# **FY2020 Financial Results**

Presentation: May 12, 2021 Santen Pharmaceutical Co., Ltd.



Copyright© 2021 Santen All rights reserved.

## **Speakers**

Presentation/Q&A

### Shigeo Taniuchi

**President & Chief Executive Officer** 

### Kenji Morishima

Corporate Officer, Head of China Product Development Department

<u>Q&A</u>

### Kazuo Koshiji

Senior Corporate Officer, Chief Financial Officer, Head of Finance and Administration Division

### Satoshi Suzuki

Senior Corporate Officer, Head of Corporate Development Division



### **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 conditions 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 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 is reliant on specific companies for supplies of certain raw materials used in production. Business performance could be affected significantly by the suspension or termination of supplies of such raw materials if such an event were to adversely affect supply capabilities for related final products.



### **CORE PRINCIPLE and WORLD VISION**

CORE PRINCIPLE

天機に参与する

Tenki ni sanyo suru

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

WORLD VISION

# **Happiness with Vision**

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

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



# Agenda

1. Vision 2020 Review

2. FY2020 Results

3. FY2021 Business Plan, and Key Growth Drivers

4. Direction for MTP2025

5. R&D Update

Appendix



## Agenda

1. Vision 2020 Review

2. FY2020 Results

3. FY2021 Business Plan, and Key Growth Drivers

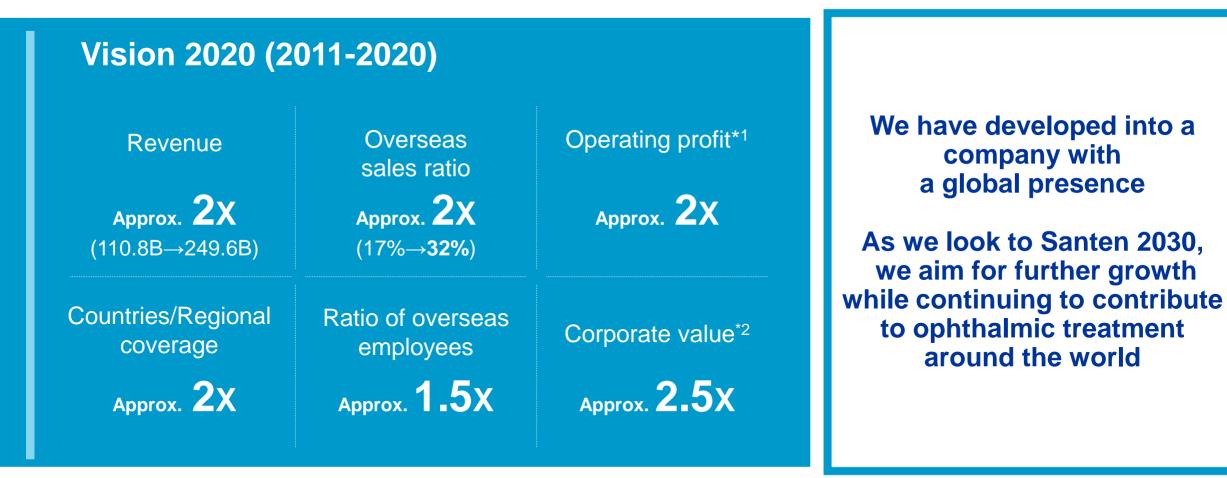
4. Direction for MTP2025

5. R&D Update

Appendix



## **Vision 2020 Highlights**



\*1. Core based. Calculated by excluding milestone income from operating profit in FY2010.

\*2. Corporate value: market capitalization + (interest-bearing debt - cash and cash equivalents - current investment securities) + non-controlling interest



### From Vision 2020 to Santen 2030

### What we have achieved

Vision 2020: Evolved into a "Specialized Pharmaceutical Company with a Global Presence"

> Rapidly expanded presence in each region by capturing inorganic growth as well as organic growth

Establish new organizational capabilities such as regulatory affairs, production and supply while entering and expanding sales in new countries

Evolved into a global organization

Drove growth by investing in R&D and business development



### Challenges

Archiving balance between strategic investment and profitability

Profit margin/ROE declined despite growth

Further clarification of financial discipline in investment decisions and value maximization of existing assets will be key

#### Improving the profit margin

While sales and profits increased, expenses for regional and business expansion depressed profit margins

Necessary to optimize SG&A and COGS

#### Establishing a global organization

Enhancing development and leadership capabilities is a work in progress

### Strengthening quality and quantity of external disclosures

Provide more concrete strategies/plans with numerical targets to address investor concerns



## Solidify Core Businesses for MTP2025

In FY2021, the first year of MTP2025, focus on steady growth by capitalizing on the foundation established in FY2020. Launch business in new areas by leveraging the potential of ophthalmology

#### **FY2020**

#### **Business performance**

- Sales
- Core OP

- 249.6B yen 50.1B ven
- **Operating profit**
- 12.9B ven

#### What we have achieved

- Strengthened global business platform
  - Achieved market share gains and sales growth in Japan, Asia and EMEA in excess of market growth

#### Expanded product portfolio

- Acquired new pipeline
- Promoted initiatives to meet I CM and various unmet needs

#### **FY2021**

#### Business performance (forecast)

260.0B yen

52.0B ven

41.5B ven

- Sales
- Core OP
- Operating profit

#### What we aim to achieve

- Maximize customer engagement in Japan, China, Asia and EMEA
- Strengthen business platform in North America
  - Complete integration with Evevance
- Global launches from abundant product pipeline
- Promote efficiency and globalization
  - e.g., New plants in China and Shiga (Japan), ERP system

#### **FY2025**

#### Business performance (target)

 To be announced as a part of MTP2025 on May 19

#### What we aim to achieve

- Further strengthen global presence and improve profitability in Rx business
- Achieve growth by leveraging the potential of ophthalmology
- Steady implementation of growth strategies for Santen 2030



# Agenda

1. Vision 2020 Review

2. FY2020 Results

3. FY2021 Business Plan, and Key Growth Drivers

4. Direction for MTP2025

5. R&D Update

Appendix



# FY2020 Consolidated Results (YoY): Revenue - Core OP Growth on revenue and core operating profit despite impact of COVID-19

	FY2019		FY2020			
(JPY billions)	Actual	vs Revenue	Actual	vs Revenue	YoY	
Revenue	241.6		249.6		+3.3%	
Cost of sales	94.8	39%	98.2	39%	+3.6%	
Gross margin	146.7	61%	151.4	61%	+3.2%	
SG&A expenses	73.4	30%	77.2	31%	+5.2%	
R&D expenses	23.3	10%	24.1	10%	+3.3%	
Core operating profit	50.0	21%	50.1	20%	+0.2%	

USD (JPY)	108.81	105.95
EUR (JPY)	120.80	123.73
CNY (JPY)	15.64	15.61

#### Revenue

Increased revenue from FY2019 through activities in response to the new normal despite COVID-19 impact

#### Revenue JPY249.6 billion (+3%)

#### **Core OP**

Increased in profit with optimization of costs

#### Core OP JPY50.1 billion (+0%)

Lower than the revised consolidated forecasts announced on April 9 due to increase in overseas SG&A



## FY2020 Consolidated Results (YoY): Core OP - Net Profit

Operating profit and net profit decreased due to impairment loss

	FY2019		FY2020		
(JPY billions)	Actual	vs Revenue	Actual	vs Revenue	YoY
Core operating profit	50.0	21%	50.1	20%	+0.2%
Non core SG&A expense			2.4	1%	
Amortization on intangible assets associated with products	9.9	4%	9.9	4%	+0.2%
Other income	0.4	0%	16.0	6%	
Other expenses	7.0	3%	40.9	16%	
Operating profit (IFRS basis)	33.5	14%	12.9	5%	-61.5%
Finance income	1.0	0%	1.3	1%	+41.7%
Finance expenses	2.4	1%	1.5	1%	-37.8%
Share of loss of Investments accounted for using equity method			0.4	0%	
Profit before tax	32.1	13%	12.4	5%	-61.3%
Income tax expenses	10.4	4%	5.8	2%	-44.4%
Actual tax ratio	32.3%		46.5%		
Net profit (IFRS basis)	21.7	9%	6.6	3%	-69.4%
ROE	8.0%		2.2%		
Core net profit	35.9	15%	37.5	15%	+4.6%
USD (JPY)	108.81		105.95		
EUR (JPY)	120.80		123.73		
CNY (JPY)	15.64		15.61		

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

 Expecting STN2000100 (DE-128) approval in US to be delayed. Recorded gain on reversal of change in fair value of contingent consideration (JPY15.2 billion) and impairment loss (JPY 40.3 billion)

#### Operating Profit (IFRS basis) JPY12.9 billion (-61%)

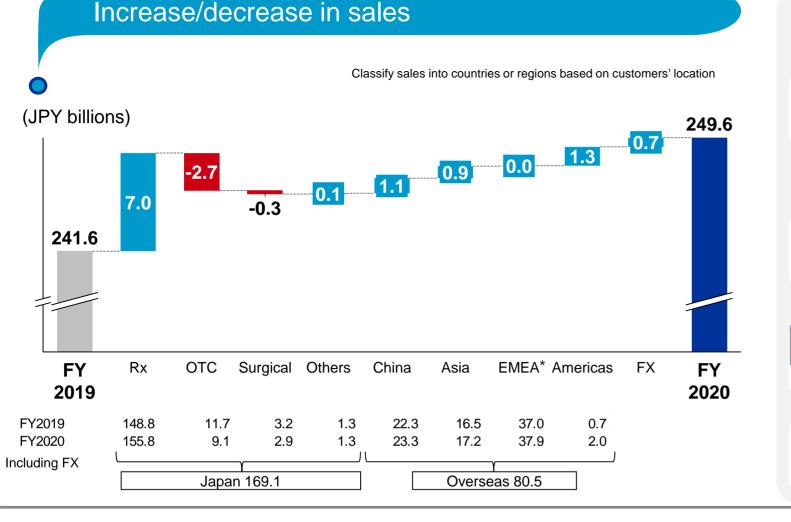
#### Net Profit (IFRS basis)

 Profit before tax declined on decrease in operating profit based on IFRS

Net Profit (IFRS basis) JPY6.6 billion (-69%)



# Sales increased in all regions despite VBP in China and COVID-19



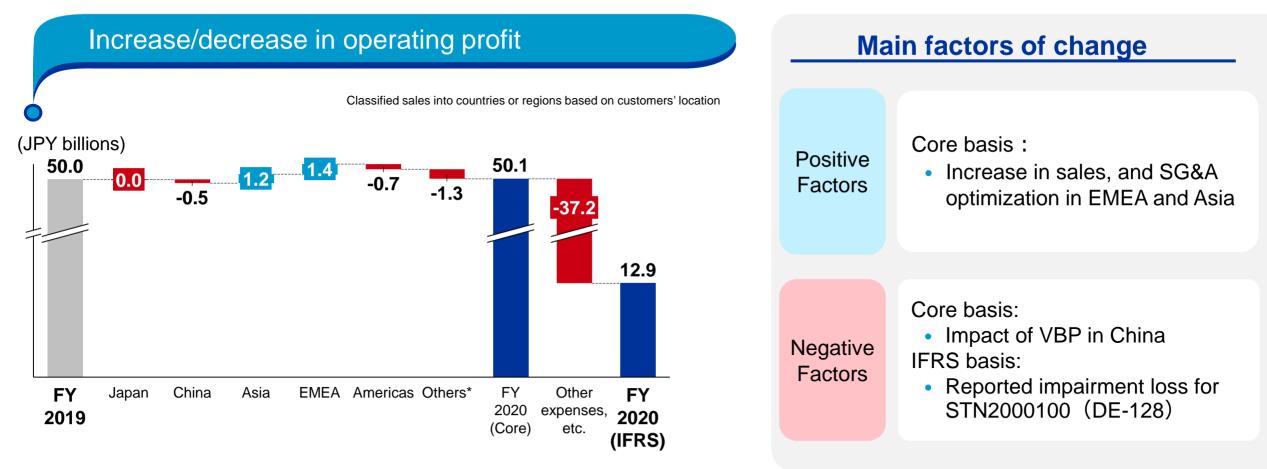
### Main factors of change

- Steady growth in Rx business
  - In particular *Alesion LX* achieved aggressive switchover and growth
- Sales of OTC declined due to decrease in inbound sales related to COVID-19
- Sales expanded in channels such as private hospitals and pharmacies, despite the impact of VBP
- Steady growth with new products (*Tapros* and *Diquas*)
- Achieved solid growth by increasing market share in key countries
- Acquired a business platform that will be the foundation for future growth through the acquisition of Eyevance





**Profit in FY2020 (YoY)** Maintained core operating profit due to optimization of costs such as temporary costs associated with acquisitions

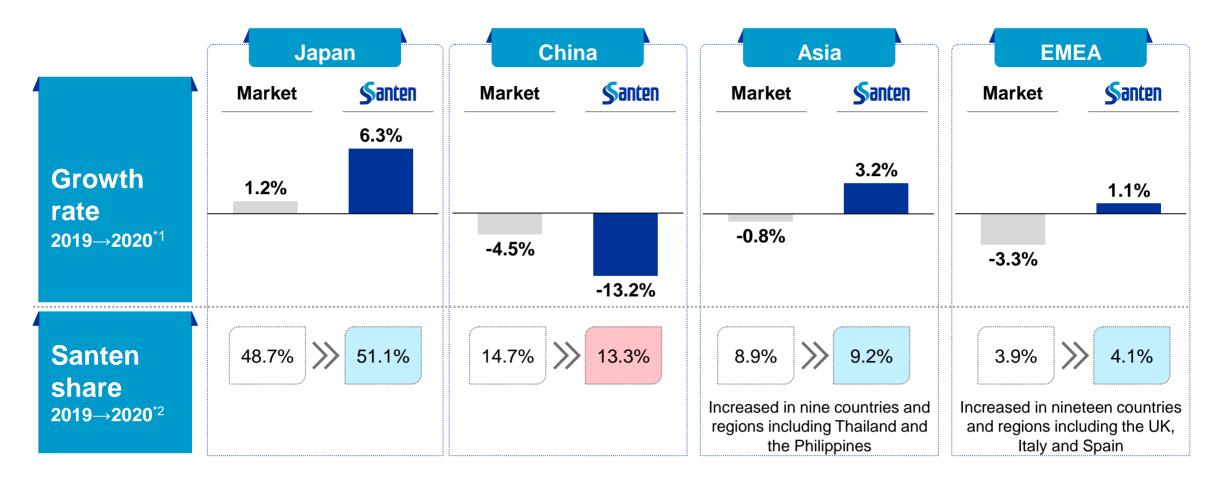


\*Includes R&D costs and indirect costs (HR, Corporate Planning etc.) which are associated with service provided in various regions



### Share by Region

Santen achieved above-market growth in Japan, Asia, and EMEA. In China, Santen is making solid progress toward a sales recovery through the expansion of new channels



\*1 Ophthalmic drug market. Santen growth rate is calculated based on IQVIA data. It differs from actual revenue. \*2 FY2019 and FY2020 for Japan, and CY2019 and CY2020 for China, Asia and EMEA. Source: Copyright © 2021 IQVIA. JPM 2019.4-2021.3, IQVIA MIDAS 2019Q1-2020Q4; Santen analysis based on IQVIA data. Reprinted with permission.





1. Vision 2020 Review

2. FY2020 Results

3. FY2021 Business Plan, and Key Growth Drivers

4. Direction for MTP2025

5. R&D Update

Appendix



## FY2021 Forecast

Focusing on maximizing the value of core businesses, aim to increase sales and profits

	FY2020		FY2021		
(JPY billions)	Actual	vs Revenue	Forecast	vs Revenue	YoY
Revenue	249.6		260.0		+4.2%
Cost of sales	98.2	39%	101.0	39%	+2.8%
Gross margin	151.4	61%	159.0	61%	+5.0%
SG&A expenses	77.2	31%	81.0	31%	+5.0%
R&D expenses	24.1	10%	26.0	10%	+7.8%
Core operating profit	50.1	20%	52.0	20%	+3.8%
Non core SG&A expense	2.4	1%	0.4	0%	-83.2%
Amortization on intangible assets associated with products	9.9	4%	8.9	3%	-10.3%
Other income	16.0	6%	0.5	0%	-96.9%
Other expenses	40.9	16%	1.7	1%	-95.8%
Operating profit (IFRS)	12.9	5%	41.5	16%	+221.3%
Finance income	1.3	1%	0.9	0%	-33.2%
Finance expenses	1.5	1%	0.2	0%	-86.6%
Investment loss by equity method	0.4	0%	1.2	0%	+235.5%
Profit before tax	12.4	5%	41.0	16%	+230.2%
Income tax expenses	5.8	2%	10.5	4%	+81.9%
Actual tax ratio	46.5%		25.6%		
Net profit (IFRS)	6.6	3%	30.5	12%	+359.0%
ROE	2.2%		10.0%		
Core net profit	37.5	15%	39.0	15%	+3.9%
	FY2020		FY2021		
USD (JPY)	105.95		105.00		
EUR (JPY)	123.73		125.00		
CNY (JPY)	15.61		16.50		

#### Revenue

• Expect to increase year-on-year due to sales expansion in each region

#### Revenue JPY260.0 billion (+4%)

#### **Operating profit**

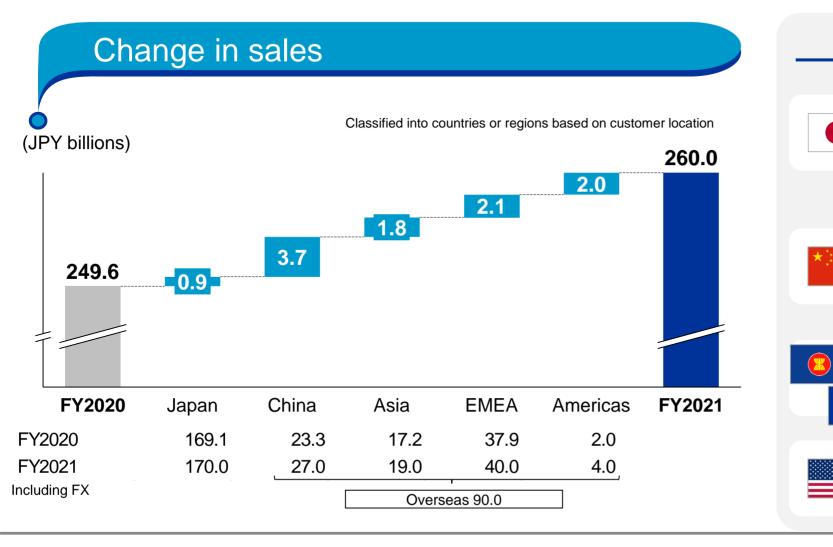
• Expect to increase profits (core) on higher sales

#### Core OP JPY52.0 billion (+4%)

Absence of impairment loss and one-off costs recorded in the previous fiscal year

#### OP (IFRS basis) JPY41.5 billion (+221%)

# **FY2021 Sales Forecast (YoY)** Forecast to increase year-on-year, led by overseas business



### Main factors of changes

- Revenue projected to increase across Japan despite the impact of NHI drug price revision for Rx and patent expiry on mainstay products
- New products such as *Tapros* and Diguas to drive sales
- Cravit sales to match the same level as previous year despite **VBP** impact
- Expect revenue increase led by glaucoma and dry eye area in major countries
- Revenue expected to double ٠ year-on-year, led by full-year sales contribution from Eyevance products



### Japan

Aim to increase sales through expansion of mainstay products in spite of NHI price drug revisions

#### **Financial KPI** Revenue +1% (JPY billions) 169.1 170.0 165.0 FY2019 FY2020 FY2021 (ACT) (ACT) (FCST)

#### **Major Activities**

#### Strengthen the earnings base of main products

- Further enhance main products (*Alesion LX/Eybelis/Diquas*) keeping the positive momentum since launch
- Alesion LX: In addition to successful shift from Alesion, expand market channels to other than ophthalmic



#### Progress on new product development

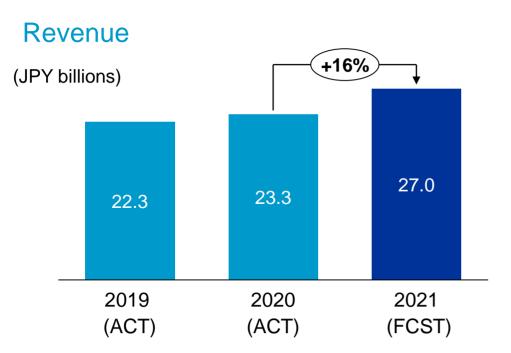
- Defense of LoE
  - *Diquas:* New formulation 3 times/day (To file in FY2021)
  - Tapros: Bottle with eyedrop applicator (To launch in FY2022)
  - Steady progress in the late stage pipeline (STN1012700)



### China

Achieved sales growth for FY2020 despite the impact of VBP Elevate focus on growing new products and shift in market channels for sustainable growth

### Financial KPI



#### **Major Activities**

#### Current lineup: Shift to new channels

- Expand by entering and developing channels incl. private hospitals and the retail market
  - Started alliances with online pharmacies
- Reduce dependence on public channels affected by VBP
  - Short-term sales impact from VBP in FY2020

#### Sales promotion of new products

- Drive sales with new products such as Tapros and Diquas
  - *Tapros* sales growth: FY2020 +52%
    - FY2021 FCST +363%
- Diquas sales growth: FY2020 +329%
   FY2021 FCST +288%

#### Measures to achieve mid-to-long term growth

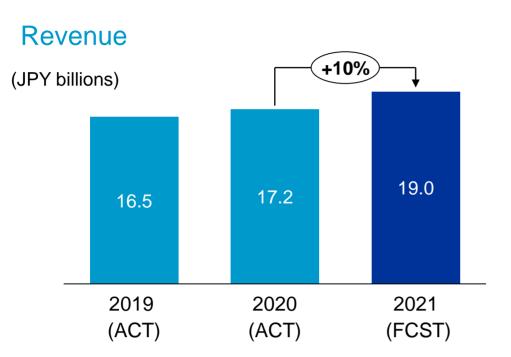
- Steady progress in new product development (Started STN1012700 study, *Verkazia* NDA (clinical trial waiver))
- Expansion of production capacity (Introduced high-speed line at Suzhou factory, Started second plant construction)
- Capture full market potential by building eco-system
  - Launched screening project in Liaoning Province



### Asia

FY2020: Sales up despite the impact of COVID-19 Aim for sustainable growth by continuously promoting mainstay lineup incl. new products

### **Financial KPI**



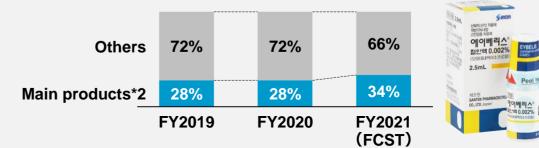
\*1: Based on: Country/Region x no. of launched products. Incl. additional indication for verkazia \*2: Main products : Tapros, Tapcom, Eybelis, Diquas, Ikervis, Alesion

#### **Major Activities**

#### Accelerating growth with new products

- Continuously launch new products incl. *Eybelis* (13 in FY2020<sup>\*1</sup>)
- Improve market penetration of mainstay products such as Tapros, Diquas and Ikervis through activities to meet customer needs

#### Ratio of revenue by products in Asia (value)



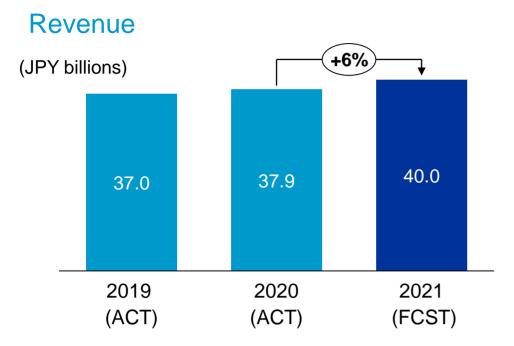
#### Contribute to regional development of ophthalmology

- Enhance awareness of diseases in collaboration with KOL and business partners
- Support training and education for ophthalmologists, in conjunction with academia and physicians

### **EMEA**

Secure steady growth by vigorously launching new lineup and promoting current products

### **Financial KPI**



#### **Major Activities**

#### Line up aligned with local demand

- Preservative-free glaucoma line-up and Ikervis
  - Add new formulations for defense of LoE
- New products to meet local needs
  - Expand target countries for *Puralid*, blepharitis, and *Ducressa*, antibiotic/steroid combination treatment

#### Enhancement of current products

- FY2020: Achieved YoY sales increase across territory
  - Sales : Italy +9%, Germany +12%, UK +11%
- Promote current products
  - Sales FCST : Italy +6% UK +4%
- Strengthen Glaucoma domain through by PRESERFLO
   MicroShunt

#### $\rightarrow$ Aim to expand market share in FY2021

(cf.) Market share for 2020 (vs 2019):

Italy 8.7% (+1.8pt), UK 2.4% (+0.2pt)

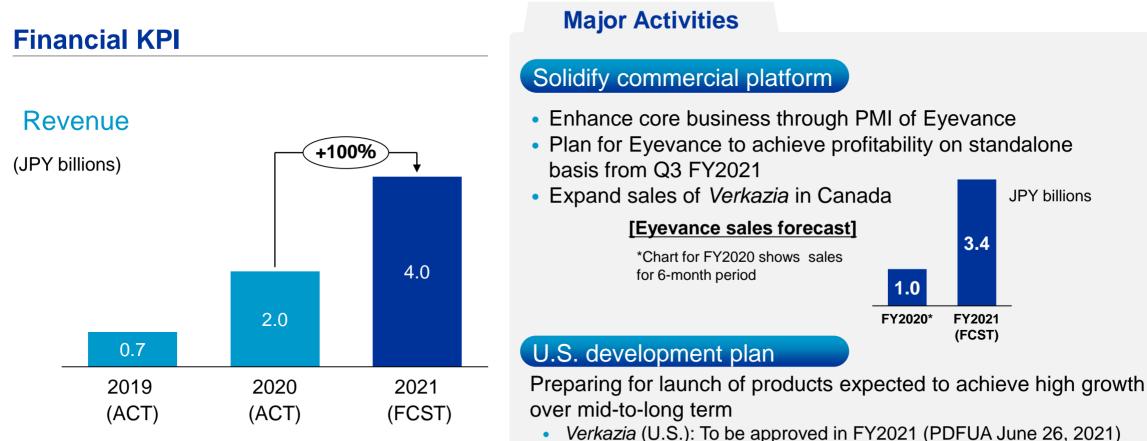






### Americas

Maximizing product value by enhancing core business through Eyevance

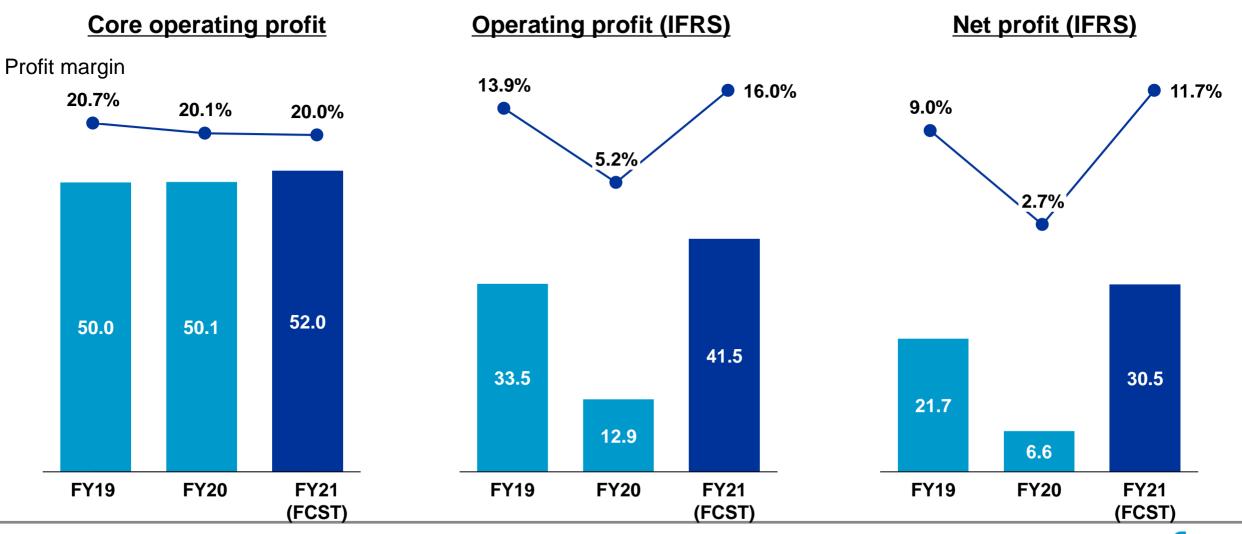


STN1011700 (DE-117): To be approved in FY2021 (PDUFA Nov 19, 2021)



# **Profits (FY2019 - FY2021)** Overall profit increase boosted by increased sales in across regions

(JPY billions)



Copyright© 2021 Santen All rights reserved.

Santen 23

### **Investing to Grow**

Strengthen global core businesses and promote efficiency by increasing capital expenditures

### **Capital Expenditures**

## FY2020 actual: JPY **11.3** billion

## FY2021 forecast: JPY 30.0 billion

Factors behind the increase from the previous year

- Increase in production investment (up approx. JPY20.0 billion)
  - > Shiga new plant and second China plant, etc
- IT-related investment (up approx. JPY1.0 billion)



Rendered image: Second China plant

Location: Industrial Park, Suzhou, Jiangsu province Total floor area: 126,000m<sup>2</sup> Production capacity: With 20 production lines, around 840 million doses/annually (5mL) Operation schedule: Operation scheduled to begin in 2025



## Pipeline: Main progress in FY2020 and outlook for FY2021

	-	—	-
siness	Glaucoma	STN2000100 (de-128)	Approved in Canada. Under negotiation for PMA approval in US. Filing in Japan, approved in Asia are being planned.
		STN10 <b>117</b> 00	Filed in US (PDUFA Nov. 2021). Launched in Korea, Plan to be filed in Asian countries
		STN10 <b>126</b> 00	Additional Phase2 started
		STN10 <b>139</b> 00 (Rhopressa)	In-licensed. Phase3 in Japan started. Development in Asian countries under planning.
	Allergy	STN10 <b>076</b> 03 (Verkazia)	<b>Filed in US</b> (PDUFA Jun. 2021) <b>and China.</b> In Asia, launched in 5 countries, approved in two countries.
	Dry Eye	STN10 <b>089</b> 03	Achieved the primary endpoint in Phase3 on Diquas new formulation. Filing is being planned.
		OTN/0/0700	Japan: completed the enrollment in Phase3
Z	Myopia	STN10 <b>127</b> 00	China: filed the application of Phase 1, which is planned to be started in 2021
	_	STN10 <b>134</b> 00	Aim to start Phase1 in Japan in FY 2021
New growth potential	Retina	STN6000100 (jCell)	Under the final preparation for Phase3 initiation
		STN10 <b>109</b> 00 (DE-109)	Improved the enrollment of Phase3, by expanding the development territory
a	Ptocis	STN10 <b>138</b> 00	Asia: Plan the filing, by using the data for US approval
	Ptosis	(RVL-1201)	Japan: aim to start clinical trial in 2021



1. Vision 2020 Review

2. FY2020 Results

3. FY2021 Business Plan, and Key Growth Drivers

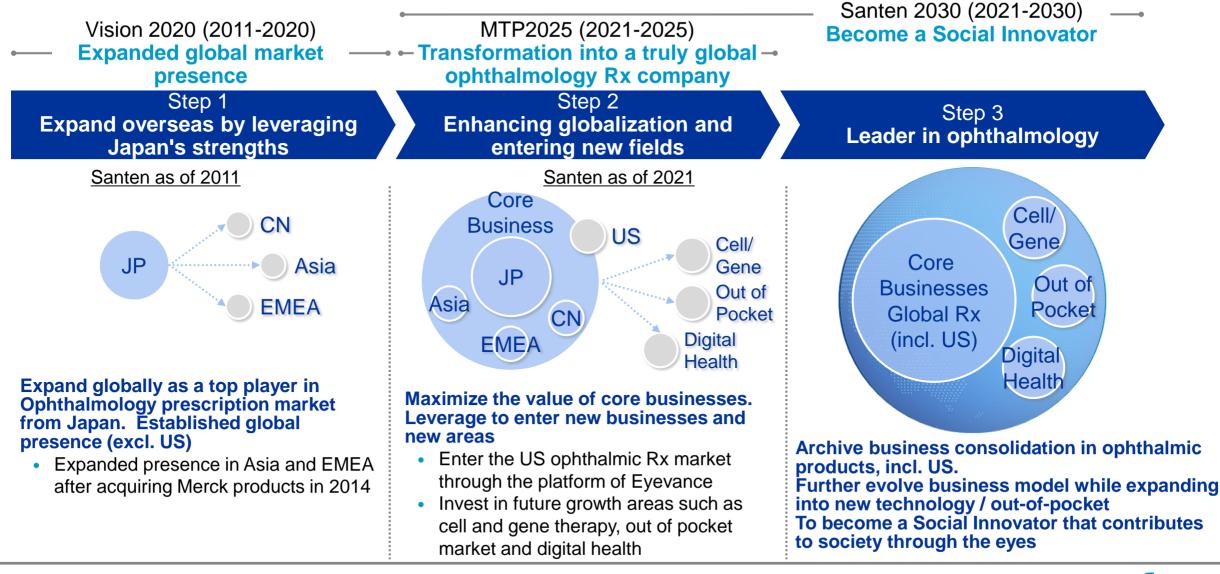
4. Direction for MTP2025

5. R&D Update

Appendix

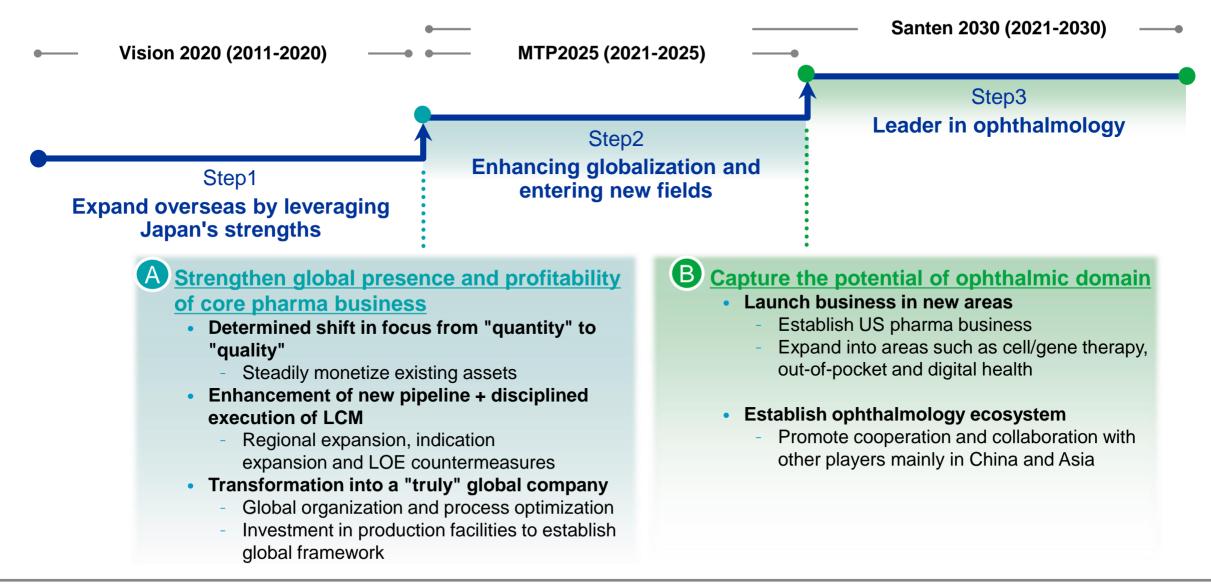


## **Evolution from Vision 2020 to Santen 2030**





### **Management Themes to be Addressed in Next MTP**





# Concepts Behind Mid-/Long-term Targets Contribute to sustainable development of society by addressing social issues. Aim to increase

corporate value over the medium- to long-term

#### Contribution to society based on our corporate philosophy

- Tenki ni sanyo suru
- Happiness with Vision

Contribute to all stakeholders, including people suffering from eye diseases and disorders, healthcare professionals and shareholders



#### Management stance and mid-/long-term targets

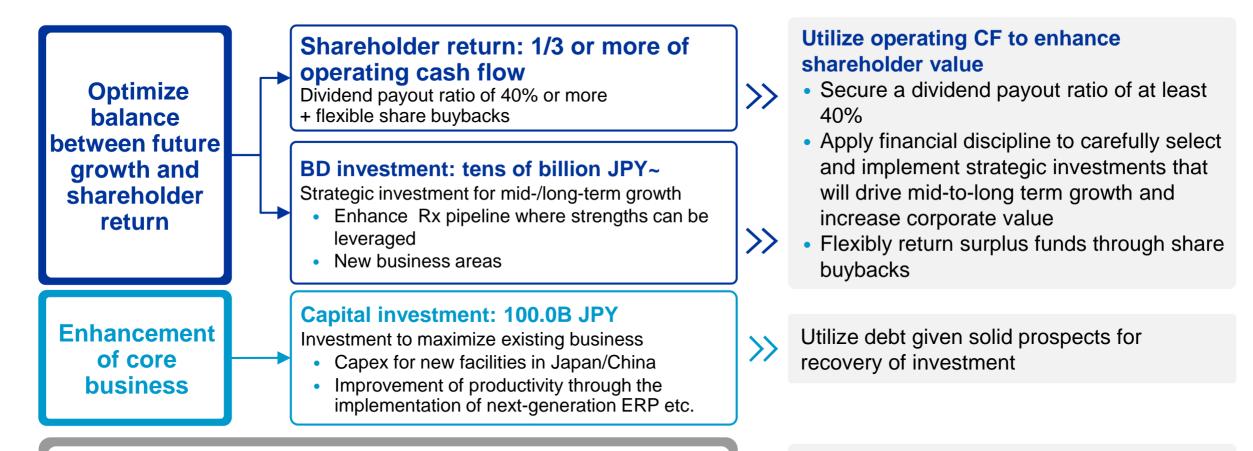
Contribute to people with eve diseases and disorders and healthcare professionals by providing products to meet needs

Commitment to improve TSR\* as a comprehensive metric for enchasing shareholder value. In addition, commitment to balance ESG strength

- Emphasize an appropriate balance between growth and profitability
- Strengthen ESG: Set clear KPIs and enhance initiatives \*Raise TSR above the industry's midpoint by 2025

Further details to be announced as a part of MTP2025 on May 19th

# **Capital Policy and Direction on Shareholder Return** We enforce the sustainable shareholder returns and BD investment to increase shareholder value.



Maintain necessary cash for business continuity

(Secure working capital)

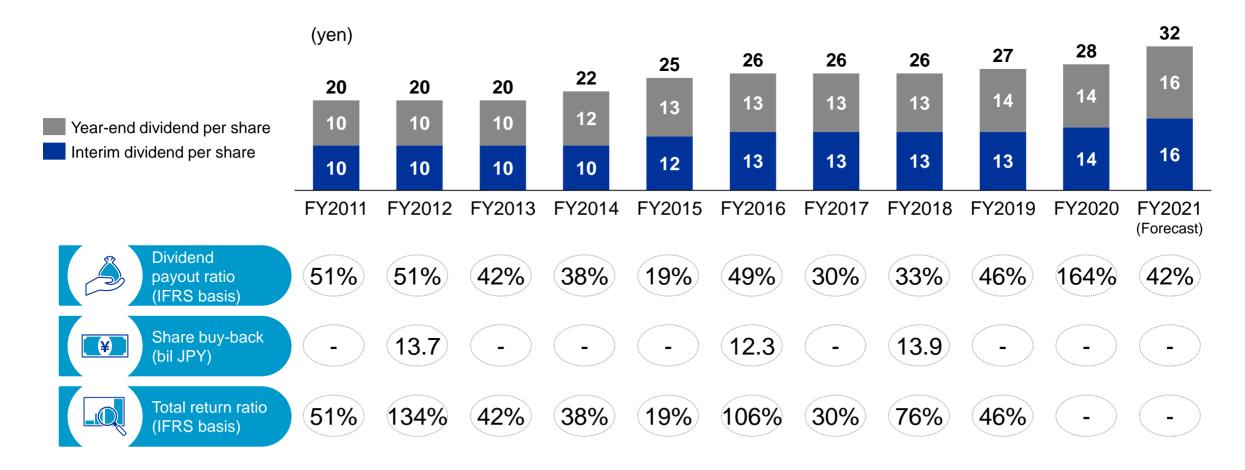
Maintain current level





### **Dividend Forecast for FY2021**

Guiding for an increase in the dividend to 32 yen in FY2021; interim dividend of 16 yen and year-end dividend of 16 yen. (Increase of 4 yen from FY2020)



FY2021 forecast total return ratio does not reflect the possibility of additional share buy-backs. Calculations are based on J-GAAP until FY2013 and IFRS from FY2014 onwards.



# Transition to a Holding Company and Accounting Period Postpone both initiatives (transition to a holding company structure and the change in accounting

period) to maximize focus on the steady implementation of MTP2025 measures

#### Initial objectives of both initiatives

- Reinforce corporate headquarter functions
- Facilitate swift decisionmaking and foster organic collaboration among regions and units
- Further reinforce the global governance system
- Further facilitate global business expansion

### Upcoming plans

#### **Postpone both initiatives** (New timing of implementation TBD)

 Focus on the steady implementation of MTP2025 by concentrating all management resources here

**Globalization of business and organization within the** current framework Continue to promote strengthening of group governance



Ag	en	da
ЛY		ua

1. Vision 2020 Review

2. FY2020 Results

3. FY2021 Business Plan, and Key Growth Drivers

4. Direction for MTP2025

5. R&D Update

Appendix



## **R&D** Highlights

Strengthen the core business, and tackle areas with high growth potential

### **Diquas** LoE measures

Achieved the primary endpoint in Phase 3 on Diguas new formulation, STN10008903.

### **New pipeline**

 Aim to start Phase 1 study on the next-generation product for myopia, STN1013400, in Japan in FY2021

### **Territory expansion**

- STN1011700 (Eyberis) : Launched in Korea
- STN2000100 (DE-128)
- STN10**076**03 (*Verkazia*)

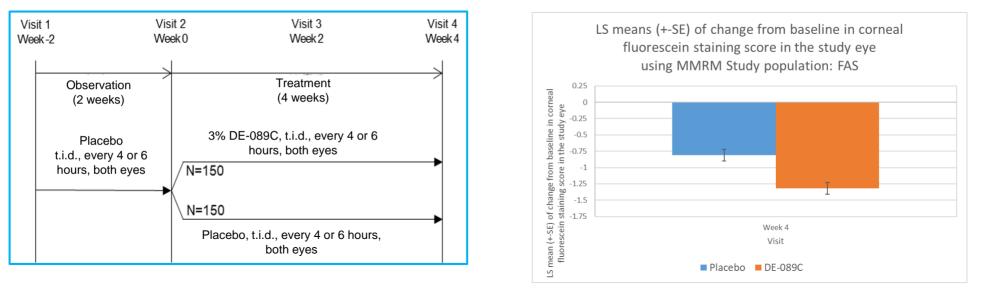
- : Approved in Canada Plan to file in Japan in FY2021 Under discussion for PMA approval in US : NDA filed in China
- Steady progress on other main pipelines compounds



# **Q4 FY2020 Topic** – Strengthening the core business to address by LoE STN1008903 (DE-089C): favorable results obtained in Phase 3 pivotal placebo controlled study

#### Objective:

A Phase 3, multicenter, double-masked randomized placebo controlled study assessing the efficacy of 3% DE-089C ophthalmic solution (t.i.d, 4 weeks) using corneal epithelial staining score by fluorescein in dry eye patients



Differences of least squares means						
Visit	Difference	Estimate	SE	P value	95% CI	
Week 4	DE-089C - Placebo	-0.51	0.123	<.0001	-0.754, -0.269	

Results: Primary endpoint achieved (corneal epithelial staining score by fluorescein)
 Filing: FY2021



## Q4 FY2020 Topic - new growth potential

Start clinical trial of STN1013400, next-generation drug for suppression of myopia progression in children, ahead of peers

Reflecting the anticipated continued increase in the myopia patient population, governments, particularly China, are adopting intensive measures for myopia. This is expected to develop into a global trend, given the strong interest of stakeholders, including physicians.

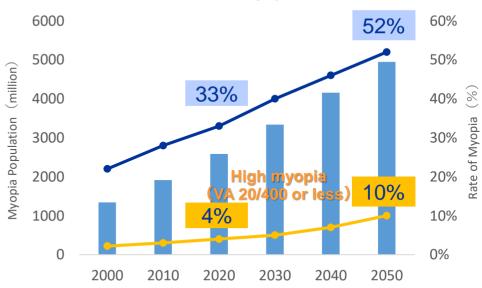
#### **Target Product Profile**

# Suppress the elongation of the eyeball axis with muscarinic antagonist

- This product, which suppresses myopia progression, is more effective than the atropine formulation in development and is not expected to show side effects typically expected with atropine formulations, including mydriasis
- Territory
  - Japan: P1 initiation in FY2021
  - Others: Development in other territories including China is under consideration / planning

#### Market potential

#### Ratios of myopia and intense myopia patients versus world population<sup>\*1</sup>



Myopia (VA 20/40 or less)

\*1 Holden, et al, 2016 Ophthalmology



# Current Status of Research and Development Main pipeline / product development (1)

As of April 2021 Updated information is underlined

	Dev. code	Indication	Region	Status
Omidenepag isopropyl	STN1011700	Glaucoma /	US	Filed <i>Plan: FY2021 approval</i>
EYBELIS	DE-117	ocular hypertension	Japan	Launched
			Asia	Launched in February 2021 in Korea
Sepetaprost	STN1012600	Glaucoma / ocular hypertension	US	P2 Plan: FY2022 additional P2 completion
Copolapiosi	DE-126		Japan	P2b (dose finding study completed)
		Glaucoma	US	Completed PMA rolling submission Discussion with FDA on-going <i>Plan: under consideration</i>
	<b>STN2000100</b> DE-128		<u>Japan</u>	<u>Plan: FY2021 filing</u>
Glaucoma implant device PRESERFLO MicroShunt			Europe	Launched
			Asia	Filed <u>Plan: FY2021 approval</u>
			Others	Approved in March 2021 in Canada Plan: FY2021 Launch



#### **Current Status of Research and Development**

Main pipeline / product development (2)

As of April 2021 Updated information is underlined

	Dev. code	Indication	Region	Status
Netarsudil dimesylate Rhopressa	<b>STN1013900</b> AR-13324	Glaucoma / ocular hypertension	Japan	Started P3 in November 2020 Plan: FY2023 P3 completion
	CTN4040700	Myopia	Japan	P2/3 Plan: FY2023 P2/3 completion
Atropine sulfate	STN1012700 DE-127		China	Plan: FY2021 P1 start
			Asia	P2 (met primary endpoint)
AFDX0250BS	STN1013400	Myopia	<u>Japan</u>	<u>Plan : FY2021 P1 start</u>
Diquafosol sodium (long-lasting) <i>Diquas</i>	<b>STN1008903</b> DE-089C	Drv eve		<u>P3 (met primary endpoint)</u> <u>Plan: FY2021 filing</u>
			US	P3 Plan: FY2022 P3 completion
Sirolimus	STN1010900	Uveitis	Japan	P3
(intravitreous injection)	DE-109		Europe	P3
			Asia	Filed



#### **Current Status of Research and Development**

Main pipeline / product development (3)

As of April 2021 Updated information is underlined

	Dev. code	Indication	Region	Status
Tafluprost / timolol maleate (combination) TAPCOM / TAPTIQOM	<b>STN1011101</b> DE-111A	Glaucoma / ocular hypertension	China	P3 Plan: FY2023 P3 completion
Latananraat	<b>STN1013001</b> DE-130A	Glaucoma /	Europe	P3
Latanoprost	Catioprost	ocular hypertension	Asia	Plan: FY2021 P3 completion
Intraocular lens Lentis Comfort	MD-16	Cataract	Japan	Launched in November 2020

- <u>China FDA accepted the NDA for STN10076 (Verkazia / generic name: ciclosporin) for the treatment of vernal keratoconjuctivitis in April 2021.</u>
- STN1013800 (RVL-1201); The company is planning to start clinical trials for blepharoptosis in FY2021 in Japan and also considering the filing in Asia with data used for US approval.
   Licensing region / Japan, China, Asia and Europe
- STN6000100 (jCell); Our partner company (jCyte) has started a phase 2 safety study (NCT04604899) for retinitis pigmentosa with an
  estimated completion in FY2022. jCyte and Santen have begun preparations to move the program to the phase 3 stage.
  Licensing region / Japan, China, Asia and Europe



# Agenda

1. Vision 2020 Review

2. FY2020 Results

3. FY2021 Business Plan, and Key Growth Drivers

4. Direction for MTP2025

5. R&D Update

Appendix



#### FY2020 Consolidated Results (vs Forecasts as of May 8th, 2020)

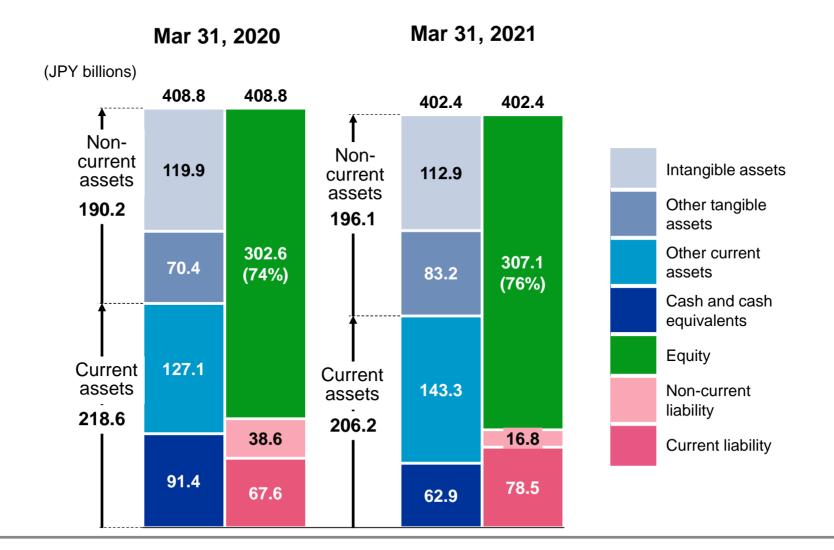
			FY2020		
(JPY billions)	Original forecast (as of May 8 <sup>th</sup> , 2020)	vs Revenue	Actual	vs Revenue	vs First forecast
Revenue	235.0		249.6		106%
Cost of sales	90.0	38%	98.2	39%	109%
Gross margin	145.0	62%	151.4	61%	104%
SG&A expenses	70.0	30%	77.2	31%	110%
R&D expenses	23.0	10%	24.1	10%	105%
Core operating	52.0	22%	50.1	20%	96%
Non core SG&A expense			2.4	1%	
Amortization on intangible assets associated with products	9.7	4%	9.9	4%	102%
Other income	0.9	0%	16.0	6%	
Other expenses	8.2	3%	40.9	16%	499%
Operating profit (IFRS)	35.0	15%	12.9	5%	37%
Finance income	0.8	0%	1.3	1%	168%
Finance expenses	1.0	0%	1.5	1%	149%
Share of loss of Investments accounted for using equity method			0.4	0%	
Profit before tax	34.8	15%	12.4	5%	36%
Income tax expenses	11.0	5%	5.8	2%	52%
Actual tax ratio	31.6%		46.5%		
Net profit (IFRS)	23.8	10%	6.6	3%	28%

Revenue growth exceeded initial forecast owing to activities in response to the new normal, despite the COVID-19 impact

Fell short of initial forecast due to the posting of gains on reversal of change in fair value of contingent consideration and impairment loss related to the expected delay to US approval of STN2000100 (DE-128)



### **FY2020** Financial Position Changes

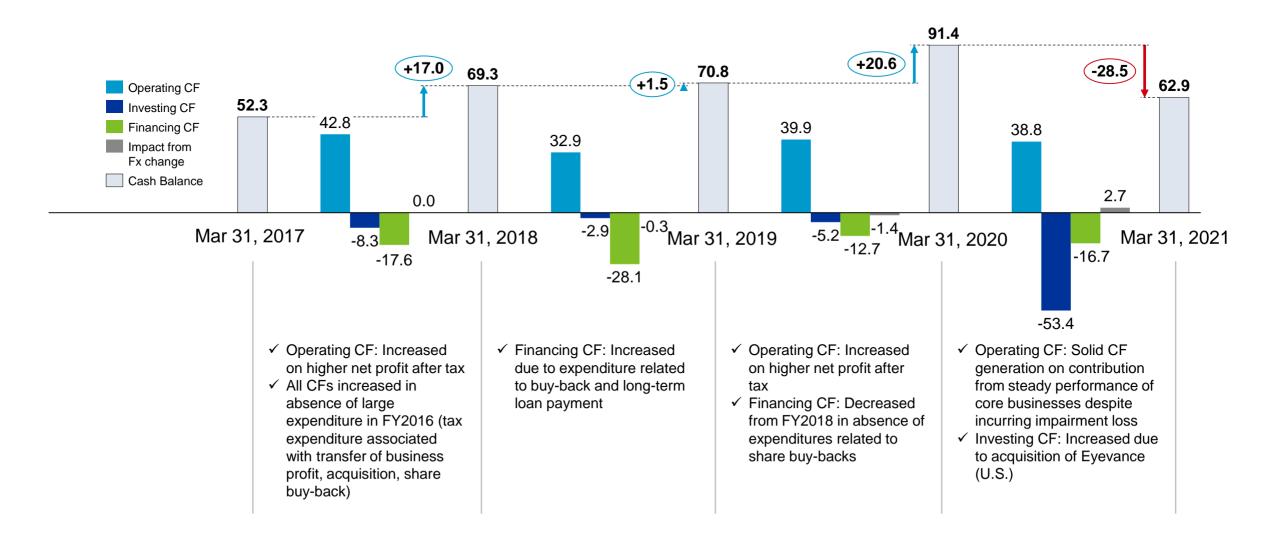


Copyright© 2021 Santen All rights reserved.



#### **Cash Flow Changes**

(JPY billions)



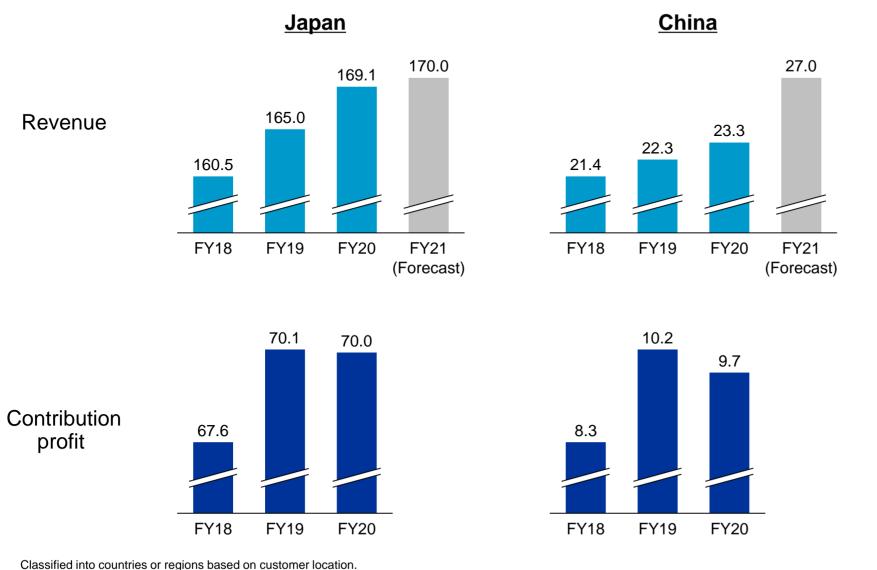


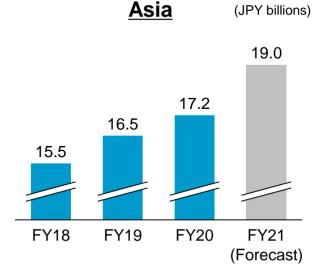
### STN2000100 (DE-128) Impairment Loss

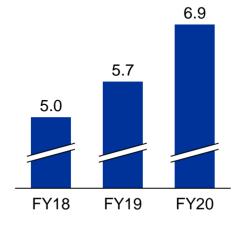
Difference between the final recorded results and the figures announced on April 9, 2021

(JPY billions)	Forecast As of April 9, 2021	Finalized number
Impairment loss	-40.5	-40.3
Development, manufacturing and sales rights	-24.8	-24.6
Goodwill	-15.7	-15.7
Gain on reversal of change in fair value of contingent consideration	14.9	14.9
Other income	15.4	15.2
Financial expenses	-0.5	-0.3

### **Revenue / Contribution Profit by Region1**



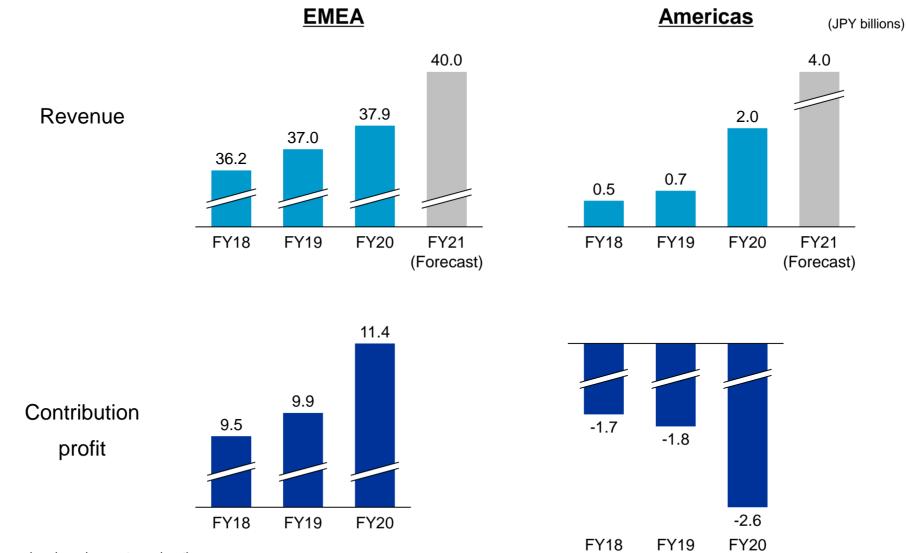




Copyright© 2021 Santen All rights reserved.



### **Revenue / Contribution Profit by Region 2**



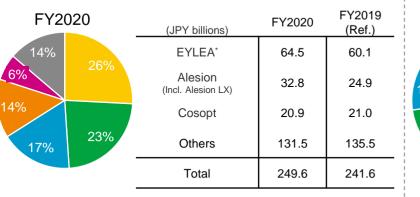
Classified into countries or regions based on customer location.

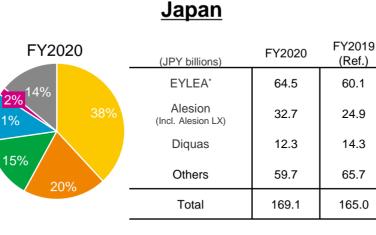


# FY2020 Revenue by Region

1%

#### Consolidated





#### China FY2020 FY2020 (IDV billiona)

112020		(JPY billions)	FY2020	(Ref.)
15%		Hyalein	9.3	7.9
1% 43%		Cravit	7.9	9.5
		Flumetholon	1.4	1.2
8%		Others	4.8	3.7
		Total	23.3	22.3

#### Asia

FY2020	(JPY billions)	FY2020	FY2019 (Ref.)	FY2020	(JPY billions)	FY20
1%13%	Cosopt	4.5	4.1	3%10%	Cosopt	9.5
15% 44%	Hyalein	2.2	1.9	2%	Tapros	6.7
	Tapros	1.9	1.9	65%	Ikervis	3.6
28%	Others	8.7	8.6		Others	18.
	Total	17.2	16.5		Total	37.
				1		-
Intravitreal VEGF inhi	bitor 📕 Glaucor	na/Device	Dry eye	Allergy Bacteria	l conjunctivitis	Others
*EYLEA: Co-promoted product of	of Bayer Yakuhin, Ltd.	(MAH)				

#### **EMEA**

FY2019

(Ref.)

9.3

6.5

3.1

18.1

37.0

FY2020

9.5

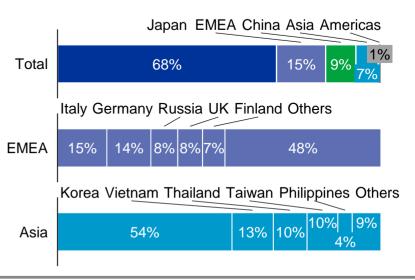
6.7

3.6

18.1

37.9

#### **Revenue in each region** (FY2020)

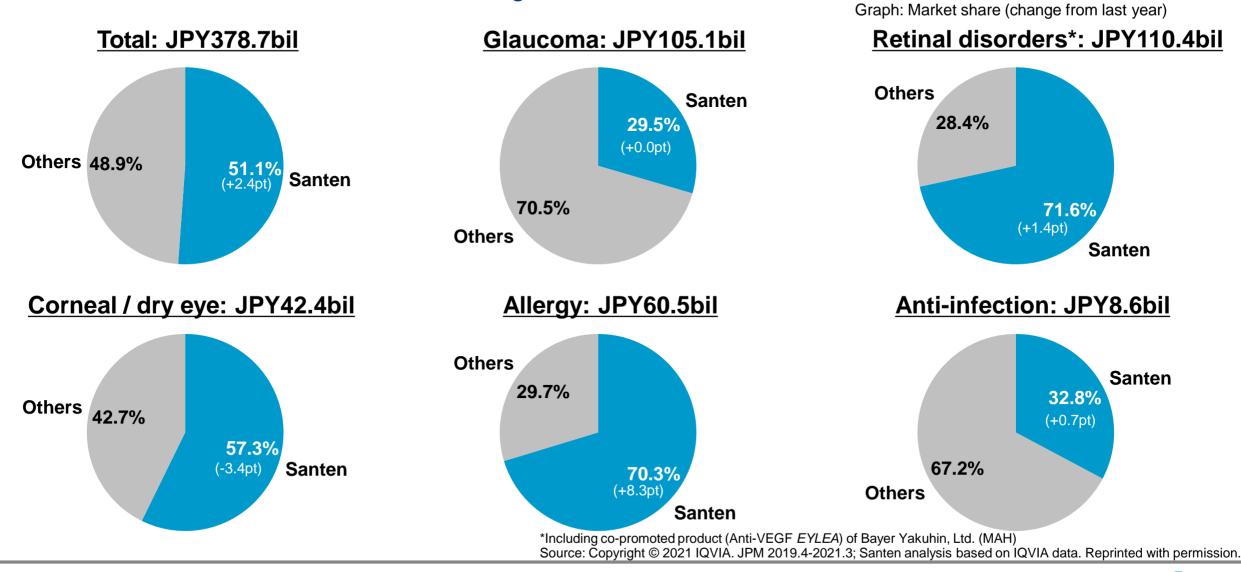




FY2019

Copyright© 2021 Santen All rights reserved.

# Prescription Ophthalmic Market in Japan (Apr. 2020-Mar. 2021) Remain No.1 for overall market and all segments Segment: Market size





### FY2020 Results: Progress of Main Pipeline Items

		~ Phase 2	Phase 3/Filing	Approval/Launch
Ð		STN10 <b>126</b> 00 Additional P2 start (US) Sepetaprost • IOP lowering	STN10 <b>117</b> 00 NDA(US) Omidenpag · IOP lowering	STN2000100 Approval (Canada) Device for glaucoma
Pipeline for			STN2000100 NDA (US) Device for glaucoma	STN10 <b>117</b> 00 Launched(Korea) Omidenpag ・IOP lowering
	New pipeline		STN10 <b>139</b> 00 P3 start(Japan) Netarsudil (Rhopressa)・IOP lowering	STN10 <b>076</b> 03 Launched(Taiwan) Ciclosporin · Vernal conjunctivitis
core bu			STN10 <b>076</b> 03 on the list (China) Ciclosporin · Vernal conjunctivitis	MD-16 Launched(Japan) IOL
business			STN10 <b>076</b> 03 NDA (US)	Total 13 products launched in Asia
less			Ciclosporin · Vernal conjunctivitis	Total 55 products launched in EMEA 🚽
	For LoE		STN10 <b>089</b> 03 PE achieved (Japan) Diquafosol sustained release • dry eye	
New		STN10 <b>127</b> 00 PE achieved (Asia) Atropine sulfate • Myopia		
' growth		STN1013800 (inlicensed RVL1201) Oximetazoline • Ptosis		Glaucoma
th pot		STN6000100 (inlicensed jCell) Cell therapy · Retinitis pigmentosa		Anterior Chamber Disease Retinal Diseases
potential		STN10 <b>134</b> 00 Non-clinical Muscarinic antagonist • Myopia		Other ophthalmic Disease Progressed in Q4 FY20

### **FY2021 Plan: Progress in Main Pipeline Items**

		~ Pha	ise 2	Phase 3/	/Filing	Approval/Launch
		STN10 <b>126</b> 00 P2 (US, Sepetaprost • IOP low		STN2000100 Filing ( Device for glaucoma	Japan, US)	STN10 <b>117</b> 00 Approval (US) Omidenpag • IOP lowering
Pipe				STN10 <b>111</b> 03 P3(Ch Tafluprost/Timolol ・IC		STN2000100 Approval (Asia) Device for glaucoma
Pipeline for				STN10 <b>130</b> 01 P3(EL Latanoprost · IOP low		STN2000100 Launched(Canada) Device for glaucoma
or core				STN10 <b>139</b> 00 P3 start Netarsudil (Rhopressa		STN10 <b>076</b> 03 Approval (US) Ciclosporin • Vernal conjunctivitis
) business				STN10 <b>076</b> 03 Filing( Ciclosporin · Vernal c		STN10 <b>076</b> 03 Launched (Asia) Ciclosporin • Vernal conjunctivitis
less				STN10 <b>109</b> 01 P3 (US Sirolimus Posterior		
	For LoE			STN10 <b>089</b> 03 Filing (J Diquafosol sustained eye		
New			STN10 <b>127</b> 00 P2/3 (Jap Atropine sulfate • Myop			
growth		STN10 <b>134</b> 00 P1 start Muscarinic antagonist				Glaucoma
h pote			STN1013800 (RVL120 Oximetazoline • Ptosis	1), New trial starts		Anterior Chamber Disease Retinal Diseases
potential			STN6000100(jCell), Retinitis pigmentosa	New trial starts		Other ophthalmic Disease Milestone in FY21

# **Examination for Dry Eye Corneal Epithelial Disorder**

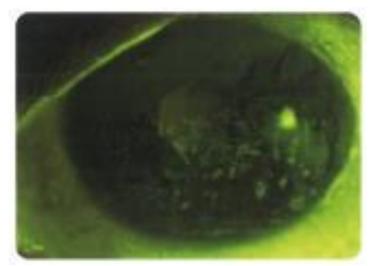
- Show the distribution and status of corneal epithelial damage, by staining defects and intercellular space of corneal / conjunctival epithelial cells
- Examine the items below by visualizing tears
  - Tear fluid retention volume (Tear meniscus)
  - Stability of tear film (BUT)
  - Tear distribution

#### Fluorescein staining :

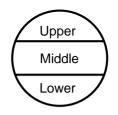
Instill fluorescein staining solution in upper, middle and lower cornea area, and score the level of staining with fluorescein in each area

#### **Evaluation criteria**

Score	Criteria
0	No defect
1	Partial defect
2	Defect in more than half of the area
3	Whole area defective



\* Image through blue free filter



Corneal epithelial defects evaluation area Division criteria



