

## Financial Performance and Outlook Interim Period Ended September 30, 2003

## November 17, 2003

## **Investor Meeting**

(A Caution Concerning Forward-Looking Statements)

Forecasts of future business results are based on the judgment of the management of Santen using information currently available. Actual results may differ materially from forecasts due to a number of factors, including but not limited to changes in the business environment, launch of new products, fluctuations in exchange rates and changes in related laws and regulations.



### **Investor Meeting for the Interim Period ended September 30, 2003**

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#### (Note)

All amounts have been rounded down to the nearest hundred million yen. For year-onyear comparison rates, amounts before rounding down have been used for calculation, and results are then rounded to one decimal.



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# Summary of the Interim Period Ended September 30, 2003

## Summary of the Interim Period Ended September 30, 2003

#### Results for the Interim Period Ended September 30, 2003

(Comparison with same period of previous year)

- Net sales: -0.6%
- Operating income: +4.0%

Slight decrease in sales, increase in net income

- Ordinary income: -4.7%
- Net income: +67.9%
- Net sales and income were higher than original projections.

### Sales

- Sales expansion in U.S. and Europe offset decrease due to factors such as stagnation in some parts of ophthalmic pharmaceutical market in Japan and wholesaler's inventory decrease for OTC eye drops.
- Large increase in U.S. sales includes temporary increase of wholesalers' inventories.

#### Expenses

- Cost of sales decreased due to changes in product mix and cost reduction
- Restrained increase in selling, general and administrative expenses

#### **Research and Development**

Applications filed: Vernal keratoconjunctivitis treatment (Japan), high-concentration

anti-infective ophthalmic solution (U.S.)

Advanced to next phase: Rheumatoid arthritis treatment (DE-096) -- Phase I

Phase II: Four products in Japan, two overseas (DE-085 in Phase II in both Japan and the U.S.), including three for treatment of glaucoma

Intraocular lenses MD-13, MD-14: In clinical development



## **Consolidated Performance Summary**

for the Interim Period Ended

**September 30, 2003** 



				(100 million yen)
	Interim Period ended	Interim Per	iod ended Septe	ember 30, 2003
	September 30, 2002 Actual	Actual	Change from previous year	% change from previous year
Net sales	464	461	-3	-0.6 %
Cost of sales	169	158	-11	-6.0 %
Selling, genenal and administrative expenses	223	228	5	1.9 %
Operating income	71	74	3	4.0 %
Non-operating income	-2	-8	-6	-
Ordinary income	69	66	-3	-4.7 %
Extraordinary gain/loss	-22	-5	17	-
Income Taxes	28	30	2	3.9 %
Net income	17	30	13	67.9 %



## Summary of Consolidated Results: Difference from Original Forecast of May 12

	Interim Period ended September 30, 2003					
	forecast May 12, 2003	Actual	change from original forecast	% change from		
Net sales	455	461	6	1.4 %		
Cost of sales	158	158	0	0.6 %		
Selling, genenal and administrative expenses	237	228	-9	-3.7 %		
Operating income	60	74	14	24.1 %		
Non-operating income	0	-8	-8	-		
Ordinary income	60	66	6	10.5 %		
Extraordinary gain/loss	-3	-5	-2	-		
Income Taxes	31	30	-1	-2.9 %		
Net income	26	30	4	16.2 %		



100 million yen ) Interim Period ended September 30, 2003 Japan **Overseas** Total % Change from % Change from % Change from Net Sales Net Sales Net Sales previous year previous year previous year Prescription pharmaceuticals 38.0 % 413.6 359.4 -2.4 % 54.2 1.5 % **Ophthalmic** 318.2 -2.7 % 53.4 39.7 % 371.7 1.8 % Anti-rheumatic 39.7 0.3 40.2 3.7 % 4.0 % Others -49.9 % 0.2 1.7 -51.4 % 1.4 --32.5 % 32.8 % **OTC** pharmaceuticals 21.9 0.0 22.0 -Medical devices 4.5 6.1 % 0.1 4.7 1.6 % Others 6.4 14.6 % 14.6 5.2 % 21.0 7.9 % 392.4 69.0 461.5 Total -4.4 % 28.4 % -0.6 %



## Sales of Major Prescription Ophthalmic Pharmaceuticals (Japan)

				( 100 mil	lion yen、%)
		Interim Period ended September 30, 2002		Interim Period ended September 30, 2003	
Indication	Brand Name	Actual	Change from previous year	Actual	Change from previous year
	Cravit	68	8.5	68	-1.0
Anti-infective	Tarivid	28	-28.1	22	-18.2
ophthalmics	Total (2 products)	96	-5.5	91	-6.0
Glaucoma	Timoptol	27	-5.7	24	-11.3
	Timoptol-EX	12	21.7	13	4.6
	Detantol	6	225.8	9	33.0
treatments	Pivalephrine	3	-25.5	2	-26.2
	Total (4 products)	50	9.0	49	-2.3
Corneal disorder treatments	Hyalein	63	10.8	65	2.7
	Livostin	7	21.6	11	40.3
Anti-allergy	Alegysal	3	4.5	3	-12.4
ophthalmics	Total (2 products)	11	15.5	14	23.5



## Overseas Sales/U.S. Ophthalmic Pharmaceutical Sales by Product

#### **Overseas Sales**

(100 million yen)

	Interim Period			ember30,2003
	ended September 30, 2002 Actual	Actual	Change from previous year	% Change from previous year
North America	21.9	34.4	12.5	57.0 %
Europe	17.4	21.3	3.9	22.9 %
Others	14.4	13.2	-1.2	-8.4 %
Total	53.8	69.0	15.2	28.4 %

#### **U.S. Ophthalmic Pharmaceutical Sales by Product**

		Interim Period Interim Period ended September			otember30,2003
Brand Name	Product type	ended September 30, 2002 Actual	Actual	Change from previous year	% Change from previous year
Quixin	Anti-infective ophthalmics	4.9	13.5	8.6	128.4 %
Alamast	Anti-allergy ophthalmics	0.9	3.1	2.2	224.1 %
Betimol	Glaucoma treatment	4.2	8.4	4.2	98.5 %
Total (3 products)		11.1	25.1	14.0	125.5 %



	Interim Period ended	Interim Period ended September 30, 2003		
	September 30, 2002 Actual	Actual	Change from previous Interim Period	Major factor for change
Cost of sales	169	158	-11	- change in product line up
(% of net sales)	36.4%	34.4%	-2.0 ppt	- reduction
Selling, general and administration expenses	223	228	5	
(% of net sales)	48.2%	49.5%	1.3 ppt	
not including R&D	160	166	6	<ul> <li>Established the Sales Force Automation System</li> </ul>
(% of net sales)	34.6%	36.0%	1.4 ppt	<ul> <li>Increase of Expenses by appreciation of yen</li> </ul>
Research & development	63	62	-1	
(% of net sales)	13.6%	13.5%	-0.1 ppt	



## **Statement of Income -- Summary Comparison (2)**

	Interim period ended	Concernance in the second second	period ended ber 30, 2003	
	September 30, 2002 Actual	Actual	Change from previous year	Major factor
Non-oparating income/expenses	-2	-8	-6	
Non-oparating income	3	4	1	
Non-oparating expenses	5	12	7	<ul> <li>Increased foreign currency exchange loss</li> </ul>
Extraordinary gain/loss	-22	-6	16	
Extraordinary gain	0	4	4	- Gain on sale of securities
Extraordinary loss	22	10	-12	2002/9 - Withdrawal from Osaka Pharmaceutical Industry Pension Fund (2.2 billion) 2003/9 - Discontinuation of investment in subsidiary Phacor Inc. (300 million) - Employee retirement benefits associated with implementation of "second career support program" (700 million)
Income taxes	28	30	2	



【 Sales 】				(100 million yen)
	Interim Period ended	Interim Peri	od ended Septer	mber 30, 2003
	Sep tember 30, 2002 Actual	Actual	Change from previous year	% change from previous year
Japan	424	404	-20	-4.9 %
Europe * <sup>1</sup>	31	49	18	56.4 %
Others * <sup>2</sup>	8	8	0	-0.1 %
Total	464	461	-3	-0.6 %
[ Operating incom	- 1			
	Interim Period ended	Interim Peri	od ended Septer	(100 million yen) mber 30, 2003
		Interim Peri Actual	od ended Septer Change from previous year	mber 30, 2003 % change from
Japan	Interim Period ended September 30, 2002		Change from	mber 30, 2003 % change from
Japan	Interim Period ended September 30, 2002 Actual	Actual	Change from previous year	mber 30, 2003 % change from previous year
	Interim Period ended September 30, 2002 Actual 106	Actual	Change from previous year -3	mber 30, 2003 % change from previous year
Japan Europe * <sup>1</sup>	Interim Period ended September 30, 2002 Actual 106 -17	Actual 103 -12	Change from previous year -3 5	mber 30, 2003 % change from previous year

\*1 Sales and marketing expenses of U.S. ophthalmic pharmaceutical business are included in Europe

\*2 Principal sales and expenses in other regions are as follows:

Sales: Consignment manufacturing of anti-infective ear drops;

Expenses: Medical equipment R&D expenses



(	100	million	yen

	March	31, 2003	September 30, 2003		
	Actual	% of total	Actual	% of total	Change
Current assets	834	56.7 %	800	56.4 %	-34
Fixed assets	637	43.3 %	617	43.6 %	-20
Total assets	1,471	100.0 %	1,418	100.0 %	-53
Current liabilities	396	26.9 %	222	15.7 %	-174
Noncurrent liabilities	103	7.1 %	196	13.9 %	93
Total liabilitites	500	34.0 %	418	29.5 %	-82
Total shareholders' equity	971	66.0 %	999	70.5 %	28
Total liabilities and shareholders' equity	1,471	100.0 %	1,418	100.0 %	-53

### [Significant changes]

<u>Current liabilities: Convertible bonds due within one year (19.9 billion decrease)</u> Redemption at maturity on September 30, 2003

Long-term liabilities: Long-term debt ( 9.7 billion increase)

10 billion borrowed as funds for redemption of convertible bonds



		Interim Period ended September 30, 2002 Actual	Major factor
Cas	h equivalence initial balance	250	
Cash equivalence increase and decrease		-2	
	cash flow from operating activities	95	<ul> <li>Income before income taxes 6 billion</li> <li>Depreciation 2.2 billion</li> <li>Increase in trade accounts payable -1.5 billion</li> <li>Income taxes paid 1.9 billion</li> </ul>
	cash flow from investing activity	12	
	cash flow from financing activity	-110	<ul> <li>Proceeds from long-term borrowings + 10 billion</li> <li>Payment for redemption of convertible bonds 19.9</li> <li>billion</li> </ul>
	translation difference of cash	0	
Cas	h equivalence term-end balance	248	

**Capital Investment / Depreciation / Leases** 

		( 100	) million yen)
	Interim Period ended September 30, 2002 Actual	Interim Per Septembe Actual	
Capital expenditures	19	17	-2
Depreciation	16	18	2
Lease expenses	3	3	0

Major capital investments for the Interim Period ended September 30, 2003

 Production lines for new *Dimple Bottle* ophthalmic solution container Noto Plant: 600 million yen, Shiga Plant: 100 million yen

• Expansion of Nara Research and Development Center: 300 million yen Factors in increase of depreciation expenses in the Interim Period ended September 30, 2003

Start of depreciation of Nara Research and Development Center



# Second-Half Forecast for the Year Ending March 31, 2004



### Market Conditions in the Second Half

- Prescription Ophthalmics in Japan: Expected to remain at the same level
- OTC Ophthalmics in Japan: Slight increase expected
- United States: Increasing competition in the anti-infective market

Measures to be Implemented in the Second Half

- U.S. Ophthalmic Pharmaceutical Business: Contract signing and start of sales & marketing alliance
- *Dimple Bottle*: Startup of two new production lines
- Conversion of sales offices to satellite offices and centralization of sales support
   operations
- Indirect goods: Start of electronic purchasing
- Start of Phase III for DE-085



## Year Ending March 31, 2004 Second-Half Forecast (2)

Full-Year Forecast for Year Ending March 31, 2004 (Year-on-Year Comparison)

Net sales:	-0.6%
Operating income:	+ 3.2%
Ordinary income:	+ 8.5%
Net income:	-28.3%

Full-Year Forecast for Year Ending March 31, 2004 (Comparison with Original Forecast)

Net sales:	-1.2%
Operating income:	-1.5%
Ordinary income:	-5.4%
Net income:	-10.3%

### Adjustment of Performance Forecast for Second Half

[Reasons]

Net sales: Prescription ophthalmics (Japan) and OTC eye drops Cost of goods: Decreased production volume, change in product mix

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## Consolidated Performance Forecast for Year Ending March 31, 2004



	Year ended	Year ending March 31,2004				
	March 31,2003 Actual	September 30 Actual	Second-Half Forecast	Full-year Forecast	% change from previous year	
Net sales	902	461	435	897	-5	
Cost of sales	322	158	160	319	-3	
Selling, general and administrative expenses	452	228	218	447	-5	
Operating income	126	74	56	131	5	
Non-operating income	2	-8	17	9	7	
Ordinary income	128	66	73	140	12	
Extraordinary gain/loss	-29	-5	-10	-16	13	
Income tax	14	30	32	63	49	
Net income	85	30	30	61	-24	

Year ending March 31, 2004 Initial Variance Variance Revised forecast forecast (amount) (%) Net sales 908 897 -11 -1.2 % 0.9 % Cost of sales 316 319 3 Selling, general and -2.6 % 459 447 -12 administrative expenses -1.5 % **Operating income** 133 131 -2 Non-operating income -40.0 % 15 9 -6 Ordinary income 148 140 -8 -5.4 % -11 -16 -5 Extraordinary gain/loss -8.7 % 69 63 -6 Income tax Net income 68 61 -10.3 % -7

Net Sales Forecast by Business Segment

(	1	0	0	m	ill	io	n	V	en)	
	<u>-</u>	-	-						/	,

		Year ending March 31, 2004					
		Ja	apan	Ove	rseas	Total	
		Sales	Year-on-Year Change(%)	Sales	Year-on-Year Change(%)	Sales	Year-on-Year Change(%)
Prescription pharmaceuticals		706.2	-1.9 %	90.7	23.7 %	797.0	0.4 %
	Ophthalmic	626.0	-2.2 %	88.0	23.8 %	714.1	0.4 %
	Anti-rheumatic	77.9	3.4 %	1.0	-	79.0	3.5 %
	Others	2.2	-50.8 %	1.6	-	3.9	-34.1 %
01	C pharmaceuticals	46.3	-17.6 %	0.1	-	46.5	-17.8 %
Medical devices		9.0	6.6 %	0.6	-	9.7	5.6 %
Others		10.6	-14.1 %	33.1	7.3 %	43.8	1.1 %
Тс	otal	772.4	-3.1 %	124.5	18.4 %	897.0	-0.6 %



## Sales Forecast for Major Prescription Ophthalmic Pharmaceuticals in Japan

Total(2 products)

				(10	0 million yen)	
		Year ended	March 31,2003	Year ending March 31,2004		
Product type	Brand name	Actual	Year-on-year change(%)	Forecast	Year-on-year change(%)	
Anti infoctivo	Cravit	126	2.9 %	126	-0.3 %	
Anti-infective Ophthalmics	Tarivid	50	-26.7 %	42	-15.4 %	
Opininainines	Total(2 products)	176	-7.7 %	168	-4.6 %	
	Timoptol	52	-7.9 %	47	-10.6 %	
Clausama	Timoptol-XE	24	15.4 %	27	10.2 %	
Glaucoma treatment	Detantol	14	152.6 %	19	32.2 %	
treatment	Pivalephrine	6	-25.9 %	4	-25.2 %	
	Total(4 products)	98	6.0 %	99	0.2 %	
Corneal disorder treatment	Hyalein	126	6.9 %	128	2.2 %	
Anti allarav	Livostin	30	36.1 %	34	14.3 %	
Anti-allergy Ophthalmics	Allegysal	8	-2.0 %	7	-8.0 %	
Spinnaninos						

38

25.4 %

42

9.4 %



### **Overseas Sales Forecast/**

## **U.S. Ophthalmic Pharmaceutical Sales Forecast by Product**

### **[Overseas sales]**

(100 million yen)

	Year ended	Year ending March 31,2004			
	March 31,2003 Actual	Forecast	Year-on-year change(amount)	Year-on-year change(%)	
North America	46.4	60.9	14.5	31.0 %	
Europe	35.0	42.8	7.8	22.3 %	
Others	23.6	20.7	-2.9	-12.1 %	
Total	105.1	124.5	19.4	18.4 %	

#### **(U.S. ophthalmic sales by product)**

		Year ended	Year ending March 31, 2004			
Brand name	Product type     March 31,2003       Actual     F		Forecast	Year-on-year change(amoun	Year-on-year change(%)	
Quixin	Anti-infective ophthalmics	13.9	20.6	6.7	47.2 %	
Alamast	Anti-allergy ophthalmics	1.9	4.8	2.9	141.2 %	
Betimol	Glaucoma treatment	8.5	13.4	4.9	56.5 %	
Total(3 products)		24.5	38.8	14.3	58.1 %	



## Statement of Income -- Summary Comparison (1)

	Year ended	Year ending	g March 31,2004		
	March 31,2003 Actual	Forecast	Change from previous year	Main factors in change	
Cost of sales	322	319	-3	-Changes in product mix	
(% of net sales)	35.7%	35.6%	-0.1 ppt	-Cost reduction	
Selling,general and administrative expenses	452	447	-5		
(% of net sales)	50.2%	49.8%	-0.3 ppt		
Except for R&D	325	317	-8	Decrease in domestic and overseas	
(% of net sales)	36.1%	35.3%	-0.7 ppt	selling expenses	
R&D expenses	127	130	3	(Factor in increase)Reinforcement of domestic clinical development	
(% of net sales)	14.1%	14.5%	0.4 ppt	(Factor in decrease)Decrease in medical equipment related business	



## **Statement of Income -- Summary Comparison (2)**

	Year ended March 31,	Year ending March 31, 2004		Major factors	
	2003 Actual	Forecast	Change from previous year	Major factors	
Non-operating income/expenses	2	9	7		
Non-operating income	12	25	13	<ul> <li>Refund on maturity payment of postal insurance</li> </ul>	
Non-operating expenses	10	16	6	<ul> <li>Foreign currency exchange loss</li> </ul>	
Extraordinary gain/loss	-29	-16	13		
Extraordinary gain	0	6	6		
Extraordinary loss	29	22	-7	<ul> <li><u>2003/3</u></li> <li>Withdrawal from Osaka Pharma-ceutical Industry Pension Fund (2.2 billion yen)</li> <li><u>2004/3</u></li> <li>Discontinuation of investment in subsidiary Phacor Inc. (0.6 billion yen)</li> <li>Employee retirement benefits associated with implementation of Second Career Support Program (0.7 billion yen)</li> <li>Loss on impairment of land, etc.</li> </ul>	
Income taxes	14	63	49	2003/3 • Decrease in taxes due to actuarial loss at subsidiary	

**S** Capital Investment / Depreciation / Leases

(100 million ye					
	Year ended	Year ending March 31, 2004			
	March 31, 2003 Actual		Change from previous year		
Capital expenditures	41	35	-6		
Depreciation	36	39	3		
Lease expenses	6	7	1		

### Major capital investments in year ending March 31, 2004

- Production lines for the new ophthalmic solution container *Dimple Bottle* Noto Plant: 800 million yen. Shiga Plant: 100 million yen
- Expansion of Nara Research and Development Center: 300 million yen

Factors in increase of depreciation expenses for year ending March 31, 2004 • Start of depreciation of Nara Research and Development Center



## **Clinical Development Status**



	Phase 1	Phase 2	Phase 3	NDA
Glaucoma		<ul> <li>DE-085 [Japan, USA]</li> <li>DE-092 olmesartan [Japan]</li> <li>DE-090 lomerizine HCL [Japan]</li> </ul>		
Anti-infective		<ul> <li>DE-094 levofloxacin (steroid combo) [USA]</li> </ul>		• <u>levofloxacin</u> <u>1.5% high concentration</u> [USA]
Dry eye		<ul> <li>Hyalein (under preparation) [USA]</li> <li>DE-089 INS365 [Japan]</li> </ul>		
Anti-allergy				• <u>cyclosporine (orphan drug)</u> [Japan] • <u>Alamast</u> [Europe]
Rheumatoid arthritis	• <u>DE-096</u> [Japan]			

- *Red-lettered italics* indicate items that proceeded to new phase after April 1, 2003
- Intraocular lenses MD-13, MD-14: In clinical development
- Development terminated: DE-081 apafant (anti-allergy)



# Status of 2003-2005 Medium-term Management Plan



- 1. Improve Profitability
  - (1) Improve earnings in the U.S.
  - (2) Re-engineer cost structure
  - (3) Maintain/improve profit base in Japan
- 2. Strengthen R&D
  - (1) Accelerate new product development
  - (2) Focus resource allocation
- 3. Reinforce Organizational Strength

Financial targets		Year ending March 31, 2006
	Net Sales	¥93.0 billion
	Operating Income	¥18.0 billion
	Net Income	¥10.0 billion
	Return on Equity	10.0%



### Initiatives under 2003-2005 Medium-term Management Plan

## 1. Improve profitability

(1) Early profitability of U.S. operations
 Negotiations in progress for sales and marketing alliance
 àClosing and start of alliance targeted for second half of this fiscal year

## (2) Reduction of expenses

# Improved productivity with full introduction of new container Dimple Bottle

à Full-scale operation of one production line started in first half. Two new lines scheduled to start up in second half

### Establishment of Cost Structure Reform Committee

à Review company-wide costs and implement measures to reduce costs and control cost increases

### Convert sales bases to satellite offices and centralize sales support operations

à Began process in first half, implementation planned in stages

Indirect goods: Electronic purchasing to start in second half
 34



Initiatives under 2003-2005 Medium-term Management Plan

- 1. Improve profitability
  - (3) Maintain/improve profit base in Japan
    - Concentrate resources on core and growth areas of prescription pharmaceuticals
    - Establish and introduce sales force automation system
      - à Start-up of SAIN (Santen Activity Improved Navigator) in September
- 2. Strengthen R&D
  - (1) Accelerating new drug development
    - Shift personnel to clinical development sections
  - (2) Focusing resource allocation
    - Concentrate resources on promising research themes à DE-085 scheduled to enter Phase 3 during second half
    - Share know-how between rheumatic/osteoarthritic and ophthalmic drug discovery
      - à Implementation of organizational changes



2003-2005 Medium-term Management Plan -- Status (3)

Initiatives under 2003-2005 Medium-term Management Plan

- 3. Reinforce organizational strength
- (1) Strengthening corporate governance
  - Appointment of outside director
  - Directors' office terms shortened from two years to one
- (2) Enhancing employee education and organizational management capabilities
  - Career Development Support System introduced Support employee skill and career development with the following three comprehensive measures:
    - i. Rank-based training
    - New employees; newly appointed managers
    - ii. Elective, topic-based training
    - •Core skills training (12 programs, some mandatory)
    - Santen Innovation Project (Elective internal business school)
    - •Global communications training (Language skills, cross-cultural training, etc.)
    - iii. Selection of career development support
      - Candidacy system
      - Internal recruiting system
      - Second career development support (career design seminars, etc.)