

**Exploring the Innovative
Promise of Glycoscience**

Financial Results for the 3rd Quarter of Fiscal Year 2023



SEIKAGAKU CORPORATION

(TSE : 4548)



■ 3Q Results	P3	■ Research and Development	P10
● Net Sales	P3-7	● SI-6603 (Lumbar disc herniation)	P11
● Income	P8	● SI-614 (Dry Eye)	P12
● Trend in R&D Expenses	P9	● SI-722 (Interstitial cystitis and bladder pain syndrome)	P13
		● SI-449 (Adhesion Barrier)	P14
		■ Basic Policy on Profit Distribution	P15

< 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 for 3Q of FY 2023

(Millions of Yen)	3Q FY2023 Results	Year-on-Year		(Reference) FY2023 Forecasts (8 th Nov)	
		Change	% of Change	FY 2023 Forecasts	Degree of Progress
Net sales	27,384	+1,221	+4.7%	36,100	75.9%
Operating Income	2,328	-1,078	-31.6%	1,300	179.1%
Ordinary Income	3,049	-1,169	-27.7%	2,250	135.5%
Net Income for the quarter*	2,701	-927	-25.6%	2,600	103.9%
R&D Expenses (Ratio to net sales excluding royalty income)	5,098 (19.1%)	-256	-4.8%	7,550 (21.3%)	67.5%
Average Exchange Rate (1US\$)	¥143.29	+¥6.76		¥145.00	

*Net income for the quarter attributable to stocks of parent company

	3Q FY2023 Results	3Q FY2022 Results
Net Income per Share	¥49.51	¥65.42

Net sales by Business Segment (3Q of FY2023)

(Millions of Yen)	3Q FY2023 Results	Year-on-Year	% of Change
Net sales	27,384	+1,221	+4.7%
Pharmaceuticals	19,727	+1,773	+9.9%
Domestic Pharmaceuticals	9,020	+170	+1.9%
Overseas Pharmaceuticals	7,533	+610	+8.8%
Bulk Products /CDMO	2,474	+295	+13.6%
Royalty Income	699	+697	—
LAL Business	7,657	-552	-6.7%
(Overseas sales)	16,817	+1,137	+7.3%

Domestic Pharmaceuticals

▶ ARTZ (Joint-function improving agent)

- Seikagaku sales up on higher shipment volume, despite the impact of NHI drug price reductions
- Deliveries to medical institutions up thanks to switching from competing products (+8.7%), and market share up (+6.8pt)
- Slight market contraction (-1.7%)

▶ JOYCLU (Joint-function improving agent)

- Sales down because of a shipping schedule adjustment
- Clinical research to identify the cause of side effects conducted. Going forward, analysis of data obtained from the research and consideration of proposals that will lead to correct use

* Foreign exchange impact on overall net sales :
approx. +1,080million yen

Net sales by Business Segment (3Q of FY2023)

(Millions of Yen)	3Q FY2023 Results	Year-on-Year	% of Change
Net sales	27,384	+1,221	+4.7%
Pharmaceuticals	19,727	+1,773	+9.9%
Domestic Pharmaceuticals	9,020	+170	+1.9%
Overseas Pharmaceuticals	7,533	+610	+8.8%
Bulk Products /CDMO	2,474	+295	+13.6%
Royalty Income	699	+697	—
LAL Business	7,657	-552	-6.7%
(Overseas sales)	16,817	+1,137	+7.3%

* Foreign exchange impact on overall net sales :
approx. +1,080million yen

Domestic Pharmaceuticals

► OPEGAN series (Ophthalmic viscoelastic devices)

- Seikagaku sales up on higher shipments, despite the impact of NHI drug price reductions
- Despite higher deliveries to medical institutions (+5.1%), due to the impact of limited shipments of competing products, market share at the prior-year level (+0.2%)
- Market growth trend accompanying population aging (+4.9%)

► MucoUp

(Submucosal injection agent for endoscopic surgery)

- Sales up, reflecting a sales partner inventory adjustment

► HERNICORE (Treatment for lumbar disc herniation)

- Sales down due to a decrease in deliveries to medical institutions



Net sales by Business Segment (3Q of FY2023)

(Millions of Yen)	3Q FY2023 Results	Year-on-Year	% of Change
Net sales	27,384	+1,221	+4.7%
Pharmaceuticals	19,727	+1,773	+9.9%
Domestic Pharmaceuticals	9,020	+170	+1.9%
Overseas Pharmaceuticals	7,533	+610	+8.8%
Bulk Products /CDMO	2,474	+295	+13.6%
Royalty Income	699	+697	—
LAL Business	7,657	-552	-6.7%
(Overseas sales)	16,817	+1,137	+7.3%

* Foreign exchange impact on overall net sales : approx. +1,080million yen

Overseas Pharmaceuticals

*Foreign exchange impact on Overseas Pharmaceuticals: approx. +510million yen

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

- Local sales volume and Seikagaku sales down, despite a gradual trend toward recovery from the impact of an insurance reimbursement system change



Gel-One: Single-injection joint function improving agent

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

- Local sales volume up thanks to greater preference for products with stable, low prices and little price fluctuation accompanying an insurance reimbursement system change
- Sales up due to a shipping schedule adjustment and yen depreciation

► ARTZ in China (Multiple injection)

- Local sales volume up, reflecting a rebound in the patient consultation rate following a decline in FY22 3Q
- Sales up sharply because there were no shipments in the prior-year first quarter and local sales volume growth

Net sales by Business Segment (3Q of FY2023)

(Millions of Yen)	3Q FY2023 Results	Year-on-Year	% of Change
Net sales	27,384	+1,221	+4.7%
Pharmaceuticals	19,727	+1,773	+9.9%
Domestic Pharmaceuticals	9,020	+170	+1.9%
Overseas Pharmaceuticals	7,533	+610	+8.8%
Bulk Products /CDMO	2,474	+295	+13.6%
Royalty Income	699	+697	—
LAL Business	7,657	-552	-6.7%
(Overseas sales)	16,817	+1,137	+7.3%

Bulk Products / CDMO

- Seikagaku sales up on higher sales of bulk products, contract development and manufacturing and other services at Dalton, and yen depreciation

*Foreign exchange impact on Bulk Products/CDMO: approx. +50million yen

Royalty Income

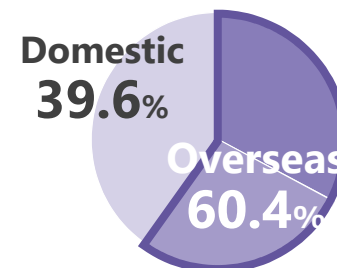
- Royalty income up (+697)

LAL Business

- Domestic sales at the prior-year level, but overall sales down because COVID-related special demand at ACC subsided

*Foreign exchange impact on LAL Business: approx. 520 million yen

Overseas Sales Ratio(excluding royalty income)



Year-on-Year
+0.5pt

* Foreign exchange impact on overall net sales : approx. +1,080million yen

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



Income for 3Q of FY2023 (Year-on-Year)

(Millions of Yen)	3Q FY2023 Results	Year-on- Year	% of Change
Net sales	27,384	+1,221	+4.7%
Cost of Sales (excluding royalty income)	13,279 (49.8%)	1,726 (+5.6pt)	+14.9%
SGA expenses	11,776	+572	+5.1%
R&D Expenses (excluding royalty income)	5,098 (19.1%)	-256 (-1.4pt)	-4.8%
Operating Income (to Net sales ratio)	2,328 (8.5%)	-1,078 (-4.5pt)	-31.6%
Ordinary Income	3,049	-1,169	-27.7%
Net Income for the quarter*	2,701	-927	-25.6%
Depreciation	1,194	+256	+27.3%

Operating Income **2,328 (-1,078)**

Cost of sales ratio (+5.6 pt)

- Cost of sales ratio up because of change in the sales mix and higher expenses

SGA Expenses (+572)

- Higher expenses at overseas subsidiaries, including foreign currency translation

Ordinary Income **3,049 (-1,169)**

Non-operating Income / Expenses (-90)

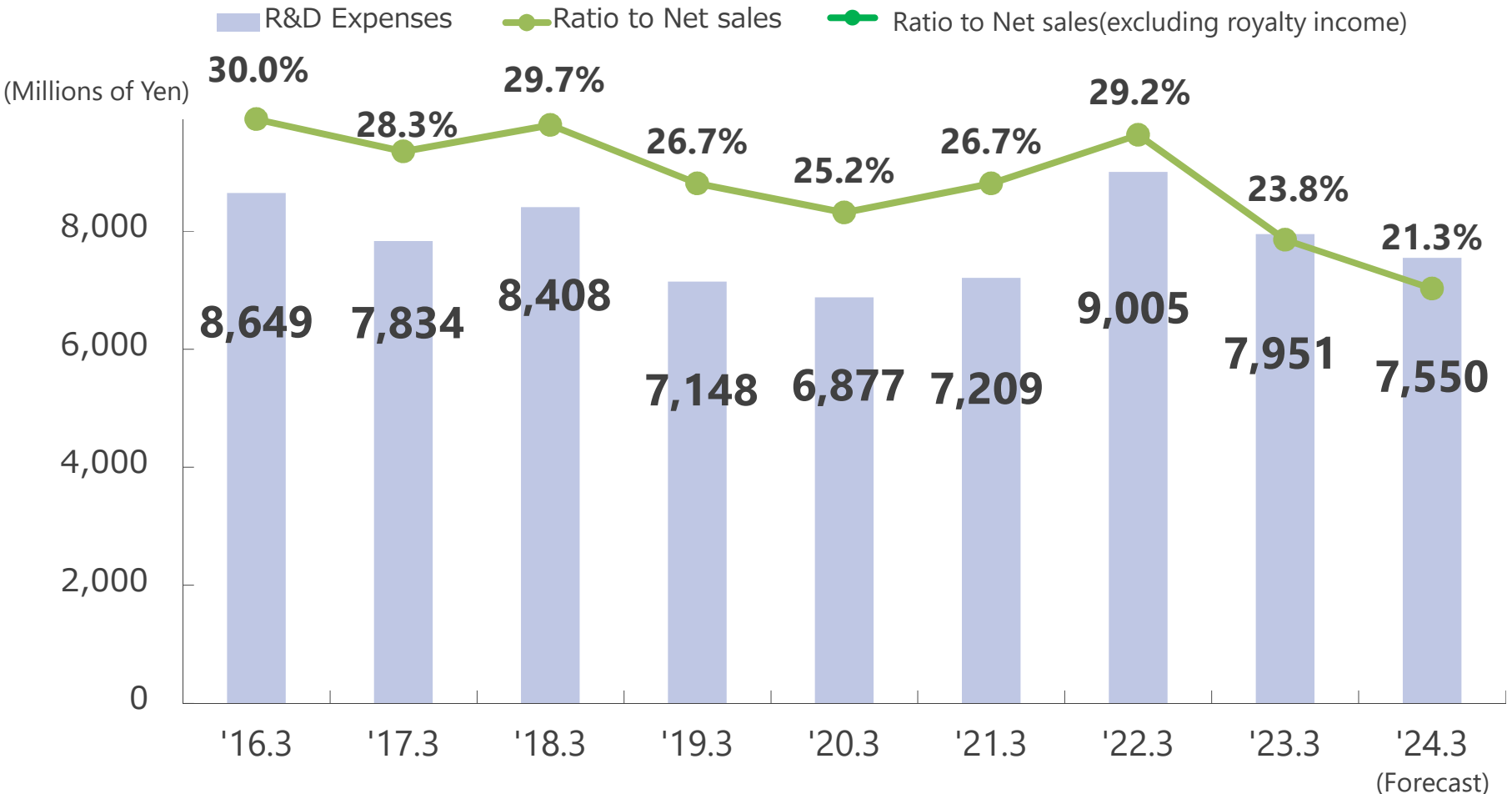
- Decrease in foreign exchange gain (-160)

*Net income for the quarter attributable to stocks of parent company



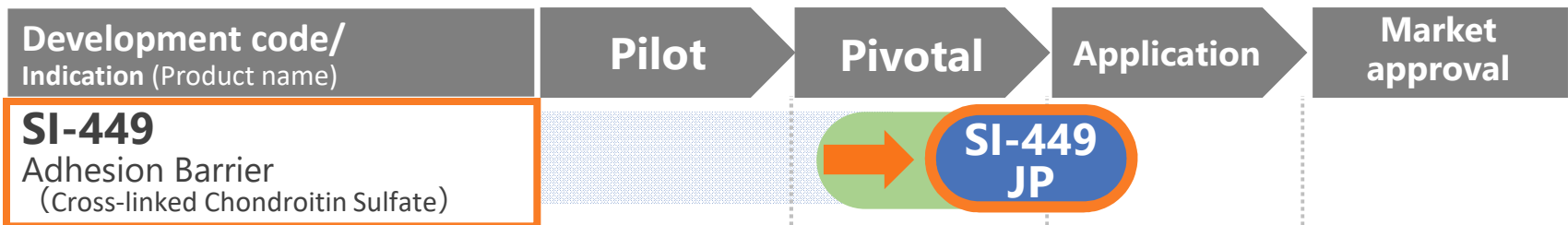
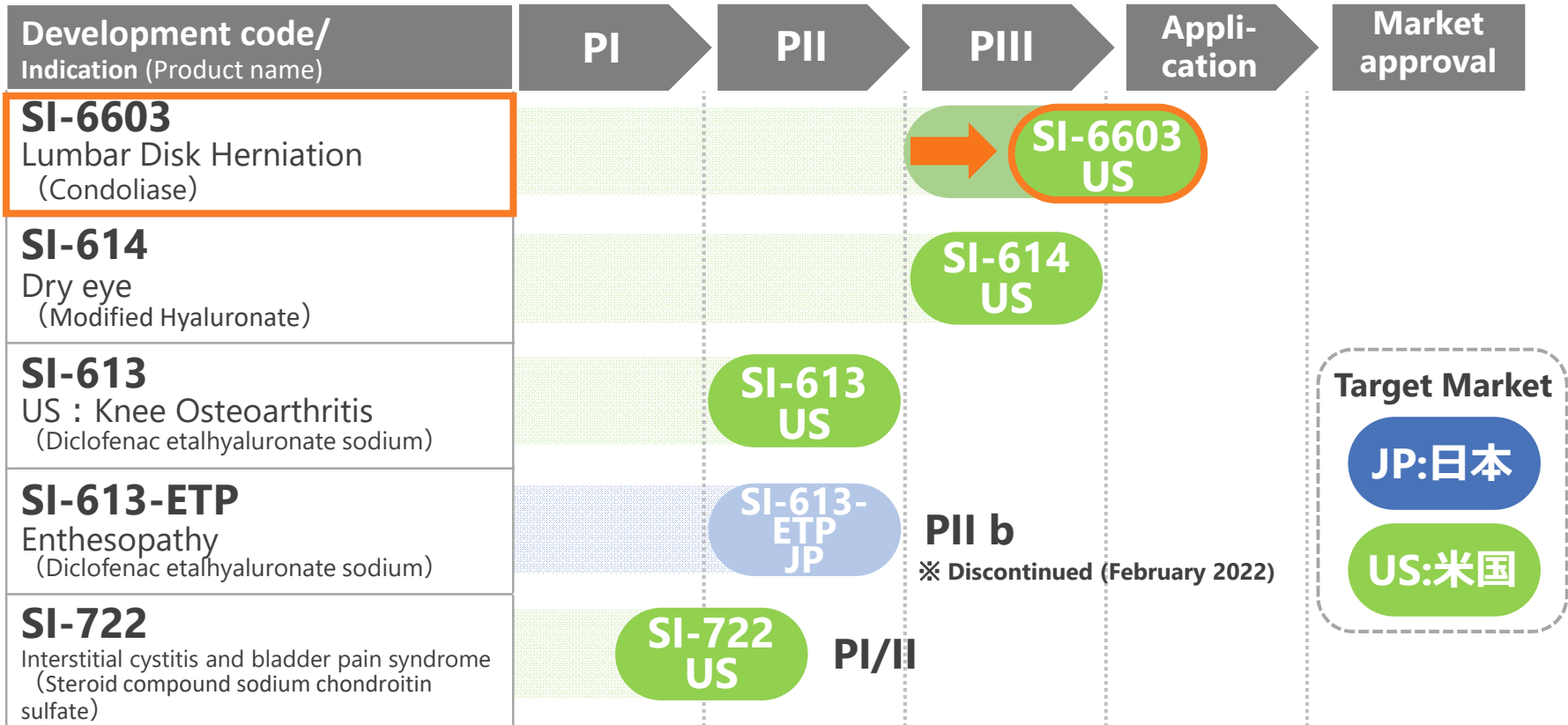
Trend in R&D Expenses


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





Pipeline List



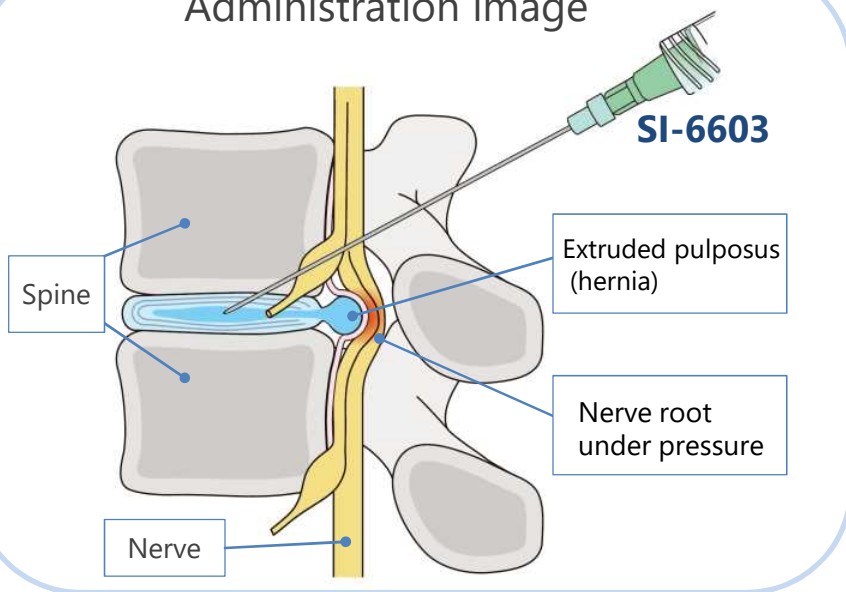
 : The primary endpoints were achieved in an additional PIII study of SI-6603 in the U.S. and a pivotal study of SI-449 in Japan, and preparations for NDAs are underway.



SI-6603 (Treatment for Lumbar Disc Herniation)

Received the results from a Phase III study in the U.S.
Proceed with preparations for an application for approval

Administration image



Development status

- ▶ Phase III additional study in the U.S.
 - Topline results indicating statistically significant improvement in the primary endpoint obtained in May 2023
- ⇒ Proceed with preparations for an application for approval at an early date

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

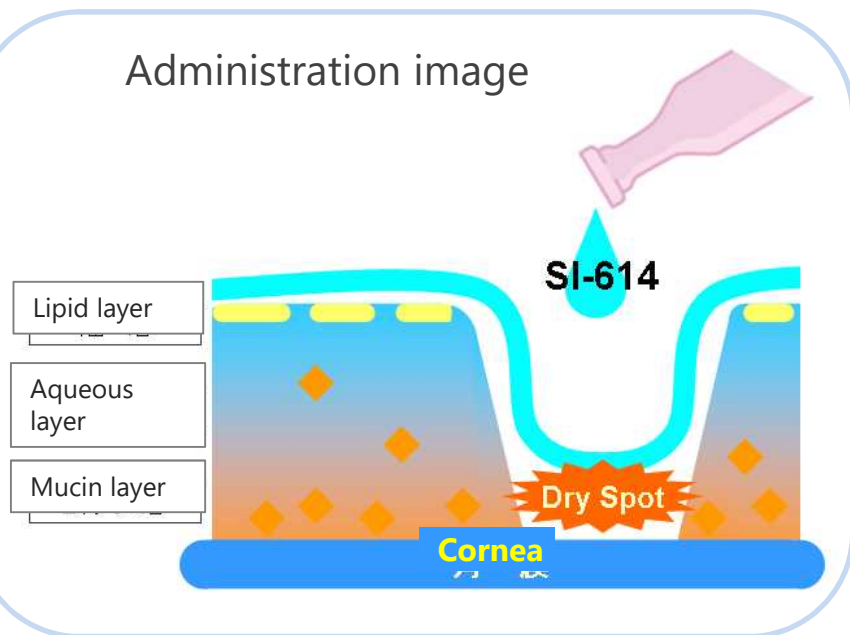
Method of use : Injection into lumbar disc (under X-ray observation)

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



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

Administration image



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

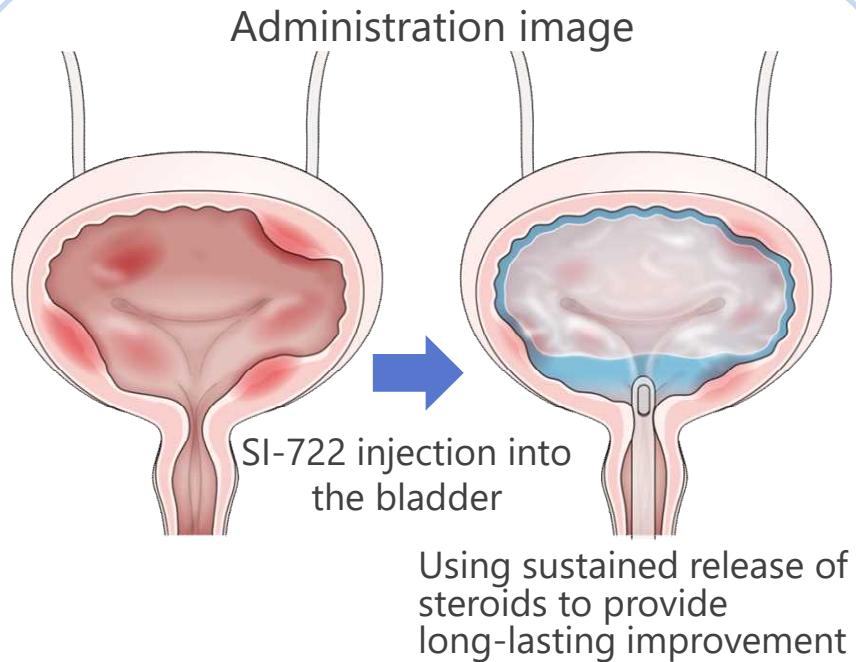
- ▶ SI-614 Improves symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing
- ▶ Dry Eye is a multifactorial disease, and Seikagaku aims to provide a treatment option based on a new mechanism unavailable from existing products

<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

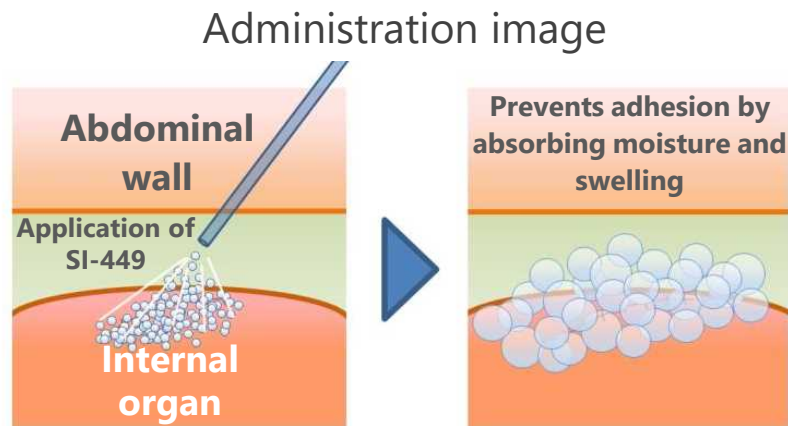
Indication : Interstitial cystitis and bladder pain syndrome

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



Expected Features

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

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; Start of U.S. study under review

<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)



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.

	FY2019	FY2020	FY2021	FY2022	FY2023 (forecast)
Net profit per share	-¥192.15	¥75.54	¥66.32	¥40.49	¥47.66
Annual dividend per share	¥26.00	¥24.00 ^{*1}	¥30.00 ^{*2}	¥26.00	¥26.00
Dividend payout ratio	—	31.8%	45.2%	64.2%	54.6%

*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.



SEIKAGAKU CORPORATION

(TSE : 4548)