

## **Q3 FY2022 Financial Results**

**February 7, 2023** 





## **■** Featuring



Takeshi Ito
President &
Chief Executive Officer



Kazuo Koshiji Chief Financial Officer & Chief Risk Officer



Peter Sallstig
Chief Medical Officer

## **Forward-looking statements**

- Materials and information provided in this announcement include so-called "forward-looking statements". The earnings forecasts and other forward-looking statements herein are based on information currently available to the Company and certain assumptions that we believe to be reasonable. The realization of these forecasts is subject to various risks and uncertainties. Please be aware that actual results could differ materially from these forward-looking statements. We assume no obligation to update the contents of this document from time to time.
- Risk factors include, but are not limited to, the following: External factors such as trends in pharmaceutical administration, social and economic conditions, changes in laws and regulations, and exchange rates. Changes in the competitive environment, such as the impact of generics. Reliance on certain products and business partners, such as dependence on mainstay products, reliance on licensed products, and reliance on certain business partners for the supply of bulk drugs. Uncertainty in the development of new drugs, the possibility that R&D investment will not produce sufficient results, the success or failure of alliances with other companies, and other R&D activities. Other factors include intellectual property rights, production slowdowns and delays caused by natural disasters, product supply issues such as discontinuations and product recalls, litigation, and risks related to global business development.
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## **CORE PRINCIPLE and WORLD VISION**





Tenki ni sanyo suru

"Exploring the secrets and mechanisms of nature in order to contribute to people's health" \*



## **Happiness with Vision**

The Happiest Life for every individual, through the Best Vision Experience



<sup>\*</sup> Santen's original interpretation of a passage from the Zhongyong (The Doctrine of the Mean) by Confucius.



■ Agenda

- 1. Q3 Results and FY2022 Forecast
- 2. R&D Update
- 3. Regrowth Agenda

## **Summary**

## **Overview**

Stable profit generation from Japan with continued strong performance in EMEA and Asia

Persistent lag in China recovery, widening losses in Americas and increase in R&D expenses result in decrease in Core base profit

Structuring reforms for profitability improvements and cost-cuttings underway but limited Q3 impact

## Q3 FY2022 Consolidated results

- Revenue: +2.0% YoY (JPY199.8bil.)
- Core operating profit (OP): -21.4% YoY (JPY27.2bil.)

## **▼ FY2022 Forecasts revised**

- Revenue/Core OP:
  - Revised down to JPY272.0/JPY41.0bil. from Q3 China results, Q4 outlook and FX trends (Forecasts at Q2: JPY280.0bil/JPY45.5bil)
- > OP (IFRS):
  - Revised net profits down to JPY-15.5bil. mainly due to additional structural reform costs incurred related to Americas as non-core SG&A expenses (Forecast at Q2: JPY-5.5bil)

## Decrease in Core base profits from lagging China recovery and R&D expense increase. Q3 impact from cost cut measures is limited

(JPY billions)	Q: FY20		Q3 FY2022				
	Actual	vs Revenue	Actual	vs Revenue	YoY		
Revenue	195.8	_	199.8		+2.0%		
Cost of sales	82.7	42%	85.4	43%	+3.3%		
Gross margin	113.1	58%	114.3	57%	+1.1%		
SG&A expenses	59.7	31%	65.5	33%	+9.6%		
R&D expenses	18.8	10%	21.7	11%	+15.3%		
Core operating profit	34.6	18%	27.2	14%	-21.4%		
Non core SG&A expense	0.6	0%	-		-100.0%		
Amortization on intangible assets associated with products	7.3	4%	7.2	4%	-0.4%		
Other income	0.3	0%	0.5	0%	+64.2%		
Other expenses	0.7	0%	30.6	15%	_		
Operating profit	26.4	13%	-10.1		-		
Finance income	1.2	1%	1.0	0%	-17.9%		
Finance expenses	0.7	0%	0.7	0%	-3.4%		
Share of loss of investments accounted for using equity method	1.2	1%	1.7	1%	+46.0%		
Profit before tax	25.7	13%	-11.6		_		
Income tax expenses	6.4	3%	4.5	2%	-29.5%		
Actual tax ratio	24.8%		-				
Net profit	19.3	10%	-16.1	-	-		
Core net profit	25.9	13%	21.2	11%	-18.2%		

#### **Gross Margin**

#### +1.1% YoY

- Revenue: YoY flat partially from positive FX impact (JPY+7.9bil.)
   China Q3/QTD sales flat to Q2/QTD on JPY basis
- COGS ratio: YoY higher from NHI price cuts, changes in product/region mix and one-time costs. Q3/QTD ratio: 41.7%
- Gross margin: Impacted JPY+6.0bil. by FX

#### **Operating Profit (Core basis)**

#### -21.4% YoY

- Increase in R&D expenses as a result of pipeline progress
- Increase in overseas personnel/SG&A expenses and R&D expenses (JPY+6.5bil. FX impact)

#### **Operating Profit (IFRS)**

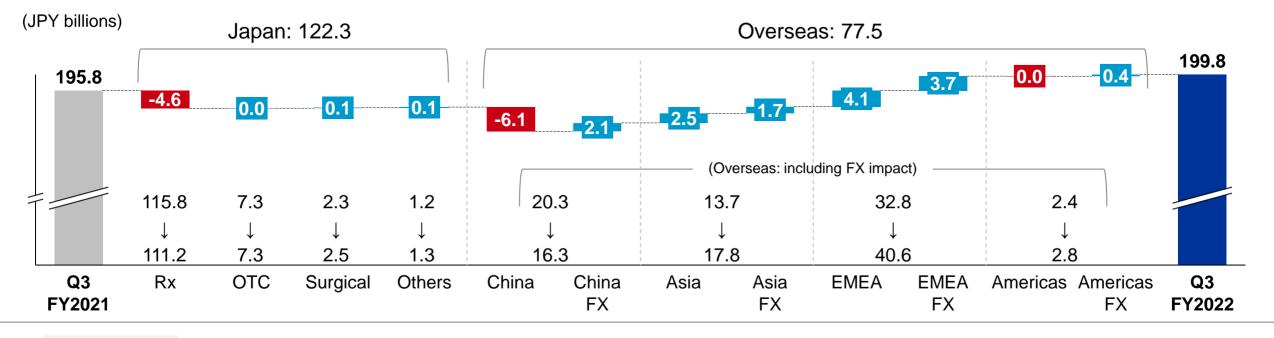
 JPY-10.1bil. primarily from impairment loss of Eyevance (JPY 30.0bil.)

#### **Net Profit (IFRS)**

Tax rate excluding one-time factor incl. impairment loss: 22.9%

## Impact from COVID-19 recovery slowdown in China absorbed by other regions

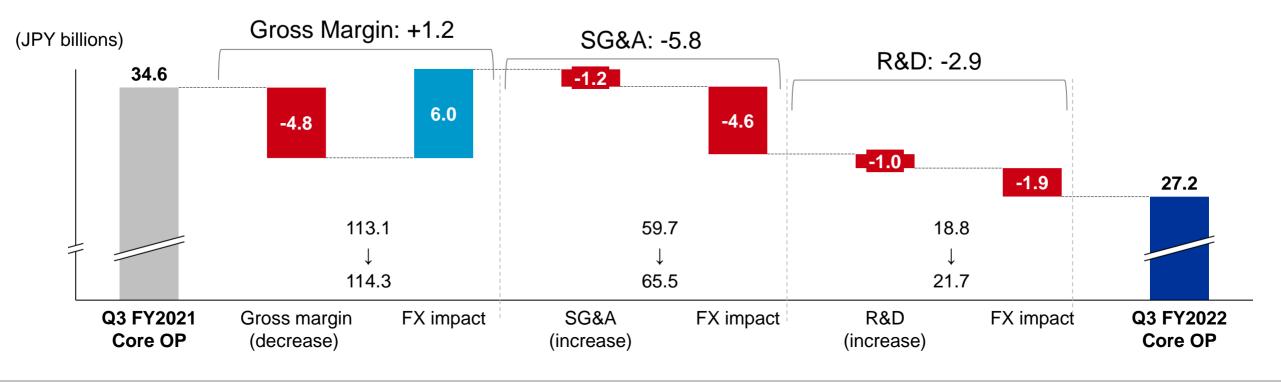




Japan	-3.4% YoY: Steady progress, core products absorb impact from NHI price cuts
China	-19.8% YoY (Ex. FX impact -30.1%): Large market contraction due to COVID-19 resurge. Expect market recovery in FY2023
Asia	+30.0% YoY (Ex. FX impact +18.0%): Solid trends led by glaucoma and dry eye in key markets
EMEA	+23.6% YoY (Ex. FX impact +12.5%): Stronger than initial FY outlook, primarily driven by glaucoma core products
Americas	+16.7% YoY (Ex. FX impact -1.7%): Flat revenue YoY from FX impact. Issues remain patient contribution and profitability

### Q3 FY2022 Core operating profit bridge

## Decrease in Core OP from widening Americas losses, continued lag in China recovery and increase in R&D expenses from pipeline progress



Gross margin	Net +1.2bil YoY. Revenue flat (incl. FX impact). COGS improving vs H1 from region & product mix
SG&A	Net -5.8bil YoY. Negatively impacted by increase in overseas expenses incl. FX impact
R&D	Net -2.9bil YoY. Increase in expenses from pipeline progress coupled with weaker JPY impact on foreign currency expenses comprising ≧60%

## Core: Revised down due to Q3 & Q4 China outlook Below Core: Add'l struc, reforms as Non-core SG&A

	FY2021ACT	FY2022FCST	FY2022FCST		
	FTZUZTACT	(Feb 7)	(Nov 8)		
JSD (JPY)	112.57	140.00	140.00		
EUR (JPY)	130.75	140.00	140.00		
CNY (JPY)	17.55	20.00	20.00		

(JPY billions)	FY2	021			F۱	/2022 (Fe	b. 7)				FY2022	(Nov 8)		
,	Actual	vs Revenue	H1 Actual	vs Revenue	H2 Forecast	vs Revenue	FY Forecast	vs Revenue	YoY	H2 Forecast	vs Revenue	FY Forecast	vs Revenue	
Revenue	266.3		128.9		143.1	-	272.0	<del>-</del>	+2.2%	151.1	-	280.0	-	
Cost of sales	109.7	41%	55.9	43%	55.1	39%	111.0	41%	+1.2%	56.1	37%	112.0	40%	
Gross margin	156.6	59%	73.0	57%	88.0	61%	2 161.0	59%	+2.8%	95.0	63%	168.0	60%	
SG&A expenses	83.9	31%	42.3	33%	48.2	34%	90.5	33%	+7.9%	49.2	33%	91.5	33%	
R&D expenses	26.4	10%	14.3	11%	15.2	11%	29.5	11%	+11.8%	16.7	11%	31.0	11%	
Core operating profit	46.3	17%	16.5	13%	24.5	17%	41.0	15%	-11.5%	29.0	19%	45.5	16%	
Non core SG&A expense	0.6	0%		-	7.5	5%	7.5	3%	-	1.5	1%	1.5	1%	
Amortization on intangible assets associated with products	9.7	4%	5.2	4%	4.2	3%	4 9.3	3%	-4.1%	4.2	3%	9.3	3%	
Other income	1.0	0%	0.3	0%	0.4	0%	0.7	0%	-37.7%	0.4	0%	0.7	0%	
Other expenses	1.1	0%	30.6	24%	0.8	1%	5 31.3	12%	_	0.8	0%	31.3	11%	
Operating profit	35.9	13%	-19.0	-	12.5	9%	-6.5	_	-	23.0	15%	4.0	1%	
Finance income	2.5	1%	1.2	1%	0.1	0%	1.3	0%	-48.9%	0.5	0%	1.7	1%	
Finance expenses	1.2	0%	0.3	0%	0.7	1%	1.0	0%	-17.3%	0.4	0%	0.7	0%	
Share of loss of investments accounted for using equity method	1.6	1%	1.1	1%	1.2	1%	2.3	1%	+43.4%	0.9	1%	2.0	1%	
Profit before tax	35.6	13%	-19.1		10.6	7%	-8.5		-	22.1	15%	3.0	1%	
Income tax expenses	8.4	3%	2.9	2%	4.1	3%	7.0	3%	-16.9%	5.6	4%	8.5	3%	
Actual tax ratio	23.7%	-	-	-	-	-	-	-	-	-	-	-	-	
Net profit	27.2	10%	-22.0		6.5	5%	-15.5	_	-	16.5	11%	-5.5	-	
ROE	8.4%						-							
Core net profit	35.2	13%	12.5	10%	18.3	13%	30.8	11%	-12.5%	21.6	14%	34.1	12%	
														1

- 1 China recovery progression and cautious estimate on FX impact from recent trends (no changes in FX forecasts)
- Reflecting COGS reduction impact in H2
- 3 Mainly additional structural reform costs
- 4 Decrease in amortization costs due to Eyevance impairment loss in H2
- 5 Eyevance impairment loss of JPY30.0bil.





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### R&D update

## Progress across both candidate product categories including launch of glaucoma product with new MOA and *Diquas LX*

New product candidates, driving mid-/long-term growth

STN1014000 Rocklatan®/Roclanda®	Glaucoma	Launched in Europe (Germany) Approved in Asia (Thailand)
STN1013900 Rhopressa®/Rhokiinsa®	Glaucoma	Approved in Asia (Thailand)
STN1012600 Sepetaprost	Glaucoma	Achieved <b>LPO</b> *1 in P2 trial (exploratory study) in Europe
STN1013600 Ursodeoxycholic acid	Presbyopia	Achieved <b>FPI</b> *2 in P2a trial in US
STN1013400 AFDX0250BS	Myopia	Started preparations for P2a trial in Japan
STN1014100 Olodaterol hydrochloride	Dry eye	Achieved <b>FPI</b> in P1/2a trial in Japan

Improvement /region expansion,

maximizing brand value of existing products

STN1008903
Diquas LX

Dry eye

Launched in Japan
Started preparations for filing in Asia

STN2000100
PRESERFLO MicroShunt

Glaucoma

Launched in Asia (Malaysia)

\*1 LPO: Last Patient Out. \*2 FPI: First Patient In.



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### Regrowth agenda

## Update on progress on "Improving Profitability" and direction of "Building our Growth Pillars"



Structural reforms for upfront recovery in business performance

- Re-assessment of investments
- Cost optimization
- Productivity improvements

3-angle approach for growth opportunities assessment to return on a Regrowth trajectory

- Scale of unmet needs
- Global trends
- Santen's competitive advantage

Set and thoroughly manage direct results-linked KPIs and establish the optimal organization for strategy execution

## Structural reforms under new leadership

Implementation to realize JPY6-8bil. scale improvements to FY2023 Core OP base



#### Re-assessment of investments

Review all past and future major investments and reevaluate those deemed to be of low strategic and cost/benefit significance



- Zero based re-assessment of new businesses incl. Americas
- Reviewing timing of sizable investments (ERP/new plant in Suzhou)



## **Cost optimization**

Strict review of budgets and optimize procurement of direct and indirect materials by thorough vendor & demand management



 Stronger budget governance and cost controls through firm-wide optimization (effective H2 FY2022 & FY2023)



### **Productivity improvement**

Firm-wide, multi-angle review of operations to improve organizational efficiency



 Conducting optimization adapted to firm-wide organization's status quo

# Maximize streamlining of pharmaceutical commercial business in Americas. Sizable contribution to FY2023 Core OP improvements

Maximize

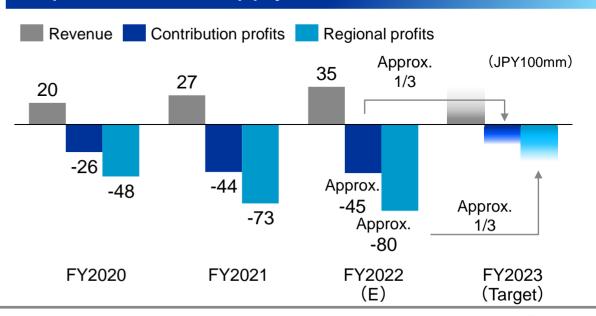
streamlining



To continue our investments in a promising pipeline & contribution to patients, improving profitability is our priority in the short-term

## **Next steps**

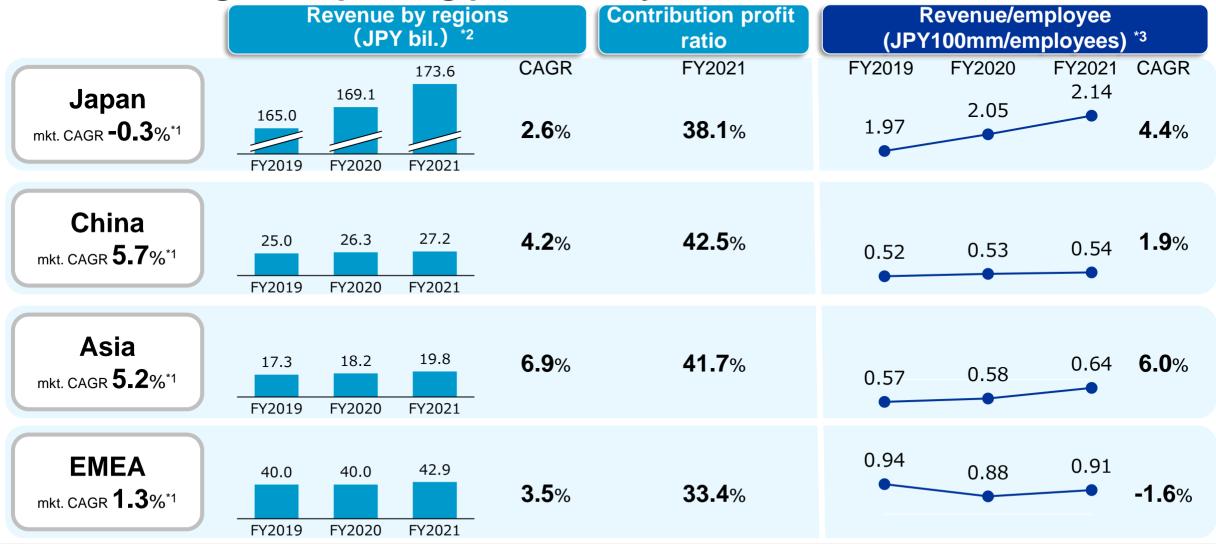
- Consider license-out/sale of products
- Aim to reduce Contribution & Region Losses to approx. 1/3 of FY2022E
- Continue global R&D and medical devices product and supply



<sup>\*</sup> Business related to STN2000100 (DE-128) with our development & commercialization collaborations with Glaukos Corporation will continue.



## Growth realized across each region's business. Next challenge is improving productivity overseas





## Thorough pursuit of contribution to ophthalmology and patients as a specialty company

Short-term

Profit growth by improving each region's productivity

- Region-specific growth by deploying essence of Japan's commercial excellence
- Securing growth investments by firm-wide profitability improvement

Long-term

Growth from innovative new drugs & business opportunities

Medium-term

Growth from new products in existing areas and development of new therapeutic areas

Business growth through patient contribution driven by products related to ptosis, myopia etc...

Sales & Market presence through scaling

Business

foundations

(Completed)

# Establish the appropriate framework to improve business productivity and maximize product and market potential

Japan

Maintain
overwhelming
presence &
continued stable profit
generation



Strengthen investments to maintain profit increase trend in long-term



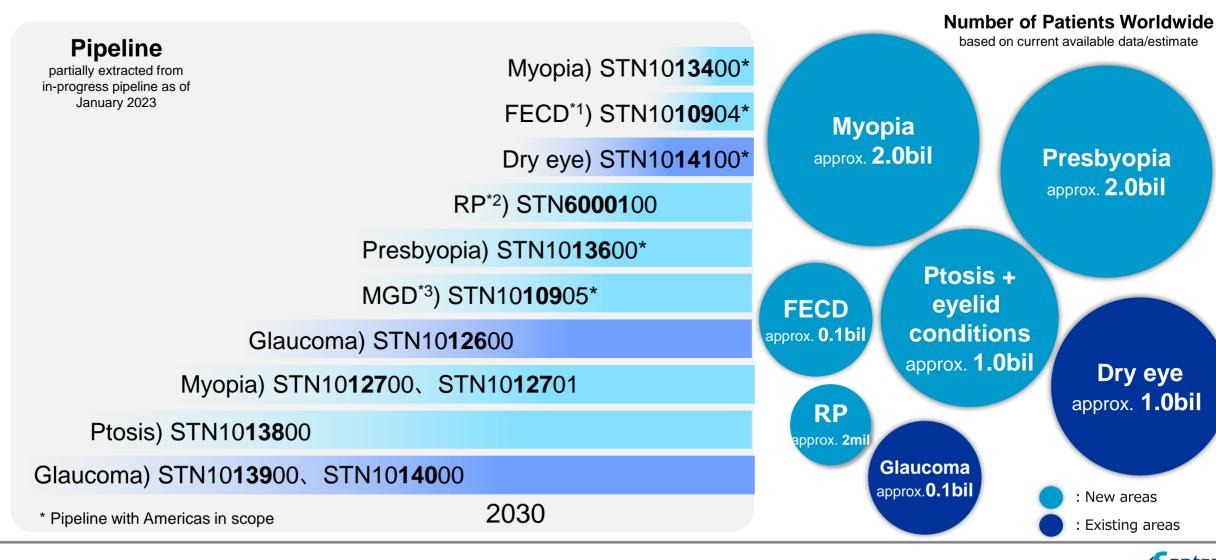
Further contribution to ophthalmology and market expansion through digital solutions and other means

China Asia EMEA Achieve high productivity to maximize profitability



Deploy Japan-incubated commercial excellence

# Contributing to more patients by delivering value globally in existing and new therapeutic areas through our strong business platform



## Direction of new medium-term plan

## **Target Core OP and EPS growth**

		FY2021	FY2022 (FCST)	FY2025					
Core OP (vs Revenue)	>	JPY <b>46.3bil.</b> (17%)	JPY <b>41.0</b> bil. (15%)	Secure 20% through profitability structure improvement					
EPS	>	JPY68.07	N/A						
ROE (IFRS)	>	8.4%	N/A	Recover to double-digit level					
Shareholder return	>	Annual dividend JPY32	Annual dividend JPY32 Share buyback JPY25.7bil.*1	Stable dividends & Opportunistic share buyback					
Share buybacks considered as a function of capital adjustments subject to market conditions, and investment opportunities									

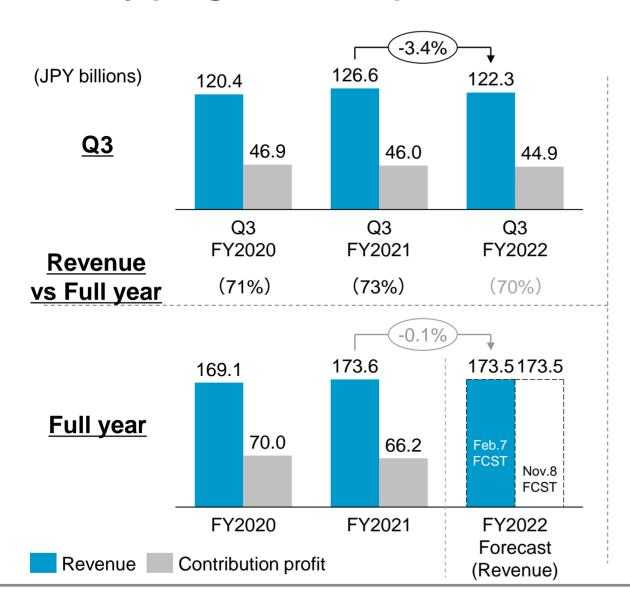
<sup>\*1</sup> Total amount of actual repurchase from May 11, 2022 to September 30, 2022 and expected repurchase from November 9, 2022 to March 24, 2023 (maximum).





**Appendix** 

## Steady progress, core products absorb impact from NHI price cuts



## **Highlights**

Market penetration of core products mitigates NHI price reduction. YoY change;

Eybelis JPY +0.45bil.

Diquas JPY +1.76bil. (LX launched in Nov. 2022)

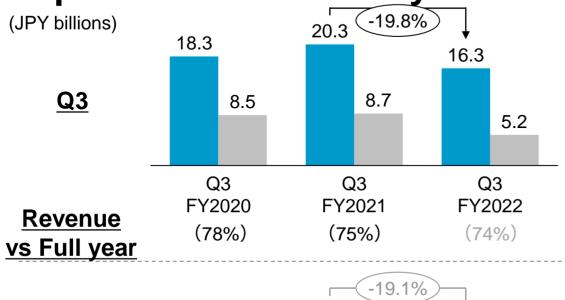
Alesion JPY -2.35bil.(YoY -16%vs-20%price cut)

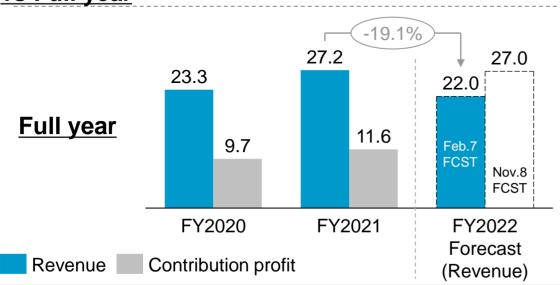
OTC products: Inbound recovery taking time

### **FY2022 Outlook**

- Core products competitive landscape: No major change
- Alesion: Certain level of volatility from airborne pollen volume and dispersal timing (same as in the past)

Large market contraction due to COVID-19 resurge. Expect market recovery in FY2023





## **Highlights**

- Market contraction due to COVID-19 resurge in Dec. 2022, despite on recovery trend. In Q3, material impact on core products (*Tapros and Diquas*) which constitute large demand portion in hospitals channels
- Verkazia listed on NRDL (National Reimbursement Drug List)

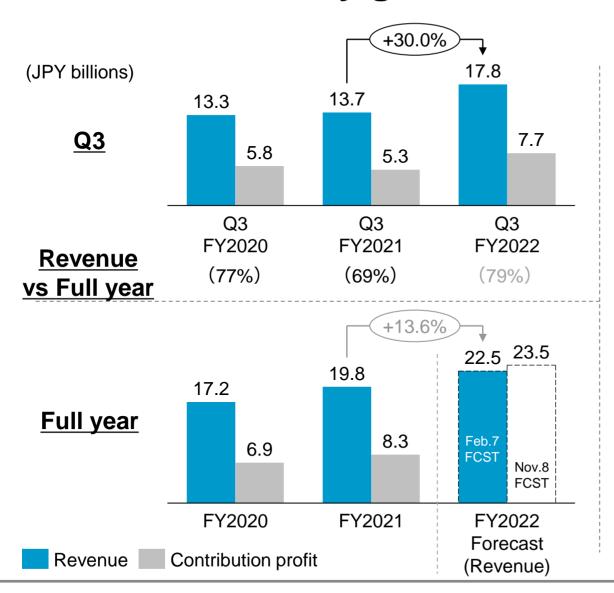
### **FY2022 Outlook**

 Revenue outlook downwardly revised with market recovery expectation in FY2023

#### FX rate (JPY)

	Q3FY2021 Actual	Q3FY2022 Actual	FY2021 Actual	FY2022 Forecast (Feb.7)	FY2022 Forecast (Nov.8)
CNY	17.28	19.86	17.55	20.00	20.00

## Solid trends led by glaucoma and dry eye in key markets



## **Highlights**

- Korea: JPY +1.28bil. (+16%), YoY
   Core products in glaucoma and dry eye led sales
- Double-digit growth in other key markets (Vietnam: +1.07bil. Thailand: +0.53bil. Taiwan: +0.40bil. Philippines: +0.27bil.)

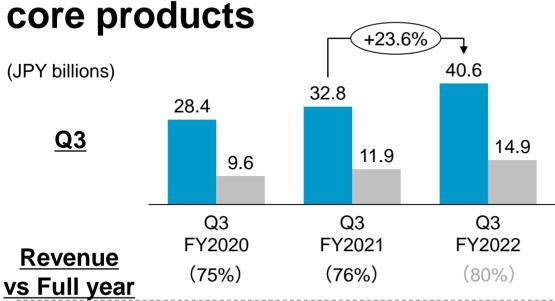
### FY2022 Outlook

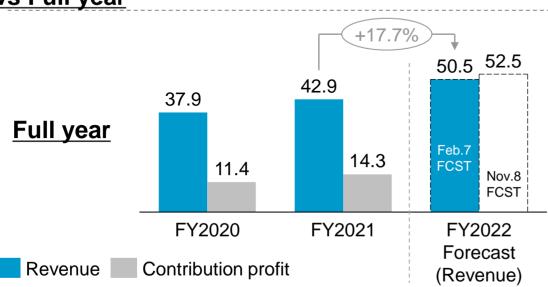
- Growth trend expected to continue subject to evolution of competitive landscape with GEs in key markets. Need to monitor changes in external environment
- Revised outlook conservatively taking account of FX trends

<sup>\*</sup>For Vietnam, factors partially include time lag related to shipping

### Q3 FY2022: Region review (EMEA)

Stronger than initial FY outlook, primarily driven by glaucoma





## **Highlights**

- West region key countries led growth. (YoY)
   (Italy JPY+1.22bil. Germany +0.88bil. UK +0.41bil.)
   Russia: +1.71bil including FX impact
- Glaucoma: Cosopt +1.89bil. Tapcom +0.89bil.
   Tapros +0.83bil. PRESERFLO MicroShunt +0.54bil.
- Dry eye: *Ikervis* +0.44bil. *Cationorm* +0.51bil.

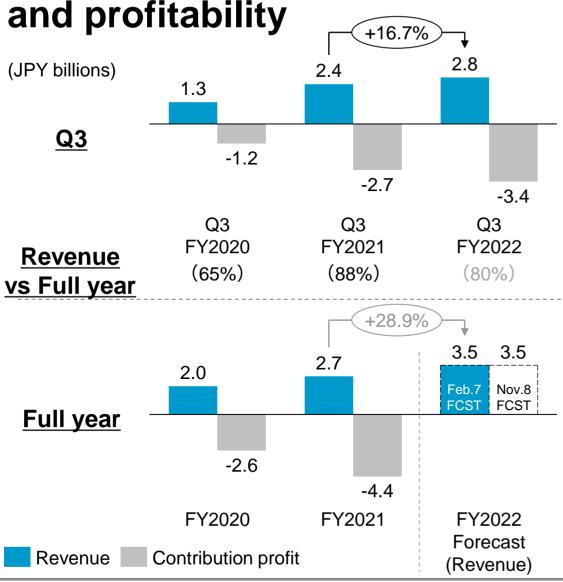
### FY2022 Outlook

- Tapros LoE: no significant change as of now.
   Expect stable growth trajectory driven by glaucoma/dry eye products
- Revised outlook conservatively taking account of FX trends

FX rate (JPY)

	Q3FY2021 Actual	Q3FY2022 Actual	FY2021 Actual	FY2022 Forecast (Feb.7)	FY2022 Forecast (Nov. 8)
EUR	130.80	140.43	130.75	140.00	140.00

Flat revenue YoY from FX impact. Issues remain patient contribution



## **Highlights**

 Eyevance: Sales have not recovered although back-orders issues resolved

### **FY2022 Outlook**

 Preparations underway for pharmaceutical commercial business streamlining

FX rate (	JPY)
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	Q3FY2021 Actual	Q3FY2022 Actual	FY2021 Actual	FY2022 Forecast (Feb.7)	FY2022 Forecast (Nov. 8)
USD	111.24	136.22	112.57	140.00	140.00

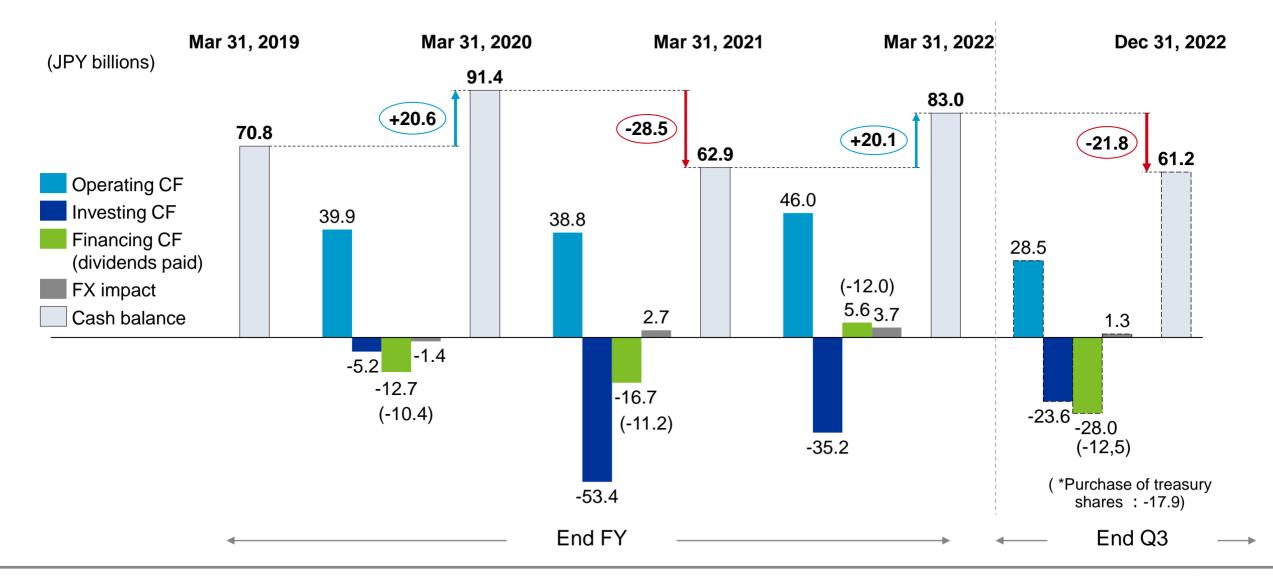
## (Reference)

## FY2022 revised outlook (Q3YTD actual and Q4/QTD forecast)

(JPY billions)	FY20	)21	FY2022 (Feb. 7)						
`	Actual	vs Revenue	Q3YTD Actual	vs Revenue	Q4/QTD Forecast	vs Revenue	FY Forecast	vs Revenue	YoY
Revenue	266.3	-	199.8		72.2		272.0	_	+2.2%
Cost of sales	109.7	41%	85.4	43%	25.6	35%	111.0	41%	+1.2%
Gross margin	156.6	59%	114.3	57%	46.7	65%	161.0	59%	+2.8%
SG&A expenses	83.9	31%	65.5	33%	25.0	35%	90.5	33%	+7.9%
R&D expenses	26.4	10%	21.7	11%	7.8	11%	29.5	11%	+11.8%
Core operating profit	46.3	17%	27.2	14%	13.8	19%	41.0	15%	-11.5%
Non core SG&A expense	0.6	0%			7.5	10%	7.5	3%	-
Amortization on intangible assets associated with products	9.7	4%	7.2	4%	2.1	3%	9.3	3%	-4.1%
Other income	1.0	0%	0.5	0%	0.1	0%	0.7	0%	-37.7%
Other expenses	1.1	0%	30.6	15%	0.7	1%	31.3	12%	
Operating profit	35.9	13%	-10.1		3.6	5%	-6.5	_	-
Finance income	2.5	1%	1.0	0%	0.3	0%	1.3	0%	-48.9%
Finance expenses	1.2	0%	0.7	0%	0.3	0%	1.0	0%	-17.3%
Share of loss of investments accounted for using equity method	1.6	1%	1.7	1%	0.6	1%	2.3	1%	+43.4%
Profit before tax	35.6	13%	-11.6		3.1	4%	-8.5		-
Income tax expenses	8.4	3%	4.5	2%	2.5	3%	7.0	3%	-16.9%
Actual tax ratio	23.7%						-	<u>-</u>	-
Net profit	27.2	10%	-16.1		0.6	1%	-15.5	_	-
ROE	8.4%						-		
Core net profit	35.2	13%	21.2	11%	9.6	13%	30.8	11%	-12.5%

#### Q3 FY2022

## **Cash flow**



## Foreign exchange rate assumptions and sensitivities

FX rate (JPY)

	Q3FY2021 Actual	Q3FY2022 Actual	Q3FY2022 Forecast (Nov. 8)	Q3FY2022 Actual vs Forecast	FY2022 Forecast (Feb. 7)
USD	111.24	136.22	140.00	97.3%	140.00
EUR	130.80	140.43	140.00	100.3%	140.00
CNY	17.28	19.86	20.00	99.3%	20.00

## **Sensitivities**

Impact of a 1% depreciation of the yen (vs FY2022 revised forecast rate, as of Feb. 7) (JPY billions)

	Total*	USD	EUR	CNY
Revenue	+0.9	+0.04	+0.44	+0.22
Core OP	+0.0	-0.16	+0.05	+0.03
OP (IFRS)	-0.1	-0.25	+0.04	+0.02

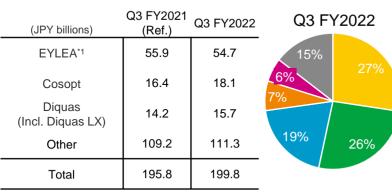
<sup>\*</sup>Total: impacts from USD, EUR, CNY and other major currencies (rounding to nearest 100 million)

FX impact on Q3 (vs FY2021)
(JPY billions)

	Total
Revenue	+7.9
Core OP	-0.5
OP (IFRS)	-6.6

## Q3 FY2022 revenue by region (YTD)

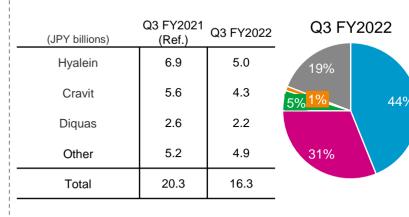




#### <u>Japan</u>

(JPY billions)	Q3 FY2021 (Ref.)	Q3 FY2022	Q3 FY2022
EYLEA*1	55.9	54.7	15%
Diquas (Incl. Diquas LX)	10.3	12.1	10%
Alesion*2 (Incl. Alesion LX)	14.4	12.0	14%
Other	45.9	43.5	15%
Total	126.6	122.3	1370

#### China



#### <u>Asia</u>

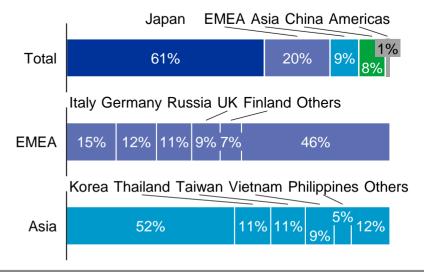
Q3 FY2021 (Ref.)	Q3 FY2022	Q3 FY2022
3.8	4.5	1%14%
1.2	2.2	13% 43%
1.2	1.8	
7.5	9.4	29%
13.7	17.8	
	(Ref.) 3.8 1.2 1.2 7.5	(Ref.)  3.8  4.5  1.2  2.2  1.2  1.8  7.5  9.4

#### **EMEA**

(JPY billions)	Q3 FY2021 (Ref.)	Q3 FY2022	Q3 FY2022
Cosopt	8.0	9.9	9%
Tapros	5.2	6.0	2%
Ikervis	3.8	4.3	22%
Other	15.8	20.4	
Total	32.8	40.6	
Allergy Bac	terial conjur	nctivitis	Others

\*2 Alesion: Trademark of alliance partner, Nippon Boehringer Ingelheim

#### Revenue in each region (Q3 FY2022)



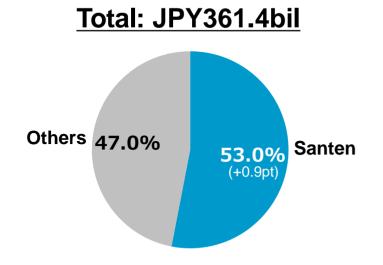
Intravitreal VEGF inhibitor Glaucoma/Device

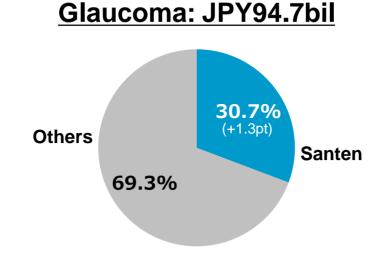
\*1EYLEA: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

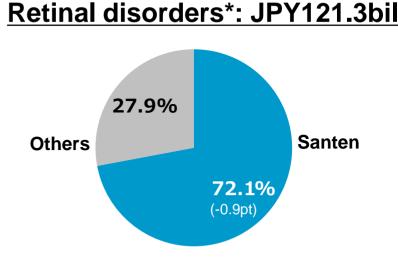
## Remain No.1 for overall market and all segments

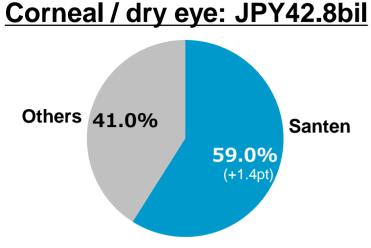
Segment: Market size

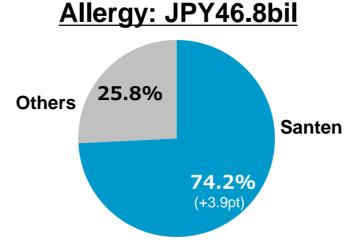
Graph: Market share (change from last year)

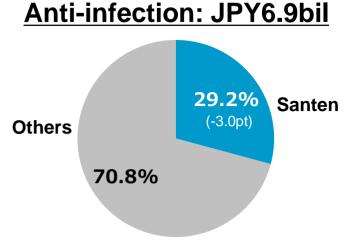












\*Including co-promoted product (Anti-VEGF EYLEA) of Bayer Yakuhin, Ltd. (MAH) Source: Copyright © 2023 IQVIA. JPM 2021.1-2022.12; Santen analysis based on IQVIA data. Reprinted with permission.

## **Current status of global development (1)**

Indication	Generic Name	Contractual territory	Dev. Code	Development Status*1		
	Omidenepag		STN10 <b>117</b> 00 DE-117	US	Approved	
	isopropyl	WW*2		Japan	Launched	
	EYBELIS / OMLONTI		DL-117	Asia	Launched	
				US	P2 (met primary endpoint)	
	Sepetaprost	WW	STN10 <b>126</b> 00 DE-126	Japan	P3 Plan: FY2023 P3 completion	
				Europe	P2 (exploratory study) Plan: FY2022 P2 (exploratory study) completion	
Glaucoma	Implant device PRESERFLO MicroShunt	WW (In-house) *Excl. Americas, Australia, New Zealand	STN <b>20001</b> 00 DE-128	Japan	Launched (soft launch)	
				Europe	Launched	
				Asia	Launched in October 2022	
	Netarsudil mesilate Rhopressa®/Rhokiinsa®	Japan, China Asia, Europe	STN10 <b>139</b> 00 AR-13324	Japan	P3 Plan: FY2024 P3 completion	
				Europe	Approved Plan: FY2022 launch	
				Asia	Approved in January 2023  Plan: FY2023 launch	

<sup>\*1</sup> Only projects where the study protocols were approved in-house are shown, \*2 World wide

## **Current status of global development (2)**

Indication	Generic Name	Contractual territory	Dev. Code	Development Status		
	Netarsudil mesilate	Japan China	CTN4.04.4000	Europe	Launched in January 2023	
Glaucoma	/latanoprost (combination) Rocklatan®/Roclanda®	Japan, China Asia, Europe	STN10 <b>140</b> 00 PG-324	Asia	Approved in January 2023  Plan: FY2023 launch	
			STN10 <b>127</b> 00 DE-127	Japan	P2/3 Plan: FY2023 P2/3 completion	
	Atropine sulfate	Japan, China Asia EMEA		China	P2/3 Plan: FY2025 P2/3 completion	
Myopia				Asia	P2 (met primary endpoint)	
Wyopia			STN10 <b>127</b> 01 SYD-101	Europe	P3 (conducted by Sydnexis Inc.)  Plan: FY2024 P3 completion	
	AFDX0250BS	WW	STN10 <b>134</b> 00	Japan	P1 (confirmed safety and tolerability)  Plan: FY2023 P2a start	
				China	Plan: FY2023 P1 start	
Presbyopia	Ursodeoxycholic		STN10 <b>136</b> 00	US	Started P2a in December 2022  Plan: FY2023 P2a completion	
	acid		2111121233	Japan	P1 (confirmed safety and tolerability)	

## **Current status of global development (3)**

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
	Our was at a stalling	Japan, China	STN10 <b>138</b> 00	Japan	P3 Plan: FY2024 P3 completion
Ptosis	Oxymetazoline hydrochloride	Asia, EMEA Canada	RVL-1201	China	Plan: FY2023 P3 start
		Carlada		Asia	Plan: FY2022 Filing
Retinitis pigmentosa	jCell	Japan, China Asia, Europe	STN <b>60001</b> 00	-	P2 safety study (US, conducted by jCyte, Plan to complete in FY2022). Considering P3 plan
Allergic conjunctivitis	Epinastine HCl (Ophthalmic cream)	Japan	STN10 <b>114</b> 02	Japan	P3 (met primary endpoints)  Plan: FY2022 filing
Vernal	Ciclosporin WW STN10 <b>076</b> 03  Verkazia (In-house) DE-076C		<b>0</b> =1400=000	US	Launched
keratoconjunc- tivitis		China	Approved Plan: FY2023 launch		
	Diquafosol sodium	Japan, China	STN10 <b>089</b> 03	Japan	Launched in November 2022
Dry eye	(long-lasting) Diquas LX	Asia, Europe	DE-089C	Asia	Plan: FY2023 filing
Diy cyc	Olodaterol hydrochloride	WW	STN10 <b>141</b> 00	Japan	Started P1/2a in January 2023  Plan: FY2023 P1/2a completion

## **Current status of global development (4)**

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Fuchs endothelial corneal dystrophy	Sirolimus (eye drop)	<u></u> *1	STN10 <b>109</b> 04*1	US France India	P2a Plan: FY2024 P2a completion
Meibomian gland dysfunction	Sirolimus (eye drop)	WW (In-house)	STN10 <b>109</b> 05	Japan	P2a (not meet primary/secondary endpoints. But observed efficacy on some exploratory endpoints and detailed analysis in progress)
	Tafluprost / timolol maleate (combination) TAPCOM / TAPTIQOM	Japan, China Asia, Europe	STN10 <b>111</b> 01 DE-111A	China	P3 Plan: FY2023 P3 completion
Glaucoma	Lotomomeot	WW	STN10 <b>130</b> 01	Europe	Filed Plan: FY2023 approval
	Latarioprost	Latanoprost (In-house) DE-130A Catioprost	Asia	P3 (met primary endpoint)	

<sup>\*1</sup> Santen retains the option right for exclusive license of this program. Santen development code to be formally assigned to the product when Santen obtains exclusive license upon the completion of Phase II trial.

