

<Reference>

**Sales of major pharmaceuticals**

(Millions of yen)

Brand name Generic name/formulation	Therapeutic category	Three months ended June 30, 2007 Actual	Six months ended September 30, 2007 Actual	Year ended March 31, 2008 Actual	Three months ended June 30, 2008 Actual	Six months ending September 30, 2008 Forecasts	Year ending March 31, 2009 Forecasts
<b>Prescription pharmaceuticals</b>		<b>24,523</b> ( 2.5 )	<b>47,886</b> ( 1.8 )	<b>95,322</b> ( 3.8 )	<b>23,797</b> ( 3.0 )	<b>48,282</b> ( 0.8 )	<b>96,172</b> ( 0.9 )
Cravit levofloxacin/ophthalmic solution	Bacterial conjunctivitis	3,378 ( 3.7 )	6,868 ( 5.0 )	12,864 ( 2.2 )	3,254 ( 3.7 )	6,296 ( 8.3 )	11,888 ( 7.6 )
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	936 ( 1.0 )	1,828 ( 10.2 )	3,139 ( 10.9 )	741 ( 20.9 )	1,436 ( 21.5 )	2,619 ( 16.6 )
Timoptol timolol maleate/ophthalmic solution	Glaucoma	973 ( 5.9 )	1,877 ( 4.9 )	3,574 ( 6.3 )	856 ( 12.1 )	1,644 ( 12.4 )	3,163 ( 11.5 )
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	893 ( 6.1 )	1,747 ( 8.2 )	3,432 ( 5.3 )	887 ( 0.6 )	1,712 ( 2.0 )	3,606 ( 5.1 )
Detantol bunazosin hydrochloride	Glaucoma	609 ( 0.6 )	1,194 ( 3.1 )	2,337 ( 2.1 )	600 ( 1.4 )	1,130 ( 5.4 )	2,337 ( 0.0 )
Rescula isopropyl unoprostone	Glaucoma	1,309 ( 1.8 )	2,529 ( 2.4 )	4,880 ( 4.8 )	1,179 ( 9.9 )	2,374 ( 6.1 )	4,461 ( 8.6 )
Livostin levocabastine hydrochloride/ ophthalmic solution	Allergy	732 ( 7.2 )	1,472 ( 11.1 )	4,341 ( 0.8 )	647 ( 11.7 )	1,644 ( 11.7 )	3,766 ( 13.2 )
Hyalein sodium hyaluronate/ophthalmic solution	Corneal disease	5,008 ( 9.0 )	9,640 ( 6.8 )	19,521 ( 9.1 )	5,049 ( 0.8 )	10,211 ( 5.9 )	20,536 ( 5.2 )
Flumetholon fluorometholone/ophthalmic solution	Inflammation	1,232 ( 1.3 )	2,390 ( 3.1 )	4,821 ( 0.7 )	1,120 ( 9.1 )	2,354 ( 1.5 )	4,606 ( 4.4 )
Kary Uni pirenoxine/ophthalmic solution	Early-stage senile cataract	980 ( 12.8 )	1,878 ( 6.7 )	3,652 ( 5.4 )	905 ( 7.7 )	1,889 ( 0.6 )	3,707 ( 1.5 )
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	833 ( 12.2 )	1,632 ( 14.9 )	3,204 ( 12.9 )	800 ( 3.9 )	1,626 ( 0.4 )	3,221 ( 0.5 )
BSS PLUS oxiglutatione/ophthalmic perfusate and lotion	Perfusate / lotion	334 ( 2.3 )	649 ( 1.4 )	1,267 ( 0.8 )	319 ( 4.7 )	621 ( 4.4 )	1,196 ( 5.6 )
Rimatil bucillamine/tablet	Rheumatoid arthritis	1,309 ( 6.1 )	2,460 ( 5.7 )	4,767 ( 3.0 )	1,198 ( 8.5 )	2,368 ( 3.7 )	4,633 ( 2.8 )
Azulfidine EN salazosulfapyridine/enteric coated tablet	Rheumatoid arthritis	1,071 ( 2.7 )	2,087 ( 6.6 )	4,121 ( 6.0 )	1,096 ( 2.4 )	2,137 ( 2.4 )	4,254 ( 3.2 )
<b>OTC pharmaceuticals</b>		<b>1,269</b> ( 0.7 )	<b>2,084</b> ( 1.7 )	<b>5,451</b> ( 2.7 )	<b>1,288</b> ( 1.5 )	<b>2,789</b> ( 0.5 )	<b>5,615</b> ( 3.0 )

lower: year on year percentage change

\*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			USA						Nov-00
	Ofraqix			Europe						May-02
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						Jul-06
				Europe						Jun-08
				USA						

Characteristics: Prostaglandin derivative treatment for glaucoma and 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, applied for approval in April, 2007 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 April 2008, the first national approval was granted in Denmark. In June 2008, Tafluprost ophthalmic solution was launched in Germany. 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						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				
				USA/Europe						

Characteristics: The angiotensin II receptor antagonist. In Japan, Europe and 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 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* (Nippon Organon -former name)	Japan						

Characteristics: The calcium antagonist. A new type of oral glaucoma treatment studied for inhibiting the progression of visual field defects. Compared with NMDA receptor antagonists, fewer systemic side effects are expected, thus having excellent safety. Marketed by Schering-Plough as a migraine treatment.  
\*Nippon Organon changed the name because of business integration on July 1, 2008.

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	USA						
				Japan						

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	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 by local injection. In order to produce sterile microsphere in commercial scale, we collaborate with Oakwood Laboratories (USA).

Generic name	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	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						
				Japan						

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	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.

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## 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 antibody)	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 May 9, 2008

[Progress]

Dev. code	Indication	Status change	Clinical trial, NDA filing, Launch Region
DE-085	Glaucoma/ Ocular hypertension	Approved→Launched	Europe *
DE-089	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Phase III →NDA Filed	Japan
DE-101	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Phase II	USA→USA/Japan

\*: Approved in Denmark, Germany, Austria, Finland, Czech, Sweden. Launched in Germany.

[New]

Dev. code	Indication	Status change	Clinical trial, NDA filing, Launch Region
DE-105	Persistent corneal epithelial defects	Preclinical→Phase I	USA
DE-109	wet age related macular degeneration(wet AMD)/ diabetic macular edema(DME)	Preparation for Phase I / IIa	Japan

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■ Capital expenditures

(Millions of yen)

	Three months ended June 30, 2007 Actual	Six months ended September 30, 2007 Actual	Year ended March 31, 2008 Actual	Three months ended June 30, 2008 Actual	Six months ending September 30, 2008 Forecasts	Year ending March 31, 2009 Forecasts
Capital expenditures	399	1,764	2,758	406	1,690	2,380

■ Depreciation and amortization

(Millions of yen)

	Three months ended June 30, 2007 Actual	Six months ended September 30, 2007 Actual	Year ended March 31, 2008 Actual	Three months ended June 30, 2008 Actual	Six months ending September 30, 2008 Forecasts	Year ending March 31, 2009 Forecasts
Consolidated total	798	1,631	3,353	808	1,750	3,700
Manufacturing cost	388	789	1,635	442	990	2,010
Selling, general and administrative expenses	159	334	626	159	310	590
R&D expenses	249	507	1,091	206	450	1,100

■ Lease expenses

(Millions of yen)

	Three months ended June 30, 2007 Actual	Six months ended September 30, 2007 Actual	Year ended March 31, 2008 Actual	Three months ended June 30, 2008 Actual	Six months ending September 30, 2008 Forecasts	Year ending March 31, 2009 Forecasts
Consolidated total	264	525	1,042	243	500	950
Manufacturing cost	232	465	925	216	430	830

■ R&D expenses

(Millions of yen)

	Three months ended June 30, 2007 Actual	Six months ended September 30, 2007 Actual	Year ended March 31, 2008 Actual	Three months ended June 30, 2008 Actual	Six months ending September 30, 2008 Forecasts	Year ending March 31, 2009 Forecasts
R&D expenses	3,139	6,355	12,941	8,482	12,600	19,400
Net sales ratio	11.8%	12.2%	12.5%	33.3%	24.2%	18.7%

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