

Reference information

Research & development

■ Pipeline of prescription pharmaceuticals (Clinical studies)

Generic name	Brand name/dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Levofloxacin (0.5%)	Cravit	Bacterial conjunctivitis	Daiichi Pharmaceutical	Japan						Apr-00
	Quixin			USA						Nov-00
	Ofaquix			Europe						May-02
Levofloxacin + prednisolone A	DE-094	Infectious keratitis	Daiichi Pharmaceutical	USA						

Characteristics: Fluoroquinolone antibacterial agent. Levofloxacin + prednisolone A is a combination treatment with steroids.

Generic name	Brand name	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Pemirolast potassium	Alegysal	Allergic conjunctivitis	Mitsubishi Pharma	Japan						Apr-95
	Alamast			USA						Jul-00
	Alamast			Europe					Dec-99	

Characteristics: A mast cell stabilizer with superior efficacy on allergic conjunctivitis and vernal keratoconjunctivitis.

Generic name	Brand name	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Ciclosporin	PAPILOCK Mini	Vernal keratoconjunctivitis	Novartis Pharma	Japan						Jan-06

Characteristics: An orphan drug. Ophthalmic application of immuno-suppressant ciclosporin. Expected to treat advanced vernal keratoconjunctivitis for which existing anti-allergic agents are not effective.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Tafluprost	DE-085	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Japan						In preparation
				Europe						In preparation
				USA						

Characteristics: Prostaglandin glaucoma treatment for ocular hypertension. In Japan, a comparison study demonstrated its non-inferiority to latanoprost and we are preparing for NDA filing. In Europe, also preparing for NDA filing based on the results of 1) the sub-analysis of the comparison study demonstrated its non-inferiority to latanoprost although it did not demonstrate its non-inferiority to latanoprost for the primary analysis, and 2) another comparison study demonstrated non-inferiority to timolol maleate ophthalmic solution. In the USA, we will decide our future development plan based on the study results and marketability.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Diquafosol tetrasodium	DE-089	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Inspire Pharm.	Japan						In preparation

Characteristics: A treatment for corneal and conjunctival epithelial disorder associated with dry eye, etc. that stimulates the ocular surface to secrete tear fluid and moisture. Expected to be used in combination with existing dry eye treatments.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Olmesartan	DE-092	Glaucoma/ Ocular hypertension	Sankyo	Japan						Suspended
				USA/Europe						Suspended

Characteristics: The angiotensin II receptor antagonist. In Japan, Europe and the USA, the Phase II studies did not demonstrate clear dose-response relationship nor sufficient IOP-lowering effect, and therefore we decided to suspend clinical studies. We will decide whether we resume the clinical studies after conducting another pilot study with different doses and different formulation since the results of the Phase II studies differed from the result of the early Phase II study conducted with different formulation in Japan.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Lomerizine HCL	DE-090	Glaucoma	Nippon Organon	Japan						

Characteristics: A new type of oral glaucoma treatment studied for inhibiting the progression of visual field defects. The only calcium antagonist in full-fledged development as a glaucoma treatment. Compared with NMDA receptor antagonists, fewer generalized side effects are expected, thus having excellent safety. Marketed by Nippon Organon as a migraine drug.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-096	Rheumatoid arthritis	Original	Japan						
		Diabetes Macular Edema		Japan						

Characteristics: An oral TNF inhibitor. Anti-rheumatic effect comparable to injectable biological agents. In addition to RA, the effect on DME was also observed in basic research, and the phase II studies are being conducted with both diseases.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Gefarnate	DE-099	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Original	Japan						

Characteristics: Treats corneal and conjunctival epithelial disorder mostly associated with dry eye, by stimulating the secretion of mucin and promoting the corneal epithelial migration. Preservative-free eye ointment that can be used in combination with existing drugs.

*Forecasts in this report are based on the currently available information. Actual results may differ materially depending on a number of factors including adverse economic conditions etc.

■ Pipeline of prescription pharmaceuticals (In preparation for clinical trials)

Generic name	Brand name	Indication	Original/in-licensor
Bucillamine	Rimatil	Osteoarthritis (additional indication)	Original

Characteristics: Shown to be effective on joint inflammation caused by osteoarthritis.

Generic name (USA)	Dev. code	Indication	Original/in-licensor
Rivoglitazone	DE-101	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Sankyo

Characteristics: It is expected to show a potent effect on corneal and conjunctival epithelial disorders by directly acting on the corneal and conjunctival epithelial cells. It has an action mechanism which differs from any other existing treatment or drug candidate in development. The compound is currently under development by Sankyo as an oral anti-diabetic in the USA.

Generic name (USA)	Dev. code	Indication	Original/in-licensor
(Undetermined)	DE-102	Diabetes Macular Edema	Co-development with Oakwood (USA)

Characteristics: A steroid microsphere product for a sustained release injectable drug delivery. Demonstrated sustained efficacy when injected around the affected area. In order to produce sterile microsphere in commercial scale, we collaborate with Oakwood Laboratories (USA).

Generic name (USA)	Dev. code	Indication	Original/in-licensor
(Undetermined)	DE-103	Allergic conjunctivitis	Ono

Characteristics: A PDE4 (Phosphodiesterase type 4) inhibitor for allergic conjunctivitis which has a different action mechanism from the existing drugs. Expected to be effective for allergic conjunctivitis through its inhibitory effect against PDE4.

Generic name (USA)	Dev. code	Indication	Original/in-licensor
(Undetermined)	DE-104	Glaucoma/ Ocular hypertension	Co-development with Ube Industries

Characteristics: A ROCK inhibitor co-development with Ube Industries for treatment of glaucoma and ocular hypertension which has a different action mechanism from other existing drugs. It is expected to show a strong IOP-reduction by promoting aqueous humor outflow by acting directly on trabecular cells.

■ Medical Device

Product under development	Product name	Region
Intraocular lens	MD-14	Japan and USA

Characteristics: Foldable intraocular lens using new material with high refractive index. Developed by U.S. subsidiary Advanced Vision Science, Inc.. NDA filed in Japan. In clinical trials in USA.

■ License out

Dev. code	Indication	Region	Licensee	Status	in-licensor
DE-098 (Anti-APO-1 antibody)	Rheumatoid arthritis	Japan	Argenes	preparing for clinical trials	Centocor

Characteristics: Joint injection that induces apoptosis in diseased joints of rheumatoid arthritis patients. Bulk pharmaceutical manufacturing process for actual production scale has been established, and drug development is being studied. Santen granted the domestic development rights to Argenes, Inc. The compound had been in-licensed from Centocor. Santen continues to hold the marketing rights in Japan and the overseas marketing and development rights.

■ Changes from November 1, 2005

[Progress]

Dev. code	Indication	Status change	Clinical trial, NDA filing, Launch Region
DE-076	Vernal keratoconjunctivitis	Approved to launched	Japan

Pharmaceutical market in Japan

■ Revision of National Health Insurance (NHI) drug prices

(%)

	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Industry average	-6.6	-	-6.8	-4.4	-9.7	-	-7.0	-	-6.3	-	-4.2	-	-6.7
Ophthalmic drugs	-1.6	-	-3.5	-1.8	-7.5	-	-6.2	-	-6.0	-	-2.7	-	-5.5
Santen	-0.4	-	-2.6	-1.3	-7.2	-	-5.7	-	-6.0	-	-3.2	-	-5.3

(Compiled by Santen)

Revision of NHI drug prices: In Japan, drug prices are generally revised every two years to reflect their market price. The drugs marketed at lower market prices will bear larger reduction margins at the revision.

■ Major healthcare reforms

	1997	Enforcement of the Revised Health Insurance System Law Increased contribution for insured employees (10% to 20%) Revision of the Insurance Law for Seniors Contribution: 500 yen/day for out-patients (up to four times a month) and 1,000 yen/day for in-patients
	2001	Revision of the Insurance Law for Seniors Contribution: fixed rate of 10% for out-patients and in-patients
April	2002	Reimbursed consulting fee for physicians were reduced by 2.7% on average Revision of prescription fee (two points are added for every prescription of generic drugs)
October	2002	Increased contribution for seniors (fixed amount system was abolished for a uniform fixed rate system of 10% contribution)
April	2003	Increased contribution for insured employees (20% to 30%)
April	2006	Revision of the prescription form from the standpoint of attempting environmental considerations of the generic use promotion

■ Market shares

(Billions of yen)

Year ended March 31	2002	2003	2004	2005	2006
Prescription ophthalmics	40.3% 197.1	38.9% 195.8	39.0% 194.7	39.6% 207.7	40.9% 213.1
Anti-rheumatic drugs	42.8% 20.3	42.1% 21.1	42.5% 22.2	42.9% 23.3	45.2% 23.8

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

- Anti-rheumatic drugs exclude immunosuppressants and biologic agents.

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Period: 2001-2006; Unauthorized copy prohibited

■ Market shares by therapeutic area - prescription ophthalmics

(Billions of yen)

Year ended March 31	2002	2003	2004	2005	2006
Anti-glaucoma	17.6% 66.1	17.3% 69.0	16.7% 71.7	20.0% 74.9	23.2% 79.0
Anti-infective	81.8% 30.2	80.9% 27.6	81.0% 26.9	80.3% 26.5	78.3% 26.7
Anti-allergy	18.2% 26.5	17.5% 25.0	20.7% 20.8	22.4% 28.4	24.8% 24.6
Agents for surgeries	41.0% 16.0	39.6% 14.8	39.1% 14.5	41.0% 13.6	42.6% 14.4
Corneal disease treatments	89.0% 17.2	85.4% 18.8	82.4% 21.0	81.0% 23.0	80.7% 25.5
Anti-cataract	50.1% 7.7	53.3% 7.7	55.4% 7.1	57.4% 6.8	60.3% 6.5
Corticosteroids	56.0% 12.5	53.1% 11.4	51.6% 10.9	52.8% 11.5	52.6% 11.2

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

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Source: Santen analysis based on IMS data

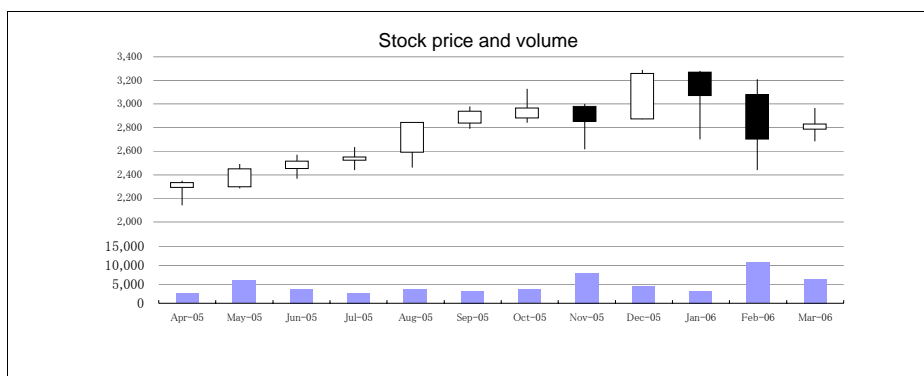
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Stock information

■ Stock price (Osaka Securities Exchange 1st market)

(Yen and thousand shares)

	Apr-05	May-05	Jun-05	Jul-05	Aug-05	Sep-05	Oct-05	Nov-05	Dec-05	Jan-06	Feb-06	Mar-06
Stock price:												
Open	2,290	2,295	2,450	2,520	2,590	2,835	2,880	2,980	2,870	3,270	3,080	2,785
High	2,350	2,490	2,570	2,635	2,845	2,980	3,130	3,000	3,290	3,280	3,210	2,965
Low	2,140	2,285	2,365	2,440	2,460	2,790	2,840	2,615	2,870	2,700	2,440	2,685
End of month	2,335	2,450	2,515	2,550	2,845	2,940	2,965	2,850	3,260	3,070	2,700	2,830
Volume	2,541	5,995	3,848	2,745	3,608	3,204	3,664	7,979	4,545	3,241	10,887	6,326



■ Major shareholders

As of March 31, 2006

Name	Number of shares Held	Percentage of voting rights
	Thousand shares	%
Northern Trust CO. (AVFC) Sub-account American Clients	8,030	9.3
Japan Trustee Service Bank, Ltd.	4,912	5.7
Mita Sangyo Co., Ltd.	4,756	5.5
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	4,296	5.0
Japan master Trust and Banking Co., Ltd.	3,922	4.5
Trust and Custody Services Bank, Ltd.	2,750	3.2
The Tokio Marine and Nichido Fire Insurance Co., Ltd.	2,668	3.1
Nippon Life Insurance Company	2,661	3.1
Mitsubishi UFJ Trust and Banking Corporation	1,930	2.2
Investors Bank and Trust Company	1,718	2.0

■ Shares and stock option

Year ended March 31	2001	2002	2003	2004	2005	2006
Number of shares outstanding (thousand shares)	92,720	90,704	90,704	87,963	86,658	86,751
Stock option balance (thousand shares)	199	243	335	472.6	504.3	541
Granted in June 1998 - 106 thousand shares at 1,540 yen/share	73	62	62	62	35	27
Granted in June 1999 - 66 thousand shares at 2,480 yen/share	66	66	66	66	66	57.3
Granted in June 2000 - 60 thousand shares at 2,705 yen/share	60	60	60	60	60	58
Granted in June 2001 - 55 thousand shares at 2,299 yen/share	-	55	55	55	55	42.6
Granted in June 2002 - 92 thousand shares at 1,326 yen/share	-	-	92	92	72.5	53.7
Granted in June 2003 - 137.6 thousand shares at 1,176 yen/share	-	-	-	137.6	137.6	95
Granted in June 2004 - 78.2 thousand shares at 1,743 yen/share	-	-	-	-	78.2	78.2
Granted in June 2005 - 129.2 thousand shares at 2,480 yen/share	-	-	-	-	-	129.2

Note: The company has a stock-based compensation plans under which stock options are granted to directors and corporate officers.

The grants are fully exercisable after two years.

■ Extinguishment of Treasury stock

	2002	2003	2004	2005	2006
An extinguished amount of money (millions of yen)	3,258	-	3,239	2,548	-
The number of the extinguished stocks (thousand stocks)	2,027	-	2,741	1,351	-

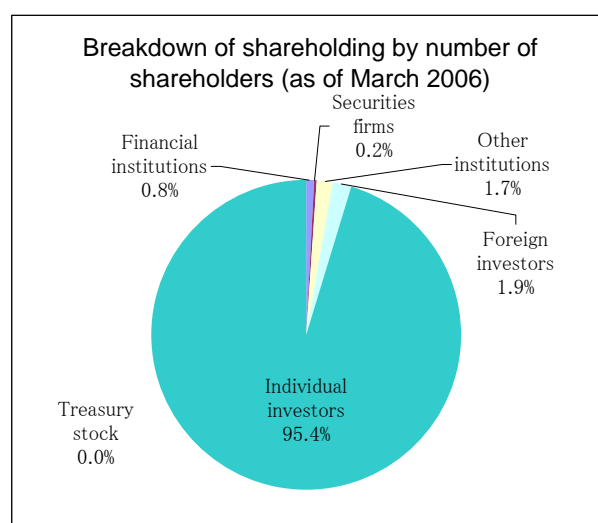
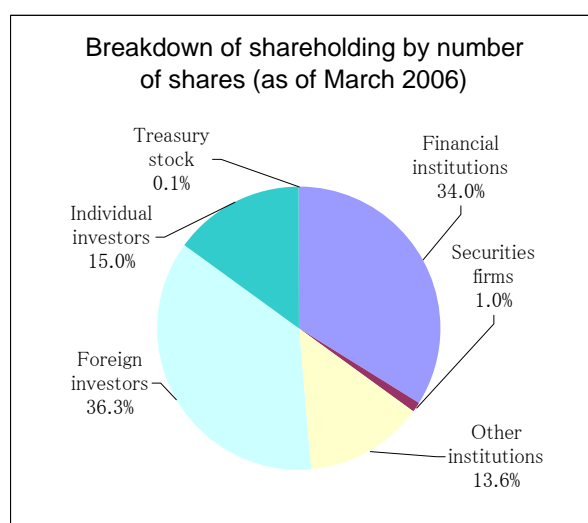
■ Breakdown of shareholding by number of shares

Year ended March 31	2002		2003		2004		2005		2006	
	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)
Financial institutions	41,005	45.2	36,302	40.0	30,740	34.9	28,423	32.8	29,514	34.0
City & regional banks	9,054	9.9	6,660	7.3	5,428	6.2	4,636	5.3	4,659	5.4
Trust banks	20,641	22.8	19,018	21.0	16,201	18.4	15,768	18.2	16,577	19.1
(concerned in trust works)	18,429		15,743		13,422		13,022		14,039	
Life and non-life insurance	11,033	12.2	10,414	11.5	9,007	10.2	7,973	9.2	8,004	9.2
Other financial institutions	276	0.3	208	0.2	103	0.1	45	0.1	274	0.3
Securities firms	646	0.7	293	0.3	368	0.4	346	0.4	865	1.0
Other institutions	10,300	11.4	10,555	11.6	10,512	12.0	11,788	13.6	11,823	13.6
Foreign investors	23,675	26.1	24,580	27.1	31,306	35.6	32,874	38.0	31,519	36.3
Individual investors	15,073	16.6	16,200	17.9	15,001	17.1	13,187	15.2	12,985	15.0
Treasury stock	2	0.0	2,771	3.1	33	0.0	39	0.0	45	0.1
Total	90,704	100.0	90,704	100.0	87,963	100.0	86,658	100.0	86,751	100.0

Note: Trading unit for Santen shares were reduced to 100 shares from 1,000 shares effective August 1, 2002

■ Breakdown of shareholding by number of shareholders

Year ended March 31	2002		2003		2004		2005		2006	
	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)
Financial institutions	107	1.8	98	1.2	83	1.0	91	1.1	107	0.8
City & regional banks	13	0.2	8	0.1	7	0.1	9	0.1	10	0.1
Trust banks	60	1.0	55	0.7	46	0.6	47	0.6	52	0.4
Life and non-life insurance	28	0.5	29	0.3	27	0.3	31	0.4	32	0.2
Other financial institutions	6	0.1	6	0.1	3	0.0	4	0.0	13	0.1
Securities firms	35	0.6	28	0.4	28	0.4	28	0.3	31	0.2
Other institutions	137	2.3	134	1.7	130	1.7	128	1.5	236	1.7
Foreign investors	148	2.5	119	1.5	122	1.5	172	2.0	255	1.9
Individual investors	5,583	92.9	7,493	95.2	7,498	95.4	8,089	95.1	12,927	95.4
Treasury stock	1	0.0	1	0.0	1	0.0	1	0.0	1	0.0
Total	6,011	100.0	7,873	100.0	7,862	100.0	8,509	100.0	13,557	100.0



News releases

News releases during April 2005-March 2006

For details, please refer to our Investor Relations Web site (<http://www.santen.co.jp/ir/en/news>).

(Date) (Summary)

2005

9-May Announcement on the New Management Organization

The board of directors of the Company was approved to increase the number of inside directors from four to five, and the number of outside directors from one to three at the 93rd Annual General Meeting of Shareholders held on June 24, 2005. Moreover, in July 2005 three committees—a Corporate Strategy Committee, a Nominating Committee and an Executive Compensation Committee—comprising inside and outside directors were reorganized or newly established. Accordingly, these committees are different from ordinary committees and are not "committees" required to be maintained by "companies with committees" (in Japanese: i-inkai tou settchi kaisha) as defined in the revised Commercial Code.

9-May Santen to Issue Stock Acquisition Rights for the Purpose of Granting Stock Options

Santen's Board of Directors adopted a resolution to issue stock acquisition rights for the purpose of granting stock options to Santen's directors, corporate officers and directors of major overseas subsidiaries. The resolution was approved at the 93rd Annual General Meeting of Shareholders held on June 24.

7-Jul Santen Opens its Shanghai Representative Office

Santen opened the Shanghai Representative Office, covering East China (Shanghai, Zhejiang, Jiangsu, Anhui and Hubei), in China on July 7, 2005.

25-Jul Santen to Reform the Organization

Santen reformed its OTC division as of September 1st, 2005. Santen set up Administration Group, Product Development Group and Sales Planning Group at the OTC head office and also relocated the head office to Tokyo. Moreover, Santen modified OTC Sales and Marketing structures to reinforce marketing efficiency and to create value-added marketing and sales activities.

12-Aug Santen's Car Including PC and Roster with Private Information Stolen

One of Santen's medical representative's car was stolen. A roster and a mobile computer with private information were taken with the vehicle. Santen's mobile computers have double-security features. Therefore, the possibility of leakage of electronic information is considered to be very low. At the time of publishing, no misuse of private information has been discovered.

25-Aug Santen to Outsource its Logistics Operations

In order to ensure high quality customer service by improving efficiency and shortening lead time and to improve capital efficiency by concentrating management resources, Santen decided to outsource its logistics operations in the western part of Japan to Hitachi Transport System, Ltd.

26-Sep Agreement Concerning CS-011 as Dry Eye Drug Candidate

Santen and Sankyo Co., Ltd. entered into an agreement concerning the worldwide exclusive development, manufacturing and marketing rights for CS-011 (rivoglitasone) as an ophthalmic treatment for corneal and conjunctival epithelial disorders, including dry eye. The compound is currently under development by Sankyo as an anti-diabetic. Sankyo has the option to co-promote the product in Japan.

29-Sep Santen Establishes Subsidiary in China

Santen established Santen Pharmaceutical (China) Co., Ltd., a 100% subsidiary in China. Santen has received an operating license from Jiangsu Administration of Industry and Commerce. The new subsidiary will develop prescription ophthalmic pharmaceuticals, construct a manufacturing plant in Suzhou Industrial Park, and establish a direct sales and marketing organization.

May 10, 2006

News releases during April 2005-March 2006

(Date) (Summary)

12-Oct Santen Receives Manufacturing and Marketing Approval for its Vernal Keratoconjunctivitis Treatment, PAPILOCK Mini Ophthalmic Solution 0.1%

Santen received a manufacturing and marketing approval for its new vernal keratoconjunctivitis treatment PAPILOCK Mini ophthalmic solution 0.1% (generic name: ciclosporin) from the Ministry of Health, Labour and Welfare on October 11. Santen believes PAPILOCK Mini ophthalmic solution 0.1% will make an important contribution to the treatment of patients with vernal keratoconjunctivitis with whom existing anti-allergy drugs are not effective and lead to their improved quality of life.

2006

23-Jan Santen Launches PAPILOCK Mini Ophthalmic Solution 0.1%

Santen launched its new vernal keratoconjunctivitis treatment PAPILOCK Mini ophthalmic solution 0.1% (generic name: ciclosporin) on January 23. Santen believes PAPILOCK Mini ophthalmic solution 0.1% will make an important contribution to the treatment of patients with vernal keratoconjunctivitis with whom existing anti-allergy drugs are not effective and lead to their improved quality of life.

14-Feb Santen Announces Preliminary Results of Overseas Clinical Trials of Two Glaucoma Drug Candidates

Santen announced preliminary results of the overseas clinical trials of two drug candidates for lowering intraocular pressure in patients with glaucoma and ocular hypertension: an angiotensin II receptor antagonist, DE-092 (International Nonproprietary Name: Olmesartan), and a prostaglandin derivative, DE-085 (INN: Tafluprost).

- In the early Phase II clinical trials of DE-092 in the United States, although data analysis indicated some IOP reduction, the efficacy was insufficient, and no clear dose-response relationship was seen among the DE-092 concentrations.
- In Phase III clinical trials of DE-085 in Europe, the drug did not demonstrate non-inferiority to latanoprost ophthalmic solution 0.005% for the primary endpoint. However, DE-085 demonstrated non-inferiority to latanoprost in Phase III clinical trials in Japan, and progress towards a Japanese NDA filing is continuing as planned.

Santen will announce its future overseas development plans for these two product candidates when a decision is made.

28-Feb Santen Announces Proposed Dividend Change

Returning profits to shareholders is an issue of key importance for Santen. Santen actively seeks to return profits through dividends. Taking our forecast of performance of the year ending March 2006 into account, Santen will propose a year-end dividend of ¥35 and an annual total dividend of ¥60 per share, to the company's 94th Annual General Meeting of Shareholders which will be held in June 2006.

22-Mar Licensing Agreement on PDE4 Inhibitor ONO-6126

Santen and Ono Pharmaceutical Co., Ltd. entered into a licensing agreement for exclusive development, manufacturing and marketing rights in Japan for ONO-6126 for allergic conjunctivitis. The mechanism of action of ONO-6126 is different from existing drugs for the treatment of allergic conjunctivitis, and Santen expects that ONO-6126 will provide a new option for treatment.

22-Mar Agreement Concerning Joint Research of Ophthalmic Drug

Santen and CytoPathfinder, Inc. signed a three-year research agreement to jointly search for target molecules for ophthalmology drug discovery and apply CytoPathfinder's cubic liquid crystal technology to ophthalmic drug formulation as part of Santen's drug discovery process for ophthalmic disorders such as glaucoma and retinal disorders.

28-Mar Agreement Concerning Microsphere-based Platform Development and License

Santen signed a development and license agreement with Oakwood Laboratories L.L.C. in the U.S. Oakwood has broad experience and high quality in microsphere-based technologies, for the development of manufacturing technology for a steroid microsphere-based product for diabetic macular edema treatment (development code named DE-102). Under the agreement, Santen will address development of manufacturing technology for DE-102 which has a concept of drug delivery system.