

Annual Report 2011

For the Year Ended March 31, 2011

# astellas Leading Light for Life

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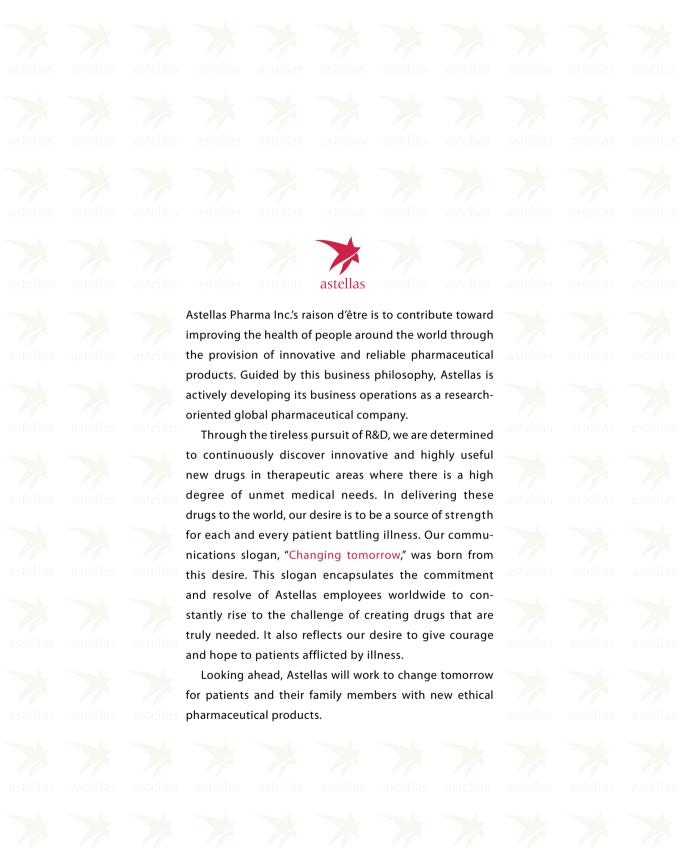
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#### Note about forward-looking statements and forecasts

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

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

### Profile





Profile

ASTELLAS PHARMA INC. ANNUAL REPORT 2011 01

#### Leveraging Our Strengths to Grow

# The Path for Astellas to Take

#### Establish a competitive edge as a Global Category Leader (GCL)

We aim to establish a presence as a leader in specialized multiple fields, or categories, where there is a high degree of unmet medical needs. We will improve our competitive edge in these categories by supplying high-value-added pharmaceuticals worldwide.

#### Proprietary ethical pharmaceutical approach

Unmet medical needs exist in the proprietary ethical pharmaceutical market. The market still has room to grow through technological innovation.

#### Innovative pharmaceutical approach

The innovative pharmaceutical business is the most attractive business model for Astellas to make the most of its strengths, i.e., assets and abilities.

#### In-house R&D approach

Drug discovery research and clinical development are core functions for GCL and will generate a future competitive advantage.

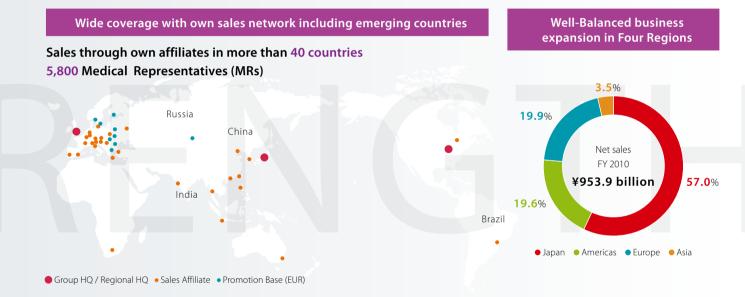
# Mid-Term Management Plan (MTP)14\*—Basic Policy and Strategy

	<ul> <li>Therapeutic area strategy</li> <li>Maintain and strengthen GCL position in urology and transplantation</li> <li>Strengthen oncology franchise to realize third GCL</li> </ul>
Growth Strategy	<ul> <li>Regional strategy</li> <li>Expand well-balanced four-region business base</li> <li>Invest further in emerging countries with high potential</li> </ul>
	<ul> <li>R&amp;D innovation strategy (Strengthen drug discovery research capabilities)</li> <li>Actively approach Precision Medicine drug discovery</li> <li>Prioritize strategic therapeutic areas</li> <li>Utilize cutting-edge technologies in drug discovery research</li> <li>Leverage global development framework to bolster pipelines</li> </ul>
Efficiency Strategy	Improve cost efficiency         • Efficiently allocate resources through execution of therapeutic area strategy         • Manage better and sharp expenditure       • Review business processes to achieve cost efficiency

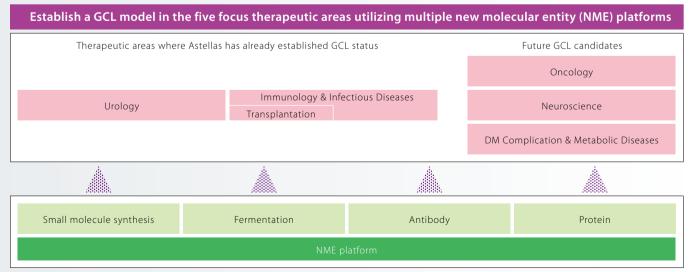
\* Five-year plan from the fiscal year ended March 2011 to the fiscal year ending March 2015

# Five Strengths of Astellas

- 1 Me Leading positions globally in the fields of transplantation and urology
- 2 Well-balanced global sales and marketing network spanning the four key regions of Japan, the Americas, Europe and Asia
- 3 Nobust sales and marketing platform in Japan
- 4 W Unique pipeline with many "first-in-class" or "best-in-class" compounds
- 5 Strong drug discovery technologies combining small molecule synthesis, fermentation, antibody, and protein drug technologies



#### Focus Research Area



Please see "Interview with the President & CEO" on Page 8 for a detailed discussion.

#### **Message to Stakeholders**

The business philosophy of Astellas describes our corporate raison d'être as that of contributing toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. To help realize this business philosophy, we formulated "Vision 2015" in 2006. Our goal is to build a business model that we call "global category leader" (GCL). This means establishing Astellas' competitive edge as a leader in highly specialized fields (categories) where there is a high degree of unmet medical needs through the supply of high-value-added drugs on a worldwide basis.

Business conditions facing the pharmaceutical industry remain as harsh as ever. Highlighting the challenges are that governments are implementing policies to restrain medical expenditures, notably in advanced countries, and regulatory processes and approval for new drugs are becoming tougher. These conditions require a company to mount swift and flexible responses based on a more accurate and precise understanding of the changing business environment in order to continuously create new drugs that will ensure it prevails in global markets.

We announced a mid-term management plan in May 2010 called MTP14, which covers the five-year period from fiscal 2010 to fiscal 2014 as a concrete course of action to achieve GCL status. We are actively working to implement this plan.

In fiscal 2010, the first year of this plan, we encountered extremely challenging conditions, not the least because it was the first full year that two mainstay products—immunosuppressant Prograf and Harnal, a treatment for the functional symptoms associated with benign prostatic hyperplasia—were impacted by competition from generic products. Nevertheless, we are convinced that we can achieve sustained growth from a starting point of fiscal 2010 by steadily implementing strategies that translate MTP14 into concrete action, making full use of our tangible and intangible assets.

Yoshihiko Hatanaka took the helm as President and CEO on June 20, 2011. Masafumi Nogimori will oversee business execution while supporting the new management team as Representative Director and Chairman.

Under the new management team, Astellas aims to establish GCL status and realize faster growth. We will work tirelessly to earn the trust and meet the expectations of patients and their families in particular—not to mention a wide range of other stakeholders that includes medical professionals, shareholders, employees and local communities.

Let us conclude this letter by expressing our heartfelt sympathies to all the people affected by the March 11 Great East Japan Earthquake. We will do what we can to help disaster-stricken areas achieve a speedy recovery.

I hope that we will continue to enjoy your collective support and understanding.

September 2011

Masafami Kogèmor

Masafumi Nogimori Representative Director and Chairman

(J. 74

Yoshihiko Hatanaka Representative Director, President and CEO



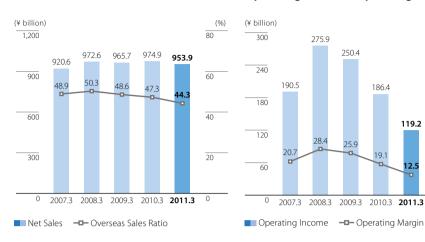
# **Financial Highlights**

Years ended March 31

				(¥ billion)	(US\$ million)		(% Change
	2008.3	2009.3	2010.3	2011.3	2011.3	10/09	11/10
For the year							
Net sales	¥ 972.6	¥ 965.7	¥ 974.9	¥ 953.9	\$11,493	1.0	(2.1
Cost of sales	279.3	264.4	289.2	296.0	3,566	9.4	2.3
SG&A expenses (incl. R&D expenses)	417.3	450.9	499.2	538.8	6,491	10.7	7.9
Operating income	275.9	250.4	186.4	119.2	1,436	(25.6)	(36.1
Operating margin (%)	28.4	25.9	19.1	12.5	—	—	_
Net income	177.4	171.0	122.3	67.7	815	(28.5)	(44.7
Overseas sales	489.6	469.0	460.7	422.5	5,091	(1.8)	(8.3
Overseas sales ratio (%)	50.3	48.6	47.3	44.3	_	_	_
R&D expenses	134.5	159.1	195.6	217.3	2,618	23.0	11.1
R&D ratio (%)	13.8	16.5	20.1	22.8	_	_	_
At year-end							
Total assets	1,439.2	1,348.4	1,364.2	1,335.1	16,085	1.2	(2.
Total net assets	1,110.9	1,030.2	1,053.9	1,021.1	12,302	2.3	(3.1
Working capital	692.7	680.1	711.4	413.5	4,982	4.6	(41.9
				(¥)	(US\$)		(% Change
Per share data							
Net income	¥ 349.89	¥ 356.11	¥ 261.84	¥ 146.49	\$ 1.76	(26.5)	(44.)
Total net assets	2,228.34	2,189.26	2,278.77	2,207.70	26.60	4.1	(3.1
Cash dividends	110.00	120.00	125.00	125.00	1.51	4.2	0.0
Major Indicators							
ROE (%)	16.1	16.0	11.7	6.5	_	_	_
DOE (%)	5.0	5.4	5.6	5.6	_	_	_
Shareholders' equity ratio (%)	77.1	76.3	77.1	76.4	_	_	_
EBITDA* (¥ billion / US\$ million)	305.8	305.6	235.3	168.9	2,035	(23.0)	(28.)
Free cash flows (¥ billion / US\$ million)	178.5	168.8	118.6	(142.0)	(1,711)	(29.7)	(20.
Average exchange rate (¥ / US\$)	114	100.0	93	86	(1,,, 11)	(29.7)	(7.
(¥ / €)	162	143	131	113	_	(7.5)	(13.)
						(0.1)	(13.
Other Indicators							
Number of shares outstanding	518 964 635	503,964,635	475 964 635	467,964,635	_	_	_

Notes: US dollars have been converted at the rate of ¥83 to US\$1, the approximate exchange rate on March 31, 2011. US dollar amounts are included solely for convenience.

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



Net Sales / Overseas Sales Ratio

#### **Operating Income / Operating Margin**

250.4

25.9

n.

<sup>0</sup> 2007.3 2008.3 2009.3 2010.3 **2011.3** 

186.4

19.1

275.9

28.4

Net Income

80

60

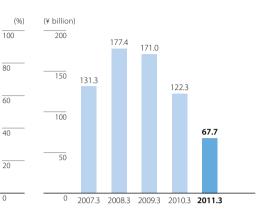
40

20

0

119.2

12.5



**R&D Expenses / R&D Ratio** 



#### Net Income per Share

300

240

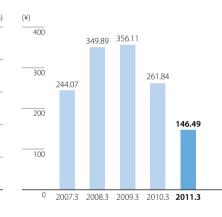
180

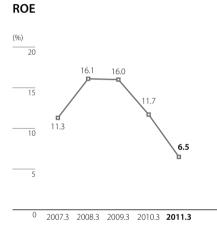
120

190.5

20.7

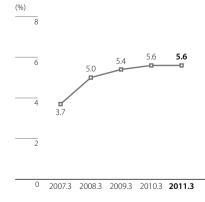
60



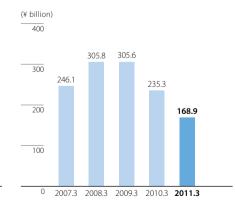


R&D Expenses -D- R&D Ratio

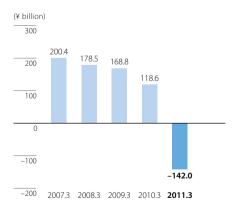
DOE







**Free Cash Flows** 



### **Interview with the President and CEO**

Yoshihiko Hatanaka Representative Director, President and CEO

#### Yoshihiko Hatanaka

Mr. Hatanaka joined the former Fujisawa Pharmaceutical Co., Ltd. in April 1980, and was appointed Vice President of the Corporate Planning Department in 2003. In April 2005, Mr. Hatanaka was appointed Vice President of the Corporate Planning Department of the Corporate Strategy Division at Astellas. In April 2006, he was appointed President & CEO of Astellas Pharma US, Inc. Later, in April 2009, he became Senior Corporate Executive of Corporate Strategy and Corporate Finance at Astellas. Mr. Hatanaka took up the post of President and CEO on June 20, 2011.

# Accelerating Astellas' growth by pursuing Global Category Leader (GCL) status is our mission.

#### **Fiscal 2010 Overview**

#### Realizing Astellas' GCL Objectives

Q. How do you view Astellas' business direction as its newly appointed CEO? In which areas do you plan to focus, and what are your ambitions for the company?

Into a New Phase of Accelerated Growth

Q. How would you describe fiscal 2010 for Astellas? What impact did the Great East Japan Earthquake have on Astellas?

#### Realizing Astellas' GCL Objectives

**Q.** How do you view Astellas' business direction as its newly appointed CEO? In which areas do you plan to focus, and what are your ambitions for the company?

**A.** My fundamental focus will be on realizing the objectives that we formulated in 2006 as part of "Vision 2015." The goal of Astellas remains to make a significant contribution to human health by supplying innovative, valuable new drugs based on in-house research across multiple areas where there exists a high degree of unmet medical needs. Astellas is uniquely strong in the therapeutic areas of urology and transplantation / immunology. In recent years, we have also made major investments in the area of oncology, and we are focused on establishing oncology as a third GCL category where we are a global leader. I see one of my key roles as keeping our oncology franchise on its current growth trajectory.

I was directly involved in the formulation of Vision 2015 and the MTP14 business plan. I have also taken part in creating many of the alliances that Astellas has forged with multiple industry players. So I share the strategic vision and direction with members of the Global Management Committee. Going forward, we remain focused on aggressively pursuing a growth strategy that is based on making Astellas a GCL in several fields. Controlling medical costs has become a major political issue in many countries, with structural ramifications for the pharmaceuticals market. Across the pharmaceutical industry, companies are changing their business models or reallocating resources to respond to this changing environment. My view is that we should accelerate efforts to establish Astellas as a GCL across a select number of fields so that we can realize our vision within this dynamically shifting environment.

Another of Astellas' strengths is our combination of a unique product portfolio with a significant presence in each of the four global regions of Japan, the Americas, Europe and Asia. Strategically, we will continue to focus on developing our regional product portfolios alongside our therapeutic area strategy to support future growth.

We have invested aggressively over the past few years to reinforce our research and technical platform, to expand and upgrade the development pipeline, and to grow our various regional business bases. We expect these efforts to translate into sustained growth in enterprise value, which will help us to build even stronger trust with all of our stakeholders and boost the value of Astellas' global enterprise. To ensure that this growth continues, we will be doing everything we can to upgrade our drug discovery capabilities, accelerate the development of our global operations, including emerging markets, and to promote the expansion of our international human resources.

#### Into a New Phase of Accelerated Growth

Q. How would you describe fiscal 2010 for Astellas?

A. Fiscal 2010, the year ended March 2011, was the first full year in which we felt the impact of generic competition in the US market for the mainstay products Prograf and Harnal. Although this led to a significant decline in sales and profits compared with fiscal 2009, our performance was generally within the scope forecast. We made significant progress in expanding our pipeline in the oncology area through the acquisition of US-based OSI Pharmaceuticals, Inc. (OSI) in June 2010 and an inward licensing agreement for cancer treatment tivozanib that we concluded with AVEO Pharmaceuticals, Inc. in February 2011. We also concluded several other important alliances during the year. In addition, we made major progress on the clinical development and regulatory fronts, filling NDAs for overactive bladder (OAB) treatment mirabegron in Japan along with a number of other projects. Fiscal 2010 will mark the bottom for Astellas in terms of the sales and earnings impact of US patent expiration on two of our leading products. I believe that we are now entering a new phase in which the company's growth will start to accelerate.

**Q.** What impact did the Great East Japan Earthquake have on Astellas?

**A.** The Great East Japan Earthquake of March 11, 2011 inflicted damage on Japan on an unprecedented scale. I would like to take this opportunity to express once again our heartfelt condolences to all those that suffered loss in this disaster.

Astellas has a number of sites in the region that were most severely affected, including research laboratories, factories, regional branches and sales offices. We were able to restore normal operations in the weeks following the disaster at all of these sites, with the exception of the Takahagi Technology Center that makes bulk compound for Harnal and other products. Recovery operations at Takahagi have been continuing steadily and we expect to restart production at the site from October 2011. The business continuity plans that we began developing three years ago worked well, and we confirmed the safety of all employees and their families, conducted damage assessments for all of the Astellas Group facilities in the region, and formulated restoration plans for each site. Since maintaining supplies of pharmaceuticals for patients is part of the social mission of a pharmaceutical company, we will continue to upgrade our risk management practices so that we can respond appropriately in the future to natural and other disasters.

In terms of the financial impact of the disaster, we booked an extraordinary loss of ¥3.0 billion in fiscal 2010 to account for the expenses for repairing damaged facilities and fixed costs related to temporary shutdowns at various sites.

Q1 / FY2010	Q2 / FY2010	Q3 / FY2010	Q4 / FY2010	
June 2010 OSI acquisition	Integration	activities	January 2011 Started reviewing strategic business alternatives for Prosidion subsidiary	June 2011 Completed integration
June 2010 Japan Kyushu area Distribution and co- promotion of vaccines	July 2010 Regeneron's VelocImmune antibody technology Extension of license agreement	Phase 1 October 2010 AKP-002 Lower urinary tract symptoms associated with BPH	April 2011 Japan Launch January 2011 ENCEVAC Japanese encephalitis vaccine	
	Phase 2 September 2010 UMN-0501 / 0502 Influenza vaccines	Phase 2 October 2010 Diannexin Prevention of DGF in kidney transplantation	Filed February 2011 fidaxomicin Clostridium difficile infection	
		December 2010 Strategic equity agreement with Cytori	Phase 3 February 2011 tivozanib Renal cell carcinoma etc.	
			March 2011 Perseid Exercised buy-out option	

#### Outcome of FY2010–Alliance Activities

DGF: Delayed Graft Function

Making steady progress with the strategic theme of "leveraging our strengths to grow." Raising our global competitiveness.

#### **MTP14 Progress**

Step Up Well-balanced Global Expansion Regional Strategy **Based Around Four Regions** Q. How is Astellas developing its international business, especially in emerging markets? Therapeutic Area Strategy Establish Astellas as a GCL in Oncology Q. Oncology is the third area designated by Astellas as a GCL target after urology and transplantation. What are you doing to strengthen your business in that area? Therapeutic Area Strategy Establish a Strong No. 1 Position Q. Urology is one area where Astellas has already established its GCL status. What progress has occurred in this field? Solidifying Our GCL Position in Transplantation Therapeutic Area Strategy Q. What is Astellas doing in the other GCL area of transplantation? R&D Innovation Strategy Aim to Produce Innovative New Drugs Q. What is Astellas doing to improve its ability to generate products? Medium-term: Manage R&D expenses at R&D Innovation Strategy 16-18% of sales

Q. How much does Astellas plan to invest in R&D?

#### Step Up Well-balanced Global Expansion Based Around Four Regions

Regional Strategy

**Q.** How is Astellas developing its international business, especially in emerging markets?

**A.** Astellas is pursuing the development of a well-balanced global business spanning the four key regions of Japan, the Americas, Europe and Asia. We now have sales operations through local affiliates in more than 40 countries worldwide, with a global sales force of some 5,800 MRs. One of our strengths is that, in addition to global products such as Prograf and OAB treatment Vesicare, we have also developed significant local product portfolios specific to each region. Growth in sales of local products makes a significant contribution to our consolidated performance. We aim to build further on the strengths of our local product portfolios and business bases so that we can generate further growth overall.

Since our business development is based on high-valueadded new drugs, markets in the advanced countries of Japan, the US and Europe will remain vital to us. We are also actively promoting business development in emerging markets in pursuit of further growth. We have established sales affiliates and are already developing our in-house sales networks in China, Russia, Brazil and India, all of which are expected to grow rapidly in the future. In China, where we set up a sales affiliate in 1994, we have been building and reinforcing our operating base for many years, and these efforts have produced results. Today, China is one of the most important markets in Asia in terms of the prospects for future growth. In fiscal 2014, the final year of the MTP14 plan, we aim to generate sales in China of at least double the figure that we achieved in fiscal 2010.

Measures to restrict healthcare expenditure or reduce drug reimbursement prices are now starting to become a political reality in developing countries as well. Although we expect these markets to continue expanding, we think healthcare costcontainment measures will be introduced faster in these countries than occurred in the developed world. As a result, we are not merely relying on market growth to drive our sales. Echoing our approach in Western markets, we plan to put our high-valueadded products at the center of our emerging markets growth strategy as well. Strategically, we aim to grow our business by aligning our pricing to the value added by each product.

#### World Prescription Pharmaceuticals Market Market Size by Region (2010)



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# Establish Astellas as a GCL in Oncology

nerapeutic Area Strategy

**Q.** Oncology is the third area designated by Astellas as a GCL target after urology and transplantation. What are you doing to strengthen your business in that area?

**A.** Oncology is an area where unmet medical needs remain extremely high. We aim to transform oncology into the third GCL area after urology and transplantation. Although it is a highly competitive field, it is also an area where we can develop valuable medicines that target specific cancers or that can be tailored to be effective in certain patient subgroups based on genetic factors.

We designated oncology as a core therapeutic area for Astellas in 2006. Since then we have established a strong drug creation platform for anticancer agents derived from antibodies through the acquisition of Agensys, Inc. and the formation of strategic technical alliances with Regeneron Pharmaceuticals, Inc. and Morpho-Sys AG among others. These successes have enabled us to create cutting-edge R&D capabilities in oncology. We have also been actively building our late-stage clinical development pipeline in the area such as by in-licensing several promising compounds. These have included prostate cancer treatment MDV3100 and acute myeloid leukemia treatment AC220, both in 2009, and tivozanib in February 2011 for renal cell carcinoma.

The acquisition of US-based OSI in June 2010 has allowed us to focus on progress of our development pipeline and near-term produt expansion potential. Functional integration of OSI into the Astellas Group has now been achieved as planned. This acquisition has provided Astellas with a fully integrated US business platform in the oncology field, from drug discovery to development and commercialization.

Astellas currently has more than 10 ongoing clinical development projects in the oncology field, making it an extremely rich pipeline. We continue to make steady progress strengthening our platform in the area of oncology, and I believe we are on course toward establishing Astellas as a GCL in oncology.

#### Establish a Strong No. 1 Position

#### herapeutic Area Strated

**Q.** Urology is one area where Astellas has already established its GCL status. What progress has occurred in this field?

**A.** Sales of Vesicare, one of our products leading Astellas' growth, have been steadily increasing worldwide. We believe there are still many OAB patients who go either undiagnosed or untreated. Over the medium term we see the growth of Vesicare being driven by the expansion of the OAB market. To date we have co-promoted this product with GlaxoSmithKline in the US, but from January 2012 we will undertake all promotional activities. This will be an opportunity for us to reinforce the leading position that we have established for Astellas in urology. We also hope to make a significant contribution to the treatment of OAB.

There has also been a great deal of progress with mirabegron, a new medicine expected to follow after Vesicare. We gained regulatory approval for this drug in Japan in July 2011, and we are currently preparing to launch the product as soon as possible after it is listed on the NHI price listing. We also submitted applications for regulatory approval of mirabegron in the US and Europe as planned in August 2011. Our target for total global sales of Vesicare and mirabegron in fiscal 2014, the final year of MTP14, is over ¥155.0 billion.

Astellas has earned the trust of urologists worldwide as we have gained experience in the field over many years. We aim to become the dominant leader in the area by maximizing the product value of Vesicare and mirabegron.

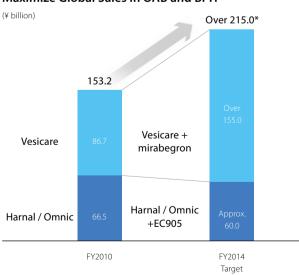
#### Solidifying Our GCL Position in Transplantation Therapeutic Area Strategy

Q. What is Astellas doing in the other GCL area of transplantation?A. Maintaining the Prograf franchise remains a key element of

A. Maintaining the Programations elemans a key element of our strategic approach. After our patent expired, we began to face generic competition in the US in August 2009. Although sales fell substantially in fiscal 2010, we expect the decline to be less marked going forward. Outside the US, once-a-day formulations Advagraf / Graceptor are contributing to sales in Europe and Japan. We are also expanding sales in Japan for treatment of certain autoimmune diseases and are expecting to expand sales of Prograf in Asian markets. Over the medium term we aim to maintain global sales of Prograf at a stable level.

Transplantation medicine is another area where there are still high unmet medical needs. Clinical challenges include reducing the incidence of chronic organ rejection after transplant, as well as bolstering the long-term efficacy and safety of transplants. We aim to discover and develop value-added medicines to address such needs. Our clinical development pipeline includes ASKP1240 for the suppression of organ rejection, the immunosuppressant ASP015K, and diannexin for the prevention of delayed graft function in kidney transplantation. All of these development compounds possess unique mechanisms of action.

Looking to the future, we aim to maintain and build on our position as a GCL within transplantation while also making a further contribution to the transplant community.



#### Maximize Global Sales in OAB and BPH

OAR

\* Revised sales target from the May 2010 announcement, due to revision of the expected foreign exchange rate.

BPH BPH

#### Aim to Produce Innovative New Drugs

&D Innovation Strate

**Q.** What is Astellas doing to improve its ability to generate products?

**A.** Our five focus therapeutic areas are urology, immunology including transplantation and infectious diseases, oncology, neuroscience, and DM complications and metabolic diseases. Within these areas of focus, we identify specific research themes at the level of individual disorders and seek to discover innovative new drugs to treat such conditions by concentrating our resources on these specific research themes.

We are actively pursuing a "Precision Medicine" approach to drug discovery. In the past, many essential drugs in each phamaceutical company have generally been developed so as to maximize prescriptions to all patients diagnosed with a certain condition. The problem is that effects can vary significantly even between patients taking the same drug. The Precision Medicine approach seeks to boost the efficacy of medicines by developing diagnostic methods for prognosticating the benefits for each patient, and prescribing medicine that is expected to have optimal benefits for an individual. Using this approach, we aim to develop medicines with a higher efficacy and a lower incidence of side effects. By targeting specific patient segments, we can improve the predictive performance of clinical trials. The smaller scale of trials also boosts R&D effectiveness and productivity. Two examples of products in our current pipeline that have applied the Precision Medicine approach are anti-cancer treatment Tarceva, where we aim to expand indications in non-small cell lung cancer, and AC220.

We are also keen to leverage our expertise in translational science to link drug-discovery research with clinical development to improve drug discovery, in the process generating earlier clinical evaluations of the critical efficacy and safety aspects of compounds. I think this is also an important approach if we are to bolster the Precision Medicine approach and remain globally competitive in R&D.

As part of efforts, we are enhancing our translational science platform and creating translational science promotion plans for each R&D theme and project. In some projects we are seeing tangible results from these efforts, such as searching for various types of biomarkers as indicators of drug efficacy and safety and testing their disease applicability of diagnostic agents.

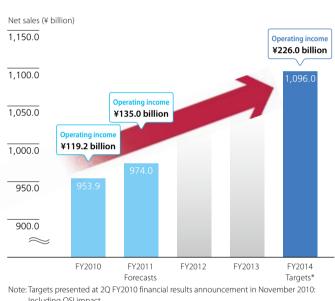
We also recognize the importance of an open approach to innovation. This means that we are prepared to develop consortia and to partner with external organizations where we do not possess the required in-house expertise, confident that this can produce greater value for both sides. I believe that such approaches will play an important role in boosting our future drug discovery capabilities. In May 2011, we opened "a<sup>3</sup> (a-cube)," a public open innovation site in Japan, a move that should increase opportunities for collaboration with outside researchers.

#### Medium-term: Manage R&D expenses at 16–18% of sales R&D Innovation Strategy

Q. How much does Astellas plan to invest in R&D?

**A.** R&D expenses were 22.8% of net sales in fiscal 2010, partly reflecting higher milestone payments linked to inward licensing of products and technologies. We believe that it is critical to continue investing actively in R&D to support the company's long-term growth. At the same time, we are seeking to reap efficiencies in R&D spending. Over the medium and longer term, we expect the ratio of R&D costs to net sales to settle in the 16–18% range.

We plan to continue actively seeking in-license opportunities and such alliances in order to acquire products, late-stage development compounds and any game-changing technologies that are aligned with our growth strategy. However, we will review individual licensing opportunities more rigorously going forward, based on our in-house development capacity. Furthermore, we will continue to consider mergers and acquisition as one option for achieving our goals. Prioritization of candidate compounds for development is becoming increasingly vital to manage escalating development costs properly. In the cases of potentially valuable compounds with less in-house development priority, we will also look at partnering with other companies. An example of this approach is an outward licensing agreement that we concluded with Cardeus Pharmaceuticals, Inc. in March 2011 for a number of compounds. This will help us to manage development costs and enable continued development while leaving the way open for Astellas to be involved in the future. We believe this is the most beneficial path for patients and other stakeholders.



#### **Continuous Growth Forecast from Fiscal 2010**

Including OSI impact Forecast exchange rates: 80 yen / US\$, 110 yen / €



# We will continuously meet stakeholder expectations.

#### **Payout Policy and Corporate Governance System**

- Aiming for a Stable and Continuous Increase Q. Is your policy regarding shareholder returns still the same?
- Building a Transparent and Independent System Q. What are the defining features of corporate governance at Astellas?
- CSR is the Embodiment of Our Business Philosophy Q. Please explain Astellas' CSR-based management.
- Fulfilling Stakeholder Expectations Q. What is your message to the company's stakeholders?

#### Aiming for a Stable and Continuous Increase

**Q.** Is your policy regarding shareholder returns still the same? **A.** Our basic policy has not changed. We still aim to generate sustained growth in enterprise value so that we can boost returns to shareholders. 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. Furthermore, Astellas will flexibly purchase treasury stock as necessary to further improve capital efficiency and the level of return to shareholders.

#### Building a Transparent and Independent System

**Q.** What are the defining features of corporate governance at Astellas?

**A.** There are several defining features to our corporate governance system. One is that we have introduced the Corporate Executives System. This system clearly separates the roles of the Directors who have management decision-making and business execution supervisory functions from the roles of the Corporate Executives who are responsible for business execution. Next, the seven-member Board of Directors includes four outside Directors with a high level of independence. This promotes decision-making and supervision of business execution from a broader viewpoint. The Board of Directors using their specialist knowledge in fields such as medicine, law and business. Such vigorous debate ensures that decisions are made via a transparent and fair process.

Astellas also adopted the Corporate Auditors System with the Board of Corporate Auditors that has four members, including two outside Corporate Auditors. Each Corporate Auditor audits the execution of duties by the Directors. In addition, we have established the Nomination Committee and the Compensation Committee as advisory bodies to the Board of Directors for the purpose of enhancing the transparency and objectivity of the deliberation process for the nomination of Directors, Corporate Executives and Corporate Auditors and of the compensation system.

#### CSR is the Embodiment of Our Business Philosophy

Q. Please explain Astellas' CSR-based management.

**A.** As a company in an industry impacting people's lives, we realize that our corporate activities have a strong social nature and connection with society. Based on this recognition, Astellas is practicing CSR-based management as a means through which we strive toward sustained enhancement of enterprise value while remaining acutely aware of our social responsibilities and taking a broad view that considers economics, society and other factors. This management approach aims to win acceptance as a valuable member of society at large. We have defined five fields of CSR-based management—compliance, which we see as the foundation of this approach, as well as employees, society, the economy and the environment. All our corporate activities are checked from a CSR perspective.

#### **Fulfilling Stakeholder Expectations**

**Q.** What is your message to the company's stakeholders?

**A.** We are determined to fulfill our mission as a company connected with people's lives. We are working to explain our plans, the background to them, and the extent of achievements to this end. We place importance on dialogue with stakeholders as we seek to grow further.

Over the past few years, Astellas has made substantial investments. These investments have been directed at strengthening our research and technology platforms, improving and expanding our R&D pipeline and extending our well-balanced global business base across four regions. These are now strengths of Astellas. We plan to leverage these strengths as a strategic theme to drive further growth. In this way, I am convinced we can become a company that is a force to be reckoned with in the world, as well as have an important presence.

Integrity sums up our corporate culture, which supports all of Astellas' business activities. This is in fact my favorite word. Through the provision of innovative new drugs, we will contribute to people's health, as well as be a source of strength for patients and their families battling illness. We will also continue fulfilling the expectations of all other stakeholders, including medical professionals, shareholders, employees and local communities.

## **Future Growth Drivers in the Current R&D Pipeline**

Astellas' R&D pipeline has expanded rapidly through compounds discovered in-house entering clinical development along with other compounds developed in collaboration with other companies. Astellas has a substantial number of compounds with unique mechanisms of action in development across several strategic therapeutic areas, notably urology, transplantation and immunology, infectious diseases, and oncology.

We aim to drive our growth as a research-oriented pharmaceutical enterprise by focusing aggressively on accelerated R&D of innovative new drugs targeting areas of high unmet medical needs. In doing so, we hope to deliver significant medical benefits for patients.

#### Urology

#### **Urology Pipeline**

	Overactive bladder (OAB)
Mirabegron	Approved (JP), Filed (EU, US)
New molecular e	entity, Beta3 receptor agonist
EB178 P2 (EU)	
Life cycle manag	ement / concomitant use of Vesicare and mirabegron
	Benign prostatic hyperplasia
EC905 P3 (EU)	
Life cycle manag	ement / concomitant use of Omnic OCAS and Vesicare
ASP0306 P1	
New molecular e	entity
ASP4901 (AKP	-002) P1
New molecular e	entity
Chi	ronic prostatitis / chronic pelvic pain syndrome
ASP3652 P2 (E	U)
New molecular e	entity

In urology, we have several compounds in development for OAB and other urological conditions such as benign prostatic hyperplasia (BPH), nocturia, and chronic prostatitis / chronic pelvic pain syndrome.

The compound we expect to drive our growth most is mirabegron. Together with Vesicare, another OAB treatment, we are aiming for sales of at least ¥155.0 billion in the year ending March 31, 2015.

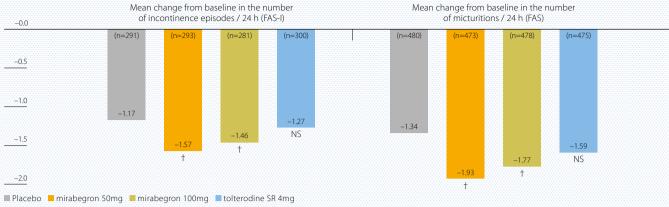
In July 2011, Astellas received manufacturing and marketing approval for mirabegron in Japan for the indication of urgency, urinary frequency, and urge urinary incontinence associated with OAB. We filed for regulatory approval of this drug in Europe and the US in August 2011 for the same indication. A Phase 3 clinical trial is nearing completion in Asia.

A novel OAB treatment, mirabegron, is a global first-in-class beta3 adrenergic receptor agonist. It selectively stimulates the beta3 adrenoceptors in bladder smooth muscle to relax the bladder. The resulting boost to the bladder's functional storage capacity helps to improve OAB symptoms such as urgency, urinary frequency, and urge urinary incontinence.

Anticholinergics such as Vesicare are the most common treatment for OAB at present. However, some patients do not respond sufficiently well to anticholinergics and side effects such as dry mouth affect continued administration by patients. Mirabegron offers a novel treatment option that could help to enhance quality of life for such patients.

The results of two pivotal Phase 3 clinical trials of mirabegron conducted in the US and Europe were presented at the European Association of Urology annual congress in March 2011. Both trials demonstrated significant efficacy and distinct tolerability for mirabegron that were administered for 12 weeks at doses of 50mg or 100mg once a day. Patients in the active treatment arms showed significant improvements over placebo in the incidence of the major OAB symptoms of incontinence and frequent urination. Across both studies, mirabegron also demonstrated good safety and tolerability, with the same level of incidence of adverse events in mirabegron and placebo.

#### Results of Phase 3 trial (Europe) Mean change from baseline\* in co-primary endpoints at Final Visit



\* Data are least squares mean adjusted for baseline, gender and geographical region; †Statistically significantly superior compared to placebo at the 0.05 level with multiplicity adjustment; FAS-I=all full analysis set patients who had at least one incontinence episode at baseline; NS=not statistically significant compared with placebo

Excerpt from poster presentation at a European Association of Urology meeting (March 21, 2011) (Presented by Dr. V Khullar, St Mary's Hospital, Imperial College, Urogynaecology Department)

# Transplantation, Immunology and Infectious Diseases

Astellas also has numerous ongoing drug development projects in the transplantation area.

One of these is ASKP1240, a compound in-licensed from Kyowa Hakko Kirin Co., Ltd. Clinical studies are in Phase 2 in the US and Phase 1 in Japan, with a target indication of prevention of organ transplant rejection. An oral small molecule immunosuppressant, ASP015K, is also being developed for the same indication. Clinical studies for ASP015K are in Phase 2 in the US and Phase 1 in Japan. Both molecules are positioned as potential successors to Prograf.

Diannexin is a protein in-licensed from Alavita Pharmaceuticals, Inc. in October 2010 that is under development for the target indication of preventing delayed graft function (DGF) in kidney

	Organ rejection suppression in transplantation
ASKP1240 F	22 (US), P1 (JP)
Antibody—Fi	ully human antibody CD40 antagonistic monoclonal antibody
ASP015K P2	2 (US), P1 (JP)
Low-molecul	e—Immunosuppressant
Preve	ntion of delayed graft function in kidney transplantation
Diannexin F	22 (US)
Protein—Inhi	bits monocyte and platelet binding to Phosphatidylserine
	Rheumatoid arthritis
ASP2408 P1	
Protein—CTL	A4-lgG protein

#### Transplant and Immunology Pipeline\*

transplantation. It is believed that there are large unmet medical needs for preventing DGF, because it is associated with a higher incidence of organ rejection and graft loss after kidney transplantation, and no approved therapy is currently available. A Phase 2a study of diannexin has been completed in the US, and preparations are underway to advance to a Phase 2b study.

Astellas aims to contribute further to the transplantation community through the development of these new compounds.

In the field of immunology, ASP2408 is currently in Phase 1 development for the target indication of rheumatoid arthritis.

Our pipeline also contains several compounds for infectious diseases, including telavancin and fidaxomicin.

#### **Infectious Disease Pipeline\***

Co	mplicated skin and soft tissue infections
Telavancin Filed (	EU)
	Hospital-acquired pneumonia
Telavancin Filed (	US, EU)
	MRSA infections
Telavancin P1 (JP	)
	Clostridium difficile infection
Fidaxomicin Filed	I (EU)
	Invasive aspergillosis
Isavuconazole P3	(US, EU)
	Candidemia / invasive candidiasis
Isavuconazole P3	(US, EU)
	Influenza prevention
ASP7373 P2 (JP)	Prophylaxis of H5N1 influenza
ASP7374 P2 (JP)	Prophylaxis of seasonal influenza
	activation in hematopoietic stem cell transplant recipients
ASP0113 TransVa	x P3 (US, EU)
Cytomegalovirus in	fection or reactivation in solid organ transplant recipients
ASP0113 TransVa	x P2 (US, EU)

\* As of August 1, 2011

### Oncology

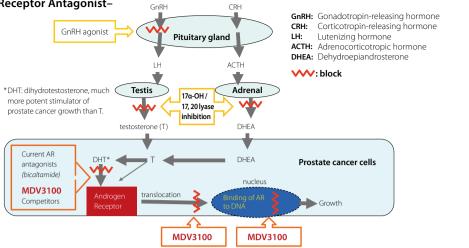
#### Oncology Pipeline (As of August 1, 2011)

	Project / Product Name	Target cancer	Characteristics	Phase 1	Phase 2	Phase 3	Filed	Region
	MDV3100	Prostate cancer	Second-generation androgen receptor antagonist					Europe, US, Japan, Asia
	tivozanib	Renal cell carcinoma, Breast cancer, Colorectal cancer	Triple VEGF receptors inhibitor	Renal cell	carcinom	a		Europe, US
				Other				
	AC220	Acute myeloid leukemia	Potent and highly selective second- generation FLT3 kinase inhibitor					Europe, US
Small	ASP3550			One-mon	th formula	ation		Japan
molecule	degarelix	Prostate cancer	First GnRH antagonist in Japan	Three-mo	nth formu	lation		Japan
	YM155	Breast cancer, Non-Hodgkin's lymphoma	A "First-in-class" survivin suppressant					Europe, US, Japan
	ASP1707	Prostate cancer, endometriosis						
	ASP3026	Cancer	Anaplastic lymphoma kinase (ALK) tyrosine inhibitor					
	ASP9521	Prostate cancer						
	Tarceva additional indication	Non-small cell lung cancer (NSCLC) (First line for patients with EGFR mutation, adjuvant), Hepatocellular carcinoma	HER1 / EGFR tyrosine kinase inhibitor					US
OSI	OSI-906	Adrenocortical carcinoma, ovarian cancer,	IGF-1R / IR tyrosine kinase inhibitor	Adrenoco	rtical carc	inoma		US
	031-900	NSCLC, hepatocellular carcinoma	IGP-IR7 IR tyrosine kinase inhibitor	Oth	ner			US
	OSI-027	Renal cell cancer	mTOR kinase inhibitor					US
	AGS-1C4D4	Pancreatic cancer	Novel antibody target (Prostate stem cell antigen)					Europe, US
A	AGS-16M8F	Renal cancer	Antibody utilizing ADC technology					
Antibody	ASG-5ME	Prostate cancer, pancreatic cancer	Antibody utilizing ADC technology					
-	AGS-22M6E	AGS-22M6E Solid tumor Antibody utilizing ADC technolo						

Astellas' oncology pipeline has expanded rapidly in recent years. It currently includes 15 projects at various stages of clinical development, including small molecules and antibodies. We filed an NDA for a one-month formulation of Degarelix (ASP3550) in Japan in October 2010 for the indication of prostate cancer. Our other anticancer agents in late-stage development include MDV3100 and tivozanib. The acquisition of OSI in June 2010 augmented our oncology drug pipeline significantly, adding three small molecules including Tarceva (now under development for additional indications) and OSI-906. Development of antibody drugs is also progressing steadily. Favorable Phase 2 clinical results were obtained for AGS-1C4D4, and we have a further three antibody drugs in clinical development based on antibody-drug conjugate (ADC) technology. MDV3100 is a compound that was in-licensed from Medivation, Inc. in October 2009. The first target indication is advanced prostate cancer, a condition where current therapeutic options are limited. We are conducting studies to support the use of MDV3100 in treating patients during the earlier stages of prostate cancer to help expand the indications for the drug. Phase 3 trials are underway worldwide, including the study in post-chemotherapy patients with advanced prostate cancer.

MDV3100 is a second-generation androgen receptor antagonist. It slows the growth and induces the cell death in prostate cancer via three complementary actions.

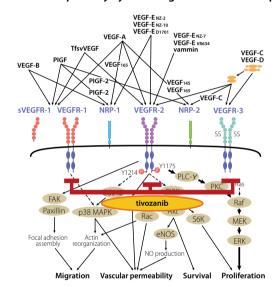
#### MDV3100: Mechanism of Action -Triple-acting Oral Androgen Receptor Antagonist-



In-licensed from AVEO Pharmaceuticals, Inc. in February 2011, tivozanib is currently in global Phase 3 clinical development for advanced renal cell carcinoma. Phase 1 studies are also underway for the treatment of breast cancer and colorectal cancer.

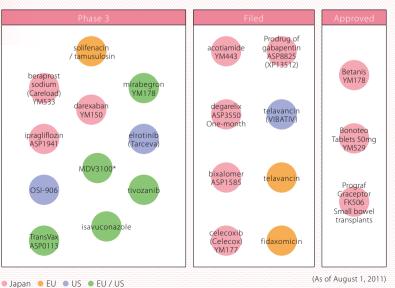
Tivozanib is an inhibitor for vascular endothelial growth factor (VEGF) receptor. VEGF is known to play an important role in the formation of new blood vessels, which is critical in cancer cell growth. Tivozanib helps to block this pathway through the selective and potent inhibition of all three VEGF receptor subtypes. This mechanism of action is expected to lead to high efficacy coupled with a lower incidence of off-target side effects.

Tivozanib: Mechanism of Action -Block the VEGF pathway by inhibiting all three VEGF receptors-



#### **Other Areas**

Astellas submitted six NDAs for Japanese regulatory approval during the year ended March 2011, including for mirabegron (YM178) and degarelix (ASP3550). In September 2010, our co-development partner Zeria Pharmaceutical Co., Ltd. submitted an NDA for acotiamide (YM443), a treatment for functional dyspepsia. In the same month, we also submitted an NDA for minodronate (YM529), an osteoporosis treatment that is administered once per four weeks. Manufacturing and marketing approval was received for this product in July 2011. In addition, NDAs were submitted in March 2011 for Bixalomer (ASP1585), a treatment for hyperphosphatemia, and for celecoxib (YM177) for the additional indication of treating post-operation, post-trauma, and post-tooth extraction pain and inflammation.



\* MDV3100: EU / US / JP

# **Pipeline List (All)**

(As of August 1, 2011)

Pipeline development at Astellas mainly targets therapeutic fields such as transplantation, infectious diseases, urology and cancer where there is a high degree of unmet medical needs and few effective treatments.

#### Approved

Code No. [Generic Name]	Product Name (Approval Date)	Classification	Therapeutic Target	Area	Dosage Form	Origin	Remarks
YM178 [mirabegron]	Betanis (Jul. 2011)	Beta 3 receptor agonist	Urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder	Japan	Oral	In-house	
YM529 [minodronic acid]	Bonoteo Tablets 50 mg (Jul. 2011)	Bisphosphonate	Osteoporosis (Once per four weeks)	Japan	Oral	In-house (co- development with Ono)	New formulation
FK506 [tacrolimus]	Prograf Graceptor (Jul. 2011)	lmmunosuppressant	Prophylaxis of organ rejection in patients receiving allogenic small bowel transplants	Japan	Oral Injection	In-house	New indication

#### **Global Development**

Code No. [Generic Name]	Classification	Therapeutic Target	Phase 1	Phase 2	Phase 3	Filed	Area	Dosage Form	Origin	Remarks
		Complicated skin and soft tissue infections				(Oct. 2009)	Europe			
[telavancin]	Lipoglycopeptide	Nosocomial pneumonia				(Jan. 2009)	US*1	Injection	Theravance	
[telavaliciii]	antibiótic					(Oct. 2009)	Europe*2	injection		
		MRSA infections					Japan			
YM178	Beta 3 receptor agonist	Urinary frequency, urinary inconti- nence or urgency associated with overactive bladder					US	Oral	In-house	
[mirabegron]		overactive bladder					Europe			
							Japan / Asia			
	Factor Xa inhibitor	Prevention of venous thromboembolism after major orthopedic surgery					Europe		In-house	
YM150							US	Oral		
[darexaban]		Prophylaxis of thromboembolic complications associated with atrial fibrillation					Europe			
							Japan / Asia			
		Acute coronary syndrome					Europe			
EC905 [solifenacin / tamsulosin]	Concomitant use of solifenacin and tamsulosin	Lower urinary tract symptoms associated with benign prostatic hyperplasia					Europe	Oral	In-house	
							US			
MDV3100	Androgen antagonist	Prostate cancer					Europe	Oral	Medivation	
							Japan			
							Asia			
							Japan			
ASP1941 [ipragliflozin]	SGLT2 inhibitor	Type 2 diabetes					US	Oral	In-house (co- development with Kotobuki)	
							Europe			

\*1 Received a Complete Response letter from the FDA in November 2009, and the second Complete Response letter in December 2010.

\*2 Received positive opinion from the CHMP in May 2011.

Code No. [Generic Name]	Classification	Therapeutic Target	Phase 1	Phase 2	Phase 3	Filed	Area	Dosage Form	Origin	Remarks
[isavuconazole]	Azole antifungal	Invasive aspergillosis Candidemia / Invasive candidiasis					US / Europe	Injection Oral	Basilea	
[erlotinib] (Tarceva)	HER1 / EGFR tyrosine kinase inhibitor	Non-small cell lung cancer (First line for patients with EGFR muta- tion, adjuvant), Hepatocellular carcinoma					US	Oral	In-house (OSI)	New indication
OSI-906	IGF-1R/IR tyrosine kinase inhibitor	Adrenocortical carcinoma					US US	Oral	In-house (OSI)	
[tivozanib]	Triple VEGF receptors	lung cancer, Hepatocellular carcinoma Renal cell carcinoma					US / Europe	Oral		
[tivozanib]	inhibitor	Breast cancer, Colorectal cancer					US / Europe		AVEO	
ASP0113 TRANSVAX	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic stem cell transplant recipients					US / Europe	· Injection	Vical	
		Cytomegalovirus infection or reactivation in solid organ transplant recipients					US / Europe			
		Breast cancer, Non-Hodgkin's					US			
YM155	Survivin suppressant	lymphoma					Europe Japan	Injection	n In-house	
AC220	FLT3 kinase inhibitor	Acute myeloid leukemia					US Europe	Oral	Ambit	
ASP1517 (FG-4592)	HIF stabilizer	Renal anemia					Europe Japan	Oral	FibroGen	
YM311 (FG-2216)	HIF stabilizer	Renal anemia					Europe Japan	Oral	FibroGen	
AGS-1C4D4	Antibody (Prostate stem cell antigen)	Pancreatic cancer					US / Europe	Injection	In-house (Agensys)	
ASP015K	Immunosuppressant	Prevention of organ transplant rejection					US Japan	Oral	In-house	
ASKP1240	Anti-CD40 antagonist	Prevention of organ transplant rejection					US Japan	Injection	Kyowa Hakko Kirin	
OSI-027	mTOR kinase inhibitor	Renal cell cancer					US	Oral	In-house (OSI)	
PSN821	GPR119 agonist	Type 2 diabetes, Obesity					Europe	Oral	In-house (OSI)	
YM905 [solifenacin]	Muscarine M₃ receptor antagonist	Neurogenic detrusor overactivity and idiopathic overactive bladder in pediatric patients					US / Europe	Oral	In-house	New indication
ASP8597 [diannexin]	Inhibition of monocyte and platelet binding to phosphatidylserine	Prevention of delayed graft func- tion in kidney transplantation					US	Injection	Alavita	
EB178 [solifenacin / mirabegron]	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary inconti- nence or urgency associated with overactive bladder					Europe	Oral	In-house	
ASP3652	Inhibition of afferent nerve activity	Chronic prostatitis / Chronic pelvic pain syndrome					Europe Japan	Oral	In-house	

#### Local Development: Japan

Code No. [Generic Name]	Classification	Therapeutic Target	Phase 1	Phase 2	Phase 3	Filed	Area	Dosage Form	Origin	Remarks
ASP8825 (XP13512)	Prodrug of gabapentin	Restless legs syndrome				(Nov. 2009)	Japan	Oral	XenoPort	
<b>YM443</b> [acotiamide]	Acetylcholine esterase inhibitor	Functional dyspepsia				(Sep. 2010)	Japan	Oral	Zeria	
ASP3550	GnRH receptor	Prostate cancer (One-month formulation)				(Oct. 2010)	Japan	Injection	Forring	
[degarelix]	antagonist	Prostate cancer (Three-month formulation)					Japan	Injection	Ferring	New formulation
ASP1585 (AMG223) [bixalomer]	Amine-functional phosphate-binding polymer	Hyperphosphatemia in patients with chronic kidney disease on dialysis				(Mar. 2011)	Japan	Oral	llypsa / Amgen	
YM177 [celecoxib]	Cyclooxygenase-ll inhibitor	Anti-inflammatory and analgesic effects in post-operation, post-trauma, and post-tooth extraction				(Mar. 2011)	Japan	Oral	Pfizer	New indication
YM533 [beraprost sodium]	Prostacyclin receptor stimulator	Chronic renal failure (primary, nephrosclerosis)					Japan / Asia	Oral	Toray	New indication New formulation
YM060	5-HT3 receptor	Irritable bowel syndrome Female patients					Japan	Oral	In-house	New indication
[ramosetron]	antagonist	Irritable bowel syndrome (Orally-disintegrating tablet)		Bio-equiv	alent study	/	Japan	Ula	m-nouse	New formulation
ASP7373	Influenza vaccine	Prophylaxis of H5N1 influenza					Japan	Injection	UMN Pharma	
ASP7374	Influenza vaccine	Prophylaxis of seasonal influenza					Japan	Injection	UMN Pharma	

#### Local Development: Europe

Code No. [Generic Name]	Classification	Therapeutic Target	Phase 1	Phase 2	Phase 3	Filed	Area	Dosage Form	Origin	Remarks
[fidaxomicin]	Macrocyclic antibiotic	Clostridium difficile infection				(Jul. 2010)	Europe	Oral	Optimer	

#### Phase 1

Code No. [Generic Name]	Therapeutic Target	Dosage Form	Origin
AGS-16M8F	Cancer (ADC)	Injection	In-house (Agensys)
ASG-5ME	Cancer (ADC)	Injection	In-house (Agensys) (co-development with Seattle Genetics)
ASP7035	Nocturia	Oral	In-house
ASP0777	Alzheimer's disease [Dementia]	Oral	In-house
ASP3291	Ulcerative colitis	Oral	In-house
FK949E [quetiapine]	Major depressive disorder	Oral	AstraZeneca
ASP4178	Type 2 diabetes	Oral	In-house
ASP5034	Type 2 diabetes	Oral	In-house
ASP1707	Prostate cancer, Endometriosis	Oral	In-house
ASP0306	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Oral	In-house

Code No. [Generic Name]	Therapeutic Target	Dosage Form	Origin
ASP4058	Multiple sclerosis	Oral	In-house
ASP0456 [linaclotide]	Irritable bowel syndrome	Oral	Ironwood
ASP4901 (AKP-002)	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Oral	ASKA
ASP8477	Neuropathic pain	Oral	In-house
ASP2408	Rheumatoid arthritis	Injection	In-house (Perseid)
ASP3026	Cancer	Oral	In-house
ASP9521	Prostate cancer	Oral	In-house
AGS-22M6E	Cancer (ADC)	Injection	In-house (Agensys) (co-development with Seattle Genetics)
ASP7147	Irritable bowel syndrome	Oral	In-house

#### Pipeline by Therapeutic Area

	Filed	Phase 3	Phase 2	Phase 1
Urology		mirabegron (OAB, E / US) solifenacin / tamusulosin (E)	YM905 (Pediatric, E / US) solifenacin / mirabegron (E) ASP3652 (E)	ASP7035 ASP0306 ASP4901 (AKP-002) ASP3652 (J)
Transplantation Immunology Infectious diseases	telavancin (cSSTI / NP, E) telavancin (NP, US) fidaxomicin (CDI, E)	isavuconazole (Aspergillosis, candidemia, E / US) TransVax (HSCT, US / E)	ASP015K (Transplant, US) ASKP1240 (Transplant, US) diannexin (Transplant, US) ASP7373 (Influenza, J) ASP7374 (Influenza, J) TransVax (SOT, US / E)	ASP015K (J) ASKP1240 (J) ASP2408 ASP3291 ASP4058 telavancin (J)
Oncology	ASP3550 (One-month, J)	MDV3100 (E / US / J / A) elrotinib (US) OSI-906 (Adrenocortical, US) tivozanib (RCC, E / US)	OSI-906 (Ovarian etc, US) YM155 (E / US) AC220 (E / US) AGS-1C4D4 (E / US) OSI-027 (US) ASP3550 (Three-month, J)	MDV3100 (J) YM155 (J) AGS-16M8F ASG-5ME ASP1707 ASP3026 ASP9521 AGS-22M6E tivozanib (Breast, etc.)
Neuroscience	ASP8825 (Restless legs syndrome, J)			ASP0777 FK949E ASP8477
DM Complications & Metabolic diseases		ASP1941 (DM, J)	ASP1941 (DM, E / US) PSN821 (DM, Obesity, E)	ASP4178 ASP5034
Others	YM443 (FD, J) ASP1585 (Hyperphosphatemia, J) YM177 (Acute pain, J)	YM150 (VTE, J / A) YM533 (Chronic renal failure, J / A)	YM150 (VTE: E / US, AF: E / J / A, ACS: E) ASP1517 (E) YM311 (E) YM060 (Female, J) YM060 (OD, J)	ASP1517 (J) YM311 (J) ASP0456 ASP7147

In-house, new molecular entity In-house, additional indication or additional formulation Licensed-in OAB: Overactive bladder

cSSTI: Complicated skin and soft tissue infections

NP: Nosocomial pneumonia CDI: Clostridium difficile infection

HSCT: Hematopoietic stem cell transplant

SOT: Solid organ transplant FD: Functional dyspepsia VTE: Venous thromboembolism

AF: Atrial fibrillation

ACS: Acute coronary syndrome

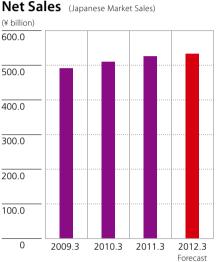
OD: Orally-disintegrating

### **Review of Global Operations**



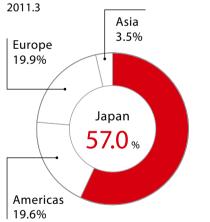
#### Core Objective:

# Achieve the No. 1 market share in Japan during MTP14 (fiscal 2010 to fiscal 2014)



#### Note: Invoiced prices base

#### Sales by Geographical Area



Note: Yen base Calculated according to the location of sellers

#### Fiscal 2010 Overview

Net sales in the Japanese prescription drugs market in the year ended March 2011 increased 3.1% year on year to ¥525.6 billion. Higher sales of mainstay products and new products more than offset the impact of the April 2010 NHI drug price cuts, resulting in increased net sales compared with the previous year.

Mainstay products making a solid contribution to growth included the global drugs Prograf and Vesicare, together with Myslee and Seroquel. Micardis and its combination drugs Micombi and Micamlo (launched in October 2010) increased sales. Recently launched products such as Symbicort and Celecox generated substantially higher sales, making a major contribution to growth.

The March 2011 Great East Japan Earthquake prompted a temporary surge in distribution inventories, which boosted sales revenue by approximately ¥5.0 billion.

#### **Sales of Major Products**

						(¥ billion)
		2010.3	2	011.3		012.3 recasts)
Prescription drugs sales in Japanese market		509.8	↗	525.6	7	533.0
Hypercholesterolemia treatment	Lipitor	99.9	И	97.2	2	92.7
Hypertension treatment (Long-acting angiotensin II receptor blocker)	Micardis	71.6	7	75.8	20 (For           .6         7           .2         1           .3         7           .6         7           .7         1           .6         7           .7         7           .6         7           .7         7           .6         7           .7         7           .6         1           .7         7           .7         7           .9         7	81.4
	Micombi	1.6	↗	6.1		-
	Micamlo (launched in October 2010)	-		2.3		-
Treatment for peptic ulcers and gastritis	Gaster	49.9	И	41.7	Ы	36.8
Immunosuppressant	Prograf	33.8	7	39.6	7	44.5
Insomnia treatment	Myslee	29.1	7	32.7	7	34.2
Treatment for the functional symptoms associated with benign prostatic hyperplasia (BPH)	Harnal	35.0	Я	29.6	Ы	27.1
Schizophrenia treatment	Seroquel	23.6	7	26.4	7	27.9
Overactive bladder (OAB) treatment	Vesicare	22.9	7	25.5	7	27.2
Anti-inflammatory agent (Selective COX-2 inhibitor)	Celecox	17.8	7	25.1	7	30.9
Vaccine		25.2	И	18.7	7	19.7
Candin-type injectable antifungal agent	Funguard	11.8	7	12.6	Ы	12.4
Treatment for adult bronchial asthma	Symbicort	1.5	7	11.9	7	24.3
Oral quinolone antibiotic	Geninax	8.1	7	10.2	7	12.0
Treatment for osteoporosis	Bonoteo	1.0	7	2.4	7	5.1
Treatment for diarrhea-predominant irritable bowel syndrome	Irribow	0.2	7	1.6	7	2.0

Note: Invoiced prices base.

#### Strengths:

- One of the biggest and best teams of MRs: approx. 2,400
- Rich product lineup (Therapeutic areas and product numbers)
- Solid sales force structure and support system
- Successful experience in marketing alliances

#### Fiscal 2011 Outlook

Share in the Japanese Prescription Drugs Market (Year ended March 2011)

6.97%

(¥ billion)

Celecox

No. 2 share in Japan Copyright 2011 IMS Japan K.K. Source: JPM Reprinted with permission Net sales in the Japanese prescription drugs market in the year ending March 2012 are projected to rise 1.4% year on year to ¥533.0 billion. In addition to Vesicare and Prograf, mainstay products such as Micardis (including Micombi and Micamlo) and Myslee are expected to grow, and recently launched products such as Symbicort, Celecox, Bonoteo and Geninax are expected to see more sales growth.

#### Further Growth on the Back of a Robust Sales and Marketing Platform

Astellas' performance in the Japanese market is underpinned by one of the largest teams of quality MRs and solid promotional and support systems capable of expanding sales across a major portfolio of products at the same time; and a rich lineup of products that covers a range of therapeutic areas. Making full use of this robust sales and marketing platform, Astellas aims to increase sales of both mainstay products and new drugs. Astellas' aim is to achieve the No. 1 market share in Japan during MTP14, which runs until March 2015.

#### Sales of Growth-driving New Products

35.0 30.0 25.0 20.0 15.0 10.0 5.0 0 2009 3 2010.3 2011.3 2012.3 Forecast Bonoteo 📒 Geninax Symbicort

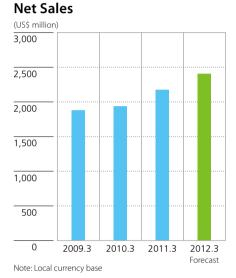
#### **Continuous Product Launches in the Japanese Market** -New Products and New Drug Candidates-

Product name	Indications, etc.
Micamlo Combination Tablets AP (Launched October 2010)	Combination drug of Micardis and amlodipine besylate
Vesicare OD Tablets (Launched April 2011)	Orally disintegrating tablet
Betanis Tablets (Approved July 2011)	Urgency, urinary frequency, and urge urinary incontinence associated with overactive bladder
Bonoteo Tablets 50mg (Approved July 2011)	Once per four weeks
Filed	
Code No.	Indications, etc.
ASP8825 (XP13512)	Restless legs syndrome
YM443	Functional dyspepsia
ASP3550	Prostate cancer (one month formulation)
ASP1585 (AMG223)	Hyperphosphatemia in patients with chronic kidney disease on dialysis
YM177	Anti-inflammatory and analgesic effects in post-operation, post- trauma, and post-tooth extraction

# Americas

#### Core Objective:

# Improve and bolster existing business platform for future growth



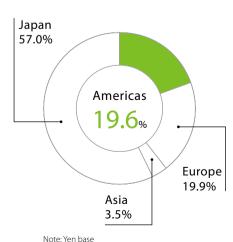
#### Fiscal 2010 Overview

Regional net sales increased 3.7% in yearon-year terms to ¥186.5 billion in the year ended March 2011. In local currency terms, sales rose by 12.4% to US\$2,176 million.

By product, sales of global product Prograf declined, reflecting the first fullyear impact of generic tacrolimus products, which were launched in August 2009. Generic product market share averaged approximately 49% on a total prescription basis in the tacrolimus market, which includes Prograf. On the other hand, VESIcare sales increased despite a sluggish OAB treatment market, boosting its market share to over 20% on a total prescription basis. Furthermore, growing products such as Mycamine and Lexiscan, which are marketed locally, yielded a steady increase in sales.

Sales related to OSI, including Tarcevarelated revenues, due to the acquisition of OSI in June 2010, also contributed to higher net sales.

# Sales by Geographical Area 2011.3



Calculated according to the location of sellers

#### **Sales of Major Products**

-					(U	S\$ million
		2010.3	2011.3		2012.3 (Forecasts)	
Sales in the Americas		1,936	7	2,176	7	2,408
Immunosuppressant	Prograf	734	И	478	И	429
Pharmacologic stress agent	Scan (Adenoscan and Lexiscan)	495	7	559	7	571
	Lexiscan	326	7	455		-
Antifungal agent	AmBisome	67	7	73	Ы	70
Treatment for atopic dermatitis	Protopic	78	7	83	7	85
Overactive bladder treatment	VESIcare	378	7	418	7	491
Candin-type antifungal agent	Mycamine	81	7	98	7	106
Hyponatremia treatment	Vaprisol	10	Ы	8	7	10
Treatment for psoriasis	Amevive	13	Ы	10	И	7
Antibiotic	VIBATIV	4	7	9		-
Anticancer	Tarceva	-		285		-
	US	-	[	165		-
	Outside of the US	-	[	120	[	-
DPP4 Royalties		-	[	80		-

#### Strengths:

US:

Focus on specialized therapeutic areas such as urology, transplantation, cardiovascular and infectious diseases for hospitals, oncology, dermatology and neuroscience / Slim, efficient and flexible organization

Canada: Solid sales platform centered on in-house products

Latin America: ) Sales affiliate in Brazil and business network in Latin America

#### Fiscal 2011 Outlook



**VESIcare Share** 

(Total prescription basis. No. 1 branded drug)

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(Volume basis share) Source: AMR data

Mycamine

VESIcare

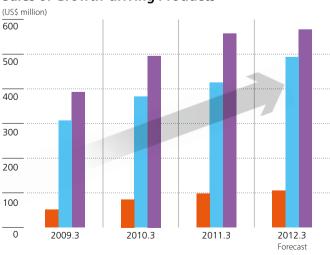
Scan

Astellas is projecting regional net sales of US\$2,408 million for the year ending March 2012, a 10.7% increase year over year. Sales are forecast to grow in fiscal 2011 due to steady expansion in sales of VESIcare and Mycamine, together with a full-year sales contribution from OSI. Sales of Prograf are expected to continue to decline primarily as a result of generic pressure.

#### Strengthen Business Platform Based on a Highly Effective Organization

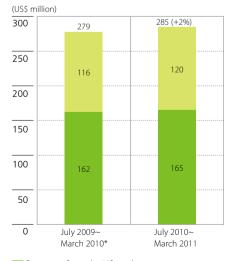
In the Americas, Astellas is focused on leveraging and improving the existing business platform for future growth. We will endeavor to maintain our leadership in the area of transplantation, while ensuring continued growth in the area of urology. In addition, the acquisition of OSI provided Astellas with a fully integrated oncology platform to enter this therapy area.

In terms of strengths by region, Astellas has established a highly effective organization in the US and also boasts a first-rate sales force. The organization is focused on specialized therapeutic areas such as urology, transplantation, and cardiovascular and infectious diseases in hospitals. In Canada, Astellas has established a solid sales platform centered on in-house products. In Latin America, Astellas is developing sales through a network of distribution partners, and also has a sales affiliate in Brazil. Reflecting the major market growth potential of Brazil, Astellas is targeting the rapid establishment of a business platform in that country by the introduction of in-house products. Harnal (Omnic), Protopic and Mycamine are already available in Brazil.



#### Sales of Growth-driving Products





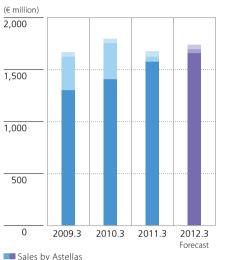
Revenues from the US market Revenues from outside of the US market \* Referred from the disclosure of OSI

# Europe

#### Core Objective:

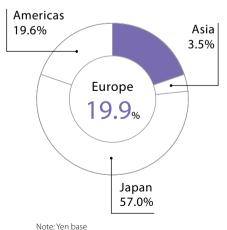
# Strengthen the business platform for continuous growth

#### Net Sales



Sales by Astellas
 Bulk and royalties
 Exports to third parties
 Note: Local currency base

# Sales by Geographical Area 2011.3



Calculated according to the location of sellers

#### Fiscal 2010 Overview

Regional net sales declined 19.5% in yearon-year terms to ¥189.9 billion in the year ended March 2011. In local currency terms, sales decreased 6.7% to €1,678 million. Excluding exports to third parties of Prograf and Harnal bulk sales and royalty income, sales (in euro terms) through Astellas' own distribution channels rose 12.1% in year-on-year terms.

By product, sales of global products Vesicare and Mycamine were higher than in fiscal 2009. Eligard, which is marketed in Europe by Astellas, also posted strong sales growth. Sales of Harnal through our own distribution channel were in a solid trend, but the launch of generic versions in the US in March 2010 resulted in a substantial decline in bulk sales and royalty income from licensees, recorded in Europe. Prograf sales (including Advagraf) increased in local currency terms due to the contribution of once-a-day formulation Advagraf and only a minimal impact from generic products following substance patent expiration.

#### Sales of Major Products

						(€ million
		2010.3		2011.3		012.3 recasts)
Sales in Europe		1,798	И	1,678	7	1,739
Treatment for the functional symptoms associated with benign prostatic hyperplasia	Harnal (Omnic, Omnic OCAS, Flomax)	533	Ы	237	Ы	213
	Sales by Astellas	185	7	190	И	178
	Bulk and Royalties	348	Ы	46	И	35
Immunosuppressant	Prograf and Advagraf (Incl. exports to third parties)	545	7	592	Ы	554
Overactive bladder treatment	Vesicare	175	7	208	7	246
Treatment for atopic dermatitis	Protopic	42	7	46	7	48
Candin-type antifungal agent	Mycamine	9	7	21	7	31
Advanced prostate cancer treatment	Eligard	107	7	122	7	129
Peripheral neuropathic pain treatment	Qutenza	-		1		-

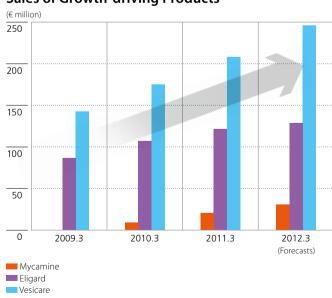
#### Strengths:

- Agile and lean organization
- Extensive geographic coverage
- Success in emerging markets

# Share of Sales\*<sup>1</sup> in EU5\*<sup>2</sup> and Non-EU5 in Europe (Ver ended March 2011) EU5: Fiscal 2005 $63\% \Rightarrow 51\%$ Non-EU5: Fiscal 2005

37<sub>%</sub> **⇒** 49<sub>%</sub>

- \*1 Excludes Harnal bulk sales and royalty income, and exports to third parties of Prograf
- \*2 Germany, Spain, France, Italy and United Kingdom

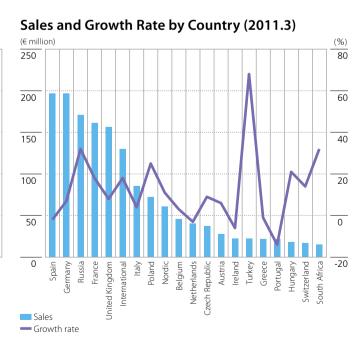


#### Fiscal 2011 Outlook

Astellas is projecting a 3.6% year-on-year increase in regional net sales to €1,739 million. Sales are forecasted to increase in fiscal 2011 in year-on-year terms due to higher sales of Vesicare, Mycamine and Eligard. Other anticipated growth drivers include royalty income from the anticancer agent bendamustine. Sales of Prograf and Harnal are expected to be lower than in fiscal 2010.

#### Further Expand Business Platform in Growing Regions

Astellas has developed a broad and solid business platform. Looking ahead, Astellas will focus on expanding business in emerging markets such as CIS countries and Southeast Europe in addition to Russia, which is already growing strongly. In December 2010, Astellas established a sales subsidiary in the Republic of Slovenia to coordinate future expansion within Southeast Europe. Astellas now has 21 sales subsidiaries in Europe, the Middle East and Africa, including newly established subsidiaries, which cover about 40 countries and regions.



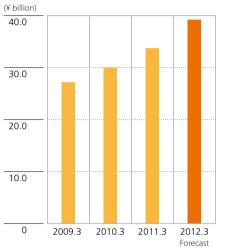
#### Sales of Growth-driving Products

# Asia & Oceania

#### Core Objective

# Realize high growth by expanding sales in each country

#### Net Sales



#### Fiscal 2010 Overview

Net sales in Asia grew 12.5% to ¥33.7 billion compared with the previous year. In China, which accounts for a large share of regional net sales, sales continued to grow at more than 20% from the previous year in local currency terms.

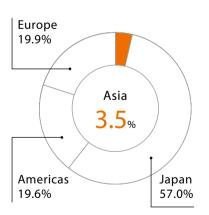
By product, sales of Prograf continued to grow steadily. Harnal posted higher sales, while Vesicare and Mycamine generated steady growth.

Notable launches in the region in fiscal 2010 included those of Advagraf in China,

Irribow in South Korea, Harnal OCAS and Vesicare in Vietnam, and Prograf XL tablets (once-daily formulation) in Australia. Astellas filed applications in various countries for regulatory approval of numerous products across the region, including Vesicare in India.

Astellas established a sales subsidiary in Australia in December 2010 to facilitate the expansion of its own sales distribution channel in Asia and Oceania.

# Sales by Geographical Area 2011.3



#### **Sales of Major Products**

-						(¥ billion
		2010.3		2011.3		012.3 recasts)
Sales in Asia & Oceania		30.0	7	33.7	7	39.2
Immunosuppressant	Prograf	12.8	7	14.8	7	15.5
Treatment for the functional symptoms associated with benign prostatic hyperplasia	Harnal	8.6	7	9.2	7	10.3
Overactive bladder treatment	Vesicare	1.0	7	1.4	7	2.5
Candin-type antifungal agent	Mycamine	1.0	7	1.6	7	3.0
Treatment for atopic dermatitis	Protopic	0.7	7	0.9	7	1.9

Note: Yen base Calculated according to the location of sellers

#### Strengths:

**China: Sales Growth Rate** 

0/0

China: Share in the Asia Sales

of Astellas

Approx.

(Year ended March 2011)

(Year ended March 2011, local currency basis)

- Expansion of sales network by own affiliates
- Business platform supporting a high growth rate
- Long track record and strong business platform in China

#### Fiscal 2011 Outlook

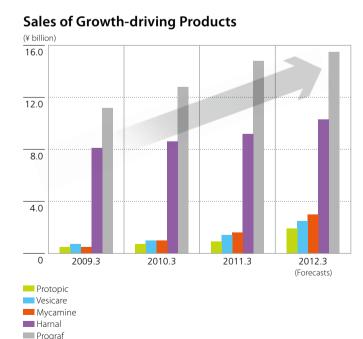
Astellas is projecting net sales of ¥39.2 billion, up 16.2% from the year ended March 2011. Prograf, Vesicare and Mycamine are expected to continue to drive sales growth in fiscal 2011, with product launches across the region expected to contribute to higher sales.

#### Broad-Based Proprietary Sales Distribution Channel to Support Major Growth Phase

Astellas is developing its own sales distribution channel that covers most major markets in Asia & Oceania. After entering China in 1994, Astellas has since established sales subsidiaries in Hong Kong, Taiwan, South Korea, Indonesia, Thailand, the Philippines, India and Australia. Astellas aims to build a highly profitable regional operation, led by in-house products in the therapeutic areas of transplantation and urology, based on an accurate understanding of markets in each country.

In China, where it generates large sales, Astellas increased the number of sales bases from five to eight to better cover the whole country, and is hiring additional MRs. Astellas intends to place utmost focus on China as a major growth driver of the Asian regional business. By expanding sales of mainstay products with a stronger MR sales force, Astellas aims to at least double sales in the year ending March 2015, compared with the year ended March 2011.

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#### Recent Achievements in Asia (NDA Approval in Fiscal 2009 and 2010)



\*1 Product name: Tacrolimus sustained-release capsules

\*2 Product name: Prograf XL

\*3 Filed by licensees

\*4 Approved in April 2011

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

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

Astellas is aware that a single-minded focus on improving product development and business indicators is insufficient to garner the trust and confidence of stakeholders including customers, employees, the environment, society, and shareholders and to enhance enterprise value. These objectives can only be achieved through interaction with society and the environment and efforts that contribute to society's sustainable development.

We take steps to ensure that our Charter of Corporate Conduct, which lays the foundation for all of our corporate activities, is aligned closely with CSR concerns. Essential countermeasures are incorporated into the Company's activities in its efforts to fulfill its CSR. This enables Astellas to better interact with stakeholders with integrity.

\* A concept that considers a company as being an organic entity—a corporation with a personality—and that enhancement of this personality is a proper responsibility for us as members of society. Therefore, it is important to aspire to enhance the company's personality through honest relationships with stakeholders.

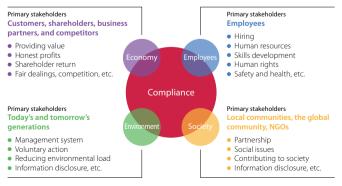
#### Positioning of CSR-Based Management



#### The Five Fields of CSR-Based Management

Astellas has defined five fields of CSR-based management—compliance, which the company sees as the foundation, as well as employees, society, the environment and the economy.

#### **The Five Fields**



In this section, we introduce specific activities in the fields of employees, society, the environment, and compliance.

Recognizing that employees are central to creating enterprise value, Astellas maintains a workplace environment that allows employees to fulfill their work, family and social responsibilities.

Astellas strives to enrich its human resources and works to provide human resource management, training and development as well as welfare and benefit systems that raise employee satisfaction. Furthermore, by respecting employees' individual rights and personalities we foster a safe, discrimination-free workplace environment. Through these means, we are endeavoring to remain an appealing and attractive company.

#### ▶ Work-Life Balance

Astellas believes that balancing both work and personal lives is important for the many diverse individuals working at the company to work with vigor and enthusiasm and fulfill their potential. The company has therefore introduced a work schedule system that acknowledges a variety of working styles, as well as systems that respond to major events in employees' lives, creating an environment where employees can concentrate on their work with a sense of security.

#### Promoting Opportunities for Women to Excel (Japan)

With the aim of assembling a diverse pool of human talent at Astellas, the company actively promotes diversity management. Astellas launched its diverse human resource initiatives by first considering the active roles of women in the workforce in Japan. Besides raising awareness among employees, managers and women themselves and encouraging new behavior, we are reforming frameworks such as the structure and operation of business processes, as we moved toward a structure able to take on a more diverse range of initiatives.

#### Employment of People with Disabilities

Astellas has established the Green Supply Support Office as a means of expanding employment opportunities for people with disabilities. This office has launched various businesses in this regard such as maintenance and management of greenery around the Tsukuba Research Center, recycling of discarded documents, and cultivation of flowers and seedlings.



# Society

# Committed to confronting society's wide-ranging problems head on, Astellas is promoting mutual prosperity as an integral member of society.

Astellas' stance toward society is defined under several core components of its Charter of Corporate Conduct. In specific terms, to disclose relevant corporate information in a timely and appropriate manner not only to stakeholders but also to all members of society at large, thereby fulfilling its obligations regarding corporate accountability; and as a good corporate citizen to actively engage in charitable and other activities to benefit society. The company commits itself in its CSR policy to incorporate society's needs and values as well as the issues that it faces into its corporate activities, and to propose ways of creating new added value for society.

#### Working to Resolve Global Issues

Supporting efforts to resolve issues that continue to challenge the international community such as those undertaken by the Millennium Development Goals (MDGs)\* are therefore a concern to Astellas as a global pharmaceutical business and responsible world citizen. As we aim to maximize the effects of these efforts, we are focusing our support on hygiene and medical-related aspects within our field in the provision of ethical drugs. Accordingly, Astellas has concentrated its commitment to the fourth, fifth and sixth MDGs, namely "reducing child mortality," "improving maternal health" and "combating HIV / AIDS, malaria and other diseases," respectively.

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

A l	Eradicate extreme poverty & hunger
	Achieve universal primary education
Q <sup>3</sup>	Promote gender equality and empower women
<b>*</b>	Reduce child mortality
Å.	Improve maternal health
•	Combat HIV / AIDS, malaria and other diseases
*	Ensure environmental sustainability
	Develop a global partnership for development

\* Millennium Development Goals are a series of eight time-bound targets with a deadline of 2015 drafted under the United Nations Millennium Declaration that was adopted in September 2000 and builds upon a decade of major United Nations conferences and summits.

#### Global Initiatives as a Corporate Citizen

Astellas celebrated the fifth anniversary of its foundation on April 1, 2010. In commemoration of this milestone, Astellas launched "Changing Tomorrow Day" as a common initiative for the entire Astellas Group, providing employees with opportunities to contribute to their local communities based on the themes of health and the environment.

In fiscal 2010, over 7,700 Astellas employees worldwide took part in volunteer activities during Changing Tomorrow Day. While benefitting local communities, Changing Tomorrow Day also proved to be a boon to volunteers by affording them the opportunity to learn first-hand about interaction and coexistence within their respective communities. While continuing to participate in these activities, Astellas looks forward to increasing its participation in each of the local communities where it operates with the confidence of preserving its good standing with society.



Japan Employees took part in a cleanup they planned on the Shiretoko seashore (Hokkaido)



Asia We distributed seedlings in Mumbai as a way of showcasing environmental conservation (India)



Europe Cooking classes were given at elementary schools based on the theme of "health." (England)



Americas Bagging of charity food for distribution (Chicago)

#### Environment

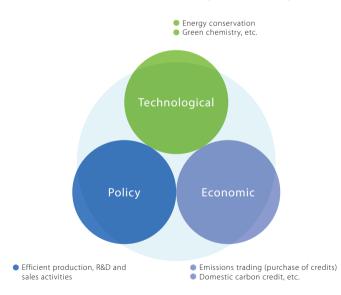
# Recognizing the environment as an important stakeholder, Astellas strives to resolve environmental issues to ensure the health of people everywhere.

Astellas understands the importance of the healthy environment as a building block to realize sustainable development. Fully recognizing the particularly undermining issues related to biodiversity and climate change, Astellas has set medium- to long-term targets that take into consideration the anticipated direction of the international community up to 2050. Additionally, Astellas is taking steps to ensure full compliance with laws and regulations in the prevention of environmental pollution on both a local and global scale.

#### Measures to Address Global Warming

In MTP14, Astellas has positioned combating global warming as an important theme. Astellas has formulated medium- and long-term action plans and investment plans for addressing this issue across the entire Astellas Group, while Astellas' Headquarters is leading the implementation of strategic measures. In addition to the technological measures such as the installation of energy-saving equipment, Astellas is looking at policy measures such as efficient production and research systems and economic means such as domestic carbon credit and other emissions trading.

#### Measures to Address Global Warming Considered by Astellas



#### Preserving Biodiversity

Astellas is working to lessen the impact of its business activities on ecosystems. In this way, the company will help maintain and preserve biodiversity as well as create a society that coexists with nature.

- We strive to lessen our overall environmental impact on biodiversity by working to prevent global warming, minimize environmental pollution and promote resource recycling.
- We are developing technologies that minimize the impact on the ecosystem, by lowering environmental burden and using as few natural resources as possible.
- We handle genetic resources in accordance with international rules and the rules of the host countries.
- We are broadening our efforts to preserve biodiversity with the aim of creating a sustainable society that coexists in harmony with nature. To this end, we promote discussion within society and among related parties, while reaching across national and geographical borders.
- We are grateful for the benefits obtained from a healthy ecosystem, and we are diligently fostering a corporate culture that will always act out of respect for biodiversity and in a manner that is harmonious with corporate activities.

Several challenges concerning biodiversity loss have been pointed, species and habitat degradation due to excessive human activity and development, ecosystem disturbances caused by the introduction of alien species and chemical contamination, and crisis caused by global warming. At Astellas, we have introduced biodiversity indexes for comprehensively evaluating the factors behind these issues in terms of three categories: environmental pollution, resource consumption and global warming. We have set standards to be achieved in the year ending March 2021. Using this index, we will quantitatively verify improvement in the impact of our business activities on the environment, and progress with measures to this end.

# TOPICS

# Search for Microorganisms Overseas in Accordance with Convention on Biological Diversity

In a joint industrial-government project with the National Institute of Technology and Evaluation (NITE), Astellas initiated a joint research project that searches for new microorganisms in Vietnam and puts them to industrial use centered on drug discovery. This collaborative project that Astellas will participate in is a framework for cooperative relationships that NITE created with the Vietnamese government in accordance with the Convention on Biological Diversity. We will jointly search, collect and isolate microorganisms in Vietnam and assess their potential for industrial use. This collaborative industrial-government research project, with the support of the Japanese government agency, provides access to biological genetic resources in Asia that would be too much of a burden for a single company to pursue after the Convention on Biological Diversity came into effect. It also ensures that the benefits from this access to genetic resources are distributed fairly and equitably.

# Compliance

Maintaining integrity and upholding the highest ethical standards represent the core of the Company's decision-making criteria and the essence of its corporate culture.

Astellas pledges to remain an organization that both embraces and practices the beliefs of its business philosophy to always manage its business with the highest sense of ethics. It is with this unwavering commitment that Astellas has positioned business ethics as much more than simply a single field within its CSR based management model. Without exception, business activities are therefore based on a broad understanding of compliance encompassing both strict observance of laws and regulations as well as the maintenance of high ethical standards.

#### Promoting Business Ethics

Taking into consideration its own unique set of circumstances and its understanding of societal issues at hand, Astellas remains constantly aware of the importance of strictly adhering to a code of business ethics. Our goal therefore is to instill a corporate culture in which each and every employee chooses to act in accordance with this code. Looking ahead, we will cultivate a workplace environment in which individual employees maintain high ethical standards when acting on their own initiative. At the same time, we will nurture a corporate culture of integrity grounded in an acute awareness of business ethics to serve as the basis for our business activities.

#### Our Ethical Principles

The "Astellas Business Ethics Policy" highlights the important values we share for maintaining high ethical standards. The policy is carefully observed by all Astellas employees worldwide.

#### Astellas Business Ethics Policy ~ Doing the right thing ~

Each of us as employees of Astellas will aspire to behave in accordance with the following ethical principles.

integrity	We will consistently do what is right.
respect	We will value each other as individuals, recognizing our diverse view- points and unique contributions.
responsibility	We will be accountable for our actions toward each other and the environment, reporting workplace concerns without fear of retribu- tion, and seeking clarification when in doubt.
fairness	We will conduct our business in an equitable manner and will make business decisions without bias.
transparency	We will conduct our business in an open and truthful manner with appropriate respect for confidentiality.

#### Business Ethics Promotion System

Chaired by the Chief Business Ethics Executive, the Business Ethics Committee has been established to enhance the Company's business ethics promotion system, and to better respond to individual issues. This Committee continues to deliberate on plans, making decisions on how best to increase awareness and understanding throughout the Group. Business Ethics promotion supervisors and Business Ethics promotion leaders have also been appointed to each division. In addition to clarifying the person responsible for business ethics in each division, efforts are being made to take tangible steps toward building a corporate culture of integrity.

#### **Business Ethics Promotion System**



#### Initiatives for Preventing Improper Act and Corruption including Bribery

Maintaining an acute and unwavering awareness of "Astellas Business Ethics Policy" serves to ensure equitable behavior while preventing improper act and corruption including bribery. In Japan, education and training emphasizes the need for individuals to discipline themselves through constant self reflection. In the United States and Europe, where legislative requirements are more austere, considerable weight is placed on training that aims to prevent any corruption and bribery. Astellas is considering introducing more globally focused training and a variety of appropriate initiatives in this field.

#### Product Liability

Ensuring the efficacy and safety of pharmaceuticals requires a system and methods that comply with laws and guidelines.

Our research, development, manufacturing, and other related departments set out specific procedures for complying with laws and guidelines. We are also building a structure that is capable of accumulating correct records while objectively evaluating the status of procedural compliance and data. Astellas recognizes that these steps and the evaluation of information pertaining to efficacy and safety as well as the provision of information to medical professionals to ensure correct pharmaceutical use are a vital component in securing trust and confidence.

At Astellas, functions for ensuring reliability from research and development through manufacturing to post-marketing study are centralized. We have, in other words, established a system to achieve objective reliability at all stages. We are working to ensure the efficacy, safety, and reliability of our pharmaceutical products by auditing test and research facilities, checking records and other documents, and collaborating closely with regulatory authorities, medical professionals and other relevant parties in sharing information and accurately identifying risks.



Please visit our website and read our CSR Report for details. http://www.astellas.com/en/corporate/csr/report.html

# **Corporate Governance**

Outside Director Yasuyuki Takai

Outside Director Shiro Yasutake

LEBERFERENCE

Outside Director Naoki Aikawa MD. Ph.D. Outside Director Kanoko Oishi Representative Director, President and Chief Executive Officer

Yoshihiko Hatanaka

Executive Vice President and Senior Corporate Executive

Yoshiro Miyokawa

Senior Corporate Executives

Katsuro Yamada Masao Yoshida Shinichi Tsukamoto Ph.D. Masaru Imahori Masaharu Asano Ph.D.



Representative Director and Chairman

Masafumi Nogimori

Outside Corporate Auditor Yukiko Kuroda Representative Director and Vice Deputy Chairman Yasuo Ishii

Outside Corporate Auditor Hideo Yamada Ph.D.

and she

Corporate Auditor Seigo Kashii

Aver Will

Corporate Auditor Shigeo Aoyagi

# Corporate Executives

Hidetoshi Shuto Masaki Doi Ph.D. Kohei Nomoto Yasumasa Masuda Hirofumi Seki Shinichiro Katayanagi Yoshiaki Nakashima Toshihiko Iwata

Yoshihiro Minami Mitsunori Matsuda Shoji Yokota Takahisa lizuka Yukihiko Sato Haruhisa Hirosaki Kenji Yasukawa Ph.D. Kenji Sumi Chihiro Yokota Wataru Uchida Ph.D. Makoto Takeuchi

#### **Basic Policy on Corporate Governance**

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

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

The company has established the "Charter of Corporate Conduct," which states this business philosophy in concrete terms of specific business conduct, and the "Astellas Business Ethics Policy" as ethical principles common to the Astellas Group in accordance with which "high ethical views" stated in the business philosophy and Charter of Corporate Conduct are realized. Furthermore, the company and Astellas Group companies have established "Our Code of Conduct" relating to the daily operational activities of officers and employees. The company defines the consistent practice of them as "CSR management." Our goal is to earn the support and trust of all our stakeholders, including customers, shareholders, employees and the general public.

#### **Overview of Corporate Governance at Astellas**

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

In respect of the Board of Directors, it now comprises seven members including four outside Directors, in order to promote the decisionmaking and supervise business execution from a broader viewpoint.

The company has established the Global Management Committee, the Corporate Administration & Finance Committee, and the Human Resources Committee. These committees discuss important issues involving global management, important issues involving finance, accounting and administration, and important issues involving human resources, respectively, of the company and Group companies.

The Board of Directors has the Nomination Committee and the Compensation Committee as advisory bodies for the purpose of enhancing the transparency and objectivity of the deliberation process for the nomination of Directors, Corporate Executives and Corporate Auditors and of the compensation system.

The Company adopted the Corporate Auditors System. Under this system a Board of Corporate Auditors is established, being comprised of four members, including two outside Corporate Auditors.

The Board of Corporate Auditors audits the performance of duties by the Directors.

#### Systems and Measures to Enhance Business Execution and Supervisory Functions

The Board of Directors meets in principle once a month. It makes decisions on important business matters, and supervises business execution. Extraordinary meetings of the Board of Directors are also held as necessary.

The terms of directors are one year from the standpoint of clarifying responsibility for management, and further strengthening corporate governance. Astellas' Nomination Committee serves as a voluntary advisory body to the Board of Directors. This committee discusses important issues pertaining to the appointment and dismissal of Directors, Corporate Executives and Corporate Auditors, ensuring the transparency and objectivity of the deliberation process for the nomination of these individuals. Furthermore, outside Directors account for the majority of members on this committee.

Astellas' Compensation Committee is another voluntary advisory body to the Board of Directors. This committee discusses matters pertaining to the compensation of Directors and Corporate Executives, ensuring the transparency and objectivity of the deliberation process under the compensation system. Furthermore, outside Directors account for the majority of members on this committee.

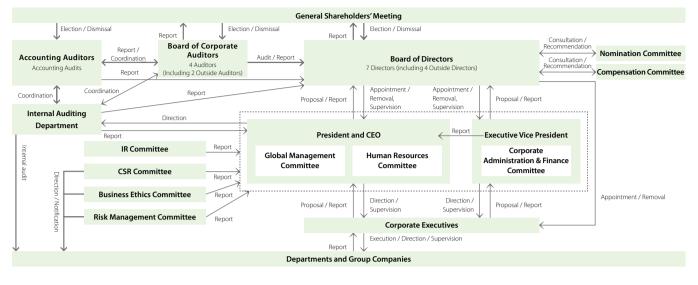
In addition to the aforementioned committees, Astellas has a number of other committees. The IR Committee discusses the promotion of IR activities, corporate information disclosure and other matters relating to IR activities. The CSR Committee discusses policies and plans for the environment, safety and other areas. The Business Ethics Committee discusses policies and plans concerning business ethics. The Risk Management Committee discusses policies, measures and other matters for risk management.

The Board of Corporate Auditors meets in principle once a month. Audits are carried out effectively by Corporate Auditors, who comprise full-time internal Corporate Auditors and outside Corporate Auditors. The former are very familiar with issues in the company, whereas the latter have a high degree of independence, and a wealth of actual experience and familiarity in various specialist fields. Furthermore, a full-time staff is assigned to assist the Corporate Auditors to carry out their duties. The function of the Corporate Auditors is enhanced through cooperation with the Accounting Auditors and the Internal Auditing Department.

#### **Business Execution Committees:**

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

#### Corporate Governance at Astellas



#### **Basic Stance on Internal Control and the System**

The company has established an internal control system in every part of the Astellas Group and will further establish, develop, and enhance systems, such as the system to improve work efficiency, the risk management system, the system for compliance with laws and other matters, and the internal audit system, as well as promote systems and an environment for ensuring audits by Corporate Auditors are carried out effectively.

Through these efforts, the company will endeavor to ensure that the entire Astellas Group's business is duly executed.

Moreover, the officers and employees of the company and Astellas Group companies share and base all of their activities on the company's business philosophy, Charter of Corporate Conduct, Business Ethics Policy and Our Code of Conduct. The company defines the faithful practice of them as "CSR management," and aims to fulfill its social responsibilities through efforts toward compliance with laws, environmental protection and safety, social contribution, and other activities.

# Regulations and Other Systems Regarding Risk (Risk of Loss) Management

In order to conduct risk management properly, the company has categorized risks according to their nature: "risks relating to strategic management decision-making (risks relating to business opportunities)" and "risks relating to appropriate and efficient business conduct (risks relating to the performance of business activities)." Each department and unit of the company and the Astellas Group companies will proactively put the company's risk management initiatives into practice as a basic rule.

With respect to the measures dealing with risks relating to business opportunities, each department and unit will implement such measures within the scope of its powers and roles, upon clarification of the rules and standards for decision-making. Among these risks, matters concerning material risks will be decided upon deliberation by the Board of Directors and the Global Management Committee. With respect to the measures dealing with risks relating to the performance of business activities, the company has established the Risk Management Committee to identify risks and devise and implement optimum methods of risk management. Matters relating to important risk management measures will be decided upon deliberation by the Board of Directors and the Corporate Administration & Finance Committee. Through these activities, the company will mitigate the risks in the Astellas Group and implement appropriate measures for such risks.

In order to enhance the effectiveness of risk management operations, the company has formulated separate policies and manuals for matters such as disaster control, crisis management, business continuity plan, information security, and personal information protection according to the characteristics and details of the risks involved.

#### Compliance System

The company engages in "CSR-based management" through its CSR Committee. Regarding the key issue of compliance, we see this not only as observing the law but also acting in accordance with prescribed social norms in a highly ethical manner. We are taking the following steps to create a system for promoting and spreading "business ethics" in a broad sense.

The company has established the Business Ethics Committee to decide the policies and plans concerning business ethics as well as to grasp the current situation. Under the control of the Chief Business Ethics Officer, the CSR Office of the General Affairs Department, with concerned departments of the company and Astellas Group companies, devises, promotes and increases awareness of the specifics of the plans. In addition, through continuous training and other measures, we create a structure in which each member of the Group can practice business ethics when acting on their own initiative.

The company has established a "helpline" so that questions, consultation, reports, proposals and the like concerning business ethics may be made to the Chief Business Ethics Officer. Callers may also consult with an outside office (a law firm) and the sexual harassment counseling office, as methods for problem solving. In dealing with such

actions, confidentiality will be strictly maintained and unfair treatment of any person who has accessed the helpline or other contacts is strictly prohibited.

#### System for Disclosure and Management of Information

The company has established the Disclosure Policy based on its policy to make timely and fair disclosure of accurate corporate information concerning financial results and other matters to the participants of the capital market and the media in accordance with laws, regulations, and listing regulations.

The company has established the IR Committee, with the aim of promoting proper IR activities to investors. The IR Committee deliberates and the chairperson makes decisions on matters such as disclosure of material information pursuant to the Disclosure Policy. The Board of Directors has established rules concerning the handling of material information acquired in the course of their duties by the officers and employees of the company to prevent violations of laws and regulations and to ensure the appropriate management of information.

#### Internal Controls Over Financial Reporting

The company has established and is operating an internal control system for financial reporting in accordance with standards generally accepted to be fair and reasonable in Japan, in order to ensure the improved reliability of financial reporting, and assesses effectiveness in an appropriate way.

The company has formulated the "Regulations for Internal Control Assessment of Financial Report" and the General Manager of the Internal Auditing Department carries out the internal control assessment for financial reports, under the direction of the President and CEO, who is responsible for assessment of the internal control system.

#### Group Management System

The company strives to promote Group management and appropriate control and operation of Astellas Group companies. With this in mind, the company has taken the following actions in order to maintain and build a sound relationship between it and Astellas Group companies:

The company applies the "Charter of Corporate Conduct" and "Astellas Business Ethics Policy" to the whole Astellas Group, and ensures that all persons concerned are fully aware of these policies and the code of conduct of each Astellas Group company that is based on these policies. The company has also created clear rules regarding the composition of executives and decision-making authority at Astellas Group companies. Further, the Astellas Group tackles risk management and compliance matters as a whole group. The "Internal Audit Regulations" are shared by all Astellas Group companies and the company has put in place an internal audit system covering the Group.

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

Position	Name	Expected Role
Outside Director	Shiro Yasutake	Shiro Yasutake currently plays a key role as an outside Director for management of the company from an independent position. The company considers that he will exercise his abundant experience in corporate management in management of the company in the future as well.
Outside Director	Yasuyuki Takai	Yasuyuki Takai currently plays a key role as an outside Director for management of the company from an independent position. The company considers that he will exercise his abundant specialized knowledge and experience as an attorney-at-law in management of the company in the future as well.
Outside Director	Kanoko Oishi	Kanoko Oishi currently plays a key role as an outside Director for management of the company from an independent position. The company considers that she will exercise her abundant experience in corporate management in management of the company in the future as well.
Outside Director	Naoki Aikawa MD. Ph.D.	Naoki Aikawa currently plays a key role as an outside Director for management of the company from an independent position. The company considers that he will exercise his abundant specialized knowledge and experience as a doctor of medicine in management of the company in the future as well.
Outside Corporate Auditor	Hideo Yamada, Ph.D.	Hideo Yamada has outstanding knowledge of finance and accounting. Based on exercise of this insight, the company believes that he will perform his duties from an independent standpoint as an outside Corporate Auditor.
Outside Corporate Auditor	Yukiko Kuroda	Yukiko Kuroda has abundant experience in business as a CEO. Based on exercise of this insight, the company believes that she will perform her duties from an independent standpoint as an outside Corporate Auditor.

# **Financial Section**

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# Overview of Year Ended March 31, 2011 (Fiscal 2010)

Consolidated operating results for fiscal 2010 include the operating results of OSI Pharmaceuticals, Inc. (OSI) from July 2010. Astellas acquired OSI in June 2010.

# **Operating Performance Overview**

In addition to growth in global products Vesicare and Funguard / Mycamine, Astellas recorded higher sales in the Japanese prescription drugs market. However, US sales of Prograf, and Harnal bulk sales and royalty income, which is recorded in Europe, declined substantially due to the impact of the launch of generics in the US. As a result, net sales decreased by 2.1% compared with the previous fiscal year to ¥953.9 billion. This included ¥31.8 billion in net sales relating to OSI following its acquisition. Operating income dropped 36.1% to ¥119.2 billion due to lower gross profit, as well as to higher R&D expenses and amortization of patents and goodwill related to the OSI acquisition. Net income dipped 44.7% year on year to ¥67.7 billion, reflecting exchange losses, and a loss on disaster related to the Great East Japan Earthquake and business integration expenses related to the OSI acquisition.

# Foreign Exchange Impact for Fiscal 2010

In fiscal 2010, the yen appreciated by ¥7 on average against the US dollar and by ¥18 on average against the euro compared with the previous fiscal year. The appreciation of the yen reduced net sales and operating income by ¥47.3 billion and ¥8.6 billion, respectively.

## Foreign Exchange Rates (Average)

	(¥)
2010.3	2011.3
¥ 93	¥ 86
131	113

# **Net Sales**

Consolidated net sales amounted to ¥953.9 billion in fiscal 2010, a year-on-year decline of ¥20.9 billion, or 2.1%.

A review of sales by product is provided below.

	(¥ billion)			(%)
Sales by Product (Global products)	2010.3	2011.3	YoY	CER*
Prograf	¥186.7	¥162.6	(12.9)	_
Japan	33.8	39.6	17.3	_
Americas	68.1	41.0	(39.9)	(34.9)
Europe	65.7	60.6	(7.8)	6.9
Asia	12.8	14.8	15.6	_
Exports	6.2	6.5	4.9	_
Harnal	113.9	66.5	(41.6)	_
Japan	35.0	29.6	(15.3)	_
Europe	24.3	21.5	(11.4)	2.7
Asia	8.6	9.2	7.6	_
Bulk / Royalties	45.6	5.2	(88.5)	(86.6)
Vesicare	82.3	86.7	5.3	_
Japan	22.9	25.5	11.2	_
Americas	35.1	35.8	2.0	10.5
Europe	22.9	23.5	2.5	18.9
Asia	1.0	1.4	32.4	_
Funguard / Mycamine	21.6	25.1	16.1	_
Japan	11.8	12.6	7.2	_
Americas	7.5	8.4	11.0	20.2
Europe	1.2	2.4	95.3	126.4
Asia	1.0	1.6	56.9	_
Protopic	16.4	16.2	(1.1)	_
Japan	2.8	2.9	2.7	_
Americas	7.3	7.1	(2.5)	5.6
Europe	5.5	5.2	(5.7)	9.3
Asia	0.7	0.9	31.2	_

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

		(¥ billion)		(%)
ales by Product (Local products)	2010.3	2011.3	YoY	CER*
Japan				
Lipitor	99.9	97.2	(2.7)	_
Micardis	71.6	75.8	5.9	_
Micombi	1.6	6.1	272.4	
Micamlo (launched in October 2010)	_	2.3	_	_
Gaster	49.9	41.7	(16.5)	
Myslee	29.1	32.7	12.1	_
Seroquel	23.6	26.4	12.0	
Celecox	17.8	25.1	41.2	
Vaccine	25.2	18.7	(26.0)	
Symbicort (launched in January 2010)	1.5	11.9	689.0	
Geninax	8.1	10.2	25.5	
Bonoteo	1.0	2.4	123.9	_
Irribow	0.2	1.6	673.8	_
Americas				
Scan (Adenoscan and Lexiscan)	46.0	47.9	4.2	12.8
Lexiscan	30.2	39.0	28.9	39.6
AmBisome	6.2	6.2	0.4	8.8
VIBATIV	0.3	0.7	109.1	126.4
Europe				
Eligard	14.1	13.8	(1.8)	13.9
Vear-on-vear comparison local currency base				

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

### **Sales by Product**

#### Prograf (Immunosuppressant)

Sales in Japan increased by ¥5.8 billion, or 17.3%, to ¥39.6 billion. In addition to the transplantation area, Prograf recorded steady sales increases for autoimmune diseases such as rheumatoid arthritis (RA), lupus nephritis, myasthenia gravis, and ulcerative colitis. The RA indication now accounts for approximately 40% of sales of Prograf in Japan. In the area of transplantation, the once-daily formulation launched under the brand name Graceptor in October 2008 recorded steady sales growth. Graceptor can be expected to enhance compliance, while delivering similar levels of efficacy and safety as Prograf. Astellas believes this could lead to further improvements in long-term transplant outcomes.

Sales in the Americas fell by ¥27.1 billion, or 39.9%, to ¥41.0 billion due to the impact from generic versions launched in the US in August 2009. In local currency terms, sales fell by US\$255 million, or 34.9%, to US\$478 million. The share of generic products in the tacrolimus market, which includes Prograf and generics, averaged approximately 49% on a total prescription basis during fiscal 2010. The share has since risen gradually. The share of Prograf in the calcineurin inhibitor (CNI) market for new organ transplant patients was approximately 81% in liver transplants, 79% in kidney transplants and 77% in heart transplants, based on data collected by the United Network for Organ Sharing (UNOS data for January-March 2011).

Reflecting the impact of yen appreciation, sales in Europe declined by ¥5.1 billion, or 7.8%, to ¥60.6 billion. In local currency terms, sales continued growing, rising by €34 million, or 6.9%, to €535 million. The share of Prograf and once-daily formulation Advagraf combined in the CNI market reached approximately 62%. Advagraf is now sold in 26 countries in Europe. Advagraf generated about 23% of total Prograf sales in the region in fiscal 2010, with sales growing steadily. The substance patent on Prograf expired in most major European markets in June 2009. The launch of generic versions of the drug were confirmed in six countries in fiscal 2010.

In Asia, sales increased by ¥2.0 billion, or 15.6%, to ¥14.8 billion. Sales expanded strongly in markets such as China and South Korea in particular. Furthermore, Astellas gained regulatory approval for the additional indication of lupus nephritis in Thailand in November 2010, and launched Advagraf in China and India in March 2011 and April 2011, respectively.

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

Sales in Japan have expanded steadily since Vesicare was launched in June 2006. Sales grew by ¥2.5 billion, or 11.2%, to ¥25.5 billion in fiscal 2010. Vesicare strengthened its hold on the top spot in this category by growing its market share to approximately 47%. In April 2011, Astellas launched sales of Vesicare OD Tablet (orally disintegrating tablet). There remain significant potential subjects in the market for OAB treatments, making it a sector with excellent growth potential. Astellas is working to further penetrate the market for Vesicare by raising public awareness of this condition.

VESIcare sales in the Americas rose by ¥0.7 billion year on year, or 2.0%, to ¥35.8 billion. In local currency terms, sales increased US\$39 million, or 10.5%, to US\$418 million. The market for OAB treatments was sluggish, declining 0.9% year on year, in line with the stagnation of the US economy. Amid this market malaise, VESIcare maintained high sales growth, due in part to increased sales through contracts with a major insurance company. Market share on a total prescription basis was 21% (as of April 2011). VESIcare expanded its market share more than any other branded drug in this category in the US in the past year. Furthermore, in January 2011 Astellas' affiliate exercised its right under its agreement with co-promotion partner GlaxoSmithKline to assume full commercial responsibility in the US for VESIcare. As a result of this move, copromotion of VESIcare in the US will end in December 2011, after which Astellas' affiliate will undertake all promotional activities from January 2012.

In Europe, Vesicare sales increased by ¥0.5 billion, or 2.5%, to ¥23.5 billion. On a local currency basis, sales grew €33 million, or 18.9%, to €208 million in fiscal 2010. Vesicare thus continues to grow at a high rate in Europe. Vesicare is marketed in 40 countries throughout Europe, and has a market share of approximately 40% (in value terms, as of February 2011). It is the leading treatment for OAB within the European regional market.

In Asia outside Japan, sales grew steadily in fiscal 2010, rising ¥0.3 billion, or 32.4%, to ¥1.4 billion. Sales started in Vietnam in August 2010.

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

Sales in Japan declined by ¥5.3 billion, or 15.3%, to ¥29.6 billion. Competition with generic products has intensified since the expiry of the substance patent in February 2005. Harnal's market share in the alpha-1 blocker market in Japan in fiscal 2010 was approximately 45%, as it maintained the position as the leading product. The share of Harnal generic products was approximately 19% in the market of the same compounds (on a volume basis, excluding direct sales).

The drug is marketed under the brand name Omnic in Europe.

Sales in fiscal 2010 dropped by ¥2.7 billion, or 11.4%, to ¥21.5 billion, reflecting the impact of the yen's appreciation. On a local currency basis, sales increased by €5 million, or 2.7%, to €190 million. Sales of the drug continued to increase steadily in fiscal 2010 due to strong sales in markets such as Russia and France, despite the expiry of the substance patent in February 2006. Sales of modified release formulation Omnic OCAS generated about 65% of regional sales of Omnic.

Sales in Asia increased ¥0.6 billion, or 7.6%, to ¥9.2 billion. This mainly reflected steady sales growth in China, South Korea and other markets. Sales commenced in Vietnam in August 2010.

Bulk sales and royalty income of Harnal, which are recorded in Europe, dropped substantially in fiscal 2010 by ¥40.3 billion, or 88.5%, to ¥5.2 billion due to the launch of generic versions in the US market in March 2010. In local currency terms, bulk sales and royalty income of Harnal dropped €301 million, or 86.6%, to €46 million.

# Funguard / Mycamine (Candin-type antifungal agent)

Sales in Japan rose ¥0.8 billion, or 7.2%, to ¥12.6 billion. Astellas has secured an approximate 54% share in the market for injectable antifungal agents and is maintaining steady growth.

Sales in the Americas increased by ¥0.8 billion, or 11.0%, to ¥8.4 billion. On a local currency basis, sales were again strong, climbing by US\$16 million, or 20.2%, to US\$98 million. The regulatory approval gained in January 2008 for the additional three indications of candidemia, acute disseminated candidiasis, and candida peritonitis and abscesses has also contributed to steady growth in sales volumes and market share gains. In terms of patient days per month, the share of Mycamine of the market for injectable candintype antifungal agents improved steadily, increasing to approximately 67% in February 2011. Sales were launched in January 2011 in Brazil, following in the footsteps of the US and Canada.

In Europe, sales increased by ¥1.1 billion to ¥2.4 billion. On a local currency basis, sales grew by €11 million to €21 million. Mycamine is now marketed in 24 countries in Europe, with countries where it is sold growing steadily, since the August 2008 launch in the UK. With the injectable antifungal agent market growing year by year in Europe, Astellas' sales are also growing as the drug is sold in more countries.

In Asia outside Japan, sales expanded steadily in fiscal 2010, rising ¥0.5 billion, or 56.9%, to ¥1.6 billion.

#### Protopic (Treatment for atopic dermatitis)

Sales in Japan rose 2.7% year on year to ¥2.9 billion. In July 2010, Astellas reached an agreement to assign detailing / promotional activities for Protopic in Japan to Maruho Co., Ltd. on April 1, 2011, and thereafter transfer distribution rights in Japan to that company on April 1, 2014.

Sales in the Americas declined by ¥0.1 billion, or 2.5%, to ¥7.1 billion. On a local currency basis, sales increased firmly, growing US\$4 million, or 5.6%, to US\$83 million.

Sales in Europe declined ¥0.3 billion, or 5.7%, to ¥5.2 billion. On a local currency basis, sales grew €3 million, or 9.3%, to €46 million. Steady growth was recorded due to ongoing activities targeting dermatologists with scientific information.

#### Lipitor (Hypercholesterolemia treatment)

Lipitor sales declined ¥2.6 billion, or 2.7%, to ¥97.2 billion. Sales volumes increased approximately 4% year on year, although the NHI drug price cut had an impact. In Japan, the market for statins declined 2.3% on an NHI drug price basis to approximately ¥297.0 billion. Lipitor recorded a 36.5% share of the market, which represented an approximate 0.6 percentage point decline from the previous fiscal year. In a fiercely competitive statins market, Astellas continues to strengthen co-promotional efforts with Pfizer Japan Inc. and take advantage of extensive clinical evidence of efficacy to maximize value for Lipitor. At the same time, Astellas continues to raise patient awareness of the importance of LDL cholesterol reduction therapy as part of broader efforts to educate patients about hypercholesterolemia.

In December 2009, Caduet Combination Tablets were launched in Japan. It is a combination drug for the treatment of hypertension and Lipitor, and the generic name is amlodipine besylate and atorvastatin calcium. In Japan, Pfizer Japan is responsible for manufacturing and sales of Caduet Combination Tablets, and Astellas is co-promoting the drug with Pfizer Japan and receiving a copromotion fee. In July 2011, the co-promotion agreement in Japan was changed, so that from October 1, 2011, Astellas will hold distribution rights and book sales. Pfizer Japan will continue to conduct co-promotion activities with Astellas.

#### Micardis (Anti-hypertensive)

Sales of Micardis rose ¥4.2 billion, or 5.9%, to ¥75.8 billion year on year. Astellas successfully expanded aggregate sales of Micardis, Micombi, a combination formulation with a diuretic that was launched in June 2009, and Micamlo, a combination drug with a calcium antagonist that was launched in October 2010. Micamlo became eligible for long-term prescription in December 2010. The Japanese angiotensin II receptor blocker (ARB) market in fiscal 2010 grew 2.4% year on year to approximately ¥576.0 billion. While competition is escalating in the market, Micardis had a market share of 14.6%, including Micombi and Micamlo, on steady sales. Astellas is co-promoting Micardis in Japan with Nippon Boehringer Ingelheim Co., Ltd.

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

Sales of Gaster declined ¥8.2 billion, or 16.5%, to ¥41.7 billion. In fiscal 2010, Gaster recorded a 15.6% share of the overall Japanese market for  $H_2$  receptor antagonists and proton pump inhibitors (PPIs), a decline of 2.8 percentage points in year-on-year terms.

Japanese authorities have introduced various measures to promote increased use of generics. As a result, the share of generics within famotidine products has grown to about 26% in the market of the same compounds (on a volume basis, excluding direct sales).

#### Myslee (Insomnia treatment)

Sales of Myslee grew strongly, increasing ¥3.5 billion, or 12.1%, to ¥32.7 billion. The market in Japan for insomnia treatment grew 1.9% in fiscal 2010 to approximately ¥82.0 billion. Myslee solidified its grip on the top spot in this category with a market share of 43.1%, a year-on-year gain of 2.9 percentage points. While the Japanese market for insomnia treatment continues to expand year after year, there remains considerable latent potential. Astellas will therefore continue to raise patient awareness, as it works to penetrate the market further. Astellas is co-promoting Myslee with Sanofi-aventis K.K. in Japan.

#### Seroquel (Schizophrenia treatment)

Sales of Seroquel grew strongly, rising ¥2.8 billion, or 12.0%, to ¥26.4 billion. The market for anti-schizophrenic agents grew by 6.8% to approximately ¥142.0 billion in fiscal 2010. Seroquel ranked second in this market with a share of 20.1%, 0.5 of a percentage point higher than in fiscal 2009. The market for anti-schizophrenic agents in Japan is expanding year by year. Astellas plans to penetrate the market further by continuing to promote the high safety and outstanding symptomatic improvement effect of this drug.

# Celecox (Selective COX-2 inhibitor)

Sales of Celecox grew robustly, climbing ¥7.3 billion, or 41.2%, to ¥25.1 billion. In addition to the initial indications of rheumatoid arthritis (RA) and osteoarthritis (OA), in June 2009 it was approved for the additional indication of lumbago, etc., which has continued to help lift sales. The market for anti-inflammatory agents was worth approximately ¥84.0 billion in fiscal 2010, about the same as the previous fiscal year. Celecox had a market share of 32.6%, up 9.3 percentage points from the previous fiscal year. Going forward, through co-promotional efforts with Pfizer Japan, Astellas aims to grow its market share further in the oral anti-inflammatory agents market.

#### Geninax (Oral quinolone antibiotic)

Sales of Geninax grew strongly, increasing ¥2.0 billion, or 25.5%, to ¥10.2 billion. The category share of Geninax increased by 4.3 percentage points to 18.6%, giving it second spot in the market for oral quinolone antibiotics. Going forward, Astellas plans to penetrate the market further, through co-promotion with Taisho Toyama Pharmaceutical Co., Ltd.

#### Bonoteo (Treatment for osteoporosis)

Sales of Bonoteo increased ¥1.3 billion to ¥2.4 billion. In April 2010, Bonoteo became eligible for long-term prescription, driving sales growth. In fiscal 2010, the osteoporosis treatment market grew approximately 1.2% to around ¥86.0 billion. Bonoteo had a market share of 3.1%, up 1.8 percentage points from the previous fiscal year. In July 2011, Bonoteo Tablets 50 mg was granted marketing approval for a once per four weeks formulation. Leveraging this, Astellas aims to expand Bonoteo sales further.

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

In fiscal 2010, Symbicort recorded net sales of ¥11.9 billion. This represented a large increase in just over one year since its launch in January 2010. The inhaled steroid treatment market in fiscal 2010 was worth approximately ¥72.0 billion, of which Symbicort had a market share of 17.5%. Symbicort became eligible for long-term prescription in January 2011, and Astellas aims to leverage this to further penetrate the market. As of March 2011, Symbicort had a market share of 24.4%. Astellas is co-promoting Symbicort with AstraZeneca K.K. in Japan.

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

Total sales of Adenoscan and Lexiscan in the US rose by ¥1.9 billion, or 4.2%, to ¥47.9 billion. On a local currency basis, total sales grew US\$63 million, or 12.8%, to US\$559 million. Sales on a local currency basis of Lexiscan, which was launched in June 2008, increased sharply by US\$129 million, or 39.6%, from fiscal 2009 to US\$455 million.

#### Tarceva (Anticancer)

Astellas booked Tarceva-related revenues in the Americas for the nine-month period from July 2010 through March 2011, following the June 2010 acquisition of OSI. In the US, Astellas is co-promoting Tarceva with Genentech, Inc., with earnings split equally. In regions other than the US, Astellas has concluded a license agreement with Roche, receiving royalties according to sales.

Tarceva-related revenues for the aforementioned nine-month period in fiscal 2010 were ¥24.4 billion. On a local currency basis, they were US\$285 million. Tarceva sales in the global market during the same period were US\$985 million, up 5% year on year. Sales in the US accounted for US\$388 million, which was 5% higher than the previous fiscal year. Sales outside the US were US\$597 million, an increase of 4%.

## Eligard (Advanced prostate cancer treatment)

Sales of Eligard in Europe declined by ¥0.2 billion, or 1.8%, to ¥13.8 billion. Boosted by a strong performance from the six-month formulation, sales in local currency terms rose  $\in$ 14 million, or 13.9%, to  $\in$ 122 million.

# Sales by Geographical Area

		(¥ billion)
	2010.3	2011.3
Consolidated	¥974.9	¥953.9
Japan	529.2	543.8
Americas	179.8	186.5
Europe	235.9	189.9
Asia	30.0	33.7

Note: Calculated according to the location of sellers

#### Japan

Sales in Japan rose 2.8% year on year, to ¥543.8 billion.

Sales of prescription drugs in the Japanese market grew steadily, increasing 3.1% to ¥525.6 billion in spite of the impact of an NHI drug price cut in April 2010.

Sales of Celecox, Myslee and Seroquel increased, in addition to Prograf and Vesicare. New products, including Symbicort, which was launched in January 2010, helped boost sales. Furthermore sales of Micardis, including combination drugs Micombi and Micamlo, also increased. On the other hand, sales of Gaster, Harnal and Lipitor declined.

## Americas

Sales in the Americas rose 3.7% year on year to ¥186.5 billion. In local currency terms, sales rose 12.4% to US\$2,176 million.

In addition to VESIcare and Mycamine, sales of Lexiscan grew steadily. However, Prograf sales were down due to the impact of the launch of generic products. Sales related to OSI of ¥31.8 billion were booked in the Americas following this company's acquisition.

#### Europe

Sales in Europe declined by 19.5% to ¥189.9 billion. In local currency terms, sales declined 6.7% to  $\in$ 1,678 million. Excluding exports to third parties of Prograf and Harnal bulk sales and royalty income, sales through Astellas' own distribution channels were  $\in$ 1,576 million, up 12.1% year on year.

Sales of Vesicare, Mycamine, and Eligard grew steadily. Sales of Prograf declined due to the impact of the yen's appreciation. However, sales in local currency terms continued to increase, in part due to the contribution from the once-daily formulation Advagraf. The launch of generic versions of Prograf has already been confirmed in multiple countries in Europe. Bulk sales and royalty income from licensees of Harnal booked in Europe dropped substantially due to the launch of generic versions in the US in March 2010.

#### Asia

Sales in Asia rose 12.5% to ¥33.7 billion.

Sales increased despite the impact of yen appreciation. Sales of Prograf, Harnal, Vesicare and Mycamine grew steadily.

#### **Overseas Sales**

		(1 billion)
	2010.3	2011.3
Consolidated	¥460.7	¥422.5
Americas	224.9	189.5
Europe	181.2	182.0
Asia Other	54.6	51.1
Overseas sales ratio	47.3%	44.3%

Overseas sales are attributed by location of customers.

The overseas sales ratio declined 3.0 percentage points in fiscal 2010 due to the impact of the yen's appreciation against the US dollar and the euro.

# **Cost of Sales**

		(¥ billion)
	2010.3	2011.3
Net sales	¥974.9	¥953.9
Cost of sales	289.2	296.0
Cost of sales ratio	29.7%	31.0%

Cost of sales increased by ¥6.7 billion, or 2.3%, to ¥296.0 billion. The cost of sales ratio rose 1.3 percentage points in fiscal 2010 to 31.0% due to the impact of changes in product mix and other factors.

(¥ hillion)

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

		(¥ billion)
	2010.3	2011.3
SG&A expenses	¥499.2	¥538.8
SG&A ratio	51.2%	56.5%
Personnel expenses	120.1	120.8
Advertising and sales promotional expenses	87.7	89.0
R&D expenses	195.6	217.3
Other	95.8	111.7

Note: SG&A expenses include R&D expenses.

SG&A expenses increased ¥39.6 billion, or 7.9%, to ¥538.8 billion. The ratio of SG&A expenses to net sales was 56.5%, an increase of 5.3 percentage points.

Personnel expenses rose ¥0.7 billion, or 0.6%, to ¥120.8 billion. The main reasons for this increase were an increase in personnel accompanying the OSI acquisition, as well as an increase in personnel such as MRs in line with strengthening sales and marketing capabilities in Europe and Asia.

Advertising and sales promotional expenses increased ¥1.3 billion, or 1.4%, year on year to ¥89.0 billion. One of the main reasons for the higher expenses was a year-on-year decline in refunds of marketing expenses from the licensee booked in Europe owing to the expiration of a co-promotion agreement for Harnal (Flomax) in the US. Furthermore, expenses related to new product launches such as Qutenza in Europe and expenses in Brazil and Asia increased. However, advertising and sales promotional expenses decreased in Japan.

Other SG&A expenses were ¥111.7 billion, up ¥15.9 billion, or 16.5%, year on year. This reflected in part the booking of amortization expenses of ¥20.1 billion for patents and goodwill recognized in accordance with business combination accounting standards in association with the OSI acquisition.

#### **R&D** Expenses

		(¥ billion)
	2010.3	2011.3
R&D expenses	¥195.6	¥217.3
R&D ratio	20.1%	22.8%

R&D expenses increased by ¥21.8 billion, or 11.1%, to ¥217.3 billion. The ratio of R&D expenses to net sales was 22.8%, an increase of 2.7 percentage points compared with the previous fiscal year. One reason was higher costs associated with progress made in clinical development projects. In addition, upfront and milestone payments increased for in-licensing, including a payment for the extension of a VelocImmune antibody technology agreement with US pharmaceutical company Regeneron Pharmaceuticals, Inc. (concluded July 2010) and a payment for the conclusion of an agreement with AVEO Pharmaceuticals, Inc. of the US related to codevelopment and commercialization of cancer treatment tivozanib (February 2011). In addition, ¥12.7 billion in R&D expenses related to OSI were recorded.

# **Operating Income**

		(¥ billion)
	2010.3	2011.3
Net sales	¥974.9	¥953.9
Operating income	186.4	119.2
Operating margin	19.1%	12.5%

Operating income declined ¥67.2 billion, or 36.1%, to ¥119.2 billion. The operating margin dropped 6.6 percentage points from fiscal 2009 due to a 1.3 point decline in the gross margin and a higher ratio of R&D expenses to sales.

#### Other Income (Expenses)

Interest and dividend income declined by ¥1.6 billion to ¥2.3 billion. This mainly reflected a decrease of cash and short-term liquidity. In fiscal 2010, an exchange loss of ¥6.6 billion was recorded, versus an exchange gain of ¥0.2 billion in fiscal 2009. In fiscal 2010, Astellas also recorded a gain on sale of investment securities of ¥1.3 billion, but a loss on sales and disposal of fixed assets of ¥1.3 billion, a loss on impairment of fixed assets of ¥2.8 billion, a loss on disaster of ¥3.0 billion, and business integration expenses of ¥4.7 billion associated with the OSI acquisition.

#### Foreign Exchange Trends (Year-end rate)

(¥)		
2011.3	2010.3	
¥ 83	5\$ ¥ 93	US\$
118	125	€

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

Income before income taxes and minority interests decreased ¥83.3 billion, or 44.6%, to ¥103.5 billion.

Income taxes decreased ¥26.8 billion, or 42.8%, to ¥35.8 billion. The tax rate rose by 1.1 percentage points to 34.6% due to higher goodwill amortization costs and other factors.

Reflecting the factors outlined above, net income decreased  $\pm$ 54.6 billion, or 44.7%, to  $\pm$ 67.7 billion.

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

The Astellas Group aims to generate sustained growth over the medium and long term through early and ongoing discovery of a stream of innovative and useful new drugs in therapeutic areas where effective treatments do not exist currently and there are large unmet medical needs. To this end, the Astellas Group actively promotes R&D activities as a priority measure.

### Drug Discovery Research Measures

Drug discovery efforts are selectively targeting the following areas of research focus: urology, immunology including transplantation and infectious diseases, oncology, neuroscience, and diabetes complications and metabolic diseases. Astellas is also actively seeking to reinforce technological platforms for drug discovery by establishing a presence in antibody and protein drug technology. This approach promises to supplement the Group's traditional strengths in small molecule synthesis and fermentation technology.

In July 2010, Astellas agreed with Regeneron to extend through 2023 a non-exclusive license agreement that allows Astellas to utilize Regeneron's VelocImmune antibody technology. The original agreement was concluded in March 2007.

#### Clinical Development Initiatives

In clinical development, the Group aims to speed up the pace of development programs by concentrating resources on the highest priority projects. In fiscal 2010, Astellas received approval in Japan for Vesicare OD Tablet (orally disintegrating tablet), an additional formulation for Vesicare. Sales were launched in April 2011. In addition, Astellas filed for regulatory approval in Japan of OAB treatment mirabegron (YM178); Bonoteo Tablets for the treatment for osteoporosis in a once per four weeks oral formulation; Degarelix (ASP3550) for the indication of prostate cancer; Bixalomer (ASP1585), a treatment for hyperphosphatemia; and additional indications for Celecox. Moreover, Zeria Pharmaceutical Co., Ltd. submitted an NDA in Japan for YM443, a treatment for functional dyspepsia, which has been co-developed in Japan by Zeria and Astellas. Astellas also made steady progress with other ongoing drug development projects. However, in February 2011, Astellas withdrew its application for marketing approval of darexaban (YM150), an oral Factor Xa direct inhibitor.

#### Status of In-licensing and Alliances

Alongside in-house drug discovery programs, the Group also actively seeks to expand and improve the development pipeline through in-licensing of compounds from and alliances in sales and marketing with other companies. In September 2010, Astellas entered into a definitive agreement with UMN Pharma Inc. for UMN-0501 and UMN-0502, which are cell culture based influenza vaccine programs developed by UMN Pharma. Under the agreement, both companies will co-develop the licensed programs and Astellas will exclusively commercialize them in Japan. In October 2010, Astellas and ASKA Pharmaceutical Co., Ltd. entered into an exclusive worldwide license agreement to develop, manufacture and commercialize AKP-002. AKP-002 is a compound being developed by ASKA for the treatment of lower urinary tract symptoms associated with benign prostatic hyperplasia. The same month Astellas concluded a definitive option agreement with Alavita Pharmaceuticals, Inc. pursuant to which Alavita Pharmaceuticals granted Astellas an exclusive option to acquire substantially all of Alavita's assets and rights relating to Diannexin for the target indication of preventing delayed graft function (DGF) in kidney transplantation. In February 2011, the Group entered into an exclusive collaboration and license agreement with Optimer Pharmaceuticals Inc. for the development and commercialization of fidaxomicin. an investigational antibiotic for Clostridium difficile infection (CDI) in Europe and certain other countries in the Middle East, Africa and the Commonwealth of Independent States (CIS). The same month, Astellas and AVEO entered into a worldwide agreement outside of Asia (including Japan) and the Middle East to develop and commercialize tivozanib, a treatment for a broad range of cancers.

In addition to these moves, in December 2010 Astellas and Cytori Therapeutics entered into a strategic equity agreement to evaluate the potential of adipose derived stem and regenerative cells for the treatment of serious illnesses for which there is no fundamental treatment. Astellas entered this agreement with a view to strengthening its base technologies for creating regenerative drugs in the future. In March 2011, Astellas exercised a buy-out option to acquire all of Maxygen, Inc.'s ownership interest in Perseid Therapeutics LLC, a joint venture between Astellas and Maxygen. Astellas paid US\$76 million in cash for that 83.3% equity interest. Perseid became a wholly owned subsidiary of Astellas in May 2011. With this move, Astellas now has sole ownership of multiple protein pharmaceutical programs, including MAXY-4, which was being co-developed by Astellas and Perseid.

#### Technical Development Initiatives

On the technical development side, in October 2010 Astellas relocated the antibody research group of the Fermentation and Biotechnology Laboratories from Kiyosu City, Aichi Prefecture, to the Tsukuba Biotechnology Research Center (Tokodai) with the aim of promoting closer cooperation with the drug discovery research functions of the Tsukuba Research Center (Miyukigaoka). A facility to manufacture drug substances for antibody development was completed in March 2011, which will further accelerate Astellas' antibody biotechnology research efforts.

#### Other Measures to Bolster the Business Platform

The Astellas Group is also pushing ahead with initiatives designed to strengthen the business platform, as follows. In fiscal 2010, Astellas concluded an exclusive distributorships agreement with Teijin Pharma Limited and two Astellas subsidiaries in mainland China and Hong Kong in April 2010 regarding the marketing of TMX-67 in China and Hong Kong. TMX-67 is a treatment for hyperuricemia in patients with gout. This follows an exclusive distributorship agreement already concluded in Taiwan. In December 2010, Astellas acquired the license extension (originally held in Europe) for commercialization of the treatment for advanced prostate cancer Eligard from TOLMAR Inc. in a selection of Asian, Middle Eastern, North African and Commonwealth of Independent States (CIS) countries. In January 2011, Astellas' affiliate exercised its right under its agreement with its co-promotion partner, a US subsidiary of GlaxoSmithKline, to assume full commercial responsibility in the US for VESIcare. As a result of this move, co-promotion of VESIcare in the US will end in December 2011, after which Astellas' affiliate will undertake all promotional activities from January 2012. In March 2011, Astellas entered into an exclusive license agreement with Cardeus Pharmaceuticals, Inc. to develop, manufacture and commercialize three Astellas compounds in all territories excluding Japan—two clinical stage compounds (If channel inhibitor YM758, and selective COX1 inhibitor ASP6537), and one pre-clinical stage compound.

# Consolidated Forecasts for Year Ending March 31,

**2012 (Fiscal 2011)** (Announced May 2011) Consolidated forecasts for fiscal 2011 are as follows.

# Fiscal 2011 Forecasts

		(¥ billion)
	2011.3	2012.3 (forecasts)
Net sales	¥953.9	¥974.0
Operating income	119.2	135.0
Net income	67.7	81.0
		(¥)
Average foreign exchange rates US\$1	¥ 86	¥ 80
€1	113	110

Net sales are forecast to increase by 2.1% to ¥974.0 billion.

Astellas expects to report higher prescription drugs sales in the Japanese market in fiscal 2011. The main contributors to growth are projected to be mainstay products such as Vesicare, Prograf (including Graceptor), Micardis (including Micombi and Micamlo) and Myslee, as well as new products such as Symbicort, Celecox, Bonoteo and Geninax.

In the Americas, while Prograf sales are expected to decline in the US due to the impact of generic products, higher sales are forecasted overall in the region. This forecast is based on steady sales growth for VESIcare, Mycamine and Scan, and the contribution to sales from Tarceva and certain other products.

In Europe, Vesicare, Mycamine and Eligard should see higher sales. Astellas is also projecting royalty income from bendamustine to contribute to sales increase in Europe. Contrastingly, sales of Prograf and Harnal (which is marketed in Europe under the brand names Omnic and Omnic OCAS) through our own distribution channel are projected to decline.

Sales in Asia are expected to grow due to products such as Prograf, Vesicare and Mycamine.

Operating income is forecast to increase 13.3% to ¥135.0 billion. Gross profit is expected to increase on the back of higher net sales.

Astellas expects an increase in overall SG&A expenses. R&D spending is expected to decline 8.4% to ¥199.0 billion, equivalent to a ratio of R&D spending to net sales of 20.4%. Upfront payments from in-licensing agreements are expected to be lower than the large amounts in fiscal 2010. Excluding R&D spending, SG&A expenses are projected to rise due to costs accompanying sales promotion and expansion of sales areas, as well as amortization expenses for patents and goodwill recognized in association with the acquisition of OSI.

Net income is projected to increase 19.7% to ¥81.0 billion.

This forecast factors in a loss of ¥1.5 billion for fixed costs arising from the suspension of operations of disaster-affected research centers, plants and assets.

## **Number of Employees**

As of March 31, 2011, the Astellas Group employed 16,279 people (a year-on-year increase of 1,118).

Employee headcount was 8,023 in Japan (up 163 from the previous year-end). This reflected efforts to strengthen functions in manufacturing divisions, and to build a stronger sales force in step with new product launches. In the Americas, regional headcount was 2,742 (up 367), reflecting in part the addition of 313 employees due to the OSI acquisition. The overall increase also reflected an increase in personnel to strengthen functions of R&D divisions, and because of the establishment of a sales affiliate in Brazil. On the other hand, the number of personnel in production divisions declined. Employee numbers in Europe were 4,102 (up 327), with 110 employees added by the OSI acquisition. In addition, the number of sales personnel was increased in step with business area expansion and new product launches. The regional headcount in Asia was 1,412 (up 261) as the Group recruited more MRs in China, as well as South Korea, Indonesia, the Philippines, and India.

The total number of MRs employed by the Astellas Group worldwide was 5,800 at the end of March 2011, a year-on-year increase in the sales force of 300 people.

#### Number of Employees by Geographical Area

		(persons)
	2010.3	2011.3
Total	15,161	16,279*
Japan	7,860	8,023
Americas	2,375	2,742*
Europe	3,775	4,102*
Asia	1,151	1,412

\* Includes OSI employees (423 in total as of March 31, 2011)

# Number of MRs by Geographical Area

		(persons)
	2010.3	2011.3
Total	5,500	5,800*
Japan	2,400	2,400
Americas	980	1,000*
Europe	1,500	1,630
Asia	670	770

\* Includes OSI MRs

# **Financial Condition**

# Assets

Total assets as of March 31, 2011 amounted to ¥1,335.1 billion. This figure was ¥29.1 billion lower than at the end of the previous fiscal year-end.

Current assets of ¥653.2 billion were ¥335.4 billion lower than a year earlier. Cash and cash equivalents and short-term investments declined ¥256.5 billion and ¥116.0 billion, respectively, mainly due to the purchase of OSI shares.

Property, plant and equipment at cost was ¥190.2 billion, ¥5.7 billion higher year on year. The increase reflected mainly new buildings at a European subsidiary. On the other hand, equipment declined in Japan.

Investments and other assets increased ¥300.6 billion to ¥491.8 billion. Investment securities declined ¥10.4 billion to ¥59.4 billion due to a decline in the balance of funds invested and the sale of shareholdings. However, patents and goodwill increased substantially in line with the OSI acquisition. Patents stood at ¥236.7 billion at March 31, 2011, compared with ¥14.5 billion at March 31, 2010, when this figure was included in other intangible assets. Goodwill was ¥101.3 billion, up ¥79.1 billion from March 31, 2010.

#### Liabilities

Total liabilities of ¥314.0 billion at March 31, 2011 represented an increase of ¥3.8 billion, compared with the previous fiscal year.

Current liabilities declined ¥37.5 billion to ¥239.6 billion. Trade under notes and accounts payable declined ¥39.7 billion.

Total long-term liabilities increased ¥41.3 billion to ¥74.3 billion. Deferred tax liabilities increased ¥42.2 billion due to the recording of deferred tax liabilities relating to business combination accounting for the purchase of OSI shares.

#### **Net Assets**

Net assets totaled ¥1,021.1 billion at March 31, 2011, a decrease of ¥32.8 billion compared with a year earlier.

Total shareholders' equity amounted to ¥1,130.7 billion at March 31, 2011, an increase of ¥9.9 billion. Major items included net income of ¥67.7 billion and payments of ¥57.7 billion in cash dividends from retained earnings.

Total accumulated other comprehensive income was negative ¥111.1 billion, ¥42.7 billion more than at March 31, 2010. Translation adjustments increased by ¥38.0 billion to negative ¥120.6 billion due to the impact of the yen's appreciation.

#### Liquidity and Financing

To strengthen and develop the ethical pharmaceutical business, the Astellas Group is constantly working to build market share in the Japanese market, while also developing a global sales and marketing network to boost Astellas' presence in overseas markets. Moreover, the Group will continue to reinforce R&D capabilities to maintain a strong drug discovery capability. In addition, the company is pursuing in-licensing activities globally in order to strengthen its pipeline as part of pursuing strategic business investment opportunities.

A sufficient level of cash and cash equivalents is maintained to enable the Group to target such strategic investment opportunities while also supplying working capital and funding capital expenditures. As of the end of March 2011, the Group's balance sheet carried no interest-bearing debt other than lease obligations.

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

# **Cash Flows**

The balance of cash and cash equivalents at the end of March 2011 was ¥175.5 billion, a decrease of ¥256.5 billion compared with the previous fiscal year-end.

#### **Cash Flows From Operating Activities**

Net cash provided by operating activities amounted to ¥100.6 billion, a decrease of ¥49.5 billion in year-on-year terms. Major factors included a fall in income before income taxes and minority interests of ¥83.3 billion to ¥103.5 billion, and a decline in income taxes paid of ¥34.9 billion to ¥44.4 billion.

#### **Cash Flows From Investing Activities**

Net cash used in investing activities increased ¥211.1 billion to ¥242.6 billion. Acquisition of subsidiaries' shares used cash of ¥284.1 billion. On the other hand, decrease in short-term investments provided cash of ¥89.6 billion.

#### **Cash Flows From Financing Activities**

Net cash used in financing activities totaled ¥93.3 billion, ¥7.4 billion more than the previous fiscal year. Cash dividends used cash of ¥57.7 billion, ¥1.3 billion more year on year. Furthermore, cash of ¥35.0 billion was used for the redemption of bonds issued by OSI. Meanwhile, cash used for purchases of treasury stock declined by ¥27.0 billion year on year.

## **Capital Expenditures**

The Astellas Group makes capital expenditures on an ongoing basis with the aim of reinforcing R&D, production, sales and marketing capabilities and boosting operational efficiency. Capital expenditures in fiscal 2010 totaled ¥35.1 billion (based on the value of property, plant and equipment). A Fermentation Technology Research Building was constructed at the Toyama Plant to reinforce production capacity for active pharmaceutical ingredients for candidate compounds derived from the fermentation of natural substances. Other capital spending was undertaken to upgrade and renew various functional capabilities and equipment across production and research.

Capital spending is forecast to increase 25.2% to ¥44.0 billion in fiscal 2011.

# Net Income, Cash Dividends and Net Assets per Share Per Share Data

		(+)
	2010.3	20011.3
Net income		
Basic	¥ 261.84	¥ 146.49
Diluted	261.62	146.33
Cash dividends	125.00	125.00
Net assets	2,278.77	2,207.70

00

#### **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 sustained growth in dividends, based on medium- to long-term consolidated earnings growth and taking the dividend-on-equity (DOE) ratio into consideration. Furthermore, Astellas will flexibly purchase treasury stock as necessary to improve capital efficiency and the level of return to shareholders.

#### **Common Stock**

	(thousands of shares)	
	2010.3	2011.3
Total number of shares issued	475,965	467,965
Shares in treasury	14,146	6,138

Treasury stock acquisitions in fiscal 2010 are summarized below.

Treasury Stock	2010.3	2011.3
Number of shares bought back*	8,200 thousand	
Acquisition cost*	¥27.0 billion	—
Number of shares cancelled	28,000	8,000
	thousand	thousand
Amount cancelled	128.1 billion	30.6 billion

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

#### **ROE and DOE**

Return on equity (ROE) was 6.5%, down 5.2 percentage points from fiscal 2009. The DOE ratio was 5.6%, the same level as fiscal 2009.

(%)		
2011.3	2010.3	
6.5	11.7	ROE
5.6	5.6	DOE

# **Business Risks**

The main risks that could significantly impact the business results and financial position of the Astellas Group are outlined below.

#### Inherent uncertainties in pharmaceutical R&D

In general, the probability of discovering a promising compound through drug discovery research is not high. Further, it takes a large amount of investments and a great deal of time to successfully launch a new product after discovery of a new compound. However, it may be necessary to discontinue clinical development if the effectiveness of a drug is not proven as initially expected, or if safety issues arise. In addition, pharmaceuticals are subject to legal restrictions in each country, so that authorization from local regulatory authorities is a prerequisite for a product launch in each country. It is difficult to accurately foresee if and when approvals for new products can be obtained.

The Astellas Group's R&D activities are subject to these inherent risks.

#### Sales-related risk

The pharmaceutical industry operates in a highly competitive environment characterized by rapid technological innovation. The Astellas Group faces fierce competition from drug makers and generics manufacturers based in Japan or overseas. The launch of competitive products by rivals could impact the Astellas Group's business results significantly.

#### • Intellectual property (IP) risk

The Astellas Group's ethical pharmaceuticals business benefits from the protection of many patents. Although the Astellas Group manages intellectual property rights properly and is vigilant against third party violation of such rights, the adverse impact on the Astellas Group's business results of actual IP violations may still be substantial. The Astellas Group's business results are also subject to the outcome of litigation undertaken by the Astellas Group to protect patents where infringement has occurred.

While the Astellas Group strives to ensure that its actions do not infringe the IP rights of other parties, there is a risk of litigation in the event of any inadvertent violations. Such litigation could also impact the Astellas Group's business results significantly.

#### • Risks relating to product side effects and safety

Any problems arising due to serious side effects or other safety issues that are caused by the Astellas Group's products could impact the Astellas Group's business results significantly.

#### • Pharmaceutical regulatory risk

The ethical pharmaceutical business is governed by a wide variety of regulations in each country. In Japan, for example, the authorities periodically revise the NHI drug prices. Governments in developed countries in particular continue to adopt measures aimed at containing medical expenditures. Any trend toward stricter regulations governing the development, manufacture or distribution of pharmaceuticals is a factor that could impact business results.

#### Environment-related risks

The Astellas Group is careful to observe laws and regulations relating to environmental or health and safety issues, and has instituted internal standards that aim to exceed most statutory requirements. Despite such precautions, the costs involved in the unlikely event of a business-related incident causing a serious breach of compliance in this area could impact the Astellas Group's business results significantly.

#### Foreign exchange rate fluctuations

The Astellas Group's business results and financial position are subject to the impact of exchange rate fluctuations due to the Astellas Group's extensive international operations.

In addition to the risks outlined above, the Astellas Group is exposed to a wide range of business-related risks, including but not limited to (1) general commercial litigation, (2) delays or suspension of manufacturing activities due to natural disasters or other factors, and (3) partial dependence on licensing or sales agreements relating to pharmaceuticals developed by other companies.

# **Consolidated Balance Sheets**

Astellas Pharma Inc. and Subsidiaries March 31, 2011 and 2010

(322,037) 190,160 59,370 2,190 236,737 101,255 29,186 52,294 10,745 491,777	(319,965) 184,490 69,772 1,251  22,159 40,601 46,900 10,460 191,143	2,291 715 26 2,852 1,220 352 630 130 5,925
190,160 59,370 2,190 236,737 101,255 29,186 52,294 10,745	184,490 69,772 1,251 — 22,159 40,601 46,900 10,460	2,291 715 26 2,852 1,220 352 630 130
190,160 59,370 2,190 236,737 101,255 29,186 52,294	184,490 69,772 1,251  22,159 40,601 46,900	2,291 715 26 2,852 1,220 352 630
190,160 59,370 2,190 236,737 101,255 29,186	184,490 69,772 1,251 – 22,159 40,601	2,291 715 26 2,852 1,220 352
190,160 59,370 2,190 236,737 101,255	184,490 69,772 1,251 — 22,159	2,291 715 26 2,852 1,220
190,160 59,370 2,190 236,737	184,490 69,772 1,251 —	2,291 715 26 2,852
190,160 59,370 2,190	184,490 69,772	2,291 715 26
190,160 59,370	184,490 69,772	2,291 715
190,160	184,490	2,291
(322,037)	(319,965)	
		(3,880
24,128	18,680	291
2,944	3,142	35
221,745	218,612	2,672
232,006	233,831	2,795
31,374	30,190	378
653,154	988,544	7,869
13,948	9,681	168
67,804	63,316	817
116,882	111,054	1,408
277,716	255,219	3,346
(1,396)	(1,651)	(17
279,112	256,870	3,363
1,338	117,354	16
¥ 175,466	¥ 431,920	\$ 2,114
2011		(Note 4)
	1,338 279,112 (1,396) 277,716 116,882 67,804 13,948 653,154 653,154 31,374 232,006 221,745 2,944 24,128	¥       175,466       ¥       431,920         1,338       117,354         279,112       256,870         (1,396)       (1,651)         277,716       255,219         116,882       111,054         67,804       63,316         13,948       9,681         653,154       988,544         31,374       30,190         232,006       233,831         221,745       218,612         2,944       3,142         24,128       18,680

			Millions of U.S. dollars
Liabilities and net assets	2011	Millions of yen 2010	(Note 4) 2011
Current liabilities:			
Notes and accounts payable (Note 17):			
Trade	¥ 124,293	¥ 163,968	\$ 1,498
Construction	14,940	14,021	180
Accrued expenses	76,590	66,050	923
Accrued income taxes (Note 9)	19,814	21,216	239
Deferred tax liabilities (Note 9)		12	_
Other (Note 6)	4,011	11,891	47
Total current liabilities	239,648	277,158	2,887
Long-term liabilities:			
Accrued retirement benefits for employees (Note 11)	17,235	17,638	208
Deferred tax liabilities (Note 9)	42,248	_	509
Other (Note 6)	14,863	15,448	179
Total long-term liabilities	74,346	33,086	896
Net assets (Notes 7 and 15):			
Shareholders' equity:			
Common stock, without par value:			
Authorized: 2,000,000,000 shares;			
lssued: 467,964,635 shares in 2011 and 475,964,635 shares in 2010	103,001	103,001	1,241
Capital surplus	176,822	176,822	2,130
Retained earnings	874,351	895,101	10,535
Treasury stock, at cost:			
6,138,000 shares in 2011 and 14,146,832 shares in 2010	(23,492)	(54,160)	(283
Total shareholders' equity	1,130,682	1,120,764	13,623
Accumulated other comprehensive income	.,,	.,	,
Unrealized holding gain on securities	9,480	14,154	114
Translation adjustments	(120,588)	(82,543)	(1,453
Total accumulated other comprehensive income	(111,108)	(68,389)	(1,339
Stock subscription rights	1,523	1,206	18
Minority interests	.,525	352	
Total net assets	1,021,097	1,053,933	12,302
Contingent liabilities (Note 14)			
Total liabilities and net assets	¥1,335,091	¥1,364,177	\$16,085

# **Consolidated Statements of Income**

Astellas Pharma Inc. and Subsidiaries Years ended March 31, 2011, 2010 and 2009

		Millions of yen		Millions of U.S. dollars (Note 4)	
	2011	2010	2009	2011	
Net sales	¥953,948	¥974,878	¥965,698	\$11,493	
Cost of sales	295,973	289,241	264,431	3,566	
Gross profit	657,975	685,637	701,267	7,927	
Selling, general and administrative expenses (Note 12)	538,794	499,230	450,872	6,491	
Operating income	119,181	186,407	250,395	1,436	
Other income (expenses):					
Interest and dividend income	2,338	3,939	11,380	28	
Exchange (loss) gain	(6,556)	225	9,251	(79)	
Equity in (losses) earnings of affiliates	(89)	84	(47)	(1)	
Gain on sale of investment securities	1,280	2,700	500	15	
Loss on impairment of fixed assets	(2,782)	(4,082)	(1,340)	(34)	
Loss on sales and disposal of fixed assets	(1,277)	(2,282)	(3,079)	(15)	
Business integration expenses	(4,723)	_	-	(57)	
Loss on disaster	(3,029)	—	-	(36)	
Loss on adjustment for changes of accounting standard for asset retirement obligations	(560)	_	_	(7)	
Special retirement benefits	_	_	(2,526)	_	
Loss on devaluation of investment securities		_	(1,976)	_	
Compensation for cancellation of contracts		_	(1,364)	_	
Other, net	(300)	(189)	1,498	(3)	
	(15,698)	395	12,297	(189)	
Income before income taxes and minority interests	103,483	186,802	262,692	1,247	
Income taxes (Note 9):					
Current	43,554	64,717	86,851	525	
Deferred	(7,722)	(2,111)	2,771	(93)	
	35,832	62,606	89,622	432	
Income before minority interests	67,651	124,196	173,070	815	
Minority interests		(1,939)	(2,084)		
Net income (Note 15)	¥ 67,651	¥122,257	¥170,986	\$ 815	

# **Consolidated Statement of Comprehensive Income**

Astellas Pharma Inc. and Subsidiaries Year ended March 31, 2011

	Millions of yen	Millions of U.S. dollars (Note 4) <b>2011</b>
Income before minority interests	¥ 67,651	\$ 815
Other comprehensive income:		
Unrealized holding gain on securities	(4,674)	(56)
Translation adjustments	(38,045)	(459)
Total other comprehensive income	(42,719)	(515)
Comprehensive income (Note 10)	¥ 24,932	\$ 300
Total comprehensive income attributable to:		
Shareholders of the Company	¥ 24,932	\$ 300
Minority interests	—	_

# **Consolidated Statements of Changes in Net Assets**

Astellas Pharma Inc. and Subsidiaries Years ended March 31, 2011, 2010 and 2009

Number of shares issued	2011	2010	2009
Beginning of year	475,964,635	503,964,635	518,964,635
Cancellation of treasury stock	(8,000,000)	(28,000,000)	(15,000,000)
End of year	467,964,635	475,964,635	503,964,635

									Millions of yen
				Shar	eholders' equity	Accumulated			
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity	other comprehensive income	Stock subscription rights	Minority interests	Total net assets
Balance as of March 31, 2008	¥ 103,001	¥ 176,822	¥ 917,206	¥(104,123)	¥ 1,092,906	¥ 16,992	¥ 637	¥ 328	¥ 1,110,863
Cash dividends paid			(58,625)		(58,625)				(58,625)
Net income			170,986		170,986				170,986
Purchase of treasury stock				(123,600)	(123,600)				(123,600)
Disposal of treasury stock			(80)	287	207				207
Cancellation of treasury stock			(72,141)	72,141					
Net change in items other than shareholders' equity						(69,878)	258	10	(69,610)
Total movements during the year			40,140	(51,172)	(11,032)	(69,878)	258	10	(80,642)
Balance as of March 31, 2009	103,001	176,822	957,346	(155,295)	1,081,874	(52,886)	895	338	1,030,221
Cash dividends paid			(56,402)		(56,402)				(56,402)
Net income			122,257		122,257				122,257
Purchase of treasury stock				(26,997)	(26,997)				(26,997)
Disposal of treasury stock			(17)	49	32				32
Cancellation of treasury stock			(128,083)	128,083					
Net change in items other than shareholders' equity						(15,503)	311	14	(15,178)
Total movements during the year			(62,245)	101,135	38,890	(15,503)	311	14	23,712
Balance as of March 31, 2010	103,001	176,822	895,101	(54,160)	1,120,764	(68,389)	1,206	352	1,053,933
Cash dividends paid			(57,728)		(57,728)				(57,728)
Net income			67,651		67,651				67,651
Purchase of treasury stock				(30)	(30)				(30)
Disposal of treasury stock			(46)	71	25				25
Cancellation of treasury stock			(30,627)	30,627					
Net change in items other than shareholders' equity						(42,719)	317	(352)	(42,754)
Total movements during the year			(20,750)	30,668	9,918	(42,719)	317	(352)	(32,836)
Balance as of March 31, 2011	¥103,001	¥176,822	¥874,351	¥(23,492)	¥1,130,682	¥(111,108)	¥1,523	¥ —	¥1,021,097

Millions of U.S. dollars (Note 4)

				Share	eholders' equity	Accumulated			
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity	other comprehensive income	Stock subscription rights	Minority interests	Total net assets
Balance as of March 31, 2010	\$ 1,241	\$ 2,130	\$ 10,785	\$ (652)	\$ 13,504	\$ (824)	\$14	\$4	\$ 12,698
Cash dividends paid			(696)		(696)				(696)
Net income			815		815				815
Purchase of treasury stock				(0)	(0)				(0)
Disposal of treasury stock			(1)	1	0				0
Cancellation of treasury stock			(368)	368					
Net change in items other than shareholders' equity						(515)	4	(4)	(515)
Total movements during the year			(250)	369	119	(515)	4	(4)	(396)
Balance as of March 31, 2011	\$1,241	\$2,130	\$10,535	\$(283)	\$13,623	\$(1,339)	\$18	\$—	\$12,302

# **Consolidated Statements of Cash Flows**

Astellas Pharma Inc. and Subsidiaries Years ended March 31, 2011, 2010 and 2009

				Millions of U.S. dollars
	2011	2010	Millions of yen 2009	(Note 4) 2011
Operating activities				
Income before income taxes and minority interests	¥ 103,483	¥186,802	¥ 262,692	\$ 1,247
Depreciation and amortization	65,674	48,466	42,890	791
Loss on impairment of fixed assets	2,782	4,082	1,340	34
Gain on sale of investment securities	(1,280)	(2,700)	(500)	(15)
Notes and accounts receivable	(43,893)	1,310	(17,487)	(529)
Inventories	(10,678)	(8,741)	(26,569)	(129)
Notes and accounts payable	(4,340)	(2,051)	26,012	(52)
Accrued expenses	7,280	12,032	(54)	88
Accrued retirement benefits for employees	1,346	1,547	(93)	16
Other	22,600	(15,391)	(16,107)	272
Subtotal	142,974	225,356	272,124	1,723
Interest and dividends received	2,288	4,098	12,196	28
Interest paid	(220)	_	_	(3)
Income taxes paid	(44,403)	(79,323)	(86,529)	(535)
Net cash provided by operating activities	100,639	150,131	197,791	1,213
<b>Investing activities</b> Purchases of property, plant and equipment	(33,630)	(39,525)	(36,653)	(405)
Proceeds from sale of property, plant and equipment	628	1,014	5,811	8
Acquisition of subsidiaries' shares	(284,148)	_	-	(3,423)
Decrease in short-term investments	89,598	28,584	24,454	1,079
Decrease (increase) in investment securities	5,385	1,940	(18,013)	65
Increase in other assets	(17,083)	(24,776)	(10,902)	(206)
Other	(3,397)	1,182	6,315	(42)
Net cash used in investing activities	(242,647)	(31,581)	(28,988)	(2,924)
Financing activities				
Redemption of bonds	(34,968)	—	-	(421)
Purchases of treasury stock	(30)	(26,997)	(123,600)	(0)
Cash dividends	(57,728)	(56,402)	(58,625)	(696)
Other	(542)	(2,503)	(2,451)	(7)
Net cash used in financing activities	(93,268)	(85,902)	(184,676)	(1,124)
Effects of exchange rate changes on cash and cash equivalents	(21,178)	(10,555)	(34,786)	(255)
(Decrease) increase in cash and cash equivalents	(256,454)	22,093	(50,659)	(3,090)
Cash and cash equivalents at beginning of year	431,920	409,827	460,486	5,204
Cash and cash equivalents at end of year	¥ 175,466	¥431,920	¥ 409,827	\$ 2,114

Astellas Pharma Inc. and Subsidiaries

# **1. Basis of Presentation**

Astellas Pharma Inc. (the "Company") and its domestic subsidiaries maintain their accounting records and prepare their financial statements in accordance with accounting principles generally accepted in Japan, and its foreign subsidiaries maintain their books of account in conformity with International Financial Reporting Standards (IFRS) or accounting principles generally accepted in the United States.

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally

accepted in Japan, which are different in certain respects as to the application and disclosure requirements of IFRS, and are compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Law.

Certain amounts in the prior years' consolidated financial statements have been reclassified to conform to the current year presentation.

# 2. Summary of Significant Accounting Policies

# (a) Basis of consolidation and accounting for investments in subsidiaries and affiliates

The accompanying consolidated financial statements include the accounts of the Company and all subsidiaries ("Astellas"). Companies over which the Company exercises significant influence in terms of their operating and financial policies are included in the consolidated financial statements on an equity basis. As of March 31, 2011, the numbers of consolidated subsidiaries, and subsidiaries and affiliates accounted for by the equity method were 82 and 3 (66 and 3 in 2010), respectively. All significant intercompany balances and transactions are eliminated in consolidation.

All subsidiaries close their books of account at March 31 for financial reporting purposes.

The excess of cost over underlying fair value of net assets at the date of acquisition is amortized over periods not exceeding 20 years on a straight-line basis except that when the excess amount is immaterial, it is fully charged to income in the year of acquisition. Such amortization is included in selling, general and administrative expenses.

#### (b) Foreign currency translation

Receivables and payables denominated in foreign currencies are translated into Japanese yen at the year-end rates, and foreign exchange gains or losses are charged to current income / expense.

Revenue and expense accounts of the foreign subsidiaries are translated into yen using the average exchange rates during the year and, except for the components of net assets excluding minority interests, the balance sheet accounts are translated into yen at the exchange rates in effect at the balance sheet date. The components of net assets excluding minority interests are translated into yen at their historical exchange rates. Differences arising from the translation are presented as translation adjustments and minority interests in the accompanying consolidated financial statements.

# (c) Cash equivalents

All highly liquid investments with a maturity of three months or less when purchased are considered as cash equivalents.

# (d) Inventories

Inventories of the Company and its domestic subsidiaries are stated principally at the lower of cost or market, cost being determined by the average method. However, inventories of the foreign subsidiaries are stated principally at the lower of cost or market, cost being determined by the first-in, first-out method.

# (e) Depreciation and amortization (excluding lease assets)

Depreciation of property, plant and equipment of the Company and its domestic subsidiaries is calculated principally by the decliningbalance method at rates based on the estimated useful lives of the respective assets. However, depreciation of property, plant and equipment of the foreign subsidiaries is calculated principally by the straight-line method. The useful lives of property, plant and equipment are summarized as follows:

Buildings and structures	2 to 60 years
Machinery and equipment	2 to 20 years

Intangible assets are amortized by the straight-line method over their estimated useful lives.

## (f) Allowance for doubtful receivables

For normal receivables, an allowance for doubtful receivables is provided using the historical experienced default ratio. For specific receivables such as bankruptcy / rehabilitation claims, an allowance for doubtful receivables is provided for the estimated amounts considered to be uncollectible after reviewing individual collectability.

# (g) Leases

Non-cancelable leases are generally classified and accounted for as either finance or operating leases. Depreciation of finance leases for which ownership of the leased assets is not transferred to the lessee is calculated principally by the straight-line method over their useful life being lease period with residual value being zero.

#### (h) Short-term investments and investment securities

Securities other than equity securities issued by the Company's subsidiaries and affiliates are classified into held-to-maturity or other securities. Held-to-maturity securities are carried at amortized cost. Marketable securities classified as other securities are carried at fair value with changes in unrealized gain or loss, net of the applicable income taxes, included directly in net assets. Non-marketable securities classified as other securities are stated at cost. Cost of securities sold is determined by the moving average method.

#### (i) Research and development expenses

Research and development expenses are charged to income as incurred.

#### (j) Income taxes

Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax bases of the

# **3. Accounting Changes**

(a) Effective April 1, 2010, Accounting Standard for Asset Retirement Obligations and Guidance on Accounting Standard for Asset Retirement Obligations have been adopted. This change negatively impacted on operating income by ¥73 million and on income before income taxes and minority interest by ¥633 million for the year ended March 31, 2011 compared to the corresponding amounts which would have been recognized under the previous method. assets and liabilities, and are measured using the effective tax rates and laws which will be in effect when the differences are expected to reverse.

#### (k) Retirement benefits

Accrued retirement benefits for employees and prepaid pension cost are recorded mainly at an amount calculated based on the retirement benefit obligation and the fair value of the pension plan assets at the balance sheet dates, as adjusted for unrecognized actuarial gain or loss and unrecognized past service cost.

Actuarial gain and loss are being amortized from the following year in which the gain or loss is recognized primarily by the straightline method over the average remaining years of service of the employees. Past service cost is being amortized as incurred by the straight-line method over the average remaining years of service of the employees.

#### (I) Derivative financial instruments

Astellas utilizes various derivatives transactions in order to manage certain risks arising mainly from adverse fluctuations in foreign currency exchange rates and interest rates. Derivative financial instruments are carried at fair value with any changes in unrealized gain or loss charged or credited to operations, except for those which meet the criteria for deferral hedge accounting under which unrealized gain or loss is deferred as a component of net assets.

#### (m) Reclassification

Certain reclassifications have been made to the prior years' consolidated financial statements to conform to the presentation for the year ended March 31, 2011.

(b) Effective April 1, 2010, the Company and its domestic subsidiaries adopted the following new standards;

Accounting Standard for Business Combinations, Accounting Standard for Consolidated Financial Statements, Partial amendments to Accounting Standard for Research and Development Costs, Revised Accounting Standard for Business Divestitures, Revised Accounting Standard for Equity Method of Accounting for Investments, and Revised Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures.

- (c) Effective the year ended March 31, 2011, Accounting Standard for Presentation of Comprehensive Income has been adopted. In accordance with this new standard, consolidated statements of comprehensive income for the year ended March 31, 2010 and 2009 are not presented. The comparative information for the year ended March 31, 2010 is disclosed in Note 10.
- (d) Effective April 1, 2009, Partial Amendments to Accounting Standard for Retirement Benefits (Part 3), has been adopted. This change had no impact on the operating results and financial conditions.

# 4. U.S. Dollar Amounts

U.S. dollar amounts presented are solely for convenience, as a matter of arithmetic computation only, translated from yen at \$83 = US \$1.00, the approximate rate of exchange on March 31, 2011. The

translation should not be construed as a representation that yen has been, could have been, or could in the future be, converted into U.S. dollars at the above or any other rates.

. .....

# 5. Inventories

Inventories as of March 31, 2011 and 2010 were as follows:

			Millions of
		Millions of yen	U.S. dollars
	2011	2010	2011
Merchandise and finished goods	¥ 82,656	¥ 82,750	\$ 996
Work in process	13,611	12,152	164
Raw materials and supplies	20,615	16,152	248
Total	¥116,882	¥111,054	\$1,408

# 6. Short-Term Borrowings and Long-Term Debt

There were no short-term borrowings or long-term debt except for lease obligations at March 31, 2011 and 2010. Current portion of lease obligations of ¥399 million (\$5 million) at March 31, 2011 and ¥525 million at March 31, 2010 were included in other current liabilities,

and lease obligations excluding current portion of ¥755 million (\$9 million) at March 31, 2011 and ¥625 million at March 31, 2010 were included in other long-term liabilities.

The aggregate annual maturities of lease obligations for 5 years subsequent to March 31, 2011 are summarized as follows:

Year ending March 31,	Millions of yen	Millions of U.S. dollars
2012	¥ 399	\$5
2013	315	4
2014	231	3
2015	141	1
2016 and thereafter	68	1
Total	¥1,154	\$14

# 7. Net Assets

Changes in net assets for the year ended March 31, 2011 were as follows:

# a. Treasury stock

				(Thousands of shares)
Types of share	Number of shares as of March 31, 2010	Increase	Decrease	Number of shares as of March 31, 2011
Treasury stock: Common stock (Notes 1 and 2)	14,146	10	8,018	6,138
	(Thousan	ds of shares)		
Jotes: 1. Breakdown of the increase of treasury stock are as follows Increase due to purchase of the stocks of less than standa 2. Breakdown of the decrease of treasury stock are as follow:	rd unit	10		
Decrease due to cancellation		8,000		
Decrease due to exercise of stock subscription rights Decrease due to sale of the stocks of less than standard unit		17 1		

# b. Dividends

1) Dividends paid during the year ended March 31, 2011

Resolution	Type of shares	Total amounts paid (Millions of yen)	Dividends per share (Yen)	Cut-off date	Total amounts paid (Millions of U.S. dollars)	Dividends per share (U.S. dollars)
Annual shareholders' meeting on June 23, 2010	Common stock	30,018	65	March 31, 2010	362	0.78
Board of Directors on November 1, 2010	Common stock	27,710	60	September 30, 2010	334	0.72

2) Dividends whose cut-off date was in the year ended March 31, 2011 and effective date is in the year ending March 31, 2012

Resolution	Type of shares	Total amounts paid (Millions of yen)	Dividends per share (Yen)	Cut-off date	Total amounts paid (Millions of U.S. dollars)	Dividends per share (U.S. dollars)
Annual shareholders' meeting on June 20, 2011	Common stock	30,019	65	March 31, 2011	362	0.78

#### c. Stock subscription rights

In July 2010, the Company issued 1,387 units of stock subscription rights, for which ¥254 million (\$3 million) was recorded as a component of net assets as of March 31, 2011. The stock subscription rights included rights unvested as of March 31, 2011.

# 8. Stock Option Plan

The Company has implemented a stock option plan under which stock subscription rights were granted to directors, corporate officers and employees of the Company.

The following table summarizes the Company's stock option plan:

		Stock subscription rights granted as a stock opti		
		Granted on July 1, 2003	Granted on July 1, 2004	Granted on August 31, 2005
Individuals covered by the plan	Directors of the Company	18	4	6
	Corporate officers of the Company	_	16	26
	Employees of the Company	37	36	
	Total	55	56	32
Type and number of shares to be issued upon the exercise of the stock subscription rights	Common stock	141,000	147,000	104,800
Vesting period				From July 1, 2005 to June 23, 2006
Exercise period		From July 1, 2005 to June 27, 2013	From July 1, 2006 to June 24, 2014	From September 1, 2005 to June 24, 2025

		Stock subscription rights granted as a stock option plar		
		Granted on February 13, 2007	Granted on August 10, 2007	Granted on September 16, 2008
Individuals covered by the plan	Directors of the Company	4	4	3
	Corporate officers of the Company	27	26	23
	Employees of the Company	—		
	Total	31	30	26
Type and number of shares to be issued upon the exercise of the	Commented	75 700	74.000	72,700
stock subscription rights	Common stock	75,700	74,000	72,700
Vesting period		From July 1, 2006 to June 26, 2007	From July 1, 2007 to June 25, 2008	From July 1, 2008 to June 23, 2009
Exercise period		From February 14, 2007 to June 27, 2026	From August 11, 2007 to June 26, 2027	From September 17, 2008 to June 24, 2028

		Stock subscription rights granted as a stoc option pla	
		Granted on July 8, 2009	Granted on July 8, 2010
Individuals covered by the plan	Directors of the Company	3	3
	Corporate officers of the Company	25	26
	Employees of the Company		
	Total	28	29
Type and number of shares to be issued upon the exercise of the			
stock subscription rights	Common stock	114,900	138,700
Vesting period		From July 1, 2009 to June 22, 2010	From July 1, 2010 to June 22, 2011
Exercise period		From July 9, 2009 to June 23, 2029	From July 9, 2010 to June 23, 2030

Conditions for the exercise of stock subscription rights are as follows:

1) For stock options granted in 2003 and 2004, there are no vesting conditions.

2) For stock options granted in 2005 and thereafter, individuals granted stock options are required to meet certain criteria.

The following table summarizes the movements of stock subscriptions rights:

	Stock subscription rights granted as a stock option plan		
	Granted on July 1, 2003	Granted on July 1, 2004	Granted on August 31, 2005
Unvested stock subscription rights (shares)			
Outstanding as of March 31, 2010	_	_	_
Granted	_	_	—
Forfeited	_	_	_
Vested	_	_	—
Outstanding as of March 31, 2011	_	_	
Vested stock subscription rights (shares)			
Outstanding as of March 31, 2010	13,800	69,100	88,000
Vested	_	_	—
Exercised	_	_	11,900
Forfeited	_	_	—
Outstanding as of March 31, 2011	13,800	69,100	76,100
Exercise price (Yen)	3,209	3,690	1
Weighted average exercise price (Yen)	_	_	3,052
Weighted average fair value per stock at the granted date (Yen)	_	_	—
Exercise price (U.S. dollars)	38.66	44.46	0.01
Weighted average exercise price (U.S. dollars)	_	_	36.77
Weighted average fair value per stock at the granted date (U.S. dollars)	_		_

	Stock subscription rights granted as a stock option plan		
	Granted on February 13, 2007	Granted on August 10, 2007	Granted on September 16, 2008
Unvested stock subscription rights (shares)			
Outstanding as of March 31, 2010	_	—	_
Granted	_	—	_
Forfeited	_	—	_
Vested	_	—	_
Outstanding as of March 31, 2011	_	_	_
Vested stock subscription rights (shares)			
Outstanding as of March 31, 2010	67,300	70,200	72,700
Vested	_	—	_
Exercised	2,700	—	_
Forfeited	_	—	_
Outstanding as of March 31, 2011	64,600	70,200	72,700
Exercise price (Yen)	1	1	1
Weighted average exercise price (Yen)	3,076	—	_
Weighted average fair value per stock at the granted date (Yen)	5,009	4,639	3,980
Exercise price (U.S. dollars)	0.01	0.01	0.01
Weighted average exercise price (U.S. dollars)	37.06	—	_
Weighted average fair value per stock at the granted date (U.S. dollars)	60.35	55.89	47.95

	Stock subscription rights	granted as a stock option plan
	Granted on July 8, 2009	Granted on July 8, 2010
Unvested stock subscription rights (shares)		
Outstanding as of March 31, 2010	28,725	_
Granted	—	138,700
Forfeited	—	_
Vested	28,725	104,025
Outstanding as of March 31, 2011	_	34,675
Vested stock subscription rights (shares)		
Outstanding as of March 31, 2010	86,175	_
Vested	28,725	104,025
Exercised	2,800	_
Forfeited	—	_
Outstanding as of March 31, 2011	112,100	104,025
Exercise price (Yen)	1	1
Weighted average exercise price (Yen)	3,142	_
Weighted average fair value per stock at the granted date (Yen)	2,942	2,440
Exercise price (U.S. dollars)	0.01	0.01
Weighted average exercise price (U.S. dollars)	37.86	_
Weighted average fair value per stock at the granted date (U.S. dollars)	35.45	29.40

Stock option expense was included in selling, general and administrative expenses for the year ended March 31, 2011 and amounted to ¥338 million (\$4 million). The fair value of options granted on July 8, 2010 was estimated using the binominal model with the following weighted average assumptions.

	Stock subscription rights granted on July 8, 2010 as a stock option plan
Expected volatility	30.38%
Expected holding period	5 years
Expected dividend per share	125 yen
Risk-free rate	1.88%

# 9. Income Taxes

Income taxes applicable to the Company and its domestic subsidiaries comprise corporation tax, inhabitants' taxes and enterprise tax which, in the aggregate, resulted in statutory tax rate of approximately 41% for 2011, 2010 and 2009. Income taxes of the foreign subsidiaries are based generally on the tax rates applicable in their countries of incorporation.

The effective tax rates reflected in the consolidated statements of income for the years ended March 31, 2011, 2010 and 2009 differ from the statutory tax rate for the following reasons:

	2011	2010	2009
Statutory tax rate	41.0%	41.0%	41.0%
Effect of:			
Tax credit for research and development expenses	(9.6)	(7.0)	(4.5)
Different tax rates applied to income of foreign subsidiaries	(9.1)	(6.3)	(4.2)
Expenses not deductible for income tax purposes	5.8	3.3	2.2
Amortization of goodwill	4.4	2.1	1.2
Other, net	2.1	0.4	(1.6)
Effective tax rates	34.6%	33.5%	34.1%

The significant components of the deferred tax assets and liabilities as of March 31, 2011 and 2010 were as follows:

		Millions of yen	
	2011	2010	2011
Deferred tax assets:			
Loss on devaluation of investment securities	¥ 2,294	¥ 2,743	\$ 28
Accrued retirement benefits	7,887	6,945	95
Depreciation and amortization	53,647	39,804	646
Loss on impairment of fixed assets	3,934	4,907	47
Accrued expenses	23,376	22,845	282
Inventories	21,598	20,401	260
Accrued enterprise and other taxes	1,519	1,779	18
Tax loss carryforwards	26,796	—	323
Other	35,958	36,899	434
Gross deferred tax assets	177,009	136,323	2,133
Valuation allowance	(10,211)	(8,581)	(123)
Total deferred tax assets	166,798	127,742	2,010
Deferred tax liabilities:			
Unrealized holding gain on securities	5,111	9,071	62
Depreciation and amortization	728	564	9
Intangible assets related to business combination	75,205	_	906
Other	7,904	7,903	95
Total deferred tax liabilities	88,948	17,538	1,072
Net deferred tax assets	¥ 77,850	¥110,204	\$ 938

# 10. Comprehensive Income

The following table shows components of other comprehensive income for the year ended March 31, 2010.

	Millions of yen 2010
Income before minority interests	¥124,196
Other comprehensive income:	
Unrealized holding gain on securities	4,135
Translation adjustments	(19,638)
Total other comprehensive income	(15,503)
Comprehensive income	¥108,693
Total comprehensive income attributable to:	
Shareholders of the Company	¥106,754
Minority interests	¥ 1,939

## **11. Retirement Benefit Plans**

The Company and its domestic subsidiaries have defined benefit plans, corporate pension fund plans and lump-sum payment plans, and defined contribution plans.

In addition, certain employees may be entitled to additional special retirement benefits upon early termination of employment

based on the conditions under which termination occurs. Such benefits are not subject to the actuarial calculation required by the accounting standard for retirement benefits.

Certain foreign subsidiaries have defined benefit plans and defined contribution plans.

The following table sets forth the funded and accrued status of the plans, and the amounts recognized in the consolidated balance sheets as of March 31, 2011 and 2010 for the defined benefit plans:

		U.S. dollars			
	2011	2010	2011		
Retirement benefit obligation	¥(146,105)	¥(146,961)	\$(1,760)		
Plan assets at fair value	117,570	120,661	1,416		
Unfunded retirement benefit obligation	(28,535)	(26,300)	(344)		
Unrecognized actuarial loss	20,367	18,647	245		
Unrecognized past service cost	(7,607)	(8,192)	(91)		
Net retirement benefit obligation	(15,775)	(15,845)	(190)		
Prepaid pension cost	1,460	1,793	18		
Accrued retirement benefits	¥ (17,235)	¥ (17,638)	\$ (208)		

The components of retirement benefit expenses for the years ended March 31, 2011, 2010 and 2009 are outlined as follows:

			Millions of U.S. dollars	
	2011	2010	2009	2011
Service cost	¥ 4,539	¥ 4,399	¥ 4,893	\$ 55
Interest cost	3,739	3,984	4,120	45
Expected return on plan assets	(4,060)	(3,778)	(4,570)	(49)
Amortization of actuarial loss	3,074	4,101	2,451	37
Amortization of past service cost	(872)	(869)	(825)	(11)
Other	5,897	5,792	7,590	71
Total	¥12,317	¥13,629	¥13,659	\$148

The assumptions used in accounting for the above plans were as follows:

	2011	2010
Discount rates	2.0% - 5.4%	2.0% - 5.2%
Expected rates of return on plan assets	3.0% - 4.4%	3.0% - 4.4%
Amortization period of actuarial gain / loss	8 – 19 years	8 – 19 years
Amortization period of past service cost	8 – 19 years	8 – 19 years

#### 12. Research and Development Expenses

Research and development expenses, all of which were included in selling, general and administrative expenses for the years ended March 31, 2011, 2010 and 2009, totaled ¥217,326 million (\$2,618 million), ¥195,570 million and ¥159,059 million, respectively.

### 13. Leases

Future minimum lease payments subsequent to March 31, 2011 on non-cancelable operating lease transactions are summarized as follows:

Year ending March 31,		lions of . dollars
2012	¥ 5,767	\$ 70
2013 and thereafter	19,271	232
Total	¥25,038	\$302

## **14. Contingent Liabilities**

Contingent liabilities of Astellas as of March 31, 2011 and 2010 were as follows:

	Millions of yen	Millions of U.S. dollars
	2011	2011
Contingent liabilities as guarantors of indebtedness of the Company's employees and affiliates	¥2,165	\$26
		Millions of yen
		2010
Contingent liabilities as guarantors of indebtedness of the Company's employees and affiliates		¥2,545

Astellas may be involved in various lawsuits during the normal course of business. The management believes the lawsuits in which

Astellas is currently involved would not have material adverse impacts on the financial conditions and / or operating results.

## 15. Amounts per Share

		Yen				
	2011	2010	2009	2011		
Net income:						
Basic	¥ 146.49	¥ 261.84	¥ 356.11	\$ 1.76		
Diluted	146.33	261.62	355.90	1.76		
Cash dividends	125.00	125.00	120.00	1.51		
Net assets	2,207.70	2,278.77	2,189.26	26.60		

Basic net income per share is computed based on net income available for distribution to shareholders of common stock and the weighted-average number of shares of common stock outstanding during the year.

Diluted net income per share is computed based on net income available for distribution to the shareholders and the weightedaverage number of shares of common stock outstanding during each year after giving effect to the dilutive potential of shares of common stock to be issued upon the exercise of stock subscription rights. There were no outstanding issues of convertible bonds during the years ended March 31, 2011 and 2010.

Cash dividends per share represent the annual cash dividends declared as applicable to the respective years including the interim cash dividends paid.

Net assets per share are computed based on the amount of net assets at the year end excluding stock subscription rights and minority interests, and the number of common stock outstanding at the year end.

## **16. Supplementary Cash Flow Information**

Astellas acquired 100% of shares of OSI Pharmaceuticals, Inc. ("OSI") during the year ended March 31, 2011. The following is reconciling the assets acquired and liabilities assumed as of the acquisition as well as the acquisition cost to net cash used in the acquisition:

	Millions of yen	Millions of U.S. dollars
Current assets	¥ 44,827	\$ 540
Long-term assets	288,616	3,477
Goodwill	92,106	1,110
Current liabilities	(43,486)	(524)
Long-term liabilities	(87,382)	(1,053)
Acquisition cost of stock of OSI	294,681	3,550
Cash and cash equivalents of OSI	(19,193)	(231)
Effect of exchange rate fluctuation	8,514	103
Net cash used in the acquisition of OSI	¥284,002	\$ 3,422

## **17. Financial Instruments**

# Basic policy to manage financial instruments and related risks

Astellas has set its financial investment policy, which aims to preserve financial assets for strategic investment opportunities, by putting priority on safety, and mitigating opportunity loss while keeping sufficient liquidity. In the case that financing is necessary, the most appropriate measure will be chosen among the various options including bank loans, bond issuance or stock offering, taking into account business circumstances and financial market conditions. Derivative transactions are utilized solely for the purpose of hedging exposure to adverse fluctuation primarily in foreign currency exchange rates or interest rates, but Astellas does not enter into such transactions for speculative or trading purposes.

### Fair value of financial instruments

The following table summarizes carrying values and fair values of financial instruments at March 31, 2011 and 2010.

		Millions of yen								Millic	ons of U.S. dollars
					2011						2011
	Carrying va	lue	Fair va	lue	Difference		Carrying	/alue	Fair	/alue	Difference
Cash and cash equivalents	¥ 175,4	66	¥ 175,4	66	¥—		\$ 2,	114	\$ 2,	114	\$—
Notes and accounts receivable	279,1	12	279,1	12	_		3,	363	3,	363	_
Short-term investments and Investment securities:											
Other securities	46,6	36	46,6	36	_			562		562	_
Notes and accounts payable	(139,2	33)	(139,2	33)	_		(1,	678)	(1,	678)	_
Derivative transactions	¥	16	¥	16	¥—		\$	0	\$	0	\$—

With regard to bank deposits, Astellas enters into transactions

only with financial institutions with high credit ratings. Although

accounts receivable are exposed to credit risk in relation to custom-

ers, the risk is managed by monitoring business conditions, credit-

worthiness and outstanding balances by individual customer. In

addition, monthly collections of accounts receivable are monitored.

With regard to listed stocks that Astellas has invested in, Astellas man-

ages the price volatility risk by monthly monitoring of market prices

of those stocks. Derivative transactions are executed based on inter-

nal rules and the balance of derivative transactions is monitored

monthly. To minimize credit risk in the event of nonperformance by

the counterparties, Astellas enters into derivative transactions only

with financial institutions with high credit ratings.

		Millions of yen
		2010
Carrying value	Fair value	Difference
¥ 431,920	¥ 431,920	¥—
256,870	256,870	_
172,146	172,146	_
¥(177,989)	¥(177,989)	¥—
	¥ 431,920 256,870 172,146	¥ 431,920       ¥ 431,920         256,870       256,870         172,146       172,146

Numbers with parenthesis represent liabilities in the above table.

The above table does not include financial instruments for which it is extremely difficult to determine fair value because no quoted market price nor future cash flow is available.

The following methods and assumptions were used in estimating fair value disclosures for financial instruments:

Cash and cash equivalents, notes and accounts receivable, notes and accounts payable: The carrying amount approximates fair value because of the short maturity of the instruments. Short-term investments and investment securities: The fair value of stocks is based on quoted market prices. The fair value of debt securities is based on either quoted market prices or prices provided by the financial institutions making markets in these securities.

## Securities

Information regarding marketable securities classified as other securities as of March 31, 2011 and 2010 is summarized as follows:

#### Other securities

			Millions of yen		Millions of U.			
			2011			2011		
			Unrealized			Unrealized		
	Acquisition cost	Carrying value	gain (loss)	Acquisition cost	Carrying value	gain (loss)		
Securities whose carrying value exceeds their acquisition cost:								
Stock	¥24,009	¥42,041	¥18,032	\$290	\$507	\$217		
Debt securities	684	695	11	8	8	0		
Other	2,000	2,094	94	24	25	1		
Subtotal	26,693	44,830	18,137	322	540	218		
Securities whose acquisition cost exceeds								
their carrying value:								
Stock	242	228	(14)	3	3	(0)		
Debt securities	9,664	9,663	(1)	116	116	(0)		
Other	24,497	24,487	(10)	295	295	(0)		
Subtotal	34,403	34,378	(25)	414	414	(0)		
Total	¥61,096	¥79,208	¥18,112	\$736	\$954	\$218		

			Millions of yen
			2010
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their			
acquisition cost:			
Stock	¥ 20,532	¥ 45,659	¥25,127
Debt securities	76,785	76,854	69
Other	2,000	2,097	97
Subtotal	99,317	124,610	25,293
Securities whose acquisition cost exceeds their			
carrying value:			
Stock	467	417	(50)
Debt securities	41,461	41,330	(131)
Other	113,513	113,513	_
Subtotal	155,441	155,260	(181)
Total	¥254,758	¥279,870	¥25,112

Proceeds from sales of securities classified as other securities and the related aggregate gains and losses for the years ended March 31, 2011, 2010 and 2009 are summarized as follows:

	Millions of yen Millions of U.S. dollars				ons of U.S. dollars		
			2011				2011
	Proceeds	Aggregate gain	Aggregate loss		Proceeds	Aggregate gain	Aggregate loss
Stock	¥ 2,793	¥1,280	¥325		\$ 34	\$16	\$4
Debt securities	82,395	105	108		993	1	1
Other	275,110	0	_		3,314	0	_
Total	¥360,298	¥1,385	¥433		\$4,341	\$17	\$ 5

			Millions of yen			Millions of yen
			2010			2009
	Proceeds	Aggregate gain	Aggregate loss	Proceeds	Aggregate gain	Aggregate loss
Stock	¥ 3,705	¥2,700	¥39			_
Debt securities	4,613	_	3	_	_	_
Other	53,558	—	_	_	_	_
Total	¥61,876	¥2,700	¥42	¥38,807	¥508	¥389

## The redemption schedule for securities with maturities as of March 31, 2011 is summarized as follows:

				Millions of yen
	Due in	Due after one	Due after five	
	one year	year through	years through	Due after
	or less	five years	ten years	ten years
Government / local bonds	¥ —	¥126	¥—	¥ 5
Corporate bonds	271	392	—	—
Other debt securities	9,399	34	—	130
Other	24,238	_	_	_
Total	¥33,908	¥552	¥—	¥135

			Mi	llions of U.S. dollars
	Due in	Due after one	Due after five	
	one year	year through	years through	Due after
	or less	five years	ten years	ten years
Government / local bonds	\$ —	\$ 2	\$—	\$ 0
Corporate bonds	3	5	_	_
Other debt securities	113	0	_	2
Other	292	_	_	_
Total	\$408	\$7	\$—	\$ 2

## Securities without determinable fair value

	Millions of yen	Millions of U.S. dollars
	2011	2011
	Carrying value	Carrying value
Non marketable stocks	¥14,889	\$179
Total	¥14,889	\$179

	Millions of yen
	2010
	Carrying value
Non marketable stocks	¥15,595
Total	¥15,595

## Impairment loss on securities

Impairment loss on securities amounted to ¥675 million in the year ended March 31, 2010.

## **Derivative Transactions**

The notional amounts and the estimated fair value of derivatives outstanding as of March 31, 2011 are summarized as follows:

			Millions of yen		Mill	ions of U.S. dollars
			2011			2011
	Notional	Fair	Unrealized	Notional	Fair	Unrealized
	amount	value	gain	amount	value	gain
Forward foreign exchange contracts						
Buy:						
U.S. dollars	¥810	¥16	¥16	\$10	\$0	\$0
Total	¥810	¥16	¥16	\$10	\$0	\$0

There were no outstanding derivative transactions as of March 31, 2010.

The notional amounts of the derivatives do not necessarily represent the amounts exchanged by the parties and, therefore, are not a direct measure of risk exposure in connection with derivatives.

## **18. Acquisitions**

## **OSI** Pharmaceuticals, Inc.

On June 8, 2010, Astellas acquired 100% shares of OSI, a US-based biotechnology company focusing on oncology and diabetes / obesity fields. Astellas has set goals of becoming a "Global Category Leader" ("GCL") in its "VISION 2015" and has defined the oncology field as one of its prioritized research areas. This acquisition provides a top-tier oncology business in the U.S., including an anti-cancer blockbuster product, Tarceva, and accelerates Astellas' initiatives to quickly establish its oncology platform to realize a GCL position in the therapeutic field.

The acquisition cost and its breakdown is as follows:

	Millions of U.S. dollars
Cost for the acquisition by tender offer	\$3,525
Direct costs for the acquisition	19
Total acquisition cost	\$3,544

The total purchase price of \$3,544 million was paid by cash.

The breakdown of assets acquired and liabilities assumed as of the date of the business combination is as follows:

	Millions of U.S. dollars
Current assets	\$ 539
Non-current assets	4,579
Total assets	\$5,118
Current liabilities	\$ 523
Non-current liabilities	1,051
Total liabilities	\$1,574

As a result of purchase price allocation, the acquisition cost has been allocated to intangible assets except goodwill by \$2,815 million, which are composed of (1) already launched or approved products amounting to \$2,024 million and (2) in-process research and development amounting to \$791 million. Amortization periods for each of those intangible assets have been individually determined based on a useful life of each asset.

The excess of cost over underlying net assets at fair value at the date of the acquisition was recognized as goodwill in the amount of \$1,108 million. The goodwill is amortized by the straight-line method over twenty years.

The consolidated statements of income for the year ended March 31, 2011 includes the results of operations of OSI from July 1, 2010. If the business combination had been completed at the beginning of the fiscal year, the effect on the net sales would have increased by approximately ¥9.3 billion, while operating income and income before income taxes and minority interests would have decreased by approximately ¥13.3 billion and ¥13.5 billion, respectively. These figures include the operating results of OSI from April 1 to June 30, 2010 and estimated amortization of goodwill and intangibles for the relevant period and have not been audited by our independent auditor.

(note) U.S. dollar amounts in this note 18 are actual figures incurred in this transaction.

### **19. Segment Information**

#### For the year ended March 31, 2011

Astellas operates business in single business segment of "Pharmaceutical."

#### Segment-related information

#### Sales by products to the third parties

Net sales

		Millions of
Year ended March 31, 2011	Millions of yen	U.S. dollars
Prograf	¥162,651	\$ 1,960
Other	791,297	9,533
Total	¥953,948	\$11,493

#### Information by regions

Net sales

Year ended March 31, 2011					Millions of yen
		U.S. (included in			
Japan	Americas	Americas)	Europe	Asia and other	Total
¥531,416	¥189,471	¥171,778	¥181,984	¥51,077	¥953,948
					Millions of U.S. dollars
\$ 6,402	\$ 2,283	\$ 2,070	\$ 2,193	\$ 615	\$ 11,493

#### Property, plant and equipment

Year ended March 31, 2011					Millions of yen
		U.S. (included in			
Japan	Americas	Americas)	Europe	Asia and other	Total
¥144,337	¥20,869	¥20,697	¥23,158	¥1,796	¥190,160
					Millions of U.S. dollars
\$ 1,739	\$ 251	\$ 249	\$ 279	\$ 22	\$ 2,291

#### Information by major customers

Net sales

Year ended March 31, 2011	Millions of yen	Millions of U.S. dollars
MEDICEO CORPORATION	¥114,339	\$1,378
Suzuken Co., Ltd.	114,039	1,374
Alfresa Corporation	106,422	1,282

## For the years ended March 31, 2010 and 2009

Business segments

Astellas' businesses were segmented into "Pharmaceutical" and "Other" based on their similarity in terms of distribution methods, the nature

and type of products sold, and manufacturing methods. As net sales, operating income and total assets in the "Pharmaceutical" segment constituted more than 90% of the consolidated totals, the disclosure of business segment information has been omitted.

## **Geographical areas**

Geographical areas, which include the results of the operation attributed by the location of the Company and its subsidiaries, for the years ended March 31, 2010 and 2009 are summarized as follows:

							Millions of yen
Year ended March 31, 2010	Japan	North America	Europe	Asia	Total	Eliminations	Consolidated
Sales to third parties	¥529,243	¥179,807	¥235,861	¥29,967	¥ 974,878	¥ —	¥ 974,878
Intergroup sales and transfers	106,851	67,496	66,193	28	240,568	(240,568)	—
Total sales	636,094	247,303	302,054	29,995	1,215,446	(240,568)	974,878
Operating expenses	521,563	232,484	258,121	27,694	1,039,862	(251,391)	788,471
Operating income	¥114,531	¥ 14,819	¥ 43,933	¥ 2,301	¥ 175,584	¥ 10,823	¥ 186,407
Total assets	¥877,072	¥202,982	¥303,872	¥18,873	¥1,402,799	¥ (38,622)	¥1,364,177

							Millions of yen
Year ended March 31, 2009	Japan	North America	Europe	Asia	Total	Eliminations	Consolidated
Sales to third parties	¥510,500	¥188,853	¥239,114	¥27,231	¥ 965,698	¥ —	¥ 965,698
Intergroup sales and transfers	130,153	68,004	54,649	18	252,824	(252,824)	—
Total sales	640,653	256,857	293,763	27,249	1,218,522	(252,824)	965,698
Operating expenses	465,066	224,013	253,937	23,882	966,898	(251,595)	715,303
Operating income	¥175,587	¥ 32,844	¥ 39,826	¥ 3,367	¥ 251,624	¥ (1,229)	¥ 250,395
Total assets	¥909,020	¥201,035	¥271,139	¥16,869	¥1,398,063	¥ (49,617)	¥1,348,446

#### **Overseas sales**

Overseas sales, which include the sales of attributed by the location of customers, for the years ended March 31, 2010 and 2009 are summarized as follows:

					Millions of yen
Year ended March 31, 2010	North America	Europe	Asia	Other	Total
Overseas sales	¥224,865	¥181,249	¥40,470	¥14,128	¥460,712
Consolidated net sales					974,878
Overseas sales as a percentage of consolidated net sales	23.1%	18.6%	4.2%	1.4%	47.3%
					Millions of yen
Year ended March 31, 2009	North America	Europe	Asia	Other	Total
Overseas sales	¥235,023	¥180,393	¥35,875	¥17,688	¥468,979
Consolidated net sales					965,698
Overseas sales as a percentage of consolidated net sales	24.3%	18.7%	3.7%	1.9%	48.6%

## 20. Impairment Loss

Astellas bases the grouping for assessing impairment losses on the business segments. However, Astellas determines whether an asset is impaired on an individual asset basis when the asset is deemed idle or if it is scheduled to be disposed of. Loss on impairment of fixed assets, which was recognized by reducing the book value of such assets to their respective realized value, for the years ended March 31, 2011, 2010 and 2009 amounted to ¥2,782 million (\$34 million), ¥4,082 million and ¥1,340 million, respectively. Loss on impairment of fixed assets for the year ended March 31, 2011 mainly consists of losses on

buildings and structures in the aggregate amount of ¥438 million (\$5 million), losses on equipment in the aggregate amount of ¥843 million (\$10 million) and losses on intangible assets in the aggregate amount of ¥1,105 million (\$13 million). Loss on impairment of fixed assets for the year ended March 31, 2010 mainly consists of losses on buildings and structures in the aggregate amount of ¥3,602 million. Loss on impairment of fixed assets for the year ended March 31, 2009 mainly consists of losses on buildings and structures in the aggregate amount of ¥1,088 million.

## **Report of Independent Auditors**

The Board of Directors Astellas Pharma Inc.

We have audited the accompanying consolidated balance sheets of Astellas Pharma Inc. (the "Company") and subsidiaries as of March 31, 2011 and 2010, the related consolidated statements of income, changes in net assets, and cash flows for each of the three years in the period ended March 31, 2011 and consolidated statement of comprehensive income for the year ended March 31, 2011, all expressed in yen. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits 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 financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Astellas Pharma Inc. and subsidiaries at March 31, 2011 and 2010, and the consolidated results of their operations and their cash flows for each of the three years in the period ended March 31, 2011 in conformity with accounting principles generally accepted in Japan.

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2011 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 4.

Ernst & Young Shin Mikon LLC

June 20, 2011

## **Principal Subsidiaries and Affiliates**

(as of July 2011)

## **Americas**

#### Holding company in North America

Astellas US Holding, Inc. Three Parkway North, Deerfield, IL 60015, U.S.A. TEL: +1-847-317-8800

#### **Headquarters in North America**

Astellas US LLC Three Parkway North, Deerfield, IL 60015, U.S.A. TEL: +1-847-317-8800

#### Other principal subsidiaries and affiliates in The Americas

Astellas Pharma US, Inc. Three Parkway North, Deerfield, IL 60015, U.S.A. TEL: +1-847-317-8800

Astellas Pharma Global Development, Inc. Three Parkway North, Deerfield, IL 60015, U.S.A. TEL: +1-847-317-8800

Astellas Pharma Canada, Inc. 675 Cochrane Drive, Suite 500, Markham, Ontario L3R 0B8, Canada TEL: +1-905-470-7990

Astellas Pharma Technologies, Inc. 3300 Marshall Avenue, Norman, OK 73072, U.S.A. TEL: +1-405-217-6501

Astellas US Technologies, Inc. Three Parkway North, Deerfield, IL 60015, U.S.A. TEL: +1-847-317-8800

Agensys, Inc. 2225 Colorado Avenue, Santa Monica, CA 90404, U.S.A. TEL: +1-310-820-8029

Astellas Research Institute of America LLC P.O. Box 188, Skokie, IL 60076-0188, U.S.A.

#### Astellas Venture Management LLC P.O. Box H, Los Altos, CA 94023, U.S.A.

**Urogenix, Inc.** P.O. Box 12035 Durham, NC 27709, U.S.A.

#### Astellas Farma Brasil Importação e Distribuição de Medicamentos Ltda.

Av. das Nações Unidas 14.171, Rochaverá Corporate Towers, Torre B – Andar 3 – Sala 302, São Paulo SP – CEP: 04794-000 TEL: +55-11-8228-3052

## OSI Pharmaceuticals, LLC

1 Bioscience Park Drive, Farmingdale, NY 11735, U.S.A. TEL: +1-631-962-0600

#### Perseid Therapeutics LLC

515 Galveston Drive Redwood City, CA 94063, U.S.A.

## Europe

#### Holding company in Europe

Astellas B.V. Elisabethhof 19, P.O. Box 108, 2350 AC, Leiderdorp, The Netherlands TEL: +31-715-455-500

## European headquarters

Astellas Pharma Europe Ltd. Lovett House, Lovett Road, Staines, Middlesex, TW18 3AZ, U.K. TEL: +44-1784-4194-00

#### Other principal subsidiaries and affiliates in Europe

Astellas Pharma Europe B.V. Manufacturing Meppel Hogemaat 2, 7942 JG Meppel, The Netherlands TEL: +31-522-235300

Astellas Ireland Co., Limited Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland TEL: +353-1-803-0800

#### Austria

Astellas Pharma Ges.mbH Linzerstraße 221/E02, A 1140 Vienna, Austria TEL: +43-1-877-26-68

#### Belgium

Astellas Pharma B.V. (Branch) Erasmus Park, Square Marie Curie 50/1, Building 5, 1070 Brussels, Belgium TEL: +32-2-558-07-10

#### Czech Republic

Astellas Pharma s.r.o Sokolovská 100/94, 186 00 Prague 8, Czech Republic TEL: +420-236-080-300

#### Export

Astellas Pharma International B.V. Elisabethhof 19, 2353 EW, Leiderdorp, The Netherlands TEL: +31-715-455-500

#### France

#### Astellas Pharma S.A.S "Le Malesherbes", 114 Rue Victor Hugo, 92686, Levallois Perret, Paris, France TEL: +33-1-55-91-75-00

#### Germany

Astellas Pharma GmbH Georg-Brauchle-Ring 64-66, 80992, München, Germany TEL: +49-89-45-44-01

#### Greece

Astellas Pharma AE Thoukididou 1, 145 65 Ag. Stefanos, Athens, Greece TEL: +30-2108-189-911

#### Hungary

**Astellas Pharma Kft.** Csörsz u. 49-51, H 1124 Budapest, Hangary TEL: +36-1-577-8200

#### Ireland

#### Astellas Pharma Co., Ltd

25 The Courtyard, Kilcarbery Business Park, Clondalkin, Dublin 22, Ireland TEL: +353-1-467-1555

#### Italy

Astellas Pharma S.p.A. Via delle Industrie 1, 20061, Carugate, Milan, Italy TEL: +39-02-92-138-1

#### Netherlands

Astellas Pharma B.V. Elisabethhof 19, 2353 EW, Leiderdorp, The Netherlands TEL: +31-71-5455854

#### Northern Europe

Astellas Pharma A/S Naverland 4, DK - 2600 Glostrup, Denmark TEL: +45-4343-0355

#### Poland

Astellas Pharma Sp.zo.o. Ul. Poleczki 21, 02-822, Warsaw, Poland TEL: +48-22-545-11-11

#### Portugal

Astellas Farma Limitada Edificio Cinema, Rua José Fontana, nº1-1 andar, 2770-101 Paço de Arcos, Portugal TEL: +351-21-440-13-00

#### Russia

ZAO Astellas Pharma Marksistskaya Ulitsa 16, 109147, Moscow, Russia TEL: +7-495-737-0755

#### Slovenia

Astellas Pharma d.o.o. Rezidenca, 3<sup>rd</sup> Floor, Šmartinska 53, 1000, Ljubljana, Slovenia TEL: +386-1-401-14-00

#### South Africa

Astellas Pharma (Pty) Limited Gillooly's View Office Park, Block F, Ground Floor, 5 Osborne Lane, Bedfordview 2007 Johannesburg, South Africa TEL: +27-011-615-9433

#### Spain

Astellas Pharma S.A. Parque Empresarial 'La Finca', Paseo del Club Deportivo nº1, Bloque 14,

2ª planta, 28223 Pozuelo de Alarcón, Madrid, Spain TEL: +34-91-495-2700

#### Switzerland

Astellas Pharma A.G. Grindelstrasse 6, CH-8304, Wallisellen, Switzerland TEL: +41-43-233-60-20

#### Turkey

Astellas Pharma ilaç Ticaret ve Sanayi A.Ş. Tekstilkent Koza Plaza, A Blok 16. Kat No: 60, 34235 Esenler, Istanbul, Turkey TEL: +90-212-440-0800

#### United Kingdom

#### Astellas Pharma Ltd.

Future House, 3<sup>rd</sup> Floor, The Glanty, Egham, TW20 9AH, U.K. TEL: +44-1784-4194-00

## Asia • Oceania

#### Astellas Pharma China, Inc.

1901-1904, SK Tower Beijing, No. 6 Jia Jianguomenwai Avenue, Chaoyang District, Beijing 100022, People's Republic of China TEL: +86-10-8567-9911

Astellas Pharma Hong Kong Co., Ltd. Unit 1103, 5-7, Level 11, Tower 1, Grand Century Place,

No. 193 Prince Edward Road West, Mongkok, Kowloon, Hong Kong TEL: +852-2377-9801

Astellas Pharma Taiwan, Inc. 5/F, No. 10, Sec 3, Min-Sheng E. Rd., Taipei 104 Taiwan, R.O.C. TEL: +886-2-2507-5799

Astellas Pharma Korea, Inc. 6/F Kumha Bldg. 41-2 Chungdam-Dong Kangnam-Ku, Seoul, 135-766 Korea TEL: +82-2-3448-0504

#### Astellas Pharma Philippines, Inc.

23/F, Salcedo Towers 169 H.V. del Costa Street Salcedo Village 1227 Makati City, Philippines TEL: +63-2-845-1558

#### Astellas Pharma (Thailand) Co., Ltd.

10/F, Wave Place, 55 Wireless Road, Lumpini, Patumwan, Bangkok 10330, Thailand TEL: +66-2-655-4050

P.T. Astellas Pharma Indonesia Wisma Kyoei Prince Building 11/F, Jl. Jend. Sudirman Kav. 3, Jakarta 10220, Indonesia TEL: +62-21-572-4344

#### Astellas Pharma India Private Limited

Unit No. 505 & 506, Meadows Sahar Plaza Complex, Andheri Kurla Road, Andheri East, Mumbai MM-4-00059, India TEL: +91-22-4075-7676

#### Astellas Pharma Australia Pty Ltd

Level 4/6 Eden Park Drive, Macquarie Park, NSW 2113, Australia TEL: +61-2-9814-1100

## Japan

#### Manufacturing subsidiaries

Astellas Pharma Tech Co., Ltd. 2-3-11, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan

## **Investor Information**

(as of March 31, 2011)

## **Company Name**

Astellas Pharma Inc.

## **Head Office**

2-3-11, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan TEL: +81-3-3244-3000 http://www.astellas.com/en/

## **Common Stock**

Authorized:2,000,000Issued:467,964,635 (including 6,138,000 treasury stock)Number of shareholders:57,088

## **Stock Exchange Listing**

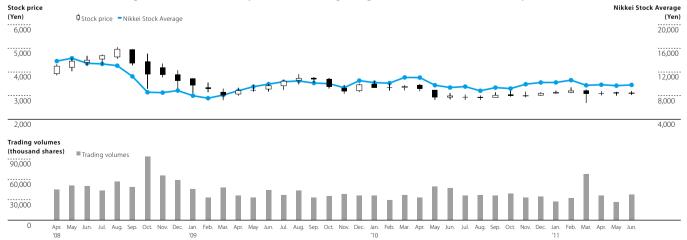
Tokyo, Osaka (Ticker Code: 4503)

## **Independent Auditors**

Ernst & Young ShinNihon LLC Hibiya Kokusai Building, 2-2-3 Uchisaiwai-cho, Chiyoda-ku, Tokyo 100-0011, Japan

## **Transfer Agent for Common Stock in Japan**

The Chuo Mitsui Trust and Banking Company, Limited 33-1, Shiba 3-chome, Minato-ku, Tokyo 105-8574, Japan



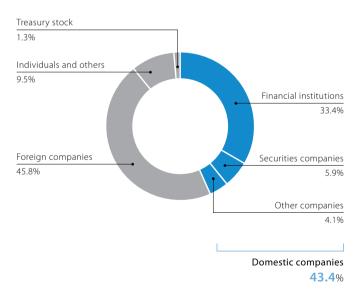
## Stock Prices and Trading Volumes on the Tokyo Stock Exchange (highest / lowest in the month; yen)

## **Major Shareholders**

Name	Shares owned (Thousand shares)	Percentage of total common shares outstanding (%)
Japan Trustee Services Bank, Ltd. (trust account)	26,842	5.73
The Master Trust Bank of Japan, Ltd. (trust account)	25,279	5.40
State Street Bank and Trust Company	23,553	5.03
Nippon Life Insurance Company	17,911	3.82
JP Morgan Chase Bank 385147	14,365	3.06
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	9,881	2.11
SSBT OD05 OMNIBUS ACCOUNT - TREATY CLIENTS	9,370	2.00
State Street Bank and Trust Company 505225	9,164	1.95
Barclays Capital Japan Limited	7,460	1.59
Northern Trust Co. (AVFC) Sub A/C American Clients	7,330	1.56

Note: Shares owned are rounded down to the nearest thousand shares, while the percentage of total common shares outstanding is rounded down to two decimal places.

## **Breakdown of Shareholders**





Astellas Pharma Inc. 2-3-11, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan http://www.astellas.com/en/