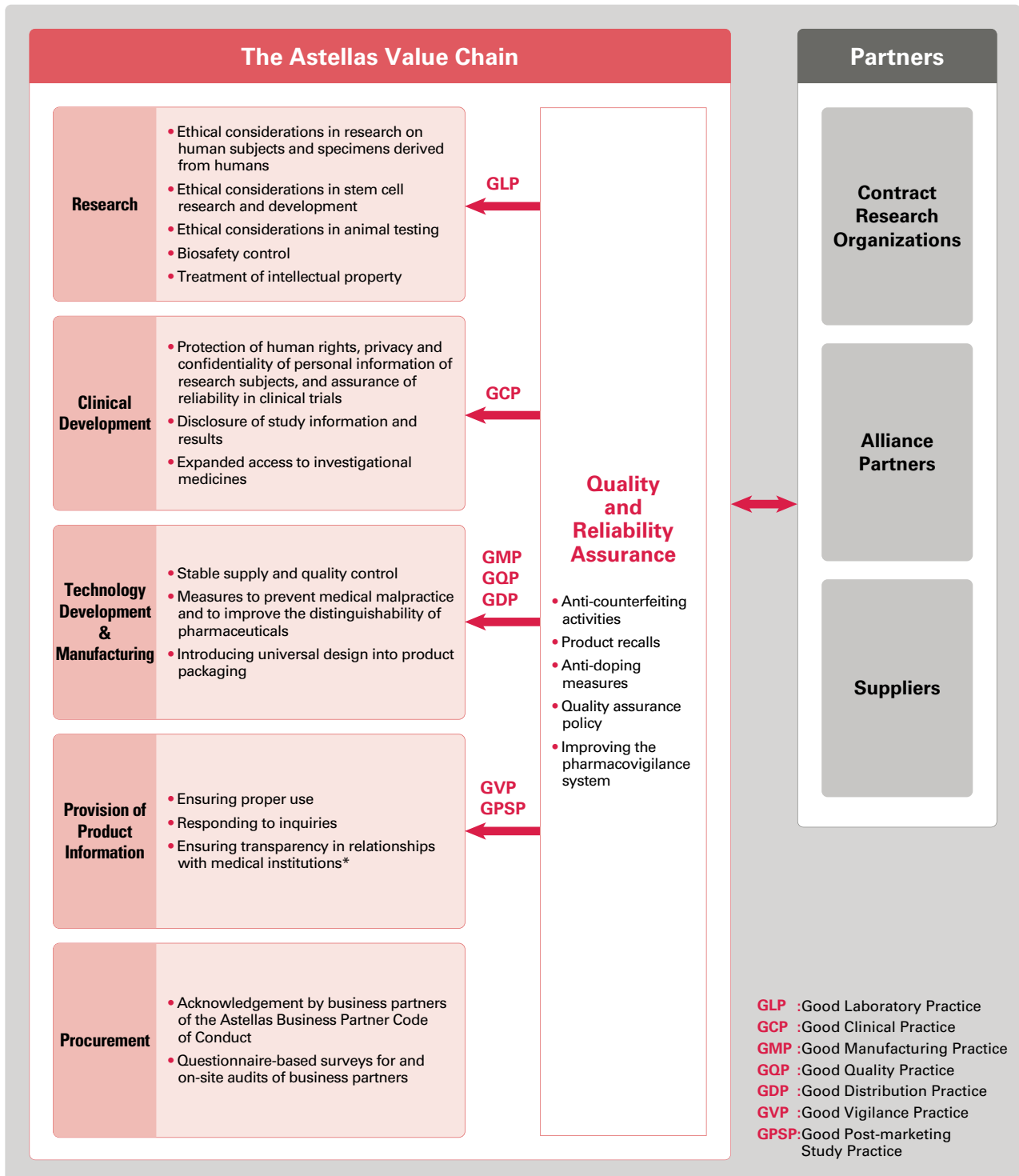
Field of CSR-based Management	Review of Fiscal 2015 Initiatives	
	Main Activities and Results	Relevant Material Issues
<b>Business Activities</b>	<ul style="list-style-type: none"> <li>• Compiled Position on Expanded Access to Investigational Medicines</li> <li>• Supported the doping prevention activities of the World Anti-Doping Agency</li> <li>• Expanded the scope of education and training programs on the safety of pharmaceutical products to all employees including contractors of affiliates</li> </ul>	<ul style="list-style-type: none"> <li>• Improvement of healthcare infrastructure and services to solve Access to Health issues</li> <li>• Socially responsible R&amp;D</li> <li>• Proper use of products</li> </ul>
<b>Employees</b>	<ul style="list-style-type: none"> <li>• Formulated a medium- to long-term plan and targets for improving the ratio of female managers at Astellas Pharma Inc.</li> <li>• Conducted engagement surveys which include globally common questionnaires in Japan, the Americas, EMEA and Asia &amp; Oceania</li> </ul>	<ul style="list-style-type: none"> <li>• Diversity and equal opportunity</li> <li>• Recruitment and retention of employees</li> </ul>
<b>Society</b>	<ul style="list-style-type: none"> <li>• Signed a new collaborative research agreement with the National Institute of Advanced Industrial Science and Technology to discover anti-protozoan parasite drugs for the treatment of Chagas disease, one of the neglected tropical diseases</li> <li>• Signed a new collaborative development agreement with the Institute of Medical Science, the University of Tokyo on a rice-based oral vaccine against diarrheal diseases caused by cholera and enterotoxigenic <i>Escherichia coli</i></li> <li>• Continued to implement Changing Tomorrow Day with attendance of more than 7,400 employees worldwide</li> </ul>	<ul style="list-style-type: none"> <li>• Societal benefit-driven product development</li> <li>• Philanthropic community support</li> </ul>
<b>Environment</b>	<ul style="list-style-type: none"> <li>• Greenhouse gas (GHG) emissions came to 162,000 tons, down 30.8% from the fiscal 2005 level. (Global target: reduce GHG emissions by 35% or more from the fiscal 2005 level by the end of fiscal 2020)</li> <li>• Water withdrawal amounted to 10,269 m<sup>3</sup>, 76.3% of the level in fiscal 2005, achieved the global target. (Global target: reduce water withdrawal to 80% or less of the fiscal 2005 level by the end of fiscal 2015)</li> <li>• Biodiversity Index came in at 3.18 times the figure recorded in fiscal 2005, achieved the global target. (Global target: raise the Index to triple the fiscal 2005 level by the end of fiscal 2020)</li> <li>• All other reduction targets for the end of fiscal 2015 (CO<sub>2</sub> emissions from sales fleets, electricity usage at our offices, the final volume of landfill waste, and the amount of volatile organic compounds (VOCs) discharged) were achieved.</li> </ul>	<ul style="list-style-type: none"> <li>• Efficient use of energy and reduction of GHG emissions</li> <li>• Water usage reduction</li> <li>• Biodiversity</li> </ul>
<b>Ethics &amp; Compliance</b>	<ul style="list-style-type: none"> <li>• Established global policies including rules on harassment, data privacy, and medical affairs and commercial activities</li> <li>• Ongoing implementation of compliance training on harassment, data privacy, anti-corruption and anti-bribery, and other areas</li> <li>• Established a structure for providing appropriate medical and product information</li> <li>• Promoted compliance management among third parties</li> </ul>	<ul style="list-style-type: none"> <li>• Customer privacy</li> <li>• Business ethics and fair competition</li> <li>• Compliance with laws and regulations</li> </ul>

Page in Annual Report	Activities to be Tackled in Fiscal 2016
<ul style="list-style-type: none"> <li>➤ P.60 Expanded Access to Investigational Medicines</li> <li>➤ P.61 Anti-doping Measures</li> <li>➤ P.61 Improving the Pharmacovigilance System</li> </ul>	<ul style="list-style-type: none"> <li>• Announce Position on Expanded Access to Investigational Medicines</li> <li>• Further strengthen the quality assurance system</li> <li>• Promote anti-doping activities</li> <li>• Globally operate a new medical information system for responding to inquiries</li> </ul>
<ul style="list-style-type: none"> <li>➤ P.64 Strengthening Competitiveness</li> <li>➤ P.65 Improving Employee Satisfaction</li> </ul>	<ul style="list-style-type: none"> <li>• Promote various measures aimed at encouraging women's success in Japan</li> <li>• Make preparations to conduct a globally common engagement survey</li> </ul>
<ul style="list-style-type: none"> <li>➤ P.67 Collaborative Research to Discover Anti-protozoan Parasite Drugs</li> <li>➤ P.67 Collaborative Research on a Rice-Based Oral Vaccine</li> <li>➤ P.69 Group-Wide Volunteer Activities Changing Tomorrow Day</li> </ul>	<ul style="list-style-type: none"> <li>• Promote collaborative research to discover anti-protozoan parasite drugs for the treatment of Chagas disease</li> <li>• Promote collaborative research of a rice-based oral vaccine</li> <li>• Continue implementation of Changing Tomorrow Day</li> </ul>
<ul style="list-style-type: none"> <li>➤ P.72 Initiatives for Realizing a Low-Carbon Society</li> <li>➤ P.73 Initiatives for Resource Recycling</li> <li>➤ P.74 Initiatives for Biodiversity</li> </ul>	<ul style="list-style-type: none"> <li>• Continue initiatives to achieve the Environmental Action Plan targets (Numerical targets for the end of fiscal 2020: Reduce GHG emissions and improve the Biodiversity Index) (Numerical targets added due to revisions based on results for fiscal 2015: Increase water resources productivity and reduce waste discharge per unit of sales)</li> </ul>
<ul style="list-style-type: none"> <li>➤ P.75 Promoting Compliance Globally</li> <li>➤ P.77 Delivering Appropriate Medical and Product Information</li> <li>➤ P.77 Anti-bribery/Anti-corruption Initiatives</li> </ul>	<ul style="list-style-type: none"> <li>• Revise the Code of Conduct</li> <li>• Formulate and develop various global policies</li> <li>• Continue to implement compliance training</li> </ul>

# Responsible Business Activities

Astellas is committed to fulfilling its social responsibilities in the course of conducting business activities, aiming to contribute to improving the health of people around the world. We respect human rights in every stage of our value

chain, from research and development to the provision of information regarding our products. We also strive to ensure compliance with the Pharmaceutical and Medical Device Act and other relevant laws and regulations.



\*Reference | Delivering Appropriate Medical and Product Information ➤ P77



## Research

### Ethical Considerations in Research on Human Subjects and Specimens Derived from Humans

Astellas conducts research on human subjects, and obtains and conducts research on specimens derived from humans after appropriately obtaining the consent of the trial subjects in accordance with the Helsinki Declaration\* as well as the laws, regulations and guidelines of relevant countries.

In Japan, Astellas provides training for researchers in areas such as bioethics, genomic research and clinical studies, based on a strong commitment to respecting the human rights of research subjects, protecting privacy and ensuring the reliability of research. In addition, Astellas has the Astellas Research Ethics Committee, comprising 10 members of both genders, including 5 outside members. The committee fairly and impartially determines the ethical acceptability and scientific propriety of research plans, including perspective from information on potential conflicts of interest on the part of research institutions, researchers and other parties. In fiscal 2015, the committee met 10 times and deliberated on 34 issues.

\* Helsinki Declaration: A statement of ethical principles for medical research involving human subjects, addressed to physicians and others who are involved in medical research on human subjects.

### Ethical Considerations in Stem Cell Research and Development

Astellas believes that there is a possibility of supplying new stem cell-based treatment methods to address diseases that previously had no known treatment methods. To achieve this, Astellas is advancing research and development activities focused on using stem cells in therapy.

Astellas also recognizes that research into human stem cells could give rise to concerns that warrant close examination. In particular, Astellas is fully aware of the necessity to pay full attention to the social and bioethical issues associated with research using human embryonic stem cells (ES cells).

Based on these principles and awareness, Astellas has established its "Policy on Human Stem Cell Research and Development\*," which sets forth the basic matters it must comply with in the course of conducting human stem cell research and development. Specifically, in all of its research and development activities involving human stem cells, Astellas will comply with the relevant laws, ordinances and regulations of the countries and regions where it undertakes these research and development activities. Moreover, Astellas will set up a committee comprising internal and external experts, from which it will obtain oversight and advice on the ethical aspects and the scientific legitimacy and merit of these research and development activities. All the proposals on research and development programs involving human stem cells will be

reviewed and approved by the committee to ensure that these research and development activities are implemented ethically and in line with a legitimate scientific purpose. Furthermore, when establishing and using human ES cells, Astellas will take steps to satisfy the ethical standards established by the world's major scientific authorities, including the guidelines laid out by the National Academy of Sciences of the United States of America.

\* For details, please visit the following website:  
[https://www.astellas.com/en/corporate/comp\\_policy/policy.html](https://www.astellas.com/en/corporate/comp_policy/policy.html)

### Ethical Considerations in Animal Testing

Astellas has established a Global Policy for Animal Care and Use, and conducts animal testing based on this policy. We have established the Corporate Institutional Animal Care and Use Committee, in which outside members participate as committee members, at our animal testing facilities.

Astellas' initiatives in animal testing are recognized by AAALAC International\*. As a result, all of our animal testing facilities have acquired accreditation from AAALAC International.

\* AAALAC International: The Association for Assessment and Accreditation of Laboratory Animal Care International. An organization that promotes the humane treatment of animals through voluntary accreditation and assessment programs. Studies are undertaken from both scientific and ethical standpoints to verify the quality of animal control and use programs.

### Biosafety Control

Astellas performs experiments using genetically modified organisms, or materials containing pathogens, under the World Health Organization Laboratory Biosafety Manual\*<sup>1</sup> and the Centers for Disease Control and Prevention / National Institute of Health Biosafety in Microbiological and Biomedical Laboratories\*<sup>2</sup>, as well as the laws of individual countries.

In Japan, Astellas has established biosafety management rules in compliance with the Cartagena Act\*<sup>3</sup> and related ministerial ordinances, and has detailed procedures in place for handling experimental materials. In addition, we have set up the Biosafety Committee as a body to review whether the experiments meet the standard required by these rules. In addition, laboratory personnel receive regular training courses once a year (995 participants in fiscal 2015), in order to rigorously enforce safe and proper biosafety management and use of these organisms and suchlike.

In the U.S., we use such experimental materials based on the rules established by the occupational health and safety authorities.

\*1 Laboratory Biosafety Manual 3rd Edition

\*2 Biosafety in Microbiological and Biomedical Laboratories 5th Edition

\*3 Cartagena Act: Law concerning the conservation and sustainable use of biological diversity through regulations on the use of living modified organisms.

**Treatment of Intellectual Property**

Astellas believes that appropriately protecting intellectual property is crucial to maintaining our competitive advantage to address unmet medical needs.

Intellectual property includes any creative works that may be protectable by intellectual property laws, such as patents, trademarks, trade secrets, copyrights, and know-how. Astellas has established a Policy on Intellectual Property\*<sup>1</sup>.

Considering the importance of improving Access to Health, Astellas is committed to not filing nor enforcing patents in select countries with significant economic challenges. These select countries are decided by referring to those designated as Least Developed Countries (LDCs) defined by the United Nations or Low Income Countries (LICs) defined by World Bank. Astellas is also committed to considering the licensing of patents in other developing countries on a case-by-case basis\*<sup>2</sup>.

**Policy on Intellectual Property**

1. In light of its importance to Astellas, appropriate steps, including compliance with all applicable laws and regulations, shall be taken to protect and maintain Astellas' intellectual property. Additionally, Astellas' intellectual property shall be used in an appropriate manner to enhance corporate value.
2. Astellas employees must promptly report any inventions or other creative works that could qualify for intellectual property protection made in the course of their work for Astellas. Astellas retains the right in such inventions or creative works in accordance with applicable laws and Astellas' policy.
3. Since the premature disclosure of an invention may preclude our ability to obtain patent protection, Astellas employees must use due care to avoid the intentional or inadvertent disclosure of patentable inventions.
4. Astellas respects the valid and enforceable intellectual property rights of others and takes necessary measures to avoid infringement.

\*1 For details, please visit the following website:  
[https://www.astellas.com/en/corporate/comp\\_policy/property.html](https://www.astellas.com/en/corporate/comp_policy/property.html)

\*2 For details, please visit the following website:  
[https://www.astellas.com/en/corporate/comp\\_policy/ip.html](https://www.astellas.com/en/corporate/comp_policy/ip.html)

**Clinical Development**

**Protection of Human Rights, Privacy and Confidentiality of Personal Information of Research Subjects, and Assurance of Reliability in Clinical Trials**

In clinical trials, we investigate new drug candidates developed through drug discovery research in further detail, and assess the efficacy and safety of the new drug candidates in patients.

Under the Declaration of Helsinki, clinical trials must be ethically planned and safely conducted with full consideration to protecting the human rights and privacy of clinical trial subjects. Furthermore, it is crucial to conduct assessments in clinical trials scientifically and accurately in order to develop new drug candidates into drugs that can be used confidently by patients.

Accordingly, Astellas has a clinical development framework in place to ensure compliance with GCP and relevant laws and regulations. Moreover, our clinical trials are conducted only at medical institutions complying with relevant laws and regulations.

Astellas has established governance committees inside the Company that evaluate the ethical acceptability and scientific validity of clinical studies from their planning phases. In addition, prior to initiating a clinical trial, Astellas obtains an approval from an Institutional Review Board independent of the Company, after the board evaluates the clinical trial from the perspectives of ethical acceptability and scientific validity. Furthermore, we implement education and training for employees and other staff members who are involved in clinical trials, and monitor medical institutions that perform trials to ensure that clinical trials are administered properly in line with GCP. In the course of performing clinical trials, Astellas confirms that clinical trial subjects have provided their informed consent to participating in clinical trials, i.e., they have given their consent based on a full explanation of the purpose and methods of the trial, the expected benefits and disadvantages, matters related to compensation for health impairment and other details. Moreover, we properly administer the trial data so as to protect the privacy and confidentiality of the personal information of clinical trial subjects. We regularly confirm that outsourced clinical trials are conducted based on the same standards.

## Disclosure of Study Information and Results

In order to enhance the transparency of clinical study information in conjunction with maximizing its value and ensuring that it leads to the advancement of science and promotion of innovation, Astellas has drawn up a global policy on the disclosure of clinical trial information and results<sup>\*1</sup>. This policy provides a detailed description of Astellas' basic point of view on enhancing accessibility to clinical study data and related study results, such as the registration of clinical trial information, disclosure of clinical trial results, and disclosure of study data to scientists and healthcare professionals.

More specifically, Astellas provides patient level data anonymized in accordance with the applicable laws and regulations to scientists and healthcare professionals who requested the data through an external website<sup>\*2</sup>. In addition, we disclose summaries of study results through an Astellas website<sup>\*3</sup> to enable doctors and the general public to access them, along with working to build a website that will give patients access to summaries of study results prepared for non-experts.

\*1 For details, please visit the following website:

[https://www.astellas.com/en/corporate/comp\\_policy/clinicalstudies.html](https://www.astellas.com/en/corporate/comp_policy/clinicalstudies.html)

\*2 Patient level data are provided through the following website:

<http://www.clinicalstudydatarequest.com>

\*3 Summaries of study results are disclosed on the following website:

<http://www.astellasclinicalstudyresults.com/Welcome.aspx>

## Expanded Access to Investigational Medicines

Astellas has set forth its approach to supplying investigational medicines to patients for purposes other than clinical studies in its Position on Expanded Access to Investigational Medicines<sup>\*</sup>.

Astellas recognizes that patients with serious or life threatening diseases may have exhausted all of their available treatment options, may not qualify for a clinical trial and may seek access to investigational medicines. In these cases, in response to a request for investigational medicines from a primary physician, Astellas fairly, impartially and rapidly evaluates whether or not the patient meets the required conditions and commits to establishing an expanded access plan as appropriate. The expanded access program will target countries where the clinical development of an investigational medicine is progressing and the drug is scheduled to obtain approval. Moreover, this procedure will be implemented in accordance with the regulations of the country where expanded access is requested.

\* For details, please visit the following website:

[https://www.astellas.com/en/corporate/comp\\_policy/ea\\_to\\_im.html](https://www.astellas.com/en/corporate/comp_policy/ea_to_im.html)

## Quality and Reliability Assurance

### Anti-counterfeiting Activities

The World Health Organization (WHO) defines a counterfeit medicine as follows: "A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source." These counterfeit medicines in legitimate supply chains not only leads to the loss of opportunities for patients to receive medical treatment, but could also have serious health consequences. Counterfeit medicines have therefore become a serious problem worldwide.

Astellas operates the Anti-Counterfeit Committee, led by the technology and quality assurance divisions, and has a product security division. Through these organizations, Astellas conducts monitoring, surveys, and countermeasures targeting not only counterfeit medicines, but also diversion, smuggling, theft and other such activities. When selling products, Astellas systematically introduces effective anti-counterfeit technologies, including serialization stipulated by regulations, based on pharmaceutical laws and regulations and risks in each market where products are sold, as well as product characteristics.

Moreover, Astellas works to gather information and implement other countermeasures in collaboration with the relevant authorities and pharmaceutical companies worldwide. One example is Astellas' participation in the activities of the PSI<sup>\*</sup>. Moreover, Astellas carries out educational activities to prevent the spread of counterfeit medicines in collaboration with members of the pharmaceutical industry and international organizations such as the WHO, as well as the PSI and the Transported Asset Protection Association. We also proactively endeavor to support and cooperate with national governments, judicial authorities and others, to crack down on counterfeit medicines.

\* PSI: Pharmaceutical Security Institute. PSI is a not-for-profit organization, founded in response to need to strengthen the anti-counterfeiting effort. Currently, PSI membership includes 33 pharmaceutical manufacturers from many nations.

### Product Recalls

Astellas has a recall system in place that is activated when the safety, efficacy or quality of a product is brought into question. The system ensures that relevant information is promptly passed on to medical institutions and other affected parties, and that a recall of the product in question is instigated. If an event affecting safety, efficacy or quality occurs, an internal committee is convened to assess the risk posed to patients, and a decision on a product recall is made based on the judgment of the committee.

In fiscal 2015, Astellas initiated three voluntarily product recalls. As of June 2016, we have not received any reports of health impairment related to these recalls.

## ■ Anti-doping Measures

Doping is an issue closely related to abuse and misuse of medicines in sports. It is a serious priority for the pharmaceutical industry given that it is not only associated with a risk of inducing serious side effects, but it can also become a breeding ground for the unauthorized distribution and counterfeiting of medicines.

To contribute to the eradication of doping and improvement of public health, in July 2016 Astellas is in discussions with the World Anti-Doping Agency (WADA) to reach an agreement on a prospectus for supplying the relevant information on the compounds under development that have the potential for being used in doping.

Additionally, Astellas is working to identify the compounds under development that have the potential to be used in doping and to prevent the misuse of those compounds.

## ■ Quality Assurance Policy

Astellas has set forth global policies concerning quality assurance in the Astellas Quality Assurance Manual. Based on this manual, we prepare guidelines and standard operating procedures concerning quality assurance systems and operational management and procedures for a variety of quality assurance related activities at the global, regional and national levels. Education and training programs are implemented to promote understanding and awareness of these matters.

These documents are revised periodically and as necessary. We respond swiftly to developments in the external environment, such as regulatory changes and amendments.

## ■ Improving the Pharmacovigilance System

Astellas is continuously improving the pharmacovigilance system by strengthening collaboration between the pharmacovigilance organization and other relevant departments, affiliates and licensing partners. This is to support provision of trustworthy products and the proper use of those products, along with addressing regulatory requirements.

In 2015, Astellas broadened the scope of training related to the handling of information concerning the safety of Astellas products from the staff closely involved with the PV system, to all employees including contractors of affiliates. Moreover, working closely with the

departments responsible for contracts and outsourcing, Astellas clarified the required conditions for pharmacovigilance activities and established the mechanism to reflect those conditions in contracts between external service providers and departments other than the pharmacovigilance organization, as necessary.

Through these and other activities, Astellas strives to undertake responsible pharmacovigilance activities on a global, Company-wide basis.

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## Technology Development & Manufacturing

### ■ Stable Supply and Quality Control

In drug manufacturing, we place the highest priority on ensuring a stable supply of safe and effective pharmaceuticals to patients. To ensure this, we have established our own quality standards in compliance with GMP and also meeting our high expectations to products' quality. We apply these standards to manufacturing facilities and equipment, as well as all stages from the procurement of raw materials through to storage, manufacturing processes and shipments. We are also working to improve packaging designs for patients and healthcare professionals to reduce the risk of any misuse of medicines.

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### ■ Measures to Prevent Medical Malpractice and to Improve the Distinguishability of Pharmaceuticals

Astellas strives to supply products from the users' perspective to ensure that healthcare professionals and patients do not mistake one pharmaceutical for another. We are working to prevent medical malpractice in this respect, through measures including printing product names directly on capsules and tablets, as well as printing product names and dosage on packaging sheets (blister sheets) so that the product name and dosage can be easily identified even after the blister sheet is split apart.

To prevent misreading of labeling on blister sheets, Astellas also endeavors to make products easier to identify visually by adopting easily discernible colors and font types for the blister sheets of certain products.

## Introducing Universal Design into Product Packaging

We have introduced universal design to certain product packaging. For example, the universal design packaging of Bonoteo 50 mg tablets, which is administered once every 4 weeks, features packaging with good openability. To prevent patients from forgetting to take the drug, there is an area provided on the packaging to write in the day when the drug should be taken. A small label to be used as a calendar is also attached. In addition, the packaging uses a universal design font type for easy reading.



Universal design packaging of Bonoteo 50mg tablets

## Provision of Product Information

### Ensuring Proper Use

Astellas' Medical Representatives (MRs) and Medical Science Liaisons (MSLs) gather and provide information to ensure that pharmaceutical products are used properly. MRs and MSLs observe high ethical standards. At the same time, MRs and MSLs make compliance their top priority, observing the Astellas Group Code of Conduct, local codes of conduct, and the relevant laws and regulations in each country.

In addition to providing information on the accurate and appropriate use of our products and possible adverse effects, our MRs supply the latest knowledge and findings on diseases associated with our products to people on the medical front lines. In these ways, they contribute to the treatment of patients. Our MSLs work to ascertain the treatment-related needs of healthcare professionals by engaging in in-depth discussions based on medical and scientific principles.

## Responding to Inquiries

Astellas believes that it has a responsibility to provide accurate medical information in response to inquiries from patients and medical professionals. By fulfilling this responsibility, Astellas seeks to assist with the safe and effective use of our products.

In countries throughout the globe, we have Medical Information Call Centers that respond to a variety of inquiries. In larger call centers, we have systems that allow for 24-hour responses to urgent inquiries, even on business holidays. Systems are also in place to ensure the continuation of the centers' functions in emergency situations, such as in the event of natural disasters. In fiscal 2015, we responded to approximately 135,000 calls.

Astellas makes continuous efforts to improve its medical information services, with the aim of providing accurate, appropriate and consistent information. As part of these efforts, in March 2015 Astellas launched a new global medical information system where global content can be developed and shared. The new system will document responses from affiliates around the world, enabling this information to be viewed on a global basis. The new system is also useful for analyzing matters of high interest based on inquiries or about which there is insufficient information. By sharing the findings of this analysis with the relevant departments, Astellas seeks to more accurately address the requests of patients and medical professionals.

## Procurement

### Promoting CSR Procurement

Astellas considers it important to fulfill its social responsibility across the entire supply chain, including suppliers. To achieve this goal, Astellas has formulated the Astellas Business Partner Code of Conduct, which requires business partners to do their business in accordance with CSR measures. We also conduct global questionnaire-based surveys based on the Code, along with requesting our business partners to sign off on the Acknowledgement of Astellas Business Partner Code of Conduct. As of March 31, 2016, we had obtained survey responses from approximately 800 companies, covering suppliers of direct materials, as well as major suppliers of indirect materials and major facility and equipment suppliers.

Furthermore, we conduct on-site audits of suppliers in countries that pose a high CSR procurement risk.



# Employees

Astellas employees play the most valuable role in shaping the Company and creating new levels of corporate value. Astellas is encouraging every employee to embrace the approach of demonstrating leadership and proactively working to shape the Company. Astellas is working to strengthen its competitiveness through initiatives for promoting diversity and fostering global human resources. In addition, Astellas is fostering a corporate culture that aims to align the aspirations of its diverse global employees in one direction to realize its business philosophy.

Astellas employees are one of our most important stakeholders as well. To this end, the Company is committed to fulfilling its corporate social responsibilities to employees.

## HR Vision

In 2015, Astellas formulated a new corporate vision. As set forth in our corporate vision, in order to turn innovative science into value for patients at the forefront of healthcare change, we believe that business strategies must be underpinned by human resources and organizational capabilities. That is why we have drawn up a new Human Resources (HR) Vision. Astellas has defined its aspirations for its human resources and organizational capabilities, along with the support structure needed for both of these elements, as a globally aligned, common approach.

## One Astellas with the Astellas Way

Under the HR Vision, we have enshrined our aspirations for human resources and organizations in the phrase “One Astellas with the Astellas Way.” Guided by the shared values laid out in the Astellas Way, we will bring together individuals from diverse backgrounds within the Company to surmount national, regional and organizational barriers, foster mutual respect, enhance our organizational capabilities, and unite our people to continuously achieve innovation.

### The Astellas Way — Five Messages for One Astellas —



**Patient Focus:**

Ask yourself if your decisions and actions contribute to improving patient health.



**Ownership:**

Embrace change and always challenge by taking ownership.



**Results:**

Commit to results each time you face a challenge, and consider fresh approaches to achieving them.



**Openness:**

Maximize your creativity through diversity and open communication.

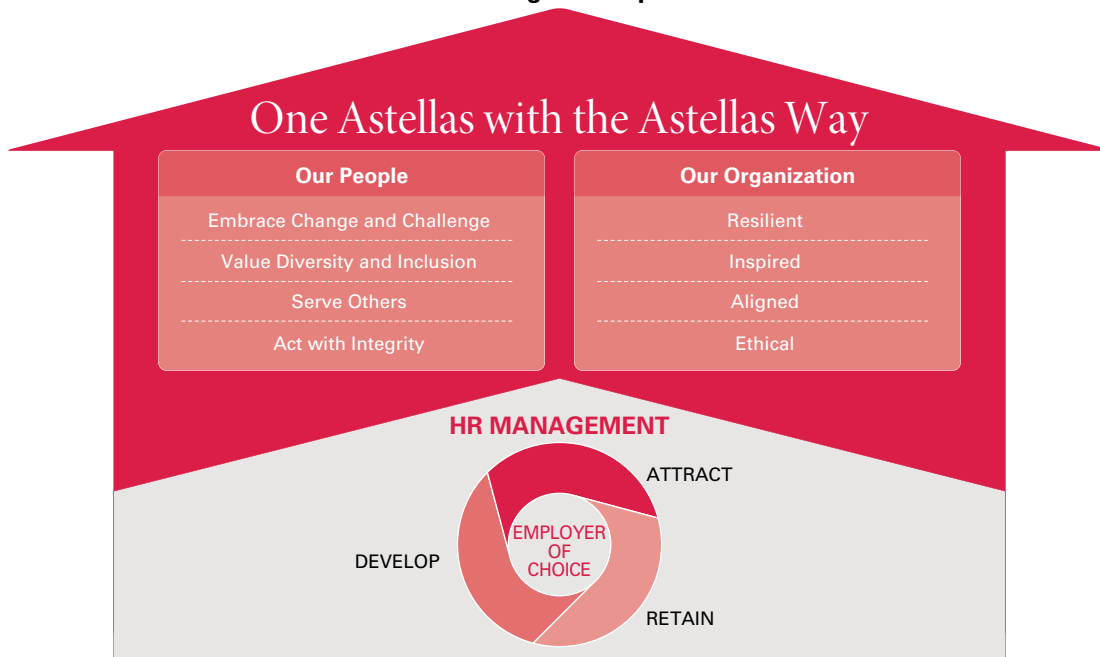


**Integrity:**

Act with integrity by always considering the implications of your actions, and then take responsibility for the outcomes.

## Overview of the HR Vision

### Towards Realizing the Corporate Vision





## Our People and Our Organization

With the formulation of the HR Vision, we revised the details of our aspirations for our human resources and organizations and organized these concepts into the specific framework shown on the previous page.

## HR and Organizational Management

Our HR and organizational management revolve around a virtuous cycle of attracting, retaining and developing personnel to ensure that we remain an employer of choice among our employees.

## Strengthening Competitiveness

### Diversity Management

Astellas is working to promote diversity so that diverse people can play a role in our company, irrespective of race, nationality, gender, or age. Respect for the diverse values of our employees will be reflected in various ways in our business activities to encourage creativity in our organization. We also believe that it will help to attract talented people as employees and enhance our competitiveness.

Promoting the career advancement of women in Japan is a high priority particularly because the country has a low ratio of women in management positions compared to many other parts of the world. We aim to develop a work environment in which life events will not hinder career advancement, and have established a target to raise our ratio of female managers in Japan to 10% or higher by 2020 on a non-consolidated basis. Employee benefit programs and work environments are being upgraded, while our people are striving to improve their awareness of diversity, to achieve this goal.

### Male/Female Employee Ratio per Region and Ratio of Female Managers (Fiscal 2015)

	Japan	Americas	EMEA	Asia & Oceania	Total
Male	72.5%	48.0%	42.4%	47.5%	56.5%
Female	27.5%	52.0%	57.6%	52.5%	43.5%
Ratio of female managers	7.4%	52.2%	49.2%	42.8%	32.2%

## Providing Opportunities for Employees to Succeed Globally

Astellas provides employees with opportunities to succeed globally. In Japan, we have developed an internal recruitment system to revitalize our organization and motivate employees to develop their own abilities and grow, while encouraging our people to succeed in roles at various overseas bases by proactively appointing employees to be assigned abroad from each division. In addition, we accept long-term and short-term assignees from Group companies outside Japan. In these and other ways, we are working to promote global interaction among our people at the divisional level.

## New Human Resource Program in the Research Divisions

In April 2016, Astellas launched a new program in its research divisions to encourage the creation of innovation from a personnel perspective. Under this program, we have set up three tracks to serve as career paths for researchers, in order to support their growth.

The track that seeks to realize innovative ideas has been designated as the Principal Investigator (PI) track. The system works by having researchers apply, pass a screening process and become designated as PIs. The goal of this program is to encourage researchers to ambitiously develop new ideas that were difficult to take on under existing systems. Researchers who obtain the PI designation will be given a certain degree of discretionary authority for personnel and budgets to initiate the development of drug development processes considered indispensable for incorporating cutting-edge science and technologies into research. Those with PI designation will also be expected to produce concrete R&D results in a timely manner.

Apart from this, Astellas will also provide a track to develop a high degree of expertise following a similar process of screening and designation. There will also be a track to pursue management roles in research. Research personnel will be able to freely revise their career tracks as they proceed with the career development process as many times as they wish.

By putting in place a personnel system that is consistent with the overall direction of the research divisions, we aim to pursue cutting-edge research based on our Best Science, Best Talent and Best Place approach to R&D.

## Developing Rewarding and Safe Work Environments

Astellas is working to ensure rewarding and safe work environments where employees are able to concentrate on their duties in confidence. This is to ensure that every employee is able to maximize their abilities and creativity on the job. In Japan, we have been promoting workstyle reforms since 2015 that include streamlining operations and encouraging our people to take the leave they have earned. This is all in an effort to strike an equilibrium that enables each person to establish their own work-life balance while improving productivity and creativity. Our efforts to promote inclusive employment and decent work, one of the United Nations' Sustainable Development Goals (SDGs), include initiatives for upgrading the work environment we provide for people with disabilities. We have been a participating member of Japan's Accessibility Consortium for Enterprises (ACE)\*. The support we provide people to overcome disabilities includes an app we have introduced for hearing-impaired employees that instantaneously converts voice data into written words.

Our efforts to provide employees with a rewarding and safe workplace have garnered praise both inside and outside the Company. The selection of our Canadian subsidiary as one of the Best Workplaces in Canada by the Great Place to Work® Institute is one example.

Additionally, our U.S. subsidiary was recognized as one of America's Best Employers by Forbes Magazine for the second consecutive year in March 2016.

Astellas continues to monitor the turnover rate of employees as an indicator for gauging the extent to which the Company provides a rewarding and safe place to work.

\* Accessibility Consortium of Enterprises (ACE): A general incorporated association that was formed to conduct activities such as the establishment of a new employment model for people with disabilities who contribute to the growth of companies.

### Number of Employees per Region and Turnover Rate

		2014.3	2015.3*2	2016.3
Japan	Number of employees	8,082	7,241	<b>7,056</b>
	Turnover rate*1	2.1%	7.5%	<b>1.1%</b>
Americas	Number of employees	2,883	2,975	<b>3,062</b>
	Turnover rate	17.8%	10.4%	<b>12.9%</b>
EMEA	Number of employees	4,580	4,628	<b>4,726</b>
	Turnover rate	8.3%	15.6%	<b>11.9%</b>
Asia & Oceania	Number of employees	2,104	2,269	<b>2,373</b>
	Turnover rate	13.8%	13.4%	<b>12.9%</b>
Total	Number of employees	17,649	17,113	<b>17,217</b>
	Turnover rate	7.7%	11.0%	<b>7.8%</b>

\*1 The turnover rate in Japan excludes people retiring at the mandatory retirement age and employees moving outside of the Group due to transfer of Group businesses.

\*2 The increase in the total turnover rate in fiscal 2014 is mainly due to the introduction of an early retirement plan in Japan.

## Improving Employee Satisfaction

Astellas is also striving to improve employee satisfaction. As part of this effort, we conducted an awareness survey of Group employees in Japan in January 2016. Through a third party, we surveyed how our employees evaluate Astellas as a company in various categories.

The survey showed that positive responses in more than 10 categories, including the overall direction of the Company, trust in management, and remuneration and employee welfare and benefits, were far higher than the average for similar surveys conducted by Japanese companies, and we found that these areas have become Astellas' strengths. Meanwhile, the results showed fewer positive responses in the category of operational efficiency, although the number was higher than the average for Japanese companies.

In response, Astellas will redouble its efforts to streamline its operations through workstyle reforms.

## Ensuring Occupational Safety and Health

We have the Astellas Environmental and Safety Policy in place to prevent work-related accidents and minimize those caused by workplace mishaps and hazards. Under this policy, each facility is independently building environmental and safety management systems and promoting associated initiatives. We are also working to ensure occupational safety from many different perspectives based on the information we share on accidents and near misses that have occurred at our workplaces around the world.

Between January and December 2015, there were two work-related injuries requiring leaves of absence in Japan. Of these two injuries, the longest leave of absence was 97 days. There were two injuries requiring leaves of absence at our overseas plants, of which the longest leave of absence was 70 days. In view of the lengthy leaves resulting from injuries in Japan and at our overseas plants, we will strive to reduce our occupational safety risks with the goal of holding our severity rate of work-related injuries under 0.005 on a global basis.

### Incidence of Work-Related Injuries in Japan

	2013.1-12	2014.1-12	2015.1-12
Number of injuries requiring leave of absence	3	5	2
Frequency rate of work-related injuries*1	0.18	0.34	0.14
Severity rate of work-related injuries*2	0.008	0.002	0.007

### Incidence of Work-Related Injuries at Overseas Plants\*3

	2015.1-12
Number of injuries requiring leave of absence	2
Frequency rate of work-related injuries*1	1.11
Severity rate of work-related injuries*2	0.047

\*1 Frequency rate of work-related injuries: This rate shows the number of employee deaths or injuries resulting from work-related accidents causing leaves 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 of work. The larger the number, the more serious the injury.  
 \*3 From 2015 onward, we began disclosing consolidated data for all five overseas plants. The data for each of the five overseas plants until 2014 is disclosed in the IR Library of the Astellas website.

### Respect for Human Rights

The Astellas Charter of Corporate Conduct clearly states that all members of the Astellas Group must respect the human rights, character and individuality of all its employees, observe all applicable international rules and local regulations, and also respect all cultures and customs. This recognition of the important respect for human rights is shared by Group companies worldwide. Based on respect for human rights, we have established the Astellas Group Code of Conduct, which sets out standards including respect for the human rights of employees, elimination of child labor or forced and compulsory labor, equal opportunities for employment, provision of opportunities for improving job skills, employee health and safety, and the prevention of harassment in the workplace.

To rigorously uphold respect for human rights, we have established a system for swiftly responding to human rights issues that includes the establishment of external and internal helplines, as well as conducting training sessions for employees. We have been globally confirming the awareness of human rights issues in the workplace and the status of human rights activities at our Group companies by conducting written surveys. In fiscal 2015, there were no urgent human rights issues or other issues of common, worldwide concern reported in the surveys.

For further information on Astellas' employees activities, please visit the following website:

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

### Message from the President of Astellas Pharma Canada

*We are building a great culture for our employees.*

Astellas Pharma Canada, Inc. takes pride in building a workplace environment and culture where employees feel respected and where they can excel.

We are proud to have received awards from the Great Place to Work® Institute Canada in two categories: the category of large, multinational corporations through our selection as one of the Best Workplaces in Canada in 2016, and the category of top workplaces for women. We believe that this recognition is especially meaningful because it is based on a survey completed by a random selection of employees, and a third-party assessment of our company culture.

This award is a testament to the engagement employees have with our core values, which have fostered a unique culture that is shaped by a commitment to living the Astellas Way. We also pride

ourselves on creating a culture of excellence driven by acknowledgment and recognition of employee performance, where employees are offered the opportunity to grow both personally and professionally.

CSR forms the core of our culture and our employees are passionate about supporting in various ways the communities in which we work and live. We are proud to be a Great Place to Work and a leader in CSR.

**Michael Tremblay**  
 President,  
 Astellas Pharma Canada, Inc.



## Society

Astellas is cooperating with a range of stakeholders in an effort to address social issues which affect people throughout the world. We are also working to enhance the sustainability of society through our activities, including addressing Access to Health issues, fostering advancement in medical science and providing support to local communities.

### Access to Health

There are many people with insufficient access to the healthcare they need due to the lack of available treatments, poverty, challenges in healthcare systems and limited healthcare information. Astellas recognizes this problem as the Access to Health issue, and works to improve Access to Health by engaging in various initiatives. Astellas believes that the relationships with governments and the local partners it develops through these initiatives will generate synergies with its business activities over the long term.

### Initiatives to Combat Tropical Diseases by Harnessing Astellas' Unique Strengths

#### Collaborative Research to Discover Anti-Protozoan Parasite Drugs

In April 2016, Astellas signed a new collaborative research agreement with the National Institute of Advanced Industrial Science and Technology (AIST).

The collaborative research is targeting Chagas disease, one of the neglected tropical diseases (NTDs)<sup>\*1</sup> caused by protozoan parasites belonging to trypanosomatidae<sup>\*2</sup>, for which a new drug is urgently needed to address unmet medical needs. Since 2012, Astellas has been collaborating with five research institutions in Japan as well as with an international non-profit organization<sup>\*3</sup> to discover new drugs for the treatment of NTDs caused by protozoan parasites belonging to trypanosomatidae. By utilizing the knowledge obtained through this collaborative research, Astellas and AIST will now pursue collaborative research to discover new drugs for the treatment of Chagas disease.

Astellas and AIST will work collaboratively to validate whether genes crucial for the survival of *Trypanosoma cruzi* (the cause of the disease) can be pinpointed in a short period of time using genome editing technology. Through this new collaborative research, Astellas will endeavor to amass the scientific knowledge that will lead to the discovery of new drugs for patients suffering from Chagas disease around the world.

In case this approach is validated, the formation of an AIST-driven research consortium, in which multiple research institutions will participate to conduct extensive genome editing studies on the genes of *Trypanosoma cruzi* and pursue discovery of new drugs for the treatment of

Chagas disease in a larger framework, is planned. Astellas also plans to consider joining the consortium.

<sup>\*1</sup> Neglected tropical diseases (NTDs): NTDs are infections caused by parasites and bacteria which are rampant mainly among underprivileged people in tropical areas of developing countries. It is estimated that over one billion people worldwide are suffering from these infections.

<sup>\*2</sup> In addition to Chagas disease, leishmaniasis and African trypanosomiasis are also caused by protozoan parasites belonging to trypanosomatidae.

<sup>\*3</sup> Collaborative research has also been undertaken with the University of Tokyo, the Tokyo Institute of Technology, Nagasaki University, the High Energy Accelerator Research Organization, AIST and the international non-profit organization Drugs for Neglected Diseases initiative (DNDi).

#### Collaborative Research on a Rice-Based Oral Vaccine

In June 2016, Astellas signed a new collaborative development agreement with the Institute of Medical Science, the University of Tokyo (IMSUT) on the rice-based oral vaccine "MucoRice-CTB" against diarrheal diseases caused by cholera and enterotoxigenic *Escherichia coli* (*E.coli*).

In developing countries, diarrhea caused by pathogenic bacteria such as *Vibrio cholerae* and enterotoxigenic *E.coli*, is a major cause of death among infants and young children. However, existing cholera vaccines present several issues, including the need to store and transport the vaccines at a constant low temperature, and their ineffectiveness against enterotoxigenic *E.coli*. MucoRice-CTB is stable at room temperature and easily produced. Therefore, it is expected to meet the unmet medical needs of existing cholera vaccines.

MucoRice-CTB is a rice-based oral vaccine expressing a cholera toxin B (CTB) subunit in the intrinsic storage protein of rice using genetic engineering. It was developed by Prof. Hiroshi Kiyono, Project Researcher Yoshikazu Yuki and their colleagues at the International Research and Development Center for Mucosal Vaccines, IMSUT.

Under the agreement, IMSUT provides investigational medicines and study data, etc., which are necessary for phase 1 and 2 of clinical trials of MucoRice-CTB for cholera and enterotoxigenic *E.coli*, and Astellas is responsible for conducting and managing the clinical trials.

Through this collaborative development, Astellas will work to develop vaccines against infectious diseases affecting developing countries.

#### Development of Pediatric Formulation for Schistosomiasis

Schistosomiasis is one of the most prevalent parasitic diseases in developing countries centered on Africa and South America. The disease has a particularly high incidence rate among children. The existing 'gold standard' treatment for schistosomiasis is praziquantel. However, one challenge is that praziquantel tablets are difficult to administer to preschool age children, including infants and toddlers, mainly due to the risk of choking stemming from their large size and the drug's bitter taste.

Having set up a consortium with other pharmaceutical



companies, research institutions and international non-profit organizations, Astellas is developing a pediatric formulation of praziquantel.

The pediatric formulation newly developed by Astellas uses its original drug formulation technology. The pediatric formulation was designed to be smaller than the existing tablet and to be orally dispersible so that it can be taken even without water, with reduction of bitterness. In addition, the pediatric formulation can be manufactured using simple production technology, while holding down production costs, and the tablets are stable even in the hot and humid environment of tropical areas. Astellas has transferred the technology and expertise needed to develop the pediatric formulation to a consortium partner in Brazil, thereby helping to build local pharmaceutical manufacturing capabilities.

The consortium is conducting Phase II clinical trials. Astellas continues to provide its expertise and technology to the consortium.



Newly developed pediatric formulation (top) and existing tablet (bottom)



Members of the Pediatric Praziquantel Consortium Team ©Lygature 2015

### Action on Fistula

Action on Fistula\*<sup>1</sup>, a program focused on urology, is led by the charity Fistula Foundation and funded by €1.5 million provided by Astellas. In the three years through 2017, the initiative launched its activities with the aim of transforming the lives of more than 1,200 women in Kenya living with this condition and building capacity in the country by training doctors who can perform surgeries.

The program is making progress ahead of its targets. As of the end of April 2016, the program had successfully treated 1,210 women with life-changing reconstructive surgery. It has established a fistula treatment network comprising 7 hospitals and has increased the number of fistula surgeons in the country. The initiative is also undertaking a major outreach program with community workers identifying patients and encouraging them to access available treatment.

\*1 For details, please visit the following website:

<http://www.astellas.eu/action-on-fistula/>

\*2 An obstetric fistula is a hole that develops between the vagina and rectum or bladder, causing incontinence. It is caused by prolonged hard labor lasting several days when emergency care is unavailable. Untreated, fistulas can lead to chronic medical problems including ulcerations, kidney diseases and nerve damage in the legs, and can cause economic hardship in some cases if patients are excluded from society. The United Nations Population Fund estimates 3,000 new cases of obstetric fistulas occur annually in Kenya.



Fistula surgeons in Kenya

### Progress in the Action on Fistula Program (May 2014-May 2016)

Patients successfully treated with reconstructive surgery	1,210 patients
Trained and certified doctors to the standard level of competency	5 Kenyan doctors
Centers in the Fistula Treatment Network	7 centers
FIGO* <sup>1</sup> -accredited fistula training center	Established the Gynocare Fistula Center
Reached counties* <sup>2</sup> of Kenya	40 counties
Trained community health volunteers	211 volunteers
Conducted outreach activities	4,339 activities
Reached community members with fistula messages	206,000 members

\*1 FIGO: International Federation of Gynecology and Obstetrics

\*2 Kenya is divided into 47 counties. There are several units of governance below the county level. These units include subcounties, wards, and villages.

## Special Programme for Research and Training in Tropical Diseases

Through the Special Programme for Research and Training in Tropical Diseases (TDR) of the World Health Organization, Astellas accepted research fellows from developing countries and provided them with job training on management skills related to clinical development. In October 2015, one trainee from the Republic of Mali, the third trainee of the programme, began training at Astellas' clinical development division in the U.S., and is scheduled to complete the training by September 2016.

## Support for Patients

Astellas conducts a variety of activities to provide assistance to patients fighting illnesses, and their family members, on a global basis.

Astellas promotes Starlight Partners Activities in Japan as part of efforts to support the self-reliance and development of patient associations. Astellas Peer Support Training Sessions are held for a wide range of participants, including patients and their families, along with those who have recently formed patient associations. In these training sessions, activities include programs for participants to learn attentive listening skills, which enable colleagues who have faced the same issues or have experienced the same problems to serve as consulting partners to one another. In fiscal 2015, Astellas Peer Support Training Sessions were held in three locations across Japan, attended by 29 organizations and 42 people.

## Group-Wide Volunteer Activities Changing Tomorrow Day

Astellas Group employees around the world are contributing to their local communities by conducting a diverse range of volunteer activities as part of Changing Tomorrow Day based on the themes of promoting healthcare and maintaining the environment. In fiscal 2015, more than 7,400 employees participated.

## Changing Tomorrow Day Held in Fiscal 2015

Region	Participants	Volunteering hours	Number of locations	Number of countries
Japan	3,665	3,447	132	1
Americas	2,179	10,220	121	3
EMEA	472	3,812	33	29
Asia & Oceania	1,133	6,278	14	9
Total	7,449	23,757	300	42

## Astellas Foundations

Astellas has established foundations in Japan, the Americas, EMEA, Asia and Oceania in order to provide financial assistance for research and other support to foster advancement in medical science, conduct philanthropic activities in local communities, and contribute relief funds to assist with disaster recovery efforts. The foundations are operated in accordance with the laws of the regions where they are active.

Of these foundations, Astellas USA Foundation carries out activities focused on health and education, including support for activities to ensure healthy lives and promote well-being for all at all ages, one of the United Nations' Sustainable Development Goals.

In fiscal 2015, with a focus on health, Astellas USA Foundation helped to immunize more than 200,000 children against measles in Latin America, in addition to providing funding for enhancements to the pediatric wings of local hospitals. To strengthen the focus on education, Astellas USA Foundation supported fostering the next generation through STEM\* education. Astellas USA Foundation provided grants for eight specialized programs, thereby providing thousands of students with mentoring and hands-on learning to cultivate critical thinking and problem-solving skills, and raising their awareness about careers in STEM.

\* STEM: Science, Technology, Engineering, and Math.

For further information on Astellas' society activities, please visit the following website:

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



### Message from Collaborative Researcher in the Project to Discover Anti-protozoan Parasite Drugs

*I was deeply impressed with Astellas' front-line focus, dedication and integrity as a pharmaceutical company.*

At the final reporting conference of the NTDs Drug-discovery Research Consortium, my supervisor asked me to share my thoughts on working for the project over the past three years. Without hesitation, I answered, "It was very enjoyable."

Through this drug-discovery research consortium initiated in 2012, we learned about Astellas' front-line focus, something that came as a big surprise to all of us. This front-line focus encompasses Astellas' research methods devoted to drug discovery and its speed of research, which is far faster than that of academia, as well as its scale and calm, level-headed decision-making. Astellas' researchers showed an incredible dedication to their work. They delivered progress reports with such an intensity that the audience would often be left in stunned silence after the presentations. That is what the process of developing a new drug is like. However, as a for-profit enterprise engaged in a social contribution effort, Astellas always conducted itself with the utmost integrity. I am deeply impressed with and grateful for Astellas' generosity in making this approach to the project possible.

In fiscal 2016, our collaborative research is about to enter the next stage of focusing on the treatment of Chagas disease as the target. To make the drug-discovery research more meaningful, the new project will commence research by seeking to identify the genes crucial for the survival of *Trypanosoma cruzi*,

the pathogenic protozoa that causes Chagas disease, and making those genes the target candidate for drug discovery. In this stage, the project will use the genetically engineered pathogenic protozoa produced by the research consortium since 2012 to efficiently create gene-deficient strains and use genetic editing technology to identify the genes.

Another feature of the new project is that it will be set up as a consortium at AIST that will be open to participation by multiple companies. The 2015 G7 Elmau Summit Leaders' Declaration underscored the need for developed countries to take steps to fight NTDs. Against this backdrop, Professor Satoshi Omura received the Nobel Prize in Physiology or Medicine. Under these social conditions, and in the sense of carrying on the legacy of the research consortium's work to date, AIST has been given an immense role to play in leading this project. We can easily anticipate that a wide range of difficulties lie ahead. That is precisely why we must advance to the next stage with extraordinary determination.

Another benefit of participating in this collaborative research has been the friendships I have developed with numerous colleagues. They are the reason why the past three years have been so enjoyable. For their sake too, I would like to continue working hard on this project.



**Koji Furukawa, Ph.D.**

Senior Researcher  
Biomedical Research Institute,  
National Institute of Advanced Industrial Science and Technology (AIST)

# Environment

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

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

## 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 to achieve its numerical targets. Going forward, we will review the plan based on various factors including progress status and social circumstances, and add new

initiatives and/or set more challenging targets.

Among the numerical targets of the Environmental Action Plan, Astellas has achieved all the items with a final target year of fiscal 2015. Accordingly, we have set new targets for water resources productivity and waste generated per unit of sales, and have begun working towards these targets from fiscal 2016.

### New Targets Added to the Environmental Action Plan

Water resources productivity:

Increase water resources productivity by around 2.5 times the fiscal 2005 result by the end of fiscal 2020

(Indicator: Net sales (¥ billion)/Water resources withdrawn (m<sup>3</sup>))

Waste generated per unit of sales:

Reduce the waste generated per unit of sales to around 1/5 of the fiscal 2005 result by the end of fiscal 2020

(Indicator: Volume of waste generated (tons)/Sales (¥ billion))

## Environmental Action Plan Performance in Fiscal 2015 (Summary)

Numerical Targets for Environmental Action Plan	Fiscal 2015 Performance
<b>1. Measures to Address Climate Change</b> (Base year: Fiscal 2005) 1) Reduce greenhouse gas emissions by 35% or more by the end of fiscal 2020 (Global) - Japan: Reduce greenhouse gas emissions by 30% or more - Overseas plants: Reduce greenhouse gas emissions by 45% or more 2) Reduce CO <sub>2</sub> emissions generated through sales activities by 30% or more by the end of fiscal 2015 (Japan) 3) Reduce electricity usage at our offices to 80% or less by the end of fiscal 2015 (Japan)	1) Ratio to the base year level: 30.8% reduction Japan: 28.5% reduction Overseas: 37.7% reduction 2) Ratio to the base year level: 39.6% reduction 3) Ratio to the base year level: 65.3%
<b>2. Measures for the Conservation of Natural Resources</b> (Base year: Fiscal 2005) Reduce water withdrawal to 80% or less by the end of fiscal 2015 (Global)	Ratio to the base year level: 76.3%
<b>3. Waste Management</b> Reduce the final volume of landfill waste to less than 2% of the total discharged (Japan)	Ratio of landfill waste to the total discharged: 0.99%
<b>4. Management of Chemical Substances</b> (Base year: Fiscal 2006) Reduce the amount of volatile organic compounds (VOCs) discharged by 25% or more by the end of fiscal 2015 (Japan)	Ratio to the base year level: 36.8% reduction
<b>5. Biodiversity</b> (Base year: Fiscal 2005) Triple the biodiversity index by fiscal 2020 (Global)	Ratio to the base year level: 3.18 times

Note: Among the greenhouse gas emissions in Japan, CO<sub>2</sub> emissions generated through electricity usage are calculated using the following two types of coefficients:

- (1) A coefficient of 0.330 kg-CO<sub>2</sub>/kWh is used to calculate results needed to evaluate progress against the Environmental Action Plan and make investment decisions and implement countermeasures to bridge the gap between results and targets. The figures shown in the table above represent the results calculated using this coefficient.
- (2) Greenhouse gas emissions (actual emissions) for each fiscal year presented in series are calculated using the Federation of Electric Power Companies of Japan (FEPC)'s actual end-use greenhouse gas emissions coefficient (hereinafter, "the electricity CO<sub>2</sub> emissions coefficient") for the previous fiscal year. The figures for the greenhouse gas emissions shown in this report represent results calculated using this coefficient. (A coefficient of 0.554 kg-CO<sub>2</sub>/kWh was used in fiscal 2015.)

## Initiatives for Realizing a Low-Carbon Society

### Reducing Astellas' Greenhouse Gas Emissions

Astellas endeavors to reduce the greenhouse gas emissions accompanying its own activities in order to help realize a low-carbon society.

Global greenhouse gas (GHG) emissions accompanying Astellas' business activities (actual emissions) totaled 226 kilotons, with activities generating approximately 80% of those emissions covered by the Environmental Action Plan.

The amount of greenhouse gas emissions accompanying electricity use at overseas production sites was revised in line with the GHG Protocol, an international guideline for the calculation of greenhouse gas emissions. As a result, global greenhouse gas emissions (actual emissions) covered by the Environmental Action Plan were 185 kilotons in fiscal 2015. This was 21.1% (49 kilotons) lower than in the base year level of fiscal 2005.

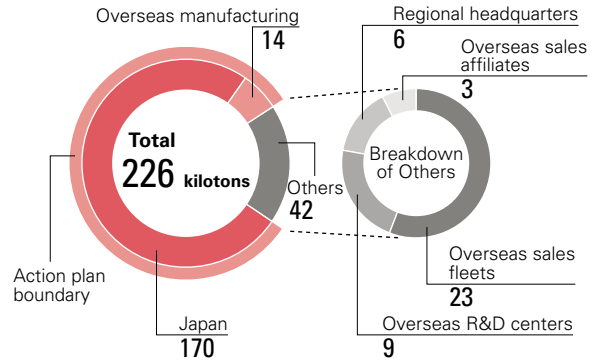
In Japan, there was a reduction of 25 kilotons due to improvement in the electricity CO<sub>2</sub> emissions coefficient compared to the previous fiscal year, along with a decrease of 2 kilotons mainly due to effective ways of mitigating climate change. However, there was an increase of 3 kilotons due to an increase in business activities such as the operation of new facilities. The difference between the coefficients for actual emissions and for use in evaluating progress against the Environmental Action Plan was 0.224 kg-CO<sub>2</sub>/kWh. As a result of the difference between these coefficients, actual emissions were 44 kilotons greater than emissions in the Environmental Action Plan.

Greenhouse gas emissions at overseas production sites decreased 22 kilotons as a result of assuming the greenhouse gas emissions accompanying electricity use derived from purchased renewable energy, were zero.

In accordance with GHG Protocol Scope 2 Guidance, Astellas has similarly adopted the market-based method as the calculation method for Scope 2 emissions (indirect emissions) in the CDP Climate Change 2016 questionnaire.

### Breakdown of Greenhouse Gas Emissions (Actual Emissions)

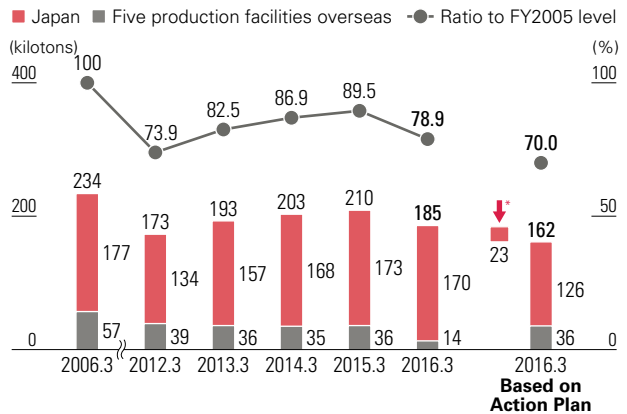
(kilotons)



Note: The above graph is based on the following energy consumption data. "Others" represents items outside the scope of the Environmental Action Plan, and includes principal office buildings, R&D centers, and office buildings of sales affiliates and sales fleets outside Japan.

### Greenhouse Gas Emissions (Actual Emissions)

Japan: All Japanese facilities and sales fleets /  
 Overseas: All five production facilities



\* The difference between the actual emissions and emissions evaluated in the Environmental Action Plan reflects differences in coefficients used in Japan (see the note on page 71) and changes in calculation methods used at overseas production sites.

### Energy Consumption in Fiscal 2015 by Energy Type

Scope Japan: All business bases and sales fleets  
 Overseas: All production bases

Outside scope Overseas: Principal office buildings, R&D centers, office buildings of sales affiliates and sales fleets

(Terajoules)

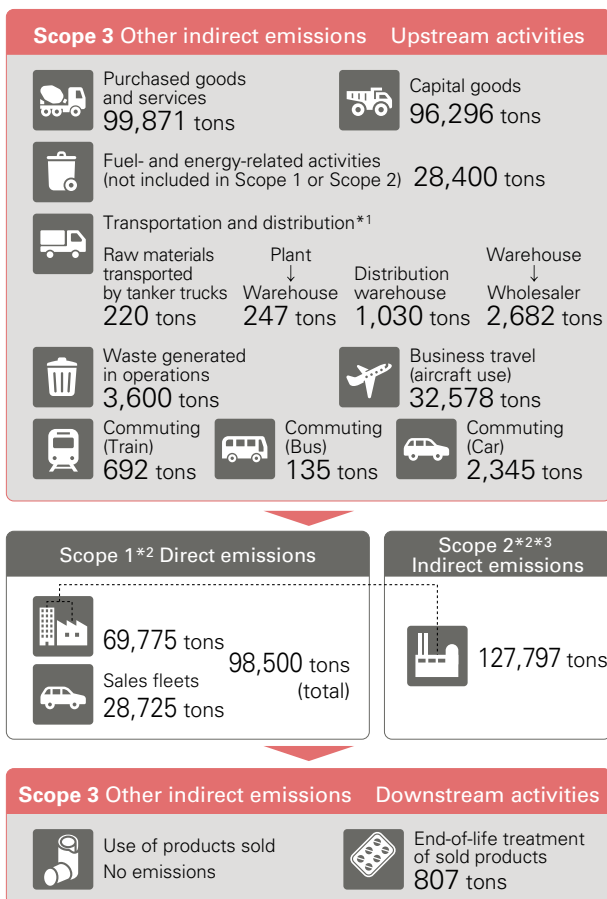
Environmental Action Plan	Total	Liquid Fuel		Gaseous Fuel		Heat Purchase	Electricity Purchase			Renewable Energy		
		Fuel Oil	Diesel Oil	City Gas	LPG/LNG		Total	Wind Power Source	Total	Wind Power Source	Woodchip Source	Photovoltaic Panels
Covered	3,917	0	83	1,083	239	24	2,443	463	43	7	36	0.3
Not Covered	729	0	353	55	0	0	322	0	0	0	0	0

## Monitoring Greenhouse Gas Emissions in the Supply Chain

In recent years, it has become increasingly important to monitor and announce not only greenhouse gas emissions by the Company, but also greenhouse gas emissions in the supply chain, including transportation of employees, raw materials purchasing, product distribution, and waste disposal.

Recognizing these social implications, we started efforts in fiscal 2011 to ascertain our greenhouse gas emissions associated with employee commuting, use of transportation systems on business trips in Japan, and transportation of products and wastes. Going forward, we intend to continue taking effective steps to expand the reporting boundary.

### Monitoring Status of Greenhouse Gas Emissions



\*1 Product shipments are handled by outside contractors.  
 \*2 Global basis (Japan: all business premises and sales fleets / Overseas: all production facilities, sales fleets, principal offices, R&D centers and sales affiliates)  
 \*3 Emissions refer to actual emissions.

## Using Renewable Energy

The direct use of renewable energy such as solar and wind power is the most effective way of mitigating climate change.

Therefore, we intend to actively incorporate technologies that can be feasibly introduced.

We operate a wind turbine system with a maximum output of 800 kW at the Kerry Plant in Ireland, which generated 1,950 MWh in 2015. Furthermore, the Kerry Plant's woodchip biomass boiler (maximum output of 1.8 MW) also used 35,927 GJ of heat. These two initiatives reduced our greenhouse gas emissions by 3,307 tons.

In Japan, we have installed photovoltaic panel systems at the Tsukuba Research Center and the Kashima R&D Center. In fiscal 2015, those systems together generated 79 MWh of electricity, reducing our greenhouse gas emissions by 44 tons.

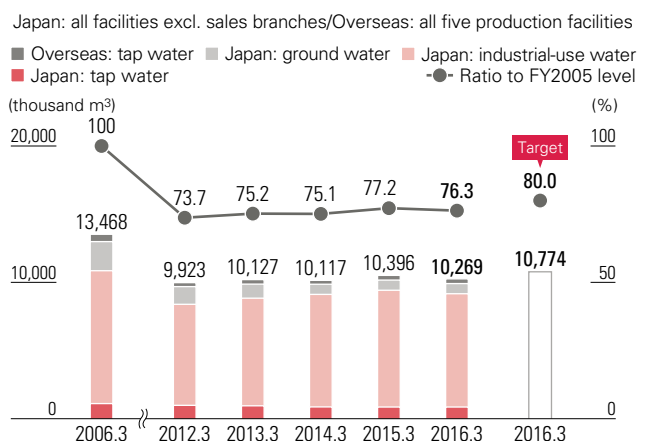
Given that Astellas' plants in Japan are not suitably located for wind power generation, we will consider introducing other forms of renewable energy in the country.

Astellas' overseas plants are taking initiatives to designate and purchase electricity generated from renewable energy such as wind and hydroelectric power. Of the electricity purchased in fiscal 2015, renewable energy comprised 20,590 MWh at the Norman Plant, 12,956 MWh at the Meppel Plant, 6,525 MWh at the Dublin Plant, and 6,382 MWh at the Kerry Plant.

## Initiatives for Resource Recycling

Astellas seeks to contribute solutions to the social issues involved in establishing a recycling-oriented society. We have therefore been striving to reduce water withdrawal and landfill waste. As a result, we were able to achieve our numerical targets for these items whose final target year is fiscal 2015. Looking ahead, we have set water resources productivity, which is defined as net sales divided by water resources withdrawn, as an enhancement target, and we will work to achieve this target.

### Amount of Water Withdrawal



## Initiatives for Biodiversity

Astellas works to preserve biodiversity by proactively reducing the impact of its business activities in all fields on the ecosystem. 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.

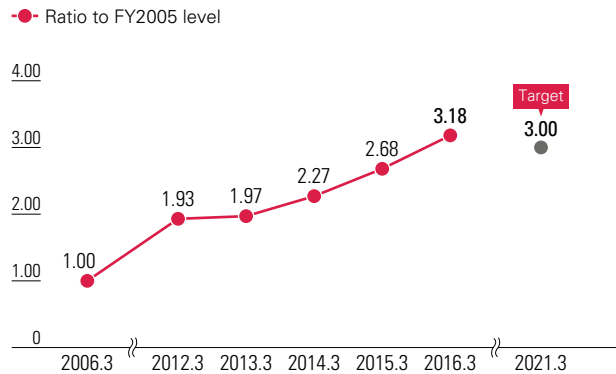
Astellas has created a Biodiversity Index\* by assessing the three main factors responsible for the deterioration of biodiversity, namely environmental pollution, resource consumption and climate change. Going forward, we will continue improving in each category while working toward achieving the target set for fiscal 2020, which is three times the fiscal 2005 level.

The Biodiversity Index for fiscal 2015 was 3.18 times that of fiscal 2005, achieving the target that was revised in the previous fiscal year. The denominator components such as pollution load and resource consumption declined, in addition to a decrease in greenhouse gas emissions due to a revision of calculation guidelines. At the same time, the numerator of net sales increased in fiscal 2015. As a result, the overall Biodiversity Index improved 0.50 points from the previous year. Since we only recently revised the

Environmental Action Plan, we have decided to continue our activities without revising the Biodiversity Index target.

\* For details on the calculation method, please visit the following website:  
[http://www.astellas.com/en/csr/environment/biodiversity\\_sub\\_02.html](http://www.astellas.com/en/csr/environment/biodiversity_sub_02.html)

### Biodiversity Index



For further information on Astellas' environmental activities, please visit the following website:

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

## Message from Environmental Management

*We were included in the CDP\* Climate Disclosure Leadership Index 2015 in recognition of a perfect disclosure score for climate change information.*

Astellas has been included for the first time in the Climate Disclosure Leadership Index 2015 issued by the CDP, in recognition of its especially good score on the disclosure of information related to climate change.

Corporations operating internationally are increasingly expected to provide transparent and forthcoming disclosure of information on environment, social, and governance (ESG) policies, and Astellas is no exception. In particular, many institutional investors place great emphasis on measures taken in response to climate change, of which the evaluation offered by CDP is one of the most important.

Aiming to continuously improve disclosure quality, Astellas has worked to advance the networking of information gathering responsibilities by developing a shared awareness among members in various countries

\* CDP: An international nonprofit organization providing the only global system for corporations and municipalities to measure, disclose, manage and share vital environmental information.

regarding the value of disclosing environmental performance in a unified fashion, along with standardizing methods for consistency of calculations and organizing the systems and work-flow that actually perform the calculations. The single-minded cooperation of Astellas members in a variety of roles across more than 40 countries in all of these areas resulted in a high quality of disclosure that has earned us a high evaluation.

I believe that these proactive actions will be the motivation for facing changing environmental issues and meeting stakeholders' expectations.

Takashi Kurihara, Ph.D.

Manager  
 General Affairs



# Ethics & Compliance

Astellas believes that acting in accordance with the highest ethical standards, which includes obeying the letter and spirit of the law, is the cornerstone of all its activities. Accordingly, the Astellas Charter of Corporate Conduct expresses the Company’s business philosophy in terms of specific corporate behavior, and is shared globally. In addition, the Astellas Group Code of Conduct is a common global code for all officers and employees around the world, requiring them to conform to laws and regulations and maintain high ethical standards.

Astellas promotes compliance and acts in accordance with the highest ethical standards through the development, implementation and continuous enhancement of policies, processes, and our global compliance structures and thereby maintains the trust of society and enhances enterprise value.

exchanging information and opinions with relevant divisions on each issue. As our business expands globally, we continue to enhance global alignment and collaboration between functional lines, and maintain consistently high standards of compliance in everything we do.

To reinforce compliant operations globally, in April 2016 the legal and compliance functions were divided structurally in Japan, the Americas, and EMEA, and a separate compliance function was established in Asia & Oceania. The new organization is named Ethics & Compliance. Furthermore, we built a global compliance framework in which the regional compliance functions report to the the Head of Ethics & Compliance.

Astellas is committed to helping each employee to conduct business with the highest integrity, and in an ethical and legal manner. We continuously work to nurture a culture where everyone feels comfortable raising concerns without fear of retaliation.

## Promoting Compliance Globally

### Structure to Promote Ethics and Compliance

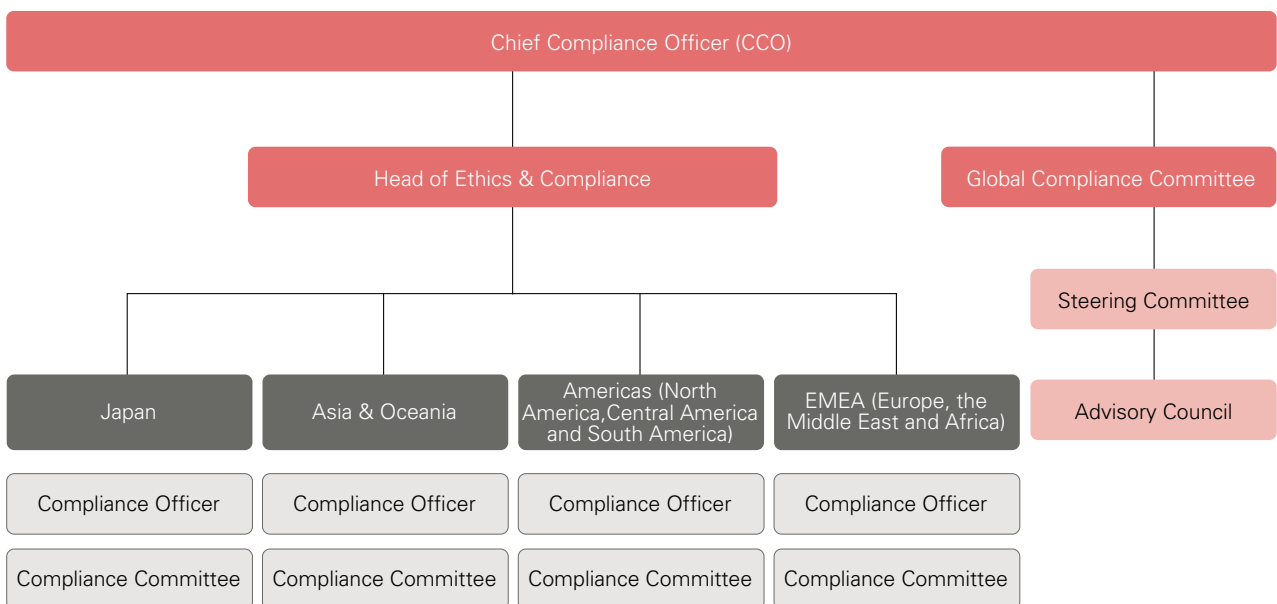
Astellas has maintained a robust compliance structure that includes a Chief Compliance Officer and Global Compliance Committee comprising regional compliance heads in the Americas, EMEA, Japan, and Asia & Oceania. Under the Global Compliance Committee, Astellas also has a Steering Committee that maintains close coordination globally to resolve compliance issues and an Advisory Council for

### Initiative Promoting Compliance

#### Revised Code of Conduct

In June 2016 we revised and enhanced the Astellas Global Code of Conduct to make it easier to understand for all employees and formulated the Astellas Group Code of Conduct to apply uniformly throughout the world.

**Global Compliance Structure** (as of April 2016)





### Global Policy Development

In fiscal 2015, representatives from each region formed global task teams to address issues identified and formulated as part of our Global Compliance Initiatives for 2015. Each task team formulated global policies regarding compliance, including anti-harassment, data privacy, and medical affairs and commercial activities.

### Compliance Training

Training based on plans developed by our global task teams nurtures a compliance mindset among all employees. In the anti-harassment training, case studies about sexual harassment and power harassment are included to further promote understanding and prevention of harassment. Data privacy training provides points to note when employees process personal information in business operations.

### Tone from Top Management to Raise Employee Awareness

In fiscal 2015, ethics and compliance messages were delivered to employees through various means in order to enhance their ethics and compliance awareness. For example, information is delivered by email and on an in-house website in Japan and in Asia & Oceania. In the Americas, information bulletins were issued throughout the year. In EMEA, a compliance week was established to provide a concentrated communication of information.

### Helpline for Employees

Astellas has external helplines in each region, which enable employees to report and receive advice on how to react in the event they discover actual or suspected misconduct. These helplines are available in employees' local languages. In many countries, an external helpline has also been put into place, and employees also receive training on how to use the helplines.

Astellas fosters an environment that encourages employees to use the helplines. There is a strict 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 Japan, a separate sexual harassment helpline is also available.

In fiscal 2015, our helplines received consultation requests in each region. Matters raised included potential harassment and promotional code violations. In response, we conducted thorough investigations and took appropriate actions.

### Global Compliance Initiative for 2015

	Financial		Information	Human
	Transfers of Value	Anti-bribery		
Policies	Global Policy Development		Medical Affairs and Commercial Activities	
	Astellas Group Code of Conduct		Protection of Confidential Information	
Control Process	Transparency	Anti-bribery	Record Information and Management	
	External Funding			
Training and Communication			Data Privacy	Conflicts of Interest
			Social Media	Anti-harassment
Issues and Investigations	Issue Management Program			
	Global Investigation Process			
Third Parties	Vendor Compliance Management			

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## Delivering Appropriate Medical and Product Information

In April 2016, Astellas implemented the Global Policy on Medical Affairs and Commercial Activities. The establishment of this policy reflects Astellas' continuing commitment to conducting business throughout the world with high ethical standards and in compliance with applicable local laws, rules, regulations, codes and guidelines.

To respond to the needs of all stakeholders, including patients, ethical collaboration and interaction in medical affairs and commercial activities complies with all regulations to advance understanding and appropriate use of Astellas products. Astellas is committed to providing appropriate scientific and medical information in compliance with applicable laws, rules, regulations, codes and guidelines in all areas.

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## Anti-bribery/Anti-corruption Initiatives

As business has become increasingly globalized, countries around the world have been stepping up their response to corruption and bribery. Enforcement authorities have prosecuted cases involving direct corruption and bribery as well as cases involving bribery that occurred through the actions of a business partner or third-party agent. Astellas is continuing to strengthen its compliance awareness to prevent corruption not only at Astellas but also at third parties with whom we conduct business.

### ■ Policies, Procedures, and Training for Preventing Corruption

As a system to prevent bribery, Astellas has established the Astellas Group Code of Conduct, which sets forth rules to prevent bribery and corruption. Furthermore, Astellas has a Global Anti-Bribery and Anti-Corruption Policy that elaborates on these rules globally and in each region. By establishing and implementing these rules, Astellas is working to ensure that bribery and corruption are not part of how we conduct our business.

To foster deeper understand around this issue among employees, Astellas implements a training program on anti-corruption and anti-bribery. In fiscal 2015, this training was attended by approximately 3,000 employees in Japan, 4,500 in the United States, 1,300 in EMEA, and 2,200 in Asia & Oceania.

### ■ Addressing Third-Party Risk

Astellas has established guidelines designed to prevent bribery occurring through third parties in each region and globally, and based on these guidelines, conducted due diligence screenings of key third parties in the Americas, Europe, and Asia. Screening of third parties will be continued in fiscal 2016.

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## Commitment to Fair Competition

Except in cases where the legal department has confirmed beforehand that there is no legal issue with doing so, Astellas does not agree with its competitors regarding sales conditions, such as prices, sales plans and strategies, and market and customer shares. In addition, when talking to competitors, we avoid any conversation concerning these topics, as it might be construed to reflect such an agreement even when there is none. If a competitor brings up these subjects in conversation, we refuse to discuss it, end the conversation immediately and unequivocally, and report the incident to the legal department.

In fiscal 2015, there were no incidences of government authorities taking legal action against Astellas for anti-competitive, anti-trust, or monopolistic practices, or of authorities imposing significant fines or other sanctions for non-compliance with laws and regulations.

For further information on Astellas' ethics and compliance activities, please visit the following website:

 <http://www.astellas.com/en/corporate/compliance/>

## Message from the Head of Ethics & Compliance

*We promote a high standard of ethics and compliance in every country where we do business.*

I'm very proud and honored to lead Astellas' new Ethics & Compliance organization, which was set up in April 2016.

As a new global function, we will provide leadership, tools, and resources to our employees to help them put integrity and compliance at the forefront of everything we do at Astellas. We are independent of the business functions, but have an important role as a strategic business partner to help our people be successful the right way. The establishment of Ethics & Compliance is a substantial investment in sustaining our success for many years to come and continuing to maintain the trust of our stakeholders.

Strong senior leaders for ethics and compliance have been appointed in each of our regions—the Americas, EMEA, Japan, and Asia & Oceania. Our new organization also includes a global lead for Anti-bribery and Anti-corruption, in recognition of the vital role of a globally integrated anti-bribery program to tackle this issue in a global organization.

Astellas operates in about 50 countries with varying laws, regulations, and codes of practice, and we want to ensure that we uphold Astellas' high standards in each country. We also recognize that we rely upon third parties in a number of countries, and that they pose a risk of non-compliance. Our role is to support these vendors and help them to maintain the high ethical standards of Astellas.

We have also begun to set up a system to help us ensure that we provide a global standard for all of our companies with policies, processes, training, monitoring tools, and resources. Our Ethics & Compliance professionals in place locally will help to inculcate our global standards, while ensuring we can comply with

any local laws, regulations, and codes of practice.

A number of global compliance programs are currently in the planning phase, and we have just launched a global compliance initiative called Integrity in Action. This program provides enhanced compliance resources and works to establish a corporate culture where our leaders and employees act as the voice and model of integrity as true compliance champions. Our message is that employees who show integrity in the workplace not only understand how to do things right, but also practice it in everything they do and they take responsibility, act ethically, and lead by example. This helps to reinforce the culture of compliance at Astellas.

Finally, even prior to becoming a new organization, we worked very hard throughout the past year with our internal stakeholders to revise and enhance the Astellas Global Code of Conduct. Our revised Astellas Group Code of Conduct replaces all regional and local codes of conduct. It embodies our commitment to operating ethically and with integrity toward improving the health of people around the world and provides a basis for us to make the right choices and take the right actions.



**Catherine Wertjes**

Senior Vice President,  
Head of Ethics & Compliance

## Dialogue with Stakeholders

Understanding the expectations and demands of patients and other diverse stakeholders is vital to increasing enterprise value. Astellas therefore uses various opportunities to communicate with stakeholders such as patients, healthcare professionals, employees, and shareholders and investors.

### Main Opportunities for Communication with Stakeholders

<b>Patients and Healthcare Professionals</b>	<ul style="list-style-type: none"> <li>• Provision of medical information through MRs</li> <li>• Responding to product inquiries</li> </ul>	<b>Business Partners</b>	<ul style="list-style-type: none"> <li>• Supplier surveys based on Astellas Business Partner Code of Conduct</li> </ul>
<b>Employees</b>	<ul style="list-style-type: none"> <li>• Regular dialogue between management and employees</li> <li>• Compliance helplines</li> </ul>	<b>Local Communities</b>	<ul style="list-style-type: none"> <li>• Roundtable talks with neighboring residents and local government bodies</li> <li>• Support of volunteer activities by employees</li> </ul>
<b>Shareholders and Investors</b>	<ul style="list-style-type: none"> <li>• General Shareholders' Meeting</li> <li>• Review of business results</li> <li>• Regular investor update on management plans, R&amp;D plans and others</li> </ul>	<b>Other</b>	<ul style="list-style-type: none"> <li>• Exchange of opinions with government agencies</li> <li>• Participation in various external activities such as economic groups and industry associations</li> </ul>

For details, please visit the following website:

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

### Dialogue with Patients

#### Reaffirming our commitment through the second annual Patient Advocacy Summit

In April 2016, Astellas hosted its second annual Patient Advocacy Summit—entitled Changing Tomorrow Together: Partnering to Improve Patients' Lives – in Washington D.C. A cornerstone of our evolving stakeholder engagement program in the Americas, the event brought together nearly 150 participants, including 105 patient advocates representing more than 90 groups from the U.S. and Canada. Attendees represented a wide range of therapeutic areas (including various forms of cancer, urologic health, kidney health, transplants, heart disease, infectious disease, arthritis and rare diseases), as well as advocates with a broader focus on R&D and access to quality care.

Issues addressed included the importance of reflecting patient priorities in the development of quality measures and value assessment frameworks, and “best practice” insights from patient advocacy leaders. Astellas leadership members also shared some of the many ways we strive to deliver value in the medicines we develop, the services we provide and our presence in the communities where we work and live.

The summit helps Astellas build and strengthen relationships with advocates who share a passion for improving and saving the lives of patients.

The day prior to the summit, Astellas also convened the inaugural meeting of a new Patient Advocates Advisory Committee. Comprised of approximately a dozen cross-therapeutic advocacy leaders, the committee serves as a resource for Astellas to better understand the priorities and collaborative opportunities within the patient community, and to gain feedback on Astellas' efforts to best reflect patient's engagement and voices throughout our business.



Annual Patient Advocacy Summit

# 4

## Corporate Governance

# Further Enhancing the Effectiveness of Corporate Governance as a Foundation for Sustained Growth in Corporate Value

Considering the expectations and demands of shareholders and other stakeholders, Astellas is working to develop a corporate governance system that ensures the transparency, appropriateness and agility of management. Astellas is currently taking concrete steps including appointing a majority of outside members to the Audit & Supervisory Board, in addition to the Board of Directors.





# Corporate Governance

## Basic Approach and Corporate Governance System\*

The Company's raison d'être is to contribute to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The Company aims to sustainably enhance enterprise value by being chosen and trusted by all stakeholders. With this business philosophy, we work to ensure and strengthen the effectiveness of corporate governance from the following perspectives:

- 1) Ensuring transparency, appropriateness and agility of management and
- 2) Fulfillment of our fiduciary duties and accountability to shareholders and appropriate collaboration with all stakeholders.

The Company's corporate governance system is summarized below.

- The Company adopts the organizational structure of a "Company with an Audit & Supervisory Board." Outside Directors and outside Audit & Supervisory Board Members constitute the majority of the Board of Directors and the Audit & Supervisory Board, respectively.
- The Board of Directors principally serves the oversight function of business execution and also makes decisions on important business execution.
- As for the framework for business execution, the Company establishes the Executive Committee and the Japan Management Committee for discussing important matters, and also appoints Executive Officers who are responsible for their respective assigned departments or functions. The responsibility and authority for the business execution by these committees, the President and CEO and the Executive Officers are clearly set out in the Corporate Decision Authority Policy.
- As advisory bodies to the Board of Directors, the Company established the Nomination Committee and the Compensation Committee, each of which are composed of a majority of outside Directors.

\* The Company has laid out its basic views and guidelines on corporate governance in the Corporate Governance Guidelines, which is published on the Company's website.  
[https://www.astellas.com/en/corporate/pdf/governance\\_guideline\\_en.pdf](https://www.astellas.com/en/corporate/pdf/governance_guideline_en.pdf)

## Directors and the Board of Directors

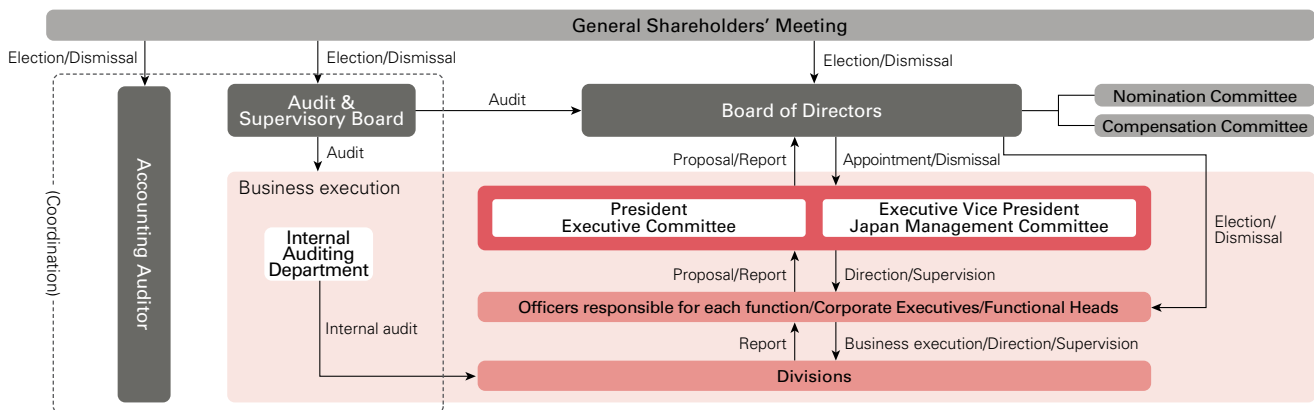
Directors are elected at the Annual Shareholders Meeting for a term of office of one year. The Board of Directors meets once per month, as a general rule, and is chaired by the Director and Chairman (when the Director and Chairman of the Board is unable to fulfill his/her duties due to accident or vacancy of the post, another Director, in the order prescribed in the Board of Directors Policy, shall assume the role).

The Board of Directors mainly performs an oversight function over business execution and also makes decisions on important business execution matters. It thereby ensures that management is transparent, appropriate, and agile. The Board has an appropriate number of Directors, in consideration of diversity and balance from the perspectives of expertise and experience. The Board has a majority of outside Directors to enable it to make decisions from a wider perspective and oversee business execution objectively.

As of the close of the 2016 Annual Shareholders Meeting, Astellas' Board of Directors comprises six Directors, with a majority of four being outside Directors. The four outside Directors meet the criteria of the Tokyo Stock Exchange for independent Directors as well as the Company's own criteria for independence\* of outside Directors. They are therefore independent Directors who have no risk of a conflict of interest with general shareholders. Each outside Director has a specific area of expertise, such as business management, law, or medicine. They participate in decision-making at Board of Directors meetings by making use of their wide-ranging experience and expertise and oversee business execution from an independent standpoint.

Through the implementation of self-assessment by

## Corporate Governance System





each Director and other means, the Board of Directors will analyze and evaluate the overall effectiveness of the Board of Directors and disclose a summary of the results every year. This is to further enhance the overall effectiveness of the Board of Directors.

\* The Company's independence standards for outside Directors and outside Audit & Supervisory Board Members are publicized on our corporate website.  
[https://www.astellas.com/en/corporate/pdf/inde\\_std\\_outside\\_en.pdf](https://www.astellas.com/en/corporate/pdf/inde_std_outside_en.pdf)

### Nomination Committee and Compensation Committee

The Company has established a Nomination Committee and Compensation Committee as advisory bodies to the Board of Directors in order to improve the transparency and objectivity of the deliberation process regarding election and dismissal of Directors, etc. and remuneration system. Each committee is chaired by an outside Director with outside Directors comprising a majority of the members.

(Role of the Nomination Committee)

- Discusses matters concerning the election and dismissal of Directors and Audit & Supervisory Board Members, and the appointment and removal of Executive Officers and others, and reports the results to the Board of Directors

(Role of the Compensation Committee)

- Discusses matters concerning remuneration to be

received by Directors, Executive Officers and others, and reports the results to the Board of Directors

### Audit & Supervisory Board Members and the Audit & Supervisory Board

Astellas uses the Audit & Supervisory Board Member system. The Audit & Supervisory Board Members are elected at the Annual Shareholders Meeting for a term of office of four years. As a general rule, the Audit & Supervisory Board meets once per month.

The Audit & Supervisory Board Members contribute to the establishment of an effective corporate governance system by auditing the Directors' performance of their duties. The Audit & Supervisory Board is the only discussion and decision-making body for forming opinions regarding the audits by Audit & Supervisory Board Members. The Audit & Supervisory Board, where necessary, provides its opinions to Directors or the Board of Directors. However, resolutions of the Audit & Supervisory Board do not obstruct the execution by each Audit & Supervisory Board Member of their authority.

As of the close of the Annual Shareholders Meeting, the Audit & Supervisory Board comprises five members, with a majority of three outside Audit & Supervisory Board Members to further enhance the independence and neutrality of the

### Expected Role of Outside Directors and Outside Audit & Supervisory Board Members

Position	Name	Expected Role	Attendance at Meetings of the Board of Directors and Audit & Supervisory Board During Fiscal 2015
Outside Directors	Yutaka Kase	Yutaka Kase has been engaged in corporate management as a business manager of a general trading company, and has abundant global experience and extensive insight. Yutaka Kase currently plays a key role as an outside Director for management of the Company from an independent standpoint. The Company is confident that he will draw on his abundant experience of corporate management in management of the Company in the future as well.	15/15 times
	Hironobu Yasuda	After successively holding important posts such as Public Prosecutor at the Supreme Public Prosecutors Office, Hironobu Yasuda has been engaged in corporate legal affairs as an attorney-at-law, and has abundant expertise and experience. Hironobu Yasuda currently plays a key role as an outside Director for management of the Company from an independent standpoint as an attorney-at-law. The Company is confident that he will draw on his abundant specialized knowledge and experience in management of the Company in the future as well.	15/15 times
	Etsuko Okajima	Etsuko Okajima has been engaged in corporate management as a business manager of a human resources consulting company, and has abundant management experience and extensive insight. Etsuko Okajima currently plays a key role as an outside Director for management of the Company from an independent standpoint. The Company is confident that she will draw on her abundant experience of corporate management in management of the Company in the future as well.	15/15 times
	Yoshiharu Aizawa	Yoshiharu Aizawa has been engaged in medical treatment while successively holding important posts at Kitasato University as a medical scientist, and has abundant specialized knowledge and experience. Yoshiharu Aizawa currently plays a key role as an outside Director for management of the Company from an independent standpoint. The Company is confident that Yoshiharu Aizawa will draw on his abundant specialized knowledge and experience as a medical scientist in management of the Company in the future as well.	12/12 times
Outside Audit & Supervisory Board Members	Toshiko Oka	Toshiko Oka has been engaged in corporate management as a business manager of a management consulting firm, and has abundant management experience and extensive insight. Toshiko Oka currently plays a key role as an outside Audit & Supervisory Board Member from an independent standpoint. The Company is confident that she will draw on her abundant experience in corporate management in auditing the Company in the future as well.	15/15 Board of Directors meetings 13/13 Audit & Supervisory Board meetings
	Hitoshi Kanamori	After successively holding important posts such as Public Prosecutor at the Tokyo District Public Prosecutors Office, Hitoshi Kanamori has been engaged in corporate legal affairs as an attorney-at-law, and has abundant expertise and experience. Hitoshi Kanamori currently plays a key role as an outside Audit & Supervisory Board Member from an independent standpoint. The Company is confident that he will draw on his abundant experience as an attorney-at-law in auditing the Company in the future as well.	11/12 Board of Directors meetings 10/10 Audit & Supervisory Board meetings
	Noriyuki Uematsu	With many years of experience as a certified public accountant, Noriyuki Uematsu has thorough knowledge of corporate consulting and auditing, and is also engaged in corporate management as a business manager of a consulting company relating to business accounting and tax accounting services. The Company is confident that Noriyuki Uematsu will draw on his abundant specialized knowledge and experience in auditing the Company from an independent standpoint.	Inaugurated in June 2016

auditing system. The three outside Audit & Supervisory Board Members meet the criteria of the Tokyo Stock Exchange for independent Audit & Supervisory Board Members as well as the Company's own criteria for independence of outside Audit & Supervisory Board Members. They are therefore independent Audit & Supervisory Board Members who have no risk of a conflict of interest with general shareholders.

Each outside Audit & Supervisory Board Member has a specific area of expertise, such as finance, accounting, legal and business management. They draw on their specific expertise and extensive experience to audit the Directors' performance of duties from an independent standpoint. The Company assigns fulltime staff members to assist the Audit & Supervisory Board Members in carrying out their duties to ensure that the Audit & Supervisory Board Members' audits are effective. The function of the Audit & Supervisory Board Members is enhanced through cooperation with the Accounting Auditors and the Internal Auditing Department.

## Remuneration for Directors and Audit & Supervisory Board Members

Remuneration for Directors and Audit & Supervisory Board Members is designed to enable the Company to recruit and retain talented individuals, and to make the remuneration levels and structures fully commensurate with the responsibilities of the position. The Company has improved the objectivity of decisions on remuneration levels through measures such as the use of survey data from specialist third-party companies.

Remuneration for internal Directors is fundamentally based upon contributions to sustainable improvements in business performance and enterprise value, and are composed of a fixed base salary, bonuses, and stock remuneration\*. The Company appropriately links remuneration with business performance. Remuneration for outside Directors and Audit & Supervisory Board Members (including outside Audit & Supervisory Board Members) comprises only a fixed base salary.

Remuneration for each Director is determined by resolution of the Board of Directors within a total ceiling amount approved by the Annual Shareholders Meeting, while remuneration for each Audit & Supervisory Board Member is determined through deliberations of the Audit & Supervisory Board Members within a total ceiling amount approved by the Annual Shareholders Meeting. Through the deliberations of the Compensation Committee, the Company enhances the transparency and objectivity of the deliberation process for remuneration for Directors.

\* In fiscal 2015, Astellas introduced a performance-linked stock compensation scheme. Following the introduction of this new plan, no more stock options under the previous stock-linked compensation plan will be issued from fiscal 2015.

## Remuneration for Directors and Audit & Supervisory Board Members in Fiscal 2015

(¥ million)

Category	Total amount of remuneration	Type of remuneration			
		Basic remuneration	Bonus	Stock remuneration	Stock options as stock-linked remuneration plan
Directors (excluding outside Directors): 3	647	258	249	115	25
Audit & Supervisory Board Members (excluding outside Audit & Supervisory Board Members): 2	88	88	-	-	-
Outside Directors and outside Audit & Supervisory Board Members: 8	81	81	-	-	-

The total amount of remuneration shown here is the amount paid as remuneration for the performance of duties during fiscal 2015, and includes the amount paid to one outside Director who retired during fiscal 2015.

## Invigorating the Annual Shareholders Meeting and Smooth Exercise of Voting Rights

The Company recognizes the Annual Shareholders Meeting as an important forum for constructive dialogue with shareholders. We have taken the following measures to invigorate the meeting for shareholders and smooth the processes of exercising voting rights.

- The Annual Shareholders Meeting is held in June each year on a date chosen to avoid dates where meetings of other companies are concentrated.
- The convocation notice is dispatched three weeks prior to the meeting date, and published before dispatch on Timely Disclosure Network (TDnet) provided by the Tokyo Stock Exchange and the Company's website.
- To enhance the environment for exercising voting rights, we utilize an electronic voting platform.
- An English translation of the convocation notice is posted on the Company's website together with the Japanese version.

## Enhancing the Management Structure

The Company establishes its global management structure and is working to strengthen it.

The Company has established the Executive Committee, chaired by the Representative Director, President and CEO, for discussing important matters regarding management of the entire Group, and the Japan Management Committee, chaired by the Executive Vice President, for discussing important matters regarding the administration of Astellas and its Group companies in Japan.

To build a management system capable of making prompt and appropriate decisions, the Company has a "matrix management" structure. It consists of a functional

axis and a regional axis, in which the Drug Discovery Research, Medical, Development, and Technology Divisions are managed globally according to their functions, and the Sales & Marketing Divisions are managed regionally.

In April 2015, the Marketing Strategy function, which was formerly under the control of Product & Portfolio Strategy, was changed to be placed directly under the Representative Director, President and CEO. Global Business Development was reorganized and the functions of in-licensing and out-licensing products and identifying and negotiating business partnerships were concentrated in Business Development of the Company. In addition, in terms of major IT functions in Japan, Americas and EMEA, a global system has been put in place which reports to Information Systems of the Company.

We have established the Global Compliance Committee which discusses global compliance policies and plans. Furthermore, in April 2016, the Company established a global compliance function under which compliance functions for each region report to the head of Ethics & Compliance. The Company also appointed people responsible for compliance around the world and strengthen the system on an ongoing basis.

Other committees established within the Company include a CSR Committee, which discusses policies and plans for important activities in fulfilling the Company's social responsibilities (environment, health and safety, social contribution activities, and so forth), a Corporate Disclosure Committee, which discusses matters related to our policy for disclosure of corporate information, and a Global Benefit Risk Committee, which discusses product risk-benefit information and policies to address this information. To manage risk on a global basis, we have also established a Global Risk Management Office as an administrative liaison for coordinating risk management around the world. This office is coordinating the global monitoring of risk and developing optimal risk management solutions for the Company.

## Accounting Audit

Ernst & Young ShinNihon LLC serves as the Company's Accounting Auditor. The Accounting Auditor and the Company's Audit & Supervisory Board Members maintain close cooperation by meeting several times a year, as well as discussing their annual audit plans and the results of audits, and sharing 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, and we assess the effectiveness of the system in a fair manner.

	Payment amount
1. Accounting Auditor's remuneration for fiscal 2015	¥168 million
2. Total amount of cash and other material benefits payable to the Accounting Auditor by the Company and its subsidiaries	¥168 million

## Measures to Improve the Internal Control System

The Company will further develop and enhance systems, such as the system to improve efficient performance of duties, the risk management system, the system for compliance with laws and other matters, and the internal audit system. We are also promoting systems and an environment for ensuring that audits by Audit & Supervisory Board Members are carried out effectively. Through these efforts, the Company is working to ensure that the entire Group's business is duly executed.

Details on this system of internal controls are available on the Company's website, and in the reports concerning corporate governance submitted to the stock exchanges, etc.

## Timely, Appropriate Information Disclosure and Constructive Dialogue with Shareholders

The Company strives to ensure timely, appropriate, and fair disclosure of information to all stakeholders, including customers, shareholders, and society. We also conduct proactive dialogue with stakeholders and strive to ensure that the opinions they share with us are reflected properly in our corporate activities.

This commitment to disclosure and dialogue helps us to improve our transparency as a corporation, and to build and maintain trust with our stakeholders. The Company has published its Disclosure Policy\*, which was formulated in line with these basic commitments, and has also established the Corporate Disclosure Committee to promote and manage information disclosure activities.

In addition, the Company established a dedicated in-house department for investor relations (IR) and has appointed an Executive Officer with responsibility for supervising dialogue with shareholders overall and for IR. Their role is to hold individual interviews with shareholders and other investors, as well as briefing meetings and other events, in order to further enhance constructive dialogue with shareholders and other investors, as well as other market participants.

\* The Company's Disclosure Policy is published on its website. [https://www.astellas.com/en/corporate/comp\\_policy/](https://www.astellas.com/en/corporate/comp_policy/)

## Profile of Directors and Audit & Supervisory Board Members

### Representative Director, President and CEO

#### Yoshihiko Hatanaka

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

### Representative Director and Executive Vice President

#### Yoshiro Miyokawa

1975: Joined the Company  
 2003: Vice President of Business Process Reengineering of the Company  
 2005: Vice President of Post-Merger Integration Operation of the Company  
 2005: Corporate Executive and Vice President of Post-Merger Integration Operation of the Company  
 2005: Corporate Executive and Vice President of Business Innovation of the Company  
 2006: Corporate Executive and Vice President of Human Resources, Corporate Administration Division of the Company  
 2007: Corporate Executive and Vice President of Human Resources of the Company  
 2008: Corporate Executive of the Company, Corporate Administration (CAO)  
 2008: Senior Corporate Executive of the Company, Corporate Administration (CAO)  
 2011: Executive Vice President and Senior Corporate Executive of the Company, Corporate Administration (CAO)  
 2013: Representative Director, Executive Vice President of the Company, Corporate Administration and Compliance (CAO & CCO) (present post)

### Outside Directors

#### Yutaka Kase

1970: Joined Nissho Iwai Corporation  
 2001: Executive Officer, Nissho Iwai Corporation  
 2003: Managing Executive Officer and Director, Nissho Iwai Corporation  
 2004: Senior Managing Executive Officer and Representative Director, Sojitz Corporation  
 2004: Executive Vice President and Representative Director, Sojitz Corporation  
 2007: President and Representative Director, Sojitz Corporation  
 2012: Chairman and Representative Director, Sojitz Corporation (present post)  
 2013: Director of the Company (present post)  
 2016: Outside Director, JAC Recruitment Co., Ltd. (present post)  
 2016: Outside Director, SEKISUI CHEMICAL CO., LTD. (present post)

#### Hironobu Yasuda

1978: Public Prosecutor, Tokyo District Public Prosecutors Office  
 2004: Public Prosecutor, Tokyo High Public Prosecutors Office  
 2005: Chief Appeals Judge (Director of Tokyo Regional Tax Tribunal)  
 2009: Chief Prosecutor, Yamaguchi District Public Prosecutors Office  
 2010: Public Prosecutor, Supreme Public Prosecutors Office  
 2010: Registered as an attorney-at-law (Dai-ichi Tokyo Bar Association)  
 2012: Partner, Seiryu Law Office (present post)  
 2013: Director of the Company (present post)  
 2015: Outside Director and Audit and Supervisory Committee Member, Remixpoint, Inc. (present post)  
 2016: Independent Auditor, Takata Corporation (present post)

#### Etsuko Okajima

1989: Joined Mitsubishi Corporation  
 2001: Joined McKinsey & Company, Inc., Japan  
 2002: Joined GLOBIS Management Bank, Inc.  
 2004: Executive Officer, GLOBIS Corporation  
 2005: President and Representative Director, GLOBIS Management Bank, Inc.  
 2007: Established ProNova Inc. President and Representative Director, ProNova Inc. (present post)  
 2014: Director of the Company (present post)  
 2014: Outside Director, MARUI GROUP CO., LTD (present post)  
 2015: External Director, SEPTENI HOLDINGS CO., LTD. (present post)  
 2016: Outside Director, Link and Motivation Inc. (present post)

#### Yoshiharu Aizawa, M.D., Ph.D.

1975: Fellow, Department of Internal Medicine, School of Medicine, Keio University  
 1980: Assistant Professor, Department of Preventive Medicine and Public Health, School of Medicine, Kitasato University  
 1983: Associate Professor, Department of Preventive Medicine and Public Health, School of Medicine, Kitasato University  
 1994: Professor, Department of Preventive Medicine and Public Health, School of Medicine, Kitasato University  
 2004: Chairperson of School of Medicine, Kitasato University  
 2006: Dean of School of Medicine, Kitasato University  
 2009: Vice President, Kitasato University  
 2010: Executive Trustee, The Kitasato Institute  
 2012: Professor Emeritus, Kitasato University (present post)  
 2015: Director of the Company (Present post)

### Audit & Supervisory Board Members

#### Tomokazu Fujisawa

1984: Joined Fujisawa Pharmaceutical Co., Ltd.  
 1999: Director of Planning, Medical Supply Business, Fujisawa Pharmaceutical Co., Ltd.  
 2006: Assistant to Senior Vice President, Corporate Finance & Accounting and Project Leader of J-SOX Project of the Company  
 2007: Project Leader of J-SOX Project of the Company  
 2013: Vice President of Internal Auditing of the Company  
 2014: Assistant to President & CEO of the Company  
 2014: Audit & Supervisory Board Member of the Company (present post)

#### Hiroko Sakai

1983: Joined the Company  
 2012: Vice President of Clinical and Research Quality Assurance, QA, RA and Pharmacovigilance Department of the Company  
 2014: Vice President of Clinical and Research Quality Assurance of the Company  
 2016: Assistant to President & CEO of the Company  
 2016: Audit & Supervisory Board Member of the Company (present post)

### Outside Audit & Supervisory Board Members

#### Toshiko Oka

1986: Joined Tohmatsu Touche Ross Consulting Limited (currently ABeam Consulting Ltd.)  
 2000: Joined Asahi Arthur Andersen Limited  
 2002: Principal, Deloitte Tohmatsu Consulting Co., Ltd. (currently ABeam Consulting Ltd.)  
 2005: President and Representative Director, ABeam Consulting Ltd. (currently PwC Advisory LLC)  
 2008: Outside Director, Netyear Group Corporation (present post)  
 2014: Audit & Supervisory Board Member of the Company (present post)  
 2015: Outside Corporate Auditor, HAPPINET CORPORATION (present post)  
 2016: Chief Executive Officer, PricewaterhouseCoopers Deals Advisory LLC (currently PwC Advisory LLC)  
 2016: Partner, PwC Advisory LLC  
 2016: Outside Director, Hitachi Metals, Ltd. (present post)  
 2016: Outside Director, Mitsubishi Corporation (present post)  
 2016: CEO, Oka & Company Ltd. (present post)

#### Hitoshi Kanamori

1984: Public Prosecutor, Tokyo District Public Prosecutors Office  
 1985: Public Prosecutor, Yamagata District Public Prosecutors Office  
 1988: Public Prosecutor, Niigata District Public Prosecutors Office  
 1990: Public Prosecutor, Tokyo District Public Prosecutors Office  
 1992: Registered as an attorney-at-law (Tokyo Bar Association)  
 1993: Partner, SANNO LAW OFFICE (present post)  
 2005: Visiting Professor, University of Tsukuba Law School  
 2015: Audit & Supervisory Board Member of the Company (present post)

#### Noriyuki Uematsu

1985: Joined Tohmatsu & Aoki Audit Corporation  
 1997: Joined Deloitte Tohmatsu Consulting Co., Ltd. (current ABeam Consulting Ltd.)  
 1999: Global Partner for manufacturing industry and Managing Director in Kyushu area, Deloitte Tohmatsu Consulting Co., Ltd. (current ABeam Consulting Ltd.)  
 2003: Joined DENTSU INC.  
 2008: Established Uematsu & Co. Managing Director, Uematsu & Co. (present post)  
 2011: President & Representative Director, SU Consultant Co., Ltd. (present post)  
 2012: Outside Audit & Supervisory Board Member, NJK Corporation (present post)  
 2015: Outside Audit & Supervisory Board Member, Kamakura Shinsho, Ltd.  
 2016: Outside Director and Audit & Supervisory Committee Member, Kamakura Shinsho, Ltd. (present post)  
 2016: Audit & Supervisory Board Member of the Company (present post)



# Messages from Outside Officers



The role of outside Directors is set to become more prominent following the formulation of Japan's Corporate Governance Code. Outside officers are expected to ask many questions from varied perspectives at Board of Directors meetings to help stimulate active discussion of issues in reviewing resolutions.

I believe the duty of a Director is to understand the tabled proposals and, having accepted them, define my position for agreement or disagreement on clear grounds. In the Board of Directors meetings I strive to check on various aspects such as risk management, including compliance, and the decision-making process. I also strive to actively provide opinions and ask questions. My aim is to contribute to an even more dynamic Astellas Board of Directors to improve transparency and ensure sound business management.

**Yutaka Kase** Outside Director



Primarily my role is to study issues for board deliberation from an independent position and to express my views using a risk management perspective, based on my years of experience as a legal professional in handling various legal issues.

Since 2015, Astellas has created opportunities for outside Directors and Audit & Supervisory Board Members to exchange opinions and share information in line with the Corporate Governance Code. This has further enhanced the corporate governance system in Astellas. Through this role, I hope to play an even more active part in helping Astellas contribute to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.

**Hironobu Yasuda** Outside Director



Innovation must be sustained and destructive if Astellas is to realize its business philosophy of contributing toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products as an R&D-led global pharmaceutical company.

Drawing on my experience as a strategic HR consultant advising more than 200 companies a year on how to develop management leadership and handle business succession issues, as an outside Director, I hope to contribute to further improvements in corporate governance by helping Astellas accelerate its efforts to create a corporate culture and environment that enables its employees to continue to generate innovation with a sense of urgency.

**Etsuko Okajima** Outside Director



Comprised of six Directors, four of whom are outside Directors, the Board of Directors oversees management from perspectives that are both diverse and broad-ranging.

Continued development of effective, safe new drugs requires employees to have a highly ethical perspective and shared goals. They also need to have faith in the Company's management and a real passion for the Company. The management team therefore needs to work ceaselessly on improving the organization and developing an environment that is conducive to good work. I will use my experience in researching, educating, and implementing industrial health policies at the university, as well as my involvement in the administration of the medical faculty and the university, to supervise and support management execution at Astellas. I aim to help Astellas to ensure and promote the health of people around the world, and to conduct transparent management that meets shareholders' expectations.

**Yoshiharu Aizawa, M.D., Ph.D.** Outside Director



The true value of corporate governance can be seen in its execution. Astellas is among the top-ranking companies in Japan in terms of its corporate governance, which is focused on ensuring that management is always based on integrity, transparency and a highly ethical perspective.

I have seen many companies in 30 years as a business consultant. Drawing on this experience from an independent position, I hope to contribute to better corporate governance and sustained growth in enterprise value at Astellas by offering a neutral and objective perspective—the perspective of common sense.

**Toshiko Oka** Outside Audit & Supervisory Board Member

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Precise judgment is required for pharmaceutical companies to develop safe, effective new medicines amid international competition. My feeling is that the management of Astellas aims to conduct management that is rational and fast-paced.

I believe firmly in the importance of even stronger corporate governance to support an accelerated business approach. In my second year in the job, I have a better understanding of the pharmaceutical industry. I will seek to contribute to improved corporate governance at Astellas by expressing my opinions freely, based on my experience as a public prosecutor and lawyer.

**Hitoshi Kanamori** Outside Audit & Supervisory Board Member

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I have served in this role since June 2016. The Board of Directors and Audit & Supervisory Board at Astellas both engage in extensive debate on issues, and I think the Company's corporate governance systems function at a high level. Astellas remains focused on its mission to contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Amid calls for even greater transparency in the future, Astellas aims to contribute to the world by working constantly to reinforce corporate governance.

In my lengthy career as a CPA, I have audited many manufacturers and other companies, and have also provided consulting services related to financial accounting. I hope to apply my experience outside of the pharmaceutical industry to help Astellas strengthen governance and build sustainable enterprise value for the medium and long terms.

**Noriyuki Uematsu** Outside Audit & Supervisory Board Member



# 5

## Financial Information and Data

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# 11-Year Financial Summary

Astellas has adopted the International Financial Reporting Standards (IFRS), effective from fiscal 2013 (March 2014). Results for each category and earnings per share are presented on a core basis for the fiscal years since March 2014.

	(¥ billion)				
	2006.3	2007.3	2008.3	2009.3	2010.3
	J-GAAP	J-GAAP	J-GAAP	J-GAAP	J-GAAP
<b>For the year</b>					
Sales	¥879.4	¥920.6	¥972.6	¥965.7	¥974.9
Cost of sales	273.0	284.1	279.3	264.4	289.2
SG&A expenses*2	413.3	446.0	417.3	450.9	499.2
R&D expenses*2	142.1	167.9	134.5	159.1	195.6
R&D ratio (%)	16.2	18.2	13.8	16.5	20.1
Operating income/profit	193.0	190.5	275.9	250.4	186.4
Operating margin (%)	22.0	20.7	28.4	25.9	19.1
Net income/Profit for the year	103.7	131.3	177.4	171.0	122.3
<b>At year-end</b>					
Total assets	1,584.5	1,470.7	1,439.2	1,348.4	1,364.2
Total net assets/Total equity	1,216.9	1,099.0	1,110.9	1,030.2	1,053.9
(¥)					
<b>Per share data*3</b>					
Net income/Profit for the year	¥183.88	¥244.07	¥349.89	¥356.11	¥261.84
Total net assets/Total equity	2,179.44	2,135.34	2,228.34	2,189.26	2,278.77
Dividends	70.00	80.00	110.00	120.00	125.00
<b>Major indicators</b>					
ROE (%)	8.8	11.3	16.1	16.0	11.7
DOE (%)	3.3	3.7	5.0	5.4	5.6
Equity ratio (%)	76.8	74.7	77.1	76.3	77.1
Free cash flows					
(¥ billion, US\$ million)	52.5	200.4	178.5	168.8	118.6
Average exchange rate (US\$/¥)	113	117	114	101	93
(€/¥)	138	150	162	143	131

\*1 US dollars have been converted at the rate of ¥113 to US\$1, the approximate exchange rate on March 31, 2016.

\*2 SG&A expenses under J-GAAP (from fiscal 2005 to fiscal 2012) include R&D expenses.

\*3 The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014. Net income/profit for the year per share and total net assets/total equity per share are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of fiscal 2012. Moreover, the number of shares outstanding has also been calculated on the assumption that the stock split was conducted at the beginning of fiscal 2012.

					(¥ billion)	(US\$ million)*1
2011.3	2012.3	2013.3	2014.3	2015.3	2016.3	2016.3
J-GAAP	J-GAAP	J-GAAP	IFRS	IFRS	IFRS	IFRS
¥953.9	¥969.4	¥1,005.6	¥1,139.9	¥1,247.3	<b>¥1,372.7</b>	<b>\$12,148</b>
296.0	318.6	324.1	330.6	333.2	<b>335.6</b>	<b>2,970</b>
538.8	519.2	527.6	397.0	452.5	<b>500.4</b>	<b>4,428</b>
217.3	189.8	182.0	191.5	206.6	<b>225.7</b>	<b>1,997</b>
22.8	19.6	18.1	16.8	16.6	<b>16.4</b>	—
119.2	131.5	153.9	186.3	216.5	<b>267.5</b>	<b>2,367</b>
12.5	13.6	15.3	16.3	17.4	<b>19.5</b>	—
67.7	78.2	82.9	132.8	153.2	<b>198.8</b>	<b>1,759</b>
1,335.1	1,400.6	1,445.6	1,653.1	1,793.6	<b>1,799.3</b>	<b>15,923</b>
1,021.1	1,018.1	1,062.0	1,268.5	1,317.9	<b>1,259.2</b>	<b>11,143</b>
					(¥)	(US\$)
¥146.49	¥169.38	¥36.08	¥59.11	¥69.37	<b>¥92.12</b>	<b>\$0.82</b>
2,207.70	2,200.64	469.92	568.53	600.93	<b>592.58</b>	<b>5.24</b>
125.00	125.00	130.00	135.00	30.00	<b>32.00</b>	<b>0.28</b>
6.5	7.7	8.0	7.4	10.5	<b>15.0</b>	—
5.6	5.7	5.7	5.0	5.1	<b>5.4</b>	—
76.4	72.6	73.3	76.7	73.5	<b>70.0</b>	—
(142.0)	146.7	95.5	187.4	116.2	<b>166.7</b>	<b>1,475</b>
86	79	83	100	110	<b>120</b>	—
113	109	107	134	139	<b>133</b>	—

# Management's Discussion and Analysis

## Overview of the Year Ended March 31, 2016 (Fiscal 2015)

In its consolidated operating results (core basis) for fiscal 2015 Astellas posted increases in sales, core operating profit and core profit for the year.

### Consolidated Financial Results (Core Basis)

	(¥ billion)	
	2015.3	2016.3
Sales	¥1,247.3	<b>¥1,372.7</b>
Operating profit	216.5	<b>267.5</b>
Profit for the year	153.2	<b>198.8</b>

The Company discloses financial results on a core basis as an indicator of its recurring profitability. Certain items reported in financial results on a full basis that are deemed to be non-recurring items by the Company are excluded as non-core items from these financial results on a core basis. These adjusted items include impairment losses, gain (loss) on sales of property, plant and equipment, restructuring costs, loss on disaster, a large amount of losses on compensation or settlement of litigation and other legal disputes, and other items that the Company judges should be excluded.

### Foreign Exchange Impact for Fiscal 2015

The exchange rates for the yen in fiscal 2015 are shown in the table below. Movements in the rates led to a ¥26.1 billion increase in the value of sales and an ¥9.5 billion increase in core operating profit.

#### Foreign Exchange Rates (Average)

	(¥)	
	2015.3	2016.3
US\$1	¥110	<b>¥120</b>
€1	139	<b>133</b>

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

	2015.3	2016.3
US\$1	¥17 (Weakening of yen)	<b>¥7</b> (Strengthening of yen)
€1	¥11 (Strengthening of yen)	<b>¥3</b> (Strengthening of yen)

## Sales

In fiscal 2015, consolidated sales increased 10.1% year on year to ¥1,372.7 billion.

In addition to XTANDI for the treatment of prostate cancer, combined sales of overactive bladder (OAB) treatments Vesicare and Betanis/Myrbetriq/BETMIGA grew. Additionally, sales of products including Prograf, an immunosuppressant, increased.

### Sales by Region

	(¥ billion)	
	2015.3	2016.3
Consolidated	¥1,247.3	<b>¥1,372.7</b>
Japan	498.7	<b>497.2</b>
Americas	361.0	<b>455.1</b>
EMEA	313.3	<b>329.3</b>
Asia & Oceania	74.2	<b>91.1</b>

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

Reference	<a href="#">Review of Operations by Therapeutic Area</a> <span style="color: red;">▶ P41</span> <a href="#">Review of Global Operations</a> <span style="color: red;">▶ P47</span> <a href="#">Sales of Main Products by Region</a> <span style="color: red;">▶ P51</span>
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## Cost of Sales and Gross Profit

Cost of sales increased 0.7% to ¥335.6 billion. The cost of sales ratio fell 2.3 percentage points in fiscal 2015, to 24.4%, mainly due to changes in the product mix.

Gross profit increased by 13.5%, to ¥1,037.1 billion, due to growing sales, as well as a decrease in the cost of sales ratio.

### Cost of Sales and Gross Profit

	(¥ billion)	
	2015.3	2016.3
Sales	¥1,247.3	<b>¥1,372.7</b>
Cost of sales	333.2	<b>335.6</b>
Cost of sales ratio (%)	26.7	<b>24.4</b>
Gross profit	914.1	<b>1,037.1</b>
Gross profit ratio (%)	73.3	<b>75.6</b>

### Selling, General and Administrative (SG&A) Expenses, Research and Development (R&D) Expenses and Amortisation of Intangible Assets

SG&A expenses increased 10.6% to ¥500.4 billion, which was partly due to increased expenditures for co-promotion of XTANDI in the U.S., in addition to the foreign exchange rate impact.

R&D expenses rose by 9.2% to ¥225.7 billion, which was partly due to increased expenses in line with progress on a development project, in addition to the foreign exchange rate impact. The ratio of R&D expenses to sales fell 0.2 of a percentage point to 16.4%.

Amortisation of intangible assets was ¥42.4 billion, up 9.6% year on year.

#### SG&A Expenses, R&D Expenses and Amortisation of Intangible Assets

	¥ billion	
	2015.3	2016.3
SG&A expenses	¥452.5	<b>¥500.4</b>
SG&A ratio (%)	36.3	<b>36.5</b>
Advertising and sales promotional expenses	138.5	<b>169.1</b>
Personnel expenses	178.1	<b>186.1</b>
Other	136.0	<b>145.1</b>
R&D expenses	206.6	<b>225.7</b>
R&D ratio (%)	16.6	<b>16.4</b>
Amortisation of intangible assets	38.7	<b>42.4</b>

#### Reconciliation of Full Basis to Core Basis

Account item	2015.3			2016.3		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Sales	¥1,247.3	—	¥1,247.3	<b>¥1,372.7</b>	—	<b>¥1,372.7</b>
Cost of sales	333.2	—	333.2	<b>335.6</b>	—	<b>335.6</b>
Gross profit	914.1	—	914.1	<b>1,037.1</b>	—	<b>1,037.1</b>
SG&A expenses	452.5	—	452.5	<b>500.4</b>	—	<b>500.4</b>
R&D expenses	206.6	—	206.6	<b>225.7</b>	—	<b>225.7</b>
Amortisation of intangible assets	38.7	—	38.7	<b>42.4</b>	—	<b>42.4</b>
Share of profits (losses) of associates and joint ventures	0.2	—	0.2	<b>(1.2)</b>	—	<b>(1.2)</b>
Other income*1	12.5	(12.5)	—	<b>1.7</b>	<b>(1.7)</b>	—
Other expense*1	43.3	(43.3)	—	<b>20.2</b>	<b>(20.2)</b>	—
Operating profit	185.7	30.8	216.5	<b>249.0</b>	<b>18.5</b>	<b>267.5</b>
Finance income*2	7.1	(5.1)	1.9	<b>14.4</b>	<b>(12.3)</b>	<b>2.1</b>
Finance expense*2	3.1	(2.7)	0.4	<b>1.6</b>	<b>(0.6)</b>	<b>1.0</b>
Profit before tax	189.7	28.4	218.1	<b>261.8</b>	<b>6.8</b>	<b>268.6</b>
Income tax expense	53.8	11.0	64.8	<b>68.1</b>	<b>1.7</b>	<b>69.8</b>
Profit for the year	135.9	17.4	153.2	<b>193.7</b>	<b>5.1</b>	<b>198.8</b>

\*1 "Other income" and "other expense" are excluded from core results. "Other income" and "other expense" include gain (loss) on sale and disposal of property, plant and equipment, impairment losses for other intangible assets, loss on restructuring and foreign exchange gains (losses), etc.

\*2 Gain (loss) on sale of available-for-sale (AFS) financial assets and impairment losses on AFS financial assets included in "finance income" and "finance expense" are excluded from core results as non-core items.

### Operating Profit (Core Basis)

As a result of the above mentioned factors, core operating profit increased 23.5%, to ¥267.5 billion. The operating margin increased 2.1 percentage points to 19.5%.

#### Operating Profit (Core Basis)

	¥ billion	
	2015.3	2016.3
Sales	¥1,247.3	<b>¥1,372.7</b>
Operating profit	216.5	<b>267.5</b>
Operating margin (%)	17.4	<b>19.5</b>

### Profit for the Year (Core Basis)

Core profit for the year increased by 29.7% to ¥198.8 billion.

Basic core earnings per share increased by 32.8% year-on-year to ¥92.12.

## Profit for the Year (Core Basis)

	2016.3	
	2015.3	2016.3
Profit before tax	¥218.1	<b>¥268.6</b>
Income tax expense	64.8	<b>69.8</b>
Profit for the year	153.2	<b>198.8</b>
Ratio of profit for the year to sales (%)	12.3	<b>14.5</b>

## Consolidated Financial Results (Full Basis)

In its consolidated operating results on a full basis for fiscal 2015, Astellas posted increases in sales, operating profit, profit before tax and profit for the year.

Various items totaling ¥20.2 billion were recorded in “other expense.” These included items excluded from core results, such as impairment losses for property, plant and equipment, and net foreign exchange losses. In addition, gain on sales of available-for-sale financial assets of ¥12.3 billion was recorded in “finance income.” “Other expense” and gain on sales of available-for-sale financial assets in the previous fiscal year were ¥43.3 billion and ¥5.1 billion, respectively.

## Consolidated Financial Results (Full Basis)

	2016.3	
	2015.3	2016.3
Sales	¥1,247.3	<b>¥1,372.7</b>
Operating profit	185.7	<b>249.0</b>
Profit before tax	189.7	<b>261.8</b>
Profit for the year	135.9	<b>193.7</b>

## Status of R&D

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 enhancing its ability to create innovation as a strategic priority. In fiscal 2015, Astellas continued to enter into joint research agreements with various research institutions in order to tap into external sources of innovation. In addition, Astellas made progress on many fronts, including regulatory approvals for multiple projects in clinical development.

Reference | R&D Topics During the Year ► **P37**

## Initiatives to Optimize the Allocation of Resources

Astellas is working to optimize the allocation of resources continuously. In fiscal 2015, Astellas took the following initiatives to optimize the allocation of resources.

In October 2015, Astellas succeeded the manufacturing and marketing approval for suxamethonium muscle relaxant to Maruishi Pharmaceutical Co., Ltd.

Additionally, in October 2015, Astellas entered into an agreement with MicroBiopharm Japan Co., Ltd. (MBJ) to transfer the business of the Kiyosu Plant (Aichi), one of Astellas’ manufacturing sites, to MBJ. In April 2016, the business of the Kiyosu Plant was transferred to MBJ.

Moreover, the Company entered into an agreement with TOA EIYO LTD. (TOA EIYO) to succeed the manufacturing and marketing approval for Cibenoil for the treatment of arrhythmia to TOA EIYO. In April 2016, Astellas succeeded this approval to TOA EIYO.

In November 2015, Astellas entered into an Asset Purchase Agreement to transfer its global dermatology business to LEO Pharma A/S (Denmark). In April 2016, Astellas transferred this business to LEO Pharma A/S.

## Business Combinations

With respect to “Creating Innovation,” Astellas is enhancing capabilities to deliver innovative medicines in existing therapeutic areas and continuously pursuing new opportunities in terms of new therapeutic areas and utilizing new technologies and modalities. Astellas selected muscle diseases and ophthalmology as focused disease areas for research and is promoting drug discovery research in earnest in those areas. Furthermore, Astellas invests proactively in regenerative medicine, particularly in cell therapy.

As part of these efforts, in February 2016, Astellas acquired Ocata Therapeutics, Inc. (“Ocata”)\*, through a tender offer to purchase all issued and outstanding shares of common stock in cash. Ocata is a clinical stage biotechnology company focused on the development and commercialization of new therapies in the field of regenerative medicine in ophthalmology. Ocata has an advanced technology that can establish fully-differentiated cells from pluripotent stem cells. Ocata also has strengths in clinical studies for cell therapy. Through this acquisition, Astellas aims to contribute to ophthalmic therapy, which has a high level of unmet medical needs, based on a cell therapy approach.

\* The company was renamed as Astellas Institute for Regenerative Medicine in May 2016.



## Consolidated Forecasts for the Year Ending March 31, 2017 (Fiscal 2016) (Announced in May 2016)

The Company's consolidated business forecasts for fiscal 2016 are presented on a core basis in the table below.

### Fiscal 2016 Forecasts (Core Basis)

	(¥ billion)	
	2016.3	2017.3 (Forecasts)
Sales	¥1,372.7	¥1,350.0
Operating profit	267.5	270.0
Profit for the year	198.8	199.0

### Foreign Exchange Rates (Average)

	(¥)	
	2016.3	2017.3 (Forecasts)
US\$1	¥120	¥110
€1	133	125

We project a decrease in sales, and increases in core operating profit and core profit for the year, compared with fiscal 2015. We assume the yen will strengthen against the U.S. dollar and the euro compared with fiscal 2015, and we expect foreign exchange factors to have a ¥71.7 billion negative impact on sales and a ¥22.3 billion negative impact on core operating profit.

## Sales

In fiscal 2016, we forecast a 1.7% year-on-year decrease in sales to ¥1,350.0 billion. Negative impacts due to the foreign exchange rate impact as well as the NHI drug price revision in Japan enforced in April 2016 are anticipated. In addition to anticipated continuous global sales growth for XTANDI, our growth driver, global sales of OAB treatments including Vesicare are forecasted to grow steadily based on the growth of Betanis/Myrbetriq/BETMIGA. The impact on sales from the transfer of the global dermatology business implemented in April 2016 is anticipated to be immaterial.

Reference | Review of Global Operations > P47  
 | Sales of Main Products by Region > P51

## Operating Profit and Profit for the Year (Core Basis)

Although we forecast a fall in the cost of sales ratio as a result of changes in the product mix and other factors, gross profit is anticipated to decrease owing to a decrease in sales.

Looking at SG&A expenses, although selling expenses related to co-promotion of XTANDI in the U.S., among other expenses, are projected to increase, the ratio of SG&A expenses to sales is expected to remain mostly unchanged from fiscal 2015 based on continuing efforts to streamline expenses, as well as the foreign exchange rate impact, which will have the effect of reducing expenses.

We project a 2.4% increase in R&D expenses to ¥231.0 billion, with a ratio of R&D expenses to sales of 17.1% (compared with 16.4% in fiscal 2015).

In addition to the above, we are anticipating the impact of an increase in core operating profit due to the transfer of the global dermatology business.

As a result, we forecast a 1.0% year-on-year increase in core operating profit to ¥270.0 billion. Core profit for the year is expected to increase 0.1% year on year to ¥199.0 billion. Basic core earnings per share is forecasted to increase 1.7% year on year to ¥93.65.

## Number of Employees

As of March 31, 2016, Astellas worldwide employed 17,217 people, a year-on-year increase of 104. The total number of Medical Representatives (MRs) was approximately 6,000.

In Japan, the number of employees was 7,056, down 185 from the previous fiscal year-end. In the Americas, the regional head count was 3,062 employees, up 87 from the previous fiscal year-end. In EMEA, we had 4,726 employees, up 98 year on year. In Asia and Oceania, we had 2,373 employees, up 104 from the previous fiscal year-end.

### Number of Employees by Region

	(persons)	
	2015.3	2016.3
Total	17,113	17,217
Japan	7,241	7,056
Americas	2,975	3,062
EMEA	4,628	4,726
Asia & Oceania	2,269	2,373

### Number of MRs

	(persons)	
	2015.3	2016.3
Total (Global)	6,400	6,000

## Assets, Liabilities and Equity

An overview of the consolidated statement of financial position as of March 31, 2016 and the main changes from the end of the previous fiscal year are shown below.

### Assets

Total assets as of March 31, 2016 amounted to ¥1,799.3 billion, up ¥5.8 billion from a year earlier.

Non-current assets increased ¥74.2 billion, to ¥901.8 billion at the fiscal year-end. Other intangible assets were ¥339.2 billion, up ¥43.4 billion from the previous fiscal year-end.

Current assets decreased ¥68.4 billion, to ¥897.5 billion at the fiscal year-end. Cash and cash equivalents were ¥360.0 billion, down ¥36.4 billion from the previous fiscal year-end.

### Equity

Total equity was ¥1,259.2 billion, a decrease of ¥58.7 billion from a year earlier.

While profit for the year stood at ¥193.7 billion, the Company paid ¥69.6 billion in dividends of surplus and acquired ¥120.1 billion in treasury shares.

The Company cancelled treasury shares worth ¥49.6 billion (38 million shares) on May 29, 2015.

### Liabilities

Total liabilities as of March 31, 2016 amounted to ¥540.1 billion, up ¥64.5 billion from a year earlier.

Total non-current liabilities rose ¥72.0 billion to ¥126.8 billion. Current liabilities decreased ¥7.5 billion to ¥413.4 billion.

Due mainly to the recording of deferred income related to the transfer of the global dermatology business, other non-current liabilities increased by ¥58.4 billion to ¥77.6 billion and other current liabilities increased by ¥27.7 billion to ¥121.1 billion from a year earlier.

### Liquidity and Financing

Astellas is strengthening its global business foundations with a focus on the strategic initiatives of “maximizing the product value,” “creating innovation,” and “pursuing operational excellence.” In addition, Astellas will actively introduce new products and otherwise pursue strategic business investment opportunities to further reinforce its product lineup.

In regard to the liquidity of funds, liquidity is maintained to enable Astellas to target a certain amount of

strategic investment opportunities, while also supplying working capital and funding capital expenditures.

As outlined in the section on business risks, Astellas’ operations face a varied set of risks that are particular to the ethical pharmaceutical business. The Group’s financial policy is to maintain a healthy balance sheet at all times so that it can finance smoothly at low costs, particularly in the event that funding requirements exceed Astellas’ internal funding capacity in the course of developing business.

## Cash Flows

### Cash Flows from Operating Activities

Net cash flows from operating activities amounted to ¥313.7 billion, an increase of ¥126.1 billion in year-on-year terms. The main components included proceeds from the transfer of the global dermatology business of ¥88.2 billion.

### Cash Flows from Investing Activities

Net cash flows used in investing activities totaled ¥147.1 billion, up ¥75.6 billion from the previous fiscal year. While purchases of property, plant and equipment used cash of ¥33.5 billion, purchase of intangible assets used cash of ¥84.6 billion, and purchase of shares of subsidiaries due to acquisition of Ocata Therapeutics, Inc. used cash of ¥42.7 billion, while proceeds from sales of available-for-sale financial assets provided cash of ¥16.7 billion.

### Cash Flows from Financing Activities

Net cash flows used in financing activities totaled ¥193.5 billion, up ¥72.4 billion from the previous fiscal year.

Dividends paid to owners of the parent totaled ¥69.6 billion, an increase in outflow of ¥7.5 billion year on year. Other outflows included cash of ¥120.1 billion used for the acquisition of Astellas’ own shares.

As a result of the above, the balance of cash and cash equivalents as of March 31, 2016 amounted to ¥360.0 billion, a decrease of ¥36.4 billion compared with the previous fiscal year-end.

## Capital Expenditures

Astellas made capital expenditures with the aim of reinforcing its manufacturing capabilities (including the construction of the new formulation facilities of the Yaizu Technology Center of Astellas Pharma Tech Co., Ltd., a production subsidiary) and reshaping of the research base. Capital expenditures in fiscal 2015 totaled ¥34.0 billion, up 11.2% year on year (accrual basis).

In fiscal 2016, capital expenditures are forecast to decrease 6.0% to ¥32.0 billion.

## Earnings per Share, Dividends and Equity Attributable to Owners of the Parent

### Per Share Data

	2015.3	2016.3
Earnings per share		
Basic	¥61.50	<b>¥89.75</b>
Diluted	61.40	<b>89.62</b>
Basic (core basis)	69.37	<b>92.12</b>
Dividends	30.00	<b>32.00</b>
Equity per share attributable to owners of the parent	600.93	<b>592.58</b>

## 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 attributable to owners of the parent (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

### Common Stock

	2015.3	2016.3
Total number of issued shares*	2,259,823	<b>2,221,823</b>
Treasury shares*	66,681	<b>96,844</b>

### Treasury Shares

	2015.3	2016.3
Number of shares bought back*	38,310 thousand	<b>68,000 thousand</b>
Acquisition cost	¥58.2 billion	<b>¥119.3 billion</b>
Cancellation of treasury shares*	25,000 thousand	<b>38,000 thousand</b>

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

As a part of profit distribution to its shareholders and as measures of its capital policy, the Company implemented acquisition of its own shares from the stock market, purchasing 68 million shares, worth ¥119.3 billion, during the fiscal year ended March 31, 2016.

Furthermore, the Company canceled 68 million shares of its treasury stock in June 2016.

## ROE and DOE

Return on equity (ROE) was 15.0%, up 4.5 percentage points from fiscal 2014. The DOE ratio was 5.4%, up 0.3 of a percentage point from fiscal 2014.

## 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 IP 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.

### Environment-Related Risks

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

### Foreign Exchange Rate Fluctuations

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

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

# Consolidated Financial Statements

## Consolidated Statement of Income

Astellas Pharma Inc. and Subsidiaries  
For the year ended 31 March 2016

	Note	(Millions of yen)		(Millions of U.S. dollars)
		2015	2016	2016
Sales	6	¥1,247,259	¥1,372,706	\$12,148
Cost of sales		(333,197)	(335,596)	(2,970)
Gross profit		914,062	1,037,110	9,178
Selling, general and administrative expenses		(452,522)	(500,359)	(4,428)
Research and development expenses		(206,594)	(225,665)	(1,997)
Amortisation of intangible assets	17	(38,664)	(42,387)	(375)
Share of profits (losses) of associates and joint ventures		217	(1,243)	(11)
Other income	7	12,503	1,689	15
Other expense	8	(43,339)	(20,159)	(178)
Operating profit		185,663	248,986	2,203
Finance income	10	7,097	14,411	128
Finance expense	11	(3,078)	(1,627)	(14)
Profit before tax		189,683	261,770	2,317
Income tax expense	12	(53,827)	(68,083)	(603)
Profit for the year		¥ 135,856	¥ 193,687	\$ 1,714
<b>Profit attributable to:</b>				
Owners of the parent		¥ 135,856	¥ 193,687	\$ 1,714
			(Yen)	(U.S. dollars)
<b>Earnings per share</b>				
Basic	13	¥ 61.50	¥ 89.75	\$ 0.79
Diluted	13	61.40	89.62	0.79

## Consolidated Statement of Comprehensive Income

Astellas Pharma Inc. and Subsidiaries  
For the year ended 31 March 2016

	Note	(Millions of yen)		(Millions of U.S. dollars)
		2015	2016	2016
<b>Profit for the year</b>		¥135,856	¥193,687	\$1,714
<b>Other comprehensive income</b>				
<b>Items that will not be reclassified subsequently to profit or loss</b>				
Remeasurements of defined benefit plans		(7,874)	(6,276)	(56)
Subtotal		(7,874)	(6,276)	(56)
<b>Items that may be reclassified subsequently to profit or loss</b>				
Foreign currency translation adjustments	14	29,645	(45,172)	(400)
Fair value movements on available-for-sale financial assets	14	11,872	(11,358)	(101)
Subtotal		41,517	(56,529)	(500)
Other comprehensive income, net of tax		33,643	(62,806)	(556)
Total comprehensive income		¥169,499	¥130,881	\$1,158
<b>Total comprehensive income attributable to:</b>				
Owners of the parent		¥169,499	¥130,881	\$1,158

## Consolidated Statement of Financial Position

Astellas Pharma Inc. and Subsidiaries  
As of 31 March 2016

	Note	(Millions of yen)		(Millions of U.S. dollars)
		2015	2016	2016
<b>Assets</b>				
<b>Non-current assets</b>				
Property, plant and equipment	15	¥ 202,869	¥ 200,955	\$ 1,778
Goodwill	16	136,337	150,660	1,333
Other intangible assets	17	295,844	339,202	3,002
Trade and other receivables	22	15,588	24,103	213
Investments in associates and joint ventures		2,007	2,435	22
Deferred tax assets	18	51,199	80,252	710
Other financial assets	19	110,091	89,424	791
Other non-current assets	20	13,685	14,769	131
Total non-current assets		827,621	901,801	7,981
<b>Current assets</b>				
Inventories	21	156,907	161,691	1,431
Trade and other receivables	22	332,923	327,599	2,899
Income tax receivable		6,918	16,403	145
Other financial assets	19	59,908	14,394	127
Other current assets	20	12,732	17,221	152
Cash and cash equivalents	23	396,430	360,030	3,186
Subtotal		965,819	897,337	7,941
Assets held for sale	24	139	200	2
Total current assets		965,958	897,537	7,943
<b>Total assets</b>		¥1,793,578	¥1,799,338	\$15,923



	Note	(Millions of yen)		(Millions of U.S. dollars)
		2015	2016	2016
<b>Equity and liabilities</b>				
<b>Equity</b>				
Share capital	25	¥ 103,001	¥ 103,001	\$ 912
Capital surplus	25	176,822	176,903	1,566
Treasury shares	25	(86,997)	(157,111)	(1,390)
Retained earnings		905,083	973,054	8,611
Other components of equity	25	220,007	163,363	1,446
Total equity attributable to owners of the parent		1,317,916	1,259,209	11,143
Total equity		1,317,916	1,259,209	11,143
<b>Liabilities</b>				
Non-current liabilities				
Trade and other payables	32	90	1,599	14
Deferred tax liabilities	18	38	—	—
Retirement benefit liabilities	28	30,059	39,797	352
Provisions	29	4,817	7,083	63
Other financial liabilities	30	626	722	6
Other non-current liabilities	31	19,142	77,569	686
Total non-current liabilities		54,771	126,769	1,122
Current liabilities				
Trade and other payables	32	226,602	181,559	1,607
Income tax payable		14,124	19,312	171
Provisions	29	85,423	89,858	795
Other financial liabilities	30	1,339	1,505	13
Other current liabilities	31	93,403	121,126	1,072
Total current liabilities		420,890	413,359	3,658
Total liabilities		475,662	540,129	4,780
<b>Total equity and liabilities</b>		¥1,793,578	¥1,799,338	\$15,923

## Consolidated Statement of Changes in Equity

Astellas Pharma Inc. and Subsidiaries  
For the year ended 31 March 2016

(Millions of yen)

	Note	Equity attributable to owners of the parent								Other components of equity		
		Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Foreign currency translation adjustments	Fair value movements on available-for-sale financial assets	Remeasurements of defined benefit plans	Total	Total	Total equity
<b>As of 1 April 2014</b>		¥103,001	¥176,822	¥ (54,535)	¥864,830	¥2,110	¥147,660	¥28,588	¥ —	¥178,359	¥1,268,476	¥1,268,476
Comprehensive income												
Profit for the year		—	—	—	135,856	—	—	—	—	—	135,856	135,856
Other comprehensive income		—	—	—	—	—	29,645	11,872	(7,874)	33,643	33,643	33,643
Total comprehensive income		—	—	—	135,856	—	29,645	11,872	(7,874)	33,643	169,499	169,499
Transactions with owners of the parent												
Acquisition of treasury shares	25	—	—	(58,229)	—	—	—	—	—	—	(58,229)	(58,229)
Disposals of treasury shares	25	—	—	369	(185)	(176)	—	—	—	(176)	8	8
Cancellation of treasury shares	25	—	—	25,398	(25,398)	—	—	—	—	—	—	—
Dividends	26	—	—	—	(62,146)	—	—	—	—	—	(62,146)	(62,146)
Share-based payments	27	—	—	—	—	307	—	—	—	307	307	307
Transfers		—	—	—	(7,874)	—	—	—	7,874	7,874	—	—
Total transactions with owners of the parent		—	—	(32,462)	(95,603)	131	—	—	7,874	8,005	(120,059)	(120,059)
<b>As of 31 March 2015</b>		103,001	176,822	(86,997)	905,083	2,241	177,306	40,461	—	220,007	1,317,916	1,317,916
Comprehensive income												
Profit for the year		—	—	—	193,687	—	—	—	—	—	193,687	193,687
Other comprehensive income		—	—	—	—	—	(45,172)	(11,358)	(6,276)	(62,806)	(62,806)	(62,806)
Total comprehensive income		—	—	—	193,687	—	(45,172)	(11,358)	(6,276)	(62,806)	130,881	130,881
Transactions with owners of the parent												
Acquisition of treasury shares	25	—	—	(120,127)	—	—	—	—	—	—	(120,127)	(120,127)
Disposals of treasury shares	25	—	—	436	(248)	(187)	—	—	—	(187)	1	1
Cancellation of treasury shares	25	—	—	49,577	(49,577)	—	—	—	—	—	—	—
Dividends	26	—	—	—	(69,615)	—	—	—	—	—	(69,615)	(69,615)
Share-based payments	27	—	81	—	—	73	—	—	—	73	154	154
Transfers		—	—	—	(6,276)	—	—	—	6,276	6,276	—	—
Total transactions with owners of the parent		—	81	(70,114)	(125,717)	(115)	—	—	6,276	6,161	(189,588)	(189,588)
<b>As of 31 March 2016</b>		¥103,001	¥176,903	¥(157,111)	¥973,054	¥2,126	¥132,134	¥29,103	¥ —	¥163,363	¥1,259,209	¥1,259,209

(Millions of U.S. dollars)

	Note	Equity attributable to owners of the parent								Other components of equity		
		Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Foreign currency translation adjustments	Fair value movements on available-for-sale financial assets	Remeasurements of defined benefit plans	Total	Total	Total equity
<b>As of 31 March 2015</b>		\$912	\$1,565	\$ (770)	\$8,010	\$20	\$1,569	\$358	\$ —	\$1,947	\$11,663	\$11,663
Comprehensive income												
Profit for the year		—	—	—	1,714	—	—	—	—	—	1,714	1,714
Other comprehensive income		—	—	—	—	—	(400)	(101)	(56)	(556)	(556)	(556)
Total comprehensive income		—	—	—	1,714	—	(400)	(101)	(56)	(556)	1,158	1,158
Transactions with owners of the parent												
Acquisition of treasury shares	25	—	—	(1,063)	—	—	—	—	—	—	(1,063)	(1,063)
Disposals of treasury shares	25	—	—	4	(2)	(2)	—	—	—	(2)	0	0
Cancellation of treasury shares	25	—	—	439	(439)	—	—	—	—	—	—	—
Dividends	26	—	—	—	(616)	—	—	—	—	—	(616)	(616)
Share-based payments	27	—	1	—	—	1	—	—	—	1	1	1
Transfers		—	—	—	(56)	—	—	—	56	56	—	—
Total transactions with owners of the parent		—	1	(620)	(1,113)	(1)	—	—	56	55	(1,678)	(1,678)
<b>As of 31 March 2016</b>		\$912	\$1,566	\$(1,390)	\$8,611	\$19	\$1,169	\$258	\$ —	\$1,446	\$11,143	\$11,143

## Consolidated Statement of Cash Flows

Astellas Pharma Inc. and Subsidiaries  
For the year ended 31 March 2016

	Note	(Millions of yen)		(Millions of U.S. dollars)
		2015	2016	2016
<b>Cash flows from operating activities</b>				
Profit before tax		¥189,683	<b>¥261,770</b>	<b>\$2,317</b>
Depreciation and amortisation		65,474	<b>69,188</b>	<b>612</b>
Impairment losses and reversal of impairment losses		10,329	<b>9,310</b>	<b>82</b>
Finance income and expense		(4,019)	<b>(12,784)</b>	<b>(113)</b>
(Increase) decrease in inventories		(18,150)	<b>(11,873)</b>	<b>(105)</b>
(Increase) decrease in trade and other receivables		3,912	<b>(15,649)</b>	<b>(138)</b>
Increase (decrease) in trade and other payables		31,756	<b>(32,391)</b>	<b>(287)</b>
Other		(23,048)	<b>136,578</b>	<b>1,209</b>
Cash generated from operations		255,937	<b>404,149</b>	<b>3,577</b>
Income tax paid		(68,251)	<b>(90,412)</b>	<b>(800)</b>
Net cash flows from operating activities		187,686	<b>313,737</b>	<b>2,776</b>
<b>Cash flows from investing activities</b>				
Purchases of property, plant and equipment		(24,159)	<b>(33,512)</b>	<b>(297)</b>
Proceeds from sales of property, plant and equipment		5,450	<b>1,753</b>	<b>16</b>
Purchase of intangible assets		(57,007)	<b>(84,605)</b>	<b>(749)</b>
Purchase of available-for-sale financial assets		(3,583)	<b>(749)</b>	<b>(7)</b>
Proceeds from sales of available-for-sale financial assets		9,739	<b>16,747</b>	<b>148</b>
Acquisition of subsidiaries, net of cash acquired	37	—	<b>(42,653)</b>	<b>(377)</b>
Interest and dividends received		2,291	<b>2,797</b>	<b>25</b>
Other		(4,207)	<b>(6,827)</b>	<b>(60)</b>
Net cash flows used in investing activities		(71,476)	<b>(147,050)</b>	<b>(1,301)</b>
<b>Cash flows from financing activities</b>				
Acquisition of treasury shares	25	(58,229)	<b>(120,127)</b>	<b>(1,063)</b>
Dividends paid to owners of the parent	26	(62,146)	<b>(69,615)</b>	<b>(616)</b>
Other		(744)	<b>(3,736)</b>	<b>(33)</b>
Net cash flows used in financing activities		(121,118)	<b>(193,478)</b>	<b>(1,712)</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>		9,966	<b>(9,609)</b>	<b>(85)</b>
<b>Net increase (decrease) in cash and cash equivalents</b>		5,057	<b>(36,401)</b>	<b>(322)</b>
<b>Cash and cash equivalents at the beginning of the year</b>	23	391,374	<b>396,430</b>	<b>3,508</b>
<b>Cash and cash equivalents at the end of the year</b>	23	¥396,430	<b>¥360,030</b>	<b>\$3,186</b>

# Notes to Consolidated Financial Statements

Astellas Pharma Inc. and Subsidiaries  
For the year ended 31 March 2016

## 1. Reporting Entity

Astellas Pharma Inc. and its subsidiaries (collectively, the “Group”) are engaged in the manufacture and sales of pharmaceutical products. The parent company of the Group, Astellas Pharma Inc. (the “Company”), is incorporated in Japan, and the registered address of headquarters and principal business offices are available on the Company’s website (<http://www.astellas.com/en/>).

Also, shares of the Company are publicly traded on the Tokyo Stock Exchange (First Section).

The Group’s consolidated financial statements for the year ended 31 March 2016 were authorised for issue on 20 June 2016 by Yoshihiko Hatanaka, Representative Director, President and Chief Executive Officer, and Yasumasa Masuda, Senior Corporate Executive and Chief Financial Officer.

## 2. Basis of Preparation

### (1) Compliance with IFRS

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (“IFRS”) issued by the International Accounting Standards Board.

presented in U.S. dollars by translating Japanese yen amounts at the exchange rate of ¥113 to U.S. \$1, the approximate rate of exchange at the end of 31 March 2016. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

### (2) Basis of measurement

The Group’s consolidated financial statements have been prepared on a historical cost basis, except for financial instruments measured at fair value.

### (4) New or amended IFRS standards and interpretations not yet adopted

The following is a list of new or amended IFRS standards and interpretations that the Group has not adopted among those issued by the date of the approval of the Group’s consolidated financial statements. Also, the effects on the Group due to the application of the standards or interpretations listed below are still under consideration and cannot be estimated at this time.

### (3) Presentation currency

The Group’s consolidated financial statements are presented in Japanese yen, which is also the Company’s functional currency, and figures are rounded to the nearest million yen, except as otherwise indicated.

For the convenience of readers outside Japan, the accompanying consolidated financial statements are also

		Effective date (fiscal years beginning on or after)	The Group’s application date (fiscal year ending)	Summaries of new or amended IFRS standards and interpretations
IFRS 9	Financial Instruments	1 January 2018	31 March 2019	Amendments related to classification and measurement of financial assets and financial liabilities, impairment, and hedge accounting
IFRS 15	Revenue from Contracts with Customers	1 January 2018	31 March 2019	Comprehensive framework for revenue recognition
IFRS 16	Leases	1 January 2019	31 March 2020	Amendments related to accounting treatment for leases

### 3. Significant Accounting Policies

The significant accounting policies of the Group are applied continuously to all periods indicated in the consolidated financial statements, except for the amended standard listed below.

The following accounting standard is newly applied by the Group from the fiscal year ended 31 March 2016. The standard does not have a material impact on the Group's consolidated financial statements.

	IFRS	Summary of amended IFRS standard
IAS 19	Employee Benefits	Clarification of accounting for contributions by employees or third parties

#### (1) Basis of consolidation

##### (i) Subsidiaries

Subsidiaries are entities controlled by the Group. The Group controls an entity when the Group has power over the entity, is exposed to, or has rights, to variable returns from its involvement with the entity, and has the ability to affect those returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group, and they are deconsolidated from the date on which the Group loses control.

All intragroup assets and liabilities, transactions and unrealised gains or losses arising from intragroup transactions are eliminated on consolidation.

##### (ii) Associates

Associates are entities over which the Group has significant influence on their financial and operating policies but does not have control or joint control. If the Group owns between 20% and 50% of the voting power of an entity, it is presumed that the Group has significant influence over the entity. The Group accounts for investments in associates using the equity method.

##### (iii) Joint arrangements

A joint arrangement is an arrangement in which the Group has joint control. Joint control is the contractually agreed sharing of control of an arrangement, which exists only when decisions about the activities that significantly affect the returns of the arrangement require the unanimous consent of the parties sharing control. Joint arrangements in which the Group has an interest are classified and accounted for as follows:

- Joint operation—when the Group has rights to the assets and obligations for the liabilities relating to an arrangement, it accounts for each of its assets, liabilities,

revenue and expenses, in relation to its interest in the joint operation.

- Joint venture—when the Group has rights only to the net assets of the arrangement, it accounts for its interest in the joint venture using the equity method in the same way as associates.

#### (2) Business combinations

Business combinations are accounted for using the acquisition method.

The consideration transferred is measured at fair value and calculated as the aggregate of the fair values of the assets transferred, liabilities assumed, and the equity interests issued by the Group. The consideration transferred also includes any assets or liabilities resulting from a contingent consideration arrangement.

The identifiable assets acquired, the liabilities and contingent liabilities assumed that meet the recognition principles of IFRS 3 “Business Combinations” are measured at their acquisition-date fair values, except:

- Deferred tax assets or liabilities, liabilities (or assets, if any) related to employee benefits, and liabilities related to share-based payment transactions are recognised and measured in accordance with IAS 12 “Income Taxes”, IAS 19 “Employee Benefits”, and IFRS 2 “Share-based Payment”, respectively; and
- Non-current assets and disposal groups classified as held for sale are measured in accordance with IFRS 5 “Non-current Assets Held for Sale and Discontinued Operations”.

The excess of the aggregate of the consideration transferred and the amount recognised for non-controlling interest in the acquiree over the acquisition-date fair value of the identifiable net assets acquired is recorded as goodwill. If the excess is negative, then a gain from a

bargain purchase is immediately recognised in profit or loss.

Acquisition-related costs incurred in connection with business combinations, such as finder's fees and advisory fees, are expensed when incurred.

### (3) Foreign currency translation

#### (i) Functional and presentation currency

The financial statements of an entity of the Group are prepared using the functional currency of the entity. The consolidated financial statements of the Group are presented in Japanese yen, which is the functional currency of the Company.

#### (ii) Transactions in foreign currencies

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions or an approximation of the rate.

At the end of each reporting period, monetary assets and liabilities denominated in foreign currencies are translated into the functional currency using the exchange rates at the closing date and exchange differences arising from translation are recognised in profit or loss.

#### (iii) Foreign operations

Assets and liabilities of foreign operations are translated into Japanese yen using the exchange rate at the end of fiscal year. Income and expenses are translated into Japanese yen using the average exchange rate for the period.

Exchange differences arising on translating the financial statements of foreign operations are recognised in other comprehensive income. On the disposal of the interest in a foreign operation, the cumulative amount of the exchange differences is reclassified to profit or loss.

### (4) Sales

#### (i) Sale of goods

Sales are measured at the fair value of the consideration received or receivable, less discounts, charge-backs and other rebates, excluding sales taxes and value added taxes. Also, the Group recognises the sales amount of transactions in which the Group is acting as an agent on a net basis.

Revenue from the sale of goods is recognised when all of the following conditions have been satisfied, namely, the significant risks and rewards of ownership of the goods have been transferred to the buyers, the Group retains neither continuing managerial involvement nor effective control over the goods sold, it is probable that the economic benefits will flow to the Group, and the amount of revenue and costs associated with the transaction can be reliably measured. Therefore, revenue is usually recognised at the time of delivery of goods to customers. Sales discounts, charge-backs and other rebates are recognised as accounts payable, provisions or as deductions from accounts receivable.

#### (ii) Royalty income

Some of the Group's revenues are generated from the agreements under which third parties have been granted rights to produce or market products or rights to use technologies. Royalty income is recognised on an accrual basis in accordance with the substance of the relevant agreement. Revenue associated with milestone agreements is recognised upon achievement of the milestones defined in the respective agreements. Upfront payments and license fees received for agreements where the rights or obligations still exist are initially recognised as deferred income and then recognised in income as earned over the period of the development collaboration or the manufacturing obligation.

### (5) Research and development expenses

Expenditure on research and development of an internal project is fully expensed as "Research and development expenses" in the consolidated statement of income when incurred.

Internally generated development expenses are recognised as an intangible asset only if the capitalisation criteria under IAS 38 are satisfied. Therefore, internal expenditure incurred for ongoing internal development projects is not capitalised until marketing approval is obtained from the regulatory authorities in a major market, which is considered the time at which the criteria of capitalisation under IAS 38 are met.

In addition to the Group's internal research and development activities, the Group has entered into research and development collaboration agreements with



some alliance partners. The expenses and income associated with the settlement of the expenditure incurred for the research and development collaboration activities are accounted for as research and development expenses on an accrual basis in the same way as research and development expenses incurred within the Group.

### (6) Finance income and finance expense

Finance income mainly comprises interest income, dividend income, and gain on sales of financial instruments. Interest income is recognised using the effective interest method. Dividend income is recognised when the right to receive payment is established.

Financial expenses mainly comprise interest expense, fees, loss on sales of financial instruments, and impairment losses for financial assets.

### (7) Income tax

Income tax expense is comprised of current and deferred taxes, and recognised in profit or loss, except for taxes related to business combinations and to items that are recognised in other comprehensive income or directly in equity.

Current taxes are calculated at the amount expected to be paid to or recovered from the taxation authority by applying the statutory tax rate and tax laws enacted or substantially enacted at the end of the fiscal year.

Deferred tax assets and deferred tax liabilities are recognised for temporary differences between the carrying amounts of certain assets or liabilities in the consolidated statement of financial position and their tax base.

However, deferred tax assets and liabilities are not recognised for:

- taxable temporary differences arising from the initial recognition of goodwill.
- taxable or deductible temporary differences arising from the initial recognition of assets and liabilities in a transaction other than a business combination that affects neither accounting profit nor taxable profit (tax loss).
- deductible temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements when it is not probable that the temporary difference will reverse in the foreseeable future or there will not be sufficient taxable profits

against which the deductible temporary differences can be utilised.

- taxable temporary differences associated with investments in subsidiaries, associates, and interests in joint arrangements when the Group is able to control the timing of the reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax assets are recognised to the extent that it is probable that taxable profits will be available against which deductible temporary differences, unused tax losses, and unused tax credits can be utilised.

Deferred tax assets and deferred tax liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates and tax laws that have been enacted or substantively enacted by the end of the fiscal year.

Deferred tax assets and deferred tax liabilities are offset if the Group has a legally enforceable right to offset current tax assets against current tax liabilities, and they are related to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend to settle current tax assets and current tax liabilities on a net basis.

### (8) Earnings per share

Basic earnings per share are calculated by dividing profit for the year attributable to owners of the parent by the weighted-average number of ordinary shares outstanding during the year, adjusting treasury shares. For the purpose of calculating diluted earnings per share, profit for the year attributable to owners of the parent and the weighted average number of shares outstanding, adjusting treasury shares, is calculated for the effects of all dilutive potential ordinary shares.

### (9) Property, plant and equipment

Property, plant, and equipment is measured by using the cost model and is stated at cost less accumulated depreciation and accumulated impairment losses. The cost of items of property, plant and equipment includes costs directly attributable to the acquisition and the initial estimate of costs of dismantling and removing the items and restoring the site on which they are located.

Costs incurred after initial recognition are recognised as an asset, as appropriate, only when it is probable that future economic benefits associated with the asset will flow to the Group and its cost can be reliably measured. Costs of day-to-day servicing for items of property, plant and equipment, such as repairs and maintenance, expensed when incurred.

When an item of property, plant and equipment has a significant component, such component is accounted for as a separate item of property, plant and equipment. Depreciation of an asset begins when it is available for use. The depreciable amount of items of property, plant and equipment is depreciated on a straight-line basis over the estimated useful lives of each component. The depreciable amount of an asset is determined by deducting its residual value from its cost.

The estimated useful lives of major classes of property, plant and equipment are as follows:

Buildings and structures	2 to 60 years
Machinery and vehicles	2 to 20 years
Tools, furniture and fixtures	2 to 20 years

The useful lives, residual values, and depreciation methods of property, plant and equipment are reviewed at the end of fiscal year, and changed, if any.

## (10) Leases

Leases are classified as finance leases whenever substantially all the risks and rewards incidental to ownership of an asset are transferred to the Group. All other leases are classified as operating leases.

Under finance lease transactions, leased assets and lease obligations are initially recognised at the lower of the fair value of the leased property or the present value of the minimum lease payments, each determined at the inception of the lease. Leased assets are depreciated on a straight-line basis over the shorter of their estimated useful lives or lease terms. Minimum lease payments made under finance leases are allocated to finance expense and the repayment amount of the lease obligations. The finance expense is allocated to each period during the lease term so as to produce a constant periodic rate of interest on the remaining balance of liabilities.

Under operating lease transactions, lease payments are recognised as an expense on a straight-line basis over the lease term.

The Group determines whether an arrangement is, or contains a lease, based on the substance of the arrangement at the date of commencement of the lease. The substance of the arrangement is determined based on the following factors:

- (a) whether the fulfillment of the arrangement is dependent on the use of a specific asset or assets and,
- (b) whether the arrangement conveys a right to use the asset.

## (11) Goodwill

Measurement of goodwill on initial recognition is described in “(2) Business combinations”. After initial recognition, goodwill is carried at cost less any accumulated impairment losses.

Impairment of goodwill is described in “(13) Impairment of property, plant and equipment, goodwill, and other intangible assets”.

## (12) Other intangible assets

Other intangible assets are identifiable non-monetary assets without physical substance, other than goodwill, including patents and technologies, marketing rights, and in-process research and development (IPR&D) acquired in a business combination or acquired separately.

Other intangible assets acquired separately are measured at cost upon initial recognition, and those acquired in a business combination are measured at fair value at the acquisition date. After initial recognition, the Group applies the cost model and other intangible assets are carried at cost less any accumulated amortisation and accumulated impairment losses.

Other intangible assets are amortised over their estimated useful lives (2-25 years) on a straight-line basis beginning at the time when they are available for use. Amortisation of other intangible assets acquired through business combinations or through the in-licensing of products or technologies is presented in the consolidated statement of income under “Amortisation of intangible assets”. The estimated useful life of other intangible assets is the shorter of the period of legal protection or its economic life, and it is also regularly reviewed.

Among rights related to products or research and development through the in-licensing of products or technologies or acquired through business combinations, those that are still in the research and development stage or have not yet obtained marketing approval from the regulatory authorities are recognised under “Other intangible assets” as IPR&D.

Subsequent expenditure, including initial upfront and milestone payments to the third parties, on an acquired IPR&D is capitalised if, and only if, it is probable that the expected future economic benefits that are attributable to the asset will flow to the Group and the asset is identifiable.

An intangible asset recognised as IPR&D is not amortised because it is not yet available for use, but instead, it is tested for impairment whenever there is an indication of impairment or at least on an annual basis irrespective of whether there is any indication.

Once marketing approval from the regulatory authorities is obtained and the asset is available for use, IPR&D is transferred to “Patents and technologies” or “Marketing rights” and amortisation begins from that time on a straight-line basis over its useful life.

### **(13) Impairment of property, plant and equipment, goodwill, and other intangible assets**

#### **(i) Impairment of property, plant and equipment and other intangible assets**

At the end of each quarter, the Group assesses whether there is any indication that its property, plant and equipment and other intangible assets may be impaired.

If there is an indication of impairment, the recoverable amount of the asset is estimated. Other intangible assets not yet available for use or with indefinite useful lives are tested for impairment annually irrespective of whether there is any indication of impairment.

When it is not possible to estimate the recoverable amount of an individual asset, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs. A cash-generating unit is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

The recoverable amount is the higher of fair value less costs of disposal and value in use. In measuring the value

in use, the estimated future cash flows are discounted to the present value using a discount rate that reflects the time value of money and the risks specific to the asset. The discount rate used for calculating the recoverable amount is set at a rate appropriate to each geographical area of operations.

If the recoverable amount of an asset or a cash-generating unit is less than its carrying amount, the carrying amount of the asset or the cash-generating unit is reduced to its recoverable amount, and the reduction is recognised in profit or loss as an impairment loss.

#### **(ii) Impairment of goodwill**

Goodwill is allocated to each of the cash-generating units, or groups of cash-generating units, that is expected to benefit from the synergies of the business combination, and it is tested for impairment annually and whenever there is an indication that the cash-generating unit may be impaired. If, at the time of the impairment test, the recoverable amount of a cash-generating unit is less than its carrying amount, the carrying amount of the cash-generating unit is reduced to its recoverable amount, and the reduction is recognised in profit or loss as an impairment loss.

Impairment loss is allocated to reduce the carrying amount of any goodwill allocated to the cash-generating unit or group of cash-generating units and then to the other assets on a pro rata basis of the carrying amount of each asset in the cash-generating unit or group of cash-generating units.

#### **(iii) Reversal of impairment loss**

At the end of each quarter, the Group assesses whether there is any indication that an impairment loss recognised in prior years for other intangible assets may no longer exist or may have decreased. If such indication exists, the recoverable amount of the asset or the cash-generating unit is estimated. If the recoverable amount of the asset or the cash-generating unit is greater than its carrying amount, a reversal of an impairment loss is recognised, to the extent the increased carrying amount does not exceed the lower of the recoverable amount or the carrying amount (net of depreciation or amortisation) that would have been determined had no impairment loss been recognised in prior years.

Any impairment loss recognised for goodwill is not reversed in a subsequent period.

## (14) Financial instruments

### (i) Initial recognition

Financial assets and financial liabilities are recognised on the trade date when the Group becomes a party to the contractual provisions of the instrument.

Financial assets and financial liabilities are measured at fair value at initial recognition. Transaction costs directly attributable to the acquisition of financial assets or issuance of financial liabilities, other than financial assets measured at fair value through profit or loss (“financial assets at FVTPL”) and financial liabilities measured at fair value through profit or loss (“financial liabilities at FVTPL”), are added to the fair value of the financial assets or deducted from the fair value of financial liabilities on initial recognition. Transaction costs directly attributable to the acquisition of financial assets at FVTPL and financial liabilities at FVTPL are recognised in profit or loss.

### (ii) Non-derivative financial assets

Non-derivative financial assets are classified into “financial assets at FVTPL”, “held-to-maturity investments”, “loans and receivables” and “available-for-sale financial assets”. The classification is determined based on the nature and purpose of the financial assets at the time of initial recognition.

#### (a) Financial assets at FVTPL

The Group classifies financial assets as FVTPL when the financial assets are either held for trading or designated as FVTPL at initial recognition.

Financial assets at FVTPL are measured at fair value, and any gain or loss resulting from changes in fair value, dividends, and interest income are recognised in profit or loss.

#### (b) Held-to-maturity investments

Non-derivative financial assets with fixed or determinable payments and fixed maturity dates that the Group has the positive intent and ability to hold to maturity are classified as held-to-maturity investments.

Subsequent to initial recognition, held-to-maturity investments are measured at amortised cost using the effective interest method, less any impairment loss.

Interest income using the effective interest method is recognised in profit or loss.

#### (c) Loans and receivables

Non-derivative financial assets with fixed or determinable payments not quoted in an active market are classified as loans and receivables.

Subsequent to initial recognition, loans and receivables are measured at amortised cost using the effective interest method, less any impairment loss. Amortisation incurred under the effective interest method is recognised in profit or loss.

#### (d) Available-for-sale financial assets

Non-derivative financial assets designated as available-for-sale financial assets or not classified as FVTPL, held-to-maturity investments or loans and receivables are classified as available-for-sale financial assets.

Subsequent to initial recognition, available-for-sale financial assets are measured at fair value, and any gain or loss resulting from changes in fair value is recognised in other comprehensive income. Dividends on available-for-sale financial assets are recognised in profit or loss. When available-for-sale financial assets are derecognised or determined to be impaired, the cumulative gain or loss that had been recognised in other comprehensive income is reclassified to profit or loss.

### (iii) Impairment of financial assets other than FVTPL

Financial assets, other than those at FVTPL, are assessed for any objective evidence of impairment at the end of each quarter. Financial assets are impaired when there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the financial assets and these events have adversely affected the estimated future cash flows of the financial assets that can be reliably estimated.

Objective evidence of impairment of financial assets includes:

- significant financial difficulty of the issuer or obligor;
- breach of contract, such as a default or delinquency in interest or principal payments;
- probability that the borrower will enter bankruptcy or other financial reorganisation; or
- disappearance of an active market for the financial assets.

In the case of equity instruments classified as available-for-sale, a significant or prolonged decline in the fair value of the equity instrument below its cost would be considered as objective evidence of impairment.

The Group assesses the existence of objective evidence of impairment for loans and receivables and held-to-maturity financial assets, individually for separately significant assets or collectively for assets with no individual significance. When there is objective evidence of impairment on those financial assets, the difference between the asset's carrying amount and the present value of estimated future cash flows discounted at the financial asset's original effective interest rate is recognised in profit or loss as an impairment loss.

The impairment loss for loans and receivables are recognised through the allowance for doubtful accounts, and the carrying amount of a loan and receivable is written off against the allowance account when it is subsequently considered uncollectible. When an event occurring after the impairment was recognised causes the amount of the impairment loss to decrease, a reversal of the impairment loss is recognised in profit or loss.

When there is objective evidence that an available-for-sale financial asset is impaired, the cumulative loss that had been recognised in other comprehensive income is transferred to profit or loss. Any subsequent recovery in the fair value of impaired equity instruments classified as available-for-sale financial assets is recognised in other comprehensive income.

#### (iv) Derecognition of financial assets

When the contractual rights with respect to the cash flows from a financial asset expire or the contractual rights to receive the cash flows from a financial asset have been transferred and substantially all the risks and rewards of ownership of the financial asset are transferred, the Group derecognises the financial asset.

#### (v) Non-derivative financial liabilities

The Group measures non-derivative financial liabilities at amortised cost using the effective interest method after initial recognition.

The Group derecognises financial liabilities when obligations are fulfilled or when obligations are discharged, cancelled, or expired.

#### (vi) Derivatives

The Group is engaged in derivative transactions and mainly uses foreign exchange forward contracts to manage its exposure to risks from changes in foreign exchange rates.

Derivatives are initially recognised at fair value of the date when the derivative contracts are entered into and are subsequently measured at their fair values at the end of each quarter.

Changes in the fair value of derivatives are recognised in profit or loss, except for the following. If the hedging relationship qualifies for hedge accounting, the gain or loss on the hedging instrument of cash flow hedges or hedges of a net investment in a foreign operation that are determined to be effective hedges are recognised in other comprehensive income. The amounts that had been recognised in other comprehensive income for cash flow hedges and hedges of a net investment in a foreign operation shall be reclassified from equity to profit or loss in the same period or periods during which the hedged items affect profit or loss and on the disposal or partial disposal of the foreign operation, respectively.

Financial assets and financial liabilities arising from derivatives are classified as either financial assets at FVTPL or financial liabilities at FVTPL.

#### (15) Cash and cash equivalents

Cash and cash equivalents comprise cash on hand, demand deposits, and highly liquid short-term investments with maturities of three months or less from the date of acquisition which are subject to an insignificant risk of changes in value.

#### (16) Inventories

Inventories are measured at the lower of cost and net realisable value. The cost of inventories includes costs of purchase, costs of conversion and all other costs incurred in bringing the inventories to their present location and condition. Net realisable value is calculated as the estimated selling price in the ordinary course of business less the estimated costs of completion and estimated costs necessary to sell. Cost of inventories is calculated mainly using the first-in, first-out (FIFO) method.

## (17) Assets held for sale

Non-current assets or disposal groups are classified as “Assets held for sale” if their carrying amounts will be recovered principally through a sale transaction rather than through continuing use. To be classified as assets held for sale, the asset must be available for immediate sale in its present condition, and the sale must be highly probable. Specifically, management of the Group must have a firm commitment to execute the plan to sell the asset and the sale is expected to be completed within one year from the date of classification, as a general rule. Assets held for sale are measured at the lower of their carrying amounts and fair values less costs to sell, and they are not depreciated or amortised while they are classified as held for sale.

## (18) Equity

### (i) Ordinary shares

Proceeds from the issuance of ordinary shares by the Company are included in share capital and capital surplus. Transaction costs of issuing ordinary shares (net of tax) are deducted from capital surplus.

### (ii) Treasury shares

When the Company reacquires its own ordinary shares, the amount of the consideration paid including transaction costs is deducted from equity. When the Company sells treasury shares, the difference between the carrying amount and the consideration received from the sale is recognised in equity.

## (19) Share-based payment

The Group operates an equity-settled share-based payment plan and a cash-settled share-based payment plan as share-based payment plans.

### (i) Equity-settled share-based payment plan

Under the equity-settled share-based payment plan, services received are measured at the fair value of the equity instruments at the grant date, and are recognised as expenses from the grant date over the vesting period, with a corresponding increase in equity.

### (ii) Cash-settled share-based payment plan

Under the cash-settled share-based payment plan, services received are measured at the fair value of the liabilities incurred and recognised as expenses over the vesting period, with a corresponding increase in liabilities. Until the liabilities are settled, the fair value of liabilities are remeasured at the end of each quarter and at the settlement date, with any changes in fair value recognised in profit or loss.

## (20) Employee benefits

### (i) Retirement benefits

The Group operates defined benefit and defined contribution retirement plans for its employees.

#### (a) Defined benefit plans

Net defined benefit assets or liabilities are calculated as the present value of the defined benefit obligation less the fair value of plan assets and they are recognised in the consolidated statement of financial position as assets or liabilities. The defined benefit obligation is calculated by using the projected unit credit method. The present value of the defined benefit obligation is calculated by the expected future payments using discount rate. The discount rate is determined by reference to market yield on high-quality corporate bonds having maturity terms consistent with the estimated term of the related pension obligations.

Service cost and net interest expense (income) on the net defined benefit liabilities (assets) are recognised in profit or loss.

Actuarial gains and losses, the return on plan assets, excluding amounts included in net interest, and any change in the effect of the asset ceiling are recognised immediately in other comprehensive income under “Remeasurements of defined benefit plans”, and transferred from other components of equity to retained earnings immediately.

#### (b) Defined contribution plans

Contributions paid for defined contribution plans are expensed in the period in which the employees provide the related service.

### (ii) Short-term employee benefits

Short-term employee benefits are expensed when the related service is provided. Bonus accrual is recognised as



a liability when the Group has present legal or constructive obligations resulting from past service rendered by the employees and reliable estimates of the obligations can be made.

**(21) Provisions**

Provisions are recognised when the Group has present legal or constructive obligations as a result of past events, it is probable that outflows of resources embodying economic benefits will be required to settle the obligations, and reliable estimates of the obligations can be made.

When the effect of the time value of money is material, provisions are measured at the present value of the

expenditures expected to be required to settle the obligations.

**(22) Government grants**

Government grants are recognised and measured at fair value, if there is reasonable assurance that the Group will comply with the conditions attached to them and that the grants will be received. Government grants that are intended to compensate for specific costs are recognised as income in the period in which the Group recognises the corresponding expenses. Government grants related to assets are recognised as deferred income and then recognised in profit over the expected useful life of the relevant asset on a regular basis.

**4. Significant Accounting Estimates, Judgments and Assumptions**

The preparation of the consolidated financial statements requires management of the Group to make estimates, judgments and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income, and expenses.

Given their nature, actual results may differ from those estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis, and the effects resulting from revisions of accounting estimates are recognised in the period in which the estimates are revised and in future periods affected by the revision.

Estimates and underlying assumptions representing a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities in the next fiscal year are as follows:

- Impairment of property, plant and equipment, goodwill and other intangible assets (Notes 15, 16 and 17)
- Provisions (Note 29)
- Retirement benefits (Note 28)
- Recoverability of deferred tax assets (Note 18)
- Income tax expense (Note 12)
- Financial assets measured at fair value which have no market price in active markets (Note 33)

## 5. Segment Information

The main activities of the Group are the manufacture and sale of pharmaceutical products, and there are no separate

operating segments. Therefore, the Group has a single reporting segment, “Pharmaceutical”.

### Information about products and services

Sales by type of product and service are as follows:

	(Millions of yen)	
	2015	2016
XTANDI	¥ 137,189	¥ 252,075
Prograf	194,712	203,556
Vesicare	135,241	135,638
Other	780,118	781,438
<b>Total</b>	<b>¥1,247,259</b>	<b>¥1,372,706</b>

### Information about geographical areas

Sales and non-current assets by geographical areas are as follows:

#### Sales by geographical areas

	(Millions of yen)	
	2015	2016
Japan	¥ 488,363	¥ 489,969
Americas	358,196	452,697
U.S.A. (included in Americas)	334,178	429,518
EMEA	320,973	334,572
Asia and Oceania	79,728	95,467
<b>Total</b>	<b>¥1,247,259</b>	<b>¥1,372,706</b>

(Note) 1. Sales by geographical areas are categorised by country or areas based on the geographical location of customers.

2. Sales to the Middle East and Africa, previously included within “Asia, Oceania and other”, are now classified in “EMEA” to better reflect association with structure of the Group. The amounts of Fiscal year ended 31 March 2015 are also reclassified to conform to the current year’s presentation.

#### Non-current assets by geographical areas (Property, plant and equipment, goodwill and other intangible assets)

	(Millions of yen)	
	2015	2016
Japan	¥308,426	¥370,894
Americas	286,413	281,544
U.S.A. (included in Americas)	286,100	281,311
EMEA	35,729	34,505
Asia and Oceania	4,481	3,874
<b>Total</b>	<b>¥635,050</b>	<b>¥690,817</b>

(Note) Non-current assets located in the Middle East and Africa, previously included within “Asia, Oceania and other”, are now classified in “EMEA” to better reflect association with structure of the Group. The amounts of Fiscal year ended 31 March 2015 are also reclassified to conform to the current year’s presentation.

### Information about major customers

External customer that accounts for 10% or more of consolidated sales of the Group is as follows:

		(Millions of yen)	
	Segment	2015	2016
<b>McKesson Corporation</b>	Pharmaceutical	¥126,308	¥156,245

## 6. Sales

The breakdown of sales is as follows:

	(Millions of yen)	
	2015	2016
<b>Sales of pharmaceutical products</b>	¥1,176,769	¥1,314,247
<b>Royalty income</b>	36,564	24,560
<b>Other</b>	33,926	33,899
<b>Total sales</b>	¥1,247,259	¥1,372,706

## 7. Other Income

The breakdown of other income is as follows:

	(Millions of yen)	
	2015	2016
<b>Gain on sales of property, plant and equipment</b>	¥ 1,420	¥ 306
<b>Gain on settlement of defined benefit plan as post-employment benefits</b>	8,017	—
<b>Other</b>	3,066	1,384
<b>Total other income</b>	¥12,503	¥1,689

(Note) “Gain on settlement of defined benefit plan as post-employment benefits” for the year ended 31 March 2015 was due to a change in the post-employment benefits of a subsidiary in the Netherlands, from a defined benefit plan to a defined contribution plan.

## 8. Other Expense

The breakdown of other expense is as follows:

	(Millions of yen)	
	2015	2016
<b>Loss on sales and disposal of property, plant and equipment</b>	¥ 1,213	¥ 743
<b>Impairment losses for property, plant and equipment</b>	580	8,837
<b>Impairment losses for other intangible assets</b>	9,749	681
<b>Restructuring costs</b>	11,501	—
<b>Litigation costs</b>	16,236	2,322
<b>Net foreign exchange losses</b>	3,568	6,996
<b>Other</b>	493	580
<b>Total other expense</b>	<b>¥43,339</b>	<b>¥20,159</b>

(Note) 1. The main item of “Impairment losses for property, plant and equipment” for the year ended 31 March 2016 was due to the closure of the Kashima R&D Center (Osaka Prefecture).

2. “Impairment losses for other intangible assets” for the year ended 31 March 2015 was principally due to the discontinuation of development activities for projects.

3. “Restructuring costs” for the year ended 31 March 2015 was mainly due to the implementation of an early retirement incentive program for employees of the Company and its domestic subsidiaries.

4. The main item of “Litigation costs” for the years ended 31 March 2015 and 2016 were due to the Prograf litigation involving a U.S. subsidiary.

5. The amount of “Net foreign exchange losses” includes foreign exchange losses resulting from foreign exchange forward contracts (¥19,749 million for the year ended 31 March 2015, and ¥9,585 million for the year ended 31 March 2016).

## 9. Employee Benefit Expenses

The breakdown of employee benefit expenses is as follows:

	(Millions of yen)	
	2015	2016
<b>Rewards and salaries</b>	¥147,449	¥154,695
<b>Bonuses</b>	54,495	58,069
<b>Social security and welfare expenses</b>	29,211	32,290
<b>Retirement benefit expenses—Defined contribution plan</b>	13,479	14,934
<b>Retirement benefit expenses—Defined benefit plan</b>	8,462	6,611
<b>Restructuring and termination benefits</b>	12,920	3,792
<b>Other employee benefit expenses</b>	3,114	2,684
<b>Total employee benefit expenses</b>	<b>¥269,130</b>	<b>¥273,075</b>

(Note) 1. Employee benefit expenses are included in “Cost of sales”, “Selling, general and administrative expenses”, “Research and development expenses” and “Other expense” in the consolidated statement of income.

2. “Retirement benefit expenses—Defined benefit plan” for the year ended 31 March 2015 do not include “Gain on settlement of defined benefit plan as post-employment benefits” recognised in “Other income.”

## 10. Finance Income

The breakdown of finance income is as follows:

	(Millions of yen)	
	2015	2016
<b>Interest income</b>		
Cash and cash equivalents	¥ 715	¥ 785
Other	89	200
<b>Dividend income</b>		
Available-for-sale financial assets	1,136	1,067
<b>Gain on sales</b>		
Available-for-sale financial assets	5,150	12,278
Other	7	19
<b>Other</b>	-	61
<b>Total finance income</b>	<b>¥7,097</b>	<b>¥14,411</b>

## 11. Finance Expense

The breakdown of finance expense is as follows:

	(Millions of yen)	
	2015	2016
<b>Impairment losses</b>		
Available-for-sale financial assets	¥2,610	¥ 370
<b>Other</b>	468	1,257
<b>Total finance expense</b>	<b>¥3,078</b>	<b>¥1,627</b>

## 12. Income Tax Expense

The breakdown of income tax expense recognised in profit or loss is as follows:

	(Millions of yen)	
	2015	2016
<b>Current income tax expense</b>	¥64,877	¥85,402
<b>Deferred income tax expense</b>	(11,051)	(17,319)
<b>Income tax expense reported in the consolidated statement of income</b>	<b>¥53,827</b>	<b>¥68,083</b>

(Note) Deferred income tax expense increased by ¥1,647 million and ¥1,627 million for the year ended 31 March 2015 and 2016, respectively, due to the effect of changes in the tax rate in Japan.

Income tax recognised in other comprehensive income is as follows:

(Millions of yen)

	2015			2016		
	Tax benefit			Tax benefit		
	Before tax	(expense)	Net of tax	Before tax	(expense)	Net of tax
Remeasurements of defined benefit plans	¥ (8,864)	¥ 990	¥ (7,874)	¥ (9,714)	¥ 3,437	¥ (6,276)
Foreign currency translation adjustments	29,645	—	29,645	(45,172)	—	(45,172)
Fair value movements on available-for-sale financial assets	15,696	(3,824)	11,872	(17,933)	6,575	(11,358)
<b>Total other comprehensive income</b>	<b>¥36,478</b>	<b>¥(2,834)</b>	<b>¥33,643</b>	<b>¥(72,818)</b>	<b>¥10,012</b>	<b>¥(62,806)</b>

### Reconciliation of effective tax rate

The Company is subject mainly to corporate tax, inhabitant tax, and enterprise tax on its income and the effective statutory tax rates calculated based on those taxes for the fiscal years ended 31 March 2015 and 2016

were 35.3% and 32.8%, respectively. Foreign subsidiaries are subject to income taxes on their income in their respective countries of domicile.

	2015	2016
<b>Effective statutory tax rate</b>	<b>35.3%</b>	<b>32.8%</b>
Tax credit for research and development expenses	(4.1)	(3.6)
Non-deductible expenses	4.2	2.5
Difference in tax rates applied to foreign subsidiaries	(9.5)	(5.2)
Undistributed earnings of foreign subsidiaries	1.1	0.9
Effect of change in tax rate in Japan	0.9	0.6
Other	0.5	(2.0)
<b>Actual tax rate</b>	<b>28.4%</b>	<b>26.0%</b>



### 13. Earnings per Share

The basis of calculation of basic earnings per share and diluted earnings per share is as follows:

(Millions of yen, except as otherwise indicated)

	2015	2016
<b>Basis of calculating basic earnings per share</b>		
Profit attributable to owners of the parent	¥ 135,856	¥ 193,687
Profit not attributable to ordinary shareholders of the parent	—	—
Profit used to calculate basic earnings per share	135,856	193,687
Weighted average number of shares during the year (Thousands of shares)	2,209,080	2,158,131
<b>Basis of calculating diluted earnings per share</b>		
Profit used to calculate basic earnings per share	¥ 135,856	¥ 193,687
Adjustment	—	—
Profit used to calculate diluted earnings per share	135,856	193,687
Weighted average number of shares during the year (Thousands of shares)	2,209,080	2,158,131
Subscription rights to shares (Thousands of shares)	3,406	3,175
Weighted average number of diluted ordinary shares during the year (Thousands of shares)	2,212,486	2,161,306
<b>Earnings per share (attributable to owners of the parent):</b>		
Basic (Yen)	¥ 61.50	¥ 89.75
Diluted (Yen)	61.40	89.62

### 14. Other Comprehensive Income

Reclassification adjustments of other comprehensive income are as follows:

(Millions of yen)

	2015	2016
<b>Other comprehensive income that may be reclassified subsequently to profit or loss</b>		
Foreign currency translation adjustments		
Amount arising during the year	¥29,645	¥(45,172)
Reclassification adjustment	—	—
Subtotal	29,645	(45,172)
Fair value movements on available-for-sale financial assets		
Amount arising during the year	18,326	(6,012)
Reclassification adjustment	(2,630)	(11,920)
Subtotal	15,696	(17,933)
Other comprehensive income that may be reclassified subsequently to profit or loss before tax effect	45,341	(63,104)
Tax effect	(3,824)	6,575
Other comprehensive income that may be reclassified subsequently to profit or loss, net of tax	¥41,517	¥(56,529)

## 15. Property, Plant and Equipment

### Movement of cost, accumulated depreciation and impairment losses for property, plant and equipment

The movement of property, plant and equipment for the year ended 31 March 2015 is as follows:

	(Millions of yen)					
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Construction in progress	Total
<b>Cost</b>						
Balance at 1 April 2014	¥187,614	¥ 151,699	¥ 82,974	¥18,728	¥ 9,023	¥ 450,039
Acquisitions	3,264	3,180	3,838	—	20,315	30,598
Disposals	(1,618)	(5,481)	(5,119)	(34)	(15)	(12,268)
Reclassification from construction in progress	2,039	2,580	466	—	(5,085)	—
Reclassification to assets held for sale	—	(313)	(2)	—	—	(314)
Other	4,498	(1,537)	402	154	555	4,073
<b>Balance at 31 March 2015</b>	<b>195,798</b>	<b>150,128</b>	<b>82,560</b>	<b>18,848</b>	<b>24,793</b>	<b>472,127</b>
<b>Accumulated depreciation and accumulated impairment losses</b>						
Balance at 1 April 2014	(73,584)	(117,979)	(67,025)	—	—	(258,588)
Depreciation	(7,417)	(8,295)	(5,610)	—	—	(21,322)
Impairment losses (or reversal of impairment losses)	(338)	(597)	(3)	(306)	(53)	(1,297)
Disposals	1,158	5,220	4,889	—	—	11,267
Reclassification to assets held for sale	—	174	1	—	—	175
Other	(590)	1,041	60	—	(5)	506
<b>Balance at 31 March 2015</b>	<b>(80,771)</b>	<b>(120,435)</b>	<b>(67,688)</b>	<b>(306)</b>	<b>(58)</b>	<b>(269,258)</b>
<b>Carrying amounts</b>						
Balance at 1 April 2014	114,030	33,721	15,950	18,728	9,023	191,451
<b>Balance at 31 March 2015</b>	<b>¥115,027</b>	<b>¥ 29,693</b>	<b>¥ 14,872</b>	<b>¥18,543</b>	<b>¥24,735</b>	<b>¥ 202,869</b>

(Note) "Other" mainly includes exchange differences.

The movement of property, plant and equipment for the year ended 31 March 2016 is as follows:

(Millions of yen)

	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Construction in progress	Total
<b>Cost</b>						
Balance at 1 April 2015	¥195,798	¥ 150,128	¥ 82,560	¥18,848	¥ 24,793	¥ 472,127
Acquisitions	10,347	4,989	5,966	—	12,725	34,027
Business combinations	38	109	4	—	—	151
Disposals	(1,038)	(2,928)	(7,767)	(704)	(114)	(12,550)
Reclassification from construction in progress	10,541	6,827	685	398	(18,451)	—
Reclassification to assets held for sale	(883)	(2,569)	(1,527)	(331)	—	(5,310)
Other	(3,638)	(2,506)	(687)	(188)	(829)	(7,849)
<b>Balance at 31 March 2016</b>	<b>211,164</b>	<b>154,051</b>	<b>79,235</b>	<b>18,023</b>	<b>18,124</b>	<b>480,597</b>
<b>Accumulated depreciation and accumulated impairment losses</b>						
Balance at 1 April 2015	(80,771)	(120,435)	(67,688)	(306)	(58)	(269,258)
Depreciation	(7,360)	(8,412)	(5,180)	—	—	(20,952)
Impairment losses (or reversal of impairment losses)	(7,174)	(1,240)	91	(305)	—	(8,629)
Disposals	817	2,591	7,380	306	—	11,094
Reclassification to assets held for sale	883	2,394	1,156	305	—	4,740
Other	1,188	1,742	430	—	4	3,364
<b>Balance at 31 March 2016</b>	<b>(92,416)</b>	<b>(123,360)</b>	<b>(63,811)</b>	<b>—</b>	<b>(54)</b>	<b>(279,642)</b>
<b>Carrying amounts</b>						
Balance at 1 April 2015	115,027	29,693	14,872	18,543	24,735	202,869
<b>Balance at 31 March 2016</b>	<b>¥118,748</b>	<b>¥ 30,691</b>	<b>¥ 15,423</b>	<b>¥18,023</b>	<b>¥ 18,069</b>	<b>¥ 200,955</b>

(Note) 1. The increase due to business combinations reflected the acquisition of Ocata Therapeutics, Inc. (The company name was changed to Astellas Institute for Regenerative Medicine in May 2016.) For details on this business combination, please refer to Note “37. Business Combination”.

2. “Other” mainly includes exchange differences.

The Group recognised impairment losses (or reversal of impairment losses) of ¥1,297 million for the year ended 31 March 2015 and ¥8,629 million for the year ended 31 March 2016, and they are mainly included in “Other expense” in the consolidated statement of income.

The Group recognised ¥1,297 million of impairment losses (or reversal of impairment losses) for land, buildings and structures, machinery and vehicles, etc.

for the year ended 31 March 2015.

Impairment losses (or reversal of impairment losses) of ¥8,629 million for the year ended 31 March 2016 mainly resulted from the closure of the Kashima R&D Center (Osaka Prefecture) owned by the Company. The assets, including buildings, are planned to be disposed of, and the recoverable amount is therefore deemed to be zero.

The carrying amounts of the assets held under finance leases included in “Property, plant and equipment” are as follows:

	(Millions of yen)		
	Machinery and vehicles	Tools, furniture and fixtures	Total
<b>Balance at 1 April 2014</b>	¥ 0	¥1,146	¥1,146
<b>Balance at 31 March 2015</b>	¥ –	¥ 991	¥ 991
<b>Balance at 31 March 2016</b>	¥95	¥1,133	¥1,228

## 16. Goodwill

The movement of cost and accumulated impairment losses for goodwill is as follows:

	(Millions of yen)		
	Cost	Accumulated impairment losses	Carrying amount
<b>Balance at 1 April 2014</b>	¥116,766	¥–	¥116,766
<b>Exchange differences</b>	19,571	–	19,571
<b>Balance at 31 March 2015</b>	136,337	–	136,337
<b>Business combinations</b>	24,332	–	24,332
<b>Exchange differences</b>	(10,009)	–	(10,009)
<b>Balance at 31 March 2016</b>	¥150,660	¥–	¥150,660

(Note) The increase due to business combinations reflected the acquisition of Ocata Therapeutics, Inc. (The company name was changed to Astellas Institute for Regenerative Medicine in May 2016.) For details on this business combination, please refer to Note “37. Business Combination”.

Goodwill recognised in the consolidated statement of financial position mainly resulted from the acquisition of OSI Pharmaceuticals, Inc. in 2010 and Ocata Therapeutics, Inc. in the year ended 31 March 2016.

The Group, in principle, regards the geographical business units, which are managed for internal reporting purposes, as cash-generating units.

For the years ended 31 March 2015 and 2016, goodwill is allocated to the Americas cash-generating unit, and the carrying amount of goodwill was ¥136,337 million and ¥150,660 million, respectively. For the impairment test, the value in use, which is calculated based on the three-year business plan approved at the board of directors meeting, is used as the recoverable amount.

The Group uses a weighted average cost of capital (WACC) determined for each geographical area as a discount rate. The after-tax WACC used for the impairment test is 8.0% and the pre-tax WACC 13.1%.

Also, a growth rate of 2.0% is reflected in calculating the terminal value after the three-year business plan. The growth rate reflects the status of the country and the industry to which the cash-generating unit belongs.

The value in use sufficiently exceeds the carrying amount of the cash-generating unit. Therefore, even if the key assumptions used in the calculation of the value in use fluctuate within a reasonable range, the Group assumes that the possibility that the value in use will be lower than the carrying amount is remote.

## 17. Other Intangible Assets

### Movement of cost, accumulated amortisation and impairment losses for other intangible assets

The movement of other intangible assets for the year ended 31 March 2015 is as follows:

(Millions of yen)

	Patents and technologies	Marketing rights	IPR&D	Software	Other	Total
<b>Cost</b>						
Balance at 1 April 2014	¥ 253,511	¥ 85,321	¥ 97,408	¥ 32,821	¥ 385	¥ 469,447
Acquisitions	25,634	157	22,169	5,847	5	53,812
Disposals	(35)	—	(11,517)	(3,080)	(97)	(14,729)
Reclassification	9,481	—	(9,481)	—	—	—
Other	26,809	2,646	114	540	104	30,214
Balance at 31 March 2015	315,401	88,125	98,693	36,128	396	538,743
<b>Accumulated amortisation and accumulated impairment losses</b>						
Balance at 1 April 2014	(100,526)	(51,691)	(18,220)	(18,674)	(215)	(189,327)
Amortisation	(27,906)	(10,758)	—	(5,463)	(26)	(44,152)
Impairment losses	(277)	—	(8,876)	(596)	—	(9,749)
Disposals	35	—	11,517	3,036	84	14,671
Other	(11,981)	(1,350)	(14)	(902)	(96)	(14,342)
Balance at 31 March 2015	(140,655)	(63,799)	(15,593)	(22,600)	(253)	(242,899)
<b>Carrying amounts</b>						
Balance at 1 April 2014	152,985	33,630	79,188	14,147	170	280,120
Balance at 31 March 2015	¥ 174,746	¥ 24,326	¥ 83,100	¥ 13,528	¥ 144	¥ 295,844

(Note) "Other" mainly includes exchange differences.

The movement of other intangible assets for the year ended 31 March 2016 is as follows:

	(Millions of yen)					
	Patents and technologies	Marketing rights	IPR&D	Software	Other	Total
<b>Cost</b>						
Balance at 1 April 2015	¥ 315,401	¥ 88,125	¥ 98,693	¥ 36,128	¥ 396	¥ 538,743
Acquisitions	31,848	15	39,742	9,123	2	80,730
Business combinations	—	—	17,456	—	—	17,456
Disposals	—	(30,288)	—	(769)	(7)	(31,064)
Reclassification	5,926	—	(5,926)	—	—	—
Other	(11,804)	(770)	(1,149)	(785)	(72)	(14,580)
Balance at 31 March 2016	341,371	57,081	148,816	43,697	319	591,285
<b>Accumulated amortisation and accumulated impairment losses</b>						
Balance at 1 April 2015	(140,655)	(63,799)	(15,593)	(22,600)	(253)	(242,899)
Amortisation	(32,775)	(9,612)	—	(5,825)	(25)	(48,236)
Impairment losses	—	—	(680)	—	(1)	(681)
Disposals	—	30,288	—	664	6	30,959
Other	7,237	629	14	829	64	8,774
Balance at 31 March 2016	(166,192)	(42,493)	(16,258)	(26,931)	(208)	(252,083)
<b>Carrying amounts</b>						
Balance at 1 April 2015	174,746	24,326	83,100	13,528	144	295,844
Balance at 31 March 2016	¥ 175,179	¥ 14,588	¥ 132,558	¥ 16,766	¥ 111	¥ 339,202

(Note) 1. The increase due to business combinations mainly reflected the acquisition of Ocata Therapeutics, Inc. (The company name was changed to Astellas Institute for Regenerative Medicine in May 2016.) For details on this business combination, please refer to Note “37. Business Combination”.

2. “Other” mainly includes exchange differences.

Amortisation of other intangible assets related to the rights of product or research and development arising from in-licensing agreements is recognised in the consolidated statement of income under “Amortisation of intangible

assets”.

Impairment losses for other intangible assets are recognised in the consolidated statement of income under “Other expense”.

### Impairment test and impairment losses for other intangible assets

For the intangible assets other than goodwill, the Group assesses the necessity of impairment by individual asset. Also, intangible assets not yet being amortised are tested for impairment annually whether or not there is any indication of impairment. For the impairment test, the value in use is mainly used as the recoverable amount. The discount rate is calculated based on the WACC, and the range of post-tax discount rate used for the calculation of the value in use is 6.0% to 9.0%, and that of pre-tax discount rate is 8.2% to 13.6%.

As a result of the impairment test, the Group recognised the following impairment losses for the years ended 31 March 2015 and 2016.

For the year ended 31 March 2015, impairment losses recognised for other intangible assets were ¥9,749 million, and the details of the main items are as follows:

Impairment losses of ¥9,153 million were mainly recognised due to the discontinuation of development activities for IPR&Ds. This is mainly due to the right of termination exercised by the Company regarding the license agreement on a beta-secretase inhibitor (Alzheimer dementia) with CoMentis, Inc. in the U.S. The Company recognised an impairment loss deeming the recoverable amount as zero.

For the year ended 31 March 2016, impairment losses recognised for other intangible assets were ¥681 million



due to the discontinuation of development activities for IPR&Ds.

### Significant intangible assets

Significant intangible assets recognised in the consolidated statement of financial position are mainly composed of the acquired license related to research and development of enzalutamide (XTANDI) through the license agreement with Medivation, Inc., the rights related to “Tarceva” resulting from the acquisition of OSI Pharmaceuticals, Inc. in 2010 and the acquired license related to the research and development of YM311/roxadustat through the license agreement with

FibroGen, Inc. The carrying amounts of those intangible assets were ¥48,240 million, ¥90,770 million, and ¥50,565 million, respectively, as of 31 March 2015 and ¥73,532 million, ¥65,003 million and ¥50,565 million, respectively, as of 31 March 2016. The remaining amortisation period of intangible assets associated with the marketed products is mainly 3 to 13 years, and the intangible assets not yet being amortised are tested for impairment annually.

## 18. Deferred Taxes

The breakdown and movement of deferred tax assets and deferred tax liabilities are as follows:

For the year ended 31 March 2015

(Millions of yen)

	As of 1 April 2014	Recognised in profit or loss	Recognised in other comprehensive income		As of 31 March 2015
				Other	
Available-for-sale financial assets	¥(14,050)	¥ 451	¥(3,824)	¥ 0	¥(17,423)
Retirement benefit assets and liabilities	8,172	(2,004)	990	(165)	6,993
Property, plant and equipment	4,877	(3,328)	—	(225)	1,324
Intangible assets	(49,940)	5,320	—	(4,638)	(49,257)
Accrued expenses	24,483	1,841	—	2,735	29,059
Inventories	43,363	6,211	—	(303)	49,272
Tax loss carry-forwards	4,668	(1,039)	—	(76)	3,554
Other	23,954	3,598	—	89	27,641
<b>Total</b>	<b>¥ 45,527</b>	<b>¥11,051</b>	<b>¥(2,834)</b>	<b>¥(2,581)</b>	<b>¥ 51,162</b>

For the year ended 31 March 2016

(Millions of yen)

	As of 1 April 2015	Recognised in profit or loss	Recognised in other comprehensive			As of 31 March 2016
			income	Business combinations	Other	
Available-for-sale financial assets	¥(17,423)	¥ (207)	¥ 6,575	¥ –	¥ (12)	¥(11,067)
Retirement benefit assets and liabilities	6,993	77	3,437	–	(59)	10,448
Property, plant and equipment	1,324	1,042	–	(12)	152	2,506
Intangible assets	(49,257)	4,608	–	(5,089)	1,718	(48,020)
Accrued expenses	29,059	(2,157)	–	–	(1,110)	25,792
Inventories	49,272	3,321	–	–	(477)	52,116
Tax loss carry-forwards	3,554	(2,583)	–	8,179	(513)	8,637
Other	27,641	13,217	–	90	(1,108)	39,841
<b>Total</b>	<b>¥ 51,162</b>	<b>¥17,319</b>	<b>¥10,012</b>	<b>¥ 3,167</b>	<b>¥(1,408)</b>	<b>¥ 80,252</b>

(Note) The increase due to business combinations mainly reflected the acquisition of Ocata Therapeutics, Inc. (The company name was changed to Astellas Institute for Regenerative Medicine in May 2016.) For details on this business combination, please refer to Note “37. Business Combination”.

Deductible temporary differences, tax loss carry-forwards, and unused tax credits for which no deferred tax asset is recognised are as follows:

(Millions of yen)

	2015	2016
Deductible temporary differences	¥31,630	¥33,600
Tax loss carry-forwards	5,198	6,330
Unused tax credits	1,268	1,877
<b>Total</b>	<b>¥38,096</b>	<b>¥41,808</b>

The expiration date and amount of tax loss carry-forwards for which no deferred tax asset is recognised are as follows:

(Millions of yen)

	2015	2016
Year 1	¥ 99	¥ 180
Year 2	192	68
Year 3	72	630
Year 4	65	158
Year 5 or later	4,771	5,295
<b>Total</b>	<b>¥5,198</b>	<b>¥6,330</b>

## 19. Other Financial Assets

The breakdown of other financial assets is as follows:

	(Millions of yen)	
	2015	2016
<b>Other financial assets (non-current)</b>		
Financial assets at FVTPL	¥ 6,466	¥ 8,092
Loans and other financial assets	10,923	11,528
Allowance for doubtful accounts	(14)	(52)
Available-for-sale financial assets	92,717	69,856
<b>Total other financial assets (non-current)</b>	<b>110,091</b>	<b>89,424</b>
<b>Other financial assets (current)</b>		
Financial assets at FVTPL	—	290
Loans and other financial assets	59,908	14,104
<b>Total other financial assets (current)</b>	<b>59,908</b>	<b>14,394</b>
<b>Total other financial assets</b>	<b>¥169,999</b>	<b>¥103,818</b>

## 20. Other Assets

The breakdown of other assets is as follows:

	(Millions of yen)	
	2015	2016
<b>Other non-current assets</b>		
Long-term prepaid expenses	¥10,307	¥12,145
Retirement benefit assets	2,544	1,784
Other	834	840
<b>Total other non-current assets</b>	<b>13,685</b>	<b>14,769</b>
<b>Other current assets</b>		
Prepaid expenses	8,132	10,213
Other	4,600	7,008
<b>Total other current assets</b>	<b>¥12,732</b>	<b>¥17,221</b>

## 21. Inventories

The breakdown of inventories is as follows:

	(Millions of yen)	
	2015	2016
Raw materials and supplies	¥ 28,243	¥ 28,165
Work in progress	13,165	14,239
Merchandise and finished goods	115,499	119,287
<b>Total</b>	<b>¥156,907</b>	<b>¥161,691</b>

The carrying amounts of inventories are measured at the lower of cost and net realisable value.

The cost of inventories recognised as an expense in “Cost of sales” for the years ended 31 March 2015 and 2016 amounted to ¥305,075 million and ¥288,841 million,

respectively.

The write-down of inventories recognised as an expense for the years ended 31 March 2015 and 2016 amounted to ¥5,094 million and ¥3,912 million, respectively.

## 22. Trade and Other Receivables

The breakdown of trade and other receivables is as follows:

	(Millions of yen)	
	2015	2016
Notes and accounts receivable	¥317,858	¥313,099
Other accounts receivable	33,148	41,423
Allowance for doubtful accounts	(2,495)	(2,820)
<b>Total trade and other receivables</b>	<b>348,511</b>	<b>351,702</b>
Non-current assets	15,588	24,103
Current assets	¥332,923	¥327,599

## 23. Cash and Cash Equivalents

The breakdown of cash and cash equivalents is as follows:

	(Millions of yen)	
	2015	2016
Cash and deposits	¥348,343	¥346,879
Short-term investments (cash equivalents)	48,087	13,151
<b>Cash and cash equivalents in the consolidated statement of financial position</b>	<b>¥396,430</b>	<b>¥360,030</b>
<b>Cash and cash equivalents in the consolidated statement of cash flows</b>	<b>396,430</b>	<b>360,030</b>

## 24. Assets Held for Sale

The breakdown of assets held for sale is as follows:

	(Millions of yen)	
	2015	2016
<b>Assets</b>		
Property, plant and equipment	¥139	¥200
<b>Total</b>	¥139	¥200

## 25. Equity and Other Components of Equity

### (1) Share capital and capital surplus

The movement of the number of issued shares and share capital is as follows:

	(Millions of yen)			
	Number of authorised shares (Thousands of shares)	Number of ordinary issued shares (Thousands of shares)	Share capital (Millions of yen)	Capital surplus (Millions of yen)
<b>As of 1 April 2014</b>	2,000,000	456,964	¥103,001	¥176,822
Increase	7,000,000	1,827,858	—	—
Decrease	—	(25,000)	—	—
<b>As of 31 March 2015</b>	9,000,000	2,259,823	103,001	176,822
Increase	—	—	—	81
Decrease	—	(38,000)	—	—
<b>As of 31 March 2016</b>	9,000,000	2,221,823	¥103,001	¥176,903

(Note) 1. Decrease in the number of ordinary issued shares during the year ended 31 March 2015 and 2016 resulted from the cancellation of treasury shares.

2. Increase in the number of authorised shares and ordinary issued shares for the year ended 31 March 2015 resulted from the five-for-one share split with an effective date of 1 April 2014.

### (2) Treasury shares

The movement of treasury shares is as follows:

	Number of shares (Thousands of shares)	Amount (Millions of yen)
<b>As of 1 April 2014</b>	10,736	¥ 54,535
Increase	81,269	58,229
Decrease	(25,323)	(25,767)
<b>As of 31 March 2015</b>	66,681	86,997
Increase	68,445	120,127
Decrease	(38,282)	(50,013)
<b>As of 31 March 2016</b>	96,844	¥157,111

(Note) The increase in the number of treasury shares during the year ended 31 March 2015 includes an increase of 42,945,000 shares due to the five-for-one share split with an effective date of 1 April 2014.

### (3) Other components of equity

#### Subscription rights to shares

The Company had adopted share option plans through the year ended 31 March 2015, and has issued subscription rights to shares under the former Commercial Code and the Companies Act of Japan. Contract conditions and amounts are described in Note “27. Share-based Payment”.

#### Foreign currency translation adjustments

This is a foreign currency translation difference that occurred when consolidating the financial statements of foreign operations denominated in foreign currencies.

#### Fair value movements on available-for-sale financial assets

This is a valuation difference between the fair value and acquisition cost of available-for-sale financial assets, which are measured at fair values.

## 26. Dividends

For the year ended 31 March 2015

### (1) Dividends paid

Resolution	Class of shares	Amount of dividends (Millions of yen)	Dividends per share (Yen)	Record date	Effective date
Ordinary general meeting of shareholders held on 18 June 2014	Ordinary shares	¥31,236	¥70.00	31 March 2014	19 June 2014
Board of directors meeting held on 31 October 2014	Ordinary shares	30,910	14.00	30 September 2014	1 December 2014

(Note) The Company completed a five-for-one share split with an effective date of 1 April 2014. “Dividends per share” whose record date is on or before 31 March 2014 shows the actual amount of dividends paid before the share split.

### (2) Dividends whose record date is in the fiscal year ended 31 March 2015 but whose effective date is in the following fiscal year are as follows:

Resolution	Class of shares	Amount of dividends (Millions of yen)	Dividends per share (Yen)	Record date	Effective date
Ordinary general meeting of shareholders held on 17 June 2015	Ordinary shares	¥35,090	¥16.00	31 March 2015	18 June 2015



For the year ended 31 March 2016

**(1) Dividends paid**

Resolution	Class of shares	Amount of dividends (Millions of yen)	Dividends per share (Yen)	Record date	Effective date
Ordinary general meeting of shareholders held on 17 June 2015	Ordinary shares	¥35,090	¥16.00	31 March 2015	18 June 2015
Board of directors meeting held on 30 October 2015	Ordinary shares	34,532	16.00	30 September 2015	1 December 2015

(Note) The amount of dividends approved by resolution of the board of directors meeting on 30 October 2015 includes dividends of ¥7 million corresponding to the Company's shares held in the executive compensation BIP trust.

**(2) Dividends whose record date is in the fiscal year ended 31 March 2016 but whose effective date is in the following fiscal year are as follows:**

Resolution	Class of shares	Amount of dividends (Millions of yen)	Dividends per share (Yen)	Record date	Effective date
Ordinary general meeting of shareholders held on 20 June 2016	Ordinary shares	¥34,007	¥16.00	31 March 2016	21 June 2016

(Note) The amount of dividends above includes dividends of ¥7 million corresponding to the Company's shares held in the executive compensation BIP trust.

**27. Share-based Payment**

**(1) Share option plans**

**(i) Outline of share option plans**

The Company had adopted share option plans through the year ended 31 March 2015, and has granted share options to directors and corporate executives of the Company. The purpose of share option plans is to improve the sensitivity to the share price and the Group's financial results and also increase the value of the Group by motivating the members to whom share options are granted.

After obtaining approval at the meeting of shareholders, share options are granted as subscription rights to shares to individuals approved at the Company's

board of directors meeting.

Holders of subscription rights to shares can exercise their share subscription rights only from the day following the date of resignation from their position as director or corporate executive of the Company.

Share options not exercised during the exercise period defined in the allocation contract will be forfeited.

The Company accounts for those share option plans as equity-settled share-based payment transactions.

(ii) Expenses recognised in the consolidated statement of income

	(Millions of yen)	
	2015	2016
<b>Total expenses recognised for share options granted</b>	¥307	¥73

(iii) Movement of the number of share options outstanding and their weighted average exercise price

	2015		2016	
	Weighted average exercise price (Yen)	Number of shares	Weighted average exercise price (Yen)	Number of shares
<b>Outstanding, beginning of the period</b>	¥ 3	3,402,000	¥ 1	3,305,400
Granted	1	226,900	—	—
Exercised	25	(323,500)	1	(282,500)
Forfeited or expired	—	—	—	—
<b>Outstanding, end of the period</b>	1	3,305,400	1	3,022,900
<b>Options exercisable, end of the period</b>	¥ 1	3,248,675	¥ 1	3,022,900

(Note) 1. The number of share options is presented as the number of underlying shares.

2. The weighted average share prices of share options at the time of exercise during the years ended 31 March 2015 and 2016 are ¥1,695 and ¥1,675, respectively.

(iv) Expiration dates and exercise prices of share options outstanding at the end of the period

	Expiration date	Exercise price per share (Yen)	Number of shares	
			2015	2016
Granted on August 2005	24 June 2025	¥1	66,500	46,000
Granted on February 2007	27 June 2026	1	143,500	123,500
Granted on August 2007	26 June 2027	1	200,000	169,500
Granted on September 2008	24 June 2028	1	221,500	173,000
Granted on July 2009	23 June 2029	1	397,000	348,500
Granted on July 2010	23 June 2030	1	531,500	489,000
Granted on July 2011	20 June 2031	1	577,500	557,500
Granted on July 2012	20 June 2032	1	587,500	557,500
Granted on July 2013	19 June 2033	1	353,500	331,500
Granted on July 2014	18 June 2034	1	226,900	226,900
<b>Total</b>		—	3,305,400	3,022,900

(Note) There are vesting conditions in which share subscription rights are vested according to the service record over approximately one year from the grant date of the share option to the vesting date.

#### (v) Measurement approach for fair value of share options granted during the period

The weighted average fair value of share options granted during the period is determined using the binominal model based on the following assumptions.

	2015	2016
Share price at the grant date	1,359 yen	—
Expected volatility (Note 1)	29.8%	—
Expected average period until the earliest exercisable date (Note 2)	3 years	—
Expected dividend (Note 3)	27 yen/share	—
Risk-free rate (Note 4)	1.4%	—

(Note) 1. Estimated by taking into account the actual share prices for the past 20 years.

2. Estimated based on the service records and term of office.

3. Calculated based on the latest dividends paid.

4. Based on the yield of government bonds corresponding to the exercise period (20 years).

## (2) Performance-linked Stock Compensation Scheme

### (i) Outline of the Performance-linked Stock Compensation Scheme

From the fiscal year ended 31 March 2016, the Group has introduced a Performance-linked Stock Compensation Scheme for directors and corporate executives (excluding outside directors) for the purpose of increasing their awareness of contributing to the sustainable growth in business results and corporate value.

The Scheme employs a framework referred to as the executive compensation BIP (Board Incentive Plan) trust (hereinafter the “BIP Trust”) for directors and corporate executives other than those residing overseas. The BIP Trust acquires the Company’s shares and delivers those shares to directors and other executives based on the level

of attainment of the medium-term management targets.

The Performance-linked Stock Compensation Scheme under which the Company’s shares are delivered from the BIP Trust is accounted for as an equity-settled share-based payment transaction.

In addition, the Company will provide cash benefits determined based on stock price of the Company to corporate executives residing overseas based on the level of attainment of the medium-term management targets. The Performance-linked Stock Compensation Scheme that provides cash benefits from the Company is accounted for as a cash-settled share-based payment transaction.

### (ii) Expenses recognised in the consolidated statement of income

	(Millions of yen)	
	2015	2016
Total expenses recognised for the Performance-linked Stock Compensation Scheme	¥—	¥88

**(iii) Measurement approach for the fair value of the Company's shares granted during the period based on the Performance-linked Stock Compensation Scheme**

The weighted average fair value of the Company's shares granted during the period is calculated based on the following assumptions.

	2015	2016
Share price at the grant date	—	1,695.5 yen
Vesting period (Note 1)	—	3 years
Expected annual dividend (Note 2)	—	32 yen/share
Discount rate (Note 3)	—	0.0%
<b>Weighted average fair value</b>	—	<b>1,600 yen</b>

(Note) 1. Refers to the number of years from the grant date until the shares are delivered.

2. Calculated based on the latest dividends paid.

3. Based on the yield of government bonds corresponding to the vesting period.

**28. Retirement Benefits**

The Group, excluding a part of foreign subsidiaries, offers post-employment benefits such as defined benefit plans and defined contribution plans. Among the defined benefit

plans offered, the defined benefit plan adopted in Japan is a major one, accounting for approximately 80% of the total defined benefit obligations.

**(i) Defined benefit plan adopted in Japan as post-employment benefit**

The Company and its domestic subsidiaries offer corporate pension plans and retirement lump-sum payment plans as defined benefit plans.

The benefits of the defined benefit plan are determined based on the base compensation calculated by accumulated points earned by the time of retirement and promised rate of return based on the yield of 10-year government bonds. Also, the option of receiving benefits in the form of a pension is available for plan participants with 15 years or more enrollments.

Defined benefit plans are administered by the Astellas Corporate Pension Fund. Directors of the pension fund are jointly liable for damages to the fund due to their neglect

of duties about management of the funds.

Contributions of the employer are made monthly and also determined as 4.0% of standard salary, which is calculated based on the estimate of the points granted during a year to each participant. When the plan assets are lower than the minimum funding standard at the end of the period, the employer will make additional contributions.

Defined benefit plans are exposed to actuarial risks. The Astellas Corporate Pension Fund assigns staff with professional knowledge and expertise about the composition of plan asset to determine the asset mix ratio and manages risks by monitoring on a quarterly basis.

**(ii) Defined benefit plans of overseas subsidiaries as post-employment benefits**

Among foreign subsidiaries, ones located in the United Kingdom, Germany, Ireland, and some other countries offer defined benefit plans as post-employment benefits.

The major defined benefit plan offered by overseas subsidiaries as post-employment benefits as of 31 March 2014, specifically the one adopted in the Netherlands, was settled during the year ended 31 March 2015. This was

due to a change of post-employment benefits of a subsidiary in the Netherlands, from a defined benefit plan to a defined contribution plan, in February 2015.

Consequently, an ¥8,017 million gain on settlement was recognised in the consolidated statement of income for the year ended 31 March 2015.

Assets and liabilities of defined benefit plans recognised in the consolidated statement of financial position are as follows:

**As of 31 March 2015**

(Millions of yen)

	Pension and lump-sum payment			Other
	Japan	Overseas	Total	
Present value of defined benefit obligations	¥ 117,128	¥ 33,950	¥ 151,078	¥2,938
Fair value of plan assets	(116,457)	(10,044)	(126,501)	—
Funded status	671	23,906	24,577	2,938
Effect of the asset ceiling	—	—	—	—
Net defined benefit liability (asset)	¥ 671	¥ 23,906	¥ 24,577	¥2,938
Amounts in the consolidated statement of financial position				
Assets (other non-current assets)	¥ (2,544)	¥ —	¥ (2,544)	¥ —
Liabilities (retirement benefit liabilities)	3,215	23,906	27,121	2,938

**As of 31 March 2016**

(Millions of yen)

	Pension and lump-sum payment			Other
	Japan	Overseas	Total	
Present value of defined benefit obligations	¥ 125,717	¥31,128	¥ 156,845	¥2,788
Fair value of plan assets	(111,799)	(9,820)	(121,620)	—
Net defined benefit liability (asset)	¥ 13,918	¥21,308	¥ 35,226	¥2,788
Amounts in the consolidated statement of financial position				
Assets (other non-current assets)	¥ (1,784)	¥ —	¥ (1,784)	¥ —
Liabilities (retirement benefit liabilities)	15,702	21,308	37,010	2,788

The movement of the present value of defined benefit obligations is as follows:

	Pension and lump-sum payment			Other
	Japan	Overseas	Total	
	(Millions of yen)			
<b>Balance at 1 April 2014</b>	¥117,862	¥ 57,182	¥175,044	¥ 2,959
Current service cost	4,869	1,955	6,824	380
Interest cost	1,211	1,878	3,088	87
<b>Remeasurements of defined benefit obligations</b>				
-actuarial (gains)/losses arising from changes in demographic assumptions	—	25	25	(1,110)
-actuarial (gains)/losses arising from changes in financial assumptions	2,633	25,660	28,293	(51)
-other	(337)	(486)	(823)	(141)
<b>Past service cost, and gains and losses arising from settlements</b>				
	—	(49,046)	(49,046)	586
<b>Contributions to the plan by plan participants</b>				
	—	487	487	—
<b>Payments from the plan</b>				
	(9,109)	(1,329)	(10,438)	(78)
<b>Effect of changes in foreign exchange rates</b>				
	—	(2,377)	(2,377)	306
<b>Balance at 31 March 2015</b>	117,128	33,950	151,078	2,938
Current service cost	4,687	1,165	5,852	284
Interest cost	1,009	622	1,630	65
<b>Remeasurements of defined benefit obligations</b>				
-actuarial (gains)/losses arising from changes in demographic assumptions	2,033	(180)	1,853	(3)
-actuarial (gains)/losses arising from changes in financial assumptions	6,543	(2,760)	3,784	(173)
-other	257	217	474	(31)
<b>Past service cost, and gains and losses arising from settlements</b>				
	—	(12)	(12)	—
<b>Contributions to the plan by plan participants</b>				
	—	83	83	—
<b>Payments from the plan</b>				
	(5,940)	(1,041)	(6,981)	(87)
<b>Effect of changes in foreign exchange rates</b>				
	—	(916)	(916)	(204)
<b>Balance at 31 March 2016</b>	¥125,717	¥ 31,128	¥156,845	¥ 2,788



The movement of fair value of plan assets is as follows:

	Pension and lump-sum payment			Other
	Japan	Overseas	Total	
Balance at 1 April 2014	¥111,719	¥ 39,904	¥151,623	¥—
Interest income	1,149	1,326	2,475	—
Remeasurements of the fair value of the plan assets				
-return on plan assets	8,008	9,310	17,318	—
-actuarial losses arising from changes in financial assumptions	(187)	(19)	(205)	—
Contributions to the plan				
-by employer	3,022	1,704	4,726	—
-by plan participants	—	487	487	—
Payments from the plan	(7,254)	(670)	(7,924)	—
Losses arising from settlements and curtailments	—	(40,993)	(40,993)	—
Effect of changes in foreign exchange rates	—	(1,005)	(1,005)	—
<b>Balance at 31 March 2015</b>	<b>116,457</b>	<b>10,044</b>	<b>126,501</b>	<b>—</b>
Interest income	1,002	206	1,208	—
Remeasurements of the fair value of the plan assets				
-return on plan assets	(2,777)	(510)	(3,287)	—
-actuarial losses arising from changes in financial assumptions	(487)	(36)	(523)	—
Contributions to the plan				
-by employer	2,758	719	3,477	—
-by plan participants	—	83	83	—
Payments from the plan	(5,154)	(394)	(5,548)	—
Effect of changes in foreign exchange rates	—	(291)	(291)	—
<b>Balance at 31 March 2016</b>	<b>¥111,799</b>	<b>¥ 9,820</b>	<b>¥121,620</b>	<b>¥—</b>

The Group expects to contribute ¥3,668 million to its defined benefit plans in the fiscal year ending 31 March 2017.

The movement of the effect of the asset ceiling is as follows:

(Millions of yen)

	Pension and lump-sum payment			Other
	Japan	Overseas	Total	
Balance at 1 April 2014	¥—	¥ 220	¥ 220	¥—
Interest income	—	7	7	—
Remeasurements				
Changes in the effect of limiting a net defined benefit asset to the asset ceiling	—	(217)	(217)	—
Effect of changes in foreign exchange rates, etc.	—	(10)	(10)	—
Balance at 31 March 2015	¥—	¥ —	¥ —	¥—

The breakdown of the fair value of plan assets is as follows:

(Millions of yen)

	2015	2016
<b>Japan</b>		
Equity	¥ 31,877	¥ 22,508
Bonds	43,675	37,104
Cash and other investments	40,905	52,188
<b>Total</b>	<b>116,457</b>	<b>111,799</b>
<b>Overseas</b>		
Equity	4,723	4,277
Bonds	2,622	2,381
Cash and other investments	2,698	3,161
<b>Total</b>	<b>10,044</b>	<b>9,820</b>
<b>Total fair value of plan assets</b>	<b>¥126,501</b>	<b>¥121,620</b>

#### (i) Japanese plan assets

Equity comprises mainly investment trust funds and it is categorised as Level 2 within the fair value hierarchy. The fair values of bonds are measured using quoted prices for identical or similar assets in markets that are not active,

and they are categorised as Level 2 within the fair value hierarchy. Cash and other investments include alternative investments.

#### (ii) Overseas plan assets

Equity is mainly composed of investments with quoted prices in active markets or with measured value using quoted prices for identical or similar assets in markets that are not active, and they are mainly categorised as Level 1 or Level 2 within the fair value hierarchy. The fair values

of bonds are measured using quoted prices for identical or similar assets in markets that are not active, and they are categorised as Level 2 within the fair value hierarchy. Cash and other investments include alternative investments.

Significant actuarial assumptions and sensitivity analysis for each significant actuarial assumption are as follows:

	(Millions of yen)	
	2015	2016
<b>Discount rate (%)</b>		
<b>Japan</b>	0.8%-0.9%	0.4%-0.5%
<b>Overseas</b>	1.5%-3.2%	1.5%-3.4%

A 0.5% increase or decrease in the discount rate as significant actuarial assumption would lead to a ¥11,077 million decrease and ¥12,535 million increase, respectively, in the defined benefit obligation.

The sensitivity analysis does not consider correlations between assumptions, assuming that all other assumptions

are held constant. In practice, changes in some of the assumptions may occur in a correlated manner. When calculating the sensitivity of the defined benefit obligations, the same method has been applied as calculating the defined benefit obligations recognised in the consolidated statement of financial position.

The weighted-average duration of the defined benefit obligations is as follows:

	2015	2016
<b>Japan</b>	12.7 years	13.1 years
<b>Overseas</b>	19.6 years	19.4 years

## 29. Provisions

The movement of provisions for the year ended 31 March 2015 is as follows:

	(Millions of yen)			
	Trade-related provisions	Asset retirement obligations	Other	Total
<b>Balance at 1 April 2014</b>	¥ 61,404	¥2,113	¥ 7,154	¥ 70,671
<b>Increase during the year</b>	73,773	261	7,022	81,057
<b>Decrease due to intended use</b>	(55,635)	(385)	(4,719)	(60,739)
<b>Reversal during the year</b>	(8,890)	(23)	(1,029)	(9,943)
<b>Other</b>	8,454	(20)	761	9,195
<b>Balance at 31 March 2015</b>	79,107	1,946	9,188	90,241
<b>Non-current</b>	2,117	1,945	756	4,817
<b>Current</b>	76,990	1	8,432	85,423
<b>Total provisions</b>	¥ 79,107	¥1,946	¥ 9,188	¥ 90,241

The movement of provisions for the year ended 31 March 2016 is as follows:

	(Millions of yen)			
	Trade-related provisions	Asset retirement obligations	Other	Total
<b>Balance at 1 April 2015</b>	¥ 79,107	¥1,946	¥ 9,188	¥ 90,241
<b>Increase during the year</b>	79,850	45	5,122	85,016
<b>Decrease due to intended use</b>	(60,614)	(35)	(1,512)	(62,162)
<b>Reversal during the year</b>	(10,889)	–	(653)	(11,542)
<b>Other</b>	(3,922)	(8)	(683)	(4,612)
<b>Balance at 31 March 2016</b>	83,531	1,948	11,462	96,941
<b>Non-current</b>	4,582	1,948	553	7,083
<b>Current</b>	78,949	–	10,909	89,858
<b>Total provisions</b>	¥ 83,531	¥1,948	¥11,462	¥ 96,941

Details of provisions are as follows:

#### (i) Trade-related provisions

The Group recognises provisions for expenditures expected to be incurred after the end of the period related to sales rebates, discounts, Medicare and Medicaid of the United States, and other price adjustments to customers,

based on the conditions of contracts and past experience.

The outflow of economic benefits is expected within one year from the end of the reporting period.

#### (ii) Asset retirement obligations

The Group recognises asset retirement obligations based on past performance in order to provide for the restoration of rented offices.

The outflow of economic benefits is expected after one year from the end of the reporting period.

### 30. Other Financial Liabilities

The breakdown of other financial liabilities is as follows:

	(Millions of yen)	
	2015	2016
<b>Other financial liabilities (non-current)</b>		
<b>Financial liabilities measured at amortised cost</b>		
<b>Finance lease liabilities</b>	¥ 626	¥ 722
<b>Total other financial liabilities (non-current)</b>	¥ 626	¥ 722
<b>Other financial liabilities (current)</b>		
<b>Financial liabilities at FVTPL</b>	¥ 373	¥ 351
<b>Financial liabilities measured at amortised cost</b>		
<b>Finance lease liabilities</b>	365	505
<b>Other</b>	600	649
<b>Total other financial liabilities (current)</b>	¥1,339	¥1,505
<b>Total other financial liabilities</b>	¥1,965	¥2,227

The maturity and the present value of finance lease liabilities are as follows:

	(Millions of yen)	
	2015	2016
<b>Minimum lease payments</b>		
Not later than one year	¥365	¥ 505
Later than one year and not later than five years	616	719
Later than five years	10	3
<b>Present value of finance lease liabilities</b>	¥991	¥1,226

### 31. Other Liabilities

The breakdown of other liabilities is as follows:

	(Millions of yen)	
	2015	2016
<b>Other non-current liabilities</b>		
Other long-term employee benefits	¥14,018	¥ 15,316
Deferred income	4,182	61,689
Other	942	564
<b>Total other non-current liabilities</b>	¥19,142	¥ 77,569
<b>Other current liabilities</b>		
Accrued bonuses	¥30,155	¥ 30,199
Accrued paid absences	9,890	10,517
Other accrued expenses	46,059	46,804
Deferred income	329	28,779
Other	6,971	4,827
<b>Total other current liabilities</b>	¥93,403	¥121,126

(Note) Deferred income under other non-current liabilities and deferred income under other current liabilities include those of ¥57,787 million and ¥28,411 million, respectively, recognised in connection with the transfer of the global dermatology business to LEO Pharma A/S.

### 32. Trade and Other Payables

The breakdown of trade and other payables is as follows:

	(Millions of yen)	
	2015	2016
<b>Accounts payable—trade</b>	¥108,137	¥110,852
<b>Other payables</b>	118,554	72,305
<b>Total trade and other payables</b>	¥226,692	¥183,157
<b>Non-current</b>	¥ 90	¥ 1,599
<b>Current</b>	226,602	181,559

## 33. Financial Instruments

### (1) Capital management

The Group's capital management principle is to maintain an optimal capital structure by improving capital efficiency and ensuring sound and flexible financial conditions in order to achieve sustained improvement in the enterprise value, which will lead to improved return to shareholders.

The Group monitors financial indicators in order to maintain an optimal capital structure. Credit ratings are monitored for financial soundness and flexibility, and so is return on equity attributable to owners of the parent (ROE) for capital efficiency.

The Group is not subject to material capital regulation.

### (2) Classification of financial assets and financial liabilities

The breakdown of financial assets and financial liabilities is as follows:

	(Millions of yen)	
	2015	2016
<b>Financial assets</b>		
Financial assets at FVTPL	¥ 6,466	¥ 8,382
Loans and receivables		
Trade and other receivables	348,511	351,702
Loans and other financial assets	70,817	25,579
Available-for-sale financial assets	92,717	69,856
Cash and cash equivalents	396,430	360,030
<b>Total financial assets</b>	<b>¥914,941</b>	<b>¥815,549</b>
<b>Financial liabilities</b>		
Financial liabilities at FVTPL	¥ 373	¥ 351
Financial liabilities measured at amortised cost		
Trade and other payables	226,692	183,157
Other	1,591	1,875
<b>Total financial liabilities</b>	<b>¥228,656</b>	<b>¥185,384</b>

(Note) 1. Financial assets at FVTPL, loans and other financial assets, and available-for-sale financial assets are included in "Other financial assets" in the consolidated statement of financial position.

2. Financial liabilities at FVTPL and "Other" of financial liabilities measured at amortised cost are included in "Other financial liabilities" in the consolidated statement of financial position.

### (3) Financial risk management policy

The Group is exposed to financial risks such as credit risks, liquidity risks, and foreign exchange risks in operating businesses, and it manages risks based on its policy to mitigate them.

The Group limits the use of derivatives to transactions for the purpose of hedging financial risks and does not use derivatives for speculation purposes.

#### (i) Credit risk

##### (a) Credit risk management

Receivables, such as trade receivables, resulting from the business activities of the Group are exposed to the customer's credit risk. This risk is managed by grasping

the financial condition of the customer and monitoring the trade receivables balance. Also, the Group reviews collectability of trade receivables depending on the credit



conditions of customers and recognises an allowance for doubtful accounts as necessary.

Securities held by the Group are exposed to the issuer's credit risk, and deposits are exposed to the credit risk of banks. Also, derivative transactions that the Group conducts in order to hedge financial risks are exposed to the credit risk of the financial institutions which are counterparties of those transactions. In regard to securities transactions and deposit transactions in fund management, the Group only deals with banks and issuers with certain credit ratings and manages investments within the defined period and credit limit, in accordance with Global Cash Investment Policy. In addition, regarding derivative transactions, the Group only deals with financial institutions with certain credit ratings in accordance with Astellas Global Treasury Policy.

**(b) Concentrations of credit risk**

In Japan, like other pharmaceutical companies, the Group sells its products through a small number of wholesalers. Sales to the four largest wholesalers amounted to approximately 75% of the Group's sales in Japan, and the

amount of trade receivables due from those four wholesalers are ¥130,148 million at 31 March 2015 and ¥121,505 million at 31 March 2016.

**(c) Maximum exposure to credit risk**

Other than guaranteed obligations, the Group's maximum exposure to credit risks without taking into account any collateral held or other credit enhancements is the carrying amount of financial instruments less impairment losses in the consolidated statement of financial position. The Group's maximum exposure to credit risks of guaranteed obligations as of 31 March 2015 and 2016 were ¥1,537 million and ¥1,379 million, respectively.

**(d) Collateral**

The Group has securities and deposits received as collateral for certain trade receivables and other receivables. The carrying amount of securities held as collateral is ¥1,478 million at 31 March 2016 (¥1,353 million at 31 March 2015), and the carrying amount of deposits received is ¥85 million at 31 March 2016 (¥85 million at 31 March 2015).

The analysis of aging of financial assets that are past due but not impaired is as follows:

(Millions of yen)

	Neither past due nor impaired	Past due but not impaired				Allowance for doubtful accounts	Total
		Within three months	Between three months and six months	Between six months and one year	Over one year		
<b>Balance at 31 March 2015</b>							
Trade and other receivables	¥325,640	¥20,291	¥1,590	¥1,478	¥1,950	¥(2,438)	¥348,511
Loans and other financial assets	70,817	—	—	—	—	—	70,817
<b>Total</b>	<b>¥396,457</b>	<b>¥20,291</b>	<b>¥1,590</b>	<b>¥1,478</b>	<b>¥1,950</b>	<b>¥(2,438)</b>	<b>¥419,328</b>
<b>Balance at 31 March 2016</b>							
Trade and other receivables	¥331,749	¥17,740	¥2,080	¥1,889	¥ 934	¥(2,689)	¥351,702
Loans and other financial assets	25,572	1	—	6	—	—	25,579
<b>Total</b>	<b>¥357,321</b>	<b>¥17,740</b>	<b>¥2,080</b>	<b>¥1,895</b>	<b>¥ 934</b>	<b>¥(2,689)</b>	<b>¥377,281</b>

Financial assets that are individually determined to be impaired are as follows:

	(Millions of yen)	
	2015	2016
Trade and other receivables (gross)	¥ 57	¥ 132
Allowance for doubtful accounts	(57)	(132)
Trade and other receivables (net)	¥ –	¥ –
Loans and other financial assets (gross)	¥ 14	¥ 52
Allowance for doubtful accounts	(14)	(52)
Loans and other financial assets (net)	¥ –	¥ –

The movement of the allowance for doubtful accounts is as follows:

	(Millions of yen)	
	2015	2016
Balance at the beginning of the year	¥1,717	¥2,509
Increase during the year	1,395	477
Decrease due to intended use	(3)	(7)
Reversal during the year	(530)	(33)
Other	(69)	(74)
Balance at the end of the year	¥2,509	¥2,873

## (ii) Liquidity risk

### Liquidity risk management

The Group is exposed to liquidity risk that the Group might have difficulty settling financial obligations. However, the Group is maintaining the liquidity on hand that enables the Group to meet the expected repayment of

financial obligations and respond flexibly to strategic investment opportunities. Also, the balance is reported monthly to a Senior Corporate Executive (i.e., Chief Financial Officer).

Financial liabilities by maturity date are as follows:

### As of 31 March 2015

	(Millions of yen)							
	Carrying amount	Contractual cash flows	Within six months	Between six months and one year	Between one year and two years	Between two years and five years	Over five years	
<b>Financial liabilities at FVTPL</b>								
Foreign exchange forward contracts								
	¥ 373	¥ 373	¥ –	¥373	¥ –	¥ –	¥ –	
Subtotal	373	373	–	373	–	–	–	
<b>Financial liabilities measured at amortised cost</b>								
Trade and other payables	226,692	226,766	226,659	17	36	54	–	
Other	1,591	1,591	795	170	287	329	10	
Subtotal	228,283	228,358	227,455	187	323	383	10	
Total	¥228,656	¥228,731	¥227,455	¥561	¥323	¥383	¥10	

As of 31 March 2016

(Millions of yen)

	Carrying amount	Contractual cash flows	Within six months	Between six	Between one	Between two	Over five years
				months and one year	year and two years	years and five years	
<b>Financial liabilities at FVTPL</b>							
Foreign exchange forward contracts	¥ 351	¥ 351	¥ –	¥ 351	¥ –	¥ –	¥–
Subtotal	351	351	–	351	–	–	–
<b>Financial liabilities measured at amortised cost</b>							
Trade and other payables	183,157	183,157	181,107	452	112	1,486	–
Other	1,875	1,875	911	242	308	411	3
Subtotal	185,033	185,033	182,018	694	420	1,897	3
<b>Total</b>	<b>¥185,384</b>	<b>¥185,384</b>	<b>¥182,018</b>	<b>¥1,045</b>	<b>¥420</b>	<b>¥1,897</b>	<b>¥3</b>

### (iii) Foreign exchange risk

#### Foreign exchange risk management

The Group operates globally and the Group's business results and financial position are exposed to foreign exchange risks.

The Group's long-term basic policy is to mitigate the foreign exchange risks by controlling the amount of the Group's net assets denominated in foreign currencies to the level corresponding to the business scale of respective area. In the short term, the Group uses derivatives such as foreign exchange forward contracts to reduce the impact of exchange rate fluctuations arising from import and export transactions

denominated in foreign currencies. Also, the balance of derivative transactions is reported monthly to a Senior Corporate Executive (Chief Financial Officer).

#### Foreign exchange sensitivity analysis

The financial impact on profit before tax for the years ended 31 March 2015 and 2016 in the case of a 10% appreciation in Japanese yen, which is the Company's functional currency, against the U.S. dollar and euro is as follows.

Also, it is based on the assumption that currencies other than the ones used for the calculation do not fluctuate and other change factors are held constant.

(Millions of yen)

	2015	2016
<b>Profit before tax</b>		
U.S. dollar	¥ (847)	¥ (190)
Euro	(1,274)	(7,912)

(Note) The above negative amounts represent the negative impact on profit before tax in the event of a 10% appreciation in Japanese yen.

## (4) Fair values of financial instruments

### (i) Fair value calculation of financial instruments

#### Financial assets at FVTPL

Financial assets at FVTPL comprise mainly debt securities and foreign exchange forward contracts. The fair value of those financial instruments is measured based on prices provided by counterparty financial institutions.

#### Loans and receivables

The carrying amount approximates fair value due to the short period of settlement terms.

## Available-for-sale financial assets

The fair value of marketable securities is based on quoted market prices at the end of the period. The fair value of unquoted equity shares is measured mainly based on the discounted future cash flows.

## Cash and cash equivalents

The carrying amount approximates fair value due to the short maturities of the instruments.

## Financial liabilities at FVTPL

Financial liabilities at FVTPL comprise foreign exchange forward contracts. The fair value is measured based on prices provided by counterparty financial institutions.

## Financial liabilities measured at amortised cost

Financial liabilities measured at amortised cost comprise trade and other payables and other financial liabilities. The carrying amount approximates fair value due to the short period of settlement terms.

## (ii) Financial instruments measured at fair value on a recurring basis

### Fair value hierarchy

The levels of the fair value hierarchy are as follows:

- Level 1: Fair value measured using quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2: Fair value measured using inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly;
- and

- Level 3: Fair value measured using significant unobservable inputs for the assets or liabilities.

The level of the fair value hierarchy is determined based on the lowest level of significant input used for the measurement of fair value.

The Group accounts for transfers between levels of the fair value hierarchy as if they occurred at the end of each quarter.

The breakdown of financial assets and liabilities measured at fair value on a recurring basis, including their levels in the fair value hierarchy, is as follows:

### As of 31 March 2015

	(Millions of yen)			
	Level 1	Level 2	Level 3	Total
<b>Financial assets</b>				
<b>Financial assets at FVTPL</b>				
Other	¥ –	¥5,715	¥ 750	¥ 6,466
Subtotal	–	5,715	750	6,466
<b>Available-for-sale financial assets</b>				
Quoted equity shares	76,596	–	–	76,596
Unquoted equity shares	–	–	15,520	15,520
Other equity securities	–	–	601	601
Subtotal	76,596	–	16,121	92,717
<b>Total financial assets</b>	76,596	5,715	16,871	99,182
<b>Financial liabilities</b>				
<b>Financial liabilities at FVTPL</b>				
Foreign exchange forward contracts	–	373	–	373
Subtotal	–	373	–	373
<b>Total financial liabilities</b>	¥ –	¥ 373	¥ –	¥ 373

(Note) Financial assets at FVTPL and available-for-sale financial assets, and financial liabilities at FVTPL are included in “Other financial assets” and “Other financial liabilities” in the consolidated statement of financial position, respectively.

As of 31 March 2016

(Millions of yen)

	Level 1	Level 2	Level 3	Total
<b>Financial assets</b>				
<b>Financial assets at FVTPL</b>				
Foreign exchange forward contracts	¥ —	¥ 290	¥ —	¥ 290
Other	—	6,087	2,005	8,092
<b>Subtotal</b>	—	6,377	2,005	8,382
<b>Available-for-sale financial assets</b>				
Quoted equity shares	55,995	—	—	55,995
Unquoted equity shares	—	—	13,861	13,861
Other equity securities	—	—	0	0
<b>Subtotal</b>	55,995	—	13,861	69,856
<b>Total financial assets</b>	55,995	6,377	15,866	78,238
<b>Financial liabilities</b>				
<b>Financial liabilities at FVTPL</b>				
Foreign exchange forward contracts	—	351	—	351
<b>Subtotal</b>	—	351	—	351
<b>Total financial liabilities</b>	¥ —	¥ 351	¥ —	¥ 351

(Note) Financial assets at FVTPL and available-for-sale financial assets, and financial liabilities at FVTPL are included in “Other financial assets” and “Other financial liabilities” in the consolidated statement of financial position, respectively.

The movement of fair value of financial assets categorised within Level 3 of the fair value hierarchy is as follows:

As of 31 March 2015

(Millions of yen)

	Financial assets at FVTPL	Available-for-sale financial assets	Total
<b>Balance at the beginning of the year</b>	¥ —	¥24,609	¥24,609
<b>Realised or unrealised gains (losses)</b>			
Recognised in profit or loss (Note 1)	(27)	(2,213)	(2,240)
Recognised in other comprehensive income	—	2,531	2,531
<b>Purchases, issues, sales, and settlements</b>			
Purchases	772	2,533	3,305
Sales	—	(2,108)	(2,108)
Transfers to/from Level 3 (Note 2)	—	(9,704)	(9,704)
Other	5	473	478
<b>Balance at the end of the year</b>	¥750	¥16,121	¥16,871
<b>Gains or losses recognised during the year in profit or loss attributable to the change in unrealised gains or losses relating to those assets held at the end of the period (Note 1)</b>	¥ (27)	¥ (2,217)	¥ (2,244)

(Note) 1. Those are included in “Finance income” and “Finance expense” of the consolidated statement of income.

2. Those financial assets were transferred from Level 3, since a significant input that affects measurement of fair value became observable.

As of 31 March 2016

(Millions of yen)

	Financial assets at FVTPL	Available-for-sale financial assets	Total
Balance at the beginning of the year	¥ 750	¥16,121	¥16,871
Realised or unrealised gains (losses)			
Recognised in profit or loss (Note 1)	(153)	240	87
Recognised in other comprehensive income	—	(1,024)	(1,024)
Purchases, issues, sales, and settlements			
Purchases	1,408	744	2,152
Sales	(1)	(664)	(664)
Transfers to Investments in associates and joint ventures	—	(576)	(576)
Transfers to/from Level 3 (Note 2)	—	(657)	(657)
Other	—	(322)	(322)
Balance at the end of the year	¥2,005	¥13,861	¥15,866
Gains or losses recognised during the year in profit or loss attributable to the change in unrealised gains or losses relating to those assets held at the end of the period (Note 1)	¥ (151)	¥ —	¥ (151)

(Note) 1. Those are included in “Finance income” and “Finance expense” of the consolidated statement of income.

2. Those financial assets were transferred from Level 3, since a significant input that affects measurement of fair value became observable.

The financial assets categorised within Level 3 are composed mainly of unquoted equity shares.

The fair value of significant unquoted equity shares is measured using discounted future cash flows. The fair value of unquoted equity shares is categorised within Level 3 because unobservable inputs such as estimates of future net operating profit after tax and WACC are used for the measurement. The WACC used for the measurement of fair value depends on region or industry. In the years ended 31 March 2015 and 2016, the WACC used for measurement was between 6.0% and 8.0%, and 8.0%, respectively. Generally, the fair value would

decrease if the WACC capital were higher.

The fair value of unquoted equity shares is measured by relevant departments of the Company and each Group company in accordance with the Group accounting policy every quarter. The results with evidences of changes in fair value are reported to a superior and, if necessary, to the Executive Committee as well.

In regards to financial instruments categorised within Level 3, there would be no significant change in fair value when one or more of the unobservable inputs is changed to reflect reasonably possible alternative assumptions.



### 34. Operating Leases

Future minimum lease payments under non-cancellable operating leases are as follows:

	(Millions of yen)	
	2015	2016
Not later than one year	¥13,091	¥13,017
Later than one year and not later than five years	30,717	26,850
Later than five years	3,756	2,349
<b>Total</b>	<b>¥47,564</b>	<b>¥42,217</b>

Future minimum sublease payments expected to be received under non-cancellable subleases is as follows:

	(Millions of yen)	
	2015	2016
<b>Future minimum sublease payments expected to be received</b>	<b>¥2,951</b>	<b>¥2,286</b>

Minimum lease payments and sublease payments received recognised as expenses are as follows:

	(Millions of yen)	
	2015	2016
Minimum lease payments	¥18,191	¥17,634
Sublease payments received	(205)	(229)
<b>Total</b>	<b>¥17,987</b>	<b>¥17,405</b>

The Group leases buildings, vehicles and other assets under operating leases.

The significant leasing arrangements have terms of renewal, but there exist no contingent rents payable, terms

of purchase options, and escalation clauses. In addition, there are no material restrictions imposed by the lease arrangements.

### 35. Commitments

The breakdown of commitments for the acquisition of property, plant and equipment and intangible assets is as follows:

	(Millions of yen)	
	2015	2016
<b>Intangible assets</b>		
Research and development milestone payments	¥238,025	¥251,978
Sales milestone payments	173,665	153,833
<b>Total</b>	<b>¥411,691</b>	<b>¥405,812</b>
<b>Property, plant and equipment</b>	<b>¥ 20,676</b>	<b>¥ 8,715</b>

#### Commitments for the acquisition of intangible assets

The Group has entered into research and development collaborations and in-license agreements of products and technologies with a number of third parties. These agreements may require the Group to make milestone payments upon the achievement of agreed objectives or when certain conditions are met as defined in the agreements.

“Research and development milestone payments” represent obligations to pay the amount set out in an individual contract agreement upon achievement of a milestone determined according to the stage of research and development.

“Sales milestone payments” represent obligations to pay the amount set out in an individual contract agreement

upon achievement of a milestone determined according to the target of sales.

The amounts shown in the table above represent the maximum payments to be made when all milestones are achieved, and they are undiscounted and not risk adjusted.

Since the achievement of the conditions for payment is highly uncertain, it is unlikely that they will all fall due and the amounts of the actual payments may vary considerably from those stated in the table.

## 36. Related Party Transactions

### (1) Major companies the Group controls

A list of major companies the Group controls is presented in “Principal Subsidiaries and Affiliates”.

### (2) Compensation of key management personnel

The table below shows, by the type, the compensation of key management personnel:

	(Millions of yen)	
	2015	2016
Rewards and salaries	¥1,255	¥1,253
Share-based payment	183	98
Other	292	420
<b>Total compensation</b>	<b>¥1,731</b>	<b>¥1,771</b>

Key management personnel consist of 22 people (20 during 2015) including Directors, Corporate Audit & Supervisory Board Members and members of the Executive Committee.

## 37. Business Combination

For the year ended 31 March 2016

### (1) Outline of business combination

#### (i) Name and business description of the acquiree

Name of the acquiree: Ocata Therapeutics, Inc. (“Ocata”) (The company name was changed to Astellas Institute for Regenerative Medicine in May 2016.)

Business description: Research and development of new therapies for ophthalmic diseases in the field of regenerative medicine

#### (ii) Acquisition date

10 February 2016

#### (iii) Percentage of voting equity interests acquired

100%

#### (iv) Acquisition method

Tender offer to purchase all issued and outstanding shares of common stock in cash

#### (v) Primary reasons for the business combination

The Group strives to create a solid and resilient continuity of growth over the mid- to long-term through the pursuit of the three main strategies of Strategic Plan 2015-2017 (“the Strategic Plan”) – “Maximizing Product Value,” “Creating Innovation” and “Pursuing Operational Excellence.” Especially in “Creating Innovation,” the Group recognises the importance of advancing into new opportunities in addition to enhancing capabilities to deliver innovative medicines. The Group added muscle diseases and ophthalmology to its focused disease areas for research and is promoting drug discovery research in those areas. Further, the Group invests proactively in regenerative medicine, particularly in cell therapy and next-generation vaccines as initiatives involving new technologies and new modalities.

Ocata is a clinical stage biotechnology company focused on the development and commercialization of

new therapies in the field of regenerative medicine. Ocata has an advanced technology that can establish fully-differentiated cells from pluripotent stem cells. Ocata also has strengths in clinical studies for cell therapy.

The acquisition of Ocata represents the coming together of two companies with significant accomplishments and a shared commitment to develop innovative therapies that address the unmet medical needs of patients suffering from severe ophthalmic diseases. The acquisition also represents a step toward achieving the Strategic Plan. Further, acquiring Ocata will enable the Group to establish a presence in ophthalmology and a leading position in cell therapy. Strategic rationale behind the acquisition:

- Establish a presence in ophthalmology
- Establish a leading position in cell therapy by obtaining Ocata’s world-class capability

#### (2) The fair values of assets acquired, liabilities assumed and purchase consideration transferred as at the date of the acquisition

	(Millions of yen)
Property, plant and equipment	¥ 151
Other intangible assets	17,456
Deferred tax assets	3,167
Cash and cash equivalents	1,084
Other assets	41
Other liabilities	(2,494)
<b>Fair value of assets acquired and liabilities assumed (net)</b>	<b>19,405</b>
<b>Goodwill</b>	<b>24,332</b>
<b>Total</b>	<b>43,737</b>
<b>Fair value of purchase consideration transferred</b>	<b>¥43,737</b>

Certain items above reflect provisional amounts based on reasonable information obtained at the end of the fiscal year as the purchase price allocation is incomplete.

Goodwill mainly comprises the value of expected synergies arising from the acquisition and future economic benefits, which is not separately recognised.

#### (3) Cash flow information

	(Millions of yen)
<b>Fair value of purchase consideration transferred</b>	<b>¥43,737</b>
<b>Cash and cash equivalents held by the acquiree</b>	<b>(1,084)</b>
<b>Acquisition of subsidiaries, net of cash acquired</b>	<b>¥42,653</b>

## (4) Acquisition-related costs

Acquisition-related costs: ¥939 million

Acquisition-related costs were recognised in selling, general and administrative expenses in the consolidated statement of income.

## (5) Effect on the consolidated statement of income

**(i) Profit (loss) before tax of the acquiree since the acquisition date included in the consolidated statement of income:**

¥(638) million

**(ii) Profit (loss) before tax of the combined entity for the fiscal year ended 31 March 2016 assuming the acquisition date had been at the beginning of the fiscal year (unaudited):**

¥(5,357) million

Note: This effect is calculated based on the business results of Ocata from 1 April 2015 to the acquisition date.

## 38. Contingent Liabilities

### Legal Proceedings

The Group is involved in various claims and legal proceedings of a nature considered common to the pharmaceutical industry. These proceedings are generally related to product liability claims, competition and antitrust law, intellectual property matters, employment claims, and government investigations. In general, since litigation and other legal proceedings contain many uncertainties and complex factors, it is often not possible to make reliable judgment regarding the possibility of losses nor to estimate expected financial effect if these matters are decided in a manner that is adverse to the Group. In these cases, disclosures would be made as appropriate, but no provision would be made by the Group.

### Prograf Litigation

Astellas Pharma US, Inc. (APUS), one of the Company's indirect U.S. subsidiaries, was named as a defendant in 2011 in several separate lawsuits brought by plaintiffs in various federal courts on behalf of themselves and proposed classes of all direct and indirect purchasers of Prograf. These lawsuits involve allegations that under the federal antitrust laws and various state laws, APUS misused the Citizen Petition process for the sole purpose

of delaying the approval of generic tacrolimus by the U.S. Food and Drug Administration, thereby injuring the plaintiffs. In June 2011, the U.S. Judicial Panel on Multi-District Litigation ordered that the cases be consolidated before the U.S. District Court for the District of Massachusetts.

In January 2015, APUS settled all claims brought against it by the direct purchaser plaintiffs.

In February 2016, APUS reached a settlement with the indirect purchaser plaintiffs, which is pending Court approval.

### Tarceva Government Investigation

In November 2011, OSI Pharmaceuticals, LLC, one of the Company's indirect U.S. subsidiaries, received a subpoena from the U.S. Department of Justice, represented by the U.S. Attorney's Office in San Francisco, California, requesting documents and other information concerning the promotion, marketing, and sale of Tarceva in the U.S. In June 2016, OSI Pharmaceuticals, LLC entered into a civil settlement agreement with the U.S. government and the states that resolves this matter.

## 39. Events after the Reporting Period

Not applicable



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Tokyo 100-0011, Japan

Tel: +81 3 3503 1100  
Fax: +81 3 3503 1197  
www.shinnihon.or.jp

## Independent Auditor's Report

The Board of Directors  
Astellas Pharma Inc.

We have audited the accompanying consolidated financial statements of Astellas Pharma Inc. and Subsidiaries, which comprise the consolidated statement of financial position as at 31 March 2016, and the consolidated statements of income, comprehensive income, changes in equity, 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 International Financial Reporting Standards, 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 Subsidiaries as at 31 March 2016, and their consolidated financial performance and cash flows for the year then ended in conformity with International Financial Reporting Standards.

### *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 2.

*Erist & Young ShinNihon LLC*

20 June 2016  
Tokyo, Japan

A member firm of Ernst & Young Global Limited

# Investor Information

## Common Stock (as of March 31, 2016)

Authorized: 9,000,000,000  
 Issued: 2,221,823,175  
 (including 96,404,912  
 treasury stock)  
 Number of shareholders: 104,166

## Transfer Agent for Common Stock in Japan

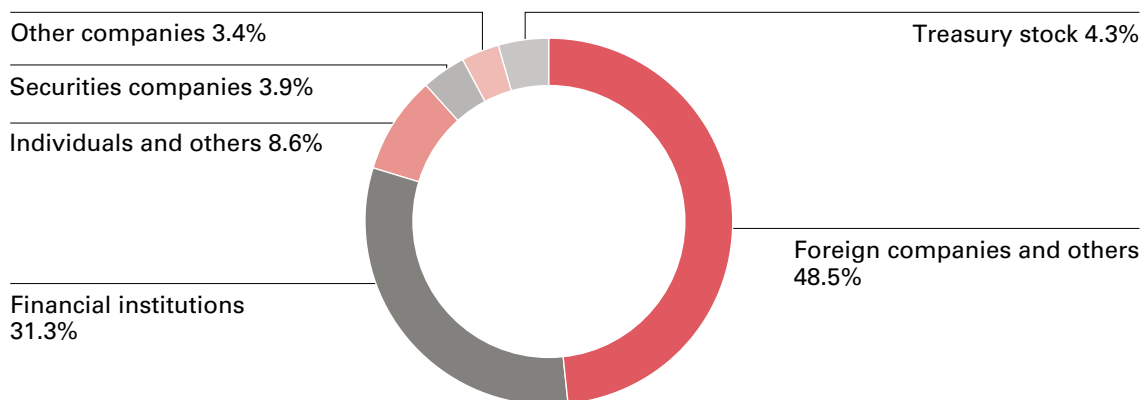
Sumitomo Mitsui Trust Bank, Limited  
 1-4-1, Marunouchi, Chiyoda-ku, Tokyo 100-8233, Japan

## Major Shareholders (as of March 31, 2016)

	Shares owned (Thousand shares)	Percentage of total common shares outstanding
The Master Trust Bank of Japan, Ltd. (trust account)	137,328	6.46
Japan Trustee Services Bank, Ltd. (trust account)	117,296	5.51
State Street Bank and Trust Company	115,303	5.42
Nippon Life Insurance Company	64,486	3.03
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	44,408	2.08
JP Morgan Chase Bank 385632	41,936	1.97
JP Morgan Chase Bank 385147	39,888	1.87
State Street Bank West Client - Treaty 505234	34,674	1.63
JP Morgan Chase Bank 380055	33,103	1.55
Japan Trustee Services Bank, Ltd. (trust account 7)	30,329	1.42

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 96,404 thousand shares of treasury stock, but it is not included in the above list of major shareholders.

## Breakdown of Shareholders (as of March 31, 2016)



# Corporate Data

## ■ 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, 2016)

¥103,001 million

## ■ Representative

Yoshihiko Hatanaka  
 Representative Director, President and CEO

## ■ Founded

1923

## ■ Professional Institution Affiliation

International Federation of Pharmaceutical  
 Manufacturers & Associations (IFPMA)

## ■ Stock Exchange Listing

Tokyo (Securities Code: 4503)

## ■ Independent Auditors

Ernst & Young ShinNihon LLC  
 Hibiya Kokusai Building, 2-2-3 Uchisaiwai-cho,  
 Chiyoda-ku, Tokyo 100-0011, Japan

# Principal Subsidiaries and Affiliates (as of July 2016)

Astellas is a group of companies engaged solely in the pharmaceutical business. The Group consists of 96 companies, which include Astellas Pharma Inc., 86 consolidated subsidiaries and 9 affiliates accounted for by the equity method. Major Group companies are listed as follows:

## ■ 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.  
 - Amgen Astellas BioPharma K.K.



## Americas

### Holding Company in North America

- Astellas US Holding, Inc.  
1 Astellas Way, Northbrook, IL 60062-6111, U.S.A.

### Regional Headquarters

- Astellas US LLC  
1 Astellas Way, Northbrook, IL 60062-6111, U.S.A.  
TEL: +1-800-888-7704

### R&D Bases

- Astellas Pharma Global Development, Inc.
- Agensys, Inc.
- Astellas Research Institute of America LLC
- Astellas Institute for Regenerative Medicine

### 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)
- Astellas Farma Columbia S.A.S (Columbia)

### Other

- Astellas Venture Management LLC

Note: All subsidiaries for which no country has been indicated are located in the U.S.

\* Astellas Pharma Technologies, Inc. was transferred to Avara Norman Pharmaceutical Services, Inc. on August 4, 2016.

## EMEA

### Holding Company in EMEA

- Astellas B.V.  
Sylviusweg 62, 2333, BE Leiden, The Netherlands  
TEL: +31-71-5455745

### Regional Headquarters (Astellas EMEA Operations)

- 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.m.b.H (Austria)
- Astellas Pharma B.V. (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. (Netherlands)
- Astellas Pharma Sp. zo.o. (Poland)
- Astellas Farma Limitada (Portugal)
- ZAO Astellas Pharma (Russia)
- Astellas Pharma d.o.o. (Slovenia)
- Astellas Pharma (Proprietary), Ltd. (South Africa)
- Astellas Pharma S.A. (Spain)
- Astellas Pharma A.G. (Switzerland)
- Astellas Pharma ilaç Ticaret ve Sanayi A.S. (Turkey)
- Astellas Pharma DMCC (United Arab Emirates)
- Astellas Pharma Ltd. (United Kingdom)

## Asia & Oceania

### Sales and Other Bases

- 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)
- Astellas Pharma Malaysia Sdn. Bhd. (Malaysia)

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**Inclusion in SRI Indexes**

Astellas is included as a constituent stock in the following global socially responsible investment (SRI) indexes.



Dow Jones Sustainability Asia Pacific Index (DJSI Asia Pacific), the Asia Pacific version of the Dow Jones Sustainability Index (DJSI)



FTSE4Good Index, an equity index series that is designed to facilitate investment in companies that meet globally recognized corporate responsibility standards.



## Astellas Pharma Inc.

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