

Mid-term Management Plan FY2022 to FY2025



- **Summary of Previous Mid-term Management**
- **Overview of Current Mid-term Management Plan**
- **Key Measures**
 - 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
- **Sustainability**
- **Numerical Targets and Basic Policy on Profit Distribution**
 - Numerical Targets
 - Basic Policy on Profit Distribution



Summary of Previous Mid-term Management Plan

I . Accelerating new drug discovery to become the pillar of new profits

- Joint function improving agent JOYCLU launched
- SI-722 (treatment for interstitial cystitis) and SI-449 (adhesion barrier) advanced to the next stage of development
- Enrollment for SI-6603 (treatment for lumbar disc herniation) completed
- SEIKAGAKU NORTH AMERICA CORPORATION established

II . Solidifying the profit foundation through market expansion of new products

- HyLink (intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis) launched in Taiwan
- Alliance agreement concerning SI-613 concluded with Eisai (China, South Korea)
- PyroSmart NextGen Recombinant LAL Reagent launched

III . Productivity improvement reforms

- DALTON CHEMICAL LABORATORIES, INC. made a subsidiary
- Business continuity system developed in response to the impact of COVID-19
- Progress with review of procurement costs and sales-related expenses



We achieved a measure of success with each of the three important measures in the management plan, successfully solidifying the profit foundation to return Seikagaku to a growth trajectory



Previous Mid-term Management Plan Numerical Targets

	FY2021 results*	FY2021 target (disclosed Nov. 2019)	Percentage achievement
Net sales	¥31.2 billion	¥28.3 billion	+ 10.5%
Ordinary income	¥5.39 billion	¥4.5 billion	+ 19.9%
SKK EBITDA	¥5.54 billion	¥5.0 billion	+ 10.9%
Overseas sales ratio (excluding royalty income)	56.6%	50.0%	+ 6.6 pt.

*Converted to previous presentation categories
SKK EBITDA: A profit indicator that adds depreciation and
royalty income to operating income



We also achieved each numerical target in the plan

Overview of Current Mid-term Management Plan

Pharmaceutical Industry Trends

Domestic pharmaceutical market

- Aging society
- Growth in healthy longevity
- Pressure on healthcare financing
- Promotion of generic drug use
- Diversification of treatment options
- Impact of drug price system
- Strengthening of quality assurance and control systems

Overseas joint function improving agent market

- Osteoarthritis patients increasing (aging, etc.)
- Greater numbers of active seniors
- Intensification of competition due to new product introductions, etc.
- A broad range of treatment options
- System change relating to price disclosure

R&D environment

- Increasing R&D costs and risks
- Depletion of seeds for drug discovery
- Appearance of new treatment methods, such as regenerative medicine
- Diversification of new drug modalities

Societal Trends

Development of international frameworks and principles

- Adoption of the SDGs by the U.N., global penetration
- Adoption of the Paris Agreement at COP21
- Revision of the Corporate Governance Code

Stakeholder expectations

- Increase in sustainable investment ratios
- Growing importance of non-financial information disclosure in investment decisions

A flexible response to an era of extreme environmental change and fulfillment of social responsibility are required

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

Key Measures



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

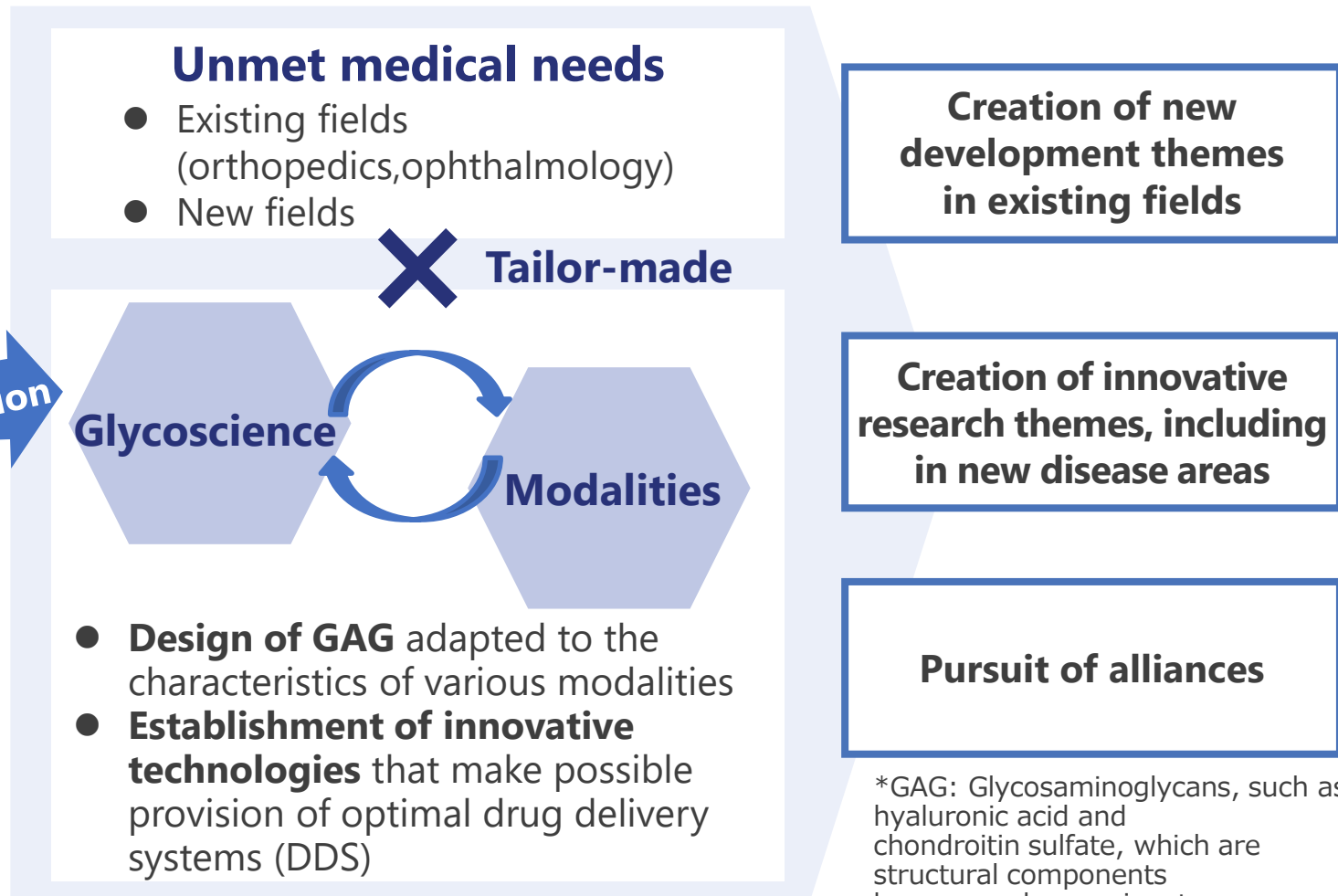
Business foundation

**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



Unmet medical needs

- Existing fields (orthopedics, ophthalmology)
- New fields

X Tailor-made

Glycoscience

Modalities

Creation of new development themes in existing fields

Creation of innovative research themes, including in new disease areas

Pursuit of alliances

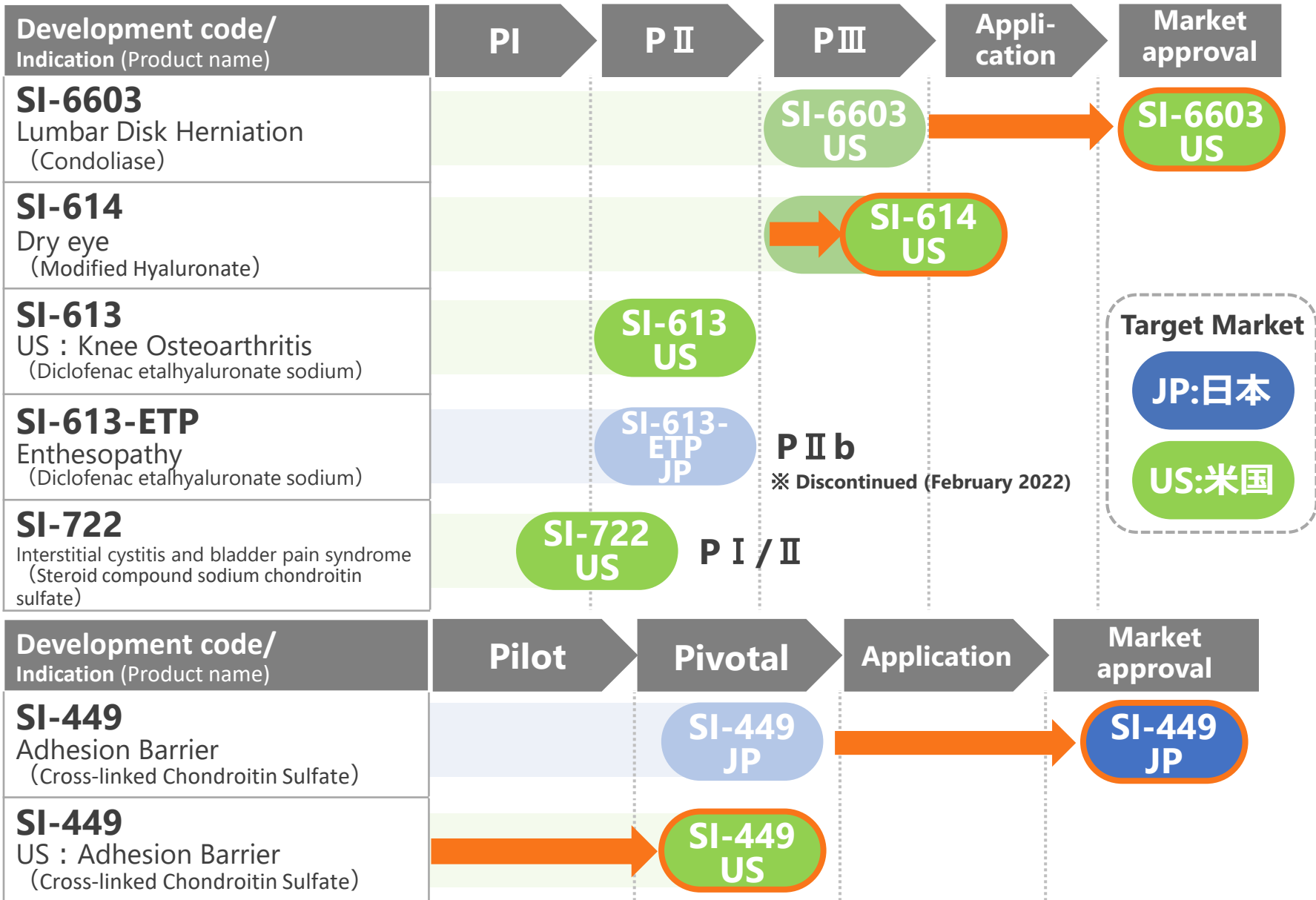
GAG-related basic technologies

- Cross-linking
- Chemical modification
- Fermentation etc.

- **Design of GAG** adapted to the characteristics of various modalities
- **Establishment of innovative technologies** that make possible provision of optimal drug delivery systems (DDS)

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

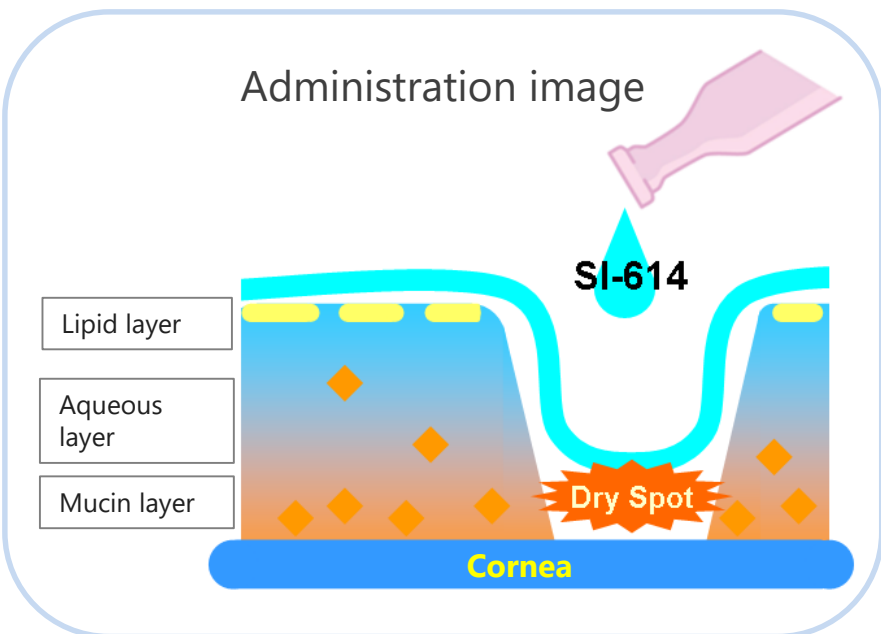
Pipeline List (Research and Development themes)





SI-614 (Dry Eye)

Phase III clinical study in the U.S. initiated in May 2022
Aiming to complete the Phase III study during the period of the mid-term management plan



Development status

▶ **U.S. : P III**

Initiated May 2022

- **Clinically beneficial effects confirmed in PII/PIII clinical studies**
- **Evaluation of efficacy and safety**

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

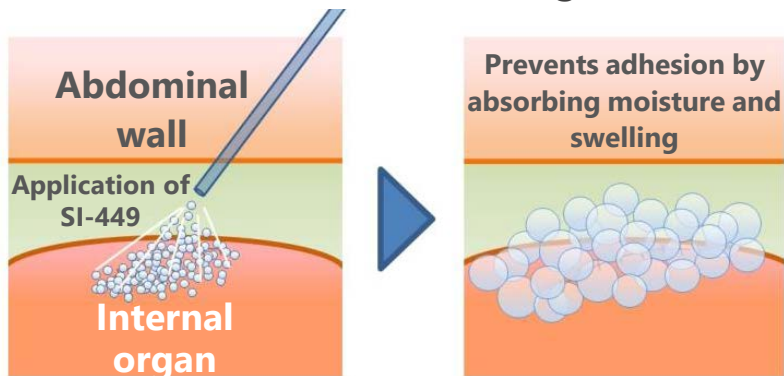
Product name : Dry eye Formulation : Ophthalmic solution

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

SI-449 (Adhesion Barrier / Medical Device)

**Subject enrollment for pivotal study completed in September 2022
Aiming to obtain approval and initiate a clinical study in the U.S.
during the mid-term management plan period**

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
 - Evaluated for effectiveness, safety, and usability
 - ⇒ **Subject enrollment complete in Sept. 2022**
- ▶ **Japan pilot study (field of gynecology)**
Starting November 2021
 - Confirming operability and safety
 - Aiming to expand range of applications
 - ⇒ **Subject enrollment complete in May 2022**
- ▶ 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)



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

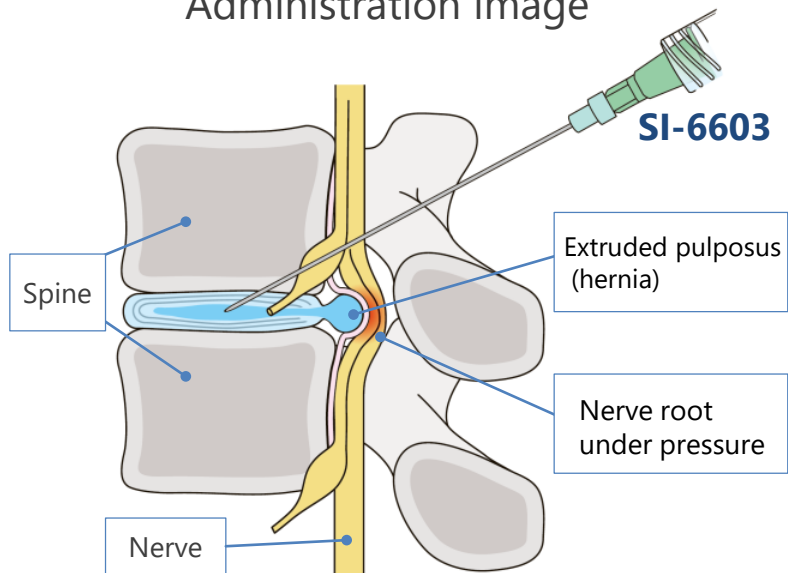
- Sales preparations in cooperation with the sales partner
- Construction of a stable supply system

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

Overview of SI-6603 (Treatment for Lumbar Disc Herniation)

Aim to provide new options in lumbar disc hernia treatment and maximize product value through early market penetration

Administration image



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

Estimated U.S. patients

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

<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)



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

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
Aim to contribute to appropriate treatment on the basis of clinical
research findings**



Construct a Global Production System

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



Initiatives for Expansion of the LAL Business

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



Overview of Key Measures -Business Foundation

Introduction of a new HR system in October 2022
Work to solidify the business foundation for achieving sustained growth through enhancement of employee engagement as well as organizational strengthening and human resource development

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**

Sustainability

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・医療機器の開発を促す	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 持続可能な経済発展を
		10 人や国の不平等をなくそう	
⑥	Engagement in environmentally friendly corporate activities	7 エネルギーと気候変動に積極的に取り組もう	13 気候変動に具体的な対策を
		14 海の豊かさを守ろう	



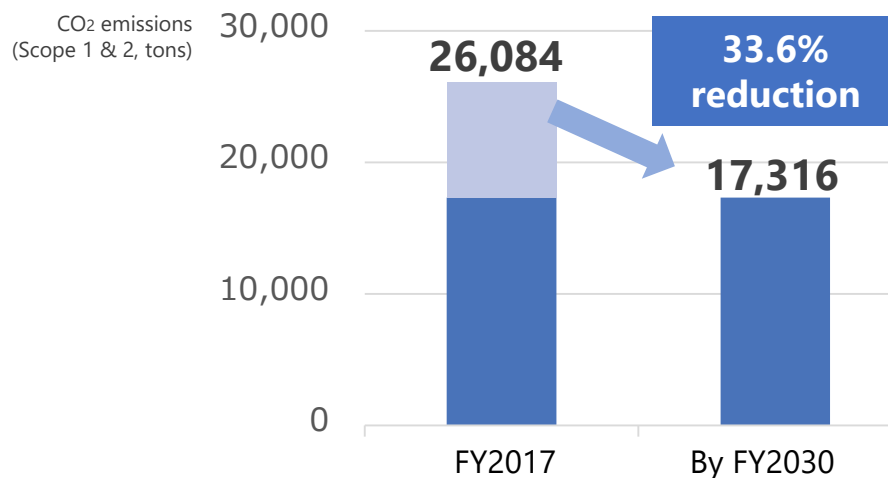
Seikagaku will focus on initiatives related to these material issues, which will become the foundation for the key measures in the mid-term management plan



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>



Initiate measures during the period of the current mid-term management plan aimed at reducing CO₂ by 33.6% from the FY2017 level by FY2030



1. Energy saving

- Conversion to LED lighting at plants and laboratories
- Review of air conditioner operation, such as introduction of nighttime mode

3. Updating of equipment

- Modification to the filtration method used for sterile water for injection production equipment

2. Fuel conversion

- Conversion of boiler fuel to liquid natural gas (LNG)

4. Introduction of renewable energy

- Introduction of solar power and other renewable energy sources

Numerical Targets and Basic Policy on Profit Distribution



Numerical Targets

	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

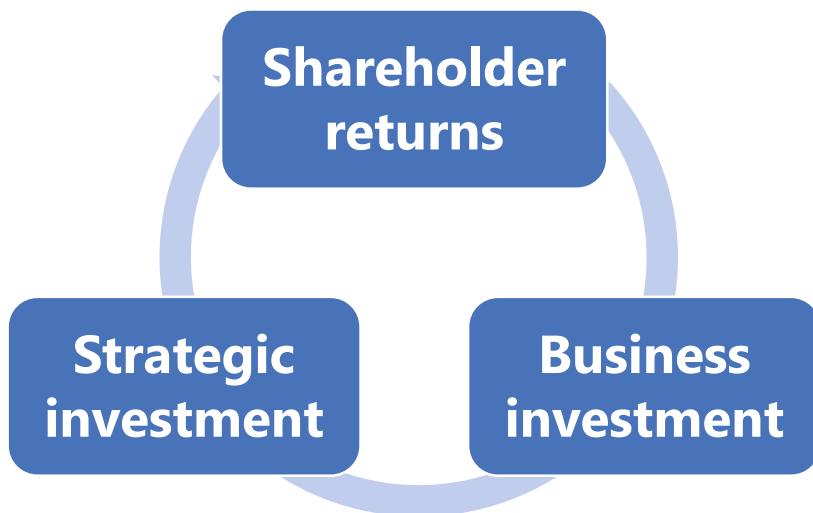


Aim to achieve record-high business results



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.



Dividends from Surplus and Treasury Stock Acquisition

Resolution to revise the dividend in accordance with the dividend policy Now purchasing treasury stock

FY2022

Annual dividend : ¥26 per share (including an interim dividend of ¥13)

Reference information Previous forecast announced May 13:

Annual dividend of ¥22 per share (including ¥11 interim dividend)

	FY2018	FY2019	FY2020	FY2021	FY2022 (forecast)
Net profit per share	¥39.76	-¥192.15	¥75.54	¥66.32	¥48.12
Annual dividend per share	¥26.00	¥26.00	¥24.00 ^{*1}	¥30.00 ^{*2}	¥26.00
Dividend payout ratio	65.4%	—	31.8%	45.2%	54.0%

*1 Includes JOYCLU approval commemorative dividend of ¥4

*2 Includes JOYCLU launch special dividend of ¥10

Treasury Stock Acquisition

Total number of shares to be acquired: 2,000,000 shares (maximum)

Total value of shares to be acquired: ¥1.5 billion (maximum)

Acquisition period: May 16, 2022 to December 30, 2022

Totals as of October 31, 2022

Total number of shares acquired: 1,327,800 shares

Total amount of acquisition cost: ¥1,127,473,900



Mid-term Management Plan Summary

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
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IV

**Construct a
global
production
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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**

■ 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)