



## **Driven by Core Competencies**

*Santen is emphasizing strong fundamentals to enhance its market position and expand its product portfolio.*



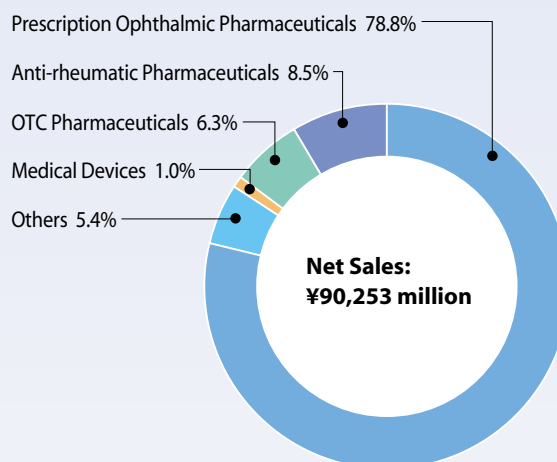
# Profile

Santen Pharmaceutical Co., Ltd. specializes in the research, development, manufacturing and marketing of ophthalmic and anti-rheumatic pharmaceuticals to protect and improve people's eyesight and health. We have created innovative pharmaceuticals for all types of ophthalmic disorders and provide information tailored to clinical needs. As a result, we lead Japan's market for prescription ophthalmics, which represent nearly 80 percent of our net sales. With marketing and development bases in Japan, the United States and Europe, backed by first-rate R&D capabilities, we aim to increase our corporate value as a world-class company that delivers unique products to people worldwide.

Deeply aware of the sanctity of human life, we apply our unique capabilities and technologies in our areas of expertise to contribute to the health and quality of life of patients and their loved ones, and society as a whole.

## SALES BY BUSINESS

Year ended March 31, 2003



Business Area	Description of Business and Major Products	Approximate Market Share/Market Position
<b>Prescription Pharmaceuticals</b>		
<b>Ophthalmic Pharmaceuticals</b>	<ul style="list-style-type: none"> <li>In Japan, Santen's staff of some 400 medical representatives (MRs), the largest in the industry, and a product lineup covering a broad array of ophthalmic disorders have secured its market-leading position. Main products include the anti-infective ophthalmic <i>Cravit</i>; the corneal disorder treatment <i>Hyalein</i>; the glaucoma treatment <i>Detantol</i>; and the anti-allergy ophthalmic <i>Livostin</i>.</li> <li>Overseas, Santen markets levofloxacin ophthalmic solution (brand names: <i>Quixin</i>, <i>Oftaquix</i> and <i>Cravit</i>) and other products through a sales network that covers the United States, Europe and Asia.</li> </ul>	40%/Number One <sup>1</sup>
<b>Anti-rheumatic Pharmaceuticals</b>	<ul style="list-style-type: none"> <li>We offer <i>Rimatil</i> and <i>Azulfidine EN</i>, physicians' disease modifying anti-rheumatic drugs (DMARDs) of choice for treating rheumatoid arthritis, in Japan.</li> </ul>	30%/Number One <sup>1</sup>
<b>Over-the-counter (OTC) Pharmaceuticals</b>	<ul style="list-style-type: none"> <li>Our OTC pharmaceuticals business consists of market-leading eye drop brands in Japan such as <i>Sante FX Neo</i>, the <i>Sante 40</i> series and the <i>Sante de u</i> series.</li> </ul>	20%/Number Two <sup>2</sup>
<b>Medical Devices</b>	<ul style="list-style-type: none"> <li>Santen handles medical devices used in cataract surgery, including intraocular lenses, phacoemulsification machines and instruments, in Japan.</li> </ul>	—

Notes: 1. Market share and market position in Japan for the year ended March 31, 2003. Source: Santen Pharmaceutical Co., Ltd.

2. Market share and market position in the Japanese OTC eye drop market for the year ended March 31, 2003. Source: Santen Pharmaceutical Co., Ltd.

## Contents

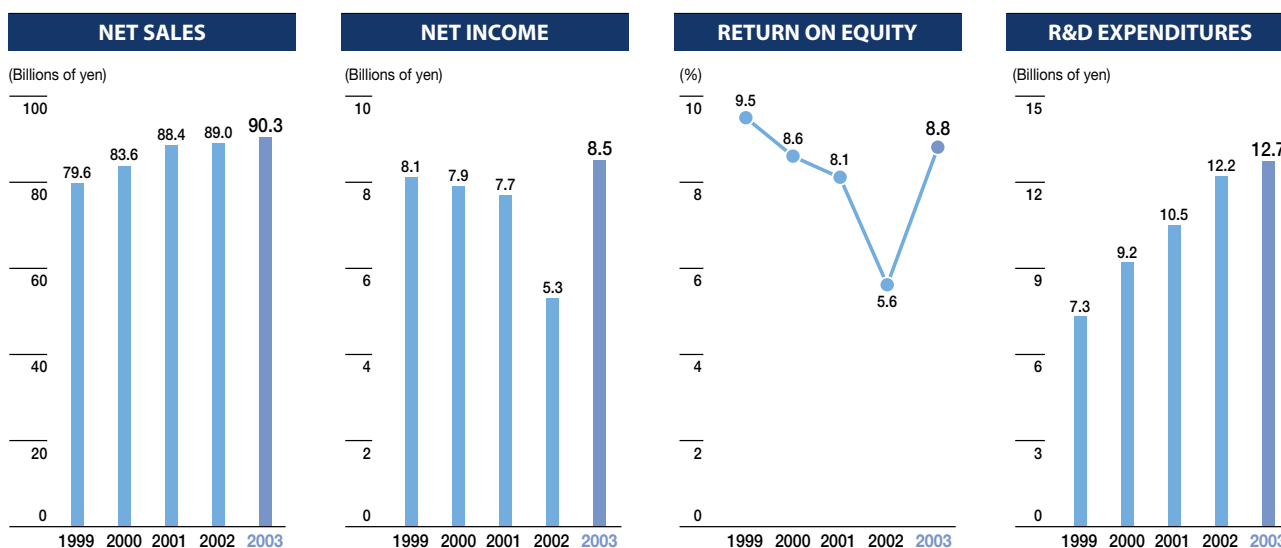
Financial Highlights.....	1	Production.....	24
To Our Shareholders.....	2	Personnel Development .....	26
An Interview with CEO Takakazu Morita on the 2003-2005 Medium-term Management Plan.....	3	Corporate Citizenship .....	27
Corporate Governance .....	8	Financial Review .....	28
Board of Directors, Corporate Auditors and Corporate Officers .....	9	Six-year Summary of Selected Financial Data .....	35
Research.....	10	Consolidated Financial Statements .....	36
Development.....	13	Independent Auditors' Report .....	51
Marketing.....	16	Major Subsidiaries and Facilities.....	52
		Corporate Information.....	53

# Financial Highlights

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
Years ended March 31, 2003 and 2002

	Millions of yen		% Change	Thousands of U.S. dollars
	2003	2002	2003/2002	2003
<b>For the year:</b>				
Net sales .....	¥ <b>90,253</b>	¥ 88,966	1.4 %	\$ <b>750,855</b>
Operating income .....	<b>12,697</b>	11,790	7.7	<b>105,631</b>
Net income .....	<b>8,503</b>	5,306	60.3	<b>70,739</b>
R&D expenditures .....	<b>12,719</b>	12,187	4.4	<b>105,819</b>
Capital expenditures .....	<b>7,046</b>	6,586	7.0	<b>58,616</b>
Depreciation and amortization .....	<b>4,311</b>	5,334	(19.2)	<b>35,867</b>
<b>Per share data (yen and U.S. dollars):</b>				
Net income .....	¥ <b>93.67</b>	¥ 57.34	63.4 %	\$ <b>0.78</b>
Cash dividends .....	<b>20.00</b>	20.00	—	<b>0.17</b>
<b>At year-end:</b>				
Total assets .....	¥ <b>147,148</b>	¥152,103	(3.3)%	\$ <b>1,224,191</b>
Total shareholders' equity .....	<b>97,126</b>	95,101	2.1	<b>808,036</b>
Return on equity (ROE) .....	<b>8.8%</b>	5.6%	—	—
Number of employees .....	<b>2,500</b>	2,463	—	—

Note: U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate prevailing on March 31, 2003 of ¥120.20 to US\$1.



Note: Graphs are based on fiscal years ended March 31.

## A 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.

# To Our *Shareholders*

During the year ended March 31, 2003, the Japanese prescription ophthalmic pharmaceuticals market decreased marginally due to National Health Insurance (NHI) drug price reductions in April 2002 and increased co-payments of medical expenses for the elderly in October 2002. These healthcare reforms had a large impact on the anti-infective ophthalmics market, our core business area, which declined by nearly 10 percent. Our other core business area, the corneal disorder treatment market, grew nearly 10 percent, led by the growth of *Hyalein*. The market for corneal disorder treatments in Japan is, however, becoming more competitive due to the launch of generic drugs. In addition, foreign pharmaceutical companies have increased their activities in the Japanese ophthalmics market, resulting in an increasingly intense operating environment.

To maintain our competitiveness amid this environment, we focused our management resources on our primary products and increased our promotional activities both quantitatively and qualitatively in our Japanese prescription ophthalmics business. In the United States, we reorganized the management structure of our local subsidiary in April 2002 and expanded sales of the anti-infective ophthalmic *Quixin* (brand name in Japan: *Cravit*). In research and development, we accelerated the development of three glaucoma treatments. We also strengthened our research and development capabilities through the injection of resources in targeted therapeutic areas. At the same time, we continued to reduce production costs and have maintained our emphasis on maximizing returns on sales promotion and R&D expenses.

As a result, net sales for the year ended March 31, 2003 increased 1.4 percent over the previous fiscal year to ¥90,253 million (US\$751 million). Operating income increased 7.7 percent to ¥12,697 million (US\$106 million). This increase in operating income after two years of decreases reflected our progress in reducing expenses. Net income increased 60.3 percent to ¥8,503 million (US\$71 million) due to a decrease in income taxes resulting from the liquidation of a subsidiary.

Cash dividends per share were set at ¥20.00, the same as the previous fiscal year. This reflects our policy of maintaining a stable level of cash dividends as a means to emphasize returns for our shareholders. We repurchased 2.7 million shares in March 2003 at a total cost of ¥3,237 million (US\$27 million) to help improve capital efficiency and increase our shareholder value. This was the third consecutive year in which we repurchased our shares.

We view return on equity (ROE) as an important way to measure performance. We are working to continuously increase corporate value as the means of achieving our goal for ROE of 10 percent by the year ending March 31, 2006.

In February 2003, we announced the 2003-2005 Medium-term Management Plan, a three-year plan that started in April 2003. Over the entire term of the plan, we will devote our every effort to fully accomplishing our objectives of improving profitability, strengthening research and development, and reinforcing our organizational strength.

By doing so, we will develop our own ability to create new products and further improve our sales and marketing capabilities, which have long been our strengths. We are determined to further enhance our approach toward maximizing profits and increasing corporate value.



Takakazu Morita  
President and Chief Executive Officer  
August 2003



# Building Core Competencies Targeted at the Next Growth Stage

## *An Interview* with CEO Takakazu Morita

### on the 2003-2005 Medium-term Management Plan

**Q** Santen did not achieve its objectives in areas such as sales or market share set out in the previous management plan, Hitomi 21, which was completed in March 2003. How do you analyze this outcome?

>>> Until the mid-1990s, we had generated strong earnings for more than 10 years, driven mainly by successful development and sales alliances with other companies — that is, developing ophthalmic formulations of systemic drugs and product in-licensing. This was possible due to our formidable sales and marketing capabilities in the Japanese prescription ophthalmics market.

Hitomi 21 assumed that we would face a gap in new product launches as well as decreasing opportunities for development and sales collaboration in ophthalmic pharmaceuticals. We also expected a slowdown in the growth of the Japanese prescription ophthalmics market. We therefore established and implemented the following three core strategies: 1) In the Japanese prescription ophthalmics business, we would enhance our sales and marketing capabilities to increase sales and generate earnings; 2) We would develop other sources of sales growth such as over-the-counter

(OTC) eye drops and related businesses in Japan, as well as a U.S. ophthalmics business; and 3) We would devote additional resources to research and development activities to enhance our product pipeline.

As indicated in the table (left), we fell short of our target figures. Moreover, our return on equity (ROE) and market share dropped below the levels for the year ended March 31, 1998.

#### Hitomi 21 Targets and Results

	Year ended March 31, 1998 (Actual)	Hitomi 21 Targets	Year ended March 31, 2003 (Actual)
Net Sales	¥77.9 billion	¥110.0 billion	¥90.2 billion
Net Income	¥7.3 billion	¥12.0 billion	¥8.5 billion
Return on Equity	9.3%	10.0% or higher	8.8%
Share of the Japanese Prescription Ophthalmics Market	Approx. 45%	50% or more	Approx. 40%

We did not achieve our net sales target because our overseas business did not exhibit the expected sales growth; OTC pharmaceuticals sales fell short of expectations due to the stagnant market; and new business development did not materialize as expected. The primary factor behind the shortfall in achieving net income and ROE targets was the increased expenses incurred as a result of starting sales and marketing activities in the United States in 2000.

We created Hitomi 21 as an extension of the solid performance we had been achieving. In my opinion, some of the reasons we did not achieve our Hitomi 21 objectives were because we did not fully account for the impact of changes in the operating environment, and because we diluted our management resources among many fields.

The rapidly expanding presence of foreign pharmaceutical companies in the Japanese prescription ophthalmics market is one example of the changes in our operating environment during the Hitomi 21 period. Contrary to our projections, the Japanese prescription ophthalmics market expanded more than 10 percent over the past five years, despite three National Health Insurance (NHI) drug price revisions. We led the growth of the market in the field of corneal disorder treatments and came close to attaining our total sales target for prescription ophthalmic pharmaceuticals. However, our overall market share dropped by a large margin, mainly because we did not launch any blockbuster products in the glaucoma segment, which expanded more than 40 percent, and because the marketing agreement for the anti-allergy ophthalmic solution *Zaditen* was terminated.



In the United States, we achieved success in clinical development. However, sales and earnings for the U.S. business did not reach our projections as our sales force faced much fiercer competition than anticipated.

## **Q** What successes did Santen achieve under Hitomi 21?

➤➤ We steadily enhanced our research and development capabilities, which I believe will provide growth over the medium and long term. As a result of our emphasis on strengthening our licensing and original development, we have successfully added a number of new drug candidates to our pipeline in such fields as glaucoma and corneal disorders, as well as rheumatoid arthritis and osteoarthritis. Furthermore, we have established international clinical development capabilities, as evidenced by the priority review and early marketing approval for two of our prescription ophthalmic drugs in the United States.

Based on our analysis of the results of Hitomi 21, we initiated the 2003-2005 Medium-term Management Plan as of April 1, 2003. In formulating this plan, we did not assume the steady growth we typically generated in the past. Instead, the plan focuses on pursuing all-out efficiency. We recognize that the paramount and pressing issues will be: 1) to improve the profitability that was mainly reduced by investment in U.S. operations; 2) to quickly regain our market position in the Japanese prescription ophthalmics market; and 3) to further enhance our product pipeline by strengthening our ability to create new drugs and accelerate our pace of development.

## **Q** What are the operating environment considerations and the basic policy underlying the 2003-2005 Medium-term Management Plan?

➤➤ The Japanese prescription pharmaceuticals business accounts for approximately 80 percent of our total sales. It is our belief that a turn-around in our operating environment is unlikely over the next three years. In spring 2003, co-payments for insured workers increased to 30 percent, and another NHI drug price revision is projected for April 2004, leading to an unfavorable outlook for market growth.

In addition, we also expect competition to intensify further due to the Japanese government's measures in April 2002 to promote the use of generic drugs; the launch of generic drugs in the market for corneal disorder treatments; the launch of competing products in the anti-infective ophthalmics market; and the advance of foreign pharmaceutical companies and other major firms into the Japanese prescription ophthalmics market.

The only new product launch scheduled during the new management plan is ciclosporin, a treatment for an eye allergy known as vernal keratoconjunctivitis, in 2004. Therefore, we cannot expect high growth in sales over this period. Consequently, during the next three years, we will focus on improving our profitability and establishing the foundations for our next phase of growth.

The three key objectives of the 2003-2005 Medium-term Management Plan are: 1) improving profitability; 2) strengthening research and development; and 3) reinforcing our organizational strength.

**2003-2005 Medium-term Management Plan**

	Year ended March 31, 2003 (Actual)	Year ending March 31, 2006 (Targets)
Net Sales	¥90.2 billion	¥93.0 billion
Operating Income	¥12.6 billion	¥18.0 billion
Net Income	¥8.5 billion	¥10.0 billion
Return on Equity	8.8%	10.0%

Basic Policies	Improve Profitability	Strengthen R&D	Reinforce Organizational Strength
Key Issues	<ul style="list-style-type: none"> <li>● Improve earnings in the U.S.</li> <li>● Re-engineer cost structure</li> <li>● Maintain/improve profit base in Japan</li> </ul>	<ul style="list-style-type: none"> <li>● Accelerate new product development</li> <li>● Enhance product pipeline through focused resource allocation</li> </ul>	<ul style="list-style-type: none"> <li>● Strengthen corporate governance</li> <li>● Enhance employee education and organizational management capabilities</li> </ul>

## Q What initiatives will improving profitability entail?

>> First of all, we aim to make the U.S. business profitable in a short period of time. Our main product in the United States is the anti-infective ophthalmic *Quixin* (brand name in Japan: *Cravit*). Looking to the future, we anticipate the launch of new branded and generic products that will intensify competition in the U.S. anti-infective ophthalmics market. To succeed under these conditions, we must substantially improve our sales and marketing, both qualitatively and quantitatively, in a short period of time. We therefore intend to shift our sales and marketing format from one that is centered on selling our products with our own sales force to one that incorporates alliances with other companies that already have a strong presence in the U.S. market. The change in sales and marketing strategy will control expenses and support steady gains in sales. We are currently examining potential alliance partners, and after we conclude an agreement, we expect operations in the United States to become profitable in the year ending March 31, 2005. In the year ending March 31, 2006, we expect an increase of about ¥2.5 billion in our overall operating income compared to the year ended March 31, 2003 from our U.S. operations.

Another core initiative we will take to improve profitability is the re-engineering of the company-wide cost structure. In early 2003, we established the company-wide Cost Structure Re-engineering Committee, which aims to maximize cost efficiency in every aspect of our operations. Initiatives to raise manufacturing productivity, including the introduction of a new container for ophthalmic solutions, should reduce annual production costs by roughly ¥1.5 billion by March 31, 2006. Over the same time frame, we also project a decrease of about ¥0.5 billion in marketing and administrative expenses from measures that include increasing efficiency of our sales and promotional activities through the use of information technology (IT). In research and development, we will review the priority of all our projects and focus our efforts on high-priority projects to improve productivity and restrain cost increases. For candidate compounds in the field of

rheumatoid arthritis and osteoarthritis, where we expect full-scale clinical development during the three-year plan, we will form development and marketing alliances that take into consideration our management resources.

On the other hand, rationalization and increasing competitiveness will require proactive investment in areas such as IT. We intend to strengthen our organizational structure to the fullest extent possible during the term of the plan, and will not hesitate to make the investments necessary to do so.

## Q How will Santen maintain its foundation and regain its position in the core prescription ophthalmics market in Japan?

➤➤ We generate approximately 70 percent of our sales in the Japanese prescription ophthalmics market, which is where we are best able to deploy our strengths. One of the most important factors that will determine our future is how we can prevail over competitors to regain our market position in Japan.

### Net Sales by Business Segment

(Billions of yen; years ended March 31)

	2003 (Actual)	2006 (Targets)
Prescription Pharmaceuticals	79.3	80.8
Ophthalmic	71.1	71.8
Anti-rheumatic	7.6	8.5
Others	0.6	0.5
OTC Pharmaceuticals	5.7	6.6
Medical Devices	0.9	2.5
Others	4.3	3.1
Net Sales	90.2	93.0
Overseas Sales	10.5	13.7

Our current management plan does not foresee market growth in the medium term. Therefore, the critical issue will be how we can increase our earnings capabilities. Our fundamental approach will be to attain objectives and effectively counter generic drugs in core fields while reinforcing our position in weak areas.

One of the key strategies will be the implementation of a Sales Force Automation system for medical representatives to raise the quality and quantity of their promotional activities. In addition, we will concentrate management resources in both the core and growth areas of corneal and conjunctival disorders, glaucoma and eye allergies.

*Hyalein* is a treatment for corneal disorders whose market has continued to expand. To build on this momentum, we will work to raise awareness of dry eye among potential patients and will

counter generic drugs by increasing our promotional activities allocated for *Hyalein*. We also plan to increase sales by aggressively promoting the superiority of our anti-infective ophthalmic *Cravit* over competing products. In the glaucoma and anti-allergy markets, where our market share is relatively low, we launched *Detantol*, a glaucoma treatment, and *Livostin*, an anti-allergy ophthalmic solution, in 2001. We intend to increase the market penetration and market share of these products.

#### Notes

1. Non-clinical studies: Studies in which in vitro and animal testing is conducted to determine pharmacology, mechanism of action, safety and other characteristics of new compounds.

2. Clinical trials: Trials in which new compounds for which efficacy and safety have been determined in non-clinical studies are administered to healthy human subjects and to patients to determine efficacy, safety, dosage and other issues.

## Q Strengthening research and development is key to generating growth. What approaches will Santen take?

➤➤ We will bolster our in-house drug discovery to achieve continuous growth. We will focus on swift development of compounds in the pipeline, particularly glaucoma treatments. To accelerate development, we will shift personnel from basic research and increase personnel in the development phase, and will shorten the approximate development period for non-clinical studies<sup>1</sup> to a year and a half from the current three years, and clinical trials<sup>2</sup> to five years from the current





seven or eight years. We plan to increase competitiveness by raising the success rate through effectively prioritizing research themes and concentrating resources in growth areas, offsetting the impact of reduced personnel in basic research and controlled R&D expenditures.

### **Q** > **What will reinforcing Santen's organizational strength entail?**

>> We will reinforce our organizational strength in terms of both management and employees. For management, we will further enhance our corporate governance. This includes shortening the term of directors from two years to one to clarify their responsibilities for each fiscal year and appointing an outside director, both implemented in June 2003. The outside director will play an active role in ensuring transparency and objectivity in management decisions. In addition, we have already established a Management Advisory Committee and an Executive Compensation Committee, each of which includes a member from outside Santen.

As for employees, we aim to enhance our human resources and organizational management. Since 2001, we have been operating an in-house business school called the Santen Innovation Project. The project has enjoyed steady results as a means of revamping our corporate culture and improving the competitive strengths of employees who adopt knowledge management and propose applicable strategies. We will continue with this sort of personnel development program in reinforcing our organizational strength.

### **Q** > **What are Santen's long-term goals and strategies for growth?**

>> Our corporate philosophy is to contribute to the health and quality of life of patients and their loved ones, and society as a whole, by applying our unique capabilities and technologies in ophthalmology and other areas of expertise. During the implementation of the 2003-2005 Medium-term Management Plan, we will develop our core competencies, which consist of our experience and know-how in ophthalmics sales and marketing, including our network of physicians and product lineup; and our research, development and licensing in the areas of ophthalmology and rheumatism/osteoarthritis.

Specifically, we will make the most of our advantages in prescription ophthalmic research and development, which include a high degree of specialized know-how and a comprehensive understanding of both leading-edge clinical needs and the future of medical treatment. We expect a continued increase in the number of glaucoma patients, and we will swiftly develop and launch the three candidate glaucoma treatments in our pipeline. In the field of retinal disorders, where there are virtually no effective treatments, we will concentrate on creating new drugs that employ our own drug delivery system (DDS) technology. We believe that filling out our product lineup in these key therapeutic fields will become the driving force of future growth for Santen.

We intend to realize consistent growth by successively launching new products that meet pronounced medical needs; disseminating our products through outstanding sales and marketing; and as a result, by contributing to the treatment of patients.

Over the long term, we aim to become a company with a global presence, capitalizing on our capabilities in our areas of expertise and contributing to patients worldwide.

# Corporate Governance

## Santen's corporate governance employs a corporate auditor system to ensure sound, transparent management that will allow continuous enhancement of shareholder value.

### Board of Directors

As of August 2003, our Board of Directors is made up of five directors — four internal and one external. The Board of Directors is kept small to facilitate thorough discussion and swift decision-making. The Board of Directors met sixteen times during the year ended March 31, 2003, and made decisions on issues including the Santen Group's management policies and strategies, business plans, acquisition and disposal of major assets, and important organizational and personnel changes. In addition, the Board of Directors supervised and directed the execution of business at Santen and its subsidiaries.

Following the approval of the 91st Annual General Meeting of Shareholders, held on June 26, 2003, we shortened the office term of directors from two years to one and appointed Kosei Furukawa, Professor at Nakamura Gakuen University and Honorary Professor at Keio University, as an outside director. We expect Director Furukawa to use his broad knowledge and expertise in corporate management to play an active role in ensuring and further enhancing transparency and objectivity in our management.

### Board of Corporate Auditors

There are four members of the Board of Corporate Auditors — two internal and two external. The Board of Corporate Auditors met eight times during the year ended March 31, 2003 to approve financial statements and proposed items for the General Meeting of Shareholders and to discuss and resolve audit plans. In addition, the Board of Corporate Auditors received reports from corporate auditors on the results of the audit of business executed by directors, as well as reports from independent accounting auditors on the results and methods of the audit. The Board of Corporate Auditors regularly reported the results of its audits to the Board of Directors, and submitted an audit report to the Board of Directors meeting held on May 9, 2003.

In order to audit the management and performance of directors, corporate auditors attended important company meetings, including Board of Directors meetings, reviewed important company documents and conducted inspections at Santen's offices and subsidiaries.

### Committees

Santen has established an Executive Compensation Committee as a specialized committee within the Board of Directors and a Management Advisory Committee headed by the president.

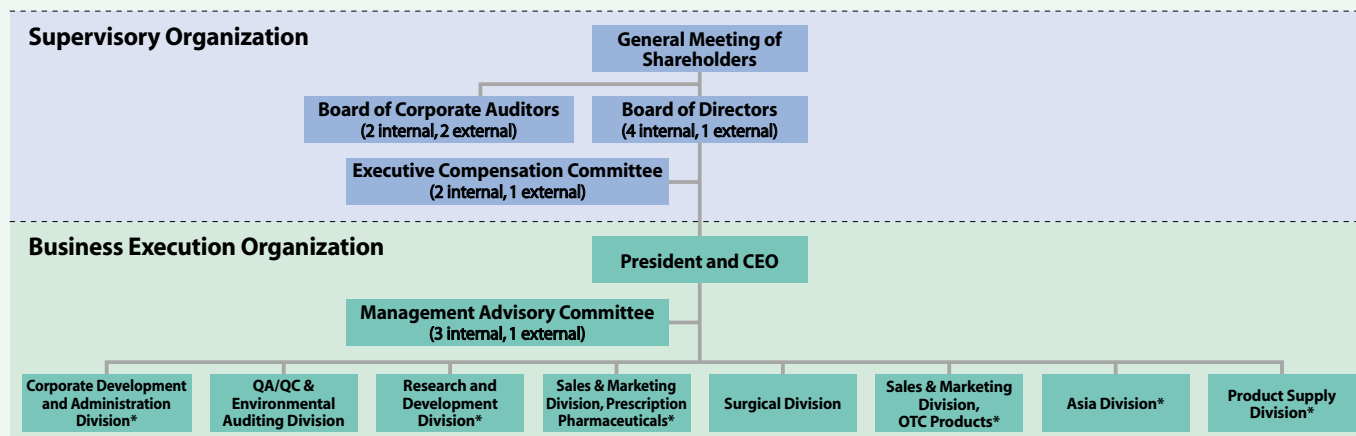
The Executive Compensation Committee has three members (the president, a managing director and the outside director) who decide on policies for the compensation of executives, review the executive compensation system and determine the compensation of individual executives. Duties also include supervising impartial decision-making of compensation issues and the fair implementation of the compensation system. This committee met twice during the year ended March 31, 2003.

In April 1999, we introduced a performance-based executive compensation system that establishes a clear link between company objectives and compensation of executives.

The Management Advisory Committee has four members (the president, a managing director, a corporate officer and a member from outside Santen) who study and discuss issues with a significant medium-term impact on Santen. This committee met twelve times during the year ended March 31, 2003 regarding the analysis of current conditions, management tasks and deliberation over the direction and strategies needed in drawing up the 2003-2005 Medium-term Management Plan, among other matters of importance.

### Corporate Officer System

We introduced the Corporate Officer System in July 1999 to separate management supervision and important decision-making from daily operations.



- Notes:**
1. Heads of divisions with an asterisk (\*) hold the position of corporate officer.
  2. Three directors serve concurrently as corporate officers.
  3. The Executive Compensation Committee and the Management Advisory Committee are different from the committees in the "Company with Committees" system as set forth in the April 2003 revisions to the Commercial Code of Japan.

# Board of Directors, Corporate Auditors and Corporate Officers



From left: Akira Kurokawa, Masahiro Mita, Takakazu Morita, Katsuhiko Waga and Kosei Furukawa

## Board of Directors

**Takakazu Morita**  
President and CEO  
Head of Sales & Marketing Division,  
OTC Products

**Masahiro Mita, M.D.,  
Ph.D.**  
Managing Director  
Head of Corporate and Regulatory  
Affairs

**Katsuhiko Waga**  
Director and Corporate Officer  
Head of Product Supply Division

**Akira Kurokawa**  
Director and Corporate Officer  
Head of Sales & Marketing Division,  
Prescription Pharmaceuticals

**Kosei Furukawa, Ph.D.**  
Director  
(Professor, Nakamura Gakuen  
University, and Honorary Professor,  
Keio University)

## Corporate Auditors

**Shushi Sakamoto**  
Standing Corporate Auditor

**Takashi Ishida**  
Standing Corporate Auditor

**Koji Hori**  
Corporate Auditor  
(Attorney-at-law)

**Tadao Kagono**  
Corporate Auditor  
(Professor, Graduate School of  
Business Administration, Kobe  
University)



From left: Ichiro Otokozaawa, Kyoichi Shimomura, Toshiaki Nishihata, Kenji Iwamoto and Hiroshi Abe

## Corporate Officers

(Excluding concurrent members of  
the Board of Directors)

**Toshiaki Nishihata, Ph.D.**  
Corporate Officer  
Head of Research and  
Development Division and Head of  
Clinical Development Center

**Kyoichi Shimomura, Ph.D.**  
Corporate Officer  
Head of Research and  
Development Center, Research and  
Development Division

**Kenji Iwamoto**  
Corporate Officer  
Head of Asia Division

**Ichiro Otokozaawa**  
Corporate Officer  
Head of Corporate Development  
and Administration Division

**Hiroshi Abe**  
Corporate Officer  
President of Santen Distribution  
Co., Ltd.

(As of August 2003)

# Research

## Key Issues in the 2003–2005 Medium-term Management Plan

- Emphasize promising research themes in allocating resources
- Strengthen drug discovery in the field of ophthalmology
- Seek alliances to maximize the potential of rheumatoid arthritis and osteoarthritis treatments



Santen's research staff combines a variety of compounds to synthesize compounds with novel mechanisms of action.

## Concentrating Resources on R&D Themes that Allow Santen to Display Its Strengths

Santen strives to create pharmaceuticals that will address unmet medical needs and contribute to enhanced quality of life of patients by making full use of its expertise in ophthalmology and rheumatism/osteoarthritis.

The key strategies to achieve this goal include:

- 1) Determine unmet needs and understand research and development trends among competitors in order to concentrate resources on themes that will allow us to display our strengths;
- 2) Emphasize prescription ophthalmics, both discovered in-house and in-licensed, to strengthen our product pipeline with therapeutically superior new products;
- 3) Out-license or form strategic alliances for our rheumatoid arthritis and osteoarthritis drug candidates to maximize their potential; and
- 4) Maintain our competitive advantages by accelerating research and development.

We will determine our research themes by evaluating the anticipated future needs in ophthalmology and rheumatism/osteoarthritis over the next ten to fifteen year time frame and prioritize resources on areas with unmet needs and good business potential.

In the field of rheumatism/osteoarthritis, we have already narrowed our focus to three promising themes. Our prior investments in ophthalmic research have yielded numerous results; we have set milestones for each research theme and will continue to focus our efforts on those with the most promise.

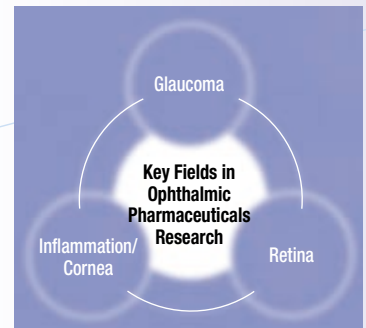
## Enhancing Ophthalmic Discovery Research

In the past, Santen's research efforts focused on developing ophthalmic formulations of systemic drugs. In recent years, however, in-licensing of compounds from other companies has become difficult. We believe that technological innovation is needed to attain future growth. Strengthening our ability to create innovative ophthalmic pharmaceuticals is therefore one of the most important tasks in the 2003-2005 Medium-term Management Plan.

We will leverage the know-how we have acquired through our research on rheumatoid arthritis treatment to strengthen our in-house ophthalmic discovery research. Rheumatoid

arthritis shares common etiological and pathological symptoms, such as angiogenesis, inflammation and edema, with retinal and other diseases in the posterior segment of the eye. By focusing on these common symptoms, we will establish novel, efficient drug discovery techniques to create innovative ophthalmic pharmaceuticals.

In November 2002, we completed an expansion of the Nara Research and Development Center and integrated the research functions of ophthalmology and rheumatism there. We expect this move to stimulate research into themes shared by ophthalmology and rheumatism.



### Focus on Next-generation Treatments for Glaucoma and Retinal Disorders

Unmet needs in ophthalmologic diseases have shifted from the anterior segment (cornea and conjunctiva) to the posterior segment (retina and optic nerve).

Glaucoma is a progressive optic neuropathy that causes optic disc and nerve fiber layer damage, usually associated with loss of visual function. Intraocular pressure<sup>1</sup> is the most important risk factor for the disease, although a significant proportion of patients do not have elevated intraocular pressure. Today, glaucoma treatment is the largest segment of the global ophthalmics market. An aging population and advances in diagnostic technology indicate that the number of glaucoma patients will continue to increase. We see glaucoma treatment as a field with great market potential, both now and in the future, and we are increasing research on glaucoma treatments such as those that reduce intraocular pressure with novel action mechanisms. Research efforts to date have added three new glaucoma drug candidates to our product pipeline.

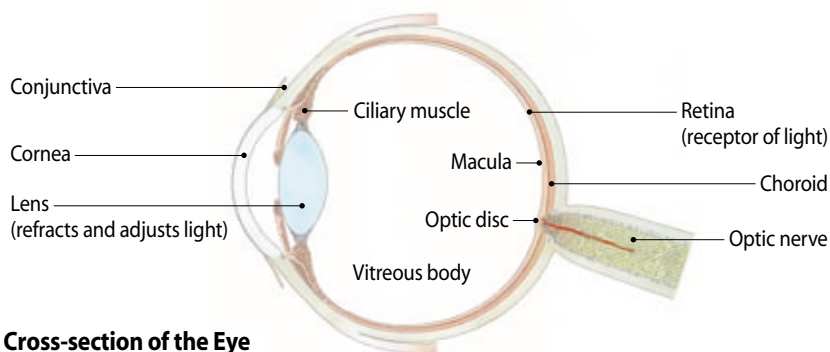
The number of patients suffering from retinal disorders such as age-related macular degeneration<sup>2</sup> and diabetic retinopathy<sup>3</sup> is also increasing as the population ages. These disorders are accompanied by angiogenesis from the choroid and retina as they progress. We are conducting research on new drugs by applying our knowledge of angiogenesis suppression

#### Notes

1. Intraocular pressure: The pressure retained within the eye. The eye must keep an adequate degree of turgidity in order for us to see objects. Secretion and excretion of aqueous humor through ciliary bodies control the balance of intraocular pressure.
2. Age-related macular degeneration: A disease caused by age-induced disorders in the macula, which is a component of the retina essential for seeing objects.
3. Diabetic retinopathy: A complication of diabetes in which defects in the capillaries of the retina damage the retina. Diabetic retinopathy can lead to bleeding in the back of the eye and detachment of the retina, and is the primary cause of vision loss.

### The Mechanism of Vision

Our eyes allow us to see by receiving light reflected off objects. The eye is constructed much like a camera. External light passes through the cornea and then refracts through the lens of the eye, which is like the lens of a camera, onto the retina. The retina is similar to the film in a camera because it registers an image of the object. The optic nerve transmits the image to the brain, which perceives what the object is.



**Cross-section of the Eye**



The Nara Research and Development Center, which was expanded to twice its previous size in 2002, features a unique "free address" system that allows researchers to select seats according to the needs of their jobs.

obtained through research into rheumatoid arthritis. Moreover, we have also developed our own drug delivery system (DDS) technologies for the efficient delivery and sustained release of active ingredients to affected areas in the posterior segment, and are now examining the possibility of applying these technologies to actual drug production. Presently, there are almost no effective treatments for retinal diseases, and therefore the development of a breakthrough, next-generation treatment will be extremely significant.

We are also conducting research on allergies, dry eye and other diseases of the surface of the eye, with a particular focus on patients with severe conditions that current treatments cannot cure. At the same time, with the aim of further improving the quality of life of patients, we have developed innovative DDS technologies that reduce administration time, increase absorption and alleviate discomfort when administering eye drops.

### Unique Compounds Being Developed for Rheumatoid Arthritis

Rheumatoid arthritis causes inflammation in the knees, elbows and other joints, gradually breaking down bone and cartilage until it eventually deforms the joints. People who suffer from this disease bear excruciating pain, and no treatment that addresses the underlying cause of rheumatoid arthritis has yet been discovered because little is known about its mechanisms. In recent years, work has gained momentum on the development of a new type of treatment called TNF inhibitors. These new drugs block the activity of tumor necrosis factor (TNF), a type of endogenous protein called a cytokine<sup>4</sup> that is associated with immune reaction and joint degeneration. This development is expected to significantly improve the quality of life of patients.

We have narrowed our target in rheumatoid arthritis research to focus on stopping the degeneration of bones and cartilage by suppressing cytokine secretion or regulating the proliferation of synovial cells. Research in this area has already led to the discovery of DE-096, an oral TNF inhibitor, and DE-098, an anti-APO-1 antibody.

The majority of other TNF inhibitors, either already on the market or in the late development stage, are injectable biological agents. However, DE-096, discovered by Santen, is a compound with a low molecular weight that can be administered orally. Basic research has demonstrated effectiveness against rheumatoid arthritis comparable to injectable biological agents. Once we develop a commercially viable formulation of DE-096, patients will no longer have to visit medical centers for their scheduled injections. Moreover, DE-096 will involve lower manufacturing costs, which will lighten the financial burden on patients.

One pathological condition of rheumatoid arthritis is the excessive proliferation of synovial cells, which causes bone and cartilage degeneration. The injectable anti-APO-1 antibody, DE-098, induces apoptosis (death) of synovial cells within damaged joints. We have already established a pilot manufacturing process for DE-098.

The launch of TNF inhibitors and other new treatments for rheumatoid arthritis is likely to make this field more competitive in the near future. Rather than limiting our scope for new drug development to rheumatoid arthritis, we are exploring a broad array of target markets covering all facets of bone and joint disease. To make the best use of our management resources, we will seek joint development, marketing alliances or out-licensing for our candidate compounds in these fields to maximize their potential.

#### Note

4. Cytokine: A type of protein with low molecular weight secreted by various kinds of cells. Cytokines involved in the pathogenesis of rheumatoid arthritis regulate the extent and length of immune reaction and mediate the exchange of information among cells. Tumor necrosis factor (TNF) is a type of cytokine.

# Development

## Key Issues in the 2003–2005 Medium-term Management Plan

- Shorten the time for non-clinical studies to approximately one and a half years
- Shorten the time between Phase I clinical trials and new drug application to approximately five years
- Restructure our R&D organization

### Accelerating and Focusing R&D

The ability to create innovative pharmaceuticals and offer them quickly to patients worldwide is essential in order to succeed in the competitive global market. Santen has made accelerating research and development one of its top priorities, and is expediting various initiatives to achieve this goal.

We have narrowed our focus to projects that will provide improvements for patients and allow us to enjoy competitive advantages. Concentrating resources on these priority projects is helping us accelerate product development.

### Restructuring Our R&D Organization

Santen reorganized its R&D divisions in December 2002 to enhance planning and leadership capabilities throughout the entire R&D process. The core change in this reorganization was the integration of five former divisions — ophthalmic research, rheumatoid arthritis research, clinical development, pharmaceutical development, and strategy coordination — into a single Research and Development Division. The planning functions that were formerly dispersed among each division are now centered in a single division. Improved decision-making and concentration of the planning functions will lead to accelerated research and development and enhanced operational efficiency.

The reorganization has strengthened the bond that links R&D with sales and marketing. Accordingly, we believe that this closer relationship has improved the quality of new drug development in terms of satisfying therapeutic needs and increasing commercial viability.

### Faster Development Time for Non-clinical Studies and Clinical Trials

The 2003-2005 Medium-term Management Plan has set the specific target of reducing the time needed for non-clinical studies to approximately one and a half years from the current three years, and the time needed for clinical trials, between Phase I and new drug application (NDA), to approximately five years from the current seven to eight years.



Clinical development staff discuss the optimal plan for clinical testing of strategic products.

Santen will shorten non-clinical studies by devising new approaches for protocols, including conducting safety studies that focus on starting clinical pharmacology studies at an earlier stage.

To accelerate clinical trials, we will increase the number of staff members involved in clinical development by shifting personnel from research divisions. We will also increase development capacity by effectively utilizing personnel from contract research organizations and site management organizations.

We have reviewed all aspects of our clinical trial operations and have begun to streamline our business processes, including the reorganization of certain functions. In addition, we will further accelerate development by using scientific evidence to optimize clinical trials.

### Strong Clinical Development Network in Japan, the U.S. and Europe

Santen has built a strong clinical development network covering Japan, the United States and Europe, and has successfully developed and launched two original drugs in the United States and one in Europe. Non-clinical studies are primarily performed in Japan, while U.S. and European operations will focus on expanding clinical capabilities to support projected growth in tripolar development projects in Japan, the United States and Europe.

### Levofloxacin Launched in International Markets

*Cravit* (levofloxacin ophthalmic solution) is a potent, broad spectrum anti-infective with an excellent ability to penetrate ophthalmic tissue. Santen launched *Cravit* in Japan in April 2000, and then launched the drug under the brand name *Quixin* in the United States in November 2000. In Europe, marketing authorization was granted in the United Kingdom in July 2001, followed by nine other countries during 2002. The drug is now marketed in Germany, Finland, Sweden, Denmark and Iceland under the brand name *Oftaquix*. In Asia, marketing approval was obtained for *Cravit* in six countries, beginning with Hong Kong in November 2000. Sales have already started in Hong Kong, Korea, Thailand, Singapore and Indonesia.

In April 2003, we submitted an NDA to the U.S. Food and Drug Administration (FDA) for levofloxacin 1.5%, a higher concentration formulation of *Quixin*, for the indication of corneal ulcers.

In August 2003, we applied for manufacturing approval in Japan for DE-076 (ciclosporin ophthalmic solution), an orphan drug<sup>1</sup> indicated for an eye allergy known as vernal keratoconjunctivitis<sup>2</sup>. The drug has been studied in patients with advanced vernal keratoconjunctivitis, against which existing anti-allergy drugs are not effective.

### Clinical Development Acceleration Centered on Glaucoma Treatments

In the field of glaucoma treatment, which offers the greatest market potential, Santen has three candidate compounds under Phase II clinical trials. We are focusing more resources in this field to accelerate their development.

DE-085, a prostaglandin (PG)-based treatment for glaucoma, is an ophthalmic solution that reduces intraocular pressure by promoting the outflow of fluid in the eye known as aqueous humor. Unlike some PGs that must be refrigerated, DE-085 can be stored at room temperature.



Supervisors of development projects at Santen's tripolar network spanning Japan, the United States and Europe receive joint training at Santen Oy.

#### Notes

1. Orphan drug: A drug whose labeled indication is for treating a relatively small number of patients. Orphan drug R&D expenses are eligible for government subsidies in Japan.
2. Vernal keratoconjunctivitis: A severe type of eye allergy in which changes in conjunctival cell propagation are evident.



## Main Prescription Pharmaceuticals in Pipeline

(As of August 2003)

Generic Name	Brand Name/Development Code	Indication	Original/Licensor	Region	Phase I	Phase II	Phase III	NDA Filed	Approved	Launched	Characteristics of Compound
Levofloxacin 0.5%	<i>Cravit</i> <i>Quixin</i> <i>Oftaquix</i>	Bacterial conjunctivitis	Daiichi Pharmaceutical	Japan						4/2000	New quinolone antibacterial ophthalmic solution. In Europe, the treatment has obtained marketing authorization in 10 countries and has been launched in five countries including Germany.
				USA						11/2000	
				Europe						5/2002	
Levofloxacin 1.5%	(Undetermined)	Bacterial corneal ulcer	Daiichi Pharmaceutical	USA						4/2003	Higher concentration formulation. Stronger antibacterial action expected.
Levofloxacin and prednisolone A	DE-094	Infectious keratitis	Daiichi Pharmaceutical	USA							Combination of levofloxacin and steroid.
Pemirolast potassium	<i>Alegysal</i> <i>Alamast</i> <i>Alamast</i>	Allergic conjunctivitis	Mitsubishi Pharma	Japan						4/1995	A mast cell stabilizer with superior efficacy on allergic conjunctivitis and vernal keratoconjunctivitis.
				USA						7/2000	
				Europe						12/1999	
Sodium hyaluronate	<i>Hyalein</i>	Corneal and conjunctival epithelial disorders Dry eye	Original	Japan						6/1995	Ophthalmic solution containing sodium hyaluronate. Treats corneal and conjunctival epithelial lesions caused by dry eye, contact lenses, etc.
				USA	In preparation						
Ciclosporin	DE-076	Vernal keratoconjunctivitis	Novartis Pharma	Japan						8/2003	An orphan drug. Expected to treat advanced vernal keratoconjunctivitis for which existing anti-allergy drugs are not effective. Because it is an ophthalmic solution, virtually no generalized side effects are noted.
(Undetermined)	DE-085	Glaucoma and ocular hypertension	Co-development with Asahi Glass	USA Japan							Prostaglandin-based treatment for glaucoma. Tripolar development planned in Japan, the United States and Europe. Can be stored at room temperature.
Olmesartan	DE-092	Glaucoma and ocular hypertension	Sankyo	Japan							The only angiotensin II receptor antagonist in full-fledged development as a glaucoma treatment. Comparable to prostaglandin-based treatments in reducing intraocular pressure.
Lomerizine hydrochloride	DE-090	Glaucoma	Nippon Organon	Japan							New type of oral glaucoma treatment studied for inhibiting the progression of visual field defects.
Diquafosol tetrasodium	DE-089	Dry eye	Inspire Pharmaceuticals	Japan							A treatment for dry eye that stimulates the eye surface to secrete tear fluid and moisture. Expected to be used in combination with existing dry eye treatments, and be effective for patients for whom existing treatments are insufficient.
(Undetermined)	DE-096	Rheumatoid arthritis	Original	Japan							An oral TNF inhibitor. Anti-rheumatic effect comparable to injectable biological agents has been observed in basic research.

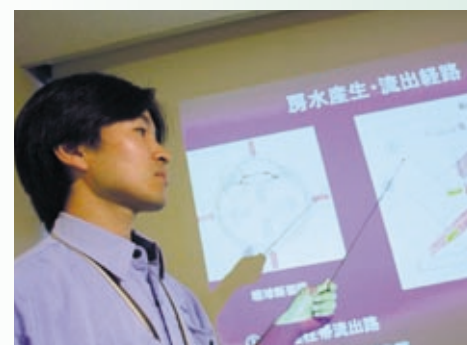
We are currently conducting Phase II clinical trials for DE-085 in Japan and the United States, and may soon start clinical trials in Europe using the results gained in the United States.

DE-092 (olmesartan ophthalmic solution) is an angiotensin II receptor antagonist that reduces intraocular pressure comparable to PGs in animal models. It is currently under Phase II clinical trials in Japan. Although angiotensin II receptor antagonists enjoy wide use for lowering blood pressure systemically, there is currently no topical solution approved for use in the eye.

DE-090 (lomerizine hydrochloride) is a new type of oral glaucoma treatment that is being studied for inhibiting the progression of visual field defects. It is currently under Phase II clinical trials in Japan, and is expected to be effective for treating glaucoma with normal intraocular pressure.

DE-089 (diquafosol tetrasodium ophthalmic solution) is currently under Phase II clinical trials in Japan as a treatment for dry eye that stimulates the eye surface to secrete tear fluid and moisture. It is expected that the treatment can be used in combination with existing dry eye treatments, and will be effective for patients for whom existing treatments are insufficient.

In Japan, we launched *Hyalein* (sodium hyaluronate ophthalmic solution), a treatment for corneal disorders associated with dry eye and other causes, in June 1995. In Phase III clinical trials conducted in the United States under unique environmental conditions specially designed for the trials, *Hyalein* significantly reduced dry eye symptoms. Unfortunately, the placebo demonstrated an effect that was greater than anticipated. As a result, we are now preparing to restart Phase II clinical trials with a new protocol.



# Marketing

## Key Issues in the 2003–2005 Medium-term Management Plan

- Maintain and improve our earnings base in the Japanese prescription ophthalmics market
- Strengthen customer ties and raise the efficiency of MR activities by implementing a Sales Force Automation system
- Improve earnings in the United States through marketing alliances



Backed by a wealth of specialized knowledge, Santen's medical representatives (MRs) provide value-added information to healthcare professionals.

## JAPAN

### Prescription Ophthalmic Pharmaceuticals

Despite growth factors such as the aging population and an anticipated increase in glaucoma patients, Santen expects the Japanese prescription ophthalmics market to remain flat over the next three years.

Factors expected to restrain growth include a scheduled National Health Insurance (NHI) drug price revision and a reduction in doctor visits due to increased patient co-payments. The markets for glaucoma and corneal disorders are expected to grow, while other fields will continue to contract.

In April 2002, the Japanese government implemented a plan to promote the use of generic drugs, spurring the aggressive market introduction of these products. In addition, foreign and major Japanese pharmaceutical corporations have strengthened their activities in the Japanese prescription ophthalmics market, and launch of competing products in the anti-infective ophthalmics market is anticipated. As a result, competition is expected to intensify further.

Since establishing the country's first prescription ophthalmics business in 1958, Santen has been contributing to the development of ophthalmology in Japan for more than 40 years. For example, our success in creating Japan's first antibiotic ophthalmic solution contributed to the eradication of trachoma, a disease that afflicted many Japanese. Today, as a leading manufacturer with a market share of approximately 40 percent of the Japanese prescription ophthalmics market, we provide a lineup of treatments for a wide range of ophthalmic disorders such as eye infections, corneal disorders, glaucoma and eye allergies. This allows us to meet the diverse array of patient needs and earn the trust of healthcare professionals who recognize our superiority over other companies in providing and collecting information.

Furthermore, with a staff of some 400 medical representatives (MRs), the largest in the industry, we provide detailed information to approximately 12,000 ophthalmologists throughout Japan, ranging from doctors at large hospitals to private clinics. Going beyond

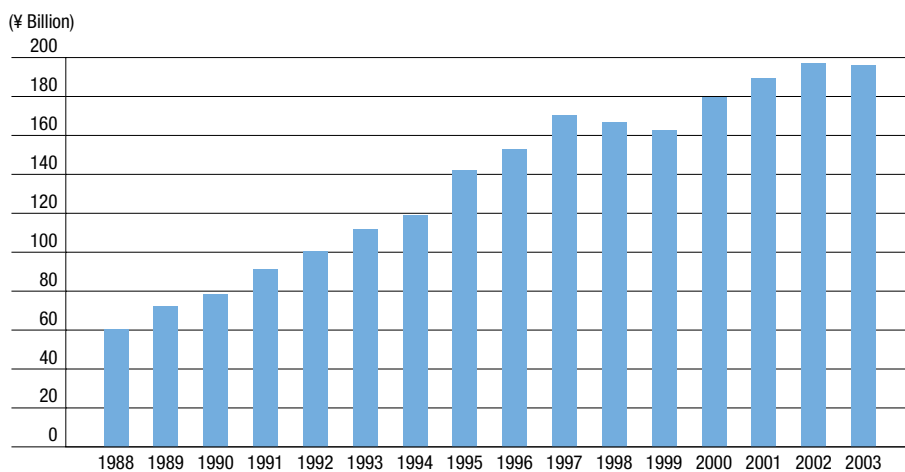
simply providing information on pharmaceuticals, we are structuring our marketing organization to support the ability of healthcare professionals to solve the treatment issues they face. As a result, according to a survey we conducted, a majority of ophthalmologists gave our MRs the highest rating.

### Concentrating Management Resources on Key Products

A key point of emphasis in the 2003-2005 Medium-term Management Plan is for Santen to maintain and recover its share of the Japanese prescription ophthalmics market, which has decreased to approximately 40 percent from a peak of 45 percent in the year ended March 1998. Specifically, Santen will allocate resources to the key growth fields of corneal and conjunctival disorders, glaucoma and allergies. In addition, we will raise the efficiency of MR activities and strengthen customer relationships through the implementation of a Sales Force Automation system.

In the year ended March 31, 2003, we concentrated our management resources on four products: the corneal disorder treatment *Hyalein*; the anti-infective ophthalmic *Cravit*; the glaucoma treatment *Detantol*; and the anti-allergy ophthalmic *Livostin*. We are devoting all of our strengths to generating steady market share gains for these products. At the same time, we will strengthen our ability to conduct appropriate marketing that incorporates a full understanding of the emerging needs of each healthcare facility and resulting changes in demand. This will further enhance our presence at each healthcare facility.

### Prescription Ophthalmics Market in Japan



Source: Santen Pharmaceutical Co., Ltd.

(Fiscal years ended March 31)

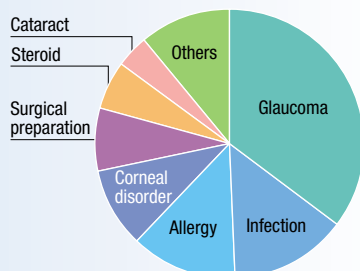
### Sales Force Automation System

In order to more effectively share information and raise the quality and efficiency of MR activities, Santen will implement a Sales Force Automation system for MRs beginning in 2003. This system will allow integrated management of information in areas including customers, medical facilities, products and scientific developments. MRs will have immediate access to data through notebook computers. The system will also decrease the amount of time MRs spend in their offices, while increasing their ability to provide information tailored to the needs of



## Japanese Prescription Ophthalmics Market by Therapeutic Field

(Year ended March 31, 2003)



Source: Santen Pharmaceutical Co., Ltd.



Hyalein

healthcare professionals. We expect the new system to improve communication among our various departments that have relationships with medical institutions, and reduce the need for MRs to return to the office to file reports and research information.

### Corneal Disorder Treatments

The market for corneal disorder treatments continues to exhibit strong growth. Santen expects the number of patients to continue to expand due to social and environmental factors such as the increasing number of people using personal computers, the aging society, expanding use of contact lenses and dry air in residential environments.

In 1995, we introduced *Hyalein*, a corneal disorder treatment associated with dry eye<sup>1</sup> and other symptoms. This marked the creation of the market for dry eye treatments in Japan, and we have led the growth of this market ever since. We maintain a formidable volume of information in this field, from basic research to post-marketing data, that other companies cannot match. Moreover, we have built an MR organization that can rapidly communicate this information to ophthalmologists throughout Japan.

With the government backing measures to promote the use of generic drugs, the issue of how to respond to their market entry will be of primary importance. We therefore plan to effectively counter generic drugs by increasing promotional activities for *Hyalein* and making extensive use of data that communicate *Hyalein*'s superiority over other products and the ease of use of its new container. At the same time, we will continue to attract potential patients by promoting education about dry eye. During the year ended March 31, 2003, we provided education on the proper diagnosis and treatment of dry eye by holding specialist lectures at 25 locations throughout Japan, in cooperation with local ophthalmologists' associations. A total of 1,400 eyecare professionals attended the lectures.

### Anti-infective Ophthalmics

Santen has assembled a lineup of anti-infective ophthalmics that are indispensable to ophthalmologists. Products include the anti-infective *Cravit*, the first-line treatment for eye infections; the anti-infective *Tarivid*; and the antibiotics *Ecolicin* and *Santemycin*.

Santen is the market leader in the field of anti-infective ophthalmic pharmaceuticals in Japan, with a share of approximately 80 percent. Clinical guidelines for the use of anti-infective systemic drugs, among other factors, have led to a gradual contraction in the anti-infective ophthalmics market in Japan. The number of prescriptions for *Cravit*, however, is growing steadily because of the confidence it has earned among eyecare professionals. In the year ending March 31, 2004, we will undertake strategic promotions of *Cravit*, and will work to further expand sales by emphasizing its superiority over other products.



Cravit

### Glaucoma Treatments

Glaucoma treatments are the largest segment of the prescription ophthalmics market in Japan, accounting for about one-third of the market. This market has been expanding due to factors such as the aging population.

An epidemiological survey by the Japan Glaucoma Society released in December 2002 found that approximately one in seventeen people aged 40 and older in Japan have

#### Note

1. Dry eye: A condition in which the surface of the eye becomes dry because of quantitative or qualitative changes in the tears that bathe the eye.

glaucoma, and that for the majority, the disease is not accompanied by elevated intraocular pressure. The glaucoma market is projected to grow as concern about the disease increases among Japanese people.

In addition to *Timoptol-XE*, which is recognized as the standard treatment for reducing intraocular pressure, Santen launched *Detantol* in 2001. We are building *Detantol's* role as an effective concomitant medication, and have achieved the number-two position in the glaucoma market.

During the year ending March 31, 2004, we will deploy the latest data showing *Detantol's* efficacy in lowering intraocular pressure and increasing ocular blood flow to further increase its market penetration.



Detantol

### Anti-allergy Ophthalmics

Although the number of patients suffering from eye allergies is increasing, the anti-allergy market continues to contract due to the impact of reforms to the NHI system. Santen markets two anti-allergy drugs with different mechanisms of action: *Livostin*, a histamine H<sub>1</sub> receptor antagonist; and *Alegysal*, a mast cell stabilizer.

Emphasis on *Livostin's* ability to rapidly relieve the itching that is the primary symptom of allergic conjunctivitis has supported sales growth. We are working to build on the solid performance of *Livostin* in further increasing our presence in the anti-allergy ophthalmics market.

### Prescription Anti-rheumatic Pharmaceuticals

Anti-rheumatic pharmaceuticals are another core product line in addition to Santen's prescription ophthalmic pharmaceuticals. The market for anti-rheumatic pharmaceuticals in Japan totals nearly ¥30 billion on a drug price basis, and has been increasing marginally for the past several years. In 2003 and beyond, launches of new anti-rheumatic pharmaceuticals including TNF inhibitors (see page 12) by various companies are expected, and we anticipate rapid market expansion and intensifying competition in this field.

We market two disease modifying anti-rheumatic drugs (DMARDs)<sup>2</sup>, *Azulfidine EN* and *Rimatil*, which have become the standard treatments for rheumatoid arthritis in Japan. Although the reductions in NHI drug prices in April 2002 reduced the price of both of these pharmaceuticals by approximately 10 percent, sales grew steadily during the year to March 2003, and we have achieved the number-one position in the anti-rheumatic pharmaceuticals market, with a share of approximately 30 percent.

MRs specializing in rheumatoid arthritis are assigned to major metropolitan areas and provide detailed information to healthcare professionals. In addition, we support research seminars for rheumatoid arthritis specialists throughout Japan.

As other companies launch TNF inhibitors in the market, we will work under the 2003-2005 Medium-term Management Plan to further establish DMARDs as a fixture in the market. By redoubling our efforts to persuade physicians of DMARDs' position as the basic drug therapy for rheumatoid arthritis, we plan to steadily increase the market share of our DMARDs.



Rimatil

#### Note

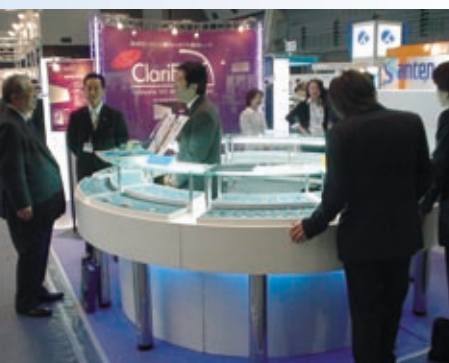
2. Disease modifying anti-rheumatic drug (DMARD): A pharmaceutical that suppresses the progression of rheumatic symptoms by alleviating the immunological abnormalities found in rheumatoid arthritis.



Actor Tetsuji Tamayama appears in advertisements for *Sante FX Neo*.



Launched in October 2002, *Sante Uruoi Contact* is a unique product that moistens the eye, particularly when wearing disposable contact lenses.



Exhibition booth at the 42nd Meeting of the Japanese Society for Cataract Research / 18th Meeting of the Japanese Society of Cataract and Refractive Surgery, held in June 2003 in Kyoto.

**Note**

3. Foldable intraocular lens: A type of intraocular lens that can be folded so that it can be inserted through a tiny incision, which has become the mainstream intraocular lens recently.

## Over-the-counter (OTC) Pharmaceuticals

Santen's OTC pharmaceuticals business specializes in the development and marketing of OTC eye drops in Japan. With the number-two share of the OTC eye drop market, we have a product lineup that includes *Sante FX Neo*, the leading brand of OTC eye drops in Japan; the *Sante 40* series of products effective against blurred vision; and the *Sante de u* series of products that are effective for eye strain.

During the year ended March 31, 2003, the OTC eye drop market grew marginally on a volume basis, but continued the trend of decreasing on a sales basis for the fourth consecutive year, affected by lower retail prices resulting from deflation and increasing competition. With consumer spending projected to remain lackluster, the OTC eye drop market is expected to remain flat or continue its gradual contraction. The share of sales at large-scale retail outlets is increasing at the expense of pharmacies and drugstores, polarizing the retail channels between regular stores and large-scale retailers.

Our core strengths are the abilities of our sales and marketing team to make sales proposals and communicate with retailers, the resulting large share we hold at large-scale retailers, a distribution network covering all of Japan, and our lineup of superior products that fully display our advanced manufacturing technology in the development of eye drops.

One focus of the 2003–2005 Medium-term Management Plan is increasing the profitability of our OTC pharmaceuticals business. We have already discontinued products with small-scale sales, and will fill out our product lineup by launching clearly differentiated products in segments with strong sales potential, thus expanding our share in the OTC eye drop market. In promoting its products, Santen will work to improve profitability by increasing the cost efficiency of television advertising and enhancing its sales capabilities.

## Medical Devices

Our medical devices business specializes in the field of cataract surgery. Products include intraocular lenses, phacoemulsification machines and surgical instruments. Seeking to be the best partner for surgeons, our surgical representatives with expertise in cataract surgery provide information to over 3,000 surgical institutions in Japan in cooperation with our 400 MRs.

Cataract is a disease in which the lens clouds with aging and other factors, causing blurred and weakened vision. Vision can be recovered through surgery that involves the insertion of an intraocular lens to replace the cloudy lens. The number of cataract surgeries in Japan has been growing by about 3 percent annually, and is projected to continue expanding at this rate. However, government policies to restrain healthcare costs and lower product prices resulting from increasing competition will cause the market to remain flat or even contract in the future.

Under the 2003–2005 Medium-term Management Plan, we will continue to enhance our high level of expertise in cataract surgery and our ability to make value-added proposals. We will further strengthen our relationships of trust with surgeons while expanding sales centered on intraocular lenses. In March 2003, Santen launched *ClariFlex*, a foldable intraocular lens<sup>3</sup>, in Japan. In the near future, we also expect to launch two intraocular lens products developed in-house. We expect an expanded product lineup of intraocular lenses to contribute to increased sales in the future.

## UNITED STATES

---

### Seeking Early Profitability through Marketing Alliances

The ophthalmic pharmaceuticals market in the United States continued to show a high growth rate in 2002, reaching over US\$26 billion<sup>4</sup>.

Santen established its U.S. subsidiary, Santen Inc., in 1993 as a base for clinical development and business development. In 2000, Santen Inc. started marketing ophthalmic pharmaceuticals. Today, with approximately 60 MRs, Santen Inc. markets three products in the United States: the anti-infective ophthalmic *Quixin* (brand name in Japan: *Cravit*), the anti-allergy ophthalmic *Alamast* (brand name in Japan: *Alegysal*), and the glaucoma treatment *Betimol*.

In April 2002, we reorganized the management structure of Santen Inc. to streamline decision-making and strengthen sales and marketing. In the year ended March 31, 2003, Santen Inc. promoted further market penetration of *Quixin* by emphasizing its superiority over other new quinolone anti-infective ophthalmics. As a result, sales of *Quixin* increased by 2.5 times over the previous fiscal year to ¥1.4 billion. Santen Inc. also aggressively marketed the other two products, emphasizing the once-a-day administration of *Betimol* and the high degree of safety and comfort of *Alamast*.

Although our U.S. ophthalmic pharmaceuticals business is achieving steady sales growth, competition has been greater than expected, and Santen Inc. has not reached the projected level of revenue it anticipated when it began independent sales and marketing. Moreover, in the U.S. anti-infective ophthalmics market, launches of new branded and generic products in 2003 and beyond will likely lead to an increasingly competitive environment for the core product *Quixin*.

We have made the profitability of our U.S. operations a primary objective in the 2003–2005 Medium-term Management Plan. We plan to strengthen sales and marketing by forming alliances with other companies that already have a strong presence in the U.S. market in order to make U.S. operations profitable (operating income before deducting R&D expenditures) in the year ending March 31, 2005. Through these alliances, we expect our superior products to be used more widely among U.S. patients. In addition, we will continue to strengthen our research and development to support medium- and long-term business expansion in the United States.



A lecture given at the Santen booth at the American Academy of Ophthalmology meeting held in October 2002 in Florida, U.S.A.

**Note**  
4. Shipping price basis

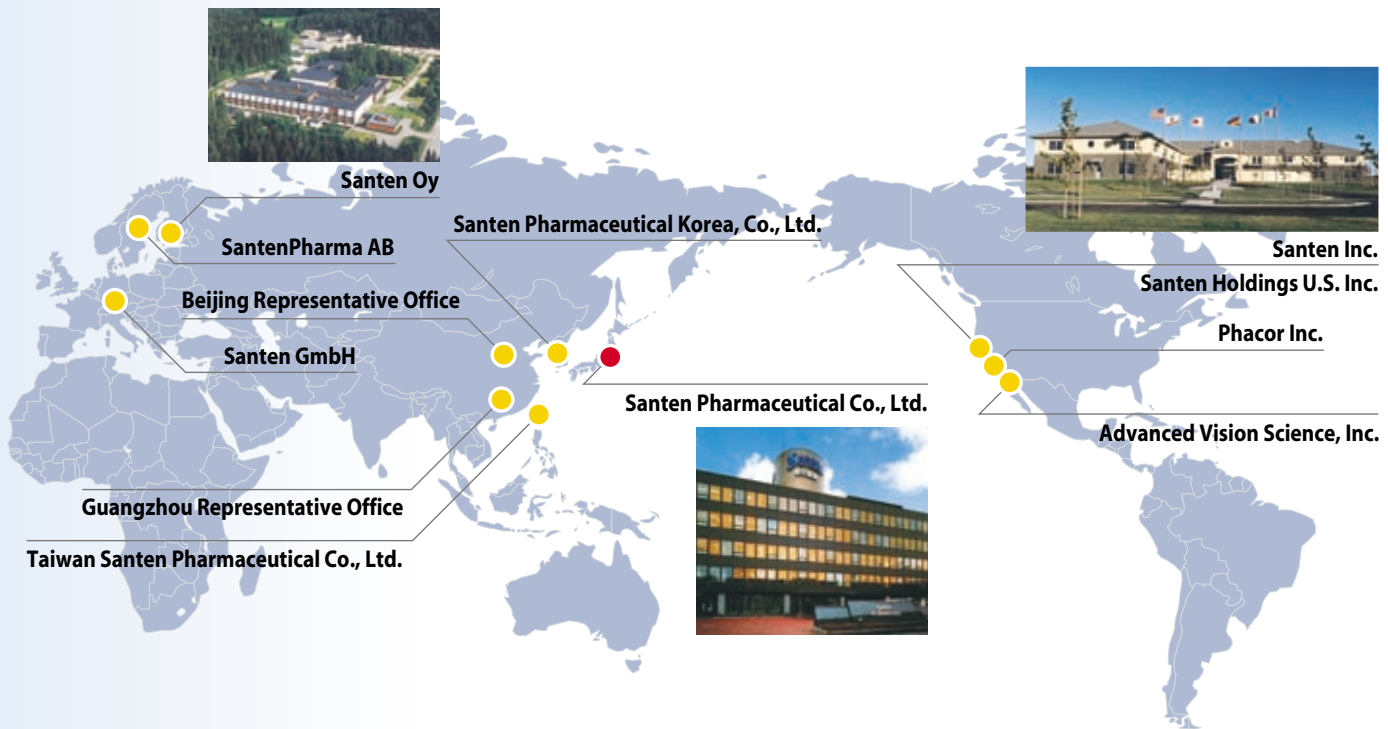
## EUROPE

---

### Aiming to be a Leader in the European Ophthalmics Market

Europe is the second-largest market for ophthalmic pharmaceuticals after the United States. The market has grown by nearly 10 percent annually in recent years, and is expected to continue steady growth. Four therapeutic fields, centered on glaucoma, and including eye allergies, dry eye and eye infections, make up more than 70 percent of the market for ophthalmic pharmaceuticals in Europe. Santen is focusing investment on products in these segments.

## Global Network



Production partnership meeting at Santen Oy

Our European business is centered on Santen Oy, a subsidiary in Finland, which has built an integrated network that extends from development of ophthalmic pharmaceuticals to production, sales and marketing. We conduct sales and marketing in more than 30 countries, including Scandinavia, the Baltic countries, Russia and Germany. In Scandinavia, we have gained recognition from patients and medical institutions as a valued partner. In particular, we have demonstrated strengths in the fields of eye infections, dry eye and glaucoma.

In May 2002, we entered the Western European market with the launch of the anti-infective ophthalmic *Oftaquix* (brand name in Japan: *Cravit*) in Germany. Sales of *Oftaquix* also began in Scandinavian countries in June 2002. With the addition of sales in other countries in Europe where marketing authorization has already been obtained, sales of *Oftaquix* are expected to grow further.

During the implementation of the 2003–2005 Medium-term Management Plan, we will place particular emphasis on enhancing our product lineup for glaucoma treatments, which comprise more than 40 percent of the European ophthalmic pharmaceuticals market. We will focus on the fast-track development of DE-085, a prostaglandin-based glaucoma treatment. In addition, we will work toward the rapid market penetration of *Oftaquix*, with the goal of making it the number-one new quinolone ophthalmic solution in every region where it is sold.



## ASIA

### Top Market Share in China and Korea

The market for ophthalmic pharmaceuticals in East Asia is expanding rapidly in tandem with economic growth. Santen imports and sells ophthalmic pharmaceuticals in ten countries and regions in Asia, including Korea, China, Hong Kong, Taiwan, the Philippines, Thailand, Singapore, Indonesia and Vietnam, primarily through local distributors. External ocular diseases such as eye infections and corneal disorders account for a larger portion of the market in East Asia, compared with the United States, Europe or Japan. Consequently, this is a market where we can realize the full potential of our main products, including the anti-infective ophthalmics *Tarivid* and *Cravit*, and the corneal disorder treatment *Hyalein*.

In the year ended March 31, 2003, we strengthened marketing and our activities to introduce scientific information to healthcare professionals. As a result, we achieved the number-one share<sup>5</sup> in the hospital market in Korea and China, our main regions of focus, outpacing major local competitors and other foreign pharmaceutical companies. Furthermore, *Tarivid* became the leading ophthalmic pharmaceutical brand in China, and all five core products, including *Hyalein* and *Alegysal*, held the top share in their respective therapeutic fields. During the year, we also focused on expanding the sales regions for *Cravit*, and sales have begun in Thailand, Singapore and Indonesia, in addition to Hong Kong and Korea, where we started marketing in previous years.

As part of our efforts to enhance provision of scientific information, we supported scientific meetings for eyecare professionals and conducted training for local staff. We held events including simultaneous lectures in 12 cities in China and a symposium on eye infection by Chinese specialists. In April 2003, we launched an internet educational site, *Asian Ophthalmology.com*, which mainly targets young ophthalmologists in Asia.

A key objective of the 2003–2005 Medium-term Management Plan is increasing the number of products registered for sale in the markets where we operate to further expand our presence, especially in the key markets of Korea and China. Success in the Chinese ophthalmic pharmaceuticals market is a crucial point as it accounts for about 70 percent of the total market size in the regions where we operate, and is expected to continue growing by more than 10 percent each year. Based on data gained from our extensive survey, we plan to develop a long-term sales and marketing strategy that will enable us to maintain and increase our leading position in China.



*Asian Ophthalmology.com* provides access to treatment guidelines from prominent ophthalmologists in the United States, Europe and Asia, as well as the content of scientific symposiums planned or supported by Santen. The site is intended as a communication medium that contributes to the development of ophthalmology in Asia.

#### Note

5. Based on data in Korea for the year ended March 31, 2003, and data in China for the first quarter (April-June) of the year ending March 31, 2004.

# Production

## Key Issues in the 2003–2005 Medium-term Management Plan

- Raise productivity through the introduction of a new eye drop container and other measures
- Optimize production and manufacturing processes



Inspection on the *Dimple Bottle* production line. The form of each container is checked by a computer.

## Continuous Cost Reduction

Santen has three plants in Japan (Noto, Shiga and Osaka), as well as a production base in Finland. This production network serves Japan, the United States, Europe and other parts of Asia.

In 1977, we became the first company in the world to apply the Blow-Fill-Seal (BFS) system<sup>1</sup> to the production of ophthalmic solutions. The BFS system allows for higher productivity due to its reduced raw material requirements for bottles. In addition, they can be manufactured much faster than bottles with the common three-piece structure of container, nozzle assembly and cap.

Over the 25 years since the introduction of the BFS system, we have continuously pursued more efficient production through unique advancements and modifications of the system.

Combined with the efforts of all our production staff members, we have successfully reduced our cost of sales ratio for the fourth consecutive year during the year ended March 31, 2003, to 35.7 percent from the 41.0 percent posted in the year ended March 31, 1999. We aim to reduce this ratio even further during the 2003–2005 Medium-term Management Plan.

## *Dimple Bottle* Improves Efficiency

In the prescription pharmaceuticals industry, intensifying global competition in research and development has made it critical for companies to establish a production system that is competitive in terms of both cost and quality. Our production division has established the goal of becoming the best supplier in the world, and is developing a production system that can compete with any company in Japan or abroad, including China.

Continuous improvement and innovation are two key factors that will be essential in achieving this goal. In addition to our continued cost-cutting efforts, centered on reducing raw material costs and improving our yield and operating ratio, we have set specific benchmarks for further raising productivity. These focus on “process optimization,” “drive and activity”

### Note

1. Blow-Fill-Seal (BFS) system: A production system in which an operating cycle forms, fills and hermetically seals containers under aseptic conditions.

(determining whether our “drive” creates customer value and re-examining our capabilities) and “one person, two roles” (creating a multi-skilled workforce). Furthermore, we will investigate the possibility of making manufacturing even more efficient in consideration of revisions to Japan’s Pharmaceutical Affairs Law<sup>2</sup>.

In 2002, we developed the *Dimple Bottle*, an ophthalmic solution container that builds on the advantages of the BFS system for greater ease of use by patients. The introduction of this new container allows us to increase production capacity per line and reduce costs on packaging materials. In two years, we will change over to the *Dimple Bottle* from the three current types of containers used for our prescription ophthalmics in Japan. We expect the *Dimple Bottle* to have a substantial impact in improving manufacturing efficiency.

### Establishing a World-class Quality Assurance System

We have established a world-class quality assurance system based on a policy of supplying reliable, high-quality pharmaceuticals that win the trust of patients. We ensure the highest level of quality control by adopting the latest technology and implementing an in-house qualification system. The qualification system mandates that only qualified staff are assigned to operations that require a high level of skill, such as sterile operations and visual inspections.

#### Note

2. Revisions to the Pharmaceutical Affairs Law: In July 2002, the Japanese Pharmaceutical Affairs Law was revised to permit pharmaceutical companies to divest their manufacturing divisions after 2005. Currently they are required to have at least one manufacturing process in-house for each of their products.

#### The *Dimple Bottle*

The shape of the *Dimple Bottle* makes it easier to hold, particularly for older patients. It also allows for easy squeezability, and a slit window lets users check the remaining volume in the bottle. A large, color-coded cap and the clear display of the product name allows easy differentiation between the various Santen products.



# Personnel Development

## Key Issues in the 2003–2005 Medium-term Management Plan

- Further enhance employee education and training programs
- Find and develop superior personnel
- Promote staff mobility within the company



Members of the Santen Innovation Project consider various aspects of Santen in their thorough discussions, and devise reform programs to meet actual management needs.

## Education and Training Programs Emphasize Autonomous Growth

Based on the belief that the source of a company's competitiveness lies in the people who work there, their talents and creativity, we are enhancing the education and training programs for our employees. At the same time, we have established an evaluation and compensation system along with other initiatives to promote career development, so that employees can demonstrate their full potential at work.

The Santen Innovation Project (SIP), initiated in 2001, is an internal business school that is attended by young and middle-management employees. Class members learn about the latest management theories and case studies, and take part in cross-divisional discussions to study, plan and implement strategies tailored to Santen's actual business conditions. A total of 85 employees have completed SIP programs to date, and 15 are currently participating in the project's fourth term. Through SIP, we hope to link our accumulated knowledge, inter-division and inter-level discussions, and a shared understanding of our current management issues to improve our corporate culture and strengthen our organization.

We have also established our Career Development Support System as a company-wide training system. As part of our efforts to nurture our employees, the system provides numerous training opportunities that help staff develop necessary skills and support individual career development.

In order to promote staff mobility within the company, we have implemented an open internal recruitment system to broaden career development opportunities by allowing employees to take on different types of work.

## A Fair Personnel System Based on the Value of Work and Performance

We have implemented a highly transparent evaluation and compensation system. This system is strictly based on the responsibilities and performance of each employee's work, and not on personal attributes such as age or gender. Rewarding achievement and providing appropriate compensation that matches the results achieved stimulate motivation. The system also promotes ambitious goal-setting and career development by clarifying the objectives and requirements for higher-level positions.

# Corporate Citizenship

As a pharmaceutical company dedicated to vision and health, Santen contributes to society with donations and support related to the field of ophthalmology. We also carry out company-wide environmental activities in line with our Basic Environmental Policy to “hand the Earth to the next generation in the best state possible.”



## Protecting the “Joy of Sight”

With the increasingly aging population, more and more attention is being given to healthy vision. Our social mission is to help people around the world maintain healthy vision and protect their “joy of sight” by developing superior pharmaceutical products.

In order to contribute to society beyond our business activities, we give donations and support to welfare organizations. For example, we are an ongoing contributor to U.S.-based Helen Keller Worldwide, and also donate funds to the Japan Eye Bank Association and the Japan National Society for the Prevention of Blindness. In the United States, we contribute regularly to Prevent Blindness America in addition to a variety of other vision-related charitable organizations. In Asia, we donate pharmaceuticals to the Blindness Prevention Program in Vietnam, and we have even established a scholarship fund to support education for distinguished ophthalmologists in China.

## Handing the Earth to the Next Generation in the Best State Possible

We carry out a variety of activities to reduce the environmental impact of our business operations, including the introduction of co-generation facilities and low-emission vehicles, as well as the promotion of segregated waste disposal, recycling and ecologically friendly purchasing.

In January 2003, the Noto Plant obtained ISO14001 certification, the international standard for environmental management systems. All facilities within the plant are working toward preserving the environment, with targets for reducing energy consumption, use of water and waste emissions, as well as recycling plastics and paper. With the certification of the Noto Plant, all three of our plants in Japan have been certified for ISO14001.

In 2002, we published our *Environmental Report 2002*<sup>1</sup> to help our stakeholders get a deeper understanding of our environmental initiatives. Contents include our top management’s position on environmental protection, our Environmental Policy and guidelines, the environmental management system and environmental initiatives at each plant and office. The report also discloses our environmental accounting, which presents our expenditures for environmental protection and the results of our efforts in numbers.



Santen employees participating in clean-up activities near Corporate Headquarters during Environment Month.



*Environmental Report 2002*

**Note**

1. Available only in Japanese.

# Financial Review

## REVIEW OF OPERATIONS

In the year ended March 31, 2003, the Japanese prescription ophthalmic pharmaceuticals market contracted slightly, impacted by National Health Insurance (NHI) drug price reductions in April 2002 and an increase in medical co-payments for elderly patients that went into effect in October 2002. Outside Japan, demand for prescription ophthalmic pharmaceuticals was strong in the United States and Europe. Demand in Asia also increased, particularly in China and Korea. The Japanese market for over-the-counter (OTC) pharmaceuticals also contracted, as deflation and intensifying competition led to lower retail prices.

To maintain our competitiveness amid this environment, we focused our management resources on our primary products and increased our promotional activities both quantitatively and qualitatively in our Japanese prescription ophthalmics business. In the United States, we reorganized the management structure of our local subsidiary in April 2002 and expanded the sales of the anti-infective ophthalmic *Quixin* (brand name in Japan: *Cravit*). In research and development, we accelerated the development of three glaucoma treatments. We also strengthened our research and development capabilities through the injection of resources in targeted therapeutic areas. At the same time, we continued to reduce production costs and have maintained our emphasis on maximizing returns on sales promotion and R&D expenses.

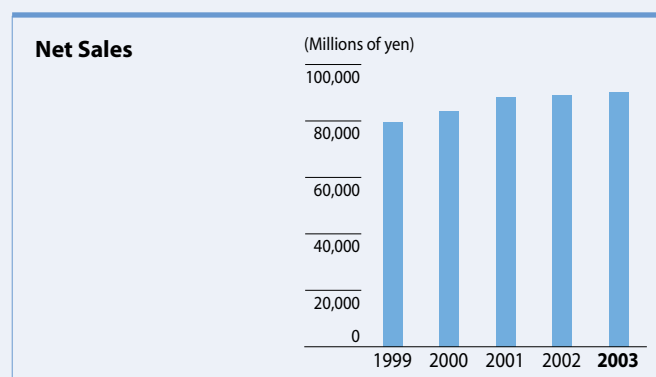
As a result, net sales for the year ended March 31, 2003 increased 1.4 percent, or ¥1,287 million, compared with the previous fiscal year to ¥90,253 million. Operating income increased 7.7 percent, or ¥907 million, to ¥12,697 million due to company-wide efforts to reduce cost of sales and other expenses. Income before income taxes decreased 21.5 percent, or ¥2,732 million, to ¥9,947 million due to the appropriation of a special premium payment incurred upon Santen's secession from a composite pension fund as an extraordinary loss. Net income increased by 60.3 percent, or ¥3,197 million, to ¥8,503 million due to a year-on-year decrease in income taxes in connection with the liquidation of a subsidiary.

## Net Sales

### Net Sales by Business Segment

(Millions of yen)

Year ended March 31	2003	2002	Change (%)
Prescription Pharmaceuticals	79,345	78,149	1.5
Ophthalmic	71,122	70,043	1.5
Anti-rheumatic	7,631	7,291	4.7
Others	591	815	(27.4)
OTC Pharmaceuticals	5,656	6,592	(14.2)
Medical Devices	918	916	0.3
Others	4,332	3,309	30.9
Total Sales	90,253	88,966	1.4



### Prescription Pharmaceuticals

Sales of prescription pharmaceuticals increased 1.5 percent, or ¥1,196 million, year-on-year to ¥79,345 million.

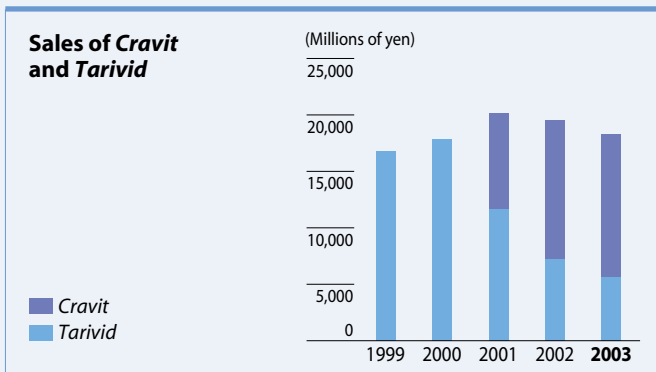
### Prescription Ophthalmic Pharmaceuticals

#### Japan

In the year ended March 31, 2003, Santen maintained its emphasis on increasing the market penetration of its products through effective marketing efforts tailored to meet the emerging needs of healthcare professionals. Despite these efforts, sales of prescription ophthalmic pharmaceuticals in Japan declined 0.6 percent, or ¥416 million, to ¥64,009 million. The factors behind this decrease include NHI drug price reductions and other measures to contain healthcare costs and intensifying competition.

## Anti-infective Ophthalmics

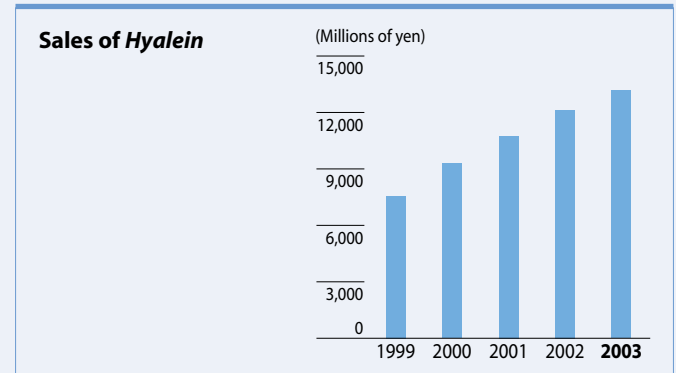
Santen's anti-infective ophthalmics category contains *Cravit* (levofloxacin ophthalmic solution) and *Tarivid* (ofloxacin ophthalmic solution). *Cravit* is an anti-infective ophthalmic solution in a class known as new quinolones, and is a potent, broad spectrum anti-infective with an excellent ability to penetrate ophthalmic tissue. Since its launch in April 2000, *Cravit* has rapidly earned a reputation among healthcare professionals as the first-line treatment for conjunctivitis, keratitis and other eye infections. The number of prescriptions written for *Cravit* steadily increased during the year, as we enhanced our promotional activities focusing on the importance of early treatment of eye infections. As a result, sales of *Cravit* rose 2.9 percent, or ¥353 million, to ¥12,691 million. The combined total sales of *Cravit* and *Tarivid* decreased 6.5 percent, or ¥1,265 million, to ¥18,257 million due to factors including a reduction in NHI drug prices and the stagnant market.



## Corneal Disorder Treatments

The number of patients with dry eye, a condition caused by quantitative and qualitative changes in tears, is increasing in correlation with heightened use of personal computers. *Hyalein* (sodium hyaluronate ophthalmic solution) is a treatment for corneal disorders associated with dry eye and other factors. *Hyalein*'s unique ability to improve the patient's quality of life, coupled with Santen's continued initiatives in educating the public about the need for early diagnosis and treatment of dry eye, have contributed to steady annual gains in sales since its launch in 1995. Santen's continuing efforts to educate the public on the importance of early diagnosis and treatment of dry eye, which included holding 25 lectures nationwide in cooperation with local ophthalmologists'

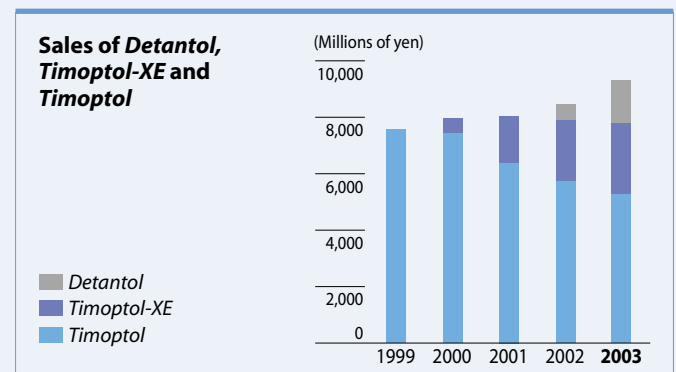
associations, resulted in an 8.5 percent, or ¥1,026 million, increase in sales of *Hyalein* to ¥13,156 million in the year ended March 31, 2003.



## Glaucoma Treatments

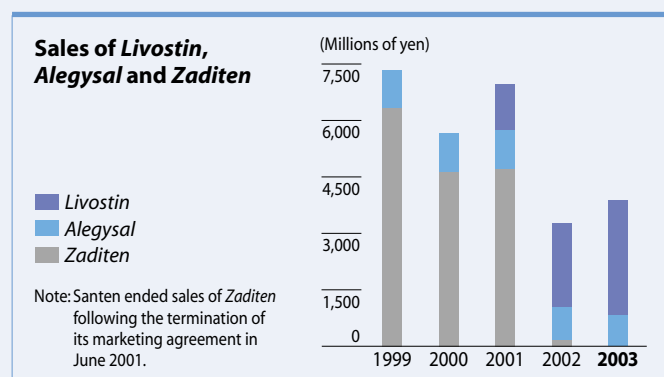
The market for glaucoma treatments continued to expand, reflecting the aging population. Launched in 2001, *Detantol* (bunazosin hydrochloride ophthalmic solution) has a novel mechanism of action different from existing glaucoma treatments. This mechanism promotes the outflow of fluid in the eye known as aqueous humor and reduces intraocular pressure by selectively blocking  $\alpha_1$  receptors in the local ocular area. Seminars to introduce the latest data in this field led to a substantial increase in the number of prescriptions during the year, and sales of *Detantol* increased 152.6 percent, or ¥905 million, to ¥1,498 million.

Sales of *Timoptol-XE*, launched in 1999 in a once-daily dosage formulation that effectively reduces intraocular pressure, increased 15.4 percent, or ¥332 million, to ¥2,477 million. Overall sales of the *Timoptol* line, including the original product *Timoptol*, decreased 1.6 percent, or ¥124 million, to ¥7,766 million.



## Anti-allergy Ophthalmics

The anti-allergy *Livostin* (levocabastine hydrochloride ophthalmic solution) was launched in 2001. This drug provides rapid relief from the itching that is a major symptom of allergic conjunctivitis. A focus on *Livostin's* superiority in our medical representatives' activities led to an increase of 36.1 percent, or ¥803 million, in sales of *Livostin* to ¥3,028 million. Total sales of anti-allergy ophthalmics, including *Alegysal* (pemirolast potassium ophthalmic solution), increased 19.0 percent, or ¥620 million, to ¥3,876 million.



## Overseas

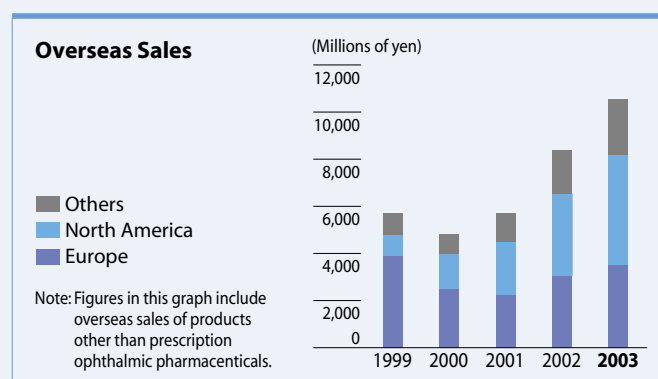
Overseas sales of prescription ophthalmic pharmaceuticals increased 26.6 percent, or ¥1,495 million, to ¥7,112 million.

In the United States, we continued our market penetration efforts on our three products: the anti-allergy ophthalmic *Alamast* (brand name in Japan: *Alegysal*), launched in July 2000; the anti-infective ophthalmic *Quixin* (brand name in Japan: *Cravit*), launched in November 2000; and the glaucoma treatment *Betimol*, which we started marketing in January 2001. In April 2002, we reorganized the management structure of our U.S. subsidiary Santen Inc. to streamline decision-making and strengthen sales and marketing. In the year ended March 31, 2003, Santen Inc. continued its efforts to increase the market share for *Quixin*, emphasizing the drug's superiority over other new quinolone anti-infectives, and sales of *Quixin* increased 156.7 percent, or ¥854 million, to ¥1,399 million.

In Europe, we have achieved solid sales growth in Northern and Eastern Europe, as Finnish subsidiary Santen Oy further enhanced sales and marketing activities. Santen launched the anti-infective ophthalmic *Oftaquix* (brand name in Japan:

*Cravit*) in Germany in May 2002 and in the Scandinavian countries in June 2002.

In Asia, Santen imports and sells its products in ten countries and regions including China and Korea. In the year ended March 31, 2003, we launched the anti-infective ophthalmic *Cravit* in Thailand, Singapore and other countries. Sales in Asia continued to increase, particularly in China and Korea, led by our enhanced marketing efforts including the provision of scientific information to local healthcare professionals.



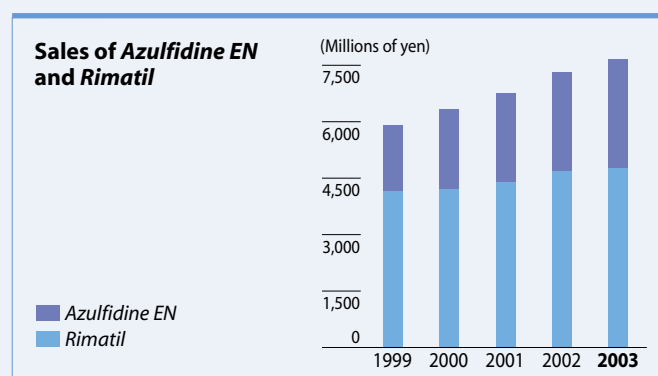
## Anti-rheumatic Pharmaceuticals

Santen markets two disease modifying anti-rheumatic drugs (DMARDs) in Japan, *Azulfidine EN* and *Rimatil*, as treatments for rheumatoid arthritis.



**Azulfidine EN**

Sales of anti-rheumatic pharmaceuticals increased 4.7 percent, or ¥340 million, to ¥7,631 million.





## Over-the-counter (OTC) Pharmaceuticals

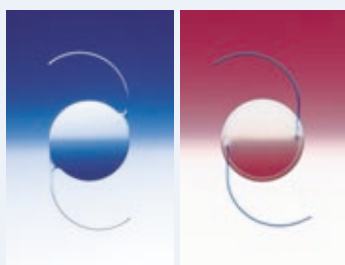
New products launched during the year include *Sante 40V*, a nutrition-fortified version of the *Sante 40* series used to treat blurred vision and eye strain, and *Sante Uruoi Contact*, which moistens the eye particularly when wearing disposable contact lenses. Sales of OTC pharmaceuticals decreased 14.2 percent, or ¥936 million, to ¥5,656 million due to a stagnant market and intensifying competition.



OTC eye drops launched during the year ended March 31, 2003

## Medical Devices

The medical devices business consists of intraocular lenses, phacoemulsification machines, surgical instruments and other devices related to cataract surgery.



Intraocular lenses used in cataract surgery

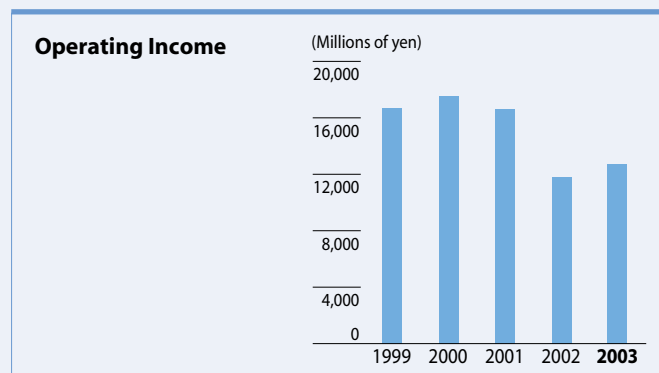
During the year ended March 31, 2003, the number of cataract surgeries in Japan increased marginally over the previous fiscal year. Higher sales of surgical instruments offset a decrease in sales of phacoemulsification machines. As a result, total sales of medical devices remained almost flat compared with the previous fiscal year at ¥918 million.

## Others

This segment mainly consists of contract manufacturing and royalty income. Sales under this segment increased 30.9 percent, or ¥1,024 million, to ¥4,332 million due to an increase in contract manufacturing of anti-infective ear medicine and because sales of *Thiola Tablet 100*, a metabolic improving and detoxicating agent, were reclassified from prescription pharmaceuticals to contract manufacturing in connection with the marketing of *Thiola* being transferred to another company.

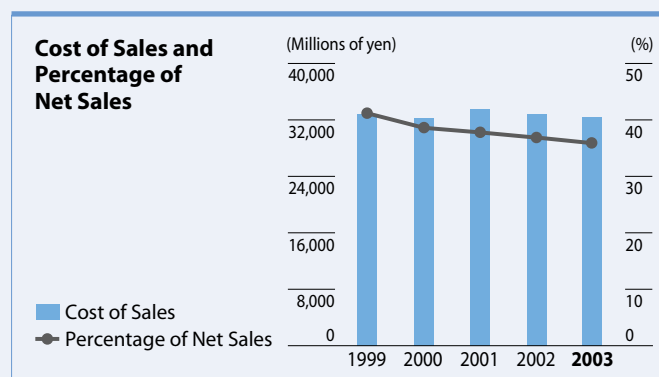
## Operating Income

Operating income increased 7.7 percent, or ¥907 million, year-on-year to ¥12,697 million. The ratio of operating income to net sales increased to 14.1 percent from 13.3 percent.

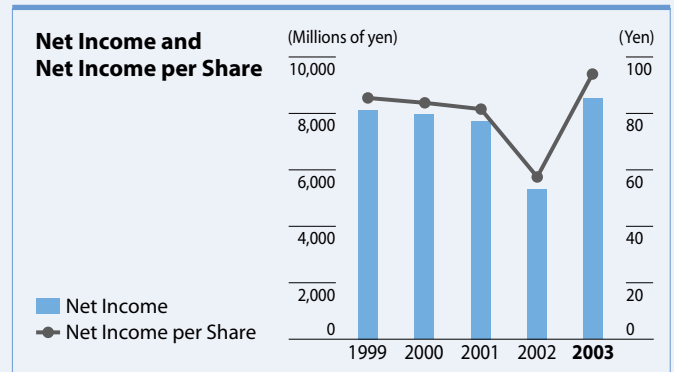
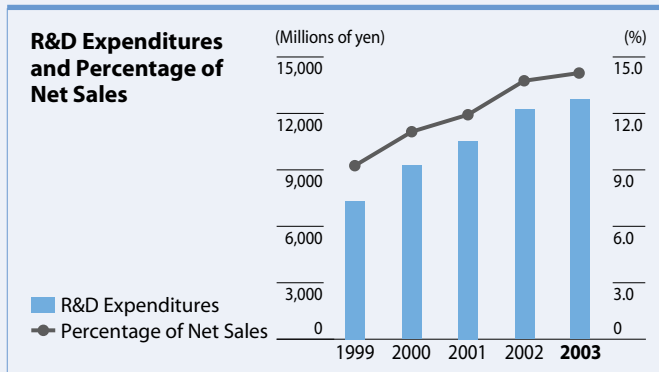


## Cost of Sales and Selling, General and Administrative (SG&A) Expenses

Cost of sales declined 1.3 percent, or ¥429 million, to ¥32,272 million as a result of increased net sales and lower lease expenses. The ratio of cost of sales to net sales improved to 35.8 percent from 36.8 percent.



SG&A expenses increased 1.8 percent, or ¥809 million, year-on-year to ¥45,284 million due to increased overseas sales and marketing expenses and a 4.4 percent, or ¥532 million, increase in R&D expenditures. The R&D expenditures increased due to enhanced clinical development activities worldwide and development of medical devices.



## ● Other Income (Expenses)

Net other expenses for the year totaled ¥2,750 million, compared to net other income of ¥889 million for the previous fiscal year.

Other income decreased 38.2 percent, or ¥794 million. Interest and dividend income decreased 11.8 percent, or ¥36 million, to ¥268 million due to lower interest rates in Japan. Other income also decreased because of the absence of the one-time receipt of ¥886 million that was recorded in the previous year in connection with compensation for damages awarded in the Princeton Notes lawsuit.

Other expenses increased 238.8 percent, or ¥2,845 million. The primary factor in this increase was the appropriation of a special premium payment of ¥2,203 million as an extraordinary loss. This resulted on secession from a composite pension fund. Weak stock market conditions also resulted in an increase of 237.3 percent, or ¥423 million, in loss on valuation of securities to ¥602 million.

## ● Income Taxes

Income taxes for the year decreased 80.4 percent, or ¥5,929 million, to ¥1,444 million as a result of the liquidation of our European subsidiary, Santen Pharmaceutical BV. The ratio of income taxes to income before income taxes (effective tax rate) declined to 14.5 percent from 58.2 percent.

## ● Net Income

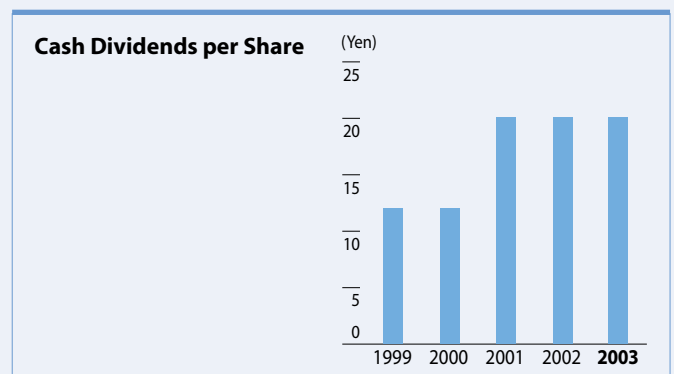
As a result, net income increased 60.3 percent, or ¥3,197 million, to ¥8,503 million. The ratio of net income to net sales improved to 9.4 percent from 6.0 percent. Net income per share increased to ¥93.67 from ¥57.34. Diluted net income per share increased to ¥85.97 from ¥53.07.

## ● Cash Dividends

Returning profits to shareholders in the form of cash dividends is an issue of key importance for Santen. Our corporate policy is to maintain a stable level of cash dividends while keeping an eye on our profit level.

Based on this philosophy, cash dividends per share for the year ended March 31, 2003 were set at ¥20.00, unchanged from the previous fiscal year.

We remain committed to maintaining solid liquidity and strengthening our financial condition with regard to the management of our internal reserves, allowing us to prepare for necessary investment in facilities and information technology (IT). At the same time, we plan to effectively utilize internal reserves for research and development and overseas business strategy to realize future growth.



## LIQUIDITY AND FINANCIAL CONDITION

### ● Capital Procurement and Liquidity Management

Santen emphasizes the maintenance of a sound balance sheet, appropriate liquidity, and sufficient capital for funding operations. Accordingly, we have committed lines of credit with financial institutions that provide flexibility in timing and amount for the acquisition of funds. We maintain internal liquidity at an appropriate level to ensure efficient capital deployment.

To improve capital efficiency and raise shareholder value, we repurchased 2,741,000 shares of our common stock at a total cost of ¥3,237 million in March 2003. This marked the third consecutive year in which we have repurchased our shares. An additional share repurchase of up to 4,000,000 shares and ¥5,000 million was approved at the 91st Annual General Meeting of Shareholders, held on June 26, 2003.

The redemption of convertible bonds totaling ¥19,945 million is scheduled for September 2003, and we entered into a contract in March 2003 for ¥10,000 million in unsecured long-term borrowings from financial institutions during the period to September 2003.

### ● Cash Flows

#### Cash Flows Summary

(Millions of yen)

Year ended March 31	2003	2002	Change
Cash Flows from Operating Activities	15,808	6,941	8,867
Cash Flows from Investing Activities	(9,951)	(6,374)	(3,577)
Cash Flows from Financing Activities	(6,507)	(5,684)	(823)
Cash and Cash Equivalents at End of Year	25,054	25,620	(566)

#### Cash Flows from Operating Activities

Net cash provided by operating activities increased 127.7 percent, or ¥8,867 million, to ¥15,808 million. Although income before income taxes decreased, trade receivables as of March 31, 2002, a bank holiday, included ¥6,172 million in accounts receivable that would have been settled had March 31, 2002 been a normal business day. Settlement therefore took place during the year to March 31, 2003, increasing net cash provided by operating activities. Reduction of inventories and

income taxes also contributed to the increase in net cash provided by operating activities.

#### Cash Flows from Investing Activities

Net cash used in investing activities increased 56.1 percent, or ¥3,577 million, to ¥9,951 million. Capital expenditures increased 7.0 percent, or ¥460 million, to ¥7,046 million. Major capital expenditure items include the expansion of the Nara Research and Development Center and the construction of production lines for a new eye drop container at the Noto and Shiga plants. A shift of cash from deposits to commercial paper and other investment securities also contributed to an increase in net cash used in investing activities.

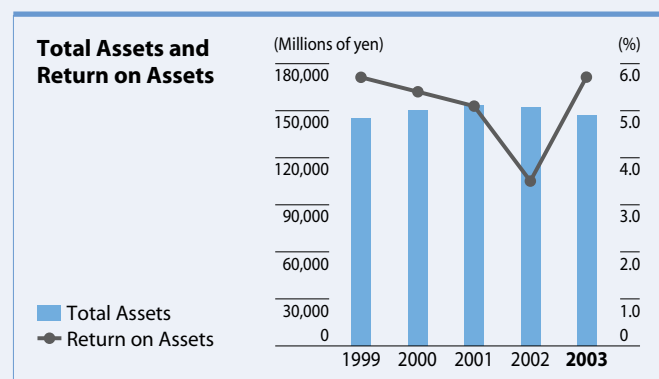
#### Cash Flows from Financing Activities

Net cash used in financing activities increased 14.5 percent, or ¥823 million, to ¥6,507 million, due largely to the repayment of long-term debt totaling ¥1,000 million.

The above factors resulted in a decrease of 2.2 percent, or ¥566 million, in cash and cash equivalents at the end of the year to ¥25,054 million.

### ● Assets, Liabilities and Shareholders' Equity

As of March 31, 2003, total assets stood at ¥147,148 million, a decrease of 3.3 percent, or ¥4,955 million, from the previous fiscal year end. Return on assets increased to 5.8 percent from 3.5 percent.



Current assets decreased 3.1 percent, or ¥2,633 million, to ¥83,431 million.

Despite the effect of net income and a decrease in trade receivables, cash and cash equivalents decreased 2.2 percent, or ¥566 million, to ¥25,054 million, due to the use of cash in funding capital expenditures and the share repurchase program. Trade receivables decreased 17.5 percent, or ¥6,899 million, to ¥32,516 million.

Net property, plant and equipment decreased 3.1 percent, or ¥1,309 million, to ¥40,850 million, due mainly to depreciation and amortization. Construction in progress decreased ¥3,233 million, reflecting the completion of the Nara Research and Development Center expansion project and the sale of some production facilities at the Noto Plant to a lease company. Buildings and structures increased with the completion of the Nara Research and Development Center expansion. Capital expenditures (on an acquisition basis) decreased 51.5 percent, or ¥4,382 million, to ¥4,134 million.

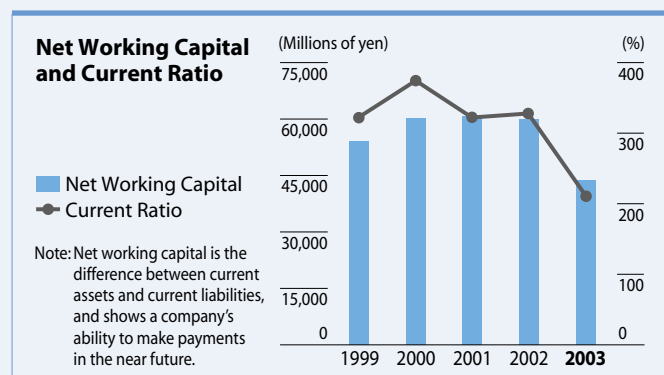
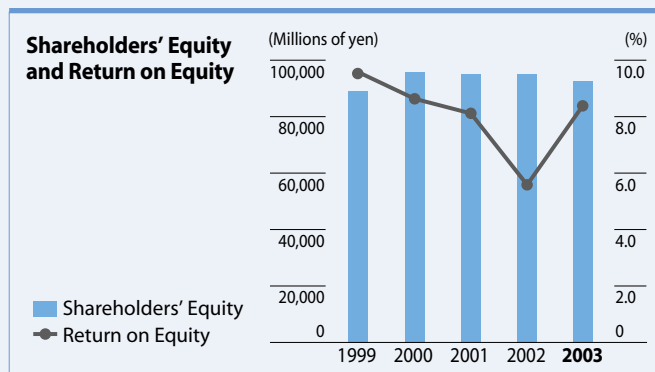
Investments and other assets decreased 4.2 percent, or ¥1,013 million, to ¥22,867 million due primarily to a decrease in goodwill.

Total liabilities, which is the sum of current and noncurrent liabilities, decreased 12.2 percent, or ¥6,980 million, to ¥50,022 million.

Current liabilities increased 50.5 percent, or ¥13,303 million, to ¥39,637 million, as we transferred ¥19,945 million in convertible bonds due in September 2003 to current liabilities.

As a result, net working capital on March 31, 2003 decreased to ¥43,794 million from ¥59,730 million. The current ratio also decreased to 210 percent from 327 percent. Noncurrent liabilities decreased 66.1 percent, or ¥20,283 million, to ¥10,385 million, as we transferred convertible bonds to be redeemed within a year to current liabilities.

Shareholders' equity increased 2.1 percent, or ¥2,025 million, to ¥97,126 million. The shareholders' equity ratio increased to 66.0 percent from 62.5 percent, while return on equity improved to 8.8 percent from 5.6 percent. Net assets per share at the end of the year totaled ¥1,104, up from ¥1,049 at the previous year end.



# Six-year Summary of Selected Financial Data

Years ended March 31

	Millions of yen						Thousands of U.S. dollars
	2003	2002	2001	2000	1999	1998	2003
<b>For the year:</b>							
Net sales .....	¥ 90,253	¥ 88,966	¥ 88,449	¥ 83,577	¥ 79,639	¥ 77,957	\$ 750,855
Cost of sales .....	32,272	32,701	33,385	32,195	32,746	31,278	268,482
Selling, general and administrative expenses.....	45,284	44,475	38,546	33,894	30,294	30,535	376,742
Operating income .....	12,697	11,790	16,518	17,488	16,599	16,144	105,631
Interest expense.....	480	465	430	462	588	654	3,995
Income before income taxes .....	9,947	12,679	15,521	14,422	15,969	14,917	82,756
Income taxes .....	1,444	7,373	7,807	6,481	7,864	7,594	12,017
Net income.....	8,503	5,306	7,714	7,941	8,105	7,323	70,739
Capital expenditures .....	7,046	6,586	4,943	2,510	3,443	5,898	58,616
Depreciation and amortization .....	4,311	5,334	5,683	5,725	6,314	6,674	35,867
R&D expenditures.....	12,719	12,187	10,511	9,221	7,335	7,731	105,819
<b>Per share data (yen and U.S. dollars):</b>							
Net income.....	¥ 93.67	¥ 57.34	¥ 81.32	¥ 83.54	¥ 85.27	¥ 77.06	\$ 0.78
Cash dividends, applicable to period....	20.00	20.00	20.00	12.00	12.00	12.00	0.17
<b>At year-end:</b>							
Current assets .....	¥ 83,431	¥ 86,064	¥ 88,025	¥ 82,218	¥ 78,018	¥ 70,892	\$ 694,102
Net property, plant and equipment .....	40,850	42,159	36,684	37,416	39,638	43,425	339,853
Total assets.....	147,148	152,103	153,243	149,968	144,913	138,822	1,224,191
Long-term debt.....	23,047	24,467	25,482	26,491	27,496	31,168	191,739
Total shareholders' equity .....	97,126	95,101	94,834	95,669	88,950	81,998	808,036
Return on equity (ROE) (%).....	8.8	5.6	8.1	8.6	9.5	9.3	—
Issued shares (thousands) .....	90,704	90,704	92,721	95,075	95,075	95,075	—
Number of employees .....	2,500	2,463	2,167	2,093	2,037	2,010	—

Notes: 1. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate prevailing on March 31, 2003 of ¥120.20 to US\$1.

2. See Notes 2.xiii) and 10 of Notes to Consolidated Financial Statements in respect of per share data.

3. Net sales in the fiscal years ended March 31, 2003, 2002 and 2001 include royalty income which was presented as "Other, net" in "Other income (expenses)" until the fiscal year ended March 31, 2000.

# Consolidated Balance Sheets

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
As of March 31, 2003 and 2002

ASSETS	Millions of yen		Thousands of U.S. dollars (Note 3)
	2003	2002	2003
<b>Current assets:</b>			
Cash and cash equivalents .....	¥ 25,054	¥ 25,620	\$ 208,431
Short-term investments (Note 4) .....	6,354	3,902	52,866
Trade receivables:			
Notes.....	685	1,183	5,701
Accounts.....	31,831	38,232	264,818
Less allowance for doubtful receivables .....	(13)	(67)	(109)
Net trade receivables .....	32,503	39,348	270,410
Inventories (Note 6) .....	11,684	12,371	97,205
Deferred tax assets (Note 13) .....	1,202	1,871	9,999
Other current assets.....	6,634	2,952	55,191
Total current assets.....	83,431	86,064	694,102
<b>Property, plant and equipment (Note 7):</b>			
Land .....	10,991	11,010	91,437
Buildings and structures.....	39,574	36,145	329,239
Machinery and equipment .....	11,059	11,815	92,005
Tools, furniture and vehicles.....	10,744	10,245	89,384
Construction in progress.....	4,967	8,200	41,320
Total .....	77,335	77,415	643,385
Less accumulated depreciation.....	(36,485)	(35,256)	(303,532)
Net property, plant and equipment.....	40,850	42,159	339,853
<b>Investments and other assets:</b>			
Investments in and advances to affiliates.....	254	350	2,111
Investment securities (Note 4) .....	9,692	9,560	80,628
Goodwill .....	1,599	2,261	13,298
Other intangibles .....	3,183	2,904	26,477
Deferred tax assets (Note 13) .....	2,331	2,515	19,396
Other assets .....	5,808	6,290	48,326
Total investments and other assets.....	22,867	23,880	190,236
<b>Total assets (Note 15).....</b>	<b>¥147,148</b>	<b>¥152,103</b>	<b>\$1,224,191</b>

See accompanying notes to consolidated financial statements.

**LIABILITIES AND SHAREHOLDERS' EQUITY**

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2003	2002	2003
<b>Current liabilities:</b>			
Current portion of long-term debt (Note 8).....	¥ 20,361	¥ 1,418	\$ 169,393
Trade accounts payable .....	5,476	4,798	45,559
Other payables.....	9,117	12,240	75,850
Accrued expenses.....	4,165	3,816	34,652
Income taxes payable (Note 13).....	2	3,428	15
Other current liabilities.....	516	634	4,291
Total current liabilities.....	39,637	26,334	329,760
<b>Noncurrent liabilities:</b>			
Long-term debt (Note 8) .....	2,686	23,049	22,346
Retirement and severance benefits (Note 9) .....	5,754	5,602	47,872
Deferred tax liabilities (Note 13).....	32	34	267
Other liabilities.....	1,913	1,983	15,910
Total noncurrent liabilities.....	10,385	30,668	86,395
<b>Shareholders' equity:</b>			
Common stock (Notes 10 and 11):			
Authorized – 155,585 thousand shares (155,585 thousand shares in 2002)			
Issued – 90,704 thousand shares (90,704 thousand shares in 2002) .....	6,214	6,214	51,698
Additional paid-in capital (Notes 10 and 11) .....	6,909	6,909	57,477
Retained earnings (Note 10) .....	90,552	83,893	753,342
Unrealized holding gains on securities (Note 4).....	294	474	2,444
Foreign currency translation adjustments .....	(3,566)	(2,383)	(29,667)
	100,403	95,107	835,294
Treasury stock at cost (Note 10):			
2,771,565 shares in 2003 and 2,852 shares in 2002 .....	(3,277)	(6)	(27,258)
Total shareholders' equity.....	97,126	95,101	808,036
<b>Contingent liabilities (Note 14)</b>			
Total liabilities and shareholders' equity.....	¥147,148	¥152,103	\$1,224,191

# Consolidated Statements of Income

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
For the years ended March 31, 2003, 2002 and 2001

	Millions of yen			Thousands of U.S. dollars (Note 3)
	2003	2002	2001	2003
Net sales (Note 15) .....	<b>¥90,253</b>	¥88,966	¥88,449	<b>\$750,855</b>
Cost of sales (Notes 7 and 9).....	<b>32,272</b>	32,701	33,385	<b>268,482</b>
Gross profit.....	<b>57,981</b>	56,265	55,064	<b>482,373</b>
Selling, general and administrative expenses (Notes 7, 9 and 12).....	<b>45,284</b>	44,475	38,546	<b>376,742</b>
Operating income (Note 15).....	<b>12,697</b>	11,790	16,518	<b>105,631</b>
Other income (expenses):				
Interest and dividend income.....	<b>268</b>	304	579	<b>2,230</b>
Interest expense.....	<b>(480)</b>	(465)	(430)	<b>(3,995)</b>
Loss on valuation of securities.....	<b>(602)</b>	(179)	—	<b>(5,007)</b>
Impairment losses on golf membership rights.....	<b>(101)</b>	(45)	(446)	<b>(837)</b>
Special premium payment on the separation from the composite pension fund.....	<b>(2,203)</b>	—	—	<b>(18,326)</b>
Expenses for the withdrawal of OTC products .....	—	—	(907)	—
Gain on settlement of Princeton Notes lawsuit.....	—	886	—	—
Other, net.....	<b>368</b>	388	207	<b>3,060</b>
Income before income taxes.....	<b>9,947</b>	12,679	15,521	<b>82,756</b>
Income taxes (Note 13):				
Current.....	<b>463</b>	6,932	8,973	<b>3,853</b>
Deferred .....	<b>981</b>	441	(1,166)	<b>8,164</b>
	<b>1,444</b>	7,373	7,807	<b>12,017</b>
Net income .....	<b>¥ 8,503</b>	¥ 5,306	¥ 7,714	<b>\$ 70,739</b>

## Per share data:

	Yen			U.S. dollars (Note 3)
	2003	2002	2001	2003
Net income.....	<b>¥ 93.67</b>	¥ 57.34	¥ 81.32	<b>\$ 0.78</b>
Net income-diluted.....	<b>85.97</b>	53.07	75.01	<b>0.72</b>
Cash dividends applicable to period.....	<b>20.00</b>	20.00	20.00	<b>0.17</b>

See accompanying notes to consolidated financial statements.



# Consolidated Statements of Shareholders' Equity

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
For the years ended March 31, 2003, 2002 and 2001

	Millions of yen			Thousands of U.S. dollars (Note 3)
	2003	2002	2001	2003
<b>Common stock</b> (Notes 10 and 11):				
Balance at beginning of year.....	¥ 6,214	¥ 6,206	¥ 6,180	\$ 51,698
Exercise of stock options .....	—	8	26	—
Balance at end of year.....	¥ 6,214	¥ 6,214	¥ 6,206	\$ 51,698
<b>Additional paid-in capital</b> (Notes 10 and 11):				
Balance at beginning of year.....	¥ 6,909	¥ 6,900	¥ 6,875	\$ 57,477
Exercise of stock options .....	—	9	25	—
Balance at end of year.....	¥ 6,909	¥ 6,909	¥ 6,900	\$ 57,477
<b>Retained earnings</b> (Note 10):				
Balance at beginning of year.....	¥83,893	¥83,735	¥82,664	\$697,941
Net income.....	8,503	5,306	7,714	70,739
Cash dividends paid .....	(1,814)	(1,854)	(1,521)	(15,090)
Bonuses to directors and corporate auditors.....	(30)	(36)	(37)	(248)
Retirement of treasury stock .....	—	(3,258)	(5,085)	—
Balance at end of year.....	¥90,552	¥83,893	¥83,735	\$753,342
<b>Unrealized holding gains on securities</b> (Note 4):				
Balance at beginning of year.....	¥ 474	¥ 1,290	¥ —	\$ 3,946
Net change.....	(180)	(816)	1,290	(1,502)
Balance at end of year.....	¥ 294	¥ 474	¥ 1,290	\$ 2,444
<b>Foreign currency translation adjustments:</b>				
Balance at beginning of year.....	¥ (2,383)	¥ (3,256)	¥ —	\$ (19,824)
Net change.....	(1,183)	873	(3,256)	(9,843)
Balance at end of year.....	¥ (3,566)	¥ (2,383)	¥ (3,256)	\$ (29,667)
<b>Treasury stock at cost</b> (Note 10):				
Balance at beginning of year.....	¥ (6)	¥ (41)	¥ (50)	\$ (50)
Repurchase of treasury stock, net.....	(3,271)	(3,223)	(5,076)	(27,208)
Retirement of treasury stock .....	—	3,258	5,085	—
Balance at end of year.....	¥ (3,277)	¥ (6)	¥ (41)	\$ (27,258)

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Cash Flows

Santen Pharmaceutical Co., Ltd. and Subsidiaries  
For the years ended March 31, 2003, 2002 and 2001

	Millions of yen			Thousands of U.S. dollars (Note 3)
	2003	2002	2001	2003
<b>Cash flows from operating activities:</b>				
Income before income taxes.....	¥ 9,947	¥12,679	¥15,521	\$ 82,756
Depreciation and amortization .....	4,311	5,334	5,683	35,867
Increase (decrease) in retirement and severance benefits .....	133	98	(330)	1,105
Interest and dividend income.....	(268)	(304)	(579)	(2,230)
Interest expense.....	480	465	430	3,995
Write down of investment securities.....	602	179	—	5,007
Impairment losses on golf membership rights.....	101	45	446	837
Decrease (increase) in trade receivables.....	6,966	1,804	(8,372)	57,950
Decrease (increase) in inventories.....	647	(184)	(765)	5,383
Increase (decrease) in trade accounts payable.....	660	(2,138)	1,813	5,492
Other, net.....	(1,456)	(2,733)	1,081	(12,112)
Subtotal.....	22,123	15,245	14,928	184,050
Interest and dividend income received .....	140	227	529	1,164
Interest expense paid.....	(458)	(465)	(406)	(3,812)
Income taxes paid .....	(5,997)	(8,066)	(8,219)	(49,889)
Net cash provided by operating activities.....	15,808	6,941	6,832	131,513
<b>Cash flows from investing activities:</b>				
Capital expenditures .....	(7,046)	(6,586)	(4,943)	(58,616)
Purchase of investment securities.....	(3,704)	(267)	(708)	(30,810)
Proceeds from sale of investment securities .....	473	857	1,976	3,931
Purchase of short-term investments.....	(5,252)	(2,841)	(3,421)	(43,698)
Proceeds from sale of short-term investments .....	4,854	1,898	3,867	40,381
Investment in a subsidiary .....	—	(537)	—	—
Proceeds from collection of loans receivable .....	12	1,012	159	98
Other, net.....	712	90	(102)	5,923
Net cash used in investing activities .....	(9,951)	(6,374)	(3,172)	(82,791)
<b>Cash flows from financing activities:</b>				
Repayment of long-term debt.....	(1,421)	(624)	(654)	(11,821)
Repurchase of treasury stock, net.....	(3,274)	(3,223)	(5,076)	(27,236)
Dividends paid.....	(1,812)	(1,854)	(1,520)	(15,080)
Other, net.....	—	17	57	—
Net cash used in financing activities .....	(6,507)	(5,684)	(7,193)	(54,137)
<b>Effect of exchange rate changes on cash and cash equivalents .....</b>				
	84	177	360	705
<b>Net decrease in cash and cash equivalents .....</b>	<b>(566)</b>	<b>(4,940)</b>	<b>(3,173)</b>	<b>(4,710)</b>
<b>Cash and cash equivalents at beginning of year ...</b>	<b>25,620</b>	<b>30,555</b>	<b>33,728</b>	<b>213,141</b>
<b>Cash and cash equivalents of a newly consolidated subsidiary .....</b>	<b>—</b>	<b>5</b>	<b>—</b>	<b>—</b>
<b>Cash and cash equivalents at end of year .....</b>	<b>¥25,054</b>	<b>¥25,620</b>	<b>¥30,555</b>	<b>\$208,431</b>

See accompanying notes to consolidated financial statements.

# Notes to Consolidated Financial Statements

Santen Pharmaceutical Co., Ltd. and Subsidiaries

## 1. Basis of Presentation of Consolidated Financial Statements

---

The accompanying consolidated financial statements have been prepared from the consolidated financial statements issued for domestic reporting purposes in Japan. Santen Pharmaceutical Co., Ltd. (the "Company") and all domestic subsidiaries maintain their accounts and records in accordance with the provisions set forth in the Japanese Commercial Code (the "Code") and in conformity with accounting principles and practices generally accepted in Japan, which may differ in some material respects from accounting principles and practices generally accepted in countries and jurisdictions other than Japan, and the accounts and records of its overseas subsidiaries in conformity with those of the countries of their domicile.

In preparing these consolidated financial statements, however, certain reclassifications have been made to the consolidated financial statements, which were originally issued and filed with the Director of the Kanto Local Finance Bureau for domestic reporting purposes in Japan, in order to present them in a form which is more familiar to readers outside Japan. In addition, the notes to the consolidated financial statements include additional information, which is not required under accounting principles and practices generally accepted in Japan but is presented herein as additional information.

### Change in accounting policy

In 2001, the Company and its subsidiaries (the "Companies") changed the presentation of royalty income, which had been

classified as other income, to include it in sales since royalty income is earned from the main operating activities of the Companies and the amount became significant. This change in accounting method resulted in operating income being ¥208 million higher for the year ended March 31, 2001 than would have been if the prior method had been used.

The Companies have accounted for a provision for sales returns, which has been included in accrued expenses in the consolidated balance sheets, for loss on returned goods based on the net trade receivables at the end of fiscal year. The Companies also changed the method of accounting for provision for sales returns from the method which was in accordance with corporate tax laws to the estimated loss on returned goods, in order to reflect the actual status more accurately.

This change in accounting method resulted in operating income being ¥31 million less for the year ended March 31, 2001 than would have been if the prior method had been used.

## 2. Summary of Significant Accounting Policies

---

### i) Principles of consolidation

The accompanying consolidated financial statements include the accounts of the Companies. All significant intercompany balances and transactions are eliminated on consolidation.

Investments in affiliated companies are stated at cost, because the Companies' equity in earnings of these companies is not significant.

### ii) Use of estimates

The preparation of the consolidated financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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

The Company and all domestic subsidiaries have adopted the new Financial Accounting Standard on Accounting for Financial Instruments, which was issued by the Financial Accounting Deliberation Council. In accordance with this standard, securities are

classified into three categories; trading, held-to-maturity, or other securities.

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

Those classified as other securities with a market value would be reported at fair value with unrealized gains, net of related taxes reported in equity. Other securities with no market value are carried at cost. The cost is determined by the moving average 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 sheet, when the market value has permanently declined.

**iv) Derivative instruments (see Note 5)**

Derivative instruments are stated at fair value, and accounted for using deferral hedge accounting. Deferral hedge accounting requires unrealized gains or losses to be deferred as liabilities or assets. Foreign exchange contracts that meet the criteria are accounted for under the allocation method. The allocation method requires recognized foreign currency receivables or payables to be translated using the corresponding foreign exchange contract rates. Interest rate swaps that meet the criteria are accounted for under the special method, as regulated in the accounting standard, as if the interest rates under interest rate swaps were originally applied to underlying borrowings. The Company has also developed a hedging policy to control various aspects of derivative instruments including authorization levels and transaction volumes. Based on this policy, the Company hedges the exposure risk arising from fluctuations in foreign currency exchange rates, interest rates, and price 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.

**v) Allowance for doubtful receivables**

Allowance for doubtful receivables is provided principally at an amount computed based on the actual ratio of bad debts in the past and the estimated uncollectible amounts based on the individual analysis of certain receivables.

**vi) Inventories (see Note 6)**

Inventories are stated at cost, determined principally by the average method.

**vii) Property, plant and equipment**

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

The principal estimated useful lives are as follows:

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

**viii) Goodwill**

Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is amortized on a straight-line basis over a period of ten years.

**ix) Leases (see Note 7)**

In Japan, finance leases other than those that are deemed to transfer the ownership of the leased assets to lessees are accounted for by a method similar to that applicable to ordinary operating leases.

**x) Retirement and severance benefits (see Note 9)**

Employees of the Company and all domestic subsidiaries are generally entitled to lump-sum severance and, in certain cases, annuity payments on retirement, based on current rates of pay, length of service and certain other factors. A portion of the prescribed benefit plan is covered by funded defined benefit pension plans.

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

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

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

**xi) 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 all domestic subsidiaries have adopted the revised Accounting Standard for Foreign Currency Transactions which was issued by the Financial Accounting Deliberation Council, and requires all monetary assets and liabilities denominated in foreign currencies to be translated at the rate of exchange prevailing on the balance sheet date, except for those items covered by forward exchange contracts.

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

**xii) Research and development and computer software**  
(see Note 12)

Research and development expenditures are charged to income when incurred.

Expenditures relating to computer software developed for internal use are charged to income when incurred except if they contribute to the generation of income or to future cost savings. Such expenditures are capitalized as an asset and are amortized using the straight-line method over their estimated useful life, five years.

**xiii) Net income and dividends per share (see Note 10)**

The computation of basic net income per share is based on the weighted average number of shares of common stock outstanding during each period. The average number of shares used in the computation is 90,452 thousand, 92,536 thousand and 94,855 thousand for the years ended March 31, 2003, 2002 and 2001, respectively.

The diluted net income per share assumes full conversion of outstanding convertible bonds at the beginning of the year (or at the time of issuance, if after the beginning of the year), and full exercise of outstanding warrants at the end of the year. The average number of shares used in the computation is 99,635 thousand, 101,731 thousand and 104,063 thousand for the years ended March 31, 2003, 2002 and 2001, respectively.

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

**xiv) Income taxes (see Note 13)**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss 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 of a change in tax rates is recognized in income in the period that includes the enactment date.

**xv) Cash and cash equivalents**

Cash and cash equivalents mainly include cash in 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 because of changes in interest rates.

### 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 ¥120.20=US\$1, the approximate exchange rate prevailing on March

31, 2003. The translation should not be construed as a representation that the Japanese yen have been, could have been, or could in the future be converted into United States dollars at that rate or any other rate.

### 4. Short-term Investments and Investment Securities

The following is a summary of held-to-maturity debt securities and other securities at March 31, 2003 and 2002:

	Millions of yen							
	2003				2002			
	Held-to-maturity debt securities				Held-to-maturity debt securities			
Book value (Carrying amount)	Gross unrealized gains	Gross unrealized losses	Estimated fair value	Book value (Carrying amount)	Gross unrealized gains	Gross unrealized losses	Estimated fair value	
Bonds and debentures.....	¥3,737	¥0	¥(16)	¥3,721	¥3,766	¥7	¥(36)	¥3,737
	Other securities				Other securities			
	Cost	Gross unrealized gains	Gross unrealized losses	Book value (Estimated fair value)	Cost	Gross unrealized gains	Gross unrealized losses	Book value (Estimated fair value)
Equity securities .....	¥4,913	¥998	¥(420)	¥5,491	¥4,536	¥1,286	¥(377)	¥5,445
Other securities.....	943	4	(75)	872	1,106	3	(94)	1,015
	¥5,856	¥1,002	¥(495)	¥6,363	¥5,642	¥1,289	¥(471)	¥6,460

Thousands of U.S. dollars				
<b>2003</b>				
Held-to-maturity debt securities				
	Book value (Carrying amount)	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Bonds and debentures.....	<b>\$31,086</b>	<b>\$ 1</b>	<b>\$(132)</b>	<b>\$30,955</b>
Other securities				
	Cost	Gross unrealized gains	Gross unrealized losses	Book value (Estimated fair value)
Equity securities .....	<b>\$40,876</b>	<b>\$8,301</b>	<b>\$(3,495)</b>	<b>\$45,682</b>
Other securities.....	<b>7,841</b>	<b>30</b>	<b>(623)</b>	<b>7,248</b>
	<b>\$48,717</b>	<b>\$8,331</b>	<b>\$(4,118)</b>	<b>\$52,930</b>

Maturities of investments at March 31, 2003 and 2002 are as follows:

	Millions of yen				Thousands of U.S. dollars	
	<b>2003</b>		2002		<b>2003</b>	
	Bonds and debentures	Other securities	Bonds and debentures	Other securities	Bonds and debentures	Other securities
Due within one year .....	<b>¥6,705</b>	<b>¥ —</b>	¥3,066	¥ —	<b>\$55,782</b>	<b>\$ —</b>
Due after one year through five years.....	<b>1,542</b>	<b>270</b>	2,710	426	<b>12,825</b>	<b>2,248</b>
Due after five years through ten years.....	<b>—</b>	<b>393</b>	—	397	<b>—</b>	<b>3,270</b>
	<b>¥8,247</b>	<b>¥663</b>	¥5,776	¥823	<b>\$68,607</b>	<b>\$5,518</b>

## 5. Derivative Instruments

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

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

The interest rate swap contracts outstanding at March 31, 2003 and 2002 are as follows:

	Currency	Millions of yen					
		<b>2003</b>			2002		
		Notional amounts	Market value	Unrealized gain (loss)	Notional amounts	Market value	Unrealized gain (loss)
Variable-rate into fixed-rate obligations.....	Yen	<b>¥1,000</b>	<b>¥(23)</b>	<b>¥(23)</b>	¥1,000	¥(44)	¥(44)

	Currency	Thousands of U.S. dollars		
		<b>2003</b>		
		Notional amounts	Market value	Unrealized gain (loss)
Variable-rate into fixed-rate obligations.....	Yen	<b>\$8,319</b>	<b>\$(188)</b>	<b>\$(188)</b>

## 6. Inventories

Inventories at March 31, 2003 and 2002 consist of the following:

	Millions of yen		Thousands of U.S. dollars
	2003	2002	2003
Merchandise.....	¥ 2,117	¥ 2,142	\$17,613
Finished goods.....	6,877	7,124	57,212
Work in process and semi-finished goods.....	662	930	5,504
Raw materials and supplies.....	2,028	2,175	16,876
	<b>¥11,684</b>	<b>¥12,371</b>	<b>\$97,205</b>

## 7. Leases

Finance leases, except for those in which ownership is deemed to be transferred to the lessee, are accounted for as operating leases.

### Finance leases:

Equivalent purchase amount, accumulated depreciation and future minimum lease payments on an "as if capitalized" basis at March 31, 2003 and 2002 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2003	2002	2003
Machinery and equipment:			
Equivalent purchase amount.....	¥11,005	¥ 9,536	\$91,553
Equivalent accumulated depreciation amount.....	9,372	9,082	77,966
Equivalent balance at year-end.....	1,633	454	13,587
Tools:			
Equivalent purchase amount.....	484	299	4,024
Equivalent accumulated depreciation amount.....	152	94	1,266
Equivalent balance at year-end.....	332	205	2,758
Total:			
Equivalent purchase amount.....	11,489	9,835	95,577
Equivalent accumulated depreciation amount.....	9,524	9,176	79,232
Equivalent balance at year-end.....	¥ 1,965	¥ 659	\$16,345
Future minimum lease payments:			
Due within one year.....	¥ 426	¥ 557	\$ 3,548
Due after one year.....	1,592	222	13,241
	<b>¥ 2,018</b>	<b>¥ 779</b>	<b>\$16,789</b>

Lease payments, equivalent depreciation and equivalent interest expense for the years ended March 31, 2003 and 2002 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2003	2002	2003
Lease payments.....	¥ 638	¥ 1,880	\$ 5,309
Equivalent depreciation.....	¥ 486	¥ 1,692	\$ 4,044
Equivalent interest expense.....	¥ 18	¥ 46	\$ 147

### Operating leases:

Future minimum rents under non-cancellable operating leases at March 31, 2003 and 2002 consist of the following:

	Millions of yen		Thousands of U.S. dollars
	2003	2002	2003
Due within one year.....	¥ 189	¥ 187	\$ 1,576
Due after one year.....	300	379	2,492
	<b>¥ 489</b>	<b>¥ 566</b>	<b>\$ 4,068</b>

## 8. Long-term Debt

Long-term debt at March 31, 2003 and 2002 consists of the following:

	Millions of yen		Thousands of U.S. dollars
	2003	2002	2003
Unsecured yen loans from domestic banks, due in installments through 2011, interest 1.78% to 4.75% .....	¥ 2,718	¥ 3,086	\$ 22,612
Unsecured loans from governmental institutions, due in installments through 2010, interest 0.00% to 0.25% .....	384	436	3,195
Unsecured yen loans from an insurance company, due in installments through 2002, interest 3.45% .....	—	1,000	—
Unsecured convertible bonds, due in installments through 2003, interest 0.8% .....	19,945	19,945	165,932
Total .....	23,047	24,467	191,739
Less: Current portion shown in current liabilities .....	(20,361)	(1,418)	(169,393)
	¥ 2,686	¥23,049	\$ 22,346

The 0.8 per cent convertible bonds maturing in 2003 are convertible into approximately 9,184 thousand shares of common stock at ¥2,171.80 per share on March 31, 2003 at the option of the holders. The conversion price of bonds is subject to adjustment for certain subsequent events such as the issue of common stock at less than par value and stock splits.

As is customary in Japan, long-term bank loans are made under

general agreements which provide that additional security and guarantees for present and future indebtedness will be given upon request of the bank under certain circumstances, and that the bank shall have the right, as the obligations become due, or in the event of their default, to offset cash deposits against such obligations due to the bank. To date, the Company has not received such a request from its banks.

The aggregate annual maturities of long-term debt at March 31, 2003 are as follows:

Years ending March 31	Millions of yen	Thousands of U.S. dollars
2004 .....	¥20,361	\$169,393
2005 .....	416	3,461
2006 .....	416	3,461
2007 .....	416	3,461
2008 .....	416	3,461
2009 and thereafter .....	1,022	8,502
Total .....	¥23,047	\$191,739

## 9. Retirement and Severance Benefits

The following tables set forth the details of benefit obligation, plan assets and funded status of the Companies at March 31, 2003 and 2002.

	Millions of yen		Thousands of U.S. dollars
	2003	2002	2003
For employees:			
Benefit obligation at end of year .....	¥(12,003)	¥(10,046)	\$(99,860)
Fair value of plan assets at end of year .....	4,591	4,534	38,193
Funded status (benefit obligation in excess of plan assets) .....	(7,412)	(5,512)	(61,667)
Unrecognized actuarial loss .....	2,124	355	17,672
For directors and corporate auditors:			
Accrued retirement benefit .....	(466)	(445)	(3,877)
Retirement and severance benefits recognized in the consolidated balance sheets .....	¥ (5,754)	¥ (5,602)	\$(47,872)

Note: All domestic subsidiaries have adopted the permitted alternative treatment, accrual for 100% of the amount required if all employees were to voluntarily terminate their employment as of the balance sheet date, prescribed by the accounting standard for retirement benefits for small business entities.



Retirement and severance costs of the Companies include the following components for the year ended March 31, 2003 and 2002.

	Millions of yen		Thousands of U.S. dollars
	2003	2002	2003
For employees:			
Service cost .....	¥ 796	¥ 706	\$ 6,618
Interest cost .....	259	288	2,157
Expected return on plan assets .....	(142)	(132)	(1,185)
Recognized actuarial loss .....	170	58	1,417
Expense for multi-employer pension plan .....	198	346	1,648
Net periodic benefit cost .....	¥1,281	¥1,266	\$10,655
For directors and corporate auditors:			
Accrual for retirement benefit .....	¥ 21	¥ 228	\$ 175

Assumptions used in the accounting for retirement and severance benefits for the year ended March 31, 2003 and 2002 are as follows:

	2003	2002
Method of attributing benefit to period of service .....	<b>Straight-line basis</b>	Straight-line basis
Discount rate .....	<b>2.00%</b>	3.00%
Expected return on plan assets .....	<b>3.00%</b>	3.00%
Amortization period for actuarial losses* .....	<b>14 years</b>	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.

## 10. Shareholders' Equity

Under the Code, at least 50% of the issue price of new shares is required to be designated as stated capital. The portion which is to be designated as stated capital is determined by resolution of the Board of Directors. Proceeds in excess of the amounts designated as stated capital have been credited to additional paid-in capital.

The Code provided that an amount equal to at least 10% of cash payments for appropriation of retained earnings with respect to each fiscal period be appropriated to a legal reserve until such reserve equals to 25% of the stated capital. The Code, amended effective on October 1, 2001, provides that an amount equal to at least 10% of cash payments for appropriation of retained earnings with respect to each fiscal period be appropriated to a legal reserve until the aggregated amount of additional paid-in capital and the legal reserve equals 25% of the stated capital. Additional paid-in capital and the legal reserve may be used to reduce a deficit by resolution of the shareholders' meeting or may be capitalized by resolution of the Board of Directors. The portion in excess of 25% of the stated capital may be used for dividend distribution. The legal reserve, which is included in retained earnings, amounted to ¥1,551 million (\$12,907 thousand) and ¥1,551 million as of March 31, 2003 and 2002, respectively.

Cash dividends charged to retained earnings during the years ended March 31, 2003, 2002 and 2001 represent dividends paid out during the years. The accompanying consolidated financial

statements do not include any provision for the semi-annual dividend of ¥10 (\$0.08) per share, aggregating ¥879 million (\$7,316 thousand) which was approved at the Company's shareholders' meeting on June 26, 2003 in respect of the year ended March 31, 2003.

Under the Code, the amount available for dividends is based on retained earnings, net of treasury stock, as recorded on the Company's book. At March 31, 2003, retained earnings, net of treasury stock, recorded on the Company's book were ¥85,315 million (\$709,779 thousand). Such retained earnings included ¥84,109 million (\$699,742 thousand) which are designated as general reserves, but are available for distribution as future dividends subject to approval of the shareholders' meeting and legal reserve requirements. Unrealized holding gains on securities, net of related taxes is not available for distribution as dividends and bonuses to directors and corporate auditors.

During the years ended March 31, 2003 and 2002, the Company repurchased 2,768,713 shares and 2,027,546 shares with aggregate value of ¥3,271 million (\$27,208 thousand) and ¥3,258 million, respectively.

On June 26, 2003, the Company's shareholders' meeting approved that the Company would be able to repurchase common shares, limited in aggregate to 4,000,000 shares and ¥5,000 million in value, in accordance with the provisions of Article 210 of the Code.

## 11. 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 grants are fully exercisable after two years and span ten years.

Information concerning option activities and balances is as follows:

	Number of shares	Weighted average exercise price	
		Yen	U.S. dollars
Balance at March 31, 1998 .....	—	—	
Granted .....	106,000	1,540	
Balance at March 31, 1999 .....	106,000	1,540	
Granted .....	66,000	2,480	
Balance at March 31, 2000 .....	172,000	1,901	
Granted .....	60,000	2,705	
Exercised .....	33,000	1,540	
Balance at March 31, 2001 .....	199,000	2,203	
Granted .....	55,000	2,299	
Exercised .....	11,000	1,540	
Balance at March 31, 2002 .....	243,000	2,255	18.76
Granted .....	<b>92,000</b>	<b>1,326</b>	<b>11.03</b>
Balance at March 31, 2003 .....	<b>335,000</b>	<b>2,000</b>	<b>16.64</b>

On June 26, 2003, the Company's shareholders' meeting approved that the Company's stock acquisition rights as stock options would be allotted to directors and corporate officers of the Company and directors of major overseas subsidiaries. These stock

option rights are exercisable from June 27, 2005 to June 25, 2013. The total number of stock acquisition rights is limited in aggregate to 145,200 common shares.

## 12. Research and Development Expenditures

Research and development expenditures charged to income for the years ended March 31, 2003, 2002 and 2001 amounted to

¥12,719 million (\$105,819 thousand), ¥12,187 and ¥10,511 million, respectively.

## 13. Income Taxes

The Company and its domestic subsidiaries are subject to a number of taxes based on earnings which, in the aggregate, resulted in an average normal tax rate of approximately 42.0 % for

the years ended March 31, 2003, 2002 and 2001. Overseas subsidiaries are subject to income taxes of the countries in which they operate.

The effective rates for the years ended March 31, 2003, 2002 and 2001 differ from the normal tax rates for the following reasons:

	2003	2002	2001
Normal tax rate.....	<b>42.0 %</b>	42.0 %	42.0 %
Change in valuation allowance allocated to income tax expenses .....	<b>12.2</b>	14.0	3.0
Lower tax rates of subsidiaries.....	<b>4.6</b>	4.2	—
Expenses not deductible for tax purposes .....	<b>3.2</b>	3.0	2.3
Unrecognized deferred tax of an overseas subsidiary.....	—	—	4.8
Tax credit for research and development expenses.....	—	(4.6)	—
Loss on the liquidation of affiliates .....	<b>(49.3)</b>	—	—
Others .....	<b>1.8</b>	(0.4)	(1.8)
Effective tax rate .....	<b>14.5 %</b>	58.2 %	50.3 %

The tax effects of temporary differences and tax loss carryforwards that give rise to significant portions of the deferred tax assets and deferred tax liabilities at March 31, 2003 and 2002 are presented below:

	Millions of yen		Thousands of U.S. dollars
	2003	2002	2003
Deferred tax assets:			
Tax loss carryforwards.....	¥5,095	¥ 3,295	\$ 42,387
Retirement and severance benefits.....	1,847	1,733	15,364
Accrued expenses .....	953	922	7,929
Deferred assets for tax purposes .....	351	494	2,921
Unrealized profits of other intangibles.....	321	321	2,668
Impairment losses on golf membership rights.....	229	206	1,910
Accrued enterprise tax .....	—	336	—
Other .....	669	1,563	5,566
Total gross deferred tax assets.....	9,465	8,870	78,745
Less valuation allowance .....	(5,296)	(4,009)	(44,059)
Net deferred tax assets .....	4,169	4,861	34,686
Deferred tax liabilities:			
Reserve for special depreciation .....	(226)	(131)	(1,877)
Net unrealized holding gains on securities.....	(213)	(344)	(1,770)
Refundable enterprise tax .....	(197)	—	(1,641)
Other .....	(32)	(34)	(270)
Total gross deferred tax liabilities.....	(668)	(509)	(5,558)
Net deferred tax assets .....	¥3,501	¥ 4,352	\$ 29,128

Net deferred tax assets at March 31, 2003 and 2002 are reflected in the accompanying consolidated balance sheets under the following captions:

	Millions of yen		Thousands of U.S. dollars
	2003	2002	2003
Current assets — deferred tax assets.....	¥1,202	¥1,871	\$ 9,999
Investments and other assets — deferred tax assets.....	2,331	2,515	19,396
Non current liabilities — deferred tax liabilities .....	(32)	(34)	(267)
Net deferred tax assets .....	¥3,501	¥4,352	\$29,128

Income taxes have not been accrued on undistributed earnings of domestic subsidiaries as distributions of such income are not taxable under present circumstances.

The Company has not recognized deferred tax liabilities for the portion of undistributed earnings of overseas subsidiaries because the Company currently does not expect those unremitted earnings to reverse and become taxable to the Company in the foreseeable future, except for the amount that will be probably distributed. Deferred tax liabilities will be recognized when the Company expects that it will recover those undistributed earnings in a taxable manner, such as through receipt of dividends or sale of the investments.

#### 14. Contingent Liabilities

At March 31, 2003, the Company has provided guarantees to financial institutions covering employee loans totaling ¥819 million (\$6,814 thousand).

#### 15. Segment Information

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

Intercompany sales between geographic areas are recorded at cost plus a mark up and intercompany sales and profits are

eliminated on consolidation. Corporate assets are composed mainly of cash and cash equivalents, short-term investments and investment securities.

Information by geographic area and overseas sales are as follows:

	Millions of yen			Thousands of U.S. dollars
	2003	2002	2001	2003
<b>Geographic areas:</b>				
Net sales:				
Japan:				
External customers .....	¥ 81,858	¥ 82,624	¥ 84,138	\$ 681,012
Intersegment.....	660	519	295	5,489
Total.....	82,518	83,143	84,433	686,501
Europe:				
External customers .....	6,643	4,845	3,017	55,265
Intersegment.....	983	1,098	863	8,180
Total.....	7,626	5,943	3,880	63,445
Other:				
External customers .....	1,752	1,498	1,294	14,579
Intersegment.....	7,648	7,414	4,600	63,625
Total.....	9,400	8,912	5,894	78,204
Corporate and eliminations.....	(9,291)	(9,032)	(5,758)	(77,295)
Consolidated.....	¥ 90,253	¥ 88,966	¥ 88,449	\$ 750,855
Operating income (loss):				
Japan.....	¥ 20,652	¥ 18,879	¥ 24,461	\$ 171,814
Europe .....	(3,816)	(3,384)	(2,307)	(31,749)
Other.....	(1,083)	(474)	45	(9,009)
Corporate and eliminations.....	(3,056)	(3,231)	(5,681)	(25,425)
Consolidated.....	¥ 12,697	¥ 11,790	¥ 16,518	\$ 105,631
Assets:				
Japan.....	¥129,750	¥117,864	¥ 94,170	\$1,079,450
Europe .....	9,865	21,397	19,447	82,068
Other.....	7,030	7,936	3,676	58,489
Corporate and eliminations.....	503	4,906	35,950	4,184
Consolidated.....	¥147,148	¥152,103	¥153,243	\$1,224,191
Note: The main countries included in Europe and Other are as follows: Europe: Finland, Sweden, Germany and the Netherlands Other: United States of America, Taiwan and Korea				
<b>Overseas sales:</b>				
Europe .....	¥ 3,506	¥ 3,009	¥ 2,252	\$ 29,165
North America .....	4,650	3,500	2,206	38,685
Other.....	2,364	1,809	1,238	19,668
Total.....	¥ 10,520	¥ 8,318	¥ 5,696	\$ 87,518
Consolidated net sales .....	¥ 90,253	¥ 88,966	¥ 88,449	\$ 750,855
Percentage of overseas sales to consolidated net sales .....	11.7%	9.3%	6.4%	11.7%

Notes: 1. Overseas sales represent the total amount of export sales of the Company and domestic subsidiaries and sales of overseas subsidiaries (intercompany sales between consolidated subsidiaries are eliminated upon consolidation).

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

Europe: Finland, Sweden, Norway, Denmark and Russia  
North America: United States of America and Canada  
Other: Korea, China and Taiwan

# Independent Auditors' Report



The Board of Directors and Shareholders  
Santen Pharmaceutical Co., Ltd.

We have audited the accompanying consolidated balance sheets of Santen Pharmaceutical Co., Ltd. and subsidiaries as of March 31, 2003 and 2002, and the related consolidated statements of income, shareholders' equity and cash flows for the years then ended, all expressed in yen. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to independently express an opinion on these consolidated financial statements based on our audits. The consolidated statements of income, shareholders' equity and cash flows of Santen Pharmaceutical Co., Ltd. and subsidiaries for the year ended March 31, 2001 were audited by other auditors whose report dated June 28, 2001 on those statements included an explanatory paragraph that described the change in the presentation of royalty income and the calculation method of provision for sales return in the year ended March 31, 2001, as described in Note 1 of the notes to the consolidated financial statements.

We conducted our audits in accordance with auditing standards, procedures and practices generally accepted and applied in Japan. Those standards, procedures and practices require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Santen Pharmaceutical Co., Ltd. and subsidiaries as of March 31, 2003 and 2002, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles and practices generally accepted in Japan.

The consolidated financial statements as of and for the year ended March 31, 2003 have been translated into United States dollars solely for the convenience of the reader. We have recomputed the translation and, in our opinion, the consolidated financial statements expressed in yen have been translated into United States dollars on the basis set forth in Note 3 of the notes to the consolidated financial statements.

A stylized, handwritten signature of the letters 'KPMG' in black ink.

Osaka, Japan  
June 26, 2003

*See Note 1 to the consolidated financial statements which explains the basis of preparation of the consolidated financial statements of Santen Pharmaceutical Co., Ltd. and subsidiaries under Japanese accounting principles and practices.*

# Major Subsidiaries and Facilities

As of March 31, 2003

## Subsidiaries

---

### **Santen Distribution Co., Ltd.**

1011-1, Oaza-godo, Omi-cho, Sakata-gun, Shiga 521-0072, Japan  
TEL: +81-749-52-4026 FAX: +81-749-52-6080  
Business: Storage and shipping of pharmaceuticals  
Equity Ownership: 100%

### **Claire Co., Ltd.**

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

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

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

### **Santen Inc.**

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

### **Phacor Inc.**

775 Fiero Lane, San Luis Obispo  
California 93401, U.S.A.  
TEL: +1-805-546-1818 FAX: +1-805-546-1826  
Business: Research and development of medical devices  
Equity Ownership: 100%\*

### **Advanced Vision Science, Inc.**

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

### **Santen Oy**

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

### **SantenPharma AB**

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

### **Santen GmbH**

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

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

5F-2, No. 139, Sung-chiang Rd., Taipei, Taiwan, R.O.C.  
TEL: +886-2-2506-1909 FAX: +886-2-2506-6740  
Business: Import and marketing of pharmaceuticals  
Equity Ownership: 100%

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

Room 1002, Center Building, 91-1, Sogong-dong, Chung-ku  
Seoul, Republic of Korea  
TEL: +82-2-754-1434 FAX: +82-2-754-2929  
Business: Import and marketing of pharmaceuticals  
Equity Ownership: 100%

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

## Offices, Laboratory and Plants

---

### **Corporate Headquarters**

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

### **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

### **Noto Plant**

2-14, Aza-shikinami, Shio-machi, Hakui-gun, Ishikawa 929-1494, Japan  
TEL: +81-767-29-2666 FAX: +81-767-29-4233

### **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

### **Osaka Plant**

9-19, Shimoshinjo 3-chome, Higashiyodogawa-ku  
Osaka 533-8651, Japan  
TEL: +81-6-6321-7070 FAX: +81-6-6321-3026

### **Beijing Representative Office**

Room 1015, Beijing Fortune Bldg., No. 5, Dongsanhuan Beilu  
Chaoyang District, Beijing City 100004, China  
TEL: +86-10-6590-8535  
FAX: +86-10-6590-8537

### **Guangzhou Representative Office**

2605 Peace World Plaza, 362-366, Huan-shi East Road  
Guangzhou 510060, China  
TEL: +86-20-8375-2212  
FAX: +86-20-8387-8799

# Corporate Information

As of March 31, 2003

**Corporate Headquarters** Santen Pharmaceutical Co., Ltd.  
9-19, Shimoshinjo 3-chome  
Higashiyodogawa-ku  
Osaka 533-8651, Japan  
URL: <http://www.santen.co.jp>  
**Investor relations contact:**  
TEL: +81-6-6321-7007  
FAX: +81-6-6321-8400  
E-mail: [ir@santen.co.jp](mailto:ir@santen.co.jp)

**Established** 1890

**Paid-in Capital** ¥6,214 million

**Number of Shareholders** 7,873

**Stock Exchange Listings** Tokyo and Osaka

**Ticker Code** 4536

**Transfer Agent** UFJ Trust Bank Limited  
6-3, Fushimicho 3-chome, Chuo-ku  
Osaka 541-8502, Japan  
TEL: +81-6-6229-3011

**Major Offices** Sapporo, Sendai, Tokyo, Nagoya,  
Osaka, Hiroshima and Fukuoka

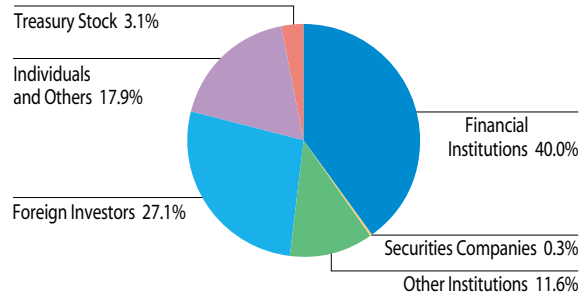
**Manufacturing Plants** Noto, Shiga and Osaka

**Research Laboratory** Nara Research and Development Center

**Number of Employees** 2,500 (non-consolidated: 1,740)

**Number of Shares Issued** 90,704,303

## Distribution of Shareholders by Number of Shares Held

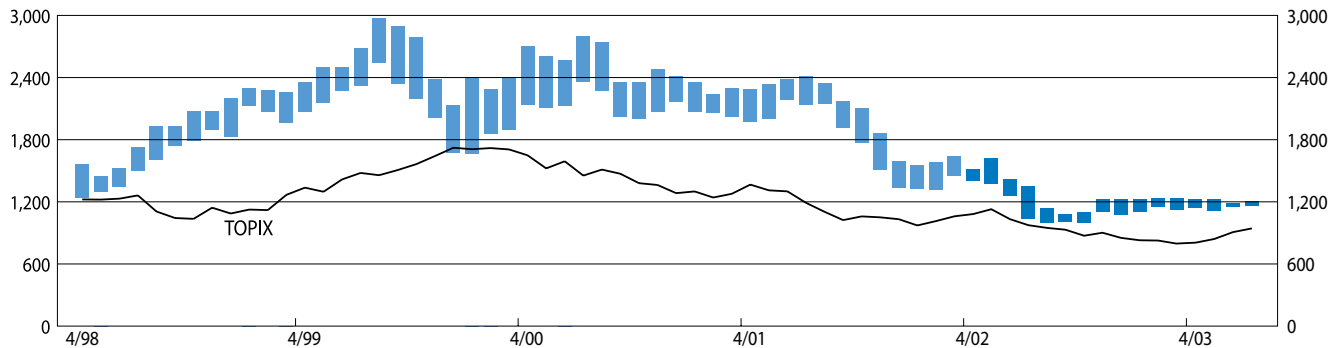


## Major Shareholders

Shareholders	Thousands of Shares	Percentage of Total Voting Rights
Northern Trust Company AVFC Sub-account American Clients	10,072	11.5%
Japan Trustee Services Bank, Ltd.	5,902	6.7
Mita Sangyo Co., Ltd.	4,756	5.4
The Master Trust Bank of Japan, Ltd.	4,483	5.1
Nippon Life Insurance Company	4,272	4.9
UFJ Bank Limited	3,221	3.7
UFJ Trust Bank Limited	3,117	3.6
The Bank of Tokyo-Mitsubishi, Ltd.	2,724	3.1
The Tokio Marine and Fire Insurance Co., Ltd.	2,668	3.0
Trust & Custody Services Bank, Ltd.	2,072	2.4

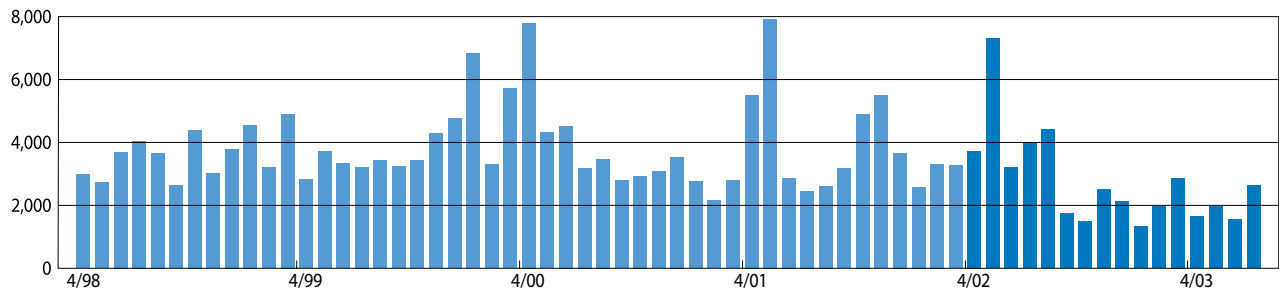
## Stock Price Range Osaka Securities Exchange (monthly basis)

(Yen)



## Trading Volume Osaka Securities Exchange (monthly basis)

(Thousands of shares)



## Yearly High and Low Prices

	1999	2000	2001	2002	2003
<b>High (yen)</b>	2,975	2,800	2,410	1,635	1,228
<b>Low (yen)</b>	1,675	1,659	1,330	990	1,099

\* Stock price data shows values after adjustment for share splits.

\* TOPIX: Tokyo stock price index

Note: Calendar years. Stock prices for 2003 are for the period to July 31.



**SANTEN PHARMACEUTICAL CO., LTD.**

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

**All trademarks appearing in italic typeface in this annual report are owned by or licensed to Santen Pharmaceutical Co., Ltd.**

**The following are registered trademarks of Santen Pharmaceutical Co., Ltd.:**

*Alamast, Ecolicin, Sante 40, Sante FX, Sante de u, Santemycin, Dimple, Thiola, Hyalein, Betimol and Rimatil.*

**The following are registered trademarks of Santen's alliance partners:**

*Cravit, Tarivid, Quixin and Oftaquix (Daiichi Pharmaceutical Co., Ltd.); Azulfidine (Pfizer Inc.); Alegysal (Mitsubishi Pharma Corporation); ClariFlex (Advanced Medical Optics Inc.); Zaditen (Novartis AG); Detantol (Eisai Co., Ltd.); Timoptol (Merck & Co., Inc.); and Livostin (Johnson and Johnson).*



Printed in Japan with soy ink on paper made with elemental chlorine-free (ECF) pulp.