



FY 2012 First Quarter Results

August 1, 2012

Santen Pharmaceutical Co., Ltd



Consolidated Results FY2012 First 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.

Financial Highlights for Q1 FY2012

	Q1 FY2011 Actual	Q1 FY2012 Actual	Var. %
Net Sales	27.85	27.95	+0.4%
Operating Income	7.76	6.12	-21.1%
Ordinary Income	8.18	6.54	-20.1%
Net Income	5.52	4.27	-22.6%

Highlights for Q1 FY2012 Results

■ Domestic business :

- In the prescription pharmaceutical segment, growth in sales of new products which were launched during the recent years, such as *Tapros*, offset the effect from the NHI price revision.
 - The sales of *Tapros*, *Diquas* and *Cosopt* showed steady progress.
 - Medical devices and OTC pharmaceuticals business grew steadily.

■ Overseas business:

- Europe: Maintained growth momentum on a local currency basis.
- China: Showed steady growth in line with the market trend.



Q1 FY2012

Net Sales: Variances (vs. Q1 FY2011)

In billions of Yen

FY2011
Q1
Net Sales
(Actual)
¥27.85billion

+¥0.10
billion



FY2012
Q1
Net Sales
(Actual)
¥27.95billion

Japan: 23.69bil (+0.16bil)

+ Prescription Ophthalmics	-0.15bil
+ Anti-rheumatics	+0.01bil
+ OTC Drugs	+0.30bil
+ Medical Devices	+0.05bil
+ Others	-0.06bil

Overseas: 4.26bil (-0.05bil)

+ U.S. (Forex impact)	-0.36bil -0.00bil)
+ Europe (Forex impact)	-0.04bil -0.23bil)
+ Asia	+0.35bil
- China	+0.60bil
(Forex impact)	+0.00bil)
- Korea	-0.24bil
(Forex impact)	-0.00bil)

Prescription Ophthalmics (Japan)

+ Anti-infective	-0.80bil	-22.5%
+ Cornea (Dry Eye)	+0.06bil	+1.2%
Diquas	+0.56bil	+108.2%
+ Glaucoma	+0.66bil	+12.2%
Tapros	+0.15bil	+8.7%
Cosopt	+0.74bil	+55.2%
+ Anti-allergy	-0.01bil	-2.1%
+ Others	-0.06bil	-1.7%

Europe

+ Prescription Ophthalmics	-0.03bil	-1.7%
-Western Europe	-0.00bil	-0.6%
-Eastern Europe	+0.04bil	+10.6%
-Northern Europe	+0.03bil	+4.1%
- Russia	-0.11bil	-24.4%

<Currency Rates>

	FY11.Q1 actual	FY12.Q1 actual
USD	JPY81.63	JPY 80.20
EUR	JPY 117.91	JPY 106.60
CNY	JPY 12.48	JPY 12.51



Changes in Income Statement

(JPY billions)	FY2011	Q1 FY2012		Major Changes												
	Q1 Actual	Actual	Variance													
Net Sales	27.85	27.95	+0.10													
Cost of Sales (% of net sales)	8.65 31.1%	9.44 33.8%	+0.79 +2.7pt	<ul style="list-style-type: none"> • Effect from NHI price revision: +1.7pt • Reduction of income from license contracts: +0.3pt • Change in model mix: +0.1pt 												
SGA excluding R&D (% of net sales)	8.31 29.9%	8.38 30.0%	+0.06 +0.1pt	<ul style="list-style-type: none"> • Japan: -0.41bil • EU/US excluding Novagali: +0.14bil • Novagali: +0.25bil • Asia: +0.18bil 												
R&D Expenses (% of net sales)	3.11 11.2%	4.00 14.3%	+0.88 +3.1pt	<ul style="list-style-type: none"> • Japan: +0.48bil • EU/US excluding Novagali: +0.22bil • Novagali: +0.18bil 												
Operating Profit (% of net sales)	7.76 27.9%	6.12 21.9%	-1.64 -6.0pt													
Non-operating Income	0.43	0.46	+0.02													
Non-operating Expense	0.01	0.04	+0.02													
Ordinary Income	8.18	6.54	-1.64													
Extraordinary Gain	0.01	0.01	+0.00	<div style="border: 1px solid black; padding: 5px;"> <p><Currency Rates></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">FY11.Q1 actual</th> <th style="text-align: center;">FY12.Q1 actual</th> </tr> </thead> <tbody> <tr> <td>USD</td> <td style="text-align: center;">JPY81.63</td> <td style="text-align: center;">JPY 80.20</td> </tr> <tr> <td>EUR</td> <td style="text-align: center;">JPY 117.91</td> <td style="text-align: center;">JPY 106.60</td> </tr> <tr> <td>CNY</td> <td style="text-align: center;">JPY 12.48</td> <td style="text-align: center;">JPY 12.51</td> </tr> </tbody> </table> </div>		FY11.Q1 actual	FY12.Q1 actual	USD	JPY81.63	JPY 80.20	EUR	JPY 117.91	JPY 106.60	CNY	JPY 12.48	JPY 12.51
	FY11.Q1 actual	FY12.Q1 actual														
USD	JPY81.63	JPY 80.20														
EUR	JPY 117.91	JPY 106.60														
CNY	JPY 12.48	JPY 12.51														
Extraordinary Loss	0.01	-	-0.01													
Net Income before Tax	8.18	6.56	-1.61													
Corporate Tax	2.65	2.28	-0.37													
Net Profit	5.52	4.27	-1.24													



**Reference:
Consolidated Results
FY2012 First Quarter**



Net Sales by Business Segment

(JPY billions)	Q1 FY2012 Actual					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var.	Sales	Var.
Pharmaceuticals	23.19	+0.5%	4.25	+6.5%	27.44	+1.4%
Prescription Pharmaceuticals	21.74	-0.9%	4.24	+6.6%	25.99	+0.2%
Ophthalmic	18.91	-0.8%	4.14	+6.5%	23.05	+0.4%
Anti-RA	2.58	+0.5%	0.01	-65.5%	2.59	-0.7%
Others	0.24	-20.0%	0.09	+71.4%	0.33	-6.5%
OTC Pharmaceuticals	1.45	+27.0%	0.00	-19.4%	1.45	+26.8%
Others	0.49	+12.7%	0.01	-96.2%	0.50	-33.8%
Medical Devices	0.49	+12.8%	0.01	-96.2%	0.50	-33.9%
Others	0.00	-5.3%	-	-	0.00	-5.3%
Total	23.69	+0.7%	4.26	-1.3%	27.95	+0.4%



Overseas Sales

(JPY billions)	FY2011 Q1 Actual	FY2012		
		Q1 Actual	Var.	Var. %
U.S.	0.51	0.15	-0.36	-70.7%
Europe	2.28	2.23	-0.04	-2.0%
Asia	1.52	1.87	+0.35	+23.4%
Others	0.00	-	-0.00	-100.0%
Total	4.31	4.26	-0.05	-1.3%



Summary of Change in Balance Sheet

(JPY billions)	As of March 31, 2012		As of June 29, 2012		
	Actual	% of Total	Actual	% of Total	Var.
Current Asset	140.28	70.6%	128.96	68.3%	-11.32
Fixed Asset	58.51	29.4%	59.92	31.7%	+1.40
Total Asset	198.80	100.0%	188.88	100.0%	-9.91
Current Liabilities	27.42	13.8%	17.56	9.3%	-9.85
Non-current Liabilities	6.51	3.3%	6.63	3.5%	+0.11
Total Liabilities	33.94	17.1%	24.20	12.8%	-9.73
Total Net Asset	164.86	82.9%	164.68	87.2%	-0.17
Total Liabilities Net Assets	198.80	100.0%	188.88	100.0%	-9.91

Major Changes

- **Current Asset:** Cash and deposits -¥12.20bil, Notes and accounts receivable-trade +¥2.76bil, Merchandise and finished products -¥1.48bil, ST deferred tax assets -¥0.87bil
- **Fixed Asset :** Buildings and structures -¥0.46bil, Construction in progress +¥0.15bil, Goodwill +¥0.37bil, Other intangible assets +¥0.56bil, Investment securities +¥0.98bil, LT deferred tax assets -¥0.16bil
- **Current Liabilities:** Accounts payable -¥3.24bil, Other payable -¥1.90bil, Income tax payable -¥3.74bil, Reserve for bonus -¥1.46bil
- **Fixed Liabilities:** LT deferred tax liability +¥0.17bil
- **Net asset :** Unrealized gains on securities +¥0.11bil, Foreign currency translation adjustments -¥0.23bil



Summary of Cash Flows

(JPY billions)	FY2012 Q1 Actual
Cash and cash equivalents at the beginning of the year	75.03
Net increase/decrease in cash and cash equivalents	-12.08
Cash flows from operating activities	-6.03
Cash flows from investing activities	-1.35
Cash flows from financial activities	-4.23
Effect of exchange rate changes on cash and cash equivalents	-0.45
Cash and cash equivalents at the end of the year	62.95

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



Capital Expenditures / Depreciation & Amortization / Lease Expenses

(JPY billions)	FY2011	FY2012	
	Q1 Actual	Q1 Actual	Var.
Capital Expenditures	0.63	0.45	-0.17
Depreciation and Amortization	0.64	0.58	-0.05
Lease Payments	0.01	0.00	-0.00



Income statement in Novagali

(EUR millions)	FY2012 Q1 Actual
Sales	0.1
COGS	0.0
SGA (excl.R&D)	2.4
(in SGA) Amortization of Goodwill	1.5
R&D	1.7
Operating Profit	-4.2



**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%	9.6%	-1.1pt
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Sales/Income Outlook for the FY2012

(JPY billions)	FY2011 Actual	FY2012	
		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

<Currency rate>	
	<u>FY2011 actual</u>
USD	JPY 79.03
EUR	JPY 110.27
CNY	JPY 12.34
	<u>FY2012 forecast</u>
USD	JPY 79.00
EUR	JPY 104.00
CNY	JPY 12.50



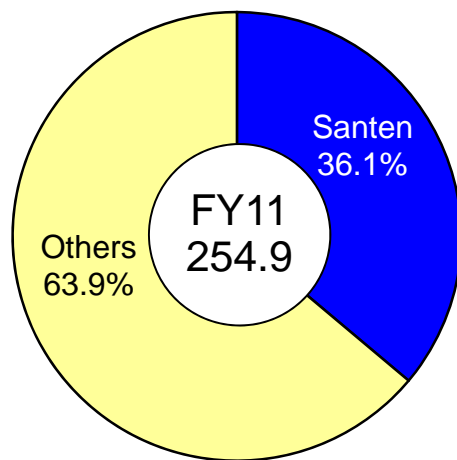
**Reference:
Market Overview of
Prescription Ophthalmics in Japan**

S Japan: Trend & Competition in Ophthalmics (1)

- **Ophthalmology Total:** Market grew by 4.0% Y to Y in 1Q FY12. The growth of retinal segment and corneal segment continued. Santen's market share was 35.4%.
- **Glaucoma:** Market grew by 3.8% Y to Y in 1Q FY12. Santen's sales grew by 15.1%. Santen held 30.3% share of the glaucoma market by the contribution of Tapros and Cosopt.
- **Corneal:** Market grew by 10.8% Y to Y in 1Q FY12. Santen's sales grew by 8.5% with the market share at 76.0%, driven by Diquas and Hyalein.

Market Size:
billions of yen
%: Value Share

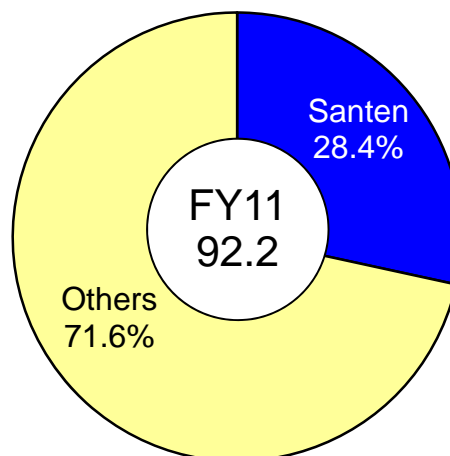
Ophthalmology Total



FY11 Q1 FY12

YoY change	Market	+3.1%	+4.0%
	Santen	+4.1%	+2.5%
Santen's Share		36.1%	35.4%

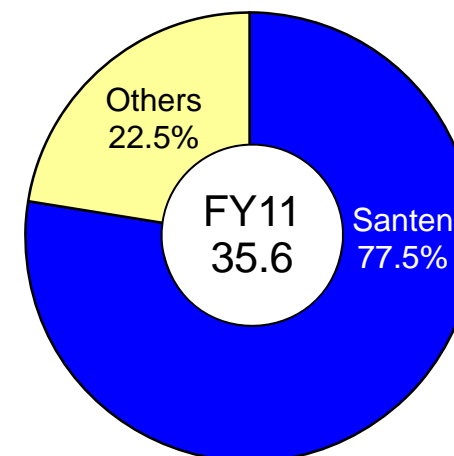
Anti-glaucoma



FY11 Q1 FY12

Market	+2.3%	+3.8%	
Santen	+13.1%	+15.1%	
Santen's Share		28.4%	30.3%

Corneal: Dry Eye



FY11 Q1 FY12

Market	+11.3%	+10.8%	
Santen	+13.7%	+8.5%	
Santen's Share		77.5%	76.0%

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

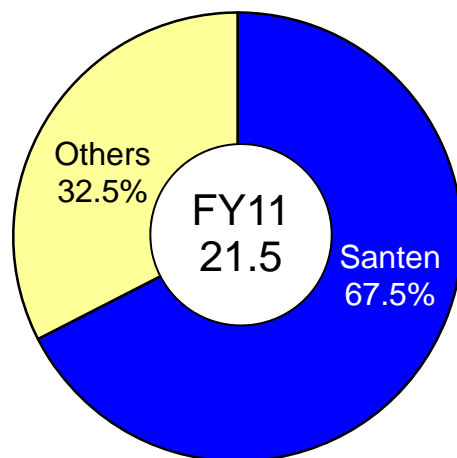
Source: ©2012 IMS Japan
IMS-JPM 2010-12
Santen analysis based on IMS data
Reprinted with permission

S Japan: Trend & Competition in Ophthalmics (2)

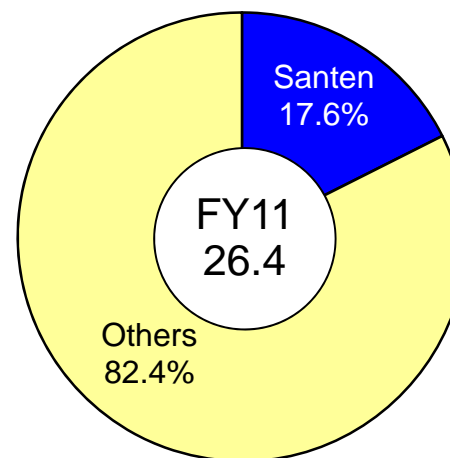
- **Anti-infection:** Market declined by 9.9% Y to Y in 1Q FY12. Santen's share was 62.0% with primary contribution by Cravit.
- **Anti-allergy:** Market declined by 8.4% Y to Y in 1Q FY12. Santen's share grew to 18.2%.

Market Size:
billions of yen
%: Value Share

Anti-infection



Anti-allergy



		FY11	Q1 FY12
YoY change	Market	-4.2%	-9.9%
	Santen	-5.5%	-17.7%
Santen's Share		67.5%	62.0%

		FY11	Q1 FY12
YoY change		-9.9%	-8.4%
Santen's Share		17.6%	18.2%

- Santen:
 - Anti-infection: Cravit, Tarivid, etc.
 - Anti-allergy: Livostin, Alegysal



FY2012 First Quarter
Status of Clinical Development

August 1, 2012

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]

(Red underlined: Change from Q4 FY11 Presentation)

Global Product

Japan (Asia)
Product

Disease	Phase 1	Phase 2	Phase 3	NDA	Approved-Launch
Glaucoma	<u>DE-117</u> EP2 Agonist		DE-111 Tafluprost/ Timolol	China	<u>DE-085</u> Tafluprost JP·Asia·EU·Latin America Australia·US
		DE-090 Lomerizine HCl		DE-118 Tafluprost	
Cornea/ Conjunctival Disease		DE-101 Rivoglitazone		DE-089 China Diquafosol Sodium Korea JP	
	US	DE-105 Peptide Combination JP			
		Cyclokot US Ciclosporin EU			
Retina Uveal Disease			<u>DE-109</u> Sirolimus		
			DE-102 Betamethasone		
Other Infection, Allergy, RA		DE-098 Anti APO-1 Antibody	DE-114 Epinastine HCl	DE-108 Korea Levofloxacin 1.5% Japan	
			Vekacia Ciclosporin		

S Major Clinical Pipeline List (2) [by Region]

(Red underlined: Change from Q4 FY11 Presentation)

Global Product

Japan (Asia) Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved - Launched
Japan			DE-102 Betamethasone	DE-118 Tafluprost	DE-085 Tafluprost
		DE-090 Lomerizine HCl	DE-111 Tafluprost/Timolol		DE-089 Diquafosol Sodium
		DE-105 Peptide Combination	DE-114 Epinastine HCl		DE-108 Levofloxacin 1.5%
		DE-098 Anti APO-1 Antibody	DE-109 Sirolimus		
North America (Including Latin America)	DE-117 EP2 Agonist		DE-109 Sirolimus		DE-085 Tafluprost
	DE-105 Peptide Combination	DE-101 Rivoglitazone			
		Cyclokat Ciclosporin			
Asia (including Oceania)				DE-085 Tafluprost China Korea Australia	
				DE-089 Diquafosol Sodium China Korea	
				DE-108 Korea Levofloxacin 1.5%	
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

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	Launched	Launched	Generic name: Tafulprost [Launched] Japan (Dec. 2008) Europe (Jun. 2008) Asia (Mar. 2010) United States (Mar. 2012) Latin America (Aug. 2010) [Out-licensed] Merck & Co. (Apr. 2009)
Europe**	Launched: 35 countries Partly out-licensed to Merck*	Launched: 27 countries Approved: 39 countries Partly out-licensed to Merck*	
Asia**	Launched: 4 countries NDA filed: China	Launched: 4 countries Approved: 7 countries NDA filed: China	
Americas**	Out-licensed to Merck* Launched: 11 countries (Including US)	Out-licensed to Merck* Launched: 5 countries Approved: 11 countries Launched: US	

[Launched] Total: 51 countries worldwide

- Santen: Japan, 4 countries in Asia, and 23 countries in EU
- Merck*: 12 countries in EU, US, and 10 countries in Latin America

[Approved] Total: More than 60 countries worldwide

*Merck areas (since April 2009): Western Europe excluding Germany, North America, South America, and Africa

**EU: Including CIS, Asia: Including Oceania, Americas: US, Latin America



Major Clinical Projects Update

■ DE-118 (Glaucoma, ocular hypertension)

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	NDA filed	NDA filed	Generic name: Tafluprost (preservative-free, unit dose, single use)

■ DE-089 (Dry eye)

Product Name: *DIQUAS* in Japan

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	Launched	Launched	Generic name: Diquafosol Sodium
Asia	China: NDA filed Korea: Approved	China: NDA filed Korea: Approved	



Major Clinical Projects Update - Glaucoma, Ocular hypertension -

■ DE-090

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

■ DE-111

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	P3	P3	Generic name: Tafluprost/ Timolol maleate (Combination drug)
Europe	P3	P3	

■ DE-117

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
US	P1/2a	—	Prostaglandin EP2 agonist

Major Clinical Projects Update – Corneal disease -

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

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
US	P2	P2	Generic Name: Rivoglitazone

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

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	P2	P2	Combination of peptides
US	Preparing P2	Preparing P2	

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

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
US	—	P2 completed	Selective glucocorticoid receptor agonist (SEGRA)

*Clinical studies suspended based on P2 results; future strategy, including formulation improvement, is under evaluation.



Major Clinical Projects Update - Retinal / Uveitis Disease -

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

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	P2/3	P2/3	Generic name: Betamethasone

■ DE-109 (Uveitis)

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
US	P3	P3	Generic name: Sirolimus
Japan	P3	P3	
EU	P3	—	



Major Clinical Projects Update – Infection, Allergy, Arthritis -

■ DE-108 (Extraocular infection)

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	Launched	Launched	Generic name: Levofloxacin 1.5%
Korea	NDA Filed	NDA Filed	

■ DE-114 (Allergic conjunctivitis)

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	P3	P3	Generic name: Epinastine HCl

■ DE-098 (Rheumatoid arthritis)

Region	Development Stage		Remarks
	As of August 1, 2012	As of May 8, 2012 (Previous announcement)	
Japan	P2 Completed	P2 Completed	Anti-APO-1 Antibody



Major Clinical Projects Update – Novagali -

■ **Cyclokat** (Severe Dry Eye)

Region	Development Stage		Remarks
	8/1	5/8 (Previous)	
EU	P3	P3	Generic Name: Ciclosporin
US	P2 Completed	P2 completed	

■ **Vekacia** (Vernal Conjunctivitis)

Region	Development Stage		Remarks
	8/1	5/8 (Previous)	
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 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.