

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 (1.5%)	DE-108	Bacterial conjunctivitis	Daiichi Sankyo	Japan						
Characteristics: Fluoroquinolone antibacterial agent. A high-concentration product for control of drug resistance.										
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						Oct-08
				Europe						Jun-08
				USA						
				Asia*						Nov-07
Characteristics: Prostaglandin derivative for treatment of glaucoma and ocular hypertension. In Japan, approved in Oct, 2008. In Europe, In April 2008, the first national approval was granted in Denmark. In Jun. 2008, launched in Germany. In the US, we will decide our future development plan based on study results and marketability. In Korea, NDA filed in Nov, 2007. In China, Phase III study is ongoing. (*: 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
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. A comparative Phase III study cleared the initial 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
Olmesartan	DE-092	Glaucoma/ Ocular hypertension	Daiichi Sankyo	Japan		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	Schering-Plough*	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.										

* Nippon Organon was merged in Schering-Plough.

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						
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.										

Generic name (USA)	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	USA						
Characteristics: DE-105 accelerate corneal epithelial migration and is expected to be highly safe and effective with intractable persistent corneal epithelial defects with existing therapy.										

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.

Generic name	Dev. Code	Indication	Original/in-licensor
Sirolimus	DE-109	wet age related macular degeneration(wet AMD)/diabetic macular edema(DME)	MacuSight (USA)

Characteristics: Subconjunctival or intravitreal injection having immunosuppressive effect, anti-angiogenic effect, etc. Phase I clinical trials in patients with wet AMD and DME have shown patients who participated in these studies exhibited 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 and conditions including wet AMD and DME .

■ License out

Dev. code	Indication	Licensee	Status	in-licensor
DE-098 (Anti-APO-1)	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 August 4, 2008

[Progress]

Dev. code	Indication	Status change	Clinical trial, NDA filing, Launch Region
DE-108	Bacterial conjunctivitis	Phase I	Japan
DE-085	Glaucoma/ Ocular hypertension	NDA Filed → Approved	Japan
		NDA Filed	Asia *
		Launched	Europe**

*: NDA Filed in Korea, Phase III in China.

** : Launched in Germany and Denmark. (Country underlined was added from 1Q of fiscal 2008.)

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%)

■ Market shares

(Billions of yen)

Half year/year to	9/2006	3/2007	9/2007	3/2008	9/2008
Prescription ophthalmics	40.9% 105.7	39.7% 214.4	39.9% 107.5	38.9% 221.0	39.1% 110.2
Anti-rheumatic drugs	46.3% 11.7	46.3% 23.2	46.3% 12.0	46.1% 24.1	45.5% 12.4

Notes: - On an NHI drug price basis.
 - Lower figures indicate market size.
 - Anti-rheumatic drugs exclude immunosuppressants and biologic agents.

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 Period: 2006.4-2008.9; Unauthorized copy prohibited

■ Market shares by therapeutic area - prescription ophthalmics

(Billions of yen)

Half year/year to	9/2006	3/2007	9/2007	3/2008	9/2008
Anti-glaucoma	22.3% 39.9	22.1% 79.9	21.3% 41.3	20.8% 83.1	19.7% 42.3
Anti-infective	76.7% 13.7	76.1% 25.9	74.0% 13.4	73.5% 25.6	72.3% 13.3
Anti-allergy	27.8% 9.7	24.3% 24.7	25.0% 9.4	22.7% 25.4	23.9% 10.0
Agents for surgeries	42.9% 7.1	42.8% 14.1	43.2% 7.5	43.0% 15.1	42.7% 7.6
Corneal disease treatments	79.5% 13.1	79.3% 26.4	78.9% 14.0	78.7% 28.8	77.9% 15.2
Anti-cataract	61.9% 3.2	62.6% 6.3	65.4% 3.1	66.2% 6.1	68.0% 3.0
Corticosteroids	51.6% 5.5	51.4% 10.8	51.5% 5.2	51.3% 10.6	50.6% 5.2

Notes: - On an NHI drug price basis.
 - Lower figures indicate market size.

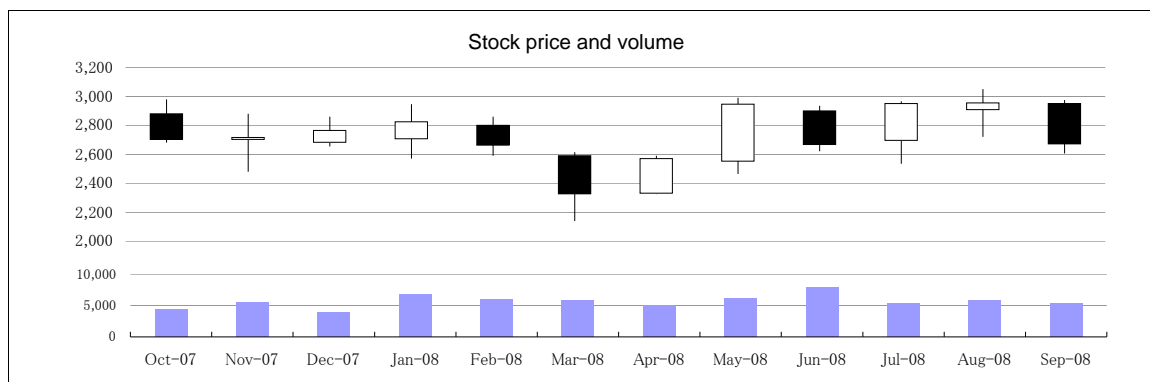
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Stock information

■ Stock price (Osaka Securities Exchange 1st market)

(Yen and thousand shares)

	Oct-07	Nov-07	Dec-07	Jan-08	Feb-08	Mar-08	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08
Stock price:												
Open	2,880	2,700	2,680	2,705	2,800	2,590	2,330	2,550	2,900	2,695	2,905	2,950
High	2,980	2,880	2,860	2,945	2,860	2,615	2,590	2,990	2,935	2,965	3,050	2,975
Low	2,680	2,480	2,655	2,570	2,590	2,140	2,325	2,465	2,620	2,535	2,720	2,605
End of month	2,700	2,715	2,765	2,825	2,660	2,325	2,570	2,945	2,665	2,950	2,955	2,670
Volume	4,339	5,471	3,827	6,859	6,027	5,805	4,952	6,183	7,886	5,282	5,877	5,414



■ Major shareholders

As of September 30, 2008

Name	Number of shares held	Percentage of investment
	Thousand shares	%
Japan Trustee Service Bank, Ltd.	11,461	13.2
Mita Sangyo Co., Ltd.	4,756	5.5
Japan master Trust and Banking Co., Ltd.	4,398	5.1
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	4,241	4.9
Nippon Life Insurance Company	3,043	3.5
Trust & Custody Services Bank, Ltd.	2,871	3.3
The Tokio Marine and Nichido Fire Insurance Co., Ltd.	2,668	3.1
The Silchester International Investors International Value Equity Trust	2,636	3.0
DAIICHI SANKYO COMPANY, LIMITED	1,642	1.9
Northern Trust CO. AVFC Re U.S. tax exempted Pension Funds	1,573	1.8

Note: Santen Pharmaceutical Co., Ltd has held the treasury stock (1,891 thousand shares), but it is excluded from the major shareholders.

■ Stock option

At half-year/year end	3/2004	3/2005	3/2006	3/2007	3/2008	9/2008
Stock option balance (thousand shares)	472.6	504.3	541	569.6	627.5	747.7
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	37
Granted in June 2000 - 60 thousand shares at 2,705 yen/share	60	60	58	48.2	46.2	45.2
Granted in June 2001 - 55 thousand shares at 2,299 yen/share	55	55	42.6	38.6	38.6	34
Granted in June 2002 - 92 thousand shares at 1,326 yen/share	92	72.5	53.7	32.1	30.9	27.4
Granted in June 2003 - 137.6 thousand shares at 1,176 yen/share	137.6	137.6	95	72.9	55.2	48.6
Granted in June 2004 - 78.2 thousand shares at 1,743 yen/share	—	78.2	78.2	73.9	66.1	64.3
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

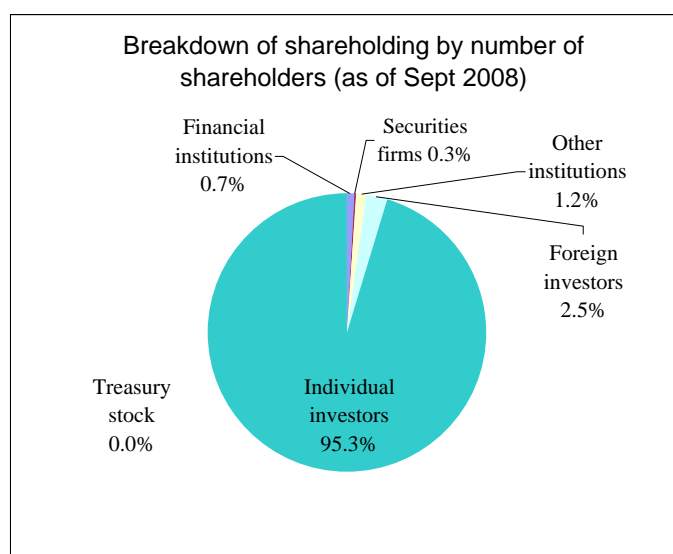
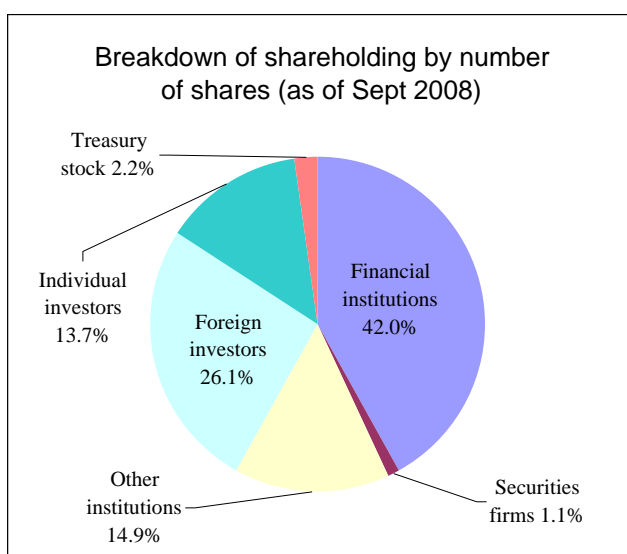
	3/2004	3/2005	3/2006	3/2007	3/2008	9/2008
A purchased amount of money (millions of yen)	—	2,569	—	—	4,800	—
The number of the purchased stocks (thousand shares)	—	1,351	—	—	1,833	—

■ Breakdown of shareholding by number of shares

At half-year/year end	9/2006		3/2007		9/2007		3/2008		9/2008	
	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)	Thousand shares	Proportion (%)
Financial institutions	31,242	36.0	30,366	35.0	31,159	35.9	33,186	38.2	36,474	42.0
City & regional banks	4,646	5.3	4,628	5.3	4,702	5.4	4,907	5.6	4,873	5.6
Trust banks (concerned in trust works)	18,561	21.4	17,049	19.6	17,068	19.7	19,133	22.0	22,428	25.8
Life and non-life insurance	7,898	9.1	8,470	9.8	9,111	10.5	8,924	10.3	8,718	10.1
Other financial institutions	135	0.2	217	0.3	278	0.3	221	0.3	455	0.5
Securities firms	1,129	1.3	1,486	1.7	488	0.6	585	0.7	924	1.1
Other institutions	11,989	13.8	12,375	14.2	12,851	14.8	13,014	15.0	13,003	14.9
Foreign investors	30,085	34.7	31,024	35.7	29,514	34.0	25,227	29.0	22,712	26.1
Individual investors	12,286	14.1	11,521	13.3	12,784	14.7	12,963	14.9	11,904	13.7
Treasury Stock	46	0.1	50	0.1	53	0.0	1,888	2.2	1,891	2.2
Total	86,781	100.0	86,825	100.0	86,849	100.0	86,866	100.0	86,908	100.0

■ Breakdown of shareholding by number of shareholders

At half-year/year end	9/2006		3/2007		9/2007		3/2008		9/2008	
	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)	Number of shareholders	Proportion (%)
Financial institutions	97	0.8	88	0.9	97	0.7	88	0.6	87	0.7
City & regional banks	8	0.1	7	0.1	10	0.1	14	0.1	11	0.1
Trust banks	49	0.4	44	0.4	37	0.3	30	0.2	29	0.2
Life and non-life insurance	27	0.2	26	0.3	34	0.2	29	0.2	34	0.3
Other financial institutions	13	0.1	11	0.1	16	0.1	15	0.1	13	0.1
Securities firms	27	0.2	37	0.4	42	0.3	38	0.3	34	0.3
Other institutions	214	1.8	133	1.3	172	1.4	150	1.2	137	1.2
Foreign investors	276	2.3	306	3.0	287	2.3	268	2.1	285	2.5
Individual investors	11,348	94.9	9,451	94.4	12,042	95.3	12,568	95.8	10,946	95.3
Treasury stock	1	0.0	1	0.0	1	0.0	1	0.0	1	0.0
Total	11,963	100.0	10,016	100.0	12,641	100.0	13,113	100.0	11,490	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	—				
Location	Suzhou, China	Paid-in capital	2,300 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 during April 2008-September 2008

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. |
| 23-May | Santen to Issue Stock Acquisition Rights to the Directors for the Purpose of Granting Stock Options
Santen to Issue Stock Acquisition Rights to the Corporate Officers for the Purpose of Granting Stock Options
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 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 Pharmaceutical Co., Ltd. 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. |
| 2-Jun | Santen and Macusight Announce Collaboration and License Agreement for Sirolimus in Ocular Diseases and Conditions
Santen Pharmaceutical Co., Ltd. and MacuSight, Inc. 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, ordinaly known as rapamycin, is a highly-potent, broad-acting compuond that has demonstrated the ability to combat a broad range of |
| 10-Jun | Revision of Performance Forecast
Santen Pharmaceutical Co., Ltd. revised its performance forecasts for the first half and full year of fiscal 2008, which were announced on May 8, 2008. |