

ANNUAL REPORT 2009 For the Year Ended March 31, 2009

# It's the Approach That Counts



## CONTENTS

# g.02 Letter to Our Shareholders

- *pg*.04 **Financial Highlights**
- pg.06 Interview With the President & CEO

### *pg*.18 **Our Approach: Value Creation**

- 20 R&D Special Feature
- 24 Pipeline List (All)
- 27 Pipeline by Therapeutic Area
- 28 Global Products/Major US Products
- 30 Major Domestic Products

### *pg.*32 Our Approach: Business Expansion (Review of Global Operations)

- 34 Japan
- 36 North America
- 38 Europe
- 40 Asia

#### *pg.*42 **Our Approach: Responsible Management**

## (Corporate Social Responsibility/Corporate Governance)

- 44 Corporate Social Responsibility
- 48 Corporate Governance
- 50 Profile of Directors
- pg.53 **Financial Section**
- *pg*.94 **Principal Subsidiaries and Affiliates**
- pg.96 Investor Information

#### 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 alunches, (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.

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

# Letter to Our Shareholders

Business conditions facing the pharmaceutical industry have become steadily harsher. The financial crisis has led to an economic slowdown; governments continue to pursue policies to restrain medical expenditures, notably in advanced countries; and regulatory processes and approval for new drugs are becoming tougher, with stricter standards and longer drug approval times. The challenge for Astellas under such conditions is to compete with other players worldwide by developing a business model we call "global category leader (GCL)."

The business philosophy of Astellas states that our *raison d'être* is to contribute toward improving the health of people around the world through the provision of innovative and reliable ethical pharmaceutical products. To help realize this business philosophy, we formulated "Vision 2015" to define the direction we must take, the company that we want Astellas to be in 2015, and the policies and strategies needed to accomplish this goal. The principal aim under this business vision is to establish Astellas as a GCL by supplying high-value-added drugs on a worldwide basis in various highly specialized fields (categories) where there is a high degree of unmet medical needs. We aim to build a competitive presence to make Astellas a global leader within each of these categories. Rather than simply gaining scale through sales expansion, our aim is to generate sustainable growth in enterprise value by developing the GCL business model so that we can maximize the value added to the lives of patients and everyone seeking a life of health.

The financial performance of the business has been growing steadily since Astellas was created in 2005 through the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd. Now, however, we are facing the expiration of patents on Prograf® and Harnal®, two of our mainstay products. We are currently taking steps to achieve our management vision by shifting up a gear under the communications slogan "Changing tomorrow." In these rapidly changing and highly stimulating times with many opportunities, we believe that generating value depends on taking a distinctive approach. We will continue to work tirelessly to meet the expectations of patients and their family members, medical professionals, shareholders, employees, local communities and all our other stakeholders to earn your collective trust as a company. We also hope to enjoy your continued support and understanding.

August 2009

Masafami Kogèmor

Masafumi Nogimori President & CEO



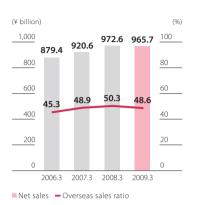
# Financial Highlights

Years ended March 31

				(¥ billion)	(US\$ million)		(% Change)
	2006.3	2007.3	2008.3	2009.3	2009.3	08/07	09/08
For the year							
Net sales	¥ 879.4	¥ 920.6	¥ 972.6	¥ 965.7	\$ 9,854	5.6	(0.7
Cost of sales	273.0	284.1	279.3	264.4	2,698	(1.7)	(5.3
SG&A expenses (incl. R&D expenses)	413.3	446.0	417.3	450.9	4,601	(6.4)	8.0
Operating income	193.0	190.5	275.9	250.4	2,555	44.8	(9.2
Operating margin (%)	22.0	20.7	28.4	25.9	—	_	_
Net income	103.7	131.3	177.4	171.0	1,745	35.2	(3.6
Overseas sales	398.3	450.1	489.6	469.0	4,786	8.8	(4.2
Overseas sales ratio (%)	45.3	48.9	50.3	48.6	—	_	_
R&D expenses	142.1	167.9	134.5	159.1	1,623	(19.9)	18.3
R&D ratio (%)	16.2	18.2	13.8	16.5	_	—	_
At year-end							
Total assets	1,584.5	1,470.7	1,439.2	1,348.4	13,760	(2.1)	(6.3
Total net assets	1,216.9	1,099.0	1,110.9	1,030.2	10,512	1.1	(7.3
Working capital	750.1	657.2	692.7	680.1	6,940	5.4	(1.8
				(¥)	(US\$)		(% Change
Per share data							
Net income	¥ 183.88	¥ 244.07	¥ 349.89	¥ 356.11	\$ 3.63	43.4	1.8
Total net assets	2,179.44	2,135.34	2,228.34	2,189.26	22.34	4.4	(1.8
Cash dividends	70.00	80.00	110.00	120.00	1.22	37.5	9.
Major Indicators							
ROE (%)	8.8	11.3	16.1	16.0			
DOE (%)*1	3.3	3.7	5.0	5.4			
Shareholders' equity ratio (%)	76.8	74.7	77.1	76.3			_
EBITDA <sup>*2</sup> (¥ billion)	216.1	246.1	305.8	305.6	3,118	23.5	(1.9
Free cash flows (¥ billion)	52.5	200.4	178.5	168.8	1,722	(10.9)	(5.4
Average exchange rate (¥/US\$)	113	117	114	101		(2.6)	(11.4
(¥/€)	138	150	162	143		8.0	(11.
Other Indicators							

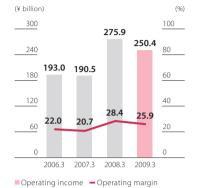
Notes: US dollars have been converted at the rate of ¥98 to US\$1, the approximate exchange rate on March 31, 2009. US dollar amounts are included solely for convenience. \*1 DOE (dividend on equity) = (payout ratio) x ROE

\*2 EBITDA = Income before income taxes and minority interests + interest expense + depreciation and amortization



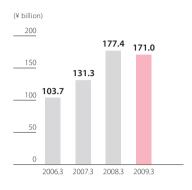
## Net Sales/Overseas Sales Ratio

# Operating Income/ Operating Margin

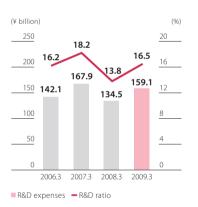


Net Income

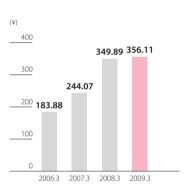
ROE

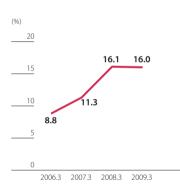


R&D Expenses/R&D Ratio

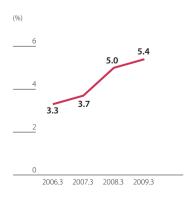


# Net Income per Share

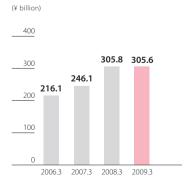




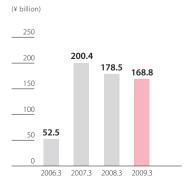
DOE



## EBITDA



#### **Free Cash Flows**



# Interview With the President & CEO

Over the past five or so years, Astellas has coped with change and forged a robust management platform by enhancing the efficiency of its organization and systems. How does the company plan to generate growth within a fiercely competitive global pharmaceutical market? In what direction should it aim? We asked President & CEO Masafumi Nogimori to find out about Astellas' strategy.

QUESTION :	ANSWER :
1. Do you regard the results for the year ended March 31, 2009 in a positive light?	Yes □ No
2. Does Astellas have a growth strategy for after the expiration of the US and European patents for Prograf <sup>®</sup> and the US patent for Harnal <sup>®</sup> ?	✔ Yes □ No
<b>3.</b> Are you confident that Astellas can emerge a winner in the face of the ongoing global changes in pharmaceutical market conditions?	✔ Yes □ No
<b>4.</b> Is it extremely difficult to discover a breakthrough new drug at this point?	□ Yes No
5. Given the increasing regulatory hurdles for new drug approval, are you satisfied with the drug development pipeline in its current form?	□ Yes ☑ No
<b>6.</b> Are you continuing with initiatives aimed at improving capital efficiency?	✔ Yes □ No
<b>7.</b> Are you actively working to strengthen corporate governance?	✔ Yes □ No

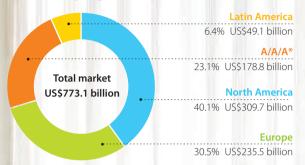
**Masafumi Nogimori** President & CEO

# Background

# Astellas' Market Environment The Ethical Pharmaceuticals Market at a Glance

# **World Ethical Pharmaceuticals Market**

### Market Size by Region (2008)

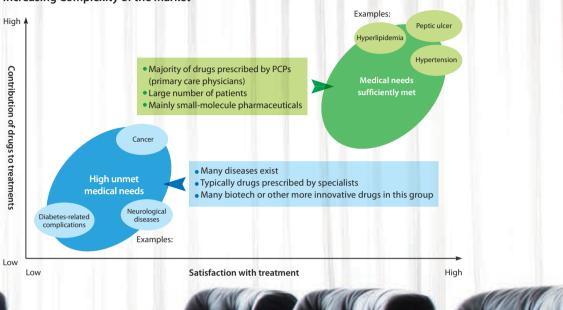


\* Africa, Asia & Australia Copyright 2009 IMS Health. All rights reserved Source: IMS World Review 2009 Reprinted with permission

## Market Size by Country—Top 20 (2008)

MS World Review

Rank	Country/region	Sales	Growth rate
		(US\$ million)	(%)
1	USA	290,980	1.1
2	Japan	77,041	2.6
3	France	42,200	2.2
4	Germany	41,291	4.9
5	Italy	26,644	4.0
6	China	24,543	27.0
7	United Kingdom	22,323	3.2
8	Spain	20,966	7.8
9	Brazil	19,181	12.0
10	Canada	18,723	6.0
11	Mexico	11,031	1.8
12	Turkey	10,624	11.1
13	South Korea	9,823	10.5
14	India	9,697	11.2
15	Australia	9,311	9.9
16	Poland	7,748	9.0
17	Greece	7,520	10.0
18	Belgium	6,353	6.5
19	Russian Federation	6,247	10.4
20	Netherlands	5,917	-3.5



# Increasing Complexity of the Market

### **Global Ethical Pharmaceutical Sales (2008)**

	0	10,000	20,000	30,000	40,000	50,000	(US\$ million)
Pfizer	1						
Sanofi-aventis	2						
GlaxoSmithKline	3						
Roche	4						
Novartis	5						
AstraZeneca	6						
Johnson & Johnson	7						
Merck	8						
Eli Lilly	9						
Wyeth	10						
Bristol-Myers Squibb	11						
Abbott Laboratories	12						
Bayer	13						
Amgen	14						
Schering-Plough	15						
Boehringer Ingelheim	16						
Takeda	17						
Genentech	18						
Teva	19		14	(autal Nta	20		
Astellas	20			Vorld: No.			
Novo Nordisk	21		Ji	apan: No.	2		
Daiichi Sankyo	22						
Eisai	23						
Merck Serono	24						
Baxter International	25						
Source: UtoBrain K.K. "Pharmace	utical Manufact	urers Global Rar	nking 2008" Fina	ledition			

### QUESTION 1.

Do you regard the results for the year ended March 31, 2009 in a positive light?

## ☑ Yes

While our sales and profits were both down on the previous year due to the impact of a stronger yen and the National Health Insurance (NHI) drug price revision, we continued to expand our business in real terms as the result of sales growth from global products and new drugs.

Unfortunately, our sales and profits both declined in the year ended March 31, 2009. We posted net sales of ¥965.7 billion (down 0.7% in year-on-year terms), operating income of ¥250.4 billion (down 9.2%) and net income of ¥171.0 billion (down 3.6%). However, the main factors reducing sales were the impact of foreign currency fluctuations (¥62.0 billion) and the impact of lower NHI drug prices (¥18.6 billion). Excluding these effects, we recorded steady performance growth in each region. So I believe that these were a positive set of results for Astellas.

In Japan, we were able to offset the impact of the NHI drug price revision (of over 5%) through steady sales expansion from our portfolio of mainstay products plus additional growth from new drugs. Net sales in Japan were ¥491.5 billion, a 2.8% increase compared with the previous year. Overseas, we generated growth, led by our global products Vesicare®, a treatment for overactive bladder (OAB) and the immunosuppressant Prograf®. In North America, sales grew in part due to the launch of Lexiscan®, a pharmacologic stress imaging agent used in cardiac function testing, and in Europe, we recorded higher sales of Eligard®, a treatment for advanced prostate cancer and increased bulk sales and royalty revenues from Harnal®, a treatment for the functional symptoms associated with benign prostatic hyperplasia (BPH). As a result, our sales increased in local currency terms, but decreased on a yen basis.

Our research and development (R&D) expenses increased substantially, rising 18.3% year on year to ¥159.1 billion. This reflected additional costs due to an upfront fee to CoMentis, Inc. of the United States relating to an alliance in the field of Alzheimer's disease, as well as further progress in the Phase 3 clinical development of beta-3 receptor agonist YM178 in Europe and the US. Selling, general and administrative (SG&A) expenses excluding R&D expenses also increased due to factors such as goodwill amortization costs relating to the acquisition of Agensys, Inc. and costs associated with the launch of new products. I believe that it is better to regard these R&D and SG&A expenses as investments necessary for future growth.

At the start of fiscal 2008, we had expected to face generic competition to Prograf<sup>®</sup> in the US because the US substance patent expired in April 2008, so the fact that no generic competitors were actually launched during fiscal 2008 also helped our performance.

#### QUESTION 2.

Does Astellas have a growth strategy for after the expiration of the US and European patents for main product Prograf<sup>®</sup> and the US patent for Harnal<sup>®</sup>?

#### Ves Yes

We aim to generate sustained growth through increased sales of our major drug portfolio, notably the global product Vesicare®, as well as the additional growth of new products.

The patent on every ethical pharmaceutical eventually expires, and pharmaceutical companies are significantly affected, including by lower sales. The approach we will take to address the patent expirations of Prograf<sup>®</sup> and Harnal<sup>®</sup> is to further expand sales of other mainstay drugs and maintain a steady stream of new products.

We see the global product Vesicare® as the first main driver of Astellas' future growth. Vesicare® is a treatment for OAB that helps to relieve associated symptoms such as urinary urgency, frequent urination and urinary incontinence. We launched Vesicare® in Europe in 2004, the United States in 2005 and Japan in 2006. Today it is available in approximately 50 countries and regions worldwide and sales are growing steadily. Global sales reached ¥71.4 billion in the year ended March 31, 2009, and we expect this figure to increase to ¥84.2 billion in the coming year. Vesicare® has the top share of the OAB market in Japan and Europe. In the United States, which is the largest market, our successful sales and marketing activities, including copromotion with GlaxoSmithKline plc (GSK), have made VESIcare® the number two branded drug in its segment in terms of share. Going forward, we aim to increase global sales to ¥10.0 billion as quickly as possible by reinforcing sales and marketing activities for Vesicare®, including raising public awareness of OAB and publicizing the product's effectiveness.

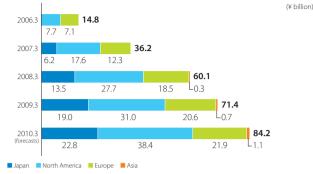
We are also seeing steady performance from Lexiscan<sup>®</sup>, which we launched in the US in June 2008. Aggregate sales during the year ended March 31, 2009 of Lexiscan<sup>®</sup> and Adenoscan<sup>®</sup>, another pharmacologic stress agent, were ¥39.3 billion. We expect this figure to grow to ¥50.0 billion in the year ending March 31, 2010. Another drug that we see making a significant contribution to future sales growth is Funguard<sup>®</sup>/ Mycamine<sup>®</sup>, a candin-type injectable antifungal agent that we have already launched in Japan and the US and began introducing to European markets in August 2008. Going forward we expect to grow sales centered on Europe, the US and Japan.

In Japan we introduce new products every year. In the year ended March 31, 2007, we launched Vesicare<sup>®</sup>. In the year ended March 31, 2008, we launched Celecox<sup>®</sup>, a non-steroidal anti-inflammatory analgesic agent, and Geninax<sup>®</sup>, an oral quinolone antibiotic; and, in the year ended March 31, 2009, we introduced Irribow<sup>®</sup>, a treatment for

\* A generic version of Prograf® was approved in August 2009.

diarrhea-predominant irritable bowel syndrome in males. In April 2009, we launched the osteoporosis treatment Bonoteo® and in June 2009 began selling Micombi®, a combination drug for the treatment of hypertension that contains the anti-hypertensive Micardis® and hydrochlorothiazide. Vesicare®, Celecox®, Geninax®, Irribow®, Bonoteo® and other new products are now positioned to drive sales growth in the Japanese market. We are targeting aggregate sales in Japan of ¥100.0 billion from these products.

#### Maximize Vesicare<sup>®</sup> Sales



# Our Approach Prograf<sup>®</sup> and Harnal<sup>®</sup> With Expiring Substance Patents

The substance patent for Prograf® expired in April 2008 and the substance patent for Harnal® will expire in October 2009 in the US and sales are expected to drop as a result. However, global sales of both products are only expected to decline gradually.

#### Prograf®

**SPECIAL FEATURE 1** 

Available in around 80 countries and regions, Prograf<sup>®</sup> is an immunosuppressant that is used to suppress organ rejection in organ transplants. It is the leading drug globally in the transplantation field.

In Japan, in addition to increased sales in the organ transplantation field, sales of Prograf® have received support from the drug's launch in 2005 for the additional indications of rheumatoid arthritis (RA) and lupus nephritis. We gained approval for the additional indication of ulcerative colitis in July 2009 and expect to gain approval for additional indications of all types of myasthenia gravis before the end of March 2010.

In Asia, sales are growing led by markets such as China and South Korea.

In the United States, the US patent for Prograf® expired in April 2008 and a generic version was approved in August 2009. However, given the special characteristics of Prograf®, we expect sales erosion to be relatively mild even after the entry of generic versions of the drug.

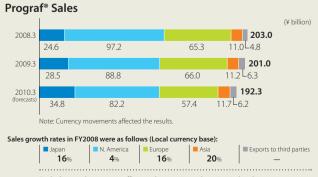
In Europe, our patents expired in major markets in June 2009. Compared with the United States, we expect the impact of generics to be less severe in Europe, although there is still a risk of price erosion.

# Harnal®

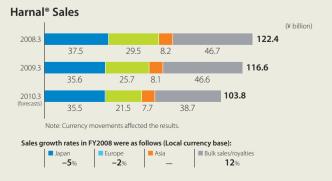
Harnal<sup>®</sup> is a treatment of functional symptoms associated with benign prostatic hyperplasia (BPH) and is sold in approximately 90 countries and regions. It is the global "gold standard" for treating BPH.

The patents on Harnal<sup>®</sup> have already expired in Japan and Europe, where sales of the drug are now in decline. Sales are strong in Asia.

In the United States, Harnal<sup>®</sup> is marketed by licensee Boehringer Ingelheim (BI) under the brand name Flomax<sup>®</sup> and Astellas receives bulk sales and royalty revenues form BI. The US patent is due to expire in October 2009, but the submission of data from pediatric clinical trials is expected to secure a six-month extension to the period of market exclusivity. However, a generic version of the drug is expected to be launched in March 2010. Bulk sales and royalties are likely to decline significantly after the advent of generic competition.



Excluding exchange rate effects, sales rose in each region in local currency terms.



"We see one of the strengths of Astellas as the quickness of our response to change. Our ability to handle changes in the business environment has become part of the company's image."

#### QUESTION 3.

Are you confident that Astellas can emerge a winner in the face of the ongoing global changes in pharmaceutical market conditions?

#### ✓ Yes

# Astellas has chosen to pursue a "global category leader" business model. We think this approach will enhance our competitive edge.

We formulated Vision 2015 to define our direction and the kind of company that we want Astellas to be in 2015. We also set out the policies and strategies needed to realize this vision. Our aim is to establish Astellas as a global category leader (GCL). The GCL business model is the strategy that we have chosen to win and thrive.

Under this approach, we are targeting specialized markets where Astellas can derive a competitive advantage based on specialist expertise in that field. These are therapeutic areas (categories) where effective treatments do not exist currently and there is a high degree of unmet medical needs—that is, where current therapeutic options are unsatisfactory. Our GCL business model seeks to realize a competitive edge by establishing a leading position in the world in these categories through the global provision of high-value-added products. We have already become a GCL in the two fields of urology and transplantation. Now our aim is to become a GCL in other categories. We are selectively focusing drug discovery research efforts at Astellas on six strategic therapeutic areas: transplantation and immunology/inflammation, urology, infectious diseases (viral diseases), CNS/pain, diabetes, and cancer. We selected these target fields primarily as areas with a high degree of unmet medical needs. The second yardstick we applied was whether Astellas possessed strengths or expertise in that area, and the third indicator was the market potential of that segment.

In order to become a GCL, it is important to devise a detailed strategy matched to the therapeutic area and regional characteristics, as well as the drug discovery ability to develop innovative drugs. The combination of these two prerequisites will establish an even stronger position in the target therapeutic field.

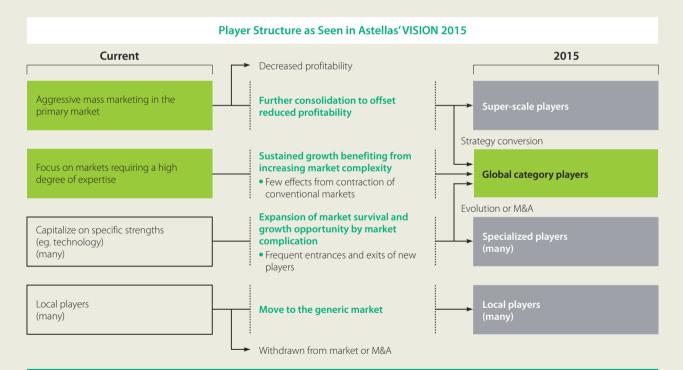
We see one of the strengths of Astellas as the quickness of our response to change. Our ability to handle changes in the business environment has become part of the company's image. Five years on from the establishment of Astellas, I believe we can take pride in the way that we have forged a robust management platform, by strengthening our product lineup and in various other ways. Leveraging this platform promises to be a critical factor in our growth going forward. Based on the catchphrase "Changing tomorrow," we are now planning to shift to a higher gear.

### Six Elements of the Global Category Leader (GCL) Concept:

- 1. Clearly define a global business segment
- 2. Orient toward specialty markets
- 3. Target areas with a high degree of unmet medical needs
- 4. Leverage specialist expertise to derive a competitive sales advantage
- 5. Create a continuous stream of products from in-house drug discovery
- 6. Build an integrated value chain spanning R&D, sales and marketing

#### SPECIAL FEATURE 2

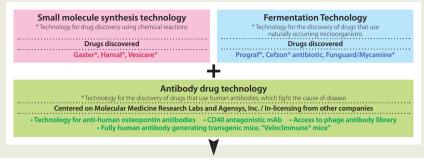
Our Approach Global Category Leader



Players in a market requiring a high degree of expertise possess high possibility of sustainable growth

We are working to reinforce our drug discovery capabilities by combining traditional strengths in small molecule synthesis and fermentation technology with the therapeutic antibody technologies that we secured through the Agensys acquisition in December 2007. Access to these three drug discovery technologies provides us with a unique blend of R&D capabilities as a pharmaceutical company. This broad range of expertise in drug discovery is one of Astellas' key strengths.

#### Strengthen Drug Discovery Capabilities by Fusing Advanced Technologies



More powerful R&D capabilities

#### SPECIAL FEATURE 3

# Our Approach Reinforcement of Drug Discovery Platform

#### **QUESTION 4.**

Is it extremely difficult to discover a breakthrough new drug at this point?

#### 🗹 No

# As new technologies continue to emerge, we believe that there are still numerous untried therapeutic approaches waiting to be discovered.

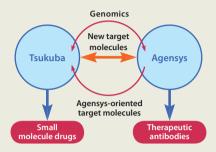
I beg to disagree with the rather harsh view adopted by some that the business of drug discovery is not attractive. As any study of history will show, humans have always been searching for the elixir of eternal youth. While this is still elusive, our collective thirst for health and longevity remains unshakeable. In view of this strong psychological foundation, my belief is that there will always be bright prospects for any business with a direct and beneficial effect on human health such as pharmaceuticals.

Despite its brief history of around a century from the introduction of aspirin, the market for pharmaceuticals has grown rapidly during the past 50–60 years. The first phase of new drug development that was focused on receptors may have reached something of a plateau, but I believe that we are now entering a higher-level second phase of drug development. The analogy is one of a two-story building: although most of the rooms on the lower floor are now full, there is still a lot of space on the floor above. In this second phase, I believe that we will see a series of new drugs emerging based on new technologies such as genomics, RNA interactions and

antibodies. I see these new technologies yielding completely new varieties of drugs. We are continually investing to make sure that Astellas has these cutting-edge drug discovery technologies. I believe that we possess sufficient in-house capabilities in these new technical areas to discover novel compounds using such methods.

We have generated large numbers of new molecules using small molecule synthesis and fermentation technologies. In addition to these two approaches, we are also involved in drug-discovery research using therapeutic antibody technologies as a way of strengthening our overall R&D capabilities further. To quickly gain technologies in the therapeutic antibody field, we have concluded licensing agreements with Regeneron Pharmaceuticals, Inc. of the US and MorphoSys AG of Germany. In December 2007, the US biotech venture firm Agensys joined Astellas. Therapeutic antibodies enable us to employ a variety of drug-discovery approaches in strategic therapeutic research areas, particularly cancer, and I believe that they will allow us to generate promising new medicines. In terms of our R&D organizational set-up, we consolidated global drug discovery functions in April 2009 at the Research Center in Tsukuba, Japan. We have also installed some of the latest equipment to help accelerate drug discovery programs and improve the quality of our research. In a unique approach, the Tsukuba Research Center of Astellas and Agensys are cooperating to extract maximum synergy from their respective expertise in small molecule synthesis and therapeutic antibodies. The Tsukuba Research Center is using target molecules identified or owned by Agensys to try to create small molecule drugs using synthetic chemistry. At the same time, Agensys is using target molecules that have been identified through searches based on genomics and bioinformatics technology introduced from Tsukuba in the production of antibodies.

### Technical Synergies Between Tsukuba Research Center and Agensys



"... my belief is that there will always be bright prospects for any business with a direct and beneficial effect on human health such as pharmaceuticals."



## QUESTION 5.

Given the increasing regulatory hurdles for new drug approval, are you satisfied with the drug development pipeline in its current form?

# 🗹 No

I'm not completely satisfied, but I believe that we are definitely making headway in drug development. Mirabegron (YM178) is set to further strengthen our franchise in urology. We are also making steady progress in other global product development programs, in addition to the ongoing development of our domestic drug pipeline.

Although we cannot deny that the development of new drugs and obtaining regulatory approvals is becoming slower as it is for all companies due to the stricter review criteria being applied by regulatory authorities, I believe that we are making steady progress in terms of our pipeline. I have high expectations for the future in this regard.

As for mirabegron (YM178), a global product in the late stages of clinical development, we have positioned it as a new product after our existing product Vesicare® in the OAB market in the field of urology. I expect YM178 to become a leading product that will substantially reinforce the position of Astellas as a GCL in urology. As mirabegron's mechanism of action is different to Vesicare®, we think we can offer a wider range of options for treating OAB. In April 2008, we established Astellas Pharma Global Development, Inc. (APGD) in the United States to act as our global development headquarters. Under this new system, the president of APGD heads up the global development function for the entire Astellas Group worldwide. In line with this change, we have taken steps to strengthen our global development systems further. We have revised the development set-up in the following ways to promote more efficient and faster drug development.

#### 1. Reinforced Global Matrix Functions

To strengthen the new global integrated set-up, project management function and development promotion function, we created three new positions: Global Development Operations Head, Global Development Project Management Head, and Global Development Planning and Administration Head.

#### 2. Enhanced Development Strategic Planning and Execution Functions by Therapeutic Area

We have created new positions as Global Development Therapeutic Area Head in an effort to promote faster and more effective global development projects in each field based on scientific considerations. We have also constructed a new system of global project teams established within centers of excellence so that we can base our drug development efforts in the best locations for that specific therapeutic area.

#### **SPECIAL FEATURE 4**

# Our Approach Reinforcing Our Global Development Set-up

We are also making steady progress in other global development projects. In February 2009, the US Food and Drug Administration (FDA) issued a Complete Response letter to the regulatory application submitted for telavancin for the indication of complicated skin and skin structure infections. A reply was submitted to the FDA in March 2009. A separate NDA application for telavancin for use in hospital-acquired infections was submitted to the FDA in January 2009. This submission has been formally accepted and is currently under review. In other project developments, we are initiating the Phase 3 clinical trial in Europe for solifenacin/ tamsulosin, which is indicated for lower urinary tract syndrome associated with benign prostatic hyperplasia (BPH). The antithrombotic YM150 is in Phase 3 development in Japan and Asia and in Phase 2b/3 in Europe for the indication of the prevention of venous thromboembolism (VTE). and in Phase 2b in Europe, Japan and Asia for the indication of prophylaxis of thromboembolic complications associated with atrial fibrillation (AF). As for ASP1941 for type 2 diabetes, good results were produced in the Phase 2b clinical trial in Japan, and in the Phase 2 clinical trial in the US. Now we are studying plans for the next phase of clinical development. We have initiated and are making steady progress through Phase 2 development with ASP1517, an oral treatment for renal anemia that we licensed from FibroGen, Inc.

The field of cancer is one where competition is becoming especially fierce. We are making steady progress with the development of the in-house anti-cancer compound YM155 and the Agensys-originated compound AGS-1C4D4 which are in Phase 2. I think Agensys antibody technology is world-class. I believe that their current pipeline, including products in the pre-clinical phase offers the Astellas Group considerable potential. While there are a few products in late-stage development in the cancer area at the moment, our early-stage portfolio has many competitive candidates, in my opinion.

In terms of our domestic pipeline, we steadily gained approvals for several new drugs during the past fiscal year. These were Irribow® for the treatment of irritable bowel syndrome and Graceptor®, the modified release formulation of Prograf®, in July 2008, Bonoteo® for osteoporosis in January 2009, and Micombi® in April 2009. We received approvals in June 2009 for the additional indication of lumbago, etc. for Celecox® and in July 2009 for the additional indication of ulcerative colitis for Prograf<sup>®</sup>. We have also seen steady progress in late-stage development. YM443 for functional dyspepsia and YM529 (once-a-month administration) for osteoporosis are currently in Phase 3 clinical trials in Japan. ASP1585, a treatment for hyperphosphatemia that we licensed from Amgen Limited, has also entered Phase 3. In March 2009, we were able to report statistically significant efficacy for the primary endpoint of the Phase 2 trial with ASP8825, a compound for restless legs syndrome that we licensed from XenoPort, Inc., and we are making preparations to file using data from foreign clinical trials. Overall, therefore, our domestic pipeline is expanding as we make progress in achieving a number-one market share position in the Japanese market.

#### Regulatory Approvals Received April 2008-August 2009

Product name	Indication	Approval date	Japan	US	Europe
Lexiscan®	Pharmacologic stress agent for radionuclide myocardial perfusion imaging (MPI) studies in patients unable to undergo adequate exercise stress	April 2008			
Mycamine®	Treatment of invasive candidiasis; treatment of esophageal candidiasis; prophylaxis of Candida infection in patients undergoing allogeneic hematopoietic stem cell transplantation	April 2008			•
Irribow®	Diarrhea-predominant irritable bowel syndrome in males	July 2008	•		
Graceptor®	Suppression of organ rejection in organ transplantation (modified release formulation)	July 2008	•		
Vaprisol®	Hyponatremia (pre-mix bag formulation)	October 2008		•	
Starsis®	Combination therapy with thiazolidines	December 2008	•		
Bonoteo <sup>®</sup>	Osteoporosis	January 2009	•		
Protopic <sup>®</sup> Ointment	Atopic dermatitis (prevention of flares)	February 2009			•
Micombi®	Hypertension (combination drug of angiotension II receptor blocker and diuretic)	April 2009	•		
Prograf <sup>®</sup>	Use of Prograf® and MMF as an adjunct therapy for the prophylaxis of organ rejection in kidney transplantation	May 2009		•	
Modigraf®	Prophylaxis of transplant rejection in kidney, liver or heart allograft recipients (granules)	May 2009			•
Celecox®	Lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, tendinitis/tendosynovitis	June 2009	•		
Prograf <sup>®</sup>	Ulcerative colitis	July 2009	•		

#### QUESTION 6.

Are you continuing with initiatives aimed at improving capital efficiency?

#### Ves Yes

# While prioritizing business investments to realize future growth, we are working to raise dividends in a sustainable fashion and to conduct share buybacks in a flexible manner.

Deciding how to prioritize investment for the future growth of the business is one of the most important challenges for management. We are actively looking to invest capital in mergers, acquisitions and inward licensing of compounds, in addition to the internal investments that we are making to realize organic growth. At the same time, we are actively working to increase returns to shareholders. As far as dividends are concerned, we are aiming to raise them in a sustainable fashion. In the year ending March 31, 2010, we plan to raise dividends by ¥5 to ¥125 per share, despite projecting net income to dip 21.0% year on year to ¥135.0 billion. We have also been working to conduct share buybacks in a flexible manner as a means of improving capital efficiency and enhancing shareholder returns.

#### QUESTION 7.

Are you actively working to strengthen corporate governance?

## ✓ Yes

# Astellas is actively engaged in reinforcing governance structures to maintain a high level of transparency.

Following the merger, we have been quick to establish highly transparent governance structures. Today, the number of directors is seven, of which the outside directors constitute a majority of four. We have also voluntarily established a Nomination Committee and a Compensation Committee as advisory bodies to the Board of Directors. This is designed to improve management transparency in order to enhance enterprise value.

The Board of Auditors consists of four statutory auditors with a 2:2 split between internal and external auditors. As with the Board of Directors, the aim is to create an audit system that strikes a balance between specialist in-house expertise and the independence provided by outside talent. Going forward, we will work to establish sound corporate governance systems with the basic policy of promoting management practices that maximize enterprise value, ensuring transparency and improving our social accountability.



# Our Approach Value Creation







\*astellas

# **R&D Special Feature**

# Astellas Making Solid Pipeline Progress

We are actively engaged in research and development of new drugs, concentrating our resources in areas with substantial unmet medical needs. We have a number of unique global development compounds in our pipeline—including YM178, YM150, ASP1941 and YM155—that will become the next generation of global products. Furthermore, we added Agensys, Inc. to the Astellas Group in December 2007 and now plan to actively enter the field of oncology.

### Mirabegron (YM178) for OAB\* and OAB Market Potential

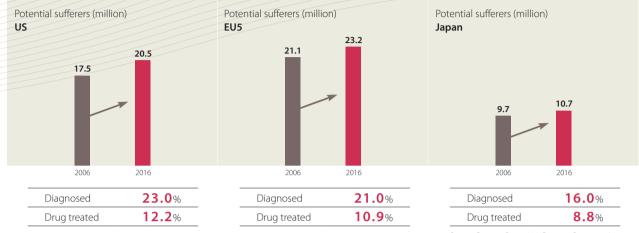
Mirabegron (YM178) is a beta-3 adrenoceptor agonist with a novel mechanism of action that will be first-in class. We are developing this compound for urinary frequency, urinary incontinence or urgency associated with overactive bladder. Phase 3 trials have been completed in Europe and the US and we initiated Phase 3 trials in Japan in summer 2009. We plan to make global approval NDA filings in fiscal 2010, the year ending March 31, 2011.

There is a substantial population of potential OAB sufferers in the US, five European countries, and Japan and patient numbers are expected to grow further. Less than a quarter of potential sufferers are diagnosed and only around 10% of potential sufferers receive drug treatment. We attribute these low numbers to limited awareness of the disease and see room for substantial market growth if efforts to develop the market are successful.

Anticholinergics are the most commonly used drug class to treat OAB and the global market is estimated at approximately ¥300 billion. Global market research by TNS Healthcare and Astellas (TNS/Astellas) in 2007 of OAB patients undergoing anticholinergic drug therapy indicated that 30–40% stopped drug treatment within 6 months because of side effects such as dry mouth, while another 25–30% stopped taking the drugs within 6 months because of insufficient efficacy. These results suggest that there are unmet medical needs in the OAB market. Because mirabegron has a different mechanism of action to anticholinergics, we think it could offer more options in the treatment of OAB.

#### Expected Product Profile of Mirabegron

- Less incidence of adverse events such as dry mouth observed with anticholinergics, the most common drug class used to treat OAB today
- Less concern of urinary retention in male patients with lower urinary tract syndromes compared to anticholinergics due to no decrease of voiding pressure
- \* OAB = Overactive bladder



## **OAB Market Potential Sufferers**

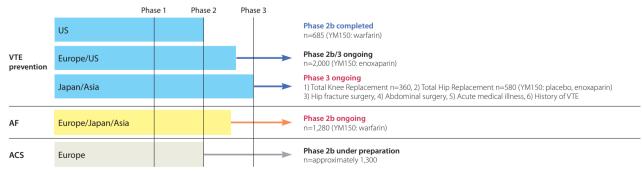
Source: DecisionBase 2008, Decision Resources Inc.

## Oral Factor Xa Inhibitor YM150 and SGLT2 Inhibitor ASP1941

Clinical trials are underway around the world on the factor Xa inhibitor YM150 for the prevention of thrombosis. The trials are designed to demonstrate the optimal dosage and administration regimen for each indication and each region.

For the indication of venous thromboembolism (VTE) prevention, Phase 3 trials have started in Japan and Asia and Phase 2b/3 trials have started in Europe. For the indication of atrial fibrillation (AF), we have started the Phase 2b trial using the same protocol in Europe, Japan, and Asia. For the indication of acute coronary syndrome (ACS), we are preparing to start the Phase 2b trial in Europe.

We face fierce competition in the development of an oral Factor Xa inhibitor as there are numerous competing products on the market or under development. However, with YM150, we intend to determine the dosage and administration regimen that provides an optimal balance of risks and benefits, i.e. an effective dosage that does not cause major bleeding.

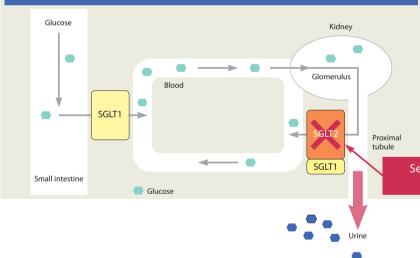


## YM150 Clinical Trial Status

We are also developing the SGLT2 inhibitor ASP1941 globally for type 2 diabetes. SGLT2 inhibitors have a new mechanism of action for type 2 diabetes. Based on the mechanism of action, we expect that ASP1941 can be used for various patient populations regardless of patients' clinical condition with no weight gain and limited hypoglycemic risk (see figure).

The results of the Japanese Phase 2b trial of ASP1941 were found out in May 2009. The result was that proof-of-concept (POC) was demonstrated, HbA1c was decreased in a dose-dependent manner and, statistical significance against placebo was detected in all ASP1941 treatment groups. No major safety concerns were seen and tolerability was confirmed. Furthermore body weight was decreased by ASP1941 treatment. The results of the Phase 2 trial in the US also demonstrated that ASP1941 was safe and well-tolerated, dose-dependent increases of urinary glucose excretion associated with the mechanism of action were observed and significant declines at the end of treatment in plasma glucose were also observed. We are now considering the next phase of clinical trials.

#### Mechanism of Action of ASP1941



SGLT2 inhibition causes excess glucose in the blood to be secreted into the urine

- SGLT1: A transporter that is highly expressed in the small intestine. It is responsible for transporting ingested glucose into the body. This transporter is also present in minute amounts in kidney tubules.
- SGLT2: A transporter that is highly expressed in kidney tubules. It is responsible for transporting glucose that has been filtered from the blood to the urine in the kidney glomerulus back into the blood in the body.

## Selective SGLT2 inhibitor

Sodium glucose cotransporter (SGLT) = a transporter that carries both sodium and glucose

#### **Building an Expansive Oncology Pipeline**

With substantial unmet medical needs also in the oncology field, we plan to actively enter the oncology area, and aim to build an oncology pipeline that can drive longterm growth.

We own technologies to search for the novel target molecules needed in innovative drug discovery. The addition of the Agensys technology platform to our target molecules already identified has enabled further expansion of our target molecule library in the field of oncology. Agensys is also pursuing cutting-edge antibody-drug conjugate (ADC) technologies (See figure). Among our current oncology projects, three small molecules and three antibody products have progressed to the clinical stages. Of these, YM155, ASP3550, and AGS-1C4D4 are in Phase 2. In addition, we aim to expand our oncology pipeline even further by transitioning promising preclinical compounds to the clinical stages as quickly as possible.

Approach	Launch – Clinical Phase	Mechanism of Action	Cancer Type
Small molecule products	Eligard® (EU launched) YM155 (Phase 2) ASP3550 (Phase 2) ASP0265 (Phase 1)	LH-RH agonist Inhibits survivin expression GnRH receptor antagonist	Advanced Prostate cancer Breast cancer, Non-Hodgkin's lymphoma, Melanoma Advanced Prostate cancer Prostate cancer
Antibody products	AGS-1C4D4 (Phase 2) AGS-16M18 (Phase 1) AGS-8M4 (Phase 1)	Antibody (recognizes prostate stem cell antigen)	Pancreatic cancer

#### \* Advanced ADC technologies

ADC technologies are at the cutting edge of research. Conjugates of antibodies and drugs bind specifically to antigens on the cancer cell surface and release a toxin inside the cancer cell. As shown in the diagram, normal antibodies bind to an

Antibody-Drug Conjugates (ADC):

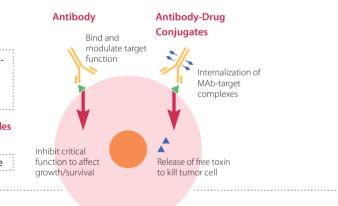
Potent and tumor cell-specific therapy

- MAb utilized as a vehicle to deliver toxins to specific targetexpressing tumor cells
- Applicable to any tumor target with proper expression
- profile (no dependency on biological function of target)

Combining ADC technology and Agensys' novel target molecules

Accelerated expansion of potential antibody oncology pipeline

antigen and thereby modulate a target function to inhibit cancer cell proliferation, but ADCs cause internalization of MAb-target complexes within the cancer cell, releasing a toxin to kill the cancer cell.



# Pipeline List (All)

(As of August 2009)

# 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.

# **Global Development**

Code No. [Generic Name]	Classification	Therapeutic Target	Phase 1	Phase 2	Phase 3	Filed	Area	Dosage Form	Origin	Remarks
FK506 [tacrolimus]	Immunosuppressant	Myasthenia gravis (all)				(Sep. 2008)	Japan	Oral	In-house	New indication
		Lower urinary tract syndrome in male patients				(June 2007)	Japan	Oral		New indication
YM617 tamsulosin]	Alpha-1 receptor antagonist	Pediatric neurogenic bladder					USA	Oral	In-house	Submitted the pediatric data to the FDA (June 2009)
		Complicated skin and skin structure				(Dec. 2006)*	USA		Theravance	
		infections (cSSSI)					Europe**			
[telavancin]	Lipoglycopeptide antibiotic					(Jan. 2009)	USA	Injection		
		Hospital-acquired pneumonia (HAP)					Europe	•		
		MRSA infections					Japan			
		Urinary frequency, urinary incontinence or urgency associated with overactive bladder					USA	Oral	In-house	
YM178 mirabegron]	Beta 3 receptor agonist						Europe			
							Japan			
							Japan/Asia			
		Prevention of venous thromboembolism (VTE) after major orthopedic surgery					Europe			
YM150	Factor Xa inhibitor						USA	Oral	In-house	
		Prophylaxis of thromboembolic					Europe			
		complications associated with atrial fibrillation (AF)					Japan/Asia			
YM443	Acetylcholine esterase						Japan			
acotiamide]	inhibitor	Functional dyspepsia					USA	Oral	Zeria	

	1		1						1	1
Code No. [Generic Name]	Classification	Therapeutic Target	Phase 1	Phase 2	Phase 3	Filed	Area	Dosage Form	Origin	Remarks
[solifenacin] [tamsulosin]	Co-administration of solifenacin and tamsulosin	Lower urinary tract syndrome associated with benign prostatic hyperplasia (BPH)					Europe	Oral	In-house	
							USA			
YM155	Survivin suppressant	Breast cancer, Non-Hodgkin's lymphoma, Melanoma					Europe	Injection	In-house	
							Japan			
ASP2151	Helicase-primase	Herpes zoster, Genital herpes					Japan	Oral	In-house	
	inhibitor						USA			
ASP0485	Immunosuppressant	Prophylaxis of kidney transplant					USA	Injection	In-house	
[alefacept]		rejection					Europe	Injection		
ASP1941	SGLT2 inhibitor	Type 2 diabetes					Japan	Oral	Kotobuki (co-development)	
							USA			
ASP9831	PDE4 inhibitor	Non-alcoholic steatohepatitis					Europe	Oral	In-house	
YM311	HIF stabilizer	Renal anemia					Europe	Oral	FibroGen	
(FG-2216)							Japan		Tiblogen	
ASP1517	HIF stabilizer	Renal anemia					Europe	Oral	FibroGen	
(FG-4592)							Japan			
YM060 [ramosetron]	5-HT3 receptor antagonist	Irritable bowel syndrome (IBS)					Europe	Oral	In-house	
YM905 [solifenacin]	Muscarine M3 receptor antagonist	Urinary frequency, urinary incontinence or urgency associated with overactive bladder (orally-disintegrating tablet)					Japan	Oral	In-house	New formulation
AGS-IC4D4	Antibody (Prostate stem cell antigen)	Pancreatic cancer					USA/Europe	Injection	In-house (Agensys)	

(Notes) \* telavancin: Received an approvable letter from the FDA in October 2007, received a complete response letter from the FDA in February 2009 \*\* telavancin: The MAA was withdrawn in Europe in October 2008

# Local Development: Japan

Code No. [Generic Name]	Classification	Therapeutic Target	Phase 1	Phase 2	Phase 3	Filed	Area	Dosage Form	Origin	Remarks
YM086 (BIBR277) [telmisartan]	Angiotensin II receptor blocker	Type 2 diabetic nephropathy				(June 2006)	Japan	Oral	Boehringer Ingelheim	New indication
ASP8825 (XP13512)	Prodrug of gabapentin	Restless legs syndrome					Japan	Oral	XenoPort	Preparation for filing
YM529 [minodronate]	Bisphosphonate	Osteoporosis (intermittent administration)					Japan	Oral	In-house (co-development with Ono)	New formulation
ASP1585 (AMG223)	Non-absorbed, polymer- based phosphate binder	Hyperphosphatemia					Japan	Oral	Ilypsa/Amgen	
YM177 [celecoxib]	Cyclooxygenase-II inhibitor	Acute pain					Japan	Oral	Pfizer	New indication
YM533 [beraprost sodium]	Prostacyclin receptor stimulator	Chronic renal failure (primary / nephrosclerosis)					Japan	Oral	Toray	New indication New formulation
ASP3550 [degarelix]	GnRH receptor antagonist	Prostate cancer					Japan	Injection	Ferring	

# Local Development: USA

Code No. [Generic Name]	Classification	Therapeutic Target	Phase 1	Phase 2	Phase 3	Filed	Area	Dosage Form	Origin	Remarks
RSD1235 [vernakalant] Antiarrhythmic agent	Antiarrhythmic agent	hythmic agent Atrial fibrillation (AF)					USA	Iniection	Cardiome	
	, and an injurit in e agente	Atrial fibrillation (AF)				(Dec. 2006)*		injection	Cardiorne	

\* Received an approvable letter from the FDA in August 2008

#### Phase 1

Code No.	Therapeutic Target	Dosage Form	Origin	
ASP0265	Prostate cancer, Endometriosis	Oral	In-house	
ASK8007	Rheumatoid arthritis	Injection	IBL Kaketsuken (co-development)	
ASP2905	Alzheimer's disease (Dementia), Schizophrenia	Oral	In-house	
ASP015K	Suppression of organ rejection in organ transplant	Oral	In-house	
AGS-16M18	Cancer	Injection	In-house (Agensys)	
AGS-8M4	Cancer	Injection	In-house (Agensys)	

Code No.	Therapeutic Target	Dosage Form	Origin	
ASKP1240	Suppression of organ rejection in organ transplant	Injection	Kyowa Hakko Kirin	
ASP3652	Overactive bladder	Oral	In-house	
ASP7035	Nocturia	Oral	In-house	
ASP0777	Alzheimer's disease (Dementia)	Oral	In-house	
ASP3291	Ulcerative colitis	Oral	In-house	
FK949E	Major depressive disorder	Oral	AstraZeneca	

# Pipeline by Therapeutic Area

(As of August 2009)

	Filed	Phase 3	Phase 2	Phase 1	
Urology	YM617 (LUTs, J)	YM178 (OAB, E, US, J)	ASP3550 (J)	ASP0265	
orology	YM617 (Pediatric, US) <sup>#</sup> " Submitted the pediatric data to the FDA	solifenacin/tamsulosin (E)	YM905 (D tablet, J)	ASP3652 ASP7035	
Transplant,			ASP0485 (E, US)	ASK8007 ASP015K	
Immunology, Inflammation	FK506 (Myasthenia gravis, J)	YM177 (Acute pain, J)	ASP9831 (E)	ASKP1240 ASP3291	
Anti-infective	telavancin (cSSSI, US) telavancin (HAP, US)	telavancin (E)	ASP2151 (US, J)	telavancin (J)	
			YM150 (VTE, E, US)		
	RSD1235 (US)	YM150 (VTE, J, A)	YM150 (AF, E, J, A)		
Diabetes, Cardiology,			ASP1941 (US, J)	YM311 (J)* ASP1517 (J)*	
Renal	YM086 (Diabetic nephropathy, J)	ASP1585 (Hyperphosphatemia, J)	YM311 (US)* ASP1517 (US)*		
			YM533 (J)		
CNS	ASP8825 (Restless legs syndrome, J)			ASP2905 ASP0777 FK949E	
Oncology			AGS-1C4D4 (E, US)	AGS-16M18	
Oncology			YM155 (E, US)	AGS-8M4 YM155 (J)	
Others		YM443 (J)	YM443 (US)		
		YM529 (1M, J)	YM060 (E)		

Japan Local New Indication, New Formulation

\* Licensed territory: E and J etc.

cSSSI: Complicated Skin and Skin Structure Infection

HAP: Hospital-acquired Pneumonia VTE: Venous thromboembolism

AF: Atrial fibrillation

## **Strengthening the Product Pipeline**

• Concluded an agreement in June 2009 with Maxygen, Inc. for establishing a joint venture with Maxygen to discover, research, and develop multiple protein pharmaceutical programs, including Maxygen's MAXY-4 program and other early stage programs (R&D of compounds for treating autoimmune diseases and transplant rejection).

In-house Global

Licensed-in Global

- In Europe, concluded a commercialization agreement in June 2009 with NeurogesX for Qutenza<sup>™</sup>, a capsaicin-based cutaneous patch to treat peripheral neuropathic pain in non-diabetic adults.
- In Taiwan, concluded a license agreement in May 2009 with Teijin for sales of TMX-67 (febuxostat), a highly potent non-purine drug that selectively inhibits xanthine oxidase for hyperuricemia in patients with gout.
- In the US, concluded a promotion agreement in August 2009 with Zogenix for Sumavel<sup>™</sup> DosePro<sup>™</sup> kits for acute treatment of migraine attacks and acute treatment of cluster headache episodes.
- Concluded an agreement in August 2009 with AstraZeneca AB for the co-promotion in Japan for an inhalant combination drug of budesonide and formoterol for the treatment of bronchial asthma in Japan.

# Global Products/Major US Products

# **Global Products**

#### PROGRAF<sup>®</sup> / ADVAGRAF<sup>®</sup> / GRACEPTOR<sup>®</sup>

- The immunosuppressant Prograf<sup>®</sup>, which is indicated for the suppression of organ rejection in organ transplants, is currently available in around 80 countries and regions. It has established a strong position as the leading drug in the transplantation field due to its status as the drug of first choice in many countries.
- In Japan, we launched Prograf<sup>®</sup> in 1993 for use in liver transplants. We have since gained additional indications for its use in organ transplants involving kidneys, bone marrow, heart, lungs and pancreas. In the United States, the largest market for organ transplants, Prograf<sup>®</sup> was launched in 1994 for use in liver transplants and has since gained additional indications for use in kidney and heart transplants. In Europe, we launched the drug in the UK in 1994 and currently sell it in approximately 30 countries and regions.
- Sales growth in Japan since 2005 has been strong, supported by additional indications for rheumatoid arthritis and lupus nephritis.

2009.3 Net sales (¥ billion)/YoY

201.0

 We launched a modified release formulation of Prograf® for once-aday dosing as Advagraf® in Europe in June 2007 and as Graceptor® in Japan in October 2008. Advagraf®, and Graceptor® are marketed in approximately 20 countries and regions, including all major European markets and Canada.

#### Net sales

Total	122.8	145.9	175.4	203.0	201.0
Exports to third parties	4.8	5.8	5.2	4.8	6.3
Asia	5.4	7.8	10.3	11.0	11.2
Europe	38.4	43.4	52.7	65.3	66.0
North America	63.5	74.5	88.0	97.2	88.8
Japan*	10.5	14.2	19.0	24.6	28.5
	2005.3	2006.3	2007.3	2008.3	2009.3
					(¥ billion)

\* Based on invoiced prices

# HARNAL<sup>®</sup> / FLOMAX<sup>®</sup> / OMNIC<sup>®</sup> / OMNIC OCAS<sup>®</sup>

- An alpha-1 blocker that is highly selective for smooth muscle in the prostate and urethra, Harnal<sup>®</sup>, a treatment of functional symptoms associated with benign prostatic hyperplasia (BPH). It was first launched in Japan in 1993 and is currently available in about 90 countries and regions. Harnal<sup>®</sup> is now established globally as the "gold standard" in the treatment of BPH.
- The substance patent expired in Japan in February 2005 and in Europe in February 2006; sales of Harnal® are declining as a result.
- We have launched an orally disintegrating tablet formulation (Harnal® D Tablet) in Japan and Asia. We have also introduced a new oral controlled absorption system (OCAS) formulation (Omnic OCAS®/Harnal OCAS®) in Europe and Asia.
- Under an out-licensing agreement with Boehringer Ingelheim (BI) for Harnal<sup>®</sup> in the US, we receive bulk sales and royalty revenues from BI. Astellas Pharma US is also co-promoting the product with BI in the US market. Sales of the drug in the US market continue to grow well under the brand name Flomax<sup>®</sup>.

2009.3 Net sale	s (¥ billion)/YoY
	116.6
	(-4.7%)

• The US substance patent will expire in October 2009. However, by submitting pediatric data to the FDA market exclusivity is expected to be extended to April 2010. Also we expect a generic version to be launched in March 2010.

#### Net sales

Total	135.9	137.8	127.0	122.4	116.6
Bulk sales/royalties	37.0	37.4	45.5	46.7	46.6
Asia	4.5	5.9	7.5	8.2	8.1
Europe	44.8	49.5	35.3	29.5	25.7
Japan*	49.4	44.9	38.5	37.5	35.6
	2005.3	2006.3	2007.3	2008.3	2009.3
					(¥ billion)

\* Based on invoiced prices

# **VESICARE**<sup>®</sup>

- A muscarine receptor antagonist, Vesicare® helps to relieve symptoms associated with overactive bladder (OAB) such as urinary urgency, frequent urination and urgency incontinence. Launched in Europe in 2004, it is now sold in approximately 50 countries and regions. We launched the product in the US in 2005 and Japan in 2006.
- Vesicare<sup>®</sup> has firmly established its position in the major markets of Europe and Japan, securing the top market share in both these regions. In Europe, it is the leading drug in its market segment in 11 of the 20 countries in which it has been launched.
- In the US, the largest market, we are co-promoting the product with GlaxoSmithKline. It is the No. 2 branded drug in its segment in the US.

 Going forward, we plan to step up the sales and marketing activities for Vesicare<sup>®</sup>, increasing awareness regarding OAB and treatment options as well as publicizing the product's effectiveness.

2009.3 Net sales (¥ billion) /YoY

2009.3 Net sales (¥ billion)/YoY

**17.5** (-1.9%)

**71.4** (18.8%)

#### Net sales

North America Europe	- 1.1 1.5	7.1	12.3	18.5	20.6
Asia	-	-	0.0	0.3	0.7
Total	2.7	14.8	36.2	60.1	71.4

\* Based on invoiced prices

# FUNGUARD<sup>®</sup> / MYCAMINE<sup>®</sup>

- The candin-type antifungal agent Funguard® has a mechanism of action that inhibits cell wall biosynthesis. Since we launched this drug in Japan in 2002, we have grown its share of the market thanks to its outstanding efficacy and safety profile.
- The product is branded as Mycamine<sup>®</sup> in Europe and the US, and was launched in the US in 2005. In Europe, it was launched in the

U.K. in August 2008 and is now also sold in Germany, France, Spain and other European countries. In January 2008, we gained regulatory approval for the additional indication of candidemia in the US, which helped boost sales. The product is currently available in 23 countries and regions, including Canada and several Asian countries.

# **Major US Products**

2009.3 Net sales(¥ billion)/YoY	
ADENOSCAN®· LEXISCAN® 39.3 (4.5%)	<ul> <li>Adenoscan<sup>®</sup> and Lexiscan<sup>®</sup> are pharmacologic stress agents for radionuclide myocardial perfusion imaging (MPI) in patients who are unable to undergo adequate exercise stress testing.</li> <li>We launched Adenoscan<sup>®</sup> in 1995 and Lexiscan<sup>®</sup> in June 2008, both in the US market.</li> <li>The market for pharmacologic stress agents has expanded as the reliability of these non-exercise-based methods for testing cardiac function has increased, driving steady sales growth of both Adenoscan<sup>®</sup> and Lexiscan<sup>®</sup>.</li> </ul>

# Major Domestic Products

2009.3 Net sales(¥ billion)/YoY	
<b>LIPITOR®</b> 95.3 (-2.5%)	<ul> <li>We have grown the market share of the hypercholesterolemia treatment Lipitor<sup>®</sup> since its Japanese launch in 2000.</li> <li>Lipitor<sup>®</sup> is now the leading statin, accounting for nearly 40% (NHI drug price basis) of this market segment in the fiscal year ended March 31, 2009.</li> <li>In the highly competitive market, we are aiming to maximize the product value of Lipitor<sup>®</sup> through our co-promotional efforts with Pfizer Japan and the utilization of a broad range of evidence obtained from clinical experience worldwide.</li> </ul>
MICARDIS*+ MICOMBI* 64.4 (2.9%)	<ul> <li>The angiotensin II receptor blocker (ARB) Micardis<sup>®</sup> was launched in Japan in December 2002 for the treatment of hypertensin and has grown market share ever since.</li> <li>Micardis<sup>®</sup> had a market share of approximately 15% (drug price basis) in the fiscal year ended March 31, 2009 Sales of Micardis<sup>®</sup> are continuing to grow in line with the expanding ARB market owing to product characteristics such as a long-acting effect and almost complete excretion in the bile.</li> <li>In June 2009, we launched Micombi<sup>®</sup> Combination Tablets, a combination of Micardis<sup>®</sup> with a diuretic.</li> <li>We are co-promoting Micardis<sup>®</sup> in Japan with Nippon Boehringer Ingelheim.</li> </ul>
GASTER® 53.0 (-12.9%)	<ul> <li>Since its launch in Japan in 1985, the H<sub>2</sub> receptor antagonist Gaster® has gained widespread clinical use as a leading treatment for peptic ulcers and gastritis.</li> <li>Its safety and efficacy profile, particularly in the treatment of gastritis, is supported by many years of clinical experience and by clinical data from the large-scale FIRE* and FORCE** studies on Japanese patients.</li> <li>* FIRE: Famotidine's Informative Research &amp; Evaluation</li> <li>** FORCE: Famotidine Or Rebamipide in Comparison by Endoscopy</li> <li>The substance patent expired in March 2004 in Japan. Gaster® recorded a market share of approximately 20% of the overall Japanese market for H<sub>2</sub> receptor antagonists and proton pump inhibitors in fiscal 2008.</li> <li>We have introduced an orally disintegrating tablet Gaster® D formulation that patients can take easily without water.</li> </ul>
MYSLEE® 25.7 (19.5%)	<ul> <li>Myslee® was launched in Japan as a hypnotic in December 2000. The drug is a hypnotic with a rapid onset of action and provides a sleep pattern close to natural sleep.</li> <li>Promoted using the slogan "Good Sleep, Good Life," Myslee® sales are growing, and the drug is the leader in the Japanese market for hypnotics. Myslee® had a market share of approximately 40% (drug price basis) in fiscal 2008.</li> <li>We are co-promoting Myslee® with Sanofi-aventis.</li> </ul>

2009.3 Net sales(¥ billion)/YoY				
SEROQUEL® 21.0 (9.6%)	<ul> <li>Seroquel<sup>®</sup> was launched in Japan in 2001 for the treatment of schizophrenia. It is an atypical antipsychotic that can treat not only the positive symptoms of schizophrenia, but also the negative symptoms, emotional symptoms and cognitive difficulties that conventional antipsychotics often fail to address adequately.</li> <li>The Japanese market for antipsychotic drugs has shifted away from conventional antipsychotics following the introduction of atypical antipsychotics and this trend is driving steady expansion in sales of Seroquel<sup>®</sup>. Seroquel<sup>®</sup> ranked third in this market with a share of approximately 17% in fiscal 2008.</li> </ul>			
GENINAX® 6.4 (71.9%)	<ul> <li>The oral quinolone antibiotic Geninax<sup>®</sup> shows strong activity against respiratory tract infection pathogens and otorhinolaryngological infection pathogens, including the multi-drug resistant <i>S. pneumoniae</i>.</li> <li>Geninax<sup>®</sup> has seen sales steadily expand since it was launched in October 2007. In fiscal 2008, Geninax<sup>®</sup> increased its market share to approximately10%.</li> <li>We are co-promoting Geninax<sup>®</sup> with Taisho Toyama Pharmaceutical.</li> </ul>			
CELECOX® 10.4 (178.7%)	<ul> <li>The non-steroidal anti-inflammatory agent Celecox® was the first selective COX-2 inhibitor on the Japanese market, and it has steadily penetrated the market for the indications of rheumatoid arthritis (RA) and osteoarthritis (OA) since its launch in June 2007. In June 2009, in addition to the relief of inflammation and pain associated with RA and OA, the drug was approved in Japan for the additional indications of lumbago, scapulohumeral periarthritis, cervico-omo-brachial syndrome, and tendinitis/tendosynovitis. We are currently developing the drug for additional indication including acute pain.</li> <li>Sales of Celecox® have grown steadily since its launch and sales volumes increased significantly in fiscal 2008 following the April 2008 lifting of restrictions on the long-term prescription of Celecox®. The drug's market share in fiscal 2008 was approximately 15%.</li> <li>We are co-promoting Celecox® with Pfizer Japan.</li> </ul>			
IRRIBOW® 1.6 (-)	<ul> <li>We launched Irribow® in Japan for the treatment of diarrhea-predominant irritable bowel syndrome (IBS) in males in October 2008. The product is the first serotonin 5-HT<sub>3</sub> receptor antagonist on the Japanese market. Administered once a day, Irribow® demonstrates efficacy in treating the various symptoms of IBS, including diarrhea and abdominal pain or discomfort.</li> <li>There are many potential patients who are unaware that they have IBS. We are actively working on patient education programs to raise awareness of this condition.</li> </ul>			



# Our Approach

# Business Expansion (Review of Global

# Astellas Pharma China, Inc.

Photos from top left

Regulatory Affairs Robert Gao

Government Affairs Hongqing Dai Sales Administration Hui Shen

Corporate Communications
Jennifer Ding

Medical Affairs Guotao Yang

President Joseph Cho



# Operations)

Regional for Northern China Jack Xiao

Marketing Alan Cheng Commercial Hong Zhang

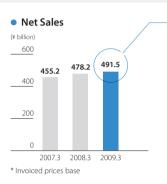
Marketing Arthur Chang Regional for Southern China Vick Zheng

Human Resource Vicky Xiao Regional for Eastern China Steven Chen

# Review of Global Operations

# Our Approach

# **JAPAN**





#### Market Size

The Japanese ethical pharmaceuticals market was worth ¥8,368.6 billion\* in fiscal 2008. Astellas has a market share of 7.2%, ranking it second in Japan by sales.

\* Copyright 2009 IMS Japan K.K. Source: JPM 2009 March MAT Reprinted with permission

### **Sales of Major Products**

(¥ billic				
	2008.3	2009.3	2010.3 (forecasts)	
Rx sales in Japan	478.2	491.5	1 507.8	
Lipitor®	97.7	95.3	1 99.0	
Micardis®	62.6	64.4	1.8	
Gaster®	60.9	53.0	50.6	
Harnal®	37.5	35.6	35.5	
Prograf®	24.6	28.5	1 34.8	
Myslee®	21.5	25.7	1 27.8	
Seroquel®	19.2	21.0	1 22.9	
Vesicare®	13.5	19.0	1 22.8	
Celecox®	3.7	10.4	15.0	
Geninax®	3.7	6.4	11.3	
Irribow®		1.6	1 3.0	

\* Sales figures based on invoiced prices.

## **Fiscal 2008 Overview**

Astellas recorded overall sales of ethical pharmaceuticals in Japan of ¥491.5 billion in fiscal 2008, an increase of 2.8% in yearon-year terms. Favorable sales of existing products together with sales contributions from recently launched products helped to offset the impact of the NHI drug price revision, which reduced sales by ¥18.6 billion. Mainstay products delivering solid sales performances included immunosuppressant Prograf®, long-acting angiotensin II receptor blocker Micardis®, insomnia treatment Myslee® and schizophrenia treatment Seroquel®. New products included the overactive bladder (OAB) treatment Vesicare®, the non-steroidal anti-inflammatory analgesic agent Celecox®, the oral quinolone antibiotic Geninax® and Irribow®, a treatment for diarrhea-predominant irritable bowel syndrome in males.

## **Business Expansion**

**\*** Core objective

## ---> Growth drivers

Secure top share of domestic market Industry-leading sales and marketing capabilities
 Sustained sales growth from existing products
 Additional growth from new products

Astellas has a rich product lineup in Japan and ranked second in Japan by sales for the year ended March 31, 2009 with a market share of 7.2%. Moreover, according to a corporate image survey in 2008 conducted by *Nikkei Medical*, Astellas' medical representatives ranked first in Japan in terms of customer satisfaction.

No. 2 Share in Japanese Ethical Pharmaceutical Market (7.2%) (NHI drug price base)

**Rich Product Lineup** 

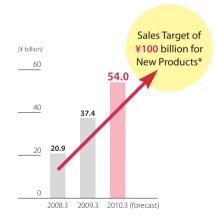
MR Customer Satisfaction Ranking: No. 1 (Company Image Survey by Nikkei Medical)

#### **Growth Strategy**

Astellas is looking to secure the top spot in the Japanese market as soon as possible as the result of growth generated by new products together with expanded sales of established mainstay products. The Company has introduced a series of new products in Japan over the past few years, with the launch of Vesicare® in June 2006, Celecox® in June 2007, Geninax® in October 2007 and Irribow® in October 2008. New products generated ¥37.4 billion in sales in the year ended March 31, 2009, up from just ¥6.2 billion two years earlier. In April 2009, Astellas launched the osteoporosis treatment Bonoteo®. In the fiscal year ending March 31, 2010, Astellas is projecting sales of ¥54.0 billion from Vesicare®, Celecox®, Geninax®, Irribow® and Bonoteo®. Target aggregate sales from new products are ¥100 billion.

April 2009 also saw Astellas gain regulatory approval for Micombi<sup>®</sup>, a combination of Micardis<sup>®</sup> with a diuretic. Astellas also gained approvals for additional indications in June 2009 for Celecox<sup>®</sup> for the treatment of lumbago and other conditions and in July 2009 for Prograf® for the treatment of ulcerative colitis. The additional approvals will contribute greatly to maximizing the value of our current mainstay products.

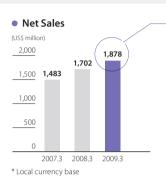
Sales of ethical pharmaceuticals in Japan in the year ending March 31, 2010 are forecast to reach ¥507.8 billion, representing 3.3% growth over the previous year.



\* For five products: Vesicare®, Celecox®, Geninax®, Irribow®, and Bonoteo®.

## Our Approach

## NORTH AMERICA





#### Market Size

The North American ethical pharmaceuticals market was worth US\$309.7 billion\* (total for the US and Canada) in 2008. In North America, Astellas currently conducts business in the US and Canada.

#### Fiscal 2008 Overview

Overall sales of ethical pharmaceuticals fell 2.9% to ¥188.9 billion on a yen basis due to currency exchange rates. In local currency (US dollar) terms however, sales rose 10.4% year on year to US\$1,878 million. Strong growth in sales of Prograf® and a contribution from VESIcare® enabled Astellas to post double-digit sales gains in North America on a US dollar basis. In anticipation of the expiry of the US substance patent on Prograf® in April 2008, Astellas has been focusing on reinforcement by building up operations in the urology and hospital franchises as a "post-Prograf®" strategy.

#### **Growth Strategy**

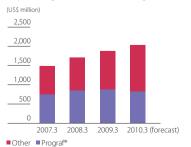
Higher sales of VESIcare® are expected to drive growth for Astellas in the North American market in the year ending March 31, 2010. Furthermore, Lexiscan®, a pharmacologic stress agent for radionuclide myocardial perfusion imaging that was launched in June 2008, posted nearly US\$100 million in sales in a successful first year on the market. Astellas also expects to launch the injectable antibiotic telavancin for the treatment of CSSSI\* in fiscal 2009. This will broaden Astellas' lineup of drugs to treat infectious diseases, which includes the antifungal agent Mycamine® and AmBisome®.

\* Complicated skin and skin structure infection

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

			(US\$ mi	llion)
	2008.3	2009.3	2010.3 (forec	asts)
Sales in the US	1,702	1,878	1 2,0	)24
Prograf®	850	884	٤ 🔪	322
Scan (Adenoscan®+Lexiscan®)	329	390	1 5	500
Lexiscan®		93		—
AmBisome®	66	61	1	62
Protopic®	70	75	1	77
VESIcare®	242	308	1 3	384
Mycamine®	41	51	1	66
Vaprisol®	7	7	1	14
Amevive®	19	16	1	19

#### Expanding Business After Prograf®



<sup>\*</sup> Copyright 2009 IMS Health. All rights reserved Source: IMS World Review 2009 Reprinted with permission

## **Business Expansion**

### **\*** Core objective

## Growth drivers

Successful development of specialty franchise-based business model Reinforcement and expansion of urology and hospital franchises

Growing sales of VESIcare°, Scan, Mycamine° and others

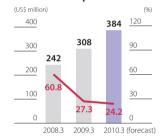
Maintenance of transplantation franchise

Although the economic downturn is expected to continue to exert an effect on the prescription pharmaceutical market in the United States, Astellas expects a relatively small impact on North American operations because the Company's business is mainly targeted at hospitals. Going forward, Astellas plans to expand the ethical pharmaceutical business in North America by maintaining the transplantation franchise while reinforcing and expanding the urology and hospital franchises.

Sales of ethical pharmaceuticals in North America in the year ending March 31, 2010 are forecast to increase to US\$2,024 million, a 7.8% gain in year-on-year terms.

In July 2009, Astellas established an affiliate in Brazil, marking the Company's foray into the Latin American market.

#### **VESIcare®** Expansion



Sales Growth rate

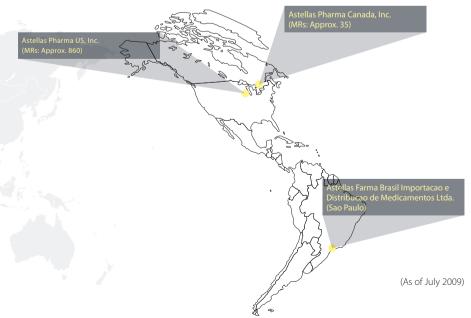
#### Scan (Adenoscan®+ Lexiscan®) Expansion



#### Mycamine® Expansion

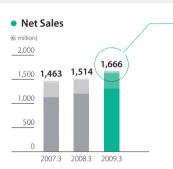


## North America: Sales and Marketing Infrastructure (US/Canada)



## Our Approach

## **EUROPE**

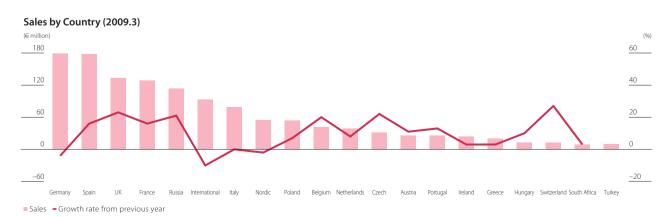


• Sales by Geographical Areas 2009.3 Asia 2.8% North America 19.6% Japan 52.9%

Sales by Astellas
Huk and Royalties
Kocal currency base
\* Local currency base
\* Local currency base

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

				(€ million)
	2008.3	2009.3	2010.3	(forecasts)
Sales in Europe	1,514	1,666	$\mathbf{x}$	1,654
Harnal (Omnic <sup>®</sup> , Omnic OCAS <sup>®</sup> , Flomax <sup>®</sup> )	472	504	1	463
Sales by Astellas (Omnic®, Omnic OCAS®)	182	179		165
Bulk Sales and Royalties	289	324		297
Prograf® and Advagraf® (Incl. exports to third parties)	434	502	~	488
Vesicare®	114	143	1	169
Protopic®	32	36	1	41
Mycamine®	_	0	1	9
Eligard®	57	87	1	104



## Market Size

The European ethical pharmaceuticals market was worth US\$235.5 billion\* in 2008. Astellas has 20 affiliates and 9 representative offices throughout Europe, the Middle East and Africa which cover about 40 countries and regions.

\* Copyright 2009 IMS Health. All rights reserved Source: IMS World Review 2009 Reprinted with permission

#### **Fiscal 2008 Overview**

On a yen basis, overall sales in the year ended March 31, 2009 declined 2.3% compared with the previous year to ¥239.1 billion, mainly reflecting the impact of a stronger yen. In local currency (euro) terms however, sales rose 10.0% year on year to 1,666 million euros. The healthy year-on-year sales growth was driven by Prograf®/Advagraf®, Vesicare®, Eligard® (for the treatment of advanced prostate cancer,) and Protopic®, while Omnic® and Omnic OCAS® maintained steady sales. Astellas successfully launched Mycamine® in Europe in 2008. In addition, bulk sales and royalty revenues from licensee Boehringer Ingelheim for Harnal increased year on year.

## **Business Expansion**

#### **\*** Core objective

## ---> Growth drivers

Expanding sales in terms of both products and geography Expansion of product lineup and sales presence
 Reinforcement of urology and infectious disease franchises
 Ensure growth in both mature and emerging markets

#### **Growth Strategy**

Astellas expects some price reduction in Europe for Prograf<sup>®</sup> in the year ending March 31, 2010 following the expiry of the substance patent in leading European markets in June 2009. However, Astellas expects major contributions from its urology franchise (Vesicare<sup>®</sup> and Eligard<sup>®</sup>), as well as growth from the new franchise of infectious diseases. Bulk sales and royalty revenues for Harnal in the US from licensee Boehringer Ingelheim under the brand name Flomax<sup>®</sup> are expected to decline due to the launch of generics.

Among Japanese pharmaceutical companies, Astellas is a clear leader in Europe. This is the result of a "matrix" approach whereby Astellas has reinforced its product portfolio while also expanding the number of countries where it has a sales and marketing presence. Having set up a new base in Turkey in fiscal 2008, Astellas now has 20 affiliates and 9 representative offices across Europe, the Middle East and Africa. Going forward, Astellas plans to continue reinforcing the product lineup while also targeting market-based expansion.

Astellas' sales in Europe in the year ending March 31, 2010 are forecast to decline 0.8% year on year to  $\leq$ 1,654 million due in part to the impact of currency movements against the euro.

#### Europe: Business Base Encompassing the Entire Region

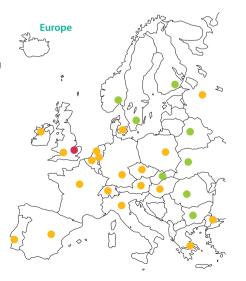
20

- European Headquarters: U.K.
- Affiliates:
- Representative Offices: 9
- International Affiliate (based in the Netherlands) covers the remaining territories through local agents.

\*Nordic Affiliate (in Copenhagen) covers Sweden, Denmark, Norway, Finland and Iceland. \*Russian Affiliate (in Moscow) covers Russia and 11 CIS countries.

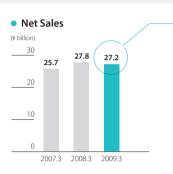






## Our Approach

## ASIA





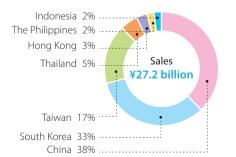
#### Market Size

The East Asian ethical pharmaceuticals market, excluding Japan, was worth ¥5,061.2 billion (IMS Prognosis 2009) in 2008. Astellas has operating bases in eight markets in the region: China, Hong Kong, Taiwan, South Korea, Indonesia, Thailand, the Philippines and India.

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

			(¥ billion)
	2008.3	2009.3	2010.3 (forecasts)
Major products in Asia	20.1	21.0	1 22.0
Prograf®	11.0	11.2	11.7
Harnal®	8.2	8.1	7.7
Vesicare®	0.3	0.7	1.1
Mycamine®	0.2	0.5	1 0.8
Protopic®	0.4	0.5	1 0.7

#### Sales by Sales Company (2009.3)



### Fiscal 2008 Overview

Sales of Prograf<sup>®</sup> and Harnal<sup>®</sup> grew strongly in Asian markets in the year ended March 31, 2009, and Vesicare<sup>®</sup> also expanded steadily. Although regional sales dipped 2.2% to ¥27.2 billion due to the impact of a stronger yen, sales were 17% higher than in the previous year in local currency terms.

Asia is a market with high growth potential due to ongoing population expansion. The markets in places such as China, India, Hong Kong and Thailand are all projected to grow at annual double-digit rates until at least 2012. Having entered India in November 2008, Astellas now has operating bases in eight markets in the region. Astellas is the largest Japanese pharmaceutical company in the East Asian market spanning China, South Korea and Taiwan. Using knowledge and expertise gained in the Japanese, US and European markets, Astellas is aiming to maximize product value in Asian markets.

## **Business Expansion**

#### **\*** Core objective

## ---> Growth drivers

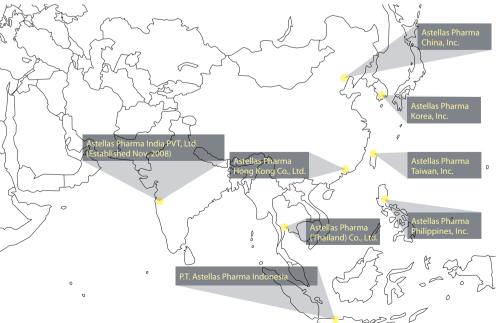
Top-ranking Japanese pharmaceutical company in the Asia and Oceania market Concentration of resources on Chinese market
 Early establishment of operations in Indian market

## **Growth Strategy**

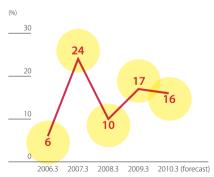
While Prograf<sup>®</sup> and Harnal<sup>®</sup> remain the primary sales drivers in Asia, Astellas aims to achieve rapid market penetration with the new products Vesicare<sup>®</sup>, Mycamine<sup>®</sup> and Advagraf<sup>®</sup>. In particular, Astellas is focusing resources on the Chinese market. In 2008, the Chinese pharmaceuticals market grew by nearly 30% to be worth approximately US\$25.0 billion. More growth is expected going forward. Astellas aims to expand sales further of Prograf<sup>®</sup> and Harnal<sup>®</sup> in the Chinese market as well as grow new products Vesicare<sup>®</sup> and Mycamine<sup>®</sup>. In addition, Astellas is working to initiate commercial operations in India after entering the market in fiscal 2008. The Indian population is approximately 1.1 billion, and the Indian economy has been growing nearly 10% annually, with further growth expected. The market is expected to grow further as intellectual property rights have been systematized after the establishment of the Product Patent regime in 2005.

Sales of ethical pharmaceuticals in Asia in the year ending March 31, 2010 are forecast at and are expected to grow 16% in local currency terms to ¥27.0 billion.





## High Growth Rate





# Our Approach Responsible Management (Corporate Social

## **Global Management Committee Members**

Photos from top left

Corporate Executive Asia International Shinichiro Katayanagi Senior Corporate Executive Drug Discovery Research Shinichi Tsukamoto, Ph.D.

Representative Director, President and Chief Executive Officer Masafumi Nogimori Corporate Executive Astellas US LLC President and CEO and Astellas Pharma US, Inc. President and CEO Seigo Kashii Senior Corporate Executive Sales & Marketing Katsuro Yamada

Representative Director, Executive Vice President and Chief Sales & Marketing Officer Yasuo Ishii



# Responsibility/Corporate Governance)

Astellas Pharma Global Development, Inc. President Steven Ryder, MD., F.A.C.P.

> Senior Corporate Executive Chief Administrative Officer Yoshiro Miyokawa

Senior Corporate Executive

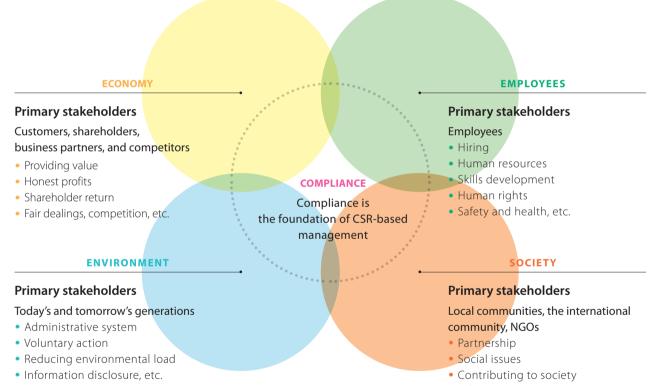
Technology Hitoshi Ohta Senior Corporate Executive Astellas Pharma Europe Limited President and CEO Masao Yoshida Corporate Executive QA, RA and Pharmacovigilance Masaharu Asano, Ph.D.

Senior Corporate Executive Chief Financial Officer and Chief Strategy Officer Yoshihiko Hatanaka

# Corporate Social Responsibility

Our CSR-based management program 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 at large. This means not only contributing to society through the provision of truly effective pharmaceutical products, but also considering how to help realize social and environmental sustainability as a good corporate citizen, and take the necessary action.

## THE FIVE FIELDS OF CSR-BASED MANAGEMENT



Information disclosure, etc.

Corporate performance is evaluated not only from an economic perspective but also in terms of the company's environmental and social performance. The determination of a company's overall rating using this "triple bottom line" has become a commonly accepted practice. At Astellas, we break this down further by making society and employees into separate categories, and add compliance as an additional factor. We call these the five fields of CSR-based management. Compliance is the very foundation of all our corporate activities, and we are strongly committed to fulfilling our social responsibilities in the other four fields as well.

### Corporate Management Rooted in High Ethical Standards

Astellas has not only designated compliance as a separate field in its CSR-based management model, but has positioned it as the foundation for all its business activities. Here, the term compliance incorporates both a strict observance of laws and regulations, and the maintenance of high ethical standards. Astellas requires employees to observe rules and procedures, in regard to both individual affairs and social issues. As a company, we are strongly committed to the strict observation of our Code of Conduct, determined by the efforts of each individual.

• COMPLIANCE

#### **Compliance Committee**

The CSR Committee was previously responsible for discussing and deciding on compliance planning and other matters, but we have now established a Compliance Committee in order to better respond to individual issues and business systems across the Astellas Group, including our overseas operations. This Committee will discuss compliance policy and planning across the entire Astellas Group, as well as other key compliance issues.

#### **Committee Members**

- Chairperson: Chief Compliance Executive
- Members: Vice President, General Affairs & CSR; Vice President, Legal; Vice President, Human Resources; Senior Director, General Affairs & CSR
- Observers: Outside legal counsel, full-time corporate auditors, a labor union representative

#### **Ethical Considerations in R&D**

Astellas takes into account ethical considerations in gene research, clinical research and animal testing.

In terms of ethical considerations in gene research, we have established an Ethics Review Board on Human Tissue Research, based primarily on the Ethics Guidelines for Human Genome/ Gene Analysis Research issued by the Japanese government. This committee, which is made up of members of the general public and experts in various fields such as ethics, law, and the natural sciences, deliberates on the ethical acceptability of research on human genome and tissue samples.

In terms of ethical considerations in clinical research, we have established an in-house Institutional Review Board that includes outside doctors and lawyers. This board checks and monitors the ethical and scientific appropriateness of clinical trial plans. Regarding ethical considerations in animal testing, along with setting policies on animal testing that balance scientific and animal welfare perspectives, the Animal Research Committee considers the "four Rs"\* before deciding whether to permit animal testing. We believe that objective assessment is important in animal testing, so our Kashima R&D Center obtained accreditation by the Association of Assessment and Accreditation of Laboratory Animal Care International.

#### \* The four Rs:

- (1) Replacement (the possibility of substituting with a non-animal test)
- (2) Reduction (reducing the number of animals used to a minimum)
- (3) Refinement (refining measures to eliminate unnecessary animal suffering)
- (4) Responsibility (being responsible for sufficiently explaining the need for and the predictability of the experiment and understanding the significance of the experiment)

## **CSR Activities Overseas**

#### Asia

Compliance managers in each of the eight sales companies across Asia play a central role, maintaining close contact with Astellas headquarters compliance departments and implementing measures to foster a culture of compliance. In fiscal 2008, the presidents or compliance managers from these Group companies met in Tokyo to exchange information.

North America

Astellas US LLC, which functions as the headquarters of our North American operations, has established a Compliance Committee and appointed a Chief Compliance Officer. The company is working to ensure employees are familiar with their own compliance guide and code of conduct. Creative approaches are being used, such as online training systems, to cover the extensive territories in North America.

Europe

Astellas Pharma Europe Ltd. has appointed a Chief Compliance Officer and has distributed its own code of conduct—translated into the various European languages—to all European group employees. This has led to a greater understanding of compliance issues in the sales companies and plants across Europe.

#### • ENVIRONMENT

## Accreditation of Our Environmental and Safety Management System

We have obtained ISO14001 certification (an international standard for environmental management) for almost all our plants in Japan and overseas. We have also acquired OHSAS18001 certification (an international standard for occupational safety and health management) at our Takahagi, Dublin, and Kerry plants. Other plants have developed their own occupational health and safety management systems and are working to continuously improve these systems. At our laboratories, we have developed an integrated management system for environmental and health and safety issues. The research divisions are working together to continuously improve their environmental and safety initiatives.

## "Green Chemistry" Initiatives at the Process Chemistry Laboratories—Eco-friendly, safe drug production processes

One of our main challenges at the Process Chemistry Laboratories is to factor in environmental and safety issues when designing manufacturing processes. We have therefore set up a specialized

• SOCIETY

research group in this field. This has meant that the Process Chemistry Laboratories are now rooted in a culture of designing manufacturing processes that take environmental and safety factors into consideration. We call this "Green Chemistry."

Our goal is not to simply develop conventional manufacturing processes that use organic solvents. Rather, we are embracing new drug manufacturing processes that incorporate revolutionary new technologies that have yet to be fully established today, such as processes that use absolutely no organic solvents, but involve reactions in aqueous solution or carbon-efficient reactions using new catalysts.



#### **Activities Supporting Asia and Africa**

# Contributing to the Construction of the Regional Health Center in Indonesia

Through PH-Japan, an international health and medical support organization, we are contributing to the setting up of a Regional Health Center in the Serang district of Banten Province, Indonesia. This center is expected to help raise the health level in the region.



Regional Health Center (Under Construction)

## Supporting the HIV/AIDS Mother and Child Protection Project in Angola

Astellas is supporting the HIV/AIDS Mother and Child Protection Project, which is being run in Angola by France-headquartered MEDECINS DU MONDE (Doctors of the World) an international medical support organization in Angola, Africa. This project aims



to improve regional medical care with specialist staff supervising and training local staff.

A tape is used to measure the thickness of this child's arm, as part of a nutritional check-up

#### **Ongoing Contributions to Local Communities**

Astellas has donated 212 ambulances, including 33 high-grade ones, to local communities since 1970. The ceremony usually takes place on First-Aid Day, September 9.





Chichibu Fire Department

Fire Department, City of Shikokuchuo

#### • EMPLOYEES

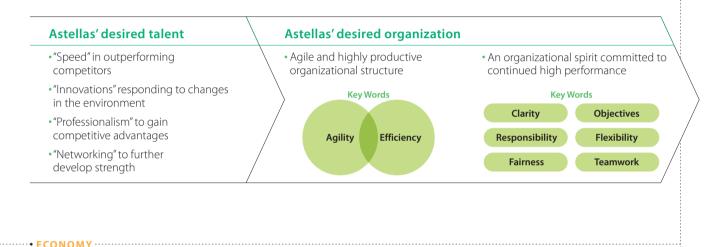
Astellas believes that proactive initiatives in the areas of human resources, employment and welfare lead to activities that contribute new value to society.

#### **Human Resources Vision**

Through its human resources vision, Astellas has clarified its employees' desired talents and its desired organizational features.

#### **Human Resources Policies**

We have clarified policies for operating our human resource management system. We believe that the human resource management system at Astellas should be attractive to potential employees who demonstrate excellence in their field, and should also create an environment that enables our talented employees to tackle greater challenges.



Sound economic activities provide value to society, and securing legitimate profit through such activities is the *raison d'être* of a company. We also recognize that Astellas' social responsibilities with respect to procurement activities call for the building of partnerships with suppliers who can carry out business activities in a fair and transparent manner, as well as initiatives that aim to develop sustainability and increased enterprise value for each party. It is for these reasons that we are implementing CSR procurement.

• For more information, please see the CSR Report at the following address:

#### http://www.astellas.com/en/csr/



## Corporate Governance

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

The Company bases its operations on fulfilling the mission of delivering forms of new value that can help people lead healthy lives. In addition, the Company strives to improve its corporate governance system, fully understanding the importance of improving business transparency and fulfilling accountability requirements to society.

The Company has 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. The Board of Directors has seven members. The board includes four outside Directors in order to promote decision-making and supervise business execution from a broader viewpoint. The Company also adopted the Corporate Auditors System with the Board of Corporate Auditors that has four members, including two outside Corporate Auditors. The Board of Corporate Auditors audits the performance of duties by the Directors. The outside Directors and outside Corporate Auditors have no business relationships with Astellas or other special interest in the company. 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 nomination of Directors, Corporate Executives and Corporate Auditors and of the compensation system. Outside Directors account for a majority of the members of both committees to ensure the autonomy of these committees.

The framework for conducting business operations by Corporate Executives and other managers includes the Global Management Committee, the Corporate Administration & Finance Committee, and the Human Resources Committee. These committees discuss important issues involving global management, finance, accounting and administration, and human resources, respectively. The Company has committees chaired by the company president that discusses fundamental policies and other important items concerning CSR, compliance, risk management and investor relations.

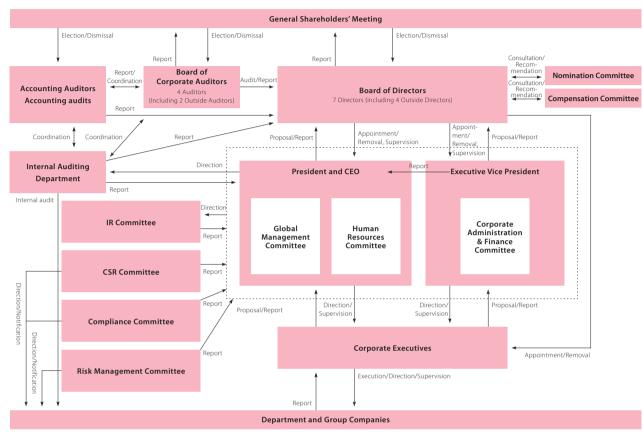
#### **Internal Control**

The Company's basic policy is to ingrain a disciplined and sound corporate culture in every part of the Astellas Group and to conduct corporate activities in good faith. For this purpose, the Company will establish an internal control system in every part of the Astellas Group and 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.

#### Internal Controls Over Financial Reporting

The Board of Directors determines fundamental policy for systems used to ensure the reliability of financial reporting. Astellas has established a policy for assessment concerning internal controls over financial reporting. Under the direction of the President & CEO, who is primarily responsible for evaluating internal control, the Vice President of Internal Auditing performs an assessment of internal controls over financial reporting.

In conducting an assessment of internal controls, we analyze the business processes falling within the scope of internal control assessment based on the results of an evaluation of company-level controls, after which we select key controls which have a significant effect on the reliability of financial reporting and evaluate the design and operating effectiveness of these key internal controls.



#### **Corporate Governance at Astellas**

#### **Business Execution Committees**

Global Management Committee	Discuss important issues concerning global management
Human Resources Committee	Discuss important issues concerning human resources
Corporate Administration & Finance Committee	Discuss important issues concerning finance, accounting and administration
IR Committee	<ul><li>Promote investor relations (IR) activities</li><li>Discuss issues concerning corporate information disclosure</li></ul>
CSR Committee	Discuss policies and plans concerning the environment, safety, etc.
Compliance Committee	Discuss policies and plans, etc., concerning compliance, etc.
Risk Management Committee	Discuss policies, measures, etc., for risk management

## Profile of Directors

(As of June 23, 2009)

#### **Representative Director and Chairman**



Toichi Takenaka, Ph.D.

 Apr. 1964
 Joined Yamanouchi Pharmaceutical Co., Ltd.

 June 1993
 Director of the Company

 June 1997
 Managing Director of the Company

 June 1999
 Senior Managing Director of the Company

 Apr. 2000
 President and Representative Director of the Company

 Apr. 2005
 Representative Director, President and CEO of Astellas Pharma Inc.

 June 2006
 Co-Chairman and Representative Director of the Company

 June 2008
 Chairman and Representative Director of the Company (present post) (Status as other companies' representative)

 President and Representative Director of Rational Drug Design Laboratories
 Laboratories

#### Representative Director, President and Chief Executive Officer



Masafumi Nogimori

- June 1997 Member of the Board of Fujisawa July 1998 President of Fujisawa GmbH June 2000 Resigned as Member of the Board of Fujisawa Corporate Vice President of Fujisawa Apr. 2001 Corporate Vice President, Associate Executive Director of Ethical Pharmaceuticals and Director of Pharmaceutical Planning Division
- of Fujisawa June 2001 Corporate Senior Vice President and Director of Global Corporate
  - Strategies Planning of Fujisawa

Apr. 1970 Joined Fujisawa Pharmaceutical Co., Ltd.

- June 2003 Member of the Board of Fujisawa
- June 2004 Corporate Executive Vice President and Member of the Board of Fujisawa

Apr. 2005 Executive Vice President and Representative Director of the Company June 2006 President and Representative Director of the Company (present post)

#### Representative Director, Executive Vice President and Chief Sales & Marketing Officer



Yasuo Ishii

- Apr 1970 Joined Yamanouchi Pharmaceutical Co., Ltd. Aug. 1994 Director of Marketing Planning Department of Sales & Marketing Division of the Company
- Aug. 1996 Director of Corporate Planning Department of the Company
- Aug. 1997 Deputy Director of Asia Business Division of the Company
- Jan. 1998 Director of International Division of the Company June 2000 Director of the Board, Director of Ethical Products Marketing
- Department of Sales & Marketing Division of the Company
- Jan. 2001 Director of the Board of the Company and Chairman of Yamanouchi Europe B.V.
- Mar. 2003 Director of the Board of the Company, Chairman of Yamanouchi U.K. Limited, and Chairman of Yamanouchi Europe B.V.
- June 2003 Managing Director of the Board of the Company
- June 2004 Senior Corporate Executive of the Company
- Apr. 2005 Senior Corporate Executive of the Company and Chairman & CEO of Astellas Pharma Europe Ltd.
- Apr. 2008 Senior Corporate Executive of the Company
- June 2008 Executive Vice President and Representative Director of the Company (present post)

#### Outside Director



Apr. 1982 Joined Fujitsu Limited

- July 1992 Joined McKinsey & Company, Inc., Japan
- Feb. 1998 Joined Amgen Limited
- Dec. 2000 Corporate Officer, Business Development, Amgen Limited
- Mar. 2003 Executive Director, Corporate Officer, CFO, Marketing, Amgen Limited
- June 2005 Project Associate Professor, Academic Planning & Coordination Office, The University of Tokyo
- June 2006 Director of the Company (present post)
- Apr. 2007 Project Associate Professor, Public Relations Division, The University of Tokyo

Takako Ebata

#### **Qualifications as Astellas Director**

Astellas considered that Ms. Ebata could apply her rich experience in business to the management of the Company from an independent position. Ms. Ebata attended all meetings of the Board of Directors held during the fiscal year that ended on March 31, 2009.

#### Outside Director



- Apr. 1969 Assistant, School of Medicine, (internal medicine), Keio University
- Apr. 1973 Instructor, School of Medicine, (internal medicine), Keio University
- Apr. 1986 Professor, Department of Internal Medicine, School of Medicine, Keio University
- Oct. 1995 Dean of School of Medicine, Keio University
- July 2001 Trustee, Keio University
- Apr. 2005 Professor Emeritus, Keio University (present post)
- Apr. 2006 Special advisor, Tokyo Saiseikai Central Hospital
- June 2007 Director of the Company (present post)
- April 2008 Special advisor, Saiseikai Yokohamashi Tobu-Hospital (present post)

## Qualifications as Astellas Director

Takao Saruta, MD, Ph.D.

Astellas considered that Dr. Saruta could apply his extensive specialized knowledge and experience to the management of the Company from an independent position as a medical doctor. Dr. Saruta attended all meetings of the Board of Directors held during the fiscal year that ended on March 31, 2009.

#### **Outside Director**



 June 1998 Managing Director, Nissho Iwai Corporation
 Oct. 1998 Managing Director and Representative Director, Nissho Iwai Corporation
 Apr. 1999 President and CEO, Representative Director, Nissho Iwai Corporation
 June 2002 Chairman and Representative Director, Nissho Iwai Corporation
 June 2009 Director of the Company (present post)

Shiro Yasutake

#### **Qualifications as Astellas Director**

Astellas considered that Mr. Yasutake could apply his rich experience in corporate management to the management of the Company from an independent position. Mr. Yasutake was elected to the Board of Directors at the shareholders' meeting held on June 23, 2009.

Apr. 1964 Joined Nissho Company June 1996 Director, Nissho Iwai Corporation

#### **Outside Director**



Apr. 1972 Public Prosecutor, Tokyo District Public Prosecutor's Office May 1996 Director of Special Investigation Division, Yokohama District Public Prosecutor's Office

- Apr. 1997 Public Prosecutor, Criminal Affairs Department, Tokyo High Public Prosecutors Office
- Sept.1997 Registered as an attorney-at-law (Dai-ichi Tokyo Bar Association) Mar. 1998 Established Takai Law Office, Partner
- Apr. 2004 Specially Appointed Professor, Aoyama Gakuin University Law School (present post)
- May 2006 Established Tokyo Seiwa Law Office, Partner (present post) June 2009 Director of the Company (present post)

Yasuyuki Takai

#### Qualifications as Astellas Director

Astellas considered that Mr. Takai could apply his extensive specialized knowledge and experience to the Company's management from an independent position as an attorney-at-law. Mr. Takai was elected to the Board of Directors at the shareholders' meeting held on June 23, 2009.

Corporate Auditors	Senior Corporate Executives	Corporate Executives	
Osamu Nagai	Hitoshi Ohta	Masaru Imahori	Kohei Nomoto
Shigeo Aoyagi	Iwaki Miyazaki	Michirou Ikeda	Yasumasa Masuda
Hideo Yamada, Ph. D.*	Katsuro Yamada	Rinta Ibuki, Ph. D.	Hirofumi Seki
Kiyomi Saito*	Yoshiro Miyokawa	Masaharu Asano, Ph. D.	Shinichiro Katayanagi
* Outside Corporate Auditor	Yoshihiko Hatanaka	Fujio Kitamura	Yoshiaki Nakashima
	Masao Yoshida	Seitaro Mutoh, Ph. D.	Toshihiko Iwata
	Shinichi Tsukamoto, Ph. D.	Seigo Kashii	Yoshihiro Minami
		Hidetoshi Shuto	Yutaka Unno
		Masaki Doi, Ph. D.	Mitsunori Matsuda

# **Financial Section**

#### CONTENTS

- *pg.*54 Management's Discussion and Analysis
- pg.68 Consolidated Balance Sheets
- *pg*.70 Consolidated Statements of Income
- *pg.*71 Consolidated Statements of Changes in Net Assets
- *pg*.72 Consolidated Statements of Cash Flows
- *pg*.73 Notes to Consolidated Financial Statements
- *pg*.93 **Report of Independent Auditors**

# Management's Discussion and Analysis

#### OVERVIEW OF YEAR ENDED MARCH 31, 2009 (FISCAL 2008)

#### **BUSINESS ENVIRONMENT**

#### • Japan

The Japanese ethical pharmaceutical market grew 2.9% in fiscal 2008 to ¥8.4 trillion. Astellas ranked second with a market share of approximately 7.2%.

The biennial NHI (National Health Insurance) drug price revision was implemented in April 2008 and drug prices were reduced by an industry-wide average of around 5.2%.

The government also continued to promote various other measures aimed at containing drug expenditures. A framework is being established to enhance the access of patients and medical professionals to generic pharmaceuticals that are safe with the stated goal of increasing the volume market share of such drugs from the current level of nearly 20% to 30% by fiscal 2012.

#### North America

The rate of growth in the North American pharmaceuticals market slowed to 1.4%, the lowest level in 5 years. The market was worth US\$309.7 billion in value terms according to *IMS World Review 2009*. The main factors depressing growth were delays with new drug approvals and the impact of the economic slowdown caused by financial uncertainty.

#### • Europe

Pharmaceutical market growth was in the 1–5% range in the major countries such as France, Germany, Italy and the UK, but reached 6–9% in Spain. Markets such as Russia and Turkey recorded double-digit growth.

#### • Asia

The region posted a robust expansion, with growth in markets such as China and South Korea reaching double digits.

#### NET SALES

- Reflecting mainly the impact of a stronger yen, consolidated net sales declined in year-on-year terms by ¥6.9 billion, or 0.7%, to ¥965.7 billion.
- Sales of overactive bladder (OAB) treatment Vesicare® increased across all regions. Global sales of the drug grew by ¥11.3 billion, or 18.8%, to ¥71.4 billion.
- In local currency terms, sales of immunosuppressant Prograf<sup>®</sup> in North America grew by US\$33 million, or 3.9%, to US\$884 million. The US substance patent expired in April 2008.

 In Japan, sales of Celecox®, the selective COX-2 inhibitor launched in June 2007, increased by ¥6.7 billion, or 178.7%, to ¥10.4 billion. Other new products such as oral quinolone antibiotic Geninax® and insomnia treatment Myslee® recorded double-digit growth in sales. The launch in June 2008 of Lexiscan®, a pharmacologic stress imaging agent used in cardiac function testing, also contributed to Astellas' sales growth.

#### PROFITS AND EXPENSES

- Cost of sales declined in year-on-year terms by ¥14.9 billion, or 5.3%, to ¥264.4 billion. This resulted in an improvement of 1.3 percentage points in the cost of sales ratio.
- R&D expenses increased by ¥24.6 billion, or 18.3%, to ¥159.1 billion. The ratio of R&D expenses to net sales was 16.5%.
- Factors behind the increase in R&D expenses included a onetime upfront fee of US\$80 million to US-based CoMentis relating to a treatment for Alzheimer's disease and a one-time payment of US\$10 million associated with the agreement with US-based Maxygen.
- Other factors behind the increase in R&D expenses included Phase 3 clinical trials in the US and Europe for YM178 and progress with the development of other clinical projects, R&D spending related to therapeutic antibodies at Agensys and depreciation costs for the new buildings at the Tsukuba Research Center.
- Reflecting the above factors, operating income declined by ¥25.5 billion, or 9.2%, to ¥250.4 billion. The operating margin was 25.9%.

#### FINANCIAL CONDITION

- Cash and cash equivalents at the fiscal year-end amounted to ¥409.8 billion, a decline of ¥50.7 billion, or 11.0%, in year-on-year terms.
- The ratio of shareholders' equity to total assets as of March 31, 2009 was 76.3%.

#### SHAREHOLDER RETURNS

- Total dividends per share in fiscal 2008 were ¥120, an increase of ¥10 compared with the previous year.
- The dividend-on-equity (DOE) ratio improved by 0.4 percentage points to 5.4%.
- During fiscal 2008, Astellas acquired 28.09 million of its own shares and canceled 15 million shares of treasury stock.

#### **OPERATING PERFORMANCE OVERVIEW**

Net sales decreased by 0.7% compared with the previous fiscal year to ¥965.7 billion. Factors negatively affecting sales included the appreciation of the yen against both the US dollar and the euro and an NHI drug price revision in Japan of a little over 5%. Growth from international operations helped to offset this drag. Operating income declined 9.2% to ¥250.4 billion due to a substantial increase in R&D expenses, which outweighed the improvement in the gross margin. Reflecting the effect of foreign exchange gains, a net improvement in other income (expenses) and a lower effective tax rate, net income declined only 3.6% to ¥171.0 billion.

## EFFECT OF EXCHANGE RATES

#### FOREIGN EXCHANGE RATES (AVERAGE)

	2008.3	2009.3
US\$1	¥114	¥101
€1	¥162	¥143

Foreign exchange rates affected net sales and operating income as indicated below.

### FOREIGN EXCHANGE IMPACT FOR FISCAL 2008

The appreciation of the yen against both the US dollar and the euro reduced net sales and operating income by ¥62.0 billion and ¥16.8 billion, respectively.

## NET SALES

Consolidated net sales amounted to ¥965.7 billion in fiscal 2008, a year-on-year decline of ¥6.9 billion, or 0.7%. A review of sales by product and by geographic segment is provided below.

		(¥ billion)		
SALES BY MAINSTAY PRODUCTS (GLOBAL)	2008.3	2009.3	YoY	CER*
Global products				
Prograf®	¥203.0	¥201.0	(1.0)	_
Japan	24.6	28.5	16.0	_
North America	97.2	88.8	(8.6)	3.9
Europe	65.3	66.0	1.1	13.8
Asia	11.0	11.2	1.7	_
Exports	4.8	6.3	30.9	_
Harnal®	122.4	116.6	(4.7)	_
Japan	37.5	35.6	(5.1)	_
Europe	29.5	25.7	(12.7)	(1.7)
Asia	8.2	8.1	(0.1)	_
Bulk/Royalties	46.7	46.6	(0.3)	12.2
Vesicare®	60.1	71.4	18.8	_
Japan	13.5	19.0	40.9	_
North America	27.7	31.0	12.0	27.3
Europe	18.5	20.6	11.1	25.1
Asia	0.3	0.7	112.0	_
Funguard <sup>®</sup> /Mycamine <sup>®</sup>	17.8	17.5	(1.9)	_
Japan	12.8	11.6	(9.0)	_
North America	4.7	5.1	8.7	23.5
Europe		0.1	_	_
Asia	0.2	0.5	100.9	_
Protopic®	16.4	16.1	(2.0)	_
Japan	2.7	2.7	(0.2)	_
North America	8.0	7.6	(5.5)	7.5
Europe	5.2	5.2	0.7	13.4
Asia	0.4	0.5	15.3	_

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

		(¥ billion)		(%)
SALES BY GEOGRAPHICAL AREA (LOCAL)	2008.3	2009.3	YoY	CER*
Japan				
Lipitor®	97.7	95.3	(2.5)	_
Micardis®	62.6	64.4	2.9	_
Gaster®	60.9	53.0	(12.9)	_
Myslee®	21.5	25.7	19.5	_
Seroquel®	19.2	21.0	9.6	_
Celecox®	3.7	10.4	178.7	_
Geninax®	3.7	6.4	71.9	_
North America				
Scan (Adenoscan® and Lexiscan®)	37.6	39.3	4.5	18.8
Lexiscan®		9.4	_	_
AmBisome®	7.6	6.1	(19.0)	(8.0)
Europe				
Eligard®	9.2	12.5	35.2	52.2

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

#### SALES BY PRODUCT

#### **PROGRAF**<sup>®</sup>

Prograf<sup>®</sup> is an immunosuppressant that is used to suppress organ rejection in organ transplants.

Sales in Japan increased by ¥3.9 billion to ¥28.5 billion, a gain of 16.0% compared with the previous year. Although the NHI drug price revision in fiscal 2008 resulted in a reduction of around 8.5% in price, sales increased due to expansion of the organ transplantation indication. The additional indications gained for rheumatoid arthritis (RA) and lupus nephritis also contributed to sales growth. The RA indication accounted for approximately 30% of sales of Prograf<sup>®</sup> in Japan.

Astellas launched a once-a-day formulation of Prograf® under the brand name Graceptor® in October 2008 in Japan. Graceptor® maintains efficacy and safety at a similar level to the existing drug, Prograf®. It is expected to improve compliance with its more convenient dosing option, and may lead to further improvements in long-term transplant outcomes.

Sales in North America fell by ¥8.3 billion, or 8.6%, to ¥88.8 billion. In local currency terms, sales grew by US\$33 million, or 3.9%, to US\$884 million. On a total prescription basis, the calcineurin

inhibitor (CNI) market grew by approximately 5% in the United States during fiscal 2008. Prograf® achieved approximate shares of the CNI market of 90% in liver transplants, 87% in kidney transplants and 72% in heart transplants, according to figures from the United Network for Organ Sharing (UNOS). The US substance patent on Prograf® expired in April 2008. (A generic version was approved in August 2009.)

Sales in Europe increased by ¥0.7 billion, or 1.1%, to ¥66.0 billion. In local currency terms, sales grew by €55 million, or 13.8%, to €460 million. Prograf® gained a share of approximately half of the CNI market. The once-daily modified release formulation Advagraf®, which was launched in the UK and Germany in June 2007, is currently marketed in approximately 20 countries and regions in Europe. Advagraf® accounted for around 10% of total Prograf® sales in the region in fiscal 2008, up from 2% in the previous year. The substance patent on Prograf® expired in most major European markets in June 2009.

In Asia, sales expanded steadily in markets such as China and South Korea. Although yen-based regional sales only increased slightly as the result of a currency translation effect due to Korean won depreciation, sales grew rapidly in local currency terms.

#### HARNAL®

Harnal<sup>®</sup> is a treatment for relieving the functional symptoms associated with benign prostatic hyperplasia (BPH). Sales in Japan declined by ¥1.9 billion, or 5.1%, to ¥35.6 billion. The NHI drug price revision for Harnal<sup>®</sup> in fiscal 2008 resulted in a price reduction of around 4.8%. The Japanese substance patent for Harnal<sup>®</sup> expired in February 2005. Sales volumes have remained steady, however, amid increasingly intense competition. Harnal<sup>®</sup> maintained a share of around 55% of the BPH market in Japan in fiscal 2008.

The drug is marketed under the brand name Omnic® in Europe. Sales dropped by  $\pm 3.7$  billion, or 12.7%, to  $\pm 25.7$  billion, reflecting appreciation of the yen against the euro. On a local currency basis, sales declined by  $\pm 3$  million, or 1.7%, to  $\pm 179$  million. Sales of the drug have continued to increase in markets such as Spain and Russia despite the expiry of the substance patent in February 2006; monthly sales remain steady. The additional OCAS® (oral controlled absorption system) formulation generated about 64% of the drug's regional sales.

Sales in Asia edged down ¥0.1 billion, or 0.1%, to ¥8.1 billion. This mainly reflected the impact of the yen's strength against the Korean won; sales grew steadily in local currency terms.

Sales in the United States by licensee Boehringer Ingelheim (BI) under the brand name Flomax<sup>®</sup> were US\$321 million higher than in the previous year, jumping 21.0% to US\$1,868 million. However, the effect of US dollar depreciation against the euro resulted in a slight overall decline in bulk sales and royalty revenues. In local currency terms, bulk sales and royalty revenues increased by €35 million, or 12.2%, to €324 million. Astellas is co-promoting Flomax<sup>®</sup> with BI in the US.

## **VESICARE®**

Global sales of Vesicare<sup>®</sup> continue to expand due to a compelling product profile that is backed by an increasing wealth of evidence.

Sales in Japan have expanded steadily since Vesicare® was launched in June 2006. Sales grew 40.9% in year-on-year terms in fiscal 2008, rising by ¥5.5 billion to ¥19.0 billion. Vesicare® secured the top spot in its category with a market share of over 40%. There remains significant untapped demand in the market for OAB treatments, making it a sector with excellent growth potential. Astellas is working to develop the market for Vesicare® further by raising public awareness of this condition.

VESIcare<sup>®</sup> was introduced in North America in January 2005. In its fourth year on the market in fiscal 2008, sales climbed by ¥3.3 billion, or 12.0%, to ¥31.0 billion. In local currency terms, sales increased US\$66 million, or 27.3%, to US\$308 million. Co-promotion with US partner GlaxoSmithKline (GSK) has been a success, producing a steady increase in market share to around 17% on a total prescription basis. VESIcare<sup>®</sup> is now the second-ranked branded drug in its category in the US. Although the overall market for pharmaceuticals in the US has slowed due to the economic downturn, the market for OAB treatments remains in a growth phase. This makes the market share gains by Vesicare<sup>®</sup> all the more remarkable.

In Europe, Vesicare<sup>®</sup> is now marketed in about 20 countries and regions and has a market share of about 32% (as of May 2009). It is the leading treatment for OAB within the European regional market. Sales increased by ¥2.0 billion, or 11.1%, to ¥20.6 billion; on a local currency basis, sales grew by €28 million, or 25.1%, to €144 million. The market in Europe for OAB treatments is expanding steadily and growth is projected to continue.

Vesicare<sup>®</sup> is available in eight countries in Asia outside Japan. Sales grew steadily in fiscal 2008, rising by ¥0.3 billion, or 112.0%, to ¥0.7 billion.

#### FUNGUARD<sup>®</sup>/MYCAMINE<sup>®</sup>

Sales in Japan were affected by the NHI drug price revision, which resulted in a reduction of about 4.1% in price. Fierce competition also reduced sales volumes slightly. Overall, domestic sales of Funguard® fell 9.0% in year-on-year terms, declining by ¥1.1 billion to ¥11.6 billion.

This injectable antifungal agent is marketed as Mycamine<sup>®</sup> outside Japan. Sales in North America increased by ¥0.4 billion, or 8.7%, to ¥5.1 billion. On a local currency basis, sales grew by US\$9 million, or 23.5%, to US\$51 million. While more intense competition caused prices to trend downward, Mycamine<sup>®</sup> recorded steady growth in sales volume and added market share in the injectable antifungal agent market. The regulatory approval gained in January 2008 for the additional indication of candidemia also contributed to sales.

Mycamine<sup>®</sup> is available in six countries in Asia outside Japan. Sales expanded steadily in fiscal 2008, rising by ¥0.2 billion, or 100.9%, to ¥0.5 billion.

After gaining regulatory approval in Europe in April 2008, Mycamine® was launched in the UK in August 2008. The European market for injectable antifungal agents is worth around €350 million and continues to expand each year. Astellas aims to reinforce its franchise within the field of infectious diseases through the launch of Mycamine®.

#### **PROTOPIC**<sup>®</sup>

Sales in North America declined ¥0.4 billion, or 5.5%, year-on-year to ¥7.6 billion. On a local currency basis, sales grew steadily by US\$5 million, or 7.5%, to US\$75 million.

Sales in Europe rose by 0.7% year-on-year to  $\pm$ 5.2 billion. In local currency terms, sales grew by  $\in$ 4 million, or 13.4%, to  $\in$ 36 million.

#### LIPITOR®

In Japan, the market for statins grew 1.3% on an NHI drug price basis to ¥281.3 billion. The hypercholesterolemia treatment Lipitor<sup>®</sup> recorded a 38.3% share of this market, which represented a year-on-year fall in share of about a percentage point.

Although the NHI drug price revision in April 2008 resulted in a price reduction of about 5.4%, this was offset by sales volume growth of around 4%. The introduction of new products further increased competition within the statins market. Amid these conditions, Astellas continues to strengthen co-promotional efforts with Pfizer Japan and take advantage of extensive clinical evidence of efficacy to maximize value for Lipitor<sup>®</sup>. At the same time, Astellas is working to raise patient awareness of the importance of LDL cholesterol reduction therapy as part of broader efforts to educate patients about hypercholesterolemia.

#### **MICARDIS®**

The Japanese angiotensin II receptor blocker (ARB) market grew to ¥514.3 billion in fiscal 2008. An NHI drug price reduction of around 10.1% was imposed on all products in this category in the April 2008 NHI drug price revision following a recalculation of the size of the ARB market. Double-digit volume gains offset this effect, resulting in growth of 4.6% over the previous year for the category as a whole. Micardis<sup>®</sup> was the third-ranked product with a market share of 14.1%, which was on a par with the figure achieved in the previous year. Sales of Micardis<sup>®</sup> are continuing to grow in line with the expanding ARB market owing to product characteristics such as a long-acting effect and almost complete excretion in the bile. Astellas is co-promoting Micardis<sup>®</sup> in Japan with Nippon Boehringer Ingelheim.

## GASTER®

The NHI drug price revision reduced prices of the H<sub>2</sub> receptor antagonist Gaster<sup>®</sup> by about 4.8% for the oral formulation and about 4.7% for the injectable formulation. Japanese authorities continue to introduce various measures to promote increased use of generics. In April 2008, the rules affecting prescribing were changed to make generic substitution easier.

As a result of this change, the share of generics within famotidine products increased from over 10% to approximately 17% (excluding direct sales).

In fiscal 2008, Gaster<sup>®</sup> recorded a 20.9% share of the overall Japanese market for  $H_2$  receptor antagonists and proton pump inhibitors (PPI), a decline of 3.1 percentage points in year-on-year terms. This result made Gaster<sup>®</sup> the second-ranked drug in this category.

## **MYSLEE®**

The market in Japan for insomnia treatments grew 6.8% in fiscal 2008 to ¥77.6 billion. Myslee® was the top drug in this category with a share of 36.8%, a year-on-year gain of 3.7 percentage points. Sales increased 19.5% despite an NHI drug price cut of around 4.1% that was implemented in April 2008.

While the Japanese market for insomnia treatments continues to expand, according to research commissioned by Japan's Ministry of Health, Labour and Welfare in 2000, there remains considerable latent potential. Astellas aims to continue strengthening detailing capabilities in qualitative and quantitative terms in the central nervous system (CNS) field by deploying specialist medical representatives. Astellas is co-promoting Myslee<sup>®</sup> with Sanofiaventis in Japan.

## SEROQUEL®

The market in Japan for anti-schizophrenic agents grew 6.2% in fiscal 2008 to ¥137.9 billion. Seroquel® ranked third in this market with a share of 17.0%, up 0.6 percentage points in year-on-year terms. This market has shifted away from conventional antipsychotics following the introduction of atypical antipsychotics, and this trend is driving the expansion of the overall market. Astellas is working to increase prescriptions of Seroquel®, primarily through the efforts of specialist CNS medical representatives.

#### **CELECOX**®

Launched in June 2007, Celecox<sup>®</sup> is a selective COX-2 inhibitor indicated in the treatment of rheumatoid arthritis (RA) and osteoarthritis (OA). Prescription growth is being generated primarily from specialists in these diseases at present. Although the NHI drug price revision in April 2008 reduced the price of Celecox<sup>®</sup> by 4.2%, sales volumes increased significantly during the year as restrictions on its long-term prescription were lifted. As a result, sales of Celecox<sup>®</sup> rose by ¥6.7 billion, or 178.7%, in year-on-year terms to ¥10.4 billion.

Regulatory approval was gained in June 2009 for the additional indication of lumbago. Going forward, Astellas plans to strengthen co-promotional efforts with Pfizer Japan while continuing to encourage appropriate product use.

### **GENINAX®**

Sales of Geninax<sup>®</sup> continued to expand steadily following its launch in October 2007. Sales in fiscal 2008 totaled ¥6.4 billion, an increase of ¥2.6 billion, or 71.9%, compared with the previous year. The category market share of Geninax<sup>®</sup> increased from 5% to 10%. Going forward, Astellas plans to continue promoting appropriate usage through co-promotional efforts with Taisho Toyama Pharmaceutical.

#### ADENOSCAN<sup>®</sup>/LEXISCAN<sup>®</sup>

Following the US launch of Lexiscan® in June 2008, total sales of these pharmacologic stress agents Adenoscan® and Lexiscan® on a local currency basis, grew by US\$61 million, or 18.8%, to US\$390 million. The introduction of Lexiscan® was smooth, and the new product notched up US\$93 million in sales in its first year on the market. Total sales of the two products in fiscal 2008 increased by ¥1.6 billion, or 4.5%, to ¥39.3 billion, reflecting the impact of the yen strengthening against the US dollar.

#### **ELIGARD**<sup>®</sup>

Boosted by a strong performance from the six-month formulation, sales in Europe of the advanced prostate cancer treatment Eligard® rose 52.2% in year-on-year local currency terms, increasing by €29 million to €87 million. Reflecting the appreciation of the yen, fiscal 2008 sales of this product increased by ¥3.2 billion, or 35.2%, to ¥12.5 billion.

#### SALES BY GEOGRAPHICAL AREA

		(
	2008.3	2009.3
Consolidated	¥972.6	¥965.7
Japan	505.6	510.5
North America	194.5	188.9
Europe	244.6	239.1
Asia	27.8	27.2

(¥ billion)

\* Sales to outside customers

• Japan

Sales of ethical pharmaceuticals in Japan rose 2.8% in fiscal 2008 to ¥491.5 billion. Sales of others, including exports to third parties, declined, reflecting lower sales to the US licensee after the expiry of the US patent on Cefzon®, an oral cephalosporin antibiotic, as well as the impact of currency movements.

#### North America

Sales in North America declined 2.9% to ¥188.9 billion as the result of the appreciation of the yen against the US dollar, among other factors. Substantially increased sales of Prograf® and VESIcare® and the launch of Lexiscan® in June 2008 contributed to a 10.4% advance in sales in local currency terms to US\$1,878 million. Other products that recorded higher sales included Protopic® and Mycamine®.

Europe

Sales in Europe declined 2.3% to ¥239.1 billion, due primarily to the appreciation of the yen against the euro during the year. Sales grew substantially on a local currency basis, boosted by strong growth in sales of Prograf<sup>®</sup>, Vesicare<sup>®</sup> and Eligard<sup>®</sup>, together with increased revenue from bulk sales and royalty revenues for tamsulosin due to favorable licensee sales under the brand name of Flomax<sup>®</sup> in the US. Sales of tamsulosin by Astellas under the brand name Omnic<sup>®</sup> were flat despite the impact of generic competition. Total sales in the region in local currency terms were €1,666million, an increase of 10.0% compared with the previous year.

• Asia

Besides growth generated by Prograf<sup>®</sup> and Harnal<sup>®</sup>, new products such as Vesicare<sup>®</sup> and Mycamine<sup>®</sup> also contributed to higher sales. Regional sales declined 2.2% to ¥27.2 billion, reflecting mainly the impact of the Korean won's depreciation against the yen.

#### **OVERSEAS SALES**

		(† DIIION)
	2008.3	2009.3
Overseas sales	¥489.6	¥469.0
North America	247.1	235.0
Europe	195.6	180.4
Asia	34.4	35.9
Other	12.4	17.7
Consolidated net sales	972.6	965.7
Overseas sales ratio	50.3%	48.6%

Overseas sales are attributed by the location of customers.

Overseas sales declined 4.2% in fiscal 2008 due to the impact of the yen's appreciation against the US dollar and the euro.

In North America, sales were boosted by strong sales performances from Prograf<sup>®</sup> and VESIcare<sup>®</sup> as well as tamsulosin bulk sales and royalty revenues from BI. In yen terms, however, sales were lower than in the previous year.

In Europe, sales declined in yen terms despite increased sales of Prograf<sup>®</sup>, Vesicare<sup>®</sup> and Eligard<sup>®</sup>.

In Asia, while sales of products such as Prograf<sup>®</sup>, Harnal<sup>®</sup> and Vesicare<sup>®</sup> increased in local currency terms, regional sales were affected by foreign exchange movements. The export sales booked within the Asia segment also increased favorably.

Overall, the overseas sales ratio for fiscal 2008 was 48.6%.

COST OF SALES		(¥ billion)
	2008.3	2009.3
Net sales	¥972.6	¥965.7
Cost of sales	279.3	264.4
Cost of sales ratio	28.7%	27.4%

Cost of sales declined by 5.3%, or ¥14.9 billion, to ¥264.4 billion.

The cost of sales ratio improved by 1.3 percentage points relative to the previous year, falling to 27.4%. Reduced manufacturing costs and the impact of foreign exchange fluctuations on elimination of unrealized gains helped to offset the effect of the NHI drug price revision in Japan. Changes in product composition did not exert any significant net effect on the cost of sales ratio.

#### SELLING, GENERAL AND ADMINISTRATIVE (SG&A) EXPENSES

		(¥ billion)
	2008.3	2009.3
SG&A expenses	¥417.3	¥450.9
SG&A ratio	42.9%	46.7%
Personnel expenses	120.1	115.1
Advertising & sales promotional expenses	83.0	84.8
R&D expenses	134.5	159.1
Other	79.6	91.8

\* SG&A expenses include R&D expenses

(V billion)

Including R&D expenses, SG&A expenses increased ¥33.5 billion, or 8.0%, in year-on-year terms to ¥450.9 billion. The ratio of SG&A expenses to net sales was 46.7%, an increase of 3.8 percentage points.

Personnel expenses fell ¥5.0 billion, or 4.2%, to ¥115.1 billion. These expenses were flat in Japan, but were ¥4.5 billion lower in Europe and the United States due to the effects of a stronger yen. The number of sales, marketing and administrative staff increased in North America, which pushed up personnel expenses in local currency terms. Personnel expenses declined in Europe due to currency effects as well as the impact of functional reorganization. The dip in personnel expenses in fiscal 2008 also reflected the payment of special incentive bonuses to employees during the previous year.

Advertising and sales promotional expenses increased by ¥1.7 billion, or 2.1%, to ¥84.8 billion. These expenses increased by ¥2.1 billion in Japan. Promotional spending in Japan included efforts to raise patient awareness of conditions such as hypercholesterolemia and insomnia as well as increased spending on corporate brand advertising. Promotional costs declined by ¥0.5 billion in Europe and the US, primarily due to the effects of yen appreciation. Factors pushing up these expenses included increased payments to GSK due to higher sales of VESIcare® in the US and launch costs relating to the introduction of Lexiscan® in the US and Mycamine® in Europe.

Other SG&A expenses were ¥12.2 billion higher than in the previous year, at ¥91.8 billion. Within this figure, goodwill amortization costs relating to the Agensys acquisition increased by ¥5.7 billion to ¥7.4 billion.

#### **R&D EXPENSES**

		(¥ billion)
	2008.3	2009.3
R&D expenses	¥134.5	¥159.1
R&D ratio	13.8%	16.5%

R&D expenses increased by ¥24.6 billion, or 18.3%, to ¥159.1 billion. The ratio of R&D expenses to net sales was 16.5%, an increase of 2.7 percentage points compared with the previous year.

Astellas is actively engaged in R&D activities with the aim of generating 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 is a high degree of unmet medical needs. Drug discovery efforts are selectively targeting the six strategic therapeutic areas of urology, inflammation/immunology, CNS/pain, diabetes, infectious diseases (including viral infections), and cancer. To further improve the speed and quality of drug discovery research, Astellas completed the construction of new research buildings at the Tsukuba Research Center (Miyukigaoka) in September 2008. Drug discovery research functions were consolidated at the Tsukuba site in April 2009. Astellas is also actively seeking to upgrade drug discovery capabilities further through the reinforcement of technological platforms by establishing a presence in therapeutic antibody technology. This approach promises to supplement the Group's traditional strengths in small molecule synthesis and fermentation technology.

In clinical development, the Group aims to speed up the pace of development programs by concentrating resources on the highest priority projects. During fiscal 2008, further progress was made in the development of in-house compounds such as YM178, YM150 and ASP1941. A number of therapeutic antibodies created by Agensys also entered clinical development. Separately, to create a management structure capable of making quick, precise development-related decisions, Astellas Pharma Global Development (APGD) was set up in the United States to act as the Group's global development headquarters. APGD commenced operations in April 2008. Further organizational changes were made in April 2009 to strengthen the operational base for global clinical development, to upgrade project management functions, and to enhance the capabilities of the Group in terms of devising and executing drug development strategy.

Alongside the development of compounds discovered inhouse, the Group also actively seeks to expand and improve the drug pipeline through the development of compounds licensed from other companies. The Group concluded a number of licensing agreements during fiscal 2008. In April 2008, Astellas signed an exclusive worldwide agreement with CoMentis of the United States to collaborate on the research, development and commercialization of beta-secretase inhibitors for the treatment of Alzheimer's disease. In September 2008, Astellas concluded an agreement with Maxygen of the United States granting Astellas worldwide rights to develop and commercialize Maxygen's MAXY-4 lead candidates for the indications of organ transplant rejection and all autoimmune diseases. In March 2009, Astellas terminated a licensing agreement with a subsidiary of NeuroSearch A/S of Denmark for the antipsychotic agent ASP2314/ACR16.

The Group withdrew two submissions for regulatory approval during fiscal 2008. In October 2008, a European marketing authorization application was withdrawn for telavancin, an antibiotic in-licensed from US-based Theravance, Inc. with a target indication in the treatment of complicated skin and soft tissue infections (cSSTI). In January 2009, the Group withdrew an application for the modified release formulation of the immunosuppressant FK506 that had been filed in the United States.

In August 2008, the US Food and Drug Administration (FDA) issued an approvable letter for vernakalant, an injectable antiarrhythmic agent that had been licensed from and jointly developed with Cardiome Pharma Corp. of Canada. In February 2009, following the issuance of an approvable letter in October 2007, the US FDA also issued a Complete Response letter to Theravance for the regulatory application submitted for telavancin for the target indication of complicated skin and skin structure infections (cSSSI) caused by Gram-positive bacteria. A reply has been submitted to the FDA.

#### OPERATING INCOME

		(1.6111011)
	2008.3	2009.3
Net sales	¥972.6	¥965.7
Operating income	275.9	250.4
Operating margin	28.4%	25.9%

(¥ billion)

Operating income declined by ¥25.5 billion, or 9.2%, to ¥250.4 billion. Although the gross margin improved by 1.3 percentage points, the operating margin was 2.5 points lower than in the previous year due to a higher ratio of R&D expenses to sales.

#### OTHER INCOME AND EXPENSES

Interest and dividend income declined by ¥3.6 billion to ¥11.4 billion. This mainly reflected a drop in interest income primarily due to lower interest rates.

Astellas recorded an exchange gain of ¥9.3 billion mainly on the US dollar-denominated assets of European subsidiaries due to the effect of the euro strengthening against the US dollar. In the previous year, euro depreciation against the US dollar had resulted in an exchange loss of ¥14.9 billion.

An expense of ¥2.5 billion was recorded for special retirement benefits relating to the implementation of an early retirement program at a US production plant in Norman, Oklahoma in October 2008, accompanying the expiry of the US patent for tamsulosin (Flomax®). Astellas had booked ¥13.0 billion in special retirement benefits in fiscal 2007 in conjunction with an early retirement program implemented in Japan.

A loss on devaluation of investment securities of ¥2.0 billion was recognized mainly due to the write-down of corporate bonds.

An expense of ¥1.4 billion was recognized as compensation for cancellation of contracts in relation to the transfer of subcontractor personnel as employees into the Group at one of the Group's domestic production subsidiaries.

#### FOREIGN EXCHANGE TRENDS

		(1)
	2008.3	2009.3
US\$	¥100	¥ 98
€	158	130

# INCOME BEFORE INCOME TAXES AND MINORITY INTERESTS, INCOME TAXES, AND NET INCOME

Income before income taxes and minority interests declined by ¥6.1 billion, or 2.3%, in year-on-year terms to ¥262.7 billion.

Incomes taxes increased by ¥0.4 billion, or 0.5%, to ¥89.6 billion. The effective tax rate was 0.9 percentage points higher at 34.1% mainly due to amortization of goodwill relating to the acquisition of Agensys.

Reflecting the factors outlined above, net income decreased by ¥6.5 billion, or 3.6%, to ¥171.0 billion.

### CONSOLIDATED FORECASTS FOR YEAR ENDING MARCH 31, 2010 (FISCAL 2009) (ANNOUNCED MAY 2009) NET SALES

Net sales are forecast to increase by  $\pm 2.3$  billion, or 0.2%, to  $\pm 968.0$  billion.

By product, Astellas expects sales of Vesicare® to continue expanding globally, with growth also coming from Funguard®/ Mycamine®. Sales of Prograf® and Harnal® are expected to decline due to increased generic competition following the expiry of the respective substance patents in Europe and the United States.

In Japan, Astellas expects sales of ethical pharmaceuticals to increase, with growth led by major products such as Lipitor<sup>®</sup> and Micardis<sup>®</sup> as well as Celecox<sup>®</sup> and other new products.

In North America, Astellas expects sales growth from VESIcare®, Mycamine® and Lexiscan® to offset an anticipated decline in sales of Prograf® following the expiry of the US substance patent.

In Europe, Astellas forecasts contributions to sales growth from Vesicare<sup>®</sup>, Eligard<sup>®</sup> and Mycamine<sup>®</sup>. Sales of Prograf<sup>®</sup> and Harnal<sup>®</sup> are expected to decline following the expiry of the European substance patents. Appreciation of the yen against the euro is also expected to depress regional sales.

In Asia, the strength of the yen against the Korean won is expected to be the main factor negatively affecting regional sales performance.

#### OPERATING INCOME

(¥)

Operating income is forecast to decline by ¥35.4 billion, or 14.1%, to ¥215.0 billion.

Gross profit is expected to be lower due to projected changes in product composition, which will tend to push up the cost of sales ratio.

R&D expenses are projected to increase by ¥9.9 billion, or 6.2%, to ¥169.0 billion. The main factors pushing up R&D expenses are late-stage clinical development projects for YM178, YM150 and other compounds, higher depreciation costs relating to the new research buildings at Tsukuba, and increased R&D costs incurred at Agensys. The ratio of R&D expenses to net sales in fiscal 2009 is estimated to rise to 17.5%.

Excluding R&D expenses, SG&A expenses are projected to increase due to higher sales promotional expenses associated with launches of new products, together with an increase in good-will amortization costs relating to the Agensys acquisition.

#### NET INCOME

Net income is projected to decline by \$36.0 billion, or 21.0%, to \$135.0 billion.

This forecast is based on an assumed deterioration in net financial income, as well as an anticipated slight increase in the effective tax rate.

#### EFFECT OF CURRENCY MOVEMENTS

Astellas forecasts negative impacts on net sales and operating income of ¥28.0 billion and ¥18.0 billion, respectively, due mainly to yen appreciation against the euro.

#### FISCAL 2009 FORECASTS

		(¥ billion)
	2009.3	2010.3 (Forecasts)
Net sales	¥965.7	¥968.0
Operating income	250.4	215.0
Net income	171.0	135.0
		(¥)
Average foreign exchange rates US\$1	¥101	¥100
€1	143	130

#### NUMBERS OF EMPLOYEES

As of March 31, 2009, the Astellas Group employed 14,261 people (a year-on-year increase of 595).

Employee headcount was 7,522 in Japan (up 69) following slight increases in personnel in sales, marketing and other divisions. Employee numbers in North America were 2,318 (up 234), reflecting further recruitment at the sales, marketing and R&D divisions as well as exceptional factors that included the classification of subcontracting expenses as personnel expenses. Employee numbers in Europe were 3,390 (up 213), reflecting the establishment of a local subsidiary in Turkey, a stronger presence within the field of infectious diseases, and the hiring of additional medical representatives (MRs) in Russia, Spain and other markets based on good prospects for further sales growth. The Group also recruited more MRs in South Korea and China, pushing up total headcount in Asia to 1,031 (up 79).

The total number of MRs employed by the Astellas Group worldwide was 5,150 at the end of March 2009, a year-on-year increase in the sales force of 150 people.

#### NUMBER OF EMPLOYEES BY GEOGRAPHICAL AREA

		(persons)
	2008.3	2009.3
Japan	7,453	7,522
North America	2,084	2,318
Europe	3,177	3,390
Asia	952	1,031
Total	13,666	14,261

#### NUMBER OF MRS BY GEOGRAPHICAL AREA

	(persons)
2008.3	2009.3
5,000	5,150
2,400	2,400
880	890
1,300	1,350
500	580
	5,000 2,400 880 1,300

## FINANCIAL CONDITION

5215

0.1.111

Total assets as of March 31, 2009 amounted to ¥1,348.4 billion. This figure was ¥90.7 billion, lower than at the previous fiscal year-end.

Current assets of ¥963.6 billion were ¥13.6 billion lower than a year earlier. This reflected a drop in cash and cash equivalents of ¥50.7 billion to ¥409.8 billion.

At ¥181.4 billion, net property, plant and equipment was ¥1.6 billion higher than a year earlier. Buildings and structures increased by ¥14.6 billion to ¥234.0 billion following the completion of new buildings at the Tsukuba Research Center in Miyukigaoka. For the same reason, the value of construction in progress was ¥11.6 billion lower at ¥14.0 billion.

Investments and other assets dropped by ¥78.6 billion to ¥203.4 billion. Investment securities as of March 31, 2009 was ¥89.3 billion, a year-on-year drop of ¥68.0 billion. This was due to a number of factors, including the transfer of some investment securities to current assets, and a decline in the carrying values of certain securities due to stock market falls. Goodwill associated with the Agensys acquisition declined by ¥2.9 billion to ¥26.4 billion. Goodwill declined from ¥29.3 billion (US\$292.6 million) at the end of March 2008 to a balance of ¥26.4 billion (US\$268.5 million) at the end of March 2009. In fiscal 2008, milestone pavments relating to the entry of therapeutic antibodies into Phase 1 development and the successful transfer of Regeneron's VelocImmune® mouse technology were booked as goodwill. Amortization expense of ¥7.4 billion (US\$74.1 million) was recorded in fiscal 2008. Other intangible assets fell by ¥6.7 billion to ¥32.0 billion.

#### LIABILITIES

Total liabilities of ¥318.2 billion at March 31, 2009 represented a decline of ¥10.1 billion, compared with the previous fiscal year-end.

Current liabilities of ¥283.6 billion were ¥1.0 billion lower than a year earlier. This reflected a decline of ¥6.4 billion in accrued expenses to ¥55.1 billion.

Total long-term liabilities of ¥34.7 billion were ¥9.1 billion lower than a year earlier. This reflected a drop of ¥2.5 billion in accrued retirement benefits for employees to ¥15.0 billion.

#### NET ASSETS

Net assets totaled ¥1,030.2 billion at the fiscal 2008 year-end. This figure was ¥80.6 billion, lower than at the previous fiscal year-end.

Total shareholders' equity amounted to ¥1,081.9 billion at March 31, 2009, a decline of ¥11.0 billion compared with a year earlier. Major items included net income of ¥171.0 billion, payments of ¥58.6 billion in cash dividends from retained earnings, and acquisition of the Company's own shares totaling ¥123.4 billion.

Valuation, translation adjustments and others became –452.9 billion. This represented a net decline of 469.9 billion from the previous fiscal year-end. Reflecting share market falls, the unrealized holding gain on securities dropped by 417.8 billion to 410.0 billion. Translation adjustments decreased by 452.0 billion in year-on-year terms to -462.9 billion. This was principally due to the year-end value of the yen being stronger than at the end of March 2008 against both the US dollar and the euro.

#### LIQUIDITY AND FINANCING

To strengthen and develop the ethical pharmaceutical business, Astellas 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 continues 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 liquidity 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 2009, 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.

Going forward, in the event of demand for funding, the Group's financial policy is to maintain a healthy balance sheet at all times by raising capital smoothly.

#### **CASH FLOWS**

The balance of cash and cash equivalents at the end of March 2009 was ¥409.8 billion, a decline of ¥50.7 billion compared with the previous fiscal year-end.

#### CASH FLOWS FROM OPERATING ACTIVITIES

Net cash provided by operating activities amounted to ¥197.8 billion, an increase of ¥10.9 billion in year-on-year terms. Major factors included a fall in income before income taxes and minority interests of ¥6.1 billion to ¥262.7 billion, and a decline in income taxes paid of ¥11.7 billion to ¥86.5 billion.

#### CASH FLOWS FROM INVESTING ACTIVITIES

Net cash used in investing activities totaled ¥29.0 billion, an increase in cash outflow of ¥20.6 billion compared with the previous year. Major factors included a sharp decline in the amount of cash generated by decreases in short-term investments, to ¥24.5 billion (a year-on-year fall of ¥39.9 billion), and an increase of ¥9.3 billion to ¥36.7 billion in cash used for purchases of property, plant and equipment, including the completion of the new buildings at the Tsukuba Research Center in Miyukigaoka. Proceeds from sales of property, plant and equipment were also lower than in the previous year, dropping by ¥12.1 billion to ¥5.8 billion. A cash outflow of ¥40.4 billion had been recorded in the previous fiscal year relating to the acquisition of shares in Agensys.

#### CASH FLOWS FROM FINANCING ACTIVITIES

Net cash used in financing activities totaled ¥184.7 billion, an increase of ¥53.3 billion compared with the previous year. Major factors included cash outflows due to purchases of treasury stock, which increased by ¥41.7 billion relative to the previous year to ¥123.6 billion, and a year-on-year increase in cash dividends of ¥12.7 billion to ¥58.6 billion.

#### **CAPITAL EXPENDITURES**

Astellas 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 2008 totaled ¥37.6 billion (based on the value of property, plant and equipment). Capital spending was financed mainly from internal cash flow.

Capital expenditures in the pharmaceutical and related products business segment were directed at improving productivity through reorganization and consolidation of drug discovery research functions. Major expenditures included the construction of new research buildings at the Tsukuba Research Center (located in Miyukigaoka, Tsukuba, Ibaraki Prefecture). Other capital spending was undertaken to upgrade and renew various functional capabilities and equipment across production and research.

Capital spending is forecast to increase 0.1% to  $\pm 37.7$  billion in fiscal 2009.

### NET INCOME, CASH DIVIDENDS AND NET ASSETS PER SHARE

#### PER SHARE DATA

		(±)
	2008.3	2009.3
Net income		
Basic	¥ 349.89	¥ 356.11
Diluted	349.71	355.90
Cash dividends	110.00	120.00
Net assets	2,228.34	2,189.26

 $\wedge \wedge$ 

#### POLICY ON SHAREHOLDER RETURNS

Astellas is working to improve capital efficiency with the aim of achieving sustained growth in enterprise value. The Group's extensive reserves of cash and cash equivalents are prioritized for use in investments to generate growth in the pharmaceuticals business. The Group also actively seeks ways to increase returns to shareholders.

Based on earnings growth over the medium and long term, the Group aims to raise dividends in a sustained fashion.

Astellas' policy is to buy back its own shares as considered appropriate as a means of providing shareholder returns. Treasury stock acquisitions in fiscal 2008 are summarized to the right.

#### TREASURY STOCK

	2008.3	2009.3
Number of shares bought back	16,330 thousand	28,085 thousand
Acquisition cost	¥81.9 billion	¥123.6 billion
Number of shares cancelled	45,000 thousand	15,000 thousand
Amount cancelled	¥219.5 billion	¥72.1 billion

#### TOTAL NUMBER OF SHARES ISSUED

TOTAL NOMBER OF SHARES 155		(thousand of share)
	2008.3	2009.3
Total number of shares issued	518,965	503,965
Shares in treasury	20,881	33,948

## ROE AND DOE

		(%)
	2008.3	2009.3
ROE	16.1	16.0
DOE	5.0	5.4

Return on equity (ROE) was 16.0% in fiscal 2008, compared with 16.1% in fiscal 2007. The DOE ratio rose by 0.4 percentage points to 5.4%.

#### **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 research and development activities are subject to these inherent risks.

#### • Sales-related risk

The pharmaceutical industry operates in a highly competitive environment characterized by rapid technological innovation. The Astellas Group faces fierce competition from drug makers and generics manufacturers based in Japan 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, 2009 and 2008

		Millions of yen	Millions of U.S. dollars (Note 4)
ASSETS	2009	2008	2009
Current assets:			
Cash and cash equivalents	¥ 409,827	¥ 460,486	\$ 4,182
Short-term investments (Note 16)	122,510	108,187	1,250
Notes and accounts receivable	242,053	238,370	2,470
Allowance for doubtful receivables	(1,020)	(648)	(10)
	241,033	237,722	2,460
Inventories (Note 5)	105,430	91,445	1,076
Deferred tax assets (Note 9)	67,564	68,000	689
Other	17,277	11,437	176
Total current assets	963,641	977,277	9,833
Property, plant and equipment, at cost:			
Land	29,115	31,297	297
Buildings and structures	233,952	219,325	2,387
Machinery and equipment	216,929	224,022	2,214
Other	2,977	847	31
Construction in progress	13,964	25,524	142
Accumulated depreciation	(315,489)	(321,132)	(3,219)
Property, plant and equipment, net	181,448	179,883	1,852
Investments and other assets:			
Investment securities (Note 16)	89,315	157,315	911
Investments in and advances to affiliates	268	458	3
Goodwill	26,377	29,319	269
Other intangible assets	31,985	38,671	326
Deferred tax assets (Note 9)	46,223	39,734	472
Other	9,189	16,495	94
Total investments and other assets	203,357	281,992	2,075
Total assets	¥1,348,446	¥1,439,152	\$13,760

See accompanying notes to consolidated financial statements.

		Millions of yen	Millions of U.S. dollars (Note 4)
LIABILITIES AND NET ASSETS	2009	2008	2009
Current liabilities:			
Notes and accounts payable:			
Trade	¥ 169,615	¥ 166,105	\$ 1,730
Construction	11,947	11,380	122
Accrued expenses	55,057	61,499	562
Accrued income taxes (Note 9)	39,682	38,047	405
Deferred tax liabilities (Note 9)	833	35	9
Other (Note 6)	6,419	7,464	66
Total current liabilities	283,553	284,530	2,894
Long-term liabilities:			
Accrued retirement benefits for employees (Note 10)	15,030	17,492	153
Deferred tax liabilities (Note 9)	-	258	_
Other (Note 6)	19,642	26,009	201
Total long-term liabilities	34,672	43,759	354
Net assets (Note 7):			
Shareholders' equity:			
Common stock, without par value:			
Authorized: 2,000,000,000 shares;			
lssued: 503,964,635 shares in 2009 and 518,964,635 shares in 2008	103,001	103,001	1,051
Capital surplus	176,822	176,822	1,804
Retained earnings	957,346	917,206	9,770
Treasury stock, at cost:			
33,948,017 shares in 2009 and			
20,881,100 shares in 2008	(155,295)	(104,123)	(1,585)
Total shareholders' equity	1,081,874	1,092,906	11,040
Valuation, translation adjustments and others			
Unrealized holding gain on securities	10,019	27,853	102
Translation adjustments	(62,905)	(10,861)	(642)
Total valuation, translation adjustments and others	(52,886)	16,992	(540)
Stock subscription rights	895	637	9
Minority interests	338	328	3
Total net assets	1,030,221	1,110,863	10,512
Contingent liabilities (Note 13)			
Total liabilities and net assets	¥1,348,446	¥1,439,152	\$13,760

# Consolidated Statements of Income

Astellas Pharma Inc. and Subsidiaries Year ended March 31, 2009, 2008 and 2007

			Millions of the	Millions of U.S. dollars
	2009	2008	Millions of yen 2007	(Note 4) 2009
Net sales	¥965,698	¥972,586	¥920,624	\$9,854
Cost of sales	264,431	279,342	284,063	2,698
Gross profit	701,267	693,244	636,561	7,156
Selling, general and administrative expenses (Note 11)	450,872	417,340	446,047	4,601
Operating income	250,395	275,904	190,514	2,555
Other income (expenses):				
Interest and dividend income	11,380	15,026	11,796	116
Interest expense	—	(53)	(343)	_
Exchange gain (loss)	9,251	(14,869)	(3,595)	94
Equity in (losses) earnings of affiliates	(47)	7,994	1,164	(0)
Gain on sales of investment securities	500	138	12,259	5
Special retirement benefits	(2,526)	(12,979)	(1,224)	(26)
Loss on devaluation of investment securities	(1,976)	—	—	(20)
Compensation for cancellation of contracts	(1,364)	—	—	(14)
Loss on impairment of fixed assets	(1,340)	(9,331)	(6,072)	(14)
Expenses for integration and closure of business bases	_	(3,308)	(17,660)	_
Gain on sales of subsidiaries' shares	_	—	21,242	_
Other, net	(1,581)	10,256	3,684	(15)
	12,297	(7,126)	21,251	126
Income before income taxes and minority interests	262,692	268,778	211,765	2,681
Income taxes (Note 9):				
Current	86,851	93,999	97,259	887
Deferred	2,771	(4,812)	(18,676)	28
	89,622	89,187	78,583	915
Income before minority interests	173,070	179,591	133,182	1,766
Minority interests	(2,084)	(2,153)	(1,896)	(21)
Net income (Note 14)	¥170,986	¥177,438	¥131,286	\$1,745

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Changes in Net Assets

Year ended March 31, 2009, 2008 and 2007

Number of shares issued	2009	2008	2007
Beginning of year	518,964,635	563,964,635	573,949,476
Conversion of convertible bonds	-	—	15,159
Cancellation of treasury stock	(15,000,000)	(45,000,000)	(10,000,000)
End of year	503,964,635	518,964,635	563,964,635

	Millions c						Millions of yen		
				Share	holders' equity	Valuation,			Minority Total net interests assets
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity	translation adjustments and others	Stock subscription rights		
Balance as of March 31, 2006	¥ 102,986	¥ 176,807	¥ 959,217	¥ (61,983)	¥ 1,177,027	¥ 39,870		¥ 444	¥ 1,217,341
Conversion of convertible bonds	15	15			30				30
Cash dividends paid			(44,066)		(44,066)				(44,066)
Bonuses to directors and corporate auditors			(94)		(94)				(94)
Net income			131,286		131,286				131,286
Purchase of treasury stock				(220,046)	(220,046)				(220,046)
Disposal of treasury stock			(118)	477	359				359
Cancellation of treasury stock			(39,632)	39,632					
Other			55		55				55
Net change in items other than shareholders' equity						13,939	¥284	(93)	14,130
Total movements during the year	15	15	47,431	(179,937)	(132,476)	13,939	284	(93)	(118,346)
Balance as of March 31, 2007	103,001	176,822	1,006,648	(241,920)	1,044,551	53,809	284	351	1,098,995
Cash dividends paid			(45,878)		(45,878)				(45,878)
Net income			177,438		177,438				177,438
Purchase of treasury stock				(81,914)	(81,914)				(81,914)
Disposal of treasury stock			(53)	197	144				144
Cancellation of treasury stock			(219,514)	219,514					
Other			(1,435)		(1,435)				(1,435)
Net change in items other than shareholders' equity						(36,817)	353	(23)	(36,487)
Total movements during the year			(89,442)	137,797	48,355	(36,817)	353	(23)	11,868
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

								Millions of U.S.	dollars (Note 4)
				Share	holders' equity	Valuation,			
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity	translation adjustments and others	Stock subscription rights	Minority interests	Total net assets
Balance as of March 31, 2008	\$ 1,051	\$ 1,804	\$ 9,360	\$ (1,063)	\$ 11,152	\$ 173	\$7	\$3	\$ 11,335
Cash dividends paid			(598)		(598)				(598)
Net income			1,745		1,745				1,745
Purchase of treasury stock				(1,261)	(1,261)				(1,261)
Disposal of treasury stock			(1)	3	2				2
Cancellation of treasury stock			(736)	736					
Net change in items other than shareholders' equity						(713)	2	0	(711)
Total movements during the year			410	(522)	(112)	(713)	2	0	(823)
Balance as of March 31, 2009	\$1,051	\$1,804	\$9,770	\$(1,585)	\$11,040	\$(540)	\$9	\$3	\$10,512

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Cash Flows

Astellas Pharma Inc. and Subsidiaries Year ended March 31, 2009, 2008 and 2007

	Millions of yen			Millions of U.S. dollars (Note 4)
	2009	2008	2007	2009
Operating activities				
Income before income taxes and minority interests	¥ 262,692	¥ 268,778	¥ 211,765	\$ 2,681
Depreciation and amortization	42,890	36,946	33,971	438
Loss on impairment of fixed assets	1,340	9,331	6,072	14
Gain on sales of investment securities	(500)	(138)	(12,259)	(5)
Gain on sales of subsidiaries' shares	_	_	(21,242)	_
Notes and accounts receivable	(17,487)	4,524	(4,996)	(178)
Inventories	(26,569)	(5,262)	3,541	(271)
Notes and accounts payable	26,012	(20,745)	14,840	265
Accrued expenses	(54)	(7,046)	12,407	(1)
Accrued retirement benefits for employees	(93)	(835)	(23,099)	(1)
Other	(16,107)	(26,082)	(11,141)	(165)
Subtotal	272,124	259,471	209,859	2,777
Interest and dividends received	12,196	25,756	10,682	124
Interest paid	_	(50)	(318)	_
Income taxes paid	(86,529)	(98,247)	(92,293)	(883)
Net cash provided by operating activities	197,791	186,930	127,930	2,018
<b>Investing activities</b> Purchases of property, plant and equipment	(36,653)	(27,314)	(24,660)	(374)
Proceeds from sales of property, plant and equipment	5,811	17,923	7,349	59
Acquisition of subsidiaries' shares		(40,407)		
Proceeds from sales of subsidiaries' shares	_	(10,107)	33,417	_
Decrease in short-term investments	24,454	64,360	65,021	250
Increase in investment securities	(18,013)	(12,660)	(5,770)	(184)
Increase in other assets	(10,902)	(12,900)	(16,078)	(104)
Other	6,315	2,656	13,152	64
Net cash (used in) provided by investing activities	(28,988)	(8,416)	72,431	(296)
Financing activities				
Purchases of treasury stock	(123,600)	(81,914)	(220,046)	(1,261)
Cash dividends	(58,625)	(45,878)	(44,066)	(598)
Other	(2,451)	(3,630)	591	(25)
Net cash used in financing activities	(184,676)	(131,422)	(263,521)	(1,884)
Effects of exchange rate changes on cash and cash equivalents	(34,786)	(8,037)	12,926	(355)
(Decrease) increase in cash and cash equivalents	(50,659)	39,055	(50,234)	(517)
Decrease in cash and cash equivalents due to decrease in subsidiaries	_	(1,082)	(676)	_
Cash and cash equivalents at beginning of year	460,486	422,513	473,423	4,699
Cash and cash equivalents at end of year	¥ 409,827	¥ 460,486	¥ 422,513	\$ 4,182

See accompanying notes to consolidated financial statements.

# Notes to Consolidated Financial Statements

Astellas Pharma Inc. and Subsidiaries Year ended March 31, 2009, 2008 and 2007

#### **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 or accounting principles generally accepted in the United States.

Effective April 1, 2008, the Company adopted the "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements (PITF No 18)." In accordance with PITF No. 18, the accompanying consolidated financial statements for the year ended March 31, 2009 have been prepared by using, the accounts of foreign consolidated subsidiaries prepared in accordance with either International Financial Reporting Standards (IFRS)

#### 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. 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, 2009, the numbers of consolidated subsidiaries and subsidiaries and affiliates accounted for by the equity method were 64 and 2 (64 and 3 in 2008), 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. Until the year ended March 31, 2006, Astellas Pharma China, Inc. had been consolidated based on the financial statements as of December 31. Astellas Pharma China, Inc. has changed its fiscal year end to March 31 during the year ended March 31, 2007 and accordingly its operating results and cash flows for 15 months ended March 31, 2007 were included in the consolidated financial statements. or accounting principles generally accepted in the United States as adjusted for certain items including those for goodwill, actuarial differences and capitalized development costs. See Note 3(b).

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 International Financial Reporting Standards, 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.

The excess of cost over underlying net assets at fair value at the date of acquisition is amortized over periods not exceeding 20 years on a straight-line basis except that when the excess 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

Revenue and expense accounts of the foreign subsidiaries are translated using the average exchange rate 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 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 cash equivalents.

#### (d) Inventories

Until the year ended March 31, 2007, inventories of the Company and its domestic subsidiaries are mainly stated at cost by the average method.

Effective April 1, 2007, 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 is calculated principally by the declining-balance method at rates based on the estimated useful lives of the respective assets. However, depreciation of property, plant and equipment of the foreign subsidiaries is calculated principally by the straightline method. The useful lives of property, plant and equipment are summarized as follows:

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

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

#### (f) Leases

Noncancelable leases of the Company and its subsidiaries 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 remaining value being zero.

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

Securities other than equity securities issued by 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. Nonmarketable securities classified as other securities are stated at cost. Cost of securities sold is determined by the moving average method.

#### (h) Research and development expenses

Research and development expenses are charged to income as incurred.

#### (i) Income taxes

Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax bases of the assets and liabilities and are measured using the enacted tax rates and laws which will be in effect when the differences are expected to reverse.

#### (j) 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 prior service cost.

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

Effective October 1, 2006, the retirement benefit plans of the former Yamanouchi Pharmaceutical Co., Ltd. and those of the

former Fujisawa Pharmaceutical Co., Ltd. have been integrated into a newly established retirement benefit plans. Actuarial gain and loss recognized before the integration for the former Fujisawa's plans are being amortized in the year following the year in which the gain or loss is recognized by the straight-line method over the period which is shorter than the average remaining years of service of the employees (10 years), and prior service cost recognized before the integration for the former Fujisawa's plans is being amortized as incurred by the straightline method over the period which is shorter than the average remaining years of service of the employees (10 years).

# 3. ACCOUNTING CHANGES

- (a) Effective April 1, 2008 the Company and its domestic subsidiaries adopted a new accounting standard for lease transactions and related implementation guidance, which requires all finance lease transactions to be capitalized. Until the year ended March 31, 2008, finance leases in which there was no transfer of ownership of leased assets upon the expiration of lease periods had been accounted for as operating leases. This change had no impact on the operating results.
- (b) Effective April 1, 2008, PITF No. 18 has been adopted. This change had no impact on the operating results and finance condition.
- (c) Effective April 1, 2007 the Company and its domestic subsidiaries implemented early adoption of a new accounting standard for measurement of inventories, which requires all the inventories to be stated at the lower of cost or market. The effect of this change was to decrease gross profit by ¥99 million and to increase operating income and income before income taxes and minority interests by ¥493 million and ¥939 million, respectively, for the year ended March 31, 2008 compared to the corresponding amounts which would have been recognized under the previous method.

#### (k) Derivative financial instruments

The Company has entered into 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.

- (d) Effective April 1, 2007, the Company and its domestic subsidiaries changed the depreciation rate and the salvage value of property, plant and equipment mainly based on the amendment of Corporate Tax Law of Japan and the change in the Company's investment strategy. The effect of these changes was to decrease gross profit by ¥449 million and to decrease operating income and income before income taxes and minority interests by ¥1,477 million for the year ended March 31, 2008.
- (e) Effective the year ended March 31, 2007, the Company adopted a new accounting standard for the presentation of net assets in the balance sheet and the related implementation guidance. In addition, effective the year ended March 31, 2007, the Company is required to prepare consolidated statements of changes in net assets instead of consolidated statements of shareholders' equity.
- (f) Effective April 1, 2006, the Company adopted a new accounting standard for share-based payment and implementation guidance. The effect of this change was to decrease operating income and income before income taxes and minority interests by ¥284 million for the year ended March 31, 2007.

(g) Effective April 1, 2006, the Company adopted a new accounting standard for bonus for directors. The effect of this change was to decrease operating income and

income before income taxes and minority interests by ¥101 million for the year ended March 31, 2007.

#### 4. U.S. DOLLAR AMOUNTS

The translation of yen amounts into U.S. dollar amounts is included solely for convenience, as a matter of arithmetic computation only, at ¥98=U.S. \$1.00, the approximate rate of exchange on March 31, 2009. The translation should not be

construed as a representation that yen have been, could have been, or could in the future be, converted into U.S. dollars at the above or any other rate.

#### 5. INVENTORIES

Inventories as of March 31, 2009 and 2008 were as follows:

		Millions of yen	Millions of U.S. dollars
	2009	2008	2009
Merchandise and finished goods	¥ 80,755	¥65,516	\$ 824
Work in process	12,506	12,360	128
Raw materials and supplies	12,169	13,569	124
	¥105,430	¥91,445	\$1,076

#### 6. SHORT-TERM BORROWINGS AND LONG-TERM DEBT

The Company had no short-term borrowings or long-term debt except for lease obligations at March 31, 2009. The Company included current portion of lease obligations of ¥598 million (\$6 million) in other current liabilities and included

lease obligations excluding current portion of ¥911 million (\$9 million) in other long-term liabilities.

The aggregate annual maturities of lease obligations for 5 years subsequent to March 31, 2009 are summarized as follows:

		Millions of
Year ending March 31,	Millions of yen	U.S. dollars
2010	¥ 598	\$ 6
2011	471	5
2012	227	2
2013	148	1
2014 and thereafter	65	1
Total	¥1,509	\$15

The Company had no short-term borrowings or long-term debt at March 31, 2008.

# 7. NET ASSETS

Information regarding changes in net assets for the year ended March 31, 2009 is as follows:

#### a. Treasury stock

				(Thousands of shares)
Types of share	Number of shares as of March 31, 2008	Increase	Decrease	Number of shares as of March 31, 2009
Treasury stock:				
Common stock (Notes 1 and 2)	20,881	28,128	15,061	33,948
	(Thousands o	f shares)		
Notes: 1. Details of the increase of treasury sto	ock are as follows:			
Increase due to purchase of the stoc	ks	28,086		
Increase due to purchase of the stoc	ks of less than standard unit	42		
2. Details of the decrease of treasury st	ock are as follows:			
Decrease due to cancellation		15,000		
Decrease due to sale of the stocks of	less than standard unit	26		
Decrease due to exercise of stock su	bscription rights	35		

#### b. Dividends

1) Dividends paid

For the year ended March 31, 2009

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 24, 2008	Common stock	29,885	60	March 31, 2008	305	0.61
Board of Directors on November 5, 2008	Common stock	28,740	60	September 30, 2008	293	0.61

2) Dividends of which the cut-off date was in the year ended March 31, 2009 and the effective date will be in the year ending March

31, 2010

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, 2009	Common stock	28,201	60	March 31, 2009	288	0.61

#### c. Stock subscription rights

In September 2008, the Company issued 727 units of stock subscription rights, for which ¥217 million (\$2 million) was recorded as a component of net assets as of March 31, 2009.

The stock subscription rights included those which were not vested as of March 31, 2009.

# 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		no	no	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				
		Granted on February 13, 2007	Granted on August 10, 2007	Granted on September 16, 2008		
Individuals covered by the plan	Directors of the Company	4	4	3		
	Corporate officers of the Company	27	26	23		
	Employees of the Company	_		_		
	Total	31	30	26		
Type and number of shares to be issued upon the exercise of the						
stock subscription rights	Common stock	75,700	74,000	72,700		
Vesting period		From July 1, 2006 to June 26, 2007	From July 1, 2007 to June 25, 2008	From July 1, 2008 to June 23, 2009		
Exercise period		From February 14, 2007 to June 27, 2026	From August 11, 2007 to June 26, 2027	From September 17, 2008 to June 24, 2028		

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	Stock subscription rights granted as a stock option plar			
	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, 2008	_	_	_		
Granted	_	_			
Forfeited		_	_		
Vested		_	_		
Outstanding as of March 31, 2009	_	_			
Vested stock subscription rights (shares)					
Outstanding as of March 31, 2008	27,700	73,600	102,100		
Vested	_	_			
Exercised	10,200	4,500	10,600		
Forfeited	_	_			
Outstanding as of March 31, 2009	17,500	69,100	91,500		
Exercise price (Yen)	3,209	3,690	1		
Weighted average exercise price (Yen)	4,332	4,019	3,295		
Weighted average fair value per stock at the granted date (Yen)	_	_			
Exercise price (U.S. dollars)	32.74	37.65	0.01		
Weighted average exercise price (U.S. dollars)	44.20	41.01	33.62		
Weighted average fair value per stock at the granted date (U.S. dollars)		_			

	Stock	subscription rights grante	d 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, 2008	_	18,500	_
Granted	_	_	72,700
Forfeited	_	_	_
Vested	_	18,500	54,525
Outstanding as of March 31, 2009	_	_	18,175
Vested stock subscription rights (shares)			
Outstanding as of March 31, 2008	75,700	55,500	_
Vested	_	18,500	54,525
Exercised	5,400	3,800	_
Forfeited	_	—	—
Outstanding as of March 31, 2009	70,300	70,200	54,525
Exercise price (Yen)	1	1	1
Weighted average exercise price (Yen)	3,704	3,368	_
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)	37.80	34.37	
Weighted average fair value per stock at the granted date (U.S. dollars)	51.11	47.34	40.61

Stock option expense was included in selling, general and administrative expenses for the year ended March 31, 2009 amounted to ¥303 million (\$3 million). The fair value of options granted on September 16, 2008 was estimated using the binominal model with the following weighted average assumptions.

	Stock subscription rights granted on September 16, 2008 as a stock option plan
Expected volatility	28.73%
Expected holding period	4 years
Expected dividend per share	110 yen
Risk-free rate	2.09%

# 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 2009, 2008 and 2007. 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, 2009, 2008 and 2007 differ from the statutory tax rate for the following reasons:

	2009	2008	2007
Statutory tax rate	41.0%	41.0%	41.0%
Effect of:			
Tax deductions for research and development expenses	(4.5)	(3.3)	(5.1)
Different tax rates applied to income of foreign subsidiaries	(4.2)	(4.0)	(2.4)
Expenses not deductible for income tax purposes	2.2	1.5	2.1
Amortization of goodwill	1.2	0.3	—
Change in valuation allowance	0.7	(0.5)	0.8
Equity in losses (earnings) of affiliates	0.0	(1.2)	(0.2)
Other, net	(2.3)	(0.6)	0.9
Effective tax rates	34.1%	33.2%	37.1%

The significant components of the deferred tax assets and liabilities as of March 31, 2009 and 2008 were as follows:

		Millions of yen	
	2009	2008	2009
Deferred tax assets:			
Loss on devaluation of investment securities	¥ 3,604	¥ 3,820	\$ 37
Accrued retirement benefits	6,401	6,660	65
Depreciation and amortization	34,396	37,296	351
Loss on impairment of fixed assets	4,663	6,704	48
Accrued expenses	23,129	26,432	236
Inventories	24,797	23,641	253
Accrued enterprise and other taxes	2,916	3,348	30
Other	44,236	43,159	450
Gross deferred tax assets	144,142	151,060	1,470
Valuation allowance	(14,940)	(13,424)	(152)
Total deferred tax assets	129,202	137,636	1,318
Deferred tax liabilities:			
Unrealized holding gain on securities	6,229	18,661	64
Depreciation and amortization	1,136	1,144	12
Other	8,883	10,390	90
Total deferred tax liabilities	16,248	30,195	166
Net deferred tax assets	¥112,954	¥107,441	\$1,152

#### **10. RETIREMENT BENEFIT PLANS**

Until October 1, 2006, the Company and its domestic subsidiaries had defined benefit plans, i.e., tax-qualified plans, corporate pension fund plans, tax-qualified plans (closed type) and lumpsum payment plans. Effective October 1, 2006, a corporate pension fund plan and a lump-sum payment plan were newly established to integrate the former Yamanouchi's and Fujisawa's retirement benefit plans. In addition, a portion of the benefit obligations under the new plans was transferred to a newly established defined contribution plan. In this connection, the pension plan assets of ¥8,791 million are being transferred to the defined contribution plan over 8 years commencing from the year ended March 31, 2007. 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, 2009 and 2008 for the Company's and the subsidiaries' defined benefit plans:

		Millions of yen	Millions of U.S. dollars
	2009	2008	2009
Retirement benefit obligation	¥(145,364)	¥(150,721)	\$(1,483)
Plan assets at fair value	106,645	130,883	1,088
Unfunded retirement benefit obligation	(38,719)	(19,838)	(395)
Unrecognized actuarial loss	33,774	13,694	345
Unrecognized prior service cost	(9,075)	(10,042)	(93)
Net retirement benefit obligation	(14,020)	(16,186)	(143)
Prepaid pension cost	1,010	1,306	10
Accrued retirement benefits	¥ (15,030)	¥ (17,492)	\$ (153)

The components of retirement benefit expenses for the years ended March 31, 2009, 2008 and 2007 are outlined as follows:

	Millions of yen			Millions of U.S. dollars	
	2009	2008	2007	2009	
Service cost	¥ 4,893	¥ 5,690	¥ 6,218	\$ 50	
Interest cost	4,120	4,323	4,249	42	
Expected return on plan assets	(4,570)	(3,768)	(3,359)	(47)	
Amortization of actuarial loss	2,451	1,681	2,234	25	
Amortization of prior service cost	(825)	(880)	(215)	(8)	
Other	7,590	16,571	10,951	77	
Total	¥13,659	¥23,617	¥20,078	\$139	

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

	2009	2008
Discount rates	2.0% - 6.1%	2.0% - 10.0%
Expected rates of return on plan assets	3.0% - 5.0%	2.0% - 8.0%

#### **11. RESEARCH AND DEVELOPMENT EXPENSES**

Research and development expenses, all of which were ¥159,059 million (\$1,623 million), ¥134,464 million and included in selling, general and administrative expenses for ¥167,946 million, respectively. the years ended March 31, 2009, 2008, and 2007, totaled

#### 12. LEASES

Future minimum lease payments subsequent to March 31, 2009 on noncancelable operating lease transactions are summarized as follows:

Year ending March 31,	Millions of yen	Millions of U.S. dollars
2010	¥ 4,388	\$ 45
2011 and thereafter	12,240	125
Total	¥16,628	\$170

See note 3(a).

# 13. CONTINGENT LIABILITIES

Contingent liabilities of the Company and its subsidiaries as of March 31, 2009 and 2008 were as follows:

	Millions of yen	Millions of U.S. dollars
	2009	2009
Contingent liabilities as guarantors of indebtedness of the Company's employees and affiliates	¥3,025	\$31

	Millions of yen
	2008
Contingent liabilities as guarantors of indebtedness of the Company's employees and affiliates	¥3,644
Other contingent liabilities relating to a debt assumption contract	120
Other	128

The Company may be involved in various lawsuits during the normal course of business. The Company's management believes the lawsuits in which the Company is currently involved would not have material adverse impacts on the Company's financial conditions or operating results.

#### 14. AMOUNTS PER SHARE

	Yen			U.S. dollars
	2009	2008	2007	2009
Net income:				
Basic	¥ 356.11	¥ 349.89	¥ 244.07	\$ 3.63
Diluted	355.90	349.71	243.99	3.63
Cash dividends	120.00	110.00	80.00	1.22
Net assets	2,189.26	2,228.34	2,135.34	22.34

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

Diluted net income per share is computed based on net income available for distribution to the shareholders and the weighted-average number of shares of common stock outstanding during each year after giving effect to the dilutive potential of shares of common stock to be issued upon the exercise of stock subscription rights and the conversion of

#### **15. SUPPLEMENTARY CASH FLOW INFORMATION**

The Company had no outstanding issue of convertible bonds during the years ended March 31, 2009 and 2008.

The conversion of convertible bonds for the year ended March 31, 2007 amounted to ¥30 million and the Company had no outstanding issue of convertible bonds as of March 31, 2007. convertible bonds. The Company had no outstanding issue of convertible bonds during the years ended March 31, 2009 and 2008.

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.

Agensys, Inc. was newly consolidated as a result of the acquisition of 100% of its stock during the year ended March 31, 2008. The following is a summary of the assets acquired and liabilities assumed:

	Millions of yen
Current assets	¥ 3,305
Property, plant and equipment	4,781
Goodwill	30,862
Current liabilities	(345)
Long-term liabilities	(7)
Acquisition cost of stock of Agensys, Inc.	¥38,596
Cash and cash equivalents of Agensys, Inc.	(3,171)
Effect of exchange rate fluctuation	4,982
Net cash used in the acquisition	¥40,407

Zepharma Inc. was sold during the year ended March 31, 2007. The following is a summary of its assets and liabilities:

	Millions of yen
Current assets	¥18,234
Long-term assets	3,975
Total assets	¥22,209
Current liabilities	¥ 6,600
Long-term liabilities	807
Total liabilities	¥ 7,407

# 16. SECURITIES

Information regarding marketable securities classified as held-to-maturity debt securities and other securities as of March 31, 2009 and 2008 is summarized as follows:

### Marketable held-to-maturity debt securities

			Millions of yen		Milli	ons of U.S. dollars
			2009			2009
	Carrying value	Estimated fair value	Unrealized gain (loss)	Carrying value	Estimated fair value	Unrealized gain (loss)
Securities whose fair value exceeds their carrying value:						
Government bonds	¥600	¥602	¥2	\$6	\$6	\$0
Corporate bonds	—	_	_	—	_	_
Other	—	—	—	—	—	_
Total	¥600	¥602	¥2	\$6	\$6	\$0

			Millions of yen
			2008
	Carrying value	Estimated fair value	Unrealized gain (loss)
Securities whose fair value exceeds their carrying value:			
Government bonds	¥1,201	¥1,202	¥1
Corporate bonds	—	_	—
Other	—	_	_
Total	¥1,201	¥1,202	¥1

# Marketable other securities

			Millions of yen		Millio	ons of U.S. dollars
			2009			2009
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:						
Stock	¥ 20,448	¥ 40,391	¥19,943	\$ 209	\$ 412	\$203
Debt securities	52,361	52,540	179	534	536	2
Other	_	_	_	_		_
Subtotal	72,809	92,931	20,122	743	948	205
Securities whose acquisition cost exceeds their carrying value:						
Stock	13,344	11,673	(1,671)	136	119	(17)
Debt securities	125,446	123,243	(2,203)	1,280	1,257	(23)
Other	2,050	2,031	(19)	21	21	(0)
Subtotal	140,840	136,947	(3,893)	1,437	1,397	(40)
Total	¥213,649	¥229,878	¥16,229	\$2,180	\$2,345	\$165

			Millions of yen
			2008
	Acquisition	Carrying	Unrealized
	cost	value	gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Stock	¥ 22,273	¥ 70,385	¥48,112
Debt securities	55,150	55,351	201
Other	1,302	2,174	872
Subtotal	78,725	127,910	49,185
Securities whose acquisition cost exceeds their carrying value:			
Stock	9,596	8,485	(1,111)
Debt securities	102,474	101,016	(1,458)
Other	976	856	(120)
Subtotal	113,046	110,357	(2,689)
Total	¥191,771	¥238,267	¥46,496

Sales amounts of securities classified as other securities and the related aggregate gain and loss for the years ended March 31, 2009, 2008 and 2007 are summarized as follows:

			Millions of yen	Millions of U.S. dollars
	2009	2008	2007	2009
Proceeds from sales	¥38,807	¥25,996	¥50,571	\$396
Gain on sales	508	123	12,506	5
Loss on sales	389	4	159	4

The redemption schedule for securities with maturities classified as other securities and held-to-maturity debt securities as of March 31, 2009 is summarized as follows:

				Millions of yen
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Government bonds	¥128,123	¥ 1,514	¥3,887	_
Corporate bonds	23,509	18,907	98	_
Other debt securities	42,775	143	_	¥202
Other	32,000	_	_	_
Total	¥226,407	¥20,564	¥3,985	¥202

			Milli	ons of U.S. dollars
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Government bonds	\$1,307	\$ 15	\$40	_
Corporate bonds	240	193	1	_
Other debt securities	436	1	_	\$2
Other	327	_	_	_
Total	\$2,310	\$209	\$41	\$2

#### Securities without determinable market value

Other securities

Other securities		Millions of yen	Millions of U.S. dollars
	2009	2008	2009
Non marketable stocks	¥ 5,016	¥ 4,534	\$ 51
Senior investment securities	5,000	5,000	51
Certificate of deposits	32,000	_	327
Commercial paper	42,775	192,797	436
Money management fund	20,056	8,579	205

#### **17. DERIVATIVE TRANSACTIONS**

The Company utilizes derivative transactions just for the purpose of hedging its exposure to adverse fluctuation primarily in foreign currency exchange rates or interest rates, but does not enter into such transactions for speculative or trading purposes.

The Company is exposed to credit risk in the event of nonperformance by the counterparties to the derivative transactions. In order to minimize such a credit risk, the Company enters into transactions only with financial institutions with high credit ratings. The Company assumes that the impacts of the derivatives on the Company's financial conditions would not be material.

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

The notional amounts and the estimated fair value of derivatives outstanding as of March 31, 2009 and 2008 are summarized as follows:

			Millions of yen		Milli	ons of U.S. dollars
			2009			2009
	Notional		Unrealized	Notional		Unrealized
	amount	Fair value	gain (loss)	amount	Fair value	gain (loss)
Forward foreign exchange contracts						
Sell:						
U.S. dollars	¥1,663	¥1,669	¥ (6)	\$17	\$17	\$(0)
Euros	3,224	3,374	(150)	33	34	(1)
British pounds	139	140	(1)	1	1	(0)
Total	¥5,026	¥5,183	¥(157)	\$51	\$52	\$(1)

			Millions of yen
			2008
	Notional amount	Fair value	Unrealized gain (loss)
Forward foreign exchange contracts			
Sell:			
Euros	¥2,355	¥2,362	¥(7)
Buy:			
U.S. dollars	298	299	1
Total	¥2,653	¥2,661	¥(6)

# 18. ACQUISITION OF STOCK OF AGENSYS, INC.

On December 18, 2007, Astellas acquired 100% of stock of Agensys, Inc., a biotechnology company specializing in therapeutic antibody research and development in cancer. The acquisition was to reinforce and to accelerate its antibody research and development in cancer, which is one of the important areas for therapeutic research. All of purchase price of ¥38,596 million was paid by cash. In addition, Astellas will pay up to a maximum of \$150 million if certain predefined milestones are achieved. The acquisition has been accounted for as a purchase business combination. Under the purchase method of accounting, the assets acquired and liabilities assumed from Agensys, Inc. were recorded at their respective fair values as of the date of acquisition. Those fair values are summarized as follows:

	Millions of yen
Current assets	¥3,305
Long-term assets	4,781
Total assets	¥8,086
Current liabilities	¥ 345
Long-term liabilities	7
Total liabilities	¥ 352

The excess of cost over underlying net assets at fair value at the date of acquisition was recognized as goodwill in the amount of ¥30,862 million and has been amortized over a period of five years on a straight-line basis. In addition, contingent payments of \$150 million will also be recognized as goodwill upon payments.

The consolidated statement of income for the year ended March 31, 2008 includes the results of operations of Agensys, Inc. from the date of acquisition. Had the business combination had completed at the beginning of the year, the effect for the year ended March 31, 2008 on sales would have been immaterial, however, operating income, and income before income taxes and minority interests would have been decreased by approximately ¥7,899 million for the year ended March 31, 2008.

### **19. SEGMENT INFORMATION**

#### **Business segments**

The Company's businesses are segmented into "Pharmaceutical" and "Other" based on their similarity in terms of distribution methods, the nature and type of products sold, and manufacturing methods. As net sales, operating income and total assets in the "Pharmaceutical" segment constituted more than 90% of the consolidated totals, the disclosure of business segment information has been omitted. Geographical areas, which include the results of the operation attributed by the location of the Company and the subsidiaries, for the years ended March 31, 2009, 2008, and 2007 are summarized as follows:

# Geographical areas

							Millions of yen
		North					
Year ended March 31, 2009	Japan	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

#### Millions of U.S. dollars

		North					
Year ended March 31, 2009	Japan	America	Europe	Asia	Total	Eliminations	Consolidated
Sales to third parties	\$5,209	\$1,927	\$2,440	\$278	\$ 9,854	\$ —	\$ 9,854
Intergroup sales and transfers	1,328	694	558	0	2,580	(2,580)	—
Total sales	6,537	2,621	2,998	278	12,434	(2,580)	9,854
Operating expenses	4,745	2,286	2,591	244	9,866	(2,567)	7,299
Operating income	\$1,792	\$ 335	\$ 407	\$ 34	\$ 2,568	\$ (13)	\$ 2,555
Total assets	\$9,276	\$2,051	\$2,767	\$172	\$14,266	\$ (506)	\$13,760

							Millions of yen
Year ended March 31, 2008	Japan	North America	Europe	Asia	Total	Eliminations	Consolidated
Sales to third parties	¥ 505,596	¥194,506	¥244,643	¥27,841	¥ 972,586	¥ —	¥ 972,586
Intergroup sales and transfers	111,792	64,497	58,048	10	234,347	(234,347)	—
Total sales	617,388	259,003	302,691	27,851	1,206,933	(234,347)	972,586
Operating expenses	441,348	202,672	261,657	25,098	930,775	(234,093)	696,682
Operating income	¥ 176,040	¥ 56,331	¥ 41,034	¥ 2,753	¥ 276,158	¥ (254)	¥ 275,904
Total assets	¥1,034,390	¥148,591	¥278,727	¥18,221	¥1,479,929	¥ (40,777)	¥1,439,152

							Millions of yen
Year ended March 31, 2007	Japan	North America	Europe	Asia	Total	Eliminations	Consolidated
Sales to third parties	¥ 501,664	¥173,559	¥219,697	¥25,704	¥ 920,624	¥ —	¥ 920,624
Intergroup sales and transfers	100,542	53,729	40,159	2	194,432	(194,432)	—
Total sales	602,206	227,288	259,856	25,706	1,115,056	(194,432)	920,624
Operating expenses	485,564	175,718	236,072	21,955	919,309	(189,199)	730,110
Operating income	¥ 116,642	¥ 51,570	¥ 23,784	¥ 3,751	¥ 195,747	¥ (5,233)	¥ 190,514
Total assets	¥1,053,068	¥175,397	¥266,521	¥21,880	¥1,516,866	¥ (46,165)	¥1,470,701

# Overseas sales

Overseas sales, which include the sales of attributed by the location of customers, for the years ended March 31, 2009, 2008 and 2007 are summarized as follows:

					Millions of yen
	North				
Year ended March 31, 2009	America	Europe	Asia	Other	Total
Overseas sales	¥235,023	¥180,393	¥35,875	¥17,688	¥468,979
Consolidated net sales					965,698

				Millio	ns of U.S. dollars
Year ended March 31, 2009	North America	Europe	Asia	Other	Total
Overseas sales	\$2,398	\$1,842	\$366	\$180	\$4,786
Consolidated net sales					9,854
Overseas sales as a percentage of consolidated net sales	24.3%	18.7%	3.7%	1.9%	48.6%

					Millions of yen
	North				
Year ended March 31, 2008	America	Europe	Asia	Other	Total
Overseas sales	¥247,129	¥195,636	¥34,399	¥12,407	¥489,571
Consolidated net sales					972,586
Overseas sales as a percentage of consolidated net sales	25.4%	20.1%	3.5%	1.3%	50.3%

					Millions of yen
	North				
Year ended March 31, 2007	America	Europe	Asia	Other	Total
Overseas sales	¥223,226	¥182,753	¥31,158	¥12,925	¥450,062
Consolidated net sales					920,624
Overseas sales as a percentage of consolidated net sales	24.2%	19.9%	3.4%	1.4%	48.9%

#### 20. LOSS ON IMPAIRMENT OF FIXED ASSETS

The Group bases its grouping for assessing impairment losses on its business segments. However, the Group 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, 2009, 2008 and 2007 amounted to ¥1,340 million (\$14 million), ¥9,331 million and ¥17,453 million, respectively. 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. Loss on impairment of fixed assets for the year ended March 31, 2008 mainly consists of losses on land in the aggregate amount of ¥3,389 million and on buildings and structures in the aggregate amount of ¥3,248 million. Loss on impairment of fixes assets for the year ended March 31, 2007 mainly consists of closure of business bases.

#### 21. SUBSEQUENT EVENTS

(a) The following appropriations of retained earnings of the Company were approved at a shareholders' meeting held on June 23, 2009:

	Millions of yen	Millions of U.S. dollars
Year-end cash dividends		
(¥60 = \$0.61 per share)	¥28,201	\$288

(b) An issuance of new stock subscription rights was approved at a shareholders' meeting and subsequently resolved at the Board of Directors' meeting, both held on June 23, 2009 in which directors, corporate officers of the Company were granted new stock subscription rights totaling 1,149 units. These stock subscription rights will be issued on July 8, 2009 and can be exercised from July 9, 2009 to June 23, 2029.

# 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, 2009 and 2008, and 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, 2009, 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, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended March 31, 2009 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, 2009 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 Nikon LLC

June 23, 2009

# Principal Subsidiaries and Affiliates

(as of July 2009)

### 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: +1-405-217-6400

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

### Europe

#### HOLDING COMPANY IN EUROPE

Astellas B.V. Elisabethhof 19, 2353 EW Leiderdorp, The Netherlands

# 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. Elisabethhof 19, 2353 EW Leiderdorp, The Netherlands

# Astellas Ireland Co., Limited

Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Republic of Ireland TEL: +353-1-803-0800

Germany
 Astellas Pharma GmbH

Georg-Brauchle-Ring 64-66, 80992, Munich, Germany TEL: +49-89-45-44-01

# • Spain

Astellas Pharma S.A. Centro Empresarial 'La Finca', Paseo del Club Deportivo nº1, Bloque 14, 2ª planta, 28223 Pozuelo de Alarcón, Madrid, Spain TEL: +34-91-495-2700

# France Astallas Dha

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

# Italy

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

# United Kingdom

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

- Export Astellas Pharma International B.V.
   Elisabethhof 19, P.O. Box 108, 2350 AC, Leiderdorp, The Netherlands
- Northern Europe
   Astellas Pharma A/S
   Naverland 4, DK 2600 Glostrup, Denmark
   TEL: +45-434-30-355
- Poland Astellas Pharma Sp.zo.o.
   Poleczki 21, 02-822, Warsaw, Poland TEL: +48-22-545-11-11

 Russia ZAO Astellas Pharma Marksistskaya Ulitsa 16, 109147, Moscow, Russia TEL: +709-5737-0755

 Netherlands Astellas Pharma B.V.
 Elisabethhof 19, P.O. Box 108, 2350 AC, Leiderdorp, The Netherlands

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

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

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

 Ireland Astellas Pharma Co., Limited
 25 The Courtyard, Kilcarbery Business Park, Clondalkin, Dublin 22, Republic of Ireland
 TEL: +353-1-467-1555

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

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

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

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

 Hungary Astellas Pharma Kft
 Kelenhegyi út 43, H 1118 Budapest, Hungary
 TEL: +36-1-361-4673

Turkey
 Astellas Pharma ilaç Ticaret ve Sanayi Anonim Şirketi
 Tekstilkent Koza Plaza, A Blok 16.Kat No:60, 34235 Esenler, Istanbul, Turkey

# Asia

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. Suite 708-709, 7/F, Prudential Tower, The Gateway, Harbour City, 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

# Japan

#### MANUFACTURING SUBSIDIARIES

Astellas Tokai Co., Ltd.

Astellas Toyama Co., Ltd.

Astellas Pharma Chemicals Co., Ltd.

# Investor Information

(as of March 31, 2009)

# 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/

### соммон этоск

Authorized: 2,000,000,000 Issued: 503,964,635 (including 33,948,017 treasury stock)

# NUMBER OF SHAREHOLDERS: 51,294

# STOCK EXCHANGE LISTING

Tokyo, Osaka (Ticker Code: 4503)

# INDEPENDENT AUDITORS

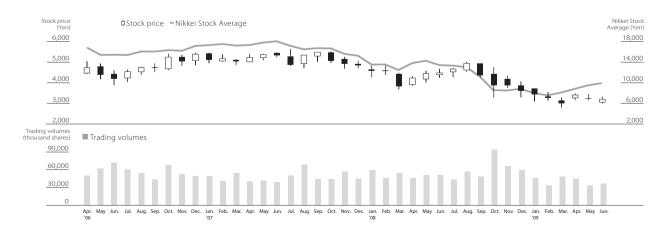
Ernst & Young ShinNihon LLC Osaka Kokusai Bldg., 2-3-13, Azuchi-machi, Chuo-ku, Osaka-shi, Osaka 541-0052, Japan

# 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 4G)	29,064	5.76
Japan Trustee Services Bank, Ltd. (trust account)	28,537	5.66
The Master Trust Bank of Japan, Ltd. (trust account)	25,812	5.12
Nippon Life Insurance Company	25,587	5.07
The Chase Manhattan Bank, NA London, SL Omnibus account	22,612	4.48
State Street Bank and Trust Company	16,985	3.37
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	13,720	2.72
State Street Bank and Trust Company 505225	9,357	1.85
Mellon Bank N.A. as agent for its client Mellon Omnibus U.S. Pension	8,389	1.66
Trust & Custody Services Bank, Ltd. (securities investment trust account)	6,358	1.26

Note: The Company owned 33,948,017 shares of treasury stock as of March 31, 2009, but they are not included in the principal shareholders stated above.

# **Breakdown of Shareholders**





#### "Leading Light for Life"

Superior pharmaceuticals that provide the promise of a healthier and more enriched life to people from all over the world. That is Astellas' earnest wish. Our challenge, our vision, and our mission are to illuminate the future and constantly seek a better life for all. As a global pharmaceutical company, Astellas is determined to be the "Leading Light for Life."

This corporate message directly reflects our business philosophy: "Contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products".



ASTELLAS PHARMA INC. 2-3-11, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan http://www.astellas.com/en/



The paper on which this annual report is printed was produced using "green" electricity that emits no CO<sub>2</sub> during papermaking. (Estim 310,000 kWh/year)