

Financial Results for the Fiscal Year 2024

(April 1, 2024 – March 31, 2025)



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.

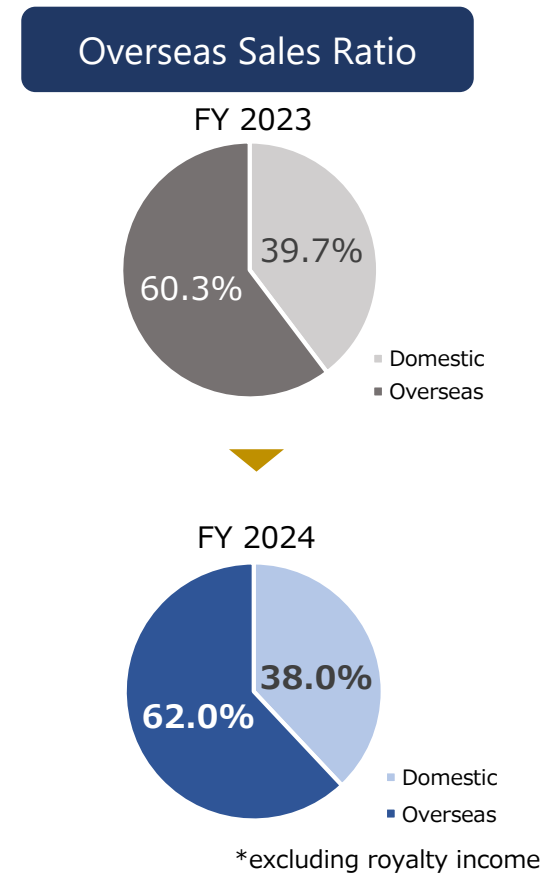
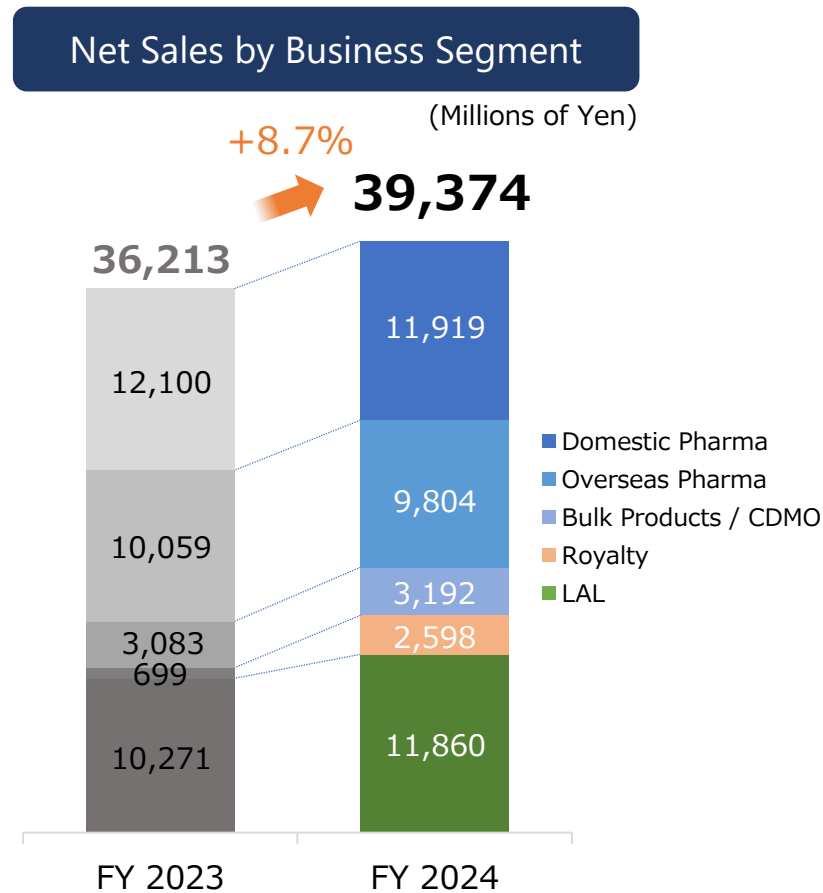
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FY2024 Results

- ◆ Net sales: Up 8.7% on increases in royalty income, and higher sales in the LAL business
- ◆ Operating Income: Up 207.8% due to the revenue increase
- ◆ Ordinary Income: Up 14.3%, below operating income growth because of recognition of foreign exchange loss
- ◆ Net Income: Down 44.5% due to higher tax expenses

(Millions of Yen)	FY 2023 Results	FY 2024 Results	% of Change
Net Income	36,213	39,374	+8.7%
Operating Income	433	1,333	+207.8%
Ordinary Income	1,691	1,933	+14.3%
Net Income	2,186	1,214	-44.5%
Net Income per Share	¥40.08	¥22.25	—

Other Performance Indicators	FY 2023	FY 2024	% of Change
R&D Expenses (Millions of Yen)	7,484	7,643	+2.1%
Ratio of R&D expenses to sales (excluding royalty income)	21.1%	20.8%	-0.3pt
Exchange rate at end of period (US\$1)	¥151.4	¥149.5	-¥1.9
Ave. exchange rate during the period (US\$1)	¥144.6	¥152.6	+¥8.0





Domestic Pharmaceuticals

➤ Net sales down 1.5% year on year due to lower sales of ARTZ and the OPEGAN series

Sales Comparison

(Millions of Yen)

-1.5%

12,100

11,919

FY 2023

FY 2024

ARTZ (Joint-function improving agent)

- Market share: Up on higher deliveries to medical institutions (Approx 83%*)
- Seikagaku sales: Facilities maintenance for the purpose of production system expansion at the Company's plant was completed, and shipment volume increased year on year. However, the Company's sales declined year on year due to a decrease in unit prices reductions.

OPEGAN series (Ophthalmic viscoelastic devices)

- Market share: At the prior-year level because of higher deliveries to medical institutions and market growth (Approx 51%*)
- Seikagaku sales: Down due to a decline in unit prices

Other Products (Seikagaku sales)

- Hernicore: Down due to shipment timing
- MucoUp: Down due to the impact of an NHI reimbursement price change
- JOYCLU: Up due to shipment timing

Continued to gather side effects reports and other information on JOYCLU and provide safety-related information.

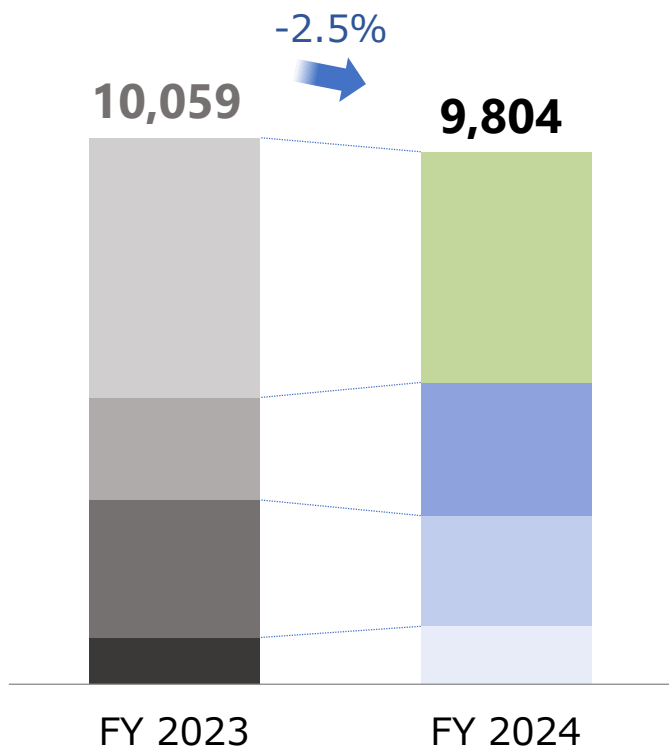
Overseas Pharmaceuticals

- Revenue down 2.5% year on year due to lower sales of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis for the U.S. market, and lower sales of ARTZ for China.

Sales Comparison

(Millions of Yen)

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



Products for the U.S.

- ◆ Gel-One (single-injection viscosupplement)
 - Local sales volume: Sales down
 - Seikagaku sales: Down due to shipment timing
- ◆ SUPARTZ FX (five-injection viscosupplement)
 - Local sales volume: At the prior-year level
 - Seikagaku sales: Up due to distributor inventory adjustments

ARTZ in China

- Local sales volume: Sales down
- Seikagaku sales: Down on lower shipment volume accompanying a materials change in Q4

Other Products (Seikagaku sales)

- ◆ HyLink in Taiwan: At the prior-year level
- ◆ SUPARTZ in Italy: Up due to shipment timing



Bulk Products / CDMO, Royalty, LAL Business

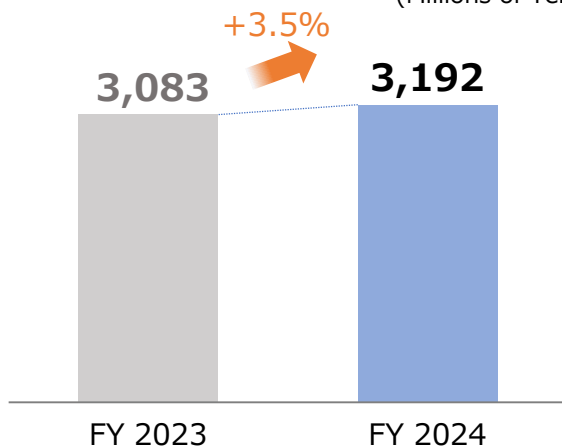
Bulk Products / CDMO

Foreign exchange impact : approx. +158million yen

- Net sales were businesses increased year on year because of increase in sales of contract development and manufacturing and other services of overseas subsidiary DCL* despite lower sales of bulk products.

Sales Comparison

(Millions of Yen)



* DALTON CHEMICAL LABORATORIES, INC.

Royalties

- ¥2,598 million in FY2024 (up 271.6% year on year), compared with ¥699 million in FY 2023

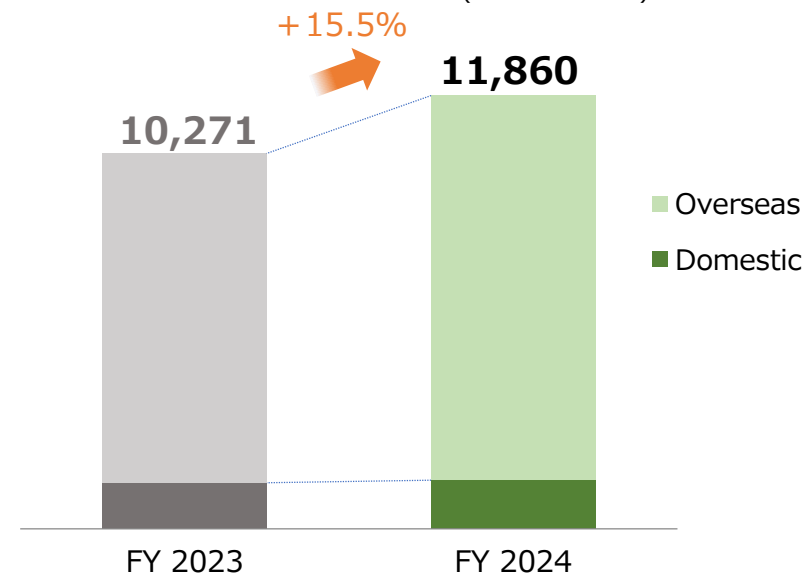
LAL Business

Foreign exchange impact : approx. +808million yen

- Sales up on higher sales in Japan coupled with the beneficial impact of yen depreciation, an increase in the number of countries where Fungitell (a beta-glucan-detecting in vitro diagnostic) is sold, and higher sales of a recombinant reagent for endotoxin detection at overseas subsidiary ACC*

Sales Comparison

(Millions of Yen)



*ASSOCIATES OF CAPE COD, INC.

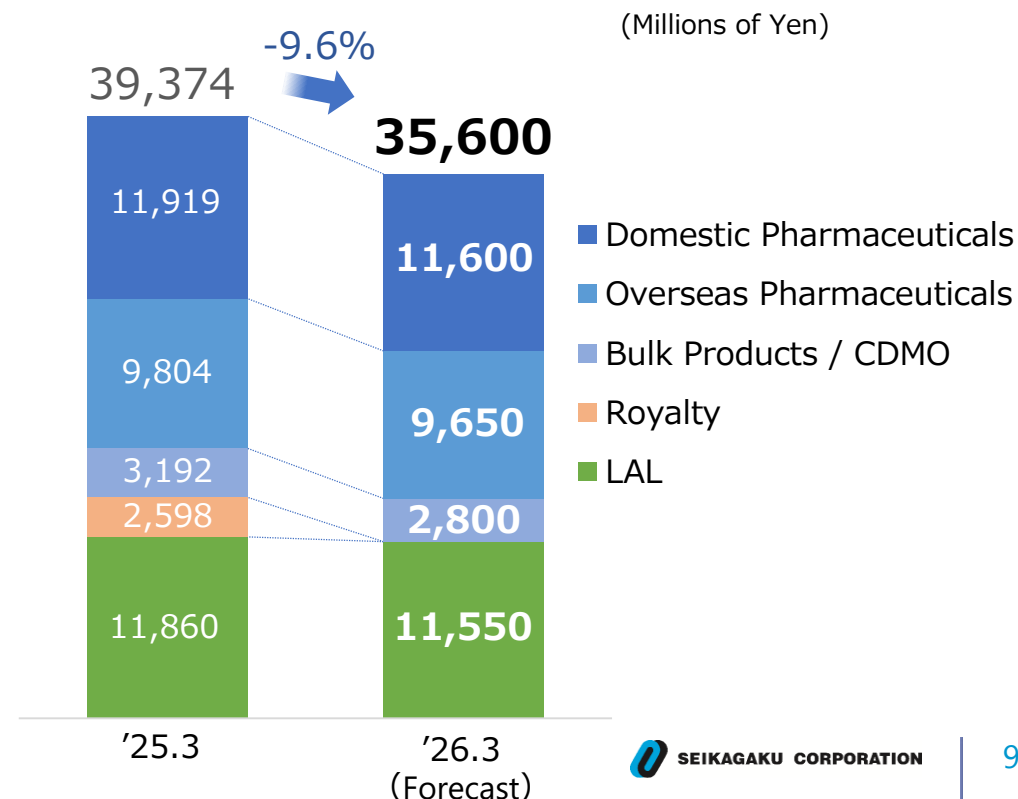
FY2025 Forecasts

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

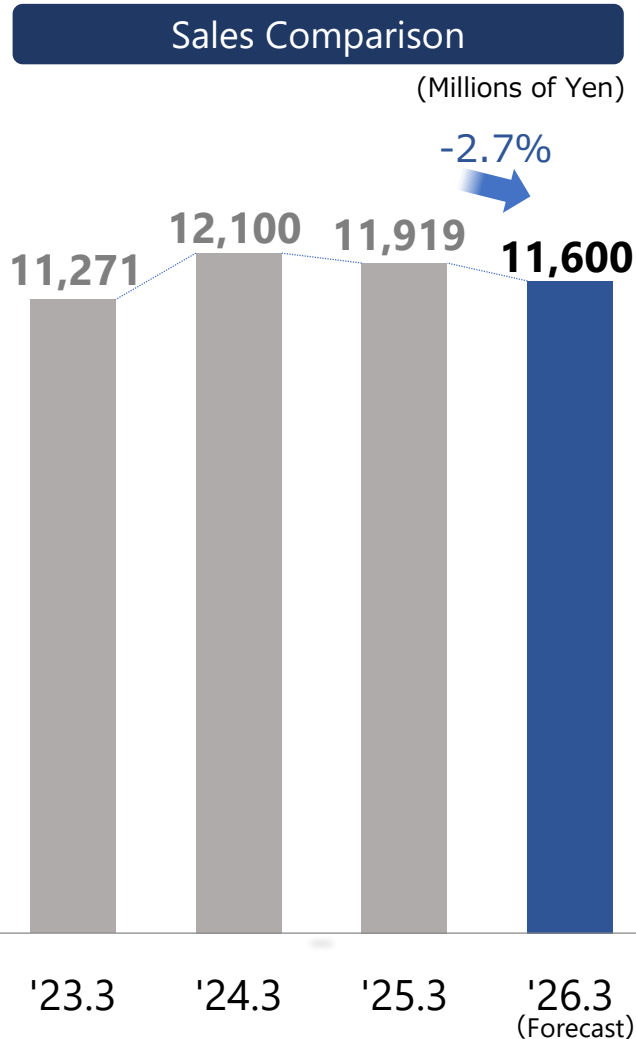
(Millions of Yen)	FY2024 Results	FY2025 Forecasts	% of Change
Net Income	39,374	35,600	-9.6%
Operating Income	1,333	(300)	- %
Ordinary Income	1,933	1,350	-30.2%
Net Income	1,214	1,350	+ 11.2%
Net Income per Share	¥22.25	¥24.74	-
R&D Expenses (excluding royalty income)	7,643	7,000	-8.4%
Average Exchange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

Net sales by Business Segment



Domestic Pharmaceuticals

- Although no major change in the market environment is expected, sales projected to decline 2.7% due to lower unit prices affecting mainly mainstay products



ARTZ (Joint-function improving agent)

- Market: Hyaluronic acid injectable treatments market to be flat or trend down due to expansion of non-injectable treatment options and other factors, despite a rising number of patients accompanying population aging
- Seikagaku sales: Projected at prior-year level

OPEGAN series (Ophthalmic viscoelastic devices)

- Market: Growth trend accompanying increase in elderly population
- Seikagaku sales: Expected decrease on lower unit prices despite a projected volume increase

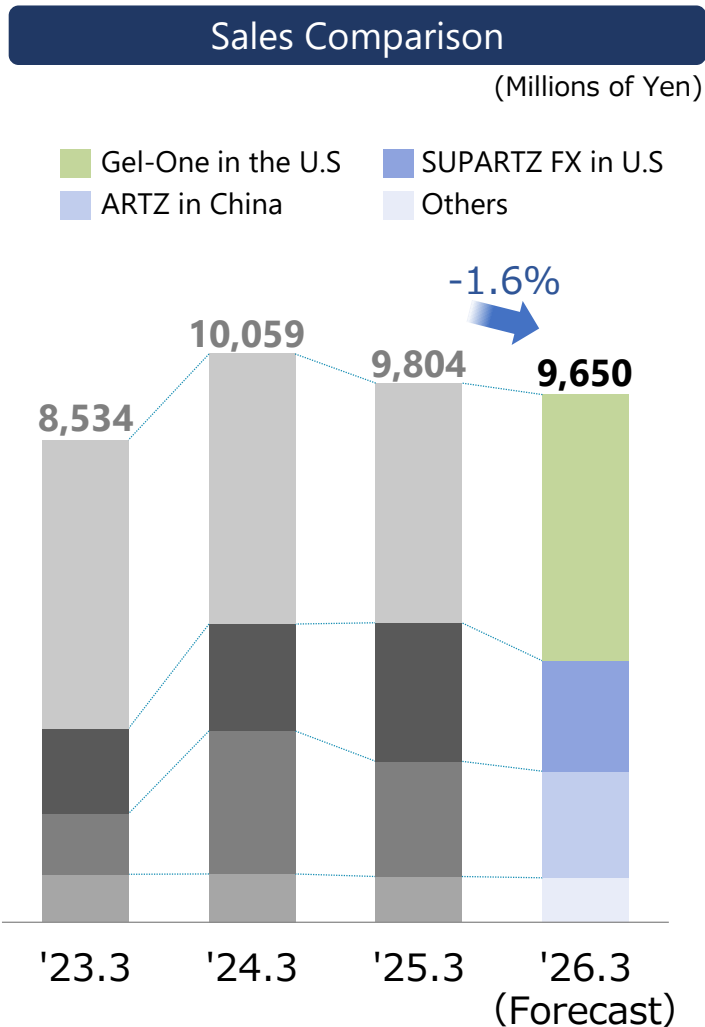
Other Products (Seikagaku sales)

- HERNICORE: Projected increase due to shipment timing
- MUCOUP: Projected at prior-year level in the absence of insurance reimbursement price revision
- JOYCLU: Projected decrease due to shipment timing

Continued to gather side effects reports and other information on JOYCLU and provide safety-related information.

Overseas Pharmaceuticals

- Projected decrease due to foreign exchange impact and other factors, despite an expected volume increase for Gel-One in the US



United States

- ◆ Market environment
 - Market expected to grow due to population aging
 - Many uncertainties at the present time due to the impact of tariffs
- ◆ Gel-One (single-injection product)
 - Seikagaku sales: Projected volume and sales increases due to shipment timing
- ◆ SUPARTZ FX (5-injection product)
 - Seikagaku sales: Projected volume and sales decreases due to shipment timing

China

- ◆ Market environment
 - Market expected to grow due to population aging
 - Uncertainty from the impact of the centralized procurement system, a unique Chinese policy
- ◆ ARTZ for China (5-injection product)
 - Seikagaku sales: Projected sales decrease due to foreign exchange impact, despite expected volume growth

Other Products (Seikagaku sales)

- ◆ HyLink in Taiwan: Projected at prior-year level
- ◆ SUPARTZ in Italy: Projected decrease due to shipment timing

Bulk Products / CDMO, Royalty, LAL Business

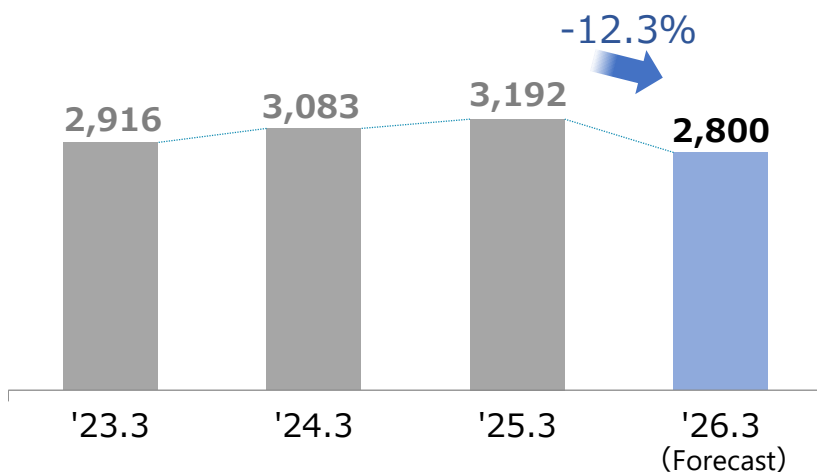
Bulk Products / CDMO

Foreign exchange impact : approx. -221million yen

- Projected lower sales of bulk products and of contract development and manufacturing and other services of subsidiary DCL*

Sales Comparison

(Millions of Yen)



* DALTON CHEMICAL LABORATORIES, INC.

Royalty

- Projected substantial decrease in royalty income

LAL Business

Foreign exchange impact : approx. -891million yen

Overseas

- Projected revenue increase due to foreign exchange impact, despite expected higher sales of endotoxin-detecting reagents, in vitro diagnostic BDG screening tests, and other products at ACC*

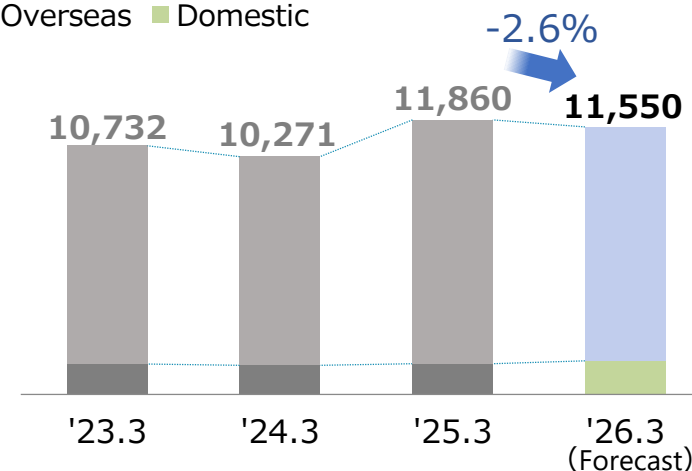
Domestic

- Projected revenue increase on solid sales of instruments and other products

Sales Comparison

(Millions of Yen)

■ Overseas ■ Domestic

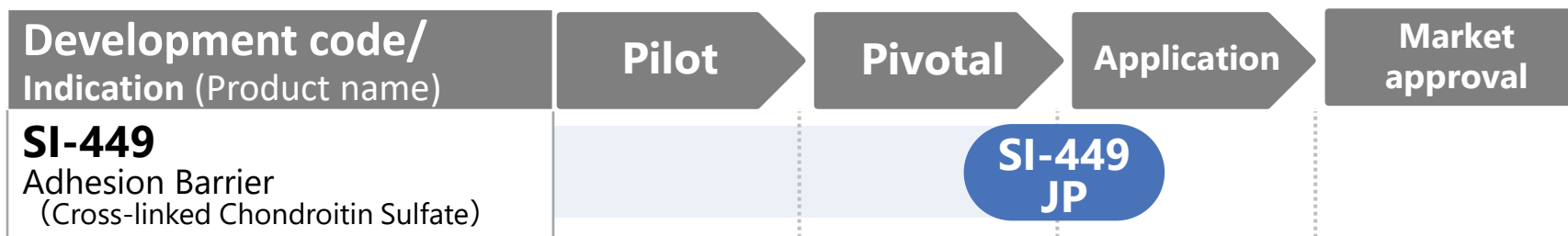
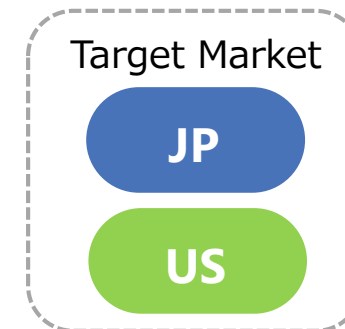
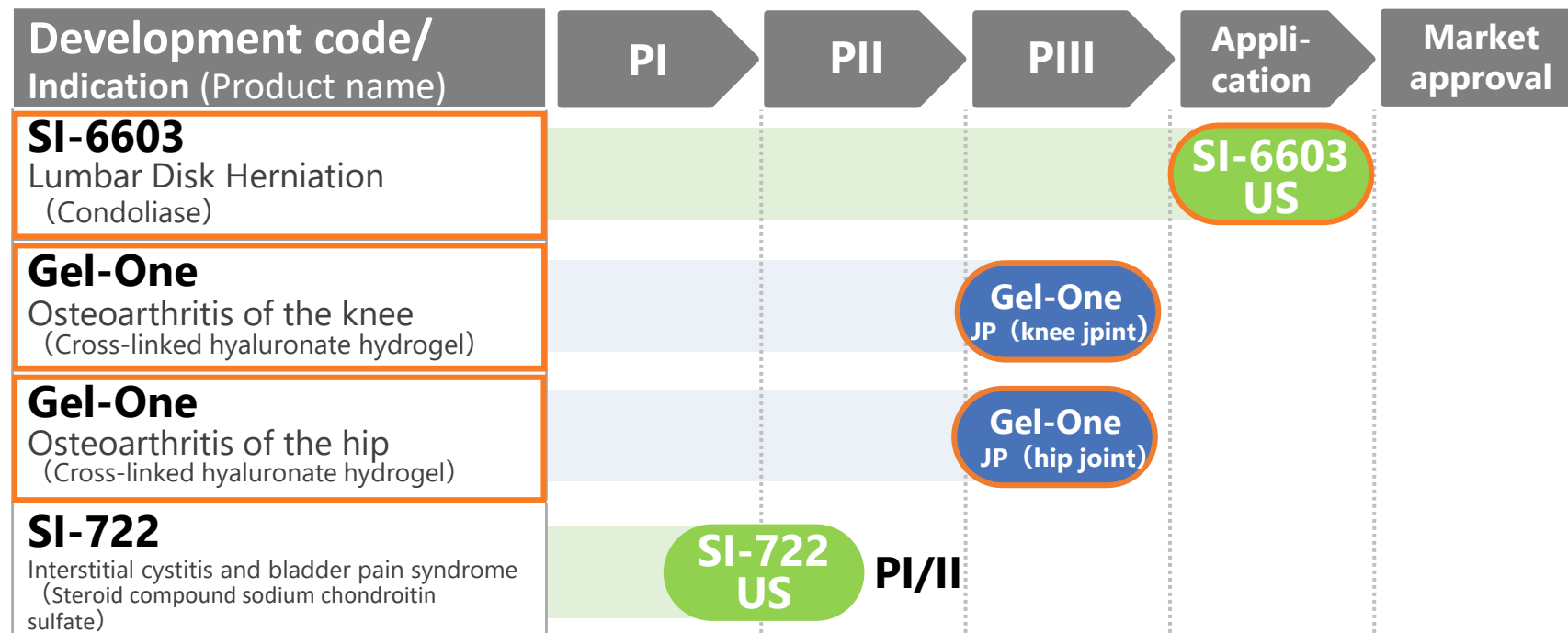


*ASSOCIATES OF CAPE COD, INC.

Research and Development



Pipeline List



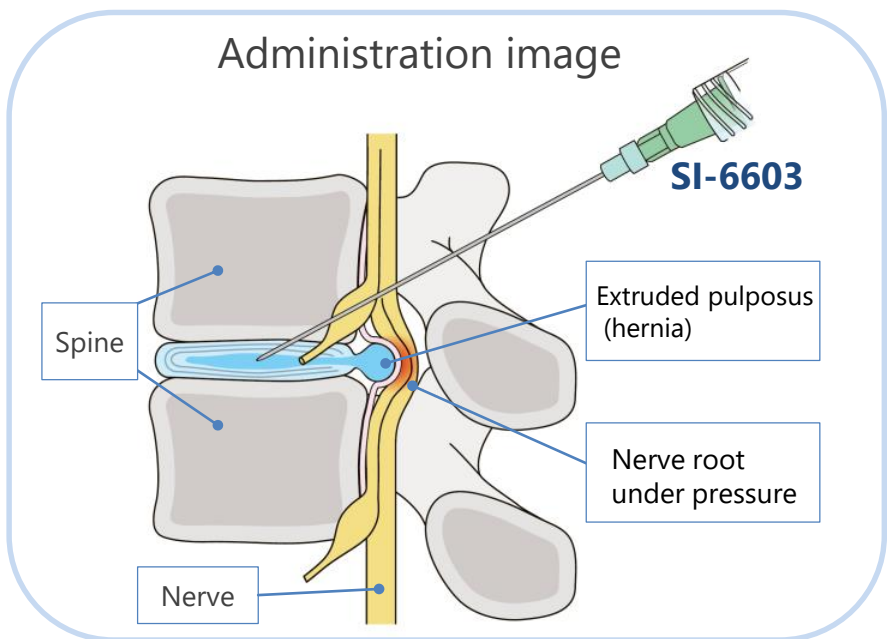
- : SI-6603 Complete Response Letter (CRL) received from the U.S. Food and Drug Administration (FDA) (March 2025)
- : Gel-One (knee joint) New addition (February 2025)
- : Gel-One (hip joint) New addition (February 2025)

※ Development discontinued : SI-613、SI-613-ETP、SI-614



SI-6603 (Treatment for Lumbar Disc Herniation)

Complete Response Letter (CRL) received from the U.S. Food and Drug Administration (FDA) (not approved)
Proceed with a response in preparation for approval within one year from receipt of the CRL



Development status

► NDA submission in the U.S.

- May 2024 FDA Acceptance of a Biologics License Application (BLA)
- No observations made concerning efficacy or safety, but additional observations made concerning the manufacturing facility and control of the drug substance and drug product

⇒ **Proceed with preparations for resubmission within one year of CRL receipt**

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

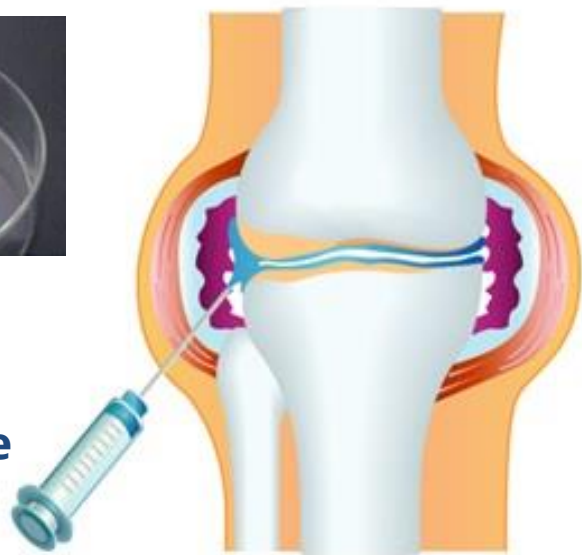
Method of use : Injection into lumbar disc (under X-ray observation)

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



Development status

▶ Phase III studies in Japan

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

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*1、 Osteoarthritis of the hip 1.2 to 5.1 million (prevalence rate of 1.0% to 4.3%*2 extrapolated to the population of Japan)

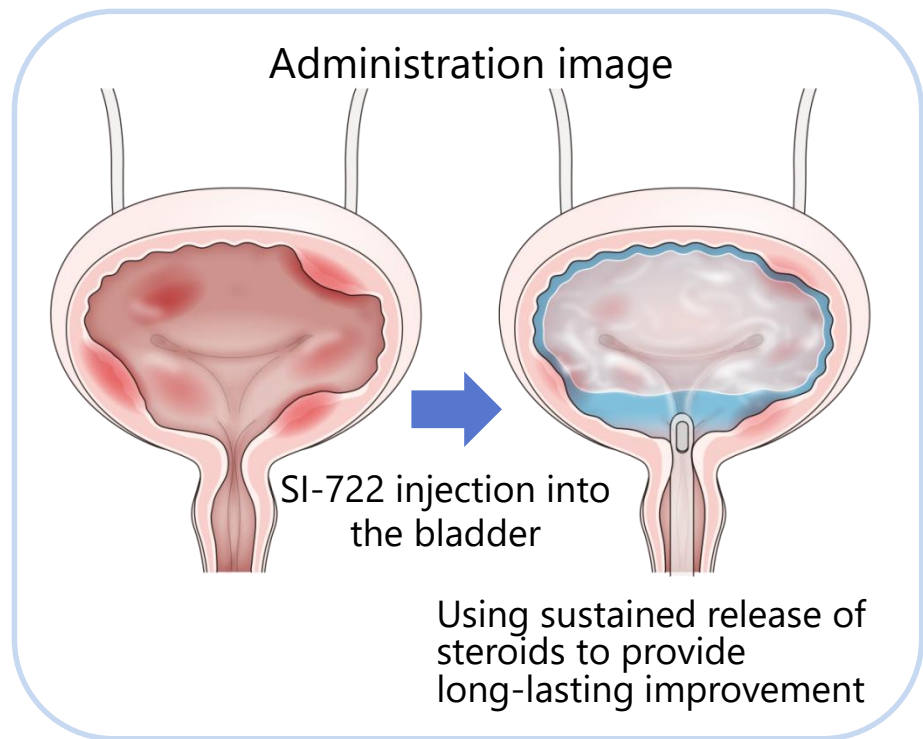
*1 : Clinical Practice Guidelines for the Management of Knee Osteoarthritis 2023

*2 : 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.

- 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

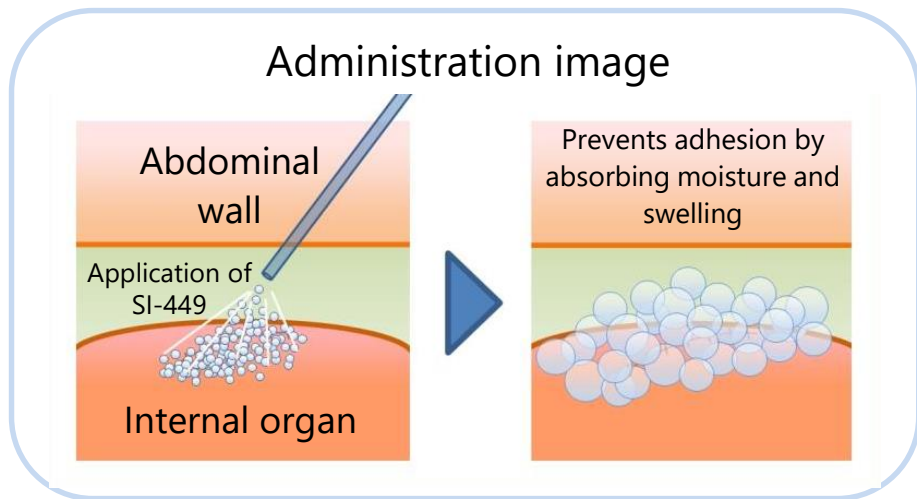
Indication : Interstitial cystitis and bladder pain syndrome / Method of use : Injection into the bladder

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



SI-449 (Adhesion Barrier / Medical Device)

Received the results from pivotal and pilot studies in Japan
Proceed with preparations for an application for approval
Aim for an approval application from Q3 to Q4 of fiscal 2025



Development status

- ▶ **Japan pivotal study (field of gastroenterological surgery)**
 - Topline results indicating statistically significant adhesion prevention performance in the primary and secondary endpoints obtained in July 2023
 - ⇒ **Proceed with sales partner selection and construction of commercial production facilities and prepare for submitting an approval application**
- ▶ **Japan pilot study (field of gynecology)**
 - Aiming to expand range of applications
 - Confirmation of usability and safety completed
- ▶ **Proceed with development with a view to global development**

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)

Other Topics

Status of Application for Approval of SI-6603 in the United States

Background

- March 2024: Approval application submitted to the U.S. Food and Drug Administration (FDA)
- May 2024: Application accepted by FDA. Start of full-scale review response
- January 2025: Holding of Advisory Committee Meeting, an FDA examination process. SI-6603 risks and benefits discussed, and broad support for approval obtained
- March 2025: Complete Response Letter(CRL) received from FDA. SI-6603 not approved

CRL Content

- No concerns relating to the clinical study results, including efficacy and safety, expressed
- Additional observations made, mainly concerning the manufacturing facility and control of the drug substance and drug product

Future Outlook

- Respond to the CRL observations as Seikagaku's highest priority matter.
- Aim for resubmission within one year of receipt of the CRL in preparation for approval at an early date.

Progress Against the Mid-Term Management Plan in Fiscal 2024

- ◆ Due to the non-approval of SI-6603 in the US, it has become difficult to achieve the numerical targets in the plan (net sales of ¥40.0 billion, operating income of ¥7.0 billion).
- ◆ In the final year of the plan, continue implementing key measures to develop the ability to embark on the next growth trajectory.

[Major Areas of Progress in Fiscal 2024]

I Maximize the product value of SI-6603 (treatment for lumbar disc herniation)

- Biologics License Application (BLA) accepted for filing by the FDA (May 2024)
- Risks and benefits of SI-6603 discussed and broad support for approval received at an Advisory Committee Meeting, an FDA examination process (January 2025)
- CRL received from the FDA. Although no concerns relating to the clinical study results, including the efficacy and safety of SI-6603, were expressed, additional observations were made concerning the manufacturing facility and control of the drug substance (March 2025)

II Accelerate R&D utilizing unique drug-discovery technologies

- Phase III clinical studies (knee joint and hip joint) of Gel-One, a treatment for osteoarthritis, initiated in Japan (February 2025)

V Expand the LAL business through recombinant technologies

- Increased the number of countries where Fungitell (a beta-glucan-detecting in vitro diagnostic test) is sold and
- entered the hospital market
- At the milestone 50th anniversary of the founding of overseas subsidiary Associates of Cape Cod, Inc., looking ahead to the next half century, renewal of the brand identity as a solutions company that utilizes recombinant technology

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.

	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025 (forecast)
Net profit per share	¥66.32	¥40.49	¥40.08	¥22.25	¥24.74
Annual dividend per share	¥30.00*	¥26.00	¥26.00	¥30.00	¥30.00
Dividend payout ratio	45.2%	64.2%	64.9%	134.8%	121.3%

* Includes JOYCLU launch special dividend of ¥10

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