

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 Sankyo	Japan						Apr-00
	Quixin			USA						Nov-00
	Oftaquix			Europe						May-02
Levofloxacin + prednisolone A	DE-094	Infectious keratitis	Daiichi Sankyo	USA						

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

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				Jul-06		
				Europe					Apr-08	
				USA						

Characteristics: Prostaglandin derivative treatment for glaucoma and ocular hypertension. In Japan, a comparison study demonstrated its non-inferiority to latanoprost and we filed for manufacturing and marketing approval for glaucoma and ocular hypertension. In Europe, applied for approval in April, 2007 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 April 2008, the first national approval was granted in Denmark. 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						

Characteristics: A treatment for corneal and conjunctival epithelial disorder mostly associated with dry eye, etc. that stimulates the ocular surface to secrete tear fluid and components. Expected to be used in combination with existing 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	Daiichi Sankyo	Japan						
				USA/Europe		pilot study				

Characteristics: The angiotensin II receptor antagonist. In Japan, Europe and the USA, the Phase II studies did not demonstrate clear dose-response, and therefore we decided to suspend clinical studies. We are now conducting the phase II pilot study in Europe with different formulation.

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 development as a glaucoma treatment. Compared with NMDA receptor antagonists, fewer systemic side effects are expected, thus having excellent safety. Marketed by Nippon Organon as a migraine treatment.

Generic name (USA)	Dev. code	Indication	Original/in-licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Rivoglitazone	DE-101	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Daiichi Sankyo	USA						

Characteristics: It is expected to show a potent effect on corneal and conjunctival epithelial disorder mostly associated with dry eye, etc. 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 Daiichi Sankyo as an oral anti-diabetic drug in the USA.

Generic name (USA)	Dev. code	Indication	Original/in-licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-102	Diabetic Macular Edema	Co-development with Oakwood (USA)	Japan		(Phase I / IIa)				

Characteristics: A steroid microsphere product for a sustained release injection. Animal studies demonstrated sustained efficacy when injected around the injected 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	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-103	Allergic conjunctivitis	Ono Pharmaceutical	Japan						

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	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-104	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	USA						
				Japan						

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 meshwork cells.

*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.

Reference information

Research & development

■ 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.			

■ License out

Dev. code	Indication	Licensee	Status	in-licensor
DE-098 (Anti-APO-1 antibody)	Rheumatoid arthritis	Argenes	Phase I / IIa	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. Santen granted the domestic development rights to Argenes, Inc. The compound had been in-licensed from Centocor. In Japan and Europe, the clinical study has been started. Santen continues to hold the marketing rights in Japan and the overseas marketing and development rights.				

■ Changes from November 2, 2007

[Progress]

Dev. code	Indication	Status change	Clinical trial, NDA filing, Launch Region
DE-103	Allergic conjunctivitis	Phase I to Phase II	Japan
DE-104	Glaucoma/ Ocular hypertension	Phase I to Phase II	USA and Japan

[Discontinued study]

Dev. code	Indication	Clinical trial Region	Status before cancellation
DE-099	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Japan	Phase II
Discontinued due to the unexpected need for large-scale clinical trials in the next phase, which would not be cost-effective.			

*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.

Pharmaceutical market in Japan

■ Revision of National Health Insurance (NHI) drug prices

(%)

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Industry average	-6.8	-4.4	-9.7	—	-7.0	—	-6.3	—	-4.2	—	-6.7	—	early -5%
Ophthalmic drugs	-3.5	-1.8	-7.5	—	-6.2	—	-6.0	—	-2.7	—	-5.5	—	late -3%
Santen	-2.6	-1.3	-7.2	—	-5.7	—	-6.0	—	-3.2	—	-5.3	—	mid -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
October	2006	Increased contribution for seniors (from the age of 70) who have a certain amount of income (20% to 30%)
April	2008	Change in prescription format in order to promote usage of generic drugs (the prescribing doctor's signature and seal are required in case the use of a generic drug is not recommended). Revised dispensing fee (basic dispensing fee was decreased from 42 points to 40 points; however, 4 points will be added in cases where 30% of total prescription drugs dispensed by a pharmacy are generic drugs.) Revised medical fee (ophthalmic drugs, eye wash, monocus will be included in basic medical fee). Unifying "medical insurance for patients over 75 years old" into "medical insurance system for late stage elderly population (long-life medical insurance system)."

■ Market shares

(Billions of yen)

Year ended March 31	2004	2005	2006	2007	2008
Prescription ophthalmics	39.0%	39.6%	40.9%	39.7%	38.9%
	194.7	207.7	213.1	214.4	221.0
Anti-rheumatic drugs	42.5%	42.9%	45.2%	46.3%	46.1%
	22.2	23.3	23.8	23.2	24.1

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

- Anti-rheumatic drugs exclude immunosuppressants and biologic agents.

Copyright IMS Japan KK, 2008

Source: Santen analysis based on IMS data(JPM)

Period: 2003.4-2008.3; Unauthorized copy prohibited

■ Market shares by therapeutic area - prescription ophthalmics

(Billions of yen)

Year ended March 31	2004	2005	2006	2007	2008
Anti-glaucoma	16.7%	20.0%	23.2%	22.1%	20.8%
	71.7	74.9	79.0	79.9	83.1
Anti-infective	81.0%	80.3%	78.3%	76.1%	73.5%
	26.9	26.5	26.7	25.9	25.6
Anti-allergy	20.7%	22.4%	24.8%	24.3%	22.7%
	20.8	28.4	24.6	24.7	25.4
Agents for surgeries	39.1%	41.0%	42.6%	42.8%	43.0%
	14.5	13.6	14.4	14.1	15.1
Corneal disease treatments	82.4%	81.0%	80.7%	79.3%	78.7%
	21.0	23.0	25.5	26.4	28.8
Anti-cataract	55.4%	57.4%	60.3%	62.6%	66.2%
	7.1	6.8	6.5	6.3	6.1
Corticosteroids	51.6%	52.8%	52.6%	51.4%	51.3%
	10.9	11.5	11.2	10.8	10.6

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

Copyright IMS Japan KK, 2008

Source: Santen analysis based on IMS data(JPM)

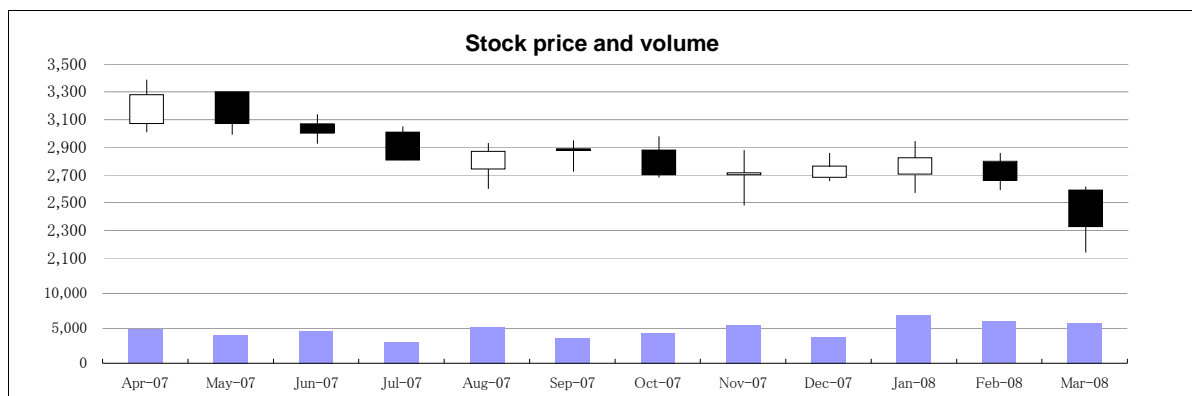
Period: 2003.4-2008.3; Unauthorized copy prohibited

Stock information

■ Stock price (Osaka Securities Exchange 1st market)

(Yen and thousand shares)

	Apr-07	May-07	Jun-07	Jul-07	Aug-07	Sep-07	Oct-07	Nov-07	Dec-07	Jan-08	Feb-08	Mar-08
Stock price:												
Open	3,070	3,300	3,070	3,010	2,740	2,890	2,880	2,700	2,680	2,705	2,800	2,590
High	3,390	3,300	3,140	3,050	2,930	2,950	2,980	2,880	2,860	2,945	2,860	2,615
Low	3,010	2,990	2,925	2,805	2,600	2,725	2,680	2,480	2,655	2,570	2,590	2,140
End of month	3,280	3,070	3,000	2,805	2,870	2,875	2,700	2,715	2,765	2,825	2,660	2,325
Volume	4,855	4,081	4,567	3,135	5,161	3,621	4,339	5,471	3,827	6,859	6,027	5,805



■ Major shareholders

As of March 31, 2008

Name	Number of shares held	Percentage of investment
	Thousand shares	%
Japan Trustee Services Bank, Ltd.	7,027	8.1
Mita Sangyo Co., Ltd.	4,756	5.5
The Master Trust Bank of Japan, Ltd.	4,420	5.1
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	4,241	4.9
Northern Trust CO. (AVFC) Sub-account American Clients	3,972	4.6
Nippon Life Insurance Company	3,151	3.6
Trust & Custody Services Bank, Ltd.	3,002	3.5
The Silchester International Investors International Value Equity Trust	2,736	3.1
Tokio Marine & Nichido Fire Insurance Co., Ltd.	2,668	3.1
Mitsubishi UFJ Trust and Banking Corporation	1,907	2.2

■ Stock option

Year ended March 31	2004	2005	2006	2007	2008
Stock option balance (thousand shares)	472.6	504.3	541	569.6	627.5
Granted in June 1998 - 106 thousand shares at 1,540 yen/share	62	35	27	24	24
Granted in June 1999 - 66 thousand shares at 2,480 yen/share	66	66	57.3	48	37
Granted in June 2000 - 60 thousand shares at 2,705 yen/share	60	60	58	48.2	46.2
Granted in June 2001 - 55 thousand shares at 2,299 yen/share	55	55	42.6	38.6	38.6
Granted in June 2002 - 92 thousand shares at 1,326 yen/share	92	72.5	53.7	32.1	30.9
Granted in June 2003 - 137.6 thousand shares at 1,176 yen/share	137.6	137.6	95	72.9	55.2
Granted in June 2004 - 78.2 thousand shares at 1,743 yen/share	—	78.2	78.2	73.9	66.1
Granted in June 2005 - 129.2 thousand shares at 2,480 yen/share	—	—	129.2	129.2	127.5
Granted in June 2006 - 102.7 thousand shares at 2,715 yen/share	—	—	—	102.7	102.7
Granted in June 2007 - 99.3 thousand shares at 3,050 yen/share	—	—	—	—	99.3

■ Purchase of Treasury stock

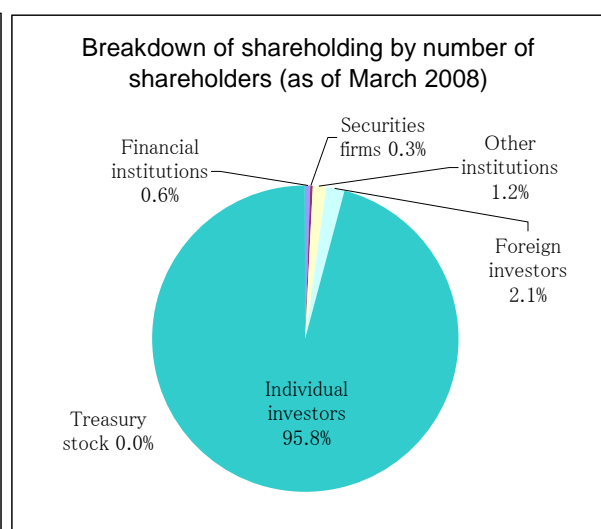
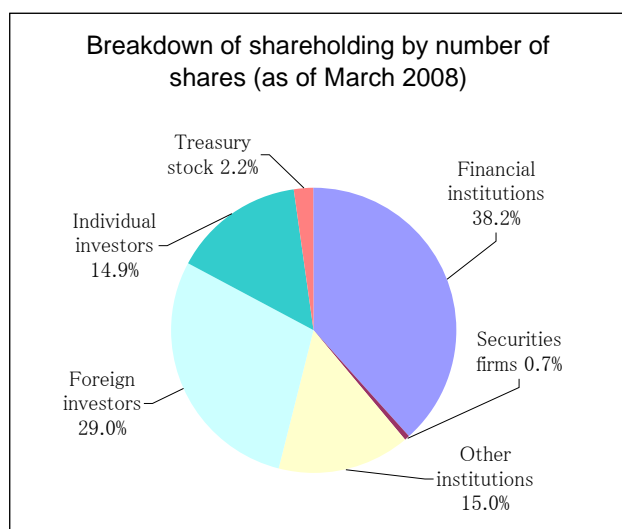
	2004	2005	2006	2007	2008
A purchased amount of money (millions of yen)	—	2,569	—	—	4,800
The number of the purchased stocks (thousand shares)	—	1,351	—	—	1,833

■ Breakdown of shareholding by number of shares

Year ended March 31	2004		2005		2006		2007		2008	
	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)
Financial institutions	30,740	34.9	28,423	32.8	29,514	34.0	30,366	35.0	33,186	38.2
City & regional banks	5,428	6.2	4,636	5.3	4,659	5.4	4,628	5.3	4,907	5.6
Trust banks	16,201	18.4	15,768	18.2	16,577	19.1	17,049	19.6	19,133	22.0
(concerned in trust works)	13,422		13,022		14,039		14,538		16,680	
Life and non-life insurance	9,007	10.2	7,973	9.2	8,004	9.2	8,470	9.8	8,924	10.3
Other financial institutions	103	0.1	45	0.1	274	0.3	217	0.3	221	0.3
Securities firms	368	0.4	346	0.4	865	1.0	1,486	1.7	585	0.7
Other institutions	10,512	12.0	11,788	13.6	11,823	13.6	12,375	14.2	13,014	15.0
Foreign investors	31,306	35.6	32,874	38.0	31,519	36.3	31,024	35.7	25,227	29.0
Individual investors	15,001	17.1	13,187	15.2	12,985	15.0	11,521	13.3	12,963	14.9
Treasury stock	33	0.0	39	0.0	45	0.1	50	0.1	1,888	2.2
Total	87,963	100.0	86,658	100.0	86,751	100.0	86,825	100.0	86,866	100.0

■ Breakdown of shareholding by number of shareholders

Year ended March 31	2004		2005		2006		2007		2008	
	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)
Financial institutions	83	1.0	91	1.1	107	0.8	88	0.9	88	0.6
City & regional banks	7	0.1	9	0.1	10	0.1	7	0.1	14	0.1
Trust banks	46	0.6	47	0.6	52	0.4	44	0.4	30	0.2
Life and non-life insurance	27	0.3	31	0.4	32	0.2	26	0.3	29	0.2
Other financial institutions	3	0.0	4	0.0	13	0.1	11	0.1	15	0.1
Securities firms	28	0.4	28	0.3	31	0.2	37	0.4	38	0.3
Other institutions	130	1.7	128	1.5	236	1.7	133	1.3	150	1.2
Foreign investors	122	1.5	172	2.0	255	1.9	306	3.0	268	2.1
Individual investors	7,498	95.4	8,089	95.1	12,927	95.4	9,451	94.4	12,568	95.8
Treasury stock	1	0.0	1	0.0	1	0.0	1	0.0	1	0.0
Total	7,862	100.0	8,509	100.0	13,557	100.0	10,016	100.0	13,113	100.0



News releases

News releases during April 2007-March 2008

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

- | (Date) | (Summary) |
|---------------|--|
| 2007 | |
| 2-Apr | Santen to open its Shenyang Representative Office
Santen opened its Shenyang Representative Office in China on April 1, 2007. The new Shenyang office will serve the Northeastern China centering on Shenyang, enabling Santen to distribute its drug information and gather information on the medical needs accurately and timely in this region. |
| 3-Apr | Santen Oy submits Marketing Approval for Glaucoma and Ocular Hypertension Drug Candidate DE-085 (INN: Tafluprost)
Santen Oy, a wholly owned subsidiary in Finland, Tampere, submitted the marketing authorization application for glaucoma and ocular hypertension treatment DE-085 (INN: Tafluprost) to 13 countries in Europe on April 2, 2007 (Europe time). DE-085 is a prostaglandin drug candidate being studied for the reduction of intraocular pressure in primary open angle glaucoma and ocular hypertension. |
| 9-Apr | Santen to launch OTC Eye Drop Sante Uruoi Contact a
Santen launched an artificial tear type OTC eye drop Sante Uruoi Contact a on April 9, 2007. Sante Uruoi Contact a moistens your contact lenses and relieves dryness and discomfort caused by contact lenses. Both increasing the moistness of the eyes, and being mild to the eyes are high needs among users. |
| 8-May | Introduction of Countermeasures to Large-scale Purchases of the Corporation's Shares (Takeover Defense Measures)
Santen's Board of Directors on May 8, 2007 determined the specific content of the Countermeasures to Large-scale Purchases of the Corporation's Shares (Takeover Defense Measures). The content was approved at the 95th Annual General Meeting of Shareholders held on June 26, 2007. |
| 10-May | Santen to Issue Stock Acquisition Rights to the Directors
Santen to Issue Stock Acquisition Rights to the Corporate Officers
Santen's Board of Directors on May 8, 2007 adopted a resolution to issue rights to subscribe for new shares as stock options without consideration to Santen directors and corporate officers. The resolution was approved at the 95th Annual General Meeting of Shareholders held on June 26, 2007. |
| 22-May | Extension of Nara Research and Development Center
Santen's Board of Directors on May 22, 2007 determined that Santen would invest more in its laboratories at the Nara Research and Development Center (Ikoma City, Nara). Through the additional investment in R&D center, a Pharmaceutical development building and an Ancillary building will be constructed in order to integrate non-clinical functions and to secure space for R&D staff increase. This will enhance the changes to generate new drug candidates. |

(Date)	(Summary)
2007	
2-Oct	Santen to Redesign Sante de U Plus E Alfa Package Santen launched an over-the-counter eye drop Sante de U plus E alfa with a new package design on October 10, 2007. Sante de U plus E alfa relieves eyestrain and improves blurred vision and focus adjustment by facilitating the flow of blood and supporting nutrition. Sante de U plus E alfa is also effective in itchy eye and inflammation.
2-Nov	Agreement Concerning Glaucoma and Ocular Hypertension Treatment RESCULA® Eye Drops R-Tech Ueno, Ltd. (Chiyoda-ku, Tokyo, Japan) and Santen Pharmaceutical Co., Ltd. (Osaka, Japan) have reached a basic agreement to extend the exclusive marketing rights in Japan for RESCULA® Eye Drops (generic name: isopropyl unoprostone). Since the current contract is to expire in September, 2008, the companies were pursuing negotiations on the contract renewal and reached the basic agreement today. Accordingly, Santen continues to hold the exclusive marketing rights in Japan for RESCULA® beyond October 2008.
2008	
11-Jan	Santen to Launch Nutritional Supplement Sante Lutax Santen Pharmaceutical Co., Ltd. launched nutritional supplement Sante Lutax 20 and Sante Lutax 15 plus vitamin & mineral for the Japanese market. Sante Lutax is developed based on the research of Japanese dietary life and it aims to support doctor's dietary instruction to their patients.
30-Jan	Santen to Purchase Own Shares Santen's Board of Directors on January 30, 2008 adopted a resolution to purchase own shares up to 1,850,000 shares and 5,000,000,000 yen.
25-Feb	Santen to Lift Condition for Approval of PAPILOCK Mini Ophthalmic Solution 0.1% Santen Pharmaceutical Co., Ltd. have announced that the conditions for the approval of vernal keratoconjunctivitis treatment PAPILOCK Mini ophthalmic solution 0.1% (generic name: ciclosporin) has been lifted. This was reported by the First Committee on New Drugs, the Pharmaceutical Affairs and Food Sanitation Council, the Ministry of Health, and Labor & Welfare on February 22, 2008.
26-Mar	Notice Regarding the Completion of Purchase of the Company's Own Shares in the Market The stock acquisition, decided at the Board of Directors meeting held on January 30, 2008, has been completed through the buy back of 1,833,800 shares and its cost of 4,800,509,500 yen.