

# Investor Meeting on FY 2015 First Quarter Results

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*A Clear Vision For Life™* 

## **Kazuo Koshiji**

Senior Corporate Officer  
Chief Financial Officer (CFO)  
Head of Finance Division

August 4, 2015

# Santen's Corporate Values

天機に参与する

*Tenki ni sanyo suru*

By focusing our efforts on ophthalmology and related areas, Santen develops 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.

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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 FY 2015 First Quarter Results**

**ended June 30, 2015**

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# Financial Highlights for 1Q FY2015

IFRS

(JPY billions) <b>IFRS basis</b>	1Q FY2014 Actual	1Q FY2015	
		Actual	Var. (YoY)
Revenue	33.7	48.0	+42.4%
Operating profit	5.9	10.8	+83.5%
Profit before tax	6.0	11.2	+88.4%
Net profit	4.1	7.5	+85.5%

## **Core basis**

Revenue	33.7	48.0	+42.4%
Core operating profit*	5.9	12.2	+108.6%
Core profit for the year	3.9	8.2	+110.3%

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

# Changes in Income Statement

(JPY billions)	1Q FY14 Actual	1Q FY15		Major Changes												
		Actual	Var.													
<b>Revenue</b>	<b>33.7</b>	<b>48.0</b>	<b>+42.4%</b>													
Cost of sales (% of revenue)	-13.6 40.3%	-17.9 37.2%	+31.5% -3.1pt	•Product mix change -2.3pt •NPM* -0.9pt												
SGA excluding R&D (% of revenue)	-10.2 30.2%	-13.3 27.8%	+30.8% -2.5pt	•Japan -0.9 •Asia -0.8 (FX-0.3) •US/EU -1.7 (FX+0.1) JPY billions												
R&D expenses (% of revenue)	-4.1 12.1%	-4.6 9.6%	+12.7% -2.5pt	•Japan -0.3 •Overseas -0.3 (FX-0.2) JPY billions												
Amortization associated with products (% of revenue)	-0.1 0.2%	-1.4 3.0%	- +2.8pt	•Amortization of Merck asset -1.3 JPY billions												
Other revenue	0.1	0.1	-20.3%													
Other expenses	0.0	-0.1	+167.8%													
<b>Operating profit</b> (% of revenue)	<b>5.9</b> <b>17.5%</b>	<b>10.8</b> <b>22.5%</b>	<b>+83.5%</b> <b>+5.0pt</b>													
Financial revenue	0.4	0.5	+7.4%	<table border="1"> <thead> <tr> <th>Currency rates</th> <th>1Q FY2014 Actual</th> <th>1Q FY2015 Actual</th> </tr> </thead> <tbody> <tr> <td>US \$</td> <td>JPY 102.17</td> <td>JPY 121.51</td> </tr> <tr> <td>Euro</td> <td>JPY 140.18</td> <td>JPY 134.01</td> </tr> <tr> <td>CYN</td> <td>JPY 16.54</td> <td>JPY 19.81</td> </tr> </tbody> </table>	Currency rates	1Q FY2014 Actual	1Q FY2015 Actual	US \$	JPY 102.17	JPY 121.51	Euro	JPY 140.18	JPY 134.01	CYN	JPY 16.54	JPY 19.81
Currency rates	1Q FY2014 Actual	1Q FY2015 Actual														
US \$	JPY 102.17	JPY 121.51														
Euro	JPY 140.18	JPY 134.01														
CYN	JPY 16.54	JPY 19.81														
Financial expenses	-0.4	0.0	-89.8%													
Profit before tax	6.0	11.2	+88.4%													
Income tax expense	-1.9	-3.7	+94.5%													
<b>Net profit</b>	<b>4.1</b>	<b>7.5</b>	<b>+85.5%</b>													
<b>Core operating profit</b>	<b>5.9</b>	<b>12.2</b>	<b>+108.6%</b>													
<b>Core profit for the year</b>	<b>3.9</b>	<b>8.2</b>	<b>+110.3%</b>													

\*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.

# Revenue by Business Segment

(JPY billions)	1Q FY15 Actual					
	Japan		Overseas		Total	
	Sales	Var. %	Sales	Var. %	Sales	Var. %
<b>Pharmaceuticals</b>	<b>34.3</b>	<b>+32.8%</b>	<b>13.0</b>	<b>+80.4%</b>	<b>47.4</b>	<b>+43.2%</b>
Prescription Pharmaceuticals	32.0	+30.2%	13.0	+80.5%	45.0	+41.6%
Ophthalmic	29.2	+32.8%	11.6	+67.3%	40.8	+41.1%
Anti-RA	2.6	+9.5%	-	-	2.6	+8.8%
Others	0.1	-16.6%	1.4	+447.1%	1.5	+272.2%
OTC Pharmaceuticals	2.4	+81.5%	0.0	+53.9%	2.4	+81.3%
<b>Others</b>	<b>0.6</b>	<b>-1.8%</b>	<b>0.0</b>	<b>-</b>	<b>0.6</b>	<b>+0.1%</b>
Medical Devices	0.5	-6.0%	0.0	-	0.5	-3.9%
Others	0.1	+44.9%	-	-	0.1	+44.9%
<b>Total</b>	<b>34.9</b>	<b>+32.0%</b>	<b>13.0</b>	<b>+80.6%</b>	<b>48.0</b>	<b>+42.4%</b>

# Overseas Revenue and Core Operating Profit

(JPY billions)	1Q FY2014	1Q FY2015		
	Actual	Actual		Operating profit**
	Revenue	Revenue	Var. %	
U.S.	0.3	1.4*	+445.6%	-0.7
Europe	3.2	5.3	+66.3%	0.6
Asia	3.8	6.3	+67.8%	2.4
China	2.5	3.6	+43.9%	
Total	7.2	13.0	+80.6%	2.3

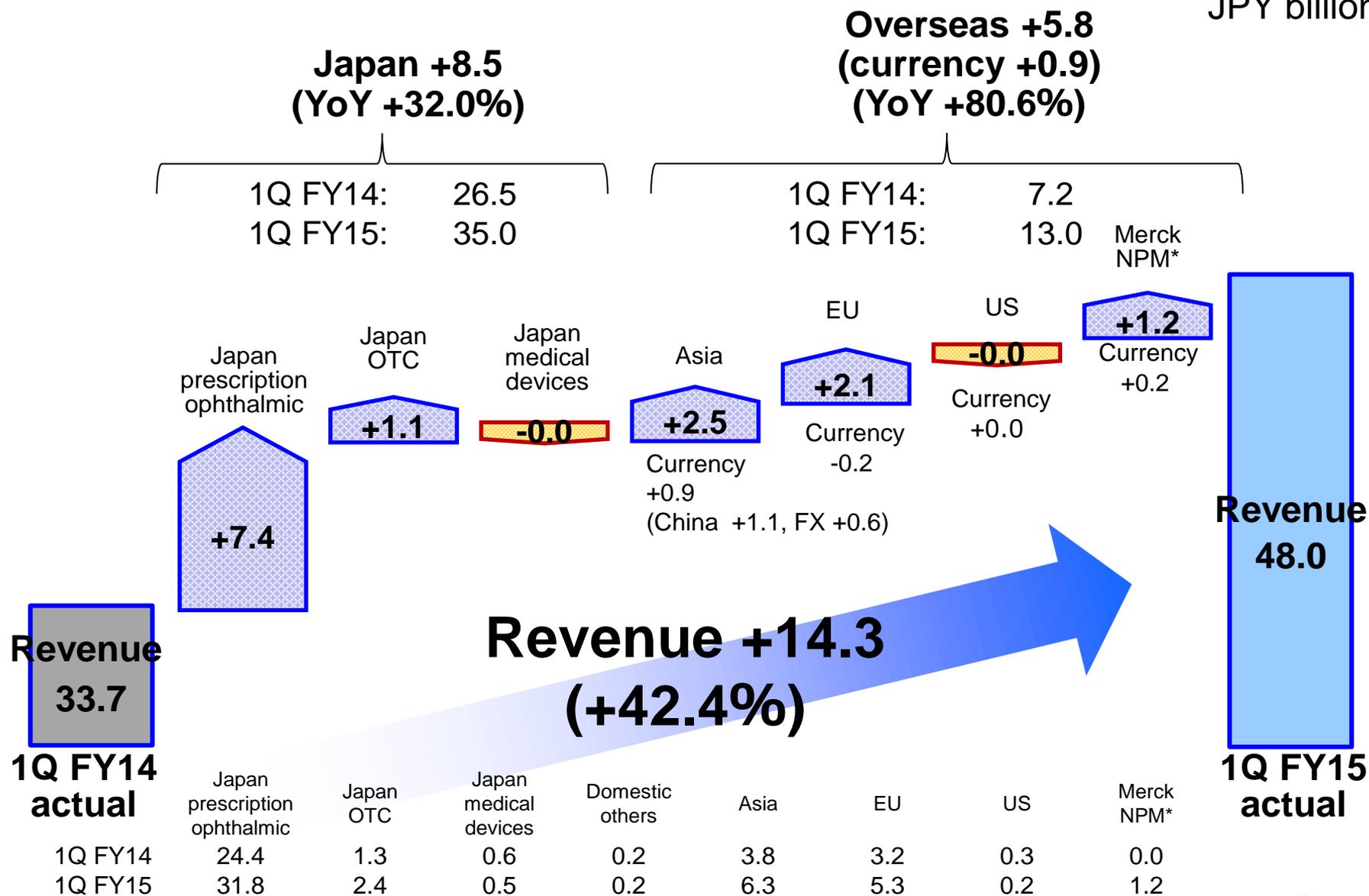
<b>Overseas sales / sales</b>	<b>21.4%</b>	<b>27.2%</b>	<b>+5.7pt</b>	<b>-</b>
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\* Net profit margin (NPM) relating to the Merck product acquisition is treated as revenue in the U.S.

\*\* 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.

# 1Q FY15 Revenue Change

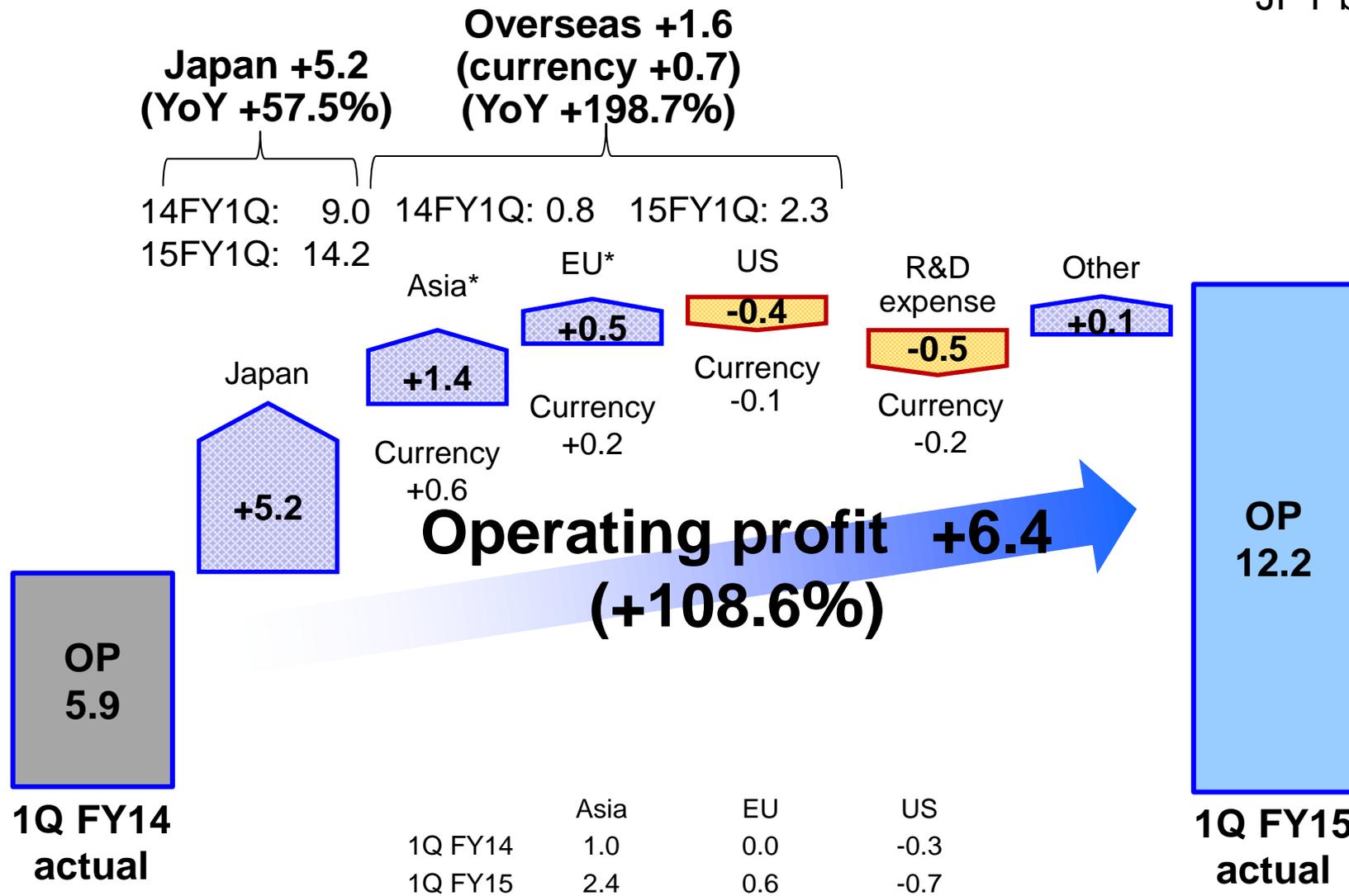
JPY billions



\*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.

# 1Q 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.

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# Merck Project Results

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# Merck Project Results

(JPY billions)	1Q FY15 Actual		FY2015 Forecast	
	Merck*	Total	Merck*	Total
<b>Revenue</b>	4.7	48.0	21.5	186.5
NPM*	1.2	1.2	4.1	4.1
Santen sales (marketing rights transferred)	3.5	46.8	17.4	182.4

## By March 2015

- Marketing authorization transferred from Merck to Santen in 11 regions (Finland, Germany, Sweden, etc.)

## Q1 April to June 2015

- Santen sales begun in 8 additional regions (Hong Kong, Iceland, Italy, Russia, Spain, etc.)

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

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# **Completion of the Transfer of Anti-Rheumatic Pharmaceutical Business**

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# Completion of the Transfer of Anti-Rheumatic Pharmaceutical Business

- On August 3, 2015, Santen completed the simplified company split relating to the transfer of its anti-rheumatic pharmaceutical business to AYUMI Pharmaceutical Corporation\* originally announced on May 12, 2015
- Upon the official completion of the company split, Santen received 45 billion yen in consideration for the transfer of all rights and obligations of the business
- The impact of this event on Santen's financial performance was reflected in the forecast announced on May 12, 2015, therefore there is no further impact on its annual forecast

\* AYUMI Pharmaceutical Corporation changed its name from Hyperion Pharma Co., Ltd. on June 2, 2015.

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# **Consolidated Forecasts of FY2015**

## **ending March 31, 2016**

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# FY2015 Consolidated Forecasts

(JPY billions)	FY2015 Forecast					
	1 <sup>st</sup> half	Var.%	2 <sup>nd</sup> half	Var.%	Full year	Var.%
<b>Revenue</b>	<b>92.5</b>	<b>+28.6%</b>	<b>94.0</b>	<b>+4.5%</b>	<b>186.5</b>	<b>+15.2%</b>
Cost of sales (% of revenue)	-32.0 34.6%	+20.4%	-34.4 36.6%	+15.5%	-66.4 35.6%	+17.8% +0.8pt
SGA excluding R&D (% of revenue)	-28.5 30.8%	+30.3%	-28.4 30.2%	+5.1%	-56.9 30.5%	+16.4% +0.3pt
R&D expenses (% of revenue)	-11.0 11.9%	+34.6%	-11.9 12.7%	+27.9%	-22.9 12.3%	+31.0% +1.5pt
Amortization associated with products (% of revenue)	-3.0 3.2%	+131.2%	-3.1 3.3%	+15.6%	-6.1 3.3%	+53.3% +0.8pt
Other revenue	45.0	-	-	-100.0%	45.0	-
Other expenses	-1.0	-	-0.2	-50.5%	-1.2	+162.0%
<b>Operating profit</b> (% of revenue)	<b>62.0</b> <b>67.0%</b>	<b>+338.7%</b>	<b>16.0</b> <b>17.0%</b>	<b>-24.7%</b>	<b>78.0</b> <b>41.8%</b>	<b>+120.5%</b> <b>+20.0pt</b>
<b>Core operating profit</b> (% of revenue)	<b>21.0</b> <b>22.7%</b>	<b>37.3%</b>	<b>19.3</b> <b>20.5%</b>	<b>-18.9%</b>	<b>40.3</b> <b>21.6%</b>	<b>+3.1%</b>

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

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# **Dividend for FY2015 Forecast**

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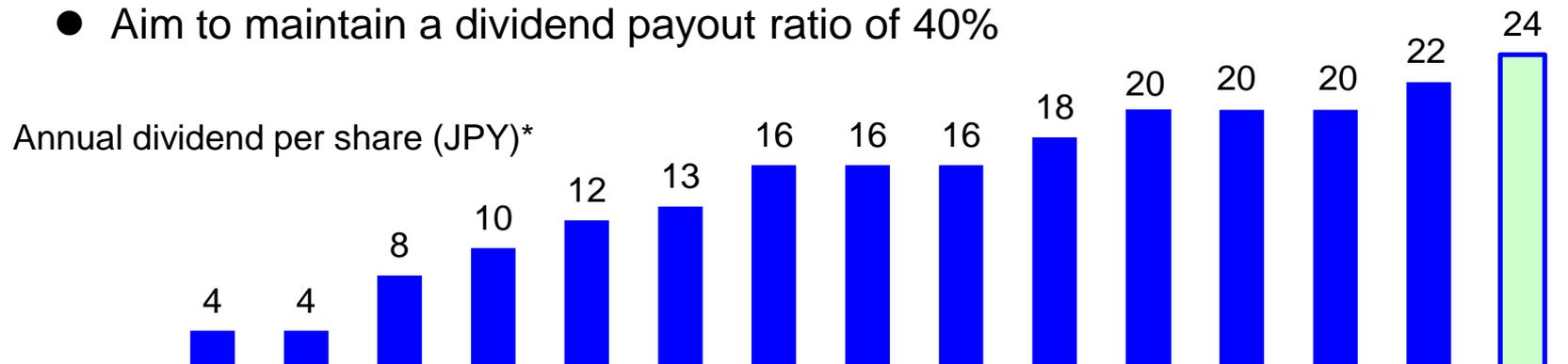
# Dividends for FY2014 Actual and FY2015 Forecast

## ■ FY2015 (Forecast)

- Annual dividend: JPY 24 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&As for future growth
- Consider share buybacks in a flexible manner
- Aim to maintain a dividend payout ratio of 40%



(¥ billion)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015e
Payout-ratio (%)**	35	21	56	40	40	43	55	67	36	36	51	51	48	38	***19
Share buy-back	3.2	3.2	0	2.6	0	0	4.8	0	0	0	0	13.7	0	0	-
Total return (%)**	96	60	56	63	40	43	86	67	36	36	51	134	48	38	-

\*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 impact of a gain related to the succession of the company's anti-rheumatic pharmaceutical business in FY15, payout ratio is forecast to be 39%.

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**Reference:  
Consolidated Results of 1Q  
FY2015**

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# Summary of Balance Sheet

(JPY billions)	As of March 31, 2015		As of June 30, 2015		
	Actual	% of Total	Actual	% of Total	Var.
Non-current assets	153.5	50.5%	153.8	51.0%	+0.3
Current assets	150.7	49.5%	147.6	49.0%	-3.1
<b>Total assets</b>	<b>304.2</b>	<b>100.0%</b>	<b>301.4</b>	<b>100.0%</b>	<b>-2.8</b>
<b>Total equity</b>	<b>211.8</b>	<b>69.6%</b>	<b>216.5</b>	<b>71.8%</b>	<b>+4.7</b>
Non-current liabilities	36.1	11.9%	34.5	11.4%	-1.6
Current liabilities	56.3	18.5%	50.5	16.8%	-5.8
<b>Total liabilities</b>	<b>92.4</b>	<b>30.4%</b>	<b>84.9</b>	<b>28.2%</b>	<b>-7.5</b>
<b>Total equity and liabilities</b>	<b>304.2</b>	<b>100.0%</b>	<b>301.4</b>	<b>100.0%</b>	<b>-2.8</b>

Shares issued\*: End of March 2015: 413,266 thousand → End of June 2015: 413,703 thousand

## Major Changes

- Non-current assets: Right of approval for manufacture and sales +¥8.5bil, In-process R&D -¥7.3bil,
- Current assets: Cash and deposits -¥9.8bil
- Non-current liabilities: Long term borrowing -¥2.9bil

\*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)		1Q FY14	1Q FY15	Var.
	Cash flows from operating activities	-5.0	-0.3	+4.6
	Cash flows from investing activities	0.2	-2.6	-2.7
	Cash flows from financial activities	31.0	-7.6	-38.5
<b>Net increase (decrease) in cash and cash equivalents</b>		<b>26.1</b>	<b>-10.5</b>	<b>-36.6</b>
<b>Cash and cash equivalents at beginning of year</b>		<b>72.4</b>	<b>65.9</b>	<b>-6.5</b>
Effect of exchange rate changes on cash and cash equivalents		-0.5	0.6	+1.1
<b>Cash and cash equivalents at end of year</b>		<b>98.0</b>	<b>56.1</b>	<b>-42.0</b>

# Capital Expenditures / Depreciation & Amortization

(JPY billions)	1Q FY14 Actual	1Q FY2015	
		Actual	Var.
Capital expenditures	0.4	0.8	+0.5
Depreciation and amortization	0.8	*2.2	+1.4

\*Includes JPY1.3 billion amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products

# 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
Amortization associated with products	- - - - ->	Excluded from core
R&D		R&D
Other revenue	- - - - ->	Excluded from core
Other expenses	- - - - ->	Excluded from core
<b>Operating profit</b>		<b>Core operating profit</b>
Financial revenue (interest, dividends, forex gains)	- - - - ->	Excluded from core
Financial expense (interest, forex losses)	- - - - ->	Excluded from core
Profit before tax		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 revenue and expenses, and financial revenue and expenses

# Reconciliation of IFRS to Core OP

(JPY billions)	FY2014 1Q (actual)	FY2015 1Q (actual)
<b>IFRS operating profit</b>	<b>5.9</b>	<b>10.8</b>
Non-core deduction items	-0.0	+1.4
Amortization associated with products	+0.1	+1.4
Other revenue	-0.1	-0.1
Other expenses	+0.0	+0.1
<b>Core operating profit</b>	<b>5.9</b>	<b>12.2</b>

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# **Reference: Consolidated Forecast of FY2015**

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# Revenue Forecast by Business Segment / Overseas Revenue

(JPY billions)	FY2015 Forecast					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var. %	Sales	Var. %
<b>Pharmaceuticals</b>	<b>129.4</b>	<b>5.8%</b>	<b>53.9</b>	<b>+45.8%</b>	<b>183.3</b>	<b>+13.3%</b>
Prescription Pharmaceuticals	123.0	6.3%	53.8	+45.9%	176.8	+11.0%
Ophthalmic	118.5	+12.5%	49.1	+59.9%	167.6	+23.2%
Anti-RA	3.6	-62.2%	0	-	3.6	-62.4%
Others	0.9	+14.4%	4.7	-23.0%	5.6	-18.9%
OTC Pharmaceuticals	6.4	-3.2%	0.1	-0.6%	6.5	-3.2%
<b>Others</b>	<b>2.8</b>	<b>+11.3%</b>	<b>0.4</b>	<b>+831.0%</b>	<b>3.2</b>	<b>+25.2%</b>
Medical devices	2.5	+9.5%	0.1	+19.1%	2.6	+9.7%
Others	0.3	+28.5%	0.4	-	0.7	+174.3%
<b>Total</b>	<b>132.2</b>	<b>+5.9%</b>	<b>54.3</b>	<b>+46.8%</b>	<b>186.5</b>	<b>+15.2%</b>

# Overseas Revenue and Core Operating Profit Forecast

(JPY billions)	FY2014 Actual	FY2015 Forecast		
	Revenue	Revenue	Var. %	Operating profit**
U.S.	6.2	4.9*	-20.0%	-2.5
Europe	14.2	25.4	+79.5%	3.8
Asia	16.7	23.9	+43.4%	5.8
China	10.7	13.5	+26.5%	-
Total	37.0	54.3	+46.8%	7.1

<b>Overseas sales / sales</b>	<b>22.9%</b>	<b>29.1%</b>	<b>+6.3pt</b>	<b>-</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

(JPY billions)	FY14 Actual	FY2015	
		Forecast	Var.
Capital expenditures	5.4	7.7	+2.3
Depreciation and amortization*	7.0	9.3	+2.4

\*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.

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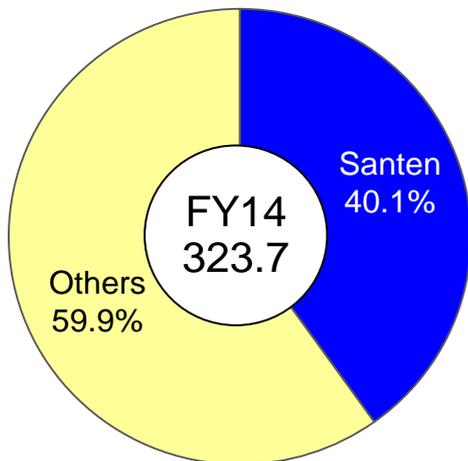
# **Reference: Market Overview of Prescription Ophthalmic in Japan**

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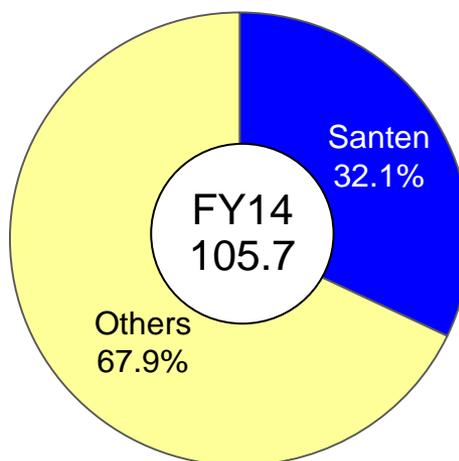
# Japan: Trend & Competition in Ophthalmics (1)

Market Size:  
billions of yen  
%: Value Share

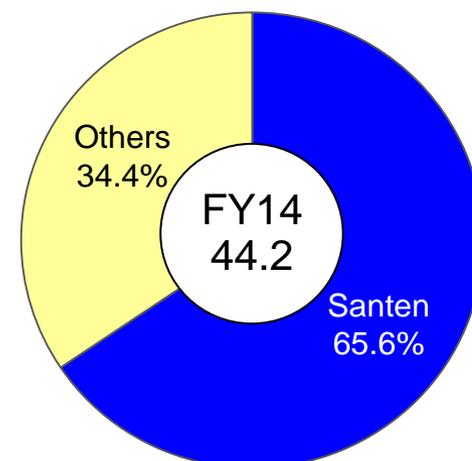
## Ophthalmology Total



## Anti-glaucoma



## Cornea / Dry Eye



		FY14	1Q FY15
YoY change	Market	+7.4%	+13.8%
	Santen	+9.3%	+25.9%
Santen's Share		40.1%	42.5%

		FY14	1Q FY15
YoY change		+0.9%	+12.1%
Santen		+6.1%	+24.7%
Santen's Share		32.1%	32.7%

		FY14	1Q FY15
YoY change		-0.0%	+10.2%
Santen		-7.0%	+5.9%
Santen's Share		65.6%	64.0%

-Santen:

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

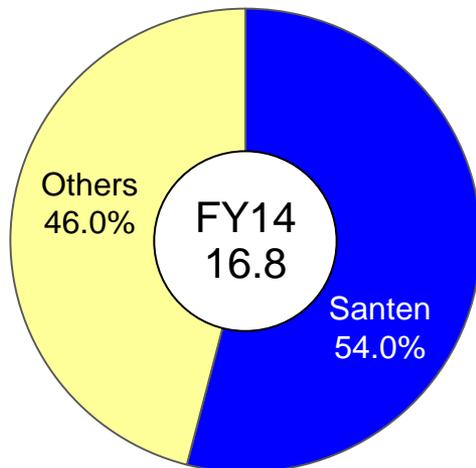
Source: ©2015 IMS Health  
IMS-JPM 2013-15  
Santen analysis based on IMS data  
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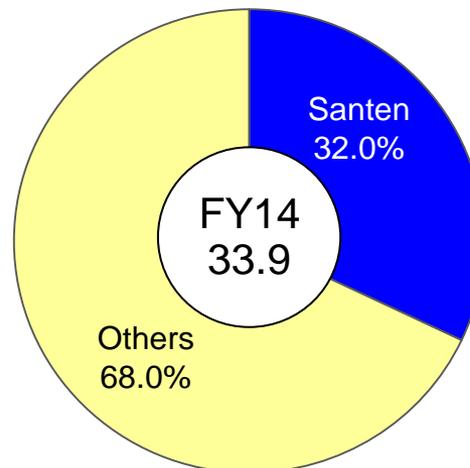
# Japan: Trend & Competition in Ophthalmics (2)

Market Size:  
billions of yen  
%: Value Share

## Anti-infection



## Anti-allergy



		FY14	1Q FY15
YoY change	Market	-8.2%	-0.3%
	Santen	-15.3%	-9.7%
Santen's Share		54.0%	51.0%

		FY14	1Q FY15
		+21.4%	+8.1%
		+83.3%	+38.5%
Santen's Share		32.0%	37.8%

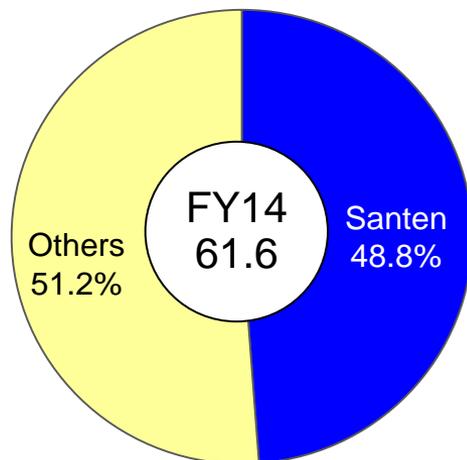
- Santen:
  - Anti-infection: Cravit, Tarivid
  - Anti-allergy: Alesion, Livostin, Alegysal

Source: ©2015 IMS Health  
IMS-JPM 2013-15  
Santen analysis based on IMS data  
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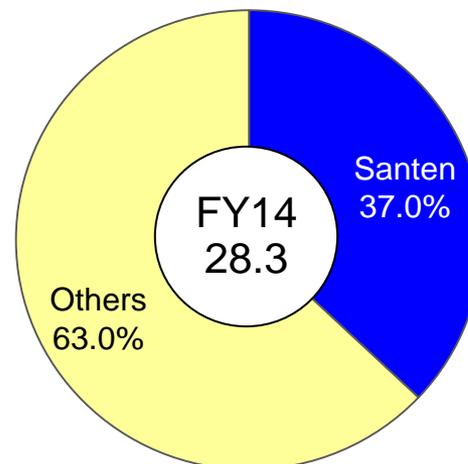
# Japan: Trend & Competition in Ophthalmics (3)

Market Size:  
billions of yen  
%: Value Share

## Anti-VEGF



## Anti-RA(DMARDs)



		FY14	1Q FY15
YoY change	Market	+42.6%	+41.2%
	Santen	+43.0%	+80.2%
Santen's Share		48.8%	57.4%

		FY14	1Q FY15
YoY change		-1.5%	+3.7%
Market		-5.1%	+1.3%
Santen's Share		37.0%	36.7%

- Santen:
- Anti-VEGF: Eylea
- Anti-RA(DMARDs): Rimatil, Azulfidine, Metolate

Source: ©2015 IMS Health  
IMS-JPM 2013-15  
Santen analysis based on IMS data  
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# Status of Clinical Development 1Q FY2015

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**Naveed Shams, M.D., Ph.D.**

Senior Corporate Officer

Chief Scientific Officer (CSO)

Head of Global Research & Development

# Status of main projects in clinical development (1)

Global

JP (Asia)

Disease Area	PJ	Compound/ MOA	Region	Development Stage					Changes from 4QFY14
				P1	P2	P3	Reg.	APV/ Launch	
Glaucoma/ ocular hypertension	DE-111	Tafluprost/ Timolol (FDC*)	JP						
			EU						
			KR					★	Approved
			Asia						
	DE-118	Tafluprost UD	JP						
			Asia					★	Approved
	DE-085	Tafluprost	CN						
	DE-117	EP2 agonist	US						
DE-090	Lomerizine	JP							
Kerato- conjunctival disease	Cyclokat	Ciclosporin	EU					★	Launched in Germany
			US						
	DE-089	Diquafosol	CN						
			Asia					★	Approved

\*Fixed dose combination

# Status of main projects in clinical development (2)

Global

JP (Asia)

Disease Area	PJ	Compound/ MOA	Region						Changes from 4QFY14
				P1	P2	P3	Reg.	APV/ Launch	
Retinal/ Uveal disease	DE-109	Sirolimus	EU						
			JP						
			US						
			Asia				★		NDA submitted
	DE-120	VEGF/PDGF inhibitor	US						
DE-122	Anti-endoglin antibody	US						IND filed	
Allergy	Vekacia	Ciclosporin	EU						

# Major Clinical Projects Update

-Glaucoma /  
Ocular hypertension-

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

Region	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 2015 (Previous announcement)	
China	NDA Filed	NDA Filed	Generic name: Tafluprost

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

Region	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 2015 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

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

Region	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 2015 (Previous announcement)	
Japan	Launched	Launched	Generic name: Tafluprost/ Timolol maleate (FDC)
Europe	Launched	Launched	
Korea	Approved	NDA Filed	
Asia	NDA Filed	NDA Filed	

# Major Clinical Projects Update

-Glaucoma /  
Ocular hypertension-  
-Corneal disease-

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

Region	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 2015 (Previous announcement)	
U.S.	<b>P2b completed</b>	<b>P2b completed</b>	<b>EP2 receptor agonist</b>

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

Region	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 2015 (Previous announcement)	
Asia	<b>Approved (Hong Kong)</b>	<b>NDA filed</b>	<b>Generic name: Tafluprost</b>

## ■ DE-089 (Dry eye)

Region	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 2015 (Previous announcement)	
Asia	<b>Approved (Thai)</b>	<b>NDA filed</b>	<b>Generic name: Diquafosol Sodium</b>

# Major Clinical Projects Update

-Retinal Disease-  
-Uveitis-

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

Region	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 2015 (Previous announcement)	
<b>U.S.</b>	<b>P2a</b>	<b>P2a</b>	<b>VEGF/PDGF dual inhib.</b>

## ■ DE-109 (Uveitis)

Region	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 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>P3</b>	
<b>Asia</b>	<b>NDA filed</b>	<b>—</b>	

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

Region	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 2015 (Previous announcement)	
<b>U.S.</b>	<b>IND filed</b>	<b>—</b>	<b>Anti-endoglin antibody</b>

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

## ■ Cyclokat / Ikervis (Severe Keratitis)

Region	Development Stage		Remarks
	As August 4, 2015	As of May 12, 2015 (Previous announcement)	
EU	<b>Launched (Germany)</b>	<b>NDA filed</b>	Generic Name: <b>Ciclosporin</b>
U.S.	<b>P2 completed</b>	<b>P2 completed</b>	

## ■ Vekacia (Vernal Keratoconjunctivitis)

	Development Stage		Remarks
	As of August 4, 2015	As of May 12, 2015 (Previous announcement)	
EU	<b>P3</b>	<b>P3</b>	Generic Name: <b>Ciclosporin</b>

\*Project evaluations are ongoing for the products below:

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

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