

Reference information

Research & development

Pipeline of prescription pharmaceuticals (Clinical study)

Generic name	Brand name/dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Levofloxacin (0.5%)	Cravit Quixin Ofraqix	Bacterial conjunctivitis	Daiichi Pharmaceutical	Japan						Apr-00
				USA						Nov-00
				Europe						May-02
Levofloxacin (1.5%)	Iquix	Bacterial corneal ulcer	Daiichi Pharmaceutical	USA						Mar-04
Levofloxacin + prednisolone A	DE-094	Infectious keratitis	Daiichi Pharmaceutical	USA						

Characteristics: Fluoroquinolone antibacterial agent. In Europe, Ofraqix has obtained marketing authorization in 11 countries and was launched in five countries including Germany. Iquix is a higher-concentrated fluoroquinolone with potent antibacterial action. 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 Alamast Alamast	Allergic conjunctivitis	Mitsubishi Pharma	Japan						Apr-95
				USA						Jul-00
				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
Sodium hyaluronate	Hyalein Hyalein	Corneal and conjunctival epithelial disorder Dry eye	Original	Japan						Jun-95
				USA					In Preparation	

Characteristics: Ophthalmic solution containing sodium hyaluronate. Treats corneal and conjunctival epithelial disorder associated with dry eye and wearing contact lenses.

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						Aug-03

Characteristics: An orphan drug. Ophthalmic application of immunosuppressant ciclosporin. Expected to treat advanced vernal keratoconjunctivitis for which existing anti-allergic agents are not effective. Because it is an ophthalmic solution, virtually no generalized side effects are noted.

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-based glaucoma treatment that reduces ocular pressure. Clinical trials are being conducted in parallel in Japan, the U.S. and Europe. Expected to have greater efficacy in reducing ocular pressure than other prostaglandin-based glaucoma treatments. 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					In Preparation	

Characteristics: The only angiotensin II receptor antagonist in full-fledged development as a glaucoma treatment. Comparable to prostaglandin-based treatments in reducing intraocular pressure. Very few side effects, including conjunctival hyperemia, are expected. Potentially big market in the U.S. and Europe where patients with ocular-hypertension consist majority of the glaucoma

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 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.

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						

Characteristics: An oral TNF inhibitor. Anti-rheumatic effect comparable to injectable biological agents has been observed in basic research.

Pipeline of prescription pharmaceuticals (In preparation for clinical trials)

Generic name	Brand name/dev. code	Indication	Original/licensor
Gefarnate	DE-099	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Original
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.			
Generic name	Brand name/dev. code	Indication	Original/licensor
(Undetermined)	DE-098 (Anti-APO-1 antibody)	Rheumatoid arthritis	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.			
Generic name	Brand name/dev. code	Indication	Original/in-licensor
Bucillamine	Rimatil	Osteoarthritis (additional indication)	Original

Pipeline of medical devices

Product under development	Product name	Region
Intraocular lens	MD-13	Japan
Characteristics: Foldable intraocular lens using new material. Already launched in Europe by Lenstec and STAAR Surgical.		
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.		

Changes from November 5, 2003

Brand name/dev. code	Indication	Region	Status change
Iquix	Bacterial corneal ulcer	USA	NDA filed to Launched
Tafluprost/DE-085	Glaucoma/ocular hypertension	Japan and USA/Europe	Phase II to Phase III
Olmesartan/DE-092	Glaucoma/ocular hypertension	USA/Europe	In preparation of phase II
Gefarnate/DE-099	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Japan	In preparation for clinical trials

Number of employees in R&D divisions

Year to	2000.3	2001.3	2002.3	2003.3	2004.3
R&D personnel (consolidated)	370	404	482	485	455

Pharmaceutical market

Revision of National Health Insurance (NHI) drug prices

(%)

	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Industry average	-8.1	-	-6.6	-	-6.8	-4.4	-9.7	-	-7.0	-	-6.3	-	-4.2
Ophthalmic drugs	-0.6	-	-1.6	-	-3.5	-1.8	-7.5	-	-6.2	-	-6.0	-	-2.7
Santen	0.9	-	-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)

Year ended March 31	2000	2001	2002	2003	2004
Prescription ophthalmics	44.2%	42.9%	40.3%	38.9%	39.0%
	179.6	189.4	197.1	195.8	194.7
Anti-rheumatic drugs	42.9%	44.9%	42.8%	42.1%	42.5%
	18.2	19.1	20.3	21.1	22.2

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: 1999-2003; Unauthorized copy prohibited

Market shares by therapeutic area - ophthalmic pharmaceuticals

(Billions of yen)

Year ended March 31	2000	2001	2002	2003	2004
Anti-glaucoma	22.4%	19.1%	17.6%	17.3%	16.7%
	55.3	60.2	66.1	69.0	71.7
Anti-infective	77.4%	80.8%	81.8%	80.9%	81.0%
	31.0	31.0	30.2	27.6	26.9
Anti-allergy	31.5%	29.2%	18.2%	17.5%	20.7%
	22.9	26.8	26.5	25.0	20.8
Agents for surgeries	42.4%	41.9%	41.0%	39.6%	39.1%
	17.7	16.0	16.0	14.8	14.5
Corneal disease treatments	89.9%	89.3%	89.0%	85.4%	82.4%
	13.9	15.3	17.2	18.8	21.0
Anti-cataract	43.5%	47.0%	50.1%	53.3%	55.4%
	8.0	7.9	7.7	7.7	7.1
Corticosteroids	55.9%	56.2%	56.0%	53.1%	51.6%
	12.5	12.7	12.5	11.4	10.9

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

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Source: Santen analysis based on IMS data

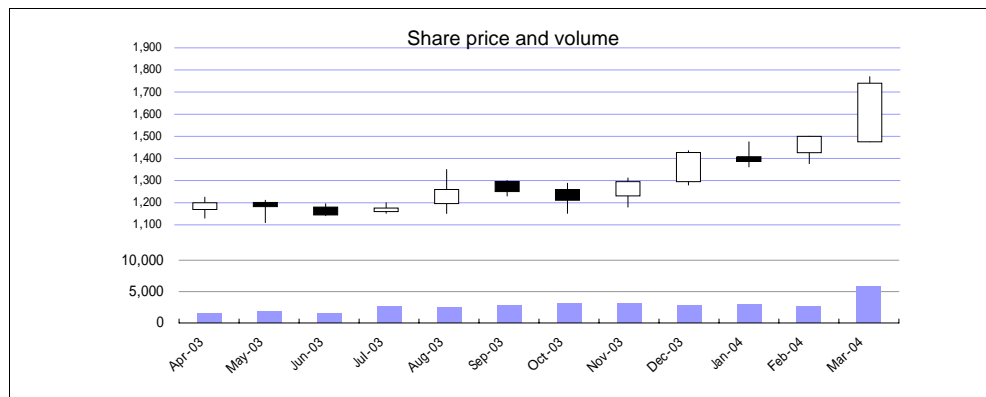
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Stock information

Share price

(Yen and thousand shares)

	Apr-03	May-03	Jun-03	Jul-03	Aug-03	Sep-03	Oct-03	Nov-03	Dec-03	Jan-04	Feb-04	Mar-04
Share price:												
Open	1,169	1,201	1,180	1,160	1,196	1,296	1,260	1,231	1,295	1,408	1,426	1,475
High	1,225	1,211	1,195	1,200	1,350	1,300	1,288	1,312	1,435	1,475	1,501	1,770
Low	1,130	1,110	1,141	1,152	1,151	1,230	1,152	1,180	1,280	1,362	1,376	1,475
End of month	1,200	1,182	1,145	1,176	1,260	1,250	1,211	1,295	1,427	1,386	1,500	1,740
Volume	1,633	1,950	1,545	2,636	2,574	2,774	3,182	3,154	2,886	3,026	2,675	5,930



Major shareholders

As of March 31, 2004

Name	Number of shares Held	Percentage of voting rights
	Thousand shares	%
Northern Trust Company AVFC Sub-account American Clients	11,746	13.4
Japan Trustee Service Bank, Ltd.	5,568	6.3
Japan master Trust and Banking Co., Ltd.	4,807	5.5
Mita Sangyo Co., Ltd.	4,756	5.4
Nippon Life Insurance Company	3,051	3.5
The Tokio Marine and Fire Insurance Co., Ltd.	2,668	3.0
UFJ Bank Limited	2,358	2.7
The Bank of Tokyo-Mitsubishi, Ltd.	2,358	2.7
Trust and Custody Services Bank, Ltd.	2,077	2.4
Royal Trust Corporation of Canada, London-Lending Account	1,691	1.9

Shares, convertible bonds and stock option

Year ended March 31	2000	2001	2002	2003	2004
Number of shares outstanding (thousand shares)	95,074	92,720	90,704	90,704	87,963
Third Unsecured Convertible Bonds -balance (millions of yen)	19,945	19,945	19,945	19,945	-
Stock option balance (thousand shares)	172	199	243	335	472.6
Granted in June 1998 - 106 thousand shares at 1,540 yen/share	106	73	62	62	62
Granted in June 1999 - 66 thousand shares at 2,480 yen/share	66	66	66	66	66
Granted in June 2000 - 60 thousand shares at 2,705 yen/share	-	60	60	60	60
Granted in June 2001 - 55 thousand shares at 2,299 yen/share	-	-	55	55	55
Granted in June 2002 - 92 thousand shares at 1,326 yen/share	-	-	-	92	92
Granted in June 2003 - 137.6 thousand shares at 1,176 yen/share	-	-	-	-	137.6

Note: 1 The company repurchased and retired 2,387 thousand shares in March 2001, 2,027 thousand shares in March 2002 and 2,741 thousand shares in March 2004.

2 The convertible bonds were redeemed on September 30, 2003.

3 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.

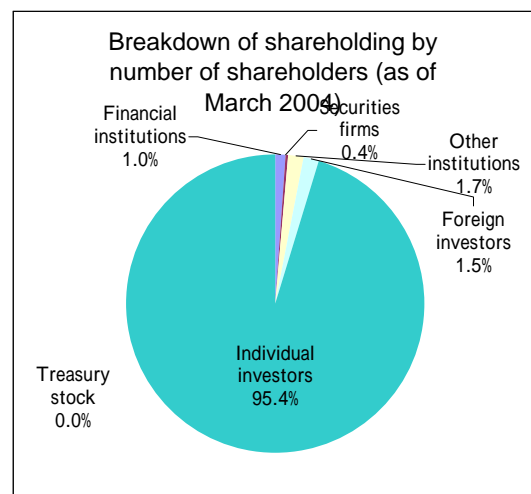
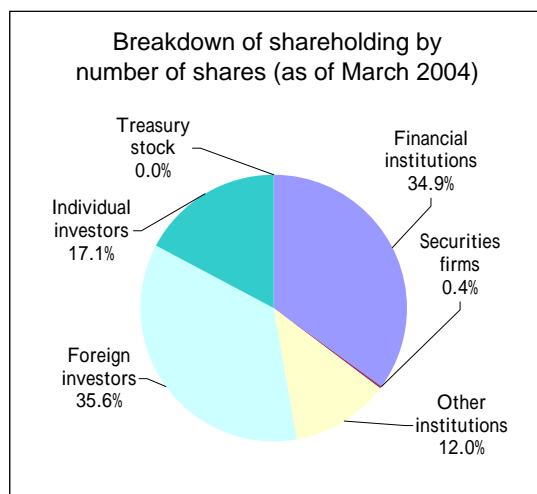
Breakdown of shareholding by number of shares

Year ended March 31	2000		2001		2002		2003		2004	
	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)
Financial institutions	50,099	52.7	52,429	56.5	41,005	45.2	36,302	40.0	30,740	34.9
City & regional banks	14,862	15.6	11,581	12.5	9,054	9.9	6,660	7.3	5,428	6.2
Trust banks	24,853	26.2	29,651	32.0	20,641	22.8	19,018	21.0	16,201	18.4
(concerned in trust works)	22,055		26,824		18,429		15,743		13,422	
Life and non-life insurance	10,255	10.8	11,136	12.0	11,033	12.2	10,414	11.5	9,007	10.2
Other financial institutions	128	0.1	61	0.1	276	0.3	208	0.2	103	0.1
Securities firms	499	0.5	385	0.5	646	0.7	293	0.3	368	0.4
Other institutions	11,497	12.1	10,398	11.2	10,300	11.4	10,555	11.6	10,512	12.0
Foreign investors	18,041	19.0	15,868	17.1	23,675	26.1	24,580	27.1	31,306	35.6
Individual investors	14,915	15.7	13,624	14.7	15,073	16.6	16,200	17.9	15,001	17.1
Treasury stock	23	0.0	18	0.0	2	0.0	2,771	3.1	33	0.0
Total	95,075	100.0	92,721	100.0	90,704	100.0	90,704	100.0	87,963	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	2000		2001		2002		2003		2004	
	Thousand shareholders	Proportion (%)	Thousand shareholders	Proportion (%)	Thousand shareholders	Proportion (%)	Thousand shareholders	Proportion (%)	Thousand shareholders	Proportion (%)
Financial institutions	114	2.2	108	2.2	107	1.8	98	1.2	83	1.0
City & regional banks	15	0.3	15	0.3	13	0.2	8	0.1	7	0.1
Trust banks	60	1.2	57	1.2	60	1.0	55	0.7	46	0.6
Life and non-life insurance	33	0.6	32	0.6	28	0.5	29	0.4	27	0.3
Other financial institutions	6	0.1	4	0.1	6	0.1	6	0.1	3	0.0
Securities firms	20	0.4	22	0.5	35	0.6	28	0.4	28	0.4
Other institutions	140	2.7	132	2.7	137	2.3	134	1.7	130	1.7
Foreign investors	168	3.3	162	3.4	148	2.4	119	1.5	122	1.5
Individual investors	4,679	91.3	4,387	91.2	5,583	92.9	7,493	95.2	7,498	95.4
Treasury stock	1	0.0	1	0.0	1	0.0	1	0.0	1	0.0
Total	5,122	100.0	4,812	100.0	6,011	100.0	7,873	100.0	7,862	100.0



News releases

News releases during April 2003-March 2004

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

- | (Date) | (Summary) |
|---------------|---|
| 8-Apr | Santen Appoints Actor Tetsuji Tamayama as the Latest Spokesperson for <i>Sante FX Neo</i>
Santen appointed actor Tetsuji Tamayama as the latest spokesperson for its over-the-counter eye drop brand <i>Sante FX Neo</i> and began new TV commercials featuring Tamayama. |
| 2-May | "Hitomi Gakuen" Internet Site Enhanced
Santen added information on back-of-the-eye diseases to "Hitomi Gakuen," its Internet educational site for patients. The site now covers all areas of ophthalmology. |
| 6-May | Santen Submits New Drug Application to FDA for Levofloxacin 1.5%
Santen submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for levofloxacin 1.5% on April 30. Levofloxacin 1.5% is a higher concentration formulation of Santen's anti-infective ophthalmic <i>Quixin</i> (Brand name in Japan: <i>Cravit</i>). |
| 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 91st Annual General Meeting of Shareholders held on June 26. |
| 9-May | Change of Accounting Auditors
The division of Shin Nihon & Co. that has been responsible for auditing Santen's financial

substantially maintain Santen's current auditing structure, Santen appointed AZSA & Co. as its new accounting auditor. |
| 9-May |
Santen's Board of Directors resolved to shorten the office term of directors from two years to one and appoint Dr. Kosei Furukawa as the Outside Director. The resolution was approved at the 91st Annual General Meeting of Shareholders held on June 26. |
| 9-May | Notice Regarding Share Buyback
Santen's Board of Directors resolved the buyback of its common stock with par value up to 4,000,000 shares and 5,000 million yen. This was approved in the 91st Annual General Meeting of Shareholders held on June 26, 2002. |
| 11-Aug | Treatment, Ciclosporin Ophthalmic Solution
Santen applied for manufacturing approval for its vernal keratoconjunctivitis treatment, ciclosporin ophthalmic solution (generic name) in Japan on August 8. The drug is expected to treat advanced |
| 28-Aug | Santen Establishes Helpline of Compliance Practice
As part of Santen's effort in strengthening corporate governance, Santen established a helpline for its |
| 5-Sep | Santen Announces Closure of its U.S. Subsidiary, Phacor Inc.
Santen decided not to invest further in Phacor Inc., its U.S. subsidiary specializing in the research and development of phacoemulsification machines. |

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- (Date) (Summary)
- 18-Sep Santen Establishes the SAIN Sales Force Automation System**
In order to more effectively share information and raise the quality and efficiency of medical representative (MR)'s activities, Santen implemented a Sales Force Automation system for MRs and named it SAIN (Santen Activity Improved Navigator).
- 18-Dec Prescription Ophthalmic Products**
Santen announced a U.S. distribution and supply agreement with Johnson & Johnson Vision Care, Inc. (JJVCI) for three prescription ophthalmic pharmaceutical agents. During first quarter 2004, JJVCI will become the exclusive U.S. distributor for the following Santen products: QUIXIN®

(pemirolast potassium ophthalmic solution).
- 22-Dec Santen Reorganizes Domestic Sales Operation**
Santen introduced the "Satellite Office System" and the "Centralized Sales Administration System" for its Japanese sales operation. The reorganization was implemented as a means to achieve the objectives set in the 2003-2005 Medium-term Management Plan to "Improve Profitability" and "Reinforce Organizational Strength."
- 2-Mar Condition**
The U.S. Food and Drug Administration (FDA) has approved Santen's new ocular anti-infective medication, IQUIX (levofloxacin ophthalmic solution) 1.5%, indicated for the treatment of bacterial
- 10-Mar Revision of Performance Forecast**
As a result of evaluating the fair market value of a U.S. subsidiary, Santen Holdings U.S. Inc. (SHUSI), Santen will write down SHUSI's shares and record an extraordinary loss of 3,000 million yen on the write down. Accordingly, Santen reduced the company forecast of its non-consolidated
- 10-Mar Santen to Retire Treasury Stock**
On March 16, Santen retired the 2,741,000 shares of its common stock, which it had repurchased on
- 10-Mar Santen Announces Proposed Dividends Change**
Santen has now decided to place greater importance on cash dividends as a means of returning profits to shareholders and thus plans to increase the annual cash dividends to 40 yen. The resolution will be submitted for, and subject to, approval at the company's Annual General Meeting of Shareholders to be held in June 2004.