

# Financial Results for the Fiscal Year 2021



**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 of Fiscal Year 2021

(Millions of Yen)	FY2021 Results	Year-on-Year		Comparison with Forecasts	
		Change	% of Change	Change	% of Change
Net sales	<b>34,851</b>	<b>+7,117</b>	<b>+25.7%</b>	<b>+2,651</b>	<b>+8.2%</b>
Operating Income	<b>4,495</b>	<b>+2,246</b>	<b>+99.9%</b>	<b>-54</b>	<b>-1.2%</b>
Ordinary Income	<b>5,395</b>	<b>+2,370</b>	<b>+78.4%</b>	<b>+745</b>	<b>+16.0%</b>
Net Income	<b>3,733</b>	<b>-528</b>	<b>-12.4%</b>	<b>+83</b>	<b>+2.3%</b>
R&D Expenses (excluding royalty income)	<b>9,005</b> <b>(29.2%)</b>	<b>+1,795</b> <b>(+2.5pt)</b>	<b>+24.9%</b>	<b>+1,105</b> <b>(+0.9pt)</b>	<b>+14.0%</b>
Average Exchange Rate (1US\$)	¥112.38	+6.32			

	FY2021 Results	FY2020 Results	FY2021 Forecasts
Net Income per Share	<b>¥66.32</b>	¥75.54	¥64.68
R O E	<b>5.7%</b>	6.9%	
SKK EBITDA*	<b>5,546million yen</b>	3,057million yen	3,150million yen

# Net sales by Business Segment (FY2021)

(Millions of Yen)	FY2021 Results	Year-on-Year	% of Change
<b>Net sales</b>	<b>34,851</b>	<b>+7,117</b>	<b>+25.7%</b>
<b>Pharmaceuticals</b>	<b>25,696</b>	<b>+4,903</b>	<b>+23.6%</b>
<b>Domestic Pharmaceuticals</b>	<b>11,447</b>	<b>-4</b>	<b>-0.0%</b>
Overseas Pharmaceuticals	7,652	+875	+12.9%
Bulk Products /CDMO	2,607	+760	+41.2%
Royalty Income	3,989	+3,271	+455.6%
LAL Business	9,155	+2,213	+31.9%
<b>(Overseas sales)</b>	<b>17,918</b>	<b>+3,557</b>	<b>+24.8%</b>

\* Foreign exchange impact on overall net sales : approx. +750million yen

## Domestic Pharmaceuticals

### ▶ ARTZ (Joint-function improving agent)

- Seikagaku sales down slightly due to NHI price reductions

### ▶ JOYCLU (Joint-function improving agent)

- May 19, 2021 launch
- Information provision efforts to ensure appropriate use

### ▶ OPEGAN series (Ophthalmic viscoelastic devices)

- Seikagaku sales down due to NHI drug price reductions and a decline in shipments from a high level in FY2020

### ▶ MucoUp

(Submucosal injection agent for endoscopic surgery)

- Seikagaku sales at prior-year level due to sales partner inventory adjustments, despite recovery from the impact of COVID-19

### ▶ HERNICORE (Treatment for lumbar disc herniation)

- Seikagaku sales up on higher deliveries to medical institutions



HERNICORE:

Japan's first treatment for lumbar disc herniation launched in August 2018

# Net sales by Business Segment (FY2021)

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\* Foreign exchange impact on overall net sales :  
approx. +750million yen

## Overseas Pharmaceuticals

\*Foreign exchange impact on Overseas Pharmaceuticals:  
approx. +350 million yen

### ► Gel-One in the U.S. (Single injection)

- Successful measures to promote switching from competing products
- Seikagaku sales up on higher local sales volume



Gel-One:  
Intra-articular single-injection  
viscosupplement for the  
treatment of knee osteoarthritis

### ► SUPARTZ FX in the U.S. (Multiple injection)

- Seikagaku sales up due to higher local sales volume and bringing forward of shipments to avoid distribution risk

### ► ARTZ in China (Multiple injection)

- Seikagaku sales up due to higher local sales volume and bringing forward of shipments in connection with a change in packaging materials

# Net sales by Business Segment (FY2021)

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\* Foreign exchange impact on overall net sales : approx. +750million yen

## Bulk Products / CDMO

\*Foreign exchange impact on Bulk Products/CDMO: approx. +180million yen

Despite sales of bulk products declining, sales of CDMO, etc. at Dalton Chemical Laboratories, Inc. increased

## Royalty Income

Substantial increase

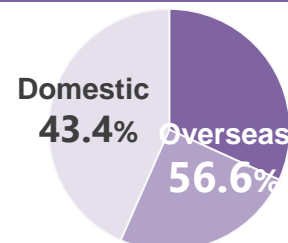
\* Royalty income reclassified from non-operating income to net sales beginning in FY2021

## LAL Business

\*Foreign exchange impact on LAL Business: approx. +220million yen

In addition to a steady trend in domestic sales, sales up on growth in sales of ACC's reagents for Bacterial Endotoxin Testing (BET), contract services and Clinical Diagnostic (Fungitell) reagents

## Overseas Sales Ratio (excluding royalty income)



Year-on-Year  
**+6.1pt**

■ Overseas LAL, Bulk/CDMO ■ Overseas Pharmaceuticals ■ Domestic sales

# Income in FY2021 (Year-on-Year)

(Millions of Yen)	FY2021 Results	Year-on-Year	% of Change
<b>Net sales</b>	<b>34,851</b>	<b>+7,117</b>	<b>+25.7%</b>
Cost of Sales (excluding royalty income)	<b>14,323</b> (46.4%)	<b>+2,210</b> (+1.6pt)	<b>+18.2%</b>
SGA expenses	<b>16,033</b>	<b>+2,660</b>	<b>+19.9%</b>
R&D Expenses (excluding royalty income)	<b>9,005</b> (29.2%)	<b>+1,795</b> (+2.5pt)	<b>+24.9%</b>
Operating Income (to Net sales ratio)	<b>4,495</b> (12.9%)	<b>+2,246</b> (+4.8pt)	<b>+99.9%</b>
Ordinary Income	<b>5,395</b>	<b>+2,370</b>	<b>+78.4%</b>
Net Income	<b>3,733</b>	<b>-528</b>	<b>-12.4%</b>
Depreciation	<b>1,051</b>	<b>+242</b>	<b>+30.0%</b>

**Operating Income 4,495(+2,246)**

**Cost of sales ratio (+1.6pt)**

- Increase due to factors including NHI price reductions and soaring energy prices

**SGA Expenses (+2,660)**

- Increase in R&D expenses due to progress with additional clinical study of SI-6603 in the U.S. (+1,795)

**Ordinary Income 5,395 (+2,370)**

**Non-operating Income / Expenses (+124)**

- Increase in foreign exchange gain (+277)

**Ordinary Income 3,733 (-528)**

**Income Taxes (+2,899)**

- Prior-year deferred taxes (-1,561)

# Income in FY2021 (Forecasts 5/13)

(百万円)	FY2021 Results	Compa. with forecasts	% of Change
<b>Net sales</b>	<b>34,851</b>	<b>+2,651</b>	<b>+8.2%</b>
Operating Income (to Net sales ratio)	<b>4,495</b> (12.9%)	<b>-54</b> (-1.2pt)	<b>-1.2%</b>
Ordinary Income	<b>5,395</b>	<b>+745</b>	<b>+16.0%</b>
<b>Net Income</b>	<b>3,733</b>	<b>+83</b>	<b>+2.3%</b>
<b>Cost of Sales</b> (excluding royalty income)	<b>46.4%</b>	<b>+1.6pt</b>	<b>—</b>
<b>R&amp;D Expenses</b> (excluding royalty income)	<b>9,005</b> (29.2%)	<b>+1,105</b> (+0.9pt)	<b>+14.0%</b>
<b>Depreciation</b>	<b>1,051</b>	<b>-98</b>	<b>-8.6%</b>

\* Foreign exchange impact on overall net sales : approx. +890million yen

## Net sales

Forecast exceeded due to strong LAL Business sales and the impact of yen depreciation

**Pharmaceuticals (+596)**

**LAL Business (+2,105)**

## Operating Income

**Cost of Sales Ratio (+1.6pt)**

- Increase due to changes in the sales mix

**SGA Expenses (+933)**

- Progress with research themes and higher R&D expenses

## Ordinary Income

**Non-operating Income / Expenses (+849)**

- Increase due to exchange gain on foreign currency-denominated investment assets

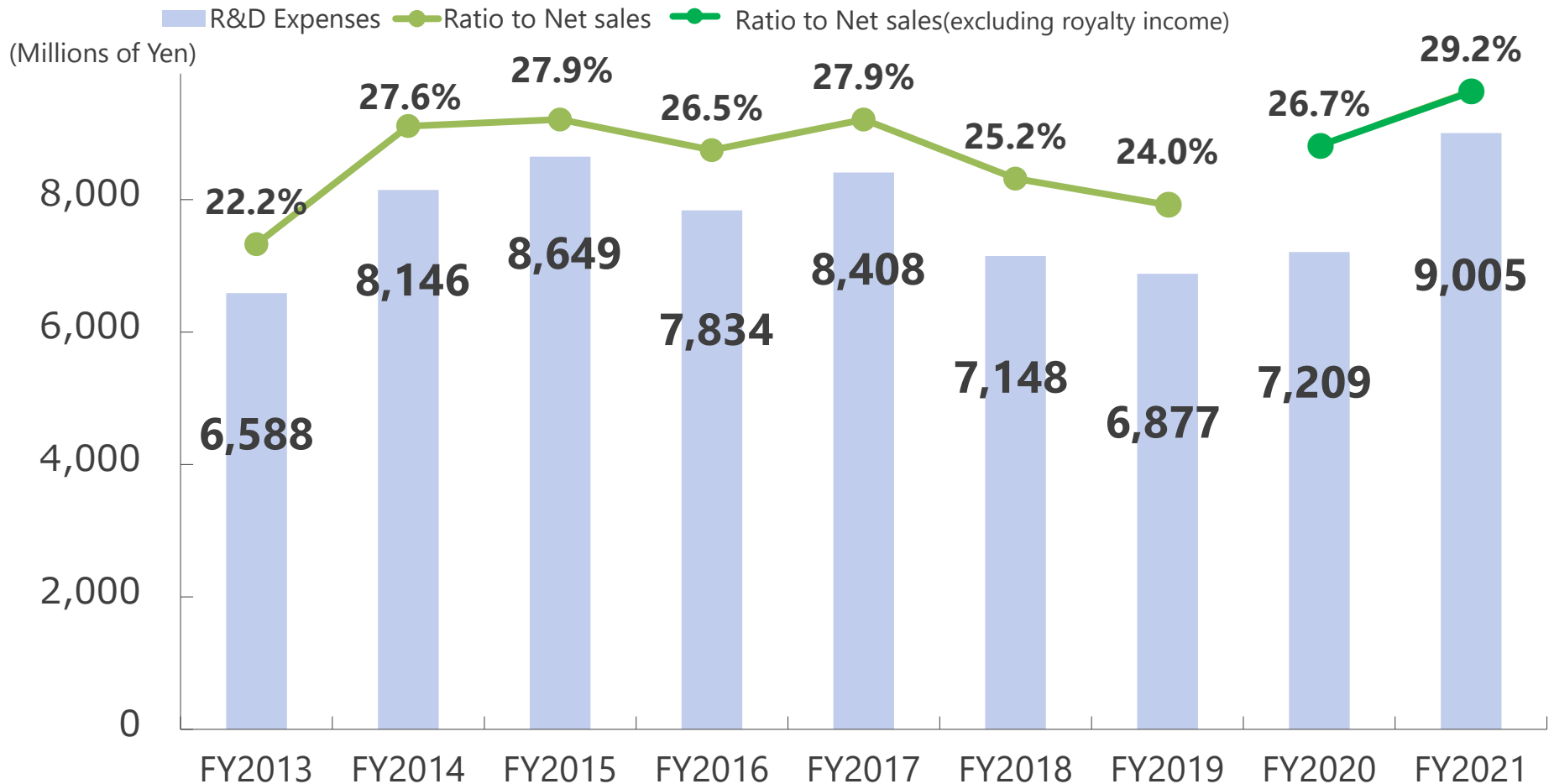
## Net Income

- Almost in line with the initial forecast



# Trend in R&D Expenses

**Continuing to focus on drug discovery specializing in Glycoscience  
Undertaking improvement in R&D efficiency**



# Forecasts for Fiscal 2022

## Fiscal 2022 financial forecasts

It is difficult at present to prepare reasonable forecasts of consolidated financial results for fiscal 2022 because it is necessary to assess the progress of efforts to identify the cause of shock or anaphylaxis occurring in patients following administration of the joint function improvement agent JOYCLU. Accordingly, the Company will refrain from announcing earnings forecasts at this time.

Once it becomes possible to prepare reasonable forecasts, the Company will promptly announce them.

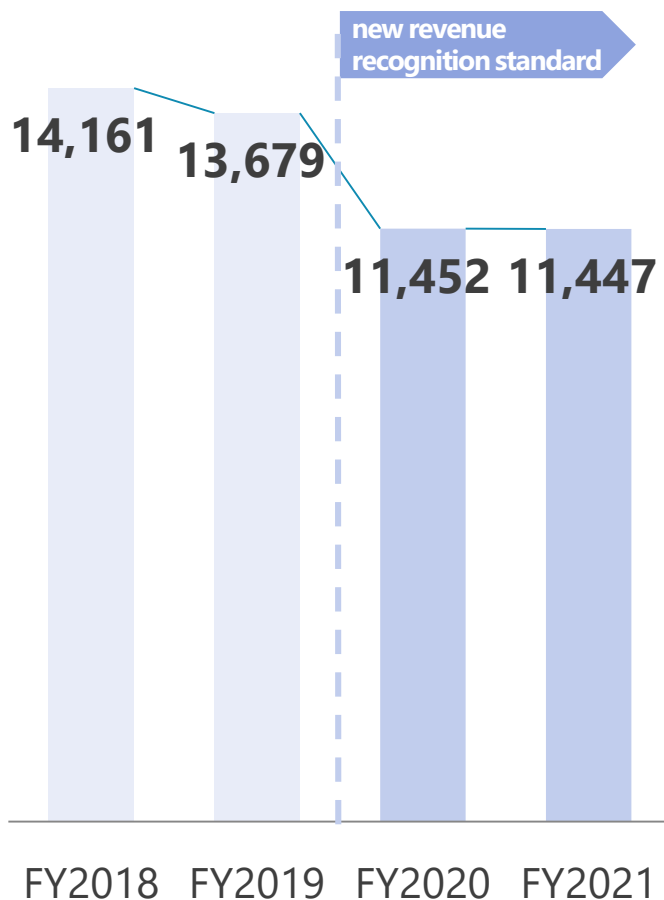
## Current Assumptions

- ▶ Drug price reductions (implemented April 2022) Approx.  
: -11% (Weighted average for domestic pharmaceuticals as a whole)  
ARTZ: -12.6% OPEGAN: -7%
- ▶ FY2021 overseas sales ratio: Approx. 56% (denominated mainly in U.S. dollars)  
Financial results will be affected by any sharp yen appreciation or depreciation from the FY2021 average exchange rate (¥112.4 to US\$1)
- ▶ Royalties: decrease expected due to non-recurrence of a prior-year one-time increase
- ▶ R&D expenses: decrease expected due to completion of subject enrollment for an additional clinical study in the U.S. for SI-6603, a treatment for lumbar disc herniation
- ▶ COVID-19 infection impact at the same level as in FY2021

# Domestic Pharmaceuticals 1/2 (FY2021 Results Year-on-Year)

## Domestic Pharmaceuticals Sales trend

(Millions of Yen)



## FY2021 Results

**-0.0%**  
(sales basis)

Sales at the prior-year level, with recovery from the impact of COVID-19 and the launch of JOYCLU compensating for the impact of NHI price reductions

## Joint-function improving agent (Unit deliveries to medical institutions)

### Market (+1.0%)

- Trend toward recovery from the impact of COVID-19

### ARTZ (+3.0%)

#### FY2021 Results

- Volume and market share increases due to market recovery and the continued impact of measures to acquire new user facilities (62.4% / +1.2pt)

#### FY2022 Assumptions

- Forecasting sales at the prior-year level due to efforts to maintain market share

### JOYCLU

#### FY2021 Results

- Negative sales of products with approaching ship-by dates recorded in 3Q in connection with issuance of the Blue Letter

#### FY2022 Assumptions

- Information provision efforts to ensure appropriate use

## Safety Information on Joint Function Improving Agent JOYCLU

**Blue Letter (rapid safety information) issued June 1**  
**Prompt provision of information to alert healthcare professionals**  
**Initiation of clinical research to identify the cause**

**Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter)**

issued on June 1 in response to multiple reports of anaphylaxis occurring in patients following administration of JOYCLU



- To ensure patient safety by promptly alerting healthcare professionals of the situation to enable the provision of appropriate treatment and measures
- Addition of a WARNING section to the drug package insert and revision of the IMPORTANT PRECAUTIONS section
- Leaflet created to alert patients and their families to the risk of side effects



**Continued gathering of safety information and provision of safety-related information in collaboration with sales partner Ono Pharmaceutical.**  
**Initiation of physician-led clinical research to identify the cause**

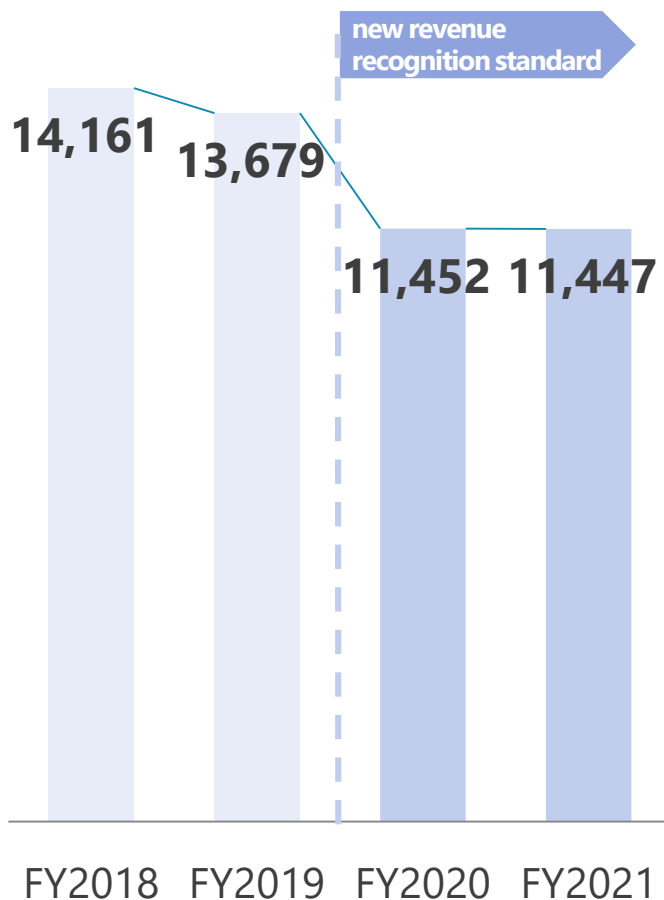
Information included in the package insert at the time of NDA approval

- Important Side Effects: Shock, anaphylaxis (0.4%)
- Contraindications: Patients with a previous history of hypersensitivity to diclofenac sodium and sodium hyaluronate (the ingredients of JOYCLU)

# Domestic Pharmaceuticals 2/2 (FY2021 Results Year-on-Year)

## Domestic Pharmaceuticals Sales trend

(Millions of Yen)



## FY2021 Results

**-0.0%**  
(sales basis)

Sales at the prior-year level, with recovery from the impact of COVID-19 and the launch of JOYCLU compensating for the impact of NHI price reductions

### Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

#### Market (+7.0%)

- Trend toward recovery from the impact of COVID-19

#### OPEGAN (+3.5%)

##### FY2021 Results

- Volume increase accompanying market recovery
- Market share contraction following a prior-year volume increase due to shipment adjustments for competing products (51.9% / -1.8pt)

##### FY2022 Assumptions

- Sales at prior-year level due to retention of newly acquired accounts

### Treatment for lumbar disc herniation (Unit deliveries to medical institutions)

#### HERNICORE

##### FY2021 Results

- Sales increase due to a trend toward recovery from the impact of COVID-19 and an increase in the number of new user facilities

##### FY2022 Assumptions

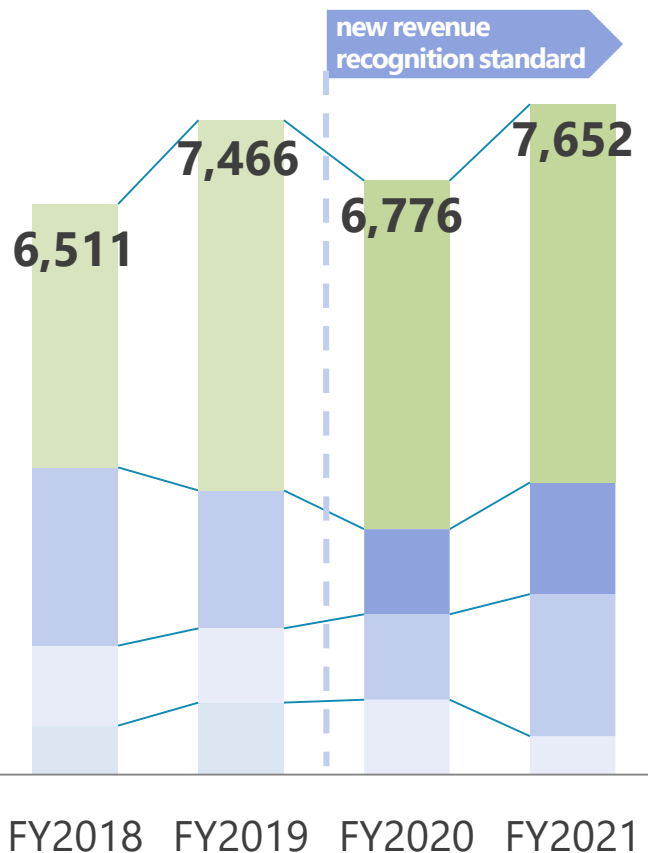
- Continuation of proper use promotion and patient awareness activities

# Overseas Pharmaceuticals 1/2 (FY2021 Results Year-on-Year / value basis)

## Overseas Pharmaceuticals Sales trend

<Breakdown> (Millions of Yen)

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



## FY2021 Results

+12.9%  
(sales basis)

Sales up due to recovery from the impact of COVID-19 and bringing forward of shipments of SUPARTZ FX and ARTZ in China

## U.S.

\* Foreign exchange impact: approx. + ¥350million

### Market in U.S.

- Trend toward recovery from the impact of COVID-19
- Continuation of a trend toward preference for products that require a low number of injections

### Gel-One

#### FY2021 Results

(approx. +15% on a volume basis)

Local sales : Sharp increase due to recovery from the impact of COVID-19

Seikagaku exports : Sales increase on higher local sales volume

#### FY2022 Assumptions

Local sales : Forecasting impact from price announcement-related system changes

### SUPARTZ FX

#### FY2021 Results

Local sales : Increase due to recovery from the impact of COVID-19  
 Seikagaku exports : Sharp increase due to shipments brought forward

#### FY2022 Assumptions

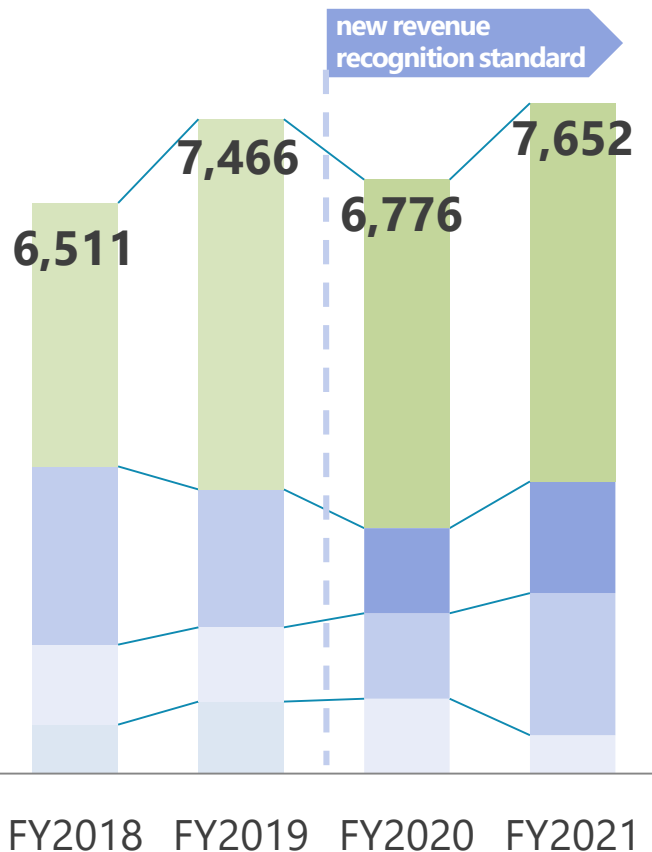
Local sales : Decrease forecasted due to a trend toward preference for products that require a low number of injections

# Overseas Pharmaceuticals 2/2 (FY2021 Results Year-on-Year / value basis)

## Overseas Pharmaceuticals Sales trend

<Breakdown> (Millions of Yen)

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



## FY2021 Results

+12.9%  
(sales basis)

Sales up due to recovery from the impact of COVID-19 and bringing forward of shipments of SUPARTZ FX and ARTZ in China

**China, Other Regions** \* Foreign exchange impact: approx. + ¥350million

### Market in China

- Start of centralized procurement by multiple provinces and regions
- Impact of COVID-19 lockdowns in some regions

### ARTZ in China

#### FY2021 Results

Local sales : Increase due to growth in regions where successful bids were submitted in the centralized procurement system and higher orders in preparation for sluggish distribution due to the spread of COVID-19

Seikagaku exports : Increase due to higher local sales volume and local inventory buildup

#### FY2022 Assumptions

Local sales : Possible decrease due to the centralized procurement trend

### Other Region

#### Seikagaku exports

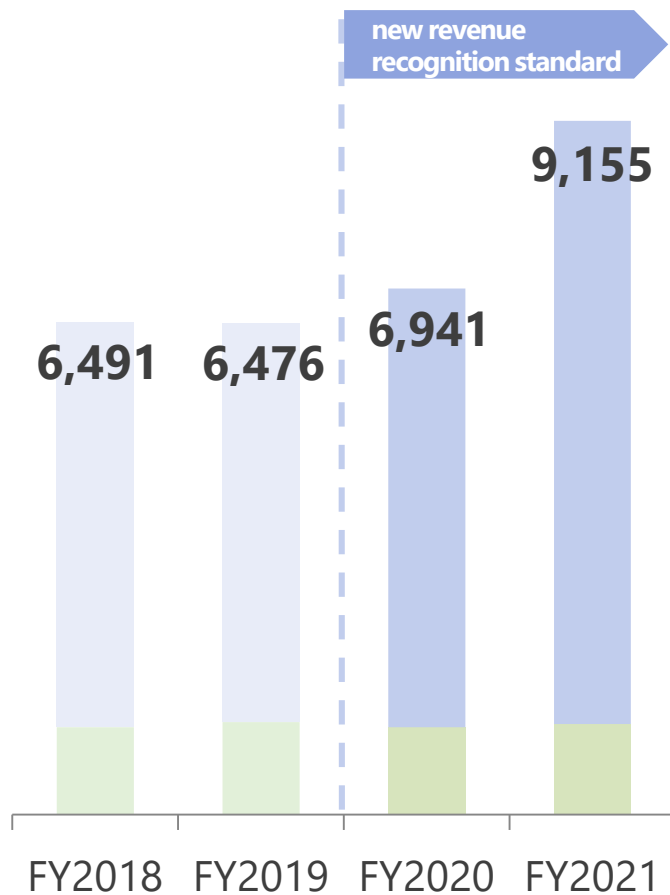
FY2021 Results : Sales down in Italy due to a resurgence of COVID-19

Sales up in Taiwan due to the launch of HyLink

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

## LAL Business Sales trend

<Breakdown> (Millions of Yen)  
 ■ Overseas ■ Domestic



## FY2021 Results : +31.9% (Year-on-Year)

\* Foreign exchange impact: approx. +¥230million

### Overseas

Increased due to growth of endotoxin detection reagents and glucan detection in vitro diagnostic agents and contract test services at overseas subsidiary ACC

### Domestic

Increased due to steady sales of endotoxin detection reagents and other products

## FY2022 Assumptions

### Overseas

Focus on strengthening sales promotion activities

### Domestic

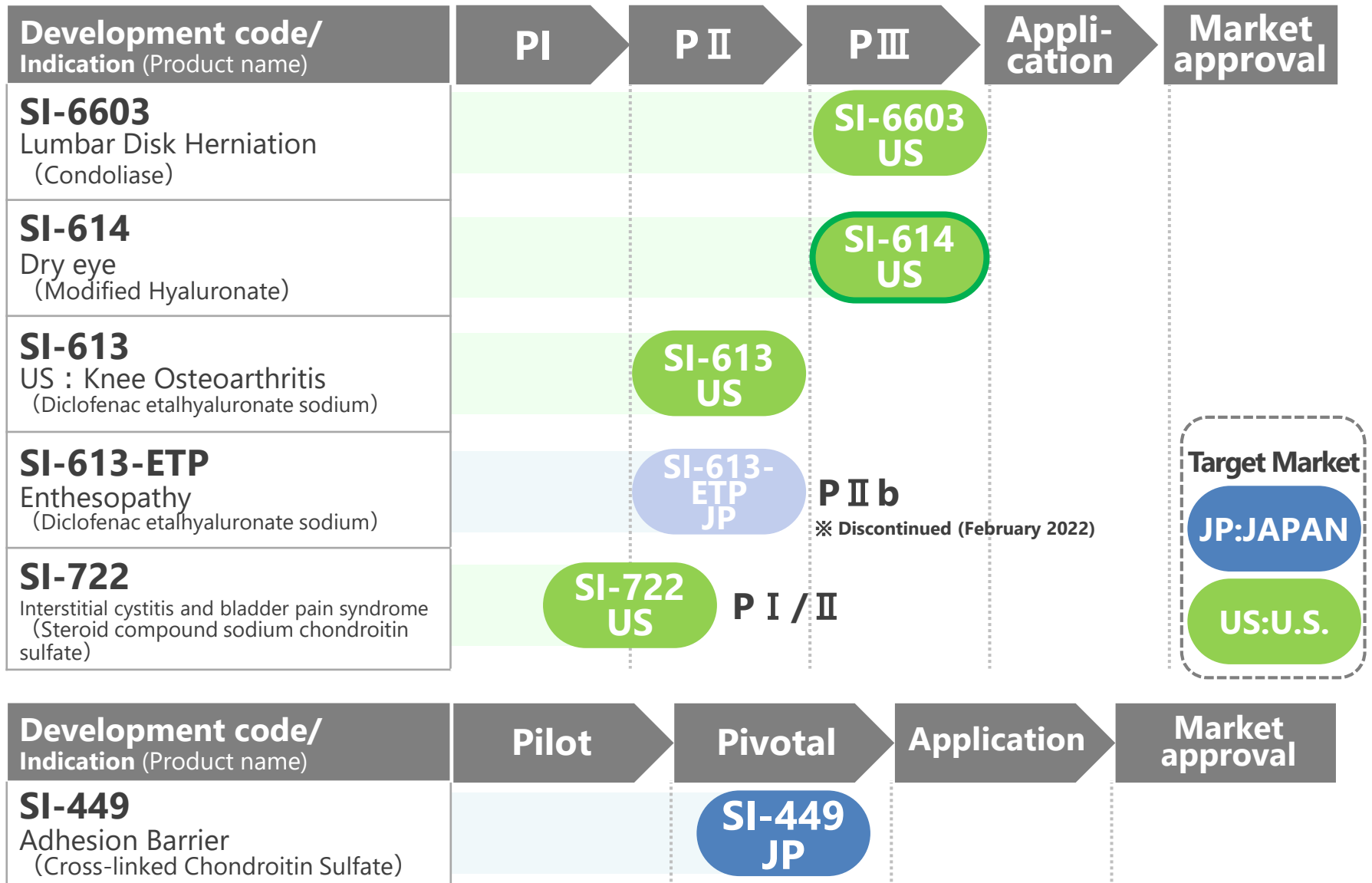
Forecast of steady sales performance

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

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



# Pipeline List (Research and Development themes)



# Outline of SEIKAGAKU NORTH AMERICA CORPORATION

**Established new company in Canada, promoting development of Seikagaku pharmaceuticals and medical devices in North America**

## SEIKAGAKU NORTH AMERICA CORPORATION

- Location : Toronto, Ontario Province, Canada
- Established : January 25, 2022
- Capital : CAD10
- Business description : Development of pharmaceuticals and medical devices in North America

## Purpose of establishment

- Enable responses with fewer constraints on time differences or distance by operating a development base in North America
  - Formulate development plans more closely aligned with local medical environment
  - Create smooth communications with U.S. Food and Drug Administration (FDA) and clinical trial sites

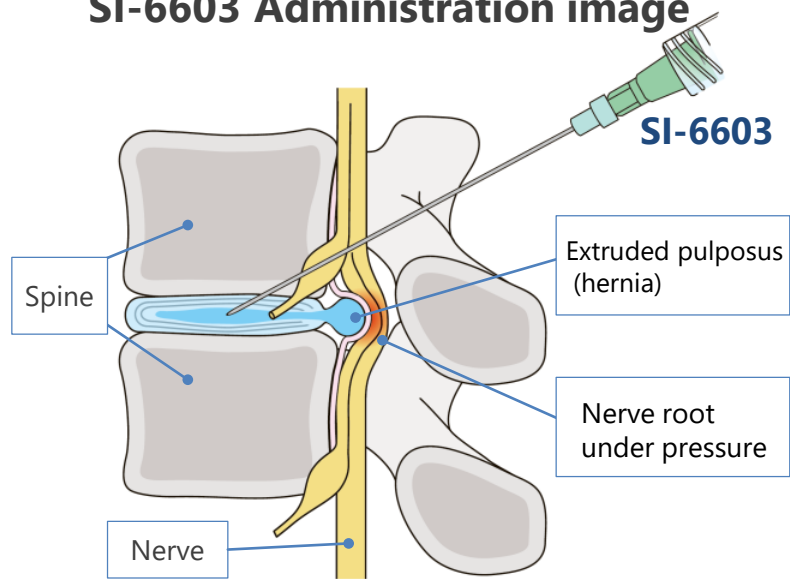


**Strengthening the development system in North America.  
Aiming to accelerate pharmaceutical and medical device development  
as well as obtaining of approvals**

# SI-6603 (Lumbar disc herniation)

**Subject enrollment completed in March 2022**  
**Move on to follow-up observation**

## SI-6603 Administration image



## Development status

- ▶ **U.S. Phase III** : Starting February 2018
  - **Subject enrollment complete in March 2022**  
 ⇒ **Conduct a one-year follow-up observation**

## Expected Features

- ▶ Relieving symptoms by decreasing intradiscal pressure and reducing the pressure on the nerve root by single injection
- ▶ It can be administered without general anesthesia, and the administration can be less invasive for the patient compared to surgical technique because of direct intradiscal injection

<SI-6603 summary>

Dev. Code : SI-6603                      Generic name : Condoliase

Indication : Lumbar disc herniation

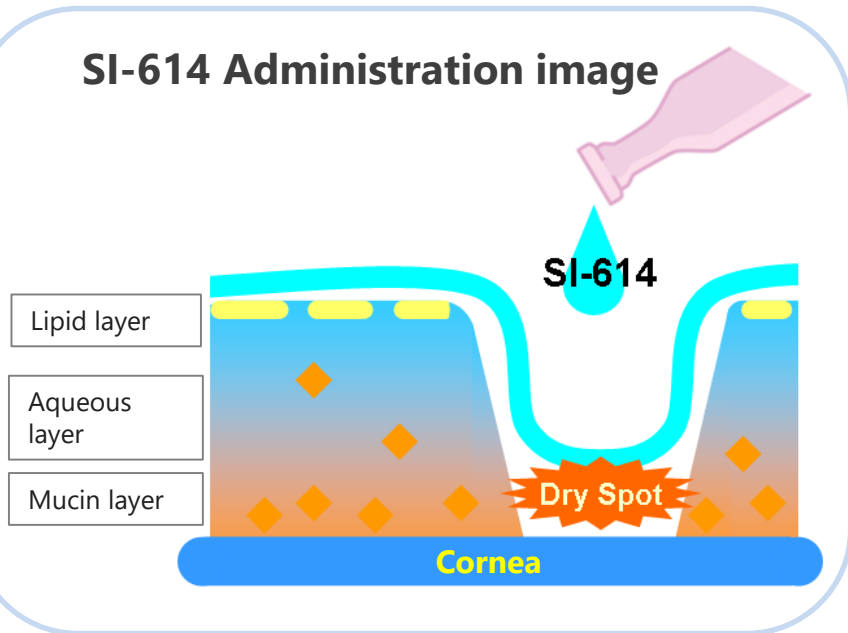
Method of use : Injection into lumbar disc (under X-ray observation)

Estimated U.S. patients : New patients with lumbar disc herniation: 3 to 5 million per year  
 (Seikagaku estimates)

# SI-614 (Dry Eye)

## PIII study in the U.S. initiated in May 2022 Evaluate efficacy and safety

### SI-614 Administration image



### Development status

#### ▶ U.S. : P III

**Initiated May 2022**

- **Clinically beneficial effects confirmed in PII/PIII clinical studies**
- **Evaluation of efficacy and safety**

### Expected Features

- ▶ SI-614 Improves symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing
- ▶ Dry Eye is a multifactorial disease, and Seikagaku aims to provide a treatment option based on a new mechanism unavailable from existing products

<SI-614 summary>

Dev. Code : SI-614

Product name : Dry eye

Estimated U.S. patients : 14 million (Seikagaku estimates)

Generic name : Modified Hyaluronate

Formulation : Ophthalmic solution

## SI-613 (Osteoarthritis/Enthesopathy)

### Development of SI-613-ETP discontinued Prioritize identification of cause of JOYCLU side effects

#### SI-613 (osteoarthritis of the knee) U.S. /China/South Korea

- ▶ Proceeding with preparation of a clinical development plan

#### SI-613 (Enthesopathy) Japan

- ▶ **February 2022: Development discontinued**

⇒ Failure of the PII clinical study to meet its primary efficacy evaluation, and to prioritize identification of the cause of shock or anaphylaxis occurring in patients following administration of JOYCLU

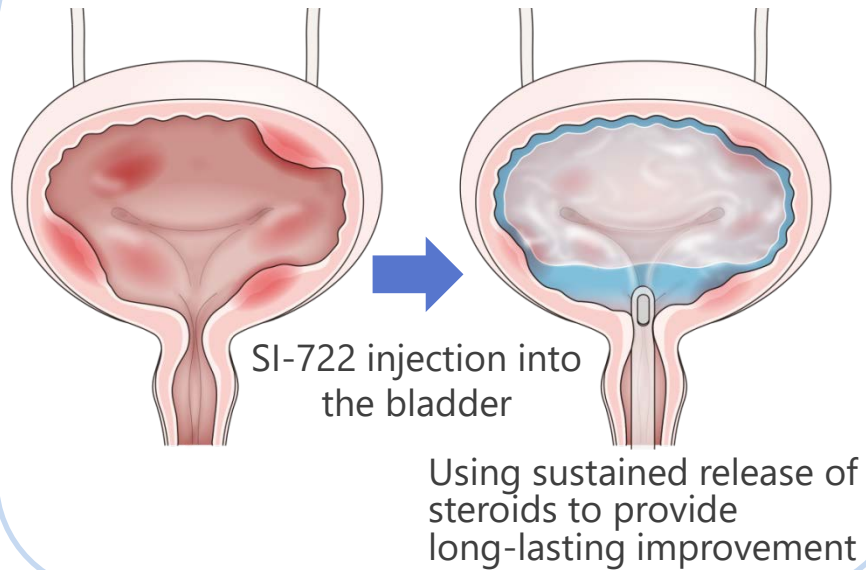
<SI-613 summary>

Dev. code : SI-613                      Generic name : Diclofenac etalhyaluronate sodium  
 Indication : Osteoarthritis/Enthesopathy  
 Method of use : Injection into joint cavity  
 Estimated patients : 24 million (U.S.) / 47 million (China)  
    3.7 million (South Korea) (Seikagaku estimates)

# SI-722 (Interstitial cystitis and bladder pain syndrome)

**Subject enrollment for PI/PII studies in the U.S. completed**  
**Analysis of study results to proceed**

## SI-722 Administration image



## Development status

- ▶ **U.S. Phase I/II** : Starting November 2019
  - Subject enrollment complete in January 2021
  - ⇒ **Tolerability confirmed (a primary objective)**
  - Will consider the next-phase study**

## Expected Features

- ▶ Designed for sustained release by bonding steroids to chondroitin sulfate
- ▶ Anti-inflammatory effects of steroids under sustained release should provide sustainable relief of frequent urination and bladder pain

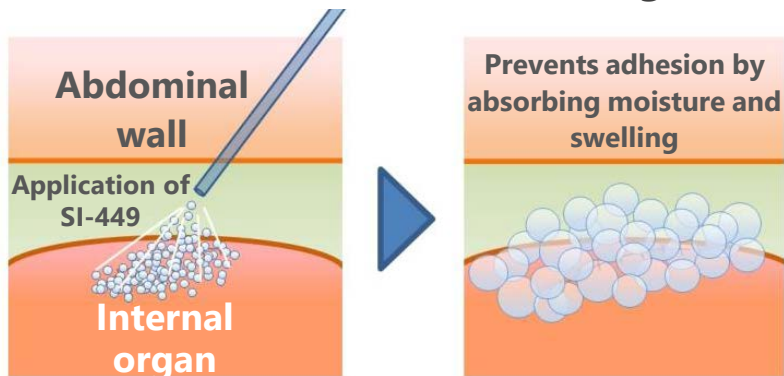
<SI-722 summary>

Dev. Code : SI-722                      Generic name : Steroid conjugated with chondroitin sulfate  
 Indication : Interstitial cystitis and bladder pain syndrome  
 Method of use : Injection into the bladder  
 Estimated U.S. patients : 1.3 million (Seikagaku estimates)

# SI-449 (Adhesion Barrier / Medical Device)

**Commenced pilot study in field of gynecology in November 2021**  
**Aiming to expand range of applications**

## SI-449 Administration image



## Expected Features

- ▶ Leveraging pulverized characteristics to respond to healthcare needs through the spreading use of laproscopic surgery

<SI-449 summary>

Dev. Code : SI-449                      Generic name : Cross-linked chondroitin sulfate  
 Product name : Adhesion barrier  
 Method of use : Intra-abdominal application (powdered formulation)  
 Adhesion barrier market : Japan: ¥14 billion, Global: ¥100 billion (Seikagaku estimates)

## Development status

- ▶ **Japan pivotal study** (field of gastroenterological surgery)  
 Starting May 2020
  - Evaluated for effectiveness, safety, and usability
 ⇒ Plans delayed by restrictions on visits to facilities due to COVID-19 infection effects
- ▶ **Japan pilot study (field of gynecology)**  
**Starting November 2021**
  - **Confirming operability and safety**
  - **Aiming to expand range of applications**
- ▶ Proceed with development with a view to global development; Start of U.S. pilot study under review

## Progress with the Mid-Term Management Plan (FY2019-FY2021)

### I . Accelerating new drug discovery to become the pillar of new profits

- **Strengthening and making use of the Company's own GAG-related core technology related to GAGs**
  - **Accelerating innovative drug discovery using the Open Innovation strategy**
  - **Steady progress of the development pipeline with an eye towards global expansion**
- 
- Launch of joint function improvement agent JOYCLU (development code: SI-613) : May 2021
    - ▶ June 2021: Issuance of Blue Letter
      - Proactive gathering and provision of safety information
      - Proceeding with identification of the cause of shock or anaphylaxis
  - Completion of subject enrollment for Phase I/II clinical study in the U.S. of SI-722, a treatment for interstitial cystitis : January 2021
  - Initiation of pivotal study for SI-449, an adhesion barrier : May 2020
  - Completion of subject enrollment for a Phase III additional clinical study in the U.S. of SI-6603, a treatment for lumbar disc herniation : March 2022
  - Establishment of SEIKAGAKU NORTH AMERICA CORPORATION (SNA) in Canada : January 2022
  - Progress with development of new disease fields and drug discovery modalities utilizing GAG technologies and activities for business domain expansion through open innovation



## Progress with the Mid-Term Management Plan (FY2019-FY2021)

### II . Solidifying the profit foundation through market expansion of new products

- **Post-marketing of HERNICORE in Japan**
  - **Accelerating multinational expansion of existing products and products in development**
  - **Global expansion of endotoxin-detecting reagents that leverage genetic recombination technology**
- 
- Launch of HyLink, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, in Taiwan : August 2021
  - Alliance agreements for SI-613, a treatment for osteoarthritis, concluded with Eisai Co., Ltd. Agreement concerning co-development and a marketing alliance in China : April 2020 Agreement concerning a marketing alliance in South Korea : September 2020:
    - ▶ Consider future development plan while prioritizing identification of the cause of JOYCLU side effects
  - Launch of PyroSmart NextGen recombinant LAL reagent, an endotoxin-detecting reagent : April 2021
  - Continued to gather and provide information to ensure proper use and safety of HERNICORE Start use of HERNICORE at facilities without full-time supervisory physicians accredited by the Japanese Society for Spine Surgery and Related Research (JSSR) : November 2019 General drug use-results survey interim results announcement : September 2021

## Progress with the Mid-Term Management Plan (FY2019-FY2021)

### III. Productivity improvement reforms

- **Thorough cost reductions**
  - **Diversifying the profit model**
  - **Creating an organization for maximizing the value of resources**
- 
- March 2020: Dalton Chemical Laboratories, Inc. (Canada) made a subsidiary  
Gradually switching to in-house production of chemical synthetics and transferring manufacturing of investigational drugs and some Seikagaku products to Dalton
  - Maintenance of a system to ensure continuity of business under impact of COVID-19 infection  
Introduction of a work-from-home system and development of the IT environment
  - Progress was made with reviews of procurement costs and sales-related expenses
    - ▶ Some issues remain with respect to fundamental cost structure improvement

**Seikagaku was able to lay a foundation for the next mid-term management plan, positioned as a time for solidifying the profit foundation to return Seikagaku to a growth trajectory**

# Numerical targets

**The spread of COVID-19 infection, nevertheless the Company was able to achieve all numerical targets announced when the plan was formulated**

	FY2021 Forecast		FY2021 targets (2019.11)	achievement ratio
	new revenue	old revenue		
Net sales	¥34.8 billion	¥31.2 billion	¥28.3 billion	+10.5%
Ordinary income	¥5.3 billion	¥5.3 billion	¥4.5 billion	+19.9%
SKK EBITDA*	¥5.5 billion	¥5.5 billion	¥5.0 billion	+10.9%
Overseas sales ratio (excluding royalty income)	56.6%	56.6%	50.0%	+6.6pt

«Assumptions (2019.11)»

- Expansion of overseas sales in the LAL business makes up for the effects of the NHI drug price revisions in Japan
- Depreciation declines as a result of impairment loss
- R&D expenses are 25–30% of sales
- Various royalty income is included as non-operating income
- Exchange rate: ¥105 to the U.S. dollar

\* SKK EBITDA : A profit indicator that adds depreciation and royalty income to operating income

# Strategic direction for the next mid-term management plan

## **Further solidification of the profit foundation**

- Nurturing of key products  
Market introduction of SI-6603, a treatment for lumbar disc herniation (U.S.)  
Identification of the cause of shock or anaphylaxis following administration of JOYCLU
- Overseas expansion of existing products and products in development, including the LAL business and contract development and manufacturing organization
- Cost reductions, cost structure review

## **R&D**

- Steady advancement of pipelines, including SI-449
- Entry into new domains and new modalities
- Business domain expansion through active utilization of open innovation

## **Sustainability**

- Engagement in business activities centered around material issues

**In view of business plans and future earnings forecasts varying substantially depending on the progress to identify the cause of JOYCLU side effects and the development trend in the U.S. of SI-6603, a treatment for lumbar disc herniation, the Company has decided to postpone the announcement planned for May 2022**

**Announcement of the next mid-term management plan  
is planned for around autumn 2022**

# Dividend of Surplus and Acquisition of Treasury

## Dividend from Retained Earnings (Commemorative Dividend, Special Dividend) Acquisition of Treasury Stocks

### FY2021

Ordinary dividend ¥20 + **JOYCUL launch special dividend ¥10**

→ Annual dividend : ¥30 per share, including the interim dividend of ¥15 per share

### FY2022

Annual dividend : ¥22 per share, including the interim dividend of ¥11 per share

	FY2018	FY2019	FY2020	FY2021 (Forecast)	FY2022 (Forecast)
Net Income per share	¥39.76	¥-192.15	¥75.54	¥66.32	—
Annual Total Dividend	¥26.00	¥26.00	¥24.00 <sup>※1</sup>	¥30.00 <sup>※2</sup>	¥22.00
Dividend Payout Ratio	65.4%	—	31.8%	45.2%	—

※1 including a JOYCUL approval commemorative dividend ¥4

※2 including a JOYCUL launch special dividend ¥10

### Acquisition of Treasury

Total number of shares to be acquired : 2,000,000 shares (maximum)

Total amount of acquisition cost : ¥1,500 million (maximum)

Acquisition period : May 16, 2022 to November 30, 2022

# Appendix

# Overview of JOYCLU

**Manufacturing and marketing approval in Japan obtained in March 2021**  
**For the indication of osteoarthritis (knee joint and hip joint)**  
**May 19 NHI drug price listing and launch**



Product name	JOYCLU® 30mg Intra-articular Injection
Generic name	diclofenac etalhyaluronate sodium
Indication	Osteoarthritis (knee joint and hip joint)
Dosage and administration	The usual adult dosage is 1 syringe per dose (30 mg of diclofenac etalhyaluronate sodium) injected intra-articularly every 4 weeks.

# Overview of JOYCLU

## Improvement of symptoms expected by administration once every 4 weeks First joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint

### features

- ▶ Hyaluronic acid and diclofenac chemically bound using a proprietary technology
- ▶ Diclofenac released by hydrolysis in the joint
- ▶ Improvement of symptoms of osteoarthritis (knee joint and hip joint) expected by administration once every four weeks
- ▶ First joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint

### Expected positioning

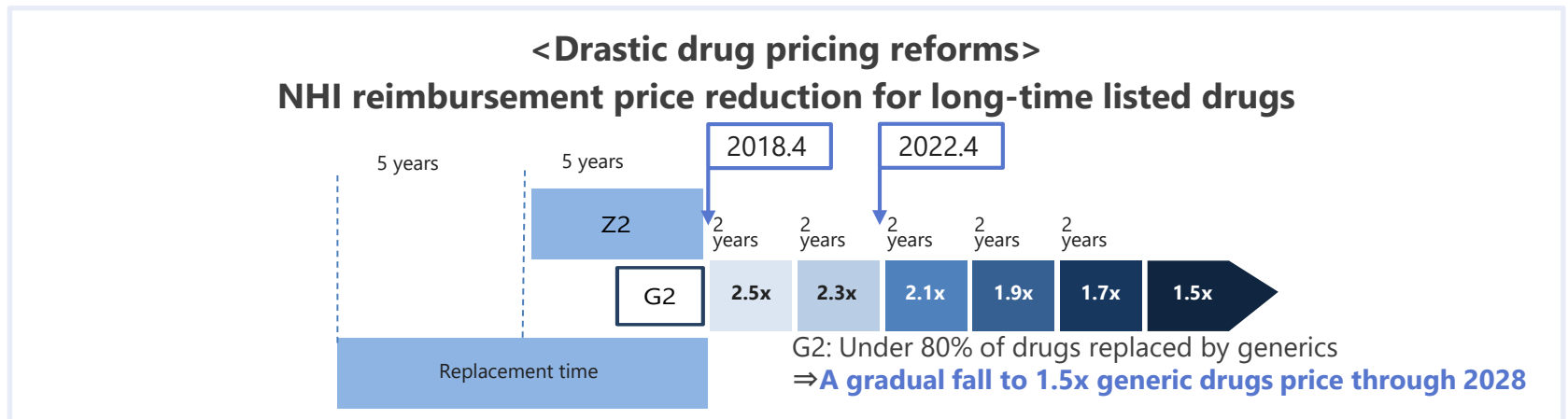
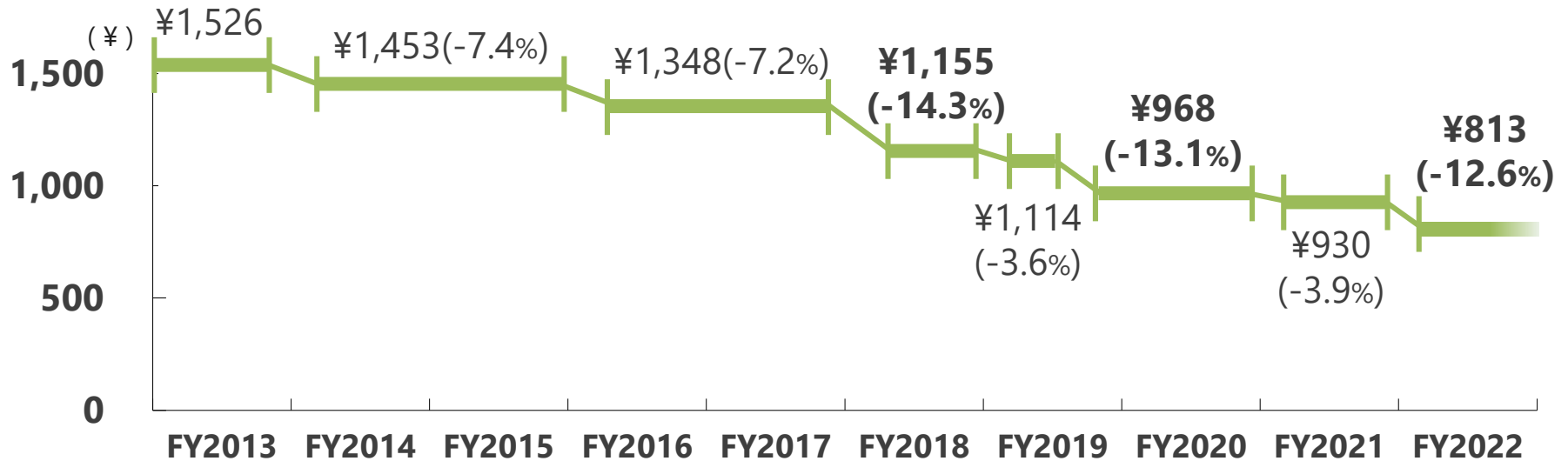
- ▶ **Establishment as a new base drug** in the treatment of osteoarthritis alongside existing hyaluronic acid formulations and NSAIDs

#### <Target Patients>

- ▷ People for whom existing hyaluronic acid formulations are insufficiently effective
- ▷ People who want to avoid NSAIDs, such as oral drugs or patches, in consideration of side effects
- ▷ People for whom frequent hospital visits are a hardship
- ▶ Provision of **a new treatment option for osteoarthritis of the hip joint**



# Trend in NHI Reimbursement Price of ARTZ to Domestic



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

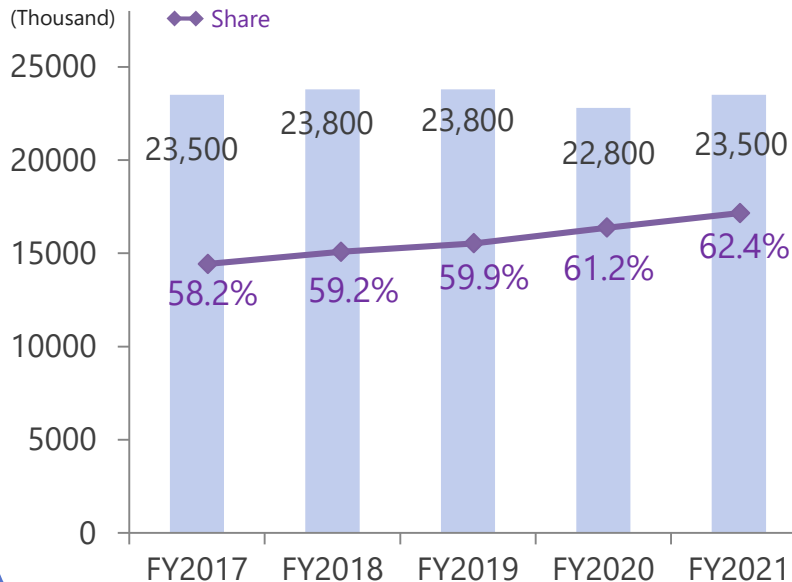
Joint-function improving agent

## 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



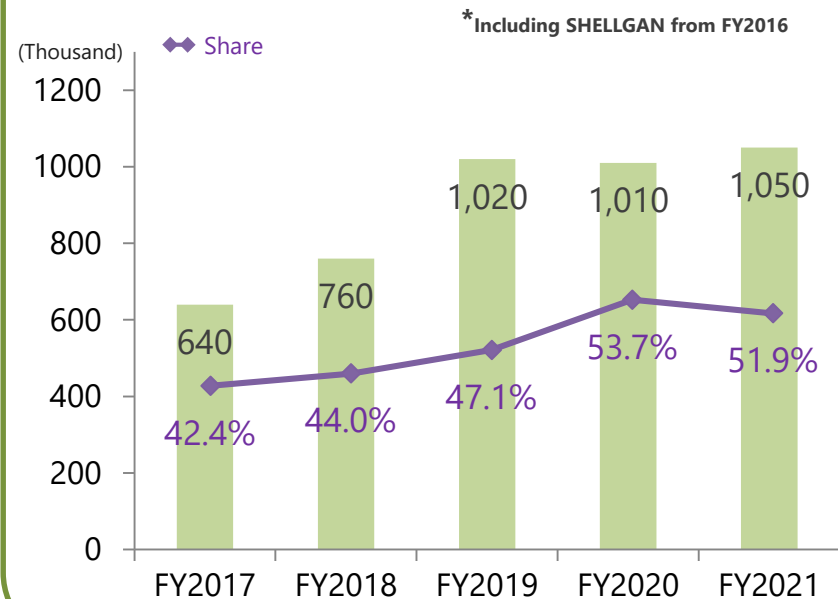
Ophthalmic viscoelastic devices

## OPEGAN



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

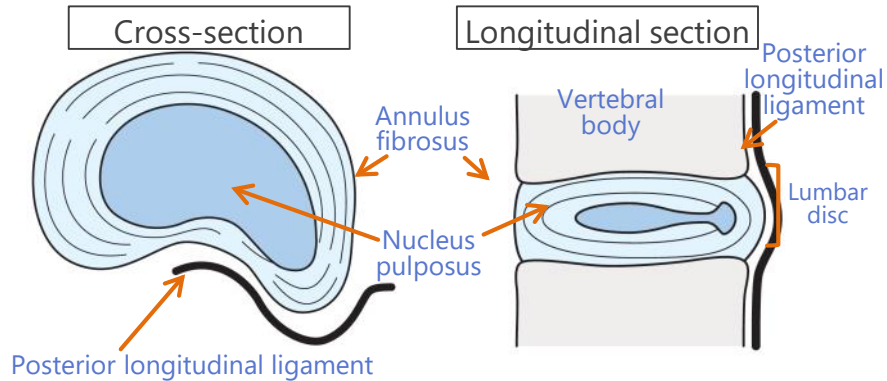
Trend in unit deliveries to medical institutions



# Four types of lumbar disc herniation

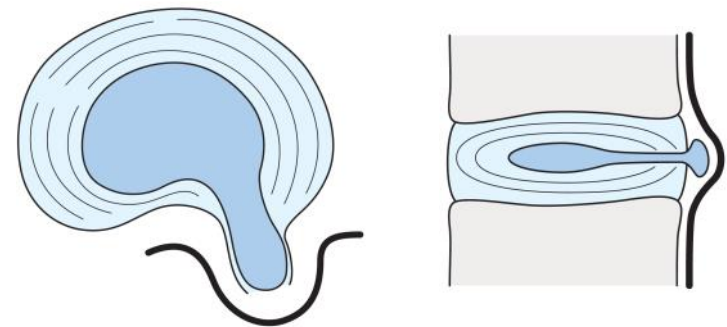
## 1. Protrusion

The hernia does not extend beyond the outermost layer of the annulus fibrosus



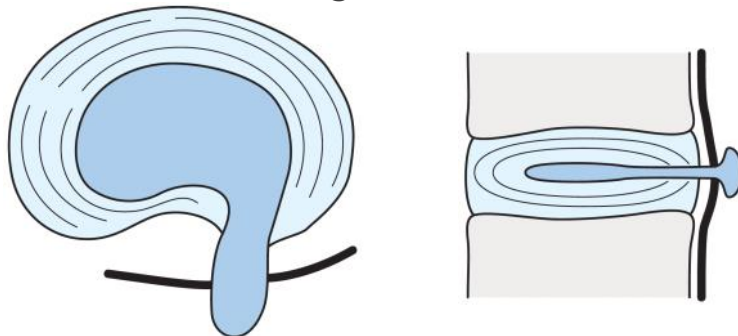
## 2. Subligamentous extrusion

Although the hernia extends beyond the outermost layer of the annulus fibrosus, it is covered by the posterior longitudinal ligament



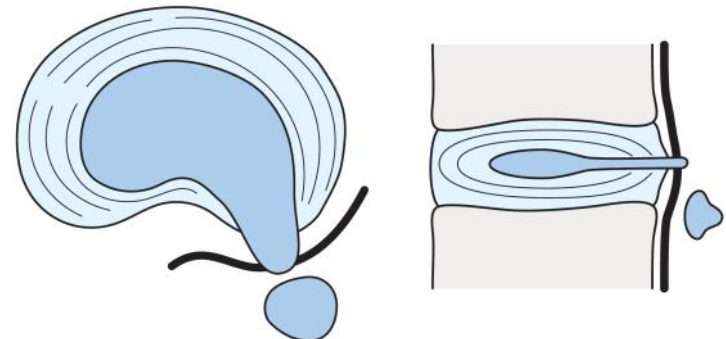
## 3. Transligamentous extrusion

The hernia perforates the posterior longitudinal ligament



## 4. Sequestration

The hernia migrates outside the dura mater



# Post-marketing of HERNICORE in Japan

## Promoting appropriate use and expanding opportunities for use; Firming up usage as new treatment options

- Coordinating with Kaken Pharmaceutical **engaging in information provision activities to ensure appropriate use and safety** through seminars with scientific societies and local workshops
- **Collecting pertinent information (post marketing surveillance)** with emphasis on safety information
- **Raising patients' recognition through awareness campaigns on the ailment**
- **Gradually expanding available physicians and facilities** through a review of requirements (expecting moderate growth)



**Roll-out to scientific societies**  
**Requirements review**  
**Adding facilities, etc.**

• November 2019  
 Non-fulltime work facilities of supervisory physicians of the JSSR

• April 2019  
 Physicians of the Neurospinal Society of Japan \*<sup>2</sup>

• August 2018  
 Physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) \*<sup>1</sup>

### Physician requirements

- ※1 ① Supervisory physicians or certified physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) or who are supervised under the JSSR, or who participated in the this clinical study  
 ② Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation
- ※2 ① Supervisory physicians or certified physicians of the Neurospinal Society of Japan  
 ② Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

# Physician and Facilities Requirements for HERNICORE Use

## Setting of physician and facility requirements for HERNICORE use to promote appropriate use and ensure safety

### **[ Physician requirements ]**

#### **[Japanese Society for Spine Surgery and Related Research]**

: Physicians under the following conditions (as of April 2019)

1. Supervisory physicians or certified physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) or who are supervised under the JSSR, or who participated in this clinical study
2. Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

#### **[ Neurospinal Society of Japan ]** : Physicians under the following conditions (as of April 2019)

1. Supervisory physicians or certified physicians of the Neurospinal Society of Japan
2. Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

### **[Facility requirements]** : Facilities under the following conditions

1. Facilities equipped with an X-ray fluoroscopic system (C-arm, etc.) capable of administering HERNICORE using clean technique
2. Facilities capable of treating shock and anaphylaxis
3. Facilities capable of performing urgent spine surgery or facilities that cooperate with facilities capable of performing spine surgery
4. Facilities with hospitalization equipment

※ Among those who meet the physician requirements, supervisory physicians in the JSSR may be used at non-fulltime work facilities that meet the facilities requirements (as of November 2019)

**We plan to review these requirements with the consent of PMDA\* approximately six months to one year after launching, following collection and careful examination of post-marketing safety information etc.**

# Ophthalmic viscoelastic devices SHELLGAN

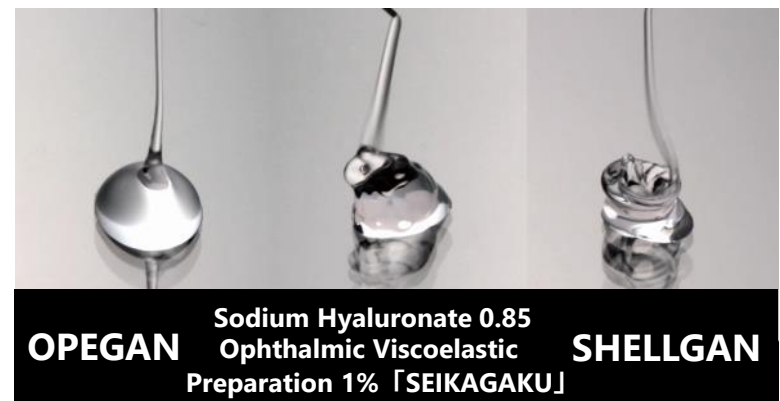


## ■ Product SHELLGAN Outline

- 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 family 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

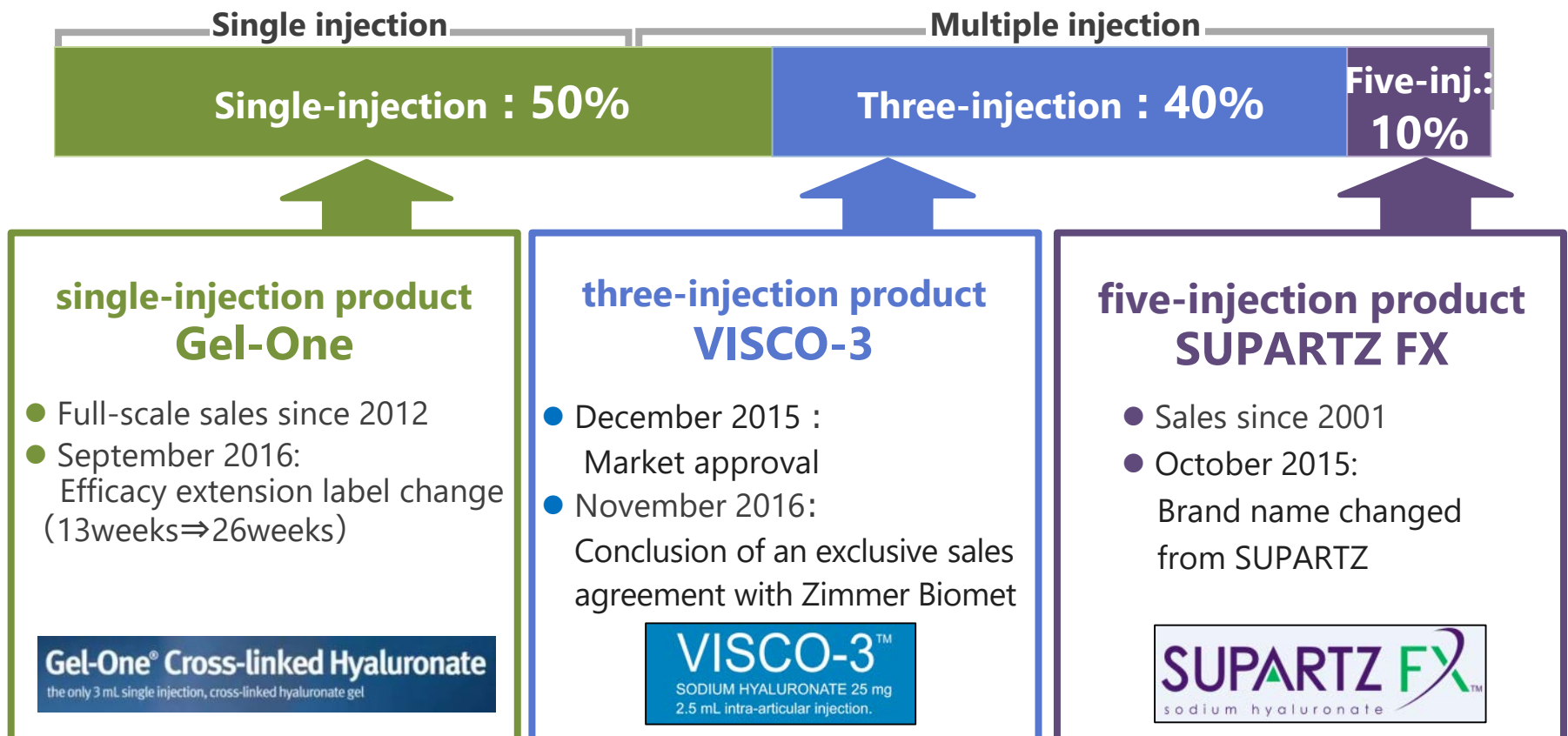


The OPEGAN family viscoelasticity comparison

# Market Situation of Hyaluronic Acid Products in the U.S.

**Market size of US\$950 mil. in 2021 (+8.3% year-on-year)**

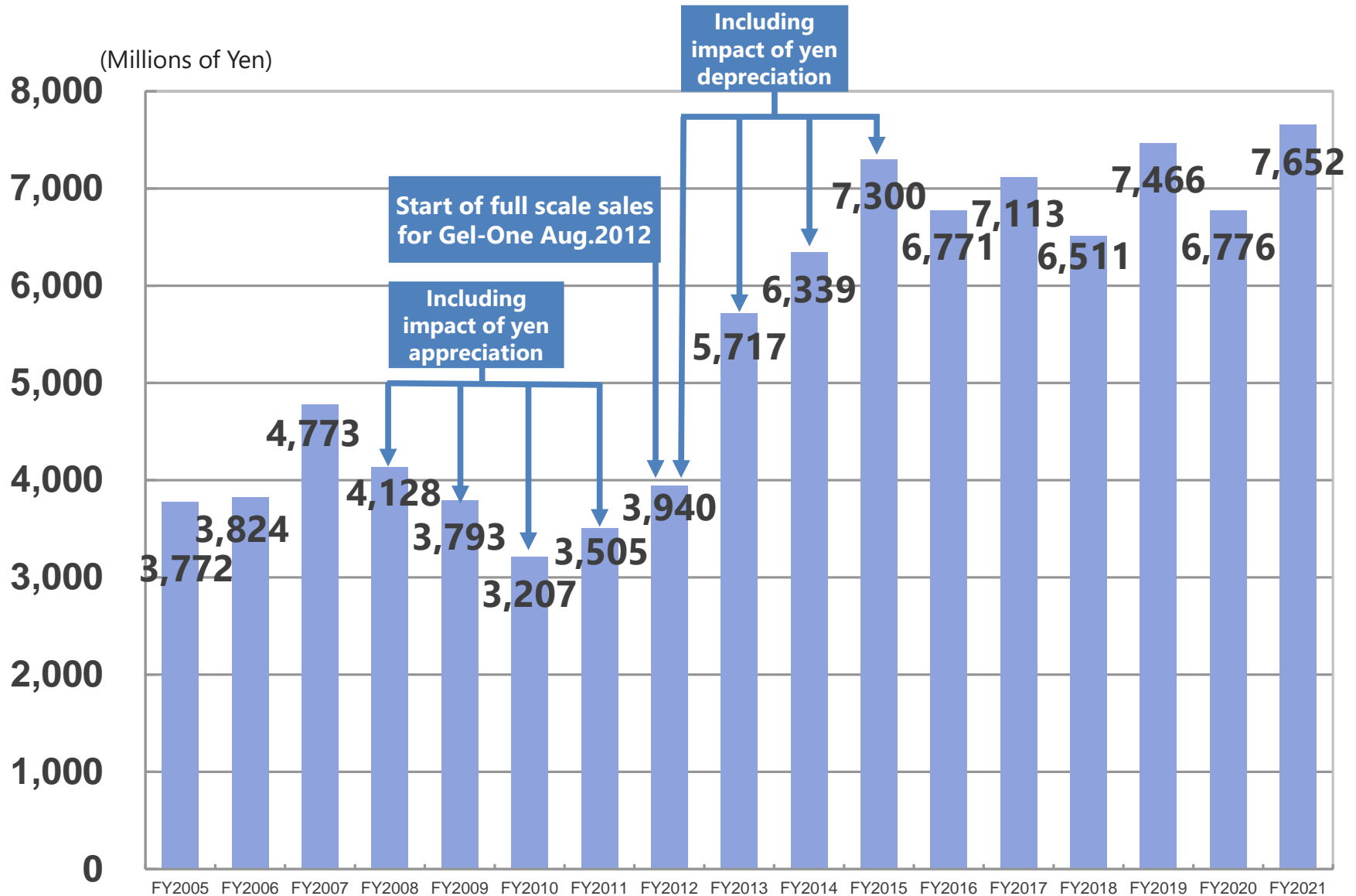
■ **U.S. market share by number of injections** (Value basis, including competitors)



\*Figures for 2021, Seikagaku estimates



# Trend in Overseas Sales of Hyaluronic Acid Products





# Recombinant LAL reagent 「PyroSmart NextGen」

April 2021 launch at ACC

Product to be marketed globally, with a launch in Japan planned for May or later in 2021



## Product Features

- ▶ Product manufactured using recombinant technology without using blood harvested from horseshoe crabs, a raw material used in traditional products
  - Ensures continuous product supply
- ▶ Ability to utilize the same test methods and instruments as naturally sourced products
  - Ensures consistency with endotoxin-testing reagents
  - A next-generation BET reagent designed to deliver highly reliable quantitation of endotoxins

# The LAL Business

## Endotoxin detection reagents (Seikagaku Corporation, ACC)

- Manufacture and sale of reagents for detecting endotoxins\* in the manufacturing process of pharmaceuticals, etc. (Japan, USA, Europe, etc.)
- Used mainly at pharmaceutical companies
- Launch of PyroSmart NextGen, a recombinant endotoxin detection reagent, in April 2021
- Accelerated global expansion of recombinant reagents

\*Since endotoxins exhibit strong pyrogenic activity even in minute amounts, they must be rigorously controlled pursuant to regulations in the manufacture of pharmaceuticals and medical devices.

▶ **Global market : Approx. ¥2.5 mil**  
(Seikagaku estimate / including related equipment)



## 受託試験サービス (ACC社)

- Contract testing for endotoxin and glucan contamination
- Contributes to quality control at pharmaceutical companies and medical institutions

## Glucan detection in vitro diagnostic agents (ACC)

- Manufacture and sales of in vitro diagnostic agents for measuring the glucan\* concentration in blood for use in the diagnosis of deep fungal infections (USA, Europe, etc.)
- Since symptoms of deep fungal infections can be similar to those of COVID-19, the products are used together with COVID tests as necessary to ensure appropriate diagnosis and treatment
- Used mainly at hospitals and testing centers
- Market expansion into additional countries

\* $(1\rightarrow3)$ - $\beta$ -D-glucans are structural components of the cell walls of fungi, as typified by molds and yeasts.



# Outline of Associates of Cape Cod, Inc.

**Developed the world's first endotoxin detection reagent and obtained FDA approval in 1977 / Sales network spanning 80 countries**

## Associates of Cape Cod, Inc.

- Headquarters : Massachusetts, U.S.A.
- Established : 1974 (became a Seikagaku subsidiary in 1997)
- Business areas : Manufacture and sale of endotoxin detection reagents and glucan detection in vitro diagnostic agents, provision of contract test services
- Number of employees : 263 (as of March 31, 2022)



Recombinant LAL reagent  
PyroSmart NextGen®



Endotoxin detection reagents  
PYROCHROME®



Exterior of the ACC office

# Outline of Acquisition

## Dalton, a Canadian CDMO, becomes a subsidiary Acquiring a pharmaceuticals manufacturing base compliant with US/Canadian GMP

### Outline of acquisition

- Name : Dalton Chemical Laboratories, Inc.
- Acquisition cost : Up to CAD 41 million
- Acquisition method : Acquired all issued shares

### Dalton Chemical Laboratories, Inc.

- Location : Toronto, Ontario Province, Canada
- Established : 1986
- Business description :  
Contract manufacturing services (CDMO\*), including the manufacturing of chemosynthesis products and active pharmaceutical ingredients (API) and API process development for pharmaceutical companies
- Employee number : 147 (2022.3)

\* CDMO : Contract Development and Manufacturing Organization

A business that supplies comprehensive services in drug development and manufacturing to pharmaceutical companies, including contract drug manufacturing, pharmaceutical formulation planning at the development stage, manufacturing of investigational drugs, and optimization of manufacturing conditions.



Exterior of the Dalton offices

# Synergistic effects of making Dalton a subsidiary

## Accelerating new drug discovery and advancing production optimization and efficiency

### Seikagaku

#### Specialized in new drug development & manufacturing

- Glycoscience R&D ability
- Final formulation technology and know-how in pharmaceuticals and medical devices

### Dalton

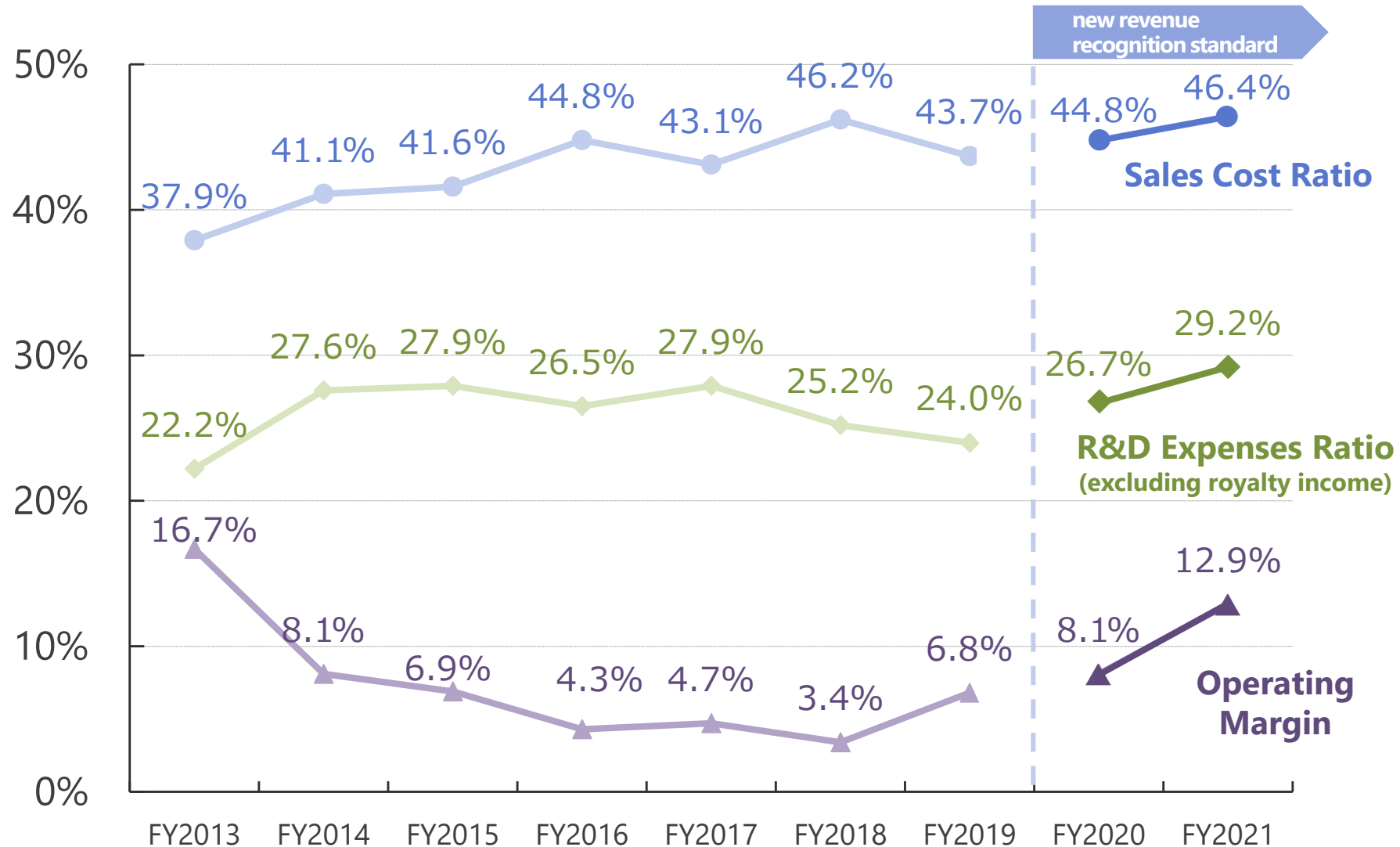
#### Technology prowess related to CDMO

- Advanced technical skills in chemosynthesis
- Know-how in investigational drug manufacturing and process development
- Overseas GMP-certified

### Synergies between the two companies

- **Seikagaku**
  - Accelerating drug discovery (applying Dalton technology)
  - In-house development of chemosynthesis products used in R&D, etc.
  - Production optimization and efficiency improvements
- **Dalton**
  - Business expansion by contracting from Seikagaku
  - Developing a final formulation business

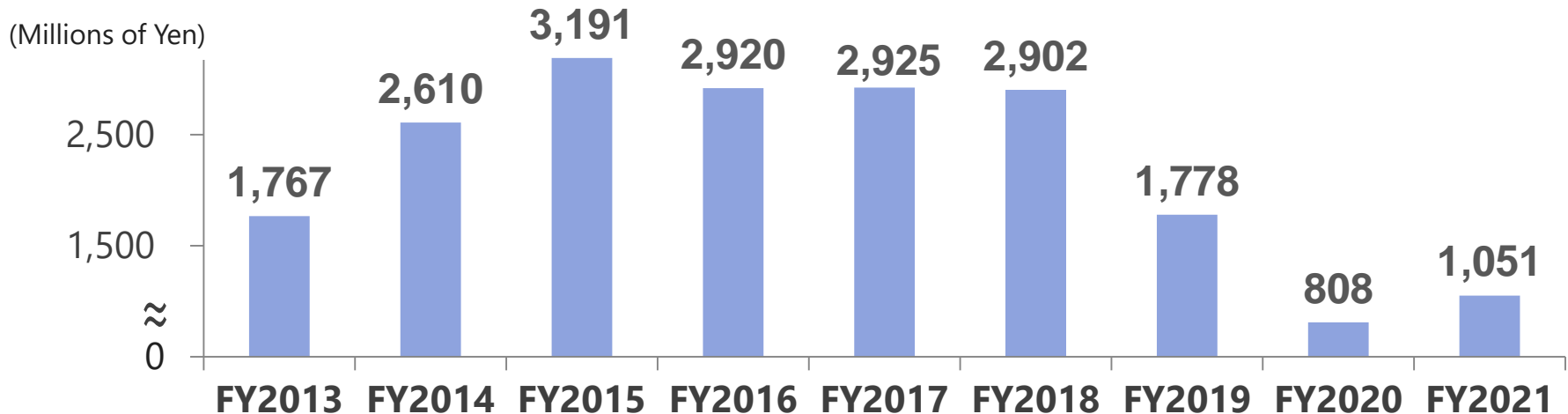
# Trend in Financial Index



# Trends in Depreciation & Capital Investments

**Impairment loss taken in FY2019**  
**Depreciation will trend toward ¥1.0 billion**

## ■ Trend in Depreciation



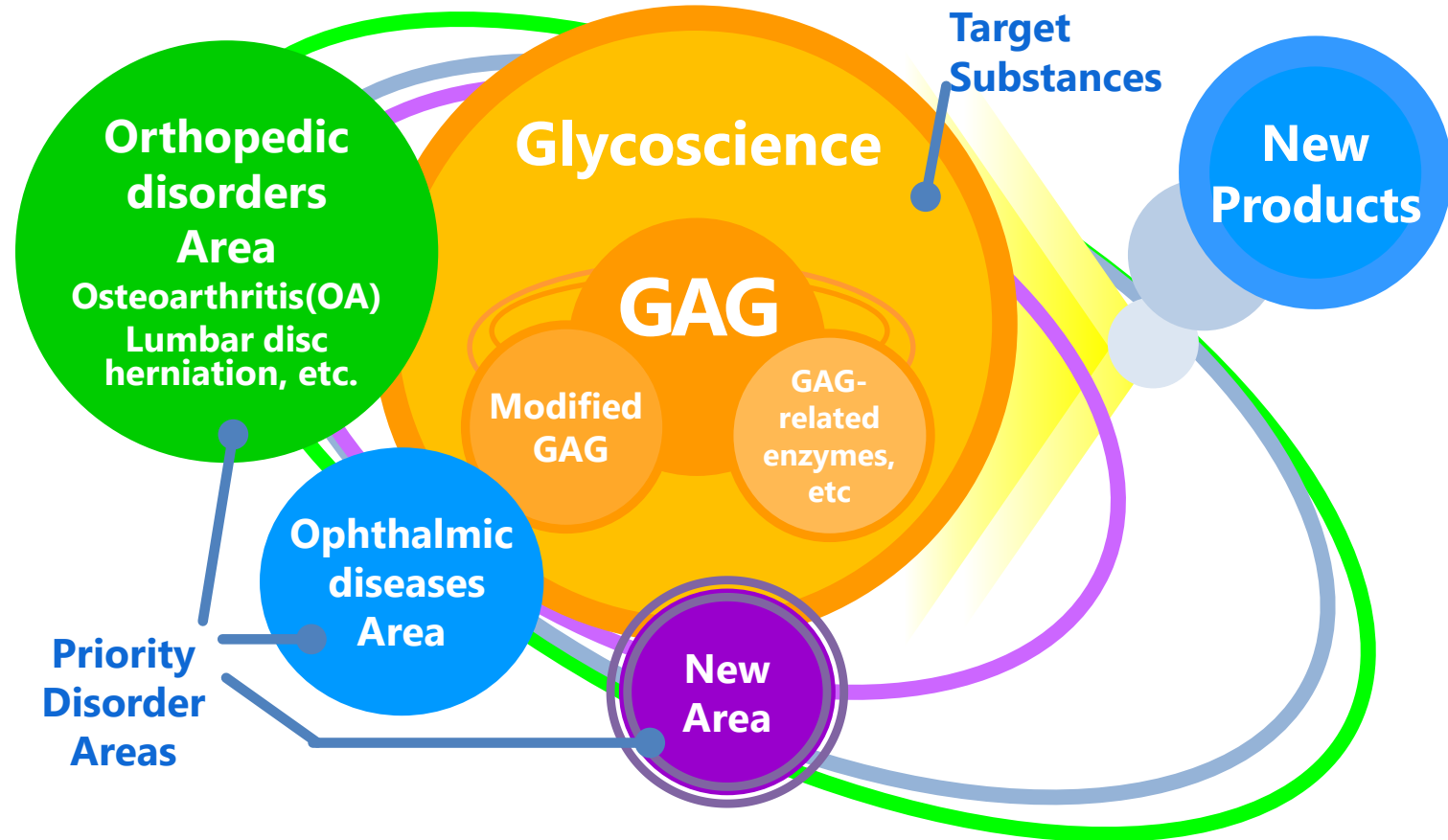
## ■ Trend in Capital Investments (Millions of Yen)

FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021
7,222	2,095	1,975	1,173	1,591	1,310	2,109	2,127	2,194



# Basic Policy on Research and Development

**Continue Our R&D policy to make the most of our technology and knowledge**



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



# Strengthening and Making Use of The Company's Own GAG-related Core Technology

## Accelerating R&D by leveraging our innovative drug discovery technology

### 1. Developing drugs through modification, processing, and bioactivity

- GAG **photo-cross-linking and chemical-cross-linking**
- **Physio-chemical functions** including viscoelasticity and retention
- Bioactive substances (degrading enzymes)

**Gel-One  
HERNICORE  
SI-449**

### 2. Applying drug delivery systems (DDS)

- **Support and delivery of** active pharmaceutical ingredients
- Expanding the lineup of supportable and deliverable drugs (low molecular→medium molecular→cells)
- DDS technology highly adaptable to general use (establishing drug discovery techniques)

**SI-613  
SI-722**

**GAG**

**New Drugs**

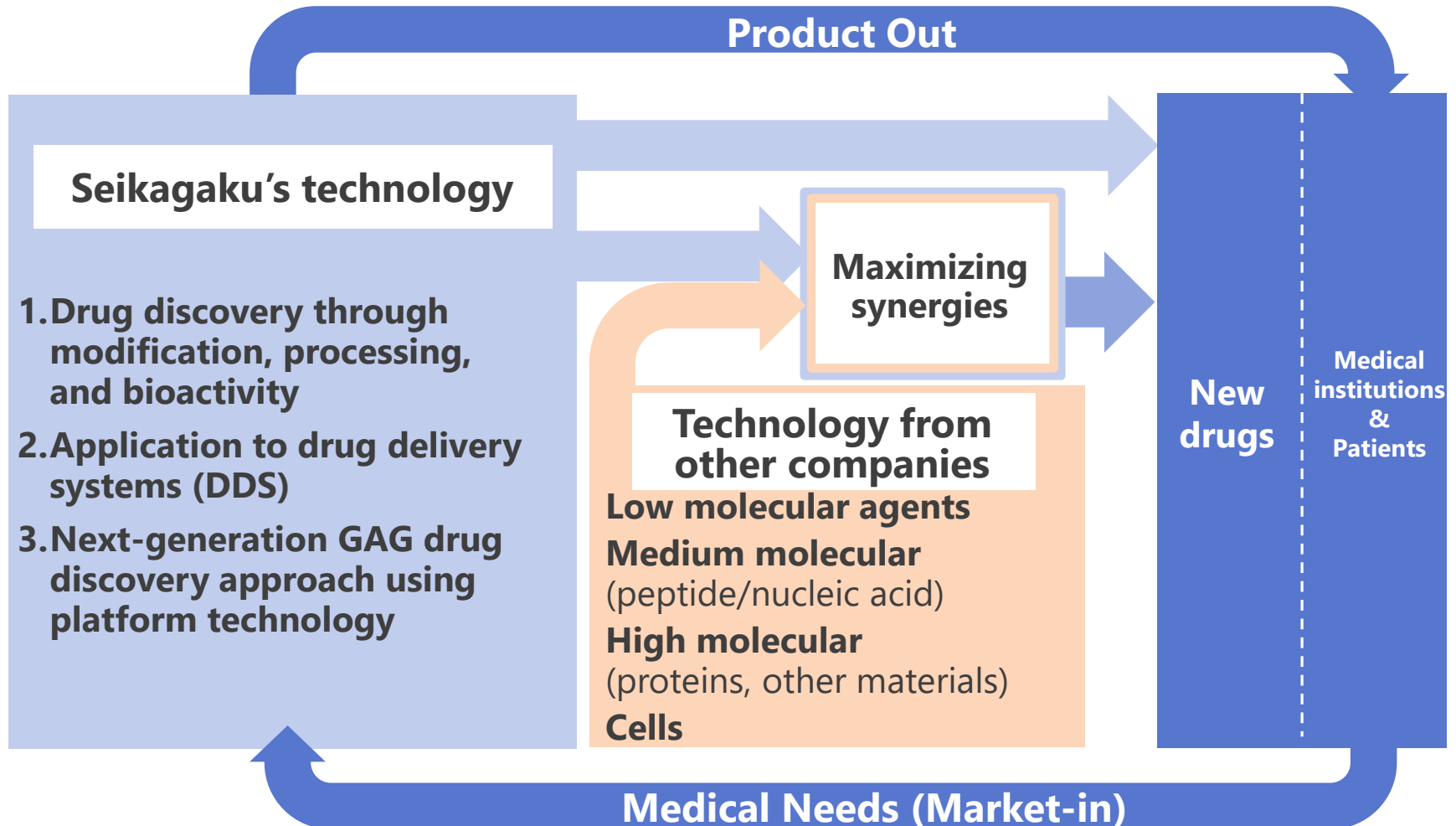
### 3. Next-generation GAG drug discovery approach using platform technology

- Conversion from natural GAG **to fermented GAG**
- Expanding the field of sugar chain drug discovery Applying to glycobiology

**SI-613  
SI-614**

# Accelerating Innovative Drug Discovery Using The Open Innovation Strategy

## Speeding up and augmenting the number of projects through a drug discovery approach using Open Innovation



# Result for SI-6603 Phase III Clinical Study in the U.S.

**Significant improvement in the primary endpoint was demonstrated in Phase III study of Japan but Phase III study in the U.S. did not meet its primary endpoint of pain improvement**

## Pharmacological effect (Objective indicator)

- Statistically significant decrease in the intervertebral disc and herniation volume assessed with MRI: **Confirmed pharmacological effect of SI-6603**

## Evaluation of safety

- No major concern such as adverse reactions was observed: **Confirmed safety of SI-6603**

## Improvement at alleviation of leg pain (Subjective indicator)

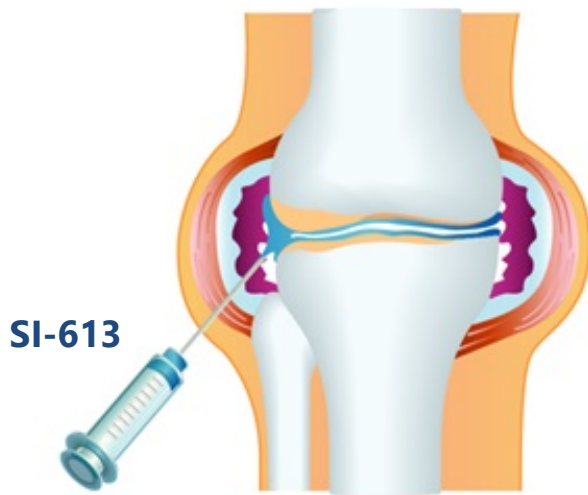
- Statistically significant improvement of leg pain at 13 weeks by VAS was not demonstrated
- ▶ ① There is a guideline for diagnostic and pathology of lumbar disc herniation in Japan, however there is no widely used guideline in the U.S. Therefore, there is possibility that some patients out of Japanese guideline were included in the clinical trial in the U.S.
- ② There is possibility that some factors such as complications biased assessment of leg pain

**Increasing the certainty of success for the additional study by reflecting the knowledge and perception obtained from result of the study**

# SI-613 (Treatment of Osteoarthritis/Enthesopathy)

**Aiming for rapid and sustained improvement of pain and other clinical manifestations associated with osteoarthritis and Enthesopathy**

SI-613 Administration image



## Expected Features

- ▶ **Hyaluronic acid and diclofenac (an anti-inflammatory drug) are bound in a formulation designed for gradual release of diclofenac over a fixed period of time**  
Sustained improvement of clinical manifestations, including pain, for 28 days from the day after administration shown in a clinical trial of osteoarthritis patients
- ▶ **The first pharmaceutical suitable for treatment of osteoarthritis in the hip joint using a hyaluronic acid formulation**
- ▶ **Directly administered to the affected area as an injectable treatment, resulting in low systemic exposure to diclofenac**  
Low risk of systemic side effects

<SI-613 summary>

Dev. code : SI-613                      Generic name : Diclofenac Etalhyaluronate Sodium

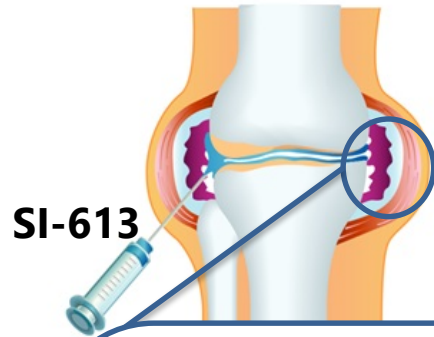
Indication : Osteoarthritis/Enthesopathy

Method of use : Injection into joint cavity

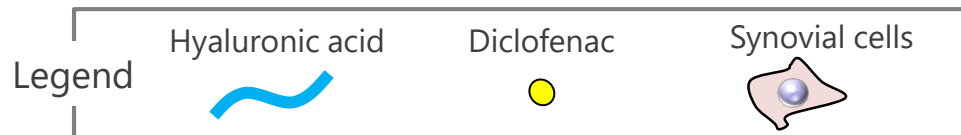
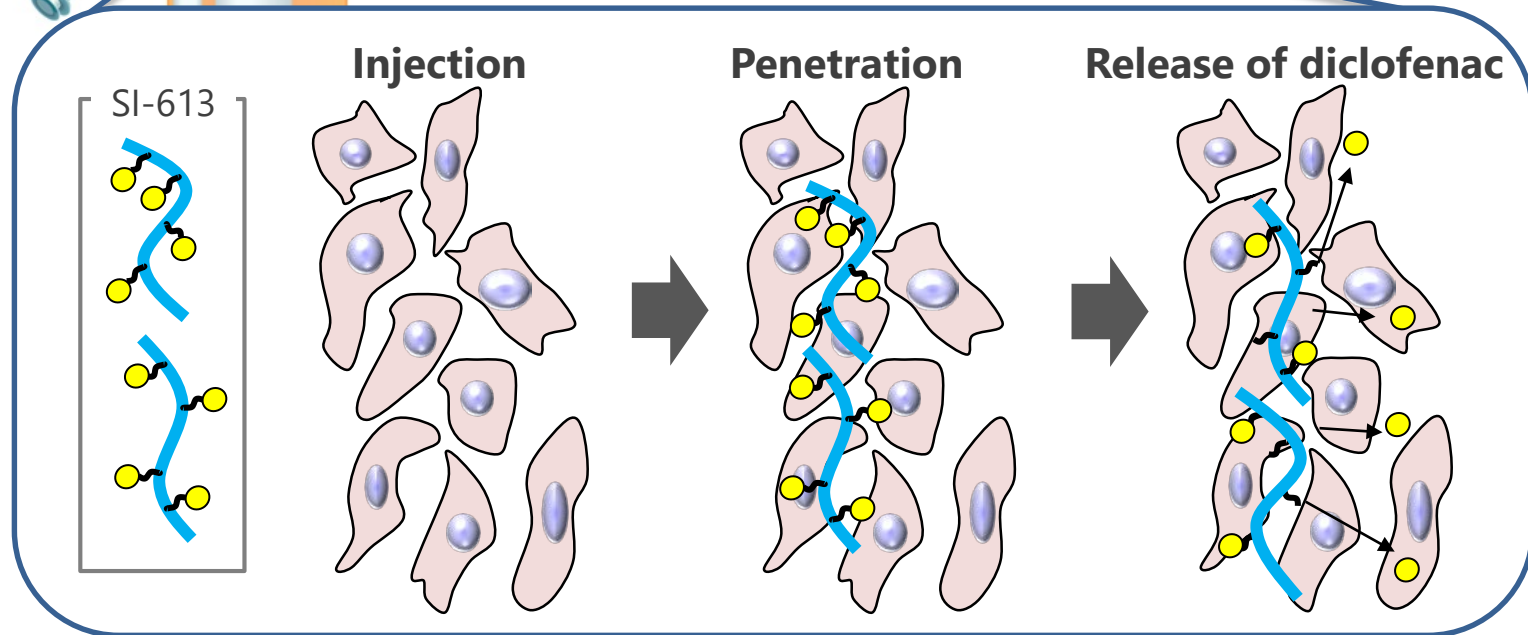
Estimated patients : 24 million (U.S.) / 47 million (China) / 3.7 million (South Korea)

(Seikagaku estimates)

# Sustained Release of Diclofenac in SI-613

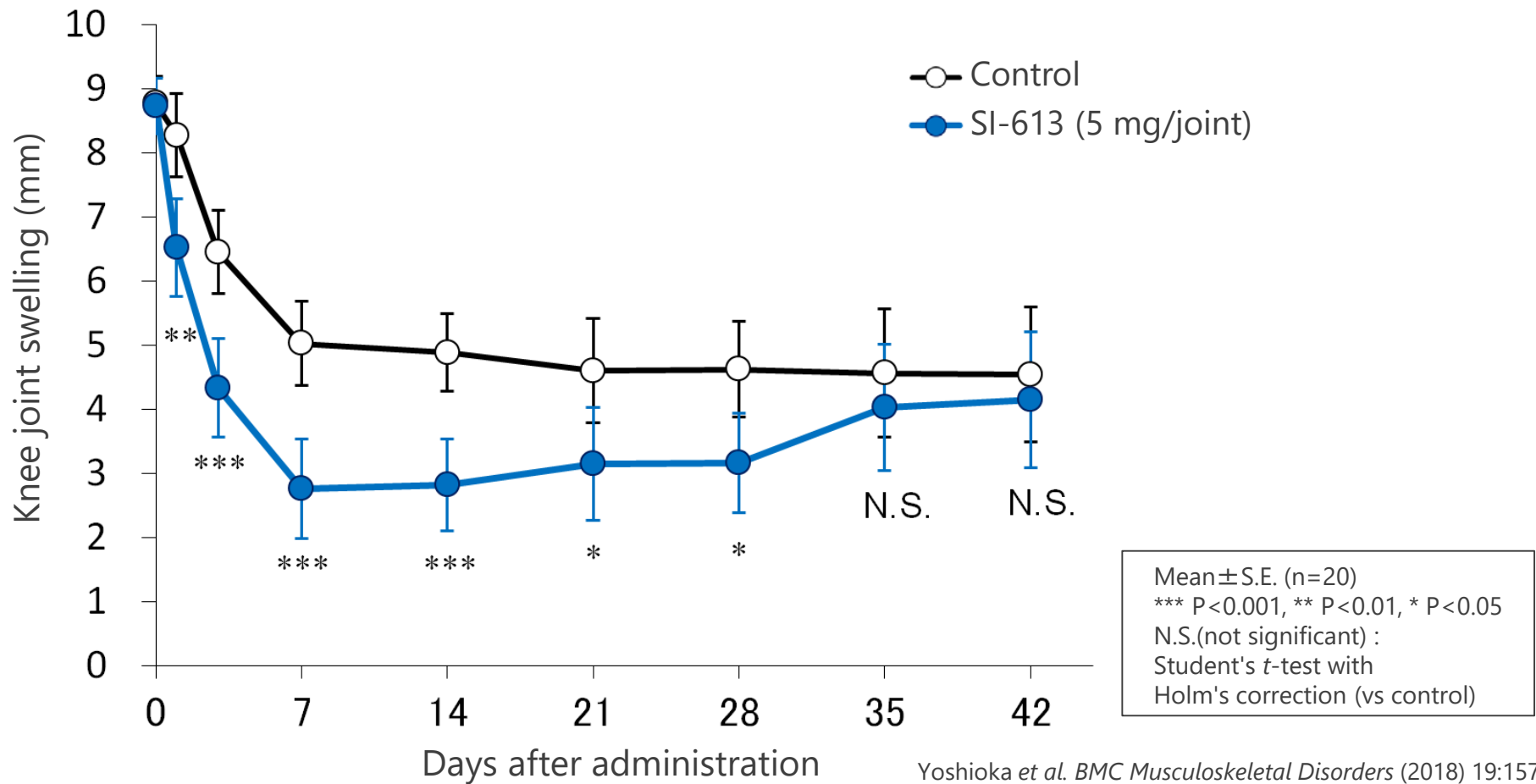


SI-613 (substance name: Diclofenac Etalhyaluronate Sodium) is thought to penetrate the synovial membrane (connective tissue within the articular capsule) and gradually release diclofenac



# Results of Non-clinical Study for SI-613

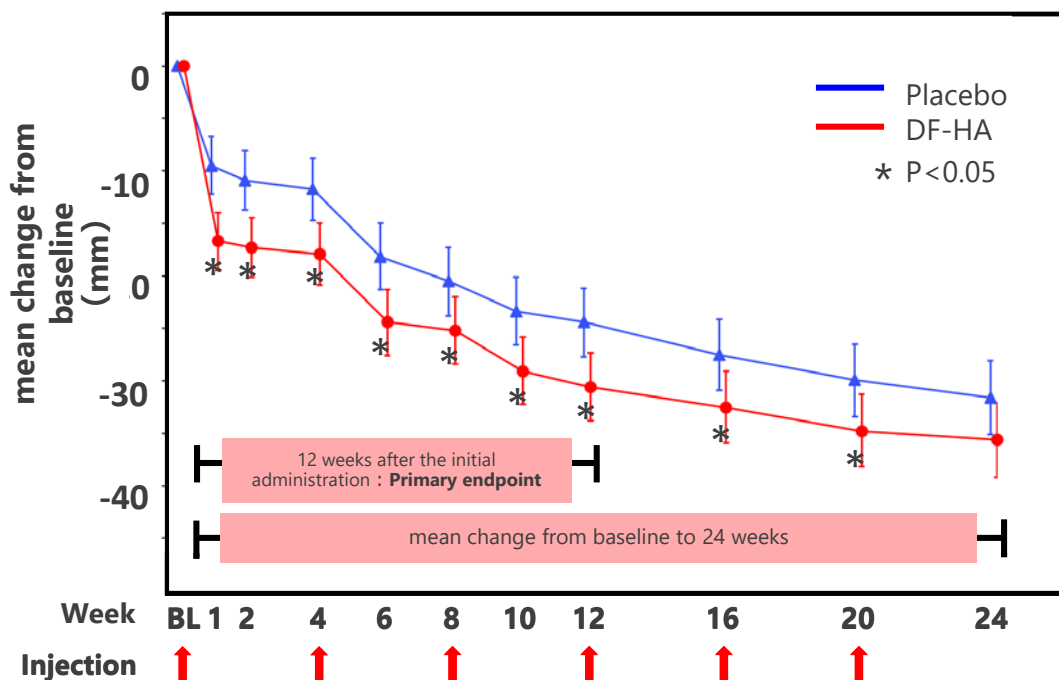
## Results of non-clinical study : Anti-inflammatory effect of SI-613 on antigen-induced arthritis in rabbits



Yoshioka et al. *BMC Musculoskeletal Disorders* (2018) 19:157  
<https://doi.org/10.1186/s12891-018-2077-8>

# SI-613 (Treatment of Osteoarthritis)

On the WOMAC A (pain) score, the primary endpoint, a statistically significant difference is recognized between the placebo group



	Placebo (n=220)	DF-HA (n=218*)
<b>mean change from baseline to 12 weeks : Primary endpoint</b>		
mean change from baseline	-17.1 [-19.8, -14.4]	-23.2 [-25.9, -20.4]
difference	-6.1 [-9.4, -2.8]	
P value	<0.001	
<b>mean change from baseline to 24 weeks</b>		
mean change from baseline	-20.8 [-23.6, -18.0]	-26.4 [-29.2, -23.6]
difference	-5.6 [-9.1, -2.2]	
P value	0.001	

least square mean [The 95% confidence interval]

Mixed model for repeated measures analysis

\*FAS : Except for two cases with no effectiveness results after administration

※ DF-HA : Diclofenac Etalhyaluronate Sodium (SI-613)

Source : The 93rd Annual Meeting of the Japanese Orthopaedic Association

The phase III study of Diclofenac etalhyaluronate (ONO-5704/SI-613) in osteoarthritis of the knee

## SI-613 (Treatment of Osteoarthritis/Enthesopathy)

### Academic conference presentation of the results of a phase III study in Japan of SI-613 in patients with knee osteoarthritis

#### Outline of Conference Presentation

The results of a phase III study in Japan of SI-613 in patients with knee osteoarthritis were presented at the 93rd Annual Meeting of the Japanese Orthopaedic Association, an online meeting held from June 11 to August 31, 2020.

#### Abstract Number: 3-12-15

The phase III study of Diclofenac Etalhyaluronate Sodium(ONO-5704/SI-613) in osteoarthritis of the knee

Conducted as a randomized, double-blind, placebo-controlled, parallel-group comparative study in 440 patients with knee osteoarthritis to evaluate efficacy and safety

#### Primary endpoint: WOMAC pain score

Statistically significant difference found versus the placebo group in difference in mean change in WOMAC score from baseline to 12 weeks after initial administration

#### Main Secondary endpoints: WOMAC stiffness score and physical function score

Statistically significant difference found versus the placebo group in difference in mean change in WOMAC scores from baseline to 12 weeks after initial administration

#### Safety evaluation:

No difference in frequency of adverse events and no clinically evident problems found



# Clinical Study Information

Development code/ Indication	Develop- ment Location	Clinical Study Title (Study ID)	Target Enroll- ment	Estimated Period	Primary End Point (Primary Follow-up period)
<b>SI-6603</b> Lumbar Disk Herniation	U.S.	Phase III additional study ( <a href="#">NCT03607838</a> )	320	May. 2018 – Nov. 2022	Leg pain (13 weeks)
<b>SI-613-ETP</b> Enthesopathy	Japan	Late-stage Phase II clinical study ( <a href="#">JapicCTI-173758</a> )	240	Oct. 2017 – Oct. 2018	Pain in motion (4 weeks)
<b>SI-613</b> Knee Osteoarthritis	U.S.	Phase II clinical study ( <a href="#">NCT03209362</a> )	80	Oct. 2017 – Nov. 2018	WOMAC(Knee pain) (12 weeks)
<b>SI-614</b> Dry eye	U.S.	Phase III clinical study	240	May. 2022 – Jan. 2023	
<b>SI-722</b> Interstitial cystitis and bladder pain syndrome	U.S.	Phase I / II clinical study ( <a href="#">NCT04208087</a> )	32	Mar. 2020 – Jan. 2021	Maximum observed plasma concentration
<b>SI-449</b> Adhesion Barrier	Japan	Pivotal study (Field of gastroenterological surgery) ( <a href="#">JapicCTI-205343</a> )	130	Jun. 2020 – Dec. 2022	Efficacy
<b>SI-449</b> Adhesion Barrier	Japan	Pilot study (Field of gynecology) ( <a href="#">jRCT2072210100</a> )	10	Dec. 2021 – Sep. 2022	Usability, Safety

Note: The table shows data registered (or planned to be registered) on clinical trial information websites. The information is updated from time to time. Refer to the websites for details and the latest information. (The websites can be accessed from the trial ID links.)

- Japan Pharmaceutical Information Center(JAPIC) [http://www.clinicaltrials.jp/user/cteSearch\\_e.jsp](http://www.clinicaltrials.jp/user/cteSearch_e.jsp)
- University hospital Medical Information Network (UMIN) Center <http://www.umin.ac.jp/ctr/index.htm>
- ClinicalTrials.gov <https://clinicaltrials.gov/ct2/search>

Note: Actual enrollments or trial periods may differ from targets and plans due to various factors.

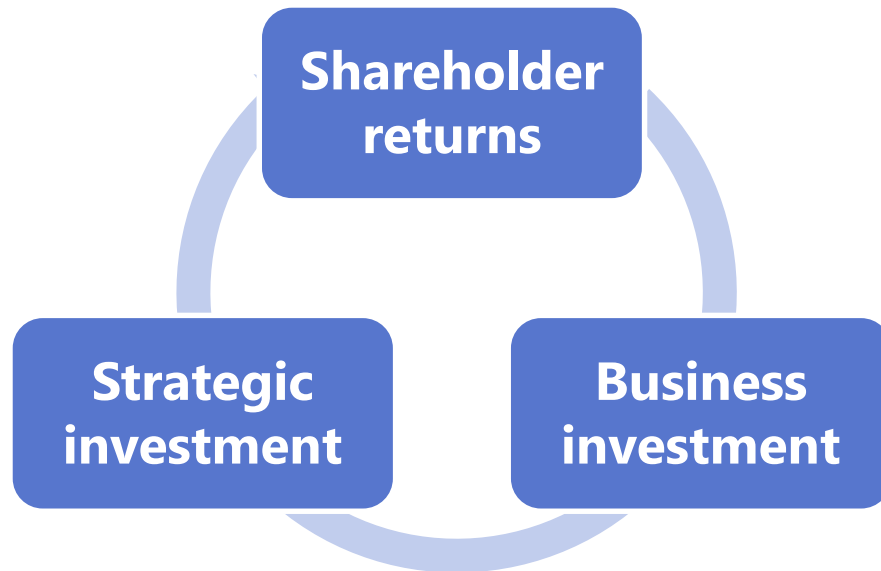
## Contract Status by R&D Theme

### Planned receipt of milestone royalties in accordance with future progress in development and marketing

Development Code Indication	Development Location	Sales Partner	Total Amount of Milestone Royalties ( of which, in upfront payment )
<b>SI-6603</b> Lumbar Disk Herniation	U.S.	Ferring Pharmaceuticals (Switzerland)	Max. US \$95 million (US \$5 million)
<b>SI-613</b> Japan: Osteoarthritis U.S. : Knee Osteoarthritis	Japan	Ono Pharmaceutical Co., Ltd.	Max. ¥12.0 billion (¥2.0 billion)
	U.S.	Searching	—
	China	Eisai Co., Ltd.	—
	Korea	Eisai Co., Ltd.	—
<b>SI-613-ETP</b> Enthesopathy	Japan	Ono Pharmaceutical Co., Ltd.	*included in the above
<b>SI-614</b> Dry eye	U.S.	Searching	—
<b>SI-722</b> Interstitial cystitis	U.S.	—	—
<b>SI-449</b> Adhesion Barrier	Japan	—	—

## Basic policy on profit distributions (FY2019-FY2021)

**Investing for sustainable profit growth and raising corporate value, implement business performance-linked dividends**



### **Shareholder returns**

- Aiming for a 50% dividend payout after considering business profits etc.
- Examining the purchase of company treasury stock when appropriate

### **Business investment**

Investing efficiently in R&D and production facilities etc. for creating new value

### **Strategic investment**

Carrying out initiatives for strategic investments with prospects for future growth and synergy effects

# Seikagaku's vision

## Our vision

A company that is valued by the world through its innovative drug discovery

## Core values (motto)

Creativity, Fairness, Dreams and Passion

## Creed

We create safe and useful products for human well-being with basic research based on glycoscience.

## Guidelines for Our Activities

- We create a corporate environment of mutual trust and communication using individual abilities.
- We create innovative and useful products through in-depth cooperation between industrial and academic circles.
- We assure the highest quality and safety of our products.
- We enhance interaction with society by establishing genuine trust. Through these efforts, Seikagaku will strive to become a sound and socially responsible company that protects the natural environment and improves quality of life.

## Mission statement

"Glycoscience for human well-being"

## Corporate slogan of the new mid-term management plan

"Innovative Thinking"  
Creating value based on innovative thinking

# 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 **70 years**

## 2

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

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

## 3

### Unique business model

- Concentration on **R&D** and **manufacturing**
- R&D staff comprising **40%** of our employees (Non-consolidated base)
- Allocation of **25% to 30%** of net sales to R&D investment

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

# Our Business Segment

**Pharmaceutical Business 73.7%**

**Domestic Pharmaceuticals → 32.8%**



Joint Function Improving Agents



Treatment for lumbar disc herniation

**Overseas Pharmaceuticals → 22.0%**



Joint Function Improving Agents



Ophthalmic Surgical Aids

**Bulk Products/CDMO → 7.5%**

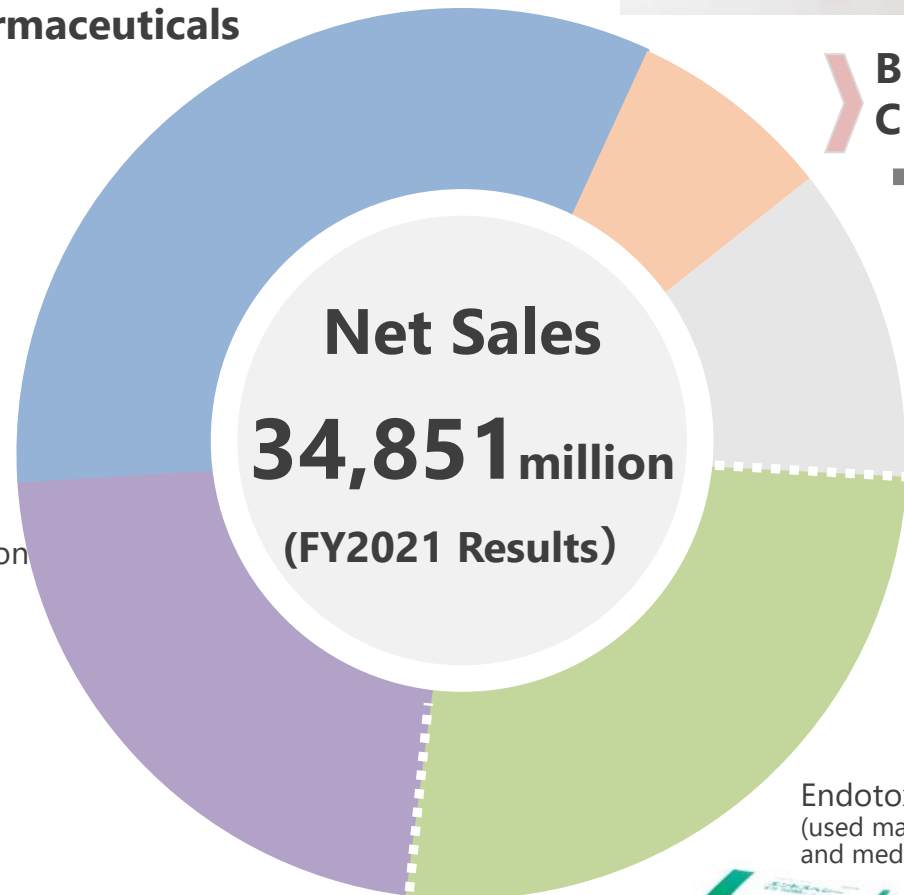


Bulk Products

**Royalty income → 11.4%**

**LAL Business 26.3%**

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



**Net Sales 34,851 million (FY2021 Results)**

# Main Hyaluronic Acid (HA) Products

## **ARTZ<sup>®</sup>** Joint function improving agent 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<sup>®</sup>** Intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis

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



## ■ Cautionary Notes

This material contains forward-looking statements regarding future management strategies or performance forecasts. These descriptions 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 descriptions due to various factors. Information about pharmaceutical products or medical devices (including products currently in development) contained in this material is not intended to constitute an advertisement or medical advice.



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