

**Exploring the Innovative Promise
of Glycoscience**

Financial Results for the 2nd Quarter of Fiscal Year 2024



SEIKAGAKU CORPORATION

(TSE : 4548)



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2Q of FY 2024 Results



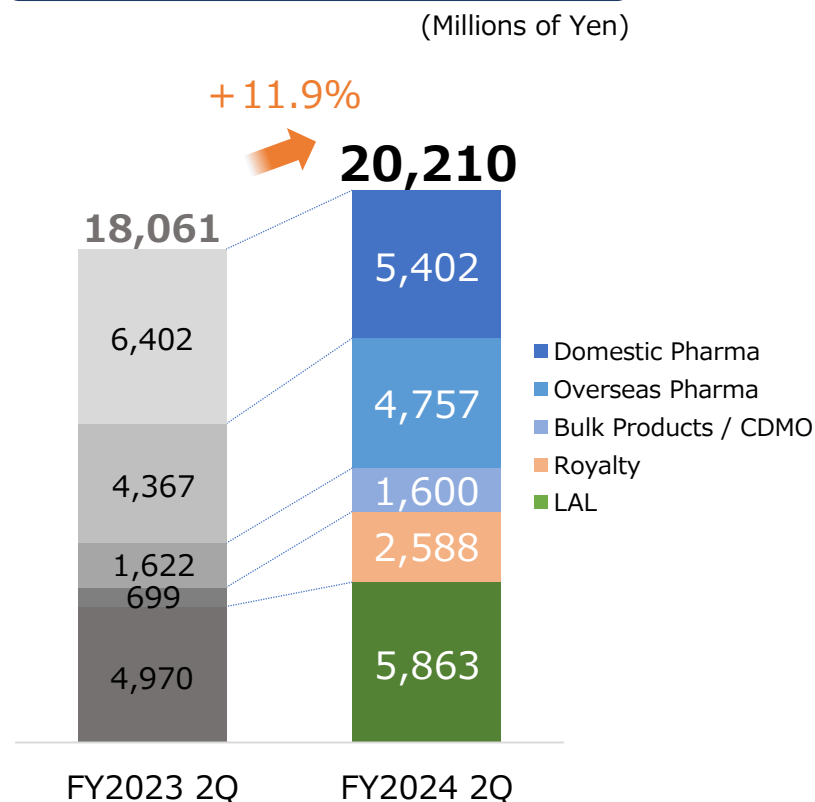
Overview for 2Q of FY 2024

- ◆ Net sales: Up 11.9% year on year on increases in royalty income and overseas sales in the LAL business
- ◆ Income: Net income attributable to owners of parent down 8.1% year on year due mainly to yen appreciation toward the end of the interim period
- ◆ Sales of overseas pharmaceuticals up 8.9% year on year, after falling 50.6% in 1Q, due mainly to higher shipments of Gel-One for the U.S. and other products, as planned

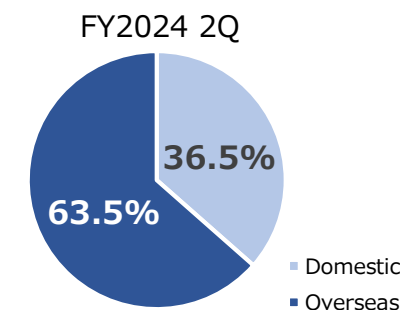
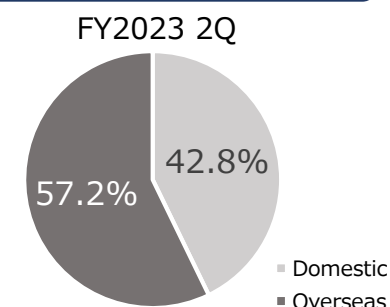
(Millions of Yen)	2Q FY2023 Results	2Q FY2024 Results	% of Change
Net Income	18,061	20,210	+11.9%
Operating Income	1,482	2,537	+71.2%
Ordinary Income	2,327	2,354	+1.2%
Net Income	2,102	1,931	△8.1%
Net Income per Share	38.54円	35.39円	—

Other Performance Indicators	FY2023 2Q	FY2024 2Q	% of Change
R&D Expenses (Millions of Yen)	3,410	3,243	△4.9%
Ratio of R&D expenses to sales (excluding royalty income)	19.6%	18.4%	△1.2%
Ave. exchange rate during the period (US\$1)	¥141.00	¥152.62	—

Net sales by Business Segment



Overseas Sales Ratio

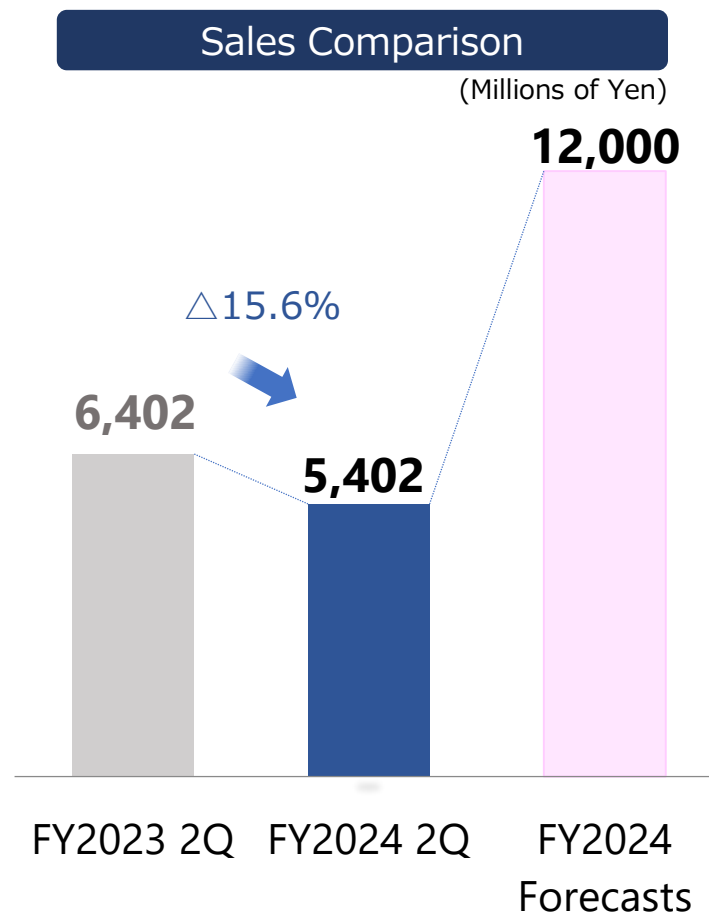


*excluding royalty income



Domestic Pharmaceuticals

- Net sales down 15.6% year on year due to lower sales of ARTZ, a joint function improvement agent for knee osteoarthritis, and the OPEGAN series of ophthalmic viscoelastic devices



ARTZ (Joint-function improving agent)

- Market share: Up on higher deliveries to medical institutions (Approx 83%*)
- Seikagaku sales: Down due to continued shipment volume adjustments accompanying facilities maintenance related to production system expansion at the Company's plant
shipment volume is expected to recover and sales are expected to develop as planned in the fourth quarter.

OPEGAN series (Ophthalmic viscoelastic devices)

- Market share: At the prior-year level because of higher deliveries to medical institutions and market growth (Approx 52%*)
- Seikagaku sales: As in 1Q, Down following a temporary increase in shipments of Seikagaku products in the prior-year first quarter due to limited shipments of competing products

Other Products (Seikagaku sales)

- Hernicore: At the prior-year level
- MucoUp: Down due to the impact of an NHI reimbursement price change
- JOYCLU: Down due to shipment timing

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

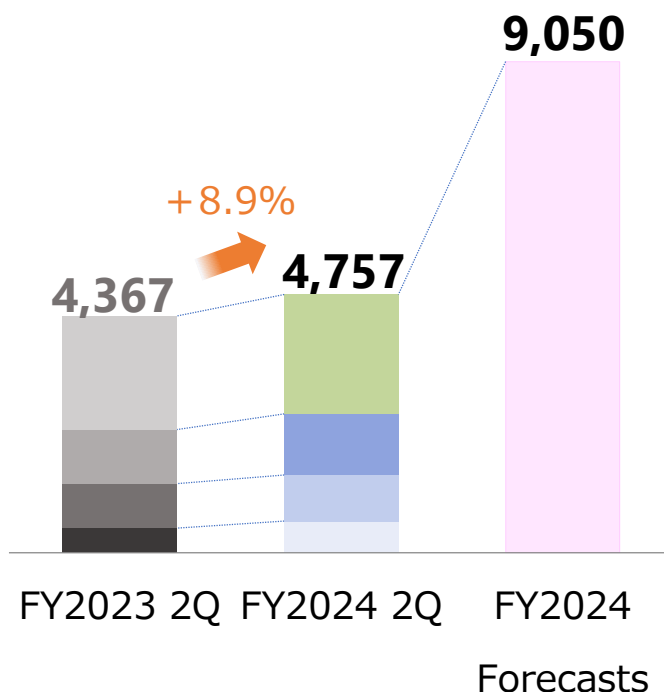


Overseas Pharmaceuticals

- Net sales up 8.9% year on year due mainly to higher sales of Gel-One and SUPARTZ FX, viscosupplements for the treatment of knee osteoarthritis for the U.S. market

Sales Comparison

(Millions of Yen)



Products for the U.S.

- ◆ Gel-One(single-injection viscosupplement)
 - Local sales volume: Sales down
 - Seikagaku sales: Up due to a rebound in shipments following a 1Q decline
- ◆ SUPARTZ FX(five-injection viscosupplement)
 - Local sales volume: At the prior-year level
 - Seikagaku sales: Up year on year, reflecting a temporary decrease in shipments in 2Q FY2023

ARTZ in China

- Local sales volume: Sales up
- Seikagaku sales: At the prior-year level, with shipments rising sharply in 2Q, as planned, following a sharp decrease in 1Q

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

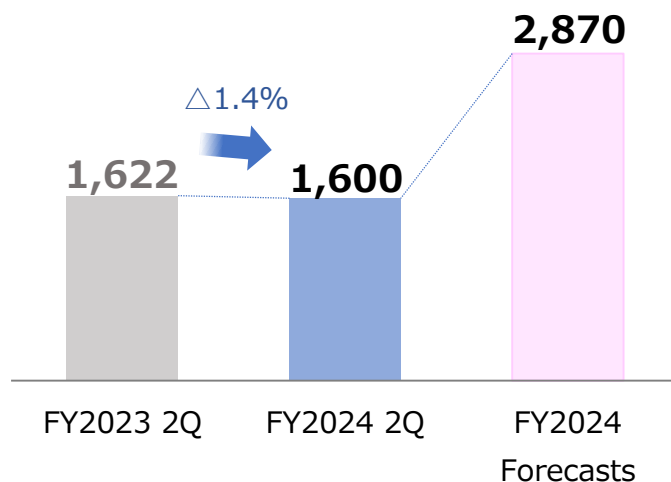
Bulk Products / CDMO

Foreign exchange impact : approx. +138million yen

- Net sales were at the prior-year level because of lower sales of bulk products and an increase in sales of contract development and manufacturing and other services of overseas subsidiary DCL*

Sales Comparison

(Millions of Yen)



* DALTON CHEMICAL LABORATORIES, INC.

Royalty

- ¥2,588 million in FY2024 (up 270.2% year on year), compared with ¥699 million in FY2023
- Full-year forecast of ¥4,550 million

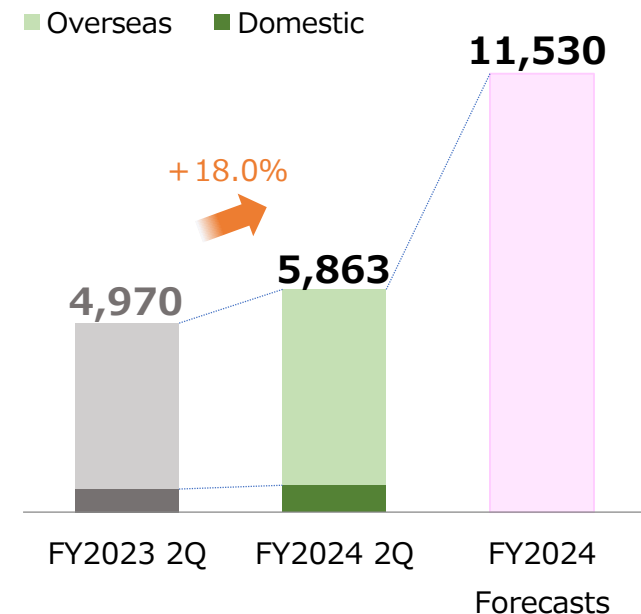
LAL Business

Foreign exchange impact : approx. +625million 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)

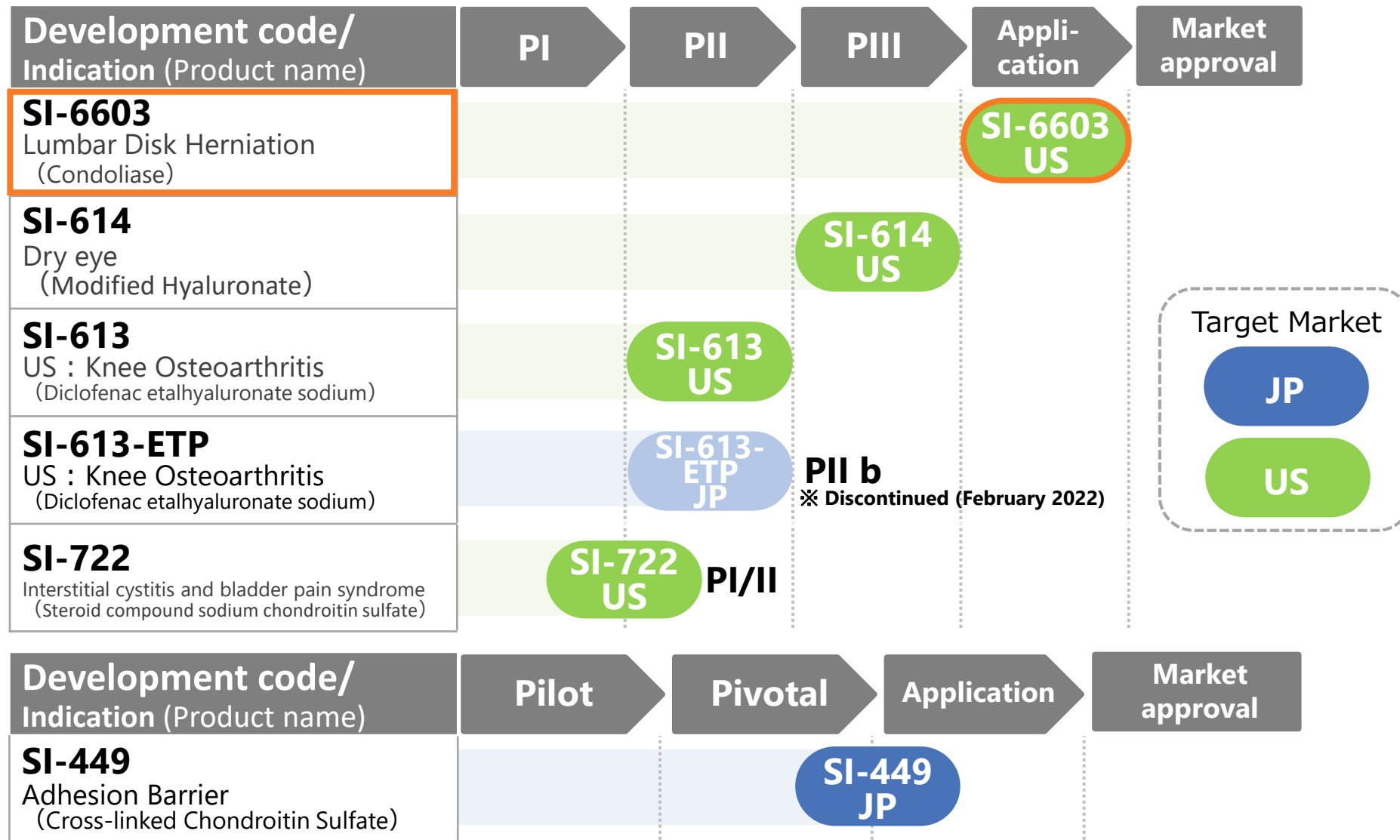


*ASSOCIATES OF CAPE COD, INC.

Research and Development



Pipeline List

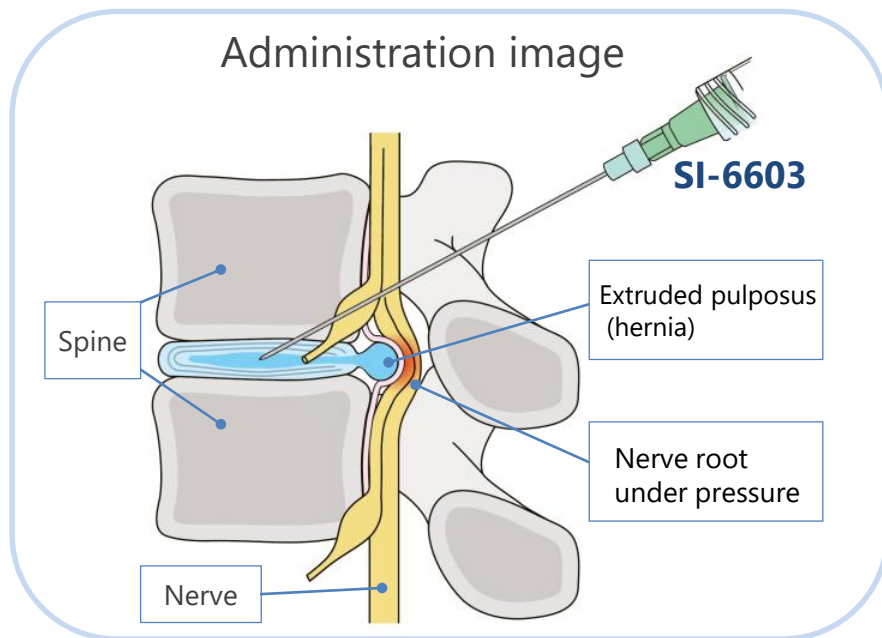


 : SI-6603 Biologics License Application accepted by the U.S. Food and Drug Administration (May 2024)



SI-6603 (Treatment for Lumbar Disc Herniation)

Biologics License Application for SI-6603 accepted by the U.S. Food and Drug Administration (FDA)
Proceed with a response to regulatory review in order to obtain approval



Development status

► NDA submission in the U.S.

- May 2024 FDA Acceptance of a Biologics License Application (BLA)
⇒ **Proceed with a response to regulatory review in order to obtain approval.**

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

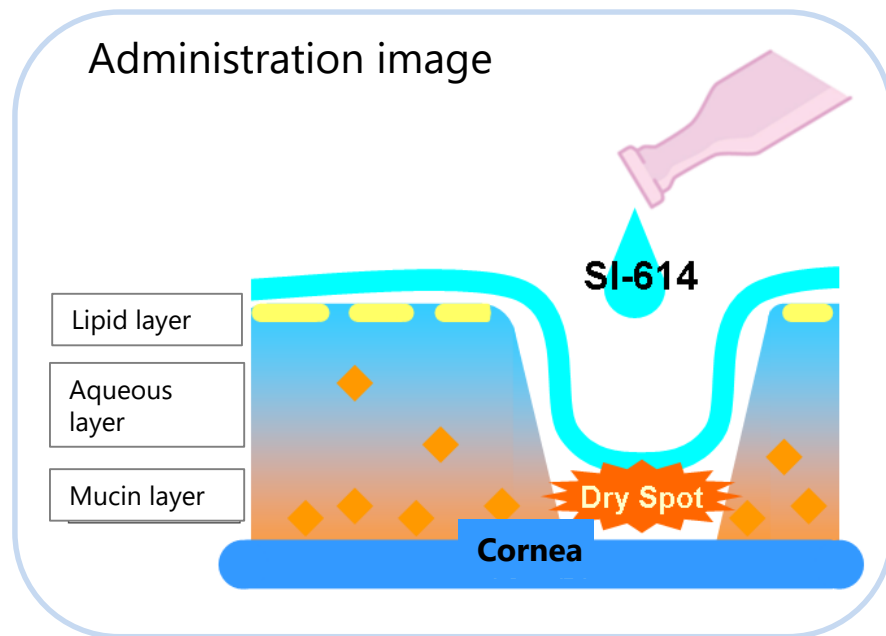
Method of use : Injection into lumbar disc (under X-ray observation)

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



SI-614 (Dry Eye)

Received the results from a Phase III study in the U.S.
Currently considering the future development policy



Development status

► Phase III study in the U.S.

- Statistically significant improvement in the primary endpoint was not observed.

⇒ Will consider the policy on future development based on the data obtained.

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>

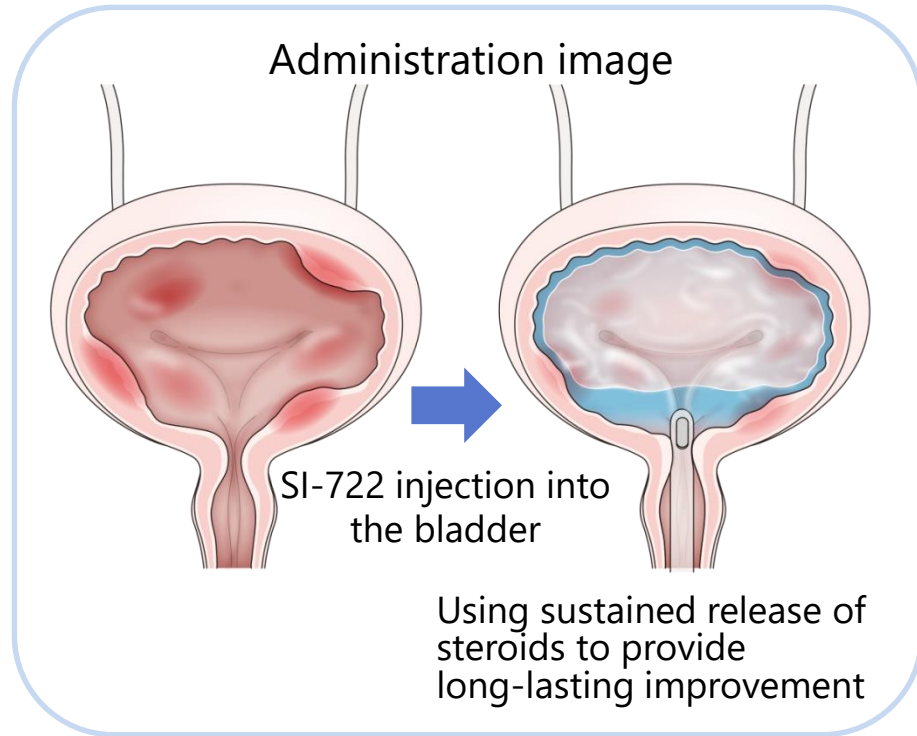
Dev. Code : SI-614 / Generic name : Modified Hyaluronate / Product name : Dry eye

Formulation : Ophthalmic solution / Estimated U.S. patients : 14 million (Seikagaku estimates)



SI-722 (Interstitial cystitis and bladder pain syndrome)

Subject enrollment for Phase I/II 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

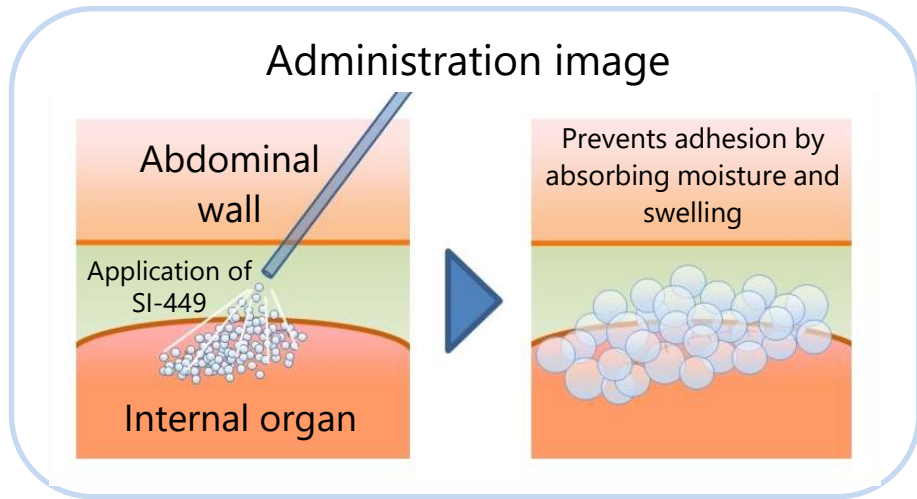
Indication : Interstitial cystitis and bladder pain syndrome / Method of use : Injection into the bladder

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



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 preparations for an NDA at an early date**

▶ 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



Approval in China of MucoUp[®], a Submucosal Injection Agent for Endoscopic Surgery

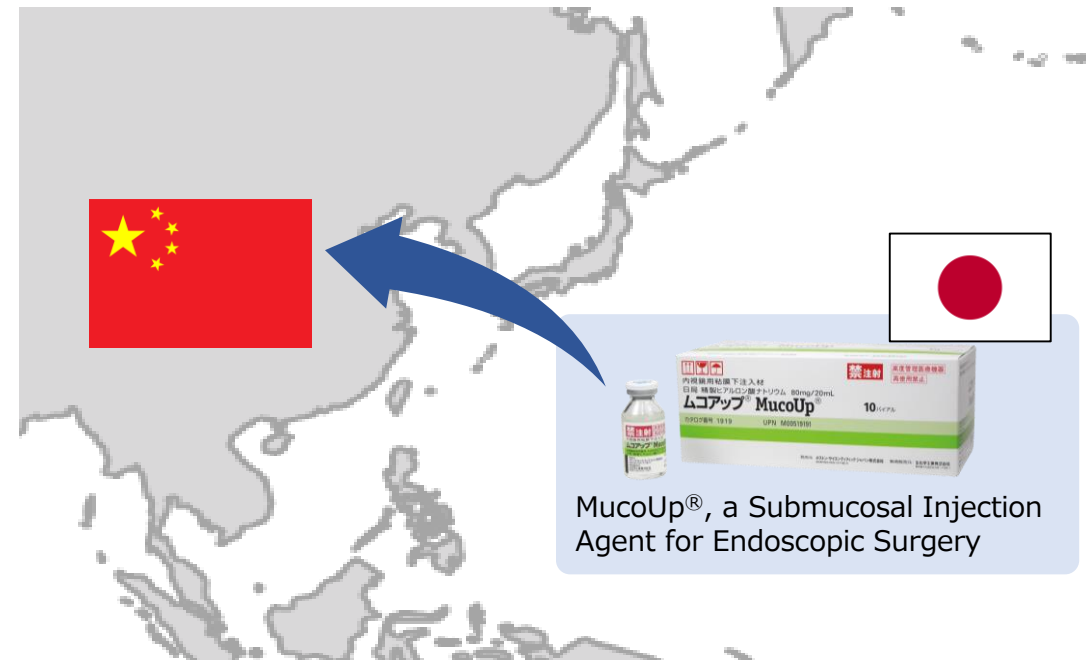
- ◆ Approval notice received from the National Medical Products Administration (“NMPA”) of China (dated Sept. 30, 2024)
- ◆ Distribution agreement for China concluded with Tozai Boeki Kaisha, Ltd.
- ◆ Launch scheduled for FY2025

MucoUp[®]

- A medical device whose main ingredient is sodium hyaluronate
- A surgical aid that improves resection and dissection operability when injected into the sub-mucosal layer of tumors during endoscopic resection of tumors in the gastrointestinal tract
- Received marketing approval in Japan in 2006 under the name MucoUp[®]

Chinese Market

- Increasing patient needs for endoscopic examination and treatment due to population aging
- Aiming to make MucoUp[®] a standard surgical aid in endoscopic therapy



Appendix

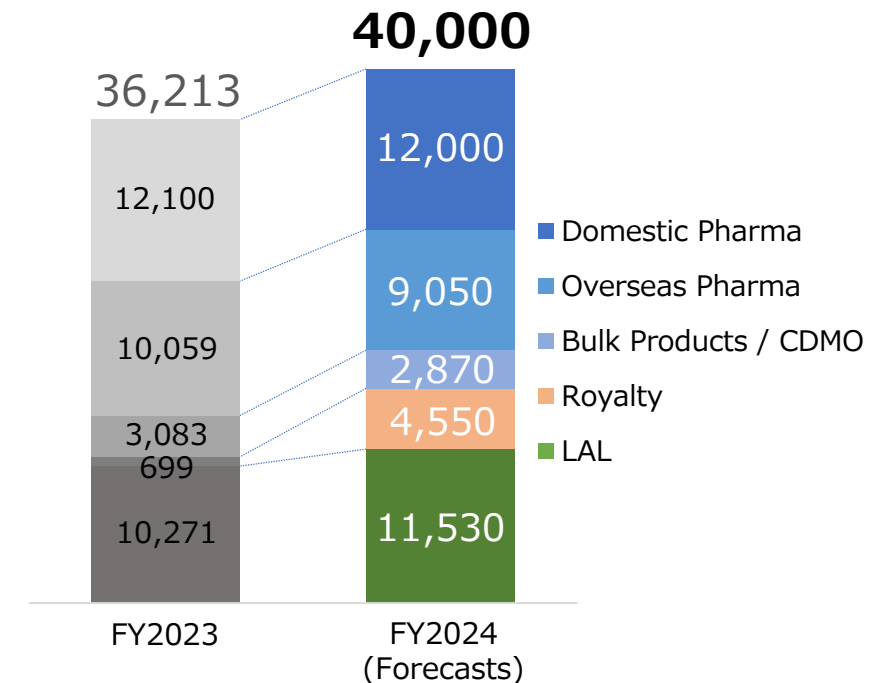


FY2024 Forecasts Overview

- ◆ **Net sales** : Projected year-on-year increase from higher royalty income
- ◆ **Operating Income** : Projected increase due to the revenue growth and lower R&D expenses
- ◆ **Ordinary Income** : Projected increase due to the revenue growth
- ◆ **Net Income** : Projected increase despite higher tax expenses

(Millions of Yen)	FY2023 Results	FY2024 Forecasts	% of Change
Net Income	36,213	40,000	+ 10.5%
Operating Income	433	3,950	+ 812.1%
Ordinary Income	1,691	4,550	+ 169.0%
Net Income	2,186	3,450	+ 57.8%
Net Income per Share	¥40.08	¥63.23	—
R&D Expenses (excluding royalty income)	7,484	6,900	△7.8%
Average Exchange Rate (1US\$)	¥144.62	¥145.00	—

Net sales by Business Segment





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.

	FY2020	FY2021	FY2022	FY2023	FY2024 (forecast)
Net profit per share	¥75.54	¥66.32	¥40.49	¥40.08	¥63.23
Annual dividend per share	¥24.00 ^{*1}	¥30.00 ^{*2}	¥26.00	¥26.00	¥30.00
Dividend payout ratio	31.8%	45.2%	64.2%	64.9%	47.4%

*1 Includes JOYCLU approval commemorative dividend of ¥4

*2 Includes JOYCLU launch special dividend of ¥10

■ 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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