

# Further Growth in Sight

SANTEN PHARMACEUTICAL CO., LTD.

Santen Pharmaceutical Co., Ltd. specializes in the research, development, manufacturing and marketing of ophthalmic and anti-rheumatic pharmaceuticals to protect and improve people's eyesight and health. Deeply aware of the sanctity of human life, we apply our unique capabilities and technologies in our areas of expertise to contribute to the health and quality of life of patients and their loved ones, and society as a whole.



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#### NOTE CONCERNING GRAPHS

Graphs in this annual report are based on fiscal years ended March 31, if no note is specified. NOTE CONCERNING DATA

Some information in this annual report is based on IMS data (JPM, MIDAS). Period: March 2004 to March 2009

#### CAUTION CONCERNING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements regarding the Company's plans, outlook, strategies and results for the future. All forward-looking statements are based on judgments derived from the information available to the Company at the time of publication Certain risks and uncertainties could cause the Company's actual results to differ materially from any projections presented in this report. These risks and uncertainties include, but are not limited to, the economic circumstances surrounding the Company's businesses, competitive pressures, changes in related laws and regulations, status of product development programs and changes in exchange rates.

## **Consolidated Financial Highlights**

Santen Pharmaceutical Co., Ltd. and Subsidiaries Years ended March 31, 2009 and 2008

	Million	Millions of yen		Thousands of U.S. dollars	
	2009	2008	2009/2008	2009	
For the year:					
Net sales	¥101,619	¥103,394	(1.7)%	\$1,034,498	
Operating income	15,494	20,371	(23.9)	157,734	
Net income	10,123	12,651	(20.0)	103,056	
R&D expenditures	18,458	12,942	42.6	187,905	
Capital expenditures	2,953	3,151	(6.3)	30,064	
Depreciation and amortization	4,210	4,593	(8.3)	42,855	
At year-end:					
Total assets	¥151,012	¥156,547	(3.5)%	\$1,537,332	
Long-term debt	154	5,278	(97.1)	1,565	
Equity	125,181	126,998	(1.4)	1,274,359	
Per share data (yen and U.S. dollars):					
Net income – basic	¥ 119.08	¥ 146.15	(18.5)%	\$ 1.21	
Net income – diluted	118.97	145.94	(18.5)	1.21	
Equity	1,472.32	1,494.48	(1.5)	14.99	
Cash dividends, applicable to period	80.00	80.00		0.81	
Other financial data:					
Operating income margin (%)	15.2	19.7			
Overseas sales to net sales (%)	12.8	14.3			
R&D expenditures to net sales (%)	18.2	12.5			
Return on equity (ROE) (%)	8.0	9.9			
Dividend on equity (DOE) (%)	5.4	5.4			
Number of employees	2,690	2,483			

Notes: 1. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥98.23 to U.S.\$1 prevailing on March 31, 2009.

2. See Notes 2. 13) and 11 of Notes to Consolidated Financial Statements in respect of per share data.

3. Figures in parentheses indicate a decrease.

Equity comprises shareholders' equity and total accumulated (losses) gains on evaluation and translation.

#### Net sales and Overseas sales to net sales Millions of yen / %



#### Operating income and Operating income margin Millions of yen / %



#### Net income and ROE Millions of yen / %



R&D expenditures and R&D expenditures to net sales Millions of yen / %



### **Overview of Santen**

## pecialty Company

#### Specializing in Ophthalmic and Anti-rheumatic Pharmaceuticals

Santen has been involved in pharmaceutical research, development, manufacturing and sales since its founding in 1890. Initially, cold medicines were the Company's mainstay products; however, we have continued to market high-quality pharmaceuticals in the ophthalmic segment since launching *Daigaku Eye Drops* in 1899. Today we are conducting business operations in Japan, Europe, the U.S. and China as a unique pharmaceutical company specializing in the areas of ophthalmology and rheumatoid arthritis (RA). Prescription ophthalmic pharmaceuticals are the Company's core business, accounting for more than 80% of Santen's sales.

## Market Leader

#### Maintaining a Strong Presence in Target Markets

A leading company in ophthalmology and RA, Santen has carved out the largest shares of the markets in these areas. Santen provides information answering the practical needs of the medical community through approximately 400 medical representatives (MRs) and has an unrivaled lineup of outstanding ophthalmic pharmaceutical products for the treatment of a broad range of ocular diseases. Santen holds 38.0% of Japan's prescription ophthalmic market; further, it boasts a dominant 45.0% share of Japan's market for disease-modifying anti-rheumatic drugs (DMARDs).

## omising Markets

#### Aiming for Growth in Promising Markets

Japan's prescription ophthalmic market is expected to grow approximately 2% annually until 2010. Moreover, growth of the glaucoma and corneal disorders areas that Santen concentrates its efforts on will likely outpace the growth of the prescription ophthalmic market as a whole. In addition, overseas prescription ophthalmic markets are growing faster than Japan's market. Especially in China, where the market is growing at an annualized rate of more than 10%, buoyed by the country's remarkable economic development. Aiming to grow in such promising markets, we are focusing our efforts on expanding overseas operations while strengthening operations in Japan as well.

## **R&D** Capabilities

#### Providing Products Rooted in R&D Capabilities

As an R&D-oriented pharmaceutical company, Santen is focusing its R&D efforts on growth areas where its strengths can be fully utilized and where there is significant growth potential. We are building a clinical development system which includes overseas subsidiaries and encompasses Japan, the U.S. and Europe. Furthermore, having begun clinical development in Asia, our efforts to the further globalization of clinical trials are progressing steadily. Also, we actively foster products by working to ensure their competitive superiority and maximizing their value through R&D focused on the generation of useful data that leads to EBM\*.

\* Evidence based medicine: This refers to medical treatment based on scientific evidence. It is a series of guidelines that require medical treatment to be based on an understanding of the most reliable evidence reasonably available as well as consideration of the unque clinical situation for each patient and the patient's values.

## Toward a Global Company

Santen has had a significant presence in Japan's ophthalmic pharmaceutical market for many years. We aim to be a company that contributes to the health and quality of life of patients and their loved ones not only in Japan but also in countries throughout the world.

## 2015 • .... Becoming a Global Company

#### Long-term Vision

- Become a global company
- Leader in ophthalmic and anti-rheumatic fields
- R&D oriented pharmaceutical company specializing in ophthalmology and other areas where we can leverage our strengths

## 2006

#### Second Step

2010

The R&D investment will generate products that will allow Santen to accelerate global growth.

#### First Step

#### 2006–2010 Medium-term Management Plan

Creating new drug candidates and generating growth in promising regions by leveraging strengths

- 1. Enhance the global strategic product pipeline through internal discovery and development, joint development projects and in-licensing efforts
- 2. Generate growth mainly in Japan, Northern/Eastern Europe, Russia and China. Focus U.S. activities on clinical and business development
- 3. Strengthen manufacturing bases
- 4. Strengthen human resources and organizational capabilities on a global basis

### A Message from the Chairman



## We are steadily moving forward to becoming a global company.

#### Aiming to Become a Global Company

Becoming a global company is the centerpiece of our long-term vision. Santen aims to be a company internationally recognized for supplying the world with highly original and effective products developed using its outstanding R&D capabilities.

Our first step on the road to becoming a global company by fiscal 2015 is to achieve the initiatives of the 2006–2010 Medium-term Management Plan. Under this plan, we aim to achieve solid growth in the medium-term by continuing to invest actively in R&D and expanding our business in regions where we can utilize our strengths.

As a second step, from fiscal 2011 to fiscal 2015, we will realize the benefits of our R&D investments and achieve faster global expansion and further growth.

#### Contributing to Society through Our Business Activities

Santen expresses its core value as follows, "We are focused on specific areas of expertise, such as eye care, developing our unique capabilities and technologies, and contributing to the health and quality of life of patients and their loved ones, and society as a whole." Based on this core value, Santen employees strive to develop innovative pharmaceutical products and ensure that patients have complete confidence in its products. By extending Santen's efforts worldwide, Santen will contribute to the health and quality of life of patients and their loved ones not only in Japan but in countries worldwide.

Moreover, Santen is actively involved in social contribution initiatives. As well as supporting the development of new medical treatments and providing donations and aid to ophthalmology and rheumatoid arthritis-related causes, we contribute to large-scale natural disaster relief projects and promote in-house environmental conservation activities.

#### Providing Stable Returns to Shareholders

Santen regards the continuous and steady return of profits to shareholders as an important management task. The current Medium-term Management Plan reflects our emphasis on returns to shareholders through dividends and improvement of capital efficiency by using the dividend on equity (DOE) ratio as an indicator for dividends. The DOE ratio combines the payout ratio with return on equity (ROE). The Medium-term Management Plan sets out a target of 5.0% for DOE in its final year, fiscal 2010.

Although fiscal 2008 saw a year-on-year decline in earnings due to a temporary increase in R&D expenditures related to the in-licensing of a new drug candidate, Santen paid a full-year dividend of ¥80 per share and achieved a DOE of 5.4%. We aim to continue achieving DOE of 5.0% or higher from the current fiscal year onward.

In closing, I would like to ask our shareholders for their continued understanding and support.

August 2009

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Takakazu Morita Chairman

### A Message from the President and CEO



We will shift to a more proactive business strategy and accelerate toward growth.

#### Foundation for Future Earnings Strengthened in Fiscal 2008

In fiscal 2008, ended March 31, 2009, net sales decreased 1.7% year on year, to ¥101.6 billion. Also, we recorded year-on-year decreases of 23.9% in operating income, to ¥15.5 billion, and 20.0% in net income, to ¥10.1 billion. These decreases in earnings were attributable to a temporary increase in R&D expenditures related to the in-licensing of a new drug candidate, the retinal disorder treatment DE-109 (sirolimus), with a view to long-term growth.

In Japan, NHI drug price revisions resulted in an average reduction of around 3.0% in the prices of Santen's products, compared with an average 5.2% reduction in the prescription ophthalmic pharmaceuticals industry. Despite such circumstances, domestic sales of prescription ophthalmic pharmaceuticals increased 0.1% year on year thanks to Santen's promotional campaigns, including the provision of medical information accurately catering to the potential needs of individual medical facilities. In particular, strong sales of the glaucoma and ocular hypertension treatment *Tapros*, launched in December 2008, and higher sales of the corneal and conjunctival epithelial disorder treatment *Hyalein* contributed significantly to overall earnings. Meanwhile, rapid appreciation of the yen resulted in a 7.4% year-on-year decrease in total overseas sales of prescription ophthalmic pharmaceuticals.

Furthermore, with a view to maximizing product values in overseas markets, we concluded licensing agreements in fiscal 2008 with Merck & Co., Inc. (of the U.S.) for tafluprost (sold as *Tapros* in Japan) as well as with Bausch & Lomb Inc. (of the U.S.) for MD-14, an intraocular lens (IOL) (sold as *Eternity* in Japan).

#### Targeting a Record Performance in Fiscal 2009

For fiscal 2009, ending March 31, 2010, we hope to achieve record net sales, operating income and net income. We project net sales of ¥111.0 billion, operating income of ¥25.5 billion and net income of ¥16.0 billion. We plan to rapidly maximize the value of *Tapros* in Japan and further increase the market penetration of *Hyalein*. In addition, we expect to benefit from favorable trends in Asia's prescription ophthalmic pharmaceutical market.

While concentrating efforts on maximizing the value of *Tapros*, we will strive to control selling, general and administrative expenses (excluding R&D expenditures). On the other hand, we anticipate R&D expenditures of ¥15.3 billion as we steadily advance development of global strategic products\*.

As a company specializing in ophthalmic and anti-rheumatic treatments, Santen will continue to provide pharmaceuticals that contribute to the health and quality of life of patients and their loved ones.

With our sights set on medium-to-long term growth, we will spare no effort to reach our targets. As we take on these challenges, I would like to ask our stakeholders for their continued support.

\* New drug candidates with a new mechanism of action that have potential to generate higher sales than existing products in Japan, the U.S. and Europe.

August 2009

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Akira Kurokawa President and Chief Executive Officer

## An Interview with the President and CEO

What were Santen's achievements in fiscal 2008 under the 2006–2010 Medium-term Management Plan?

## In my view, it was a year in which we successfully laid the foundations for medium-to-long term growth.

In fiscal 2008, we implemented policies and strategies in line with the Medium-term Management Plan and achieved significant targets. In my view, it was a year in which we successfully laid the foundations for medium-to-long term growth.

First and foremost, we began marketing the glaucoma and ocular hypertension treatment *Tapros* in Japan and Europe. I think this is extremely important in the context of our efforts to achieve medium-to-long term growth. *Tapros* is a prostaglandin analogue, which are first-line treatments for glaucoma and ocular hypertension worldwide. The new product is selling well in Japan, while in Europe we have received approval in around 20 countries, and launched in five countries.

In China, the Suzhou Plant, completed in 2007, started up operations, and Santen Pharmaceutical (China) Co., Ltd., began direct marketing operations. Among China's urban hospitals, Santen has claimed the largest share of the market for six consecutive years. We aim to further increase revenues by providing high-quality medical information through our medical representatives (MRs) to earn the trust of ophthalmologists. Given that China's prescription ophthalmic pharmaceutical market will likely continue double-digit growth, we expect to achieve further growth in this market.

As for R&D, in Japan we have filed for approval of DE-089 (diquafosol sodium), a treatment for corneal conjunctival epithelial disorders. DE-089 has a different mechanism of action from the corneal and conjunctival epithelial disorder treatment *Hyalein*, a mainstay product that accounts for a substantial share of the corneal disorders market segment. Also, we successfully in-licensed DE-109 (sirolimus) to strengthen our pipeline in the retinal disorders segment, which has significant unmet medical needs. In another initiative, we launched an IOL, MD-14 (sold as *Eternity* in Japan), featuring a unique hydrophobic acrylic material, the most popular type of IOL material used in cataract surgery worldwide.

Could you please explain your priorities for fiscal 2009, especially regarding prescription ophthalmic pharmaceutical operations in Japan?

## We will further strengthen our position as the holder of the largest share of Japan's prescription ophthalmic pharmaceutical market.

Japan's prescription ophthalmic pharmaceutical market is expected to continue growing despite government efforts to promote the use of generic products. However, the market's growth is softening, and competition in our business environment is intensifying as more competitors enter the market. In response to these conditions, we will concentrate management resources on segments that promise continuous growth, such as the glaucoma segment and the corneal disorders segment.



In fiscal 2009, we will focus efforts on maximizing the product value of *Tapros*. The glaucoma segment is very large and success in this segment will cement the foundations of our operations in Japan. The *Tapros* launch expanded and enriched our product lineup in the glaucoma segment and the product roll-out will enable us to offer prescribing information suited to patients' symptoms. We will conduct promotional campaigns providing high-quality data that leads to EBM (evidence based medicine) and will leverage our enhanced product lineup to increase Santen's presence in the glaucoma segment.

In the corneal disorders segment, we will continue to conduct campaigns to increase awareness of dry eye and the importance of regular checkups to ensure that patients receive appropriate diagnosis and treatment. Through such campaigns, we hope to continue to grow sales of *Hyalein*.

Based on such initiatives, we will further strengthen our position as the holder of the largest share of Japan's prescription ophthalmic pharmaceutical market. Further, we will invest the earnings from pharmaceutical operations in Japan to expand our R&D and overseas operations and thereby pave the way to future growth.



Regarding R&D, how are Santen's efforts to "enhance the global strategic pipeline" progressing?

## We will bring products quickly to market and win out in markets.

Santen's basic R&D strategy is to focus its research themes in the glaucoma, corneal disorders and retinal disorders segments, which promise growth and where Santen can utilize its strengths. By concentrating R&D resources on these segments, we aim to shorten lead times from development through to product creation and marketing. In the context of this basic strategy, we view the period of the Medium-term Management Plan as a phase for preparing new drug candidates for global launches. Accordingly, we are focusing efforts on the clinical development of the global strategic products DE-104 in the glaucoma segment and DE-101 (rivoglitazone) in the corneal disorders segment. Further, as I mentioned, we have filed for approval of DE-089 (diquafosol sodium) in Japan. Also in Japan, we are progressing steadily with the development of DE-108 (levofloxacin 1.5%) in the ophthalmic infections segment and DE-109 in the retinal disorders segment.

Santen will use all of its resources to confirm the proof of concept of these global strategic products, develop the optimum product profile, increase their likelihood of approval and advance them to the next stage of clinical development. Santen will work to improve the efficiency of its development process in order to bring products quickly to market and win out in markets.

Also, further enriching our R&D pipeline is critical if we are to achieve long-term growth. With this in mind, we consolidated our pharmaceutical development by expanding and upgrading the facilities of the Nara Research and Development Center in fiscal 2008. In addition, we intend to continue developing operations in mainstay areas and areas where we can fully utilize our strengths.

Lastly, how do you intend to develop overseas operations?

## We are eager to take on diverse challenges to maximize the market value of our products.

We will expand our businesses in markets where we can capitalize on our strengths, focusing on China, Russia, Northern Europe and Eastern Europe. We expect to grow in such markets as we already have operational platforms in these regions, which are likely to see high growth rates.

Looking at China first, we began direct marketing efforts and started up operations at our new plant in Suzhou in October 2008. In fiscal 2009, we will strengthen systems for direct marketing.

Even in a worldwide recession, China's market is continuing to grow at a high rate. Although there are moves to curb China's medical treatment costs, the percentage of patients covered by health insurance systems will likely increase as these systems evolve and so we expect China's prescription ophthalmic pharmaceutical market will maintain strong growth. Santen will increase sales of such mainstay offerings as the anti-infective ophthalmic solution *Cravit* and the corneal and conjunctival epithelial disorder treatment *Hyalein* through promotional campaigns providing high-quality scientific information to ophthalmologists. Furthermore, Phase III trials are currently underway in China for DE-085 (tafluprost). Santen will advance R&D rapidly and efficiently to strengthen its product lineup in China's market.

In Europe, tafluprost has received approval in about 20 countries. We concluded a licensing agreement with Merck & Co., Inc. (of the U.S.) in April 2009 to help maximize the value of this product. As a result of this agreement, we look forward to seeing an expansion of the marketing of tafluprost beyond the regions such as Northern Europe and Germany where we have established sales platforms. In addition, we will continue efforts to maximize the product value of *Oftaquix* (sold as *Cravit* in Japan), a first-choice anti-infective ophthalmic solution, which is marketed in 27 countries, including Russia.

For the MD-14 IOL (sold as *Eternity* in Japan), we concluded an agreement with Bausch & Lomb Inc. (of the U.S.) in March 2009, granting it worldwide rights, excluding Japan, for the development, manufacturing and marketing of the MD-14 IOL and lens material.

Based on active consideration of a broad range of strategic options, including such licensing agreements, we are eager to take on diverse challenges to maximize the market value of our products.



## **Status of Medium-term Management Plan**

_		FY2006–08 achievements	FY2009 plans	FY2010 plans	
1. Enl	hance global strategic pipeline				
		DE-101: Phase IIa (Japan, U.S.)	Phase IIa or IIb (Japan, U.S.)	Phase IIb or later	
		DE-104: Phase I / IIa (U.S.) Phase IIa (Japan)	Phase I / IIa or IIb (Japan, U.S.)	Phase IIb or later	
1-1.	Development of global strategic product candidates	DE-085: Approved (Japan, Europe)*	Additional applications, approval (Asia, Europe)*	Additional applications, approval (Asia, Europe)*	
		DE-089: Applied*		Approval*	
	* To be applied and launched mainly in Japan	MD-14: Injector approved*	Improve injector*		

#### 2. Generate growth in Japan, Northern/Eastern Europe, Russia and China Focus U.S. activities on clinical and business development

	Japan: Successf	ul launch of new g	glaucoma, corneal and IOL produ	cts and early maximization of	their product value							
	Glaucoma	(New product)	DE-085 launched November 2008	Early maximization of product value of DE-085	Early maximization of product value of DE-085 (Continue)							
2-1.	Glaucoma	(Existing product)	Implemented promotional campaigns, increased sales									
		(New product)			DE-089 launch expected							
	Corneal disorder	(Existing product)	Disease awareness campaign for dry eye	Reap benefits of disease awareness campaign for dry eye	Increase prescription by further improving ability to provide prescription recommendations							
	Intraocular lens (IO	L)	Launched MD-14									
	Northern/Eastern Europe and Russia: Maximize value of Oftaquix and existing products; Launch DE-085											
	Maximize value of new and existing products		Reinforced promotions for existing products									
2-2.			Launched Oftaquix (Russia)	Early maximization of product value of <i>Oftaquix</i>	Early maximization of product value of <i>Oftaquix</i> (Continue)							
			Marketed, introduced DE-085 (in five European countries)	Early maximization of product value of DE-85	Early maximization of product value of DE-85 (Continue)							
	China: Strength	nen business base	and competitiveness by starting c	of local production and establ	ishing direct sales organization							
2-3.			Began direct marketing (in stages)	Undertake direct marketing in earnest								
	Establish direct sale	es organization	Increased prescriptions by providing specialist academic information	Further increase prescriptions								
2-4.	U.S.: Focus on c	linical and busines	s development	·								

#### 3. Strengthen manufacturing bases

#### (Strengthen manufacturing bases by reorganizing production lines and sites in Japan, Finland and China)

		Formulated reorganization plan	Continue	Implement reorganization plan
3-1.	Promote efficiency by reorganizing production lines (preparation for emergency)	Started and completed China plant construction Started packaging operations		

#### 4. Strengthen human resources and organizational capabilities on a global basis

#### (Develop human resources; reorganization)

4-1	Develop core human resources	Assessed HR and formulated HR development plan	Implement plan	Continue
4-2	2. Develop organizational capabilities	Enhanced planning and business development	Enhance global organization	Continue

## Leveraging a Growth Driver

## —Aiming for Further Growth by Maximizing *Tapros* Product Value-

Santen launched the glaucoma and ocular hypertension treatment *Tapros* ophthalmic solution (tafluprost) in Japan on December 16, 2008. As the glaucoma market holds high potential for growth, introduction of *Tapros* to the market is very important for Santen. Consequently, we expect *Tapros* to be a major driving force for Santen's mediumto-long term growth.

## Aiming For an Enhanced Presence in the Glaucoma Segment

Santen's 2006–2010 Medium-term Management Plan sets out the Company's basic policy: "Santen's Global Development: Creating New Drug Candidates, and Generating Growth in Promising Regions by Leveraging Strengths." Reflecting this policy, we have worked toward the launch of the glaucoma and ocular hypertension treatment drug *Tapros* and rapid maximization of its product value for further growth in Japan, where we have a strong operational platform.

The glaucoma segment is a particularly promising market and it continues to expand primarily due to the growth of the geriatric population. In fiscal 2008, the glaucoma segment generated revenues of ¥460 billion, maintaining its position as the largest segment of the world's prescription ophthalmic pharmaceutical market, with a share of 36%. Meanwhile, the Japanese glaucoma market showed 2.2% growth in fiscal 2008 and is expected to grow by approximately 2% in fiscal 2009.

Although Santen continues to hold the largest share of Japan's prescription ophthalmic pharmaceutical market, its share of the glaucoma segment has remained around 20%, partly because it has lacked blockbuster drugs in this segment for several years. Aiming to strengthen and increase our presence in the glaucoma segment in Japan as well as overseas, we have concentrated efforts on developing *Tapros*.

## **Developing Promising New Drugs**

In Japan, Santen obtained regulatory approval for *Tapros* on October 16, 2008. *Tapros* is a prostaglandin analogue, which is the most commonly used first-line treatment for glaucoma and ocular hypertension.

Glaucoma is a disease characterized by optic nerve damage, caused by factors such as increased intraocular pressure. The basic treatment for glaucoma is to lower intraocular pressure and to keep it under control over a long period of time. *Tapros* shows a potent and stable intraocular pressure-lowering effect by promoting uveoscleral outflow of the aqueous humor, which was demonstrated in Japanese clinical trials.

However, some glaucoma patients develop visual field defects even if they have normal or even low intraocular pressure. *Tapros* is the first drug to have undergone clinical trials for normal tension glaucoma, a disease commonly seen among Japanese people. These clinical trials produced clinical data that will facilitate EBM (evidence based medicine)\* for the product as an intraocular pressurelowering agent for normal tension glaucoma. The clinical trials showed its efficacy for increasing retinal arterial blood flow around the optic disk, as well as increasing blood flow in the retinal tissue. Also, *Tapros* has excellent stability, retaining consistent quality for three years when stored at room temperature. Although *Tapros* is the fourth prostaglandin analogue on the market, it has the added value of patient-friendly innovations such as the Dimple Bottle ophthalmic solution container. As results of these strengths, medical professionals have expressed considerable expectations for this product.

#### The Dimple Bottle Wins Good Design Award

In fiscal 2008, the Dimple Bottle—Santen's independently developed container for prescription ophthalmics—won a Good Design Award\* from the Japan Industrial Design Promotion Organization. We developed the Dimple Bottle from scratch, starting by reassessment of existing containers for prescription ophthalmics. We aimed for a container that patients and medical professionals would find easy to use.

The Dimple Bottle is the container used for *Tapros*. Because glaucoma requires long-term treatment, we hope that the functionality and patient-friendliness of the Dimple Bottle will contribute significantly to glaucoma treatment.

\* Organized by Japan Industrial Design Promotion Organization with the support of METI, it is Japan's only system for presenting general design evaluations and commendations for products with outstanding designs.



Yasuhito Hayashi, "Investigation of Glaucoma Eyedrop Bottle Usability by Elderly Patients" Atarashii Ganka, Vol. 24, 371, 2007

## Achieving Success with "Network-based Drug Discovery"

As well as working with its in-house resources to develop new drug candidates, Santen has introduced a unique method called "network-based drug discovery." This method involves combining the knowledge and experience that Santen has developed with the state-of-the-art technologies of other pharmaceutical companies and research institutions, primarily based in Japan. *Tapros* was successfully developed as a result of this "network-based drug discovery."

Tafluprost is a compound that Santen discovered jointly with Asahi Glass Co., Ltd. Based on a prostaglandin derivative that Asahi Glass had, the drug was developed using screening methods which utilized Santen's wealth of evaluation models for ophthalmics, and the fluorine chemical technology of Asahi Glass. After narrowing down the candidate compounds, with the exception of API (active pharmaceutical ingredient) development such as research on physical properties and API manufacturing, Santen proceeded with development by advancing the compound from pharmaceutical development through preclinical to clinical stage.

In this way, we can reduce costs, because co-development of drugs costs less than in-licensing drugs at the clinical stage. Therefore, we believe that *Tapros* will contribute significantly not only to sales but also to profits.

#### Nara Research and Development Center

Tapros was the first development product that began from drug discovery at the Nara Research and Development Center to obtain approval.

The Nara Research and Development Center began operations as a facility for state-of-the-art research in 1996. We expanded and upgraded the center in 2002, and we added a pharmaceutical development building and an ancillary building in 2008 in order to consolidate preclinical functions and accommodate an increase in research personnel. By



locating research functions and pharmaceutical development functions at the same site, we expect to shorten lead times from R&D to market launch.

With the new task of creating new drugs to follow *Tapros*, the Nara Research and Development Center is advancing R&D initiatives.

## Targeting the Top Share of the Glaucoma Segment

*Tapros* has produced concrete results, generating sales of more than ¥1.0 billion within three months of its launch. While this achievement is, of course, attributable to the drug's potent efficacy, it is also supported by market penetration, which is powered by the high-quality medical information provided by Santen's medical representatives (MRs).

In the ophthalmology field, Santen has a team of approximately 400 MRs, who call on roughly 10,500 hospitals and 13,000 ophthalmologists. Santen's strength is its ability to provide very detailed information and services for all ocular diseases, rather than being restricted to a particular ophthalmic disease field. Taking advantage of this strength, Santen has been promoting a doctor marketing (DM) strategy since 2005.

Our DM strategy involves gathering information in order to understand the needs of each physician along with the needs of the patients. Santen aims to develop closer relationships with physicians and to establish a competitive edge by responding promptly and precisely to these needs as well as providing appropriate recommendations for prescriptions and treatments. Other companies may not able to replicate Santen's DM strategy, as they mainly focus on product-based strategies. Consequently, DM strategy based on detailed analysis of individual physicians has become one of Santen's unique assets.

The introduction of *Tapros* has strengthened our DM strategy in the glaucoma segment by providing a wider range of prescription and treatment options. Following this strategy, we will analyze the needs of individual physicians in relation to glaucoma treatment, with the goal of increasing *Tapros* sales.

For fiscal 2009, we are targeting *Tapros* sales of ¥4.8 billion in Japan. With our goals set on achieving the largest share of the glaucoma market, we will continue to promote initiatives to maximize the product value of *Tapros*.

## **Preparing for Overseas Growth**

The overseas glaucoma market is large, and its growth potential is also as large as that of Japan's market if not greater. Therefore, we look forward to increasing tafluprost sales in overseas markets

Prior to the launch of *Tapros* in Japan, Santen launched it in Europe as *Taflotan*. In Europe, we have already received approval for this product in approximately 20 countries and begun sales in five countries. In particular, *Taflotan* is penetrating Germany's market faster than planned. In April 2009, Santen concluded a licensing agreement for tafluprost with Merck & Co., Inc. (of the U.S.). Based on this agreement, Santen granted sales rights in areas of the world where Santen does not have strong sales platforms, such regions as Western Europe (excluding Germany), North America, South America and Africa.

Furthermore, Santen will continue promotional campaigns to support direct marketing efforts in regions where it has developed powerful marketing platforms (Germany, Eastern Europe, Northern Europe and Asia Pacific, including Japan). In conjunction with these initiatives, we will actively increase product value through efforts that include realizing the benefits of the collaboration with Merck & Co.

## Looking to Achieve Further Growth

In this way, *Tapros* is expected to become a significant promoter of Santen's medium-to-long term growth. Further, the successful development of *Tapros* has important ramifications for R&D.

Tapros was developed based on Santen's basic R&D strategy, which is to narrow down research themes in order to focus resources on growth areas where Santen can fully utilize its strengths and where there is significant growth potential. Santen has been taking steps to develop new drugs focusing especially on such areas as glaucoma, corneal disorders and retinal disorders—its highest-priority disease fields. This strategic approach to R&D resulted in the development of *Tapros*, and successful development of this product has given us a great deal of confidence to proceed further with R&D efforts.

*Tapros* is Santen's first global development product. First obtaining regulatory approval in Denmark in April 2008, we now have obtained approval for the product in about 20 European countries. Obtaining approval not only in Japan but also in Europe, despite the differences in regulations concerning clinical trial systems and medical environments has been a valuable experience. As we look toward the globalization of clinical trials, not limiting ourselves to Europe, we are also promoting clinical development of *Tapros* in Asia.

For Santen's future growth, acceleration of global development is essential. With that in mind, we will apply the R&D capabilities cultivated through *Tapros* development to clinical and pharmaceutical development in a range of products, including the global strategic product DE-101 (rivoglitazone), a drug for corneal and conjunctival epithelial disorders, and DE-104, a drug for glaucoma and ocular hypertension. Also, we will extend our clinical development efforts by adding Asia to existing initiatives in Japan, the U.S. and Europe, and we will make our R&D even more rapid and efficient. Santen will achieve medium-to-long-term growth by achieving results from R&D investments, growing in areas where it can exploit strengths and realizing globalization.

#### **Our Mission is to Provide Outstanding Pharmaceuticals**

Santen's core value calls on the Company to contribute to society with a particular focus on patients and their loved ones.

Glaucoma is a serious disease that in the worst cases leads to blindness and requires long-term treatment. By contributing to the treatment of glaucoma patients through *Tapros*, we are putting into practice our core value, based on which "we apply our unique capabilities and technologies in our areas of expertise to contribute to the health and quality of life of patients and their loved ones, and society as a whole."

Including glaucoma, there are still many diseases with regard to which patients are not fully satisfied with existing treatments. Santen is conducting R&D rapidly and efficiently in order to bring pharmaceuticals to market for such diseases as quickly as possible. We will further upgrade the medical information we provide through MRs to ensure that medical professionals and patients use newly developed pharmaceuticals appropriately and safely. We are convinced that this is our social mission.



Akira Kurokawa President and Chief Executive Officer

### **Research and Development**



#### Basic R&D Strategy

The fundamental R&D strategy of Santen is to focus its resources on growth areas where its strengths can be fully utilized and where there is significant growth potential. As part of this strategy, we have strengthened our R&D capabilities by consolidating existing preclinical divisions into the Nara Research and Development Center, specializing in the fields of ophthalmology and rheumatology. Within ophthalmology, we narrowed our focus even further to target the core therapeutic fields of glaucoma, corneal disorders and retinal disorders to enable us to pursue more effective and faster new drug development.

The markets for glaucoma and corneal disorder treatments are expanding as the global population ages, and the number of patients in these segments grows. The number of patients with retinal disorders is also rising. However, there are few treatments available in this area, resulting in a considerable need to develop effective new drugs. Therefore, Santen will develop new drugs in these important fields to fulfill unmet medical needs and help enhance patients' quality of life.

#### Building a Rich Development Pipeline

While working to discover new drug candidates using our own research capabilities, we are proceeding in parallel with a unique method called "networkbased drug discovery," which utilizes external resources. This method of drug design takes simultaneous advantage of Santen's considerable accumulated knowledge and technologies as well as leading-edge technologies from other pharmaceutical companies and research institutions, primarily based in Japan. For example, by accessing the chemical library of a collaborating pharmaceutical company and applying our own abundant resources in an ophthalmic diseasemodel, we can select and strategically introduce highly effective compounds in our target market segments. We also engage in joint research efforts to develop strong candidate compounds based on in-house ideas, including the glaucoma and ocular hypertension treatment Tapros (tafluprost) and DE-104, which is currently under development.

By applying these drug discovery methods, we aim to create a rich development pipeline that will generate a steady flow of marketable new products. Further, we actively introduce new drug candidates, and have successfully acquired DE-109 (sirolimus). Santen also secures backup compounds for each development candidate to reduce the inherent risk of additional R&D activities and expenses.

#### Strengthening R&D Capabilities

Competition among pharmaceutical companies is becoming fiercer on the global stage. To stay ahead of competitors, it is essential to quickly develop and launch globally innovative and competitive new drugs. To achieve this, we place a strong emphasis on "accelerating" and "globalizing" our R&D efforts.

On the "accelerating" front, Santen has worked steadily to achieve the specific time-reduction targets set out in its 2003–2005 Medium-term Management Plan to shorten preclinical testing to one and a half years (from a previous timeframe of approximately three years) and clinical testing to five years (from approximately seven to eight years). The 2006-2010 Medium-term Management Plan also highlights acceleration through ongoing reviews of in-house R&D processes. In 2008, aiming to build an even more efficient R&D system, we built a pharmaceutical development building and an ancillary building within the Nara Research and Development Center in order to consolidate preclinical functions and accommodate a future increase in research staff.

In "globalizing" efforts, we now have a clinical development network spanning three centers—Japan, the U.S. and Europe—and we are currently carrying out clinical trials for several products in Europe and the U.S. As well as Japan, the U.S. and Europe, we are developing a system for simultaneous international joint development including China and other major Asian countries. As a result of this initiative, we hope to realize joint international trials with an even greater global scope. We further aim to continue reducing clinical development lead times and costs by standardizing clinical trial protocols and sharing data among regions.

We classify new drug candidates slated for marketing overseas as either global strategic products or global products. Global strategic products are drug candidates based on new mechanisms and that promise to surpass the sales of existing products. We look to market such products globally. Global products are drug candidates that are based on upgraded existing mechanisms and that will likely generate sales of a magnitude comparable with those of existing products. Generally, global products are marketed in Japan and in certain overseas regions. Santen gives priority to developing global strategic products.

Moreover, in order to develop marketed products we generate clinical evidence to enable us to recommend prescriptions and treatments that take advantage of product characteristics.

#### Development Advances

Santen focuses R&D on core therapeutic fields: glaucoma, corneal disorders and retinal disorders. The progress of our development efforts as of July 31, 2009, is as follows.

#### **Glaucoma Segment**

In December 2008, we began sales of the prostaglandin derivative DE-085 (tafluprost, sold as *Taflotan* in Europe) in Japan. In Europe, we launched sales in Germany in June 2008, and at present we are directly marketing *Taflotan* in five countries. In South Korea, we obtained marketing approval in June 2009, and in China Phase III clinical trials are underway. We cancelled development of the angiotensin II receptor antagonist DE-092 (olmesartan) because the results of a pilot study in Europe using a modified formulation revealed that it would be difficult for DE-092 to meet the criteria we expected of it as a new treatment. Based on the results of early Phase II clinical trials in Japan and the U.S. for the ROCK inhibitor DE-104, for glaucoma and ocular hypertension, we are currently conducting additional clinical trials in the U.S.—Phase I / early Phase II clinical trials—based on higher dosages, aiming to increase efficacy for alleviation of ocular hypertension.

## Corneal and Conjunctival Epithelial Disorder Segment

In May 2008, we filed an NDA in Japan for DE-089 (diguafosol sodium), a treatment for corneal and conjunctival epithelial disorders associated with dry eye. This application is currently under evaluation. Regarding DE-101 (rivoglitazone), based on the results of early Phase II clinical trials in the U.S. we are currently implementing early Phase II clinical trials in Japan to establish dosages. Phase I clinical trials for DE-105, a development candidate for a treatment for intractable persistent corneal epithelial defects, have been completed in the U.S., and preparations are currently underway for early Phase II clinical trials We cancelled

**About Research and Development** 

development of the phosphodiesterase type 4 inhibitor for allergic conjunctivitis, DE-103, because it became clear that it would be difficult for it to meet the criteria expected of a new treatment. Retinal Disorder Segment

A treatment for diabetic macular edema (DME), DE-102, is in Phase I / early Phase II clinical trials in Japan to determine safety and efficacy in patients. Santen acquired rights from MacuSight, Inc. (of the U.S.) in May 2008 to develop and sell DE-109. Accordingly, we began Phase I / early Phase II clinical trials in April 2009 in Japan to determine safety and efficacy for patients with wet age-related macular degeneration (wet AMD) and with DME. Other Areas

For the bacterial conjunctivitis treatment DE-108 (levofloxacin 1.5%), Phase III clinical trials are underway in Japan. Further, DE-098, an anti-APO-1 antibody rheumatoid arthritis treatment licensed to Argenes, Inc. for development in Japan, is in Phase I / II clinical trials in Europe and Japan to determine safety and efficacy.



### PIPELINE OF PRESCRIPTION PHARMACEUTICALS (Clinical Development)

As of July 31, 2009

Category Global strategic product Global product Domestic (Japan) product

Dev. Code/ Generic Name	Indication	Region		has	e	NDA	Approved	Characteristics
(Original/Licensor)		J	Т	П	ш	Filed	11	

#### Glaucoma

			Launched, December 2008				Prostaglandin derivative treatment for glaucoma and ocular hypertension.
DE-085/ Tafluprost	Glaucoma	Europe			Launche	d, June 2008	Launched in Japan in December 2008. In Europe, launched in June 2008 in Germany and currently marketed directly in five countries. Granted U.S.
(Co-development) with Asahi Glass)	Ocular hypertension	U.S.		(License out)		se out)	development rights to Merck & Co. in April 2009. Marketing approval was granted in South Korea in June 2009, and Phase III trials are underway in China.
With Asam Glass/	ni Glass)	Asia*				June 2009	(* excluding Japan
DE-090/ Lomerizine HCl (Schering-Plough)	Glaucoma	Japan					A new type of glaucoma treatment studied for inhibiting the progression of visual field defects. The only calcium antagonist in development as an oral glaucoma treatment. Compared with NMDA receptor antagonists, fewer systemic side effects are expected, thus having excellent safety. Marketed by Schering-Plough as a migraine treatment.
DE-104/ Undetermined	Glaucoma	U.S.	Phase	e I/II			ROCK inhibitor co-developed with Ube Industries for treatment of glaucoma and ocular hypertension has a different action mechanism from other existing drugs.
(Co-development with Ube Industries)	Co-development Ocular hypertension						It is expected to show a strong intraocular pressure reduction by promoting aqueous humor outflow by acting directly on trabecular meshwork cells.

#### Corneal and conjunctival epithelial disorders

DE-089/ Diquafosol sodium (Inspire Pharm.)	Corneal and conjunctival epithelial disorder associated with dry eye	Japan	Ma	y 2008	A treatment for corneal and conjunctival epithelial disorder mostly associated with dry eye that stimulates the ocular surface to secrete tear fluid and components. It is expected to be used in combination with existing treatments. A comparative Phase III study met the primary objective and we filed for manufacturing and marketing approval.
DE-101/	conjunctival enithelial	U.S.			Expected to show a potent effect on corneal and conjunctival epithelial disorder mostly associated with dry eye by directly acting on the corneal and
Rivoglitazone (Daiichi Sankyo)	disorder associated with dry eye	associated conjunctival epithelial cells	conjunctival epithelial cells. Unique mechanism of action which differs from		
DE-105/ Undetermined (Original)	Persistent corneal epithelial defects	U.S.			Expected to accelerate corneal epithelial migration and demonstrate high safety for intractable persistent corneal epithelial defects compared with existing therapy.

#### **Retinal disorders**

DE-102/ Undetermined (Co-development with Oakwood)	lanan	Phase I/II	Steroid microsphere product for a sustained release injection. Animal studies demonstrated sustained efficacy by local injection. In order to produce sterile microsphere in commercial scale, we collaborate with Oakwood Laboratories.
DE-109/ Wet age- Sirolimus (wet AME (MacuSight) Diabetic m edema (D	egeneration )) Japan nacular	Phase I/II	Subconjunctival or intravitreal injection having immunosuppressive effect, and anti-angiogenic effect, etc. Phase I clinical trials in patients with wet AMD and DME have shown patients who participated in these studies exhibited improve- ments in visual acuity that were consistent with morphological changes following a single administration of sirolimus. In May 2008, Santen made an R&D collaboration and license agreement with MacuSight (of the U.S.), for the Japanese and Asian development and commercialization of sirolimus.

#### **Ophthalmic infections**

DE-108/ Levofloxacin 1.5% (Daiichi Sankyo)	Bacterial conjunctivitis	Japan				Fluoroquinolone antibacterial agent. A higher-concentration product for control of drug resistance. Levofloxacin 0.5% was launched as a treatment for bacterial conjunctivitis in Japan in April 2004 (sold as <i>Cravit)</i> , in the U.S. in November 2000 (sold as <i>Quixin</i> ) and in Europe in May 2002 (sold as <i>Oftaquix</i> ).	
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#### **Rheumatoid arthritis**

DE-098/ Undetermined	Rheumatoid arthritis	Japan	Phase I/	1	Joint injection that induces apoptosis in diseased joints of rheumatoid arthritis patients. Bulk pharmaceutical manufacturing process for actual production scale has been established. Santen granted the domestic development rights
(license out)	Kieumatoid artinius	Europe	Phase I/	I	to Argenes. The compound had been in-licensed from Centocor (of the U.S.). Clinical trials are underway in Japan and Europe. Santen continues to hold the marketing rights in Japan and the overseas marketing and development rights.

## **Review of Operations**

Year ended March 31, 2009



All comparisons are with the previous fiscal year unless otherwise stated.

Business Area	Description of Business	Market Share; Market Position
Ophthalmic Pharmaceuticals	In Japan, Santen markets a broad range of ophthalmic pharmaceutical products, such as treatments for corneal and conjunctival epithelial disorders, anti-infective ophthalmics, treatments for glaucoma and anti-allergy ophthalmics. Overseas, Santen markets <i>Cravit</i> and <i>Tapros</i> (brand names differ according to region) and other products through sales networks in the U.S., Europe and Asia.	38.0%; Number One <sup>1</sup> Santen enjoys its position as the leader of the Japanese prescription ophthalmics market. We deploy approximately 400 medical representatives (MRs) and our product lineup covers a broad array of ophthalmic disorders.
Anti-Rheumatic Pharmaceuticals	In Japan, we offer <i>Rimatil</i> and <i>Azulfidine EN</i> , the physicians' disease modifying anti-rheumatic drugs (DMARDs) <sup>2</sup> of choice for treating rheumatoid arthritis.	45.0%; Number One <sup>1</sup>
Over-the-Counter (OTC) Pharmaceuticals	Our OTC pharmaceuticals business consists of market-leading eye drop brands in Japan, such as <i>Sante FX Neo</i> , the <i>Sante 40</i> series and the <i>Sante de U</i> series.	Approx. 20%; Number Two <sup>3</sup>
Medical Devices	In Japan, Santen handles medical devices used in cataract surgery, including intraocular lenses.	_

Notes: 1. Market share and market position in Japan for the year ended March 31, 2009. The share and position for anti-rheumatic pharmaceuticals represent those in the DMARDs segment. Source: Santen analysis based on IMS data.

2. A class of medicines that are used not only to alleviate symptoms but also to treat the causes of disease. The anti-rheumatic effect works by calming inflammation through the correction of immune abnormalities, which are considered a cause of rheumatoid arthritis.

3. Market share and market position in the Japanese OTC eye drop market for the year ended March 31, 2009. Source: Santen Pharmaceutical Co., Ltd.

## **Prescription Pharmaceuticals Ophthalmic Pharmaceuticals**

For fiscal 2008, ended March 31, 2009, net sales of prescription ophthalmic pharmaceuticals decreased 1.1%, to ¥84,488 million. Santen's domestic sales of prescription ophthalmic pharmaceuticals rose 0.1%, to ¥72,357 million, and overseas sales decreased 7.4%, to ¥12,131 million.

Net Sales  $\mathbf{x84,}488$  million -1.1%

Net Sales of Prescription Ophthalmic Pharmaceuticals Millions of yen



#### JAPAN

The Japanese prescription ophthalmic pharmaceutical market grew 2.6% overall, to ¥226,900 million, in fiscal 2008, which benefited from the growth in sales of products for glaucoma and corneal disorders and anti-allergy ophthalmics due to the prevalence of cedar hay fever. This combined growth offset an average 5.2% reduction in product prices in the prescription ophthalmic pharmaceuticals industry due to NHI drug price revisions that took effect April 2008. Amid these market conditions, Santen's domestic prescription ophthalmic pharmaceutical sales edged up 0.1%, to ¥72,357 million. This increase was

Prescription Ophthalmic Pharmaceuticals Market Millions of ven



achieved despite an average reduction of around 3.0% in the prices of Santen's products due to NHI drug price revisions and other factors, which counteracted promotional activities in which Santen's medical representatives (MRs) provide individual medical facilities with scientific information tailored to their changing needs.

#### **Treatments for Corneal and Conjunctival Epithelial Disorders**

Santen products hold an 80% share of the market for treatment for corneal and conjunctival epithelial disorders associated with dry eye. This market expanded 5.7%, to ¥30,500 million, in fiscal 2008. Since dry eye—caused by inadequate tear fluid volume or a change in tear fluid composition—is a condition that can result in corneal damage, it is important that dry eye is correctly diagnosed and treated through regular consultations with an ophthalmologist. As this is not widely recognized, many patients with obvious symptoms do not consult a doctor. In addition, the number of people suffering from dry eye is trending upward with increased use of personal computers and contact lenses and the aging of Japan's population. As a result,

the market for effective treatments for corneal and conjunctival epithelial disorders is expected to continue growing.

Santen's mainstay product, Hyalein, a treatment for corneal and conjunctival epithelial disorders, has earned unequivocal endorsement as the first choice in treatment for dry eye. It is a highly water-retentive ophthalmic solution that increases tear film stability and demonstrates superior efficacy in alleviating corneal and conjunctival epithelial disorders associated with dry eye. In fiscal 2008, sales of Hvalein grew steadily. increasing 3.8%, to ¥18,541 million, thanks to these product characteristics and Santen's dry eye awareness campaign targeting patients and medical professionals.



#### Sales of Hyalein Millions of yen



Santen plans to continue promoting greater understanding of the diagnosis and treatment of dry eye to further raise awareness and expect that new patients will consult their physicians and existing patients will maintain appropriate courses of treatment. We believe this will contribute to growth in the market for dry eye medications as well as strengthen our presence in that market. Furthermore, we are continuing efforts to expand and improve our development pipeline to enhance our product lineup for corneal and conjunctival epithelial disorders.

#### **Anti-Infective Ophthalmics**

The anti-infective ophthalmic pharmaceutical market is trending slightly downward due to the shortening of the treatment duration for anti-infective ophthalmic products after cataract and other surgeries.

Santen dominates the anti-infective ophthalmic pharmaceutical market with a share of approximately 70%, supported by its two key products, *Cravit* and *Tarivid*, which both display strong antibacterial properties, broad-spectrum coverage (effective against a wide range of infections) and excellent intraocular penetration and safety. Both are widely used for conjunctivitis, keratitis and preventing post-operative eye infection. As a result of market contraction and increased competition, combined sales of *Cravit* and *Tarivid* declined 5.5%, to ¥13,838 million, in fiscal 2008.

We will continue to promote *Cravit*, highlighting the scientific data supporting its superior clinical efficacy and safety. In addition, providing the latest information on ophthalmic disease will help reinforce the position of *Cravit* as the gold standard among treatments for ophthalmic infections, and allow it to maintain its leading position in the market for antiinfective ophthalmic products.



Sales of Cravit and Tarivid Millions of yen



#### **Treatments for Glaucoma**

Glaucoma treatments represent the largest sector of the domestic prescription ophthalmic pharmaceutical market, accounting for approximately 37% of the total. Rising intraocular pressure is a significant risk factor for damage caused to the optic nerve, leading to visual field loss and in some cases blindness. Glaucoma is one of the most common causes of blindness in people with ophthalmic disease. According to recent epidemiological studies, there are a high number of potential glaucoma patients who have not been diagnosed by doctors. Early detection and treatment of the disorder has become a major issue. Combined with increasing patient numbers from Japan's aging population, the glaucoma market has expanded steadily, growing 2.2% in fiscal 2008.

In December 2008, Santen introduced a new ophthalmic solution, *Tapros*, to this market, which meets the treatment needs of patients with glaucoma and ocular hypertension. Reflecting advancing market penetration, *Tapros* accounted for sales of ¥1,058 million in fiscal 2008. Meanwhile, despite continued efforts to increase the market penetration and presence of *Rescula* and other glaucoma products, there was a 6.1% decrease in the combined sales of our four leading products—*Rescula*, *Detantol*, *Timoptol XE* and *Timoptol*—to ¥13,359 million.

Santen aims to rapidly maximize the value of its new product *Tapros*. Further, Santen will continue to highlight the particular benefits of *Rescula* and *Detantol*. We will heighten our presence in the glaucoma treatment sector by providing the latest glaucoma-related information and advice on prescribing pharmaceuticals to meet the needs of medical professionals.



Sales of Timoptol, Timoptol XE, Detantol, Rescula and Tapros Millions of yen



#### **Anti-Allergy Ophthalmics**

The prevalence of cedar hay fever precipitated a rise in the incidence of allergic conjunctivitis in Japan during fiscal 2008, contributing to an 11.0% growth in the antiallergy ophthalmic pharmaceutical market.

Santen maintained its strong presence in the anti-allergy ophthalmic pharmaceutical market, holding a 21.0% share. Against this backdrop, we continued strong product marketing and disease-related educational efforts. However, *Livostin* sales edged down 0.9%, to ¥4,302 million, partly due to increased competition in this sector. On the other hand, *Alegysal* sales were up 3.0%, to ¥601 million. Total sales of these products decreased 0.4%, to ¥4,903 million.

*Livostin* provides rapid relief from year-round and seasonal allergy symptoms such as itching and redness and thus contributes to an improved patient quality of life. By continuing to emphasize these product characteristics, we aim to expand both sales and market share of this product.



Sales of Livostin and Alegysal Millions of yen



#### **OVERSEAS**

Markets for prescription ophthalmic pharmaceuticals were solid in the U.S., Europe and Asia. Amid these conditions, Santen focused efforts on promotional campaigns for its products by providing medical information. However, due to the effect of foreign exchange rates, we saw revenues decline in each of these markets. In fiscal 2008, we registered a decrease in total overseas sales of prescription ophthalmic pharmaceuticals of 7.4%, to ¥12,131 million.

#### Overseas Sales Millions of yen



#### **Overview of Markets**

In the year ended March 31, 2009, overseas sales, which consist of prescription ophthalmics and other products, declined 12.3%, to ¥12,999 million, mostly due to foreign exchange rate fluctuations. By region, Santen recorded decreases in sales of 2.6% in Europe, to ¥8,311 million, 13.4% in Asia, to ¥3,748 million, and 51.9% in North America, to ¥938 million.

#### • Europe

The European market for prescription ophthalmic pharmaceuticals has been growing for several years at over 10% per annum, triggered by a combination of rising numbers of patients diagnosed with glaucoma and dry eye disorders and increasing economic prosperity in Eastern Europe and Russia. At the same time, various European governments actively encourage the use of generic products as part of their healthcare cost-containment policies, so conditions surrounding the European prescription ophthalmic pharmaceutical market are becoming increasingly severe. In addition, the European market is characterized by its diversity—each country in the region has a different health insurance system and different medical treatment practices.

Santen is advancing its sales and marketing activities in 32 European countries, including Russia, Germany and those in Northern and Eastern Europe. The anti-infective ophthalmic solution preparation *Oftaquix* (sold as *Cravit* in

Japan) has gained an excellent reputation among ophthalmic surgeons for its superior reliability in preventing pre-operative and post-operative eye infections and is now available in 27 countries. Additionally, Santen has obtained approval for Taflotan (tafluprost, sold as Tapros in Japan) in about 20 countries. In June 2008, we introduced this new product in Germany, and currently market this product directly in five countries. Furthermore, our subsidiary in Finland, Santen Oy, manufactures pharmaceuticals for the European and the U.S. markets, and it also conducts R&D and clinical development as our European R&D center.

Santen will continue promotional campaigns for its existing products as well as work to increase sales of *Taflotan* in its existing markets. At the same time, we will advance preparations to launch the product in new markets. In another effort to maximize the value of *Taflotan*, we seek to enable sales of the product more globally. To this end, we concluded a licensing agreement with Merck & Co., Inc., granting it sales rights in Western Europe (except Germany), North America, South America and Africa, areas in which Santen does not have strong sales platforms.



The 17th Congress of the European Society of Ophthalmology held in Amsterdam in the Netherlands in June 2009

#### Asia

In Asia, Santen operates in China, South Korea and the ASEAN nations. Our vision for the Asian market is to become the top ophthalmic drug manufacturer. Accordingly, we are striving to enhance trustbased relationships with patients and medical professionals, thereby contributing to the improvement of ophthalmic treatment in the region. In fiscal 2008, we stepped up marketing activities and provided academic information on ophthalmology. Also, in China, our main market in the region. Santen Pharmaceutical (China) Co., Ltd., started up operations at our plant in Suzhou and began direct marketing in October 2008.

The Chinese market is expected to see strong sales growth in the medium-tolong term as the country continues its upward economic trend and the numbers of physicians and patients increase in step with the development of medical infrastructure. Santen Pharmaceutical (China) has a sales headquarters in Beijing and 29 sales offices throughout China. We are concentrating our development of business on these urban centers. Until recently, we used indirect marketing through local sales agents for prescription ophthalmic pharmaceutical products, such as Cravit anti-infective eye drops, and Hyalein, a corneal and conjunctival epithelial disorder treatment. In October 2008, Santen switched to direct marketing. To coincide with this change, we began providing specialists with high-guality academic information on ophthalmic disease. We are also working to increase the penetration of the Santen brand in the South Korean and ASEAN markets through Santen Pharmaceutical Korea, Co., Ltd. and local agencies.



The Suzhou Plant, started up by Santen Pharmaceutical (China) Co., Ltd. in October 2008

#### North America

In the U.S., Santen is advancing the clinical development of DE-101 (rivoglitazone). DE-104 and DE-105. which are key areas of focus for Santen's new product development. In conjunction with these initiatives, we are increasing business development activities to expand and improve our development pipeline. Further, we market the following products under a licensing agreement with VISTAKON Pharmaceuticals, LLC (of the U.S.): the anti-infective Quixin (sold as Cravit in Japan), the glaucoma treatment Betimol, the anti-allergy ophthalmic solution Alamast (sold as Alegysal in Japan) and the high-concentration levofloxacin ophthalmic solution Iquix.

## Prescription Pharmaceuticals Anti-Rheumatic Pharmaceuticals

NHI drug price revisions and competing products affected *Rimatil, Azulfidine EN* and *Metolate*. However, Santen's net sales of prescription anti-rheumatic pharmaceuticals grew 1.2%, to ¥9,742 million, in fiscal 2008 because these products are each highly recommended under the Guidelines for the Management of Rheumatoid Arthritis. Net Sales

¥9,742 million +1.2%

Sales of Prescription Anti-Rheumatic Pharmaceuticals Millions of yen



Although the causes of rheumatoid arthritis (RA) are not yet well understood, RA is thought to be a chronic inflammatory disorder that affects the whole body. Inflammation occurs particularly in the joints, causing pain and swelling, and can often lead to bone and cartilage damage and subsequent joint deformity. It is estimated that there are approximately 700.000 people with RA in Japan today. The Japanese market for DMARDs\* expanded 2.8%, to ¥24,800 million, in fiscal 2008, as the number of patients grew in line with population aging and prescriptions of higher-priced medications increased.

Santen has built its leading position in the prescription anti-rheumatic pharmaceuticals market through active promotion of Rimatil, Azulfidine EN and Metolate in hospitals and clinics. Among sales results of core products in the period under review, Rimatil fell 4.8%; Azulfidine EN, which displays early-onset effect characteristics, grew a solid 1.6%; and Metolate, launched in July 2004, made good inroads in the market. As a result, net sales of prescription anti-rheumatic pharmaceuticals increased 1.2%, to ¥9,742 million, and Santen maintained its dominant position as leader of the DMARDs market with a 45.0% share.

The Manual on the Medical Treatment of Rheumatoid Arthritis and Medical Treatment Guidelines Based on EBM, compiled by a study group of the Ministry of Health, Labour and Welfare and published by the Japan Rheumatism Foundation, recommends treating RA with DMARDs from the early stages to improve patients' quality of life by retarding the progress of joint destruction and so avoiding the development of joint deformity. Santen's Rimatil, Azulfidine EN and Metolate are each rated "Grade A -Highly Recommended" under the guidelines, which gives them a high profile as strongly recommended treatment options. To broaden the market share of these three products even further, we will continue to emphasize this solid independent support for their superior efficacy in our promotional activities.

\* A class of medicines that are used not only to alleviate symptoms but also to treat the causes of disease. The antirheumatic effect works by calming inflammation through the correction of immune abnormalities, which are considered a cause of RA.

#### Sales of Rimatil, Azulfidine EN and Metolate Millions of yen





## Over-the-Counter Pharmaceuticals

Santen continued promotional activities focusing on products for tired eyes, blurred vision and eye refreshment. Amid tough competitive conditions, Santen's OTC pharmaceuticals net sales declined 4.1%, to ¥5,225 million.



Santen's OTC pharmaceuticals sales are mostly generated in the Japanese OTC ophthalmic market. In fiscal 2008, this market grew as demand rose for products for eye fatigue, contact lens wearers and allergies.

Our OTC business specializes in a range of ophthalmic products, including *Sante FX Neo*, Japan's top-selling ophthalmic solution brand, and the *Sante 40* series, highly effective in improving blurred vision. Fiscal 2008 saw the launches of an ophthalmic solution that improves blurred vision, *Sante 40i*, in October 2008 and an ophthalmic solution that refreshes the eyes, *Sante FX V Plus*, in March 2009. However, such efforts did not fully compensate for tough competitive conditions, and OTC pharmaceuticals net sales were down 4.1%, to ¥5,225 million. With fierce competition set to continue in this market, we will continue promoting sales of new products while maintaining the market share of our existing product range, concentrating on ophthalmic products for tired eyes, blurred vision and eye refreshment.



Sante FX V Plus

Sante 40i

#### **Medical Devices**

Santen's concentration on promotional campaigns for its foldable intraocular lens (IOL) *Eternity* led to an increase of 50.1% in net sales of medical devices, to ¥623 million.



Santen's medical devices business specializes in the cataract surgery field, focusing primarily on IOLs. In recent years, IOL demand has shifted primarily to foldable lenses that can be inserted through a small incision. Targeting this trend, Santen sells the *Eternity* foldable IOL, which is made of a new highly refractive acrylic optical material and manufactured by Advanced Vision Science, Inc., a U.S. subsidiary of Santen. In fiscal 2008, we focused efforts on promotional campaigns for *Eternity*, which resulted in a 50.1% increase in net sales of medical devices, to ¥623 million. Moreover, in March 2009 we granted worldwide rights, excluding Japan, for the development, manufacturing and marketing rights for *Eternity* and its materials to Bausch & Lomb Inc. (of the U.S.). Santen will continue efforts to increase sales of medical devices.

## Society and the Environment



#### Earning the Trust of Society

As a company involved in medicine, Santen is committed to becoming a company trusted by all stakeholders, including healthcare professionals, members of the community, patients and their loved ones. Aiming to deepen the relationship of trust we have fostered with society at large and fulfill our corporate duties and responsibilities through robust business practices, we formulated the Santen Corporate Ethics Mission in 1999.

This mission expresses our fundamental approach to society, customers, shareholders, business partners and employees, and we revise it in accordance with changes in society. Santen aims to be a good, socially responsible corporate citizen based on the high ethical principles outlined in the Santen Corporate Ethics Mission.

#### Relationship with Society

Santen makes a variety of social contributions, which include supporting advances in medical treatment and benefiting local communities.

To achieve advances in medical treatment, developing personnel is important. Santen has formed a joint lecture program with the Nara Institute of Science and Technology, in which Santen's research personnel instruct students at the Company's training facilities. Also, Santen continuously donates to a number of charities, including the Japan Eye Bank Association, the Japan National Society for the Prevention of Blindness and the non-profit organization Helen Keller International, which is devoted to fighting and treating preventable blindness in developing countries. In those Asian nations where standards of medical treatment have not yet reached globally accepted levels, we aim to raise the standard of medical treatment by supporting the education of ophthalmologists. We also support the Chinese Ophthalmology Scholarship Program in China and the Ophthalmology Training Fund in South Korea. Further, we donated IOLs to Sri Lanka to support cataract surgery in September 2008.

Santen contributes to the local community by making concerted efforts to beautify and promote the greening of the areas surrounding its research facilities, manufacturing plants and offices. In recognition of these efforts, our Noto Plant received the *Furusato Kigyo Taisho* Minister for Internal Affairs and Communications Award in 2008.



Santen donates IOLs in Sri Lanka in September 2008

We make donations and provide free supplies of such pharmaceuticals as *Cravit* ophthalmic solution in response to relief efforts for large-scale natural disasters, including the earthquake that occurred on the Noto Peninsula, Japan, and the major earthquake in Sichuan, China.

## Relationship with Customers and Business Partners

Santen strives to discover innovative new drugs that improve quality of life of patients and their loved ones and can be used by patients in a safe and appropriate manner.

Japan's Medicine Act strictly details the standards required for pharmaceutical guality control and post-marketing safety supervision. In addition to adhering to these requirements, Santen has established its own world-class quality assurance system based on an in-house product guality policy. It is necessary to provide information about indications, side effects and method of use in order to ensure correct usage of products. Santen has a sales force of approximately 400 medical representatives (MRs) in Japan. Through our MRs, we provide quick, accurate and pertinent information to healthcare professionals, and by continuously updating MR professional training we are able to keep our standards high.

Further, we established a Customer Service Center to deal comprehensively with customer requests and suggestions. By responding to this feedback, we are able to improve our products and enhance our information services. Winning a Good Design Award in October 2008 underscored the high acclaim our ergonomically designed Dimple Bottle has earned for its patient-friendliness. In addition, viewing our suppliers as important business partners, we aim to evolve with them by working together to realize and bring to market even higher quality products. **Relationship with Employees** 

Santen promotes the creation of pleasant working environments.

Santen works to maintain safe, clean and comfortable workplace environments and provides support systems for employees' physical and emotional well-being. To ensure no discrimination or harassment occurs in the workplace, we continually promote human rights awareness activities and encourage understanding and consideration.

To create a culture that encourages our employees' individual abilities to shine, we set up a range of training systems and instituted an employee performance evaluation system that better recognizes individual achievement. To assist employees in balancing work and raising children, we actively support employees' family responsibilities. In October 2007, we were approved Industry Participant status in Supporting the Development of the Next Generation. Further, in October 2008 we received an award from the Minister of Health, Labour and Welfare, in the Family-Friendly Company category, in recognition of our initiatives to support employees combining work and child rearing or nursing care of family members.



Training for new MRs

#### Conserving the Global Environment

Protecting the Earth's resources and preserving the natural environment for future generations is a major concern for everyone. Santen has placed environmental conservation high on its list of management goals. In order to clarify our basic approach to the environment and environmental conservation activities, we formulated a Basic Environmental Policy in 1998 and set up our corporate Environmental Guidelines in 2000. Based on these, we have been pushing forward with environmental conservation activities. To increase the effectiveness of these activities, all of our plants in Japan have now been certified to ISO 14001 standards. Throughout the Company, Santen has established environmental management systems which now operate continually. Overseas, Santen Oy built a system integrating environmental management and health and safety management and acquired ISO 14001 certification in September 2008.

Aiming for green procurement, Santen chooses environment-friendly goods when sourcing product raw materials and manufacturing materials. Having drawn up Green Procurement Guidelines, we are advancing green procurement by seeking the understanding and cooperation of our suppliers. Moreover, we follow a policy of Green Purchasing by purchasing environmentfriendly office supplies.

To make our environmental conservation activities even more effective, we try to inspire all our employees to be more environmentally aware. In addition, we conduct environmental education and environmental awareness campaigns as well as participate in regional environmental conservation activities.



Inspection for ISO 14001 certification (Santen Oy)

#### **Initiatives to Prevent Global Warming**

To help prevent global warming, we are taking ongoing measures to reduce our  $CO_2$  emission volumes. Our emission volumes have decreased every year since peaking at 36,489 t-CO<sub>2</sub> in the year ended March 31, 2003. In the year ended March 31, 2009, Santen achieved a 3.7% year-on-year reduction in CO<sub>2</sub> emission volume, to 32,624 t-CO<sub>2</sub>.

CO<sub>2</sub> Emission Volumes (10,000 t-CO<sub>2</sub>)



## **Corporate Governance**

Santen recognizes that it is vital to upgrade and strengthen corporate governance in order to achieve and enhance corporate value, and thus returns to shareholders. Accordingly, Santen is working to raise business performance while maintaining transparent and sound management practices through the development of effective corporate governance systems.

## Governance Systems

#### **Board of Directors**

In addition to various statutory functions, the Board of Directors formulates management policies, strategies and business plans for the Santen Group. The Board of Directors makes decisions relating to the acquisition or disposal of major financial assets and important organizational or personnel-related moves, and oversees the execution of business at Santen and its subsidiaries. The Board convenes once a month in principle. As of July 31, 2009, the Board comprised seven members including three outside directors. The Board of Directors convened 14 times during fiscal 2008.

#### **Board of Corporate Auditors**

Santen has adopted a governance system using corporate auditors. The Board of Corporate Auditors consists of four members, including outside auditors. Corporate auditors formulate auditing policies and plans and attend Board of Directors' and other important business meetings as well as oversee the execution of duties by directors through auditing the operational and financial status of Santen's head office, major operating sites and subsidiaries. The Board of Corporate Auditors convened eight times during fiscal 2008

#### **Voluntary Committees**

Santen has established the following three committees composed of inside and outside directors as deliberative bodies to further strengthen corporate governance and to improve management transparency and objectivity.

- The Corporate Strategy Committee deliberates on key strategic issues such as business strategies.
- The Nominating Committee deliberates on the selection of directors and submits recommendations to the Board of Directors as well as deliberating on the selection of corporate officers and corporate auditors and submitting recommendations to the Board of Directors.
- The Executive Compensation Committee deliberates on the compensation of directors and corporate officers and submits recommendations to the Board of Directors.

Note that these committees are not part of any statutory "Company with Committees" under Japan Corporate Law. Corporate Officer System

Santen has introduced a corporate officer system to strengthen management while improving the quality and speed of strategic decision-making processes. There were eight corporate officers at the end of July 2009, excluding some serving concurrently as directors.

#### Internal Governance System

Santen benefits society with a particular focus on contributing to the health and quality of life of patients and their loved ones, which includes Santen's core value, as a company active in the pharmaceuticals industry. At the same time, aiming to heighten society's recognition of our value and achieve sustainable growth, we are developing the following internal control systems.

Our compliance system, the Santen Corporate Ethics Mission, which was formulated in December 1999 and revised in line with changing social conditions, consists of a corporate action declaration and a corporate code of conduct that defines strict ethical standards governing corporate activities. The Santen Corporate Ethics Mission stipulates that the Company will not respond to any demands whatsoever made by



antisocial forces that threaten the order and stability of civilian society.

In addition, we have established a CSR Committee as a Companywide lateral organization tasked with ensuring rigorous compliance. Further, we maintain an internal system for compliance-related enquiries and an external helpline to an attorney, which enable employees to report directly any suspected compliance violations or to receive advice.

Santen has built a system for responding appropriately to major risks related to its business activities, which is based on a risk management manual that sets out basic policies and a code of conduct for crisis management. Operating divisions and headquarters avoid or minimize risk by routinely gathering information and preparing risk management policies and countermeasures for their operations. Further, the Risk Evaluation Committee discusses risk management policies and countermeasures for significant risks that transcend several divisions.

An emergency situation affecting Santen beyond a certain level triggers the operation of a Crisis Response Committee headed by a representative director. Based on Santen's Risk Management Manual, this committee coordinates efforts to minimize any losses or damages and institutes measures to prevent recurrence. The Administration division checks the status of such risk management efforts from a Companywide viewpoint, while the Internal Audit Group examines them from an independent standpoint.

Regarding information control systems, Santen appropriately stores and controls information relating to the execution of duties by directors based on in-house rules for basic information security, decision-making authority and document control.

Santen aims to increase the appropriateness of the Santen Group's operations, which comprise the operations of the Company and its subsidiaries, by building a control system in which the Company provides recommendations and guidance on increasing appropriateness, developing regulations for the control of Group companies to clarify their roles and responsibilities and strengthening audit functions at major Group companies.

As a department independent from operating divisions, the Internal Audit Group—comprised of three people including the chief officer—verifies that the above internal control systems work efficiently.

Regarding internal control related to the reliability of financial reports, Santen has established a system whereby divisions and principal subsidiaries check the appropriateness of their systems, and the Internal Audit Group checks the suitability of these self-checks. In fiscal 2008, Santen did not discover any significant deficiencies or omissions that could undermine the reliability of its financial reports. Santen will continue to develop and maintain systems that consistently meet the requirements of the internal control reporting system, which is based on Japan's Financial Instruments and Exchange Law.

#### Internal Audits and Corporate Auditors' Audits

#### Cooperation between Corporate Auditors and Independent Auditors

The corporate auditors hold a meeting with the independent auditors at the beginning of each fiscal year to receive presentations on the financial auditing plans for the year and any key audit-related issues, and to exchange opinions including corporate auditors' requests. The independent auditors present audit findings to the corporate auditors at meetings twice a year to exchange opinions.

In addition, the corporate auditors attend an audit review meeting with the independent auditors after the conclusion of the quarterly and year-end audit review to share comments on audit results and procedures.

#### Cooperation between Corporate

Auditors and the Internal Audit Group The corporate auditors inform the Internal Audit Group of any specific audit-related issues or future risk-related items that may be identified in the course of auditing Santen's head office or operating sites.

The Internal Audit Group also reports to the corporate auditors any important information gained from internal audits and related measures. The corporate auditors may provide support to the Internal Audit Group in implementing countermeasures as deemed necessary.

#### Compensation for Directors and Corporate Auditors

Total remuneration for directors and corporate auditors for fiscal 2008 equaled ¥314 million. The breakdown is as follows:

1. Compensation paid to directors:

¥268 million (of which ¥31 million was paid to outside directors) 2. Compensation paid to corporate auditors: ¥46 million (of which ¥22 million was paid to outside auditors)

#### Relationships between the Company and its Outside Directors and Outside Auditors

There are no special interest relationships between the Company and its outside directors and outside auditors.

#### Outline of Agreements to Limit Responsibilities

To invite and appoint competent experts to work for the Company as outside directors or outside auditors to ensure further management transparency and objectivity and further reinforce the audit system, the Company stipulates in its Articles of Incorporation that it can enter into an agreement with outside directors and outside auditors to limit their liabilities for compensation of damage they might incur within a certain range.

## **Board of Directors, Corporate Auditors and Corporate Officers**

As of July 2009



#### Board of Directors

- 1 Takakazu Morita Chairman
- ② Akira Kurokawa President and Chief Executive Officer
- 3 Masahiro Mita, M.D., Ph.D. Managing Director Corporate and Regulatory Affairs

#### Toshiaki Nishihata, Ph.D. Member of the Board Senior Corporate Officer Head of Research and Development Division

- (5) Isao Muramatsu<sup>1</sup> Member of the Board
- Oboru Kotani<sup>1</sup> Member of the Board
- Tatsuhiko Hamamoto<sup>1</sup> Member of the Board

#### Corporate Auditors

Yukinori Mizumoto Standing Corporate Auditor

Tadao Kagono<sup>2</sup> Corporate Auditor

Yasuo Sato<sup>2</sup>

Corporate Auditor Eiju Miyauchi<sup>2</sup>

Corporate Auditor

1. Outside Director 2. Outside Corporate Auditor



### Corporate Officers

- 8 Sadatoshi Furukado Senior Corporate Officer Sales and Marketing Division, Prescription Pharmaceuticals
- Skenji Iwamoto Corporate Officer Head of Asia Division

#### Masamichi Sato Corporate Officer Head of Corporate Development Division

- Adrienne Graves, Ph.D. Corporate Officer President of Santen Inc.
- Use State of State

(3) Kenji Morishima Corporate Officer Head of Product Supply Division (4) Yoshihiro Noutsuka

Corporate Officer Community and Environment Relations

(5) Satoshi Harada Corporate Officer Head of Administration Division

## **Financial Section**

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## **Report and Analysis of Operating Results and Financial Condition**

#### **OPERATING RESULTS**

#### Net Sales

Sales of the Santen Group are comprised of four segments: prescription pharmaceuticals, over-the-counter (OTC) pharmaceuticals, medical devices and others. Consolidated net sales for the year ended March 31, 2009 declined 1.7%, to ¥101,619 million, primarily due to a decrease in revenues from mainstay prescription pharmaceuticals and OTC pharmaceuticals, which reflected the effect of foreign exchange rates.

#### PRESCRIPTION PHARMACEUTICALS

Santen's prescription pharmaceuticals are divided into three categories: ophthalmics, anti-rheumatics and other pharmaceuticals. In the year under review, a slight decrease in ophthalmic sales resulted in a 0.8% decline in prescription pharmaceutical net sales, to ¥94,538 million, which represented 93.0% of consolidated net sales.

#### Ophthalmics

Santen mounted successful promotional campaigns in Japan to provide individual medical facilities with scientific information tailored to their specific and changing needs, which counteracted an average reduction of around 3.0% in the prices of Santen's products due to NHI drug price revisions, and as a result domestic sales of prescription ophthalmic pharmaceuticals edged up 0.1%, to ¥72,357 million.

Overseas, prescription ophthalmic pharmaceutical revenues were down 7.4% after conversion to yen, to ¥12,131 million. In Europe, we concentrated on promotional campaigns centered on providing medical information to ophthalmic professionals. However, revenues decreased primarily due to foreign exchange rates. In Asia, foreign exchange rates also lowered revenues from China and South Korea.

As a result, prescription ophthalmic pharmaceuticals net sales decreased 1.1%, to ¥84,488 million.

#### Anti-Rheumatics

*Rimatil, Azulfidine EN* and *Metolate 2mg* were highly recommended under the *Manual on the Medical Treatment of Rheumatoid Arthritis and Medical Treatment Guidelines Based on EBM*, compiled by a study group of the Ministry of Health, Labour and Welfare and published by the Japan Rheumatism Foundation. Net sales of anti-rheumatics rose 1.2%, to ¥9,742 million, amid the effects of NHI drug price revisions and competition.

#### OTC PHARMACEUTICALS

Despite effective promotional campaigns for our range of ophthalmic products for tired eyes, blurred vision and eye refreshment, challenging competitive conditions resulted in a 4.1% decrease in net sales of OTC pharmaceuticals, to ¥5,225 million.

#### MEDICAL DEVICES

As a result of focusing initiatives on promotional campaigns for a new foldable IOL made of a new highly refractive acrylic optical material, *Eternity*, net sales of medical devices were up 50.1%, to ¥623 million.

#### OTHERS

Due to the ending of the contract manufacturing of an antiinfective otic pharmaceutical product, net sales decreased 44.1%, to ¥1,233 million.

#### Net Sales by Business Segment

	ivinion.	s or yerr	/0
	2009	2008	Change
Prescription pharmaceuticals	¥ 94,538	¥ 95,322	(0.8)
Ophthalmics	84,488	85,426	(1.1)
Anti-rheumatics	9,742	9,627	1.2
Other pharmaceuticals	308	269	14.5
OTC pharmaceuticals	5,225	5,451 (4.1)	
Medical devices	623	415 50.1	
Others	1,233	2,206	(44.1)
Total	¥101,619	¥103,394	(1.7)

Millions of ven



#### Cost of Sales

In line with a decrease in net sales, cost of sales declined 1.6%, to ¥35,947 million. The ratio of cost of sales to net sales was roughly level with the previous period, at 35.4%.

#### Cost of Sales and as Percentage of Net Sales Millions of yen / %

2009	35.4		35,947
2008	35.3		36,513
2007	35.3		35,484
2006	35.1		34,535
2005	36.4	1	33,710
	Cost of sales As percentage of net sales		

#### Selling, General and Administrative Expenses

We implemented several activities during the year to encourage future sales growth, including promotional campaigns accompanying the marketing of *Tapros* ophthalmic solution, a dry eye awareness campaign and defensive strategies to combat competition in the Japanese market as well as promotional campaigns in Europe and Asia implemented in accordance with our business plans. As a result of these activities, selling, general and administrative expenses increased 7.9%, to ¥50,178 million.

Further, R&D expenditures were up 42.6%, to ¥18,458 million, which was due to the recognition of a one-time payment of US\$50 million for the in-licensing of development and marketing for all ophthalmic indications of the retinal disorder treatment DE-109 (sirolimus) in Japan and Asia from MacuSight, Inc. (of the U.S.) in May 2008.

#### Selling, General and Administrative Expenses Millions of yen



#### Operating Income

Operating income declined 23.9%, to ¥15,494 million, due to the recognition of a one-time payment accompanying the conclusion of a license agreement for a new compound. As a result, the ratio of operating income to net sales dropped to 15.2%, down 4.5 percentage points from 19.7% in the previous year.

#### Operating Income and Operating Income Margin Millions of yen / %



#### Other Income and Expenses

Net other income for the year ended March 31, 2009 was ¥330 million.

Other income decreased ¥145 million, to ¥1,449 million, due to a ¥237 million gain on sale of investment securities recognized for the previous fiscal year, which offset the recognition of net exchange gains of ¥185 million.

Other expenses declined ¥363 million, to ¥1,119 million, resulting from a ¥317 million loss on impairment of fixed assets and net exchange losses of ¥746 million recognized in the previous fiscal year, which counteracted the recognition of equity in losses of affiliates of ¥679 million.

#### Income Taxes

Income taxes totaled ¥5,701 million. The effective tax rate declined to 36.0%, compared with 38.2% for the previous year.

#### Net Income

Net income was down 20.0%, to ¥10,123 million, in the year ended March 31, 2009. The ratio of net income to net sales was 10.0%, compared with 12.2% in the previous year. Basic net income per share was ¥119.08, compared with ¥146.15 in the previous fiscal year, and diluted net income per share was ¥118.97, down from ¥145.94.

#### Net Income and Net Income per Share–Basic Millions of yen / Yen



#### FINANCIAL CONDITION

#### Assets

As of March 31, 2009, total assets were ¥151,012 million, down ¥5,535 million, or 3.5%, from the previous year-end. Return on total assets (ROA) was 6.6%, down 1.4 percentage points from 8.0% in the previous year. Total current assets were ¥101,053 million, and the ratio of total current assets to total assets rose 1.3 percentage points, to 66.9%, from 65.6% in the previous year.

Within fixed assets, net property, plant and equipment totaled ¥28,665 million, other total investments and other assets amounted to ¥21,294 million.

#### Total Assets and ROA Millions of yen / %



#### Liabilities

Total liabilities at March 31, 2009 were ¥25,643 million, down ¥3,786 million, or 12.9%, from the previous year-end. Interestbearing debt was ¥700 million, a decline of ¥4,578 million, or 86.7%, from the previous fiscal year-end. Total current liabilities were ¥22,440 million, and total noncurrent liabilities were ¥3,203 million.

#### Net Assets

Net assets amounted to ¥125,369 million, down ¥1,749 million, or 1.4%, from the previous fiscal year-end. This decrease was attributable to a decline in unrealized gains on securities, net of taxes, due to a decrease in valuation of investment securities, and lower foreign currency translation adjustments stemming from foreign exchange fluctuations, which outweighed a rise in retained earnings. The equity ratio increased to 82.9%, up 1.8 percentage points from 81.1% at the previous year-end. Return on equity (ROE) declined to 8.0%, down 1.9 percentage points from 9.9% at the previous year-end. Equity per share was ¥1,472.32, a decrease of ¥22.16, or 1.5%, from the previous year-end.





#### Capital and Liquidity

Santen strives to maintain a healthy balance sheet and to ensure an appropriate level of liquidity and sufficient resources to fund its business activities. Cash and cash equivalents at end of year amounted to ¥45,957 million, down ¥5,713 million, or 11.1%. Net cash provided by operating activities was ¥11,849 million, of which ¥5,619 million was used in investment activities and ¥11,373 million in financing activities.
## Cash Flows

Net cash provided by operating activities was ¥11,849 million, which mainly resulted from income before income taxes of ¥15,824 million, depreciation and amortization of ¥4,210 million, increase in inventories of ¥1,334 million, increase in trade receivables of ¥916 million and income taxes paid of ¥8,431 million.

Net cash used in investment activities was ¥5,619 million. Increase in fixed deposits of ¥4,421 million, payments for acquisition of fixed assets of ¥2,953 million and purchase of investment securities of ¥2,081 million offset decrease in fixed deposits of ¥3,359 million.

Net cash used in financing activities was ¥11,373 million, which resulted primarily from repayment of long-term debt of ¥5,168 million and dividends paid of ¥6,799 million.

As a result, cash and cash equivalents at end of year was ¥45,957 million, a decrease of ¥5,713 million.

#### Cash Flows Summary

	ivillions of yen							
	2009	2008	Change					
Cash flows from operating activities	¥ 11,849	¥ 15,468	¥(3,619)					
Cash flows from investing activities	(5,619)	(2,083)	(3,536)					
Cash flows from financing activities	(11,373)	(11,415)	42					
Cash and cash equivalents at end of year	¥ 45,957	¥ 51,670	¥(5,713)					

Millions of you

Note: Figures in parentheses indicate a decrease

## Distribution of Profits

Santen views returns to shareholders as one of its most important management goals and has instituted the following fundamental policies for the distribution of profits:

- To enhance corporate value, we will focus on increasing capital efficiency and on securing internal reserves to fund R&D and the implementation of growth strategies.
- We will strive to increase the level of dividends in line with such factors as the Company's demand for funds and financial position.
- We will consider the repurchase and retirement of treasury stock as a flexible method of providing a return to shareholders.

To maintain a stable level of dividends, we target the dividend on equity (DOE) ratio, which combines the dividend payout ratio and ROE. For fiscal 2010, the final year of the current Medium-term Management Plan, our DOE goal is 5.0%.

For fiscal 2008, the annual dividend per share was ¥80. As a result, the DOE ratio was 5.4%. In the future, we will maintain our DOE target at more than 5.0% and consider the possibility of further treasury stock repurchase and retirement.

#### Dividend per Share and DOE Ratio Yen / %



## **Risks Related to Our Business**

## Forward-looking Information and Factors that Might Affect Future Results

Any statements that we make, other than historical facts, contain forward-looking information based on our business plans and assumptions at the time of disclosure. Such forwardlooking information includes, but is not limited to, our expected growth strategies, projected operating results, market forecasts and anticipated timing for developing, obtaining approval and bringing products to market. Our business, as well as each product we develop and market, is subject to various risks and uncertainties beyond our control. Therefore, these forwardlooking statements might differ substantially from actual results. Risks and uncertainties that could affect the Company's future results and financial conditions include, but are not limited to, the factors described below.

## External Factors

## **REGULATORY CONTROLS**

Our prescription pharmaceuticals business is subject to government regulatory controls regarding healthcare programs and drug prices in Japan and other countries. Although our current operating and / or financial projections were made fully in consideration of drug price revisions in Japan to the extent possible, those revisions that may take place beyond the scope of our anticipated projections or other revisions in healthcare programs might also affect our operating and / or financial results. In April 2008, NHI drug price revisions went into effect, resulting in an average 3.8% reduction for the prescription ophthalmic pharmaceuticals industry. In other countries and markets where we manufacture and sell our products, we continue to face a variety of regulatory controls over prices of prescription pharmaceuticals and government pressures for drug price reduction.

# SOCIAL AND ECONOMIC CONDITIONS AND CHANGES IN THE LAW

Santen's future results might be affected by political and economic changes in key markets worldwide in which we operate. Our anticipated performance and financial conditions might also be affected by changes in applicable accounting principles, and laws and regulations concerning taxes, the Product Liability Law, the Antitrust Law, environmental laws and regulations and other factors.

## FOREIGN EXCHANGE

Overseas sales and expenses, as well as assets of overseas subsidiaries, affect our sales, profits and financial conditions depending on foreign exchange rate fluctuations. Overseas sales for the year ended March 31, 2009 accounted for 12.8% of our consolidated net sales.

## Dependency on Specific Products and Business Partners

## DEPENDENCY ON MAINSTAY PRODUCTS

Total sales of *Hyalein* and *Cravit* accounted for 30% of Santen's consolidated net sales for the year ended March 31, 2009. Should any sales suspension or a decline in sales occur due to any unanticipated negative influences, such as potential product defects or newly discovered side effects, our business results and financial performance might be negatively affected.

## DEPENDENCY ON IN-LICENSED PRODUCTS

Many products that the Santen Group sells are licensed by other companies. We hold exclusive rights to manufacture and sell ophthalmic formulations such as *Cravit* and *Detantol*. We also have sales rights in Japan for *Timoptol*, *Timoptol* XE and *Livostin*, and exclusive sales rights in Japan for *Azulfidine EN* and *Rescula*. Should changes be made in the terms and conditions after the expiration of such contracts or should the agreements not be renewed, our business performance might be affected.

### DEPENDENCY ON SPECIFIC BUSINESS PARTNERS

In the U.S., we have a distribution agreement with VISTAKON Pharmaceuticals, LLC for certain prescription ophthalmics. In the event that VISTAKON cannot achieve sufficient sales of such products we consigned, our financial results might be affected.

We depend on specific business partners for the supply of certain raw materials such as the active pharmaceutical ingredient for *Cravit* and containers for our OTC pharmaceuticals. If supply of these materials is interrupted or discontinued for any reason, our pharmaceutical production might be adversely affected. Should it subsequently affect the supply of our products and cause any interruption or discontinuance, it would adversely affect our business performance.

The percentage of our business conducted with the top 10 wholesalers in Japan has reached 70% of our consolidated net sales. If our wholesale partners experience bankruptcy leading to a lending loss, our business performance might be adversely affected.

## R&D Activities

## UNCERTAINTIES IN NEW PRODUCT DEVELOPMENT

Years are required to bring new drugs from initial R&D to final approval and marketing. Various uncertainties exist at every stage in the development process that could sidetrack a new product, such as discontinuance of development or disapproval after the application is filed. It is difficult for us to accurately predict when new products, new indications or formulations under development will reach the approval stage and be ready for launching manufacturing and sales. Forecasting a precise timeline for project development and completion depends on a number of variable factors, including, but not limited to, delayed government reviews, conflicting or unusable clinical data that do not indicate significance in relation to competitor products, safety and efficacy concerns and unexpected side effects-which might lead to discontinued development or delayed product release and thereby negatively affect projected sales of new drugs.

## POTENTIALLY INSUFFICIENT RETURNS ON R&D INVESTMENT

The creation of new pharmaceuticals, as well as the development of new indications and formulations, is critical for the future growth of Santen. Every year we invest significantly in R&D, and there is a possibility that future investments will not result in sales of new products sufficient to provide an adequate return.

## **ISSUES OF ALLIANCES**

Forecasts for new pharmaceuticals include various assumptions of alliances in development and / or sales. Actual results of these alliances might affect our overall sales and financial conditions.

## Other Factors

### PRODUCTION INTERRUPTIONS OR DELAYS

The interruption or delay of production activities due to natural disasters or other catastrophes such as fire might affect our financial performance and conditions. Certain products are only manufactured at one location. If a specific plant is forced to halt production, supply of some products might be interrupted or delayed.

# CANCELLATION OF SALES AND PRODUCT WITHDRAWALS

If sales of products are cancelled, or if we withdraw products due to a batch defect, unexpected side effects, tampering or other causes, our overall financial results might be negatively affected.

## LITIGATION

Our main business involves the production and sales of prescription pharmaceuticals. The nature of our business makes us vulnerable to litigation related to patents, the Product Liability Law, violation of the Antitrust Law and consumer-related and environmental lawsuits. If such legal actions take place, the proceedings might affect our overall performance and financial conditions. Currently, we are involved in no litigation that substantially impacts the management of the Company.

## **Eleven-year Summary of Selected Financial Data**

Years ended March 31

	1999	2000	2001	2002	
For the year:					
Net sales	¥ 79,639	¥ 83,577	¥ 88,449	¥ 88,966	
Cost of sales	32,746	32,195	33,385	32,701	
Selling, general and administrative expenses	30,294	33,894	38,546	44,475	
Operating income	16,599	17,488	16,518	11,790	
Interest expense	588	462	430	465	
Income before income taxes	15,969	14,422	15,521	12,679	
Income taxes	7,864	6,481	7,807	7,373	
Net income	8,105	7,941	7,714	5,306	
Capital expenditures	3,443	2,510	4,943	6,586	
Depreciation and amortization	6,314	5,725	5,683	5,334	
R&D expenditures	7,335	9,221	10,511	12,187	
Per share data (yen and U.S. dollars):					
Net income-basic	¥ 85.27	¥ 83.54	¥ 81.32	¥ 57.34	
Net income-diluted	78.63	77.04	75.01	53.07	
Equity	935.71	1,006.48	1,022.99	1,048.51	
Cash dividends, applicable to period	12.00	12.00	20.00	20.00	
Cash flows:					
Net cash provided by operating activities	¥ 16,339	¥ 9,372	¥ 6,832	¥ 6,941	
Net cash (used in) provided by investing activities	(8,305)	837	(3,172)	(6,374)	
Net cash used in financing activities	(3,857)	(3,817)	(7,193)	(5,684)	
Interest coverage ratio (times)	27.8	20.3	16.8	14.9	
Debt to cash flow ratio (%)	173.8	274.7	367.3	352.5	
At year-end:					
Total current assets	¥ 78,018	¥ 82,218	¥ 88,025	¥ 86,064	
Net property, plant and equipment	39,638	37,416	36,684	42,159	
Total assets	144,913	149,968	153,243	152,103	
Long-term debt	27,496	26,491	25,482	24,467	
Equity	88,950	95,669	94,834	95,101	
Return on equity (ROE) (%)	9.5	8.6	8.1	5.6	
Return on total assets (ROA) (%)	5.7	5.4	5.1	3.5	
Equity ratio (%)	61.4	63.8	61.9	62.5	
Equity ratio on stock price basis (%)	145.0	139.4	134.3	86.6	
Price earnings ratio (PER) (times)	25.9	26.3	27.3	25.3	
Dividend on equity (DOE) (%)	1.3	1.2	2.0	1.9	
Issued shares (thousands)	95,075	95,075	92,721	90,704	
Number of employees	2,037	2,093	2,167	2,463	

Notes: 1. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥98.23 to U.S.\$1 prevailing on March 31, 2009.

2. See Notes 2. 13) and 11 of Notes to Consolidated Financial Statements in respect of per share data.

3. Net sales in the nine years ended March 31, 2009 include royalty income which was presented as "Other, net" in "Other income (expenses)" through

the year ended March 31, 2000.

4. Equity comprises shareholders' equity and total accumulated (losses) gains on evaluation and translation.

Thousands of U.S dollars						ns of yen	Millior
2009	2009	2008	2007	2006	2005	2004	2003
\$1,034,498	¥ 101,619	¥ 103,394	¥ 100,486	¥ 98,398	¥ 92,696	¥ 89,858	¥ 90,253
365,948	35,947	36,513	35,484	34,535	33,710	31,859	32,272
510,816	50,178	46,510	44,590	42,868	40,004	43,475	45,284
157,734	15,494	20,371	20,412	20,995	18,982	14,524	12,697
666	65	97	91	94	182	366	480
161,090	15,824	20,483	21,039	20,342	18,436	13,775	9,947
58,034	5,701	7,832	7,891	7,319	7,413	7,454	1,444
103,056	10,123	12,651	13,148	13,023	11,023	6,321	8,503
30,064	2,953	3,151	3,556	2,106	4,907	3,226	7,046
42,855	4,210	4,593	4,761	4,824	4,750	4,521	4,311
187,905	18,458	12,942	13,663	13,971	12,620	11,853	12,719
\$ 1.21	¥ 119.08	¥ 146.15	¥ 151.58	¥ 150.26	¥ 125.85	¥ 71.65	¥ 93.67
1.21	118.97	145.94	151.31	150.01	125.71	71.64	85.97
14.99	1,472.32	1,494.48	1,481.83	1,368.27	1,249.32	1,176.83	1,104.21
0.81	80.00	80.00	65.00	60.00	50.00	40.00	20.00
\$ 120,628	¥ 11,849	¥ 15,468	¥ 14,959	¥ 20,879	¥ 6,619	¥ 23,196	¥ 15,808
(57,204)	(5,619)	(2,083)	(5,846)	(1,330)	(2,907)	5,246	(9,951)
(115,782)	(11,373)	(11,415)	(5,691)	(5,900)	(12,712)	(12,122)	(6,507)
	165.5	163.6	164.3	218.7	36.1	70.6	34.5
	5.5	34.1	36.4	26.9	104.0	54.7	145.8
\$1,028,740	¥ 101,053	¥ 102,754	¥ 100,820	¥ 93,893	¥ 82,735	¥ 91,231	¥ 83,431
291,814	28,665	29,849	30,485	30,395	32,676	37,237	40,850
1,537,332	151,012	156,547	159,099	150,458	139,980	150,238	147,148
1,565	154	5,278	5,446	5,614	6,882	12,686	23,047
1,274,359	125,181	126,998	128,587	118,637	108,240	103,500	97,126
	8.0	9.9	10.6	11.5	10.4	6.3	8.8
	6.6	8.0	8.5	9.0	7.6	4.3	5.7
	82.9	81.1	80.8	78.9	77.3	68.9	66.0
	154.3	126.2	165.3	163.0	142.3	101.8	68.7
	23.0	15.9	20.0	18.8	18.3	24.3	12.3
	5.4	5.4	4.6	4.6	4.1	3.5	1.9
	86,916	86,867	86,825	86,751	86,659	87,963	90,704
	2,690	2,483	2,409	2,312	2,308	2,335	2,500

## **Consolidated Balance Sheets**

Santen Pharmaceutical Co., Ltd. and Subsidiaries As of March 31, 2009 and 2008

	Million	Thousands of U.S. dollars (Note 3)	
ASSETS	2009	2008	2009
Current assets:		N/ 54 670	* *** ***
Cash and cash equivalents	¥ 45,957	¥ 51,670	\$ 467,847
Short-term investments (Note 4)	2,557	182	26,033
Trade receivables:		224	
Notes	473	221	4,812
Accounts	35,538	35,393	361,790
Allowance for doubtful receivables	(1)	(1)	(12)
Net trade receivables	36,010	35,613	366,590
Inventories (Note 6)	12,236	11,333	124,563
Deferred tax assets (Note 14)	1,941	1,699	19,763
Other current assets	2,352	2,257	23,944
Total current assets	101,053	102,754	1,028,740
Property, plant and equipment (Notes 7 and 8):		0.550	
Land	8,679	8,558	88,349
Buildings and structures	41,476	39,860	422,231
Machinery and equipment	10,967	10,988	111,647
Tools, furniture and vehicles	10,684	10,628	108,770
Lease assets	53	-	540
Construction in progress	99	1,879	1,009
Total	71,958	71,913	732,546
Accumulated depreciation and impairment loss	(43,293)	(42,064)	(440,732)
Net property, plant and equipment	28,665	29,849	291,814
Investments and other assets:	E90	190	E 005
Investments in unconsolidated subsidiaries and affiliates	580	480	5,905
Investment securities (Note 4) Goodwill	11,239	16,470	114,413
	1 540	301	
Other intangibles Deferred tax assets (Note 14)	1,549 6,410	1,933	15,772
Other assets		1,822	65,254 15 434
Total investments and other assets	1,516	2,938	15,434
וטנמו ווועפגנווופוונג מווע טנוופו מגצפנג	21,294	23,944	216,778
Total assets	¥151,012	¥156,547	\$1,537,332

	Million	Thousands of U.S. dollars (Note 3)	
LIABILITIES AND NET ASSETS	2009	2008	2009
Current liabilities:			
Short-term borrowings (Note 9)	¥ 546	¥ —	\$ 5,555
Current portion of long-term debt (Note 9)	110	5,168	1,120
Trade accounts payable	6,018	5,634	61,266
Other payables	7,414	7,690	75,477
Accrued expenses	3,475	3,249	35,377
Income taxes payable (Note 14)	4,164	4,324	42,388
Other current liabilities	713	496	7,260
Total current liabilities	22,440	26,561	228,443
Noncurrent liabilities:			
Long-term debt (Note 9)	44	110	445
Retirement and severance benefits (Note 10)	2,899	2,302	29,509
Deferred tax liabilities (Note 14)	20	18	207
Other liabilities	240	438	2,451
Total noncurrent liabilities	3,203	2,868	32,612
Contingent liabilities (Note 15) Total liabilities	25,643	29,429	261,055
Net assets (Note 11):			
Common stock (Note 12):			
Authorized-220,000,000 shares			
(220,000,000 shares in 2008)			
Issued-86,916,203 shares			
(86,866,703 shares in 2008)	6,457	6,419	65,734
Capital surplus (Note 12)	7,152	7,114	72,811
Retained earnings	121,134	117,787	1,233,163
Treasury stock, at cost:			
1,893,769 shares in 2009 and 1,888,743 shares in 2008	(4,934)	(4,921)	(50,234)
Total shareholders' equity	129,809	126,399	1,321,474
Unrealized (losses) gains on securities, net of taxes (Note 4)	(247)	2,273	(2,511)
Foreign currency translation adjustments	(4,381)	(1,674)	(44,604)
Total accumulated (losses) gains on evaluation and translation	(4,628)	599	(47,115)
Stock subscription rights (Note 12)	188	120	1,918
Total net assets	125,369	127,118	1,276,277
Total liabilities and net assets	¥151,012	¥156,547	\$1,537,332

## **Consolidated Statements of Income**

Santen Pharmaceutical Co., Ltd. and Subsidiaries For the years ended March 31, 2009, 2008 and 2007

		Millions of yen		Thousands of U.S. dollars (Note 3)
	2009	2008	2007	2009
Net sales	¥101,619	¥103,394	¥100,486	\$1,034,498
Cost of sales	35,947	36,513	35,484	365,948
Gross profit	65,672	66,881	65,002	668,550
Selling, general and administrative expenses	50,178	46,510	44,590	510,816
Operating income	15,494	20,371	20,412	157,734
Other income (expenses):				
Interest and dividend income	549	607	460	5,587
Exchange gains (losses), net	185	(746)	(182)	1,881
Dividends received from investment limited partnership	—	—	72	—
Interest expense	(65)	(97)	(91)	(666)
Equity in losses of affiliates	(679)	—		(6,917)
Gain on sale of investment securities	—	237		—
Gain on sale of fixed assets	—	0	251	—
Loss on impairment of fixed assets (Note 8)	—	(317)	—	—
Other, net	340	428	117	3,471
Income before income taxes	15,824	20,483	21,039	161,090
Income taxes (Note 14):				
Current	8,269	8,146	7,902	84,185
Deferred	(2,568)	(314)	(11)	(26,151)
	5,701	7,832	7,891	58,034
Net income	¥ 10,123	¥ 12,651	¥ 13,148	\$ 103,056

			U.S. dollars (Note 3)			
Per share data:	2009	2008	2007		2009	
Net income – basic	¥ 119.08	¥ 146.15	¥ 151.58	\$	1.21	
Net income – diluted	118.97	145.94	151.31		1.21	
Cash dividends, applicable to the period	80.00	80.00	65.00		0.81	

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

Santen Pharmaceutical Co., Ltd. and Subsidiaries For the years ended March 31, 2009, 2008 and 2007

					Millions of	yen			
	Common stock	Capital surplus	Retained earnings	S	easury tock, t cost	Unrealized (losses) gains on securities, net of taxes	Unrealized gains on hedging derivatives, net of taxes	Foreign currency translation adjustments	Stock subscription rights
Balance at March 31, 2006	¥ 6,319	¥ 7,014	¥ 104,134	¥	(90)	¥ 3,996	¥ —	¥ (2,736)	¥ —
Exercise of stock options	63	63							
Cash dividends			(5,637)						
Net income			13,148						
Repurchase of treasury stock, net					(17)				
Retirement of treasury stock		0			1				
Other						1,207	3	1,119	59
Balance at March 31, 2007	¥ 6,382	¥ 7,077	¥ 111,645	¥	(106)	¥ 5,203	¥ 3	¥ (1,617)	¥ 59
Exercise of stock options	37	37							
Cash dividends			(6,509)						
Net income			12,651						
Repurchase of treasury stock, net				(4	4,816)				
Retirement of treasury stock		0			1				
Other						(2,930)	(3)	(57)	61
Balance at March 31, 2008	¥ 6,419	¥7,114	¥ 117,787	¥ (4	4,921)	¥2,273	¥ —	¥ (1,674)	¥ 120
Effect of changes in accounting policies applied to foreign subsidiaries			210						
Changes during the fiscal year:	••••		2.0						
Exercise of stock options	38	38							
Cash dividends			(6,800)						
Net income			10,123						
Repurchase of treasury stock, net	••••				(15)				
Retirement of treasury stock		0			2				
Effect of applying									
the equity method of accounts			(186)						
Other						(2,520)		(2,707)	68
Balance at March 31, 2009	¥ 6,457	¥ 7,152	¥121,134	¥ (4	4,934)	¥ (247)	¥—	¥ (4,381)	¥ 188

		Thousands of U.S. dollars (Note 3)								
	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Unrealized (losses) gains on securities, net of taxes	Unrealized gains on hedging derivatives, net of taxes	Foreign currency translation adjustments	Stock subscription rights		
Balance at March 31, 2008	\$65,342	\$72,419	\$1,199,091	\$(50,096)	\$ 23,149	\$ —	\$(17,039)	\$1,221		
Effect of changes in accounting policies applied to foreign subsidiaries			2,133							
Changes during the fiscal year:										
Exercise of stock options	392	392								
Cash dividends			(69,223)							
Net income			103,056							
Repurchase of treasury stock, net				(158)						
Retirement of treasury stock		0		20						
Effect of applying the equity method of accounts			(1,894)							
Other					(25,660)		(27,565)	697		
Balance at March 31, 2009	\$65,734	\$72,811	\$1,233,163	\$(50,234)	\$ (2,511)	\$ —	\$(44,604)	\$1,918		

## **Consolidated Statements of Cash Flows**

Santen Pharmaceutical Co., Ltd. and Subsidiaries For the years ended March 31, 2009, 2008 and 2007

Income before income taxes    ¥ 15,824    ¥ 20,483    ¥ 21,039    \$ 161,090      Depreciation and amortization    4,210    4,593    4,761    42,855      Loss on inpairment of fixed assets (Note 8)    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -			Millions of yen		Thousands of U.S. dollars (Note 3)
Income before income taxes    ¥ 15,824    ¥ 20,483    ¥ 21,039    \$ 161,090      Depreciation and amortization    4,210    4,593    4,761    42,855      Loss on inpairment of fixed assets (Note 8)    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -    -		2009	2008	2007	2009
Depreciation and amortization    4,210    4,593    4,761    42,855      Loss on impairment of fixed assets (Note 8)    —    317    —    —      Increase in retirement and severance benefits    554    412    160    5,633      Increase in transment of fixed assets (Note 8)    (607)    (460)    (5,587)      Increase in tarde receivables    (616)    (587)    (414)    (9,327)      Increase in tarde receivables    (916)    (587)    (414)    (9,327)      Increase in tarde receivables    (916)    (587)    (414)    (9,327)      Increase in tarde accounts payable    509    (430)    4,01    5,186      Other, net    759    (522)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest expense paid    (72)    (95)    (91)    (729)      Increase in tarkey paid    (8,431)    (7,758)    (8,914)    (8,8381)      Net cash provided by operating activities:    Cash flows from investing activities:    Cash flows from investing activities <td>Cash flows from operating activities:</td> <td></td> <td></td> <td></td> <td></td>	Cash flows from operating activities:				
Loss on impairment of fixed assets (Note 8)    —    317    —    —      Increase in retirement and severance benefits    554    412    160    5,636      Interest and dividend income    (649)    (607)    (460)    (5,587)      Interest expense    65    97    91    666      Equity in losses of affilates    679    —    —    6,917      Increase in wrothores    (1,334)    (1,006)    (357)    (13,582)      Increase (decrease) in trade accounts payable    509    (430)    401    5,186      Other, net    759    (562)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest expense paid    (722)    (95)    (91)    (729)      Income taxes paid    (722)    (95)    (3,064)    Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of investment securities    (2,081)    (3,266)    (    4,712      Proceeds from sale of property, plant and equipment	Income before income taxes	¥ 15,824	¥ 20,483	¥ 21,039	\$ 161,090
Increase in retirement and severance benefits    554    412    160    5,636      Interest and dividend income    (649)    (607)    (460)    (5,587)      Interest expense    65    97    91    6666      Equity in losses of affiliates    679    —    6,917      Increase in inventories    (1,1334)    (1,006)    (537)    (13,582)      Increase (acrease) in trade accounts payable    509    (430)    401    5,186      Other, net    759    (562)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest expense paid    (72)    (95)    (91)    (729)      Income taxes paid    (8,431)    (7,758)    (8,914)    (8,831)      Net cash provided by operating activities    11,849    15,468    14,259    120,628      Cash flows from investing activities    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purc	Depreciation and amortization	4,210	4,593	4,761	42,855
Interest and dividend income    (549)    (607)    (460)    (5,587)      Interest expense    65    97    91    666      Equity in losses of affiliates    679    —    —    6,917      Increase in trade receivables    (916)    (587)    (414)    (9,327)      Increase (decrease) in trade accounts payable    509    (430)    401    5,186      Other, net    759    (552)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest and dividend income received    551    611    460    5,607      Interest application of the property parting activities    11,849    15,468    14,959    120,628      Cash flows from investing activities:    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    611    26      Proceeds from sale of short-term investments    (2,953)    (3,151)    (3,556)    (30,03)      Proceeds from sale of short-term investments    (2,081)    (3,266) <td>Loss on impairment of fixed assets (Note 8)</td> <td></td> <td>317</td> <td></td> <td>—</td>	Loss on impairment of fixed assets (Note 8)		317		—
Interest expense    65    97    91    666      Equity in losses of affiliates    679    —    —    6,917      Increase in trade receivables    (916)    (587)    (414)    (9,327)      Increase in inventories    (1,334)    (1,006)    (357)    (13,582)      Increase (decrease) in trade accounts payable    509    (430)    401    5,186      Other, net    759    (562)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest expense paid    (72)    (95)    (91)    (729)      Income taxes paid    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities:    11,849    15,468    14,959    120,628      Cash flows from investing activities:    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of short-term investments    (4,421)    (1,518)    (1,223)    (45,003)	Increase in retirement and severance benefits	554	412	160	5,636
Equity in losses of affiliates    679    —    —    6,917      Increase in trade receivables    (916)    (587)    (414)    (9,327)      Increase (arcease) in trade accounts payable    509    (430)    401    5,186      Other, net    759    (562)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest expense paid    (72)    (95)    (91)    (729)      Increase (decrease) in trade accounts payable    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities    11,849    15,468    14,959    120,628      Cash flows from investing activities    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of investment securities    (2,081)    (3,266)    (2,209)    (21,183)      Proceeds from sale of investment securities    (4,421)    (1,518)    (1,223)    (45,003)      Proceeds from sale of investment securities    (3,355)    3,160    554    34,195      Increase in loans receivable    311<	Interest and dividend income	(549)	(607)	(460)	(5,587)
Increase in trade receivables    (916)    (587)    (414)    (9,327)      Increase in inventories    (1,334)    (1,006)    (357)    (13,582)      Increase (decrease) in trade accounts payable    509    (430)    401    5,186      Other, net    759    (562)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest and dividend income received    551    611    460    5,607      Interest expense paid    (72)    (95)    (91)    (729)      Income taxes paid    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities:    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of short-term investments    (4,421)    (1,518)    (1,223)    (43,003)      Proceeds from sale of investment securities    (300)    -    -    4,712      Proceeds from sale of short-term investments    (4,421)    (1,518)	Interest expense	65	97	91	666
Increase in inventories    (1,334)    (1,006)    (357)    (13,582)      Increase (decrease) in trade accounts payable    509    (430)    401    5,186      Other, net    759    (562)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest and dividend income received    551    611    460    5,607      Income taxes paid    (6,841)    (7,758)    (8,914)    (68,881)      Net cash provided by operating activities    11,849    15,468    14,959    120,628      Cash flows from investing activities    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of short-term investments    (4,421)    (1,518)    (1,223)    (45,003)      Proceeds from sale of short-term investments    (4,421)    (1,518)    (1,223)    (45,003)      Proceeds from sale of short-term investments    (4,421)    (1,518)    (1,223)    (45,003)      Proceeds from collection of loans receivable </td <td>Equity in losses of affiliates</td> <td>679</td> <td>—</td> <td>—</td> <td>6,917</td>	Equity in losses of affiliates	679	—	—	6,917
Increase (decrease) in trade accounts payable    509    (430)    401    5,186      Other, net    759    (562)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest and dividend income received    551    611    460    5,607      Interest expense paid    (72)    (95)    (91)    (729)      Income taxes paid    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities    11,849    15,468    14,959    120,628      Cash flows from investing activities:    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of short-term investment securities    463    2,660    -    4,712      Purchase of short-term investments    3,359    3,160    554    34,195      Increase in loans receivable    300    -    -    3,054)      Proceeds from callection of loans receivable    3111    -    -	Increase in trade receivables	(916)	(587)	(414)	(9,327)
Other, net    759    (562)    (1,717)    7,727      Subtotal    19,801    22,710    23,504    201,581      Interest and dividend income received    551    611    460    5,607      Interest expense paid    (72)    (95)    (91)    (729)      Income taxes paid    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities:    11,849    15,468    14,959    120,628      Cash flows from investing activities:    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of investment securities    (2,081)    (3,266)    (2,209)    (21,183)      Proceeds from sale of short-term investments    3,359    3,160    554    34,195      Increase in loans receivable    (300)    —    —    3,166      Proceeds from collection of loans receivable    311    —    —    3,166      Other, net    0    27    (13)    1 <td< td=""><td>Increase in inventories</td><td>(1,334)</td><td>(1,006)</td><td>(357)</td><td>(13,582)</td></td<>	Increase in inventories	(1,334)	(1,006)	(357)	(13,582)
Subtotal    19,801    22,710    23,504    201,581      Interest and dividend income received    551    611    460    5,607      Interest expense paid    (72)    (95)    (91)    (729)      Income taxes paid    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities    11,849    15,468    14,959    120,628      Cash flows from investing activities:    Capital expenditures    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of investment securities    (2,081)    (3,266)    (2,209)    (21,183)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of investment securities    (463    2,660    -    4,712      Proceeds from sale of property, envertiments    3,359    3,160    554    34,195      Increase in loans receivable    (300)    -    -    (3,054)      Proceeds from collection of loans receivable </td <td>Increase (decrease) in trade accounts payable</td> <td>509</td> <td>(430)</td> <td>401</td> <td>5,186</td>	Increase (decrease) in trade accounts payable	509	(430)	401	5,186
Interest and dividend income received    551    611    460    5,607      Interest expense paid    (72)    (95)    (91)    (729)      Income taxes paid    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities    11,849    15,468    14,959    120,628      Cash flows from investing activities:    2    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of investment securities    (2,081)    (3,266)    (2,209)    (21,183)      Proceeds from sale of investments securities    463    2,660    -    4,712      Purchase of short-term investments    (3,359)    3,160    554    34,195      Increase in solar seceivable    (300)    -    -    (3,054)      Proceeds from sale of investing activities    (5,619)    (2,083)    (5,846)    (5,7204)      Net cash used in investing activities    (5,619)    (2,083)    (5,82)    (5,7204)      Reparyment of long-term borrowings	Other, net	759	(562)	(1,717)	7,727
Interest expense paid    (72)    (95)    (91)    (729)      Income taxes paid    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities    11,849    15,468    14,959    120,628      Cash flows from investing activities:    Capital expenditures    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of investment securities    (2,081)    (3,266)    (2,209)    (21,183)      Proceeds from sale of investment securities    463    2,660     4,712      Purchase of short-term investments    (4,421)    (1,518)    (1,223)    (45,003)      Proceeds from sale of short-term investments    3,359    3,160    554    34,195      Increase in loans receivable    311    -     3,166      Other, net    0    27    (13)    1      Net cash used in investing activities:    (5,619)    (2,083)    (5,846)    (52,611)      Increase in short-term borrowings	Subtotal	19,801	22,710	23,504	201,581
Income taxes paid    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities    11,849    15,468    14,959    120,628      Cash flows from investing activities:    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of investment securities    (2,081)    (3,266)    (2,209)    (21,183)      Proceeds from sale of short-term investments    (4,421)    (1,518)    (1,223)    (45,003)      Proceeds from sale of short-term investments    (3,359)    3,160    554    34,195      Increase in loans receivable    311    —    —    (3,054)      Proceeds from collection of loans receivable    311    —    —    3,166      Other, net    0    27    (13)    1    1    Net cash used in investing activities:    (5,619)    (2,083)    (5,846)    (57,204)      Cash flows from financing activities:    115    (4,815)    (17)    (158)      Increase in short-term borrowings	Interest and dividend income received	551	611	460	5,607
Income taxes paid    (8,431)    (7,758)    (8,914)    (85,831)      Net cash provided by operating activities    11,849    15,468    14,959    120,628      Cash flows from investing activities:    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of investment securities    (2,081)    (3,266)    (2,209)    (21,183)      Proceeds from sale of short-term investments    (4,421)    (1,518)    (1,223)    (45,003)      Proceeds from sale of short-term investments    (3,359)    3,160    554    34,195      Increase in loans receivable    311    —    —    (3,054)      Proceeds from collection of loans receivable    311    —    —    3,166      Other, net    0    27    (13)    1    1    Net cash used in investing activities:    (5,619)    (2,083)    (5,846)    (57,204)      Cash flows from financing activities:    115    (4,815)    (17)    (158)      Increase in short-term borrowings	Interest expense paid	(72)	(95)	(91)	••••
Cash flows from investing activities:    (2,953)    (3,151)    (3,556)    (30,064)      Proceeds from sale of property, plant and equipment    3    5    601    26      Purchase of investment securities    (2,081)    (3,266)    (2,209)    (21,183)      Proceeds from sale of investment securities    463    2,660    —    4,712      Purchase of short-term investments    (4,421)    (1,518)    (1,223)    (45,003)      Proceeds from sale of short-term investments    3,359    3,160    554    34,195      Increase in loans receivable    (300)    —    —    3,166      Other, net    0    27    (13)    1      Net cash used in investing activities:    (5,619)    (2,083)    (5,846)    (57,204)      Cash flows from financing activities:    1    —    —    5,555      Repayment of long-term debt    (5,168)    (168)    (168)    (52,611)      Repurchase of treasury stock, net    (15)    (4,815)    (17)    (158)      Dividends paid    (6,799)    (6,506)	Income taxes paid	(8,431)	(7,758)	(8,914)	(85,831)
Capital expenditures  (2,953)  (3,151)  (3,556)  (30,064)    Proceeds from sale of property, plant and equipment  3  5  601  26    Purchase of investment securities  (2,081)  (3,266)  (2,209)  (21,183)    Proceeds from sale of investment securities  463  2,660   4,712    Purchase of short-term investments  (4,421)  (1,518)  (1,223)  (45,003)    Proceeds from sale of short-term investments  3,359  3,160  554  34,195    Increase in loans receivable  (300)    (3,054)    Proceeds from collection of loans receivable  311    3,166    Other, net  0  27  (13)  1    Net cash used in investing activities  (5,619)  (2,083)  (5,846)  (57,204)    Cash flows from financing activities:  -  -  5,555  55    Repayment of long-term debt  (5,168)  (168)  (168)  (52,611)    Repurchase of treasury stock, net  (15)  (4,815)  (17)  (158)    Dividends paid  (6,799) <td>Net cash provided by operating activities</td> <td>11,849</td> <td>15,468</td> <td>14,959</td> <td>120,628</td>	Net cash provided by operating activities	11,849	15,468	14,959	120,628
Capital expenditures  (2,953)  (3,151)  (3,556)  (30,064)    Proceeds from sale of property, plant and equipment  3  5  601  26    Purchase of investment securities  (2,081)  (3,266)  (2,209)  (21,183)    Proceeds from sale of investment securities  463  2,660   4,712    Purchase of short-term investments  (4,421)  (1,518)  (1,223)  (45,003)    Proceeds from sale of short-term investments  3,359  3,160  554  34,195    Increase in loans receivable  (300)    (3,054)    Proceeds from collection of loans receivable  311    3,166    Other, net  0  27  (13)  1    Net cash used in investing activities  (5,619)  (2,083)  (5,846)  (57,204)    Cash flows from financing activities:  -  -  5,555  55    Repayment of long-term debt  (5,168)  (168)  (168)  (52,611)    Repurchase of treasury stock, net  (15)  (4,815)  (17)  (158)    Dividends paid  (6,799) <td>Cash flows from investing activities:</td> <td></td> <td></td> <td></td> <td></td>	Cash flows from investing activities:				
Purchase of investment securities  (2,081)  (3,266)  (2,209)  (21,183)    Proceeds from sale of investment securities  463  2,660  —  4,712    Purchase of short-term investments  (4,421)  (1,518)  (1,223)  (45,003)    Proceeds from sale of short-term investments  3,359  3,160  554  34,195    Increase in loans receivable  (300)  —  —  (3,054)    Proceeds from collection of loans receivable  311  —  —  3,166    Other, net  0  27  (13)  1    Net cash used in investing activities:  (5,619)  (2,083)  (5,846)  (57,204)    Cash flows from financing activities:   —  —  5,555    Repayment of long-term debt  (5,168)  (168)  (168)  (52,611)    Repurchase of treasury stock, net  (15)  (4,815)  (17)  (158)    Dividends paid  (6,799)  (6,506)  (5,632)  (69,211)    Other, net  63  74  126  643    Net cash used in financing activities  (11,373)  (11,415)	Capital expenditures	(2,953)	(3,151)	(3,556)	(30,064)
Proceeds from sale of investment securities  463  2,660  —  4,712    Purchase of short-term investments  (4,421)  (1,518)  (1,223)  (45,003)    Proceeds from sale of short-term investments  3,359  3,160  554  34,195    Increase in loans receivable  (300)  —  —  (3,054)    Proceeds from collection of loans receivable  311  —  —  3,166    Other, net  0  27  (13)  1    Net cash used in investing activities  (5,619)  (2,083)  (5,846)  (57,204)    Cash flows from financing activities:	Proceeds from sale of property, plant and equipment	3	5	601	26
Purchase of short-term investments  (4,421)  (1,518)  (1,223)  (45,003)    Proceeds from sale of short-term investments  3,359  3,160  554  34,195    Increase in loans receivable  (300)	Purchase of investment securities	(2,081)	(3,266)	(2,209)	(21,183)
Proceeds from sale of short-term investments    3,359    3,160    554    34,195      Increase in loans receivable    (300)      (3,054)      Proceeds from collection of loans receivable    311      3,166      Other, net    0    27    (13)    1      Net cash used in investing activities    (5,619)    (2,083)    (5,846)    (57,204)      Cash flows from financing activities:      5,555      Repayment of long-term borrowings    546      5,555      Repayment of long-term debt    (5,168)    (168)    (168)    (52,611)      Repurchase of treasury stock, net    (15)    (4,815)    (17)    (158)      Dividends paid    (6,799)    (6,506)    (5,632)    (69,211)      Other, net    63    74    126    643      Net cash used in financing activities    (11,373)    (11,415)    (5,691)    (115,782)      Effect of exchange rate changes on cash and cash equivalents    (5,713)    1,829    3,736    (58,160)<	Proceeds from sale of investment securities	463	2,660		4,712
Increase in loans receivable  (300)  —  —  (3,054)    Proceeds from collection of loans receivable  311  —  —  3,166    Other, net  0  27  (13)  1    Net cash used in investing activities  (5,619)  (2,083)  (5,846)  (57,204)    Cash flows from financing activities:	Purchase of short-term investments	(4,421)	(1,518)	(1,223)	(45,003)
Proceeds from collection of loans receivable311——3,166Other, net027(13)1Net cash used in investing activities(5,619)(2,083)(5,846)(57,204)Cash flows from financing activities:5,555Increase in short-term borrowings546——5,555Repayment of long-term debt(5,168)(168)(168)(52,611)Repurchase of treasury stock, net(15)(4,815)(17)(158)Dividends paid(6,799)(6,506)(5,632)(69,211)Other, net6374126643Net cash used in financing activities(11,373)(11,415)(5,691)(115,782)Effect of exchange rate changes on cash and cash equivalents(5,713)1,8293,736(58,00)Net (decrease) increase in cash and cash equivalents(5,713)1,8293,736(58,160)Cash and cash equivalents at beginning of year51,67049,84146,105526,007	Proceeds from sale of short-term investments	3,359	3,160	554	34,195
Other, net    0    27    (13)    1      Net cash used in investing activities    (5,619)    (2,083)    (5,846)    (57,204)      Cash flows from financing activities:     5,555      Increase in short-term borrowings    546     5,555      Repayment of long-term debt    (5,168)    (168)    (168)    (52,611)      Repurchase of treasury stock, net    (15)    (4,815)    (17)    (158)      Dividends paid    (6,799)    (6,506)    (5,632)    (69,211)      Other, net    63    74    126    643      Net cash used in financing activities    (11,373)    (11,415)    (5,691)    (115,782)      Effect of exchange rate changes on cash and cash equivalents    (570)    (141)    314    (5,802)      Net (decrease) increase in cash and cash equivalents    (5,713)    1,829    3,736    (58,160)      Cash and cash equivalents at beginning of year    51,670    49,841    46,105    526,007	Increase in loans receivable	(300)			(3,054)
Net cash used in investing activities  (5,619)  (2,083)  (5,846)  (57,204)    Cash flows from financing activities:	Proceeds from collection of loans receivable	311			3,166
Cash flows from financing activities:    546    —    —    5,555      Increase in short-term borrowings    546    —    —    5,555      Repayment of long-term debt    (5,168)    (168)    (168)    (52,611)      Repurchase of treasury stock, net    (15)    (4,815)    (17)    (158)      Dividends paid    (6,799)    (6,506)    (5,632)    (69,211)      Other, net    63    74    126    643      Net cash used in financing activities    (11,373)    (11,415)    (5,691)    (115,782)      Effect of exchange rate changes on cash and cash equivalents    (570)    (141)    314    (5,802)      Net (decrease) increase in cash and cash equivalents    (5,713)    1,829    3,736    (58,160)      Cash and cash equivalents at beginning of year    51,670    49,841    46,105    526,007	Other, net	0	27	(13)	1
Increase in short-term borrowings  546  —  —  5,555    Repayment of long-term debt  (5,168)  (168)  (168)  (52,611)    Repurchase of treasury stock, net  (15)  (4,815)  (17)  (158)    Dividends paid  (6,799)  (6,506)  (5,632)  (69,211)    Other, net  63  74  126  643    Net cash used in financing activities  (11,373)  (11,415)  (5,691)  (115,782)    Effect of exchange rate changes on cash and cash equivalents  (570)  (141)  314  (5,802)    Net (decrease) increase in cash and cash equivalents  (5,713)  1,829  3,736  (58,160)    Cash and cash equivalents at beginning of year  51,670  49,841  46,105  526,007	Net cash used in investing activities	(5,619)	(2,083)	(5,846)	(57,204)
Repayment of long-term debt  (5,168)  (168)  (168)  (52,611)    Repurchase of treasury stock, net  (15)  (4,815)  (17)  (158)    Dividends paid  (6,799)  (6,506)  (5,632)  (69,211)    Other, net  63  74  126  643    Net cash used in financing activities  (11,373)  (11,415)  (5,691)  (115,782)    Effect of exchange rate changes on cash and cash equivalents  (570)  (141)  314  (5,802)    Net (decrease) increase in cash and cash equivalents  (5,713)  1,829  3,736  (58,160)    Cash and cash equivalents at beginning of year  51,670  49,841  46,105  526,007	Cash flows from financing activities:				
Repurchase of treasury stock, net  (15)  (4,815)  (17)  (158)    Dividends paid  (6,799)  (6,506)  (5,632)  (69,211)    Other, net  63  74  126  643    Net cash used in financing activities  (11,373)  (11,415)  (5,691)  (115,782)    Effect of exchange rate changes on cash and cash equivalents  (570)  (141)  314  (5,802)    Net (decrease) increase in cash and cash equivalents  (5,713)  1,829  3,736  (58,160)    Cash and cash equivalents at beginning of year  51,670  49,841  46,105  526,007	Increase in short-term borrowings	546	_	<u> </u>	5,555
Repurchase of treasury stock, net  (15)  (4,815)  (17)  (158)    Dividends paid  (6,799)  (6,506)  (5,632)  (69,211)    Other, net  63  74  126  643    Net cash used in financing activities  (11,373)  (11,415)  (5,691)  (115,782)    Effect of exchange rate changes on cash and cash equivalents  (570)  (141)  314  (5,802)    Net (decrease) increase in cash and cash equivalents  (5,713)  1,829  3,736  (58,160)    Cash and cash equivalents at beginning of year  51,670  49,841  46,105  526,007	Repayment of long-term debt	(5,168)	(168)	(168)	(52,611)
Other, net    63    74    126    643      Net cash used in financing activities    (11,373)    (11,415)    (5,691)    (115,782)      Effect of exchange rate changes on cash and cash equivalents    (570)    (141)    314    (5,802)      Net (decrease) increase in cash and cash equivalents    (5,713)    1,829    3,736    (58,160)      Cash and cash equivalents at beginning of year    51,670    49,841    46,105    526,007	Repurchase of treasury stock, net	(15)	(4,815)	(17)	(158)
Net cash used in financing activities    (11,373)    (11,415)    (5,691)    (115,782)      Effect of exchange rate changes on cash and cash equivalents    (570)    (141)    314    (5,802)      Net (decrease) increase in cash and cash equivalents    (5,713)    1,829    3,736    (58,160)      Cash and cash equivalents at beginning of year    51,670    49,841    46,105    526,007	Dividends paid	(6,799)	(6,506)	(5,632)	(69,211)
Effect of exchange rate changes on cash and cash equivalents(570)(141)314(5,802)Net (decrease) increase in cash and cash equivalents(5,713)1,8293,736(58,160)Cash and cash equivalents at beginning of year51,67049,84146,105526,007	Other, net	63	74	126	643
Net (decrease) increase in cash and cash equivalents    (5,713)    1,829    3,736    (58,160)      Cash and cash equivalents at beginning of year    51,670    49,841    46,105    526,007	Net cash used in financing activities	(11,373)	(11,415)	(5,691)	(115,782)
Net (decrease) increase in cash and cash equivalents    (5,713)    1,829    3,736    (58,160)      Cash and cash equivalents at beginning of year    51,670    49,841    46,105    526,007	Effect of exchange rate changes on cash and cash equivalents	(570)	(141)	314	(5,802)
Cash and cash equivalents at beginning of year    51,670    49,841    46,105    526,007	Net (decrease) increase in cash and cash equivalents			3,736	
	Cash and cash equivalents at beginning of year				••••
	Cash and cash equivalents at end of year			¥ 49,841	

## **Notes to Consolidated Financial Statements**

Santen Pharmaceutical Co., Ltd. and Subsidiaries

## **1. Basis of Presentation of Consolidated Financial Statements**

The consolidated financial statements of Santen Pharmaceutical Co., Ltd. (the "Company") have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act and its related accounting regulations, and in conformity with accounting principles generally accepted in Japan ("Japanese GAAP"), which are different in certain respects as to application and disclosure requirements of International Financial Reporting Standards.

Prior to the year ended March 31, 2009, the accounts of consolidated overseas subsidiaries are based on their accounting records maintained in conformity with generally accepted accounting principles prevailing in the respective countries of domicile.

### 2. Summary of Significant Accounting Policies

#### 1) Principles of consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries (the "Companies"). All significant intercompany balances and transactions are eliminated on consolidation.

Investment in an unconsolidated subsidiary is accounted for using the equity method.

Investment in an affiliated company is stated at cost due to immateriality.

### 2) Use of estimates

The preparation of the consolidated financial statements in conformity with Japanese GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

# 3) Short-term investments, investment securities and golf membership rights (see Note 4)

The Company and its domestic subsidiaries have adopted "Accounting Standard for Financial Instruments" which was issued by the Business Accounting Council in Japan. In accordance with this standard, securities are classified into three categories; trading, held-to-maturity, or other securities.

Based on this classification, all trading securities and, any held-to-maturity and other securities with a maturity of less than one year, are included in current assets. All other securities are included in investment securities as noncurrent assets.

Those classified as other securities with an available market value are reported at fair value with unrealized holding gains (losses), net of related taxes reported as a separate component of net assets.

Realized gains and losses on sales of such securities are determined by the moving average cost method. Other securities with no available market value are carried at cost, which is determined by the moving average cost method. As discussed in Note 2, 16), (i), the accounts of consolidated overseas subsidiaries for the year ended March 31, 2009 are prepared in accordance with either International Financial Reporting Standards or U.S. generally accepted accounting principles.

The consolidated financial statements have been restructured and translated into English (with certain expanded disclosures) from the consolidated financial statements of the Company prepared in accordance with Japanese GAAP and filed with the appropriate Local Finance Bureau of the Ministry of Finance as required by the Financial Instruments and Exchange Act. Certain supplementary information included in the statutory Japanese language consolidated financial statements is not presented in the consolidated financial statements.

In addition, this standard also requires the recognition of an impairment loss on golf membership rights, included in other assets, on the consolidated balance sheets, when the market value shows a substantial decline and is not anticipated to recover.

#### 4) Derivative instruments (see Note 5)

Derivative instruments are stated at fair value, and accounted for using deferred hedge accounting. Recognition of gains or losses resulting from changes in fair values of derivative financial instruments are deferred until the related losses or gains on the hedged items are recognized if derivative financial instruments are used as hedges and meet certain hedging criteria. Foreign exchange contracts that meet the criteria are accounted for under the allocation method. The allocation method requires recognized foreign currency receivables or payables to be translated using the corresponding foreign exchange contract rates. Interest rate swaps that meet the criteria are accounted for under the special method, as regulated in the accounting standard, as if the interest rates under interest rate swaps were originally applied to underlying borrowings.

The Company has also developed a hedging policy to control various aspects of derivative instruments including authorization levels and transaction volumes. Based on this policy, the Company hedges the exposure risk arising from fluctuations in foreign currency exchange rates, interest rates, and prices of securities. The Company evaluates hedge effectiveness by comparing the cumulative changes in cash flows from hedged items and corresponding changes in hedging derivative instruments. With respect to interest rate swaps under the special method, the evaluation of hedge effectiveness is omitted.

#### 5) Allowance for doubtful receivables

Allowance for doubtful receivables is provided principally at an amount determined based on the historical experience of bad debts and the estimated uncollectible amounts based on the specific analysis of receivables with default possibility.

### 6) Inventories (see Note 6)

Prior to April 1, 2008, inventories of the Company and its domestic subsidiaries are stated at cost determined principally by the average method. As discussed in Note 2, 16), (ii), effective April 1, 2008, the Company and its domestic subsidiaries adopted a new accounting standard for measurement of inventories and stated the inventories at the lower of average cost or net realizable value at March 31, 2009.

Inventories of consolidated foreign subsidiaries are stated at the lower of average cost or market.

7) Property, plant and equipment (excluding lease assets)

Property, plant and equipment is stated at cost. Depreciation of buildings, acquired prior to April 1, 1998, and other property, plant and equipment is computed over the estimated useful lives of the assets using the declining-balance method for the Company and its domestic subsidiaries. Buildings (other than leasehold improvements), which were acquired on or after April 1, 1998, are depreciated using the straight-line method for the Company and its domestic subsidiaries. Depreciation is computed over the estimated useful lives of the assets using the straight-line method for all overseas subsidiaries.

The principal estimated useful lives are as follows:

Buildings and structures	31 to 50 years
Machinery and equipment	7 to 8 years
Tools, furniture and vehicles	4 to 10 years

#### 8) Leases (see Note 7)

Finance leases, except for certain immaterial leases, are capitalized and depreciated over the estimated useful lives or lease terms, as applicable. However, as permitted and discussed in Note 2,16), (iii), the Company and its domestic subsidiaries account for finance leases commencing prior to April 1, 2008 which do not transfer ownership of the leased property to the lessee as operating leases with disclosure of certain "as if capitalized" information.

## 9) Impairment of fixed assets (see Note 8)

In accordance with "Accounting Standards for Impairment of Fixed Assets" which was issued by the Business Accounting Council in Japan, fixed assets, such as property, plant and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset, or group of assets, to estimated undiscounted future cash flows expected to be generated. If the carrying amount of an asset, or group of assets, exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the greater of its net realizable value or value in use.

## **10)** Retirement and severance benefits (see Note 10) Employees of the Company and its domestic subsidiaries are

generally entitled to lump-sum severance and, in certain cases, annuity payments on retirement, based on current rates of pay, length of service and certain other factors.

The Company and its domestic subsidiaries have adopted "Accounting Standard for Retirement Benefits" which was issued by the Business Accounting Council. In accordance with this standard, the allowance for retirement benefits for employees is provided based on the estimated retirement benefit obligation and the pension assets. Actuarial gains and losses are amortized, from the year in which the actuarial gains and losses are incurred, using the straight-line method, over the estimated average remaining service years of employees.

The Company has a retirement benefit scheme, which is a combination of lump-sum severance plan, cash balance and defined contribution pension plan. The Company also has a retirement benefits trust.

In addition, the Company has an unfunded retirement benefit plan for directors and corporate auditors. The amounts required under the plan have been fully accrued. Accrued severance indemnities for the members of the board and corporate auditors of the Company are provided based on internal regulations. The accrued provision for severance indemnities for members of the board and corporate auditors is not funded.

Certain overseas subsidiaries have defined contribution plans covering substantially all of their employees. The amounts contributed under the plans are charged to income.

#### 11) Foreign currency translation

All monetary assets and liabilities denominated in foreign currencies are translated at the rate of exchange prevailing on the balance sheet date, except for those items covered by forward exchange contracts.

The Company and its domestic subsidiaries have adopted "Accounting Standard for Foreign Currency Transactions" which was issued by the Business Accounting Council in Japan.

Financial statements of overseas subsidiaries are translated into Japanese yen at year-end rates for all assets and liabilities and at weighted average rates for income and expense accounts. Adjustments resulting from the translation of financial statements are reflected under the caption, "Foreign currency translation adjustments", in net assets.

# 12) Research and development and computer software (see Note 13)

Research and development expenditures are charged to income when incurred.

Expenditures relating to computer software developed for internal use are charged to income when incurred except if they contribute to the generation of income or to future cost savings. Such expenditures are capitalized as an asset and are amortized using the straight-line method over their estimated useful life, five years. **13) Net income and dividends per share (see Note 11)** The computation of basic net income per share is based on the weighted average number of shares of common stock outstanding during each period. The average number of shares used in the computation is 85,011 thousand, 86,561 thousand and 86,735 thousand for the years ended March 31, 2009, 2008 and 2007, respectively.

The diluted net income per share assumes the dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock. The average number of shares used in the computation is 85,089 thousand, 86,683 thousand and 86,891 thousand for the years ended March 31, 2009, 2008 and 2007, respectively.

Cash dividends per share shown in the accompanying consolidated statements of income are the amounts applicable to the respective years.

### 14) Income taxes (see Note 14)

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating loss carry forwards and foreign tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

#### 15) Cash and cash equivalents

Cash and cash equivalents mainly include cash on hand, readily available deposits and all highly liquid debt investments, generally with a maturity of three months or less, that are readily convertible to known amounts of cash and are so near maturity that they present insignificant risk of changes in value.

### 16) Changes in Accounting Policies

## (i) Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements

On May 17, 2006, the Accounting Standards Board of Japan issued Practical Issues Task Force No.18 "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements" ("PITF No. 18"). PITF No. 18 requires that accounting policies and procedures applied by a parent company and its subsidiaries to similar transactions and events under similar circumstances should, in principle, be unified for the preparation of the consolidated financial statements. PITF No. 18, however, as a tentative measure, allows a parent company to prepare consolidated financial statements using foreign subsidiaries' financial statements prepared in accordance with either International Financial Reporting Standards or U.S. generally accepted accounting principles. In this case, adjustments for the following six items are required in the consolidation process so that their impact on net income are accounted for in accordance with Japanese GAAP unless the impact is not material.

- (a) Goodwill not subject to amortization
- (b) Actuarial gains and losses of defined-benefit retirement plans recognized outside profit or loss
- (c) Capitalized expenditures for research and development activities
- (d) Fair value measurement of investment properties, and revaluation of property, plant and equipment and intangible assets(e) Retrospective treatment of a change in accounting policies
- (f) Accounting for net income attributable to minority interests

As a result of adopting PITF No. 18, effective April 1, 2008, retained earnings at April 1, 2008 was increased by ¥210 million (\$2,133 thousand), and operating income ,income before income taxes and net income were increased by ¥240 million (\$2,445 thousand ),¥223million (\$2,271 thousand) and ¥581 million (\$5,915 thousand), respectively.

## (ii) New accounting standard for measurement for inventories

On July 5, 2006, the Accounting Standards Board of Japan issued ASBJ Statement No. 9, "Accounting Standard for Measurement of Inventories". As permitted under the superseded accounting standard, the Company and its domestic subsidiaries previously stated inventories at cost. The new accounting standard requires that inventories held for sale in the ordinary course of business be measured at the lower of cost or net realizable value. Replacement cost may be used in lieu of the net realizable value, if appropriate.

There are no material effects on the Company's consolidated financial statements.

# (iii) New accounting standards for lease transactions as lessee

On March 30, 2007, the Accounting Standards Board of Japan issued Statement No. 13, "Accounting Standard for Lease Transactions" and Guidance No. 16, "Guidance on Accounting Standard for Lease Transactions". The new accounting standards require that all finance lease transactions be treated as capital leases.

Effective April 1, 2008, the Company and its domestic subsidiaries adopted the new accounting standards for finance leases commencing after March 31, 2008 and capitalized assets used under such leases, except for certain immaterial or short-term finance leases, which are accounted for as operating leases. As permitted, finance leases which commenced prior to April 1, 2008 and have been accounted for as operating leases, continue to be accounted for as operating leases with disclosure of certain "as if capitalized" information.

### 17) Reclassifications

Certain reclassifications have been made to prior years' consolidated financial statements to conform with the presentation used for the year ended March 31, 2009.

## **3. Translation into United States Dollars**

The accompanying consolidated financial statements are expressed in Japanese yen and, solely for the convenience of the reader, have been translated into United States dollars at the rate of ¥98.23=US\$1, the approximate exchange rate prevailing on March 31, 2009. The translation should not be construed as a representation that the Japanese yen have been, could have been, or could in the future be converted into United States dollars at that rate or any other rate.

## 4. Short-term Investments and Investment Securities

The following is a summary of other securities with a market value at March 31, 2009 and 2008:

	Millions of yen							
		2009		2008				
	Acquisition cost	Book value	Difference	Acquisition cost	Book value	Difference		
Securities with book values exceeding acquisition costs:								
Equity securities	¥ 4,121	¥ 4,982	¥ 861	¥ 7,136	¥11,351	¥4,215		
Securities with book values not exceeding acquisition costs:								
Equity securities	6,693	5,461	(1,232)	3,693	3,308	(385)		
	¥10,814	¥10,443	¥ (371)	¥10,829	¥14,659	¥3,830		

	Thousands of U.S. dollars			
		2009		
	Acquisition cost	Book value	Difference	
Securities with book values exceeding acquisition costs:				
Equity securities	\$ 41,952	\$ 50,718	\$ 8,766	
Securities with book values not exceeding acquisition costs:				
Equity securities	68,133	55,590	(12,543)	
	\$110,085	\$106,308	\$ (3,777)	

The market price in the table above does not include the negative value of shares amounting to ¥43 million (\$438 thousand) of securities held by investment limited partnerships.

Maturities of investments at March 31, 2009 and 2008 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Due within one year	¥2,557	¥ 182	\$26,033
Due after one year through five years	—	1,500	—
	¥2,557	¥1,682	\$26,033

## 5. Derivative Instruments

The Company principally utilizes derivative instruments such as foreign exchange contracts and interest rate swaps to hedge the exposure risk arising from fluctuations in foreign currency exchange rates, interest rates and market price of securities.

The Company is exposed to the risk that the counterparties

will not be able to fully satisfy their obligations under contracts, but the Company believes that such risk is mitigated by the high credit ratings of the counterparties.

There is no outstanding derivative transaction for which hedge accounting was not applied at March 31, 2009 and 2008.

## 6. Inventories

Inventories at March 31, 2009 and 2008 consist of the following:

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Merchandise and finished goods	¥10,236	¥ 9,387	\$104,202
Work in process	76	260	771
Raw materials and supplies	1,924	1,686	19,590
	¥12,236	¥11,333	\$124,563

## 7. Leases

Finance leases, commenced prior to April 1, 2008, which do not transfer ownership of lease assets to lessees, are accounted for as operating leases and equivalent purchase amount, accumulated depreciation and future minimum lease payments on an "as if capitalized" basis at March 31, 2009 and 2008 are as follows\*:

	Millions of yen		Thousands of U.S. dollars	
	2009	2008	2009	
Machinery and equipment:				
Equivalent purchase amount	¥3,147	¥12,577	\$32,036	
Equivalent accumulated depreciation amount	2,727	11,453	27,766	
Equivalent balance at year-end	420	1,124	4,270	
Tools:				
Equivalent purchase amount	356	558	3,620	
Equivalent accumulated depreciation amount	221	346	2,243	
Equivalent balance at year-end	135	212	1,377	
Total:				
Equivalent purchase amount	3,503	13,135	35,656	
Equivalent accumulated depreciation amount	2,948	11,799	30,009	
Equivalent balance at year-end	¥ 555	¥ 1,336	\$ 5,647	
Future minimum lease payments:				
Due within one year	¥ 425	¥ 872	\$ 4,331	
Due after one year	154	581	1,563	
	¥ 579	¥ 1,453	\$ 5,894	

\*The amount for renewed lease contracts were excluded since the year ended March 31, 2009.

Lease payments, equivalent depreciation and equivalent interest expense for the three years ended March 31, 2009 are as follows\*:

	Millions of yen			Thousands of U.S. dollars
	2009	2008	2007	2009
Lease payments	¥865	¥1,013	¥1,032	\$8,802
Equivalent depreciation	¥821	¥ 942	¥ 970	\$8,362
Equivalent interest expense	¥ 18	¥ 33	¥ 47	\$ 188

\*The amount for renewed lease contracts were excluded since the year ended March 31, 2009.

## **Operating leases:**

Future minimum rents under non-cancellable operating leases at March 31, 2009 and 2008 consist of the following:

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Due within one year	¥198	¥112	\$2,019
Due after one year	111	124	1,125
	¥309	¥236	\$3,144

## 8. Impairment of Fixed Assets

The Company and its domestic subsidiaries account for impairment of fixed assets in accordance with "Accounting Standards for Impairment of Fixed Assets."

The Company and its domestic subsidiaries review the recorded value of their property, plant and equipment and intangible assets to determine if the future cash flows to be derived from these properties will be sufficient to recover the remaining recorded asset values.

The impairment losses recognized for the three years ended March 31, 2009 are as follows:

	Millions of yen			Thousands of U.S. dollars
	2009	2008	2007	2009
Land	¥ —	¥253	¥ —	\$ —
Buildings and structures	—	64	—	—
	¥ —	¥317	¥ —	\$ —

The Company recorded impairment losses related to land and buildings for dormitory due to the Company's decision to close down during the year ended March 31, 2008. The fair value of the land, buildings and structures was based on local tax authority's valuation.

## 9. Short-tem Borrowings and Long-term Debt

Short-term borrowings at March 31, 2009 consist of bank loans.

The weighted average interest rates of short-term borrowings as of March 31, 2009 were 5.3%.

Long-term debt at March 31, 2009 and 2008 consists of the following:

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Unsecured yen syndicated loans from domestic banks, due in 2008, interest 1.4%	¥ —	¥ 5,000	\$ —
Unsecured yen loans from domestic banks, due in installments through 2009, interest 4.8%	110	278	1,120
Lease obligation	44	—	445
Total	154	5,278	1,565
Current portion shown in current liabilities	(110)	(5,168)	(1,120)
	¥ 44	¥ 110	\$ 445

The aggregate annual maturities of long-term debt at March 31, 2009 are as follows:

Years ending March 31	Millions of yen	Thousands of U.S. dollars
2010	¥110	\$1,120
2011	39	387
2012	4	46
2013	1	12
	¥154	\$1,565

As is customary in Japan, short-term borrowings and longterm bank loans are made under general agreements which provide that under certain circumstances, additional security and guarantees for present and future indebtedness will be given upon the bank requests and that the bank shall have the right, as the obligations become due, or in the event of default, to offset cash deposits against the obligations due to the bank. To date, the Company has not received such a request from its banks.

In March 2009, the Company entered into a commitment line contract with five domestic banks. The maximum aggregate credit facility available to the Company is ¥16,000 million (\$162,883 thousand). The credit facility has not been used as of March 31, 2009.

## **10. Retirement and Severance Benefits**

As discussed in Note 2, 10), the Company has a retirement benefit scheme, which is a combination of lump-sum severance plan, cash balance and defined contribution pension plan. The Company also has a retirement benefit trust.

The following table sets forth the details of benefit obligation, plan assets and funded status of the Companies at March 31, 2009 and 2008.

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
For employees:			
Benefit obligation at end of year	¥(13,234)	¥ (12,613)	\$(134,729)
Fair value of plan assets at end of year	8,766	9,427	89,237
Funded status (benefit obligation in excess of plan assets)	(4,468)	(3,186)	(45,492)
Unrecognized actuarial loss	2,075	1,371	21,125
For directors and corporate auditors:			
Accrued retirement benefit	(506)	(487)	(5,142)
Retirement and severance benefits recognized in the consolidated balance sheets	¥ (2,899)	¥ (2,302)	\$ (29,509)

Retirement and severance costs of the Companies include the following components for the three years ended March 31, 2009.

		Millions of yen		
	2009	2008	2007	2009
For employees:				
Service cost	¥ 805	¥ 802	¥ 701	\$ 8,191
Interest cost	246	226	218	2,501
Expected return on plan assets	(189)	(187)	(179)	(1,919)
Recognized actuarial loss	209	143	79	2,124
Contribution to defined contribution pension plan	830	901	807	8,452
Net periodic benefit cost	¥1,901	¥ 1,885	¥ 1,626	\$19,349
For directors and corporate auditors:				
Accrual for retirement benefit	¥ 18	¥ 17	¥ 79	\$ 179

Assumptions used in the accounting for retirement and severance benefits for the three years ended March 31, 2009 are as follows:

	2009	2008	2007
Method of attributing benefit to period of service	Straight-line basis	Straight-line basis	Straight-line basis
Discount rate	2.00%	2.00%	2.00%
Expected return on plan assets	2.00%	2.00%	2.00%
Amortization period for actuarial losses*	14 years	14 years	14 years

\* Amortized on a straight-line basis over the average remaining service period for employees in service starting from the year in which the losses occur.

Domestic subsidiaries has adopted the permitted alternative treatment, accruing for 100% of the amount required if all employees were to voluntarily terminate their employment as of the balance sheet date, in accordance with the accounting

standard for retirement benefits for small business entities. Domestic subsidiary and 2 overseas subsidiaries have lumpsum severance plans.

## **11. Net Assets**

Under the Japanese laws and regulations, the entire amount paid for new shares is required to be designated as common stock. However, a company may, by a resolution of the Board of Directors, designate an amount not exceeding one-half of the price of the new shares as additional paid-in capital, which is included in capital surplus.

Under the Japanese Corporate Law ("The Law"), in cases where dividend distribution of surplus is made, the smaller of an amount equal to 10% of the dividend and the excess, if any, of 25% of common stock over the total of additional paid-in capital and legal earnings reserve must be set aside as additional paid-in capital or legal earnings reserve. Legal earnings reserve is included in retained earnings in the accompanying consolidated balance sheets and amounted to ¥1,551 million (\$15,794 thousand) and ¥1,551 million as of March 31, 2009 and 2008, respectively.

Cash dividends charged to retained earnings during the three years ended March 31, 2009 represent dividends paid out during the periods. The accompanying consolidated financial statements do not include any provision for the year end dividend of ¥40 (\$0.41) per share, aggregating ¥3,401 million (\$34,622 thousand) which was approved at the Company's shareholders' meeting on June 24, 2009 in respect of the year ended March 31, 2009.

## 12. Stock Options

The Company has stock-based compensation plans under which stock options are granted annually to directors and corporate officers at the market price on the date of the grant. The stock options are fully exercisable after two years and expires ten years from the date of grant.

Stock options granted	2008	2007	2006	2005
Persons granted	Directors and corporate officers:12	Directors and corporate officers: 12	Directors and corporate officers: 15	Directors and corporate officers: 15
Number of shares	Common Stock 161,700	Common Stock 99,300	Common Stock 102,700	Common Stock 129,200
Date of grant	July 2, 2008	July 3, 2007	July 4, 2006	July 4, 2005
Vesting conditions	No provisions	No provisions	No provisions	No provisions
Service period	No provisions	No provisions	No provisions	No provisions
Exercise period	From June 28, 2010 to June 25, 2018	From June 27, 2009 to June 26, 2017	From June 28, 2008 to June 24, 2016	From June 25, 2007 to June 23, 2015
Stock options granted	2004	2003	2002	2001
Persons granted	Directors and corporate officers: 11	Directors and corporate officers: 12	Directors and corporate officers: 14	Directors and corporate officers: 14
Number of shares	Common Stock 78,200	Common Stock 137,600	Common Stock 92,000	Common Stock 55,000
Date of grant	July 5, 2004	July 4, 2003	July 5, 2002	July 9, 2001
Vesting conditions	No provisions	No provisions	No provisions	No provisions
Service period	No provisions	No provisions	No provisions	No provisions
Exercise period	From June 26, 2006 to June 24, 2014	From June 27, 2005 to June 25, 2013	From June 27, 2004 to June 25, 2012	From June 29, 2003 to June 27, 2011
Stock options granted	2000	1999	1998	
Persons granted	Directors and corporate officers: 16	Directors: 10 Management: 6	Directors: 12	
Number of shares	Common Stock 60,000	Common Stock 66,000	Common Stock 106,000	
Date of grant	July 10, 2000	July 8, 1999	July 1, 1998	
Vesting conditions	No provisions	No provisions	No provisions	
Service period	No provisions	No provisions	No provisions	
Exercise period	From June 30, 2002 to June 28, 2010	From June 30, 2001 to June 28, 2009	From June 27, 2000 to June 25, 2008	

Number, movement and price of stock options for the year ended March 31, 2009 are as follows:

## Before vesting options (Number of shares):

Stock options granted	2008	2007	2006	2005	2004	2003
Balance at April 1, 2008	_	—		_	—	_
Granted	161,700	_	—	—	—	
Vested	161,700	—	—	—	—	
Balance at March 31, 2009	_	—	_	—	—	
Stock options granted	2002	2001	2000	1999	1998	
Balance at April 1, 2008	—	—	—	—	—	
Granted	—	—	—	—	—	
Vested	—	—	—	—	—	
	_	_	_	—	—	
Balance at March 31, 2009 After vesting options (Number Stock options granted Balance at April 1, 2008	<b>of shares):</b> 2008	2007	2006	2005	2004	2003
After vesting options (Number						2003 55,200 —
After vesting options (Number Stock options granted Balance at April 1, 2008 Vested Exercised	2008					
<b>After vesting options (Number</b> Stock options granted Balance at April 1, 2008 Vested Exercised	2008 — 161,700 —	99,300 — —	102,700 — —	127,500 — —	66,100 — 4,800	55,200 — 10,400
After vesting options (Number Stock options granted Balance at April 1, 2008 Vested Exercised Balance at March 31, 2009	2008 — 161,700 —	99,300 — —	102,700 — —	127,500 — —	66,100 — 4,800	55,200 — 10,400
After vesting options (Number Stock options granted Balance at April 1, 2008 Vested Exercised Balance at March 31, 2009 Stock options granted	2008 — 161,700 — <b>161,700</b>	99,300 — — <b>99,300</b>	102,700 — — <b>102,700</b>	127,500 — — <b>127,500</b>	66,100 — 4,800 <b>61,300</b>	55,200 — 10,400
After vesting options (Number Stock options granted Balance at April 1, 2008 Vested Exercised Balance at March 31, 2009 Stock options granted Balance at April 1, 2008	2008 — 161,700 — <b>161,700</b> 2002	99,300 — <b>99,300</b> 2001	102,700 — — <b>102,700</b> 2000	127,500 — — <b>127,500</b> 1999	66,100 — 4,800 <b>61,300</b> 1998	55,200 — 10,400
After vesting options (Number Stock options granted Balance at April 1, 2008 Vested	2008 — 161,700 — <b>161,700</b> 2002	99,300 — <b>99,300</b> 2001	102,700 — — <b>102,700</b> 2000	127,500 — — <b>127,500</b> 1999	66,100 — 4,800 <b>61,300</b> 1998	55,200 — 10,400

## Price information (yen):

Stock options granted	2008	2007	2006	2005	2004	2003
Option price	2,734	3,050	2,715	2,480	1,743	1,176
Weighted-average stock price	_	—	_	_	2,789	2,725
Fair value at grant date*	423.16	609.45	579.05	—	—	

Stock options granted	2002	2001	2000	1999	1998	
Option price	1,326	2,299	2,705	2,480	1,540	
Weighted-average stock price	2,737	2,870	2,870	_	2,614	
Fair value at grant date*	—	—	—	—	—	

\* Omitted due to stock options which had been granted before the Law became effective on May 1, 2006.

On June 24, 2009, the Company's shareholders' meeting approved that the Company's stock subscription rights for allotment as stock options to directors and corporate officers of the Company. These stock subscription rights are exercisable from June 27, 2011 to June 24, 2019. The maximum number of stock subscription rights that can be exercised is 168,400 common shares.

## **13. Research and Development Expenditures**

Research and development expenditures charged to income for the years ended March 31, 2009, 2008 and 2007 are ¥18,458 million (\$187,905 thousand), ¥12,942 and ¥13,663 million, respectively.

## 14. Income Taxes

The Company and its domestic subsidiaries are subject to a number of taxes based on earnings which, in the aggregate, resulted in an average normal tax rate of approximately 40.4% for the three years ended March 31, 2009. Overseas subsidiaries are subject to income taxes of the countries in which they operate.

The effective rates for the three years ended March 31, 2009 differ from the normal tax rates for the following reasons:

	2009	2008	2007
Normal tax rate	40.4 %	40.4 %	40.4 %
Equity in losses of affiliates	1.7		_
Expenses not deductible for tax purposes	1.5	1.6	1.4
Lower tax rates of subsidiaries	1.3	(0.2)	(0.4)
Change in valuation allowance allocated to income tax expenses	(1.5)	1.6	1.5
Tax credit for research and development expenses	(8.0)	(5.5)	(5.8)
Others	0.6	0.3	0.4
ffective tax rate	36.0 %	38.2 %	37.5 %

The tax effects of temporary differences and tax loss carryforwards that give rise to significant portions of the deferred tax assets and deferred tax liabilities at March 31, 2009 and 2008 are presented below:

	Million	s of yen	Thousands of U.S. dollars
	2009	2008	2009
Deferred tax assets:			
Tax loss carryforwards	¥ 5,986	¥ 6,074	\$60,935
Retirement and severance benefits	2,708	2,487	27,565
Deferred assets for tax purposes	2,222	458	22,620
Accrued expenses	1,139	1,072	11,598
Depreciation and amortization	828	892	8,433
Accrued enterprise taxes	369	363	3,759
Loss on impairment of fixed assets	271	272	2,758
Loss on impairment of golf membership rights	209	208	2,129
Loss on valuation of inventories	193	84	1,969
Net unrealized holding losses on securities	167	—	1,705
Loss on valuation of securities	43	43	441
Other	860	925	8,736
Subtotal	14,995	12,878	152,648
Valuation allowance	(6,508)	(7,674)	(66,254)
Total gross deferred tax assets	8,487	5,204	86,394
Deferred tax liabilities:			
Reserve for special depreciation	(133)	(131)	(1,357)
Net unrealized holding gains on securities	(1)	(1,551)	(8)
Other	(22)	(19)	(219)
Total gross deferred tax liabilities	(156)	(1,701)	(1,584)
Net deferred tax assets	¥ 8,331	¥ 3,503	\$84,810

Net deferred tax assets at March 31, 2009 and 2008 are reflected in the accompanying consolidated balance sheets under the following captions:

	Million	s of yen	Thousands of U.S. dollars
	2009	2008	2009
Current assets – deferred tax assets	¥1,941	¥1,699	\$19,763
Investments and other assets – deferred tax assets	6,410	1,822	65,254
Noncurrent liabilities – deferred tax liabilities	(20)	(18)	(207)
Net deferred tax assets	¥8,331	¥3,503	\$84,810

## **15. Contingent Liabilities**

At March 31, 2009, the Company has provided guarantees to financial institutions covering employee loans totaling ¥446 million (\$4,539 thousand).

## **16. Segment Information**

The Companies operate predominantly in a single industry segment: the production, sale and marketing of pharmaceuticals.

Intercompany sales between geographic areas are recorded at cost plus a markup and intercompany sales and profits are eliminated on consolidation. Corporate assets are composed mainly of cash and cash equivalents, short-term investments and investment securities.

Information by geographic area and overseas sales are as follows:

		Millions of yen		Thousands of U.S. dollars
	2009	2008	2007	2009
Geographic areas:				
Net sales:				
Japan:				
External customers	¥ 91,405	¥ 92,098	¥ 90,695	\$ 930,522
Intersegment	2,422	1,978	1,167	24,659
Total	93,827	94,076	91,862	955,181
Europe:				
External customers	9,453	10,617	9,186	96,226
Intersegment	1,838	2,041	2,028	18,714
Total	11,291	12,658	11,214	114,940
Other:				
External customers	761	679	605	7,750
Intersegment	2,879	2,761	2,611	29,304
Total	3,640	3,440	3,216	37,054
Corporate and eliminations	(7,139)	(6,780)	(5,806)	(72,677)
Consolidated	¥101,619	¥ 103,394	¥ 100,486	\$1,034,498

		Millions of yen			
	2009	2008	2007	2009	
Operating income (loss):					
Japan	¥ 18,284	¥ 22,633	¥ 21,768	\$ 186,139	
Europe	178	555	980	1,817	
Other	(662)	(819)	(755)	(6,738)	
Corporate and eliminations	(2,306)	(1,998)	(1,581)	(23,484)	
Consolidated	¥ 15,494	¥ 20,371	¥ 20,412	\$ 157,734	
Assets:					
Japan	¥138,095	¥ 129,610	¥ 125,822	\$1,405,832	
Europe	10,017	10,908	10,635	101,974	
Other	5,387	5,745	4,880	54,845	
Corporate and eliminations	(2,487)	10,284	17,762	(25,319)	
Consolidated	¥151,012	¥ 156,547	¥ 159,099	\$1,537,332	

The main countries included in Europe and Other are as follows:

Europe: Finland, Germany and Sweden

Other: United States of America, China, Korea and Taiwan

As discussed in Note 2, 16), (i), the Companies applied the new PITF, "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements (ASBJ PITF No.18, May 17, 2006)" for the year ended March 31, 2009. The effect of this adoption was to increase operating income of Europe segment by ¥1 million (\$15 thousand) and other segment by ¥239 million (\$2,430 thousand).

		Thousands of U.S. dollars		
	2009	2008	2007	2009
Overseas sales:				
Europe	¥ 8,311	¥ 8,533	¥ 6,917	\$ 84,604
North America	938	1,951	2,129	9,549
Asia	3,748	4,326	4,247	38,153
Other	2	17	41	23
Total	¥ 12,999	¥ 14,827	¥ 13,334	\$ 132,329
Consolidated net sales	¥101,619	¥ 103,394	¥ 100,486	\$1,034,498
Percentage of overseas sales to consolidated net sales	12.8%	14.3%	13.3%	

The main countries included in Europe, North America, Asia and Other are as follows:

Europe: Finland, Russia, Germany, Sweden and Norway

North America: United States of America

Asia: Korea, China, Vietnam and Taiwan

Other: Australia

Overseas sales represent the total amount of export sales of the Company and its domestic subsidiaries and sales of overseas subsidiaries (intercompany sales between consolidated subsidiaries are eliminated upon consolidation).

## **17. Subsequent Event**

License agreement with Merck & Co., Inc On April 15, 2009, the Company and Merck & Co., Inc ("Merck") signed a worldwide licensing agreement for Tafluprost, a treatment for glaucoma and ocular hypertension.

The summary of the agreement is as follows:

- (i) The Company grants Merck exclusive commercial rights to Tafluprost in Western Europe, (excluding Germany), North America, South America and Africa.
- (ii) The Company retains commercial rights to Tafluprost in Germany, Eastern Europe, Northern Europe and Asia Pacific, including Japan.
- (iii) Under the terms of this agreement, Merck will pay a fee as milestones are achieved and as royalty based on future sales of Tafluprost according to the license agreement.
- (iv) Merck will provide promotional support to the Companies in Germany and Poland. If Tafluprost is approved in the United States of America, the Company will have the option to co-promote the product in the United States of America.

## **Internal Control Report**

#### 1 FRAMEWORK OF INTERNAL CONTROL OVER FINANCIAL REPORTING

I, as President and CEO of Santen pharmaceutical Co., Ltd. (the Company), am responsible for the design and operation of internal controls over financial reporting ("ICOFR") and establishing and maintaining an ICOFR based on the framework of ICOFR in Japan in accordance with "On the Setting of the Standards and Practice Standards for Management Assessment and Audit concerning Internal Control Over Financial Report (Business Accounting Council (Council Opinions), February 15, 2007)".

Internal control aims at achieving the objectives to a reasonable extent with the organized and integrated function of individual component as a whole. Therefore ICOFR does not provide an absolute assurance for preventing and detecting all errors to consolidated financial statements.

#### 2 ASSESSMENT SCOPE, TIMING AND PROCEDURES

#### Basis of Presenting Internal Control Report

The report on ICOFR of the consolidated financial statements of the Company ("Internal Control Report") is prepared on the basis of generally accepted assessment standards of internal control over financial reporting in Japan ("Assessment Standards") and is compiled from the Internal Control Report prepared by the Company as required by the Financial Instruments and Exchange Law of Japan ("Law").

The Assessment Standards require management to assess ICOFR, which consists of the internal controls over the consolidated financial statements included in the Annual Securities Report filed under the Law and the internal control over disclosure information and others included in the Annual Securities Report that materially affects the reliability of the financial statements.

The scope of management's assessment of ICOFR in this annual report is different from the scope required by the Assessment Standards. Management assessment of ICOFR in this annual report covers the ICOFR with respect to the accompanying consolidated financial statements only. In addition, as explained in Note 1 on the basis of presentation of consolidated financial statements, the accompanying consolidated financial statements are reclassified and modified from the consolidated financial statements prepared for the purpose of the Law. Supplementary information is also added to the consolidated financial statements. The process of making reclassifications and modifications and the addition of certain information is for the convenience of readers outside Japan. Management voluntarily includes the process in its assessment of ICOFR, even though it is outside the scope of the Assessment Standards.

#### Scope of Assessment

Management's assessment of ICOFR was conducted as of March 31, 2009 in accordance with the Assessment Standards.

In evaluating internal controls, management first assessed internal controls that have a material impact on overall consolidated financial reporting ("company-level controls") and, based on the results, selected business process to be assessed. For assessment of process level controls management analyzed the selected business processes, identify a key control that would have a material impact on the reliability of financial reporting, and assessed effectiveness of internal controls through assessing design and operation of the key controls.

Management assessed the effectiveness of the ICOFR applicable for the Company, its subsidiaries and its affiliates, to extent necessary in light of their degree of impact on the reliability of financial reporting. Management determined materiality for reliability of financial reporting in light of their degree of quantitative and qualitative impact on financial reporting. From the results of the company-level controls assessment of the Company and a subsidiary, management determined a reasonable scope for process level controls to be assessed.

Management selected the Pharmaceuticals business unit of the Company as the significant business unit for assessing process level controls, as its sales was more than 80% of the previous fiscal year's consolidated net sales. The process related to net sales, account receivables and inventories from the Pharmaceuticals business unit of the Company was selected for process level control assessment as they have significant relation to the business objectives of the Company. Apart from selected significant business units, including other business units, processes whose accounts were determined to have a high risk of misstatement and involves significant use of management estimate and projection, and processes whose businesses or operations included high risk transactions were additionally selected for controls assessment.

#### 3 RESULTS OF ASSESSMENT

Based on our assessment procedures noted above, I concluded the Company's internal control over financial reporting was effective as of March 31, 2009.

#### 4 SUPPLEMENTARY INFORMATION

No subsequent events have arisen that has caused to materially effect our evaluation of the effectiveness on the internal control over financial reporting as of March 31, 2009.

5 OTHER None.

a. Konshawa

Akira Kurokawa President & CEO

June 24, 2009

## **Independent Auditors' Report**



To the Board of Directors of Santen Pharmaceutical Co., Ltd.:

#### Financial statement audit

We have audited the accompanying consolidated balance sheets of Santen Pharmaceutical Co., Ltd. and consolidated 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-year in the period ended March 31, 2009, expressed in Japanese yen. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to independently express an opinion on these consolidated 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Santen Pharmaceutical Co., Ltd. and subsidiaries as of March 31, 2009 and 2008, and the results of their operations and their cash flows for the each of the three-year 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 of the reader. 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 3, to the consolidated financial statements.

#### Internal control audit

We also have audited the accompanying report on internal control over financial reporting of the consolidated financial statements of Santen Pharmaceutical Co., Ltd. as of March 31, 2009 ("Internal Control Report"). The design and operation of internal control over financial reporting and the preparation of the Internal Control Report are the responsibility of the Company's management. Our responsibility is to independently express an opinion on the Internal Control Report based on our audit. Internal control over financial reporting may not completely prevent or detect financial statement misstatements.

We conducted our internal control audit in accordance with auditing standards for internal control over financial reporting generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the Internal Control Report is free of material misstatement. An internal control audit is performed on a test basis and includes evaluating the appropriateness of the scope, procedures and result of the assessment determined and presented by management and the overall Internal Control Report presentation. We believe that our internal control audit provides a reasonable basis for our opinion.

In our opinion, the Internal Control Report referred to above, in which Santen Pharmaceutical Co., Ltd. states that internal control over financial reporting of the consolidated financial statements was effective as of March 31, 2009, presents fairly, in all material respects, the assessment of internal control over financial reporting in conformity with assessment standards for internal control over financial reporting generally accepted in Japan.

KPMG AZSA & G.

Osaka, Japan June 24, 2009

## **Major Subsidiaries and Facilities**

As of July 2009



## Subsidiaries

#### 1 Claire Co., Ltd.

348-3, Aza-suwa, Oaza-shide, Taga-cho, Inukami-gun, Shiga 522-0314, Japan TEL: +81-749-48-2234 FAX: +81-749-48-2239 Business: Cleaning of antidust and sterilized clothing Equity Ownership: 100%

#### **2** Santen Holdings U.S. Inc.

555 Gateway Drive, Napa, California 94558, U.S.A. Business: Holding company for North American businesses and business development Equity Ownership: 100%

#### **3** Santen Inc.

555 Gateway Drive, Napa, California 94558, U.S.A. TEL: +1-707-254-1750 FAX: +1-707-254-1755 Business: Clinical development of pharmaceuticals Equity Ownership: 100%\*

#### 4 Advanced Vision Science, Inc.

5743 Thornwood Drive, Goleta, California 93117, U.S.A. TEL: +1-805-683-3851 FAX: +1-805-964-3065 Business: Research and development of medical devices Equity Ownership: 100%\*

\* Indirect investment through Santen Holdings U.S. Inc.

## Offices, Laboratory and Plants

### 1) Corporate Headquarters

9-19, Shimoshinjo 3-chome, Higashiyodogawa-ku, Osaka 533-8651, Japan TEL: +81-6-6321-7000 FAX: +81-6-6328-5082

#### ② Nara Research and Development Center

8916-16, Takayama-cho, Ikoma-shi, Nara 630-0101, Japan TEL: +81-743-79-4501 FAX: +81-743-79-4521

### **5** Santen Oy

Niittyhaankatu 20, P.O. Box 33, FIN-33721 Tampere, Finland TEL: +358-3-284-8111 FAX: +358-3-318-1900 Business: Development, production, marketing of pharmaceuticals and contract manufacturing Equity Ownership: 100%

#### 6 SantenPharma AB

Solna torg 3, SE-17145 Solna, Sweden TEL: +46-8-83-4140 FAX: +46-8-83-4145 Business: Marketing support of pharmaceuticals Equity Ownership: 100%

#### Santen GmbH

Industriestrasse 1, Germering D-82110, Germany TEL: +49-89-848078-0 FAX: +49-89-848078-60 Business: Marketing of pharmaceuticals, regulatory affairs, scientific marketing and business development Equity Ownership: 100%

#### 3 Taiwan Santen Pharmaceutical Co., Ltd.

16F, No. 57, Sec. 2, Tun-Hwa South Rd., Taipei, R.O.C. TEL: +886-2-2700-1553 FAX: +886-2-2700-1730 Business: Import and marketing of pharmaceuticals Equity Ownership: 100%

#### 9 Santen Pharmaceutical Korea, Co., Ltd.

Room 805, Center Building, 91-1, Sogongdong, Chung-ku, Seoul, 10070, R.O.K. TEL: +82-2-754-1434 FAX: +82-2-754-2929 Business: Import and marketing of pharmaceuticals Equity Ownership: 100%

#### **()** Santen Pharmaceutical (China) Co., Ltd.

No. 169 Tinglan Road, Suzhou Industrial Park, Jiangsu Province, 215026, P.R.C. TEL: +86-512-6295-7500 FAX: +86-512-6295-7800 Business: Production and marketing of pharmaceuticals Equity Ownership: 100%

### ③ Noto Plant

2-14, Shikinami, Houdatsushimizu-cho, Hakui-gun, Ishikawa 929-1494, Japan TEL: +81-767-29-2666 FAX: +81-767-29-4233

#### ④ Shiga Plant

348-3, Aza-suwa, Oaza-shide, Taga-cho, Inukami-gun, Shiga 522-0314, Japan TEL: +81-749-48-2900 FAX: +81-749-48-2901

#### **⑤** Osaka Plant

9-19, Shimoshinjo 3-chome, Higashiyodogawa-ku, Osaka 533-8651, Japan TEL: +81-6-6321-9976 FAX: +81-6-6321-7149

#### 6 Beijing Representative Office

Suit 1204 to 1206, TOWER W3, Oriental Plaza, No. 1 East Chang An Ave., Dong Cheng District, Beijing, 100738, P.R.C. TEL: +86-10-8515-1515 FAX: +86-10-8515-1020

## **Corporate Information / Stock Information**

As of March 31, 2009

Corporate Headquarters	Santen Pharmaceutical Co., Ltd. 9-19, Shimoshinjo 3-chome,	olding			
Established	Higashiyodogawa-ku, Osaka 533-8651, Japan URL: http://www.santen.com Investor relations contact: TEL: +81-6-6321-7007 FAX: +81-6-6321-8400 E-MAIL: ir@santen.co.jp 1890	Breakdown of shareholding Individual Treasury stock 13.3% Foreign Financial Securities firms 0.6%	Breakdown of sharehold Financial institutions 0.7% Individual investors 94.6%	Constraints Securities firms 0.3% Other institut 1.2% Foreign investors 3.2%	tions
Paid-in Capital	¥6,457 million	Other institutions 15.0%	Treasury stock 0.0%		
Number of Shareholders	11,180				
Stock Exchange Listings	Tokyo and Osaka	Major Shareholders			ercentage of
Ticker Code	4536	Name		shares held	investment
Transfer Agent	Mitsubishi UFJ Trust and Banking Corporation	Japan Trustee Service Bank, Ltd.		12,388 Thousands of shares	14.3%
-	1-5, Dojimahama 1-chome, Kita-ku,	The Master Trust Bank of Japan, Lte	d.	6,308	7.3
	Osaka 530-0004, Japan	Mita Sangyo Co., Ltd.		4,756	5.5
Major Offices	Sendai, Tokyo, Saitama, Nagoya,	The Bank of Tokyo-Mitsubishi UFJ,	Ltd.	4,241	4.9
	Osaka, Hiroshima and Fukuoka	Nippon Life Insurance Company		3,017	3.5
Manufacturing Plants	Noto, Shiga and Osaka	Tokio Marine and Nichido Fire Insu	rance Co., Ltd.	2,668	3.1
Research Laboratory	Nara Research and Development Center	Trust and Custody Services Bank, L	td.	2,057	2.4
Number of Employees	2,690 (nonconsolidated: 1,908)	RBC Dexia Investor Services, Londo	on-lending account	1,905	2.2
Number of Shares Issued	86.916.203	DAIICHI SANKYO COMPANY, LIMI	1,642	1.9	
		ONO PHARMACEUTICAL CO., LTD		1,630	1.9

Note: Santen Pharmaceutical Co., Ltd. holds treasury stock (1,893 thousand shares), but is excluded from the major shareholders.

#### Stock Price Range Yen

Osaka Securities Exchange (monthly basis)



## Trading Volume Thousands of shares



## Yearly High and Low Prices

	2005	2006	2007	2008	2009
High (yen)	3,290	3,370	3,450	3,050	3,040
Low (yen)	2,050	2,440	2,480	2,125	2,460

Note: Calendar years. Stock prices for 2009 are for the period to the end of June.

# History

## Company History

1890	Founder Kenkichi Taguchi opens Taguchi Santendo in Kitahama, Osaka
1925 1936 1945	Operations incorporated as Santendo Co., Ltd. Yodogawa Plant established in Higashiyodogawa-ku, Osaka Head Office transferred to Yodogawa Plant (current site) Company name changed to Santendo Pharmaceutical Co., Ltd.
1958	Company name changed to current form of Santen Pharmaceutical Co., Ltd. Santen enters prescription pharmaceuticals business
1977 1982 1985	Stock listed on First Section of Tokyo Stock Exchange and Osaka Securities Exchange Production system introduced to allow filling of solution into molded containers to make bottle-packed eye drops Central Research Laboratories established Noto Plant established
1990	Long-term business vision formulated to mark centenary
1993 1994	Subsidiary Santen Inc. established in the U.S. Subsidiary Santen GmbH established in Germany
1996 1997 1998	Representative office established in Beijing, China Nara Research and Development Center and Shiga Plant established Finnish ophthalmics pharmaceutical company acquired and Santen Oy established Subsidiary Taiwan Santen Pharmaceutical Co., Ltd. established Medium-term Plan "Hitomi 21" formulated
2000 2001	Subsidiary Santen Pharmaceutical Korea, Co., Ltd. established Representative office established in Guangzhou, China U.Sbased Advanced Vision Science, Inc. acquired
2002	Introduced Dimple Bottle, an innovative patient-oriented container
2003	for ophthalmic solutions 2003–2005 Medium-term Management Plan Formulated ISO 14001 certification acquired by Noto Plant Santen Activity Improved Navigator (SAIN) medical information support system developed
2004	U.S. sales partnership with Johnson & Johnson Vision Care, Inc. (currently: VISTAKON Pharmaceuticals, LLC) started
2005	Representative office established in Shanghai, China Subsidiary Santen Pharmaceutical (China) Co., Ltd. established
2006	2006–2010 Medium-term Management Plan formulated
2007	Representative office established in Shenyang, China
2008	Santen Pharmaceutical (China) Co., Ltd. established Suzhou Plant Operations start up at Suzhou Plant, commencement of direct marketing Completion of pharmaceutical development building and ancillary building at Nara Research and Development Center

## Product History

1890s	Main product is Heburin-gan, a cold medicine
1899	Launch of Daigaku Eye Drops
1952 1953 1954 1956	Launch of <i>Daigaku Penicillin Eye Drops</i> Launch of <i>Daigaku Mycillin Eye Drops</i> Launch of <i>Daigaku Super Eye Drops</i> Launch of <i>Sante de U</i>
1962	Launch of <i>Mydrin-P</i> , a mydriatic drug (for pupil dilation) Launch of <i>Super Sante</i> marks first use of plastic eye drop containers in Japan
1963	Launch of Thiola, an original liver detoxification agent
1970 1975	Launch of antibiotic ophthalmic <i>Ecolicin</i> Launch of anti-inflammatory ophthalmic <i>Flumetholon</i>
1978 1981	Santen commences sales of medical devices Launch of <i>Timoptol</i> , a treatment for glaucoma
1985 1986 1987	Launch of <i>Sante 40 NE</i> Santen commences sales of intraocular lenses Launch of anti-infective ophthalmic <i>Tarivid</i>
1991	Launch of anti-rheumatic <i>Rimatil</i> Launch of <i>Sante FX</i>
1992	Launch of <i>BSS PLUS</i> , an ophthalmic perfusion and bathing solution Launch of <i>Kary Uni</i> , a treatment for early-stage senile cataracts
1995	Launch of <i>Hyalein</i> a drug for treating corneal and conjunctival epithelial disorders Launch of anti-allergy ophthalmic <i>Alegysal</i> Launch of anti-rheumatic <i>Azulfidine EN</i> Launch of <i>OPEGAN Hi</i> , an adjuvant for ophthalmic operations
1999	Launch of Timoptol XE, a treatment for glaucoma
2000	Launch of <i>Sante FX Neo</i> Launch of anti-infective ophthalmic <i>Cravit</i>
2001	Launch of <i>Detantol</i> , a treatment for glaucoma
2002	Launch of anti-allergy ophthalmic <i>Livostin</i> Launch of <i>Sante de U Plus E Alpha</i>
2003	Launch of <i>Sante 40</i> Launch of <i>ClariFlex</i> foldable intraocular lenses
2004	Launch of <i>Rescula</i> , a treatment for glaucoma Launch of anti-rheumatic <i>Metolat</i> e
2006	Launch of PAPILOCK Mini ophthalmic solution 0.1%, a treatment for vernal keratoconjunctivitis Launch of Sante Medical 10 Launch of Sante AL Cool II Launch of Sante Uruoi Contact a
2008	Launch of nutritional supplement Sante Lutax
	Launch of <i>Sante 40i</i> Launch of <i>Eternity</i> foldable intraocular lens Launch of <i>Tapros</i> , a treatment for glaucoma and ocular hypertension
2009	Launch of <i>Sante FX V Plus</i> Note: Based on the years when sales were launched by Santen Pharmaceutical.



www.santen.com

The following are registered trademarks of Santen's alliance partners: Cravit, Tarivid, Iquix, Oftaquix and Quixin (Daiichi Sankyo Company, Limited); Azulfidine (Pfizer Inc.); Alegysal (Mitsubishi Tanabe Pharma Corporation); ClariFlex (Advanced Medical Optics Inc.); Detantol (Eisai Co., Ltd.); Timoptol (Merck & Co., Inc.); Livostin (Johnson & Johnson); and Rescula (R-Tech Ueno).

