

# Investor Meeting on FY2015 Third Quarter Results and Revised FY2015 Forecasts



## **Kazuo Koshiji**

Senior Corporate Officer

Chief Financial Officer

Head of Finance Division

February 2, 2016

# Santen's Corporate Values

天機に参与する

*Tenki ni sanyo suru*

By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, their loved ones and consequently to society.

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# **Long-Term Strategic Vision, Medium-Term Management Plan for FY2014-2017**

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# Long-Term Strategic Vision

To Become a Specialized Pharmaceutical Company with a Global Presence

- Deep Understanding of True Customer Needs\*
- Distinct Advantage Against Competitors
- Global Competitiveness and Presence

\* True customer needs: Unmet medical needs of patients, consumers, doctors and healthcare professionals.

# Long-Term Growth Targets

2013

- Strengthen the Japan business
- Prepare for business expansion in Asia/Europe

Ranks #5 globally

Overseas sales: 16% of total sales

2017

## Medium-term Goal

- Grow business in Asia/Europe and improve profitability
- Prepare for business expansion in the U.S. and other regions

Overseas sales: 30% of total sales

2020

Santen

## What we aim to achieve by 2020

“To become a Specialized Pharmaceutical Company with a Global Presence”

Become global #3

Overseas sales: 40%-50% of total sales

# Basic Policy of Medium-Term Management Plan for FY2014-2017

## Product development

Transform product development to realize enhanced productivity and achieve sustained growth

Active investment in sustainable growth

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## Business expansion

Grow business in Asia/Europe and strengthen market presence by entering into new markets

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## Organization and talent

Develop talent and organization to realize sustained growth and strengthen the global management system

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# **Financial Results for FY2015 Third Quarter Results**

**Nine month period ended December 31, 2015**

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# Financial Highlights for 3Q FY2015

## *IFRS basis*

(JPY billions)	3Q FY2014 Actual	3Q FY2015	
		Actual	Var. (YoY)
Revenue	116.8	149.2	+27.7%
Operating profit	26.0	74.4	+186.3%
Profit before tax	26.3	74.5	+183.1%
Net profit for the period	17.3	49.9	+189.0%

## *Core basis*

Revenue	116.8	149.2	+27.7%
Core operating profit*	28.4	35.1	+23.8%
Core net profit for the period	18.7	23.6	+26.5%

\* Core operating profit = operating profit + amortization associated with products – other revenue + other expenses

# Financial Highlights for 3Q FY2015

## ■ Japan business maintains positive momentum

- Increased revenue from new products such as *EYLEA* and *Alesion*
- Domestic share in prescription ophthalmic pharmaceuticals grew to 43.9% (3Q FY15)

## ■ Overseas business continues strong growth

- Asia: Continued growth in key countries, particularly China
- Europe: Successful integration of products acquired from Merck, *Ikervis* rolled out in more European countries

## ■ Upward revision of FY2015 earnings forecasts

## ■ DE-117: Started Phase 2b/3 in Japan

## ■ Transfer of anti-rheumatic pharmaceutical business completed in August

# Changes in Income Statement

(JPY billions)	3Q FY14	3Q FY15		Major Changes												
	Actual	Actual	Var. (YoY)													
<b>Revenue</b>	<b>116.8</b>	<b>149.2</b>	<b>+27.7%</b>													
Cost of sales (% of revenue)	-41.4 35.5%	-56.7 38.0%	+36.9% +2.6pt	Product mix: •Japan +2.3pt •Overseas +0.3pt												
SGA excluding R&D (% of revenue)	-34.5 29.6%	-43.1 28.9%	+24.7% -0.7pt	•Japan -0.7 •Asia -2.6 (FX-0.5) •US/EU -5.2 (FX+0.2) JPY billions												
R&D expenses (% of revenue)	-12.5 10.7%	-14.3 9.6%	+14.6% -1.1pt	•Japan -0.3 •Overseas -1.5 (FX-0.4) JPY billions												
Amortization associated with products (% of revenue)	-2.6 2.2%	-4.6 3.1%	+75.5% +0.8pt	•Amortization of Merck assets -1.4 JPY billions												
Other income	0.4	44.8	-	•Transfer of anti-rheumatic business +43.9 JPY billions												
Other expenses	-0.1	-0.9	-													
<b>Operating profit</b> (% of revenue)	<b>26.0</b> <b>22.3%</b>	<b>74.4</b> <b>49.9%</b>	<b>+186.3%</b> <b>+27.6pt</b>													
Finance income	0.7	0.8	+2.9%	<table border="1"> <thead> <tr> <th>Currency rates</th> <th>3Q FY14 Actual</th> <th>3Q FY15 Actual</th> </tr> </thead> <tbody> <tr> <td>US \$</td> <td>JPY 107.11</td> <td>JPY 121.65</td> </tr> <tr> <td>Euro</td> <td>JPY 140.43</td> <td>JPY 133.93</td> </tr> <tr> <td>CYN</td> <td>JPY 17.35</td> <td>JPY 19.45</td> </tr> </tbody> </table>	Currency rates	3Q FY14 Actual	3Q FY15 Actual	US \$	JPY 107.11	JPY 121.65	Euro	JPY 140.43	JPY 133.93	CYN	JPY 17.35	JPY 19.45
Currency rates	3Q FY14 Actual	3Q FY15 Actual														
US \$	JPY 107.11	JPY 121.65														
Euro	JPY 140.43	JPY 133.93														
CYN	JPY 17.35	JPY 19.45														
Finance expenses	-0.4	-0.7	+69.1%													
Profit before tax	26.3	74.5	+183.1%													
Income tax expenses	-9.0	-24.6	+171.8%													
<b>Net profit for the period</b>	<b>17.3</b>	<b>49.9</b>	<b>+189.0%</b>													
<b>Core operating profit</b>	<b>28.4</b>	<b>35.1</b>	<b>+23.8%</b>													
<b>Core net profit for the period</b>	<b>18.7</b>	<b>23.6</b>	<b>+26.5%</b>													

# Revenue by Business Segment

(JPY billions)	3Q FY15 Actual					
	Japan		Overseas		Total	
	Sales	Var. (YoY)	Sales	Var. (YoY)	Sales	Var. (YoY)
<b>Pharmaceuticals</b>	<b>106.2</b>	<b>+18.9%</b>	<b>41.0</b>	<b>+60.3%</b>	<b>147.2</b>	<b>+28.1%</b>
Prescription Pharmaceuticals	98.2	+16.2%	40.9	+60.4%	139.1	+26.5%
Ophthalmic	94.3	+23.0%	36.5	+63.9%	130.8	+32.2%
Anti-RA	3.5	-52.2%	-	-100.0%	3.5	-52.4%
Others	0.4	-16.7%	4.4	+37.8%	4.7	+30.8%
OTC Pharmaceuticals	8.1	+64.5%	0.1	+12.9%	8.1	+64.0%
<b>Others</b>	<b>1.9</b>	<b>+3.1%</b>	<b>0.1</b>	<b>+213.4%</b>	<b>2.0</b>	<b>+5.7%</b>
Medical devices	1.7	-0.1%	0.1	+172.1%	1.8	+2.1%
Others	0.2	+33.2%	0.0	-	0.3	+38.3%
<b>Total</b>	<b>108.2</b>	<b>+18.6%</b>	<b>41.0</b>	<b>+60.5%</b>	<b>149.2</b>	<b>+27.7%</b>

# Overseas Revenue and Operating Profit

(JPY billions)	3Q FY2014	3Q FY2015		
	Actual	Actual		Operating profit**
	Revenue	Revenue	Var. (YoY)	
U.S.	3.2	4.5*	+40.4%	-1.7
Europe	9.9	18.7	+88.7%	3.2
Asia	12.5	17.8	+43.0%	5.6
China	8.3	10.9	+31.8%	
Total	25.6	41.0	+60.5%	7.1

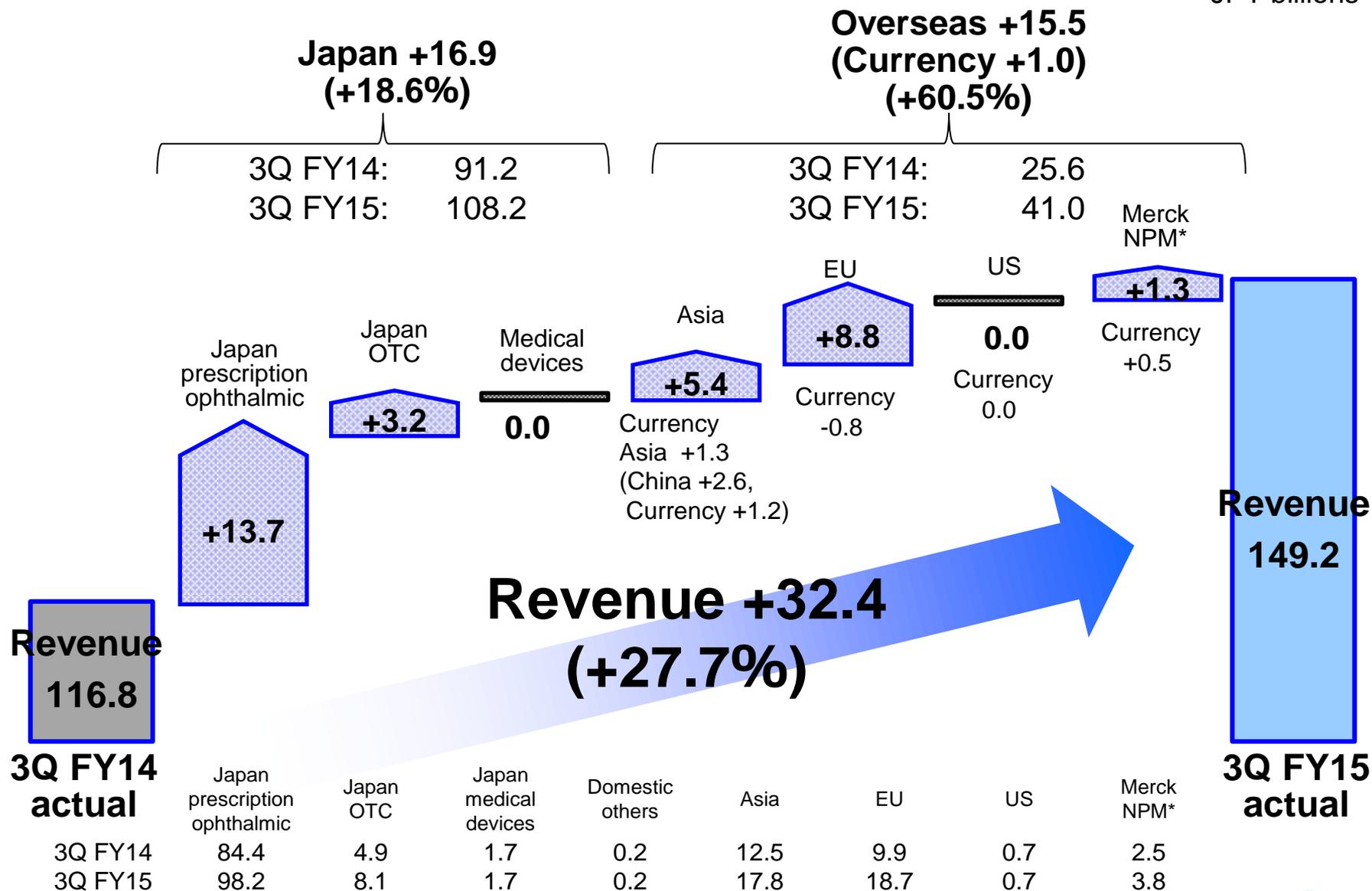
<b>Overseas sales / sales</b>	<b>21.9%</b>	<b>27.5%</b>	<b>+5.6pt</b>	
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\* Net profit margin (NPM) relating to the Merck product acquisition is treated as revenue in the U.S.

\*\* Company policy on accounting for profit excludes certain SG&A and R&D expenses. NPM is distributed by region after operationally transferred from Merck to Santen.

# 3Q FY15 Revenue Change

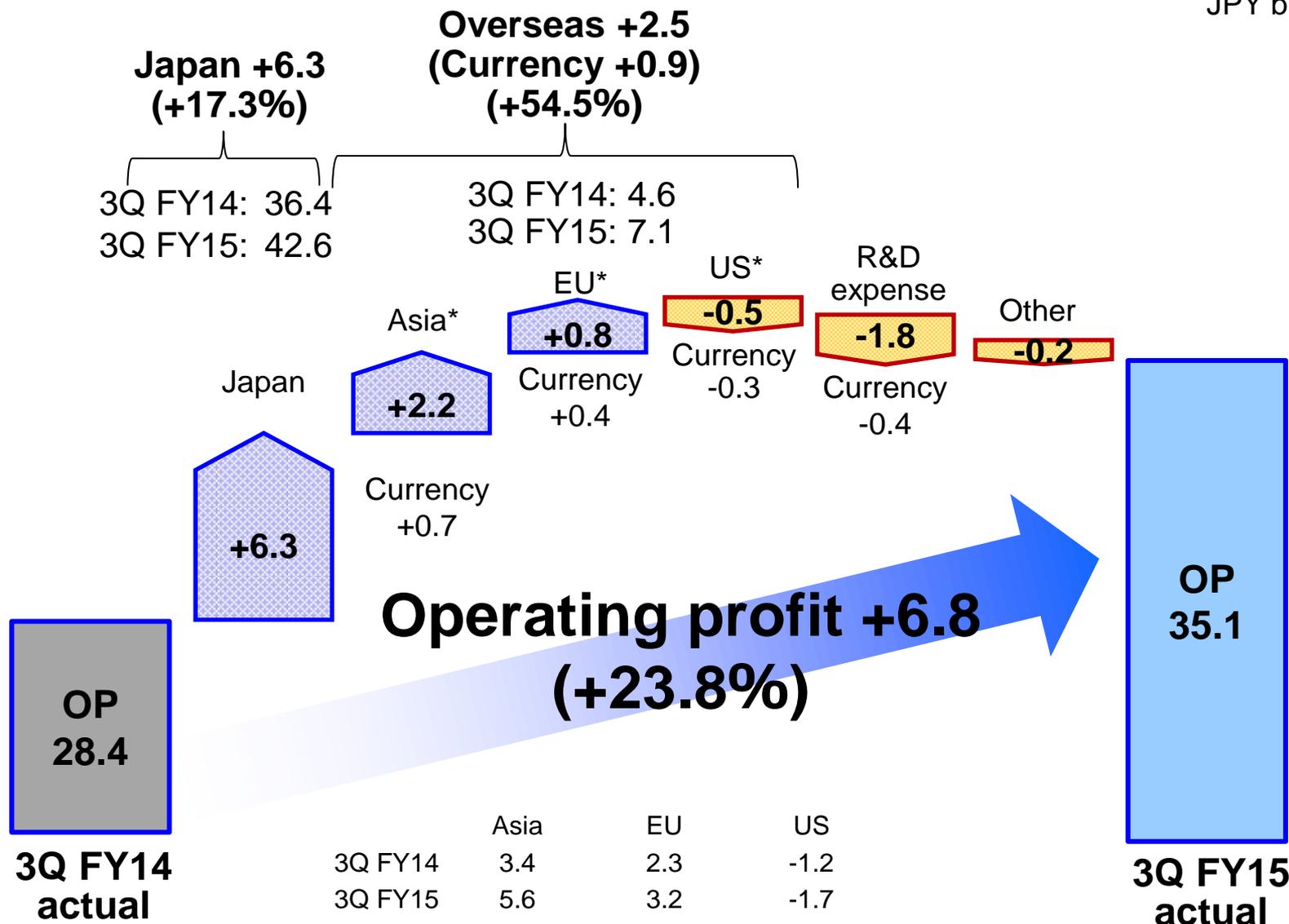
JPY billions



\* Net Profit Margin(NPM): Profit generated from US Merck ophthalmic products which Santen has acquired and has consigned them to Merck until the completion of transfer of the underlying marketing rights.

# 3Q FY15 Core Operating Profit Change

JPY billions



\* Company policy on accounting for profit excludes certain SG&A and R&D expenses. NPM is distributed by region after operationally transferred from Merck to Santen.

# Merck Project Results

(JPY billions)	3Q FY15 Actual		FY2015 Forecast (Revised)	
	Merck	Total	Merck	Total
<b>Revenue</b>	16.7	149.2	21.5	197.5
NPM*	3.8	3.8	4.1	4.1
Santen sales (marketing rights transferred)	12.9	145.4	17.4	193.4

## As of December 31, 2015

- MA\*\* transfers completed: 26 countries
- Further MA transfer plans: 17 countries
  - Includes 13 countries (European region) in which pre-marketing activities have begun
  - Includes 4 countries in which MSD label distribution has begun

\* Net profit margin (NPM) relating to the Merck product acquisition is treated as revenue in the U.S.

\*\*Marketing authorization

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# **FY2015 Consolidated Revised Forecasts**

**Year ending March 31, 2016**

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# FY2015 Consolidated Forecasts (Revised)

(JPY billions)	FY2014 Full year		FY2015 Full year			
	Actual	Var. (YoY)	Forecast (Previous)	Forecast (Revised)	Forecast Var.	Var. (YoY)
<b>Revenue</b>	<b>161.8</b>	<b>+10.6%</b>	<b>186.5</b>	<b>197.5</b>	<b>+11.0</b>	<b>+22.0%</b>
Cost of sales (% of revenue)	-56.4 34.8%	-1.7% -4.4pt	-66.4 35.6%	-75.0 38.0%	-8.6	+33.0% +3.1pt
SGA excluding R&D (% of revenue)	-48.9 30.2%	+17.4% +1.7pt	-56.9 30.5%	-59.0 29.9%	-2.1	+20.7% -0.3pt
R&D expenses (% of revenue)	-17.5 10.8%	+3.7% -0.7pt	-22.9 12.3%	-20.5 10.4%	+2.4	+17.3% -0.4pt
Amortization associated with products (% of revenue)	-4.0 2.5%	- +2.3pt	-6.1 3.3%	-6.2 3.1%	-0.1	+55.8% +0.7pt
Other income	0.7	+6.3%	45.0	44.7	-0.3	-
Other expenses	-0.5	-54.9%	-1.2	-1.5	-0.3	+227.5%
<b>Operating profit</b> (% of revenue)	<b>35.4</b> <b>21.9%</b>	<b>+18.4%</b> <b>+1.4pt</b>	<b>78.0</b> <b>41.8%</b>	<b>80.0</b> <b>40.5%</b>	<b>+2.0</b>	<b>+126.2%</b> <b>+18.6pt</b>
Profit before tax	35.9	+18.1%	78.5	80.5	+2.0	+124.5%
<b>Net profit</b>	<b>24.0</b>	<b>+21.9%</b>	<b>52.5</b>	<b>53.0</b>	<b>+0.5</b>	<b>+120.5%</b>
<b>Core operating profit</b> (% of revenue)	<b>39.1</b> <b>24.2%</b>	<b>+28.6%</b>	<b>40.3</b> <b>21.6%</b>	<b>43.0</b> <b>21.8%</b>	<b>+2.7</b>	<b>+10.0%</b>
<b>Core ROE</b>	<b>13.0%</b>	-	<b>11.5%</b>	<b>11.9%</b>	<b>+0.4pt</b>	<b>-1.1pt</b>

Foreign exchange	FY14 actual	FY15 forecast previous	FY15 forecast revised
US \$	JPY 110.14	JPY 125.00	JPY 125.00
Euro	JPY 139.01	JPY 135.00	JPY 135.00
CNY	JPY 17.84	JPY 20.00	JPY 20.00

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# **FY2015 Dividend Forecast**

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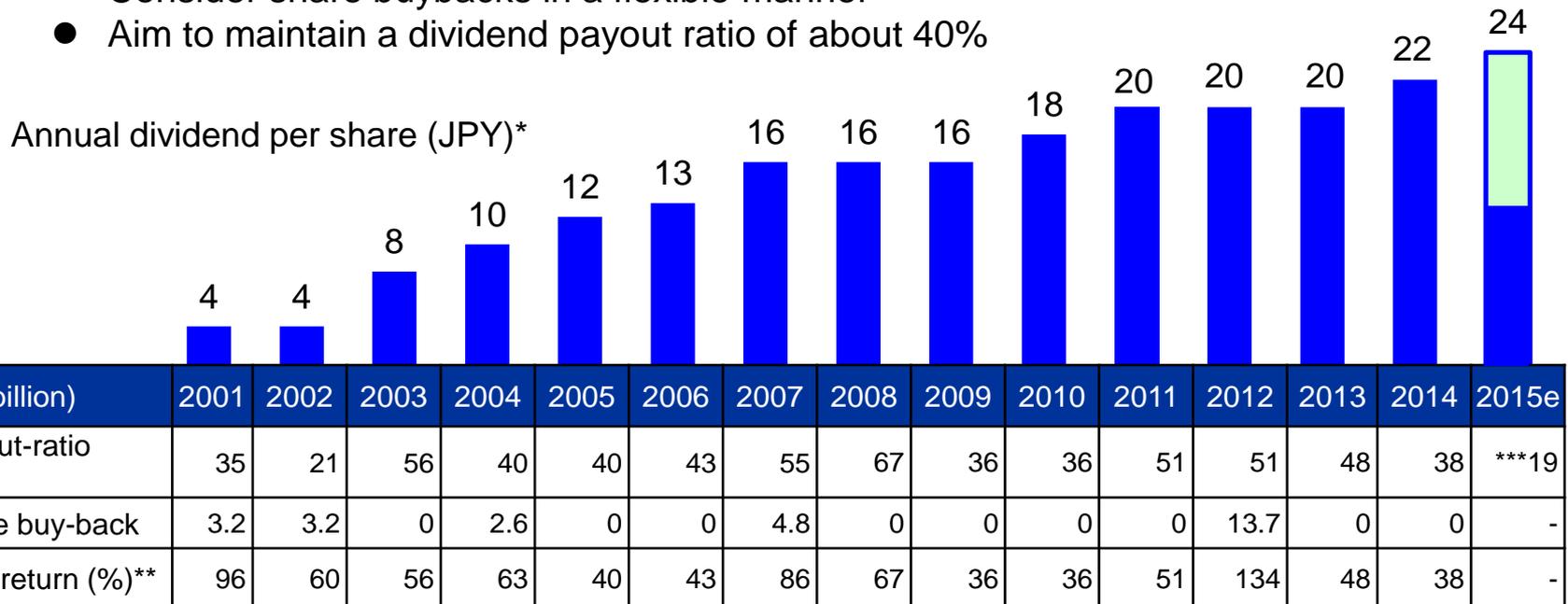
# Dividends for FY2014 Actual and FY2015 Forecast

## ■ FY2015

- 1H Dividend: 12 yen per share
- Annual dividend (forecast): 24 yen per share

## ■ FY2014-FY2017 Shareholder return policy

- Stable and sustained return to shareholders
- Maintain a sound and flexible financial position to enable product acquisitions and M&A for future growth
- Consider share buybacks in a flexible manner
- Aim to maintain a dividend payout ratio of about 40%



\* The company implemented a 5-for-1 stock split on April 1, 2015. Accordingly, the calculations of annual dividends per share have been adjusted in all periods for comparison purposes.

\*\* J-GAAP standards used until 2013, IFRS applied from 2014.

\*\*\*Removing the related impact of the succession of the company's anti-rheumatic pharmaceutical business, the payout ratio is forecast to be 38% in FY15.

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**Reference:**

**FY2015 Third Quarter Results**

**Nine month period ended December 31, 2015**

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# Summary of Financial Position

(JPY billions)	As of March 31, 2015		As of December 30, 2015		
	Actual	% of Total	Actual	% of Total	Var. (YoY)
Non-current assets	153.5	50.5%	161.9	45.0%	+8.3
Current assets	150.7	49.5%	198.0	55.0%	+47.3
<b>Total assets</b>	<b>304.2</b>	<b>100.0%</b>	<b>359.8</b>	<b>100.0%</b>	<b>+55.6</b>
<b>Total equity</b>	<b>211.8</b>	<b>69.6%</b>	<b>258.7</b>	<b>71.9%</b>	<b>+46.9</b>
Non-current liabilities	36.1	11.9%	30.0	8.3%	-6.1
Current liabilities	56.3	18.5%	71.2	19.8%	+14.8
<b>Total liabilities</b>	<b>92.4</b>	<b>30.4%</b>	<b>101.1</b>	<b>28.1%</b>	<b>+8.7</b>
<b>Total equity and liabilities</b>	<b>304.2</b>	<b>100.0%</b>	<b>359.8</b>	<b>100.0%</b>	<b>+55.6</b>

Shares issued: End of March 2015: 413,266 thousand\* → End of December 2015: 413,895 thousand

## Major Changes

- Non-current assets: Right of approval for manufacture and sales +8.1 billion yen, In-process R&D -7.4 billion yen, Investment securities +10.8 billion yen
- Current assets: Cash and deposits +38.1 billion yen, Accounts receivable +6.4 billion yen
- Equity: Retained earnings +40.4 billion yen, Net gain or loss on financial assets measured at fair value through other comprehensive income +6.3 billion yen
- Non-current liabilities: Long term borrowing -8.8 billion yen
- Current liabilities: Income taxes payable +12.2 billion yen

\*The company implemented a 5-for-1 stock split on April 1, 2015. Accordingly, the calculations of the number of shares issued have been adjusted in all periods for comparison purposes.

# Summary of Cash Flows

(JPY billions)		3Q FY14	3Q FY15	Var. (YoY)
	Cash flows from operating activities	14.0	18.0	+4.0
	Cash flows from investing activities	-61.7	38.8	+100.5
	Cash flows from financial activities	31.9	-18.3	-50.2
<b>Net increase (decrease) in cash and cash equivalents</b>		<b>-15.8</b>	<b>38.5</b>	<b>+54.3</b>
<b>Cash and cash equivalents at the beginning of period</b>		<b>72.4</b>	<b>65.9</b>	<b>-6.5</b>
Effect of exchange rate changes on cash and cash equivalents		1.7	-0.3	-2.0
<b>Cash and cash equivalents at the end of period</b>		<b>58.3</b>	<b>104.1</b>	<b>+45.8</b>

# Capital Expenditures / Depreciation & Amortization

(JPY billions)	3Q FY14 Actual	3Q FY2015	
		Actual	Var. (YoY)
Capital expenditures	2.6	3.1	+0.5
Depreciation and amortization	4.8	6.9*	+2.1

\*Includes 3.8 billion yen amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products

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**Reference:  
FY2015 Consolidated Revised  
Forecast**

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# Revenue Forecast by Business Segment / Overseas Revenue (Revised)

(JPY billions)	FY2015 Forecast (Revised)					
	Japan		Overseas		Total	
	Sales	Var. (YoY)	Sales	Var. (YoY)	Sales	Var. (YoY)
<b>Pharmaceuticals</b>	<b>139.7</b>	<b>+14.3%</b>	<b>55.0</b>	<b>+48.8%</b>	<b>194.7</b>	<b>+22.3%</b>
Prescription Pharmaceuticals	129.7	+12.1%	54.9	+48.8%	184.5	+21.0%
Ophthalmic	125.5	+19.2%	49.9	+62.5%	175.4	+28.9%
Anti-RA	3.5	-63.4%	-	-	3.5	-63.6%
Others	0.6	-18.0%	5.0	-18.5%	5.6	-18.5%
OTC Pharmaceuticals	10.1	+51.9%	0.1	+31.1%	10.2	+51.7%
<b>Others</b>	<b>2.7</b>	<b>+7.7%</b>	<b>0.1</b>	<b>+36.7%</b>	<b>2.8</b>	<b>+8.2%</b>
Medical devices	2.4	+6.1%	0.0	-6.6%	2.4	+5.9%
Others	0.3	+21.4%	0.0	-	0.3	+28.8%
<b>Total</b>	<b>142.5</b>	<b>+14.1%</b>	<b>55.0</b>	<b>+48.8%</b>	<b>197.5</b>	<b>+22.0%</b>

# Overseas Revenue and Operating Profit Forecast (Revised)

(JPY billions)	FY2014 Actual	FY2015 Forecast (Revised)		
	Revenue	Revenue	Var. (YoY)	Operating profit**
U.S.	6.2	5.1*	-17.2%	-2.3
Europe	14.2	25.9	+83.0%	3.3
Asia	16.7	24.0	+43.9%	6.1
China	10.7	14.1	+31.7%	
Total	37.0	55.0	+48.8%	7.1

<b>Overseas sales / sales</b>	<b>22.9%</b>	<b>27.9%</b>	<b>+5.0pt</b>	
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\* Net profit margin (NPM) relating to the Merck product acquisition is treated as revenue in the U.S.

\*\* Company policy on accounting for profit excludes certain SG&A and R&D expenses. NPM is distributed by region after operationally transferred from Merck to Santen.

# Forecast of Capital Expenditures / Depreciation & Amortization (Revised)

(JPY billions)	FY14 Actual	FY2015	
		Forecast (Revised)	Var. (YoY)
Capital expenditures	5.4	5.0	-0.4
Depreciation and amortization*	7.0	9.2	+2.2

\*Amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products was recorded of 3.7 billion yen in FY14 and forecast to be 5.1 billion yen in FY15.

# IFRS and Core Comparisons

IFRS		Core
<b>Revenue</b>		<b>Revenue</b>
Cost of sales		Cost of sales
<b>Gross profit</b>		<b>Gross profit</b>
SG&A		SG&A
R&D		R&D
Amortization associated with products	-->	Excluded from core
Other income	-->	Excluded from core
Other expenses	-->	Excluded from core
<b>Operating profit</b>		<b>Core operating profit</b>
Finance income (interest, dividends, forex gains)	-->	Excluded from core
Finance expenses (interest, forex losses)	-->	Excluded from core
Profit before tax		Core profit before tax
Income tax expense		Income tax expense
<b>Net profit</b>		<b>Core net profit</b>

## Use of Core Basis Indicators

- Core results are now used as financial indicators to better express underlying business performance by removing certain gains and expenses from IFRS results
- Items excluded from IFRS to calculate core results:  
Amortization associated with products, other income and expenses, and finance income and expenses

# Reconciliation of IFRS to Core OP

(JPY billions)	3Q FY2014 Actual	3Q FY2015 Actual	FY2015 Forecast (Revised)
<b>IFRS operating profit</b>	<b>26.0</b>	<b>74.4</b>	<b>80.0</b>
Non-core deduction items	+2.4	-39.3	-37.0
Amortization associated with products	+2.6	+4.6	+6.2
Other income	-0.4	-44.8	-44.7
Other expenses	+0.1	+0.9	+1.5
<b>Core operating profit</b>	<b>28.4</b>	<b>35.1</b>	<b>43.0</b>

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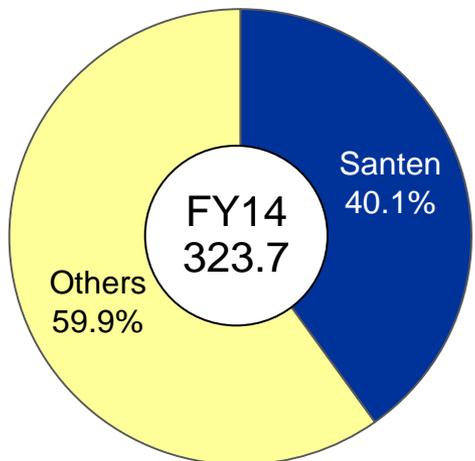
# **Reference: Market Overview of Prescription Ophthalmic in Japan**

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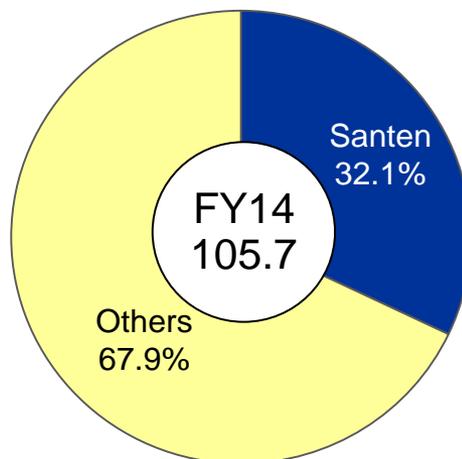
# Japan: Trend & Competition in Ophthalmics (1)

Market Size:  
billions of yen  
%: Value Share

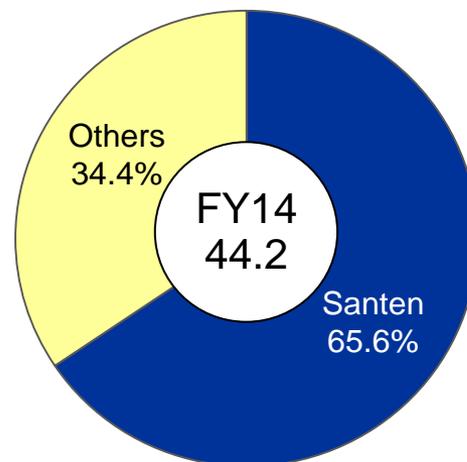
## Ophthalmology Total



## Anti-Glaucoma



## Cornea / Dry Eye



		FY14	3Q FY15
YoY change	Market	+7.4%	+9.1%
	Santen	+9.3%	+20.0%
Santen's Share		40.1%	43.9%

		FY14	3Q FY15
YoY change		+0.9%	+7.8%
Santen		+6.1%	+11.2%
Santen's Share		32.1%	32.7%

		FY14	3Q FY15
YoY change		-0.0%	+5.8%
Santen		-7.0%	+2.0%
Santen's Share		65.6%	63.6%

-Santen:

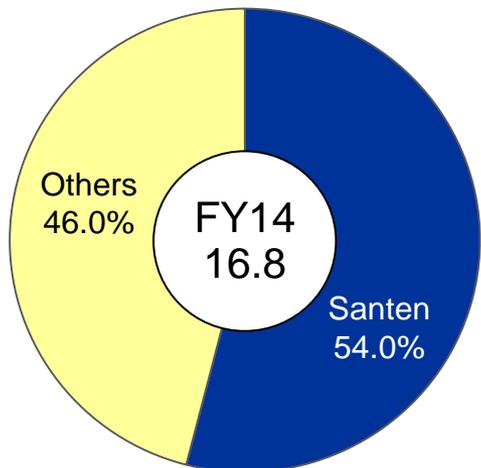
- Anti-Glaucoma : Tapros, Cosopt, Timoptol/XE, Trusopt, Rescula, Detantol, Tapcom
- Cornea / Dry Eye : Hyalein, Diquas

Source: ©2016 IMS Health  
IMS-JPM 2013-15  
Santen analysis based on IMS data  
Reprinted with permission

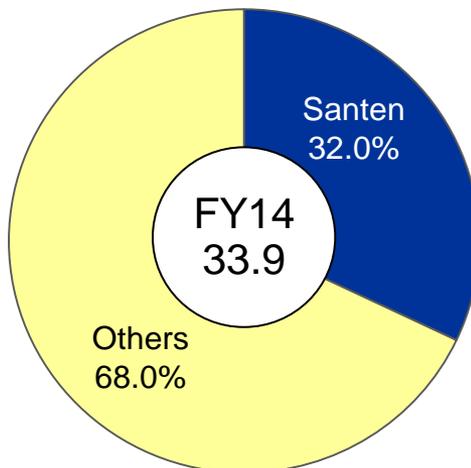
# Japan: Trend & Competition in Ophthalmics (2)

Market Size:  
billions of yen  
%: Value Share

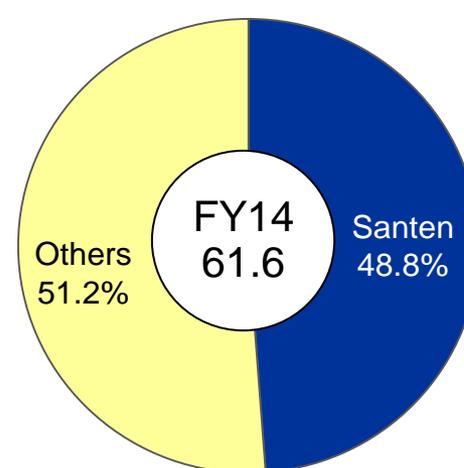
## Anti-infection



## Anti-allergy



## Anti-VEGF



		FY14	3Q FY15
YoY change	Market	-8.2%	-1.7%
	Santen	-15.3%	-9.3%
Santen's Share		54.0%	50.3%

		FY14	3Q FY15
		+21.4%	+10.2%
		+83.3%	+26.7%
Santen's Share		32.0%	36.6%

		FY14	3Q FY15
		+42.6%	+25.1%
		+43.0%	+70.9%
Santen's Share		48.8%	64.0%

-Santen:

- Anti-infection: Cravit, Tarivid
- Anti-allergy: Alesion, Livostin, Alegysal
- Anti-VEGF: Eylea

Source: ©2016 IMS Health  
IMS-JPM 2013-15  
Santen analysis based on IMS data  
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# Status of Clinical Development FY2015 Third Quarter

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*A Clear Vision For Life™* 

## **Kenji Morishima**

Corporate Officer

Head of Global Pharmaceutical

Technology Development

# Status of main projects in clinical development (1)

Global

JP (Asia)

Disease Area	Project	Compound/ MOA	Region	Development Stage					Changes from 2QFY15
				P1	P2	P3	Filed	APV/ Launch	
Glaucoma/ ocular hypertension	DE-111	Tafluprost/ Timolol (FDC*)	EU	█	█	█	█	█	
			KR	█	█	█	█	█	
			Asia	█	█	█	█	█	
	DE-118	Tafluprost UD	JP	█	█	█	█	█	
			Asia	█	█	█	█	█	
	DE-085	Tafluprost	CN	█	█	█	█	█	
	DE-117	EP2 agonist	US	█	█	█			
JP			█	█	█	★		Started Phase2b/3	
DE-090	Lomerizine HCl	JP	█	█	█				
Kerato-conjunctival disease	Cyclokat/ Ikervis	Ciclosporin	EU	█	█	█	█	█	
			US	█	█	█			
			KR	█	█	█	█	★	NDA Filed
			Asia	█	█	█	█	★	NDA Filed
	DE-089	Diquafosol sodium	CN	█	█	█	█	█	
			Asia	█	█	█	█	█	

\*Fixed dose combination



# Status of main projects in clinical development (2)

Global

JP (Asia)

Disease Area	Project	Compound/ MOA	Region	Development Stage					Changes from 2QFY15
				P1	P2	P3	Filed	APV/ Launch	
Retinal/ Uveal disease	DE-109	Sirolimus	EU	█	█	█	█		
			JP	█	█	█			
			US	█	█	█			
			Asia	█	█	█	█		
	DE-120	VEGF/PDGF inhibitor	US	█	█				
DE-122	Anti-endoglin antibody	US	█	█					
Allergy	Vekacia	Ciclosporin	EU	█	█	█			

# Major Clinical Projects Update

-Glaucoma /  
Ocular hypertension-

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

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
China	Approved	Approved	Generic name: Tafluprost

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

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

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

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
Europe	Launched	Launched	Generic name: Tafluprost/ Timolol maleate (FDC)
Korea	Approved	Approved	
Asia	NDA Filed	NDA Filed	

# Major Clinical Projects Update -Glaucoma / Ocular hypertension-

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

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
U.S.	<b>P2b completed</b>	<b>P2b completed</b>	<b>EP2 receptor agonist</b>
Japan	<b>P2b/3</b>	-	

## ■ DE-118 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
Asia	<b>Approved</b>	<b>Approved</b>	<b>Generic name: Tafluprost</b>

# Major Clinical Projects Update -Corneal disease-

## ■ DE-089 (Dry eye)

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
Asia	Approved	Approved	Generic name: Diquafosol sodium

## ■ Cyclokot / Ikervis (Severe keratitis in adult patients with dry eye)

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
EU	Launched	Launched	Generic Name: Ciclosporin
U.S.	P2 completed	P2 completed	
Korea	NDA Filed	-	
Asia	NDA Filed	-	

## ■ Vekacia (Vernal Keratoconjunctivitis)

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
EU	P3	P3	Generic Name: Ciclosporin

# Major Clinical Projects Update -Retinal Disease- -Uveitis-

## ■ DE-109 (Uveitis)

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
<b>U.S.</b>	<b>P3</b>	<b>P3</b>	<b>Generic name: Sirolimus</b>
<b>Japan</b>	<b>P3</b>	<b>P3</b>	
<b>EU</b>	<b>NDA filed</b>	<b>NDA filed</b>	
<b>Asia</b>	<b>NDA filed</b>	<b>NDA filed</b>	

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

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
<b>U.S.</b>	<b>P2a</b>	<b>P2a</b>	<b>VEGF/PDGF dual inhib.</b>

## ■ DE-122 (Wet Age-related Macular Degeneration (w-AMD))

Region	Development Stage		Remarks
	As of February 2, 2016	As of November 4, 2015 (Previous announcement)	
<b>U.S.</b>	<b>P1/2</b>	<b>P1/2</b>	<b>Anti-endoglin antibody</b>

# 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.

The logo for Santen features a stylized letter 'S' on the left, composed of two overlapping curved shapes in shades of blue. To the right of the 'S' is the word 'Santen' in a bold, blue, sans-serif typeface.

**Santen**

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