

**Exploring the Innovative
Promise of Glycoscience**

Financial Results for the 1st Quarter of Fiscal Year 2023



SEIKAGAKU CORPORATION

(TSE : 4548)



■ 1Q 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
		■ Appendix	P16

< 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 1Q of FY 2023

(Millions of Yen)	1Q FY2023 Results	Year-on-Year		(Reference) Comparison with Forecasts	
		Change	% of Change	Change	Degree of Progress
Net sales	9,661	+1,353	+16.3%	32,550	29.7%
Operating Income	1,298	+172	+15.3%	100	1,298.8%
Ordinary Income	1,959	+244	+14.3%	1,550	126.4%
Net Income	1,887	+394	+26.4%	1,450	130.2%
R&D Expenses (excluding royalty income)	1,738 (19.4%)	+50	+3.0%	7,200 (22.6%)	24.1%
Average Exchange Rate (1US\$)	¥137.37	+¥7.80		¥130.00	

	1Q FY2023 Results	1Q FY2022 Results	(Reference) FY2023 Forecasts
Net Income per Share	¥34.62	¥26.62	¥26.59

Net sales by Business Segment (1Q of FY2023)

(Millions of Yen)	1Q FY2023 Results	Year-on-Year	% of Change
Net sales	9,661	+1,353	+16.3%
Pharmaceuticals	7,172	+1,683	+30.7%
Domestic Pharmaceuticals	3,312	+347	+11.7%
Overseas Pharmaceuticals	2,324	+536	+30.0%
Bulk Products /CDMO	835	+102	+14.0%
Royalty Income	699	+697	—
LAL Business	2,488	-330	-11.7%
(Overseas sales)	5,820	+1,053	+22.1%

Domestic Pharmaceuticals

▶ ARTZ (Joint-function improving agent)

- Slight market contraction (-1.9%)
- Deliveries to medical institutions up thanks to switching from competing products (+6.6%)
- Market share up (+5.4 pt)
- Seikagaku sales up on higher shipment volume, despite the impact of NHI drug price reductions

▶ JOYCLU (Joint-function improving agent)

- Seikagaku sales down due to 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. +510million yen

Net sales by Business Segment (1Q of FY2023)

(Millions of Yen)	1Q FY2023 Results	Year-on-Year	% of Change
Net sales	9,661	+1,353	+16.3%
Pharmaceuticals	7,172	+1,683	+30.7%
Domestic Pharmaceuticals	3,312	+347	+11.7%
Overseas Pharmaceuticals	2,324	+536	+30.0%
Bulk Products /CDMO	835	+102	+14.0%
Royalty Income	699	+697	—
LAL Business	2,488	-330	-11.7%
(Overseas sales)	5,820	+1,053	+22.1%

* Foreign exchange impact on overall net sales :
approx. +510million yen

Domestic Pharmaceuticals

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

- Market growth trend accompanying population aging (+5.4%)
- Deliveries to medical institutions up due to the impact of limited shipments of competing products (+5.7%)
- Market share at prior-year level (+0.1 pt)
- Seikagaku sales up sharply on higher shipments, despite the impact of NHI drug price reductions

▶ **MucoUp** (Submucosal injection agent for endoscopic surgery)

- Seikagaku sales down due to a sales partner inventory adjustment

▶ **HERNICORE** (Treatment for lumbar disc herniation)

- Deliveries to medical institutions and Seikagaku sales at the prior-year level

Net sales by Business Segment (1Q of FY2023)

(Millions of Yen)	1Q FY2023 Results	Year-on-Year	% of Change
Net sales	9,661	+1,353	+16.3%
Pharmaceuticals	7,172	+1,683	+30.7%
Domestic Pharmaceuticals	3,312	+347	+11.7%
Overseas Pharmaceuticals	2,324	+536	+30.0%
Bulk Products /CDMO	835	+102	+14.0%
Royalty Income	699	+697	—
LAL Business	2,488	-330	-11.7%
(Overseas sales)	5,820	+1,053	+22.1%

* Foreign exchange impact on overall net sales : approx. +510million yen

Overseas Pharmaceuticals

*Foreign exchange impact on Overseas Pharmaceuticals: approx. +190million yen

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

- Local sales volume and Seikagaku sales down due to the impact of a health insurance system change



Gel-One: Single-injection joint function improving agent

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

- Local sales volume up due to a changing market environment associated with a health insurance system change
- Seikagaku 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 1Q due to the impact of COVID-19
- Seikagaku sales up because there were no shipments in FY22 1Q due to a packaging material change

Net sales by Business Segment (1Q of FY2023)

(Millions of Yen)	1Q FY2023 Results	Year-on-Year	% of Change
Net sales	9,661	+1,353	+16.3%
Pharmaceuticals	7,172	+1,683	+30.7%
Domestic Pharmaceuticals	3,312	+347	+11.7%
Overseas Pharmaceuticals	2,324	+536	+30.0%
Bulk Products /CDMO	835	+102	+14.0%
Royalty Income	699	+697	—
LAL Business	2,488	-330	-11.7%
(Overseas sales)	5,820	+1,053	+22.1%

Bulk Products / CDMO

- Sales up on growth from bulk products and the positive effect of yen depreciation on contract development and manufacturing and other services of Dalton

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

Royalty Income

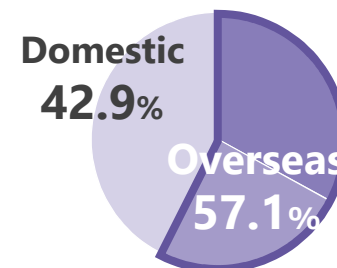
- Royalty income up

LAL Business

- Sales in Japan at the prior-year level
- Sales at ACC down due to subsiding of COVID-related special demand, despite the positive effect of yen depreciation

*Foreign exchange impact on LAL Business: approx. 280 million yen

Overseas Sales Ratio(excluding royalty income)



Year-on-Year
-0.3pt

* Foreign exchange impact on overall net sales : approx. +510million yen

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



Income for 1Q of FY2023 (Year-on-Year)

(Millions of Yen)	1Q FY2023 Results	Year-on- Year	% of Change
Net sales	9,661	+1,353	+16.3%
Cost of Sales (excluding royalty income)	4,477 (50.0%)	+854 (+6.4pt)	+23.6%
SGA expenses	3,885	+326	+9.2%
R&D Expenses (excluding royalty income)	1,738 (19.4%)	+50 (-0.9pt)	+3.0%
Operating Income (to Net sales ratio)	1,298 (13.4%)	+172 (-0.2pt)	+15.3%
Ordinary Income	1,959	+244	+14.3%
Net Income	1,887	+394	+26.4%
Depreciation	375	+84	+29.0%

Operating Income **1,298 (+172)**

Cost of sales ratio (+6.4pt)

- Cost of sales ratio up because of NHI drug price reductions and change in the sales mix

SGA Expenses (+326)

- Higher expenses at overseas subsidiaries, including foreign currency translation

Ordinary Income **1,959(+244)**

Non-operating Income / Expenses (+72)

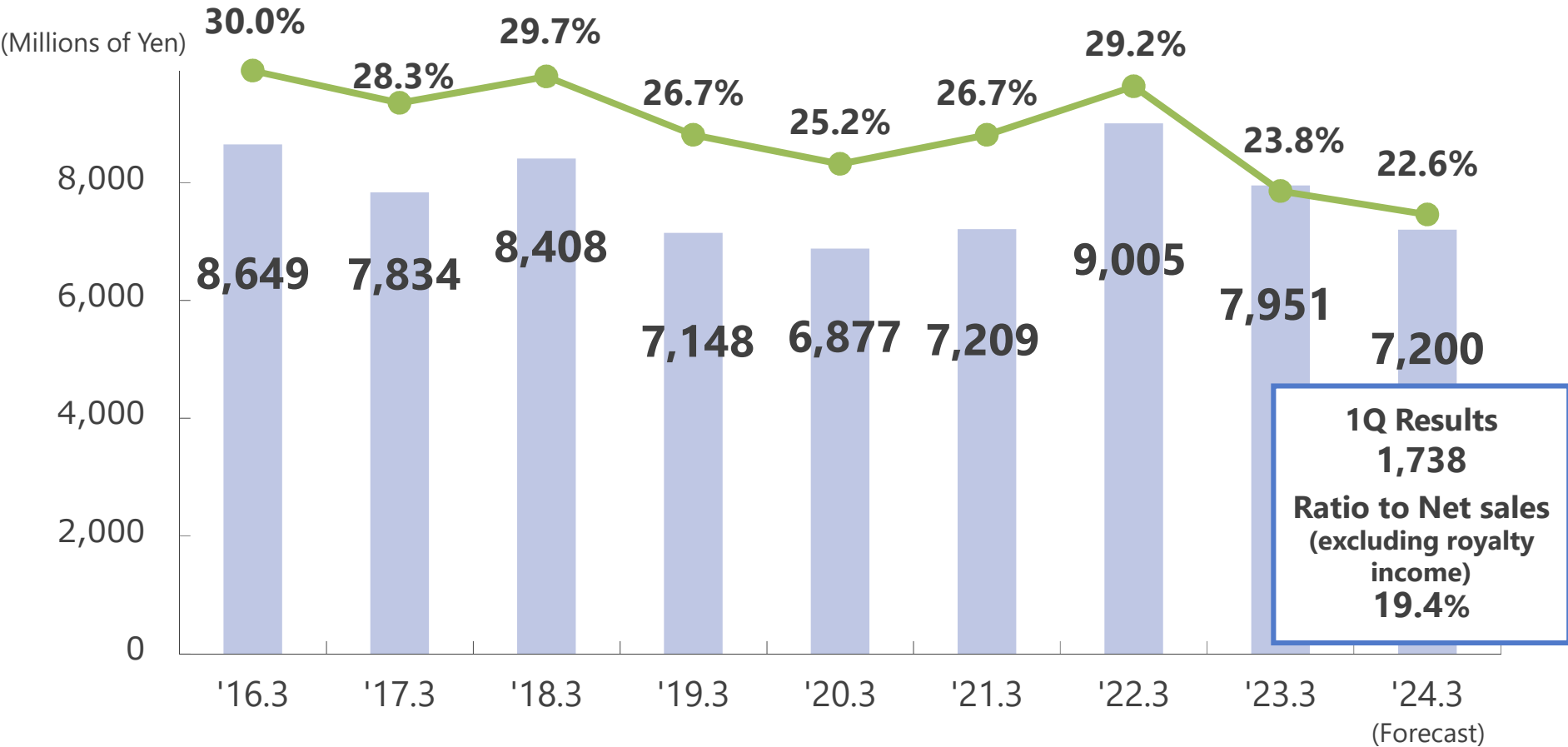
- Increase in foreign exchange gain (+22)



Trend in R&D Expenses

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

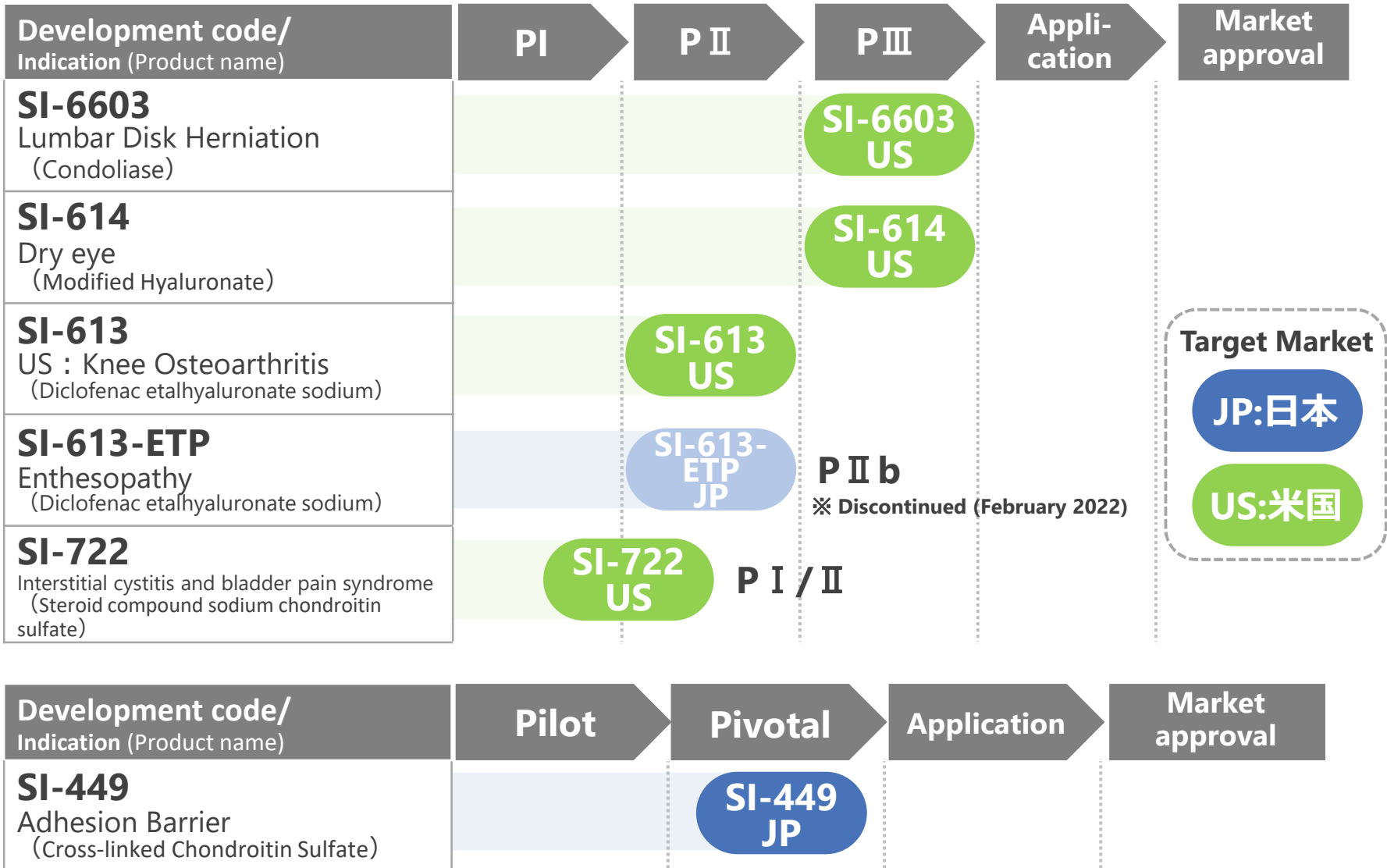
R&D Expenses Ratio to Net sales Ratio to Net sales(excluding royalty income)



1Q Results
1,738
Ratio to Net sales
(excluding royalty
income)
19.4%



Pipeline List

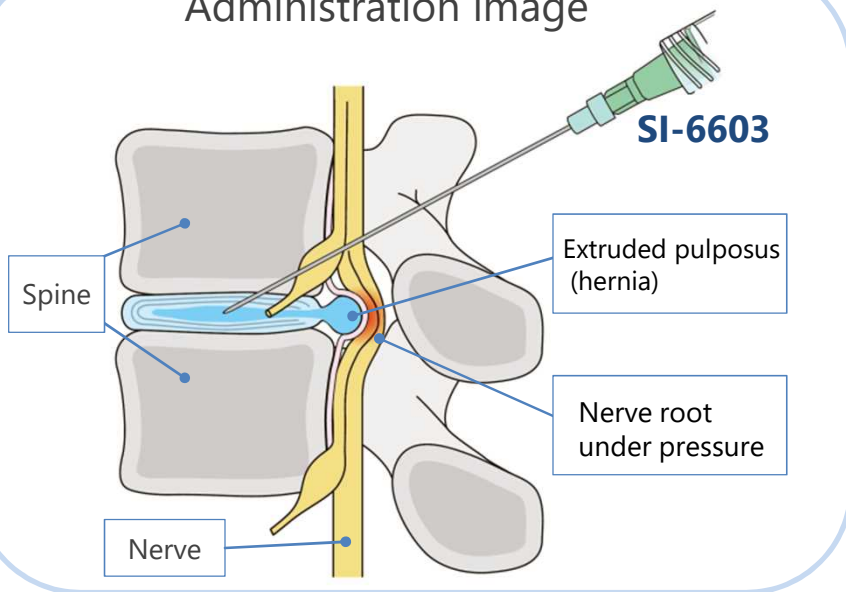




SI-6603 (Treatment for Lumbar Disc Herniation)

Statistically significant results in the primary endpoint obtained in May 2023

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**
- ⇒ **Plan to proceed with preparations for a Biologics License Application (BLA)**

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

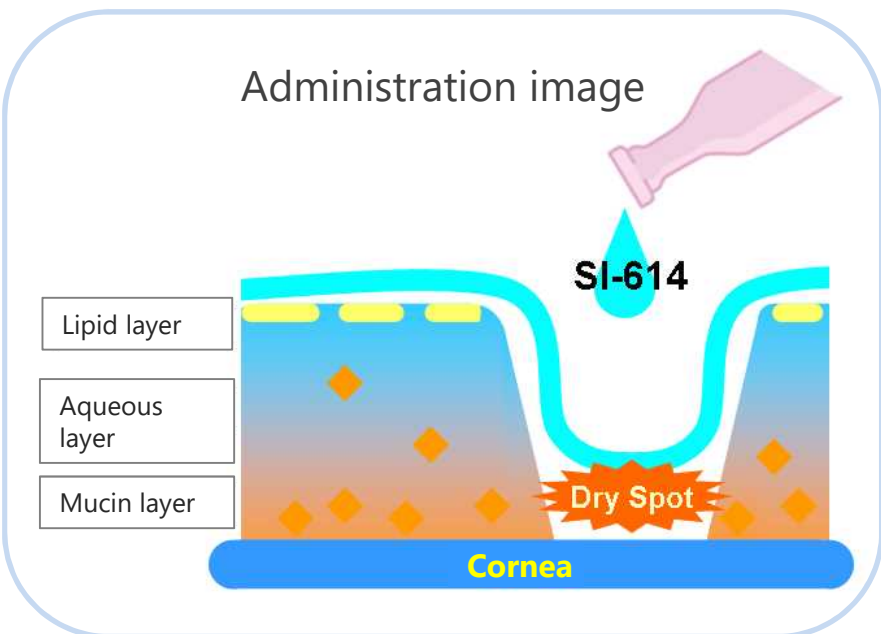
Indication : Lumbar disc herniation

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)



Phase III clinical study in the U.S. initiated in May 2022 Follow-up observation completed in June 2023



Development status

- ▶ **U.S. : P III** Starting May 2022
 - Evaluation of efficacy and safety
 - **Follow-up observation completed in June 2023**
- ⇒ **Data analysis now underway**

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>

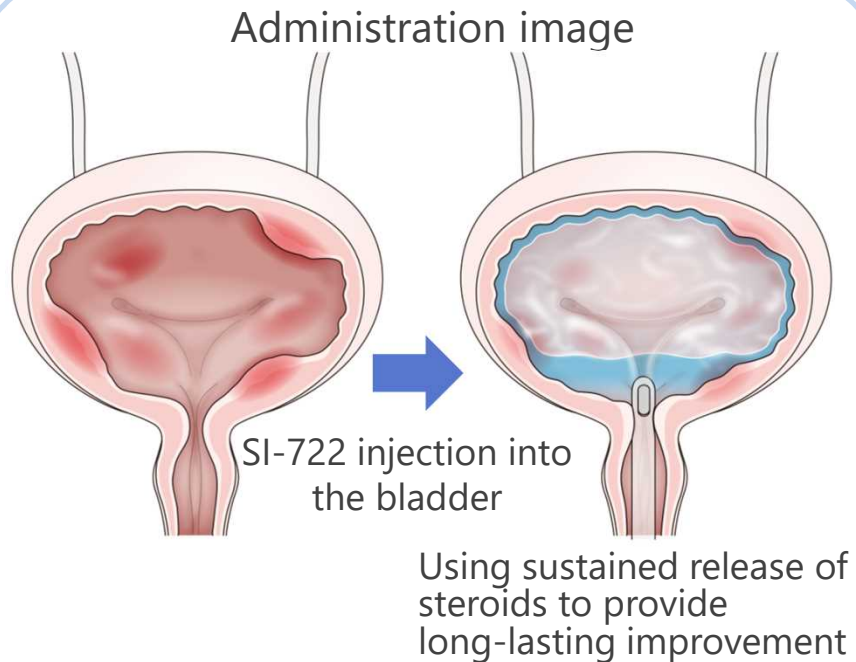
Dev. Code : SI-614 Generic name : Modified Hyaluronate

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

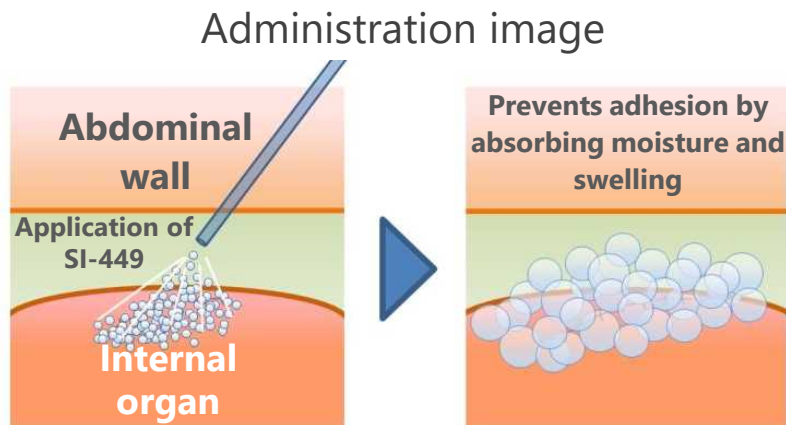
Indication : Interstitial cystitis and bladder pain syndrome

Method of use : Injection into the bladder

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

SI-449 (Adhesion Barrier / Medical Device)

Follow-up observation in a pivotal study completed in June 2023
Statistically significant results in the primary and secondary endpoints
obtained in July 2023



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
- ⇒ **Plan to proceed with an application for approval following detailed analysis of data**
- ▶ **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	¥26.59
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%	97.8%

*1 Includes JOYCLU approval commemorative dividend of ¥4

*2 Includes JOYCLU launch special dividend of ¥10

Appendix



Overview of Forecasts in FY2023

(Millions of Yen)	FY2023 Forecasts	FY2022 Results		
		Results	Change	% of Change
Net sales	32,550	33,456	-906	-2.7%
Operating Income	100	2,114	-2,014	-95.3%
Ordinary Income	1,550	3,069	-1,519	-49.5%
Net Income	1,450	2,236	-786	-35.2%
R&D Expenses (Ratio to net sales excluding royalty income)	7,200 (22.6%)	7,951 (23.8%)	-751 (-1.2pt)	-9.5%
Average Exchange Rate (1US\$)	¥130.00	¥135.48		

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

Exchange Rate Sensitivity (Impact of a change of ¥1 against the US\$)	
Net sales	Approx. ¥150 million
Operating income	Approx. ¥50 million



Forecasts (Net sales) in FY2023

(Millions of Yen)	FY2023 Forecasts	Year-on-Year	
		Change	% of Change
Net sales	32,550	-906	-2.7%
Pharmaceuticals	22,550	-173	-0.8%
Domestic Pharmaceuticals	11,950	+678	+6.0%
Overseas Pharmaceuticals	7,300	-1,234	-14.5%
Bulk Products /CDMO	2,650	-266	-9.1%
Royalty income	650	+648	—
LAL Business	10,000	-732	-6.8%
(Overseas sales)	18,700	-1,348	-6.7%

* Foreign exchange impact on overall net sales :
approx. +90million yen

Net sales

Forecasting a sales decrease to result from the impact of shipment timing on sales of overseas pharmaceuticals, despite projected increases in domestic pharmaceuticals volume and royalty income

Pharmaceuticals

Domestic pharmaceuticals :

Sales increase, with higher volume offsetting NHI price reductions

Overseas pharmaceuticals :

Sales decrease due to lower local sales volumes and the impact of shipment timing

Bulk products/CDMO :

Sales decrease reflecting the non-recurrence of yen depreciation benefits experienced in FY2021

Royalty income :

Substantial decline

LAL Business

Expected sales decrease due to the end of COVID-related demand and the non-recurrence of yen depreciation benefits experienced in FY2021



Forecasts (Income) in FY2023

(Millions of Yen)	FY2023 Forecasts	Year-on-Year	
		Change	% of Change
Net sales	32,550	-906	-2.7%
Operating Income (Ratio to net sales)	100 (0.3%)	-2,014 (-6.0pt)	-95.3%
Ordinary Income	1,550	-1,519	-49.5%
Net Income	1,450	-786	-35.2%
Cost of Sales ratio (excluding royalty income)	52.2%	+6.1pt	—
R&D Expenses	7,200	-751	-9.5%
R&D Expenses ratio (excluding royalty income)	22.6%	-1.2pt	—
Depreciation	1,700	+372	+28.0%

Operating Income

Cost of sales ratio

- Increase reflecting soaring fuel costs and development of an expanded production system

SGA expenses

- Decrease in R&D expenses due to completion of an additional study in the U.S. for SI-6603 and other major clinical studies

Ordinary Income

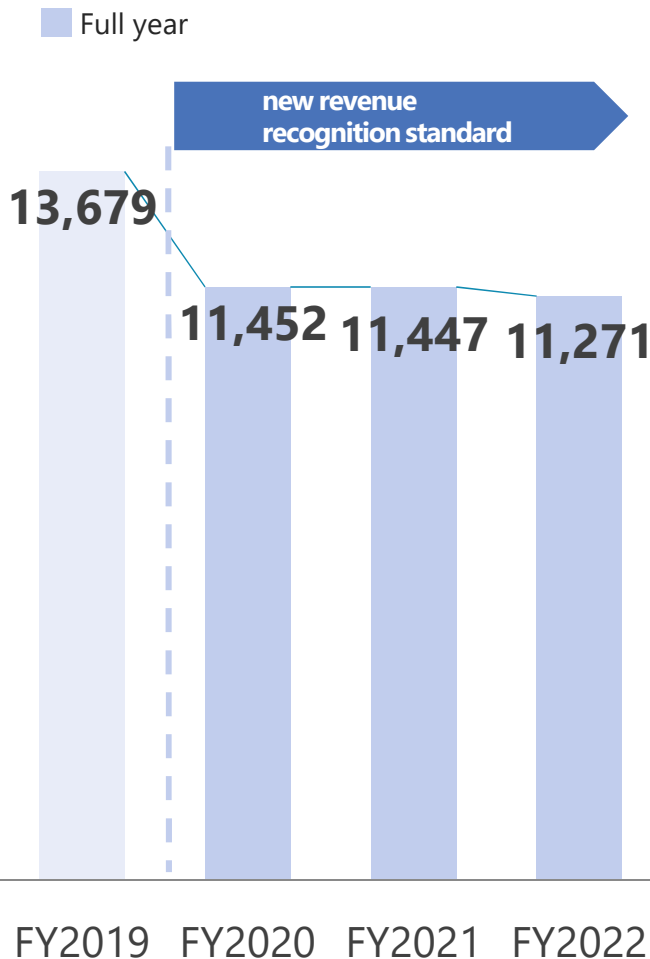
Non-operating Income/Expenses

- Expected increase in gain on sale of investment securities

Domestic Pharmaceuticals (Year-on-Year)

Domestic Pharmaceuticals Sales trend

(Millions of Yen)



FY2022 Results

-1.5%

(Sales)

Sales at the prior-year level, 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 (+0.2%)

- Recovery from the impact of COVID-19

ARTZ (+3.0%)

- Volume and market share expansion due to successful measures to promote switching from competing products (64.1%/+1.7 pt)

JOYCLU

- Information provision efforts to ensure appropriate use

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market (+10.8%)

- Expansion due to recovery from COVID-19 and a market growth trend

OPEGAN series (+11.1%)

- Volume increase due to market expansion and the impact of limited shipments of competing products
- Market share at the prior-year level (52.1%/+0.2 pt)

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

HERNICORE

- Sales at the prior-year level



Safety Information on Joint Function Improving Agent JOYCLU

**Blue Letter (rapid safety information) issued in June 2021
Seikagaku is further raising awareness among healthcare
professionals and taking measures to identify the cause**

Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter)

issued on June 1 in response to multiple reports of anaphylaxis occurring in patients following administration of JOYCLU

- To ensure patient safety by promptly alerting healthcare professionals of the situation to enable the provision of appropriate treatment and measures
- Addition of a WARNING section to the drug package insert and revision of the IMPORTANT PRECAUTIONS section
- Leaflet created to alert patients and their families to the risk of side effects



- Continued gathering of safety information and provision of safety-related information
- Physician-led clinical research to identify the cause initiated in April 2022



**Continue gathering of safety information and provision of safety-related
information in collaboration with sales partner Ono Pharmaceutical**

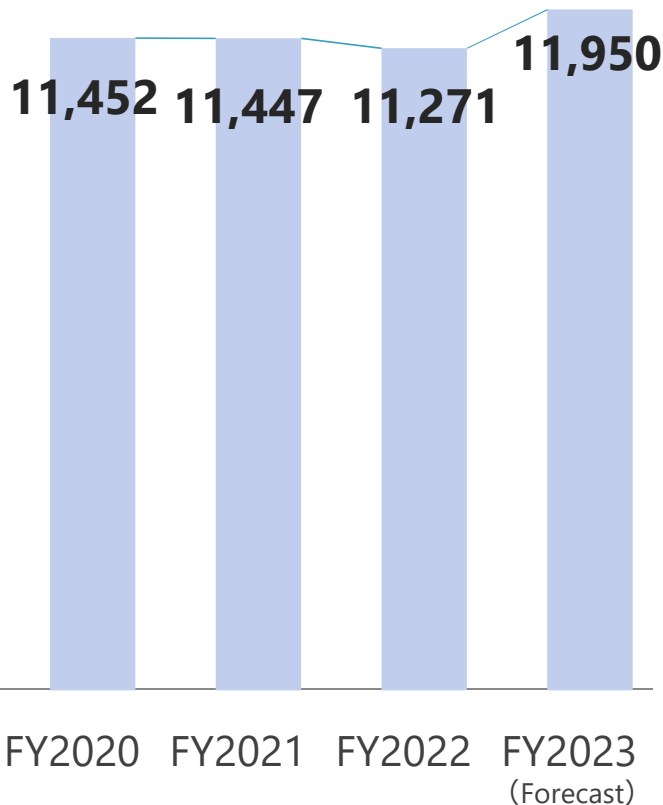
**Analyze the data obtained from clinical research and
continue to consider proposals that will lead to correct use**



Domestic Pharmaceuticals (FY2023 Forecast Year-on-Year)

Domestic Pharmaceuticals Sales trend

Full year (Millions of Yen)



FY2023 Forecast

+ 6.0%
(Sales)

Projected sales increase, with volume increases for ARTZ and other products offsetting NHI drug price reductions

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

Market

- Market size at the prior-year level

ARTZ

- Sales increase attributable to discontinuation of competing product

JOYCLU

- Information provision efforts to ensure appropriate use

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market

- Return to the pre-COVID-19 growth trend

OPEGAN series

- Forecasting sales to remain at the high level of FY2022

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

HERNICORE

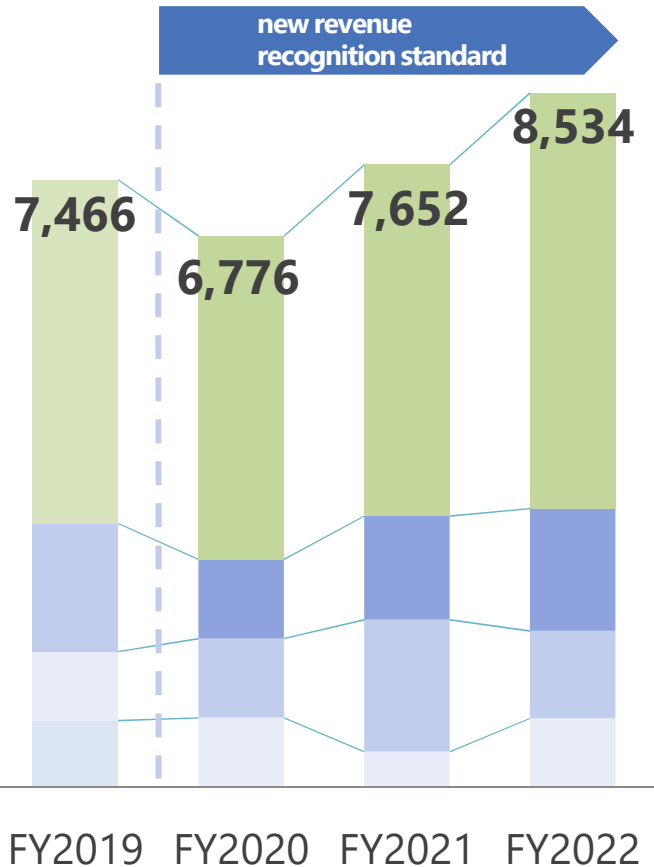
- Forecasting sales at the prior-year level
- Continuation of promotion to ensure correct use and patient awareness activities

Overseas Pharmaceuticals (Year-on-Year)

Overseas Pharmaceuticals Sales trend

<Breakdown> (Millions of Yen)

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



FY2022 Results

+ 11.5%
(Sales)

Sales increase, with the positive impact of yen depreciation offsetting the impact of ARTZ shipment adjustments and the spread of COVID-19 in China

* Foreign exchange impact: approx. + 1,150million

U.S. (Value basis) Market in the U.S.

Health insurance system change relating to price disclosure implemented in July 2022

Gel-One

(approx. -25% on a volume basis)

Local sales: Decrease due to the impact of the system change
Seikagaku sales: Substantial increase due to yen depreciation

SUPARTZ FX

Local sales: Increase due to change in the market environment resulting from the system change
Seikagaku sales: Increase due to yen depreciation

China, Other Regions. (Value basis) Market in China

Impact of limitation of access to outpatient services accompanying the renewed spread of COVID-19

ARTZ in China

Local sales: Substantial decrease due to the impact of COVID-19
Seikagaku sales: Substantial decrease because of shipment adjustments due to a packaging material change as well as the decline in local sales

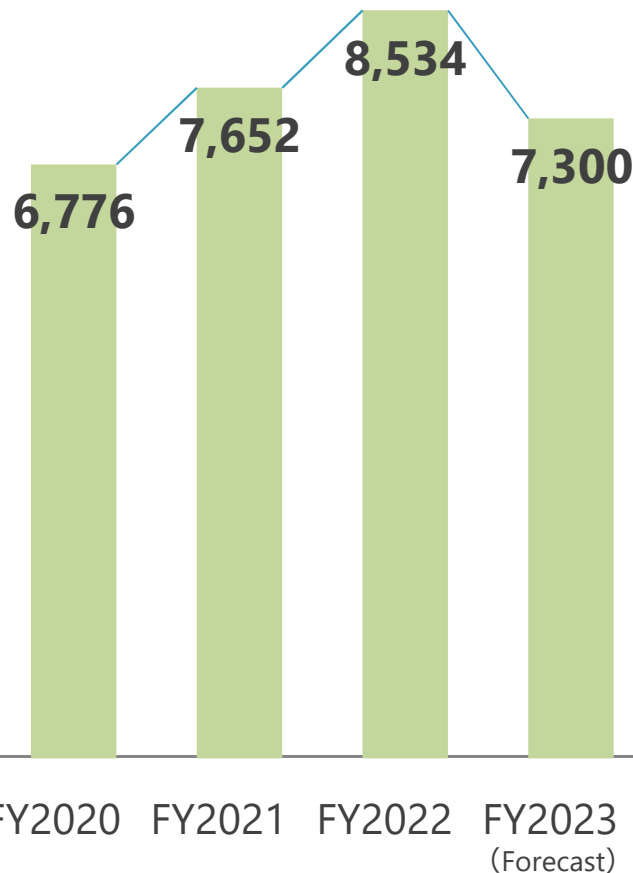
Other Regions

Seikagaku sales: Recovery from COVID-19 in Italy / Higher sales of HyLink in Taiwan

Overseas Pharmaceuticals (FY2023 Forecast Year-on-Year)

Overseas Pharmaceuticals Sales trend

■ Full year (Millions of Yen)



FY2023 Forecast

-14.5%

(Sales)

Projected decrease to result from lower local sales because of a system change in the U.S. and the impact of shipment timing

* Foreign exchange impact: approx. - 15million

U.S. (Value basis)

Market in the U.S.

Continuing impact from a system change relating to price disclosure

Gel-One

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

Seikagaku sales: Decrease due to the impact of shipment timing

SUPARTZ FX

Local sales: Projected increase

Seikagaku sales: Decrease due to the impact of shipment timing

China, Other Regions. (Value basis)

Market in China

Expected recovery from the impact of COVID-19

ARTZ in China

Local sales: Increase due to recovery from the impact of COVID-19

Seikagaku sales: Increase accompanying recovery in local sales

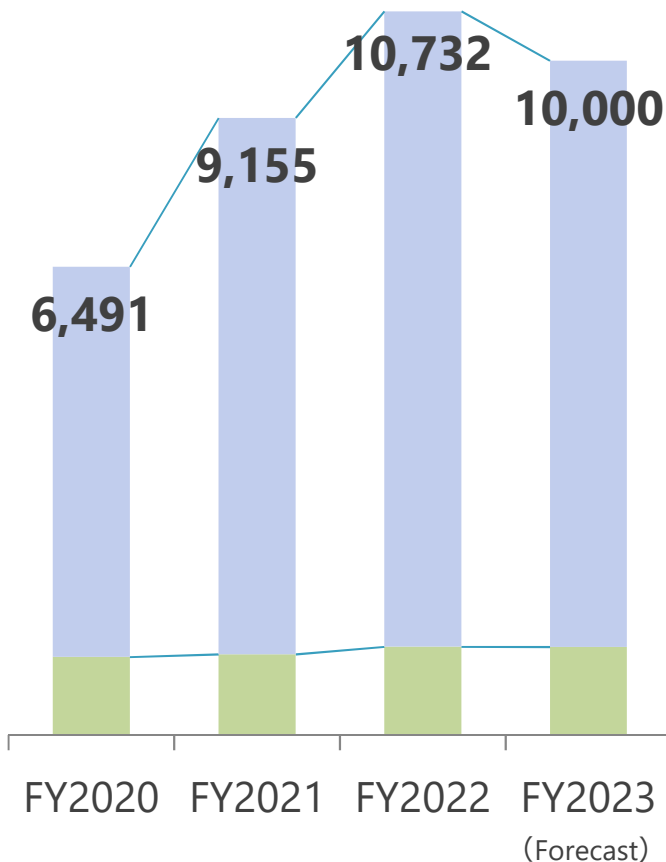
Other Regions

Seikagaku sales: Decrease in Italy due to the impact of shipment timing

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

LAL Business Sales trend

<Breakdown> (Millions of Yen)
■ Overseas ■ Domestic



FY2022 Results : +17.2% (Year-on-Year)

* Foreign exchange impact: approx. + 1,650million

Overseas

Sales increase due to the impact of yen depreciation on sales of Bacterial Endotoxin Testing (BET) reagents, Clinical Diagnostic (Fungitell) reagents, and other products at overseas subsidiary ACC

Domestic

Sales increase on solid sales of reagents and other products

FY2023 Forecasts : - 6.8% (Year-on-Year)

* Foreign exchange impact: approx. + 110million

Overseas

Sales decrease due to the end of Covid-related demand and the non-recurrence of yen depreciation benefits experienced in FY2021

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)

Progress Against the Mid-Term Management Plan in Fiscal 2022

I Accelerate R&D utilizing unique drug-discovery technologies

- Sept. 2022 Completion of subject enrollment for a pivotal clinical study in Japan of SI-449 (an adhesion barrier)
- Feb. 2023 Completion of subject enrollment for a Phase III clinical study in the U.S. for SI-614 (a treatment for dry eye)

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

- March 2023 Completion of follow-up observation in a Phase III additional clinical study in the U.S.
⇒ Aim to accelerate approval through smooth communications with the FDA in cooperation with SNA.

III Maintain and enhance the business value of joint function improving agents

- Accommodation of product material changes for construction of an expanded production system for ARTZ and cost structure improvement
- Continued gathering and provision of safety information on JOYCLU and conduct of clinical research

IV Construct a global production system

- Consideration of construction of a manufacturing system at Canadian subsidiary Dalton Chemical Laboratories to create dual production bases.

V Expand the LAL business through recombinant technologies

- Continued gathering of scientific data relating to PyroSmart NextGen® recombinant LAL reagent and co-authoring of academic papers with ACC
- Increasing the number of countries where in-vitro diagnostic reagents (Fungitell) are sold and further acceleration of new expansion into the hospital market

**Progress being made broadly in line with the plan
Seikagaku will strive to achieve the targets for the plan's final year**



Overview of Current Mid-term Management Plan

FY2025 numerical targets

Net sales ¥40.0 billion

Operating income ¥7.0 billion

**Next mid-term
management plan**

Next Stage

**Current mid-term management plan
Fiscal 2022 to Fiscal 2025**

A period for achieving growth

**Previous mid-term
management plan**

**Solidification of the
profit foundation**

**Based on a solidified profit foundation, nurture the capability to maintain
a constant growth trajectory by energetically implementing
the key measures**

Aim to achieve record-high business results in the final year of the plan



Five Key Measures (Strategic Pillars)

I

Accelerate
R&D utilizing
unique drug-
discovery
technologies

II

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

III

Maintain and
enhance the
business value
of joint
function
improving
agents

IV

Construct a
global
production
system

V

Expand the
LAL business
through
recombinant
technologies

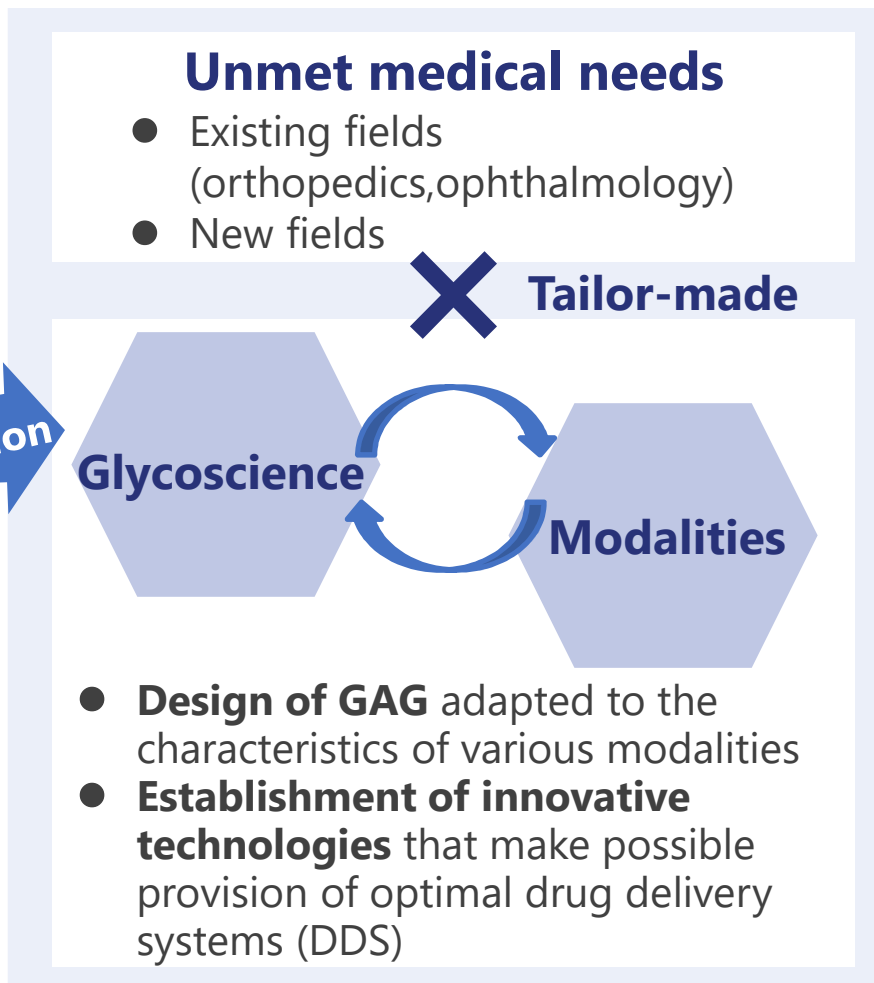
Business foundation

Enhancement of employee engagement/
Organizational strengthening and human resource development



Accelerate R&D Utilizing Unique Drug-Discovery Technologies

Aim to leverage Seikagaku's GAG-related technologies to create products needed by patients



Creation of new development themes in existing fields

Creation of innovative research themes, including in new disease areas

Pursuit of alliances

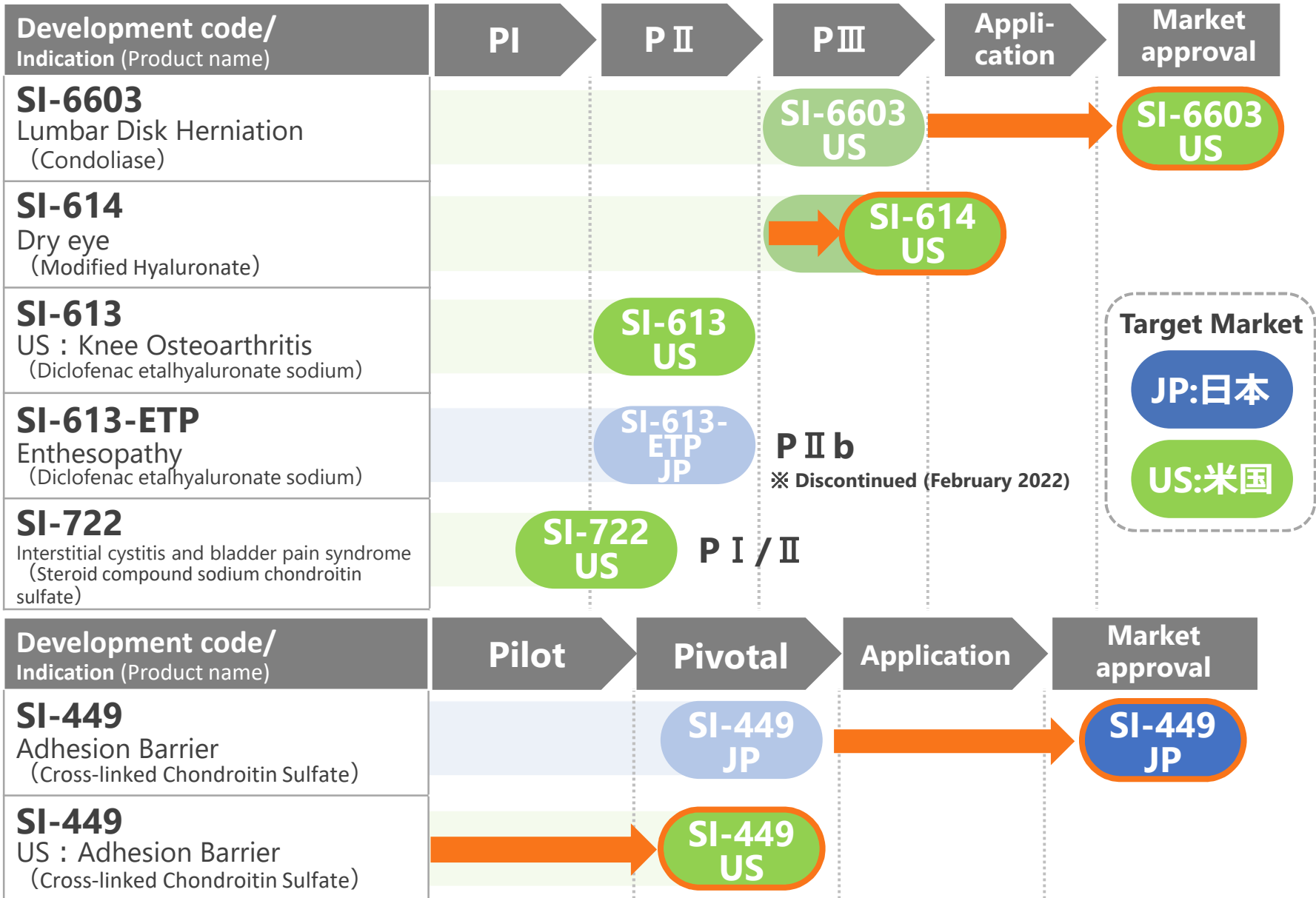
*GAG: Glycosaminoglycans, such as hyaluronic acid and chondroitin sulfate, which are structural components known as glycoconjugates.



- GAG-related basic technologies**
- **Cross-linking**
 - **Chemical modification**
 - **Fermentation etc.**



Pipeline List (Research and Development themes)





Obtain clinical study findings during FY2025 Aim for an NDA and approval during the period of the current mid-term management plan

Steps leading up to market introduction



March 2022
Subject enrollment for a Phase III additional clinical study in the U.S. completed

- Cooperation with SNA* in prompt and accurate NDA and response to regulatory review to obtain approval
- Timely, close communication with the regulatory authorities

- Sales preparations in cooperation with the sales partner
- Construction of a stable supply system

* SEIKAGAKU NORTH AMERICA: Established in January 2022 in Canada with the aim of accelerating development of pharmaceuticals and medical devices and obtaining regulatory approval



Pursue corporate value enhancement through maximization of Seikagaku products in the market for joint function improving agents and cost structure improvement

Maximization of Seikagaku products in the market for joint function improving agents

ARTZ

- Share expansion through switching from competing products

JOYCLU

- Conduct of clinical research to identify the cause of shock and anaphylaxis
- Continuation of information provision to ensure appropriate treatment and measures

Cost structure improvement

- Packaging material specification change
- Manufacturing process efficiency improvement



Maintenance and enhancement of business value that supports business management



Further reinforce a stable supply of products on the basis of a GMP-compliant, appropriate governance system



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



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



Undertake construction of a global production system with Japan and North America as dual production bases, including transfer of production of some products

Aim to be a leading company in the market for recombinant endotoxin detection reagents and glucan detection in vitro diagnostics

Pursuit of Unique Value

Refine the joint development system on the basis of further collaboration with ACC.*

- ▶ Next-generation products
(recombinant technologies, new reagents, new measurement systems)

Collaboration with Affiliated Companies

Create value from business models and operating systems that cannot be created independently

- ▶ Automatic measurement devices



* Associates of Cape Cod: Overseas subsidiary responsible for overseas expansion of the LAL business

Creation of unique value that competitors cannot imitate in a market with strong customer needs



Accomplish a transformation necessary from a long-term perspective in addition to continuation of current businesses and product improvement

1. Endotoxin detection reagent business

- Acceleration of global expansion of endotoxin detection reagents leveraging recombinant technologies
- Accumulation of reliable scientific data utilizing PyroSmart NextGen Recombinant LAL Reagent (launched in 2021) and market penetration and sales promotion through support for early adopters

2. Diagnostics business

- Increase in the number of countries where glucan detection in vitro diagnostics are sold and acceleration of new expansion into the hospital market
- Progress in development of recombinant glucan detection in vitro diagnostics and product portfolio expansion

3. Measurement equipment and software business

- Promotion of development and improvement of automatic measurement equipment and software in Japan and overseas in collaboration with an affiliated company



Seikagaku has identified important issues that should be addressed on a priority basis in the interest of achieving sustainable development of society and enhancement of corporate value

①	Creation of truly useful pharmaceuticals and medical devices	9 医薬品・医療機器の革新を促す	17 パートナーシップで目標を達成しよう
②	Provision of a stable supply of pharmaceuticals and medical devices of guaranteed quality	12 つくる責任 つかう責任	
③	Expansion of healthcare access and appropriate provision of high-quality medical information	3 すべての人に健康と福祉を	
④	Fair and ethical business activities and strengthening of corporate governance	16 平和と公正な社会を築こう	
⑤	Promotion of diversity and development of human resources	5 ジェンダー平等を推進しよう	8 持続可能な経済活動を奨励しよう
⑥	Engagement in environmentally friendly corporate activities	7 エネルギーと気候変動に責任を負おう	13 気候変動に具体的な対策を
		10 人や国の不平等をなくそう	14 海の豊かさを守ろう



Seikagaku will focus on initiatives related to these material issues, which will become the foundation for the key measures in the mid-term management plan



Healthcare	<ul style="list-style-type: none">● Acceleration of multinational expansion and new drug development.● Strengthening and utilization of original GAG-related basic technologies● Product improvement and post-marketing product development aligned with medical needs <p>Related material issues : ①、②、③</p>
Environment	<ul style="list-style-type: none">● CO2 emissions reduction (33.6% reduction from the reference year by FY2030)● Zero waste emissions and promotion of use of recycled raw materials● Biodiversity preservation activities, including reduction or elimination of use of animal-derived materials in products <p>Related material issues : ⑥</p>
Society	<ul style="list-style-type: none">● Strengthening of initiatives for respect of human rights in the supply chain● Boosting of employee motivation through strengthened HR systems and introduction of diversity measures and work-life balance measures that lead to employee retention <p>Related material issues : ⑤</p>
Governance	<ul style="list-style-type: none">● Development and operation of a highly effective corporate governance system● Fostering of compliance awareness and a quality culture● Enhancement of preventive maintenance activities for a stable supply of products <p>Related material issues : ④</p>



	FY2021 results	FY2025 target
Net sales	¥34.8 billion	¥40.0 billion
Operating income	¥4.4 billion	¥7.0 billion

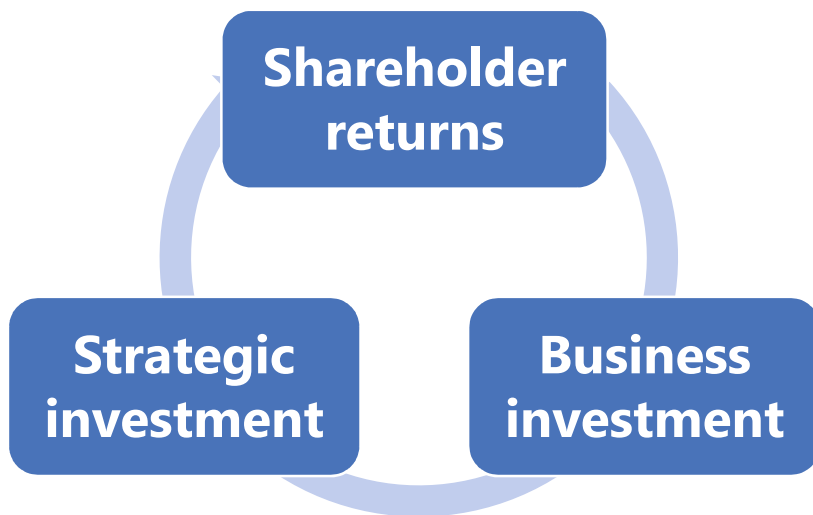
«Assumptions»

- U.S. market introduction of SI-6603 (treatment for lumbar disc herniation)
- Profit expansion from joint function improving agents in Japan
- Expansion of the overseas pharmaceutical and LAL businesses
- Ratio of R&D expenses to sales (excluding royalty income): target of 25%
- Exchange rate: ¥135/US\$1



Aim to achieve record-high business results

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.



A period for achieving growth

I

Accelerate
R&D utilizing
unique drug-
discovery
technologies

II

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

III

Maintain and
enhance the
business value
of joint
function
improving
agents

IV

Construct a
global
production
system

V

Expand the
LAL business
through
recombinant
technologies

Business foundation

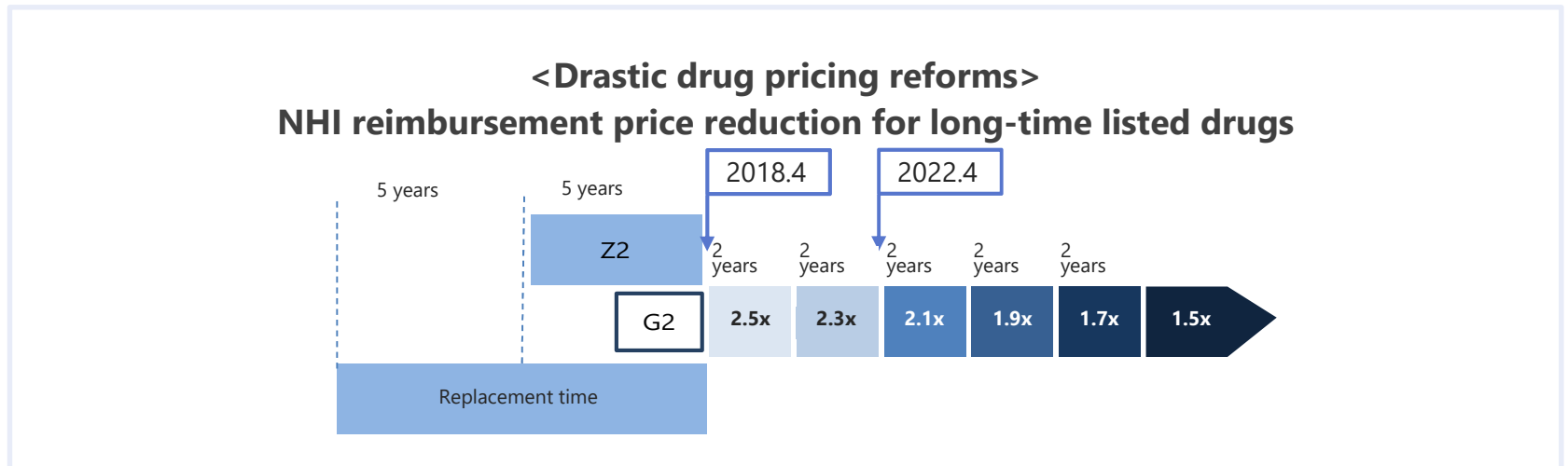
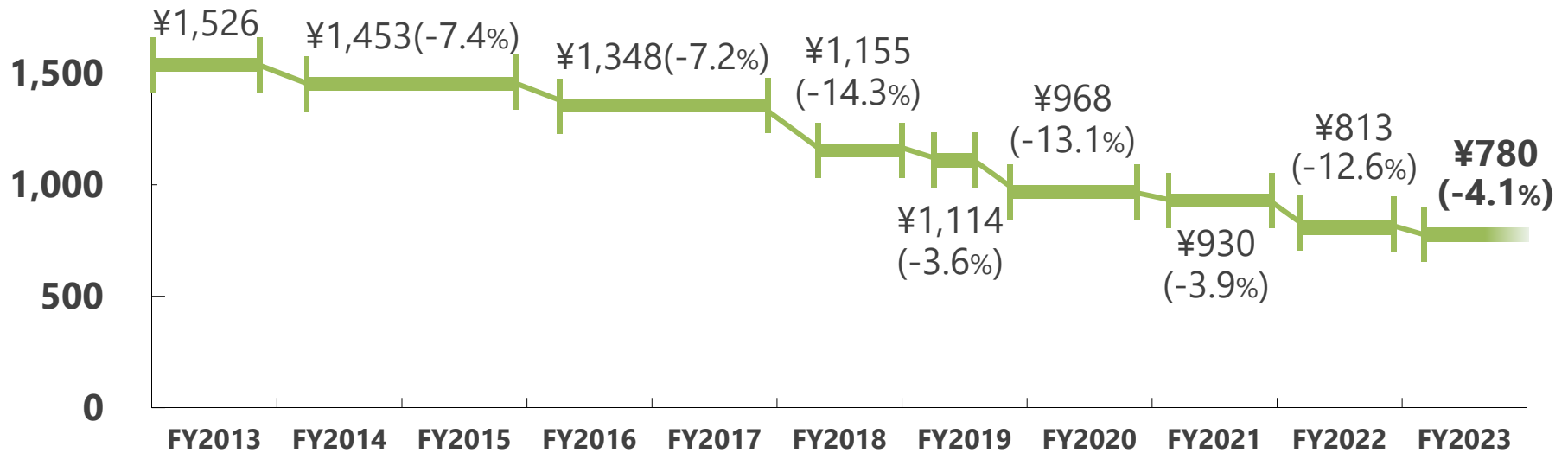
Enhancement of employee engagement/
Organizational strengthening and human resource development



**Nurture the capability to maintain a constant growth trajectory
by energetically implementing the key measures**



Trend in NHI Reimbursement Price of ARTZ to Domestic



Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

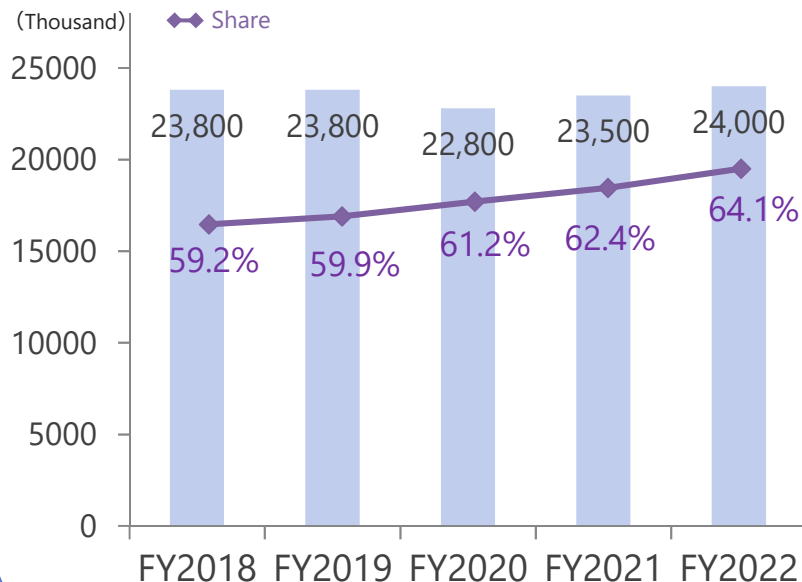
Joint-function improving agent

ARTZ



- The first HA joint function improving agent in the world
- Knee osteoarthritis (OA) pain relief
- Distributor: Kaken Pharmaceutical

Trend in unit deliveries to medical institutions



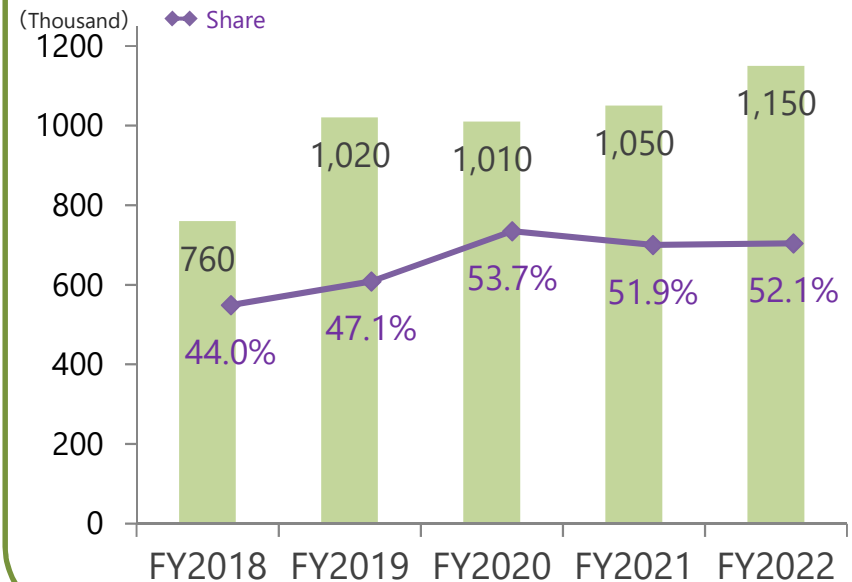
Ophthalmic viscoelastic devices

OPEGAN



- The first domestically HA formulation
- Used in cataract surgery to anterior chamber expansion
- Distributor: Santen Pharmaceutical

Trend in unit deliveries to medical institutions





**Manufacturing and marketing approval in Japan obtained in March 2021
For the indication of osteoarthritis (knee joint and hip joint)
May 19 NHI drug price listing and launch**



Product name	JOYCLU® 30mg Intra-articular Injection
Generic name	diclofenac etalhyaluronate sodium
Indication	Osteoarthritis (knee joint and hip joint)
Dosage and administration	The usual adult dosage is 1 syringe per dose (30 mg of diclofenac etalhyaluronate sodium) injected intra-articularly every 4 weeks.



Improvement of symptoms expected by administration once every 4 weeks First joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint

Features

- ▶ Hyaluronic acid and diclofenac chemically bound using a proprietary technology
- ▶ Diclofenac released by hydrolysis in the joint
- ▶ Improvement of symptoms of osteoarthritis (knee joint and hip joint) expected by administration once every four weeks
- ▶ First joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint

Expected positioning

- ▶ **Establishment as a new base drug** in the treatment of osteoarthritis alongside existing hyaluronic acid formulations and NSAIDs

<Target Patients>

- ▷ People for whom existing hyaluronic acid formulations are insufficiently effective
 - ▷ People who want to avoid NSAIDs, such as oral drugs or patches, in consideration of side effects
 - ▷ People for whom frequent hospital visits are a hardship
- ▶ Provision of **a new treatment option for osteoarthritis of the hip joint**



SI-613 (Treatment of Osteoarthritis/Enthesopathy)

Development of SI-613-ETP discontinued Prioritize identification of cause of JOYCLU side effects

Administration image



Development status

- ▶ **SI-613 (osteoarthritis of the knee)**
U.S. /China/South Korea
 - Proceeding with preparation of a clinical development plan
- ▶ **SI-613 (Enthesopathy) Japan**
 - **February 2022: Development discontinued**
⇒ Failure of the PII clinical study to meet its primary efficacy evaluation, and to prioritize identification of the cause of shock or anaphylaxis occurring in patients following administration of JOYCLU

<SI-613 summary>

Dev. code : SI-613

Generic name : Diclofenac etalhyaluronate sodium

Indication : Osteoarthritis/Enthesopathy Method of use : Injection into joint cavity

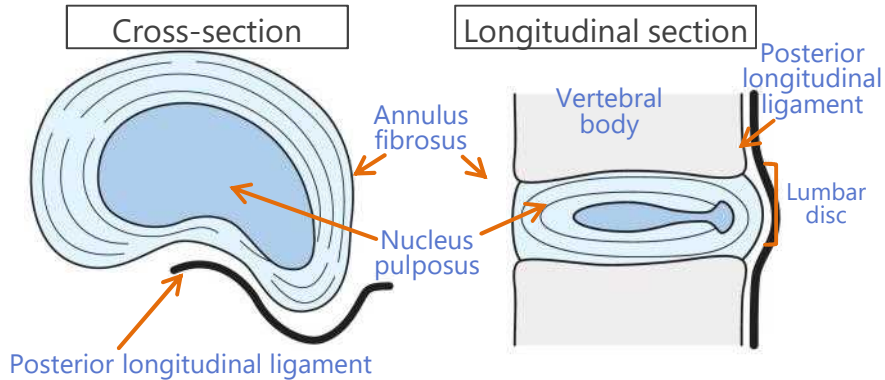
Estimated patients : 24 million (U.S.) / 47 million (China) 3.7 million (South Korea)



Four types of lumbar disc herniation

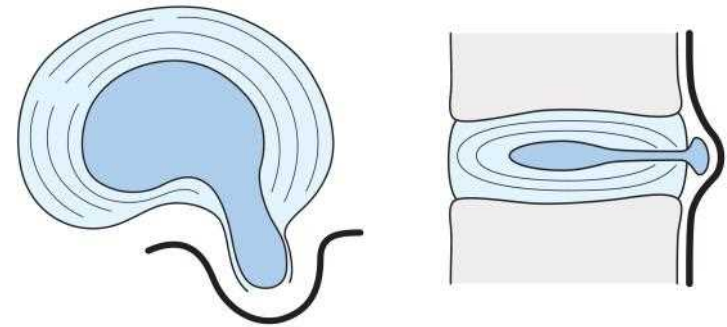
1. Protrusion

The hernia does not extend beyond the outermost layer of the annulus fibrosus



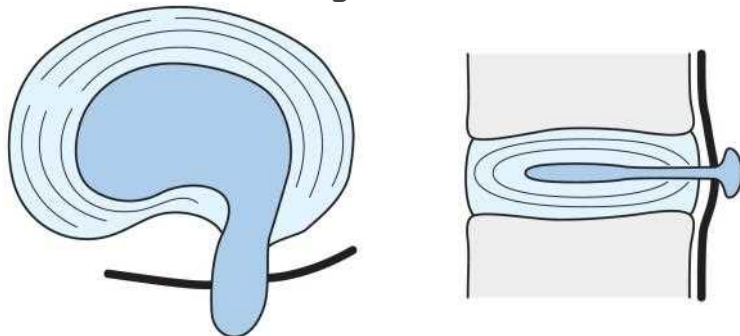
2. Subligamentous extrusion

Although the hernia extends beyond the outermost layer of the annulus fibrosus, it is covered by the posterior longitudinal ligament



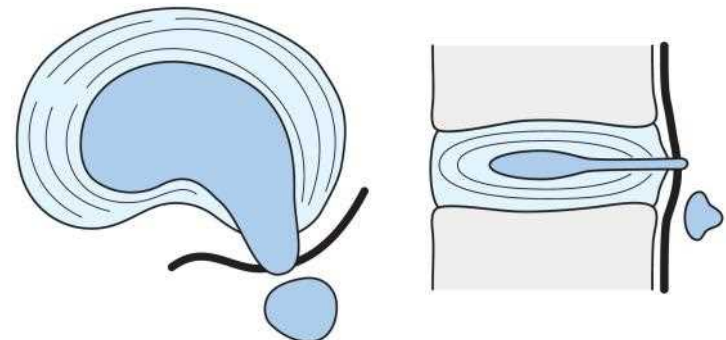
3. Transligamentous extrusion

The hernia perforates the posterior longitudinal ligament



4. Sequestration

The hernia migrates outside the dura mater





Physician and Facilities Requirements for HERNICORE Use

Setting of physician and facility requirements for HERNICORE use to promote appropriate use and ensure safety

【Physician requirements】

【Japanese Society for Spine Surgery and Related Research】

: Physicians under the following conditions (as of April 2019)

1. Supervisory physicians or certified physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) or who are supervised under the JSSR, or who participated in this clinical study
2. Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

【Neurospinal Society of Japan】 : Physicians under the following conditions (as of April 2019)

1. Supervisory physicians or certified physicians of the Neurospinal Society of Japan
2. Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

【Facility requirements】 : Facilities under the following conditions

1. Facilities equipped with an X-ray fluoroscopic system (C-arm, etc.) capable of administering HERNICORE using clean technique
2. Facilities capable of treating shock and anaphylaxis
3. Facilities capable of performing urgent spine surgery or facilities that cooperate with facilities capable of performing spine surgery
4. Facilities with hospitalization equipment

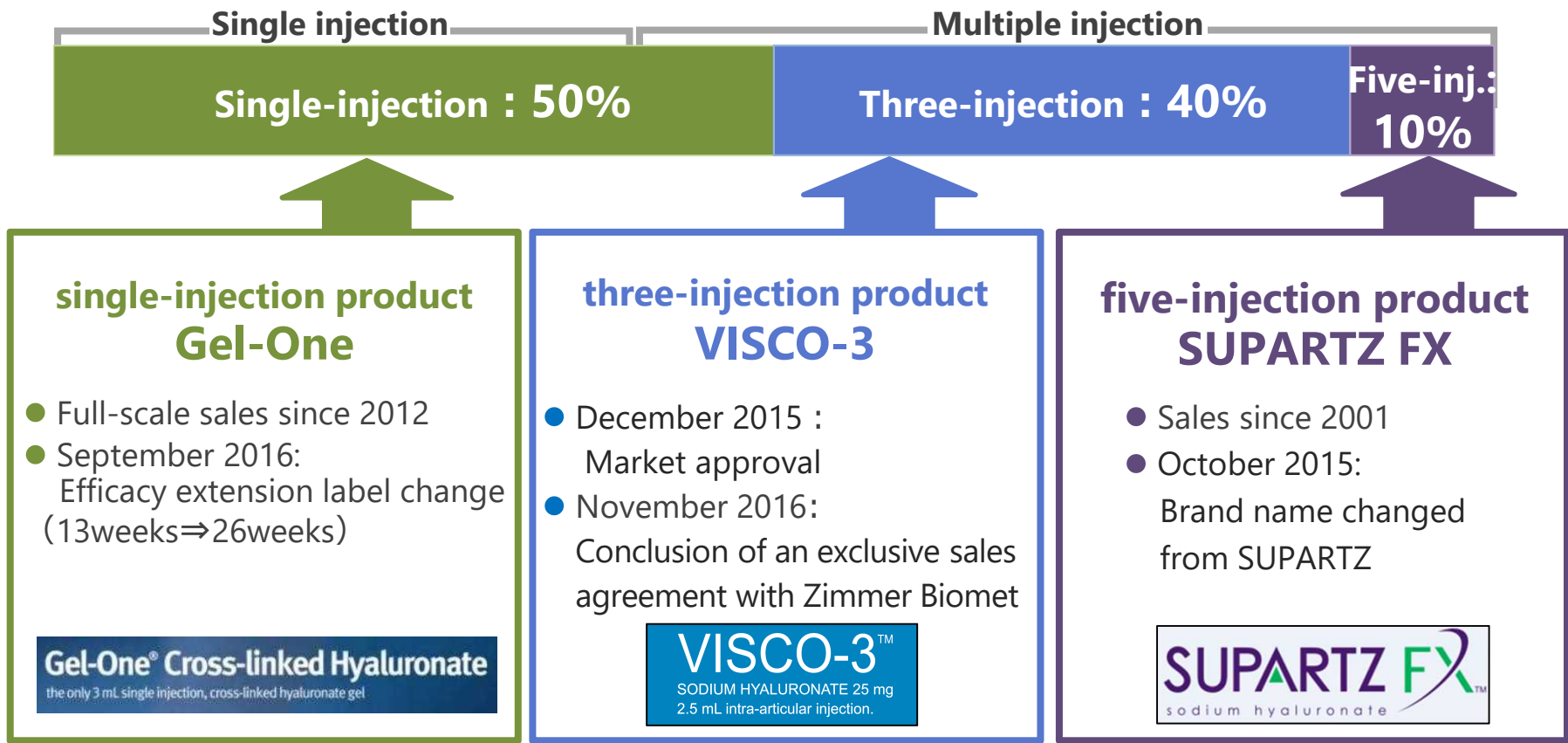
※ Among those who meet the physician requirements, supervisory physicians in the JSSR may be used at non-fulltime work facilities that meet the facilities requirements (as of November 2019)



Market Situation of Hyaluronic Acid Products in the U.S.

Market size of US\$980 mil. in 2022

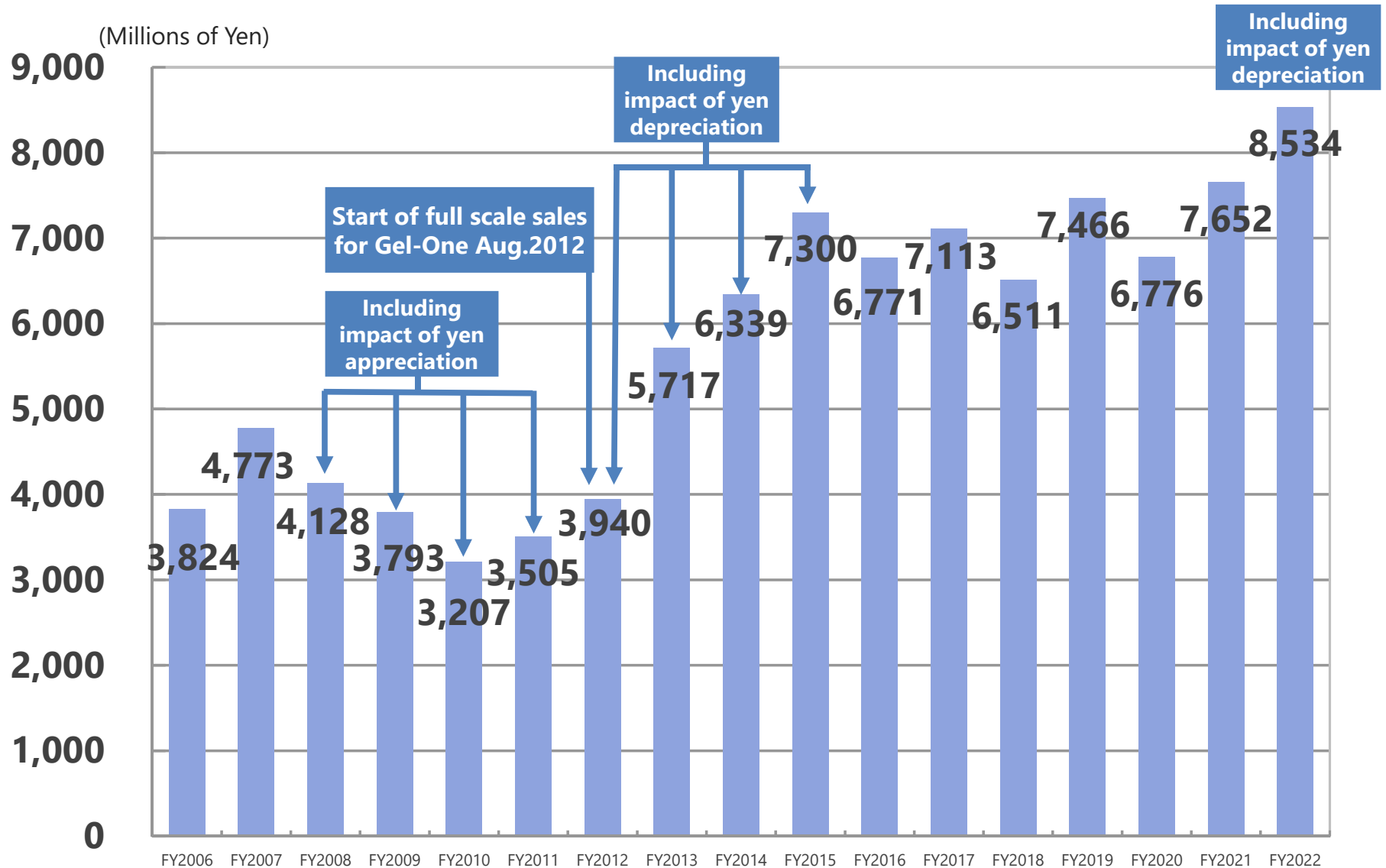
■ U.S. market share by number of injections (Value basis, including competitors)



*Figures for 2022, Seikagaku estimates



Trend in Overseas Sales of Hyaluronic Acid Products





Recombinant LAL reagent 「PyroSmart NextGen」

April 2021 launch at ACC
Product to be marketed globally, with a launch in Japan planned for May or later in 2021



Product Features

- ▶ Product manufactured using recombinant technology without using blood harvested from horseshoe crabs, a raw material used in traditional products
 - Ensures continuous product supply
- ▶ Ability to utilize the same test CPE methods and instruments as naturally sourced products
 - Ensures consistency with endotoxin-testing reagents
 - A next-generation BET reagent designed to deliver highly reliable quantitation of endotoxins



Endotoxin detection reagents (Seikagaku Corporation, ACC)

- Manufacture and sale of reagents for detecting endotoxins* in the manufacturing process of pharmaceuticals, etc. (Japan, USA, Europe, etc.)
- Used mainly at pharmaceutical companies
- Launch of PyroSmart NextGen, a recombinant endotoxin detection reagent, in April 2021
- Accelerated global expansion of recombinant reagents

*Since endotoxins exhibit strong pyrogenic activity even in minute amounts, they must be rigorously controlled pursuant to regulations in the manufacture of pharmaceuticals and medical devices.

▶ **Global market : Approx. ¥2.5 mil**
(Seikagaku estimate / including related equipment)



受託試験サービス (ACC社)

- Contract testing for endotoxin and glucan contamination
- Contributes to quality control at pharmaceutical companies and medical institutions

Glucan detection in vitro diagnostic agents (ACC)

- Manufacture and sales of in vitro diagnostic agents for measuring the glucan* concentration in blood for use in the diagnosis of deep fungal infections (USA, Europe, etc.)
- Since symptoms of deep fungal infections can be similar to those of COVID-19, the products are used together with COVID tests as necessary to ensure appropriate diagnosis and treatment
- Used mainly at hospitals and testing centers
- Market expansion into additional countries

*(1→3) -β-D-glucans are structural components of the cell walls of fungi, as typified by molds and yeasts.





Outline of Associates of Cape Cod, Inc.

Developed the world's first endotoxin detection reagent and obtained FDA approval in 1977 / Sales network spanning 80 countries

Associates of Cape Cod, Inc. (ACC社)

- Headquarters : Massachusetts, U.S.A.
- Established : 1974 (became a Seikagaku subsidiary in 1997)
- Business areas : Manufacture and sale of endotoxin detection reagents and glucan detection in vitro diagnostic agents, provision of contract test services
- Number of employees : 291 (as of March 31, 2023)



Recombinant LAL reagent
PyroSmart NextGen®



Endotoxin detection reagents
PYROCHROME®



Exterior of the ACC office



Dalton, a Canadian CDMO, becomes a subsidiary Acquiring a pharmaceuticals manufacturing base compliant with US/Canadian GMP

Outline of acquisition

- Name : Dalton Chemical Laboratories, Inc.
- Acquisition cost : Up to CAD 41 million
- Acquisition method : Acquired all issued shares

Dalton Chemical Laboratories, Inc.

- Location : Toronto, Ontario Province, Canada
- Established : 1986
- Business description :
Contract manufacturing services (CDMO*), including the manufacturing of chemosynthesis products and active pharmaceutical ingredients (API) and API process development for pharmaceutical companies
- Employee number : 145 (2023.3)



Exterior of the Dalton offices

* CDMO : Contract Development and Manufacturing Organization

A business that supplies comprehensive services in drug development and manufacturing to pharmaceutical companies, including contract drug manufacturing, pharmaceutical formulation planning at the development stage, manufacturing of investigational drugs, and optimization of manufacturing conditions.



Outline of SEIKAGAKU NORTH AMERICA CORPORATION

Established new company in Canada, promoting development of Seikagaku pharmaceuticals and medical devices in North America

SEIKAGAKU NORTH AMERICA CORPORATION

- Location : Toronto, Ontario Province, Canada
- Established : January 25, 2022
- Capital : CAD10
- Business description : Development of pharmaceuticals and medical devices in North America

Purpose of establishment

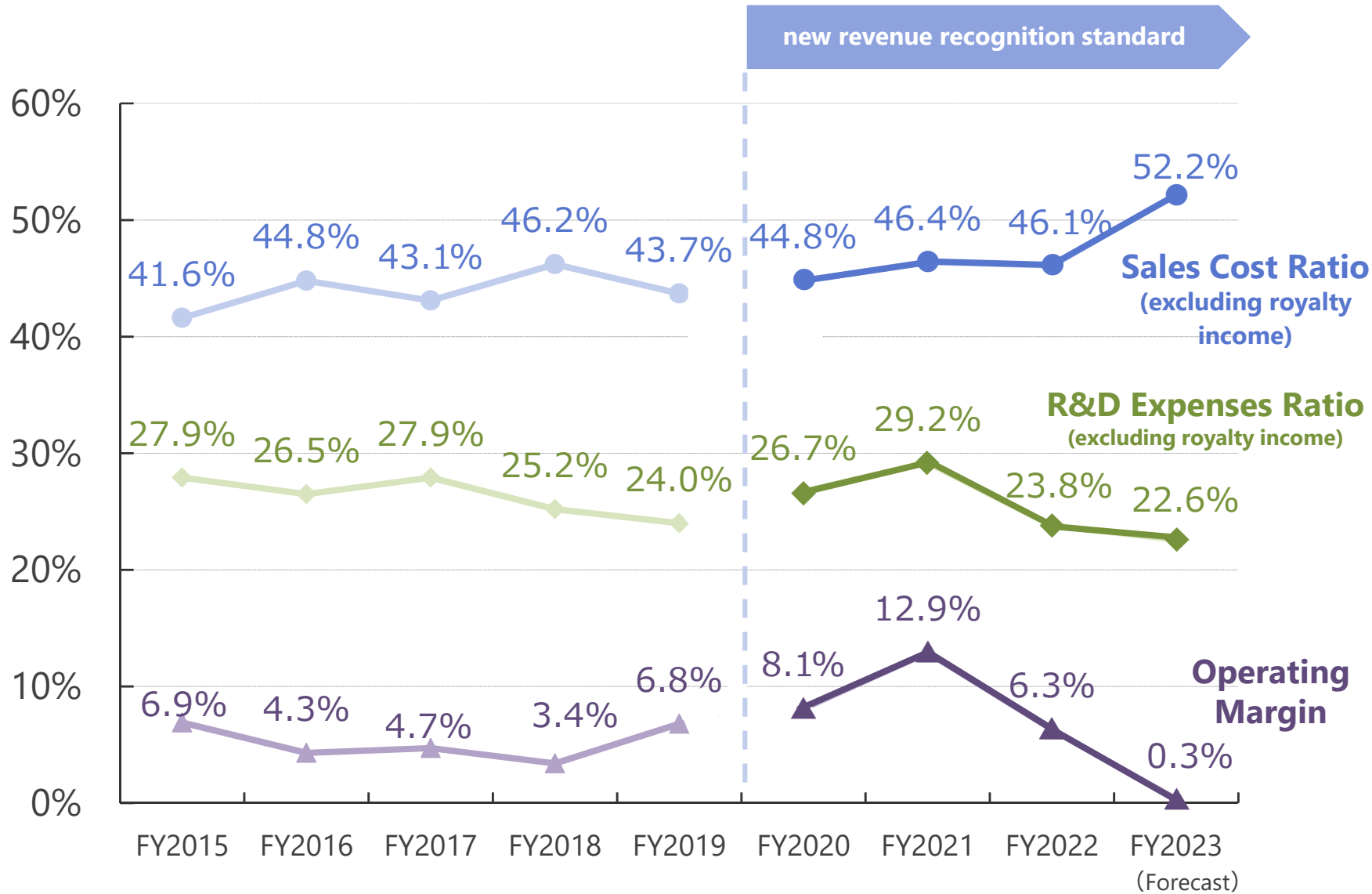
- Enable responses with fewer constraints on time differences or distance by operating a development base in North America
 - Formulate development plans more closely aligned with local medical environment
 - Create smooth communications with U.S. Food and Drug Administration (FDA) and clinical trial sites



**Strengthening the development system in North America.
Aiming to accelerate pharmaceutical and medical device development
as well as obtaining of approvals**



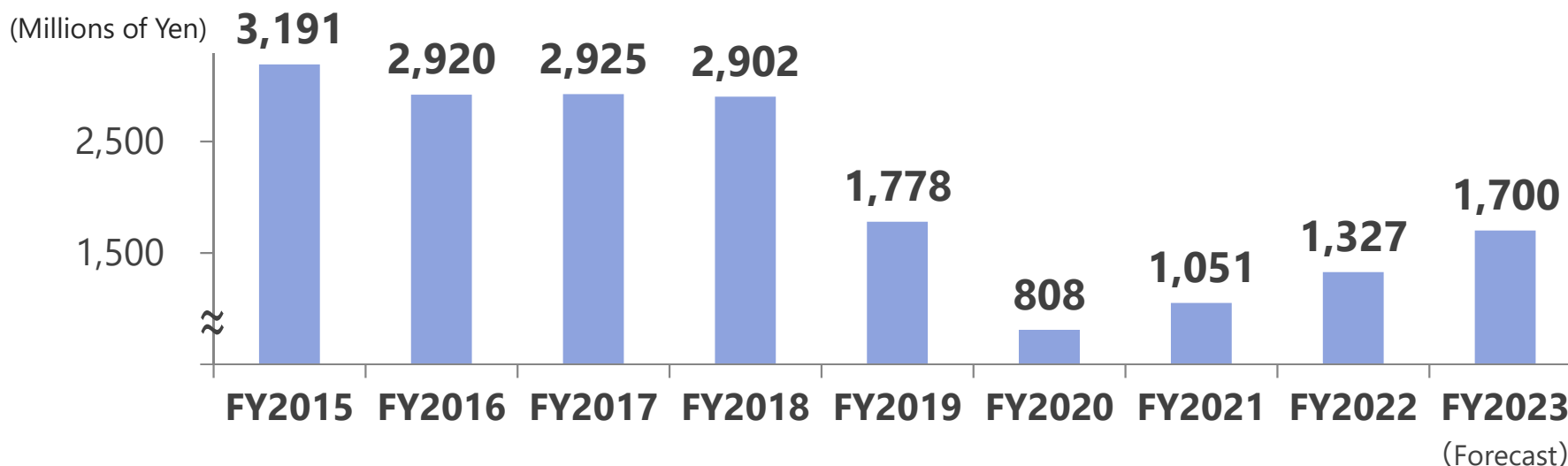
Trend in Financial Index





Impairment loss taken in FY2019 Depreciation will trend toward ¥1.0 billion

■ Trend in Depreciation



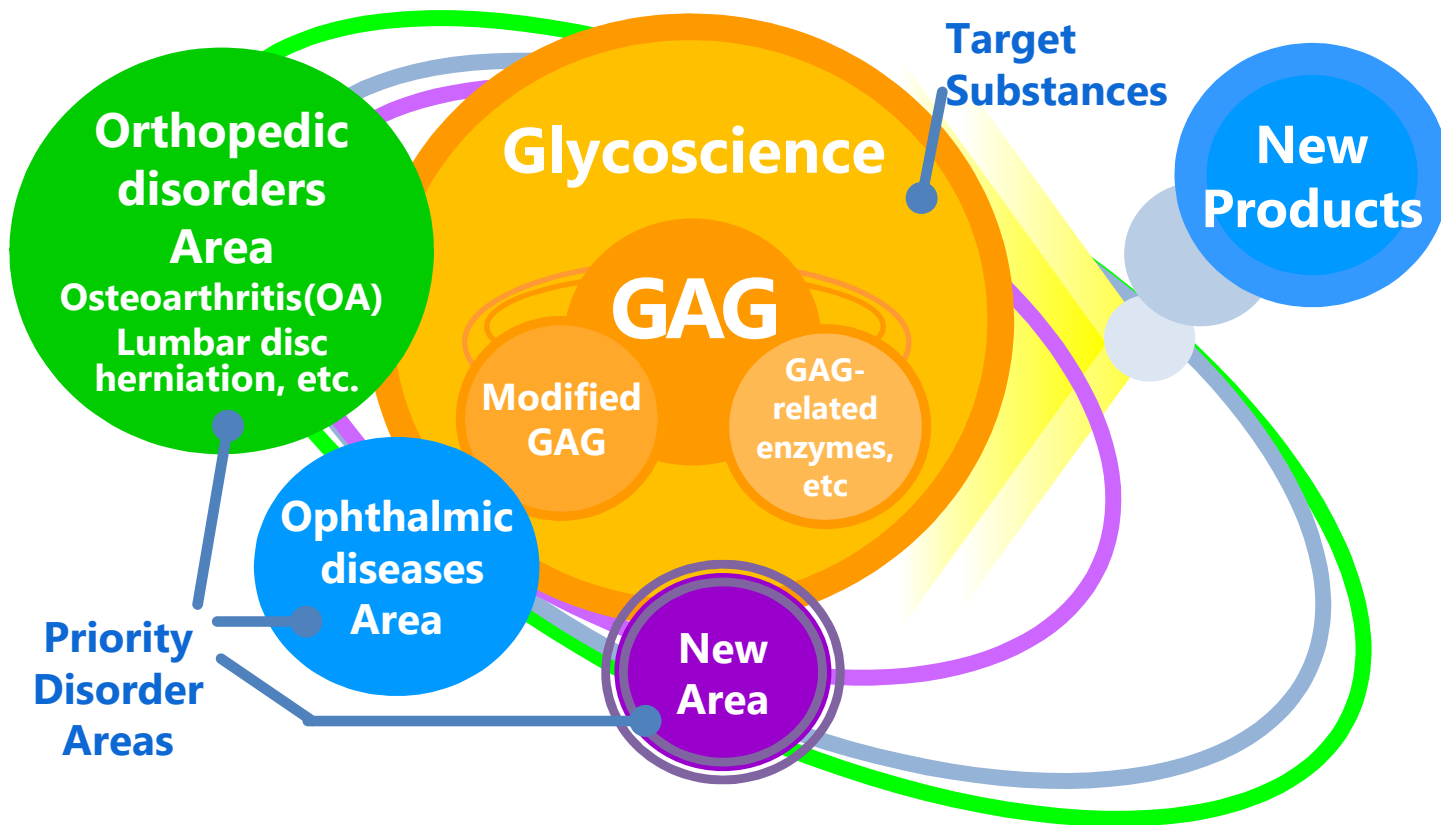
■ Trend in Capital Investments (Millions of Yen)

FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023 (Forecast)
1,975	1,173	1,591	1,310	2,109	2,127	2,194	2,091	3,350



Basic Policy on Research and Development

Continue Our R&D policy to make the most of
our technology and knowledge



GAG: Glycosaminoglycans
(One of the constituents of complex carbohydrates)



Clinical Study Information

Development code/ Indication	Develop- ment Location	Clinical Study Title (Study ID)	Target Enroll- ment	Estimated Period	Primary End Point (Primary Follow-up period)
SI-6603 Lumbar Disk Herniation	U.S.	Phase III additional study (NCT03607838)	320	May. 2018 – Mar. 2023	Leg pain (13 weeks)
SI-613-ETP Enthesopathy	Japan	Late-stage Phase II clinical study (jRCT2080223702)	240	Oct. 2017 – Oct. 2018	Pain in motion (4 weeks)
SI-613 Knee Osteoarthritis	U.S.	Phase II clinical study (NCT03209362)	80	Oct. 2017 – Nov. 2018	WOMAC(Knee pain) (12 weeks)
SI-614 Dry eye	U.S.	Phase III clinical study (NCT05411367)	230	May. 2022 – May. 2023	
SI-722 Interstitial cystitis and bladder pain syndrome	U.S.	Phase I / II clinical study (NCT04208087)	32	Mar. 2020 – Jan. 2021	Maximum observed plasma concentration
SI-449 Adhesion Barrier	Japan	Pivotal study (Field of gastroenterological surgery) (jRCT1080225247)	130	Jun. 2020 – Jun. 2023	Efficacy
SI-449 Adhesion Barrier	Japan	Pilot study (Field of gynecology) (jRCT2072210100)	10	Dec. 2021 – Sep. 2022	Usability, Safety

Note: The table shows data registered (or planned to be registered) on clinical trial information websites.
The information is updated from time to time. Refer to the websites for details and the latest information.
(The websites can be accessed from the trial ID links.)

- Japan Registry of Clinical Trials (jRCT) <https://jrct.niph.go.jp/>
- ClinicalTrials.gov <https://clinicaltrials.gov/ct2/search>

Note: Actual enrollments or trial periods may differ from targets and plans due to various factors.



Planned receipt of milestone royalties in accordance with future progress in development and marketing

Development Code Indication	Development Location	Sales Partner	Total Amount of Milestone Royalties (of which, in upfront payment)
SI-6603 Lumbar Disk Herniation	U.S.	Ferring Pharmaceuticals (Switzerland)	Max. US \$95 million (US \$5 million)
SI-613 Japan: Osteoarthritis U.S. : Knee Osteoarthritis	Japan	Ono Pharmaceutical Co., Ltd.	Max. ¥12.0 billion (¥2.0 billion)
	U.S.	Searching	—
	China	Eisai Co., Ltd.	—
	Korea	Eisai Co., Ltd.	—
SI-613-ETP Enthesopathy	Japan	Ono Pharmaceutical Co., Ltd.	*included in the above
SI-614 Dry eye	U.S.	Searching	—
SI-722 Interstitial cystitis	U.S.	—	—
SI-449 Adhesion Barrier	Japan	—	—



Our vision

A company that is valued by the world through its innovative drug discovery

Core values (motto)

Creativity, Fairness, Dreams and Passion

Creed

We create safe and useful products for human well-being with basic research based on glycoscience.

Guidelines for Our Activities

- We create a corporate environment of mutual trust and communication using individual abilities.
- We create innovative and useful products through in-depth cooperation between industrial and academic circles.
- We assure the highest quality and safety of our products.
- We enhance interaction with society by establishing genuine trust. Through these efforts, Seikagaku will strive to become a sound and socially responsible company that protects the natural environment and improves quality of life.

Mission statement

"Glycoscience for human well-being"



1

Specialization in Glycoscience

- Niche field, market not big enough for the major pharmaceutical companies to penetrate
- Focusing on this field more than **70 years**

2

State-of-the-art technology related to GAG

- Drug discovery expertise using **modified-GAG, GAG-related enzymes**, etc.
- **Extraction, Purification, Fermentation**, etc. technology to manufacture GAG related products




3

Unique business model

- Concentration on **R&D** and **manufacturing**
- R&D staff comprising **35%** of our employees (Non-consolidated base)
- Allocation of **20~30%** of net sales to R&D investment



Our Business Segment


Pharmaceutical Business **67.9%**

Domestic Pharmaceuticals

→ 33.7%



Ophthalmic Surgical Aids



Joint Function Improving Agents



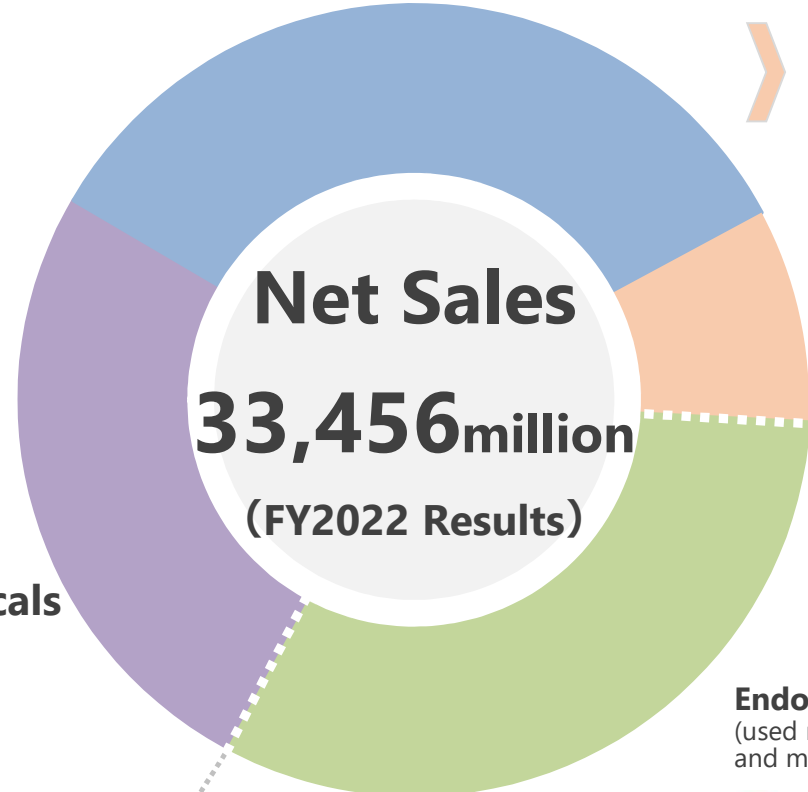
Treatment for lumbar disc herniation




Overseas Pharmaceuticals

→ 25.5%



Joint Function Improving Agents




Bulk Products/CDMO

→ 8.7%



Bulk Products


Royalty income

→ 0.0%


LAL Business
32.1%

Endotoxin-detecting reagents
 (used mainly for quality control of pharmaceuticals and medical devices)





Main Hyaluronic Acid (HA) Products

ARTZ[®] Joint function improving agent by multiple injections

- The first HA joint function improving agent in the world
- Main distributors:

Kaken Pharmaceutical (Japan): ARTZ

Bioventus (U.S.): SUPARTZ FX

Kunming Baker Norton

Pharmaceutical (China): ARTZ



Gel-One[®] Intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis

- Requires only 3ml to be as effective as multiple injections
- Full-scale sales since August 2012
- Distributor: Zimmer (U.S.)



■ 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)