

FY 2012 Third Quarter Results

February 5, 2013 Santen Pharmaceutical Co., Ltd



Consolidated Results FY2012 Third Quarter

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Head of Finance & Administration Division

Medium-term Policies FY2011-2013

To become a specialized pharmaceutical company with 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 Q3 FY2012

	Q3.FY2011 Actual	Q3 FY2012 Actual	Var. %
Net Sales	86.43	88.42	+2.3%
Operating Income	22.22	20.57	-7.4%
Ordinary Income	23.03	21.26	-7.7%
Net Income	14.76	14.13	-4.3%



Highlights for Q3 FY2012 Results (1)

Domestic business :

- In the prescription pharmaceutical segment, growth in sales of new products offset the impact of the NHI price revision.
 - The sales of *Diquas* and *Cosopt* showed 2digiet growth.
 - Glaucoma Market share increased due to the sales growth of Tapros and Cosopt.
 - The treatment of wet-AMD "Eylea" launched on November 27th.
 - The campaign drove the sales growth of OTC pharmaceutical segment.

Overseas business:

- Europe: The sale was slightly down due to the fluctuation of foreign exchange, while the sales based on a local currency maintained steady growth.
- Asia: Steady growth of China increased the sales of Asian business.



Highlights for Q3 FY2012 Results (2)

Cost of sales:

Cost of sales increased mainly due to the NHI price cut and the change of product mix.

SG&A and R&D cost

- Focusing on the cost management
- Increase the R&D cost due to the progress of late stage of clinical development.



Net Sales: Variances (vs. Q3 FY2011)

In billions of Yen

FY20110 Net Sale (Actual) ¥86.43bill



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<u> </u>	Japan: 74.74bil (+	-1.59bil)	Prescription (Jag	Ophthalmio ban)	cs
Q3 es)	 Prescription Ophthalmics Anti-rheumatics OTC Drugs 	+0.04bil -0.12bil +1.60bil	 Anti-infective Cornea (Dry Eye) Diquas Glaucoma 	-2.21bil +0.55bil +2.10bil +1.68bil	-20.7% +3.1% +109.2% +9.8%
llion 8 /	+ Medical Devices+ Others	+0.16bil -0.09bil	Tapros Cosopt Anti-allergy Others	+0.43bil +2.16bil -0.03bil -0.61bil	+7.9% +46.8% -1.6% -5.3%
	Overseas: 13.68bi + U.S. (Forex impact	<u>I (+0.39bil)</u> -0.65bil -0.00bil)	Euro	ре	
Q3	+ Europe (Forex impact	-0.28bil -0.67bil)	 Prescription Ophthalmics Western Europe 	-0.28bil +0.01bil	-4.2% +0.9%
es)	+ Asia - China (Forex impact	+1.32bil +1.39bil +0.05bil)	-Eastern Europe -Northern Europe - Russia	+0.03bil -0.05bil -0.28bil	+2.9% -2.1% -22.3%
llion	- Korea (Forex impact	-0.29bil -0.01bil)	USD JP' EUR JP	<u>Q3 actua</u> l <u>FY12.0</u> Y 79.09 JF Y 112.94 JF	Q <u>3 actua</u> l PY 80.01 PY 102.12 PY 12.53

Changes in Income Statement

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(IDV hillions)	FY2011	Q3 FY	2012		
(JPY billions)	Q3 Actual	Actual	Variance	Major Changes	
Net Sales	86.43	88.42	+1.98		
Cost of Sales (% of net sales)	26.95 31.2%	29.75 33.7%	+2.80 +2.5pt	 Effect from NHI price revision: +1.5pt Change of product mix +0.6pt Reduction of income from license contracts: +0.2pt 	
SGA excluding R&D (% of net sales)	25.02 28.9%	25.99 29.4%	+0.97 +0.5pt	 Japan: -0.18bil EU/US excluding Novagali: +0.28bil Novagali: +0.73bil Asia: +0.45bil Head Quarter: -0.29bil 	
R&D Expenses (% of net sales)	12.24 14.2%	12.09 13.7%	-0.14 -0.5pt	 Japan: -0.96bil EU/US excluding Novagali: +0.19bil Novagali: +0.61bil 	
Operating Profit (% of net sales)	22.22 25.7%	20.57 23.3%	-1.64 -2.4pt		
Non-operating Income Non-operating Expense	0.86 0.05	0.85 0.15	-0.01 +0.09		
Ordinary Income	23.03	21.26	-1.76		
Extraordinary Gain Extraordinary Loss	0.06 0.02	0.01 0.00	-0.04 -0.01	<currency rates=""> <u>FY11.Q3 actual</u> USD JPY 79.09 JPY 80.01</currency>	
Net Income before Tax	23.06	21.27	-1.78	EUR JPY 112.94 JPY 102.12 CNY JPY 12.38 JPY 12.53	
Corporate Tax	8.29	7.14	-1.15		
Net Profit	14.76	14.13	-0.63		



Reference: Consolidated Results FY2012 Third Quarter

Net Sales by Business Segment(3QYTD)

(JPY billions)					Q3 FY201	2 Actual		
			Japan		Overseas		Total	
			Sales	Var.	Sales	Var.	Sales	Var.
Pł	harr	maceuticals	73.18	+2.0%	13.62	+7.7%	86.81	+2.9%
		rescription narmaceuticals	67.99	-0.3%	13.61	+7.7%	81.61	+1.0%
		Ophthalmic	59.53	+0.1%	13.31	+7.4%	72.85	+1.3%
		Anti-RA	7.66	-1.6%	0.06	-24.6%	7.72	-1.9%
		Others	0.80	-10.4%	0.23	+47.9%	1.03	-1.7%
	-	TC narmaceuticals	5.18	+44.6%	0.00	-4.3%	5.19	+44.5%
Oi	ther	rs	1.55	+11.6%	0.05	-91.4%	1.61	-20.7%
		Medical Devices	1.55	+11.7%	0.05	-91.4%	1.60	-20.7%
		Others	0.00	-9.2%	-	-	0.00	-9.2%
Тс	otal		74.74	+2.2%	13.68	+3.0%	88.42	+2.3%





	FY2011	FY2012			
(JPY billions)	Q3 Actual	Q3 Actual	Var.	Var. %	
U.S.	1.01	0.36	-0.65	-64.1%	
Europe	6.75	6.46	-0.28	-4.3%	
Asia	5.51	6.84	+1.32	+24.1%	
Others	0.00	0.00	+0.00	+130.7%	
Total	13.28	13.68	+0.39	+3.0%	



Summery of Change in Balance Sheet

(IDV hillions)	As of March 31, 2012		As of December 31, 2012		
(JPY billions)	Actual	% of Total	Actual	% of Total	Var.
Current Asset	140.28	70.6%	124.22	67.3%	-16.06
Fixed Asset	58.51	29.4%	60.39	32.7%	+1.87
Total Asset	198.80	100.0%	184.61	100.0%	-14.19
Current Liabilities	27.42	13.8%	21.14	11.5%	-6.27
Non-current Liabilities	6.51	3.3%	6.55	3.6%	+0.04
Total Liabilities	33.94	17.1%	27.70	15.0%	-6.23
Total Net Asset	164.86	82.9%	156.90	85.0%	-7.95
Total Liabilities Net Assets	198.80	100.0%	184.61	100.0%	-14.19

Major Changes

■Current Asset:	Cash and deposits -¥18.92bil, Notes and accounts receivable-trade +¥4.18bil, Merchandise and finished products -¥0.90bil, Raw materials and supplies +¥0.84bil ST deferred tax assets -¥0.80bil
Fixed Asset :	Buildings and structures -¥0.60bil, Construction in progress +¥1.17bil, Goodwill -¥0.49bil, Investment securities +¥0.86bil, LT deferred tax assets -¥0.40bil, Other investments +¥1.2bil
Fixed Liabilities: Net asset :	Accounts payable -¥0.54bil, Income tax payable -¥4.35bil, Reserve for bonus -¥1.27bil Employee retirement benefits +¥0.11bil Capital surplus -¥0.50bil, Retained earnings -¥7.41bil
■Issued shares:	End of September 87,168,000 \rightarrow end of December 82,322,000 (Cancellation of treasury shares as of November 16, 2012)



Summary of Cash Flows

(JPY billions)		FY2012 Q3 Actual
Cash an	d cash equivalents at the beginning of the year	75.03
Net increase/decrease in cash and cash equivalents		-18.80
	Cash flows from operating activities	6.20
	Cash flows from investing activities	-3.32
	Cash flows from financial activities	-21.86
	Effect of exchange rate changes on cash and cash equivalents	0.17
Cash an	d cash equivalents at the end of the year	56.23

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



Capital Expenditures / Depreciation & Amortization / Lease Expenses

	FY2011	FY2012		
(JPY billions)	Q3 Actual	Q3 Actual	Var.	Full Year Forecast*
Capital Expenditures	2.70	2.59	-0.10	5.00
Depreciation and Amortization	2.02	1.83	-0.18	2.84
Lease Payments	0.02	0.00	-0.01	0.01



Income statement in Novagali

(EUR millions)	FY2012 Q3 Actual
Sales	0.4
COGS	0.3
SGA (excl.R&D)	7.1
(in SGA) Amortization of Goodwill	4.6
R&D	6.0
Operating Profit	-13.1





Reference: FY2012 Financial Forecasts

Financial Forecast for FY2012

(JPY billions)	FY2011 Actual	FY2012 Forecast	Var. %
Net Sales	114.41	114.50	+0.1%
Operating Income	26.73	23.50	-12.1%
Ordinary Income	27.78	24.00	-13.6%
Net Income	17.16	16.00	-6.8%

ROE	10.7%	10.0%	-0.7pt
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*Forecast as of: May 8, 2012. ROE reflects the cancellation of treasury shares.

Sales/Income Outlook for the FY2012

	FY2011	FY2	012
(JPY billions)	Actual	Forecast	Var.
Net Sales	114.41	114.50	+0.08
Cost of Sales	35.38	38.00	+2.61
(% of net sales)	30.9%	33.2%	+2.3pt
SG&A excluding R&D	35.07	35.50	+0.42
(% of net sales)	30.7%	31.0%	+0.4pt
R&D Expense	17.22	17.50	+0.27
(% of net sales)	15.1%	15.3%	+0.2pt
Operating Income	26.73	23.50	-3.23
(% of net sales)	23.4%	20.5%	-2.8pt
Non-operating Income/Loss	1.04	0.50	-0.54
Ordinary Income	27.78	24.00	-3.78
Extraordinary Income/Loss	0.01	0.00	-0.01
Net Income before Tax	27.79	24.00	-3.79
Income Taxes	10.63	8.00	-2.63
Net Income	17.16	16.00	-1.16

Santen *Forecast as of: May 8, 2012

<Currency rate>

USD

EUR

CNY

USD EUR

CNY

FY2011 actual JPY 79.03

JPY 110.27

JPY 12.34

FY2012 forecast JPY 79.00

JPY 104.00

JPY 12.50

Net Sales by Business Segment(12FY)

(၂	JPY billion)			FY2012 F	Forecast*		
		Japan		Overseas		Total	
		Sales	Var.	Sales	Var.	Sales	Var.
P	harmaceuticals	93.28	-0.2%	18.31	-0.5%	111.59	-0.2%
	Prescription Pharmaceuticals	87.17	-1.9%	18.26	-0.7%	105.43	-1.7%
	Ophthalmic	76.71	-1.3%	17.57	+10.8%	94.28	+0.7%
	Anti-RA	9.45	-4.3%	0.09	-13.1%	9.54	-4.4%
	Others	1.00	-17.8%	0.59	-75.2%	1.60	-55.9%
	OTC Pharmaceuticals	6.11	+33.3%	0.04	+377%	6.16	+34.1%
0	thers	2.89	+50.2%	0.01	-98.4%	2.90	+12.9%
	Medical devices	2.88	+50.6%	0.01	-98.4%	2.89	+13.0%
	Others	0.01	-11.9%	_	_	0.01	-11.9%
Тс	otal	96.17	+0.8%	18.32	-3.8%	114.50	+0.1%

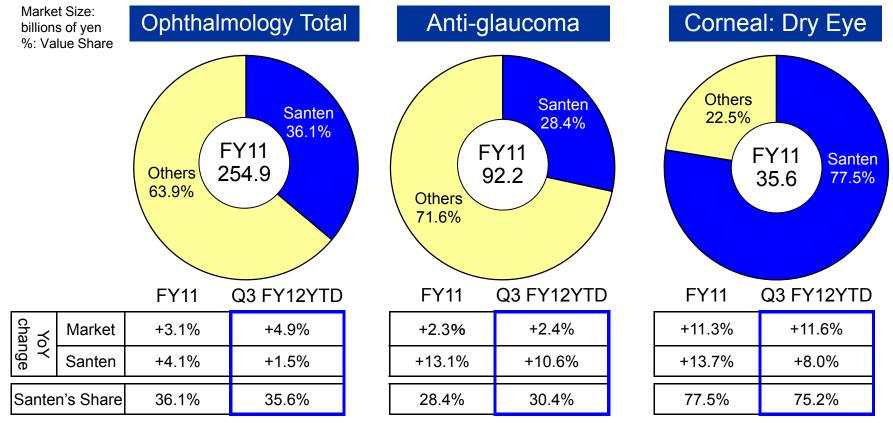
Santen *Forecast as of: May 8, 2012



Reference: Market Overview of Prescription Ophthalmics in Japan

Japan: Market Trends in Ophthalmics (1)

- Market Total: Grew by 4.9% Y to Y in 3QFY12(YTD). The growth of retinal and corneal segment continued. Santen's market share was 35.6%.
- Glaucoma: Grew by 2.4% Y to Y in 3Q FY12. Santen's sales expanded by 10.6% due the increase of Tapros and Cosopt. Santen held 30.4%.
- Corneal: Grew by 11.6% Y to Y in 3Q FY12. Santen's sales increased by 8.0% with the market share at 75.2%, driven by Diquas and Hyalein.



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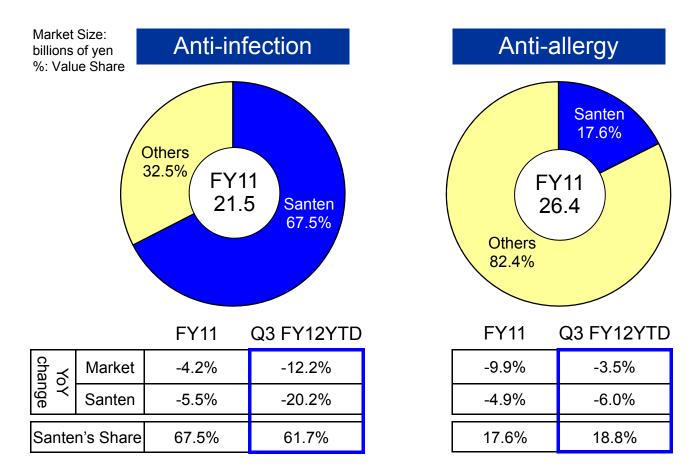


-Santen:

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

Japan: Market Trends in Ophthalmics (2)

- Anti-infection: Declined by 12.2% Y to Y in 3QFY12(YTD). Santen's share was 61.7%, mainly the sales of Cravit.
- Anti-allergy: Declined by 3.5% Y to Y in 3QFY12. Santen's share was 18.8%.



-Santen:

- Anti-infection: Cravit, Tarivid, etc.

Anti-allergy: Livostin, Alegysal



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FY2012 Third Quarter Status of Clinical Development

February 5, 2013 Toshiaki Nishihata, Ph.D. Director, Executive Corporate Officer, U.S. and Europe Business, Head of Research and Development Division

Major Clinical Pipeline List (1) [by Disease]

(<u>Red underlined</u>: Change from 12FY2Q Presentation)

Global Product

Japan (Asia)Product

Disease	Phase 1	Pha	se 2	Phase 3	NDA	Approved • Launched
Glaucoma	DE-117 EP2 Agonis				China	JP·Asia·EU· Latin America Australia·US
		DE- Lomeriz		EU Tafluprost	- PL	DE-118 Tafluprost
Corneal/ Conjunctival		DE- Rivogli	-		• mina	-089 Korea JP sol Sodium
Disease		-105 combination	JP			
		US	Cycl Ciclos			
Retina Uveal Disease				DE-109 Sirolimus		
				DE-102 etamethasone		
Other Infection, Allergy,		DE- Anti APO-1			DE-114 Epinastine HCI	
RA				Vekacia Ciclosporin		



Major Clinical Pipeline List (2) [by Region]

(Red underlined: Change from 12FY2Q Presentation)

Global Product

Japan (Asia)Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved • Launched
Japan		E	DE-102 Betamethasone		DE-085 Tafluprost
		DE-090 Lomerizine HCI		DE-111 Tafluprost/Timolol	DE-089 Diquafosol Sodium
		DE-105 Peptide Combination		DE-114 Epinastine HC	DE-118 Tafluprost
		DE-098 Anti APO-1 Antibody	DE-109 Sirolimus		
North America	DE-117 EP2 Agonist		DE-109 Sirolimus		DE-085 Tafluprost
America (Including Latin America)	DE-105 Peptide Combination	DE-101 Rivoglitazone			
		Cyclokat Ciclosporin			
Asia (including Oceania)					-085 Korea Iprost Australia
					-089 ol Sodium
EU			DE-111 Tafluprost/Timolol		DE-085 Tafluprost
			DE-109 Sirolimus		
			Cyclokat Ciclosporin		
			Vekacia Ciclosporin		



Major Clinical Projects Update (DE-085)

DE-085 (Glaucoma, Ocular hypertension) TAPROS, TAFLOTAN, SAFLUTAN, ZIOPTAN

	Development Stage	
Region	As of February 5, 2013	Remarks
Japan	Launched	Generic name:
Europe**	Launched: 38 countries Partly out-licensed to Merck*	Tafulprost [Launched] Japan (Dec. 2008)
Asia**	Launched: 5 countries NDA filed: China Partly out-licensed to Merck*	Europe (Jun. 2008) Asia (Mar. 2010) United States (Mar. 2012)
Americas**	Out-licensed to Merck* Launched: 17 countries (Launched : Including US)	Latin America (Aug. 2010) [Out-licensed] Merck & Co. (Apr. 2009)

[Launched] Total: 60 countries worldwide

- Santen: Japan, 4 countries in Asia, and 20 countries in EU

- Merck*: 15 countries in EU, US, and 16 countries in Latin America, Australia

[Approved] Total: More than 60 countries worldwide

*Merck areas (since April 2009): Western Europe excluding Germany, North America, South America, Africa, Oceania **EU: Including CIS, Asia: Including Oceania, Americas: Including US, Latin America

'We correct the number of launched countries in EU from previous materials. [erratum] launched: 50 countries \rightarrow [correct] **14**: 38 countries.

Major Clinical Projects Update

DE-118 (Glaucoma, ocular hypertension)

	Developm		
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks
Japan	Approved	NDA filed	Generic name: Tafluprost (preservative-free, unit dose, single use)

■ DE-089 (Dry eye)

Product Name: DIQUAS in Japan

	Developm		
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks
Japan	Launched	Launched	Generic name:
Asia	China: NDA filed Korea: Approved	China: NDA filed Korea: Approved	Diquafosol Sodium



Major Clinical Projects Update - Glaucoma, Ocular hypertension -

DE-090

	Developme		
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks
Japan	P2	P2	Generic name: Lomerizine HCI

■ DE-111

	Developm		
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks
Japan	NDA Filed	NDA Filed	Generic name: Tafluprost/
Europe	P3	P3	Timolol maleate (Combination drug)



Major Clinical Projects Update - Glaucoma, Ocular hypertension -

■ DE-117

	Developm		
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks
US	P1/2a	P1/2a	Prostaglandin EP2 agonist



Major Clinical Projects Update - Corneal disease -

■ **DE-101** (Corneal and conjunctival epithelial disorders associated with dry eye, etc.)

	Developn		
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks
US	P2	P2	Generic Name: Rivoglitazone

■ **DE-105** (Persistent corneal epithelial defects)

	Developr		
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks
Japan	P2	P2	Combination of
US	Preparing P2	Preparing P2	peptides



Major Clinical Projects Update - Retinal / Uveitis Disease -

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

	Development Stage			
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks	
Japan	P2/3	P2/3	Generic name: Betamethasone	

DE-109 (Uveitis)

	Development Stage		Remarks	
Region	As of February 5, 2013 As of November 1, 2012 (Previous announcement)			
US	P3	P3		
Japan	Р3	P3	Generic name: Sirolimus	
EU	P3	P3		



Major Clinical Projects Update - Infection, Allergy, Arthritis -

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

	Development Stage			
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks	
Japan	NDA filed	Preparing for NDA	Generic name: Epinastine HCI	

■ **DE-098** (Rheumatoid arthritis)

	Development Stage			
Region	As of February 5, 2013	As of November 1, 2012 (Previous announcement)	Remarks	
Japan	P2 Completed	P2 Completed	Anti-APO-1 Antibody	



Major Clinical Projects Update - Novagali -

■ **Cyclokat** (Severe Dry Eye)

Region	Development Stage		Domorko	
	2/5	11/1 (Previous)	Remarks	
EU	P3	P3	Generic Name:	
US	P2 Complete	P2 complete	Ciclosporin	

Vekacia (Vernal Conjunctivitis)

Region	Development Stage		Remarks	
	2/5	11/1 (Previous)	Remarks	
EU	P3	P3	Generic Name: Ciclosporin	

*Project evaluations are ongoing for the products below.

Product Name	Indication	Region	Stage	Remarks
Catioprost	Glaucoma/ ocular hypertension	EU	P2	Generic Name: Latanoprost
Cortiject Diabetic macular edema		US	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.

