

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
	Oftaquix			Europe						May-02
Levofloxacin + prednisolone A	DE-094	Infectious keratitis	Daiichi Pharmaceutical	USA						

Characteristics: Fluoroquinolone antibacterial agent. In Europe, Ofaquix has obtained marketing authorization in 13 countries and was launched in seven countries including Germany. Levofloxacin + prednisolone A is a combination treatment with steroids.

Generic name	Brand name/dev. code	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/dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Ciclosporin	DE-076	Vernal keratoconjunctivitis	Novartis Pharma	Japan					Oct-05	

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	Brand 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						
				USA/Europe						

Characteristics: Prostaglandin glaucoma treatment that reduces intraocular pressure. Clinical trials are being conducted in parallel in Japan, the U.S. and Europe. Expected to have greater efficacy in reducing intraocular pressure than other prostaglandin products. Can be stored at room temperature.

Generic name	Brand 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						
				USA/Europe						

Characteristics: The only angiotensin II receptor antagonist in full-fledged development as a glaucoma treatment. Comparable to prostaglandin products in reducing intraocular pressure. Very few side effects, including conjunctival hyperemia, are expected. Great potential for the U.S. and European markets where patients with ocular hypertension account for the majority of the glaucoma population.

Generic name	Brand 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	Brand name/dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Diquafosol tetrasodium	DE-089	Dry eye	Inspire Pharm.	Japan						

Characteristics: A treatment for dry eye that stimulates the ocular 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.

Generic name	Brand 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 has been observed in basic research. In addition to RA the effect on DME was also observed in basic research, clinical studies are being conducted with both diseases.

Generic name	Brand 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.

Pipeline of prescription pharmaceuticals (In preparation for clinical trials)

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

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

Generic name (USA)	Code name	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.

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

Brand name/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 May 9, 2005

[Progress]

Brand name/dev. code	Indication	Region	Status change
Ciclosporin / DE-076	Vernal keratoconjunctivitis	Japan	NDA filed to Approved
DE-096	Diabetes Macular Edema	Japan	In preparation for phase II to Phase II
DE-101	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	USA	In preparation for clinical study

[Suspended launch plan]

Generic/Brand name	Indication	Region
Levofloxacin(1.5%) / IQUIX	Bacterial corneal ulcer	USA

Pharmaceutical market in Japan

Revision of National Health Insurance (NHI) drug prices

(%)

	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Industry average	-	-6.6	-	-6.8	-4.4	-9.7	-	-7.0	-	-6.3	-	-4.2	-
Ophthalmic drugs	-	-1.6	-	-3.5	-1.8	-7.5	-	-6.2	-	-6.0	-	-2.7	-
Santen	-	-0.4	-	-2.6	-1.3	-7.2	-	-5.7	-	-6.0	-	-3.2	-

(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%)

Market shares

(Billions of yen)

Half year/year to	9/2003	3/2004	9/2004	3/2005	9/2005
Prescription ophthalmics	39.6%	39.0%	39.4%	39.6%	41.5%
	97.3	194.7	100.3	207.7	107.0
Anti-rheumatic drugs	42.8%	42.5%	42.4%	42.9%	45.1%
	11.1	22.2	11.7	23.3	12.0

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

- Anti-rheumatic drugs exclude immunosuppressants and biologic agents.

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Source: Santen analysis based on IMS data

Period: 2003-2005; Unauthorized copy prohibited

Market shares by therapeutic area - prescription ophthalmics

(Billions of yen)

Half year/year to	9/2003	3/2004	9/2004	3/2005	9/2005
Anti-glaucoma	16.9%	16.7%	16.3%	20.0%	23.4%
	35.5	71.7	37.6	74.9	39.7
Anti-infective	80.8%	81.0%	81.2%	80.3%	78.4%
	14.1	26.9	14.1	26.5	14.1
Anti-allergy	21.2%	20.7%	23.4%	22.4%	25.7%
	9.7	20.8	9.7	28.4	11.4
Agents for surgeries	39.4%	39.1%	39.9%	41.0%	42.8%
	7.4	14.5	6.8	13.6	7.2
Corneal disease treatments	82.9%	82.4%	81.2%	81.0%	80.7%
	10.1	21.0	11.4	23.0	12.5
Anti-cataract	54.7%	55.4%	56.7%	57.4%	59.6%
	3.7	7.1	3.5	6.8	3.3
Corticosteroids	51.8%	51.6%	52.1%	52.8%	52.8%
	5.6	10.9	5.6	11.5	5.8

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

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Source: Santen analysis based on IMS data

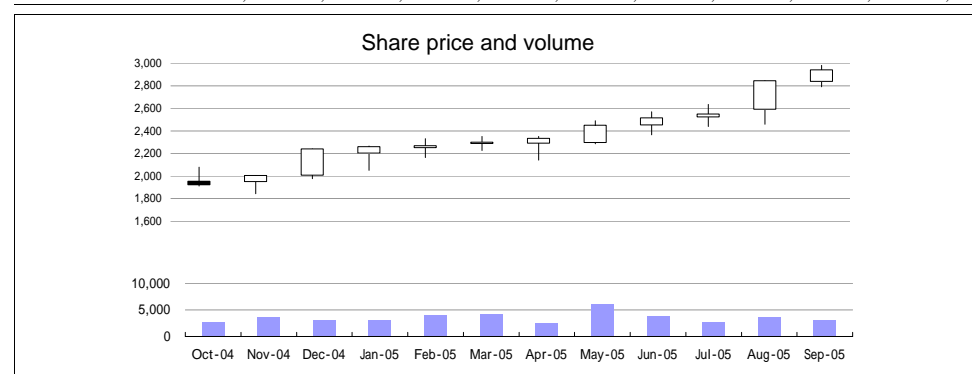
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Stock information

Stock price (Osaka Securities Exchange 1st market)

(Yen and thousand shares)

	Oct-04	Nov-04	Dec-04	Jan-05	Feb-05	Mar-05	Apr-05	May-05	Jun-05	Jul-05	Aug-05	Sep-05
Share price:												
Open	1,955	1,950	2,005	2,200	2,250	2,285	2,290	2,295	2,450	2,520	2,590	2,835
High	2,080	2,005	2,240	2,265	2,330	2,350	2,350	2,490	2,570	2,635	2,845	2,980
Low	1,911	1,843	1,976	2,050	2,165	2,225	2,140	2,285	2,365	2,440	2,460	2,790
End of month	1,920	2,005	2,240	2,260	2,270	2,300	2,335	2,450	2,515	2,550	2,845	2,940
Volume	2,661	3,611	3,122	3,069	3,989	4,264	2,541	5,995	3,848	2,745	3,608	3,204



Major shareholders

As of September 30, 2005

Name	Number of shares Held	Percentage of voting rights
	Thousand shares	%
Northern Trust CO.(AVFC) Sub-account American Clients	6,073	7.0
Japan Trustee Service Bank, Ltd.	4,812	5.6
Mita Sangyo Co., Ltd.	4,756	5.5
Japan master Trust and Banking Co., Ltd.	3,881	4.5
The Tokio Marine and Nichido Fire Insurance Co., Ltd.	2,668	3.1
Nippon Life Insurance Company	2,661	3.1
Trust and Custody Services Bank, Ltd.	2,610	3.0
Northern Trust CO. AVFC Re U.S. tax exempted Pension Funds	2,591	3.0
UFJ Bank Limited	2,148	2.5
The Bank of Tokyo-Mitsubishi, Ltd.	2,148	2.5

Shares and stock option

At half-year/year end	3/2001	3/2002	3/2003	3/2004	3/2005	9/2005
Number of shares outstanding (thousand shares)	92,720	90,704	90,704	87,963	86,658	86,696
Stock option balance (thousand shares)	199	243	335	472.6	504.3	596.2
Granted in June 1998 - 106 thousand shares at 1,540 yen/share	73	62	62	62	35	29
Granted in June 1999 - 66 thousand shares at 2,480 yen/share	66	66	66	66	66	66
Granted in June 2000 - 60 thousand shares at 2,705 yen/share	60	60	60	60	60	60
Granted in June 2001 - 55 thousand shares at 2,299 yen/share	-	55	55	55	55	53
Granted in June 2002 - 92 thousand shares at 1,326 yen/share	-	-	92	92	72.5	67.6
Granted in June 2003 - 137.6 thousand shares at 1,176 yen/share	-	-	-	137.6	137.6	113.2
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

	3/2001	3/2002	3/2003	3/2004	3/2005	9/2005
An extinguished amount of money(millions of yen)	5,084	3,258	-	3,239	2,548	-
The number of the extinguished stocks(thousand stocks)	2,387	2,027	-	2,741	1,351	-

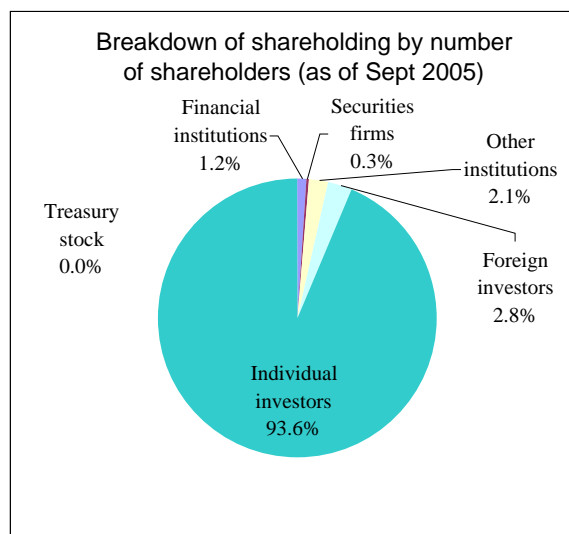
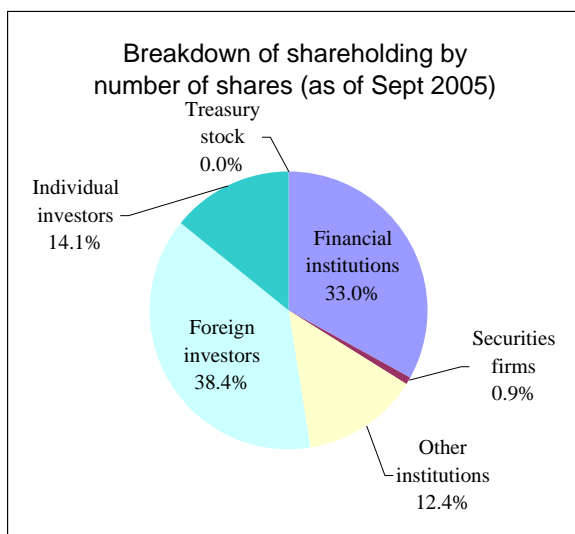
Breakdown of shareholding by number of shares

At half-year/year end	9/2003		3/2004		9/2004		3/2005		9/2005	
	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)
Financial institutions	32,568	35.9	30,740	34.9	31,089	35.33	28,423	32.8	28,597	33.0
City & regional banks	6,592	7.3	5,428	6.2	5,429	6.17	4,636	5.3	4,655	5.4
Trust banks	15,535	17.1	16,201	18.4	16,072	18.2	15,768	18.2	15,790	18.2
(concerned in trust works)	12,371		13,422	0	13,515		13,022		13,290	
Life and non-life insurance	10,012	11.0	9,007	10.2	9,542	10.8	7,973	9.2	8,021	9.3
Other financial institutions	428	0.5	103	0.1	46	0.05	45	0.1	129	0.1
Securities firms	661	0.7	368	0.4	330	0.37	346	0.4	747	0.9
Other institutions	10,585	11.7	10,512	12	10,944	12.44	11,788	13.6	11,779	13.6
Foreign investors	27,593	30.4	31,306	35.6	32,154	36.6	32,874	38	33,259	38.4
Individual investors	16,523	18.2	15,001	17.1	13,430	15.26	13,187	15.2	12,271	14.1
Treasury stock	2,773	3.1	33	0.0	36	0.0	39	0.0	41	0.0
Total	90,704	100.0	87,963	100.0	87,982	100.0	86,658	100.0	86,696	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

At half-year/year end	9/2003		3/2004		9/2004		3/2005		9/2005	
	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)
Financial institutions	88	1.0	83	1.0	86	1.2	91	1.1	99	1.2
City & regional banks	7	0.1	7	0.1	7	0.1	9	0.1	10	0.1
Trust banks	46	0.5	46	0.6	48	0.7	47	0.6	51	0.6
Life and non-life insurance	28	0.3	27	0.3	30	0.4	31	0.4	28	0.4
Other financial institutions	7	0.1	3	0.0	1	0.0	4	0.0	10	0.1
Securities firms	37	0.4	28	0.4	27	0.4	28	0.3	28	0.3
Other institutions	134	1.6	130	1.7	124	1.8	128	1.5	178	2.1
Foreign investors	127	1.5	122	1.5	153	2.2	172	2.0	236	2.8
Individual investors	8,134	95.5	7,498	95.4	6,608	94.4	8,089	95.1	7,844	93.6
Treasury stock	1	0.0	1	0.0	1	0.0	1	0.0	1	0.0
Total	8,521	100.0	7,862	100.0	6,999	100.0	8,509	100.0	8,386	100.0



News releases

News releases during April 2005-October 2005

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 (rivoglitazone) 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.

News releases during April 2005-October 2005

(Date)	(Summary)
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 ophthalmics, construct a manufacturing plant in Suzhou Industrial Park, and establish a direct sales and marketing organization.
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.

