

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. 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			In preparation			
				USA						

Characteristics: Prostaglandin glaucoma treatment for 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, 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						

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		In preparation				

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 (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.	Sankyo	USA						

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.

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	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	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	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 acrylic material with high refractive index. Developed by U.S. subsidiary Advanced Vision Science, Inc. Approved in October, 2006 in Japan. Preparing for NDA filing 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 May 9, 2006

[Progress]

Dev. code	Indication	Status change	Clinical trial, NDA filing, Launch Region
DE-085	Glaucoma/ ocular hypertension	In preparation for NDA filing to filed NDA	Japan
DE-089	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	In preparation for phase III to Phase III	Japan
DE-099	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Phase I to in preparation for Phase II	Japan
DE-101	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	In preparation for phase I to Phase I	USA

Product under development	Product name	Status change	Clinical trial, NDA filing, Launch Region
Intraocular lens	MD-14	NDA filed to Approved	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)

Half year/year to	9/2004	3/2005	9/2005	3/2006	9/2006
Prescription ophthalmics	39.4% 100.3	39.6% 207.7	41.5% 107.0	40.9% 213.1	40.9% 105.7
Anti-rheumatic drugs	42.4% 11.7	42.9% 23.3	45.1% 12.0	45.2% 23.8	46.3% 11.7

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: April 2004-Sept 2006; Unauthorized copy prohibited

Market shares by therapeutic area - prescription ophthalmics

(Billions of yen)

Half year/year to	9/2004	3/2005	9/2005	3/2006	9/2006
Anti-glaucoma	16.3% 37.6	20.0% 74.9	23.4% 39.7	23.2% 79.0	22.3% 39.9
Anti-infective	81.2% 14.1	80.3% 26.5	78.4% 14.1	78.3% 26.7	76.7% 13.7
Anti-allergy	23.4% 9.7	22.4% 28.4	25.7% 11.4	24.8% 24.6	27.8% 9.7
Agents for surgeries	39.9% 6.8	41.0% 13.6	42.8% 7.2	42.6% 14.4	42.9% 7.1
Corneal disease treatments	81.2% 11.4	81.0% 23.0	80.7% 12.5	80.7% 25.5	79.5% 13.1
Anti-cataract	56.7% 3.6	57.4% 6.8	59.6% 3.3	60.3% 6.5	61.9% 3.2
Corticosteroids	52.1% 5.6	52.8% 11.5	52.8% 5.8	52.6% 11.2	51.6% 5.5

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

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Source: Santen analysis based on IMS data

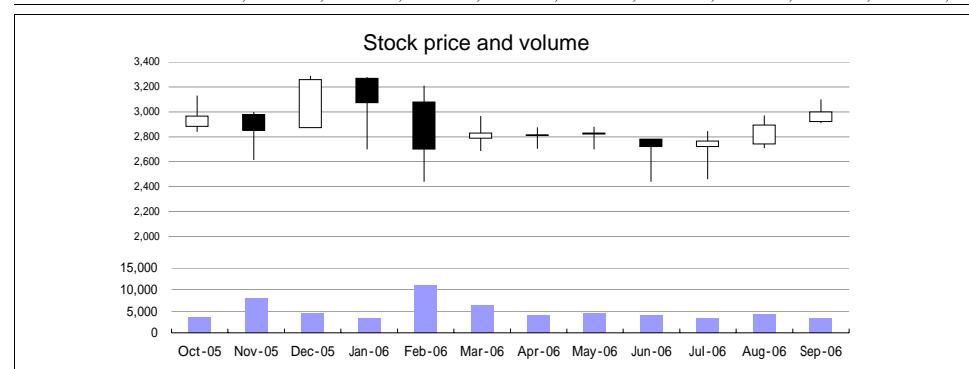
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Stock information

Stock price (Osaka Securities Exchange 1st market)

(Yen and thousand shares)

	Oct-05	Nov-05	Dec-05	Jan-06	Feb-06	Mar-06	Apr-06	May-06	Jun-06	Jul-06	Aug-06	Sep-06
Stock price:												
Open	2,880	2,980	2,870	3,270	3,080	2,785	2,810	2,830	2,780	2,720	2,740	2,920
High	3,130	3,000	3,290	3,280	3,210	2,965	2,875	2,880	2,780	2,845	2,970	3,100
Low	2,840	2,615	2,870	2,700	2,440	2,685	2,705	2,700	2,440	2,460	2,710	2,910
End of month	2,965	2,850	3,260	3,070	2,700	2,830	2,815	2,820	2,720	2,765	2,895	3,000
Volume	3,664	7,979	4,545	3,241	10,887	6,326	4,103	4,537	4,166	3,321	4,276	3,243



Major shareholders

As of September 30, 2006

Name	Number of shares Held	Percentage of voting rights
	Thousand shares	%
Northern Trust CO.(AVFC) Sub-account American Clients	8,024	9.2
Japan Trustee Service Bank, Ltd.	5,493	6.3
Japan master Trust and Banking Co., Ltd.	5,216	6.0
Mita Sangyo Co., Ltd.	4,756	5.5
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	4,296	5.0
Trust and Custody Services Bank, Ltd.	2,794	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	1,992	2.3
Mellon Bank, N.A. As Agent For Its Client Mellon Omnibus		
US Pension	1,704	2.0

Shares and stock option

At half-year/year end	3/2002	3/2003	3/2004	3/2005	3/2006	9/2006
Number of shares outstanding (thousand shares)	90,704	90,704	87,963	86,658	86,751	86,781
Stock option balance (thousand shares)	243	335	472.6	504.3	541	613.7
Granted in June 1998 - 106 thousand shares at 1,540 yen/share	62	62	62	35	27	24
Granted in June 1999 - 66 thousand shares at 2,480 yen/share	66	66	66	66	57.3	57
Granted in June 2000 - 60 thousand shares at 2,705 yen/share	60	60	60	60	58	55
Granted in June 2001 - 55 thousand shares at 2,299 yen/share	55	55	55	55	42.6	39.6
Granted in June 2002 - 92 thousand shares at 1,326 yen/share	-	92	92	72.5	53.7	49
Granted in June 2003 - 137.6 thousand shares at 1,176 yen/share	-	-	137.6	137.6	95	83.3
Granted in June 2004 - 78.2 thousand shares at 1,743 yen/share	-	-	-	78.2	78.2	73.9
Granted in June 2005 - 129.2 thousand shares at 2,480 yen/share	-	-	-	-	129.2	129.2
Granted in June 2006 - 102.7 thousand shares at 2,715 yen/share	-	-	-	-	-	102.7

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

	3/2002	3/2003	3/2004	3/2005	3/2006	9/2006
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	-	-

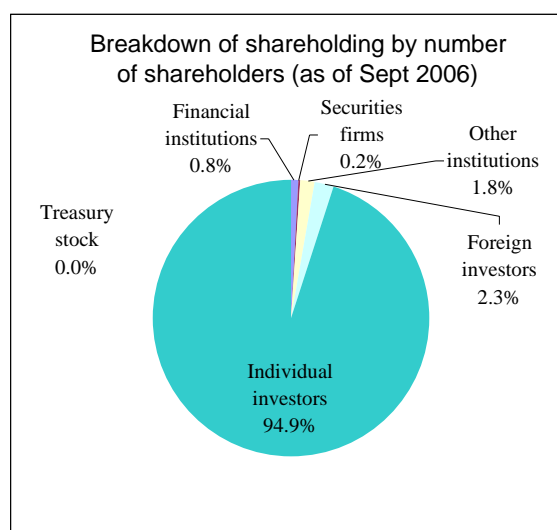
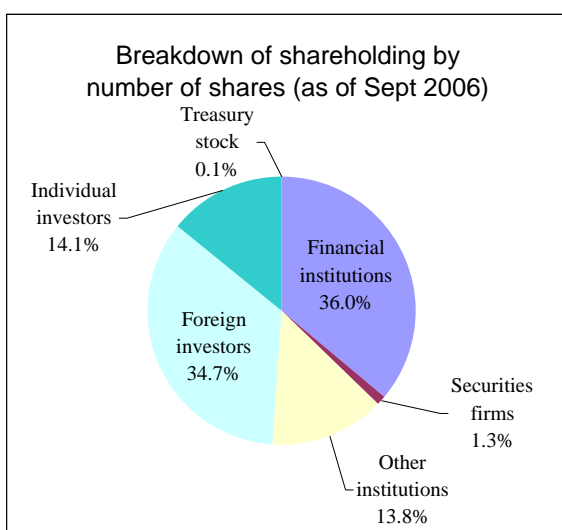
Breakdown of shareholding by number of shares

At half-year/year end	9/2004		3/2005		9/2005		3/2006		9/2006	
	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)
Financial institutions	31,089	35.3	28,423	32.8	28,597	33.0	29,514	34.0	31,242	36.0
City & regional banks	5,429	6.2	4,636	5.3	4,655	5.4	4,659	5.4	4,646	5.3
Trust banks	16,072	18.2	15,768	18.2	15,790	18.2	16,577	19.1	18,561	21.4
(concerned in trust works)	13,515		13,022		13,290		14,039		16,049	
Life and non-life insurance	9,542	10.8	7,973	9.2	8,021	9.3	8,004	9.2	7,898	9.1
Other financial institutions	46	0.1	45	0.1	129	0.1	274	0.3	135	0.2
Securities firms	330	0.4	346	0.4	747	0.9	865	1.0	1,129	1.3
Other institutions	10,944	12.4	11,788	13.6	11,779	13.6	11,823	13.6	11,989	13.8
Foreign investors	32,154	36.6	32,874	38.0	33,259	38.4	31,519	36.3	30,085	34.7
Individual investors	13,430	15.3	13,187	15.2	12,271	14.1	12,985	15.0	12,286	14.1
Treasury Stock	36	0.0	39	0.0	41	0.0	45	0.1	46	0.1
Total	87,982	100.0	86,658	100.0	86,696	100.0	86,751	100.0	86,781	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	9/2004		3/2005		9/2005		3/2006		9/2006	
	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)
Financial institutions	86	1.2	91	1.1	99	1.2	107	0.8	97	0.8
City & regional banks	7	0.1	9	0.1	10	0.1	10	0.1	8	0.1
Trust banks	48	0.7	47	0.6	51	0.6	52	0.4	49	0.4
Life and non-life insurance	30	0.4	31	0.4	28	0.4	32	0.2	27	0.2
Other financial institutions	1	0.0	4	0.0	10	0.1	13	0.1	13	0.1
Securities firms	27	0.4	28	0.3	28	0.3	31	0.2	27	0.2
Other institutions	124	1.8	128	1.5	178	2.1	236	1.7	214	1.8
Foreign investors	153	2.2	172	2.0	236	2.8	255	1.9	276	2.3
Individual investors	6,608	94.4	8,089	95.1	7,844	93.6	12,927	95.4	11,348	94.9
Treasury stock	1	0.0	1	0.0	1	0.0	1	0.0	1	0.0
Total	6,999	100.0	8,509	100.0	8,386	100.0	13,557	100.0	11,963	100.0



News releases

News releases during April 2006-September 2006

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

- | (Date) | (Summary) |
|---------------|--|
| 2006 | |
| 14-Apr | Announcement of Change of Representative Directors
At the meeting of the Board of Directors held on June 27, 2006, Takakazu Morita was elected as Representative Director, Chairman and Chief Executive Officer; and Akira Kurokawa as Representative Director, President and Chief Operating Officer. They all assumed their offices. |
| 9-May | Joint Development of ROCK Inhibitor for Glaucoma and Ocular Hypertension Drug Candidate
Santen and Ube Industries, Ltd. reached a basic agreement to jointly develop ROCK inhibitor (development code: DE-104) as an agent for glaucoma and ocular hypertension, for which they discovered an application possibility for ophthalmic treatment in joint research. DE-104 is considered to have a different action mechanism from any other existing anti-glaucoma agents. And it is expected to show potent intraocular pressure lowering effect by facilitating aqueous humor outflow from the main route among multiple routes. |
| 9-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 adopted a resolution to issue rights to subscribe for new shares without consideration to Santen's directors and corporate officers. The resolution was approved at the 94th Annual General Meeting of Shareholders held on June 27, 2006. |
| 25-Jul | 2006-2010 Medium-term Management Plan
Santen formulated its five-year management plan for the period FY2006 to 2010. The basic policies of the Plan are to develop new drug candidates and to generate growth in promising regions by leveraging Santen's strength in global development. As a step to become a leading global ophthalmic company in the coming decade, Santen will actively address the following goals during the medium-term management plan: enhancement of the global strategic product pipeline; growth in Japan as well as in Northern/Eastern Europe, Russia and China; and a focus on clinical and business development in the U.S. |
| 1-Aug | Santen Files for Manufacturing and Marketing Approval for its Glaucoma and Ocular Hypertension Drug Candidate DE-085 (INN: Tafluprost)
Santen applied manufacturing and marketing approval for its glaucoma and ocular hypertension treatment DE-085 (INN: Tafluprost) on July 31, 2006. DE-085 is a novel prostaglandin drug candidate being studied for the reduction of intraocular pressure in primary open angle glaucoma and ocular hypertension which is under co-development by Santen and Asahi Glass Co., Ltd. Santen is conducting pharmaceutical and clinical development, while Asahi Glass is responsible for manufacturing development of the active pharmaceutical ingredient. DE-085 demonstrated a potent and stable inter ocular pressure lowering effect by promoting uveoscleral outflow in a Phase studies conducted in Japan. |
| 25-Sep | Santen to Launch OTC Eye Drops Sante Medical 10
Santen launched the new OTC eye drop Sante Medical 10, which focused on visual fatigue relief in response to 90% of the eye drop users needs, on October 10, 2006. Sante Medical 10 contains 10 active ingredients formulated to relieve visual fatigue for overworked eyes, and is highly effective against eye fatigue symptoms by improving the ciliary muscle that controls focus adjustment and by stimulating the eye metabolism. |