# Q3 FY2024 Financial Results

February 6, 2025



# **Financial Results**

Kazuo Koshiji

Chief Financial Officer



### Q3 FY2024 Overview

Solid progress versus FY forecast. Overseas business absorbed impacts of *Diquas LX* and other factors Increased year-end dividend, considering mid-to long term earnings prospects

### Q3 FY2024 results

- Revenue: -0.0% YoY (JPY 222.8 billion) / 74% vs FY forecast
- Core OP: -11.4% YoY (JPY 43.7 billion) / 79% vs FY forecast
- Net profit attributable to owners of the company: +3.2% YoY (JPY 27.5 billion) / 85% vs FY forecast

### Business update

- Diquas LX: Root cause identification and countermeasures progress. Preparing to consult authorities
- Mid-to long term growth: STN1012700 (myopia) approval and STN1013800 (ptosis) filing in Japan

### FY2024 forecast

- Forecast: Solid progress, no change in forecast considering swing seasonal factor related to pollen
- Dividend: Increased year-end dividend to JPY 19, equivalent to JPY 36 per share annually.
   Forecast JPY 38/share for FY2025 based on progressive dividend policy



|           | Q3 FY2023 | Q3 FY2024 |
|-----------|-----------|-----------|
|           | ACT       | ACT       |
| USD (JPY) | 143.61    | 152.63    |
| EUR (JPY) | 155.60    | 164.96    |
| CNY (JPY) | 20.07     | 21.33     |

## YoY increase in net profit

| (JPY billions)   | Q<br>FY2 |               |        | Q3<br>FY2024  |         |
|--|----------|---------------|--------|---------------|---------|
|  | Actual   | vs<br>Revenue | Actual | vs<br>Revenue | YoY     |
| Revenue  | 222.8    | -             | 222.8  | -             | -0.0%   |
| Cost of sales  | 91.4     | 41%           | 97.6   | 44%           | +6.8%   |
| Gross profit   | 131.4    | 59%           | 125.1  | 56%           | -4.8%   |
| SG&A expenses  | 64.1     | 29%           | 64.7   | 29%           | +1.0%   |
| R&D expenses   | 18.0     | 8%            | 16.8   | 8%            | -7.1%   |
| Core operating profit  | 49.3     | 22%           | 43.7   | 20%           | -11.4%  |
| Non-core expenses  | 1.0      | 0%            | -      | -             | -100.0% |
| Amortization on intangible assets associated with products     | 7.1      | 3%            | 6.6    | 3%            | -6.3%   |
| Other income   | 1.4      | 1%            | 0.4    | 0%            | -71.9%  |
| Other expenses   | 6.4      | 3%            | 2.2    | 1%            | -65.5%  |
| Operating profit   | 36.2     | 16%           | 35.2   | 16%           | -2.7%   |
| Finance income   | 1.3      | 1%            | 1.4    | 1%            | +8.9%   |
| Finance expenses   | 1.0      | 0%            | 1.3    | 1%            | +34.1%  |
| Share of loss of investments accounted for using equity method | 2.9      | 1%            | -      | -             | -100.0% |
| Profit before tax  | 33.6     | 15%           | 35.3   | 16%           | +5.2%   |
| Income tax expenses  | 7.0      | 3%            | 8.0    | 4%            | +14.1%  |
| Actual tax ratio   | 21%      |               | 23%    | -             | +1.7pt  |
| Net profit   | 26.6     | 12%           | 27.3   | 12%           | +2.9%   |
| Net profit attributable to owners of the company               | 26.6     | 12%           | 27.5   | 12%           | +3.2%   |
| Core net profit  | 39.6     | 18%           | 33.8   | 15%           | -14.7%  |

### **Major factors in YoY differences**

### Revenue: -0.0%

Overseas business (China, Asia and EMEA)
 : +9%, +3% excluding FX

### **Gross profit: -4.8%**

Increased COGS ratio mainly due to region/product mix

### **Core OP: -11.4%**

- SG&A: Absorbed FX impact and almost flat to previous year
- R&D expenses: Decrease mainly from clinical trials status quo and cost optimizations

### **OP (IFRS): -2.7%**

Completed structural reforms previous FY.
 Related expenses decreased

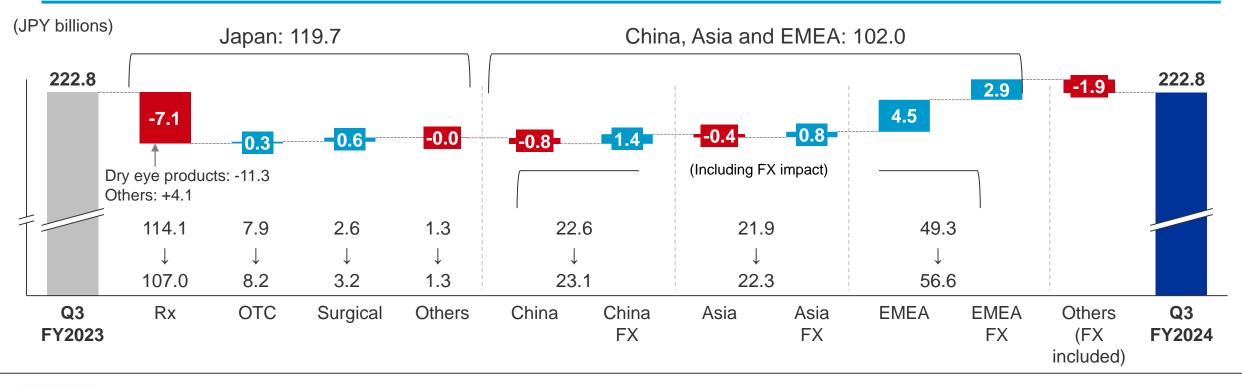
### Net profit (IFRS): +2.9%

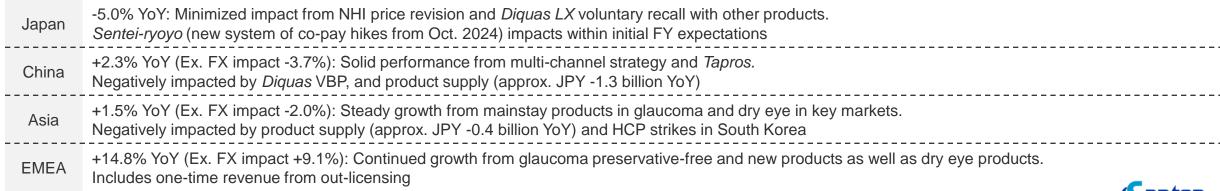
- No share of loss of investments YTD
- Tax ratio excluding one-time factors: 21.1%



### Q3 FY2024 Sales bridge

# Flat YoY: Product supply impact mitigated by solid progress from other products in Japan and EMEA including one-time revenue







## Minimized *Diquas LX* impact with cost optimization and one-time revenue



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

Overseas (including FX)

China: Maintained profit despite impact from *Diquas* VBP and product supply

Asia: Increased profit despite product supply and other factors

EMEA: Solid progress with increased profit coupled with one-time revenue from out-licensing

Others

Increased expenses with FX. Positive impact from completion of structural reforms including streamlining in Americas pharmaceutical commercial

business



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

# **Faster-than-expected progress**

| (JPY billions)   | FY2    | 023           |                   | FY2           | 024     |                |
|--|--------|---------------|-------------------|---------------|---------|----------------|
|  | Actual | vs<br>Revenue | Forecast (Aug. 6) | vs<br>Revenue | YoY     | Q3<br>Progress |
| Revenue  | 302.0  |               | 302.0             |               | +0.0%   | 74%            |
| Cost of sales  | 123.1  | 41%           | 129.0             | 43%           | +4.8%   | 76%            |
| Gross profit   | 178.9  | 59%           | 173.0             | 57%           | -3.3%   | 72%            |
| SG&A expenses  | 90.8   | 30%           | 91.0              | 30%           | +0.2%   | 71%            |
| R&D expenses   | 25.3   | 8%            | 27.0              | 9%            | +6.9%   | 62%            |
| Core operating profit  | 62.8   | 21%           | 55.0              | 18%           | -12.4%  | 79%            |
| 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%  | 79%            |
| 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%  | 78%            |
| 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%  | 82%            |
| Net profit attributable to owners of the company               | 26.6   | 9%            | 32.5              | 11%           | +22.0%  | 85%            |
| ROE  | 9%     |               | 11%               |               |         |                |
| Core ROE   | 16%    |               | 14%               |               |         |                |
| Core net profit  | 48.5   | 16%           | 41.3              | 14%           | -15.0%  | 82%            |
|  |        |               |                   |               |         |                |

### **Factors to consider for FY forecast**

Japan: Pollen-levels

Overseas: Material FX fluctuations

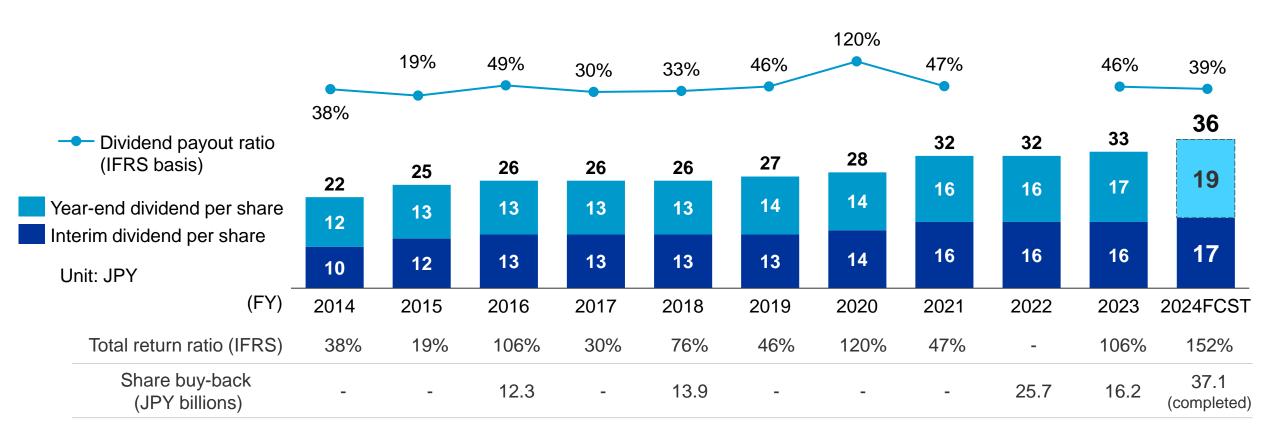
Cost optimization

FYE fluctuations in sub-Core items



# Increased year-end dividend to JPY 19 based on progressive dividend policy

- Dividend raised considering mid-to long term prospects in earnings
- Approx.16% / JPY 79.0 billion of OTSD shares repurchase since FY2022





# **R&D Update**

# **Peter Sallstig**

**Chief Medical Officer** 



# Final stages before launch – Myopia approved and Ptosis filed Existing area: Multiple milestone achievements on late stage pipelines

| New           | Atropine sulfate<br>STN10 <b>127</b> 00 <b>/</b> 01<br>RYJUSEA Mini             | Myopia                     | Received <b>approval</b> in Japan <b>Filed</b> in March 2024 in Europe <b>Started preparations for filing</b> in Asia |
|---------------|---|----------------------------|---|
| area          | Oxymetazoline hydrochloride<br>STN10 <b>138</b> 00                              | Ptosis                     | <b>Filed</b> in Japan<br>Achieved <b>FPI</b> <sup>1</sup> in P3 trial in Europe                                       |
|               | AFDX0250BS<br>STN10 <b>134</b> 00   | Myopia                     | Achieved <b>LPO</b> <sup>2</sup> in P2a trial in Japan  |
|               | Latanoprost cationic emulsion<br>STN10 <b>130</b> 01<br>Catiolanze              | Glaucoma                   | Filed in Asia   |
|               | Netarsudil mesylate<br>STN10 <b>139</b> 00<br>Rhopressa®/Rhokiinsa®             | Glaucoma                   | Confirmed long-term safety and efficacy in P3 (long-term treatment) trial in Japan                                    |
| Existing area | Epinastine hydrochloride<br>(twice a day, eye drop)<br>STN10 <b>114</b> 03      | Allergic<br>conjunctivitis | Achieved primary endpoints in P3 trial in China   |
|               | Omidenepag isopropyl<br>STN10 <b>117</b> 02<br><i>Eybelis Mini</i>              | Glaucoma                   | Achieved <b>FPI</b> in P3 trial in China  |
|               | Netarsudil mesylate /latanoprost<br>STN10 <b>140</b> 03<br>Rocklatan®/Roclanda® | Glaucoma                   | Started preparations for P3 trial in Japan  |



Myopia: STN10**127**00 (*RYJUSEA Mini*, atropine sulfate hydrate)

# Received approval for *RYJUSEA Mini* ophthalmic solution 0.025%, Japan's first ophthalmic solution for slowing myopia progression

Planning to launch in April-May 2025 as a drug not listed in the National Health Insurance Drug Price Standard. Selling price for patients is set by each medical institution due to out-of-pocket treatment.



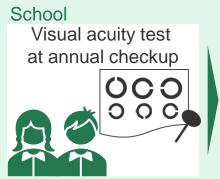
Contributing to resolving the social issue concerning increasing prevalence of myopia in children by providing products and information based on scientific knowledge as a company specialized in ophthalmology

RYJUSEA Mini ophthalmic solution 0.025%



- Typically, one drop per use, once a day before bedtime
- Single-dose unit
- Preservative-free formulation
- Although there are no explicit age restrictions, it is primarily intended for children

Information on diseases, diagnosis and treatment



#### **Medical Institution**

Examination & diagnosis

Confirming eligible patients Initiation of treatment

1<sup>st</sup> visit after initiation

1 week-1 month after prescribing Subsequent visits after initiation

 Every 3-6 months after prescribing Treatment end date considerations

 It is desirable to continue treatment until late teens.

This shows the generally expected flow based on the environment in Japan and the <u>IMI Clinical Myopia Management Guidelines Report provided</u> by the International Myopia Institute. In practice, it may vary depending on the patient's condition and the doctor's judgment.



Myopia: STN1012701 (atropine sulfate, SYD-101)

# Filed in Europe in March 2024 with P3 data which met primary endpoint. Expecting to receive approval early in FY2025

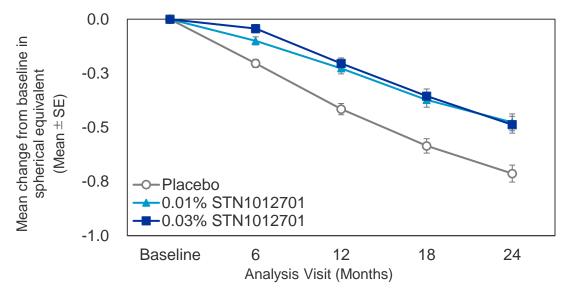
Confirmed statistically significant lower annual progression rate (primary endpoint) and change from baseline in spherical equivalent of 0.01% and 0.03% STN1012701 (SYD-101) compared to placebo at Month 24. Safety and tolerance confirmed for 0.01% and 0.03% STN1012701.

### Primary endpoint

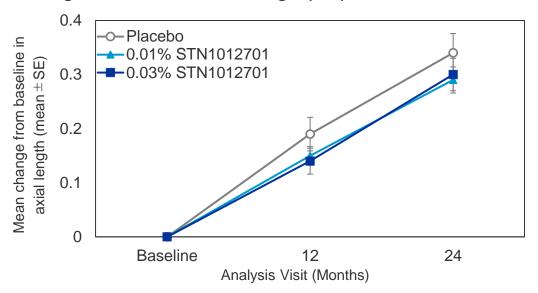
Annual progression rate of myopia at month 24 (diopter/year)

| , , , , , , , , , , , , , , , , , , , |              |                  |                  |  |  |  |  |
|---------------------------------------|--------------|------------------|------------------|--|--|--|--|
|                                       | Placebo      | 0.01% STN1012701 | 0.03% STN1012701 |  |  |  |  |
| LS mean rate                          | -0.44        | -0.31            | -0.32            |  |  |  |  |
| 95% CI                                | -0.50, -0.38 | -0.37, -0.25     | -0.38, -0.26     |  |  |  |  |
| P-value                               | NA           | 0.0003           | 0.0009           |  |  |  |  |

### ■ Change from baseline in spherical equivalent (diopter)



### ■ Change from baseline in axial length (mm) \*<50% sites collected AL Data



- ◆ Showed numerically better effect of 0.01% and 0.03% STN1012701 compared to placebo on axial length change (not powered statistical significance).
- The most frequently reported treatment-emergent adverse event at 24 Months was photophobia (Placebo: 16.7%, 0.01% STN1012701: 24.1%, 0.03% STN1012701: 30.4%).
- This study (STAR study) was designed to continue for a total of 48 months and is estimated to be completed in the summer of 2025.

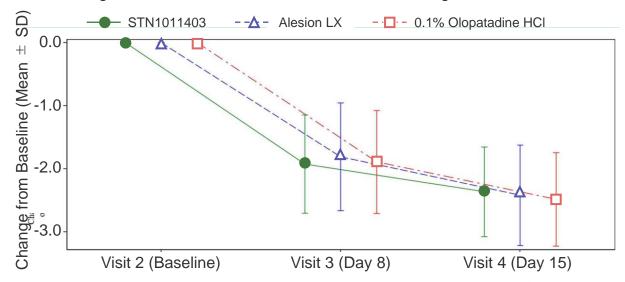


# Epinastine hydrochloride designed formulation for China, twice-daily eye drop, achieved primary endpoints on pivotal trial (P3)

Demonstrated non-inferiority of STN1011403 compared to *Alesion LX* and 0.1% olopatadine hydrochloride at Day 15 on both primary endpoints, ocular itching score and bulbar conjunctival hyperemia score change from baseline and confirmed safety and tolerance. STN1011403 for China market is a reformulated version of *Alesion LX*, a twice-daily eye drop sold in Japan and South Korea.

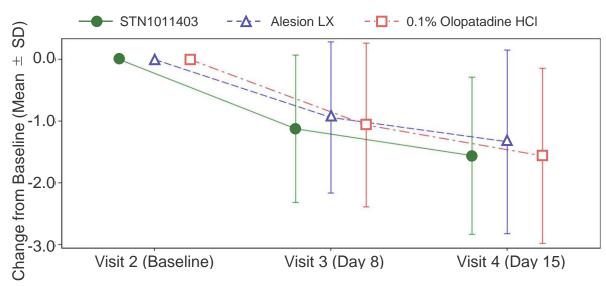
### Ocular Itching Score

Change from baseline in the most severe ocular itching score within 24 hours



### Bulbar Conjunctival Hyperemia Score

Change from baseline in bulbar conjunctival hyperemia score



### LS mean differences between groups at Day 15 (95% confidence interval)

|                     | Alesion LX                  | 0.1% Olopatadine HCl        |
|---------------------|-----------------------------|-----------------------------|
| STN10 <b>114</b> 03 | 0.05 ( <b>-0.11, 0.21</b> ) | 0.05 ( <b>-0.12, 0.21</b> ) |

Non-inferiority margin: **0.5** 

### LS mean differences between groups at Day 15 (95% confidence interval)

|                     | Alesion LX                   | 0.1% Olopatadine HCl         |
|---------------------|------------------------------|------------------------------|
| STN10 <b>114</b> 03 | -0.10 ( <b>-0.24, 0.03</b> ) | -0.03 ( <b>-0.16, 0.10</b> ) |

Non-inferiority margin: 0.4

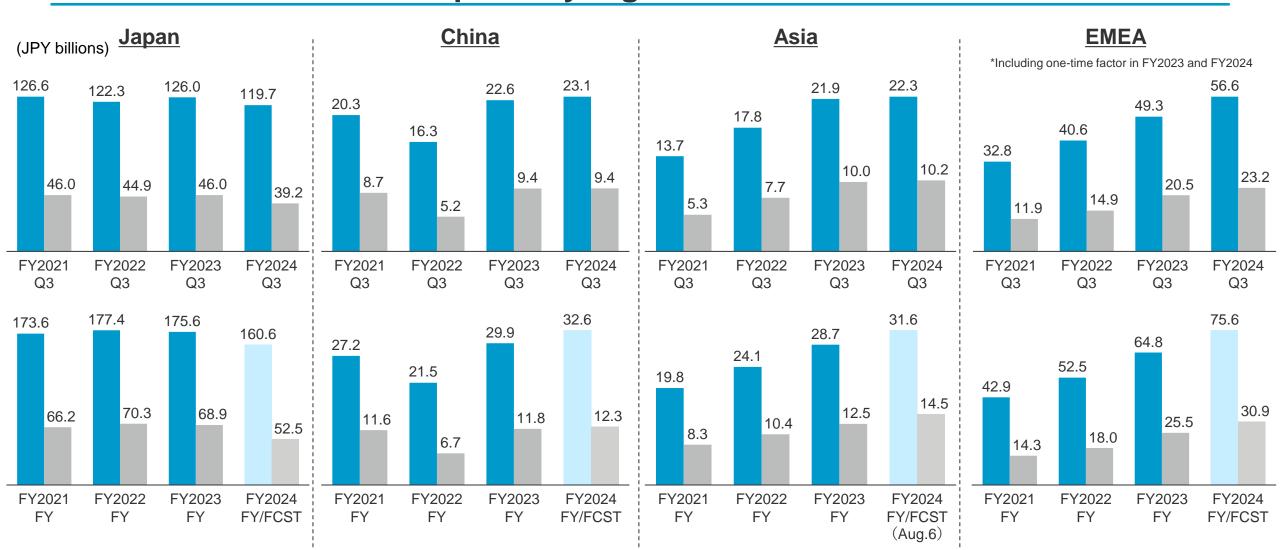


# **Appendix**



## Revenue and contribution profit by region





Note) Contribution profit: Deducting cost of sales and expenses related to revenue generation from regional revenue.

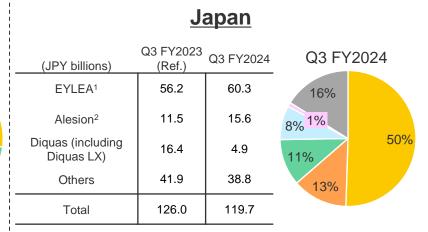
Reorganization in overseas in FY2023 reflects to contribution profits in FY2023 and FY2024.



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.

# Q3 FY2024 revenue by region

#### Consolidated Q3 FY2023 Q3 FY2024 Q3 FY2024 (JPY billions) (Ref.) EYLEA1 56.2 60.3 15% 27% 7% 19.2 20.4 Cosopt 8% 15.8 Alesion<sup>2</sup> 11.6 17% 135.8 126.2 26% Others 222.8 222.8 Total



| <br>           | <u>C</u>            | <u>China</u> |      |       |
|----------------|---------------------|--------------|------|-------|
| (JPY billions) | Q3 FY2023<br>(Ref.) | Q3 FY2024    | Q3 F | Y2024 |
| Cravit         | 7.0                 | 7.0          | 16%  |       |
| Hyalein        | 6.3                 | 6.7          | 8%0% | 39%   |
| Diquas         | 2.8                 | 2.1          |      |       |
| Others         | 6.5                 | 7.2          | 36%  |       |
| Total          | 22.6                | 23.1         |      |       |

### **Asia**

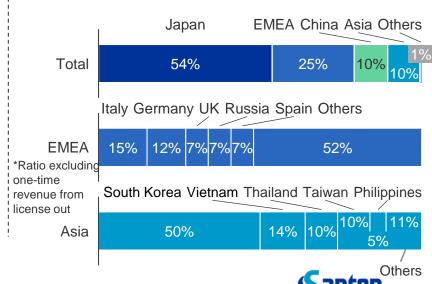
| (JPY billions) | Q3 FY2023<br>(Ref.) | Q3 FY2024 | Q3 FY2 | 2024 |
|----------------|---------------------|-----------|--------|------|
| Cosopt         | 5.1                 | 5.3       | 2%12%  |      |
| Hyalein        | 2.5                 | 2.9       | 14%    | 43%  |
| Cravit         | 2.7                 | 2.2       |        |      |
| Others         | 11.7                | 11.9      | 30%    |      |
| Total          | 21.9                | 22.3      |        |      |

### **EMEA**

| (JPY billions) | Q3 FY2023<br>(Ref.) | Q3 FY2024 | Q3 FY2024                            |
|----------------|---------------------|-----------|--------------------------------------|
| Cosopt         | 10.9                | 13.0      | 12%                                  |
| Ikervis        | 8.4                 | 6.8       | 4%3%                                 |
| Tapros         | 6.2                 | 6.6       | 23% 58%                              |
| Others         | 23.8                | 30.2      |                                      |
| Total          | 49.3                | 56.6      | *Including one-time                  |
|                |                     |           | revenue from license out in "Others" |

Bacterial conjunctivitis Others

### Revenue in each region (Q3 FY2024)



Intravitreal VEGF inhibitor Glaucoma/Device Dry eye Allergy

<sup>1</sup> Co-promoted product of Bayer Yakuhin, Ltd. (MAH), including EYLEA 8mg

<sup>2</sup> Alesion: Trademark of alliance partner, Boehringer Ingelheim KG, including Alesion LX and Alesion eyelid cream

### Financial supplement

# Sentei-ryoyo (new system of co-pay hike from Oct. 2024) impact: Revenue and forecast (within expectations)

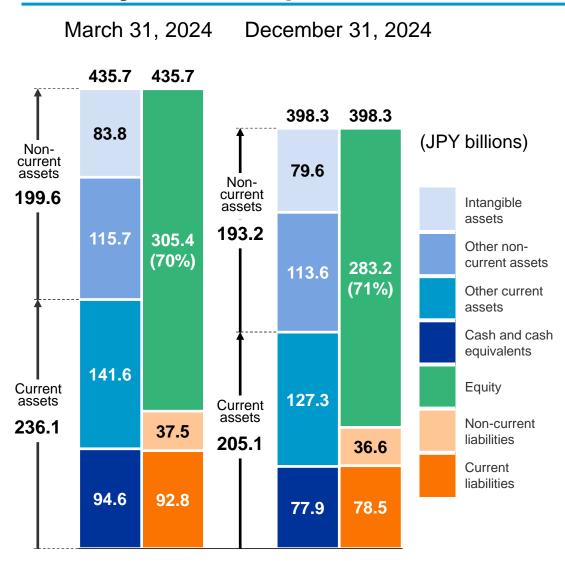
Listed 17 products<sup>1</sup> (including different strength products, as of Feb. 2025) and consists of 5-6% in Japan business.

Anticipate some more products to be listed including *Diquas*, *Tapros*, *Tapcom* and *Alesion LX* which GEs have been launched (JPY millions)

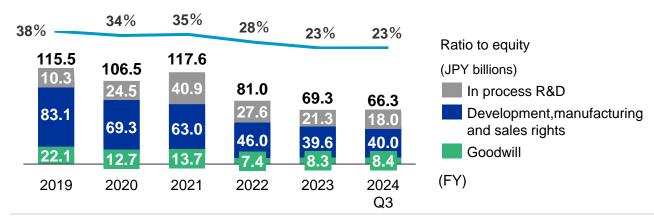
| Product                      | Therapeutic area         | FY2021  | FY2022  | FY2023      | FY2024<br>Q1 | FY2024<br>Q2 | FY2024<br>Q3 | FY2024<br>YTD | FY2024<br>FCST   |      |      |                          |       |       |
|------------------------------|--------------------------|---------|---------|-------------|--------------|--------------|--------------|---------------|------------------|------|------|--------------------------|-------|-------|
| Cosopt <sup>2</sup>          | Glaucoma                 | 5,047   | 4,039   | 3,347       | 814          | 716          | 510          | 2,040         | 2,111            |      |      |                          |       |       |
| Alesion (4 times/day)        | Allergy                  | 4,440   | 2,987   | 1,807       | 219          | 202          | 146          | 568           | 786              |      |      |                          |       |       |
| Hyalein 0.1/0.3 <sup>2</sup> | Dry eye                  | 5,800   | 4,949   | 4,268       | 1,031        | 1,130        | 915          | 3,077         | 3,590            |      |      |                          |       |       |
| Cravit 0.5/1.5               | Bacterial conjunctivitis | 1,754   | 1,285   | 1,126       | 234          | 212          | 127          | 572           | 674              |      |      |                          |       |       |
| Timoptol XE 0.25/0.5         | Glaucoma                 |         |         |             |              |              |              |               |                  |      |      |                          |       |       |
| Timoptol 0.25/0.5            | Glaucoma                 | 3,092   | 3,092   | 3,092 2,807 |              |              |              |               | i<br>!<br>!<br>! |      |      |                          |       |       |
| Alegysal                     | Allergy                  |         |         |             | 3,092        | 3,092        |              |               | į                |      |      | i<br> <br> -<br> -<br> - |       |       |
| Livostin                     | Allergy                  |         |         |             |              |              | 2.002        | 0.007         | 2 445            | 40.4 | 44.0 | 240                      | 4 407 | 4.550 |
| Flumetholon 0.1              | Others                   |         |         |             |              |              | 2,807        | 2,445         | 434              | 416  | 346  | 1,197                    | 1,550 |       |
| Santeson 0.02/0.1            | Others                   |         |         |             |              |              |              |               |                  |      |      |                          |       |       |
| Sancoba                      | Others                   |         |         |             |              |              |              |               |                  |      |      |                          |       |       |
| Mydrin-M                     | Others                   |         |         |             |              |              |              |               |                  |      |      |                          |       |       |
| Total                        |                          | 20,134  | 16,067  | 12,994      | 2,732        | 2,677        | 2,045        | 7,454         | 8,710            |      |      |                          |       |       |
| Japan business total         |                          | 173,633 | 177,373 | 175,608     | 40,553       | 38,876       | 40,231       | 119,660       | 160,649          |      |      |                          |       |       |
| Ratio vs Japan busines       | ss total                 | 11.6%   | 9.1%    | 7.4%        | 6.7%         | 6.9%         | 5.1%         | 6.2%          | 5.4%             |      |      |                          |       |       |



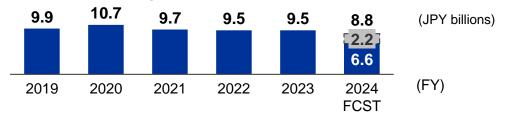
# Healthy financial position maintained. Reduce assets to improve ROE, ROIC



### Status of intangible assets related to products and goodwill



### Status of intangible assets amortization related to products

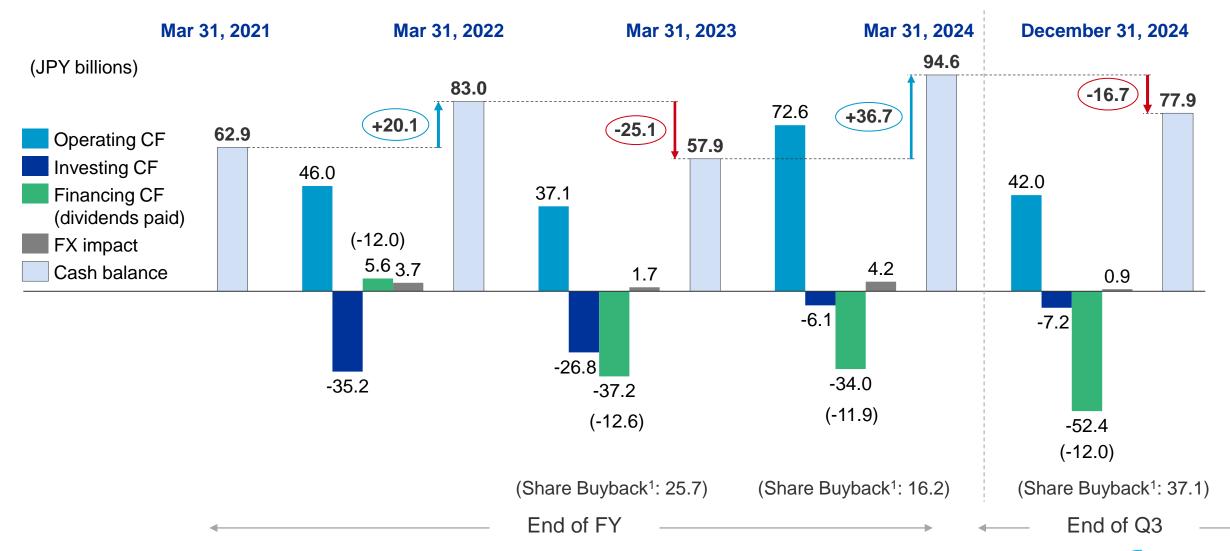


### ROE, Core ROE, ROIC

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



### **Cash flow**





# Foreign exchange rate assumptions and sensitivities

FX rate (JPY)

|     | FY2023<br>Actual | FY2024<br>Forecast<br>(No change from<br>Aug.6) | FY2024 vs<br>FY2023 | Q3 FY2023<br>Actual | Q3 FY2024<br>Actual | Q3 FY2024 vs<br>Q3 FY2023 |
|-----|------------------|---|---------------------|---------------------|---------------------|---------------------------|
| USD | 144.80           | 155.00  | 107.0%              | 143.61              | 152.63              | 106.3%                    |
| EUR | 156.88           | 165.00  | 105.2%              | 155.60              | 164.96              | 106.0%                    |
| CNY | 20.24            | 21.30   | 105.2%              | 20.07               | 21.33               | 106.3%                    |

### **Sensitivities**

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

|           | Total <sup>1</sup> | 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 |

<sup>1</sup> Total: impacts from USD, EUR, CNY and other major currencies (rounding to nearest 100 million)

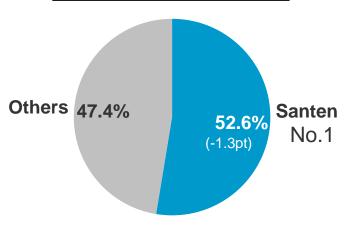
FX impact on Q3 FY2024 (vs Q3 FY2023)
(JPY billions)

|           | Total |
|-----------|-------|
| Revenue   | +5.1  |
| Core OP   | +0.7  |
| OP (IFRS) | +0.5  |

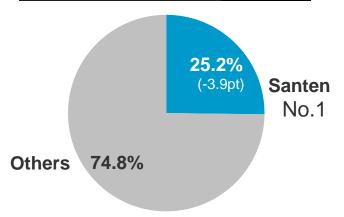


# Prescription ophthalmic market in Japan (Jan. 2024 - Dec. 2024)

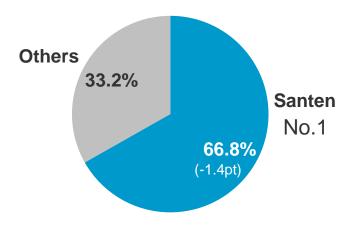
Total: JPY 360.6 bil



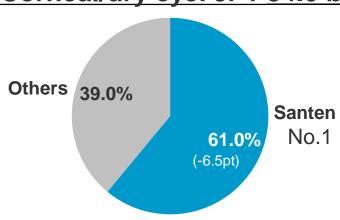
Glaucoma: JPY 81.2 bil



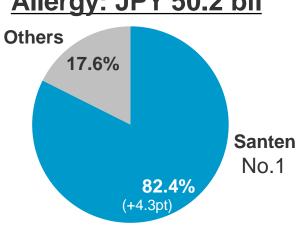
Retinal disorders\*: JPY 140.6 bil



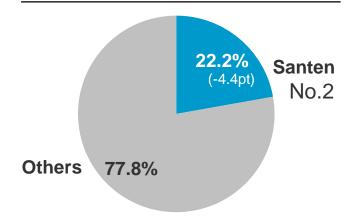
Corneal/dry eye: JPY 34.0 bil



Allergy: JPY 50.2 bil



Anti-infection: JPY 5.8 bil



<sup>\*</sup>Including co-promoted product (Anti-VEGF EYLEA, EYLEA 8mg) of Bayer Yakuhin, Ltd. (MAH). Based on Santen Pharmaceutical (distributor) records. Source: Copyright © 2025 IQVIA. JPM 2023.1-2024.12; Santen analysis based on IQVIA data. Reprinted with permission.



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

Glaucoma and ocular hypertension area

| Indication        | Generic Name   | Dev. Code                      |   | Development Status <sup>1</sup>                         |
|-------------------|--|--------------------------------|---|---|
|                   | Tafluprost / timolol maleate (combination) Tapcom / Taptiqom | STN10 <b>111</b> 01<br>DE-111A | China   | Filed<br>Plan: FY2024 approval                          |
|                   | Omidenepag<br>isopropyl<br>Eybelis Mini                      | STN10 <b>117</b> 02            | China   | Started P3 in November 2024  Plan: FY2026 P3 completion |
|                   |  |                                | US  | P2 (met primary endpoint)                               |
| Glaucoma          | Glaucoma Sepetaprost   | STN10 <b>126</b> 00<br>DE-126  | Japan   | Filed<br>Plan: FY2025 approval                          |
|                   |  |                                | Europe  | P2 (exploratory study) completion                       |
| Catiolanze DE-130 | STN10 <b>130</b> 01  | Europe                         | Launched                                      |   |
|                   | DE-130A<br>Catioprost  | Asia                           | Filed in November 2024  Plan: FY2026 approval |   |



<sup>1</sup> Only projects for which the study protocols were approved in-house are shown,

# **Current status of global development (2)**

## Glaucoma and ocular hypertension area

| Indication | Generic Name  | Dev. Code                       |                               | Development Status  |
|------------|---|---------------------------------|-------------------------------|---|
|            |   | STN10 <b>139</b> 00<br>AR-13324 | Japan                         | P3 (Met primary endpoints in pivotal trials and confirmed long-term safety and efficacy)  Plan: FY2025 filing |
|            | Netarsudil mesylate Rhopressa®/Rhokiinsa®  Glaucoma |                                 | Europe                        | Launched  |
| Glaucoma   |   |                                 | Asia                          | Launched  |
|            | Netarsudil mesylate                                 | STN10 <b>140</b> 03             | Japan                         | Plan: FY2024 P3 start   |
|            | /latanoprost<br>(combination)                       | STN10 <b>140</b> 00             | Europe                        | Launched  |
|            | Rocklatan®/Roclanda® PG-324                         | Asia                            | Approved  Plan: FY2024 launch |   |



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

Keratoconjunctival disease area including dry eye

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

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

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

### Refractive disorder

| Indication | Generic Name                               | Dev. Code                      | Development Status |  |
|------------|--|--------------------------------|--------------------|--|
|            |  |                                | Japan              | Approved in December 2024  Plan: FY2025 launch |
|            | Atropine sulfate<br>RYJUSEA Mini<br>Myopia | STN10 <b>127</b> 00<br>DE-127  | China              | P2/3<br>Plan: FY2026 P2/3 completion           |
| Myopia     |  |                                | Asia               | P2 (met primary endpoint)  Plan: FY2025 filing |
|            |  | STN10 <b>127</b> 01<br>SYD-101 | Europe             | Filed in March 2024  Plan: FY2025 approval     |
| AFDX02     | AFDX0250BS                                 | STN10 <b>134</b> 00            | Japan              | P2a<br>Plan: FY2024 P2a completion             |
|            |  |                                | China              | P1 (confirmed safety and tolerability)         |



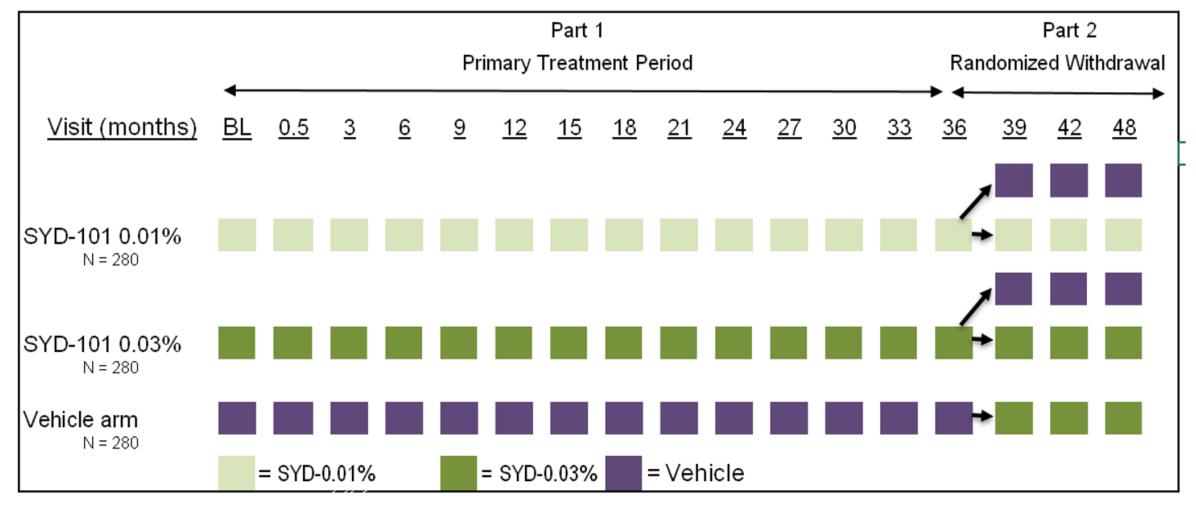
# **Current status of global development (5)**

### Others

| Indication              | Generic Name                       | Dev. Code                       | Development Status |   |
|-------------------------|------------------------------------|---------------------------------|--------------------|---|
|                         | Ptosis Oxymetazoline hydrochloride | STN10 <b>138</b> 00<br>RVL-1201 | Japan              | Filed in December 2024  Plan: FY2025 approval           |
| Ptosis                  |                                    |                                 | Europe             | Started P3 in December 2024  Plan: FY2025 P3 completion |
|                         |                                    |                                 | China              | P3<br>Plan: FY2026 P3 completion                        |
|                         |                                    |                                 | Asia               | Plan: FY2026 filing                                     |
| Retinitis<br>pigmentosa | jCell                              | STN <b>60001</b> 00             | -                  | jCyte Planning P3                                       |



# Pivotal P3 trial protocol in Europe and US (NCT03918915)

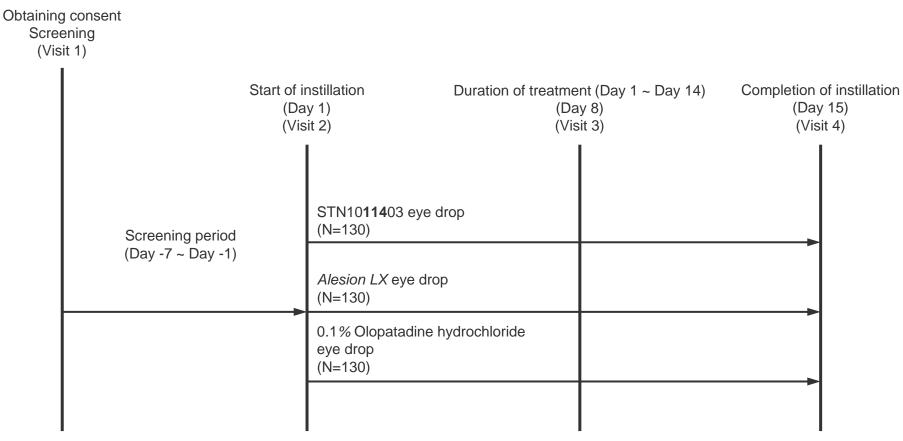


This study (STAR study) was designed to continue for a total of 48 months and is estimated to be completed in the Summer of 2025.



## Pivotal P3 trial protocol in China

Multicenter, randomized, observer-masked, active control Phase III study to evaluate the efficacy and safety of STN1011403 ophthalmic solution in Chinese patients with allergic conjunctivitis



Both eyes, twice a day (8:00  $\pm$  2 hours, 20:00  $\pm$  2 hours), one drop for each eye



# **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.



