



SANTEN PHARMACEUTICAL CO., LTD.

Annual Report 2012

Year Ended March 31, 2012

A Global Perspective on R&D

C O N T E N T S

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).

Source: ©2012 IMS Japan

Santen analysis is based on IMS-JPM data from April 2007 to March 2012.

All rights reserved.

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.

1 Santen's Values

2 Realizing Santen's Values

6 Consolidated Financial Highlights

7 At a Glance

8 A Message from the President and CEO/Interview

14 **Special Feature:** **Promoting Globally Oriented R&D**

22 Pipeline of Prescription Pharmaceuticals

26 Review of Operations

26 Domestic Operations

32 Overseas Operations

34 Corporate Social Responsibility

38 Corporate Governance

42 Board of Directors, Corporate Auditors and Corporate Officers

43 Financial Section

79 Corporate Information/Stock Information

80 Business Bases

82 History



Santen's Values

Core Value

*Tenki ni sanyo suru*¹

We think carefully about what is essential, decide clearly what we should do, and act quickly.

Mission Statement

By focusing our efforts on ophthalmology and related areas, we develop scientific knowledge and organizational capabilities which are unique and original to Santen. We use our unique capabilities to contribute to patients and their loved ones, and consequently to society.

1. Santen's original interpretation of a passage from chapter 22 of *Zhongyong (The Doctrine of the Mean)* by Confucius, meaning "exploring the secrets and mechanisms of nature in order to contribute to people's health"

Santen's Values embody what the Company has continued to recognize as important since its foundation in 1890. Based on Santen's Values—the essence of which is "*tenki ni sanyo suru*"—we have put in place a virtuous cycle of creation and innovation while contributing to the protection and improvement of eyesight and health as a specialty company in the ophthalmic and anti-rheumatic fields. Building on the scientific knowledge and organizational capabilities that Santen has nurtured for over 120 years, the Company will continue to contribute to society, working primarily for the benefit of patients and their loved ones.



Our Long-Term Strategic Vision for 2020

**A Specialized
Pharmaceutical Company
with a Global Presence**

Fiscal 2011-2013 Medium-Term Management Plan

Strategic Objectives

1. Promote globally oriented research and development.
2. Obtain high domestic market share and achieve growth through the promotion of new products and implementation of marketing strategies.
3. Accelerate growth in both Asia and Europe by reinforcing marketing platforms.
4. Establish a global product supply system with our existing four plants¹, which enable us to meet emerging market needs.
5. Develop talents and organizational capabilities to promote “creation and innovation” on a global level.

1. Four plants: Noto and Shiga (both in Japan); Suzhou (China); Tampere (Finland)

Santen has set forth the goal of becoming a specialized pharmaceutical company with a global presence as its long-term strategic vision for 2020. To achieve this, we will deliver innovative products and services in the global ophthalmic pharmaceutical business to be a company trusted by patients and medical professionals. Santen is focusing its collective power to execute the Fiscal 2011–2013 Medium-Term Management Plan as the first step of its long-term strategic vision.



Further Information

P.8 A Message from the President and CEO

1 Santen's Business Domains

Japan's Market for
Disease-Modifying
Anti-Rheumatic Drugs

No.2

Prescription
Anti-Rheumatic
Pharmaceuticals

Over-the-Counter Pharmaceuticals

Medical Devices

Others



Ratio of Prescription
Ophthalmic Pharmaceutical
Business Sales
to Total Net Sales

Over 80%

Japan's Prescription
Ophthalmic
Pharmaceutical Market

No.1

MRs in Japan **Approx. 400**

The number of ophthalmologists in Japan is currently around 13,000. Santen's approximately 400-strong medical representative (MR) workforce strives diligently to call on virtually every one of Japan's ophthalmologists to provide detailed pharmaceutical information.

We are focusing our efforts on ophthalmology and related areas.

Since its foundation in 1890, Santen has continued to bolster its accumulated experience in the creation and innovation of products and services, consistent with "Santen's Values," and specialized in the prescription pharmaceutical business in the fields of ophthalmology and anti-rheumatics, growing into a company with a competitive edge. We will channel management resources into the specialized fields of ophthalmology and anti-rheumatics to create outstanding drugs and provide high-quality medical information based on market needs. In this way, we will build trust with physicians and patients so that we can enhance Santen's market reputation.



Further Information
P.26 Review of Operations



Made a Wholly Owned Subsidiary in January 2012

Novagali Pharma S.A.S.

Novagali is a French ophthalmic pharmaceutical company that conducts R&D for ophthalmic medicines. It has some of the few late-stage prescription ophthalmic pharmaceuticals in the dry eye field worldwide.

Research & Development
Clinical Development

Europe



Santen Oy (Finland)



Santen Inc.

U.S.

Clinical Development



Nara
Research and Development Center

Research & Development
Clinical development function
attached to head office

Japan

We develop scientific knowledge and organizational capabilities which are unique and original to Santen.

To date, Santen has conducted R&D activities leveraging the respective strengths of research bases in Japan, the U.S. and Europe. Under the Fiscal 2011–2013 Medium-Term Management Plan, we intend to strengthen R&D in the U.S. as the base for global clinical development, as we look to expand and enhance our late-stage pipeline. In January 2012, we made Novagali Pharma S.A.S. (Novagali) a wholly owned subsidiary, further increasing our potential in the dry eye domain, a mainstay area for us. Looking ahead, we will accelerate “creation and innovation” through the combination of new wisdom and organizational capabilities.



Further Information
P.14 Special Feature



Products Are Sold in
Over
50 countries

Annual Production Capacity of
Ophthalmic Solutions

Approx. **300** million bottles

Santen is steadily developing business overseas, with 13 bases in 10 countries at present.



Tafluprost, a glaucoma and ocular hypertension treatment, has expanded the boundary of sales to 51 countries. (As of August 1, 2012)

We use our unique capabilities to contribute to patients and their loved ones, and consequently to society.

Based on Santen's Values, the Company aims to contribute to the enhancement on a global basis of Quality of Life (QOL) for patients and their loved ones. In order to conduct business activities based on this principle, Santen has built a network of 13 operating bases across 10 countries to facilitate sales of products in over 50 countries worldwide. Direct promotional activities by our own sales force started in China in 2009 and in Korea in 2010. Stably supplying high-quality drugs to patients around the world, Santen produces around 300 million bottles¹ of ophthalmic solutions each year at four plants—in Noto, Shiga, Finland and China. That makes us a world leader in the production of ophthalmic solutions.

1. On a 5 mL bottle conversion basis



Further Information
P.32 Overseas Operations

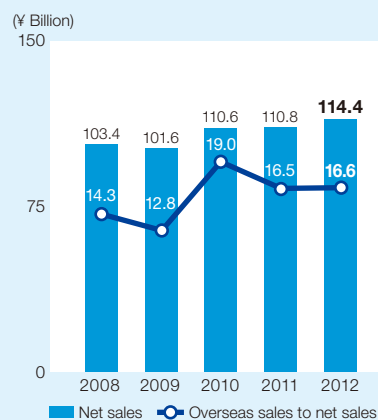
Consolidated Financial Highlights

Santen Pharmaceutical Co., Ltd. and Subsidiaries
Years ended March 31, 2012, 2011, 2010, 2009 and 2008

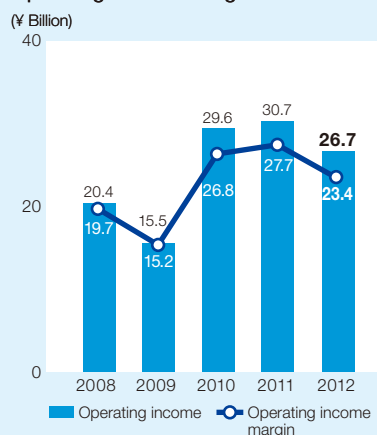
| | Millions of yen | | | | | Change | Thousands of U.S. dollars |
|---|-----------------|-----------|-----------|-----------|-----------|-----------|---------------------------|
| | 2012 | 2011 | 2010 | 2009 | 2008 | 2012/2011 | 2012 |
| For the year: | | | | | | | |
| Net sales | ¥ 114,416 | ¥ 110,812 | ¥ 110,594 | ¥ 101,619 | ¥ 103,394 | 3.3% | \$ 1,392,101 |
| Operating income | 26,732 | 30,739 | 29,640 | 15,494 | 20,371 | (13.0) | 325,260 |
| Net income | 17,161 | 21,333 | 18,723 | 10,123 | 12,651 | (19.6) | 208,796 |
| Comprehensive income | 16,966 | 19,797 | 18,826 | 4,896 | 9,663 | (14.3) | 206,435 |
| R&D expenditures | 17,225 | 13,221 | 14,123 | 18,458 | 12,942 | 30.3 | 209,580 |
| Capital expenditures | 3,281 | 1,651 | 1,315 | 2,953 | 3,151 | 98.7 | 39,915 |
| Depreciation and amortization | 2,949 | 2,976 | 3,421 | 4,210 | 4,593 | (0.9) | 35,886 |
| At year-end: | | | | | | | |
| Total assets | ¥ 198,801 | ¥ 184,801 | ¥ 166,878 | ¥ 151,012 | ¥ 156,547 | 7.6% | \$ 2,418,807 |
| Long-term debt | 179 | 152 | 75 | 154 | 5,278 | 17.5 | 2,184 |
| Equity | 164,514 | 156,099 | 137,343 | 125,181 | 126,998 | 5.4 | 2,001,637 |
| Per share data (yen and U.S. dollars): | | | | | | | |
| Net income – basic | ¥ 196.96 | ¥ 249.71 | ¥ 220.10 | ¥ 119.08 | ¥ 146.15 | (21.1)% | \$ 2.40 |
| Net income – diluted | 196.76 | 249.42 | 219.85 | 118.97 | 145.94 | (21.1) | 2.39 |
| Equity | 1,887.81 | 1,793.15 | 1,614.08 | 1,472.32 | 1,494.48 | 5.3 | 22.97 |
| Cash dividends, applicable to the period | 100.00 | 90.00 | 80.00 | 80.00 | 80.00 | 11.1 | 1.22 |
| Other financial data: | | | | | | | |
| Operating income margin (%) | 23.4 | 27.7 | 26.8 | 15.2 | 19.7 | | |
| Overseas sales to net sales (%) | 16.6 | 16.5 | 19.0 | 12.8 | 14.3 | | |
| R&D expenditures to net sales (%) | 15.1 | 11.9 | 12.8 | 18.2 | 12.5 | | |
| Return on equity (ROE) (%) | 10.7 | 14.5 | 14.3 | 8.0 | 9.9 | | |
| Dividend on equity (DOE) (%) | 5.4 | 5.3 | 5.2 | 5.4 | 5.4 | | |
| Number of employees | 3,053 | 2,867 | 2,756 | 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 ¥82.19 to U.S.\$1.00, the exchange rate prevailing on March 31, 2012.
2. See Notes 2, 15) and 13 of Notes to Consolidated Financial Statements in respect of per share data.
3. Figures in parentheses indicate a decrease.
4. Equity comprises shareholders' equity and accumulated other comprehensive income.

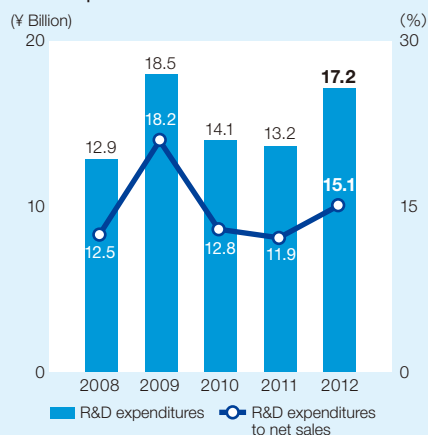
Net Sales and Overseas Sales to Net Sales



Operating Income and Operating Income Margin




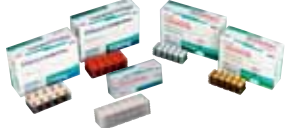


R&D Expenditures and R&D Expenditures to Net Sales



At a Glance

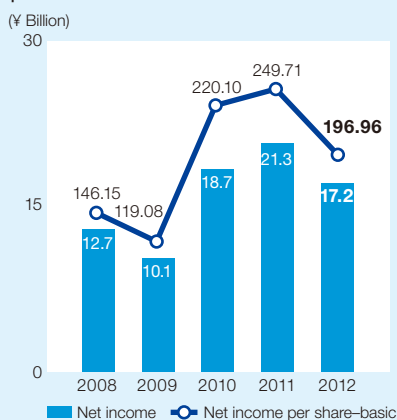
Sales Composition

Operations

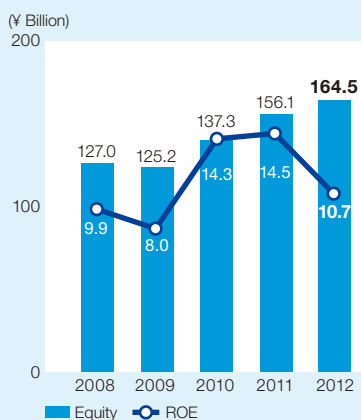
| | |
|---|---|
| <p>Prescription Ophthalmic Pharmaceuticals</p>  <p>81.8%</p> <p>Share of Japanese Market 36.1% Position in Japanese Market No.1¹</p> | <p>Domestic Operations</p> <ul style="list-style-type: none"> Approximately 400 medical representatives (MRs) implement promotional campaigns. Markets a broad range of ophthalmic pharmaceutical products, such as treatments for corneal and conjunctival epithelial disorders including dry eye, glaucoma, anti-infective ophthalmics and anti-allergy ophthalmics. We maintain market-leading positions. <p>Overseas Operations</p> <ul style="list-style-type: none"> Markets <i>Hyalein</i>, <i>Cravit</i> and <i>Tapros</i> (brand names differ according to region) and other products through sales networks in Europe and Asia. <p>Further Information P.26 Domestic Operations/Prescription Ophthalmic Pharmaceuticals P.32 Overseas Operations</p> |
| <p>Prescription Anti-Rheumatic Pharmaceuticals</p>  <p>8.7%</p> <p>Share of Japanese Market 41.0% Position in Japanese Market No.2¹</p> | <ul style="list-style-type: none"> In Japan, we offer <i>Rimatil</i>, <i>Azulfidine EN</i> and <i>Metolate</i>, the doctors' disease-modifying anti-rheumatic drugs (DMARDs)² of choice for treating rheumatoid arthritis (RA). <p>Further Information P.30 Domestic Operations/ Prescription Anti-Rheumatic Pharmaceuticals</p> |
| <p>Over-the-Counter Pharmaceuticals</p>  <p>4.0%</p> <p>Share of Japanese Market 19.6% Position in Japanese Market No.2³</p> | <ul style="list-style-type: none"> Markets eye drop brands in Japan, such as the <i>Sante FX</i> series, our core brand which has marked its 20th anniversary; the <i>Sante 40</i> series, which improves blurred vision; and the <i>Sante Medical</i> series, for tired eyes. <p>Further Information P.31 Domestic Operations/Over-the-Counter Pharmaceuticals</p> |
| <p>Medical Devices</p>  <p>2.2%</p> | <ul style="list-style-type: none"> In Japan, Santen handles medical devices used in cataract surgery, including the acrylic intraocular lenses <i>Eternity</i> and <i>Eternity Natural</i>. <p>Further Information P.31 Medical Devices</p> |
| <p>Others</p> <p>3.3%</p> | <ul style="list-style-type: none"> Including other pharmaceuticals and related products. |

Notes: 1. Market share and market position in Japan for the fiscal year ended March 31, 2012. The share and position for anti-rheumatic pharmaceuticals represent those in the DMARDs segment. Source: ©2012 IMS Japan
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 RA.
3. Market share and market position in the Japanese OTC eye drop market for the fiscal year ended March 31, 2012. Source: Santen Pharmaceutical Co., Ltd.

Net Income and Net Income per Share—Basic



Equity and ROE



Dividend per Share and DOE



A Message from the President and CEO



We are focusing the resources of Santen to secure sustainable growth as we work to realize our vision of becoming a specialized pharmaceutical company with a global presence.

Santen is tackling a variety of challenges as we seek to realize our long-term strategic vision of becoming a specialized pharmaceutical company with a global presence by 2020. Achieving this vision requires that we earn the trust of patients worldwide by supplying innovative drugs and related services based on a detailed understanding of market needs to build a strong corporate reputation in ophthalmology.

Today, it is ever more vital that we target areas of unmet medical needs as we aim to supply products and services that have been rapidly evaluated and developed in the global clinical setting. During the first year of our Fiscal 2011-2013 Medium-Term Management Plan, we tackled medium- to long-term business development issues and took a variety of steps such as strengthening our development pipeline, to realize our long-term strategic vision. In fiscal 2012, we will continue to focus our collective resources to secure sustainable growth.

As we endeavor to accomplish our goals, we kindly ask for the continued support of all stakeholders.

September 2012

A handwritten signature in black ink, which appears to read "A. Kurokawa".

Akira Kurokawa
President and Chief Executive Officer

Q How do you evaluate the first year of the Fiscal 2011–2013 Medium-Term Management Plan?

A We posted record net sales. We invested aggressively for future growth as well. Although this caused profits to dip, these investments will help us realize our vision of becoming a specialized pharmaceutical company with a global presence by 2020.

In line with the Fiscal 2011–2013 Medium-Term Management Plan, we made a number of capital investments in fiscal 2011 to secure medium- to long-term growth. We invested heavily in R&D and also invested resources to create a stronger operating platform, particularly in Europe and Asia. Sales grew steadily in Japan and in overseas markets in fiscal 2011; consolidated net sales increased 3.3% in year-on-year terms to ¥114.4 billion. Reflecting increases in R&D spending and selling, general and administrative expenses, operating income fell 13.0% to ¥26.7 billion and net income fell 19.6% to ¥17.2 billion.

Several new products drove growth in our prescription ophthalmics business. Our glaucoma and ocular hypertension treatment tafluprost (sold as *Tapros* in Japan), one of Santen's growth drivers, made steady market inroads and posted global net sales of ¥9,406 million, an increase of 14.9% over the prior year. Tafluprost was launched in the U.S. in March 2012 and is now sold in 51 countries¹ worldwide. Other new products that drove sales growth included *Cosopt*, our combination ophthalmic solution for glaucoma and ocular hypertension, and our treatment for dry eye, *Diquas* (diquafosol sodium).

We are investing actively in globally oriented R&D to accelerate the development of our late-stage clinical pipeline. In January 2012, we acquired French ophthalmic pharmaceutical company Novagali, thereby obtaining Cyclokot (cyclosporin), a late-stage drug that is expected to become the first prescription medicine in Europe for dry eye and the proprietary drug formulation technology Novasorb². We expect both Cyclokot and Novasorb to become powerful growth drivers for Santen.

We have also been focusing our efforts on alliance activities, including licensing. In May 2012, we signed a co-promotion agreement with Bayer Yakuhin, Ltd. covering VEGF Trap-Eye (aflibercept intravitreal injection), a treatment for wet age-related macular degeneration (wet AMD). Bayer Yakuhin has submitted an application for approval in Japan. This agreement covering the Japanese market is important

to Santen as a specialized company of ophthalmology because it strengthens our portfolio of retinal products and allows us to better meet patient needs and improve their quality of life.

1. Including sales based on licensing agreements with Merck & Co., Inc. of the U.S. (As of August 1, 2012)
2. Novasorb aids rapid absorption of ophthalmic solutions over the ocular surface by applying a positive electric charge to an ophthalmic emulsion. This causes the drug to be attracted to the negatively charged ocular tissues and helps to protect the eye's surface.

Improving Shareholder Returns

Santen has positioned the return of profits to shareholders as a key management priority. In order to ensure the continuous and stable payment of dividends to shareholders, the Company has adopted the dividend on equity (DOE) ratio, which multiplies the dividend payout ratio by ROE, as an indicator for determining dividends.

For fiscal 2011, we paid a full-year dividend of ¥100 per share, ¥10 higher than the dividend applicable to fiscal 2010. This resulted in a DOE of 5.4%, which means DOE has now exceeded 5.0% for 5 years in a row. In fiscal 2012, we remain committed to the stable return of profits to shareholders and a DOE of 5.0% or more. At the same time, we will continue to retain funds primarily for R&D investments, while adopting a flexible stance that includes the acquisition of treasury stock.

FY2011–2013 Medium-Term Management Plan Objectives and Progress

| | FY2011 | FY2013 Objectives |
|--------------------|----------------|----------------------|
| Net Sales | ¥114.4 billion | Over ¥121 billion |
| Operating Income | ¥26.7 billion | Over ¥31 billion |
| Net Income | ¥17.2 billion | Over ¥20 billion |
| R&D Expenditures | ¥17.2 billion | Around ¥15.5 billion |
| Dividend on Equity | 5.4% | Around 5% |

Q What progress have you made with the Fiscal 2011-2013 Medium-Term Management Plan? Please start by discussing research and development.

A We are promoting globally oriented R&D through a variety of initiatives, including the Novagali acquisition and other actions designed to reinforce our clinical development structure. We expect such measures to further accelerate drug development.

One of the core strategic objectives of the Fiscal 2011-2013 Medium-Term Management Plan is the promotion of globally oriented R&D. We tackled this challenge with a sense of urgency during the first year of the plan.

Under our globally optimized structure, our clinical development process through POC¹ is centered on the U.S., with late-stage clinical trials also conducted in Europe, Japan and Asia. Through this setup, we aim to achieve faster global clinical development of our development pipeline. We are conducting Phase 3 clinical trials in the U.S., EU, Japan and other areas for DE-109 (sirolimus), an immunosuppressant indicated for the treatment of uveitis, which has received an orphan drug² status by regulators in both the U.S. and Europe. We expect that this innovative drug will make a valuable contribution to improving the QOL of patients around the world that suffer from this rare disease.

The Novagali acquisition is a major step forward in business development terms. We have high expectations for the Novasorb formulation technology and a drug candidate that Novagali owns. These Novagali assets should be useful not only for creating new products, but also to enhance the value of Santen's existing product lineup. The purchase significantly improves our late-stage clinical development pipeline in the form of Cyclokot (ciclosporin), which is expected to be the first prescription treatment for dry eye in Europe, and Vekacia (ciclosporin) for the indication of vernal keratoconjunctivitis. These drugs both use Novasorb formulations.

Going forward, in addition to seeking to maintain and reinforce profitability through in-house drug discovery, we plan to invest aggressively in further development of our business such as the acquisition of actual pipelines, licensing and joint development.

1. Proof of Concept (POC) is the realization of a certain method or ideas to demonstrate feasibility or safety.
2. An orphan disease is one that only affects a relatively small number of patients. In the U.S., this criterion is set at fewer than 200,000 patients. Regulators worldwide support the development of orphan drugs in various ways.

Progress with R&D in Fiscal 2011 (As of August 1, 2012)

| | | |
|---|---|--|
| Corneal and Conjunctival Epithelial Disorders | DE-089 DE-101 | Approved (Korea), NDA Filed (China) Phase 2 (U.S.) |
| Glaucoma | DE-085 DE-117 DE-118 | Approved (Australia, U.S.) Phase 1/2a (U.S.) NDA Filed (Japan) |
| Retinal and Uveal Disorders | DE-102 DE-109 | Phase 2/3 (Japan) Phase 3 (Japan, Europe) |
| Ocular Infections | DE-108 | NDA Filed (Korea) |

Novagali's Pipeline of Prescription Pharmaceuticals

| | | |
|---|-----------------|------------------------------------|
| Corneal and Conjunctival Epithelial Disorders | Cyclokot | Phase 3 (Europe) Phase 2 (U.S.) |
| Allergy | Vekacia | Phase 3 (Europe) |

Note: Catioprost and Cortject are under project evaluation.

Q Next, please discuss sales and marketing, starting with the domestic business.

A We have sought to maximize the value generated by new products launched in the prior medium-term management plan. In the face of fierce competition, we must foster the evolution of a stronger sales organization capable of fulfilling more complex and diversified medical needs.

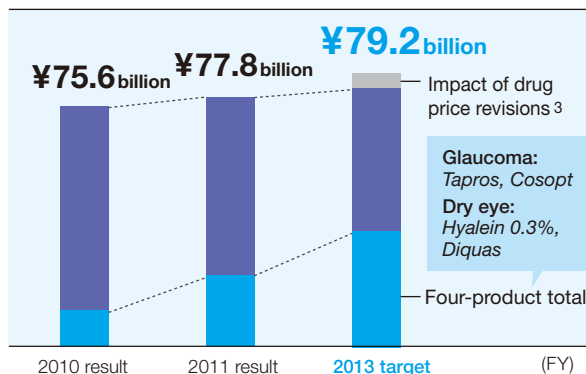
In a fiercely competitive marketplace, our aim is to forge a stronger Santen sales organization that can understand and respond appropriately to the changing needs of patients and medical professionals. This is based on medical detailing and other promotional activities to supply information on new or existing drugs.

In Japan, with the aim of generating further growth, our focus has been on sales promotion for new products that were launched during the previous medium-term management plan.

Our share of the glaucoma market increased to 28.4% in fiscal 2011, which was a 2.7-point increase over the prior year. Santen regained the No.1 position in glaucoma due to our success in maximizing the market value of *Tapros* and *Cosopt*. In corneal and conjunctival epithelial disorders, we strengthened Santen's market position by promoting the mainstay product *Hyalein* (sodium hyaluronate) while actively marketing *Diquas*, a new product with a novel mechanism of action. Our share of this market rose 1.5 points to 77.5% in fiscal 2011 based on increased sales.

Building a highly competitive product portfolio is vital to expanding business opportunities and realizing sustainable

Target Prescription Ophthalmic Pharmaceutical Sales in Japan



growth. Our co-promotion agreement with Bayer Yakuin, Ltd. for VEGF Trap-Eye, which is awaiting approval in Japan as a treatment for wet AMD, not only enriches our product portfolio, but will also enable us to fulfill unmet medical needs in the posterior segment of the eye.

3. Estimate when the Fiscal 2011-2013 Medium-Term Management Plan was released



Q Please discuss Santen's overseas operations. What progress are you making in developing the business platform in markets outside Japan?

A Our priority in overseas business development at present is to strengthen our existing operations in Asia and Europe. Using the expertise Santen developed in Japan as a specialty company, we are actively developing our business platform in markets we believe have growth potential.

Sales in Asia grew slightly in fiscal 2011 from the previous fiscal year to ¥6.7 billion. In China, a critical market in terms of our strategy to expand in the region, we maintained growth in line with our forecast despite a change in our distribution policy to reinforce our direct marketing system. In Korea, however, our sales fell due to significant cuts in NHI drug prices.

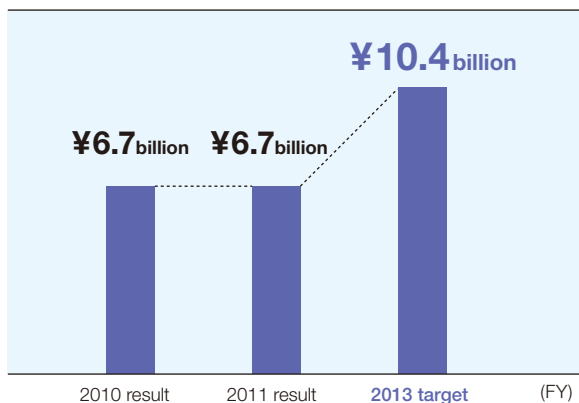
In China, a market which is a growth driver for Santen, we continued to strengthen our business platform based on the in-house production and direct marketing systems that we had set up under the previous medium-term management plan. We have expanded our sales force of local MRs and developed advanced detailing capabilities befitting a company that is a specialist in ophthalmic medicine. We also promoted our in-house sales team which is modeled on the doctor marketing¹ strategy that we pioneered in Japan. Since starting to export products to China in the 1980s, we have commanded a leading share of the market. We expect fast-growing China to lead the way in driving growth of around 20% in sales in Asia in fiscal 2012.

In Europe, we are steadily expanding our operations base both in developed country markets such as Germany, and emerging markets across Russia and Eastern Europe. In fiscal 2011, sales in Europe increased 4.3% to ¥8.9 billion despite the negative impact of the yen's appreciation against the euro. This reflected higher penetration in markets such as Germany for tafluprost, which we market in Europe under the brand name *Taflotan* as a treatment for glaucoma and ocular hypertension. In fiscal 2012, we expect to leverage the pipeline and proprietary drug formulation technology of Novagali to reinforce our development pipeline and help add more value to existing products. At the same time, we plan to boost Santen's competitiveness within Europe through region-wide marketing activities. In February 2012, we established Santen Holdings EU B.V. as a holding company for our existing subsidiaries in Europe with the aim of reinforcing governance functions and centralizing financial controls for

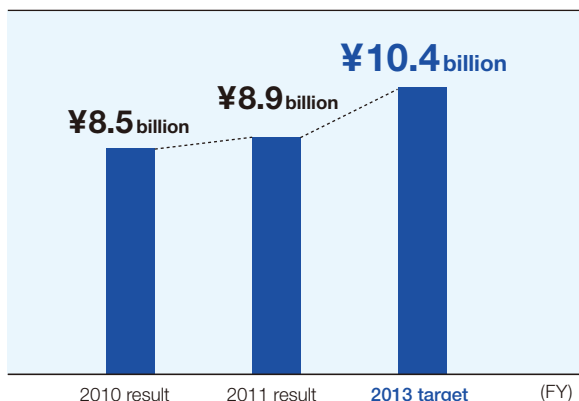
our operations in this region. We aim to create a highly profitable business in Europe through product portfolio management, including new product launches and changes to the product mix, our promotion strategy and other means.

1. Doctor marketing (DM) is a strategy original to Santen. Under this strategy, we provide solutions suited to the needs of each doctor and offer appropriate recommendations for prescriptions. This develops closer relationships with doctors and thereby secures a competitive advantage, which leads to favorable business results.

Target Sales in Asia



Target Sales in Europe



Q How is the development of the global manufacturing system progressing? What is Santen doing to strengthen its organization and develop human resources?

A We have been steadily preparing to begin integrated production at the Suzhou Plant in China as part of creating a highly competitive global manufacturing system. We are also actively seeking to foster a new corporate culture.

It is important for us to construct a system to supply high-quality products at competitive prices around the world in order to realize sustainable growth in a rapidly changing global pharmaceutical market.

Our global production system is based on four plants: the main factory in Noto, Japan; our core global facility in Shiga, Japan; and overseas plants in Suzhou, China and Tampere, Finland. These four facilities enable Santen to maintain stable supplies and high-level quality control while also supplying the needs of different regions. We plan to commence integrated production at Suzhou in fiscal 2012 including filling and packing. We continue to build a highly competitive globalized product supply system based on optimal usage and rationalization of our global production capabilities.

We are also investing in a stronger organization and the development of human resources. We recognize the urgent

need to foster globally capable leaders to support Santen's medium- and long-term growth and business expansion. We started formulating HR development performance goals for Santen worldwide in fiscal 2011 and began building related systems. We have also created an internal "Vision Caravan" communications initiative to deepen employees' understanding of our long-term strategic vision for 2020 and the medium-term management plan. I have been involved personally in fostering a direct dialogue with employees in Japan and overseas about related business issues and goals so that everyone in Santen has a better understanding of what we are trying to do and the challenges we face. This will foster the motivation to take action and cultivate change. We will continue to promote active dialogue involving managers and employees on how we realize our business vision.

Q How does Santen approach Corporate Social Responsibility activities?

A We see maintaining a constant supply of the products demanded by patients and medical professionals as the core of Santen's commitment to CSR. We are also actively engaged in CSR activities. This includes responding to large-scale natural disasters as well as undertaking social and environmental activities.

We believe our business operations constitute CSR activities because their goal is to supply products and services that enhance quality of life for patients worldwide, based on Santen's Values.

In promoting CSR activities, we work to enhance employee understanding of Santen's Values and the Santen Corporate Ethics Mission that we expect people in Santen to uphold, since these concepts underpin our business activities. Employees acting ethically and with integrity are the foundation of Santen fulfilling its social responsibility, in my view. We have also incorporated the internationally recognized social responsibility standard ISO 26000 into our approach so that stakeholders can feel confident that we are focused on meeting global standards in this area.



Special Feature

Promoting Globally Oriented R&D

The promotion of globally oriented research and development is a strategic objective of Santen's Fiscal 2011–2013 Medium-Term Management Plan. Under this plan, Santen is accelerating initiatives aimed at furthering Santen's Values, contributing to society by helping patients and their loved ones. This feature section reviews various fiscal 2011 achievements and looks at the creativity and strengths of R&D activities that make Santen a specialized pharmaceutical company with a global presence.



A Global Perspective on R&D

In pursuit of our long-term strategic vision, we aim to bring products tailored to unmet medical needs to the global market as fast as possible.



Toshiaki Nishihata, Ph.D.

Director
Executive Corporate Officer,
U.S. and Europe Business,
Head of Research and Development Division

Developing Competitive New Drugs Based on Global Medical Needs

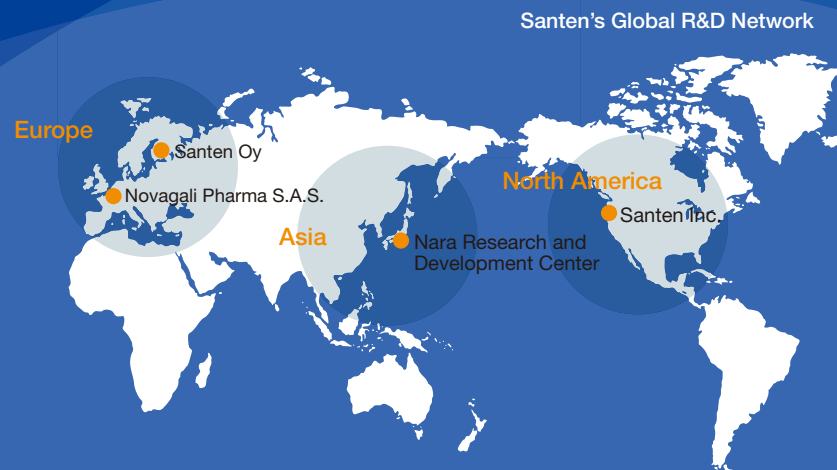
Santen strives to create outstanding pharmaceuticals that fulfill unmet medical needs in a timely manner. To this end, we engage in research and development focusing mainly on the ophthalmic and anti-rheumatic fields. While doing so, we harness our inherent strengths and maintain a basic R&D

policy of channeling management resources into fields that we believe offer the promise of future growth.

In the ophthalmic field in particular, there is strong demand for the early development of effective new drugs focusing mainly on such areas as corneal disorders, where treatments are yet to be fully developed from a global perspective, as well as glaucoma and retinal disorders, where the number of patients is increasing due to population aging and other factors. By promptly addressing this need, we are committed to enhance the quality of life (QOL) of patients worldwide.

To fulfill unmet medical needs, it is critical that we have a good understanding of current treatment conditions in the clinical setting. In the ophthalmic clinical setting, medical treatments are tailored to details such as the symptoms and medical histories of patients. We must grasp the status of current treatments so we can pinpoint where medical needs are not being met and understand what characteristics new drugs need to differentiate them from existing therapies. In order to grasp the status of current treatments in the clinical setting, we continue to develop a framework with strong connections from basic research to clinical development and marketing.

The most important points are to re-examine current treatment conditions, and to deeply understand the needs of patients and doctors.



Research Activities That Harness the Inherent Strengths of a Specialized Company

Santen engages in proprietary discovery research as well as the development of ophthalmic formulations of systemic drugs. We are enriching our development pipeline, centered on three fields (corneal disorders, glaucoma and retinal disorders) while building on our accumulated ophthalmic research capabilities to further enhance the quality, volume, and speed of our R&D activities.

As one example, Santen works to discover new compounds using its own research capabilities while also proceeding in parallel with a unique method called “network-based drug discovery,” which involves effectively utilizing external resources. This method of drug design takes simultaneous advantage of our considerable accumulated specialist knowledge and drug formulation technologies as a specialized ophthalmic company as well as leading-edge technologies from other pharmaceutical companies and research institutions. Through this approach, the potential for the early discovery of effective new compounds increases significantly. In addition, as a network-based drug discovery innovation in technology, Santen has identified the significant goal of developing medicines that retain their efficacy over longer periods by utilizing drug formulation technologies including drug delivery systems (DDSs)¹. Currently, Santen is developing DE-102 (betamethasone), a drug candidate in the retinal disorder field that will provide sustained release while working in collaboration with other companies with respect to the development of formulation technologies that incorporate the DDS concept.

Furthermore, by leveraging drug formulation and other production technology, we are working to expand drug indications and to improve formulation,



usage and dosage. This is part of a more proactive life cycle management² approach for products aimed at making more effective use of existing compounds. Among other advantages, it should result in increased therapeutic options for medical professionals and patients.

1. A system (technology) for ensuring that drugs reach the targeted tissue site.
2. Aligning one compound to treatment needs over the long term and augmenting through variations in use, dosage, formulation and combination products to increase product value.

Measures to Enrich the Development Pipeline

Enriching our development pipeline, discovering new drugs in a timely manner and successfully launching them is essential as we work towards realizing the long-term strategic vision of being a specialized pharmaceutical company with a global presence by fiscal 2020.

In R&D, under the Fiscal 2011–2013 Medium-Term Management Plan, we aim to invest actively in clinical development to enrich our product pipeline. We are also putting emphasis on activities for reinforcing our drug-discovery capabilities through the acquisition of external resources.

We took a major step forward during fiscal 2011 with the acquisition of the French ophthalmic pharmaceutical company Novagali. Besides drug formulation technology, including Novasorb technologies, Novagali provides Santen with Cyclokat (cyclosporin), which is in Phase 3 clinical trials for dry eye. Cyclokat is positioned to be Europe's first prescription drug treatment for dry eye. Going forward, we plan to reinforce our development pipeline for dry eye further. The Novagali acquisition should help us achieve increased synergies and improve the competitiveness of our existing products.





Reinforcing the Clinical Development System

In fiscal 2011, Santen shifted its global clinical development base from Japan to the U.S. In specific terms, the process through to POC³ establishment will first be undertaken mainly in the U.S. Then we will pursue late-stage clinical development which is based on the characteristics of new drug candidate compounds and the needs of each market. We also plan to oversee efforts aimed at strategically augmenting Santen's product lineup in accordance with individual regional needs.

With the differences in pharmaceutical approval systems between the U.S. and Japan, it is generally possible to shorten the time required for certain clinical development stages in the U.S. where the relevant authorities also promote adaptive design⁴. We can also get higher returns on our investment in clinical development in the U.S. because we can typically receive earlier regulatory input on the balance between clinical efficacy and risk for

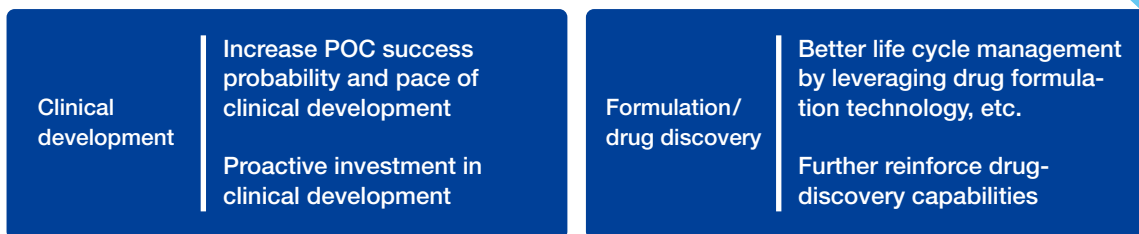
development compounds. We received orphan drug status⁵ in a short time in the U.S. and Europe for DE-109 (sirolimus) for uveitis that is currently in Phase 3 clinical trials in the U.S., Japan and Europe.

Santen Inc., the core Group U.S. subsidiary for global clinical development, moved its head office in July 2011 to Emeryville, California, a suburb of San Francisco. We have made progress in hiring specialists familiar with clinical development in the U.S. and highly talented people with ophthalmology qualifications. The new, restructured organization is also much stronger. We are seeking to make clinical development faster and more efficient, based on a solid grasp of current treatment conditions and the participation of people with strong connections to the ophthalmology community.

3. Proof of Concept (POC) is the realization of a certain method or idea to demonstrate feasibility or safety in clinical trials.
4. An adaptive design allows modifications to be made to the procedures of ongoing clinical trials based on accrued data without impacting trial validity and integrity.
5. An orphan disease is one that only affects a relatively small number of patients. In the U.S., this criterion is set at fewer than 200,000 patients. Regulators worldwide support the development of orphan drugs in various ways.

FY2011-2013 Medium-Term Management Plan R&D Strategy

Promoting Globally Oriented R&D



Main achievements in fiscal 2011



Promotion
of Global
Clinical
Development

We are promoting clinical development on a global basis to hasten delivery of drugs that will fulfill unmet medical needs.

Reinforcing the Late-Stage Clinical Pipeline to Support Continuous Growth

Under the Fiscal 2011–2013 Medium-Term Management Plan, we are increasing our investment in the late-stage clinical pipeline so that Santen can achieve continuous future growth. The pipeline is expanding steadily as a result.

In the field of glaucoma, we are conducting Phase 3 clinical trials in Japan and Europe with DE-111 (tafluprost/timolol maleate), a combination drug. We filed an NDA in Japan in February 2012 to gain manufacturing and marketing approval for DE-118 (tafluprost) in a preservative-free, unit-dose, single-use formulation. In the field of retinal disorders, we have begun Phase 3 clinical trials in Europe with DE-109 (sirolimus); we were already conducting clinical trials in the U.S. and Japan. In the field of ocular infections and allergy, DE-114 (epinastine HCl) is in Phase 3 clinical trials in Japan. With these and other developments, we are thus making steady progress with late-stage clinical development.

The acquisition of Novagali also means that we have two further compounds in Phase 3 clinical trials in Europe. These are Cyclokot (ciclosporin), a treatment for severe dry eye, and Vekacia (ciclosporin), which is indicated for vernal keratoconjunctivitis. Together these drugs have further enhanced our late-stage clinical development pipeline.



Accelerated Global Clinical Development Based on New and More Efficient System



Akihiro Tsujimura

President & CEO, Santen Inc.

Since fiscal 2011, Global Clinical Development & Medical Affairs, headquartered in the U.S. has played a central role in promoting globally oriented clinical development. To improve efficiency, new decision-making processes, new clinical study planning tools, drug safety systems and access to information have been established.

In order to meet needs globally, as well as a desire to engage regulators, ophthalmologists, and our patients, we have hired experts with strong experience and interest in clinical operations, ophthalmic clinical sciences/disease areas, biostatistics and data management, and drug safety. This will help us to respond to regulatory issues and enable us to take the initiative in negotiating with potential partners. Our U.S. operations are providing strong leadership in promoting our global clinical development programs.

Going into fiscal 2012, a key challenge is to assess the product value of the development pipeline. With a better understanding of unmet medical needs, as well as a good grasp of the pathobiology of ophthalmic diseases, we hope to improve the chances of technical success in late-stage clinical development and life cycle management of our products. To supplement in-house research, we must still aim to in-license more drugs from external partners or sourced from the compound libraries of research institutions so that we can expand the number of early-stage compounds. We will continue to try to accelerate clinical development by tapping our human capital and seeking to exploit the potential of our more efficient organization.

Accelerating Clinical Development with New Thinking and Methods



Naveed Shams, M.D. Ph.D.

Head of Global Clinical Development & Medical Affairs,
Global R&D Division
Vice President, Santen Inc.

One of our most significant achievements in fiscal 2011 in terms of promoting Santen's global clinical development program was the approval of orphan drug status by regulators in the U.S. and Europe for DE-109, which we are developing in the U.S. and Japan for the indication of non-infectious posterior uveitis.

DE-109 is currently the subject of a Phase 3 clinical study known as SAKURA¹. The main issue with the development of orphan drugs is that the number of patients with the disease in question is small, meaning that it takes time to enroll patients in clinical trials. We have solved this issue by conduct-

ing global clinical trials at 140 sites in some 70 countries. We are monitoring the data collected in each country in real time so that we can respond quickly if any related issues arise.

Santen has taken up the challenge of trying to foster "creation and innovation." Santen Inc. has cultivated a talented workforce that shares this vision. We remain committed to doing our utmost to realize this vision based on fulfilling the potential of every individual.

1. Study Assessing double-masked Uveitis tReAtment

DE-109 Phase 3 clinical trials

SAKURA Study

The enrollment of about 500 uveitis patients for the SAKURA Phase 3 study began in May 2011. This multinational, multicenter, randomized, double-masked trial is assessing the safety and efficacy of three different doses of DE-109 (sirolimus).

Message.....

A Shared Determination with Colleagues Worldwide to Help Uveitis Patients

I am extremely honored to be involved in Santen's Global Clinical Development programs. It is very exciting to know that each one of us can significantly contribute to assist the Company to reach our Vision 2020 Goal. DE-109 is an important global development project for Santen that focuses on a disease state with a worldwide patient population that is greatly underserved. The potential for

DE-109 to provide a beneficial therapeutic option for a sight-threatening disease and improve patient quality of life on a global scale is very exciting. Each investigator we interact with reminds us of the importance of the work we are doing on a daily basis to develop new products that will have a positive impact for patients.



Laura Wilson, M.D.

Head of Retina, Medical Monitor DE-109,
Global Clinical Development and Medical Affairs,
Santen Inc.

Acquisition and integration of Novagali to enhance Santen's external collaborative links and strengthen R&D functions.

Linking Santen's Knowledge and Expertise with Advanced External Technology

To globally create a succession of new drugs tailored to medical needs, we are pursuing a proactive business development program aimed at in-licensing promising compounds from outside and using a "network-based drug discovery" approach to supplement our in-house drug discovery programs. We are also using original formulation technology to develop the value of active ingredients of compounds where Santen already owns relevant intellectual property.

Joint Development Agreement for Glaucoma and Ocular Hypertension Treatment DE-117

DE-117 is an EP2 agonist¹ that was licensed in from Ube Industries, Ltd. Recent ophthalmic research has demonstrated that EP2 agonists can lower intraocular pressure with a high degree of efficacy. They offer a possible alternative to existing treatments for glaucoma because they possess a different mechanism of action.

Santen and Ube concluded an in-licensing and joint development agreement for DE-117 in October 2011 that grants Santen the right to develop, manufacture and commercialize the drug on a global basis as an ophthalmic solution for treating ocular diseases such as glaucoma and ocular hypertension. Phase 1 and Phase 2a clinical trials began in the U.S. in July 2012. Santen and Ube will collaborate in developing this prostaglandin derivative treatment with a novel mechanism of action with the aim of securing manufacturing and marketing approval worldwide.

1. A molecule that promotes the activity of a prostaglandin E2 receptor subtype.



The Nara Research and Development Center plays a central role in R&D.



Acquisition and Integration of Novagali, Owner of Proprietary Technology in Dry Eye Field

In September 2011, Santen announced an agreement to acquire French ophthalmic pharmaceutical company Novagali, which became a 100% subsidiary of Santen in January 2012. Novagali conducts R&D of prescription ophthalmic pharmaceuticals in dry eye and other fields, and has world-class R&D capabilities and drug formulation technology. We expect its proprietary formulation technology called Novasorb to play a particularly valuable role in the development of ophthalmic medicines.

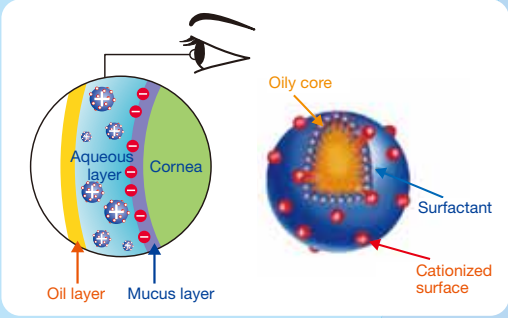
Ophthalmic solutions work best when the active ingredient is water-soluble. Recently, however, increasing numbers of drugs have poor solubility in water. The application of Novasorb formulation technology promises to improve ocular absorption of such drugs. This could be valuable not only with newly discovered compounds, but also help to boost the value of existing products.

Cationorm, an OTC dry eye treatment using Novasorb technology, has already been launched in around 10 countries in Europe, Southeast Asia and North America. Santen plans to use its strong local sales network to expand sales of this product within Europe, especially in Eastern Europe, Northern Europe and Russia.

Acquisition of Late-Stage Drugs Expected to Become First Prescription Medicines for Dry Eye in Europe

Only four prescription drugs are available worldwide for dry eye, including Santen's products *Hyalein* (sodium hyaluronate) and *Diquas* (diqafosol sodium). In Europe, no prescription dry eye treatments are available. Cyclokot, which uses Novasorb technology, is in Phase 3 clinical trials in Europe for the indication of severe dry eye. Phase 2 clinical trials involving Cyclokot are also underway in the U.S. If manufacturing and marketing approval is obtained in Europe, Cyclokot would become the first prescription medicine sold in Europe for treatment of dry eye. This would go a long way to helping meet unmet medical needs among dry eye sufferers.

Novagali is also in Phase 3 clinical trials in Europe with a Novasorb formulation of Vekacia for the indication of vernal keratoconjunctivitis.



What Is Novasorb Technology?

Novasorb enables the creation of cationic (positively charged) ophthalmic emulsions, which are more easily absorbed into the eye due to attraction to the negatively charged ocular surface. Novasorb solutions also protect and heal the ocular surface. This boosts the clinical effect (improves the ocular absorption of drugs with poor solubility in water), lowers the dosage frequency, and reduces side effects. These benefits are expected to make drugs using Novasorb technology more convenient for patients. This new technology has potential applications in treatments for many ophthalmic conditions, including dry eye, allergies and glaucoma.

Message

Taking on Greater Challenges with Global Links

The beauty of Novasorb's proprietary technology lies in ophthalmic emulsions which are positively charged. When applied, the positively charged emulsion oily droplets are strongly attracted to the negatively charged ocular surface, quickly spreading over the eye while permeating through the oil layer and the aqueous layer down to the mucin layer, the deepest layer of the tear film, thereby exerting high efficacy. In addition, the oily components contained in the emulsion are recognized as having a protective effect on the ocular surface.

Santen has a broad portfolio of superior

compounds such as tafluprost. A global initiative known as FIT¹ was launched to leverage this portfolio along with all human resources and technologies such as Novasorb to develop value-added products. We expect these growing global links to produce innovation and success.

1. [Formulation Innovation Team](#)

Jean-Sébastien Garrigue, Pharm.D.

R&D Pharmaceutical Director,
Novagali Pharma S.A.S.



Corneal and Conjunctival Epithelial Disorders

| Dev. Code | Generic Name | Indication | Original / Licensor | Region | Phase | | | NDA Filed | Approved |
|---------------|-------------------|--|---------------------|------------------------|--------------------------|---|---|-----------|-------------------------|
| | | | | | 1 | 2 | 3 | | |
| DE-101 | Rivoglitazone | Corneal and conjunctival epithelial disorder associated with dry eye, etc. | Daiichi Sankyo | U.S. | [Phase 1-3 progress bar] | | | | |
| DE-105 | Undetermined | Persistent corneal epithelial defects | Original | U.S. | [Phase 1-3 progress bar] | | | | |
| | | | | Japan | [Phase 1-3 progress bar] | | | | |
| DE-089 | Diquafosol sodium | Dry eye | Inspire | Japan | [Phase 1-3 progress bar] | | | | Launched, December 2010 |
| | | | | Asia (excluding Japan) | [Phase 1-3 progress bar] | | | | December 2011 |
| | | | | China | [Phase 1-3 progress bar] | | | | January 2012 |

Glaucoma

| Dev. Code | Generic Name | Indication | Original / Licensor | Region | Phase | | | NDA Filed | Approved |
|---------------|--------------------------------|---------------------------------|------------------------------------|------------------------|--------------------------|---|---|-----------|-------------------------------------|
| | | | | | 1 | 2 | 3 | | |
| DE-085 | Tafluprost | Glaucoma Ocular hypertension | Co-development with Asahi Glass | Japan | [Phase 1-3 progress bar] | | | | Launched, December 2008 |
| | | | | Europe | [Phase 1-3 progress bar] | | | | Launched, June 2008 |
| | | | | U.S. | [Phase 1-3 progress bar] | | | | (License out) Launched, March 2012 |
| | | | | Latin America | [Phase 1-3 progress bar] | | | | (License out) Launched, August 2010 |
| | | | | Asia (excluding Japan) | [Phase 1-3 progress bar] | | | | Launched, March 2010 |
| | | | | China | [Phase 1-3 progress bar] | | | | January 2011 |
| DE-111 | Tafluprost/ timolol maleate | Glaucoma Ocular hypertension | Co-development with Asahi Glass | Japan | [Phase 1-3 progress bar] | | | | |
| | | | | Europe | [Phase 1-3 progress bar] | | | | |
| DE-117 | Undetermined | Glaucoma Ocular hypertension | Co-development with Ube Industries | U.S. | [Phase 1-3 progress bar] | | | | |
| DE-118 | Tafluprost | Glaucoma Ocular hypertension | Co-development with Asahi Glass | Japan | [Phase 1-3 progress bar] | | | | February 2012 |
| DE-090 | Lomerizine HCl | Glaucoma | MSD ¹ | Japan | [Phase 1-3 progress bar] | | | | |

1. Formerly Banyu Pharmaceutical

As of August 1, 2012

DE-101 (generic name: rivoglitazone)

A PPARgamma agonist which is thought to improve the condition, quality and volume of tear film. DE-101 is in Phase 2 clinical trials in the U.S.

DE-105 (generic name: undetermined)

A new drug candidate that is expected to provide high levels of safety for persistent corneal epithelial defects compared with existing therapy, DE-105 helps repair corneal epithelial defects by accelerating corneal epithelial migration. Phase 2 clinical trials are being conducted in Japan with preparations being made for Phase 2 clinical trials in the U.S.

DE-085 (generic name: tafluprost)

A prostaglandin derivative for the treatment of glaucoma and ocular hypertension, DE-085 increases uveoscleral outflow of the aqueous humor and shows a potent and stable IOP-lowering effect. DE-085 was launched in Germany in June 2008 and in Japan in December 2008. It is currently directly marketed in 23 countries throughout Europe as well as in Asia—beginning with Hong Kong in March 2010, Korea in May 2010, and Indonesia and Singapore in 2011. An NDA has been filed in China. A licensing agreement with U.S.-based Merck & Co. was concluded in April 2009 that granted sales rights in Western Europe (excluding Germany), North America, South America and Africa. Tafluprost has been marketed by Merck & Co. in a total of 23 countries including the United Kingdom, Spain, Italy and the U.S. since September 2009. Incorporating sales under this licensing agreement, tafluprost is currently sold in a total of 51 countries worldwide.

DE-111 (generic name: tafluprost / timolol maleate)

A combination prostaglandin derivative and beta-adrenergic receptor blocker drug for the treatment of glaucoma and ocular hypertension, DE-111 is in Phase 3 clinical trials in Japan and also in Europe.

DE-089 (generic name: diquafosol sodium)

A treatment for dry eye that stimulates the ocular surface to secrete mucin and tear fluid, DE-089 offers a different mechanism of action from the existing ophthalmic solution *Hyalein* (sodium hyaluronate). It was launched as a dry eye treatment in Japan under the name *Diquas* in December 2010. Manufacturing and marketing approval was received in Korea in December 2011. An NDA has been filed in China.

DE-117 (generic name: undetermined)

A prostaglandin EP2 agonist with a new mechanism of action. DE-117 is in Phase 1 and Phase 2a clinical trials in the U.S.

DE-118 (generic name: tafluprost)

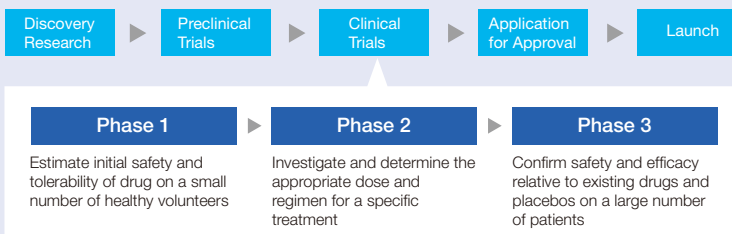
A prostaglandin derivative for the treatment of glaucoma and ocular hypertension, DE-118 is a preservative-free, unit-dose, single-use type product. An application has been filed in Japan for manufacturing and marketing approval.

DE-090 (generic name: lomerizine HCl)

A new type of glaucoma treatment which inhibits the progression of visual field defects, DE-090 is in Phase 2 clinical trials conducted in Japan. It is the only calcium antagonist being developed as an oral glaucoma treatment. Compared to NMDA receptor antagonists, systematic adverse drug reactions are mild, offering an excellent safety profile. The compound is also marketed by MSD K.K. in Japan as a migraine treatment drug.

About Research and Development

After passing preclinical trials for safety and efficacy, new drug candidates are put through the clinical trial phases outlined on the right. Upon receiving manufacturing and marketing approval, they can be sold as prescription pharmaceuticals.



Retinal and Uveal Disorders

| Dev. Code | Generic Name | Indication | Original / Licensor | Region | Phase | | | NDA Filed | Approved |
|---------------|---------------|---|-----------------------------|--------|-------|---|---|-----------|----------|
| | | | | | 1 | 2 | 3 | | |
| DE-102 | Betamethasone | Macular edema secondary to diabetes and BRVO ¹ | Co-development with Oakwood | Japan | | | | Phase 2/3 | |
| | | | | U.S. | | | | | |
| DE-109 | Sirolimus | Uveitis | Original | Europe | | | | | |
| | | | | Japan | | | | | |

1. BRVO: branch retinal vein occlusion

Ocular Infections/Allergy

| Dev. Code | Generic Name | Indication | Original / Licensor | Region | Phase | | | NDA Filed | Approved |
|---------------|---------------------|--------------------------|-----------------------------|--------|-------|---|---|-----------|---------------------|
| | | | | | 1 | 2 | 3 | | |
| DE-108 | Levofloxacin (1.5%) | Bacterial conjunctivitis | Daiichi Sankyo | Japan | | | | | Launched, June 2011 |
| | | | | Asia | | | | | |
| DE-114 | Epinastine HCl | Allergic conjunctivitis | Nippon Boehringer Ingelheim | Japan | | | | | |

Novagali's Pipeline of Prescription Pharmaceuticals

| Dev. Code | Generic Name | Indication | Original / Licensor | Region | Phase | | | NDA Filed | Approved |
|-------------------|-------------------------|---------------------------------|---------------------|--------|-------|---|---|-----------|----------|
| | | | | | 1 | 2 | 3 | | |
| Cyclokat | Ciclosporin | Severe dry eye | Original | Europe | | | | | |
| | | | | U.S. | | | | | |
| Vekacia | Ciclosporin | Vernal keratoconjunctivitis | Original | Europe | | | | | |
| Catioprost | Latanoprost | Glaucoma Ocular hypertension | Original | Europe | | | | | |
| Cortiject | Dexamethasone palmitate | Diabetic macular edema | Original | U.S. | | | | Phase 1/2 | |

*Catioprost and Cortiject are under project evaluation

Rheumatoid Arthritis

| Dev. Code | Generic Name | Indication | Original / Licensor | Region | Phase | | | NDA Filed | Approved |
|---------------|--------------|----------------------|---------------------|--------|-------|---|---|-----------|----------|
| | | | | | 1 | 2 | 3 | | |
| DE-098 | Undetermined | Rheumatoid arthritis | Janssen Biotech | Japan | | | | | |

As of August 1, 2012

DE-102 (generic name: betamethasone)

A steroid microsphere product for sustained release injection, DE-102 is in Phase 2 and Phase 3 clinical trials in Japan as a treatment for macular edema secondary to diabetes and BRVO¹. Animal studies demonstrated sustained efficacy when injected around the affected area. Santen is collaborating with Oakwood Laboratories of the U.S. in the development of the microsphere delivery platform for this product.

1. BRVO: branch retinal vein occlusion

DE-108 (generic name: levofloxacin (1.5%))

A fluoroquinolone antibacterial agent with higher concentration, DE-108 was launched in Japan in June 2011 as an indication for bacterial conjunctivitis under the name *Cravit Ophthalmic Solution 1.5%*. An application has been filed in Korea for manufacturing and marketing approval.

DE-114 (generic name: epinastine HCl)

An H₁ receptor antagonist with membrane-stabilizing function as a treatment for allergic conjunctivitis, DE-114 was licensed from Nippon Boehringer Ingelheim Co., Ltd. and is currently in Phase 3 clinical trials in Japan.

Cyclokot (generic name: ciclosporin)

This is a topical ophthalmic emulsion which improves symptoms and signs of severe dry eye by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. It is currently in Phase 3 clinical trials in Europe and Phase 2 clinical trials have been completed in the U.S.

Vekacia (generic name: ciclosporin)

This is a topical ophthalmic emulsion which improves vernal keratoconjunctivitis symptoms by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. It is in Phase 3 in Europe.

DE-098 (generic name: undetermined)

A joint injection that induces apoptosis in diseased joints of rheumatoid arthritis patients, DE-098 is an anti-APO-1 antibody in-licensed from Janssen Biotech, Inc. for the treatment of rheumatoid arthritis. We are currently considering the next development plan based on the results of Phase 2 clinical trials in Japan.

Responding to Unmet Medical Needs

Development of Therapy for Orphan Disease Uveitis

The uvea is the vascular middle layer of the eye that connects the iris at the front to the ciliary body and choroid toward the back of the eye. Uveitis covers a range of conditions. The development indication for DE-109 of “non-infectious posterior uveitis” is an orphan disease for which there are currently few therapeutic options.

DE-109 (generic name: sirolimus)

An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. In June 2010, Santen acquired global rights from U.S.-based MacuSight, Inc. for the development, manufacturing, and marketing of sirolimus. Phase 3 clinical trials have now begun in Europe; Phase 3 clinical trials were already underway for uveitis in the U.S. and Japan.

Catioprost (generic name: latanoprost)

This is a topical ophthalmic emulsion of a prostaglandin F_{2α} derivative, for the treatment of glaucoma and ocular hypertension. It is currently under project evaluation.

Cortiject (generic name: dexamethasone palmitate)

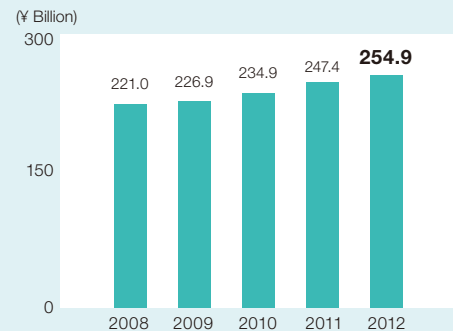
An intravitreal injection with anti-inflammatory effect. It is currently under project evaluation.

[Domestic Operations]

Prescription Ophthalmic Pharmaceuticals

The Japanese prescription ophthalmic pharmaceuticals market grew 3.1%, to ¥254,899 million in fiscal 2011, due to growth in sales of products for retinal disorders and corneal and conjunctival epithelial disorders. Amid these market conditions, Santen's domestic prescription ophthalmic pharmaceutical sales increased 2.9%, to ¥77,753 million. This increase was due to our advancement of promotional activities in which our MRs provided individual doctors and medical facilities with scientific information tailored to their changing needs. Based on these results, Santen maintained its top share of the domestic prescription ophthalmic pharmaceutical market, which currently stands at 36.1%.

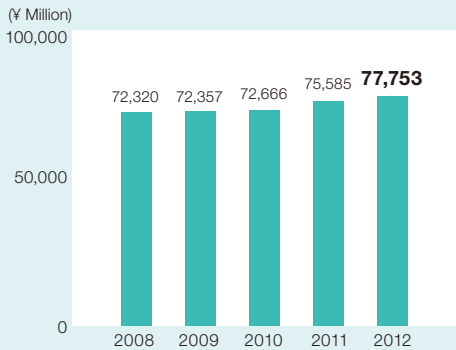
Prescription Ophthalmic Pharmaceutical Market



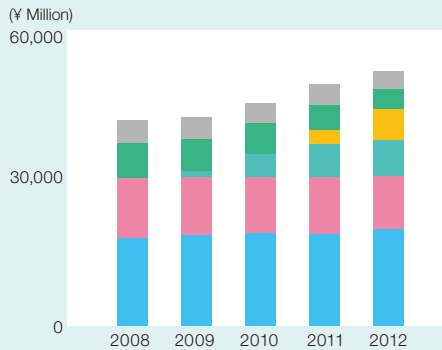
Sales

¥77,753 million +2.9%

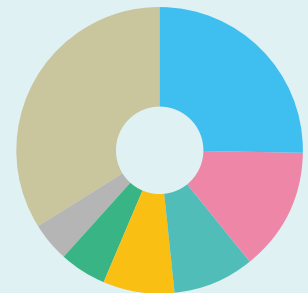
Sales of Prescription Ophthalmic Pharmaceuticals



Sales Trends for the Top Six Products in Japan



Composition of the Top Six Products in Japan by Sales



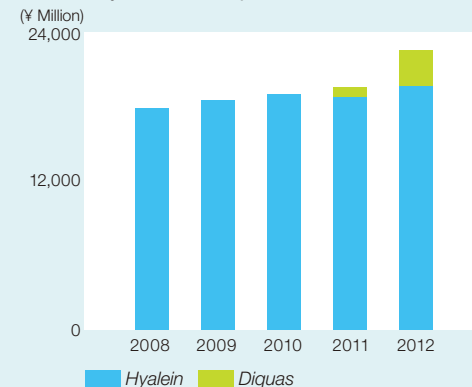
■ Hyalein ■ Cravit ■ Tapros ■ Cosopt ■ Timoptol and related products ■ Flumetholon ■ Others

Treatments for Corneal and Conjunctival Epithelial Disorders

Market Trends

The market for corneal and conjunctival epithelial disorder treatments associated with dry eye expanded 11.3%, to ¥35,622 million, in fiscal 2011. Dry eye is a disorder caused by inadequate tear fluid volume or a change in tear fluid composition that can result in corneal damage. Proper treatment is dependent upon proper diagnosis through regular consultations with an ophthalmologist. As this disorder 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 PCs and contact lenses as well as the aging of Japan's population. Based on the aforementioned, the market for corneal and conjunctival epithelial disorder treatments is expected to continue growing.

Sales of Hyalein and Diquas



Operating Results

In fiscal 2011, sales of *Hyalein*, a mainstay Santen product, grew steadily. This was largely due to the product's attributes, which help improve patients' quality of life (QOL), and Santen's dry eye awareness campaign targeting patients and medical professionals. In total, sales of *Hyalein* rose 5.0%, to ¥19,696 million. Furthermore, sales of *Diquas*, which was launched in December 2010, totaled ¥2,846 million. Santen's share of the corneal and conjunctival epithelial disorder treatment market rose further year on year, to 77.5%, as the Company maintained a solid market position. This growth in market share was attributable to Santen providing more options for treating dry eye, for which there are high unmet medical needs.

Santen plans to continue promoting a greater understanding toward the diagnosis and treatment of dry eye to further raise awareness. In strongly advocating that new patients—there are estimated to be at least 8 million in Japan alone—and existing patients consult their doctors to receive proper and continuous treatment, Santen will link efforts to further enhance awareness toward the treatment of dry eye with aims to strengthen the Company's presence and standing within the corneal and conjunctival epithelial disorder field.

Moving forward, as a leader in the dry eye market in Japan, Santen will continue to actively bolster its product lineup and bring new additional treatment methods to market that address the needs of patients and medical professionals.

Hyalein (Released in 1995)

Hyalein was Japan's first corneal and conjunctival epithelial disorder treatment. It is a highly water-retentive ophthalmic solution that increases tear film stability. *Hyalein* accelerates corneal epithelial bonding and migration, which in turn helps repair corneal epithelial damage. It is generally used as a treatment for damage to the eye caused by dry eye, eye surgery, contact lens use or Sjogren's syndrome¹.



1. An auto-immune disease characterized mainly by a general dryness, especially of the eyes and mouth. Middle-aged and elderly women are particularly prone to this disease.

Diquas (Released in 2010)

Diquas is the first approved P2Y₂ receptor agonist in the world to be formulated as an ophthalmic pharmaceutical and has a new mechanism of action for the treatment of dry eye. *Diquas* promotes the secretion of mucin² and tear fluid, helping to heal damage to the ocular surface by improving the condition of tears.



2. The surface of the cornea contains an aqueous layer and a mucin layer containing complex glycoproteins. Loss of mucin makes it easier for the tear film covering the surface of the eye to break up, which can be a cause of dry eye.

Message

In the previous medium-term management plan, we launched three new products in the Japanese market: *Diquas* for use in corneal and conjunctival epithelial disorders, together with *Tapros* and *Cosopt* as glaucoma treatments. Ophthalmologists have responded positively to these ophthalmic solutions because they are able to offer novel therapeutic options. All three products have steadily gained market share.

We have built a strong position in the prescription ophthalmic pharmaceutical market, having held the No. 1 share for many years. We also have an OTC business with well-accepted brand drugs, handle medical devices such as intraocular lenses, and our surgical business has grown rapidly in recent years. By organically combining these businesses, we are confident that we can provide new value, contributing further to the improvement of ophthalmic treatments.

In a recent move, we entered into a co-promotion agreement with Bayer Yakuin, Ltd., which has added an outstanding product to our portfolio in VEGF Trap-Eye in the back-of-the-eye area, where there are unmet medical needs. By drawing on Santen's assets to take on new fields, we aim to raise our presence further in the Japanese market.



Takeshi Ito

Corporate Officer
Head of Prescription,
Pharmaceuticals Sales Department,
Sales and Marketing Division,
Prescription Pharmaceuticals

[Domestic Operations]

Treatments for Glaucoma

Market Trends

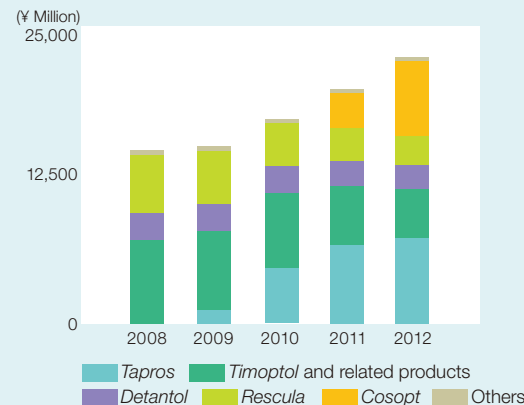
The glaucoma treatment market grew 2.3%, to ¥92,162 million. Treatments for glaucoma represent the largest segment of Japan's prescription ophthalmic pharmaceutical market, accounting for approximately 36% of the total. Increased intraocular pressure is a significant risk factor resulting in damage to the optic nerve. This can lead to visual field loss and in some cases blindness. Glaucoma is the most common cause of blindness in people with ophthalmic disease in Japan. According to epidemiological studies, there are a large number of individuals with glaucoma who have not been diagnosed by doctors. A key issue remains early detection and treatment of this disorder. The glaucoma market is expected to continue expanding going forward, mainly due to the increase in patient numbers owing to population aging.

Operating Results

In December 2008, Santen introduced *Tapros*, which meets the treatment needs of patients with glaucoma and ocular hypertension. Reflecting steady market penetration, *Tapros* sales grew 9.1% year on year in fiscal 2011, to ¥7,179 million. In June 2010, Santen launched *Cosopt Combination Ophthalmic Solution*. Sales of this product have also climbed steadily to reach ¥6,271 million, and the Company's share of the glaucoma treatment market improved to 28.4% in fiscal 2011, securing Santen the top market share.

Santen aims to push ahead with maximizing the value of new mainstay products *Tapros* and *Cosopt Combination Ophthalmic Solution* and continue to highlight the particular benefits of *Rescula* and *Detantol*, while upgrading and expanding its product lineup in the glaucoma field. Looking ahead, we will increase our presence in the glaucoma market by actively providing the latest glaucoma-related information and advice on prescribing pharmaceuticals as well as medical information that meets the needs of medical professionals.

Sales of Treatments for Glaucoma



Tapros (Released in 2008)

Tapros is a prostaglandin-related treatment with strong intraocular pressure-reduction properties. It is the first product of its kind to undergo clinical trials as a treatment for normal tension glaucoma, the most common glaucoma disorder among Japanese people. *Tapros* is also effective in increasing retinal arterial and tissue blood flow, which is thought to affect the progress of normal tension glaucoma.



Cosopt (Released in 2010)

Cosopt is a leading treatment for glaucoma that combines dorzolamide hydrochloride and timolol maleate, delivering a significant reduction in ocular pressure in a single agent. Moreover, in decreasing frequency of use, *Cosopt Combination Ophthalmic Solution* helps enhance dosage and administration compliance.



Anti-Infective Ophthalmics

Market Trends

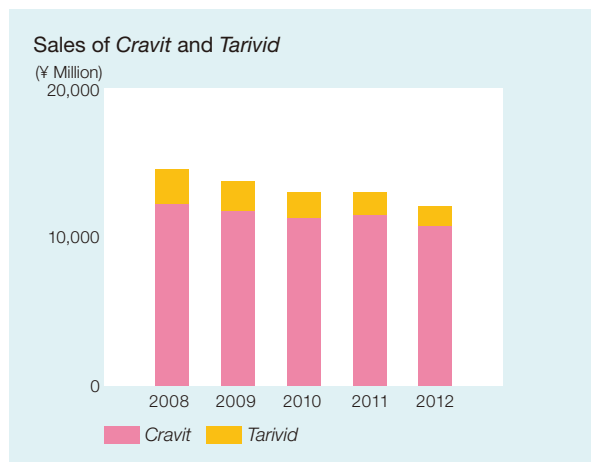
The overall scale of the anti-infective ophthalmic market contracted 4.2%, to ¥21,468 million, continuing the declining trend over recent years. One reason is the shortening of the duration of treatment for anti-infective ophthalmic products after cataract and other ocular surgeries.

Operating Results

In fiscal 2011, sales of the Company's two key products, *Cravit* and *Tarivid*, declined 7.0% year on year, to ¥12,103 million, due to the market's contraction and the impact of competitor products. Santen's share of the anti-infective ophthalmic market fell slightly to 67.5% year on year. However, the Company continues to maintain a dominate

position in this market.

In June 2011, amid strong demand for higher concentration anti-infective ophthalmic pharmaceuticals in step with advances in pharmacokinetics research, Santen released the higher concentration *Cravit Ophthalmic Solution 1.5%*, which leverages the high solubility of levofloxacin. Clinical trials have confirmed significant efficacy. *Cravit Ophthalmic Solution 1.5%* has won high marks in clinical settings since its launch for the early dissipation of major symptoms.



Cravit (Released in 2000)

Cravit is a fluoroquinolone antibacterial agent. Its active ingredient, levofloxacin, is an optically active isomer of ofloxacin, the active ingredient of *Tarivid Ophthalmic Solution*. *Cravit* offers strong antibacterial properties and intraocular penetration. It has effectively double the antibacterial activity of ofloxacin, and approximately 10 times the neutral domain solubility.



Tarivid (Released in 1987)

Tarivid is the world's first fluoroquinolone anti-infective ophthalmic pharmaceutical. It is a synthetic antibacterial drug containing the active ingredient ofloxacin that was developed by Daiichi Sankyo Company, Limited. With a broad spectrum coverage, *Tarivid Ophthalmic Solution* displays strong antibacterial activity and boasts high clinical utility when compared with existing antibiotic ophthalmic solutions.



Anti-Allergy Ophthalmics

Market Trends

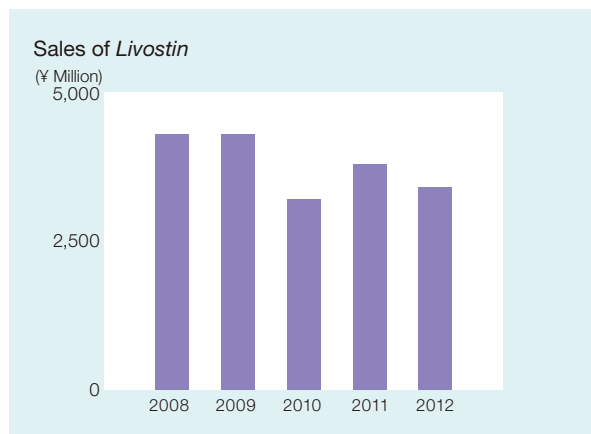
In fiscal 2011, the anti-allergy ophthalmic pharmaceutical market decreased 9.9%, to ¥26,435 million. This was mainly attributable to cedar pollen levels, a major cause of allergic conjunctivitis, which were lower in Japan during the fiscal year under review.

Operating Results

In fiscal 2011, Santen focused on providing information on its products as well as allergic disorders. Sales of *Livostin*

decreased 11.9%, to ¥3,346 million. Santen's share of the anti-allergy ophthalmic pharmaceutical market, however, rose to 17.6%, as the Company maintained a high market presence.

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



Livostin (Released in 2001)

Livostin is an H1 blocker ophthalmic solution that boasts high compatibility and specificity with respect to histamine H1-receptors and a long duration of antihistaminic action. In 2010, in an effort to improve comfort at the time of application, steps were taken to alleviate irritation and to change to a Dimple Bottle developed by the Company.



Prescription Anti-Rheumatic Pharmaceuticals

Market Trends

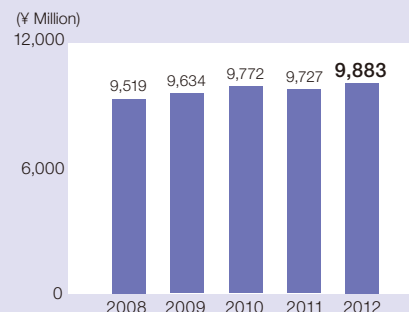
The Japanese market for disease-modifying anti-rheumatic drugs (DMARDs)¹ expanded 6.7% year on year, to ¥27,185 million mainly due to progress in diagnostic technologies, greater access to these technologies and increased prescriptions of higher-priced medications. Although the causes of rheumatoid arthritis (RA) are yet to be fully identified, RA is thought to be a chronic inflammatory disorder that affects the whole body. Inflammation occurs particularly in the joints, causing pain and swelling. It can also 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 number of RA patients is expected to rise in the future in line with the nation's aging population. The overall size of the market is also projected to increase for this reason.

1. 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 RA.

Sales

¥9,883 million
+1.6%

Sales of Prescription Anti-Rheumatic Pharmaceuticals



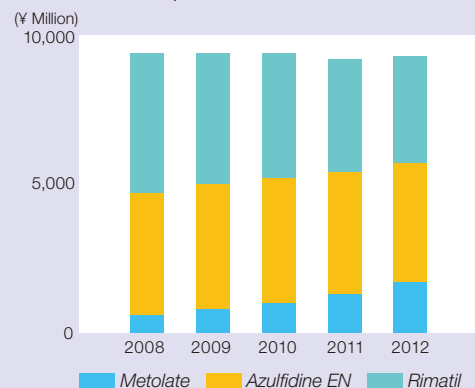
Operating Results

In fiscal 2011, sales of mainstays *Rimatil* and *Azulfidine EN* declined 6.9% and 1.9%, respectively, compared with the previous fiscal year. However, sales of *Metolate*, a product which continues to make steady inroads in the market since its launch in July 2004, registered another year of sharp growth, climbing 36.4%. As a result, sales of prescription anti-rheumatic pharmaceuticals increased 1.6%, to ¥9,883 million. Santen continues to maintain its position as leader of the DMARDs market with a 41.0% share.

With the introduction of biological drugs and other factors, the market environment for RA treatments is undergoing significant change. The American College of Rheumatology, which was revamped in 2012, has recommended DMARDs for treatment both independently or in combination. This suggests that DMARDs will be essential drugs for the treatment of RA going forward. Santen's *Rimatil*, *Azulfidine EN* and *Metolate* are each rated "Grade A – Highly Recom-

mended" under medical treatment guidelines based on Evidence Based Medicine (EBM), by a study group of the Ministry of Health, Labour and Welfare of Japan. This gives them a high profile as strongly recommended treatment options. In this context, the Company will endeavor to promote increased market penetration so that it can contribute to an improvement in the Quality of Life of RA patients.

Sales of *Metolate*, *Azulfidine EN* and *Rimatil*



Rimatil (Released in 1987)

Azulfidine EN (Released in 1995)

Rimatil, which marked its 25th year on the market in 2012, and *Azulfidine EN*, which is used extensively worldwide, are standard treatments for RA. Used by a large number of patients, these products help improve symptoms as well as patients' QOL.



Metolate (Released in 2004)

Metolate is a methotrexate drug formulation that plays a central role in the treatment of RA. Offering the improved dividing property of a scored tablet, *Metolate* has received positive acclaim from patients for its ease of consumption.



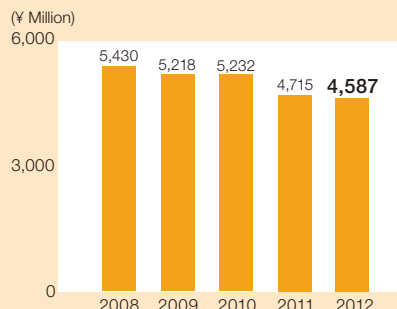
Over-the-Counter Pharmaceuticals

Market Trends

In fiscal 2011, the OTC pharmaceuticals market contracted year on year. In addition to a drop in demand, there was also a decline in distribution prices.

Sales
¥4,587 million -2.7%

Sales of Over-the-Counter Pharmaceuticals



Operating Results

The Company's OTC business is centered on a range of ophthalmic products, including the *Sante FX* series, one of Japan's top-selling ophthalmic solution brands, and the *Sante 40* series, highly effective in improving blurred vision. In fiscal 2011, Santen concentrated efforts on promotional activities, centered on a 20th anniversary campaign for



Sante FX. Despite these efforts, OTC pharmaceutical sales declined 2.7%, to ¥4,587 million, compared with the previous fiscal year owing mainly to a decrease in demand and the impact of competing products. In March 2012, we launched *Sante Medical Guard* as a sister product to *Sante Medical 10*, which was launched in 2006. With fierce competition set to continue in this market, Santen will continue promoting sales while maintaining the market share of its existing product range, concentrating on ophthalmic products for eye refreshment, blurred vision, and eye fatigue.

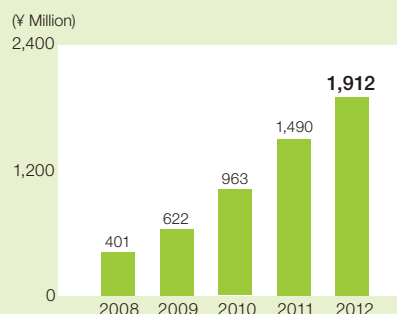
Medical Devices

Market Trends

Santen's medical device business specializes in the cataract surgery field, focusing primarily on intraocular lenses (IOLs). In recent years, IOL demand has shifted primarily to foldable lenses that can be inserted through a small incision.

Sales
¥1,912 million +28.3%

Sales of Medical Devices



Operating Results

Santen sells the *Eternity* series of foldable IOL, which is made of a new glistening-free hydrophobic acrylic optical material manufactured by Advanced Vision Science, Inc., a U.S. subsidiary of Santen. In fiscal 2011, Santen focused on boosting the market penetration of its *Eternity* foldable IOL. The Company released *Eternity Natural*, a blue-light blocking foldable IOL, in December 2009 to enhance its product lineup. In November 2011, Santen launched sales of *Accuject*, an injector that enables the insertion of IOL

through a smaller hole. Thanks to faster market penetration through further improvements aimed at making surgery easier for physicians and patients, sales of medical devices were up 28.3%, to ¥1,912 million. Santen will continue efforts to enhance awareness and use of the *Eternity* series, leveraging the strength of a product concept built on high-quality lenses boasting outstanding transparency, and thereby increase sales of medical devices.

[Overseas Operations]

Santen is actively developing overseas operations in order to contribute to the treatment of patients around the world. In Europe, Santen grew sales, particularly in Eastern Europe, Germany and Russia, in fiscal 2011 by focusing on gaining a foothold in markets for its new treatment for glaucoma and ocular hypertension, *Taflotan* (tafluprost, sold as *Tapros* in Japan). Santen also undertook promotional campaigns throughout Asia focusing mainly on China and Korea. Thanks to these endeavors, the Company successfully increased its share in each market. On a Yen basis, overseas sales of prescription ophthalmic pharmaceuticals increased 4.3%, to ¥15,866 million.

Under the Company's Fiscal 2011-2013 Medium-Term Management Plan, one of Santen's strategic objectives is to accelerate growth in both China and Europe by reinforcing marketing platforms.

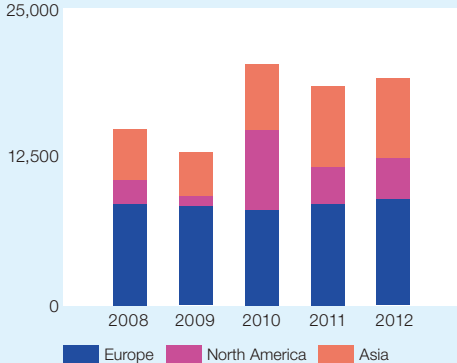
Europe

The European market for prescription ophthalmic pharmaceuticals has been growing at an annual rate of approximately 10%, supported by a combination of rising numbers of patients diagnosed with glaucoma and dry eye syndrome as well as increasing economic prosperity in Eastern Europe and Russia. At the same time, the European market is characterized by its diversity—each country in the region has a different health insurance system and different medical treatment practices. Under these circumstances, it is imperative that the Company engage in sales and marketing activities that capture the specific characteristics of each country.

Santen is advancing its sales and marketing activities in 33 European countries, including Russia, Germany and countries in Northern and Eastern Europe. The anti-infective ophthalmic solution *Oftaquin* (levofloxacin, sold as *Cravit* in Japan) has

Overseas Sales

(¥ Million)
25,000



Steady Growth in the Regions in Which Tafluprost Is Sold

Tafluprost has been approved for sale in 41 countries in Europe and 7 countries in Asia. Currently, Santen directly markets tafluprost in 28 countries worldwide including Japan. The Company has granted tafluprost sales rights in certain countries under a licensing agreement with Merck & Co., Inc. Together with this relationship with Merck & Co., tafluprost is sold in 51 countries around the globe (As of August 1, 2012).



Message

In November last year I joined Santen Europe, being based in the German office in Munich. Our core mission is to enhance the presence of Santen in the European ophthalmic pharmaceutical arena through continuous commercial growth based on the trust of medical professionals in the quality of our products.

Taflotan is a key growth driver for Santen's European business. Its sales growth rate has outpaced the market since its launch in 2008, and this has greatly enhanced Santen's presence in Europe as a result. Ophthalmologists are so impressed by *Taflotan* that in a short time it has become one of the first-choice drugs for treatment of glaucoma and ocular hypertension. This is helping to drive market penetration of the Santen brand in the region, notably within our Northern European markets, Eastern Europe and Germany. In addition, the acquisition and integration of Novagali opens up some fresh possibilities for the European business in the field of prescription dry eye drugs. This will enable us to gain a foothold for future business expansion in Western European markets such as France, Italy, the UK and Spain.



Christiane Hanke-Harloff

Vice President Sales & Marketing, Europe,
Santen GmbH

gained an excellent reputation for preventing and healing eye infections and is now available in 29 countries. Additionally, Santen has already obtained approval for *Taflotan*, a treatment for glaucoma and ocular hypertension, in 41 countries throughout Europe. Currently, we market this product directly in 23 countries including Germany. Furthermore, in Western Europe (except Germany), an area in which Santen does not have a sales platform, we have granted sales rights for tafluprost to U.S.-based Merck & Co., Inc.; tafluprost is sold in 12 countries in Europe under this agreement.

Furthermore, the Company's subsidiary in Finland, Santen Oy, manufactures pharmaceuticals for the European and the U.S. markets at its Tampere Plant, and is one of Santen's global R&D bases. In January 2012 Santen acquired the French ophthalmic pharmaceutical company Novagali which adds proprietary dry eye compounds and a unique formulation platform applicable across several ophthalmic segments.

Asia

The Company's vision for the Asian market is to become the top ophthalmic specialty pharmaceutical company. Accordingly, Santen is striving to enhance long-term relationships with patients and medical professionals, thereby contributing to the improvement of ophthalmic treatment in the region. Santen is conducting business in China, Korea and the ASEAN nations guided by this vision.

Santen began exporting in China in the 1980s and since then has established the Santen brand in this market. However, as a market that is key to growth going forward, Santen is redoubling its efforts to strengthen its operating platform in China. In 2005, the Company established Santen Pharmaceutical (China) Co., Ltd., which

commenced operations at the Suzhou Plant in 2008 and began marketing using its own MRs in 2009. Santen Pharmaceutical (China) is extending its operations from China's major metropolitan cities to major outlying cities. Through these activities, the company is providing high-quality academic information. Santen Pharmaceutical (China) sells prescription ophthalmic pharmaceutical products including *Cravit* anti-infective eye drops, and *Hyalein*, a corneal and conjunctival epithelial disorder treatment. In fiscal 2012, the company is planning to commence integrated production at the Suzhou Plant.

Also, Santen is working to increase market awareness and penetration of the Santen brand in the Korean and ASEAN markets through Santen Pharmaceutical Korea Co., Ltd. in conjunction with local distributors and agents. In May 2010, *Taflotan*, a glaucoma and ocular hypertension treatment, was launched in Korea. At the same time, Santen commenced direct marketing through Santen Pharmaceutical Korea and is providing academic information on ophthalmic disease through its own MRs.

North America

In the U.S., Santen is currently conducting clinical development of DE-109 (sirolimus), which is in Phase 3 clinical trials, DE-101 (rivoglitazone), and DE-105. It is also bolstering human resources with considerable experience in ophthalmology in the U.S. as a base that will play a central role in promoting clinical development globally at Santen. On the device side, Santen granted worldwide rights, excluding Japan, for the development, manufacture and marketing of the *Eternity* IOL product and its materials to Bausch & Lomb Inc. in March 2009.

Message

Santen's commitment to core values in terms of contributing to the QOL of patients and their loved ones is also well-respected in China. Santen China currently has a sales force of about 200 MRs, which is the second-largest next to Japan in Santen. While conducting business in China over the past decade, our HR development programs have led to substantial growth by the locally hired MRs. Those who were trained earlier are now helping to train and develop the new sales recruits. Efforts to strengthen the organization are guided by local needs.

The entire process of manufacturing/production will be performed in the Suzhou Plant in 2012. This will be a major step forward to have a chain of key operations, R&D, manufacturing and sales, which will enable Santen China to develop regionally accepted products fulfilling customers' needs. We aim to raise Santen's presence globally by creating new growth models that draw on our strengths in the fast-growing Asian region.



Isao Takahashi

General Manager
Product Marketing Group
Asia Division

Corporate Social Responsibility

Guided by Santen's Values—the core value of which is *“tenki ni sanyo suru”*—Santen continues to help enrich the quality of life (QOL) of patients around the world through the provision of outstanding products and services via its business activities.



Contributing to Society through Sound Business Activities

At Santen, we believe that our business activities—the provision of outstanding pharmaceutical products and services as a pharmaceutical company, which is our social mission—are in and of themselves connected with CSR.

In 1999, the Company formulated the Santen Corporate Ethics Mission (“Ethics Mission”), a clearly identified set of principles designed to govern employee conduct. We have continued to revise the Ethics Mission in response to changes in society and our operating environment, and in 2010 we took steps to better incorporate the three specific perspectives of building relationships of trust with customers, promoting employee responsibility and growth, and maintaining harmony with society.

Building a Platform to Better Fulfill Our Social Responsibilities

In order to promote CSR, we established the CSR Division in April 2011.

One of the roles of the CSR Division is to ensure that the Ethics Mission is more widely disseminated and understood within the Group. Second is to put in place a CSR management system that facilitates business activities and conduct consistent with the Ethics Mission. In specific terms, the CSR Division supports the creation of a framework for operating the PDCA cycle¹ in order to avoid risk in operating divisions and headquarters. A third role of the CSR Division is to strengthen the Group's crisis management function to help minimize the impact of any crisis. By steadfastly implementing measures according to these roles, Santen will work toward mitigating any and all risks that hinder its ability to provide products, information,

and services.

Regarding efforts to develop specific activities, Santen will establish a CSR Promotion Concept (Refer to diagram on page 35) and create a CSR promotion framework. We will also determine details of activities unique to Santen and targets, while considering the impact on stakeholders by core field for CSR promotion.

In October 2011, we realigned the CSR Division's functions, and at the same time we restructured the Risk Management Committee and the CSR Committee in order to further enhance effectiveness. We also engaged in direct dialogue with experts to look at issues concerning our CSR activities.

1. A method to facilitate the smooth management of business activities through a P (Plan), D (Do), C (Check) and A (Action) business activity cycle.

Steadfastly Responding to Priority Issues

At Santen, we are pushing ahead with initiatives to address the following priority issues:

- (1) Rigorous compliance
- (2) Promotion of occupational health and safety activities
- (3) Promotion of environmental conservation activities
- (4) Promotion of social contribution activities

At present, we are aiming to expand overseas business to provide outstanding pharmaceuticals to patients worldwide. We will continue to engage in communication that best fits the needs of stakeholders. Furthermore, to respond to diversity and differences in culture and lifestyles, we will develop globally using approaches matching each country and region based on know-how for promoting business in Japan.

Becoming a Company That Can Consistently Contribute to Society

With regard to the Company's crisis management, maintaining a structure and the systems that can ensure the uninterrupted delivery of pharmaceuticals during unprecedented periods of crisis like the Great East Japan Earthquake is extremely important. Measures that address such risks as the loss of business continuity must be carefully determined. In addition to putting the utmost effort into avoiding expected risks and implementing preventive measures to ensure business continuity, we will take all necessary precautions and preparatory steps to lower damages as much as possible in the event of a crisis situation.

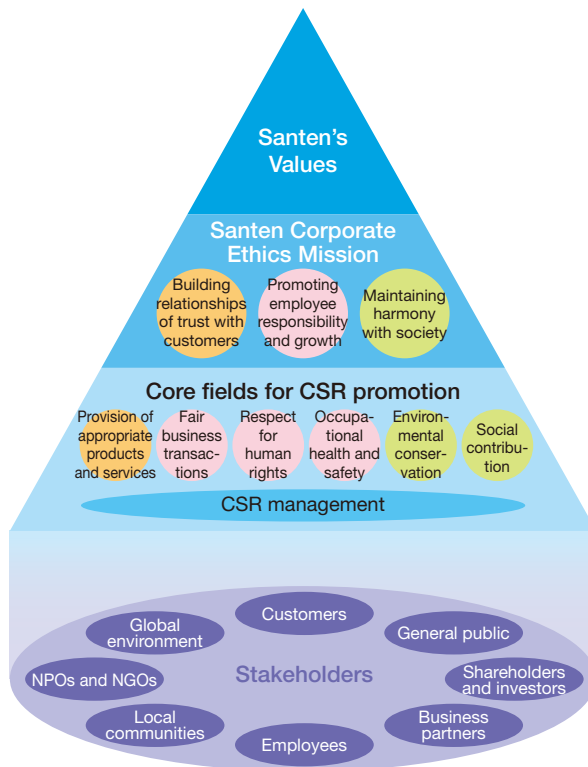
It is also vital that we put in place business continuity management (BCM)² that covers new risk scenarios such as an unclear outlook for the resumption of nuclear power generation and insufficient supplies of electric power. Moreover, as risks surrounding overseas business development differ depending on country and region, we must put in place the necessary countermeasures while gaining a deep understanding of the systems, cultures and norms of other countries.

Moving forward, Santen will continue to strengthen its CSR activities with the aim of being a company that is trusted by society.

2. A management method that aims to ensure business continuity, or the early resumption of business activities, in the event of an unforeseen event including natural disaster, accident, the outbreak of an infectious disease or system failure.

CSR Promotion Scheme

We have specified core fields for CSR promotion reflecting the thinking of ISO 26000³, with Santen's Values and the Santen Corporate Ethics Mission as primary concepts.



3. ISO 26000 was issued by the International Organization for Standardization (ISO) in November 2010 to provide guidance on social responsibility. It is applicable not only to corporations but also to all organizations, including governments, schools, and NGOs.

Message

Santen's social mission is to provide outstanding pharmaceutical products and services as a specialty company in the ophthalmic and anti-rheumatic fields. Therefore, I believe that we should pursue CSR activities within the context of our business activities. The CSR Division has rebuilt our CSR management system with reference to ISO 26000 for ensuring that business activities and actions follow the Ethics Mission by making sure Santen's Values are widely disseminated and understood within the Group. This is because we understand that practicing rigorous compliance to ensure fair and transparent activities and promoting occupational health and safety are priority issues and prerequisites for providing outstanding pharmaceuticals to patients worldwide. Furthermore, we are determined to enhance our environmental conservation activities and social contribution activities as we see this as the responsibility of any company developing business globally.

Looking ahead, we will refine our approach to CSR activities related to the ophthalmic and anti-rheumatic fields, with the strong commitment to help patients and their loved ones even more.



Kenji Morishima

Corporate Officer
Head of Human Resources Development
and CSR Division

Building Relationships of Trust with Customers

Developing and Providing Outstanding Pharmaceuticals

The Quality Compliance Division is deeply involved in such wide-ranging processes as product research and development, manufacture and sales. In this manner, the division strives diligently to maintain product quality. In Japan, the Pharmaceutical Affairs Law stipulates strict standards for pharmaceutical quality control and post-marketing safety supervision. In addition to adhering to these standards, Santen has established a world-class quality assurance system based on its own specifications and standards.

From a manufacturing perspective, Santen maintains a domestic plant network encompassing Noto and Shiga. Overseas, the Company operates plants in Tampere in Finland and Suzhou in China. Collectively, this represents a structure that ensures the stable manufacture of approximately 300 million bottles per year of ophthalmic solutions to patients worldwide.



Ophthalmic solution filling in a clean room

Providing Accurate Information in a Timely Manner

Providing medical professionals with information about indications, side effects, and methods of use is essential to ensuring the safe and correct use of products. Santen accordingly has a sales force of MRs across Japan who provide accurate information in a timely manner. In order to maintain and enhance the quality of this flow of information, we continuously update MR training with specialized education.

Moreover, our Customer Service Center deals comprehensively with customer inquiries on a centralized basis. And we channel customer feedback to the product development process to improve our products and enhance our information services. The Dimple Bottle, an eye drop container that was developed by Santen in response to customers' needs, is one example of this feedback. This Dimple Bottle has earned high praise for its patient-friendliness and won the Good Design Award in 2008.

Moreover, we disseminate information through our websites to the public and medical professionals about eye diseases, the correct usage of ophthalmic solutions, rheumatoid arthritis, and pharmaceuticals and medical devices.

Promoting Employee Responsibility and Growth

Respect for Human Rights

At Santen, we have formulated a policy on human rights education and an action plan, as well as promote human rights awareness. Specifically, we work to foster an awareness of respect for human rights through training based on rank and position within ordinary training programs, the issuance of news related to human rights, solicitation of human rights slogans and other actions.

We are also promoting the employment of people with disabilities. In 1997, we established Claire Co., Ltd., a specified subsidiary, for this purpose. In order to provide a workplace in which people with disabilities can work with vigor and enthusiasm, we consistently improve conditions while encouraging the development of competencies.

Ensuring a Safe and Comfortable Workplace Environment

Santen has put in place the Occupational Health and Safety Principal Policies as well as its Occupational Health and Safety Action Guidelines, which collectively set the direction and principles for occupational health and safety. The Company strives to maintain a safe, clean and comfortable workplace environment while promoting improved employee health. In order to maintain and enhance occupational health and safety standards at plants, research facilities and its head office, Santen established the Occupational Health and Safety Committee. Based on the annual policies and plans of offices, Santen engages in various activities including workplace patrols as well as risk assessments. An evaluation of the status of activities is reflected in the following year's policies and plans. In this manner, we are working to continuously implement improvements.

Furthermore, Santen has also set up healthcare teams staffed by industrial doctors and nurses at its head office, plants and research facilities to assist employees in maintaining and improving their health. In addition to establishing an in-house health consulting service for its employees covering physical as well as mental health, we also provide access to an external consulting service for employee families.

At the same time, we promote systems that help employees balance the commitments of their professional and private lives, actively supporting employees in their efforts to manage workplace, childrearing and nursing care responsibilities. In fiscal 2005, we launched a project with the aim of developing the next generation and thereafter introduced a broad spectrum of follow-up programs.

Santen acquired the so-called "Kurumin" certification based on Japan's Act for Measures to Support the Development of the Next Generation in 2007 and 2010.



Maintaining Harmony with Society

In Partnership with the Global Environment

Santen has placed environmental conservation activities high on its list of management priorities. The Basic Environmental Policy and the Environmental Guidelines underscore our environmental conservation promotion activities. To increase the effectiveness of these activities, all of our manufacturing plants in Japan and overseas subsidiary Santen Oy have obtained and maintain certification under ISO 14001, the international standard for environmental management systems. Major activities to reduce our environmental burden include taking steps to reduce CO₂ emissions, the effective use of water resources, the reduction of waste, and the proper management of chemical substances.

We have formulated a set of green procurement guidelines covering policies relating to the purchase of various items required for manufacturing. While gaining the understanding and cooperation of our suppliers, we are working to procure environmentally friendly raw materials and products. Furthermore, we also engage in the green procurement of office supplies.

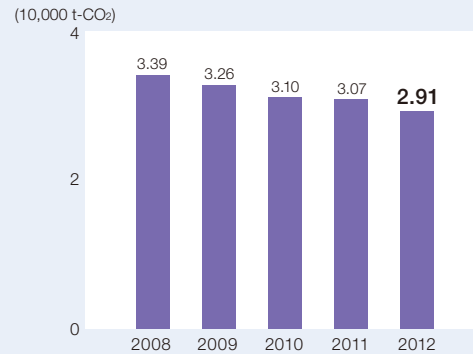
And we are working to raise the awareness of each and every employee through environmental education programs, encouraging participation in regional environmental conservation activities and in other ways.

As a Good Corporate Citizen

Santen engages in social contribution activities centered on medical care and welfare connected with its business domains and on local communities.

In the medical care and welfare fields, Santen continuously donates to a number of organizations including Helen Keller International, an NGO that is devoted to fighting and treating preventable blindness in developing countries, as well as the Japan Eye Bank Association and the Japan National Society for the Prevention of Blindness. Furthermore, a joint lecture program was formed with the Nara

CO₂ Emission Volumes



Institute of Science and Technology to develop personnel who will advance leading-edge science and technology in the future. In this program, researchers from the Nara Research and Development Center instruct students at research facilities. We also support the Chinese Ophthalmology Scholarship Program in China and the Ophthalmology Training Fund in Korea in support of the education of ophthalmologists.

In addition, Santen contributes to local communities through concerted efforts to beautify and promote the greening of the areas surrounding its headquarters, research facilities, manufacturing plants, and other main business sites while actively participating in crime prevention campaigns.

We also make donations and provide free supplies of pharmaceuticals in response to relief efforts for large-scale disasters. In addition to the delivery of pharmaceuticals to areas affected by the Great East Japan Earthquake that struck the nation in March 2011, we donated ¥100 million to relief efforts. Moreover, Santen has introduced a contribution matching system under which the Company donates an amount equivalent to contributions provided by employees. We also dispatched employees who volunteered to conduct activities for helping the disaster-hit regions recover.



Beach cleanup at Chirihama (Ishikawa Pref.)



Employees conducted volunteer activities after the Great East Japan Earthquake



Signing ceremony for a scholarship program with the Chinese Ophthalmology Scholarship Program

For more detailed information, please read our Corporate Social Responsibility Report in Japanese or Environmental Data Book in English on our website.

Japanese: <http://www.santen.co.jp/> English: <http://www.santen.com/>

Corporate Governance

Santen recognizes that it is vital to upgrade and strengthen corporate governance systems 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

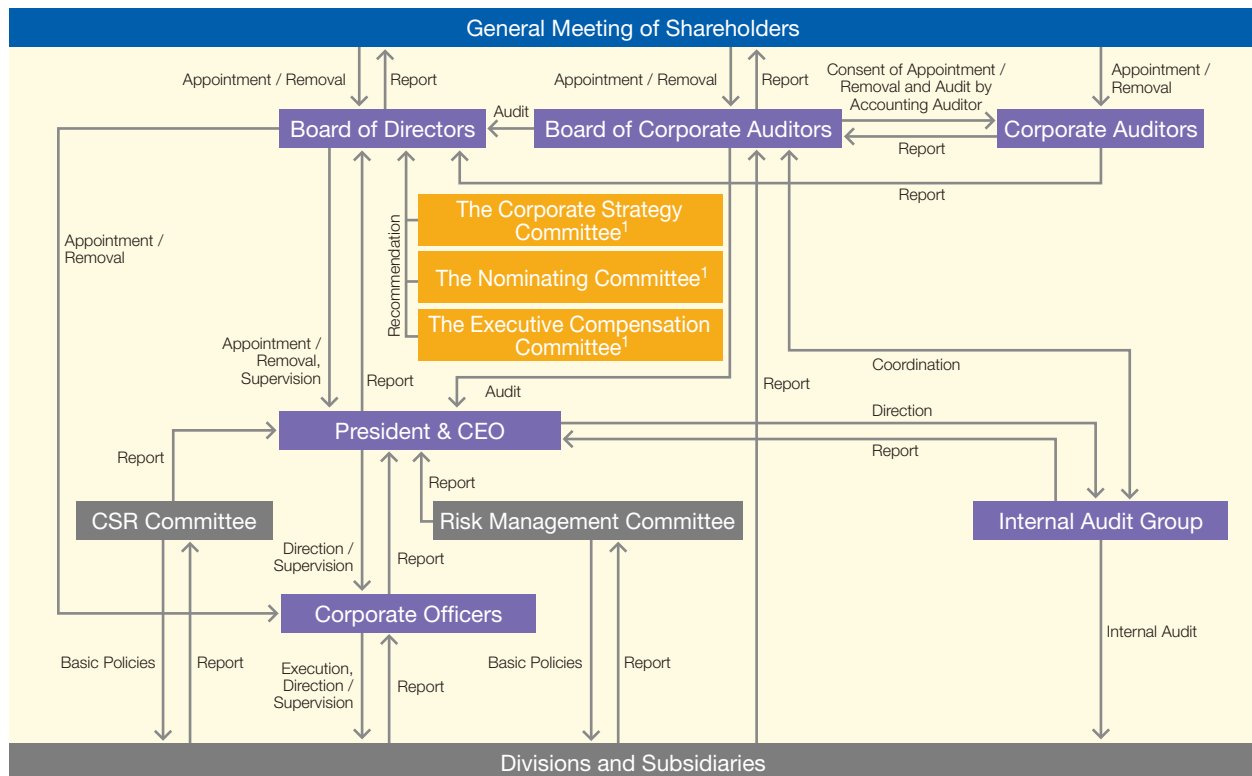
In addition to various statutory functions, the Board of Directors formulates management policies, strategies, and business plans for Santen. The Board of Directors makes decisions relating to the acquisition or disposal of major financial assets and important organizational or personnel-related matters, as well as oversees the execution of business at Santen and its subsidiaries. The board convenes once a month in principle. As of July 2012, the board comprised six members including three outside directors. The Board of Directors convened 11 times during fiscal 2011.

■ Board of Corporate Auditors

Santen has adopted a governance system using corporate auditors. Santen will continue to further heighten the effectiveness and efficiency of this auditing system in collaboration with internal audit divisions. The Board of Corporate Auditors consists of four members, including three outside auditors. Corporate auditors formulate auditing policies and plans as well as attend meetings of the board of directors and other important business meetings. In addition, corporate auditors oversee the execution of duties by directors through auditing the operational and financial status of Santen's headquarters, major operating sites, and subsidiaries. The Board of Corporate Auditors convened eight times during fiscal 2011.

Santen Internal Governance System

As of July 2012



1. These committees are voluntary and not part of any statutory

■ 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 deliberates on the selection of corporate officers and corporate auditors and submits recommendations to the Board of Directors.
- The Executive Compensation Committee deliberates on the compensation of directors and corporate officers as well as submits recommendations to the Board of Directors.

Note that these committees are not part of any statutory “Company with Committees” system under the Japanese Company Act.

■ 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 seven corporate officers at the end of July 2012, excluding some serving concurrently as directors.

Relationships between the Outside Directors and Outside Corporate Auditors and the Company

None of the three outside directors or three outside corporate auditors are appointees from Santen’s subsidiaries or affiliates, major shareholders or leading business partners. Each maintains a degree of independence to avoid conflicts of interest with ordinary shareholders. The outside directors are experienced managers from various industries who oversee executive operations from an objective viewpoint. Based on their specialist knowledge of accounting, business strategy and other areas, the outside corporate auditors exchange views periodically with the Internal Audit Group and provide advice. They also work to ensure that business management is objective, transparent and appropriate, based on observation of internal audit processes.

Directors’ and Corporate Auditors’ Remuneration

| Position | Total Remuneration (Millions of yen) | Total Remuneration by Category (Millions of yen) | | | | | No. of Eligible People |
|---|--------------------------------------|--|-----------------------------|---------------|-------|-----------------------|------------------------|
| | | Basic Remuneration | Results-linked Remuneration | Stock Options | Bonus | Retirement Allowances | |
| Directors (Excl. Outside Directors) | 277 | 62 | 116 | 26 | – | 72 | 5 |
| Corporate Auditors (Excl. Outside Corporate Auditors) | 23 | 23 | – | – | – | – | 1 |
| Outside Directors and Outside Corporate Auditors | 57 | 57 | – | – | – | – | 9 |

Note: In addition to the above, the Company paid ¥384 million in retirement allowances to 2 directors based on a resolution passed at the Annual General Meeting of Shareholders held on June 22, 2011. This includes retirement allowances included in prior years.

Please refer to Santen’s Corporate Governance Report (Japanese only) posted on the Company’s website for details.

<http://www.santen.co.jp/>

Compliance

Internal Governance System

Santen benefits society through its business activities, with a particular focus on contributing to patients and their loved ones—which incorporates Santen’s Values—as a company active in the pharmaceutical industry. At the same time, aiming to heighten society’s recognition of our values to society 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 civil society.

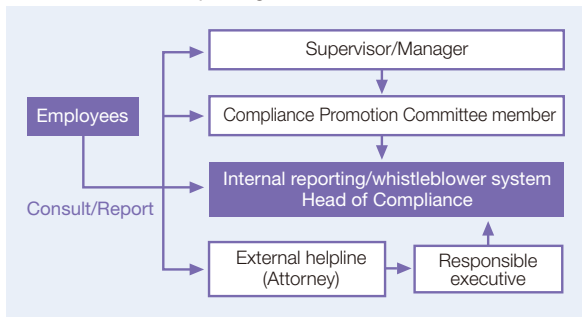
In addition, we have established the CSR Committee as a Companywide lateral organization tasked with ensuring rigorous compliance. Further, we maintain an internal system for compliance-related inquiries and an external helpline to an independent attorney, which enable employees to report directly any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

Santen aims to increase the appropriateness of Santen’s operations, 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 four 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, while the Internal Audit Group checks the suitability of these self-checks. In fiscal 2011, 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 Act.

Consultation and Reporting Flow



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 as well as to exchange opinions, including requests from the corporate auditors. The independent auditors present audit findings to the corporate auditors at meetings three times 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 exchange opinions 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, comprising four members, also reports to the corporate auditors any important information gained from internal audits and related countermeasures. The corporate auditors may provide support to the Internal Audit Group in implementing these countermeasures as deemed necessary.

Risk Management

Risk Management Promotion Framework

Santen has built a system for responding appropriately to major risks related to its business activities, which is based on a Risk Management Procedure 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 as well as 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 the Crisis Response Committee headed by a representative director. Based on Santen's Risk Management Procedure Manual, the committee coordinates efforts to minimize any losses or damages and ensure a quick recovery, and institutes measures to prevent a recurrence. The Company has established a permanent secretariat with designated executives to check the status of such risk management efforts from a Companywide viewpoint, while the Internal Audit Group examines them from an independent standpoint.

Business Continuity Management

Medicines are high-priority necessities for people affected by natural disasters or other emergencies. Santen believes it is essential to maintain supplies of drugs to patients and healthcare workers in affected areas. To this end, Santen has analyzed business continuity-related risks, clarified policies and identified those areas critical to maintaining product supplies. Detailed plans have been formulated to guide the response to an emergency, including the necessary organizational actions. To ensure systems will work, business continuity and disaster preparedness planning and activities are also part of the PDCA-based management cycle.

Information Security

Regarding information control systems, Santen safely stores and controls information based on in-house rules such as for basic information security and document control. Furthermore, Santen has established personal information protection guidelines and a compliance program regarding personal information protection, which are explained to corporate officers and employees at training events. The Company also works to ensure that they are working properly.

Message

Message from Outside Directors

I have been involved in the management of many firms as a management consultant, and have also established and listed a firm as a representative director. This experience should prove useful in my role at Santen as an outside director.

The role of outside director covers a range of things, but I think what is important is for Santen to continue to address the right challenges. The pharmaceutical industry is unusual in that it takes a long time for investments to generate results amid huge uncertainties. This makes it difficult to see the connection between management decisions and results obtained while executives are in office. Long-term success depends on continuing to assume the right risks and challenges rather than being caught up in internal politics, trying to protect oneself or responding to superficial demands from outside. I believe I can serve shareholders and customers best by doing what I can to ensure Santen stays on the right path.



Noboru Kotani
Outside Director



Akihiro Okumura
Outside Director

As a management scholar, I have studied the management of numerous Japanese and Western firms over many years. I have coached and researched management of a number of global companies from the specialist viewpoints of business strategy and organizations. I believe that I can use this experience to contribute to the further progress of Santen's management.

Santen is currently at a major turning point created by globalization, where the business must shift from a domestic focus to build an organization that has global scale. This will require considerable business innovation. In my view, the success of such innovation will determine Santen's future corporate value. As an outside director, I plan to provide the current management team with any specialist advice that I can, while at the same time seeking to ensure that value is maximized for shareholders.

I note that Santen has continued to be highly rated by the market at a time when many Japanese companies are performing poorly due to worsening economic conditions and natural disasters. The fact that institutional investors from overseas have bought more of its shares is further evidence of this market appraisal. In my view, the continuous growth of the Company's business value over the long term has been enabled by its sheer focus on the prescription ophthalmic pharmaceuticals business, combined with its pursuit of customer-oriented "creation and innovation." I am delighted to participate in Board processes as a newly appointed director, and hope to provide effective support for senior management members as they work to accelerate a growth strategy aimed at realizing Santen's long-term business vision. I believe it is also important to give proper counsel in the best interests of shareholders. I hope my experience in and knowledge of corporate management, albeit in a different sector, will prove valuable.



Takayuki Katayama
Outside Director

Board of Directors, Corporate Auditors and Corporate Officers

As of August 2012

Directors

- ① **Akira Kurokawa**
President and Chief Executive Officer
- ② **Toshiaki Nishihata, Ph.D.**
Director
Executive Corporate Officer
U.S. and Europe Business
Head of Research and Development Division
- ③ **Sadatoshi Furukado**
Director
Executive Corporate Officer
Japan and Asia Business
Head of Sales and Marketing Division, Prescription Pharmaceuticals
- ④ **Noboru Kotani¹**
Director
- ⑤ **Akihiro Okumura¹**
Director
- ⑥ **Takayuki Katayama¹**
Director



Corporate Auditors

Yoshihiro Noutsuka
Standing Corporate Auditor

Yasuo Sato²
Corporate Auditor

Yasuaki Tsuchiya²
Corporate Auditor

Yutaka Mizuno²
Corporate Auditor

1. Outside Director
2. Outside Corporate Auditor

Corporate Officers (Not including directors that also serve as corporate officers)

- ① **Masamichi Sato**
Senior Corporate Officer
Head of Santen European Group
President of Santen Holdings
EU B.V.
- ② **Jyrki Liljeroos**
Corporate Officer
President of Santen Oy
- ③ **Kenji Morishima**
Corporate Officer
Head of Human Resources
Development and CSR Division
- ④ **Akihiro Tsujimura**
Corporate Officer
President and Chief Executive
Officer of Santen Inc.
- ⑤ **Atsutoshi Ota**
Corporate Officer
Head of Product Supply Division
- ⑥ **Akio Kimura**
Corporate Officer
Head of Quality Compliance Division
- ⑦ **Takeshi Ito**
Corporate Officer
Head of Prescription
Pharmaceuticals Sales Department,
Sales and Marketing Division,
Prescription Pharmaceuticals



| | |
|--|----|
| Report and Analysis of Operating Results and Financial Condition | 44 |
| Risk Related to Our Business | 48 |
| Eleven-year Summary of Selected Financial Data | 50 |
| Consolidated Balance Sheets | 52 |
| Consolidated Statements of Income and Comprehensive Income | 54 |
| Consolidated Statements of Changes in Net Assets | 55 |
| Consolidated Statements of Cash Flows | 56 |
| Notes to Consolidated Financial Statements | 58 |
| Internal Control Report | 77 |
| Independent Auditor's Report | 78 |

Financial Section

Report and Analysis of Operating Results and Financial Condition

[OPERATING RESULTS]

Net Sales

Santen's activities essentially encompass the pharmaceutical and other businesses. At 97.8%, the vast majority of sales come from the pharmaceuticals segment. In fiscal 2011, ended March 31, 2012, sales from the pharmaceuticals segment rose 3.0% compared with the previous year, to ¥111,846 million. Sales from the other segment climbed 14.9%, to ¥2,570 million. On this basis, total net sales for the fiscal year under review rose 3.3%, to ¥114,416 million.

Pharmaceuticals Business

Prescription Pharmaceuticals

Santen's prescription pharmaceuticals are divided into three categories: ophthalmics, anti-rheumatics and other pharmaceuticals. In fiscal 2011, prescription pharmaceutical sales increased 3.3%, to ¥107,249 million, representing 93.7% of consolidated net sales. This increase was attributable to higher sales in ophthalmics and anti-rheumatics.

■ Ophthalmics

Domestic sales of prescription ophthalmic pharmaceuticals improved 2.9%, to ¥77,753 million. This was largely attributable to successful promotional campaigns in Japan to provide individual medical facilities with scientific information tailored to their specific and changing needs.

Overseas, prescription ophthalmic pharmaceutical revenues were up 4.3%, to ¥15,866 million, after conversion to yen. In Europe, our concentration on promotional campaigns centered on providing medical and other information saw *Taflofan* (sold as *Tapros* in Japan), a new glaucoma and ocular hypertension treatment, increase its market share in Germany. In Asia, market penetration of the Company's products also progressed mainly in China and Korea. This was again attributable to successful promotional campaigns.

As a result, total prescription ophthalmic pharmaceutical sales increased 3.1%, to ¥93,620 million.

■ Anti-Rheumatics

Rimatil, *Azulfidine EN* and *Metolate* are highly recommended in 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 of Japan and published by the Japan Rheumatism Foundation. Due in part to this strong recommendation, sales of anti-rheumatics rose 1.6%, to ¥9,987 million.

■ Other Pharmaceuticals

Other pharmaceuticals includes revenues derived from technology-sharing agreements as well as contract work and manufacturing. Sales of other pharmaceuticals increased 13.0%, to ¥3,642 million.

OTC Pharmaceuticals

The Company focused on promotional campaigns, notably a 20th anniversary campaign for *Sante FX* in the year ended March 31, 2012. Despite these efforts, sales of OTC pharmaceuticals declined 2.7%, to ¥4,597 million, due mainly to lower demand in Japan and the impact of increased competition.

Other Businesses

Medical Devices

As a result of focusing initiatives on promotional campaigns for the *Eternity* foldable intraocular lens, which is made of a glistening-free hydrophobic acrylic optical material, sales of medical devices increased 15.0%, to ¥2,558 million.

Others

Other sales totaling ¥12 million, up 2.1% year on year, come from the cleaning of antidust and sterilized clothing operations of consolidated subsidiary Claire Co., Ltd.

Net Sales by Business Segment

| | Millions of yen | | % |
|---------------------------------|-----------------|----------|--------|
| | 2012 | 2011 | Change |
| Pharmaceuticals Business | ¥111,846 | ¥108,576 | 3.0 |
| Prescription pharmaceuticals | 107,249 | 103,853 | 3.3 |
| Ophthalmics | 93,620 | 90,797 | 3.1 |
| Anti-rheumatics | 9,987 | 9,834 | 1.6 |
| Other pharmaceuticals | 3,642 | 3,222 | 13.0 |
| OTC pharmaceuticals | 4,597 | 4,723 | (2.7) |
| Other Businesses | 2,570 | 2,236 | 14.9 |
| Medical devices | 2,558 | 2,225 | 15.0 |
| Others | 12 | 11 | 2.1 |
| Total | ¥114,416 | ¥110,812 | 3.3 |

Note: Net sales for each segment refer to sales to outside customers.

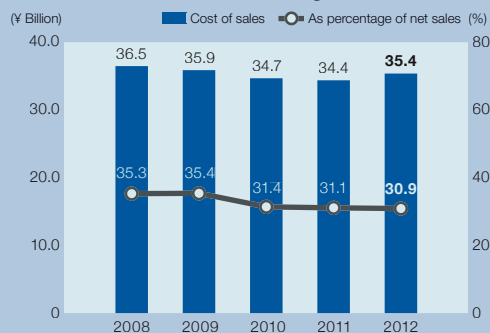
Net Sales



Cost of Sales

Cost of sales increased 2.8%, to ¥35,385 million. The cost of sales as a percentage of net sales improved 0.2 of a percentage point, to 30.9%.

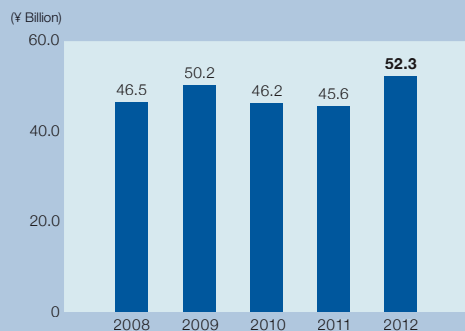
Cost of Sales and As Percentage of Net Sales



Selling, General and Administrative Expenses

Selling, general and administrative expenses increased 14.6%, to ¥52,299 million, which included a 30.3% rise in R&D expenditures, to ¥17,225 million.

Selling, General and Administrative Expenses



Operating Income

Operating income was down 13.0%, to ¥26,732 million. The operating income margin was 23.4%, down from 27.7% in the previous fiscal year.

Operating Income and Operating Income Margin



Other Income and Expenses

Net other income for the fiscal year ended March 31, 2012 was ¥1,059 million.

Other income was up ¥155 million, to ¥1,181 million. This mainly reflected a ¥57 million gain on sale of investment securities, and increases in dividends income of insurance, and interest and dividend income.

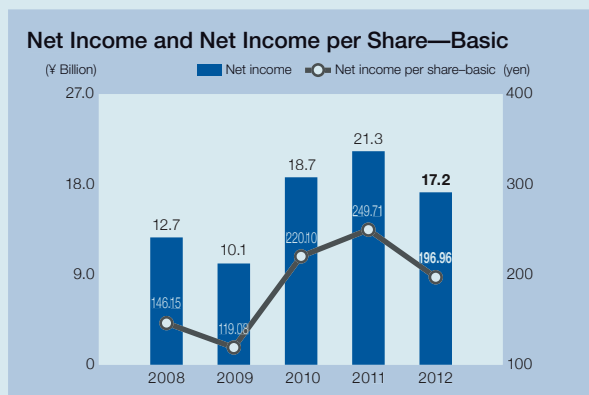
Other expenses decreased ¥567 million, to ¥122 million. This was mainly attributable to the absence of other expenses due to office relocation, loss on adjustment for changes of accounting standard for asset retirement obligations, and write-down of investment securities recorded in the fiscal year ended March 31, 2011.

Income Taxes

Income taxes totaled ¥10,630 million. The effective tax rate increased from 31.3% to 38.3%.

Net Income

Net income was down 19.6%, to ¥17,161 million. The ratio of net income to net sales was 15.0%, down from 19.3% in the previous fiscal year. Basic net income per share was ¥196.96, down from ¥249.71, and diluted net income per share was ¥196.76, down from ¥249.42 in the previous fiscal year.

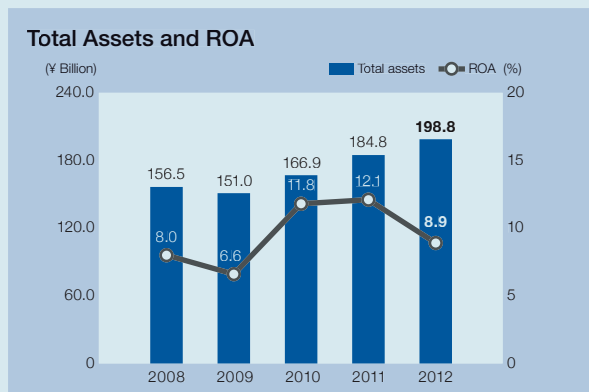


FINANCIAL CONDITION

Assets

As of March 31, 2012, total assets stood at ¥198,801 million, up ¥14,000 million, or 7.6%, compared with the previous fiscal year-end. The main reason was an increase in goodwill due to the acquisition of Novagali. Return on total assets (ROA) was 8.9%, down from 12.1% in the previous fiscal year.

Total current assets were ¥140,288 million, and the ratio of total current assets to total assets declined from 74.5% as of the previous fiscal year-end to 70.6%. Within total fixed assets of ¥58,513 million, net property, plant and equipment totaled ¥25,523 million, and total investments and other assets amounted to ¥32,990 million.



Liabilities

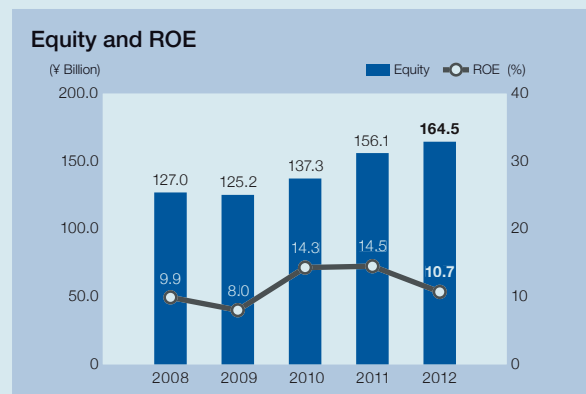
Total liabilities as of March 31, 2012 were ¥33,940 million, up ¥5,543 million, or 19.5%, compared with the previous fiscal year-end. This was largely attributable to an increase in trade accounts payable.

Total current liabilities were ¥27,426 million, and total non-current liabilities were ¥6,514 million. Interest-bearing debt was ¥115 million, a decline of ¥37 million, or 24.2%, compared with the previous fiscal year-end.

Net Assets

Total net assets amounted to ¥164,861 million, up ¥8,457 million, or 5.4%, compared with the end of the previous fiscal year-end. This increase principally reflected higher retained earnings.

The equity ratio declined from 84.5% to 82.8%. Equity per share was ¥1,887.81, an increase of ¥94.66, or 5.3%, compared with the end of the previous fiscal year. Return on equity (ROE) decreased from 14.5% to 10.7%.



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 as of the end of the fiscal year under review amounted to ¥75,035 million, up ¥2,553 million, or 3.5%, compared with the previous fiscal year-end. Net cash provided by operating activities was ¥21,483 million, of which ¥10,273 million was used in investing activities and ¥8,559 million in financing activities.

Cash Flows

Net cash provided by operating activities was ¥21,483 million, which mainly resulted from income before income taxes of ¥27,791 million and income taxes paid of ¥9,268 million.

Net cash used in investing activities was ¥10,273 million. This mainly reflected an outflow of ¥10,804 million for acquisition of subsidiary, net of cash acquired, due to the acquisition of Novagali.

Net cash used in financing activities was ¥8,559 million. The principal cash outflow was dividends paid of ¥8,706 million.

As a result, cash and cash equivalents as of the end of the fiscal year amounted to ¥75,035 million, an increase of ¥2,553 million.

Cash Flows Summary

| | Millions of yen | | |
|--|-----------------|---------|---------|
| | 2012 | 2011 | Change |
| Cash flows from operating activities | ¥ 21,483 | ¥17,768 | ¥ 3,715 |
| Cash flows from investing activities | (10,273) | (7,676) | (2,597) |
| Cash flows from financing activities | (8,559) | (1,570) | (6,989) |
| Cash and cash equivalents at end of year | ¥ 75,035 | ¥72,482 | ¥ 2,553 |

Note: Figures in parentheses indicate a decrease.

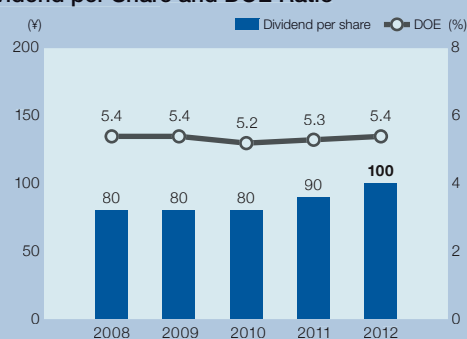
Distribution of Profits

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:

- We will implement an appropriate dividend policy based on the Company's operating results while taking into consideration the need to secure sufficient internal reserves to fund R&D and the implementation of growth strategies for the purposes of enhancing capital efficiency and expanding corporate value.
- We will strive to increase the level of dividends in line with such factors as the Company's demand for funds and the Company's 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 a dividend on equity (DOE) ratio, which combines the dividend payout ratio and ROE. Taking into consideration returns to shareholders through dividends and the improvement of capital efficiency, for fiscal 2013—the final year of the Company's Fiscal 2011–2013 Medium-Term Management Plan—our DOE target is 5.0%. On this basis, the annual dividend per share was ¥100, an increase of ¥10 per share compared with the previous fiscal year, resulting in a DOE ratio of 5.4%.

Dividend per Share and DOE Ratio



Risk 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 forward-looking 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 forward-looking statements might differ substantially from actual results. Risks and uncertainties that could affect the Company's future results and financial condition include, but are not limited to, the factors described below.

External Factors

Regulatory Controls

Our prescription pharmaceutical 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 in full consideration of drug price revisions in Japan to the best 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 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 pressure 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 condition 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 the assets of overseas subsidiaries, affect our sales, profits and financial condition depending on foreign exchange rate fluctuations. Overseas sales for the fiscal year ended March 31, 2012 accounted for 16.6% of our consolidated net sales.

Competitive Factors

Generic Products

The sale of generic products both in and outside Japan has the potential of impacting the Company's performance.

Other companies have already released generic products in Japan for such items as *Hyalein* and *Cravit*. Looking ahead, the impact from generic products is projected to grow.

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 fiscal year ended March 31, 2012. 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*, *Detantol*, *Tapros* and *Diquas*. We also have sales rights in Japan for *Timoptol*, *Timoptol XE* and *Livostin*, and exclusive sales rights in Japan for *Cosopt*, *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 bad debts, 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 rejection 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 launch. 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 does not indicate significant differences 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 and development 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 with 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 condition.

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 condition. 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 certain products are cancelled, or if we withdraw products due to product quality defects, 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 condition. 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

| | 2002 | 2003 | 2004 | 2005 |
|---|----------|----------|----------|----------|
| For the year: | | | | |
| Net sales | ¥ 88,966 | ¥ 90,253 | ¥ 89,858 | ¥ 92,696 |
| Cost of sales | 32,701 | 32,272 | 31,859 | 33,710 |
| Selling, general and administrative expenses | 44,475 | 45,284 | 43,475 | 40,004 |
| Operating income | 11,790 | 12,697 | 14,524 | 18,982 |
| Interest expense | 465 | 480 | 366 | 182 |
| Income before income taxes | 12,679 | 9,947 | 13,775 | 18,436 |
| Income taxes | 7,373 | 1,444 | 7,454 | 7,413 |
| Net income | 5,306 | 8,503 | 6,321 | 11,023 |
| Capital expenditures | 6,586 | 7,046 | 3,226 | 4,907 |
| Depreciation and amortization | 5,334 | 4,311 | 4,521 | 4,750 |
| R&D expenditures | 12,187 | 12,719 | 11,853 | 12,620 |
| Per share data (yen and U.S. dollars): | | | | |
| Net income – basic | ¥ 57.34 | ¥ 93.67 | ¥ 71.65 | ¥ 125.85 |
| Net income – diluted | 53.07 | 85.97 | 71.64 | 125.71 |
| Equity | 1,048.51 | 1,104.21 | 1,176.83 | 1,249.32 |
| Cash dividends, applicable to period | 20.00 | 20.00 | 40.00 | 50.00 |
| Cash flows: | | | | |
| Net cash provided by operating activities | ¥ 6,941 | ¥ 15,808 | ¥ 23,196 | ¥ 6,619 |
| Net cash (used in) provided by investing activities | (6,374) | (9,951) | 5,246 | (2,907) |
| Net cash (used in) financing activities | (5,684) | (6,507) | (12,122) | (12,712) |
| Interest coverage ratio (times) | 14.9 | 34.5 | 70.6 | 36.1 |
| Debt to cash flow ratio (%) | 352.5 | 145.8 | 54.7 | 104.0 |
| At year-end: | | | | |
| Total current assets | ¥ 86,064 | ¥ 83,431 | ¥ 91,231 | ¥ 82,735 |
| Net property, plant and equipment | 42,159 | 40,850 | 37,237 | 32,676 |
| Total assets | 152,103 | 147,148 | 150,238 | 139,980 |
| Long-term debt | 24,467 | 23,047 | 12,686 | 6,882 |
| Equity | 95,101 | 97,126 | 103,500 | 108,240 |
| Return on equity (ROE) (%) | 5.6 | 8.8 | 6.3 | 10.4 |
| Return on total assets (ROA) (%) | 3.5 | 5.7 | 4.3 | 7.6 |
| Equity ratio (%) | 62.5 | 66.0 | 68.9 | 77.3 |
| Equity ratio on stock price basis (%) | 86.6 | 68.7 | 101.8 | 142.3 |
| Price earnings ratio (PER) (times) | 25.3 | 12.3 | 24.3 | 18.3 |
| Dividend on equity (DOE) (%) | 1.9 | 1.9 | 3.5 | 4.1 |
| Issued shares (thousands) | 90,704 | 90,704 | 87,963 | 86,659 |
| Number of employees | 2,463 | 2,500 | 2,335 | 2,308 |

Notes: 1. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥82.19 to U.S.\$1.00, the exchange rate prevailing on March 31, 2012.

2. See Notes 2, 15) and 13 of Notes to Consolidated Financial Statements in respect of per share data.

3. Equity comprises shareholders' equity and accumulated other comprehensive income.

| Millions of yen | | | | | | | Thousands of U.S. dollars | |
|-----------------|-----------|-----------|-----------|-----------|-----------|------------------|---------------------------|--|
| 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2012 | |
| ¥ 98,398 | ¥ 100,486 | ¥ 103,394 | ¥ 101,619 | ¥ 110,594 | ¥ 110,812 | ¥ 114,416 | \$1,392,101 | |
| 34,535 | 35,484 | 36,513 | 35,947 | 34,710 | 34,437 | 35,385 | 430,527 | |
| 42,868 | 44,590 | 46,510 | 50,178 | 46,244 | 45,636 | 52,299 | 636,314 | |
| 20,995 | 20,412 | 20,371 | 15,494 | 29,640 | 30,739 | 26,732 | 325,260 | |
| 94 | 91 | 97 | 65 | 53 | 36 | 23 | 276 | |
| 20,342 | 21,039 | 20,483 | 15,824 | 28,610 | 31,074 | 27,791 | 338,133 | |
| 7,319 | 7,891 | 7,832 | 5,701 | 9,887 | 9,741 | 10,630 | 129,337 | |
| 13,023 | 13,148 | 12,651 | 10,123 | 18,723 | 21,333 | 17,161 | 208,796 | |
| 2,106 | 3,556 | 3,151 | 2,953 | 1,315 | 1,651 | 3,281 | 39,915 | |
| 4,824 | 4,761 | 4,593 | 4,210 | 3,421 | 2,976 | 2,949 | 35,886 | |
| 13,971 | 13,663 | 12,942 | 18,458 | 14,123 | 13,221 | 17,225 | 209,580 | |
| ¥ 150.26 | ¥ 151.58 | ¥ 146.15 | ¥ 119.08 | ¥ 220.10 | ¥ 249.71 | ¥ 196.96 | \$ 2.40 | |
| 150.01 | 151.31 | 145.94 | 118.97 | 219.85 | 249.42 | 196.76 | 2.39 | |
| 1,368.27 | 1,481.83 | 1,494.48 | 1,472.32 | 1,614.08 | 1,793.15 | 1,887.81 | 22.97 | |
| 60.00 | 65.00 | 80.00 | 80.00 | 80.00 | 90.00 | 100.00 | 1.22 | |
| ¥ 20,879 | ¥ 14,959 | ¥ 15,468 | ¥ 11,849 | ¥ 26,110 | ¥ 17,768 | ¥ 21,483 | \$ 261,392 | |
| (1,330) | (5,846) | (2,083) | (5,619) | (829) | (7,676) | (10,273) | (124,992) | |
| (5,900) | (5,691) | (11,415) | (11,373) | (6,753) | (1,570) | (8,559) | (104,141) | |
| 218.7 | 164.3 | 163.6 | 165.5 | 558.1 | 488.5 | 1,285.0 | | |
| 26.9 | 36.4 | 34.1 | 5.5 | 2.5 | 1.1 | 1.1 | | |
| ¥ 93,893 | ¥ 100,820 | ¥ 102,754 | ¥ 101,053 | ¥ 118,832 | ¥ 137,668 | ¥ 140,288 | \$1,706,882 | |
| 30,395 | 30,485 | 29,849 | 28,665 | 26,574 | 24,957 | 25,523 | 310,538 | |
| 150,458 | 159,099 | 156,547 | 151,012 | 166,878 | 184,801 | 198,801 | 2,418,807 | |
| 5,614 | 5,446 | 5,278 | 154 | 75 | 152 | 179 | 2,184 | |
| 118,637 | 128,587 | 126,998 | 125,181 | 137,343 | 156,099 | 164,514 | 2,001,637 | |
| 11.5 | 10.6 | 9.9 | 8.0 | 14.3 | 14.5 | 10.7 | | |
| 9.0 | 8.5 | 8.0 | 6.6 | 11.8 | 12.1 | 8.9 | | |
| 78.9 | 80.8 | 81.1 | 82.9 | 82.3 | 84.5 | 82.8 | | |
| 163.0 | 165.3 | 126.2 | 154.3 | 143.1 | 156.2 | 155.0 | | |
| 18.8 | 20.0 | 15.9 | 23.0 | 12.7 | 13.3 | 17.9 | | |
| 4.6 | 4.6 | 5.4 | 5.4 | 5.2 | 5.3 | 5.4 | | |
| 86,751 | 86,825 | 86,867 | 86,916 | 86,992 | 87,053 | 87,147 | | |
| 2,312 | 2,409 | 2,483 | 2,690 | 2,756 | 2,867 | 3,053 | | |

Consolidated Balance Sheets

Santen Pharmaceutical Co., Ltd. and Subsidiaries
As of March 31, 2012 and 2011

| | Millions of yen | | Thousands of U.S. dollars (Note 3) |
|--|-----------------|-----------------|--|
| | 2012 | 2011 | 2012 |
| ASSETS | | | |
| Current assets: | | | |
| Cash and cash equivalents (Note 6) | ¥ 75,035 | ¥ 72,482 | \$ 912,950 |
| Short-term investments (Notes 6 and 7) | 3,939 | 6,409 | 47,925 |
| Trade receivables (Note 6): | | | |
| Notes | 625 | 984 | 7,605 |
| Accounts | 37,299 | 37,997 | 453,812 |
| Allowance for doubtful receivables | (1) | (2) | (14) |
| Net trade receivables | 37,923 | 38,979 | 461,403 |
| Inventories (Note 8) | 17,949 | 14,704 | 218,389 |
| Deferred tax assets (Note 16) | 1,921 | 1,987 | 23,373 |
| Other current assets | 3,521 | 3,107 | 42,842 |
| Total current assets | 140,288 | 137,668 | 1,706,882 |
| Property, plant and equipment (Notes 9 and 10): | | | |
| Land | 8,213 | 8,216 | 99,929 |
| Buildings and structures | 41,058 | 40,720 | 499,551 |
| Machinery and equipment | 11,258 | 11,050 | 136,976 |
| Tools, furniture and vehicles | 11,320 | 11,041 | 137,726 |
| Lease assets | 242 | 234 | 2,944 |
| Construction in progress | 1,366 | 186 | 16,617 |
| Total | 73,457 | 71,447 | 893,743 |
| Accumulated depreciation and impairment loss | (47,934) | (46,490) | (583,205) |
| Net property, plant and equipment | 25,523 | 24,957 | 310,538 |
| Investments and other assets: | | | |
| Investments in affiliates (Note 6) | 16 | 16 | 190 |
| Investment securities (Notes 6 and 7) | 12,396 | 12,126 | 150,825 |
| Goodwill | 5,802 | — | 70,591 |
| In-process research and development | 5,942 | — | 72,295 |
| Other intangible assets | 1,134 | 991 | 13,793 |
| Deferred tax assets (Note 16) | 6,500 | 7,538 | 79,087 |
| Other assets | 1,200 | 1,505 | 14,606 |
| Total investments and other assets | 32,990 | 22,176 | 401,387 |
| Total assets | ¥198,801 | ¥184,801 | \$2,418,807 |

See accompanying notes to consolidated financial statements.

| LIABILITIES AND NET ASSETS | Millions of yen | | Thousands of U.S. dollars (Note 3) |
|--|-----------------|----------|--|
| | 2012 | 2011 | 2012 |
| Current liabilities: | | | |
| Trade accounts payable (Note 6) | ¥ 8,075 | ¥ 6,031 | \$ 98,242 |
| Other payables (Note 6) | 9,009 | 8,444 | 109,619 |
| Accrued expenses | 4,486 | 3,614 | 54,580 |
| Income taxes payable (Notes 6 and 16) | 5,283 | 4,631 | 64,276 |
| Other current liabilities | 573 | 1,385 | 6,966 |
| Total current liabilities | 27,426 | 24,105 | 333,683 |
| Non-current liabilities: | | | |
| Long-term debt (Note 11) | 179 | 152 | 2,184 |
| Retirement and severance benefits (Note 12) | 3,459 | 3,266 | 42,086 |
| Retirement and severance benefits for directors (Note 12) | 223 | 454 | 2,713 |
| Deferred tax liabilities (Note 16) | 1,996 | 21 | 24,290 |
| Asset retirement obligation | 162 | 160 | 1,970 |
| Other liabilities | 495 | 239 | 6,022 |
| Total non-current liabilities | 6,514 | 4,292 | 79,265 |
| Contingent liabilities (Note 17) | | | |
| Total liabilities | 33,940 | 28,397 | 412,948 |
| Net assets (Note 13): | | | |
| Shareholders' equity: | | | |
| Common stock (Note 13): | | | |
| Authorized – 220,000,000 shares (220,000,000 shares in 2011) | | | |
| Issued – 87,146,803 shares (87,053,103 shares in 2011) | 6,695 | 6,615 | 81,457 |
| Capital surplus (Note 13) | 8,049 | 7,969 | 97,933 |
| Retained earnings | 156,030 | 147,578 | 1,898,410 |
| Treasury stock, at cost: | | | |
| 1,246 shares in 2012 and 464 shares in 2011 | (4) | (2) | (53) |
| Total shareholders' equity | 170,770 | 162,160 | 2,077,747 |
| Accumulated other comprehensive income (loss): | | | |
| Unrealized gains (losses) on securities, net of taxes (Note 7) | 51 | (443) | 626 |
| Foreign currency translation adjustments | (6,307) | (5,618) | (76,736) |
| Total accumulated other comprehensive income (loss) | (6,256) | (6,061) | (76,110) |
| Stock subscription rights (Note 14) | 347 | 305 | 4,222 |
| Total net assets | 164,861 | 156,404 | 2,005,859 |
| Total liabilities and net assets | ¥198,801 | ¥184,801 | \$2,418,807 |

Consolidated Statements of Income and Comprehensive Income

Santen Pharmaceutical Co., Ltd. and Subsidiaries

For the years ended March 31, 2012, 2011 and 2010

| | Millions of yen | | | Thousands of U.S. dollars (Note 3) |
|---|-----------------|----------|----------|--|
| | 2012 | 2011 | 2010 | 2012 |
| Net sales | ¥114,416 | ¥110,812 | ¥110,594 | \$1,392,101 |
| Cost of sales | 35,385 | 34,437 | 34,710 | 430,527 |
| Gross profit | 79,031 | 76,375 | 75,884 | 961,574 |
| Selling, general and administrative expenses | 52,299 | 45,636 | 46,244 | 636,314 |
| Operating income | 26,732 | 30,739 | 29,640 | 325,260 |
| Other income (expenses): | | | | |
| Interest and dividend income | 529 | 521 | 418 | 6,431 |
| Gain on insurance received | 162 | 39 | 43 | 1,969 |
| Dividends income of insurance | 143 | 137 | 128 | 1,742 |
| Exchange gains (losses), net | 107 | (123) | (383) | 1,297 |
| Interest expense | (23) | (36) | (53) | (276) |
| Equity in losses of affiliates | — | — | (564) | — |
| Gain on sale of investment securities | 57 | — | 74 | 694 |
| Loss on sale of investment securities | (15) | — | (197) | (183) |
| Write-down of investment securities (Note 7) | — | (150) | (254) | — |
| Office transfer expenses of U.S. subsidiaries | — | (135) | — | — |
| Loss on adjustment for change of accounting standard for asset retirement obligations | — | (109) | — | — |
| Loss on impairment of fixed assets (Note 10) | (19) | — | (397) | (235) |
| Other, net | 118 | 191 | 155 | 1,434 |
| Income before income taxes | 27,791 | 31,074 | 28,610 | 338,133 |
| Income taxes (Note 16): | | | | |
| Current | 9,912 | 9,970 | 10,687 | 120,605 |
| Deferred | 718 | (229) | (800) | 8,732 |
| | 10,630 | 9,741 | 9,887 | 129,337 |
| Income before minority interests | 17,161 | 21,333 | 18,723 | 208,796 |
| Net income | 17,161 | 21,333 | 18,723 | 208,796 |
| Income before minority interests | 17,161 | 21,333 | 18,723 | 208,796 |
| Other comprehensive income (loss) (Note 4): | | | | |
| Unrealized gains (losses) on securities, net of taxes | 494 | (579) | 383 | 6,021 |
| Foreign currency translation adjustments | (689) | (957) | (280) | (8,382) |
| Other comprehensive income (loss) | (195) | (1,536) | 103 | (2,361) |
| Total comprehensive income | 16,966 | 19,797 | 18,826 | 206,435 |
| Total comprehensive income attributable to: | | | | |
| Owners of the parent | ¥ 16,966 | ¥ 19,797 | ¥ 18,826 | \$ 206,435 |
| Minority interests | — | — | — | — |
| | | Yen | | U.S. dollars (Note 3) |
| Per share data: | 2012 | 2011 | 2010 | 2012 |
| Net income-basic | ¥ 196.96 | ¥ 249.71 | ¥ 220.10 | \$ 2.40 |
| Net income-diluted | 196.76 | 249.42 | 219.85 | 2.39 |
| Cash dividends, applicable to the period | 100.00 | 90.00 | 80.00 | 1.22 |

See accompanying notes to consolidated financial statements.

Consolidated Statements of Changes in Net Assets

Santen Pharmaceutical Co., Ltd. and Subsidiaries
For the years ended March 31, 2012, 2011 and 2010

Millions of yen

| | Common stock | Capital surplus | Retained earnings | Treasury stock, at cost | Unrealized gains (losses) on securities, net of taxes | Foreign currency translation adjustments | Stock subscription rights |
|-----------------------------------|---------------|-----------------|-------------------|-------------------------|---|--|---------------------------|
| Balance at April 1, 2009 | ¥6,457 | ¥7,152 | ¥121,134 | ¥(4,934) | ¥(247) | ¥(4,381) | ¥188 |
| Exercise of stock options | 82 | 82 | | | | | |
| Cash dividends | | | (6,804) | | | | |
| Net income | | | 18,723 | | | | |
| Repurchase of treasury stock, net | | | | (24) | | | |
| Disposal of treasury stock | | 0 | | 0 | | | |
| Other, net | | | | | 383 | (280) | 72 |
| Balance at March 31, 2010 | ¥6,539 | ¥7,234 | ¥133,053 | ¥(4,958) | ¥ 136 | ¥(4,661) | ¥260 |
| Exercise of stock options | 76 | 76 | | | | | |
| Cash dividends | | | (6,808) | | | | |
| Net income | | | 21,333 | | | | |
| Repurchase of treasury stock, net | | | | (26) | | | |
| Disposal of treasury stock | | 659 | | 4,982 | | | |
| Other, net | | | | | (579) | (957) | 45 |
| Balance at March 31, 2011 | ¥6,615 | ¥7,969 | ¥147,578 | ¥ (2) | ¥(443) | ¥(5,618) | ¥305 |
| Exercise of stock options | 80 | 80 | | | | | |
| Cash dividends | | | (8,709) | | | | |
| Net income | | | 17,161 | | | | |
| Repurchase of treasury stock, net | | | | (2) | | | |
| Disposal of treasury stock | | 0 | | 0 | | | |
| Other, net | | | | | 494 | (689) | 42 |
| Balance at March 31, 2012 | ¥6,695 | ¥8,049 | ¥156,030 | ¥ (4) | ¥ 51 | ¥(6,307) | ¥347 |

Thousands of U.S. dollars (Note 3)

| | Common stock | Capital surplus | Retained earnings | Treasury stock, at cost | Unrealized gains (losses) on securities, net of taxes | Foreign currency translation adjustments | Stock subscription rights |
|----------------------------------|-----------------|-----------------|--------------------|-------------------------|---|--|---------------------------|
| Balance at April 1, 2011 | \$80,479 | \$96,956 | \$1,795,575 | \$(22) | \$(5,396) | \$(68,354) | \$3,719 |
| Exercise of stock options | 978 | 977 | | | | | |
| Cash dividends | | | (105,961) | | | | |
| Net income | | | 208,796 | | | | |
| Repurchase of treasury stock | | | | (31) | | | |
| Disposal of treasury stock | | 0 | | 0 | | | |
| Other, net | | | | | 6,022 | (8,382) | 503 |
| Balance at March 31, 2012 | \$81,457 | \$97,933 | \$1,898,410 | \$(53) | \$ 626 | \$(76,736) | \$4,222 |

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows

Santen Pharmaceutical Co., Ltd. and Subsidiaries

For the years ended March 31, 2012, 2011 and 2010

| | Millions of yen | | | Thousands of U.S. dollars (Note 3) |
|---|-----------------|-----------------|-----------------|--|
| | 2012 | 2011 | 2010 | 2012 |
| Cash flows from operating activities: | | | | |
| Income before income taxes | ¥ 27,791 | ¥ 31,074 | ¥ 28,610 | \$ 338,133 |
| Depreciation and amortization | 2,949 | 2,976 | 3,421 | 35,886 |
| Loss on impairment of fixed assets (Note 10) | 19 | — | 397 | 235 |
| Increase in retirement and severance benefits | 179 | 359 | 517 | 2,174 |
| Interest and dividend income | (529) | (521) | (418) | (6,431) |
| Interest expense | 23 | 36 | 53 | 276 |
| Equity in losses of affiliates | — | — | 564 | — |
| Decrease (increase) in trade receivables | 1,037 | (3,893) | 699 | 12,621 |
| Increase in inventories | (3,294) | (1,299) | (1,438) | (40,081) |
| Increase (decrease) in trade accounts payable | 2,034 | 522 | (248) | 24,746 |
| Other, net | 10 | (11) | 1,873 | 121 |
| Subtotal | 30,219 | 29,243 | 34,030 | 367,680 |
| Interest and dividend income received | 549 | 513 | 419 | 6,685 |
| Interest expense paid | (17) | (36) | (47) | (203) |
| Income taxes paid | (9,268) | (11,952) | (8,292) | (112,770) |
| Net cash provided by operating activities | 21,483 | 17,768 | 26,110 | 261,392 |
| Cash flows from investing activities: | | | | |
| Capital expenditures | (3,281) | (1,651) | (1,315) | (39,915) |
| Proceeds from sale of property, plant and equipment | 6 | 188 | 3 | 78 |
| Purchase of investment securities | (2,420) | (4,296) | (1,028) | (29,445) |
| Proceeds from sale of investment securities | 377 | 20 | 309 | 4,589 |
| Purchase of short-term investments | (1,783) | (5,873) | (5,836) | (21,700) |
| Proceeds from sale of short-term investments | 7,632 | 3,922 | 7,036 | 92,863 |
| Acquisition of subsidiary, net of cash acquired | (10,804) | — | — | (131,457) |
| Increase in loans receivable | (7) | (1) | (49) | (83) |
| Proceeds from collection of loans receivable | 8 | — | 49 | 93 |
| Other, net | (1) | 15 | 2 | (15) |
| Net cash used in investing activities | (10,273) | (7,676) | (829) | (124,992) |
| Cash flows from financing activities: | | | | |
| Proceeds from short-term borrowings | — | 259 | 548 | — |
| Repayment of short-term borrowings | — | (776) | (521) | — |
| Repayment of long-term debt | — | — | (110) | — |
| Repurchase of treasury stock | (2) | (26) | (24) | (31) |
| Disposal of treasury stock | 0 | 5,641 | 0 | 0 |
| Dividends paid | (8,706) | (6,808) | (6,804) | (105,923) |
| Other, net | 149 | 140 | 158 | 1,813 |
| Net cash used in financing activities | (8,559) | (1,570) | (6,753) | (104,141) |
| Effect of exchange rate changes on cash and cash equivalents | (98) | (389) | (136) | (1,196) |
| Net increase in cash and cash equivalents | 2,553 | 8,133 | 18,392 | 31,063 |
| Cash and cash equivalents at beginning of year | 72,482 | 64,349 | 45,957 | 881,887 |
| Cash and cash equivalents at end of year | ¥ 75,035 | ¥ 72,482 | ¥ 64,349 | \$ 912,950 |

See accompanying notes to consolidated financial statements.

| | Millions of yen | | | Thousands of U.S. dollars (Note 3) |
|---|-----------------|------|------|--|
| | 2012 | 2011 | 2010 | 2012 |
| Additional cash flow information | | | | |
| Assets and liabilities increased by acquisition of shares of subsidiary | | | | |
| Current assets | ¥ 1,171 | ¥— | ¥— | \$ 14,247 |
| Non-current assets | 6,251 | — | — | 76,056 |
| Goodwill | 6,195 | — | — | 75,376 |
| Current liabilities | (340) | — | — | (4,134) |
| Non-current liabilities | (2,320) | — | — | (28,227) |
| Foreign currency translation adjustments | (2) | — | — | (32) |
| Acquisition price | 10,955 | — | — | 133,286 |
| Other payables | (32) | — | — | (387) |
| Cash and cash equivalents | (119) | — | — | (1,442) |
| Payments for purchases of shares of subsidiary | ¥10,804 | ¥— | ¥— | \$131,457 |

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 from International Financial Reporting Standards.

The accounts of consolidated overseas subsidiaries have been prepared in accordance with either International Financial Reporting Standards or U.S. generally accepted accounting principles, as required under "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements" issued and revised by the Accounting Standards Board of Japan ("ASBJ"). In this case, adjustments for the following five items are required in the consolidation process so that their impact on net income is 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 and 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) Accounting for net income attributable to minority interests

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 these consolidated financial statements.

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.

During the year ended March 31, 2012, the Company established two new subsidiaries (Santen India Private Limited, Santen Holdings EU B.V.) and acquired one subsidiary (Novagali Pharma S.A.S. ("Novagali")).

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 Notes 6 and 7)

The Company and its domestic subsidiary have adopted the "Accounting Standard for Financial Instruments" which was issued and revised 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 non-current 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 accumulated other comprehensive income.

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.

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 declines substantially and the decline is not expected to recover.

4) Derivative instruments (see Note 6)

Derivatives are initially measured at fair value and are subsequently remeasured to fair value at each reporting date. Apart from those derivatives designated as qualifying hedging instruments, all changes in carrying value are recognized in profit. The Company utilizes derivatives for hedging the risk arising from fluctuation in foreign currency exchange rates and interest rates and does not enter into derivatives for trading or speculative purposes. Derivatives that are designated as qualifying hedging instruments are 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 realized if the 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 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 8)

Inventories of the Company and its domestic subsidiary are stated at the lower of average cost or net realizable value under the "Accounting Standard for Measurement of Inventories" which was issued by ASBJ.

Inventories of consolidated foreign subsidiaries are principally stated at the lower of first-in, first-out cost or net realizable value.

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

Property, plant and equipment is stated at cost. For the Company and its domestic subsidiary, 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. 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 subsidiary. For all overseas subsidiaries, depreciation is computed over the estimated useful lives of the assets using the straight-line method.

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) In-process research and development and Other intangible assets (excluding lease assets)

In-process research and development resources acquired through a business combination are capitalized as intangible assets at the fair value allocated in the acquisition accounting. In-process research and development and other intangible assets are amortized over their useful lives on a straight-line-method from the point when they are available for use.

9) Leases (see Note 9)

Finance leases, except for certain immaterial leases, are capitalized and depreciated over the leased property's estimated useful lives or lease terms, in accordance with the "Accounting Standard for Lease Transactions" and the "Guidance on Accounting Standard for Lease Transactions" which were issued by ASBJ. As permitted under the accounting standard, the Company and its domestic subsidiary 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.

10) Goodwill

Goodwill recognized through the acquisition of Novagali is amortized using the straight-line method over the period of expected benefit (10 years).

11) Impairment of fixed assets (see Note 10)

In accordance with the "Accounting Standards for Impairment of Fixed Assets" which was issued by the Business Accounting Council in Japan, fixed assets, such as property,

Notes to Consolidated Financial Statements

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 comparing the carrying amount of an asset, or group of assets, to the 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.

12) Retirement and severance benefits (see Note 12)

Employees of the Company and certain 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 Companies have adopted the "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 plan 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.

Certain overseas subsidiaries have a retirement benefit scheme which is a combination of a cash balance and defined contribution pension plan, and other overseas subsidiaries have defined contribution pension plans. The amounts contributed under the plans are charged to income.

In addition, the Company has an unfunded retirement benefit plan for directors. The amounts required under the plan have been fully accrued according to internal regulations.

13) 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 subsidiary have adopted the "Accounting Standard for Foreign Currency Transactions" which was issued by the Business Accounting Council in Japan.

Financial statements of overseas subsidiaries are translated into 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.

14) Research and development (see Note 15)

Research and development expenditures are charged to income when incurred.

15) Net income and dividends per share (see Note 13)

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 for the years ended March 31, 2012, 2011 and 2010 was 87,127 thousand, 85,433 thousand and 85,065 thousand, 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 for the years ended March 31, 2012, 2011 and 2010 was 87,214 thousand, 85,534 thousand and 85,162 thousand, respectively.

Cash dividends per share shown in the accompanying Consolidated Statements of Income and Comprehensive Income are the amounts applicable to the respective years.

16) Income taxes (see Note 16)

Income taxes are accounted for by 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 carryforwards and foreign tax credit carryforwards. 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 resulting from a change in tax rates is recognized in income in the period that includes the enactment date.

17) 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.

18) Reclassifications

Certain reclassifications have been made to prior years' consolidated financial statements to conform with the presentation used for the year ended March 31, 2012.

19) Changes in accounting policies

Effective April 1, 2010, the Company and its domestic subsidiary adopted the "Accounting Standards for Asset Retirement Obligations" (ASBJ Statement No. 18 issued on March 31, 2008) and the "Guidance on Accounting Standards for Assets Retirement Obligations" (ASBJ Guidance No. 21 issued on March 31, 2008).

Effective March 31, 2011, the Company adopted the "Accounting Standard for Presentation of Comprehensive Income" (ASBJ Statement No. 25 issued on June 30, 2010) and the "Revised Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22 revised on June 30, 2010).

Effective April 1, 2011, the Company and its domestic subsidiary adopted the "Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Statement No. 24 on December 4, 2009) and the "Guidance on Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Guidance No. 24 on December 4, 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 ¥82.19 to U.S.\$1.00, the exchange rate prevailing on March 31, 2012. 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. Other Comprehensive Income (Loss)

Amounts reclassified to net income in the current period that were recognized in other comprehensive income (loss) in the current or previous periods and the tax effects for each component of other comprehensive income (loss) were as follows:

| | Millions of yen | Thousands of U.S. dollars |
|--|-----------------|---------------------------|
| | 2012 | 2012 |
| Unrealized gains on securities | | |
| Increase during the year | ¥ 881 | \$10,723 |
| Reclassification adjustments | (57) | (694) |
| Sub-total, before tax | 824 | 10,029 |
| Tax (expense) or benefit | (330) | (4,008) |
| Sub-total, net of tax | 494 | 6,021 |
| Foreign currency translation adjustments | | |
| Decrease during the year | (689) | (8,382) |
| Total other comprehensive income (loss) | ¥(195) | \$ (2,361) |

5. Business Combination

1) Over view of the business combination

i. Name and business of the acquired company

Name of the acquired company Novagali Pharma S.A.
Business of the acquired company Development and commercializing of ophthalmic products

ii. Main reasons for the business combination

Novagali is a pharmaceutical company that develops ophthalmic products in the dry eye domain and it also

commercializes OTC pharmaceuticals. The Company believes that Novagali will play an important role with its outstanding R&D capability as well as its unique pharmaceutical technologies.

Especially, Novasorb technology will enhance the Companies' drug formulation ability as a whole. Based on Novasorb technology, Cyclokot (generic name: ciclosporin) is currently undergoing development. This is a development product in late stage pipeline in the dry eye domain. When Cyclokot is approved for production

Notes to Consolidated Financial Statements

and marketing, it will be released as Europe's first prescription pharmaceutical for the treatment of dry eye and it will be also able to strengthen the Companies' global business.

iii. Date of the business combination

October 11, 2011

iv. Legal format of the business combination

Acquisition of the shares for cash consideration

v. Name of the company after business combination

Novagali Pharma S.A.

vi. Shareholding status after business combination

Wholly owned subsidiary of the Company

vii. Main basis behind the determination of the acquiring company

Acquired 100% of the shares of Novagali for cash consideration

2) Operating result of the acquired company for the year ended March 31, 2012

Operating results of the acquired company from October 11, 2011 to December 31, 2011 were included in the consolidated results of the Company for the year ended March 31, 2012.

3) Acquisition cost of the acquired company

| | | |
|--|-----------------|----------------------|
| Cash payment for acquisition | ¥10,402 million | (\$126,559 thousand) |
| Other direct costs for the acquisition | ¥553 million | (\$6,727 thousand) |
| Total acquisition cost | ¥10,955 million | (\$133,286 thousand) |

4) Goodwill recognized and method and period of amortization

i. Goodwill recognized at the date of the business combination

¥6,195 million (\$75,376 thousand)

ii. Method and period of amortization

The excess of cost over the fair value of the underlying net assets at fair value at the date of the acquisition was recognized as goodwill. The goodwill is being amortized using the straight-line method over 10 years.

5) Breakdown of acquired assets and liabilities as of date of business combination

| | | |
|---------------------|-----------------|----------------------|
| Current assets | ¥1,171 million | (\$14,247 thousand) |
| Fixed assets | ¥12,446 million | (\$151,432 thousand) |
| Total assets | ¥13,617 million | (\$165,679 thousand) |
| Current liabilities | ¥340 million | (\$4,134 thousand) |
| Fixed liabilities | ¥2,320 million | (\$28,227 thousand) |
| Total liabilities | ¥2,660 million | (\$32,361 thousand) |

6) Significant intangible assets other than goodwill acquired in the business combination included in the acquisition cost

In-process research and development
¥6,170 million (\$75,065 thousand)
This intangible asset is amortized over the estimated useful life.

7) Estimated impact on the consolidated statements of income and comprehensive income for the year ended March 31, 2012 if the business combination had been completed as of the beginning of the year ended March 31, 2012

Since estimated impact is minimal, it is omitted.

Note: In March, 2012, Novagali changed its company form, and it became Novagali Pharma S.A.S. under the French regulation.

6. Financial Instruments

The Companies have adopted the "Accounting Standard for Financial Instruments" and the "Guideline on Disclosures about Fair Value of Financial Instruments."

Information on Financial instruments for the year ended March 31, 2012 and 2011 is as follows:

1) Policies for financing activities

The Companies principally use highly liquid and safe financial instruments in financing activities. The Companies basically rely on their own resources to finance operations and use derivative financial instruments only to hedge foreign exchange rate risk for foreign currency denominated

assets and liabilities and do not use derivative financial instrument for speculative purposes.

2) Risk management

Trade receivables are exposed to customer credit risk. To manage this risk, the Company performs due date and credit limit controls in accordance with the Companies' credit management rules and periodically assesses the financial reliability of each customer taking into account the customer's financial position and other factors.

Bonds in short-term investments are exposed to the credit risk of the issuing institution. The Company invests

only in high-rated bonds.

Investment securities are exposed to market risk, most of which are stocks of companies with which the Company has business relationships. The Company periodically reviews the fair market values of these securities and reports on them at the Company's board meeting.

Trade accounts payable, other payables and income taxes payable (the "operating payables") are due within one year.

Bank loans in short-term borrowings and long-term

debt do not occur regularly. The Companies use them as short-term funding for business necessities according to the situation.

Operating payables and the bank loans are exposed to liquidity risk. The Company manages the risk by monitoring the monthly cash flows of each group company.

To reduce credit risk, the Company uses derivative instruments according to its policies for hedging, including rules for authorization levels, transaction volumes and entering into transactions only with highly rated banks.

The book value and fair value of the financial instruments on the consolidated balance sheet at March 31, 2012 and 2011 were as follows:

| | Millions of yen | | | | | |
|---|-----------------|------------|------------|------------|------------|------------|
| | 2012 | | | 2011 | | |
| | Book value | Fair value | Difference | Book value | Fair value | Difference |
| Cash and cash equivalents | ¥75,035 | ¥75,035 | ¥ (0) | ¥72,482 | ¥72,482 | ¥ (0) |
| Trade receivables | 37,924 | 37,924 | — | 38,981 | 38,981 | — |
| Short-term investments and Investment securities: | | | | | | |
| Time deposits | 198 | 198 | — | 2,075 | 2,075 | — |
| Held-to-maturity | 4,239 | 4,236 | (3) | 5,373 | 5,360 | (13) |
| Other securities | 11,754 | 11,754 | — | 10,941 | 10,941 | — |
| Trade accounts payable | (8,075) | (8,075) | — | (6,031) | (6,031) | — |
| Other payables | (9,009) | (9,009) | — | (8,444) | (8,444) | — |
| Income taxes payable | (5,283) | (5,283) | — | (4,631) | (4,631) | — |
| Derivatives | — | — | — | — | — | — |

| | Thousands of U.S. dollars | | |
|---|---------------------------|------------|------------|
| | 2012 | | |
| | Book value | Fair value | Difference |
| Cash and cash equivalents | \$ 912,950 | \$ 912,943 | \$ (7) |
| Trade receivables | 461,417 | 461,417 | — |
| Short-term investments and Investment securities: | | | |
| Time deposits | 2,413 | 2,413 | — |
| Held-to-maturity | 51,576 | 51,543 | (33) |
| Other securities | 143,017 | 143,017 | — |
| Trade accounts payable | (98,242) | (98,242) | — |
| Other payables | (109,619) | (109,619) | — |
| Income taxes payable | (64,276) | (64,276) | — |
| Derivatives | — | — | — |

Notes: 1. Instruments with no fair market value are excluded in the table above.

2. Figures in parentheses indicate a liability or a decrease.

3. The following methods and assumptions were used to estimate fair value:

Cash and Trade receivables

– As these assets are settled in a short period of time, the fair value approximates book value.

Cash equivalents

– The fair values of held-to-maturity debt securities included in Cash and cash equivalents are based on the quoted market prices or the prices provided by corresponding financial institutions.

Short-term investments and Investment securities

– The fair values of listed stocks are based on year-end quoted stock market prices and those of bonds are based on the quoted market prices or the prices provided by corresponding financial institutions.

Notes to Consolidated Financial Statements

- The fair value of time deposits approximates the book value.
- Short-term borrowings, Trade accounts payable, Other payables and Income taxes payable
- As these liabilities are settled in a short period, fair value approximates book value.
- Derivatives
- There were no outstanding transactions at March 31, 2012 and 2011.

4. Financial Instruments with no fair market value as of March 31, 2012 and 2011 were as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---------------------------------|-----------------|------|---------------------------|
| | 2012 | 2011 | 2012 |
| Other securities: | | | |
| Unlisted securities | ¥138 | ¥138 | \$1,682 |
| Investment limited partnerships | 21 | 23 | 253 |
| | ¥159 | ¥161 | \$1,935 |

These instruments are excluded from investment securities in the table above since there are no fair market values available for these instruments.

5. The maturity profile of the anticipated future contractual cash flows in relation to the Companies' financial assets at March 31, 2012 and 2011 were as follows:

| | Millions of yen | | | | Thousands of U.S. dollars | |
|---|---------------------|--------------------|---------------------|--------------------|---------------------------|--------------------|
| | 2012 | | 2011 | | 2012 | |
| | Due within one year | Due after one year | Due within one year | Due after one year | Due within one year | Due after one year |
| Cash and cash equivalents | ¥ 75,035 | ¥ — | ¥ 72,482 | ¥ — | \$ 912,950 | \$ — |
| Trade receivables | 37,924 | — | 38,981 | — | 461,417 | — |
| Short-term investments and investment securities: | | | | | | |
| Time deposits | 198 | — | 2,075 | — | 2,413 | — |
| Held-to-maturity | 3,721 | 500 | 4,300 | 1,021 | 45,273 | 6,083 |
| Other securities | — | — | — | — | — | — |
| | ¥116,878 | ¥500 | ¥117,838 | ¥1,021 | \$1,422,053 | \$6,083 |

6. See Note 11 of Notes to Consolidated Financial Statements in respect to maturities of long-term debt at March 31, 2012 and 2011.

7. Short-term Investments and Investment Securities

The following was a summary of held-to-maturity at market value at March 31, 2012 and 2011:

| | Millions of yen | | | | | |
|--|-----------------|------------|------------|------------|------------|------------|
| | 2012 | | | 2011 | | |
| | Book value | Fair value | Difference | Book value | Fair value | Difference |
| Securities with fair values exceeding book values: | | | | | | |
| Corporate bonds | ¥ — | ¥ — | ¥— | ¥ — | ¥ — | ¥ — |
| Securities with fair values not exceeding book values: | | | | | | |
| Corporate bonds | 4,239 | 4,236 | (3) | 5,373 | 5,360 | (13) |
| | ¥4,239 | ¥4,236 | ¥ (3) | ¥5,373 | ¥5,360 | ¥(13) |

| | Thousands of U.S. dollars | | |
|--|---------------------------|------------|------------|
| | 2012 | | |
| | Book value | Fair value | Difference |
| Securities with fair values exceeding book values: | | | |
| Corporate bonds | \$ — | \$ — | \$ — |
| Securities with fair values not exceeding book values: | | | |
| Corporate bonds | 51,576 | 51,543 | (33) |
| | \$51,576 | \$51,543 | \$(33) |

The following was a summary of other securities at market value at March 31, 2012 and 2011:

| | Millions of yen | | | | | |
|--|------------------|------------|------------|------------------|------------|------------|
| | 2012 | | | 2011 | | |
| | Acquisition cost | Book value | Difference | Acquisition cost | Book value | Difference |
| Securities with book values exceeding acquisition costs: | | | | | | |
| Equity securities | ¥ 4,043 | ¥ 5,195 | ¥ 1,152 | ¥ 4,057 | ¥ 4,567 | ¥ 510 |
| Other | 3 | 3 | — | — | — | — |
| Securities with book values not exceeding acquisition costs: | | | | | | |
| Equity securities | 7,628 | 6,556 | (1,072) | 7,629 | 6,374 | (1,255) |
| Other | — | — | — | — | — | — |
| | ¥11,674 | ¥11,754 | ¥ 80 | ¥11,686 | ¥10,941 | ¥ (745) |

| | Thousands of U.S. dollars | | |
|--|---------------------------|------------|------------|
| | 2012 | | |
| | Acquisition cost | Book value | Difference |
| Securities with book values exceeding acquisition costs: | | | |
| Equity securities | \$ 49,197 | \$ 63,215 | \$ 14,018 |
| Other | 35 | 35 | — |
| Securities with book values not exceeding acquisition costs: | | | |
| Equity securities | 92,817 | 79,767 | (13,050) |
| Other | — | — | — |
| | \$142,049 | \$143,017 | \$ 968 |

The market prices in the table above do not include the unlisted securities. The book value of the unlisted securities at March 31, 2012 and 2011 were ¥143 million (\$1,744 thousand) and ¥146 million, respectively.

Held-to-maturity debt securities sold during the year ended March 31, 2012 and 2011 were as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|-------------------------|-----------------|------|---------------------------|
| | 2012 | 2011 | 2012 |
| Cost of securities sold | ¥809 | ¥— | \$9,849 |
| Proceeds | 794 | — | 9,666 |
| Loss on sale | ¥ (15) | ¥— | \$ (183) |

Impairment loss on investment securities was ¥150 million for the year ended March 31, 2011.

If the year-end value of an investment security has declined by more than 50% of its acquisition cost, an impairment loss is recognized. When the year-end value has declined by less than 50% but more than 30%, an impairment loss is recognized if there is no possibility that the security will recover its value.

8. Inventories

Inventories at March 31, 2012 and 2011 consisted of the following:

| | Millions of yen | | Thousands of U.S. dollars |
|--------------------------------|-----------------|---------|---------------------------|
| | 2012 | 2011 | 2012 |
| Merchandise and finished goods | ¥14,672 | ¥11,784 | \$178,515 |
| Work in process | 600 | 450 | 7,303 |
| Raw materials and supplies | 2,677 | 2,470 | 32,571 |
| | ¥17,949 | ¥14,704 | \$218,389 |

9. Leases

Finance leases, commenced prior to April 1, 2008, which did not transfer ownership of the leased assets to the lessees, are accounted for as operating leases.

Finance leases

The equivalent purchase amount, accumulated depreciation and future minimum lease payments on an “as if capitalized” basis at March 31, 2012 and 2011 were as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|--|-----------------|------|---------------------------|
| | 2012 | 2011 | 2012 |
| Tools, furniture and vehicles: | | | |
| Equivalent purchase amount | ¥— | ¥126 | \$— |
| Equivalent accumulated depreciation amount | — | 114 | — |
| Equivalent balance at year-end | — | 12 | — |
| Future minimum lease payments: | | | |
| Due within one year | ¥— | ¥ 13 | \$— |
| Due after one year | — | — | — |
| | ¥— | ¥ 13 | \$— |

Lease payments, equivalent depreciation and equivalent interest expense for the three years ended March 31, 2012 were as follows:

| | Millions of yen | | | Thousands of U.S. dollars |
|-----------------------------|-----------------|------|------|---------------------------|
| | 2012 | 2011 | 2010 | 2012 |
| Lease payments | ¥13 | ¥143 | ¥432 | \$164 |
| Equivalent depreciation | ¥12 | ¥133 | ¥410 | \$150 |
| Equivalent interest expense | ¥ 0 | ¥ 1 | ¥ 6 | \$ 1 |

Operating leases

Future minimum rents under non-cancellable operating leases at March 31, 2012 and 2011 consisted of the following:

| | Millions of yen | | Thousands of U.S. dollars |
|---------------------|-----------------|------|---------------------------|
| | 2012 | 2011 | 2012 |
| Due within one year | ¥201 | ¥209 | \$2,443 |
| Due after one year | 491 | 306 | 5,981 |
| | ¥692 | ¥515 | \$8,424 |

10. Impairment of Fixed Assets

The Company and its domestic subsidiary account for impairment of fixed assets in accordance with the “Accounting Standard for Impairment of Fixed Assets.”

The Company and its domestic subsidiary review the recorded value of their property, plant and equipment and intangible assets to determine if the future cash flows from these properties will be sufficient to support the asset's covering values.

Impairment loss recognized for the three years ended March 31, 2012 was as follows:

| | Millions of yen | | | Thousands of U.S. dollars |
|--------------------------|-----------------|------|------|---------------------------|
| | 2012 | 2011 | 2010 | 2012 |
| Land | ¥— | ¥— | ¥249 | \$ — |
| Buildings and structures | 19 | — | 147 | 235 |
| Others | — | — | 1 | — |
| | ¥19 | ¥— | ¥397 | \$235 |

For the year ended March 31, 2012, the Company recorded impairment loss related to building and structures for its plant due to the decision to stop the use of a generator. The fair value was based on the disposal value.

For the year ended March 31, 2010, the Company recorded impairment loss of ¥284 million related to land, buildings and structures and others for the closed dormitory which was expected to be sold due to the anticipated loss

on sale. The Company also recorded impairment loss of ¥113 million related to land for the logistics operations since it was not expected to be used and the recoverable amount had decreased. The fair value of the land, buildings and structures and others for the closed dormitory was based on selling price. The fair value of the land for the logistics operations was based on disposal value.

11. Long-term Debt

Long-term debt at March 31, 2012 and 2011 consisted of the following:

Long-term borrowings are executed by Novagali.

| | Millions of yen | | Thousands of U.S. dollars |
|---|-----------------|------|---------------------------|
| | 2012 | 2011 | 2012 |
| Unsecured loan from governmental institution, due in installments by September 30, 2013, no interest | ¥ 14 | ¥ — | \$ 169 |
| Unsecured loan from governmental institution, due in installments by September 30, 2015, no interest | 50 | — | 613 |
| Lease obligations | 115 | 152 | 1,402 |
| Total | ¥179 | ¥152 | \$2,184 |

The aggregate annual maturities of long-term debt at March 31, 2012 were as follows:

| Years ending March 31 | Millions of yen | Thousands of U.S. dollars |
|-----------------------|-----------------|---------------------------|
| 2014 | ¥ 65 | \$ 789 |
| 2015 | 51 | 625 |
| 2016 | 44 | 538 |
| 2017 | 4 | 55 |
| 2018 and thereafter | 15 | 177 |
| | ¥179 | \$2,184 |

12. Retirement and Severance Benefits

As discussed in Note 2. 12), 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. Certain overseas subsidiaries also have a retirement benefit scheme, which is a combination of cash balance

and defined contribution pension plan and other overseas subsidiaries have defined contribution pension plans. The Company has an unfunded retirement benefit plan for directors. The amounts required under the plan have been fully accrued based on internal regulations.

The following table sets forth the details of the benefit obligation, plan assets and funded status of the Companies at March 31, 2012 and 2011.

| | Millions of yen | | Thousands of U.S. dollars |
|---|-----------------|-----------|---------------------------|
| | 2012 | 2011 | 2012 |
| For employees: | | | |
| Benefit obligation at end of year | ¥(14,926) | ¥(14,187) | \$(181,607) |
| Fair value of plan assets at end of year | 10,286 | 9,795 | 125,154 |
| Funded status (benefit obligation in excess of plan assets) | (4,640) | (4,392) | (56,453) |
| Unrecognized actuarial loss | 1,181 | 1,126 | 14,367 |
| For directors: | | | |
| Accrued retirement benefit | (223) | (454) | (2,713) |
| Retirement and severance benefits recognized in the consolidated balance sheets | ¥ (3,682) | ¥ (3,720) | \$ (44,799) |

Retirement and severance costs of the Companies included the following components for the three years ended March 31, 2012.

| | Millions of yen | | | Thousands of U.S. dollars |
|---|-----------------|--------|--------|---------------------------|
| | 2012 | 2011 | 2010 | 2012 |
| For employees: | | | | |
| Service cost | ¥ 896 | ¥ 921 | ¥ 956 | \$10,900 |
| Interest cost | 279 | 276 | 257 | 3,399 |
| Expected return on plan assets | (198) | (195) | (145) | (2,415) |
| Recognized actuarial loss | 182 | 169 | 179 | 2,217 |
| Contribution to defined contribution pension plan | 862 | 791 | 813 | 10,491 |
| Net periodic benefit cost | ¥2,021 | ¥1,962 | ¥2,060 | \$24,592 |
| For directors: | | | | |
| Accrual for retirement benefit | ¥ 69 | ¥ 38 | ¥ 16 | \$ 842 |

Assumptions used in the accounting for retirement and severance benefits for the three years ended March 31, 2012 were as follows:

| | 2012 | 2011 | 2010 |
|--|----------------------------|---------------------|---------------------|
| Method of attributing benefit to period of service | Straight-line basis | Straight-line basis | Straight-line basis |
| Discount rate | mainly, 2.00% | mainly, 2.00% | mainly, 2.00% |
| Expected return on plan assets | mainly, 2.00% | mainly, 2.00% | mainly, 2.00% |
| Amortization period for actuarial losses* | mainly, 14 years | mainly, 14 years | mainly, 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.

The domestic subsidiary and the overseas subsidiary have a lump-sum severance plan and 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.

13. 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 (\$18,876 thousand) and ¥1,551 million as of March 31, 2012 and 2011, respectively.

Cash dividends charged to retained earnings during the three years ended March 31, 2012 represent dividends paid out during the periods. The accompanying consolidated financial statements do not include any provision for the year-end dividend of ¥50 (\$0.61) per share, aggregating ¥4,357 million (\$53,015 thousand) which was approved at the Company's shareholders' meeting on June 20, 2012 in respect of the year ended March 31, 2012.

14. 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 existing as of March 31, 2012 were as follows:

| Stock options granted | 2011 | 2010 | 2009 | 2008 |
|-----------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| Persons granted | Directors and corporate officers: 10 | Directors and corporate officers: 10 | Directors and corporate officers: 12 | Directors and corporate officers: 12 |
| Number of shares | Common Stock 114,500 | Common Stock 120,500 | Common Stock 168,400 | Common Stock 161,700 |
| Date of grant | July 5, 2011 | July 6, 2010 | July 3, 2009 | July 2, 2008 |
| Vesting conditions | No provisions | No provisions | No provisions | No provisions |
| Service period | No provisions | No provisions | No provisions | No provisions |
| Exercise period | From June 24, 2013 to June 22, 2021 | From June 25, 2012 to June 23, 2020 | From June 27, 2011 to June 24, 2019 | From June 28, 2010 to June 25, 2018 |

Notes to Consolidated Financial Statements

| Stock options granted | 2007 | 2006 | 2005 | 2004 |
|-----------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| Persons granted | Directors and corporate officers: 12 | Directors and corporate officers: 15 | Directors and corporate officers: 15 | Directors and corporate officers: 11 |
| Number of shares | Common Stock 99,300 | Common Stock 102,700 | Common Stock 129,200 | Common Stock 78,200 |
| Date of grant | July 3, 2007 | July 4, 2006 | July 4, 2005 | July 5, 2004 |
| Vesting conditions | No provisions | No provisions | No provisions | No provisions |
| Service period | No provisions | No provisions | No provisions | No provisions |
| Exercise period | From June 27, 2009 to June 26, 2017 | From June 28, 2008 to June 24, 2016 | From June 25, 2007 to June 23, 2015 | From June 26, 2006 to June 24, 2014 |

| Stock options granted | 2003 | 2002 | 2001 |
|-----------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| Persons granted | Directors and corporate officers: 12 | Directors and corporate officers: 14 | Directors and corporate officers: 14 |
| Number of shares | Common Stock 137,600 | Common Stock 92,000 | Common Stock 55,000 |
| Date of grant | July 4, 2003 | July 5, 2002 | July 9, 2001 |
| Vesting conditions | No provisions | No provisions | No provisions |
| Service period | No provisions | No provisions | No provisions |
| Exercise period | From June 27, 2005 to June 25, 2013 | From June 27, 2004 to June 25, 2012 | From June 29, 2003 to June 27, 2011 |

Number, movement and price of stock options for the year ended March 31, 2012 were as follows:

Before vesting options (Number of shares):

| Stock options granted | 2011 | 2010 | 2009 | 2008 | 2007 | 2006 |
|----------------------------------|----------|----------|----------|----------|----------|----------|
| Balance at April 1, 2011 | — | — | — | — | — | — |
| Granted | 114,500 | — | — | — | — | — |
| Vested | 114,500 | — | — | — | — | — |
| Balance at March 31, 2012 | — | — | — | — | — | — |

| Stock options granted | 2005 | 2004 | 2003 | 2002 | 2001 |
|----------------------------------|----------|----------|----------|----------|----------|
| Balance at April 1, 2011 | — | — | — | — | — |
| Granted | — | — | — | — | — |
| Vested | — | — | — | — | — |
| Balance at March 31, 2012 | — | — | — | — | — |

After vesting options (Number of shares):

| Stock options granted | 2011 | 2010 | 2009 | 2008 | 2007 | 2006 |
|----------------------------------|----------------|----------------|----------------|----------------|---------------|---------------|
| Balance at April 1, 2011 | — | 120,500 | 168,400 | 160,900 | 99,300 | 97,400 |
| Vested | 114,500 | — | — | — | — | — |
| Exercised | — | — | — | 4,100 | — | 5,300 |
| Balance at March 31, 2012 | 114,500 | 120,500 | 168,400 | 156,800 | 99,300 | 92,100 |

| Stock options granted | 2005 | 2004 | 2003 | 2002 | 2001 |
|----------------------------------|----------------|---------------|------------|----------|----------|
| Balance at April 1, 2011 | 117,500 | 39,600 | 35,800 | 23,000 | 4,700 |
| Vested | — | — | — | — | — |
| Exercised | 16,500 | 8,900 | 34,900 | 23,000 | 1,000 |
| Canceled | — | — | — | — | 3,700 |
| Balance at March 31, 2012 | 101,000 | 30,700 | 900 | — | — |

Price information (Yen):

| | | | | | | |
|----------------------------|--------|--------|--------|--------|--------|--------|
| Stock options granted | 2011 | 2010 | 2009 | 2008 | 2007 | 2006 |
| Option price | 3,230 | 3,170 | 2,920 | 2,734 | 3,050 | 2,715 |
| Weight-average stock price | — | — | — | 3,110 | — | 3,101 |
| Fair value at grant date* | 402.99 | 403.71 | 427.73 | 423.16 | 609.45 | 579.05 |
| Stock options granted | 2005 | 2004 | 2003 | 2002 | 2001 | |
| Option price | 2,480 | 1,743 | 1,176 | 1,326 | 2,299 | |
| Weight-average stock price | 3,163 | 3,129 | 3,094 | 3,095 | 3,160 | |
| 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 20, 2012, 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 23, 2014 to June 20, 2022. The maximum number of stock subscription rights that can be exercised is 124,300 common shares.

15. Research and Development Expenditures

Research and development expenditures charged to income as incurred for the years ended March 31, 2012, 2011 and 2010 were ¥17,225 million (\$209,580 thousand), ¥13,221 and ¥14,123 million, respectively.

16. Income Taxes

The Company and its domestic subsidiary 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, 2012. Overseas subsidiaries are subject to income taxes of the countries in which they operate.

The reasons for the effective rates for the years ended March 31, 2012, 2011 and 2010 differ from the normal tax rates were as follows:

| | 2012 | 2011 | 2010 |
|--|--------------|-------|-------|
| Normal tax rate | 40.4% | 40.4% | 40.4% |
| Tax effect from change in tax rates by tax reform | 2.7 | — | — |
| Expenses not deductible for tax purposes | 1.1 | 0.7 | 0.9 |
| Lower tax rates of subsidiaries | 0.3 | (0.5) | (0.1) |
| Equity in losses of affiliates | — | — | (1.2) |
| Tax credit for research and development expenses | (6.2) | (4.3) | (4.4) |
| Change in valuation allowance allocated to income tax expenses | (0.3) | (5.2) | (1.4) |
| Others | 0.2 | 0.2 | 0.4 |
| Effective tax rate | 38.2% | 31.3% | 34.6% |

Notes to Consolidated Financial Statements

The tax effects of temporary differences and tax loss carryforwards that gave rise to significant portions of the deferred tax assets and deferred tax liabilities at March 31, 2012 and 2011 were as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|---|-----------------|---------|---------------------------|
| | 2012 | 2011 | 2012 |
| Deferred tax assets: | | | |
| Tax loss carryforwards | ¥ 5,605 | ¥ 3,148 | \$ 68,195 |
| Retirement and severance benefits | 2,633 | 2,860 | 32,037 |
| Deferred assets for tax purposes | 1,279 | 1,998 | 15,559 |
| Depreciation and amortization | 894 | 925 | 10,877 |
| Accrued expenses | 876 | 935 | 10,662 |
| Advance payment | 812 | — | 9,883 |
| Accrued enterprise taxes | 418 | 386 | 5,086 |
| Net unrealized holding losses on securities | — | 301 | — |
| Retirement and severance benefits for directors | 79 | 184 | 962 |
| Loss on impairment of golf membership rights | 58 | 66 | 708 |
| Loss on valuation of securities | 57 | 65 | 692 |
| Loss on valuation of inventories | 30 | 59 | 366 |
| Loss on impairment of fixed assets | 18 | 189 | 213 |
| Other | 1,419 | 1,493 | 17,266 |
| Subtotal | 14,178 | 12,609 | 172,506 |
| Valuation allowance | (5,683) | (3,013) | (69,144) |
| Total gross deferred tax assets | 8,495 | 9,596 | 103,362 |
| Deferred tax liabilities: | | | |
| In-process research and development | (1,980) | — | (24,096) |
| Reserve for special depreciation | (32) | (56) | (391) |
| Other | (58) | (36) | (705) |
| Total gross deferred tax liabilities | (2,070) | (92) | (25,192) |
| Net deferred tax assets | ¥ 6,425 | ¥ 9,504 | \$ 78,170 |

Net deferred tax assets at March 31, 2012 and 2011 were reflected in the accompanying consolidated balance sheets under the following captions:

| | Millions of yen | | Thousands of U.S. dollars |
|--|-----------------|---------|---------------------------|
| | 2012 | 2011 | 2012 |
| Current assets – deferred tax assets | ¥ 1,921 | ¥ 1,987 | \$ 23,373 |
| Investments and other assets – deferred tax assets | 6,500 | 7,538 | 79,087 |
| Non-current liabilities – deferred tax liabilities | (1,996) | (21) | (24,290) |
| Net deferred tax assets | ¥ 6,425 | ¥ 9,504 | \$ 78,170 |

Adjustment of deferred tax assets and liabilities for enacted changes in tax laws and rates

According to the promulgation of the “Act for Partial Revision of the Income Tax Act, etc. for the Purpose of Creating Taxation System Responding to Changes in Economic and Social Structures” (Act No. 114 of 2011) and the “Act on Special Measures for Securing Financial Resources Necessary to Implement Measures for Reconstruction Following the Great East Japan Earthquake” (Act No. 117 of 2011),

effective from the fiscal year beginning on and after April 1, 2012, the corporate tax rate will be reduced and a special recovery tax will be imposed.

In accordance with this reform, the effective statutory tax rates which are used to calculate deferred tax assets and deferred tax liabilities will be reduced to 37.86% from 40.44% for temporary differences expected to be reversed on or after April 1, 2012, and to 35.48% for temporary differences expected to be recovered or settled on or after

April 1, 2015.

As a result of this change in effective statutory tax rates, deferred tax assets (after offsetting deferred tax liabilities) have been decreased by ¥632 million (\$7,688 thousand),

Income taxes-Deferred has been increased by ¥636 million (\$7,736 thousand) and unrealized gains on securities have been increased by ¥4 million (\$48 thousand).

17. Contingent Liabilities

The Company has provided guarantees to financial institutions covering employee loans. As of March 31, 2012, the total amount of outstanding guarantees was ¥180 million (\$2,201 thousand).

18. Segment Information

General information about reportable segments

The determination of the Companies' operating segments is based on the organization units for which information is reported to the Company's chief operating decision making body, the Board of Directors. The Board of Directors reviews the internal report in order to assess performance and allocate resources. "Pharmaceuticals" is the Companies' only one reportable segment and includes manufacturing and distribution of prescription and OTC pharmaceuticals.

Basis of measurement about reported segment profit or loss, segment assets, segment liabilities and other material items

The accounting policies for the reportable segments are basically the same as those described in Note 2, Summary of Significant Accounting Policies. Performance is measured based on segment operating profit. Transfer pricing between reportable segments are determined on an arm's length basis.

Information about reported segment profit (loss), segment assets, segment liabilities and other material items were as follows:

| For the year ended March 31, 2012 | Millions of yen | | | | |
|---|-----------------|--------|----------|-------------|--------------|
| | Pharmaceuticals | Other | Total | Adjustments | Consolidated |
| Net Sales: | | | | | |
| External customers | ¥111,846 | ¥2,570 | ¥114,416 | ¥ — | ¥114,416 |
| Intersegment | — | 113 | 113 | (113) | — |
| Total | 111,846 | 2,683 | 114,529 | (113) | 114,416 |
| Segment profit | 26,684 | 48 | 26,732 | — | 26,732 |
| Segment assets | 106,535 | 2,126 | 108,661 | 90,140 | 198,801 |
| Other items: | | | | | |
| Depreciation and amortization | 2,718 | 69 | 2,787 | — | 2,787 |
| Amortization of goodwill | 162 | — | 162 | — | 162 |
| Increase in property, plant and equipment and intangible assets | 15,902 | 69 | 15,971 | — | 15,971 |

| For the year ended March 31, 2011 | Millions of yen | | | | |
|---|-----------------|--------|----------|-------------|--------------|
| | Pharmaceuticals | Other | Total | Adjustments | Consolidated |
| Net Sales: | | | | | |
| External customers | ¥108,576 | ¥2,236 | ¥110,812 | ¥ — | ¥110,812 |
| Intersegment | — | 122 | 122 | (122) | — |
| Total | 108,576 | 2,358 | 110,934 | (122) | 110,812 |
| Segment profit | 30,518 | 221 | 30,739 | — | 30,739 |
| Segment assets | 90,067 | 1,814 | 91,881 | 92,920 | 184,801 |
| Other items: | | | | | |
| Depreciation and amortization | 2,901 | 75 | 2,976 | — | 2,976 |
| Increase in property, plant and equipment and intangible assets | 2,143 | 44 | 2,187 | — | 2,187 |

Notes to Consolidated Financial Statements

| For the year ended March 31, 2010 | Millions of yen | | | | |
|---|-----------------|--------|----------|-------------|--------------|
| | Pharmaceuticals | Other | Total | Adjustments | Consolidated |
| Net Sales: | | | | | |
| External customers | ¥109,057 | ¥1,537 | ¥110,594 | ¥ — | ¥110,594 |
| Intersegment | — | 119 | 119 | (119) | — |
| Total | 109,057 | 1,656 | 110,713 | (119) | 110,594 |
| Segment profit (loss) | 29,859 | (219) | 29,640 | — | 29,640 |
| Segment assets | 84,732 | 1,464 | 86,196 | 80,682 | 166,878 |
| Other items: | | | | | |
| Depreciation and amortization | 3,310 | 111 | 3,421 | — | 3,421 |
| Increase in property, plant and equipment and intangible assets | 1,423 | 44 | 1,467 | — | 1,467 |

| For the year ended March 31, 2012 | Thousands of U.S. dollars | | | | |
|---|---------------------------|----------|-------------|-------------|--------------|
| | Pharmaceuticals | Other | Total | Adjustments | Consolidated |
| Net Sales: | | | | | |
| External customers | \$1,360,832 | \$31,269 | \$1,392,101 | \$ — | \$1,392,101 |
| Intersegment | — | 1,377 | 1,377 | (1,377) | — |
| Total | 1,360,832 | 32,646 | 1,393,478 | (1,377) | 1,392,101 |
| Segment profit | 324,673 | 587 | 325,260 | — | 325,260 |
| Segment assets | 1,296,203 | 25,873 | 1,322,076 | 1,096,731 | 2,418,807 |
| Other items: | | | | | |
| Depreciation and amortization | 33,065 | 849 | 33,914 | — | 33,914 |
| Amortization of goodwill | 1,972 | — | 1,972 | — | 1,972 |
| Increase in property, plant and equipment and intangible assets | 193,484 | 841 | 194,325 | — | 194,325 |

Notes: 1. "Other" mainly includes the medical device business segments.

2. "Segment profit" is reconciled for operating income described in the Consolidated Statements of Income and Comprehensive Income.

3. "Adjustments" represents unallocated corporate assets which principally include surplus operating capital (cash and cash equivalents, short-term investments and investment securities) and deferred tax assets.

4. "Depreciation and amortization" and "Increase in property, plant and equipment and intangible assets" include long-term prepaid expenses and its amortization.

Information about products and services were as follows:

| | Millions of yen | | | Thousands of U.S. dollars |
|------------------------------------|-----------------|----------|----------|---------------------------|
| | 2012 | 2011 | 2010 | 2012 |
| Pharmaceuticals: | | | | |
| Prescription pharmaceuticals: | | | | |
| Ophthalmic | ¥ 93,620 | ¥ 90,797 | ¥ 86,867 | \$1,139,070 |
| Anti-rheumatic pharmaceuticals | 9,987 | 9,834 | 9,908 | 121,514 |
| Other prescription pharmaceuticals | 3,642 | 3,222 | 7,031 | 44,312 |
| OTC pharmaceuticals | 4,597 | 4,723 | 5,251 | 55,936 |
| Other: | | | | |
| Medical devices | 2,558 | 2,225 | 1,521 | 31,129 |
| Other | 12 | 11 | 16 | 140 |
| Total | ¥114,416 | ¥110,812 | ¥110,594 | \$1,392,101 |

Information about geographic areas were as follows:

| | Millions of yen | | | Thousands of U.S. dollars |
|---------------------------------------|-----------------|----------|----------|---------------------------|
| | 2012 | 2011 | 2010 | 2012 |
| Net Sales: | | | | |
| Japan | ¥ 95,374 | ¥ 92,549 | ¥ 89,585 | \$1,160,411 |
| Europe | 8,880 | 8,517 | 8,714 | 108,048 |
| North America | 3,451 | 3,070 | 6,715 | 41,985 |
| Asia | 6,706 | 6,668 | 5,576 | 81,590 |
| Other | 5 | 8 | 4 | 67 |
| Total | ¥114,416 | ¥110,812 | ¥110,594 | \$1,392,101 |
| Property, plant and equipment: | | | | |
| Japan | ¥ 21,157 | ¥ 20,939 | ¥ 22,218 | \$ 257,417 |
| Europe | 2,245 | 1,962 | 1,973 | 18,076 |
| North America | 635 | 478 | 529 | 27,318 |
| Asia | 1,486 | 1,578 | 1,854 | 7,727 |
| Total | ¥ 25,523 | ¥ 24,957 | ¥ 26,574 | \$ 310,538 |

Information about major customers were as follows:

| | Millions of yen | | | Thousands of U.S. dollars | Related business segment |
|-------------------------------|-----------------|---------|---------|---------------------------|--------------------------|
| | 2012 | 2011 | 2010 | 2012 | |
| Suzuken Co., Ltd. | ¥23,297 | ¥21,465 | ¥21,024 | \$283,448 | Pharmaceuticals |
| Mediceo Corporation | 20,392 | 20,712 | 19,555 | 248,108 | Pharmaceuticals |
| Toho Pharmaceutical Co., Ltd. | 11,825 | 11,567 | 11,097 | 143,874 | Pharmaceuticals |

Information about loss on impairment of fixed assets by reportable segment were as follows:

| | Millions of yen | | | Thousands of U.S. dollars |
|-----------------|-----------------|------|------|---------------------------|
| | 2012 | 2011 | 2010 | 2012 |
| Pharmaceuticals | ¥19 | ¥— | ¥397 | \$235 |
| Other | — | — | — | — |
| Total | ¥19 | ¥— | ¥397 | \$235 |

Information about amortization of goodwill and unamortized balances by reportable segment were as follows:

| | Millions of yen | | Thousands of U.S. dollars |
|----------------------------------|-----------------|------|---------------------------|
| | 2012 | 2011 | 2012 |
| Amortization of goodwill: | | | |
| Pharmaceuticals | ¥ 162 | ¥— | \$ 1,972 |
| Other | — | — | — |
| Total | ¥ 162 | ¥— | \$ 1,972 |
| Balance at end of period: | | | |
| Pharmaceuticals | ¥5,802 | ¥— | \$70,591 |
| Other | — | — | — |
| Total | ¥5,802 | ¥— | \$70,591 |

19. Subsequent Events

On April 27, 2012, the Company's board of Directors made a resolution in which the Company and Bayer Yakuhin, Ltd. ("Bayer Yakuhin") reached an agreement for the co-promotion of VEGF Trap-Eye (afibercept intravitreal injection) in the Japanese market on May 7, 2012. Bayer Yakuhin has submitted an authorization application to the Ministry of Health, Labour and Welfare (MHLW) for the marketing of this product for the treatment of wet age-related macular degeneration (wet AMD).

With this agreement, medical representatives (MRs) of both companies will start promotional activities of VEGF Trap-Eye after Bayer Yakuhin obtains a marketing authorization from the MHLW. The Company will distribute the product in Japan and Bayer Yakuhin will hold the marketing authorization for the product.

By adding an outstanding product, i.e., VEGF Trap-Eye, in the product market for the back-of-the-eye area that is associated with wet AMD, for which the Company offers less treatment options at present, the Company expects to meet the treatment needs of patients and further contribute to the improvement in patients' quality of life (QOL).

On August 1, 2012, the Company's Board of Directors made a resolution to acquire treasury stock specifically by means of tender offer ("Tender Offer") pursuant to Article 156, Paragraph 1, applied with certain replacement of terms as provided in Article 165, Paragraph 3 of the Japanese Corporate Law and the provisions of the Company's Articles of Association.

1. Purpose of Tender Offer

The Company was notified by a large shareholder that the shareholder intended to sell its holding common shares of the Company. In response to this notification, the Company started a specific review of acquiring the relevant common shares as treasury stock based on a comprehensive assessment of the liquidity of the Company's common shares and the impact on the market price as a result of the one-time release of not a small amount of shares in the market, as well as the Company's financial status. The Company presumed that the Company's acquisition of new treasury stock would improve capital efficiency and lead to return of profit to the shareholders and would not affect the Company's financial status and dividend policy, and concluded that the acquisition of new treasury stock would be in line with the Company's basic policy on return of profit.

With regard to the specific method of acquiring new treasury stock, the Company judged from the perspectives of shareholder equality and transactional transparency that the method of tender offer would be appropriate.

2. Detail of the Board Resolution Regarding Acquisition of Treasury Stock

- (1) Class of Shares
Common Stock
- (2) Total Number of Shares
Up to 5,000,100 shares
- (3) Period of Acquisition
From August 2, 2012 through September 24, 2012
- (4) Aggregate Purchase Amount
Up to 14,000,000,000 yen

3. Outline of Tender Offer

- (1) Class of Shares of Tender Offer
Common Stock
- (2) Period of Tender Offer
From August 2, 2012 through August 29, 2012
(20 business days)
- (3) Purchase Price
2,782 yen per share
- (4) Number of Shares to be Acquired
5,000,000 shares
- (5) Commencement Date of Payment
September 21, 2012

All of treasury stock newly acquired in the Tender Offer is scheduled to be canceled by December 2012.

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, 2012 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 and its subsidiaries, 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 two subsidiaries, 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, 2012.

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, 2012.

5 Other

None.



Akira Kurokawa
President & CEO

August 10, 2012

Independent Auditor's Report



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

Report on the Consolidated Financial Statements

We have audited the accompanying consolidated financial statements of Santen Pharmaceutical Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheets as at March 31, 2012 and 2011, and the consolidated statements of income and comprehensive income, statements of changes in net assets and statements of cash flows for each of the three-year in the period ended March 31, 2012, and a summary of significant accounting policies and other explanatory information.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to 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 comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgement, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Santen Pharmaceutical Co., Ltd. and its consolidated subsidiaries as at March 31, 2012 and 2011, and their financial performance and cash flows for each of the three-year in the period ended March 31, 2012, in accordance with accounting principles generally accepted in Japan.

Emphasis of Matter

Without qualifying our opinion, we draw attention to Note 19 to the consolidated financial statements, on August 1, 2012, the Company's Board of Directors made a resolution to acquire treasury stock by means of tender offer.

Convenience Translation

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2012 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 3, to the consolidated financial statements.

Report on the Internal Control Report

We also have audited the accompanying report on internal control over financial reporting of the consolidated financial statements of Santen Pharmaceutical Co., Ltd. as at March 31, 2012 ("Internal Control Report").

Management's Responsibility for the Internal Control Report

Management is responsible for the design and operation of internal control over financial reporting and the preparation and fair presentation of the internal control report in conformity with assessment standards for internal control over financial reporting generally accepted in Japan. Internal control over financial reporting may not completely prevent or detect financial statement misstatements.

Auditor's Responsibility

Our responsibility is to independently express an opinion on the internal control report based on our internal control audit. 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 comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the Internal Control Report is free from material misstatement.

An internal control audit involves performing procedures to obtain audit evidence about the assessment of internal control over financial reporting in the Internal Control Report. The procedures selected depend on the auditor's judgement, including significance of effect on the reliability of financial reporting. Also, an internal control audit 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 the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Internal Control Report, in which Santen Pharmaceutical Co., Ltd. states that internal control over financial reporting was effective as at March 31, 2012, 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.

August 10, 2012
Osaka, Japan

Corporate Information / Stock Information

As of March 31, 2012

Corporate Headquarters Santen Pharmaceutical Co., Ltd.
9-19, Shimoshinjo 3-chome,
Higashiyodogawa-ku,
Osaka 533-8651, Japan
URL: <http://www.santen.com>
Investor relations contact:
TEL: +81-6-6321-7007
E-MAIL: ir@santen.co.jp

Established 1890

Paid-in Capital ¥6,695 million

Number of Shareholders 8,288

Stock Exchange Listings Tokyo and Osaka

Ticker Code 4536

Transfer Agent Mitsubishi UFJ Trust and Banking Corporation
6-3, Fushimi-cho 3-chome, Chuo-ku,
Osaka 541-8502, Japan

Major Offices Sendai, Tokyo, Nagoya, Osaka and Fukuoka

Manufacturing Plants Noto, Shiga and Osaka

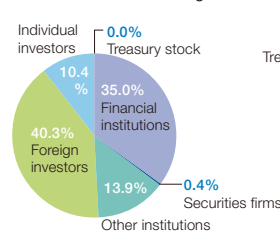
Research Laboratory Nara Research and Development Center

Number of Employees 3,053 (non-consolidated: 1,927)

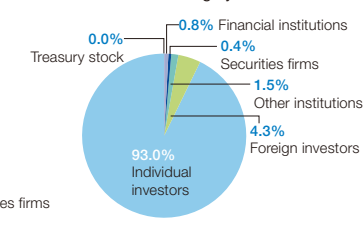
Number of Shares Issued 87,146,803

Breakdown of Shareholding

Breakdown of shareholding



Breakdown of shareholding by number of shares

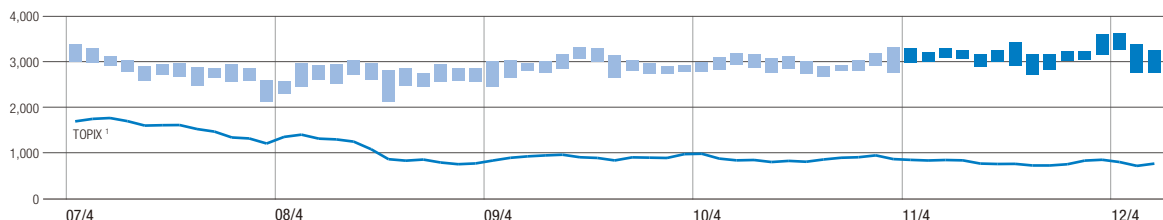


Major Shareholders

| Name | Number of shares held | Percentage of investment |
|---|---|--------------------------|
| Japan Trustee Services Bank, Ltd. | 11,424 <small>Thousands of shares</small> | 13.1% |
| Mita Sangyo Co., Ltd. | 4,756 | 5.5 |
| State Street Bank and Trust Company 505223 | 3,776 | 4.3 |
| The Master Trust Bank of Japan, Ltd. | 3,456 | 4.0 |
| Development Bank of Japan Inc. | 3,310 | 3.8 |
| Nippon Life Insurance Company | 2,717 | 3.1 |
| The Bank of Tokyo-Mitsubishi UFJ, Ltd. | 2,120 | 2.4 |
| Trust and Custody Services Bank, Ltd. | 2,065 | 2.4 |
| Mellon Bank Treaty Clients Omnibus | 1,994 | 2.3 |
| RBC Dexia Investor Services Trust, London Lending Account | 1,984 | 2.3 |

Stock Price Range (Yen)

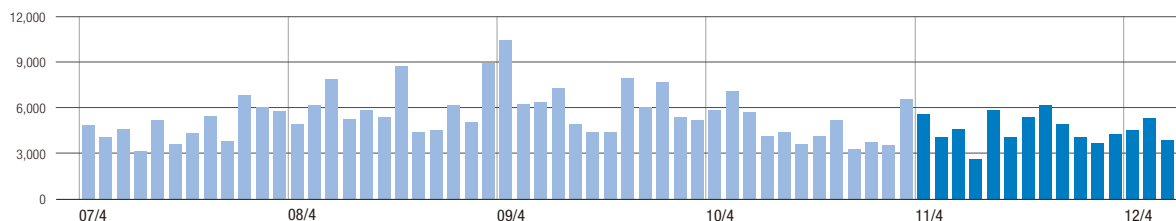
Osaka Securities Exchange (monthly basis)



1. TOPIX: Tokyo stock price index

Trading Volume (Thousands of shares)

Osaka Securities Exchange (monthly basis)



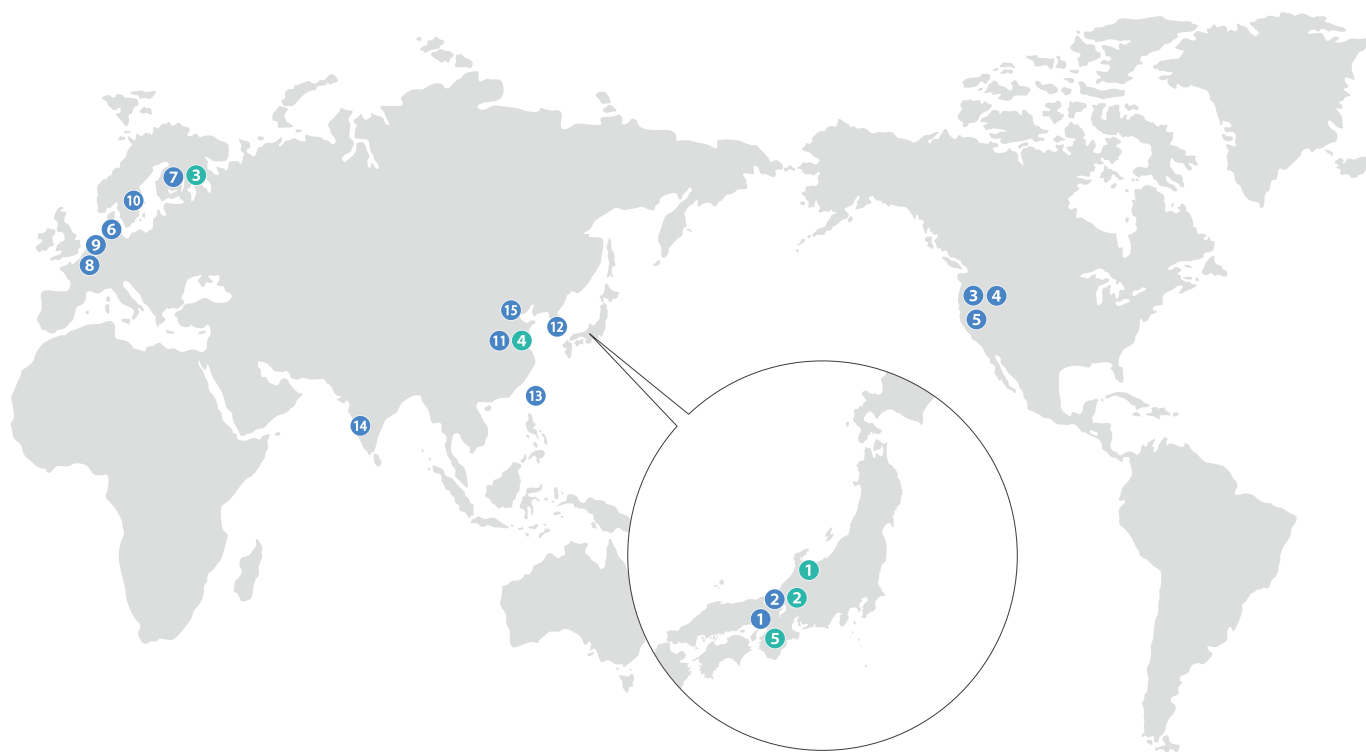
Yearly High and Low Prices

| | 2008 | 2009 | 2010 | 2011 | 2012 |
|------------|-------|-------|-------|-------|-------|
| High (yen) | 3,050 | 3,340 | 3,195 | 3,445 | 3,655 |
| Low (yen) | 2,125 | 2,460 | 2,694 | 2,731 | 2,778 |

Note: Calendar years. Stock prices for 2012 are for the period to the end of June.

Business Bases

As of August 2012



Plants and Laboratory



① Noto Plant

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



② 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



③ Tampere Plant

Niittyhaankatu 20, P.O. Box 33,
FIN-33721 Tampere, Finland
TEL: +358-3-284-8111 FAX: +358-3-318-1900



④ Suzhou Plant

No. 169 Tinglan Road, Suzhou Industrial Park,
Jiangsu Province 215026, P.R.C.
TEL: +86-512-6295-7500 FAX: +86-512-6295-7800



⑤ 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

Note: Osaka Plant details have been omitted due to the planned transfer of its operations to the Shiga Plant by the end of fiscal 2012.

| Corporate Headquarters and Subsidiaries | | | Business | Equity Ownership |
|--|--|---|----------------------------|------------------|
| 1 Corporate Headquarters | 9-19, Shimoshinjo 3-chome, Higashiyodogawa-ku, Osaka 533-8651, Japan TEL: +81-6-6321-7000 FAX: +81-6-6328-7395 | Research, development, production, marketing of pharmaceuticals and medical devices | | |
| 2 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 | Cleaning of antidust and sterilized clothing | 100% | |
| 3 Santen Holdings U.S. Inc. | 2100 Powell Street, Suite 1600, Emeryville, California 94608, U.S.A. | Holding company for North American businesses and business development | 100% | |
| 4 Santen Inc. | 2100 Powell Street, Suite 1600, Emeryville, California 94608, U.S.A. TEL: +1-415-268-9100 FAX: +1-510-655-5682 | Clinical development of pharmaceuticals and business development | 100% ¹ | |
| 5 Advanced Vision Science, Inc. | 5743 Thornwood Drive, Goleta, California 93117, U.S.A. TEL: +1-805-683-3851 FAX: +1-805-964-3065 | Development, production, marketing of medical devices | 100% ¹ | |
| 6 Santen Holdings EU B.V. | Herikerbergweg 238, 1101CM Amsterdam Zuidoost, Netherlands | Centralization of financial controls for European operations | 100% | |
| 7 Santen Oy | Niittyhaankatu 20, P.O. Box 33, FIN-33721 Tampere, Finland TEL: +358-3-284-8111 FAX: +358-3-318-1900 | Production, marketing, clinical development of pharmaceuticals | 100% | |
| 8 Novagali Pharma S.A.S. | 1 rue Pierre Fontaine, Genavenir IV, F-91058 Evry cedex, France TEL: +33-1-69-87-40-20 FAX: +33-1-69-87-40-30 | Clinical development, marketing of pharmaceuticals | 100% | |
| 9 Santen GmbH | Erika-Mann-Strasse 21 80636 Munchen, Germany TEL: +49-89-848078-0 FAX: +49-89-848078-60 | Marketing of pharmaceuticals, business development | 100% | |
| 10 SantenPharma AB | Solna torg 3, SE-17145 Solna, Sweden TEL: +46-8-83-4140 FAX: +46-8-83-4145 | Marketing support of pharmaceuticals | 100% | |
| 11 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 | Production, marketing, clinical development of pharmaceuticals | 100% | |
| 12 Santen Pharmaceutical Korea Co., Ltd. | 3F, Seocho G-WELL Tower, 1678-4, Seocho-dong, Seocho-gu, Seoul 137-070, Korea TEL: +82-2-754-1434 FAX: +82-2-754-2929 | Marketing of pharmaceuticals | 100% | |
| 13 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 | Marketing, clinical development of pharmaceuticals | 100% | |
| 14 Santen India Private Limited | No. 216, Raheja Chambers, 12 Museum Road, Bangalore 560 001, India TEL: +91-80-4932-3700 FAX: +91-80-4932-3799 | Pharmaceutical market research | 99.9% 0.1% ¹ | |

1. Indirect investment through Santen Holdings U.S. Inc.

Other Office

| | |
|----------------------------------|---|
| 15 Beijing Representative Office | Suit 1206B, 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 |
|----------------------------------|---|

Company History

1890

Founder Kenkichi Taguchi opens Taguchi Santendo in Kitahama, Osaka

1925

Operations incorporated as Santendo Co., Ltd.

1935

Yodogawa Plant established in Higashiyodogawa-ku, Osaka

1944

Head Office transferred to Yodogawa Plant (current site)

1945

Company name changed to Santendo Pharmaceutical Co., Ltd.

1958

Company name changed to current form of Santen Pharmaceutical Co., Ltd.

Santen enters prescription pharmaceutical business

1977

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

1982

Central Research Laboratories established

1985

Noto Plant established

1990

Long-term business vision formulated to mark centenary

1993

Subsidiary Santen Inc. established in the U.S.

1994

Subsidiary Santen GmbH established in Germany

1996

Representative office established in Beijing, China

Nara Research and Development Center and Shiga Plant established

1997

Finnish ophthalmics pharmaceutical company acquired and Santen Oy established

Subsidiary Taiwan Santen Pharmaceutical Co., Ltd. established

1998

Medium-term Plan "Hitomi 21" formulated

1900

1890s

Main product is *Heburin-gan*, a cold medicine



1899

Launch of *Daigaku Eye Drops*



1952

Launch of *Daigaku Penicillin Eye Drops*

1953

Launch of *Daigaku Mycillin Eye Drops*

1954

Launch of *Daigaku Super Eye Drops*

1956

Launch of *Sante de U*

1962

Launch of *Mydrin-P*, a mydriatic drug (for pupil dilation)



Launch of *Super Sante* marks first use of plastic eye drop containers in Japan



1963

Launch of *Thiola*, an original liver detoxification agent



1970

Launch of antibiotic ophthalmic *Ecolicin*

1975

Launch of anti-inflammatory ophthalmic *Flumetholon*

1978

Santen commences sales of medical devices

1981

Launch of *Timoptol*, a treatment for glaucoma and ocular hypertension

1985

Launch of *Sante 40 NE*



1986

Santen commences sales of intraocular lenses



1987

Launch of anti-rheumatic *Rimatil*

Launch of anti-infective ophthalmic *Tarivid*



1990

1991

Launch of *Sante FX*



1992

Launch of *BSS PLUS*, an ophthalmic perfusion and bathing solution

Launch of *Kary Uni*, a treatment for early-stage senile cataracts



1995

Launch of *Hyalein*, a treatment for corneal and conjunctival epithelial disorders



Launch of anti-allergy ophthalmic *Alegysal*

Launch of anti-rheumatic *Azulfidine EN*



Launch of *Opegan Hi*, an adjuvant for ophthalmic operations

Product History

Note: Based on the years when sales were launched by Santen Pharmaceutical.

2000

Subsidiary Santen Pharmaceutical Korea Co., Ltd. established

Representative office established in Guangzhou, China

2001

U.S.-based Advanced Vision Science, Inc. acquired

2002

Introduced Dimple Bottle, an innovative patient-oriented container for ophthalmic solutions

2003

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

Santen Pharmaceutical (China) Co., Ltd. established Suzhou Plant

2008

Completion of pharmaceutical development building and ancillary building at Nara Research and Development Center

2009

Santen Pharmaceutical (China) Co., Ltd. commenced direct marketing

2010

Santen Pharmaceutical Korea Co., Ltd. commenced direct marketing

2011

2011-2013 Medium-Term Management Plan formulated

Subsidiary Santen India Private Limited established in India

2012

Acquired Novagali Pharma S.A.S. and made it a wholly owned subsidiary

Established Santen Holdings EU B.V. as a holding company

2000

1999

Launch of *Timoptol XE*, a treatment for glaucoma and ocular hypertension

Launch of *Sante FX Neo*

2000

Launch of anti-infective ophthalmic *Cravit*



2001

Launch of *Detantol*, a treatment for glaucoma and ocular hypertension



Launch of anti-allergy ophthalmic *Livostin*



2002

Launch of *Sante de U Plus E Alpha*

Launch of *Sante 40*

2003

Launch of *ClariFlex* foldable intraocular lenses

2004

Launch of *Rescula*, a treatment for glaucoma and ocular hypertension

Launch of anti-rheumatic *Metolate*

2006

Launch of *Papilock Mini*, a treatment for vernal keratoconjunctivitis

Launch of *Sante Medical 10*

Launch of *Sante AL Cool II*



2007

Launch of *Sante Uruoi Contact a*

2008

Launch of nutritional supplement *Sante Lutax*

Launch of *Sante 40i*



Launch of *Eternity* foldable intraocular lens



Launch of *Tapros*, a treatment for glaucoma and ocular hypertension



2009

Launch of *Sante FX V Plus*



Launch of *Eternity Natural*

foldable intraocular lens

2010

Launch of *Cosopt*, a treatment for glaucoma and ocular hypertension

Launch of *Diquas*, a treatment for dry eye



2012

Launch of *Sante Medical Guard*





www.santen.com

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



This report is printed with
vegetable oil ink.

Printed in Japan