

**Exploring the Innovative Promise of Glycoscience**

# **Financial Results for the 2nd Quarter of Fiscal Year 2025**



**SEIKAGAKU CORPORATION**

(TSE : 4548)



|                                                                                                                                                                                                                                                      |               |
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# 2Q of FY2025 Results



# Overview for 2Q of FY2025

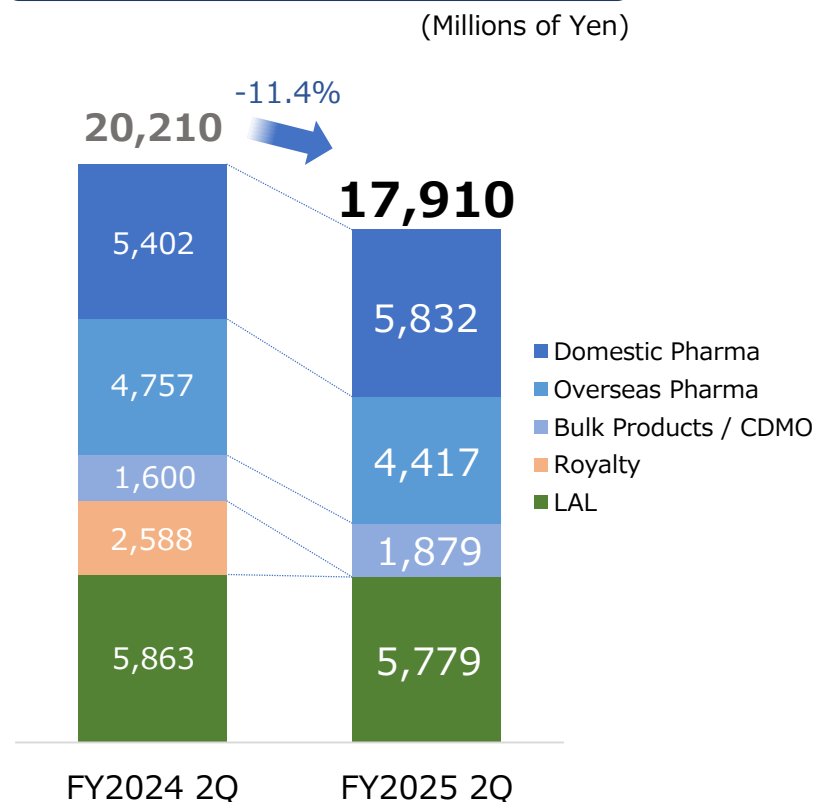
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Promise of Glycoscience

- Net sales: Down 11.4% on a steep decline in royalty income, despite higher sales of domestic pharmaceuticals.
- Income: Down sharply due to the decrease in royalty income. Ordinary income and interim net income improved from the first quarter because of the sale of investment securities.
- No revision to the forecast because of anticipated sales of investment securities.
- Capital investment for establishing a global production system is proceeding as planned.

| (Millions of Yen)    | 2Q FY2024<br>Results | 2Q FY2025<br>Results | % of<br>Change |
|----------------------|----------------------|----------------------|----------------|
| Net Sales            | 20,210               | <b>17,910</b>        | -11.4%         |
| Operating Income     | 2,537                | <b>(557)</b>         | —%             |
| Ordinary Income      | 2,354                | <b>531</b>           | -77.4%         |
| Net Income           | 1,931                | <b>229</b>           | -88.1%         |
| Net Income per Share | ¥35.39               | <b>¥4.21</b>         | —              |

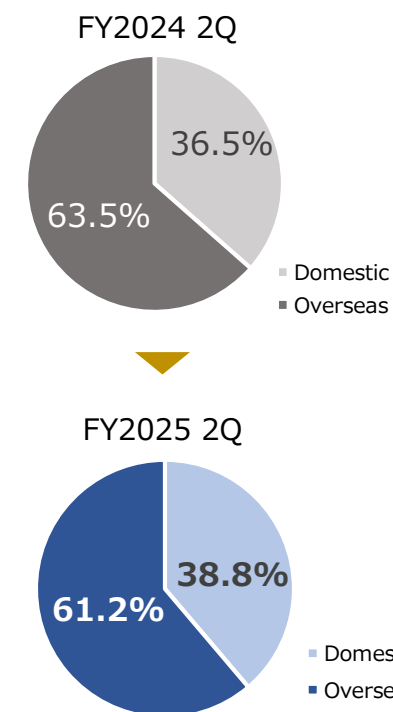
| Other Performance Indicators                              | FY2024 2Q | FY2025 2Q    | % of Change |
|-----------------------------------------------------------|-----------|--------------|-------------|
| R&D Expenses (Millions of Yen)                            | 3,243     | <b>3,027</b> | -6.6%       |
| Ratio of R&D expenses to sales (excluding royalty income) | 18.4%     | <b>16.9%</b> | -1.5Pt      |
| Ave. exchange rate during the period (1USD)               | ¥152.6    | ¥146.0       | -¥6.6       |

## Net Sales by Business Segment



## Overseas Sales Ratio

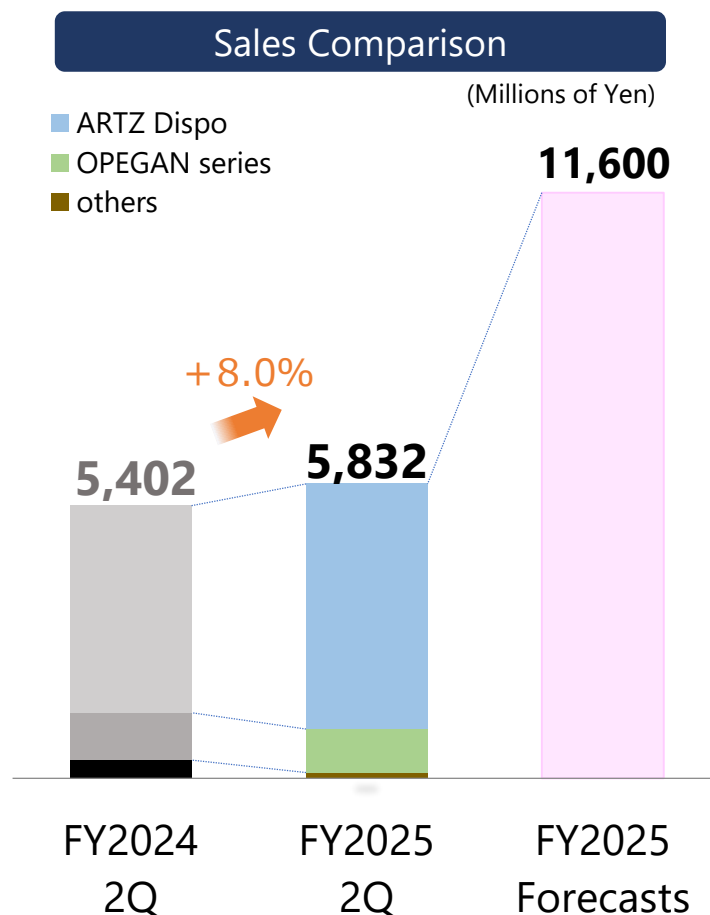
\*excluding royalty income





# Domestic Pharmaceuticals

- Net sales up 8.0% year on year, due mainly to higher sales of ARTZ attributable to shipment timing.



## ARTZ (Joint-function improving agent)

### ◆ Market environment:

- Number of patients increasing accompanying a rising elderly population. However, slight declining market for hyaluronic acid injectable treatments due to factors including expansion of treatment options, such as topical preparations and oral medications.
- Top share maintained. (approx. 80%\*)  
Maintaining trust by leveraging status as an original drug through appropriate provision of information to medical institutions together with the sales partner. Continuous holding of seminars at academic conferences.

### ◆ Seikagaku sales: Up due to shipment timing.

## OPEGAN series (Ophthalmic viscoelastic devices)

### ◆ Market environment:

- Because of use mainly for cataract surgery, market expansion trend accompanying growth in the elderly population.
- Top share maintained. (approx. 50%\*)  
Pursuit of further market penetration in cooperation with the sales partner.

### ◆ Seikagaku sales: Down due to a decrease in unit prices.



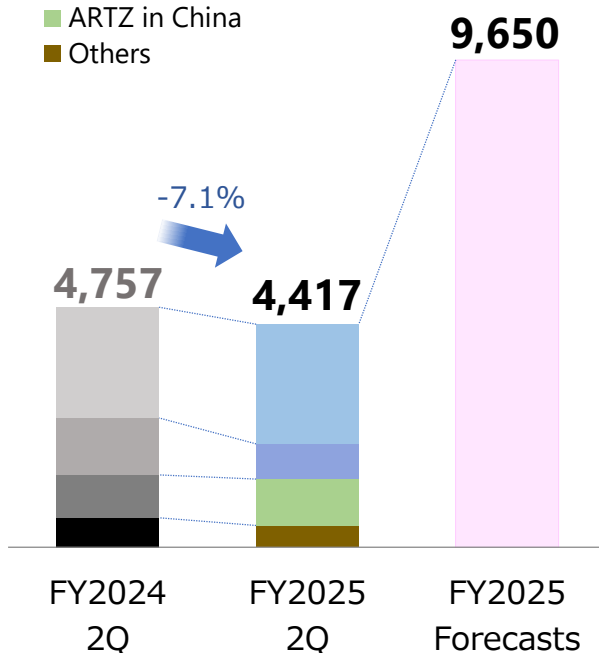
## Overseas Pharmaceuticals

- Sales down 7.1% year on year on lower sales of SUPARTZ FX, a treatment of knee osteoarthritis for the U.S. market, despite higher sales of Gel-One in the U.S. and ARTZ in China.
- Results for all of them attributable to shipment timing.

### Sales Comparison

(Millions of Yen)

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



### Products for the U.S.

#### ◆ Market environment:

- Market growth against a backdrop of expansion of the elderly population, but uncertainty surrounding the impact of government policies on the pharmaceutical industry.
- Single-injection and 2-5 multiple injection products available, with single-injection products making up about half the total market.
- Seikagaku continue sales promotion activities appropriate for each product, gazing the trend of competing products.

#### ◆ Seikagaku sales:

- Gel-One (single-injection viscosupplement): Up due to shipment timing.
- SUPARTZ FX (five-injection viscosupplement): Down due to shipment timing.

### ARTZ in China

#### ◆ Market environment:

- Despite gradual market growth against the backdrop of expansion of the elderly population, future trend difficult to forecast due to expansion of the centralized procurement system by the national government and provinces.
- Appropriately providing information to medical institutions and at relevant academic conferences and continuing activities to expanded sales while earning trust as an original product.

#### ◆ Seikagaku sales: Up due to shipment timing.

Foreign exchange impact: -155million yen



# Bulk Products / CDMO, Royalty, LAL Business

## Bulk Products / CDMO

- Net Sales: 1,879 million yen (Up 17.4% year on year, Foreign exchange impact: -101 million yen)
- Seikagaku sales increased mainly in contract development and manufacturing services.

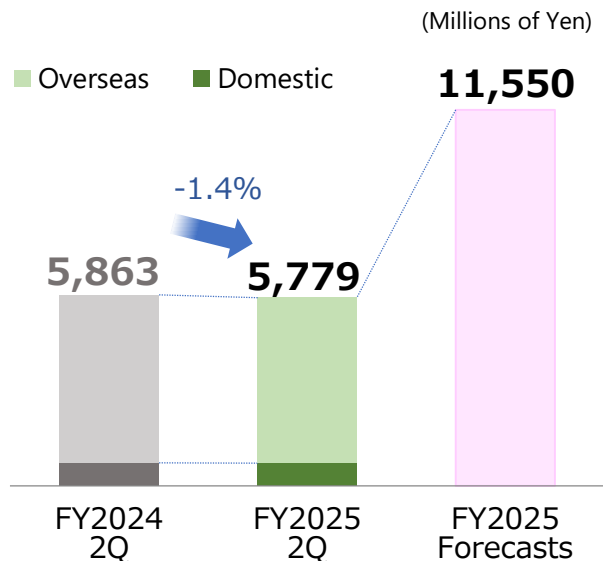
## Royalties

- Net Sales: 1 million yen. (Down 99.9% year on year)
- 2,588 million yen in the same period of the previous year.

## LAL Business

- Sales down 1.4% year on year due to the impact of yen appreciation, despite continuing strong sales of Fungitell (a beta-glucan-detecting in vitro diagnostic).

### Sales Comparison



### ◆ Market environment:

#### • Endotoxin-detecting reagents

Used mainly in quality control of pharmaceutical manufacturing processes.  
Projected stable growth from conventional products produced using horseshoe crab blood as well as from recombinant products manufactured from non-animal-derived raw materials.

#### • Beta-glucan-detecting in vitro reagent

Used mainly as a diagnostic for deep fungal infections.  
Sales growing, mainly in the U.S. Increased the number of countries where the products is sold and expand the product range with further growth forecast.

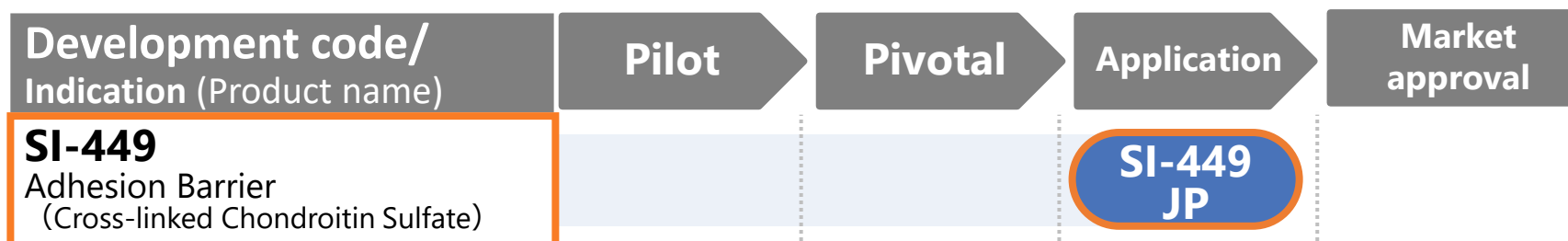
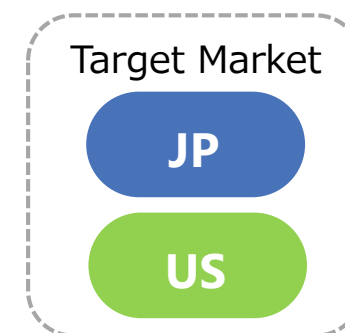
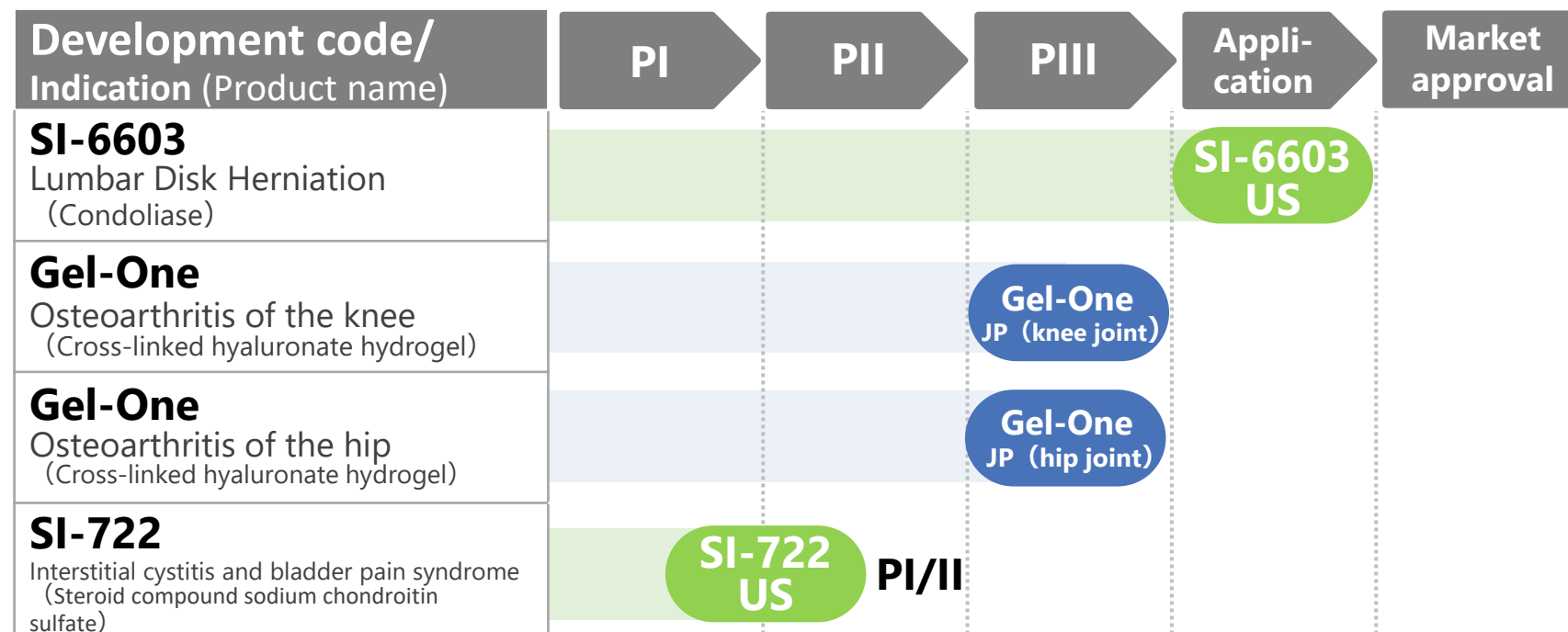
### ◆ Seikagaku sales:

Down due to yen appreciation year on year.

# Research and Development



## Pipeline List

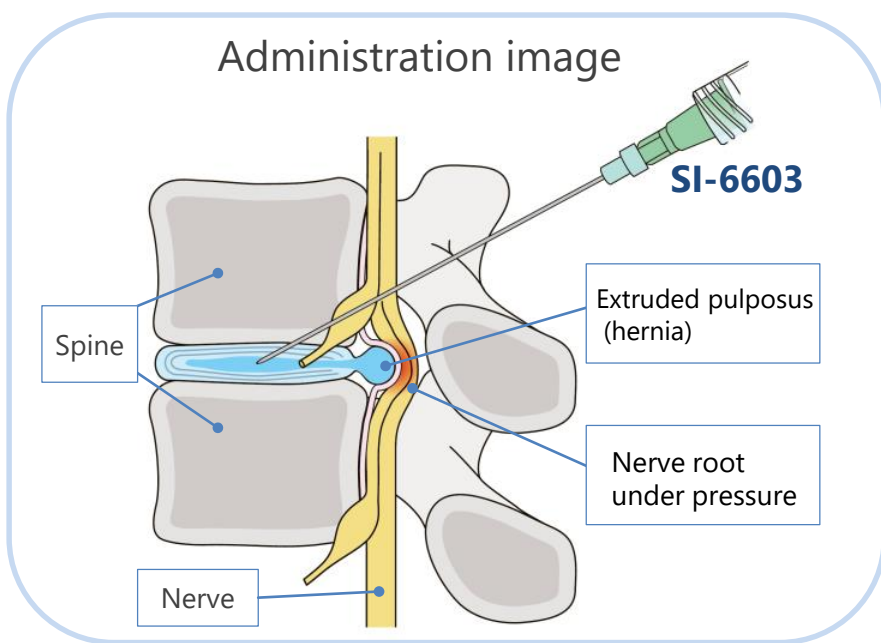


○ SI-449: Submitted an application for marketing approval as a medical device (August 2025)



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

- Complete Response Letter (CRL) received from the U.S. Food and Drug Administration (FDA) (not approved).
- The Company will respond to the observations in preparation for obtaining approval aim to resubmit an application by March 2026 (within one year of receipt of the CRL).



### Development status

#### ► Response to resubmission in the U.S.

- March 2025: CRL received from FDA.
- No observations made concerning efficacy or safety, but additional observations made concerning the manufacturing facility and control of the drug substance and drug product.

### 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

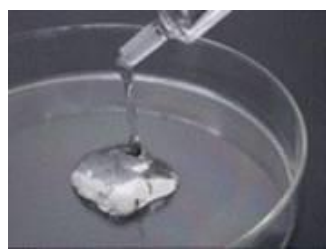
Method of use : Injection into lumbar disc (under X-ray observation)

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

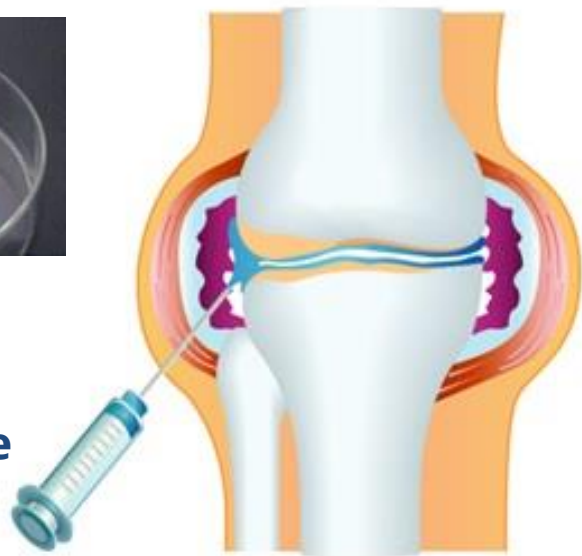


# Gel-One (Osteoarthritis of the knee and hip)

- Intra-articular injection whose main ingredient is a cross-linked hyaluronate hydrogel made using Seikagaku's unique cross-linking technology.
- Phase III clinical study in Japan initiated in February 2025.



**Gel-One**



## Development status

### ► Phase III studies in Japan started

- Initiated Phase III clinical studies of the knee joint and hip joint in February 2025.
- Conclusion of an agreement on joint development and sales partnership with Ono Pharmaceutical Co., Ltd. In August 2025.

## Expected Features

- Confirmed to remain in the knee joint cavity for a long period of time after injection and expected to provide long-term pain relief.
- At this time, no other hyaluronic acid monotherapy is indicated for osteoarthritis.

### <Gel-One summary >

Dev. Code : Gel-One / Generic name : Cross-linked hyaluronate hydrogel

Indication : Osteoarthritis of the knee and the hip / Method of use : Injection into the joint cavity

Estimated Japan patients : Osteoarthritis of the knee    Approx. 8 million<sup>\*1</sup>、 Osteoarthritis of the hip    1.2 to 5.1 million (prevalence rate of 1.0% to 4.3%<sup>\*2</sup> extrapolated to the population of Japan)

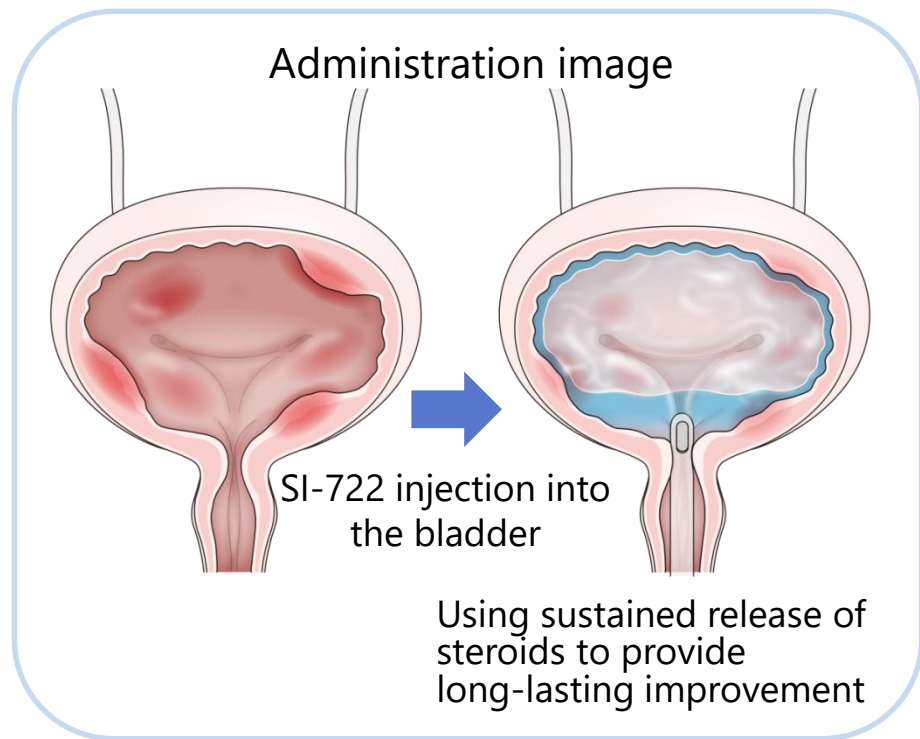
<sup>\*1</sup> : Clinical Practice Guidelines for the Management of Knee Osteoarthritis 2023

<sup>\*2</sup> : Clinical Practice Guidelines for the Management of hip Osteoarthritis



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

- Phase I/II clinical studies in the U.S. completed. Currently considering the future development policy.



### Development status

#### ▶ Phase I/II studies in the U.S. Completed

- Subject enrollment complete in January 2021, and tolerability confirmed. (a primary objective)

### 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

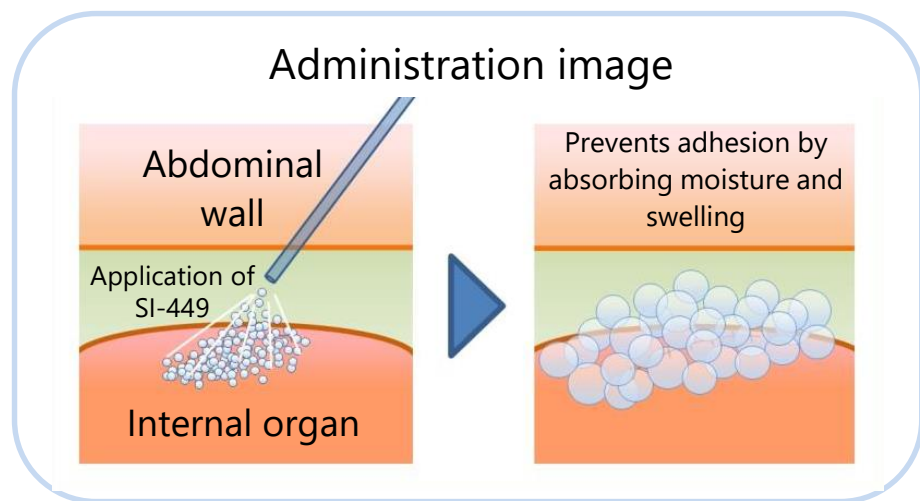
Indication : Interstitial cystitis and bladder pain syndrome / Method of use : Injection into the bladder

Estimated U.S. patients : 1.3 million (Seikagaku estimates)



## SI-449 (Adhesion Barrier / Medical Device)

- Submitted an application for marketing approval as a medical device in August 2025.
- Proceed with a response to regulatory review in preparation for obtaining approval and with preparations for market introduction.



### Development status

#### ▶ Approval application submitted in Japan

- Submitted an application for marketing approval as a medical device in August 2025.

#### ▶ Proceed with development with a view to global development.

### Expected Features

- ▶ A powdered adhesion barrier agent primarily composed of cross-linked chondroitin sulfate created using our own glycosaminoglycan cross-linking technology.
- ▶ 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)

# Other Topics



# Status of Initiative for Constructing a Global Production System

- Preparations underway for construction of an overseas production system for SI-449 and other products under development as well as some current products.
- Now implementing capital investment and technology transfers to an overseas subsidiary.



**Seikagaku Corporation Takahagi Plant**  
( Ibaraki Prefecture, Japan )

## 【Overseas Subsidiaries】



**DALTON CHEMICAL LABORATORIES, INC.**  
( Toronto, Canada )

# Appendix

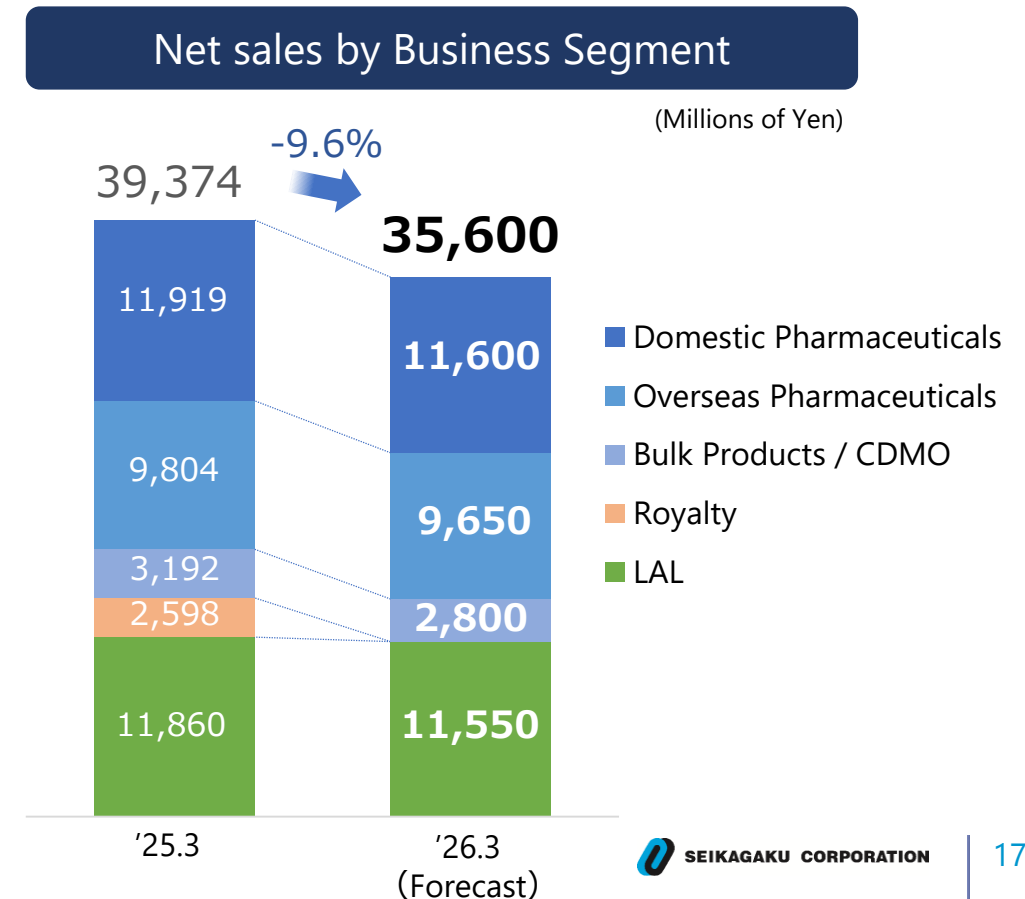


## FY2025 Forecasts Overview

- Projected 11.2% increase in net income attributable to owners of parent on sale of investment securities and lower tax expenses, despite projected operating loss due mainly to lower royalty income.
- **Net sales:** Projected year-on-year decrease from lower royalty income and yen appreciation.
- **Operating Income:** Projected decrease despite lower R&D expenses.
- **Ordinary Income:** Projected decrease due to the sales decrease, despite expected sale of investment securities.
- **Net Income:** Projected increase due to tax expenses decrease.

| (Millions of Yen)                             | FY2024<br>Results | FY2025<br>Forecasts | % of<br>Change |
|-----------------------------------------------|-------------------|---------------------|----------------|
| Net Sales                                     | 39,374            | <b>35,600</b>       | -9.6%          |
| Operating Income                              | 1,333             | <b>(300)</b>        | — %            |
| Ordinary Income                               | 1,933             | <b>1,350</b>        | -30.2%         |
| Net Income                                    | 1,214             | <b>1,350</b>        | + 11.2%        |
| Net Income<br>per Share                       | ¥22.25            | <b>¥24.74</b>       | —              |
| R&D Expenses<br>(excluding royalty<br>income) | 7,643             | <b>7,000</b>        | -8.4%          |
| Average Exchange<br>Rate (1USD)               | ¥152.6            | <b>¥140.0</b>       | -¥12.6         |

- Exchange rate sensitivity (against the USD)  
Net sales: Approx. ¥60 million / Operating income: Approx. ¥35 million





# Basic Policy on Profit Distribution

Make investments for sustained profit growth and corporate value enhancement and pay stable dividends.

## Shareholder returns

- Consider dividend increases with ¥26 per share as a guideline, taking into account business performance, etc.
- Consider treasury stock purchases as appropriate.

## Business investment

- Continue efficient investments related to R&D and production.
- Make active business investments in sustainable activities.

## Strategic investment

- Flexibly consider strategic investments offering prospects for future growth and synergy effects.

|                           | FY2021              | FY2022 | FY2023 | FY2024 | FY2025<br>(forecast) |
|---------------------------|---------------------|--------|--------|--------|----------------------|
| Net profit per share      | ¥66.32              | ¥40.49 | ¥40.08 | ¥22.25 | <b>¥24.74</b>        |
| Annual dividend per share | ¥30.00 <sup>*</sup> | ¥26.00 | ¥26.00 | ¥30.00 | <b>¥30.00</b>        |
| Dividend payout ratio     | 45.2%               | 64.2%  | 64.9%  | 134.8% | <b>121.3%</b>        |

\* Includes JOYCLU launch special dividend of ¥10



## Main products and Key Alliances with Companies in Japan and Overseas (Including Products under Development)

- Seikagaku has product and R&D operations in Japan, the United States, China, Taiwan, and Italy.

### Joint function improving agent/Treatment of osteoarthritis

- ARTZ Dispo (Japan)
- JOYCLU (Japan)
- Gel-One (Products under Development: Japan)
- Gel-One (U.S.)
- SUPARTZ FX (U.S.)
- VISCO-3 (U.S.)
- ARTZ (China)
- HyLink (Taiwan, Italy)
- ARTZ Dispo (Taiwan)

### Treatment for lumbar disc herniation

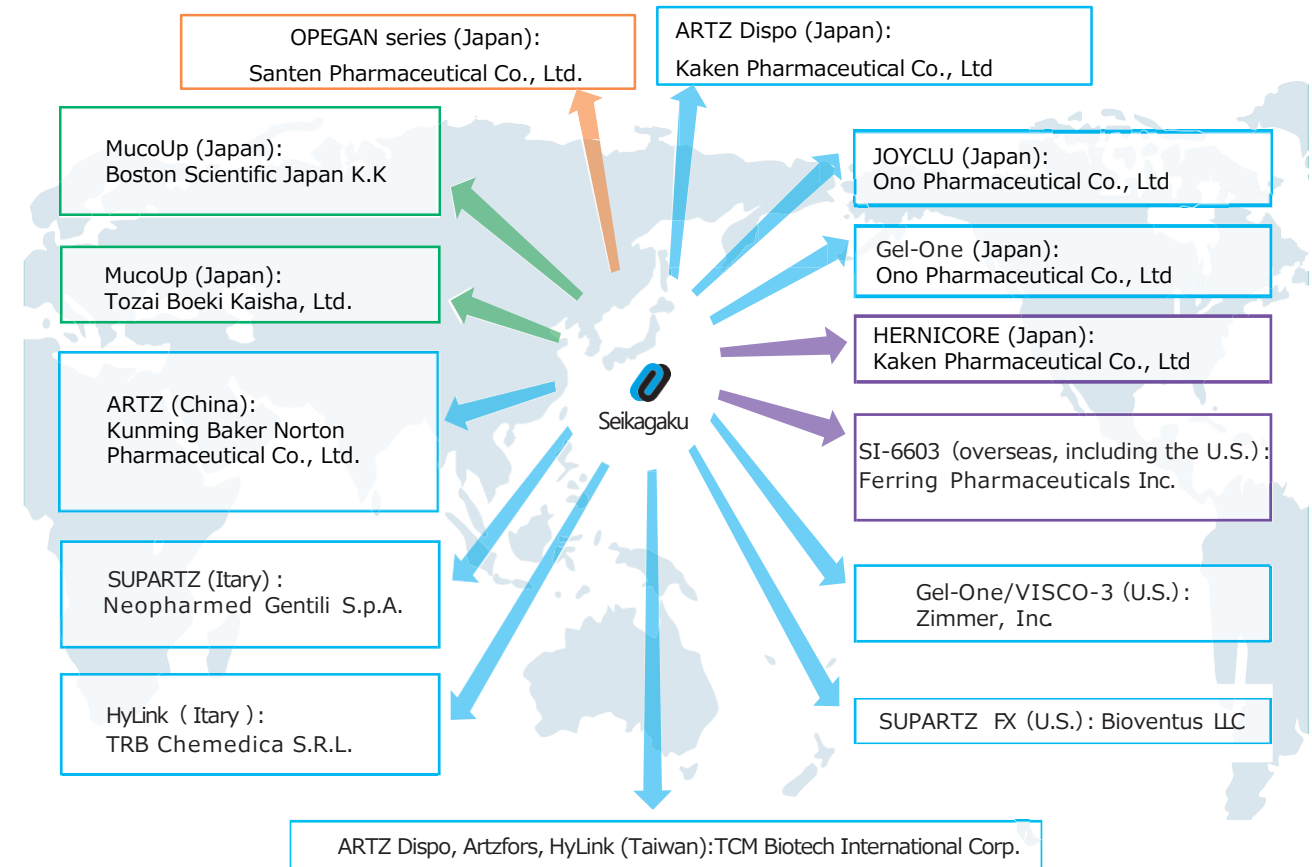
- HERNICORE (Japan)
- SI-6603 (Products under Development: U.S.)

### Ophthalmic viscoelastic device

- OPEGAN series (Japan)

### Surgical aid for endoscopic mucosal resection

- MucoUp (Japan, China)



### ■ 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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