

FY2020 Financial Results

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

Q&A

Kazuo Koshiji

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

Satoshi Suzuki

Senior Corporate Officer,
Head of Corporate Development Division

Taniuchi: Hello, everyone. I am Taniuchi, CEO of Santen Pharmaceutical. Thank you very much for taking time out of your busy schedule to participate in this briefing today.

Yesterday, we announced our financial results for FY2020. Today, in addition to the business results for FY2020, I would like to talk about our initiatives for the current FY2021, as well as the contents of our Medium-Term plan, which is scheduled to be released on May 19.

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.

Please see page 3.

This is also the origin of our company name: "Exploring the secrets and mechanisms of nature in order to contribute to people's health." With these words as our basic philosophy, we are working every day to realize "Happiness with Vision" by contributing to society through our participation.

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

Please go to page 6. Let me start with a review of our previous long-term vision, Vision 2020.

Over the past 10 years, we have been aggressively expanding our business overseas in addition to growing our business in Japan. As a result, over the past 10 years, we have more than doubled our revenue and nearly doubled our overseas sales ratio to over 30% compared to the end of FY2010 and have expanded our global presence. In addition, we were able to significantly increase our corporate value by 2.5 folds.

As we move into the next decade, we will continue to grow globally and contribute to ophthalmic treatment around the world under our new long-term vision, Santen 2030.

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

Please go to page 7.

We have been able to increase our presence in the world over the past 10 years by accelerating our global expansion to become a specialized company with a global presence, as stated in Vision 2020. We believe that this is very significant.

By leveraging Santen's strengths, such as the commercial excellence, we have cultivated in Japan and lifecycle management rooted in medical needs that only a company specializing in ophthalmology can provide, we have achieved business expansion and earnings growth in the Chinese market, where sales were still extremely small 10 years ago, as well as in the Asian and European markets.

In the last few years, we have also been reorganizing our global organization along regional and functional axes in line with the globalization of our business and have been investing in new areas, such as cell therapy and digital technology for future growth.

At the same time, we have identified issues that need to be addressed in the future. First of all, in terms of the balance between strategic investments and earnings, there was an increase in the number of strategic investment projects for which we have yet to establish a basis for earnings, and this led to a decline in the current profit margin and ROE. In addition, in FY2020, PL was significantly affected by the impairment loss on MicroShunt. We are deeply aware of this issue and recognize the urgent need to improve our current profit margin and ROE.

With regard to growth investments, in addition to making investment decisions based on a more rigorous approach to financial discipline than ever before, we would like to focus our maximum management efforts on ensuring that the assets we currently own are linked to earnings, improving profit margins, and achieving earnings growth.

In order to achieve this, we will continue to strengthen our global organization, while further enhancing our strategy execution system and refining our strengths. We will strive to enhance our corporate value while communicating with our investors in a more concrete and proactive manner than ever before.

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



Please see page 8. Next is our new Medium-Term plan. I will explain MTP2025 and our goals for its first fiscal year, 2021.

In MTP2025, we will focus on 2 main areas: first, to thoroughly strengthen our core business of prescription pharmaceuticals, and second, to improve profitability. In addition, we will steadily promote the development of solutions in new business areas, such as cell therapy and digital health, which are expected to drive our growth in the medium-to-long term. Through these efforts, we will steadily promote medium-to-long term growth by leveraging the high potential of the ophthalmology field.

In the current FY2021, we will first prioritize strengthening our prescription pharmaceuticals business. We have already established a presence in Japan, China, Asia, and EMEA. In these markets, we will continue to launch new products, penetrate the market, strengthen contact with physicians, and by doing this, deliver more of our products to more patients and continue to steadily grow.

In addition, in North America, the world's largest market, we will complete the integration of Eyevance, which we acquired last year, to strengthen our business foundation. In order to support our global growth, we will steadily develop and advance our pipeline, expand our production bases with an eye to the future, and improve the global efficiency of our business base by introducing a new ERP system.

FY2020 Consolidated Results (YoY): Revenue - Core OP

Growth on revenue and core operating profit despite impact of COVID-19

(JPY billions)	FY2019		FY2020		YoY
	Actual	vs Revenue	Actual	vs Revenue	
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

From page 10, I will talk about the outline of our business performance for FY2020.

In FY2020, the world was affected by COVID-19. Under such circumstances, our thorough activities that fit the situation in each region resulted in our market share improving in many regions. Revenue increased by 3% from the previous year to JPY249.6 billion, the highest ever for our company. Core operating profit increased slightly from last year, and this is also a record high core operating profit.

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

Operating profit and net profit decreased due to impairment loss

(JPY billions)	FY2019		FY2020		YoY
	Actual	vs Revenue	Actual	vs Revenue	
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%
<i>Actual tax ratio</i>	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)	109.81	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

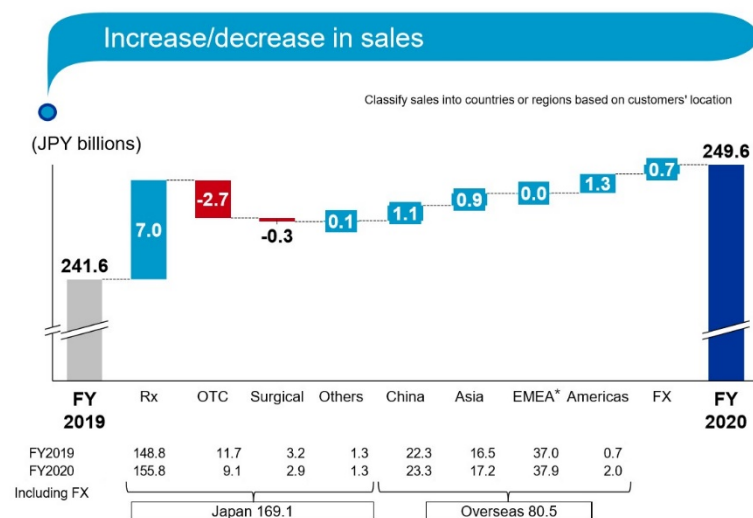
Net Profit (IFRS basis) JPY6.6 billion (-69%)

Please go to page 11.

On the other hand, operating income on a full basis decreased significantly due to the impairment loss on STN2000100, MicroShunt, in the US, which occurred in this April.

Sales in FY2020 (YoY)

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 each country
- Acquired a business platform that will be the foundation for future growth through the acquisition of Eyevence

On page 12, I will explain the factors behind the YoY increase and decrease in sales.

In Japan, sales of prescription pharmaceuticals, *Alesion LX*, and other mainstay products drove steady growth. In China, our performance was affected by *Cravit* being subjected to value-based

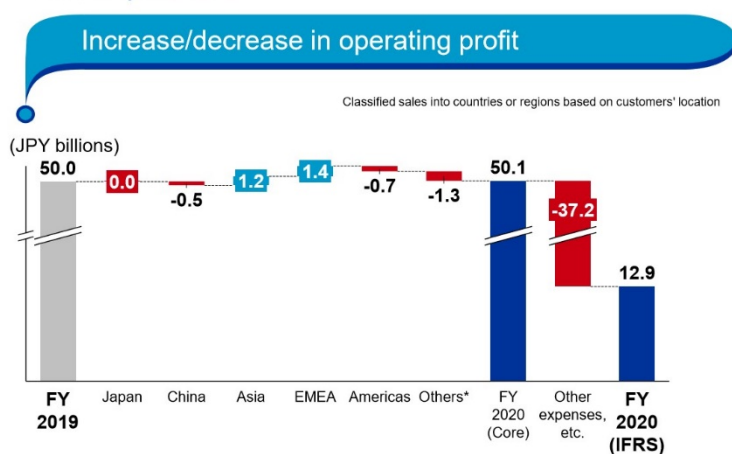
purchasing at large national hospitals, but we have shifted our marketing resources to new channels, such as private hospitals and pharmacies, and have thus achieved sales growth.

For *Hyalein*, which has been subject to value-based purchasing since FY2021, we have already started to strategically shift channels and products. In addition, the rapid growth of new products such as *Tapros* and *Diquas* helped us achieve a YoY increase in sales. We are steadily realizing a recovery to a growth trend.

In addition, despite negative market growth in Asia, EMEA, Europe, the Middle East, and Africa, the Company has achieved sales growth and market share gains in many countries through the penetration of new products and improved customer satisfaction. In the US, we acquired a business base through the acquisition of Eyevance, which contributed to our sales from the second half of the fiscal year.

Profit in FY2020 (YoY)

Maintained core operating profit due to optimization of costs such as temporary costs associated with acquisitions



Main factors of change

Positive Factors

Core basis :

- Increase in sales, and SG&A optimization in EMEA and Asia

Negative Factors

Core basis:

- Impact of VBP in China

IFRS basis:

- Reported impairment loss for STN2000100 (DE-128)

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

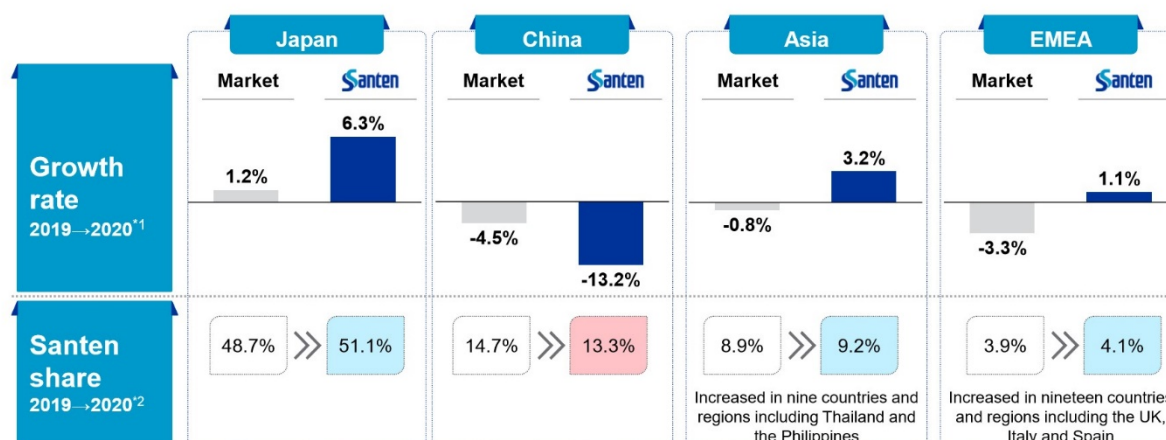
On page 13, I will explain the factors behind the increase and decrease in profit.

First of all, while sales and profits increased in Asia and EMEA compared to the previous year, the impact of value-based purchasing in China and the expenses, including one-time expenses associated with the acquisition and integration of Eyevance in the US, were the main reasons for the decrease in our profits.

As a result, core operating income increased slightly YoY to JPY50.1 billion, while our full operating income was JPY12.9 billion due to impairment losses on STN2000100, MicroShunt, in the US.

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.

Copyright© 2021 Santen All rights reserved.

14

Page 14 shows the changes in market share.

In FY2020, the ophthalmic market was also very severely affected by COVID-19. Under these circumstances, we have been able to increase our global market share, which, in addition to the contribution of new products, shows the fundamental strength of Santen as a company specializing in ophthalmology.

In Japan, we captured 51% of the market, which would be more than a majority share. In Asia and EMEA, despite negative market growth, we achieved steady positive growth and increased our market share in many countries.

In China, our market share has decreased slightly due to the impact of value-based purchasing at national hospitals, but we are continuing to improve our presence by developing new channels and expanding sales of new products. The data cited here is currently focused on national hospitals, so it does not necessarily reflect sales at private ophthalmology hospitals and pharmacies, which are the channels through which we are currently expanding sales.

FY2021 Forecast

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

(JPY billion)	FY2020		FY2021		YoY
	Actual	vs Revenue	Forecast	vs Revenue	
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%	+7.5%
Core OP	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	10.0	4%	0.5	0%	-96.9%
Other expenses	40.9	16%	1.7	1%	-95.8%
OP (IFRS basis)	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%	+205.0%
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 basis)	6.6	3%	30.5	12%	+359.0%
ROE	2.2%		10%		+780.0%
Core net profit	37.5	15%	38.8	15%	+3.9%
USD (JPY)	106.86		106.90		
EUR (JPY)	120.72		120.90		
CNY (JPY)	16.81		16.90		

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%)

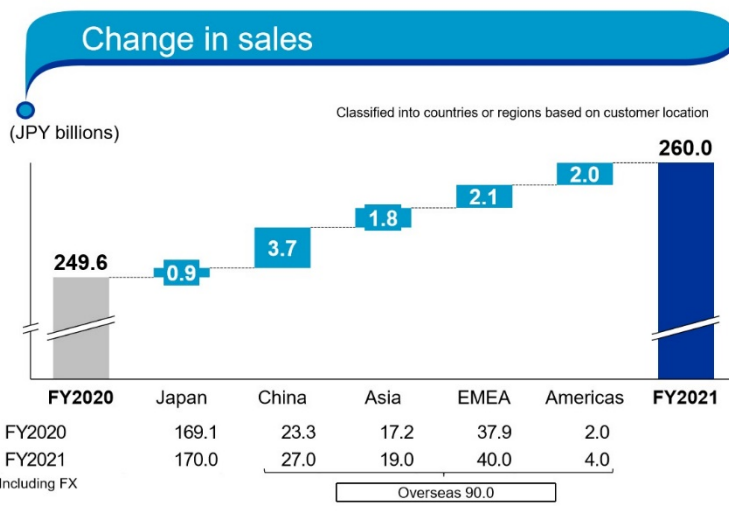
Now, I would like to talk about the earnings forecast and business plan for FY2021. Please see page 16.

As disclosed in a timely manner yesterday, due to the postponement of the change of accounting period, the plan for FY2021 is also for 12 months from April to March.

First, sales revenue will increase by 4.2% YoY to JPY260 billion. Operating income on a core basis is planned to increase by 3.8% to JPY52 billion. Operating profit on a full basis is JPY41.5 billion. With net income of JPY30.5 billion, we plan to improve profitability compared to the previous year but also compared to FY2019.

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 *Diquas* 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 year-on-year, led by full-year sales contribution from Eyevance products

This is page 17. Now let's talk about how to achieve sales growth first.

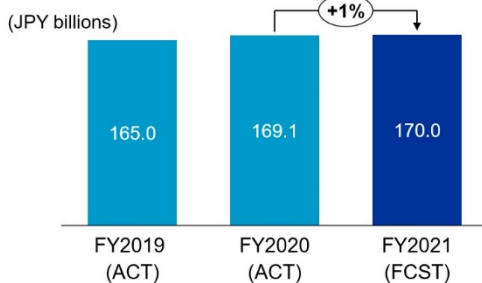
Sales in Japan are expected to reach JPY170 billion, up JPY900 million from the previous year. In overseas business, there will be growth in all regions. Overall, we expect sales to grow 12% YoY to JPY90 billion. As a result, the overseas sales ratio is expected to increase by 2 percentage points to 35%.

Japan

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

Financial KPI

Revenue



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)

From page 18, we will discuss the details by region.

First of all, in the Japanese business, we are steadily continuing to penetrate the market with new products such as *Alesion LX*, *Diquas*, and *Eybelis*, leveraging our overwhelming market presence.

Japan is Santen's home ground and most important region of the world. In order to maintain our revenue base over the medium-to-long term, we are also taking various measures to prepare for the expiration of patents on our main products. One of them is the progress of the improved formulation of *Diquas*, which Mr. Morishima will explain in detail later in the R&D portion.

China

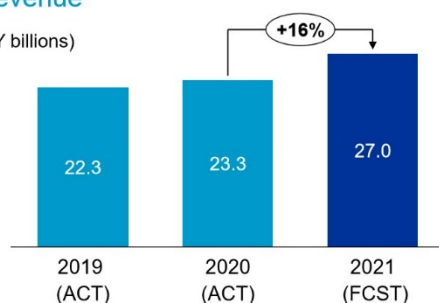
Achieved sales growth for FY2020 despite the impact of VBP

Elevate focus on growing new products and shift in market channels for sustainable growth

Financial KPI

Revenue

(JPY billions)



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 new China plant construction)
- Capture full market potential by building eco-system
 - Launched screening project in Liaoning Province

Now, let's go to China. Please turn to page 19.

We apologize for any concerns regarding the impact of the value-based purchasing of *Cravit* and *Hyalein* in FY2020, but our performance has been steadily recovering and we plan to achieve 16% growth in FY2021 compared to the previous year. The development of new sales channels, such as private hospitals and retail stores, is progressing well. Sales in this area increased significantly compared to the same period of the previous year, raising overall sales.

In addition, the growth of our new products, *Tapros* and *Diquas* is also progressing steadily. Since its inclusion in the insurance system, sales of *Tapros* have been steadily increasing, mainly at large hospitals, and it has become the top prostaglandin drug in terms of volume. We have been strategically promoting sales of *Diquas*, which is positioned as a high value-added product, mainly to private hospitals, and as you can see here, it has continued to grow at a high rate.

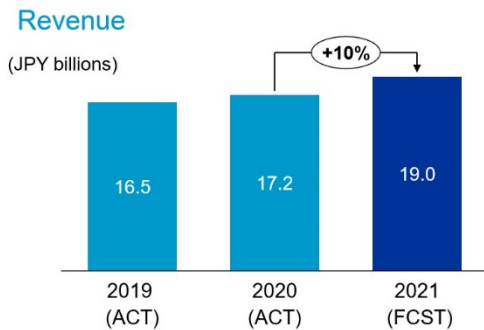
We are also taking steps to achieve medium-to-long term growth in parallel. We have made progress in the development of new products, of course, but we have also recently started construction of a new plant in Suzhou.

Asia

FY2020: Sales up despite the impact of COVID-19

Aim for sustainable growth by continuously promoting mainstay lineup incl. new products

Financial KPI



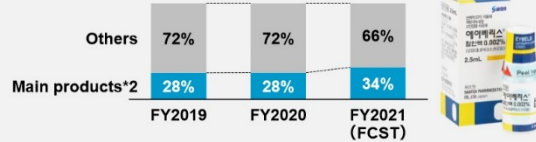
*1: Based on: Country/Region x no. of launched products. Incl. additional indication for Verkazia
*2: Main products : Tapros, Tapcom, Eybelis, Diquas, Ikervis, Alesion

Major Activities

Accelerating growth with new products

- Continuously launch new products incl. *Eybelis* (13 in FY2020*1)
- 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

Next, let's go to Asia. See page 20.

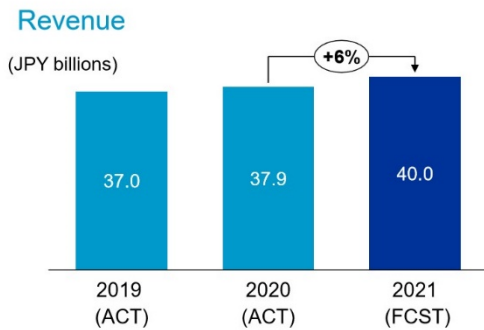
Although the impact of COVID-19 still remains significant in some countries, we achieved an increase in sales in FY2020, thanks to contributions from major markets such as South Korea. We launched around 13 new products in the entire region, but in South Korea, for example, we also launched *Eybelis*, making it the first time it is released outside of Japan.

We will continue to aim for high growth in FY2021, focusing on our core products, such as *Eybelis*, *Tapros*, *Tapcom*, *Diquas*, and *Ikervis*. At the same time, we will work with medical professionals and partners to ensure continued high growth over the long term through the development of eye care.

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 *Duressa*, 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*

→ Aim to expand market share in FY2021

(cf.) Market share for 2020 (vs 2019):
Italy 8.7% (+1.8pt), UK 2.4% (+0.2pt)

Source : Copyright © IQVIA MIDAS 2019.1-2020.12 Santen analysis based on IQVIA data. Reprinted with permission.

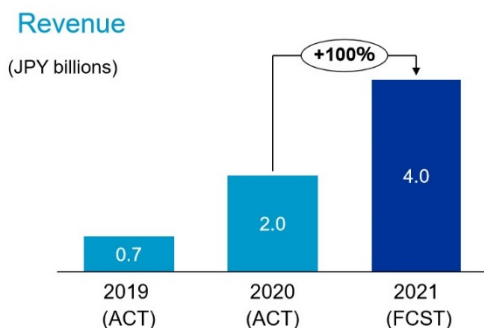
On page 21 is EMEA.

In Europe, COVID-19 had a relatively large impact on the region, as many countries had intermittent lockdowns in FY2020, but we were still able to grow faster than the market despite this. We plan to achieve 6% growth in FY2021 by continuing to improve our business growth and presence through the market penetration of various new products including *PRESERFLO MicroShunt*.

Americas

Maximizing product value by enhancing core business through Eyevence

Financial KPI



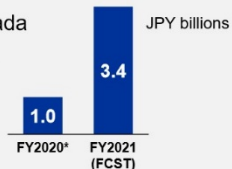
Major Activities

Solidify commercial platform

- Enhance core business through PMI of Eyevence
 - Plan for Eyevence to achieve profitability on standalone basis from Q3 FY2021
- Expand sales of *Verkazia* in Canada

[Eyevence sales forecast]

*Chart for FY2020 shows sales for 6-month period



U.S. development plan

Preparing for launch of products expected to achieve high growth over mid-to-long term

- *Verkazia* (U.S.): To be approved in FY2021 (PDFUA June 26, 2021)
- STN1011700 (DE-117): To be approved in FY2021 (PDUFA Nov 19, 2021)

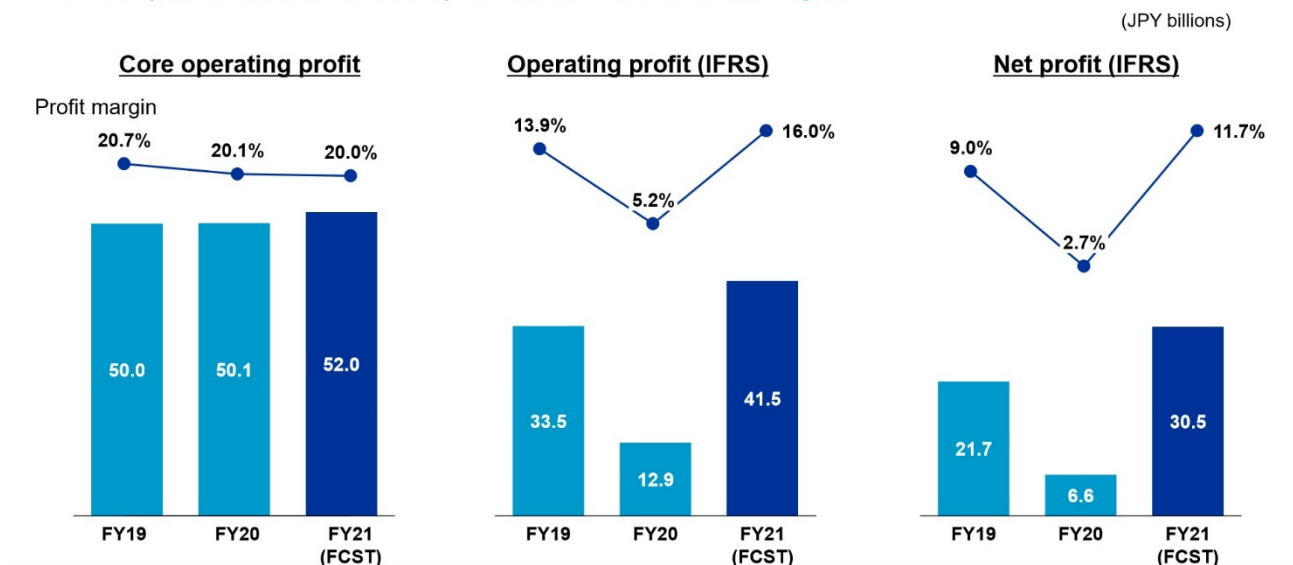
And on page 22, let's look at North America.

With the acquisition of Eyeveance in September last year, we acquired a business base with multiple ophthalmic drugs. In FY2021, we expect sales of approximately JPY4 billion, double the FY2020 level, in our North American business as a whole through mainly the Eyeveance products.

Pipeline development continues with the aim of increasing our presence among prescription pharmaceuticals. We are planning to obtain the approval of *Verkazia*, DE-117, and *Eybelis* during FY2021.

Profits (FY2019 - FY2021)

Overall profit increase boosted by increased sales in across regions



Copyright© 2021 Santen All rights reserved.

23

This is page 23.

By continuing this trend of increasing revenue and improving profitability in each region, we will achieve significant growth in core operating profit, full operating profit, and net income, as shown on page 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 new China plant, etc
- IT-related investment (up approx. JPY1.0 billion)



Rendered image: New China plant

Location: Industrial Park, Suzhou, Jiangsu province
Total floor area: 126,000m²
Production capacity: With 20 production lines, around 840 million doses/annually (5mL)
Operation schedule: Operation scheduled to begin in 2025

Next, please look at page 24. I would like to talk about capital investment among growth investments.

In FY2021, we plan to make a large-scale capital investment of JPY30 billion, approximately 3 times the amount in the previous year. This increase is mainly due to production-related investments. We are currently constructing a new building at the Shiga Plant and a new plant in Suzhou, both of which are designed to meet future demand growth and reduce environmental impact.

In addition, we are making IT-related investments, such as the development of a new ERP system, with the aim of improving operational efficiency on a global scale. We are determined to firmly establish our footing for future growth.

Pipeline: Main progress in FY2020 and outlook for FY2021

	STN ID	Progress
Pipeline for core business	STN2000100 (DE-128)	Approved in Canada. Under negotiation for PMA approval in US. Filing in Japan, approved in Asia are being planned.
	STN1011700	Filed in US (PDUFA Nov. 2021). Launched in Korea , Plan to be filed in Asian countries
	STN1012600	Additional Phase2 started
	STN1013900 (Rhopressa)	In-licensed. Phase3 in Japan started. Development in Asian countries under planning.
Allergy	STN1007603 (Verkazia)	Filed in US (PDUFA Jun. 2021) and China . In Asia, launched in 5 countries, approved in two countries, filed in two countries.
Dry Eye	STN1008903	Achieved the primary endpoint in Phase3 on <i>Diquas</i> new formulation. Filing is being planned.
New growth potential	STN1012700	Japan: completed the enrollment in Phase3 China: filed the application of Phase 1 , which is planned to be started in 2021
	STN1013400	Aim to start Phase1 in Japan in FY 2021
	STN6000100 (jCell)	Under the final preparation for Phase3 initiation
	STN1010900 (DE-109)	Improved the enrollment of Phase3, by expanding the development territory
	Ptosis	STN1013800 (RVL-1201)

Next, on page 25, are the highlights of the pipeline.

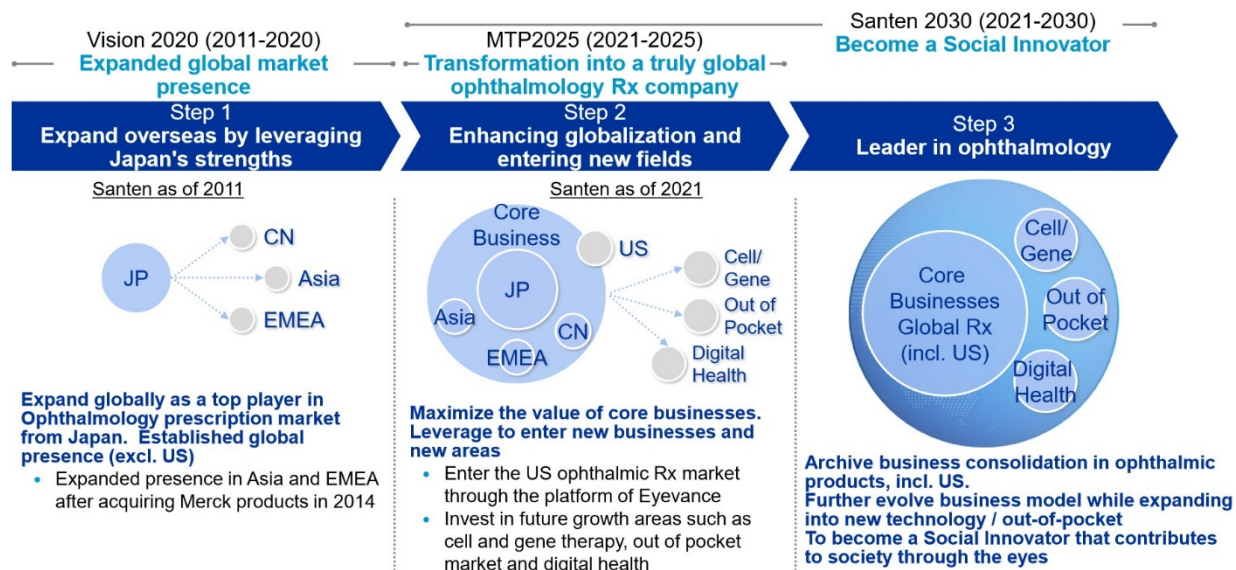
As you can see here, in addition to the steady progress of our existing pipeline, we have started Phase 3 trials in Japan for STN1013900, a ROCK inhibitor that we in-licensed last year, and we are also preparing for its development in Asia.

In the area of myopia, where high growth is expected in the future, we will begin clinical trials of STN1013400, a next-generation myopia treatment, ahead of other companies this FY2021. We are also planning to develop this globally in the future.

In addition, we have completed Phase 3 clinical trials for STN1012700, an atropine currently under development in Japan, and have filed for Phase 1 clinical trials in China, which are scheduled to begin in FY2021.

Further, the cell therapy STN6000100, jCell, and the ptosis drug STN1013800, which were introduced in FY2020, are progressing as planned.

Evolution from Vision 2020 to Santen 2030



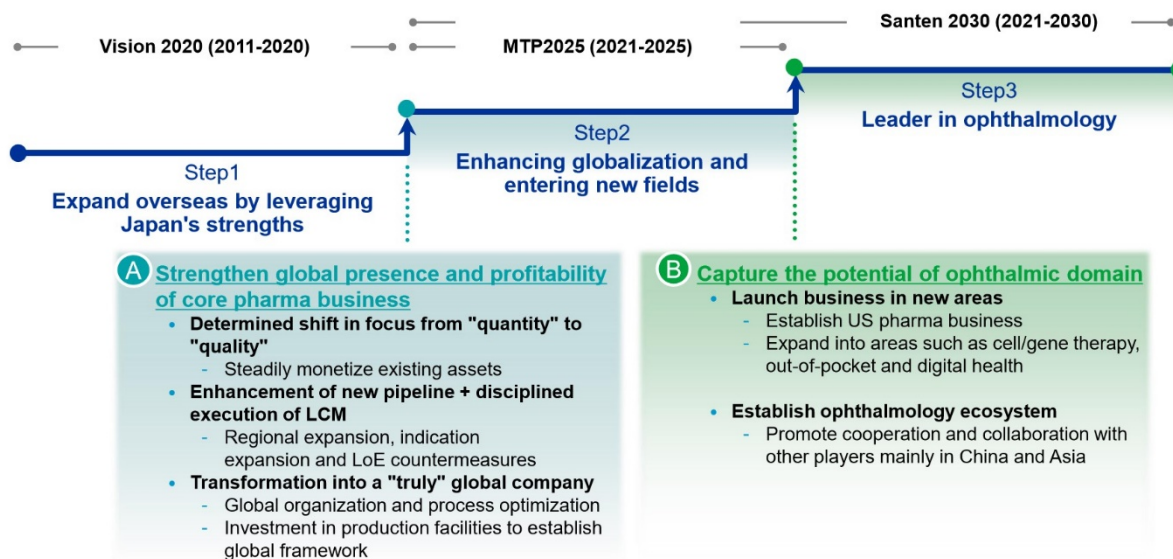
Please refer to page 27.

In FY2021, we expect business growth and pipeline expansion to continue steadily, but what about growth beyond that? I would like to briefly introduce the direction of the MTP2025, which I am scheduled to talk about next week on the 19th.

Over the past 10 years, we have rapidly expanded our business overseas in China, Asia, and EMEA, while leveraging our strengths as a top player in ophthalmic pharmaceuticals that we cultivated in Japan. In the next 10 years, we will further accelerate our global expansion, including in the US, where we have established a new business foundation. This will further solidify our presence in ophthalmology.

In addition, we aim to deepen our business model by expanding into business areas that are expected to grow in the future, such as cells, gene therapy, the out-of-pocket medical care, and digital health, and to become a social innovator that can bring happiness to people through the eyes. MTP2025, our next Medium-Term plan, is the first half of our 10-year effort to achieve this goal.

Management Themes to be Addressed in Next MTP



Please see page 28. I would like to explain the 2 initiatives we are taking to realize our vision.

First of all, in the pharmaceutical field, we will generate earnings by thoroughly utilizing the assets we have established and strengthened, including acquisitions. We will also enhance the value of our product portfolio by further strengthening the lifecycle management of existing products and steadily developing and launching new and improved products around the world. Of course, new pipelines will be added and strengthened.

Next, we will build a revenue base in new business areas with the aim of achieving continuous growth over the medium-to-long term. Specifically, in the area of pharmaceuticals, we will establish a business presence in the US and make it profitable. We are also planning to enter new areas, such as ptosis and myopia. Further, we aim to grow in the areas of cells, gene therapy, and digital health.

In addition, in China and Asia, where high potential exists, we will capture compounded growth opportunities and contribute to the development of ophthalmology by actively contributing to the development of the ophthalmology ecosystem while strategically collaborating with medical professionals and partners.

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 eye diseases and disorders and healthcare professionals by providing products to meet needs



Commitment to improve TSR* as a comprehensive metric for enhancing 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

This is page 29. I would like to discuss our approach related to the goals for this Medium-Term plan period.

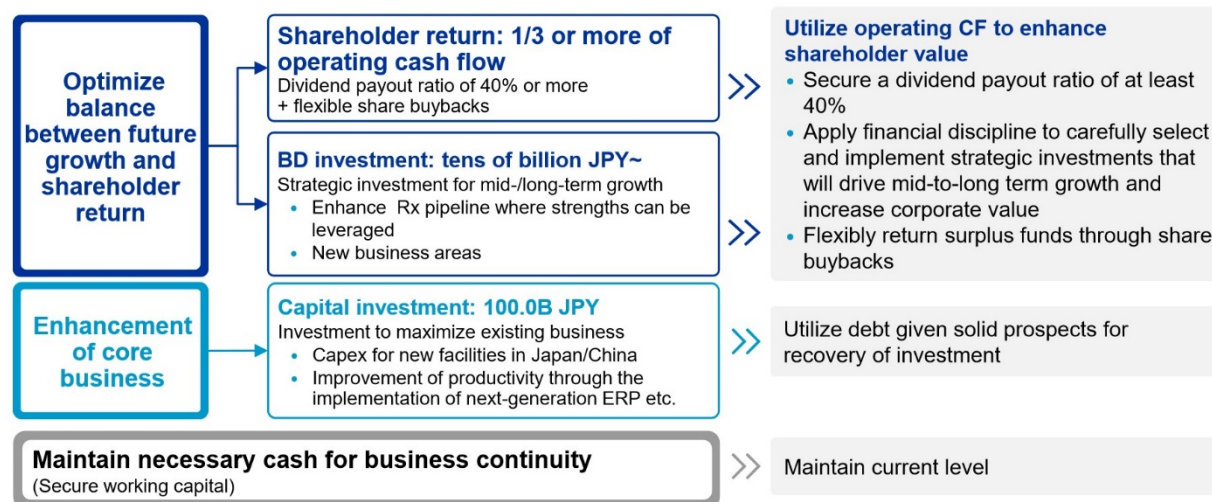
We will continue to contribute to our stakeholders based on our basic philosophy of "exploring the secrets and mechanisms of nature in order to contribute to people's health." We define "Happiness with Vision" as what we should aim for or as our purpose and aim to grow through solving social issues.

The right-hand side shows our management stance and our approach to medium and long term goals. In collaboration with medical professionals and partners, we will strive to enhance our corporate value by providing products and services to people suffering from eye diseases and problems, while contributing to the resolution of social issues related to the eyes. In addition to balancing growth and profitability, we believe it is important to further strengthen ESG, so we will step up our efforts in this area.

We will aim to increase shareholder value by improving TSR toward FY2025.

Capital Policy and Direction on Shareholder Return

We enforce the sustainable shareholder returns and BD investment to increase shareholder value.



Page 30 shows our capital policy and policy on shareholder return.

We have always tried to maintain a balance between shareholder returns and strategic investments, but we will now do so based on a clearer idea of shareholder returns.

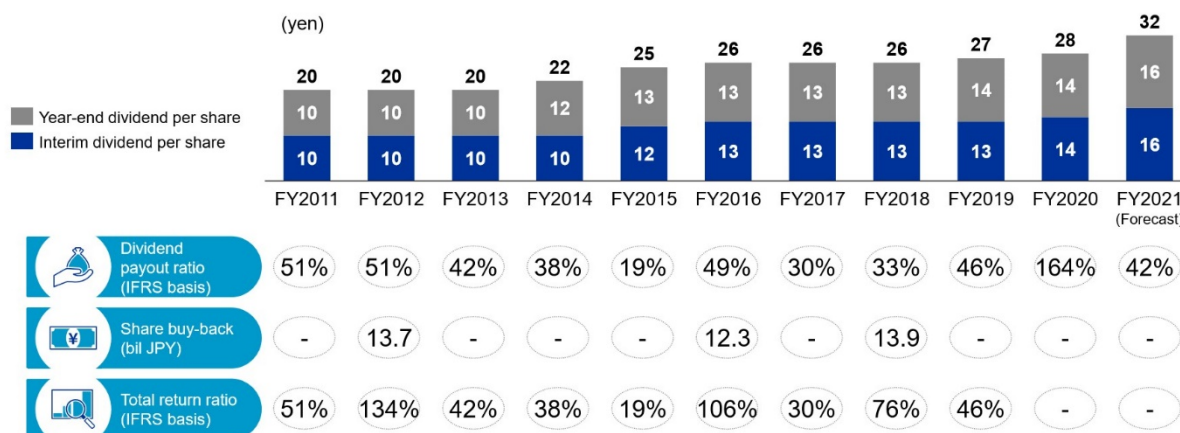
First, we will ensure a dividend payout ratio of 40% or more to return profits to shareholders. Next, we will make strategic investments that will contribute to our medium-to-long term growth and enhancement of corporate value. We will do this based on stricter financial discipline than ever before. Specifically, we are investing in RX areas, where we can leverage our strengths, and in promising business areas.

Capital investment is important for future growth. While it will mainly be for new plants and ERP, we plan to invest about JPY100 billion over the next 5 years. However, since steady investment recovery is expected, we plan to utilize debt in the future from the perspective of balance sheet optimization. A certain amount of cash reserves is necessary for business continuity, but we will maintain this at the current level.

Therefore, if there is no demand for funds for investment projects, we will flexibly return surplus funds through share buybacks. As a result, we intend to allocate more than one-third of our operating cash flow to shareholder returns. In this way, we will enhance shareholder returns while firmly securing future growth.

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.

Copyright© 2021 Santen All rights reserved.

31

Please see page 31. This is our dividend forecast for FY2021.

As I have said, in FY2021, we expect to increase profits. So, based on the concept of return mentioned earlier, we will pay an interim dividend of JPY16 and a year-end dividend of JPY32. The dividend will be increased by JPY4 compared to the previous year. The dividend payout ratio is planned to be 42%.

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 decision-making 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

Copyright© 2021 Santen All rights reserved.

32

Finally, let's go to page 32. I would like to provide some additional information on the postponement of our transition to a holding company structure and the change in accounting period, which was disclosed yesterday.

We had been planning to shift to a holding company and change our accounting period in order to promote globalization and strengthen group governance. However, in light of the current short-term changes in the business environment, we have decided to postpone both of these measures and prioritize the reliable launch of MTP2025 and the thorough implementation of various important measures to achieve it.

On the other hand, regardless of the timing of the implementation of these 2 measures, we will steadily promote the globalization of our business and the strengthening of our group governance within the current framework.

That's all the explanation I have for you. Next Wednesday, May 19, we will have an opportunity to explain our new Medium-Term plan. I would like to talk about how Santen will achieve growth over the next 5 years toward the future, the future envisioned under Santen 2030. We hope that you will find the time to join us again.

Now, Mr. Morishima will give us an update on R&D.

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 *Diquas* new formulation, STN100**08903**.

New pipeline

- Aim to start Phase 1 study on the next-generation product for myopia, STN10**13400**, in Japan in FY2021

Territory expansion

- STN10**11700** (*Eyberis*) : Launched in Korea
- STN2000**100** (DE-**128**) : Approved in Canada
Plan to file in Japan in FY2021
Under discussion for PMA approval in US
- STN100**7603** (*Verkazia*) : NDA filed in China

Steady progress on other main pipelines compounds

Morishima: I'm Morishima from Research and Development. I would like to share with you some of the highlights of our R&D activities for the fourth quarter of FY2020. Please see page 34.

As Mr. Taniuchi explained earlier, we were able to achieve the primary endpoint in the Phase 3 study of STN1008903, the new formulation of *Diquas* that we are working on as a countermeasure for LoE. I will explain this in a little more detail on the next slide.

As for new pipelines, we were able to add STN1013400, a next-generation myopia treatment, to our pipeline, and we are currently preparing for its clinical development in Japan in FY2021. This will also be explained later on another slide.

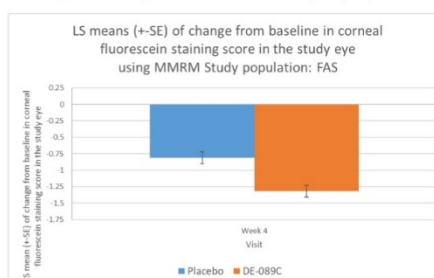
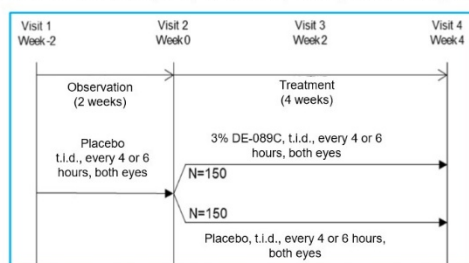
In addition, we are steadily advancing the regional development of our main products, STN1011700, which is *Eyberis*, STN2000100, which is DE-128, MicroShunt, and STN1007603, which is *Verkazia*. I would also like to report that the number of enrolled subjects for DE-109 has exceeded 100 and that

we are steadily advancing the development of our main pipeline in general, even under this pandemic of coronavirus.

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

Next, let's go to page 35. Regarding the new formulation of *Diquas*, which Mr. Taniuchi talked about earlier, this slide shows an overview of the Phase 3 trials.

The clinical trial is designed to show the superiority of the new formulation over placebo in dry eye patients. After the observation period, subjects were assigned to either the test group or the placebo group, and each group received eye drops 3 times a day for 4 weeks, with the primary endpoint being the amount of change in staining of the corneal epithelium by fluorescein after 4 weeks.

Staining by fluorescein can determine the distribution and condition of corneal epithelial damage. As shown in the figure on the right, the fluorescein staining of the new formulation showed a statistically significant improvement over placebo after 4 weeks of eye drops.

This pipeline will halve the number of ophthalmic administration compared to the current formulation and is expected to meet the needs of a wider range of patients than ever before. Although clinical trials have confirmed the therapeutic effects of eye drops 6 times a day, we have heard that 6 times a day is a heavy burden for actual patients and that some patients do not achieve the expected effects because they forget to use the drops.

The 3-times-daily formulation is expected to reduce the burden on patients and ensure reliable treatment, and we hope that it will be accepted by many patients and differentiated from generic products. Santen plans to file an application for this drug in FY2021 and aims to be able to market it before generic products are launched.

Q4 FY2020 Topic - new growth potential

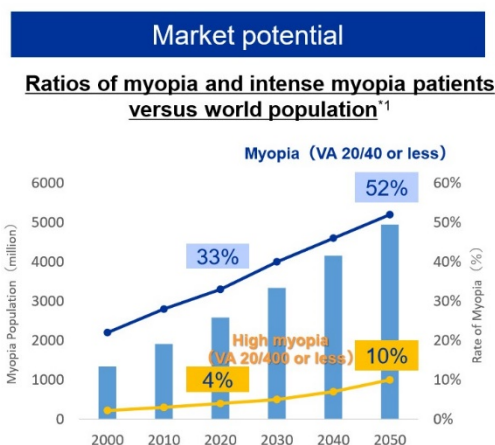
Start clinical trial of STN1013400, next-generation drug for suppression of myopia progression in children, ahead of peers

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



^{*1} Holden, et al, 2016 Ophthalmology

Next, we come to page 36.

In the field of myopia, which we have positioned as a pillar of our medium-to-long term growth, we were able to add a new pipeline in FY2020.

As we all know, the number of myopia patients has been increasing in recent years due to changes in the living environment. Since myopia is a cause of various eye diseases in adulthood, governments, especially in Greater China, have been actively implementing policies to curb myopia, and this trend is expected to spread globally in the future, including the interest of doctors and other stakeholders.

While several atropine products have already been in development pipeline, Santen is now the first company to add STN1013400, a next-generation treatment for inhibiting myopia progression in children with a new mechanism of action, to our pipeline. Due to its selective muscarinic antagonism, STN1013400 is expected to show higher efficacy in inhibiting ocular axial elongation than existing atropine preparations being developed by various companies and to reduce the side effects of atropine preparations, such as mydriasis.

Santen plans to initiate Phase I trials of the drug in Japan during FY2021 and is also preparing a development plan for China to promote the global development of the drug.

For more information on the pipeline, please refer to the following pages. That is all.

Question & Answer

Q-1-1:

Thank you very much. Now, I would like to ask about your business in China. This is about the impact of the value-based purchasing of *Cravit* and *Hyalein* this year. The projection for *Cravit* this year is that its sales YoY will be flat, but based on this, I would like to know how much *Cravit*'s sales in large

hospitals were at the end of the current fiscal year and if you could explain in more detail about the expansion of sales in channels other than large hospitals.

With regard to *Hyalein*, it has also become subject to value-based purchasing in February this year. At that time, I think the 0.3% was not subject to value-based purchasing, but is it correct to say that the sales forecast for the start of this fiscal year is based on the assumption that it will be subject to value-based purchasing?

A-1-1

Suzuki: First of all, we understand that we have already absorbed the impact of value-based purchasing to a certain extent in terms of *Cravit*'s sales in hospital. Therefore, we have made the assumption that sales for this fiscal year will be about the same.

As for your second question, we have not yet heard that the 0.3 MD (Multi-dose) will be subject to value-based purchasing. One of the reasons is that we are actively working on the dry eye treatment where we are going to switch to *Diquas*, while the other reason is that we are not going to switch to 0.3 but to 0.1. Hence, we are taking a conservative view of the situation. That will be my answer to the question.

Q-1-2

Thank you very much. By the way, do you have any figures on the current sales of *Cravit* in large hospitals?

A-1-2

Suzuki: As I recall, we do not disclose this information. I'm sorry.

Q-1-3

Okay. Thank you. My second question is about dividends. I think the dividend has always been flat or increased by JPY1 in the past. I think you have increased the dividend by JPY4 this time, which is quite a large increase. Am I correct in my understanding that the reason why you increased the dividend by JPY4 is because you are more confident in your medium-to-long term growth potential?

A-1-3

Koshiji: With this understanding, I think it is fair to say that we are confident in our long-term future and that we will return profits to shareholders in line with our profit growth.

Taniuchi: I would like to add something. Earlier, I talked about our shareholder return policy. In the past, we have always said that we would pay stable dividends and that we would continue to pay stable dividends. This time, we have clearly taken it one step further.

In this context, we have been able to see the current progress toward growth in Japan, China, and overseas in the form of what I mentioned earlier, as well as the path toward resolving issues. Based on the idea I mentioned, we have increased the dividend by JPY4 as a result of our efforts to firmly guarantee up to 40%. I hope you can understand this kind of confidence in our growth.

Q-2-1

I would like to ask for 2 things about China. The first one is about *Hyalein*. I was told a long time ago that your company would shift to *Diquas* for value-based purchasing starting in April. What is the status of the shift? Do you feel that things are going pretty well?

A-2-1

Suzuki: As for *Diquas*, there are 2 points: first, it has quadrupled its growth from FY2018 to FY2019*¹. This year, we are looking at tripling sales against FY2020*². In addition, the ratio of private hospitals to public hospitals was originally about 4:6, but as of last year, it has already switched to 6:4, so we are making good progress.

Looking in terms of current shipment, shipments continue to be in line with our expectations, so in that sense, we know that we are making steady progress. That's all.

*1 post script: approximately quadrupled from FY19 to FY20

*2 post script: quadrupled for FY21

Q-2-2

So, the strategy of both *Cravit* and *Hyalein* is to concentrate on this area, since the leverage of private hospitals is the result of value-based purchasing, correct?

A-2-2

Suzuki: Yes, you are right.

Q-2-3

This means things are going well.

A-2-3

Taniuchi: I would like to add something. As I have mentioned, *Hyalein*, 0.1, is a product that has been sold mostly outside of large hospitals since February. Therefore, the impact of value-based purchasing has been taken into account in the current situation at private hospitals.

It's fine to think that *Diquas* is being carried there, so after becoming dependent on large hospitals, including for *Cravit*, we were able to steadily increase sales channels at private hospitals and other retail stores, where we are currently expanding sales, in FY2020. Hence, we think that we will succeed as a whole in FY2021.

Q-2-4

I understand very well. The other question is in the area of development. China seems concerned about myopia, and while your company is currently doing in Japan, you are supposed to work in China, too. I think the Department of Public Health in China is quite aware of the seriousness of myopia, unlike in Japan. What is your perspective on this?

A-2-4

Morishima: I would like to start with the development matters. This year, we started Phase 1 trials of atropine in China, and since China established guidelines last year, we are following those guidelines and starting development a little later than in Japan. Once that is done, we would like to proceed with Phase 3 study similar to that in Japan.

In addition, the government has been supporting these development activities to a great extent, and patient enrolment is progressing relatively well, although not only in Santen.

Q-2-5

Okay. This is for the global market, including China. Is it correct to say that the target market is basically China?

A-2-5

Taniuchi: I would like to add something. First of all, as you asked earlier, it is true that the Chinese government is putting a lot of effort in this area. The national guidelines and the efforts to reduce and eradicate by the treatment have been clearly stated, and each local government has started such efforts.

Therefore, all of us, including myself, are working with a firm understanding of the potential of myopia and the fact that we are targeting a population of 100 million myopic children.

I believe that the myopia market, including atropine, will be established on a global scale in the future, and we are basically thinking in terms of global development. But as you pointed out, China and other Asian countries with large populations have a large number of myopias, or rather, they overlap with each other. I hope you understand that this is our main focus.

Q-3-1

First, I would like to ask you about the situation of *Cravit* in China. In your earlier explanation about *Cravit*, you said that you were able to absorb the impact of value-based purchasing to a large extent, so this is the plan. What do you mean by the fact that you have been able to absorb the impact? I think it means that your retail initiatives for private hospitals and pharmacies have been successful.

In fact, looking at the trends and figures for January-March alone, it looks like the plan for this fiscal year is still a little high. What is the current situation, and what are the risk factors for this plan, and conversely, what are the possible upside factors?

A-3-1

Suzuki: First of all, the reason why I said that we have been able to absorb the impact is because the tendering for value-based purchasing has settled down to a certain extent, and the tendering and product supply of hospitals have already been completed to a certain extent. Hence, we do not foresee more damage than this in public hospitals.

At the same time, the development of so-called private hospitals and the retail market is progressing smoothly, so we are absorbing both the positive and negative effects of these developments. That's all.

Q-3-2

Regarding this point, when you gave us a briefing in February, I think you said that public hospitals have about 50% exposure. Can you explain a little bit more about whether this part is now almost zero and whether you are making up for it to some extent with private hospitals or retail?

A-3-2

Suzuki: As far as we were concerned, we have not actually fallen to zero. So, from this point, even though we have been envisioning a rather pessimistic scenario, we have not really fallen to that level.

In addition, as I mentioned, there was some expansion in private hospitals, so the overall scenario was not as negative as expected.

Taniuchi: I also have something to say. As you can see, national public hospitals now account for about 30% of the total, and they were originally more than half of the total. They may have decreased rapidly, but it has not yet reached zero.

At the moment, the percentage of non-national hospitals is around 70%, so we are working to increase the number of hospitals that are not subject to value-based purchasing. As Mr. Suzuki explained earlier, the situation at national and public hospitals has largely settled down.

Q-3-3

Thank you very much. Secondly, please tell us about 134. I understand that you will start clinical trials this term. I think the indications are the same, but the mechanism of action is different.

In the case of the second-generation products, the timing of development may be different from that of 127. What priority will be given to the development of the new drug? Is it all right not to have to think about the risk of competing for patients within your own company as the development is carried out at the same time? Could you please comment on the positioning of the drug and the development strategy?

A-3-3

Morishima: I will give you an explanation on this. Basically, the mechanism is the same, so there is a possibility that patients will overlap. However, we have already entered Phase 3 for atropine, and we are about to enter Phase 1 for 134, so there is some lag. We are envisioning a scenario in which we develop the market with atropine and grow significantly with 134.

Q-4-1

As you have explained earlier about the products that are doing well in China, the forecast for *Tapros* is quite high, or rather, the growth is quite high. I think the sales has quadrupled or quintupled. As you mentioned earlier, could you explain one more time the assumptions used in the forecast for the current fiscal year for *Tapros*? This is my first question.

A-4-1

Suzuki: As I mentioned earlier, as of last fiscal year, *Tapros* has already become the number one in terms of market share based on volume*, with the latest figure of more than 30% in market share.

Post script: in prostaglandin drugs

We are helping with the guidelines shaping, and we are also promoting training within hospitals. Because it is on the NRDL, it is spreading to the ministry quite quickly. In this sense, we have been able to deliver our products to hospitals in Beijing and Shanghai. So, looking at the latest shipment status, I think we will be able to achieve our current target. Of course, there are various risks, such as stopping continuous prescriptions when a patient contracts COVID-19 somewhere, but looking at the current trend in the numbers, I think we can achieve this goal. That's all.

Q-4-2

Thank you very much. My second question is about the domestic *Alesion*. It was also extremely strong in the previous fiscal year, and the Q4 results should be in support of that.

There are seasonal factors, of course, but until now, the number has been increasing, partly because of Mitsubishi Tanabe, right? However, if you look at the current term, it has leveled off. What are your assumptions or thoughts in this area?

A-4-2

Suzuki: Let's go to *Alesion*. We believe that there is still room for our target practitioners to switch. The percentage of *LX* in the *Alesion* family is roughly 60%. We believe that there is still room to switch to the new system in the future, considering compliance and other factors, so we have made the assumption that there is room for expansion in this area.

Q-4-3

The forecast is for flat growth, but will that be enough?

A-4-3

Suzuki: The other thing is that there will be generics for the older generation, and I understand that there are more than 10 companies there that are currently submitting applications. Therefore, the figures will remain unchanged after factoring in the impact of that. In addition, the drug price revision is also reflected in the situation.

Q-5-1

Thank you very much. With regard to *Alesion*, what do you think about this risk that the number of patients switching from *LX* to generics may increase more than expected? That would be my first question.

A-5-1

Suzuki: Sorry, I meant the assumption that the risk of switching is from the older generation of *Alesion*. We are not saying that it will start from *LX*, so the generic will be available around June. Therefore, we understand that the older generation will be switched over.

Q-5-2

Is this something that is unlikely to happen in actual practice, such as switching to cheaper generics? Sorry, this is a layman's question.

A-5-2

Suzuki: *LX*, including its usage and ease of use, has become a very user-friendly formulation for patients, so if we were to look at it in terms of cost and return to the old, easy-to-use product with a higher prescription frequency, we believe that patients who have already used *LX* would not return to that.

Taniuchi: I would like to add something. This is a product that has only been on the market for a short time, and we just started selling it amid the COVID-19 pandemic. We believe that there is a difference in the effectiveness of 4 times eye drops versus 2 times eye drops for allergy patients. So, for this fiscal year in particular, the switch to *LX* has been very smooth. I believe that this is where the difference and differentiation of the product lines. So, as you say, we will make sure to prepare for what will happen to generics, but for now, we believe that the value of this product is well understood by patients.

Q-6-1

What can you tell us about *Eybelis*? In terms of the sales of individual products attached to the brief report, there is a slight difference between the sales in Japan and the rest of the world. I think this is the sales you were expecting in the US this fiscal year.

I think that *Eybelis* was originally a product that had a hard time getting off the ground even in Japan. I also thought that the side effects of coloring, or adversarial events, were a bit of a problem, especially in the United States and Europe. I have heard that in the United States, especially in the case of glaucoma, it is difficult to compete as a single drug unless you have several therapeutic drugs, or combinations of drugs, in your lineup.

Could you tell us your thoughts on this?

A-6-1

Taniuchi: I'll start. First of all, this is for Asia. The product has been launched in South Korea, so please understand that a small number of sales from that market is added to the sales in Japan.

As for the US, as you pointed out, it is still in the pre-approval stage, so I have not included it in this brief. As you mentioned, the idea is that this product has a unique profile, and a safety profile that is different from existing prostaglandins. In the US, this is a key differentiator.

The PDUFA is coming up in the second half of this year, so once we know more about the situation with the FDA, we will be able to talk about the detailed approval schedule, sales schedule, and sales strategy.

Q-6-2

I understand. Eyevance does not have any glaucoma-related medications, right?

A-6-2

Taniuchi: At present, Eyevance mainly covers the anterior segment of the eye, but it also covers so-called general ophthalmology and comprehensive ophthalmologists, so I think the Eyevance platform will be the first basic platform.

Since there are glaucoma specialists in the US, Eyevance does not cover them at present, so I think we will be considering whether to transfer Eyevance's sales resources to this area, or whether to increase the number of resources. We hope to talk about this when we have a better idea about the approval process.

Q-6-3

Thank you very much. I was quite surprised to see the figure of minus 4.5% for the entire Chinese market on page 14. Is that what this is? The impact of value-based purchasing is mostly seen here. I think this is IQVIA's figure for how it was the previous year. It would be very helpful if there were. Do you have any data on that?

A-6-3

Taniuchi: As you know, this is the IQVIA data, and it is exactly as it is, with no alterations on our part. As for the actual market, as I mentioned earlier, this data does not necessarily cover the entire market, so maybe what's behind this is the increase in other markets due to the shift of patients from large hospitals. We have no choice but to guess.

I don't think the entire country has fallen like that. Of course, China was affected by the COVID, but it has already started to recover relatively quickly, so I think that if the coverage expands in the future and we can see the market outside of hospitals, we may see things differently.

In fact, our sales trends are naturally different from those supplemented by IQVIA here. I have the impression that this data will become more like reference data in the future. In a place where there is a slightly different view of the market, we are trying to find a way onsite on how to do it.

Q-6-4

That's basically it. Retailers are not covered; that's what the data says, isn't it?

A-6-4

Taniuchi: That's right.

Q-7-1

I would like to talk about page 41 of the slides. In the last fiscal year, sales exceeded the original plan, but core operating profit was lower than the original plan. One of the reasons for this was that SG&A expenses were 10% higher than the forecast at the beginning of the fiscal year.

At the beginning of the fiscal year, you explained that there were a lot of uncertainties in sales due to the impact of COVID-19 and other factors but that you would aim to achieve core operating income by controlling costs.

What should we think is the reason you arrived at that goal as a result? As we look to the future, I would like to ask you to comment on the degree of precision in the planning outlook and how management should be adapted to changing conditions.

A-7-1

Koshiji: I will answer that. SG&A expenses have increased compared to the figures announced at the beginning of the fiscal year in May last year. This is the main reason why profits declined to 50.1 billion versus 52 billion in core operating income. Therefore, is financial discipline working? That's how I understand it. In conclusion, the expenses are being managed properly and well. This is how we evaluate ourselves.

With regard to why it increased by 10%, first of all, gross profit increased more than we had expected at the beginning of the term. This is because the impact of COVID-19 was relatively less than we had originally expected, or rather, less than we had anticipated. In light of this situation, we have increased the size of our SG&A expenses based on the judgment that it is appropriate to invest in upfront marketing expenses for the future and to drive the business forward, which will lead to medium-term profits.

On the other hand, there is a slight increase in SG&A expenses compared to the forecast we disclosed on April 9, but we cannot deny that this is mainly different from our forecast. This was mainly due to a difference in estimates for SG&A expenses, which we originally thought could be booked in FY2021, but had to be booked in FY2020.

In addition, the payment of bonuses to employees and adjustments to the method of calculating such bonuses have been factored in, resulting in a slight increase in expenses. As a result, there was a slight shortfall in the increase compared to the revised forecast on April 9. That's how I see it. Again, I hope you can see that we are managing our expenses appropriately.

[END]