

Development Status of STN2000100 (DE-128) and Timely Disclosure

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Forward-Looking Statements

- Information given in this presentation contains certain forward-looking statements concerning forecasts, projections and plans whose realization is subject to risk and uncertainty from a variety of sources. Actual results may differ significantly from forecasts.
- Business performance and financial condition are subject to the effects of medical regulatory changes made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.
- The process of drug research and development from discovery to final approval and sales is long, complex and uncertain. Individual compounds are subject to a multitude of uncertainties, including the termination of clinical development at various stages and the non-approval of products after a regulatory filing has been submitted. Forecasts and projections concerning new products take into account assumptions concerning the development pipelines of other companies and any co-promotion agreements, existing or planned. The success or failure of such agreements could affect business performance and financial condition significantly.
- Business performance and financial conditions could be affected significantly by a substantial drop in sales of a major drug, either currently marketed or expected to be launched, due to termination of sales as a result of factors such as patent expiry and complications, product defects or unforeseen side effects. Santen also sells numerous products under sales and / or manufacturing license from other companies. Business performance could be affected significantly by changes in the terms and conditions of agreements and/or the non-renewal of agreements.
- Santen is reliant on specific companies for supplies of certain raw materials used in production. Business performance could be affected significantly by the suspension or termination of supplies of such raw materials if such an event were to adversely affect supply capabilities for related final products.

CORE PRINCIPLE and WORLD VISION

CORE PRINCIPLE

天機に参与する

Tenki ni sanyo suru

“Exploring the secrets and mechanisms of nature in order to contribute to people’s health” *

WORLD VISION

Happiness with Vision

The Happiest Life for every individual, through the Best Vision Experience

* Santen’s original interpretation of a passage from the Zhongyong (The Doctrine of the Mean) by Confucius.

Agenda

- 1. Development Plan of STN2000100 (DE-128) in the U.S. and Impairment Loss**
- 2. Objectives in Medium-term Plan (MTP2025)**

Development Plan of STN2000100 (DE-128) in the U.S. and Impairment Loss

Development plan of STN2000100 (hereinafter DE-128) in the U.S.

Premarket Approval (PMA) application approval is still under discussion with FDA

History of the development and approval process of DE-128

Aug 2013	InnFocus, Inc. started P2/3 study INN-005
Aug 2016	Santen acquired InnFocus
Jun 2020	Completed PMA application with data at P2/3 study INN-005
End of Feb 2021	Received FDA's notification on assessment and continued negotiation → The approval may delay from the original schedule (H1 FY2021)

Impact due to Impairment Loss

Conservatively incorporated the risk of asset value and recorded impairment loss and a gain on reversal of change in fair value of contingent consideration and reversal of deferred tax liabilities*¹, which caused JPY 22.5B loss (Net profit basis) for FY20

*¹ Including reversal of deferred tax liabilities at JPY 3.0B other than following.

Intangible assets related to InnFocus

(Forecast for the end of Q4 FY2020)

(JPY B)

Impact on PL*²



Total impairment loss
JPY 40.5B

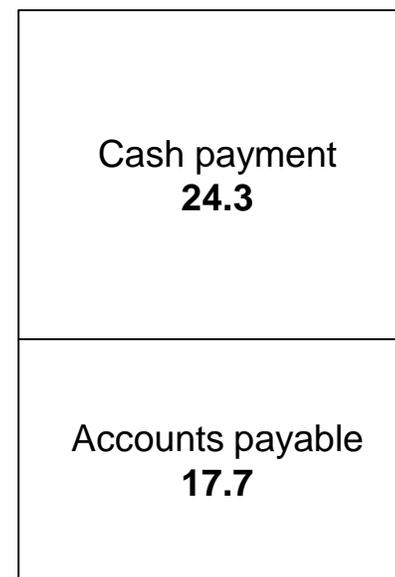
*² The difference between the impact on BS and that on PL is mainly due to the difference in exchange rates



Equivalent to consideration payment

(including future payments)

(Forecast for the end of Q4 FY2020)



Gain on reversal of change in fair value of contingent consideration
JPY 14.9B

Revised Consolidated Financial Results Forecast: Core Basis

Sales have shown steady growth in the mainstay prescription pharmaceuticals business, achieving year-on-year revenue growth

Consolidated performance forecast in FY2020 (Core basis)

	Revenue (JPY millions)	Core operating profit (JPY millions)	Core net profit for the year (JPY millions)	Basic core earnings per share (JPY)
Forecast announced on May 8, 2020 (A)	235,000	52,000	38,700	97.67
Revised forecast (B)	249,000	51,000	38,000	95.13
Increase/decrease (B-A)	14,000	-1,000	-700	
Increase/decrease (%)	+6.0	-1.9	-1.8	
(Ref.) Consolidated results for the year ended March 31, 2020	241,555	50,023	35,894	90.00

Q4

- Mainstay products such as *Alesion LX* has enjoyed strong sales
- Revenue in China has steadily increased mainly in private hospitals while being influenced by value-based purchasing

Revised Consolidated Financial Results Forecast: IFRS Basis

Net profit is 7.0 B yen, down 69.6 % from the previous forecast due to the impairment loss.
No impact is expected on cash flow

Consolidated performance forecast in FY2020 (IFRS basis)

	Revenue (JPY millions)	Operating profit (JPY millions)	Profit before tax (JPY millions)	Net profit for the year (JPY millions)	Basic earnings per share (JPY)
Forecast announced on May 8, 2020 (A)	235,000	35,000	34,000	23,000	58.35
Revised forecast (B)	249,000	14,500	14,000	7,000	18.27
Increase/decrease (B-A)	14,000	-20,500	-20,000	-16,000	
Increase/decrease (%)	+6.0	-58.6	-58.8	-69.6	
(Ref.) Consolidated results for the year ended March 31, 2020	241,555	33,535	32,091	21,714	59.16

DE-128 Sales / Development Status outside the U.S.

Steady area expansion in EMEA and development conducted in other areas for launch / approval

EMEA

- Sold in 17 countries and regions, and used for more than 7,500 cumulative cases under controlled launch since Jan 2018
- Aim to increase sales to approx. 5.0 B yen in FY2025

Canada

- Approved in Mar 2021 and expected to launch in FY2021

Asia

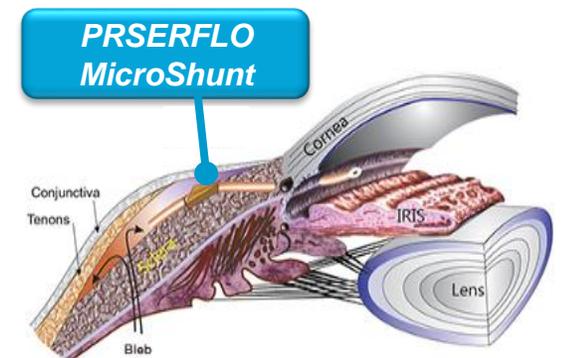
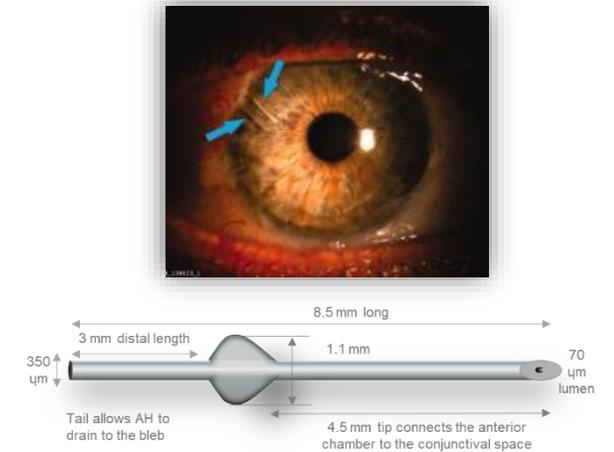
- Application submitted in 7 countries and regions incl. South Korea since Mar 2020 and expected to be approved in FY2021

China

- Started a program to use unapproved medical device at special medical zone in Jan 2021

Japan

- Negotiation with PMDA for application is underway



Aiming to generate total revenue of JPY 10.0 B at peak sales (except for the U.S.)

Objectives in Medium-term Plan (MTP2025)

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MTP2025 is under consideration with the perspectives of To-Be, the management commitment, strategic direction, “strengthening foundation”

To-Be in 2025

For Santen 2030 , pursue results through utilizing assets prepared so far

In the past 10 years, achieved topline growth through regional expansion
In the next 5 years, focus more on profit, while keep on pursuing growth

The mgmt.
commitment

Pursuing shareholder value improvement: ROIC improvement, ESG and etc.

Strategic
direction

**Enhancement of core
business**

**Steady execution of
investment PJ**

”Strengthening
foundation”

**Global strategy
execution**

**R&D organization
capability**

**KPI-based business
management**

Management's Commitment

Committing to increase shareholder value

Policy

The management commits to shareholder value for maximizing profit of investors / stakeholders

- Clarify strategies for shareholder value enhancement and shareholder return policy
- Commit to TSR and define financial KPIs as the management's commitment
- Define KPIs and implement initiatives of ESG, which has increasingly grown in importance
- Enhance disclosure



1 Business growth

- Profits temporarily decreased in FY2020 due to impairment, but aiming for revenue/profit growth FY2021 or later
- Will pursue solid and continuous growth while focusing on profit generation

2 Multiple

- Clarify growth strategies and equity stories
- Disclose business plan based on the quantitative information that leads to conviction of growth potential

3 Shareholder return

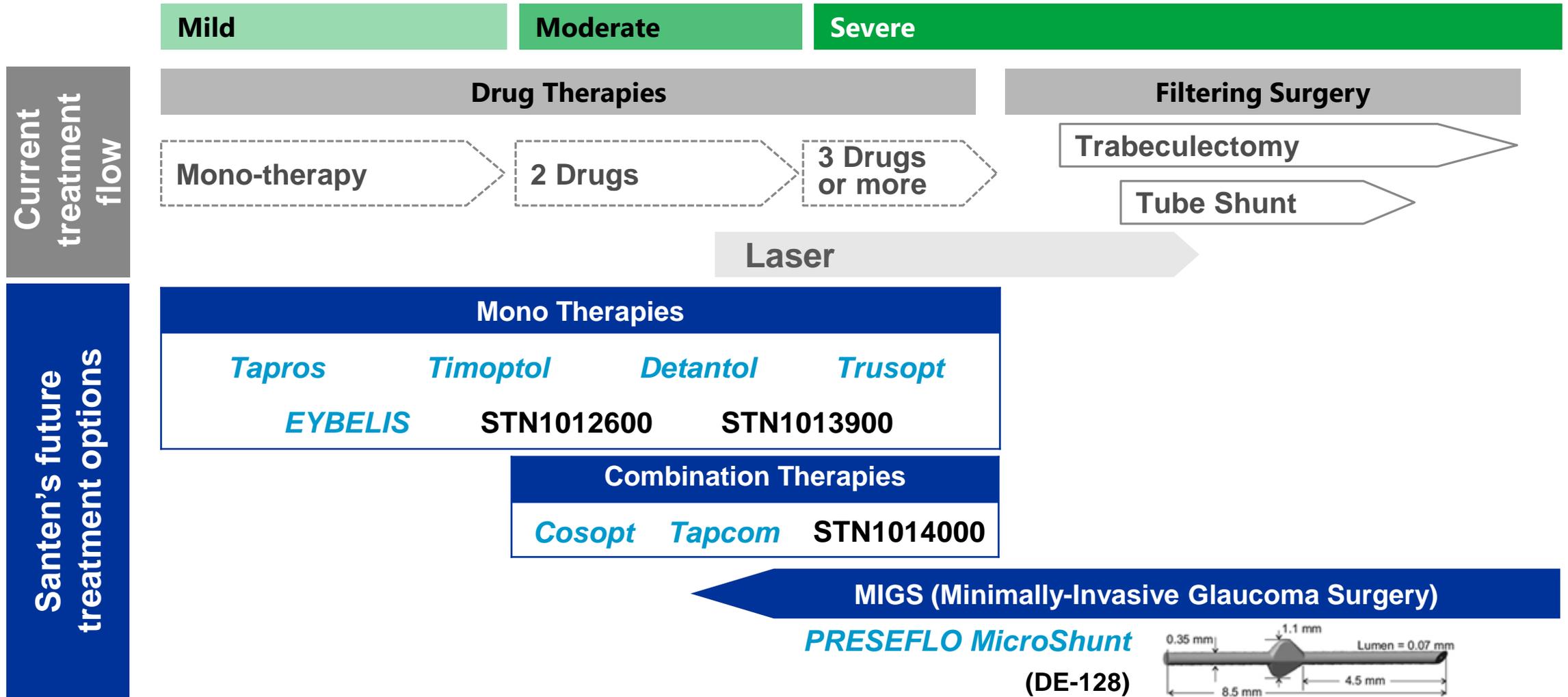
- Enhancement of shareholder return including share buybacks and dividend increases

Future Process

- **May 11: FY2020 financial results announcement**
- **May 12: FY2020 financial results investor meeting**
- **May 19: MTP2025 announcement
MTP2025 investor meeting**

Appendix

Blueprint to Strengthen Glaucoma Portfolio



Overview of Pivotal Study in the U.S.

INN-005 (NCT01881425)	
Study Title	A Randomized Study Comparing the Safety and Efficacy of the InnFocus MicroShunt™ Glaucoma Drainage System to Standard Trabeculectomy In Subjects With Primary Open Angle Glaucoma
Study Design	Prospective, randomized, single blind (subject), multicenter
Enrollment	857
Country	US, Europe
Phase	Phase 2/3
Indication	Primary Open Angle Glaucoma
Primary Endpoint	20% decrease in diurnal intraocular pressure from baseline to 12 months follow-up
Secondary Endpoint	Reduction in diurnal intraocular pressure from baseline to 12 months follow-up

Value Proposition: Addressing Unmet Need

Patients with Mild, Moderate & Severe Glaucoma

Trabeculectomy:

High Treatment Burden for the Patient, Caregivers, and Physicians leading to poor quality of life:

- Unpredictable effectiveness & safety outcomes in the near term post operation leading to repeated visits to the Clinic and multiple interventions
- Procedure related adverse effect such as hypotony, on recovery of vision & progression of Lens Opacities
- Higher cost of care

Micro Surgical Approach using MicroShunt:

Intraocular Pressure (mmHg) in Study Eye by Visit by Device

