

Financial Results for the Fiscal Year 2023

(April 1, 2023 – March 31, 2024)



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.

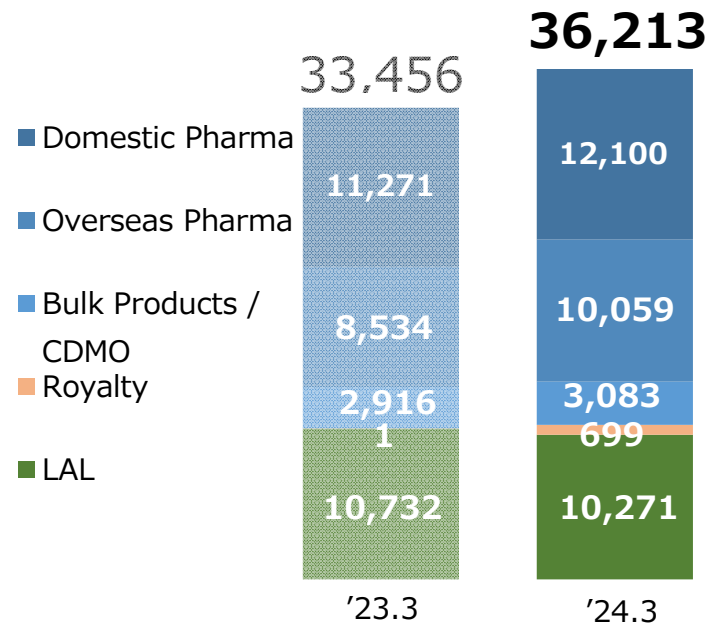
Information about pharmaceutical products or medical devices (including products currently in development) included in this material is not intended to constitute an advertisement or medical advice.

FY2023 Results

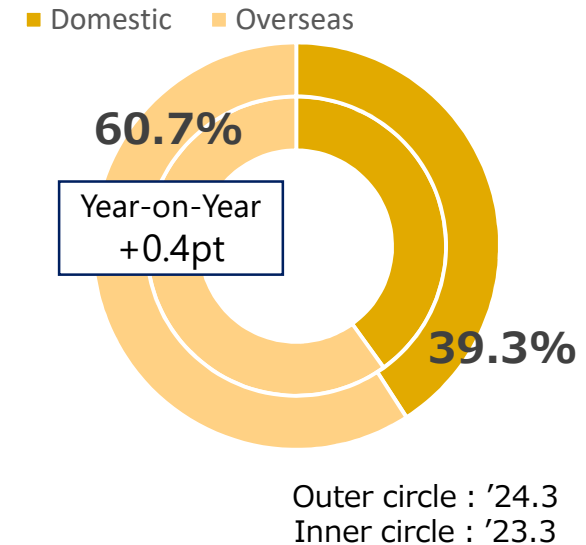
- ◆ **Net sales** : Up 8.2% on sales volume growth from domestic pharmaceuticals and from ARTZ for China and other overseas pharmaceuticals, in addition to an increase in royalty income
- ◆ **Operating Income** : Down 79.5% due mainly to an inventory write-down, bringing forward of facilities maintenance, and higher expenses in the LAL business
- ◆ **Ordinary Income** : Down 44.9%, falling less steeply than operating income due to an increase in foreign exchange gain
- ◆ **Net Income** : Down 2.2%

(Millions of Yen)	FY2022 Results	FY2023 Results	% of Change
Net Income	33,456	36,213	+8.2%
Operating Income	2,114	433	-79.5%
Ordinary Income	3,069	1,691	-44.9%
Net Income	2,236	2,186	-2.2%
Net Income per Share	¥40.49	¥40.08	—
R&D Expenses (excluding royalty income)	7,951	7,484	-5.9%
ROE	3.3%	3.1%	-0.2%
Average Exchange Rate (1US\$)	¥135.48	¥144.62	—

Net sales by Business Segment



Overseas Sales Ratio
 (excluding royalty income)

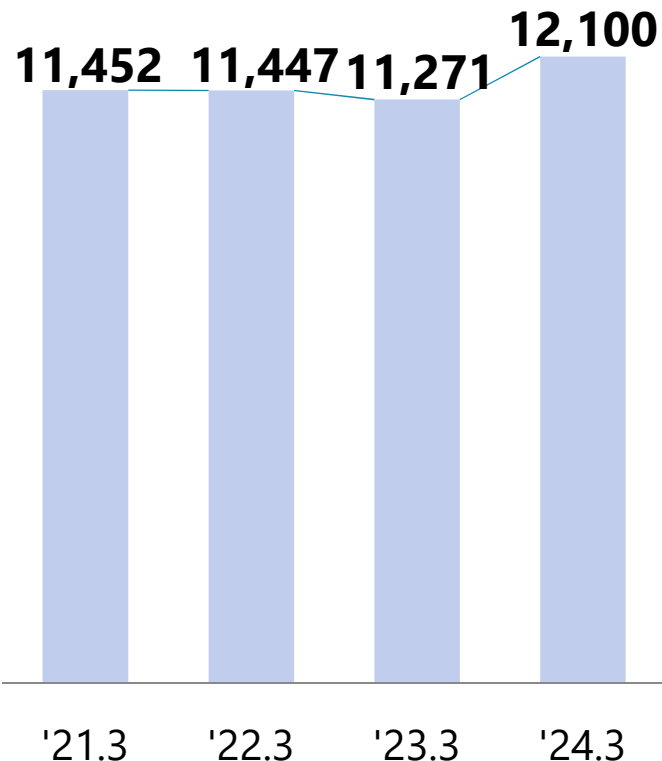




Domestic Pharmaceuticals

Sales trend

(Millions of Yen)



FY2023 Results

+ 7.3%

(Sales)

Sales up, with volume increases for ARTZ and the OPEGAN Series, compensating for the impact of NHI price reductions

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

Market (-1.8%*)

- Slight market contraction

ARTZ (+9.3%*)

- Volume and market share up (71.4%/+7.3pt*)

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market (+2.8%*)

- Market growth trend accompanying population aging

OPEGAN Series (+2.6%*)

- Volume down due to market expansion and the impact of limited shipments of competing products
- Market share at the prior-year level (51.9%/-0.2pt*)

Other Products (Unit deliveries to medical institutions)

JOYCLU

- Gathering of side effects reports and other information and provision of safety-related information

HERNICORE / MucoUp

- Volume at the prior-year level

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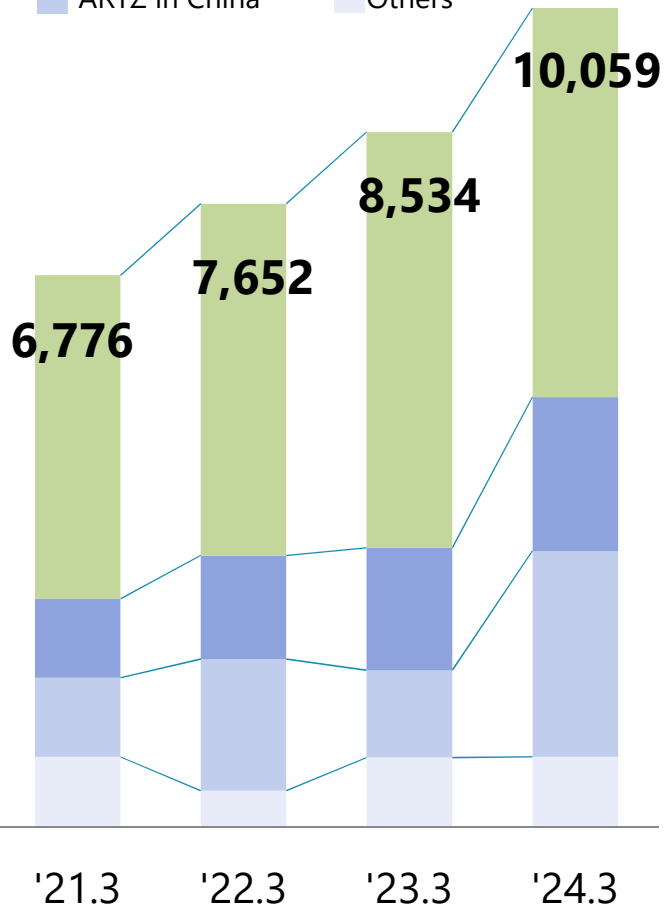
Overseas Pharmaceuticals

Sales trend

(Millions of Yen)

<Breakdown>

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



FY2023 Results

+ 17.9%

(Sales)

Sales up, with volume growth from ARTZ for China and SUPARTZ FX compensating for lower sales of Gel-One

*Foreign exchange impact on Overseas Pharmaceuticals: approx. +775 million yen

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 : Down despite a gradual trend toward recovery from the impact of an insurance reimbursement system change

SUPARTZ FX

Local sales : Up because of preference for a low-priced product due to a system change
 Seikagaku sales : Up due to a shipping timing adjustment and yen depreciation

China, Other Regions. (Value basis)

Market in China

Trend toward recovery from the impact of COVID-19

ARTZ in China

Local sales : Up amid recovery in the patient consultation rate following a COVID-related decline
 Seikagaku sales : Up sharply, reflecting a rebound following the absence of shipments in 1Q FY2022 due to a packaging material change and bringing forward of product shipments

Other Regions

Seikagaku sales : Increase from HyLink in Taiwan, decrease from SUPARTZ in Italy



Bulk Products / CDMO, Royalty, LAL Business

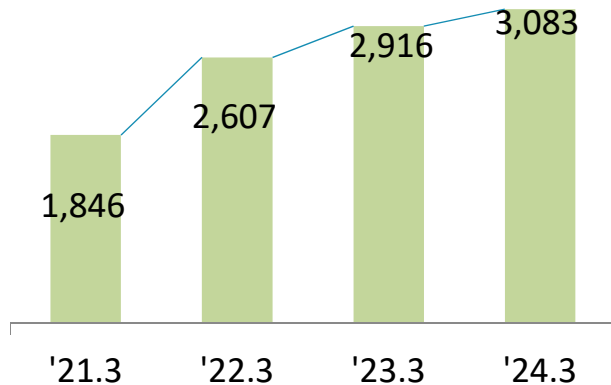
Bulk Products / CDMO

FY2023 Results : + 5.7%

*Foreign exchange impact on Bulk Products/CDMO: approx. +70million yen

Revenue up on higher sales of contract development and manufacturing and other services of subsidiary Dalton Chemical Laboratories and yen depreciation

Sales trend (Millions of Yen)



Royalty

Up from ¥1 million yen in FY2022 (+ ¥697 mil)

LAL Business

FY2023 Results : - 4.3%

*Foreign exchange impact on LAL Business : approx. +620million yen

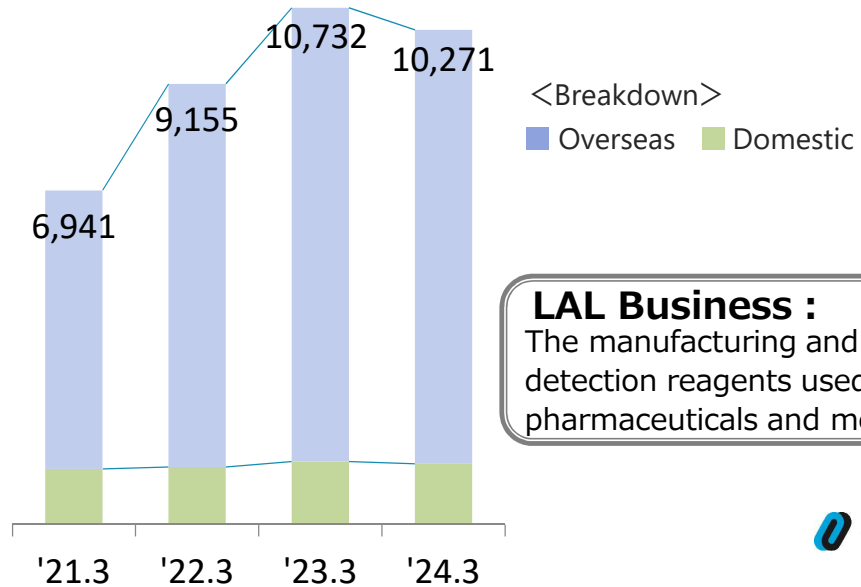
Overseas

Sales down as special demand at subsidiary ACC accompanying the spread of COVID-19 infection subsided, despite the positive impact of yen depreciation

Domestic

Sales at the prior-year level

Sales trend (Millions of Yen)



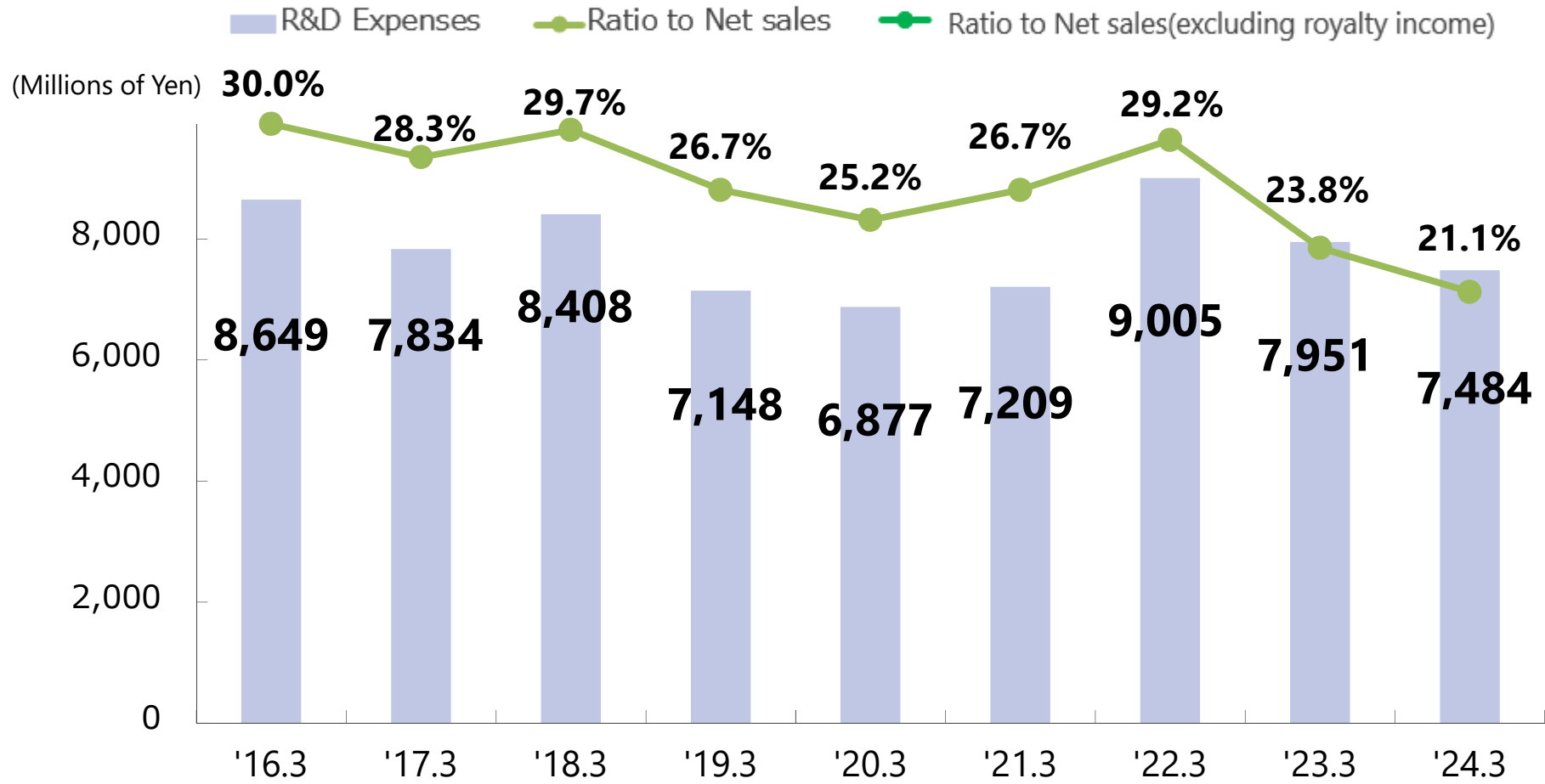
LAL Business :

The manufacturing and sales of Endotoxin detection reagents used in the quality control of pharmaceuticals and medical devices



Trend in R&D Expenses

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



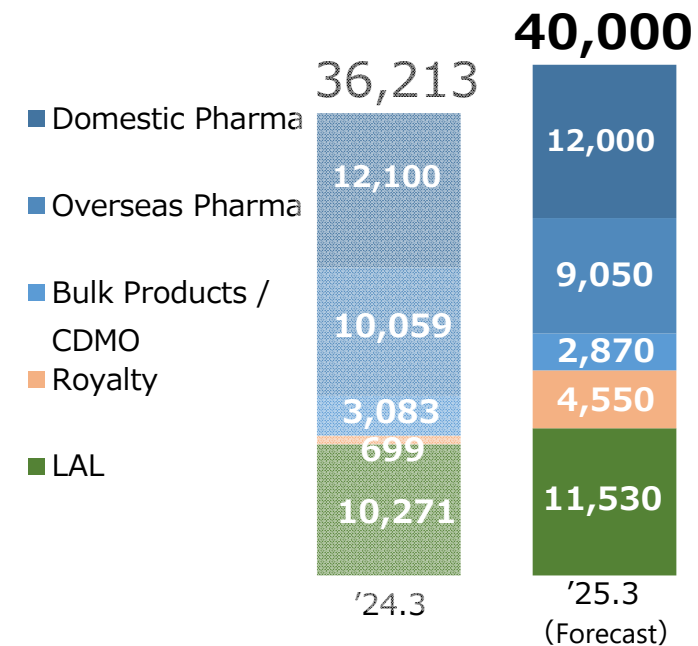
FY2024 Forecasts



- ◆ **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

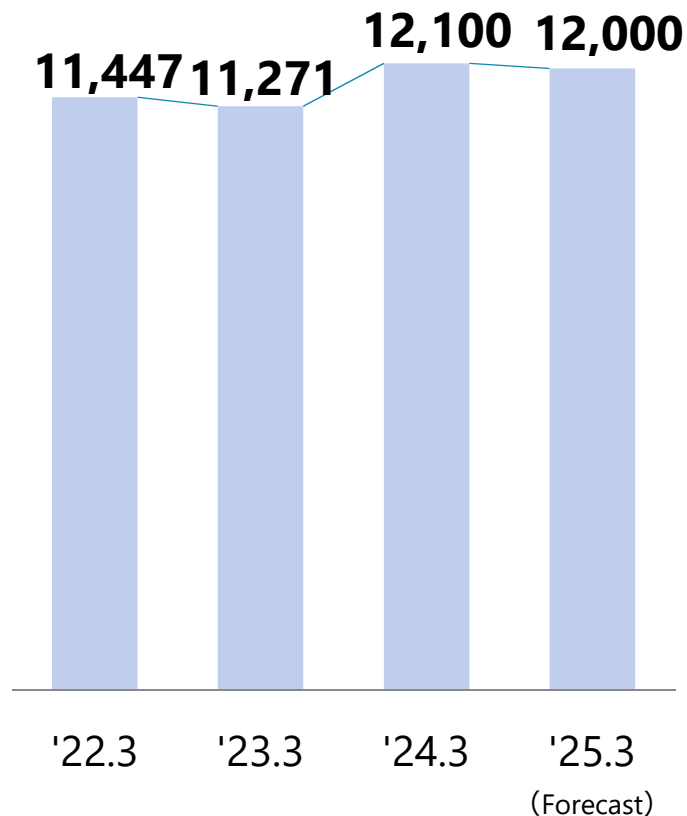




Domestic Pharmaceuticals

Sales trend

(Millions of Yen)



FY2024 Forecast

- 0.8%

(Sales)

Sales projected to remain at the prior-year level due to NHI price reductions, despite higher volumes of ARTZ and other products

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

Market

- Market size projected to remain at the prior-year level

ARTZ

- Projected volume increase on continued switching from competing products

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market

- Expected continuation of the pre-COVID growth trend

OPEGAN series

- Volume projected to be at the prior-year level

Other Products (Unit deliveries to medical institutions)

JOYCLU

- Continuation of efforts to gather and provide safety information

HERNICORE

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

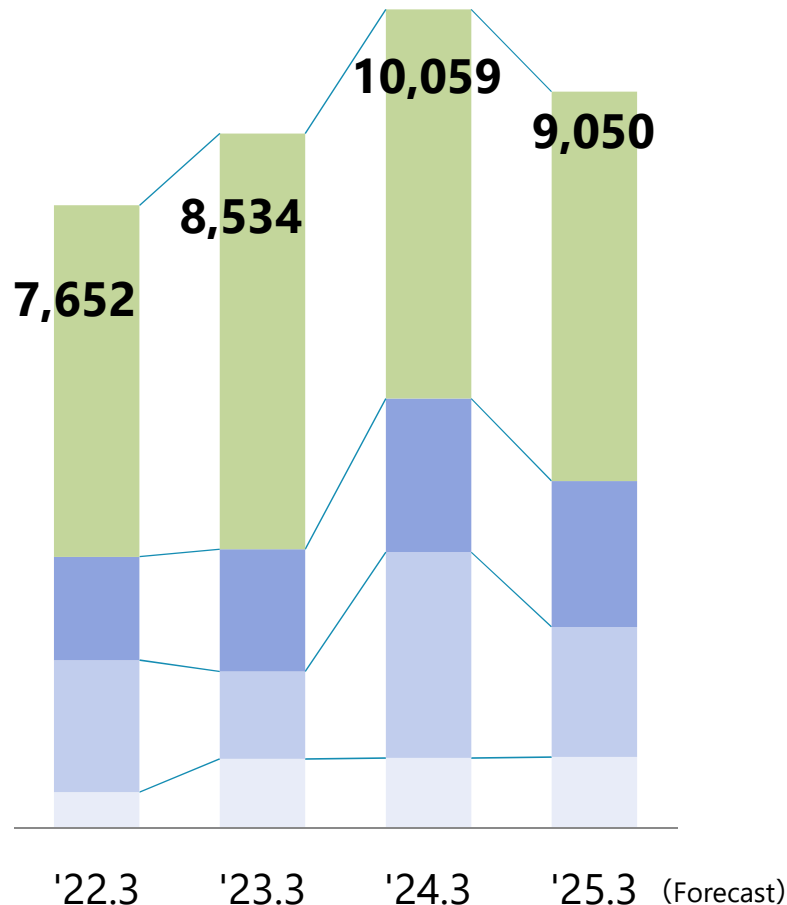
Overseas Pharmaceuticals

Sales tend

(Millions of Yen)

<Breakdown>

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



FY2024 Forecast
- 10.0%

(Sales)

Projected decrease due mainly to bringing forward of shipments of ARTZ for China to FY2023

* Foreign exchange impact: approx. -5million

U.S. (Value basis)

Market in the U.S.

Market size projected to remain at the prior-year level

Gel-One

Shipments projected to remain at the prior-year level

SUPARTZ FX

Shipments projected to remain at the prior-year level

China, Other Regions. (Value basis)

Market in China

Trend toward relaxation of COVID-19

ARTZ in China

Projected sharp decline due to bringing forward of shipments to FY2023

Other Regions

Projected decrease in sales to Taiwan due to a distributor inventory adjustment

Projected increase in sales to Italy



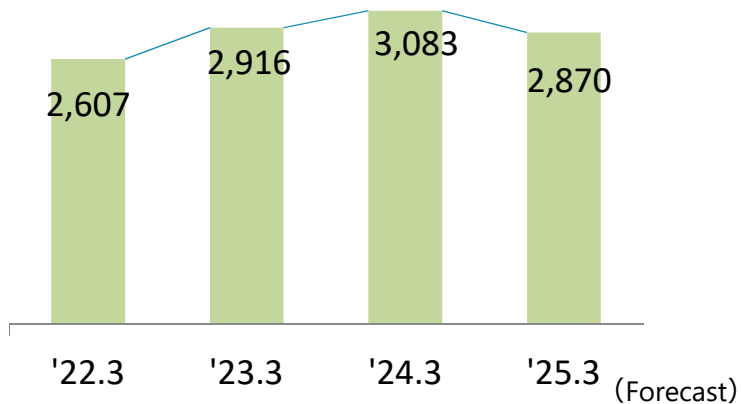
Bulk Products / CDMO, Royalty, LAL Business

Bulk Products / CDMO FY2024 Forecast : - 6.9% (Year-on-Year)

* Foreign exchange impact: approx. +135million

Projected revenue decrease on lower sales of bulk products and contract development and manufacturing and other services of subsidiary Dalton Chemical Laboratories

Sales trend (Millions of Yen)



Royalty FY2024 Forecasts : + 550.9% (Year-on-Year)

Projected increase

LAL Business FY2024 Forecast : + 12.3% (Year-on-Year)

* Foreign exchange impact: approx. +330million

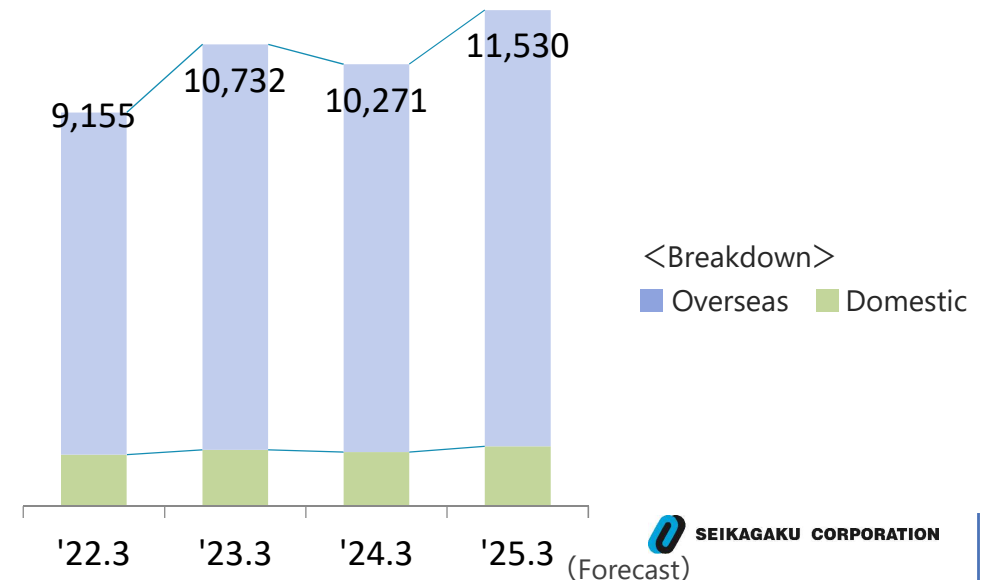
Overseas

Projected revenue increase from higher sales of endotoxin-detecting reagents, in vitro diagnostic BDG screening tests, and other products at ACC

Domestic

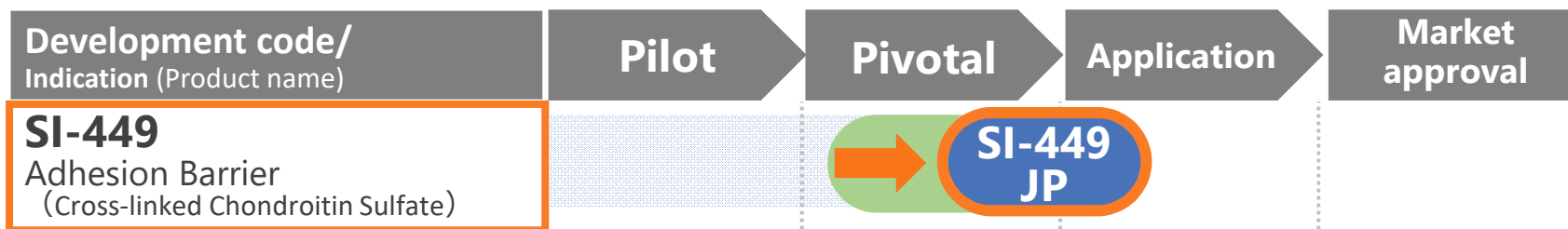
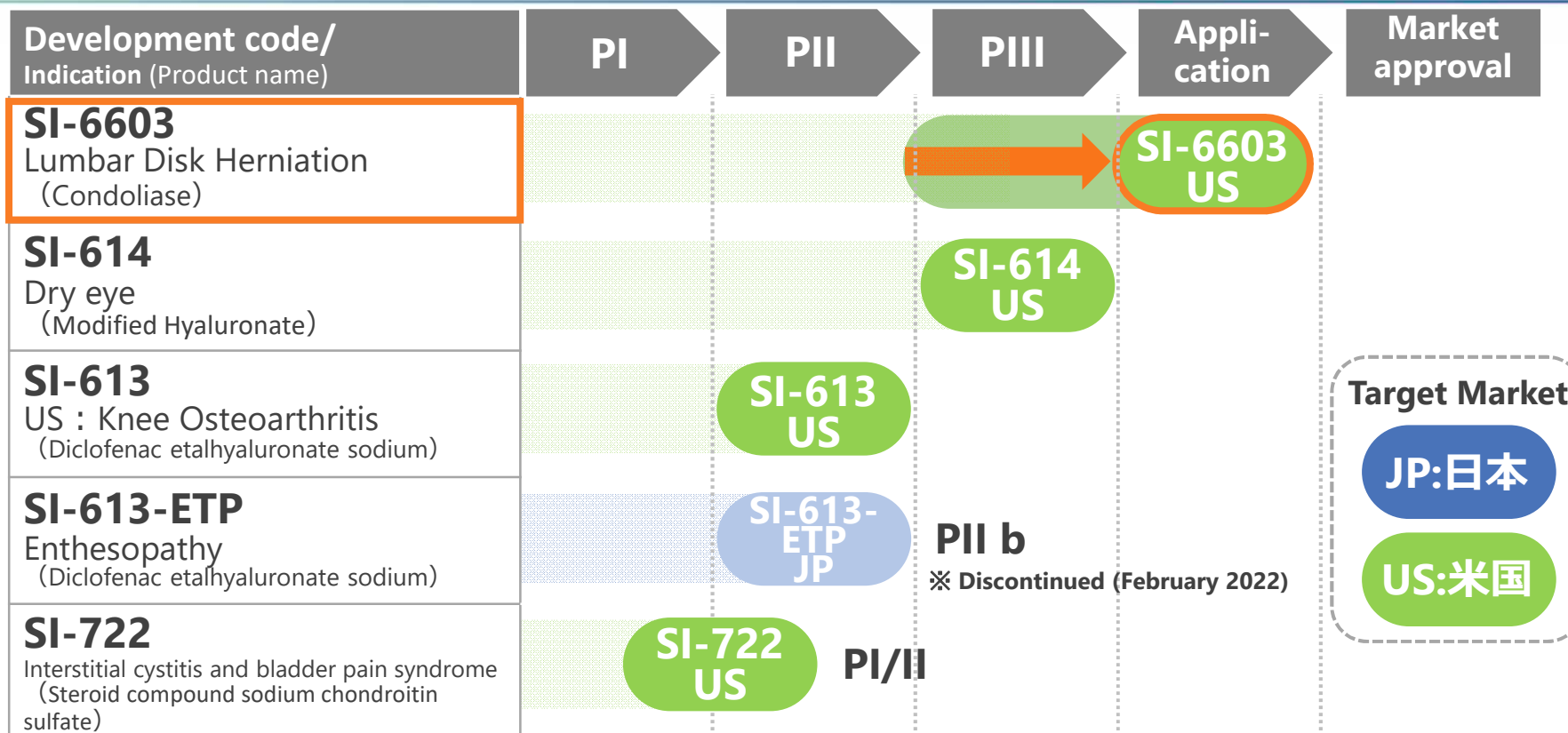
Projected revenue increase on solid sales of instruments and other products

Sales trend (Millions of Yen)



Research and Development

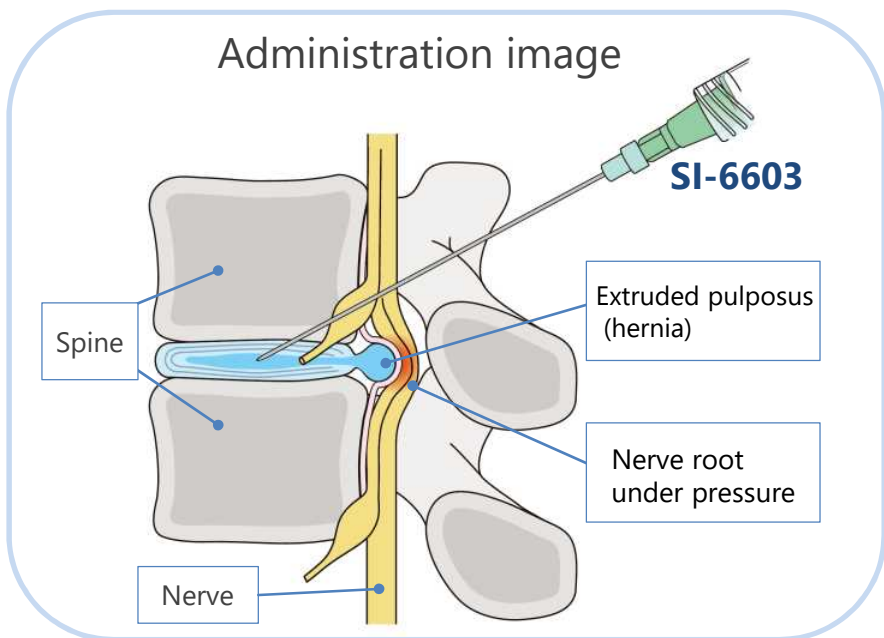
Pipeline List



○ : SI-6603 Biologics License Application accepted by the U.S. Food and Drug Administration (FDA)
 SI-449 The primary endpoints were achieved in a pivotal study of SI-449 in Japan

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

► Phase III additional study in the U.S.

- Topline results indicating statistically significant improvement in the primary endpoint obtained in May 2023
- **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>

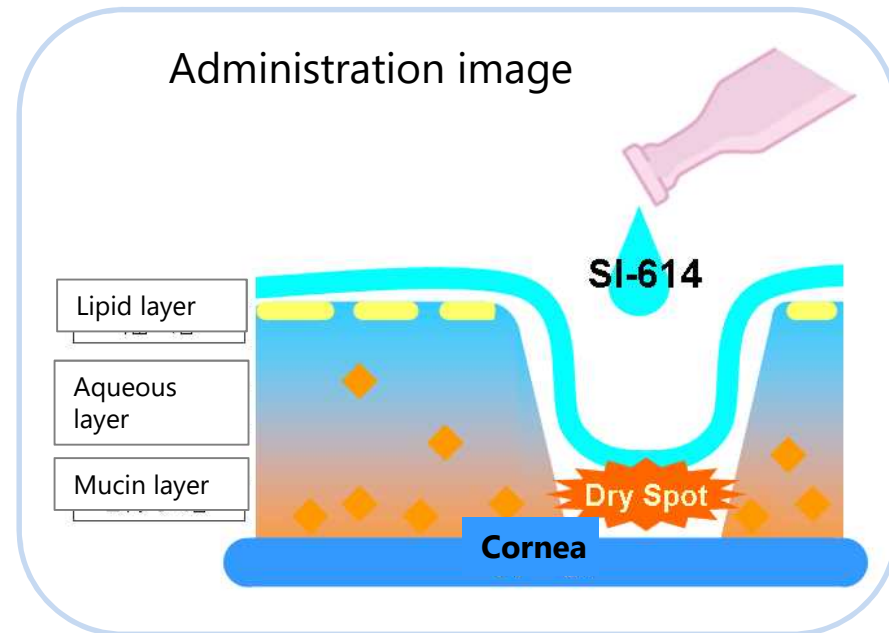
Dev. Code : SI-6603 / Generic name : Condoliase / Indication : Lumbar disc herniation

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

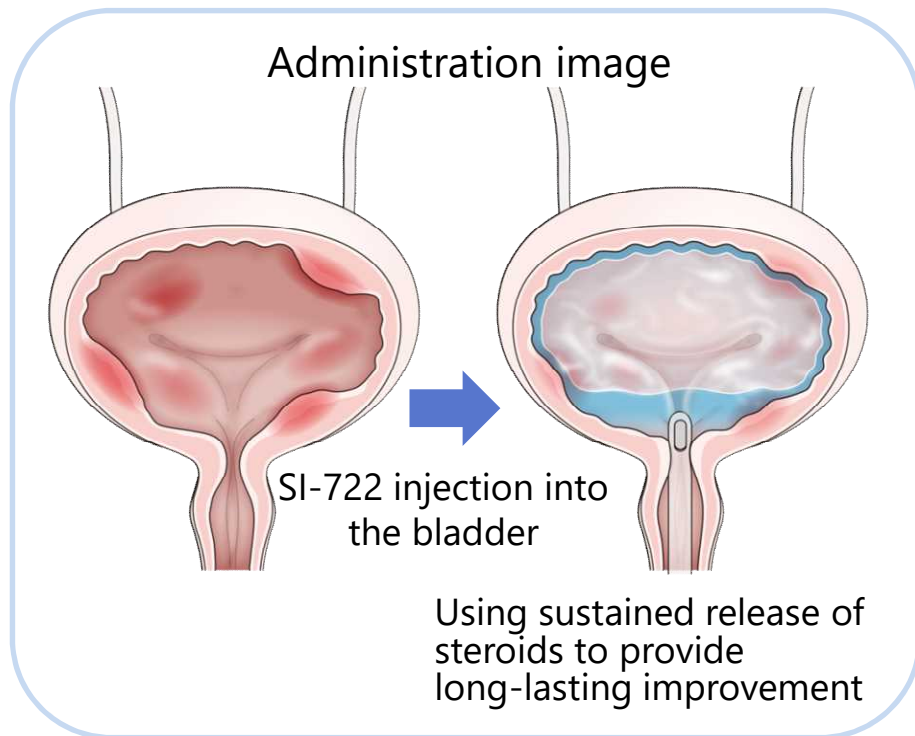
▶ **Phase I/II studies in the U.S.**

- 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>

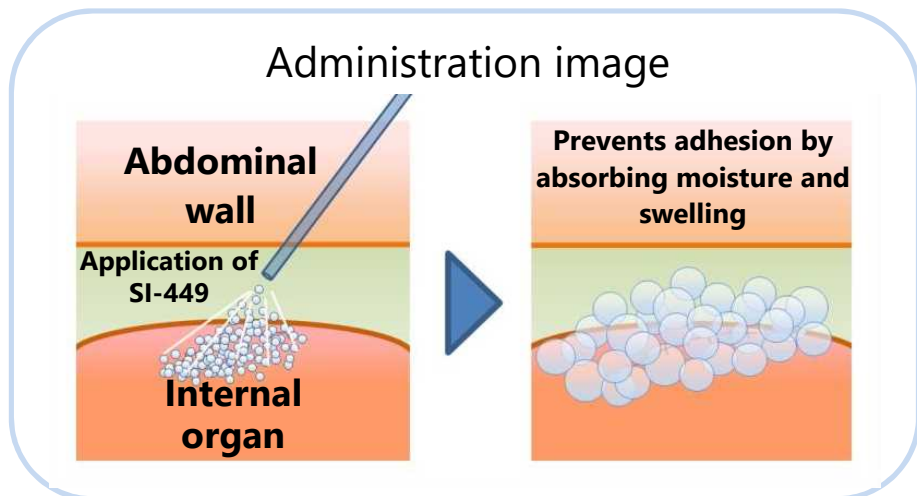
Dev. Code : SI-722 / Generic name : Steroid conjugated with chondroitin sulfate

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; Start of U.S. study under review

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

Progress Against the Mid-Term Management Plan in Fiscal 2023

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

- Topline results indicating statistically significant improvement in the primary endpoint obtained in an additional Phase III clinical study in the U.S. (May 2023)
- Biologics License Application accepted by the U.S. FDA (May 2024)

II Accelerate R&D utilizing unique drug-discovery technologies

- Results showing statistically significant improvement in both the primary endpoint and secondary endpoints obtained in a pivotal study being conducted in Japan of SI-449, a powdered adhesion barrier. (July 2023)

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

- Proceeded with construction of an expanded production system to maintain a stable supply of ARTZ, a joint function improvement agent
- Responded to product material specification changes for the purpose of cost structure improvement
- Maintained a system for the collection and provision of safety information and other information about JOYCLU, a joint function improvement agent

IV Construct a global production system

- Proceeded with manufacturing system construction at Canadian subsidiary Dalton Chemical Laboratories Inc.

V Expand the LAL business through recombinant technologies

- Continued gathering scientific data relating to PyroSmart NextGen (a recombinant LAL reagent) and co-authoring of academic papers with ACC
- Increased the number of countries where Fungitell (a beta-glucan-detecting in vitro diagnostic test) is sold and entered the hospital market

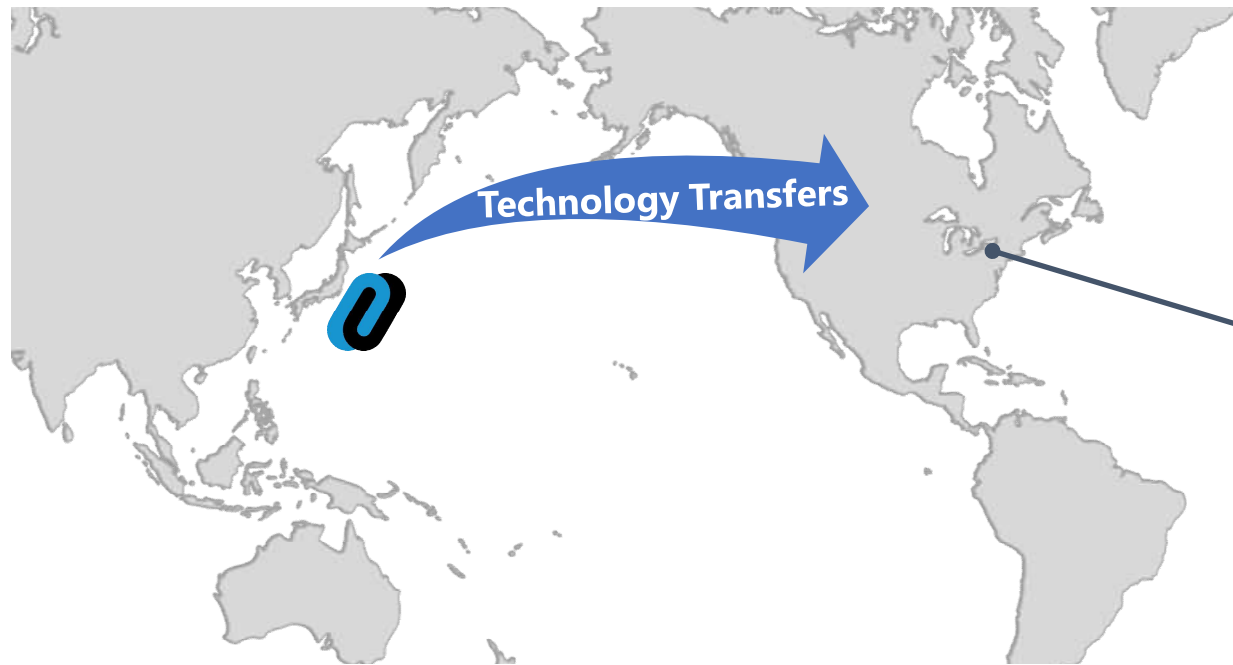
Progress being made broadly in line with the plan
Seikagaku will strive to achieve the targets for the plan's final year



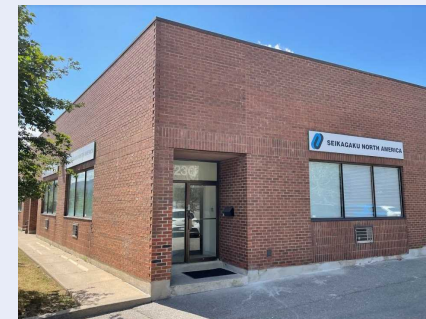
New Initiatives for Construction of a Global Production System

Acceleration of Initiatives for Establishment of a Production System in North America

- Strengthening of investment for construction of a production system for products in development and some finished products at Dalton
- Establishment of a production planning department that supports the transfer of manufacturing technologies at SNA*



DALTON CHEMICAL LABORATORIES, INC.
(Toronto, Canada)



SEIKAGAKU NORTH AMERICA CORPORATION

*SEIKAGAKU NORTH AMERICA CORPORATION (SNA)
Established in January 2022 with the aim of accelerating development and regulatory approval of pharmaceuticals and medical devices

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	¥30.00	¥26.00	¥26.00	¥30.00
Dividend payout ratio	31.8%	45.2%	64.2%	64.9%	47.4%

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