

# Financial Results for the Fiscal Year 2015

(April 1, 2015 – March 31, 2016)



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



**SEIKAGAKU CORPORATION**

(TSE:4548)

# Overview of Fiscal Year 2015

| (Millions of Yen)                                | FY2015 Results           | Year-on-Year             |               | Comparison with Forecasts |               |
|--|--------------------------|--------------------------|---------------|---------------------------|---------------|
|  |                          | Change                   | % of Change   | Change                    | % of Change   |
| <b>Net sales</b>                                 | <b>30,962</b>            | <b>+1,440</b>            | <b>+4.9%</b>  | <b>+312</b>               | <b>+1.0%</b>  |
| <b>Operating Income</b>                          | <b>2,144</b>             | <b>-238</b>              | <b>-10.0%</b> | <b>-255</b>               | <b>-10.6%</b> |
| <b>Ordinary Income</b>                           | <b>3,500</b>             | <b>-507</b>              | <b>-12.7%</b> | <b>-299</b>               | <b>-7.9%</b>  |
| <b>Net Income</b>                                | <b>2,578</b>             | <b>-1,072</b>            | <b>-29.4%</b> | <b>-321</b>               | <b>-11.1%</b> |
| <b>R&amp;D Expenses<br/>(Ratio to net sales)</b> | <b>8,649<br/>(27.9%)</b> | <b>+502<br/>(+0.3pt)</b> | <b>+6.2%</b>  | <b>+799<br/>(+2.3pt)</b>  | <b>+10.2%</b> |
| Average Exchange Rate (1US\$)                    | ¥120.14                  | +¥10.20                  |               | +¥2.14                    |               |

|                              | FY2015 Results  | FY2014 Results | FY2015 Forecasts |
|------------------------------|-----------------|----------------|------------------|
| <b>Net Income per Share</b>  | <b>¥45.39</b>   | ¥64.27         | ¥51.05           |
| <b>Dividend per Share</b>    | <b>¥26.00 *</b> | ¥26.00         | ¥26.00           |
| <b>Dividend Payout Ratio</b> | <b>57.3% *</b>  | 40.5%          | 50.9%            |
| <b>R O E</b>                 | <b>3.7%</b>     | 5.4%           |                  |

# Net sales by Business Segment (FY2015)

| (Millions of Yen)        | FY2015 Results | Year-on-Year | % of Change |
|--------------------------|----------------|--------------|-------------|
| Net sales                | 30,962         | +1,440       | +4.9%       |
| Pharmaceuticals          | 25,518         | +871         | +3.5%       |
| Domestic Pharmaceuticals | 16,928         | +30          | +0.2%       |
| Overseas Pharmaceuticals | 7,300          | +960         | +15.1%      |
| Bulk Products            | 1,289          | -118         | -8.4%       |
| LAL Business             | 5,444          | +568         | +11.7%      |
| (Overseas sales)         | 11,581         | +1,583       | +15.8%      |

\*Foreign exchange impact on overall net sales:  
approx. +¥1,100 million

## Domestic Pharmaceuticals

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

Slight increase, attributable sales efforts by the sales partner, despite the impact for promotion of generics



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

### ➤ OPEGAN (ophthalmic surgical aid)

Slight decrease amid continuing fierce competition



OPEGAN:  
Ophthalmic surgical aid used primarily in cataract surgery

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

Increase, partly attributable to an increase in shipments accompanying a change in sales partner in April 2016

# Net sales by Business Segment (FY2015)

| (Millions of Yen)               | FY2015 Results | Year-on-Year | % of Change   |
|---------------------------------|----------------|--------------|---------------|
| Net sales                       | 30,962         | +1,440       | +4.9%         |
| <b>Pharmaceuticals</b>          | <b>25,518</b>  | <b>+871</b>  | <b>+3.5%</b>  |
| Domestic Pharmaceuticals        | 16,928         | +30          | +0.2%         |
| <b>Overseas Pharmaceuticals</b> | <b>7,300</b>   | <b>+960</b>  | <b>+15.1%</b> |
| Bulk Products                   | 1,289          | -118         | -8.4%         |
| LAL Business                    | 5,444          | +568         | +11.7%        |
| (Overseas sales)                | 11,581         | +1,583       | +15.8%        |

\*Foreign exchange impact on overall net sales:  
approx. +¥1,100 million

## Overseas Pharmaceuticals

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

Local sales and Seikagaku sales up  
Gradual appearance of the effects of enhancement of the local sales structure through an acquisition made by the sales partner



Gel-One:  
Single-injection joint function improving agent

### ➤ ARTZ (multiple injection)

#### ● SUPARTZ in the U.S:

Local sales at the prior-year level  
Seikagaku sales slightly up, mainly as a result of yen depreciation

#### ● VISCO-3 in the U.S:

Sales partner selection in progress

#### ● ARTZ in China:

Local sales on a downward turn  
Seikagaku sales up as a result of sales partner inventory build-up by and yen depreciation

# Net sales by Business Segment (FY2015)

| (Millions of Yen)        | FY2015 Results | Year-on-Year | % of Change |
|--------------------------|----------------|--------------|-------------|
| Net sales                | 30,962         | +1,440       | +4.9%       |
| Pharmaceuticals          | 25,518         | +871         | +3.5%       |
| Domestic Pharmaceuticals | 16,928         | +30          | +0.2%       |
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| (Overseas sales)         | 11,581         | +1,583       | +15.8%      |

\*Foreign exchange impact on overall net sales:  
approx. +¥1,100 million

## Bulk Products

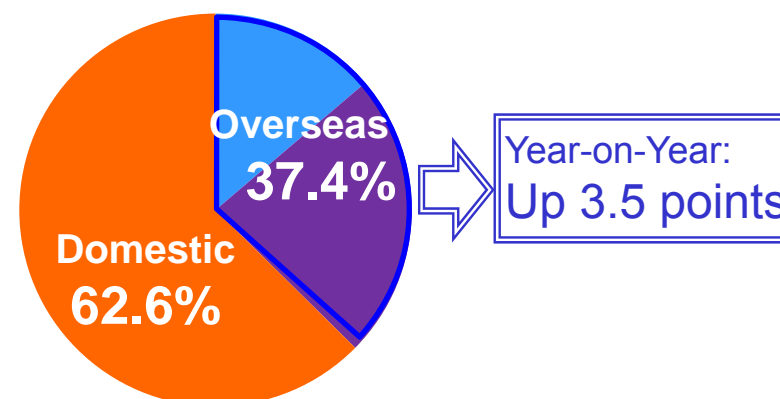
Sales down amid intensification of competition in the market for hyaluronic acid

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

## LAL Business

Sales up as a result of increases in overseas sales of endotoxin-detecting reagents and other products, due in part to the impact of yen depreciation

## Overseas Sales Ratio



# Income in FY2015 (Year-on-Year)

| (Millions of Yen)                        | FY2015 Results           | Year-on-Year            | % of Change   |
|--|--------------------------|-------------------------|---------------|
| Net sales                                | <b>30,962</b>            | <b>+1,440</b>           | <b>+4.9%</b>  |
| Cost of Sales<br>(Cost of Sales ratio)   | <b>12,871</b><br>(41.6%) | <b>+740</b><br>(+0.5pt) | <b>+6.1%</b>  |
| SGA expenses                             | <b>15,946</b>            | <b>+938</b>             | <b>+6.3%</b>  |
| R&D Expenses<br>(to Net sales ratio)     | <b>8,649</b><br>(27.9%)  | <b>+502</b><br>(+0.3pt) | <b>+6.2%</b>  |
| Operating Income<br>(to Net sales ratio) | <b>2,144</b><br>(6.9%)   | <b>-238</b><br>(-1.2pt) | <b>-10.0%</b> |
| Ordinary Income                          | <b>3,500</b>             | <b>-507</b>             | <b>-12.7%</b> |
| Net Income                               | <b>2,578</b>             | <b>-1,072</b>           | <b>-29.4%</b> |
| Depreciation                             | <b>3,191</b>             | <b>+581</b>             | <b>+22.3%</b> |

## Operating Income

### Cost of Sales (+0.5pt):

Increase due to factors including higher depreciation of the No. 5 Production Building at the Takahagi Plant

### SGA Expenses (+938):

- R&D expenses: Increase accompanying progress with development themes, such as SI-6603 in the U.S.
- Increase in expenses at the U.S. subsidiary, partly due to yen depreciation

## Net Income

### Non-operating Income/Expenses (-268):

- Increase in royalty income (+120)
- Foreign exchange losses on foreign currency-denominated assets due to strengthening of the yen appreciation toward the end of year(-572)

### Income Taxes (+564):

Tax rate increase due to factors including expiration of temporary tax rate reducing factors applied in FY2014 (tax rate decrease accompanying a capital reduction with compensation at a U.S. subsidiary)(+17.4pt) (FY2014: 8.9% → FY2015: 26.3%)

# Income in FY2015 (Comparison with forecasts)

| (Millions of Yen)                        | FY2015 Results         | Compa. with forecasts   | % of Change   |
|--|------------------------|-------------------------|---------------|
| Net sales                                | <b>30,962</b>          | <b>+312</b>             | <b>+1.0%</b>  |
| Operating Income<br>(to Net sales ratio) | <b>2,144</b><br>(6.9%) | <b>-255</b><br>(-0.9pt) | <b>-10.6%</b> |
| Ordinary Income                          | <b>3,500</b>           | <b>-299</b>             | <b>-7.9%</b>  |
| Net Income                               | <b>2,578</b>           | <b>-321</b>             | <b>-11.1%</b> |

|                                      |                         |                         |               |
|--------------------------------------|-------------------------|-------------------------|---------------|
| Cost of Sales ratio                  | <b>41.6%</b>            | <b>-0.2pt</b>           |               |
| R&D Expenses<br>(to Net sales ratio) | <b>8,649</b><br>(27.9%) | <b>+799</b><br>(+2.3pt) | <b>+10.2%</b> |
| Depreciation                         | <b>3,191</b>            | <b>-108</b>             | <b>-3.3%</b>  |

## Net Sales

### Pharmaceuticals Business (+118):

- Domestic Pharmaceuticals: In line with forecast
- Overseas Pharmaceuticals: Forecasts exceeded as Gel-One compensated for underperformance of multiple-injection ARTZ

### LAL Business (+194):

Increase at the U.S. subsidiary

\*Foreign exchange impact on overall sales: approx. +190

## Operating Income

### SGA Expenses (approx. +490):

- Some sales-related expenses were higher than expected
- R&D expenses: Increase due to factors including acceleration of enrollment for an open-label trial for SI-6603 in the U.S.

## Net Income

### Non-operating Income/Expenses (approx. -40):

Higher-than-expected gain on sale of investment securities, lower-than-expected royalty income

# Overview of Forecasts in FY2016

| (Millions of Yen)                    | FY2016 Forecasts | FY2015 Results   |                  |             |
|--------------------------------------|------------------|------------------|------------------|-------------|
|                                      |                  | Results          | Change           | % of Change |
| Net sales                            | 29,550           | 30,962           | -1,412           | -4.6%       |
| Operating Income                     | 1,000            | 2,144            | -1,144           | -53.4%      |
| Ordinary Income                      | 3,350            | 3,500            | -150             | -4.3%       |
| Net Income                           | 2,550            | 2,578            | -28              | -1.1%       |
| R&D Expenses<br>(to Net sales ratio) | 8,400<br>(28.4%) | 8,649<br>(27.9%) | -249<br>(+0.5pt) | -2.9%       |
| Average Exchange Rate<br>(1US\$)     | ¥110.00          | ¥120.14          | - ¥10.14         |             |

|                       | FY2016 Forecasts | FY2015 Results | Exchange Rate Sensitivity<br>(Impact of a change of ¥1 against the US\$) |                      |
|-----------------------|------------------|----------------|--|----------------------|
| Net Income per share  | ¥44.89           | ¥45.39         | Net sales  | Approx. ¥100 million |
| Dividend per share    | ¥26.00           | ¥26.00*        | Operating income   | Approx. ¥40 million  |
| Dividend Payout ratio | 57.9%            | 57.3%*         |  |                      |

\*Year-end dividend of ¥13 per share to be decided at the general meeting of shareholders on June 2016.



# Forecasts (Net sales) in FY2016

| (Millions of Yen)        | FY2016<br>Forecasts | Year-on-Year |             |
|--------------------------|---------------------|--------------|-------------|
|                          |                     | Change       | % of Change |
| Net sales                | 29,550              | -1,412       | -4.6%       |
| Pharmaceuticals          | 24,300              | -1,218       | -4.8%       |
| Domestic Pharmaceuticals | 15,900              | -1,028       | -6.1%       |
| Overseas Pharmaceuticals | 7,350               | +49          | +0.7%       |
| Bulk Products            | 1,050               | -239         | -18.5%      |
| LAL Business             | 5,250               | -194         | -3.6%       |
| (Overseas sales)         | 11,400              | -181         | -1.6%       |

\*Foreign exchange impact on overall net sales:  
approx. - ¥1,060 million

## Net Sales

Forecast of lower sales due to NHI drug price reductions and the impact of yen appreciation

\*Domestic sales of SI-6603 are not included in the forecasts

## Pharmaceuticals Business

### Domestic Pharmaceuticals:

- Forecast of lower sales due to NHI drug price reductions, despite a slight increase on a volume basis

### Overseas Pharmaceuticals:

- Higher shipments of Gel-One to compensate for the impact of yen appreciation and lower sales of SUPARTZ in the U.S.

## LAL Business

Sales decrease due to yen appreciation, despite higher local sales at the U.S. subsidiary

# Forecasts (Income) in FY2016

| (Millions of Yen)                        | FY2015<br>Forecasts | Year-on-Year       |                |
|--|---------------------|--------------------|----------------|
|  |                     | Change             | % of<br>Change |
| Net sales                                | 29,550              | -1,412             | -4.6%          |
| Operating Income<br>(to Net sales ratio) | 1,000<br>(3.4%)     | -1,144<br>(-3.5pt) | -53.4%         |
| Ordinary<br>Income                       | 3,350               | -150               | -4.3%          |
| Net Income                               | 2,550               | -28                | -1.1%          |
| Cost of Sales<br>ratio                   | 42.0%               | +0.4pt             |                |
| R&D Expenses<br>(to Net sales ratio)     | 8,400<br>(28.4%)    | -249<br>(+0.5pt)   | -2.9%          |
| Depreciation                             | 3,000               | -191               | -6.0%          |

## Income

Net income at nearly the prior-year level as a result of projected lower operating income and higher royalty income

## Operating Income

### Cost of Sales (approx. -470):

- Decrease in depreciation, but a slight increase in the cost of sales ratio due to the impact of drug price reduction (+0.4pt)

### SGA Expenses (approx. +200):

- Forecast of lower R&D expenses.
- Higher U.S.-related expenses, including at the subsidiary

## Net Income

### Increase in Non-operating Income (approx. +1,000):

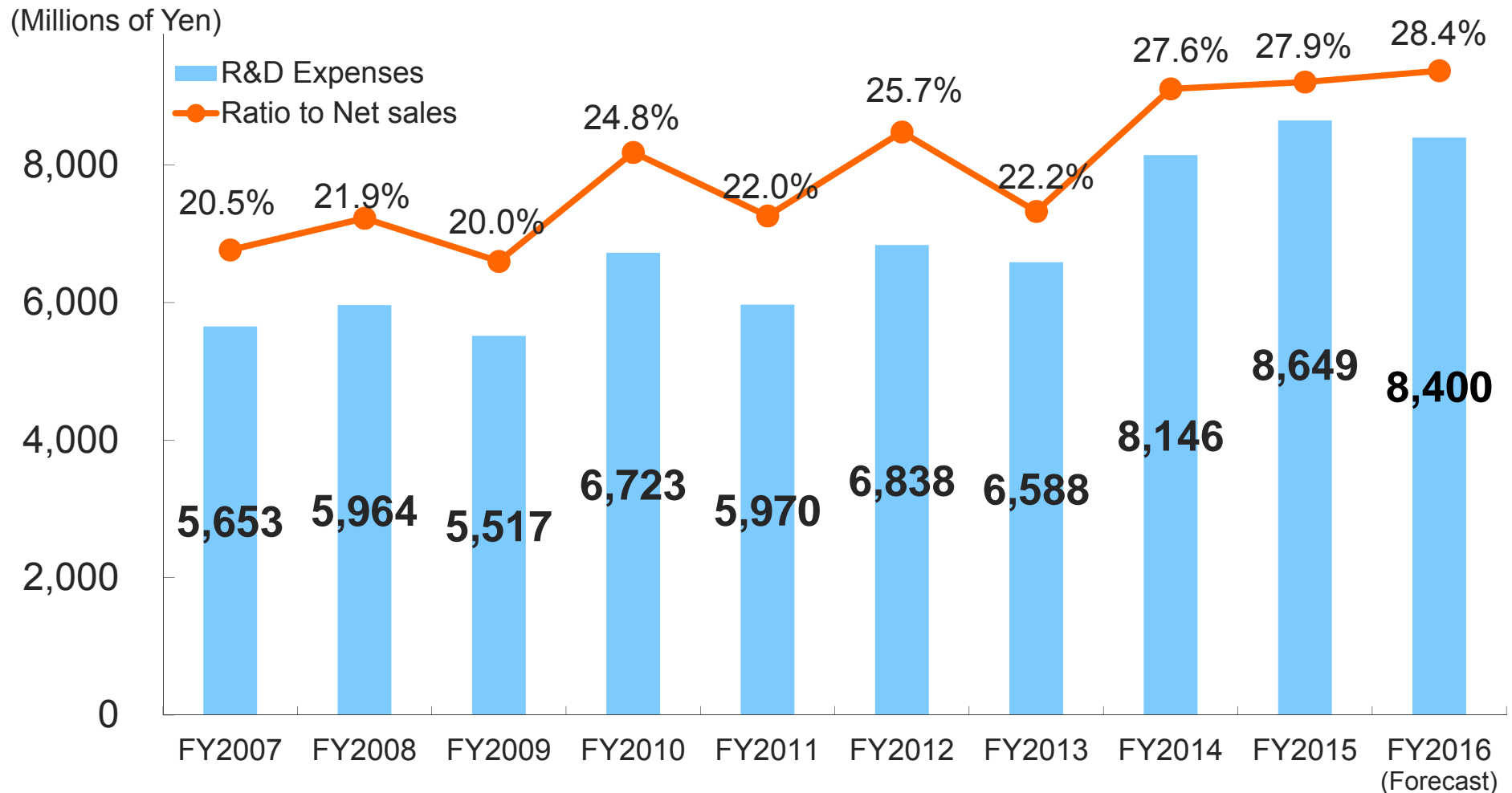
- Forecast of substantially higher royalty income

### Tax Rate Decrease:

- Decrease accompanying tax reform


# Trend in R&D Expenses


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



# Domestic Pharmaceuticals

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

|   | FY2015 Results   | FY2016 Forecasts   |                                 |
|---|--|--|---------------------------------|
| Joint-function improving agent<br><b>ARTZ</b>                                     | <ul style="list-style-type: none"> <li>Continued impact for the promotion of generics</li> <li>Sales growth consistent with market growth</li> </ul> | <ul style="list-style-type: none"> <li>Sales reinforcement through introduction of new syringes</li> <li>Share expansion from competitors</li> </ul> |                                 |
|  | ARTZ growth rate: +0.6%<br>(Market growth rate: +0.6%)<br>Market share: 57.7%  | ARTZ growth rate<br>+1.1%(forecast)  | Market share<br>57.9%(forecast) |

|   | FY2015 Results  | FY2016 Forecasts   |                                 |
|---|---|--|---------------------------------|
| Ophthalmic surgical aids<br><b>OPEGAN*</b>  | <ul style="list-style-type: none"> <li>Continuing fierce market competition</li> <li>Market share decrease</li> </ul> | <ul style="list-style-type: none"> <li>Launching of SHELLGAN, new product in July 2016</li> <li>Strengthening of information provision activities</li> </ul> |                                 |
|  | OPEGAN growth rate: -0.9%<br>(Market growth rate: +2.2%)<br>Market share: 33.4%                                       | OPEGAN growth rate*<br>+9.2%(forecast)   | Market share<br>35.3%(forecast) |

# 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
  - Target launch timing of 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

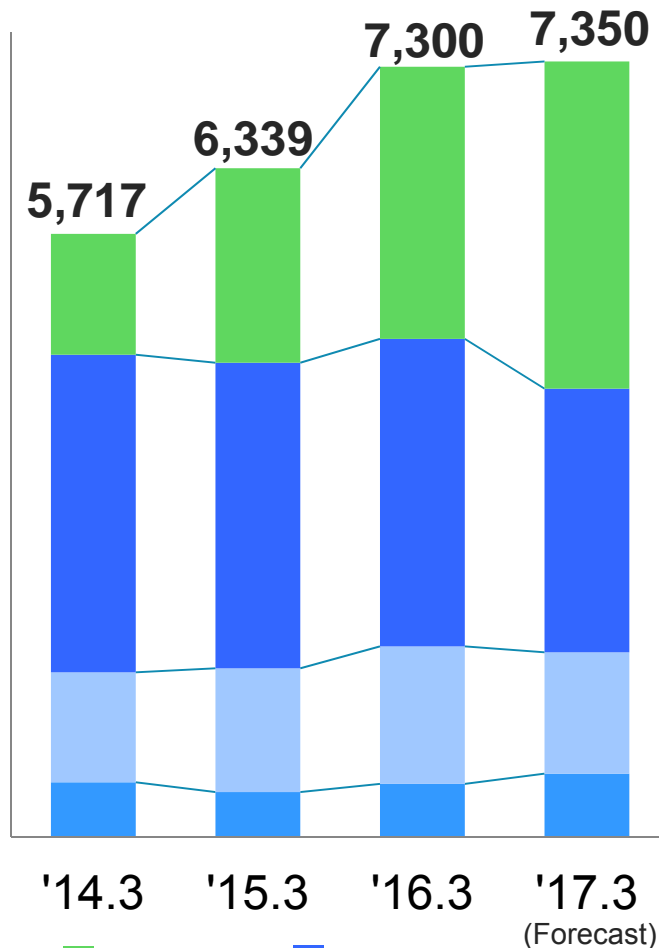


MucoUp surgical aids for endoscopic mucosal resection

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

## Overseas Pharmaceuticals Sales trend

(Millions of Yen)



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

**FY2015 Results**  
**+15.1%**

Sales increase on higher volumes of Gel-One and the impact of yen depreciation

\*Foreign exchange impact:  
approx. +¥510 million (of which, +8.0%)

## Gel-One (single injection)

- Gradual appearance of the effects of enhancement of the local sales structure through an acquisition made by the sales partner
- ⇒ Increase in U.S. local sales(+30%) and Seikagaku sales

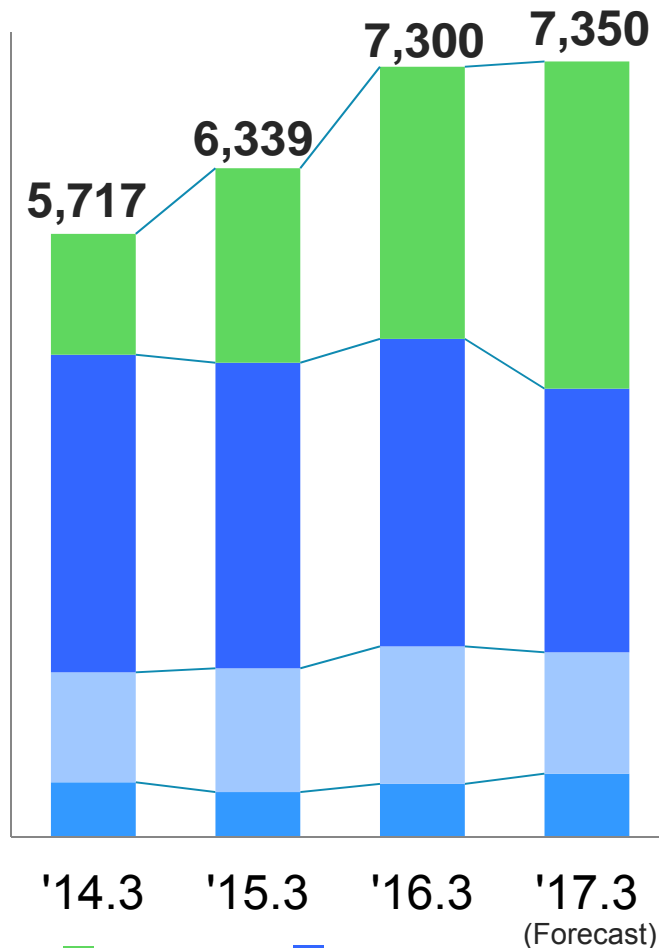
## ARTZ (multiple injection)

- **SUPARTZ FX in the U.S:**  
Despite preference for products efficacious with a low number of injections, local sales at prior-year level thanks to sales company efforts
- **ARTZ in China:**  
Decline in market size and local sales due to the impact of such as price curb policy (local sales: -3%)
- **Seikagaku exports:**  
Increase due to the impact of yen depreciation and a sales partner inventory build-up

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

## Overseas Pharmaceuticals Sales trend

(Millions of Yen)



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

**FY2016 Forecast**  
**+0.7%**

Sales at the prior-year level. Higher sales of Gel-One offset by yen appreciation

\*Foreign exchange impact:  
approx. -¥620 million (of which, -8.5%)

## Gel-One (single injection)

- Aim for continued growth in local sales (+30%) due to factors such as measures to increase awareness
- **Seikagaku exports:**  
Forecast of product an increase as higher volume compensates for the impact of yen appreciation

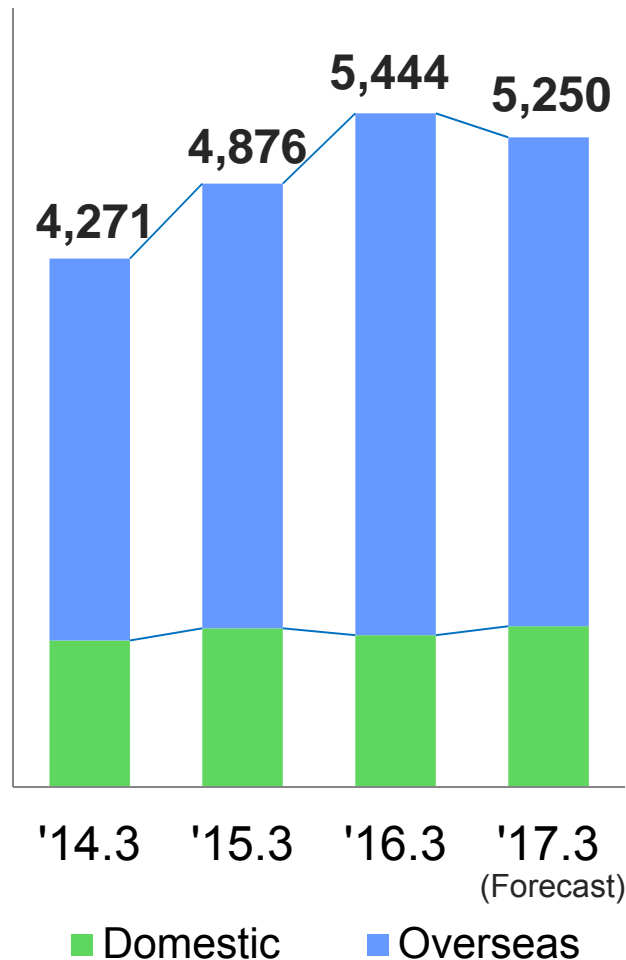
## ARTZ (multiple injection)

- **SUPARTZ FX in the U.S:**  
Forecast of fierce competition and a local sales decline
- **ARTZ in China:**  
Sales at almost the prior-year level
- **Seikagaku exports:**  
Forecast decrease by lower shipments to the U.S. and the impact of yen appreciation

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

## LAL Business Sales trend

(Millions of Yen)



## FY2015 Results: +11.7% (Year-on-Year)

### Overseas

Contribution from higher volumes of quality control endotoxin detection reagents used by pharmaceutical companies and in-vitro diagnostic reagents, and the impact of yen depreciation

### Domestic

Slight decrease due to the impact of shipment timing

## FY2016 Forecast: -3.6% (Year-on-Year)

### Overseas

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

### Domestic

Forecast of an increase in sales of endotoxin detection reagents and related equipment

### LAL Business:

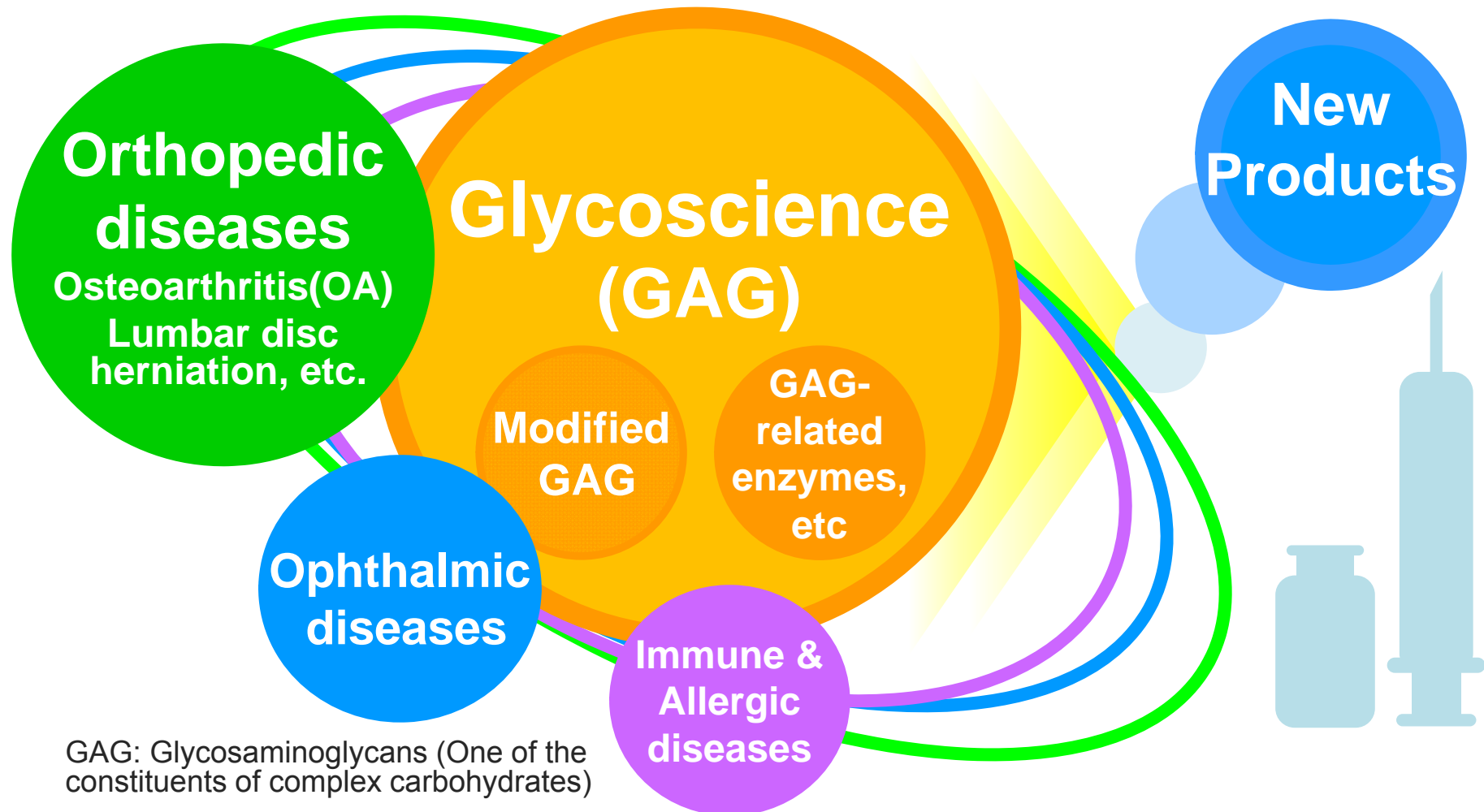
The manufacturing and sales of Endotoxin detection reagents\* used in the quality control of pharmaceuticals

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



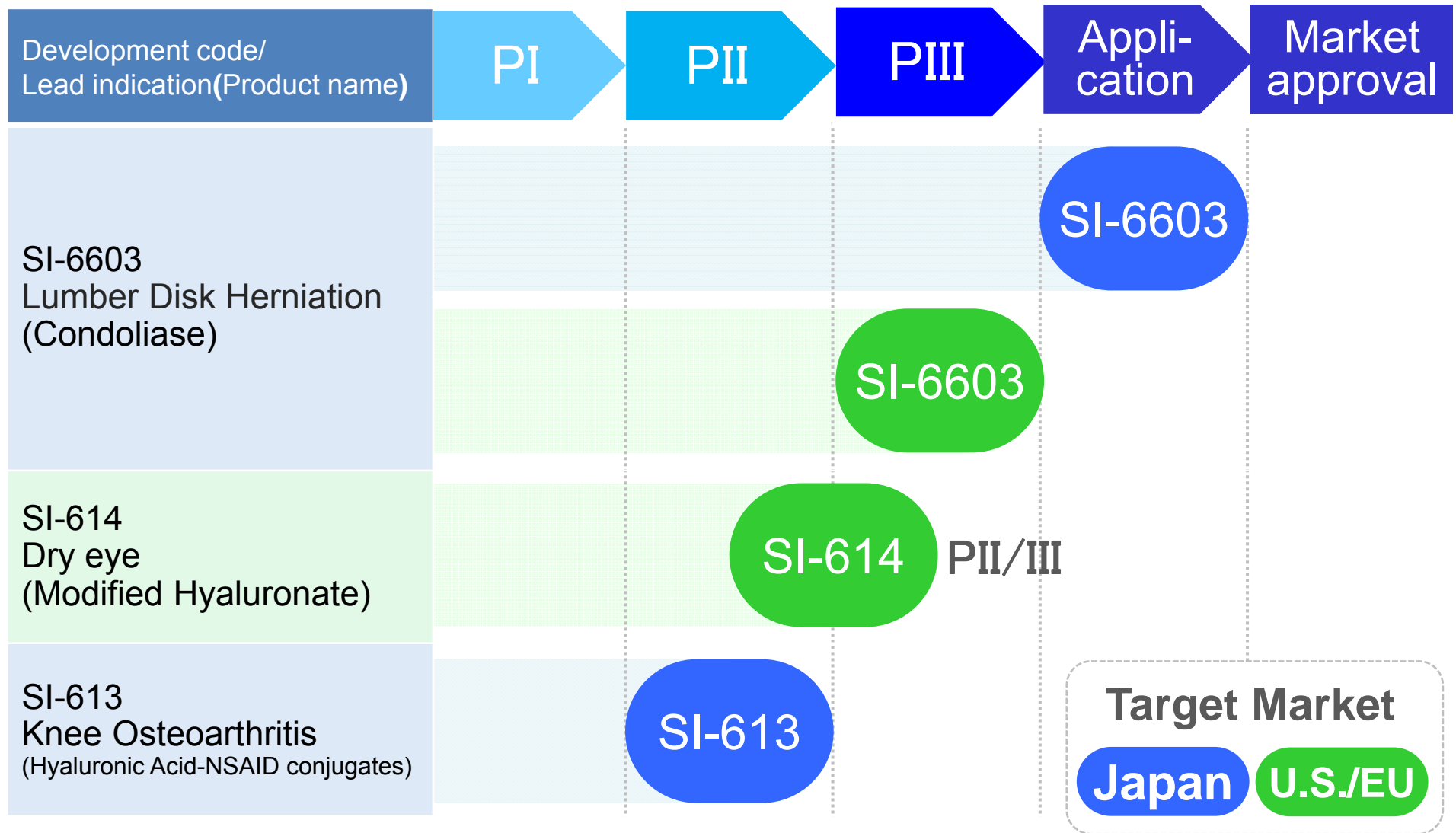
# Basic Policy on Research and Development

Aiming for the 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)

# Pipeline List

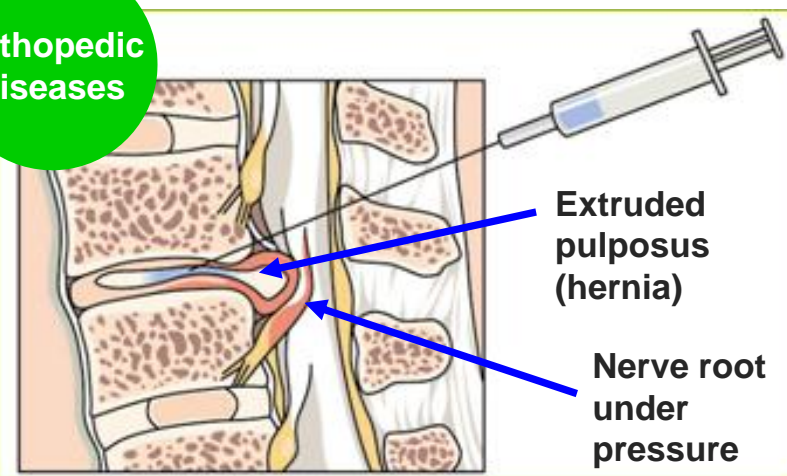


Note: Development of SI-657, an additional indication for ARTZ, was discontinued in February 2016.

# SI-6603 Outline (treatment for 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)**

### 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

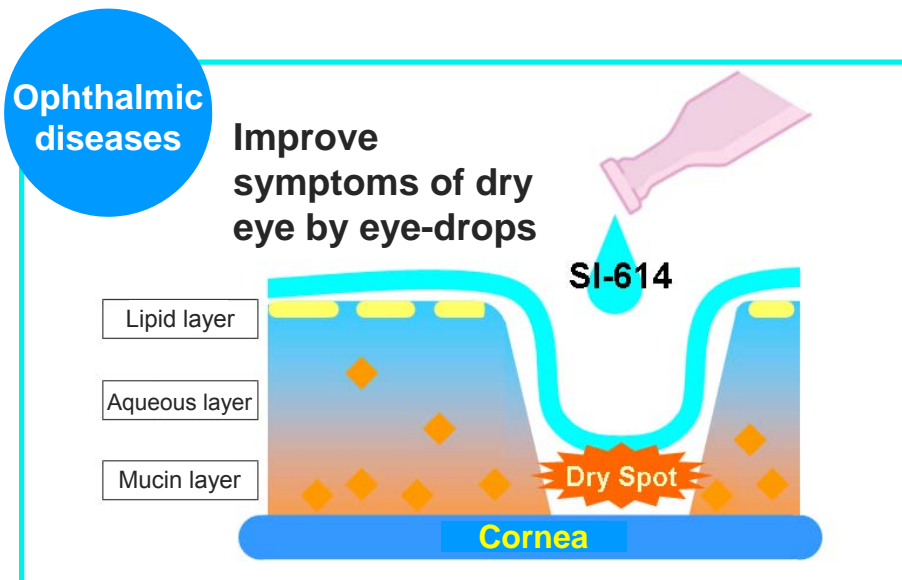
- **July 2015: Case registration of PIII completed**
  - ⇒ **Now Observation period**
- **April 2015: Open-label for the purpose of safety evaluation started**

### 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

# 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. / EU : PII/III

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

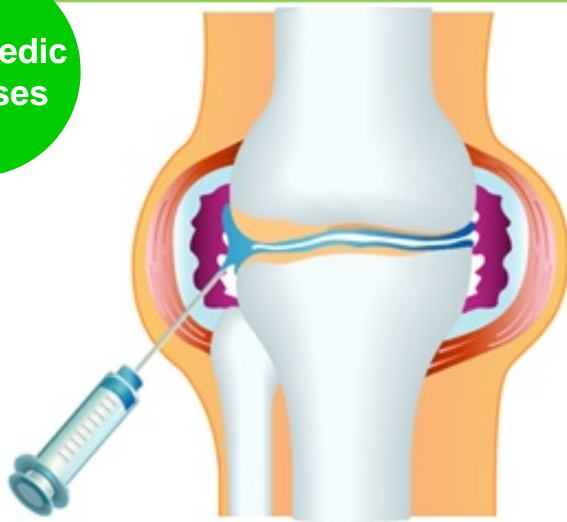
## Features :

- 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

- July 2015: Case registration completed
  - January 2016: Phase II completed  
(multiple dose study)
- ⇒ Now under the process of statistical analysis

### 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

# The Seikagaku Corporation Ten-Year Vision

(Est. March 2009)

## Ten-Year Vision “Global Category Pharma”

Focus research and development on glycoscience establishes global competitiveness

Build up a new market every three years, by launching a new product, and/or developing new regions

## *ACT for the future*

Advance · Challenge · Transparency

Cultivation of new leads  
for achieving the Ten-Year Vision

Cultivation of basic strength  
and systems development

Step1

FY2009 ~ FY2011

Step2

FY2012 ~ FY2015

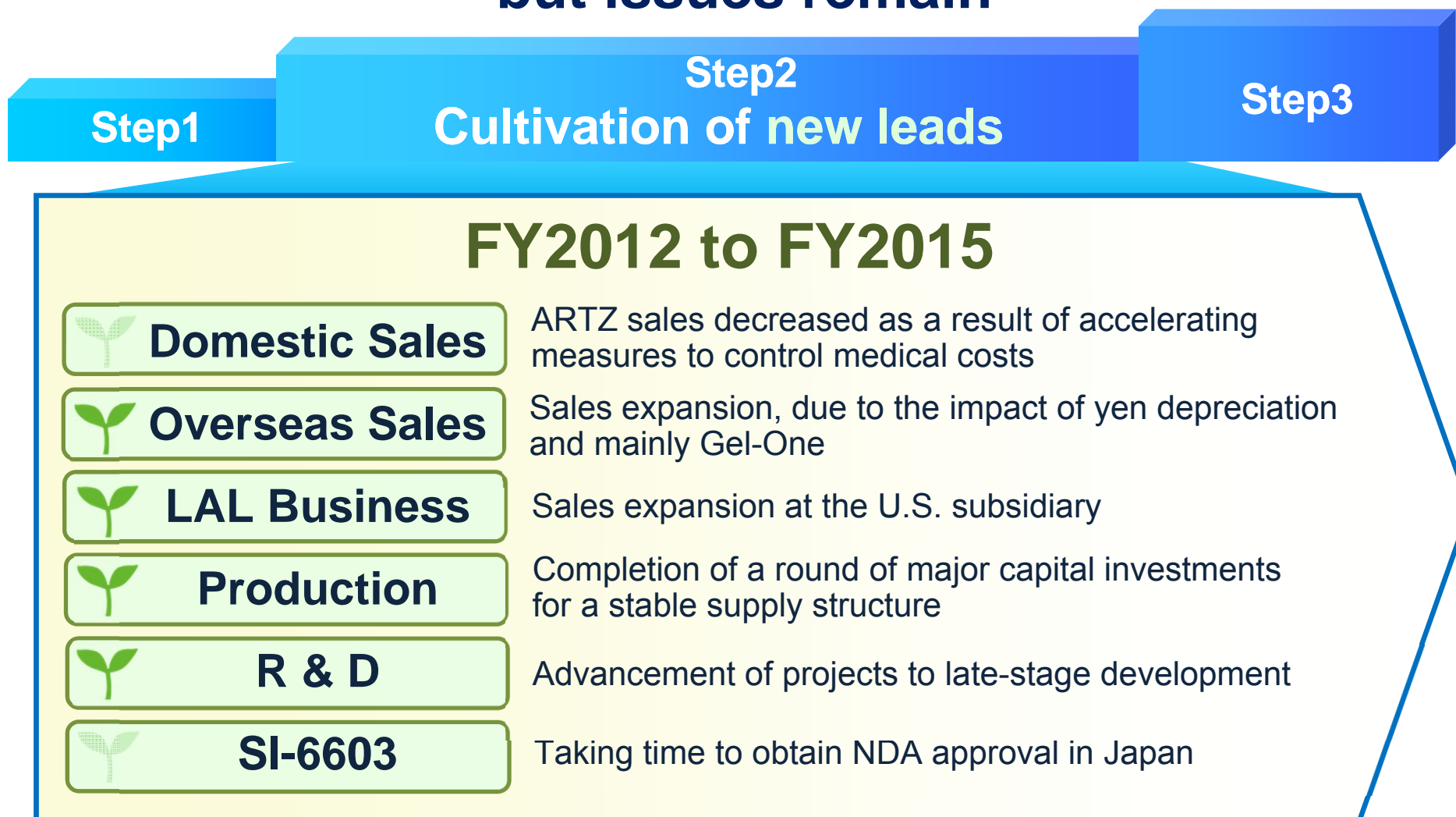
Step3

FY2016 ~ FY2018

# 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)

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

***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》

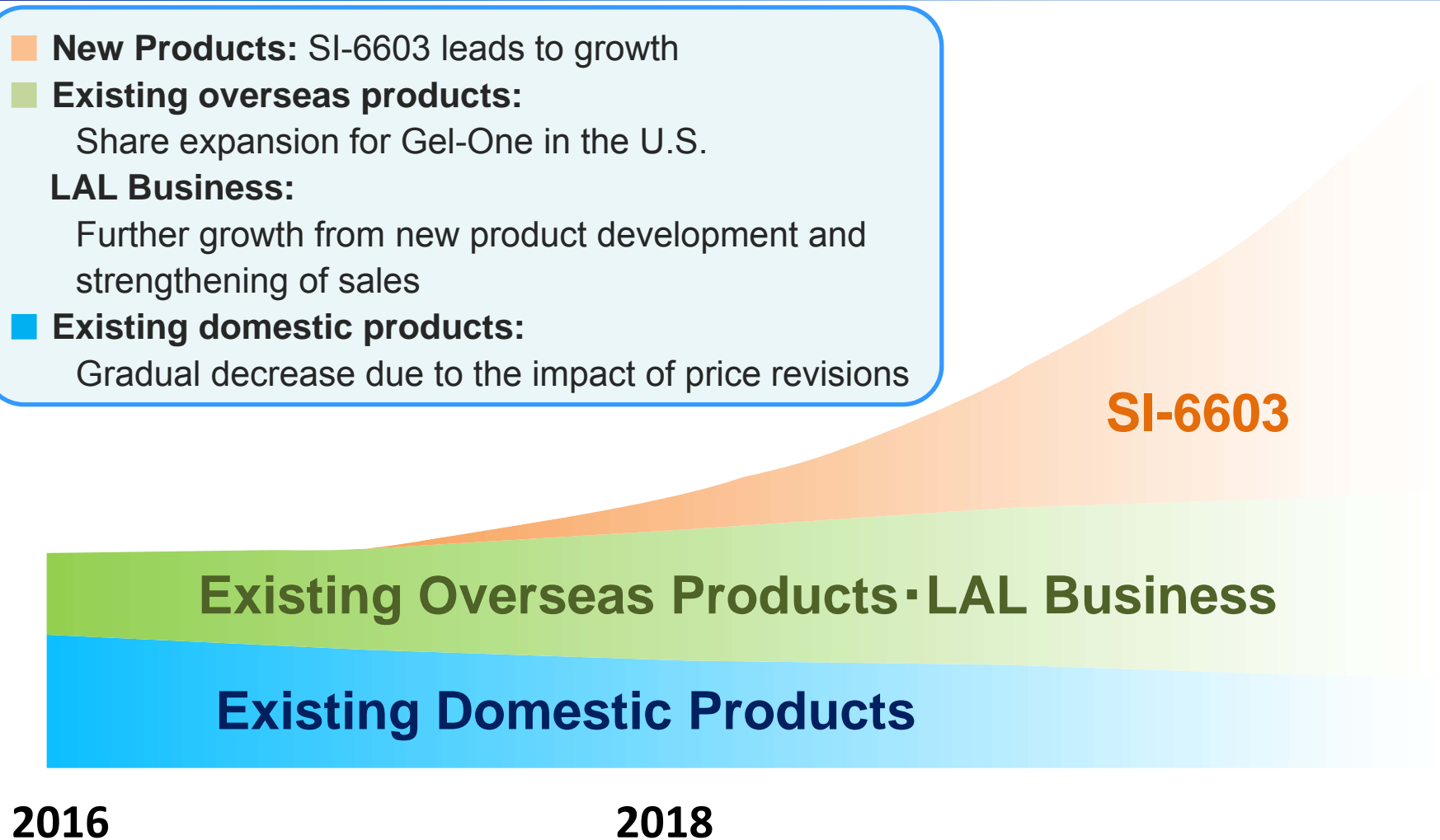
- Overseas business expansion to compensate for a decrease in revenue due to NHI drug price reductions in Japan (overseas sales ratio: 45%)
- A high level of R&D expenses (ratio of R&D expenses to net sales: 25% to 30%)
- Various royalty incomes as non-operating income
- Exchange rate: ¥110 to the U.S.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

# 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

## Business Investment

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

|                       | FY2012 | FY2013 | FY2014 | FY2015  | FY2016<br>(Forecast) |
|-----------------------|--------|--------|--------|---------|----------------------|
| Net Income per share  | ¥57.33 | ¥83.55 | ¥64.27 | ¥45.39  | ¥44.89               |
| Annual Total Dividend | ¥25.00 | ¥26.00 | ¥26.00 | ¥26.00* | ¥26.00               |
| Dividend Payout Ratio | 43.6%  | 31.1%  | 40.5%  | 57.3%*  | 57.9%                |

\*Year-end dividend of ¥13 per share to be decided at the general meeting of shareholders on June 2016.

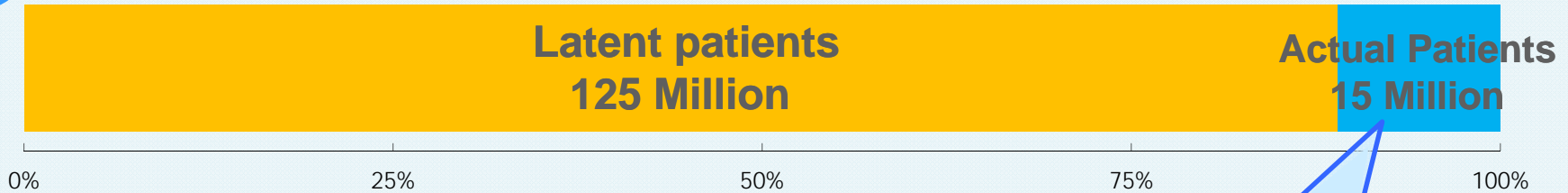
# Appendix





# 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)

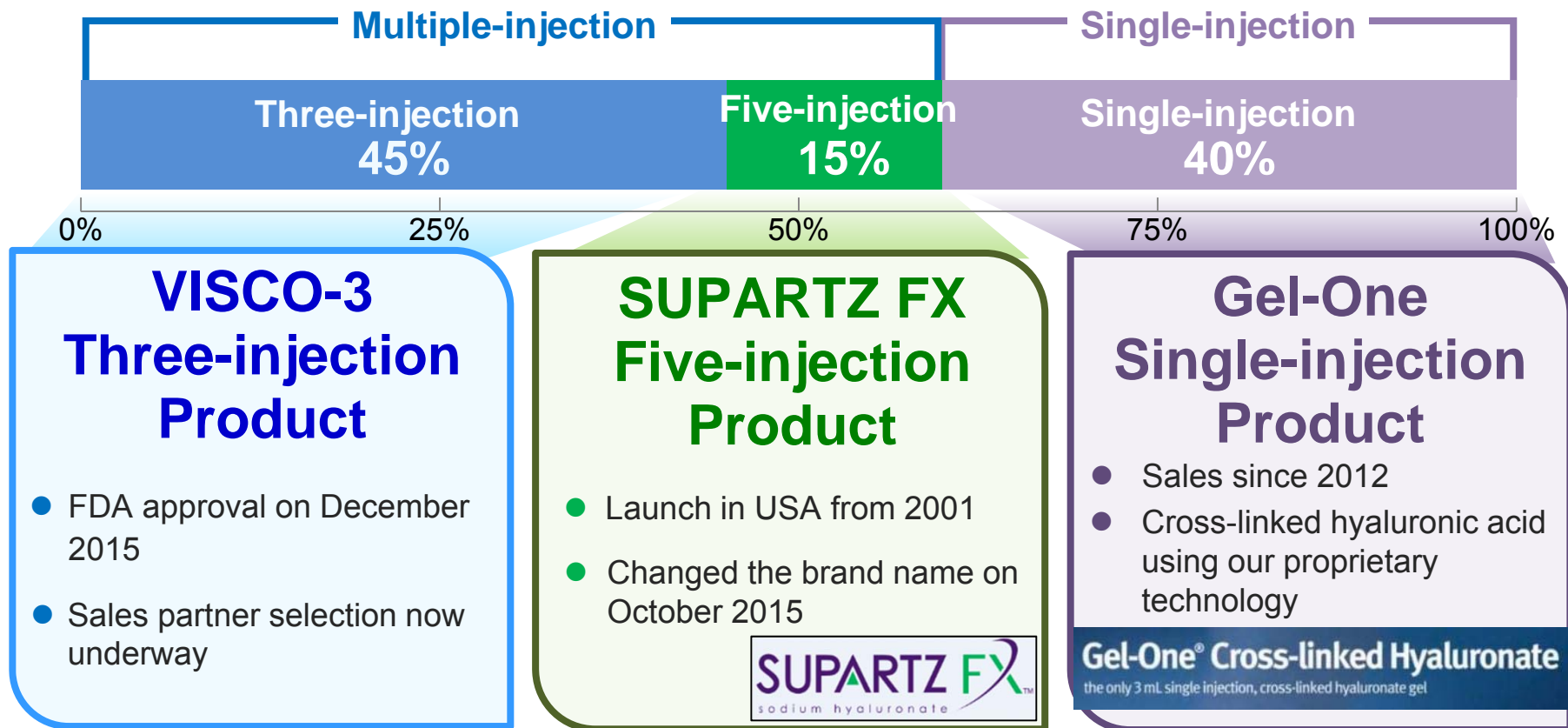


\* Numbers in this slide are estimated by Seikagaku

# Product Line Enhancement Measures in the U.S.

Expand the product line and try to seek intensification for presence of Seikagaku's products

■ U.S. Market Share Breakdown by Number of Injections  
(2015, Seikagaku estimate)



# 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

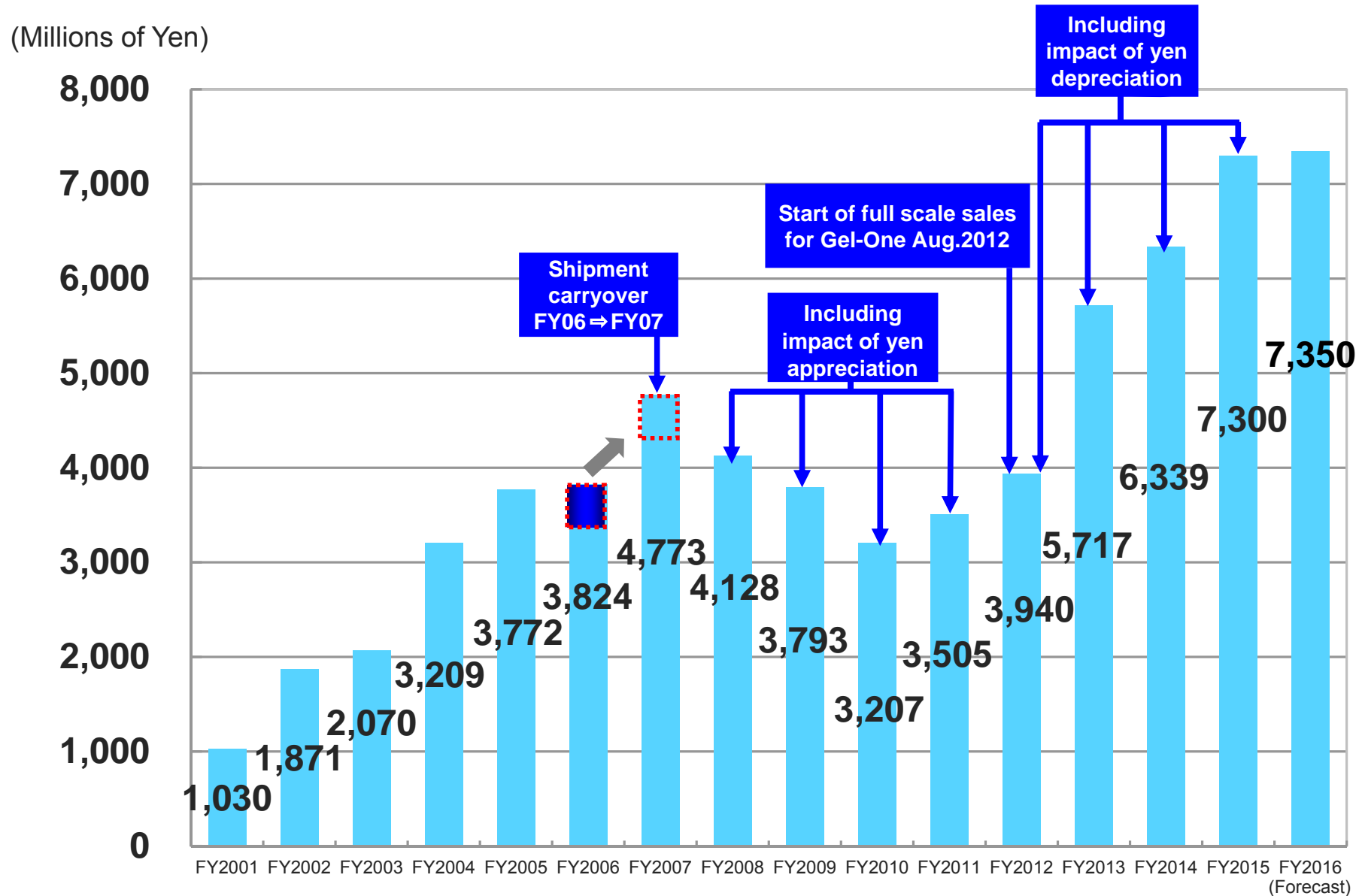
### ◆ **Zimmer Biomet** : Strengthening of sales capabilities

- 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.

# Trend in Overseas Sales of Hyaluronic Acid Products



# 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



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

➤ **Size of the global market: Approx. ¥25.0 billion**  
(Seikagaku estimate, including associated equipment)

## 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

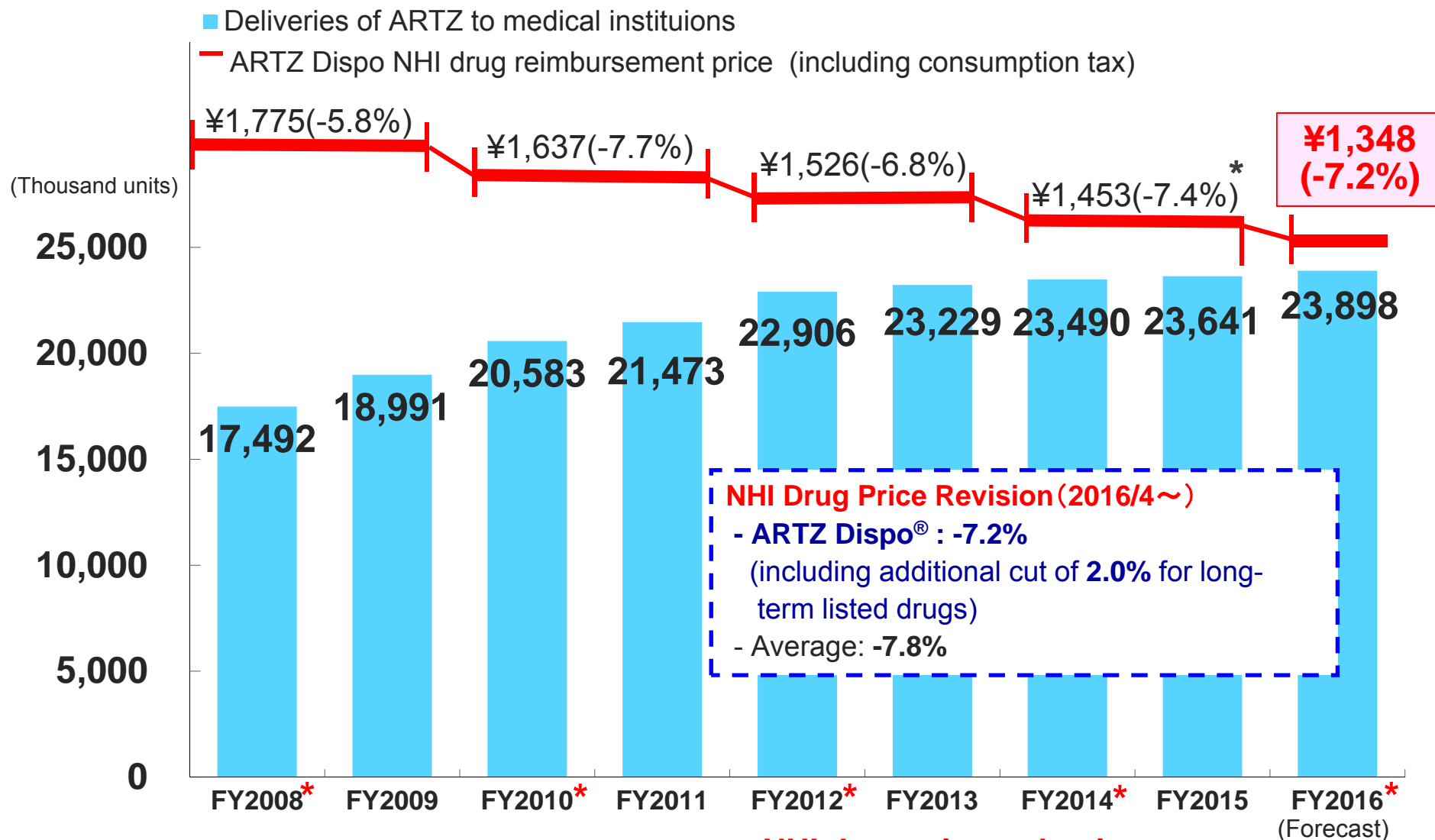


PYROCHROME®



Exterior of the ACC offices

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



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

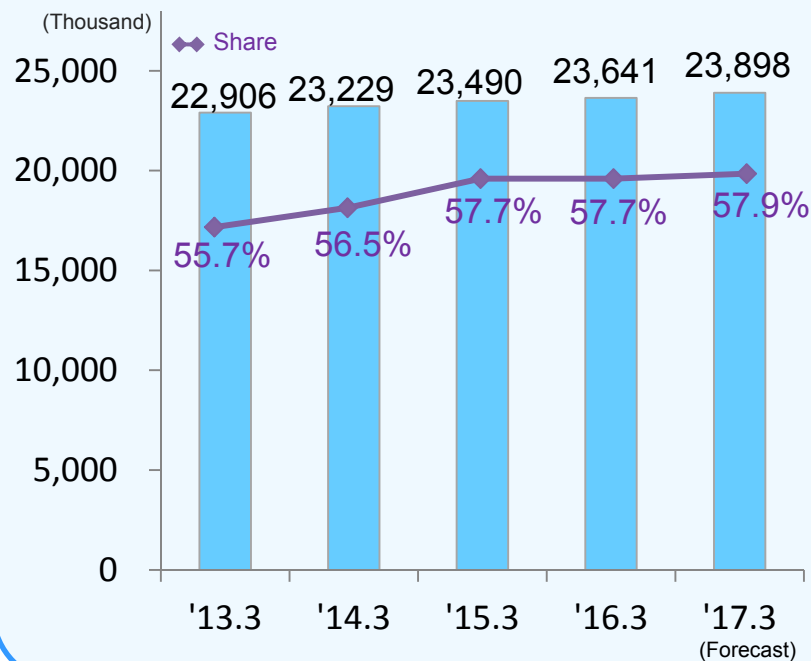
Joint-function improving agent

## 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



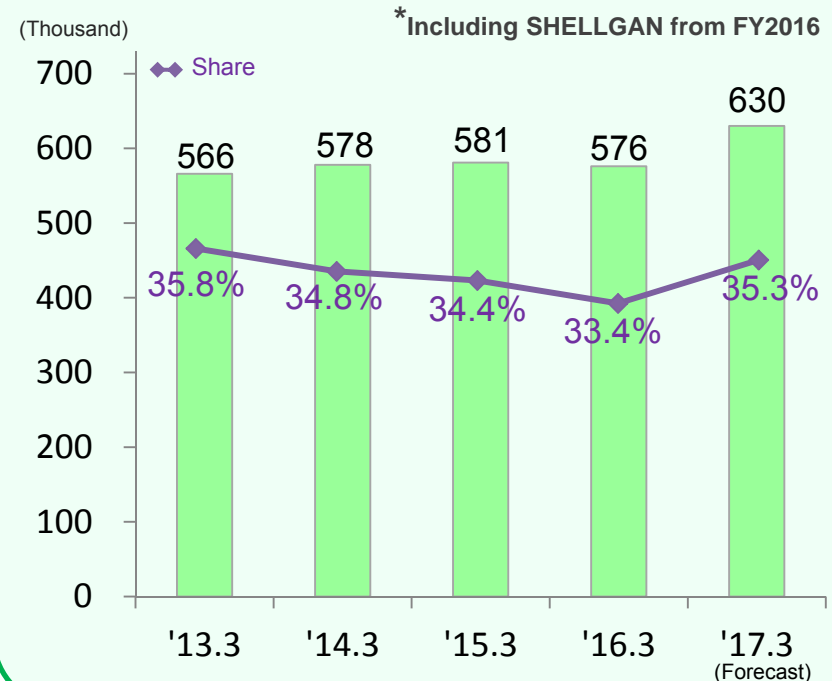
Ophthalmic surgical aids

## OPEGAN



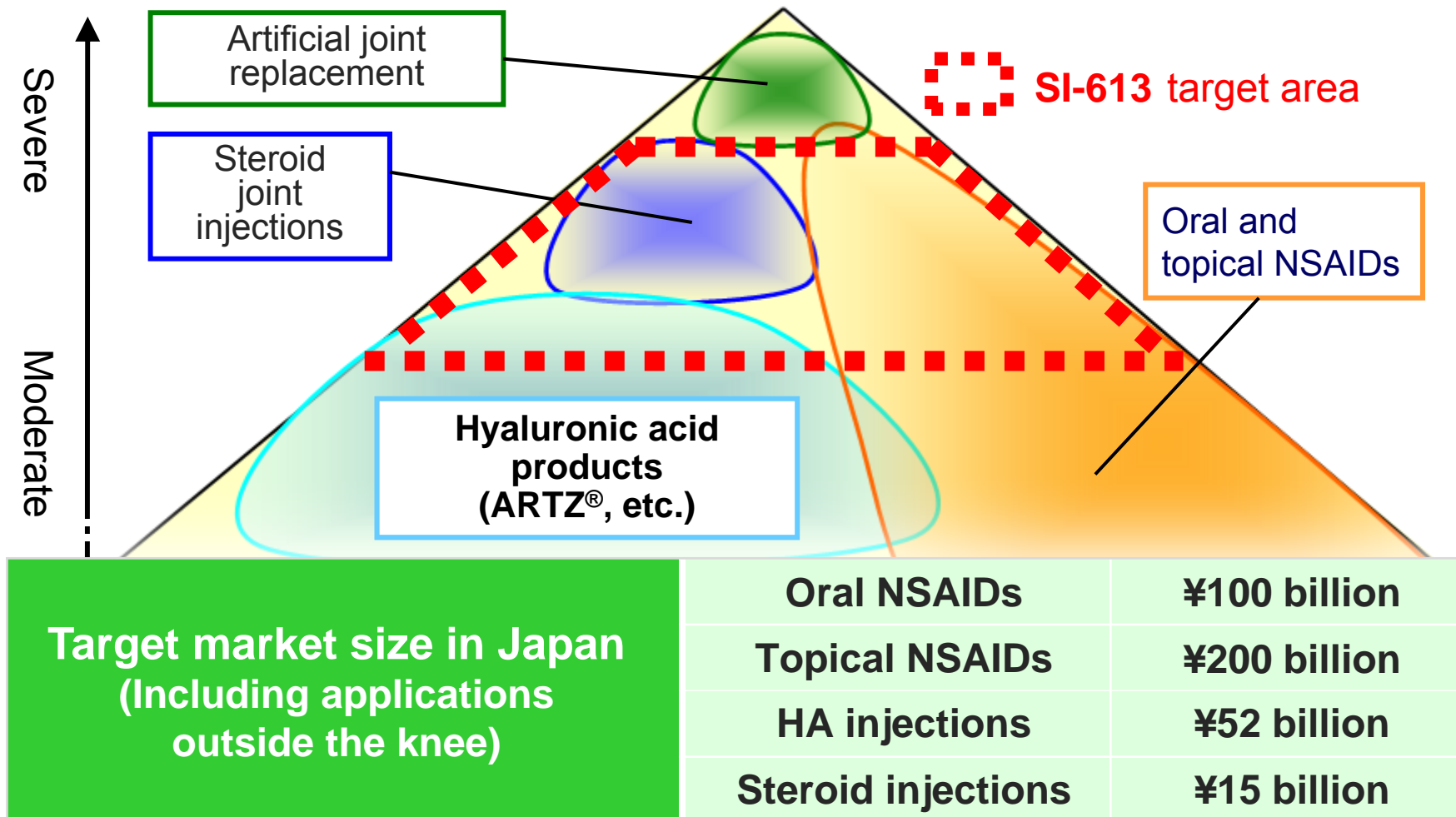
- The first domestically HA formulation
- Used in cataract surgery to anterior chamber expansion
- Distributor: Santen Pharmaceutical

Trend in unit deliveries to medical institutions



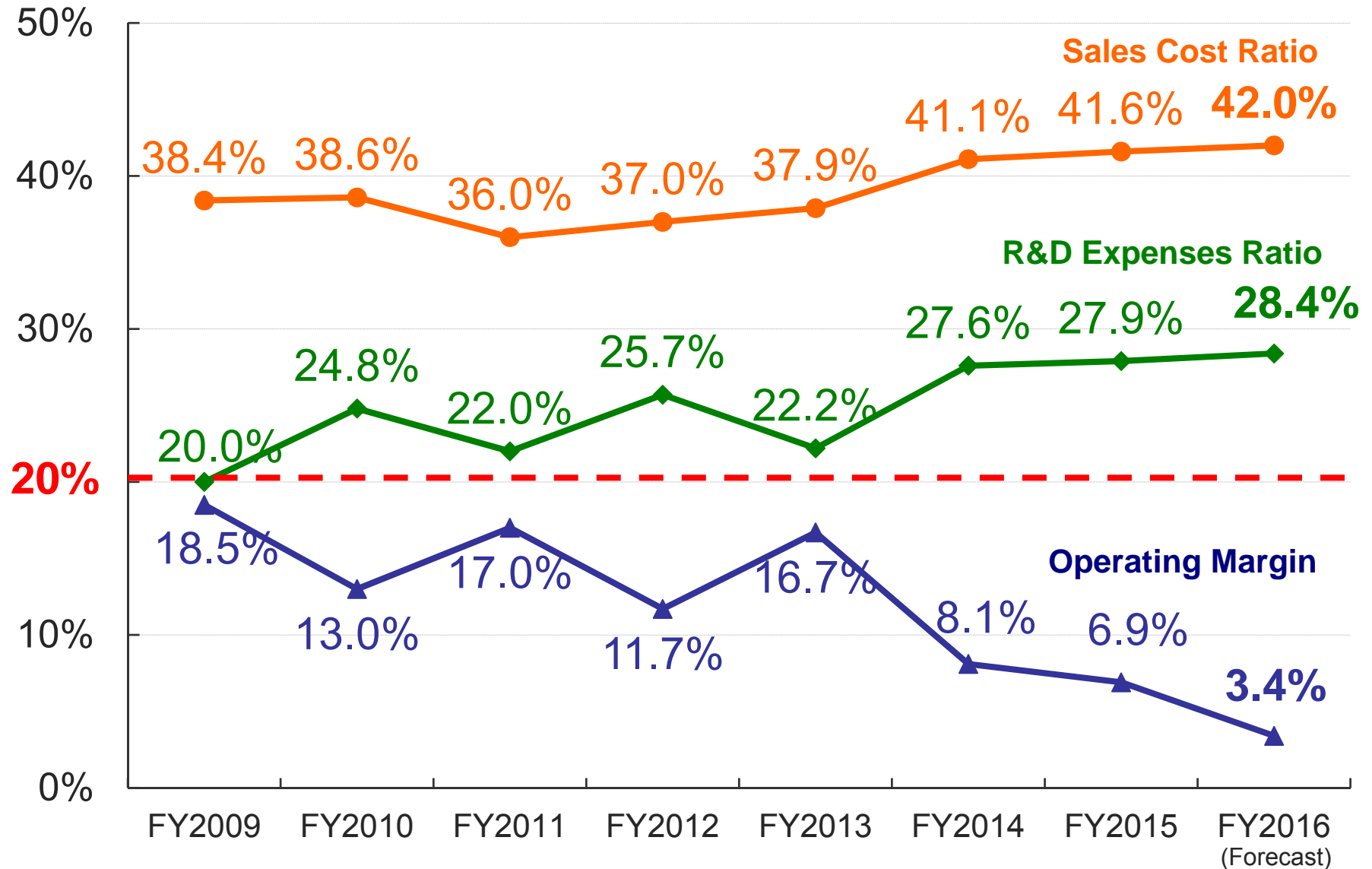
# SI-613 Target Patients

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

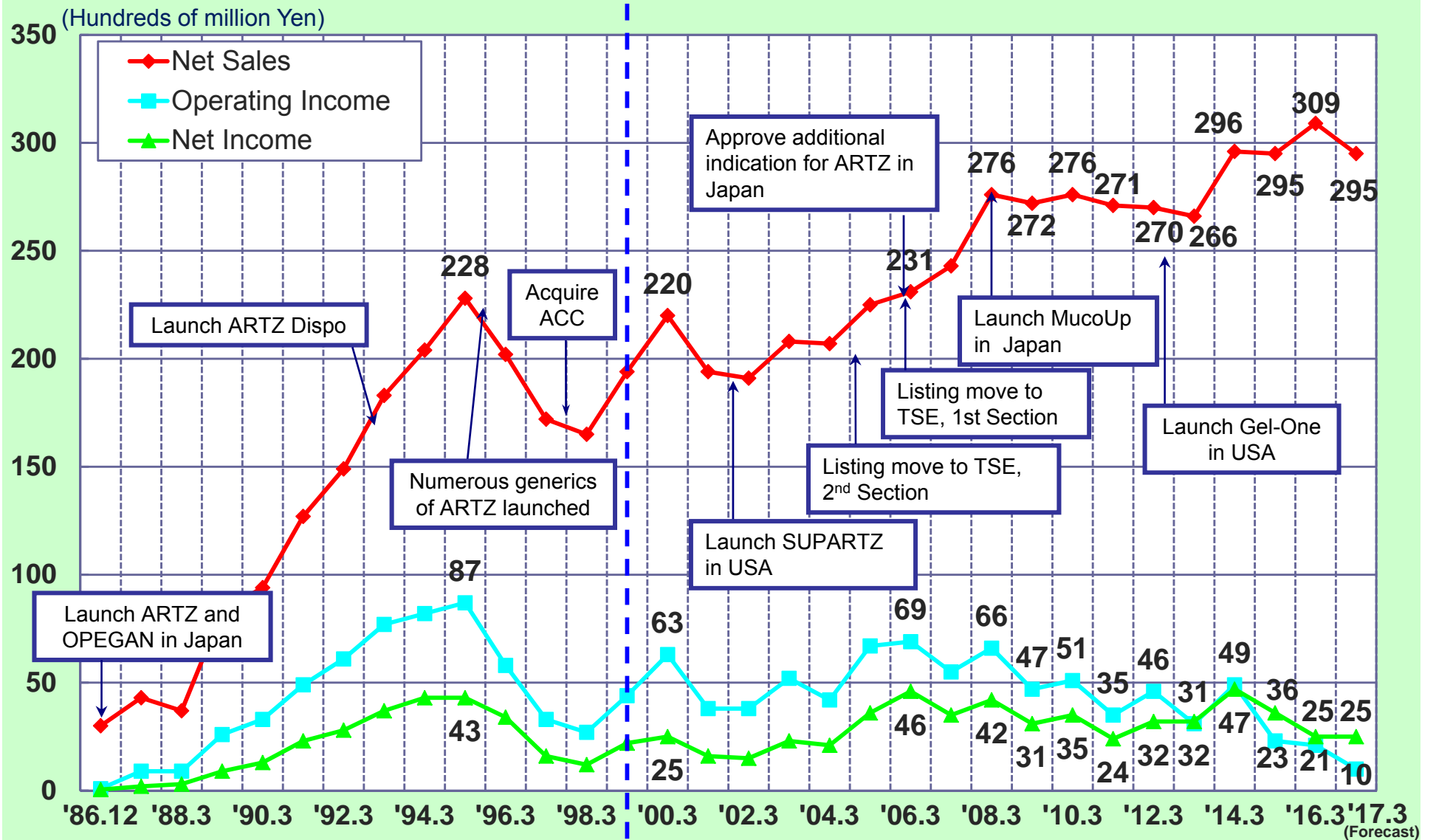




# Trend in Financial Index



# Business Progress & Highlights

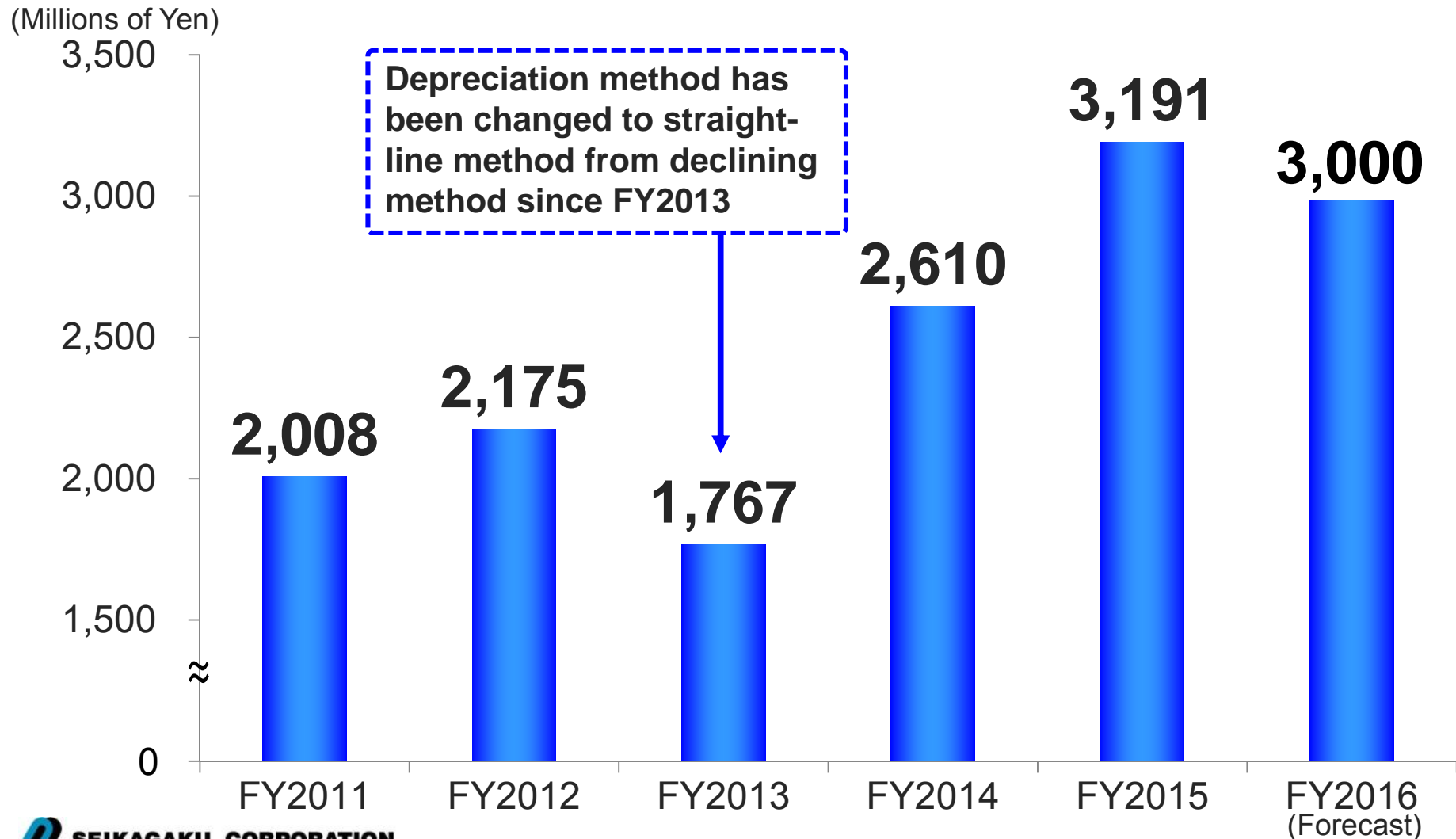


# Trend in Capital Investments

| Facilities                                     | Amounts<br>(¥ bill.) | FY2011       | FY2012          | FY2013       | FY2014           | FY2015          | FY2016<br>(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<br/>(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>1,700</b>         |

# Trend in Depreciation

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



# Special Profile

**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 **25% to 30%** of net sales to R&D investment

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

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

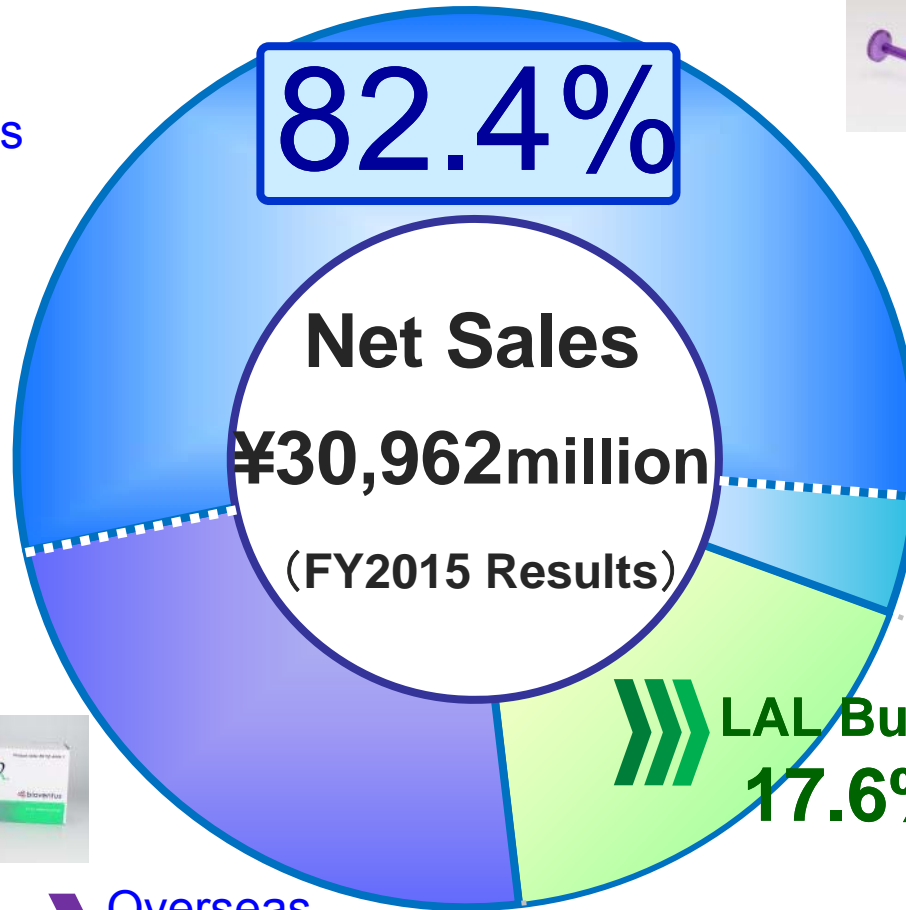
- The **first company** to have successfully developed chondroitin sulfate for industrial use
- ARTZ has been approved in Japan, the U.S., China and Europe as well from 1897

# Our Business Segment

## Pharmaceutical Business

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)



# 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**