



# **FY 2009 First Quarter Results**

**August 4, 2009**

**Santen Pharmaceutical Co., Ltd**



# **Consolidated Results for the 1Q of FY2009**

Corporate Officer  
Head of Administration Division  
Satoshi Harada

# Performance Overview of 1Q FY2009

(billions of yen)

	Actual 1Q FY2008	Actual 1Q FY2009	Var. %
<b>Net sales</b>	25.46	29.3	15.1%
<b>Operating income</b>	-0.10	10.30	—
<b>Ordinary income</b>	0.13	10.47	—
<b>Net income</b>	0.13	6.54	—

\*¥5.3 billions of initial upfront payment for the collaboration and license agreement of DE-109 (Sirolimus) with MacuSight Inc. was expensed in 1Q FY2008.



# Net Sales by Business Segment/ Oversea Sales

## ■ Sales by Business Segment

(billions of yen)

	1Q FY2009 Actual Results					
	Domestic		Oversea		Total	
	Sales	Var. %	Sales	Var. %	Sales	Var. %
<b>Prescription Pharmaceuticals</b>	<b>20.89</b>	<b>2.5 %</b>	<b>3.46</b>	<b>1.4 %</b>	<b>24.35</b>	<b>2.3 %</b>
Ophthalmic	18.27	2.8 %	3.43	1.0 %	21.71	2.5 %
Anti-rheumatic	2.53	-0.6 %	0.01	—	2.55	0.2 %
Others	0.07	27.2 %	0.00	-52.9 %	0.08	17.3 %
<b>OTC Drugs</b>	<b>1.28</b>	<b>0.4 %</b>	<b>0.00</b>	<b>128.6 %</b>	<b>1.29</b>	<b>0.7 %</b>
<b>Medical Devices</b>	<b>0.20</b>	<b>128.4 %</b>	<b>—</b>	<b>—</b>	<b>0.20</b>	<b>128.4 %</b>
<b>Others</b>	<b>0.17</b>	<b>241.0 %</b>	<b>3.26</b>	<b>—</b>	<b>3.44</b>	<b>—</b>
<b>Total</b>	<b>22.56</b>	<b>3.4 %</b>	<b>6.73</b>	<b>84.6 %</b>	<b>29.30</b>	<b>15.1 %</b>

## ■ Oversea Sales

(billions of yen)

	1Q FY2008 Actual	1Q FY2009 Actual		
		Actual	Var.	Var. %
<b>Europe</b>	<b>2.24</b>	<b>1.96</b>	<b>-0.28</b>	<b>-12.4 %</b>
<b>U.S.</b>	<b>0.25</b>	<b>3.33</b>	<b>3.08</b>	<b>—</b>
<b>Asia</b>	<b>1.14</b>	<b>1.43</b>	<b>0.29</b>	<b>24.6 %</b>
<b>Total</b>	<b>3.64</b>	<b>6.73</b>	<b>3.09</b>	<b>84.6 %</b>

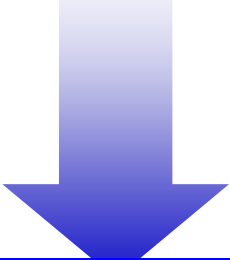


# Net Sales Variances (vs. 1Q FY2008)

(billions of yen)

**1Q FY2008**  
**Actual Sales**  
**¥25.46**

**+¥3.84**



**1Q FY2009**  
**Actual Sales**  
**¥29.30**

## Domestic +¥0.75

### [Increase factors]

- + Prescription Ophthalmics +¥0.50
- + Medical Devices +¥0.11
- + Others +¥0.12

### [Decrease factors]

- + Anti-RA -¥0.02

## Overseas +¥3.09

### [Decrease factors]

- + Europe -¥0.28  
 (currency impact -¥0.46)
- + North America +¥3.08  
 (currency impact -¥0.06)
- + Asia +¥0.29  
 China +¥0.17  
 (currency impact -¥0.03)  
 Korea +¥0.12  
 (currency impact -¥0.05)

## Prescription ophthalmics (Japan)

- + Anti-infective -¥0.20
- + Corneal disease +¥0.24
- + Glaucoma +¥0.57  
 Tapros +¥0.85
- + Allergy -¥0.10

## Europe

- + Prescription ophthalmics -¥0.22
  - W. Europe +¥0.02
  - E. Europe -¥0.02
  - Russia -¥0.06
  - N. Europe -¥0.12
- + Contract manufacturing, others -¥0.05

<Exchange rate>		(yen)	
	1Q FY2008 Actual	1Q FY2009 Actual	
US\$	¥104.22	¥97.20	
Euro	¥160.19	¥129.76	



# Summary of Changes in Income Statement (vs. 1Q FY08)

(100 millions of yen)

	1Q FY2008	1Q FY2009		Major changes
	Actual	Actual	Var.	
Net Sales	254.6	293.0	38.4	
Cost of Sales	91.4	85.8	▲ 5.6	Change of product mix
(% of net sales)	35.9%	29.3%	▲ 6.6 pt	
SGA Total	164.2	104.0	▲ 60.2	
(% of net sales)	64.5%	35.5%	▲ 29.0 pt	
SGA excluding R&D	79.4	74.6	▲ 4.8	Decrease of selling expense -Japan (-1.5) -Europe (-2.1 of currency impact) -U.S. (-0.2) -Asia (-0.8)
(% of net sales)	31.2%	25.5%	▲ 5.7 pt	
R&D Expense	84.8	29.3	▲ 55.5	In-licensed, retina segment (-51)
(% of net sales)	33.3%	10.0%	▲ 23.3 pt	
Operating Income	-1.0	103.0	104.0	
(% of net sales)	—	35.2%	—	
Non-operating Income of Loss	2.4	1.7	▲ 0.7	
Non-operating Income	3.5	3.8	0.3	
Non-operating Expense	1.1	2.1	1.0	
Ordinary Income	1.3	104.7	103.4	
Extraordinary Gain or Loss	▲ 0.2	0.0	0.2	
Extraordinary Gain	—	—	—	
Extraordinary Loss	0.2	0.0	▲ 0.2	
Net Income before Tax	1.0	104.6	103.6	
Income Taxes	▲ 0.2	39.2	39.4	Tax rate of FY2009 37.5%
Net Income	1.3	65.4	64.1	

Exchange rate  
**1Q FY08 Actual**  
 US\$ ¥104.22  
 Euro ¥160.19

**1Q 09FY Actual**  
 US\$ ¥97.20  
 Euro ¥129.76

# Performance by Geographic Segment

## ■ Net Sales

(billions of yen)

	Actual 1Q FY2008	1Q FY2009	
		Actual	Var.
Japan	22.76	26.50	3.74
Europe	2.52	2.25	-0.27
Others*	0.17	0.53	0.36
<b>Total</b>	<b>25.46</b>	<b>29.30</b>	<b>3.84</b>

## ■ Operating Income

	Actual 1Q FY2008	1Q FY2009	
		Actual	Var.
Japan	0.47	10.58	10.11
Europe	0.08	0.2	0.12
Others*	-0.06	-0.01	0.05
Elimination	-0.59	-0.47	0.12
<b>Total</b>	<b>-0.10</b>	<b>10.30</b>	<b>10.40</b>

\* "Others" are U.S., China, Korea and Taiwan.

Note: Sales by geographic region differ from overseas sales (i.e. sales by destination).



# Balance Sheet

(billions of yen)

	As of March 31, 2009		As of June 30, 2009		
	Actual	% of Total	Actual	% of Total	Var.
Current Assets	101.05	66.9 %	102.95	66.9 %	1.90
Fixed Assets	49.95	33.1 %	51.03	33.1 %	1.07
Deferred Assets	-	-	-	-	-
<b>Total Assets</b>	<b>151.01</b>	<b>100.0 %</b>	<b>153.98</b>	<b>100.0 %</b>	<b>2.97</b>
Current Liabilities	22.43	14.9 %	20.09	13.0 %	-2.34
Non-current Liabilities	3.20	2.1 %	3.89	2.5 %	0.69
<b>Total Liabilities</b>	<b>25.64</b>	<b>17.0 %</b>	<b>23.98</b>	<b>15.6 %</b>	<b>-1.65</b>
<b>Total Net Assets</b>	<b>125.36</b>	<b>83.0 %</b>	<b>129.99</b>	<b>84.4 %</b>	<b>4.62</b>
<b>Total Liabilities Net Assets</b>	<b>151.01</b>	<b>100.0 %</b>	<b>153.98</b>	<b>100.0 %</b>	<b>2.97</b>

## Major Changes:

(billions of yen)

- Current Assets: Cash & deposits +¥2.7, marketable securities -¥0.8
- Fixed Assets: Investment securities +¥1.7, deferred tax assets -¥0.4
- Current Liabilities: Notes & accounts payable -¥0.9, income taxes payable -¥1.0, reserve for bonuses -¥1.3, other current liabilities +¥1.2
- Non-current Liabilities: Other fixed liabilities +¥0.6
- Net Assets: Retained earnings +¥3.1, unrealized gains on securities, net of taxes +¥0.5, foreign currency translation adjustments +¥0.8



# Summary of Cash Flow

(billions of yen)

	<b>Actual of 1Q FY2009</b>
<b>Cash and cash equivalents at the beginning of the year</b>	<b>45.95</b>
<b>Net increase/decrease in cash and cash equivalents</b>	<b>2.88</b>
Cash flows from operating activities	6.27
Cash flows from investing activities	-0.26
Cash flows from financial activities	-3.21
Effect of exchange rate changes on cash and cash equivalents	0.08
<b>Cash and cash equivalents at the end of the year</b>	<b>48.83</b>

Note: "Cash and cash equivalents" include cash equivalents thus differ from "cash and deposits" in the Balance Sheets.



# Capital Expenditures / Depreciation & Amortization / Lease Expenses

(billions of yen)

	Actual 1Q FY2008	1Q FY2009	
		Actual	Var.
Capital Expenditures	0.40	0.20	-0.20
Depreciation and Amortization	0.80	0.78	-0.02
Lease	0.24	0.18	-0.06

■ Major capital expenditure of FY2009 1Q

- R&D Equipment



# **FY2009 First Quarter Status of Clinical Development**

Member of the Board  
Senior Corporate Officer  
Head of Research and Development Division  
Toshiaki Nishihata, Ph.D.

# S Major Clinical Pipeline List (Red Letters: Changes from FY084Q)

Global strategic Product

Global Product

Japan (Asia) Product

Domain	Phase I	Phase II	Phase III	NDA Filed	Approved
Glaucoma		<p><b>DE-104</b> ROCK inhibitor</p>		<p><b>DE-085</b> Tafluprost</p>	<p>Japan Europe (launch)</p>
		<p><b>DE-090</b> Lomerizine HCl</p>	<p>China</p>		<p>Korea (approved)</p>
Corneal Disease (Dry Eye)		<p><b>DE-101</b> Rivoglitazone</p>		<p><b>DE-089</b> Diquafosol sodium</p>	
	<p><b>DE-105</b> Combination of peptides</p>				
Retinal Disease		<p><b>DE-109</b> Sirolimus</p>			
		<p><b>DE-102</b> Steroid DDS</p>			
Others Inflammation, Allergy, RA			<p><b>DE-108</b> Levofloxacin</p>		
		<p><b>DE-098</b> Apoptosis inducer</p>			

# Status of Major Drug Candidate (DE-085)

- **DE-085** *Tapros* in Japan, *Taflotan* in Europe (Glaucoma, Ocular hypertension)

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
Japan	Launched (December 2008 - )	Launched (December 2008 - )	Approved (October 2008 )
Europe	Launched* (June 2008 - )	Launched (June 2008 - )	Approved (April 2008 - )
Asia	Korea: Approved China: P3	Korea: Filed China: P3	Korea: Filed (Nov. 2007)

\* : Launched in Germany, Denmark, Finland, Sweden, Norway.

Granted Marketing authorization for 19 countries (including CIS).

Filed in EU (including CIS) and Asian countries.

U.S.	Out-licensed development and marketing rights to Merck (Apr.2009)
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# Status of Major Drug Candidate (DE-089)

- **DE-089** (Corneal and conjunctival epithelial disorders associated with dry eye)

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
Japan	Filed	Filed	Generic name: <b>Diquafosol sodium</b>  Filed in May 2008



# Status of Major Pipeline - Glaucoma, Ocular hypertension -

- **DE-090**

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
Japan	P2	P2	Generic name: <b>Lomerizine HCl</b>

- **DE-104**

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
U.S.	P1/P2	P1/P2	ROCK inhibitor
Japan	P2	P2	



# Status of Major Pipeline - Corneal and conjunctival disease -

- **DE-101** (Corneal and conjunctival epithelial disorders associated with dry eye)

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
U.S.	Preparing P2b	P2a	Generic name: <b>Rivoglitazone</b>
Japan	Preparing P2b	P2a	

- **DE-105** (Persistent corneal epithelial defects)

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
Japan U.S.	Preparing P2	Preparing P2	Combination of peptides





# Status of Major Pipeline - Retinal Disease -

- **DE-102** (Diabetic macular edema)

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
Japan	P1 / 2	P1 / 2	Steroid DDS

- **DE-109\*** (Wet age related macular degeneration, diabetic macular edema)

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
Japan	P1 / 2	P1 / 2	Generic name: <b>Sirolimus</b>

\* Santen made a research and development collaboration and license agreement with MacuSight Inc. for the Japanese and Asian development and commercialization of sirolimus for the treatment of ocular diseases.

# Status of Major Pipeline - Others -

- **DE-108** (Bacterial conjunctivitis)

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
Japan	P3	P3	higher-concentration Levofloxacin

- **DE-098\*** (Rheumatoid arthritis)

Region	Development Stage		Remarks
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	
Japan	P1 / 2	P1 / 2	Anti-APO-1 antibody
Europe	P1 / 2	P1 / 2	

\* Domestic development rights were licensed to Argenes, Inc. Domestic marketing rights and oversea development and marketing rights belong to Santen.



## Forward-Looking Statements

- Information given in this announcement and accompanying documentation contains certain forward-looking statements concerning forecasts, projections and plans whose realization is subject to risk and uncertainty from a variety of sources. Actual results may differ significantly from forecasts.
- Business performance and financial condition are subject to the effects of medical regulatory changes made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.
- The process of drug research and development from discovery to final approval and sales is long, complex and uncertain. Individual compounds are subject to a multitude of uncertainties, including the termination of clinical development at various stages and the non-approval of products after a regulatory filing has been submitted. Forecasts and projections concerning new products take into account assumptions concerning the development pipelines of other companies and any co-promotion agreements, existing or planned. The success or failure of such agreements could affect business performance and financial condition significantly.
- Business performance and financial conditions could be affected significantly by a substantial drop in sales of a major drug, either currently marketed or expected to be launched, due to termination of sales as a result of factors such as patent expiry and complications, product defects or unforeseen side effects. Santen Pharmaceutical also sells numerous products under sales and/or manufacturing license from other companies. Business performance could be affected significantly by changes in the terms and conditions of agreements and/or the non-renewal of agreements.
- Santen Pharmaceutical is reliant on specific companies for supplies of certain raw materials used in production. Business performance could be affected significantly by the suspension or termination of supplies of such raw materials if such an event were to adversely affect supply capabilities for related final products.



## **Reference**

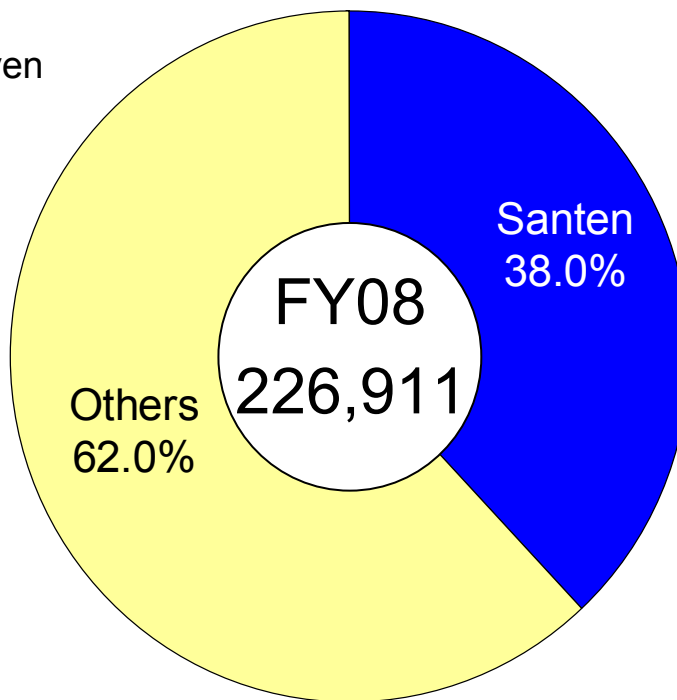
**Domestic Prescription Pharmaceutical Market  
-Ophthalmics and Anti-rheumatics-**



# Trend & Competition by Category (Ophthalmics Total)

- Santen holds no.1 share in ophthalmic market.
- Santen's market share of 1Q FY2009 is 38.1%, and its market share June 2009 is 38.7%.

Market Size: millions of yen  
%: Value Share



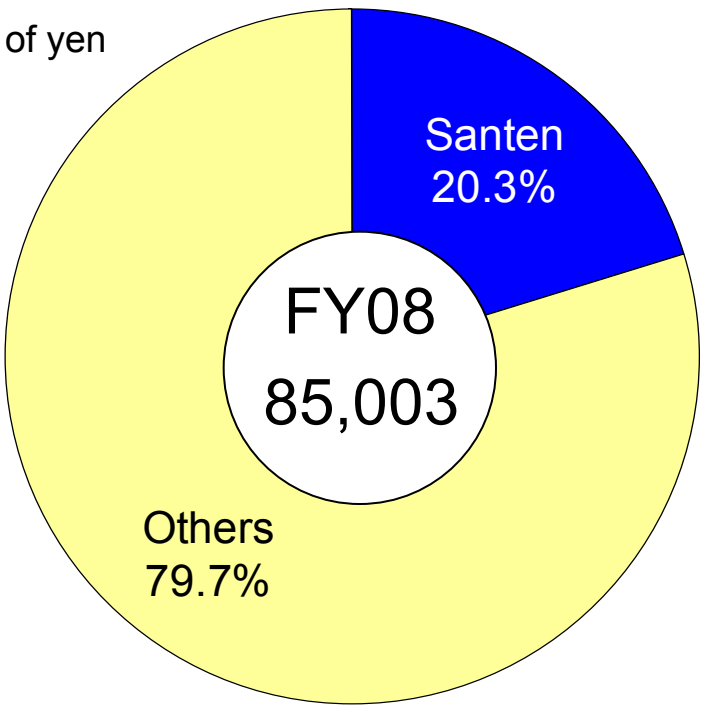
Source: ©2009 IMS  
Japan  
IMS-JPM 2006-09  
Santen analysis based  
on IMS data

		FY06	FY07	FY08	09FY1Q	
Santen Value Share		39.7%	38.9%	38.0%	38.1%	
Growth Rate vs. year-ago	Santen Value	-2.2%	+0.8%	+0.3%	+2.7%	
	Market	Value	+0.6%	+3.1%	+2.6%	+4.3%
		Volume	+2.1%	+0.2%	+2.5%	-0.4%

# S Trend & Competition by Category (Glaucoma)

- Glaucoma, the largest category in ophthalmics, is ¥85 billion with 2.2% value growth FY2008, in spite of the drug price revision.
- While Santen is currently the second largest, sales grows steadily with the launch of Tapros. Santen's market share of 4Q FY2008 is 20.9%, it grows 22.4% in 1Q FY2009.

Market Size: millions of yen  
%: Value Share



\*\*Santen:  
Timoptol, Timoptol XE,  
Rescula, Detantol,  
Tapros, etc.

Source: ©2009 IMS  
Japan  
IMS-JPM 2006-09  
Santen analysis based  
on IMS data

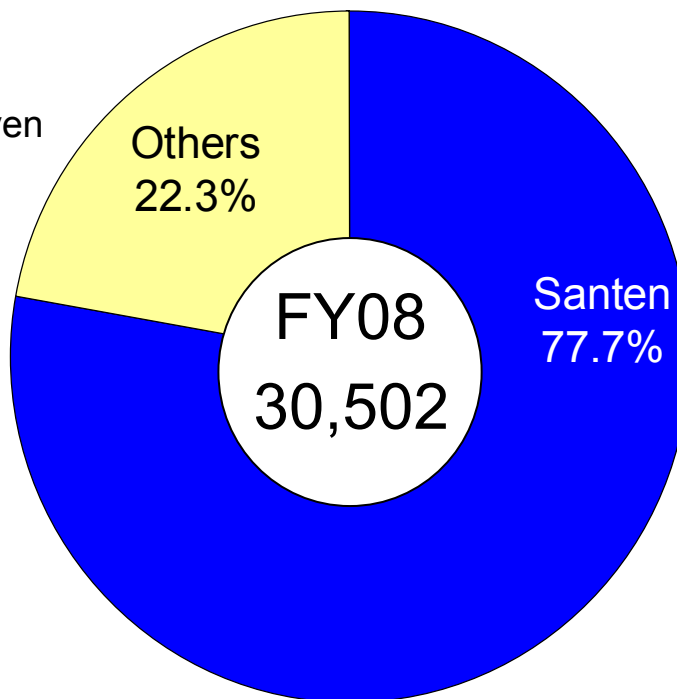
		FY06	FY07	FY08	09FY1Q	
Santen Value Share		22.1%	20.8%	20.3%	22.4%	
Growth Rate vs. year-ago	Santen Value	-3.6%	-2.1%	-0.4%	+17.5%	
	Market	Value	+1.1%	+4.0%	+2.2%	+3.7%
		Volume	+4.4%	+1.2%	+2.9%	-0.2%



# Trend & Competition by Category (Cornea: Dry Eye)

- Dry eye is one of the highest potential category. Its size is over ¥30 billion with 5.7% growth from FY2008.
- Dry eye is the strongest category in competition where Santen has around 80%.
- Santen's value share increases +4.3% for FY2009 1Q, and +9.4% for June, 2009.

Market Size: millions of yen  
%: Value Share



\*Santen:  
Hyalein, etc.

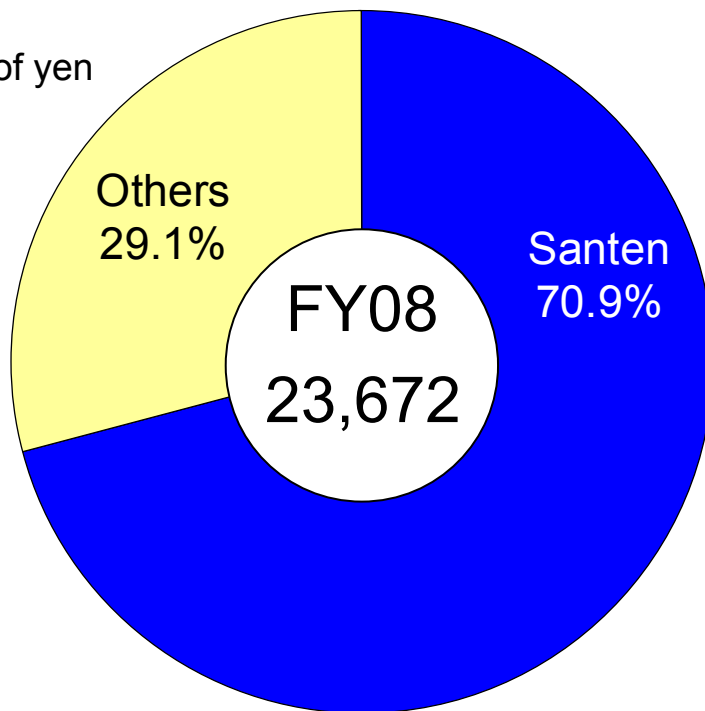
Source: ©2009 IMS Japan  
IMS-JPM 2006-09  
Santen analysis based on  
IMS data

		FY06	FY07	FY08	09FY1Q	
Santen Value Share		79.3%	78.7%	77.7%	77.4%	
Growth Rate vs. year-ago	Santen Value	+1.9%	+8.1%	+4.4%	+4.3%	
	Market	Value	+3.6%	+9.0%	+5.7%	+5.1%
		Volume	+6.8%	+7.2%	+7.9%	+3.9%

# S Trend & Competition by Category (Anti-infection)

- Market size is around ¥24 billion. Value growth in 1Q FY2009 is slightly in declining trend by -6.1%.
- For Santen, it is another strongest category in competition, with 70% market share.

Market Size: millions of yen  
%: Value Share



\*Santen:  
Cravit, Tarivid, etc.

Source: ©2009 IMS Japan  
IMS-JPM 2006-09  
Santen analysis based on  
IMS data

		FY06	FY07	FY08	09FY1Q	
Santen Value Share		75.1%	72.4%	70.9%	69.7%	
Growth Rate vs. year-ago	Santen Value	-6.0%	-4.9%	-5.0%	-6.2%	
	Market	Value	-3.1%	-1.3%	-3.1%	-4.8%
		Volume	+0.9%	-3.3%	-1.0%	-6.1%

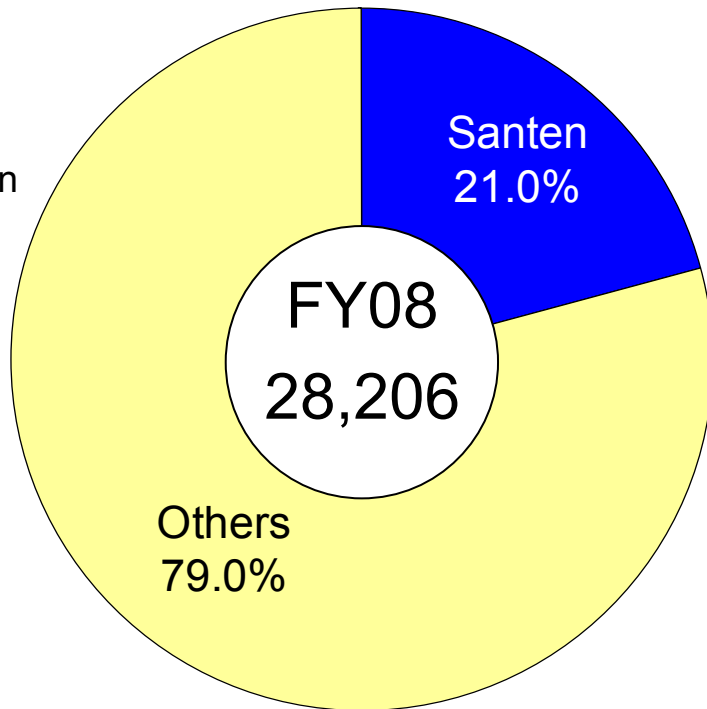




# Trend & Competition by Category (Anti-allergy)

• Santen's market share slightly increases to 21.8% under such circumstances as rapid growth of competitors' products.

Market Size: millions of yen  
%: Value Share



\*Santen:  
Livostin, Alegysal

Source: ©2009 IMS Japan  
IMS-JPM 2006-09  
Santen analysis based on  
IMS data

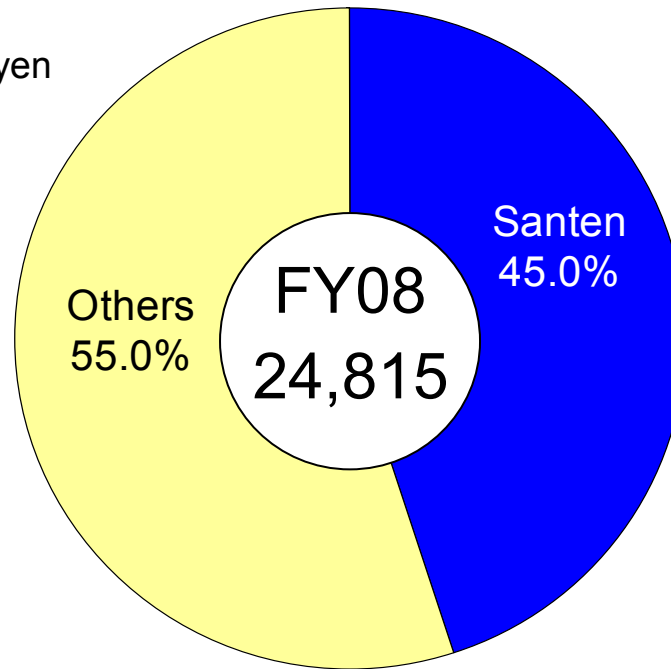
		FY06	FY07	FY08	09FY1Q	
Santen Value Share		24.3%	22.7%	21.0%	21.8%	
Growth Rate vs. year-ago	Santen Value	-1.7%	-4.0%	+2.3%	-11.8%	
	Market	Value	+0.3%	+2.6%	+11.0%	-2.1%
		Volume	+6.5%	+1.0%	+14.9%	-2.8%



# Trend & Competition by Category (RA: DMARDs)

- Market size of DMARDs is ¥24.8 billion in FY2009, and it grows +3.7% in 1Q FY2009.
- Santen leads DMARDs market with 44.1% value share in 1Q FY2009, led by the three products which all have the “recommended level A” authorized by the guideline of RA society.

Market Size: millions of yen  
%: Value Share



\*DMARDs:  
Disease Modifying  
Anti-rheumatic Drugs  
  
\*Santen:  
Rimatil, Azulfidine EN,  
Metolate

Source: ©2009 IMS Japan  
IMS-JPM 2006-09  
Santen analysis based on  
IMS data

		FY06	FY07	FY08	09FY1Q	
Santen Value Share		46.3%	46.1%	45.0%	44.1%	
Growth Rate vs. year-ago	Santen Value	0.0%	+3.3%	+0.4%	+0.2%	
	Market	Value	-2.3%	+3.7%	+2.8%	+3.7%
		Volume	+3.7%	+0.4%	+3.8%	-1.2%