Summary of Consolidated Financial Results for the Six Months Ended September 30, 2023 (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 9, 2023
Distribution of Dividends (Scheduled):	November 30, 2023
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, 2023

(1) Operating Results

(Core basis)

	Six months ended September 30, 2022	Six months ended September 30, 2023	Change
Revenue	128,915	145,806	+13.1%
Core operating profit	16,451	31,533	+91.7%
Core net profit for the period	12,465	25,861	+107.5%
Core net profit for the period attributable to owners of the company	12,484	25,877	+107.3%
Basic core earnings per share (yen)	31.73	69.88	
Diluted core earnings per share (yen)	31.69	69.68	

(IFRS)

	Six months ended September 30, 2022	Six months ended September 30, 2023	Change
Revenue	128,915	145,806	+13.1%
Operating profit (loss)	(19,021)	25,099	—
Profit (loss) before tax	(19,103)	24,075	—
Net profit (loss) for the period	(22,019)	19,274	—
Net profit (loss) for the period attributable to owners of the company	(22,041)	19,280	—
Total comprehensive income for the period	(8,412)	30,597	—
Basic earnings per share (yen)	(56.05)	52.06	
Diluted earnings per share (yen)	(56.05)	51.92	

(2) Financial Position

	March 31, 2023	September 30, 2023
Total assets	421,179	426,984
Total equity	293,297	306,454
Total equity attributable to owners of the company	293,979	307,190
Total equity attributable to owners of the company ratio (%)	69.8	71.9
Equity per share attributable to owners of the company (yen)	783.30	837.80

2. Dividends

	Year to March 2023	Year to March 2024	(Forecasts) Year to March 2024
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, 2024

(Core basis)

	Year to March 2024	Year-on-year change
Revenue	302,000	+8.2%
Core operating profit	58,000	+31.1%
Core net profit for the year	43,500	+30.9%
Basic core earnings per share (yen)	118.87	

(IFRS)

	Year to March 2024	Year-on-year change
Revenue	302,000	+8.2%
Operating profit	41,000	—
Profit before tax	38,300	—
Net profit for the year	29,500	—
Basic earnings per share (yen)	80.64	

(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 5 of the attached material for details of the reconciliation from IFRS basis figures to core-based figures.
2. At a meeting of the Board of Directors on May 11, 2023, the Board resolved to undertake a share repurchase. The share repurchase has been factored into the basic core earnings per share and earnings per share forecasts.

*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	: Yes

(3) Number of ordinary shares issued

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

September 30, 2023	375,964,354 shares
March 31, 2023	375,885,854 shares

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

September 30, 2023	9,013,100 shares
March 31, 2023	345,065 shares

(iii) Average number of outstanding shares

The second quarter ended September 30, 2023	370,273,119 shares
The second quarter ended September 30, 2022	393,314,840 shares

(Note):
The number of treasury shares at the end of the period includes shares (41,909 shares at the end of the fiscal year ended March 31, 2023 and 42,245 shares at the second quarter of the fiscal year ending March 31, 2024) owned in trust for the stock compensation system. 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 conference call on the results for securities analysts and institutional investors on November 7, 2023. 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) Core basis[*1] (please refer to page 5)

(JPY millions)

	Six months ended September 30, 2022	Six months ended September 30, 2023	Year-on-year change
Revenue	128,915	145,806	13.1%
Core perating profit	16,451	31,533	91.7%
Core net profit for the period	12,465	25,861	107.5%
Core net profit for the period attributable to owners of the company	12,484	25,877	107.3%

[Revenue]

Revenue in the six months ended September 30, 2023 increased by 13.1% year-on-year to ¥145.8 billion.

In the mainstay prescription pharmaceuticals business, sales grew globally by 13.5% year-on-year to ¥135.4 billion. Despite the impact of drug price revisions in Japan, sales increased mainly as a result of a focus on expanding sales of mainstay products in Japan, a recovery from the resurgence of COVID-19 in China in the previous fiscal year, and a firm performance from mainstay products in Asia/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	73,303	14,932	13,433	32,031	1,694	135,393
	2.2%	52.2%	21.5%	28.3%	(3.2%)	13.5%
	【－】	【52.4%】	【15.3%】	【21.2%】	【(6.5%)】	【11.4%】
OTC pharmaceuticals	5,365	136	412	－	－	5,914
	5.9%	19.3%	(9.6%)	－	－	4.9%
Medical devices	1,683	28	27	1,473	362	3,573
	3.6%	407.7%	－	29.1%	50.1%	18.6%
Others	848	28	50	－	－	926
	0.8%	45.6%	(29.7%)	－	－	(0.6%)
Total	81,199	15,125	13,923	33,504	2,056	145,806
	2.4%	52.0%	20.2%	28.3%	3.3%	13.1%
	【－】	【52.2%】	【14.2%】	【21.0%】	【(0.1%)】	【11.1%】

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

<Prescription pharmaceuticals>

◇ Japan

Revenue in the six months ended September 30, 2023 increased by 2.2% year-on-year to ¥73.3 billion. This was due to the focus on growing mainstay products, including *Diquas LX* which was launched in November 2022, despite the mid-2% impact of drug price revisions and the impact of inventories adjustments for *Alesion LX*[*2] from strong pollen concentration season at the end of previous fiscal year. Revenues of major products are as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥3.4 billion	(YoY -15.0%)
Tapcom ophthalmic solution	¥1.3 billion	(YoY -7.6%)
Cosopt ophthalmic solution	¥2.1 billion	(YoY -16.2%)
Eybelis ophthalmic solution	¥2.1 billion	(YoY +11.0%)
Dry eye		
Diquas ophthalmic solution[*3](refer to Page5)	¥10.3 billion	(YoY +52.7%)
Allergy		
Alesion ophthalmic solution[*2](refer to Page5)	¥6.5 billion	(YoY -17.3%)
Intravitreal VEGF inhibitor		
EYLEA[*4](refer to Page5) (solution for intravitreal injection)	¥36.8 billion	(YoY +2.7%)

◇ China

On a JPY basis, revenue in the six months ended September 30, 2023 increased by 52.2% year-on-year (+52.4% excluding FX impact), to ¥14.9 billion, boosted by the strong performance of mainstay products, recovering from the resurgence of COVID-19 in the previous fiscal year. Revenues of major products are as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥0.8 billion	(YoY +88.8%)
Dry eye		
Diquas ophthalmic solution	¥2.4 billion	(YoY +44.4%)
Hyalein ophthalmic solution	¥4.1 billion	(YoY +58.3%)
Bacterial conjunctivitis		
Cravit ophthalmic solution	¥4.3 billion	(YoY +64.5%)

◇ Asia (excluding China)

On a JPY basis, revenue in the six months ended September 30, 2023 increased by 21.5% year-on-year (+15.3% excluding FX impact), to ¥13.4 billion, due to steady growth of mainstay products as listed below, posted in major countries including South Korea.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥1.1 billion	(YoY -1.5%)
Tapcom ophthalmic solution	¥0.6 billion	(YoY +15.4%)
Cosopt ophthalmic solution	¥3.3 billion	(YoY +13.8%)
Dry eye		
Diquas ophthalmic solution	¥1.3 billion	(YoY +41.7%)
Ikervis	¥0.9 billion	(YoY +5.3%)
Bacterial conjunctivitis		
Cravit ophthalmic solution	¥1.5 billion	(YoY +39.0%)

◇ EMEA

On a JPY basis, revenue in the six months ended September 30, 2023 increased by 28.3% year-on-year (+21.2% excluding FX impact), to ¥32.0 billion. This is due to hefty growth in sales of glaucoma products, the disease area in which Santen holds top market share, as well as the impact of a reevaluation of the reimbursement claim settlement for *Ikervis* in the first quarter of the fiscal year under review. Revenues of major products are as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥4.3 billion	(YoY +10.8%)
Tapcom ophthalmic solution	¥2.9 billion	(YoY +30.1%)
Cosopt ophthalmic solution	¥7.2 billion	(YoY +18.7%)
Trusopt ophthalmic solution	¥1.8 billion	(YoY +6.4%)
Dry eye		
Ikervis	¥6.2 billion	(YoY +115.4%)
Cationorm	¥1.5 billion	(YoY +7.0%)
Allergy		
Verkazia	¥0.6 billion	(YoY +48.1%)

◇ Americas

On a JPY basis, revenue in the six months ended September 30, 2023 decreased by 3.2% year-on-year (-6.5% excluding FX impact), to ¥1.7 billion as an effort to streamline sales and marketing activities.

<OTC pharmaceuticals>

Revenue in the six months ended September 30, 2023 increased by 4.9% year-on-year to ¥5.9 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, *Sante FX series* and *Well-Wash EYE*.

<Medical devices>

Revenue in the six months ended September 30, 2023 increased by 18.6% year-on-year to ¥3.6 billion, boosted by intraocular lens such as *LENTIS Comfort* in Japan as well as the strong performance in EMEA of *PRESERFLO MicroShunt*. Revenues of major products are as follows.

LENTIS Comfort	¥0.7 billion	(YoY +2.5%)
PRESERFLO MicroShunt	¥1.7 billion	(YoY +55.4%)

<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.

[Core operating profit]

Gross profit in the six months ended September 30, 2023 increased by 18.4 % year-on-year to ¥86.5 billion.

SG&A expenses on a core basis in the six months ended September 30, 2023 increased by 0.7% year-on-year (-2.3% excluding FX impact) to ¥42.6 billion.

R&D expenses in the six months ended September 30, 2023 decreased by 13.6% year-on-year (-16.7% excluding FX impact) to ¥12.3 billion.

As a result, operating profit on a core basis in the six months ended September 30, 2023 increased by 91.7 % year-on-year (+90.4% excluding FX impact) to ¥31.5 billion.

*1 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 and initiatives for the resumption of growth such as productivity improvements and streamlining measures

*2 Includes *Alesion LX*
*3 Includes *Diquas LX*
*4 Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

B) IFRS basis

(JPY millions)

	Six months ended September 30, 2022	Six months ended September 30, 2023	Year-on-year amount chnage	Year-on-year change
Revenue	128,915	145,806	16,891	13.1%
Operating profit (loss)	(19,021)	25,099	44,120	－%
Net profit (loss) for the period	(22,019)	19,274	41,294	－%
Net profit (loss) for the period attributable to owners of the company	(22,041)	19,280	41,322	－%

[Revenue]

There are no adjustments from the core basis.

[Operating profit]

For the adjustments from the core basis, with regard to expenses related to the streamlining of costs in the Americas, deductions of ¥0.1 billion, ¥0.6 billion and ¥0.1 billion were made to Cost of Sales, SG&A and R&D expenses respectively.

Amortization on intangible assets associated with products in the six months ended September 30, 2023 decreased by 9.0% year-on-year (-11.7% excluding FX impact) to ¥4.7 billion. This is mainly due to the amortization on intangible assets associated with products acquired from Merck & Co., Inc. (U.S.) in 2014, *PRESERFLO MicroShunt* acquired in connection with the acquisition of InnFocus, Inc. (U.S.) in 2016, *Ikervis* which was launched in Europe in 2015, and *Rhopressa* / *Rocklatan* which Santen began selling in Europe in 2023.

Other income amounted to ¥1.2 billion. This is mainly due to the asset transfer of part of pharmaceutical products in the Americas.
Other expenses amounted to ¥2.1 billion. This is mainly due to the expenses related to structural reforms associated with maximizing the streamlining of the pharmaceutical commercial business in the Americas.

As a result, operating profit on an IFRS basis in the six months ended September 30, 2023 was ¥25.1 billion (operating loss of ¥19.0 billion for the same period of previous fiscal year).

[Quarterly net profit]

Finance income amounted to ¥1.1 billion.
Finance expenses amounted to ¥0.6 billion.
Share of loss of investments accounted for using equity method amounted to ¥1.6 billion from Twenty Twenty Therapeutics LLC (U.S.), a joint venture with Verily Life Sciences LLC (U.S.).
Income tax expenses amounted to ¥4.8 billion, up ¥1.9 billion year-on-year. This is due to the increase in quarterly profit before tax associated with the aforementioned increase in operating profit on an IFRS basis.

As a result, net profit in the period ended September 30, 2023 was ¥19.3 billion (net loss of ¥22.0 billion for the same period of previous fiscal year).

[Quarterly net profit attributable to owners of the company]

Quarterly net profit attributable to owners of the company in the six months ended September 30, 2023 was ¥19.3 billion (net loss attributable to owners of the company of ¥22.0 billion for the same period of previous fiscal year).
The ratio to revenue was 13.2%.

(II) Research & Development Activities

<Glaucoma and ocular hypertension area>

STN1011101 (DE-111A, generic name: tafluprost / timolol maleate) is a fixed dose combination drug of a prostaglandin F_{2a} derivative and a beta-adrenergic receptor blocker. The Company filed for marketing approval in December 2022 in China.

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 trial was completed in June 2023 in Japan. Phase 2 trial (exploratory study) was completed in Europe.

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 Asia. CHMP adopted a positive opinion, recommending the granting of a marketing authorization in September 2023 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 and the Company launched in February 2023 in Sweden. The Company has successively filed for marketing approval in Asian countries and received approval in Thailand and other countries from January 2023 onward.

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 and the Company launched in January 2023 in Germany. The Company has successively filed for marketing approval in Asian countries and received marketing approval in Thailand and other countries from January 2023 onward.

<Keratoconjunctival disease area including dry eye >

STN1007603 (DE-076C, generic name: ciclosporin) for vernal keratoconjunctivitis has been approved and launched in Europe, Asia, and Canada. Marketing approval has been received in April 2022 in China. It was launched in the U.S. in May 2022. In July 2023, the Company granted Harrow Health, Inc. (U.S.) exclusive rights in the U.S. and Canada for product manufacturing and commercialization.

STN1008903 (DE-089C, generic name: diquafosol sodium) is for the treatment of dry eye. The Company launched the product in November 2022 in Japan. In Asia, the Company filed for marketing approval in March 2023 in South Korea.

STN1014100 (generic name: olodaterol hydrochloride) is for the treatment of dry eye. Phase 1/2a trial started in January 2023 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 trial has been under way in U.S., France and India since 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.)

STN1010905 (generic name: sirolimus) is for the treatment of meibomian gland dysfunction. Phase 2a trial was completed in August 2022 in Japan and the Company is considering future development plans.

STN1011402 (generic name: epinastine hydrochloride) is for the treatment of allergic conjunctivitis. The Company filed for manufacturing and marketing approval in March 2023 in Japan.

<Refractive error>

STN1012700 (DE-127, generic name: atropine sulfate) is for the treatment of myopia in children. Phase 2/3 trial was completed in October 2023 in Japan. Phase 2/3 trial has been under way since 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. The Company started Phase 2a trial in May 2023 in Japan and Phase 1 trial in August 2023 in China.

STN1013600 (generic name: ursodeoxycholic acid) is for the treatment of presbyopia. Phase 2a trial was completed in

September 2023 in the U.S.. 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 has been underway since 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 Alcon Inc. (Switzerland) and Sydnexis Inc. (U.S.) respectively.
※ STN1011700 (DE-117, generic name: omidenepag isopropyl) is sold as *Eybelis* in Japan and Asia. In the U.S., Santen has received approval as *OMLONTI* and has granted exclusive rights for product manufacturing and commercialization to Visiox Pharmaceuticals, Inc. (U.S.) in July 2023.

(2) Summary of Financial Position

(I) Assets, equity and liabilities

Total assets at the end of the second quarter amounted to ¥427.0 billion, up ¥5.8 billion from the end of the previous fiscal year. Despite a decrease of trade and other receivables, there was an increase in cash, inventories and property, plant and equipment associated with a new plant building in Suzhou, China.

Equity amounted to ¥306.5 billion. There was an increase of ¥13.2 billion from the end of the previous fiscal year ended
March 31, 2023. This was due to an increase in retained earnings and other components of equity despite the effect of capital reduction through share repurchases.

Liabilities amounted to ¥120.5 billion, falling by ¥7.4 billion from the end of the previous fiscal year ended March 31, 2023. This was due to a decrease in other financial liabilities, deferred tax liabilities due to the payment of corporate taxes, and other current liabilities including the payment of bonus.

As a result, the ratio of equity attributable to owners of the company to total assets increased by 2.1% points from the end of the previous fiscal year ended March 31, 2023 to 71.9%

The Santen Group views ROE (equity attributable to owners of the company profit ratio) as its most important management metric. The Company aims to maximize shareholder value by focusing on both maximizing cash flow and lowering the cost of capital. While the inflow of cash from operating activities is considered the basic source of cash, the Company is also implementing measures to maximize cash-generating capability by improving working capital efficiency through the management of the cash conversion cycle.

(II) Cash Flows

Cash flows from operating activities amounted to ¥27.7 billion (¥18.3 billion in the six months ended September 30, 2022). This was mainly due to the quarterly profit of ¥19.3 billion, ¥8.9 billion of depreciation and amortization, a decrease of ¥15.0 billion in trade and other receivables, and a ¥6.8 billion corporate tax payment.

Cash flows from investing activities amounted to an outflow of ¥3.8 billion (¥18.8 billion in the six months ended September 30, 2022). This was mainly due to payments for the acquisition of property, plant and equipment and intangible assets amounting to ¥4.6 billion and ¥0.6 billion respectively. Reflecting the Company’s accelerated review of strategic equity holdings, there was a cash inflow of ¥0.8 billion owing to the sale of 1 equity holding in the second quarter of the fiscal year under review.

Cash flows from financing activities amounted to ¥19.7 billion. (¥16.1 billion in the six months ended September 30, 2022). This was mainly due to share repurchases and cash dividends paid of ¥11.8 billion and ¥6.0 billion respectively.

As a result, cash and cash equivalents at the end of the second quarter ended September 30, 2023 increased by ¥6.8 billion from the end of the fiscal year ended March 31, 2023 to ¥64.7 billion.

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

Better-than-expected and strong trends in our performance have been observed as a result of strong growth from mainly our overseas business, accelerated streamlining of our pharmaceutical commercial business in the Americas, and continued progress in company wide cost optimizations. In addition, we have completed our impact evaluation from generic products in Japan and as a result, forecasts for our consolidated financial results announced on September 20, 2023, have been revised as follows.

(Core basis)

(JPY millions)

	Revenue	Core operating profit	Core net profit for the year	Basic core earnings per share (yen)
Initial Forecast (Announced on May 11, 2023)	273,000	46,000	34,500	94.27
Latest Forecast (A) (Announced on September 20, 2023)	285,000	50,000	37,500	102.47
Revised Forecast (B)	302,000	58,000	43,500	118.87
Increase/Decrease (B-A)	17,000	8,000	6,000	
Change	6.0%	16.0%	16.0%	
(Reference) Consolidated results ended March 31, 2023	279,037	44,242	33,235	85.86

(IFRS)

(JPY millions)

	Revenue	Operating profit	Profit before tax	Net profit (loss) for the year	Basic earnings per share (yen)
Initial Forecast (Announced on May 11, 2023)	273,000	32,000	29,800	22,400	61.24
Latest Forecast (A) (Announced on September 20, 2023)	285,000	35,000	32,900	25,000	68.34
Revised Forecast (B)	302,000	41,000	38,300	29,500	80.64
Increase/Decrease (B-A)	17,000	6,000	5,400	4,500	
Change	6.0%	17.1%	16.4%	18.0%	
(Reference) Consolidated results ended March 31, 2023	279,037	(3,090)	(5,799)	(14,983)	(38.60)

2. Condensed Interim Consolidated Financial Statements

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

IFRS (JPY millions)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Revenue	**128,915**	**145,806**
Cost of sales	(55,902)	(59,455)
Gross profit	**73,013**	**86,351**
Selling, general and administrative expenses	(42,296)	(43,174)
Research and development expenses	(14,267)	(12,461)
Amortization on intangible assets associated with products	(5,166)	(4,699)
Other income	260	1,211
Other expenses	(30,566)	(2,128)
Operating profit (loss)	**(19,021)**	**25,099**
Finance income	1,245	1,123
Finance expenses	(262)	(575)
Share of loss of investments accounted for using equity method	(1,064)	(1,573)
Profit (loss) before tax	**(19,103)**	**24,075**
Income tax expenses	(2,917)	(4,800)
Net profit (loss) for the period	**(22,019)**	**19,274**
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	2,092	1,245
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	10,052	9,091
Cash Flow Hedge	—	(23)
Share of other comprehensive income of investments accounted for using equity method	1,464	1,010
Other comprehensive income	**13,607**	**11,323**
Total comprehensive income	**(8,412)**	**30,597**
Profit (loss) attributable to		
Owners of the company	(22,041)	19,280
Non-controlling interests	22	(6)
Net profit (loss) for the period	**(22,019)**	**19,274**
Total comprehensive income attributable to		
Owners of the company	(8,400)	30,650
Non-controlling interests	(12)	(53)
Total comprehensive income	**(8,412)**	**30,597**
Earnings per share		
Basic earnings (loss) per share (yen)	(56.05)	52.06
Diluted earnings (loss) per share (yen)	(56.05)	51.92

Core basis (JPY millions)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Revenue	128,915	145,806
Core operating profit	16,451	31,533
Core net profit for the period	12,465	25,861
Basic core earnings per share (yen)	31.73	69.88
Diluted core earnings per share (yen)	31.69	69.68
Core profit attributable to		
Owners of the company	12,484	25,877
Non-controlling interests	(19)	(17)
Core net profit for the period	**12,465**	**25,861**

(2) Condensed Interim Consolidated Statements of Financial Position

Assets

(JPY millions)

	As of March 31, 2023	As of September 30, 2023
Non-current assets		
Property, plant and equipment	66,173	69,487
Intangible assets	96,309	94,832
Financial assets	28,038	29,703
Retirement benefit assets	3,438	3,094
Investments to which equity method has been applied	9,321	8,621
Deferred tax assets	2,810	3,615
Other non-current assets	1,763	1,656
Total non-current assets	**207,853**	**211,009**
Current assets		
Inventories	39,352	45,569
Trade and other receivables	107,165	93,486
Other financial assets	774	1,631
Income tax receivable	60	–
Other current assets	8,072	10,561
Cash and cash equivalents	57,903	64,728
Total current assets	**213,326**	**215,975**
Total assets	**421,179**	**426,984**

Equity and liabilities (JPY millions)

	As of March 31, 2023	As of September 30, 2023
Equity		
Equity attributable to owners of the company		
Share capital	8,702	8,756
Capital surplus	9,789	9,373
Treasury shares	(364)	(11,324)
Retained earnings	238,071	251,706
Other components of equity	37,781	48,679
Total equity attributable to owners of the company	**293,979**	**307,190**
Non-controlling interests	**(683)**	**(735)**
Total equity	**293,297**	**306,454**
Liabilities		
Non-current liabilities		
Financial liabilities	33,513	33,901
Net defined benefit liabilities	1,271	1,370
Provisions	691	706
Deferred tax liabilities	1,592	1,860
Other non-current liabilities	1,312	1,611
Total non-current liabilities	**38,378**	**39,447**
Current liabilities		
Trade and other payables	44,945	43,878
Other financial liabilities	25,858	22,512
Income tax payable	6,745	5,349
Provisions	4,212	3,741
Other current liabilities	7,744	5,603
Total current liabilities	**89,504**	**81,083**
Total liabilities	**127,883**	**120,530**
Total equity and liabilities	**421,179**	**426,984**

(3) Condensed Interim Consolidated Statements of Changes in Equity

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	Foreign currency translation adjustments
Balance at April 1, 2022	8,672	9,370	(718)	290,477	—	8,438	19,950
Comprehensive income							
Net profit (loss) for the period				(22,041)			
Other comprehensive income						2,092	10,086
Total comprehensive income	—	—	—	(22,041)	—	2,092	10,086
Transactions with owners							
Issuance of new shares	6	6					
Repurchase of treasury shares		(28)	(13,007)				
Disposal 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	30,037

(JPY millions)

	Other components of equity				Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Cash flow hedge	Share of other comprehensive income of investments accounted for using equity method	Subscription rights to shares	Total			
Balance at April 1, 2022	—	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		1,464		13,642	13,642	(35)	13,607
Total comprehensive income	—	1,464	—	13,642	(8,400)	(12)	(8,412)
Transactions with owners							
Issuance of new shares			(5)	(5)	7		7
Repurchase of treasury shares				—	(13,035)		(13,035)
Disposal 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	—	2,378	380	42,807	310,072	(657)	309,415

Six months ended September 30, 2023 (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	Foreign currency translation adjustments
Balance at April 1, 2023	8,702	9,789	(364)	238,071	—	7,917	27,971
Comprehensive income							
Net profit (loss) for the period				19,280			
Other comprehensive income						1,245	9,137
Total comprehensive income	—	—	—	19,280	—	1,245	9,137
Transactions with owners							
Issuance of new shares	54	54					
Repurchase of treasury shares		(14)	(11,767)				
Disposal of treasury shares		1	807				
Dividends				(6,009)			
Share-based payments		(458)					
Other				364		(364)	
Total transactions with owners	54	(416)	(10,960)	(5,646)	—	(364)	—
Balance at September 30, 2023	8,756	9,373	(11,324)	251,706	—	8,798	37,109

(JPY millions)

	Other components of equity				Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Cash flow hedge	Share of other comprehensive income of investments accounted for using equity method	Subscription rights to shares	Total			
Balance at April 1, 2023	—	1,562	331	37,781	293,979	(683)	293,297
Comprehensive income							
Net profit (loss) for the period				—	19,280	(6)	19,274
Other comprehensive income	(23)	1,010		11,370	11,370	(47)	11,323
Total comprehensive income	(23)	1,010	—	11,370	30,650	(53)	30,597
Transactions with owners							
Issuance of new shares			(108)	(108)	0		0
Repurchase of treasury shares				—	(11,781)		(11,781)
Disposal of treasury shares				—	808		808
Dividends				—	(6,009)		(6,009)
Share-based payments				—	(458)		(458)
Other				(364)	—		—
Total transactions with owners	—	—	(108)	(472)	(17,440)	—	(17,440)
Balance at September 30, 2023	(23)	2,572	223	48,679	307,190	(735)	306,454

(4) Condensed Interim Consolidated Statements of Cash Flows

(JPY millions)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Ⅰ. Cash flows from operating activities:		
Net profit (loss) for the period	(22,019)	19,274
Depreciation and amortization	9,020	8,933
Impairment losses	30,501	2
Business structure improvement expenses	—	1,833
Shares of loss (profit) of entities accounted for using equity method	1,064	1,573
Finance expenses (income)	(227)	(143)
Income tax expenses	2,917	4,800
Decrease (increase) in trade and other receivables	13,827	15,049
Decrease (increase) in inventories	(1,263)	(4,774)
Increase (decrease) in trade and other payables	(4,430)	(1,727)
Increase (decrease) in provisions and net defined benefit liabilities	(7)	(963)
Decrease (increase) in other current assets	(1,241)	(2,304)
Increase (decrease) in accounts payable - bonuses	(3,765)	(2,643)
Increase (decrease) in accounts payable-other	(2,434)	(3,828)
Other	(110)	(571)
Subtotal	21,831	34,510
Interest received	113	155
Dividends received	226	242
Interest paid	(199)	(358)
Income tax paid	(3,639)	(6,818)
Net cash flows from (used in) operating activities	**18,332**	**27,732**
Ⅱ. Cash flows from investing activities:		
Payments for acquisition of investments	(313)	(6)
Proceeds from sales of investments	991	768
Payments for acquisition of property, plant and equipment	(11,241)	(4,644)
Payments for acquisition of intangible assets	(4,683)	(551)
Proceeds from sales of intangible assets	—	778
Payments for acquisition of investments accounted for using equity method	(3,470)	(135)
Other	(94)	6
Net cash flows from (used in) investing activities	**(18,811)**	**(3,784)**
Ⅲ. Cash flows from financing activities:		
Repayments of short-term loans	(11,089)	—
Proceeds from long-term loans	15,544	—
Repayments of long-term loans	(0)	(216)
Purchase of treasury shares	(13,007)	(11,781)
Dividends paid	(6,402)	(6,008)
Repayments of lease obligation	(1,717)	(1,658)
Other	547	0
Net cash flows from (used in) financing activities	**(16,123)**	**(19,663)**
Ⅳ. Net increase (decrease) in cash and cash equivalents	**(16,602)**	**4,286**
Ⅴ. Cash and cash equivalents at the beginning of period	**83,014**	**57,903**
Ⅵ. Effect of exchange rate changes on cash and cash equivalents	**2,727**	**2,539**
Ⅶ. Cash and cash equivalents at the end of period	**69,140**	**64,728**

(5) Notes to Condensed Interim Consolidated Financial Statements

(Going Concern Assumption)

Not applicable.

(Changes in Accounting Estimates)

The Company measures revenues on a net basis, excluding returns, rebates and discounts. With regards to revenue amounts which include a variable consideration, when the uncertainty related to the variable consideration is eliminated, only in instances where there is an extremely high possibility that there will not be a significant reversal of the recognized cumulative amount does the Company reflect this in the transaction price. As the variable consideration is based on an estimate, the Company may make changes upon new, meaningful information becoming available. During the first quarter under review, as a part of discussions related to the *Ikervis* reimbursement claim settlement, the Company changed its estimate of the claim settlement amount. As a result, revenue in the six months ended September 30, 2023 increased 2,315 million yen.

(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)

Six months ended September 30, 2023

The Company recorded the business restructuring reform expenses related to initiatives for the resumption of growth such as productivity improvements and streamlining measures of ¥1,833 million, included into other expenses of Condensed Interim Consolidated Statements of Income and Comprehensive Income. The business restructuring reform expenses mainly include premium severance pay.

(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

Six months ended September 30, 2023

At a meeting of the Board of Directors on May 11, 2023, 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 8,809,300 of its own shares for a total value of 11,124 million yen during the period between May 12, 2023 to September 30, 2023.

(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	18,750,000 shares (maximum) *Representing 5.0% of the total number of shares outstanding (excluding treasury shares)
(3) Total amount of acquisition	24.5 billion yen (maximum)
(4) Period of acquisition	May 12, 2023 to March 22, 2024
(5) Method of acquisition	Open-market repurchase through discretionary trading method
(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). There is a possibility that some of the purchases may not be made depending on investment opportunities or market conditions.

(Significant Subsequent Events)

Not applicable.

3. Consolidated Reference

(1) Revenue of Major Products

(JPY millions)

Brand Name	Region	Year ended March 31, 2023				Year ending March 31, 2024			
		Six months ended September 30, 2022 Actual	Changes from the same period of previous year	Year ended March 31, 2023 Actual	Changes from the same period of previous year	Six months ended September 30, 2023 Actual	Changes from the same period of previous year	Forecast for the fiscal year ending March 31, 2024	Changes from the same period of previous year
Glaucoma and ocular hypertension									
Cosopt	Total	11,496	6.9%	23,702	9.0%	12,640	9.9%	24,902	5.1%
	Japan	2,468	(18.2%)	4,675	(17.3%)	2,068	(16.2%)	3,949	(15.5%)
	Asia	2,930	19.0%	6,110	18.5%	3,335	13.8%	6,481	6.1%
	EMEA	6,098	15.6%	12,917	18.0%	7,237	18.7%	14,472	12.0%
Tapros	Total	9,416	2.5%	18,744	1.7%	9,609	2.1%	18,421	(1.7%)
	Japan	3,999	(9.1%)	7,761	(7.7%)	3,398	(15.0%)	6,334	(18.4%)
	China	443	(4.7%)	1,045	(10.7%)	836	88.8%	1,561	49.4%
	Asia	1,124	14.4%	2,277	9.6%	1,107	(1.5%)	2,425	6.5%
	EMEA	3,850	15.3%	7,660	13.2%	4,268	10.8%	8,100	5.7%
Tapcom	Total	4,092	19.0%	8,202	17.7%	4,737	15.8%	9,202	12.2%
	Japan	1,357	(3.9%)	2,649	(3.2%)	1,254	(7.6%)	2,177	(17.8%)
	Asia	524	39.6%	1,051	28.9%	604	15.4%	1,352	28.7%
	EMEA	2,212	33.8%	4,502	31.7%	2,879	30.1%	5,672	26.0%
Trusopt	Total	2,430	6.0%	4,882	11.6%	2,488	2.4%	4,930	1.0%
	Japan	516	(12.1%)	980	(11.6%)	454	(12.2%)	885	(9.7%)
	Asia	210	8.5%	454	18.8%	222	5.6%	426	(6.1%)
	EMEA	1,703	12.7%	3,448	19.6%	1,813	6.4%	3,619	4.9%
Eybelis	Total	2,045	22.4%	4,156	21.5%	2,349	14.9%	4,820	16.0%
	Japan	1,933	18.7%	3,905	18.2%	2,146	11.0%	4,372	12.0%
	Asia	112	166.1%	251	116.9%	203	81.3%	448	78.6%
Dry eye									
Diquas (Including Diquas LX)	Total	9,342	1.7%	20,988	11.4%	14,026	50.1%	27,369	30.4%
	Japan	6,768	1.8%	16,259	21.9%	10,336	52.7%	20,882	28.4%
	China	1,629	(3.1%)	2,772	(32.0%)	2,353	44.4%	3,886	40.2%
	Asia	944	10.5%	1,957	37.9%	1,338	41.7%	2,601	32.9%
Hyalein	Total	6,916	(16.8%)	14,781	(16.9%)	8,328	20.4%	16,910	14.4%
	Japan	2,934	(11.7%)	5,718	(11.6%)	2,624	(10.6%)	5,008	(12.4%)
	China	2,591	(38.6%)	6,433	(28.1%)	4,102	58.3%	8,793	36.7%
	Asia	1,392	80.1%	2,630	11.0%	1,602	15.1%	3,110	18.2%
Ikervis	Total	3,686	22.4%	6,839	16.8%	7,052	91.3%	12,338	80.4%
	Asia	807	50.3%	1,549	40.0%	850	5.3%	2,194	41.6%
	EMEA	2,879	16.4%	5,290	11.4%	6,203	115.4%	10,144	91.8%
Cationorm	Total	2,313	41.5%	4,010	24.2%	2,220	(4.0%)	4,862	21.2%
	Asia	260	41.0%	441	(5.4%)	200	(23.3%)	553	25.2%
	EMEA	1,432	34.1%	2,626	26.3%	1,533	7.0%	2,931	11.6%
	Americas	621	62.3%	943	37.7%	487	(21.5%)	1,322	40.3%
Allergy									
Alesion (Including Alesion LX)	Total	7,965	(16.7%)	33,550	14.1%	6,615	(16.9%)	30,350	(9.5%)
	Japan	7,878	(17.1%)	33,400	14.1%	6,516	(17.3%)	30,173	(9.7%)
	Asia	86	41.4%	149	40.2%	99	14.1%	177	18.4%
Verkazia	Total	537	71.3%	914	44.4%	866	61.4%	1,477	61.5%
	EMEA	420	43.8%	748	28.0%	622	48.1%	1,234	64.9%
	Americas	116	451.3%	166	241.2%	244	109.1%	244	34.2%
Intravitreal VEGF inhibitor									
EYLEA	Total	35,848	(1.7%)	71,257	(1.7%)	36,804	2.7%	73,812	3.6%
	Japan	35,848	(1.7%)	71,257	(1.7%)	36,804	2.7%	73,812	3.6%
Bacterial conjunctivitis									
Cravit	Total	5,079	(26.0%)	11,381	(2.8%)	7,092	39.6%	14,073	23.7%
	Japan	695	(28.5%)	1,285	(26.7%)	612	(11.9%)	1,221	(5.0%)
	China	2,587	(41.4%)	6,309	(9.4%)	4,256	64.5%	8,279	31.2%
	Asia	1,045	19.6%	2,380	27.5%	1,453	39.0%	3,148	32.3%
	EMEA	753	25.6%	1,408	25.0%	771	2.5%	1,425	1.2%
Medical devices									
LENTIS Comfort	Total	639	(4.4%)	1,331	(6.4%)	655	2.5%	1,430	7.4%
	Japan	639	(4.4%)	1,331	(6.4%)	655	2.5%	1,430	7.4%
PRESERFLO MicroShunt	Total	1,124	54.4%	2,429	50.6%	1,746	55.4%	3,934	62.0%
	Japan	4	–	94	–	255	–	504	438.7%
	EMEA	1,119	53.8%	2,326	44.3%	1,464	30.8%	3,359	44.4%
OTC Pharmaceuticals	Total	5,639	10.8%	10,628	8.7%	5,914	4.9%	11,266	6.0%
	Japan	5,068	5.8%	9,595	4.5%	5,365	5.9%	10,147	5.8%
	China	114	–	262	–	136	19.3%	303	15.7%
	Asia	456	54.1%	771	31.2%	412	(9.6%)	817	5.9%

(2) FOREX

(JPY)

Exchange rate (yen)	Major currency	2nd quarter ended September 30, 2022	Fiscal year ended March 31, 2023	2nd quarter ended September 30, 2023	Fiscal year ending March 31, 2024(Forecasts)
	USD	133.46	135.40	141.46	145.00
	EUR	138.61	140.97	153.66	155.00
	CNY	19.84	19.72	19.81	20.00

Forecasts in this report 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 2023

Pipeline Development Status (Clinical Stage)

<Glaucoma and ocular hypertension area>

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				Dec-2022		

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. Filed marketing approval in December 2022 in China.

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.. Completed Phase 3 in June 2023 in Japan. Completed Phase 2 (exploratory study) in Europe.

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 Asia. Filed for marketing approval in September 2022 and adopted a positive opinion by CHMP in September 2023 in Europe.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesilate	STN1013900 / AR-13324	Glaucoma / Ocular hypertension	Alcon	Japan						
				Europe						Feb-2023
				Asia					Jan-2023	

A ROCK (Rho-associated kinase) inhibitor. Developed and sold by Alcon in the U.S.. Conducting Phase 3 from November 2020 in Japan. Received marketing approval in Europe and launched in February 2023 in Sweden. Filed successively for marketing approval in Asian countries and received marketing approval in Thailand and other countries from January 2023 onward.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesilate / latanoprost	STN1014000 / PG-324	Glaucoma / Ocular hypertension	Alcon	Europe						Jan-2023
				Asia					Jan-2023	

A fixed dose combination drug of a ROCK (Rho-associated kinase) inhibitor and a prostaglandin $F_{2\alpha}$ derivative. Developed and sold by Alcon in the U.S.. Received marketing approval in Europe and launched in January 2023 in Germany. Filed successively for marketing approval in Asian countries and received marketing approval in Thailand and other countries from January 2023 onward.

<Keratoconjunctival disease area including dry eye >

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
ciclosporin	STN1007603 / DE-076C	Vernal keratoconjunctivitis	Original	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 expansion 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. In July 2023, the Company granted Harrow Health, Inc. (U.S.) exclusive rights in the U.S. and Canada for product manufacturing and commercialization.

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						Nov-2022
				Asia					Mar-2023	

A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Long-acting drug. Launched in November 2022 in Japan. In Asia, filed for marketing approval in March 2023 in South Korea.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
olodaterol hydrochloride	STN1014100	Dry eye	Boehringer Ingelheim	Japan	(Phase 1/2a)					

β2 receptor agonist. Started Phase 1/2a in January 2023 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. Conducting Phase 2a in U.S., France and India from 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. Considering future development plans.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
epinastine hydrochloride	STN1011402	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan				Mar-2023		
A histamine H_1 receptor antagonist with mediator release inhibitor function, as treatment for allergic conjunctivitis. Ophthalmic cream. Filed for manufacturing and marketing approval in March 2023 in Japan.										

<Refractive error>

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. Completed Phase 2/3 in October 2023 in Japan. Conducting Phase 2/3 from 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.										

Compound name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
AFDX0250BS	STN1013400	Myopia	Boehringer Ingelheim	Japan		(Phase 2a)				
				China						
Selective muscarinic M2 antagonist which reduces progression of juvenile myopia. Reduces mydriasis by selectively inhibiting a subtype of receptors. Started Phase2a in May 2023 in Japan. Started Phase1 in August 2023 in China.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
ursodeoxycholic acid	STN1013600	Presbyopia	Original	U.S.		(Phase 2a)				
				Japan						
Improvement of presbyopia by improving lens elasticity. Completed P2a in September 2023 in the U.S.. Completed Phase 1 in April 2022 in Japan.										

<Others>

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.. Conducting Phase 3 from October 2022 in Japan.										

Changes from Q1 FY2023 (August 3, 2023)

Dev. Code	Changes
STN1013400	Started Phase1 in August 2023 in China.

※ STN1011700 (DE-117, generic name: omidenepag isopropyl) is sold as *Eybelis* in Japan and Asia. In the U.S., Santen has received approval as *OMLONTI* and granted exclusive rights for product manufacturing and commercialization to Visiox Pharmaceuticals, Inc. (U.S.) in July 2023.

(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, 2022	Year ended March 31, 2023	Six months ended September 30, 2023	Year ending March 31, 2024
	Actual			Forecast
Consolidated	13,175	21,144	4,624	13,000

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

Depreciation and amortization (JPY millions)

	Six months ended September 30, 2022	Year ended March 31, 2023	Six months ended September 30, 2023	Year ending March 31, 2024
	Actual			Forecast
Manufacturing cost	1,164	2,342	1,560	3,550
Selling, general and administrative expenses	986	1,986	1,123	2,720
R&D expenses	295	615	310	690
Consolidated total	2,445	4,943	2,993	6,960

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

Amortization on intangible assets associated with products (JPY millions)

	Six months ended September 30, 2022	Year ended March 31, 2023	Six months ended September 30, 2023	Year ending March 31, 2024
	Actual			Forecast
Intangible assets (Merck products)	2,904	5,808	2,904	5,810
Intangible assets (Rhopressa/Rocklatan)	—	281	612	1,120
Intangible assets (PRESERFLO MicroShunt)	566	1,149	600	1,100
Intangible assets (Ikervis)	393	798	435	790
Intangible assets (Eyevance)	1,126	1,142	—	—
Other	177	340	148	580
Consolidated total	5,166	9,518	4,699	9,400

Research and development expenses (JPY millions)

	Six months ended September 30, 2022	Year ended March 31, 2023	Six months ended September 30, 2023*	Year ending March 31, 2024
	Actual			Forecast
Consolidated	14,267	28,297	12,461	29,000
Percent of revenue	11.1%	10.1%	8.5%	9.6%

* IFRS basis. R&D expenses on a core basis amounted to 12,321 million yen, excluding 0.1 billion yen of expenses related to streamlining the Americas.

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.