

## Reference information

# Research & development

### ■ Pipeline of prescription pharmaceuticals (Clinical trials)

Generic name	Brand name/dev. code	Indication	Original/Licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Levofloxacin (1.5%)	DE-108	Bacterial conjunctivitis	Daiichi Sankyo	Japan				Feb-10		
A fluoroquinolone antibacterial agent with higher-concentration.										
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						Dec-08
				Europe						Jun-08
				U.S.					(Licensed Out)	
				Asia					Mar-10	
Prostaglandin derivative for treatment of glaucoma and ocular hypertension. Commercially launched in Japan in December, 2008. It has also been launched in Europe such as in Germany, Denmark, etc. Development rights in the U.S. have been granted to Merck in April, 2009. It has been launched in Hong Kong in March, 2010, and in Korea in May, 2010. Phase III clinical trials are currently being conducted in China.										
Generic name	Dev. code	Indication	Original/Licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Diquafosol sodium	DE-089	Dry eye	Inspire Pharm.	Japan						Apr-10
				Asia						
A treatment for dry eye that stimulates the ocular surface to secrete mucin and tear fluid. It has a different mechanism of action from existing treatments. It has been approved for manufacturing and marketing in Japan in April, 2010. Phase III clinical trials are currently being conducted in China.										
Generic name	Dev. code	Indication	Original/Licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Lomerizine HCl	DE-090	Glaucoma	Schering-Plough	Japan						
A new type of glaucoma treatment studied for inhibiting the progression of visual field defects. The only calcium antagonist in development as an oral glaucoma treatment. Compared with NMDA receptor antagonists, fewer systemic side effects are expected, thus having excellent safety. Marketed by Schering-Plough as a migraine treatment.										
Generic name	Dev. code	Indication	Original/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	U.S.	(Phase I / II)					
				Japan						
Expected to show a potent effect on corneal and conjunctival epithelial disorder mostly associated with dry eye by directly acting on the corneal and conjunctival epithelial cells. It has unique mechanism of action which differs from existing treatments.										
Generic name	Dev. code	Indication	Original/Licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-102	Diabetic macular edema	Co-development with Oakwood (U.S.)	Japan	(Phase I / II)					
A steroid microsphere product for a sustained release injection. Animal studies demonstrated sustained efficacy when injected around the affected area. Collaborated with Oakwood Laboratories (U.S.) for technical development in commercial scale.										
Generic name	Dev. code	Indication	Original/Licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-104	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.	(Phase I / II)					
				Japan						
A ROCK inhibitor co-developed with Ube Industries for treatment of glaucoma and ocular hypertension has a different action mechanism from any other existing drugs. Expected to show a strong IOP-reduction by promoting aqueous humor outflow by directly acting on trabecular meshwork cells.										
Generic name	Dev. code	Indication	Original/Licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-105	Persistent corneal epithelial defects	Original	U.S.						
				Japan						
Expected to accelerate corneal epithelial migration and demonstrate high safety for intractable persistent corneal epithelial defects compared with existing therapy.										
Generic name	Dev. code	Indication	Original/Licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Sirolimus	DE-109	Wet age related macular degeneration(wet AMD)/ Diabetic macular edema(DME)	MacuSight (U.S.)	Japan	(Phase I / II)					
Subconjunctival or intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Santen made a research and development collaboration and license agreement with MacuSight for the Japanese and Asian development and commercialization of sirolimus for the treatment of ocular diseases.										

### ■ Pipeline of prescription pharmaceuticals (Clinical trials)

Generic name	Dev. code	Indication	Original/Licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-110	Allergic conjunctivitis	Original	U.S.						
A new type of anti-allergic agent with non-steroidal chemical structure. A selective glucocorticoid receptor agonist (SEGRA).										

Generic name	Dev. code	Indication	Original/Licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-098 (Anti-APO-1 antibody)	Rheumatoid arthritis	Centocor	Europe	(Phase I / II)					
				Japan	(Phase I / II)					
Joint injection that induces apoptosis in diseased joints of rheumatoid arthritis patients. Bulk pharmaceutical manufacturing process for actual production scale has been established. The compound had been in-licensed from Centocor. Clinical trials are being conducted in Japan and Europe.										

### ■ Changes from February 2, 2010

Dev. Code	Indication	Status change	Region of clinical trial
DE-108	Bacterial conjunctivitis	NDA Filed	Japan
Dev. Code	Indication	Status change	Region of clinical trial
DE-085	Glaucoma/Ocular hypertension	Launched	Hong Kong/Korea
Dev. Code	Indication	Status change	Region of clinical trial
DE-089	Dry eye	Approved	Japan
Dev. Code	Indication	Status change	Region of clinical trial
DE-101	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Started Phase I/II	U.S.

# Pharmaceutical market in Japan

## ■ Revision of National Health Insurance (NHI) drug prices

(%)

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Industry average	-9.7	—	-7.0	—	-6.3	—	-4.2	—	-6.7	—	early -5%	—	mid -6%
Ophthalmic drugs	-7.5	—	-6.2	—	-6.0	—	-2.7	—	-5.5	—	late -3%	—	early -3%
Santen	-7.2	—	-5.7	—	-6.0	—	-3.2	—	-5.3	—	mid -3%	—	mid -5%

(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.

## ■ Market shares

(Billions of yen)

Year ended March 31	2006	2007	2008	2009	2010
Prescription ophthalmics	40.9%	39.7%	38.9%	38.0%	37.3%
	213.1	214.4	221.0	226.9	234.9
Anti-rheumatic drugs	45.2%	46.3%	46.1%	45.0%	43.9%
	23.8	23.3	24.1	24.8	25.7

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(JPM)

Period: 2005.4-2010.3; Unauthorized copy prohibited

## ■ Market shares by therapeutic area - prescription ophthalmics

(Billions of yen)

Year ended March 31	2006	2007	2008	2009	2010
Anti-glaucoma	23.2%	22.1%	20.8%	20.3%	23.0%
	79.1	80.0	83.2	85.0	88.5
Anti-infective	78.3%	76.1%	73.6%	72.1%	71.0%
	26.7	26.0	25.7	25.0	24.0
Anti-allergy	24.8%	24.3%	22.7%	21.0%	19.8%
	24.7	24.8	25.4	28.2	24.0
Agents for surgeries	42.6%	42.8%	43.0%	42.8%	43.0%
	14.4	14.1	15.1	15.3	15.7
Corneal disease treatments	80.7%	79.3%	78.7%	77.7%	77.1%
	25.6	26.5	28.9	30.5	31.7
Anti-cataract	60.3%	62.6%	66.2%	68.8%	72.1%
	6.5	6.3	6.1	5.9	5.6
Corticosteroids	52.6%	51.4%	51.3%	50.7%	49.8%
	11.3	10.9	10.7	10.5	9.9

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

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Source: Santen analysis based on IMS data(JPM)

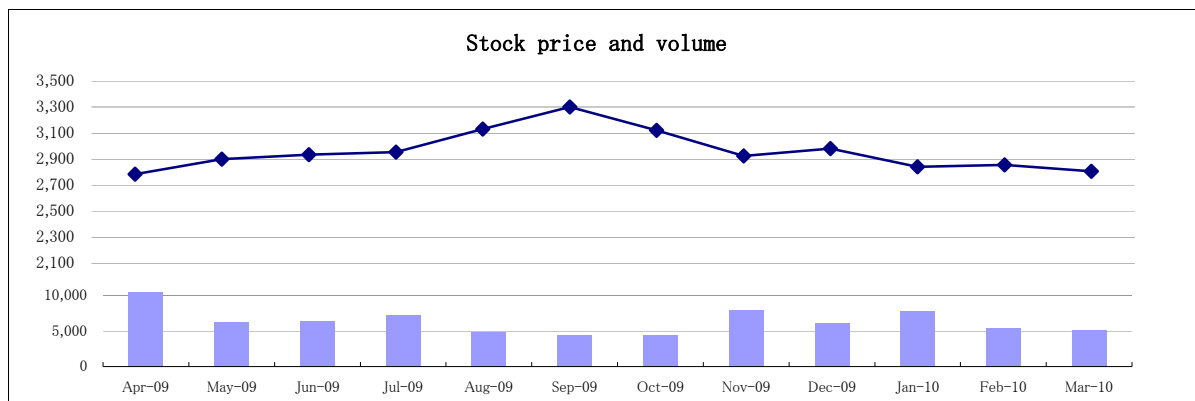
Period: 2005.4-2010.3; Unauthorized copy prohibited

# Stock information

## ■ Stock price (Osaka Securities Exchange 1st market)

(Yen and thousand shares)

	Apr-09	May-09	Jun-09	Jul-09	Aug-09	Sep-09	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10
Stock price:												
End of month	2,785	2,900	2,935	2,955	3,130	3,300	3,120	2,925	2,980	2,841	2,855	2,806
Volume	10,477	6,230	6,351	7,304	4,913	4,393	4,392	7,992	6,079	7,731	5,387	5,161



## ■ Major shareholders

As of March 31, 2010

Name	Number of shares held	Percentage of investment
	Thousand shares	%
Japan Trustee Service Bank, Ltd.	12,925	14.9
The Master Trust Bank of Japan, Ltd.	5,093	5.9
Mita Sangyo Co., Ltd.	4,756	5.5
Nippon Life Insurance Company	3,022	3.5
State Street Bank and Trust Company 505223	2,694	3.1
Tokio Marine & Nichido Fire Insurance Co., Ltd.	2,668	3.1
Trust & Custody Services Bank, Ltd.	2,147	2.5
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	2,120	2.4
RBC Dexia Investor Servicestrust, London-lending account	1,685	1.9
Daiichi Sankyo Company, Limited	1,642	1.9

Note: Santen Pharmaceutical Co., Ltd. has held the treasury stock (1,902 thousand shares), but it is excluded from the major shareholders.

## ■ Major stock information

Year ended March 31	2006	2007	2008	2009	2010
Issued shares (thousands)	86,751	86,825	86,866	86,916	86,992
Treasury stock (thousands)	45	50	1,888	1,893	1,902
Market Capitalization (million)	245,378	262,928	197,573	232,961	238,763
A purchased amount of money (millions of yen)	—	—	4,800	—	—
The number of the purchased stocks (thousand shares)	—	—	1,833	—	—

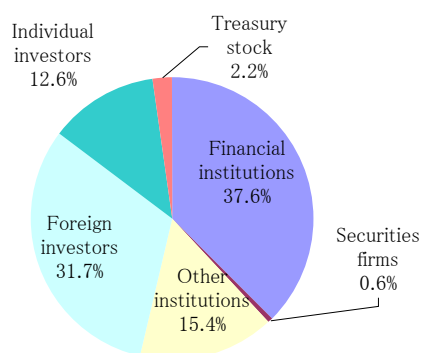
### ■ Breakdown of shareholding by number of shares

Year ended March 31	2006		2007		2008		2009		2010	
	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)
Financial institutions	29,514	34.0	30,366	35.0	33,186	38.2	36,226	41.6	32,693	37.6
City & regional banks	4,659	5.4	4,628	5.3	4,907	5.6	4,794	5.5	2,558	2.9
Trust banks	16,577	19.1	17,049	19.6	19,133	22.0	23,714	27.3	22,466	25.8
(concerned in trust works)	14,039		14,538		16,680		21,167		19,948	
Life and non-life insurance	8,004	9.2	8,470	9.8	8,924	10.3	7,254	8.3	7,022	8.1
Other financial institutions	274	0.3	217	0.3	221	0.3	462	0.5	645	0.7
Securities firms	865	1.0	1,486	1.7	585	0.7	526	0.6	518	0.6
Other institutions	11,823	13.6	12,375	14.2	13,014	15.0	13,071	15.0	13,392	15.4
Foreign investors	31,519	36.3	31,024	35.7	25,227	29.0	23,679	27.3	27,553	31.7
Individual investors	12,985	15.0	11,521	13.3	12,963	14.9	11,516	13.3	10,931	12.6
Treasury stock	45	0.1	50	0.1	1,888	2.2	1,893	2.2	1,902	2.2
Total	86,751	100.0	86,825	100.0	86,866	100.0	86,916	100.0	86,992	100.0

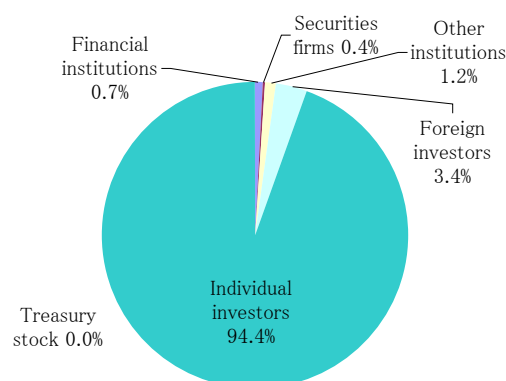
### ■ Breakdown of shareholding by number of shareholders

Year ended March 31	2006		2007		2008		2009		2010	
	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)
Financial institutions	107	0.8	88	0.9	88	0.6	81	0.7	81	0.7
City & regional banks	10	0.1	7	0.1	14	0.1	11	0.1	8	0.1
Trust banks	52	0.4	44	0.4	30	0.2	26	0.2	29	0.2
Life and non-life insurance	32	0.2	26	0.3	29	0.2	33	0.3	34	0.3
Other financial institutions	13	0.1	11	0.1	15	0.1	11	0.1	10	0.1
Securities firms	31	0.2	37	0.4	38	0.3	36	0.3	41	0.4
Other institutions	236	1.7	133	1.3	150	1.2	137	1.2	127	1.2
Foreign investors	255	1.9	306	3.0	268	2.1	355	3.2	366	3.4
Individual investors	12,927	95.4	9,451	94.4	12,568	95.8	10,570	94.6	10,296	94.4
Treasury stock	1	0.0	1	0.0	1	0.0	1	0.0	1	0.0
Total	13,557	100.0	10,016	100.0	13,113	100.0	11,180	100.0	10,912	100.0

Breakdown of shareholding by number of shares (as of March 2010)



Breakdown of shareholding by number of shareholders (as of March 2010)



# Consolidated subsidiaries

## 【Domestic】

Claire Co., Ltd.					
Main business	Cleaning of antidust and sterilized clothing				
Location	Shiga, Japan	Paid-in capital	90 million yen	Equity owned	100%

## 【Overseas】

Santen Holdings U.S. Inc.					
Main business	Holding company for North American businesses and business development				
Location	California, U.S.A.	Paid-in capital	24,784 thousand US\$	Equity owned	100%

Santen Inc.					
Main business	Clinical development of pharmaceuticals				
Location	California, U.S.A.	Paid-in capital	8,765 thousand US\$	Equity owned	100%*

Advanced Vision Science, Inc.					
Main business	Research and development, production and marketing of medical devices				
Location	California, U.S.A.	Paid-in capital	10 thousand US\$	Equity owned	100%*

Phacor Inc.					
Main business	—				
Location	California, U.S.A.	Paid-in capital	10 thousand US\$	Equity owned	100%*

Santen Oy					
Main business	Development, production and marketing of pharmaceuticals				
Location	Tampere, Finland	Paid-in capital	20,000 thousand euros	Equity owned	100%

SantenPharma AB					
Main business	Marketing support of pharmaceuticals				
Location	Stockholm, Sweden	Paid-in capital	500 thousand S.KR	Equity owned	100%

Santen GmbH					
Main business	Marketing of pharmaceuticals and business development				
Location	Germaring, Germany	Paid-in capital	25 thousand euros	Equity owned	100%

Santen Pharmaceutical (China) Co., Ltd.					
Main business	Development, production and marketing of pharmaceuticals				
Location	Suzhou, China	Paid-in capital	3,300 million yen	Equity owned	100%

Taiwan Santen Pharmaceutical Co., Ltd.					
Main business	Import and marketing of pharmaceuticals				
Location	Taipei, Taiwan	Paid-in capital	42,000 thousand Taiwan dollars	Equity owned	100%

Santen Pharmaceutical Korea, Co., Ltd.					
Main business	Import and marketing of pharmaceuticals				
Location	Seoul, Korea	Paid-in capital	1,500,000 thousand won	Equity owned	100%

\* Indirect investment through Santen Holdings U.S. Inc.

# News releases

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## News releases during April 2009-March 2010

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

- | (Date)        | (Summary)   |
|---------------|---|
| <b>2009</b>   |   |
| <b>15-Apr</b> | <b>Santen and Merck &amp; Co., Inc Sign Licensing Agreement for Tafluprost, Treatment for Glaucoma and Ocular Hypertension</b><br>Santen and Merck & Co., Inc (Whitehouse Station, New Jersey, U.S) signed a worldwide licensing agreement for tafluprost (sold as TAPROS® in Japan, TAFLOTAN® in approved European countries marketed by Santen), a treatment for glaucoma and ocular hypertension.  |
| <b>12-May</b> | <b>Santen to Issue Stock Acquisition Rights to the Directors for the Purpose of Granting Stock Options</b><br><b>Santen to Issue Stock Acquisition Rights to the Corporate Officers for the Purpose of Granting Stock Options</b><br>Santen's Board of Directors on May 12, 2009 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 97th Annual General Meeting held on June 24, 2009.                |
| <b>10-Nov</b> | <b>Revision of Financial Forecast</b><br>Santen Pharmaceutical Co., Ltd announces the variances between its business results for the first half of fiscal year 2009 which were announced today, and the forecasts previously announced on August 4, 2009, and it also announces that it has revised its financial forecasts for the full year of fiscal year 2009.  |
| <b>2010</b>   |   |
| <b>2-Mar</b>  | <b>Santen Files Manufacturing/Marketing Approval of its Broad Spectrum Anti-Infective Ophthalmic Solution DE-108 (Generic name: Levofloxacin, high</b><br>Santen Pharmaceutical Co., Ltd. announced that it had filed manufacturing and marketing approval in Japan of its broad spectrum anti-infective ophthalmic solution DE-108 (Generic name: Levofloxacin) with the Japanese Ministry of Health, Labour and Welfare as of February 10, 2010.  |
| <b>2-Mar</b>  | <b>Banyu and Santen Announce Co-Promotion Agreement for Combination Ophthalmic Solution, Treatment for Glaucoma and Ocular Hypertension</b><br>Banyu Pharmaceutical, Co., Ltd. and Santen Pharmaceutical, Co., Ltd. announced that they have concluded an agreement for co-promotion in Japanese domestic territory, for dorzolamide hydrochloride/ timolol maleate combination ophthalmic solution, a treatment agent for glaucoma and ocular hypertension, which is now under review for manufacturing and marketing approval by Banyu. |

