

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			U.S.						Nov-00
	Oftaquix			Europe						
Levofloxacin (1.5%)	DE-108	Bacterial conjunctivitis	Daiichi Sankyo	Japan						
Fluoroquinolone antibacterial agent. A higher-concentration product for control of drug resistance.										
Levofloxacin + prednisolone A	DE-094	Infectious keratitis	Daiichi Sankyo	U.S.						
A combination treatment of Fluoroquinolone antibacterial agent and 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						Dec-08
				Europe						Jun-08
				U.S.					(License out)	
				Asia*					Nov-07	
Prostaglandin derivative for treatment of glaucoma and ocular hypertension. Launched in Japan in Dec, 2008, and launched in Germany, Denmark, etc. Granted U.S. development rights to Merck in April 2009. NDA filed in Korea in Nov, 2007, and Phase III study is ongoing in China. (*excluding Japan)										

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Diquafosol sodium	DE-089	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Inspire Pharm.	Japan						May-08
A treatment for corneal and conjunctival epithelial disorder mostly associated with dry eye that stimulates the ocular surface to secrete tear fluid and components. Expected to be used in combination with existing treatments. A comparative Phase III study met the primary objective and we filed for manufacturing and marketing approval for corneal and conjunctival epithelial disorder associated with dry eye, etc.										

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/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	U.S.						
				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. Unique mechanism of action which differs from existing treatments. Clinical study has currently been conducted as an oral anti-diabetic drug by Daiichi Sankyo in Japan and the U.S.										

Generic name	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 (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/in-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 which 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/in-licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-105	Persistent corneal epithelial defects	Original	U.S.						
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/in-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. Phase I clinical trials in patients with wet AMD and DME have shown improvements in visual acuity that were consistent with morphological changes following a single administration of sirolimus. 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.										

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
Confirmed 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 / II	Centocor
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 Feb. 5, 2009

[Status Change]

Dev. code	Indication	Status change	Clinical trial Region
DE-104	Glaucoma/ Ocular hypertension	Phase II → Phase I / II	U.S.
DE-109	Wet age related macular degeneration (wet AMD)/Diabetic macular edema(DME)	Preparing Phase I / II → Phase I / II	Japan

[License out]

Generic name	Indication	Licensee	Status	Region
Taf luprost	Glaucoma/ Ocular hypertension	Merck	Phase III*	U.S.

*: Santen Inc. has completed Phase III study

Pharmaceutical market in Japan

■ Revision of National Health Insurance (NHI) drug prices

(%)

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Industry average	-4.4	-9.7	—	-7.0	—	-6.3	—	-4.2	—	-6.7	—	early -5%	0.0
Ophthalmic drugs	-1.8	-7.5	—	-6.2	—	-6.0	—	-2.7	—	-5.5	—	late -3%	0.0
Santen	-1.3	-7.2	—	-5.7	—	-6.0	—	-3.2	—	-5.3	—	mid -3%	0.0

(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	2005	2006	2007	2008	2009
Prescription ophthalmics	39.6% 207.7	40.9% 213.1	39.7% 214.4	38.9% 221.0	38.0% 226.9
Anti-rheumatic drugs	42.9% 23.3	45.2% 23.8	46.3% 23.2	46.1% 24.1	45.0% 24.8

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: 2003.4-2009.3; Unauthorized copy prohibited

■ Market shares by therapeutic area - prescription ophthalmics

(Billions of yen)

Year ended March 31	2005	2006	2007	2008	2009
Anti-glaucoma	20.0% 74.9	23.2% 79.0	22.1% 79.9	20.8% 83.1	20.3% 85.0
Anti-infective	80.3% 26.5	78.3% 26.7	76.1% 25.9	73.5% 25.6	72.1% 24.9
Anti-allergy	22.4% 28.4	24.8% 24.6	24.3% 24.7	22.7% 25.4	21.0% 28.2
Agents for surgeries	41.0% 13.6	42.6% 14.4	42.8% 14.1	43.0% 15.1	42.8% 15.2
Corneal disease treatments	81.0% 23.0	80.7% 25.5	79.3% 26.4	78.7% 28.8	77.7% 30.5
Anti-cataract	57.4% 6.8	60.3% 6.5	62.6% 6.3	66.2% 6.1	68.8% 5.9
Corticosteroids	52.8% 11.5	52.6% 11.2	51.4% 10.8	51.3% 10.6	50.7% 10.5

Notes: - On an NHI drug price basis.

- Lower figures indicate market size.

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Source: Santen analysis based on IMS data(JPM)

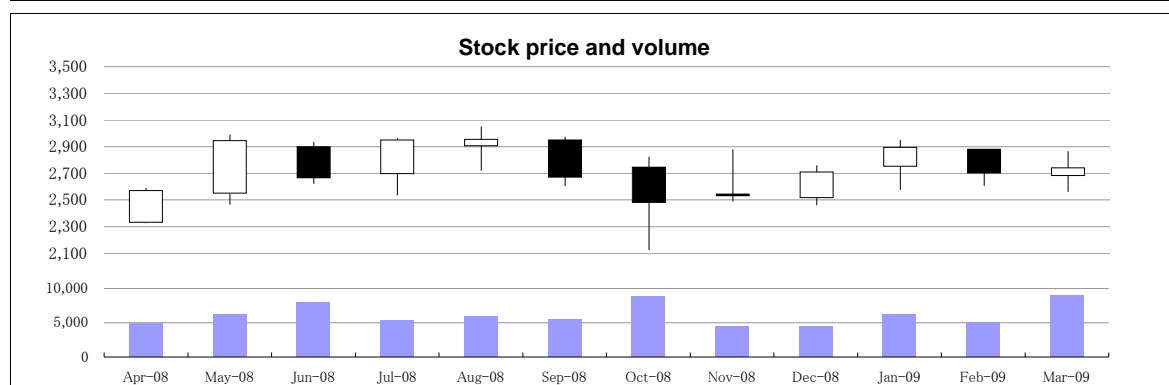
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Stock information

■ Stock price (Osaka Securities Exchange 1st market)

(Yen and thousand shares)

	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09
Stock price:												
Open	2,330	2,550	2,900	2,695	2,905	2,950	2,745	2,545	2,515	2,750	2,880	2,680
High	2,590	2,990	2,935	2,965	3,050	2,975	2,825	2,880	2,760	2,950	2,880	2,865
Low	2,325	2,465	2,620	2,535	2,720	2,605	2,125	2,490	2,460	2,575	2,605	2,560
End of month	2,570	2,945	2,665	2,950	2,955	2,670	2,480	2,530	2,710	2,895	2,700	2,740
Volume	4,952	6,183	7,886	5,282	5,877	5,414	8,765	4,427	4,501	6,172	5,068	8,958



■ Major shareholders

As of March 31, 2009

Name	Number of shares held	Percentage of investment
	Thousand shares	%
Japan Trustee Services Bank, Ltd.	12,388	14.3
The Master Trust Bank of Japan, Ltd.	6,308	7.3
Mita Sangyo Co., Ltd.	4,756	5.5
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	4,241	4.9
Nippon Life Insurance Company	3,017	3.5
Tokio Marine & Nichido Fire Insurance Co., Ltd.	2,668	3.1
Trust & Custody Services Bank, Ltd.	2,057	2.4
RBC Dexia Investor Servicestrust, London-lending account	1,905	2.2
Daiichi Sankyo Company, Limited	1,642	1.9
Ono Pharmaceutical Co., Ltd.	1,630	1.9

Note: Santen Pharmaceutical Co., Ltd has held the treasury stock (1,893 thousand shares), but it is excluded from the major share

■ Stock option

Year ended March 31	2005	2006	2007	2008	2009
Stock option balance (thousand shares)	504.3	541.0	569.6	627.5	739.7
Granted in June 1998 - 106 thousand shares at 1,540 yen/share	35.0	27.0	24.0	24.0	0.0
Granted in June 1999 - 66 thousand shares at 2,480 yen/share	66.0	57.3	48.0	37.0	37.0
Granted in June 2000 - 60 thousand shares at 2,705 yen/share	60.0	58.0	48.2	46.2	45.2
Granted in June 2001 - 55 thousand shares at 2,299 yen/share	55.0	42.6	38.6	38.6	34.0
Granted in June 2002 - 92 thousand shares at 1,326 yen/share	72.5	53.7	32.1	30.9	26.2
Granted in June 2003 - 137.6 thousand shares at 1,176 yen/share	137.6	95.0	72.9	55.2	44.8
Granted in June 2004 - 78.2 thousand shares at 1,743 yen/share	78.2	78.2	73.9	66.1	61.3
Granted in June 2005 - 129.2 thousand shares at 2,480 yen/share	—	129.2	129.2	127.5	127.5
Granted in June 2006 - 102.7 thousand shares at 2,715 yen/share	—	—	102.7	102.7	102.7
Granted in June 2007 - 99.3 thousand shares at 3,050 yen/share	—	—	—	99.3	99.3
Granted in June 2008 - 161.7 thousand shares at 2,734 yen/share	—	—	—	—	161.7

■ Purchase of Treasury stock

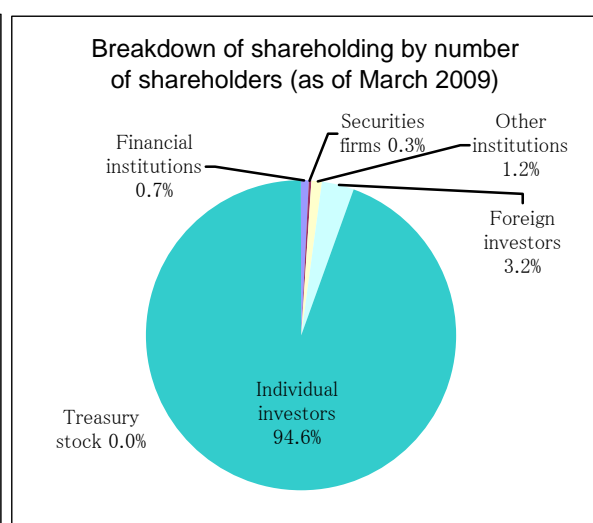
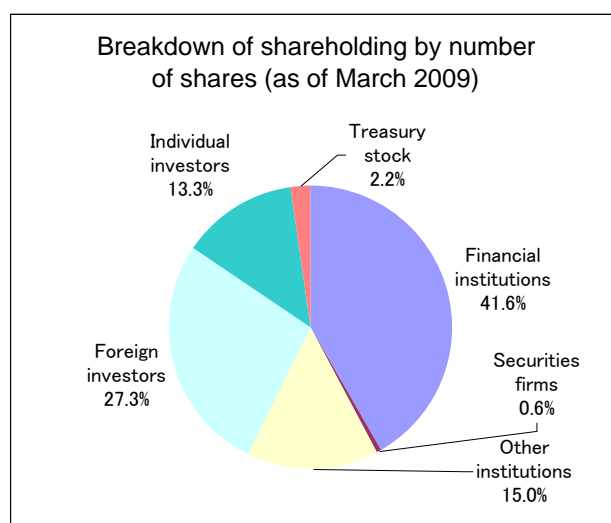
Year ended March 31	2005	2006	2007	2008	2009
A purchased amount of money (millions of yen)	2,569	—	—	4,800	—
The number of the purchased stocks (thousand shares)	1,351	—	—	1,833	—

■ Breakdown of shareholding by number of shares

Year ended March 31	2005		2006		2007		2008		2009	
	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)
Financial institutions	28,423	32.8	29,514	34.0	30,366	35.0	33,186	38.2	36,226	41.6
City & regional banks	4,636	5.3	4,659	5.4	4,628	5.3	4,907	5.6	4,794	5.5
Trust banks	15,768	18.2	16,577	19.1	17,049	19.6	19,133	22.0	23,714	27.3
(concerned in trust works)	13,022		14,039		14,538		16,680		21,167	
Life and non-life insurance	7,973	9.2	8,004	9.2	8,470	9.8	8,924	10.3	7,254	8.3
Other financial institutions	45	0.1	274	0.3	217	0.3	221	0.3	462	0.5
Securities firms	346	0.4	865	1.0	1,486	1.7	585	0.7	526	0.6
Other institutions	11,788	13.6	11,823	13.6	12,375	14.2	13,014	15.0	13,071	15.0
Foreign investors	32,874	38.0	31,519	36.3	31,024	35.7	25,227	29.0	23,679	27.3
Individual investors	13,187	15.2	12,985	15.0	11,521	13.3	12,963	14.9	11,516	13.3
Treasury stock	39	0.0	45	0.1	50	0.1	1,888	2.2	1,893	2.2
Total	86,658	100.0	86,751	100.0	86,825	100.0	86,866	100.0	86,916	100.0

■ Breakdown of shareholding by number of shareholders

Year ended March 31	2005		2006		2007		2008		2009	
	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)
Financial institutions	91	1.1	107	0.8	88	0.9	88	0.6	81	0.7
City & regional banks	9	0.1	10	0.1	7	0.1	14	0.1	11	0.1
Trust banks	47	0.6	52	0.4	44	0.4	30	0.2	26	0.2
Life and non-life insurance	31	0.4	32	0.2	26	0.3	29	0.2	33	0.3
Other financial institutions	4	0.0	13	0.1	11	0.1	15	0.1	11	0.1
Securities firms	28	0.3	31	0.2	37	0.4	38	0.3	36	0.3
Other institutions	128	1.5	236	1.7	133	1.3	150	1.2	137	1.2
Foreign investors	172	2.0	255	1.9	306	3.0	268	2.1	355	3.2
Individual investors	8,089	95.1	12,927	95.4	9,451	94.4	12,568	95.8	10,570	94.6
Treasury stock	1	0.0	1	0.0	1	0.0	1	0.0	1	0.0
Total	8,509	100.0	13,557	100.0	10,016	100.0	13,113	100.0	11,180	100.0



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	2,500 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

News releases during April 2008-March 2009

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

- | (Date) | (Summary) |
|---------------|--|
| 2008 | |
| 7-May | Santen Oy Receives Marketing Authorization for its Glaucoma and Ocular Hypertension Treatment, TAFLOTAN in Denmark
Santen Oy, a wholly owned subsidiary in Finland, Tampere, received the marketing authorization for its new glaucoma and ocular hypertension treatment drug TAFLOTAN (development code: DE-085, generic name: Tafluprost) in Denmark on April 30, 2008. TAFLOTAN is a prostaglandin analogue developed for reduction of intraocular pressure in primary open angle glaucoma and ocular hypertension, which was co-developed by Santen Pharmaceutical Co., Ltd. and Asahi Glass Co., Ltd. |
| 23-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 20, 2008 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 96th Annual General Meeting of Shareholders held on June 25, 2008. |
| 2-Jun | Santen Files Manufacturing and Marketing Approval for Corneal and Conjunctival Epithelial Disorder Treatment DE-089 (JAN: Diquafosol sodium)
Santen filed manufacturing and marketing approval for its corneal and conjunctival epithelial disorder treatment DE-089 (JAN: Diquafosol sodium) to the Japanese Ministry of Health, Labour and Welfare on May 30, 2008. DE-089 was licensed from Inspire Pharm (U.S.A) and developed by Santen as a treatment for corneal and conjunctival epithelial disorder mostly associated with dry eye. |
| 2-Jun | Santen and MacuSight Announce Collaboration and License Agreement for Sirolimus in Ocular Diseases and Conditions
Santen and MacuSight entered into a research and development collaboration and license agreement for the Japanese and Asian development and commercialization of sirolimus for the treatment of ocular diseases and conditions including wet age related macular degeneration (wet AMD) and diabetic macular edema (DME). Sirolimus, originally known as rapamycin, is a highly-potent, broad-acting compound that has demonstrated the ability to combat a broad range of ocular diseases and conditions. |
| 10-Jun | Santen to Revise its Performance Forecast
As Santen made collaboration and license agreement for the Japanese and Asian development and commercialization of Sirolimus (DE-109) with MacuSight, announced on June 2, 2008, Santen makes an initial upfront payment of \$50 million. This payment has an impact on operating income of both consolidated and non-consolidated. Consequently, Santen revised performance forecasts for the half and full year of FY2008. Ordinary income and net income for the first quarter have been forecast to fall below the previously announced forecast. |

(Date)	(Summary)
2008	
3-Oct	Santen to Launch Sante 40i OTC Eye Drop Santen launched the new Sante 40i OTC eye drop on October 10, 2008. The recent development of Sante 40i focuses on changes in the environment influencing people's eyes and has been developed using Santen's own technology. Sante 40i is highly effective for the treatment of bleary eyes associated with blurred vision and visual fatigue symptoms due to its refreshing and moist sensation.
14-Oct	Santen's Dimple Bottle Received the Good Design Award Santen's Dimple Bottle received the Good Design Award, which is coordinated by Japan Industrial Design Promotion Organization. Dimple Bottle, a new type of bottle for ophthalmologic solutions, pursues user friendliness from patients and medical practitioners' viewpoint.
17-Oct	Santen Announces Approval of TAPROS for Glaucoma and Ocular Hypertension Treatment in Japan Santen announced that MHLW of Japan granted approval for its new glaucoma and ocular hypertension treatment drug, "TAPROS Ophthalmic Solution 0.0015%" (Generic name: tafluprost) on October 16, 2008. "TAPROS Ophthalmic Solution 0.0015%" is the first Prostaglandin Analogue developed in Japan for the reduction of intraocular pressure (IOP) in glaucoma and ocular hypertension. The drug was co-developed by Santen Pharmaceutical Co., Ltd. and Asahi Glass Co., Ltd. (Headquarters: Chiyoda-ku, Tokyo).
2009	
3-Mar	Santen Pharmaceutical Co., Ltd. (Santen) Licenses Development, Manufacturing and Marketing Rights of its Hydrophobic Acrylic Lens Material to Bausch & Lomb Inc. (B&L) Advanced Vision Science, Inc. (California), Santen's consolidated subsidiary, signed a license agreement with Bausch & Lomb Inc. (New York) for the development, manufacturing and marketing rights of its foldable hydrophobic acrylic intraocular lens material in all geographic regions except Japan. The AVS material has been marketed by Santen in Japan since July 2008 as the Eternity intraocular lens (IOL). The Eternity IOL was designed to provide superior fundus visibility, and feedback from Japanese surgeons has been very positive with many doctors commenting that the lens helps them to better manage cataract patients with retinal complications such as diabetes milletus.
3-Mar	Santen to Launch Sante FX V Plus OTC Eye Drop Santen launched the new Sante FX V Plus OTC eye drop on Mach 10, 2009. The recent development of Sante FX V Plus is a premium version of the existing eye drop, (Sante FX neo), and it contains effective active ingredients. Sante FX V Plus is highly effective for eye fatigue and red-eye relief offering a refreshing and long lasting cooling sensation.