R&D in the Next Decade
Santen’s R&D Transformation

R&D Meeting
September 11, 2015
Today’s agenda

Naveed Shams
Takeshi Matsugi
Masatsugu Nakamura
Kenji Morishima
Terri Phillips
Franz Buchholzer
Naveed Shams

Santen’s R&D Transformation
Non-Clinical Research
Disease Area Strategy
Ocular Drug Delivery
Global Medical Affairs
Global Regulatory Affairs
Concluding Remarks
R&D in the next decade

Santen’s R&D transformation

Naveed Shams MD Ph.D.
Senior Corporate Officer
Head Global R&D and Chief Scientific Officer
President & CEO Santen Inc, USA

September 11, 2015
Santen’s corporate values

By focusing our efforts on ophthalmology and related areas, Santen develops scientific knowledge and organizational capabilities which are unique and original to Santen. We use our unique capabilities to contribute to patients and their loved ones, and consequently to society.
Global R&D leadership

Naveed Shams
Senior Corporate Officer & CSO, Head of R&D Division

Masatsugu Nakamura
Head of Global Ophthalmic Disease Area Strategy

Najam Sharif
Head of Global Biomedical Science, Santen Inc.

Yoshihito Tsukushi
Head of Global R&D Portfolio and Resource Planning

Tetsuo Kawaguchi
Head of Global Program Leaders

Elo Kent
Head of Innovation Office, Santen Inc.

Kenji Morishima
Corporate Officer, Head of Global Pharma Technology Development, Regional Rep., Asia

Takeshi Matsugi
Head of Global Non-Clinical Research

Yoshikazu Matsumoto
Head of Global Clinical Operations, Santen Inc.

Terri L. Phillips
Head of Global Medical Affairs, Santen Inc.

Franz Buchholzer
Head of Global Regulatory Affairs, Santen Switzerland SA

Yusuf Ali
Regional Representative, USA

Kazuyuki Nishioka
Regional Representative, Europe

(As of July 1, 2015)
A specialty pharmaceutical company with a global presence

Utilizing unique technologies and pathobiology understanding to develop differentiated products and drive global growth

Strong, stable position in Japan & Asia, pursuing growth in key regions

Aiming to become a global top-3 ophthalmology company
Transforming Santen R&D

• Reduce **time to launch**; Faster with focus on the right products to the right patients

• Significantly improve **probability of technical success** in all target disease areas

• Target and address region-specific **unmet medical needs**
Reducing time to launch

Pursuing first-in-man adaptive design

Early evaluation in man in regions of interest or feasibility

Rolling regional submissions

New indications/adaptation for better outcomes

Achieve 30% reduction in time to launch
Improving PTS

1. Disease knowledge via public domains
   - Biology
   - Epidemiology
   - Genomics etc.
   - Other

2. Understanding contextual pathophysiology
   - Disease subtype
   - Mechanisms
   - Targets
   - Biomarkers
   - Safety

3. Testable Hypotheses
4. Early Human Studies

Evidence to make the case
   - Targets
   - Molecular entities
   - Patient subpopulation
   - Disease-specific biomarkers
   - Efficacy biomarkers
   - Safety biomarkers
Interaction and interface with customers in real time

- Patients
- Patient Support Groups
- Care Givers
- Santen R&D
- Payers/Providers
- Partners
Address UMN in specific regions

Addressing the needs of a changing world

<table>
<thead>
<tr>
<th>Region</th>
<th>Developing world</th>
<th>Developed world</th>
<th>Worldwide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia</td>
<td>Myopia</td>
<td>Myopia</td>
<td>Myopia</td>
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<tr>
<td>Developing world</td>
<td>Developing world</td>
<td>Developed world</td>
<td>Developed world</td>
</tr>
<tr>
<td>Myopia</td>
<td>Infectious disease</td>
<td>Age related diseases / dry eye</td>
<td>Infectious</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chronic illness / complications</td>
<td>Myopia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>of diabetes</td>
<td>Infectious</td>
</tr>
<tr>
<td>Worldwide</td>
<td>Myopia</td>
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<tr>
<td>Worldwide</td>
<td>Myopia</td>
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Disease area strategy

• Focus on differentiated life-cycle management and GE products
• Improve PTS by developing deep understanding of pathobiology and unmet needs through translational research, biomarkers and diagnostics
• Boost productivity by prioritizing programs that can be Best-in-Class (BIC)*
• Pursue partnered R&D through clearly defined business development and in-licensing opportunities

*BIC: Any new product candidate that has POC in human with ophthalmic or other systemic indications
Non-Clinical Research

Takeshi Matsugi Ph.D.
Head of Global Non-Clinical Research

September 11, 2015

Santen’s R&D Transformation
Santen’s Non-Clinical Research organization and R&D capabilities

500+ R&D scientists developing innovative and differentiated products meeting global medical needs in Ophthalmology

Global Non-Clinical Research

- Ophthalmic Pharmacology
  - Pharmacology
  - Translational Research

- Toxicology and Pharmacokinetics
  - Toxicology
  - Pathology
  - Pharmacokinetics

Santen SAS France
Santen Oy Finland
Santen Inc USA
Nara R&D Center Japan
Unique initiatives of Non-Clinical Research

- New Pipeline Products
- Filing of Differentiated Products
  - Focus on minimum Requirements for filing
- Translational Research

\[ P \propto \frac{WIP \times V \times PTS}{C \times CT} \]

- \( P \) = Productivity
- \( WiP \) = Work-in-Progress
- \( V \) = Value
- \( PTS \) = Probability of Technical Success
- \( C \) = Invested cost
- \( CT \) = Cycle Time

(Reference for Productivity formula: Nature Reviews, 2010; 9, 203-214)
Translational research / biomarkers

To optimize proof of concept and increase probability of technical success (PTS)

Our initiatives include translational research / biomarker exploration
What are biomarkers?

A biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.

The power of biomarkers

Biomarkers will help increase PTS and develop the best medicines for patients.

Human sample analysis

Identifying **biomarker** candidates

Deep understanding of the target disease

Applying **biomarker** for clinical trial

Identifying appropriate drug target

The right drug candidate for the right patient population with right endpoint

Increase PTS
The power of biomarkers

Example:
DE-122 appears effective for Wet AMD patients with Endoglin over-expression in the retina

- VEGF
  - Proliferation
  - Lumen formation
  - Hyper-permeability

- Hypoxia
- Anti-VEGF

- Leaky

- Overexpression of escape factors

- Endoglin
  - Reactivation
  - Leaky
  - Pericyte
Ongoing translational research projects

Potential target (pathway analysis) → Responder Analysis → Risk Management

Target lead → Candidate → Phase 1: POC → Phase 2 → Phase 3: NDA approval → Launch and LCM

- Anti-Endoglin antibody IVT: DE-122
  - VEGF, Endoglin in serum and aqueous humor

- VEGF, PDGF dual inhibitor IVT: DE-120
  - VEGF in serum

- EP2 receptor agonist Eye drop: DE-117
  - DNA banking

- mTOR inhibitor IVT: DE-109
  - DNA banking
  - T-cell phenotype and function

IVT: Intravitreal Injection, LCM: Lifecycle management
Summary

• Translational research is key to improving PTS, thereby raising productivity

• We will deepen our exploration of biomarkers in humans to increase PTS and achieve early approval of products
Disease Area Strategy

Masatsugu Nakamura Ph.D.
Head of Global Ophthalmic Disease Area Strategy

September 11, 2015

Santen’s R&D Transformation
Disease Area Strategy (DAS)

Global Disease Area Strategy

- Ophthalmic DAS Group
  - FOTE, BOTE, Glaucoma

- Translational Research Team

- Research Planning & Networking Team
Disease Area Strategy

• Focus on differentiated life-cycle management and GE products
• Improve PTS by developing deep understanding of pathobiology and unmet needs through translational research, biomarkers and diagnostics
• Boost productivity by prioritizing programs that can be Best-in-Class (BIC)*
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*BIC: Any new product candidates that has POC in human with ophthalmic or other systemic indications
Targeting drivers of pathobiology / molecular pathways (1)  

Dry Eye Strategy: Focus on tear film stability

**Santen strategy**

- All types of abnormal tear fluid
  - Decreased stability of tear film
  - Decreased wetness of epithelium
  - Vicious cycle
  - Epithelium disorder
  - Inflammation

**General strategy**

- Lacrimal gland disorder, meibomian gland disorder
  - Decreased lacrimal secretion
  - Promoted evaporation
  - Increased osmotic pressure
  - Decreased stability of tear film
  - Decreased goblet cells
  - Epithelium disorder
  - Inflammation

In Japan/Asia, tear film instability is the core mechanism of dry eye: TFOT (tear film oriented therapy) concept.

In the US, inflammation is the core mechanism of dry eye, but many candidates have failed in clinical trials.

Targeting drivers of pathobiology / molecular pathways (2)  
Pathogenesis of dry eye and UMN

Risk factors: Older age, Female, Postmenopausal estrogen therapy, Androgen deficiency, Connective tissue disease, LASIK

- Aqueous deficient
- Evaporative

Lacrimal deficiency
Meibomian oil deficiency
Disorders of lid aperture

Abnormality of tears
Instability of tear film (TBUT)
Decrease of Wettability (TBUT)
Epithelium disorder (Staining)

Objective symptom
Ocular surface inflammation

Vicious cycle
Stabilization of tear film

- Treatment of aqueous/mucin Layer (DIQUAS, Hyalein, Rebamipide etc.)
- Safety formulation, better usability » DIQUAS LCM
- Treatment of anti-inflammatory (Cyclosporine)
Improving productivity: Biomarker identification / validation

Imaging for FOTE: evaluation of vital staining

<table>
<thead>
<tr>
<th>Panel</th>
<th>Grade</th>
<th>Criteria</th>
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<tr>
<td>A</td>
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<td>Equal to or less than panel A</td>
</tr>
<tr>
<td>B</td>
<td>I</td>
<td>Equal to or less than panel B, greater than A</td>
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<tr>
<td>C</td>
<td>II</td>
<td>Equal to or less than panel C, greater than B</td>
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<tr>
<td>D</td>
<td>III</td>
<td>Equal to or less than panel D, greater than C</td>
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<tr>
<td>E</td>
<td>IV</td>
<td>Equal to or less than panel E, greater than D</td>
</tr>
<tr>
<td>&gt;E</td>
<td>V</td>
<td>Greater than panel E</td>
</tr>
</tbody>
</table>

The Oxford grading scale (Oxford)

The grading system recommended by the NEI Workshop (NEI)

- OD: Fluorescein staining score
  - Grade 0
  - Grade 1
  - Grade 2
  - Grade 3

- OS: Rose bengal staining score
  - Grade 2
  - Grade 3
  - Grade 4
  - Grade 5

Grading scale used in Santen clinical trial

Establish grading system of keratoconjunctival damage
Improving productivity: Biomarker identification / validation

Imaging for FOTE: evaluation of tear film stability

Establish quantitative evaluation with standardized methods
Selection of appropriate patients for dry eye

- Identify appropriate patients for treatment using biomarkers
  - Santen is exploring innovations including development of our own biomarkers and modification of use of existing systems (such as those below)

- Search for dry-eye specific symptoms
  - Meta-analysis using Santen’s clinical data
Improving productivity: Open innovation / network strategy

Joint activity with associations

Strategic joint research with academia

Partnerships with systemic pharmaceutical companies: BIC strategy
Summary

Critical elements for Santen Vision 2020 and beyond:

- Focus on differentiation
- Expand geographic network
- Focus on disease drivers
- Improve probability of success
- Improve productivity
- Enhance business development & licensing activities
Aggressive Life Cycle Management of marketed products

Regional Expansion
- Overcome severe competition through DEVELOPMENT SPEED

Modified Products
- Improve current therapeutic EASE-OF-USE DEVICE or FORMULATION

Innovative Products
- Shift therapeutic paradigm through DRUG DELIVERY SYSTEM

Business value

Advance in technology
Unmet medical needs as DDS targets

Drug Delivery System (DDS): Formulation technology engineered to deliver the right amount of the drug to hit the right target at the right time.

Front of the eye
- Improve adherence
- Reduce frequency of instillation
- Reduce systemic and topical adverse events

Glaucoma
- Strong intraocular pressure (IOP) reduction over Latanoprost
  - Improve adherence
  - Reduce frequency of instillation
  - Reduce systemic and topical adverse events
  - Mid-term sustained delivery

Back of the eye
- Long-term sustained delivery
- Strong efficacy over ranibizumab and aflibercept
  - Reduce frequency of instillation
Network-based development at Santen

Connect (unmet medical needs + external technologies) and Develop

Open innovation
Utilize an open innovation consultant
Inviting new technology from all over the world

KOL field visits
Field Visits
Questionnaires

Advisory panel
Drug Delivery
Advisory Panel

Global partnerships
Academia
Research Institutes
Start-up company
Benefits of DDS: improving adherence through ease of use

Adherence among new glaucoma patients is significantly low

Adherence to prescribed drugs

Source: ©2015 IMS Health
Calculated based on IMS-NPA 2009-11
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Recent examples of ease of use

Unit Dose
Original products
60 ampules

Preservative-Free
Multi Dose
New dosage form
1 bottle

Original products
5 min. interval between drops

New dosage form
Combination Product
If drug A is followed by drug B within 30 secs, 50% of drug A is washed out

and less frequency
Increased market share through ease of use

Original product
Must be mixed and dissolved before use

New dosage form
Need only be shaken before use

<table>
<thead>
<tr>
<th>Product Share (%)</th>
<th>Santen</th>
<th>Original product</th>
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<tbody>
<tr>
<td>92FY</td>
<td>100</td>
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<td>100</td>
</tr>
<tr>
<td>13FY</td>
<td>0</td>
<td>100</td>
</tr>
</tbody>
</table>
Benefits of DDS development: Overcoming transport barrier

Only drug with MW <5kDa and log P of 10-100 can pass through cornea

Nano particles
Liposomes
Nano-emulsions etc.

Dr. Makoto Araie, 1994
Benefits of DDS development: Overcoming transport barrier

**Twice a day**
Higher corneal delivery (Novasorb)

**Once a day**

<table>
<thead>
<tr>
<th>Concentration (ng/hr/g of tissue)</th>
<th>0.5mg/mL Ciclosporin in anionic formulation</th>
<th>0.5mg/mL Ciclosporin in cationic emulsion</th>
<th>1.0mg/mL Ciclosporin in cationic formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal Concentration (AUC0-72hr)</td>
<td>1.9 x HIGHER</td>
<td>3.6 x HIGHER</td>
<td>1.0mg/mL</td>
</tr>
</tbody>
</table>

**Oil Core**
Solubilizes the drugs

**Surfactant**
Stabilizes the interface

**Cationic agent**
Brings the Positive Charges

**150 nm**

AUC = Area under curve

**CORNEAL CONCENTRATION**
(Results of animal model)

**Rabbit cornea**
Benefits of DDS development: Diversified routes for targeted delivery

Santen is going beyond being an “eye-drop” company
DDS: Driving paradigm shift in ophthalmic therapy

Drug Level

Therapeutic range

Time

Drug Level

with Sustained release from Depot

with DURECT
Benefits of DDS development: Ease of access to choroid

Suprachoroidal Delivery

Injection between sclera and choroid
Summary

Santen is changing ophthalmic therapy by:

• Increasing the PTS (probability of technical success) by connecting unmet medical needs with external technologies
• Accelerating regional expansion through rapid development
• Improving adherence through easy-to-use devices and formulations
• Innovating DDS development
Global Medical Affairs: Mission and organization

Mission: Create value for Santen and all stakeholders and help realize Vision 2020

Organization: Creating a Medical Affairs capability that is global, efficient and supports the realization of Global 2020
Transforming Santen Medical Affairs for the 21st century

Developing GMA: Proactive, value-generating, global

• Healthcare stakeholders worldwide are demanding evidence based, real world, comparative effectiveness data

• Increasing number and sophistication of medical stakeholders

• Increasing demand for data transparency
Key elements of GMA support
Medical scientific liaison (MSL) activities impact the slope of product awareness

MSL increased awareness, knowledge

MSL effect

Unaided product activity & awareness

Prelaunch | Launch | Post-launch
---|---|---
Clinical & Regulatory | Marketing & Sales | MSL activities
Coordinated and timed MA activities will support successful product launch

<table>
<thead>
<tr>
<th>Early Market (T-24 m)</th>
<th>Pre-launch (T-12-24m)</th>
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</thead>
<tbody>
<tr>
<td>• Identify and engage TLs</td>
<td>• Expand TL awareness of data</td>
</tr>
<tr>
<td>• Provide disease education</td>
<td>• Understand payer perceptions of UMN and value</td>
</tr>
<tr>
<td>• Publish clinical data, burden of illness, MOA</td>
<td>• Present pivotal data</td>
</tr>
<tr>
<td>• Qualify and communicate treatment landscape and UMN</td>
<td>• Prepare medical information</td>
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<tr>
<td></td>
<td>• Define further research needs</td>
</tr>
<tr>
<td></td>
<td>• Train country teams</td>
</tr>
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</table>

Currently focusing development of Santen’s GMA capabilities in the U.S. and Europe
Coordinated and timed MA activities will support successful product launch

<table>
<thead>
<tr>
<th>Launch (T-12 m)</th>
<th>Post-Launch</th>
</tr>
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<tbody>
<tr>
<td>• Communicate value proposition</td>
<td>• Communicate product safety and effectiveness</td>
</tr>
<tr>
<td>• Educate and advocate for patients</td>
<td>• Provide training and education</td>
</tr>
<tr>
<td>• Inform stakeholders of emerging therapies and</td>
<td>• Promote patient adherence</td>
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<tr>
<td>competitive intelligence</td>
<td>• Pursue LCM</td>
</tr>
<tr>
<td>• Engage, educate and train TLs</td>
<td>• Generate real-world data</td>
</tr>
<tr>
<td></td>
<td>• Expand HCP engagement</td>
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Currently focusing development of Santen’s GMA capabilities in the U.S. and Europe
Payer trends demand communication of health outcomes data

- Increased focus on cost
- Increased competition and availability of generics
- More healthcare plans tie outcomes data to contract decisions
- Demand for data tailored to plan-specific population
- Category management increase driving demand for head-to-head trials
- Adoption of Least-Costly-Alternative policies

Greater Need for Health Outcomes and Pharmacoeconomic Data
Market Access and GMA collaboration ensures availability of drugs to patients in need

Reimbursement and access; Generate and publish real world evidence to support value over existing therapies

Health economics & outcomes research: Publish the burden of illness and unmet medical needs

GMA / Market Access collaboration

Peer-to-peer engagement with medical thought leaders who influence health policy

Peer-to-peer engagement with medical decision makers
250 Medical Thought Leaders*
identified globally

<table>
<thead>
<tr>
<th>Region</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>105</td>
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<tr>
<td>South America</td>
<td>18</td>
</tr>
<tr>
<td>Europe</td>
<td>70</td>
</tr>
<tr>
<td>Asia</td>
<td>57</td>
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</table>

* MTLs relating to area of uveitis
GMA - Key accomplishments YTD (FY2015)

• Conducted 199 scientific interactions with U.S. MTLs (Advisors, symposium faculty, publications authors)
• Established 1.3m customer contact points (Congress, med ed, 1:1, publications)
• Supported 14 global congress medical affairs booths
• Hosted 7 global uveitis scientific symposia
• Grants in support of 8 CME monographs
• Held 10 scientific advisory board meetings
• Hosted 3 scientific open house events
• Published 8 manuscripts
Realizing Vision 2020 and beyond

Patients’ Success → Success with Doctors → Success for Santen

• Advance **scientific knowledge** that affects disease awareness and health outcomes and empowers evidence-based decision making

• Deliver real-world **clinical insights** that inform and influence scientific objectives, product development, global registration, commercialization and value

• Translate clinical data into multi-faceted **scientific assets**

Creating value for Santen and stakeholders
Global Regulatory Affairs

Franz Buchholzer Ph.D.
Head of Global Regulatory Affairs

September 11, 2015

Santen’s R&D Transformation
Global Regulatory Affairs (RA) leadership

- Director, U.S.
- General Manager, Japan
- Asia Pacific Team Lead
- Director, Europe
- Manager Global RA Activities Coordination
- Director, China

About 70 regulatory experts worldwide

Accelerating market access to benefit patients and Santen in a new global regulatory era
Making a major contribution to Vision 2020

Global capability
Strong capability in key regions, optimal balance of global and local teams, respect for cultures, languages, people

Regulatory leadership and excellence
Knowledge, compliance and intelligence; at the forefront of regulatory trends and new standards

Business mindset
Dynamic and innovative approach; accelerating time to market; Make the impossible possible

Win-win relationships
Partner with government bodies and regulators; lobby as appropriate
New RA agenda for success in the 21st century

Global RA

Registration
• Traditional Market Needs
• Life registrations

Payer/Provider Needs
• Patients
• Economic aspects
• Ethical aspects

Government Affairs/Public Policy Issues
• Shared responsibility

Geographic Needs
• Emerging Markets
• Mutual recognition
Global regulatory affairs – new era

Current development process

8 years

Phase I  Phase II  Phase III  Submission MAA/NDA  Phase IIIb/IV
2 years  3 years  1.5 years

What the development process might look like in 2020

First into Man (Adaptive Design) 20 – 100 patients

1.5 years

1 year  0.5 year  Limited Clinical use

Automated submission / approvals

Pharma 2020: The vision, PricewaterhouseCoopers
Summary

Global RA – new era

● Shorten developmental programs: Adaptive design, conditional approval

● Share responsibility and risk: Early collaboration and communication with regulators, payers, and government bodies

● Prioritize mutual recognition of data throughout agencies

● Accelerate patient access to new medicines: Time to market, registrations on limited data
DISCLOSURE NOTICE

- Information given in this announcement and accompanying documentation 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 and event were to adversely affect supply capabilities for related final products.

- This presentation includes discussions of certain Santen products marketed in certain markets and compounds in clinical trials, as well as competitors’ products and compounds in clinical trials which are given for illustrative purposes only. Such discussions may include views subject to data interpretation that may or may not be views shared by regulatory authorities in the various regions in which the Company operates.