

### **FY 2011 Third Quarter Results**

### February 7, 2012 Santen Pharmaceutical Co., Ltd



## **Consolidated Results FY2011 Third Quarter**

### Satoshi Harada

Corporate Officer Head of 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.

# **S** Financial Highlights for Q3 FY2011

	Q3.FY2010 Actual	Q3.FY2011 Actual	Var. %
Net Sales	82.10	86.43	+5.3%
Operating Income	22.10	22.22	+0.5%
Ordinary Income	22.82	23.03	+0.9%
Net Income	14.67	14.76	+0.6%

# S Highlights for Q3-FY2011 Results

### Sales :

- Domestic sales increased in the prescription pharmaceutical segment. Increased market shares in the glaucoma and dry-eye segments.
- Overseas sales sustained growth in Europe and China. In Europe, steady penetration of Taflotan drove the growth.

### Operating Profit:

- SG&A excluding R&D expense has increased due to costs related to strengthening sales platforms of European and Chinese businesses.
- Increased investment in R&D pipeline in line with the Medium-tem Management Plan.

### Progress in Novagali Acquisition :

- Successful completions of tender offer and mandatory squeeze-out process. Santen now holds 100% of Novagali shares.
- Integration of operations in progress.

### S Q3 FY2011 Net Sales: Variances (vs. Q3 FY2010)

FY2010 Q3 Net Sales (Actual) ¥82.10billion

> +¥4.33 billion

FY2011 Q3 Net Sales (Actual) ¥86.43billion

#### Japan: +3.41billion

Prescription
 Ophthalmics
 Anti-rheumatics

+2.66bil

+0.21bil

-0.01bil

+0.32bil

+0.23bil

+0.15bil

-0.07bil

+0.51bil

-0.09bil

+0.24bil

+0.16bil

-0.19bil

+0.04bil

-0.02bil

- OTC Drugs
- Medical Devices
- Others

#### Overseas + ¥0.91billion

- U.S.(Forex impact)
- Europe(Forex impact)
- 🕈 Asia
- (- China
- (Forex impact:
- Korea
- (Forex impact:

Prescriptio (J	nics	
Anti-infective	-0.54bil	-4.8%
Cornea (Dry Eye)	+2.05bil	+13.0%
Diquas	+1.56bil	—
Glaucoma	+2.07bil	+13.7%
Tapros:	+0.44bil	+8.9%
Cosopt:	+2.68bil	+138%
Anti-allergy	+0.09bil	+4.9%
Others	-1.02bil	-8.1%
Eu		

+0.83bil	+14.2%
+0.03bil	+1.9%
+0.30bil	+31.0%
+0.17bil	+7.6%
+0.32bil	+34.4%
	+0.03bil +0.30bil +0.17bil

# FY10.Q3 actual FY11.Q3 actual US\$ JPY 86.72 JPY 79.09 Euro JPY 114.50 JPY 112.94 CNY JPY 13.15 JPY 12.38

# **S** Changes in Income Statement

(IDV hillions)	FY2010	Q3.FY	2011	
(JPY billions)	Q3 Actual	Actual	Variance	Major Changes
Net Sales	82.10	86.43	+4.33	
Cost of Sales (% of net sales)	26.19 31.9%	26.95 31.2%	+0.75 -0.7pt	Fixed production cost -0.1pt, Change in product mix +0.1pt, Overseas business -0.2pt, Effect from income related to license contracts -0.1pt, etc.
SGA excluding R&D (% of net sales)	24.05 29.3%	25.02 28.9%	+0.97 - <mark>0.3</mark> pt	Japanese business promotion expense -0.64bil, European and US subsidiaries +0.79bil, Asian business +0.53bil, etc.
R&D Expenses (% of net sales)	9.75 11.9%	12.24 14.2%	+2.48 +2.2pt	
Operating Profit (% of net sales)	22.10 26.9%	22.22 25.7%	+0.11 -1.2pt	
Non-operating Income Non-operating Expense	0.84 0.12	0.86 0.05	+0.02 -0.07	
Ordinary Income	22.82	23.03	+0.21	
Extraordinary Gain Extraordinary Loss	0.01 0.26	0.06 0.02	+0.04 -0.24	<currency rates=""></currency>
Net Income before Tax	22.56	23.06	+0.50	FY10.Q3actual FY11.Q3 actual US\$ JPY 86.72 JPY 79.09
Corporate Tax	7.88	8.29	+0.41	Euro JPY114.50 JPY 112.94 CNY JPY 13.15 JPY 12.38
Net Profit	14.67	14.76	+0.08	



# Reference: Consolidated Results FY2011 Third Quarter

# **S** Net Sales by Business Segment

(JPY billions)		Q3.FY2011 Actual					
		Jap	an	Over	seas	Tot	al
		Sales	Var.	Sales	Var.	Sales	Var.
Pł	harmaceuticals	71.75	+4.5%	12.64	5.6%	84.40	4.7%
	Prescription Pharmaceuticals	68.16	+4.8%	12.63	5.6%	80.80	4.9%
	Ophthalmic	59.48	+4.7%	12.39	8.2%	71.88	5.3%
	Anti-RA	7.78	+2.9%	0.08	9.1%	7.87	2.9%
	Others	0.89	+35.8%	0.15	-63.5%	1.05	-3.5%
	OTC Pharmaceuticals	3.58	-0.6%	0.00	41.5%	3.59	-0.5%
Ot	others	1.39	+30.0%	0.63	60.2%	2.03	38.2%
	Medical Devices	1.38	+30.2%	0.63	60.2%	2.02	38.4%
	Others	0.00	+4.3%	_	-	0.00	4.3%
Т	otal	73.15	+4.9%	13.28	7.4%	86.43	5.3%



	FY2010	FY2011			
(JPY billions)	Q3 Actual	Q3 Actual	Var.	Var. %	
U.S.	0.85	1.01	+0.15	+18.5%	
Europe	6.23	6.75	+0.51	+8.3%	
Asia	5.27	5.51	+0.24	+4.6%	
Others	0.00	0.00	-0.00	-	
Total	12.37	13.28	+0.91	+7.4%	

# **Summery of Change in Balance Sheet**

	As of Mar	As of March 31, 2011		As of December 31, 2011		
(JPY billions)	Actual	% of Total	Actual	% of Total	Var.	
Current Asset	137.66	74.5%	129.13	68.8%	-8.53	
Fixed Asset	47.13	25.5%	58.44	31.1%	+11.31	
Total Asset	184.80	100.0%	187.57	100.0%	+2.77	
Current Liabilities	24.10	13.0%	19.52	10.4%	-4.57	
Non-current Liabilities	4.29	2.3%	6.26	3.3%	+1.97	
Total Liabilities	28.39	15.4%	25.79	13.8%	-2.60	
Total Net Asset	156.40	84.6%	161.78	86.2%	+5.38	
Total Liabilities Net Assets	184.80	100.0%	187.57	100.0%	+2.77	

#### Major Changes

Current Asset:	Cash and deposits -¥7.94bil, Merchandise and finished products +¥1.16bil, Marketable securities -¥0.39bil, Inventories -¥0.55bil, ST deferred tax assets -¥0.79bil
■Fixed Asset :	Buildings and structures -¥0.83bil, Construction in progress +¥1.28bil, Goodwill +¥6.19bil, Investment securities -¥0.30bil, LT deferred tax assets -¥0.87bil,
<ul> <li>Current Liabilities:</li> <li>Fixed Liabilities :</li> <li>Net asset :</li> </ul>	Other intangible assets +¥6.29bil, Accounts payable -¥1.08bil, Income tax payable -¥2.44bil, Provision for bonus -¥1.17bil Provisions for directors' retirement fund -¥0.24bil, LT deferred tax liability +¥2.05bil Retained earnings +¥6.05bil, Foreign currency translation adjustments -¥0.95bil



(JPY billion	FY2011 Q3 Actual		
Cash an	id cash equivalents at the beginning of the year	72.48	
Net incr	Net increase/decrease in cash and cash equivalents		
	Cash flows from operating activities	12.23	
	-9.94		
	-8.48		
	-0.50		
Cash an	Cash and cash equivalents at the end of the year		

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

	FY2010	FY2	2011
(JPY billions)	Q3 Actual	Q3 Actual	Var.
Capital Expenditures	0.91	2.70	+1.78
Depreciation and Amortization	2.08	2.02	-0.06
Lease Payments	0.14	0.02	-0.12



### **Reference:** Acquisition of Novagali



### NOVAGALI P H A R M A

#### Purpose of the Acquisition

In line with Santen's long term strategic vision for 2020, to strengthen its global business platform, especially its business franchise in Europe.

Novagali has outstanding R&D capabilities as well as unique pharmaceutical formulation technologies.

Cyclokat, Novagali's dry-eye treatment under a late-stage development, which uses a unique Novasorb technology, has a potential to become Europe's first prescription dry-eye drug, when launched successfully.

#### **Acquisition Process**

September, 2011:	Acquired 50.55% of outstanding shares of Novagali pursuant to the Share Purchase Agreement.
December, 2011:	Acquired up to 96.73% of Novagali shares through public tender offer.
January, 2012 :	Executed a mandatory squeeze-out. Novagali gets delisted, and becomes a wholly owned subsidiary of Santen.
Total acquisition price:	Euro 107.1 million (about JPY 10.94 billion), including associated costs and expenses.







#### **Acquisition Price Allocation**

Acquisition Price	JPY' billions
Acquisition of shares	10.40
Associated costs and expenses	0.54
Total acquisition cost	10.94

#### **Breakdown of Acquired Assets**

Assets	JPY' billions
Existing assets	1.21
In-process R&D	6.16
Goodwill	6.19
Total assets acquired	13.56



### **Reference: FY2011 Financial Forecasts**

# **S** Financial Forecast for FY2011

(JPY billions)	FY2010 Actual	FY2011 Forecast	Var. %
Net Sales	110.81	116.00	+4.7%
Operating Income	30.73	30.00	-2.4%
Ordinary Income	31.48	30.50	-3.1%
Net Income	21.33	20.50	-3.9%

ROE	14.5%	12.6%	-1.9pt
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\*Forecast as of: May 10, 2011

### Sales/Income Outlook for the FY2011

(IDV billions)	FY2010	FY2	FY2011	
(JPY billions)	Actual	Forecast	Var.	
Net Sales	110.81	116.00	+5.18	
Cost of Sales	34.43	36.00	+1.56	
(% of net sales)	31.1%	31.0 %	-0.0 pt	
SG&A excluding R&D	32.41	34.00	+1.58	
(% of net sales)	29.3 %	29.3 %	+0.1 pt	
R&D Expense	13.22	16.00	+2.77	
(% of net sales)	11.9 %	13.8 %	+1.9 pt	
Operating Income	30.73	30.00	-0.73	
(% of net sales)	27.7 %	25.9%	- 1.9 pt	
Non-operating Income/Loss	0.74	0.50	-0.24	
Ordinary Income	31.48	30.50	- 0.98	
Extraordinary Income/Loss	- 0.40	0.00	+0.40	
Net Income before Tax	31.07	30.50	- 0.57	
Income Taxes	9.74	10.00	+0.25	
Net Income	21.33	20.50	- 0.83	
ROE	14.5 %	12.6%	- 1.9 pt	

 <Currency rate>

 FY2010 actual

 US\$ ¥85.57

 Euro ¥113.45

 CNY ¥12.94

 FY2011 forecast

 US\$ ¥82.00

 Euro ¥113.00

 CNY ¥12.50



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

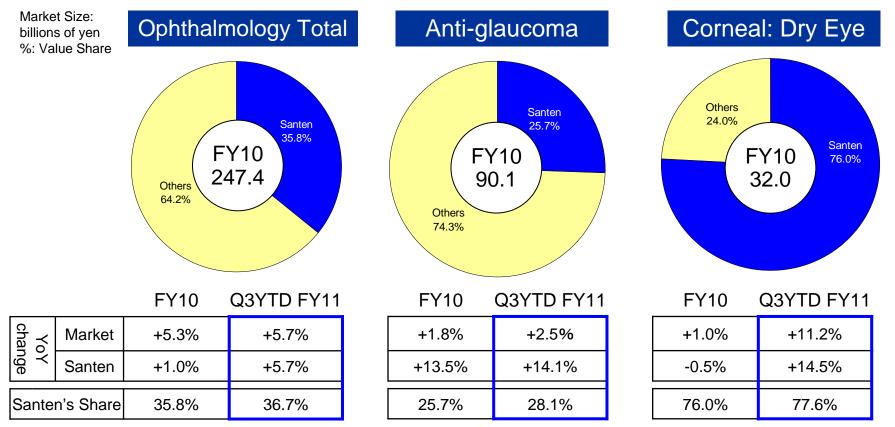
# S Japan: Trend & Competition in Ophthalmics (1)

• **Ophthalmology Total**: Market grew by 5.7% in the period up to 3rd quarter FY11. Retinal segment and corneal segment lead the market growth. Santen's market share was 36.7%.

• Glaucoma:

• Corneal:

Market grew by 2.5% in the period up to 3rd quarter FY11. Santen's sales grew by 14.1%. Santen held 28.1% share of the glaucoma market by the contribution of Tapros and Cosopt. Market grew by 11.2% in the period up to 3rd quarter FY11. Santen's sales grew by 14.5%, and Santen's market share increased to 77.6% with growth of Hyalein and Diquas.



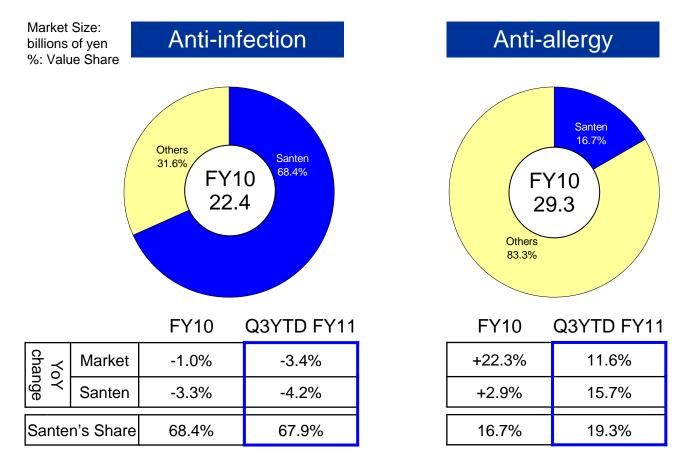
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-Santen:

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

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

- Anti-infection: Market declined by 3.4% in the period up to 3rd quarter FY11. Santen maintained 67.9% of market share with primary contribution from Cravit.
- Anti-allergy: Market grew by 11.6% in the period up to 3rd quarter FY11. Santen's share was 19.3%.



-Santen:

- Anti-infection: Cravit, Tarivid, etc.

- Anti-allergy: Livostin, Alegysal

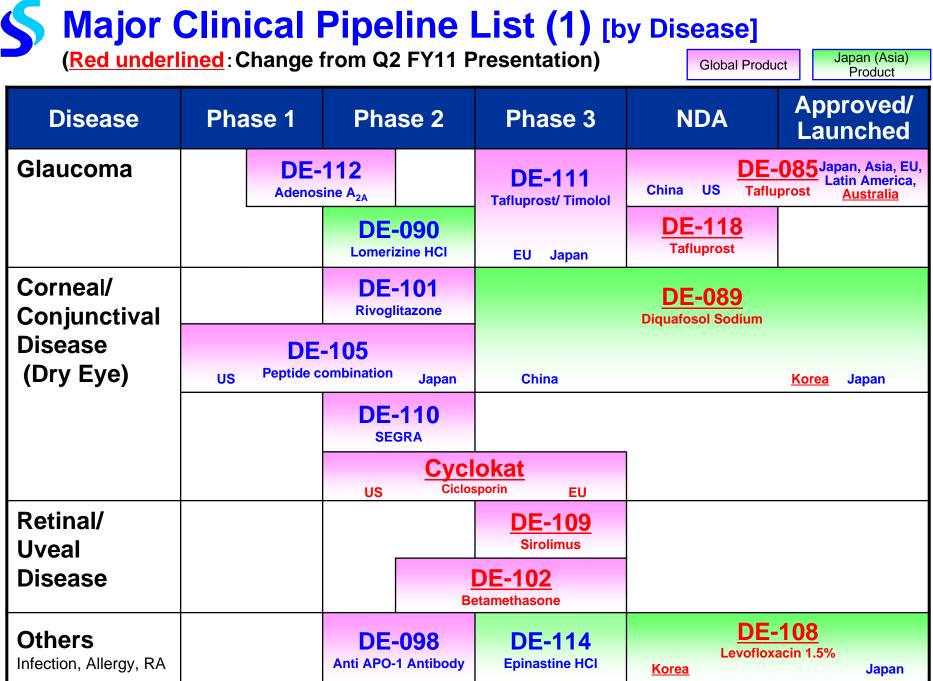
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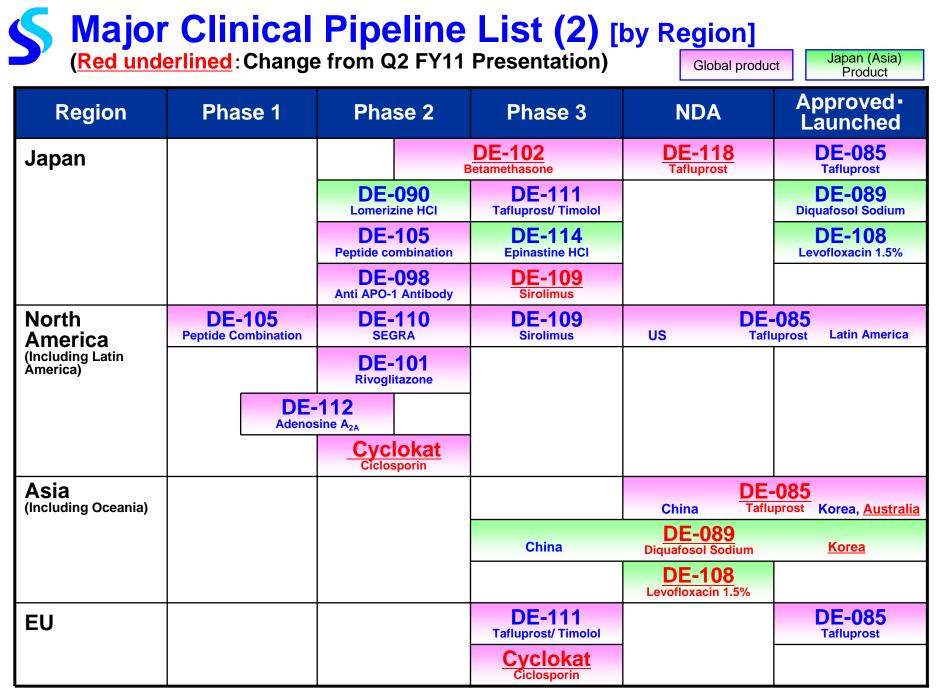
### FY2011 Third Quarter Status of Clinical Development

### Toshiaki Nishihata, Ph.D.

Director Executive Corporate Officer, U.S. and Europe Business, Head of Research and Development Division



\*Project evaluations are ongoing for other Novagali products



\*Project evaluations are ongoing for other Novagali products

Major Clinical Projects Update (DE-085)

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

TAPROS, TAFLOTAN, SAFLUTAN

Pagion	Development Stage		Remarks
Region	As of February 7, 2012	As of November 1, 2011	Remarks
Japan	Launched	Launched	Generic name:
Europe**	Launched: 27 countries Approved: 39 countries Partly out-licensed to Merck*	Launched: 27 countries Approved: 39 countries Partly out-licensed to Merck*	Tafulprost Launched in:
Asia**	Launched: 4 countries Approved: 7 countries NDA filed: China	Launched: 4 countries Approved: 6 countries NDA filed: China	Japan (Dec. 2008) Europe (Jun. 2008) Asia (Mar. 2010)
U.S.**/ Others	Out-licensed to Merck* Launched: 4 countries Approved: 10 countries NDA filed: U.S.	Out-licensed to Merck* Launched: 4 countries Approved: 10 countries NDA filed: U.S.	Latin America (Aug. 2010) Out-licensed to: Merck & Co. (Apr. 2009)

Launched: Total of 36 countries worldwide

- Santen: Japan and 4 countries in Asia (Hong Kong, Korea, Indonesia, Singapore) 20 countries in Europe (Germany, Finland and 18 other countries)

- Merck\*: 7 countries in Europe (U.K., Spain, Netherlands, Italy, Portugal, Austria, Switzerland)

4 countries in Latin America (Bahamas, etc.)

#### Approved: Total of 57 countries worldwide

(Newly added 1 country: Australia)

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



• **DE-118** (Glaucoma, ocular hypertension)

	Development Stage		
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks
Japan	NDA filed	-	Generic name: Tafluprost (preservative-free, unit dose, single use)

#### • DE-089 (Dry eye)

Product Name: DIQUAS in Japan

	Development Stage		
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks
Japan	Launched	Launched	Generic name:
Asia	China: Preparing NDA Korea: Approved	China: Preparing NDA Korea: NDA filed	Diquafosol Sodium

### S Major Clinical Projects Update - Glaucoma, Ocular hypertension -

#### • DE-090

	Development Stage		
Region	RegionAs of February 7, 2012As of November 1, 2011 (Previous announcement)		Remarks
Japan	P2	P2	Generic name: Lomerizine HCI

#### • DE-111

Development Stage			
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks
Japan	P3	P3	Generic name: Tafluprost/
Europe	P3	P3	Timolol maleate (Combination drug)

#### • DE-112

	Development Stage		
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks
U.S.	P1/2a	P1/2a	Adenosine A <sub>2A</sub> receptor agonist

### S Major Clinical Projects Update – Corneal disease -

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

	Development Stage		
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks
U.S.	P2	P2	Generic Name: Rivoglitazone

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

	Development Stage		
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks
Japan	P2	P2	Combination of
U.S.	Preparing P2	Preparing P2	peptides

#### •DE-110 (Corneal and conjunctival epithelial disorders associated with dry eye, etc)

	Development Stage			
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks	
U.S.	P2	P2	Selective glucocorticoid receptor agonist (SEGRA)	

### S 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 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks	
Japan	P2/3*	P2/3	Generic name: Betamethasone	

\*Study for macular edema secondary to BRVO has been added

#### • DE-109 (Uveitis)

	Development Stage			
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks	
US	P3	Р3	Generic name:	
Japan	P3	_	Sirolimus	

### S Major Clinical Projects Update – Infection, Allergy, Arthritis -

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

	Development Stage			
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks	
Japan	Launched (June, 2011)		Generic name:	
Korea	NDA Filed	—	Levofloxacin 1.5%	

#### • **DE-114** (Allergic conjunctivitis)

	Development Stage			
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks	
Japan	P3	P3	Generic name: Epinastine HCI	

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

	Development Stage			
Region	As of February 7, 2012	As of November 1, 2011 (Previous announcement)	Remarks	
Japan	P2	P2	Anti-APO-1 antibody	

### S Major Clinical Projects Update – Novagali -

• Cyclokat (Severe Dry Eye)

Pagian	Development Stage	Domorko
Region	As of February 7, 2012	Remarks
EU	P3	Generic Name:
US	P2 Completed	Ciclosporin

\*Project evaluations are ongoing for the products below.

Product Name	Indication	Region	Stage	Remarks
Vekacia	Vernal conjunctivitis	EU	P3	Generic Name: Ciclosporin
Cationrost	Glaucoma/ ocular hypertension	EU	P2	Generic Name: Latanoprost
Catioprost		US	P2	
Cortiject	Diabetic macular edema	US	P1/2	<b>Generic Name:</b> Dexamethasone Palmitate

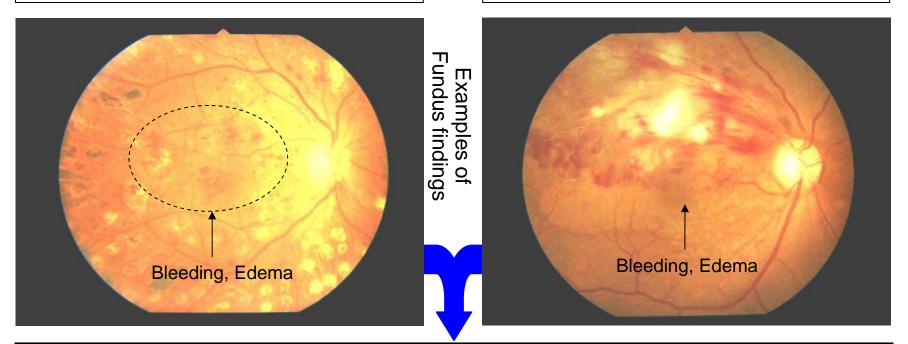
### S Reference: DME and BRVO

#### Diabetic Macular Edema (DME)

Edema (swelling) occurs in the macula by leakage of blood components or capillary aneurism, due to retinal circulation/ vascular disorders secondary to diabetes mellitus. It is a chronic clinical state.

#### Branch Retinal Vein Occlusion (BRVO)

Retinal vein, which branches out from the optic disc, is occluded due to blood clot or arterial sclerosis, causing bleeding or edema (swelling) in the peripheral retina. It is an acute clinical state.



Visual acuity loss accompanied by inflammation, retinal hemorrhage, edema, etc.



### **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.