

Santen Pharmaceutical Co., Ltd. Investor Meeting on FY2013 Results

Financial Results for the FY2013 Financial Forecast for the FY2014

May 14th, 2014
Akira Kurokawa
President & CEO

Santen's Values



"Tenki ni sanyo-suru"

Mission Statement

By focusing our efforts on ophthalmology and related areas, we develop scientific knowledge and organizational capabilities which are unique and original to Santen. We use our unique capabilities to contribute to patients and their loved ones, and consequently to society.

* Santen's original interpretation of a passage from chapter 22 of Zhongyong (The Doctrine of the Mean) by Confuctious, meaning "exploring the secrets and mechanisms of nature in order to contribute to people's health."

Long-term Strategic Vision A Specialized Pharmaceutical Company with a Global Presence

Prescription Ophthalmics
Business in Market

- #1 in Japan and Asia
- Top 3 position globally

Overseas sales in 2020

Up to 40 - 50% of Total Sales

Maximize New Product Value Globally

Establish & Reinforce
Overseas Business Platform

Strengthen Domestic Business Platform and Competitiveness

2011

2020

FY2011-FY2013 Medium Term Management Plan

Santen group has unified the accounting period from the fiscal year ended March 31, 2014, for voluntary adoption of International Financial Reporting Standards (IFRS) from the fiscal year ending March 31, 2015.

(JPY billions)		FY2013 (Objectives※)	FY2013* Actual	FY2013** Actual	
Net Sales		Over 121.00	148.66	146.01	
Operating Profit		Over 31.00	27.41	28.83	
Net Income		Over 20.00	17.10	18.92	
R&D Cost		15.50	19.04	18.23	
DOE (dividend rates for stockholder equity)		Around 5.0%	4.8%	4.7%	
ROE		_	9.9%	10.8%	
Santon	Foreign Exchage US \$ Euro RMB	FY13 <u>※</u> JPY 83.0 JPY 110.0 JPY 12.5	FY13 Actual JPY 100.04 JPY 132.98 JPY 15.93	FY13Actual JPY 100.04 JPY 132.34 JPY 15.72	





Consolidated Results FY2013

Financial Highlights for FY2013

(JPY billions)	FY2012 Actual	FY2013* Actual	Var. %
Net Sales	119.06	148.66	+24.9%
Cost of Sales (% of net sales)	41.50 34.9%	58.10 39.1%	+40.0% +4.2pt
SGA excluding R&D (% of net sales)	36.16 30.4%	44.10 29.7%	+22.0% -0.7pt
R&D Cost (% of net sales)	16.71 14.0%	19.04 12.8%	+13.9% -1.2pt
Operating Profit (% of net sales)	24.68 20.7%	27.41 18.4%	+11.1% -2.3pt
Ordinary Income	25.60	27.92	+9.1%
Net Income	16.52	17.10	+3.6%

FY2013** Actual	Var. %
146.01	+22.6%
57.17	+37.8%
39.2%	+4.3pt
41.77	+15.5%
28.6%	-1.8pt
18.23	+9.1%
12.5%	-1.6pt
28.83	+16.8%
19.7%	-1.0pt
29.33	+14.6%
18.92	+14.5%

^{*} Unification of Accounting Period.

Foreign Exchange	FY12 Actual	FY13 Actual
US\$	JPY 82.91	JPY 100.04
Euro	JPY 106.01	JPY 132.98
RMB	JPY 12.64	JPY 15.93

^{**} Before Unification of Accounting Period.

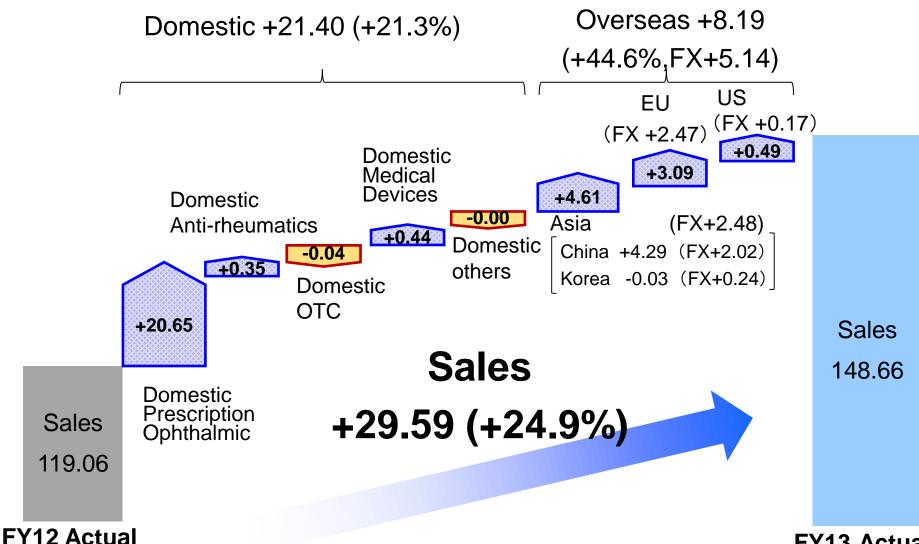
FY13 Actual
JPY 100.04
JPY 132.34
JPY 15.72



Sales Increase/Decrease

JPY billions

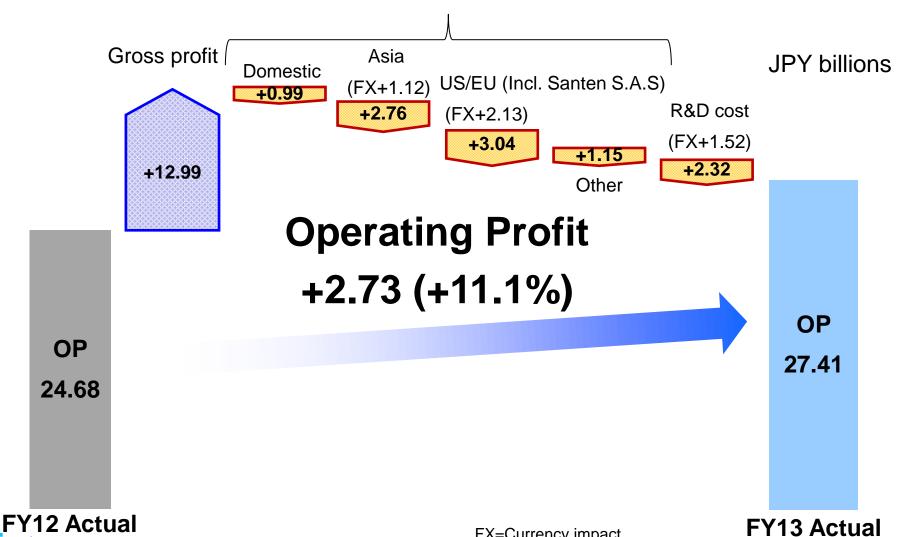
(Reflecting Unification of Accounting Period in FY13)



Operating Profit Change

(Reflecting Unification of Accounting Period in FY13)

SG&A (excl. R&D cost) +7.94 (+22.0%)





FY2014 Financial Forecast

FY2014 Financial Forecast

(JPY b	villions)	FY2013* Actual	FY2014 Forecast (Japanese Standard)	Var. %	FY2014 Forecast (IFRS)
Net Sal	les	148.66	151.00	+1.6%	151.00
Cost of	f Sales net sales)	58.10 39.1%	57.50 38.1%	-1.0% -1.0pt	57.50 38.1%
	cluding R&D net sales)	44.10 29.7%	46.50 30.8%	+5.4% +1.1pt	45.60 30.1%
R&D Co	ost net sales)	19.04 12.8%	19.00 12.6%	-0.2% -0.2pt	18.80 12.4%
=	ing Profit net sales)	27.41 18.4%	28.00 18.5%	+2.1% +0.1pt	29.10* 19.2%
Profit b	pefore tax	27.92	28.50	+2.1%	29.60
Net Income		17.10	18.60	+8.7%	19.60
ROE		9.9%	10.0%	+0.1pt	10.2%**
	Foreign Exchange	FY13 Actual	FY14 Forecast	* [Variance between	J-GAAP and IFRS]

Foreign Exchange US\$ Euro **RMB**



* Unification of Accounting Period.

JPY 100.04 JPY 103.00 JPY JPY 132.98 141.00 JPY 15.93 JPY 16.90

Goodwill not subject to amortization

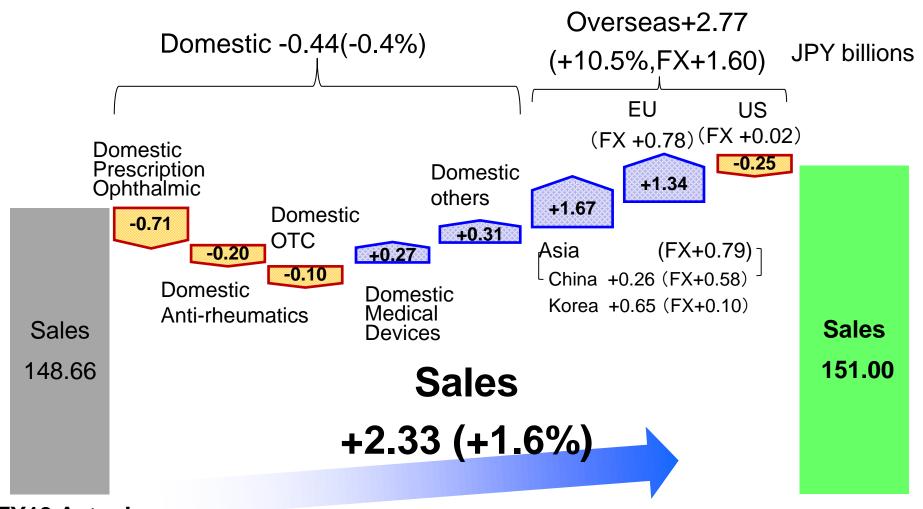
Capitalized expenditures for R&D activities

^{** [} Reason of Increase of ROE]

[•]Due to Increase of Net Income and Net asset by before-mentioned adjustments

FY2014 Forecast (Japanese Standard)

Sales Increase/Decrease



FY13 Actual (Unification of Accounting Period)

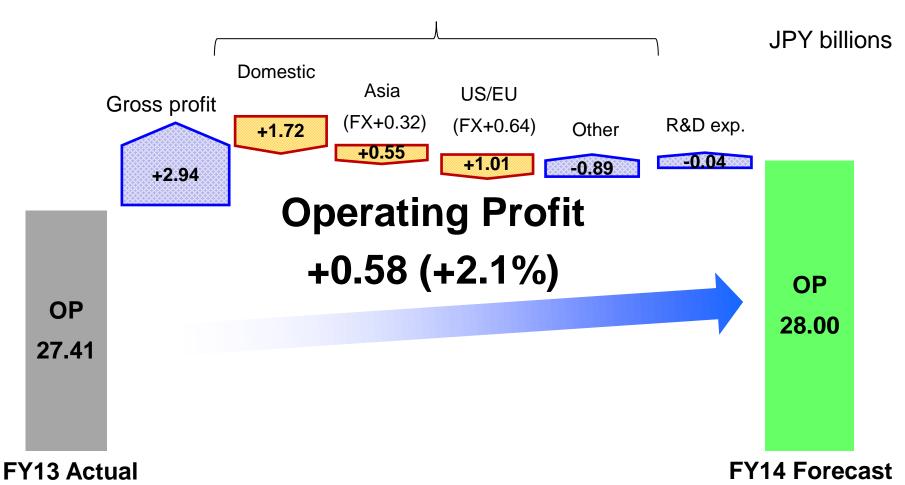
FY14 Forecast



FY2013 Forecast (Japanese Standard)

Operating Profit Change

SG&A (excl. R&D cost) +2.39 (+5.4%)



(Unification of Accounting Period)





Dividend for FY2013 Actual and FY2014 Forecast

Dividend for FY2013 Actual and FY2014 Forecast

FY2013

FY2013 Annual Dividend : JPY 100 per share

■ DOE: 4.8%

Dividend payout ratio:48.2%

FY2014

FY2014 Annual Dividend Forecast: JPY 100 per share

■ DOE: 4.4%

Dividend payout ratio:44.4%

FY2011-2013 (Medium-Term Management Plan)

Annual Dividend : JPY 100 per share





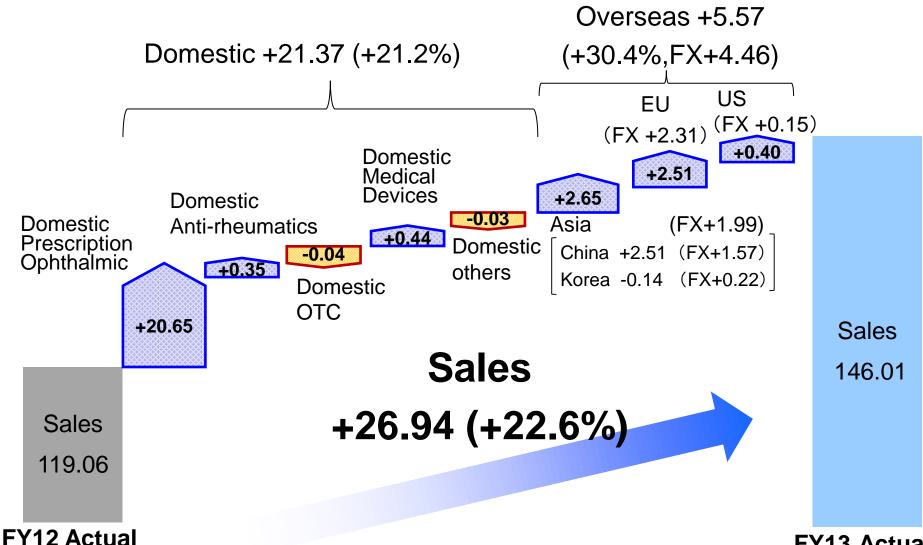


Reference: Consolidated Results FY2013

Sales Increase/Decrease

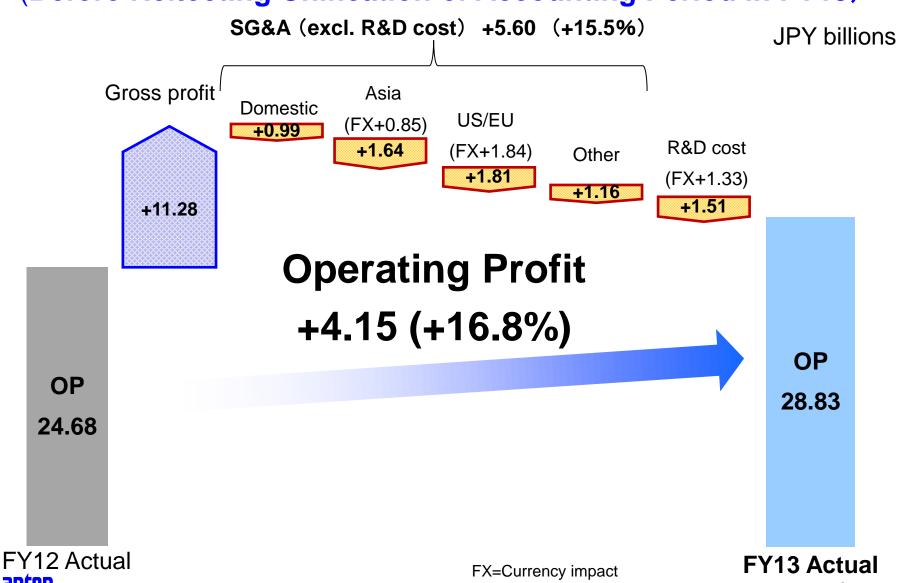
JPY billions

(Before Reflecting Unification of Accounting Period in FY13)



Operating Profit Change

(Before Reflecting Unification of Accounting Period in FY13)



Net Sales by Business Segment(Reflecting Unification of Accounting Period in FY13)

(J	PY billions)		FY2013 Actual					
		Jap	oan	Over	seas	Total		
		Sales	Var.	Sales	Var.	Sales	Var.	
Pharmaceuticals		119.21	+21.0%	26.49	+44.9%	145.71	+24.7%	
	Prescription Pharmaceuticals	112.79	+22.5%	26.45	+44.8%	139.25	+26.2%	
	Ophthalmic	101.77	+25.5%	25.61	+43.5%	127.39	+28.7%	
	Anti-RA	10.16	+3.6%	0.08	+40.1%	10.25	+3.8%	
	Others	0.85	-24.0%	0.75	+113.0%	1.61	+8.8%	
	OTC Pharmaceuticals	6.41	-0.6%	0.03	+150.9%	6.45	-0.3%	
Ot	thers	2.89	+32.3%	0.05	-20.3%	2.95	+30.8%	
	Medical Devices	2.62	+20.5%	0.05	-20.3%	2.67	+19.3%	
	Others*	0.27*				0.27*		
To	otal	122.11	+21.3%	26.55	+44.6%	148.66	+24.9%	



Net Sales by Business Segment(Before Reflecting Unification of Accounting Period in FY13)

(JI	PY billions)	FY2013 Actual					
		Jap	Japan Overseas				tal
		Sales	Var.	Sales	Var.	Sales	Var.
Pł	narmaceuticals	119.18	+21.0%	23.87	+30.6%	143.06	+22.5%
	Prescription Pharmaceuticals	112.76	+22.5%	23.84	+30.5%	136.61	+23.8%
	Ophthalmic	101.77	+25.5%	23.01	+28.9%	124.79	+26.1%
	Anti-RA	10.16	+3.6%	0.08	+40.1%	10.25	+3.8%
	Others	0.82	-26.7%	0.74	+110.0%	1.56	+6.0%
	OTC Pharmaceuticals	6.41	-0.6%	0.03	+136.3%	6.45	-0.3%
Ot	hers	2.89	+32.3%	0.05	-20.3%	2.95	+30.8%
	Medical Devices	2.62	+20.5%	0.05	-20.3%	2.67	+19.3%
	Others*	0.27*				0.27*	
То	otal	122.08	+21.2%	23.93	+30.4%	0.4% 146.01 +22.6%	



Oversea Sales (Reflecting Unification of Accounting Period in FY13)

(IDV hillians)	FY2012	FY2013			
(JPY billions)	Actual	Actual	Var.	Var. %	
U.S.	0.58	1.07	+0.49	+84.3%	
Europe	9.20	12.29	+3.09	+33.6%	
Asia	8.55	13.17	+4.61	+53.9%	
China	5.50	9.79	+4.29	+78.1%	
Korea	2.14	2.10	-0.03	-1.7%	
Others	0.01	0.00	-0.00	-16.0%	
Total	18.35	26.55	+8.19	+44.6%	

Oversea sales/total sales	15.4%	17.9%	+2.4pt	
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Oversea Sales (Before Reflecting Unification of Accounting Period in FY13)

(IDV h:II: a.a.a.)	FY2012	FY2013			
(JPY billions)	Actual	Actual	Var.	Var. %	
U.S.	0.58	0.98	+0.40	+69.6%	
Europe	9.20	11.71	+2.51	+27.3%	
Asia	8.55	11.21	+2.65	+31.1%	
China	5.50	8.01	+2.51	+45.7%	
Korea	2.14	1.99	-0.14	-6.7%	
Others	0.01	0.00	-0.00	-16.9%	
Total	18.35	23.93	+5.57	+30.4%	

Oversea sales/total sales 15.4%	16.4%	+1.0pt	-
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Summery of Balance Sheet

(IDV hillions)	As of Mar	ch 31, 2013	As	of March 31, 2	014
(JPY billions)	Actual	% of Total	Actual	% of Total	Var.
Current Asset	132.58	66.4%	156.00	67.5%	+23.42
Fixed Asset	67.05	33.6%	75.09	32.5%	+8.04
Total Asset	199.64	100.0%	231.10	100.0%	+31.46
Current Liabilities	27.01	13.5%	39.09	16.9%	+12.08
Non-current Liabilities	7.49	3.8%	10.80	4.7%	+3.30
Total Liabilities	34.50	17.3%	49.89	21.6%	+15.38
Total Net Asset	165.13	82.7%*	181.20	78.4%	+16.07
Total Liabilities Net Assets	199.64	100.0%	231.10	100.0%	+31.46

^{*}Capital adequacy ratio: End of March, 2013: 82.6% → End of March, 2014: 78.2%, Issued shares: End of March, 2013: 82,469 thousands → End of March, 2014: 82,582 thousands

Major Changes

Current Asset: Cash and deposits +¥12.62bil, Notes and account receivable +¥8.24bil, Securities +¥2.10bil,

Products -¥0.48bil

■Fixed Asset: Buildings and structures +¥0.71bil, Machinery, equipment and vehicles+¥0.62bil,

Construction in progress -\(\frac{\pmathbf{4}}{1.63}\)bil, Goodwill +\(\frac{\pmathbf{4}}{0.36}\)bil, In-Process R&D +\(\frac{\pmathbf{4}}{1.58}\)bil, Software +\(\frac{\pmathbf{4}}{0.67}\),

Investment securities +¥3.56bil, Deferred tax assets +¥1.02bil

■Current Liabilities: Accounts payable +¥5.00bil, Income tax payable +¥5.13bil, Reserve for bonus +¥0.48bil,

■ Fixed Liabilities: LT deferred tax debt +¥0.52bil, Liabilities relating to retirement +¥1.73bil,

Restructuring fee allowance +¥0.80bil

■Net asset : Retained earnings +¥9.11bil, Unrealized gains on securities +¥2.11bil, Foreign currency translation

adjustments +¥5.54bil, Cumulative adjustment to retirement benefits - ¥1.12bil



Summery of Income Statement

(Reflecting Unification of Accounting Period in FY13)

(IDV hillions)	FY2012	FY2012 FY2013			
(JPY billions)	Actual	Actual	YoY %	Major Changes	
Net Sales	119.06	148.66	+24.9%		
Cost of Sales (% of net sales)	41.50 34.9%	58.10 39.1%	+40.0% +4.2pt	•Impact of product mix change +4.9pt •Decrease of Sales cost ratio -0.5pt	
SGA excluding R&D (% of net sales)	36.16 30.4%	44.10 29.7%	+22.0% -0.7pt	Domestic +0.99 Asia +2.76 (FX +1.12) US/EU +3.04 (FX +2.13)	
R&D Expenses (% of net sales)	16.71 14.0%	19.04 12.8%	+13.9% -1.2pt	•Domestic +0.52 •Overseas +1.79 (FX +1.52)	
Operating Profit (% of net sales)	24.68 20.7%	27.41 18.4%	+11.1% -2.3pt	<currency rates=""> FY12 Actual FY13 Actual FY13 Actual FY14 Actual FY15 Actual</currency>	
Non-operating Income Non-operating Expense	1.00 0.08	0.97 0.46	-3.2% +437.5%	US\$ JPY 82.91 JPY 100.04 Euro JPY106.01 JPY 132.98 CNY JPY 12.64 JPY 15.93	
Ordinary Income	25.60	27.92	+9.1%	•Gain on sale of investment securities +0.47	
Extraordinary Gain Extraordinary Loss	0.01 0.02	0.47 1.50	-	Provision of restructuring fee regarding Santen Oy +1.32	
Net Income before Tax	25.59	26.89	+5.1%		
Corporate Tax	9.07	9.78	+7.9%		
Net Profit	16.52	17.10	+3.6%		



Summery of Income Statement

(Before Reflecting Unification of Accounting Period in FY13)

(IDV hillions)	FY2012	FY2013			
(JPY billions)	Actual	Actual	YoY %	Major Changes	
Net Sales	119.06	146.01	+22.6%		
Cost of Sales (% of net sales)	41.50 34.9%	57.17 39.2%	+37.8% +4.3pt	Change of product mix +4.9pt Decrease of Sales cost ratio -0.5pt	
SGA excluding R&D (% of net sales)	36.16 30.4%	41.77 28.6%	+15.5% -1.8pt	Domestic +0.99 Asia +1.64 (FX +0.85) US/EU +1.81 (FX +1.84)	
R&D Expenses (% of net sales)	16.71 14.0%	18.23 12.5%	+9.1% -1.6pt	Domestic +0.52 Overseas +0.99 (FX +1.33)	
Operating Profit (% of net sales)	24.68 20.7%	28.83 19.7%	+16.8% -1.0pt	<pre><currency rates=""></currency></pre>	
Non-operating Income Non-operating Expense	1.00 0.08	0.90 0.40	-10.4% +368.8%	Euro JPY 106.01 JPY 132.34 CNY JPY 12.64 JPY 15.72	
Ordinary Income	25.60	29.33	+14.6%		
Extraordinary Gain Extraordinary Loss	0.01 0.02	0.47 1.01	-	Gain on sale of investment securities +0.47 Provision of restructuring fee regarding Santen Oy +0.84	
Net Income before Tax	25.59	28.79	+12.5%		
Corporate Tax	9.07	9.86	+8.8%		
Net Profit	16.52	18.92	+14.5%		

Summary of Cash Flows(Reflecting Unification of Accounting Period in FY13)

(JPY billion	FY2013 Actual	
Cash an	d cash equivalents at the beginning of FY13	59.79
Net incr	+12.59	
	Cash flows from operating activities	+25.95
	Cash flows from investing activities	-6.69
	Cash flows from financial activities	-7.95
	Effect of exchange rate changes on cash and cash equivalents	+1.28
Cash an	d cash equivalents at the end of FY13	72.39

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



Capital Expenditures / Depreciation & Amortization (Reflecting Unification of Accounting Period in FY13)

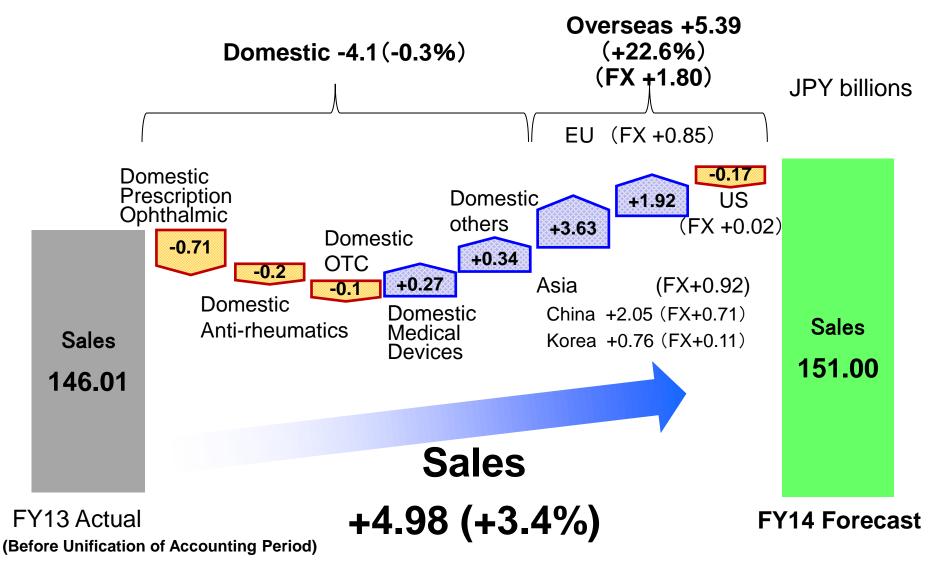
(15)(1,111)	FY2012	FY2	013	
(JPY billions)	Actual	Actual	Var.	
Capital Expenditures	4.20	3.15	-1.04	
Depreciation and Amortization	2.53	2.61	+0.08	





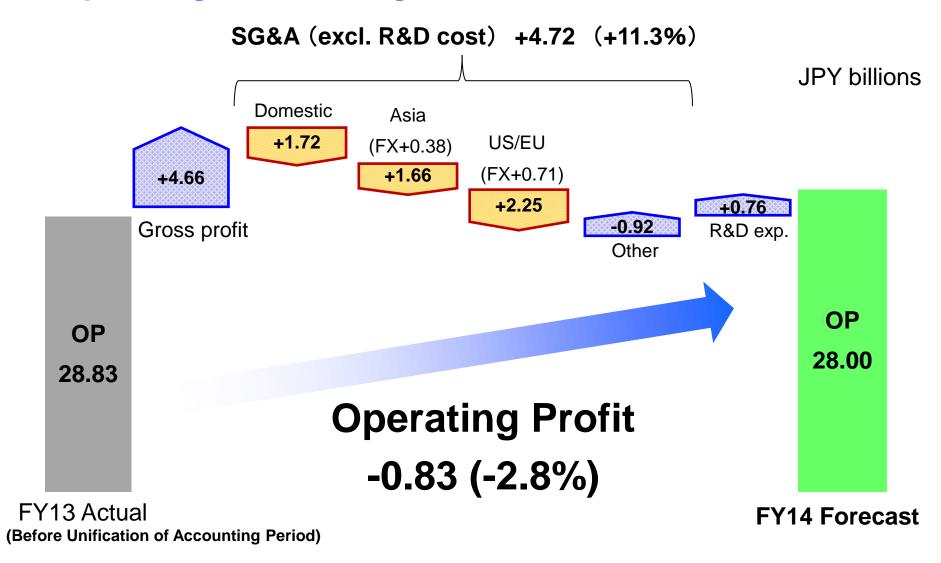
Reference: FY2014 Financial Forecasts

FY2014 Forecast (Japanese Standard) Sales Increase/Decrease





FY2014 Forecast (Japanese Standard) Operating Profit Change





FY2014 Financial Forecast 1st Half • 2nd Half

(JPY billions)	FY2014 Forecast (J-GAAP)						
(JP i billions)	1 st Half	Var.	2 nd Half	Var.	FY2014	Var.*	
Net Sales	71.50	+3.2%	79.50	+0.1%	151.00	+1.6%	
Cost of Sales (% of net sales)	27.90 39.0%	+2.7% -0.2pt	29.60 37.2%	-4.3% -1.7pt	57.50 38.1%	- 1.0% -1.0pt	
SGA excluding R & D (% of net sales)	22.00 30.8%	+12.4% +2.5pt	24.50 30.8%	-0.2% -0.1pt	46.50 30.8%	+5.4% +1.1pt	
R &D Cost (% of net sales)	9.00 12.6%	+11.4% +0.9pt	10.00 12.6%	-8.8% -1.2pt	19.00 12.6%	-0.2% -0.2pt	
Operating Profit (% of net sales)	12.60 17.6%	-12.8% -3.3pt	15.40 19.4%	+18.9% +3.1pt	28.00 18.5%	+2.1% +0.1pt	
Ordinary Income	12.90	-13.2%	15.60	+19.4%	28.50	+2.1%	
Net Income	8.40	-6.6%	10.20	+25.7%	18.60	+8.7%	

* Unification of Accounting Period

Foreign Exchange	FY14 Forecast
US\$	JPY 103.00
Euro	JPY 141.00
RMB	JPY 16.90



Sales Forecast by Business Segment / Overseas Sales (Japanese Standard)

		FY2014 Forecast						
 (JI	PY billions)	Jap	oan	Over	Overseas		Total	
	·	Sales	Var.	Sales	Var.	Sales	Var.	
Pł	narmaceuticals	118.75	-0.4%	29.27	+10.5%	148.03	+1.6%	
	Prescription Pharmaceuticals	112.45	-0.3%	29.25	+10.6%	141.70	+1.8%	
	Ophthalmic	101.06	-0.7%	28.35	+10.7%	129.41	+1.6%	
	Anti-RA	9.95	-2.0%	0.03	-61.4%	9.99	-2.5%	
	Others	1.43	+67.2%	0.86	+15.0%	2.29	+42.8%	
	OTC Pharmaceuticals	6.30	-1.7%	0.02	-36.6%	6.33	-1.9%	
Ot	hers	2.91	+0.5%	0.04	-6.7%	2.96	+0.4%	
	Medical Devices	2.90	+10.5%	0.04	-20.7%	2.94	+9.8%	
	Others	0.01	-95.6%	0.00		0.01	-92.8%	
Total 121.67		121.67	-0.4%	29.32	+10.5%	151.00	+1.6%	



Oversea Sales Forecast (Japanese Standard)

	EV2042	F	st	
(JPY billions)	FY2013 Actual	Forecast	Var.	Var. %
U.S.	1.07	0.81	-0.25	-23.8%
Europe	12.29	13.64	+1.34	+11.0%
Asia	13.17	14.85	+1.67	+12.8%
China	9.79	10.06	+0.26	+2.7%
Korea	2.10	2.75	+0.65	+31.1%
Others	0.00	0.01	+0.00	+71.9%
Total	26.55	29.32	+2.77	+10.5%

Oversea sale/sales	17.9%	19.4%	+1.6pt	
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Capital Expenditures / Depreciation & Amortization (Japanese Standard)

(IDV hillions)	FY2013	FY2	014
(JPY billions)	Actual	Forecast	Var.
Capital Expenditures	3.15	6.69	+3.53
Depreciation and Amortization	2.61	3.00	+0.39





Reference: Market Overview of Prescription Ophthalmic in Japan

Japan: Trend & Competition in Ophthalmics (1)

• Ophthalmology Total: Market grew by 10.2% Y on Y in FY13. The growth of retinal, and corneal segment

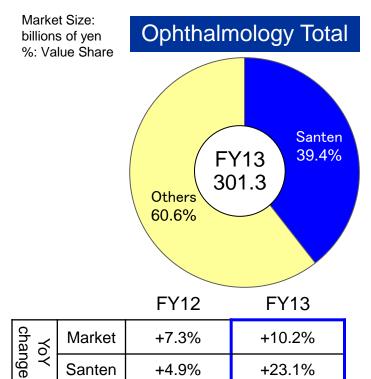
continued. Santen's market share was 39.4%.

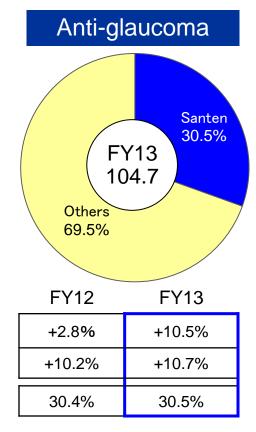
• Anti-Glaucoma: Market grew by 10.5% Y on Y in FY13. Santen's sales grew by 10.7%. Santen held 30.5%

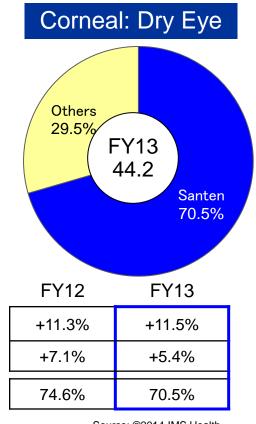
share of the anti-glaucoma market by the contribution of Tapros and Cosopt.

• **Corneal**: Market grew by 11.5% Y on Y in FY13. Santen's sales grew by 5.4% led by the sales

increase of Diquas and Santen's market share was 70.5%.







-Santen:

Santen's Sharel

- Anti-Glaucoma: Tapros, Cosopt, Timoptol/XE, Rescula, Detantol

39.4%

- Cornea / Dry Eye : Hyalein, Diquas

35.3%



Japan: Trend & Competition in Ophthalmics (2)

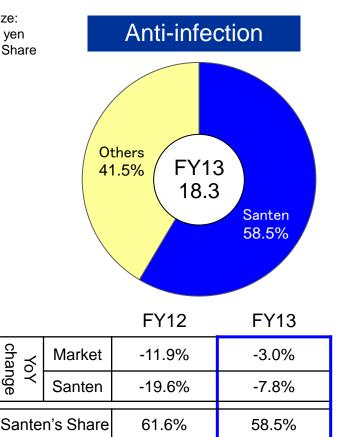
 Anti-infection: Market declined by -3.0% Y on Y in FY13. Santen maintained 58.5% of market share with

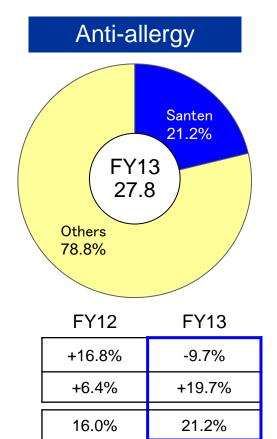
primary contribution by Cravit.

Anti-allergy: Market declined by -9.7% Y on Y in FY13. Santen's share was 21.2%.

The launch of Alesion generated the increase of Santen market share.

Market Size: billions of yen %: Value Share







change

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- Anti-infection: Cravit. Tarivid

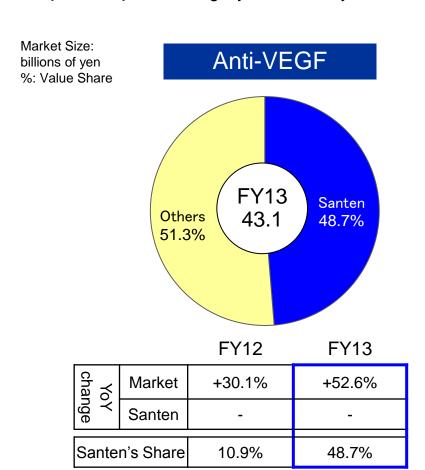
- Anti-allergy: Livostin, Alesion, Alegysal

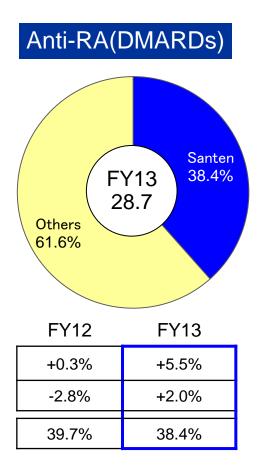


Japan: Trend & Competition in Ophthalmics (3)

• Anti-VEGF: Market increased by 52.6% Y on Y in FY13. Eylea has continued the strong growth. Santen's share was 48.7%.

• Anti-RA(DMARDs): Market slightly increased by 5.5% in FY13. Santen maintained 38.4% of market share.







- Anti-VEGF: Eylea

- Anti-RA(DMARDs): Rimatil, Azulfidine, Metolate



FY2013 Status of Clinical Development

Naveed Shams, Ph.D.
Corporate Officer,
Chief Scientific Officer

Major Clinical Pipeline List (1) [by Disease]

(Red underlined: Change from 3Q FY13 Presentation)

Global Product

Japan (Asia)Product

Disease	Phase 1	Phas	se 2	Phase 3	NDA	Approved - Launched
Glaucoma/ Ocular	P2b	prep DE-			China DE-085 Tafluprost	DE-118 Tafluprost UD
Hypertension		DE-l Lomeriz				E-111 JP ost/Timolol
Corneal/ Conjunctival					China	-089 esol Sodium Korea
Disease		U.S. Cyclo	okat _{porin}		Cyclokat EU	
Retina/ Uveitis	u.s. DE-120 VEGF/PDGF inh			DE-109 Sirolimus		
			E	DE-102 Betamethasone		
Other Infection, Allergy, RA				Vekacia Ciclosporin		DE-114 Epinastine HCI



Major Clinical Pipeline List (2) [by Region]

(Red underlined: Change from 3Q FY13 Presentation)

Global Product

Japan (Asia)Product

Region	Phase 1	Pha	se 2	Phase 3	NDA	Approved - Launched
Japan				DE-102 Betamethasone		DE-118 Tafluprost UD
		DE- Lomeriz				DE-111 Tafluprost/Timolol
				DE-109 Sirolimus		DE-114 Epinastine HCI
North America	P2h		117 tor Agonist	DE-109 Sirolimus		
(Including Latin America)	DE-120 VEGF/PDGF inh					
		Cyc Ciclos	l <mark>okat</mark> sporin			
Asia (including Oceania)					China DE-085 Tafluprost	
						089 Korea ol Sodium
EU				DE-109 Sirolimus	DE-111 Tafluprost/Timolol	
				Vekacia Ciclosporin	Cyclokat Ciclosporin	



^{*}Project evaluations are ongoing for other Santen S.A.S. products.

Major Clinical Projects Update - Glaucoma / Ocular ■ DE-085 (Glaucoma / Ocular hypertension) hypertension -

Development Stage			
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks
China	NDA Filed	NDA Filed	Generic name: Tafluprost

■ **DE-090** (Glaucoma / Ocular hypertension)

	Development Stage		
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks
Japan	P2	P2	Generic name: Lomerizine HCI

■ **DE-111** (Glaucoma / Ocular hypertension)

	Developm		
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks
Japan	Approved	Approved	Generic name: Tafluprost/
Europe	NDA Filed	NDA Filed	Timolol maleate (Combination drug)

Major Clinical Projects Update

- -Glaucoma -
- -Corenal disease-

■ **DE-117** (Glaucoma / Ocular hypertension)

-Allergy-

	Developme		
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks
U.S.	P2b preparation	P2b preparation	EP2 receptor agonist

■ DE-089 (Dry eye)

	Developm		
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks
Asia	China: NDA filed Korea: Launched	China: NDA filed Korea: Launched	Generic name: Diquafosol Sodium

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

	Development Stage			ı
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks	
Japan	Launched	Launched	Generic name: Epinastine HCI	

Major Clinical Projects Update - Retinal Disease -

■ **DE-102** (Macular edema associated with diabetes or branch. Uveitis - retinal vein occlusion (BRVO))

	Developm		
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks
Japan	P2/3 Completed	P2/3	Generic name: Betamethasone

■ **DE-120** (Wet Age-related Macular Degeneration (w-AMD))

	Developm		
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks
U.S.	P1/2a	P1/2a	VEGF/PDGF dual inhibitor

^{*}Drug Delivery System: A system (technology) for ensuring that drugs reach the targeted tissue site.

■ **DE-109** (Uveitis)

	Development Stage		
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks
U.S.	Р3	P3	•
Japan	Р3	P3	Generic name: Sirolimus
EU	P3	P3	

Major Clinical Projects Update - Arthritis -

■ **DE-098** (Rheumatoid arthritis)

	Developr		
Region	As of May 13, 2014	As of February 4, 2014 (Previous announcement)	Remarks
Japan	Discontinued	P2 Completed	Anti-APO-1 Antibody

Major Clinical Projects Update - Santen S.A.S.-

■ Cyclokat (Severe Dry Eye)

Region	Development Stage		Domonko	
	As of May 13, 2014	Feb 4, 2014 (Previous)	Remarks	
EU	NDA filed	NDA filed	Generic Name:	
U.S.	P2 Completed	P2 Completed	Ciclosporin	

■ **Vekacia** (Vernal Keratoconjunctivitis)

Region	Development Stage		Domonico	
	As of May 13, 2014	Feb 4, 2014 (Previous)	Remarks	
EU	Р3	Р3	Generic Name: Ciclosporin	

*Project evaluations are ongoing for the products below.

Development Name	Indication	Region	Stage	Remarks
Catioprost	Glaucoma/ Ocular hypertension	EU	P2	Generic Name: Latanoprost
Cortiject Diabetic macular edema		U.S.	P1/2	Generic Name: Dexamethasone Palmitate

About DE-109:Sakura Study1

■ Sakura Study

- ➤ Subjects are 347patients with non-infectious uveitis posterior, intermediate or panuveitis.
- ➤ The first of two Global Phase III studies evaluating intravitreal injections of sirolimus (DE-109) in patients with non-infectious posterior segment uveitis.

■ Clinical Trial

- Primary endpoint: vitreous haze score
 (Standardized Uveitis Nomenclature [SUN] Photographic scale)
- The proportion of patients achieving a vitreous haze score of zero at month five
- Eligible patients were randomized into three treatment arms, each receiving different doses ($44\mu g$, $440 \mu g$ and $880 \mu g$) of sirolimus by intravitreal injection.
- \triangleright Comparisons are being made between 44 μ g vs 440 μ g, or 880 μ g.



Study 1met its primary endpoint.



What is Vitreous Haze Score?

- Vitreous Haze Score (VH Score)
 - > Standardized Uveitis Nomenclature [SUN] Photographic scale
 - ➤ It is used to evaluate the vitreous haze. The score range from Grade0 to Grade4.

	Vitreous Haze					
Vitreous Haze Score	4+	3+	2+	1+	Trace	0
Evaluation	No optic nerve head not visible	Optic nerve head border blurry, but still visible	Moderate blurring of optic nerve and vessels	Slight blurring of optic nerve and vessels	Slight blurring of optic disc area (Trace Inflammation)	No Haze

XScore 0.5 in Sakura Study1is same as Trace



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 and event were to adversely affect supply capabilities for related final products.

