

# **FY 2013 Third Quarter Results**

# February 4, 2014 Santen Pharmaceutical Co., Ltd



### Financial Results for the FY2013 Third Quarter; Financial Forecast for the FY2013;

### Kazuo Koshiji

Corporate Officer, Head of Finance & Administration Division

# Med-term Policies FY2011-2013

### To become a specialized pharmaceutical company with a global presence

- 1. Promote global oriented research and development operation.
- 2. Boost domestic business by maximizing new product value and implementation of sales/marketing strategies.
- 3. Accelerate growth in both Asia and Europe by reinforcing marketing platform.
- 4. Establish global product supply system with existing 4 plants which enables to meet the emerging market needs.
- 5. Develop talents and organizational capabilities to promote "Creation and Innovation" on a globally level.



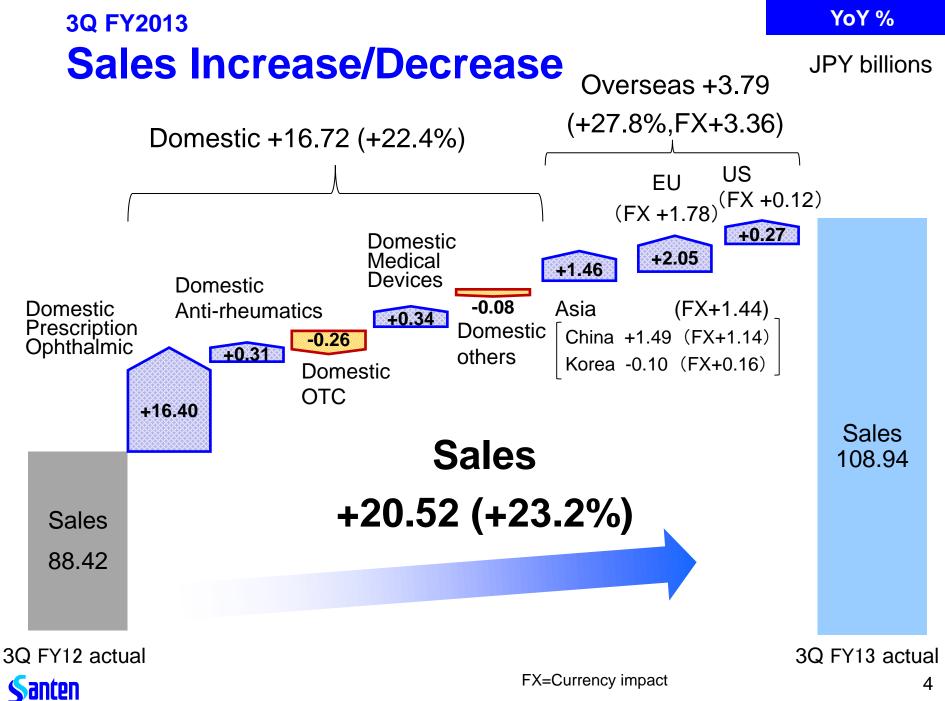
\*4 plants: Noto and Shiga (both in Japan); Suzhou (China); Tampere (Finland)

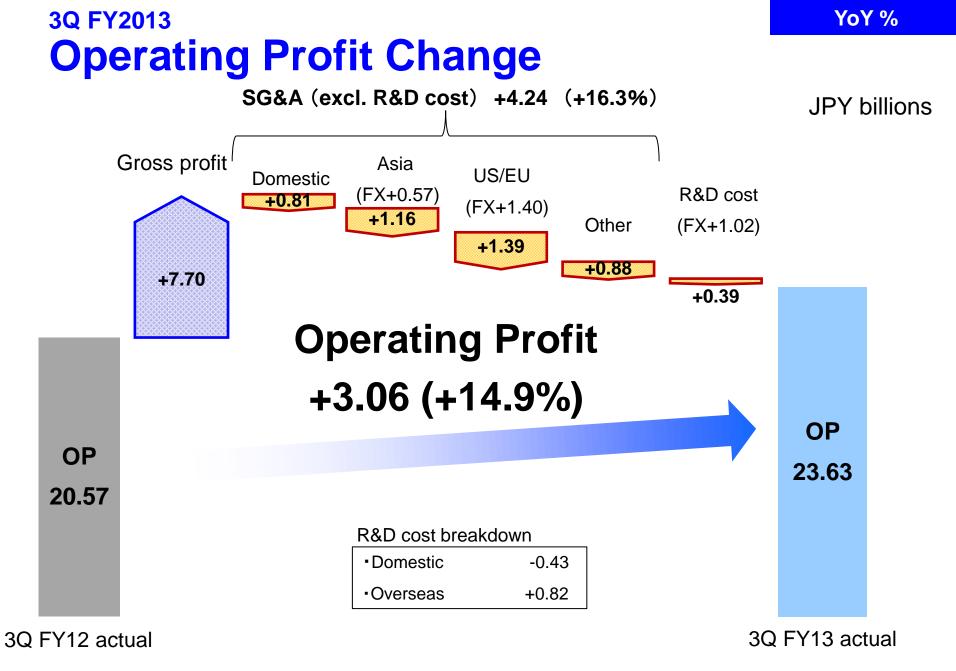
# **Financial Highlights for 3Q FY2013**

(JPY billions)	3Q FY2012 Actual	3Q FY2013 Actual	Var. %
Net Sales	88.42	108.94	+23.2%
Cost of Sales	29.75	42.57	+43.1%
(% of net sales)	33.7%	39.1%	+5.4pt
SGA excluding R&D	25.99	30.24	+16.3%
(% of net sales)	29.4%	27.8%	-1.6pt
R&D Cost	12.09	12.49	+3.3%
(% of net sales)	13.7%	11.5%	-2.2pt
Operating Profit	<b>20.57</b>	<b>23.63</b>	<b>+14.9%</b>
(% of net sales)	23.3%	21.7%	-1.6pt
Ordinary Income	21.26	24.29	+14.2%
Net Income	14.13	15.37	+8.8%

Foreign Exchange	3Q FY12 actual	<u>3QFY13 actual</u>
US\$	JPY 80.01	JPY 99.17
Euro	JPY 102.12	JPY 129.59
RMB	JPY 12.53	JPY 15.49







**S**anten

FX=Currency impact



# **FY2013 Financial Forecasts**

### **Revised Financial Forecast for FY2013** (Before Reflecting Unification of Accounting Period in FY13)

(JPY billions)	FY2012 Actual	FY2013 Forecast*	Var. %	Previous FY2013 Forecast
Net Sales	119.06	146.00	+22.6%	141.50
Cost of Sales (% of net sales)	<b>41.50</b> 34.9%	<b>57.00</b> 39.0%	<b>+37.3%</b> +4.2pt	<b>55.00</b> 38.9%
SGA excluding R&D (% of net sales)	36.16 30.4%	43.00 29.5%	+18.9% -0.9pt	42.00 29.7%
R&D cost (% of net sales)	16.71 14.0%	18.50 12.7%	+10.6% -1.4pt	18.20 12.9%
Operating Profit (% of net sales)	<b>24.68</b> 20.7%	<b>27.50</b> 18.8%	<b>+11.4%</b> -1.9pt	<b>26.30</b> 18.6%
Ordinary Income	25.60	28.50	+11.3%	26.80
Net Income	16.52	18.50	+12.0%	18.20
ROE	10.0%	10.6%	+0.6pt	10.7%

	Foreign Exchange	Foreign Exchange <u>FY12 actual</u>	
	US\$	JPY 82.91	JPY 100.42
	Euro	JPY 106.01	JPY 132.68
Santen	RMB	JPY 12.64	JPY 15.72

\* 12month period

### **Revised Financial Forecast for FY2013** (After Reflecting Unification of Accounting Period in FY13)

(JPY billions)	FY2012 Actual	FY2013 Forecast	Var. %
Net Sales	119.06	149.00	+25.1%
Cost of Sales	41.50	58.00	+39.8%
(% of net sales)	34.9%	38.9%	+4.1pt
SGA excluding R&D	36.16	45.00	+24.4%
(% of net sales)	30.4%	30.2%	-0.2pt
R&D cost	16.71	19.50	+16.6%
(% of net sales)	14.0%	13.1%	-1.0pt
Operating Profit	24.68	26.50	+7.4%
(% of net sales)	20.7%	17.8%	-2.9pt
Ordinary Income	25.60	27.50	+7.4%
Net Income	16.52	17.50	+5.9%
ROE	10.0%	10.1%	+0.1pt
Foreign Exchange	FY12 actual	FY13 forecast	-
US\$	JPY 82.91	JPY 100.42	
Euro	JPY 106.01	JPY 133.37	
RMB	JPY 12.64	JPY 16.00	



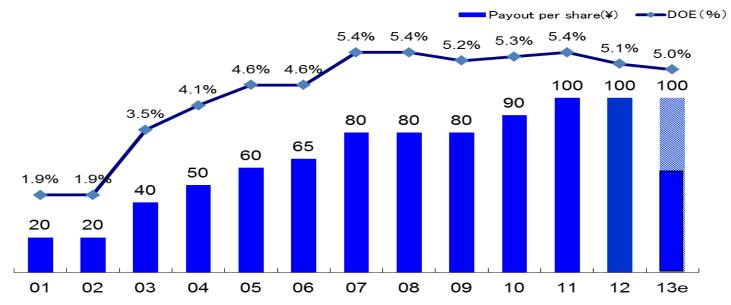
# Dividend for 1H FY2013 Actual and FY2013 Forecast



### **Dividend for 1H FY2013 Actual and FY2013 Forecast**

#### FY2013

- FY2013 First Half Dividend : JPY 50 per share
- FY2013
  - FY2013 Annual Dividend : JPY 100 per share
  - Target DOE: around 5.0%



(¥ billion)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013e
Payout-ratio (%)	34.9	21.4	55.8	39.7	39.9	42.9	54.7	67.2	36.3	36.0	50.8	51.1	48.2
Share Buy-back	3.2	3.2	0	2.6	0	0	4.8	0	0	0	0	13.7	
Total Return (%)	96.4	59.5	55.8	63.3	39.9	42.9	85.8	67.2	36.4	36.7	50.8	137.0	



# Adaptation of International Financial Reporting Standards (IFRS)



### **Schedule of IFRS Adoption**

- Voluntarily adoption of the IFRS from FY 2014
  - ➢ May, 2014 :
  - Annual financial results and consolidated financial statements for FY2013 (ending in March 2014, J-GAAP)
  - -Financial forecast for FY2014 (J-GAAP)

(Financial forecast of IFRS will be disclosed as reference.)

- **≻** May, 2015:
- Annual financial results and consolidated financial statements for FY2014 (ending in March 2015) (IFRS)
- For reference, financial results of FY2013 (IFRS) will be released.
- Consolidated financial results for the first quarter to the third quarter of FY2014 (ending in March 2015) will be disclosed under J-GAAP
- Changes approved from FY 2013 under J-GAAP
- Already implemented: Depreciation method,

New accounting on retirement allowance

•Planned: Unification of accounting term for group companies





# Reference: Consolidated Results 3Q FY2013

### **Net Sales by Business Segment**

(J	PY billions)			3Q FY20 <sup>2</sup>	13 Actual			
		Japan		Over	seas	То	Total	
		Sales	Var.	Sales	Var.	Sales	Var.	
Pł	narmaceuticals	89.38	+22.1%	17.43	+28.0%	106.82	+23.1%	
	Prescription Pharmaceuticals	84.45	+24.2%	17.41	+27.9%	101.87	+24.8%	
	Ophthalmic	75.93	+27.6%	16.90	+26.9%	92.84	+27.4%	
	Anti-RA	7.98	+4.2%	0.07	+12.2%	8.05	+4.2%	
	Others	0.54	-32.6%	0.43	+85.5%	0.97	-6.0%	
	OTC Pharmaceuticals	4.92	-5.1%	0.02	+214.5%	4.95	-4.7%	
Ot	thers	2.08	+33.9%	0.03	-32.5%	2.12	+31.6%	
	Medical Devices	1.89	+22.4%	0.03	-32.5%	1.93	+20.5%	
	Others	0.18				0.18		
Тс	otal	91.46	+22.4%	17.47	+27.8%	108.94	+23.2%	



### **Oversea Sales**

	3Q FY2012	3Q FY2013			
(JPY billions)	Actual	Actual	Var.	Var. %	
U.S.	0.36	0.63	+0.27	+74.2%	
Europe	6.46	8.51	+2.05	+31.8%	
Asia	6.84	8.31	+1.46	+21.5%	
China	4.47	5.97	+1.49	+33.5%	
Korea	1.63	1.52	-0.10	<b>▲</b> 6.7%	
Others	0.00	0.01	+0.00	+28.0%	
Total	13.68	17.47	+3.79	+27.8%	



### **Summery of Balance Sheet**

	As of March 31, 2013		As of December 31, 2013		
(JPY billions)	Actual	% of Total	Actual	% of Total	Var.
Current Asset	132.58	66.4%	143.80	65.7%	+11.21
Fixed Asset	67.05	33.6%	74.94	34.3%	+7.89
Total Asset	199.64	100.0%	218.75	100.0%	+19.10
Current Liabilities	27.01	13.5%	29.55	13.5%	+2.54
Non-current Liabilities	7.49	3.8%	10.77	4.9%	+3.27
Total Liabilities	34.50	17.3%	40.33	18.4%	+5.82
Total Net Asset	165.13	82.7%*	178.41	81.6%*	+13.28
Total Liabilities Net Assets	199.64	100.0%	218.75	100.0%	+19.10

\*Capital adequacy ratio: End of March, 2013: 82.6%  $\rightarrow$  End of December, 2013: 81.4%,

Issued shares: End of March, 2013: 82,469 thousand  $\rightarrow$  End of December, 2013: 82,547 thousand

#### **Major Changes**

- **Current Asset:** Cash and deposits +¥3.74bil, Notes and account receivable +¥8.84bil, Securities +¥1.40bil, Goods and products -¥2.68bil,
- Fixed Asset : Buildings and structures +¥0.77bil, Machinery equipment and transportation cost +¥0.76bil, Construction in progress -¥1.34bil, Goodwill +¥0.31bil, In-Process R&D product +¥1.01bil, Investment securities +¥5.42bil

#### Current Liabilities: Accounts payable +¥1.64bil, Other account payable -¥0.78bil, Income tax payable +¥1.57bil, Reserve for bonus -¥1.12bil, Other current liabilities +¥1.20bil

Fixed Liabilities: Liabilities relating to retirement benefits(previous account: Retirement and severance benefits)+¥2.22bil<sup>\*</sup>, Retirement benefits for directors -¥0.24bil, Restructuring fee allowance +¥0.78bil
 Net asset : Capital +¥0.12bil, Additional paid in capital +¥0.12bil, Retained earnings +¥7.38bil, Foreign currency

- translation adjustments +¥4.59bil, Cumulative adjustment to retirement benefits ¥1.56bil
- Sonten X Change in accounting standard increased +¥2.29bil (previous unrecognized debt is recognized and adjusted). Account title is revised at the change in accounting standard.

### **Summery of Income Statement**

(IDV hillions)	3Q FY2012	3Q FY	2013	
(JPY billions)	Actual	Actual	YoY %	Major Changes
Net Sales	88.42	108.94	+23.2%	
Cost of Sales (% of net sales)	<b>29.75</b> 33.7%	<b>42.57</b> 39.1%	<b>+43.1%</b> +5.4pt	Impact of product mix change +6.3pt     Decrease the fixed manufacturing cost -0.2pt     Other -0.7pt
SGA excluding R&D (% of net sales)	25.99 29.4%	30.24 27.8%	+16.3% -1.6pt	• Domestic         +0.81           • Asia         +1.16 (FX +0.57)           • US/EU         +1.38 (FX +1.40)
R&D Expenses (% of net sales)	12.09 13.7%	12.49 11.5%	+3.3% -2.2pt	•Domestic -0.43 •Overseas +0.82 (FX +1.02)
Operating Profit (% of net sales)	<b>20.57</b> 23.3%	<b>23.63</b> 21.7%	<b>+14.9%</b> -1.6pt	<pre><currency rates="">     <u>3QFY12 actual</u>     US\$ JPY 80.01 JPY 99.17</currency></pre>
Non-operating Income Non-operating Expense	0.85 0.15	0.86 0.20	+1.6% +30.6%	US\$ JPY 80.01 JPY 99.17 Euro JPY 102.12 JPY 129.59 CNY JPY 12.53 JPY 15.49
Ordinary Income	21.26	24.29	+14.2%	
Extraordinary Gain Extraordinary Loss	0.01 0.00	0.47 0.89	-	Provision of restructuring fee regarding Santen     Oy +0.82
Net Income before Tax	21.27	23.87	+12.2%	
Corporate Tax	7.14	8.49	+19.0%	
Net Profit	14.13	15.37	+8.8%	



# **Summary of Cash Flows**

(JPY billion	(JPY billions)			
Cash an	d cash equivalents at the beginning of FY13	59.79		
Net incr	+3.73			
	Cash flows from operating activities	+16.03		
	Cash flows from investing activities	-5.94		
	Cash flows from financial activities	-7.92		
	Effect of exchange rate changes on cash and cash equivalents	+1.56		
Cash an	d cash equivalents at the end of 3Q FY13	63.52		

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



# Capital Expenditures / Depreciation & Amortization

	3Q FY2012	3Q FY2013		
(JPY billions)	Actual	Actual	Var.	
Capital Expenditures	2.59	2.08	-0.51	
Depreciation and Amortization	1.83	1.83	-0.00	





# **Reference:** FY2013 Financial Forecasts

### Sales Forecast by Business Segment / Overseas Sales (Before Reflecting Unification of Accounting Period in FY13)

				FY2013 F	FY2013 Forecast*		
(JPY billions)		Jap	an	Over	seas	То	tal
		Sales	Var.	Sales	Var.	Sales	Var.
Pł	narmaceuticals	119.70	+21.5%	23.35	+27.7%	143.05	+22.5%
	Prescription Pharmaceuticals	113.26	+23.0%	23.27	+27.4%	136.54	+23.8%
	Ophthalmic	102.47	+26.3%	22.59	+26.5%	125.06	+26.4%
	Anti-RA	9.94	+1.4%	0.08	+38.2%	10.03	+1.6%
	Others	0.85	-24.2%	0.59	+68.9%	1.45	-1.9%
	OTC Pharmaceuticals	6.43	-0.3%	0.07	+386.3%	6.50	+0.6%
Ot	thers	2.89	+32.2%	0.04	-28.0%	2.94	+30.4%
	Medical Devices	2.64	+21.2%	0.04	-28.0%	2.68	+19.7%
	Others	0.25				0.25	
То	otal	122.59	+21.7%	23.40	+27.5%	146.00	+22.6%



\* 12month period

# Sales Forecast by Business Segment / Overseas Sales (After reflecting Unification of Accounting Period in FY13)

		FY2013 Forecast					
(JPY billions)		Jap	an	Over	seas	То	tal
		Sales	Var.	Sales	Var.	Sales	Var.
Ph	narmaceuticals	119.70	+21.5%	26.35	+44.1%	146.05	+25.0%
	Prescription Pharmaceuticals	113.26	+23.0%	26.27	+43.8%	139.54	+26.5%
	Ophthalmic	102.47	+26.3%	25.59	+43.3%	128.06	+29.4%
	Anti-RA	9.94	+1.4%	0.08	+38.2%	10.03	+1.6%
	Others	0.85	-24.2%	0.59	+68.9%	1.45	-1.9%
	OTC Pharmaceuticals	6.43	-0.3%	0.07	+386.3%	6.50	+0.6%
Ot	hers	2.89	+32.2%	0.04	-28.0%	2.94	+30.4%
	Medical Devices	2.64	+21.2%	0.04	-28.0%	2.68	+19.7%
	Others	0.25				0.25	
То	otal	122.59	+21.7%	26.40	+43.8%	149.00	+25.1%



#### **Oversea Sales Forecast** (Before Reflecting Unification of Accounting Period in FY13)

(JPY billions)	FY2012	FY2013 Forecast*			
	Actual	Forecast	Var.	Var. %	
U.S.	0.58	0.82	+0.24	+41.6%	
Europe	9.20	11.25	+2.05	+22.3%	
Asia	8.55	11.27	+2.71	+31.7%	
Others	0.01	0.03	+0.02	+286.2%	
Total	18.35	23.40	+5.04	+27.5%	

Oversea sale/sales	15.4%	16.0%	+0.6pt	
	1011/0	101070	· oropt	

\* 12month period



#### **Oversea Sales Forecast** (After reflecting Unification of Accounting Period in FY13)

(JPY billions)	EV2012	FY2013 Forecast			
	FY2012 Actual	Forecast	Var.	Var. %	
U.S.	0.58	0.82	+0.24	+41.6%	
Europe	9.20	12.25	+3.05	+33.2%	
Asia	8.55	13.27	+4.71	+55.1%	
Others	0.01	0.03	+0.02	+286.2%	
Total	18.35	26.40	+8.04	+43.8%	

Oversea sale/sales	15.4%	17.7%	+2.3pt	



# **Capital Expenditures / Depreciation & Amortization**

(IDV hilliona)	FY2012	FY2013		
(JPY billions)	Actual	Forecast	Var.	
Capital Expenditures	4.20	3.40	▲0.80	
Depreciation and Amortization	2.53	2.50	▲0.03	

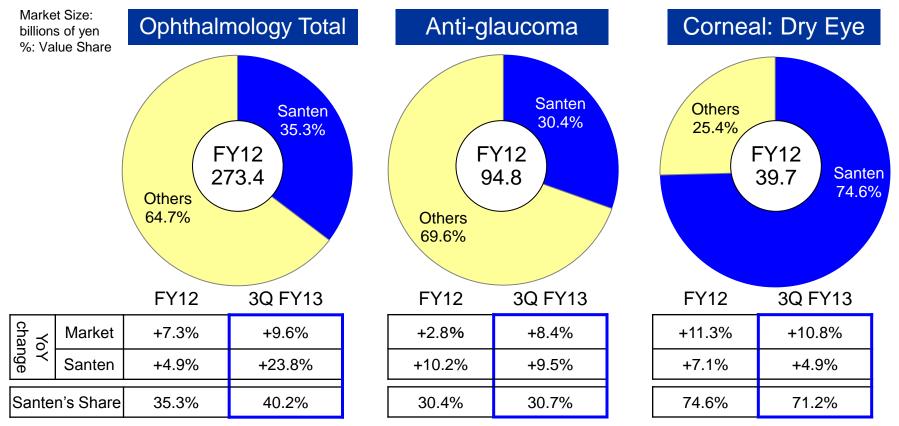




# Reference: Market Overview of Prescription Ophthalmic in Japan

### Japan: Trend & Competition in Ophthalmics (1)

- **Ophthalmology Total**: Market grew by 9.6% Y to Y in 3Q FY13. The growth of retinal, and corneal segment continued. Santen's market share was 40.2%.
- Anti-Glaucoma: Market grew by 8.4% Y to Y in 3Q FY13. Santen's sales grew by 9.5%. Santen held 30.7% share of the anti-glaucoma market by the contribution of Tapros and Cosopt.
- Corneal: Market grew by 10.8% Y to Y in 3Q FY13. Santen's sales grew by 4.9% led by the sales increase of Diquas and Santen's market share was 71.2%.



Source: ©2014 IMS Health IMS-JPM 2011-13

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Santen analysis based on IMS data

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#### -Santen:

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

- Cornea / Dry Eye : Hyalein, Diquas

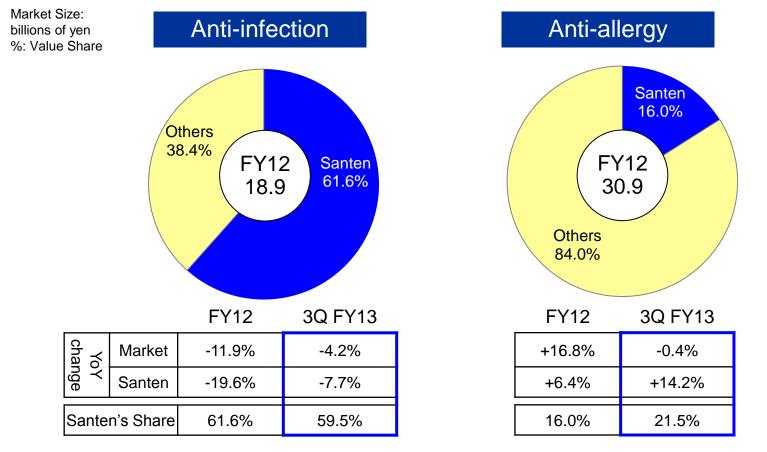
- 3Q = 3Q cumulative

### Japan: Trend & Competition in Ophthalmics (2)

Anti-infection:

Market declined by -4.2% Y to Y in 3Q FY13. Santen maintained 59.5% of market share with primary contribution by Cravit.

• Anti-allergy: Market declined by -0.4% Y to Y in 3Q FY13. Santen's share was 21.5%.(18.3% share in 1H FY13. The launch of Alesion generated the increase of Santen market share.



#### -Santen:

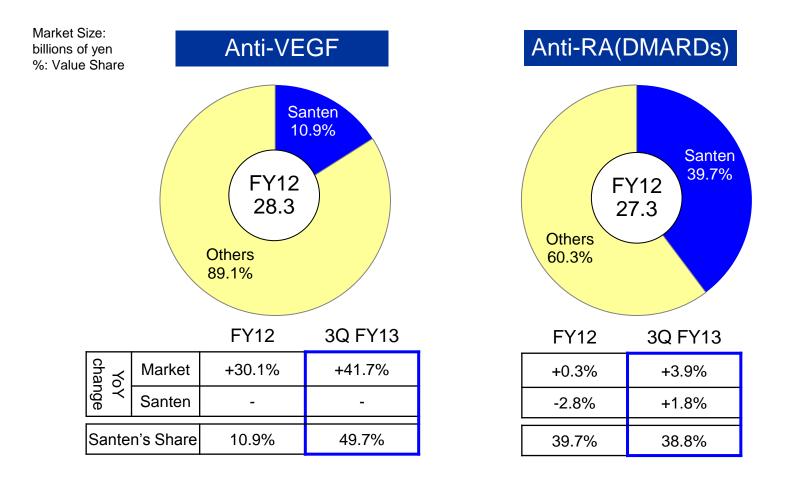
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- Anti-infection: Cravit, Tarivid
- Anti-allergy: Livostin, Alesion, Alegysal
- 3Q = 3Q cumulative

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### Japan: Trend & Competition in Ophthalmics (3)

- Anti-VEGF: Market increased by 41.7% Y to Y in 3Q FY13. Eylea has continued the strong growth. Santen's share was 49.7%.
- Anti-RA(DMARDs): Market slightly increased by 3.9% in 3Q FY13. Santen maintained 38.8% of market share.





- Anti-RA(DMARDs): Rimatil, Azulfidine, Metolate
- 3Q = 3Q cumulative

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# 3Q FY2013 Status of Clinical Development

Takashi Kaneko, M.D. Ph.D. Corporate Officer, Head of Research and Development Division

# Major Clinical Pipeline List (1) [by Disease]

(Red underlined: Change from 2Q FY13 Presentation)

Global Product

Japan (Asia)Product

Disease	Phase 1	Phas	se 2	Phase 3	NDA	Approved • Launched
Glaucoma/ Ocular	<u>P2b</u>	prep DE- EP2 Recept			China <mark>DE-085</mark> Tafluprost	DE-118 Tafluprost UD
Hypertension		DE-I			EU	<b>-111</b> JP ost/Timolol
Corneal/ Conjunctival					China	-089 sol Sodium
Disease		U.S. Cycle Ciclos	okat <sup>porin</sup>		Cyclokat <u>Ciclosporin</u> EU	
Retina/ Uveitis	U.S. DE-120 VEGF/PDGF inh	_		DE-109 Sirolimus		
				DE-102 Betamethasone		
Other DE-098 Infection, Allergy, Anti APO-1 Antibody				DE-114 Epinastine HCI		
RA				Vekacia Ciclosporin		



# Major Clinical Pipeline List (2) [by Region]

(Red underlined: Change from 2Q FY13 Presentation)

Global Product

Japan (Asia)Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved • Launched
Japan			DE-102 Betamethasone		DE-118 Tafluprost UD
		DE-090 Lomerizine HCI			DE-111 Tafluprost/Timolol
		DE-098 Anti APO-1 Antibody	DE-109 Sirolimus		DE-114 Epinastine HCI
North America	<u>P2</u>	prep <u>DE-117</u> EP2 Receptor Agonis	DE-109 Sirolimus		
(Including Latin America)	DE-120 VEGF/PDGF inh				
		Cyclokat Ciclosporin			
<b>Asia</b> (including Oceania)				China DE-085 Tafluprost	
					•089 Korea ol Sodium
EU			DE-109 Sirolimus	DE-111 Tafluprost/Timolol	
			Vekacia Ciclosporin	Cyclokat <u>Ciclosporin</u>	



# Major Clinical Projects Update - Glaucoma / Ocular

#### DE-085 (Glaucoma / Ocular hypertension) hypertension -

	Developme	ent Stage	
Region As of Fe	As of February 4, 2014	As of Nov. 6, 2013 (Previous announcement)	Remarks
China	NDA Filed	NDA Filed	Generic name: Tafluprost

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

	Developme			
Region	As of February 4, 2014	As of Nov. 6, 2013 (Previous announcement)	Remarks	
Japan	P2	P2	Generic name: Lomerizine HCI	

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

	Development Stage		
Region	As of February 4, 2014	As of Nov. 6, 2013 (Previous announcement)	Remarks
Japan	Approved	Approved	Generic name: Tafluprost/
Europe	NDA Filed	NDA Filed	Timolol maleate (Combination drug)

### Major Clinical Projects Update - Glaucoma -- Corneal disease -

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

	Development Stage		
Region	As of February 4, 2014 As of Nov. 6, 2013 (Previous announcement)		Remarks
U.S.	P2b preparation	P1/2a	EP2 receptor agonist

**DE-089** (Dry eye)

Product Name: DIQUAS in Japan

	Development Stage		
Region	As of February 4, 2014	As of Nov. 6, 2013 (Previous announcement)	Remarks
Asia	China: NDA filed Korea: Launched	China: NDA filed Korea: Launched	Generic name: Diquafosol Sodium

## Major Clinical Projects Update - Allergy, Arthritis -

#### **DE-114** (Allergic conjunctivitis) Product Name: *ALESION* in Japan

	Developn	Development Stage	
Region	As of February 4, 2014	As of Nov. 6, 2013 (Previous announcement)	Remarks
Japan	Launched	Approved	Generic name: Epinastine HCI

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

	Development Stage		
Region	As of February 4, 2014	As of February 4, 2014 As of Nov. 6, 2013 (Previous announcement)	
Japan	P2 Completed	P2 Completed	Anti-APO-1 Antibody

# Major Clinical Projects Update - Retinal Disease -

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

	Development Stage		
Region	As of February 4, 2014	As of Nov. 6, 2013 (Previous announcement)	Remarks
Japan	P2/3	P2/3	Generic name: Betamethasone

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

	Development Stage		
Region	As of February 4, 2014	As of Nov. 6, 2013 (Previous announcement)	Remarks
U.S.	P1/2a		VEGF/PDGF dual inhibitor

#### **DE-109** (Uveitis)

	Development Stage		
Region	As of February 4, 2014	As of Nov. 6, 2013 (Previous announcement)	Remarks
U.S.	P3	P3	O an a si a sa a sa a sa
Japan	P3	P3	Generic name: Sirolimus
EU	P3	P3	

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

#### **Cyclokat** (Severe Dry Eye) Product Name: *IKERVIS* in Europe

Pagion	Develop	ment Stage	Domorko
Region	As of Feb. 4, 2014	11/6 (Previous)	Remarks
EU	NDA filed	Preparing NDA filing	Generic Name:
U.S.	P2 Completed	P2 Completed	Ciclosporin

#### Vekacia (Vernal Keratoconjunctivitis)

Decien	Develop	ment Stage	Remarks
Region As of Feb. 4, 2014		11/6 (Previous)	Remarks
EU	P3	P3	Generic Name: Ciclosporin

#### \*Project evaluations are ongoing for the products below.

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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

#### **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 nonapproval 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.

