Q2 FY2024 Financial Results

November 7, 2024

Santen Pharmaceutical Co., Ltd.

Featuring

Takeshi Ito
President &
Chief Executive Officer

Kazuo Koshiji
Chief Financial Officer

Peter Sallstig
Chief Medical Officer

Agenda

Strong progress versus full-year forecast

Q2 FY2024 results: Absorbed impacts from supply constraints including *Diquas LX* and Noto plant

- Revenue: JPY 146.4 billion (+0.4% YoY), Core OP: JPY 29.7 billion (-5.7% YoY)
- Launched: *Catiolanze* in EMEA and ROCK inhibitor in Asia
- Business development for future growth: 2 opportunities tapped

Full-year forecast: No change, although better-than-expected progress

- Product supply: *Diquas LX* re-shipment timing yet to be determined but progress in identifying cause
  Noto plant in full operation since late September
- License-out: Licensing agreement for development and marketing rights of glaucoma pipeline[1] in South America
- Expecting approval of STN1012700 (slowing myopia progression), and filing for STN1013800 (ptosis) in Japan

Shareholder returns: JPY10.0 billion share buyback announced in addition to H1

- Interim dividend: JPY 17/share. Year-end dividend expected to be JPY 17/share. Potential dividend hike conditional on profit levels according to our progressive dividend policy
- JPY 28.6 billion of executed share buyback decided in H1 FY2024

1 Relevant pipelines are: STN10139 (*Rhopressa*/*Rhokiinsa*), STN10140 *(Rocklatan*/*Roclanda*), STN10117 (*Eybelis*), and STN10126 (sepetaprost).
2 Period of repurchase: May 10, 2024 to November 6, 2024

Solid and higher-than-expected progress versus full year forecast

	Q2 FY2023 ACT	Q2 FY2024 ACT
USD (JPY)	141.46	153.20
EUR (JPY)	153.66	166.19
CNY (JPY)	19.81	21.40

(JPY billions)	Q2 FY2023 Actual	Q2 FY2023 vs Revenue	Q2 FY2024 Actual	Q2 FY2024 vs Revenue	Q2 FY2024 YoY
Revenue	145.8	-	**146.4**	**-**	**+0.4%**
Cost of sales	59.3	41%	63.5	43%	+7.0%
Gross profit	86.5	59%	**82.9**	**57%**	**-4.1%**
SG&A expenses	42.6	29%	42.2	29%	-0.9%
R&D expenses	12.3	8%	10.9	7%	-11.2%
Core operating profit	31.5	22%	**29.7**	**20%**	**-5.7%**
Non-core expenses	0.8	1%	-	-	-100.0%
Amortization on intangible assets associated with products	4.7	3%	4.5	3%	-4.1%
Other income	1.2	1%	0.2	0%	-82.9%
Other expenses	2.1	1%	1.6	1%	-26.3%
Operating profit	25.1	17%	**23.9**	**16%**	**-4.9%**
Finance income	1.1	1%	1.0	1%	-10.2%
Finance expenses	0.6	0%	1.0	1%	+81.5%
Share of loss of investments accounted for using equity method	1.6	1%	-	-	-100.0%
Profit before tax	24.1	17%	23.8	16%	-1.0%
Income tax expenses	4.8	3%	5.1	4%	+7.0%
Actual tax ratio	*20%*	-	*22%*	-	+1.6pt
Net profit	19.3	13%	**18.7**	**13%**	**-3.0%**
Core net profit	25.9	18%	23.2	16%	-10.3%

Major factors in YoY differences

Revenue: +0.4%

- Overseas business (China, Asia and EMEA)
  : +6% YoY including FX, -1% excluding FX,
  +2% excluding FX and one-time factor in FY2023

Gross profit: -4.1%

- Increased COGS ratio mainly due to region/product mix

Core OP: -5.7%

- Decreased SG&A amount/ratio with cost optimization
- Decreased R&D expenses mainly due to clinical trials' progress and effects of structural reforms
- +1% YoY excluding one-time factor in FY2023

OP (IFRS): -4.9%

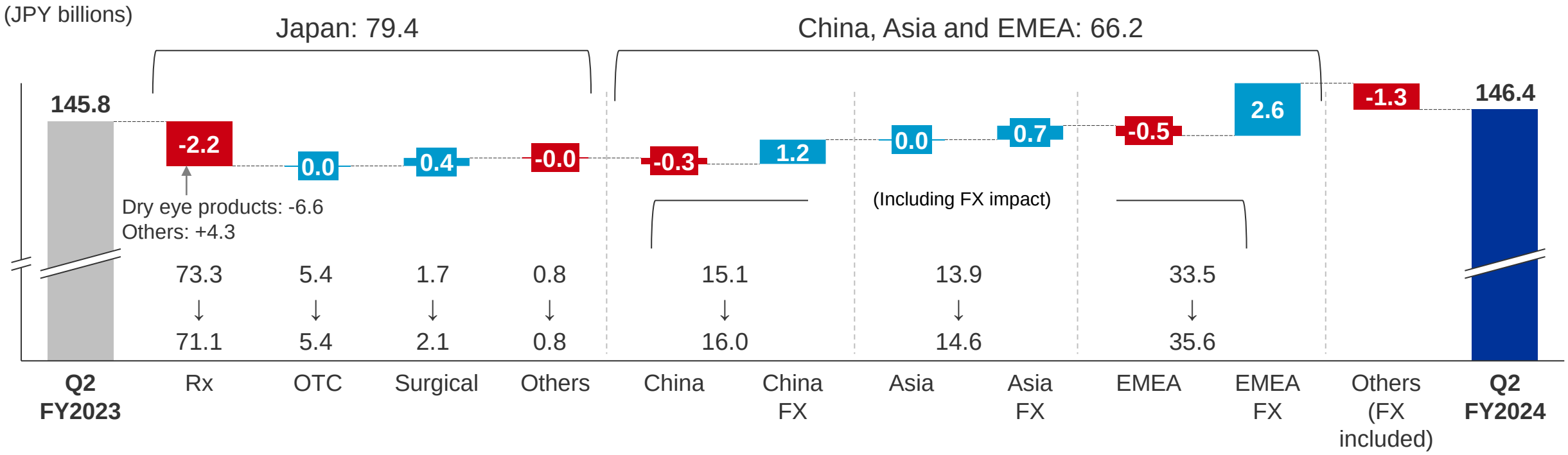
- Other income: Included one-time factor of JPY 0.7 billion related to Americas in FY2023

Net profit (IFRS): -3.0%

- No share of loss of investments this FY
- Tax ratio excluding one-time factors: 20.4%

Q2 FY2024 Sales bridge

YoY Sales increase: *Diquas LX* and product supply impact mitigated by other mainstay products in Japan and strong overseas contribution incl. FX

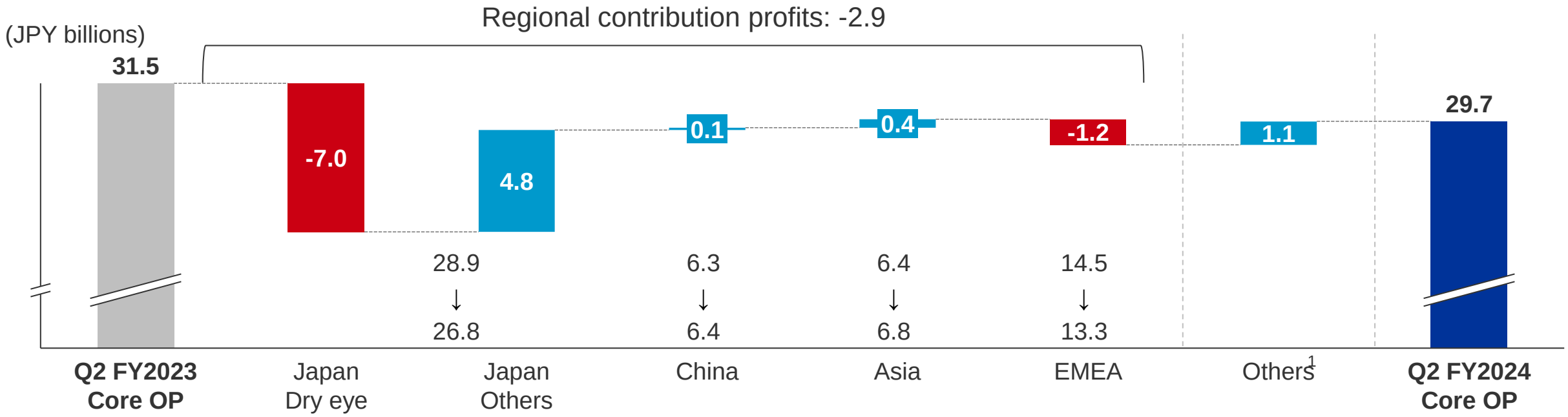


Japan	-2.2% YoY: Minimized impact from NHI price reduction and *Diquas LX* voluntary recall with *Alesion* eyelid cream and others
China	+5.6% YoY (Ex. FX impact -2.2%): Solid performance from multi-channel strategy and *Tapros.* Negatively impacted by *Diquas* VBP and product supply (approx. JPY -1.1 billion YoY)
Asia	+5.1% YoY (Ex. FX impact +0.0%): Steady growth from mainstay products in glaucoma and dry eye in key markets. Negatively impacted by product supply (approx. JPY -0.2 billion YoY) and HCP strikes in S. Korea
EMEA	+6.3% YoY (Ex. FX impact -1.4%): Continued growth from glaucoma preservative-free and dry eye products. Includes reactionary drop from *Ikervis* one-time factor (JPY 2.3 billion) in FY2023

*Sales classified into countries or regions based on customer's location. EMEA: Europe, Middle East and Africa

Q2 FY2024 Core OP bridge

Minimized *Diquas LX* impact with other products/regions and cost optimization. Faster-than-expected progress versus FY forecast



Regional contribution profits	<u>Japan</u> Dry eye products: Mainly due to decrease in revenue from *Diquas LX* voluntary recall and NHI price revision, coupled with *Diquas LX* recall related expenses (FY2024 NHI price revision *Diquas*: -32%, *Hyalein 0.1*: -10%) Others: Steady progress in other therapeutic areas, and decrease in SG&A <u>Overseas</u> China: Increased profit despite impact from *Diquas* VBP and product supply Asia: Increased profit despite product supply and other factors EMEA: Mainly due to reactionary drop from *Ikervis* one-time factor in FY2023. Ex one-time factor, solid progress with increased profit.
Others	Completion of structural reforms including streamlining in Americas pharmaceutical commercial business and promotion of cost optimization

1 R&D and back-office expenses in region and global functions, and contribution profit not related to the regions above

Faster-than-expected progress, but maintain Aug. 6 forecast with co-pay hikes and other factors in H2 to be considered

	FY2023 ACT	FY2024 FCST (Aug.6)
USD (JPY)	144.80	155.00
EUR (JPY)	156.88	165.00
CNY (JPY)	20.24	21.30

(JPY billions)	FY2023		FY2024			
	Actual	vs Revenue	Forecast (Aug. 6)	vs Revenue	YoY	Q2 Progress
Revenue	302.0	-	**302.0**	**-**	**+0.0%**	**48%**
Cost of sales	123.1	41%	129.0	43%	+4.8%	49%
Gross profit	178.9	59%	**173.0**	**57%**	**-3.3%**	**48%**
SG&A expenses	90.8	30%	91.0	30%	+0.2%	46%
R&D expenses	25.3	8%	27.0	9%	+6.9%	41%
Core operating profit	62.8	21%	**55.0**	**18%**	**-12.4%**	**54%**
Non-core expenses	1.0	0%	-	-	-100.0%	
Amortization on intangible assets associated with products	9.5	3%	8.8	3%	-7.1%	
Other income	1.5	1%	0.7	0%	-54.8%	
Other expenses	15.3	5%	2.4	1%	-84.3%	
Operating profit	38.5	13%	**44.5**	**15%**	**+15.5%**	**54%**
Finance income	1.6	1%	2.0	1%	+27.2%	
Finance expenses	2.7	1%	1.5	0%	-43.7%	
Share of loss of investments accounted for using equity method	7.6	3%	-	-	-100.0%	
Profit before tax	29.9	10%	45.0	15%	+50.6%	53%
Income tax expenses	3.2	1%	11.5	4%	+262.6%	
Actual tax ratio	*11%*	-	*26%*	-	-	
Net profit	26.7	9%	**33.5**	**11%**	**+25.5%**	**56%**
ROE	9%		11%			
Core ROE	16%		14%			
Core net profit	48.5	16%	41.3	14%	-15.0%	56%

Factors to consider post forecast revision on August 6

- Revenue and profits resulting from license-out of glaucoma assets (already factored in the forecast as of August 6[1])

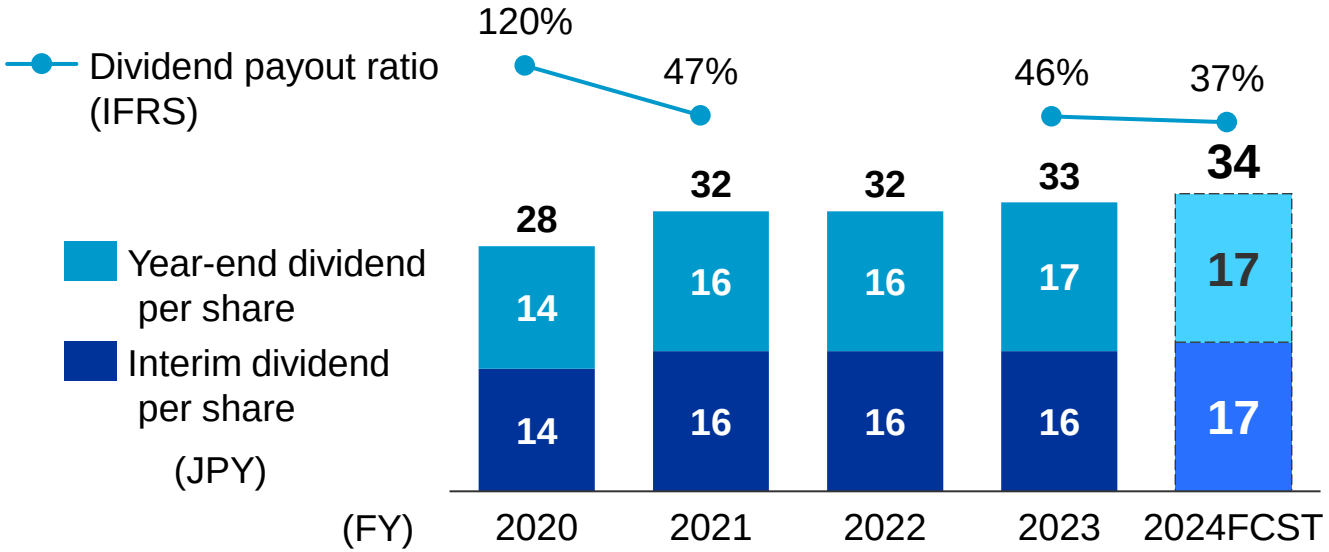
Other factors

- Japan:
  Pollen-levels, impacts from co-pay hikes for long-listed products
- Overseas: Product supply, significant FX fluctuation
- Cost optimization

1: Including in “Others” on the page of 8-9 in Q1 FY24 presentation
https://www.santen.com/content/dam/santen/global/pdf/en/ir/document/202503/mtg2025_1q.pdf

Share repurchase in H2 taking share price and capital considerations

- Approx. JPY 28.6 billion of repurchase was made from May 10 to November 6, 2024, in accordance with the capital allocation policy in the medium-term management plan (FY2023-2025) . The Company also decided to make another repurchase of JPY 10.0 billion (maximum) to enhance capital efficiency based on a consideration of factors including investment opportunities.
- Approx. JPY 80.0 billion/16% of OTSD shares (expected) repurchase since FY2022



	2020	2021	2022	2023	2024FCST
Total return ratio (IFRS)	120%	47%	-	106%	155%
Share buy-back (JPY billions)	-	-	25.7	16.2	38.6 (max.)

Share buyback

1. Results (May 10 to Nov. 6)

- Total number of shares repurchased: 16,985,400 shares
- Total amount of repurchase: JPY 28,644,715,800

2. Overview (Nov. 8 to Mar. 21, 2025)

- Total number of shares to be repurchased: 5.0 million shares (maximum)
- Total amount of repurchase: JPY 10.0 billion (maximum)

Launched *Catiolanze and Rhopressa*, growth drivers in mid-/long- term in EMEA and Asia, respectively

Existing area	Latanoprost cationic emulsion STN10**130**01 *Catiolanze*	Glaucoma	**Launched** in Europe (Spain etc.)
	Netarsudil mesilate STN10**139**00 *Rhopressa®/Rhokiinsa®*	Glaucoma	**Launched** in Asia (South Korea)
	Sepetaprost STN10**126**00	Glaucoma	**Filed** in Japan
	Epinastine HCl (twice a day, eye drop) STN10**114**03	Allergic conjunctivitis	Achieved **LPO**[1] in P3 trial in China
New area	Oxymetazoline HCl STN10**138**00 RVL-1201	Ptosis	Achieved **FPI**[2] in P3 trial in China

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

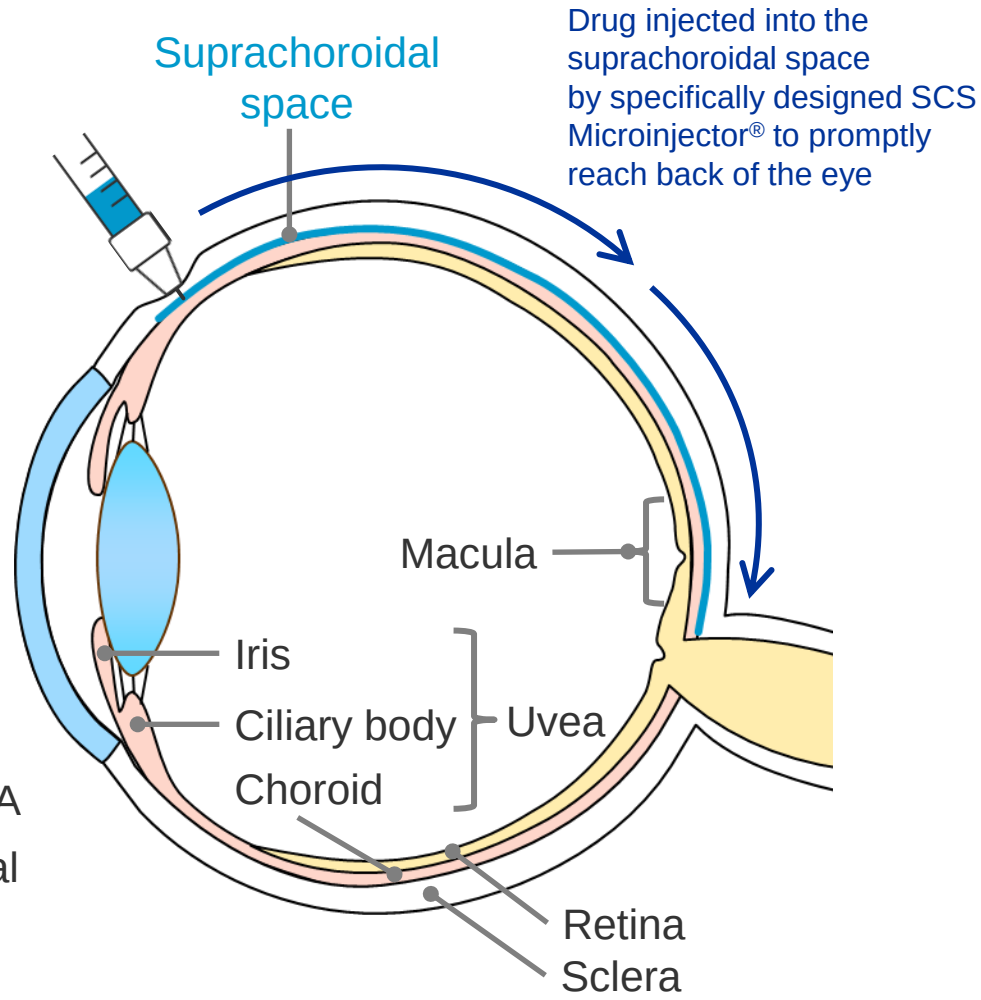
Obtained exclusive commercialization right of ARVN001 in China. Arctic Vision is developing it to be the first drug indicated for UME in China

Uveitic macular edema (UME)

- Uveitis is an intraocular inflammation that occurs in the uvea, and often chronic and relapsing. It can cause vision loss and blindness.
- UME is a type of uveitis characterized by the development of edema in the macula, which is the central part of the retina and critical for vision.
- Approximately 490,000 patients with UME in China.[1]
- Currently, approved drugs with other indications are used for UME treatment as off-label in China.

ARVN001

- Triamcinolone acetonide injectable suspension for suprachoroidal space (SCS®)
- Launched under the name of *XIPERE*® in US following approval by FDA
- Arctic Vision announced ARVN001 achieved primary endpoint in P3 trial for UME in China and plans to file NDA in FY2024

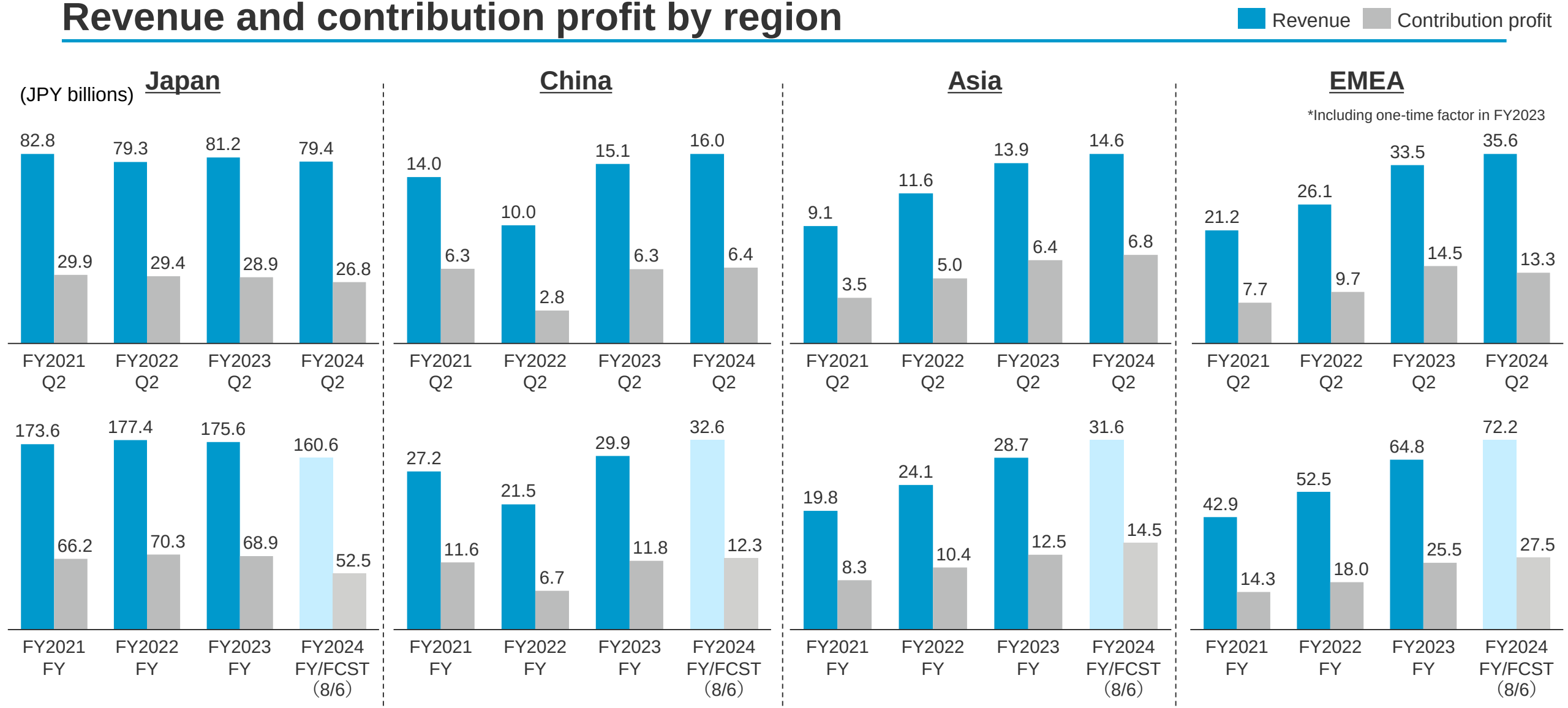


1 Santen estimated.

XIPERE®, SCS®, and SCS Microinjector® are trademarks of Clearside Biomedical, Inc. used under license.

Appendix

Revenue and contribution profit by region

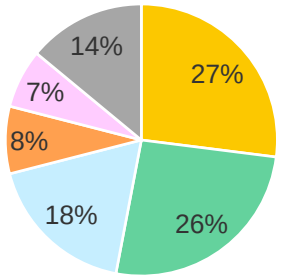


Note) Contribution profit: Deducting cost of sales and expenses related to revenue generation from regional revenue.
Regional revenue related to regional business are used to calculate contribution profit and regional revenue may differ from revenue (location basis) in the above chart.
Reorganization in overseas in FY2023 reflects to contribution profits in FY2023 and FY2024.

Q2 FY2024 revenue by region

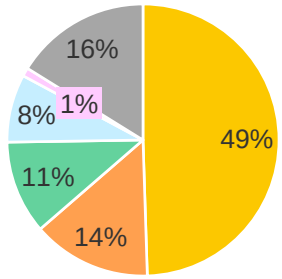
Consolidated

(JPY billions)	Q2 FY2023 (Ref.)	Q2 FY2024
EYLEA[1]	36.8	39.2
Cosopt	12.6	14.1
Alesion[2]	6.6	10.7
Others	89.7	82.4
Total	145.8	146.4



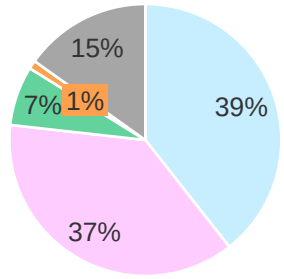
Japan

(JPY billions)	Q2 FY2023 (Ref.)	Q2 FY2024
EYLEA[1]	36.8	39.2
Alesion[2]	6.5	10.6
Diquas (including Diquas LX)	10.3	3.3
Others	27.5	26.3
Total	81.2	79.4



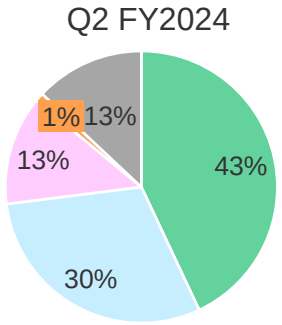
China

(JPY billions)	Q2 FY2023 (Ref.)	Q2 FY2024
Cravit	4.3	5.1
Hyalein	4.1	4.5
Diquas	2.4	1.7
Others	4.4	4.7
Total	15.1	16.0



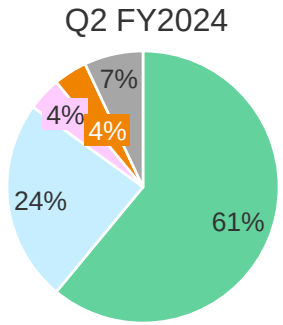
Asia

(JPY billions)	Q2 FY2023 (Ref.)	Q2 FY2024
Cosopt	3.3	3.5
Hyalein	1.6	1.9
Cravit	1.5	1.4
Others	7.5	7.8
Total	13.9	14.6

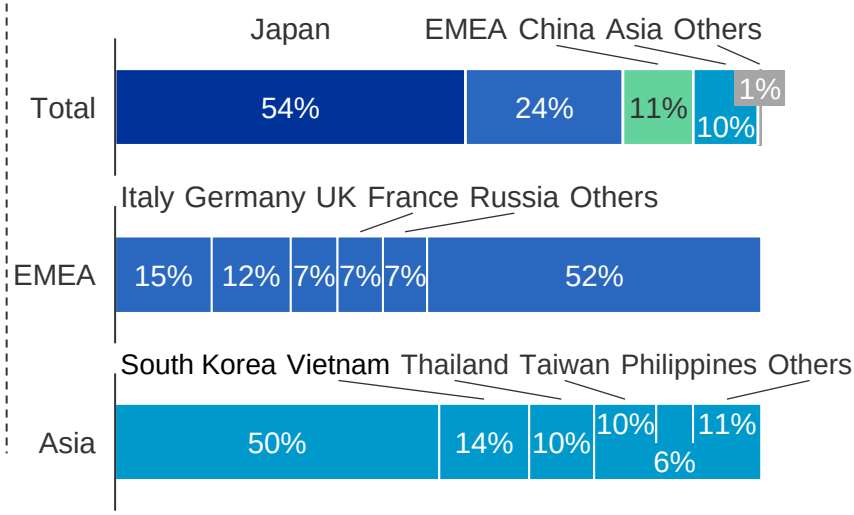


EMEA

(JPY billions)	Q2 FY2023 (Ref.)	Q2 FY2024
Cosopt	7.2	9.0
Ikervis	6.2	4.3
Tapros	4.3	4.3
Others	15.8	18.0
Total	33.5	35.6



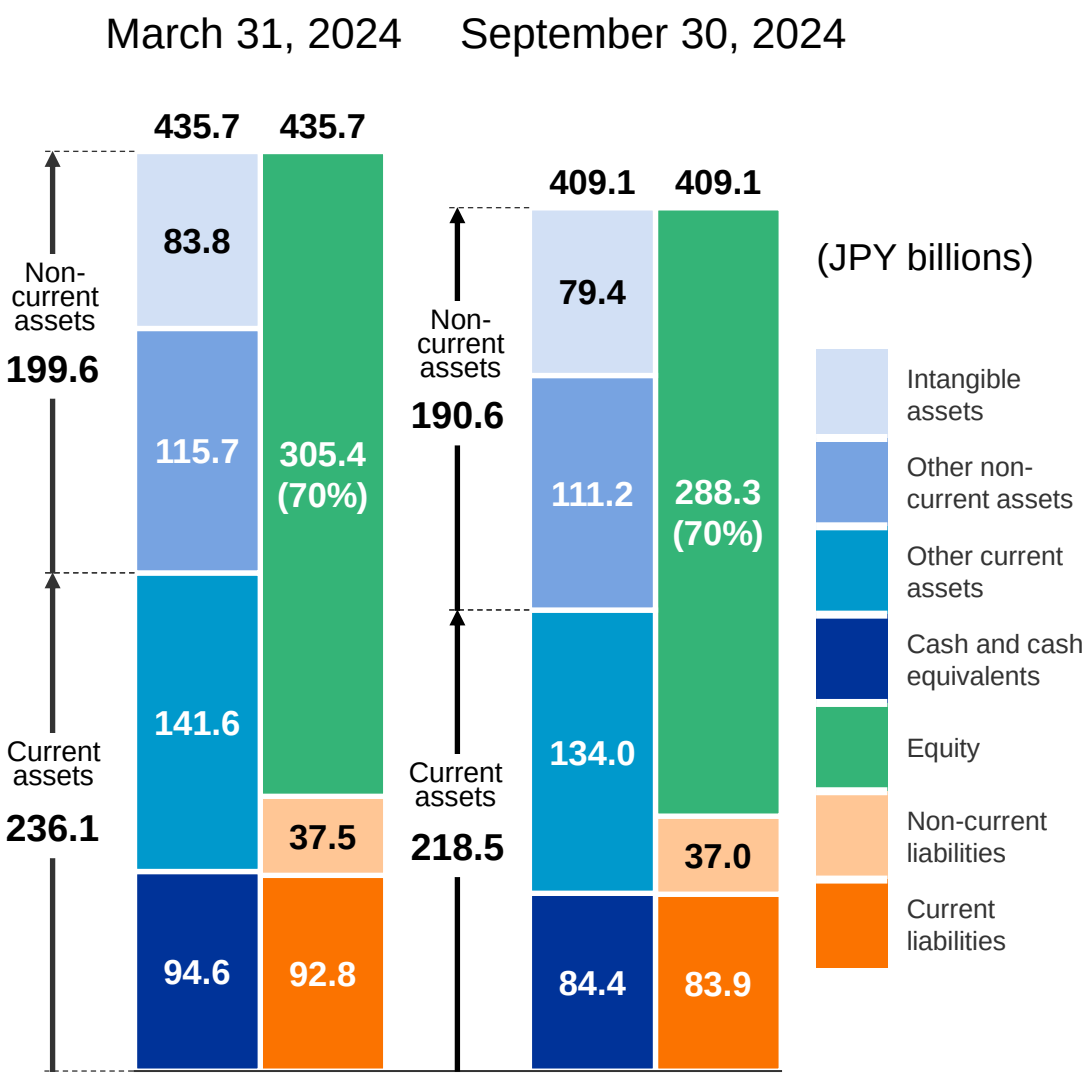
Revenue in each region (Q2 FY2024)



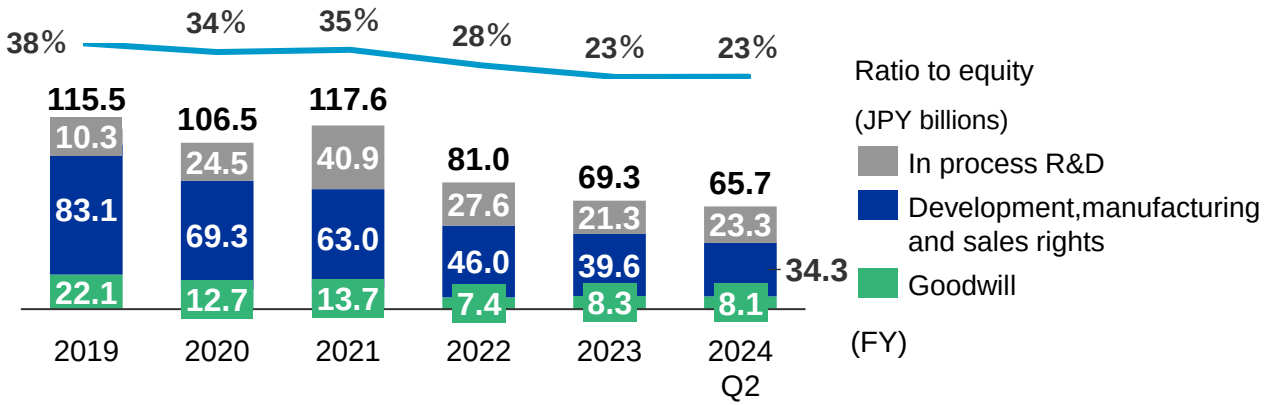
Intravitreal VEGF inhibitor | Glaucoma/Device | Dry eye | Allergy | Bacterial conjunctivitis | Others

1 Co-promoted product of Bayer Yakuhin, Ltd. (MAH), including *EYLEA* 8mg
2 *Alesion*: Trademark of alliance partner, Boehringer Ingelheim KG, including *Alesion LX* and *Alesion* eyelid cream

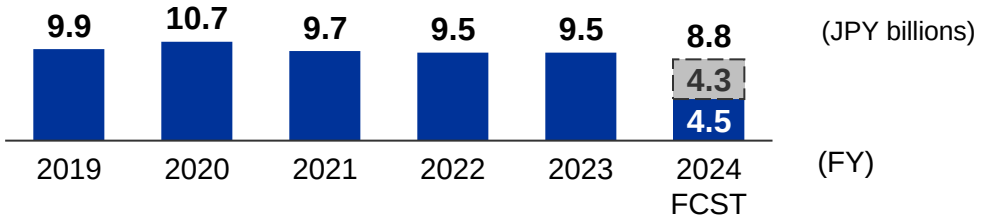
Healthy financial position maintained. Reduce assets to improve ROE, ROIC



Status of intangible assets related to products and goodwill



Status of intangible assets amortization related to products

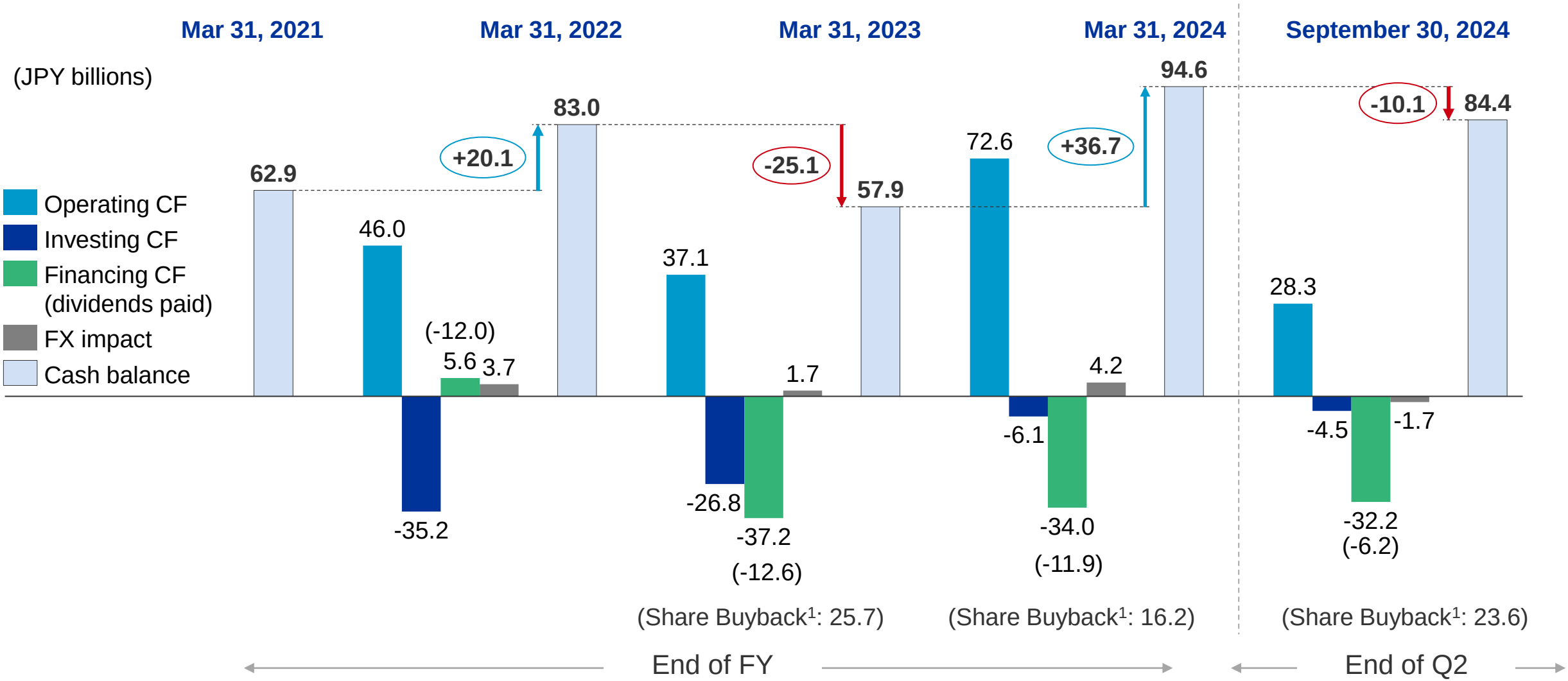


ROE, Core ROE, ROIC

FY	2019	2020	2021	2022	2023	2024 (FCST)
Core ROE	12%	12%	11%	11%	16%	14%[1]
ROE	8%	3%	8%	-	9%	11%[1]
ROIC	11%	5%	12%	-	16%	17%[2]

1 Including share buy-back 2 Including factoring

Cash flow



1 Treasury shares through open-market repurchase

Foreign exchange rate assumptions and sensitivities

FX rate

(JPY)

	FY2023 Actual	FY2024 Forecast (No change from Aug.6)	FY2024 vs FY2023	Q2 FY2023 Actual	Q2 FY2024 Actual	Q2 FY2024 vs Q2 FY2023
USD	144.80	155.00	107.0%	141.46	153.20	108.3%
EUR	156.88	165.00	105.2%	153.66	166.19	108.2%
CNY	20.24	21.30	105.2%	19.81	21.40	108.0%

Sensitivities

Impact of a 1% depreciation of the yen
(vs FY2024 revised forecast rate on August 6)

(JPY billions)

	Total*	USD	EUR	CNY
Revenue	+1.3	+0.06	+0.66	+0.32
Core OP	+0.2	-0.03	+0.09	+0.06
OP (IFRS)	+0.1	-0.04	+0.07	+0.05

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

FX impact on Q2 FY2024 (vs Q2 FY2023)

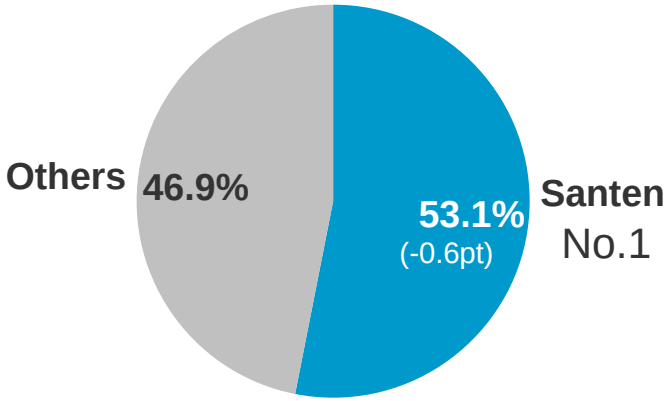
(JPY billions)

	Total
Revenue	+4.6
Core OP	+0.7
OP (IFRS)	+0.6

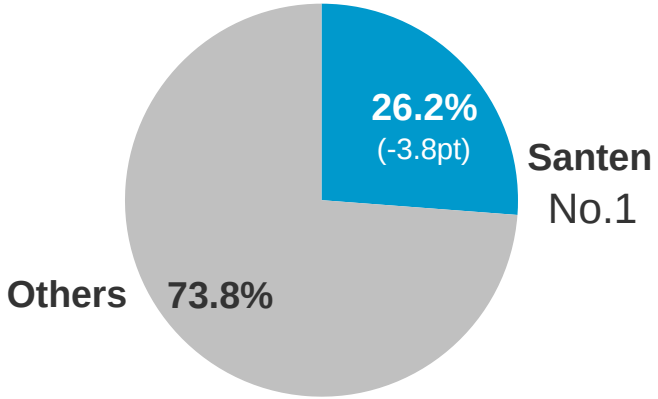
Segment: Market size
Graph: Market share (change from last year)

Prescription ophthalmic market in Japan （Oct. 2023 - Sep. 2024）

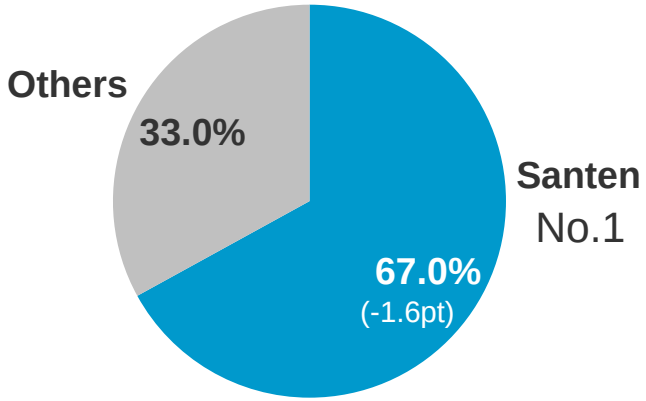
Total: JPY 365.5 bil



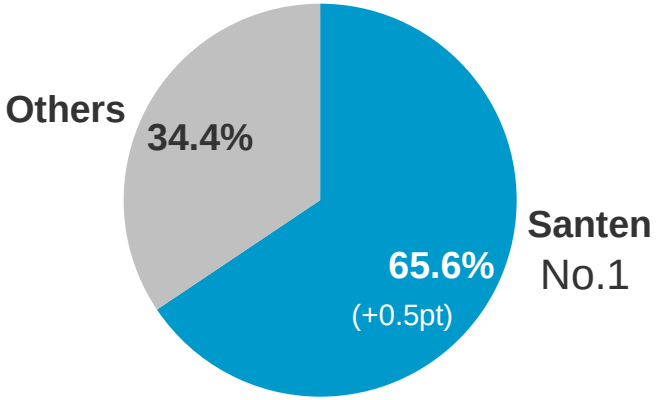
Glaucoma: JPY 84.3 bil



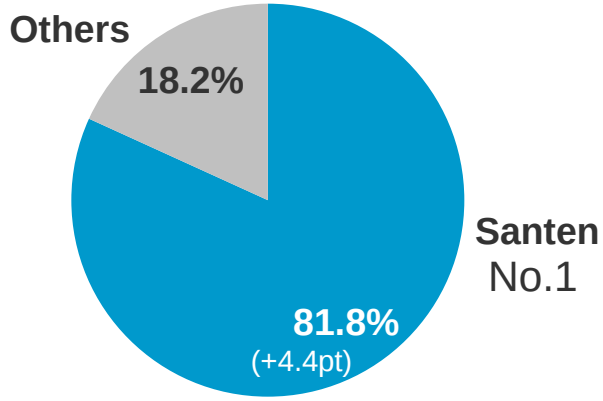
Retinal disorders*: JPY 136.6 bil



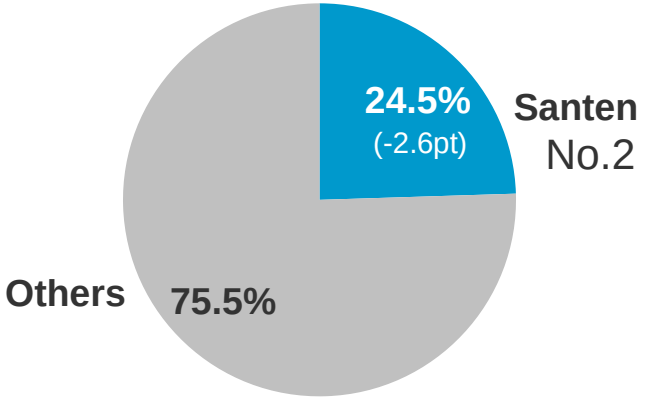
Corneal/dry eye: JPY 39.5 bil



Allergy: JPY 50.0 bil



Anti-infection: JPY 6.1 bil



*Including co-promoted product (Anti-VEGF *EYLEA*, *EYLEA 8mg*) of Bayer Yakuhin, Ltd. (MAH). Based on Santen Pharmaceutical (distributor) records.

Current status of global development (1)

As of November 1, 2024
Updated information is in blue

Glaucoma and ocular hypertension area

Indication	Generic Name	Dev. Code	Development Status[1]	
Glaucoma	Tafluprost / timolol maleate (combination) *Tapcom / Taptiqom*	STN10**111**01 DE-111A	China	Filed *Plan: FY2024 approval*
	Omidenepag isopropyl *Eybelis Mini*	STN10**117**02	China	*Plan: FY2024 P3 start*
	Sepetaprost	STN10**126**00 DE-126	US	P2 (met primary endpoint)
			Japan	Filed in September 2024 *Plan: FY2025 approval*
			Europe	P2 (exploratory study) completion
	Latanoprost *Catiolanze*	STN10**130**01 DE-130A Catioprost	Europe	Launched in several countries including Spain in August 2024
			Asia	P3 (met primary endpoint) *Plan: FY2024 filing*

1. Only projects for which the study protocols were approved in-house are shown,

Current status of global development (2)

As of November 1, 2024
Updated information is in blue

Glaucoma and ocular hypertension area

Indication	Generic Name	Dev. Code	Development Status	
Glaucoma	Netarsudil mesilate *Rhopressa®/Rhokiinsa®*	STN10**139**00 AR-13324	Japan	P3 *Plan: FY2024 P3 completion*
			Europe	Launched
			Asia	Launched in South Korea in November 2024
	Netarsudil mesilate /latanoprost (combination) *Rocklatan®/Roclanda®*	STN10**140**00 PG-324	Europe	Launched
			Asia	Approved *Plan: FY2024 launch*

Current status of global development (3)

As of November 1, 2024
Updated information is in blue

Keratoconjunctival disease area including dry eye

Indication	Generic Name	Dev. Code	Development Status	
Vernal keratoconjunctivitis	Ciclosporin *Verkazia*	STN10**076**03 DE-076C	China	Approved
Dry eye	Diquafosol sodium (long-acting) *Diquas LX*	STN10**089**03 DE-089C	Japan	Launched
			Asia	Received approval in March 2024 but deregistered product license in August 2024 in S. Korea
	Olodaterol hydrochloride	STN10**141**00	Japan	P1/2a (met primary endpoint), planning late-stage clinical trials
Fuchs endothelial corneal dystrophy	Sirolimus (eye drop)	STN10**109**04[1]	US France India	P2a *Plan: FY2025 P2a completion*
Meibomian gland dysfunction	Sirolimus (eye drop)	STN10**109**05	Japan	An additional P2a *Plan: FY2025 additional P2a completion*
Allergic conjunctivitis	Epinastine HCl (eyelid cream)	STN10**114**02	Japan	Launched
	Epinastine HCl (twice a day, eye drop)	STN10**114**03	China	P3 *Plan: FY2024 P3 completion*

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

Current status of global development (4)

As of November 1, 2024
Updated information is in blue

Refractive error

Indication	Generic Name	Dev. Code	Development Status	
Myopia	Atropine sulfate	STN10**127**00 DE-127	Japan	Filed *Plan: FY2024 approval*
			China	P2/3 *Plan: FY2026 P2/3 completion*
			Asia	P2 (met primary endpoint)
		STN10**127**01 SYD-101	Europe	P3 (conducted by Sydnexis Inc.) *Plan: FY2024 P3 completion*
	AFDX0250BS	STN10**134**00	Japan	P2a *Plan: FY2024 P2a completion*
			China	P1 (confirmed safety and tolerability)

Current status of global development (5)

As of November 1, 2024
Updated information is in blue

Others

Indication	Generic Name	Dev. Code	Development Status	
Ptosis	Oxymetazoline hydrochloride	STN10**138**00 RVL-1201	Japan	P3 (met primary endpoint) *Plan: FY2024 filing*
			Europe	*Plan: FY2024 P3 start*
			China	Started P3 in October 2024 *Plan: FY2026 P3 completion*
			Asia	*Plan: FY2026 filing*
Retinitis pigmentosa	jCell	STN**6000100**	-	Planning P3

Forward-looking statements

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