

# Financial Results for the First Half of Fiscal Year 2015

(April 1, 2015 – September 30, 2015)



<http://healthy-knee.com/>



**SEIKAGAKU CORPORATION**

(TSE:4548)

# Overview for 1H of FY2015

(Millions of Yen)	1H FY2015 Results	Year-on-Year		Initial FY2015 Forecasts for 1H	
		Change	% of Change	Change	% of Change
Net sales	15,954	+1,706	+12.0%	+204	+1.3%
Operating Income	2,050	+486	+31.1%	+300	+17.2%
Ordinary Income	2,575	+465	+22.1%	+325	+14.5%
Net Income	1,941	+253	+15.0%	+241	+14.2%
R&D Expenses (Ratio to net sales)	3,749 (23.5%)	+351 (-0.3pt)	+10.3%	+99 (+0.3pt)	+2.7%
Average Exchange Rate (1US\$)	¥121.80	+¥18.75		+¥3.80	

	1H FY2015 Results	1H FY2014 Results	Initial FY2015 Forecasts
Net Income per Share	¥34.18	¥29.71	¥29.93

# Net sales by Business Segment (1H of FY2015)

(Millions of Yen)	1H FY2015 Results	Year-on-Year	% of Change
Net sales	15,954	+1,706	+12.0%
Pharmaceuticals	13,201	+1,435	+12.2%
Domestic Pharmaceuticals	8,709	+45	+0.5%
Overseas Pharmaceuticals	3,830	+1,381	+56.4%
Bulk Products	661	+9	+1.4%
LAL Business	2,753	+270	+10.9%
(Overseas sales)	6,013	+1,694	+39.2%

\*Foreign exchange impact on overall net sales:  
approx. +¥910 million

## Domestic Pharmaceuticals

### ➤ ARTZ (joint-function improvement agent)

Sales at the prior-year level due to promotion of generic drugs use



ARTZ:  
Joint-function improvement agent with hyaluronic acid as its main ingredient

### ➤ OPEGAN (ophthalmic surgical aid)

Sales slight decrease amid fierce competition



OPEGAN:  
Ophthalmic surgical aid used primarily in cataract surgery

### ➤ MucoUp (surgical aids for endoscopic mucosal resection)

Increased deliveries to medical institutions.  
Seikagaku sales down, reflecting a high level of shipments in FY2014 1H

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\*Foreign exchange impact on overall net sales:  
approx. +¥910 million

## Overseas Pharmaceuticals

### ➤ ARTZ (multiple injection)

#### ● SUPARTZ in the U.S:

Local sales at the prior-year level.

Seikagaku sales up due to advance shipment of product in new packaging accompanying a change of brand name\* and yen depreciation

\*Brand name changed to SUPARTZ FX in Oct. 2015

#### ● ARTZ in China:

Local sales flat.

Seikagaku sales up due to a sales partner inventory adjustment coupled with yen depreciation

### ➤ Gel-One in the U.S. (single injection)

Local sales and Seikagaku sales up



Gel-One®:  
Single-injection joint function  
improving agent

# Net sales by Business Segment (1H of FY2015)

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## Bulk Products

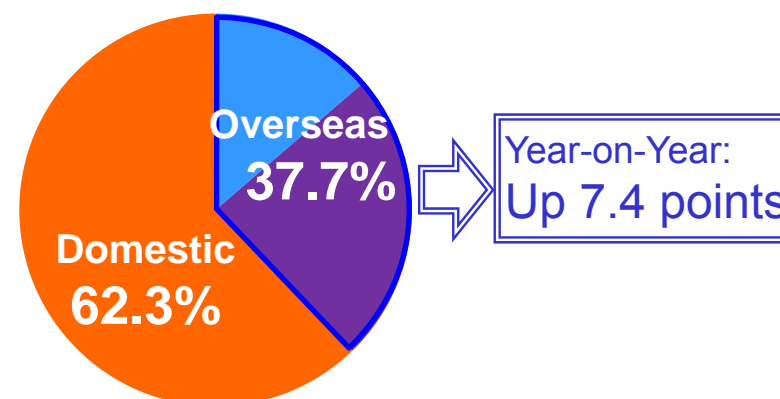
Sales essentially flat, with higher sales of chondroitin sulfate compensating for lower sales of hyaluronic acid

\*Bulk Products:  
High-purity, high-quality hyaluronic acid and chondroitin sulfate for pharmaceuticals

## LAL Business

Sales up on higher overseas sales volume of endotoxin-detecting reagents and other products and yen depreciation

## Overseas Sales Ratio



■ Overseas LAL/Bulk ■ Overseas Pharmaceuticals ■ Domestic sales

# Income for 1H of FY2015 (Year-on-Year)

(Millions of Yen)	1H FY2015 Results	Year-on-Year	% of Change
Net sales	<b>15,954</b>	<b>+1,706</b>	<b>+12.0%</b>
Cost of Sales (Cost of Sales ratio)	<b>6,544</b> (41.0%)	<b>+658</b> (-0.3pt)	<b>+11.2%</b>
SGA expenses	<b>7,358</b>	<b>+561</b>	<b>+8.3%</b>
R&D Expenses (to Net sales ratio)	<b>3,749</b> (23.5%)	<b>+351</b> (-0.3pt)	<b>+10.3%</b>
Operating Income (to Net sales ratio)	<b>2,050</b> (12.9%)	<b>+486</b> (+1.9pt)	<b>+31.1%</b>
Ordinary Income	<b>2,575</b>	<b>+465</b>	<b>+22.1%</b>
Net Income	<b>1,941</b>	<b>+253</b>	<b>+15.0%</b>
Depreciation	<b>1,567</b>	<b>+363</b>	<b>+30.1%</b>

## Operating Income

### Cost of Sales (-0.3pt):

Improvement due to factors including a volume increase for overseas pharmaceuticals and the impact of yen depreciation, despite higher depreciation of the No. 5 Production Building at the Takahagi Plant

### SGA Expenses (+561):

- R&D expenses: Increase accompanying progress with development themes, such as SI-6603 in the U.S.

## Net Income

### Non-operating Income/Expenses (-20):

Decrease in foreign exchange gains on foreign currency-denominated assets (-75)

### Income Taxes (+211):

Tax rate increase following expiration of a temporary tax rate reduction in FY2014 (+4.6pt) (1H FY2014: 20.0% → 1H FY2015: 24.6%)

# Results for 1H of FY2015 (comparison with the initial forecast)

(Millions of Yen)	1H FY2015 Results	Compa. with forecasts	% of Change
Net sales	15,954	+204	+1.3%
[Pharmaceuticals]	13,201	+51	+0.4%
Domestic Pharmaceuticals	8,709	-40	-0.5%
Overseas Pharmaceuticals	3,830	+130	+3.5%
Bulk Products	661	-38	-5.5%
[LAL Business]	2,753	+153	+5.9%
Operating Income (to Net sales ratio)	2,050 (12.9%)	+300 (+1.8pt)	+17.2%
Ordinary Income	2,575	+325	+14.5%
Net Income	1,941	+241	+14.2%
R&D Expenses (to Net sales ratio)	3,749 (23.5%)	+99 (+0.3pt)	+2.7%

## Net sales

- Domestic Pharmaceuticals: ARTZ in Japan below forecast
- Overseas Pharmaceuticals: ARTZ in China below forecast, but sales volume of Gel-One in the U.S. above forecast
- LAL Business: Increase in sales of endotoxin-detecting reagents

\*Foreign exchange impact on sales overall: Approx. +150

## Operating Income

### SGA Expenses (approx. -110):

Increase in R&D expenses accompanying progress with SI-6603 in the U.S., but decreases in other SGA expenses

## Net Income

### Non-operating Income/Expenses:

- Foreign exchange gains on foreign currency-denominated assets above forecast (+45)
- Impairment loss: ¥29 million loss recorded\*

\*Accompanying partial deactivation of the No. 2 Production Building at the Takahagi Plant



# Overview of Forecasts in FY2015

\* There is no change in forecast announced on May 12, 2015.

(Millions of Yen)	FY2015 Forecasts	FY2014 Results			(Reference) Degree of Progress
		Results	Change	% of Change	
Net sales	30,650	29,522	+1,127	+3.8%	52.1%
Operating Income	2,400	2,383	+16	+0.7%	85.4%
Ordinary Income	3,800	4,008	-208	-5.2%	67.8%
Net Income	2,900	3,650	-750	-20.6%	66.9%
R&D Expenses (to Net sales ratio)	7,850 (25.6%)	8,146 (27.6%)	-296 (-2.0pt)	-3.6%	47.8%
Average Exchange Rate (1US\$)	¥118.00	¥109.94	+¥8.06		

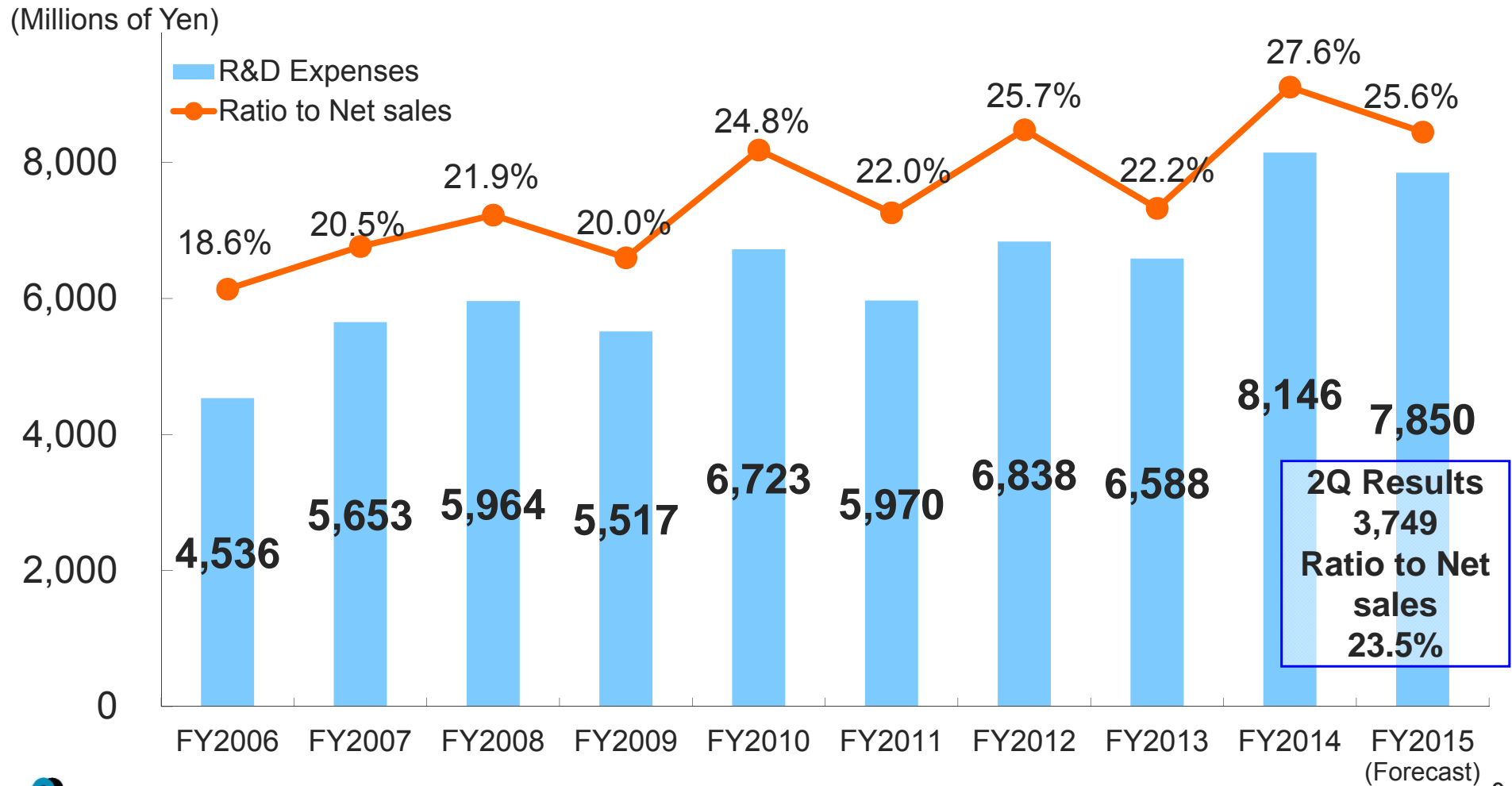
	FY2015 Forecasts	FY2014 Results	Exchange Rate Sensitivity (Impact of a change of ¥1 against the US\$)	
Net Income per share	¥51.05	¥64.27	Net sales	Approx. ¥95 million
Dividend per share	¥26.00	¥26.00	Operating income	Approx. ¥35 million
Dividend Payout ratio	50.9%	40.5%		



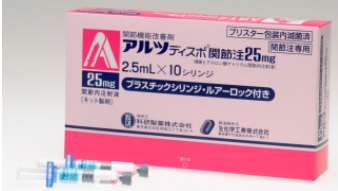

# Trend in R&D Expenses

\* There is no change in forecast announced on May 12, 2015.

**R&D expenses to remain at a high level in FY2015 due to progress with an open-label trial for SI-6603 in the U.S. and other projects**



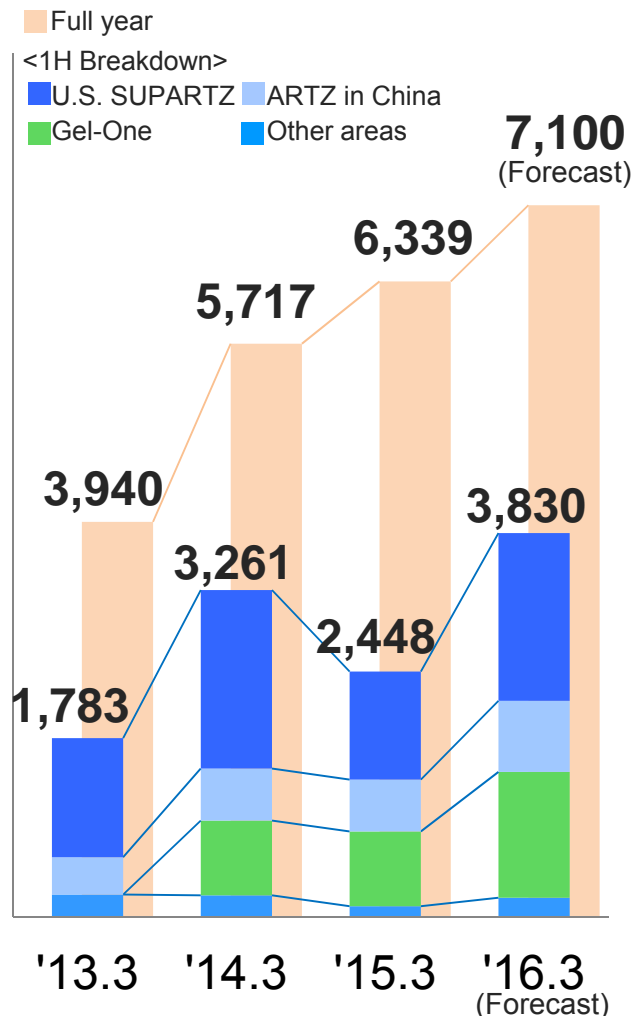
# Domestic Sales (unit deliveries to medical institutions/Year-on-Year)

	1H FY2015 Results	FY2015 Forecasts	
Joint-function improving agent <b>ARTZ</b> 	<b>Slight decrease as a result of the impact of promotion of generic drugs use</b>  ARTZ growth rate: -0.8% (Market growth rate: +0.1%) Market share: 57.3%	<ul style="list-style-type: none"> <li>Engage in sales activities in selected key areas</li> <li>Take share from competitors</li> </ul> <ul style="list-style-type: none"> <li>ARTZ growth rate <b>+0.6%</b>(forecast)</li> </ul>	<ul style="list-style-type: none"> <li>Market share <b>57.5%</b>(forecast)</li> </ul>
Ophthalmic surgical aids <b>OPEGAN</b> 	<b>Market share decrease amid fierce competition</b>  OPEGAN growth rate: -1.4% (Market growth rate: +1.5%) Market share: 33.8%	<ul style="list-style-type: none"> <li>Implement measures to increase market presence, such as utilization of sales promotion materials and information provision activities</li> </ul> <ul style="list-style-type: none"> <li>OPEGAN growth rate <b>+0.2%</b>(forecast)</li> </ul>	<ul style="list-style-type: none"> <li>Market share <b>33.7%</b>(forecast)</li> </ul>

# Overseas Pharmaceuticals (value basis/Year-on-Year)

## Overseas Pharmaceuticals Sales trend

(Millions of Yen)



## FY2015 1H Results

+56.4%

Increase on higher volumes and impact of yen depreciation \*Foreign exchange impact: + approx. ¥560 million

### ARTZ (multiple injection)

- SUPARTZ in the U.S: Local sales at roughly prior-year level because of sales partner efforts
- ARTZ in China: Flat sales, due in part to a change in the pricing policy by the government
- Seikagaku exports: Increase due to an inventory build-up by the sales partner and the impact of yen depreciation

### Gel-One (single injection)

- Increase in both local sales and Seikagaku sales

## FY2015 Forecast

+12.0%

Expected increases for Gel-One and ARTZ in China and impact of yen depreciation

### ARTZ (multiple injection)

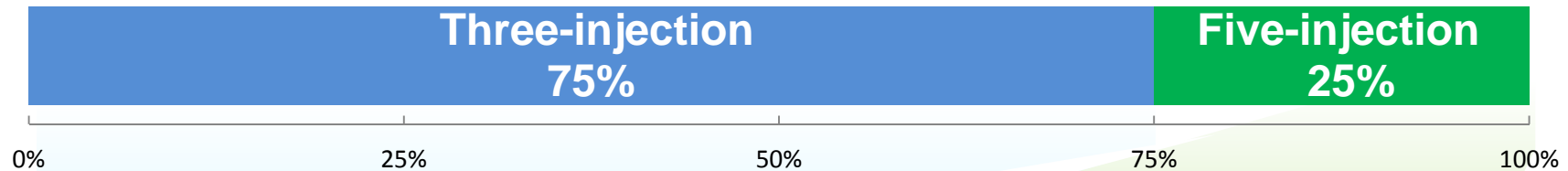
- SUPARTZ in the U.S: Sales at roughly prior-year level
- ARTZ in China: Aim for continued growth while watching trends in the market.
- Seikagaku exports: Increase on growth from ARTZ in China and the impact of yen depreciation

### Gel-One (single injection)

- Aim for a further sales volume increase through reinforcement of sales partner sale capabilities.

# Product Line Enhancement Measures in the U.S.

■ Share Breakdown of Multiple-Injection Products in the U.S. (2014, Seikagaku estimate)



## Three-injection Product (NDA filed)

- NDA filed with the FDA in July 2015
- Sales partner: Bioventus  
(Same as for SUPARTZ FX)

## Five-injection product SUPARTZ FX™

- Approval for the safety of retreatment injection obtained
- Brand name changed from SUPARTZ in October 2015



**Endeavor to strengthen the presence of Seikagaku products in the U.S. market through product line expansion.**

# Gel-One Challenges and Future Initiatives

## Gel-One Challenges

- ◆ Low product awareness
- ◆ Slower than expected pace of market penetration

### ◆ **Seikagaku**: Establishment of organizations focused solely on the U.S. market

- Oct. 2014: Opening of the SEIKAGAKU U.S.A. Representative Office
- May 2015: Opening of the North American Business Unit at headquarters

- Formulate sales strategy
- Enhance our monitoring of local marketing activities

### ◆ **Zimmer Biomet** : Strengthening of sales capabilities

- Jun. 2015: Increasing the number of dedicated sales reps accompanying an acquisition

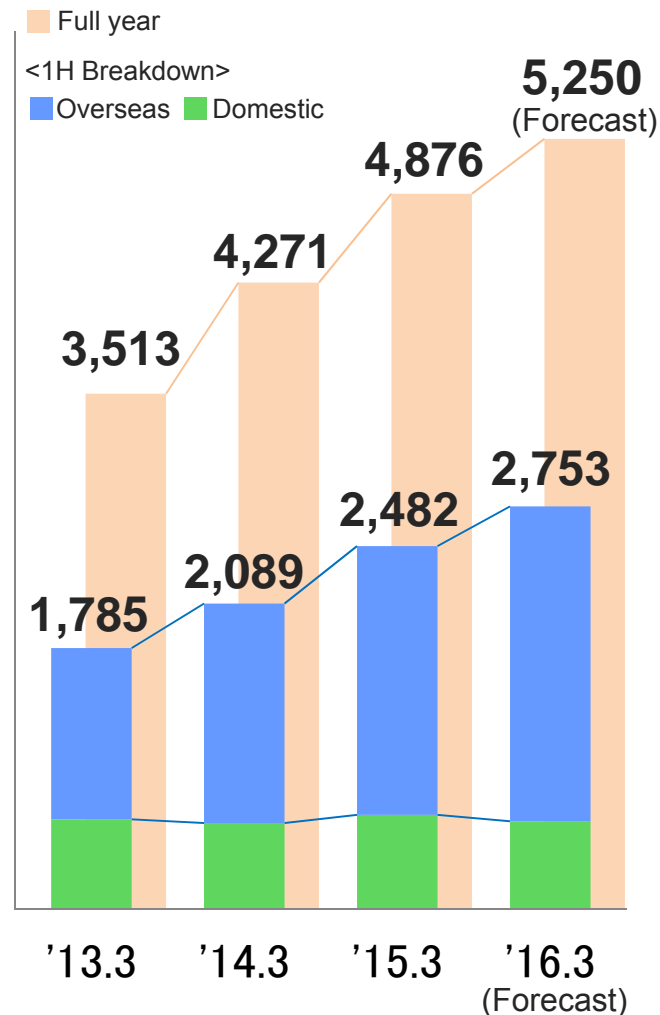


Accelerate Gel-One share expansion through support for the local sales structure, which has been expanded through an acquisition.

# Sales of LAL Business (value basis/year-on-year)

## LAL Business Sales trend

(Millions of Yen)



**1H FY2015 Results: +10.9%** (Year-on-Year)

### Overseas

Contribution from volume increases for endotoxin-detecting reagents used by pharmaceuticals manufacturers and in-vitro diagnostic reagents and the impact of yen depreciation

### Domestic

Slight decrease due to the impact of shipment timing

**FY2015 Forecast: +7.7%** (Year-on-Year)

\* No change from the forecast announced on May 12, 2015.

### Overseas

Expected strong sales of endotoxin-detecting reagents and in-vitro diagnostic reagents

### Domestic

Forecast of an increase in sales of reagent-associated equipment due to sales campaigns and other factors

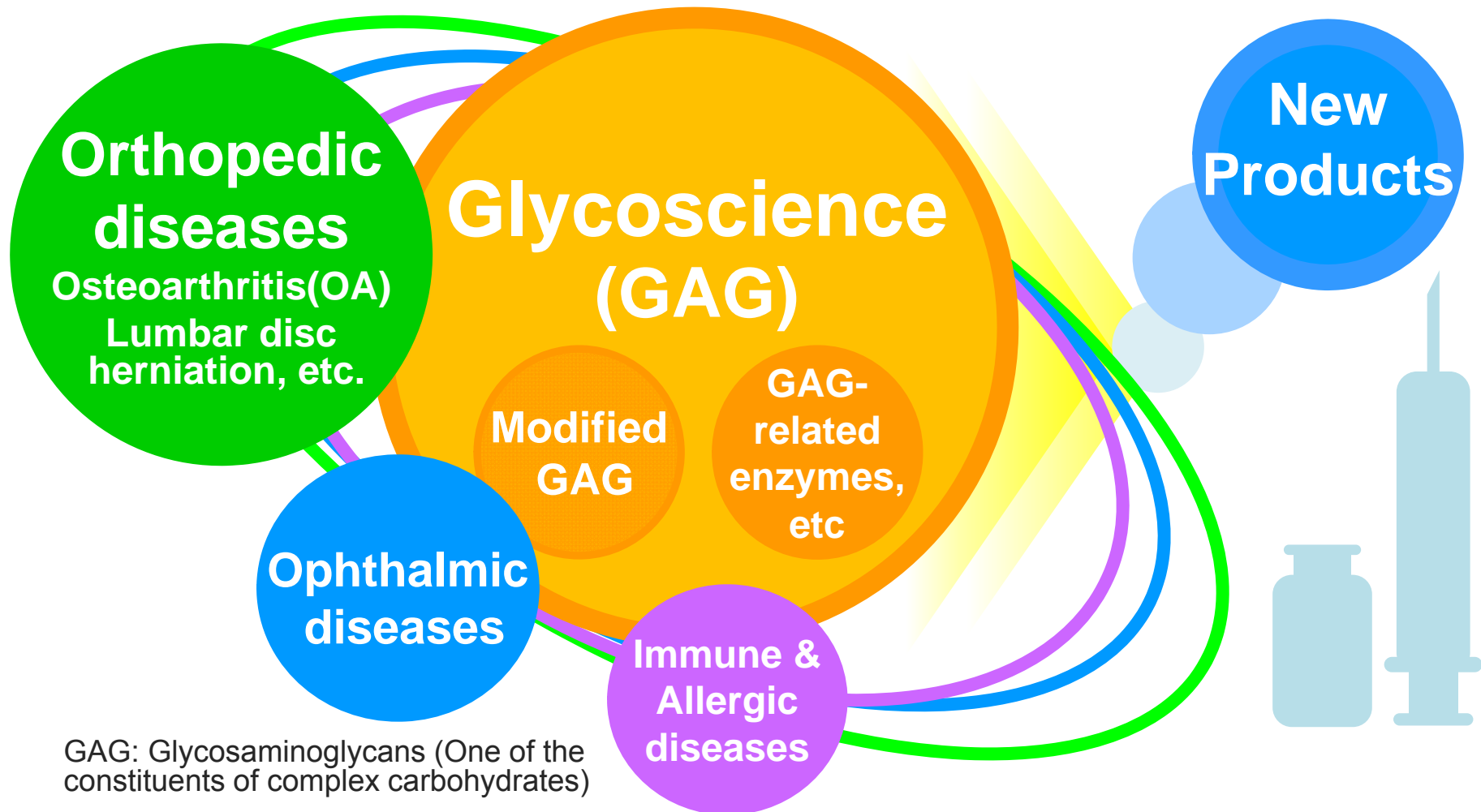
**LAL Business:** The manufacturing and sales of Endotoxin detection reagents\* used in the quality control of pharmaceuticals

\*Endotoxin detection reagents are reagents whose main ingredient is Limulus Amebocyte Lysate (LAL).



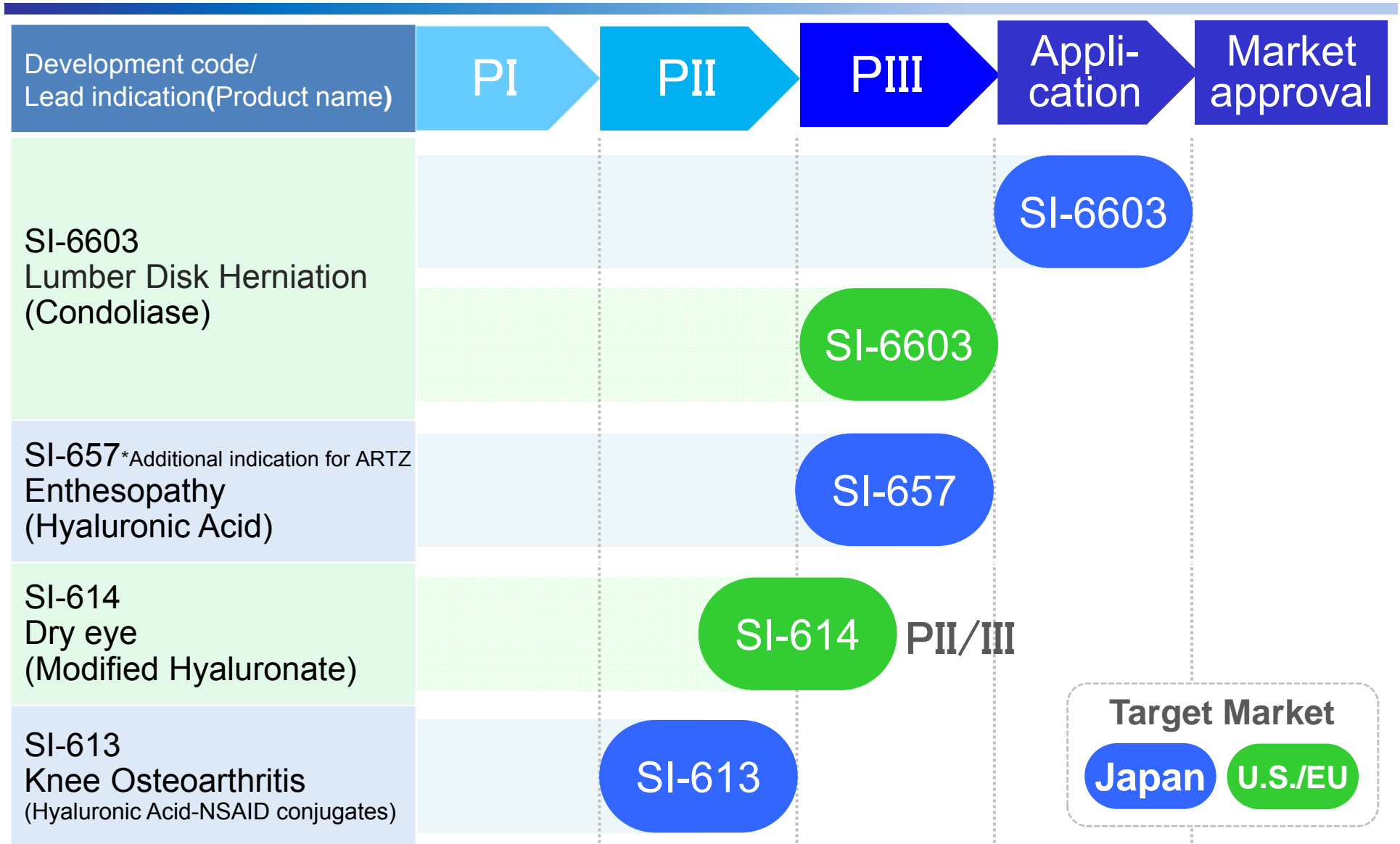
# Basic Policy on Research and Development

- Aiming for the rapid, continuous introduction of new products that meet high treatment needs, focusing on glycoscience as an area of specialization.





# Pipeline List

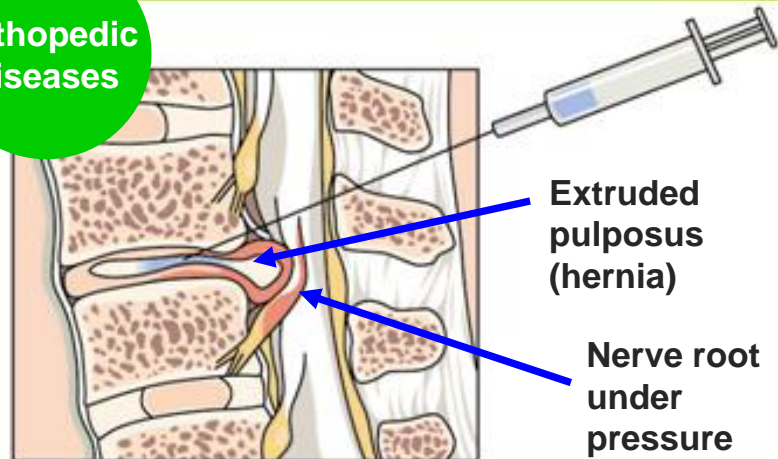


Note: The license agreement for SI-615, a treatment for rheumatoid arthritis, was terminated in August 2015.

# SI-6603 Outline (treatment of lumbar disc herniation)

Reduces nerve pressure and alleviates pain by shrinking

Orthopedic  
diseases



- Substance: Condoliase
- Indication: Lumbar disc herniation
- Method of use: Injection into lumbar disc (under X-ray observation)

## Features:

- Pain alleviated by reducing hernia-related nerve pressure through the specific degradation of GAGs (chondroitin sulfate, etc.), which are the main components of the nucleus pulposus
- No breakdown of proteins, so no adverse effect on other tissues (blood vessels, nerves, etc.)
- Single-injection treatment with SI-6603 expected to become an alternative to surgery

## Japan : NDA filed

- **January 2014: NDA filed, examination ongoing**
- Trial results announced at academic conferences:
  - Nov. 2014: NASS 29th Annual Meeting (San Francisco)
  - Apr. 2015: 44th Japanese Society for Spine Surgery and Related Research Annual Meeting (Fukuoka)
  - Sep. 2015: EUROSPINE 2015 (Copenhagen)

## U.S. / EU : PIII

- **April 2015: Open-label for the purpose of safety evaluation started**
- **July 2015: Case registration completed**

# SI-657 Outline (an additional indication for ARTZ)

Exerts an inhibitory action to improve symptoms of enthesopathy

## Japan : PIII

Orthopedic diseases

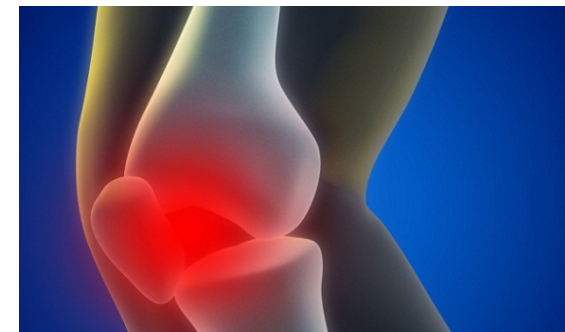
- January 2015: Follow-up observation completed  
⇒ Future development policy now being considered



- Lateral epicondylitis (tennis elbow)



- Achilles tendinitis
- plantar fasciitis



- patellar tendinitis (jumper's knee)

- **Substance:** Hyaluronic acid (additional indication for ARTZ®)
- **Indication :** Enthesopathy (targets; four conditions)
- **Development:** Joint development with Kaken Pharmaceutical

Estimated annual number of patients (total for four conditions) :  
About 570,000

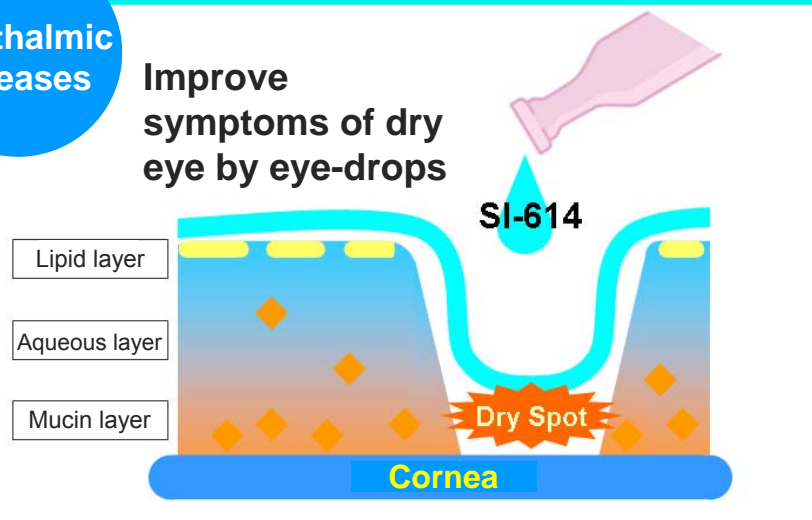
The aim is to contribute to symptom improvement in more patients by further increasing the added value of ARTZ

# SI-614 Outline (treatment of dry eye)

Improves symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing

Ophthalmic diseases

Improve symptoms of dry eye by eye-drops



- Substance : SI-614(Modified Hyaluronate)
- Indication : Dry eye
- Formulation : Ophthalmic solution

U.S. / EU : PII/III

- January 2015: Phase II/III clinical trials completed
- ⇒ Next phase trial being considered

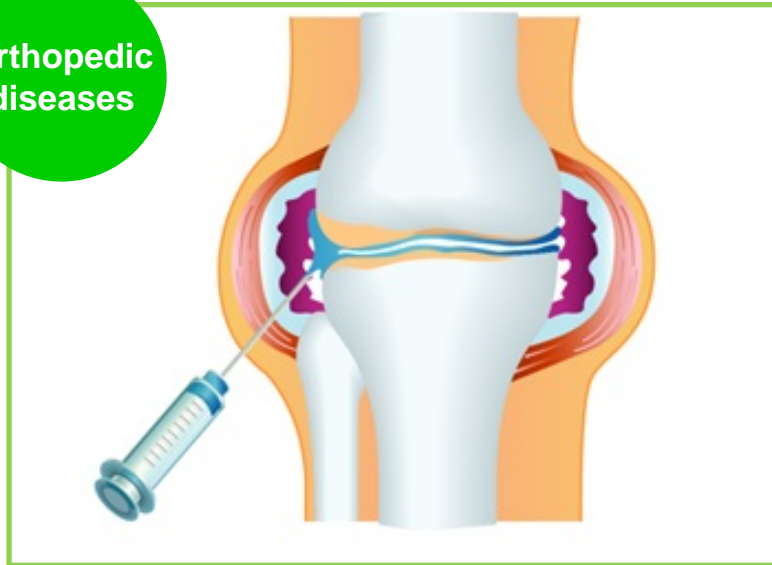
## Features :

- SI-614 is a modified hyaluronate produced by Seikagaku's proprietary technology.
- It is expected to improve symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing in dry eye patients.
- Although dry eye is a multifactorial disease, only an anti-inflammatory drug is available in the U.S. currently. SI-614 will provide a new alternative to the treatment of dry eye through the promising mode of action

# SI-613 Outline (treatment of knee osteoarthritis)

Prompt and long-term relief of severe pain and inflammation associated with knee osteoarthritis

Orthopedic diseases



- **Substance: SI-613**  
(Hyaluronic acid-NSAID<sup>\*1</sup> conjugates)
- **Indication: Knee Osteoarthritis**
- **Formulation: Injection into knee joint**

## Japan : PII

- October 2014: Submission of notification of a phase II trial (multiple dose study)
- **July 2015: Case registration completed**

### Features:

- Hyaluronic acid combined with NSAID<sup>\*1</sup> for relief of severe pain and inflammation of OA using Seikagaku's unique technology
- Sustained-release<sup>\*2</sup> of the NSAID for long-term improvement of severe pain and inflammation
- Minimal side effects compared to oral or topical treatment of the NSAID
- Aiming global deployment including Japan and U.S.

\*1 NSAID: Non-Steroidal Anti-Inflammatory Drug

\*2 Sustained release: Gradual release of active ingredients to produce a sustained therapeutic effect over a long period

# Basic Policy on Profit Distribution

\* There is no change in forecast announced on May 12, 2015.

## ● Dividends

Aim for stable and continuous dividends with a basis of an annual dividend of ¥26 per share.

## ● Internal Reserve

Appropriated for R&D, and capital investment, etc., in accordance with medium-to-long term perspective

## ● Flexible Capital Policy

Share buy-back is an option for improving capital efficiency

	FY2011	FY2012	FY2013	FY2014	FY2015 (Forecast)
Net Income per share	¥57.58	¥57.33	¥83.55	¥64.27	¥51.05
Annual Total Dividend	¥25.00	¥25.00	¥26.00	¥26.00	¥26.00
Dividend Payout Ratio	43.4%	43.6%	31.1%	40.5%	50.9%

# Appendix

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# Ten-Year Vision and Mid-term Management Plan

Ten-Year Vision “Global Category Pharma”  
Converge major R&D resources on Glycoscience and  
establish global competitiveness

**ACT for the future**

**Advance · Challenge · Transparency**

**Cultivation of new leads**

**for Achieving  
the Ten-Year Vision**

Fostering of basic corporate  
strength and development  
of core systems

**Step 1**

FY2009 ~ 2011

**Step 2**

FY2012 ~ 2015

**Vision realization**

**Step 3**

FY2016 ~ 2018

# Trend in Capital Investments

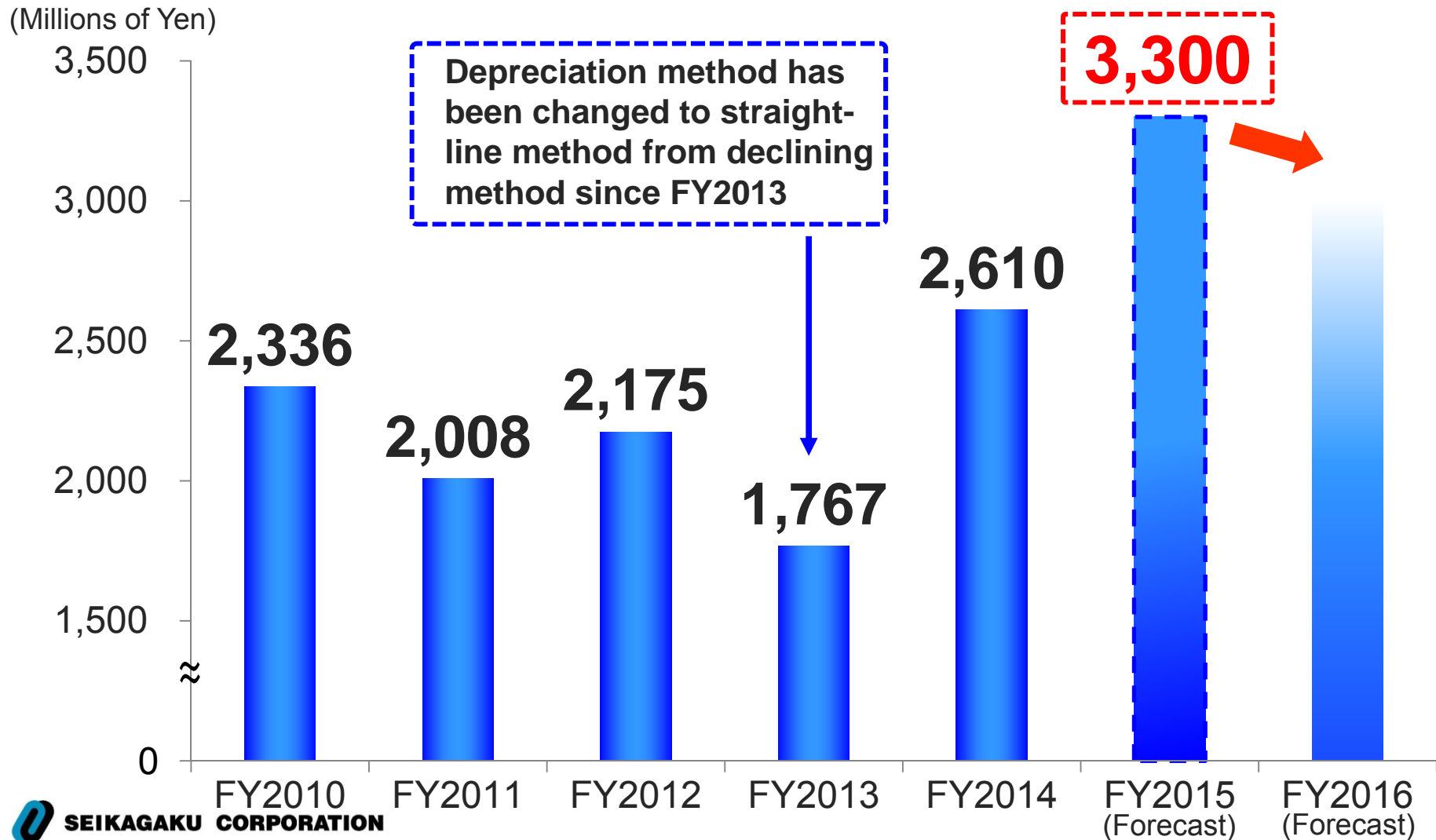
\* There is no change in forecast announced on May 12, 2015.

Facilities	Amounts (¥ bill.)	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015 (Forecast)
SI-6603 Bulk Production Facilities	1.1					Start '14.10	
No. 5 Production Building (for ARTZ Dispo®)	9.6		Start '12.3				Operation '15.1
Hyaluronic Acid Bulk Production Facilities	3.1		Start '12.1			Operation '14.2	
Facilities for Gel-One®	3.0		Start '11.12			Operation '13.10	
Chondroitin Sulfate Bulk Production Facilities	1.2		Start '11.6	Operation '12.7			
<b>Amounts (Millions of Yen)</b>		<b>1,306</b>	<b>5,718</b>	<b>9,164</b>	<b>7,222</b>	<b>2,095</b>	<b>2,600</b>

# Trend in Depreciation

\* There is no change in forecast announced on May 12, 2015.

Depreciation will peak with ¥3,300 million at FY2015 by active capital investments



# Forecasts(Net sales) in FY2015

\* There is no change in forecast announced on May 12, 2015.

(Millions of Yen)	FY2015 Forecasts	Year-on-Year	
		Change	% of Change
Net sales	30,650	+1,127	+3.8%
Pharmaceuticals	25,400	+753	+3.1%
Domestic Pharmaceuticals	16,950	+51	+0.3%
Overseas Pharmaceuticals	7,100	+760	+12.0%
Bulk Products	1,350	-57	-4.1%
LAL Business	5,250	+373	+7.7%
(Overseas sales)	11,150	+1,152	+11.5%

## Net sales

Forecast of higher sales due to the impact of yen depreciation and growth from overseas pharmaceuticals

## Pharmaceuticals

### Domestic Pharmaceuticals:

- Forecast of sales at the prior-year level

### Overseas Pharmaceuticals

- Higher volumes of Gel-One and ARTZ in China and the contribution from yen depreciation

## LAL Business

Sales increase at the U.S. subsidiary

\*Foreign exchange impact on overall net sales:  
approx. +¥870 million

# Forecasts(Income) in FY2015

\* There is no change in forecast announced on May 12, 2015.

(Millions of Yen)	FY2015 Forecasts	Year-on-Year	
		Change	% of Change
Net sales	30,650	+1,127	+3.8%
Operating Income (to Net sales ratio)	2,400 (7.8%)	+16 (-0.3pt)	+0.7%
Ordinary Income	3,800	-208	-5.2%
Net Income	2,900	-750	-20.6%
Cost of Sales ratio	41.8%	+0.7pt	
R&D Expenses (to Net sales ratio)	7,850 (25.6%)	-296 (-2.0pt)	-3.6%
Depreciation	3,300	+689	+26.4%

## Income

Despite lower R&D expenses, a decrease in net income on higher depreciation and the end of a temporary tax rate reduction

## Operating Income

### Cost of Sales (approx. +650):

- Increase in depreciation of new production facilities

### SGA Expenses (approx. +450):

- Forecast of lower R&D expenses
- Increase in sales-related expenses for Gel-One and other products

## Net Income

### Decrease in Non-operating Income (approx. -200):

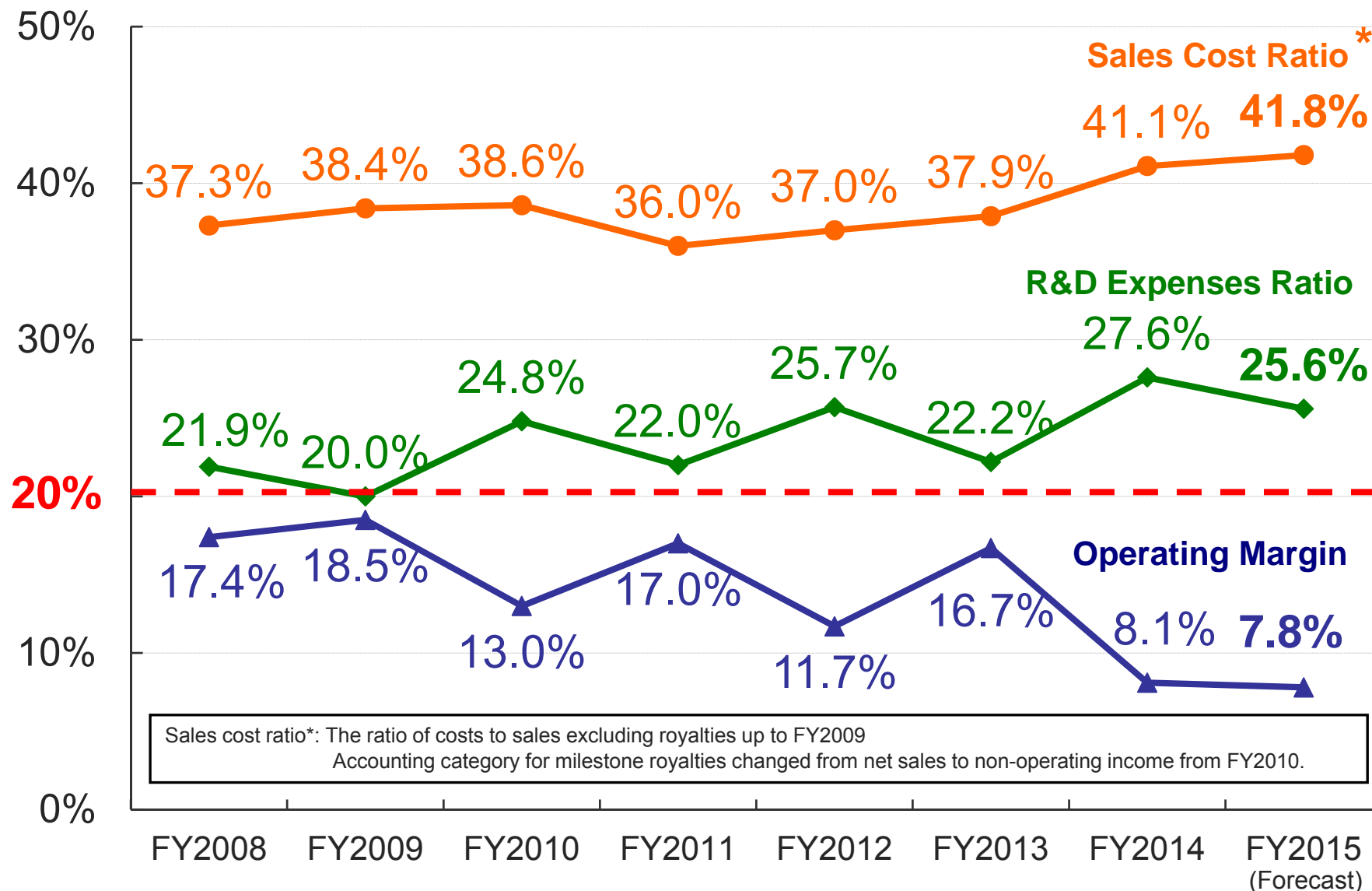
- Forecast of higher royalty income but lower foreign exchange gains

### Tax Rate Increase:

- The end of a temporary reduction

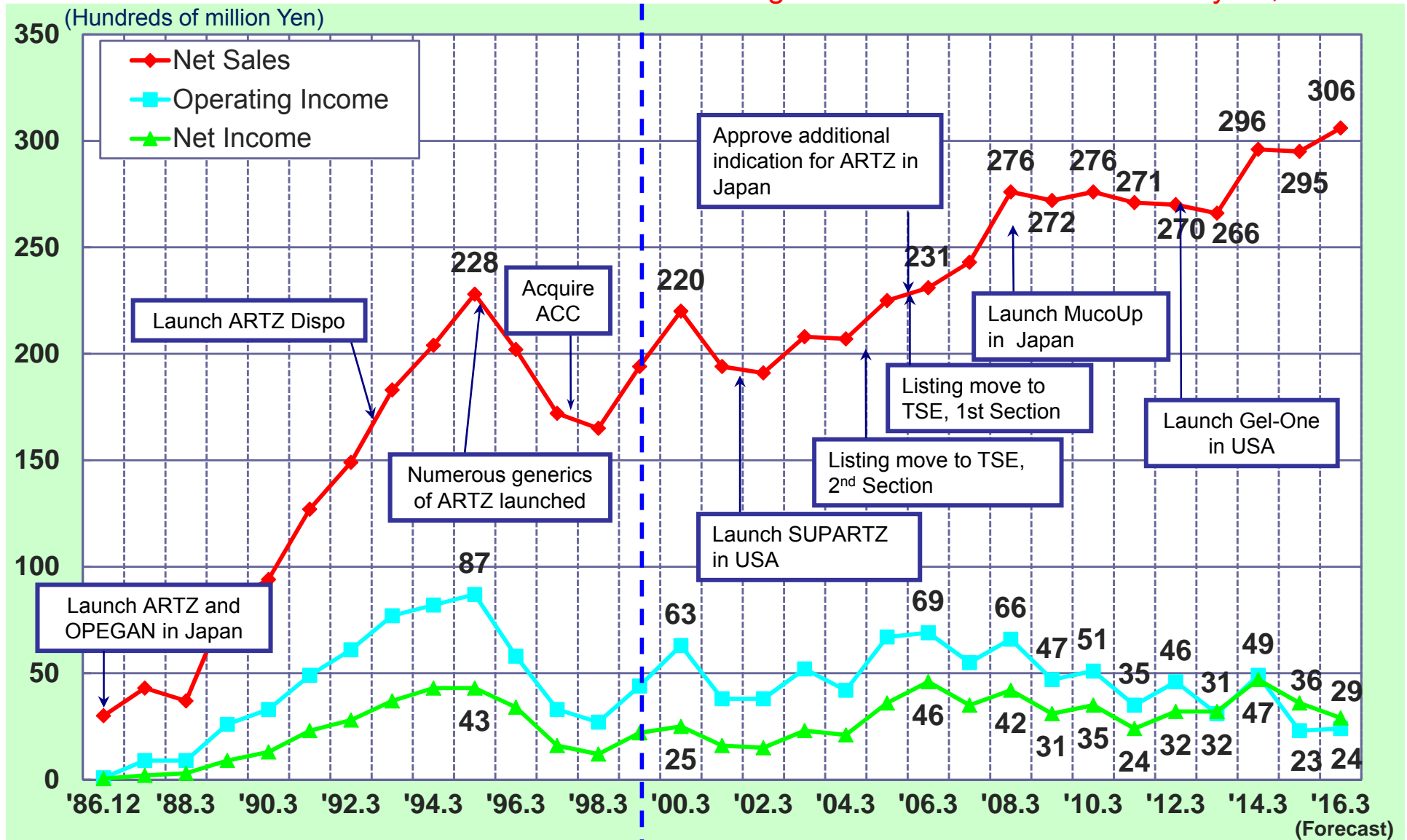
# Trend in Financial Index

\* There is no change in forecast announced on May 12, 2015.



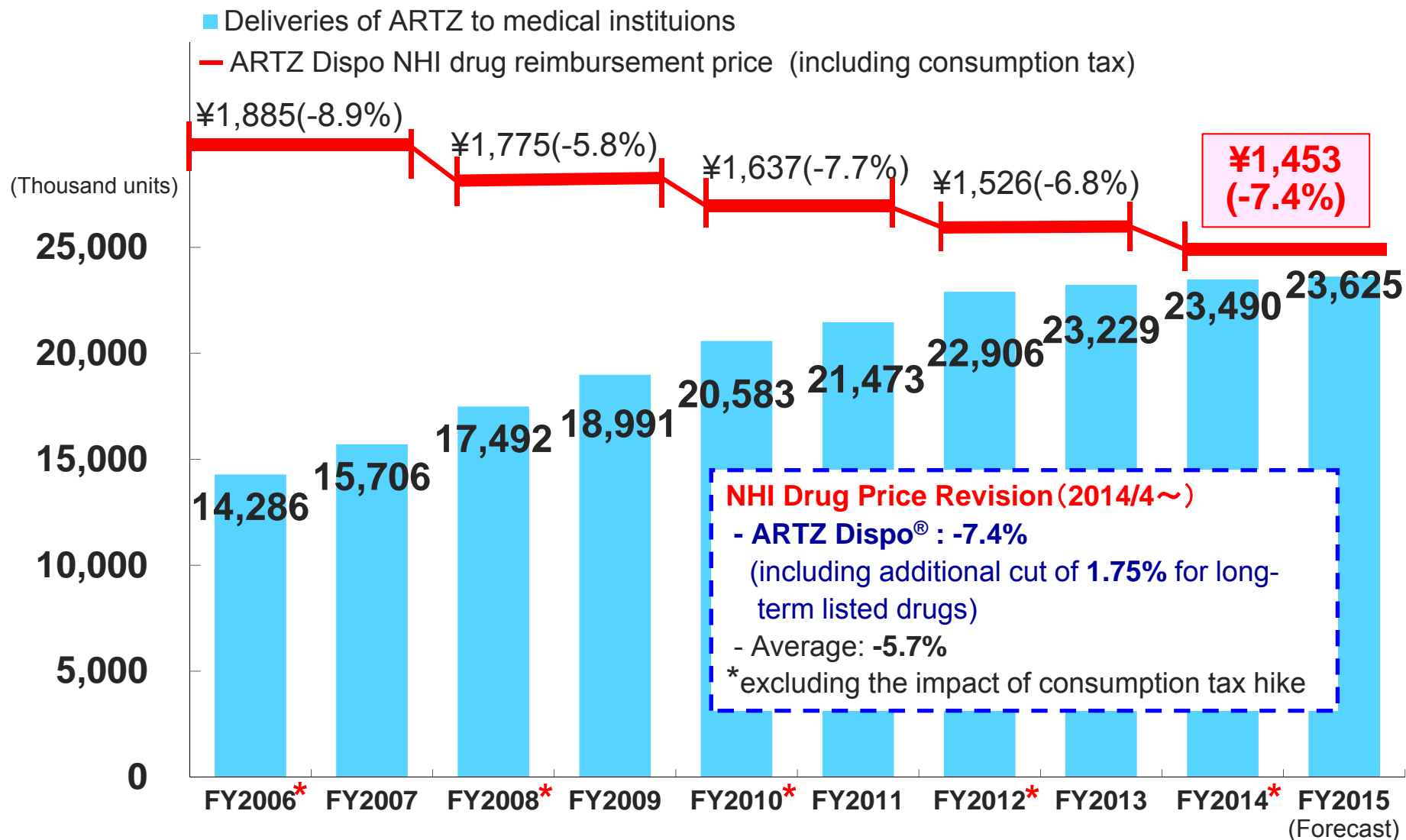
# Business Progress & Highlights

\* There is no change in forecast announced on May 12, 2015.





# Trend in NHI Reimbursement Price and Trend in Deliveries of ARTZ to Domestic Medical Institutions



**\* NHI drug price reduction**

# Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

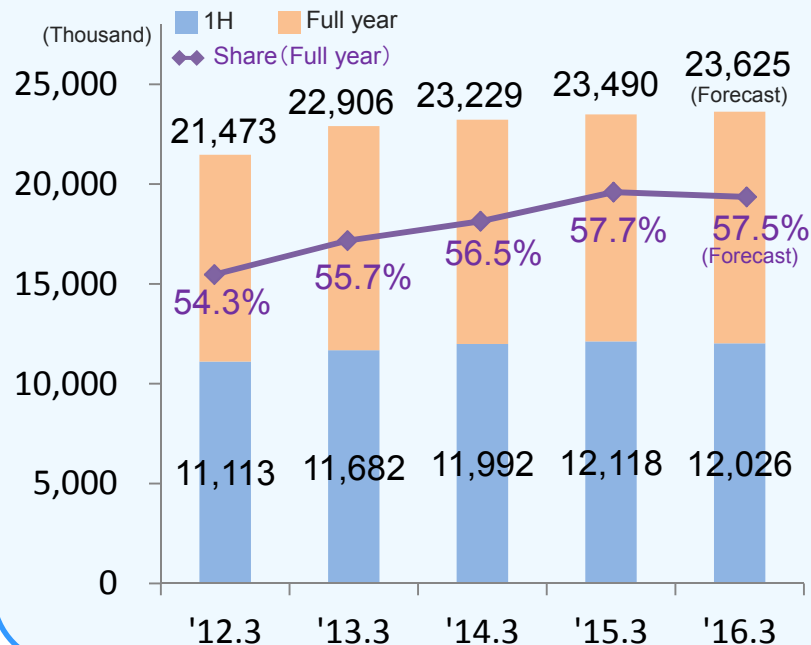
Joint-function improving agent

## ARTZ



- The first HA joint function improving agent in the world
- Knee osteoarthritis (OA) pain relief
- Distributor: Kaken Pharmaceutical

Trend in unit deliveries to medical institutions



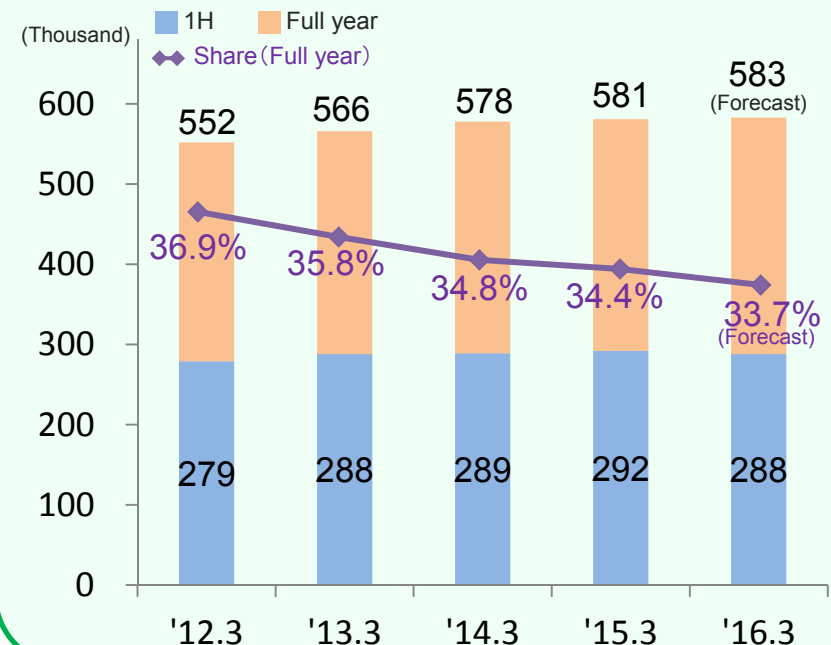
Ophthalmic surgical aids

## OPEGAN



- The first domestically HA formulation
- Used in cataract surgery to anterior chamber expansion
- Distributor: Santen Pharmaceutical

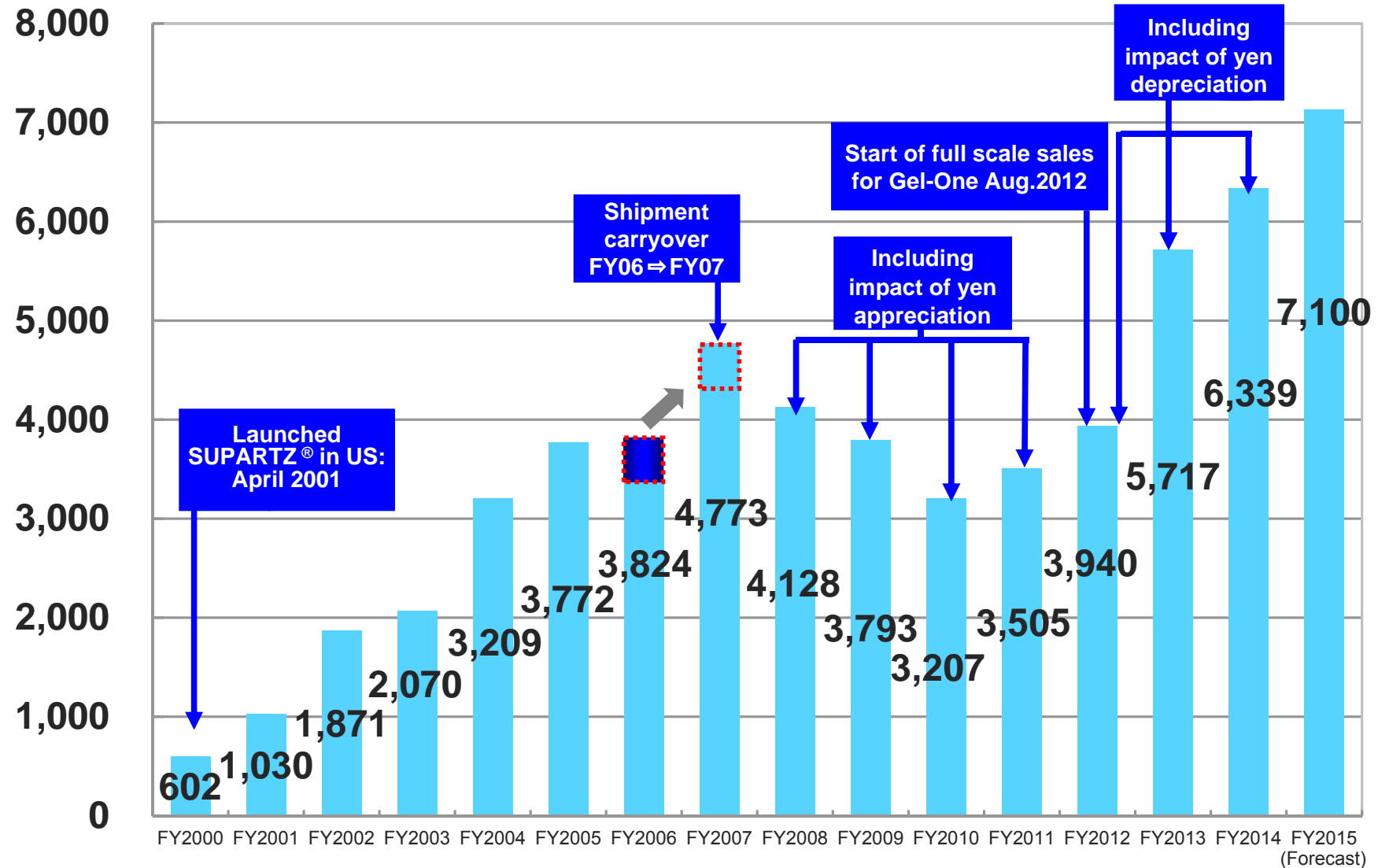
Trend in unit deliveries to medical institutions



# Trend in Overseas Sales of Hyaluronic Acid Products

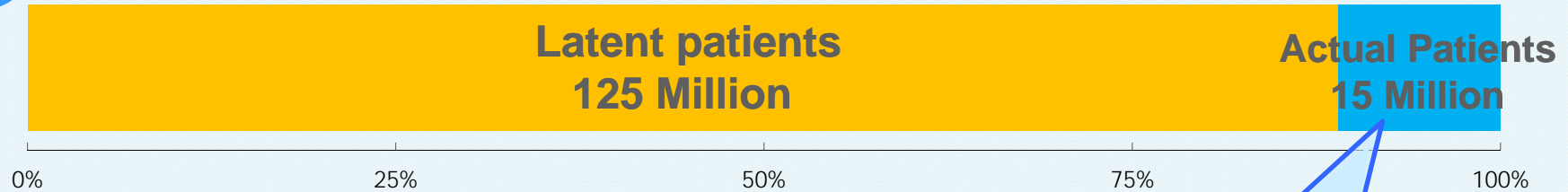
\* There is no change in forecast announced on May 12, 2015.

(Millions of Yen)



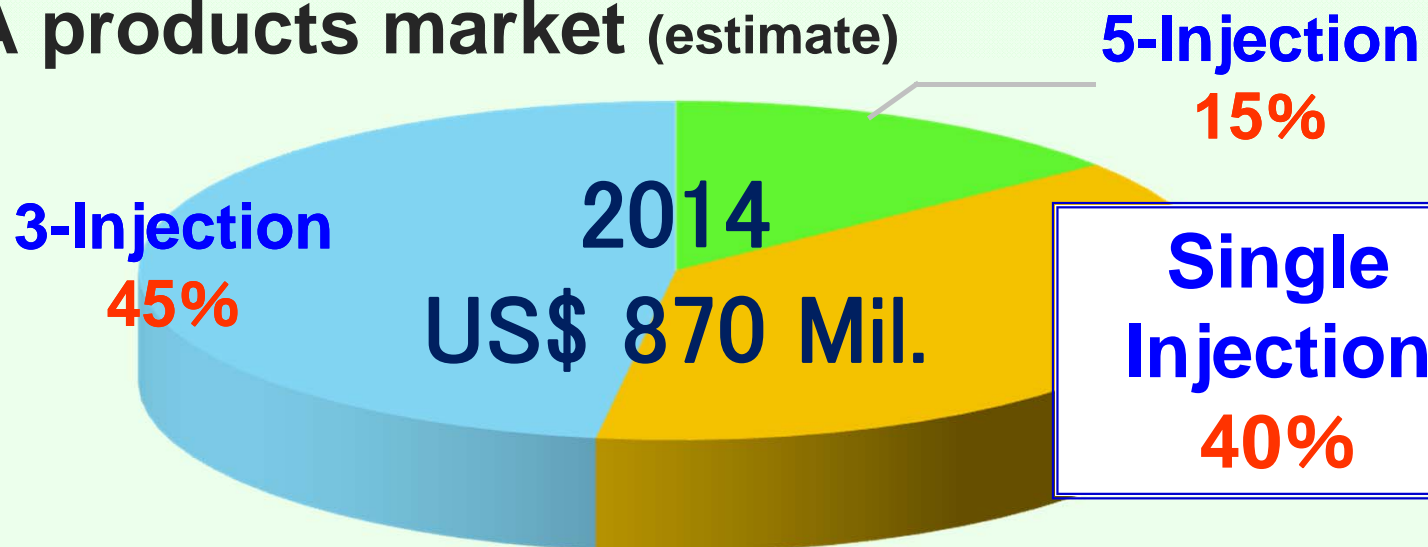
# U.S. Market for HA Products

## Number of osteoarthritis patients (estimate)



Ratio of patients using HA products is less than 10% of patients receiving any treatment for osteoarthritis.  
⇒ There is large room to expand.

## HA products market (estimate)



\* Numbers in this slide are estimated by Seikagaku

# Measures for business expansion in the U.S.



## Measure to increase product awareness

- Advertising targeting physicians and release of a mobile app for patients

## Measure to increase product value

- Gel-One/SUPARTZ labeling change clinical trials



SUPARTZ FX: Multiple injection-product

## Strengthening of sales promotion

- Product education / Preparation of sales promotion tools
- Reinforcement of sales promotion in channels where insurance reimbursement is possible



Gel-One: Single-injection product

Promote and initiate the sales partners and ACC

## Expansion of the LAL business

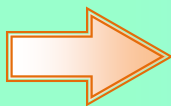
- Capturing of share from competitors through new product development and reinforcement of sales activities



Endotoxin detection reagents

Establishment of **North American Business Unit** in May 2015

- Opening of **SEIKAGAKU U.S.A. Representative Office** in October 2014

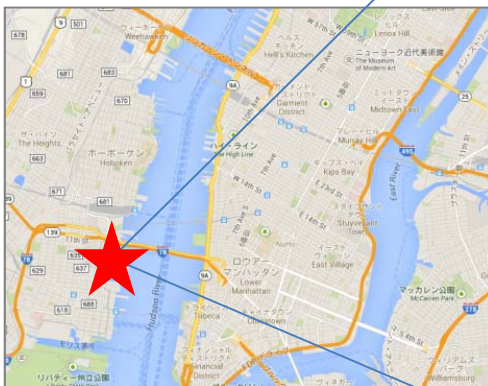


**Accelerate business development in the U.S., a key region.**

# Opening of the SEIKAGAKU U.S.A. Representative Office



## SEIKAGAKU U.S.A. Representative Office



Jersey City, NJ



Single-injection product Gel-One®



Multiple-injection product  
SUPARTZ FX™

### ◆ Overview of the Representative Office ◆

- ◆ Date of opening: October 15, 2014 (local time)
- ◆ Purpose: Provision of product education to local sales reps, gathering of information on the U.S. market

**Further acceleration of sales of Gel-One® and SUPARTZ FX™ through reinforcement of support for sales activities**



# The LAL Business

## What is the LAL business?

The manufacturing and sale of reagents used in the quality control of pharmaceuticals and in water quality Control in dialysis at hospitals

\*Endotoxin detection reagents are reagents whose main ingredient is Limulus Amebocyte Lysate (LAL).

\*Endotoxins are substances derived from bacteria. Since they cause fever even in minute amounts, testing for endotoxin contamination in pharmaceuticals is compulsory

➤ **Size of the global market: Approx. ¥20.0 billion**  
(Seikagaku estimate, including associated equipment)



Endotoxin detection reagents  
(for quality control of pharmaceuticals  
and medical devices)

## Associates of Cape Cod, Inc. (ACC)

- U.S. subsidiary of Seikagaku Corporation (established in 1974, acquired by Seikagaku in 1997)
- Developed the world's first endotoxin detection reagent and obtained FDA approval in 1977
- A sales network spanning 80 countries
- Solid business performance in recent years



PYROCHROME®

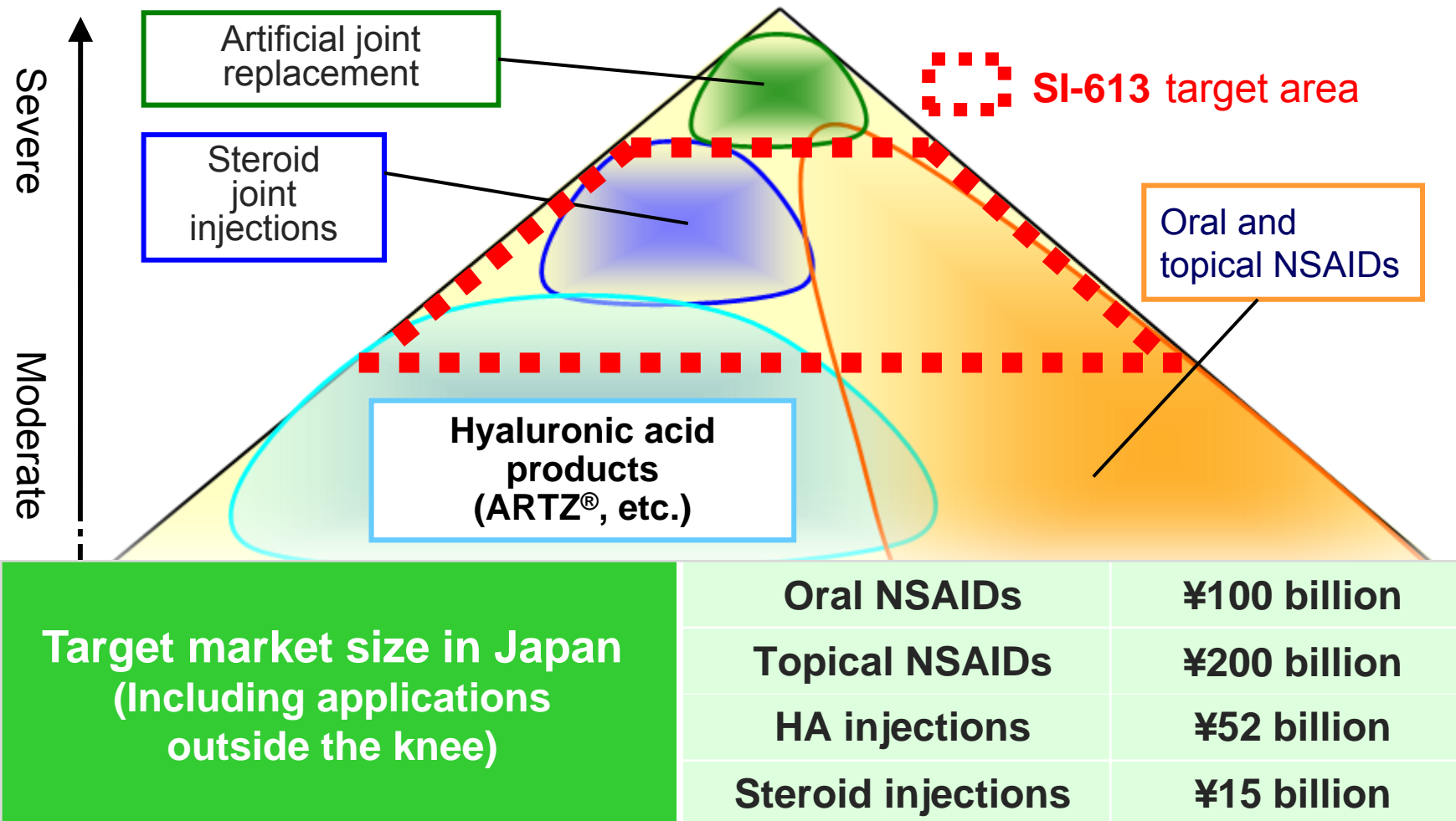


Exterior of the ACC offices



# SI-613 Target Patients

Patients with severe pain and being treated with oral or topical NSAIDs or intra-articular steroid injection



# Special Profile

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**1<sup>st</sup>**

## **Specialization in glycoscience**

- Niche field, market not big enough for the major pharmaceutical companies to penetrate
- Focusing on this field more than **60 years**

**2<sup>nd</sup>**

## **Unique business model**

- Concentration on **R&D** and **manufacturing**
- R&D staff comprising **one-third** of our total employees
- Allocation of over **20%** of net sales to R&D investment

**3<sup>rd</sup>**

## **High-level extraction & purification technologies**

- ARTZ<sup>®</sup> (main product) has been administered in more than **360 million** injections without major side effects over more than **25 years**

# Our Business Segment

## Pharmaceutical Business

Domestic  
Pharmaceuticals  
⇒ 57.2%

Joint Function  
Improving Agents



83.5%

Net Sales  
¥29,522million  
(FY2014 Results)

LAL Business  
16.5%

Ophthalmic Surgical Aids



Surgical Aids for Endoscopic  
Mucosal Resection



Bulk Products  
⇒ 4.8%

Bulk Products



Endotoxin-detecting reagents  
(used mainly for quality control of  
pharmaceuticals and medical devices)



# Main Hyaluronic Acid (HA) Products

## **ARTZ<sup>®</sup>** Knee osteoarthritis (OA) pain relief by multiple injections

- The first HA joint function improving agent in the world
- Main distributors:

Kaken Pharmaceutical (Japan): ARTZ<sup>®</sup>

Bioventus (U.S.): SUPARTZ FX<sup>™</sup>

Kunming Baker Norton

Pharmaceutical (China): ARTZ<sup>®</sup>



## **Gel-One<sup>®</sup>** Knee OA pain relief by a single injection

- Requires only 3ml to be as effective as multiple injections
- Full-scale sales since August 2012
- Distributor: Zimmer (U.S.)



## ***Exploring the Innovative Promise of Glycoscience***

### **Cautionary statement regarding forward-looking information**

This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launch, pricing and product initiatives of competitors, the inability of the company to market existing and new products effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation.

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**SEIKAGAKU CORPORATION**