

<Reference>

■ **Sales of major pharmaceuticals**

(Millions of yen)

Brand name Generic name/formulation	Therapeutic category	Three months ended June 30, 2008 Actual	Six months ended September 30, 2008 Actual	Year ended March 31, 2009 Actual	Three months ended June 30, 2009 Actual	Six months ending September 30, 2009 Forecasts	Year ending March 31, 2010 Forecasts
<b>Prescription pharmaceuticals</b>		23,797 (3.0) %	48,606 1.5 %	94,538 (0.8) %	24,353 2.3 %	49,721 2.3 %	99,526 5.3 %
Cravit levofloxacin/ophthalmic solution	Bacterial conjunctivitis	3,254 (3.7) %	7,008 2.0 %	12,443 (3.3) %	3,100 (4.7) %	6,738 (3.9) %	12,802 2.9 %
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	741 (20.9) %	1,451 (20.6) %	2,488 (20.7) %	756 2.0 %	1,430 (1.4) %	2,510 0.9 %
Tapros tafluprost/ophthalmic solution	Glaucoma	— — %	— — %	1,058 — %	856 — %	1,964 — %	4,818 355.2 %
Timoptol timolol maleate/ophthalmic solution	Glaucoma	856 (12.1) %	1,741 (7.3) %	3,213 (10.1) %	766 (10.5) %	1,580 (9.2) %	3,143 (2.2) %
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	887 (0.6) %	1,822 4.3 %	3,477 1.3 %	901 1.5 %	1,790 (1.7) %	3,560 2.4 %
Detantol bunazosin hydrochloride	Glaucoma	600 (1.4) %	1,182 (1.1) %	2,283 (2.3) %	575 (4.2) %	1,062 (10.1) %	2,112 (7.5) %
Rescula isopropyl unoprostone	Glaucoma	1,179 (9.9) %	2,308 (8.7) %	4,386 (10.1) %	1,013 (14.1) %	1,748 (24.3) %	3,455 (21.2) %
Livostin levocabastine hydrochloride/ ophthalmic solution	Allergy	647 (11.7) %	1,390 (5.5) %	4,302 (0.9) %	565 (12.7) %	1,674 20.4 %	3,809 (11.5) %
Hyalein sodium hyaluronate/ophthalmic solution	Corneal disease	5,049 0.8 %	10,539 9.3 %	20,030 2.6 %	5,403 7.0 %	10,568 0.3 %	21,399 6.8 %
Flumetholon fluorometholone/ophthalmic solution	Inflammation	1,120 (9.1) %	2,303 (3.6) %	4,671 (3.1) %	1,124 0.4 %	2,387 3.6 %	4,757 1.9 %
Kary Uni pirenoxine/ophthalmic solution	Early-stage senile cataract	905 (7.7) %	1,852 (1.4) %	3,572 (2.2) %	940 3.9 %	1,950 5.3 %	3,855 7.9 %
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	800 (3.9) %	1,634 0.2 %	3,236 1.0 %	875 9.3 %	1,751 7.2 %	3,416 5.5 %
BSS PLUS oxiglutatione/ophthalmic perfusate and lotion	Perfusate / lotion	319 (4.7) %	638 (1.7) %	1,241 (2.0) %	322 1.0 %	652 2.2 %	1,276 2.8 %
Rimatil bucillamine/tablet	Rheumatoid arthritis	1,198 (8.5) %	2,339 (4.9) %	4,539 (4.8) %	1,155 (3.6) %	2,169 (7.3) %	4,333 (4.5) %
Azulfidine EN salazosulfapyridine/enteric coated tablet	Rheumatoid arthritis	1,096 2.4 %	2,150 3.0 %	4,187 1.6 %	1,095 (0.1) %	2,197 2.2 %	4,369 4.3 %
<b>OTC pharmaceuticals</b>		1,288 1.5 %	2,722 (2.9) %	5,225 (4.1) %	1,298 0.7 %	2,932 7.7 %	5,591 7.0 %

lower : year on year percentage change

Percentages in parentheses indicate a decrease.

\*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 (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						May-02
Levofloxacin (1.5%)	DE-108	Bacterial conjunctivitis	Daiichi Sankyo	Japan						

Fluoroquinolone antibacterial agent. A higher-concentration product for control of drug resistance.

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*					Jun-09	

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. Approved in Korea in June, 2009, and Phase III study is currently conducted 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 mostly associated with dry eye	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.

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. It has unique mechanism of action which differs from existing treatments.

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 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

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### ■ 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. 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 May.12, 2009

[ Status Change]

Generic name (Dev. Code)	Indication	Status change	Clinical trial Region
Tafluprost(DE-085)	Glaucoma/ Ocular hypertension	Koria: NDA Filed→ Approved	Asia

DE-094 (generic name: levofloxacin + prednisolone A) and Rimatil for joint inflammation caused by osteoarthritis, which had been reported up to fiscal 2008, have been removed from the pipeline list due to continued suspension of their development.

■ Capital expenditures

(Millions of yen)

	Three months ended June 30, 2008 Actual	Six months ended September 30, 2008 Actual	Year ended March 31, 2009 Actual	Three months ended June 30, 2009 Actual	Six months ending September 30, 2009 Forecasts	Year ending March 31, 2010 Forecasts
Capital expenditures	406	1,005	2,744	202	1,170	1,830

■ Depreciation and amortization

(Millions of yen)

	Three months ended June 30, 2008 Actual	Six months ended September 30, 2008 Actual	Year ended March 31, 2009 Actual	Three months ended June 30, 2009 Actual	Six months ending September 30, 2009 Forecasts	Year ending March 31, 2010 Forecasts
Consolidated total	808	1,645	3,391	784	1,650	3,410
Manufacturing cost	442	898	1,822	407	840	1,730
Selling, general and administrative expenses	159	323	622	143	290	620
R&D expenses	206	423	946	232	520	1,060

■ Lease expenses

(Millions of yen)

	Three months ended June 30, 2008 Actual	Six months ended September 30, 2008 Actual	Year ended March 31, 2009 Actual	Three months ended June 30, 2009 Actual	Six months ending September 30, 2009 Forecasts	Year ending March 31, 2010 Forecasts
Consolidated total	243	485	931	177	330	520
Manufacturing cost	216	431	821	153	290	430

■ R&D expenses

(Millions of yen)

	Three months ended June 30, 2008 Actual	Six months ended September 30, 2008 Actual	Year ended March 31, 2009 Actual	Three months ended June 30, 2009 Actual	Six months ending September 30, 2009 Forecasts	Year ending March 31, 2010 Forecasts
R&D expenses	8,482	11,832	18,457	2,939	7,800	15,300
Net sales ratio	33.3%	22.7%	18.2%	10.0%	13.7%	13.8%

\*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..