Q1 FY2024 Financial Results

August 6, 2024

Santen Pharmaceutical Co., Ltd.

Financial Results

Kazuo Koshiji

Chief Financial Officer

Q1 FY2024 Overview

YoY increase in revenue and Core OP - successful launch of new products and strong progress overseas including FX absorbed impact of *Diquas LX* recall in Japan
Full year revenue forecast raised, no-change in profit forecasts

Q1 FY2024 results

- Revenue growth +3.3% YoY (JPY 74.8 billion) / 25% vs FY2024 forecast
- Core OP growth +2.2% YoY (JPY 15.9 billion) / 29% vs FY2024 forecast

Product supply update

- Unit dose line in Noto plant (Jan. earthquake-impacted): Target to restart within 1H of FY2024
- *Diquas LX*: Assuming no shipments in FY2024 given time required to determine cause

FY2024 forecast

- Revenue: JPY 302.0 billion (Revised)
- Core OP: JPY 55.0 billion
- EPS: JPY 92.22

	Q1 FY2023 ACT	Q1 FY2024 ACT
USD (JPY)	138.01	156.88
EUR (JPY)	149.80	168.77
CNY (JPY)	19.58	21.80

YoY increased revenue and operating profit

(JPY billions)	Q1 FY2023 Actual	Q1 FY2023 vs Revenue	Q1 FY2024 Actual	Q1 FY2024 vs Revenue	Q1 FY2024 YoY
Revenue	72.4	-	**74.8**	**-**	**+3.3%**
Cost of sales	30.0	41%	32.0	43%	+6.8%
Gross profit	42.4	59%	**42.8**	**57%**	**+0.8%**
SG&A expenses	20.7	29%	21.4	29%	+3.5%
R&D expenses	6.2	9%	5.5	7%	-11.5%
Core operating profit	15.5	21%	**15.9**	**21%**	**+2.2%**
Non-core expenses	0.5	1%	-	-	-100.0%
Amortization on intangible assets associated with products	2.3	3%	2.4	3%	+4.5%
Other income	0.3	0%	0.1	0%	-79.1%
Other expenses	0.2	0%	0.4	0%	+61.2%
Operating profit	12.7	18%	**13.2**	**18%**	**+3.2%**
Finance income	1.1	1%	0.7	1%	-33.2%
Finance expenses	0.2	0%	0.4	1%	+141.8%
Share of loss of investments accounted for using equity method	0.8	1%	-	-	-100.0%
Profit before tax	12.9	18%	13.5	18%	+4.5%
Income tax expenses	2.5	3%	2.8	4%	+15.8%
Actual tax ratio	*19.1%*	-	*21.1%*	-	+2.0pt
Net profit	10.4	14%	**10.6**	**14%**	**+1.9%**
Core net profit	12.8	18%	12.5	17%	-2.1%

Revenue: +3.3%

- Overseas business (China, Asia and EMEA) : +11% YoY (including FX), -0.4%(excluding FX, +8% excluding FX and one-time factor of JPY 2.3 billion related to *Ikervis* (EMEA) in FY2023)

Gross profit: +0.8%

- Increased COGS ratio mainly due to region/product mix

Core OP: +2.2%

- Maintain SG&A ratio with cost optimization. Increased SG&A in amount caused by weaker JPY
- Decreased R&D expenses mainly due to quarterly variation in number of clinical trials and effects of structural reforms

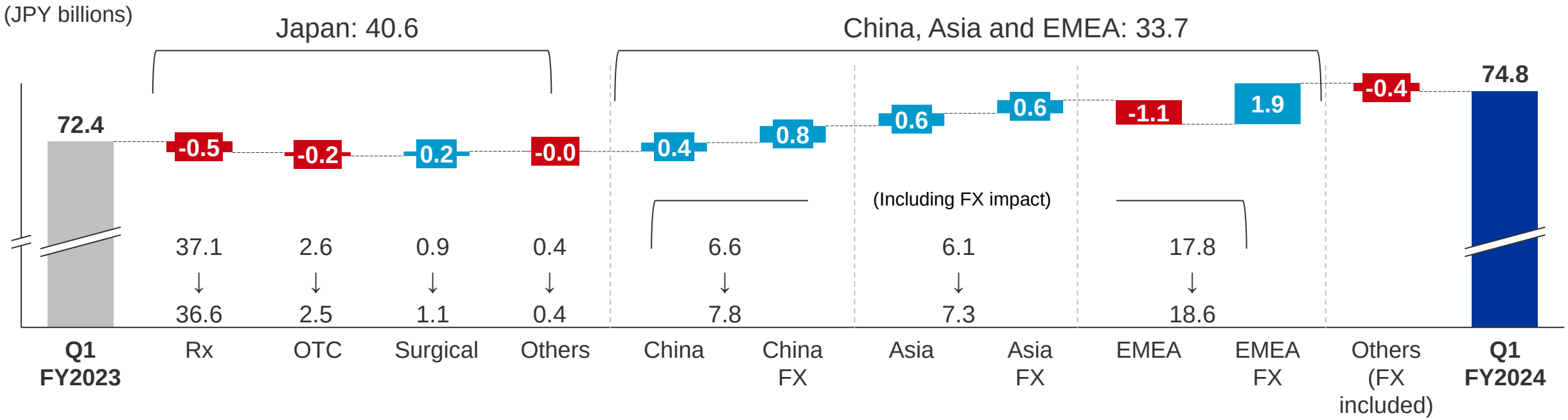
OP (IFRS): +3.2%

- Completed structural reforms in FY2023

Net profit (IFRS): +1.9%

- Not amounted share of loss of investments
- Tax ratio excluding one-time factors: 18.4%

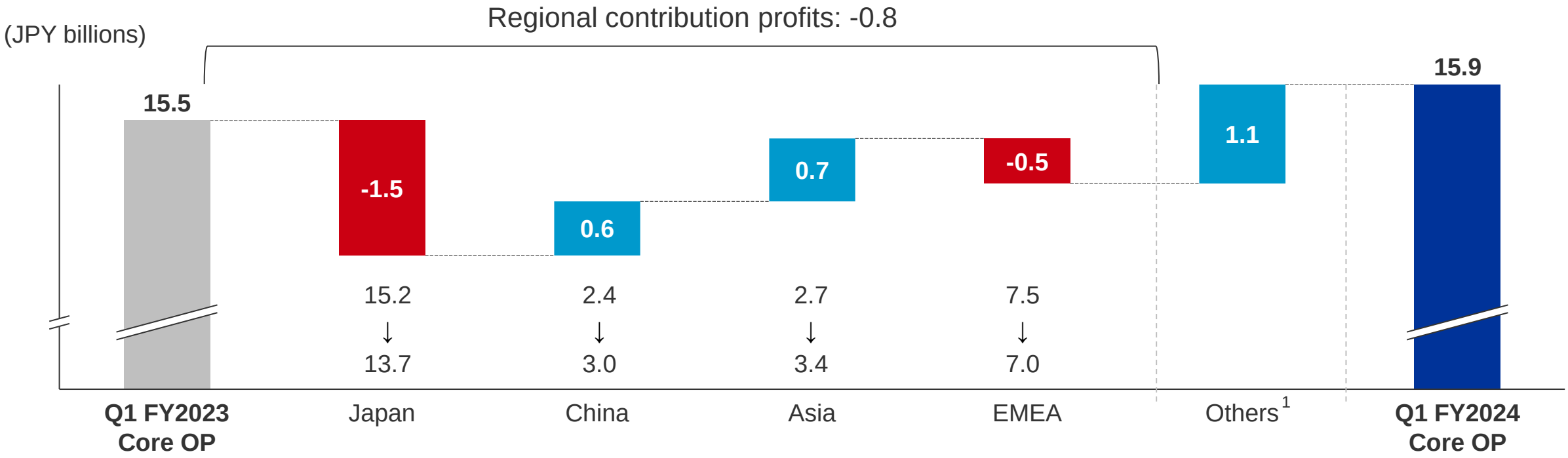
Solid performance overseas including FX pared decrease in Japan



Japan	-1.1% YoY: Minimize impact from *Diquas LX* voluntary recall with *Alesion eyelid cream* and others
China	+18.4% YoY (Ex. FX impact +6.4%): Solid performance from multi-channel strategy absorbed impact of *Diquas* VBP (volume-based purchasing)
Asia	+20.0% YoY (Ex. FX impact +9.9%): Steady growth from mainstay products in glaucoma and dry eye in key markets such as South Korea and Vietnam
EMEA	+4.5% YoY (Ex. FX impact -6.4%): Continued growth in glaucoma and dry eye products. Includes reactionary drop from *Ikervis* one-time factor (2.3 billion) in FY2023

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

Overseas business contributes to Core OP YoY increase



Regional contribution profits	Japan: Decrease in contribution profit, mainly due to product mix including decreased sales including *Diquas LX* voluntary recall and associated costs as well as NHI price revision Overseas: Increase in contribution profit in China and Asia resulting from revenue increase and cost optimization. In EMEA, decrease in contribution profit mainly from reactionary drop related to *Ikervis*'s one-time factor in FY2023
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

	FY2023 ACT	FY2024 FCST (8/6)	FY2024 FCST (5/9)
USD (JPY)	144.80	155.00	145.00
EUR (JPY)	156.88	165.00	155.00
CNY (JPY)	20.24	21.30	20.00

No change in profit outlook

(JPY billions)	FY2023		FY2024 (Aug 6)			FY2024 (May 9)	
	Actual	vs Revenue	Forecast	vs Revenue	YoY	Forecast	vs Revenue
Revenue	302.0	-	1 **302.0**	**-**	**+0.0%**	297.0	-
Cost of sales	123.1	41%	2 129.0	43%	+4.8%	127.5	43%
Gross profit	178.9	59%	**173.0**	**57%**	**-3.3%**	169.5	57%
SG&A expenses	90.8	30%	3 91.0	30%	+0.2%	88.5	30%
R&D expenses	25.3	8%	27.0	9%	+6.9%	26.0	9%
Core operating profit	62.8	21%	**55.0**	**18%**	**-12.4%**	55.0	19%
Non-core expenses	1.0	0%	-	-	-100.0%	-	-
Amortization on intangible assets associated with products	9.5	3%	8.8	3%	-7.1%	8.8	3%
Other income	1.5	1%	0.7	0%	-54.8%	0.7	0%
Other expenses	15.3	5%	2.4	1%	-84.3%	2.4	1%
Operating profit	38.5	13%	**44.5**	**15%**	**+15.5%**	44.5	15%
Finance income	1.6	1%	2.0	1%	+27.2%	2.0	1%
Finance expenses	2.7	1%	1.5	0%	-43.7%	1.5	1%
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%	45.0	15%
Income tax expenses	3.2	1%	11.5	4%	+262.6%	11.5	4%
Actual tax ratio	*10.6%*	-	*26%*	-	-	*26%*	-
Net profit	26.7	9%	**33.5**	**11%**	**+25.5%**	33.5	11%
ROE	8.9%		11%			11%	
Core ROE	16.2%		14%			14%	
Core net profit	48.5	16%	41.3	14%	-15.0%	41.3	14%

(Revised forecast, August 6)

Revenue: JPY 302.0 billion

Increased revenue with FX changes, but no change in P/L composition

Core OP: JPY 55.0 billion (no-change)

No changes under core OP and maintain initial EPS forecast of JPY 92

1 Revenue

- Japan: Including decrease in *Diquas LX* and increase in other products
- Overseas: Including changes in FX assumption

2 COGS

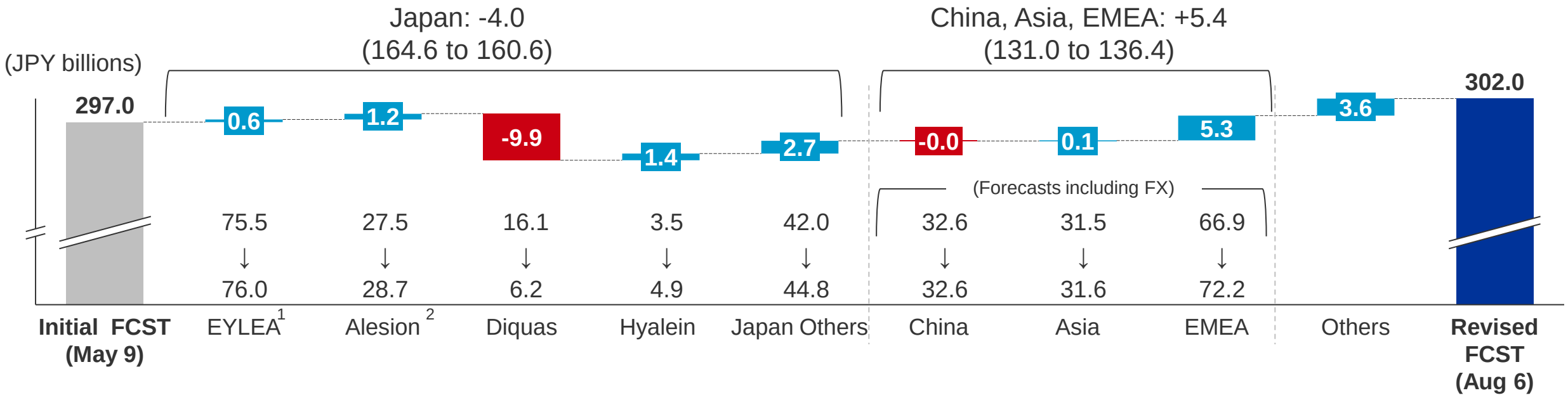
Maintain COGS ratio regardless of region/product mix

3 SG&A and R&D expenses

- Increased due to FX
- Including cost optimization

FY2024 Revenue outlook by region

Diquas LX negative impact covered by other products and regions. Further upside potential



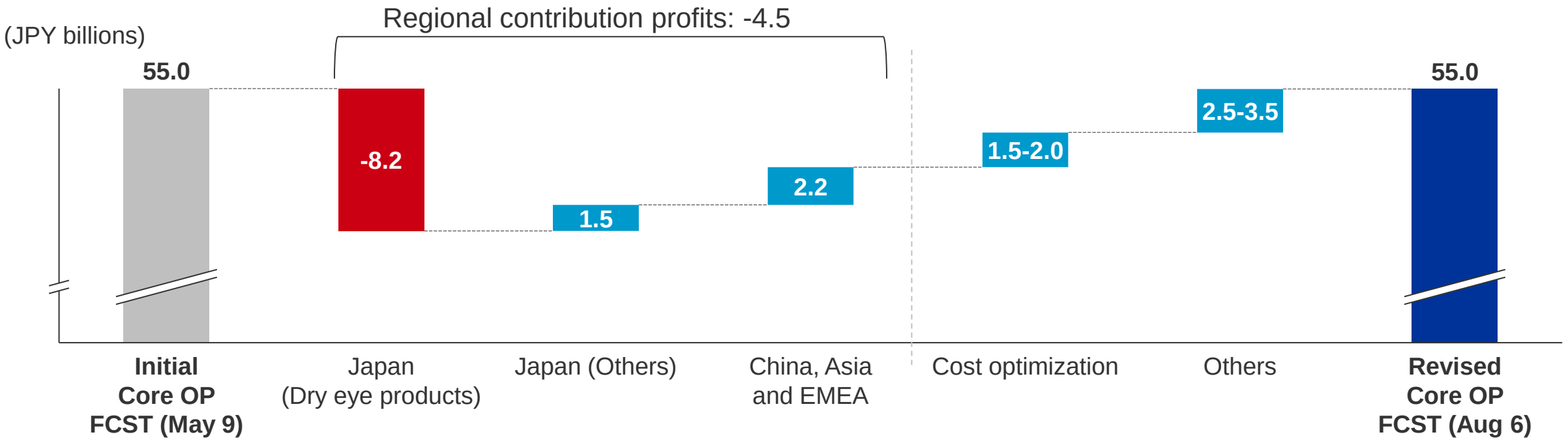
Japan	• *EYLEA*: Incorporated that biosimilar was approved with limited indications • *Alesion* : Factored solid initial sales of *Alesion* eyelid cream (*Alesion* eyelid cream: 6.7(initial) to 7.3 (revised) / JPY billions) • *Diquas* and *Hyalein:* Factored increases in *Diquas* and *Hyalein* and decrease in *Diquas LX* resulting from voluntary recall. (*Diquas LX*: 13.4 (initial) to zero (revised) / JPY billions) • Others: Changes other than 4 products above. Including re-allocation of supply risk factors from Japan to other regions
China, Asia, EMEA	Factored FX impacts and impacts due to supply risk considerations in China and Asia
Others	Factored upside potential including inorganic opportunities

Company-wide adjustment: Supply risk considerations from the Noto peninsula earthquake impact were included in Japan and Others in the initial FY2024 forecast. These risks have been allocated to China and Asia accordingly in the revised forecasts

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

FY2024 Outlook: Core OP forecast bridge

Core OP forecast maintained.
Overseas business contribution including FX and further cost optimizations



Regional contribution profits	• Japan (Decrease in contribution profit): Factored changes from dry eye products (including *Diquas LX* full-year shipment stop, costs pertaining to voluntary recall, and forecast changes in *Diquas* and *Hyalein*) (Increase in contribution profit): Increase in sales from other products and decrease of SG&A • Overseas: Mainly due to increase from FX assumption change in EMEA
Cost optimization	Continued work-in-progress
Others	Factored upside potential including inorganic opportunities

R&D Update

Peter Sallstig

Chief Medical Officer

Launched *Alesion* eyelid cream in Japan in May
Fixed a development plan of Ptosis in Europe following Japan, China and Asia

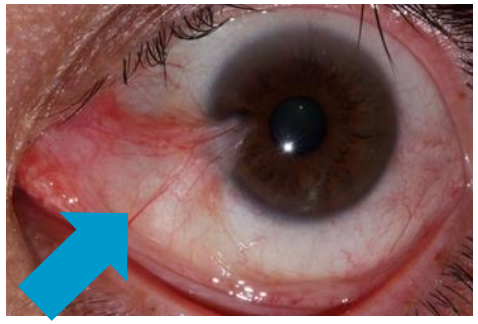
Existing area	Epinastine HCl STN10**114**02 *Alesion* eyelid cream	Allergic conjunctivitis	**Launched** in Japan
	Omidenepag isopropyl STN10**117**02 *Eybelis Mini*	Glaucoma	**Started preparations for P3 trial** in China
New area	Oxymetazoline HCl STN10**138**00 RVL-1201	Ptosis	**Started preparations for P3 trial** in Europe in addition to China
	Sirolimus (eye drop) STN10**109**05	Meibomian gland dysfunction	**Achieved FPI**[1] in an additional P2a trial in Japan

1. FPI: First Patient In

Alesion is a registered trademark of Boehringer Ingelheim KG.

Aim to offer a new therapeutic option through an ophthalmic application of systemic drugs, for pterygium, currently mainly treated through surgery

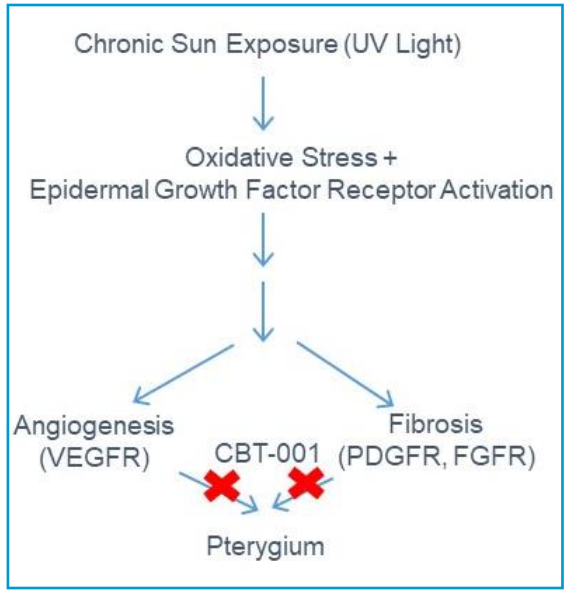
Pterygium



- Triangular abnormal proliferative tissue originating conjunctiva with blood vessels, penetrating into the center of the cornea
- Often occurring from nasal limbus and not malicious
- Major risk factor is exposure to sunlight (ultraviolet)
- Most common in geographic latitude 40 degrees around the equator, where sun exposure is common
- Cause foreign body sensation, hyperemia and astigmatism
- Dry eye medications and corticosteroids may be prescribed for symptom relief, but radical treatment is currently only surgery
- Depending on the procedure, recurrence risk is considered an issue in pterygium surgery
- Prevalence: 4% in Japan aged 40 years or older.[1] 3.8% in S. Korea.[2] 10.1% in Vietnam, Malaysia, the Philippines, and Thailand in ages 40 years or older.[3]

CBT-001

- Eye drops containing nintedanib as the active ingredient
- Multikinase inhibitor that inhibits angiogenesis and fibrosis by acting on VEGF, PDGF and FGF receptors
- Completion of P2a in US (see next page)
  P3 is ongoing as a multinational study (excl. Japan)

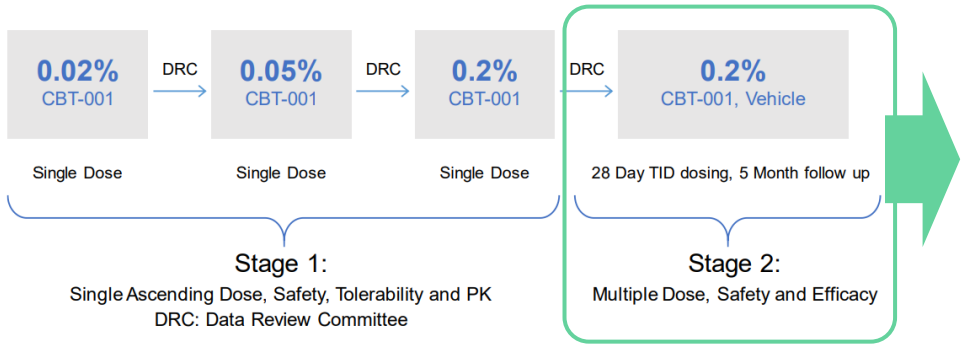


P3 design（NCT05456425）	
Arms	• 0.1% CBT-001 • 0.2% CBT-001 • Vehicle
Dosing frequency	Twice a day
Duration	24 months
Enrollment	600 eyes
Primary endpoints	• Conjunctival hyperemia • Pterygium length • Eye symptom score
Final data collection date	December 31, 2025
Location	AU/CN/IN/NZ/US

1. Tano et al, *Acta Ophthalmol* 91(3):e232-6, 2013 2. Rim TH et al, *PLOS One* 12(3) e0171954, 2017
3. Ang M et al, *Ophthalmology* 119(8):1509e15, 2012

Obtained POC in P2a trial in US

Safety and Efficacy of CBT-001 Ophthalmic Solution in Patients With Pterygium (NCT03049852)



Stage 2 Results

- The most commonly reported adverse events associated with CBT-001 were ocular, mild in severity (Conjunctival Discoloration), resolved after therapy, and did not result in discontinuation
- Baseline demographic characteristics were similar between patients receiving CBT-001 (n=25) and vehicle (n=23).
- After 4 weeks of dosing, mean vascularity scores significantly decreased in patients receiving CBT-001 (-0.8) compared to vehicle (0.0) ($p<0.001$).
- Vascularity remained at significantly decrease levels at weeks 8 and 16, but not at week 24.
- CBT-001 group showed significantly greater mean reductions in lesion length at weeks 4 and 8 ($p<0.05$).

Figure 1. Pterygia vascularity mean grade change from baseline (Statistically significant drug vs vehicle p-values are shown)

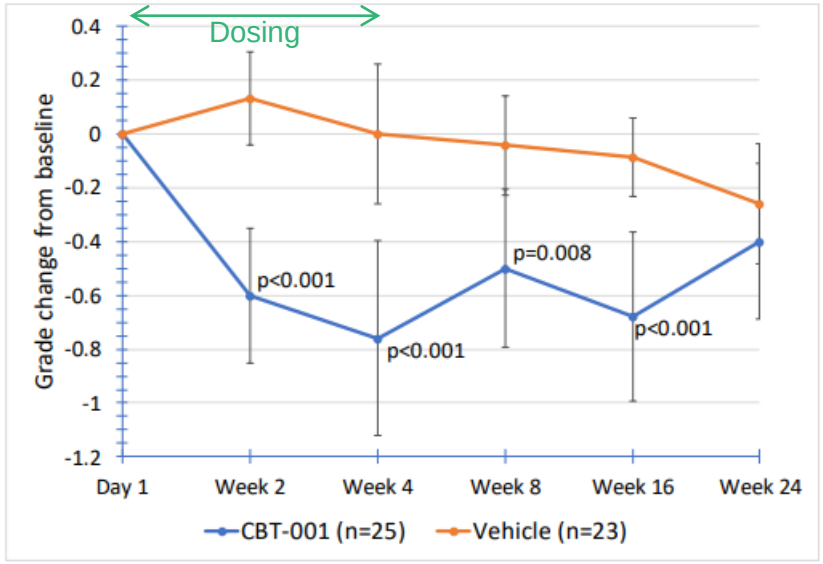
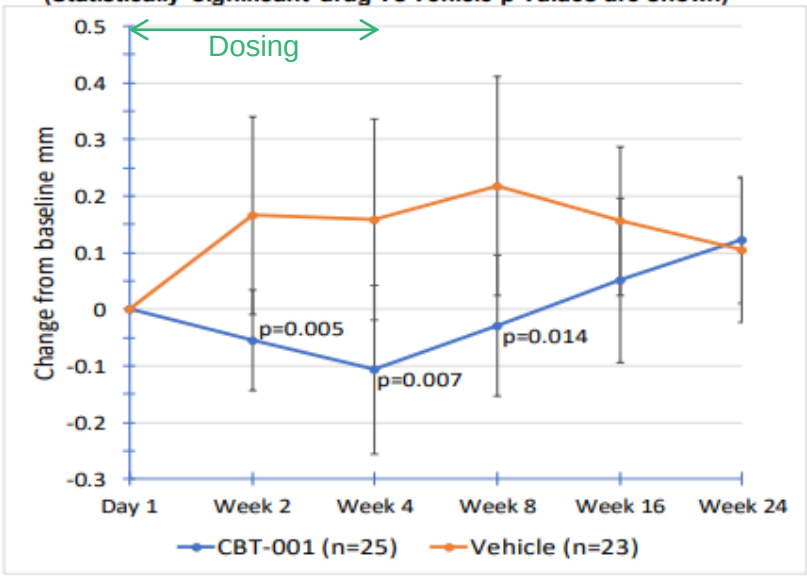


Figure 4. Pterygia lesion length mean change from baseline (Statistically significant drug vs vehicle p-values are shown)



A Phase 2 Multicenter, Randomized, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of CBT-001 for Pterygia
https://cloudbreakpharma.com/wp-content/uploads/2024/05/ARVO-2019-Poster_Scott.pdf

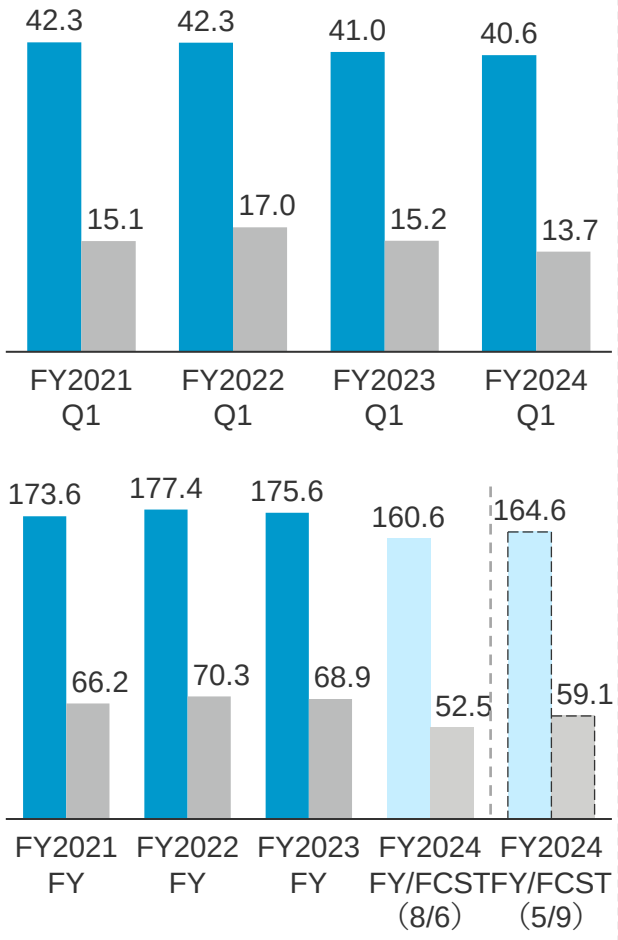
Appendix

Revenue and contribution profit by region

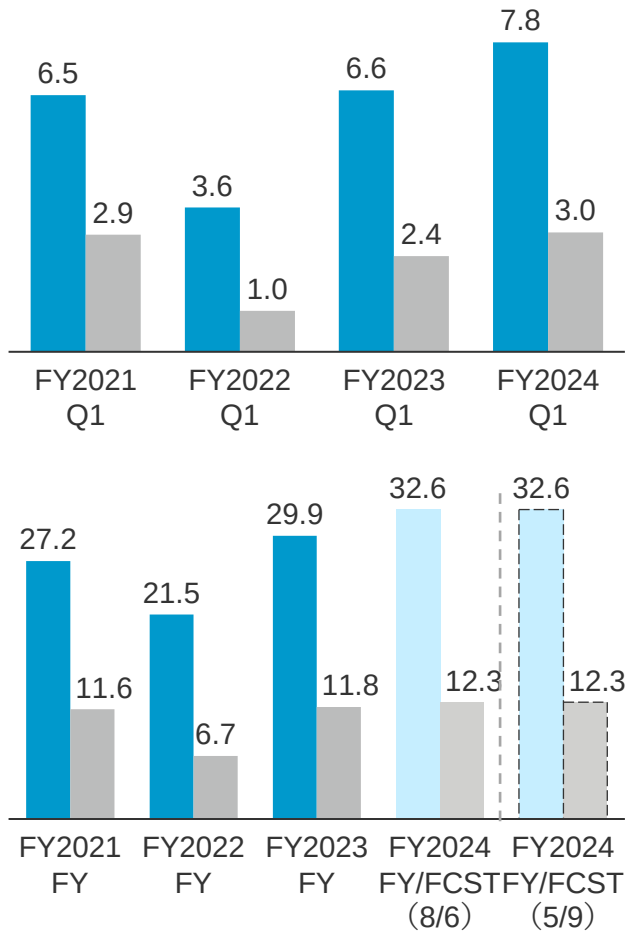
Revenue Contribution profit

(JPY billions)

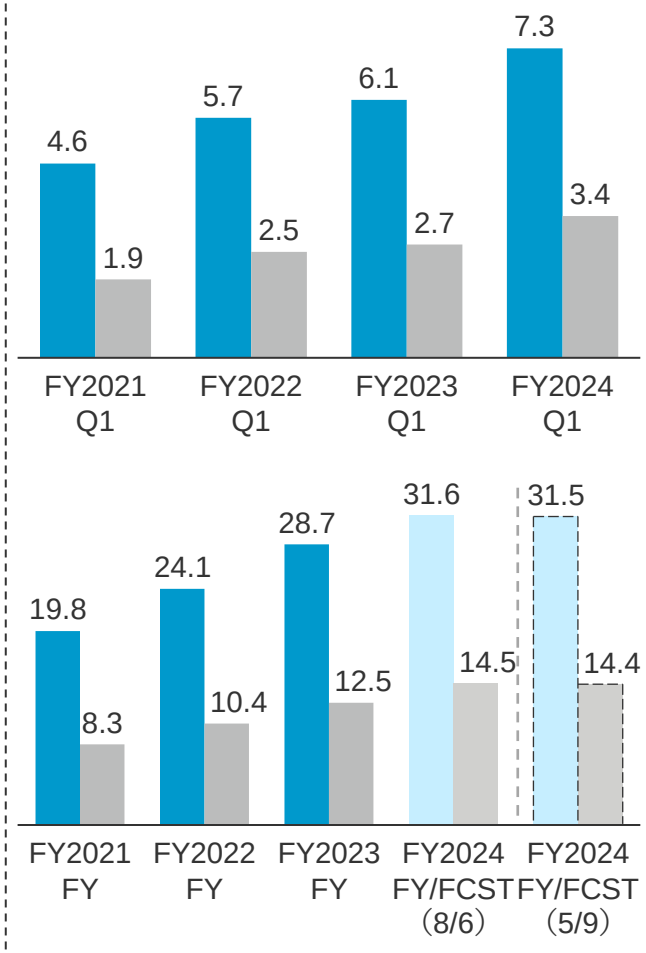
Japan



China

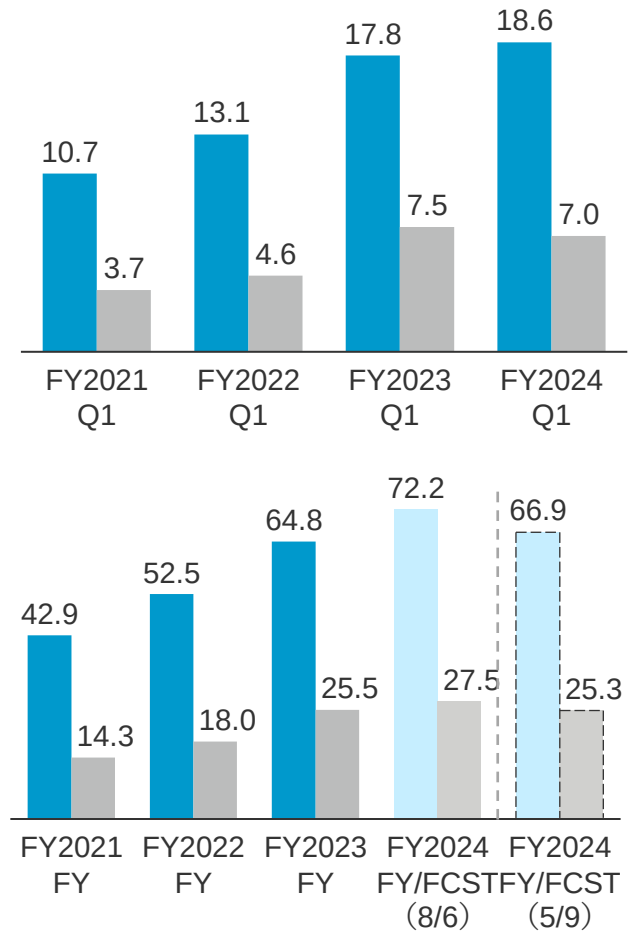


Asia



EMEA

*Including one-time factor in FY23

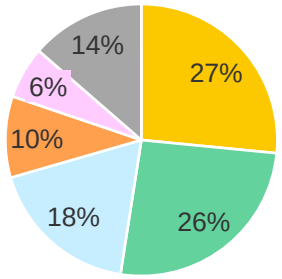


Note) Contribution profit: Deducting cost of sales and expenses related to revenue generation from regional revenue.
Regional revenue related to regional business are used to calculate contribution profit and regional revenue may differ from revenue (location basis) in the above chart.
Reorganization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

Q1 FY2024 revenue by region

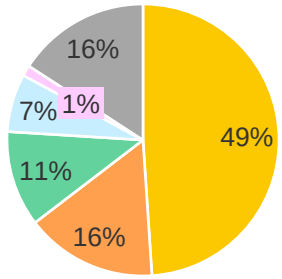
Consolidated

(JPY billions)	Q1 FY2023 (Ref.)	Q1 FY2024
EYLEA[1]	18.5	19.9
Cosopt	6.3	7.2
Alesion[2]	2.8	6.3
Others	44.8	41.4
Total	72.4	74.8



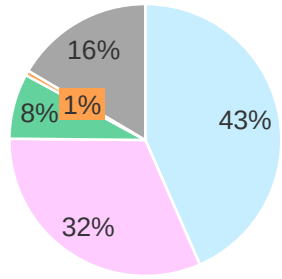
Japan

(JPY billions)	Q1 FY2023 (Ref.)	Q1 FY2024
EYLEA[1]	18.5	19.9
Alesion[2]	2.8	6.3
Hyalein	1.4	1.2
Others	18.4	13.2
Total	41.0	40.6



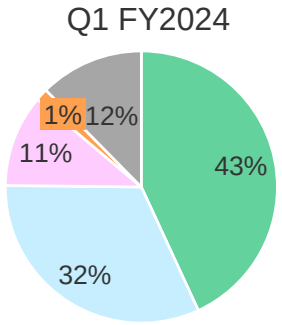
China

(JPY billions)	Q1 FY2023 (Ref.)	Q1 FY2024
Hyalein	2.0	2.2
Cravit	1.6	2.1
Diquas	1.1	1.0
Others	1.9	2.4
Total	6.6	7.8



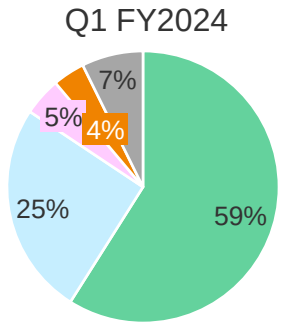
Asia

(JPY billions)	Q1 FY2023 (Ref.)	Q1 FY2024
Cosopt	1.6	1.8
Hyalein	0.6	1.0
Diquas	0.5	0.6
Others	3.4	3.9
Total	6.1	7.3

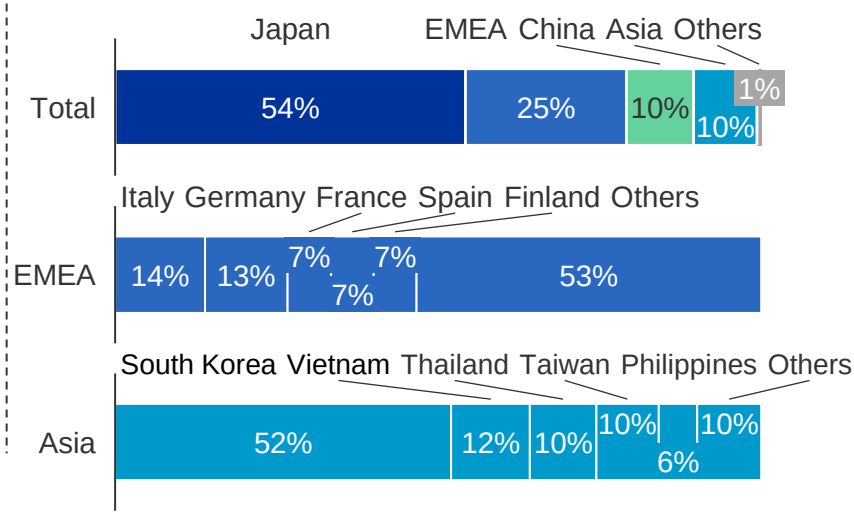


EMEA

(JPY billions)	Q1 FY2023 (Ref.)	Q1 FY2024
Cosopt	3.5	4.5
Ikervis	4.1	2.3
Tapros	2.1	2.1
Others	8.1	9.6
Total	17.8	18.6



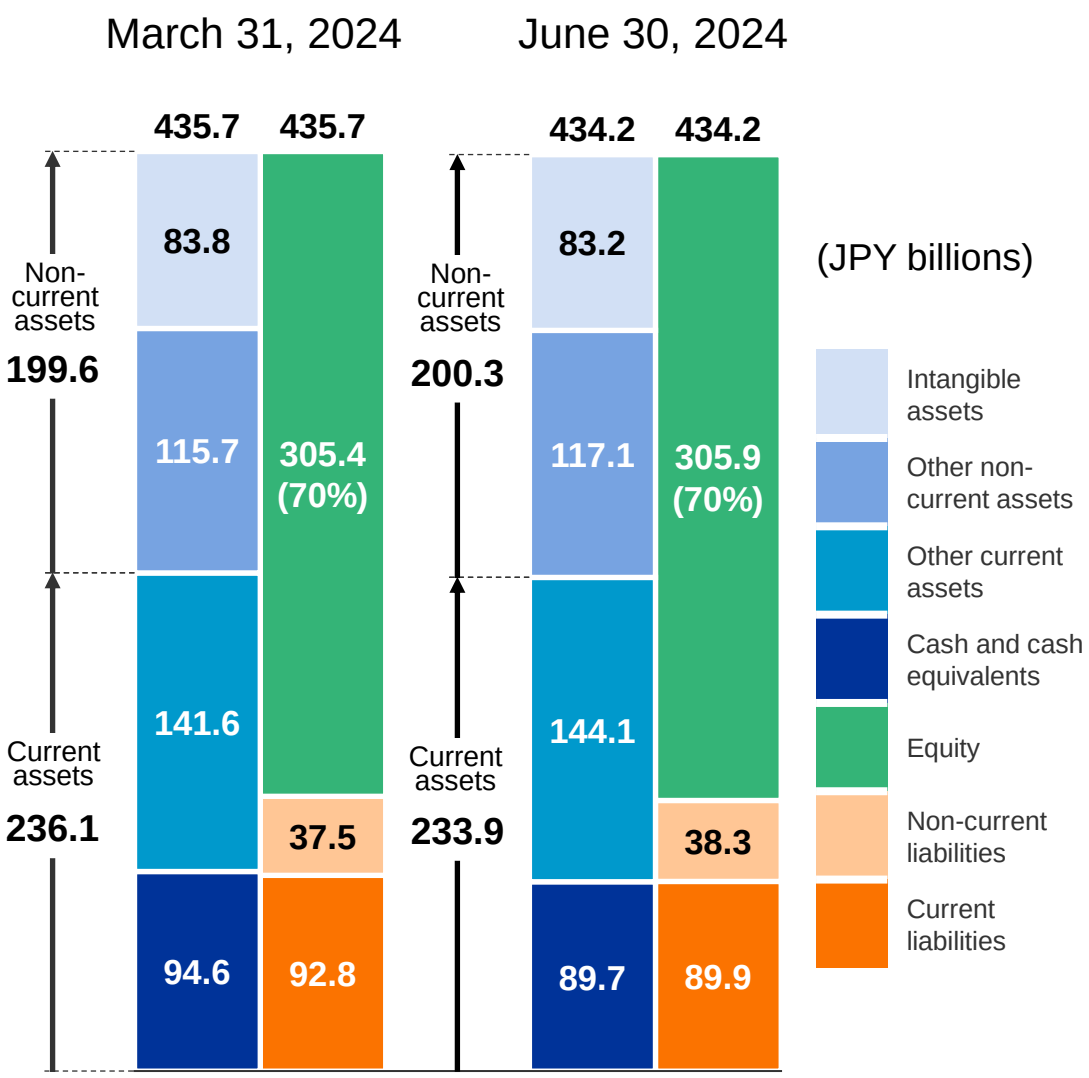
Revenue in each region (Q1 FY2024)



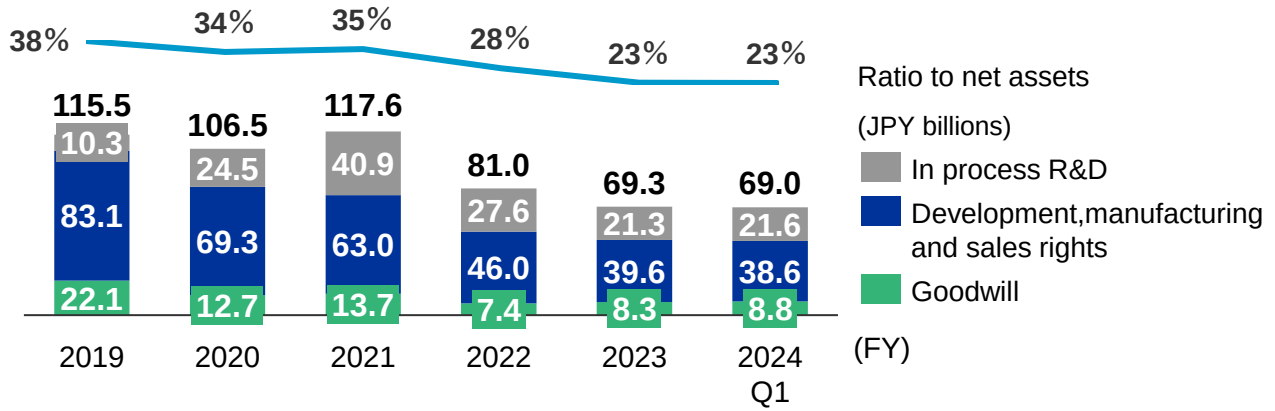
Intravitreal VEGF inhibitor | Glaucoma/Device | Dry eye | Allergy | Bacterial conjunctivitis | Others

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

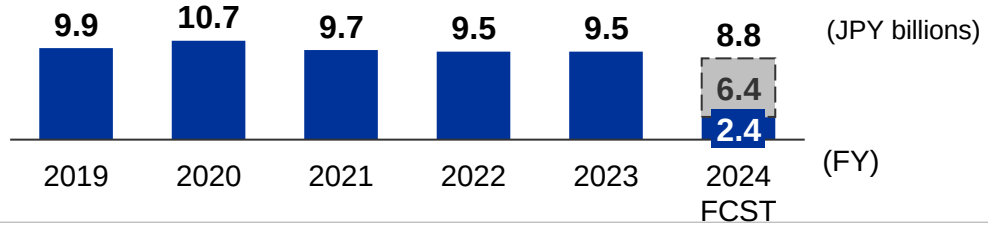
Healthy financial position maintained. Reduce assets to improve ROE, ROIC



Status of intangible assets related to products and goodwill



Status of intangible assets amortization related to products

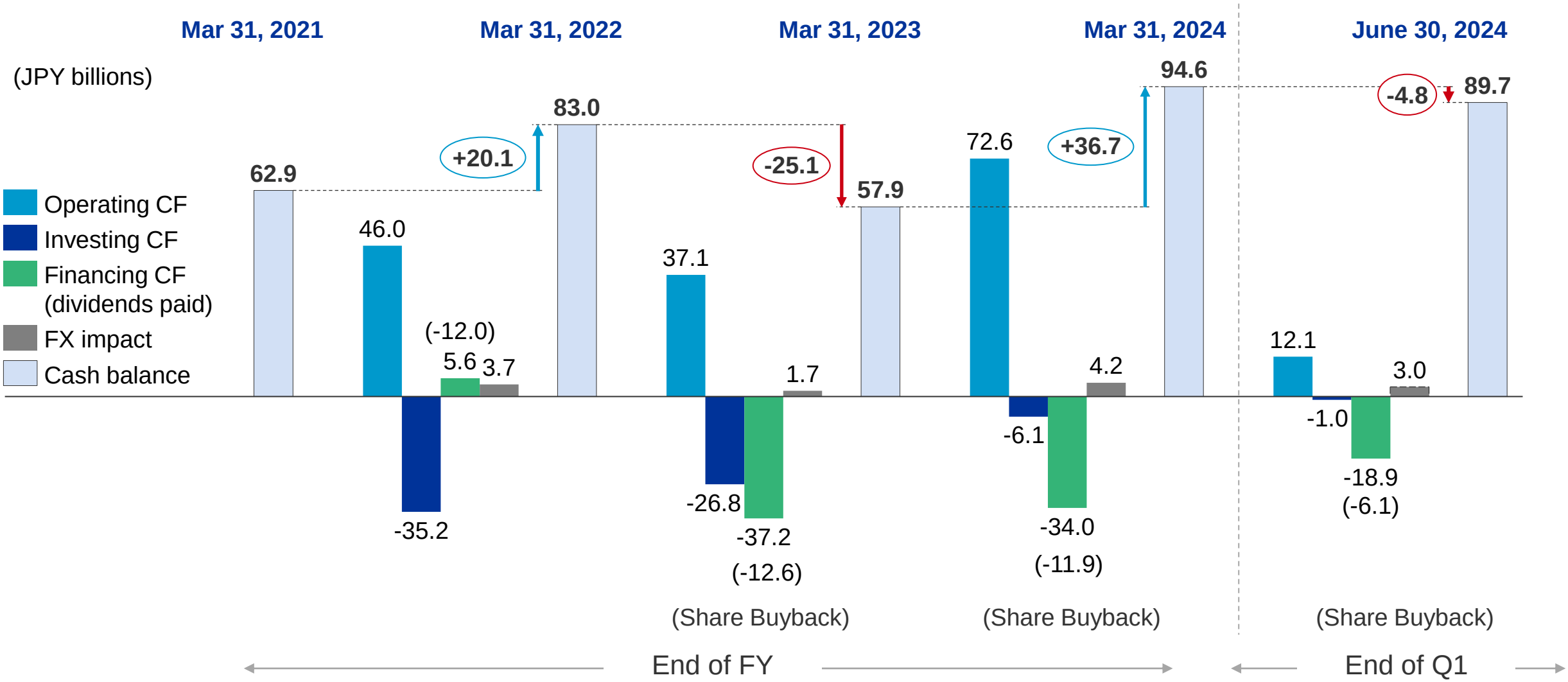


ROE, Core ROE, ROIC

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



Foreign exchange rate assumptions and sensitivities

FX rate

(JPY)

	Q1 FY2023 Actual	Q1 FY2024 Actual	vs FY2024 Forecast	FY2023 Actual	FY2024 Forecast (8/6)
USD	138.01	156.88	101.2%	144.80	155.00
EUR	149.80	168.77	102.3%	156.88	165.00
CNY	19.58	21.80	102.3%	20.24	21.30

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 Q1 FY2024 (vs Q1 FY2023)

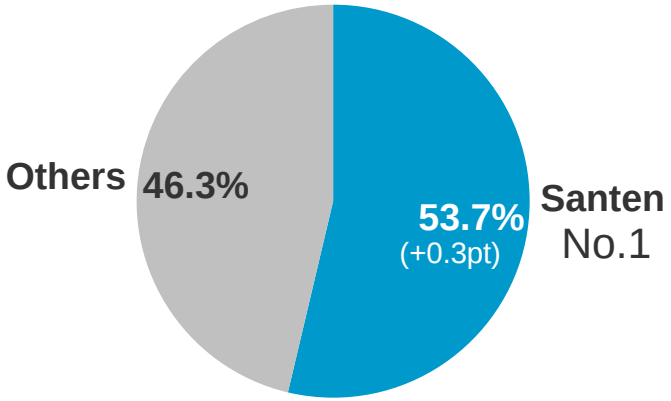
(JPY billions)

	Total
Revenue	+3.5
Core OP	+0.5
OP (IFRS)	+0.4

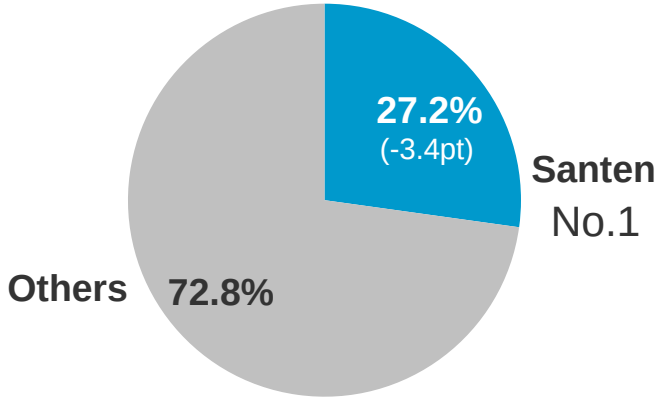
Segment: Market size
Graph: Market share (change from last year)

Prescription ophthalmic market in Japan (Jul. 2023 - Jun. 2024)

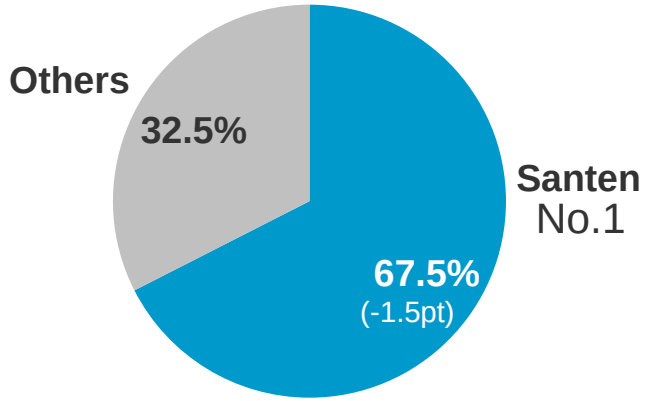
Total: JPY 369.4 bil



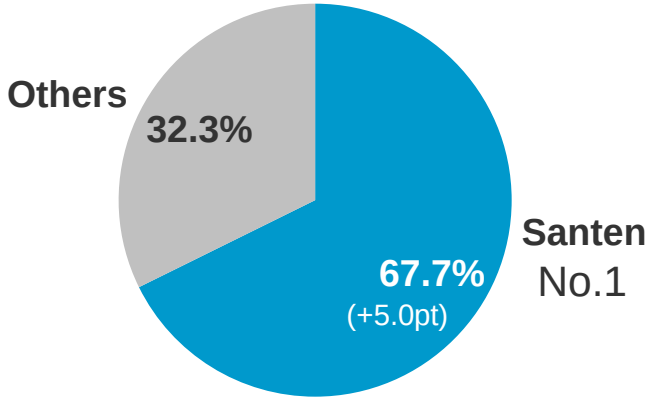
Glaucoma: JPY 86.2 bil



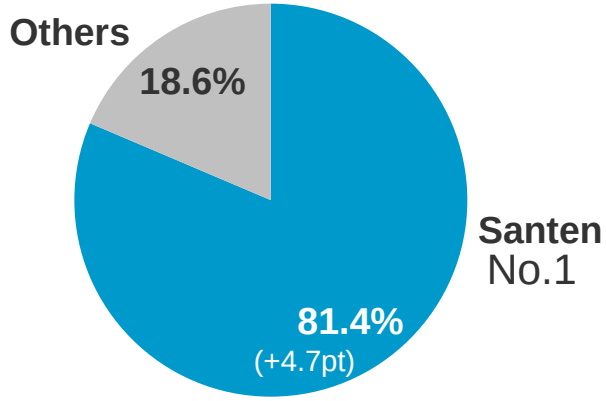
Retinal disorders*: JPY 133.4 bil



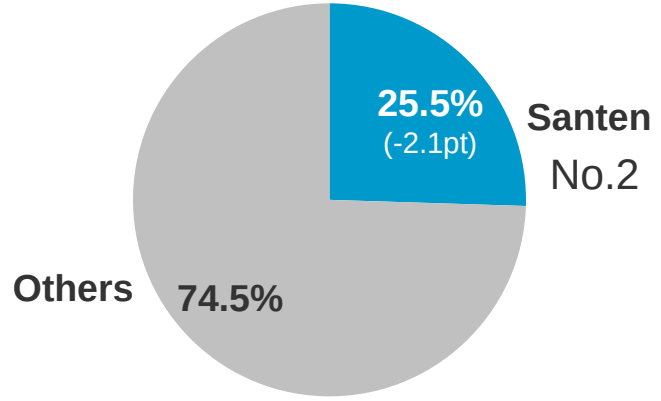
Corneal/dry eye: JPY 44.6 bil



Allergy: JPY 49.7 bil



Anti-infection: JPY 6.4 bil



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

Source: Copyright © 2024 IQVIA. JPM 2022.7-2024.6; Santen analysis based on IQVIA data. Reprinted with permission.

Current status of global development (1)

As of July 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	P3 (met primary endpoint) *Plan: FY2024 filing*
			Europe	P2 (exploratory study) completion
	Latanoprost *Catiolanze*	STN10**130**01 DE-130A Catioprost	Europe	Approved *Plan: FY2024 launch*
			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 July 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	Approved *Plan: FY2024 launch*
	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 July 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-lasting) *Diquas LX*	STN10**089**03 DE-089C	Japan	Launched
			Asia	Approved
	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	Started an additional P2a in June 2024 *Plan: FY2025 additional P2a completion*
Allergic conjunctivitis	Epinastine HCl (eyelid cream)	STN10**114**02	Japan	Launched in May 2024
	Epinastine HCl (twice a day, eye drop)	STN10**114**03	China	P3 *Plan: FY2025 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 July 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 July 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	*Plan: FY2024 P3 start*
			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.
- This document contains information about pharmaceutical products (including products under development) but is not intended for advertising or medical advice.
- The purpose of this document is to disclose information that serves as a reference to investors, and it does not constitute a solicitation or recommendation for investment. You should make investment decisions based on your own judgment.
- The information contained in this document is subject to change without notice. The use of these materials is the responsibility of the user, and we assume no responsibility for any damages caused by the use of these materials, including errors in the stated information.