

# Financial Results for the First Half of Fiscal Year 2016

(April 1, 2016 – September 30, 2016)



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



**SEIKAGAKU CORPORATION**

(TSE:4548)

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### < Cautionary Notes >

This material contains forward-looking statements regarding future management strategies or performance forecasts. These statements are based on judgments derived from information that is currently available to Seikagaku and are subject to risk and uncertainty. Actual results and developments may differ significantly from these forward-looking statements due to various factors.

Information about pharmaceutical products or medical devices (including products currently in development) included in this material is not intended to constitute an advertisement or medical advice.

# Overview for 1H of FY2016

(Millions of Yen)	1H FY2016 Results	Year-on-Year		(Reference) FY2016 Revised Forecasts	
		Change	% of Change	Full Year Forecasts	Degree of Progress
<b>Net sales</b>	<b>15,085</b>	<b>-868</b>	<b>-5.4%</b>	<b>29,650</b>	<b>50.9%</b>
<b>Operating Income</b>	<b>783</b>	<b>-1,267</b>	<b>-61.8%</b>	<b>1,250</b>	<b>62.6%</b>
<b>Ordinary Income</b>	<b>1,376</b>	<b>-1,198</b>	<b>-46.5%</b>	<b>2,650</b>	<b>51.9%</b>
<b>Net Income</b>	<b>1,013</b>	<b>-927</b>	<b>-47.8%</b>	<b>2,000</b>	<b>50.7%</b>
<b>R&amp;D Expenses (Ratio to net sales)</b>	<b>4,109 (27.2%)</b>	<b>+359 (+3.7pt)</b>	<b>+9.6%</b>	<b>7,850 (26.5%)</b>	<b>52.3%</b>
Average Exchange Rate (1US\$)	¥105.35	-¥16.45		2H forecast ¥103.00	

	1H FY2016 Results	1H FY2015 Results	(Reference) FY2016 Revised Forecasts
<b>Net Income per Share</b>	<b>¥17.87</b>	<b>¥34.18</b>	<b>¥35.30</b>

# Net sales by Business Segment (1H of FY2016)

(Millions of Yen)	1H FY2016 Results	Year-on-Year	% of Change
Net sales	15,085	-868	-5.4%
Pharmaceuticals	12,281	-919	-7.0%
Domestic Pharmaceuticals	8,518	-190	-2.2%
Overseas Pharmaceuticals	3,227	-603	-15.7%
Bulk Products	536	-125	-18.9%
LAL Business	2,803	+50	+1.8%
(Overseas sales)	5,408	-604	-10.1%

\*Foreign exchange impact on overall net sales:  
approx. -710 million yen

## Domestic Pharmaceuticals

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

- Sales decrease as a result of the impact of NHI drug price reductions (-7.2%), despite a volume increase accompanying introduction of new syringes



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

### ➤ OPEGAN series (ophthalmic surgical aid)

- SHELLGAN launched in July and off to a favorable start
- Slight sales increase, with a volume increase offsetting the impact of NHI drug price reductions



OPEGAN:  
Ophthalmic surgical aid used primarily in cataract surgery

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

- Seikagaku sales up partly attributable to an inventory buildup accompanying a change in sales partner in April 2016

# Net sales by Business Segment (1H of FY2016)

(Millions of Yen)	1H FY2016 Results	Year-on-Year	% of Change
Net sales	15,085	-868	-5.4%
<b>Pharmaceuticals</b>	<b>12,281</b>	<b>-919</b>	<b>-7.0%</b>
Domestic Pharmaceuticals	8,518	-190	-2.2%
<b>Overseas Pharmaceuticals</b>	<b>3,227</b>	<b>-603</b>	<b>-15.7%</b>
Bulk Products	536	-125	-18.9%
LAL Business	2,803	+50	+1.8%
(Overseas sales)	5,408	-604	-10.1%

\*Foreign exchange impact on overall net sales:  
approx. -710 million yen

## Overseas Pharmaceuticals

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

- Continued solid growth in local sales (30% up)
- Seikagaku sales up, with a volume increase compensating for the impact of yen appreciation



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

### ➤ ARTZ (multiple injection)

#### ● SUPARTZ FX in the U.S:

- Local sales down slightly amid fierce competition
- Seikagaku sales down, reflecting the backlash against a high level of shipments in FY2015 1H and the impact of yen appreciation

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

#### ● ARTZ in China:

- Local sales down because of the government's price-curbing policy
- Seikagaku sales down due to the added impact of yen appreciation

# Net sales by Business Segment (1H of FY2016)

(Millions of Yen)	1H FY2016 Results	Year-on-Year	% of Change
Net sales	15,085	-868	-5.4%
Pharmaceuticals	12,281	-919	-7.0%
Domestic Pharmaceuticals	8,518	-190	-2.2%
Overseas Pharmaceuticals	3,227	-603	-15.7%
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LAL Business	2,803	+50	+1.8%
(Overseas sales)	5,408	-604	-10.1%

\*Foreign exchange impact on overall net sales:  
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## Bulk Products

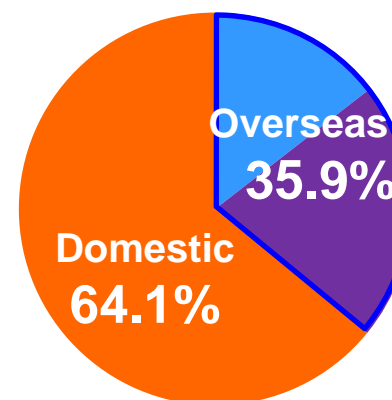
- Sales of chondroitin sulfate at the prior-year level, but overall sales down, reflecting fierce competition in the market for hyaluronic acid

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

## LAL Business

- Sales up on higher sales of endotoxin-detecting reagents and other products, compensating for the impact of yen appreciation on overseas sales

## Overseas Sales Ratio



Year-on-Year:  
Down 1.8 pt

■ Overseas LAL/Bulk ■ Overseas Pharmaceuticals ■ Domestic sales

# Income for 1H of FY2016 (Year-on-Year)

(Millions of Yen)	1H FY2016 Results	Year-on-Year	% of Change
Net sales	<b>15,085</b>	<b>-868</b>	<b>-5.4%</b>
Cost of Sales (Cost of Sales ratio)	<b>6,570</b> (43.6%)	<b>+26</b> (+2.6pt)	<b>+0.4%</b>
SGA expenses	<b>7,731</b>	<b>+372</b>	<b>+5.1%</b>
R&D Expenses (to Net sales ratio)	<b>4,109</b> (27.2%)	<b>+359</b> (+3.7pt)	<b>+9.6%</b>
Operating Income (to Net sales ratio)	<b>783</b> (5.2%)	<b>-1,267</b> (-7.7pt)	<b>-61.8%</b>
Ordinary Income	<b>1,376</b>	<b>-1,198</b>	<b>-46.5%</b>
Net Income	<b>1,013</b>	<b>-927</b>	<b>-47.8%</b>
Depreciation	<b>1,452</b>	<b>-115</b>	<b>-7.4%</b>

## Operating Income

### Cost of Sales ratio (+2.6pt):

Increase due to the impact of yen appreciation and NHI drug price reductions

### SGA Expenses (+372):

Increase in R&D expenses accompanying progress with the open-label trial for SI-6603 in the U.S. (+359)

## Net Income

### Non-operating Income/Expenses (+68):

- Recording of royalty income (+565)
- Recording of foreign exchange losses on foreign currency-denominated assets accompanying yen appreciation (-287)
- Decrease in profit on sale of investment securities (-258)

### Income Taxes (Tax Rate: 26.4%):

Tax rate increase accompanying contribution of the U.S. subsidiary profit (+1.8pt)

# Revised Forecasts in FY2016

(Millions of Yen)	FY2016 Revised Forecasts	Initial Forecasts		FY2015 Results		(Reference) Degree of 1H Progress
		Change	% of Change	Change	% of Change	
Net sales	29,650	+100	+0.3%	-1,312	-4.2%	50.9%
Operating Income	1,250	+250	+25.0%	-894	-41.7%	62.6%
Ordinary Income	2,650	-700	-20.9%	-850	-24.3%	51.9%
Net Income	2,000	-550	-21.6%	-578	-22.4%	50.7%
R&D Expenses (to Net sales ratio)	7,850 (26.5%)	-550 (-1.9pt)	-6.5%	-799 (-1.4pt)	-9.2%	52.3%
Average Exchange Rate (1US\$)	<sup>2H forecast</sup> ¥103.00	-¥7.00		-¥17.14		

	FY2016 Revised Forecasts	FY2016 Initial Forecasts	FY2015 Results	Exchange Rate Sensitivity (Impact of a change of ¥1 against the US\$)	
Net Income per share	¥35.30	¥45.00	¥45.39	Net sales (2H only)	Approx. ¥55 million
Dividend per share	¥26.00	¥26.00	¥26.00	Operating income (2H only)	Approx. ¥25 million
Dividend Payout ratio	73.7%	57.8%	57.3%		



# Revised Net Sales in FY2016 (Comparison with the initial forecast)

(Millions of Yen)	FY2016 Revised Forecasts	Initial Forecasts	
		Change	% of Change
Net sales	<b>29,650</b>	<b>+100</b>	<b>+0.3%</b>
Pharmaceuticals	<b>24,500</b>	<b>+200</b>	<b>+0.8%</b>
Domestic Pharmaceuticals	<b>16,250</b>	<b>+350</b>	<b>+2.2%</b>
Overseas Pharmaceuticals	<b>7,100</b>	<b>-250</b>	<b>-3.4%</b>
Bulk Products	<b>1,150</b>	<b>+100</b>	<b>+9.5%</b>
LAL Business	<b>5,150</b>	<b>-100</b>	<b>-1.9%</b>
(Overseas sales)	<b>11,000</b>	<b>-400</b>	<b>-3.5%</b>

\*Foreign exchange impact on overall net sales:  
approx. -530 million yen

## Net sales

Sales in line with the initial forecast on strong domestic pharmaceuticals sales, despite the impact of yen appreciation on overseas sales

## Pharmaceuticals

### Domestic Pharmaceuticals:

- Steady sales of SHELLGAN and other products

### Overseas Pharmaceuticals:

- Sales decrease due to yen appreciation exceeding the initial assumption

### Bulk Products:

- Sales increase due to change of shipping schedule

## LAL Business

Despite volume in line with the initial forecast, sales decrease due to yen appreciation exceeding the initial assumption

# Revised Income in FY2016 (Comparison with the initial forecast)

(Millions of Yen)	FY2016 Revised Forecasts	Initial Forecasts	
		Change	% of Change
Net sales	29,650	+100	+0.3%
Operating Income (to Net sales ratio)	1,250 (4.2%)	+250 (+0.8pt)	+25.0%
Ordinary Income	2,650	-700	-20.9%
Net Income	2,000	-550	-21.6%
Cost of Sales ratio	43.8%	+1.8pt	
R&D Expenses (to Net sales ratio)	7,850 (26.5%)	-550 (-1.9pt)	-6.5%
Depreciation	2,950	-50	-1.7%

## Income

Operating income revised upward following a review of expenses

Ordinary income revised downward due to a decrease in non-operating income

## Operating Income

### Cost of Sales ratio (43.8%):

- Increase due to one-time factor accompanying the introduction of new ARTZ syringes and yen appreciation (+1.8pt)

### SGA Expenses (approx. -750):

- Review of R&D expenses, sales promotion expenses, and other expenses in light of the current situation

## Net Income

### Decrease in Non-operating Income (approx. -950):

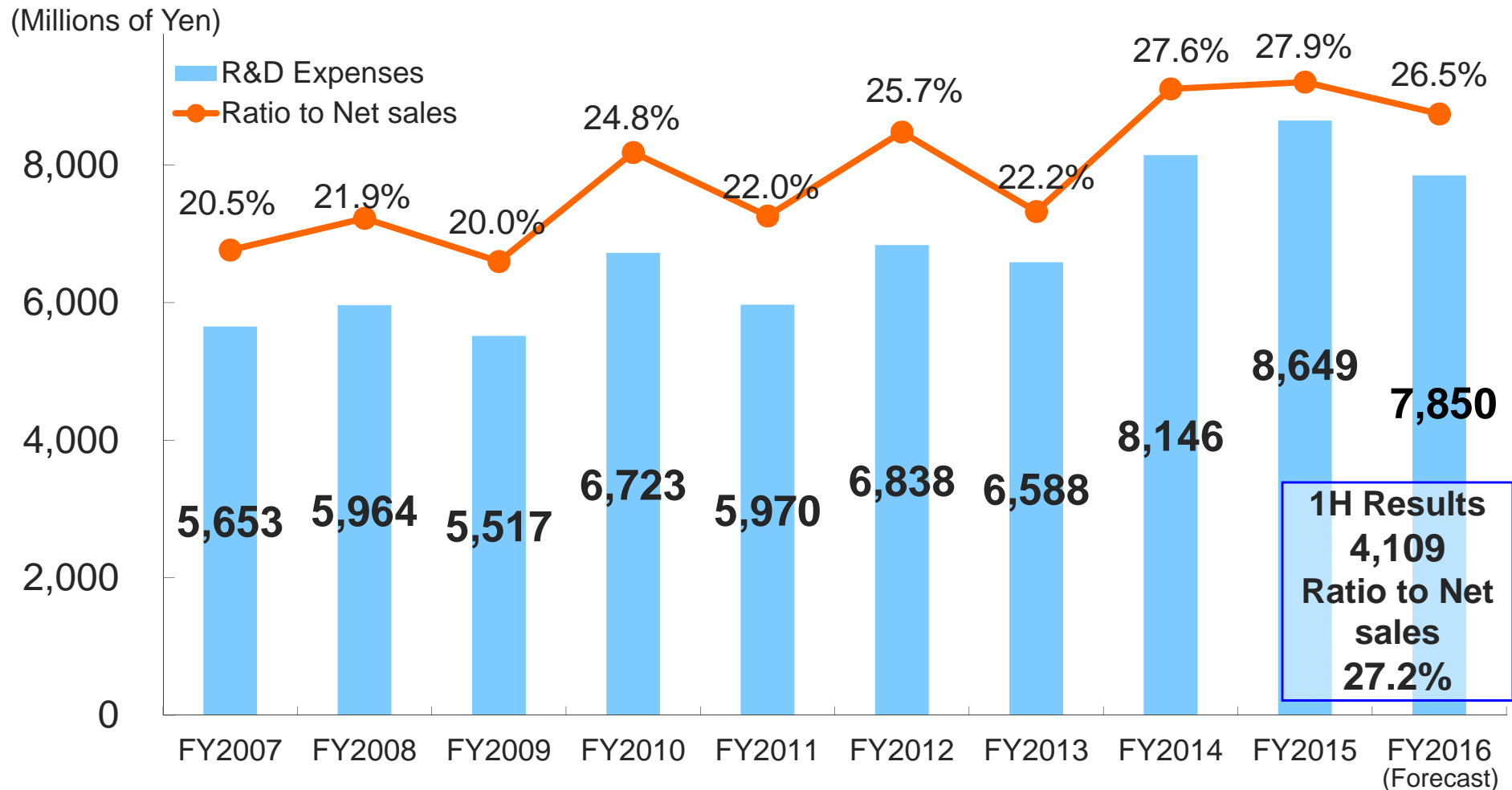
- Decrease in royalty income
- Increase in foreign exchange losses accompanying continued yen appreciation

### Tax Rate Increase:

- Increase in the profit contribution of the U.S. subsidiary



# Trend in R&D Expenses

Although R&D expenses remain at a high level, engaging in efficient, prioritized R&D



# Domestic Pharmaceuticals

(unit deliveries to medical institutions/Year-on-Year)

	1H FY2016 Results	FY2016 Forecasts	
Joint-function improving agent <b>ARTZ</b> 	<ul style="list-style-type: none"> <li>Conducted sales promotion actively accompanying introduction of a new syringe</li> <li>Captured share from competitors</li> </ul> <p>ARTZ growth rate: +3.5% (Market growth rate: +0.4%) Market share: 59.0%</p>	<ul style="list-style-type: none"> <li>Engage in sales activities in selected key areas</li> </ul> <p>ARTZ growth rate <b>+2.5%</b> (forecast)</p>	<ul style="list-style-type: none"> <li>Market share <b>59.0%</b> (forecast)</li> </ul>
	1H FY2016 Results	FY2016 Forecasts	
Ophthalmic surgical aids <b>OPEGAN</b> (including SHELLGAN) 	<ul style="list-style-type: none"> <li>New product SHELLGAN launched in July and off to a favorable start</li> <li>Recovered market share</li> </ul> <p>OPEGAN growth rate: +4.8% (Market growth rate: +4.3%) Market share: 34.0%</p>	<ul style="list-style-type: none"> <li>Publicize SHELLGAN's product features</li> <li>Retake share from competitors</li> </ul> <p>OPEGAN growth rate <b>+12.7%</b> (forecast)</p>	<ul style="list-style-type: none"> <li>Market share <b>36.5%</b> (forecast)</li> </ul>

# Ophthalmic Surgical Aid SHELLGAN (Launched July 2016)

眼科手術補助剤 薬価基準収載  
**シェルガン® 0.5 眼粘弾剤**

精製ヒアルロン酸ナトリウム/コンドロイチン硫酸エステルナトリウム

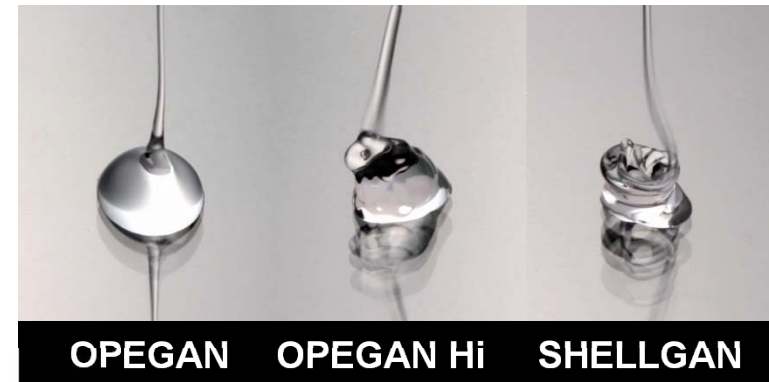


## Launch of the new product SHELLGAN

- Suited to a surgical procedure that has become more pervasive in recent years
- Can be stored at room temperature
  - ⇒ A product feature unavailable from competitors
- Strengthening of the OPEGAN series product line
  - ⇒ Seven-product line up provides a wider range of options appropriate to symptoms and physician needs



The OPEGAN series, used mainly in cataract surgery



The OPEGAN series viscoelasticity comparison

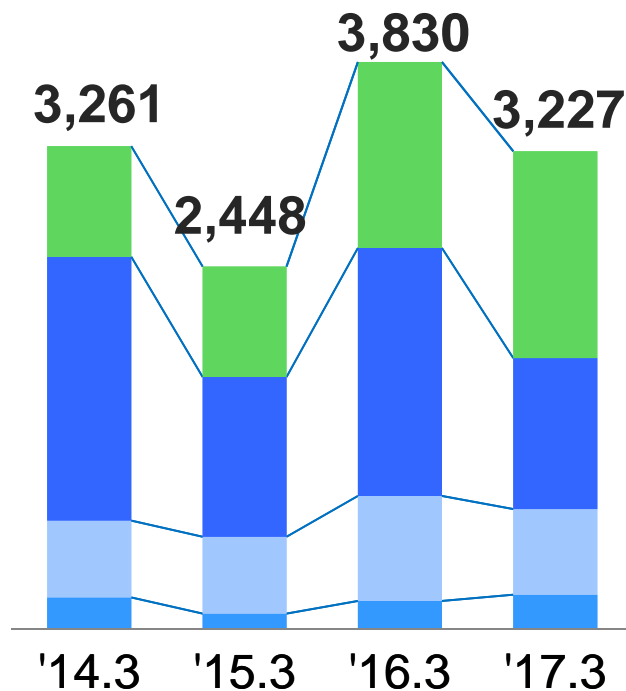
# Overseas Pharmaceuticals (value basis / Year-on-Year)

## Overseas Pharmaceuticals 1H Sales trend

(Millions of Yen)

<Breakdown>

■ Gel-One      ■ SUPARTZ FX in the U.S.  
■ ARTZ in China    ■ Other areas



**FY2016 1H  
Results**  
**-15.7%**

Decrease due to yen appreciation and lower volumes of SUPARTZ FX sold in the U.S.

\*Foreign exchange impact: approx. -¥530 million

## Gel-One (single injection)

- Local sales: Solid growth (Approx. 30% up)
- Seikagaku exports: Increased as volume growth compensated for the impact of yen appreciation

## ARTZ (multiple injection)

- **SUPARTZ FX in the U.S.**  
Slight decrease in local sales amid fierce competition in the market for multiple injection products
- **ARTZ in China**  
Decrease in local sales because of the impact of the government's price-curbing policy (10% down)
- **Seikagaku exports**  
Decrease due to yen appreciation and a decrease in SUPARTZ FX shipments from a high level in FY2015 1H  
\*Brand name changed to SUPARTZ FX in Oct. 2015

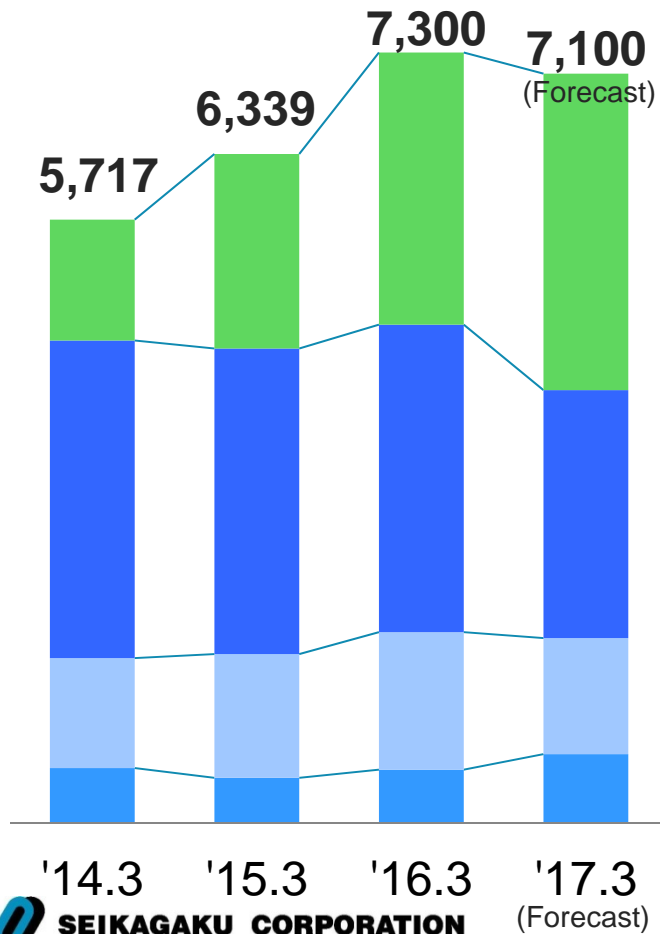
# Overseas Pharmaceuticals (value basis / Year-on-Year)

## Overseas Pharmaceuticals Full Year Sales trend

(Millions of Yen)

<Breakdown>

- Gel-One
- SUPARTZ FX in the U.S.
- ARTZ in China
- Other areas



**FY2016 Forecast**  
-2.7%

Sales decrease due to the impact of yen appreciation, despite an expected 2H increase in shipments

\*Foreign exchange impact: approx. -¥1,050 million

## Gel-One (single injection)

- Local sales: Forecast of a further increase of 30%
- Seikagaku exports: Increase as higher volumes compensate for yen appreciation  
Slight decrease from the initial forecast accompanying a review of the 2H exchange rate (¥110 ⇒ ¥103 to the US\$)

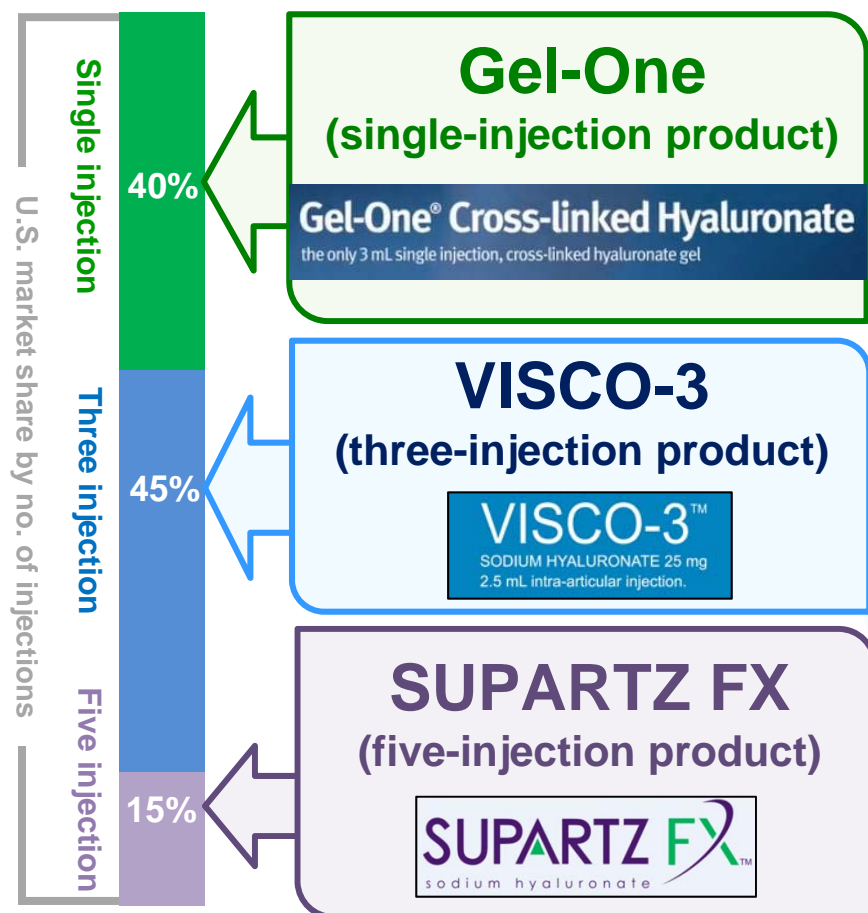
## ARTZ (multiple injection)

- **SUPARTZ FX in the U.S.**  
Forecast of fierce competition and a continued decline in local sales
- **ARTZ in China**  
Review of the full-year sales forecast in light of current circumstances (10% down)
- **Seikagaku exports**  
Planned concentration of shipments in 2H  
Decrease from the initial forecast due to a review of the 2H exchange rate

# Measures to Strengthen Product Presence in the U.S.

## Product value enhancement and product line reinforcement as the leading company in the joint function improving agent field

■ U.S. market share by number of injections (2015 figures, including competitors. Seikagaku estimates)



### 【Gel-One】

- September 2016: Efficacy extension label change (13 weeks ⇒ 26 weeks)
- August 2015: Safe use in retreatment label change

### 【VISCO-3】

- November 2016: Conclusion of an exclusive sales agreement with Zimmer Biomet



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

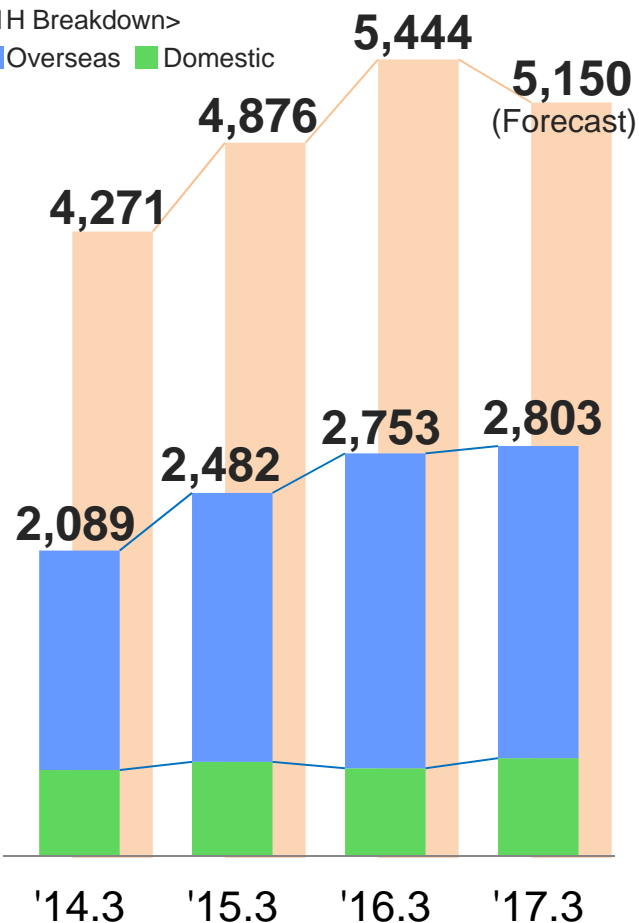
## LAL Business Sales trend

(Millions of Yen)

Full year

<1H Breakdown>

Overseas Domestic



1H FY2016 Results: +1.8% (Year-on-Year)

## Overseas

Favorable sales of in-vitro diagnostic reagents, but sales at the prior-year level due to the impact of yen appreciation

## Domestic

Increase in sales of endotoxin detection reagents and related equipment

FY2016 Forecast: -5.4% (Year-on-Year)

## Overseas

Decrease due to the impact of yen appreciation, despite a forecast of local sales increase

## Domestic

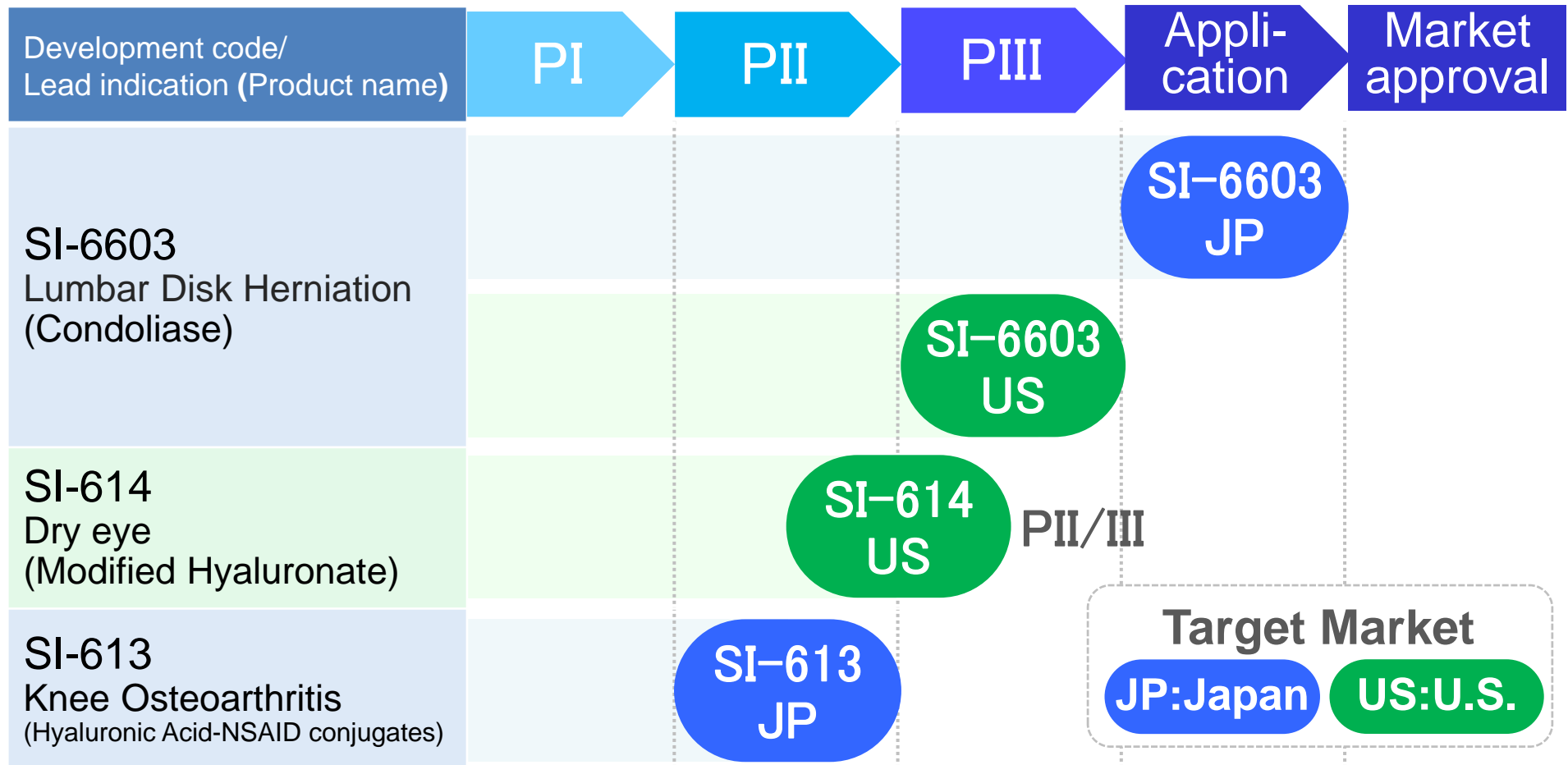
Steady sales of endotoxin detection reagents and other products

**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).

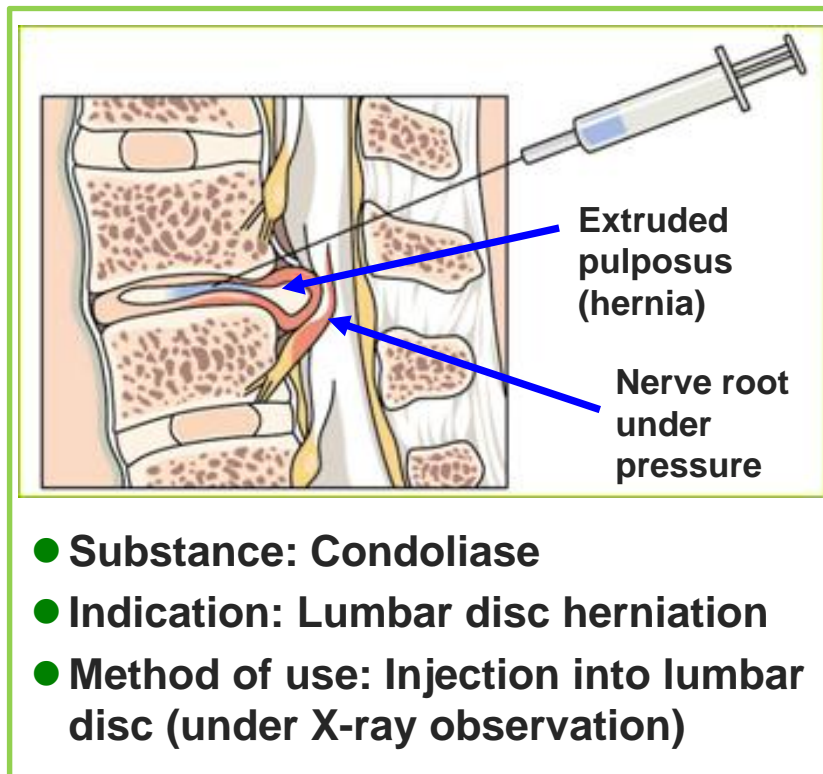
# Pipeline List (Research and Development themes)

Aiming for the early, continuous introduction of new products, focusing on glycoscience as an area of specialization



# SI-6603 Outline (Treatment for Lumbar Disc Herniation)

Reduces nerve pressure and alleviates pain by shrinking



## Japan : NDA filed

- January 2014: NDA filed, examination ongoing
  - \*Approval during FY2016 is difficult because the review response relating to product quality control taking longer than expected. Aiming to obtain approval continuously

## U.S. : PIII

- July 2015: PIII case registration completed
  - ⇒ Follow-up observation ongoing
- August 2016: Open-label trial case registration completed
  - ⇒ Follow-up observation ongoing
- August 2016: Conclusion of a license agreement with Ferring Pharmaceuticals

### 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

# Agreements Status for SI-6603 (Treatment for Lumbar Disc Herniation)

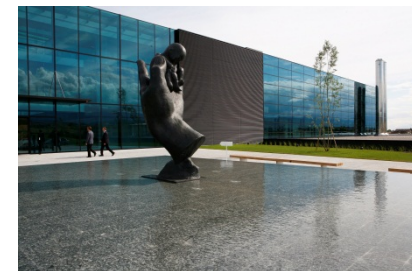
**Licensing of exclusive overseas development and marketing rights to Ferring Pharmaceuticals**  
**Planned receipt of milestone royalties of up to \$90 million in accordance with future progress**

## Overseas: Ferring Pharmaceuticals (Switzerland)



**SEIKAGAKU CORPORATION**

- An R&D-driven biopharmaceutical group established in 1950
- Worldwide sales: 1.8 billion euros (2015)
- August 2016: Conclusion of an exclusive worldwide (excluding Japan) license agreement



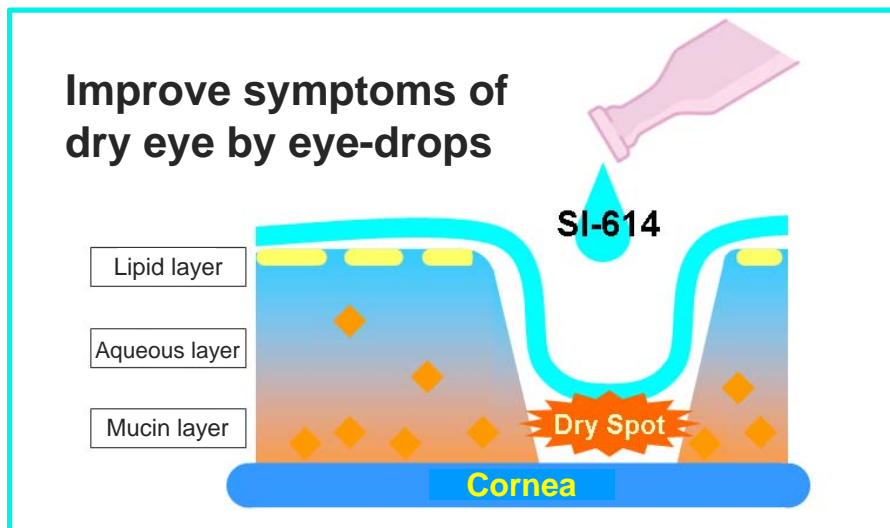
Ferring Pharmaceuticals headquarters (Saint-Prex, Switzerland)

## Japan: Kaken Pharmaceutical Co., Ltd.

- Sales partner for the joint function improving agent ARTZ
- December 2012: Conclusion of an exclusive distribution agreement in Japan

# SI-614 Outline (Treatment of Dry Eye)

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



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

**U.S. : PII/III**

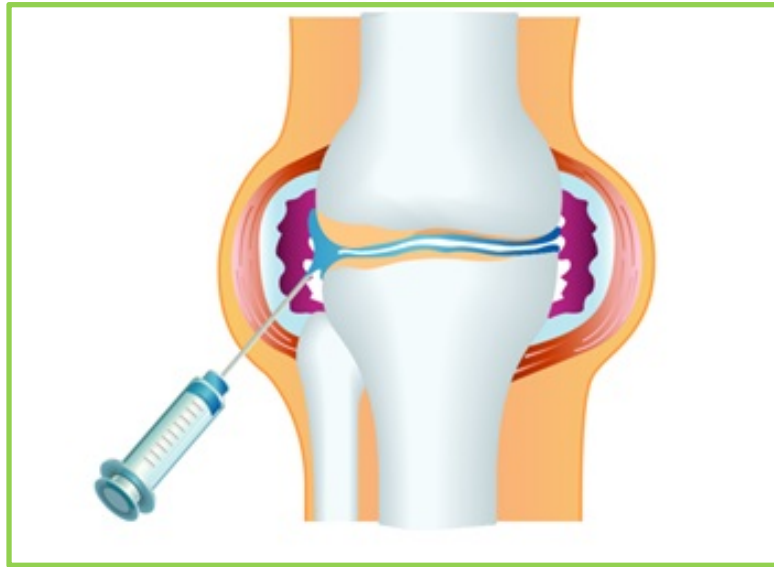
- January 2015: Phase II/III clinical trials completed
- ⇒ Proceed with consideration of a PIII trial and sales partner search

## 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



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

### Japan : PII

- July 2015: Case registration completed
- January 2016: Phase II (multiple dose study) completed
  - ⇒ Preparation ongoing for a PIII trial based on PII results

### 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

**Aim to enhance shareholder returns and realize sustained growth by engaging in well-balanced business investment**

## Shareholder Return Policy

- Aim for stable and continuous dividends from a medium to long term perspective
  - ⇒ Continue to pay **an annual dividend of ¥26 per share**
- Consider purchases of treasury stock, as appropriate, taking into account future business development and the total return ratio
  - ⇒ **Treasury stock purchases in July 2016** (200,000 shares / ¥332 million)

## Business Investment

- Business investment in R&D, production system development, and other areas

	FY2012	FY2013	FY2014	FY2015	FY2016 (Forecast)
Net Income per share	¥57.33	¥83.55	¥64.27	¥45.39	¥35.30
Annual Total Dividend	¥25.00	¥26.00	¥26.00	¥26.00	¥26.00
Dividend Payout Ratio	43.6%	31.1%	40.5%	57.3%	73.7%

# Appendix

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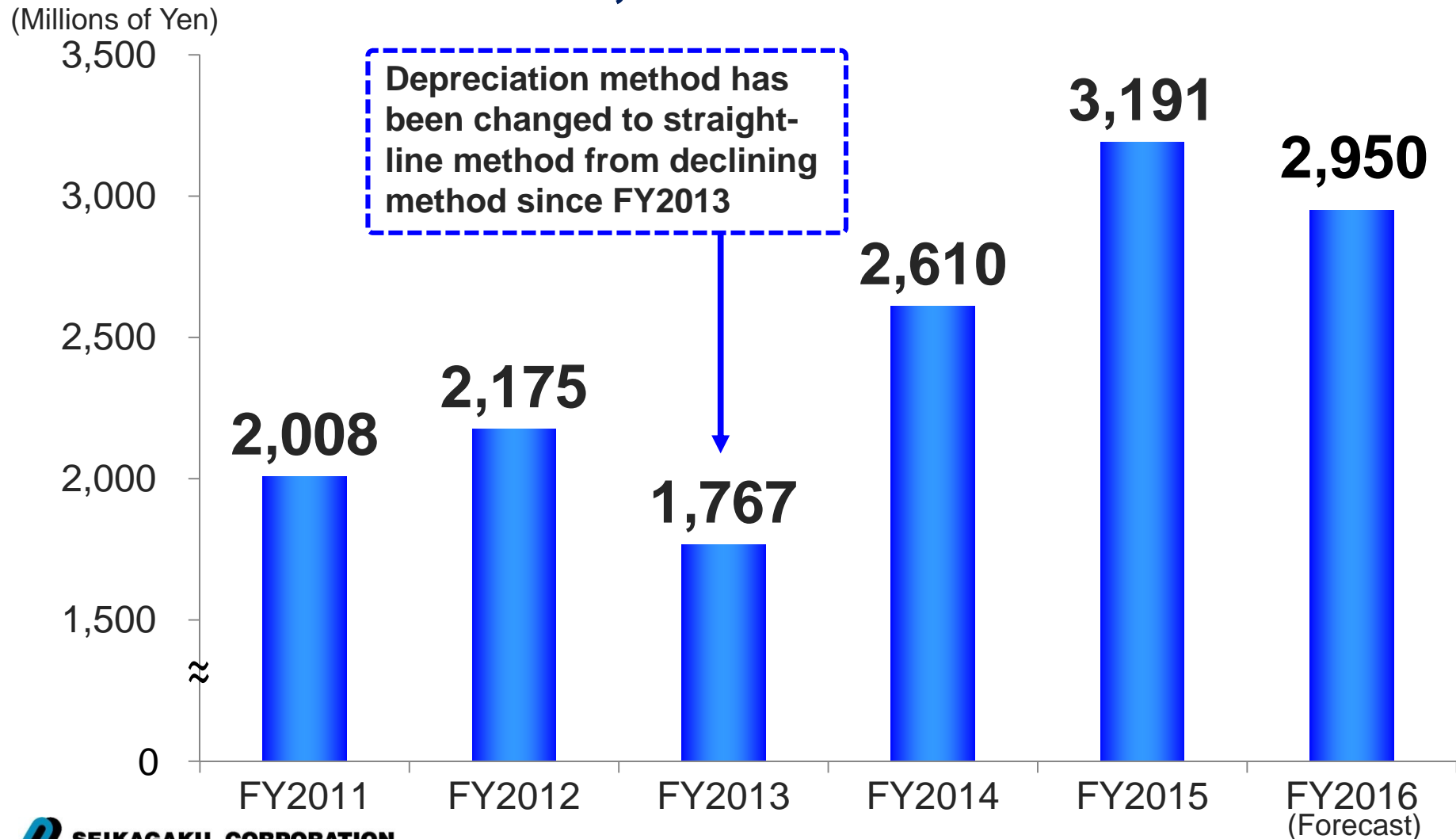


# Trend in Capital Investments

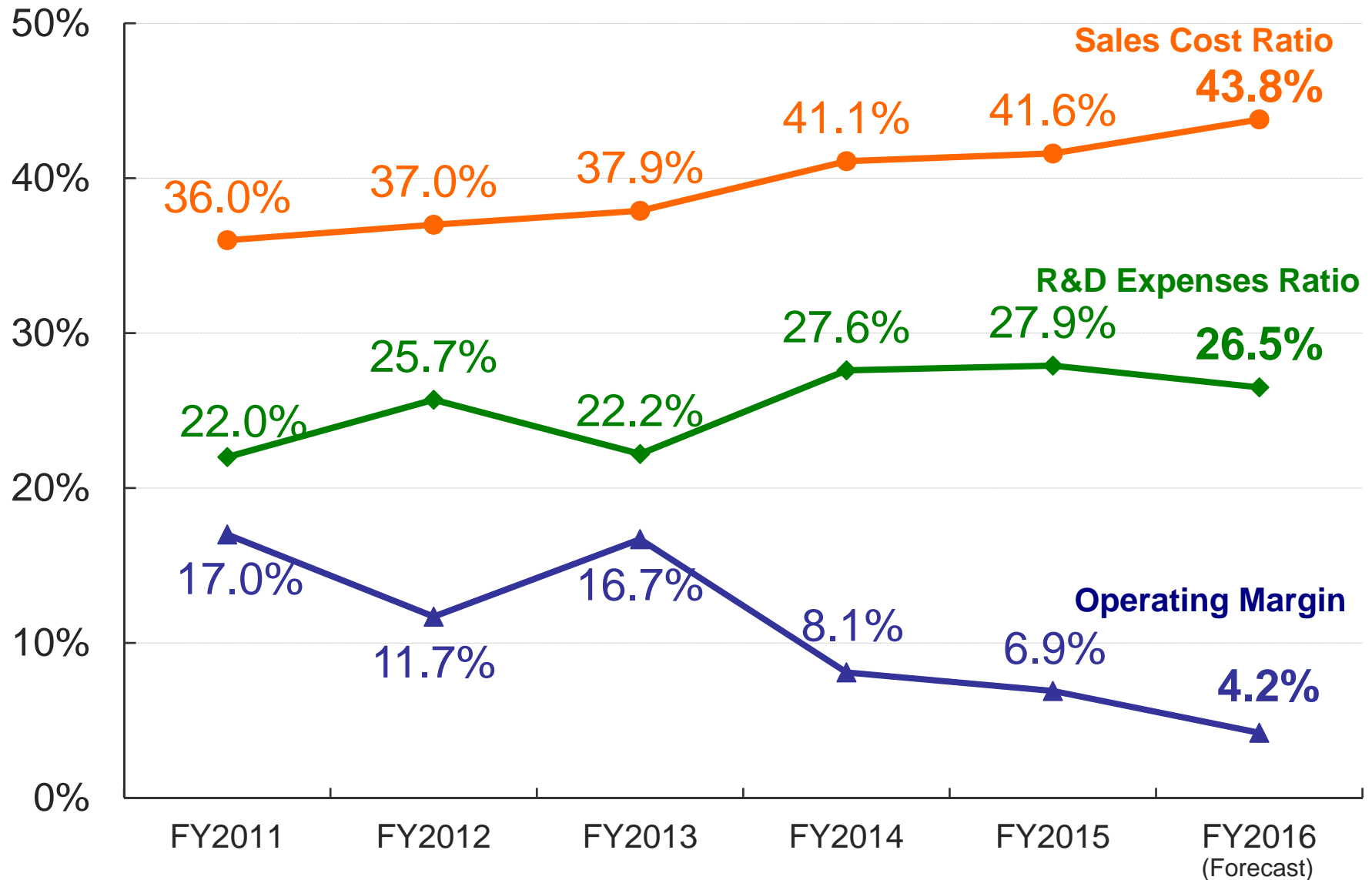
Facilities	Amounts (¥ bill.)	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016 (Forecast)
SI-6603 Bulk Production Facilities	1.1				Start '14.10		
No. 5 Production Building (for ARTZ Dispo®)	9.6	Start '12.3				Operation '15.1	
Hyaluronic Acid Bulk Production Facilities	3.1	Start '12.1			Operation '14.2		
Facilities for Gel-One®	3.0	Start '11.12			Operation '13.10		
Chondroitin Sulfate Bulk Production Facilities	1.2		Operation '12.7				
<b>Amounts (Millions of Yen)</b>		<b>5,718</b>	<b>9,164</b>	<b>7,222</b>	<b>2,095</b>	<b>1,975</b>	<b>1,550</b>

# Trend in Depreciation

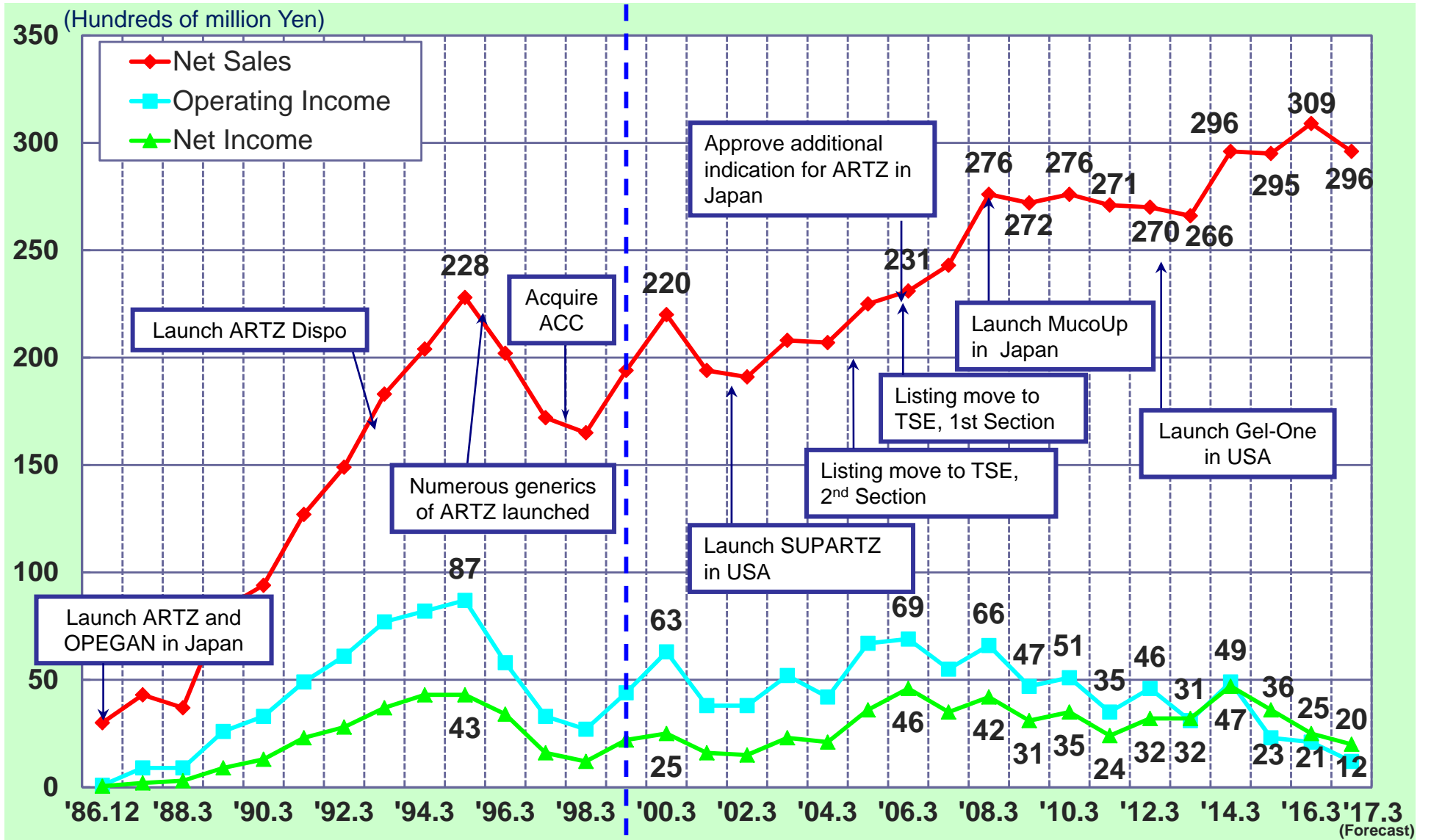
**Depreciation peaked out at FY2015 and anticipate the level of ¥3,000 million from now on**



# Trend in Financial Index

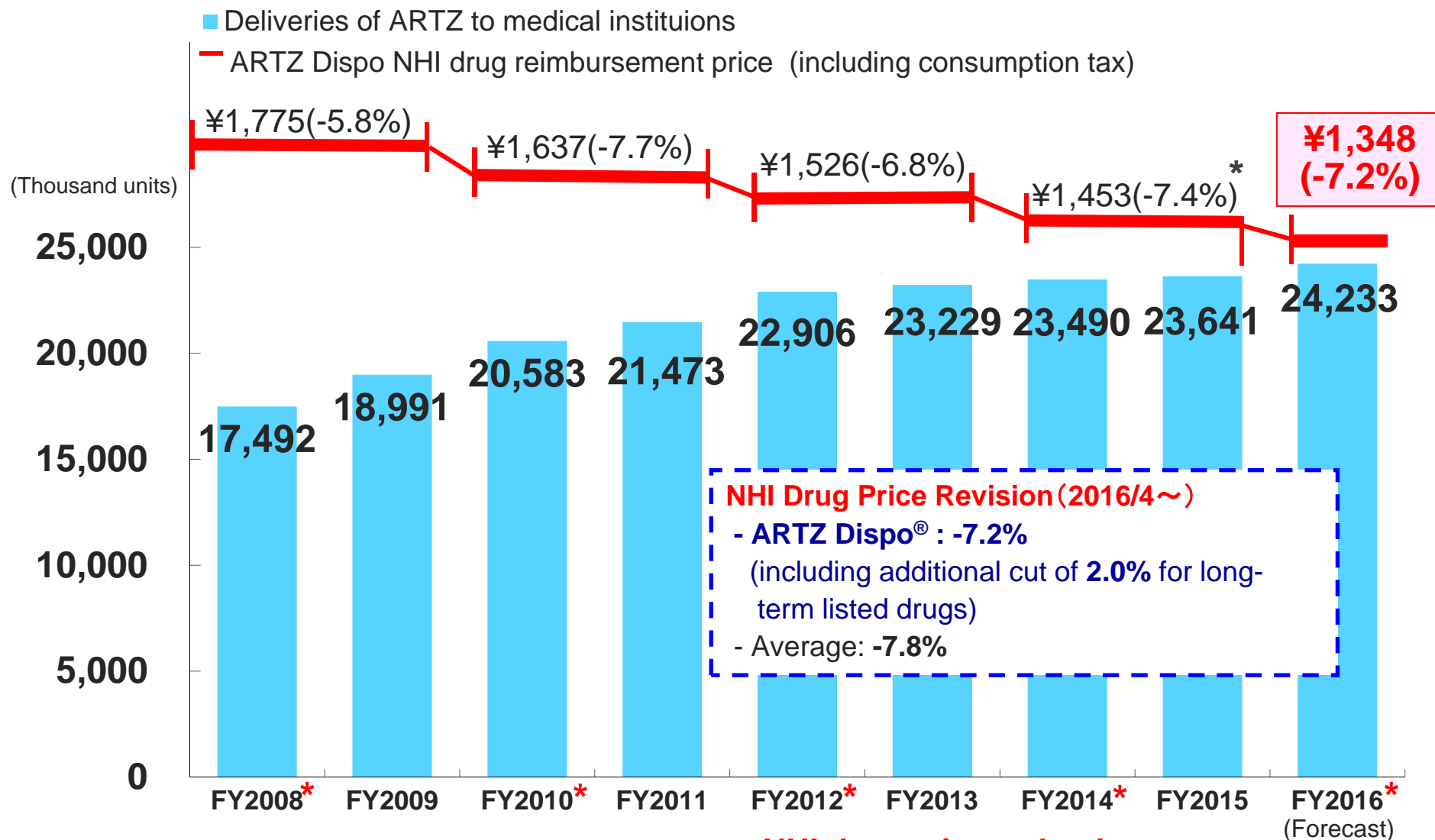


# Business Progress & Highlights



⇒ Consolidated results from '99.3

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



\* NHI drug price reduction

\*excluding the impact of consumption tax hike

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

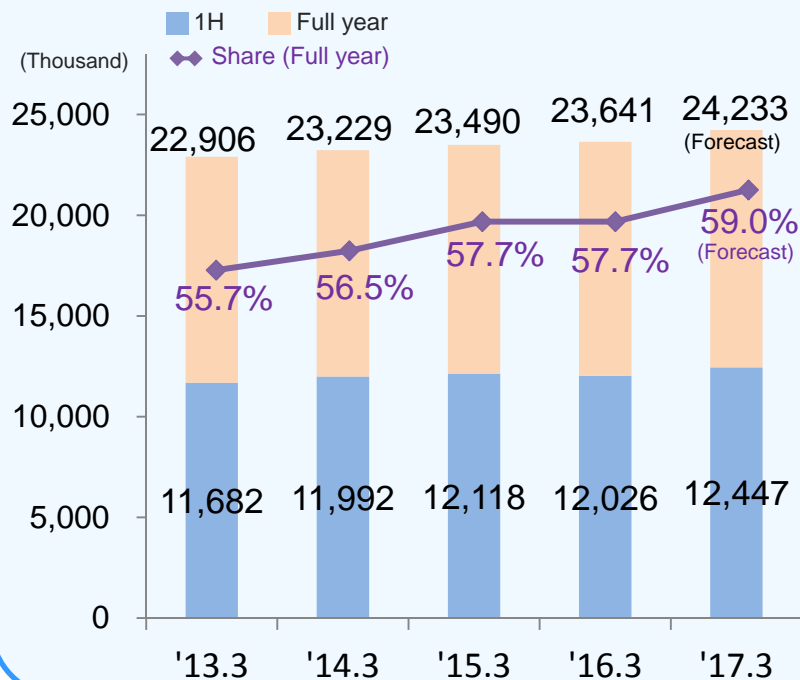
Joint-function improving agent

## 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



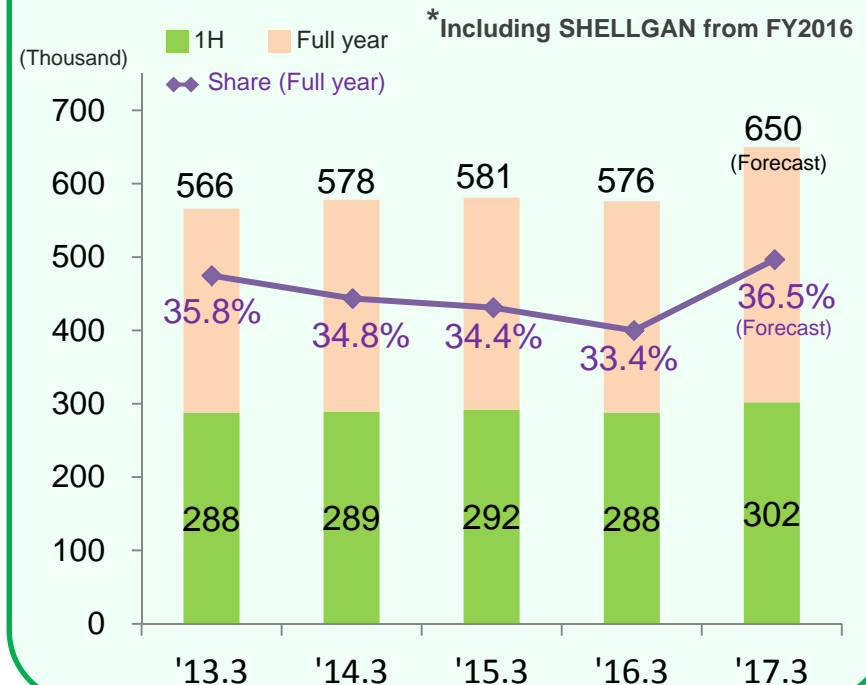
Ophthalmic surgical aids

## OPEGAN



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

### Trend in unit deliveries to medical institutions



# New Measures Relating to Domestic Pharmaceuticals

## Introduction of New ARTZ Syringes

- Introduction of luer fit plastic syringes in April 2016
  - Reduction of the syringe breakage rate, meeting of user needs
- ⇒ Seeking differentiation from competitors and share expansion



Joint function improvement agent ARTZ Dispo

## Launch of the New Product SHELLGAN

- Active ingredients: Hyaluronic acid and chondroitin sulfate
  - Launched July 2016
- ⇒ Strengthening of the OPEGAN series product line



Ophthalmic surgical aid SHELLGAN 0.5

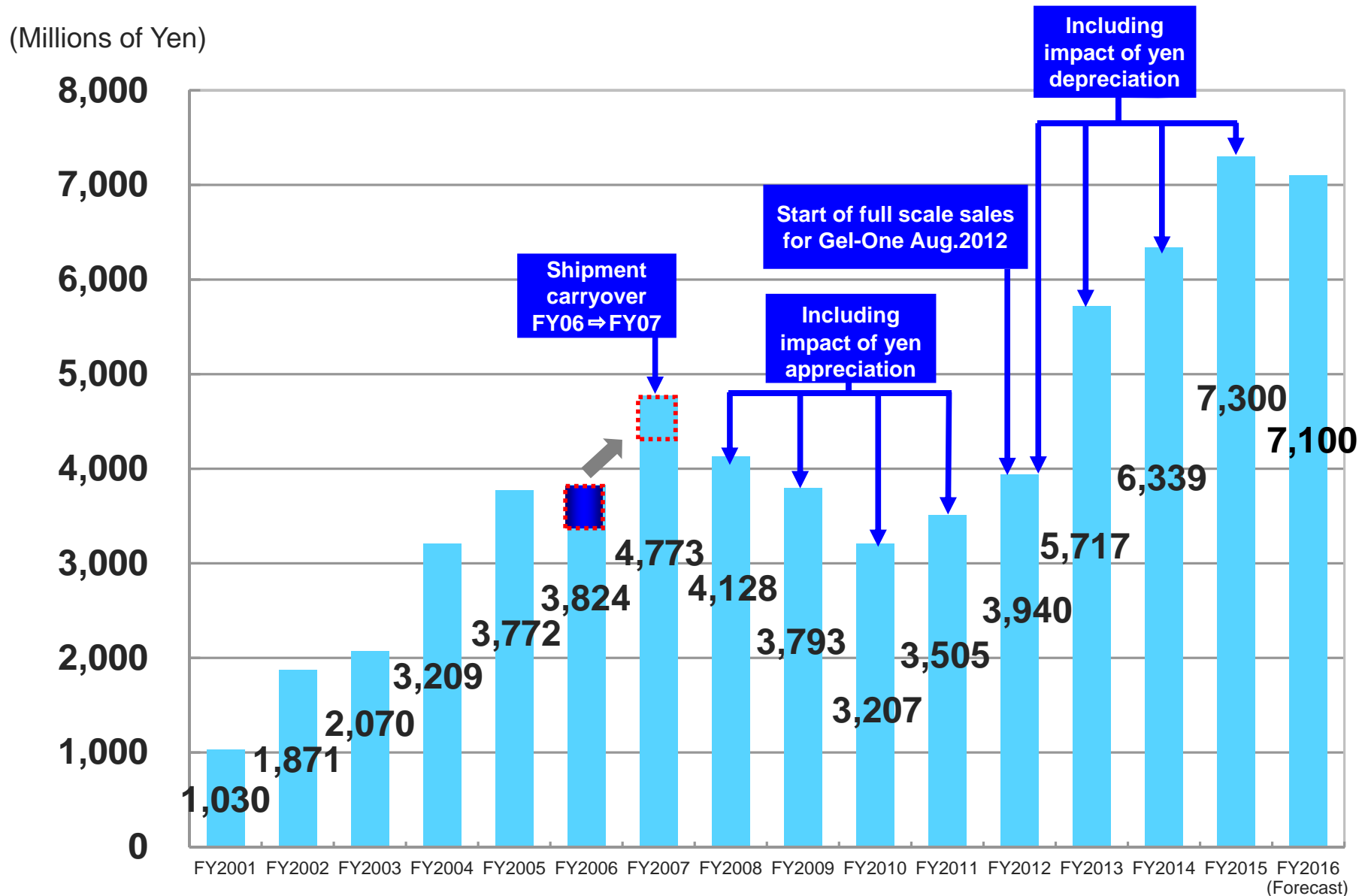
## Change of MucoUp Sales Partner (Starting from April 2016)

- New sales partner: Boston Scientific Japan
  - The company involved with medical devices used in endoscopic surgery
- ⇒ Expected synergies leading to higher sales of MucoUp



MucoUp surgical aids for endoscopic mucosal resection

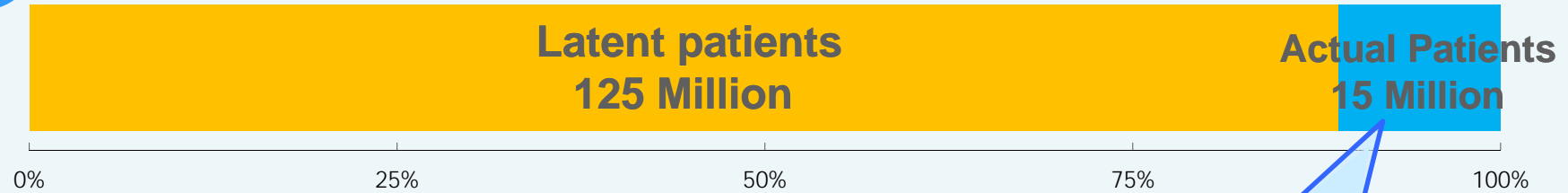
# Trend in Overseas Sales of Hyaluronic Acid Products





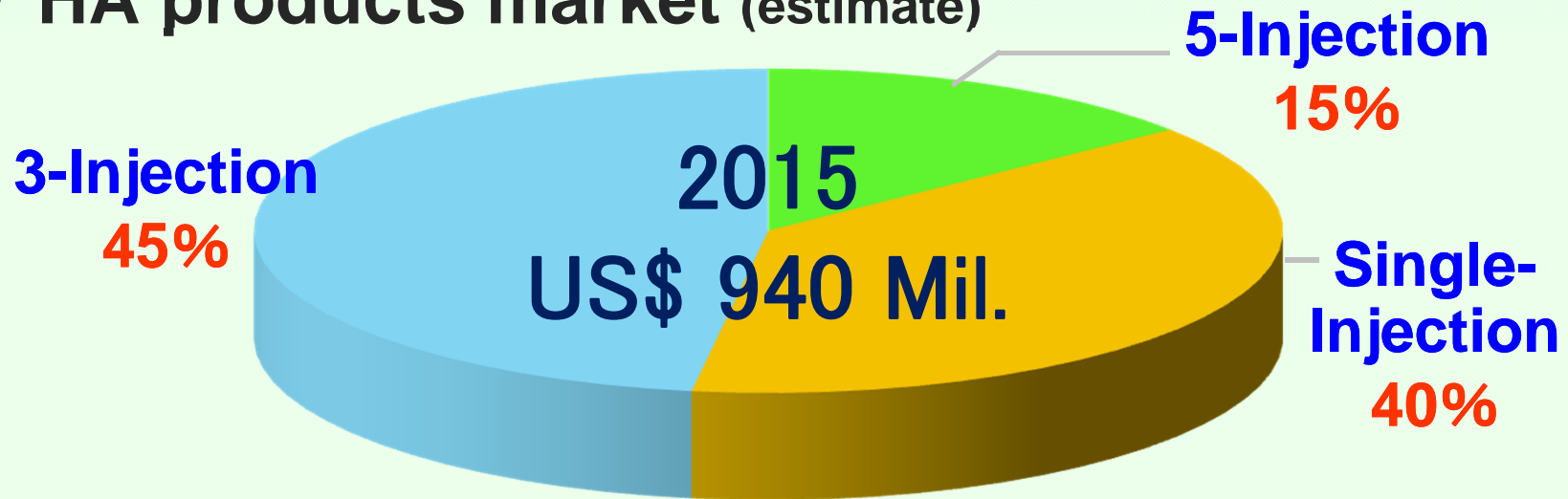
# U.S. Market for HA Products

## 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

# Gel-One Future Initiatives

## ◆ **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.**

# 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. ¥25.0 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



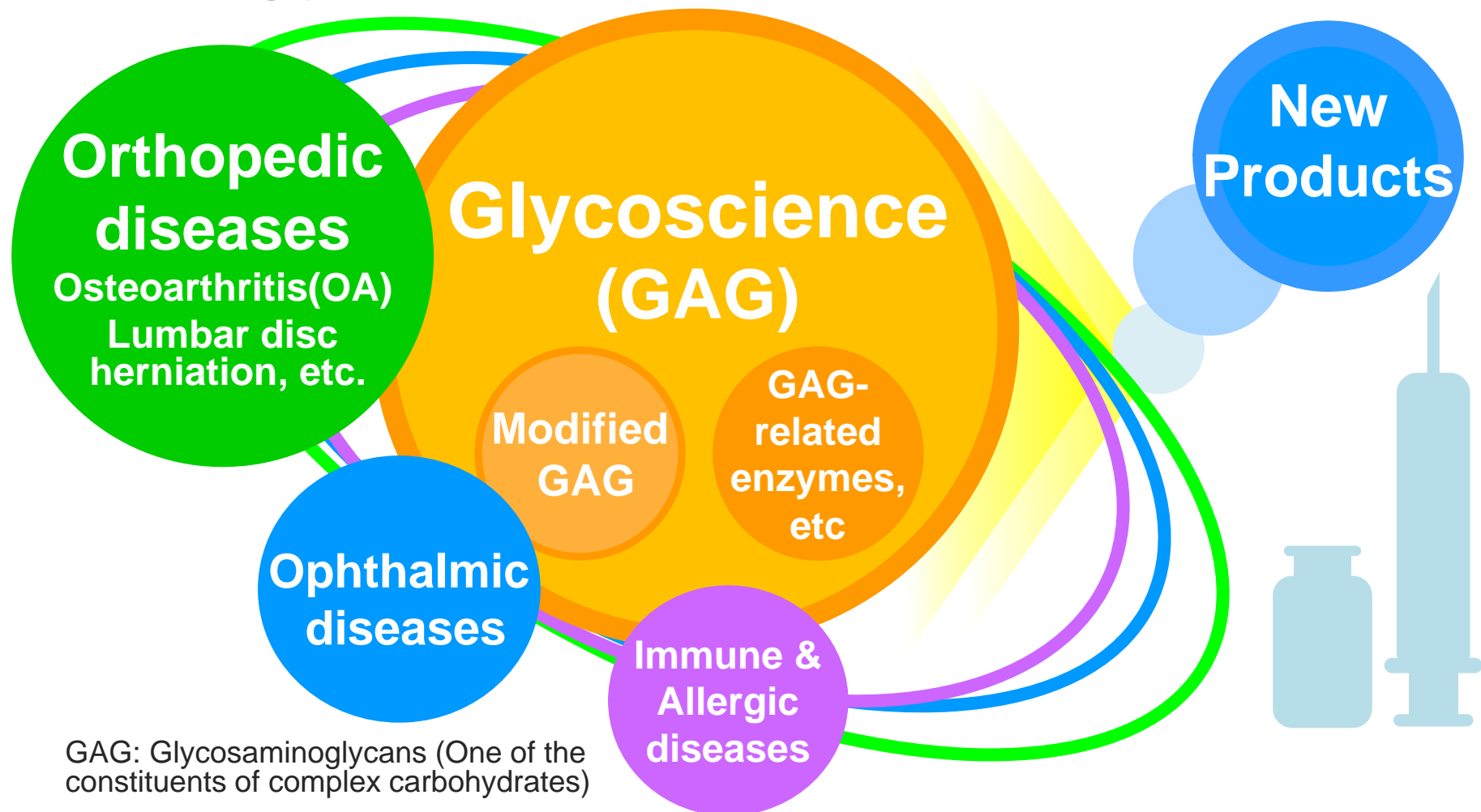
PYROCHROME®



Exterior of the ACC offices

# Basic Policy on Research and Development

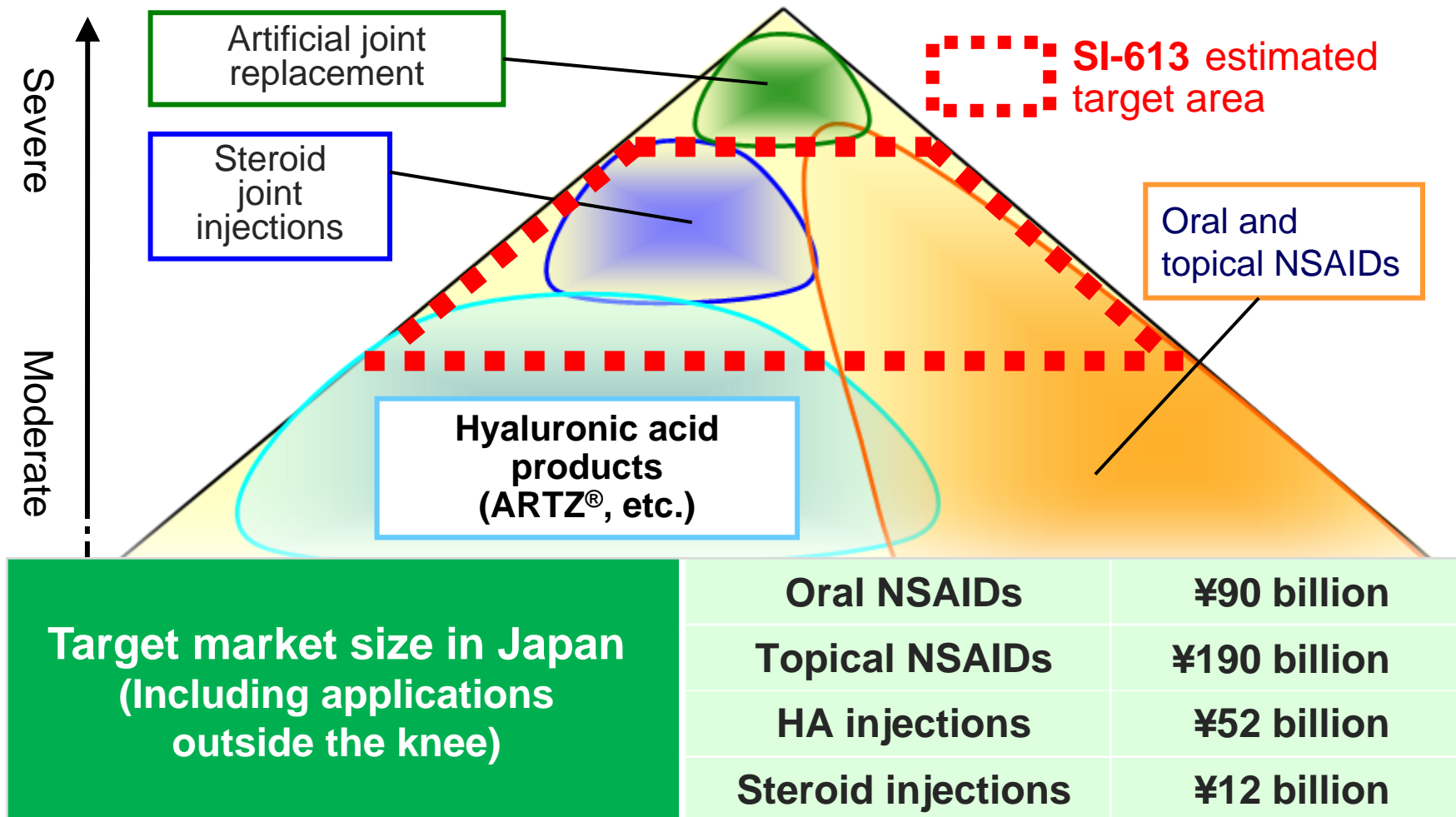
Aiming for the early, continuous introduction of new products that meet high treatment needs, focusing on glycoscience as an area of specialization



GAG: Glycosaminoglycans (One of the constituents of complex carbohydrates)

# SI-613 Estimated Target Patients

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



# Summary of the Previous Mid-term Management Plan

(FY2012 to FY2015)

## Results attained in cultivating new leads, but issues remain



# New Mid-term Management Plan (FY2016 to FY2018)

## Ten-Year Vision “Global Category Pharma”

Focus research and development on glycoscience  
establishes global competitiveness

### 【Final Step】

Achieving the Ten-Year Vision  
and Making a Further Leap  
Forward

### Step 2

Cultivation of new leads  
for achieving the Ten-Year Vision

2016-2018

### Step 1

Cultivation of basic strength  
and systems development

2012-2015

2009-2011

## ACT for the Vision

Active spirit · Creative mind · Takeoff

Overcome severe environment in the business,  
achieve the Ten-Year Vision, and  
survive as a “Global Category Pharma”

## New Mid-term Management Plan: **Four High-Priority Strategies**

**1.**

**Preparing for launch of SI-6603, a treatment for lumbar disc herniation**

**2.**

**Powering up as a leader in the knee osteoarthritis market**

**3.**

**Enhancement of the development pipeline**

**4.**

**Pursuit of an optimal production system**

**Achieving the Ten-Year Vision and Making a Further Leap Forward**



## **1.** Preparing for launch of SI-6603, a treatment for lumbar disc herniation

- Proceed with a launch in Japan and realize sales expansion in accordance with appropriate use.
- Aim for commercialization in the U.S., which is potential big market.

## **2. Powering up as a leader in the knee osteoarthritis market**

- Promote sales expansion in the U.S. and new market development for growth driver Gel-One.
- Maintain sales volumes of ARTZ in Japan through product improvements.
- Proceed with development of SI-613, a joint function improving agent positioned as a next generation product.

### **3. Enhancement of the development pipeline**

- Maintain basic technologies superior to those of competitors in the field of glycoscience, accelerate exploratory research, and continuously originate and create development themes.
- Steadily advance the stages of projects in the pipeline by enhancing clinical development capabilities.

### **4. Pursuit of an optimal production system**

- Ensure a stable supply of products and realize cost reductions by implementing further production efficiency improvements.
- Strengthen production and quality control systems compliant with global standards and capable of rapidly responding to regulatory trends.

## New Mid-term Management Plan: Numerical Targets

### **FY2018 Target**

**Net sales: ¥32.0 billion**  
**Operating income: ¥2.5 billion**  
**Ordinary income: ¥4.5 billion**

#### 《Key Assumptions of Numerical Targets》

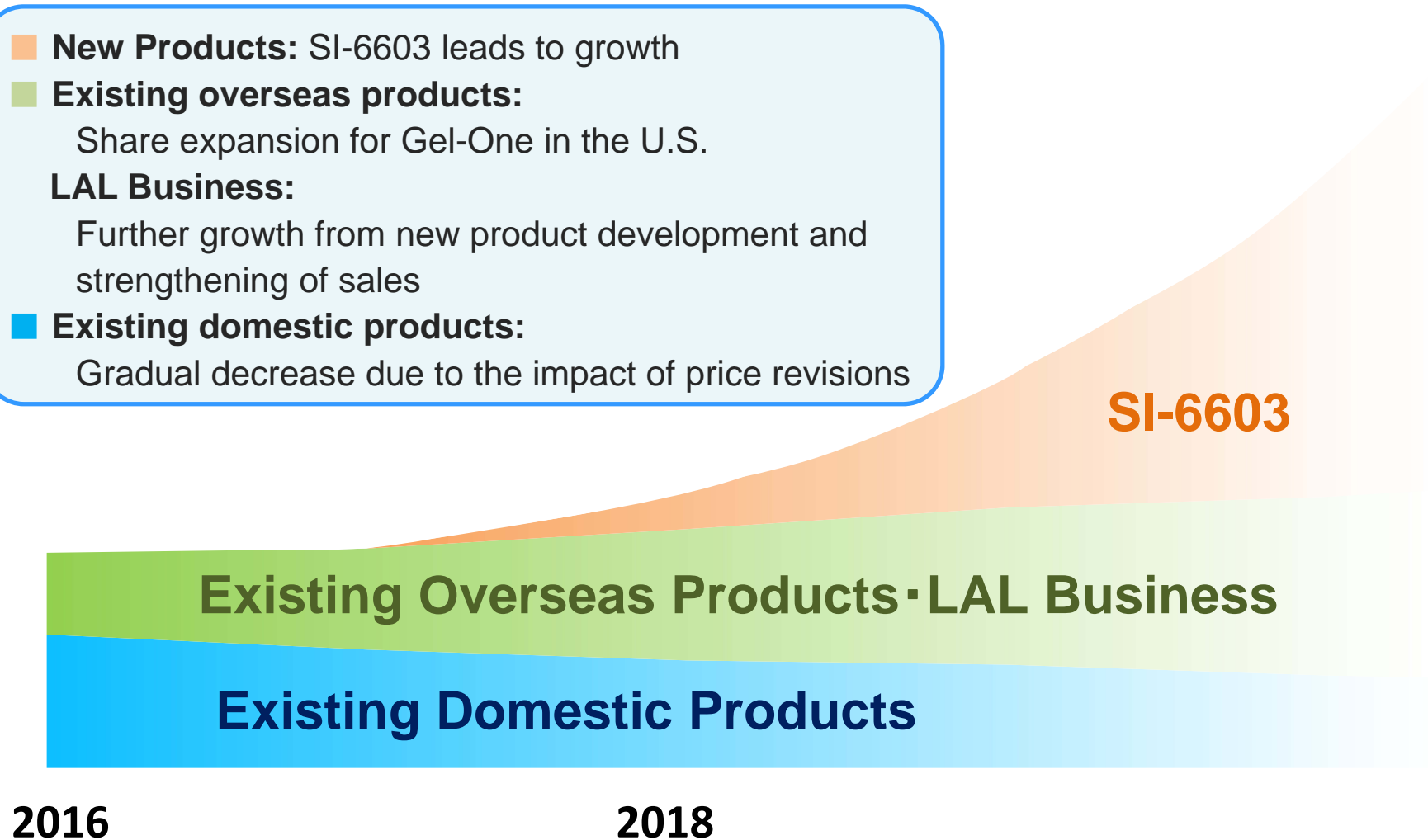
- Overseas business expansion to compensate for a decrease in revenue due to NHI drug price reductions in Japan (overseas sales ratio: 45%)
- A high level of R&D expenses (ratio of R&D expenses to net sales: 25% to 30%)
- Various royalty incomes as non-operating income
- Exchange rate: ¥110 to the U.S. dollar

**Achieving the Ten-Year Vision and  
Making a Further Leap Forward**

# Topics for Advancing to the Next Stage

(Schematic Representation of Growth)

- **New Products:** SI-6603 leads to growth
- **Existing overseas products:**  
Share expansion for Gel-One in the U.S.
- **LAL Business:**  
Further growth from new product development and strengthening of sales
- **Existing domestic products:**  
Gradual decrease due to the impact of price revisions



**Achieving the Ten-Year Vision and Making a Further Leap Forward**

# Special Profile

1

## 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

## Unique business model

- Concentration on **R&D** and **manufacturing**
- R&D staff comprising **one-third** of our total employees
- Allocation of **25% to 30%** of net sales to R&D investment

3

## State-of-the-art technology related to GAG

- **Extraction, Purification, Fermentation**, etc. technology to manufacture GAG related products
- Drug discovery expertise using modified-GAG, GAG-related enzymes, etc.

# Our Business Segment

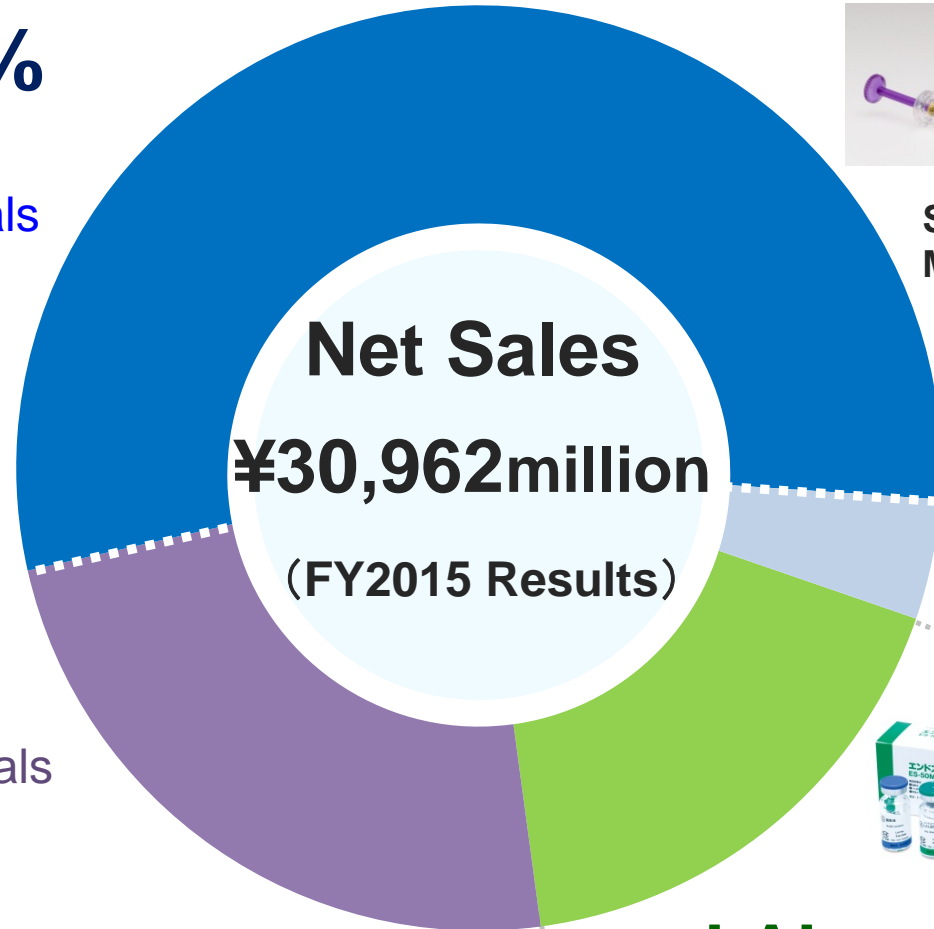
## Pharmaceutical Business 82.4%

Domestic  
Pharmaceuticals  
⇒ 54.7%

Joint Function  
Improving Agents



Overseas  
Pharmaceuticals  
⇒ 23.6%



Ophthalmic Surgical Aids



Surgical Aids for Endoscopic  
Mucosal Resection



Bulk Products  
⇒ 4.2%

Bulk Products



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

## LAL Business 17.6%

# Main Hyaluronic Acid (HA) Products

## **ARTZ®** Knee osteoarthritis (OA) pain relief by multiple injections

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

Kaken Pharmaceutical (Japan): ARTZ®

Bioventus (U.S.): SUPARTZ FX™

Kunming Baker Norton  
Pharmaceutical (China): ARTZ®



## **Gel-One®** 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**