

**Exploring the Innovative
Promise of Glycoscience**

Financial Results for the 2nd Quarter of Fiscal Year 2023



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 for 2Q of FY 2023

(Millions of Yen)	2Q FY2023 Results	Year-on-Year		(Reference) FY2023 Full Year Forecasts	
		Change	% of Change	FY 2023 Forecasts	Degree of Progress
Net sales	18,061	+803	+4.7%	36,100	50.0%
Operating Income	1,482	-1,128	-43.2%	1,300	114.0%
Ordinary Income	2,327	-1,273	-35.4%	2,250	103.4%
Net Income	2,102	-1,039	-33.1%	2,600	80.9%
R&D Expenses (Ratio to net sales excluding royalty income)	3,410 (19.6%)	+3	+0.1%	7,550 (21.3%)	45.2%
Average Exchange Rate (1US\$)	¥141.00	+¥7.02		¥145.00	

	2Q FY2023 Results	2Q FY2022 Results	(Reference) FY2023 Forecasts
Net Income per Share	¥38.54	¥56.32	¥47.66

Net sales by Business Segment (2Q of FY2023)

(Millions of Yen)	2Q FY2023 Results	Year-on-Year	% of Change
Net sales	18,061	+803	+4.7%
Pharmaceuticals	13,091	+1,399	+12.0%
Domestic Pharmaceuticals	6,402	+594	+10.2%
Overseas Pharmaceuticals	4,367	-17	-0.4%
Bulk Products /CDMO	1,622	+124	+8.3%
Royalty Income	699	+697	—
LAL Business	4,970	-595	-10.7%
(Overseas sales)	10,628	+274	+2.7%

* Foreign exchange impact on overall net sales :
approx. +760million yen

Domestic Pharmaceuticals

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

- Sales up due to an increase in deliveries to medical institutions, which offset NHI drug price reductions

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

- Sales down because of a shipping schedule adjustment

▶ **OPEGAN series** (Ophthalmic viscoelastic devices)

- Sales up due to market growth and higher shipment volume, despite the impact of NHI drug price reductions

▶ **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 (2Q of FY2023)

(Millions of Yen)	2Q FY2023 Results	Year-on-Year	% of Change
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* Foreign exchange impact on overall net sales :
approx. +760million yen

Overseas Pharmaceuticals

*Foreign exchange impact on Overseas Pharmaceuticals:
approx. +320million yen

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

- Sales down due to the impact of an insurance reimbursement system change



Gel-One: Single-injection joint function improving agent

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

- Sales up on higher local sales volumes, reflecting a changing market environment associated with the insurance reimbursement system change, coupled with yen depreciation

► ARTZ in China (Multiple injection)

- Sales up sharply on higher local sales volumes due to a rebound in the patient consultation rate following a decline in 1H FY2022 as well as a complete absence of shipments in 1Q FY2022

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Bulk Products / CDMO

- Sales up on bulk products growth and the positive impact of yen depreciation on Dalton's contract development, manufacturing and other services

*Foreign exchange impact on Bulk Products/CDMO: approx. +40million yen

Royalty Income

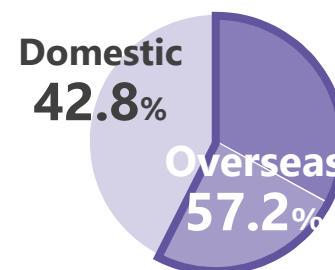
- Royalty income up

LAL Business

- Sales down on lower sales in Japan and the subsiding of COVID-related special demand at ACC

*Foreign exchange impact on LAL Business: approx. 400 million yen

Overseas Sales Ratio(excluding royalty income)



Year-on-Year
-2.8pt

* Foreign exchange impact on overall net sales : approx. +760million yen

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



Income for 2Q of FY2023 (Year-on-Year)

(Millions of Yen)	2Q FY2023 Results	Year-on- Year	% of Change
Net sales	18,061	+803	+4.7%
Cost of Sales (excluding royalty income)	8,869 (51.1%)	1,442 (+8.1pt)	+19.4%
SGA expenses	7,709	+489	+6.8%
R&D Expenses (excluding royalty income)	3,410 (19.6%)	+3 (-0.1pt)	+0.1%
Operating Income (to Net sales ratio)	1,482 (8.2%)	-1,128 (-6.9pt)	-43.2%
Ordinary Income	2,327	-1,273	-35.4%
Net Income	2,102	-1,039	-33.1%
Depreciation	771	+161	+26.4%

Operating Income **1,482 (-1,128)**

Cost of sales ratio (+8.1pt)

- Cost of sales ratio up because of change in the sales mix and soaring fuel costs

SGA Expenses (+489)

- Higher expenses at overseas subsidiaries, including foreign currency translation

Ordinary Income **2,327(-1,273)**

Non-operating Income / Expenses (-145)

- Decrease in foreign exchange gain (-191)



Revised Forecasts in FY2023

(Millions of Yen)	FY2023 Revised Forecasts	Initial Forecasts		FY2022 Results		(Reference) Degree of 2Q Progress
		Change	% of Change	Change	% of Change	
Net sales	36,100	+3,550	+10.9%	+2,643	+7.9%	50.0%
Operating Income	1,300	+1,200	—	-814	-38.5%	114.0%
Ordinary Income	2,250	+700	+45.2%	-819	-26.7%	103.4%
Net Income	2,600	+1,150	+79.3%	+363	+16.2%	80.9%
R&D Expenses (Ratio to net sales excluding royalty income)	7,550 (21.3%)	+350 (-1.3pt)	+4.9%	-401 (-2.5pt)	-5.1%	45.2%
Average Exchange Rate (1US\$)	3Q forecast ¥145.00	+ ¥15.00		—		

	FY2023 Revised Forecasts	FY2023 Initial Forecasts	FY2022 Results
Net Income per share	¥47.66	¥26.59	¥40.49
Dividend per share	¥26.00	¥26.00	¥26.00
Dividend Payout ratio	54.6%	97.8%	64.2%

Exchange Rate Sensitivity (Impact of a change of ¥1 against the US\$)	
Net sales (second half)	Approx. ¥55 million
Operating income (second half)	Approx. ¥25 million

Revised Net Sales in FY2023 (Comparison with the initial forecast)

(Millions of Yen)	FY2023 Revised Forecasts	Initial Forecasts	
		Change	% of Change
Net sales	36,100	+3,550	+10.9%
-Pharmaceuticals	25,800	+3,250	+14.4%
-LAL Business	10,300	+300	+3.0%
Operating Income (Ratio to net sales)	1,300 (3.6%)	+1,200 (+3.3pt)	—
Ordinary Income	2,250	+700	+45.2%
Net Income	2,600	+1,150	+79.3%
Cost of Sales ratio	51.6%	-0.6pt	
R&D Expenses (Ratio to net sales excluding royalty income)	7,550 (21.3%)	+350 (-1.3pt)	+4.9%
Depreciation	1,750	+50	+2.9%

Net sales and income forecasts revised upward due to higher revenue from the pharmaceuticals business and yen depreciation

Net sales +3,550

Greater-than-expected growth from ARTZ in China and domestic pharmaceuticals and the impact of yen depreciation

* Foreign exchange impact on overall net sales : approx. 1,430million yen

Operating Income +1,200

Revenue increase to meet rising SGA expenses, including higher expenses at overseas subsidiaries due to yen appreciation

Ordinary Income +700

Increase in foreign exchange gain and a review of gain on sales of investment securities

Income +1,150

Decrease in income taxes due to lower profits at overseas subsidiaries



Trend in R&D Expenses

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

R&D Expenses Ratio to Net sales Ratio to Net sales(excluding royalty income)

30.0%

28.3%

29.7%

26.7%

25.2%

26.7%

29.2%

23.8%

21.3%

8,649

7,834

8,408

7,148

6,877

7,209

9,005

7,951

7,550

'16.3

'17.3

'18.3

'19.3

'20.3

'21.3

'22.3

'23.3

'24.3

(Forecast)

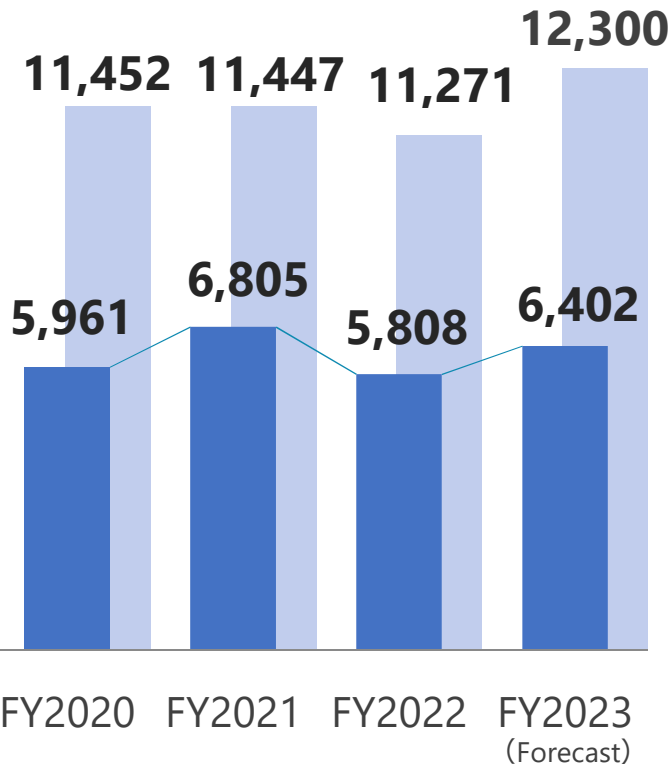


Domestic Pharmaceuticals (Year-on-Year)

Domestic Pharmaceuticals Sales trend

(Millions of Yen)

<Breakdown> ■ Full year ■ 2Q



2Q FY2023 Results

+10.2%
(Sales)

Sales up, with higher volume due to switching from competitors of ARTZ and OPEGAN offsetting NHI drug price reductions

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

Market (-2.9%)

- Contraction of the joint-function improving agent market

ARTZ (+6.6%)

- Volume and market share expansion due to successful measures to promote switching from competing products (69.8%/+6.1 pt)

JOYCLU

- Clinical research to identify cause of side effects. Analysis of the data and continuous consideration of proposals that will lead to correct use

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market (+5.0%)

- Market growth trend accompanying population aging

OPEGAN series (+5.6%)

- Volume growth due to market expansion and the impact of limited shipment of competing products
- Market share at the prior-year level (52.0%/+0.3 pt)

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

HERNICORE

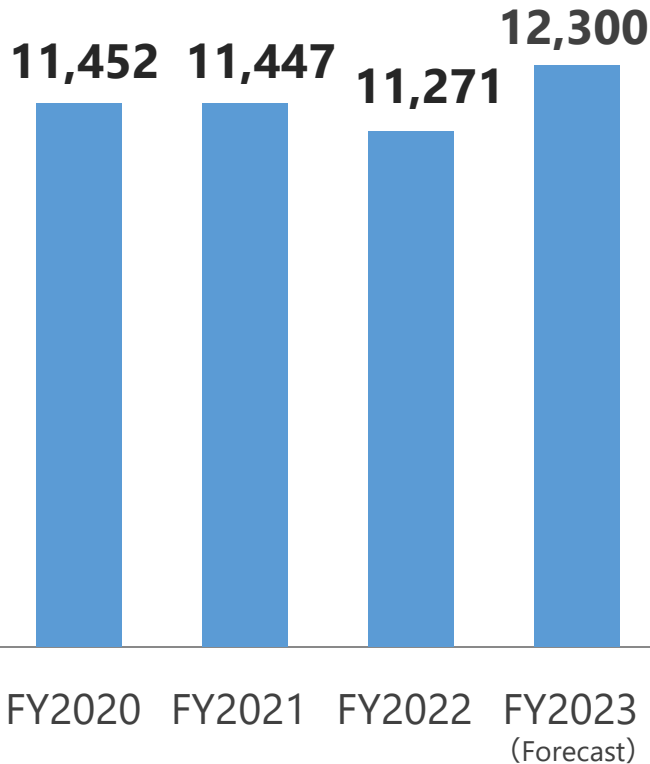
- Deliveries to medical institutions down, reflecting a sales partner inventory adjustment



Domestic Pharmaceuticals (FY2023 Forecast Year-on-Year)

Domestic Pharmaceuticals Sales trend

■ Full year (Millions of Yen)



FY2024 Forecast

+ 9.1%
(Sales)

Projected sales increase, with higher volume of ARTZ and OPEGAN offsetting NHI drug price reductions

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

Market

- Joint-function improving agent market contraction trend

ARTZ

- Upward revision due to switching from competing products

JOYCLU

- Volume projected to be at the prior-year level
- Information provision efforts to ensure appropriate use

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market

- Market growth trend accompanying population aging

OPEGAN series

- Upward revision because of volume growth due to market expansion and the impact of limited shipment of competing products

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

HERNICORE

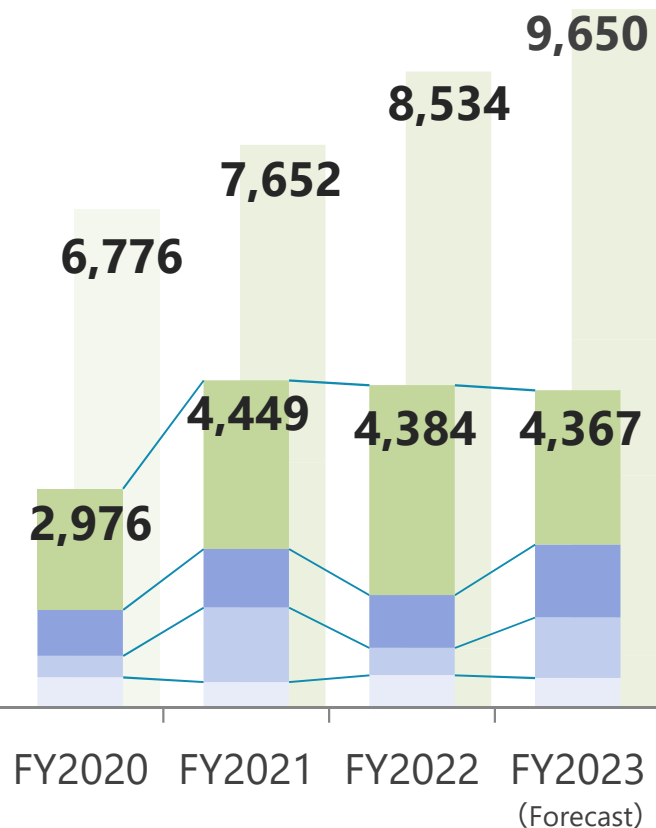
- Volume projected to be at the prior-year level
- Continuation of promotion of correct use and patient awareness activities

Overseas Pharmaceuticals (Year-on-Year)

Overseas Pharmaceuticals Sales trend

(Millions of Yen)

- Full year
<Breakdown>
- Gel-One in the U.S
 - ARTZ in China
 - SUPARTZ FX in U.S
 - Others



2Q FY2023 Results

-0.4 %

(Sales)

Sales at the prior-year level, with shipments of ARTZ to China and the impact of yen depreciation offsetting lower sales of Gel-One

* Foreign exchange impact: approx. + 320million

U.S. (Value basis)

Market in the U.S.

Insurance reimbursement system change in effect since July 2022

Gel-One

Local sales and Seikagaku sales: Decrease due to the impact of the system change

SUPARTZ FX

Local sales: Sales increase, reflecting a changing market environment associated with the system change
Seikagaku sales: Increase due to adjusted shipping schedule and yen depreciation

China, Other Regions. (Value basis)

Market in China

Trend toward relaxation of COVID-19 lockdowns in major cities

ARTZ in China

Local sales: Increase on rebound in the patient consultation rate following a decline in 1H FY2022 due to lockdowns
Seikagaku sales: Sharp increase following a curtailment of shipments in 1Q FY2022 due to a packaging material change

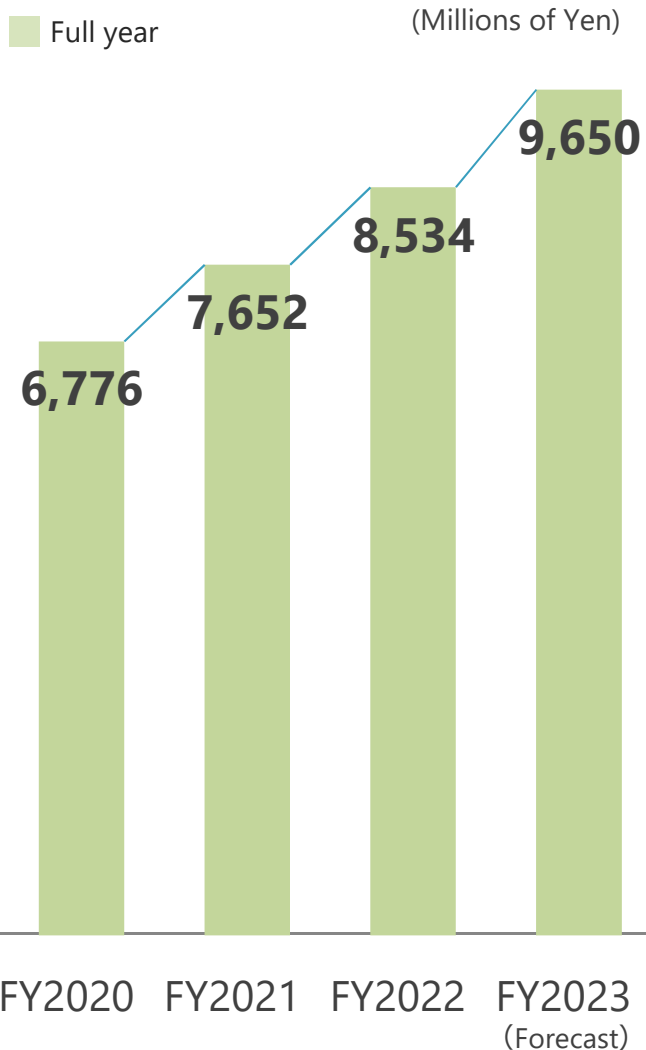
Other Regions

Seikagaku sales: Increase from HyLink in Taiwan



Overseas Pharmaceuticals (FY2023 Forecast Year-on-Year)

Overseas Pharmaceuticals Sales trend



FY2024 Forecast

+13.1%
(Sales)

Projected sales increase due to volume growth from ARTZ in China and SUPARTZ FX and the impact of yen appreciation

* Foreign exchange impact: approx. +630million

U.S. (Value basis)

Market in the U.S.

Projected impact from the insurance reimbursement system change

Gel-One

Local sales: Decrease due to the impact of the system change

Seikagaku sales: Upward revision on shipment adjustments and yen depreciation

SUPARTZ FX

Local sales: Increase due to greater preference for low-priced products because of the system change

Seikagaku sales: Upward revision on shipment adjustments and yen depreciation

China, Other Regions. (Value basis)

Market in China

Projected recovery from the impact of COVID-19

ARTZ in China

Local sales: Sharp increase due to a rebound from COVID-19 lockdowns and expansion of local inventory

Seikagaku sales: Upward revision on shipment adjustments accompanying a packaging material change

Other Regions

Seikagaku sales: Upward revision due to a projected increase from HyLink in Taiwan

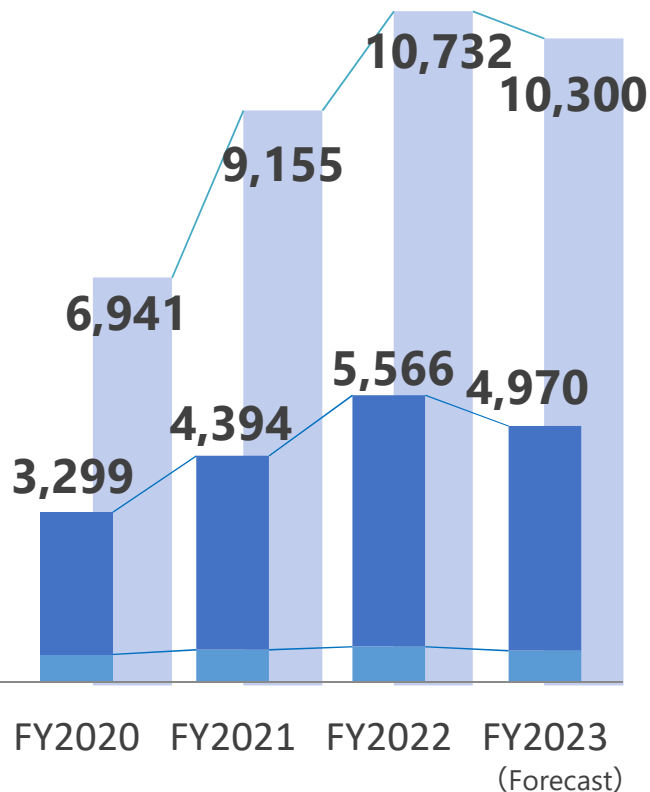
Sales of LAL Business (year-on-year / value basis)

LAL Business Sales trend

(Millions of Yen)

Full year
<Breakdown>

Overseas Domestic



2Q FY2023 Results : -10.7% (Year-on-Year)

* Foreign exchange impact: approx. + 400million

Overseas

Subsiding of special demand at overseas subsidiary ACC associated with the spread of COVID-19

Domestic

Decline due to non-recurrence of a large equipment sale recorded in 2Q FY2022

FY2024 Forecasts : -4.0% (Year-on-Year)

* Foreign exchange impact: approx. + 570million

Overseas

Subsiding of special demand associated with the spread of COVID-19

Domestic

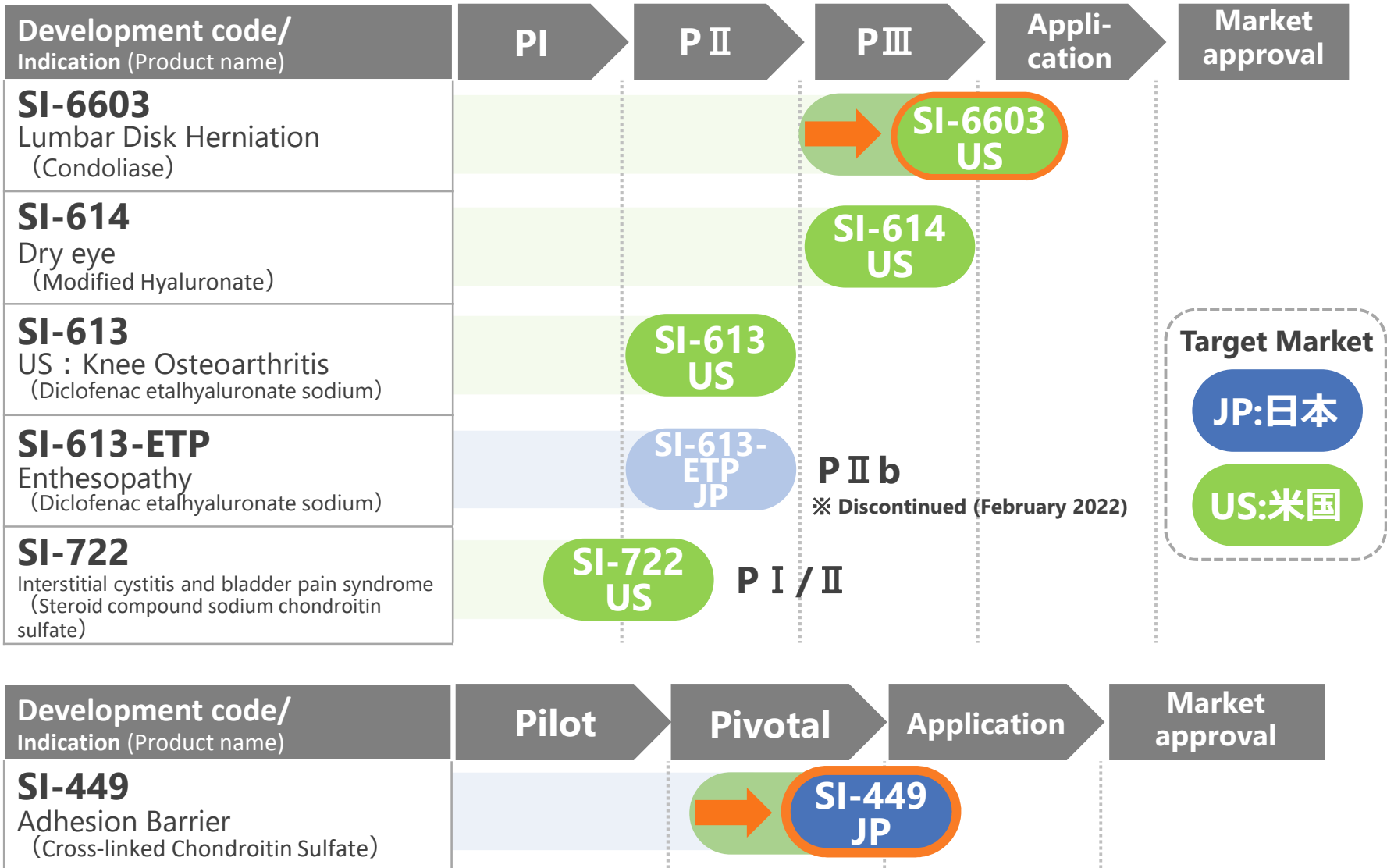
Forecast of sales at the prior-year level

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)



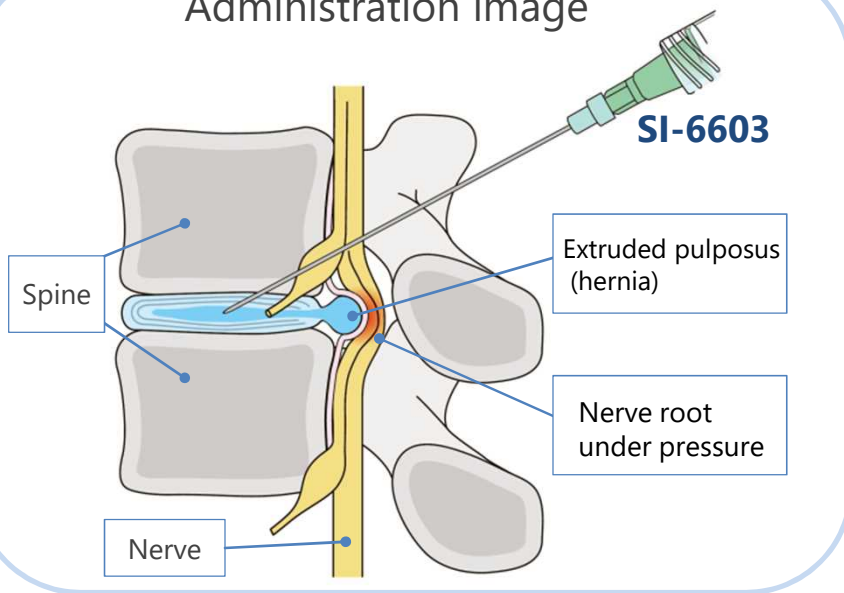
Pipeline List



SI-6603 (Treatment for Lumbar Disc Herniation)

Obtained results indicating statistically significant improvement in the primary endpoint

Administration image



Development status

- ▶ **U.S. Phase III** : Starting February 2018
 - Follow-up observation completed in March 2023
 - **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

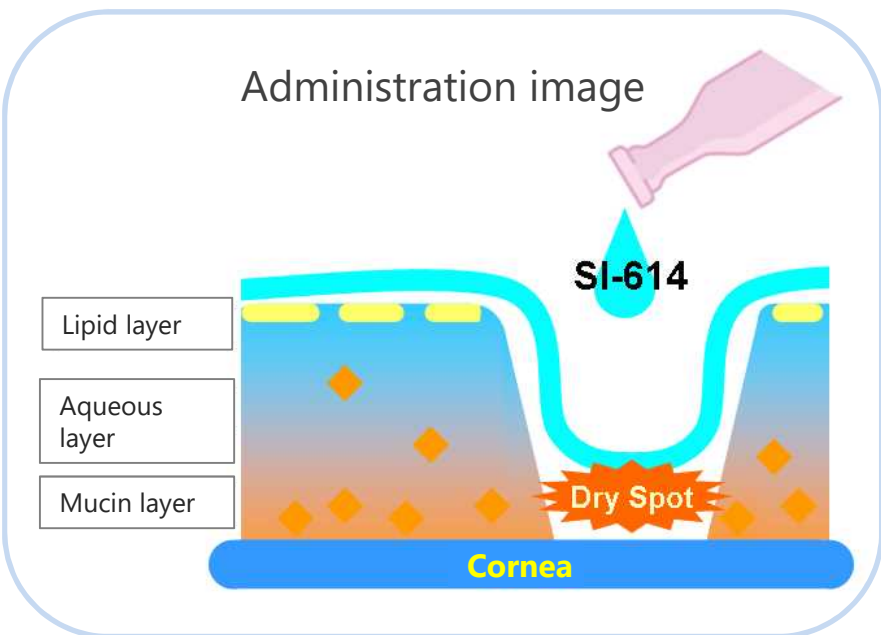
Indication : Lumbar disc herniation

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.
Considering future development policy while analyzing the data obtained



Development status

- ▶ **U.S. : P III** Starting May 2022
 - **Statistically significant improvement in the primary endpoint was not observed.**
 - ⇒ **Proceed with analysis of the data obtained while considering the future development policy.**

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

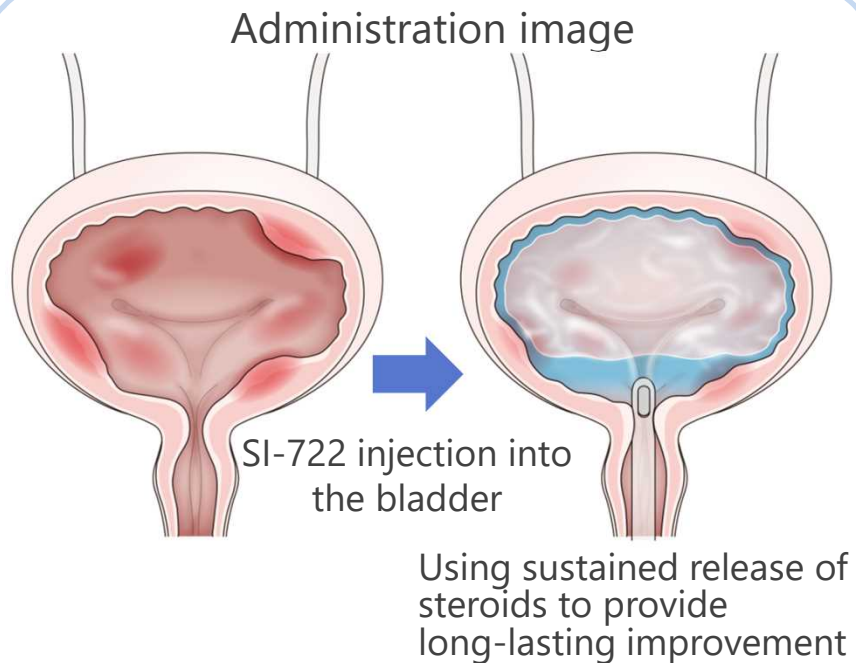
Product name : Dry eye Formulation : Ophthalmic solution

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



SI-722 (Interstitial cystitis and bladder pain syndrome)

Subject enrollment for PI/PII studies in the U.S. completed
Currently considering the future development policy



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

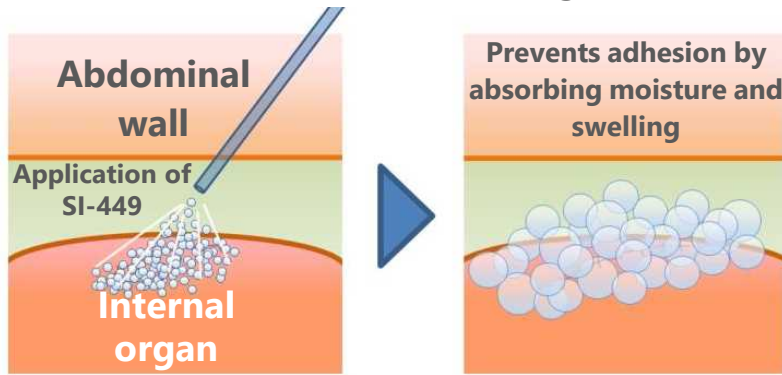
Estimated U.S. patients : 1.3 million (Seikagaku estimates)



SI-449 (Adhesion Barrier / Medical Device)

Obtained results indicating statistically significant improvement in the primary and secondary endpoints.

Administration image



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)
Starting May 2020
 - Follow-up observation completed in June 2023
 - Topline results indicating statistically significant adhesion prevention performance in the primary and secondary endpoints obtained in July 2023
- ⇒ **Proceed with preparations for an application for approval at an early date**
- ▶ **Japan pilot study (field of gynecology)**
Starting November 2021
 - 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

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