



FY 2011 First Quarter Results

August 2, 2011

Santen Pharmaceutical Co., Ltd



Consolidated Results FY2011 First Quarter

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Head of Administration Division

Financial Highlights for Q1 FY2011

	Actual Q1.FY2010	Actual Q1.FY2011	Var. %
Net Sales	26.21	27.85	+6.2%
Operating Income	6.63	7.76	+17.0%
Ordinary Income	7.14	8.18	+14.6%
Net Income	4.57	5.52	+20.7%



Q1 FY2011

Net Sales: Variances (vs. Q1 FY2010)

**FY2010
Q1
Net Sales
(Actual)
¥26.21billion**

**+¥1.63
billion**



**FY2011
Q1
Net Sales
(Actual)
¥27.85billion**

Japan: +0.97billion

- + Prescription Ophthalmics +¥0.55billion
- + Anti-rheumatics +¥0.00billion
- + OTC Drugs +¥0.15billion
- + Medical Devices +¥0.12billion
- + Others +¥0.13billion

Overseas + ¥0.66billion

- + U.S. +¥0.30billion
(Forex impact -¥0.05billion)
- + Europe +¥0.25billion
(Forex impact -¥0.07billion)
- + Asia +¥0.10billion
 - China -¥0.06billion
(Forex impact: -¥0.03billion)
 - Korea +¥0.17billion
(Forex impact: -¥0.01billion)

Prescription Ophthalmics (Japan)

- + Anti-infective -¥0.11billion
- + Cornea (Dry Eye) +¥0.64billion
 - Diquas +¥0.52billion
- + Glaucoma +¥0.53billion
 - Tapros: +¥0.12billion
 - Cosopt: +¥0.93billion
- + Anti-allergy +¥0.05billion
- + Others -¥0.55billion

Europe

- + Prescription Ophthalmics +¥0.32billion
 - Western Europe -¥0.00billion
 - Eastern Europe +¥0.13billion
 - Northern Europe +¥0.06billion
 - Russia +¥0.12billion

<Currency Rates>

	FY10.Q1 actual	FY11.Q1 actual
US\$	JPY 91.98	JPY 81.63
Euro	JPY 121.59	JPY 117.91
CNY	JPY 13.29	JPY 12.48



Changes in Income Statement

(JPY billions)	Q1.FY2010	Q1.FY2011		
	Actual	Actual	Variance	Major Changes
Net Sales	26.21	27.85	+1.63	
Cost of Sales (% of net sales)	8.54 32.6%	8.65 31.1%	+0.11 -1.5pt	
SGA excluding R&D (% of net sales)	7.65 29.2%	8.31 29.9%	+0.66 +0.7pt	<ul style="list-style-type: none"> •Domestic +¥0.04bil •Europe & US +¥0.28bil •Asia +¥0.17bil
R&D Expenses (% of net sales)	3.38 12.9%	3.11 11.2%	-0.26 -1.7pt	Forex impact : -¥0.09 bil
Operating Profit (% of net sales)	6.63 25.3%	7.76 27.9%	+1.12 +2.5pt	
Non-operating Income	0.52	0.43	-0.08	
Non-operating Expense	0.01	0.01	-0.00	
Ordinary Income	7.14	8.18	+1.04	
Extraordinary Gain	0.00	0.01	+0.00	
Extraordinary Loss	0.11	0.01	-0.09	
Net Income before Tax	7.04	8.18	+1.14	
Corporate Tax	2.46	2.65	+0.19	
Net Profit	4.57	5.52	+0.94	

<Currency Rates>

	<u>FY10 Q1 actual</u>	<u>FY11 Q1 actual</u>
US\$	JPY 91.98	JPY 81.63
Euro	JPY 121.59	JPY 117.91
CNY	JPY 13.29	JPY 12.48



**Reference:
Consolidated Results
FY2011 First Quarter**



Net Sales by Business Segment

(JPY billions)	Q1.FY2011 Actual					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var.	Sales	Var.
Pharmaceuticals	23.08	3.8 %	3.99	13.4 %	27.08	5.1%
Prescription Pharmaceuticals	21.94	3.2 %	3.98	13.3 %	25.93	4.7 %
Ophthalmic	19.07	3.0 %	3.88	14.5 %	22.95	4.8 %
Anti-RA	2.57	0.0 %	0.04	138.0 %	2.61	1.1 %
Others	0.30	75.8 %	0.05	-48.0 %	0.35	29.9 %
OTC Pharmaceuticals	1.14	16.2 %	0.00	401.4 %	1.14	16.5 %
Others	0.44	40.9 %	0.32	135.4 %	0.77	70.1 %
Medical Devices	0.43	41.2 %	0.32	135.4 %	0.76	70.5 %
Others	0.00	4.8 %	—	—	0.00	4.8 %
Total	23.53	4.3 %	4.31	18.1 %	27.85	6.2 %



Oversea Sales

(JPY billions)	Q1.FY2010 Actual	Q1.FY2011 Actual		
		Actual	Var.	Var. %
U.S.	0.20	0.51	0.30	149.1 %
Europe	2.02	2.28	0.25	12.5 %
Asia	1.41	1.52	0.10	7.3 %
Others	0.00	0.00	- 0.00	-
Total	3.65	4.31	0.66	18.1 %



Summary of Change in Balance Sheet

(JPY billions)	As of March 31, 2011		As of June 31, 2011		
	Actual	% of Total	Actual	% of Total	Var.
Current Asset	137.66	74.5%	135.38	74.4%	-2.28
Fixed Asset	47.13	25.5%	46.61	25.6%	-0.51
Deferred Asset	-	-	-	-	-
Total Asset	184.80	100.0%	182.00	100.0%	-2.79
Current Liabilities	24.10	13.0%	19.95	11.0%	-4.15
Non-current Liabilities	4.29	2.3%	3.89	2.1%	-0.40
Total Liabilities	28.39	15.4%	23.84	13.1%	-4.55
Total Net Asset	156.40	84.6%	158.16	86.9%	1.76
Total Liabilities Net Assets	184.80	100.0%	182.00	100.0%	-2.79

Major Changes

- **Current Asset:** Cash and deposits -¥2.1bil, Marketable securities -¥1.2bil, Merchandise and finished goods +¥0.9bil
- **Fixed Asset :** Buildings and structures -¥0.1bil, Construction in progress +¥0.3bil, Software -¥0.1bil, Investment securities -¥0.1bil, LT deferred tax assets -¥0.3bil
- **Current Liabilities:** Income tax payable -¥2.9bil, Provision for bonus -¥1.3bil
- **Fixed Liabilities :** Provisions for directors' retirement fund -¥0.2bil
- **Net asset :** Retained earnings +1.1bil, Foreign currency translation adjustments +0.3bil



Summary of Cash Flows

(JPY billions)	FY2011 Q1 Actual
Cash and cash equivalents at the beginning of the year	72.48
Net increase/decrease in cash and cash equivalents	-1.21
Cash flows from operating activities	1.06
Cash flows from investing activities	1.85
Cash flows from financial activities	-4.13
Effect of exchange rate changes on cash and cash equivalents	-0.00
Cash and cash equivalents at the end of the year	71.26

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



Capital Expenditures / Depreciation & Amortization / Lease Expenses

(JPY billions)	FY2010		FY2011	
	Q1 Actual	Full Year Actual	Q1 Actual	Full Year Forecast
Capital Expenditures	0.19	1.70	0.63	6.21
Depreciation and Amortization	0.68	2.80	0.64	2.95
Lease Payments	0.06	0.15	0.01	0.16



**Reference:
FY2011 Financial Forecasts**

Financial Forecast for FY2011

(JPY billions)	FY2010 Actual	FY2011 Forecast	Var. %
Net Sales	110.81	116.00	4.7%
Operating Income	30.73	30.00	-2.4%
Ordinary Income	31.48	30.50	-3.1%
Net Income	21.33	20.50	-3.9%

ROE	14.5%	12.6%	-1.9pt
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Sales/Income Outlook for the FY2011

(JPY billions)	FY2010 Actual	FY2011	
		Forecast	Var.
Net Sales	110.81	116.00	5.18
Cost of Sales	34.43	36.00	1.56
(% of net sales)	31.1%	31.0 %	-0.0 pt
SG&A excluding R&D	32.41	34.00	1.58
(% of net sales)	29.3 %	29.3 %	0.1 pt
R&D Expense	13.22	16.00	2.77
(% of net sales)	11.9 %	13.8 %	1.9 pt
Operating Income	30.73	30.00	-0.73
(% of net sales)	27.7 %	25.9%	- 1.9 pt
Non-operating Income or Loss	0.74	0.50	-0.24
Ordinary Income	31.48	30.50	- 0.98
Extraordinary Income or Loss	- 0.40	0.00	0.40
Net Income before Tax	31.07	30.50	- 0.57
Income Taxes	9.74	10.00	0.25
Net Income	21.33	20.50	- 0.83
ROE	14.5 %	12.6%	- 1.9 pt

<Currency rate>	
	FY2010 actual
US\$	¥85.57
Euro	¥113.45
CNY	¥12.94
	FY2011 forecast
US\$	¥82.00
Euro	¥113.00
CNY	¥12.50



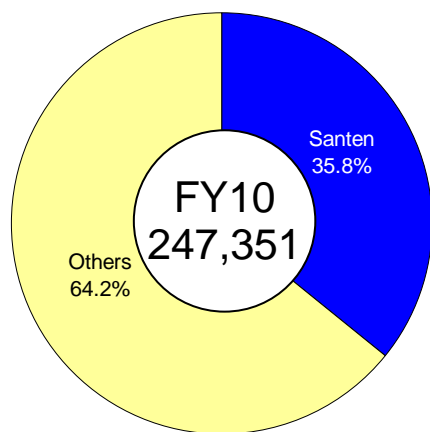
**Reference:
Market Overview of
Prescription Ophthalmics in Japan**

S Japan: Trend & Competition in Ophthalmics - 1

- **Ophthalmology Total:** Market grew by 5.8% in the 1st quarter FY11. Santen's market share was 36.0% under the situation of growth in the retinal segment and anti-allergy segment.
- **Glaucoma:** Market was almost flat at -0.8% in the 1st quarter FY11. Santen's sales grew by 13.8%. Santen held 27.3% of the share by the contribution of Tapros and Cosopt.
- **Corneal:** Market grew by +9.5% in the 1st quarter FY11. Santen's sales grew by 13.0% and the market share of Santen increased to 77.6% with the contribution of Hyalein and new product, Diquas.

Market Size:
millions of yen
%: Value Share

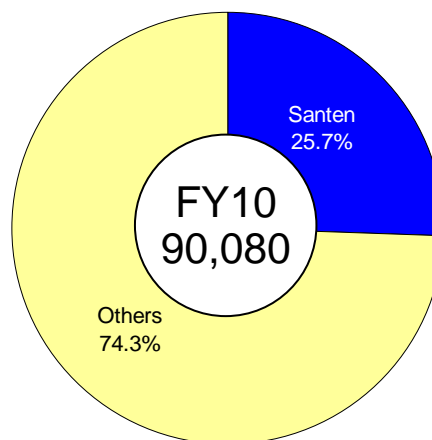
Ophthalmology Total



FY10 Q1.FY11

YoY change	Market	+5.3%	+5.8%
	Santen	+1.0%	+5.0%
Santen's Share		35.8%	36.0%

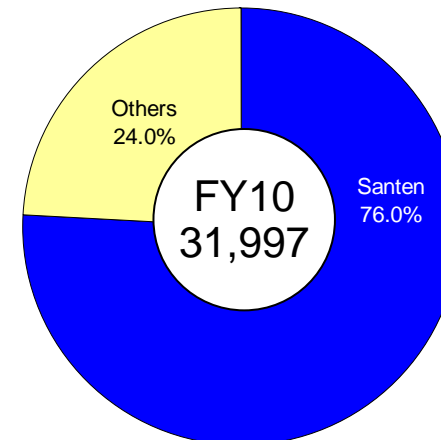
Anti-glaucoma



FY10 Q1.FY11

Market	+1.8%	-0.8%	
Santen	+13.5%	+13.8%	
Santen's Share		25.7%	27.3%

Corneal: Dry Eye



FY10 Q1.FY11

Market	+1.0%	+9.5%	
Santen	-0.5%	+13.0%	
Santen's Share		76.0%	77.6%

-Santen:
-Glaucoma : Tapros, Cosopt, Timoptol/XE, Rescula, Detantol, etc.
-Cornea / Dry Eye : Hyalein, Diquas etc.

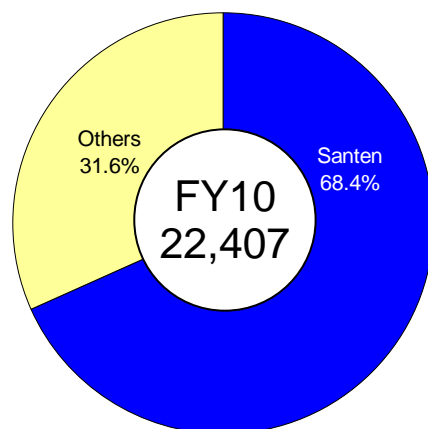
Source: ©2011 IMS Japan
IMS-JPM 2009-11
Santen analysis based on IMS data
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S Japan: Trend & Competition in Ophthalmics - 2

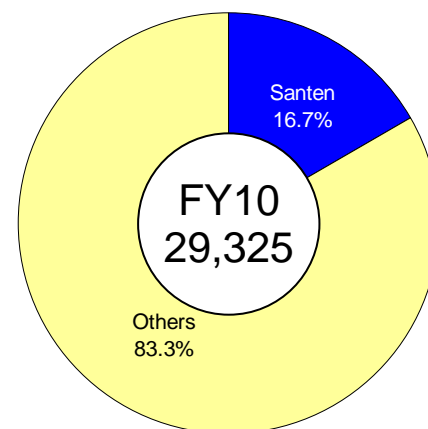
- **Anti-infection:** Market declined by 3.1%. Santen maintained 67.9% of market share with primary contribution of Cravit.
- **Anti-allergy:** Market grew by 31.2% in the 1st quarter FY11. Santen's share was 18.2% in the situation that competitor's growth continues.

Market Size:
millions of yen
%: Value Share

Anti-infection



Anti-allergy



		FY10	Q1.FY11
YoY change	Market	-1.0%	-3.1%
	Santen	-3.3%	-3.7%
Santen's Share		68.4%	67.9%

		FY10	Q1.FY11
YoY change		+22.3%	+31.2%
Market		+2.9%	+27.4%
Santen's Share		16.7%	18.2%

- Santen:
- Anti-infection: Cravit, Tarivid, etc.
 - Anti-allergy: Livostin, Alegysal

Source: ©2011 IMS Japan
IMS-JPM 2009-11
Santen analysis based on IMS data
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FY2011 First Quarter Status of Clinical Development

Toshiaki Nishihata, Ph.D.

Member of the Board
Executive Corporate Officer, U.S. and Europe
Business,
Head of Research and Development Division



Major Clinical Pipeline List (1) [by Disease]

(Red underlined: Change from Q4 FY10 Presentation)

Global Product

Japan (Asia) Product

Disease	Phase 1	Phase 2	Phase 3	NDA	Approved/ Launched
Glaucoma		DE-112 Adenosine A _{2A}	DE-111 Tafluprost/Timolol EU JP	China US	<u>DE-085</u> Tafluprost JP·Asia· EU·Latin America
		DE-090 Lomerizine HCl			
Corneal/ conjunctival disease (Dry eye)		<u>DE-101*</u> Rivoglitazone	DE-089 Diquafosol Sodium China Korea Japan		
	US	DE-105 Peptide combo	JP		
		DE-110 SEGRA			
Retinal/ Uveal disease			DE-109 Sirolimus		
			<u>DE-102</u> Betamethasone DDS		
Other Infection, Allergy, RA		DE-098 Anti APO-1 Antibody	DE-114 Epinastine HCl		<u>DE-108</u> Levofloxacin 1.5%

*P2 study with new target profile is newly under preparation in US



Major Clinical Pipeline List (2) [by Region]

(Red underlined: Change from Q4 FY10 Presentation)

Global product

Japan (Asia)
Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved/ Launched
Japan			<u>DE-102</u> Betamethasone DDS		<u>DE-085</u> Tafluprost
		DE-090 Lomerizine HCl	DE-111 Tafluprost/Timolol		DE-089 Diquafosol Sodium
		DE-105 Peptide Combo	DE-114 Epinastine HCl		<u>DE-108</u> Levofloxacin 1.5%
		DE-098 Anti APO-1 Antibody			
North America (Including Latin America)	DE-105 Peptide combo	DE-110 SEGRA	DE-109 Sirolimus	US	<u>DE-085</u> Tafluprost <u>Latin America</u>
		<u>DE-101*</u> Rivoglitazone			
	DE-112 Adenosine A _{2A}				
Asia				China	<u>DE-085</u> Tafluprost <u>Korea, etc</u>
			DE-089 China Diquafosol Sodium Korea		
Europe			DE-111 Tafluprost/Timolol		<u>DE-085</u> Tafluprost

*P2 study with new target profile is newly under preparation in US

Major Clinical Projects (DE-085)

- DE-085 (Glaucoma, Ocular hypertension)

TAPROS, TAFLOTAN in Santen areas, SAFLUTAN in Merck* areas

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011	
Japan	Launched	Launched	Generic name: Tafulprost Launched in: Japan (Dec. 2008) Europe (Jun. 2008) Asia (Mar. 2010) Latin America (Aug. 2010) Out-licensed to: Merck & Co. (Apr. 2009)
Europe**	Launched: 27 countries Approved: 37 countries Partly out-licensed to Merck*	Launched: 27 countries Approved: 30 countries Partly out-licensed to Merck*	
Asia	Launched: 4 countries Approved: 5 countries NDA filed: China	Launched: 2 countries Approved: 4 countries NDA filed: China	
U.S./ Others	Out-licensed to Merck* Launched: 4 countries Approved: 9 countries NDA filed: U.S.	Out-licensed to Merck* Launched: 4 countries Approved: 6 countries NDA filed: U.S.	

Launched: Total of 36 countries worldwide (newly added: 2 countries)

- Santen: Japan, 4 countries in Asia (Hong Kong, Korea, Indonesia, Singapore), and 20 countries in Europe (Germany, Finland and 18 other countries)
- Merck*: 7 countries in Europe (U.K., Spain, Netherlands, Italy, Portugal, Austria, Switzerland), and 4 countries in Latin America (Bahamas, etc.)

Approved: Total of 52 countries worldwide (newly added: 11 countries; Taiwan, France, Belgium, Greece, Ireland, Slovenia, Cyprus, Malta, Brazil, Argentina, Honduras)

*Merck areas (since April 2009): Western Europe excluding Germany, North America, South America, and Africa

**Including CIS



Major Clinical Projects Update (DE-089)

- **DE-089 (Dry eye)**
DIQUAS in Japan

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
Japan	Launched	Launched (December, 2010)	Generic name: Diquafosol sodium
Asia	China: P3 Korea: NDA filed	China: P3 Korea: NDA filed	



Major Clinical Projects Update - Glaucoma, Ocular hypertension -

- DE-090

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

- DE-111

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
Japan	P3	P3	Generic name: Tafluprost/ Timolol maleate (Combination drug)
Europe	P3	P3	

- DE-112

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
U.S.	P1/2a	P1/2a	Adenosine A _{2A} receptor agonist

Major Clinical Projects Update – Corneal / Conjunctival disease -

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

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
U.S.	P1/2 completed	P1/2	Generic name: Rivoglitazone
	Preparing P2*	-	
Japan	P2b completed	P2b	

*Product Profile changed, US P2 under preparation targeting improvement of tear quality & quantity

•DE-105 (Persistent corneal epithelial defects)

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
U.S.	Preparing P2	Preparing P2	Combination of peptides
Japan	P2	P2	

•DE-110 (Corneal and conjunctival epithelial disorders associated with dry eye)

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
U.S.	P2	P2	Selective glucocorticoid receptor agonist (SEGRA)



Major Clinical Projects Update - Retinal / Uveitis Disease -

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

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
Japan	P2/3	P1/2	Betamethasone DDS

- **DE-109** (Uveitis)

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
Japan	P3	P3	Generic name: Sirolimus



Major Clinical Projects Update - Others -

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

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
Japan	Launched (June 2011)	Approved	Generic name: Levofloxacin (1.5%)

- **DE-114** (Allergic conjunctivitis)

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
Japan	P3	P3	Generic name: Epinastine HCl

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

Region	Development Stage		Remarks
	As of August 2, 2011	As of May 10, 2011 (Previous announcement)	
Japan	P2	P2	Anti-APO-1 antibody



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.