# Investor Meeting on FY2017 Results and FY2018 Forecasts



#### Akira Kurokawa

Chairman & Chief Executive Officer (CEO)

### Shigeo Taniuchi

President & Chief Operating Officer (COO)

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## **Santen's Values**

天機に参与する Tenki ni sanyo suru

By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the wellbeing of patients, their loved ones and consequently to society.



# FY2017 Financial Results ended March 31, 2018



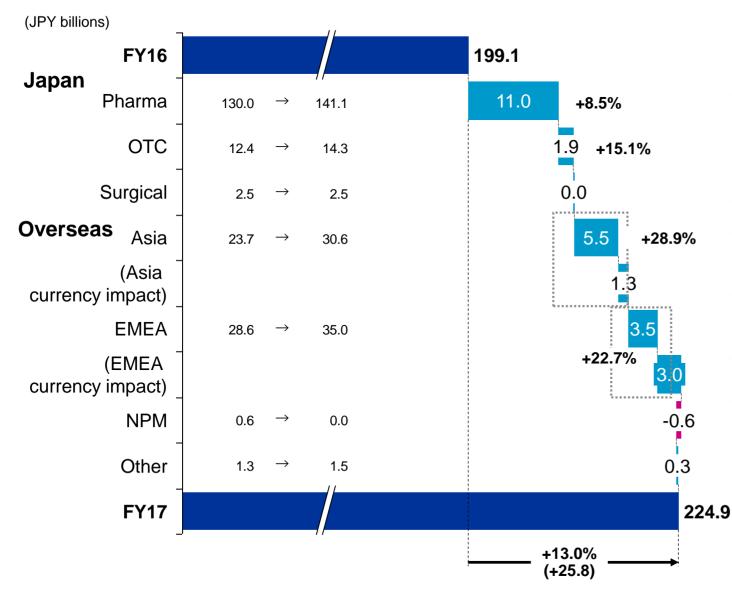
## **FY2017 Financial Highlights**

#### Revenue and profit both achieve double-digit year-on-year growth

Revenue	Double-digit revenue growth with strong increases in all businesses in Japan and overseas							
	<b>224.9 bil yen</b> YoY: <b>+13.0%</b> vs Forecast: 100.4%							
	Double-digit operating profit growth or revenue growth rate	n SGA and R&D expense control within						
Operating profit	<b>Core basis</b> <u><b>45.4 bil yen</b></u> YoY: <b>+14.3%</b> vs Forecast: 103.1%	IFRS basis <u>38.7 bil yen</u> YoY: <b>+19.1%</b> vs Forecast: 103.5%						
		.7 bil yen FY17 forecast: 69.0 .8 bil yen FY17 forecast: 25.0						



## FY2017 Revenue Strong growth in all businesses in Japan and overseas



#### Japan business

Japan pharma	Revenue growth of new products, such as <i>Eylea*</i> <sup>1</sup> (+14.1%), <i>Alesion</i> (+37.7%) and <i>Diquas</i> (+16.4%), helped boost overall revenue +8.5%									
отс	products and sales promot	In addition to inbound sales, good results from new products and sales promotions for domestic consumers added to +15.1% revenue growth								
Surgical	Promoting sales activities pharma business	Promoting sales activities in cooperation with Japan								
Oversea	is business									
	Strong growth in each market (China +32.2%, Korea +24.0%, ASEAN +27.9%) resulted in overall growth in +28.9% (JPY)									
Asia	+24.0%, ASEAN +27.9%)									
Asia EMEA	+24.0%, ASEAN +27.9%)	resulted in overal major countries , France +9.7%,	l growth in (Italy Russia							
	+24.0%, ASEAN +27.9%) +28.9% (JPY) Continued strong growth ir +31.9%, Germany +10.4%	resulted in overal n major countries , France +9.7%, erall revenue +22	l growth in (Italy Russia .7% (JPY)							
EMEA	+24.0%, ASEAN +27.9%) +28.9% (JPY) Continued strong growth ir +31.9%, Germany +10.4% +22.8%) contributed to ove Negligible NPM receipts at	resulted in overal n major countries , France +9.7%, erall revenue +22	l growth in (Italy Russia .7% (JPY)							
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EMEA	+24.0%, ASEAN +27.9%) +28.9% (JPY) Continued strong growth ir +31.9%, Germany +10.4% +22.8%) contributed to ove Negligible NPM receipts at transfers from MSD	resulted in overal major countries France +9.7%, erall revenue +22 ter the completio	l growth in (Italy Russia .7% (JPY) n of MA FY17							

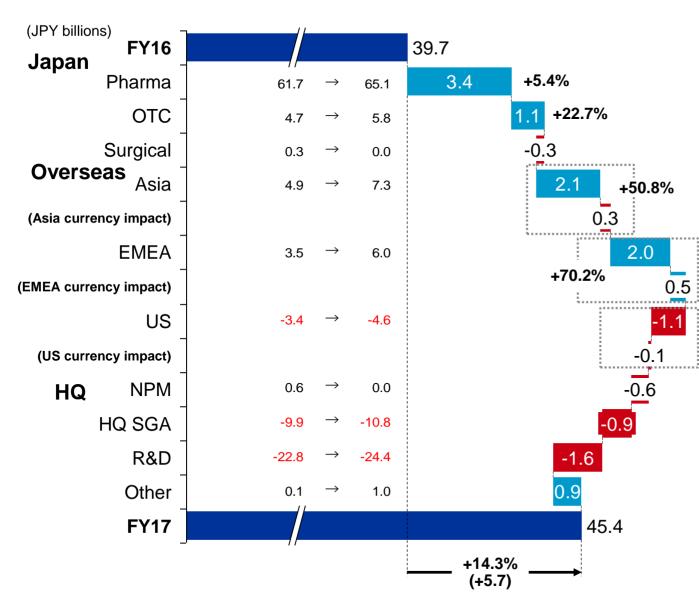
Eylea\*1: co-promoted product of Bayer Yakuhin, Ltd. (MAH)

Net Profit Margin (NPM)\*<sup>2</sup>: Profit generated from products which Santen acquired from and consigned to MSD until completion marketing right transfers



## **FY2017 Core Operating Profit**

Both Japan and Overseas businesses drive high growth

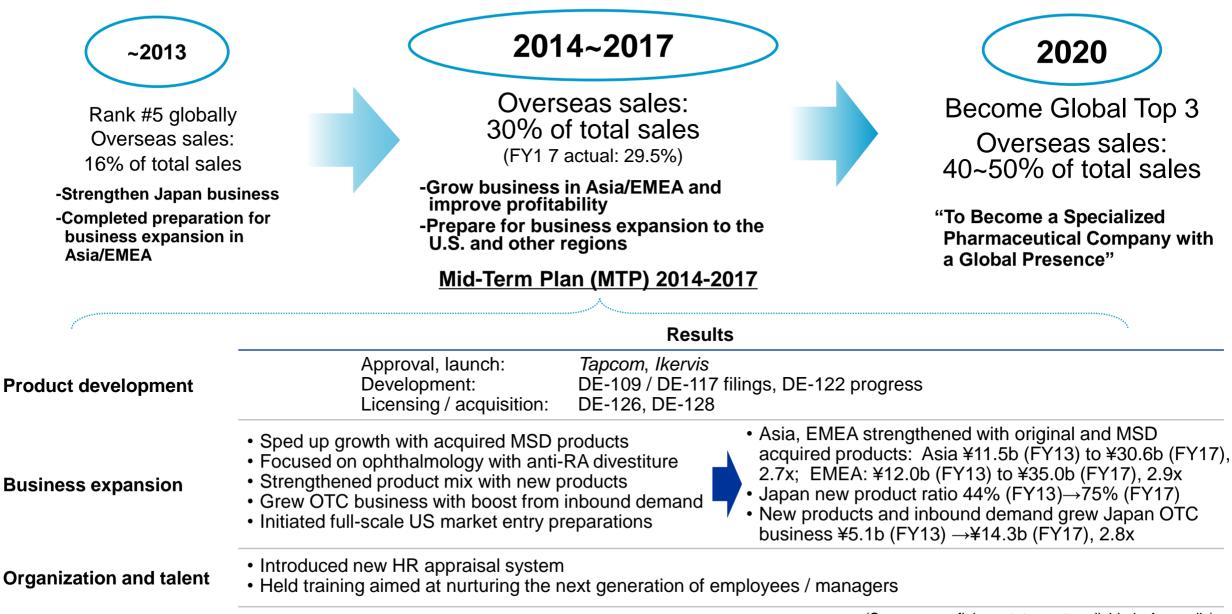


Japan bus	iness
Japan pharma	Despite transitory factor that lowered COGS in the prior year and less favorable product mix in FY17, operating profit increased by +5.4% mainly due to revenue growth of new products
отс	Overall higher with revenue growth, +22.7%
Overseas I	ousiness
Asia	Higher with revenue growth and expense
EMEA	management (Asia +50.8%, EMEA +70.2%)
US	While expenses increased mainly due to U.S. market entry preparation and administration expenses of InnFocus, a suspension of DE-109 expenses limited actual spending to 75% vs. total expense budget
R&D expenses	Despite higher expenses due to pipeline progress (DE-114A, 126, 128), succeeded to keep within the budget by optimization of the expenditure
	FY16 FY17

	FY16	FY17
USD	JPY 108.64	JPY 110.94
EUR	JPY 118.96	JPY 129.92
CNY	JPY 16.14	JPY 16.84



## **Completion of Mid-Term Plan 2014-2017**





7

## **FY2018 Forecast**



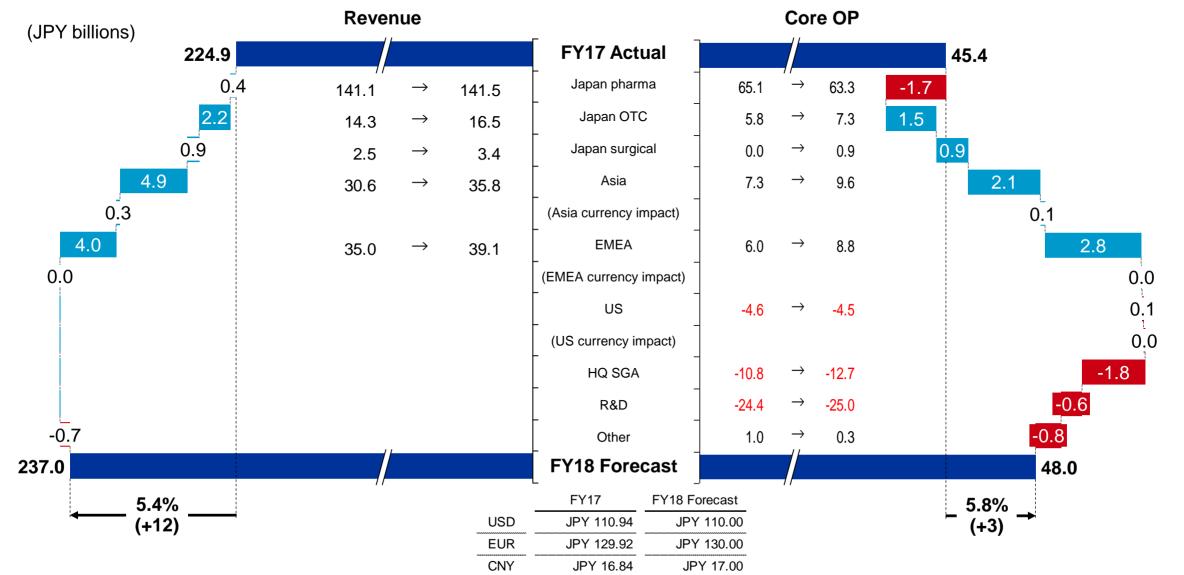
## **FY2018 Forecast Overview**

#### First year of new MTP striving toward Vision 2020 with growth and efficiency

Revenue	Growth achieved with overseas business expansion more than offsetting the negative impact from NHI price cuts in Japan pharma
	237.0 bil yen YoY: +5.4%

	SGA expenses: Enhancement of organization to support global growth R&D expenses: Strategic investment to lead growth, 2020 and beyond					
Operating profit	Core basis <u>48.0 bil yen</u> YoY: <b>+5.8%</b>	<b>RS basis</b> <u>40.7 bil yen</u> YoY: <b>+5.2%</b>				
	<b>SGA 73.0 bil yen</b> FY17 actual: 68.8 bi <b>R&amp;D 25.0 bil yen</b> FY17 actual: 24.4 bi	-				

### **FY2018 Forecast** Japan business to maintain growth with overseas businesses to further drive growth of the group

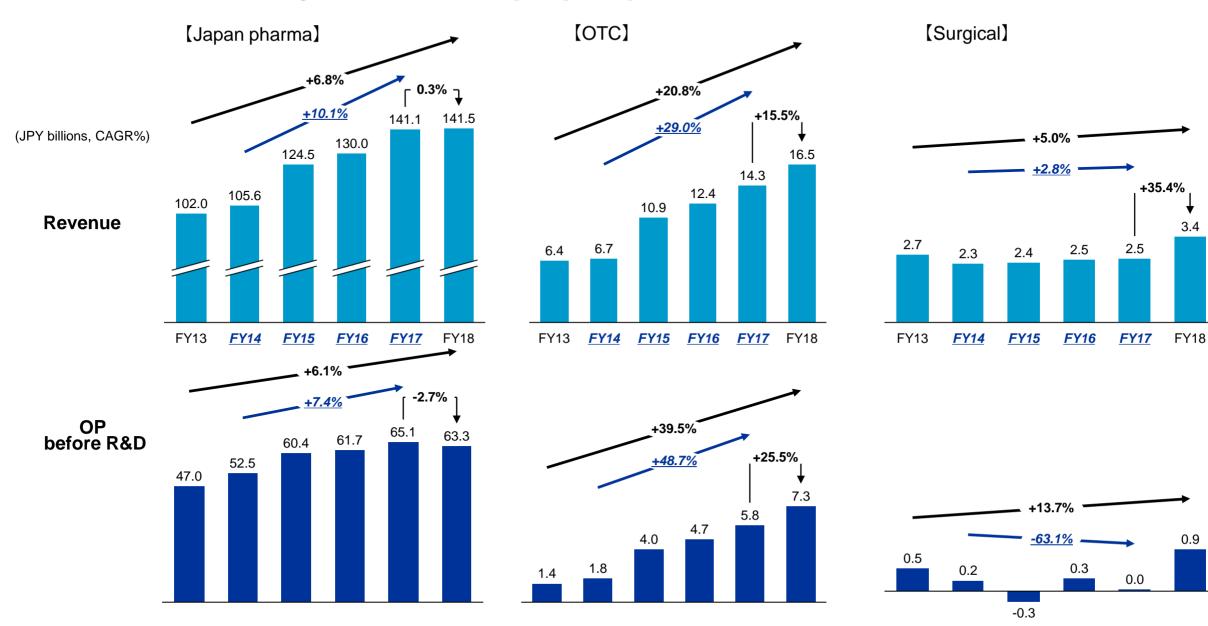




3.4

0.9

### **Performance by Business (Japan)**



## Performance by Business (Asia) Japan yen basis (JPY billions, CAGR%)

22.5

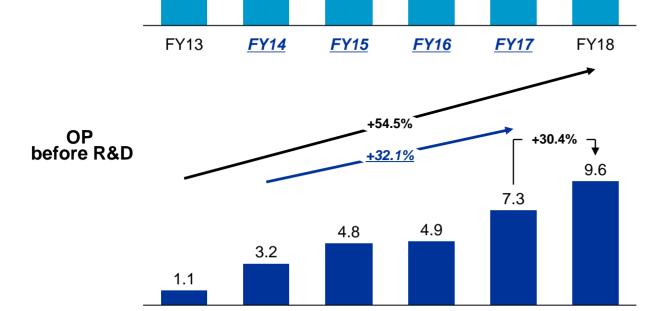
16.5

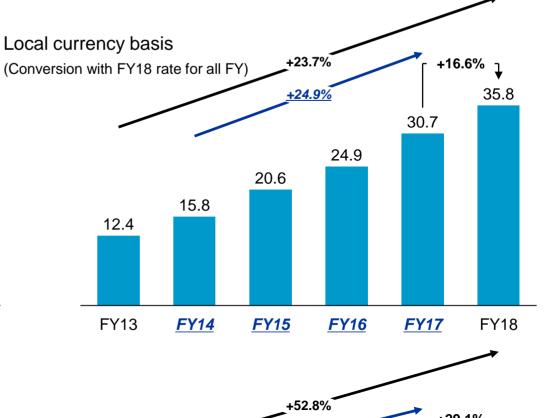
11.5

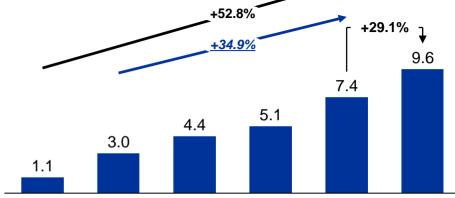
Revenue

30.6

23.7



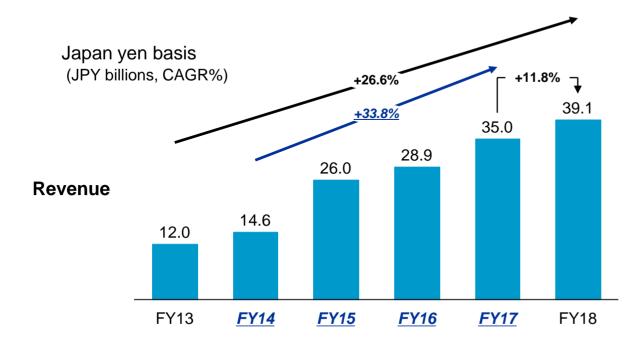


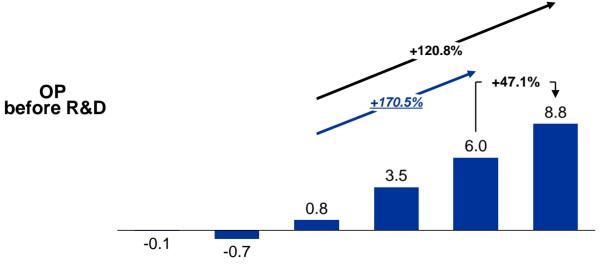


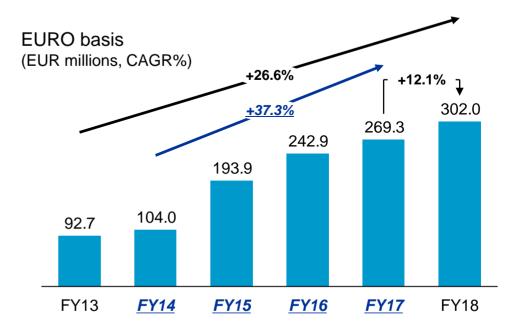
Santen

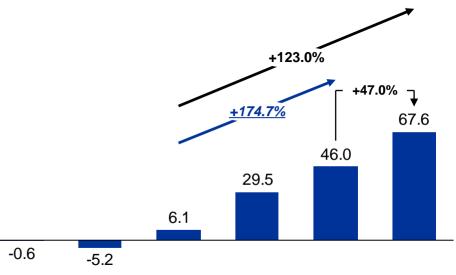


### **Performance by Business (EMEA)**





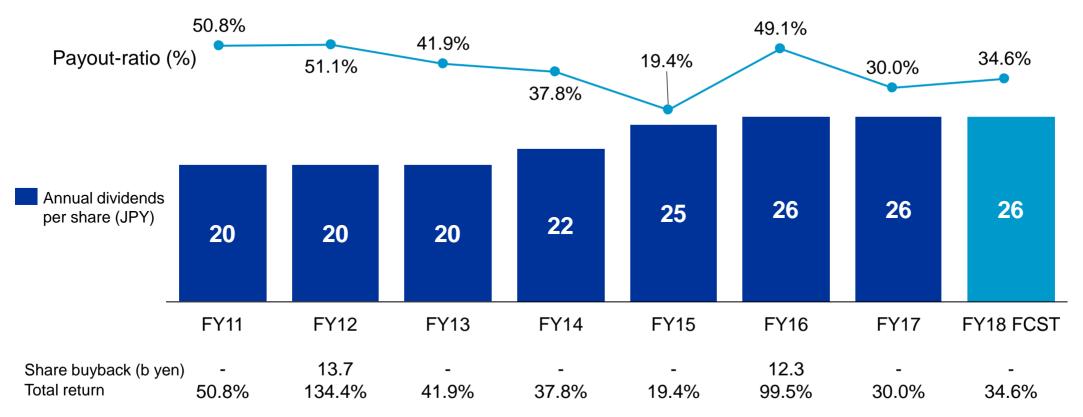




#### Santen

## **Dividend for FY2017 and FY2018 Forecast**

- Stable and sustained return to shareholders
- Mid and Long term strategic investment for the growth beyond 2020 >>>Implementing shareholder returns policy to achieve the best balance between above two priorities considering dividends and total shareholder return approach



The company implemented a 5-for-1 stock split on April 1, 2015. Accordingly, the calculations of annual dividend per share have been adjusted in all periods for comparison purposes. J-GAAP standards used until FY13, IFRS applied from FY14.

## Status of Research & Development May 2018



#### Naveed Shams, M.D., Ph.D.

Senior Corporate Officer Chief Scientific Officer (CSO) Head of Global Research & Development

## **Pipeline / Product Development Status (1)**



	Indication	Region	Status
		US	P2
<b>DE-117</b> EP2 receptor agonist	Glaucoma / ocular hypertension	Japan	Filed <i>Plan: 2<sup>nd</sup> half FY2018 approval</i>
		Asia	P3 Plan: 2 <sup>nd</sup> half FY2018 P3 completion
DE-126	Glaucoma /	US	P2b
FP/EP3 receptors dual agonist	ocular hypertension	Japan	Plan: Jan~Jun 2018 P2b completion
DE-128	Glaucoma	US	P2/3 Plan: Calendar 2018~2019 P2/3 completion, Calendar 2020~2021 launch
InnFocus MicroShunt		Europe	CE mark granted
		US	P3 Planning an additional clinical trial
DE-109	Lhuoitio	Japan	P3
IVT sirolimus	Uveitis	Europe	P3
		Asia	Filed
<b>DE-122</b> Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a Plan: Jan~Jun 2019 P2a completion

## **Pipeline / Product Development Status (2)**



	Indication	Region	Status		
<b>DE-089</b> Diquas	Dry eye China		Approved Plan: FY2018 launch		
DE-076B	Severe keratitis in patients	Asia	Launched		
Cyclokat / <i>Ikervis</i> ciclosporin	with dry eye	US	P2		
<b>DE-076C</b> Vekacia / <i>Verkazia</i> ciclosporin	Vernal kerato-conjunctivits	Europe	Filed (received positive CHMP opinion)		
<b>DE-114A</b> epinastine HCI (high dose)	Allergic conjunctivitis	Japan	P3 (pivotal study, CAC, met primary endpoints) Plan: 1 <sup>st</sup> half of FY2018 P3 completion		
DE-127 Myopia atropine sulfate		Asia	P2 Plan: 2 <sup>nd</sup> half of FY2019 P2 completion		

In April 2018, Santen received a Notice of Non-Compliance (NON) from Health Canada for DE-076B (Cyclokat / Ikervis).

Updated information is underlined. See Santen Consolidated Results for more details.



## Appendix

#### Santen

## Summary Profit / Loss Statements FY16, FY17, FY18 (FCT)

(JPY billions)	FY2016		FY201	FY20	)18		
Core basis	Full Year actual	Full Year actual	YoY	Full year forecast	vs FY forecast	Forecast	vs FY2017
Revenue	199.1	224.9	+13.0%	224.0	100.4%	237.0	+5.4%
COGS	-75.0	-86.4	15.2%	-86.0	100.4%	-91.0	5.4%
SGA	-61.7	-68.8	11.6%	-69.0	99.7%	-73.0	6.1%
R&D expenses	-22.8	-24.4	7.1%	-25.0	97.6%	-25.0	2.5%
OP	39.7	45.4	+14.3%	44.0	103.1%	48.0	+5.8%
Net profit	29.1	33.5	+14.9%	31.2	107.2%	35.3	+5.5%
ROE	11.3%	12.4%	1.1pt			12.0%	-0.4pt
IFRS							
OP	32.5	38.7	+19.1%	37.4	103.5%	40.7	+5.2%
Net profit	21.7	35.3	+62.3%	32.0	110.2%	30.4	-13.8%
ROE	8.4%	13.0%	4.6pt			10.3%	-2.7pt
USD	JPY 108.64	JPY 110.94	-2.1%	JPY 110.00	-0.9%	JPY 110.00	0.85%
EUR	JPY 118.96	JPY 129.92	-9.2%	JPY 120.00	-8.3%	JPY 130.00	-0.06%
CNY	JPY 16.14	JPY 16.84	-4.3%	JPY 16.50	-2.1%	JPY 17.00	-0.94%

+: JPY appreciation, -: JPY depreciation



## FY2017 Profit / Loss

		FY2016		FY2	017			
(JPY billions)	prior*	Actual	vs Revenue	Actual	vs Revenue	YoY	·***	Increase from transitory impact in FY2016 and
Revenue	199.1	199.1		224.9		13.0%	********	change in product mix in FY2017
COGS	-75.0	-75.0	-37.7%	-86.4	-38.4%	15.2%	****	
Gross margin								
SGA expenses	-62.2	-62.2	-31.2%	-68.8	-30.6%	10.6%	***	
R&D expenses	-22.8	-22.8	-11.4%	-24.4	-10.8%	7.1%	*******	000
Amortization on intangible assets assosiated with products	-6.4	-6.4	-3.2%	-6.7	-3.0%	5.1%		<ul> <li>SGA increases:</li> <li>Japan pharma 0.7 bil yen</li> <li>Asia 3.2 bil yen, EMEA 1.7 bil yen, US 1.1 bil yen</li> </ul>
Other income	0.5	0.5	0.2%	0.4	0.2%	-10.9%		• HQ 0.9 bil yen
Other expenses	-0.7	-0.7	-0.4%	-0.4	-0.2%	-50.0%		
Operating profit (IFRS)	32.5	32.5	16.3%	38.7	17.2%	19.1%		
Finance income	0.9	1.1	0.6%	1.0	0.4%	-9.2%		
Finance expenses	-1.6	-3.5	-1.8%	-0.4	-0.2%	-87.7%		
Profit before tax	31.8	30.1	15.1%	39.3	17.5%	30.6%		
Income tax expenses	-8.8	-8.3	-4.2%	-4.0	-1.8%	-52.0%		
Actual tax ratio	27.6%	27.7%		10.2%		-17.5pt		Mainly due to US corporate tax rate reduction
Net profit (IFRS)	23.1	21.7	10.9%	35.3	15.7%	62.3%	·	·······
Core operating profit	39.7	39.7	19.9%	45.4	20.2%	14.3%		
Core net profit	28.7	29.1	14.6%	33.5	14.9%	14.9%		

	Q4 FY16	Q4 FY17		
USD	JPY 108.64	JPY 110.94		
EUR	JPY 118.96	JPY 129.92		
CNY	JPY 16.14	JPY 16.84		

#### Notes:

Santen results describe FY17 results as the year ended March 31, 2018. Prior\*: FY16 results announced on May 10, 2017. These FY16 results are corrected retroactively from prior announced results upon the finalization of the purchase price allocation relating to the acquisition of InnFocus.

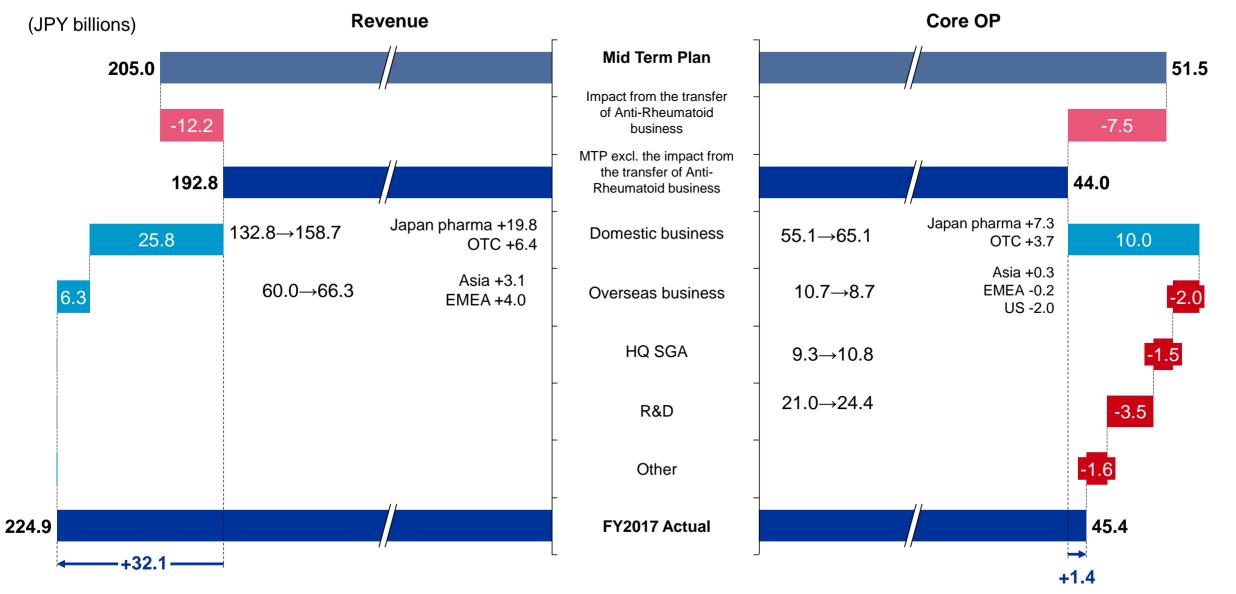
# Summary Profit/Loss statement for FY2017 (vs MTP 2014-2017)

(JPY billions)	FY2017				
		Full Year	vs MTP		
Core basis	MTP	actual	Diff.		
Revenue	205.0	224.9	19.9	109.7%	
Domestic	145.0	158.7	13.7	109.4%	
Overseas	60.0	66.3	6.3	110.5%	
Asia	27.5	30.6	3.1	111.2%	
EMEA	31.0	35.0	4.0	112.9%	
R&D expenses	-21.0	-24.4	-3.4	116.2%	
OP	51.5	45.4	-6.1	88.1%	
Net profit	35.0	33.5	-1.5	95.6%	
IFRS					
OP	45.0	38.7	-6.3	86.0%	
Net profit	31.0	35.3	4.3	113.7%	
	13.0%	13.0%	0.0pt		
USD	JPY 103.00	JPY 110.94	-7.7%		
EUR	JPY 141.00	JPY 129.92	7.9%		
CNY	JPY 16.90	JPY 16.84	0.4%		
		⊦ .IPY appreciat	ion - IPY de	preciation	

+: JPY appreciation, -: JPY depreciation



### FY2017 vs MTP 2014-2017 Difference



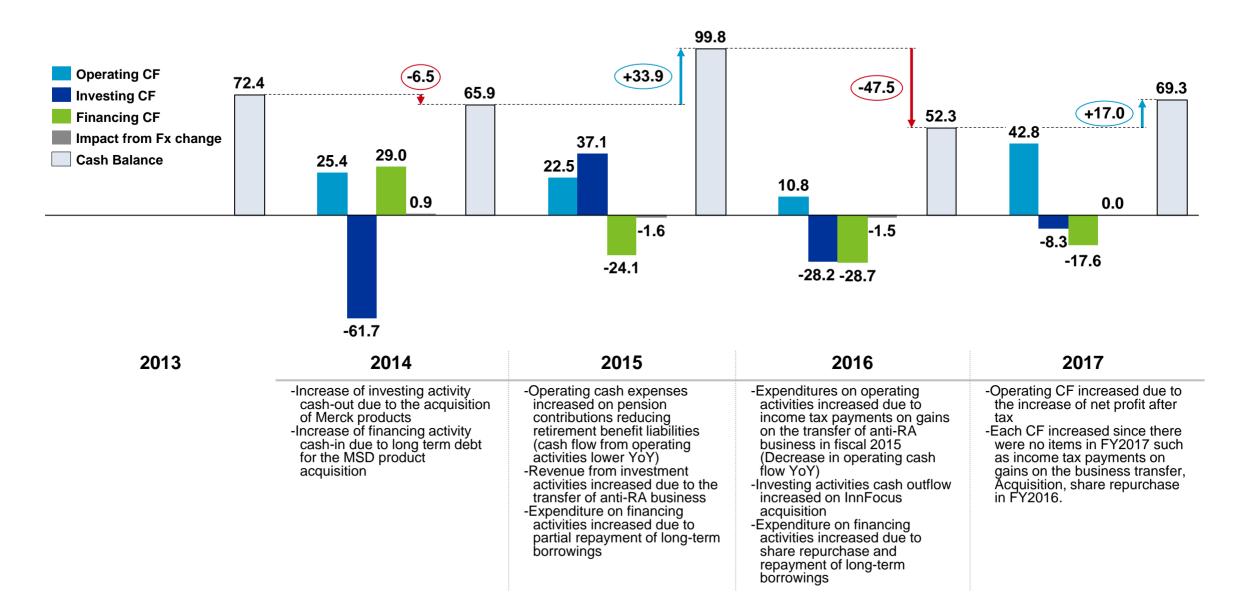


## **FY2017 Financial Position**

		March 3 <sup>2</sup> (After F		Mar 31, 2018 Increased trade receivables, cash and cash equivalents						March 31, 2017 Before PPA After PPA			Mar 31, 2018	Change
			/						Total assets	322.8	358.9	36.1	388.5	29.6
				mainly due to sales		les growth			Non-current assets	165.8	201.9	36.1	205.1	3.2
	. 、								Property, plant and equipment	28.6	28.6	-	29.7	1.2
(JPY billi	ions)				388.5	388.5			Intangible assets	102.8	138.9	36.1	134.5	-4.4
		358.9	358.9	1	-				Financial assets	29.9	29.9	-	35.8	5.9
¥		000.0	000.5	, I					Other	4.5	4.5	-	5.1	0.6
	on- rrent sets 1.9			Non- current					Current assets	157.0	157.0	-	183.4	26.4
		420.0		assets	134.5				Inventories	28.5	28.5	-	30.6	2.1
ass				I		- 287.6 (74%)		Intangible assets	Trade and other receivables	71.0	71.0	-	78.7	7.7
1		138.9		205.1					Cash and cash equivalents	53.3	53.3	-	69.3	16.0
201								Other tangible assets	Other	4.2	4.2	-	4.8	0.6
201			255.9											
		63.0	(71%)		70.6		( <b>-</b> /0)	Other current assets	Equity	253.9	255.9	2.0	287.6	31.6
					-			Cash and cash	Non-current liabilities	15.5	49.5	34.0	38.7	-10.8
				Ť			equivalents	Financial liabilities	7.6	7.6	-	3.5	-4.1	
Ť				∎ Current	114.1	38.7	Equity	Accrued payable	-	18.7	18.7	17.7	-1.0	
∎ Curr				assets			_qany	Deferred tax liabilities	2.6	18.0	15.4	12.9	-5.1	
asse		103.7						Non-current	Other	5.3	5.3	-	4.6	-0.6
 			40 E	183.4				liability	Current liabilities	53.4	53.5	0.0	62.2	8.7
157			49.5				Current liability	Trade and other liabilities	23.9	23.9	-	29.7	5.8	
								Current nability	Other financial liabilities	17.6	17.6	0.0	14.4	-3.2
		53.3	53.5		69.3	62.2			Income tax payable	3.3	3.3	-	7.7	4.4
									Other	8.6	8.6	-	10.4	1.8



## **Cash Flow Changes**





## **FY2017 Segment Revenue**

Segment Revenue									
		Japan		Overseas			Total		
(JPY billions)	FY17 Actual	YoY	FY18 Forecast	FY17 Actual	YoY	FY18 Forecast	FY17 Actual	YoY	FY18 Forecast
Pharamaceuticals	158.7	9.1%	161.3	66.3	23.4%	75.7	224.9	13.0%	237.0
Prescription	141.1	8.5%	139.8	65.9	23.3%	75.0	207.0	12.8%	214.7
Ophthalmic	140.4	8.3%	139.4	65.5	25.2%	74.1	205.9	13.2%	213.6
Others	0.7	59.1%	0.3	0.4	-62.3%	0.8	1.1	-31.1%	1.1
OTC	14.3	15.1%	16.1	0.3	121.8%	0.4	14.6	16.3%	16.5
Medical devices	2.5	0.5%	2.7	0.1	153.6%	0.2	2.6	1.8%	3.0
Others	0.8	87.4%	2.7	0.0	-69.8%	0.2	0.8	48.6%	2.8
Sales ratio	70.5%			29.5%		31.9%			

#### Sagmant Davanua



## **Capital Expenditures / Depreciation & Amortization**

	FY2016	FY2017		FY2	018	
(JPY billions)	Actual	Actual	YoY	Forecast	YoY	
Capital expenditures	5.2	5.4	4.4%	7.5	37.4%	
Depreciation and amortization*	3.5	4.2	19.7%	4.3	2.5%	
Amortization on intangible assets associated with products	6.4	6.7	5.1%	6.9	2.8%	
Intangible assets -Merck products	5.4	5.6	4.4%	5.8	3.9%	
Intangible assets -lkervis	0.7	0.7	9.2%	0.7	0.6%	

\*Excludes amortization on intangible assets associated with products and long-term prepaid expenses



## **Prescription Ophthalmic Market in Japan**

	FY2016							FY2017					
	Santen*		Market		Santen		Santen*		Market		Santen		
JPY billions	Value	Change (YoY)	Value	Change (YoY)	market share*		Value	Change (YoY)	Value	Change (YoY)	market share*		
Total	157.3	3.0%	345.5	-0.6%	45.5%	#1	167.9	6.7%	363.3	5.1%	46.2%	#1	
Glaucoma	36.8	0.1%	114.3	1.5%	32.2%	#1	35.9	-2.4%	114.9	0.5%	31.2%	#1	
Anti-VEGF	53.9	10.2%	74.5	-0.0%	72.4%	#1	61.2	13.5%	85.3	14.5%	71.8%	#1	
Corneal/dry eye	28.5	-2.9%	45.5	-1.8%	62.7%	#1	29.0	1.7%	46.6	2.5%	62.2%	#1	
Allergy	16.2	24.8%	37.7	5.5%	42.9%	#1	20.5	26.7%	42.9	13.5%	47.9%	#1	
Anti-infection	6.4	-21.5%	14.6	-11.2%	44.1%	#1	5.6	-13.4%	13.9	-4.7%	40.0%	#1	
			-	-									

\*Including co-promoted product of Bayer Yakuhin, Ltd. (MAH) (Anti-VEGF Eylea)

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## **DE-117:** New Mechanism of Action, EP2 Receptor Agonist

- Different target receptor from existing prostaglandin analogues
- Increasing aqueous humor outflow through both the uveoscleral and trabecular meshwork pathways

AYAME	FUJI	RENGE				
<ul> <li>IOP reduction achieved with OMDI 0.002% was found to be non-inferior to that of latanoprost 0.005%</li> </ul>	<ul> <li>Treatment with OMDI ophthalmic solution 0.002% demonstrated a clinically significant reduction in mean diurnal IOP in subjects with POAG or OHT who were</li> </ul>	<ul> <li>Treatment with OMDI 0.002% ophthalmic solution demonstrated clinically significant IOP reduction and tolerable safety throughout the 26 weeks</li> <li>There were no AE reports of increased pigmentation of the iris, eyelid, or eyelashes in either group</li> </ul>				
<ul> <li>The mean difference in the change in diurnal IOP from baseline to Week 4 for OMDI 0.002% versus latanoprost 0.005% was 0.63 mmHg (95% CI: 0.01, 1.26 mmHg) in favor of latanoprost</li> <li>The difference was statistically significant (P=0.0477), but was not considered to be clinically significant</li> </ul>	<ul> <li>non/low responders to latanoprost 0.005%</li> <li>-The mean (SD) diurnal IOP at the end of the 4-week treatment period was 19.63 (3.04) mmHg, representing a mean (SD) change from baseline (Day 1) of -2.99 (2.18) mmHg (95% confidence interval -3.87, -2.11; P&lt;0.0001)</li> </ul>					
$\begin{array}{c} 0\\ -1\\ -2\\ -2\\ -2\\ -3\\ -3\\ -3\\ -3\\ -3\\ -3\\ -3\\ -3\\ -3\\ -3$	$26 - 25.00 \pm 2.66 \text{ mmHg}$ $22 - 20 - 20 - 23.12 \pm 2.80 \text{ mmHg}$ $18 - 16 - 23.12 \pm 2.80 \text{ mmHg}$ $19.63 \pm 3.04 \text{ mmHg}$ $19.63 \pm 3.04 \text{ mmHg}$	Comparison of the second secon				

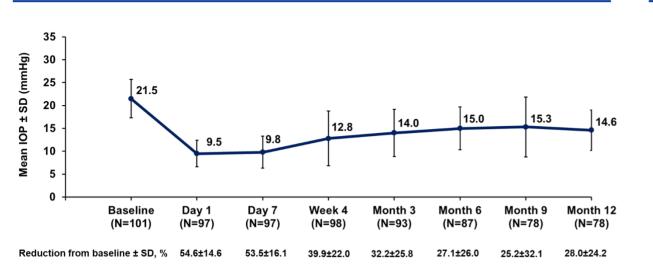
Source: ARVO 2018 Annual Meeting

IOP, intraocular pressure; OMDI, omidenepag isopropyl; CI, confidence interval; LS, least squares; SE, standard error; SD, standard deviation 27



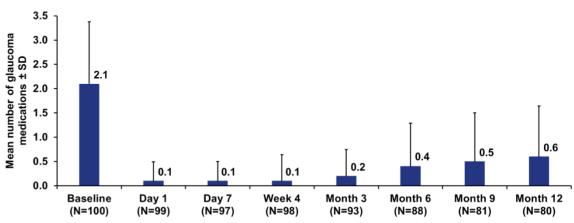
### DE-128: Glaucoma Implant Device with Micro-Invasive Surgical Design and Innovative Bio-Inert Material

- Conducting pivotal study (INN-005) that compares InnFocus MicroShunt to Trabeculectomy
- INN-007 (NCT02177123) interim results demonstrated the *InnFocus MicroShunt* decreased IOP and the number of glaucoma medications with an acceptable safety and tolerability profile.



**IOP** Outcomes up to Month 12







## **Forward-Looking Statements**

- Information given in this presentation 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 and event were to adversely affect supply capabilities for related final products.

