

# Santen Acquisition of InnFocus, Developer of MicroShunt Glaucoma Implant Device



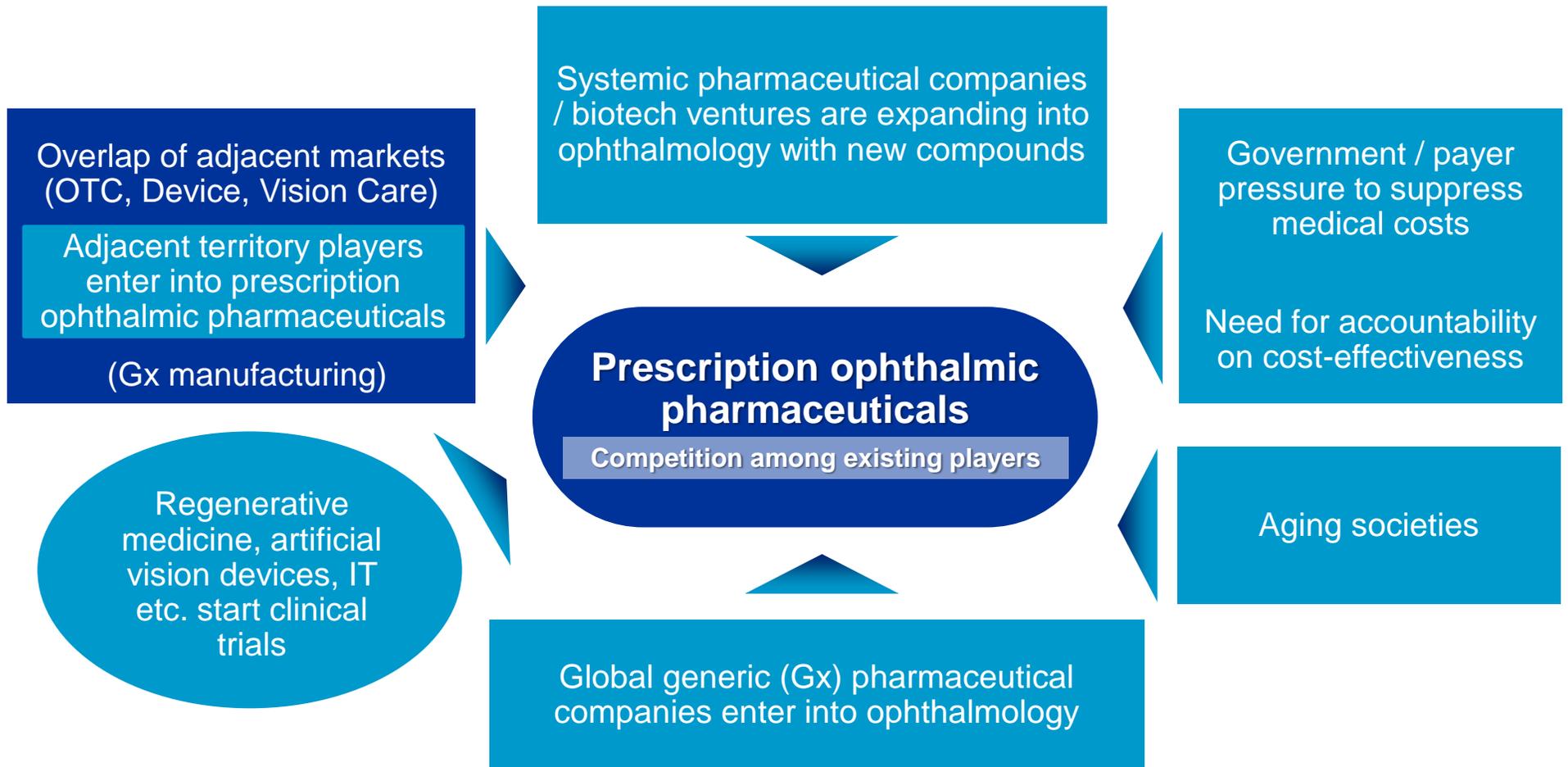
**Akira Kurokawa**

President & CEO

August 2, 2016

**SANTEN PHARMACEUTICAL CO., LTD.**

# External Environment for Prescription Ophthalmic Pharmaceuticals



# Santen Makes Another Strategic Step in Business and R&D Specialization in Ophthalmology

**2012**

## Novagali Pharma acquisition

- Strengthened R&D, including Novasorb<sup>®</sup> formulation technology
- IKERVIS (now launched in several European countries)
- Supported growth in global business platform

**2014**

## Merck & Co., Inc. ophthalmology product acquisition

- Acquired product sales: 21.6b yen in FY15
- Reinforced global presence
- Accelerated EU and Asia growth
- Increased profitability
- Expanded key glaucoma franchise

**2015**

## Anti-rheumatic (RA) pharmaceutical business divestment

7% RA  
93% Op  **100%**  
Ophthalmology

- 45b yen received to support future investment

**2016**

## InnFocus acquisition

Enhancing Pipeline with InnFocus MicroShunt<sup>®</sup> Glaucoma Implant Device

- Santen to enter high growth glaucoma device area
- USD225m upfront plus milestones
- MicroShunt U.S. launch expected in 2020/2021
- CE marked in Europe
- Developing globally including Asia

# InnFocus Strategic Value to Santen

**InnFocus builds upon the execution of our strategy  
“To Become a Specialized Pharmaceutical Company  
with a Global Presence”**

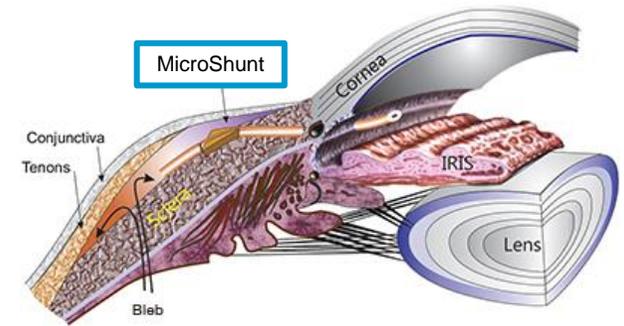
- **To provide glaucoma patients and doctors with new and innovative treatment options**
  - Enhance customer satisfaction as a specialized company
- **To strengthen Glaucoma business through synergy**
  - Synergy with existing and developing products, customer relationships and commercial infrastructure to strengthen our market presence in glaucoma
- **To add to mid- and long-term growth**
  - Enhance pipeline to create mid- and long-term growth opportunity, contributing to strategic vision to 2020 and beyond
- **Medical devices have high probability of development / approval success**

# InnFocus, Inc. Acquisition Overview

|                                       |  |
|---------------------------------------|--|
| Company name                          | InnFocus, Inc.   |
| Founded                               | 2004   |
| Headquarters                          | Miami, Florida, U.S.   |
| Lead product                          | MicroShunt glaucoma implant device<br>(U.S. studies ongoing) |
| Acquisition price                     | USD 225 million plus milestones                              |
| Anticipated closing                   | Within Santen's Q2, ending Sep 30, 2016                      |
| Revenue opportunity estimate (annual) | Over USD 200 million   |

# MicroShunt

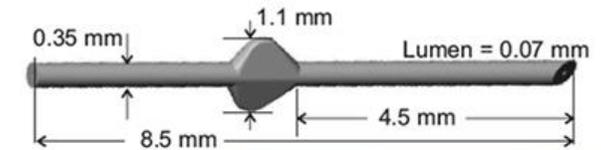
– Designed to Offer Differentiating Features



## Micro-Invasive Surgical Design

### ■ Designed to address invasiveness of Trabeculectomy

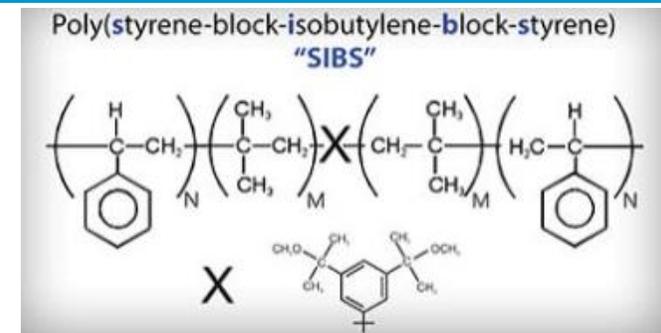
- Extremely small micro-tube (twice the size of an eyelash)
- Minimize incision size and scarring
- Reduce post surgical complications rates
- <15 minute implant time



## Innovative Bio-Inert Product Material

### ■ Designed to avoid stimulation of immune response that leads to stent occlusions and surgical failures

- SIBS technology is bioinert
- Proven effective in TAXUS™ cardiovascular stents at minimizing occlusions & stent failures



# MicroShunt Will Allow Santen Broader Coverage of Disease Phases and Enhance Portfolio

## Therapy Initiation



## Disease Progression



## Santen glaucoma portfolio

| <u>Prostaglandin</u> | <u>Prostaglandin + BB Combination</u> | <u>Beta Blocker + CAI Combination</u> | <u>Beta Blocker</u> | <u>Carbonic Anhydrase inhibitor</u> |
|----------------------|---------------------------------------|---------------------------------------|---------------------|-------------------------------------|
|                      |                                       |                                       |                     |                                     |
|                      |                                       |                                       |                     |                                     |
|                      |                                       |                                       |                     |                                     |

# Glaucoma is a Key Growth Driver for Santen

**2.5x**

- Over past five years, sales grew 2.5 times to 55 billion yen in FY15
- Glaucoma is highly profitable

**25%**

- Santen is focused on glaucoma, already our largest therapeutic area at 25% of revenue

**7%**

- Santen has 7% global share in glaucoma\*, room to grow

**Products &  
platform**

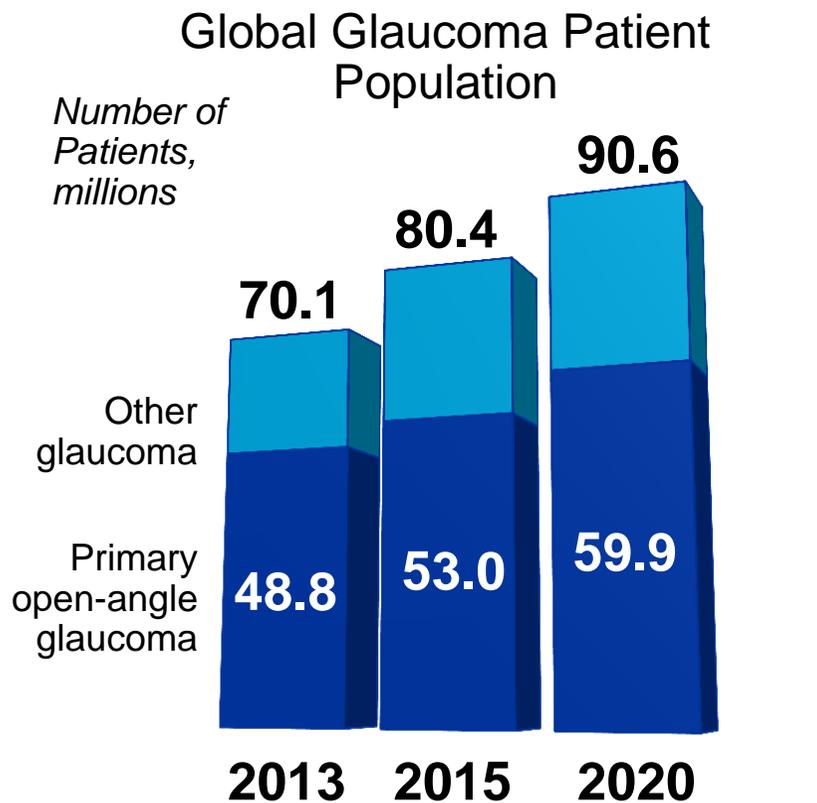
- Glaucoma business is boosted by acquired MSD products and new business platforms in EMEA\*\* and Asia

**Growing market**

- The market is expected to grow substantially

# Glaucoma Market is Growing

Blindness from open-angle glaucoma forecast to reach 5.9 million people globally by 2020

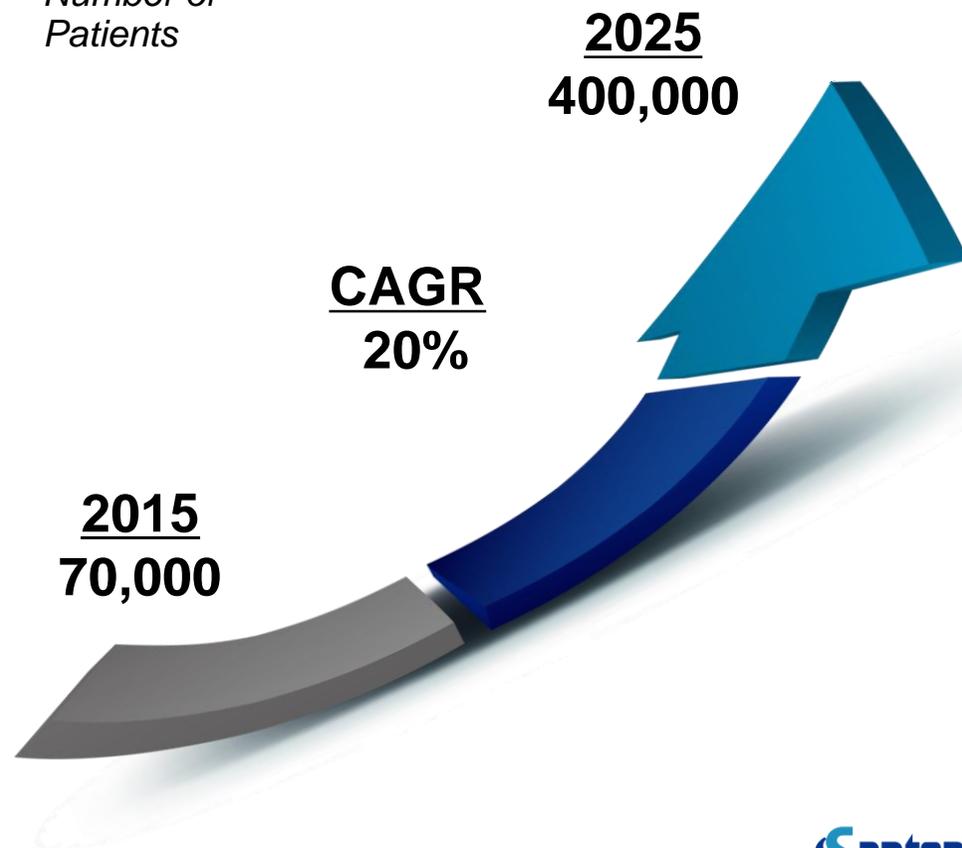


U.S. primary open-angle glaucoma

| 2013 | 2015 | 2020 |
|------|------|------|
| 3.3  | 3.5  | 3.8  |

U.S. Demand for Micro-Invasive Glaucoma Surgery (MIGS)

Number of Patients



# Strategic Acquisition Strengthens Santen's Position in Ophthalmology

- MicroShunt is expected to provide an important new option for physicians and patients in the elusive goal of IOP management
- Significant opportunity for Santen to enter the high growth glaucoma device segment
- Strong synergy with existing portfolio, organization, capabilities and customer base
- Key step in the realization of our vision to become a specialty pharmaceutical in ophthalmology

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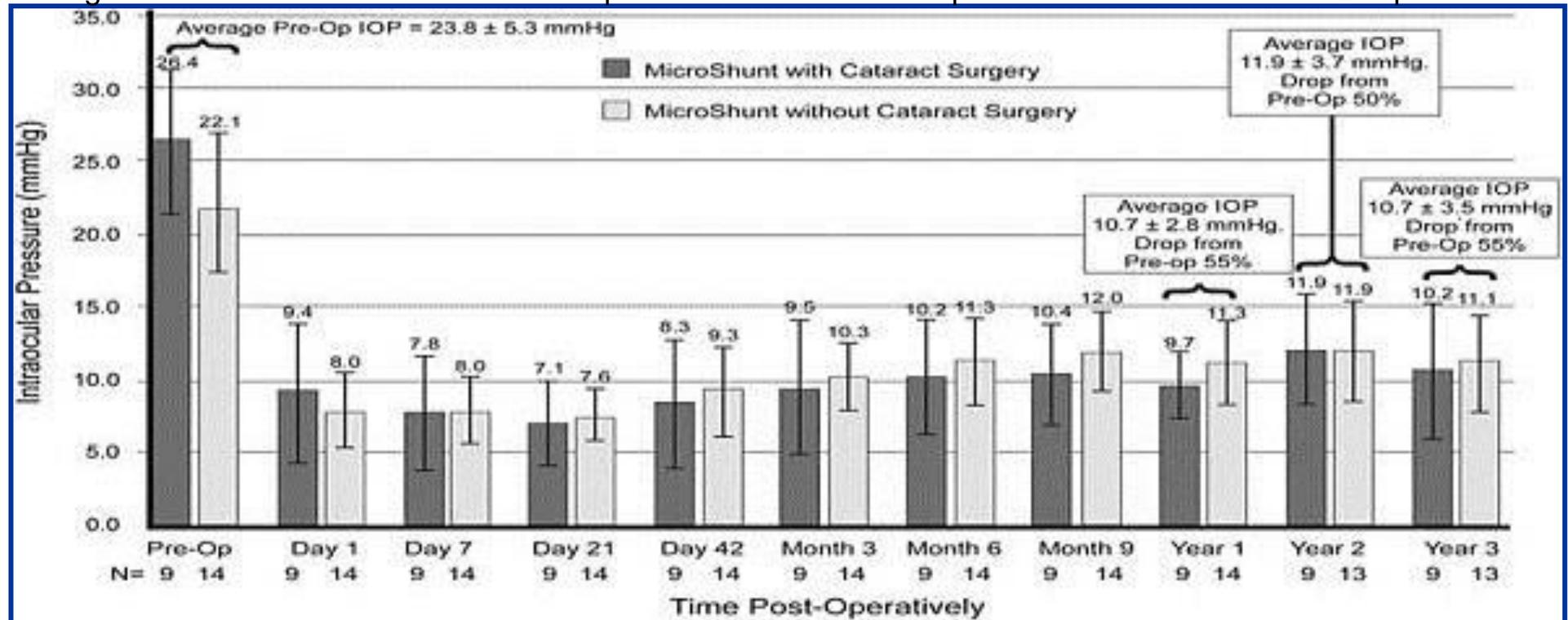
# Appendix

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# MicroShunt Technology Can Deliver Consistent and Sustained Gold Standard IOP Lowering

- MicroShunt has the ability to fundamentally transform patient outcomes by delivering gold standard efficacy and addressing the issues limiting widespread surgical use in moderate-severe patients
- Capable of optimizing vision preservation and limiting the progression to blindness\*

Change in IOP with time for MicroShunt implanted with and without phacoemulsification with IOL implantation\*\*



# Late Stage Clinical Study Underway

|                             |   |
|-----------------------------|---|
| <b>Trial No.</b>            | <b>INN-005 (NCT01881425)</b>  |
| <b>Study Title</b>          | 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 |
| <b>Study Design</b>         | Prospective, randomized, single blind (subject), multicenter  |
| <b>Enrollment</b>           | 857   |
| <b>Country</b>              | US  |
| <b>Phase</b>                | Phase 2/3   |
| <b>Indication</b>           | Primary Open Angle Glaucoma   |
| <b>Primary Endpoint</b>     | 20% decrease in diurnal intraocular pressure from baseline to 12 months follow-up   |
| <b>Secondary Endpoint</b>   | Reduction in diurnal intraocular pressure from baseline to 12 months follow-up  |
| <b>Estimated Completion</b> | July 2019<br>(final data collection date for primary outcome measure in July 2018)  |

# Challenges Associated with Trabeculectomy

## Invasiveness of Surgical Procedures

Trabeculectomy is a non-microinvasive surgical technique that requires a larger ocular incision and produces increased levels of scarring

## Post – Operate Complication Rates

50% of patients undergoing trabeculectomy suffer from serious short and long-term post surgical complications\*

## Surgical Failure Rates

30% of trabeculectomies fail within 24 months of surgery\*

## Post Operative Care

Glaucoma surgeons spend 10 – 20 hours on post operative patient care due to serious post surgical complications and current failure rates\*\*

Gold standard glaucoma surgical interventions have seen limited use historically despite their unparalleled ability to deliver sustained target IOP in moderate-severe glaucoma patients and potential to transform visual outcomes

# 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 Pharmaceutical 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 Pharmaceutical 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.

The logo for Santen features a stylized 'S' on the left, composed of two overlapping curved shapes in light blue and dark blue. To the right of the 'S' is the word 'anten' in a bold, dark blue, sans-serif font. The 'a' is lowercase, while 'n', 't', 'e', and 'n' are uppercase.

**Santen**

*A Clear Vision For Life*