

# **Become A Social Innovator**



# **Participants**



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# 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.
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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.

# Santen 2030

#### Toward 2030 and beyond

# Santen's VISION

# **Become A Social Innovator**

Orchestrate and mobilize key technologies and players around the world, to deliver happiness through vision.

### **GOAL**

Aim to reduce the loss of social and economic opportunities for people around the world due to eye conditions.

#### **STRATEGY**

- A Ophthalmology
  Innovation in Ophthalmology and Acceleration of Ecosystem Development
- B Wellness
  Awareness and Proactive Care toward Better Eye Condition
- C Inclusion
  Building Society that is Inclusive regardless of Visual Impairment

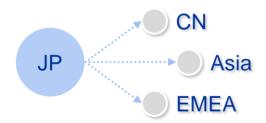
# **Evolution from Vision 2020 to Santen 2030**

Vision 2020 (2011-2020)

**Expanded global market** presence

Step 1
Expand overseas by leveraging
Japan's strengths

Santen as of 2011



Expand globally as a top player in Ophthalmology prescription market from Japan. Established global presence (excl. US)

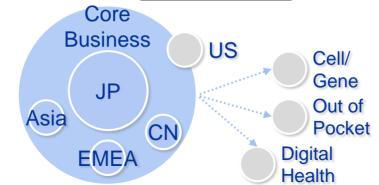
 Expanded presence in Asia and EMEA after acquiring Merck products in 2014 MTP2025 (2021-2025)

Transformation into a truly global → ophthalmology Rx company

Step 2

Enhancing globalization and entering new fields

Santen as of 2021

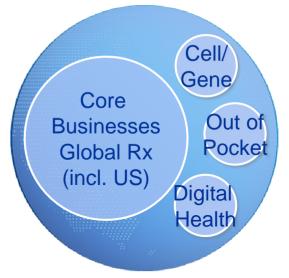


Maximize the value of core businesses. Leverage to enter new businesses and new areas

- Enter the US ophthalmic Rx market through the platform of Eyevance
- Invest in future growth areas such as cell and gene therapy, out of pocket market and digital health

Santen 2030 (2021-2030) - Become a Social Innovator

Step 3
Leader in ophthalmology



Achieve business consolidation in ophthalmic products, incl. US

Further evolve business model while expanding into new technology / out-of-pocket

To become a Social Innovator that contributes to society through the eyes

# EMT: Bolster organization and accelerate execution as a global company



# Agenda

# 1. Overview

- 2. FY2021 Financial Results
- 3. FY2022 Outlook
- 4. R&D Update

**Appendix** 

# Increased revenues, decline in Core profits Paving the way for medium-term growth

Profit ratio improvement in core businesses

#### Accelerating global profit growth

- > Revenue: JPY 266.3 bil. (+7%), Core OP: JPY 46.3 bil. (-7%)
- Contribution profit ratio by region
   Japan: Overseas(excl. US) = 66: 34 (excluding US)
- > Further focus on productivity and profitability enhancement (Consolidated OP CF +19% YoY)

# Expansion of new areas

### Achieved: Pipeline enhancement, Work in progress: U.S. profitability

- ➤ US: Slower growth momentum from new product launch delays and existing products sales Completed preparations as U.S. market-access platform
- > Progress in mid-to-long term growth drivers: Ptosis/Myopia/Presbyopia/Cell therapies

# Strengthening of foundation as a global company

#### **Steady progress**

- > Product development: Strengthen function in US & China, pipeline prioritization
- > Production: Strengthen cost competitiveness from new plants (Shiga and Suzhou)
- ➤ Management: Revamping to reinforce execution in strategy & governance
- > ESG: ESG metrics-linked executive compensation

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#### FY2021 Consolidated results

### Core operating profit: Below forecast and YoY decline

(JPY billions)	FY2	020	FY2021						
	Actual	vs Revenue	Actual	vs Revenue	YoY	Forecast	vs forecast		
Revenue	249.6	-	266.3	-	+6.7%	260.0	102%		
Cost of sales	98.2	39%	109.7	41%	+11.7%	101.0	109%		
Gross margin	151.4	61%	156.6	59%	+3.4%	159.0	98%		
SG&A expenses	77.2	31%	83.9	31%	+8.7%	81.0	104%		
R&D expenses	24.1	10%	26.4	10%	+9.4%	26.0	101%		
Core operating profit	50.1	20%	46.3	17%	-7.5%	52.0	89%		
Non core SG&A expense	2.4	1%	0.6	0%	-73.2%	0.4	159%		
Amortization on intangible assets associated with products	10.7	4%	9.7	4%	-8.6%	8.9	109%		
Other income	16.0	6%	1.0	0%	-93.5%	0.5	209%		
Other expenses	40.9	16%	1.1	0%	-97.2%	1.7	67%		
Operating profit	12.2	5%	35.9	13%	+194.5%	41.5	86%		
Finance income	1.3	1%	2.5	1%	+88.9%	0.9	283%		
Finance expenses	1.5	1%	1.2	0%	-18.8%	0.2	604%		
Share of loss of Investments accounted for using equity method	0.4	0%	1.6	1%	+348.6%	1.2	134%		
Profit before tax	11.7	5%	35.6	13%	+204.7%	41.0	87%		
Income tax expenses	2.6	1%	8.4	3%	+228.9%	10.5	80%		
Actual tax ratio	21.9%		23.7%		+1.7pt	25.6%	-1.9pt		
Net profit	9.1	4%	27.2	10%	+197.9%	30.5	89%		
ROE	3.0%		8.4%			10%			
Core net profit	37.5	15%	35.2	13%	-6.3%	39.0	90%		

#### **Gross Margin**

#### +3% YoY

- YoY revenues increase from sales expansion in each region
- Gross margin ratio slightly impacted from product mix and onetime contractual-related costs

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

#### -7% YoY

 Increased from carried-over domestic sales promotion expenses (JPY 0.9 bil), Eyevance consolidation, strategic investments (cell therapies, etc.) and FX impact

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

#### +194% YoY

 Other income and expenses: Reactionary drop of impairment loss on STN2000100 from previous year

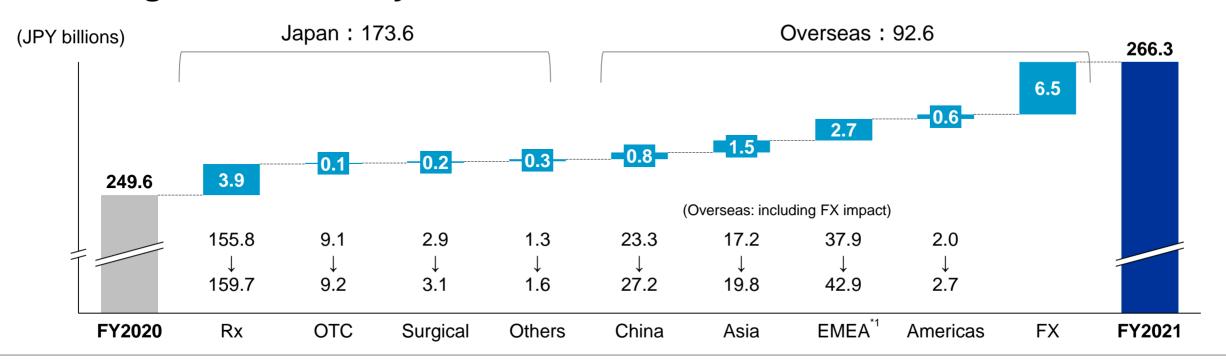
#### **Net Profit (IFRS)**

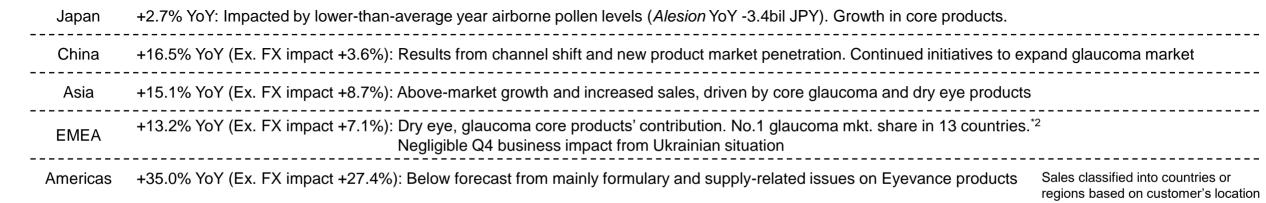
#### +198% YoY

• Increase in strategic invest. (equity-method investment loss)

# FY2020 ACT FY2021ACT FY2021FCST USD (JPY) 105.95 112.57 105.00 EUR (JPY) 123.73 130.75 125.00 CNY (JPY) 15.61 17.55 16.50

### Sales growth driven by overseas core businesses

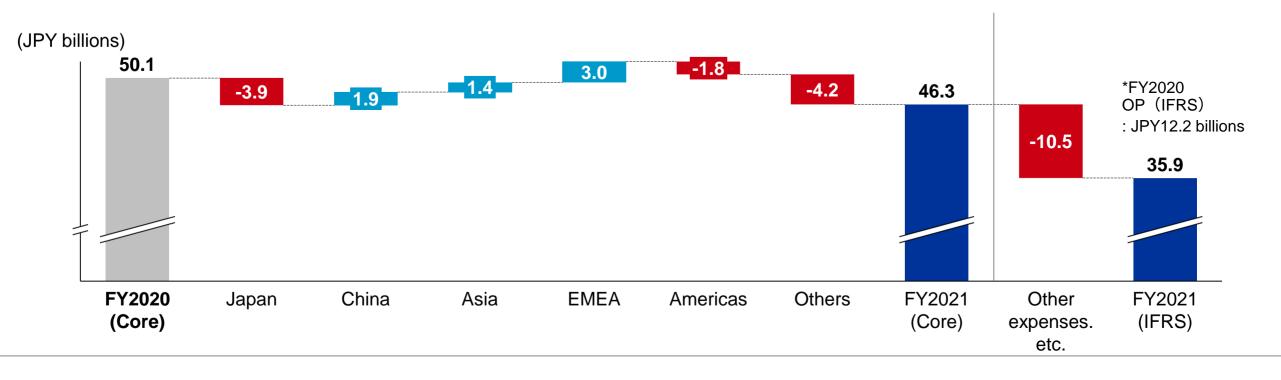


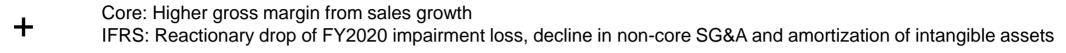




#### FY2021 Operating profit bridge

# **Decline in Core operating profit**





Core: Product mix, carried-over sales promotion expenses (JPY 0.9 billion), Eyevance delay in turning profitable, strategic investments and FX impact

Regions reported on Contribution profit basis. "Others" include global R&D expenses and indirect costs associated with service provided in each region

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#### FY2022-23: Transition to a resilient structure

2021 2022~2023 ~2025 FY2022 Revenue Revenue Revenue JPY 266.3bil. JPY 264.0bil. JPY315.0bil. (overseas: 35%) (overseas: 41%) (overseas: 50%) COGS COGS COGS 2. Increase revenue 36% 41% 39% 1. Prioritize & overseas sales profitability with improved SG&A SG&A SG&A profitability (incl. non-core SG&A) improvement 30% level 34% 32% Core OP Core OP Core OP 17% 17% 24% OP OP OP 13% 13% 21%

### Towards a global competitive company by building financial resilience

# Short/ Mid-tem impact Actions

#### Accelerate and strengthen strategy execution and governance through EMT

- > Core business: increase profitability of China/Asia/EMEA
- > Manufacturing: cost reduction through production efficiency and management
- > SG&A: optimization and Zero-based review of all costs
- > R&D expenses: prioritization and optimization of R&D pipeline
- > New business: accelerating all measures deemed necessary to turn U.S. profitable

# Long-term impact Actions

#### Strengthening foundations as a global company

- > Pipeline: building out by prioritizing projects and optimizing portfolio
- > Next generation ERP: firm-wide roll out to improve productivity

#### FY2022 Outlook

# -1% YoY revenue from price revisions in Japan. OP margins YoY flat. Transforming to deliver second-half of MTP2025

(JPY billions)	FY2	021	FY2022				
	Actual	vs Revenue	Forecast	vs Revenue	YoY		
Revenue	266.3	-	264.0	-	-0.8%		
Cost of sales	109.7	41%	103.0	39%	-6.1%		
Gross margin	156.6	59%	161.0	61%	+2.8%		
SG&A expenses	83.9	31%	88.5	34%	+5.5%		
R&D expenses	26.4	10%	27.0	10%	+2.4%		
Core operating profit	46.3	17%	45.5	17%	-1.8%		
Non core SG&A expense	0.6	0%	-	-	-		
Amortization on intangible assets associated with products	9.7	4%	10.3	4%	+5.8%		
Other income	1.0	0%	0.5	0%	-52.0%		
Other expenses	1.1	0%	1.5	1%	+32.4%		
Operating profit	35.9	13%	34.2	13%	-4.7%		
Finance income	2.5	1%	0.9	0%	-64.6%		
Finance expenses	1.2	0%	0.6	0%	-50.4%		
Share of loss of Investments accounted for using equity method	1.6	1%	2.0	1%	+24.7%		
Profit before tax	35.6	13%	32.5	12%	-8.7%		
Income tax expenses	8.4	3%	8.1	3%	-3.6%		
Actual tax ratio	23.7%		25.0%		+1.3pt		
Net profit	27.2	10%	24.4	9%	-10.3%		
ROE	8.4%		7%				
Core net profit	35.2	13%	34.1	13%	-3.1%		

#### **Gross margin**

#### +3% YoY

Impact by change in product mix and measures to reduce manufacturing costs

#### **Operating profit (core basis)**

#### -2% YoY

- Increase allocation to R&D from FY2021
- Reducing SG&A

#### **Operating profit (IFRS)**

-5% YoY

#### **Net profit (IFRS)**

#### -10% YoY

 Increase in strategic investments (equity-method investment loss)

# Accelerating global dissemination of Japan's "Commercial excellence" Improving productivity and profitability coupled with growth overseas

#### Revenue outlook

#### **Action items**

Japan

JPY156.0 bil.

- Maximize value of existing products
- Launch of new products/LCM products
- Improve diagnosis/adherence through digital tool

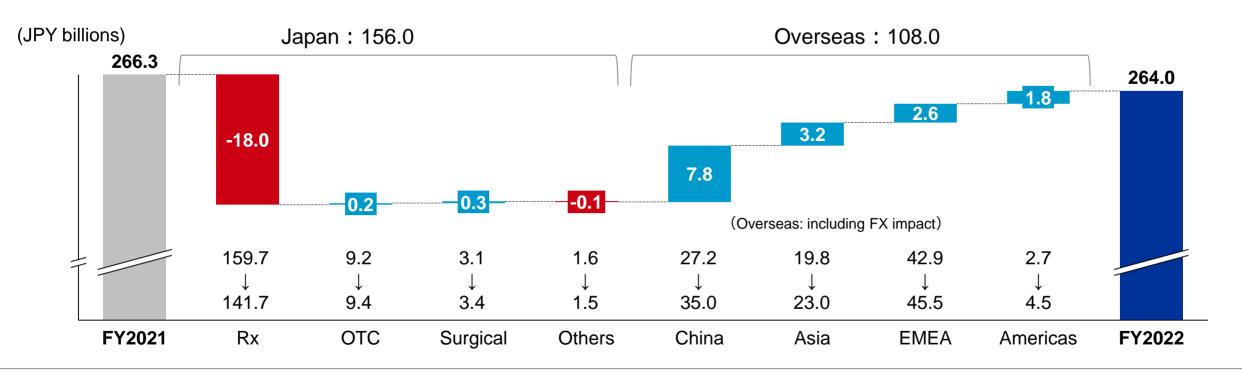


JPY108.0 bil. (YoY +17%) \*Overseas sales ratio: 41%

- China/Asia/EMEA:
  Core countries & Core products-centered growth with productivity increase through cost controls
- US: accelerate trajectory to turn profitable

# FY2021ACT FY2022FCST USD (JPY) 112.57 125.00 EUR (JPY) 130.75 135.00 CNY (JPY) 17.55 19.00

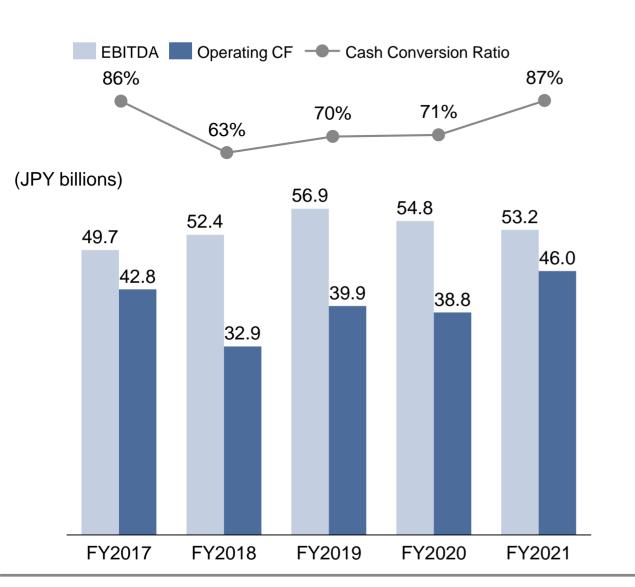
# Overseas core businesses-driven profit contribution expected

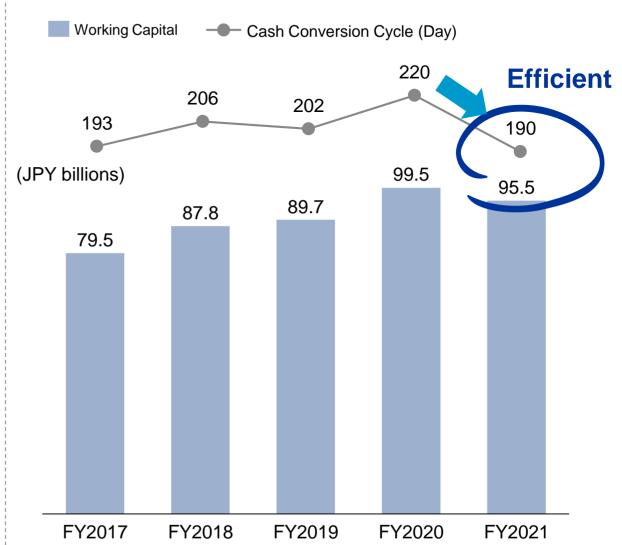


 Japan	-10% YoY: Impact of NHI price reduction including market expansion re-pricing for Alesion (mid -4% overall, -20% for Alesion)
China	+29% YoY (incl. FX impact): Mainly from new products ( <i>Tapros</i> and <i>Diquas</i> )
 Asia	+16% YoY (incl. FX impact): Mainly from core products (Cosopt, Diquas and Ikervis)
 EMEA	+6% YoY (incl. FX impact): Mainly from core products ( <i>Tapros, Tapcom, Ikervis</i> ) and <i>PRESERFLO Microshunt.</i> New products' ( <i>Ducressa</i> etc.) contribution expected
 Americas	+66% YoY (incl. FX impact): Sales growth from U.S. launch of <i>Verkazia</i> and other existing products

#### Cash flow

# Stable cash-generating ability





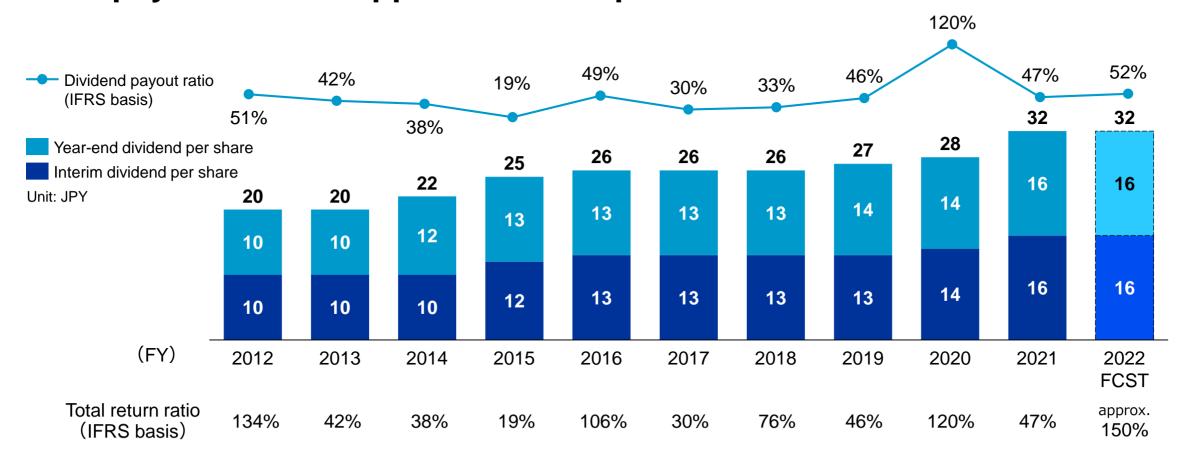
#### Cash allocation

### Proactive allocation to strategic investments and shareholder returns

MTP2025 policy **FY2022** Dividend maintained (annual JPY 32) Shareholder return: 1/3 or more of operating cash flow Dividend payout: 52% **Optimize** Dividend payout ratio of 40% or more Repurchase shares as additional + flexible share buybacks balance shareholder return measure between future growth and Total payout expected: approx. 150% BD investment: tens of billion JPY~ (accum.) shareholder Strategic investment for mid-/long-term growth R&D expenses: JPY 27.0bil Enhance Rx pipeline where strengths can be return leveraged New business areas Capital investment: JPY 100.0B (cum.) **Enhancement** Investment to maximize existing business CAPEX: JPY 25.0bil of core Capex for new facilities in Japan/China **business** Improvement of productivity through the implementation of next-generation ERP etc. Maintain necessary cash for business continuity (Secure working capital)

#### Shareholder returns

# Annual dividend of JPY32 (JPY16 for interim/year-end) Total payout ratio of approx. 150% expected for FY2022



FY2022 return ratio forecast includes the share buy-back announced on May 10. Calculations are based on J-GAAP until FY2013 and IFRS from FY2014 onwards. Dividend payout ratio and total return ratio in FY2020 are adjusted due to the completion of the allocation of consideration for acquisition of Eyevance. Share buy-back: Representing 2.0% of the total number of shares outstanding (excluding treasury shares) in FY2016 and FY2018



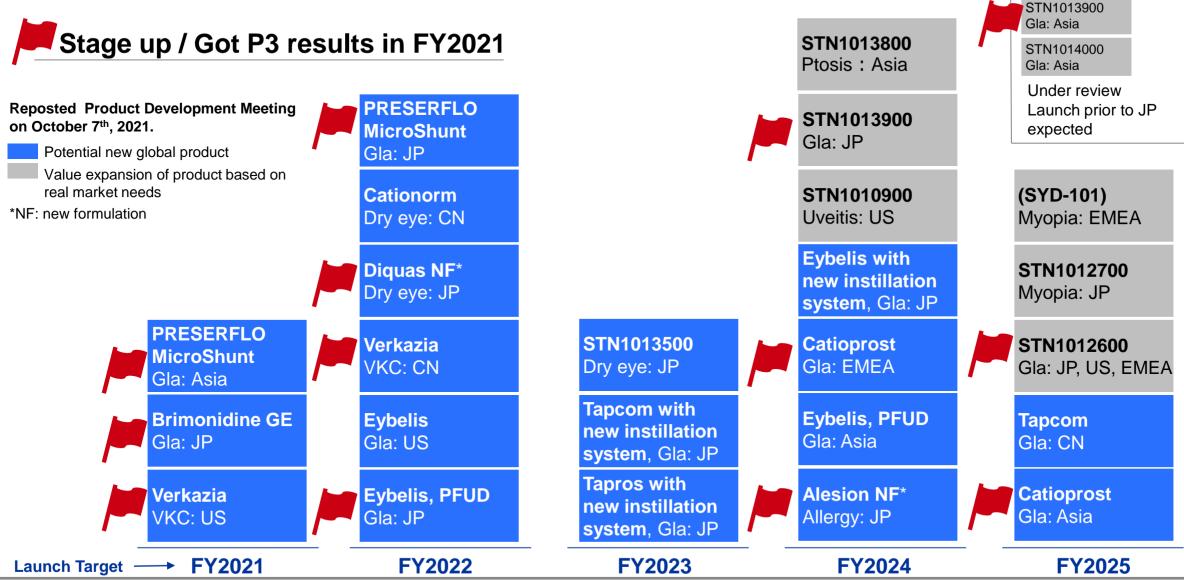
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# Progress in 12 of 24 projects with launch plans by FY2025



#### Q4 FY2021 R&D update

# Pipeline progress in core-business & new areas

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	STN10 <b>117</b> 02 EYBELIS PFUD	Approved as EYBELIS Mini ophthalmic solution 0.002% in Japan
	STN10 <b>126</b> 00 Sepetaprost	Started preparations for P3 trial in Japan
Glaucoma	STN <b>20001</b> 00 PRESERFLO MicroShunt	Approved in Japan
	STN10 <b>139</b> 00 Rhopressa®/Rhokiinsa®	Filed in Asia
	STN1013001 Catioprost	Met primary endpoint in P3 trial in Europe and Asia
Myopia	STN10 <b>127</b> 00 Atropine sulfate	Confirmed safety and tolerability in P1 trial in China Started preparations for P3 trial in China
Presbyopia	STN1013600 Ursodeoxycholic acid	Confirmed safety and tolerability in P1 trial in Japan Started preparations for P2a trial in US
Ptosis	STN1013800 Oxymetazoline hydrochloride	Started preparations for P3 trial in Japan Expanded licensed territories including additional EMEA countries and Canada
Allergic conjunctivitis	STN1011402 Epinastine ophthalmic cream	Achieved <b>FPI</b> <sup>*1</sup> in P3 trial in Japan
VKC*2	STN10 <b>076</b> 03 Verkazia	Launched in US. Approved in China
Uveitis	STN1010900 Sirolimus ivtravitreal injection	Discontinued development upon reassessment of business feasibility

# Aim to provide new treatment option for glaucoma in Europe / Asia

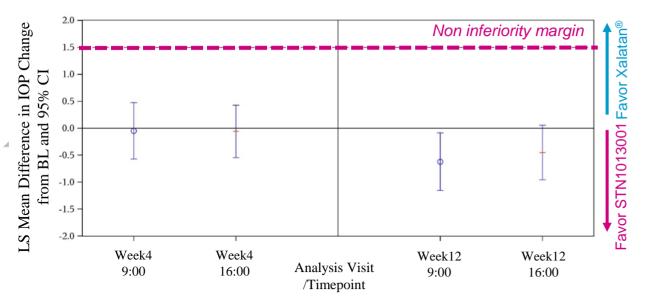
Item	Notes
Product	Latanoprost 50µg/mL eye drops emulsion in single-dose container (cationic emulsion)
	<ul> <li>The vehicle of STN1013001 is <u>similar to Cationorm®</u>, which is a product approved as artificial tears in many countries</li> </ul>
Background	Ocular Surface Disease (OSD) is an emerging problem in the management of glaucoma
	Glaucoma is a leading common cause of blindness worldwide
	<ul> <li>It is reported that up to 60% of glaucoma patients have ocular surface disease (OSD)*1 which manifest as signs and symptoms of dry eye disease</li> </ul>
	<ul> <li>OSD negatively influences QoL, compromises compliance and can jeopardize the efficacy of anti-glaucoma therapy*<sup>2</sup></li> </ul>
	<ul> <li>Santen developed STN1013001 as a glaucoma treatment that <u>reduces intraocular</u> <u>pressure</u> and also improves OSD</li> </ul>
Plan	Market Authorization Application (MAA) in FY2022 in Europe

<sup>\*1</sup> Erb et al. *Graefes Arch Clin Exp Ophthalmol* 2008;246:1593–160; Fechtner, et al. *Cornea* 2010;29:618–621; Leung et al. *J Glaucoma* 2008;17:350–355; Pai et al. *Asian J Ophthalmol* 2018;16:101-109. 
\*2 Rossi et al. *Eur J Ophthalmol* 2009;9:572-9; Zhang et al. *Eye Contact Lens* 2019;45(1):11–18.

# Achieved primary endpoint on IOP (non-inferiority vs Xalatan®), Superiority vs Xalatan® on key secondary endpoint (CFS)

#### **Primary endpoint**

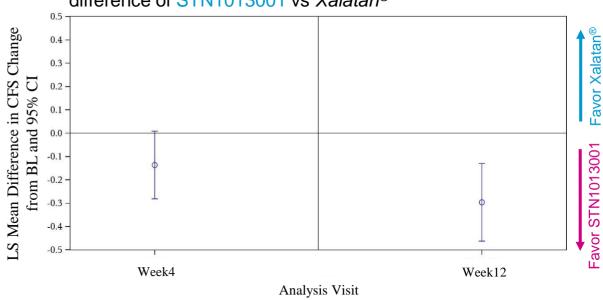
IOP LS mean treatment difference of STN1013001 vs Xalatan®



- STN1013001 statistically non-inferior to Xalatan<sup>®</sup> at all time points
- Superiority of STN1013001 showed at 9am (peak) at W12 vs Xalatan<sup>®</sup>

#### Key efficacy secondary endpoint

CFS (corneal fluorescein staining) LS Mean treatment difference of STN1013001 vs Xalatan®



 Superiority of STN1013001 was demonstrated vs Xalatan<sup>®</sup> at W12with a 0.3 CFS difference on modified Oxford Scale

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# Foreign exchange rate assumptions and sensitivities

#### **FX** rate

	FY2020 Actual	FY2021 Actual	FY2022 Forecast
USD	105.95	112.57	125.00
EUR	123.73	130.75	135.00
CNY	15.61	17.55	19.00

#### **Sensitivities**

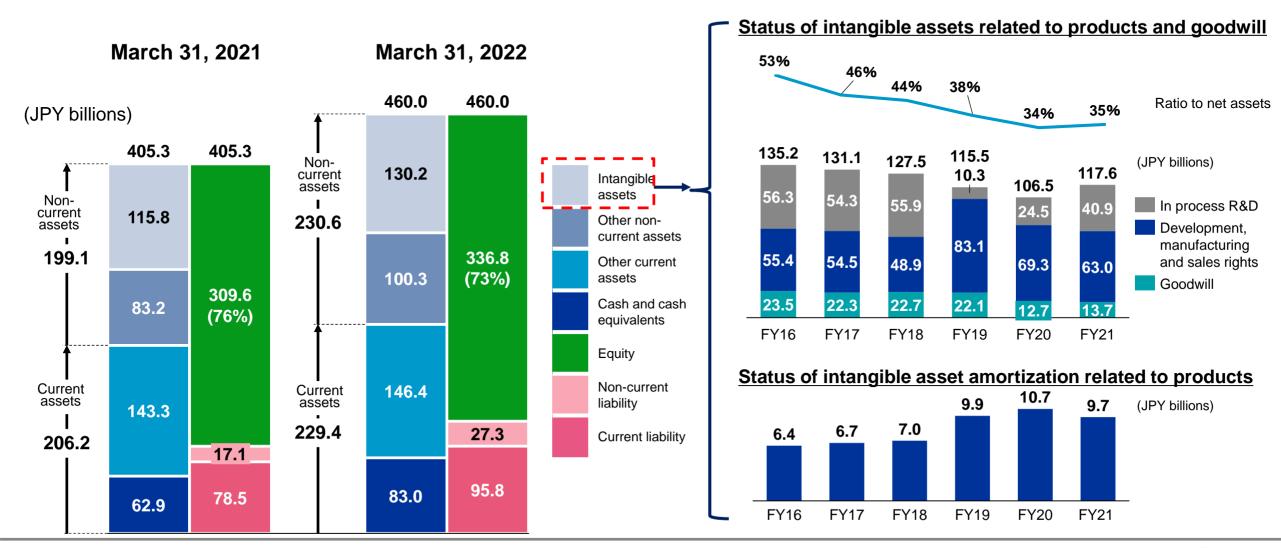
(JPY billions)

	USD	EUR	CNY
Revenue	+0.05	+0.45	+0.35
Core OP	-0.16	+0.05	+0.11

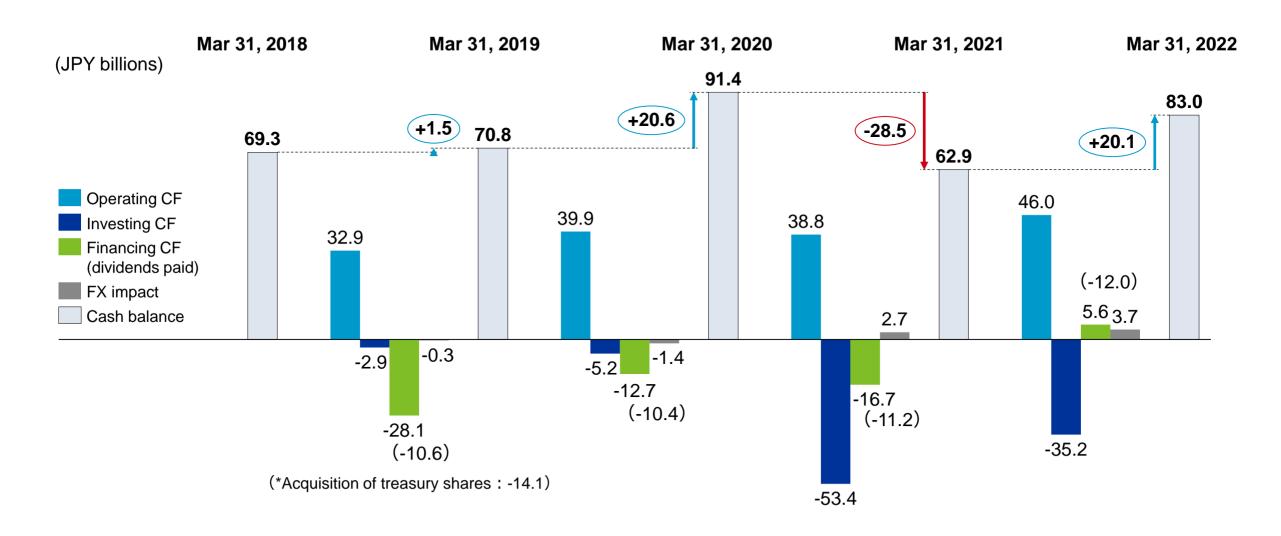
<sup>\*</sup>Impact of a 1% depreciation of the yen on revenue and core operating profit (vs FY2022 forecast rate)

#### FYE March 2022 financial position

# Appropriate balance between financial health & assets increase from investments. Aim for ROE improvement through capital turnover



### **Cash flow**

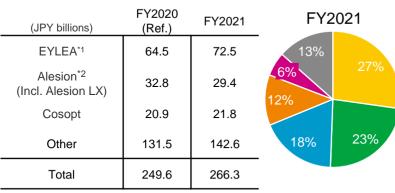


# Revenue and contribution profit by region

Upper: Revenue Lower: Contribution profit (JPY billions) China **Asia EMEA Americas** Japan 35.0 23.0 173.6 45.5 4.5 169.1 165.0 42.9 156.0 19.8 37.9 37.0 27.2 17.2 16.5 23.3 22.3 2.7 2.0 0.7 FY20 FY21 FY22 FY20 FY22 FY22 FY20 FY21 FY22 FY20 FY19 FY21 FY19 FY21 FY19 FY19 FY21 FY22 (FCST) (FCST) (FCST) (FCST) (FCST) 70.0 11.6 8.3 14.3 70.1 66.2 10.2 9.7 6.9 11.4 9.9 5.7 -1.8 -2.6 -4.4 FY20 FY21 FY20 FY21 FY20 FY20 FY21 FY19 FY20 FY21 **FY19** FY19 FY19

### FY2021 revenue by region

# Consolidated

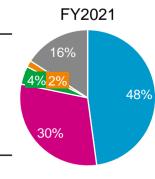


#### <u>Japan</u>

(JPY billions)	FY2020 (Ref.)	FY2021	FY2021
EYLEA*1	64.5	72.5	14%
Alesion*2 (Incl. Alesion LX)	32.7	29.3	2% <sup>14%</sup> 11%
Diquas	12.3	13.3	14%
Other	59.7	58.5	17%
Total	169.1	173.6	1770

#### China

(JPY billions)	FY2020 (Ref.)	FY2021	_
Hyalein	9.3	8.9	1
Cravit	7.9	7.0	4%2
Diquas	0.7	4.1	
Other	5.4	7.2	30%
Total	23.3	27.2	



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

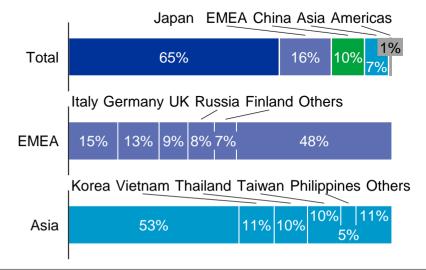
(JPY billions)	FY2020 (Ref.)	FY2021	FY2021
Cosopt	4.5	5.2	14%
Hyalein	2.2	2.4	1% 14% 45%
Tapros	1.9	2.1	
Other	8.7	10.2	27%
Total	17.2	19.8	

#### **EMEA**

(JPY billions)	FY2020 (Ref.)	FY2021	FY2021
Cosopt	9.5	10.9	3%
Tapros	6.7	6.8	2%
Ikervis	3.6	4.7	22%
Other	18.1	20.4	
Total	37.9	42.9	
			•
Allergy Bac	terial conjur	nctivitis	Others

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

#### Revenue in each region (FY2021)





Intravitreal VEGF inhibitor Glaucoma/Device

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

#### Financial results (IFRS)

# **Quarterly consolidated statements of income**

			FY2020					FY2021			FY2022
(JPY millions)	Q1	Q2	Q3	Q4	Full	Q1	Q2	Q3	Q4	Full	Full Forecast
Revenue	57,563	61,342	62,881	67,819	249,605	64,986	63,773	67,042	70,456	266,257	264,000
YoY	-2.7%	2.9%	-1.1%	14.5%	3.3%	12.9%	4.0%	6.6%	3.9%	6.7%	-0.8%
Cost of sales	-24,741	-24,964	-26,192	-22,324	-98,221	-26,924	-25,943	-29,837	-26,967	-109,671	-103,000
YoY	2.6%	3.2%	0.5%	9.0%	3.6%	8.8%	3.9%	13.9%	20.8%	11.7%	-6.1%
(Percent of revenue)	43.0%	40.7%	41.7%	32.9%	39.4%	41.4%	40.7%	44.5%	38.3%	41.2%	39.0%
Gross profit	32,822	36,377	36,690	45,495	151,384	38,062	37,829	37,205	43,489	156,586	161,000
YoY	-6.3%	2.6%	-2.1%	17.4%	3.2%	16.0%	4.0%	1.4%	-4.4%	3.4%	2.8%
(Percent of revenue)	57.0%	59.3%	58.3%	67.1%	60.6%	58.6%	59.3%	55.5%	61.7%	58.8%	61.0%
SG&A expenses	-15,551	-17,691	-19,579	-26,732	-79,554	-20,447	-19,205	-20,671	-24,176	-84,499	-88,500
YoY	-3.1%	1.8%	0.9%	30.2%	8.4%	31.5%	8.6%	5.6%	-9.6%	6.2%	5.5%
(Percent of revenue)	27.0%	28.8%	31.1%	39.4%	31.9%	31.5%	30.1%	30.8%	34.3%	31.7%	33.5%
R&D expenses	-5,616	-5,507	-6,530	-6,459	-24,112	-6,121	-6,218	-6,464	-7,574	-26,377	-27,000
YoY	-9.0%	5.1%	13.8%	4.4%	3.3%	9.0%	12.9%	-1.0%	17.3%	9.4%	2.4%
(Percent of revenue)	9.8%	9.0%	10.4%	9.5%	9.7%	9.4%	9.7%	9.6%	10.8%	9.9%	10.2%
Amortization on intangible assets associated with products	-2,448	-2,430	-2,866	-2,907	-10,650	-2,421	-2,366	-2,468	-2,479	-9,734	-10,300
YoY	-1.2%	-1.2%	15.7%	16.7%	7.6%	-1.1%	-2.6%	-13.9%	-14.7%	-8.6%	5.8%
(Percent of revenue)	4.3%	4.0%	4.6%	4.3%	4.3%	3.7%	3.7%	3.7%	3.5%	3.7%	3.9%
Other income	176	174	174	15,483	16,007	120	82	116	724	1,043	500
Other expenses	-1,367	-253	330	-39,599	-40,889	-39	-473	-143	-478	-1,133	-1,500
Operating profit	8,016	10,670	8,219	-14,718	12,187	9,156	9,650	7,575	9,505	35,886	34,200
YoY	-13.3%	9.3%	-17.2%	_	-63.7%	14.2%	-9.6%	-7.8%	_	194.5%	-4.7%
(Percent of revenue)	13.9%	17.4%	13.1%	_	4.9%	14.1%	15.1%	11.3%	13.5%	13.5%	13.0%

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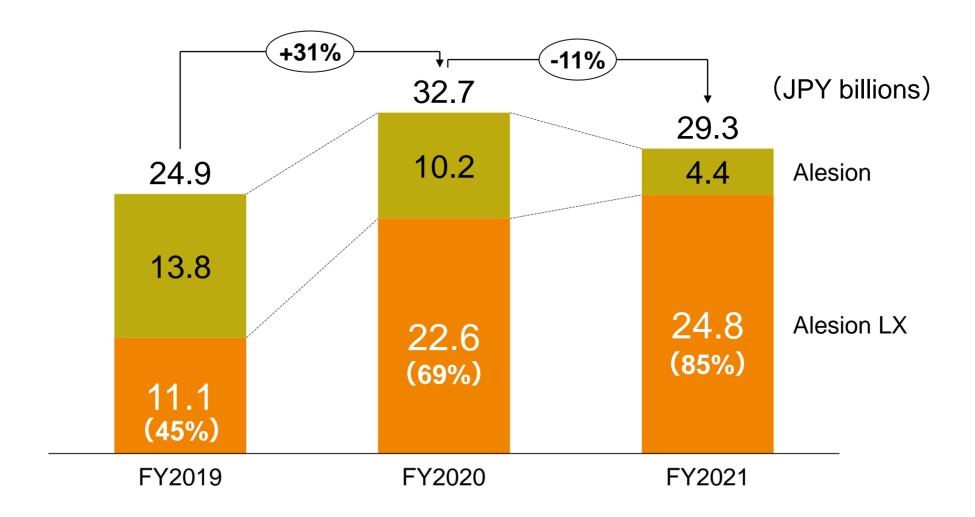
#### Financial results (core basis)

# **Quarterly consolidated statements of income**

(JPY millions)	FY2020					FY2021					FY2022
	Q1	Q2	Q3	Q4	Full	Q1	Q2	Q3	Q4	Full	Full Forecast
Revenue	57,563	61,342	62,881	67,819	249,605	64,986	63,773	67,042	70,456	266,257	264,000
YoY	-2.7%	2.9%	-1.1%	14.5%	3.3%	12.9%	4.0%	6.6%	3.9%	6.7%	-0.8%
Cost of sales	-24,741	-24,964	-26,192	-22,324	-98,221	-26,924	-25,943	-29,837	-26,967	-109,671	103,000
YoY	2.6%	3.2%	0.5%	9.0%	3.6%	8.8%	3.9%	13.9%	20.8%	11.7%	-6.1%
(Percent of revenue)	43.0%	40.7%	41.7%	32.9%	39.4%	41.4%	40.7%	44.5%	38.3%	41.2%	39.0%
Gross profit	32,822	36,377	36,690	45,495	151,384	38,062	37,829	37,205	43,489	156,586	161,000
YoY	-6.3%	2.6%	-2.1%	17.4%	3.2%	16.0%	4.0%	1.4%	-4.4%	3.4%	2.8%
(Percent of revenue)	57.0%	59.3%	58.3%	67.1%	60.6%	58.6%	59.3%	55.5%	61.7%	58.8%	61.0%
Operating profit	11,655	14,035	10,738	13,673	50,101	11,713	12,593	10,247	11,794	46,348	45,500
YoY	-8.9%	9.3%	-13.0%	13.5%	0.2%	0.5%	-10.3%	-4.6%	-13.7%	-7.5%	-1.8%
(Percent of revenue)	20.2%	22.9%	17.1%	20.2%	20.1%	18.0%	19.7%	15.3%	16.7%	17.4%	17.2%

**\$**anten

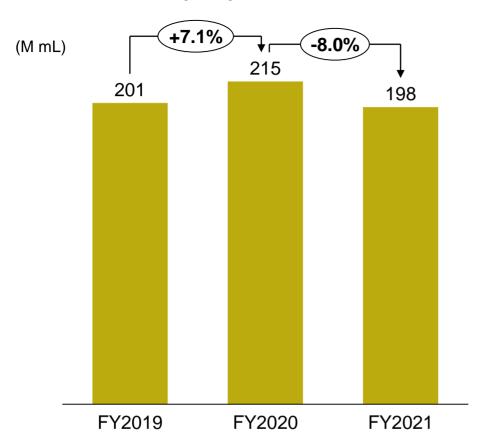
### Alesion revenue



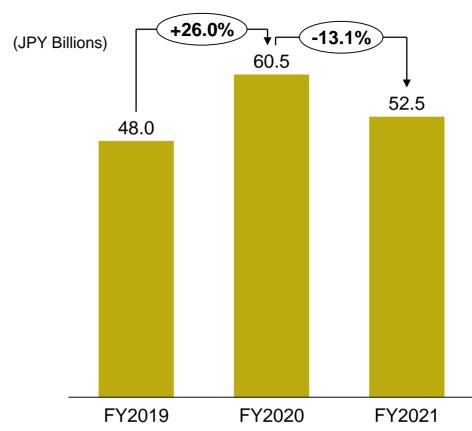
## **Allergy market**

- Market size shrank on lower than normal airborne pollen level
- GE launch of major products such as *Alesion* also impacted the market growth on a value basis

#### Volume (mL) basis



#### Value basis

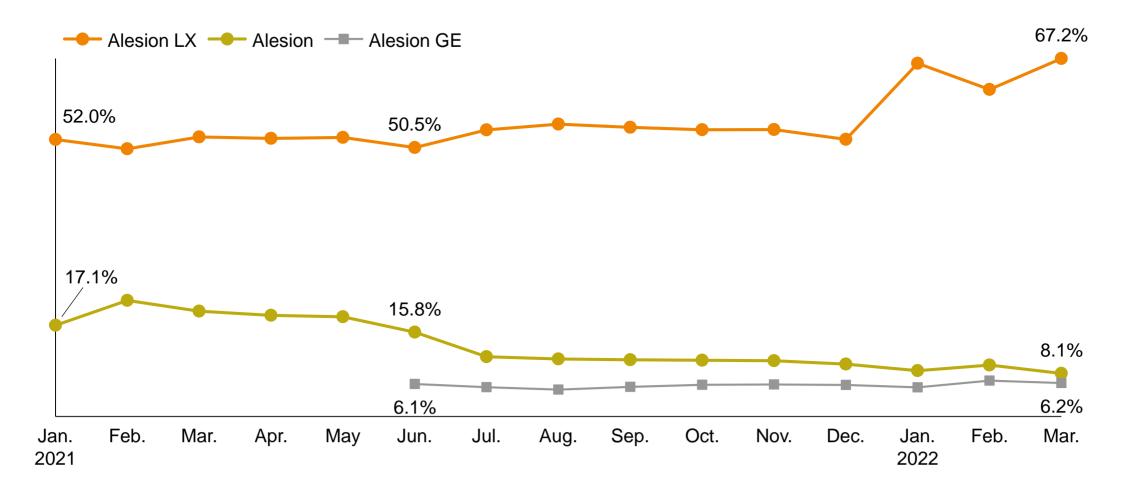


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#### Japan

## Alesion market share in allergy market (value basis)



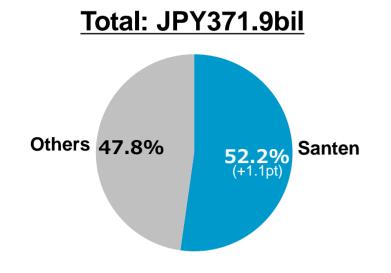
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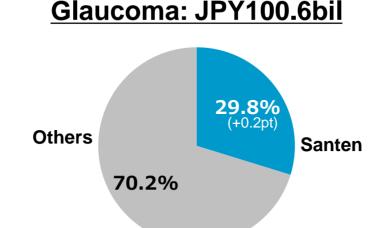


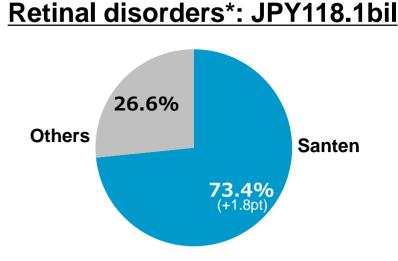
### Remain No.1 for overall market and all segments

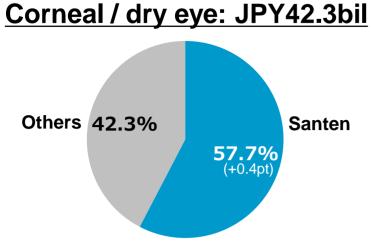
Segment: Market size

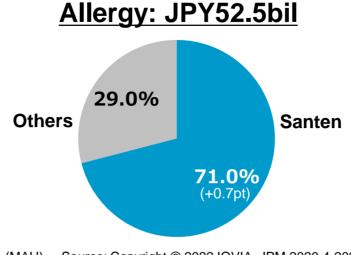
Graph: Market share (change from last year)

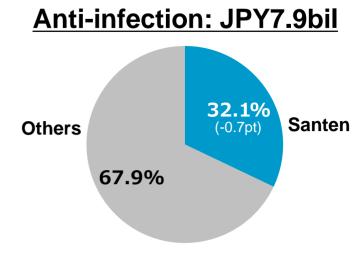








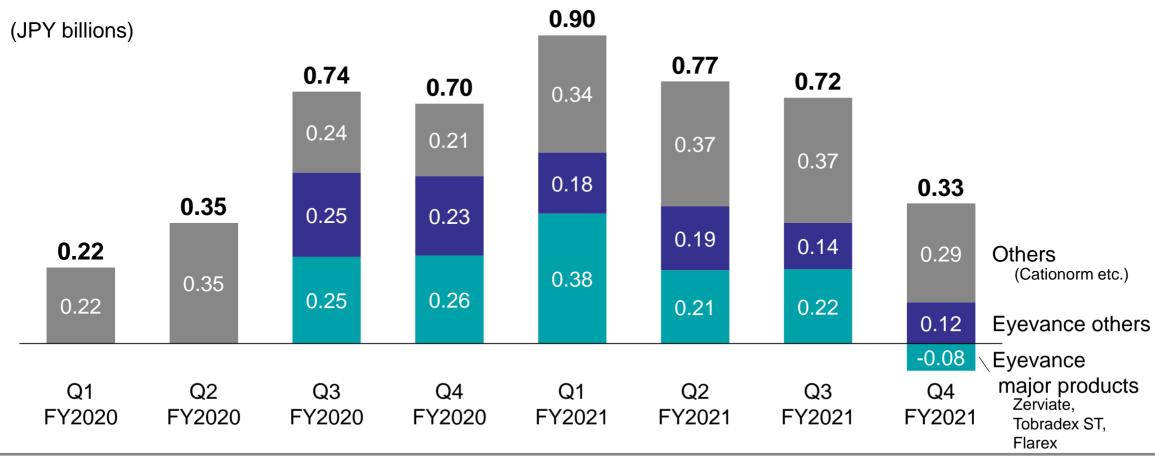




\*Including co-promoted product (Anti-VEGF EYLEA) of Bayer Yakuhin, Ltd. (MAH) Source: Copyright © 2022 IQVIA. JPM 2020.4-2022.3; Santen analysis based on IQVIA data. Reprinted with permission.

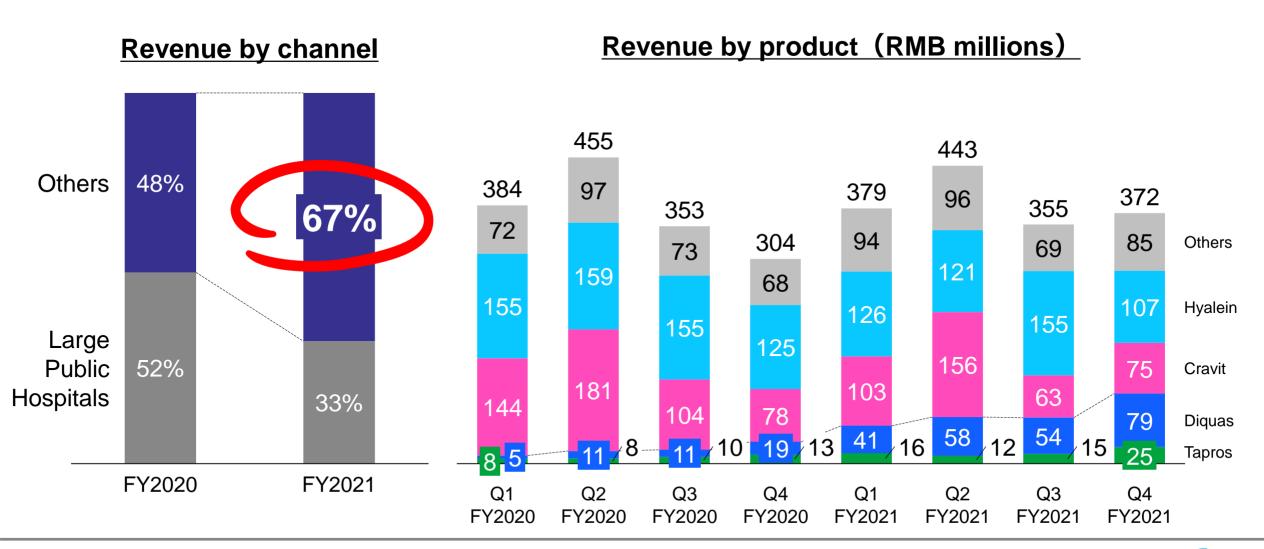
#### **Americas**

#### Americas business revenue trend



#### China

## Maintaining growth trend in channel shift and new products



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

Indication	Generic Name	Contractual territory	Dev. Code	Development Status <sup>*1</sup>	
	Omidenepag isopropyl EYBELIS	WW* <sup>2</sup>	<b>STN1011700</b> DE-117	US	Received CRL from FDA in November 2021  Plan: May 2022, re-filing
				Japan	Launched
				Asia	Launched
Glaucoma	Sepetaprost	WW	<b>STN1012600</b> DE-126	US	P2 (met primary endpoint)
				Japan	P2b (dose finding study completed)  Plan: FY2022 P3 start
				Europe	P2 (exploratory study) Plan: FY2022 P2 (exploratory study) completion
	Implant device PRESERFLO MicroShunt	WW (In-house) *Excl. Americas, Australia, New Zealand	<b>STN2000100</b> DE-128	Japan	Approved in February 2022  Plan: FY2022 soft launch
				Europe	Launched
				Asia	Approved Plan: FY2022 launch

License-out to Glaukos in Americas, Australia and New Zealand in May 2021.

US: Received a not approvable letter of PMA from FDA

Canada: Approved. Australia: Approved.

<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 mesylate Rhopressa®/Rhokiinsa®	Japan, China Asia, Europe	<b>STN1013900</b> AR-13324	Japan	P3 Plan: FY2023 P3 completion
Glaucoma				Asia	Filed in March 2022  Plan: FY2023 approval
	Netarsudil mesylate /latanoprost Japa (combination) Asia		<b>STN1014000</b> PG-324	Asia Plan: FY2022 filing	
	Atropine sulfate	Japan, China Asia	<b>STN1012700</b> DE-127	Japan	P2/3 Plan: FY2023 P2/3 completion
				China	P1 (confirmed safety and tolerability)  Plan: FY2022 P3 start
Myopia				Asia	P2 (met primary endpoint)
		EMEA	<b>STN1012701</b> SYD-101	Europe	P3 (conducted by Sydnexis Inc.)  Plan: FY2024 P3 completion
	AFDX0250BS	WW	STN1013400	Japan	P1 (confirmed safety and tolerability)
Presbyopia	Ursodeoxycholic acid	WW (In-house)	STN1013600	US	Plan: FY2022 P2a start
. roosyopia				Japan	P1 (confirmed safety and tolerability)

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

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Ptosis	Oxymetazoline hydrochloride	Japan, China Asia, EMEA Canada	<b>STN1013800</b> RVL-1201	Japan	Plan: FY2022 P3 start
1 10313				Asia	Plan: FY2022 Filing
Retinitis pigmentosa	jCell	Japan, China Asia, Europe	STN6000100	-	P2 safety study (US, conducted by jCyte, Plan to complete in FY2022). Considering P3 plan
Allergic conjunctivitis	Epinastine HCI (Ophthalmic cream)	Japan	STN1011402	Japan	Started P3 in February 2022  Plan: FY2022 P3 completion
Vernal	Ciclosporin <i>Verkazia</i>	WW (In-house)	<b>STN1007603</b> DE-076C	US	Launched in May 2022
keratoconjunc- tivitis				China	Approved in April 2022  Plan: FY2022 launch
Dry eye	Diquafosol sodium (long-lasting) Diquas	Japan, China Asia, Europe	<b>STN1008903</b> DE-089C	Japan	Filed Plan: FY2022 Approval
Fuchs endothelial corneal dystrophy	Sirolimus (eye drop)	*1	STN1010904*1	US France India	P1 completion (Japan)  Plan: FY2022 P2a start
Meibomian gland dysfunction	Sirolimus (eye drop)	WW (In-house)	STN1010905	Japan	P2a Plan: FY2022 P2a completion

<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.

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

Indication	Generic Name	Contractual territory	Dev. Code	Development Status		
	Tafluprost / timolol maleate (combination) TAPCOM / TAPTIQOM	Japan, China Asia, Europe	<b>STN1011101</b> DE-111A	China	P3 Plan: FY2023 P3 completion	
Glaucoma	Latanoprost	WW (In-house)	STN1013001 DE-130A Catioprost	Europe	P3 (met primary endpoint)  Plan: FY2022 filing	
				Asia	P3 (met primary endpoint)	

STN1010900 (sirolimus invtravitreal injection): the Company has discontinued development upon reassessment of business feasibility.

# **FY2021 Results: Progress of main pipelines**

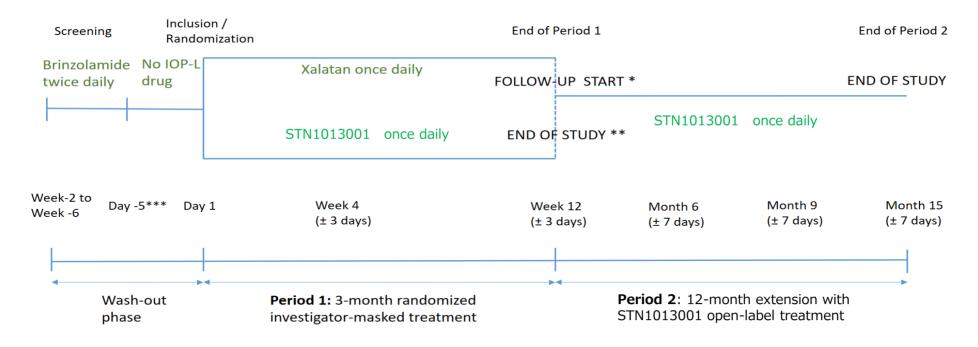
		~ Phase 2	Phase 3/Filing	Approval/Launch
	New pipeline	STN10 <b>126</b> 00 Additional P2 completion (US) Exploratory P2 start (Europe)	STN10 <b>139</b> 00 NDA (Asia)	STN2000100 Approval (Japan, Asia)
Pipe for core t	New pipeline	STN10 <b>109</b> 05 P2a start (Japan)	STN10 <b>130</b> 01 P3 completion (Europe, Asia)	STN10 <b>076</b> 03 Launch (US), Approval (China)
Pipeline core business	LCM		STN10 <b>089</b> 03 NDA (Japan)	STN10 <b>117</b> 02 Approval (Japan)
	Lom		STN10 <b>114</b> 02 P3 start (Japan)	Total 10 products launched in Asia Total 22 products launched in EMEA
New gr		STN1013400 P1 completion (Japan)		
New growth potential		STN10 <b>136</b> 00 P1 start (Japan)		Glaucoma
tential		STN1012700 P1 completion (China)		Anterior Chamber Disease Other ophthalmic Disease

# Plan for FY2022 and beyond: Progress in main pipelines

		~ Phase 2	Phase 3/Filing	Approval/Launch
fo		STN10 <b>126</b> 00 Exploratory completion (Europe) P2 (US)	STN10 <b>130</b> 01 NDA (Europe), P3 (Asia)	STN10 <b>117</b> 00 NDA, Approval (US)
			STN10 <b>139</b> 00 NDA (Asia) P3 (Japan)	STN10 <b>117</b> 02 Launch (Japan)
r cor	New pipeline	STN10 <b>109</b> 04 P2a start (US etc.)	STN10 <b>140</b> 00 NDA (Asia)	STN2000100 Launch (Japan, Asia)
peli e bı	New pipeline	STN10 <b>109</b> 05 P2a completion(Japan)	31111014000 NDA (ASIA)	31112000100 Laurich (Japan, Asia)
Pipeline for core business			STN1011103 P3 (China)	STN10 <b>076</b> 03 Launch(China)
SS			STN10 <b>126</b> 00 P3 start (Japan)	
	LCM		STN10 <b>114</b> 02 P3 completion (Japan)	STN10 <b>089</b> 03 Approval (Japan)
		STN10 <b>134</b> 00 P1(Japan)	STN1013800 P3 start (Japan), NDA (Asia	
Z Z		STN10 <b>136</b> 00 P1 (Japan)	STN10 <b>127</b> 00 P3 (Japan), P3 start (China)	
New growth potential			STN10 <b>127</b> 01 P3 (Europe)	Glaucoma
			STN10 <b>136</b> 00 P2a (US)	<ul><li>Anterior Chamber Disease</li><li>Retinal Diseases</li><li>Other ophthalmic Disease</li></ul>
			STN6000100 Considering pivotal study plan	Milestone in FY2022

## STN1013001: P3 study design

3-month phase III study, prospective, interventional, multinational, multicenter investigator-masked, randomized, active-controlled trial to demonstrate the non-inferior IOP reducing effect of STN1013001 (latanoprost 50 µg/mL preservative-free eye drops emulsion) compared to *Xalatan*<sup>®</sup> (latanoprost 50 µg/mL BAK-preserved eye drops) over a 12 weeks treatment period (Period 1) in patients with OAG or OHT. In addition, after Week 12, a 12-month follow-up with open-label STN1013001 in a subgroup of subjects (n=130) and some Belgium subjects will estimate the long-term safety and tolerance and explore the long-term efficacy of STN1013001 (Period 2).



<sup>\*</sup> Start of the open-label DE-130A 12-month safety follow-up for the first 130 patients who complete their Week 12 visit and agree to participate in the open-label period of the study. \*\* End of study for patients who do not participate in the open-label period of the study. \*\* Brinzolamide will be stopped 5 days before randomisation (6 to 7 days if over the weekend). At Day 1, if IOP is <22 mmHg, the wash-out period can be extended and the IOP should be re-assessed two to three days after the first measurement. If the IOP is still < 22 mmHg at the second measurement. If the IOP is still < 22 mmHg at the third measurement, the patient cannot be randomized in the study.

