

### Santen Pharmaceutical Co., Ltd.

### **Investor Meeting on 1st Half of FY2009 Results**

### Financial Results for the 1st Half of FY2009; Financial Forecast for the FY2009;

November 11, 2009 President & CEO Akira Kurokawa



# Financial Results for the 1st Half FY2009

# **S** Performance Overview of 1st Half FY2009

(billions of yen)

	FY2008 1st Half Actual	FY2009 1st Half Actual	Var. %	FY2009 1st Half Forecast*	Achieve -ment %
Net Sales	52.21	59.12	13.2%	57.00	103.7%
Operating Income	5.63	19.03	237.8%	14.00	136.0%
Ordinary Income	6.01	18.87	213.8%	14.00	134.8%
Net Income	3.72	11.67	213.4%	8.50	137.3%

# Summary of FY2009 1st Half

### Sales

#### Domestic Sales:

Steady progress in Glaucoma & Corneal Disease segments

Glaucoma: Contribution from the market penetration of new product Tapros

Corneal Disease: Steady progress

#### Overseas Sales:

Contribution from the licensing fees

China: Smooth transformation to direct marketing sales organization has contributed to increase in sales

### **Operating Income**

- **COGS**: Improved gross margin due to change in production mix
- **R&D Cost**: Large one time license fee payment in the FY08
- SG&A Cost: Decrease in SG&A costs due to unutilized SG&A budget such as sales promotion expenses and foreign exchange impact

1st Half FY2009
Net Sales: Variances (vs. 1st Half FY2008)

FY2008 1st Half Net Sales (Actual) ¥52.21billion

+¥6.91billion

FY2009 1st Half Net Sales (Actual) ¥59.12billion

#### Japan: +1.08billion

- Prescription Ophthalmics
   +¥0.68billion
- Anti-rheumatics +¥0.07billion
- Medical Devices +¥0.21billion

+¥0.06billion

+¥0.04billion

- OTC Drugs
- Others

#### Prescription Ophthalmics (Japan)

- Anti-infective
- Cornea (Dry Eye) +¥0.20billion
- 👲 Glaucoma
- (Tapros:
- Anti-allergy
- Others

+¥1.32billion +¥1.98billion)

-¥0.67billion

- -¥0.14billion
- -¥0.03billion

#### Europe

- Prescription Ophthalmics -¥0.38billion
   Western Europe +¥0.14billion
  - (Germany +¥0.18billion)
  - Eastern Europe -¥0.04billion
  - Northern Europe -¥0.26billion
  - Russia -¥0.21billion ノ
- Contract Manufacturing, etc. -¥0.08billion

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	<u>FY08 2Q</u>	<u>FY09 Q2</u>		
US\$	JPY 105.75	JPY 95.48		
Euro	JPY 163.13	JPY 132.14		
CNY	JPY 14.90	JPY 14.00		

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<b>Outside Ja</b>	pan +¥5	.83billion

- Europe -¥0.46billion (Forex loss impact -0.96billion)
- - (Forex loss impact: -¥0.10billion)

1st Half FY2009 **Net Sales: Variances** (vs. Aug.09 Announcement)

**FY2008 1st Half Net Sales** (Forecast\*) ¥57.00billion

+¥2.12billion

**FY2009 1st Half Net Sales** (Actual) ¥59.12billion

\*As of: August 4, 2009

	,
Japan: -¥0.18billion	Prescription Ophthalmics (Japan)
<ul> <li>Prescription Ophthalmics +¥0.08billion</li> <li>Anti-rheumatics +¥0.11billion</li> <li>OTC Drugs -¥0.14billion</li> <li>Medical Devices -¥0.12billion</li> </ul>	<ul> <li>♦ Anti-infective -¥0.02billion (99.8%)</li> <li>♦ Cornea (Dry Eye) +¥0.36billion (103.5%)</li> <li>♦ Glaucoma +¥0.24billion (102.8%) (Tapros +¥0.02billion) (101.1%)</li> <li>♦ Anti-allergy -¥0.44billion (77.3%)</li> <li>♦ Others -¥0.20billion (97.9%)</li> </ul>
Outside Japan       +¥2.30billion         ◆       U.S.       +¥2.35billion         (Forex loss impact       -¥0.04billion)         ◆       Europe       -¥0.15billion         (Forex gain impact       +0.07billion)         ◆       Asia       +¥0.11billion         (- China       -¥0.07billion)         (Forex loss impact       ×0.07billion)	Europe              Prescription Ophthalmics -¥0.16billion          - Western Europe +¥0.10billion         (Germany +¥0.07billion)         - Northern Europe -¥0.01billion         - Eastern Europe -¥0.12billion         - Russia -¥0.13billion
(Forex loss impact -¥0.05billion) - Korea +¥0.14billion	Currency Rates > <u>FY09</u> <u>FY09 2Q</u> Forecast Actual US\$ JPY100.00 JPY 95.48

Euro

CNY

JPY 130.00

JPY 14.50

JPY 132.14

JPY 14.00

### Summary of Changes in Income Statement (billions of yen)

		FY2008	FY2008		Y2009	
		1 <sup>st</sup> Half Actual	1 <sup>st</sup> Half Actual	Var.	Major Changes	
Ne	t Sales	52.21	59.12	6.91	(Details in pervious slide.)	
	st of Sales of net sales)	18.42 35.3%	17.76 30.1%	▲0.66 ▲5.2pt	Impact from product mix. Impact from reduced fixed costs.	
	A Total of net sales)	28.15 53.9%	22.31 37.7%	▲5.84 ▲16.2pt		
	SGA excluding R&D (% of net sales)	16.32 31.3%	15.39 26.0%	▲0.93 ▲5.3pt	Decrease in SGA •Domestic(JPY ▲0.2bil) •Europe(JPY ▲0.3bil) •Asia(JPY ▲0.1bil)	
	R&D Expenses (% of net sales)	11.83 22.7%	6.92 11.7%	▲4.91 ▲11.0pt	Licensing-in expense of JPY5.3bil relating to DE-109 in FY2008.	
	erating Profit of net sales)	5.63 10.8%	19.03 32.2%			
No	n-operating Income	0.78	0.44			
No	n-operating Expense	0.40	0.60			
Or	dinary Income	6.01	18.87			
Ex	traordinary Gain	0.01	_			
Ex	traordinary Loss	0.03	0.20			
Net Income before Tax		5.99	18.66			
Со	rporate Tax	2.27	6.99			
Ne	t Profit	3.72	11.67			

<Currency Rate $>$	
<u>FY2008 1st Half Actual</u>	FY2008 1st Half Actual
US\$ JPY105.75	US\$ JPY95.48
Euro JPY 163.13	Euro JPY 132.14



# Financial Forecast for the FY2009

# **S** Overall Outlook of FY2009

(billions of yen)

	FY2008 Actual	FY2009 Previous Forecast	FY2009 Revised Forecast	Var. vs. FY2008
Net Sales	101.61	111.00	113.50	11.7%
Operating Income	15.49	25.50	29.00	87.2%
Ordinary Income	15.93	25.50	29.00	82.0%
Net Income	10.12	16.00	18.00	77.8%
ROE	8.0%	12.3%	13.7%	5.7pt



### **Steady Market Penetration of TAPROS**

### **Control COGS at Appropriate Level**

### **Conitnue Appropriate R&D Spending**

# **Sales/Income Outlook for FY2009**

(billions of yen)

	FY2008		FY2009		
	Actual	Previousl Forecast	Revised Forecast	Var. vs. FY2008	
Net Sales	101.61	111.00	113.50	11.89	
Cost of Sales	35.94	37.00	36.00	0.06	
(% of net sales)	35.4 %	33.3 %	31.7%	▲3.7pt	
SGA Total	50.17	48.50	48.50	<b>▲</b> 1.67	
(% of net sales)	49.4 %	43.7 %	42.7%	<b>▲</b> 6.7 pt	
SGA excluding R&D	31.72	33.20	33.20	1.48	
(% of net sales)	31.2 %	29.9 %	29.3%	<b>▲</b> 1.9 pt	
R&D Expense	18.45	15.30	15.30	▲3.15	
(% of net sales)	18.2 %	13.8 %	13.5%	<b>▲</b> 4.7 pt	
Operating Income	15.49	25.50	29.00	13.51	
(% of net sales)	15.2 %	23.0 %	25.6%	10.4pt	
Ordinary Income	15.93	25.50	29.00	13.07	
Net Income before Tax	15.82	25.50	29.00	13.18	
Income Taxes	5.70	9.50	11.00	5.30	
Net Income	10.12	16.00	18.00	7.88	
ROE	8.0%	12.3%	13.7%	5.7 pt	
		< Currence	y Rate > <u>FY08 Actual</u> US\$ JPY 100.81 Euro JPY 146.71	FY09 Forecast JPY 100.00 JPY 130.00	

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### **FY2009 Net Sales: Variances** (vs. FY2008)

O

**FY2008 Net Sales** (Actual) ¥101.61billion

> +¥11.89 billion

**FY2009 Net Sales** (Revised Forecast) ¥113.50billion

a	pan +¥4.23b	illion	Opht
Þ	Prescription O +¥2.89billion Anti-rheumatic OTC Drugs Medical Device	s +¥0.23billion	<ul> <li>Anti-infective</li> <li>Cornea (Dry E</li> <li>Glaucoma (Tapros</li> <li>Anti-allergy</li> <li>Viscoelastics</li> </ul>
Du F	(Currency impact U.S. (Currency impact Asia - China (Currency impact - Korea	+¥0.19billion -¥1.09billion) +¥5.45billion	<ul> <li>Prescription O</li> <li>Eastern Europe</li> <li>Russia</li> <li>Germany</li> <li>Western Europe</li> <li>Northern Europe</li> <li>Contract Manue</li> </ul>

#### Prescription thalmics (Japan)

Anti-infective	-¥0.46billion
Cornea (Dry Eye)	+¥0.65billion
Glaucoma	+¥2.67billion
(Tapros	+¥3.75billion)

- -¥0.53billion

+¥0.20billion

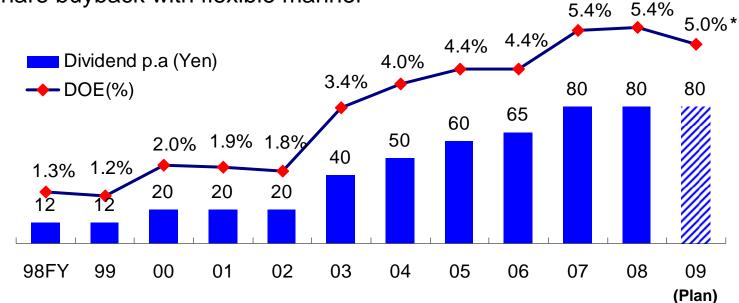
#### Europe

Ф	Prescription Ophtha	almics +¥	0.29billion
	- Eastern Europe	+¥0.31billi	on
	- Russia	+¥0.10billi	on
	- Germany	+¥0.06billi	on
	- Western Europe (ex	cl. Germany	/)
		-¥0.05billio	on 🧷
	- Northern Europe	-¥0.08billio	on –
<b>\</b>	Contract Manufactu	uring etc.	-
		¥0.10bill	ion

<currency rate=""></currency>			
	FY08 Actual	FY09 Forecast	
US\$	JPY 100.81	JPY 100.00	
Euro	JPY 146.71	PY 130.00	
CNY	JPY 14.86	PY 14.50	

# **S** Enhancing Return to Shareholders

- Firstly, we consider the cash demand and financial forecast for R&D expense and investment for future growth
- Return to shareholders:
  - Focus primarily on dividend
- Mid-term target DOE ratio: 5%
- Consider share buyback with flexible manner



<sup>\*</sup>Based on the results as of Sep.30, 2009

Pay out ratio(%)	14.1	14.4	24.6	34.9	21.4	55.8	39.7	39.9	42.9	54.7	67.2	42.5
Sum of share buyback (billions of yen)	0	0	5.1	3.2	3.2	0	2.6	0	0	4.8	-	-
Total return ratio (%)	14.1	14.4	92.0	96.4	59.5	55.8	63.3	39.9	42.9	85.8	-	-



# References



### **Reference:** Financial Results for the 1st Half FY2009

### S Net Sales by Business Segment / Overseas Sales

Sales by Business Segment

(billions of yen)

		FY2009 1st Half					
	Dom	estic	Over	seas	Total		
	Actual	Var.	Actual	Var.	Actual	Var.	
Prescription Pharmaceuticals	42.48	1.9 %	7.24	5.0 %	49.73	2.3 %	
Ophthalmics	37.29	1.9 %	7.17	4.7 %	44.47	2.3 %	
Anti-rheumatics	5.03	1.5 %	0.05	173.4 %	5.09	2.2 %	
Others	0.15	17.6 %	0.00	<b>▲</b> 57.7 %	0.16	7.8 %	
OTC Drugs	2.77	2.2 %	0.01	205.2 %	2.79	2.6 %	
Medical Devices	0.43	92.0 %	_	_	0.43	92.0 %	
Others	0.27	14.9 %	5.88	_	6.16	832.9 %	
Total	45.98	2.4 %	13.14	79.6 %	59.12	13.2 %	

Overseas Sales

(billions of yen)

	FY2008 1st	FY2009 1st Half			
	Half Actual	Actual	Var.	Var.	
Europe	4.54	4.08	<b>▲</b> 0.46	<b>▲10.2</b> %	
U.S.	0.44	5.99	5.55	1234.5 %	
Asia	2.32	3.06	0.74	32.0 %	
Others	000	0.00	0.00	_	
Total	7.31	13.14	5.83	79.6 %	

# **S** Performance by Geographic Segment

#### Net Sales

(billions of yen)

	FY2008	FY2009 1st Half		
	1st Half Actual	Actual	Var.	
Japan	46.70	52.85	6.15	
Europe	5.08	4.65	<b>▲</b> 0.43	
Others*	0.43	1.61	1.18	
Total	52.21	59.12	6.91	

#### **Operating Income**

(billions of yen)

	FY2008	FY2009 1st Half		
	1st Half Actual	Actual	Var.	
Japan	6.89	19.44	12.55	
Europe	0.11	0.38	0.27	
Others*	▲0.10	0.19	0.29	
Elimination	<b>▲</b> 1.27	▲0.99	0.28	
Total	5.63	19.03	13.40	

\* "Others" are U.S., China, Korea and Taiwan.

Note: Sales by geographic region differ from overseas sales (i.e. sales by destination).

# **Summary of Balance Sheet**

(billions of yen)

	As of End-M	/larch, 2009	As of	End-September	, 2009
	Actual	% of Total	Actual	% of Total	Var.
Current Assets	101.05	66.9 %	114.01	69.3 %	12.96
Fixed Assets	49.95	33.1 %	50.50	30.7 %	0.55
Deferred Assets	-	-	-	-	-
Total Assets	151.01	100.0 %	164.52	100.0 %	13.51
Current Liabilities	22.43	14.9 %	25.32	15.4 %	2.89
Non-current Liabilities	3.20	2.1 %	3.80	2.3 %	0.60
Total Liabilities	25.64	17.0 %	29.12	17.7 %	3.48
Total Net Assets	125.36	83.0 %	135.39	82.3 %	10.03
Total Liabilities Net Assets	151.01	100.0 %	164.52	100.0 %	13.51

#### Major Changes

(billions of yen)

**Current Assets:** Cash & cash equivalent +12.2billion, Accounts & notes receivables +1.2billion, Marketable securities -0.08billion

Fixed Assets: Buildings & fixtures -0.4billion, Investment securities +2.1billion, Deferred assets -0.5billion
 Current Liabilities: Unpaid corporate tax +3.2billion, Account payables -0.8billion

**Net Assets:** Retained earnings +8.2billion, Revaluation profit from other marketable securities +0.9billion, Forex adjustment account +0.6billion



		(billions of yen)
		FY2009 1st Half Actual
	sh and cash equivalents at the ginning of the year	45.95
-	t increase/decrease in cash and sh equivalents	11.44
	Cash flows from operating activities	16.01
	Cash flows from investing activities	<b>▲</b> 1.25
	Cash flows from financial activities	▲3.12
	Effect of exchange rate changes on cash and cash equivalents	<b>▲</b> 0.19
	sh and cash equivalents at the end the year	57.39

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

# **S** Capital Expenditures / Depreciation & Amortization / Lease Expenses

**FY2008** FY2009 1st Half **1st Half** Actual Actual Var. **Capital Expenditures** 1.00 0.37 -0.63 **Depreciation and** 1.64 1.58 -0.06 Amortization -0.15 0.48 0.33 Lease Payments

(billions of yen)



## Reference: Financial Forecasts for the FY2009

### Sales Forecast by Business Segment / Overseas Sales

Sales by Business Segment

(billions of yen)

			FY2009				
		Dom	estic	Over	seas	То	tal
		Forecast	Var.	Forecast	Var.	Forecast	Var.
	scription rmaceuticals	85.38	3.8 %	14.34	16.9 %	99.72	5.5 %
	Ophthalmics	75.24	4.0 %	14.22	17.3 %	89.47	5.9 %
	Anti-rheumatics	9.86	2.4 %	0.10	-5.9 %	9.96	2.3 %
	Others	0.27	0.1 %	0.01	-58.3 %	0.29	-5.6 %
ото	C Drugs	5.56	6.7 %	0.02	259.5 %	5.59	7.0 %
Mec	lical Devices	1.34	115.5 %	_	_	1.34	115.5 %
Oth	ers	0.55	9.9 %	6.28	767.8 %	6.84	455.0 %
Tota	al	92.85	4.8 %	20.65	58.8 %	113.50	11.7 %

Overseas Sales

(billions of yen)

	FY2008		FY2009			
	Actual	Forecast	Var.	Var.		
Europe	8.31	8.50	0.19	2.3 %		
U.S.	0.93	6.39	5.45	581.4 %		
Asia	3.74	5.74	2.00	53.2 %		
Others	0.00	0.01	0.01	_		
Total	12.99	20.65	7.66	58.8 %		

# **S** Forecast by Geographic Segment

#### Net Sales

(billions of yen)

	FY2008	FY2009		
	Actual	Forecast	Var.	
Japan	91.40	100.30	8.90	
Europe	9.45	9.47	0.02	
Others*	0.76	3.72	2.96	
Total	101.61	113.50	11.89	

#### Operating Income

(billions of yen)

	FY2008	FY2009		
	Actual	Forecast	Var.	
Japan	18.28	30.95	12.67	
Europe	0.17	0.66	0.49	
Others*	-0.66	0.03	0.69	
Elimination	-2.30	-2.65	—0.35	
Total	15.49	29.00	13.51	

\* "Others" are U.S., China, Korea and Taiwan.

Note: Sales by geographic region differ from overseas sales (i.e. sales by destination).

# **S** Capital Expenditures / Depreciation & Amortization / Lease Expenses

	FY2008	FY2009		
	Actual	Forecast*	Var.	
Capital Expenditures	2.74	1.83	<b>▲</b> 0.91	
Depreciation and Amortization	3.39	3.41	0.02	
Lease	0.93	0.52	<b>▲</b> 0.41	

(billions of yen)

### Major capital expenditure FY2008

Addition and upgrade of manufacturing facilities

Upgrade of R&D equipments

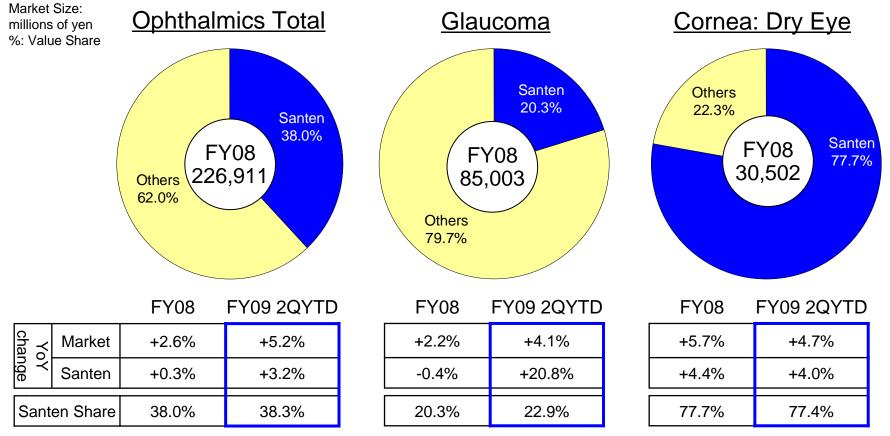


### Reference

### Domestic Prescription Pharmaceutical Market -Ophthalmics and Anti-rheumatics-

# **S** Japan: Trend & Competition by Category - 1

- Ophthalmics total: Market grew by +5.2% YoY at the end of 2Q-FY09. Santen secured 38.3% share under the rapid growth of retinal drug category.
- •Glaucoma: Santen YTD sales grew by +20.8% YoY due to the growth of Tapros. Narket share increased to 22.9%.
- Dry eye: Steady market growth of +4.7%. Santen7s market share was 77.4%.

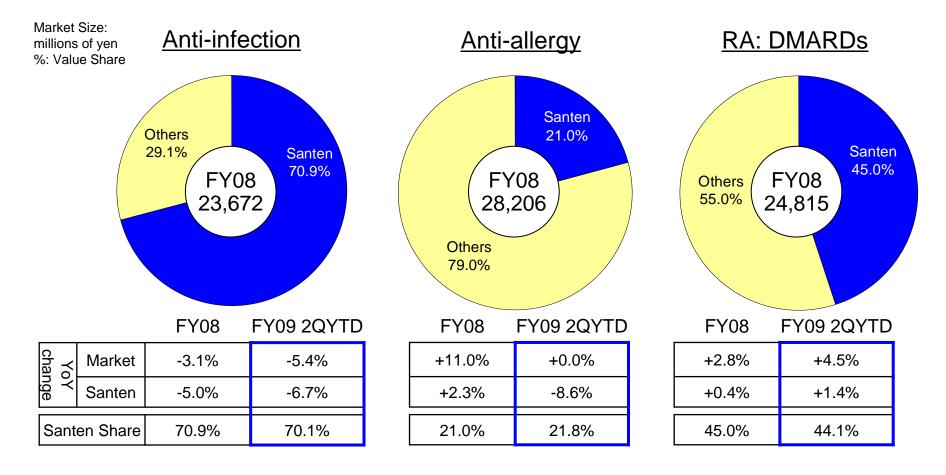


-Santen: -Glaucoma : Tapros, Timoptol/XE, Rescula, Detantol - -Cornea / Dry Eye : Hyalein

Source: ©2009 IMS Japan IMS-JPM 2007-09 Santen analysis based on IMS data 27

### Japan: Trend & Competition by Category - 2

Anti-infection: Market shrunk by -5.4% YoY in FY09 2QYTD. Treatment days/head is in declining trend.
Anti-allergy: Market maintained by +0.0%, and Santen share at 21.8%. Competitor's growth continues.
Anti-rheumatics: Solid market growth by +4.5%. Santen maintains its leading position by 44.1% share.



-Santen:

•Anti-infection: Cravit, Tarivid, etc.

·Anti-allergy : Livostin, Alegysal

•RA /DMARDs: Rimatil, Azulfidine EN, Metolate

\*DMARDs: Disease Modifying Anti-Rheumatic Drugs

Source: ©2009 IMS Japan IMS-JPM 2007-09 Santen analysis based on IMS data 28



# FY2009 Second Quarter Status of Clinical Development

Member of the Board Senior Corporate Officer Head of Research and Development Division Toshiaki Nishihata, Ph.D.

# **S** Major Clinical Pipeline List (Red Letters: Changes from FY09 1Q)

			Global stra Produc		ct Japan (Asia) Product
Domain	Phase I	Phase II	Phase <b>Ⅲ</b>	NDA Filed	Approved
Glaucoma		104 nhibitor DE-090 Lomerizine HCI	China	DE-085 Tafluprost	Japan Europe (launch) Korea (approved)
Corneal Disease (Dry Eye)		DE-101 Rivoglitazone DE-105 Combination of peptides		DE-089 Diquafosol sodium	
Retinal Disease	DE- Siroli DE- Steroi	109 <sup>mus</sup> 102			
Others Inflammation, Allergy, RA	DE- Apop indu		DE-108 Levofloxacin		

### Status of Major Drug Candidate (DE-085)

• DE-085 Tapros in Japan, Taflotan in Europe (Glaucoma, Ocular hypertension)

Region	Develop	- Remarks	
	As of Nov. 11, 2009	As of Aug. 4, 2009 (Previous announcement)	Remarks
Japan	Launched	Launched	Approved
	(December 2008 - )	(December 2008 - )	(October 2008 )
Europe	Launched*	Launched	Approved
	(June 2008 - )	(June 2008 - )	(April 2008 - )
Asia	Korea: Approved	Korea: Approved	Korea: Filed
	China: P3	China: P3	(Nov. 2007)

\*: Launched in Germany, Denmark, Finland, Sweden, Norway, <u>Poland</u>.
 Merck launched <u>UK</u> and <u>Spain</u>. (countries underlined were added from 1Q of FY2009).
 Granted Marketing authorization to Merck for 21 countries (including CIS).

U.S.	Out-licensed development and marketing rights to Merck		
	(Apr.2009)		

# Status of Major Drug Candidate (DE-089)

• **DE-089** (Corneal and conjunctival epithelial disorders associated with dry eye)

Developm		nent Stage	
Region	As of Nov. 11, 2009	As of Aug. 4, 2009 (Previous announcement)	Remarks
Japan	Filed	Filed	Generic name: Diquafosol sodium
			Filed in May 2008

# **Status of Major Pipeline** - Glaucoma, Ocular hypertension -

• DE-090

	Developm	oment Stage	
Region	As of Nov. 11, 2009	As of Aug. 4, 2009 (Previous announcement)	Remarks
Japan	P2	P2	Generic name: Lomerizine HCI

• DE-104

	Developm	ent Stage	
Region	As of Nov. 11, 2009	As of Aug. 4, 2009 (Previous announcement)	Remarks
U.S.	P1/P2	P1/P2	ROCK inhibitor
Japan	P2	P2	

# **Status of Major Pipeline** - Corneal and conjunctival disease -

• **DE-101** (Corneal and conjunctival epithelial disorders associated with dry eye)

	Development Stage			
Region	As of Nov. 11, 2009	As of Aug. 4, 2009 (Previous announcement)	Remarks	
U.S.	Preparing P2b	Preparing P2b	Generic name:	
Japan	P2b	Preparing P2b	Rivoglitazone	

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

	Development Stage		
Region	As of Nov. 11, 2009	As of Aug. 4, 2009 (Previous announcement)	Remarks
U.S.	Preparing P2	Preparing P2	Combination of
Japan	P2	Preparing P2	peptides

# **Status of Major Pipeline** - Retinal Disease -

• **DE-102** (Diabetic macular edema)

	Developm	Development Stage	
Region	As of Nov. 11, 2009	As of Aug. 4, 2009 (Previous announcement)	Remarks
Japan	P1 / 2	P1 / 2	Steroid DDS

• **DE-109**\* (Wet age related macular degeneration, diabetic macular edema)

	Development Stage			
Region	As of Nov. 11, 2009	As of Aug. 4, 2009 (Previous announcement)	Remarks	
Japan	P1 / 2	P1 / 2	Generic name: Sirolimus	

 Santen made a research and development collaboration and license agreement with MacuSight Inc. for the Japanese and Asian development and commercialization of sirolimus for the treatment of ocular diseases.



#### • DE-108 (Bacterial conjunctivitis)

	Development Stage			
Region	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	Remarks	
Japan	P3	P3	higher-concentration Levofloxacin	

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

Region	Developn	nent Stage	
	As of Aug. 4, 2009	As of May 13, 2009 (Previous announcement)	Remarks
Japan	P1 / 2	P1 / 2	Anti ABO 1 antibady
Europe	P1 / 2	P1 / 2	Anti-APO-1 antibody

\*Domestic development rights were licensed to Argenes, Inc. Domestic marketing rights and oversea development and marketing rights belong to Santen.



### **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.