

# Review of Operations

Year ended March 31, 2008

Consolidated Net Sales      ¥ **103,394** million    + **2.9%**

## SALES BY BUSINESS

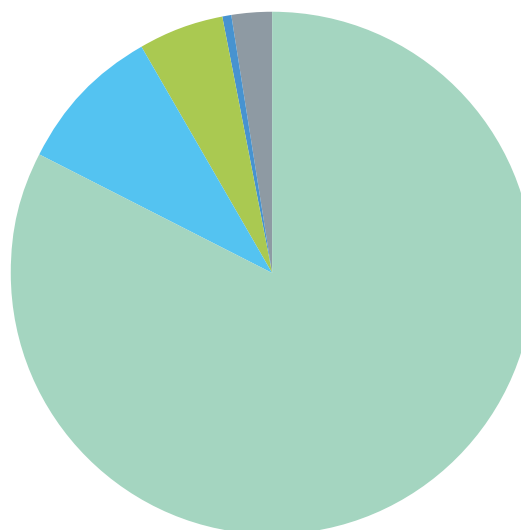
Prescription Ophthalmic Pharmaceuticals      **82.6%**

Prescription Anti-Rheumatic Pharmaceuticals      **9.3%**

Over-the-Counter Pharmaceuticals      **5.3%**

Medical Devices      **0.4%**

Others      **2.4%**



Note: All graphs in this section, Review of Operations, are based on fiscal years ended March 31.

Business Area	Description of Business	Market Share; Market Position
Prescription Pharmaceuticals	<b>Ophthalmic Pharmaceuticals</b> In Japan, Santen markets a broad range of ophthalmic pharmaceutical products, such as treatments for corneal and conjunctival epithelial disorders, anti-infective ophthalmics, treatments for glaucoma and anti-allergy ophthalmics. Overseas, Santen markets levofloxacin ophthalmic solution (brand names: <i>Quixin</i> , <i>Ofraqix</i> , <i>Cravit</i> and <i>Iquix</i> ) and other products through a sales network in the U.S., Europe and Asia.	38.9%; Number One <sup>1</sup> Santen enjoys its position as the leader of the Japanese prescription ophthalmics market. We deploy approximately 400 medical representatives (MRs) and our product lineup covers a broad array of ophthalmic disorders.
	<b>Anti-Rheumatic Pharmaceuticals</b> In Japan, we offer <i>Rimatil</i> and <i>Azulfidine EN</i> , physicians' disease modifying anti-rheumatic drugs (DMARDs) <sup>2</sup> of choice for treating rheumatoid arthritis.	46.1%; Number One <sup>1</sup>
<b>Over-the-Counter (OTC) Pharmaceuticals</b>	Our OTC pharmaceuticals business consists of market-leading eye drop brands in Japan, such as <i>Sante FX Neo</i> , the <i>Sante 40</i> series and the <i>Sante de U</i> series.	Approx. 20%; Number Two <sup>3</sup>
<b>Medical Devices</b>	In Japan, Santen handles medical devices used in cataract surgery, including intraocular lenses.	—

Notes: 1. Market share and market position in Japan for the year ended March 31, 2008. The share and position for anti-rheumatic pharmaceuticals represent those in the DMARDs segment.

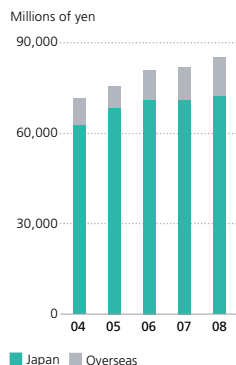
Source: Santen analysis based on IMS data. Copyright IMS Japan KK, 2008. All rights reserved.

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

3. Market share and market position in the Japanese OTC eye drop market for the year ended March 31, 2008. Source: Santen Pharmaceutical Co., Ltd.

## Prescription Pharmaceuticals Ophthalmic Pharmaceuticals

### Net Sales of Prescription Ophthalmic Pharmaceuticals



Santen's domestic sales of prescription ophthalmic pharmaceuticals rose 1.5%, to ¥72,320 million, and overseas sales increased 20.5% in yen terms, to ¥13,106 million. Combined, this represents a 4.0% rise, to ¥85,426 million, in net sales of prescription ophthalmic pharmaceuticals for the year ended March 31, 2008.

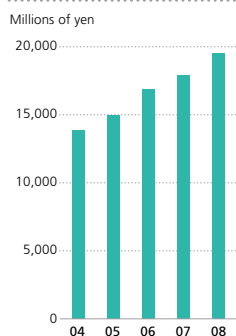
Net Sales      ¥ **85,426** million    + **4.0%**

### ● JAPAN



The Japanese prescription ophthalmic pharmaceuticals market benefited from the growth in sales of products for glaucoma and corneal and conjunctival epithelial disorders, rising 3.1% overall, to ¥221,000 million, in fiscal 2007. Santen's domestic prescription ophthalmic pharmaceuticals sales increased 1.5%, to ¥72,320 million, supported by promotional activities in which its medical representatives (MRs) provide individual medical facilities with scientific information tailored to their changing needs.

### Sales of Hyalein



### Treatments for Corneal and Conjunctival Epithelial Disorders

The market for preparations to treat corneal and conjunctival epithelial disorders associated with conditions such as dry eye, of which Santen products hold an 80% share, expanded 9.0% for fiscal 2007. Since dry eye—caused by inadequate tear fluid volume or a change in tear fluid composition—is a condition that can result in corneal damage, it is important that it is correctly diagnosed and treated through regular consultations with an ophthalmologist. This is not widely recognized, however, and many patients with obvious symptoms do not consult a doctor. In addition, the number of people suffering from dry eye is trending upward with increased use of personal computers (PCs) and contact lenses and the aging of population. As a result, the market for effective treatments for corneal and conjunctival epithelial disorders is expected to continue growing.

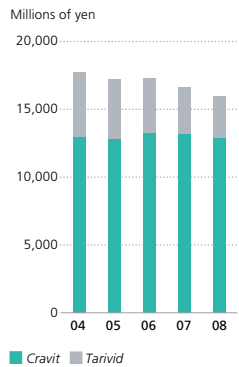
Santen's mainstay product, *Hyalein*, is a highly water-retentive ophthalmic solution that increases tear film stability and demonstrates superior efficacy in alleviating corneal and conjunctival epithelial disorders associated with conditions such as dry eye. As a result of an active disease awareness campaign of dry eye to patients and medical professionals, sales of *Hyalein*, renowned as the first choice of treatment for dry eye, grew steadily, increased 9.3% year on year, to ¥17,860 million.

We plan to continue promoting greater understanding of the diagnosis and treatment of dry eye to further raise awareness, so new patients will consult their physicians and existing patients will maintain an appropriate course of treatment. We believe this will contribute to growth in the market for dry eye medications and also strengthen our own position in the market. Furthermore, we are working on new preparations for the development pipeline to enhance our product lineup in this sector of the market.



Hyalein

### Sales of Cravit and Tarivid



### Anti-Infective Ophthalmics

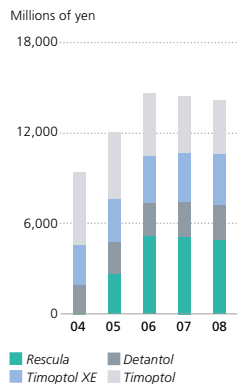
The anti-infective ophthalmic pharmaceuticals market is trending very slightly downwards. One likely reason for this is the shortening of the administration period for anti-infective ophthalmic products after cataract and other surgeries.

Santen dominates the anti-infective ophthalmic pharmaceuticals market with a share of approximately 75%, supported by its two key products, *Cravit* and *Tarivid*, which both display strong antibacterial properties, broad-spectrum coverage (effective against a wide range of infections) and excellent intraocular penetration and safety. Both are widely used for conjunctivitis, keratitis and preventing post-operative eye infection. As a result of increased competition, combined sales of *Cravit* and *Tarivid* declined 4.4% to ¥14,646 million in fiscal 2007.

We will continue to strongly promote *Cravit*, highlighting the scientific data supporting its superior clinical efficacy and safety. Combined with providing the latest information on ophthalmic disease, this will help reinforce *Cravit's* position as the gold standard among treatments for ophthalmic infections and allow it to maintain its leading position in the market for anti-infective ophthalmic products.



### Sales of Rescula, Detantol, Timoptol XE and Timoptol



### Treatments for Glaucoma

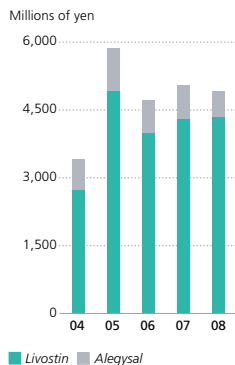
Glaucoma treatments represent the largest sector of the domestic prescription ophthalmic pharmaceuticals market, accounting for approximately 37% of the total. In glaucoma, rising intraocular pressure is a significant risk factor for damage caused to the optic nerve, leading to visual field loss and in some cases blindness. It is one of the most common causes of blindness in people with ophthalmic disease. Recent epidemiological studies indicate a high potential incidence of glaucoma, so early detection and treatment of the disorder has become a major issue. This, combined with increasing patient numbers from Japan's aging population, has led to a steady expansion of the glaucoma market, which increased 4.0% year on year in fiscal 2007.

In fiscal 2007, Santen maintained its MR program of providing the latest information about glaucoma and its treatment, and worked diligently to increase the market penetration and presence of its glaucoma product line. Competition in this sector was strong, however, and sales of our four leading products—*Rescula*, *Detantol*, *Timoptol XE* and *Timoptol*—fell 1.8% in aggregate, to ¥14,224 million.

Santen will continue to spotlight the particular benefits of *Rescula* and *Detantol* in treating glaucomatous ocular hypertension. With the prospective launch of DE-085 (Tafluprost), currently awaiting manufacturing and marketing approval, we will be in an even better position to actively meet the needs of the medical profession, providing new information so this new Santen offering will rapidly gain a high profile in the glaucoma sector.



### Sales of *Livostin* and *Alegysal*



### Anti-Allergy Ophthalmics

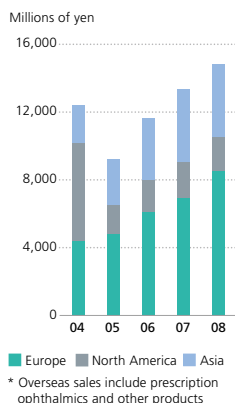
Higher pollen counts precipitated a rise in the incidence of allergic conjunctivitis in Japan during fiscal 2007, compared with the previous year, contributing to a 2.6% growth in the anti-allergy ophthalmic pharmaceuticals market.

Santen maintained its leading 22.7% share of the anti-allergy ophthalmic pharmaceuticals market. We continued strong product marketing and disease-related educational efforts, so in an environment of significantly increased competition in this sector, *Livostin* sales increased 0.8%, to ¥4,341 million, while *Alegysal* sales decreased 14.3%, to ¥583 million. This represents a 1.2% decline in combined sales of these products, to ¥4,924 million.

*Livostin* provides rapid relief from such symptoms of year-round and seasonal allergies as itching and redness and thus contributes to patients being able to reclaim a comfortable life. By continuing to appeal to these characteristics, we aim to expand both sales and market share of this product.



### Overseas Sales



### OVERSEAS



Markets for prescription ophthalmic pharmaceuticals were strong in the U.S., Europe and Asia. Santen saw sales grow in Northern and Eastern Europe, as well as Russia, Germany, the U.S. and Asia. In fiscal 2007, we registered a year-on-year increase in total overseas sales of prescription ophthalmic pharmaceuticals of 20.5% in yen terms, to ¥13,106 million.

### United States

The U.S. prescription ophthalmic pharmaceuticals market, already the world's largest, is continuing to expand as increasing numbers of the baby boomer generation develop age-related disorders such as glaucoma and macular degeneration. Competition in the U.S. prescription anti-infective pharmaceuticals market is also broadening.

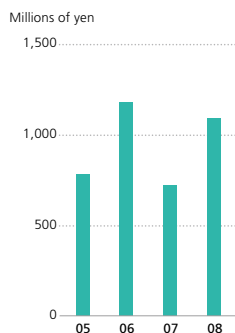
We market four products under a licensing agreement with VISTAKON Pharmaceuticals, LLC: the anti-infective *Quixin* (sold as *Cravit* in Japan), the glaucoma treatment *Betimol*, the anti-allergy ophthalmic solution *Alamast* (sold as *Alegysal* in Japan) and the well-received *Iquix*, high-concentration levofloxacin ophthalmic solutions, which was launched in October 2007. With the support of greater exposure in the local anti-infective ophthalmic pharmaceuticals market and the launch of *Iquix*, total sales of Santen products licensed to VISTAKON Pharmaceuticals rose 55.1%, to ¥1,089 million. Contract manufacture of *Floxin* ear drops, however, dropped sharply during fiscal 2007 due to new generic competition, resulting in an 8.3% decline in the U.S. sales of this product, to ¥1,951 million. In the U.S., we have completed Phase II clinical trials of DE-101 (Rivoglitazone) and Phase I clinical trials of DE-104, on or ahead of schedule. At present, we are considering plans to advance DE-101 (Rivoglitazone) to the next stage of trials and have already begun the next stage of DE-104 trials.

Going forward, we will continue to expand our R&D pipeline with new drug candidates and work to further strengthen our business-development activities.



The 111th American Academy of Ophthalmology (AAO) meeting held in New Orleans, Louisiana, U.S. in November 2007

### Sales of Products Licensed to VISTAKON Pharmaceuticals



\* Sales in the year ended March 31, 2008 includes sales of *Iquix*

## Europe

The European market for prescription ophthalmic pharmaceuticals has been growing for several years at 5% to 10% per annum, triggered by a combination of rising numbers of patients with glaucoma and dry eye disorders, and increasing economic prosperity in Eastern Europe and Russia. At the same time, various European governments actively encourage the use of generic products as part of their health care cost-containment policies, so conditions surrounding the European prescription ophthalmic pharmaceuticals market are becoming increasingly difficult. In addition, the European market is characterized by its diversity—each country in the region has a different health insurance system and different medical treatment practices.

Santen Oy, our subsidiary in Finland, manufactures pharmaceuticals for sale in Europe and the U.S. It is also home to our European R&D and clinical development endeavors. Santen Oy now conducts marketing operations in 31 European countries, including Northern Europe, Eastern Europe, Russia and Germany. The anti-infective ophthalmic solution preparation *Oftaquix* (sold as *Cravit* in Japan) is now available in 24 countries, including Russia, Finland, Germany and Sweden, and has gained an excellent reputation among ophthalmic surgeons for its superior reliability in preventing post-operative eye infection. In fiscal 2007, effective educational and promotional activities and favorable exchange rates generated sales growth in Northern and Eastern Europe, Russia and Germany, resulting in an annual increase of 23.4% in total European sales, to ¥8,533 million.

In the upcoming fiscal period, we plan to continue raising the profile and reach of our existing products through promotional activities. In April 2007, we applied for *Taflotan* (Tafluprost) marketing approval in 13 European countries. The first approval was received in April 2008, in Denmark, followed shortly thereafter by Germany and several other countries. We are currently preparing to launch this product across the region.



European Glaucoma Society (EGS) 8th meeting held in Berlin, Germany, in June 2008

## Asia

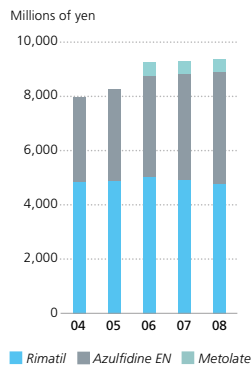
Santen operates actively in 10 countries and regions in Asia, including China, South Korea and the ASEAN nations, and carries out export and marketing activities through local sales agents. Our vision for the Asian market is to become the top ophthalmic drug manufacturer. To this end, we are striving to enhance trust-based relationships with patients and medical professionals, thereby contributing to the improvement of ophthalmic treatment in Asia.

As a result of successful sales promotions combined with specialist academic information on ophthalmology and sales growth in China, total sales in Asia rose 1.9% year on year, to ¥4,326 million.

In the Chinese market there is an upward economic trend as well as increasing population, so we expect sales to grow strongly in the medium to long term. In addition to representative offices in Beijing, Guangzhou and Shanghai, Santen opened a new office in Shenyang in April 2007. We are concentrating our promotional activities on these urban centers and marketing the prescription ophthalmic pharmaceuticals products *Cravit* anti-infective eye drops and *Hyalein* a corneal and conjunctival epithelial disorder treatment, through local sales agents. In September 2005, we founded a wholly owned subsidiary, Santen Pharmaceutical (China) Co., Ltd., in Suzhou, Jiangsu Province, China. Santen Pharmaceutical (China) completed construction of a plant in August 2007 and is preparing for direct marketing. We are also working to increase the penetration of the Santen brand in the South Korean and ASEAN markets through Santen Pharmaceutical Korea, Co., Ltd. and local agencies.

## Prescription Pharmaceuticals Anti-Rheumatic Pharmaceuticals

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



*Rimatil*, *Azulfidine EN* and *Metolate* are each highly recommended under the Guidelines for the Management of Rheumatoid Arthritis and as a result of their steadily expanding use as preferred treatment options, Santen's prescription anti-rheumatic pharmaceuticals net sales grew 2.6% to ¥9,627 million in fiscal 2007.

Net Sales      ¥9,627 million    +2.6%

The causes of rheumatoid arthritis (RA) are not yet well understood, but it is thought to be a chronic inflammatory disorder that affects the whole body. Inflammation occurs particularly in the joints, causing pain and swelling, and can often lead to bone and cartilage damage and subsequent joint deformity. It is estimated that there are approximately 700,000 people with RA in Japan today. The Japanese market for DMARDs\* expanded 3.7%, to ¥24,100 million, in fiscal 2007, as the number of patients grew in line with population aging and prescriptions of higher-priced medications increased.

Santen has built its leading market share of the prescription anti-rheumatic pharmaceuticals market through active promotion of *Rimatil*, *Azulfidine EN* and *Metolate* in hospitals and clinics. Among sales results of core products in the period under review, *Rimatil* fell 3.0%, sales of *Azulfidine EN*, which displays early-onset effect characteristics, grew a favorable 6.0% year on year, and effective promotional activities propelled *Metolate*, launched in July 2004, to make good inroads in the market. As a result, net sales of prescription anti-rheumatic pharmaceuticals increased 2.6%, to ¥9,627 million, and Santen maintained its dominant position as leader of the DMARDs market, with a 46.1% share.

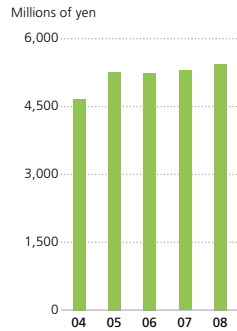
The Guidelines for the Management of Rheumatoid Arthritis, announced in April 2004 by the Japan College of Rheumatology, recommends treating RA with DMARDs from the early stages to improve patients' quality of life (QOL) by retarding the progress of joint destruction and so avoiding the development of joint deformity. Santen's *Rimatil*, *Azulfidine EN* and *Metolate* are each rated "Grade A – Highly Recommended" under the guidelines, which gives them a high profile as strongly recommended treatment options. To broaden the market share of these three products even further, we will continue to emphasize this solid independent support for their superior efficacy in our promotional activities.

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



## Over-the-Counter Pharmaceuticals

### Net Sales of OTC Pharmaceuticals



Sante FX Neo



Sante Medical 10

As a result of continued promotional activities focusing on products for tired eyes, blurred vision and eye refreshment, Santen's OTC net sales rose 2.7%, to ¥5,451 million.

Net Sales      ¥ **5,451** million + **2.7%**

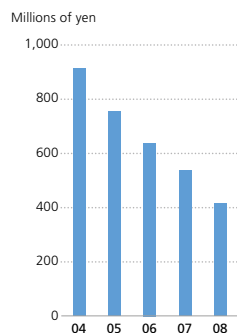
Santen's OTC pharmaceuticals sales are almost entirely generated in the Japanese OTC ophthalmic market. In fiscal 2007, that market grew as demand rose for products for eye fatigue, contact lens wearers and allergies.

Our OTC business specializes in a range of ophthalmic products, including *Sante FX Neo*, Japan's top-selling ophthalmic solution brand, and the *Sante 40* series, highly effective in improving blurred vision. As a result of promotional activities focusing on products for tired eyes, blurred vision and eye refreshment, especially *Sante Medical 10*—a sophisticated formulation with 10 different active ingredients to specifically relieve eye fatigue, which we launched in October 2006—OTC net sales rose 2.7%, to ¥5,451 million.

With fierce competition set to continue in this market, we will promote sales of new products while maintaining the market share of our existing range.

## Medical Devices

### Net Sales of Medical Devices



The number of cataract surgeries in Japan rose only slightly in fiscal 2007, and combined with heightened competition, this led to a decline in Santen's intraocular lens (IOL) sales and a reduction of 22.8% in net sales of its medical devices, to ¥415 million.

Net Sales      ¥ **415** million - **22.8%**

Santen's medical devices business specializes in the cataract surgery field, focusing primarily on IOLs. The number of cataract surgeries in Japan rose slightly in fiscal 2007, but heightened competition led to a fall in the overall unit price of IOLs. As a result, net sales of medical devices declined 22.8%, to ¥415 million.

IOL demand in recent years has shifted primarily to foldable lenses that can be inserted through a small incision. Santen will soon be beginning full-scale marketing in Japan of *Eternity* foldable IOL made of a new highly refractive optical material. *Eternity* is made by Advanced Vision Science, Inc., a U.S. subsidiary of Santen, and will contribute to the expansion in sales of medical devices.