Summary of Consolidated Financial Results for the Six Months Ended September 30, 2022 (IFRS)

Listed Company Name:	Santen Pharmaceutical Co.,Ltd
Exchanges Listed:	Tokyo (Prime Market)
Stock Code:	4536
URL:	https://www.santen.com/en/
Representative:	Takeshi Ito, President and CEO
Contact:	Guillaume Sakuma, Global Head of IR (+81-6-7664-8621)
Filing of Securities Report (Scheduled):	November 10, 2022
Distribution of Dividends (Scheduled):	November 30, 2022
Preparation of Supplementary Material of the Financial Results:	Yes
Holding of Presentation of Financial Results:	Yes (for securities analysts and institutional investors)

(JPY millions)

1. Consolidated Performance for the Six Months Ended September 30, 2022

(1) Operating Results

(IFRS)

	Six months ended September 30, 2021	Six months ended September 30, 2022	% change
Revenue	128,759	128,915	+0.1%
Operating profit	18,805	(19,021)	—
Profit before tax	18,393	(19,103)	—
Net profit for the period	14,254	(22,019)	—
Net profit for the period attributable to owners of the company	14,307	(22,041)	—
Total comprehensive income for the period	14,858	(8,412)	—
Basic earnings per share (yen)	35.79	(56.05)	
Diluted earnings per share (yen)	35.73	(56.05)	

(Core basis)

	Six months ended September 30, 2021	Six months ended September 30, 2022	% change
Revenue	128,759	128,915	+0.1%
Core operating profit	24,306	16,451	(32.3%)
Core net profit for the period	18,556	12,465	(32.8%)
Core net profit for the period attributable to owners of the company	18,586	12,484	(32.8%)
Basic core earnings per share (yen)	46.50	31.73	
Diluted core earnings per share (yen)	46.41	31.69	

(2) Financial Position

	March 31, 2022	September 30, 2022
Total assets	459,976	426,580
Total equity	336,844	309,415
Total equity attributable to owners of the company	337,488	310,072
Total equity attributable to owners of the company ratio	73.4%	72.7%
Equity per share attributable to owners of the company (yen)	843.60	799.94

2. Dividends

	Year to March 2022	Year to March 2023	(Forecasts) Year to March 2023
First quarter dividends per share (yen)	—	—	—
Second quarter dividends per share (yen)	16.00	16.00	—
Third quarter dividends per share (yen)	—	—	—
Year-end dividends per share (yen)	16.00	—	16.00
Annual dividends per share (yen)	32.00	—	32.00

(Note) Revisions to the forecasts of dividends from the latest announcement: No

3. Consolidated Forecasts of Results for the Year Ending March 31, 2023

(IFRS)

	Year to March 2023	% change
Revenue	280,000	+5.2%
Operating profit	4,000	(88.9%)
Profit before tax	3,000	(91.6%)
Net profit for the year	(5,500)	—
Basic earnings per share (yen)	(14.20)	

(Core basis)

	Year to March 2023	% change
Revenue	280,000	+5.2%
Core operating profit	45,500	(1.8%)
Core net profit for the year	34,100	(3.1%)
Basic core earnings per share (yen)	88.04	

(Note) Revisions to the forecasts of consolidated results from the latest announcement: Yes

1. Please refer to "1. Summary of Quarterly Consolidated Results (1) Summary of Consolidated Results" on page 6 of the attached material for details of the reconciliation from IFRS-based figures to core-based figures.
2. At the Board of Directors meeting held on October 4, 2022, the Board resolved to cancel treasury shares and completed the cancellation on October 31, 2022. Subsequently, at a meeting of the Board of Directors on Nov 8, 2022, the Board resolved to undertake a share repurchase. The share cancellation and repurchase have been factored into the basic earnings per share and basic core earnings per share forecasts. Please refer to "2. Condensed Interim Consolidated Financial Statements (5) Notes to Condensed Interim Consolidated Financial Statements on page 18 of the attached material for details.

*Notes

(1) Changes in significant subsidiaries during the period
(Changes in specified subsidiaries resulting in changes in scope of consolidation): No

(2) Changes in accounting policies and accounting estimates
(i) Changes in accounting policies required by IFRS : No
(ii) Changes in accounting policies other than (i) : No
(iii) Changes in accounting estimates : No

(3) Number of ordinary shares issued
(i) Number of shares outstanding at the end of period (including treasury shares)

September 30, 2022	400,708,354 shares
March 31, 2022	400,694,754 shares

(ii) Number of treasury shares at the end of period

September 30, 2022	12,858,160 shares
March 31, 2022	423,668 shares

(iii) Average number of outstanding shares

The second quarter ended September 30, 2022	393,314,840 shares
The second quarter ended September 30, 2021	399,679,863 shares

(Note)The number of treasury shares at the end of the period includes shares owned in trust for the stock compensation system (16,271 shares at the end of the fiscal year ended March 31, 2022 and 55,202 shares as of the second quarter of the fiscal year ending March 31, 2023). Treasury shares are also included in the calculation of the average number of shares outstanding during the period.

*This financial summary is not subject to audit by a certified public accountant or auditing firm.

*Explanations and other special notes concerning the appropriate use of business performance forecasts

(Notes on forward-looking statements)
The earnings forecasts and other forward-looking statements contained in this report are based on information currently available to the Company and on certain assumptions deemed to be reasonable by the Company. Actual results may differ from these forecasts due to various factors.

(Method of obtaining supplementary explanatory materials for financial results and results presentation contents)
The Santen Group plans to hold a briefing on the results for securities analysts and institutional investors on November 8, 2022. The materials used in this briefing will be posted on our website.

Accompanying Materials – Contents

1. Summary of Quarterly Consolidated Results

(1) Summary of Consolidated Results
(I) Consolidated Results
A) IFRS

(JPY millions)

	Six months ended September 30, 2021	Six months ended September 30, 2022	Year-on-year amount change	Year-on-year change
Revenue	128,759	128,915	157	0.1%
Operating profit (loss)	18,805	(19,021)	(37,826)	－%
Net profit (loss) for the period	14,254	(22,019)	(36,274)	－%
Net profit (loss) for the period attributable to owners of the company	14,307	(22,041)	(36,349)	－%

[Revenue]

Revenue in the six months ended September 30, 2022 increased by 0.1% year-on-year to ¥128.9 billion.

In the mainstay prescription pharmaceuticals business, sales decreased by 0.9% year-on-year to ¥119.3 billion. Despite the strong impact of strict measures in China to prevent the spread of COVID-19, the Company was able to minimize the impact of drug price revisions in Japan and posted stable growth in mainstay products in Asia and EMEA. The breakdown of revenue is as follows:

Upper: Value
Lower: Year-on-year change
【】: Year-on-year change excluding FX impact

(JPY millions)

	Japan	China	Asia	EMEA	Americas	Total
Prescription pharmaceuticals	71,749	9,812	11,059	24,964	1,749	119,333
	(5.2%)	(29.9%)	26.7%	21.8%	19.1%	(0.9%)
	【－%】	【(39.8%)】	【15.9%】	【12.0%】	【2.3%】	【(4.7%)】
OTC pharmaceuticals	5,068	114	456	－	－	5,639
	5.8%	－	54.1%	－	－	10.8%
Medical devices	1,624	5	－	1,141	241	3,012
	5.3%	－	－	53.9%	21.8%	21.4%
Others	841	19	71	－	－	932
	9.3%	10.5%	116.3%	－	－	13.6%
Total	79,283	9,951	11,586	26,105	1,990	128,915
	(4.2%)	(29.0%)	27.9%	22.9%	19.4%	0.1%
	【－%】	【(38.9%)】	【16.8%】	【13.1%】	【2.1%】	【(3.6%)】

(Note)
Represents revenue from sales to external customers.
Classified into countries or regions based on customer location. China is not included in Asia.
EMEA refers to Europe, the Middle East and Africa.

<Prescription pharmaceuticals>

◇ Japan

Revenue in the six months ended September 30, 2022 decreased by 5.2% year-on-year to ¥71.7 billion. The Company was able to minimize the impact of drug price revisions of mid 4% including market expansion re-pricing for mainstay product, *Alesion*. Revenue of major products is as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥4.0 billion	(YoY -9.1%)
Tapcom ophthalmic solution	¥1.4 billion	(YoY -3.9%)
Cosopt ophthalmic solution	¥2.5 billion	(YoY -18.2%)
Eybelis ophthalmic solution	¥1.9 billion	(YoY +18.7%)
Dry eye		
Diquas ophthalmic solution	¥6.8 billion	(YoY +1.8%)
Allergy		
Alesion ophthalmic solution*1(refer to Page5)	¥7.9 billion	(YoY -17.1%)
Intravitreal VEGF inhibitor		
EYLEA®*2(refer to Page5) (solution for intravitreal injection)	¥35.8 billion	(YoY -1.7%)

◇ China

On a JPY basis, revenue in the six months ended September 30, 2022 decreased by 29.9% year-on-year (-39.8% excluding FX impact), to ¥9.8 billion having an impact from strict COVID-19 measures in China and others. Revenue of major products is as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥0.4 billion	(YoY -4.7%)
Dry eye		
Diquas ophthalmic solution	¥1.6 billion	(YoY -3.1%)
Hyalein ophthalmic solution	¥2.6 billion	(YoY -38.6%)
Bacterial conjunctivitis		
Cravit ophthalmic solution	¥2.6 billion	(YoY -41.4%)

◇ Asia (excluding China)

On a JPY basis, revenue in the six months ended September 30, 2022 increased by 26.7% year-on-year (+15.9% excluding FX impact), to ¥11.1 billion. This was due to improved market penetration on the expansion of the promotion framework, despite the impact of COVID-19. Revenue of major products is as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥1.1 billion	(YoY +14.4%)
Tapcom ophthalmic solution	¥0.5 billion	(YoY +39.6%)
Cosopt ophthalmic solution	¥2.9 billion	(YoY +19.0%)
Dry eye		
Diquas ophthalmic solution	¥0.9 billion	(YoY +10.5%)
Ikervis	¥0.8 billion	(YoY +50.3%)
Bacterial conjunctivitis		
Cravit ophthalmic solution	¥1.0 billion	(YoY +19.6%)

◇ EMEA

On a JPY basis, revenue in the six months ended September 30, 2022 increased by 21.8% year-on-year (+12.0% excluding FX impact), to ¥25.0 billion, despite the impact from Russia-Ukraine conflict. Revenue of major products is as follows.

Glaucoma and ocular hypertension		
	Tapros ophthalmic solution	¥3.9 billion (YoY +15.3%)
	Tapcom ophthalmic solution	¥2.2 billion (YoY +33.8%)
	Cosopt ophthalmic solution	¥6.1 billion (YoY +15.6%)
	Trusopt ophthalmic solution	¥1.7 billion (YoY +12.7%)
Dry eye		
	Ikervis	¥2.9 billion (YoY +16.4%)
	Cationorm	¥1.4 billion (YoY +34.1%)
Allergy		
	Verkazia	¥0.4 billion (YoY +43.8%)

◇ Americas

On a JPY basis, revenue in the six months ended September 30, 2022 increased by 19.1% year-on-year (+2.3% excluding FX impact), to ¥1.7billion.

<OTC pharmaceuticals>

Revenue in the six months ended September 30, 2022 increased by 10.8% year-on-year to ¥5.6 billion.

Santen continues to focus on high-end products such as the *Sante Medical* series, *Sante Beauteye* series, and *Soft Santear* series as well as *Hyalein S*, which is a switch OTC product and *Sante FX* series and eye drop-type eye wash, *Well-Wash EYE*, which Santen launched in the previous fiscal year.

<Medical devices>

Revenue in the six months ended September 30, 2022 increased by 21.4% year-on-year to ¥3.0 billion, boosted by the full -fledged rollout of *PRESERFLO MicroShunt*. Revenue of major products is as follows.

Lentis Comfort	¥0.6 billion (YoY -4.4%)
PRESERFLO MicroShunt	¥1.1 billion (YoY +54.4%)

<Others>

Other revenues amounted to ¥0.9 billion. This is due to sales of supplements, and cleaning of dustless and aseptic clothing at consolidated subsidiary Claire Co., Ltd.

[Operating Loss]

Gross profit in the six months ended September 30, 2022 decreased by 3.8% year-on-year to ¥73.0 billion.

SG&A expenses on an IFRS basis in the six months ended September 30, 2022 increased by 6.7% year-on-year (-0.1% excluding FX impact) to ¥42.3 billion.

R&D expenses in the six months ended September 30, 2022 increased by 15.6% year-on-year (+6.2% excluding FX impact) to ¥14.3 billion.

Amortization on intangible assets associated with products in the six months ended September 30, 2022 increased by 7.9% year-on-year (+1.3% excluding FX impact) to ¥5.2 billion. This was mainly due to the amortization on intangible assets associated with products acquired from Merck & Co., Inc. (U.S.) in 2014, *Ikervis* which was launched in Europe in 2015, and *PRESERFLO MicroShunt* acquired in connection with the acquisition of InnFocus, Inc. (U.S.) in 2016 and ophthalmic products from Eyevance Pharmaceuticals Holdings Inc. (U.S.) which Santen acquired in 2020.

Other income amounted to ¥0.3 billion.

Other expenses amounted to ¥30.6 billion. This is due to the recording of impairment of the all amount of book value on fixed and intangible assets (goodwill and development and sales rights) associated with Eyevance Pharmaceuticals Holdings Inc.(U.S) and its business unit Eyevance Pharmaceuticals LLC (U.S).

As a result, operating loss on an IFRS basis in the six months ended September 30, 2022 amounted to ¥19.0 billion (operating profit of ¥18.8 billion for the same period of previous fiscal year)

[Net loss for the period]

Finance income amounted to ¥1.2 billion.

Finance expenses amounted to ¥0.3 billion.

Share of loss of investments accounted for using equity method amounted to ¥1.1 billion from Twenty Twenty Therapeutics LLC (U.S.), a joint venture with Verily Life Sciences LLC (U.S.)

Income tax expenses amounted to ¥2.9 billion, down ¥1.2 billion year-on-year. This is due to the decrease in profit before tax for the period, associated with the decrease of operating profit on an IFRS basis aforementioned.

As a result, net loss in the period ended September 30, 2022 was ¥22.0 billion (net profit of ¥14.3 billion for the same period of the previous fiscal year)

[Net loss for the period attributable to owners of the company]

Quarterly net loss attributable to owners of the company in the six months ended September 30, 2022 was ¥22.0 billion (Quarterly net profit of ¥14.3 billion for the same period of the previous fiscal year)

*1 Includes *Alesion LX*

*2 Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

B) Core basis[*3]

(JPY millions)

	Six months ended September 30, 2021	Six months ended September 30, 2022	Year-on-year change
Revenue	128,759	128,915	0.1%
Core Operating profit	24,306	16,451	(32.3%)
Core Net profit for the period	18,556	12,465	(32.8%)
Core Net profit for the period attributable to owners of the company	18,586	12,484	(32.8%)

[Revenue]

There are no adjustments from the IFRS basis.

[Core operating profit]

There are no adjustments to gross profit from the IFRS basis.
SG&A expenses in the six months ended September 30, 2022 increased by 7.8% year-on-year to ¥42.3 billion.
Note that for the second quarter of the previous fiscal year, expenses related to new consolidations associated with business combinations were deducted from IFRS results. However, this adjustment is not applicable to the second quarter under review.
There are no adjustments to R&D expenses from the IFRS basis.

As a result, operating profit on a core basis in the six months ended September 30, 2022 decreased by 32.3 % year-on-year to ¥16.5 billion.

*3 With the adoption of IFRS in the fiscal year ended March 31, 2015, the Santen Group discloses financial information on a core basis, which is calculated by excluding certain income and expense items from the IFRS basis, as an indicator of ordinary performance. The core basis is calculated by adjusting the following income and expense items, which are deducted from IFRS results, and the related income tax expenses.

- Amortization on intangible assets associated with products
- Other income
- Other expenses
- Finance income
- Finance expenses
- Share of profit (loss) of investments accounted for using equity method
- Expenses related to acquisitions of companies included in SG&A

(II) Research & Development Activities

<Glaucoma and the ocular hypertension area>

STN1011101 (DE-111A, generic name: tafluprost / timolol maleate) is a fixed dose combination drug of a prostaglandin $F_{2\alpha}$ derivative and a beta-adrenergic receptor blocker. Conducting Phase 3 trial since January 2019 in China.

STN1011700 (DE-117, generic name: omidenepag isopropyl) is an EP2 receptor agonist. The Company received marketing approval in September 2022 in the U.S. The product was launched in November 2018 in Japan. The Company has successively launched in Asian countries since launch in Korea in February 2021.

STN1012600 (DE-126, generic name: sepetaprost) is a dual agonist that activates both FP and EP3 receptors. An additional Phase 2 trial was completed in December 2021 in the U.S. Phase 3 trials were started in August 2022 in Japan. A Phase 2 trial (exploratory study) was started in September 2021 in Europe.

STN2000100 (DE-128) is a device for glaucoma. The Company launched (soft launch) in July 2022 in Japan. The device was launched in April 2019 in Europe. The Company has successively filed for marketing approval in Asian countries since March 2020 and received approval in Singapore and other countries from September 2021.

STN1013001 (DE-130A, generic name: latanoprost) is an ophthalmic emulsion of a prostaglandin $F_{2\alpha}$ derivative. Phase 3 trial was completed in March 2022 in Europe and Asia. The company filed for marketing approval in September 2022 in Europe.

STN1013900 (AR-13324, generic name: netarsudil mesilate) is a ROCK inhibitor. Phase 3 trial has been under way since November 2020 in Japan. Marketing approval has been received in Europe. The Company filed for marketing approval in March 2022 in Asia.

STN1014000 (PG-324, generic name: netarsudil mesilate / latanoprost) is a fixed dose combination drug of a ROCK inhibitor and a prostaglandin $F_{2\alpha}$ derivative. Marketing approval has been received in Europe. The Company filed for marketing approval in May 2022 in Asia.

<Keratoconjunctival disease area including dry eye >

STN1007603 (DE-076C, generic name: cyclosporin) for vernal keratoconjunctivitis has been approved and launched in Europe, Asia, and Canada. Marketing approval has been received in April 2022 in China. Launched in the U.S. in May 2022.

STN1008903 (DE-089C, generic name: diquafosol sodium) is for the treatment of dry eye. The Company received manufacturing and marketing approval in June 2022 in Japan.

STN1010905 (generic name: sirolimus) is for the treatment of meibomian gland dysfunction. Phase 2a trial completed in August 2022 in Japan.

STN1011402 (generic name: epinastine hydrochloride) is for the treatment of allergic conjunctivitis. Phase 3 trial completed in October 2022 in Japan.

STN1010904* (generic name: sirolimus) is for the treatment of Fuchs endothelial corneal dystrophy. The Company has executed a joint development agreement with ActualEyes Inc. Phase 2a trials started in U.S., France and India in May 2022. (*The development code (STN1010904) is due to be assigned to the product when Santen obtains an exclusive license upon completion of Phase 2 clinical trial.)

<Refractive error>

STN1012700 (DE-127, generic name: atropine sulfate) is for the treatment of myopia in children. Conducting Phase 2/3 trial since August 2019 in Japan. Phase 2/3 trial was started in June 2022 in China. Phase 2 trial was completed in April 2020 in Asia.

STN1012701 (SYD-101, generic name: atropine sulfate) is for the treatment of progressive myopia in children. Sydnexis Inc., (U.S.) the licensor, is conducting Phase 3 trials in Europe and the U.S. Santen has obtained the exclusive license for Europe, Middle East and Africa.

STN1013400 (compound name: AFDX0250BS) is for the treatment of myopia. Phase 1 trial was completed in September 2021 in Japan.
STN1013600 (generic name: ursodeoxycholic acid) is for the treatment of presbyopia. Phase 1 trial was completed in April 2022 in Japan.

<Others>

STN1013800 (generic name: oxymetazoline hydrochloride) is for the treatment of ptosis. Phase 3 trial was started in October 2022 in Japan.

※ The numbering method for development codes has changed. Both existing development codes (DE-XXX) and new development codes (STNXXXXXXX) are shown. AR-13324/PG-324 and SYD-101 are the development codes of Aerie Pharmaceuticals, Inc. (U.S.) and Sydnexis Inc. (U.S.) respectively.

(2) Summary of Financial Position

(I) Assets, equity and liabilities

Total assets at the end of the second quarter amounted to ¥426.6 billion, down ¥33.4 billion from the end of the previous fiscal year. Despite an increase in property, plant and equipment related to the construction of the No. 3 plant for the manufacturing of prescription pharmaceutical eye-drops at the Shiga Product Supply Center, there was a decrease in intangible assets associated with the impairment of intangible assets (goodwill and development and sales rights) related to the business review of Eyevance Pharmaceuticals Holdings Inc. (U.S.) and Eyevance Pharmaceuticals LLC (U.S.), trade and other receivables and cash associated with payments including dividends and share repurchases.

Equity amounted to ¥309.4 billion. This was an decrease of ¥27.4 billion from the end of the previous fiscal year ended March 31, 2022 which was due to share repurchases and a decrease in retained earnings from net loss for the period, despite an increase in other components of equity.

Liabilities amounted to ¥117.2 billion, falling by ¥6.0 billion from the end of the previous fiscal year. This was due to decreases in trade and other payables, other financial liabilities related to the repayment of short-term loans, and other current liabilities related to bonus payments, despite an increase in financial liabilities associated with a long-term loan to finance capital expenditures for the construction of the No. 3 plant for the manufacture of prescription pharmaceutical eye-drops at the Shiga Product Supply Center.

As a result, the ratio of equity attributable to owners of the company to total assets decreased by 0.7 points from the end of the previous fiscal year ended March 31, 2022 to 72.7%

(II) Cash Flows

Cash flows from operating activities at the end of the second quarter amounted to ¥18.3 billion. (¥27.1 billion in the six months ended September 30, 2021). This was mainly due to ¥22.0 billion quarterly loss, the impairment loss of ¥30.5 billion from impairment recording mainly on intangible assets of Eyevance Pharmaceuticals Holdings Inc. (U.S.) and Eyevance Pharmaceuticals LLC (U.S.), ¥9.0 billion depreciation and amortization, ¥13.8 billion decrease in trade and other receivables and ¥4.4 billion decrease in trade and other payables.

Cash flows from investing activities amounted to an outflow of ¥18.8 billion. (¥17.1 billion in the six months ended September 30, 2021). This was mainly due to payments for the acquisition of property, plant and equipment and intangible assets amounting to ¥11.2 billion and ¥4.7 billion respectively. There was a cash inflow of ¥1.0 billion owing to the sale of 1 equity holding in the second quarter of the fiscal year under review as part of accelerating the ongoing review of cross-shareholdings.

Cash flows from financing activities amounted to an outflow of ¥16.1 billion. (¥3.0 billion in the six months ended September 30, 2021). Despite the cash inflow of ¥15.5 billion from long-term loans, there was mainly a cash outflow of ¥11.1 billion from short-term loan payments, ¥13.0 billion from share repurchases and ¥6.4 billion from dividends.

As a result, cash and cash equivalents at the end of the second quarter ended September 30, 2022 decreased by ¥13.9 billion from the end of the fiscal year ended March 31, 2022 to ¥69.1 billion.

(3) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements

Due to the recording of impairment loss on assets related to Eyevance Pharmaceuticals Holdings Inc. (U.S.) and Eyevance Pharmaceuticals LLC (U.S.) and changes in regional sales forecast impacted by the yen depreciation and progress in Japan exceeding expectations, the forecasts of consolidated financial results for the fiscal year ending March 31, 2023 announced on May 10, 2022 have been changed as follows:

(IFRS)

(JPY millions)

	Revenue	Operating profit	Profit before tax	Net profit for the year	Basic earnings per share (yen)
Previous Forecast (A) (Announced on May 10, 2022)	264,000	34,200	32,500	24,400	61.96
Revised Forecast (B)	280,000	4,000	3,000	(5,500)	(14.20)
Increase/Decrease (B-A)	16,000	(30,200)	(29,500)	(29,900)	
change	6.1%	(88.3%)	(90.8%)	—	
(Reference) Consolidated results ended March 31, 2022	266,257	35,886	35,616	27,189	68.07

(Core basis)

(JPY millions)

	Revenue	Core operating profit	Core net profit for the year	Basic core earnings per share (yen)
Previous Forecast (A) (Announced on May 10, 2022)	264,000	45,500	34,100	86.59
Revised Forecast (B)	280,000	45,500	34,100	88.04
Increase/Decrease (B-A)	16,000	0	0	
change	6.1%	0.0	0.0	
(Reference) Consolidated results ended March 31, 2022	266,257	46,348	35,195	88.16

2. Condensed Interim Consolidated Financial Statements

(1) Condensed Interim Consolidated Statements of Income and Comprehensive Income

IFRS (JPY millions)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Revenue	**128,759**	**128,915**
Cost of sales	(52,867)	(55,902)
Gross profit	**75,891**	**73,013**
Selling, general and administrative expenses	(39,652)	(42,296)
Research and development expenses	(12,338)	(14,267)
Amortization on intangible assets associated with products	(4,787)	(5,166)
Other income	203	260
Other expenses	(512)	(30,566)
Operating profit (loss)	**18,805**	**(19,021)**
Finance income	672	1,245
Finance expenses	(440)	(262)
Share of loss of investments accounted for using equity method	(643)	(1,064)
Profit (loss) before tax	**18,393**	**(19,103)**
Income tax expenses	(4,139)	(2,917)
Net profit (loss) for the period	**14,254**	**(22,019)**
Other comprehensive income		
Items that will not be reclassified subsequently to profit or loss		
Net gain on financial assets measured at fair value through other comprehensive income	(134)	2,092
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	653	10,052
Share of other comprehensive income of investments accounted for using equity method	85	1,464
Other comprehensive income	**604**	**13,607**
Total comprehensive income	**14,858**	**(8,412)**
Profit (loss) attributable to		
owners of the company	14,307	(22,041)
Non-controlling interests	(53)	22
Net profit (loss) for the period	**14,254**	**(22,019)**
Total comprehensive income attributable to		
owners of the company	14,927	(8,400)
Non-controlling interests	(69)	(12)
Total comprehensive income	**14,858**	**(8,412)**
Earnings per share		
Basic earnings (loss) per share (yen)	35.79	(56.05)
Diluted earnings (loss) per share (yen)	35.73	(56.05)

Core basis (JPY millions)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Revenue	128,759	128,915
Core operating profit	24,306	16,451
Core net profit for the period	18,556	12,465
Basic core earnings per share (yen)	46.50	31.73
Diluted core earnings per share (yen)	46.41	31.69
Core profit attributable to		
owners of the company	18,586	12,484
Non-controlling interests	(30)	(19)
Core net profit for the period	**18,556**	**12,465**

(2) Condensed Interim Consolidated Statements of Financial Position

Assets (JPY millions)

	As of March 31, 2022	As of September 30, 2022
Non-current assets		
Property, plant and equipment	56,287	65,609
Intangible assets	130,217	103,081
Financial assets	28,673	31,832
Net defined benefit assets	3,011	2,650
Investments from application of equity method	7,565	11,435
Deferred tax assets	3,103	3,161
Other non-current assets	1,695	1,963
Total non-current assets	**230,551**	**219,730**
Current assets		
Inventories	37,141	39,100
Trade and other receivables	99,591	87,683
Other financial assets	1,293	800
Other current assets	8,387	10,127
Cash and cash equivalents	83,014	69,140
Total current assets	**229,426**	**206,850**
Total assets	**459,976**	**426,580**

Equity and liabilities (JPY millions)

	As of March 31, 2022	As of September 30, 2022
Equity		
Equity attributable to owners of the company		
Share capital	8,672	8,678
Capital surplus	9,370	9,411
Treasury shares	(718)	(13,373)
Retained earnings	290,477	262,550
Other components of equity	29,688	42,807
Total equity attributable to owners of the company	**337,488**	**310,072**
Non-controlling interests	**(645)**	**(657)**
Total equity	**336,844**	**309,415**
Liabilities		
Non-current liabilities		
Financial liabilities	22,023	38,127
Net defined benefit liabilities	1,077	1,142
Provisions	738	758
Deferred tax liabilities	2,526	4,785
Other non-current liabilities	948	1,360
Total non-current liabilities	**27,312**	**46,172**
Current liabilities		
Trade and other payables	41,185	37,178
Other financial liabilities	38,533	24,707
Income tax payable	4,198	2,371
Provisions	939	982
Other current liabilities	10,965	5,756
Total current liabilities	**95,821**	**70,994**
Total liabilities	**123,133**	**117,165**
Total equity and liabilities	**459,976**	**426,580**

(3) Condensed Interim Consolidated Statements of Changes in Equity

Six months ended September 30, 2021 (JPY millions)

	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Remeasurements of defined benefit plans	Net gain or loss on financial assets measured at fair value through other comprehensive income
Balance at April 1, 2021	8,525	8,954	(934)	273,238	—	11,075
Comprehensive income						
Net profit (loss) for the period				14,307		
Other comprehensive income						(134)
Total comprehensive income	—	—	—	14,307	—	(134)
Transactions with owners						
Issuance of new shares	12	12				
Acquisition of treasury shares			(12)			
Retirement of treasury shares		15	228			
Dividends				(5,598)		
Share-based payments		(121)				
Other				349		(349)
Total transactions with owners	12	(93)	216	(5,249)	—	(349)
Balance at September 30, 2021	8,538	8,860	(718)	282,296	—	10,593

(JPY millions)

	Other components of equity				Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Foreign currency translation adjustments	Share of other comprehensive income of investments accounted for using equity method	Subscription rights to shares	Total			
Balance at April 1, 2021	8,634	170	518	20,398	310,181	(535)	309,646
Comprehensive income							
Net profit (loss) for the period				—	14,307	(53)	14,254
Other comprehensive income	669	85		620	620	(16)	604
Total comprehensive income	669	85	—	620	14,927	(69)	14,858
Transactions with owners							
Issuance of new shares			(13)	(13)	12		12
Acquisition of treasury shares				—	(12)		(12)
Retirement of treasury shares				—	243		243
Dividends				—	(5,598)		(5,598)
Share-based payments				—	(121)		(121)
Other				(349)	—		—
Total transactions with owners	—	—	(13)	(362)	(5,476)	—	(5,476)
Balance at September 30, 2021	9,303	255	505	20,656	319,632	(603)	319,029

Six months ended September 30, 2022 (JPY millions)

	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Remeasurements of defined benefit plans	Net gain or loss on financial assets measured at fair value through other comprehensive income
Balance at April 1, 2022	8,672	9,370	(718)	290,477	—	8,438
Comprehensive income						
Net profit (loss) for the period				(22,041)		
Other comprehensive income						2,092
Total comprehensive income	—	—	—	(22,041)	—	2,092
Transactions with owners						
Issuance of new shares	6	6				
Acquisition of treasury shares		(28)	(13,007)			
Retirement of treasury shares		(2)	352			
Dividends				(6,405)		
Share-based payments		65				
Other				519		(519)
Total transactions with owners	6	41	(12,655)	(5,886)	—	(519)
Balance at September 30, 2022	8,678	9,411	(13,373)	262,550	—	10,012

(JPY millions)

	Other components of equity				Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Foreign currency translation adjustments	Share of other comprehensive income of investments accounted for using equity method	Subscription rights to shares	Total			
Balance at April 1, 2022	19,950	914	384	29,688	337,488	(645)	336,844
Comprehensive income							
Net profit (loss) for the period				—	(22,041)	22	(22,019)
Other comprehensive income	10,086	1,464		13,642	13,642	(35)	13,607
Total comprehensive income	10,086	1,464	—	13,642	(8,400)	(12)	(8,412)
Transactions with owners							
Issuance of new shares			(5)	(5)	7		7
Acquisition of treasury shares				—	(13,035)		(13,035)
Retirement of treasury shares				—	351		351
Dividends				—	(6,405)		(6,405)
Share-based payments				—	65		65
Other				(519)	—		—
Total transactions with owners	—	—	(5)	(523)	(19,017)	—	(19,017)
Balance at September 30, 2022	30,037	2,378	380	42,807	310,072	(657)	309,415

(4) Condensed Interim Consolidated Statements of Cash Flows

(JPY millions)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Ⅰ. Cash flows from operating activities:		
Net profit (loss) for the period	14,254	(22,019)
Depreciation and amortization	8,302	9,020
Impairment losses	48	30,501
Shares of loss (profit) of entities accounted for using equity method	643	1,064
Finance expenses (income)	(343)	(227)
Income tax expenses	4,139	2,917
Decrease (increase) in trade and other receivables	9,885	13,827
Decrease (increase) in inventories	1,468	(1,263)
Increase (decrease) in trade and other payables	(338)	(4,430)
Increase (decrease) in provisions and net defined benefit liabilities	378	(7)
Decrease (increase) in other current assets	(2,705)	(1,241)
Increase (decrease) in accounts payable - bonuses	(1,516)	(3,765)
Increase (decrease) in accounts payable-other	(1,381)	(2,434)
Other	(1,058)	(110)
Subtotal	31,777	21,831
Interest received	136	113
Dividends received	250	226
Interest paid	(102)	(199)
Income tax paid	(4,966)	(3,639)
Net cash flows from (used in) operating activities	**27,096**	**18,332**
Ⅱ. Cash flows from investing activities:		
Payments for acquisition of investments	(536)	(313)
Proceeds from sales of investments	746	991
Payments for acquisition of property, plant and equipment	(9,792)	(11,241)
Payments for acquisition of intangible assets	(4,711)	(4,683)
Payments for acquisition of investments accounted for using equity method	(2,759)	(3,470)
Other	(4)	(94)
Net cash flows from (used in) investing activities	**(17,057)**	**(18,811)**
Ⅲ. Cash flows from financing activities:		
Repayments of short-term loans	—	(11,089)
Proceeds from long-term loans	10,000	15,544
Purchase of treasury shares	(12)	(13,007)
Dividends paid	(5,596)	(6,402)
Repayments of lease obligation	(1,432)	(1,717)
Other	12	547
Net cash flows from (used in) financing activities	**2,972**	**(16,123)**
Ⅳ. Net increase (decrease) in cash and cash equivalents	**13,011**	**(16,602)**
Ⅴ. Cash and cash equivalents at the beginning of period	**62,888**	**83,014**
Ⅵ. Effect of exchange rate changes on cash and cash equivalents	**136**	**2,727**
Ⅶ. Cash and cash equivalents at the end of period	**76,036**	**69,140**

(5) Notes to Condensed Interim Consolidated Financial Statements

(Going Concern Assumption)

Not applicable.

(Other expenses)

Six months ended September 30, 2022

The Company recorded the impairment loss of ¥30,501 million included into other expenses of Condensed Interim Consolidated Statements of Income and Comprehensive Income.

This is mainly due to the recognition of impairment loss of ¥30,008 million related to intangible assets associated with products, goodwill and property, plant and equipment of Eyevance Pharmaceuticals Holdings Inc.(U.S) and its business unit Eyevance Pharmaceuticals LLC (U.S), calculating downward from book value to recoverable amount.

(¥22,296 million of intangible assets associated with products, ¥7,418 million of goodwill, ¥294 million of property, plant and equipment)

(Statement of Significant Changes in Shareholders' Equity)

Six months ended September 30, 2022

(Repurchase of own shares)

At a meeting of the Board of Directors on May 10, 2022, the Board resolved to repurchase its own shares in accordance with Article 156 of the Companies Act (Japan), as applied pursuant to Article 165, paragraph 3.

Santen repurchased a total of 12,500,000 of its own shares for a total value of 12,733 million yen during the period between May 11, 2022 to September 30, 2022. Santen completed the share buyback based on the resolution above on September 8, 2022 (execution date basis).

(I) Reasons for repurchase of own shares

To enhance capital efficiency and improve return of profits.

(II) Details of repurchase

(1) Class of shares to be acquired	Common shares
(2) Total number of shares to be acquired	12,500,000 shares (maximum) *Representing 3.1% of the total number of shares outstanding (excluding treasury shares)
(3) Total amount of acquisition	15.0 billion yen (maximum)
(4) Period of acquisition	May 11, 2022 to September 30, 2022
(5) Method of acquisition	Open-market repurchase through discretionary investment contract
(6) Other	After repurchase, Santen plans to cancel the repurchased shares within the fiscal year ending March 2023 by the resolution of its Board of Directors in accordance with Article 178 of the Companies Act (Japan).

(Significant Subsequent Events)

(I) Cancellation of Treasury Shares in accordance with Article 178 of the Companies Act (Japan)
Santen resolved at the Board of Directors meeting held on October 4, 2022 to cancel treasury shares, in accordance with Article 178 of the Companies Act (Japan), and completed the cancellation on October 31, 2022. The shares the Company cancelled are the treasury shares Santen repurchased based on the resolution at the Board of Directors meeting held on May 10, 2022.

(1) Class of shares to be canceled	Common shares
(2) Total number of shares to be canceled	12,500,000 shares (The ratio against total number of the outstanding shares before the Cancellation: 3.1%)
(3) Completion date of cancellation	October 31, 2022

(II) Repurchase of own shares in accordance with Article 165, paragraph 2 of the Companies Act (Japan)
At a meeting of the Board of Directors on November 8, 2022, the Board resolved to repurchase its own shares in accordance with Article 156 of the Companies Act (Japan), as applied pursuant to Article 165, paragraph 3.

(A) Reasons for repurchase of own shares
To enhance capital efficiency and improve return of profits.

(B) Details of repurchase

(1) Class of shares to be acquired	Common shares
(2) Total number of shares to be acquired	13,000,000 shares (maximum) *Representing 3.4% of the total number of shares outstanding (excluding treasury shares)
(3) Total amount of acquisition	13.0 billion yen (maximum)
(4) Period of acquisition	November 9, 2022 to March 24, 2023
(5) Method of acquisition	Open-market repurchase through discretionary trading contract
(6) Other	After repurchase, Santen plans to cancel the repurchased shares by the resolution of its Board of Directors in accordance with Article 178 of the Companies Act (Japan).

3. Consolidated Reference
(1) Revenue of Major Products

(JPY millions)

Brand Name		Six months ended September 30, 2021 Actual	Changes from the same period of previous year	Year ended March 31, 2022 Actual	Changes from the same period of previous year	Six months ended September 30, 2022 Actual	Changes from the same period of previous year	Forecast for the fiscal year ending March 31, 2023	Changes from the same period of previous year
Glaucoma and ocular hypertension									
Cosopt	Total	10,758	0.3%	21,752	4.2%	11,496	6.9%	22,225	2.2%
	Japan	3,018	(20.9%)	5,650	(18.6%)	2,468	(18.2%)	4,677	(17.2%)
	Asia	2,463	17.3%	5,157	15.6%	2,930	19.0%	5,796	12.4%
	EMEA	5,277	9.7%	10,945	15.5%	6,098	15.6%	11,752	7.4%
Tapros	Total	9,186	0.8%	18,423	2.8%	9,416	2.5%	19,069	3.5%
	Japan	4,399	(4.5%)	8,409	(3.4%)	3,999	(9.1%)	7,673	(8.8%)
	China	465	101.9%	1,170	94.3%	443	(4.7%)	1,802	53.9%
	Asia	983	3.0%	2,077	8.9%	1,124	14.4%	2,325	12.0%
	EMEA	3,340	0.4%	6,767	1.1%	3,850	15.3%	7,269	7.4%
Tapcom	Total	3,440	16.3%	6,971	15.5%	4,092	19.0%	8,201	17.7%
	Japan	1,412	5.7%	2,738	5.1%	1,357	(3.9%)	2,629	(4.0%)
	Asia	375	63.2%	815	49.3%	524	39.6%	1,090	33.7%
	EMEA	1,653	18.7%	3,417	18.4%	2,212	33.8%	4,483	31.2%
Trusopt	Total	2,292	1.3%	4,374	0.2%	2,430	6.0%	4,476	2.3%
	Japan	587	(12.4%)	1,108	(9.7%)	516	(12.1%)	973	(12.2%)
	Asia	194	9.2%	382	10.9%	210	8.5%	390	2.1%
	EMEA	1,511	6.8%	2,883	3.2%	1,703	12.7%	3,112	7.9%
Eybelis	Total	1,671	38.2%	3,420	34.8%	2,045	22.4%	4,181	22.3%
	Japan	1,629	34.8%	3,304	31.3%	1,933	18.7%	3,836	16.1%
	Asia	42	—	116	475.4%	112	166.1%	289	150.1%
Dry eye									
Diquas	Total	9,186	29.2%	18,835	30.8%	9,342	1.7%	25,693	36.4%
	Japan	6,651	9.4%	13,342	8.6%	6,768	1.8%	18,009	35.0%
	China	1,681	591.4%	4,074	468.5%	1,629	(3.1%)	5,660	38.9%
	Asia	855	8.9%	1,419	1.1%	944	10.5%	2,024	42.6%
Hyalein	Total	8,314	(14.4%)	17,779	(3.5%)	6,916	(16.8%)	13,822	(22.3%)
	Japan	3,323	(7.8%)	6,466	(7.2%)	2,934	(11.7%)	5,078	(21.5%)
	China	4,219	(11.6%)	8,943	(3.4%)	2,591	(38.6%)	6,463	(27.7%)
	Asia	773	(41.9%)	2,370	8.0%	1,392	80.1%	2,282	(3.7%)
Ikervis	Total	3,011	45.0%	5,856	29.3%	3,686	22.4%	7,158	22.2%
	Asia	537	28.7%	1,106	24.2%	807	50.3%	1,465	32.4%
	EMEA	2,475	49.1%	4,750	30.6%	2,879	16.4%	5,693	19.9%
Cationorm	Total	1,635	1.9%	3,230	5.5%	2,313	41.5%	4,183	29.5%
	Asia	185	47.4%	467	82.5%	260	41.0%	440	(5.7%)
	EMEA	1,068	4.3%	2,078	5.6%	1,432	34.1%	2,564	23.4%
	Americas	382	(16.0%)	685	(18.3%)	621	62.3%	1,179	72.2%
Allergy									
Alesion (Including Alesion LX)	Total	9,567	24.3%	29,392	(10.3%)	7,965	(16.7%)	28,840	(1.9%)
	Japan	9,506	23.5%	29,286	(10.5%)	7,878	(17.1%)	28,660	(2.1%)
	Asia	61	—	106	465.8%	86	41.4%	180	69.3%
Verkazia	Total	313	501.2%	633	255.2%	537	71.3%	1,300	105.2%
	EMEA	292	557.3%	585	260.6%	420	43.8%	806	37.8%
	Americas	21	175.6%	49	201.0%	116	451.3%	438	799.7%
Intravitreal VEGF inhibitor									
EYLEA	Total	36,475	9.6%	72,484	12.5%	35,848	(1.7%)	67,237	(7.2%)
	Japan	36,475	9.6%	72,484	12.5%	35,848	(1.7%)	67,237	(7.2%)
Bacterial conjunctivitis									
Cravit	Total	6,859	(9.5%)	11,712	(7.4%)	5,079	(26.0%)	11,870	1.4%
	Japan	971	(10.0%)	1,754	(11.0%)	695	(28.5%)	1,360	(22.5%)
	China	4,415	(10.7%)	6,966	(12.1%)	2,587	(41.4%)	7,016	0.7%
	Asia	874	(20.4%)	1,866	8.3%	1,045	19.6%	2,210	18.5%
	EMEA	599	32.1%	1,126	9.4%	753	25.6%	1,284	14.1%
Medical devices									
Lentis comfort	Total	668	43.9%	1,422	18.9%	639	(4.4%)	1,547	8.8%
	Japan	668	43.9%	1,422	18.9%	639	(4.4%)	1,547	8.8%
PRESERFLO MicroShunt	Total	728	104.5%	1,612	80.9%	1,124	54.4%	2,385	47.9%
	EMEA	728	104.5%	1,612	80.9%	1,119	53.8%	2,363	46.6%
OTC Pharmaceuticals	Total	5,087	1.7%	9,780	3.9%	5,639	10.8%	10,347	5.8%
	Japan	4,791	(0.7%)	9,185	1.4%	5,068	5.8%	9,331	1.6%
	China	—	—	7	—	114	—	288	—
	Asia	296	67.1%	588	67.1%	456	54.1%	728	23.9%

(2) FOREX

(JPY)

Exchange rate (yen)	Major currency	2nd quarter ended September 30, 2021	Fiscal year ended March 31, 2022	2nd quarter ended September 30, 2022	Fiscal year ending March 31, 2023 (Forecasts)
	USD	110.09	112.57	133.46	140.00
	EUR	131.14	130.75	138.61	140.00
	CNY	17.05	17.55	19.84	20.00

Forecasts in this reports are based on the currently available information. Actual results may differ materially depending on a number of factors including changes to the business environment and others. Our full-year forecasts are based on our foreign exchange assumptions. Revenue by region shows that of major countries or regions.

(3) Research & Development

As of October 2022

Pipeline Development Status (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
cyclosporin	STN1007603 / DE-076C	Vernal keratoconjunctivitis	Original	U.S.					May-2022	
				China					Apr-2022	

An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue penetration. Launched successively in European countries since October 2018. Launched successively in Asian countries after receiving approval for an indication extension for Ikervis in August 2019. Launched in November 2019 in Canada. Launched in May 2022 in the U.S. and received marketing approval in April 2022 in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
diquafosol sodium	STN1008903 / DE-089C	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	Japan					Jun-2022	

A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Long-lasting drug. Received manufacturing and marketing approval in June 2022 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010904	Fuchs endothelial corneal dystrophy	Joint development with ActualEyes	U.S. France India	(Phase 2a)					

An ophthalmic suspension which treats Fuchs endothelial corneal dystrophy via mTOR inhibition. Started Phase 2a in U.S., France and India in May 2022. (*The development code (STN1010904) is due to be assigned to the product when Santen obtains an exclusive license upon completion of Phase 2 clinical trial.)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010905	Meibomian gland dysfunction	Original	Japan	(Phase 2a)					

An ophthalmic suspension which improves meibomian gland function via mTOR inhibition. Completed Phase 2a in August 2022 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
tafluprost/ timolol maleate	STN1011101 /DE-111A	Glaucoma/ Ocular hypertension	Co-development with AGC	China						

A fixed dose combination drug of a prostaglandin $F_{2\alpha}$ derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Launched successively in European countries since January 2015. Launched successively in Asian countries since April 2016. Started Phase 3 in January 2019 in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
epinastine hydrochloride	STN1011402	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan						

A histamine H_1 receptor antagonist with mediator release inhibitor function, as treatment for allergic conjunctivitis. Ophthalmic cream. Completed Phase 3 in October 2022 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
omidenepag isopropyl	STN1011700 /DE-117	Glaucoma/ Ocular hypertension	Co-development with UBE Corporation	U.S.				Sep-2022		
				Japan					Nov-2018	
				Asia					Feb-2021	

An EP2 receptor agonist with a new mechanism of action. Received marketing approval in September 2022 in the U.S. Launched in November 2018 in Japan. Launched successively in Asian countries since launch in February 2021 in Korea.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sepetaprost	STN1012600 / DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.						
				Japan						
				Europe	(Exploratory study)					

A prostaglandin analogue eye drop drug product with a novel mode of action that is a dual agonist for both FP and EP3 receptors for the treatment of glaucoma and ocular hypertension. Completed an additional Phase 2 in December 2021 in the U.S. Started Phase 3 in August 2022 in Japan. Started Phase 2 (exploratory study) in September 2021 in Europe.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	STN1012700 / DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Japan		(Phase 2/3)				
				China		(Phase 2/3)				
				Asia						

Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Conducting Phase 2/3 from August 2019 in Japan. Started Phase 2/3 in June 2022 in China. Completed Phase 2 in April 2020 in Asia.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	STN1012701 / SYD-101	Myopia	Sydnexis Inc.	Europe						
Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Sydnexis Inc., the licensor, is conducting Phase 3 trial in Europe and the U.S. Santen has obtained the exclusive license for Europe, Middle East and Africa.										

–	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
glaucoma implant device	STN2000100 / DE-128	Glaucoma	Original	Japan						Jul-2022
				Europe						Apr-2019
				Asia					Sep-2021	
A drainage implant device designed to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Launched (soft launch) in July 2022 in Japan. Launched in Europe in April 2019. Filed successively for marketing approval in Asian countries since March 2020 and received approval in Singapore and other countries since September 2021.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	STN1013001 /DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe				Sep-2022		
				Asia						
An ophthalmic emulsion of a prostaglandin $F_2\alpha$ derivative, for the treatment of glaucoma and ocular hypertension. Completed Phase 3 in March 2022 in Europe and Asia. Filed for marketing approval in September 2022 in Europe.										

Compound name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
AFDX0250BS	STN1013400	Myopia	Boehringer Ingelheim	Japan						
Selective muscarinic M2 antagonist which reduces progression of juvenile myopia. Reduce mydriasis by selectively inhibiting a subtype of receptors. Completed Phase1 in September 2021 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
ursodeoxycholic acid	STN1013600	Presbyopia	Original	Japan						
Improvement of presbyopia by improving lens elasticity. Completed Phase 1 in April 2022 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
oxymetazoline hydrochloride	STN1013800	Ptosis	RVL Pharmaceuticals	Japan						
A direct-acting alpha adrenergic receptor agonist. Developed and sold by RVL Pharmaceuticals in the U.S. Started Phase 3 in October 2022 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesilate	STN1013900 / AR-13324	Glaucoma / Ocular hypertension	Aerie	Japan						
				Europe						
				Asia					Mar-2022	
A ROCK (Rho-associated kinase) inhibitor. Developed and sold by Aerie in the U.S. Conducting Phase 3 from November 2020 in Japan. Received marketing approval in Europe. Filed for marketing approval in March 2022 in Asia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesilate / latanoprost	STN1014000 / PG-324	Glaucoma / Ocular hypertension	Aerie	Europe						
				Asia					May-2022	
A fixed dose combination drug of a ROCK (Rho-associated kinase) inhibitor and a prostaglandin $F_2\alpha$ derivative. Developed and sold by Aerie in the U.S. Received marketing approval in Europe. Filed for marketing approval in May 2022 in Asia.										

Changes from Q1 FY2022 (August 4, 2022)

Dev. Code	Changes
STN1011700 / DE-117	Received marketing approval in September 2022 in the U.S.
STN1012600 / DE-126	Started Phase 3 in August 2022 in Japan.
STN1013001 / DE-130A	Filed for marketing approval in September 2022 in Europe.
STN1013800	Started Phase 3 in October 2022 in Japan.

(4) Capital Expenditures, Depreciation and Amortization, Amortization of Intangible Assets Related to Products, and Research and Development Expenses

Capital expenditures (JPY millions)

	Six months ended September 30, 2021	Year ended March 31, 2022	Six months ended September 30, 2022	Year ending March 31, 2023
	Actual			Forecast
Consolidated	13,737	22,244	13,175	25,000

Note: Excluding the increase in right-of-use assets.

Depreciation and amortization (JPY millions)

	Six months ended September 30, 2021	Year ended March 31, 2022	Six months ended September 30, 2022	Year ending March 31, 2023
	Actual			Forecast
Manufacturing cost	1,141	2,309	1,164	2,400
Selling, general and administrative expenses	792	1,654	986	2,300
R&D expenses	289	577	295	780
Consolidated total	2,222	4,540	2,445	5,480

Note: Excluding amortization of intangible assets associated with products, long-term advance expense and right-of-use assets.

Amortization of intangible assets associated with products (JPY millions)

	Six months ended September 30, 2021	Year ended March 31, 2022	Six months ended September 30, 2022	Year ending March 31, 2023
	Actual			Forecast
Intangible assets (Merck products)	2,870	5,740	2,904	5,740
Intangible assets (Eyevance)	929	1,899	1,126	1,180
Intangible assets (PRESERFLO MicroShunt)	467	955	566	1,190
Intangible assets (Ikervis)	371	741	393	790
Other	150	398	177	430
Consolidated total	4,787	9,734	5,166	9,330

Research and development expenses (JPY millions)

	Six months ended September 30, 2021	Year ended March 31, 2022	Six months ended September 30, 2022	Year ending March 31, 2023
	Actual			Forecast
Consolidated	12,338	26,377	14,267	31,000
Percent of revenue	9.6%	9.9%	11.1%	11.1%

Forecasts in this report are based on the currently available information. Actual results may differ materially depending on a number of factors including adverse economic conditions and others.